Effective Health Care Program

Comparative Effectiveness Review
Number 36

Nonsurgical Treatments for Urinary Incontinence in Adult Women: Diagnosis and Comparative Effectiveness

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Prepared by:
Minnesota Evidence-based Practice Center
Minneapolis, Minnesota

Investigators:
Tatyana Shamliyan, M.D., M.S.
Jean Wyman, Ph.D.
Robert L. Kane, M.D.

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The information in this report is intended to help health care decisionmakers—patients and clinicians, health system leaders, and policymakers, among others—make well-informed decisions and thereby improve the quality of health care services. This report is not intended to be a substitute for clinical judgment. Anyone who makes decisions concerning the provision of clinical care should consider this report in the same way as any medical reference and in conjunction with all other pertinent information, i.e., in the context of available resources and circumstances presented by individual patients.

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Preface

The Agency for Healthcare Research and Quality (AHRQ) conducts the Effective Health Care Program as part of its mission to organize knowledge and make it available to inform decisions about health care. As part of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Congress directed AHRQ to conduct and support research on the comparative outcomes, clinical effectiveness, and appropriateness of pharmaceuticals, devices, and health care services to meet the needs of Medicare, Medicaid, and the Children's Health Insurance Program (CHIP).

AHRQ has an established network of Evidence-based Practice Centers (EPCs) that produce Evidence Reports/Technology Assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care. The EPCs now lend their expertise to the Effective Health Care Program by conducting Comparative Effectiveness Reviews (CERs) of medications, devices, and other relevant interventions, including strategies for how these items and services can best be organized, managed, and delivered.

Systematic reviews are the building blocks underlying evidence-based practice; they focus attention on the strength and limits of evidence from research studies about the effectiveness and safety of a clinical intervention. In the context of developing recommendations for practice, systematic reviews are useful because they define the strengths and limits of the evidence, clarifying whether assertions about the value of the intervention are based on strong evidence from clinical studies. For more information about systematic reviews, see www.effectivehealthcare.ahrq.gov/reference/purpose.cfm.

AHRQ expects that CERs will be helpful to health plans, providers, purchasers, government programs, and the health care system as a whole. In addition, AHRQ is committed to presenting information in different formats so that consumers who make decisions about their own and their family's health can benefit from the evidence.

Transparency and stakeholder input are essential to the Effective Health Care Program. Please visit the Web site (www.effectivehealthcare.ahrq.gov) to see draft research questions and reports or to join an email list to learn about new program products and opportunities for input. Comparative Effectiveness Reviews will be updated regularly.

We welcome comments on this CER. They may be sent by mail to the Task Order Officer named below at: Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, MD 20850, or by email to epc@ahrq.hhs.gov.

Carolyn M. Clancy, M.D.
Director
Agency for Healthcare Research and Quality

Jean Slutsky, P.A., M.S.P.H.
Director, Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

Stephanie Chang, M.D., M.P.H.
Director and Task Order Officer
Evidence-based Practice Program
Center for Outcomes and Evidence
Agency for Healthcare Research and Quality

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Key Informants

Alan M. Adelman, M.D., M.S.
Penn State University
Hershey, PA

Apostolos Panagiotis Dallas, M.D.
Carilion Roanoke Memorial Hospital
Roanoke, VA

Catherine DuBeau, M.D.
UMass Memorial Medical Center
Worcester, MA

Mary Forciea, M.D., FACP
University of Pennsylvania
Philadelphia, PA

Jessica Griffin, M.S.
Oregon Evidence-based Practice Center
Portland, OR

Leah Hole-Curry, J.D.
Washington Health Care Authority
Olympia, WA

Lore Joplin
Oregon Health & Science University
Portland, OR

Kay Mattson, M.S.W., M.P.H.
Oregon Health and Science University
Portland, OR

Diane Newman, R.N.C., M.S.N., CRNP
FAAN
University of Pennsylvania Medical Center
Philadelphia, Pennsylvania

Ingrid Nygaard, M.D.
University of Utah School of Medicine
Salt Lake City, UT

Mary Patrick, R.N.
Department of Public Health & Human Services
Helena, MT

Suzanne Pope, M.B.A.
American Urological Association
Linthicum, MD

Amir Qaseem, M.D., Ph.D., M.H.A., FACP
American College of Physicians
Philadelphia, PA

Kenneth G. Schellhase, M.D., M.P.H.
Medical College of Wisconsin
Milwaukee, WI

Paul Shekelle, M.D.
RAND Corporation
Santa Monica, CA

J. Christian Winters, M.D., FACS
LSU Health Sciences Center
Metairie, LA

Technical Expert Panel

In designing the study questions and methodology at the outset of this report, we consulted several technical and content experts. Broad expertise and perspectives are sought. Divergent and conflicted opinions are common and perceived as health scientific discourse that results in a thoughtful, relevant systematic review. Therefore, in the end, study questions, design, and/or methodologic approaches do not necessarily represent the views of individual technical and content experts.

Alan M. Adelman, M.D., M.S.
Penn State University
Hershey, PA

Apostolos Panagiotis Dallas, M.D.
Carilion Roanoke Memorial Hospital
Roanoke, VA

Catherine DuBeau, M.D.
UMass Memorial Medical Center
Worcester, MA

Mary Forciea, M.D., FACP
University of Pennsylvania
Philadelphia, PA

Leah Hole-Curry, J.D.
Washington Health Care Authority
Olympia, WA

Diane Newman, R.N.C., M.S.N., CRNP, FAAN
University of Pennsylvania Medical Center
Philadelphia, PA

Ingrid Nygaard, M.D.
University of Utah School of Medicine
Salt Lake City, UT

Mary Patrick, R.N.
Department of Public Health & Human Services
Helena, MT

Suzanne Pope, M.B.A.
American Urological Association
Linthicum, MD

Amir Qaseem, M.D., Ph.D., M.H.A., FACP
American College of Physicians
Philadelphia, PA

Kenneth G. Schellhase, M.D., M.P.H.
Medical College of Wisconsin
Milwaukee, WI

Paul Shekelle, M.D.
RAND Corporation
Santa Monica, CA

J. Christian Winters, M.D., FACS
LSU Health Sciences Center
Metairie, LA

Peer Reviewers

We considered peer reviewer comments on a preliminary draft of this report in the preparation of this final report. Synthesis of the scientific literature presented here does not necessarily represent the views of individual reviewers.

Matthew Barber, M.D.
Cleveland Clinic
Cleveland, OH

Sandra Engberg, Ph.D., R.N., CRNP
University of Pittsburgh
Pittsburgh, PA

Ingrid Nygaard, M.D.
University of Utah School of Medicine
Salt Lake City, UT

Eric Rovner, M.D. Medical University of South Carolina
Charleston, SC

David Thom, M.D. M.P.H., Ph.D.
San Francisco General Hospital
San Francisco, CA

Nonsurgical Treatments for Urinary Incontinence in Adult Women: Diagnosis and Comparative Effectiveness

Structured Abstract

Objectives. Our objectives were to assess methods to diagnose urinary incontinence (UI) and monitor treatment effectiveness in community-dwelling adult women, and to assess clinical efficacy and comparative effectiveness of pharmacological and nonsurgical treatments for UI.

Data Sources. We searched major electronic bibliographic databases, the FDA (Food and Drug Administration) reviews, trial registries, and research grant databases up to December 30, 2011.

Review Methods. A systematic review of diagnostic studies and therapeutic randomized and nonrandomized studies published in English was performed to synthesize diagnostic accuracy; minimally clinically important differences in validated tools for diagnosing UI; and rates of continence, improvements in UI, and harms of examined treatments. We calculated pooled absolute risk differences to estimate the number needed to treat (NNT) to achieve continence or avoid harms with random effects models.

Results. From a total of 905 eligible references, 99 studies showed minimal diagnostic value of tests to distinguish urodynamic stress or urgency UI; 57 studies suggested specific ranges of improvement in UI frequency (based on voiding diaries) that women considered important, as well as the value of quality-of-life assessment with validated checklists or scales. Pretreatment urodynamic diagnoses were not associated with better predictions of nonsurgical treatment outcomes. Continence was achieved in one woman with urgency UI for every eight women treated with fesoterodine (NNT 8, 95 percent CI [confidence interval], 5 to 17), 12 with tolterodine (NNT=12, 95 percent CI, 8 to 25), nine with oxybutynin (NNT=9, 95 percent CI, 6 to 16), nine with solifenacin (NNT=9, 95 percent CI, 6 to 17), and nine with trospium (NNT=9, 95 percent CI, 7 to 12). Discontinuation of treatment due to adverse effects occurred in one woman for every 33 treated with fesoterodine (NNT=33, 95 percent CI, 18 to 102), 16 with oxybutynin (NNT=16, 95 percent CI, 8 to 86), 56 with trospium (NNT=56, 95 percent CI, 30 to 228), and 78 with solifenacin (NNT=78, 95 percent CI, 39 to 823). Discontinuation due to adverse effects occurred more often with fesoterodine or oxybutynin than with tolterodine. Continence was achieved in one woman for every three treated with pelvic floor muscle training (NNT=3, 95 percent CI, 2 to 5), six with pelvic floor muscle training combined with bladder training (NNT=6, 95 percent CI, 4 to 16), and six with intravaginal electrical stimulations (NNT=6, 95 percent CI, 4 to 16). Weight loss improved UI in obese women. Improvement in UI and quality of life were examined using different definitions, which hampered the synthesis of evidence. Evidence was insufficient from which to conclude prediction of treatment effects by age, race, baseline severity of UI, and comorbidities.

Conclusions. Clinical evaluation with validated tools for diagnosis of UI, its type, frequency, severity, and impact on quality of life informs nonsurgical treatment decisions. Women determine treatment satisfaction and success according to clinically important reductions in UI frequency as recorded in voiding diaries and with clinically important improvements on

condition-specific quality-of-life scales. Benefits from pelvic floor muscle training, bladder training, and electrical stimulation are large, and adverse effects are uncommon. Benefits from drugs are small. Drugs for urgency UI have comparable effectiveness. Evidence about long-term adherence to and safety of all available treatments is insufficient.

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Executive Summary

Background

Urinary incontinence (UI) is the involuntary loss of urine.[1] About 25 percent of young women,[2] 44 to 57 percent of middle-aged and postmenopausal women,[3] and about 75 percent of older women experience some involuntary urine loss.[4] UI can affect women's physical, psychological, and social well-being, and sometimes imposes significant lifestyle restrictions. The effects of UI range from slightly bothersome to debilitating.

The cost of incontinence care in the United States averaged $19.5 billion in 2004.[5] Six percent of nursing home admissions of older women are attributable to UI,[5] and by one estimate, the annualized cost of women's nursing home admissions due to UI was $3 billion.[6]

Nonpharmacological therapies target strengthening the pelvic floor and changing behaviors that influence bladder function, whereas pharmacological therapies address innervating the bladder and sphincter. The etiology of incontinence is multifactorial; risk factors include age, pregnancy, pelvic floor trauma after vaginal delivery, menopause, hysterectomy, obesity, urinary tract infections, functional and/or cognitive impairment, chronic cough, and constipation.[7] Assessments of women complaining of UI begin with exclusion of underlying causes such as pelvic organ prolapse, urinary tract infection, and poor bladder emptying,[8] all of which are beyond the scope of this review, as is neurogenic UI associated with spinal cord injury or stroke.[9] We focus specifically on women with stress UI associated with sphincter function, and with urgency UI, often associated with overactive bladder (Table 1 in the full report).

Incontinence types are distinguished by their baseline mechanisms. Stress incontinence is associated with impaired sphincter function, and results in an inability to retain urine during coughing or sneezing.[9] Urgency incontinence is defined as involuntary loss of urine associated with the sensation of a sudden compelling urge to void that is difficult to defer.[9] Mixed UI is the term applied when both stress and urgency UI are present. These definitions reflect the consensus definitions developed by the International Urogynecological Association/International Continence Society.[9] Overactive bladder is defined as urinary urgency with or without incontinence, usually accompanied by frequency and nocturia (the need to urinate at night).[9] Approximately one-third of women with overactive bladder also experience urgency UI.

The types of UI imply different attendant risk factors and recommended treatments; however, UI etiology is frequently mixed.[8] Stress UI is more common in younger women in association with pelvic floor trauma and uterine prolapse, both of which are often related to vaginal delivery and may require surgical treatments.[7] Urgency and mixed UI are more common in older women in association with overactive bladders with or without sphincter dysfunction.[1,7]

Although UI can be diagnosed based on patients' reports of involuntary urine leakage,[7] researchers have also proposed clinical methods for objective diagnosis of different UI types. Urodynamic diagnosis of pure stress UI without detrusor overactivity has demonstrated usefulness for women undergoing surgery for stress UI.[9] Diagnostic studies use multichannel urodynamics as a reference standard test to compare with noninvasive tests applicable to ambulatory care. However, researchers disagree on whether urodynamic examination represents the gold standard for UI diagnosis.[8] Furthermore, urodynamic examination is not possible in ambulatory primary care. Previously published systematic reviews have reported a weak association between urodynamic test results and self-reported symptoms,[10] but these reviews did not focus on the most appropriate methods to distinguish different types of UI in ambulatory care

settings. The role of invasive diagnostic methods in predicting which patients will benefit from specific treatments for UI remains unclear.

Standard UI treatments for women include lifestyle changes, pelvic floor muscle training, and, for predominant stress UI, surgical treatments.[1] In addition, several drugs have been approved for adults with overactive bladder, with or without urgency UI.[1] Clinical interventions to reduce the frequency of UI episodes in women have been extensively reviewed in recent years,[8,11] but the reviews did not emphasize continence or women's perceptions of treatment success and satisfaction. Continence (complete voluntary control of the bladder) has been considered a primary goal in UI treatment[8,12] and is the most important outcome associated with quality of life in women with UI;[13] yet, it is rarely examined as a primary outcome in syntheses of evidence.[14] Thus, we focus on continence and quality of life as primary outcomes for this Comparative Effectiveness Review.

While definitions of continence are similar, the definitions most commonly applied to improvement in UI vary and include different degrees of change in frequency and severity of symptoms.[15] Furthermore, improvement in UI has been viewed very differently by women and by researchers. Women define improvement according to reduced lifestyle restrictions or improved overall perception of bladder symptoms, especially resolution of urine leakage, whereas researchers define improvement as a decrease in the amount of lost urine during pad tests, or any statistically significant decrease in the frequency of UI episodes.[15] Treatments for overactive bladder aim to decrease the frequency and intensity of urgency sensations, as well as the frequency of urgency UI episodes. Previous reviews of treatments for overactive bladder have considered clinical success as any statistically significant decrease in the frequency of UI episodes and voiding, irrespective of whether women perceived improvement.[14] Measurement of treatment outcomes should be patient centered and based on factors important to women, rather than on the results of invasive tests.[12] Thus, treatment success and failure should be evaluated according to what women report in validated questionnaires or scales. Ultimately, discussions of UI are complicated by the wide variety of measures used to describe the problem and its treatment outcomes. This review examines improvement thresholds of clinical importance in validated scales and checklists that can be applied to judge UI treatment success according to women's own perceptions.

This report synthesizes published evidence about diagnosis and management of UI in adult women. We focused on adult women in ambulatory care settings and on nonsurgical nonpharmacological treatments and pharmacological agents available in the United States. This report is intended as a companion piece to an earlier Evidence-based Practice Center report[7] that examined a wide range of treatment alternatives, including surgery. We focus on techniques appropriate to primary care ambulatory practice and nonsurgical interventions for women with refractory UI.

Our report also addresses the role of urodynamic testing, which is not typically performed in primary care. We include it here primarily as background information for primary care practitioners, and because it raises a conundrum. As we have emphasized, the primary outcome for UI should be patient-centered reports of the UI experience, especially the presence or absence of UI. Although we typically think of physiological testing as more objective than patient reports, these results are, at best, akin to intermediate outcomes. In the diagnostic context, physiological testing can inform in one of three ways: (1) establishing a diagnosis, (2) determining an etiology with therapeutic implications, and (3) generating a prognosis. In the case of UI, it is unclear whether physiological measures represent a gold standard against which

other measures can be compared, or whether they should be viewed as information that may predict key patient-centered outcomes. Hence, we may be more interested in levels of agreement between physiological measures and patient outcomes but hard pressed to interpret differences between them. We examine the role of urodynamic testing in diagnosing and treating UI to provide insight into this conundrum.

Our systematic review is intended to help clinicians, consumers, and policymakers make clinical recommendations and informed decisions based on synthesized evidence and other relevant factors.

Objectives

We present a comprehensive synthesis of evidence regarding valid methods to diagnose UI in adult women and to monitor treatment benefits and harms. We evaluated the clinical efficacy and comparative effectiveness of pharmacological and nonsurgical treatments for UI in adult women following the principles from the Methods Guide for Effectiveness and Comparative Effectiveness Reviews from the Agency for Healthcare Research and Quality (AHRQ) (www.effectivehealthcare.ahrq.gov). We examined the following questions:

Key Question 1. What constitutes an adequate diagnostic evaluation for women in the ambulatory care setting on which to base treatment of urinary incontinence?

- What are the diagnostic values of different methods—questionnaires, checklists, scales, self-reports of UI during a clinical examination, pad tests, and ultrasound—when compared with multichannel urodynamics?
- What are the diagnostic values of different methods—questionnaires, checklists, scales, self-reports of UI during a clinical examination, pad tests, and ultrasound—when compared with a bladder diary?
- What are the diagnostic values of the methods listed above for different types of UI, including stress, urgency, and mixed incontinence?
- What is the association between patient outcomes (continence, severity and frequency of UI, quality of life) and UI diagnostic methods?

Key Question 2. How effective is the pharmacological treatment of UI in women?

1. How do pharmacologic treatments affect continence, severity and frequency of UI, and quality of life when compared with no active treatment or with combined treatment modalities?
2. What is the comparative effectiveness of pharmacological treatments when compared with each other or with nonpharmacological treatments of UI?
3. What are the harms from pharmacological treatments when compared with no active treatment?
4. What are the harms from pharmacological treatments when compared with each other or with nonpharmacological treatments of UI?
5. Which patient characteristics, including age, type of UI, severity of UI, baseline disease that affects UI, adherence to treatment recommendations, and comorbidities, can modify the effects of the pharmacological treatments on patient outcomes, including continence, quality of life, and harms?

Key Question 3. How effective is the nonpharmacological treatment of UI in women?

1. How do nonpharmacological treatments affect incontinence, UI severity and frequency, and quality of life when compared with no active treatment?
2. How do combined modalities of nonpharmacological treatments with drugs affect incontinence, UI severity and frequency, and quality of life when compared with no active treatment or with monotherapy?
3. What is the comparative effectiveness of nonpharmacological treatments when compared with each other?
4. What are the harms from nonpharmacological treatments when compared with no active treatment?
5. What are the harms from nonpharmacological treatments when compared with each other?
6. Which patient characteristics, including age, type of UI, severity of UI, baseline disease that affects UI, adherence to treatment recommendations, and comorbidities, can modify the effects of the nonpharmacological treatments on patient outcomes, including continence, quality of life, and harms?

Methods

Input From Stakeholders

We developed research questions and an analytic framework after discussions with key informants and technical experts. Research questions for the systematic review were posted for public comment, based on which we identified interventions eligible for this review. Stakeholders recommended a focus on patient-centered outcomes and interventions most relevant for ambulatory care and not evaluated in previous systematic reviews. Stakeholders also recommended reviewing nonsurgical interventions relevant to women with refractory UI. Comprehensive information about all nonsurgical treatment choices can lead to evidence-based referral practices for women with refractory UI.

Candidates to serve as key informants, technical experts, and peer reviewers were approved by the Task Order Officer from AHRQ after disclosure of conflicts of interest. The protocol was developed with input from the Technical Expert Panel.

Data Sources and Selection

We sought studies from MEDLINE® via OVID and via PubMed®, the Cochrane Library, SCIRUS, Google Scholar, other databases, and manual searches of reference lists from systematic reviews. We identified studies published in English from 1990 through December 30, 2011.

Study Selection

Three investigators independently determined the eligibility of the studies. For Key Question 1, we included studies that evaluated different methods to diagnose UI in women that are applicable to ambulatory care settings. Index methods that are applicable to ambulatory care settings were compared in eligible studies with urodynamic or clinical diagnosis of UI made by investigators in specialized clinics.

For Key Questions 2 and 3, we included randomized controlled trials (RCTs) that combined men and women if they reported outcomes in women separately or included more than 75 percent women. We excluded studies of men, children, or residents of long-term care facilities. We excluded studies of surgical treatments for UI or urogenital prolapse and studies of drugs not available in the United States.We analyzed harms regardless of how authors perceived the causality of treatments. We included observational studies with adjusted treatment estimates. We included observational studies of treatments not examined in RCTs.

Data Extraction

Evaluations of the studies, data extraction, and quality control were conducted by four researchers using a standardized form. We abstracted minimum datasets for diagnostic and therapeutic studies. We abstracted inclusion of minorities, inclusion of women who failed prior therapy for UI, inclusion of mixed UI, baseline daily UI, and presence of urogenital prolapse or hysterectomy in female participants. We focused on urgency UI in women with overactive bladder and did not analyze urgency, voiding frequency, or nocturia.

Quality Assessment

We evaluated the quality of studies and classified them by their designs. We evaluated studies for Key Question 1 with predefined criteria for assessing the quality of the diagnostic accuracy of studies. We evaluated the quality of therapeutic studies using predefined criteria to assess the risk of bias, which included randomization, adequacy of randomization and allocation concealment, masking of the treatment status, and intention-to-treat analyses. We examined sponsorship and conflict of interest but did not downgrade quality using this information. We incorporated quality in the synthesis of evidence, conducting meta-regression, subgroup, and sensitivity analysis for each quality criterion rather than for the overall quality score. Well-designed RCTs are believed to have a low risk of bias. We defined studies as having a medium or high risk of bias if one or more quality criteria were not met.

Applicability of the population was estimated by evaluating the selection of women in observational studies and clinical trials. For each study, we examined settings, including ambulatory care or specialized clinics, recruitment in the clinical settings or in the community, inclusion age and type of UI, and exclusion criteria.

Data Synthesis and Analysis

For Key Question 1, results of individual studies were summarized to analyze sensitivity, specificity, predictive values, diagnostic odds ratios, and predictive likelihood ratios for correct diagnosis of any, stress, and urgency UI. We focused on the predictive likelihood ratios of UI in women examined with index tests when compared to women who had urodynamic or clinical diagnosis. Ratios of 1 indicated that the tests likely do not provide accurate UI diagnosis. Ratios of more than 10 provided large and often conclusive increases in the likelihood of UI. We pooled diagnostic test data with random effects models using an inverse variance weighting method with Meta-Analyst software. Random effects meta-analyses incorporate heterogeneity by assuming a normal distribution of underlying effects. In cases of heterogeneity, we used bivariate pooling methods.

Following guidelines and recommendations from key informants and members of our Technical Expert Panel, we focused on patient-centered outcomes, including continence,

improvement in UI, quality of life, adverse effects, and discontinuation due to adverse effects. Voiding frequency in women with overactive bladder had been reviewed previously and was outside of our scope. The methods to assess harms were not assessed for validity. For Key Questions 2 and 3, we calculated relative risk, absolute risk differences, number needed to treat, and the number of events attributable to active treatment per 1,000 persons treated for binary outcomes. We assessed missing data across studies, including loss to followup and dropout patterns, and forced intention-to-treat analyses using the number of randomized subjects for all calculations.

Meta-analysis was conducted when clinical populations, interventions, and outcomes were deemed sufficiently similar. We chose the random-effects inverse variance weights model to incorporate in the pooled analysis differences across trials in patient populations, baseline rates of the outcomes, dosage of drugs, and other factors. We analyzed adverse effects with drugs for urgency UI using double arcsine transformations of the event rates. We examined consistency in results across studies with Chi square tests and I square statistics. Using a standard preplanned algorithm, we explored heterogeneity with meta-regression, subgroup, and sensitivity analysis by clinical diversity, treatment dose and duration, and quality criteria of individual studies, and whether conflict of interest was disclosed by study authors. When exploring heterogeneity, we did not use subject-level variables to avoid an ecological fallacy. We calculated Bayesian odds ratios with 95 percent credible intervals. All calculations were performed using Meta-Analyst and STATA (Statistics/Data analysis, 10.1) software at 95 percent confidence limits. We assumed publication bias, and did conduct formal statistical tests.

We assessed strength of evidence and judged it according to the domains of risk of bias, consistency, directness, and precision for each major outcome. We defined evidence as strong when several well-designed RCTs with a low risk of bias demonstrated consistent treatment effects. Significant dose-response association or large magnitude of treatment effects increased the level of evidence. We defined evidence as insufficient when only a single study examined treatment effects or associations.

Results

We identified and retrieved 5,185 references. We included 905 references for this review.

Diagnosis of UI

For Key Question 1, 99 studies of 81,043 women provided information on different methods for diagnosing UI. Described use of urodynamic testing as a reference standard test was very similar across the studies. Diagnostic methods to establish a clinical diagnosis of UI were described with different levels of detail and included patient history, physical and pelvic examination, urine culture, and other instrumental measures.

The majority of studies demonstrated that the tests had only small diagnostic value in distinguishing women with urodynamic stress or urgency UI (Table A). The diagnostic values were similar after random effects versus bivariate pooling methods. The quality of the studies did not explain statistical heterogeneity in pooled estimates.

Measuring Treatment Success

Urodynamic evaluation, which was used as a reference method in many diagnostic studies, detects the presence of UI but not the frequency and severity of UI episodes. Validated tools to

measure UI treatment success based on meaningful changes in symptoms and quality of life for women include the Incontinence Severity Index; Patient Global Impression of Improvement and of Severity; Patient Perception of Bladder Condition; Urogenital Distress Inventory; Bladder Self-Assessment Questionnaire; International Consultation on Incontinence Modular Questionnaire-SF; Incontinence Impact Questionnaire; Urinary Incontinence-Specific Quality of Life Instrument; King's Health Questionnaire; and Protection, Amount, Frequency, Adjustment, Body Image assessment tool.

A reduction in UI episode frequency assessed with a 3- to 7-day diary was the most common primary outcome in the included RCTs. Importantly, women with daily stress UI perceived important clinical benefit at reductions of approximately 50 percent and important incremental clinical value at reductions of 75 percent and 90 to 100 percent. Women reported improved quality of life and clinical success only when they experienced a greater than 70 percent reduction in urinary episode frequency assessed by a voiding diary. Smaller decreases (20 to 40 percent) in UI episode frequency were not clinically important when the results from a voiding diary were analyzed in association with the validated Incontinence Quality of Life questionnaire. The quality-of-life impact was similar for stress UI episode reductions of >40 percent to <70 percent. In the case of women with persistent urge, stress, or mixed UI, more than 60 percent reported complete treatment satisfaction on the Global Perception of Improvement and Incontinence Impact Questionnaire when they experienced more than 70 percent reduction in UI episodes according to voiding diaries.

The few RCTs that analyzed differences in outcomes depending on baseline urodynamic diagnosis versus self-reported symptoms of stress, urgency, or mixed UI suggested no advantage with urodynamic diagnosis. However, baseline urodynamic evaluation resulted in better prediction of harms from surgery for stress UI refractory to conservative treatments.

Evidence was insufficient for the superiority of urodynamic evaluation's prediction of nonsurgical treatment outcomes compared to diagnosis based on self-reported symptoms. Women's perceptions of treatment success depend upon clinically important differences in their voiding diaries, scales, questionnaires, and impressions of global improvement.

Efficacy of Pharmacological Treatments

We synthesized the evidence of efficacy and comparative effectiveness of the drugs for predominant stress UI (including topical estrogen and serotonin-noradrenalin uptake inhibitors) and drugs for overactive bladder. Table B demonstrates how many studies were examined for each outcome, how many subjects participated in the studies, and what percentage of subjects experienced the outcomes. The last column indicates our level of confidence that the evidence reflects the true effect of the treatment and that future research is unlikely to change the estimate of effect (Appendix Table F1 in the full report). Drugs were more effective than placebo in achieving continence and improving UI, but the magnitude of effect was low. The absolute risk difference in continence was less than 20 percent for all drugs. Pharmacological treatments resulted in fewer than 200 cases of continence attributable to the drugs per 1,000 treated. The studies had good quality with low risk of bias. Individual quality criteria and disclosure of conflict of interest were not associated with differences in the results.

Stress UI

Estrogen

Individual RCTs indicated greater continence and improvement in UI with vaginal estrogen formulations and worsening of UI with transdermal patches.

Duloxetine

Duloxetine did not resolve stress UI when compared to placebo (Table B). The risk of adverse effects was significantly higher with duloxetine than with placebo. Duloxetine resulted in improved UI in 75-140 women per 1,000 treated, while 129 women per 1,000 treated stopped taking duloxetine because of adverse effects.

Urgency UI

Oxybutynin

Oxybutynin increased continence rates and improved UI more often than placebo but also resulted in treatment discontinuation due to adverse effects. Oxybutynin resolved UI in 114 women per 1,000 treated (95% CI, 64 to 163), while 63 women per 1,000 treated (95% CI, 12 to 127) discontinued oxybutynin because of adverse effects.

Tolterodine

Tolterodine increased continence rates and significantly improved UI more often than placebo. Tolterodine resolved UI in 85 women per 1,000 treated (95% CI, 40 to 129), while 83 women per 1,000 treated (95% CI, 47 to 120) experienced adverse effects. Discontinuation of treatment due to adverse effects did not differ between tolterodine and placebo.

Darifenacin

Darifenacin significantly improved urgency UI and several domains of quality of life more often than placebo. Darifenacin improved UI in 117 women per 1,000 treated (95% CI 57 to 177), while 190 women per 1,000 treated (95% CI, 118 to 260) experienced adverse effects. Treatment discontinuation rates due to adverse effects did not differ between darifenacin and placebo.

Solifenacin

Solifenacin increased continence rates; higher doses resulted in greater benefits. Treatment discontinuation due to adverse effects was more common with solifenacin than with placebo. Solifenacin resolved UI in 107 women per 1,000 treated (95% CI, 58 to 156), while 13 women per 1,000 (95% CI, 1 to 26) discontinued treatment because of adverse effects.

Fesoterodine

Fesoterodine increased continence rates. Significant improvement in UI with fesoterodine compared to placebo was dose responsive. Fesoterodine resulted in higher rates of adverse effects and discontinuation of treatment due to adverse effects than placebo. Fesoterodine resolved UI in 130 women per 1,000 treated (95 percent CI, 58 to 202), while 31 women per 1,000 (95 percent CI, 10 to 56) stopped treatment due to adverse effects.

Trospium

Trospium increased continence rates more often than placebo. Risk of adverse effects was greater with trospium than with placebo. Trospium resolved UI in 114 women per 1,000 treated (95% CI, 83 to 144), while 18 women per 1,000 (95% CI, 4 to 33) stopped treatment because of harmful adverse effects.

Comparative Effectiveness of Pharmacological Treatments

Evidence of the comparative effectiveness of different drugs was insufficient for the majority of comparisons. Oxybutynin and tolterodine had the same benefits, but tolterodine was safer. The numbers needed to treat (NNT) to achieve continence in one woman were similar across drugs. Treatment discontinuation due to adverse effects was greater than with placebo for all drugs, excluding darifenacin and tolterodine; NNT to achieve discontinuation due to adverse effects was highest with solifenacin (NNT=78) and lowest with oxybutynin (NNT=16). Several retrospective observational studies analyzed the long-term comparative effectiveness and safety of pharmacological treatments for UI. The evidence-based cost utility analysis reported that more than half of patients stop taking drugs for UI after 1 year of treatment. The lowest rates of treatment discontinuation were with 5 mg of solifenacin.[16]

Role of Patient Characteristics on Outcomes of Pharmacological Treatments

Age

Treatment response was similar across age groups. Solifenacin increased continence rates more often than placebo, regardless of age.

Oxybutynin, trospium, and darifenacin improved UI in older women. Oxybutynin reduced UI frequency and produced subjective benefits compared to placebo in frail community-dwelling older people. Darifenacin improved UI when compared to placebo in older women. The drug needed to be given to eight older patients to achieve more than a 50 percent reduction in UI episodes in one person. Cognitive function changes did not differ between darifenacin and placebo in short-term (2-week) treatment. Trospium improved UI and quality of life in older subjects with overactive bladder. Solifenacin caused serious adverse effects less often than oxybutynin in older patients, with no differences between the drugs in younger patients.

Race

We found limited evidence about treatment responses in race subgroups. Only one study, of duloxetine, examined clinical outcomes in different race groups. Evidence was inconclusive about racial differences in the treatment effects of duloxetine in women with stress UI.

Comorbidities

One RCT examined the role of comorbidities. Duloxetine was no better than placebo in women with depression, diabetes, and chronic lung diseases. Trospium was effective in resolving UI regardless of body mass index in obese and normal weight women.

Baseline UI

Evidence was limited from which to conclude any differences in benefits by baseline frequency and severity of UI. Studies found no differences in outcomes between tolterodine and solifenacin in subjects with baseline mixed or pure urgency UI. Subjects with mixed UI may require a larger dose and longer treatment than women with urgency UI to achieve clinical benefits from solifenacin. Inclusion of women with mixed UI did not significantly modify the treatment benefits from oxybutynin and solifenacin across the studies in meta-regression and subgroup analyses.

The baseline frequency of UI did not dramatically modify the effects of the drugs on clinical outcomes. Subjects with more frequent UI had slightly greater benefits with solifenacin or fesoterodine than with placebo. In contrast, trospium was better than placebo at resolving UI only in subjects with fewer than five UI episodes per day. Trospium did not resolve UI in subgroups with more than five episodes of UI per day (relative risk [RR] 1.2, 95% CI, 0.93 to 1.56).

Prior Treatment Response

Solifenacin was effective regardless of the response to previous treatments; however, poor responders did not benefit from increasing the dose of the drug. We could not examine differences in the treatment response to other drugs among those who failed prior treatments because the studies provided neither subgroup analyses within trials nor consistent reporting of the percentage of nonresponders for subgroup analyses across the trials.

Concomitant Treatments

Trospium reduced the number of urgency UI episodes irrespective of concomitant medications. Adverse effects were more common in those taking seven or more concomitant medications.

Efficacy of Nonpharmacological Treatments

Nonpharmacological treatments were better than no active treatment in achieving continence and improving UI, according to RCTs (Table B). The magnitude of effect was large. The majority of the studies included women with mixed UI. Inclusion of women with mixed UI did not dramatically modify the treatment effects in meta-regression and subgroup analyses. We examined the effects of the interventions on predominant stress or urgency UI when the authors reported that information. A summary of the evidence of effectiveness of all treatments, including strength of evidence, is found in Table B.

Stress UI

Pelvic Floor Muscle Training

Pelvic floor muscle training (PFMT) increased continence rates and improved UI more often than usual care. PFMT combined with bladder training increased continence rates and improved mixed UI. PFMT with biofeedback improved UI.

Vaginal Cones

Evidence was insufficient from which to draw valid conclusions. Uncontrolled high risk of bias studies of other intravaginal and intraurethral devices demonstrated that they improved UI but also resulted in high discontinuation rates and adverse effects.

Intravaginal Electrical Stimulation

Intravaginal electrical stimulation increased continence rates and improved UI more often than sham stimulation.

Magnetic Stimulation

Magnetic stimulation improved UI but did not increase continence more than sham stimulation.

Urgency UI

Bladder Training

Bladder training improved UI when compared to usual care.

Percutaneous Tibial Nerve Stimulation

Percutaneous tibial nerve stimulation improved UI. Individual RCTs indicated no difference in adverse effects and treatment discontinuation with active or sham stimulation.

Mixed UI

Specialized Continence Services

Studies indicated no consistently greater benefits for continence or improvement of UI with continence services implemented by specialized providers compared to usual care. Comparison across studies was difficult because of the variety of interventions that constituted complex continence services.

Weight Loss

Weight loss and exercise improved UI in obese women without evident harms.

Comparative Effectiveness of Nonpharmacological Treatments

Clinical outcomes of one nonpharmacological treatment versus another were reported in 54 RCTs, but these trials rarely compared the same treatment effects, which decreased the strength of evidence to low.

We found no differences in UI between supervised PFMT combined with bladder training and self-administered PFMT. Continence did not differ between bladder training combined with PFMT and bladder training alone.

Indirect comparison indicated the comparable effectiveness of nonpharmacological treatments on continence. Cases of continence achieved per 1,000 treated were 299 for PFMT, 162 for electrical stimulation, and 166 for PFMT combined with bladder training. Rates of continence were comparable with different treatments: 38 percent of women became continent with PFMT, 23 percent became continent with electrical stimulation, and 21 percent became continent with PFMT combined with bladder training.

Discussion

Our findings agree with those of previously published systematic reviews of diagnosis and treatment of UI by AHRQ, the Cochrane Collaborative Group, and the International Consultation on Incontinence. Our report offers a comprehensive analysis of patient-centered outcomes, including continence, improvement in UI, and harms from nonsurgical treatments for female UI that are available in the United States.

Diagnosis of predominant stress or urgency UI in ambulatory care settings includes clinical history and evaluation, voiding diary, and validated scales.[17] Urodynamic diagnosis is more invasive and not applicable to ambulatory settings. Although it more sensitively distinguishes UI mechanisms, including detrusor overactivity, this added sensitivity did not better predict treatment benefits for patients undergoing nonsurgical UI treatments. It did, however, better predict harms from surgery for women with refractory UI by identifying women with detrusor overactivity, which is associated with greater risk of postsurgical urgency UI, an important quality-of-life outcome.[18] Studies of pharmacological treatments for urgency UI included women treated surgically for stress UI but did not distinguish treatment effects within this subpopulation.[19]

Outcome evaluations for treatments of female UI address issues that women consider important: continence, 50 to 70 percent or more reduction in UI episode frequency, meaningful changes in scales measuring quality of life, and treatment satisfaction.[20] However, previous reviews of drugs for overactive bladder have focused on other outcomes, such as reduction in frequency of both urgency micturition and urgency UI episodes.[14,21,22] The majority of drug RCTs were designed to test differences in the frequency of UI episodes. Medical and statistical reviews by the Food and Drug Administration also focused on reduction in the frequency of UI. Based on women's definitions of clinical success, we focused on clinical outcomes, including continence and quality of life.

Policymakers should consider patient-centered outcomes when making regulatory decisions. Research based on patient-centered outcomes provides patients and clinicians the necessary information for effective and informed decisions about health care services.[23] Prescription drugs for UI all demonstrated more effectiveness than placebo in some women. The magnitude of the association was not strong, with fewer than 200 attributable cases of continence per 1,000 patients treated. Adverse effects were common with all drugs and varied between the drugs. Nonpharmacological treatments for UI showed clinically significant benefit with a large magnitude of effect and very few adverse effects.

Direct evidence for the comparative effectiveness of nonpharmacological treatments and drugs was insufficient. However, the few RCTs that compared clinical outcomes between nonpharmacological treatments and drugs found similar effectiveness but better safety with nondrug interventions. This finding is significant, considering that side effects from drugs were common and frequently bothersome enough to negatively affect treatment compliance and continuation. The synthesis of evidence was hampered by differences in definitions of improvement in UI, quality of life, and treatment-related adverse effects. Valid comparisons of benefits and harms with different treatments were possible only for studies that used similar definitions of the outcomes.

While the comparative safety of UI drugs could inform clinical decisions, information on long-term comparative safety was rarely available in RCTs, despite high discontinuation rates suggesting that there were adverse effects. Continuous monitoring of the drugs' adverse effects in clinical practice could provide information about long-term comparative safety. For example,

continuous prescription-event monitoring as a part of postmarketing surveillance has provided valuable information about the unfavorable long-term effects of tolterodine, which has been shown to have a significantly higher risk of hallucinations than 10 drugs of other therapeutic classes.[24]

Additionally, RCTs have not yet examined the role of concurrent treatments, but postmarketing surveillance could address the long-term safety of UI drugs when combined with other medications. For instance, relative risks of ventricular arrhythmias (adjusted RR 5.5, 95 percent CI, 1.3 to 22.3) or sudden death (adjusted RR 21.5, 95 percent CI, 5.2 to 88.3) were very high among older people using UI medications in combination with antihistamine/cytochrome inhibitors.[25]

Meanwhile, very few studies provided evidence for individualized treatment decisions. Evidence of aggregate treatment effects may not be applicable to individuals with specific characteristics.[26] An average treatment effect in a clinically diverse population may not reflect the actual effect for a specific group.[27] Yet few existing studies examined the role of clinical predictors of treatment failure and success in patient subpopulations.[28] Patient comorbidity and baseline severity of UI were associated with differences in treatment benefits. The direction and magnitude of the association varied. Benefits from solifenacin and fesoterodine were greater in those with more than two or three daily episodes of UI; trospium was not better than placebo in those with frequent baseline UI (>5 episodes/day). Which factors are associated with differences in harms remains unclear.

Adherence to UI treatments is poor. Treatment discontinuation due to adverse effects of drugs is common. Yet, very few studies have addressed adherence to treatment, pharmacological or nonpharmacological. Observational economic drug evaluations[29,30] have demonstrated greater absolute rates of treatment discontinuation due to adverse effects or treatment failure than have been demonstrated in RCTs. One possible explanatory factor for poor adherence is that polypharmacy or previous use of the drugs for urinary tract infections was associated with adherence to the drugs for overactive bladder in California Medicaid program beneficiaries.[31] Cost-effectiveness analyses[29,32] that should incorporate comparative effectiveness, safety, and adherence to treatments were beyond the scope of our review. High discontinuation rates also apply to nonpharmacologic treatments such as PFMT and bladder training. Reasons for poor adherence are not well established.

The nonsurgical treatments included in this review are applicable to ambulatory care settings. Appropriately trained continence nurses and physical therapists can provide high quality UI care for women; women were satisfied with care provided by continence nurses.[33-35] A large cross-sectional community survey by mail of women with UI in France, Germany, Spain, and the United Kingdom found that many women actually prefer to be treated for UI by primary care providers, despite easy access to specialized services.[36] However, adherence to evidence-based recommendations by ambulatory care providers is not satisfactory and should be improved.[37,38]

The quality of most drug RCTs was good. The majority of drug studies were double blind with adequate randomization and clear reporting of planned intention-to-treat analysis. Benefits and harms with drugs did not differ by individual quality criteria. We concluded that there was a low risk of bias in the drug studies.

Most nonpharmacological RCTs had good quality. Baseline data demonstrated the adequacy of randomization in the majority of RCTs. Double or single blinding was reported in approximately half of the RCTs. The quality of the studies, including intention-to-treat analysis and adequacy of allocation concealment, did not demonstrate significant modification of the

association between treatments and patient outcomes. We concluded that there was a moderate risk of bias in the nonpharmacological studies.

Our review has limitations. We restricted our review to English-language studies published in journals, presented at scientific meetings, reviewed by the Food and Drug Administration,[39] or reported on the ClinicalTrials.gov Web site. Even after such an exhaustive review of evidence, we do not know how many funded and unregistered studies we missed in our review. Evidence was insufficient for individualized treatment recommendations by age, race, comorbidity, and baseline UI. Evidence was also insufficient regarding women whose prior treatments had failed. However, previous research has demonstrated that women with stress UI whose conservative treatments failed may benefit from a tension-free vaginal tape procedure.[40] For women with urgency UI whose conservative treatments failed, percutaneous tibial nerve stimulation,[41] sacral neuromodulation,[42] and botulinum toxin injections[43] may be of benefit. Invasive treatments, including midurethral slings, sacral nerve stimulation, and radiofrequency ablation, were beyond our scope. We were unable to explain why drug efficacy studies reported substantially different outcome rates for the same comparator placebo treatments. Therefore, we avoided making indirect comparisons of drugs never tested in head-to-head RCTs.

Our report has implications for future research. Such research should clarify which characteristics of women, including age, race, genitourinary characteristics, and comorbidities, are associated with greater treatment benefits and adherence and fewer adverse events. Future studies should assess treatment success with primary outcomes centered on women, including long-term continence, reduction of 50 to 70 percent or more in UI episodes, and clinically important improvement in scales of severity and quality of life. All harms should be analyzed, regardless of investigator judgment about possible association with tested treatments. Nonsurgical treatments for predominant stress UI are limited to PFMT, with very few ongoing studies of bulking agents and devices. Future research should explore new treatment options for women with stress UI. The results from all studies, including 25 closed and 124 ongoing registered studies, should be made available for future reviews of evidence. A comparison of different methods of delivery of nonpharmacological interventions—Internet-based, group-based, and self-management—is also a possible area of future research, with great applicability for ambulatory care populations. Future research should address which factors might increase adherence to UI treatments. Finally, the preventive effects of PFMT, bladder training, and electrical stimulation in premenopausal women should be examined, and future large well-designed head-to-head randomized trials should examine whether combined drug and nonpharmacological treatment modalities are superior to mono-drug therapy.

Key Findings

Diagnosis

- Clinical evaluation with validated tools for diagnosis of UI, its type, frequency, severity, and impact on quality of life informs nonsurgical treatment decisions.
- Compared with diagnosis by patients' symptom reports, multichannel urodynamics did not better predict which patients would benefit from nonsurgical treatments.

Measuring Treatment Success

- Women with daily stress UI perceived important clinical benefit from reductions of approximately 50 percent in UI frequency and important incremental clinical value from reductions of 75 percent and 90 to 100 percent.
- Women reported improved quality of life and clinical success only when they experienced a greater than 70 percent reduction in UI episode frequency assessed by a voiding diary.
- More than 60 percent of women with persistent urgency, stress, or mixed UI reported complete treatment satisfaction when they experienced more than 70 percent reduction of UI episodes. Validated tools have been used to assess threshold values of clinical importance for evaluating treatment success in women.

Pharmacological Treatments

- All anticholinergic medications were more effective than placebo in achieving continence and improving UI, but the degree of benefit was low for all drug**s**, with fewer than 200 cases of continence attributable to treatment per 1,000 patients treated (absolute risk difference with placebo <20 percent).
- Treatment benefits, including continence, were achieved with antimuscarinic drugs, including trospium, solifenacin, fesoterodine, tolterodine, and oxybutynin.
- Drugs for urgency UI demonstrated similar effectiveness. Treatment discontinuation due to adverse effects was most common with oxybutynin and least common with solifenacin.
- Pharmacological treatments for stress UI, including off-label use of low-dose topical estrogen formulations, may improve stress UI in postmenopausal women.
- Duloxetine has an unfavorable balance between improvement in stress UI and treatment discontinuation due to adverse effects.
- Compliance rates for prescription drugs are low; discontinuation due to side effects is common. Dry mouth, constipation, and blurred vision were among the most frequent adverse effects.
- Evidence is insufficient for the long-term safety of pharmacological treatments.
- Women with urgency UI whose prior treatments failed may benefit from solifenacin; however, poor responders would not benefit from increasing the dose of the drug.
- Oxybutynin, trospium, and darifenacin improved UI in older women.

Nonpharmacological Treatments

- Nonpharmacological treatments result in significant clinical benefit with a low risk of adverse effects. The magnitude of benefit is large, with more than 100 percent relative difference in continence rates.
- Women with stress UI can achieve continence performing PFMT. Continence rates are similar between those who undergo PFMT with and without biofeedback.

Glossary

AHRQ	Agency for Healthcare Research and Quality
CI	Confidence interval

NNT	Number needed to treat
PFMT	Pelvic floor muscle training
RCT	Randomized controlled trial
RR	Relative risk
UI	Urinary incontinence

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Table A. Diagnostic value of the test for urinary incontinence (UI) in women (pooled with random effects models and bivariate pooling)

Type of incontinence	Method index	Reference standard	# of studies # of subjects	Sensitivity/ bivariate pooling	Specificity/ bivariate pooling	Positive likelihood ratio[1]	Negative likelihood ratio[1]	Positive predictive value	Negative predictive value
Urodynamic stress UI	Symptoms of stress UI	Urodynamic test	27 5,780	0.93[2] (0.90 to 0.95) 0.94 (0.91 to 0.96)	0.41[2] (0.34 to 0.49) 0.41 (0.31 to 0.51)	1.54 (1.40 to 1.7)	0.20 (0.14 to 0.27)	0.74 (0.68 to 0.80)	0.74 (0.67 to 0.81)
Detrusor overactivity	Symptoms of urgency UI	Urodynamic test	23 5,485	0.82[2] (0.76 to 0.87) 0.82 (0.75 to 0.88)	0.51[2] (0.44 to 0.59) 0.52 (0.40 to 0.65)	1.54 (1.38 to 1.73)	0.39 (0.30 to 0.50)	0.56 (0.48 to 0.63)	0.80 (0.73 to 0.86)
Detrusor overactivity	Symptoms of urgency	Urodynamic test	9 6,418	0.84[2] (0.59 to 0.95) 0.82 (0.70 to 0.92)	0.39[2] (0.17 to 0.67) 0.39 (0.24 to 0.55)	1.36 (1.18 to 1.58)	0.47 (0.33 to 0.67)	0.48 (0.39 to 0.57)	0.75 (0.67 to 0.81)
Detrusor overactivity[3]	Symptoms of urgency UI	Urodynamic test	17 3,924	0.84[2] (0.78 to 0.89) 0.84 (0.79 to 0.90)	0.43[2] (0.36 to 0.50) 0.44 (0.34 to 0.54)	1.48 (1.31 to 1.66)	0.40 (0.29 to 0.54)	0.33 (0.26 to 0.41)	0.89 (0.83 to 0.93)
Detrusor overactivity[3]	Symptoms of urgency	Urodynamic test	6 1,598	0.86 (0.83 to 0.89) 0.86 (0.80 to 0.90)	0.31[2] (0.24 to 0.39) 0.31 (0.20 to 0.45)	1.21 (1.11 to 1.32)	0.523 (0.41 to 0.67)	0.27 (0.17 to 0.40)	0.86 (0.76 to0.93)
Mixed UI	Symptoms of stress and urgency UI	Urodynamic test	11 2,767	0.73[2] (0.61 to 0.82) 0.72 (0.58 to 0.83)	0.53[2] (0.40 to 0.66) 0.53 (0.34 to 0.72)	1.45 (1.27 to 1.67)	0.61 (0.52 to 0.71)	0.26 (0.20 to 0.34)	0.89 (0.85 to 0.92)
Urodynamic stress UI	Pad test	Urodynamic test	3 574	0.84 (0.76 to 0.90) 0.83 (0.75 to 0.91)	0.77 (0.72 to 0.82) 0.77 (0.17 to 0.97)	3.62 (2.88 to 4.57)	0.22 (0.15 to 0.32)	0.82 (0.77 to 0.86)	0.78 (0.73 to 0.83)
Detrusor overactivity	Pad	Urodynamic test	2 469	0.72[2] (0.30 to 0.94)	0.56[2] (0.38 to 0.72)	1.56 (0.62 to 3.90)	0.47 (0.10 to 2.33)	0.32 (0.04 to 0.83)	0.88 (0.83 to 0.91)

Table A. Diagnostic value of the test for urinary incontinence (UI) in women (pooled with random effects models and bivariate pooling) (continued)

Type of incontinence	Method index	Reference standard	# of studies # of subjects	Sensitivity/ bivariate pooling	Specificity/ bivariate pooling	Positive likelihood ratio[1]	Negative likelihood ratio[1]	Positive predictive value	Negative predictive value
Urodynamic stress UI	Symptoms of stress UI	Clinical diagnosis	5 947	0.88[2] (0.68 to 0.96) 0.86 (0.70 to 0.96)	0.67[2] (0.54 to 0.78) 0.67 (0.51 to 0.81)	2.35 (1.97 to 2.81)	0.19 (0.09 to 0.41)	0.80 (0.66 to 0.89)	0.75 (0.58 to 0.87)
Detrusor overactivity	Symptoms of urgency UI	Clinical diagnosis	4 735	0.82[2] (0.73 to 0.89) 0.82 (0.73 to 0.90)	0.67[2] (0.53 to 0.79) 0.67 (0.45 to 0.86)	2.52 (1.81 to 3.50)	0.26 (0.18 to 0.38)	0.72 (0.48 to 0.88)	0.79 (0.54 to 0.92)
Mixed UI	Symptoms of stress and urgency UI	Clinical diagnosis	3 654	0.65[2] (0.36 to 0.86) 0.64 (0.38 to 0.85)	0.54[2] (0.21 to 0.84) 0.52 (0.06 to 0.94)	1.57 (0.68 to 3.59)	0.74 (0.28 to 1.95)	0.36 (0.27 to 0.47)	0.80 (0.43 to 0.96)
Urodynamic stress UI	Q-tip test	Urodynamic test	3 267	0.62 (0.53 to 0.70) 0.62 (0.49 to 0.74)	0.60[2] (0.40 to 0.78) 0.58 (0.00 to 1.00)	1.70 (0.89 to 3.23)	0.60 (0.31 to 1.17)	0.58 (0.26 to 0.85)	0.67 (0.34 to 0.89)

[1]Clinical interpretations of likelihood ratios:

Likelihood ratio	Interpretation
>10	Large and often conclusive increase in the likelihood of disease
5-10	Moderate increase in the likelihood of disease
2-5	Small increase in the likelihood of disease
1-2	Minimal increase in the likelihood of disease
1	No change in the likelihood of disease

[2]Significant heterogeneity

[3]Pure type

Table B. Clinical outcomes with treatments for UI (pooled with random effects estimates from head-to-head RCTs)

Treatments	Outcomes	Number of studies	Patients	Rate, % active/ control	Relative risk (95% CI)	Absolute risk difference* (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)	Effect in relative/ absolute scale	Evidence
Pharmacological treatments for stress UI										
Duloxetine vs. placebo	Continence	2	736	38/40	0.92 (0.86 to 0.99)	-0.03 (-0.12 to 0.06)			↓/NS	Low
Duloxetine vs. placebo	Improved UI	4	1,138	37/29	1.68 (0.94 to 3.00)	0.08 (0.01 to 0.14)	13 (7 to 143)	75 (7 to 142)	NS/↑	High
Duloxetine vs. placebo	Discontinuation due to adverse effects	9	3,252	16/3	4.4 (3.24 to 5.86)	0.13 (0.06 to 0.19)	8 (5 to 16)	129 (64 to 193)	↑	High
Pharmacological treatments for urgency UI										
Darifenacin vs. placebo	Improved UI	3	1,011	48/33	1.3 (1.2 to 1.5)	0.12 (0.06 to 0.17)	9 (6 to 18)	117 (57 to 177)	↑	High
Darifenacin vs. placebo	Discontinuation due to adverse effects	7	3,138	5/3	1.2 (0.8 to 1.8)	0.00 (-0.01 to 0.02)			NS	High
Darifenacin vs. placebo	Discontinuation due to failure	4	1,280	1/2	0.6 (0.2 to 1.7)	-0.01 (-0.02 to 0.01)			NS	Moderate
Fesoterodine vs. placebo	Continence	2	2,465	61/48	1.3 (1.1 to 1.5)	0.13 (0.06 to 0.20)	8 (5 to 17)	130 (58 to 202)	↑	Low
Fesoterodine vs. placebo	Improved UI	2	1,896	42/32	1.3 (1.2 to 1.5)	0.10 (0.06 to 0.15)	10 (7 to 18)	100 (56 to 145)	↑	High
Fesoterodine vs. placebo	Adverse effects	4	4,145	51/38	1.4 (1.2 to 1.6)	0.16 (0.11 to 0.20)	6 (5 to 9)	156 (112 to 200)	↑	High
Fesoterodine vs. placebo	Discontinuation due to adverse effects	4	4,433	6/3	2.0 (1.3 to 3.1)	0.03 (0.01 to 0.06)	33 (18 to 102)	31 (10 to 56)	↑	High
Fesoterodine vs. placebo	Discontinuation due to failure	2	1,896	2/3	0.6 (0.2;2.5)	-0.01 (-0.03 to 0.02)			NS	Moderate
Oxybutynin vs. placebo	Continence	4	992	27/16	1.7 (1.3 to 2.1)	0.11 (0.06 to 0.16)	9 (6 to 16)	114 (64 to 163)	↑	High
Oxybutynin vs. placebo	Improved UI	9	1,244	53/32	1.5 (1.2 to 1.9)	0.17 (0.10 to 0.24)	6 (4 to 11)	167 (95 to 240)	↑	Moderate
Oxybutynin vs. placebo	Discontinuation due to adverse effects	5	1,483	10/5	1.7 (1.1 to 2.5)	0.06 (0.01 to 0.13)	16 (8 to 86)	63 (12 to 127)	↑	High

Table B. Clinical outcomes with treatments for UI (pooled with random effects estimates from head-to-head RCTs) (continued)

Treatments	Outcomes	Number of studies	Patients	Rate, % active/ control	Relative risk (95% CI)	Absolute risk difference* (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)	Effect in relative/ absolute scale	Evidence
Propiverine vs. placebo	Continence	2	691	53/37	1.4 (1.2 to 1.7)	0.16 (0.09 to 0.24)	6 (4 to 12)	163 (86 to 239)	↑	Low
Propiverine vs. placebo	Improved UI	3	985	55/35	1.6 (1.3 to 2.0)	0.19 (0.13 to 0.25)	5 (4 to 8)	192 (132 to 252)	↑	Moderate
Propiverine vs. placebo	Discontinuation due to adverse effects	2	1,401	5/2	2.6 (1.4 to 5.00)	0.03 (0.01 to 0.06)	29 (16 to 77)	34 (13 to 61)	↑	Low
Solifenacin vs. placebo	Continence	5	6,304	39/28	1.5 (1.4 to 1.6)	0.11 (0.06 to 0.16)	9 (6 to 17)	107 (58 to 156)	↑	High
Solifenacin vs. placebo	Improved UI	2	1,507	60/42	1.5 (1.0 to 2.1)	0.18 (0.10 to 0.26)	6 (4 to 10)	180 (97 to 263)	↑	Low
Solifenacin vs. placebo	Adverse effects	3	1,713	52/36	1.7 (1.2 to 2.4)	0.18 (0.09 to 0.27)	6 (4 to 12)	177 (85 to 267)	↑	High
Solifenacin vs. placebo	Discontinuation due to adverse effects	7	9,080	5/4	1.3 (1.1 to 1.7)	0.01 (0.00 to 0.03)	78 (39 to 823)	13 (1 to 26)	↑	High
Solifenacin vs. placebo	Discontinuation due to failure	4	2,812	2/1	1.0 (0.5 to 1.8)	0.00 (-0.01 to 0.01)			NS	Moderate
Tolterodine vs. placebo	Continence	4	3,404	53/44	1.2 (1.1 to 1.4)	0.09 (0.04 to 0.13)	12 (8 to 25)	85 (40 to 129)	↑	High
Tolterodine vs. placebo	Improved UI	7	6,119	45/37	1.3 (1.1 to1.4)	0.10 (0.04 to 0.15)	10 (7 to 24)	96 (42 to 149)	↑	High
Tolterodine vs. placebo	Adverse effects	12	4,162	45/38	1.2 (1.1 to 1.3)	0.08 (0.05 to 0.12)	12 (8 to 21)	83 (47 to 120)	↑	High
Tolterodine vs. placebo	Discontinuation due to adverse effects	10	4,466	4/3	1.0 (0.6 to 1.7)	0.01 (-0.01 to 0.03)			NS	High
Tolterodine vs. placebo	Discontinuation due to failure	5	4,049	1/2	0.5 (0.2 to 0.9)	-0.01 (-0.01 to 0.00)			NS	High
Trospium vs. placebo	Continence	4	2,677	28/17	1.7 (1.5 to 2.0)	0.11 (0.08 to 0.14)	9 (7 to 12)	114 (83 to 144)	↑	High
Trospium vs. placebo	Improved UI	2	1,176	32/25	1.1 (0.6 to 2.0)	0.08 (-0.10 to 0.25)			NS	Low
Trospium vs. placebo	Adverse effects	5	2,967	41/29	1.4 (1.2 to 1.7)	0.12 (0.09 to 0.16)	8 (6 to 11)	123 (88 to 159)	↑	Moderate

Table B. Clinical outcomes with treatments for UI (pooled with random effects estimates from head-to-head RCTs) (continued)

Treatments	Outcomes	Number of studies	Patients	Rate, % active/ control	Relative risk (95% CI)	Absolute risk difference* (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)	Effect in relative/ absolute scale	Evidence
Trospium vs. placebo	Discontinuation due to adverse effects	6	3,936	6/4	1.5 (1.1 to 1.9)	0.02 (0.00 to 0.03)	56 (30 to 228)	18 (4 to 33)	↑	High
Fesoterodine vs. tolterodine	Continence	2	3,312	61/56	1.10 (1.04 to 1.16)	0.06 (0.02 to 0.09)	18 (11 to 48)	55 (21 to 88)	↑	Low
Fesoterodine vs. tolterodine	Improved UI	3	4,425	44/35	1.06 (1; 1.2)	0.03 (0; 0.06)	36 (17 to 1000)	28 (1 to 57)	↑/↑	High
Fesoterodine vs. tolterodine	Discontinuation due to adverse effects	4	4,440	5/4	1.54 (1.21 to 1.97)	0.02 (0.01 to 0.03)	58 (33 to 206)	17 (5 to 31)	↑	Moderate
Oxybutynin vs. tolterodine	Improved UI	3	947	50/45	1.11 (0.94 to 1.31)	0.05 (-0.03 to 0.13)			NS	Moderate
Oxybutynin vs. tolterodine	Discontinuation due to adverse effects	6	2,323	13/6	1.9 (1.1 to 3.3)	0.07 (0.01 to 0.15)	14 (7 to 145)	72 (7 to 154)	↑	High
Solifenacin vs. tolterodine	Discontinuation due to adverse effects	3	2,755	4/3	1.28 (0.86 to 1.91)	0.01 (0.00 to 0.03)			NS	Moderate
Trospium vs. oxybutynin	Discontinuation due to adverse effects	2	2,015	5/7	0.75 (0.52; 1.1)	0.00 (-0.03 to 0.05)			NS	Low
Nonpharmacological treatments										
Bladder training vs. no active treatment	Improved UI	2	283	61.4/19.2	3.22 (2.25 to 4.60)	0.43 (0.28 to 0.59)	2 (2 to 4)	430 (275 to 585)	↑	Low
Continence service vs. no active treatment	Continence	3	3,939	29/20	1.6 (1.1 to 2.3)	0.30 (-0.01 to 0.60)			↑/NS	Moderate
Continence service vs. no active treatment	Improved UI	2	4,038	62.6/53.5	1.33 (1.06 to 1.68)	0.20 (-0.01 to 0.41)			↑/NS	Low

Table B. Clinical outcomes with treatments for UI (pooled with random effects estimates from head-to-head RCTs) (continued)

Treatments	Outcomes	Number of studies	Patients	Rate, % active/ control	Relative risk (95% CI)	Absolute risk difference* (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)	Effect in relative/ absolute scale	Evidence
Electrical stimulation vs. no active treatment	Continence	7	420	23/8	2.9 (1.6 to 5.2)	0.16 (0.06 to 0.26)	6 (4 to 16)	162 (64 to 259)	↑	High
Electrical stimulation vs. no active treatment	Improved UI	8	582	31.7/15.1	2.01 (1.28 to 3.15)	0.16 (0.08 to 0.23)	6 (4 to 12)	156 (84 to 228)	↑	High
Magnetic stimulation vs. no active treatment	Improved UI	3	153	46.8/21.2	2.30 (1.43 to 3.71)	0.27 (0.11 to 0.42)	4 (2 to 9)	265 (112 to 417)	↑	Moderate
Magnetic stimulation vs. no active treatment	Continence	3	171	30.7/17.8	1.22 (0.78 to 1.88)	0.09 (-0.01 to 0.18)			NS	Moderate
Percutaneous electrical stimulation vs. no active treatment	Improved UI	3	405	40/20	1.9 (1.1 to3.2)	0.31 (0.04 to0.58)	3 (2 to 25)	308 (40 to 577)	↑	Moderate
PFMT vs. no active treatment	Continence	10	959	38/12	3.8 (2.1 to 6.8)	0.30 (0.19 to 0.41)	3 (2 to 5)	299 (188 to 410)	↑	High
PFMT vs. no active treatment	Improved UI	6	510	56.9/14.7	5.44 (1.57 to 18.83)	0.41 (0.17 to 0.65)	2 (2 to 6)	412 (174 to 649)	↑	High
PFMT with bladder training vs. no active treatment	Continence	5	1,369	21/12	3.8 (1.5 to 9.3)	0.17 (0.06 to 0.27)	6 (4 to 16)	166 (63 to 268)	↑	High
PFMT with bladder training vs. no active treatment	Improved UI	4	1,171	53.3/22.5	4.13 (1.58 to 10.78)	0.39 (0.17 to 0.60)	3 (2 to 6)	387 (171 to 603)	↑	High

Table B. Clinical outcomes with treatments for UI (pooled with random effects estimates from head-to-head RCTs) (continued)

Treatments	Outcomes	Number of studies	Patients	Rate, % active/ control	Relative risk (95% CI)	Absolute risk difference* (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)	Effect in relative/ absolute scale	Evidence
PFMT with biofeedback vs. no active treatment	Continence	2	185	42/2	11.2 (2.2 to 56.4)	0.49 (-0.10 to 1.08)			↑/NS	Low
PFMT with biofeedback vs. no active treatment	Improved UI	4	383	60.1/18.6	3.93 (1.00 to 15.49)	0.39 (0.17 to 0.61)	3 (2 to 6)	390 (170 to 610)	↑	High
Weight Loss vs. no active treatment	Improved UI	2	386	42.8/20.8	2.17 (1.26 to 3.76)	0.27 (0.06 to 0.50)	4 (2 to 18)	273 (57 to 490)	↑	Moderate
PFMT + bladder training vs. bladder training	Continence	2	271	21/21	1 (0.4 to 2. 8)	0.001 (-0.2 to 0.2)			NS	High
PFMT vs. electrical stimulation	Continence	3	99	24/29	0.85 (0.45 to 1.61)	-0.04 (-0.20 to 0.11)			NS	Moderate
PFMT vs. electrical stimulation	Improved UI	4	136	31/45	0.97 (0.62 to 1.51)	-0.01 (-0.17 to 0.16)			NS	Moderate
PFMT vs. vaginal cone	Continence	3	320	22/27	0.78 (0.58 to 1.06)	-0.11 (-0.26 to 0.04)			NS	Moderate
PFMT vs. vaginal cone	Improved UI	4	440	41/41	1.02 (0.91 to 1.14)	0.01 (-0.08 to 0.09)			NS	Moderate
PFMT with biofeedback vs. PFMT	Continence	6	542	30/25	1.27 (0.88 to 1.85)	0.08 (-0.03 to 0.19)			NS	High
Supervised PFMT vs. self-PFMT	Continence	4	300	35/22	1.92 (0.87 to 4.23)	0.20 (-0.03 to 0.43)			NS	High
Supervised PFMT vs. self-PFMT	Improved UI	4	283	50/33	1.51 (0.85 to 2.67)	0.14 (-0.05 to 0.32)			NS	Moderate

Note: CI=confidence interval; PFMT=pelvic floor muscle training; NS=not significant; RCT=randomized controlled trial; UI=urinary incontinence; ↑=effect of active drug is greater than control; ↓=effect of active drug is lower than control. * Risk differences for drug adverse effects were calculated using arcsine transformation

Introduction

Urinary incontinence (UI) is the involuntary loss of urine.[1] UI affects a significant number of women in the United States and other countries.[1] About 25 percent of young women,[2] 44 to 57 percent of middle-aged and post-menopausal women,[3,4] and about 75 percent of older women experience some involuntary urine loss.[5] The impact of UI can be serious, affecting women's physical, psychological, and social wellbeing, and sometimes imposing significant lifestyle restrictions. The effects of UI on an individual may range from slightly bothersome to debilitating.

The cost of UI care in the United States averaged $19.5 billion in 2004.[6] Six percent of nursing home admissions of older women is attributable to UI[6] and, by one estimate, the annualized cost of nursing home admissions of elderly women due to UI was $3 billion.[7,8]

Voluntary voiding requires a balance between sphincter activity and bladder function. UI in women is related to actions of the bladder and the urinary sphincter. Stress incontinence is a sphincter failure attributed to intra-abdominal pressure. Urgency incontinence is attributable to sphincter failure with or without overactive bladder contractions. Conversely, an inactive bladder may result in overflow incontinence, whereby urine is retained until bladder capacity is exceeded. In many women, stress and urgency occur together in what is called mixed incontinence. Sphincter failure in women is often associated with weakness of the pelvic floor muscles.

The etiology of incontinence is multifactorial. Known risk factors include age, pregnancy, pelvic floor trauma after vaginal delivery, menopause, hysterectomy, obesity, urinary tract infections, functional and/or cognitive impairment, chronic cough, and constipation.[9] Assessments of women complaining of UI begin with exclusion of underlying causes such as pelvic organ prolapse, urinary tract infection, and poor bladder emptying,[1] all of which are conditions beyond the scope of this review. We focus specifically on women with stress UI associated with sphincter function, and with urgency UI, often associated with overactive bladder.

Incontinence types are distinguished by their baseline mechanisms. Stress incontinence is associated with sphincter function, and results in an inability to retain urine when coughing or sneezing.[10] Urgency incontinence is defined as involuntary loss of urine associated with the sensation of a sudden, compelling urge to void that is difficult to defer.[10] Mixed UI is the term applied when both stress and urgency UI are present. These definitions reflect the consensus definitions developed by the International Urogynecological Association (IUGA)/International Continence Society (ICS)[10] (Table 1).

Overactive bladder is defined as urinary urgency with or without incontinence, usually accompanied by frequency and nocturia (the need to urinate at night).[10] Approximately one-third of women with overactive bladder also experience urgency UI. Other diagnoses for female pelvic floor dysfunction beyond the scope of our review include poor bladder emptying, voiding dysfunction, pelvic organ prolapse, and recurrent urinary tract infections, as well as neurogenic UI associated with spinal cord injury or stroke.[10]

Stress incontinence was the most prevalent type in women 19 to 44 years of age (31 percent)[11-24] and in those 45 to 64 years of age (33 percent).[3,11,13,14,16,18,19,21,24-49] The prevalence of urgency UI gradually increased from 13 percent in younger women[11-19,21-24,50] to 17 percent in women 45 to 64 years of age[11,13,14,25-35] and to 25 percent in women older than 65.[13,14,18,19,21,23,24,27,30,34,51-68] Older women suffer from both types, and so-called mixed UI; 33 percent of older women[13,14,18,19,24,30,52,54,56-60,62,63,66-68] reported mixed UI.[13,30,56]

The types of UI imply different attendant risk factors and recommended treatments; however, UI etiology is frequently mixed. Stress UI is associated with pelvic floor trauma and uterine prolapse (both of which are conditions associated with vaginal delivery that often require surgical treatments).[9] Urgency and mixed UI are associated with overactive bladder with or without sphincter dysfunction and may benefit from nonsurgical treatments, including pharmacological and nonpharmacological options.[1,9]

Although diagnosis of UI can be made based on patients' reports of involuntary urine leakage,[9] researchers have also proposed instrumental methods for objective diagnosis of different types of UI. Urodynamic evaluation may help to distinguish pure stress UI without urgency UI for women undergoing surgery for stress UI.[10] Diagnostic studies use multichannel urodynamics as a reference standard test to compare with noninvasive tests. However, researchers disagree over whether urodynamic examination represents the gold standard for UI diagnosis.[69-71] Previously published systematic reviews reported a weak association between urodynamic results and self-reported symptoms;[72,73] however, previous reviews did not focus on the most appropriate methods to distinguish different types of UI in ambulatory care clinical settings.[74-77] The role of invasive diagnostic methods in better predicting treatment outcomes for UI remains unclear.

Our report also addresses the role of urodynamic testing, which is not typically performed in primary care. We include it here primarily as background information for primary care practitioners and because it raises a conundrum. As we have emphasized, the primary outcome for UI should be patient-centered reports of the UI experience, especially the presence or absence of UI. Although we typically think of physiological testing as more objective than patient reports, these results are, at best, akin to intermediate outcomes. In the diagnostic context, physiological testing can inform in one of three ways: (1) establishing a diagnosis; (2) determining an etiology with therapeutic implications; and (3) generating a prognosis. In the case of UI, it is unclear whether physiological measures represent a gold standard against which other measures can be compared or whether they should be viewed as information that may predict key patient-centered outcomes. Hence, we may be more interested in levels of agreement between physiological measures and patient outcomes but hard pressed to interpret differences between them. We examine the role of urodynamic testing in diagnosing and treating UI to provide insight into this conundrum.

Measuring Outcomes of UI Treatment

The variations in definitions of UI complicate evaluation of treatment success. Standard UI treatment for women includes lifestyle changes, pelvic floor muscle training (PFMT), and surgical treatments for stress UI.[1] In addition, several drugs have been approved for adults with overactive bladder with or without urgency UI.[1] Clinical interventions to reduce the frequency of UI episodes in women have been extensively reviewed in recent years,[69,78-107] but reviews have not emphasized outcomes of continence or womens' perceptions of treatment success and satisfaction. However, continence has been considered a primary goal in UI treatment.[69,108] Continence is also the most important outcome associated with quality of life in women with UI,[109-111] but it is rarely examined as a primary outcome in syntheses of evidence.[112] Thus, we focus on continence and quality of life as primary outcomes for this comparative effectiveness review.[112]

While continence is similarly defined across studies, the definitions most often applied to improvement of UI vary and include different degrees of change in frequency and severity of

symptoms.[113] The Food and Drug Administration (FDA) clinical reviews defined treatment success as a significant reduction in daily UI episodes.[112,114,115] An average effect was a significant reduction by two UI episodes per day.[112] Clinical importance of this reduction was not clear. Women with severe UI may not even notice this reduction, let alone judge it as a treatment success. Other studies and reviews defined treatment success differently. In addition to varied definitions across studies, improvement in UI has been judged by researchers and women very differently. Researchers have defined improvement as a decrease in the amount of lost urine during pad tests or any statistically significant decrease in the frequency of UI episodes,[113] whereas women have defined improvement according to reduced restrictions in lifestyle or improved overall perception of bladder symptoms, especially resolution of urine leakage. Measurement of treatment outcomes should be patient-centered and based on factors important to women, rather than on the results of invasive tests.[108] Thus, treatment success and failure should be evaluated according to what women report in validated questionnaires or scales. However, meaningful differences in questionnaires or scales have not been systematically reviewed. Ultimately, discussions of UI are complicated by the wide variety of measures used to describe the problem and its treatment outcomes. We focus on continence as the primary outcome for this comparative effectiveness review.[69,108]

Clinical interventions to reduce the progression of UI have been extensively reviewed during recent years by the Agency for Healthcare Research and Quality (AHRQ),[79,80] the Cochrane Collaborative Group,[81-88,90-107,116,117] the International Consultation on Incontinence (ICI),[69,78] and the National Institute for Health and Clinical Excellence.[118] However, the comparative effectiveness of different UI treatments, including pharmacological therapies and their effects on patient morbidity[119] and quality of life,[120] were beyond the scope of previously published evidence-based reports.[121] In addition, previously published reports did not include pharmacological treatments for urgency UI.[9,81] Systemic estrogens have been associated with increased risk of UI.[9] Selective estrogen receptor modulators did not demonstrate consistent benefits for UI prevention.[122,123] Based on discussions with key informants and Technical Expert Panel members, we excluded systemic estrogen treatments from our review.

Pharmacological agents to treat urgency UI act as muscarinic antagonists.[124-126] The drugs bind to muscarinic receptors but do not activate them, thereby blocking the actions of acetylcholine, the endogenous neurostimulator of urinary bladder tone. Such blocking leads to less frequent urination and thus potential improvement in UI. However, antimuscarinic drugs also block many other effects of acetylcholine, including secretions of the respiratory tract, gastrointestinal system, and salivary glands, and actions on the central nervous system, the iris and ciliary muscle of the eye, heart, and blood vessels. Acetylcholine blocking leads to adverse effects, including dry mouth, dry eye, constipation, confusion, headache, blurred vision, and others.[124,127-129] Previously published advocacy reviews did not focus on comparative safety of these drugs in adult women.[130-137] Moreover, many recently published studies have not yet been synthesized into clinical recommendations for physicians.

Comprehensive and up-to-date reviews of treatment options for women with UI are necessary in order to develop evidence-based guidelines and recommendations for patients, clinicians, and policymakers.[8,138-140]

This report synthesizes published evidence about diagnosis and management of UI in adult women. We focused on adult women and on nonsurgical, nonpharmacological treatments appropriate to primary care ambulatory practice, as well as pharmacological agents available in

the United States. This report is intended as a companion piece to an earlier Evidence-based Practice Center report[9] that examined a wide range of treatment alternatives, including surgery.

Our systematic review is intended to help clinicians, consumers, and policymakers make clinical recommendations and informed decisions based on synthesized evidence and other relevant factors.

We examined the following questions:

Key Question 1. What constitutes an adequate diagnostic evaluation for women in the ambulatory care setting on which to base treatment of urinary incontinence?

1. What are the diagnostic values of different methods—questionnaires, checklists, scales, self-reports of UI during a clinical examination, pad tests, and ultrasound—when compared with multichannel urodynamics?
2. What are the diagnostic values of different methods—questionnaires, checklists, scales, self-reports of UI during a clinical examination, pad tests, and ultrasound—when compared with a bladder diary?
3. What are the diagnostic values of the methods listed above for different types of UI, including stress, urgency, and mixed incontinence?
4. What is the association between patient outcomes (continence, severity and frequency of UI, quality of life) and UI diagnostic methods?

Key Question 2. How effective is the pharmacological treatment of UI in women?

1. How do pharmacologic treatments affect continence, severity and frequency of UI, and quality of life when compared with no active treatment or with combined treatment modalities?
2. What is the comparative effectiveness of pharmacological treatments when compared with each other or with nonpharmacological treatments of UI?
3. What are the harms from pharmacological treatments when compared with no active treatment?
4. What are the harms from pharmacological treatments when compared with each other or with nonpharmacological treatments of UI?
5. Which patient characteristics, including age, type of UI, severity of UI, baseline disease that affects UI, adherence to treatment recommendations, and comorbidities, can modify the effects of the pharmacological treatments on patient outcomes, including continence, quality of life, and harms?

Key Question 3. How effective is the nonpharmacological treatment of UI in women?

1. How do nonpharmacological treatments affect incontinence, UI severity and frequency, and quality of life when compared with no active treatment?
2. How do combined modalities of nonpharmacological treatments with drugs affect incontinence, UI severity and frequency, and quality of life when compared with no active treatment or with monotherapy?
3. What is the comparative effectiveness of nonpharmacological treatments when compared with each other?
4. What are the harms from nonpharmacological treatments when compared with no active treatment?

5. What are the harms from nonpharmacological treatments when compared with each other?
6. Which patient characteristics, including age, type of UI, severity of UI, baseline disease that affects UI, adherence to treatment recommendations, and comorbidities, can modify the effects of the nonpharmacological treatments on patient outcomes, including continence, quality of life, and harms?

Table 1. Definitions of urinary incontinence (UI) and treatment outcomes[9]

Outcome	Definition
Symptoms of UI[141]	Complaint of involuntary loss of urine
Signs of UI	Observation of involuntary loss of urine on examination; may be urethral or extraurethral
Transient UI[142,143]	Potentially reversible incontinence resulting from conditions that may resolve if the underlying cause is managed: delirium/confusional state; urinary tract infection (symptomatic); atrophic urethritis/vaginitis; use of pharmaceuticals; psychological conditions, especially depression; excessive urine output related to another medical condition (e.g., congestive heart failure, hyperglycemia); restricted mobility; stool impaction
Established UI[142,143]	UI that is attributed to bladder or urethral dysfunction, such as detrusor overactivity, detrusor underactivity, urethral obstruction, urethral incompetence
Stress UI	Complaint of involuntary loss of urine on effort or physical exertion (or on sneezing or coughing)
Pure (urodynamic) stress UI	The finding of involuntary leakage during filling cystometry, associated with increased intra-abdominal pressure (stress test), in the absence of a detrusor contraction
Urgency UI[10]	Complaint of involuntary loss of urine associated with urgency
Pure (urodynamic) detrusor overactivity	Observation of involuntary leakage from the urethra synchronous with the sensation of a sudden compelling desire to void that is difficult to defer; involuntary detrusor muscle contractions occur during filling cystometry
Overactive bladder[144]	Urinary urgency, usually accompanied by frequency and nocturia, with or without urgency UI, in the absence of urinary tract infection or other obvious pathology. Treatment effectiveness is judged based on decreased voiding and urgency frequency and urgency UI
UI associated with poor bladder emptying[145]	UI associated with: bladder over distention; a contractile detrusor; hypotonic or underactive detrusor, occurring secondarily to drugs, fecal impaction, diabetes, lower spinal cord injury, or disruption of the motor innervations of the detrusor muscle
Mixed UI[141]	Complaint of involuntary loss of urine associated with urgency and also with effort or physical exertion or on sneezing or coughing
Predominant stress UI	Mixed UI with predominant, more frequent symptoms of stress UI
Predominant urgency UI	Mixed UI with predominant, more frequent symptoms of urgency UI
Postural UI	Complaint of involuntary loss of urine associated with change of body position, for example, rising from a seated or lying position
Continuous UI	Complaint of continuous involuntary loss of urine
Coital incontinence	Complaint of involuntary loss of urine with coitus; this symptom might be further divided into that occurring with penetration or intromission and that occurring at orgasm
Insensible UI	Complaint of UI where the woman has been unaware of how it occurred
Nocturnal enuresis	Complaint of involuntary urine loss that occurs during sleep
Acute UI[146]	Sudden onset of symptoms related to an illness, treatment, or medication
Chronic UI	Persistent UI, including disorders of storage (stress and urgency) and of emptying (overflow) and functional and mixed incontinence

Table 1. Definitions of urinary incontinence (UI) and treatment outcomes[9] (continued)

Outcome	Definition
Severity of UI	Measured as incontinent episodes/unit time, pad changes/unit time, pad weight/unit time, number of micturitions/unit time, urine loss on a pad test; also indicated by urodynamically diagnosed detrusor overactivity, urodynamic stress incontinence
Outcomes to examine treatment effectiveness	
Continence	Absence of any involuntary leakage of urine Author's reports of cure, absence of incontinent episodes in bladder diaries, negative pad stress, or no abnormalities noted on urodynamics
Resolved stress UI	No involuntary urine leakage on physical exertion or effort or with sneezing or coughing
Resolved urgency UI	No involuntary leakage accompanied by or immediately proceeded by urgency
Resolved mixed UI	No involuntary leakage associated with urgency or with exertion, effort, sneezing, or coughing
Improvement in UI	Reduction in frequency and severity of incontinence episodes by >50% Reduction in pad stress test by >50% Reduction in restrictions of daily activities due to incontinence Women's perception of improvement in their bladder condition
Treatment failure	Progression of incontinence: increase in frequency and severity of incontinence episodes Increase in restrictions of daily activities because of incontinence Continence not achieved No reduction in the frequency and severity of incontinent episodes
Discontinuation of treatment	Subject refusal to continue treatment
Discontinuation of treatment due to adverse effect	Subject refusal to continue treatment due to adverse effects or physician decision to withdraw treatment due to adverse effects
Discontinuation of treatment due to treatment failure	Subject refusal to continue treatment due to lack of efficacy
Quality of life	Subject's reports about emotional, physical, and social wellbeing
Adverse effects	Any harmful and undesired effect in treated subjects

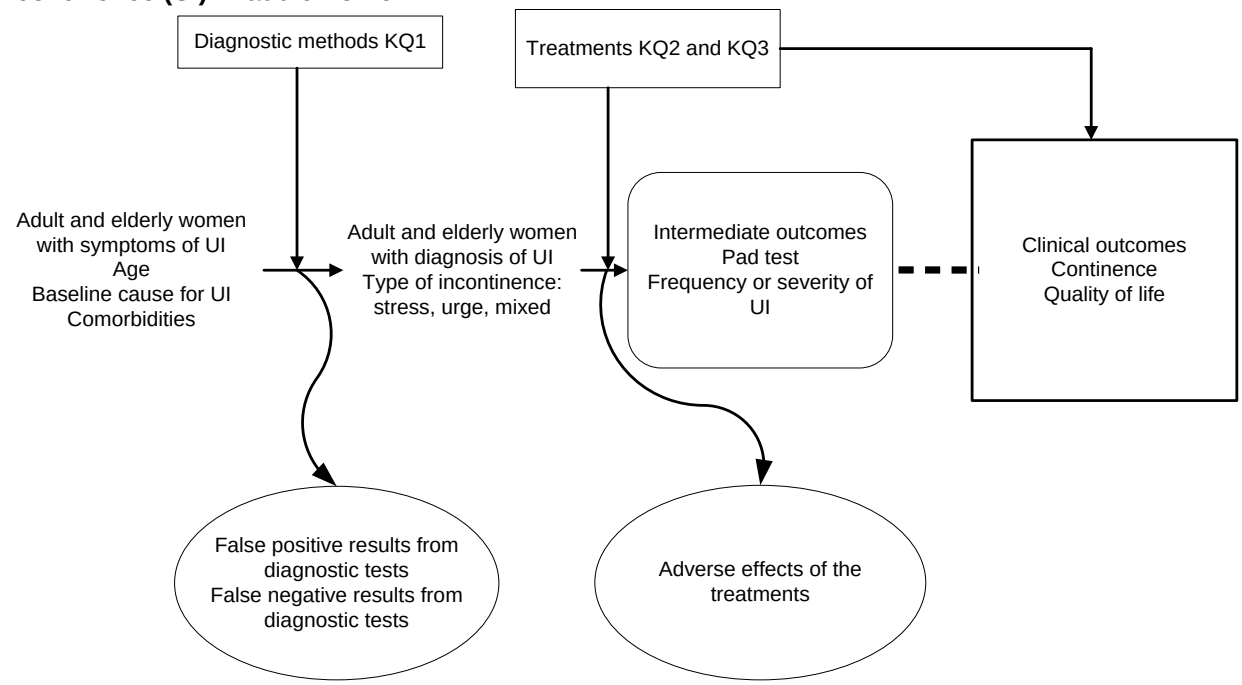
Methods

Input From Stakeholders

We developed research questions and an analytic framework (Figure 1) after discussions with key informants and technical experts. Research questions for the systematic review were posted for public comment, based on which we identified interventions eligible for this review. Stakeholders recommended a focus on patient-centered outcomes and interventions most relevant for ambulatory care and not evaluated in previous systematic reviews. Stakeholders also recommended reviewing nonsurgical interventions relevant to women with refractory UI. Comprehensive information about all nonsurgical treatment choices can lead to evidence-based referral practices for women with refractory UI.

Candidates to serve as key informants, technical experts, and peer reviewers were approved by the Task Order Officer from AHRQ after disclosure of conflicts of interest. The protocol was developed with input from the Technical Expert Panel.

Figure 1. Analytic framework of diagnosis and comparative effectiveness of treatments for urinary incontinence (UI) in adult women



Literature Search Strategy and Eligibility Criteria

Search Strategy

We sought studies from a wide variety of sources, including MEDLINE® via OVID and via PubMed®, the Cochrane Library, SCIRUS, Google Scholar, and manual searches of reference lists from systematic reviews, the proceedings of the ICS, and systematic reviews by the ICI. We also reviewed grey literature packets from the Scientific Resource Center (SRC) (Appendix Table A1). This search included regulatory documents and conducted clinical trials. The regulatory documents included medical and statistical reviews from the U.S. FDA, Health

Canada - Drug Monographs, and Authorized Medicines for the European Union - Scientific Discussions. We searched the Web site www.ClinicalTrials.gov on May 20, 2010, to find closed studies of urinary incontinence or overactive bladder. In addition, the following clinical trial registries were searched for completed trials related to the key questions: Current Controlled Trials (United Kingdom), Clinical Study Results (Pharmaceutical Research and Manufacturers of America), and World Health Organization Clinical Trials (International). Scopus and Physical Education Index was searched for conference papers and abstracts related to UI. We identified ongoing studies in ClinicalTrials.gov and the National Institutes of Health Research Portfolio Online Reported Tools (report) http://report.nih.gov/index.aspx Web sites.

The search strategies for the three research questions are described in Appendix A. Exact search strategies were developed through consultation with qualified librarians and guided by the SRC. We developed an a priori search strategy based on relevant medical subject headings (MeSH) terms, text words, and weighted word frequency algorithms to identify related articles. We documented each recommended, included, and excluded study in the master library. We identified studies published in English from 1990 until December 30, 2011.

Excluded references are shown in Appendix B. Our analysis of the results from ongoing studies is presented in Appendix C. The protocol was developed with input from the Technical Expert Panel.

Eligibility

Three investigators independently determined the eligibility of the studies according to recommendations from the Cochrane Manual for Systematic Reviews.[147] The algorithm to define study eligibility was developed for each research question (Appendix Table D1). We followed the Comparative Effectiveness Manual to select evidence from controlled trials and observational studies.[148] We defined the target population, eligible independent and dependent variables, outcomes, time, and setting following the PICOS framework (Appendix Table D2). We formulated a list of eligible interventions following the discussion with key informants and technical experts, and after considering public comments (Appendix Table D3). We included nonsurgical, nonpharmacological treatments for UI. We included the drugs available in the United States for predominant stress UI (topical estrogens and antidepressants) and those approved by the FDA for overactive bladder (Appendix Table D4). We excluded systemic estrogens[9] and selective estrogen receptor modulators[122,123] that failed to prevent or improve UI. We included bulking agents and ingestible neurotoxins to review all nonsurgical treatment options for women with refractory UI. We reviewed abstracts to exclude news, reviews, letters, comments, and case reports. Then we confirmed eligible target populations of adult women residing in the community.

Inclusion Criteria

- Studies published in English after 1989.
- Studies that examined eligible interventions of drug therapies or nonsurgical treatments for women with UI (Appendix D).
- Studies that examined eligible outcomes of UI (total, mixed, stress, urgency), quality of life in women with UI, and harms of the treatments.

We included all RCTs, pooled individual patient data from RCTs, nonrandomized multicenter clinical trials, and observational studies that used strategies to reduce bias (adjustment, stratification, matching, or propensity scores).

For Key Question 1 we included studies that evaluated different diagnostic methods for UI in women that are applicable to ambulatory care settings. We applied criteria for assessing whether a body of study data was sufficient to answer the question of diagnostic methods.[149] We included any observational studies that reported true and false positive and negative cases, sensitivity, and specificity of diagnostic methods for different types of female UI.

For Key Questions 2 and 3 we defined efficacy and effectiveness trials following criteria from the CER manual.[149] We compared the results from observational studies and RCTs on positive clinical outcomes and harms.[149] We included randomized controlled trials (RCTs) that combined men and women if they reported outcomes in women separately or included more than 75 percent women. We examined unpublished RCTs from the medical and statistical reviews that were conducted by the FDA. We included observational studies of treatments that were not examined in RCTs.

Exclusion Criteria

- Studies of children, adolescents, or men.
- Studies of incontinence caused by neurological disease.
- Studies of dual fecal and UI.
- Studies of surgical treatments for UI or urogenital prolapsed.
- Studies of drugs not available in the United States.
- Studies with no clinical outcomes relevant to UI.
- Case series with fewer than 100 subjects that reported short-term (less than 4 weeks) crude rates of the outcomes and/or did not use strategies to reduce bias.
- Secondary data analysis, nonsystematic reviews, letters, or comments.
- Studies that reported absolute values of the diagnostic tests in incontinent women.
- Studies that did not report true and false positive and negative cases of diagnostic tests.

To assess harms of the treatments we followed the recommendations from the CER manual[149,150] and reviewed published and unpublished evidence of the adverse effects of eligible drugs and nonsurgical treatments for female urinary incontinence including:

- Randomized controlled trials.
- Unpublished supplemental trials data from the Web site http://www.clinicalstudyresults.org.
- Observational cohort and case control studies.
- Observational studies based on patient registries or large databases.
- Case reports and post-marketing surveillance.

We defined harms as the totality of all possible adverse consequences of an intervention.[150] We analyzed harms regardless of how authors perceived the causality of treatments.

We did not contact the investigators of the primary studies.

Quality Assessment

We rated the quality of studies according to recommendations from the Methods Guide for Effectiveness and Comparative Effectiveness Review.[149] We classified the studies by design to

distinguish randomized and nonrandomized controlled clinical trials from observational studies. We evaluated reporting and methodological quality of the studies for Key Question 1 with predefined criteria for assessing the quality of diagnostic accuracy studies.[151-156] We evaluated the quality of therapeutic studies using predefined criteria, which included randomization, adequacy of randomization and allocation concealment, masking of the treatment status, intention to treat principles, and justification of the sample size.[147] We evaluated disclosure of conflict of interest by the authors of individual studies and funding sources but did not use this information to downgrade quality of individual studies. We did not downgrade methodological quality of poorly reported studies. We did synthesize evidence from poorly reported studies separately.

We defined well-designed RCTs with adequate allocation concealment, intention to treat principles in analysis, and appropriate measurements of clinically important outcomes as studies with low risk of bias.

We defined studies as having a medium risk of bias if they were susceptible to some bias but not sufficient bias to invalidate the results. Examples of studies with medium risk of bias include open label RCTs, RCTs with unclear allocation concealment, RCTs with a short term of followup, and crossover RCTs without assessment of carryover effect.

We defined studies as having a high risk of bias if they had significant flaws that imply biases of various types that may invalidate the results, including nonrandom treatment allocation, no strategies to reduce bias, and ignoring randomization in analysis.

Grading the Evidence for Each Key Question

We assessed strength of evidence following the guidelines in the CER Manual.[157] We judged the strength of evidence according to the domains of risk of bias, consistency, directness, and precision for each major outcome.[149] When appropriate, we also included dose response association, presence of confounders that would diminish an observed effect, and strength of association. We evaluated strength of the association defining a priori large effect when relative risk was >2 or <0.5) and very large effect when relative risk was >5 or <0.2.[147] We defined low magnitude of the effect when relative risk was significant but less than 2.

We defined evidence as strong when several well-designed RCTs with a low risk of bias demonstrated consistent treatment effects. These are findings for which future research would be very unlikely to change the estimate of effect. We assigned a moderate level of evidence when RCTs with medium risk of bias reported consistent treatment effects or large observational studies reported consistent associations. We assigned a low level of evidence to data from RCTs with serious flaws in design/analysis, and from post hoc subgroup analysis; these are findings for which further research is likely to change the estimate. We defined insufficient evidence when a single study examined treatment effects or associations. We graded the level of evidence for primary outcomes across studies as illustrated in Table 2.

Table 2. Overall ranking of evidence

Grade	Definition
High	**High confidence that the evidence reflects the true effect.** Further research is very unlikely to change our confidence in the estimate of effect.
Moderate	**Moderate confidence that the evidence reflects the true effect.** Further research may change our confidence in the estimate of effect and may change the estimate.
Low	**Low confidence that the evidence reflects the true effect.** Further research is likely to change the confidence in the estimate of effect and is likely to change the estimate.
Insufficient	Evidence either is unavailable or does not permit a conclusion.

Applicability

Applicability of the population was estimated by evaluating the female population from which samples have been selected in observational studies and clinical trials.[158] We examined settings of the studies including ambulatory care or specialized clinics, recruitment in clinical settings or in the community, inclusion age and type of UI, and exclusion criteria for each study. The studies that recruited women from the population had better applicability.

We assumed the presence of publication bias and did not use statistical tests for bias defined as the tendency to publish positive results.[159-162] We used several strategies to reduce bias, including a comprehensive literature search of published and unpublished evidence in several databases, reference lists of systematic reviews, proceedings of scientific meetings, contacts with experts for additional references, and agreement on the eligibility status by several investigators.

Data Extraction

Four researchers manually and independently performed evaluations of the studies and data extraction. The data abstraction forms are shown in Appendix E. We did multiple quality controls of all data from RCTs and in a 30 percent random sample of observational studies. Errors in data extractions were assessed by a comparison with the established ranges for each variable and the data charts with the original articles. Any discrepancies were detected and discussed. We abstracted the number of positive (true and false) and negative (true and false) after index diagnostic tests when compared to multichannel urodynamics or diary. We abstracted descriptive information about populations, interventions, controls, outcomes, settings, and time to measure outcomes in relation to the randomization or beginning of the treatment. We abstracted the number randomized into active and control treatments, doses of the drugs, events or rates, or means and standard deviations after active and control treatments. We abstracted sponsorship of the studies, sponsor participation in design and data analysis and presentation, and conflict of interest by the authors of the studies. We abstracted inclusion of minorities in the studies, inclusion of women who failed prior therapy for UI, inclusion of mixed UI, baseline daily UI, and presence of urogenital prolapse or hysterectomy in women who participated in the studies. Adjustments for age, race, comorbidities, socioeconomic status, previous treatments, and baseline severity of UI were extracted from observational studies.

Data Synthesis

For Key Question 1 results of individual studies were summarized in evidence tables to analyze sensitivity, specificity, predictive values, diagnostic odds ratios, and predictive likelihood ratios for correct diagnosis of any, stress, and urgency UI (Appendix Table D5). We focused on the predictive likelihood ratios of UI in women examined with index tests when compared to women who had urodynamic or clinical diagnosis.[163-166] Ratios of 1 indicated that the tests likely do not provide accurate UI diagnosis.[167] Ratios of more than 10 provided large and often conclusive increases in the likelihood of UI.[167] Tabulation was performed for each article regarding symptoms or results of diagnostic tests and the diagnosis of stress incontinence or detrusor overactivity, using either urodynamic testing or clinical final diagnosis separately as the criterion standard. Specifically, the diagnostic value of history of three symptoms was evaluated: symptoms of stress incontinence for stress UI and symptoms of urgency incontinence and urgency for detrusor overactivity. We pooled diagnostic test data with random effects

models using Meta-Analyst software.[168] In cases of heterogeneity, we used bivariate pooling methods.[166,169,170]

Urodynamic evaluation detects a presence of UI but not severity and frequency of UI. However, doctors need information about frequency and severity of UI to make treatment decisions and evaluate treatment effectiveness. To address the diagnostic methods of frequency and severity of UI we synthesized content and applicability of checklists and scales to assess symptom frequency and bothersomeness, quality of life, and women's satisfaction with treatments. We evaluated validation, reliability, and the proposed minimal important differences in total scores when this information was available.

For Key Questions 2 and 3 we calculated relative risk, absolute risk differences, number needed to treat (NNT), and the number of events attributable to active treatment per 1,000 persons treated for binary outcomes. We used the number of randomized subjects forcing intention to treat principles independent of the ambulatory studies analyses. We calculated mean differences from the reported means and standard deviations among randomized to active and control treatments. We used correction coefficients, forced intention to treat, and recommended calculations for missing data.[147] We used Meta-Analyst[168] and STATA (Statistics/Data analysis, 10.1) software to calculate individual study estimates with a 95 percent confidence interval (CI).

Following guidelines[69,108] and recommendations from key informants and Technical Expert Panel members we focused on patient-centered outcomes including continence, improvement in UI, quality of life, adverse effects, and discontinuation due to adverse effects. We used the definitions of signs and symptoms of UI promoted by the IUGA/ICS (Appendix Table D2), including mixed, stress, and urgency UI.[10] We defined continence when the authors reported cure, absence of incontinent episodes in bladder diaries, or negative pad or stress tests (Table 1). We defined improvement in UI when the authors reported reduction by more than 50 percent in frequency of UI in diaries or patient-reported significant improvement in UI. We defined failure when frequency of UI did not change or became worse in diaries or according to patient reported worsening of UI. We relied on patient outcomes rather than continuous measures of UI episodes or urine loss.[108] We analyzed discontinuation rates independent of investigator judgments about association with tested drugs. We analyzed adverse effects as reported by the authors.

Pooling criteria included the same operational definitions of clinical populations, incontinence outcomes, the same clinical interventions, and the time of the assessment of the outcomes.[171] Meta-analysis was used to assess the consistency of the association between treatments and incontinence outcomes with random effects models using an inverse variance weighting method (Appendix Table D5).[168,172] We chose the random effects model to incorporate in the pooled analysis differences across trials in patient populations, baseline rates of the outcomes, dosage of drugs, and other factors.[173] For pooled relative risks (RR) and absolute risk difference (ARD) we excluded trials with no events in both groups and added a correction coefficient of 0.5 in the trials with no events only in one group.[173] We used pooled ARD to calculate the number needed to treat and the number of events attributable to active treatment per 1,000 persons treated.[174,175] We calculated means and 95 percent CI for the number needed to treat as reciprocal to pooled ARD when ARD was significant.[176] We calculated means and 95 percent CI for treatment events per 1,000 treated, multiplying pooled absolute risk difference by 1,000.[168,172,174-176] We assessed missing data across studies, including loss to followup and dropout patterns, and forced intention-to-treat analysis using the number of randomized subjects for all calculations. We also used maximum likelihood method for pooling continence, clinically important improvement in UI, and treatment discontinuation due to adverse effects.[168]We

calculated split placebo sample sizes and events in multi-arm drug trials proportionally to the randomization ratio to avoid double counting control groups. We synthesized sparse data defined as rates less than 2 percent by calculating fixed Mantel-Haenszel relative risk, and Peto odds ratio.[177] We analyzed adverse effects with drugs for urgency UI using double arcsine transformation for event rates. When studies had no events with active, control, or both treatments, we used correction coefficients and calculated odds ratios from random-effects generalized nonlinear mixed-effect models.[168,178-181]

We examined the association between age, race, obesity, comorbidities, UI type, baseline severity, and response to prior treatments with clinical outcomes as reported by the authors of the original studies. We synthesized the evidence by the baseline type of UI as pure or predominant stress, pure or predominant urgency, and mixed UI. We compared clinical outcomes by the type of UI within each study and across the studies. We evaluated inclusion and exclusion criteria and baseline characteristics of the subject to determine whether all or a proportion of the subjects had mixed UI. Then we conducted quantitative meta-regression and subgroup analysis to determine treatment effects by baseline type of UI. When exploring heterogeneity, we did not use subject level variables to avoid an ecological fallacy.

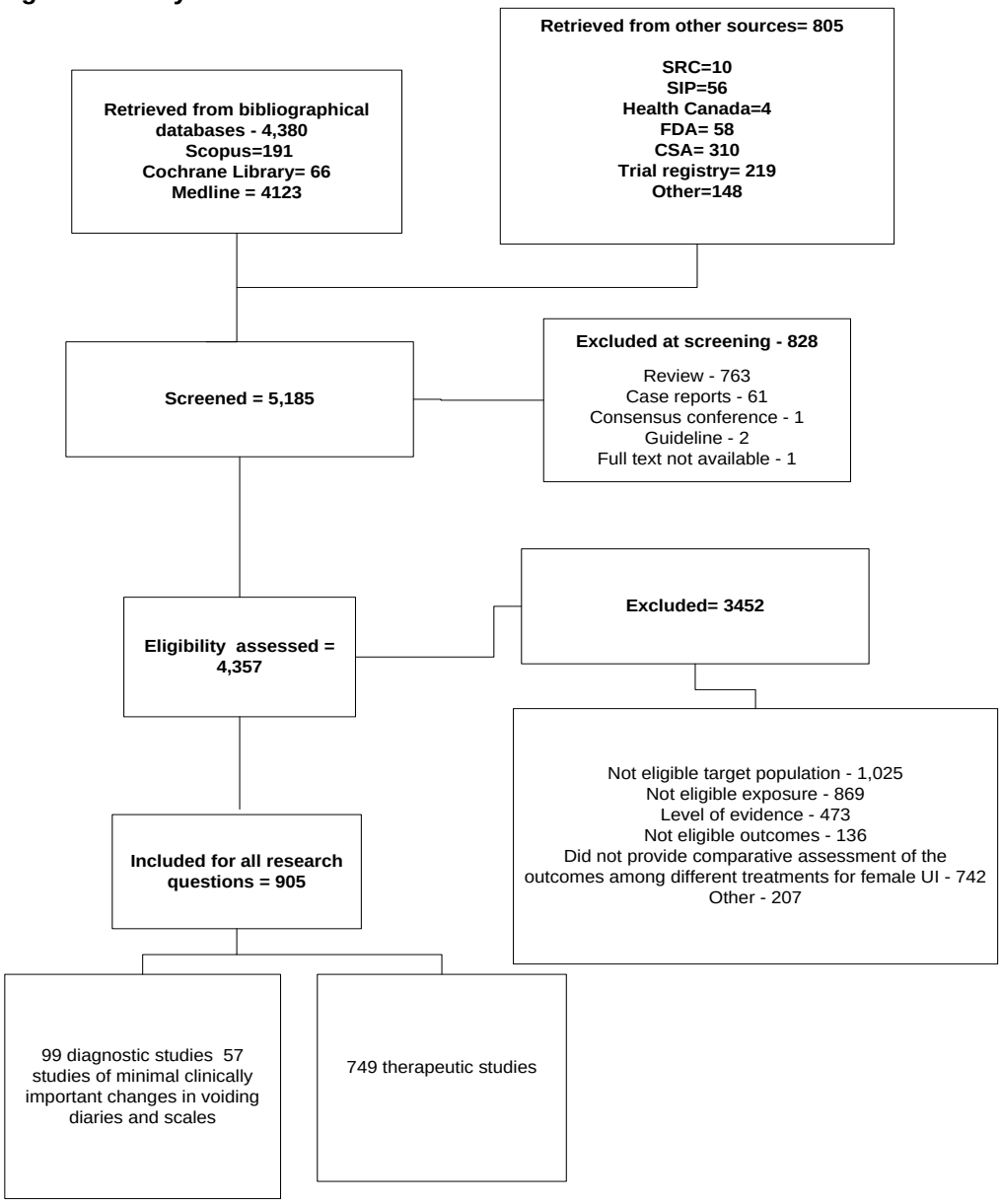
We examined consistency in results across the studies with Chi square tests and I square statistics.[182,183] We explored heterogeneity with meta-regression, subgroup, and sensitivity analysis and reported the results from random effects models only.[173] Using a standard preplanned algorithm, we explored heterogeneity by clinical diversity, comprised of the proportion of women, proportion of minority population, age of women, severity of UI, failure after prior treatments, concomitant treatments, inclusion of women with urogenital prolapse, and inclusion of women with mixed UI.[173] We explored heterogeneity by dose (when applicable), by duration of the treatments, and by control rate of the outcomes. We explored heterogeneity by quality criteria of individual studies and by whether conflict of interest was disclosed by study authors.[173] We explored heterogeneity by each quality criterion rather than the global quality score.[184,185] We calculated pooled relative risk, absolute risk difference with 95 percent CI, and Bayesian odds ratios with 95 percent credible intervals using STATA 10.1 and Meta-Analyst software.[168,174] We analyzed the probability that active treatments increased the chances of continence, improvements of UI, or adverse effects with the Bayesian approach using noninformative prior probability of the events.[168] The analytic framework and algorithms for the meta-analysis are shown in Appendix Table D5.

Results

Study Flow

We identified and retrieved 5,185 references (Figure 2). We excluded 3,452 references (Appendix B). We included 905 references for this review. Abstracted data is available at https://netfiles.umn.edu/xythoswfs/webui/_xy-17667196_1-t_lUjda8AM. Eligible references presented the results from individual studies, several publications of the same study, pooled analyses of the aggregate data, pooled analyses of the individual patient data, or statistical analyses of several studies with strength of evidence (Appendix Table F1). As an example of the latter, the FDA medical and statistical reviews contained 43 eligible studies (Appendix Table F2).

Figure 2. Study flow



Key Question 1. What constitutes an adequate diagnostic evaluation in the ambulatory care setting on which to base treatment of urinary incontinence (UI)?

Reporting quality of the studies precluded definitive conclusions about methodological quality (Appendix Table F3).[151,166] We did not identify the studies that reported sensitivity or specificity of different methods when compared to bladder diaries.

We identified 99 studies that provided diagnostic values of different methods for UI (Appendix Table F4).[3,32,186-278]

The studies included a total of 81,043 women. The sample size of individual studies varied from the largest study of 42,724 Australian women[263] to the small studies of fewer than 100 women[186,189,190,198,201,204,205,211,213,215,230,233,240,241,245,251,268-270,278] (Appendix Figure F1).

We summarized diagnostic values of diagnostic methods to differentiate stress, urgency, and mixed UI when compared to multichannel urodynamics or to clinical diagnosis. Described use of urodynamic testing as a reference standard test was very similar across the studies. Diagnostic methods to establish a clinical diagnosis of UI were described with different levels of detail and included history, physical examination, pelvic examination, urine culture, Q-tip test, diary, cytometry,[218] cough stress test, 48-hour home pad test,[259] evaluation of sacral nerves 2 to 4 (deep tendon reflexes, anal wink, perineal sensation), and measurement of postvoid residual volume (by catheter or ultrasonography).

Diagnostic Evaluation for UI

Diagnostic Value of the Symptoms of Stress UI To Distinguish Urodynamic Stress UI Was Low

The diagnostic value of symptoms of stress incontinence compared to multichannel urodynamics for stress UI was examined in 27 studies of 5,780 patients (Appendix Table F5).[188,189,191,193,195,197,200,202,203,206,207,209,213,217,228,229,238,244,246,251,253,273,279-283] Sensitivity was more than 70 percent, while specificity varied from 10 to13 percent[213,273,280] to 79 to 88 percent.[197,238]

Pooled sensitivity was 93 percent (95 percent CI, 90 to 95 percent) (Appendix Figure F2). The test was not specific with pooled specificity of 41 percent (95 percent CI, 34 to 49 percent) (Appendix Figure F3). Positive predictive likelihood ratio was small at 1.5 (95 percent CI, 1.4 to 1.7) (Appendix Table F6).

Diagnostic Value of Urgency Symptoms of UI To Distinguish Urodynamic Detrusor Overactivity Was Low

The diagnostic value of the symptoms of urgency UI compared to multichannel urodynamics to distinguish detrusor overactivity was examined in 23 studies of 5,485 patients (Appendix Table F7).[188,191,195,200,202,203,213,216,217,228,229,238,244,246,251,273,279-281,284] Sensitivity varied across the individual studies from 14 percent[280] to more than 90 percent.[188,216,244,251,279,284] Specificity varied across the individual studies from 21 percent[207] to more than 90 percent.[203,280] Pooled sensitivity was 82 percent (95 percent CI, 76 to 87 percent) (Appendix Figure F4) for any detrusor overactivity while pooled specificity was as low as 51 percent (95 percent CI, 44 to 59 percent) (Appendix Figure F5)**.** The positive predictive likelihood ratio was small at 1.5 (95 percent CI, 1.4 to 1.7).

Urgency Symptoms of UI Had a Low Diagnostic Value To Distinguish Pure Detrusor Overactivity

The diagnostic value of the symptoms of urgency UI compared to multichannel urodynamics to distinguish pure detrusor overactivity was examined in 17 studies of 3,924 subjects[191,195,200,203,206,207,209,211-213,217,228,229,244,251,273,279] (Appendix Table F8). Pooled sensitivity was 84 percent (95 percent CI, 78 to 89 percent) (Appendix Figure F6). Pooled specificity was as small as 43 percent (95 percent CI, 36 to 50 percent) (Appendix Figure F7). The positive predictive likelihood ratio was small at 1.5 (95 percent CI, 1.3 to 1.7) (Appendix Table F9).

Urgency Symptoms Alone, With, or Without UI Had a Minimal Diagnostic Value in Distinguishing Detrusor Overactivity in Women

The diagnostic value of urgency symptoms with or without UI compared to multichannel urodynamics to distinguish detrusor overactivity was examined in nine studies of 6,418 patients[202,206,209,213,217,229,247,279,284] (Appendix Table F10). Pooled sensitivity was 84 percent (95 percent CI, 59 to 95 percent) (Appendix Figure F8). Pooled specificity was as low as 39 percent (95 percent CI, 17 to 67 percent) with substantial heterogeneity across the studies (Appendix Figure F9). The positive likelihood ratio was also low at 1.36 (95 percent CI, 1.2 to 1.6) (Appendix Table F11).

Urgency Symptoms Had Minimal Diagnostic Value to Distinguish Pure Detrusor Overactivity in Women

The diagnostic value of urgency symptoms with or without UI compared to multichannel urodynamics to distinguish pure detrusor overactivity was examined in six studies of 1,598 subjects[206,209,213,217,229,279] (Appendix Table F12). Pooled sensitivity was 86 percent (95 percent CI, 83 to 89 percent) (Appendix Figure F10). Pooled specificity was as low as 31 percent (95 percent CI, 24 to 39 percent) (Appendix Figure F11). The positive likelihood ratio was also low at 1.21 (95 percent CI, 1.1 to 1.3) (Appendix Table F13).

Mixed Symptoms Had Minimal Diagnostic Value for Urodynamic Criteria of Mixed UI

The diagnostic value of mixed UI symptoms compared to multichannel urodynamics for mixed UI was examined in 11 studies of 2,767 subjects[191,195,199,200,203,207,228,244,246,251,273] (Appendix Table F14). Pooled sensitivity was 73 percent (95 percent CI, 61 to 82 percent) (Appendix Figure F12). Pooled specificity was as low as 53 percent (95 percent CI, 40 to 66 percent) (Appendix Figure F13). Positive likelihood ratio was also low at 1.5 (95 percent CI, 1.3 to 1.7) (Appendix Table F15). Sensitivity and specificity differed across individual studies. Quality of the studies was not associated with differences in sensitivity or specificity. The results were similar after pooling with random effects models that incorporated heterogeneity across the studies in pooled estimates and bivariate pooling as recommended in cases of detected heterogeneity (Table 3).

Diagnostic Value of Pad Tests Compared to Multichannel Urodynamics

The diagnostic value of a 1-hour pad test compared to multichannel urodynamics for stress UI was examined in three studies of 574 women[207,271,275] (Appendix Table F16). Pooled sensitivity was 84 percent (95 percent CI, 76 to 90 percent) (Appendix Figure F14). Pooled specificity was 77 percent (95 percent CI, 72 to 82 percent) (Appendix Figure F15). The positive likelihood ratio was below 5 (3.6, 95 percent CI, 2.9 to 4.6), pointing out a small increase in the likelihood of urodynamic stress UI in women with positive pad tests (Appendix Table F17).

The diagnostic value of a 1-hour pad test compared to multichannel urodynamics for detrusor overactivity was examined in two studies of 469 subjects. Sensitivity varied in studies with pooled estimates of 72 percent (95 percent CI, 30 to 94 percent)[271,275] (Appendix Figure F16). Pooled specificity was as low as 56 percent (95 percent CI, 38 to 72 percent) (Appendix Figure F17). The positive likelihood ratio was as small as 1.56 (95 percent CI, 0.6 to 3.9) (Appendix Table F18).

Diagnostic Value of Symptoms of UI to Clinical Diagnosis

Clinical diagnosis of UI was based on history, physical examination, pelvic examination, urine culture, Q-tip test, diary, cytometry,[218] cough stress test, 48-hour home pad test,[259] and measurement of postvoid residual volume (by catheter or ultrasonography).[223,266]

Women With Urgency Symptoms Had a Small Likelihood of a Clinical Diagnosis of Detrusor Overactivity

The diagnostic value of urgency UI symptoms compared to clinical diagnosis for any detrusor overactivity was examined in four studies of 735 subjects[218,223,259,266] (Appendix Table F19). Pooled sensitivity was 82 percent (95 percent CI, 73 to 89 percent) (Appendix Figure F18). Pooled specificity was 67 percent (95 percent CI, 53 to 79 percent) (Appendix Figure F19). The positive likelihood ratio was above 2 (2.5, 95 percent CI, 1.8 to 3.5) (Appendix Table F20).

Women With Symptoms of Stress UI Had a Minimal Likelihood of a Clinical Diagnosis of Stress UI

The diagnostic value of symptoms of stress UI compared to a clinical diagnosis of stress UI was examined in five studies of 947 subjects[218,223,259,266,285] (Appendix Table F19). Pooled sensitivity was 88 percent (95 percent CI, 68 to 96 percent) (Appendix Figure F20). Pooled specificity was 67 percent (95 percent CI, 54 to 78 percent) (Appendix Figure F21). The positive likelihood ratio was above 2 (2.4, 95 percent CI, 2.0 to 2.8) (Appendix Table F21). The diagnostic value of symptoms of mixed UI compared to clinical diagnosis of mixed UI was examined in three studies of 654 subjects. Pooled sensitivity was 65 percent (95 percent CI, 36 to 86 percent) (Appendix Figure F22). Pooled specificity was 54 percent (95 percent CI, 21 to 84 percent) (Appendix Figure F23). The positive likelihood ratio was as small as 1.6 (95 percent CI, 0.7 to 3.6) (Appendix Table F22).

Women With Urgency Symptoms Had a Minimal Likelihood of Having a Clinical Diagnosis of Pure Detrusor Overactivity

The diagnostic value of urgency UI symptoms compared to clinical diagnosis for pure detrusor overactivity was examined in two studies of 551 women (Appendix Table F23). Pooled sensitivity was 70 percent (95 percent CI, 43 to 88 percent) (Appendix Figure F24). Pooled speicificty was 55 percent (95 percent CI, 28 to 79 percent) (Appendix Figure F25). The positive likelihood ratio was as small as 1.6 (95 percent CI, 0.6 to 4.2) (Appendix Table F24).

Individual studies reported diagnostic values of the tests that did not meet pooling criteria (Table 3). One study of 488 women analyzed diagnostic value of the symptoms reported in mailed questionnaires compared to multichannel urodynamics.[258] Questionnaires had a minimal diagnostic value for stress (positive likelihood ratio=1.8) and urgency (positive likelihood ratio=1.8) UI.

Diagnostic Value of Complex Clinical Algorithms

The diagnostic values of complex clinical algorithms were high and varied depending on components of algorithms and reference methods to diagnose UI.

Diagnostic Value of a Clinical Algorithm Versus Urodynamics

Diagnostic value of complex clinical algorithms for UI was high when compared to urodynamic evaluation. Two studies examined diagnostic value of algorithms for stress UI. One

study of 1,455 women examined diagnostic value of a clinical algorithm versus urodynamics. Included subjects had predominant symptoms of stress UI with more than four episodes of UI per week, normal diurnal and nocturnal frequency, a bladder capacity of 400 ml or greater, and a positive cough stress (sign of stress UI) and stress pad test.[254] The authors reported positive predictive values of 90.2 percent for urodynamic stress UI and 76.9 percent for pure urodynamic stress UI.[254] Diagnostic accuracy was the same across age categories and among those with previous surgery for stress UI.[254] The authors did not report positive predictive likelihood of the clinical algorithm. Another study of 652 women examined the diagnostic value of a clinical algorithm that required the presence of a predominant complaint of stress UI, positive cough stress test results, postvoid residual urine volume of no more than 50 ml, and a functional bladder capacity of at least 400 ml as determined by a completed 24-hour frequency volume chart.[230] This study also used urodynamics as a reference standard test. The algorithm had a positive predictive value of 97 percent when compared to multichannel urodynamics to diagnose stress UI.[230]

One study examined diagnostic value of algorithms for urgency UI. The diagnosis of pure detrusor overactivity was accurate when compared to urodynamics in scoring frequency, urgency, nocturia, and self-reported urgency UI.[276,277] The algorithm demonstrated good diagnostic value with a positive predictive likelihood ratio of 12.6 and a diagnostic odds ratio of 27.3. The same study proposed scoring of urodynamic stress UI based on self-reported frequency of incontinent episodes and the amount of protection.[276,277] The diagnostic value of such composite scores was moderate with a positive predictive likelihood ratio of 3.8 and a diagnostic odds ratio of 11.

Diagnostic Value of Clinical Algorithms Based on the Epidemiology of a Pelvic Organ Prolapse and Incontinence Questionnaire When Compared to Clinical Diagnosis

This comparison was tested in one study of 110 women.[262] The questionnaire had a moderate likelihood of identifying women with detrusor overactivity (positive likelihood ratio=7.7) and a large likelihood of identifying women with stress UI (positive likelihood ratio=19).[262] One study demonstrated moderate diagnostic value of the Three Incontinence Questions Questionnaire (3IQ) when compared to clinical diagnosis in 301 women to detect those with stress or urgency UI.[266]

Diagnostic Values of Individual Tests When Compared to Urodynamics

In individual studies, other examined tests using urodynamics as a reference standard, including the Q-tip test,[208,286] UDI-6,[244,287] questionnaire for urinary incontinence diagnosis (QUID) stress score,[288] or Bristol Female Lower Urinary Tract Symptoms Questionnaire,[253] demonstrated minimal diagnostic value for UI with positive predictive likelihood ratios less than 2 (Table 3). The studies of the Gaudenz questionnaire reported different results depending on the country where the study was conducted.[220,238]

Diagnostic Values of Ultrasound Versus Urodynamics as a Reference Standard

The diagnostic values of ultrasound using urodynamics as a reference standard were examined in five studies of 540 women.[289-293] Perineal ultrasound had a small diagnostic value

with a positive predictive likelihood ratio of 3 for urodynamic stress UI.[289] Vaginal ultrasound had a moderate diagnostic value with a positive predictive likelihood ratio of 5.3 for urodynamic stress UI.[293] Transrectal ultrasound that detected a decreased angle of UV junction demonstrated a large and conclusive increase in the likelihood of urodynamic stress UI.[291,292]

Comparison of Diagnostic Values of Different Tests

The majority of studies demonstrated that the tests had only small diagnostic value in distinguishing women with urodynamic stress or urgency UI. Complex clinical algorithms demonstrated better diagnostic performance. Individual studies suggested a good diagnostic value of the epidemiology of prolapse and incontinence questionnaires. Post-test probability of mixed or urgency UI increased in aging women.[294]

We compared the accuracy of diagnostic tests for different types of UI across studies (Table 3). Urodynamic stress UI was accurately diagnosed in 80 percent of women using 1-hour pad test, and in 75 percent of women using self-reported symptoms of stress UI (Figure 3). Urge symptoms accurately diagnosed urodynamic urgency UI in 66 percent of women. Pad tests accurately diagnosed urodynamic urgency UI in 61 percent of women. Accuracy of the symptoms of mixed UI to diagnose urodynamic stress UI combined with detrusor overactivity was low (56 percent). Clinical diagnosis of stress UI was accurately detected with self-reported symptoms of stress UI in 80 percent of women. Clinical diagnosis of detrusor overactivity was accurately detected with self-reported symptoms of urgency UI in 73 percent. The pooled diagnostic odds ratio demonstrated the same pattern with the best discriminatory performance of symptoms of stress UI and pad test when compared to urodynamic diagnosis of stress UI (Figure 4). The diagnostic odds ratio was the more than 10 for the symptoms for stress and urgency UI when compared to a clinical diagnosis.

We also compared predictive values of diagnostic tests for different type of UI across the studies (Table 4). The predictive values in ambulatory settings depend on prevalence of UI in community dwelling women.[167] Positive predictive values were less than 50 percent for most comparisons while negative predictive values were larger than 90 percent. Positive predictive value of the symptoms of mixed UI and urgency UI increased with age. The majority of women without symptoms of UI did not have clinical diagnosis of UI.

Minimal Clinically Important Differences in Diagnostic Tools To Monitor Effectiveness of Treatments

Women considered a reduction of 50 percent or more in UI episode frequency a clinical success.[295] Quality of life was improved with more than 70 percent reduction in UI episode frequency. However, clinical trials and the FDA reviews did not define women centered outcomes as primary outcomes.

Clinically important differences have been determined for several questionnaires and scales. Among validated diagnostic questionnaires, The Leicester Urinary Symptom Questionnaire (LUSQ)[296] and Medical, Epidemiological, and Social Aspects of Aging Questionnaire (MESA)[297] provided information about presence and severity of UI in categorical terms. Other tools suggested scoring of the symptoms of any UI[259,298] or urgency UI.[264] The overall score varied for different tools (Table 5). The Bladder Self-Assessment Questionnaire and Bladder Control Self-Assessment Questionnaires defined minimal important differences in scores that can be used to detect treatment success in clinical settings.[299]

A variety of validated tools are available to monitor quality of life in women with UI and with different UI types. Several tools that define clinically important differences in scores can be used to assess treatment success in clinical settings.

Patient satisfaction can be assessed with several validated tools, including the Overactive Bladder Symptom Score,[300] the Benefit, Satisfaction with Treatment, and Willingness,[301] the Estimated Percent Improvement,[328] or the Global Perception of Improvement[302] (Table 5). Some tools focused on satisfaction with treatments in women with urgency UI,[300,301,303] while other tools were proposed for any UI type. These instruments are brief and do not require much time to complete. Clinical importance of different responses is self-explanatory. Patient satisfaction measures define treatment success but do not provide many details to explain treatment failure.

We analyzed validity and reliability of the tools and sought literature to find definitions of the minimum important differences in continuous measures of severity of UI, bothersomeness, or quality of life (Table 5). We evaluated the scales and questionnaires recommended by the ICI for diagnosis, monitoring of treatment, and assessment of quality of life in women with UI.[304]

Effectiveness of treatments in randomized controlled clinical trials was assessed with 3 to 7 day diaries. A reduction in UI episode frequency was the most common primary outcome that RCTs were designed to examine.[115,305-326] Medical and statistical reviews conducted by the FDA focused on the same primary outcomes that RCTs were designed to examine—absolute changes in UI episode frequency.[115,306,307,327-330] Some RCTs further categorized treatment success as any reduction in UI episode frequency or reduction by 50, 75, or 90 percent in UI episode frequency.

One pooled analysis of individual data of 1,913 women with predominant stress UI who participated in four RCTs examined what reduction in UI episode frequency was important for the patients.[295] The authors examined the relationship between relative reduction in UI episode frequency and improvement meaningful for women in the Incontinence Quality of Life questionnaire.[295] Women with daily stress UI perceived important clinical benefit at reductions of approximately 50 percent and important incremental clinical value at reductions of 75 percent and 90 to100 percent. The study concluded that women noticed improvement in quality of life when UI episode frequency was reduced by more than 70 percent.[295] Small changes of 20 to 40 percent in incontinence episode frequency were not important to women when the results from a voiding diary were analyzed in association with the validated Incontinence Quality of Life (I-QOL) questionnaire. The quality of life impact was similar for stress UI episode reductions of >40 percent to <70 percent.[295] In the case of women with persistent urge, stress or mixed urinary incontinence, more than 60 percent reported complete treatment satisfaction using the Global Perception of Improvement of Incontinence Impact Questionnaire when they experienced a more than 70 percent reduction in UI episode.[302] No studies examined clinically important reduction in UI episode frequency for women with predominant urgency UI.

All tools to assess symptom bother have been validated. Tools that distinguish symptom bother for stress UI include Patient Global Impression of Improvement PGI-I,[331] PGI-S Patient Global Impression of Improvement and Severity,[331] or Symptom Severity Index and Symptom Impact Index for stress UI in women.[332] The Primary OAB Symptom Questionnaire provided four scales to assess symptom bother for urgency UI.[333] Other tools evaluated symptom bother for any type of UI (Table 5). The Incontinence Severity Index,[334,335] Patient Global Impression of Improvement and of Severity,[331] Urogenital Distress Inventory,[222,336,337] and Patient Perception of Bladder Condition[333,338,339] developed definitions of minimum important differences in any UI that can be used to define treatment success in clinical settings. The Urogenital Distress Inventory stress subscale also can distinguish minimum important differences in stress UI.[336]

Women reported improvement in UI when the incontinence episode frequency was reduced by ≥63percent.[331]

Several tools have been validated to assess quality of life in women with UI (Table 5). All tools provided scoring for different domains of quality of life and overall total scores that varied by direction and magnitude across the scales. Comparing efficacy of the tools was difficult because of such variability in content and psychometric properties. Few tools addressed quality of life depending on the type of incontinence.

Association Between Methods of Diagnosis and Prediction of Patient Outcomes

We found no evidence that outcomes of conservative treatments were better predicted by urodynamic diagnosis.

However, women who failed conservative treatments and/or decided to have surgery for stress UI may benefit from a multichannel urodynamic evaluation. In all cases, a diagnostic algorithm assumes adequate assessment of baseline conditions that may result in UI, including pelvic organ prolapse, urinary tract infection, or pelvic floor trauma.

A few studies tested the effect of baseline urodynamic examination in association with better prediction of treatment outcomes. The studies generally showed that urodynamic findings did not better predict response to conservative treatments. One extension of RCTs of conservative treatment concluded that continence (RR 1.24, 95 percent CI, 0.30 to 5.23), improvement in UI (RR 0.85, 95 percent CI, 0.55 to 1.31), or treatment failure with worsening of UI (RR 1.24, 95 percent CI, 0.47 to 3.29) did not differ between women who did or did not have a baseline urodynamic evaluation.[340] The second RCT randomized women to conservative treatments depending on baseline urodynamics or clinical symptoms.[341] Treatments included fluid management, physical therapy, and drugs, depending on urodynamic or clinical diagnosis. Quality of life measured with King's Health Questionnaire and the frequency of UI episodes measured with voiding diary did not differ between randomized groups.[341] The authors concluded that baseline urodynamic diagnosis was not associated with better predicting outcomes.

Drug studies showed that in women with severe stress UI, duloxetine versus placebo decreased the frequency of UI episodes independent of baseline urodynamic findings.[319] Women with intrinsic sphincter deficiency experienced more than a 50 percent decrease in daily UI (RR 6.15, 95 percent CI, 1.54 to 24.54), as did women without intrinsic sphincter deficiency (RR 4.20, 95 percent CI, 1.81 to 9.76). The RCT, however, was not designed to detect differences in duloxetine effect by using a baseline urodynamic evaluation. One multicenter RCT examined clinical outcomes with fesoterodine in subgroups by urodynamic findings of detrusor overactivity.[342] Treatment response, discontinuation rate, and adverse effects did not differ between individuals with versus without urodynamic diagnosis of detrusor overactivity (Appendix Table F25).[342] One RCT that compared clinical outcomes with tolterodine-ER versus placebo also did not demonstrate differences in treatment effects in women with and without urodynamic detrusor overactivity.[343] Baseline urodynamic examination did not better predict treatment outcomes. Case series also found no differences in treatment response with oxybutynin between those with versus without urodynamically verified symptoms (Appendix Table F26).[344]

In contrast, one large analysis of 6,276 women with UI from the United Kingdom suggested that urodynamic evaluation is essential to predict outcomes, but only with surgery for UI.[345] The authors examined the accuracy of the history of pure stress UI in predicting only urodynamic

stress UI compared to the NICE guidance and found very low sensitivity of 11 percent and good specificity of 98 percent (NICE, 83 percent; 95 percent CI, 49 to 92 percent). The study suggested that a multichannel urodynamic evaluation is indicated for women whose conservative treatments failed and who decided to have surgery for stress UI.[345] A recent study also concluded that all women whose conservative treatments failed and who undergo surgery for stress UI should have multichannel urodynamic evaluation.[346]

Table 3. Diagnostic value of the test for UI in women (pooled with random effects models and bivariate pooling)

Type of incontinence	Method index/ Reference Standard	Number of studies References Number of subjects in analyses	Sensitivity/ Bivariate pooling	Specificity/ Bivariate pooling	Positive likelihood ratio†	Negative likelihood ratio†	Positive predictive value	Negative predictive value
Urodynamic stress UI	Symptoms of stress UI/ Urodynamic test	27[188,189,191,193,195,197,200,202,203,206,207,209,213,217,228,229,238,244,246,251,253,273,279-283] 5,780	0.93^ (0.90 to 0.95) 0.94 (0.91to 0.96)	0.41^ (0.34 to 0.49) 0.41 (0.31 to 0.51)	1.54 (1.40 to 1.7)	0.20 (0.14 to 0.27)	0.74 (0.68 to 0.80)	0.74 (0.67 to 0.81)
Detrusor overactivity	Symptoms of urgency UI/ Urodynamic test	23[188,191,195,200,202,203,206,207,209,213,216,217,228,229,238,244,246,251,273,279-281,284] 5,485	0.82^ (0.76 to 0.87) 0.82 (0.75 to 0.88)	0.51^ (0.44 to 0.59) 0.52 (0.40 to 0.65)	1.54 (1.38 to 1.73)	0.39 (0.30 to 0.50)	0.56 (0.48 to 0.63)	0.80 (0.73 to 0.86)
Detrusor overactivity	Symptoms of urgency/ Urodynamic test	9[202,206,209,213,217,229,247,279,284] 6,418	0.84^ (0.59 to 0.95) 0.82 (0.70 to 0.92)	0.39^ (0.17 to 0.67) 0.39 (0.24 to 0.55)	1.36 (1.18 to 1.58)	0.47 (0.33 to 0.67)	0.48 (0.39 to 0.57)	0.75 (0.67 to 0.81)
Detrusor overactivity*	Symptoms of urgency UI/ Urodynamic test	17[191,195,200,203,206,207,209,211-213,217,228,229,244,251,273,279] 3,924	0.84^ (0.78 to 0.89) 0.84 (0.79 to 0.90)	0.43^ (0.36 to 0.50) 0.44 (0.34 to 0.54)	1.48 (1.31 to 1.66)	0.40 (0.29 to 0.54)	0.33 (0.26 to 0.41)	0.89 (0.83 to 0.93)
Detrusor overactivity*	Symptoms of urgency/ Urodynamic test	6[206,209,213,217,229,279] 1,598	0.86 (0.83 to 0.89) 0.86 (0.80 to, 0.90)	0.31^ (0.24 to 0.39) 0.31 (0.20 to 0.45)	1.21 (1.11 to 1.32)	0.523 (0.41 to 0.67)	0.27 (0.17 to 0.40)	0.86 (0.76 to 0.93)
Mixed UI	Symptoms of stress and urgency UI/ Urodynamic test	11[191,195,199,200,203,207,228,244,246,251,273] 2,767	0.73^ (0.61 to 0.82) 0.72 (0.58 to 0.83)	0.53^ (0.40 to 0.66) 0.53 (0.34 to 0.72)	1.45 (1.27 to 1.67)	0.61 (0.52 to 0.71)	0.26 (0.20 to 0.34)	0.89 (0.85 to 0.92)
Urodynamic stress UI	Pad test/ Urodynamic test	3[225,271,275] 574	0.84 (0.76 to 0.90) 0.83 (0.75 to 0.91)	0.77 (0.72 to 0.82) 0.77 (0.17 to 0.97)	3.62 (2.88 to 4.57)	0.22 (0.15 to 0.32)	0.82 (0.77 to 0.86)	0.78 (0.73 to 0.83)
Detrusor overactivity	Pad test/ Urodynamic test	2[271,275] 469	0.72^ (0.30 to 0.94)	0.56^ (0.38 to 0.72)	1.56 (0.62 to 3.90)	0.47 (0.10 to 2.33)	0.32 (0.04 to 0.83)	0.88 (0.83 to 0.91)

Table 3. Diagnostic value of the test for UI in women (pooled with random effects models and bivariate pooling) (continued)

Type of incontinence	Method index/ Reference Standard	Number of studies References Number of subjects in analyses	Sensitivity/ Bivariate pooling	Specificity/ Bivariate pooling	Positive likelihood ratio†	Negative likelihood ratio†	Positive predictive value	Negative predictive value
Urodynamic stress UI	Symptoms of predominant stress UI/clinical diagnosis	5[218,223,259,266,285] 947	0.88^ (0.68 to 0.96) 0.86 (0.70 to 0.96)	0.67^ (0.54 to 0.78) 0.67 (0.51 to 0.81)	2.35 (1.97 to 2.81)	0.19 (0.09 to 0.41)	0.80 (0.66 to 0.89)	0.75 (0.58 to 0.87)
Detrusor overactivity	Symptoms of predominant urgency UI/clinical diagnosis	4[218,223,259,266] 735	0.82^ (0.73 to 0.89) 0.82 (0.73 to 0.90)	0.67^ (0.53 to 0.79) 0.67 (0.45 to 0.86)	2.52 (1.81 to 3.50)	0.26 (0.18 to 0.38)	0.72 (0.48 to 0.88)	0.79 (0.54 to 0.92)
Mixed UI	Symptoms of stress and urgency UI/clinical diagnosis	3[223,259,266] 654	0.65^ (0.36 to 0.86) 0.64 (0.38 to 0.85)	0.54^ (0.21 to 0.84) 0.52 (0.06 to 0.94)	1.57 (0.68 to 3.59)	0.74 (0.28 to 1.95)	0.36 (0.27 to 0.47)	0.80 (0.43 to 0.96)
Urodynamic stress UI	Logistic regression model/ Urodynamic test	1[258] 488	0.77	0.56	1.76	0.41	0.68	0.65
Detrusor overactivity	Logistic regression model/ Urodynamic test	1[258] 488	0.63	0.65	1.81	0.57	0.63	0.67
Urodynamic stress UI	Clinical algorithm/ Urodynamic test	1[254] 173					0.90 (0.85 to 0.94)	
Urodynamic stress UI	Clinical algorithm/ Urodynamic test	1[230] 74					0.97	
Urodynamic stress UI	Clinical algorithm based on EPIQ/Clinical diagnosis	1[262] 110	0.80	0.92	10.00	0.22	0.88	0.87
Detrusor overactivity	Clinical algorithm based on EPIQ/Clinical diagnosis	1[262] 110	0.77	0.90	7.70	0.26	0.77	0.90

Table 3. Diagnostic value of the test for UI in women (pooled with random effects models and bivariate pooling) (continued)

Type of incontinence	Method index/ Reference Standard	Number of studies References Number of subjects in analyses	Sensitivity/ Bivariate pooling	Specificity/ Bivariate pooling	Positive likelihood ratio†	Negative likelihood ratio†	Positive predictive value	Negative predictive value
Detrusor overactivity	Clinical algorithm based on OAB-V8/Clinical diagnosis	1[264] 1,260	0.98	0.83	5.66	0.02	0.44	1.00
Urodynamic stress UI	Q-tip test/ Urodynamic test	3[208,286,291] 267	0.62 (0.53 to 0.70) 0.62 (0.49 to 0.74)	0.60^ (0.40 to 0.78) 0.58 (0.00 to 0.99)	1.70 (0.89 to 3.23)	0.60 (0.31 to 1.17)	0.58 (0.26 to 0.85)	0.67 (0.34 to 0.89)
Detrusor overactivity	Q-tip test/ Urodynamic test	1[208] 100	0.40	0.40	0.66	1.50	0.33	0.47
Urodynamic stress UI	UDI-6 question 3 score ≥2/ Urodynamic test**	1[234] 128	0.85	0.63	2.32	0.24		
Urodynamic stress UI	UDI-6 question 3 score ≥2/ Urodynamic test**	1[244] 202	0.88	0.55	1.97	0.21	0.86	0.60
Urodynamic stress UI	DIS	1[208] 250	0.60	0.77	2.61	0.52	0.82	0.52
Detrusor overactivity	UDI-6 question 1 score ≥2/ Urodynamic test	1[234] 128	0.83	0.50	1.67	0.33		
Detrusor overactivity	UDI-6 question 2 score ≥2/ Urodynamic test	1[234] 128	0.75	0.33	1.11	0.77		
Detrusor overactivity	UDI-6 question 1 and 2 score ≥2/ Urodynamic test	1[234] 128	0.69	0.64	1.90	0.49		
Urodynamic stress UI	QUID stress score ≥4/Clinical diagnosis	1[259] 117	0.85	0.71	2.93	0.21	0.90	0.61

Table 3. Diagnostic value of the test for UI in women (pooled with random effects models and bivariate pooling) (continued)

Type of incontinence	Method index/ Reference Standard	Number of studies References Number of subjects in analyses	Sensitivity/ Bivariate pooling	Specificity/ Bivariate pooling	Positive likelihood ratio†	Negative likelihood ratio†	Positive predictive value	Negative predictive value
Detrusor overactivity	QUID urge score ≥6/Clinical diagnosis	1[259] 117	0.79	0.79	3.76	0.27	0.95	0.43
Detrusor overactivity	BIDI from diary/ Urodynamic test	1[288] 217	0.88	0.83	5.12	0.14	0.41	0.98
Detrusor overactivity	Logistic regression model/ Urodynamic test	1[277] 200	0.81	0.72	2.89	0.26	0.74	0.79
Detrusor overactivity*	Logistic regression model/ Urodynamic test	1[276] 207	0.56	0.96	12.56	0.46	0.80	0.87
Urodynamic stress UI	Gaudenz-Incontinence-questionnaire predominant stress UI symptoms/ Urodynamic test	1[220] 1,911	0.56	0.45	1.01	0.99	0.88	0.18
Detrusor overactivity	Gaudenz-Incontinence-questionnaire predominant urgency UI symptoms/ Urodynamic test	1[220] 1,911	0.62	0.56	1.40	0.69	0.03	0.99
Urodynamic stress UI*	Logistic regression/ Urodynamic test	1[276] 207	0.95	0.43	1.66	0.13	0.48	0.93
Urodynamic stress UI	Logistic regression/ Urodynamic test	1[277] 200	0.72	0.81	3.79	0.35	0.79	0.74

Table 3. Diagnostic value of the test for UI in women (pooled with random effects models and bivariate pooling) (continued)

Type of incontinence	Method index/ Reference Standard	Number of studies References Number of subjects in analyses	Sensitivity/ Bivariate pooling	Specificity/ Bivariate pooling	Positive likelihood ratio†	Negative likelihood ratio†	Positive predictive value	Negative predictive value
Urodynamic stress UI*	Clinical algorithm based on I-QOL/ Urodynamic test	1[250] 86					0.76	
Urodynamic stress UI	Clinical algorithm based on I-QOL/ Urodynamic test	1[250] 86					0.92	
Urodynamic stress UI*	Clinical algorithm/ Urodynamic test	1[254] 173					0.77 (0.7 to 0.83)	
Urodynamic stress UI	Clinical algorithm/clinical diagnosis	1[254] 173					0.98 (0.95 to 1.00)	
Urodynamic stress UI*	Clinical algorithm/clinical diagnosis	1[254] 173					0.85 (0.79 to 0.90)	
Urodynamic stress UI*	Clinical algorithm/ Urodynamic test	1[230] 74					0.82	
Urodynamic stress UI*	Clinical algorithm retrospective/ Urodynamic test	1[232] 57	0.90	1.00		0.10	1.00	0.82
Urodynamic stress UI*	Clinical algorithm prospective/ Urodynamic test	1[232] 19	0.62	1.00		0.38	1.00	0.55
Urodynamic stress UI*	Clinical algorithm combining retrospective and prospective/ Urodynamic test	1[232] 76	0.83	1.00		0.17	1.00	0.73

Table 3. Diagnostic value of the test for UI in women (pooled with random effects models and bivariate pooling) (continued)

Type of incontinence	Method index/ Reference Standard	Number of studies References Number of subjects in analyses	Sensitivity/ Bivariate pooling	Specificity/ Bivariate pooling	Positive likelihood ratio†	Negative likelihood ratio†	Positive predictive value	Negative predictive value
Urodynamic stress UI*	Q-tip test/ Urodynamic test	1 [208] 100	0.38	0.44	0.67	1.42	0.22	0.63
Detrusor overactivity*	Q-tip test/ Urodynamic test	1 [208] 100	0.63	0.56	1.45	0.65	0.47	0.71
Urodynamic stress UI	Self reported questionnaire/Urodynamic test	1 [197] 161	0.68	0.79	3.23	0.40	0.82	0.63
Detrusor overactivity	Self reported questionnaire/UD	1 [197] 166	0.67	0.66	1.94	0.51	0.13	0.96
Detrusor overactivity	Bristol Female Lower Urinary Tract Symptoms Questionnaire, interview/ Urodynamic test	1 [253] 72	0.85	0.16	1.01	0.94		
Detrusor overactivity	Bristol Female Lower Urinary Tract Symptoms Questionnaire, self report/ Urodynamic test	1 [253] 72	0.81	0.12	0.92	1.58		
Urodynamic stress UI	Bristol Female Lower Urinary Tract Symptoms Questionnaire, interview/ Urodynamic test	1 [253] 72	0.89	0.30	1.27	0.37		

Table 3. Diagnostic value of the test for UI in women (pooled with random effects models and bivariate pooling) (continued)

Type of incontinence	Method index/ Reference Standard	Number of studies References Number of subjects in analyses	Sensitivity/ Bivariate pooling	Specificity/ Bivariate pooling	Positive likelihood ratio†	Negative likelihood ratio†	Positive predictive value	Negative predictive value
Urodynamic stress UI	Bristol Female Lower Urinary Tract Symptoms Questionnaire, self report/ Urodynamic test	1[253] 72	0.88	0.29	1.24	0.41		
Urodynamic stress UI	Discriminant score/ Urodynamic test	1[253] 252	0.78	0.84	4.97	0.26	0.81	0.81
Urodynamic stress UI*	Gaudenz-Incontinence-questionnaire score predominant stress UI symptoms/ Urodynamic test	1[253] 198	0.83	0.92	10.12	0.18	0.95	0.76
Urodynamic stress UI*	3IQ predominant stress UI symptoms/clinical diagnosis	1[266] 301	0.77	0.79	3.63	0.29	0.74	0.82
Urodynamic stress UI*	Clinical algorithm of predominant stress UI symptoms based on UITN/ Urodynamic test	1[267] 655	0.91					
Detrusor overactivity*	3IQ predominant stress UI symptoms/ clinical diagnosis	1[238] 301	0.57	0.87	4.52	0.49	0.75	0.76
Urodynamic stress UI	3IQ predominant stress UI symptoms/clinical diagnosis	1[238] 301	0.68	0.85	4.57	0.37	0.86	0.66

Table 3. Diagnostic value of the test for UI in women (pooled with random effects models and bivariate pooling) (continued)

Type of incontinence	Method index/ Reference Standard	Number of studies References Number of subjects in analyses	Sensitivity/ Bivariate pooling	Specificity/ Bivariate pooling	Positive likelihood ratio†	Negative likelihood ratio†	Positive predictive value	Negative predictive value
Detrusor overactivity	3IQ predominant stress UI symptoms/ clinical diagnosis	1[238] 301	0.48	0.91	5.22	0.57	0.86	0.60
Detrusor overactivity*	Gaudenz-Incontinence-questionnaire score predominant urgency UI symptoms/ Urodynamic test	1[238] 198	0.86	0.96	24.28	0.14	0.81	0.98
Mixed UI	Gaudenz-Incontinence-questionnaire score mixed UI symptoms/ Urodynamic test	1[238] 198	0.61	0.87	4.56	0.45	0.54	0.89
Urodynamic stress UI	Gaudenz-Incontinence-questionnaire score predominant stress UI symptoms/ Urodynamic test	1[238] 198	0.98	0.55	2.18	0.03	0.79	0.95
Detrusor overactivity	Gaudenz-Incontinence-questionnaire score predominant urgency UI symptoms/ Urodynamic test	1[238] 198	0.90	0.70	2.97	0.15	0.34	0.98

Table 3. Diagnostic value of the test for UI in women (pooled with random effects models and bivariate pooling) (continued)

Type of incontinence	Method index/ Reference Standard	Number of studies References Number of subjects in analyses	Sensitivity/ Bivariate pooling	Specificity/ Bivariate pooling	Positive likelihood ratio†	Negative likelihood ratio†	Positive predictive value	Negative predictive value
Urodynamic stress UI	Symptoms, Q-tip, and cough test/ Urodynamic test	1[347] 87	0.94	0.84	5.85	0.08	0.94	0.84
Detrusor overactivity	Symptoms, Q-tip, and cough test/ Urodynamic test	1[347] 87	0.78	0.87	5.98	0.25	0.84	0.82
Urodynamic stress UI*	Symptoms, Q-tip, and cough test/ Urodynamic test	1[347] 87	0.92	0.45	1.67	0.18	0.56	0.88
Detrusor overactivity*	Symptoms, Q-tip, and cough test/ Urodynamic test	1[347] 87	0.88	0.67	2.69	0.18	0.39	0.96
Mixed UI	Symptoms, Q-tip, and cough test/ Urodynamic test	1[347] 87	0.67	0.89	6.00	0.38	0.70	0.88
Urodynamic stress UI	Ultrasound (perineal, BND)/ Urodynamic test	1[289] 102	0.73	0.77	3.16	0.35	0.64	0.83
Urodynamic stress UI	Ultrasound (perineal, BND)/ Urodynamic test	1[290] 38	0.72					
Urodynamic stress UI	Ultrasound (transrectal, drop of UV junction)/ Urodynamic test	1[291] 91	0.86	0.96	20.30	0.14	0.95	0.88
Urodynamic stress UI	Ultrasound (transrectal, drop of UV junction)/ Urodynamic test	1[292] 85	0.94	0.87	7.10	0.07	0.81	0.96

Table 3. Diagnostic value of the test for UI in women (pooled with random effects models and bivariate pooling) (continued)

Type of incontinence	Method index/ Reference Standard	Number of studies References Number of subjects in analyses	Sensitivity/ Bivariate pooling	Specificity/ Bivariate pooling	Positive likelihood ratio†	Negative likelihood ratio†	Positive predictive value	Negative predictive value
Urodynamic stress UI	Ultrasound (vaginal, opening of bladder neck/proximal urethral with leakage during cough)/ Urodynamic test	1[293] 124	0.96	0.82	5.33	0.05		
Detrusor overactivity	Symptoms and pad test/ Urodynamic test	1[348] 100	0.88					

* pure type

** not pooled because of poor reporting quality

\# 68% women and 32% men, the golden standard was not clearly defined

^ significant heterogeneity

† Clinical interpretations of likelihood ratios[197]

Likelihood Ratio	Interpretation
>10	Large and often conclusive increase in the likelihood of disease
5 - 10	Moderate increase in the likelihood of disease
2 - 5	Small increase in the likelihood of disease
1 - 2	Minimal increase in the likelihood of disease
1	No change in the likelihood of disease

Figure 3. Accuracy of diagnostic methods for female UI (pooled with random effects model results)

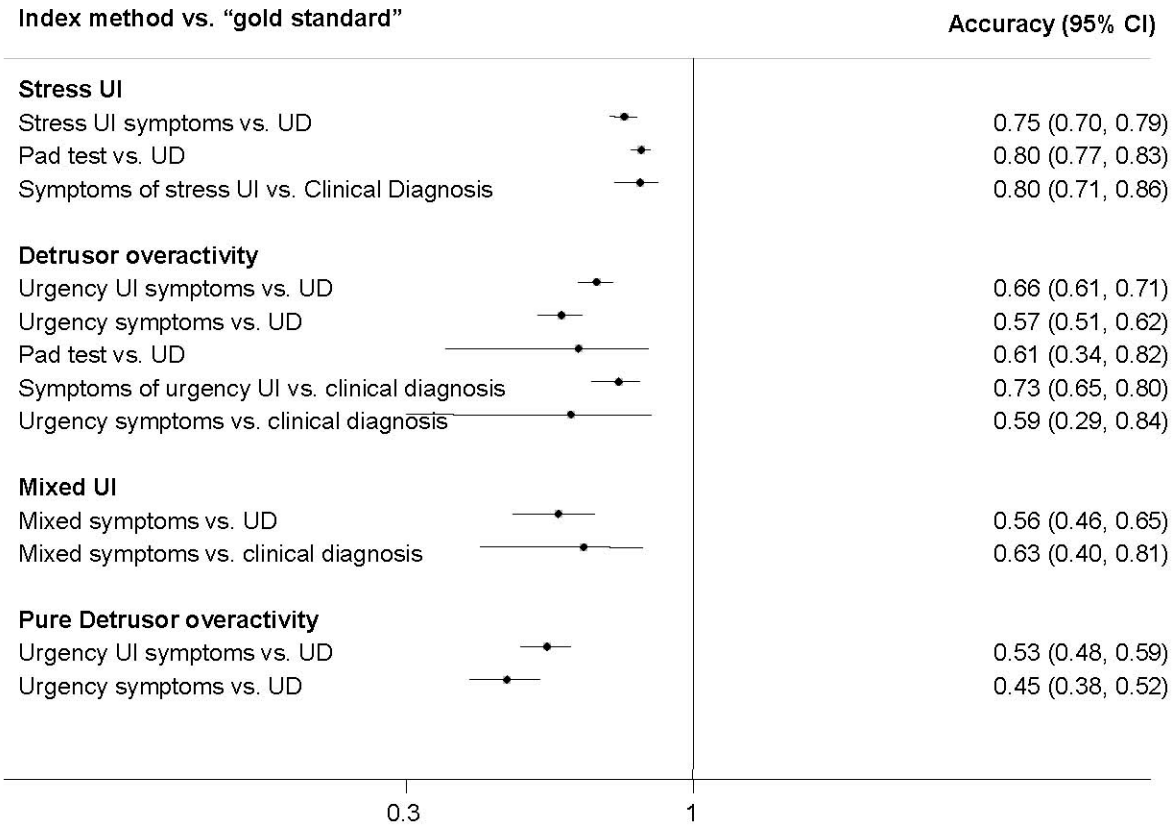


Figure 4. Diagnostic odds ratio of diagnostic methods for female UI (pooled with random effects model results)

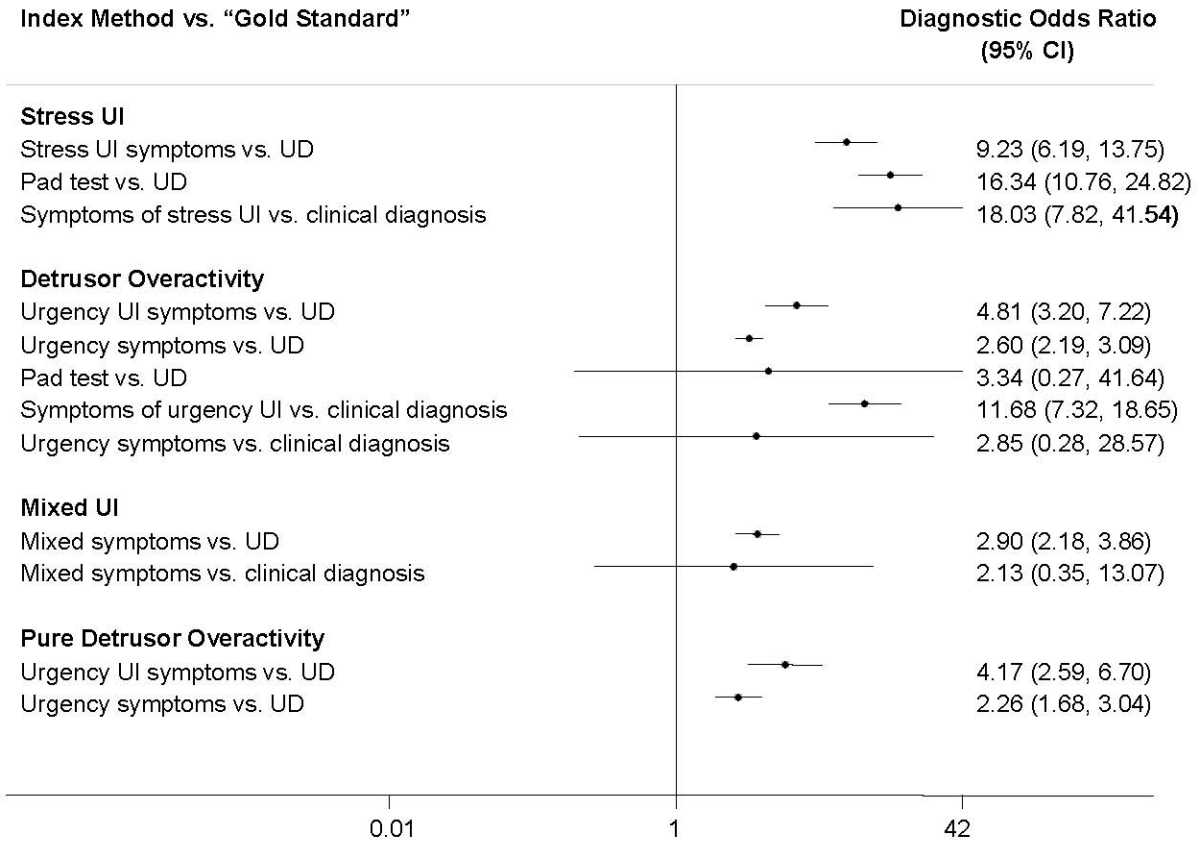


Table 4. Predictive value of diagnostic tests for different types of UI by age subgroups

Age groups	Prevalence of UI,%	Symptoms of mixed UI compared to clinical diagnosis for mixed UI		Symptoms of mixed UI compared to urodynamic diagnosis of stress UI	
	Mixed UI	PPV+, %	PPV-, %	PPV+, %	PPV-, %
19-44	21.6	28.0	84.8	30.0	87.7
45-64	20.2	26.4	85.9	28.3	88.6
65+	33.4	41.4	75.5	43.7	79.7
80+	32.8	40.8	76.0	43.1	80.1
		Symptoms of stress incontinence compared to clinical diagnosis for stress UI		**Symptoms of stress incontinence compared to urodynamic stress UI**	
	Stress UI	PPV+, %	PPV-, %	PPV+, %	PPV-, %
19-44	30.6	50.3	94.5	40.9	93.0
45-64	33.4	53.6	93.7	44.2	92.1
65+	28.6	47.9	94.9	38.7	93.6
80+	25.1	43.5	95.7	34.6	94.6
		Symptoms of urgency UI compared to clinical diagnosis for detrusor overactivity		**Symptoms of urgency UI compared to urodynamic diagnosis of detrusor overactivity**	
	Urgency UI	PPV+, %	PPV-, %	PPV+, %	PPV-, %
19-44	13.2	27.5	96.1	20.3	94.9
45-64	17.4	34.3	94.7	26.0	93.1
65+	25.4	45.8	91.6	36.3	89.3
80+	24.7	45.0	91.9	35.5	89.6

Table 5. Diagnostic tools to assess clinical importance and monitor effectiveness of treatments of UI

Tools*	References (all that mentioned)	Conditions	Domain	Minimal important differences	Worst to best	Validity/ reliability
Symptom Bother ISI	Sandvik, 1993[334] Sandvik, 2000[335]	Any/not specified	Frequency Severity	1993 version* 6-8 as severe UI (pad test mean 56-63g/24 hours) 3-4 as moderate UI (pad test 17g/24 hours) 2000 version 8-9 as severe UI(pad test mean 52g/24 hours) 12 as very severe UI (pad test mean 122g/24 hrs)	1993 version 8 to 1 2000 version 12 to 1	Yes/No
Symptom Bother PGI-I	Yalcin, 2003[331]	Stress UI	1 item for improvement	Change incontinence episode frequency* -92% in very much better group -63% in much better group	7 to 1 for improvement	Yes/No
Symptom Bother PGI-S	Yalcin, 2003[331]	Stress UI	1 item for severity	Mean incontinence episode frequency* 32.8 per week for severe cases	4 to 1 for severity	Yes/No
Symptom Bother POSQ	Matza, 2005[333]	Urgency UI or OAB	4 bother scales for OAB symptoms 1 item to indicate the most bother symptom	Not available	5 to 1 for first 4 items	Yes/Yes
Symptom Bother PPBC	Coyne, 2005[338] Capo, 2008[339] Matza, 2005[333]	Any/not specified	Single-Item Global Measure	Incontinence episodes/7days diary* 7.4 in many severe cases 3.3 in very severe cases 2.0 in moderate severe cases	6 to 1	Yes/Yes
Symptom Bother SSI/SII	Black, 1996[338]	Stress UI	Severity Incontinence impact	Not available	20 to 0 for SSI 16 to 0 for SII	Yes/Yes
Symptom Bother SUIQQ	Kulseng-Hanssen, 2003[252]	Stress UI or Urgency UI (OAB)	Total QoL	Not available	12 to 0 for the stress incontinence index 8 to 0 for the urgency incontinence index 16 to 0 for the QoL index	Yes/Yes
Symptom Bother UDI	Uebersax,1995[336] Shumaker, 1994[222] Barber,2009[337] Dyer, 2010[349]	Stress UI or Urgency UI (OAB)	Symptom: irritative, stress, obstructive	-6.4 to -22.4 -35 to -43 (anchor-based) or -10 to -25 (distribution-based) for UUI -4.6 to -16.5 for UDI-stress subscale	100 to 0 for each subscale	Yes/Yes
Symptom Bother UDI-6	Uebersax, 1995[336]	Any/not specified	Symptom: irritative, stress, obstructive	Not available	18 to 0	Yes/Yes
Screening 3IQ	Brown, 2006[266]	Any/not specified	3 questions to classify UUI and SUI	Not available	Categorical variables	No/No

Table 5. Diagnostic tools to assess clinical importance and monitor effectiveness of treatments of UI (continued)

Tools*	References (all that mentioned)	Conditions	Domain	Minimal important differences	Worst to best	Validity/ reliability
Screening B-SAQ	Basra, 2007[299]	Any/not specified	Symptoms Bother	Symptom score 7-9: significant problem* Symptom score 10-12: very significant problem Bother score 7-9: significant problem Bother score 10-12: major problem	12 to 0	Yes/Yes
Screening ISQ	Gunthorpe, 20002[240]	Any/not specified	Five items for predicting UI Three items for concerns	Not available	Algorism for predicting UI 12 to 3 for concerns of UI	Yes/Yes
Screening LUSQ	Shaw, 2002[296]	Any/not specified	Presence of incontinence Severity Urgency Frequency Nocturia	Not available	Categorical variables	Yes/Yes
Screening MESA	Diokno, 1986[297]	Any/not specified	General medical Urological: severity (frequency and quantity) and nature (stress, urge, or mixed) Social Mental health	Not available	Categorical variables	Yes/Yes
Screening OAB-V8	Yalcin, 2003[331]	Urgency UI or OAB	8 items for screening	Not available	40 to 0	Yes/No
Screening QUID	Bradley, 2005[259]	Any/not specified	Stress score Urge score	Not available	15 to 0 for each score	Yes/Yes
Screening USP	Haab, 2008[298]	Any/not specified	Stress urinary incontinence Overactive bladder Low stream	Not available	9 to 0 for SUI 21 to 0 for OAB 9 to 0 for low stream	Yes/Yes
Quality of Life BFLUTS-SF	Jackson, 1996[227] Brookes, 2004[350] Reid, 2007[351]	Any/not specified	Symptom Severity Bothersome Sexual function Total QoL	Not available	20 to 0 for the incontinence score 12 to 0 for the voiding score 15 to 0 for the filling score 6 to 0 for the sexual function score 18 to 0 for the QoL score	Yes/Yes

Table 5. Diagnostic tools to assess clinical importance and monitor effectiveness of treatments of UI (continued)

Tools*	References (all that mentioned)	Conditions	Domain	Minimal important differences	Worst to best	Validity/ reliability
Quality of Life CONTLIFE	Amarenco, 2003[248]	Any/not specified	Global health and quality of life Daily Activities Emotions Sexual function Effort Activities Self-Image Well-Being	-7 to -20 (graph only), depending on the domain, in improved population defined by decrease of at least 50% in the number of urinary leaks under treatment	0 to 100	Yes/Yes
Quality of Life EPIQ	Lukacz, 2005[262]	Any/not specified	QoL Defecatory dysfunction Pelvic organ prolapse Stress urinary incontinence Overactive bladder Pain and difficult voiding Anal incontinence	Not available	Not available	Yes/Yes
Quality of Life IBS	Abdel-Fattah, 2007[352]	Any/not specified	Simple visual analogue scale	Not available	100 to 0	No/No
Quality of Life ICIQ	Avery, 2004[353]	Any/not specified	Frequency Severity Bothersome Social limitation Sexual function Interference with everyday life Total QoL	Not available	21 to 0	Yes/Yes
Quality of Life ICIQ-SF	Klovning, 2009[354]	Any/not specified	Frequency Severity Total QoL	With QoL* Mean 16.3 for very severe UI (defined by 2000 ISI) 12.3 for severe UI Without QoL 9.4 for very severe UI 6.8 for severe UI	21 to 0 with QoL 11 to 0 without QoL	Yes/Yes

Table 5. Diagnostic tools to assess clinical importance and monitor effectiveness of treatments of UI (continued)

Tools*	References (all that mentioned)	Conditions	Domain	Minimal important differences	Worst to best	Validity/ reliability
Quality of Life ICS	Stothers, 2004[355]	Any/not specified	Global health and quality of life Social interaction Sexual function Financial impact Satisfaction Personal strain	Not available	45 to 0	Yes/Yes
Quality of Life IHI	Rai, 1994[356]	Urgency UI or OAB	Health/function Emotion	Not available	68 to 0	Yes/No
Quality of Life IIQ	Shumaker,1994[222] Uebersax, 1995[336] Hagen, 2002[357] Barber, 2009[337] Dyer, 2010[349]	Any/not specified	Travel Physical activity Social Emotional Total QoL	-6.5 to -22 for stress UI -18 to -50 for UUI	100 to 0 for each domain	Yes/Yes
Quality of Life IIQ-7	Uebersax, 1995[336]	Any/not specified	Travel Physical activity Social Emotional Total QoL	Not available	21 to 0	Yes/No
Quality of Life IOQ	Bjelic-Radisic, 2007[358]	Stress UI	Symptom Complication Satisfaction QoL	Not available	2100 to 0	Yes/Yes
Quality of Life I-QOL	Patrick,1999[359] Bushnell, 2005[360] Wagner, 1996[361] Oh, 2007[362] Schurch, 2007[363] Yalcin, 2006[364] Yalcin, 2010[321] Hollingworth, 2010[365]	Any/not specified Neurogenic UI	Avoidance and Limiting behavior Psychological impact Social embarrassment Total QoL	2 to 5 for UI 6.3 for the within-group MCID: Patients appear to recognize important clinical value at reductions of 50-70% or more incontinence episode frequency 2.5 for the between-group MCID 4 to 11 for neurogenic UI A ≥10-point increase was associated with a 0.05 SF- 6D increase in patients with neurogenic UI	0 to 100	Yes/Yes

Table 5. Diagnostic tools to assess clinical importance and monitor effectiveness of treatments of UI (continued)

Tools*	References (all that mentioned)	Conditions	Domain	Minimal important differences	Worst to best	Validity/ reliability
Quality of Life KHQ	Kelleher, 1997[366] Reese, 2003[367] Sand, 2007[368] Kelleher, 2004[369] Mostafa, 2010[370]	Any/not specified Urgency UI or OAB	Severity Incontinence impact Role limitation Physical limitation Social limitation Personal relationship Emotions Sleep and energy General health	-3 to -4 for general health and severity domains -5 to -6 for other domains "Very Much improved or Much improved" in PGI-I corresponds to a mean change in KHQ of 46 & 35 points (Range 17 – 60 points) with clear demarcation from those reporting "no change and/or worse condition" (mean 2 & -21; Range −25 – 10)*	100 to 0 for each domain	Yes/Yes
Quality of Life LIS	Shaw, 2 004[371]	Any/not specified	Impact on activities Impact on feelings	Not available	22 to 0 for activities 20 to 10 on feelings	Yes/Yes
Quality of Life Quality of Life OAB-q	Coyne, 2002[372] Coyne, 2006[373]	Urgency UI or OAB	Bothersome Social interaction Sleep and energy Concern/worry Coping Total QoL	Bothersome: 16-19 Social interaction: 4.5-9.3 Sleep and energy: 13-20) Concern/worry: 12-19 Coping: 11-19 Total QoL: 12-16 (within-treatment	0 to 100 for bother score 100 to 0 for QoL	Yes/Yes
Quality of Life PISQ	Rogers, 2001[374]	Any/not specified	Behavioral/emotive Physical activity Partner-related Total score	Not available	0 to 125	Yes/Yes
Quality of Life PRAFAB	Hendriks, 2007[375] Hendriks, 2008[376] Hendriks, 2008[377]	Any/not specified	Protection Amount Frequency Adjustment Body image	>14 points for severe UI (>2 g/hour urine loss)* SUI: 2.5-3.1 Urgency UI: 3.0-4.0	20 to 5. 4 points/ item (1–4) with a total PRAFAB-Q score of 20 points	Yes/Yes
Quality of Life UISS	Stach-Lempinen, 2001[245]	Any/not specified	The amount of leakage the degree to which UI affects aspects of women's daily lives	>11.02 points for severe UI (>30 g/24 hour urine loss)*	100 to 0	Yes/Yes

Table 5. Diagnostic tools to assess clinical importance and monitor effectiveness of treatments of UI (continued)

Tools*	References (all that mentioned)	Conditions	Domain	Minimal important differences	Worst to best	Validity/ reliability
Quality of Life UQ	Matza, 2005[333]	Stress UI or Urgency UI (OAB)	15 Likert-scale items nocturia Fear of incontinence Time to control urge Impact on daily activities 4 visual analog scales Urinary urgency's severity Intensity Impact Discomfort	Not available	1 (or 5) to 5 (or 1) for Likert-scale 10 to 1 for visual analog scales	Yes/Yes
Quality of Life YIPS	Lee, 1995[378]	Any/not specified	Eight-item seven-point rating scales a unidimensional measure Three single-item measures of self-perceptions of change in continence status, health status, amount of leakage	Not available	0 to 7 for eight rating scales Categorical variables for three single-item measures	Yes/Yes
Patient Satisfaction OAB-SS	Blaivas, 2007[300]	Urgency UI or OAB	5 items for urgency 2 items for frequency	Not available	5 points Likert scales	Yes/Yes
Satisfaction BSW	Pleil, 2005[301]	Urgency UI or OAB	Benefit Satisfaction Willingness to continue	-2.21 mean number of incontinence episodes per 24 hours for much benefit population	Categorized for each domain	Yes/No
Satisfaction EPI	Burgio, 2006[302]	Any/not specified	One item for estimated percent improvement	Not available	0 to 100	Yes/No
Satisfaction GPI	Burgio, 2006[302]	Any/not specified	One item for global perception of improvement	Not available	5 categories	Yes/No
Satisfaction PSQ	Burgio, 2006[302]	Any/not specified	One item for patient satisfaction	A 70% improvement in the frequency of incontinence episodes on bladder diary as a critical threshold	3 categories	Yes/No

Table 5. Diagnostic tools to assess clinical importance and monitor effectiveness of treatments of UI (continued)

Tools*	References (all that mentioned)	Conditions	Domain	Minimal important differences	Worst to best	Validity/ reliability
Satisfaction TBS	Colman, 2008[303]	Urgency UI or OAB	One item for patient-reported benefits	UUI episodes/24 hours +1.31 in "4" group -0.52 in "3" group -1.62 in "2" group -2.38 in "1" group	4 to 1	Yes/Yes

Abbreviations: *3IQ: Three Incontinence Questions Questionnaire; **BFLUTS:** Bristol Female Lower Urinary Tract Symptoms Questionnaire; **B-SAQ:** Bladder Self-Assessment Questionnaire or Bladder Control Self-Assessment Questionnaire (BCSQ); **BSW:** Benefit, Satisfaction with treatment, and Willingness; **Contilife:** Quality of Life Assessment Questionnaire Concerning Urinary Incontinence; **EPI:** Estimated Percent Improvement; **EPIQ:** Epidemiology of Prolapse and Incontinence Questionnaire; **GPI:** Global Perception of Improvement; **IBS:** Incontinence Bothersome Scale; **ICIQ:** International Consultation on Incontinence Modular Questionnaire; **ICS:** Incontinence Classification System; **IHI:** Urinary Incontinence Handicap Inventory; **IIQ:** Incontinence Impact Questionnaire; **IIQ-7:** Incontinence Impact Questionnaire - short form; **IOQ:** Incontinence Outcome Questionnaire; **I-QOL:** Urinary Incontinence- Specific Quality of Life Instrument; **ISI:** Incontinence Severity Index; **ISQ:** Incontinence Screening Questionnaire; **KHQ:** King's Health Questionnaire; **LIS:** Leicester Impact Scale; **LUSQ:** The Leicester Urinary Symptom Questionnaire; **MESA:** Medical, Epidemiological, and Social Aspects of Aging Questionnaire; **OAB-q:** Overactive Bladder Questionnaire; **OAB-S:** Overactive Bladder Satisfaction Questionnaire; **OAB-SS:** Overactive Bladder Symptom Score; **OAB-V8:** OAB Awareness Tool; **PGI-I and PGI-S:** Patient Global Impression of Improvement and of Severity; **PISQ:** Pelvic Organ Prolapse–Urinary Incontinence Sexual Function Questionnaire; **POSQ:** Primary OAB Symptom Questionnaire; **PPBC:** Patient Perception of Bladder Condition; **PRAFAB:** Protection, Amount, Frequency, Adjustment, Body image tool; **PSQ:** Patient Satisfaction Question; **PUF:** patient symptom scale (Pelvic Pain, Urgency, and Frequency; **QUID:** Questionnaire for Urinary Incontinence Diagnosis; **SF:** Short Form**; SSI and SII:** Symptom Severity Index and Symptom Impact Index for stress incontinence in women; **SUIQQ:** Stress and Urge Incontinence and Quality of Life Questionnaire; **TBS:** Treatment Benefit Scale; **UDI:** Urogenital Distress Inventory; **UDI-6:** Urogenital Distress Inventory-6; **UISS:** Urinary Incontinence Severity Score; **UI:** Urinary Incontinence Score; **UQ:** Urgency Questionnaire; **USP:** Urinary Symptom Profile; **YIPS:** York Incontinence perceptions scale. *clinically important cut-off values

Key Question 2. How effective is the pharmacological treatment of UI in women?

We synthesized evidence of efficacy and comparative effectiveness of the drugs for stress UI, including topical estrogen and serotonin-noradrenalin uptake inhibitors and drugs used in the treatment of overactive bladder.[69] We integrated information about inclusion, exclusion criteria, sponsorship, conflict of interest (Appendix Table F27) and quality of the studies (Appendix Table F28) in the synthesis of evidence. We report here study characteristics that could influence the treatment effects of drugs for UI.

Pharmacological Treatments for Stress UI

Clinical Effectiveness of Topical Estrogen Therapy

Evidence from individual RCTs indicated greater continence and improvement in UI with vaginal estrogen formulations and worsening of UI with transdermal patches (Appendix Table F29). Evidence was insufficient to draw conclusions about clinical efficacy of different topical estrogen treatments for UI.

Four RCTs of 640 women examined the effects of topical estrogen formulations compared to placebo on UI (Appendix Table F27). The studies enrolled postmenopausal women with urodynamic stress,[379,380] clinical symptoms of any UI,[381] clinical symptoms of any UI,[381] or with urge syndrome.[382] Estrogen was administered in vaginal tablets, gel,[379] subcutaneous implants,[382] intravaginal ovules,[380] or transdermal patches.[380,381] The length of treatment varied from 6 months[379] to 2 years.[381] Three studies aimed to treat UI.[379,380,382] One study examined very low dose transdermal estrogen formulation proposed for prevention of osteoporosis in postmenopausal women.[381]

Continence

Two RCTs examined urinary continence[379,382] (Appendix Table F30). Vaginal estrogen tablets increased continence rates more often than placebo (RR 20.68, 95 percent CI, 1.23 to 346.46).[379] The authors needed to treat five women with estrogen tablets to achieve continence in one woman (NNT 5, 95 percent CI, 3 to 12).[379] In contrast, 25 mg 17 beta-estradiol implant did not resolve stress or urgency UI compared to placebo.[382]

Improvement in UI

Improvement in UI was significantly greater than placebo with vaginal estrogen tablets[379] and vaginal ovules[380] (Appendix Table F31). Women complained of stress UI less frequently with intravaginal estrogen formulations than with placebo.[380] Unchanged incontinence was less frequent with intravaginal estrogen than with placebo.[379] In contrast, transdermal patches with very low doses of estrogen worsened any UI and stress UI at 2 years[381] (Appendix Table F32). Adjusted for clinical site odds ratios of worsened UI demonstrated increases in odds of stress UI at 4 months (OR 2.05, 95 percent CI, 1.09 to 3.85) but not 4 years. In addition to worsening of UI, women experienced vaginal bleeding with estradiol implants more often than with placebo.[382]

Clinical Effectiveness of Duloxetine

A high level of evidence indicated significant improvement in stress UI with duloxetine, while a low level of evidence suggested that duloxetine did not resolve stress UI when compared to placebo. A low level of evidence suggested improvement in quality of life in women with UI. Evidence was insufficient to conclude benefits of duloxetine in women with urgency UI. The risk of adverse effects was significantly higher with duloxetine than with placebo. Duloxetine resulted in improved UI in 75 to 140 women per 1,000 treated,[319,364,383-387] while 129 women per 1,000 treated stopped taking duloxetine because of adverse effects.

The 24 publications that reported clinical outcomes with duloxetine[250,319,364,383-404] included six primary RCTs of 4,292 women,[319,383,386,387,401,402] collaborative publications from the DESIRE Study group (3,983 subjects),[388] Duloxetine Dose Escalation Study Group (516 subjects), [389] Duloxetine OAB Study Group (306 subjects),[385] Duloxetine Urinary Incontinence Study Group (2,741 patients),[250,384,390-392] Duloxetine/Pelvic Floor Muscle Training Clinical Trial Group (201 subjects), pooled analyses of individual patient data (52,891 subjects),[364,396-400,404] safety evaluation using pooled analysis of 42 placebo-controlled clinical trials of 8,504 patients[403] (Appendix Table F27), and nonrandomized prospective observational studies[394,395] (Appendix Table F33).

Continence

Two studies of 736 women demonstrated greater continence with placebo than with duloxetine (pooled RR 0.92, 95 percent CI, 0.86 to 0.99)[384,390] (Appendix Table F34). One publication from the Duloxetine Urinary Incontinence Study Group did not find significant dose response increase in continence with 40 mg of the drug versus 20 mg/day[390] (Appendix Table F35).

Improvement in UI

Women experienced more than a 50 percent reduction in the frequency of UI episodes with duloxetine[319,364,384,386,387] (Appendix Table F36). More women perceived an improvement in UI as either much better or better with duloxetine than with placebo[319,383-385] (Appendix Table F36). Seven women had to take duloxetine to achieve a 50 percent reduction in UI episodes in one woman (Table 6). Thirteen women (NNT 13, 95 percent CI, 7 to 143) needed to be treated so one woman would perceive an improvement as either much better or better. Improvement in UI was greater with 40 mg/day compared to 20 mg/day[390] (Appendix Table F37). Treatment failure did not differ between duloxetine and placebo[319,383,385,402] (Appendix Table F38).

Improvement in quality of life measures with duloxetine was inconsistent across the studies. Quality of life was examined in eight studies of 5,001 women[319,364,384-386,390,391,398] (Appendix Table F39). Pooled analysis of two RCTs of 1,133 women with predominant stress UI demonstrated improved Incontinence Quality of Life scores using 80 mg of duloxetine.[364] The Multinational Duloxetine UI Study Group found significant improvement in quality of life in North American women,[391] with no benefit for women in other continents.[384] One study indicated significant dose response improvements in the Incontinence Quality of Life questionnaire with 40 mg compared to 20 mg of duloxetine/day.[390] Women with severe stress UI[319] and women with overactive bladder did not experience better quality of life with duloxetine[385] compared to placebo.

Adverse Effects

Adverse effects with duloxetine versus placebo were examined in 15 studies with 26,703 subjects.[319,383-387,389-393,397,401,402,404] Results demonstrated the importance of definitions and measurements of harms. Studies of any adverse effects or treatment-related adverse effects (as judged by investigators) reported less relative harm from the drug than studies of individual adverse effects. For example, the relative increase in treatment-related adverse effects (as judged by investigators) was 36 percent (pooled RR 1.36, 95 percent CI, 1.28 to 1.44)[319,383-387,391,392,401] (Appendix Table F40). At the same time, the relative increase in several harms was much larger. For instance, relative increase in somnolence was 761 percent (pooled RR 8.61, 95 percent CI, 4.58 to 16.20).[319,383-387,389,391-393,397,401,402] Nausea (NNT 5, 95 percent CI, 4 to 7),[319,384,390,392,393,397,401] dry mouth (NNT 9, 95 percent CI, 7 to 11),[319,383-387,389-393,397,401,402] and fatigue (NNT 13, 95 percent CI, 10 to 19)[319,383-387,390-392,397,401,402] were among the most common adverse effects of duloxetine when compared to placebo (Appendix Table F41).

The studies did not show consistent dose response associations between duloxetine and adverse effects (Appendix Table F42). The Duloxetine Dose Escalation study reported lower risks of adverse effects at a starting dose of 20 mg with slow escalation to 80 mg/day.[389] Large pooled analysis that examined cardiovascular adverse effects of duloxetine[403] demonstrated electrocardiographic abnormalities that were statistically but not clinically significant.

Women stopped taking duloxetine because of adverse effects more often than placebo (Appendix Table F43). The relative increase in discontinuation of duloxetine treatment for any adverse effects was 340 percent (pooled RR 4.4, 95 percent CI, 3.24 to 5.86).[319,383,384,386,389-392,394,402] Discontinuation rates differed across the studies. We explored heterogeneity by women's age, prior treatments, and concurrent medications for UI, and baseline type and severity of UI (Appendix Table F44) and did not find significant association with the outcome (Appendix Table F45). We explored heterogeneity by study quality (Appendix Table F46) and did not find significant association with the outcome (Appendix Table F45).

Among individual adverse effects leading to treatment discontinuation, every tenth woman stopped taking duloxetine because of effects such as nausea,[384,386,389-393,397,402] somnolence,[386,390,391,393,397,402] insomnia,[384,386,389,391-393,397] dizziness,[384,386,389-393,397] headache,[389,390,402] fatigue,[389,391,397,402] diarrhea,[397,402] and constipation,[393,397] which were the most common adverse effects leading to treatment discontinuation (Appendix Table F41).

Pharmacological Treatments for Urgency UI

Clinical Effectiveness of Oxybutynin

A high level of evidence indicated that oxybutynin increased continence rates and improved UI more often than placebo but also resulted in treatment discontinuation due to adverse effects (see Table ES2 in the Executive Summary). Dry mouth was the most common adverse effect. Oxybutynin resulted in resolved UI in 114 women per 1,000 treated, while 63 women per 1,000 treated stopped taking oxybutynin because of adverse effects. Evidence was insufficient to conclude improved quality of life with oxybutynin. A low level of evidence indicated greater rates of adverse effects and dry mouth with immediate release oxybutynin than with controlled release oral or transdermal oxybutynin. A low level of evidence indicated that larger versus lower doses of extended oxybutynin resulted in greater improvement in UI and the same rates of dry mouth, but greater treatment withdrawal.

We identified 15 publications of individual RCTs,[115,310,322,405-416] one RCT of intravesicular injection of oxybutynin in 52 women,[417] one post hoc analysis of RCTs,[418] and 10 RCTs that compared different doses and formulations of oxybutynin[419-428] (Appendix Table F27). We also reviewed a noncontrolled Ditropan XL study of 256 women,[429] a Multicentre Assessment of Transdermal Therapy in Overactive Bladder With Oxybutynin (MATRIX) study of 2,888 women, pooled analysis of dosing studies,[323,430,431] and five observational studies of harms and discontinuation rates of oxybutynin therapy[432-436] (Appendix Table F33).

Continence

Urinary continence was greater with oxybutynin than with placebo[409,413,416,437,438] (Appendix Table F47). Pooled results were consistent with nonsignificant heterogeneity across the studies despite differences in populations and doses of the drug. The pooled results, however, were sensitive to one multicenter study at 76 clinics in the United States that demonstrated significant increase in resolved UI with oxybutynin.[413] The drug needed to be given to nine women to achieve continence in one woman (Table 7).

Improvement in UI

Oxybutynin improved UI more often than placebo[322,406,415,416,418,437-443] (Appendix Table F47). The drug needed to be given to six women to improve UI in one woman (Table 7). The magnitude of the effect varied across the studies with significant heterogeneity in pooled estimates. Dose of the drug did not explain heterogeneity (p value for meta-regression >0.5). Differences in definitions of improved UI may contribute to heterogeneity. The studies that defined improvement as a reduction of 75 percent in UI episodes[415,437] reported similar relative risk and absolute risk difference. In contrast, the studies that did not quantify improvement in UI tended to demonstrate very large benefits from oxybutynin compared to placebo (Appendix Table F47).

We explored heterogeneity by characteristics of women, treatment, and study and found no significant association with the outcomes (Appendix Table F48).

Change in quality of life was inconsistent within and across the studies[407,410,437,442,444] (Appendix Tables F49 and F50). Transdermal oxybutynin did not improve quality of life and did not result in treatment satisfaction compared to placebo in women with overactive bladder (OAB).[445]

Treatment failure with unchanged or worsened UI was less common with oxybutynin than with placebo[415,437,439,441,443] (Appendix Table F47).

Adverse Effects

Discontinuation of treatments did not differ between oxybutynin and placebo[406,413,437,439,446] (Appendix Table F47). However, discontinuation of treatment due to adverse effects was greater with active drugs than with placebo (Appendix Table F47).[87,412,413,441,442,446] Among every 16 treated, one woman stopped taking the drug because of adverse effects. Interestingly, the relative increase in total adverse effects[411,439,441] or serious adverse effects[411,413,441] did not differ from placebo (Appendix Table F47). The differences across the studies in definitions and methods to assess harms may contribute to discrepancies.

Dry mouth was the most common adverse effect[322,405,406,410,413,416,437,441,442,446] (Appendix Table F47). Oxybutynin caused dry mouth on one woman for every three treated (NNT 3, 95 percent CI, 2 to 6) (Table 7).

Several studies compared formulations and doses of oxybutynin (Appendix Table F51). The Uromax Study demonstrated greater improvement in UI with larger doses of extended oxybutynin (15 mg versus 5 or 10 mg).[427] The larger doses, however, resulted in greater treatment withdrawal for 15 versus 5 mg/day.[427]

The Transdermal Oxybutynin Study found that severe dry mouth and constipation were less common with transdermal than with oral immediate-release oxybutynin.[423] Adverse effects were less common with once-daily, controlled-release formulation oxybutynin than with immediate-release oxybutynin.[447] Dry mouth was less common with transdermal versus oral immediate-release oxybutynin,[423] with controlled versus immediate-release oxybutynin,[419] and with lower versus larger doses of controlled-release oxybutynin.[427]

Clinical Effectiveness of Tolterodine

A high level of evidence indicated increased continence rates and significant improvement in UI with tolterodine treatments than with placebo in women with UI (see Table ES2 in the Executive Summary). A low level of evidence indicated improvement in quality of life with tolterodine treatment. Adverse effects including autonomic nervous system disorders, abdominal pain, dry mouth, dyspepsia, and fatigue were significantly more common with tolterodine than with placebo. Per 1,000 women treated, tolterodine resulted in resolved UI in 85 women, and resulted in adverse effects in 83 women. Discontinuation of the treatment and stopping treatment due to adverse effects did not differ between tolterodine and placebo.

We identified 24 RCTs that examined clinical outcomes with tolterodine versus placebo,[309,312,314,317,321,343,448-465] publications of secondary data analyses,[87,466-468] multicenter nonrandomized clinical trials,[469] including the IMPACT study (Appendix Table F27)[470-472] and several noncontrolled observational studies of harms with tolterodine treatments (Appendix Table 33).[473-476]

Continence

Urinary continence was achieved more often with tolterodine than with placebo in pooled analysis (pooled RR 1.2, 95 percent CI, 1.1 to 1.4)[309,312,313,343] (Appendix Table F47). The drug had to be given to 12 women to achieve continence in one woman (NNT 12, 95 percent CI, 8 to 25) (Table 7).

Improvement in UI

Tolterodine improved UI more often than placebo[88,309,313,454,456,461,463,464] (Appendix Table F47). The drug needed to be given to 10 women to achieve improvement in UI in one (Table 7). The magnitude of the association differed across the studies, probably because of different definitions of improvement. Women's characteristics, treatment dose and duration, and study quality were not associated with the outcome (Appendix Table F48).

Secondary data analyses demonstrated that 4mg/day of tolterodine, but not 2 mg/day, improved subjects' perceptions of their bladder condition (Appendix Table F52).[87,88,456] Women evaluated treatment success as "much better" more often with 4 mg/day of tolterodine than with placebo[456] (Appendix Table F52). One pooled analysis reported a greater decrease in the urgency perception scale score with 4 mg of tolterodine daily than with placebo.[456] An evidence-based report about treatment of overactive bladder in women showed a significant decrease in the frequency of UI episodes with immediate release (weighted mean difference 1.45, 95 percent CI, 1.24 to 1.66) and with controlled release tolterodine (weighted mean difference 1.75, 95 percent

CI, 1.65 to 1.85).[112] One nonrandomized study reported that 79 percent of subjects experience improvement in UI after 12 weeks of tolterodine.[470-472]

Adverse Effects

Adverse effects were more common with tolterodine than with placebo[309,312,321,322,343,449,450,453,457,460,465,477] (Appendix Table F47). Active drugs needed to be given to 12 women in order cause adverse effects in one woman (Table 7). Half of the women experienced adverse effects with 4 mg/day of tolterodine in the IMPACT noncontrolled study.[470-472] According to pooled analysis of the aggregate data,[309,448,450-452] and one pooled analysis of individual patient data, women did not have serious adverse effects more often with tolterodine than with placebo.[87] The same pooled analysis, however, reported that dose reduction in the case of intolerance was more common with 2 mg twice/day of tolterodine than with placebo[87] (Appendix Table F52). The rates of all[449,453] or serious adverse effects with different doses and formulations of tolterodine did not differ[451,452] (Appendix Table F53).

Among individual adverse effects, tolterodine significantly increased rates of autonomic nervous system disorders,[448-450] constipation,[321,449,451-453,455,457,458,477,478] dyspepsia,[309,322,343,451,452,455,457] and fatigue[309,460,463] (Table 8). Tolterodine also increased rates of abdominal pain.[309,451-453,455,457] Pooled analysis of individual patient data demonstrated greater rates of abdominal pain,[456] autonomic nervous system disorder,[87] fatigue,[88,468] and dry mouth[88,456,468] (Appendix Table F52). Autonomic nervous system disorder was less common with 1 mg twice daily versus 2 mg daily.[87,448] Differences in adverse effects of different doses and formulations of tolterodine were not consistent across the individual studies and pooled data from individual patients (Appendix Table F53). Tolterodine caused dry mouth in one woman among seven treated according to our pooled analysis (Table 7).[309,312,313,321,322,343,451,453,460,461,463,465,477,478] Increases in the rates of dry mouth were not greater with higher doses of tolterodine (p value for meta-regression >0.5).

Treatment discontinuation rates[309,450,451,454,458,460-462,477,478] and treatment discontinuation due to adverse effects did not differ between tolterodine and placebo[309,313,321,322,450,452,453,457,458,460,461,463,478] (Table 7). Pooled analyses also demonstrated no differences in discontinuation rates between 2 mg of tolterodine twice daily[87] and 4 mg of tolterodine once daily[468] (Appendix Table F52). One pooled analysis reported that treatment discontinuation was lower with 1 mg twice daily than with 2 mg daily of tolterodine (Appendix Table F53). Treatment discontinuation due to adverse effects did not differ in individual RCTs[453] and in pooled analyses of individual patient data from RCTs that examined 2 mg of tolterodine twice [450,452,453] or 4 mg daily[457,458,460] (Appendix Table F54).

Clinical Effectiveness of Darifenacin

A high level of evidence indicated significant improvement in urgency UI episodes and several domains of quality of life with 7.5 and 15 mg of darifenacin compared to placebo. Adverse effects were more common with darifenacin than with placebo. Darifenacin increased rates of constipation, dry mouth, dyspepsia, and headache. Darifenacin improved UI in 117 women per 1,000 treated while 190 women per 1,000 treated experienced various adverse effects. Evidence was insufficient from which to conclude better benefits with 30 mg of darifenacin/day. The largest dose, however, resulted in greater rates of adverse effects. Treatment discontinuation rates due to adverse effects were the same between darifenacin and placebo.

Seven RCTs reported clinical outcomes of darifenacin versus placebo[306,307,311,479-483] and several publications of secondary data analyses[484-489] (Appendix Tables F27 and F28).

Continence

Urinary continence outcomes were not examined with darifenacin treatment. One pooled analysis demonstrated that women did not experience continence for more than 7 consecutive days more often with 15 mg of darifenacin than with placebo[486] (Appendix Table F55). The rates of more than 3 dry days/week were greater than placebo with 7.5 mg of darifenacin (RR 1.47, 95 percent CI, 1.02 to 2.13) and with 15 mg of darifenacin (RR 1.48, 95 percent CI, 1.04 to 2.09).[486] The drug had to be given to 17 women to achieve 3 dry days/week in one woman.[486]

Improvement in UI

Darifenacin improved UI more often than placebo[479,481,482] (Appendix Table F47). Darifenacin needed to be given to nine women in order to improve UI in one woman (Table 7). Pooled individual patient data from three RCTs also indicated a significant reduction of more than 90 percent in UI episodes more often with 7.5 mg and 15 mg of darifenacin than with placebo[486] (Appendix Table F55). Women experienced reductions of more than 50 percent[479,481,482] or more than 70 percent[479,482] in UI episodes more often with darifenacin than with placebo.

Adverse Effects

Adverse effects were more common with 7.5[479,482] and 15 mg/day of darifenacin than with placebo.[482,483] Adverse effects were experienced by one woman among every five treated with darifenacin[479,482,483] (Table 7). The Darifenacin Study found a significant dose response association with a greater rate of adverse effects with larger doses of darifenacin (Appendix Tables F56 and F57). The rates of serious adverse effects did not differ between darifenacin and placebo.[482,483]

Rates of individual adverse effects did not demonstrate a consistent dose response association with darifenacin (Appendix Table F57). Among individual adverse effects, darifenacin increased rates of constipation.[479,480,482,483,489] The association was not dose responsive because constipation with 15 mg/day did not differ from placebo.[480,482,483,489] Dry mouth was more common with 7.5 mg darifenacin than with placebo.[479,480,482,483,489] Much less expected was the fact that rates of dry mouth did not differ from placebo, even with larger doses of darifenacin of 15 mg[480,482,483,489] or 30 mg/day.[482,489] Dyspepsia was more common with darifenacin than with placebo[480,482,483,489] (Table 8).

One RCT examined short-term effects of darifenacin controlled release (3.75, 7.5, or 15 mg once daily), darifenacin immediate-release (5 mg three times daily), or placebo on cognitive function in elderly volunteers without clinical dementia.[480] The authors did not find statistically significant differences, except increased memory scanning speed, with 7.5 and 15 mg of darifenacin.[480]

Treatment discontinuation rates[483,489] and discontinuation because of adverse effects did not differ between darifenacin and placebo[306,307,479,481-483,489] (Table 7). The Darifenacin Study Group reported a significant dose response association with greater rates of withdrawals due to adverse effects with 30 mg than with 7.5 mg of darifenacin/day[482] (Appendix Table F57).

Clinical Effectiveness of Solifenacin

A high level of evidence suggested that solifenacin increased continence rates with greater benefits with the larger dose of the drug in women with urgency and mixed UI. Evidence was insufficient that solifenacin improved quality of life. A high level of evidence suggested greater risk of dry mouth, constipation, and blurred vision with the drug. A high level of evidence suggested that 10 mg of solifenacin increased the risk of severe dry mouth and constipation. Treatment discontinuation due to adverse effects was more common with solifenacin than with placebo. Solifenacin resolved UI in 107 women per 1,000 treated, while 13 women per 1,000 treated stopped taking the drug because of adverse effects.

We identified nine publications of individual RCTs[477,478,490-496] and pooled analysis of individual patient data from four RCTs[497-499] that examined clinical outcomes with solifenacin compared to placebo (Appendix Table F27). We also reviewed the results from the nonrandomized VOLT flexible-dosing trial (VESIcare Open-Label Trial) that examined quality of life in subjects with OAB and urgency UI at 207 centers in the United States.[500,501]

Continence

Solifenacin resolved UI more often than placebo (pooled RR 1.5, 95 percent CI, 1.4 to 1.6)[492,494,496,497,499] (Appendix Table F47). Solifenacin needed to be given to nine women to achieve continence in one woman (Table 7). The effect was consistent across the studies. Complete urinary continence was greater with 10 mg of solifenacin than with placebo in two pooled analyses of individual patient data with a relative increase of 43 percent[499] to 53 percent[497] (Appendix Table F58). One pooled analysis of individual patient data from four RCTs demonstrated significant dose response increase in continence with better effect with 10 versus 5 mg of solifenacin in women with mixed UI[499] (Appendix Table F59). Another previously published pooled analysis of individual patient data, however, did not find better continence rates with the larger dose of the drug in women with urgency UI.[497]

Improvement in UI

Solifenacin improved UI more often than placebo[492,495] (Table 7). The drug needed to be given to six women to achieve improvement in one woman.[492,495]

Solifenacin in a dose of 5 mg/day improved all examined domains of quality of life measured with King's Health Questionnaire in one RCT.[499] The largest improvement was in role limitations (mean difference -10.92, 95 percent CI, -11.25 to -10.59), coping/severity measures (mean difference -8.21, 95 percent CI, -8.48 to -7.94), emotions (mean difference -7.84, 95 percent CI, -8.18 to -7.51), and physical limitations (mean difference -7.54, 95 percent CI, −7.88 to -7.21). The VOLT study found that 80.4 percent of the subjects reported improvement in their Patient Perception of Bladder Condition.[501] The VESIcare Investigation of Bother and Quality of Life in Subjects With OAB VIBRANT study reported greater perceived benefit (RR 1.78, 95 percent CI, 1.48 to 2.14), satisfaction (RR 1.42, 95 percent CI 1.26 to 1.61), and willingness to continue (RR 1.39, 95 percent CI, 1.23 to 1.57) with flexible 5 to 10 mg doses of solifenacin[492] (Appendix Table F60).

Adverse Effects

Adverse effects were more common with solifenacin than with placebo[477,494-496] (Table 7). The association was significant but not dose responsive (p value for meta-regression >0.5). Among individual adverse effects, dry mouth was the most common with both doses of

solifenacin.[477,492-495,497,499,502] Pooled analysis of individual patient data reported significant positive dose response association between dry mouth and the larger dose of the drug[497,499] (Appendix Table F59). The larger dose of the drug caused blurred vision and mild blurred vision more often than placebo (Appendix Table F58).[497,499] Constipation and severe constipation were more common with 10 mg of solifenacin than with placebo.[497,499]

Adverse effects leading to discontinuation were more common with solifenacin than with placebo (Table 7).[478,493-497,499,502] Every 78th woman discontinued the treatment with solifenacin because of adverse effects. Much less expected was the fact that two pooled analyses of individual patient data demonstrated no difference in treatment discontinuation with 5 or 10 mg of solifenacin than with placebo[497,499] (Appendix Table F58). One pooled analysis of individual patient data of four RCTs reported that women with mixed UI stopped treatment because of adverse effects more often with 10 mg of solifenacin than with 5 mg of the drug[499] (Appendix Table F59).

Clinical Effectiveness of Fesoterodine

A low level of evidence indicated a significant increase in continence with fesoterodine. A high level of evidence indicated a significant improvement in urgency UI with fesoterodine compared to placebo, with a better response with 8 mg versus 4 mg. Evidence was low that fesoterodine improved quality of life in women with urgency UI. Fesoterodine treatment resulted in higher rates of adverse effects and related discontinuation of treatment than placebo. Adverse effects were more common with 8 mg than with 4 mg of fesoterodine. Women experienced dry mouth and severe dry mouth with fesoterodine more often than with placebo, with a greater risk with the larger dose of the drug. Fesoterodine resolved UI in 130 women per 1,000 treated, while 31 women per 1,000 treated stopped taking the drug because of adverse effects.

Nine publications of RCTs[309,313,316,460,461,503-506] and four publications of individual patient data analyses[88,468,507,508] reported clinical outcomes with fesoterodine compared to placebo (Appendix Table F27). All RCTs were double blinded (Appendix Table F28).

Continence

Continence was greater with fesoterodine than with placebo in two RCTs[309,313] (Appendix Table F47).

Improvement in UI

Fesoterodine improved UI more often than placebo.[309,461,503,505] The drug needed to be given to 10 women to achieve improvement in UI in one (Table 7). One pooled analysis of individual patient data from two RCTs found that the proportion of women indicating that their condition greatly improved or improved was significantly larger with 4 or 8 mg of fesoterodine than with placebo[88] (Appendix Table F61). Treatment response was significantly better with the higher dose of the drug[88] (Appendix Table F62). An evidence-based report about treatment of OAB in women found a significant reduction in daily UI episodes with fesoterodine (weighted mean difference 2.03, 95 percent CI, 1.74 to 2.31).[112]

Adverse Effects

Adverse effects were more common with fesoterodine than with placebo (Appendix Table F47).[309,460,505,506] One pooled analysis of individual patient data from two RCTs also demonstrated increased rates of adverse effects with fesoterodine than with placebo, showing

that the drug given to six to ten women results in adverse effects in one woman.[508] The risk of adverse effects was dose responsive with significantly higher rates with 8 mg than with 4 mg of the drug (Appendix Table F62).[460,506] Dry mouth was the most common adverse effect with fesoterodine[309,313,316,460,461,503,505,506] (Appendix Table F47). An increased risk of dry mouth was dose responsive with greater rates with 8 mg than with 4 mg of the drug[460,506,507] (Appendix Table F62).

Among other adverse effects, individual RCTs (Appendix Table F47), pooled analyses of aggregate (Table 7), and pooled analyses of individual patient data (Appendix Table F61),[88,468,507] found higher rates of constipation with fesoterodine than with placebo.[309,313,316,460,461,503,505,506] Increased risk of urinary tract infection was small but significant with fesoterodine versus placebo in one RCT[461] while pooled analysis of individual patient data did not show statistically significant differences in the rates of urinary tract infection between 4 or 8 mg of darifenacin and placebo[508] (Appendix Table F63).

Discontinuation due to adverse effects was more common with fesoterodine than with placebo[309,313,316,461,503,505] (Appendix Table F47). The drug given to 33 women resulted in discontinuation of treatment due to adverse effects in one woman (Table 7). One pooled analysis of individual patient data from two RCTs[507] examined withdrawal rates due to adverse effects with fesoterodine and placebo (Appendix Table F61). Discontinuation rates due to adverse effects did not differ between 4 mg of fesoterodine and placebo but were significantly higher with 8 mg of darifenacin than with placebo.[507]

Clinical Effectiveness of Trospium

A high level of evidence indicated increased continence rates with trospium compared to placebo. Individual RCTs found that trospium improved quality of life. Women experienced dry mouth, dry eye, dry skin, and constipation more often with the drug than with placebo. Adverse effects resulted in treatment discontinuation with the drug more often than with placebo. Trospium resolved UI in 114 women per 1,000 treated, while 18 women per 1,000 treated stopped taking the drug because of adverse effects.

Eight publications of RCTs,[308,325,329,330,509-512] two publications of the Trospium Study Group,[513,514] and one pooled analysis of individual patient data from two RCTs[512] examined the effects of trospium on clinical outcomes compared to placebo (Appendix Table F27).

Continence

Trospium increased continence rates more often than placebo[325,512-514] (Appendix Table F47). The drug needed to be given to nine women to achieve continence in one woman[515] (Table 7). Trospium increased rates of a complete response defined as continence and normal voiding in a pooled analysis of individual subject data from two RCTs.[515] The drug had to be given to 11 women (95 percent CI, 8 to 20) to achieve complete response in one woman.[515]

Improvement in UI

Trospium improved UI more often than placebo.[509,513] The Trospium Study Group demonstrated a significant improvement in UI, defined as a greater than 50 percent decrease in the number of incontinent episodes per 24 hours.[513]

An evidence-based report about treatments for overactive bladder in women demonstrated a significant reduction in urgency UI by 2.45 episodes per day (mean difference 2.45, 95 percent CI, 2.19 to 2.7).[112]

Adverse Effects

Adverse effects were more common with trospium than with placebo[325,465,510,512,514] (Appendix Table F47). The drug had to be given to eight women to observe an adverse effect in one woman (Table 7). Constipation rates were greater with trospium than with placebo.[325,510,512-514]

Women using trospium experienced dry eye,[512,514] dry mouth,[325,465,510,512-514] and dry skin[512,514] more often than those using a placebo.[515] The most common adverse effect was dry mouth, experienced by one woman of every nine treated (Table 7). Discontinuation rates due to adverse effects were also higher with trospium than with placebo[329,330,510,512-514] (Table 7).

Clinical Effectiveness of Propiverine

A low level of evidence indicated that propiverine resolved UI. A moderate level of evidence indicated that propiverine improved urgency UI and increased the risk of adverse effects, including abnormal vision, constipation, and dry mouth in a dose responsive manner. Propiverine resolved UI in 163 women per 1,000 treated, while 34 women per 1,000 treated stopped taking the drug because of adverse effects.

Five RCTs examined clinical outcomes of propiverine compared to placebo or to different doses of the drug[320,502,516-518] (Appendix Tables F27 and F28).

Continence

Propiverine increased continence rates more often than placebo[320,516] (Appendix Table F47). The drug had to be given to six women to achieve continence in one. One study concluded higher rates of continence with immediate- than with extended-release propiverine (RR 1.3, 95 percent CI, 1.1 to 1.6).[320]

Improvement in UI

Propiverine improved UI more often than placebo[320,516,518] (Appendix Table F47). The drug was effective in resolving symptoms of urgency but not UI in older women with mixed UI (Appendix Table F64).[516] One study compared immediate- versus extended-release propiverine and concluded an opposite association depending on the definition of improvement.[320] Investigators rated better overall efficacy with the extended-release drug. In contrast, patients reported better overall efficacy with the immediate-release drug.[320]

Adverse Effects

Propiverine caused adverse effects more often than placebo[320,517,518] (Appendix Table F47). Propiverine caused adverse effects in one woman of every six treated. Rates of adverse effects were relatively higher with 20 mg of propiverine and 45 mg/day of propiverine than with placebo.[517] Treatment discontinuation due to adverse effects was more common with propiverine than with placebo[320,502] (Appendix Table F47).

Clinical Effectiveness of Botulinum Toxin

A high level of evidence suggested a reduction in UI episodes due to treatment with botulinum toxin, with an increased risk of elevated post-void residual in patients with severe urgency UI refractory to antimuscarinic drugs.

Four RCTs of 185 subjects reported clinical outcomes after intravesicular injection of botulinum toxin[315,519-521] (Appendix Table F27). We found one systematic review of the literature about the efficacy and safety of botulinum toxin in the management of OAB.[522]

Continence

Two RCTs demonstrated that botulinum injections resolved urgency UI. A single published RCT randomized 313 adults with idiopathic OAB and daily urgency UI to placebo or different doses of botulinum toxin.[523] The outcomes were compared after intradetrusor injections of 50, 100, 150, 200, or 300 U of botulinum toxin or placebo.[523] Continence rates were greater with the active drug (29.8 to 57.1 percent) than with placebo (15.9 percent, P <0.5) in a dose responsive fashion.[523] One unpublished RCT[315] demonstrated a significant increase in continence after a single injection of 100U to 300U of botulinum toxin.

Improvement in UI

One RCT reported greater rates of significant improvement in UI (>75 percent decrease in daily UI episodes) with botulinum toxin than with placebo[520] (Appendix Table F65). Recently published RCTs examined different doses of the drug and demonstrated minimal additional or clinically relevant improvement in symptoms with doses higher than 150 U.[523] One RCT reported improvement in several domains in King's Health Questionnaire on quality of life after botulinum toxin compared to placebo[519] (Appendix Table F66). The differences were small but statistically significant for UI impact, severity measure, and sleep-energy disturbances.[519]

A systematic review demonstrated a significant reduction in daily UI episodes by 3.88 episodes per day (95 percent CI, -6.15 to -1.62) after botulinum.[522] Botulinum toxin, however, increased the risk of elevated post-void residual (pooled RR 8.55, 95 percent CI, 3.2 to 22.71).[522]

Published RCTs found that the drug caused treatment-related adverse effects in 40 percent, and post-void residual (PVR) related catheterization in 20 percent of patients.[523] The rates of urinary tract infection increased in a dose responsive manner from 37 percent with 100 U to 47.2 percent with 300 U.[523] The rates of urinary retention also increased in a dose responsive manner from 19 percent with 100 U to 25 percent with 300 U.[523] Treatment failure with unchanged or increased UI was less common with botulinum than with placebo (RR 0.29, 95 percent CI, 0.14 to 0.63).[520]

Clinical Effectiveness of Resiniferatoxin

Evidence on the benefits and harms of resiniferatoxin versus placebo in women with urgency UI was insufficient for definitive conclusion about benefits and harms with the drug.

A single RCT enrolled 58 women with idiopathic detrusor overactivity and urgency incontinence to examine clinical outcomes of resiniferatoxin versus placebo (Appendix Table F27).[524] The study did not demonstrate benefits of resiniferatoxin versus placebo[524] (Appendix Table F67). The rates of the expected adverse effects, including hypogastric pain, dysuria, and minor hematuria, did not differ between resiniferatoxin and placebo.[524]

Clinical Effectiveness of Nimodipine

Evidence was insufficient for the benefits or harms of nimodipine compared to placebo in older women with predominant urgency UI.

A single RCT enrolled 86 older adult women with urodynamic urgency UI and without clinically important stress UI to examine outcomes after 3 weeks of 30 mg nimodipine twice

daily or placebo[525] (Appendix Table F27). Nimodipine reduced incontinent episodes but did not improve IIQ scores and American Urological Association symptom scores (Appendix Table F68). Treatment discontinuation did not differ between nimodipine and placebo.[525]

Table 6. Clinical outcomes with duloxetine treatments (pooled with random effects estimates from head-to-head RCTs)

Reference Number of studies	Number of subjects	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number deeded to treat (95% CI)	Attributable events/1000 treated (95% CI)	Bayesian odds ratio median (2.5; 97.5%)	Evidence
Continence 2 studies[384,390]	736	0.92 (0.86 to 0.99)	-0.03 (-0.12 to 0.06)			0.67 (0.23 to 1.88)	Low
Improvement in PGI rating: very much or much better 4 studies[319,384,385]	1,138	1.68 (0.94 to 3.00)	0.08 (0.01 to 0.14)	13 (7 to 143)	75 (7 to 142)	1.99 (1.10 to 4.19)	High
Improvement in UI: >50% reduction in UI episodes 5 studies[319,364,384,386,387]	4,304	1.5 (1.3 to 1.7)	0.14 (0.08 to 0.21)	7 (5 to 13)	140 (80 to 210)	1.9 (1.4 to 2.9)	High
Deterioration in PGI-I rating scale: very much worse 4 studies[319,384,385,402]	1,268	0.74 (0.54 to 1.02)	0.00 (-0.02 to 0.02)			0.68 (0.20 to 2.82)	Moderate
Deterioration in PGI-I rating scale: much worse 3 studies[384,385,402]	1,159	1.19 (0.29 to 4.90)	0.00 (-0.01 to 0.01)			1.18 (0.27 to 5.44)	Moderate
No improvement in PGI-I rating scale: no change 3 studies[384,385,402]	1,159	0.78 (0.65 to 0.94)	-0.07 (-0.12 to −0.02)			0.71 (0.44 to 1.17)	Low
Deterioration in PGI-I rating scale: a little worse 3 studies[384,385,402]	1,160	0.58 (0.32 to 1.05)	-0.03 (-0.06 to; 0.01)			0.51 (0.23 to 1.11)	Low
Adverse Effects That Resulted in Discontinuation of the Treatment							
Anxiety 2 studies[384,397]	2,371	10.92 (1.41 to 84.60)	0.01 (0.00 to 0.02)		8 (0 to 16)		Low
Asthenia 4 studies[386,389,393,402]	1,166	3.71 (0.79 to 17.52)	0.01 (0.00 to 0.02)				Low
Constipation 2 studies[393,397]	2,114	1.29 (0.15 to 11.00)	0.00 (0.00 to 0.01)			1.42 (0.12 to 14.77)	Low
Dizziness 8 studies[384,386,389-393,397]	4,404	5.49 (2.56 to 11.74)	0.02 (0.01 to 0.02)	59 (43 to 91)	17 (11 to 23)	8.25 (3.59 to 24.02)	High
Fatigue 4 studies[389,391,397,402]	3,440	4.02 (0.91 to 17.71)	0.01 (0.00 to 0.02)	91 (45 to 1000)	11 (1 to 20)	5.04 (1.63 to 16.90)	High
Insomnia 7 studies[384,386,389,391-393,397]	4,126	5.70 (2.46 to 13.19)	0.02 (0.01 to 0.02)	67 (48 to 111)	15 (9 to 21)	8.53 (3.37 to 25.41)	High
Nausea 9 studies[384,386,389-393,397,402]	4,992	11.27 (5.69 to 22.30)	0.04 (0.03 to 0.05)	25 (20 to 32)	40 (31 to 50)	20.92 (9.26 to 60.26)	High

Table 6. Clinical outcomes with duloxetine treatments (pooled with random effects estimates from head-to-head RCTs) (continued)

Reference Number of studies	Number of subjects	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number deeded to treat (95% CI)	Attributable events/1000 treated (95% CI)	Bayesian odds ratio median (2.5; 97.5%)	Evidence
Somnolence 6 studies[386,390,391,393,397,402]	3,784	6.68 (2.34 to 19.08)	0.01 (0.01 to 0.02)	91 (59 to 167)	11 (6 to 17)	15.73 (4.14 to 148.80)	High
Diarrhea 2 studies [397,402]	2,501	2.42 (0.47 to 12.54)	0.00 (0.00 to 0.01)			2.91 (0.45 to 29.21)	Low
Headache 3 studies[389,390,402]	1,122	4.31 (0.93 to 20.02)	0.01 (0.00 to 0.03)	71 (40 to 500)	14 (2 to 25)	11.67 (1.71 to 263.20)	Moderate

Table 7. Continence, improvement in UI, treatment failure, and adverse effects with pharmacological interventions compared to placebo (pooled with random effects estimates from head-to-head RCTs)

Active drug	Outcome	RCTs, Reference	Patients in analyses	Rate Active/ control %	Risk Difference* (95% CI)	Attributable events per 1000 treated	Bayesian odds ratio median (2.5 to 97.5%)	Strength of evidence
Darifenacin	Clinically important improvement in incontinence	3[479,481,482]	1,011	48.4/33	0.12 (0.06 to 0.17)	117 (57 to 177)	1.7 (1.04 to 2.9)	High
Darifenacin	Serious adverse effects	2[482,483]	655	1.2/2.1	-0.01 (-0.02 to 0.01)		0.6 (0.1 to 2.6)	Low
Darifenacin	Discontinuation: Adverse effects	7[306,307,479,481-483,489]	3,138	4.6/3.3	0.00 (-0.01 to 0.02)		1.2 (0.7 to 2.0)	High
Darifenacin	Discontinuation: Treatment failure	4[306,307,482,483]	1,280	1.0/1.7	-0.01 (-0.01 to 0.01)		0.6 (0.2 to 1.7)	Moderate
Darifenacin	Dry mouth	5[479,480,482,483,489]	2,382	22.0/5.6	0.16 (0.07 to 0.27)	158 (65 to 269)	4.1 (2.1 to 8.1)	High
Darifenacin	Dyspepsia	4[480,482,483,489]	1,772	4.4/1.3	0.03 (0.01 to 0.06)	31 (7 to 62)	3.6 (1.7 to 7.9)	High
Darifenacin	Headache	3[480,482,483]	1,155	4.1/1.1	0.03 (0.01 to 0.06)	34 (13 to 61)	4.2 (1.6 to 12.3)	Moderate
Darifenacin	Nausea	2[480,483]	573	1.3/0.7	0.00 (-0.01 to 0.03)		1.4 (0.2 to 9.9)	Low
Darifenacin	Urinary tract infection	2[482,483]	655	2.9/2.3	0.01 (-0.01 to 0.04)		1.2 (0.3 to 4.1)	Low
Darifenacin	Constipation	5[479,480,482,483,489]	2,239	14.6/5.7	0.08 (0.02 to 0.15)	80 (24 to 148)	2.6 (1.4 to 4.4)	High
Fesoterodine	Continence	2[309,313]	2,465	61.0/48.5	0.13 (0.06 to 0.20)	130 (58 to 202)	1.7 (0.9 to 3.3)	Low
Fesoterodine	Clinically important improvement in incontinence	2[309,461,503]	1,896	42/32	0.10 (0.06 to 0.15)	100 (56 to 145)	1.5(0.8 to 2.9)	High
Fesoterodine	Treatment failure	2[309,461,503,505]	1,896	4/8	-0.04 (-0.06 to -0.02)	-43 (-59 to -24)	0.4 (0.2 to 1.0)	High
Fesoterodine	Serious adverse effects	2[309,505]	1,905	1.8/1.9	0.00 (-0.01 to 0.01)		0.9 (0.3 to 2.3)	Low
Fesoterodine	Discontinuation: adverse effects	4[309,313,316,461,503,505]	4,433	6/3	0.03 (0.01 to 0.06)	31 (10 to 56)	2.0 (1.2 to 3.2)	High
Fesoterodine	Discontinuation: treatment failure	2[309,461,503,505]	1,896	2/3	-0.01 (-0.03 to 0.02)		0.6 (0.2 to 1.7)	Moderate
Fesoterodine	Abdominal pain	[309,316]	1,747	3.7/2.7	0.02 (0.00 to 0.04)		1.9 (0.8 to 4.0)	Low
Fesoterodine	Abnormal vision	1[316]	1,094	0.3/1.0	-0.01 (-0.01 to 0.00)		0.2 (0.0 to 1.4)	Insufficient
Fesoterodine	Back pain	2[309,316]	2,116	2.1/3.0	-0.01 (-0.02 to 0.01)		0.8 (0.4 to 1.7)	Low

Table 7. Continence, improvement in UI, treatment failure, and adverse effects with pharmacological interventions compared to placebo (pooled with random effects estimates from head-to-head RCTs) (continued)

Active drug	Outcome	RCTs, Reference	Patients in analyses	Rate Active/ control %	Risk Difference* (95% CI)	Attributable events per 1000 treated	Bayesian odds ratio median (2.5 to 97.5%)	Strength of evidence
Fesoterodine	Constipation	7[309,313,316,460,461,503,505,506]	7,695	11/3	0.04 (0.00 to 0.10)	41 (1 to 97)	2.4 (1.4 to 3.9)	High
Fesoterodine	Cough	3[309,316,505]	2,999	1.8/1.9	0.00 (-0.01 to 0.02)		1.1 (0.6 to 2.2)	Moderate
Fesoterodine	Diarrhea	2[309,461,505]	1,896	2/3	0.00 (-0.03 to 0.03)		0.8 (0.3 to 2.1)	Low
Fesoterodine	Dizziness	2[309,316]	3,138	1.2/0.9	0.00 (-0.01 to 0.01)		0.9 (0.4 to 2.0)	Low
Fesoterodine	Dry eye	4[309,460,503,505,506]	4,145	2/1	0.03 (0.01 to 0.06)	28 (6 to 60)	3.4 (1.6 to 8)	High
Fesoterodine	Dry mouth	5[309,313,316,460,461,503,505,506]	6,674	27/7	0.20 (0.16 to 0.24)	199 (161 to 239)	4.9 (3.8 to 6.3)	High
Fesoterodine	Fatigue	2[309,505]	1,905	2.0/0.3	0.02 (0.01 to 0.04)	24 (11 to 41)	10.3 (2.2 to 88.5)	Low
Fesoterodine	Headache	5[309,316,460,461,503,505, 506]	5,230	7/6	0.00 (-0.01 to 0.02)		1.1 (0.8 to 1.4)	High
Fesoterodine	Influenza-like symptoms	1[316]	1,094	5.7/8.0	-0.03 (-0.05 to 0.01)			Insufficient
Fesoterodine	Nasopharyngitis	4[309,460,505,506]	4,145	2.5/3.3	-0.01 (-0.02 to 0.00)		0.8 (0.5 to 1.2)	Moderate
Fesoterodine	Nausea	5[309,316,460,505,506]	5,239	2.0/3.1	-0.01 (-0.02 to 0.00)		0.6 (0.4 to 1.0)	High
Fesoterodine	Upper respiratory tract infection	2[309,505]	1,905	2.0/3.5	-0.01 (-0.02 to 0.01)		0.6 (0.1 to 1.9)	Low
Fesoterodine	Urinary tract infection	2[309,461,505]	1,896	2/2	0.01 (-0.01 to 0.05)		1.2 (0.4 to 3.7)	Low
Oxybutynin	Continence	4[409,413,416,437,438]	992	27/16	0.11(0.06 to 0.16)	114(64 to 163)	2.1(1.2 to 3.9)	High
Oxybutynin	Clinically important improvement in incontinence	9[322,406,415,416,418,437-443]	1,244	53/32	0.17 (0.10 to 0.24)	167 (95 to 240)	2.5(1.7 to 3.7)	Moderate
Oxybutynin	Treatment failure	5[415,437,439,441,443]	874	12.2/22.9	-0.11 (-0.16 to -0.05)	-110 (-161 to -46)	0.4 (0.2 to 0.7)	Moderate
Oxybutynin	Serious adverse effects	3[321,413,441]	1,393	3.7/2.0	0.02 (-0.02 to 0.15)		1.5 (0.3 to 6.4)	Moderate
Oxybutynin	Discontinuation: adverse effects	5[322,413,415,441,442,446]	1,483	10/5	0.06 (0.01 to 0.13)	63 (12 to 127)	2.0 (1.1 to 3.8)	High
Oxybutynin	Blurred vision	5[405,406,437,441,446]	663	10.4/9.1	0.10 (0.02 to 0.19)	98 (22 to 187)		Moderate
Oxybutynin	Constipation	7[405,410,413,416,437,441,446]	1,743	7.3/5.5	0.03 (-0.01 to 0.09)		1.4 (0.8 to 2.6)	Moderate
Oxybutynin	Dizziness	5[410,413,416,441,446]	1,541	2.3/1.7	0.01 (0.00 to 0.03)			Moderate

Table 7. Continence, improvement in UI, treatment failure, and adverse effects with pharmacological interventions compared to placebo (pooled with random effects estimates from head-to-head RCTs) (continued)

Active drug	Outcome	RCTs, Reference	Patients in analyses	Rate Active/ control %	Risk Difference* (95% CI)	Attributable events per 1000 treated	Bayesian odds ratio median (2.5 to 97.5%)	Strength of evidence
Oxybutynin	Dry mouth	9[322,405,406,410,413,416, 437,441,442,446]	2,238	34/15	0.35 (0.16 to 0.54)	347 (158 to 536)	7.2 (3.2 to 16.5)	High
Oxybutynin	Dry skin	3[405,406,441]	493	10.0/10.4	0.09 (-0.07 to 0.35)			Low
Oxybutynin	Dyspepsia	3[322,408,441]	613	12.1/3.3	0.08 (0.03 to 0.16)	85 (27 to 158)	3.9 (1.2 to 12.2)	Moderate
Oxybutynin	Dysuria	2[410,413]	1,046	0.8/0.2	0.01 (0.00 to 0.07)		5.8 (0.5 to 254.9)	Low
Oxybutynin	Headache	3[408,413,441]	1,299	4.1/4.5	-0.01 (-0.03 to 0.01)		0.9 (0.4 to 2.2)	Moderate
Oxybutynin	Nausea	7[322,405,408,410,413,416, 439]	1,743	3.9/3.0	0.00 (-0.02 to 0.05)		1.0 (0.4 to 2.4)	High
Oxybutynin	Retention	3[413,437,441]	1,287	3.2/0.5	0.04 (-0.01 to 0.16)		6.1 (0.2 to 57.0)	Moderate
Oxybutynin	Somnolence	3[410,413,441]	1,412	0.9/0.8	0.00 (-0.01 to 0.02)			Low
Oxybutynin	Vision disorder	3[410,415,439]	589	8.1/4.7	0.00 (-0.04 to 0.09)		1.1 (0.2 to 3.4)	Low
Oxybutynin	Vomiting	2[408,439]	361	2.3/1.4	0.03 (-0.01 to 0.14)		2.0 (0.3 to 19.0)	Low
Solifenacin	Continence	5[492,494,496,497,499]	6,304	39.2/28.1	0.11 (0.06 to 0.16)	107 (58 to 156)	1.7 (1.3 to 2.1)	High
Solifenacin	Clinically important improvement in incontinence	2[492,495]	1,507	60.2/42.0	0.18 (0.10 to 0.26)	180 (97 to 263)	2.2 (1.1 to 4.3)	Low
Solifenacin	Treatment failure	4[478,492,493,495]	2,918	27.7/30.1	-0.14 (-0.22 to -0.06)	-143 (-217 to -60)		Moderate
Solifenacin	Discontinuation: adverse effects	7[478,493-497,499,502]	9,080	5/4	0.01 (0.00 to 0.03)	13 (1 to 26)	1.3 (1.0 to 1.7)	High
Solifenacin	Discontinuation: treatment failure	4[478,493,495,496]	2,812	1.5/1.3	0.00 (-0.01 to 0.01)		1.0 (0.4 to 2.2)	Moderate
Solifenacin	Blurred vision	9[477,478,492-497,499,502]	12,922	4/2	0.02 (0.01 to 0.03)	17 (10 to 26)	2 (1.4 to 2.7)	High
Solifenacin	Dry mouth	7[477,492-495,497,499,502]	11,089	21/5	0.17 (0.12 to 0.23)	175 (122 to 232)	5.2 (3.7 to 7.2)	High
Solifenacin	Dyspepsia	3[477,492,496]	1,663	3.4/0.4	0.04 (0.02 to 0.06)	37 (16 to 64)	11.4 (3.3 to 53.4)	Moderate
Solifenacin	Fatigue	2[492,494,495]	1,507	2/1	0.01 (0.00 to 0.03)	12 (0 to 28)	2.6 (0.8 to 9.4)	Low
Solifenacin	Headache	4[477,492,494-496]	2,481	3/4	-0.01 (-0.02 to 0.01)		0.8 (0.4 to 1.4)	Moderate
Solifenacin	Nausea	2[492,496]	1,440	3.2/2.7	0.00 (-0.01 to 0.03)		1.1 (0.3 to 3.1)	Low
Solifenacin	Urinary retention	2[477,496]	747	2.4/0.8	0.03 (-0.01 to 0.12)		3.6 (0.8 to 23.4)	Low

Table 7. Continence, improvement in UI, treatment failure, and adverse effects with pharmacological interventions compared to placebo (pooled with random effects estimates from head-to-head RCTs) (continued)

Active drug	Outcome	RCTs, Reference	Patients in analyses	Rate Active/ control %	Risk Difference* (95% CI)	Attributable events per 1000 treated	Bayesian odds ratio median (2.5 to 97.5%)	Strength of evidence
Solifenacin	Constipation	8[477,492-497,499,502]	11,765	11/3	0.07 (0.05 to 0.10)	73 (49 to 99)	3.1 (2.3 to 4.2)	High
Solifenacin	Dizziness	2[494-496]	1,411	3/2	0.01 (-0.01 to 0.03)		1.5 (0.6 to 3.8)	Low
Tolterodine	Continence	4[309,312,313,344]	3,404	53.2/43.7	0.09 (0.04 to 0.13)	85 (40 to 129)	1.5 (1.0 to 2.1)	High
Tolterodine	Clinically important improvement in incontinence	7[88,309,313,454,456,461,463,464]	6,119	45/37	0.10 (0.04 to 0.15)	96(42 to 149)	1.5(1.2 to 2.0)	High
Tolterodine	Treatment failure	6[309,312,454,456,461,463,464]	4,260	9/16	-0.05 (-0.10 to 0.01)		0.6 (0.4 to 1.0)	High
Tolterodine	Serious adverse effects	5[309,448,450-452]	3,550	1.8/3.1	-0.01 (-0.02 to 0.00)		0.6 (0.3 to 1.1)	Moderate
Tolterodine	Discontinuation: adverse effects	10[309,313,321,322,450,452, 453,457,458,460,461,463,478]	4,466	4/3	0.01 (-0.01 to 0.03)		1.1 (0.8 to 1.7)	High
Tolterodine	Discontinuation: treatment failure	5[309,457,461,463,478]	4,049	0.7/1.6	-0.01 (-0.01 to 0.00)		0.4 (0.2 to 0.9)	High
Tolterodine	Autonomic nervous system disorders	3[448-450]	831	27.2/15.5	0.12 (0.05 to 0.20)	117 (46 to 195)	2.0 (1.1 to 3.5)	Moderate
Tolterodine	Blurred vision	2[477,478]	608	1.3/3.0	-0.03 (-0.02 to 0.03)		0.4 (0.1 to 1.7)	Low
Tolterodine	Constipation	14[309,312,313,321,449,451-453,455,457,458,460,461,463, 477,478]	9,592	4/3	0.01 (0.00 to 0.02)	12 (3 to 22)	1.4 (1.1 to 1.9)	High
Tolterodine	Diarrhea	4[309,451,452,455,457,461]	4,056	2/2	0.01 (0.00 to 0.02)		1.2 (0.7 to 2.2)	High
Tolterodine	Dizziness	6[309,451,452,455,457,460, 463]	5,257	2/2	0.00 (0.00 to 0.01)		1.0 (0.6 to 1.7)	High
Tolterodine	Dry mouth	14[309,312,313,321,322,343, 451,453,460,461,463,465,477, 478]	7,637	18.4/6.7	0.14 (0.10 to 0.18)	139 (104 to 175)	3.4 (2.7 to 4.5)	High
Tolterodine	Dyspepsia	6[309,322,343,451,452,455, 457]	3,525	3/2	0.02 (0.00 to 0.05)	22 (1 to 53)	2.1 (1.1 to 4.4)	High
Tolterodine	Fatigue	4[309,451,460,463]	3,234	1.9/0.7	0.02 (0.01 to 0.03)	17 (7 to 29)	3.1 (1.3 to 7.8)	High
Tolterodine	General body disorders	2[449,450]	308	22.3/18.6	0.03 (-0.09 to 0.18)		1.1 (0.3 to 3.5)	Low

Table 7. Continence, improvement in UI, treatment failure, and adverse effects with pharmacological interventions compared to placebo (pooled with random effects estimates from head-to-head RCTs) (continued)

Active drug	Outcome	RCTs, Reference	Patients in analyses	Rate Active/ control %	Risk Difference* (95% CI)	Attributable events per 1000 treated	Bayesian odds ratio median (2.5 to 97.5%)	Strength of evidence
Tolterodine	Headache	11[309,312,343,449,451-453,455,457,458,460,461,463,477]	6,766	4/4	0.01 (0.00 to 0.03)		1.3 (1.0 to 1.8)	High
Tolterodine	Insomnia	2[312,451,455]	1,428	1.7/1.3	0.02 (-0.01 to 0.10)		1.5 (0.5 to 5.8)	Moderate
Tolterodine	Nasopharyngitis	5[88,309,312,460,463,468]	2,835	3/3	0.00 (-0.01 to 0.02)		1.1 (0.7 to 1.9)	High
Tolterodine	Nausea	7[309,322,451,452,455,457,460]	5,642	1.6/2.0	0.00 (-0.01 to 0.01)		0.8 (0.5 to 1.3)	High
Tolterodine	Somnolence	2[451,455,457]	1,869	1/1	0.00 (-0.01 to 0.02)		0.9 (0.1 to 3.7)	Low
Tolterodine	Urinary tract infection	5[309,312,449,451,455,457,461]	4,465	2/3	0.00 (-0.01 to 0.01)		0.9 (0.6 to 1.5)	High
Tolterodine	Abdominal pain	5[309,451-453,455,457]	4,637	3/2	0.01 (0.00 to 0.02)	9 (1 to 20)	1.6 (0.9 to 2.8)	High
Tolterodine	Abnormal vision	2[321,451,455]	1,141	2/1	0.00 (-0.01 to 0.02)		1.4 (0.4 to 5.5)	Moderate
Trospium	Continence	4[325,512-514]	2,677	28.3/16.6	0.11 (0.08 to 0.14)	114 (83 to 144)	2.0 (1.4 to 2.9)	High
Trospium	Clinically important improvement in incontinence	2[509,513]	1,176	32.4/25.4	0.08 (-0.10 to 0.25)		1.4 (0.4 to 3.8)	Low
	Discontinuation: adverse effects	6[329,330,510,512-514]	3,936	5.8/3.9	0.02 (0.00 to 0.03)	18 (4 to 33)	1.5 (1.0 to 2.2)	High
Trospium	Abdominal distention	2[512,514]	989	1.0/0.3	0.01 (0.00 to 0.02)	8 (0 to 21)	3.4 (0.8 to 19.1)	Low
Trospium	Abdominal pain	3[512-514]	2,113	1.7/0.7	0.01 (0.00 to 0.02)	10 (1 to 23)	2.7 (1.0 to 8.1)	Moderate
Trospium	Central Nervous System Disorders	2[325,509]	1,217	3.9/3.8	0.00 (-0.02 to 0.03)		1.0 (0.4 to 2.6)	
Trospium	Constipation	5[325,510,512-514]	3,335	9.3/2.6	0.07 (0.05 to 0.09)	70 (47 to 95)	3.9 (2.5 to 6.3)	High
Trospium	Diarrhea	2[510,513]	1,181	2.5/4.6	-0.02 (-0.04 to 0.00)		0.5 (0.2 to 1.4)	Low
Trospium	Dry eye	2[512,514]	1,590	1.7/0.2	0.01 (0.00 to 0.03)	14 (4 to 29)	8.0 (1.7 to 59.3)	Low
Trospium	Dry mouth	6[325,465,510,512-514]	3,490	15.1/4.5	0.11 (0.07 to 0.14)	106 (75 to 140)	3.9 (2.6 to 5.8)	High
Trospium	Dry skin	2[512,514]	1,590	1.0/0.1	0.01 (0.00 to 0.02)	11 (2 to 24)	12.3 (1.6 to 420.5)	Low
Trospium	Dyspepsia	2[512,514]	1,590	1.5/0.9	0.00 (-0.01 to 0.02)		1.8 (0.6 to 6.4)	Low
Trospium	Headache	4[510,512-514]	2,771	3.3/3.5	-0.01 (-0.02 to 0.01)		0.9 (0.4 to 1.7)	High

Table 7. Continence, improvement in UI, treatment failure, and adverse effects with pharmacological interventions compared to placebo (pooled with random effects estimates from head-to-head RCTs) (continued)

Active drug	Outcome	RCTs, Reference	Patients in analyses	Rate Active/ control %	Risk Difference* (95% CI)	Attributable events per 1000 treated	Bayesian odds ratio median (2.5 to 97.5%)	Strength of evidence
Trospium	Nausea	2[512,514]	1,590	1.3/0.4	0.01 (0.00 to 0.02)		3.7 (0.8 to 20.0)	Low
Trospium	Urinary tract infection	3[510,512,514]	2,248	2.6/1.3	0.01 (0.00 to 0.03)		2.0 (0.9 to 4.6)	Moderate

*Risk differences for adverse effects were calculated using arcsine transformation

Table 8. Rates of adverse effects after drugs vs. placebo (significant differences only, pooled with random effects estimates from head-to-head RCTs)

Drug	Adverse effect	Subjects in analyses	Rates,% of adverse effects with drug vs. (placebo)	Number needed to treat to harm one patient (95% CI)	Number of attributable effects per 1000 treated (95% CI)
Darifenacin	All adverse effects	1495	57.0 (43.2)	5 (4 to 8)	190 (118 to 260)
Fesoterodine	All adverse effects	4145	51.4 (37.8)	6 (5 to 9)	156 (112 to 200)
Propiverine	All adverse effects	985	32.9 (18.9)	6 (4 to 12)	163 (83 to 248)
Solifenacin	All adverse effects	1713	51.9 (36.3)	6 (4 to 12)	177 (85 to 267)
Tolterodine	All adverse effects	4162	44.7 (38.1)	12 (8 to 21)	83 (47 to 120)
Trospium	All adverse effects	2967	40.5 (28.7)	8 (6 to 11)	123 (88 to 159)
Fesoterodine	Bothersome adverse effects leading to treatment discontinuation	4433	6.2 (3.2)	33 (18 to 102)	31 (10 to 56)
Oxybutynin	Bothersome adverse effects leading to treatment discontinuation	1483	10.4 (4.8)	16 (8 to 86)	63 (12 to 127)
Propiverine	Bothersome adverse effects leading to treatment discontinuation	1401	4.7 (2.0)	29 (16 to 77)	34 (13 to 61)
Solifenacin	Bothersome adverse effects leading to treatment discontinuation	9080	5.4 (4.2)	78 (39 to 823)	13 (1 to 26)
Trospium	Bothersome adverse effects leading to treatment discontinuation	3936	5.8 (3.9)	56 (30 to 228)	18 (4 to 33)
Darifenacin	Constipation	2239	14.6 (5.7)	12 (7 to 41)	80 (24 to 148)
Fesoterodine	Constipation	6673	11.5 (2.8)	24 (10 to 995)	41 (1 to 97)
Propiverine	Constipation	1793	7.5 (2.4)	10 (6 to 26)	101 (39 to 180)
Solifenacin	Constipation	11765	10.7 (3.4)	14 (10 to 20)	73 (49 to 99)
Tolterodine	Constipation	9592	3.8 (2.8)	84 (46 to 329)	12 (3 to 22)
Trospium	Constipation	3335	9.3 (2.6)	14 (11 to 21)	70 (47 to 95)
Darifenacin	Dry mouth	2382	22.0 (5.6)	6 (4 to 15)	158 (65 to 269)
Fesoterodine	Dry mouth	6674	27.4 (7.0)	5 (4 to 6)	199 (161 to 239)
Oxybutynin	Dry mouth	2238	34.1 (14.6)	3 (2 to 6)	347 (158 to 536)
Propiverine	Dry mouth	1793	22.6 (6.2)	6 (5 to 9)	163 (110 to 221)
Solifenacin	Dry mouth	11089	21.4 (4.5)	6 (4 to 8)	175 (122 to 232)
Tolterodine	Dry mouth	7637	18.4 (6.7)	7 (6 to 10)	139 (104 to 175)
Trospium	Dry mouth	3490	15.1 (4.5)	9 (7 to 13)	106 (75 to 140)
Trospium	Dry skin	1590	1.0 (0.1)	94 (42 to 442)	11 (2 to 24)

Table 8. Rates of adverse effects after drugs vs. placebo (significant differences only, pooled with random effects estimates from head-to-head RCTs) (continued)

Drug	Adverse effect	Subjects in analyses	Rates,% of adverse effects with drug vs. (placebo)	Number needed to treat to harm one patient (95% CI)	Number of attributable effects per 1000 treated (95% CI)
Fesoterodine	Dry eye	4145	2.3 (0.7)	35 (17 to 160)	28 (6 to 60)
Trospium	Dry eye	1590	1.7 (0.2)	70 (34 to 258)	14 (4 to 29)
Darifenacin	Dyspepsia	1772	4.4 (1.3)	32 (16 to 139)	31 (7 to 62)
Oxybutynin	Dyspepsia	613	12.1 (3.3)	12 (6 to 36)	85 (27 to 158)
Solifenacin	Dyspepsia	1663	3.4 (0.4)	27 (16 to 61)	37 (16 to 64)
Tolterodine	Dyspepsia	3525	2.8 (1.6)	45 (19 to 991)	22 (1 to 53)
Fesoterodine	Fatigue	1905	2.0 (0.3)	42 (25 to 91)	24 (11 to 41)
Tolterodine	Fatigue	3234	1.9 (0.7)	60 (34 to 149)	17 (7 to 29)
Darifenacin	Headache	1155	4.1 (1.1)	30 (16 to 76)	34 (13 to 61)
Trospium	Abdominal pain	2113	1.7 (0.7)	97 (43 to 849)	10 (1 to 23)
Tolterodine	Autonomic nervous system disorders	831	27.2 (15.5)	9 (5 to 22)	117 (46 to 195)
Oxybutynin	Blurred vision	663	10.4 (9.1)	10 (5 to 46)	98 (22 to 187)
Propiverine	Blurred vision	1401	4.2 (1.5)	31 (13 to 674)	32 (1 to 77)
Solifenacin	Blurred vision	12922	3.5 (1.8)	57 (38 to 102)	17 (10 to 26)

Comparative Effectiveness of Pharmacological Treatments

Comparative Effectiveness of Topical Estrogen on Stress UI

Evidence was insufficient to determine whether an estrogen releasing intravaginal ring was more effective in resolving and improving UI than a pessary or to determine whether an intravaginal tablet was more effective than intravaginal estrogen cream (Appendix Table F69).

Two RCTs of 291 women compared different estrogen formulations (Appendix Table F27).[526,527] The studies enrolled postmenopausal women with lower urinary tract symptoms including UI.[526,527] The first study compared an intravaginal tablet with intravaginal conjugated estrogen cream administered for 8 weeks.[526] The second study compared an estrogen releasing ring with an estrogen pessary administered for 24 weeks.[527] Continence rates did not differ between the intravaginal tablet and the intravaginal cream[526] (Appendix Table F70). Women treated with an estrogen releasing ring did not experience urgency UI more often than those treated with a pessary.[527] The rates of resolved stress UI did not differ between estrogen rings and pessaries.[527] Women were satisfied with the estrogen ring more often than with the estrogen pessary.[527]

An estradiol vaginal ring and oral oxybutynin demonstrated similar effects in decreasing the number of daily voids in postmenopausal women with overactive bladder.[528] Quality of life score did not differ with two drugs.[528] Women experienced constipation and dry mouth more often with oxybutynin than with an estrogen ring.[528] Bothersome adverse effects leading to treatment discontinuation did not differ between the drugs.[528]

Comparative Effectiveness of Darifenacin and Oxybutynin on Urgency UI

Evidence was insufficient from which to conclude comparative effectiveness between darifenacin and oxybutynin on continence or improved UI. A low level of evidence indicated lower rates of total adverse effects and dry mouth with darifenacin, with no differences in adverse effects leading to treatment discontinuation.

Two RCTs[446,529] compared clinical outcomes of oxybutynin and darifenacin.

Continence

The studies did not examine continence outcomes of oxybutynin compared to darifenacin.

Improvement in UI

The studies found no differences in improvement of UI between the two drugs. Both drugs significantly reduced incontinence episodes compared to placebo, with no differences between drugs.[446]

Adverse Effects

Darifenacin was safer than oxybutynin. Total rates of adverse effects were lower with darifenacin than with oxybutynin[529] (Appendix Table F71). Rates of dry mouth were lower with darifenacin than oxybutynin.[446] Severe dry mouth was less common with 7.5 mg/day of darifenacin than with 7.5mg/day of oxybutynin, and lower with 15 mg/day of darifenacin than with 15 mg/day of oxybutynin[529] (Appendix Table F72). Only one adverse effect, constipation, was more common with 30 mg of darifenacin than with 15 mg of oxybutynin[529] (Appendix Table

F73). Discontinuations from the study due to treatment-related adverse effects were lower with darifenacin than with oxybutynin in one RCT[446] (Appendix Table F74). Pooled analysis of two RCTs found no significant differences between the two drugs in adverse effects leading to treatment discontinuation (Table 9).

Comparative Effectiveness of Oxybutynin and Tolterodine on Urgency UI

Evidence was insufficient from which to draw conclusions about comparative effectiveness between oxybutynin and tolterodine on continence. A moderate level of evidence indicated no difference between the drugs for UI improvement. A high level of evidence indicated more frequent treatment discontinuation due to adverse effects with oxybutynin than with tolterodine. Women experienced dry mouth and several other adverse effects more often with oxybutynin than with tolterodine. Thus, the drugs offered equal benefits, but tolterodine resulted in fewer harms.

We identified 15 publications that compared clinical outcomes of oxybutynin and tolterodine,[87,322,408,411,441,442,450,530-537] including secondary data analyses,[87,535,536] OBJECT Study group,[530] OPERA Study group (Overactive bladder: Performance of Extended Release Agents),[533] Transdermal Oxybutynin Study Group,[411] and Japanese and Korean Tolterodine Study Group[441] (Appendix Table F27).

Continence

Urinary continence was reported in the OPERA trial of 790 women.[533] Ten mg/day of oxybutynin, compared to 4mg/day of tolterodine, resulted in greater rates of continence[533] (Appendix Table F75). Drugs had to be given to 16 women to achieve continence in one (Table 10).

Improvement in UI

We found no difference between the two drugs[322,441,531] (Figure 5). Treatment-related rates of improved bladder condition did not differ between the two drugs in a pooled analysis of individual patient data from four RCTs[87](Appendix Table F76).

Adverse Effects

Tolterodine demonstrated better safety than oxybutynin in several individual RCTs and secondary data analyses (Appendix Table F71). Total adverse effects did not differ between the drugs according to the pooled aggregate data from the published studies.[450,531,532] However, one pooled analysis of individual patient data from four RCTs demonstrated higher rates of moderate and severe adverse effects with 10 mg/day of oxybutynin compared to 4 mg/day of extended-release tolterodine[536] (Appendix Table F77). Even though another pooled analysis of individual patient data from four RCTs found no differences in serious adverse effects between oxybutynin and tolterodine, dose reduction rates due to intolerance were more common with oxybutynin than with tolterodine.[87]

Among individual adverse effects, dry mouth was more common with oxybutynin than with tolterodine[441,442,450,530,531,533,534] (Figure 5). Severe dry mouth was also more common with 5 mg/day of oxybutynin than with 2mg/day or 1mg/day of tolterodine.[87] In addition to dry mouth, women experienced asthenia,[536] autonomic nervous system disorder,[87] gastrointestinal

disorders,[87] dyspepsia,[87] nausea,[536] pain,[536] palpitations,[87] rhinitis,[536] and urinary tract infections[536] more often with oxybutynin than with tolterodine.

Women stopped taking oxybutynin more often that tolterodine because of adverse effects (Figure 5).[411,441,442,450,530,531,533,534] During the studies, 13 percent of women stopped taking oxybutynin and six percent of women stopped taking tolterodine because of adverse effects[87,322,442,450,530,531,533-536] (Table 9).

Comparative Effectiveness of Propiverine and Oxybutynin on Urgency UI

Evidence was insufficient from which to draw conclusions about comparative effectiveness and safety of propiverine and oxybutynin.

One RCT compared clinical outcomes of propiverine and oxybutynin.[439]

Improvement in UI and subject satisfaction did not differ between the two drugs (Appendix Table F76). Total adverse effects did not differ between the two drugs (Appendix Table F71). Fewer subjects experienced severe dry mouth with propiverine than with oxybutynin.[439] No studies compared rates of treatment discontinuation due to adverse effects between the two drugs.

Comparative Effectiveness of Flavoxate and Oxybutynin on Urgency UI

Evidence was insufficient from which to draw conclusions about comparative effectiveness and safety of flavoxate and oxybutynin.

A single RCT of 100 subjects compared clinical outcomes of 1,200 mg/day of flavoxate hydrochloride and 15mg/day of oxybutynin.[538] Neither urinary continence nor improvement in UI differed between the two drugs[538] (Appendix Tables F75 and F76). Neither treatment failure with worsening of UI nor total number of adverse effects differed between the two drugs.[538] Rates of dry mouth and dry eyes were significantly lower with flavoxate than with oxybutynin. Nausea was also significantly less common with flavoxate than with oxybutynin.[538]

Comparative Effectiveness of Tolterodine and Propiverine on Urgency UI

Evidence was insufficient from which to draw conclusions about comparative effectiveness and safety of propiverine and tolterodine.

We identified one RCT of 202 patients treated with 15 mg of propiverine twice daily or 2 mg of tolterodine twice daily.[539] No studies compared continence and improvement in UI with the two drugs.[539] Improvement in urodynamic criteria of detrusor overactivity did not differ between the two drugs.[539] Both drugs improved quality of life scores without significant differences between them. The rates of total adverse effects did not differ between the two drugs (Appendix Table F71).

Comparative Effectiveness of Tolterodine and Fesoterodine on Urgency UI

A low level of evidence indicated greater continence rates with fesoterodine than with tolterodine. A high level of evidence indicated greater rates of improvement in UI with fesoterodine than with tolterodine. A moderate level of evidence indicated higher rates of adverse effects that led to treatment discontinuation with fesoterodine than with tolterodine.

Six publications of RCTs compared clinical outcomes of fesoterodine and tolterodine.[88,309,313,460,461,468]

Continence

Urinary continence was more often achieved with fesoterodine than with tolterodine[309,313] (Table 10).

Improvement in UI

Rates of improvement in UI were greater with fesoterodine.[88,309,313,461] Pooled analysis of individual patient data from two RCTs that included 1,548 women analyzed self-rated substantial benefits from the treatments[88] and found no difference in the rates of this outcome between fesoterodine and tolterodine (Appendix Table F78).

Quality of life did not differ between fesoterodine (4 or 8 mg) and tolterodine extended release in pooled analysis of individual subject data from two RCTs.[540]

Adverse Effects

Rates of total adverse effects did not differ between 4 mg of tolterodine and 4 mg of fesoterodine, but were less with tolterodine than with 8 mg of fesoterodine.[460] Rates of dry mouth were less with tolterodine than with 4 mg of fesoterodine. Pooled analysis of individual patient data from two RCTs found that dry mouth was less common in women treated with tolterodine than with 8 mg/day of fesoterodine, with no significant differences when compared to 4 mg of fesoterodine.[88] Urinary tract infection was also less common in women treated with tolterodine than with 8 mg/day of fesoterodine, with no significant differences compared to 4 mg of fesoterodine.[88]

Adverse effects resulting in treatment discontinuation were more common with fesoterodine than with tolterodine[309,313,460,461] (Table 9).

Comparative Effectiveness of Solifenacin and Tolterodine on Urgency UI

Comparative effectiveness evidence was insufficient for solifenacin and tolterodine. A moderate level of evidence indicated that adverse effects leading to treatment discontinuation did not differ between the two drugs.

Six publications of RCTs compared clinical outcomes of solifenacin and tolterodine,[114,477,478,541-543] including the Solifenacin and Tolterodine as an Active comparator in a Randomized STAR study group that compared clinical outcomes of 5 or 10 mg of solifenacin and 4 mg of extended-release tolterodine.[541,542] The studies examined different doses of the drugs on a variety of outcomes that hampered the synthesis of evidence.

Continence

Urinary continence was greater with solifenacin than with tolterodine[541] (Table 10).

Improvement in UI

Solifenacin resulted in greater rates of improvement than tolterodine[541] (Appendix Table F79). Both drugs improved quality of life without evidence of differences between them.

Adverse Effects

Total rates of adverse effects did not differ between solifenacin and tolterodine[114,477] (Appendix Table F71). However, one published RCT demonstrated a significant increase in adverse effects with the highest dose of solifenacin (20mg once daily) compared to tolterodine. A lower dose of solifenacin resulted in the same rates of adverse effects as tolterodine in one published[477] and one unpublished RCT.[114] Dry mouth and constipation were more common in women treated with solifenacin than with tolterodine.[542] Blurred vision was less common with solifenacin than with tolterodine[542] (Appendix Table F80).

Treatment discontinuation rates due to adverse effects did not differ between the two drugs.[114,478,542,543]

Comparative Effectiveness of Solifenacin and Darifenacin on Urgency UI

Evidence was insufficient from which to conclude comparative effectiveness and safety of solifenacin and darifenacin.

One unpublished RCT, the Solidair study, compared solifenacin and darifenacin.[544]

No studies compared continence and improvement in UI with solifenacin and darifenacin.

The Solidair study found that women taking solifenacin had to increase the dose of the drug more often than women taking darifenacin.[544] The Solidair study found that the rates of treatment discontinuation due to adverse effects did not differ between solifenacin and darifenacin.

Comparative Effectiveness of Solifenacin and Oxybutynin on Urgency UI

Evidence was insufficient from which to conclude comparative effectiveness and safety of solifenacin oxybutynin.

A single RCT, the VECTOR trial, compared 5 mg solifenacin once daily versus 5 mg oxybutynin immediate release three times daily.[545] Both drugs improved results in the Patient Perception of Bladder Condition scale and Overactive Bladder Questionnaire, without evident differences between them.

Rates of adverse effects were lower with solifenacin than with oxybutynin.[545] Dry mouth was less common with solifenacin than with oxybutynin.[545] Rates of dry mouth leading to treatment discontinuation were lower with solifenacin than with oxybutynin.[545] Rates of other adverse effects resulting in treatment discontinuation did not differ between the two drugs.[545]

Comparative Effectiveness of Solifenacin and Propiverine on Urgency UI

Evidence was insufficient from which to conclude comparative effectiveness and safety of solifenacin and propiverine.

A single RCT compared clinical outcomes of solifenacin and propiverine.[502]

This study reported a significant reduction in UI episodes with both drugs, without significant differences between them.[502]

The highest dose of solifenacin, 10 mg daily, caused greater rates of constipation and dry mouth than propiverine.[502]

The rates of dry mouth did not differ between 5mg/day of solifenacin and propiverine.[502]

Adverse effects leading to treatment discontinuation did not differ between the two drugs.

Comparative Effectiveness of Trospium and Oxybutynin on Urgency UI

Evidence was insufficient from which to conclude comparative effectiveness between trospium and oxybutynin. Individual studies found lower rates of dry mouth with trospium than with oxybutynin. A low level of evidence indicated no differences in treatment discontinuation due to adverse effects between the two drugs.

Two RCTs compared clinical outcomes of oxybutynin and trospium chloride.[305,546]

Continence

Urinary continence was achieved more often with trospium than with oxybutynin[546] (Appendix Table F75).

Improvement in UI

One RCT compared improvement in UI with oxybutynin and trospium and did not find significant differences[305] (Appendix Table F76). Dose escalation of either trospium or oxybutynin reduced frequency of urge UI without statistically significant differences between the two drugs.[547]

Adverse Effects

Trospium was better tolerated with fewer adverse effects than oxybutynin[546] (Appendix Table F71). Dry mouth was less common with trospium than with oxybutynin[546] (Appendix Table F72). With dose escalation, worsening of dry mouth was lower in the trospium groups than in the oxybutynin groups.[547] Treatment discontinuation due to adverse effects did not differ between the two drugs[305,546] (Table 9).

Comparative Effectiveness of Trospium and Tolterodine on Urgency UI

Evidence was insufficient from which to conclude the comparative effectiveness and safety of trospium and tolterodine.

A single unpublished study compared clinical outcomes of trospium and tolterodine.[465]

The rates of total adverse effects and dry mouth were the same with trospium and tolterodine.[465]

Indirect Evidence of Comparative Effectiveness of Pharmacological Treatments on Urgency UI

Indirect evidence did not indicate substantial differences in resolving or improving UI with different drugs. Differences in discontinuation due to adverse effects, including dry mouth, were more evident than differences in benefits. However, head-to-head comparisons were rarely available in more than one study, and the studies used different definitions of treatment success and different tools to measure quality of life.

We compared relative benefits and harms of drugs compared to placebo. Such indirect evidence from all RCTs that examined clinical outcomes of active drugs versus placebo indicated that trospium was the most effective to resolve UI (Figure 6), but the differences across the drugs were not significant. Absolute rates of continence were the highest with solifenacin and fesoterodine (Figure 7). Indirect statistical comparisons were difficult because of substantial variability in continence rates with placebo. For instance, women became continent with placebo

in RCTs of fesoterodine (48 percent), oxybutynin (16 percent), solifenacin (28 percent), tolterodine (44 percent), and trospium (17 percent).

We analyzed which factors might contribute to such differences in continence with placebo. The studies that did not report whether they included cases of mixed incontinence had lower rates of continence with placebo (18 percent) than studies that excluded women with stress UI (30 percent). The studies that included women with severe daily UI reported higher rates of continence with placebo (28 percent) than the studies that omitted baseline daily frequency of UI (15 percent).

From quality criteria of the studies, masking of treatment would be the most obvious candidate to explain continence with placebo. All drug studies that examined continence, however, were double blinded. From other quality criteria, the studies that reported justification of the sample size had higher continence with placebo (28 percent) than the studies that did not justify sample size (17 percent). Considering substantial variability in continence rates with drugs and placebo, but comparable relative effectiveness of the drugs, comparative safety of the drugs may influence decisions on which drug offers a better balance between benefits and harms.

Compared to placebo, all drugs except darifenacin and tolterodine led to more treatment discontinuation due to adverse effects. The number needed to treated was the highest with solifenacin (NNT=78) and the lowest with oxybutynin (NNT=16). The absolute rates of adverse effects leading to treatment discontinuation were the highest with oxybutynin, and were comparable between other drugs (Figure 8). Dry mouth was the most common adverse effect (Figure 9). Rates of dry mouth were the highest with oxybutynin. Among other adverse effects, constipation and blurred vision were the most common (Figure 10).

Indirect comparisons indicated comparable effectiveness of the drugs on continence. Oxybutynin had higher rates of dry mouth and treatment discontinuation due to adverse effects than other drugs.

Several retrospective observational studies analyzed comparative effectiveness and safety of pharmacological treatments for UI. The evidence-based cost utility analysis reported that more than half of patients stop taking drugs for UI after 1 year of treatment (Figure 11).[548] The lowest rates of treatment discontinuation were with 5 mg of solifenacin.[548] The authors estimated quality adjusted life years using treatment response rates and discontinuation rates for all drugs and demonstrated the largest gain in quality adjusted life years per 1,000 treated with solifenacin (Figure 12). Trospium, which demonstrated the highest continence rates, was not included in this analysis (Appendix Figure F26).

Table 9. Discontinuation due to adverse effects with pharmacological treatments for urgency UI (pooled with random effects estimates from head-to-head RCTs)

Active drug	Control drug	RCTs, Reference	Patients In analyses	Rate in active group, %	Rate in control group, %	Absolute risk difference* (95% CI)	Attributable events per 1000 treated (95% CI)	Strength of evidence
Darifenacin 7.5 daily	Oxybutynin 7.5 daily	1[529]	16	0	12.5	-0.13 (-0.41 to .16)		Insufficient
Darifenacin 7.5-15mg daily	Oxybutynin 15 mg daily	2[446,529]	62	3.2	12.9	-0.065 (-0.35 to 0.223)	Not significant	Low
Darifenacin control release 30 mg daily	Oxybutynin-IR 1 5mg daily	2[446,529]	63	6.25	19.4	-0.13 (-0.19 to0.04)	Not significant	Low
Solifenacin	Darifenacin	1[544]	77	20	21.6	-0.02(-0.20 to .17)		Insufficient
Fesoterodine	Tolterodine	4[309,313,460,461]	4,440	5.4	3.5	0.02 (0.00 to 0.03)	17 (5 to 31)	Moderate
Oxybutynin	Tolterodine	6[87,322,442,450,530, 531,533-536]	2,323	13	6	0.07 (0.01 to 0.15)	72 (7 to 154)	High
Solifenacin	Tolterodine	3[114,478,542,543]	2,755	4	3	0.01 (0.00 to 0.03)		Moderate
Trospium	Oxybutynin	2[305,546]	2,015	5	7	0.00 (-0.03 to 0.05)		Low
Trospium 20mg twice daily	Oxybutynin 5mg twice daily	1[546]	357	3.7	6.7	-0.029(-0.086 to 0.027)		Insufficient
Solifenacin	Oxybutynin IR	1[545]	132	10.3	10.9	-0.006 (-0.112 to 0.099)		Insufficient

* Risk differences were calculated using arcsine transformation

Table 10. Continence with pharmacological treatments for urgency UI

Active drug	Control drug	RCTs, Reference	Patients in analyses	Rate in active group, %	Rate in control group, %	Relative risk (95% CI)	Absolute risk difference (95% CI)	Strength of evidence
Fesoterodine 4 to 8 mg once daily	Tolterodine 4 to 8 mg once daily	2 [309,313]	3,312	61.0	55.5	1.10 (1.04 to 1.16)	0.06 (0.02 to 0.09)	Low
Trospium 20 mg twice daily	Oxybutynin 5 mg twice daily	1 [546]	357	22.5	12.2	1.84 (1.01 to 3.34)	0.1 (0.02 to 0.19)	Insufficient
Oxybutynin 10 mg daily	Tolterodine 4 mg daily	1 [533]	790	23.0	16.8	1.37 (1.03 to 1.82)	0.06 (0.01 to 0.12)	Insufficient
Solifenacin 5-10 mg once daily	Tolterodine 4 mg once daily	1 [541]	1,177	59.0	49.0	1.20 (1.08 to 1.34)	0.1 (0.04 to 0.16)	Insufficient

Figure 5. Comparative effectiveness of oxybutynin vs. tolterodine (pooled results from individual RCTs)[87,322,411,441,442,450,530-536]

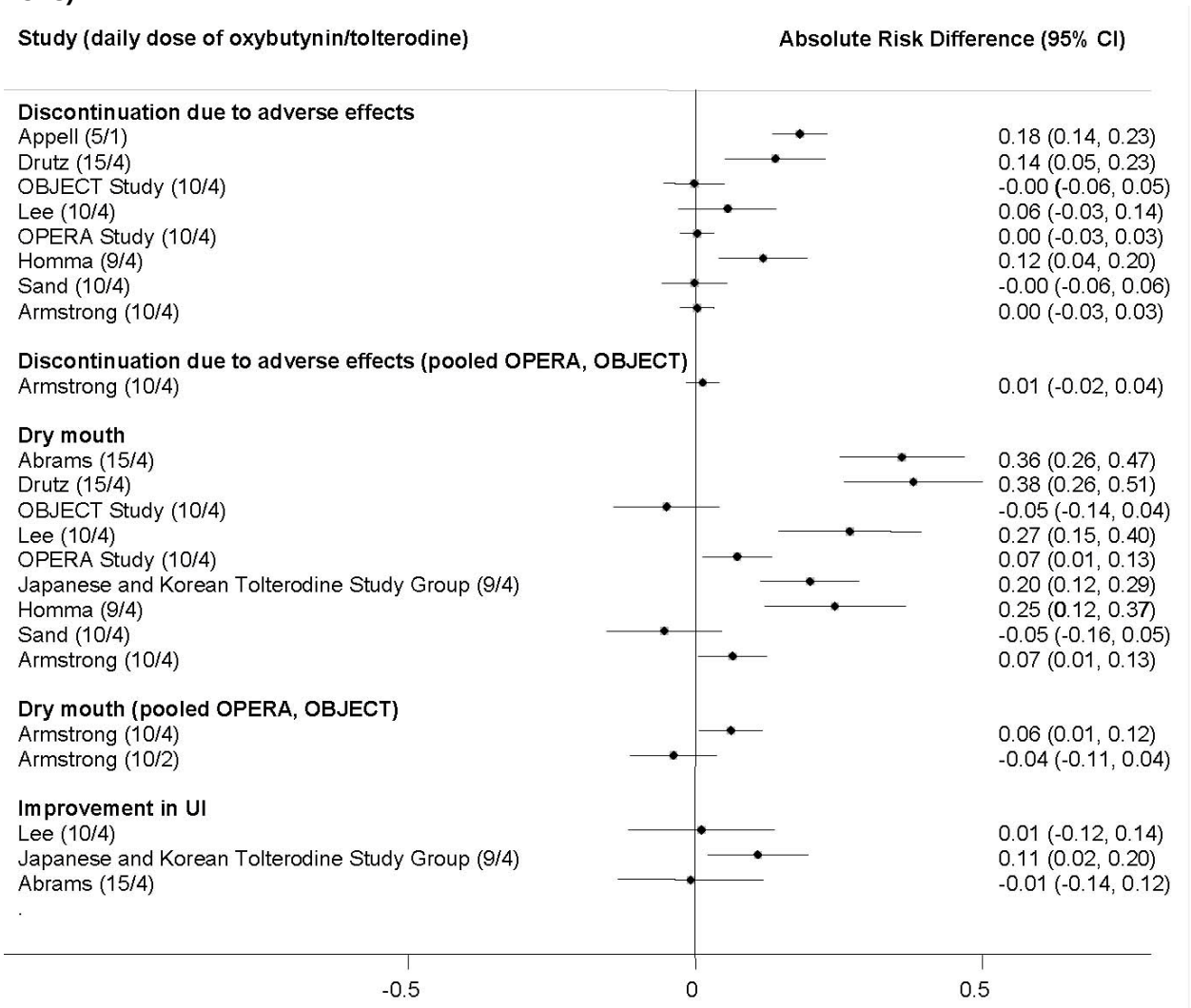


Figure 6. Continence with drugs for overactive bladder when compared to placebo (pooled with random effects estimates from head-to-head RCTs)

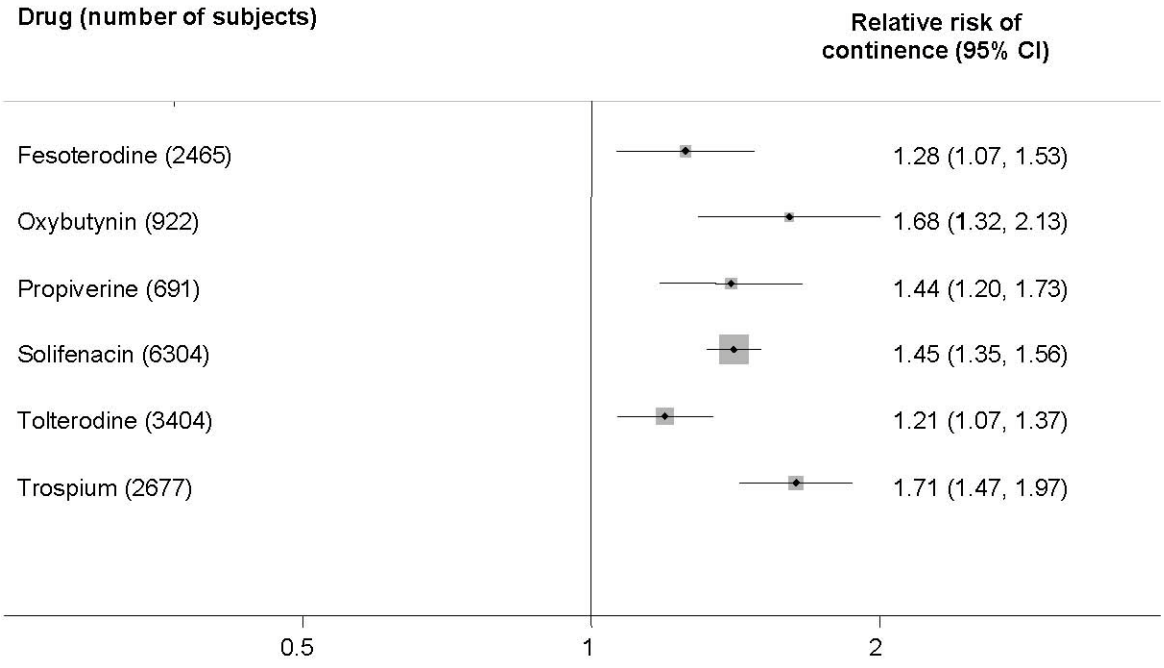
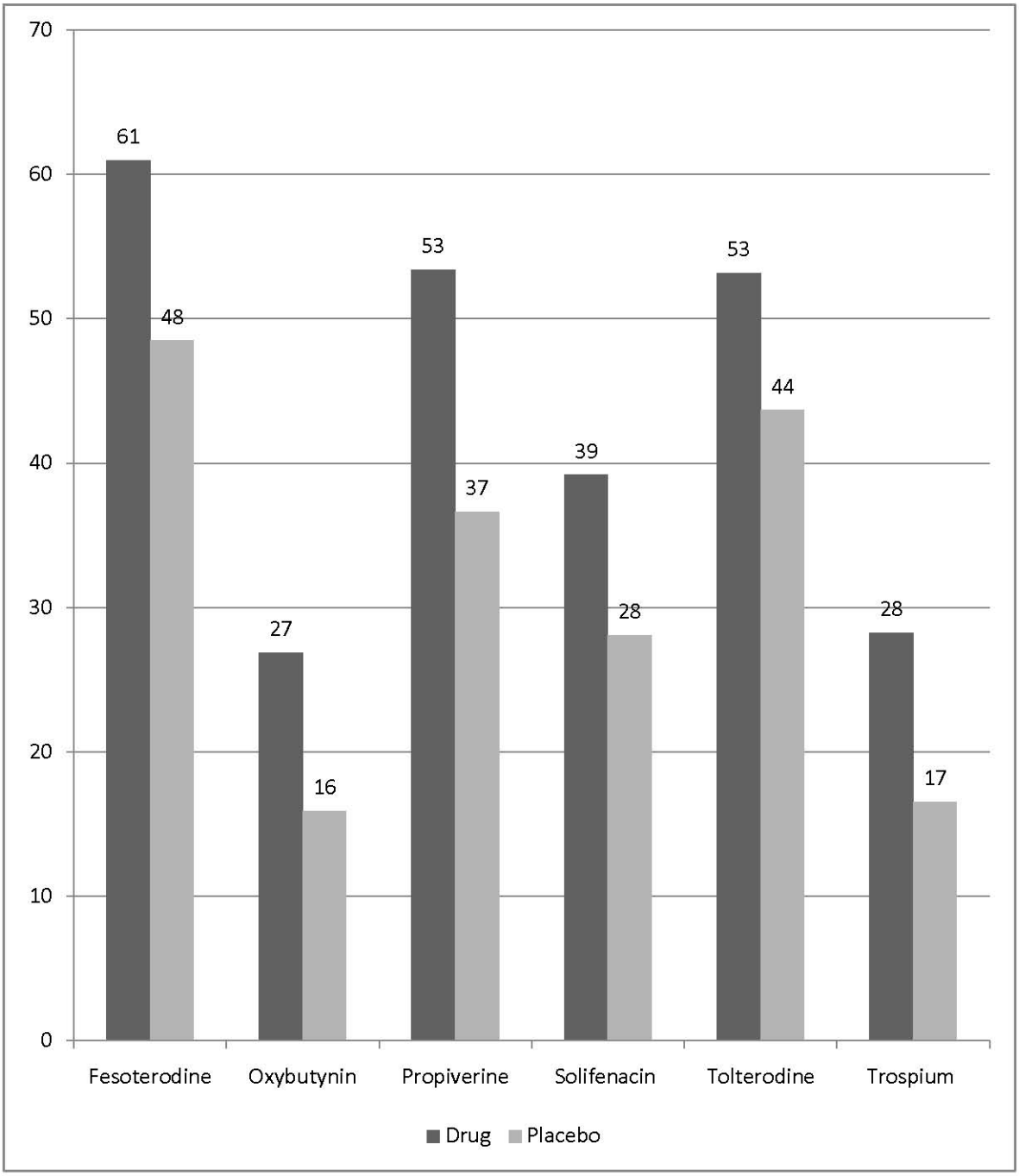
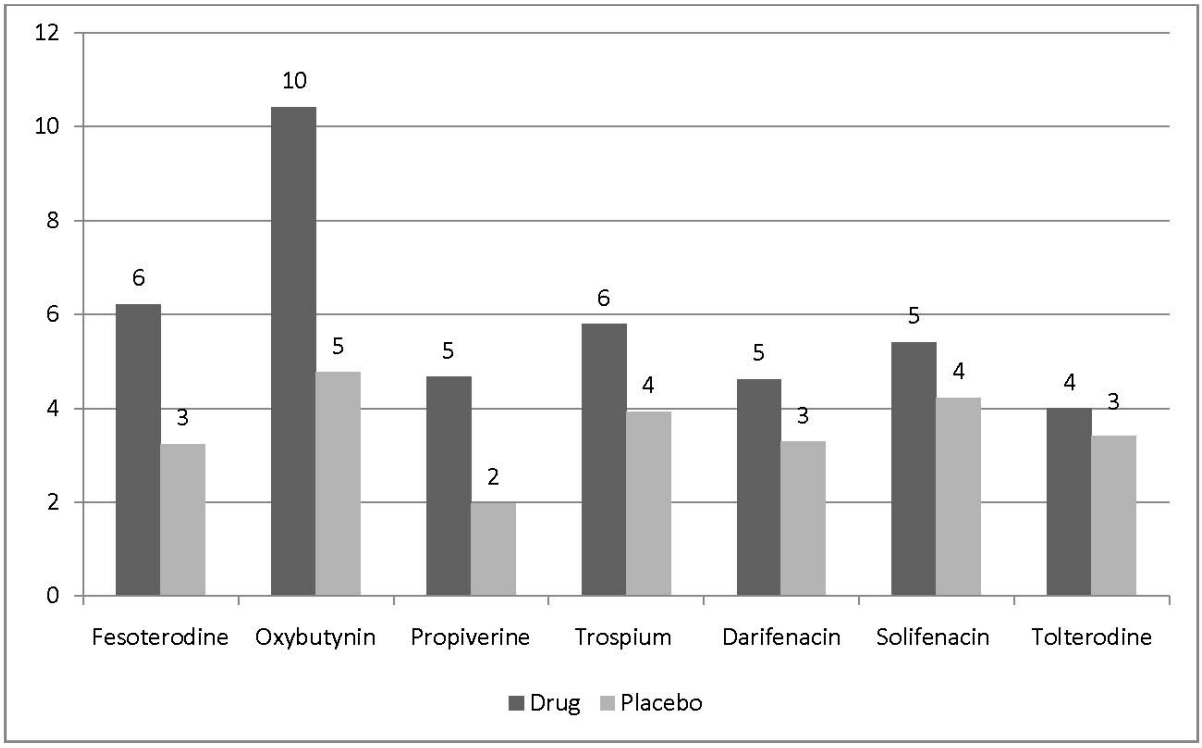


Figure 7. Continence rates (%) with drugs vs. placebo (pooled results from RCTs)



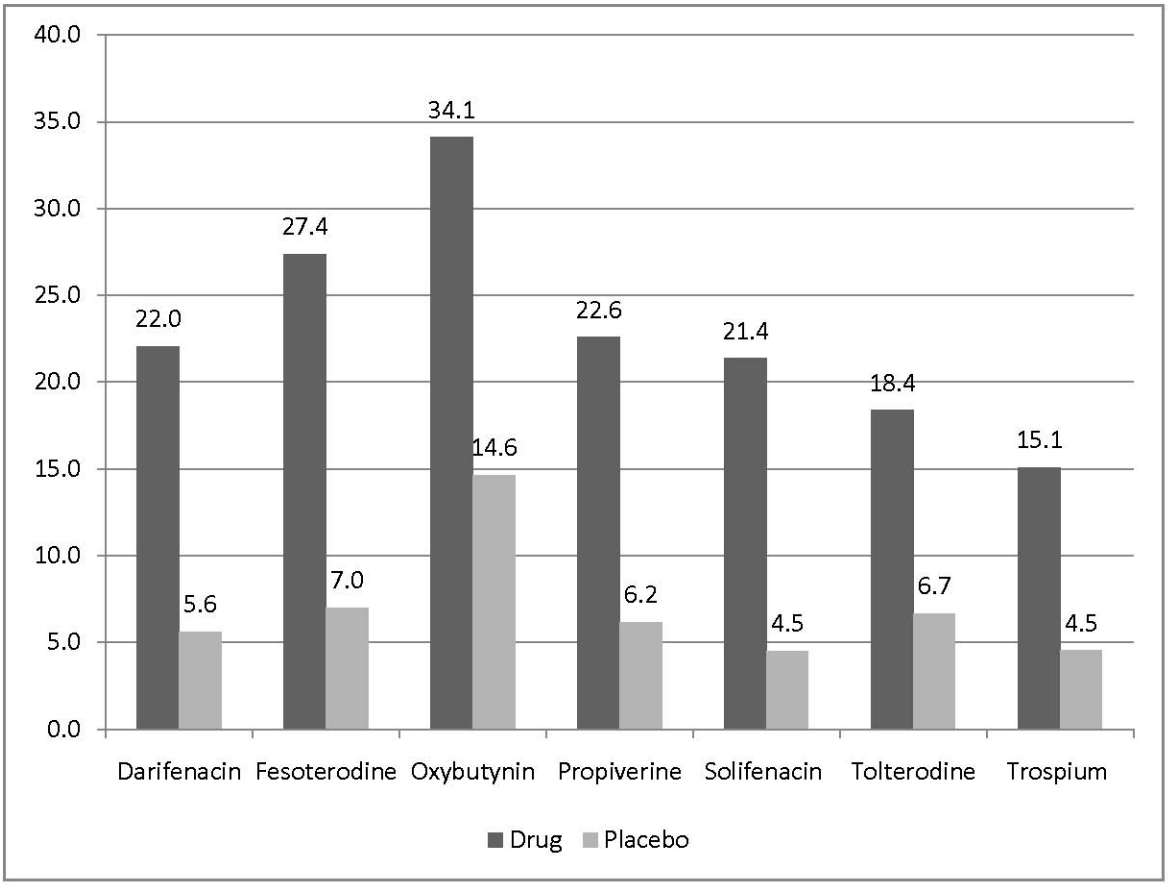
Vertical axis = percentage of continent with treatments
Horizontal axis = treatments with drug or placebo

Figure 8. Discontinuation of treatments due to adverse effects (%) with drugs vs. placebo (pooled results from RCTs)



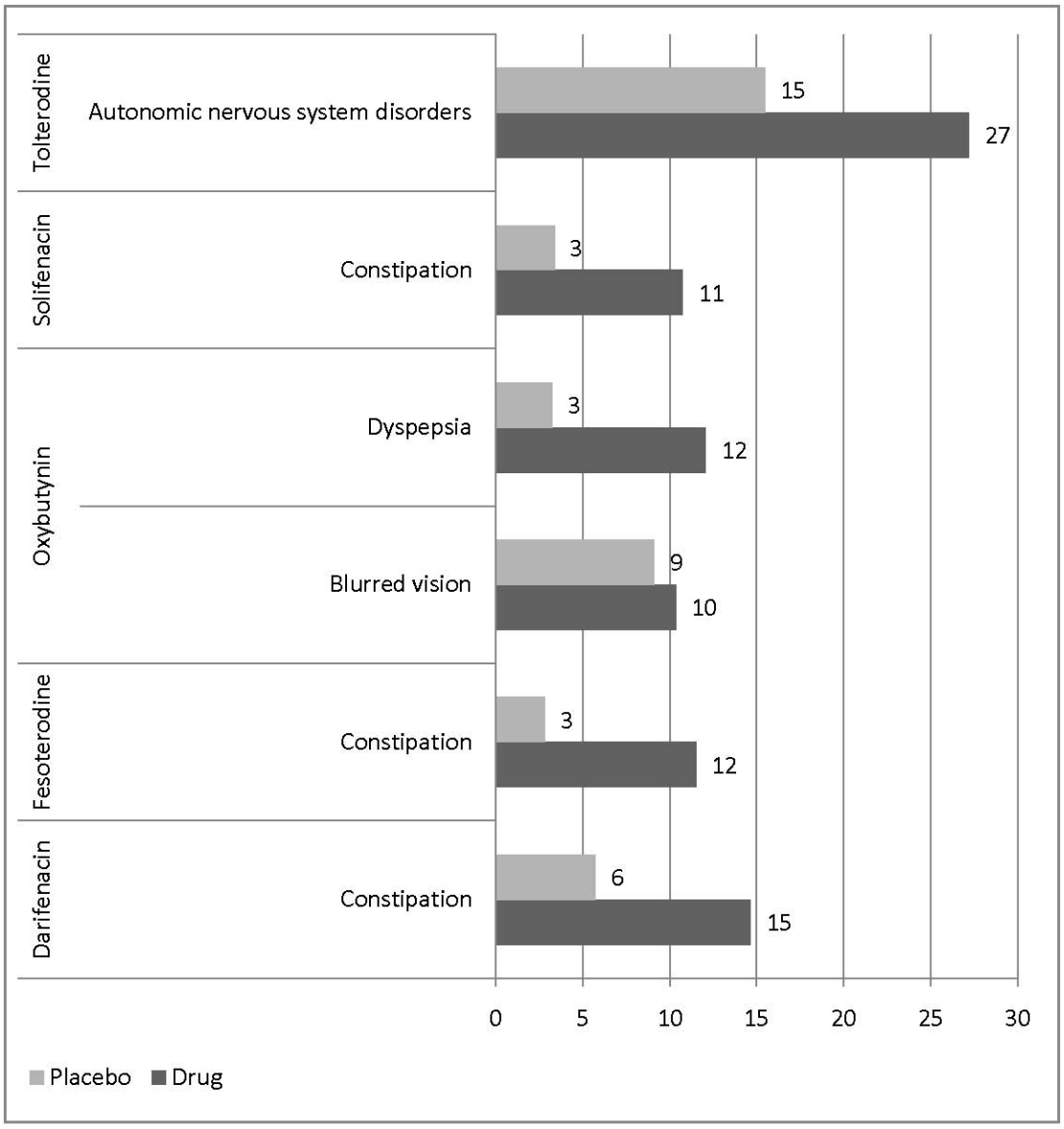
Vertical axis = percentage of those who discontinued treatments due to adverse effects
Horizontal axis = treatments with drug or placebo

Figure 9. Dry mouth rates (%) with drugs vs. placebo (pooled results from RCTs)



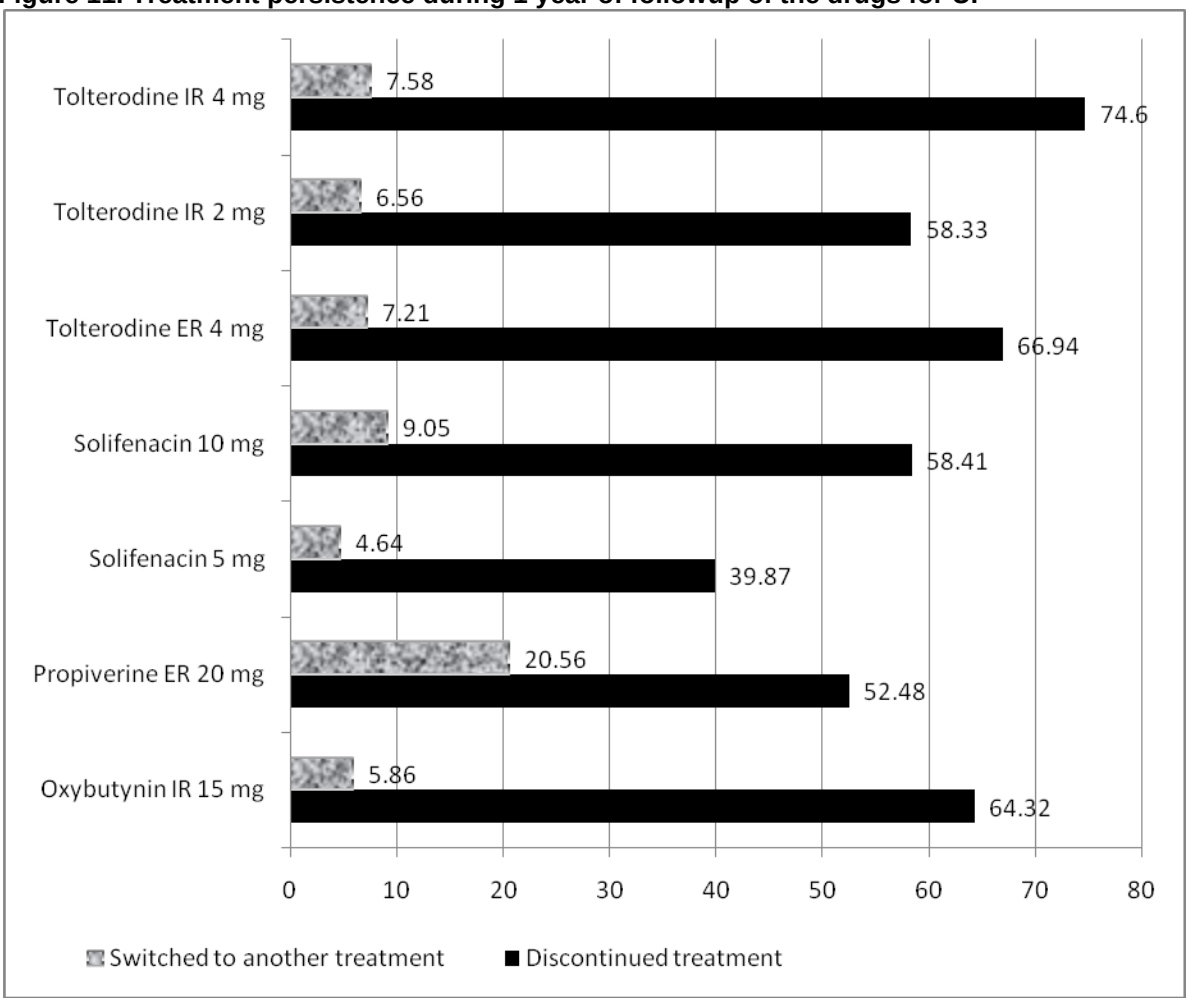
Vertical axis = percentage of subjects with dry mouth with treatment
Horizontal axis = treatments with drug or placebo

Figure 10. Rates (%) of the most common (>10%) adverse effects with drugs vs. placebo (pooled results from RCTs)



Horizontal axis = percentage of subjects with adverse effects

Figure 11. Treatment persistence during 1 year of followup of the drugs for UI[548]



The Role of Patient Characteristics on Patient Outcomes With Pharmacological Treatments

Age

The rates of clinical outcomes were similar in age subgroups**.** Clinical outcomes in age subgroups were reported in four studies involving duloxetine,[398] solifenacin,[497] tolterodine,[314] and oxybutynin.[314,398,497,534]Active and control treatments, outcomes, and definitions of age subgroups varied across the studies. We describe clinical outcomes in age subgroups treated with the drugs from individual studies and pooled analyses of individual subject data.

In 1,913 women ages 22 to 83 years with predominant stress UI, duloxetine compared to placebo did not improve UI in older women (Figure 12).[398]

In contrast, younger women reported improvement in UI more often with duloxetine than with placebo.[398] Duloxetine prevented worsening of UI in older women, but was not better than placebo in women younger than 50 years of age.[398]

Solifenacin increased continence rates more often than placebo in all age groups (Figure 13).[497] The drug tended to benefit older women more than younger women. For instance, the relative increase in continence with 5 mg was 38 percent in younger and 69 percent in older individuals.[497] We observed the same tendency with 10 mg of solifenacin, with a relative increase in continence of 49 percent in younger people and of 63 percent in older people.[497] This tendency was not statistically significant.

Tolterodine extended release, when compared to placebo in 1,015 individuals with urgency UI, improved UI more than placebo in older but not younger subjects[314] (Figure 14).

Oxybutynin reduced the number of urgency and total UI episodes more often than tolterodine in women younger than 64 years with urgency or mixed UI in one RCT.[534] The rates of adverse effects did not differ between age groups.

Several studies did not directly compare the outcomes among treatment groups but aimed to test treatment effects in older populations. Oxybutynin, trospium, and darifenacin improved UI in older women. Oxybutynin reduced UI frequency and produced subjective benefits compared to placebo in frail community-dwelling older people.[406] Darifenacin was examined in older populations in two RCTs[479,480] and one pooled analysis of three RCTs.[487] Darifenacin resulted in improvement in UI when compared to placebo in the older women.[479] The drug needed to be given to eight older patients to achieve more than a 50 percent reduction in UI episodes in one person. Cognitive function changes did not differ between darifenacin and placebo in short-term (2-week) treatment.[480] Dry mouth, constipation, and dyspepsia were the most common adverse effects in the older subjects.

Evidence suggested that age did not modify the effects of the tested drugs on examined clinical outcomes. Trospium was effective improving UI and quality of life in older subjects with overactive bladder.[549] A high level of evidence suggested that duloxetine was no better than a placebo in improving UI in older women. A high level of evidence suggested that solifenacin increased continence rates more often than placebo, regardless of age. Oxybutynin, trospium, and darifenacin improved UI in older women.

Race

Evidence was inconclusive about differences among racial groups in the effects of duloxetine for stress UI. Only one study, DESIRE (Duloxetine Efficacy and Safety for Incontinence in

Racial and Ethnic Populations) examined clinical outcomes in different race groups.[388] Women with stress UI were treated with 80 mg of duloxetine per day. Weekly UI episodes were reduced compared to baseline in all race groups, by 65.7 percent in African Americans, by 73.0 percent in Hispanics, and by 75.0 percent in Caucasian women. Clinical outcomes rarely differed between racial subgroups (Figure 15).[388] African American women reported improvement in UI more often than Caucasian women. Hispanic women experienced a reduction in UI by more than 50 percent less often than Caucasian women. Several adverse effects, including dizziness, headache, and somnolence, were less common among African American women and more common among Hispanic women than among Caucasian women. The biological plausibility of such differences is not clear.

Baseline Type of UI

Evidence was not sufficient for individualized prediction of benefits by the urodynamic type of UI.

The studies of antimuscarinic drugs enrolled subjects with overactive bladder and predominant urgency UI. The studies of duloxetine enrolled subjects with predominant stress UI. Few studies compared the outcomes in subgroups with the predominant type of UI. One RCT of tolterodine compared continence rates, reduction in UI episodes, and pad utilization in subjects with predominant urgency and pure urgency UI, and concluded the same treatment benefits in all subjects regardless of the type of UI.[469] Two pooled analyses of individual patient data compared clinical outcomes between 5 or 10 mg of solifenacin and placebo.[497,498]

Both doses of solifenacin increased continence rates compared to placebo. Solifenacin increased continence rates in subjects with pure urgency and mixed UI. The effect size did not differ between subgroups with different types of UI (Figure 16). The relative increase in continence rates was greater with 5 mg of solifenacin in patients with pure urgency UI than those with mixed UI. One pooled analysis demonstrated that 5 mg of solifenacin was not better than placebo in achieving continence in subjects with mixed UI.[498] Individuals with mixed UI required longer treatment duration to achieve greater benefits from solifenacin. At the end of 40 weeks of treatment, 52 percent of the people with mixed UI reported regaining continence, and 34 percent reported resolution of symptomatic urgency on uncontrolled extension in one RCT.[499]

Clinical outcomes of tolterodine and solifenacin did not differ in individuals with baseline mixed or pure urgency UI. Individuals with mixed UI may require a larger dose and longer treatment than women with urgency UI to achieve clinical benefits from solifenacin.

Baseline Frequency of UI

The baseline frequency of UI demonstrated no significant or consistent association with clinical outcomes of any drug. Individuals with more frequent UI had slightly greater benefits with drugs than with placebo. Variability in definitions of baseline severity and clinical outcomes lowered the level of evidence.

Three secondary data analyses of drug trials examined clinical outcomes among subgroups with different baseline frequency of UI.[467,497,508] The results indicated that baseline frequency of UI tended to modify the treatment effects of the drugs; however, statistical significance of such modifications was not consistent across the definitions of baseline severity, drugs, and treatment outcomes.

Several drugs resulted in greater benefits for patients with more frequent baseline UI. In a post hoc analysis of an RCT, tolterodine extended-release increased continence rates compared

to placebo in patients with symptoms of urinary frequency and pure urgency UI. Urinary continence rates varied by diary-recorded duration and frequency of UI at baseline (Figure 17).[467] Individuals with more frequent baseline UI had a larger relative benefit with the drug than with placebo. Five or 10 mg of solifenacin per day increased the rates of continence regardless of baseline frequency of UI in a pooled analysis of 1,873 people with OAB.[497] Those with more than three episodes of urgency UI per day at baseline experienced a slightly larger relative benefit than those with less frequent UI.[497] Patients with more than two urgency UI episodes per day experienced a greater reduction in the number of urgency UI episodes with 8 mg of fesoterodine in a pooled analysis of two RCTs.[508] In contrast, trospium was better than placebo at resolving UI only in subjects with fewer than five UI episodes/day.[550] Trospium did not resolve UI in subgroups with more than five episodes of UI /day.[550]

Adverse effects leading to discontinuation were more common with 8 mg of fesoterodine in patients with two to four episodes of urgency UI per day (Figure 18).[508]

Prior Treatment Status

Solifenacin was effective regardless of the response to previous treatments, even though poor responders did not benefit from increasing the dose of the drug (high level of evidence). One study reported that darifenacin was effective in those for whom previous treatments failed. Tolterodine was no better than placebo in achieving clinical benefits among poor responders to the previous muscarinic antagonists in one RCT.

Many studies reported prior treatment status, but very few reported clinical outcomes in subgroups by the response to previous treatments. In a pooled analysis of individual patient data from four RCTs, solifenacin increased continence rates when compared to placebo, regardless of the response to previous treatments (Figure 19).[497] Previous nonresponders experienced a greater relative benefit than those who responded to previous treatments.[497] Patients who did not respond to previous treatments did not benefit from increasing the dose of solifenacin.[497] Post hoc analysis of the OPERA trial demonstrated greater rates of continence with oxybutynin than with tolterodine in patients with prior treatments with antimuscarinic drugs, but no difference was demonstrated between the two drugs in treatment of naïve patients.[551] In one RCT, tolterodine was not better than placebo among poor responders to the previous muscarinic antagonists.[453]

In one nonrandomized study, darifenacin improved clinical outcomes in OAB patients who expressed dissatisfaction with prior extended-release (ER) oxybutynin or tolterodine therapy.[485] Darifenacin improved the Patient's Perception of Bladder Condition regardless of previous treatments by 108 percent (OR 2.08, 95 percent CI, 1.48 to 2.92) in oxybutynin treated patients and by 77 percent (OR 1.77, 95 percent CI, 1.29 to 2.43) in tolterodine treated patients.[485]

Concomitant Treatments

Trospium reduced the number of urgency UI episodes irrespective of concomitant medications. Adverse effects were more common in those taking seven or more concomitant medications.[552]

Comorbidities

Duloxetine was no better than placebo in women with stress UI and comorbidities (one RCT).

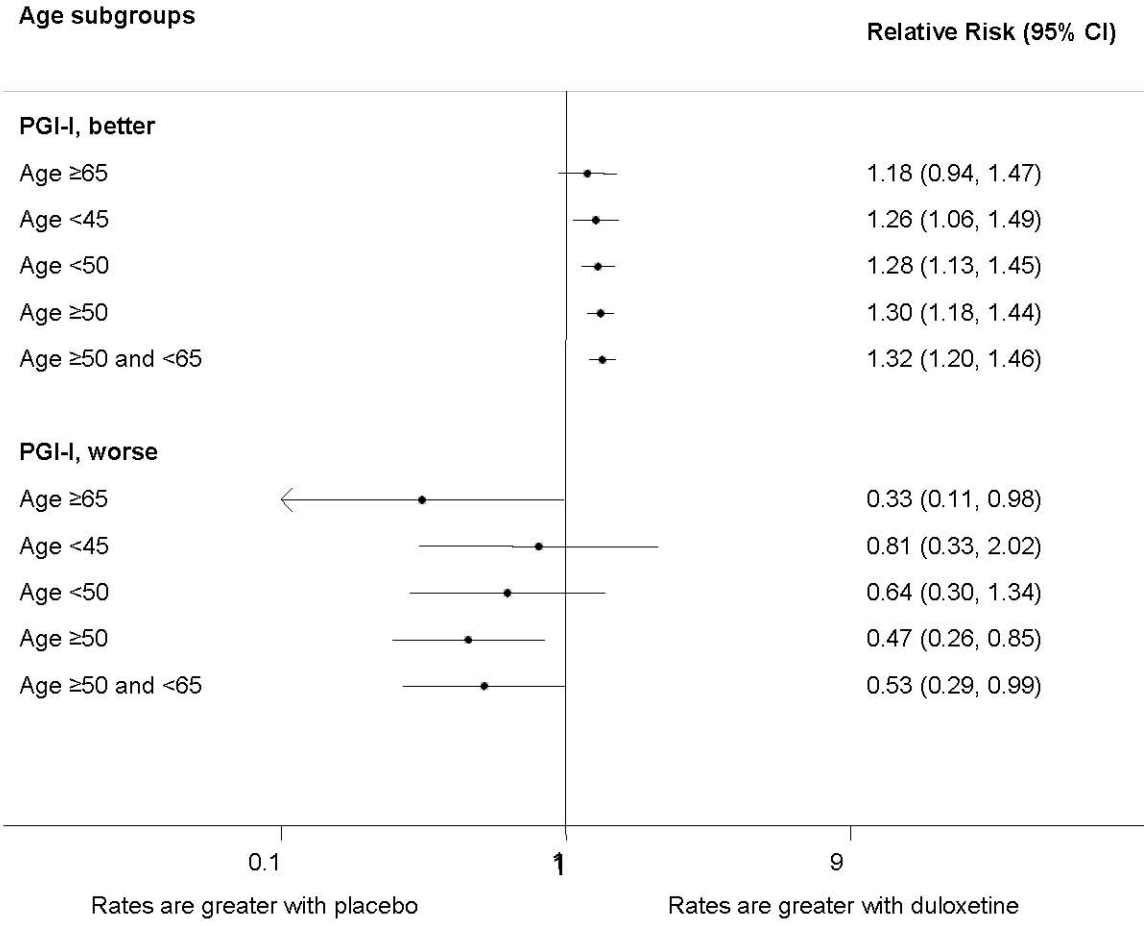
One RCT examined clinical outcomes with duloxetine compared to placebo in women with comorbidities (Figure 20).[398] Duloxetine was not better than placebo in women with depression,

diabetes, and chronic lung diseases, nor was it better than placebo in preventing worsening of UI in underweight women and women with depression, diabetes, and chronic lung diseases.[398]

Obesity

Baseline obesity did not modify the effect of trospium in pooled analysis of individual patient data from RCTs (Table 11).[553] Trospium was more effective than placebo in achieving continence in obese and nonobese adults.[553] The magnitude of the benefit was similarly low in subgroups with different baseline body mass index (BMI). Trospium resolved urgency UI in 140 per 1,000 treated adults with normal weight or obesity.

Figure 12. Clinical outcomes with duloxetine vs. placebo in age subgroups (pooled analysis of individual data on women from four RCTs)[425]



PGI-I = Patient Global Impression of Improvement

Figure 13. Urinary continence with solifenacin when compared to placebo (pooled analysis of individual patient data from four RCTs)[497]

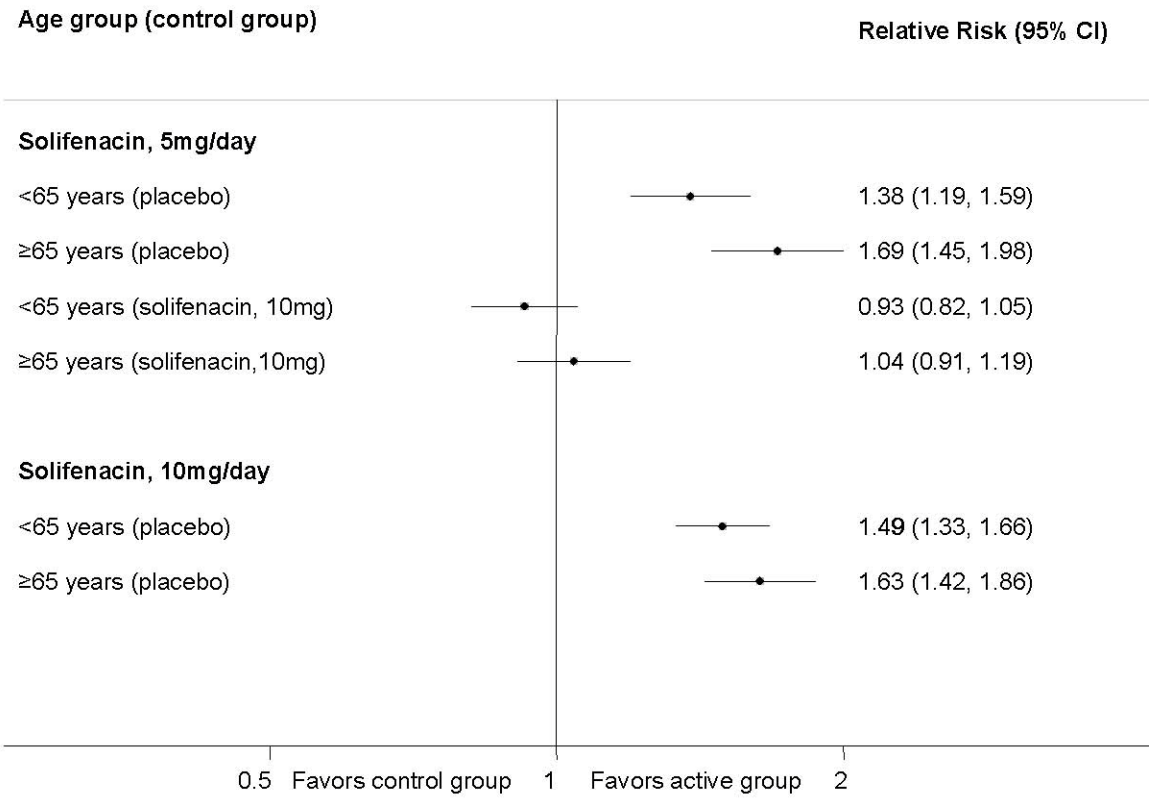


Figure 14. Clinical outcomes with tolterodine vs. placebo in age subgroups (individual RCTs)[314]

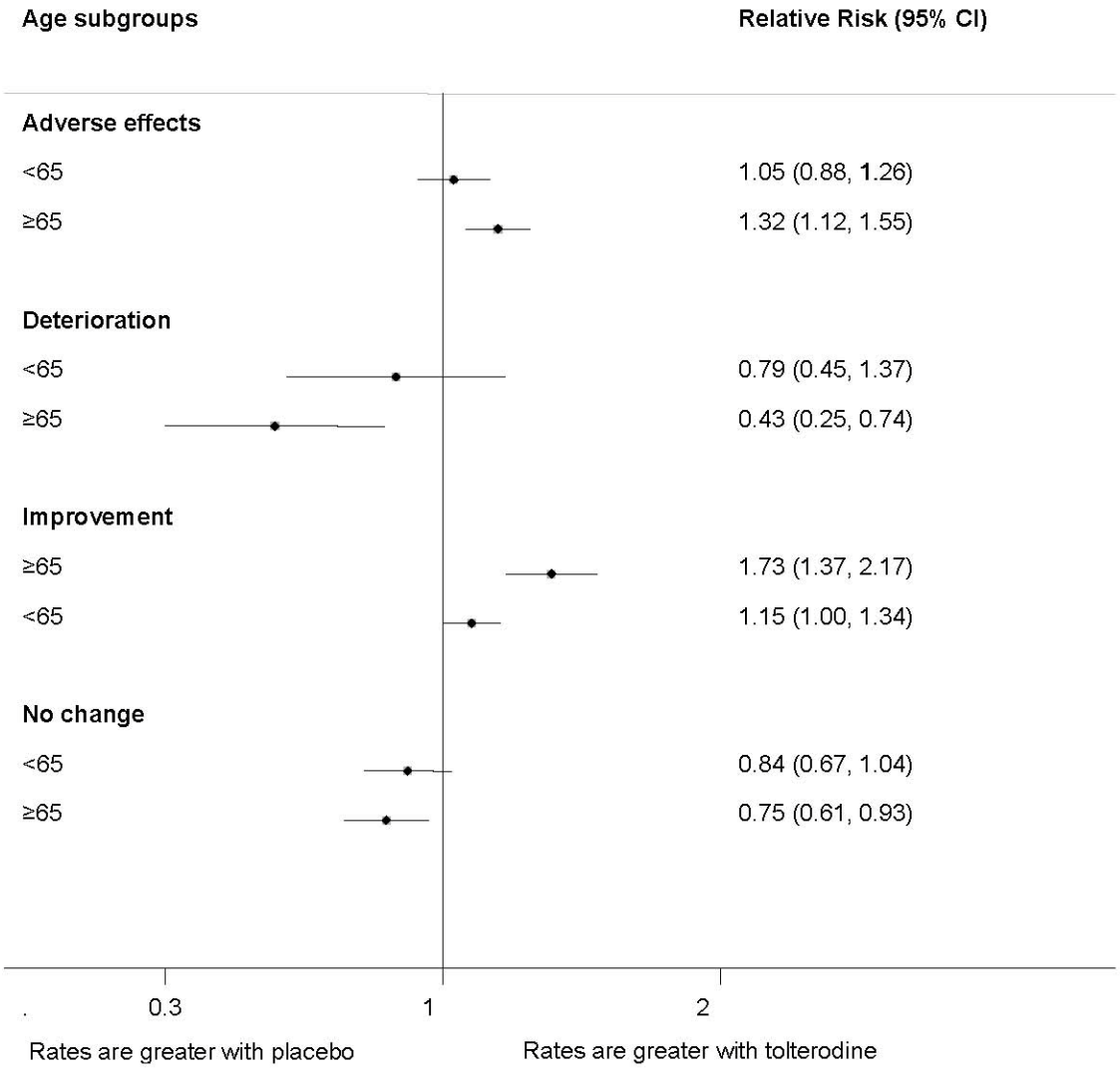


Figure 15. Clinical outcomes with duloxetine in racial subgroups of women with stress UI, DESIRE (Duloxetine Efficacy and Safety for Incontinence in Racial and Ethnic populations)[388]

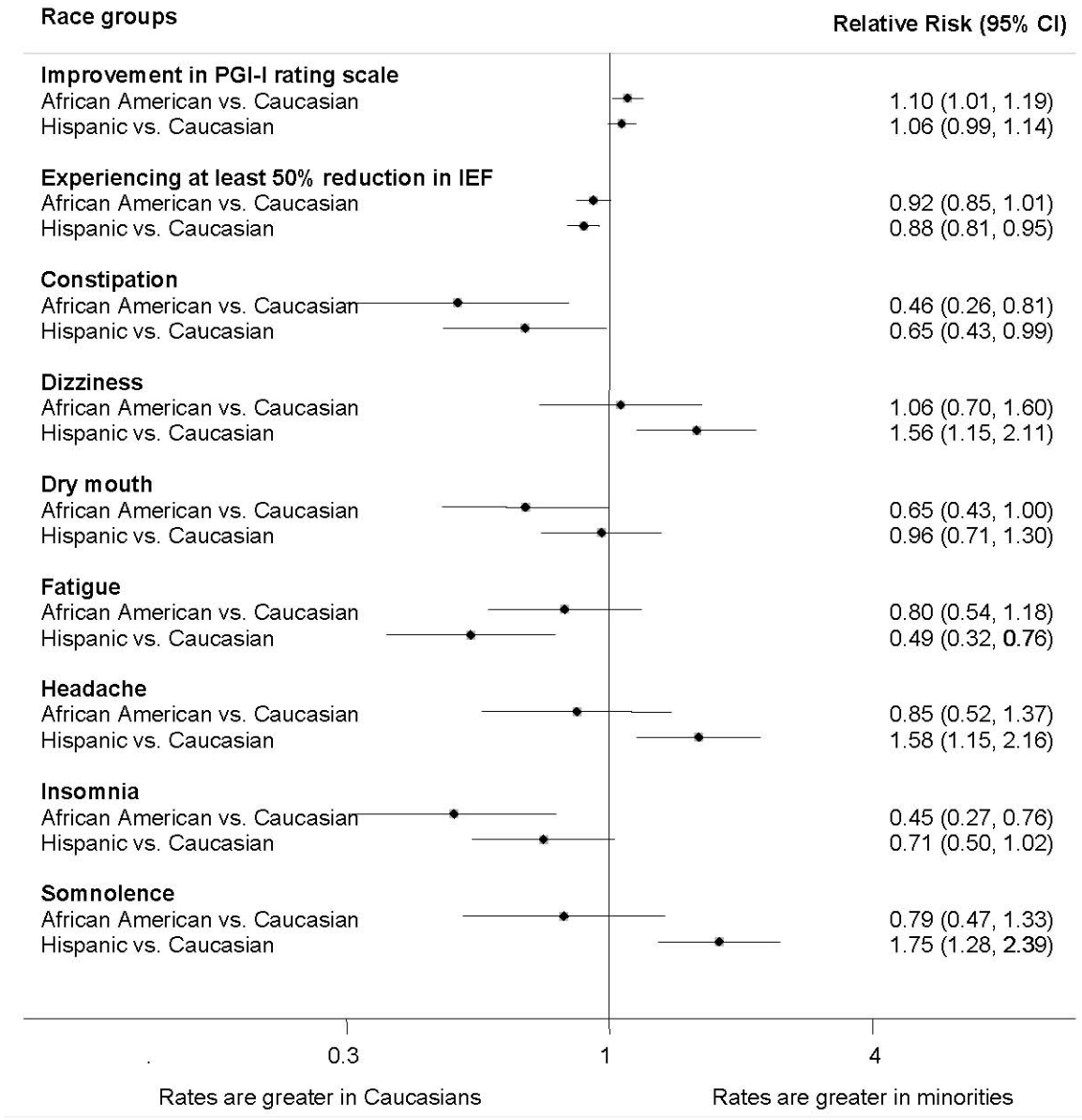


Figure 16. Continence with solifenacin compared to placebo in patients with mixed or pure urgency UI (pooled analyses of individual patient data)[497,498]

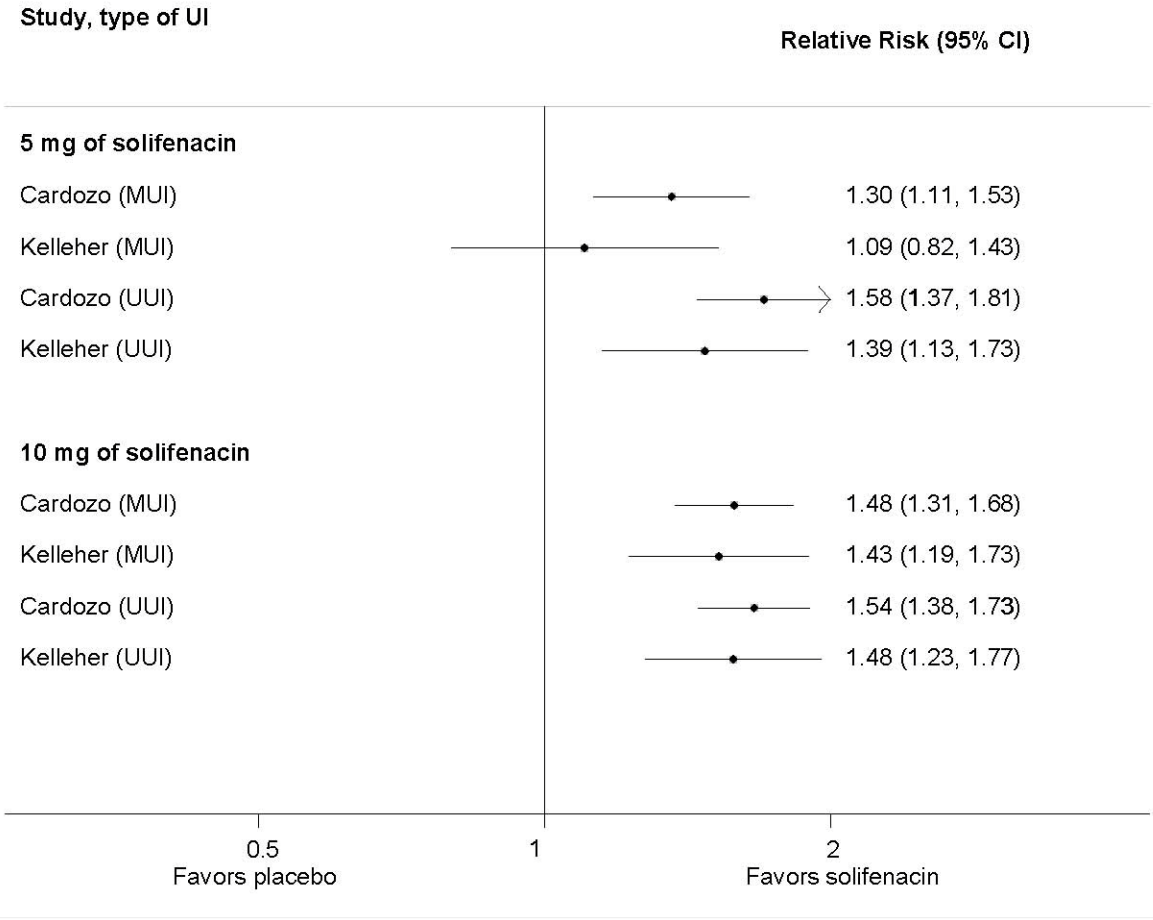


Figure 17. Complete continence with tolterodine, extended release of 4 mg/day vs. placebo in groups with different baseline frequency UI (episodes/week)[467]

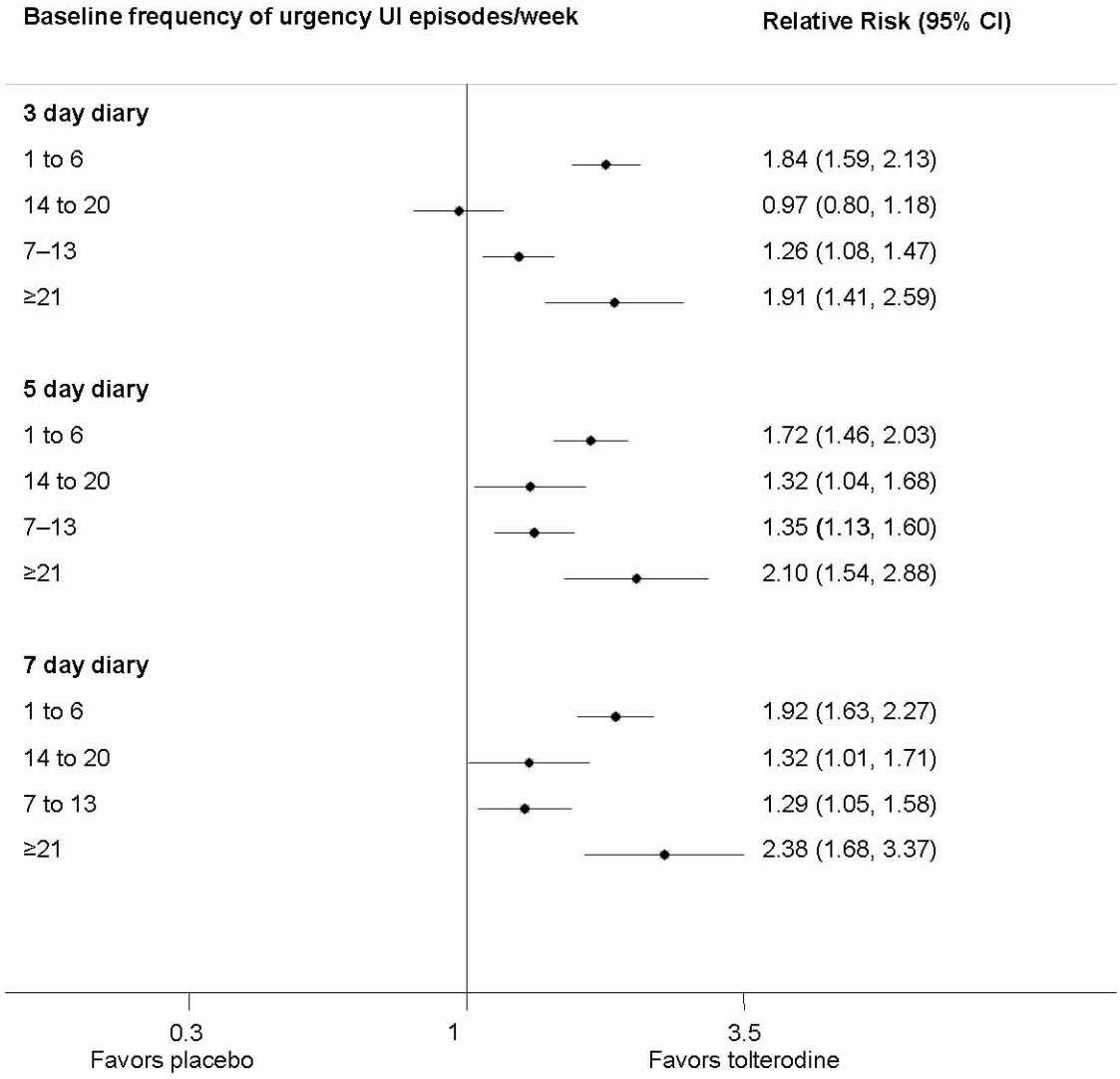


Figure 18. Adverse effects of fesoterodine compared to placebo in subgroups with different baseline frequency of urgency UI (pooled analysis of four RCTs)[508]

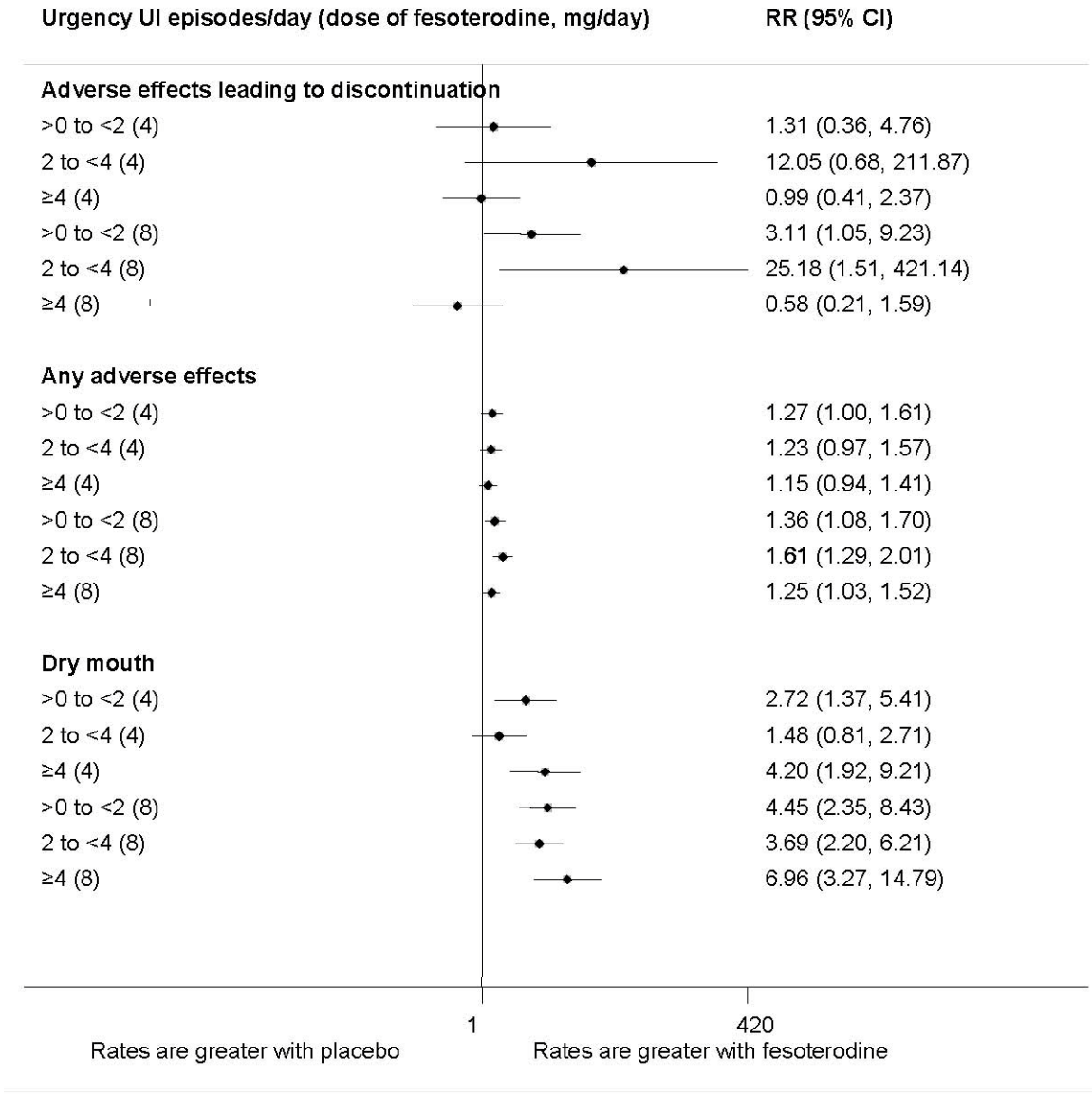


Figure 19. Continence with solifenacin vs. placebo in subgroup by response to the previous treatment with antimuscarinic medications (pooled analysis of RCT)[497]

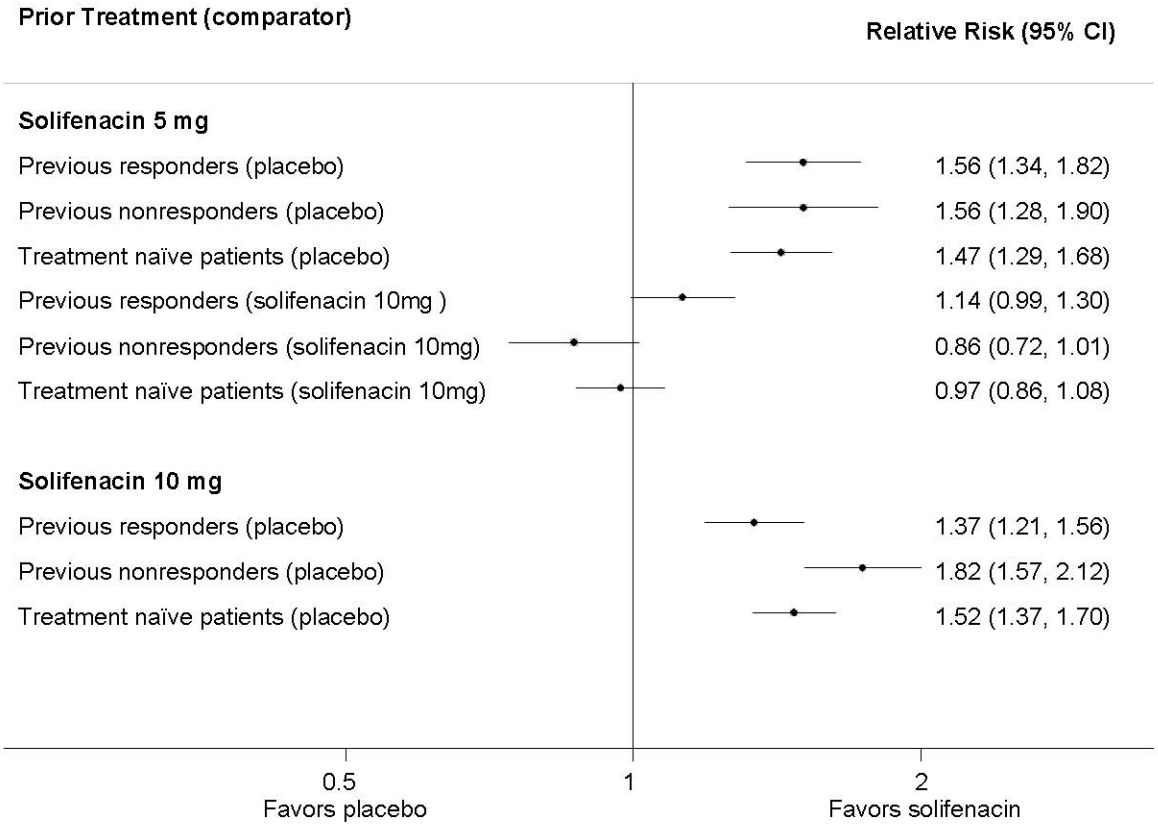


Figure 20. Patient global impression of improvement rating as "better" with duloxetine when compared to placebo in subgroups with different comorbidity status (duloxetine urinary incontinence study group)[398]

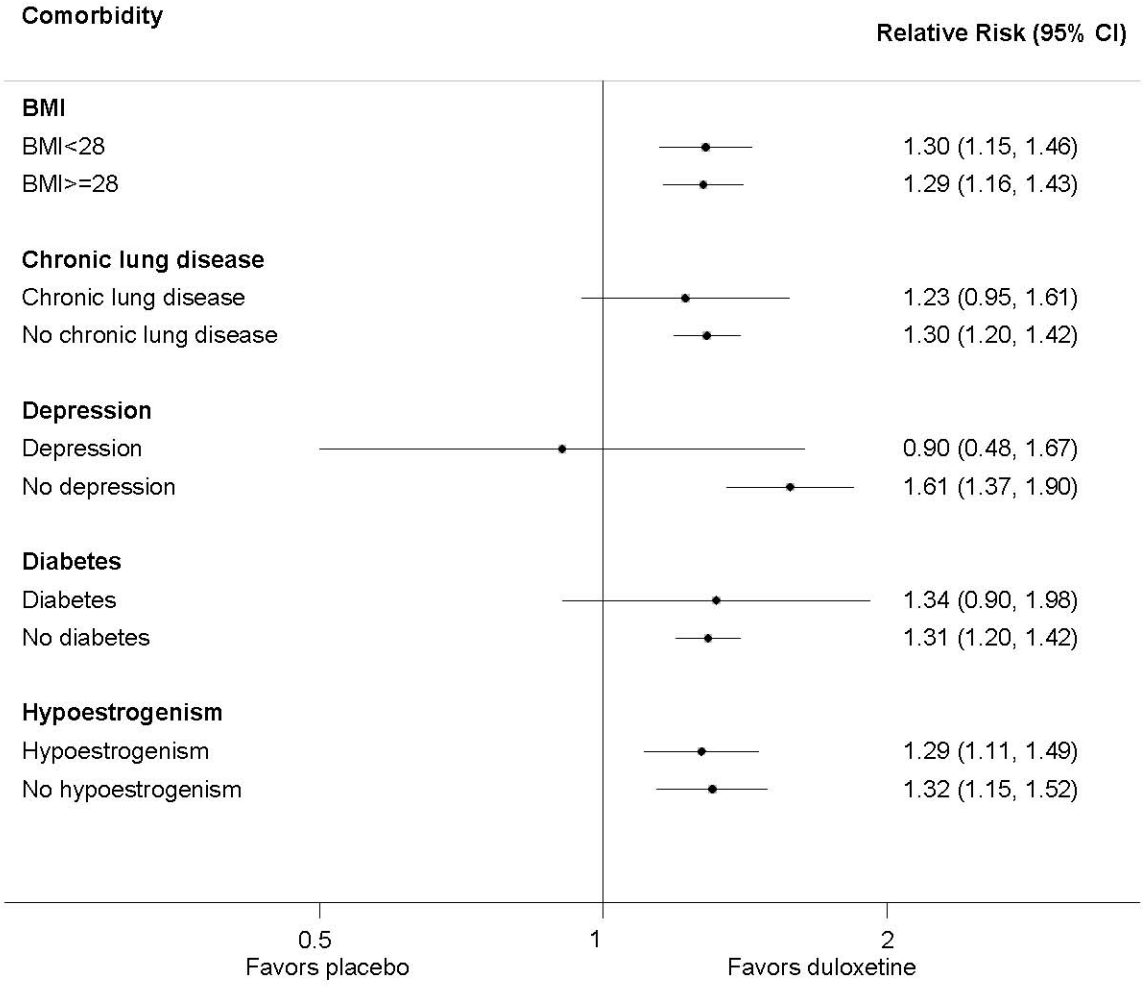


Table 11. Continence with 60 mg once daily of trospium vs. placebo in obese and nonobese adults with overactive bladder (pooled results from RCTs using the WHO criteria for obesity)[553]

Baseline body mass index	Drug events/ randomized	Placebo events/ randomized	Rate (%) in active/ control	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events per 1,000 treated (95% CI)
BMI <30kg/m^2	214/578	133/578	37/23	1.6 (1.3 to 1.9)	0.14 (0.09 to 0.19)	7 (5 to 11)	140 (88 to 192)
BMI <35kg/m^2	202/578	133/578	35/23	1.5 (1.3 to 1.8)	0.12 (0.07 to 0.17)	8 (6 to 15)	119 (68 to 171)
BMI >30kg/m^2	191/578	127/578	33/22	1.5 (1.2 to 1.8)	0.11 (0.06 to 0.16)	9 (6 to 17)	111 (60 to 162)
BMI >35kg/m^2	202/578	121/578	35/21	1.7 (1.4 to 2.0)	0.14 (0.09 to 0.19)	7 (5 to 11)	140 (89 to 191)

Key Question 3. How effective is the nonpharmacological treatment of UI?

One hundred forty eight RCTs tested nonsurgical nonpharmacological treatments for UI (Appendix Table F81). A small proportion of RCTs reported sponsorship and conflict of interest (Appendix Table F82). Sample size was justified in 63 RCTs (43 percent) (Appendix Table F83). Quality of the studies, including intention to treat principle and adequacy of allocation concealment, did not demonstrate significant modification of the association between treatments and patient outcomes (Appendix Table F84). In addition, we reviewed five RCTs that examined eligible treatments for female UI, but did not report the rates of clinical outcomes that can be reproduced and synthesized (Appendix Table F85). We also reviewed the results from 45 nonrandomized studies that reported crude rates of outcomes with medical devices that have never been tested in RCTs (Appendix Table F26). Here, we review clinical effects of nonpharmacological treatments compared to regular care or no active treatment. The majority of the trials included women with mixed UI. We examined the effects of predominantly stress or urgency UI when reported by the authors (Appendix Table F86).

Efficacy of Nonpharmacological Treatments for Stress UI

Clinical Effects of Pelvic Floor Muscle Training (PFMT)

A high level of evidence indicated significant benefits from PFMT for women with UI. Compared to regular care, PFMT increased urinary continence rates and improvement in UI. Benefits were consistent across different regimens of training and definitions of improvement in UI.

Eleven studies[554-564] examined PFMT compared to regular care or no active treatment.

Continence

Despite differences in exercise regimens, the majority of the studies reported significant increases in urinary continence rates with PFMT compared to no active treatment (Appendix Table F87).[554,555,557,558,560-564] The studies that included women with pure stress UI reported greater benefits from PFMT (pooled RR 6.8, 95 percent CI, 3.2 to 14.9)[554,558,560] than the studies with mixed UI (pooled RR 3.5 95 percent CI, 1.9 to 6.4).[554,557,561]

Improvement in UI

The majority of the studies also demonstrated a significant benefit from PFMT on improvement of UI (Appendix Table F87).[555-557,560,563,564] Women reported improvement in UI with PFMT more often than with regular care.[555-557,560,563,564] PFMT improved UI in one of every two women treated. Improvement rates did not differ in the studies with pure stress, mixed, or unreported types of UI.

Quality of life improved after PFMT[555,559] (Appendix Table F88). Women expressed improvement in psychological impact of UI and in activity restrictions,[555] less overall interference of UI with life, fewer problems with painful intercourse and other interactions of UI with sexual life, and less dissatisfaction from spending the rest of their lives with their present symptoms.[559] Several studies reported inconsistent improvement in scores of quality of life after PFMT when compared to no active treatment[559,560,565-567] (Appendix Table F89).

Clinical Effects of Vaginal Cones and Pessaries

Evidence was insufficient to draw valid conclusions about the benefits of vaginal cones. Two RCTs compared clinical outcomes with vaginal cones and no active treatment[558,563] (Appendix Table F81). One study treated women with clinical and urodynamic stress UI with vaginal cones of 20, 40, and 70g for 20 minutes per day.[558] Another study examined nine cones of equal shape and volume, increasing in weight from 20 to 100g.[563]

Continence

Vaginal cones increased continence rates (pooled RR 2.88, 95 percent CI, 1.10 to 7.55) (Appendix Table F90), but the absolute rate difference was not statistically significant.

Improvement in UI

Use of vaginal cones improved UI[563] (Appendix Table F90). Use of vaginal cones reduced the Leakage Index but did not change the Social Activity Index (Appendix Table F91).[561]

Several noncontrolled studies reported clinical outcomes after pessary use.[568-575]

Continence rates varied from 36 percent among women with urgency UI to 47 percent among those with stress UI after using Pessary Uresta/EastMed Inc.[574] More than half the women (53 percent) reported improvement.[574]Among women who used the pessary ring with floor45 percent reported improved stress UI, and 21 percent reported improved urgency UI; however, 6 percent reported newly developed urgency UI.[573] Discontinuation rates varied from 11 percent[571] after different pessaries to 34 percent[574] after Pessary Uresta/EastMed Inc, and to 47 percent after Pessary Gelhorn.[572] Unsuccessful fitting was the most commonly reported reason for discontinuation.

Clinical Effects of PFMT With Biofeedback Using Vaginal Electromyography (EMG) Probe

A low level of evidence indicated increased urinary continence with PFMT with biofeedback when compared to usual care. Evidence was high that this treatment improved UI.

Four RCTs examined PFMT with biofeedback using a vaginal EMG probe.[440,556,557,560]

The studies included women over 55 years of age with urodynamic UI[440,556,557,560] (Appendix Table F81).

Continence

PFMT with biofeedback increased urinary continence in both RCTs that reported this outcome[557,560] (Appendix Table F92). Overall, continence rates were significantly greater with active treatment than with usual care.[557,560] Increase in continence was greater in the study of pure stress UI[560] than of mixed UI.[557] Pooled absolute risk difference was not significant, however.[557,560]

Improvement in UI

PFMT with biofeedback improved UI.[440,556,557,560] On average, three women needed to be treated to achieve UI improvement in one (Table 10). The study of weekly sessions of PFMT reported larger improvement in UI.[556,557] One study reported impact from UI, finding a small significant improvement on the Social Activity Index[560] (Appendix Table F93). One of four studies[560] included women with pure stress UI and found no significant improvement in UI. Improvement was consistent in studies of mixed UI.

One study examined the effects of PFMT supervised weekly by skilled physical therapists in women with pure urodynamic stress UI[558] (Appendix Table F94). The study reported a large and significant increase in continence (RR 13.24, 95 percent CI, 1.83 to 95.63).[558] The treatment had to be provided to three women to achieve continence in one. The same study reported a small but significant improvement in the Leakage Index and in the Social Activity Index (Appendix Table F95).

One noncontrolled study examined the effects of pelvic fitness and education classes taught by a lay instructor to women with urgency UI.[576] The training improved quality of life and sexual function measured with Urogenital Distress Inventory-Short Form (UDI-SF) scores. Achievement of self-selected goals was reported by 71 percent at 11 weeks and by 67 percent at 1 year of followup. Evidence was insufficient to draw valid conclusions that PFMT performed under the supervision of nonmedical instructors may improve continence or quality of life in women with UI.

Clinical Effects of Electrical Stimulation

A high level of evidence suggests increased continence rates and improvement in UI with electrical stimulation.

Nine studies examined intravaginal electrical stimulation.[558,577-584] The studies included women with predominant urgency UI,[581,583] clinical[579,580] or urodynamic stress UI,[558,577] or urodynamic mixed UI[578] (Appendix Table F81). Few studies excluded women with detrusor overactivity.[577,579] Electrical stimulation was described with different levels of detail and had variable stimulation parameters, depending on the UI type being treated, including the use of 4 Hz,[583] 10 Hz,[581] 20 Hz,[578] or 50 Hz[558,579,580] frequency for 4 weeks,[558,581] 7 to 8 weeks,[578,583] 12 weeks,[579] or 15 weeks.[577]

Continence

Electrical stimulation increased continence rates more often than sham stimulation (Appendix Table F96).[558,563,577,579-581,584] The benefit was consistent across the studies, despite differences in women and treatment characteristics. One RCT reported significantly higher rates of continence with electrical stimulation.[584] Increase in continence did not differ across the studies with mixed versus pure stress UI. Electrical stimulation needed to be administered in nine women to achieve continence in one (Table 12).

Improvement in UI

Electrical stimulation improved UI in pooled analysis of RCTs[558,563,577-581,583] (Appendix Table F97). Benefit was consistent across the studies, despite differences in women and treatment characteristics, and mixed versus pure stress UI (heterogeneity was not significant). Electrical stimulation needed to be administered in six women to improve UI in one woman (Appendix Table F97).

Improvement in UI was also demonstrated in a large prospective cohort study of 3,198 women treated with home-managed vaginal/anal stimulators (20–50 Hz) for at least 3 months before evaluation of the effect[585] (Appendix Table F26). Women experienced daily urine loss, substantial urine loss, and severe UI less often with treatment when compared to baseline.[585]

Electrical stimulation improved quality of life in the majority of RCTs that examined this outcome[558,565,580,582] (Appendix Table F98). We could not conclude consistency in improvement across the studies because the studies used different tools to measure quality of life. Electrical stimulation did not reduce prevalence of detrusor overactivity or urgency UI in the few studies that reported this outcome[578,583,586] (Appendix Table F99). One RCT found that discontinuation of the treatment did not differ between active and sham stimulation[582] (Appendix Table F100). A cohort study found that 12 percent of women stopped using electrical stimulation at home at 2 years of followup.[585]

Clinical Effects of Magnetic Stimulation

A moderate level of evidence indicated that magnetic stimulation improved UI but did not increase urinary continence more than sham stimulation. Evidence of improved quality of life was low.

Five RCTs examined magnetic stimulation.[587-591] The studies of magnetic stimulation included women with UI,[588] stress UI,[587,590] mixed,[590] or predominant urgency UI[589] (Appendix Table F81). Magnetic stimulation was described with different levels of detail using 10 Hz,[588,591] 15Hz,[587,590] or 18.5Hz[589] for 1,[587] 2,[590] 6,[591] or 8 weeks.[588,589] The studies compared active with sham stimulation using double blind,[587,589,590] single blind,[588] or open label[591] designs.

Continence

Magnetic stimulation increased continence rates in one RCT[588] of three[587,589,591] that examined this outcome (Appendix Table F101). Pooled analysis demonstrated no significant increase in continence after active versus sham stimulation.[587,589,591]

Improvement in UI

Active magnetic stimulation, however, improved UI in two[587,588] of three RCTs[587-589] that examined this outcome (Appendix Table F101). A single RCT of pure stress UI demonstrated a greater increase in improvement rates.[587] Pooled analysis demonstrated a 130 percent relative increase in improved UI[587-589] (Appendix Table F102). Magnetic stimulation had to be administered in four women to achieve improvement in UI in one woman (Appendix Table F97).

Limited evidence from nonrandomized studies demonstrated that 28 percent of women reported continence with magnetic innervations (ExMI) therapy[592] (Appendix Table F26).

Magnetic stimulation improved quality of life in one[591] of two RCTs[590,591] that examined this outcome (Appendix Table F103).

Clinical Effects of Medical Devices

Evidence was insufficient to draw valid conclusions about the benefits of using intravaginal and intraurethral devices. Uncontrolled studies demonstrated improvement in UI, but also high discontinuation rates due to adverse effects.

Clinical outcomes with a variety of medical devices were reported in nonrandomized, noncontrolled studies[568-572,574,575,593-608] (Appendix Table F26). Continence rates were 82 percent after using the CapSure (Re/Stor) continence [593] and 20 percent[594] to 54 percent[595] after using the Contiform intravaginal device. Rates of continence and improved UI were 58 percent[598] to 69 percent[596,597] after using the Conveen Continence Guard. Improvement in quality of life was reported by 50 percent[600] to 59 percent[601] of women after using the FemAssist silicone cup. The continence rate was 93 percent at 48 months after using the FemSoft urethral insert.[602] Some studies reported discontinuation rates that varied from 27 percent[601] to 41 percent.[602] A few studies reported adverse effects in women after using the devices, including urinary tract infection in 31.3 percent, mild trauma in 6.7 percent, hematuria in 3.3 percent,[602] local discomfort in 62 percent,[597] acute bacterial cystitis in 5 percent, a small degree of fracture of the curvature of the device in 22 percent,[594] or residual volume >100 ml in 5.4 percent.[595]

Clinical Effects of Bulking Agents for Refractory Stress UI

A low level of evidence suggests that bulking agents did not demonstrate improvement in UI when compared to placebo. Evidence was insufficient to draw valid conclusions about improvement in quality of life. Uncontrolled studies reported high rates of improvement, but also adverse effects.

Clinical outcomes after bulking agents compared to placebo or sham treatments were reported in two RCTs of 241 women[609,610] (Appendix Table F81). The studies enrolled women with urodynamic stress UI and without detrusor overactivity. Women were treated with periurethral injections of autologous fat.[610] Active treatments did not improve UI[609,610] (Appendix Table F104). Periurethral injections of autologous fat did not improve the mean incontinence quality of life score[610] (Appendix Table F105).

Uncontrolled studies reported outcomes after injection of copolymer system[611] or nonendoscopic injection of nonanimal stabilized hyaluronic acid/dexranomer (NASHA/Dx) gel.[612,613] Improvement rate after NASHA/Dx was 76 percent,[613] improvement in quality of life was 67 percent,[612] but 36 percent had adverse effects.[613]

Efficacy of Nonpharmacological Treatments for Urgency UI

Clinical Effects of Bladder Training

A low level of evidence indicated an improvement in UI with bladder training compared to usual care. Evidence of benefits from bladder training for urinary incontinence was insufficient.

Two RCTs examined bladder training compared to no active treatment.[614,615]

Continence

Urinary continence was reported in one RCT that found a borderline significant increase in continence rates with bladder training compared to usual care.[614] (Appendix Table F106)

Improvement in UI

Bladder training improved UI (Appendix Table F106).[637,638] Both trials included older women with mixed UI. Bladder training needed to be provided to two women to achieve an improvement in UI in one woman[637,638] (Appendix Table F97).

One study found clinically important improvement in quality of life measured with the Incontinence Impact Questionnaire[639] (Appendix Table F107). The evidence from individual RCTs was insufficient to extrapolate results for all women with UI.

Clinical Effects of Percutaneous Tibial Nerve Stimulation

Percutaneous tibial nerve stimulation improved UI in adults with OAB.

Four RCTs examined clinical effects of percutaneous tibial nerve stimulation,[617-620] including the Study of Urgent PC versus Sham Effectiveness in Treatment of Overactive Bladder Symptoms (SUmiT) trial[617] and the Overactive Bladder Innovative Therapy Trial (OrBIT)[618,621] (Appendix Table F108). The studies treated adults with either active stimulation with a current level of 0.5 to 9 mA at 20 Hz, or with sham stimulation.

Continence

No RCTs compared continence after percutaneous tibial nerve stimulation versus sham stimulation in adults with UI. Participants in OrBIT Trial reported 16 to 20 percent cure rates with 12 months of active stimulation.[621] The study did not report cure rates with sham stimulation. Continence rates were 94 percent among women with predominant urgency UI and 91 percent in women with mixed UI in an uncontrolled trial.[622] Continence did not differ with more frequent stimulation (three versus one time/week).[623]

Improvement in UI

Percutaneous tibial nerve stimulation improved UI.[617,618] Three women need to be treated with percutaneous tibial nerve stimulation to achieve improvement in one woman (Appendix Table F97). Improvement in UI was attributable to active treatment in 308 women per 1,000 treated (95 percent CI, 40 to 557). Participants in the OrBIT Trial experienced 76 to 80 percent improvement rates with 12 months of active stimulation.[621] Nonrandomized studies reported 63 to 64 percent success rate with active stimulation.[624,625]

Adverse Effects

Patients experienced ankle bruising (1 of 110, 0.9 percent), discomfort at the needle site (2 of 110, 1.8 percent), bleeding at the needle site (3 of 110, 2.7 percent), and tingling in the leg (1 of 110, 0.9 percent) without statistical significance when compared to sham stimulation.[617] Treatment discontinuation did not differ with active versus sham stimulation. One patient did not complete the treatment because of aggravating pre-existing cardiac arrhythmia in an uncontrolled clinical trial of 39 subjects with voiding dysfunction.[626]

Efficacy of Nonpharmacological Treatments for Mixed UI

Clinical Effects of PFMT Combined With Bladder Training

A high level of evidence indicated significant benefits from PFMT combined with bladder training on urinary continence and improvement in UI. The evidence was low that this treatment reduced bother of UI and was insufficient that it improved quality of life.

Six publications of five RCTs examined PFMT combined with bladder training in adults with mixed UI.[627-632]

Continence

Urinary continence was significantly more common in women with PFMT combined with bladder training than with no active treatment (Appendix Table F109).[627-629,631,632] One study reported very large significant increases in continence.[632] Excluding that study, sensitivity analysis demonstrated smaller but still highly significant increases in continence with PFMT combined with bladder training.[627,629] PFMT combined with bladder training needed to be administered to six women to achieve continence in one (Table 12).

Improvement in UI

PFMT combined with bladder training resulted in a significant improvement in UI in all studies that examined this outcome (Appendix Table F97).[627-629,631] PFMT combined with bladder training had to be administered in three women to improve UI in one woman.

PFMT combined with bladder training reduced severity of UI (Appendix Table F110).[627,632,633] One study found that self-reported severe UI was reduced by 82 percent.[627] Another study demonstrated that self-reported bothersome UI was reduced by 31 percent.[633] Use of absorbent pads for UI was reduced by 29 percent in one study.[633] One study found a significant reduction in stress and urgency UI, but not in mixed UI[632] (Appendix Table F100).

Quality of life was examined in one study that reported significant changes in IIQ score after treatment and at the 6 month-followup[632] (Appendix Table F111). Evidence was insufficient to determine improvement in quality of life with PFMT combined with bladder training (Table 13).

Clinical Effects of Continence Services That Were Implemented by Specialized Health Care Providers

A low level of evidence indicated no consistent benefits from continence services implemented by specialized health care providers on continence and improvement of UI when compared to usual care. Promising results on improved quality of care need further confirmation. Comparison across the studies was difficult because of the variety of interventions that constituted complex continence services.

Clinical outcomes were reported in four RCTs that compared continence services with usual care[634-637] (Appendix Table F81). Continence services were described with different levels of detail and usually included advice on diet and fluids, bladder training, pelvic floor muscle education and awareness, lifestyle advice,[634] use of an audiovisual program, calendar, counseling, voiding schedule recommendations, and assessing self-care methods.[635] The services were implemented by continence nurse advisors[636,637] and consulting urogynecologists.[636] The studies included subjects with any UI.

Continence

Continence was reported in three studies (Appendix Table F112).[634-636] The Continence Efficacy Intervention Program increased the rate of continence when compared to conventional care by 556 percent in women with pure stress UI.[635] Among every 1,000 women treated with the program, 743 cases of continence would be attributable to the Continence Efficacy Intervention Program.[635] The largest RCT of 2,248 women with mixed UI reported smaller benefits from continence service than with usual care, with 90 additional cases of continence

attributable to active treatment per 1,000 treated.[634] Pooled analysis of three studies found a significant relative increase of 58 percent with continence services, but no significant differences in absolute rates of continence.[634-636]

Improvement in Incontinence

Improvement was inconsistent across the studies (Appendix Table F113).[634,637] Pooled analysis of two studies[634,637] found significant improvement in UI (33 percent) but no significant differences in absolute rates of improved incontinence. Continence services improved quality of life (Appendix Table F114).[634,638] With services delivered by a continence nurse and a multidisciplinary team consisting of a general practitioner, urologist, and physiotherapist, women did not experience pain or discomfort at 1 year of followup (RR 3.88, 95 percent CI, 1.57 to 9.58), did not have a UI related problem with usual activities (RR 3.74, 95 percent CI, 1.66 to 8.44), and did not complain about anxiety/depression more often than with usual care.[638] Two to four women needed to be treated with a multidisciplinary team to achieve improved quality of life in one woman.[638] Another study that compared continence services to usual care found that continence services resulted in a 21 percent relative increase in the proportion of women satisfied with their level of current urinary symptoms for the rest of their lives (RR 1.21, 95 percent CI, 1.12 to 1.30).[634] Such services needed to be provided to nine women to achieve improved quality of life in one woman.[634] Several RCTs reported quality of life scores with continence services when compared to usual care (Appendix Table F115).[635,636,638-640] The differences rarely achieved statistical significance. Significant differences were not consistent across domains of quality of life (Table 13). The magnitude of the differences was unlikely of any clinical importance.

Clinical Effects of Group Behavioral Modification Program (BMP)

Group BMP was a combination of PFMT and bladder-training education.[641] Evidence from one RCT was insufficient for valid conclusions about the effectiveness of behavioral modification programs in women with mixed UI.

A single study randomized 44 adult women with mixed UI to a behavioral modification program consisting of a group lecture by two trained urology nurses with individualized meetings and assessment of knowledge and modification of behavior.[641] The control group received no treatments for UI. The behavioral modification program significantly improved UI (ARD 0.38, 95 percent CI, 0.13 to 0.63).[641] The program improved UI in every third woman (NNT 3 95 percent CI, 2 to 8) when compared to no active treatment.[641] Improvement in UI was achieved in 379 per 1,000 treated women (95 percent CI, 126 to 632).

Clinical Effects of Weight Loss

A moderate level of evidence indicated improvement in UI after weight loss and exercise in obese women. The evidence was insufficient to conclude if there was an increase in continence or improved quality of life.

Three studies reported clinical outcomes after weight loss programs (Appendix Table F116).[642-644] One RCT compared an intensive 6-month weight loss program to no active treatment.[642] The trial enrolled women with a BMI of 25 to 50kg/m^2 with any daily UI. The program included self-administered diet, exercise, and behavior modification, and aimed to produce an average loss of 7 to 9 percent of initial body weight. The second study treated women with a BMI between 25 and 45 kg/m^2 and at least four incontinent episodes per week.[643] A diet

study provided a 3-month standard low calorie liquid diet (800 kcals/day or less), increased physical activity to 60 minutes/day, and training by a nutritionist, exercise physical therapist, or behavioral therapist.[643]

Continence

Weight loss did not increase continence rates when compared to regular care (Appendix Table F116).[642]

Improvement in UI

Significant improvement in UI was demonstrated in both studies (Appendix Table F116).[642,643] Weight loss had to be maintained in four women to achieve improvement in UI in one woman (Appendix Table F97). Bayesian analysis also found improvement in UI after weight loss in obese women with UI.

Quality of life after weight loss was examined in two RCTs (Appendix Table F117).[642,644] Women reported that UI became somewhat or much less of a problem more often after 6 months of treatment. The PRIDE study (Program to Reduce Incontinence by Diet and Exercise) examined the effects of intensive weight loss on sexual function in overweight and obese women with BMI of 25 to 50 kg/m^2 and daily UI.[644] The study found no significant increase in the odds of overall sexual satisfaction (OR 1.28, 95 percent CI, 0.83 to 1.99) or sexual desire (OR 1.12, 95 percent CI, 0.79 to 1.61).[644]

An uncontrolled study of a low calorie diet and exercise with a target loss of 5 to 10 percent of body weight reported significant improvement in quality of life when compared to baseline.[645]

Discontinuation rates were significantly lower with weight loss programs than with structured education[642,644] (Appendix Table F118).

Clinical Outcomes of Soy-Enriched Diet

One study tested the effects of the soy-enriched diet on urogenital symptoms in perimenopausal and postmenopausal Thai women, and demonstrated no reduction in UI (Appendix Table F119).[646]

Clinical Effects of Acupuncture

Evidence was insufficient to conclude improvement in UI after acupuncture. Low evidence suggested possible improvement in quality of life after active acupuncture.

Clinical outcomes of active acupuncture versus acupuncture of inactive points were reported in two RCTs of 137 women[647,648] (Appendix Table F81) and one uncontrolled study.[649] The RCTs enrolled women with symptoms of overactive bladder with urgency incontinence[647] or with stress UI.[648] Active acupuncture did not resolve urgency UI[647] (Appendix Table F120). An uncontrolled study reported an improvement rate of 80 percent in older women for whom previous treatments had failed.[649] Improvement in quality of life was inconsistent across two RCTs[647,648] (Appendix Table F121).

Comparative Effectiveness of Nonpharmacological Treatments

We concluded with high confidence that PFMT alone and in combination with bladder training or biofeedback, electrical stimulation, or weight loss with exercise was effective to achieve continence and improvement in UI. These treatments had comparable effects when

compared to each other. Evidence was not sufficient to conclude better effects from medical devices or bulking agents when compared to each other.

Clinical outcomes with one nonpharmacological treatment versus another were reported in 54 RCTs (Appendix Table F81). These trials rarely compared the same treatment effects, which decreased the level of evidence to low or insufficient.

Comparative Effectiveness of Nonpharmacological Treatments for Stress UI

(Appendix Tables F122-F146)

Comparative Effectiveness of Supervised PFMT and Self-Administered PFMT

A high level of evidence indicated no difference in UI outcomes between supervised PFMT combined with bladder training and self-administered PFMT.

Supervised PFMT combined with bladder training was not more effective than self-administered PFMT[650-654] (Appendix Table F122). Continence rates were similar between the two interventions (Table 15).[650-654] Improvement in UI was similar between supervised and self-administered PFMT (Appendix Table F123).[650-654] Rates of treatment failure and treatment discontinuation did not differ between the two treatments (Appendix Table F122).[650-653] One RCT reported better patient satisfaction with supervised versus self-administered PFMT in 44 women with urodynamic stress UI.[652]

Differences in quality of life were inconsistent across studies. One RCT did not demonstrate better quality of life with supervised versus self-administered PFMT in 88 women with mixed UI[655] (Appendix Table F125). Supervised PFMT versus self-administered PFMT worsened two domains of King's Health Questionnaire (physical limitations and physical activity limitations), with no differences in other domains in 61 women with urodynamic stress UI[651] (Appendix Table F126).

Prevalence of UI did not differ between supervised and self-administered PFMT.[650,655-657] Only one RCT of intensive PFMT under the supervision of a physical therapist for 6 months in 52 women with urodynamic stress UI demonstrated no sustained reduction in prevalence of severe UI (RR 0.18, 95 percent CI, 0.02 to 1.33) and urgency UI (RR 0.37, 95 percent CI, 0.12 to 1.18) at 15 years (Appendix Table F125).[650]

The studies of individual PFMT did not report better outcomes than group PFMT in individual RCTs of women with different types of UI (Appendix Table F127).[658,659]

Comparative Effectiveness of PFMT With and Without Biofeedback Using Vaginal EMG Probe

A high level of evidence indicated no differences in clinical outcomes between PFMT with or without biofeedback using vaginal EMG probe.

The studies that compared PFMT with or without biofeedback using vaginal EMG probe found no consistent differences in continence (Table 15, Appendix Table F124). Nor did quality of life rates differ.[660,661] Scores of Leakage Index,[660,662] Social Activity Index,[660] Incontinence Impact Questionnaire,[663] or IIQ-7 scores[664] did not differ between PFMT with and without biofeedback (Appendix Table F128). Prevalence and impact of UI did not differ between treatments, either[660,663] (Appendix Table F129).

Comparative Effectiveness of PFMT and Electrical Stimulation

A moderate level of evidence suggested no differences in UI with PFMT and electrical stimulation. PFMT did not result in better outcomes than electrical stimulation[563,665,666] (Appendix Table F130). Rates of improvement in UI and treatment failure also did not differ between the two treatments[563,665,666] (Appendix Table F123).

Comparative Effectiveness of PFMT Combined With Electrical Stimulation Versus PFMT

Evidence was insufficient to draw conclusions about comparative effectiveness of PFMT combined with electrical stimulation versus PFMT alone. A combination of PFMT with electrical stimulation reduced the frequency of UI and improved quality of life more often than PFMT alone[667] (Appendix Table F131).

Comparative Effectiveness of PFMT and Medical Devices

A moderate level of evidence indicated no difference in outcomes for UI treated with PFMT compared to vaginal cones. Evidence was insufficient to draw valid conclusions about comparative effectiveness of PFMT and vaginal rings and balls.

Relative benefits of PFMT compared to medical devices were inconsistent across the studies. The rates of continence or improvement in predominant stress UI did not differ between PFTM and vaginal cones[561,563,668] (Appendix Table F132). PFMT combined with biofeedback did not result in greater continence rates than use of vaginal cones[669] (Appendix Table F131). Rates of treatment discontinuation did not differ between the two treatments.[669] PFMT with biofeedback resulted in the same quality of life as vaginal cones[670,671] (Appendix Table F133).

PFMT using weighted vaginal balls 50 to 100 g resulted in increased continence rates and improvement in UI compared to regular PFMT in one study that examined this association[672] in 37 women with stress UI (Appendix Table F131).

PFMT resulted in greater improvement in UI and lower treatment discontinuation than vaginal rings[673] (Appendix Table F131).

PFMT combined with the use of a vaginal ring resulted in greater improvement in UI and lower rates of treatment discontinuation than a ring alone[673] (Appendix Table F131).

PFMT and the use of a vaginal ring did not differ from PFMT alone in causing improvement of UI or treatment discontinuation[673] (Appendix Table F131).

Comparative Effectiveness of Circular Muscle Exercises and PFMT

Evidence was insufficient to draw valid conclusions about comparative effectiveness of muscle training regimens.

Continence and improvement in predominant stress UI were greater with circular muscle exercises (Paula method) than PFMT[674] in women with UI (Appendix Table F134). Quality of life was reported in two RCTs that compared circular muscle exercises with PFMT, with no consistent differences[674,675] (Appendix Table F135). With circular muscle exercises, women experienced less “leakage annoyance” but not less frequency of UI[674] (Appendix Table F136). Back pain was more common with the Paula method than with regular PFMT.[674]

Quality of life did not differ significantly in studies that compared PFMT with other active treatments[561,660,661,674,676] (Appendix Tables F137 and F138).

Comparative Effectiveness of Interventions To Increase Adherence to PFMT

Evidence was insufficient to draw valid conclusions about comparative effectiveness of interventions to increase adherence to PFMT.

Adding personal reminders to enhance adherence to PFMT did not improve outcomes in 129 women with UI[677] (Appendix Table F139). Providing women with an audiocassette tape to enhance adherence to PFMT increased routine pelvic floor muscle exercise more often than usual verbal instructions for PFMT.[678] Women performed pelvic floor exercises twice per day more often after listening to audiocassette tapes.[678] Providing audiocassette tapes resulted in better adherence to PFMT in 698 women per 1,000 treated (Appendix Table F139).

Comparative Effectiveness of PFMT in Different Positions

Available evidence did not indicate differences in benefits between different regimens and combinations of PFMT treatments.

PFMT with EMG biofeedback in both supine and upright positions versus supine position resulted in the same outcomes in 44 women with stress UI.[679]

Comparative Effectiveness of Electrical Stimulation Methods

Evidence was insufficient to conclude comparative effectiveness of electrical stimulation and other nonpharmacological treatments for UI.

Comparative effectiveness of once versus three times per week posterior tibial nerve simulation resulted in the same outcomes in 35 subjects with urgency UI who failed oxybutynin treatment.[623]

Frequency of UI episodes, pad test, quality of life, and treatment discontinuation rates did not differ between intravaginal electrical stimulation with or without biofeedback[680] (Appendix Table F131).

Electrical stimulation compared to the use of vaginal cones resulted in the same rates of continence, improvement in UI, and discontinuation of treatments due to failure to improve UI[563] (Appendix Table F131).

Physical therapy that included PFMT in combination with biofeedback compared to physical therapy alone increased rates of continence and improvement in UI in one study of 40 women with stress UI.[661]

Comparative Effectiveness of Medical Devices

Evidence was insufficient to conclude comparative effectiveness of examined medical devices.

Clinical outcomes were examined in seven RCTs of vaginal cone therapy, Contrelle Continence Tampon, CCT, Conveen Continence disposable Intravaginal device Guard, CCG, Hodge pessary with support and Durasphere and Urethral device (NEAT), sterile urethral insert[561,670,681-684] (Appendix Table F140). The studies did not demonstrate significant differences in outcomes. One RCT of 94 women with the predominant symptom of stress UI found that women reported “no bother from UI” more often after Contrelle Continence Tampon versus Conveen Continence Disposable Intravaginal Device Guard.[681] Quality of life did not differ after examined devices[561,670,683] (Appendix Tables F141 and F142). One cross-over RCT of 20 women with light UI examined patient comfort, absorbency, and leakage performance after different pads, and found no significant differences[685] (Appendix Table F143).

Comparative Effectiveness of Various Bulking Agents for Refractory Stress UI

Evidence was insufficient to conclude comparative effectiveness of examined bulking agents.

Seven RCTs examined clinical outcomes after different bulking agents in women with pure stress UI and did not find consistent differences[686-692] (Appendix Table F144). Continence was greater after Macroplastique versus Contigen® in 260 women[693] and after autologous myoblasts and fibroblasts versus collagen in 63 women.[690]Autologous myoblasts and fibroblasts versus collagen improved quality of life scores in 63 women with intrinsic sphincter insufficiency or stress UI[690] (Appendix Table F145). Adverse effects were more common with Zuidex Implacer than with Contigen Endoscopic guidance in 344 women with stress UI[692] (Appendix Table F146). Continence rates were greater with durasphere than with contigen in one RCT in 52 women with stress UI.[683]

Comparative Effectiveness of Nonpharmacological Treatments for Urgency UI

Comparative Effectiveness of Bladder Training

Evidence indicated that continence did not differ between bladder training combined with PFMT and bladder training alone. Evidence was insufficient to draw conclusions based on other tested comparisons.

Bladder training by listening to an audiotape daily improved UI more often than bladder training without the audiotape[694] (Appendix Tables F131 and F147).

Continence did not differ between bladder training and PFMT.[660] Satisfaction with current UI and feelings of no impact from UI on quality of life did not differ between bladder training and PFMT.[561] Transcutaneous tibial nerve combined with bladder and PFMT increased rates of continence or clinically important reduction in daily UI episodes in older women with urgency UI compared to bladder and PFMT (Appendix Table F148). Bladder training combined with PFMT did not increase continence or improve UI more often than bladder training alone[93,695] (Appendix Table F149). Bladder training did not increase continence more often than use of vaginal cones (Appendix Table F131).[561]

Comparative Effectiveness of Nonpharmacological Treatments for Mixed UI

Comparative Effectiveness of Continence Services Implemented by Specialized Health Care Providers

Evidence was insufficient to draw valid conclusions about comparative effectiveness of continence services and other tested individual treatments (Table 14).

Outpatient continence services involving bladder retraining and physical therapy resulted in the same continence as treatment with an inpatient 5-day hospital stay in 74 women with any UI[696] (Appendix Table F131).

The Continence Efficacy Intervention Program increased continence rates more often than PFMT in 48 women with stress or mixed UI.[635] Quality of life scores, however, did not differ between the two treatments[635] (Appendix Table F150). Face-to-face behavioral consultation by the nurse specialist giving digital assessment feedback on pelvic floor contraction resulted in the

same continence as video conferences with continence nurses in 32 older women with symptoms of urgency or stress incontinence[697] (Appendix Table F131).

Comparative Effectiveness of Group Versus Individual Physical Therapy Sessions

Evidence was insufficient to draw conclusions about comparative effectiveness of group versus individual therapy for UI.

Women reported lower benefits from group versus individual physical therapy sessions for mixed UI at 5 months of followup (RR 0.79, 95 percent CI, 0.65 to 0.98) in one RCT.[698] Symptom severity or quality of life outcomes did not differ between treatment groups.[698]

Comparative Effectiveness of Behavioral Weight Loss and Education

Evidence was insufficient to conclude comparative effectiveness between behavioral weight loss intervention and education. Women reported more frequent improvement in mixed UI (defined as more than 70 percent reduction in weekly UI episodes) at 12 months with a behavioral weight loss intervention than with education[699] (Appendix Table F131). The differences remained significant only for urgency UI at 18 months posttreatment.[699]

Indirect Evidence of Comparative Effectiveness of Nonpharmacological Treatments

Indirect comparisons indicated similar effectiveness of nonpharmacological treatments on continence.

We evaluated the effectiveness of different nonpharmacological treatment compared to no active treatment. Such indirect evidence from all RCTs indicated that all active treatments increased continence rates without evident differences (Figure 21). Absolute rate differences were significant for electrical stimulation, PFMT, and PFMT combined with bladder training. Attributable cases of continence were 299 per 1,000 for PFMT compared to 162 cases for electrical stimulation, and 166 cases for PFMT combined with bladder training. Rates of continence were similar between different treatments: 38 percent of women became continent with PFMT, 23 percent became continent with electrical stimulation, and 21 percent became continent with PFMT combined with bladder training.

Statistical indirect comparisons were difficult because of substantial variability in continence rates with control treatment (Figure 21). We analyzed which factors potentially contribute to such differences in continence with the control treatment, and found no statistically significant associations.

Comparative Effectiveness of Nonpharmacological Treatments When Compared to Drugs or Combined Modalities

Evidence was insufficient to draw valid conclusions about comparative effectiveness and safety of nonpharmacological treatments compared to drugs or combined modalities (Table 16).

Comparative Effectiveness of Nonpharmacological Treatments When Compared to Drugs or Combined Modalities for Stress UI

Duloxetine

Evidence was insufficient to conclude comparative effectiveness or harms of duloxetine combined with PFMT compared to duloxetine alone.

One study, Duloxetine/Pelvic Floor Muscle Training Clinical Trial Group, compared clinical outcomes of duloxetine with and without PFMT in 201 women with stress UI.[393] Women were enrolled in 17 continence clinics in the Netherlands, the United Kingdom, and the United States, and randomized to one of four combinations of 80 mg duloxetine daily, placebo, PFMT, and imitation PFMT.[393] Combined treatment with duloxetine and PFMT resulted in a greater reduction in UI episode frequency than PFMT alone.[393] Response rates (defined as >50 percent decrease in incontinent episode frequency), clinically important improvement in I-QOL score, and perceived treatment success did not differ between treatment groups.[393] Women who completed paper diaries at each visit experienced greater improvement in UI, quality of life, and perceived treatment success with PFMT than with duloxetine. Adverse effects and treatment discontinuation due to adverse effects were more often associated with duloxetine combined with PFMT than with PFMT or placebo.[393]

Comparative Effectiveness of Nonpharmacological Treatments When Compared to Drugs or Combined Modalities for Urgency UI

Oxybutynin

Oxybutynin Compared to Biofeedback-Assisted PFMT

Evidence was insufficient to conclude effectiveness and safety with behavioral biofeedback-assisted PFMT versus oxybutynin in older women.

Adjustable doses of oxybutynin and behavioral biofeedback-assisted PFMT resulted in the same rates of continence and improvement in UI in 197 older women with urgency or predominant urgency UI.[418,437,438] Women perceived their bladder condition as "much better"[437] and were completely satisfied with the treatment more often with biofeedback-assisted training.[438] Adverse effects, including inability to void, constipation, and dry mouth, were less common with biofeedback-assisted PFMT than with oxybutynin.[437]

Oxybutynin Combined With PFMT and Urge Suppression Techniques Compared to Individualized Drug Therapy Alone

Evidence was insufficient to conclude comparative effectiveness of oxybutynin combined with PFMT and urge suppression techniques compared to individualized drug therapy alone. Adjustable doses of oxybutynin combined with behavioral therapy resulted in the same reduction in UI episodes, perceived improvement in UI, and treatment satisfaction as oxybutynin alone[324] (Appendix Table F151).

Oxybutynin Compared to Electrical Stimulation

Available limited evidence was insufficient to draw valid conclusions about comparative effectiveness of electrical stimulation compared to oxybutynin or with combined treatments compared to electrical stimulation alone.

Electrical stimulation with a 10-Hz frequency resulted in greater effects on UI episodes and quality of life scores than oxybutynin 7.5 mg/day.[443] The rates of resolved urgency and reduction in OAB symptoms did not differ between the electrical stimulation and drug therapy groups[443] (Appendix Table F151).

Electrical stimulation with frequency 20 Hz and amplitude 0.5 to 10 mA combined with 5 mg of oral oxybutynin resulted in the same rates of urinary continence and UI improvement as electrical stimulation alone[700] (Appendix Table F151).

Transdermal Oxybutynin Combined With Behavioral Intervention Compared to Transdermal Oxybutynin Alone

Evidence was insufficient to conclude significant benefits from combined therapy compared to the drug alone. The Multicenter Assessment of Transdermal Therapy in Overactive Bladder with Oxybutynin trial compared 3.9 mg of transdermal oxybutynin plus the behavioral intervention of enhanced patient education with transdermal oxybutynin alone.[428] Combined treatment resulted in lower negative impact from UI on sexual life (RR 0.77, 95 percent CI, 0.69 to 0.86).[428]

Tolterodine

Tolterodine Combined With PFMT, Bladder Control Techniques, Fluid Management Versus Tolterodine Alone

Evidence was insufficient to conclude comparative effectiveness and safety of tolterodine combined with PFMT, bladder control techniques, fluid management versus tolterodine alone. The Urinary Incontinence Treatment Network compared clinical outcomes in 307 women with predominant urgency UI treated with a combination of tolterodine plus supervised behavioral training versus tolterodine alone[701-703] (Appendix Table F152). Combined therapy resulted in greater rates of complete satisfaction with therapy at the end of the treatment and at 8 months followup.[702] The rates of perceived improvement with UI as "better" or "much better" were also higher with combined treatment at the end of the trial and at 8 months followup.[702]

Standard educational programs that included printed information and an explanation about OAB, medication use, and behavioral treatments combined with tolterodine were compared to tolterodine alone in one RCT of 84 adults with OAB (Kegel exercise, bladder stretching, fluid regulation with medication treatment alone).[704] Self-reported perception of treatment success and the use of behavior modification therapies were greater with combined therapy than with tolterodine alone.[704] More women used Kegel exercises and urge suppression techniques, regulated fluid intake, and limited caffeine intake with combined treatment than with drugs alone. Patient satisfaction was associated with changes in Urogenital Distress Inventory (UDI) score, but not with a reduction in UI daily episodes.[705] After multivariable analysis, every 10-point increase in UDI score was associated with 11 percent higher odds of treatment satisfaction (OR 1.11, 95 percent CI, 1.04 to 1.19).[705]

Tolterodine Versus Percutaneous Tibial Nerve Stimulation

Evidence from one study was insufficient to conclude better effectiveness of percutaneous tibial nerve stimulation compared to tolterodine. The Overactive Bladder Innovative Therapy trial compared clinical outcomes with percutaneous tibial nerve stimulation and extended-release tolterodine in 100 adults with urinary frequency[706] (Appendix Table F153). Patient assessment and investigator assessment of improvement or cure were greater with stimulation than with

tolterodine. Self-reported change in health-related quality of life score did not differ between stimulation and drug treatment.[706] Subjects reported worsening of the symptoms less often with stimulation than with the drug.[706]

Tolterodine Versus Intravaginal Electrical Stimulation

Evidence from one RCT was insufficient to conclude better effectiveness of intravaginal electrical stimulation compared to tolterodine.[707] Women with overactive bladder and predominant urgency UI experienced improvement in symptoms from baseline with electrical stimulation and with tolterodine, without significant differences between treatment groups.[707] Dry mouth was less common with stimulation than with the drug (ARD -0.26, 95 percent CI, −0.41 to −0.11).[707] Both treatments improved quality of life. Improvement in severity of urinary symptoms and in social and personal relationships were significantly greater with electrical stimulation than with tolterodine at 6 months followup.[707]

Tolterodine Combined With Simplified Bladder Training Versus Tolterodine Alone

The Tolterodine Scandinavian Study Group compared clinical outcomes with tolterodine combined with simplified bladder training versus tolterodine alone. This randomized trial enrolled adults with OAB, including 75 percent of women.[708] The number of UI episodes and perceived improvement in symptoms did not differ between treatment groups.[708] Symptom deterioration tended to be lower with combined treatment, but the difference did not reach statistical significance.[708] The total number of adverse effects, including dry mouth, headache, and constipation, were similar between combined treatment and drug treatment alone.[708]

Solifenacin

Evidence was insufficient to conclude comparative effectiveness and safety of a combination of solifenacin with bladder training and the drug alone. The SOLifenacin Alone and with simplified bladder Re-training (SOLAR) RCT compared clinical outcomes of flexible-dose solifenacin 5/10 mg with and without bladder training in patients with overactive bladder[709] (Appendix Table F154). Combined therapy was better in reducing micturition frequency.[709] Quality of life scores did not differ between treatment groups.[709]Adverse effects did not differ between treatments.[709]

Trospium

Evidence was insufficient to conclude comparative effectiveness and safety of trospium and electrical stimulation. Trospium was compared with intravaginal electrical stimulation in women with overactive bladder syndrome[326] (Appendix Table F155). Improvement in UI did not differ between trospium and electrical stimulation.[326] Both treatments improved VAS urgency severity and Beck Depression Inventory scores when compared to baseline levels. However, neither post-treatment VAS urgency severity nor Beck Depression Inventory scores differed between the drug and electrical stimulation. Dry mouth was more common with drug (ARD 0.29, 95 percent CI, 0.07 to 0.52).[326]

Darifenacin

Darifenacin Compared to Behavioral Modification Program

We found insufficient evidence to conclude differences in benefits and harms of darifenacin combined with behavioral modification compared to darifenacin alone. The ABLE trial

randomized adults with OAB to the flexible dose of darifenacin (7.5 to 15 mg/day) alone or combined with behavioral brochures on modification of diet and daily habits and training for pelvic floor muscle exercise.[710] The differences between the two groups for both the Overactive Bladder Questionnaire (OAB-q) and the Overactive Bladder Satisfaction with Treatment Questionnaire (OAB-SAT-q) at week 12 were not significant. However, the rate of adverse effects leading to discontinuation of treatment was higher in the combined treatment group (RR 3.24, 95 percent CI, 1.34 to 7.86).[710]

Table 12. Continence with nonpharmacological treatments compared to no active treatment (pooled with random effects estimates from head-to-head RCTs)

Treatment	Studies Patients	Rate in active/ control	Relative risk (95% CI)	Absolute risk difference 95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)	Bayesian odds ratio median (2.5% to 97.5%)	Level of evidence
Continence Service	3[634-636] 3,939	28.8/20.4	1.58 (1.07 to 2.34)	0.30 (-0.01 to 0.60)				Moderate
Bladder Training	1[614] 131	12.3/3	4.06 (0.90 to 18.41)	0.09 (0.00 to 0.18)	10 (5 to 353)	93 (3 to 18)		Insufficient
Pelvic Floor Muscle Training	10[554,555,557,558,560-564] 959	37.5/12.3	3.77 (2.09 to 6.80)	0.30 (0.19 to 0.41)	3 (2 to 5)	299 (188 to 410)	8 (5 to 15)	High
Pelvic Floor Muscle Training + Bladder Training	5[627-629,631,632] 1,369	21.2/12.2	3.79 (1.55 to 9.27)	0.17 (0.06 to 0.27)	6 (4 to 16)	166 (63 to 268)	5 (5 to 18)	High
Pelvic Floor Muscle Training with EMG Biofeedback	2[557,560] 185	42.0/2.4	11.17 (2.21 to 56.44)	0.494 (-0.10 to 1.08)				Low
Electrical Stimulation	7[558,563,577,579-581,584] 420	22.7/7.7	2.86 (1.57 to 5.23)	0.16 (0.06 to 0.26)	6 (4 to 16)	162 (64 to 259)	4 (2 to 9)	High
Magnetic Stimulation	3[587,589,591] 171	30.7/17.8	1.22 (0.78 to 1.88)	0.09 (-0.01 to 0.18)				Moderate
Vaginal Cones	2[558,563] 118	23/8	2.88 (1.10 to 7.55)	0.14 (-0.01 to 0.29)				Low
Weight Loss	1[642] 338		Urgency UI 1.78 (0.98 to 3.23)	0.08 (0.01 to 0.16)	12 (6 to 16)	83 (6 to 160)		Insufficient
			Stress: 1.78 (1.09 to 2.90)	0.12 (0.03 to 0.21)	8 (5 to 33)	118 (30 to 206)		Insufficient

Table13. Improvement in severity of incontinence and quality of life with nonpharmacological treatments compared to no active treat

Treatment	Studies Reference	Number of subjects	Significance of the effect	Evidence
Continence service	2 studies[634,638]	3,847	Significant improvement in both RCTs	Moderate
Continence service	5 studies that reported scores[635,636,638-640]	1,598	Inconsistent differences in scoring	Moderate
Bladder training	1 study[616]	131	Significant improvement in scoring	Single RCT
Pelvic floor muscle training	2 studies[555,559]	125	Significant improvement	Moderate
Pelvic floor muscle training	6 studies that reported scores[559,560,565-567]	199	Significant improvement in scoring	Moderate
Pelvic floor muscle training + bladder training	1 study[632]	164	Significant improvement in scoring	Single RCT
Pelvic floor muscle training + biofeedback	1 study[560]	30	Significant improvement in scoring	Single RCT
Supervised pelvic floor muscle training	1 study[558]	61	Significant improvement in scoring	Single RCT
Acupuncture	2 studies[647,648]	137	Inconsistent differences in scoring	Low
Electrical stimulation	4 studies[558,565,580,582]	274	Significant improvement in scoring	Moderate
Magnetic stimulation	2 studies[590,591]	90	Improvement in scoring in one of two RCTs	Low
Vaginal cones	1 study[558]	61	Significant improvement in scoring	Single RCT
Percutaneous Tibial Nerve Stimulation	3 studies[617-619]	405	Significant improvement in UI	Moderate
Bulking agent	1 study[610]	68	Not significant changes in scoring	Single RCT
Weight loss	2 studies[642,644]	651	Inconsistent differences	Low

Table 14. Continence with nonpharmacological treatments

Active	Control	Individual RCTs Reference	Number of subjects	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events 95% CI)
Continence service	Bladder training	1 study[696]	74	Not significant			
Continence service	PFMT	1 study[635]	33	7.44 (2.00 to 27.70)	0.76 (0.53 to 0.98)	1 (1 to 2)	757 (534 to 980)
Continence service	Tele continence service	1 study[697]	58	Not significant			
PFMT+ reminder	PFMT+ bladder training	1 study[677]	103	Not significant			
PFMT in the supine position	PFMT in both supine and upright positions	1 study[679]	44	Not significant			
Group physical therapy	Biofeedback	1 study[658]	40	Not significant			
Individual PFMT+BT	Group PFMT	1 study[659]	530	1.58 (1.05 to 2.36)	0.08 (0.00 to 0.16)	12 (6 to 1003)	81 (1 to 161)
Circular muscle exercises (Paula method)	PFMT	1 study[674]	245	1.50 (1.11 to 2.03)	0.17 (0.05 to 0.29)	6 (3 to 21)	171 (48 to 295)
PFMT	PFMT+ Balls	1 study[672]	37	0.11 (0.01 to 1.83)	-0.22 (-0.43 to -0.02)	5 (2 to 52)	222 (19 to 425)
Physical therapy in combination with biofeedback	Physical therapy	1 study[661]	40	3.67 (1.20 to 11.19)	0.40 (0.13 to 0.67)	3 (1 to 8)	400 (132 to 668)
Weekly posterior tibial nerve simulation	Posterior tibial nerve simulation three times per week	1 study[623]	35	Not significant			
Vaginal cone	behavioral intervention	1 study[561]	238	Not significant			
Conveen Continence Device Guard, CCG	Contrelle Continence Tampon, CCT	1 study[681]	94	Not significant			
Hodge pessary with support	Super tampon	1 study[682]	40	Not significant			

Table 14. Continence with nonpharmacological treatments (continued)

Active	Control	Individual RCTs Reference	Number of subjects	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events 95% CI)
Durasphere	Contigen	1 study[683]	52	3.33 (1.03 to 10.74)	0.27 (0.05 to 0.49)	4 (2 to 22)	269 (46 to 493)
Urethral device (NEAT)	Reliance insert sterile balloon	1 study[684]	24	Not significant			
Calcium hydroxylapatite (CaHA	Bovine Dermal Collagen	1 study[686]	296	Not significant			
Peri or transurethral porcine dermal implant injection (Permacol)	Transurethral silicone injection (Macroplastique	1 study[687]		Not significant			
Periurethral route of injection of bulking agent-dextran copolymer	Transurethral route of injection of bulking agent-dextran copolymer	1 study[688]		Not significant			
Macroplastique	Contigen®	1 study[689]	247	1.49 (1.01 to 2.18) NS for self reported continence	0.12 (0.01 to 0.24)	8 (4 to 152)	121 (7 to 235)
Autologous myoblasts and fibroblasts	Collagen	1 study[690]	63	9.50 (2.53 to 35.63)	0.81 (0.66 to 0.96)	1 (1 to 2)	810 (656 to 963)
Zuidex Implacer	Contigen Endoscopic guidance	1 study[692]	344	Not significant			

Table 15. Continence rates compared between nonpharmacological treatments (pooled with random effects estimates from head-to-head RCTs)

Active treatment	Control treatment	Studies	Patients	Rate active/ control, %	Relative risk (95% CI)	Absolute risk difference (95% CI)	Level of evidence
Pelvic floor muscle training + bladder training	Bladder training	3[93,695]	406	22/19	1.17 (0.60 to 2.28)	0.03 (-0.10 to 0.16)	High
Pelvic floor muscle training +biofeedback	Pelvic floor muscle training	6[653,660,661,711-713]	542	30/25	1.27 (0.88 to 1.85)	0.08 (-0.03 to 0.19)	High
Supervised pelvic floor muscle training	Pelvic floor muscle training	4[650-653]	300	35/22	1.92 (0.87 to 4.23)	0.20 (-0.03 to 0.43)	High
Pelvic floor muscle training	Electrical stimulation	3[563,665,666]	99	24/29	0.85 (0.45 to 1.61)	-0.04 (-0.20 to 0.11)	Moderate
Pelvic floor muscle training	Vaginal cone	3[561,563,668]	320	22/27	0.78 (0.58 to 1.06)	-0.11 (-0.26 to 0.04)	Moderate

Figure 21. Continence with nonpharmacological treatments for UI when compared to no active treatment (pooled with random effects estimates from head-to-head RCTs)

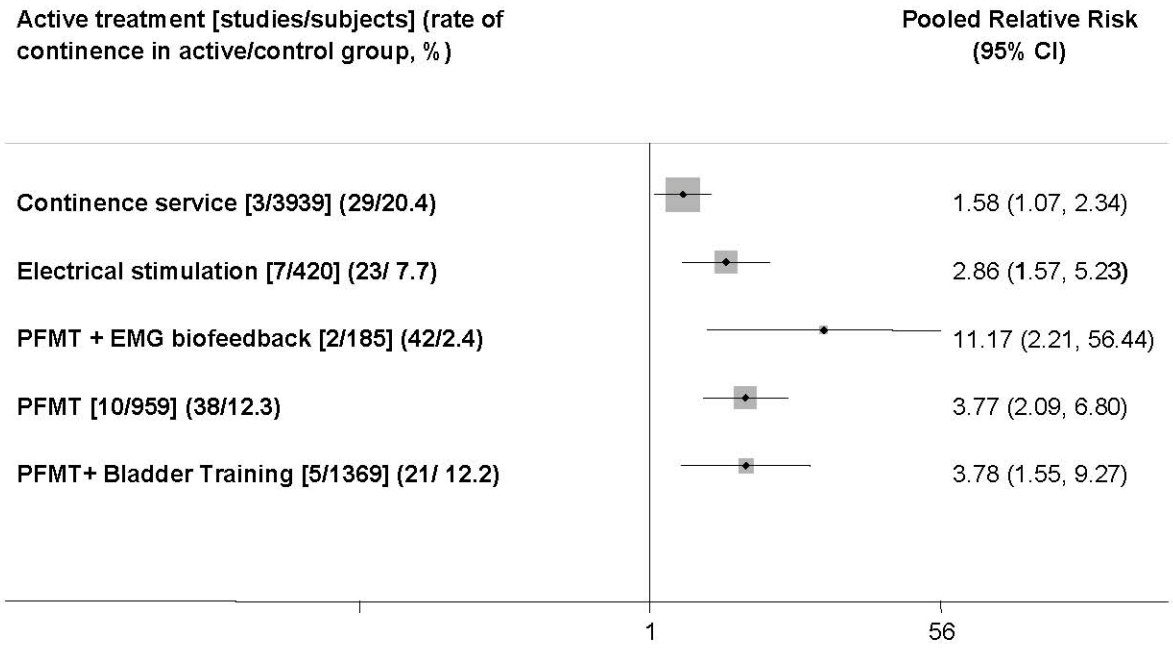


Table 16. Continence with pharmacological treatments compared to nonpharmacological treatments or combined modalities

Outcome	Active	Control	Individual RCTs Reference	Patients	Relative risk (95% CI)	Absolute risk difference (95% CI)
Cured from urgency UI	Stoller afferent neurostimulation	Stoller afferent neurostimulation + oxybutynin	Karademir, 2005[700]	44	1.10 (0.25 to 4.84)	0.01 (-0.19 to 0.22)
Subject assessment OAB symptom cured	Percutaneous Tibial Nerve Stimulation	Tolterodine	Peters, 2009[706]	100	0.50 (0.05 to 5.34)	-0.02 (-0.09 to 0.05)
Investigator assessment OAB symptom cured	Percutaneous Tibial Nerve Stimulation	Tolterodine	Peters, 2009[706]	100	1.00 (0.15 to 6.82)	0.00 (-0.08 to 0.08)
Subject reported OAB symptom improvement or cure	Percutaneous Tibial Nerve Stimulation	Tolterodine	Peters, 2009[706]	100	1.48(1.11 to1.98)	0.26(0.083 to 0.437)
Investigator assessment OAB symptom improvement or cure	Percutaneous Tibial Nerve Stimulation	Tolterodine	Peters, 2009[706]	100	1.33(1.02 to1.74)	0.2(0.025 to 0.375)
Totally dry	Tolterodine + PFMT	Tolterodine	Burgio, 2008[702]	307	1.22 (0.77 to 1.95)	0.04 (-0.05 to 0.13)
Continence	PFMT biofeedback-assisted	Oxybutynin, 7.5 to 15	Goode, 2004[438]	132	1.37 (0.77 to 2.44)	0.08 (-0.07 to 0.23)
Continence	PFMT biofeedback-assisted	Oxybutynin, 7.5 to 15	Burgio, 1998[437]	132	1.31 (0.73 to 2.34)	0.07 (-0.08 to 0.22)

Discussion

Key Findings

A number of important findings emerged from this review.

Diagnosis

Clinical evaluation with validated tools for diagnosis of UI, its type, frequency, severity, and impact on quality of life informs nonsurgical treatment decisions.

Compared with diagnosis by patients' symptom reports, multichannel urodynamics did not better predict which patients would benefit from nonsurgical treatments.

Measuring Treatment Success

Women with daily stress UI perceived important clinical benefit from reductions of approximately 50 percent in UI frequency, and important incremental clinical value from reductions of 75 percent and 90 to 100 percent.

Women reported improved quality of life and clinical success only when they experienced a greater than 70 percent reduction in UI episode frequency assessed by a voiding diary.

More than 60 percent of women with persistent urgency, stress, or mixed UI reported complete treatment satisfaction when they experienced more than 70 percent reduction of UI episodes. Validated tools have been used to assess minimum important differences in UI in women.

Validated tools have been used to assess threshold values of clinical importance for evaluating treatment success.

Pharmacological Treatments

All anticholinergic medications were more effective than placebo in achieving continence and improving UI, but the degree of benefit was low for all drugs, with fewer than 200 cases of continence attributable to treatment per 1,000 patients treated (absolute risk difference with placebo <20 percent).

Treatment benefits, including continence, were achieved with antimuscarinic drugs, including trospium, solifenacin, fesoterodine, tolterodine, and oxybutynin.

Drugs for urgency UI demonstrated similar effectiveness. Treatment discontinuation due to adverse effects was most common with oxybutynin and least common with solifenacin.

Pharmacological treatments for stress UI, including off-label use of low-dose topical estrogen formulations, may improve stress UI in postmenopausal women.

Duloxetine has an unfavorable balance between improvement in stress UI and treatment discontinuation due to adverse effects.

Compliance rates for prescription drugs are low; discontinuation due to side effects is common. Dry mouth, constipation, and blurred vision were among the most frequent adverse effects.

There is insufficient evidence of the long-term safety of pharmacological treatments.

Women with urgency UI whose prior treatments failed may benefit from solifenacin; however, poor responders would not benefit from increasing the dose of the drug.

Oxybutynin, trospium, and darifenacin improved UI in older women.

Nonpharmacological Treatments

Nonpharmacological treatments result in significant clinical benefit with a low risk of adverse effects. The magnitude of benefit is large, with more than 100 percent relative difference in continence rates. Women with stress UI can achieve continence performing PFMT. Continence rates are similar between those who undergo PFMT with and without biofeedback.

UI Diagnosis

Diagnosis of different types of UI in ambulatory care settings includes clinical history and evaluation, voiding diary, and validated scales**.** Urodynamic diagnosis is more invasive and not applicable to ambulatory settings. Although it more sensitively distinguishes detrusor overactivity, it did not better predict treatment benefits for patients undergoing nonsurgical UI treatments. Baseline urodynamic diagnosis did, however, better predict harms from surgery for women with refractory stress UI by identifying women with detrusor overactivity, which is associated with greater risk of postsurgical urgency UI. Diagnosis of pure urodynamic stress UI or detrusor overactivity can influence treatment decisions for women undergoing surgical treatments for urogenital prolapse or pelvic floor trauma.[345,714] An ongoing trial conducted by the Urinary Incontinence Treatment Network will shed light on the association between utility of urodynamic testing and better prediction of outcomes of stress UI surgery.[715]

Previously published systematic reviews also demonstrated a weak association between self-reported UI symptoms and instrumental urodynamic findings.[73,716] However, investigators still use urodynamic evaluation as a reference method. In contrast, guidelines recommend urodynamic evaluation as one component of the complex algorithm for women with pelvic floor dysfunction.[10] Evaluations of women who report UI symptoms begin with physical examination and exclusion of several potential underlying conditions, including urinary tract infection, pelvic organ prolapse, poor bladder emptying, and post-void residual volume determination.[69] Examination methods for urinary tract infection and pelvic organ prolapse have been addressed by previous reviews, and are beyond our scope.[69,717] Measurement of PVR urine volume can be used to diagnose UI associated with poor bladder emptying. Some experts consider urinary catheterization the gold standard for measuring PVR.[718] However, invasive urinary catheterization can be performed only in specialized care settings. Portable ultrasound is an accurate and feasible method for estimating PVR urine volume in ambulatory care settings.[719,720] Ultrasound is preferable to catheterization when decreased bladder emptying is suspected.[69] Vaginal and transrectal ultrasound accurately diagnosed urodynamic stress UI.[291,292] Other instrumental radiological and magnetic resonance imaging is useful for diagnosis of anatomical pelvic pathology including fibroids, ovarian and uterine tumors, foreign bodies, or diverticulum.[10] Associations are unclear between the criteria for excessive bladder neck mobility identified via ultrasound or MRI and UI treatment outcomes.

Considering the multifactorial syndromatic nature of UI, any one instrument, symptom, or test cannot accurately diagnosis UI type. Clinicians utilize several aspects of patient history, pelvic exam, and other assorted factors to determine UI type and severity.

Diagnosis of Baseline Frequency, Severity, and Bothersomeness of UI

Urodynamic evaluations diagnose the presence of UI but not baseline severity, frequency, or bothersomeness of the condition, all of which help inform the best treatment options. Ambulatory care physicians may choose between several validated tools for diagnosing

predominant stress or urgency UI and for judging treatment effectiveness. Treatment effectiveness for female UI should be assessed according to issues women value: 50 to 70 percent or greater reduction in UI episode frequency, meaningful changes in quality of life measures, and overall treatment satisfaction.[721] Women do not consider small reductions in UI frequency or in urinary loss as treatment success, even though such reductions are statistically significant.[295] Clinically important differences have been determined for several questionnaires and scales.[259,264,296-299] Many validated tools are available to monitor quality of life in women with different UI types. Several tools that define clinically important differences in scores can be used to assess treatment success in clinical settings.[300-302] All tools for assessing symptom bother have been validated. The Incontinence Severity Index,[334,335] Patient Global Impression of Improvement and of Severity,[331] Urogenital Distress Inventory,[222,336,337] and Patient Perception of Bladder Condition[333,338,339] have identified minimum thresholds levels for improvements of clinical importance in UI. Treatment success in clinical settings can be determined according to improvements that meet or exceed these threshold levels.

UI Treatment

Defining and Measuring Outcomes of Treatments for UI

Meaningful assessment of treatment outcomes depends on how those outcomes are defined. Market approval and coverage decisions have been made based on intermediate outcomes rather than on continence or on women's treatment satisfaction. Despite intensive discussions about the importance of patient centered outcomes, the majority of drug studies aimed to detect statistical differences in the frequency of UI episodes. The most common outcome examined by RCTs was a reduction in UI episode frequency.[115,305-326] Previous reviews of drugs for overactive bladder also focused on a reduction in the frequency of UI episodes and the frequency of micturitions.[112,722,723] The FDA reviews focused primarily on the same continuous reduction in UI episode frequency, and not on continence or self-reported treatment success and satisfaction.[115,306,307,327-330] In contrast, our review emphasized the role of clinical outcomes, including continence, quality of life, and adverse effects of treatment.

Treatments for UI

PFMT, bladder training, and electrical stimulation more often result in continence than does no active treatment. Weight loss and exercise improve UI in obese women. Long-term adherence to and benefits of these treatments are not clear, nor are specific characteristics of women associated with better benefits and compliance. The best time to start pelvic muscle floor exercise and bladder training in relation to either menopause or the onset of UI is not clear. Adverse effects with nonpharmacological treatments were uncommon and the magnitude of effect was large.

All drugs for overactive bladder, when compared to placebo, demonstrated better rates of continence and improved UI. All drugs offered similar benefits, but treatment discontinuation due to adverse effects was most common with oxybutynin. Informed decisions, therefore, should consider the drugs' adverse effects. RCTs rarely reported long-term comparative drug safety. In contrast with RCTs, continuous prescription-event monitoring as a part of postmarketing surveillance has provided valuable information about unfavorable long-term safety of tolterodine, which posed significantly higher risk of hallucinations than 10 drugs of other therapeutic classes.[724] Postmarketing surveillance may provide data on long-term safety of UI

drugs when combined with other medications for comorbidities. RCTs did not examine the role of concurrent treatments. For instance, limited information exists on the cognitive effects of drugs in older adults. Older adults had lower risk of depression with tolterodine ER than with oxybutynin IR group (HR, 0.865; 95 percent CI, 0.78 to 0.95).[725] The relative risks of ventricular arrhythmias (adjusted RR 5.5, 95 percent CI, 1.3 to 22.3) or sudden death (adjusted RR 21.5, 95 percent CI, 5.2 to 88.3) were very high in elderly patients using UI medications in combination with antihistamine/cytochrome inhibitors.[726]

Only a few RCTs examined the comparative effectiveness of drugs and nonpharmacological treatments. Direct evidence was insufficient to draw valid conclusions about the benefits of combined modalities compared to monotherapy. Existing guidelines recommend PFMT combined with stress and bladder training as the first treatment choice for women with urgency UI but do not provide evidence-based recommendations about combined therapy.[118] Other guidelines list many treatment options, including electrical intravaginal stimulation and percutaneous tibial nerve stimulation, but do not provide evidence-based recommendations about first therapy options or combined modalities. Existing guidelines may provide individualized treatment recommendations based on age or predominant type of UI, but they do not address baseline severity of UI or comorbidities.

Meanwhile, very few studies provided evidence for individualized treatment decisions. Evidence of aggregate treatment effects may not be applicable to individuals with specific characteristics.[727] An average treatment effect in a clinically diverse population may not reflect the actual effect for a specific group.[728] Yet, few existing studies examined the role of clinical predictors of treatment failure and success in patient subpopulations.[729] Patient comorbidity and baseline severity of UI were associated with differences in treatment benefits. The direction and magnitude of the association varied. Benefits from solifenacin and fesoterodine were greater in those with more than two or three daily episodes of UI; trospium was not better than placebo in those with frequent baseline UI (>5 episodes/day). We are not certain which factors are associated with differences in harms.

Very limited evidence exists for long-term benefits and harms from drugs and nonpharmacological treatments for UI. The bulk of RCTs reported clinical outcomes at 12 to 24 weeks of treatment. A few nonrandomized studies and long-term followup RCTs reported rates of benefits and harms with active treatments, but did not include control comparisons. Such uncontrolled crude rates cannot provide valid information about long-term effects.

Very few studies addressed adherence to prescribed nonpharmacological and drug regimens. Observational economic evaluations[730-732] demonstrated greater absolute rates of treatment discontinuation due to adverse effects or treatment failure than have been demonstrated in RCTs. Long-term adherence to drug treatment for overactive bladder was as low as 13 percent.[725] Among possible explanatory factors for poor adherence is that polypharmacy or previous use of the drugs for urinary tract infections was associated with adherence to drugs for overactive bladder in California Medicaid program beneficiaries.[731]

Cost-effectiveness analyses[730,733-736] were beyond the scope of our review. Our review provides valid information about treatment benefits according to patient-centered outcomes including continence, and about adverse effects that can be used for cost-effectiveness analyses.

The quality of most drug RCTs was good. The majority of drug studies were double blind with adequate randomization, clear reporting of planned intention to treat analysis, and adequate allocation concealment. Benefits and harms with drugs did not differ by individual quality criteria. We concluded low risk of bias in drug studies.

The quality of most nonpharmacological RCTs was good. Baseline data demonstrated adequacy of randomization in the majority of RCTs. Double or single blinding was reported in approximately half of RCTs. Quality of the studies, including intention to treat principle and adequacy of allocation concealment, did not demonstrate significant modification of the association between treatments and patient outcomes. We concluded moderate risk of bias in nonpharmacological studies.

Our review has limitations. We restricted our review to English language studies published in journals, presented at scientific meetings, reviewed by the FDA,[737] or reported on the ClinicalTrials.gov Web site. Even after such an exhaustive review of evidence, we do not know how many studies we missed in our review. We did not review regulatory documents or grant databases from other countries. Evidence was insufficient for individualized treatment recommendations by age, race, comorbidity, and baseline UI. Evidence specific to women whose prior treatments had failed was also insufficient. However, previous research has demonstrated that women with stress UI whose conservative treatments failed may benefit from tension-free vaginal tape procedure.[738] For women with urgency UI whose conservative treatments failed, percutaneous tibial nerve stimulation,[739] sacral neuromodulation,[740] and botulinum toxin injections[741] may be of benefit. We were unable to explain the substantial variability in outcome rates with placebo treatments. Future large, well-designed head-to-head randomized trials may conclude superior efficacy of combined treatment modalities with nonsurgical treatments.

Our findings can inform clinicians' evidence-based recommendations for UI diagnosis and management (Tables 17 and 18). Ambulatory care physicians may arrive at treatment decisions and monitor treatment effectiveness by diagnosing predominant stress or urgency UI and evaluating the frequency, severity, and quality of life at baseline and with treatment. Nonpharmacological treatments offer a better balance between benefits and adverse effects than do drugs. First treatment choice, therefore, might be based on known benefits and harms with nonpharmacological and drug treatments, along with patient preference. Evidence was insufficient to conclude better benefits from nonpharmacological treatments combined with drugs. Women's opinions about treatment success should be considered before combining nonpharmacological treatments with available drugs or increasing the doses of the drugs.

Future Research

Our report points to areas for future research (Table 19). First, future research should clarify which female characteristics are associated with greater benefits and lower harms of treatments and better treatment adherence. Second, treatment success should be assessed with outcomes centered on women, including long-term continence, clinically important reduction in UI episodes, and improvement in scales of severity and quality of life. More work is needed on how physiological measures correspond with symptoms. Third, all harms should be analyzed, regardless of investigator judgment about possible association with tested treatments. Fourth, better drugs are needed. Few of the currently used medications are sustained for even a year, and fewer still are very effective. Fifth, nonsurgical treatments for predominant stress UI are limited to PFMT, with very few ongoing studies of bulking agents and devices. One issue with PFMT is sustaining it. Programs should explore how to extend the period of adherence. Future research should explore new treatment options for women with stress UI and should also address the preventive potential of various nonpharmacological treatments, including PFMT, bladder training, and electrical stimulation, for premenopausal women. The results from all studies,

including 25 closed and 124 ongoing registered studies, should be made available for future reviews of the evidence.

Table 17. Conclusions about diagnosis of UI in women

Conclusions about diagnosis of UI	Level of evidence
Symptoms of stress UI, urgency, or urgency UI have minimal or small diagnostic value to identify women with urodynamic stress UI or detrusor overactivity.	High
Complex clinical algorithms demonstrated better diagnostic performance than symptoms. Individual studies suggested good diagnostic value for questionnaires on the epidemiology of prolapse and incontinence.	Moderate
Women in ambulatory care settings can be accurately diagnosed with UI after obtaining clinical history and evaluation, a voiding diary to assess predominant stress or urgency UI, cough stress test, and exclusion of urogenital prolapse and urinary tract infections.	High
Decisions to start treatments can be based on assessment of frequency, severity, and bothersomeness of UI with validated tools.	High
Urodynamic examination was not associated with better outcomes after nonsurgical treatments for UI.	Moderate
Monitoring treatment success can address differences in the voiding diary (>50-70 percent in frequency of UI episodes) and scales measuring quality of life that are important for women, and womens' impressions of global improvement and treatment satisfaction. A variety of the validated tools are available to monitor quality of life in women with UI and with different UI types. Several tools that can define clinically important differences in scores can be used to assess treatment success in clinical settings.	High

Table 18. Conclusions about management of UI in women

Conclusions	Level of evidence
Drug treatment for predominant stress UI	
Duloxetine was worse than placebo at resolving stress UI.	Low
Duloxetine improved stress UI in women.	High
Risk of adverse effects was significantly higher with duloxetine compared to placebo. Women stopped taking the drug because of nausea, somnolence, insomnia, dizziness, headache, fatigue, diarrhea, and constipation.	High
Drug treatment for predominant urgency UI	
Oxybutynin increased continence rates and improved UI compared to placebo.	High
Oxybutynin increased treatment discontinuation due to adverse effects compared to placebo. Dry mouth was the most common adverse effect.	High
Immediate-release oxybutynin resulted in greater rates of adverse effects and dry mouth when compared to controlled-release oral or transdermal oxybutynin.	Low
Higher vs. lower doses of oxybutynin resulted in greater improvement in UI, the same rates of dry mouth, but greater treatment withdrawal.	Low
Tolterodine increased continence rates and improved UI when compared to placebo.	High
Tolterodine improved quality of life in women with urgency UI.	Low
Adverse effects, including autonomic nervous system disorders, abdominal pain, dry mouth, dyspepsia, and fatigue, were significantly more common in women taking tolterodine compared to placebo.	High
Discontinuation of the treatment and stopping the treatment due to adverse effects did not differ with tolterodine compared to placebo.	High
Darifenacin, 7.5 and 15 mg, improved urgency UI and several domains of quality of life when compared to placebo.	High
Adverse effects were more common with darifenacin than placebo. Among examined adverse effects, darifenacin increased rates of constipation, dry mouth, dyspepsia, and headache.	Moderate
Larger dose, 30 mg of darifenacin/day, did not result in better benefits but caused greater rates of adverse effects.	High
Treatment discontinuation rates because of adverse effects were the same with darifenacin vs. placebo.	High
Solifenacin increased continence rates, with greater benefits with the larger dose of the drug in women with urgency and mixed UI.	High
Solifenacin increased risk of dry mouth, constipation, and blurred vision; 10 mg of solifenacin increased the risk of severe dry mouth and constipation.	High
Treatment discontinuation because of adverse effects was more common with solifenacin compared to placebo.	High
Fesoterodine increased continence rate when compared to placebo.	Low
Fesoterodine improved urgency UI compared to placebo, with a better response with 8 mg vs. 4 mg.	High
Fesoterodine improved quality of life in women with urgency UI.	Low
Fesoterodine treatment resulted in higher rates of adverse effects and discontinuation of the treatments because of adverse effects compared to placebo. Adverse effects were more common with 8 mg compared to 4 mg of fesoterodine.	High
Trospium increased continence rate when compared to placebo.	High
Women experienced dry mouth, dry eye, dry skin, and constipation more often with the drug than with placebo.	Moderate
Treatment discontinuation because of adverse effects was more common with trospium than with placebo.	High
Fesoterodine resulted in greater rates of continence when compared to tolterodine.	Low
Fesoterodine resulted in greater rates of improved UI when compared to tolterodine.	High
Fesoterodine resulted in greater treatment discontinuation due to adverse effects when compared to tolterodine.	Moderate
Oxybutynin resulted in greater treatment discontinuation due to adverse effects when compared to tolterodine.	High
Improvement in UI did not differ with oxybutynin when compared to tolterodine.	Moderate
Adherence to drug treatments is low; more than 50 percent of women stopped treatments within 1 year.	Moderate

Table 18. Conclusions about management of UI in women (continued)

Conclusions	Level of evidence
Role of women characteristics in association with treatment effects	
Age did not modify the effects of the tested drugs on examined clinical outcomes.	Moderate
Duloxetine was no better than a placebo in improving UI in older women.	High
Solifenacin increased continence rate when compared to placebo, irrespective of age.	High
Baseline frequency of UI did not dramatically modify the effects of the drugs on clinical outcomes. Subjects with more frequent UI had slightly greater benefits when compared to placebo.	Low
Solifenacin was effective irrespective of the response to previous treatments, even though poor responders did not benefit from increasing the dose of the drug.	High
Trospium was more effective than placebo in achieving continence in obese and nonobese adults.	High
Trospium reduced number of urgency UI episodes irrespective of taking concomitant drugs. Adverse effects were more common in those taking seven or more concomitant medications.	Moderate
Nonpharmacological treatments	
Stress UI	
Pelvic floor muscle training increased continence rate and improved UI when compared to no active treatment.	High
PFMT also improved several domains of quality of life in women with UI.	Low
PFMT with biofeedback increased continence rate when compared to usual care.	Low
PFMT with biofeedback improved UI when compared to usual care.	High
Electrical stimulation increased continence rate and improved UI when compared to sham stimulation.	High
Electrical stimulation improved quality of life when compared to sham stimulation.	Moderate
Magnetic stimulation improved UI but did not increase urinary continence rates when compared to sham stimulation.	Moderate
Magnetic stimulation improved quality of life.	Low
Uncontrolled studies of intravaginal and intraurethral devices demonstrated improvement in UI but also high discontinuation rates and evident harms.	Low
Continence did not differ with PFMT + biofeedback when compared to PFMT.	High
Continence did not differ with supervised PFMT when compared to PFMT.	High
Continence did not differ with PFMT when compared to electrical stimulation.	Moderate
Urgency UI	
Bladder training improved UI compared to usual care.	Low
PFMT combined with bladder training increased continence rate and improved UI.	High
PFMT combined with bladder training reduced severity of UI.	Low
Percutaneous tibial nerve stimulation improved predominant urgency UI.	Moderate
Continence did not differ with PFMT + bladder training when compared to bladder training.	High
Mixed UI	
Continence services that were implemented by specialized health care providers increased continence and improved UI when compared to usual care.	Low
Weight loss and exercise improved UI in obese women.	Moderate
Acupuncture improved quality of life when compared to sham acupuncture.	Low

Table 19. Future research recommendations

Key question	Results of literature review	Types of studies needed to answer question	Future research recommendation
What constitutes an adequate diagnostic evaluation for women in the ambulatory care setting on which to base treatment of urinary incontinence (UI)?	Symptoms of stress UI, urgency, or urgency UI have minimal or small diagnostic value to identify women with pure urodynamic stress UI or detrusor overactivity. Urodynamic examination was not associated with better outcomes after nonsurgical treatments for UI. Monitoring treatment success can address differences in the voiding diary (>70 percent in the frequency of UI episodes) and scales measuring quality of life that are important for women, and women's impressions of global improvement and treatment satisfaction.	Observational studies	Examine the association between diagnostic algorithms that include voiding diary, validated questionnaires to determine frequency and severity of pure or predominant stress and urgency UI, and baseline quality of life with or without portable ultrasound with the effects of nonpharmacological treatments. Determine minimal clinically important reduction in frequency and severity of different types of UI in women subpopulations by age, baseline severity and frequency, and bothersomeness. Examine the association between diagnostic values with women's treatment preferences. Determine whether women in clinical settings receive adequate diagnostic evaluation to differentiate pelvic floor trauma, pelvic organ prolapsed, urinary tract infection, and UI associated with poor bladder emptying. Examine treatment effects in women who failed initial diagnostic evaluation (delayed diagnosis).
How effective is the pharmacological treatment of UI in women?	Women with predominant urgency UI may achieve continence taking antimuscarinic drugs including trospium, solifenacin, fesoterodine, tolterodine, or oxybutynin. Degree of the benefits was low for all drugs (absolute risk difference <20 percent). Drugs demonstrated similar effectiveness, but treatment discontinuation due to adverse effects was most common after oxybutynin and least common after solifenacin. Dry mouth, constipation, and blurred vision are among the most frequent adverse effects. Evidence of long-term safety of pharmacological treatments is insufficient.	Head-to-head trials Pooled analysis of individual patient data	Examine effectiveness of the drugs on long term continence and adverse effects in women with pure urgency vs. mixed UI. Examine comparative effectiveness of all available antimusarinic drugs on continence, reduction by 70% in UI episodes, quality of life, adverse effects, and discontinuation due to adverse effects in female subgroups by age, race, baseline predominant type and severity of UI, comorbidities, and prior treatment status.

Table 19. Future research recommendations (continued)

Key question	Results of literature review	Types of studies needed to answer question	Future research recommendation
How effective is the nonpharmacological treatment of UI in women?	Nonpharmacological treatments result in significant clinical benefit with low risk of adverse effects. Women with predominant stress UI can achieve continence performing PFMT. Continence rates are similar between those who undergo PFMT with and without biofeedback. Women with predominant urgency UI can achieve continence performing PFMT with bladder training and/or electrical stimulation. Weight loss may improve UI in obese women.	Head-to-head trials Pooled analysis of individual patient data	Examine effectiveness of nonpharmacological treatments on long-term continence and treatment adherence in women with pure urgency or stress vs. mixed UI. Examine comparative effectiveness of nonpharmacological treatments on continence, reduction by 70% in UI episodes, quality of life, and treatment adherence in female subgroups by age, race, baseline predominant type and severity of UI, comorbidities, and prior treatment status. Examine continence in women with UI by the onset time of UI and the order of the prescribed nonpharmacological treatments. Examine which women subpopulations may benefit from combined (drugs + nondrug) treatments. Examine the effectiveness of different methods for delivering nonpharmacological treatments on short-term and long-term continence, reduction by 70% in UI episodes, quality of life, and treatment adherence in female subgroups by age, race, baseline predominant type and severity of UI, comorbidities, and prior treatment status.

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Abbreviations

AHRQ	Agency for Healthcare Research and Quality
ARD	Absolute risk difference
BMI	Body Mass Index
CI	Confidence interval
ER	Extended release
FDA	Food and Drug Administration
ICI	International Consultation on Incontinence
ICS	International Continence Society
I-QOL	Incontinence Quality of Life
IUGA	International Urologynecological Association
MeSH	Medical Subject Headings
NNT	Number needed to treat
OAB	Overactive bladder
OPERA	Overactive bladder: Performance of Extended Release Agents
PFMT	Pelvic floor muscle training
PVR	Post-void residual
RCTs	Randomized controlled trials
RR	Relative risk
SRC	Scientific Resource Center
UDI	Urogenital Distress Inventory
UI	Urinary incontinence

Appendix A. Search Strings

April 14, 2009

Literature Strings	Result
Search ("Urinary Incontinence/radiotherapy"[Mesh] OR "Urinary Incontinence/rehabilitation"[Mesh] OR "Urinary Incontinence/surgery"[Mesh] OR "Urinary Incontinence/therapy"[Mesh]) Limits: Humans, Randomized Controlled Trial, English	612
Search ("Urinary Incontinence/radiotherapy"[Mesh] OR "Urinary Incontinence/rehabilitation"[Mesh] OR "Urinary Incontinence/surgery"[Mesh] OR "Urinary Incontinence/therapy"[Mesh]) Limits: Humans, Journal Article, English	9,182
Search "Epidemiologic Studies"[Mesh] AND #4 Limits: Humans, Journal Article, English	2,367
Search "Epidemiologic Studies"[Mesh] Limits: Humans, Journal Article, English	901,758
Search ("Urinary Incontinence/radiotherapy"[Mesh] OR "Urinary Incontinence/rehabilitation"[Mesh] OR "Urinary Incontinence/surgery"[Mesh] OR "Urinary Incontinence/therapy"[Mesh])	13,222

April 16, 2009
Question 1.
Database: Ovid MEDLINE(R) <1950 to April Week 1 2009> Search Strategy:
>---
>1 exp Urinary Incontinence/di [Diagnosis] (2,523)
>2 limit 1 to (english language and humans and (guideline or practice guideline)) (13)
>3 exp Clinical Protocols/ (91,702)
>4 1 and 3 (18)
>5 exp Decision Trees/ (6,776)
>6 1 and 5 (19)
>7 6 or 4 (34)
>8 limit 7 to (English language and humans) (25)
>9 2 or 8 (37)

Question 3.
>Database: Ovid MEDLINE(R) <1950 to April Week 2 2009> Search Strategy:
>---
>1 exp urinary incontinence/dh, th, su, rt (9,205)
>2 exp urinary incontinence/dt (1,539)
>3 1 not 2 (8,998)
>4 (non pharmacologic or nonpharmacologic).mp. (2,448)
>5 1 and 4 (8)
>6 exp treatment outcome/ (383,394)
>7 exp epidemiologic studies/ (1,103,515)
>8 3 or 5 (9,001)
>9 6 and 7 and 8 (939)
>10 exp quality of life/ (73,696)
>11 7 and 8 and 10 (230)
>12 9 or 11 (1,032)
>13 limit 12 to (English language and humans) (908)
>14 limit 13 to journal article (893)

Questions 2, 5, and 9

>Database: Ovid MEDLINE(R) <1950 to April Week 2 2009> Search Strategy:
>----------
>1 exp urinary incontinence/dt (1,539)
>2 exp treatment outcome/ (383,394)
>3 exp quality of life/ (73,696)
>4 3 or 2 (444,907)
>5 4 and 1 (365)
>6 exp epidemiologic studies/ (1,103,515)
>7 6 and 5 (96)
>8 limit 7 to (English language and humans) (85)
>9 limit 8 to journal article (84)

Question 4.
>Database: Ovid MEDLINE(R) <1950 to April Week 2 2009> Search Strategy:
>----------
>1 exp Urinary Incontinence/dh, nu, th, su, rt, dt, rh [Diet Therapy, Nursing, Therapy, Surgery, Radiotherapy, Drug Therapy, Rehabilitation] (12,453)
>2 exp Office Visits/ or exp Medical Office Buildings/ (4554)
>3 exp Hospitals/ (161857)
>4 exp Nursing Homes/ (26676)
>5 4 or 3 or 2 (191276)
>6 1 and 5 (314)
>7 exp epidemiologic studies/ (1103515)
>8 6 and 7 (52)
>9 limit 8 to (English language and humans) (48)

Question 6.
>Database: Ovid MEDLINE(R) <1950 to April Week 2 2009> Search Strategy:
>----------
>1 exp urinary incontinence/ (20,881)
>2 exp primary health care/ (55,252)
>3 1 and 2 (124)
>4 exp epidemiologic studies/ (1,103,515)
>5 4 and 3 (16)
>6 exp physician-patient relations/ (48,990)
>7 6 and 4 and 1 (12)
>8 7 or 5 (26)
>9 limit 8 to English language (23)
>10 limit 9 to journal article (22)

Question 7.
>Database: Ovid MEDLINE(R) <1950 to April Week 2 2009> Search Strategy:
>----------
>1 exp Urinary Incontinence/di [Diagnosis] (2,529)
>2 exp Diagnosis, Differential/ (316,330)
>3 1 and 2 (190)
>4 limit 3 to (English language and humans) (115)

Question 8.
>Database: Ovid MEDLINE(R) <1950 to April Week 2 2009> Search Strategy:
>----------
>1 exp Urinary Incontinence/th, su, dt, rh [Therapy, Surgery, Drug Therapy, Rehabilitation] (11,383)
>2 exp Treatment Outcome/ (383,394)
>3 1 and 2 (2,157)
>4 exp Evidence-Based Practice/ or exp Evidence-Based Medicine/ or evidence.mp. (756,148)
>5 4 and 3 (146)
>6 limit 3 to "therapy (optimized)" (399)
>7 6 or 5 (502)
>8 limit 7 to (English language and humans) (463)
>9 exp epidemiological studies/ (1,103,515)
>10 8 and 9 (180)
>11 limit 10 to journal article (177)

April 27, 2009

Literature Strings	Results
Search "Health Services Research"[Mesh] AND "Urinary incontinence" [Mesh] NOT review Limits: Humans, Journal Article, English	137

April 20, 2009
#10 Select 12 document(s) 17:17:22 12 #9 Search "Evidence-Based Medicine"[Mesh] Urinary incontinence Limits: Humans, English 17:03:46 124
#17 Search "Caregivers"[Mesh] AND "Urinary Incontinence"[Mesh] NOT review Limits: Humans, Journal Article, English 17:32:56 22

Search	Literature Strings	Result
Search #6 or #7 Limits: Humans, Randomized Controlled Trial, English		46
Search #6 or #7 Limits: Humans, English		758
Search #9 and #1 and #3 Limits: Humans, Randomized Controlled Trial, English		402
Search #9 and #1 and #3 Limits: Humans, English		5,442
Search clinic or office or hospital or nursing home or longterm care, Limits: Humans, English		1,645,316
Search "health services research"[MeSH Terms] and urine incontinence Limits: Humans, English		214
Search #4 or #5 Limits: Humans, English		588
Search "Physician's Practice Patterns"[MeSH Terms] and urine incontinence Limits: Humans, English		64
Search #1 and #2 and #3		539
Search treatment or outcome		3,837,858
Search primary care or specialized care or urologist or urogynecologist		118,680
Search urine incontinence		18,607
Search urine incontinence and professional practice Limits: Humans, English		228
Stem cell AND "urinary incontinence" Limits: Humans, Journal Article, English		42
Estrogen AND "urinary incontinence" Limits: Humans, Journal Article, English		368
Adrenergic Uptake Inhibitors AND "urinary incontinence" Limits: Humans, Journal Article, English		162
Imipramine hydrochloride AND "urinary incontinence" Limits: Humans, Journal Article, English		76
Tricyclic antidepressant AND "urinary incontinence" Limits: Humans, Journal Article, English		81
Botulinum toxin AND "urinary incontinence" Limits: Humans, Journal Article, English		109
Alpha-blockers AND "Urinary Incontinence" Limits: Humans, Journal Article, English		101
Solifenacin AND "Urinary Incontinence" Limits: Humans, Journal Article, English		48
Vesicare AND "Urinary Incontinence" Limits: Humans, Journal Article, English		4
Enablex AND "Urinary Incontinence" Limits: Humans, Journal Article, English		54
Sanctura AND "Urinary Incontinence" Limits: Humans, Journal Article, English		3
Ditropan AND "Urinary Incontinence" Limits: Humans, Journal Article, English		286
Detrol AND "Urinary Incontinence" Limits: Humans, Journal Article, English		198
"Urinary Incontinence" Limits: Humans, Randomized Controlled Trial, English		789
("Urinary Incontinence/radiotherapy"[Mesh] OR "Urinary Incontinence/rehabilitation"[Mesh] OR "Urinary Incontinence/surgery"[Mesh] OR "Urinary Incontinence/therapy"[Mesh]) Limits: Humans, Randomized Controlled Trial, English		621
("Urinary Incontinence/radiotherapy"[Mesh] OR "Urinary Incontinence/rehabilitation"[Mesh] OR "Urinary Incontinence/surgery"[Mesh] OR "Urinary Incontinence/therapy"[Mesh])		13,302
"Caregivers"[Mesh] AND "Urinary Incontinence" Limits: Humans, Journal Article, English		40
"Physician-Patient Relations" [Mesh] AND "Urinary incontinence"		48
"Delivery of Health Care"[Mesh] AND "Urinary incontinence" Limits: Humans, Journal Article, English		1,438
"Health services re"[MeSH] AND "Urinary incontinence" Limits: Humans, Journal Article, English		186
"Physician's Practice Patterns"[MeSH] AND "Urinary incontinence" Limits: Humans, Journal Article, English		57
"Quality of life" AND "Urinary incontinence" Limits: Humans, Journal Article, English		1,689
"Urinary Incontinence/diagnosis"[Mesh] Limits: Humans, Randomized Controlled Trial, English		83
"Urinary Incontinence/diagnosis"[Mesh] Limits: Humans, Journal Article, English		2,328
"Epidemiologic Studies"[Mesh] AND "Urinary Incontinence/diagnosis"[Mesh] Limits: Humans, Randomized Controlled Trial, Controlled Clinical Trial, Multicenter Study, Validation Studies, English		66
"Urinary Incontinence" AND urologist Limits: Humans, Journal Article, English		78
"Urinary Incontinence" AND urogynecologist Limits: Humans, Journal Article, English		7
"Urinary Incontinence" AND gynecologist Limits: Humans, Journal Article, English		29

June 26, 2009

Search (Urinary incontinence) AND systematic[sb]	581
Search diary AND "urinary incontinence" AND sensitivity Limits: Humans, English	20

July 20, 2009

Cochrane RCT database:

Urinary incontinence and Women	457
Urinary incontinence NOT surgery	138

Updated search August 20, 2009

Search ("Urinary Incontinence/diagnosis"[Mesh] OR "Urinary Incontinence/diet therapy"[Mesh] OR "Urinary Incontinence/drug therapy"[Mesh] OR "Urinary Incontinence/therapy"[Mesh]) Limits: published in the last 180 days, Humans, Journal Article, English, All Adult: 19+ years	86

October 13, 2009

Search "Duloxetine Urinary Incontinence Study Group"[Corporate Author]	4

Updated search November 10, 2009

Search (("Urinary incontinence"[Text Word]) AND ("2009/04/01"[Publication Date] : "3000"[Publication Date])) AND (Urinary incontinence) Limits: Randomized Controlled Trial English	33

March 25, 2010

Search tolterodine Limits: Randomized Controlled Trial ("2009/04/01"[Publication Date] : "3000"[Publication Date])) AND (Urinary incontinence) Limits: Randomized Controlled Trial, English	134
Search fesoterodine	48
Search Solifenacin	194

March 30, 2011

"urinary incontinence" OR "overactive bladder" OR fesoterodine OR oxybutynin OR trospium OR solifenacin OR tolterodine Limits: Female, Randomized Controlled Trial, English, All Adult: 19+ years	865

Grey Literature search using key words ”Urinary incontinence” on July 27, 2010:

Regulatory Information
FDA
Health Canada
Authorized Medicines for EU

Clinical Trial Registries
ClinicalTrials.gov - 120
Search for UI among all close studies: additional -100 records
Australian New Zealand Clinical Trials Registry (ANZCTR) - 1
Clinical Study Results - 4
WHO Clinical Trials - 18
Clinical Trials Registry - India (CTRI) - 1
Japanese Registry of clinical trials (JPRN) - 4
Netherlands Trial Register - 6

Abstracts and Conference Papers
Conference Papers Index - 318
Scopus - 243
International Continence Society and the International Urogynecological Association – 2010 meeting

Grants and Federally Funded Research
NIH RePORTER (a searchable database of federally funded biomedical research projects conducted at universities, hospitals, and other research institutions)- 487

September 2010

"Urinary incontinence" OR "overactive bladder" OR fesoterodine OR oxybutynin OR trospium OR solifenacin OR tolterodine Limits: Female, Randomized Controlled Trial, English, All Adult: 19+ years	794
"Urinary incontinence" Limits: Humans, Journal Article, English, All Adult: 19+ years, Publication Date from 2009/01/01 to 2010/12/31	903

Additional searches recommended by the peer reviewers

Contigen "urinary incontinence" Limits: Humans, Randomized Controlled Trial, Multicenter Study, English	10
Search "transcutaneous tibial nerve stimulation" AND "urinary incontinence" NOT review Limits: Humans, English	11
Search "tibial nerve stimulation" AND "urinary incontinence" NOT review Limits: Humans, English	16

Table A1. Results of the request for Scientific Information Packets (SIP) by the Scientific Resource Center

Company	SIP Letter Sent	SIP Received
Abbott Laboratories	8/13/2010	[no SIP]
Accelerated Care Plus	8/13/2010	[no SIP]
ACP - Accelerated Care Plus Corporation	8/13/2010	[no SIP]
Actavis US	8/13/2010	[no SIP]
AL Voss Associates	8/13/2010	[no SIP]
Allergan, Inc.	8/13/2010	[no SIP]
Astellas Pharmaceuticals	8/13/2010	[no SIP]
AstraZeneca Pharmaceuticals, LP	8/13/2010	[no SIP]
Bioness, Inc.	8/13/2010	[no SIP]
BIOTEQUE AMERICA, INC.	8/13/2010	[no SIP]
Bristol-Myers Squibb	8/13/2010	[no SIP]
Duramed Subsidiary of Barr Pharmaceuticals	8/13/2010	[no SIP]
Eli Lilly & Co	8/13/2010	[no SIP]
Hollister Incorporated	8/13/2010	[no SIP]
Impax Laboratories, Inc.	8/13/2010	[no SIP]
Ivax Pharmaceuticals (Teva Pharmaceuticals)	8/13/2010	[no SIP]
Laborie Medical Technologies	8/13/2010	[no SIP]
Mentor Corp	8/13/2010	[no SIP]
Mikart	8/13/2010	[no SIP]
Mutual Pharma (URL Pharma Inc)	8/13/2010	[no SIP]
Mylan Pharmaceuticals	8/13/2010	[no SIP]
New River Pharmaceuticals	8/13/2010	[no SIP]
Nexstim Inc	8/13/2010	[no SIP]
Novartis Pharmaceuticals Corporation	8/13/2010	[no SIP]
Novavax Inc.	8/13/2010	[no SIP]
Nycomed US Inc	8/13/2010	[no SIP]
Odyssey Pharmaceuticals, Inc	8/13/2010	[no SIP]
Ortho-McNeil Janssen Scientific Affairs, LLC	8/13/2010	8/31/2010
Osmotica Pharmaceutical Corp	8/13/2010	[no SIP]
Pfizer Inc	8/13/2010	[no SIP]
Purepac Pharmaceuticals	8/13/2010	[no SIP]
Ranbaxy	8/13/2010	[no SIP]
Reliant Technologies, Inc.	8/13/2010	[no SIP]
Roche Laboratories	8/13/2010	[no SIP]
Rochester Medical Corporation	8/13/2010	9/10/2010
Roxane	8/13/2010	[no SIP]
Sandoz Inc	8/13/2010	[no SIP]
Sanofi Aventis US	8/13/2010	[8/27/2010 nothing to supply]
Schering-Plough Corporation	8/13/2010	[no SIP]
Silarx Pharmaceuticals, Inc.	8/13/2010	[no SIP]
Somaxon Pharmaceuticals	8/13/2010	[no SIP]
Taro Pharmaceuticals	8/13/2010	[no SIP]
Teva Pharmaceuticals USA	8/13/2010	[no SIP]
UCB, Inc	8/13/2010	[no SIP]
USL Pharmaceuticals	8/13/2010	[no SIP]
Vanguard Pharma	8/13/2010	[no SIP]
Warner Chilcott Company, Inc.	8/13/2010	[no SIP]
Wockhardt	8/13/2010	[no SIP]
Wyeth Pharmaceuticals Headquarters	8/13/2010	[no SIP]
PLIVA HRVATSKA DOO	8/13/2010	[no SIP]
Tyco Healthcare UK Commercial Ltd.	8/13/2010	[no SIP]

Appendix B. Excluded Studies

(Note that this set of references is different from those in the text, and the numbers are different.)

(Reason for exclusion shown in italics at the end of each reference.)

1. Evaluation and treatment of urinary incontinence. Urologic Clinics of North America 1991; 18(2):175-407. *Level of evidence*
2. Safety in the therapy of urinary incontinence. A workshop on the occasion of the 22nd Congress of the International Urology Society, Seville, 4 November 1991. Sicherheitin der Harninkontinenz-Therapie. Workshop anlässlich des 22. Kongresses der Societé International d'Urologie, Sevilla, 4, November 1991. 1992; 31(2 Suppl):1-12. *Level of evidence*
3. Safety in the therapy of urinary incontinence. II. Specialty workshop, 22nd Congress of the International Society of Urology. Seville, 4 November 1991. Sicherheit in der Harninkontinenz-therapie. II. Fachpresse-workshop, 22. Kongresses der Societé International d'Urologie. Sevilla, 4 November 1991. 1992; 25(1 Suppl):1-12. *Level of evidence*
4. Stress urinary incontinence in clinical practice. Advanced Studies in Medicine 2003; 3(8 E). *Level of evidence*
5. Successful treatment possibilities for urinary incontinence - The 2 nd Urogynecology Congress in St. Veit a.d. Glan. Erfolgreiche behandlungs-möglichkeiten bei harninkontinenz - 2. Urogynäkologie-Kongress in St. Veit a.d. Glan 2004; 11(2):43. *Level of evidence*
6. Advancing the treatment of fecal and urinary incontinence through research: trial design, outcome measures, and research priorities. Proceedings of a consensus conference. November 3-5, 2002. Milwaukee, Wisconsin, USA. Gastroenterology 2004; 126(1 Suppl 1). *Level of evidence*
7. Aaronson PS, Loehner D, Bingham W, et al. Intravaginal electrical stimulation in the treatment of genuine stress urinary incontinence and detrusor instability: A controlled study. Paper presented at: American Urological Society 90th Annual Meeting, Las Vegas, NV (USA), 23-28 April 1995. (World Meeting Number 952 0772). *Level of evidence*
8. Abdelbary A. Evaluation of prolene mesh as a trans-obturator tape for treatment of female stress urinary incontinence. Paper presented at: 38th Annual Meeting of the International Continence Society (ICS 2008), Cairo International Congress Center (CICC), Cairo (Egypt), 20-24 Oct 2008. *Level of evidence*
9. Abdel-Karim AM, Hassouna ME, Koraitem MA, et al. Vaginal Inter-Pubic Perineorraphy for Treatment of Female Stress Urinary Incontinence: A New Technique. Paper presented at: 31st Annual Meeting of the International Urogynecological Association, Athens Hilton Hotel, Athens (Greece), 6-9 Sep 2006. *Level of evidence*

10. Abramov Y, Rosen T, Feiner B, et al. Does a 'One Stop' Urogynecologic Clinic Improve Patients' Compliance for Behavioral Therapy for Urinary Incontinence? Paper presented at: 31st Annual Meeting of the International Urogynecological Association, Athens Hilton Hotel, Athens (Greece), 6-9 Sep 2006. *Level of evidence*

11. Accorsi-Neto AC. Long-term evaluation of patients with Kelly Kennedy surgery for urinary incontinence treatment. Paper presented at: XVII FIGO World Congress of Gynecology and Obstetrics, Santiago (Chile), 2-7 Nov 2003. (World Meeting Number 000 7240). *Level of evidence*

12. ACTRN12605000755639. Efficacy of non-invasive magnetic stimulation of the pelvic floor in the control of urinary incontinence. *Not eligible exposure*

13. Adamiak A, Jankiewicz K, Miotla P, et al. Efficacy and safety of transobturator approach in the treatment of female stress urinary incontinence. Paper presented at: 12th World Congress on Human Reproduction, Venice (Italy), 10-13 Mar 2005. (World Meeting Number 000 0000). *Level of evidence*

14. Adile B. New treatment for stress urinary incontinence. Paper presented at: XVII FIGO World Congress of Gynecology and Obstetrics, Santiago (Chile), 2-7 Nov 2003. (World Meeting Number 000 7240). *Level of evidence*

15. Adile B, Gugliotta G, Adile G. A two-year follow-up of a new readjustable transobturator approach for surgical treatment of female stress urinary incontinence. Urogynaecologia International Journal 2006; 20(2):307-9. *Level of evidence*

16. Adile B, Liguori P, Pisapia G, et al. Tension-free vaginal tape for surgical treatment of stress urinary incontinence. An Italian multicenter study and two year follow-up. TVT per il trattamento chirurgico della incontinenza urinaria da sforzo. Studio multicentrico italiano. Follow-up a due anni 2001; 15(1 SUPPL.):68. *Level of evidence*

17. Adile B, Palma P, Thiel R, et al. Female sexual function before and after treatment of urinary incontinence. Urogynaecologia International Journal 2005; 19(1 SUPPL.):365-72. *Level of evidence*

18. Adile BA, Gugliotta GG, Adile GA. A Two-Year Follow-Up of a New Readjustable Transobturator Approach for Surgical Treatment of Female Stress Urinary Incontinence. Paper presented at: 31st Annual Meeting of the International Urogynecological Association, Athens Hilton Hotel, Athens (Greece), 6-9 Sep 2006. *Level of evidence*

19. Aguirre OA. Acute Pudendal Nerve Stimulation Improves Cystometric Volumes in Urge Incontinent Patients. Paper presented at: 31st Annual Meeting of the International Urogynecological Association, Athens Hilton Hotel, Athens (Greece), 6-9 Sep 2006. *Level of evidence*

20. Agur W, Steggles P, Waterfield M, et al. Is Antenatal Pelvic Floor Muscle Training Still Effective after Eight Years? Paper presented at: 31st Annual Meeting of the International Urogynecological Association, Athens Hilton Hotel, Athens (Greece), 6-9 Sep 2006. *Level of evidence*

21. Al-Hazmi HH. Endoscopic Polydimethylsiloxane Treatment of Intractable Sphincteric Urinary Incontinence. Paper presented at: 18th Annual Saudi Urological Conference, Jeddah (Saudi Arabia), 20-23 Feb 2006. *Level of evidence*

22. Alio L, Accursio MC, Incandela S, et al. Pelvic perineal kinesitherapy combined with functional electric stimulation in the treatment of urinary incontinence in women. Elettrostimolazione funzionale associata alla chinesi terapia pelvi-perineale nel trattamento conservativo della I.U. femminile 2001; 15(1 SUPPL.):46-7. *Level of evidence*

23. Almeida SHM, Gregório E, Grando JPS, et al. Pubovaginal sling using cadaveric allograft fascia for the treatment of female urinary incontinence. Transplantation Proceedings 2004; 36(4):995-6. *Level of evidence*

24. Amarenco G. On the subject of the ANAES Recommendations for good practice: Management of female urinary incontinence in general medicine (May 2003). À propos des RPC de l'ANAES: Prise en en charge de l'incontinence urinaire de la femme en ḿdecine ǵ ńrale (mai 2003) 2004; 32(12):1082. *Level of evidence*

25. Amaro JL, Jesus CMN, Yamamoto H, et al. A New Surgical Approach to Treatment of Urethral Stenosis Associated with Stress Urinary Incontinence in Woman. Paper presented at: 2008 Annual Meeting of the American Urological Association, Orlando, Florida (USA), 17-22 May 2008. *Level of evidence*

26. Amaro JL, Yamamoto HA, Kawano PR, et al. A Prospective Randomized Trial of Autologous Fascial Sling (AFS) Versus Tension-Free Vaginal Tape (TVT) for Treatment of Stress Urinary Incontinence (SUI). Paper presented at: 2007 Annual Meeting of the American Urological Association (AUA 2007), Anaheim, California (USA), 19-24 May 2007. *Level of evidence*

27. Amaye-Obu FA, Drutz HP. Surgical management of recurrent stress urinary incontinence: A 12-year experience. American Journal of Obstetrics and Gynecology 1999; 181(6):1296-309. *Level of evidence*

28. Amicarelli F, Bougnaguidi A, Pifarotti P, et al. Combined treatment of anterior vaginal prolapse associated with stress urinary incontinence using tension-free vaginal tape and endopelvic tascia plication. Trattamento combinato del prolasso vaginale anteriore associato ad incontinenza utinaria da sforza mediante tension-free vaginal tape e duplicatura dell fascia pubovescicocervicale 2001; 15(1 SUPPL.):51-4. *Level of evidence*

29. Anaf V, Simon P, Buxant F. Treatment of stress urinary incontinence in women and the place of physiotherapy. Le traitement de l'incontinence urinaire chez la femme et la place de la kinésithérapie 2003; 24(4). *Level of evidence*

30. Andersson KE. Muscarinic receptor antagonists in the treatment of urinary incontinence - Clinical experience. Paper presented at: The 9th Symposium on Subtypes of Muscarinic Receptors, Houston, Texas (USA), 31 Oct-4 Nov 2000. (World Meeting Number 000 5147). *Level of evidence*

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215. ISRCTN34759911. Colposuspension or tension free vaginal tape with anterior repair for urinary incontinence and prolapse: a pilot study. *Not eligible exposure*

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Appendix C. Analysis of Results From Ongoing Studies

Appendix Table C1. Distribution of studies of nonsurgical treatments for UI closed in www.clinicaltrials.gov on May 20, 2010

Categories	Type	Frequency	Percent
Gender	Both	95	57.23
	Female	71	42.77
Age Groups	Adult	15	9.04
	Adult |Senior	147	88.55
	Child |Adult |Senior	4	2.41
Diagnosis	Incontinence	3	1.81
	Overactive Bladder	96	57.83
	Stress Urinary Incontinence	13	7.83
	Urge Incontinence	4	2.41
	Urinary Incontinence	50	30.12
Funding Sources	Industry	122	73.49
	NIH	5	3.01
	NIH/Other	1	0.6
	Other	23	13.86
	Other/Industry	10	6.02
	Other/NIH	1	0.6
	Other/U.S. Fed	1	0.6
	Other|Unknown/U.S. Fed	1	0.6
	U.S. Fed	2	1.2
Study Types	Interventional	145	87.35
	Observational	21	12.65
Phases of Clinical Trials	Phase I	9	6.57
	Phase II	32	23.36
	Phase III	59	43.07
	Phase II/Phase III	3	2.19
	Phase IV	32	23.36
	Phase I/Phase II	2	1.46
Interventions	Behavioral	8	5.3
	Biological	4	2.65
	Device	10	6.62
	Dietary supplement	1	0.66
	Drug	121	80.13
	Genetic	1	0.66
	Other	4	2.65
	Procedure	2	1.32
Recruitment	Active, not recruiting	26	15.66
	Completed	120	72.29
	Enrolling by invitation	5	3.01
	Terminated	12	7.23
	Withdrawn	3	1.81
Study Results	Has Results	7	4.22
	No Results Available	159	95.78
Publication	No	138	83.13
	Yes	28	16.87

The numbers may not round to the same sum of 166 studies because of missing information.

Appendix Table C2. Posting of results of UI studies by study category in www.clinicaltrial.gov

Categories	Type	Has results	No results available	Total	% with results
Gender	Both	7	88	95	7.4
	Female	0	71	71	0.0
Age	Adult	0	15	15	0.0
	Adult/Senior	7	140	147	4.8
	Child/Adult/Senior	0	4	4	0.0
Diagnosis	Incontinence	0	3	3	0.0
	Overactive Bladder	6	90	96	6.3
	Stress Urinary Incontinence	0	13	13	0.0
	Urge Incontinence	0	4	4	0.0
	Urinary Incontinence	1	49	50	2.0
Sponsorship	Industry	6	116	122	4.9
	NIH	0	5	5	0.0
	NIH/Other	0	1	1	0.0
	Other	0	23	23	0.0
	Other/Industry	0	10	10	0.0
	Other/NIH	1	0	1	100.0
	Other/U.S. Fed	0	1	1	0.0
	Other/Unknown/U.S. Fed	0	1	1	0.0
	U.S. Fed	0	2	2	0.0
Study Type	Interventional	7	138	145	4.8
	Observational	0	21	21	0.0
Phase of Clinical Trials	Phase I	0	9	9	0.0
	Phase I/Phase II	0	2	2	0.0
	Phase II	1	31	32	3.1
	Phase II/Phase III	0	3	3	0.0
	Phase III	4	55	59	6.8
	Phase IV	1	31	32	3.1
Intervention	Behavioral	0	8	8	0.0
	Biological	1	3	4	25.0
	Device	0	10	10	0.0
	Dietary Supplement	0	1	1	0.0
	Drug	5	116	121	4.1
	Genetic	0	1	1	0.0
	Other	1	3	4	25.0
	Procedure	0	2	2	0.0
Recruitment	Active, not recruiting	0	26	26	0.0
	Completed	7	113	120	5.8
	Enrolling by invitation	0	5	5	0.0
	Terminated	0	12	12	0.0
	Withdrawn	0	3	3	0.0
Publication	No	4	134	138	2.9
	Yes	3	25	28	10.7

Appendix Table C3. Reporting of results by sponsors of closed studies of UI (sorted by total number of funded studies, shown if more than one study was funded)

Sponsors	Has results	No results available	Total	% with results
Total	7	159	166	4
Pfizer	3	26	29	10
Astellas Pharma, Inc.	0	14	14	0
Eli Lilly and Company/Boehringer Ingelheim Pharmaceuticals	0	12	12	0
GlaxoSmithKline	0	6	6	0
Allergan	1	3	4	25
Alza Corporation, DE, USA	0	4	4	0
Eli Lilly and Company	0	4	4	0
Duramed Research	0	3	3	0
Merck	0	3	3	0
Novartis/Procter and Gamble	0	3	3	0
Ono Pharma	0	3	3	0
Uroplasty, Inc	0	3	3	0
Astellas Pharma Inc./Astellas Pharma Europe BV	0	2	2	0
Astellas Pharma Inc./Astellas Pharma Korea, Inc.	0	2	2	0
Bayer	0	2	2	0
Cleveland Clinic Florida/Astellas Pharma US, Inc.	0	2	2	0
Department of Veterans Affairs	0	2	2	0
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)	0	2	2	0
Kissei Pharmaceutical Co., Ltd.	0	2	2	0
Medtronic Neuro	0	2	2	0
Novartis	0	2	2	0
Sanofi-Aventis	0	2	2	0
University of Michigan	0	2	2	0
William Beaumont Hospitals	0	2	2	0
Watson Pharmaceuticals	1	1	2	50

Appendix Table C4. Publication of results in peer reviewed journals by categories of studies of UI

Category	Type	Not Published in peer reviewed journals	Published in peer review journals	Total	% published
Gender	Both	80	15	95	16
	Female	58	13	71	18
Age	Adult	14	1	15	7
	Adult/Senior	121	26	147	18
	Child/Adult/Senior	3	1	4	25
Diagnosis	Incontinence	3	0	3	0
	Overactive Bladder	80	16	96	17
	Stress Urinary Incontinence	12	1	13	8
	Urge Incontinence	4	0	4	0
	Urinary Incontinence	39	11	50	22
Sponsorship	Industry	105	17	122	14
	NIH	1	4	5	80
	NIH/Other	1	0	1	0
	Other	18	5	23	22
	Other/Industry	9	1	10	10
	Other/NIH	1	0	1	0
	Other/U.S. Fed	1	0	1	0
	Other/Unknown/U.S. Fed	1	0	1	0
	U.S. Fed	1	1	2	50
Study Type	Interventional	119	26	145	18
	Observational	19	2	21	10
Phase of Clinical Trials	Phase I	9	0	9	0
	Phase I |Phase II	2	0	2	0
	Phase II	30	2	32	6
	Phase II| Phase III	1	2	3	67
	Phase III	45	14	59	24
	Phase IV	25	7	32	22
Intervention	Behavioral	4	4	8	50
	Biological	4	0	4	0
	Device	10	0	10	0
	Dietary Supplement	1	0	1	0
	Drug	99	22	121	18
	Genetic	1	0	1	0
	Other	4	0	4	0
	Procedure	2	0	2	0
Recruitment	Active, not recruiting	24	2	26	8
	Completed	95	25	120	21
	Enrolling by invitation	5	0	5	0
	Terminated	12	0	12	0
	Withdrawn	2	1	3	33

Appendix Table C5. Publication of results in peer reviewed journals by sponsors of studies of UI (sorted by total number of sponsored studies; shown if more than one study was sponsored)

Sponsors	Not published in peer review journals	Published in peer review journals	Total	% published
	No	Yes		
Total	138	28	166	17
Pfizer	25	4	29	14
Astellas Pharma, Inc.	10	4	14	29
Eli Lilly and Company/Boehringer Ingelheim Pharmaceuticals	11	1	12	8
GlaxoSmithKline	6	0	6	0
Allergan	4	0	4	0
Alza Corporation, DE, USA	3	1	4	25
Eli Lilly and Company	3	1	4	25
Duramed Research	3	0	3	0
Merck	3	0	3	0
Novartis/Procter and Gamble	2	1	3	33
Ono Pharma	3	0	3	0
Uroplasty, Inc.	3	0	3	0
Astellas Pharma Inc./Astellas Pharma Europe BV	2	0	2	0
Astellas Pharma Inc./Astellas Pharma Korea, Inc.	1	1	2	50
Bayer	2	0	2	0
Cleveland Clinic Florida/Astellas Pharma US, Inc.	1	1	2	50
Department of Veterans Affairs	1	1	2	50
Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)	0	2	2	100
Kissei Pharmaceutical Co., Ltd.	2	0	2	0
MedtronicNeuro	2	0	2	0
Novartis	1	1	2	50
Sanofi-Aventis	2	0	2	0
University of Michigan	0	2	2	100
Watson Pharmaceuticals	0	2	2	100
William Beaumont Hospitals	2	0	2	0

Appendix D. Analytical Framework

AppendixTable D1. Algorithm to define eligibility of studies

Research Question.

1. What constitutes an adequate diagnostic evaluation in the primary care setting on which to base treatment of UI?

Verification/Selection of Study Eligibility

Criteria 1 - Confirm eligibility of the target population

Eligible descriptors:			
Adult women in the community	Yes	No	Combined
Elderly women in the community	Yes	No	Combined

If NO – exclude

Criteria 2 - Confirm eligibility of the outcomes

Eligible descriptors:			
Diagnosis of urinary incontinence	Yes	No	Combined
Incidence of urinary incontinence	Yes	No	Combined

If NO – exclude

Criteria 3 - Confirm eligibility of diagnostic strategies

Questionnaire
Scale
Diary
Interview
Pad test
Multichannel urodynamics

If NO – exclude

Criteria 4 – Confirm eligibility of the outcomes assessment:

Eligible descriptors:		
True positive	Yes	No
True negative	Yes	No
False positive	Yes	No
False negative	Yes	No
Sensitivity	Yes	No
Specificity	Yes	No
Positive predictive likelihood of the test	Yes	No
Validity of the scale	Yes	No
Validity of the questionnaire	Yes	No
Reliability of the scale	Yes	No
Reliability of the questionnaire	Yes	No

If NO for all descriptors – exclude

Criteria 5. Confirm eligible level of evidence

Eligible descriptors:		
Randomized controlled clinical trials	Yes	No
Multicenter controlled clinical trials	Yes	No
Large (>100 subjects) observational studies	Yes	No
Case-control studies with >10 cases	Yes	No

If NO for all descriptors – exclude

AppendixTable D1. Algorithm to define eligibility of studies (continued)

2-3. How effective is the pharmacologic treatment of UI? How effective is the nonpharmacologic treatment of UI?

Verification/Selection of Study Eligibility

Criteria 1 - Confirm eligibility of the target population
Eligible descriptors:

Adult women with urinary incontinence in the community	Yes	No	Combined
Elderly women with urinary incontinence in the community	Yes	No	Combined

If NO – exclude

Criteria 2 – Confirm eligibility of the outcomes
Eligible descriptors:

Prevalence of urinary incontinence/types	Yes	No	Combined
Progression of urinary incontinence/types	Yes	No	Combined
Improvement in urinary incontinence/types	Yes	No	Combined
Continence	Yes	No	Combined
Changes in severity or frequency of urinary incontinence/types	Yes	No	Combined
Quality of life related to urinary incontinence/types	Yes	No	Combined
Adverse events	Yes	No	Combined

If NO – exclude

Criteria 3 – Confirm eligibility of interventions
Eligible drugs and nonpharmacologic treatments
If NO – exclude

Criteria 4 – Confirm eligible level of evidence
Eligible descriptors for clinical outcomes:

Randomized controlled clinical trials	Yes	No
Multicenter controlled clinical trials	Yes	No
Large (>100 subjects) observational studies	Yes	No

If No for all descriptors – exclude
If adverse events reported – include

Appendix Table D2. Definitions of population, interventions, comparators, outcomes, and settings (PICOS) framework

Population(s):
For KQ1. Adult and elderly women with symptoms of UI.
For KQ2 and KQ3. Adult and elderly women with diagnosed UI.
Interventions:
For KQ1 about diagnostic methods, the method that was defined as the gold standard
- Gold standard
- Multichannel urodynamics
- Bladder diary

Appendix Table D2. Definitions of population, interventions, comparators, outcomes, and settings (PICOS) framework (continued)

For KQ2 and KQ3 about treatments for urinary incontinence:

Variable	Definition
Health education	Education that increases the awareness and favorably influences the attitudes and knowledge relating to the early detection and prevention of urinary incontinence
Behavioral therapy	The application of behavioral changes to detect and manage incontinence, including: education about urinary structure and function; development of individualized diaries of daily dietary, physical activities, urinary habits; pelvic floor muscle exercises; voiding schedules: prompted, timed, habit retraining, patterned urge response toileting
Biofeedback	Process by which a person uses biofeedback information to gain voluntary control over the function of pelvic floor muscles and urination process
Pelvic floor muscle training for urinary incontinence	A systematic program of pelvic floor muscle exercises (Kegel exercises) designed to improve the strength and coordination of the pelvic floor muscles in order to improve urinary sphincter function and to control urgency
Vaginal cones	Insertion of vaginal cone (weighted device) into the vagina and contraction of the pelvic floor muscles in an effort to hold the device in place
Electrical stimulation	Application of electric current in treatment without the generation of perceptible heat Using low-voltage electric current to stimulate the correct group of muscles by using an anal or vaginal probe for delivery
Urethral plugs and patches	Insertion of plastic shapes into the urethra to stop the flow of urine or placed externally at the urinary meatus to prevent urine leakage; used for female stress urinary incontinence
Pessaries	A plastic or silicone device that is inserted into the vagina to provide support to the uterus, vagina, bladder, or rectum when there is pelvic organ prolapse; special pessaries with knobs are available to treat urinary incontinence
Magnetic stimulation	Stimulation with a brief magnetic field on the pelvic floor muscles and sacral roots without insertion of an anal or vaginal probe
Urethral bulking: Transurethral or periurethral injection techniques for women	Artificially inflating the submucosal tissues of the bladder neck; FDA-approved urethral bulking agents include collagen (Contigen®), autologous fat, and carbon bead particles (Durasphere®).
Topical estrogen therapy	Topical vaginal administration of estrogen
Pharmacological interventions	Ditropan® (oxybutynin chloride) Sanctura® (trospium chloride) Enablex® (darifenacin) Vesicare® (solifenacin succinate) Fesoterodine Tolterodine
Other tested pharmaceuticals	Propiverine Botulinum toxin injections Tricyclic antidepressants Imipramine hydrochloride

Appendix Table D2. Definitions of population, interventions, comparators, outcomes, and settings (PICOS) framework (continued)

Devices that have been examined in women with urinary incontinence available at http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070852.htm

Classification (21 CFR)	Class	Product Code	Description
Gastroenterology-Urology Devices			
876.5270 Implanted electrical urinary continence device	III	EZT	Pacemaker, bladder
III	EZW	Stimulator, electrical, implantable, for incontinence	
876.5280 Implanted mechanical/hydraulic urinary continence device	III	EZY	Device, incontinence, mechanical/hydraulic
	III	LNM	Agent, bulking, injectable for gastro-urology use
	III	OCK	Transurethral occlusion insert, urinary incontinence-control, female
Classification (21 CFR)	**Class**	**Product Code**	**Description**
Gastroenterology-Urology Devices			
876.5310 Nonimplanted, peripheral electrical continence device	II	NAM	Stimulator, peripheral nerve, nonimplanted, for pelvic floor dysfunction
876.5320 Nonimplanted electrical continence device	II	KPI	Stimulator, electrical, nonimplanted, for incontinence
876.5920 Protective garment for incontinence	I 510(k) Exempt	EYQ	Garment, protective, for incontinence
N/A	Unclassified	MNG	External urethral occluder, urinary incontinence-control, female
Obstetrical and Gynecological Devices			
884.1425 Perineometer	II	HIR	Perineometer
884.3575 Vaginal pessary	II	HHW	Pessary, vaginal

Appendix Table D2. Definitions of population, interventions, comparators, outcomes, and settings (PICOS) framework (continued)

Comparator

For KQ1 about diagnostic methods, the index methods that were tested:

Questionnaires
Checklists and scales
Self-reported UI during a clinical examination
Provocation stress test
Frequency volume chart
Pad tests
Paper towel test
Ultrasound

For KQ2 and KQ3 about treatments:

Efficacy	Placebo, no active treatment, or regular care
Comparative effectiveness	Active pharmacological treatment, education, behavioral therapy, biofeedback, bladder retraining (Kegel exercises), electrical stimulation, pads, and urethral plugs and pessaries in women

Outcomes

Outcomes for KQ1 about diagnostic methods:

- True positive for any, stress, and urgency incontinence
- True negative for any, stress, and urgency incontinence
- False positive for any, stress, and urgency incontinence
- False negative for any, stress, and urgency incontinence
- Sensitivity for any, stress, and urgency incontinence
- Specificity for any, stress, and urgency incontinence
- Positive predictive likelihood ratio for any, stress, and urgency incontinence

Primary outcomes after treatments (clinical outcomes):

- Continence
- Quality of life: measured by using a validated generic or condition-specific measure of quality of life developed to address issues related specifically to UI

Secondary outcomes	Definition
Remission of incontinence	Diminution of symptoms and signs of incontinence
Contained incontinence	Urine contained with pads or appliances
Dependent continence	Dry with toileting assistance, behavioral treatment, and/or medications
Independent continence	Dry, not dependent on ongoing treatment
Symptoms of incontinence[1,2]	The subjective indicator of incontinence or change in its severity, as perceived by the patient, caregiver, or partner, and may lead her to seek help from health-care professionals
Signs of incontinence	Observed by the physician, including simple means, to verify symptoms and quantify them
Urodynamic observations	Observations made during urodynamic studies that have a number of possible underlying causes and do not represent a definitive diagnosis of a disease
Measures of the frequency, severity, and impact of urinary incontinence[2]	
Micturition time chart	Records of times of micturitions (day and night) for at least 24 hours
Frequency volume chart (FVC)	Records of volumes voided and the time of each micturition (day and night) for at least 24 hours
Bladder diary	Records of times of micturitions, voided volumes, incontinence episodes, pad usage, and other information, such as fluid intake, the degree of urgency, and the degree of incontinence
Daytime frequency	The number of voids recorded during waking hours, including the last void before sleep and the first void after waking and rising in the morning
24-hour frequency	The total number of daytime voids and episodes of nocturia during a specified 24-hour period
24-hour production	All urine produced during 24 hours
Maximum voided volume	The largest volume of urine voided during a single micturition, as determined either from the frequency/volume chart or the bladder diary
Pad testing	The amount of urine lost during incontinence episodes (comparison of a short provocative test to a 24-hour pad test)

Appendix Table D2. Definitions of population, interventions, comparators, outcomes, and settings (PICOS) framework (continued)

Improvement in incontinence	Reduction frequency and severity of incontinence episodes Reduction in restrictions of daily activities due to incontinence
Progression of incontinence	Increase in frequency and severity of incontinence episodes Increase in restrictions of daily activities because of incontinence Continence not achieved No reduction in the frequency and severity of incontinent episodes

Harms
Adverse events resulting from drugs
Adverse events resulting from nonpharmacological treatments

Settings
Primary care clinic
Specialized clinic (nurse practitioners)
Cointerventions as reported in the studies

Definition of Terms
The first step is to define what is meant by the term "incontinence," which has many different implications for different groups of patients. Treating incontinence as a universal construct may impede understanding of the condition and its treatment. For example, incontinence in younger women occurs most likely because of pelvic floor failure, whereas in frail older persons it is often the result of problems with mobility or intellectual performance.

Definitions of urinary incontinence:

Variable	Definition
Symptoms of urinary incontinence[2]	Any involuntary leakage of urine
Signs of urinary incontinence	Urine leakage seen during physical examination; this leakage may be urethral or extraurethral
Extra-urethral incontinence	Urine leakage occurring through channels other than the urethra
Uncategorized incontinence	Involuntary urine leakage that cannot be classified into any of the categories listed above on the basis of signs and symptoms
Transient urinary incontinence[3,4]	Potentially reversible incontinence resulting from conditions that may resolve if the underlying cause is managed: delirium/confusional state; urinary tract infection (symptomatic); atrophic urethritis/vaginitis; use of pharmaceuticals; psychological conditions, especially depression; excessive urine output related to another medical condition (e.g., congestive heart failure, hyperglycemia); restricted mobility; stool impaction
Established urinary incontinence[3,4]	Urinary incontinence that is attributed to bladder or urethral dysfunction, such as: detrusor overactivity; detrusor underactivity; urethral obstruction; urethral incompetence
Stress urinary incontinence	Involuntary urine leakage on physical exertion or effort or with sneezing or coughing
Urgency UI[5]	Involuntary leakage accompanied by or immediately preceded by urgency
Overflow incontinence[6]	Urinary incontinence associated with: bladder overdistention; a contractile detrusor; hypotonic or underactive detrusor, occurring secondarily to drugs, fecal impaction, diabetes, lower spinal cord injury, or disruption of the motor innervation of the detrusor muscle
Mixed urinary incontinence[1,2]	Involuntary leakage associated with urgency and also with exertion, effort, sneezing, or coughing
Situational urinary incontinence	Incontinence during sexual intercourse or when giggling
Continuous urinary leakage	Continuous urinary leakage
Acute incontinence[7]	Sudden onset of symptoms related to an illness, treatment, or medication
Chronic incontinence	Persistent urinary incontinence, including disorders of storage (stress and urgency) and of emptying (overflow) and functional and mixed incontinence

Appendix Table D2. Definitions of population, interventions, comparators, outcomes, and settings (PICOS) framework (continued)

Variable	Definition
Severity of incontinence	Measured as incontinent episodes/unit time; pad changes/unit time; pad weight/unit time; number of micturitions/unit time; urine loss on a pad test Also indicated by urodynamically diagnosed detrusor overactivity; urodynamic stress incontinence
Sandvik's severity index[8]	Multiplied reported frequency (4 levels) by the amount of leakage (2 levels).
Slight incontinence	Leakage of drops a few times a month (~6 g/24 hours, 95% confidence interval 2–9)
Moderate incontinence	Daily leakage or drops (~17 g/24 hours, 95% confidence interval 13–22)
Severe incontinence	Leakage of large amount of urine at least once a week (~56 g/24 hours, 95% confidence interval 44–67)

We prioritized clinical outcomes and measure of quality of life following the FDA guideline for UI[9]

Endpoint	Potential Advantages	Potential Disadvantages
1-Hour Pad Weight Test (Amount of urine leakage experienced by the subject in 1 hour during a standardized series of activities or exercises in the investigator's office)[2]	* Objective	* Outcomes other than dryness may not be meaningful to patients
	* Standardized	* Not correlated with patients' daily activities
	* Assesses severity of urine leakage	* Poor to moderate sensitivity
		* Subject to variability
24-Hour Pad Weight Test (Amount of urine leakage experienced by the subject at home during a 24-hour period; all pads used during the test period are weighed before and after use)	* Objective	* Outcomes other than dryness may not be meaningful to patients
	* Correlated with patients' daily activities	* Less standardized
	* High sensitivity	* Subject to variability
	* Assesses severity of urine leakage	* Requires patient compliance
Number of Incontinence Episodes/Day (Obtained using a voiding diary)	* Objective	* May not directly correlate with the severity of urine leakage
	* Meaningful to patients	* Less standardized
	* Correlated with patients' daily activities	* Subject to variability
		* Requires patient compliance
Number of Pads Used/Day (Obtained using a voiding diary)	* Objective	* May not directly correlate with the severity of urine leakage
	* Meaningful to patients	* Less standardized
	* Correlated with patients' daily activities	* Subject to variability
		* Requires patient compliance
Quality of Life (Assessed using a validated questionnaire)	* Meaningful to patients	* Significant placebo effect
	* Standardized	* Subjective
	* Patient's daily activities taken into account	* Subject to variability * Not correlated with the severity of urine leakage
Urodynamics Measure (Measurement such as leak point pressure, cystometric outcome, etc.)	* Objective	*Not Meaningful to patients
	* Standardized	* Not correlated with patients' daily activities
	* Less subject to variability	

Appendix Table D3. Refinement of the questions following PICOS framework

Question	Population	Intervention (Independent Variable)	Comparator	Outcomes (dependent variables)	Settings
What constitutes an adequate diagnostic evaluation on which to base treatment of UI? Are there validated tools to distinguish stress from urge incontinence in primary care? Do validated tools to distinguish stress from urge incontinence in primary care make a clinical difference in response to treatment?	Adult and elderly women with symptoms of UI	Questionnaires Checklists and scales Self reported UI during clinical exam Provocation stress test Frequency volume chart Pad tests Paper towel test Ultrasound	Gold standard: multichannel urodynamics; Diary	Diagnostic value of the tests, validity of questionnaires for any, stress, urgency, mixed UI Patient outcomes	Primary Care Specialized on UI clinic (nurse practitioners)
How effective is pharmacologic treatment of UI? Do medication interventions with their adverse drug reactions make QoL sense vs. pads? Do medications have evidence of clinical benefit in the treatment of patients with incontinence? Are there clinical predictors of response to the (above) interventions?	Adult and elderly women with diagnosed UI Patient adherence and overcoming of barriers Clinical predictors of the effects : Patient age, comorbities, baseline disease/condition for UI	Detrol (tolterodine tartrate), Ditropan (oxybutynin chloride), Sanctura (trospium chloride), Enablex (darifenacin), and Vesicare (solifenacin succinate). - Other tested therapy: botulinum toxin injections, tricyclic antidepressant imipramine hydrochloride	Placebo <u>Comparative effectiveness with:</u> Active pharmacological treatment Education Behavioral therapy Biofeedback Bladder retraining (“Kegel exercises”) Electrical stimulation Pads Urethral “plugs” and pessaries in females	Continence Quality of life Improvement in frequency and severity of incontinence Adverse effects Differences in outcomes among subgroups of patients with different categories of the predictor (interaction models) Level of outcomes in subgroups of patients with different levels of predictors (subgroup analyses)	Primary Care Specialized on UI clinic (nurse practitioners)

Appendix Table D3. Refinement of the questions following PICOS framework (continued)

Question	Population	Intervention (Independent Variable)	Comparator	Outcomes (dependent variables)	Settings
How effective is non-pharmacologic treatment of UI? Do any of the following have evidence of clinical benefit in the treatment of patients with incontinence: Kegel exercises Minimally invasive techniques (e.g. collagen injection, etc.) Pessary Are there clinical predictors of response to the (above) interventions?	Adult and elderly women with diagnosed UI Patient adherence and overcoming of barriers Clinical predictors of the effects : Patient age, comorbities, baseline disease/condition for UI	Education Behavioral therapy Biofeedback Bladder retraining ("Kegel exercises") External electrical stimulation (tibial nerve stimulation Urethral "plugs" and pessaries in females Collagen injection devices	No active treatment Comparative effectiveness with: Pharmacological treatment Other nonpharmacological treatments	Continence Quality of life Improvement in frequency and severity of incontinence Adverse effects Differences in outcomes among subgroups of the patients with different categories of the predictor (interaction models) Level of outcomes in subgroups of patients with different levels of predictors (subgroup analyses)	Primary Care Specialized on UI clinic (nurse practitioners)

Appendix Table D4. Pharmacological treatments for UI[9]

Drug Name	Active Ingredients	Dose	Dosage Form/Route
Labeled for UI			
DETROL	TOLTERODINE TARTRATE	1MG	TABLET; ORAL
DETROL	TOLTERODINE TARTRATE	2MG	TABLET; ORAL
DETROL LA	TOLTERODINE TARTRATE	2MG	CAPSULE, EXTENDED RELEASE; ORAL
DETROL LA	TOLTERODINE TARTRATE	4MG	CAPSULE, EXTENDED RELEASE; ORAL
OXYTROL	OXYBUTYNIN	3.9MG/24HR	FILM, EXTENDED RELEASE; TRANSDERMAL
GELNIQUE	OXYBUTYNIN CHLORIDE	10%(100MG/ PACKET)	GEL; TRANSDERMAL
DITROPAN XL	OXYBUTYNIN CHLORIDE	5MG	TABLET, EXTENDED RELEASE; ORAL
DITROPAN XL	OXYBUTYNIN CHLORIDE	10MG	TABLET, EXTENDED RELEASE; ORAL
DITROPAN XL	OXYBUTYNIN CHLORIDE	15MG	TABLET, EXTENDED RELEASE; ORAL
DITROPAN	OXYBUTYNIN CHLORIDE	5MG	TABLET; ORAL
SANCTURA	TROSPIUM CHLORIDE	20MG	TABLET; ORAL
SANCTURA XR	TROSPIUM CHLORIDE	60MG	CAPSULE, EXTENDED RELEASE; ORAL
ENABLEX	DARIFENACIN HYDROBROMIDE	EQ 7.5MG BASE	TABLET, EXTENDED RELEASE; ORAL
ENABLEX	DARIFENACIN HYDROBROMIDE	EQ 15MG BASE	TABLET, EXTENDED RELEASE; ORAL
VESICARE	SOLIFENACIN SUCCINATE	5MG	TABLET; ORAL
VESICARE	SOLIFENACIN SUCCINATE	10MG	TABLET; ORAL
TOVIAZ	FESOTERODINE FUMARATE	4MG	TABLET, EXTENDED RELEASE; ORAL
TOVIAZ	FESOTERODINE FUMARATE	8MG	TABLET, EXTENDED RELEASE; ORAL
Off label use			
BOTOX	Botulinum Toxin Type A	100U/VIAL	VIAL; SINGLE-USE
CYMBALTA	DULOXETINE HYDROCHLORIDE	EQ 20MG BASE	CAPSULE, DELAYED REL PELLETS; ORAL
CYMBALTA	DULOXETINE HYDROCHLORIDE	EQ 30MG BASE	CAPSULE, DELAYED REL PELLETS; ORAL
CYMBALTA	DULOXETINE HYDROCHLORIDE	EQ 60MG BASE	CAPSULE, DELAYED REL PELLETS; ORAL
IMIPRAMINE HYDROCHLORIDE	IMIPRAMINE HYDROCHLORIDE	50MG	TABLET; ORAL
PREMARIN	ESTROGENS, CONJUGATED	0.625MG/GM	CREAM; TOPICAL, VAGINAL
SYNTHETIC CONJUGATED ESTROGENS A	ESTROGENS, CONJUGATED SYNTHETIC A	0.625MG/GM	CREAM; VAGINAL

Pharmacological classification of the drugs for UI that was used by the l4th International Consultation on Incontinence[18] served as a guide to synthesize comparative effectiveness and harms from available treatments.

Drug therapy for stress urinary incontinence[18]

SEROTONIN-NORADRENALINE
UPTAKE INHIBITORS

Duloxetine
Imipramine

ESTROGENS

Estrogen topical

Drugs used in the treatment of OAB/ DO[1:]

Antimuscarinic drugs

Tolterodine
Trospium
Solifenacin
Darifenacin
Fesoterodine
Propantheline

Drugs with mixed actions

Oxybutynin
Propiverine; Flavoxate

Appendix Table D5. Data synthesis

For question 1 we calculated diagnostic values of different tests to diagnose incontinence:
Sensitivity=TP/(TP+FN)
Specificity=TN/(FP+TN)
Prevalence=(TP+FN)/(TP+FN+FP+TN)
Predictive value positive=TP/(TP+FP)
Positive predictive likelihood ratio:
probability of an individual **with** the condition having a positive test
LR+ = probability of an individual **without** the condition having a positive test
LR+ = sensitivity
1-specificity

Clinical interpretations of likelihood ratios[10]

LR	Interpretation
> 10	Large and often conclusive increase in the likelihood of disease
5 - 10	Moderate increase in the likelihood of disease
2 - 5	Small increase in the likelihood of disease
1 - 2	Minimal increase in the likelihood of disease
1	**No change in the likelihood of disease**
0.5 - 1.0	Minimal decrease in the likelihood of disease
0.2 - 0.5	Small decrease in the likelihood of disease
0.1 - 0.2	Moderate decrease in the likelihood of disease
< 0.1	Large and often conclusive decrease in the likelihood of disease

Algorithms of meta-analysis[11]

Pooled estimate as a weighted average:

$$\theta_{IV} = \frac{\sum_i w_i \theta_i}{\sum_i w_i}$$

Weights are inverse of variance (standard error):

$$w_i = \frac{1}{SE(\theta_i)^2}$$

Standard error of pooled estimate:

$$SE(\theta_{IV}) = \frac{1}{\sqrt{\sum_i w_i}}$$

Heterogeneity (between-study variability) measured by:

$$Q = \sum_i w_i (\theta_i - \theta_{IV})^2$$

Assumptions for random effects model: true effect sizes *qi* have a normal distribution with mean *q* and variance *t2*; *t2* is the between-study variance

Between study variance:

$$\tau^2 = \frac{Q - (k-1)}{\sum_i w_i - \left(\frac{\sum_i w_i^2}{\sum_i w_i} \right)}$$

Where:
wi are the weights from the fixed effect inverse-variance method
Q is the heterogeneity test statistic from before (either from inverse-variance method or Mantel-Haenszel method)
k is the number of studies, and
t2 is set to zero if *Q*<*k*-1
Random effect pooled estimate is weighted average:

$$\theta_{DL} = \frac{\sum_i w'_i \theta_i}{\sum_i w'_i}$$

Weights used for the pooled estimate are similar to the inverse-variance, but now incorporate a component for between-study variation:

$$w'_i = \frac{1}{SE(\theta_i)^2 + \tau^2}$$

Standard error of pooled estimate

$$SE(\theta_{DL}) = \frac{1}{\sqrt{\sum_i w'_i}}$$

Meta regression with random effects was obtained using aggregate level data.

Additive component of variance tau2 was estimated:

$$y[i] = a + B*x[i] + u[i] + e[i],$$

where u[i] is a normal error (standard deviations that may vary across units), e[i] is a normal error with variance tau2 to be estimated, assumed equal across units.
t-distribution was used calculating p-values and confidence intervals[12,13]
Attributable risk was calculated as the outcome events rate in patients exposed to different clinical interventions[14-16]
Attributable risk of the outcome = rate of events in patients in the control group x (relative risk −1)

Number needed to treat to prevent one event of incontinence was calculated as reciprocal to absolute risk differences in rates of outcomes events in the active and control groups:[15,17]
1/(control group event rate - treatment group event rate).

The number of avoided or excess events (respectively) per 1000 population is the difference between the two event rates multiplied by 1000:

(control group event rate - treatment group event rate)*1000

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Appendix E. Abstraction Forms

Data Abstraction Form for Question 1
What constitutes an adequate diagnostic evaluation in the primary care setting on which to base treatment of UI?

(Complete for each study)

Number of the study in the database (PubMed ID, Cochrane accession number, ISBN)_____
First author_____
Year of the publication_____
Purpose/aim of study_____
Sponsorship_____

Conflict of interest_____

Design of the study (check one)
☐ prospective cohort
☐ retrospective cohort
☐ cross-sectional
☐ descriptive study
☐ case-control
☐ case-series
☐ randomized controlled clinical trial
☐ not randomized clinical interventions
☐ other (specify)

Population variables (target population)

Data source for population variables (define) _____
Recruitment_____
Consent _____

Settings:
Community (general population)_____
Primary clinic_____
Specialized clinic_____

Location:
Country _____
Urban _____
Rural _____

Subjects:
Race
Define _____
African Continental Ancestry Group, %_____
Asian Continental Ancestry Group, %_____
European Continental Ancestry Group, %_____
Ethnicity:
Define _____
African Americans, %_____
Arabs, %_____
Asian Americans, %_____
Hispanic Americans, %_____
Age:
Mean age, years_____ **Standard deviation**_____
Age intervals:_____

Health status
Primary Health Condition, Diagnosis _____
Sample size:

Sampling strategy:
Random _____
Self-selected _____
Inclusion criteria:_____

Incontinence (dependent variable)
Definition of incontinence _____
Urinary_____
Combined_____

"Gold standard" to detect urinary incontinence used in the article_____

Multichannel urodynamics cut points of continence
- Maximal urethral pressure (MUP)_____
- Functional urethral length (FUL)_____
- Maximal cystometric capacity (MCC)_____
- Abdominal leak point pressure (ALPP)_____

Index diagnostic tests for urinary incontinence:
Define_____
Cut points of continence_____

Clinical history
Nature _____
Duration _____
Symptoms and their severity _____
Symptom bothersomeness or impact _____
Functional and mental status _____
Medical, surgical and gynecological history _____
Exacerbating factors: diet, fluid, and medications _____

Diagnostic tests for urinary incontinence:
Provocation stress test_____
Frequency volume chart_____
Post-void residual volume (PVR)_____
Distal Urethral Electrical Conductance test_____
Pad tests_____
Paper towel test_____
Ultrasound_____
Q-Tip test_____

Questionnaire _____
Scales_____
Define_____

For each test provide comparison with "gold standard":
True positives_____
False positives_____
False negatives_____
True negatives
Sensitivity, % _____
Specificity, % _____

Reliability:
Cronbach alpha _____
Kappa statistics _____
Correlation coefficients _____

Inter-observer variability_____

Level of evidence of the individual study (check one)

Interventions:
☐ I Well-designed randomized controlled trial
☐ II-1A Well-designed controlled trial with pseudo-randomization
☐ I-1B Well-designed controlled trial without randomization

Observational studies
☐ I-2A Well-designed cohort (prospective) study with concurrent controls
☐ I-2B Well-designed cohort (prospective) study with historical controls
☐ II-2C Well-designed cohort (retrospective) study with concurrent controls
☐ II-3 Well-designed case-controlled (retrospective) study
☐ III Large differences from comparisons between times and/or places
☐ IY Opinion of respected authorities based in clinical experience

Data Abstraction Form for Questions 2 and 3
How effective is the pharmacological treatment of UI?
How effective is the nonpharmacological treatment of UI?

(Complete for each study)

Number of the study in the database (PubMed ID, Cochrane accession number, ISBN) _____
First author_____
Year of the publication _____
Purpose/aim of study _____
Sponsorship_____

Conflict of interest_____

Design of the study (check one)
☐ prospective cohort
☐ retrospective cohort
☐ cross-sectional
☐ descriptive study
☐ case-control
☐ case-series
☐ randomized controlled clinical trial
☐ not randomized clinical interventions
☐ other (specify)

Length of intervention_____
Length of followup_____

Population variables (target population)
Recruitment of the subjects

Settings
Community (general population)_____
Primary care_____
Specialized clinic_____

Subjects
Race
African Continental Ancestry Group, %_____
Asian Continental Ancestry Group, %_____
European Continental Ancestry Group, %_____
Ethnicity
African Americans, %_____
Arabs, %_____

Asian Americans, %_____
Hispanic Americans, %_____
Age_____
Health status_____
Sample size:_____
Inclusion criteria _____
Exclusion criteria _____
Loss of followup _____

Incontinence (dependent variable)
1. Provide the definition of urinary incontinence used in the article.
2. Provide the data source to measure incontinence.
3. Mark how the outcome was reported.

/*Complete with values reported in article with page number in articles where data was extracted for quality control*/
/*Add as many lines for categories as necessary*/
/*Median is calculated when ranges only reported assuming normal distribution*/
/*Increment is analyzed when regression coefficients only reported*/
/*Provide means and standard deviation (95% CI) when reported*/

Methods to assess urinary incontinence:
Self report_____
Medical diagnosis_____
Medical procedure_____

Urinary Incontinence, Incidence
Define _____
Symptoms_____
Signs_____
Acuity_____
Severity_____
Length_____
Bothersomeness_____

Urinary Incontinence, Progression
Define _____
Symptoms_____
Signs_____
Acuity_____
Severity_____
Frequency_____

Urinary Continence
Define _____
Dependent Continence_____
Independent Continence_____

Clinical Interventions (independent variables)
Provide the definition of each variable used in the article.
For drug and devices: Manufacturing company with the address, trade name

Health Education
Define _____
Behavioral Therapy
Define_____
Education _____
Development of individualized diaries of daily dietary, physical activities, urinary habits
Development of individualized voiding schedules
Voiding schedules: prompted, timed, habit retraining
Patterned urge response toileting
Dose of intervention:
Length of therapy_____
Intensity of therapy, section number _____

Biofeedback
Define_____
Dose of intervention:
Length of therapy_____
Intensity of therapy _____
Monitoring device_____

Pelvic Floor Muscle Training
Define_____
Dose of intervention:
Length of training_____ Intensity of training _____

Weight Loss
Define _____
Dose of intervention:
Length of therapy_____
Intensity of therapy _____

Diet Therapy
Define_____
Dose of intervention:
Length of therapy_____
Intensity (dose) of therapy _____

Vaginal Cones
Define _____

Electrical Stimulation
Define_____
Dose of intervention:
Length of therapy_____
Intensity of therapy _____

Inserts Urethral Patch or Urethral Insert
Define_____

Vaginal Pessary
Define_____

Detrol (tolterodine tartrate)
Define_____
Dose of intervention:
Length of therapy_____
Dose _____

Ditropan
Define _____
Dose of intervention:
Length of therapy_____
Dose _____

Sanctura (trospium chloride)
Define_____
Dose of intervention:
Length of therapy_____
Dose _____

Enablex (darifenacin)

Define_____
Dose of intervention:
Length of therapy_____
Dose _____

Vesicare (solifenacin succinate)
Define_____
Dose of intervention:
Length of therapy_____
Dose _____

Botulinum Toxin Injections
Define _____
Dose of intervention:
Length of therapy_____
Intensity (dose) of therapy _____

Oral Estrogen Therapy
Define_____
Dose of intervention:
Length of therapy_____
Intensity (dose) of therapy _____

Topical Estrogen Therapy
Define_____
Dose of intervention:
Length of therapy_____
Intensity (dose) of therapy _____

Magnetic Stimulation
Define_____
Dose of intervention:
Length of therapy_____
Intensity (dose) of therapy _____

Urethral Bulking Procedures
Define_____
Dose of intervention:
Length of therapy_____
Intensity (dose) of therapy _____

Intervention	Control	Outcomes Definition	Number in Active	Number in Control	Outcome Level in Active Group	Outcome Level in Control Group	Events in Active Group	Events in Control Group	Relative Risk, (95% CI)	Absolute Risk Difference, (95% CI)
		Urinary in-continence								

Quality of the studies:
For clinical trials
Random allocation ☐ Yes ☐ No
Intention to treat:
☐ Yes ☐ No ☐ not stated but all subjected included in analysis

Masking of treatment status:
Double blind _____
Single blind _____
Open label _____

Randomization regime_____
Adequate: computer-generated random numbers or random numbers tables
Inadequate: alternation, case record numbers, birth dates, or days of the week

Adequacy of randomization_____
Baseline data not reported_____
Baseline data confirmed the adequacy of randomization_____

Allocation concealment _____
Not reported_____
Adequate_____
Not adequate_____
Adequate approaches to concealment of allocation:
Centralized or pharmacy-controlled randomization
Serially-numbered identical containers
On-site computer based system with a randomization sequence that is not readable until allocation
Inferior approaches to concealment of allocation:
Use of alternation
Case record numbers
Birth dates or days of the week
Open random numbers lists
Serially numbered envelopes (even sealed opaque envelopes can be subject to manipulation)

For observational studies
Strategies to reduce bias_____
Relevant characteristics of providers_____
Justification for sample size_____

Level of evidence of the individual study (check one)
Interventions:
☐ I Well-designed randomized controlled trial
☐ II-1A Well-designed controlled trial with pseudo-randomization
☐ I-1B Well-designed controlled trial without randomization

Observational studies
☐ I-2A Well-designed cohort (prospective) study with concurrent controls
☐ I-2B Well-designed cohort (prospective) study with historical controls
☐ II-2C Well-designed cohort (retrospective) study with concurrent controls
☐ II-3 Well-designed case-controlled (retrospective) study
☐ III Large differences from comparisons between times and/or places
☐ IY Opinion of respected authorities based in clinical experience

Appendix F. Evidence Tables and Evidence Figures

Evidence Tables

Evidence Figures

Appendix Table F1. Grading the level of evidence for clinical outcomes that were examined in RCTs (direct evidence)

Treatment	Outcome	Studies	Assumed risk of bias	Consistency	Statistical heterogeneity relative/absolute scale	Precision	Dose response	Magnitude of the effect	Evidence
Duloxetine vs. placebo	Continence	2	Low	No	NS/Yes	No	NS	Low	Low
Duloxetine vs. placebo	Improved UI	4	Low	Yes	NS/Yes	Yes	NS	Low	High
Duloxetine vs. placebo	Discontinuation due to adverse effects	9	Low	Yes	NS/Yes	Yes	Yes	Moderate	High
Darifenacin vs. placebo	Improved UI	3	Low	Yes	NS/NS	Yes	NS	Low	High
Darifenacin vs. placebo	Discontinuation due to adverse effects	7	Low	Yes	NS/NS	NA	Yes	Low	High
Darifenacin vs. placebo	Discontinuation due to failure	4	Low	Yes	NS/NS	NA	NS	Low	Moderate
Fesoterodine vs. placebo	Continence	2	Low	Yes	Yes/NS	No		Low	Low
Fesoterodine vs. placebo	Improved UI	4	Low	Yes	NS/NS	Yes	Yes	Low	High
Fesoterodine vs. placebo	Adverse effects	4	Low	Yes	Yes/NS	Yes	Yes	Low	High
Fesoterodine vs. placebo	Discontinuation due to adverse effects	6	Low	Yes	NS/Yes	Yes	Yes	Moderate	High
Fesoterodine vs. placebo	Discontinuation due to failure	4	Low	No	NS/Yes	NA		Low	Moderate
Oxybutynin vs. placebo	Continence	5	Low	Yes	NS/NS	Yes		Low	High
Oxybutynin vs. placebo	Improved UI	12	Low	No	Yes/Yes	No	Yes	Low	Moderate
Oxybutynin vs. placebo	Discontinuation due to adverse effects	6	Low	Yes	NS/NS	Yes	Yes	Low	High
Propiverine vs. placebo	Continence	2	Medium	Yes	NS/NS	No		Low	Low
Propiverine vs. placebo	Improved UI	3	Medium	Yes	NS/NS	Yes		Low	Moderate

Appendix Table F1. Grading the level of evidence for clinical outcomes that were examined in RCTs (direct evidence) (continued)

Treatment	Outcome	Studies	Assumed risk of bias	Consistency	Statistical heterogeneity relative/absolute scale	Precision	Dose response	Magnitude of the effect	Evidence
Propiverine vs. placebo	Discontinuation due to adverse effects	2	Medium	Yes	NS/NS	Yes		Moderate	Low
Solifenacin vs. placebo	Continence	5	Low	Yes	NS/Yes	Yes	Yes	Low	High
Solifenacin vs. placebo	Improved UI	2	Low	Yes	Yes/NS	No		Low	Low
Solifenacin vs. placebo	Adverse effects	4	Low	Yes	Yes/Yes	Yes	Yes	Low	High
Solifenacin vs. placebo	Discontinuation due to adverse effects	8	Low	Yes	NS/NS	Yes	Yes	Low	High
Solifenacin vs. placebo	Discontinuation due to failure	4	Low	No	NS/NS	NA		Low	Moderate
Tolterodine vs. placebo	Continence	4	Low	Yes	NS/NS	Yes		Low	High
Tolterodine vs. placebo	Improved UI	8	Low	Yes	Yes/Yes	Yes		Low	High
Tolterodine vs. placebo	Adverse effects	12	Low	Yes	NS/NS	Yes		Low	High
Tolterodine vs. placebo	Discontinuation due to adverse effects	13	Low	No	NS/NS	NA		Low	High
Tolterodine vs. placebo	Discontinuation due to failure	5	Low	No	NS/NS	NA		Low	High
Trospium vs. placebo	Continence	4	Low	Yes	NS/NS	Yes		Low	High
Trospium vs. placebo	Improved UI	2	Low	Yes	NS/Yes	NA		Low	Low
Trospium vs. placebo	Adverse effects	5	Low	Yes	Yes/NS	Yes		Low	Moderate
Trospium vs. placebo	Discontinuation due to adverse effects	6	Low	Yes	NS/NS	Yes			High
Fesoterodine vs. tolterodine	Continence	2	Medium	Yes	NS/NS	Yes		Low	Low
Fesoterodine vs. tolterodine	Improved UI	4	Low	Yes	NS/NS	No		Low	High
Fesoterodine vs. tolterodine	Discontinuation due to adverse effects	4	Low	Yes	NS/NS	No		Low	Moderate

Appendix Table F1. Grading the level of evidence for clinical outcomes that were examined in RCTs (direct evidence) (continued)

Treatment	Outcome	Studies	Assumed risk of bias	Consistency	Statistical heterogeneity relative/absolute scale	Precision	Dose response	Magnitude of the effect	Evidence
Oxybutynin vs. tolterodine	Improved UI	3	Low	No	NS/NS	NA		Low	Moderate
Oxybutynin vs. tolterodine	Discontinuation due to adverse effects	10	Low	Yes	Yes/Yes	Yes		Low	High
Solifenacin vs. tolterodine	Discontinuation due to adverse effects	4	Low	No	NS/NS	NA		Low	Moderate
Trospium vs. oxybutynin	Discontinuation due to adverse effects	2	Low	No	NS/NS	NA		Low	Low
Bladder training vs. no active treatment	Improved UI	2	Medium	Yes	NS/NS	Yes		High	Low
Continence service vs. no active treatment	Continence	3	Medium	Yes	NS/Yes	NA		Moderate	Moderate
Continence service vs. no active treatment	Improved UI	2	Medium	Yes	Yes/Yes	NA		Moderate	Low
Electrical stimulation vs. no active treatment	Continence	9	Low	Yes	NS/NS	Yes		Moderate	High
Electrical stimulation vs. no active treatment	Improved UI	8	Low	Yes	NS/NS	Yes		Moderate	High
Magnetic stimulation vs. no active treatment	Improved UI	3	Medium	Yes	NS/NS	Yes		High	Moderate
Magnetic stimulation vs. no active treatment	Continence	3	Medium	No	NS/NS	NA		Low	Moderate
Percutaneous electrical stimulation vs. no active treatment	Improved UI	2	Medium	Yes	NS/NS	Yes		Low	Moderate

Appendix Table F1. Grading the level of evidence for clinical outcomes that were examined in RCTs (direct evidence) (continued)

Treatment	Outcome	Studies	Assumed risk of bias	Consistency	Statistical heterogeneity relative/absolute scale	Precision	Dose response	Magnitude of the effect	Evidence
PFMT vs. no active treatment	Continence	10	Medium	Yes	Yes/Yes	Yes		High	High
PFMT vs. no active treatment	Improved UI	6	Medium	Yes	Yes/Yes	Yes		High	High
PFMT + bladder training vs. no active treatment	Improved UI	4	Medium	Yes	Yes/Yes	Yes		High	High
PFMT with biofeedback vs. no active treatment	Continence	2	Medium	No	NS/Yes	NA		High	Low
PFMT with biofeedback vs. no active treatment	Improved UI	4	Medium	Yes	Yes/Yes	NA		High	High
PFMT with bladder training vs. no active treatment	Continence	5	Medium	Yes	Yes/Yes	Yes		Moderate	High
Weight Loss vs. no active treatment	Improved UI	2	Medium	Yes	NS/NS	Yes		High	Moderate
PFMT + bladder training vs. bladder training	Continence	3	Medium	Yes	NS/NS	NA		Low	High
PFMT + bladder training vs. no active treatment	Improved UI	4	Medium	Yes	Yes/Yes	Yes		High	High
PFMT vs. electrical stimulation	Continence	3	Medium	Yes	NS/NS	NA		Low	Moderate
PFMT vs. electrical stimulation	Improved UI	4	Medium	Yes	NS/NS	NA		Low	Moderate
PFMT vs. vaginal cone	Continence	3	Medium	No	NS/NS	NA		Low	Moderate
PFMT vs. vaginal cone	Improved UI	4	Medium	No	NS/NS	NA		Low	Moderate

Appendix Table F1. Grading the level of evidence for clinical outcomes that were examined in RCTs (direct evidence) (continued)

Treatment	Outcome	Studies	Assumed risk of bias	Consistency	Statistical heterogeneity relative/absolute scale	Precision	Dose response	Magnitude of the effect	Evidence
PFMT with biofeedback vs. PFMT	Continence	6	Medium	Yes	NS/NS	NA		Low	High
Supervised PFMT vs. self PFMT	Continence	4	Medium	No	Yes/Yes	NA		Moderate	High
Supervised PFMT vs. self-PFMT	Improved UI	4	Medium	No	Yes/Yes	NA		Low	Moderate

PFMT = Pelvic floor muscle training
NS = Not significant
NA = Not applicable

Appendix Table F2. Review of grey literature

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
510(k) Summary for Pelvex hometrainer U.S. Food and Drug Administration, 2001[1]	FDA 510 (K) review	510(k) Summary for pelvex hometrainer	K002043	Purdue Technology Park, West Lafayette, IN	pelvex	Perineometer	884.1425
510(k) summary for Vitala(tm) continence Control Device U.S. Food and Drug Administration, 2008[2]	FDA 510 (K) review	510(k) summary for Vitala(tm) continence Control Device	K083785	ConvaTec Inc. Skillman, Nj	Vitala Continence Control Device	Not reported	EZQ -C.F.R. Section 876.5900
510(k) Summary for uresta pessary U.S. Food and Drug Administration, 2008[3]	FDA 510 (K) review	510(k) Summary for uresta pessary	K081385	EastMed Inc., Halifax, Nova Scotia	Uresta Pessary	Vaginal Pessary	21CFR 884.3575
510(k) Summary for PelvicFlexer U.S. Food and Drug Administration, 2001[4]	FDA 510 (K) review	510(k) Summary for PelvicFlexer	K011688	PelvicFlex Inc., Sarasota, FL	PelvicFlexer Exercise Device	Pelvic Muscle Exerciser	884.1425
510(k) Summary for Hollister Contimed Pressure Biofeedback device U.S. Food and Drug Administration, 1996[5]	FDA 510 (K) review	510(k) Summary for Hollister Contimed Pressure Biofeedback device	K960311	Hollister Incorporated, Libertyville, IL	Hollister Contimed Pressure Biofeedback device	Not reported	Not reported
510(k) Summary of pathway vaginal emg/stimulation perineometer sensor U.S. Food and Drug Administration, 2000[6]	FDA 510 (K) review	510(k) Summary of pathway vaginal emg/stimulation perineometer sensor	K993976	The Prometheus Group, Dover, NH	Pathway Vaginal EMG/Stimulation Perineometer; Pathway Anal EMG/Stimulation Perineometer	Perineometer Sensor	876.5320; 884.1425

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
501(k) summary for UroMed Alternative Bladder Control Continence Device U.S. Food and Drug Administration, 1997[7]	FDA 510 (K) review	501(k) summary for UroMed Alternative Bladder Control Continence Device	K971992	UroMed Corporation, Needham, MA	UroMed Alternative Bladder Control Continence Device	Penile Clamp/Urological Clamp	21 CFR 876.5160
510(k) Summary for InCare Pelvic Floor Therapy System with Desktop Computer U.S. Food and Drug Administration, 1997[8]	FDA 510 (K) review	510(k) Summary for InCare Pelvic Floor Therapy System with Desktop Computer	K974048	Hollister Incorporated, Libertyville, IL	InCare Pelvic Floor Therapy System with Desktop Computer	Not reported	876.5320; 884.1425
510(k) summary review for perineometer and vaginal probe U.S. Food and Drug Administration, 1997[9]	FDA 510 (K) review	510(k) summary review for perineometer and vaginal probe	K970145	BioSearch Medical Products, Inc., Somerville, NJ	Perineometer and Vaginal Probe	Not reported	884.1425
510(k) summary for vaginal stimulation/emg probe - tampon U.S. Food and Drug Administration, 1997[10]	FDA 510 (K) review	510(k) summary for vaginal stimulation/ emg probe - tampon	K971541	Hollister Incorporated, Libertyville, IL	Vaginal Stimulation/EMG Probe -Tampon		876.5320; 884.1425
510(k) Summary for innoSense pelvic floor stimulation and electromyography system U.S. Food and Drug Administration, 1997[11]	FDA 510 (K) review	510(k) Summary for innoSense pelvic floor stimulation and electromyography system	K971527	Empi Inc., St.Paul, Minnesota	Innosense Pelvic Floor Stimulation and Electromyography System	Pelvic Floor Stimulation and BioFeedback Device	876.5320; 884.1425

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
510(k) summary for vaginal stimulation/emg probe - small U.S. Food and Drug Administration, 1997[12]	FDA 510 (K) review	510(k) summary for vaginal stimulation/ emg probe - small	K970602	Hollister Incorporated, Libertyville, IL	Vaginal Stimulation/EMG Probe -Small	Not reported	Not reported
510(k) summary for periform perineometric probe and pelvic floor contraction indicator U.S. Food and Drug Administration, 1998[13]	FDA 510 (K) review	510(k) summary for periform perineometric probe and pelvic floor contraction indicator	K981277	NEEN Healthcare, England, UK	Periform	Perineometer Probe	884.1425
510(k) summary review for peritron perineometer U.S. Food and Drug Administration, 1998[14]	FDA 510 (K) review	510(k) summary review for peritron perineometer	K983052	Cardio Design Pty Ltd	Peritron, Model 9300A with Anal Sensor; Model 9300V with Vaginal Sensor	Not reported	884.1425
510(k) summary for reflex treatment system U.S. Food and Drug Administration, 1999[15]	FDA 510 (K) review	510(k) summary for reflex treatment system	K994079	DesChutes Medical Products, Inc., Bend, OR	The Reflex Treatment System	Pelvic Muscle Exerciser	884.1425
510(k) Summary for Mentor EvaCare Vaginal Pessaries U.S. Food and Drug Administration, 1999[16]	FDA 510 (K) review	510(k) Summary for Mentor EvaCare Vaginal Pessaries	K993308	Mentor Corporation, Santa Barbara, CA	Mentor EvaCare Vaginal Pessaries	Vaginal Pessary	884.3575
510(k) Summary for PelvX Incontinence Dish U.S. Food and Drug Administration, 1999[17]	FDA 510 (K) review	510(k) Summary for PelvX Incontinence Dish	K990593	DesChutes Medical Products, Inc., Bend, OR	PelvX Incontinence Dish	Vaginal Pessary	884.3575
Summary for pelvic muscle therapy U.S. Food and Drug Administration, 2000[18]	FDA 510 (K) review	510(k) Summary for pelvic muscle therapy	K002830	Colonial Medical Supply, Las Vegas, Nv	Pelvic Muscle Therapy	Pelvic Muscle Exerciser	884.1425

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
510(k) summary accuset sensor U.S. Food and Drug Administration, 2000[19]	FDA 510 (K) review	510(k) summary accuset sensor	K001386	PelviCare Inc., Laguna Niguel,CA	Accuset Sensor	Not reported	876.1620; 884.1425
510(k) summary for femiscan clinic system and personal system U.S. Food and Drug Administration, 2000[20]	FDA 510 (K) review	510(k) summary for femiscan clinic system and personal system	K993411	Mahoney Enterprises, East Longmeadow, MA	FemiScan Clinic System and the FemiScan Personal System	Biofeedback Monitoring device with vaginal EMG probe	876.5320; 884.1425
Summary Review for InCare Pelvic Floor Therapy System U.S. Food and Drug Administration, 2001[21]	FDA 510 (K) review	510(k) Summary Review for InCare Pelvic Floor Therapy System	K013612	Hollister Incorporated, Libertyville, IL	InCare Pelvic Floor Therapy System	Not reported	876.5320; 884.1425
510(k) Summary for InCare Pressure Biofeedback Vaginal and Anal Pressure Probes U.S. Food and Drug Administration, 2001[22]	FDA 510 (K) review	510(k) Summary for InCare Pressure Biofeedback Vaginal and Anal Pressure Probes	K013653	Hollister Incorporated, Libertyville, IL	InCare Pressure Biofeedback Vaginal Pressure Probe; InCare Pressure Biofeedback Anal Pressure Probe	Not reported	884.1425
510(k) Summary for MTI ST#1 Silicone Pessary U.S. Food and Drug Administration, 2002[23]	FDA 510 (K) review	510(k) Summary for MTI ST#1 Silicone Pessary	K020512	Medical Technology & Innovations, Inc., Lee's Summit, MO	MTI ST#1 Silicone Pessary	Vaginal Pessary	884.3575
510(k) Summary for Portex Ring Pessary U.S. Food and Drug Administration, 2002[24]	FDA 510 (K) review	510(k) Summary for Portex Ring Pessary	K012277	SIMS Registration Manager, Kent, CT	Portex Ring Pessary	Not reported	884.3575
510(k) Summary for marina Medical Silicone Pessary U.S. Food and Drug Administration, 2003[25]	FDA 510 (K) review	510(k) Summary for marina Medical Silicone Pessary	K031463	Marina Medical Instruments, Inc., Alpharetta, GA	Marina Medical silicone Pessary	Not reported	884.3575

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
510(k) Summary for Kolpexin Sphere U.S. Food and Drug Administration, 2004[26]	FDA 510 (K) review	510(k) Summary for Kolpexin Sphere	K032644	ADAMED ltd., Poland	KOLPEXIN Sphere	Training Aid for Pelvic Floor Muscle or Kegel Exercise and Pessary for Vaginal Prolapse	884.3575
510(k) Summary for Intra-vaginal stress incontinence device U.S. Food and Drug Administration, 2006[27]	FDA 510 (K) review	510(k) Summary for Intra-vaginal stress incontinence device	K060526	ConTIPI Ltd., Israel, c/o ProMedic, Incorporated, Mccordsville, IN	Vaginal Pessary	Intra-vaginal stress incontinence device	884.3575
510(k) Summary for pathway vaginal/rectal perineometer probe U.S. Food and Drug Administration, [28]	FDA 510 (K) review	510(k) Summary for pathway vaginal/rectal perineometer probe	K974036	The Prometheus Group, Portsmouth, NH	Pathway Vaginal/Rectal Perineometer Probe	Perineometer Probe	884.1425
510(k) summary for anal stimulation/emg probe - w/Stop U.S. Food and Drug Administration, 1999[29]	FDA 510 (K) review	510(k) summary for anal stimulation/ emg probe - w/Stop	K990456	Hollister Incorporated, Libertyville, IL	Anal Stimulation/EMG Probe-w/Stop	Not reported	876.5320; 884.1425
510(k) Summary for uresta Pessary U.S. Food and Drug Administration, 2008[3]	FDA 510 (K) review	510(k) Summary for uresta Pessary	K083769	EastMed Inc., Halifax, Nova Scotia B3J 1S5	Uresta Pessary	Vaginal Pessary	884.3575
510(k) Summary for InCare Pelvic Floor Therapy System with Desktop Computer U.S. Food and Drug Administration, 1996[30]	FDA 510 (K) review	510(k) Summary for InCare Pelvic Floor Therapy System with Desktop Computer	K961872	Hollister Incorporated, Libertyville, IL	InCare Pelvic Floor Therapy System with Desktop Computer	Not reported	Not reported
510(k) Summary for liberty plus system pfs-300 U.S. Food and Drug Administration, 1997[31]	FDA 510 (K) review	510(k) Summary for liberty plus system pfs-300	K970077	Utah Medical Products Inc.	Liberty Plus System, PFS-300	Electrical Pelvic Floor Stimulation System with Biofeedback	876.5320; 884.1425

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
Medical Review for Gelnique (oxybutynin chloride) 10% gel U.S. Food and Drug Administration, 2009[32] Staskin, 2009[33]	Medical review	Medical Review for Gelnique (oxybutynin chloride) 10% gel	22-204	Watson's laboratories	Gelnique	oxybutynin chloride	Not reported
Medical Review for PAMELOR (Brand Name Drug) U.S. Food and Drug Administration, 2001[34] No information about trials	Medical review	Medical Review for PAMELOR (Brand Name Drug)	18-012/S-024 & 18-013/S-053	Tyco Healthcare	Pamelor	Nortriptyline	Not reported
Medical Review for Sanctura (Trospium Chloride) Tablets U.S. Food and Drug Administration, 2004[35] Rudy, 2006[36] Zinner, 2004[37]	Medical review	Medical Review for Sanctura (Trospium Chloride) Tablets	21-595	Indevus Pharmaceuticals	Sanctura	Trospium chloride	Not reported
Medical Review for VesiCare (Solifenacin Succinate) Tablets U.S. Food and Drug Administration, 2004[38] Staskin, 2006[39]	Medical review	Medical Review for VesiCare (Solifenacin Succinate) Tablets	21-518	Yamanouchi Pharma America, Inc	Vesicare	Solifenacin Succinate	Not reported
Medical Review for Sanctura XR (Trospium Chloride) Extended Release Capsules U.S. Food and Drug Administration, 2007[40] Not published	Medical review	Medical Review for Sanctura XR (Trospium Chloride) Extended Release Capsules	NDA 22-103	Indevus Pharmaceuticals	Sanctura	Trospium chloride	Not reported
Medical Review for Ditropan XL(Oxybutynin Chloride) Tablets U.S. Food and Drug Administration, 1998[41] Versi, 2000[42]	Medical review	Medical Review for Ditropan XL (Oxybutynin Chloride) Tablets	NDA-20-897	Alza Corporation	DitropanXL	oxybutynin	Not reported

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
Medical Review for Enablex (Clarifenacin) Extended Release Tablets U.S. Food and Drug Administration, 2004[43] Hill, 2006[44] Steers, 2005[45]	Medical review	Medical Review for Enablex (Clarifenacin) Extended Release Tablets	NDA-21-513	Novartis	Enablex	Darifenacin	Not reported
Statistical Review for Sanctura (Trospium Chloride) Tablets U.S. Food and Drug Administration, 2007[46] Staskin, 2007[47] Dmochowski, 2008[48]	Statistical review	Statistical Review for Sanctura (Trospium Chloride) Tablets	22-103	Indevus Pharmaceuticals	Sanctura XR	Trospium chloride-extended release	Not reported
Product Monograph for ENABLEX Health Canada, 2006[49] Abrams, 2008[50]	Statistical review	Product Monograph for ENABLEX	Not reported	Novartis	Enablex	Darifenacin-extended release	Not reported
Product Monograph for SANCTURA XR U.S. Food and Drug Administration, 2010[51] Staskin, 2009[52]	Statistical review	Product Monograph for SANCTURA XR	Not reported	Indevus Pharmaceuticals	Sanctura XR	Trospium chloride-extended release	Not reported
Product Monograph for VESICARE Health Canada, 2006[49] Cardozo, 2004[53] Chapple, 2004[54]	Statistical review	Product Monograph for VESICARE	Not reported	Astellas Pharma Canada, Inc.	Vesicare	Solifenacin Succinate	Not reported
NCT00168454 Posted results NCT00168454, 2008[55] Not published	Completed unpublished study from Clinicaltrials.gov	A Research Study for Patients With Overactive Bladder	191622-077	Allergan	botulinum toxin Type A	botulinum toxin	Not reported
NCT00178191 Posted results NCT00178191, [56] Not published	Completed unpublished study from Clinicaltrials.gov	Randomized Trial for Botox Urinary Incontinence	10466	University of Rochester |National Institutes of Health (NIH)	Bladder diary; Questionnaires; Urodynamics	Bladder diary; Questionnaires; Urodynamics	Not reported

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
NCT00269750 A Study Comparing the Efficacy and Safety of OROS® Oxybutynin to That of Ditropan® (Immediate-release Oxybutynin) for the Treatment of Patients With Urge or Mixed Urinary Incontinence NCT00269750, 2005[57] Not published	Completed unpublished study from Clinicaltrials.gov	A Study Comparing the Efficacy and Safety of OROS® Oxybutynin to That of Ditropan® (Immediate-release Oxybutynin) for the Treatment of Patients With Urge or Mixed Urinary Incontinence	CR005968	Alza Corporation	OROS	oxybutynin chloride	Not reported
NCT00444925 Posted results NCT00444925, [58] Not published	Completed unpublished study from Clinicaltrials.gov	Clinical Trial to Evaluate the Efficacy and Safety of Fesoterodine in Comparison to Tolterodine for Overactive Bladder (OAB)	A0221008	Pfizer	Fesoterodine fumarate	Fesoterodine	Not reported
NCT00536484 Posted results NCT00536484, [59] Not published	Completed unpublished study from Clinicaltrials.gov	Fesoterodine Flexible Dose Study	A0221014	Pfizer	Fesoterodine	Fesoterodine	Not reported

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
905-EC-001 Solifenacin in a flexible dose regimen with tolterodine as an active comparator in a double-blind, double-dummy, randomized overactive bladder symptom trial (STAR) U.S. Food and Drug Administration, [60] Chapple, 2005[61]	Synopsis posted in the website http://www.clinicalstudyresults.org	Solifenacin in a flexible dose regimen with tolterodine as an active comparator in a double-blind, double-dummy, randomized overactive bladder symptom trial (STAR)	905-EC-001	Astellas Pharma Europe B.V.	Solifenacin Succinate	Solifenacin	Not reported
Solifenacin in the treatment of urgency symptoms of overactive bladder in a rising dose, randomized, placebo-controlled, double-blind trial (SUNRISE) U.S. Food and Drug Administration, [62] Cardozo, 2008[63]	Synopsis posted in the website http://www.clinicalstudyresults.org	Solifenacin in the treatment of urgency symptoms of overactive bladder in a rising dose, randomized, placebo-controlled, double-blind trial (SUNRISE)	905-EC-002	Astellas Pharma Europe B.V.	Solifenacin Succinate	Solifenacin	Not reported

Appendix Table F2. Review of grey literature (continued)

Title references	Type of review	Title	ID	Manufacturer	Trade name	Common name	Classification number
Solifenacin succinate in a flexible dose regimen with simplified bladder training versus solifenacin succinate in a flexible dose regimen alone in a prospective, randomized, parallel group, overactive bladder symptom study U.S. Food and Drug Administration, [64] Mattiasson, 2009[65]	Synopsis posted in the website http://www.clinicalstudyresults.org	Solifenacin succinate in a flexible dose regimen with simplified bladder training versus solifenacin succinate in a flexible dose regimen alone in a prospective, randomized, parallel group, overactive bladder symptom study	905-EC-003	Astellas Pharma Europe B.V.	Vesicare	Solifenacin Succinate	Not reported

Appendix Table F3. Quality Assessment of Diagnostic Accuracy Studies (QUADAS)[66,67]

Criteria* reference	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Digesu, 2003[68]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Khan, 2004[69]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	yes	not relevant	yes	yes
Versi, 1996[70]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	no
Sandvik, 1995[71]	no	unclear	yes	unclear	yes	yes	no	yes	unclear	yes	yes	not relevant	yes	no
Clarke, 1997[72]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Jarvis, 1980[73]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Hilton, 1981[74]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Dundiff, 1997[75]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Brown, 2006[76]	yes	yes	yes	unclear	yes	no	no	yes	unclear	yes	yes	not relevant	yes	yes
Costantini, 2008[77]	no	yes	no	unclear	yes	yes	yes	yes	unclear	yes	unclear	not relevant	yes	yes
Ishiko, 2000[78]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Shepherd, 1982[79]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	yes	not relevant	yes	yes
Versi, 1988[80]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Bradley, 2005[81]	no	yes	yes	unclear	yes	yes	no	yes	no	yes	unclear	not relevant	yes	yes
FitzGerald, 2002[82]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Sand, 1988[83]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Cantor, 1980[84]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Valente, 1988[85]	no	no	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Hastie, 1989[86]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Bent, 1983[87]	no	unclear	yes	unclear	yes	yes	no	yes	no	yes	unclear	not relevant	no	yes
De Muylder, 1992[88]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Farrar, 1975[89]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Lagro-Janssen, 1991[90]	yes	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Ouslander, 1987[91]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Bergman, 1990[92]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Haylen, 1989[93]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Versi, 1986[94]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Bates, 1973[95]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Arnold, 1973[96]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Moolgaoker, 1972[97]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Warrell, 1965[98]	unclear	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Klingele, 2002[99]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Niecestro, 1992[100]	no	yes	no	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Diokno, 1990[101]	yes	unclear	no	unclear	yes	yes	no	yes	no	yes	unclear	not relevant	yes	yes
Tyagi, 2010[102]	no	yes	yes	unclear	unclear	yes	yes	yes	yes	yes	unclear	not relevant	yes	no
Thiede, 1987[103]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Awad, 1983[104]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes

Appendix Table F3. Quality Assessment of Diagnostic Accuracy Studies (QUADAS)[66,67] (continued)

Criteria* reference	1	2	3	4	5	6	7	8	9	10	11	12	13	14
Glezerman, 1986[105]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Walters, 1988[106]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Versi, 1991[107]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Bump, 2003[108]	unclear	yes	yes	unclear	unclear	yes	yes	yes	yes	yes	yes	not relevant	yes	unclear
Yalcin, 2004[109]	unclear	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	not relevant	yes	unclear
Videla, 1998[110]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Dinokno, 1999[111]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	yes	not relevant	yes	yes
Lemack, 1999[112]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Ramsay, 1995[113]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	yes	not relevant	yes	yes
Ramsay, 1993[114]	unclear	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Montz, 1986[115]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	yes	not relevant	yes	yes
Haeusler, 1995[116]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Nager, 2007[117]	unclear	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Matharu, 2005[118]	no	unclear	yes	no	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Coyne, 2005[119]	yes	yes	no	unclear	yes	yes	no	yes	no	yes	unclear	not relevant	yes	yes
Lukacz, 2005[120]	no	unclear	no	unclear	yes	yes	no	yes	yes	yes	yes	not relevant	unclear	yes
Diokno, 1990[101]	yes	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Fischer-Rasmussen, 1986[121]	no	unclear	yes	unclear	yes	yes	unclear	yes	unclear	yes	unclear	not relevant	yes	yes
Summitt, 1992[122]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Griffiths, 1992[123]	no	yes	yes	yes	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Chen, 1997[124]	no	no	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Kiilholma, 1994[125]	unclear	no	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Contreras Ortiz, 1993[126]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Bergman, 1988[127]	no	yes	yes	yes	yes	yes	yes	yes	yes	yes	yes	not relevant	yes	yes
Bergman, 1988[128]	no	yes	yes	yes	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Bergman, 1987[129]	no	yes	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Klovning, 1996[130]	no	no	yes	unclear	yes	yes	yes	yes	yes	yes	yes	not relevant	yes	yes
Sunshine, 1989[131]	unclear	no	yes	no	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Kujansuu, 1982[132]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Diokno, 1987[133]	no	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Korda, 1987[134]	unclear	unclear	yes	unclear	yes	yes	yes	yes	yes	yes	unclear	not relevant	yes	yes
Quinn, 1989[135]	no	unclear	yes	unclear	yes	yes	unclear	yes	unclear	yes	yes	not relevant	no	yes

***QUADAS Criteria**	**Used Codes**
(1) Was the spectrum of patient's representative of the patients who will receive the test in practice?	Yes if community or primary care; no if others; unclear if not specified
(2) Were the selection criteria clearly described?	Yes if inclusion and exclusion criteria exist; unclear if missing one of them; no if missing both
(3) Is the reference standard likely to correctly classify the target intervention?	Yes if UD or clinical diagnosis; no if others

Criteria* reference	1	2	3	4	5	6	7	8	9	10	11	12	13	14
(4) Is the time period between reference standard and index test short enough to be reasonably sure the target condition did not change between the two tests?							Yes if no more than 2 weeks, no if more than 2 weeks, unclear if unknown							
(5) Did the whole sample or a random selection of the sample receive verification using a reference standard of diagnosis?							Yes if random selection or no sampling; no if non-random selection; unclear is unknown							
(6) Did the patients receive the same reference standard regardless of the index test?							Yes if all received gold standard method							
(7) Was the reference standard independent of the index test (i.e., the index test did not form part of the reference standard)?							Yes if UD as gold standard; no if clinical diagnosis							
(8) Was the execution of the index test described in sufficient detail to permit replication of the test?							All yes (inclusion criteria of the studies)							
(9) Was the execution of the reference standard described in sufficient detail to permit its replication?							Y if UD or ICS; unclear if clinical diagnosis without clear definitions							
(10) Were the index test results interpreted without knowledge of the results of the reference standard?							All yes							
(11) Were the reference standard results interpreted without knowledge of the index test?							Yes if blinding, no if not blinding; unclear if not mentioned							
(12) Were the same clinical data available when test results were interpreted as would be available when the test is used in practice?							Not relevant-omitted from quality assessment as Whiting's suggestions[66]							
(13) Were uninterpretable/intermediate test results reported?							No if the results did not have mixed UI							
(14) Were withdrawals for the study explained?							No if there are withdraw cases							

Appendix Table F4. Eligible studies of diagnostic methods

Reference country funding and sample size	Settings, % of women, age	Inclusion and exclusion criteria
Abdel-fattah, 2004[136] Country: UK Funding: not reported Sample: 160	Settings: District general hospital % of women: 100 Age: 58; Range: 42-73	Inclusion: Women undergoing surgical treatment for urodynamic stress incontinence Exclusion: Not reported
Amarenco, 2003[137] Country: Europe Funding: not reported Sample: 505	Settings: A multicentre clinical study % of women: 100 Age: 51; Range: 18-75	Inclusion: Women enrolled in a European multicentre clinical study, ages 18-75, good health, mild to moderate genuine stress incontinence GSI with at least 3 leakages per week and 24 hour pad test 8-100g Exclusion: Not reported Only Cronbach's alpha coefficients in the English language group were abstracted
Amundsen, 1999[138] Country: USA Funding: not reported Sample: 115	Settings: urogynecologic clinic % of women: 100 Age: 53; Range: 21-79	Inclusion: Consecutive women with various complaints of urinary symptoms completed a 27-item questionnaire Exclusion: Not reported
Arnold, 1973[96] Country: UK Funding: not reported Sample: 217	Settings: urodynamic unit % of women: 100 Age : Not available; Range: Not reported	Inclusion: Women with incontinence Exclusion: Women with neurologic disease, pelvic disease, a history of major pelvic operations, and the urethral syndromes
Awad, 1983[104] Country: Canada Funding: other Sample:108	Settings: urodynamic unit % of women:100 Age: Not available; Range: Not available	Inclusion: Women referred to authors' department for symptomatic UI Exclusion: Not available
Bates, 1973[95] Country: UK Funding: not reported Sample: 75	Settings: referral clinic % of women: 100 Age: 56; Range: 33-72	Inclusion: Patients referred for investigation of recurrent or persistent incontinence after one or more operations for presumed stress UI Exclusion: Neurologic disorders
Bent, 2005[139] Country: USA Funding: not reported Sample: 723	Settings: The principal investigators included urologists, gynecologists, and primary care physicians % of women: 100 Age: 53.6; Range: 19-85	Inclusion: Women older than 18 years, an average of at least 4 incontinence episodes per week, could not have received treatment for incontinence by a continence expert within the past 5 years, prior surgery, including correction of incontinence, was allowed if the procedure was completed 6 months before a subject entered the study; participants who performed pelvic floor muscle training could not initiate or change their regimen within 3 months before study entry or during the study, and written informed consent Exclusion: Not reported
Bent, 1983[87] Country: USA Funding: not reported Sample: 100	Settings: urodynamic unit % of women: 100 Age: Over age 60; Range: Not reported	Inclusion: Consecutive patients over age 60 referred to authors' institute and a negative urine culture Exclusion: Not reported
Bergman,1990[92] Country: USA Funding: not reported Sample: 154	Settings: referral clinic % of women: 100 Age: 54; Range: 17-78	Inclusion: 122 women referred for evaluation of urinary complaints and 32 no complaints as control Exclusion: Mixed urinary incontinence
Borup, 2008[140] Country: Denmark Funding: government Sample: 96	Settings: community-dwelling % of women: 100 Age: Not reported; Range: 20-59	Inclusion: Women with symptomatic UI invited in a stress UI test Exclusion: Not reported

Appendix Table F4. Eligible studies of diagnostic methods (continued)

Reference country funding and sample size	Settings, % of women, age	Inclusion and exclusion criteria
Bradley, 2005[81] Country: USA Funding: other Sample: 117	Settings: tertiary referral % of women: 100 Age: 56; Range: 22-87	Inclusion: Consecutive women have symptoms of UI and agree to participate Exclusion: A history of current pregnancy or within 6 months after delivery, extraurethral UI, urethral diverticulum, and active UTI
Brown, 2006[76] Country: USA Funding: industry Sample: 301	Settings: community-dwelling % of women: 100 Age: 56.4; Range: 40-94	Inclusion: Ambulatory, were 40 years of age or older, reported 3 or more episodes of incontinence per week for at least 3 months, did not have urinary tract infection, and were bothered enough by their incontinence to seek treatment Exclusion: Women with incontinence who had complex problems that were more appropriate for specialist referral, including 4 or more urinary tract infections in the preceding year; pregnancy within 6 months; previous anti-incontinence or urethral surgery or procedures; previous major pelvic or abdominal surgery; pelvic radiation within 6 months; or known diseases of the genitourinary tract, such as lower urinary tract or rectal fistula, congenital abnormality leading to incontinence, interstitial cystitis, severe symptomatic pelvic prolapse, current or past urogenital cancer, spinal cord lesions, multiple sclerosis, stroke with clinically significant residual disability, Parkinson disease, or other major central nervous system abnormality affecting the lower urinary tract, or women who had been treated for incontinence in the previous 3 months
Bump, 2003[108] Country: USA Funding: industry Sample: 553	Settings: Randomized clinical trial % of women: 100 Age: 49.6; Range:18-65	Inclusion: Female outpatients ages 18 to 65 years who had a clinical diagnosis of stress UI for at least 3 months in duration Exclusion: If they had prolapse stage II or greater; had a postvoid residual volume of 50 mL or more; were using any pharmacologic agent or device for urinary incontinence; had adopted or changed behavioral management for urinary incontinence
Byrne,1987[141] Country: UK Funding: not reported Sample: 69	Settings: hospital % of women: 100 Age: Not reported; Range: Not reported	Inclusion: Women with the complaint of stress UI unassociated with other symptoms Exclusion: Not reported
Cantor, 1980[84] Country: UK Funding: not reported Sample: 214	Settings: urodynamic unit % of women: 100 Age: 47; Range: 16-84	Inclusion: Women complaining of urine incontinence Exclusion: Under age 16
Caputo, 1993[142] Country: USA Funding: not reported Sample: 114	Settings: urodynamic unit % of women:100 Age: Not reported; Range: Not reported	Inclusion: Women with UI or genital prolapse Exclusion: Genital prolapse that protruded beyond the introitus while straining in the upright position
Cardozo, 1980[143] Country: UK Funding: not reported Sample: 100	Settings: urogynecologic clinic % of women: 100 Age: 50; Range: Not reported	Inclusion: All patients with stress incontinence complaints with GSI or DI confirmed Exclusion: Not reported

Appendix Table F4. Eligible studies of diagnostic methods (continued)

Reference country funding and sample size	Settings, % of women, age	Inclusion and exclusion criteria
Chiarelli, 1999[144] Country: Australia Funding: government +industry Sample: 41,724	Settings: % of women:100 Age: Not reported; Range: 18-75	Inclusion: The women were selected randomly from the national health insurance (Medicare) database Exclusion: Not reported Only "lower quality of life among women who report leaking urine, compared with those who do not" was abstracted.
Clarke, 1997[72] Country: Australia Funding: not reported Sample: 1000	Settings: urogynecologic clinic % of women:100 Age: Not reported; Range: Not reported	Inclusion: Consecutive women with lower urinary tract symptomatology referred for UD Exclusion: Those records did not conform to the standard diagnoses (18 cases)
Costantini, 2008[77] Country: Italy Funding: not reported Sample: 158	Settings: tertiary referral % of women:100 Age: 69; Range: 20-90	Inclusion: Consecutive women with or without UI referred for pelvic organ prolapse repair or anti-UI surgery Exclusion: Patients with a specific condition known to adversely affect the way the test works and that would inflate diagnosis accuracy
Cundiff, 1997[75] Country: USA Funding: not reported Sample: 535	Settings: Medical college of Virginia or Duke university medical center % of women: 100 Age: 55.7; Range: 21-95	Inclusion: Consecutive women with urinary incontinence. Exclusion: Without incontinence or advanced pelvic organ prolapse (stage III or IV)
De Muylder, 1992[88] Country: Belgium Funding: not reported Sample: 408	Settings: Urodynamic unit % of women: 100 Age: 48.2; Range: 18-78	Inclusion: Women with UI Exclusion: Not reported
Digesu, 2003[68] Country: UK Funding: not reported Sample: 4500	Settings: tertiary referral % of women: 100 Age: 55.4; Range: 22-73	Inclusion: Women with lower urinary tract symptoms referred to a tertiary urodynamic clinic Exclusion: Women with neurological disorders
Diokno,1990[101] Country: USA Funding: not reported Sample: 167	Settings: community-dwelling % of women: 100 Age: Not reported; Range: 60-86	Inclusion: Noninstitutionalized elderly participated in a household survey and 60 years and older accepted to free urodynamic testing Exclusion: Not reported
Dinokno, 1999[111] Country: USA Funding: not reported Sample: 101	Settings: Continence clinic % of women: 100 Age: No response; Range: No response	Inclusion: Women with incontinence seen at the Continence Clinic and underwent office based basic evaluation Exclusion: Incomplete documentation of office based or urodynamic data
Drutz, 1979[145] Country: Canada Funding: not reported Sample: 188	Settings: urodynamic unit % of women: 100 Age: 50.2; Range: 20-84	Inclusion: Women with complaints of UI and/or other lower urinary tract symptoms Exclusion: Not reported
Eastwood, 1984[146] Country: UK Funding: not reported Sample: 65	Settings: referral clinic % of women: 100 Age: 82; Range: 68-94	Inclusion: Consecutively women referred for UD Exclusion: Not reported
Eastwood,1979[147] Country: No response Funding: not reported Sample: 30	Settings: urodynamic unit % of women:0 Age: 84; Range: 64-96	Inclusion: Elder patients referred to a geriatric service with the main presenting clinical features of UI Exclusion: Not reported

Appendix Table F4. Eligible studies of diagnostic methods (continued)

Reference country funding and sample size	Settings, % of women, age	Inclusion and exclusion criteria
Farrar,1975[89] Country: UK Funding: not reported Sample: 251	Settings: urodynamic unit % of women: 100 Age: Not reported; Range: Not reported	Inclusion: Women with mainly complaints of UI, normal bladder capacity, normal pressure and flow rates, and be able to void to completion Exclusion: Women with overt or possible neurologic disorders, fistula, and ectopic ureter as well as those who have had extensive surgical procedures of the pelvis Results were abstracted from a review by Jensen, 1994[148]
FitzGerald, 2002[82] Country: USA Funding: not reported Sample: 293	Settings: tertiary referral % of women: 100 Age: 57; Range: 15-87	Inclusion: Women referred to a tertiary urogynecology practice who completed all the questionnaires and underwent UD Exclusion: Not reported
Glezerman, 1986[105] Country: Israel Funding: not reported Sample:130	Settings: medical center % of women:100 Age:47.8; Range:22-74	Inclusion: Women referred to authors' department for stress incontinence Exclusion: Not available
Gunthorpe, 2000[149] Country: Australia Funding: government Sample: 89	Settings: Primary care % of women: 100 Age: 42.4; Range: 19-79	Inclusion: Patients were invited to participate in the study with 89 consented to complete the ISQ and 48h pad test Exclusion: younger than 18 years or too ill to participate
Haeusler,1995[116] Country: Austria Funding: not reported Sample: 1938	Settings: referral clinic % of women: 100 Age: 52.4; Range: 26-78	Inclusion: Consecutively patients referred for UD Exclusion: Pathologic types of incontinence due to calculi, fistula, upper motor neuron lesion, or carcinoma
Harvey, 2001[150] Country: United Kingdom Funding: not reported Sample: 154	Settings: A prospective before/ after clinical trial % of women: 100 Age: Not reported; Range: Not reported	Inclusion: Ambulatory women with symptoms of UI Exclusion: Women who were pregnant or had recently given birth, those with urinary tract infections, those presently undergoing treatment for UI, and patients with other debilitating medical conditions
Hastie,1989[86] Country: No response Funding: not reported Sample: 89	Settings: urodynamic unit % of women: 100 Age: Not reported; Range: Not reported	Inclusion: Women whose only reason for referral was symptom of stress incontinence Exclusion: Patients with urge incontinence and mixed incontinence
Haylen, 1989[93] Country: Australia Funding: not reported Sample: 494	Settings: referral clinic % of women:100 Age: Not reported; Range: Not reported	Inclusion: Women with complain of stress incontinence Exclusion: Previous surgery for urine incontinence
Hilton, 1981[74] Country: UK Funding: other Sample: 100	Settings: Urodynamic unit % of women: 100 Age: 74.6; Range: 65-93	Inclusion: Women referred to the urodynamic unit for urine incontinence Exclusion: Not reported
Homma, 2004[151] Country: Japan Funding: not reported Sample: 293	Settings: A randomized controlled trial % of women: 67 Age: 65.6; Range: Not reported	Inclusion: Details were presented in an abstract Exclusion: Details were presented in an abstract Only women's results were abstracted
Ishiko, 2000[78] Country: Japan Funding: not reported Sample: 198	Settings: tertiary referral % of women: 100 Age: 59.1; Range: 27-73	Inclusion: Women with UI Exclusion: Not reported
Jackson,1996[152] Country: UK Funding: not reported Sample: 105	Settings: Urodynamic unit % of women: 100 Age: 51; Range: 24-80	Inclusion: Consecutive women attending the department for a urodynamic assessment Exclusion: Not reported

Appendix Table F4. Eligible studies of diagnostic methods (continued)

Reference country funding and sample size	Settings, % of women, age	Inclusion and exclusion criteria
James,1999[153] Country: UK Funding: not reported Sample: 555	Settings: urodynamic unit % of women: 100 Age: 50; Range: 18-88	Inclusion: All women undergoing urodynamic studies Exclusion: Women with bladder filling symptoms (frequency, urgency, urge incontinence or bladder pain) or an abnormal urinary diary (daytime frequency ≥8, nighttime frequency ≥2, or a fluid intake of ≥4L/24 hours)
Jarvis, 1980[73] Country: UK Funding: not reported Sample: 100	Settings: urogynecologic clinic % of women:100 Age: Not reported; Range: Not reported	Inclusion: Consecutive women with urinary incontinence. Exclusion: Not reported
Khan, 2004[69] Country: UK Funding: not reported Sample: 114	Settings: tertiary referral % of women: 100 Age: 55.5 or 52.9; Range: 24-86	Inclusion: Women with lower urinary tract symptoms referred to a tertiary urogynecology clinic Exclusion: Abnormal urinalysis
Kinchen, 2007[154] Country: USA Funding: industry Sample: 3344	Settings: community-dwelling % of women: 100 Age: Not reported; Range: 21-75	Inclusion: All members aged 21-75 within 1 week of seeking care for any reason from a primary care physician Exclusion: Not reported
Klingele, 2002[99] Country: USA Funding: not reported Sample: 239	Settings: urogynecologist clinic % of women: 100 Age: 54.1(s),54.7(m), 52.3(DO); Range: Not reported	Inclusion: Consecutive women referred to a urogynecologist for UI Exclusion: No symptoms or missing data
Kulseng-Hanssen, 2003[155] Country: Norway Funding: not reported Sample: 628	Settings: Tertiary referral urogynecology units % of women:100 Age: Not reported; Range: Not reported	Inclusion: Pre-operative forms from 20 departments Exclusion: Not reported
Lagro-Janssen, 1991[90] Country: Netherlands Funding: not reported Sample: 103	Settings: general practice % of women: 100 Age: Not reported; Range: 20-65	Inclusion: Women with UI in general practitioner setting Exclusion: A previous operation for UI, underlying neurological etiology, DM, a temporary cause of UI, or UTI
Lagro-Janssen, 1990[156] Country: Netherlands Funding: not reported Sample: 1442	Settings: community-dwelling % of women: 100 Age: Not reported; Range: 50-65	Inclusion: 2400 women were randomly selected in the eastern part of the Netherlands, and 1442 consented to take part Exclusion: Not reported
Lemack, 1999[112] Country: USA Funding: not reported Sample: 128	Settings: tertiary referral % of women:100 Age:61 Range:27-86	Inclusion: Women for an initial evaluation of LUTS or incontinence who had completed a UDI-6 questionnaire and UD study; patients with previous vaginal surgery were included Exclusion: Women with known neurologic diagnoses
Lemack,2000[157] Country: USA Funding: not reported Sample: 174	Settings: medical center % of women: 100 Age: No response; Range: No response	Inclusion: All women completed UDI-6 and underwent UD Exclusion: With known neurological conditions
Lin, 2004[158] Country: Taiwan Funding: not reported Sample: 120	Settings: tertiary referral % of women: 100 Age: 51; Range: 43-64	Inclusion: Consecutive women complaining of lower urinary tract symptoms Exclusion: Women without symptoms suggestive of OAB
Lowenstein, 2008[159] Country: USA Funding: industry Sample: 47	Settings: tertiary referral % of women: 100 Age: 62; Range: 34-86	Inclusion: Women with MUI Exclusion: Not reported

Appendix Table F4. Eligible studies of diagnostic methods (continued)

Reference country funding and sample size	Settings, % of women, age	Inclusion and exclusion criteria
Lukacz, 2005[120] Country: USA Funding: not reported Sample: 120	Settings: In either the general gynecology or the pelvic floor disorders clinic % of women: 100 Age: 52.6; Range: 25-84	Inclusion: Women awaiting appointments in either the general gynecology or the pelvis floor disorders clinic Exclusion: The inability to read or to participate in the informed consent process
Massolt, 2005[160] Country: Netherlands Funding: not reported Sample: 109	Settings: urogynecologic clinic % of women: 100 Age: Not reported; Range: Not reported	Inclusion: All women visiting the authors' urogynecologic practice with complaints of UI Exclusion: Not reported
Matharu, 2005[118] Country: UK Funding: government Sample: 1003	Settings: community % of women: 100 Age: 56.3; Range: 40-88	Inclusion: Women aged 40 years or over living in the community in Leicestershire and Rutland, who responded to a questionnaire and home interview, with symptoms of UI, enrolled in CNP arm, completed urodynamics. Exclusion: Not reported
Miller,1999[161] Country: USA Funding: government Sample: 51	Settings: community-dwelling % of women: 100 Age: 69; Range: 59-84	Inclusion: Female, >60 years, ambulatory, mental intact (Mini-Mental State score >23, community dwelling, and history of leakage with coughing Exclusion: Prior urethral or bladder surgery, UTI, prolapse below the level of the hymenal ring
Montz, 1986[115] Country: UK Funding: not reported Sample: 100	Settings: urodynamic unit % of women: 100 Age: 49.7; Range: Not reported	Inclusion: Consecutive women with complaints of UI Exclusion: Not reported
Moolgaoker,1972[97] Country: UK Funding: not reported Sample: 95	Settings: referral clinic % of women: 100 Age: Not reported; Range: Not reported	Inclusion: Women with UI and no neurological abnormalities Exclusion: neurological lesions or fistulae
Morkved,1999[162] Country: Norway Funding: not reported Sample: 144	Settings: local hospital % of women: 100 Age: 28; Range: 19-40	Inclusion: All women delivering at the local hospital and gave their written consent Exclusion: Those who did not understand or speak Norwegian
Nager, 2007[117] Country: USA Funding: government Sample: 655	Settings: A multicenter surgical trial % of women: 100 Age: 52; Range: 28-81	Inclusion: (1) predominant SUI with MESA3 stress score >MESA urge score; (2) positive stress test (observed leakage from the external urethral meatus coincident with a cough or Valsalva maneuver) with a bladder volume ≤300 ml; (3) urethral hypermobility as evidenced by Q-tip angle; (4) maximum cystometric capacity (MCC) ≥200 ml; and (5) non-obstructed voiding in the absence of Stage II–IV prolapse5 defined as: (a) postvoid residual (PVR) <150 ml; (b) maximum flow rate (Qmax) ≥12 ml/sec; and (c) detrusor pressure (pdet) at Qmax <50 cm H2O Exclusion: Not reported
Niecestro,1992[100] Country: USA Funding: not reported Sample: 66	Settings: urodynamic unit % of women: 100 Age: Not reported; Range: Not reported	Inclusion: Women >18 years referred to the urodynamic center for voiding symptoms Exclusion: Presence of UTI, patients with STD, and judged unfit for participation by the investigator
Oh, 2005[163] Country: Korea Funding: not reported Sample: 109	Settings: tertiary referral % of women: 100 Age: 54.9; Range: 31-77	Inclusion: Age 18 years or older, good visual acuity, and the ability to communicate, understand, and comply with the study requirements Exclusion: A confused state or depression, an inability to read the questionnaire, urinary tract infection, malignancy, pregnancy, or failure to provide consent, or incomplete workup and incomplete information

Appendix Table F4. Eligible studies of diagnostic methods (continued)

Reference country funding and sample size	Settings, % of women, age	Inclusion and exclusion criteria
Ouslander,1978[91] Country: USA Funding: not reported Sample: 135	Settings: referral clinic % of women: 100 Age: Not reported; Range: 65-95	Inclusion: Consecutive women referred to the clinics Exclusion: Not reported
Phua, 1992[164] Country: Singapore Funding: not reported Sample:84	Settings: hospital % of women:100 Age: Not available; Range: Not available	Inclusion: Women complained of UI and/or other urinary symptoms and were suspected of suffering from stress incontinence or detrusor instability Exclusion: With known or suspected neurological disease, urinary fistula or ectopic ureters
Ramsay, 1993[114] Country: UK Funding: not reported Sample: 200	Settings: No response % of women: 100 Age: 51.6; Range: Not reported	Inclusion: Patients with either pure DI or pure GSI Exclusion: Incontinence during intercourse
Ramsay, 1995[113] Country: UK Funding: not reported Sample: 207	Settings: urogynecology clinic % of women: 100 Age: Not reported; Range: Not reported	Inclusion: Consecutive women attending urogynecology clinics Exclusion: Not reported
Rosenzweig, 1992[165] Country: USA Funding: not reported Sample: 22	Settings: gynecology clinic of medical center % of women: 100 Age: 60.3; Range: 34-77	Inclusion: Women with severe genitourinary prolapse (prolapse of pelvic structure through the vaginal introitus) and with no symptoms of UI except for an occasional episode (less than 1 per week) Exclusion: Not reported
Sand, 1991[166] Country: USA Funding: not reported Sample: 100	Settings: urodynamic unit % of women: 100 Age: 51.6; Range: 20-84	Inclusion: Consecutive neurologically normal women with complaint of UI who agreed to undergo two cystometrogram on two different days Exclusion: Not reported
Sand,1988[83] Country: USA Funding: not reported Sample: 218	Settings: urodynamic unit % of women: 100 Age: 51.8; Range: 18-80	Inclusion: Patient referred for UD for lower urinary tract complaints Exclusion: Without thorough, detailed histories and preliminary evaluations
Sandvik,1995[71] Country: Norway Funding: not reported Sample: 250	Settings: Outpatient clinic of University hospital % of women: 100 Age: Not reported; Range: Not reported	Inclusion: Consecutive patients referred for urine incontinence Exclusion: Not reported
Scarpero,2003[167] Country: USA Funding: not reported Sample: 1232	Settings: urology practice % of women: 100 Age: 54.6; Range: 18-93	Inclusion: Women presenting to a female urology practice, and all those who completed the AUASI, SPI, and QOL questions Exclusion: Younger than 18 years, with neurogenic diseases, and missing information
Shepherd, 1982[79] Country: UK Funding: other Sample: 1800	Settings: urodynamic unit % of women: 100 Age: Not reported; Range: Not reported	Inclusion: Women referred to the urodynamic unit Exclusion: Not reported
Shimabukuro, 2006[168] Country: Japan Funding: not reported Sample: 1052	Settings: community-dwelling % of women: 100 Age: 46.8; Range: 18-83	Inclusion: Apparently health participants for medical checkup Exclusion: Not reported
Shumaker,1994[169] Country: USA Funding: not reported Sample: 162	Settings: community-dwelling % of women: 100 Age: 61.3; Range: ≥45	Inclusion: >45 years, mentally competent, capable of independent toileting, at least 1 episode of UI per week, and fulfilling urodynamic criteria of GSI and/or DI Exclusion: Metabolic decompensation, marked cyclical variation in UI, lower UTI, urinary obstruction, diverticulum, fistula, persistent indwelling catheter, and reversible cause of UI

Appendix Table F4. Eligible studies of diagnostic methods (continued)

Reference country funding and sample size	Settings, % of women, age	Inclusion and exclusion criteria
Stach-Lempinen, 2001[170] Country: Finland Funding: not reported Sample: 82	Settings: University hospital % of women: 100 Age: 52; Range: 25-80	Inclusion: Women referred to authors' department for symptomatic UI Exclusion: Diabetic neuropathy, recently diagnosed cancer or other serious chronic conditions that may have caused neurogenic bladder disease and patients with incontinence surgery within the past 5 years
Stav, 2009[171] Country: Australia Funding: not reported Sample: 601	Settings: medical center % of women: 100 Age: 59.2; Range: 30-91	Inclusion: The medical records of 1,136 consecutive women who had urodynamic stress UI and underwent a suburethral sling operation at authors' institute Exclusion: Not reported
Sutherst, 1984[172] Country: UK Funding: not reported Sample:100	Settings: Incontinent clinic % of women:100 Age:47 Range:22-78	Inclusion: Women enrolled in a single blind crossover trial Exclusion: Not reported
Swift, 1995[173] Country: USA Funding: not reported Sample: 108	Settings: referral clinic % of women: 100 Age: 57.9; Range: Not reported	Inclusion: Consecutive women with lower urinary tract complaints referred for UD Exclusion: Not reported
Swithinbank,1999[174] Country: UK Funding: not reported Sample: 2075	Settings: community-dwelling % of women: 100 Age: 52; Range: 19-97	Inclusion: All women aged 19 years and over, registered with one group general practice of 7000 patients, were invited to participate Exclusion: Not reported
Thiede, 1987[103] Country: USA Funding: other Sample:200	Settings: urogynecologic clinic % of women:100 Age: Not available; Range: Not available	Inclusion: Women referred to authors' department for symptomatic UI Exclusion: Not available
Theofrastous, 1996[175] Country: USA Funding: not reported Sample: 120	Settings: referral clinic % of women:100 Age: 57; Range: 22-81	Inclusion: Consecutive women who were referred to the urodynamic lab for evaluation of their UI Exclusion: Not reported
Tyagi, 2010[102] Country: UK Funding: not reported Sample:159	Settings: urodynamic unit % of women:100 Age: Not available; Range: Not available	Inclusion: patients referred for urodynamic investigations Exclusion: recurrent SUI after failed surgery for SUI or prior to POP surgery
Valente,1998[85] Country: Italy Funding: not reported Sample: 102	Settings: urodynamic unit % of women: 100 Age: Not reported; Range: Not reported	Inclusion: consecutive women with clinical diagnosis of UI Exclusion: Not reported
Versi, 1996[70] Country: UK Funding: not reported Sample: 161	Settings: urogynecologic clinic % of women: 100 Age: Not reported; Range: Not reported	Inclusion: Patients presenting to a urogynecologic clinic at a teaching hospital Exclusion: 44 detrusor instability, sensory urgency, voiding difficulties or a combination of these diagnosis
Versi, 1991[107] Country: UK Funding: other Sample: 252	Settings: referral urodynamic center % of women: 100 Age: Not reported; Range: Not reported	Inclusion: Consecutive patients studied with a urodynamic diagnosis Exclusion: Not reported
Versi, 1988[80] Country: UK Funding: other Sample: 311	Settings: urodynamic unit % of women: 100 Age: Not reported; Range: Not reported	Inclusion: Women presenting to the urodynamic unit for investigation of their urinary complaints Exclusion: Not reported

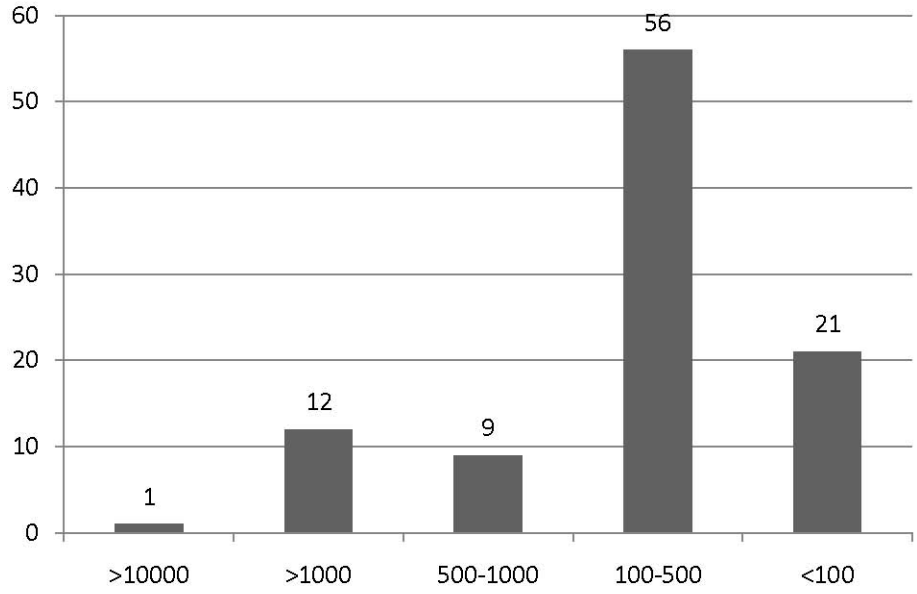
Appendix Table F4. Eligible studies of diagnostic methods (continued)

Reference country funding and sample size	Settings, % of women, age	Inclusion and exclusion criteria
Versi, 1986[94] Country: UK Funding: other Sample: 99	Settings: urodynamic unit % of women: 100 Age: Not reported; Range: Not reported	Inclusion: 99 postmenopausal women with urodynamic proven GSI and 90 women without UI as control group Exclusion: Not reported
Videla, 1998[110] Country: USA Funding: not reported Sample: 74	Settings: urogynecologic clinic % of women: 100 Age: 54; Range: 30-86	Inclusion: Women with a variety of lower urinary tract complaints and 1) a predominant complaint of stress incontinence, 2) positive cough stress-test results, 3) postvoid residual urine volume no more than 50 mL, 4) a functional bladder capacity of at least 400 mL as determined by a completed 24-hour frequency-volume chart, and 5) a full multichannel urodynamic evaluation Exclusion: The absence of any of five criteria
Walters, 1988[106] Country: USA Funding: not reported Sample:106	Settings: urodynamic unit % of women:100 Age:46.3; Range: Not available	Inclusion: consecutive women complaining of urine incontinence who were referred to the authors' department Exclusion: postmenopausal women who became asymptomatic after estrogen therapy
Warrell, 1965[98] Country: UK Funding: not reported Sample: 81	Settings: Not reported % of women: 100 Age: Not reported; Range: Not reported	Inclusion: Women with UI despite prolapse repair have been investigated Exclusion: Not reported
Weidner, 2001[176] Country: USA Funding: not reported Sample: 950	Settings: urogynecologic clinic % of women: 100 Age: 55.4 Range: Not reported	Inclusion: Consecutive patients referred for multichannel UD testing Exclusion: Women with stage III or IV pelvic organ prolapse, no reports of urinary incontinence, and undergoing repeated examinations
Wyman,1988[177] Country: USA Funding: government Sample: 50	Settings: Community dwelling % of women: 100 Age: 65.1; Range: 55-86	Inclusion: 55 years or older, ambulatory, mental intact (Mini-Mental State score >23), independent residence in the community, and at least one episode of incontinence reported per week Exclusion: Percent catheterization, persistent UTI, reversible cause of incontinence, metabolic decompensation, or outlet obstruction
Wyman, 1987[178] Country: USA Funding: government Sample: 69	Settings: Community-dwelling % of women: 100 Age: 67.8; Range: No response	Inclusion: Women had to be 55 years or older, reside independently in the community, mentally intact, ambulatory, and at least one episode of incontinence per week Exclusion: Permanent catheterization, intractable UTI, reversible cause of incontinence, metabolic decompensation, bladder atony or obstruction, and no evidence of urodynamic abnormality
Yalcin, 2004[109] Country: Europe and North America Funding: not reported Sample: 1455	Settings: 3 randomized trials % of women: 100 Age: 51.3; Range: 28-81.7	Inclusion: Female outpatients aged 18 to 65 (phase 2 study) years who had a clinical diagnosis of SUI for at least 3 months in duration enrolled in 1 phase 2 study and 2 phase 3 studies Exclusion: if they had stage II or greater anterior segment prolapse, a post-void residual volume of 50 ml or greater, were on any pharmacological agent or device for UI, or had adopted or changed behavioral management for UI within the last 3 months, or women with previous continence surgery were excluded from the phase 2 study but not from the phase 3 studies.

Appendix Table F4. Eligible studies of diagnostic methods (continued)

Reference country funding and sample size	Settings, % of women, age	Inclusion and exclusion criteria
Yoon, 1998[179] Country: USA Funding: not reported Sample: 174	Settings: Not reported % of women: 100 Age: 52; Range: 22-89	Inclusion: Women presented with primary complaints of UI and successfully completed a 24 hour voiding diary Exclusion: Not reported

Appendix Figure F1. Distribution of sample sizes of studies of diagnostic values of tests for UI

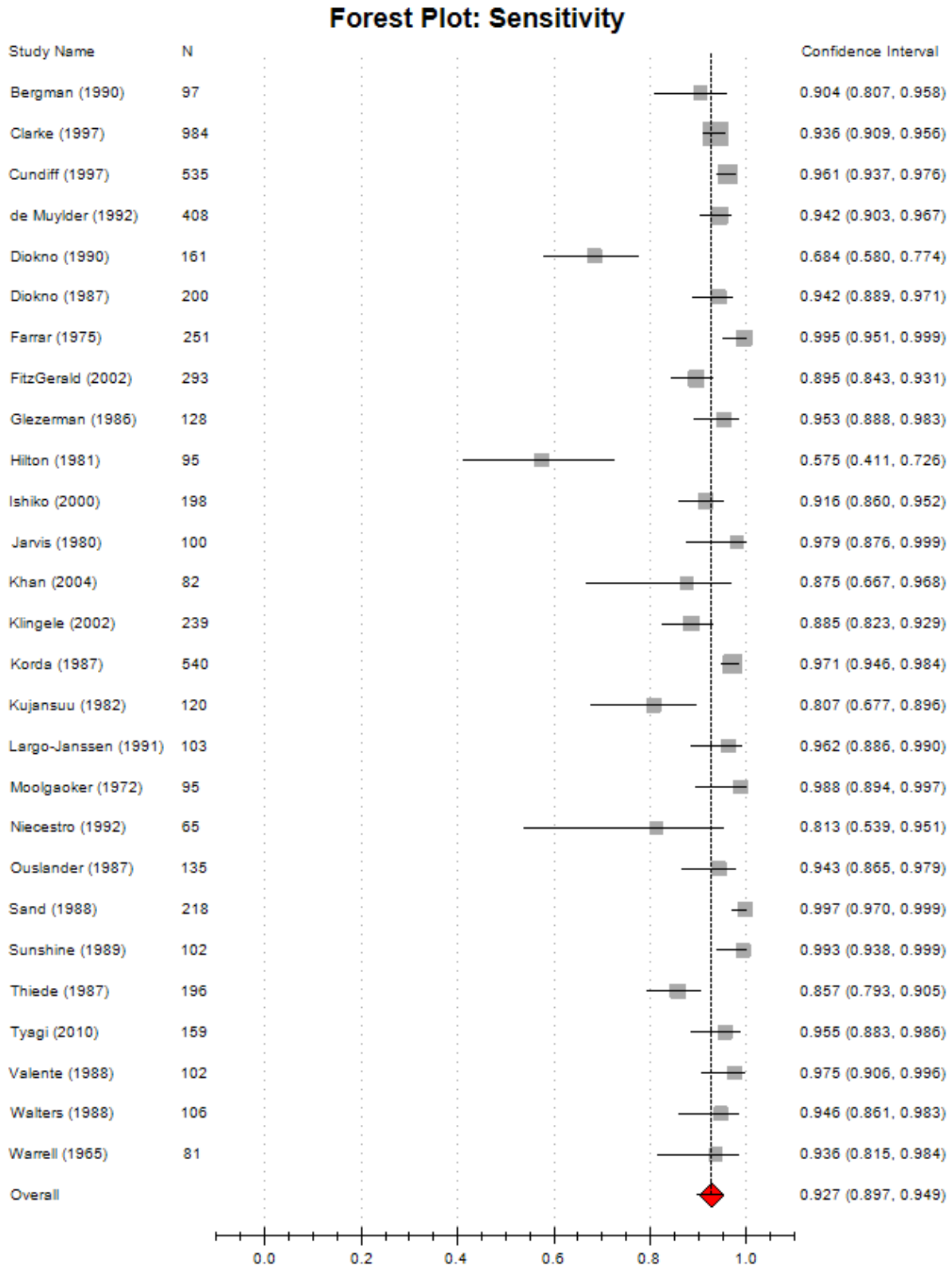


Horizontal axis - categories of the sample size of the studies
Vertical axis - number of studies

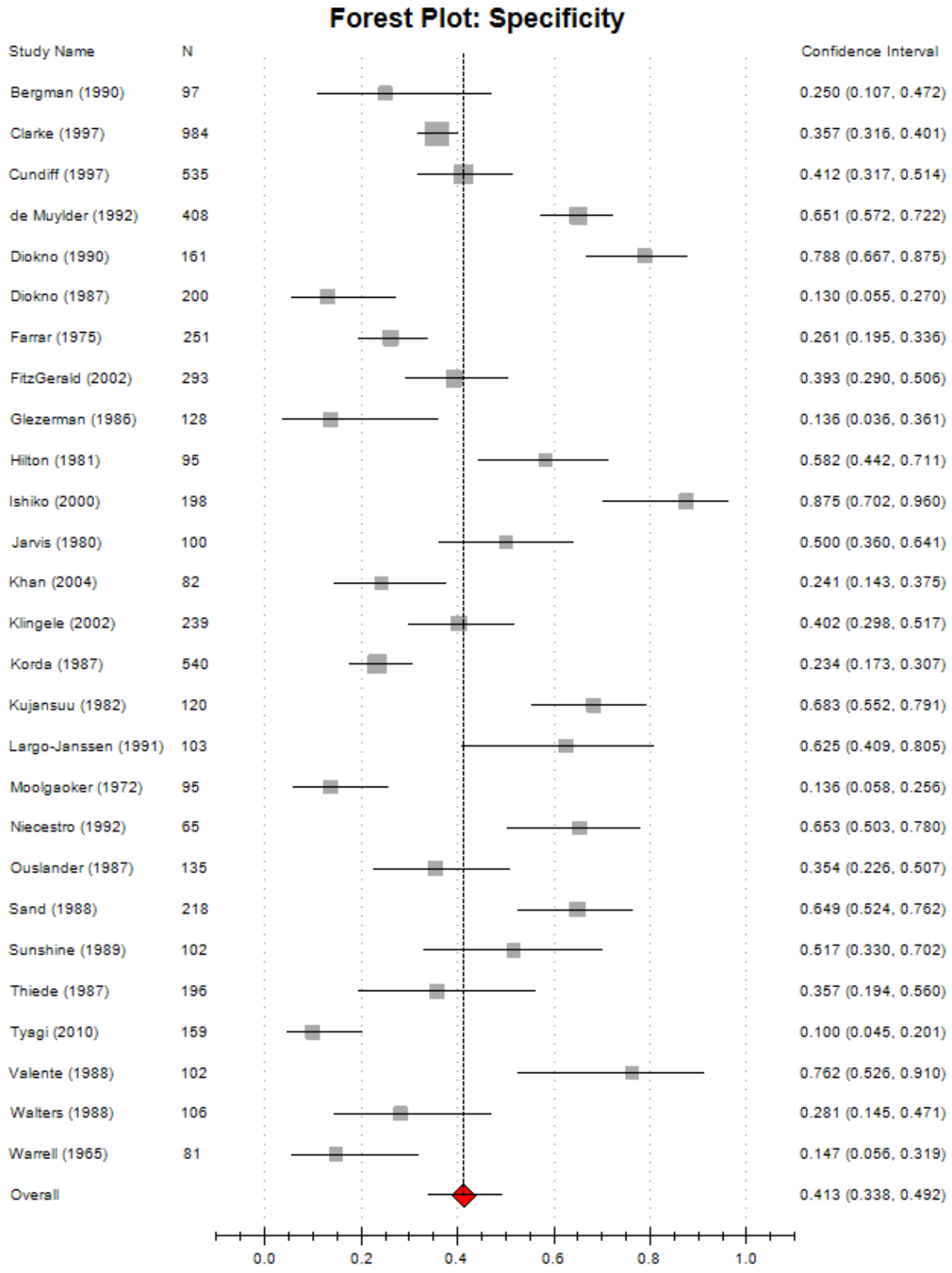
Appendix Table F5. Diagnostic value of symptoms of stress incontinence compared to multichannel urodynamics ("gold standard") for stress UI

Reference	True positive	False negative	True negative	False positive	Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio
Bergman, 1990[92]	66	7	6	18	0.90	0.25	1.21	0.38
Clarke, 1997[72]	439	30	184	331	0.94	0.36	1.46	0.18
Cundiff, 1997[75]	416	17	42	60	0.96	0.41	1.63	0.09
De Muylder, 1992[88]	228	14	108	58	0.94	0.65	2.70	0.09
Diokno, 1990[101]	65	30	52	14	0.68	0.79	3.23	0.40
Diokno, 1987[133]	145	9	6	40	0.94	0.13	1.08	0.45
Farrar, 1975[89]	93	0	41	117	1.00	0.26	1.35	0.00
FitzGerald, 2002[82]	187	22	33	51	0.90	0.39	1.47	0.27
Glezerman, 1986[105]	101	5	3	19	0.95	0.14	1.10	0.35
Hilton, 1981[74]	23	17	32	23	0.58	0.58	1.38	0.73
Ishiko, 2000[78]	152	14	28	4	0.92	0.88	7.33	0.10
Jarvis, 1980[73]	47	1	26	26	0.98	0.50	1.96	0.04
Khan, 2004[69]	21	3	14	44	0.88	0.24	1.15	0.52
Klingele, 2002[99]	139	18	33	49	0.89	0.40	1.48	0.29
Korda, 1987[134]	362	11	39	128	0.97	0.23	1.27	0.12
Kujansuu, 1982[132]	46	11	43	20	0.81	0.68	2.55	0.28
Lagro-Janssen, 1991[90]	76	3	15	9	0.96	0.63	2.57	0.06
Moolgaoker, 1972[97]	41	0	7	47	1.00	0.13	1.15	0.00
Niecostro, 1992[100]	13	3	32	17	0.81	0.65	2.34	0.29
Ouslander, 1987[91]	82	5	17	31	0.94	0.35	1.46	0.16
Sand, 1988[83]	152	0	43	23	1.00	0.65	2.87	0.00
Sunshine, 1989[131]	73	0	15	14	1.00	0.52	2.07	0.00
Thiede, 1987[103]	144	24	10	18	0.86	0.36	1.33	0.40
Tyagi, 2010[102]	85	4	7	63	0.96	0.10	1.06	0.45
Valente, 1988[85]	79	2	16	5	0.98	0.76	4.10	0.03
Walters, 1988[106]	70	4	9	23	0.95	0.28	1.32	0.19
Warrell, 1965[98]	44	3	5	29	0.94	0.15	1.10	0.44

Appendix Figure F2. Sensitivity of symptoms of stress incontinence compared to multichannel urodynamics ("gold standard") for any stress UI[69,72-75,78,82,83,85,88-92,97-103,105,106,131-134]



Appendix Figure F3. Specificity of symptoms of stress incontinence compared to multichannel urodynamics ("gold standard") for any stress UI[69,72-75,78,82,83,85,88-92,97-103,105,106,131-134]



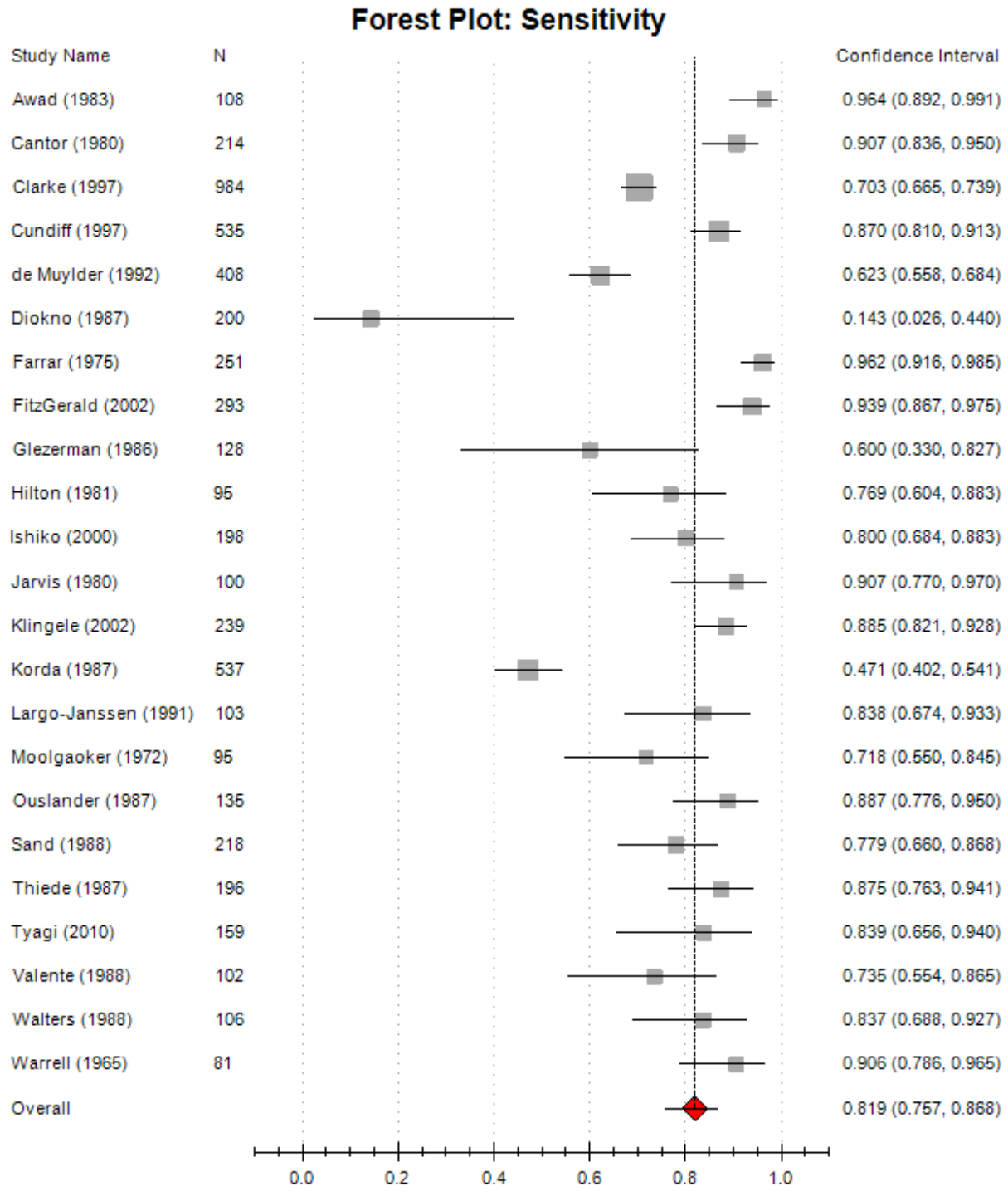
Appendix Table F6. Pooled diagnostic value of symptoms of stress incontinence compared to multichannel urodynamics ("gold standard") for any stress UI[69,72-75,78,82,83,85,88-92,97-103,105,106,131-134]

	Estimate	Lower 95% CI	Upper 95% CI	Tau-sq	I^2	Q statistics	Degree of freedom	P-value
Specificity	0.413	0.338	0.492	0.605	0.906	266.152	26.000	0.000
Sensitivity	0.927	0.897	0.949	0.698	0.855	171.848	26.000	0.000
Positive Predictive Value	0.743	0.683	0.795	0.548	0.943	438.683	26.000	0.000
Negative Predictive Value	0.743	0.669	0.805	0.571	0.786	116.605	26.000	0.000
Accuracy	0.745	0.699	0.786	0.321	0.926	338.902	26.000	0.000
Diagnostic Odds Ratio	9.226	6.190	13.753	0.714	0.765	106.452	26.000	0.000
Positive Likelihood Ratio	1.542	1.398	1.700	0.048	0.880	207.663	26.000	0.000
Negative Likelihood Ratio	0.196	0.142	0.270	0.457	0.796	122.714	26.000	0.000

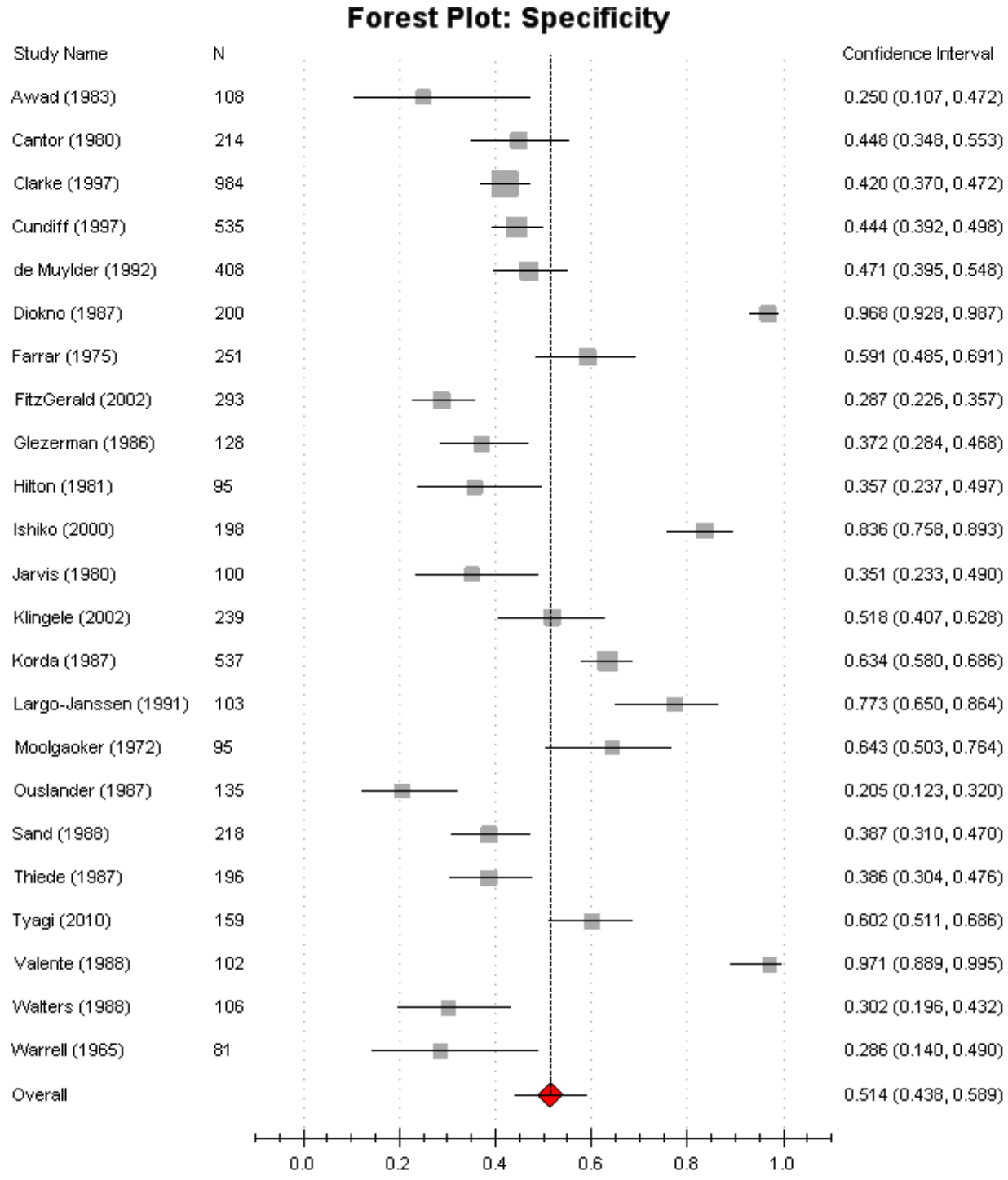
Appendix Table F7. Diagnostic value of urgency UI symptoms compared to multichannel urodynamics ("gold standard") for detrusor overactivity

Reference	True positive	False negative	True negative	False positive	Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio
Awad, 1983[104]	81	3	6	18	0.96	0.25	1.29	0.14
Cantor, 1980[84]	107	11	43	53	0.91	0.45	1.64	0.21
Clarke, 1997[72]	429	181	157	217	0.70	0.42	1.21	0.71
Cundiff, 1997[75]	160	24	156	195	0.87	0.44	1.56	0.29
De Muylder, 1992[88]	147	89	81	91	0.62	0.47	1.18	0.80
Diokno, 1987[133]	2	12	180	6	0.14	0.97	4.47	0.89
Farrar, 1975[89]	152	6	55	38	0.96	0.59	2.35	0.06
FitzGerald, 2002[82]	92	6	56	139	0.94	0.29	1.32	0.21
Glezerman, 1986[105]	9	6	42	71	0.60	0.37	0.96	1.08
Hilton, 1981[74]	30	9	20	36	0.77	0.36	1.20	0.65
Ishiko, 2000[78]	56	14	107	21	0.80	0.84	4.88	0.24
Jarvis, 1980[73]	39	4	20	37	0.91	0.35	1.40	0.26
Klingele, 2002[99]	138	18	43	40	0.89	0.52	1.84	0.22
Korda, 1987[134]	97	109	210	121	0.47	0.63	1.29	0.83
Lagor-Janssen, 1991[90]	31	6	51	15	0.84	0.77	3.69	0.21
Moolgaoker, 1972[97]	28	11	36	20	0.72	0.64	2.01	0.44
Ouslander, 1987[91]	55	7	15	58	0.89	0.21	1.12	0.55
Sand, 1988[83]	53	15	58	92	0.78	0.39	1.27	0.57
Thiede, 1987[103]	56	8	51	81	0.88	0.39	1.43	0.32
Tyagi, 2010[102]	26	5	77	51	0.84	0.60	2.11	0.27
Valente, 1988[85]	25	9	66	2	0.74	0.97	25.34	0.27
Walters, 1988[106]	36	7	19	44	0.84	0.30	1.20	0.54
Warrell, 1965[98]	48	5	8	20	0.91	0.29	1.27	0.33

Appendix Figure F4. Sensitivity of urgency UI symptoms compared to multichannel urodynamics ("gold standard") for any detrusor overactivity[72-75,78,82-85,88-91,97-99,102-106,133,134]



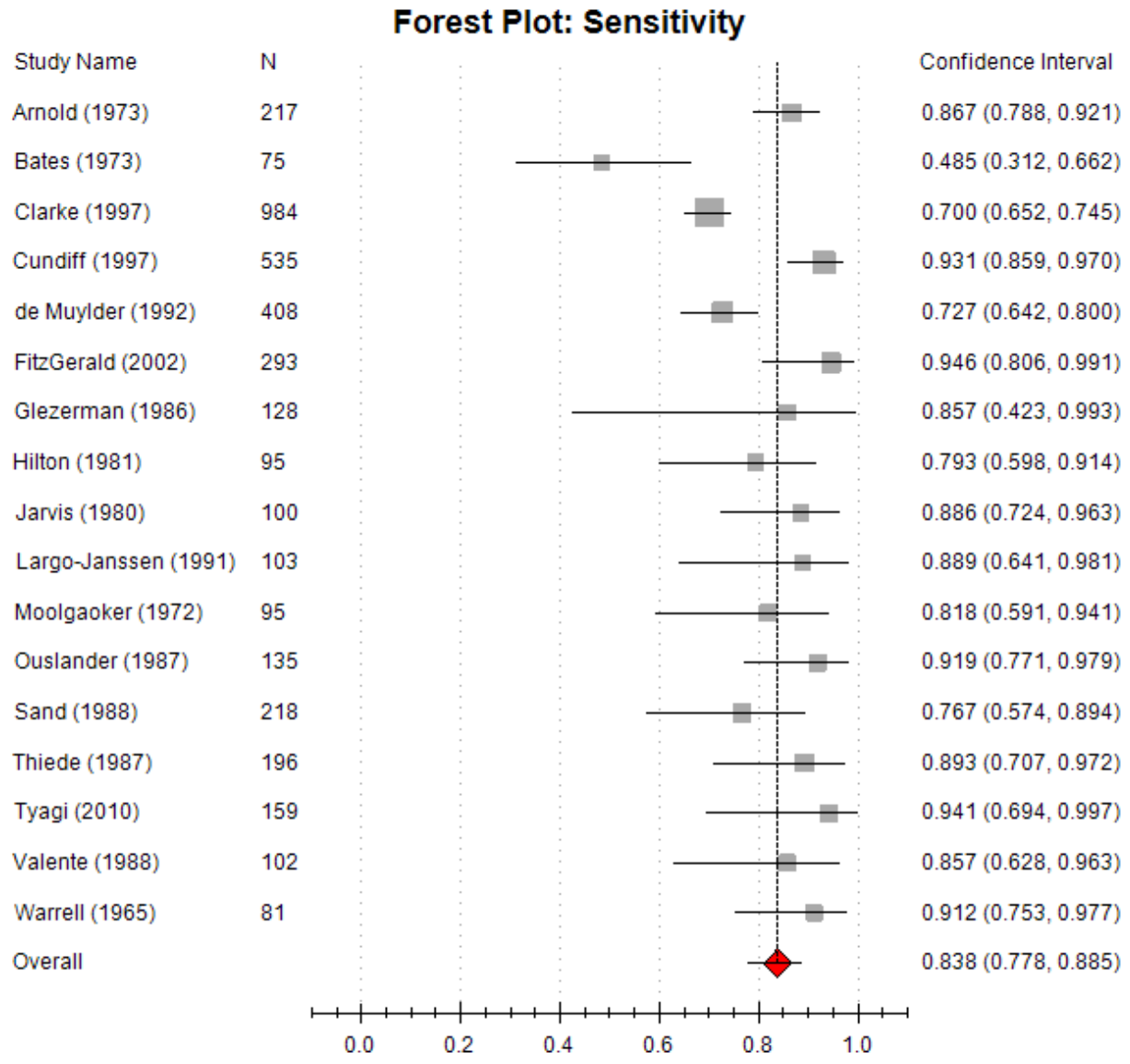
Appendix Figure F5. Specificity of urgency UI symptoms compared to multichannel urodynamics ("gold standard") for any detrusor overactivity[72-75,78,82-85,88-91,97-99,102-106,133,134]



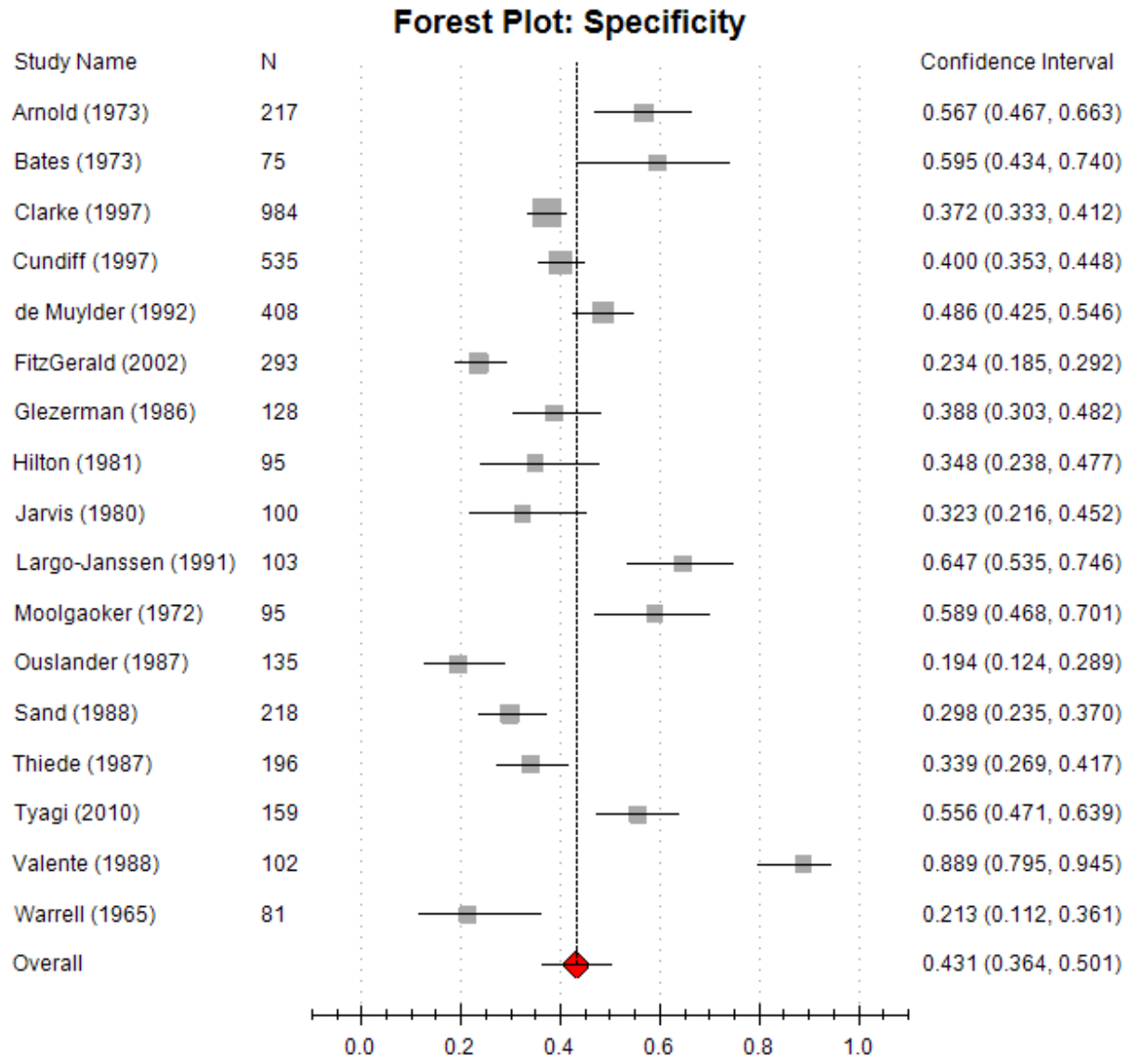
Appendix Table F8. Diagnostic value of urgency UI symptoms compared to multichannel urodynamics ("gold standard") for pure detrusor overactivity

Reference	True positive	False negative	True negative	False positive	Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio
Arnold, 1973[96]	98	15	59	45	0.87	0.57	2.00	0.23
Bates, 1973[95]	16	17	25	17	0.49	0.60	1.20	0.87
Clarke, 1997[72]	271	116	222	375	0.70	0.37	1.11	0.81
Cundiff, 1997[75]	95	7	173	260	0.93	0.40	1.55	0.17
De Muylder, 1992[88]	96	36	134	142	0.73	0.49	1.41	0.56
FitzGerald, 2002[82]	35	2	60	196	0.95	0.23	1.23	0.23
Glezerman, 1986[105]	6	1	47	74	0.86	0.39	1.40	0.37
Hilton, 1981[74]	23	6	23	43	0.79	0.35	1.22	0.59
Jarvis, 1980[73]	31	4	21	44	0.89	0.32	1.31	0.35
Lagor, Janssen, 1991[90]	16	2	55	30	0.89	0.65	2.52	0.17
Moolgaoker, 1972[97]	18	4	43	30	0.82	0.59	1.99	0.31
Ouslander, 1987[91]	34	3	19	79	0.92	0.19	1.14	0.42
Sand, 1998[83]	23	7	56	132	0.77	0.30	1.09	0.78
Thiede, 1987[103]	25	3	57	111	0.89	0.34	1.35	0.32
Tyagi, 2010[102]	16	1	79	63	0.94	0.56	2.12	0.11
Valente, 1988[85]	18	3	72	9	0.86	0.89	7.72	0.16
Warrell, 1965[98]	31	3	10	37	0.91	0.21	1.16	0.41

Appendix Figure F6. Sensitivity of urgency UI symptoms compared to multichannel urodynamics ("gold standard") for pure detrusor overactivity[72-75,82,83,85,88,90,91,95-98,102,103,105]



Appendix Figure F7. Specificity of urgency UI symptoms compared to multichannel urodynamics ("gold standard") for pure detrusor overactivity[72-75,82,83,85,88,90,91,95-98,102,103,105]



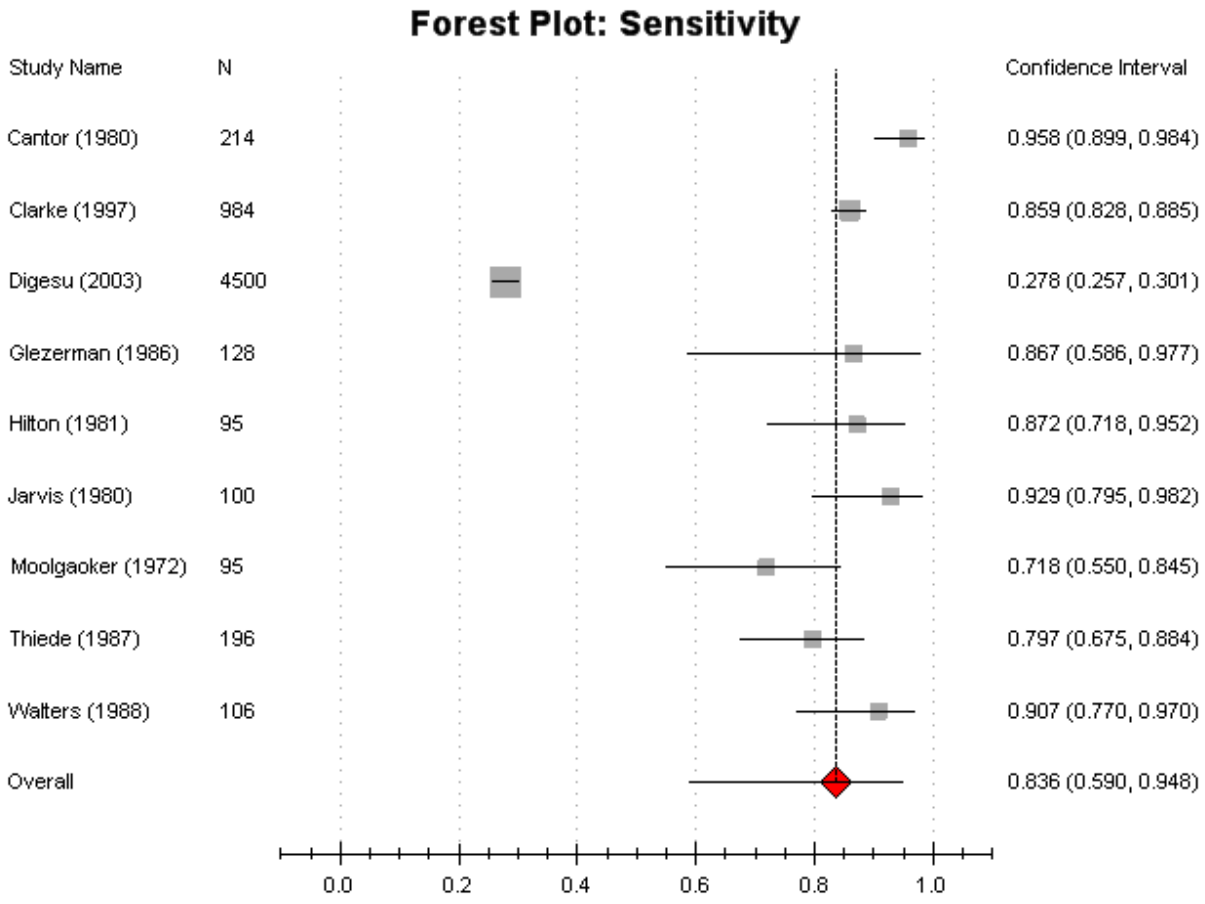
Appendix Table F9. Pooled Diagnostic value of urgency UI symptoms compared to multichannel urodynamics ("gold standard") for pure detrusor overactivity[72-75,82,83,85,88,90,91,95-98,102,103,105]

	Estimate	Lower 95% CI	Upper 95% CI	Tau^2	I^2	Q-statistic	Degree of freedom	P-value
Specificity	0.43	0.36	0.50	0.30	0.92	184.82	16.00	0.00
Sensitivity	0.84	0.78	0.89	0.41	0.77	66.16	16.00	0.00
Positive predictive value	0.33	0.26	0.41	0.44	0.93	209.80	16.00	0.00
Negative predictive value	0.89	0.83	0.93	0.86	0.88	123.86	16.00	0.00
Accuracy	0.53	0.48	0.59	0.21	0.92	183.24	16.00	0.00
Diagnostic odds ratio	4.17	2.59	6.70	0.66	0.80	75.47	16.00	0.00
Positive likelihood ratio	1.48	1.31	1.66	0.05	0.87	117.02	16.00	0.00
Negative likelihood ratio	0.40	0.29	0.54	0.24	0.74	58.69	16.00	0.00

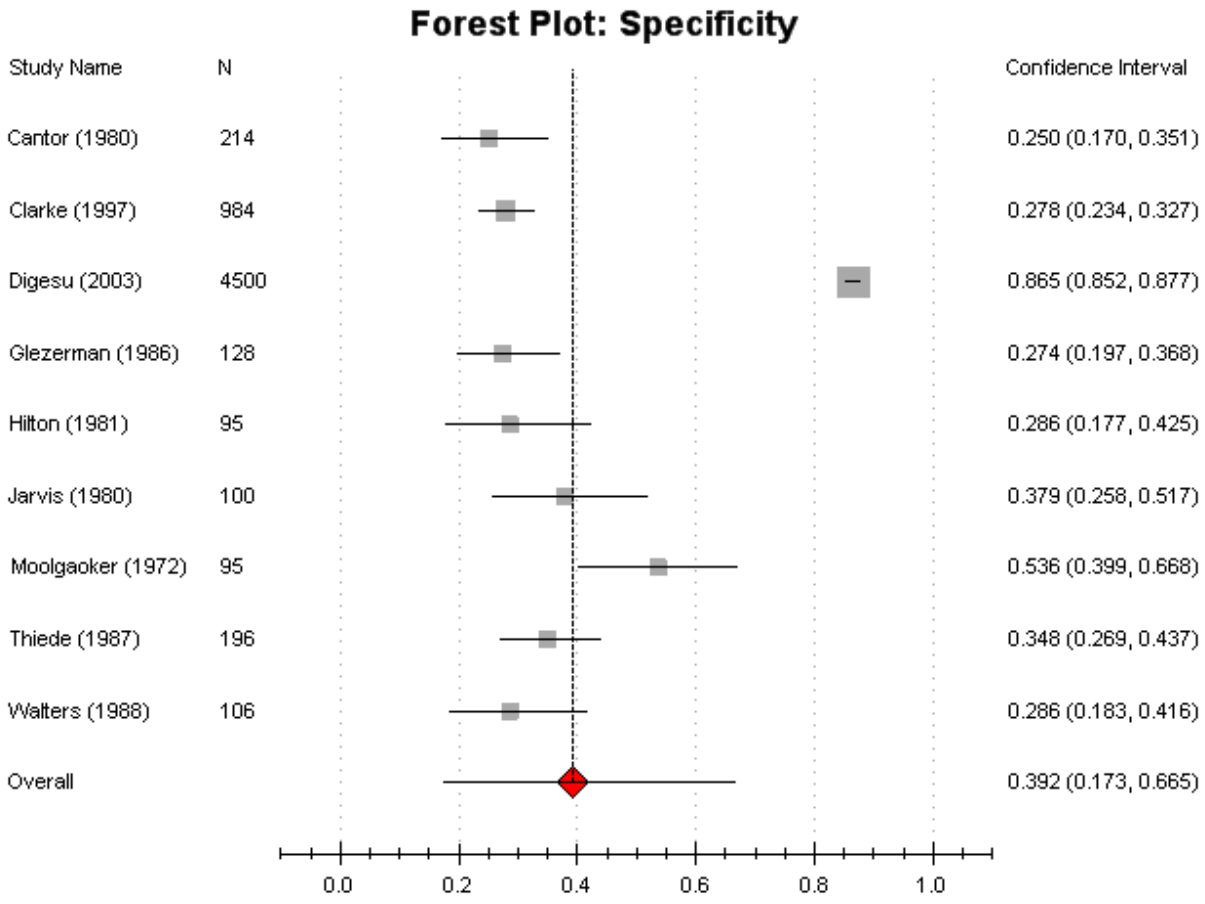
Appendix Table F10. Diagnostic value of urgency symptoms with or without UI compared to multichannel urodynamics ("gold standard") for detrusor overactivity

Reference	True positive	False negative	True negative	False positive	Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio
Cantor, 1980[84]	113	5	24	72	0.96	0.25	1.28	0.17
Clarke, 1997[72]	524	86	104	270	0.86	0.28	1.19	0.51
Digesu, 2003[68]	457	1184	2473	386	0.28	0.87	2.06	0.83
Glezerman, 1986[105]	13	2	31	82	0.87	0.27	1.19	0.49
Hilton, 1981[74]	34	5	16	40	0.87	0.29	1.22	0.45
Jarvis, 1980[73]	39	3	22	36	0.93	0.38	1.50	0.19
Moolgaoker, 1972[97]	28	11	30	26	0.72	0.54	1.55	0.53
Thiede, 1987[103]	51	13	46	86	0.80	0.35	1.22	0.58
Walters, 1988[106]	39	4	18	45	0.91	0.29	1.27	0.33

Appendix Figure F8. Sensitivity of urgency symptoms with or without UI compared to multichannel urodynamics ("gold standard") for any detrusor overactivity[68,72-74,84,97,103,105,106]



Appendix Figure F9. Specificity of urgency symptoms with or without UI compared to multichannel urodynamics ("gold standard") for any detrusor overactivity[68,72-74,84,97,105 103,106]



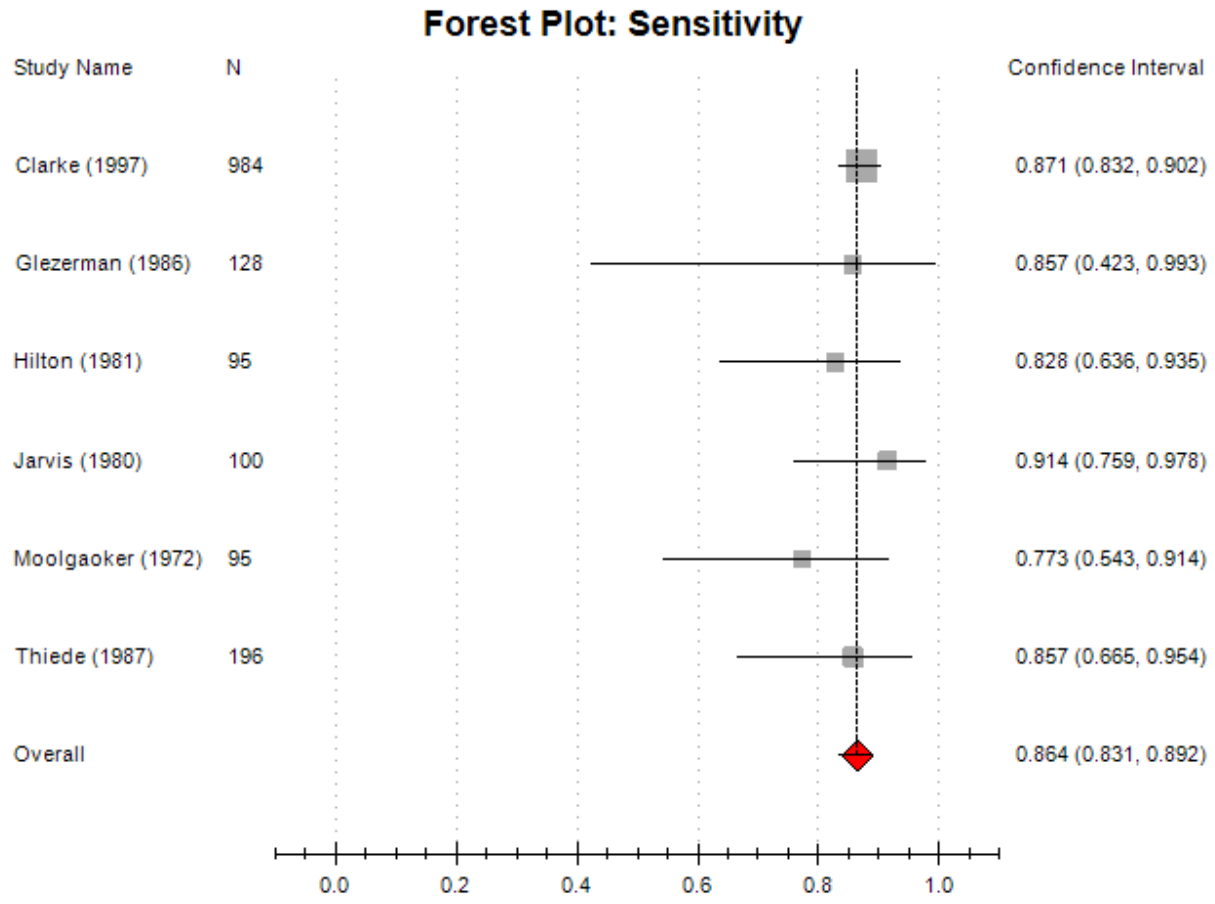
Appendix Table F11. Pooled diagnostic value of urgency symptoms with or without UI compared to multichannel urodynamics ("gold standard") for any detrusor overactivity[68,72-74,84,97,105 103,106]

	Estimate	Lower 95% CI	Upper 95% CI	Tau^2	I^2	Q-statistic	Degree of freedom	P-value
Specificity	0.39	0.17	0.67	2.91	0.99	898.68	8.00	0.00
Sensitivity	0.84	0.59	0.95	3.54	0.99	640.98	8.00	0.00
Positive predictive value	0.48	0.39	0.57	0.25	0.94	109.04	8.00	0.00
Negative predictive value	0.75	0.67	0.81	0.18	0.798	34.63	8.00	0.00
Accuracy	0.57	0.51	0.62	0.09	0.90	72.29	8.00	0.00
Diagnostic odds ratio	2.60	2.19	3.09	0.01	0.20	8.75	8.00	0.36
Positive likelihood ratio	1.36	1.18	1.58	0.04	0.89	64.89	8.00	0.00
Negative likelihood ratio	0.47	0.33	0.67	0.17	0.83	41.66	8.00	0.00

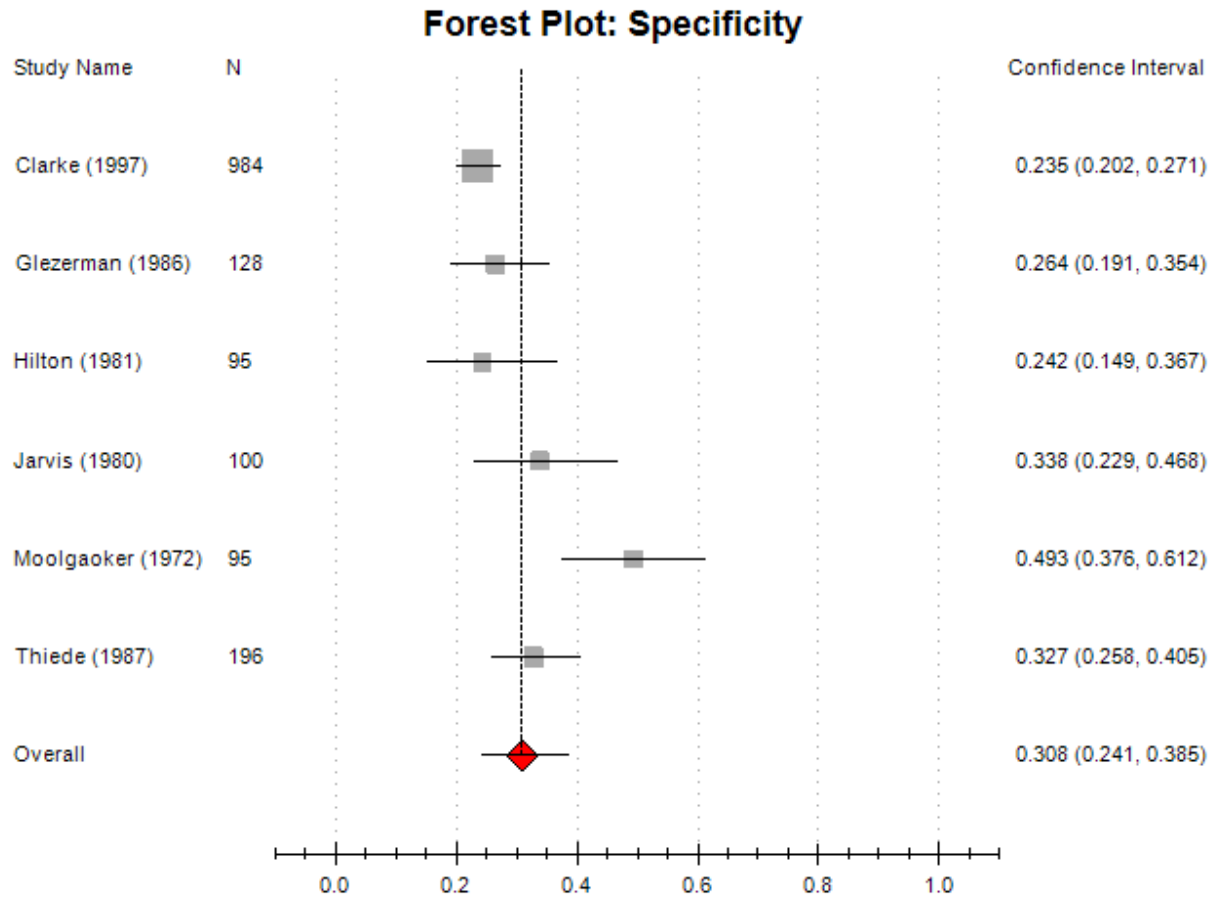
Appendix Table F12. Diagnostic value of urgency symptoms with or without UI compared to multichannel urodynamics ("gold standard") for pure detrusor overactivity

Reference	True positive	False negative	True negative	False positive	Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio
Clarke, 1997[72]	337	50	140	457	0.87	0.24	1.14	0.55
Glezerman, 1986[105]	6	1	32	89	0.86	0.26	1.16	0.54
Hilton, 1981[74]	24	5	16	50	0.83	0.24	1.09	0.71
Jarvis, 1980[73]	32	3	22	43	0.91	0.34	1.38	0.25
Moolgaoker, 1972[97]	17	5	36	37	0.77	0.49	1.52	0.46
Thiede, 1987[103]	24	4	55	113	0.86	0.33	1.27	0.44

Appendix Figure F10. Sensitivity of urgency symptoms with or without UI compared to multichannel urodynamics ("gold standard") for pure detrusor overactivity[72-74,97,103,105]



Appendix Figure F11. Specificity of urgency symptoms with or without UI compared to multichannel urodynamics ("gold standard") for pure detrusor overactivity[72-74,97,103,105]



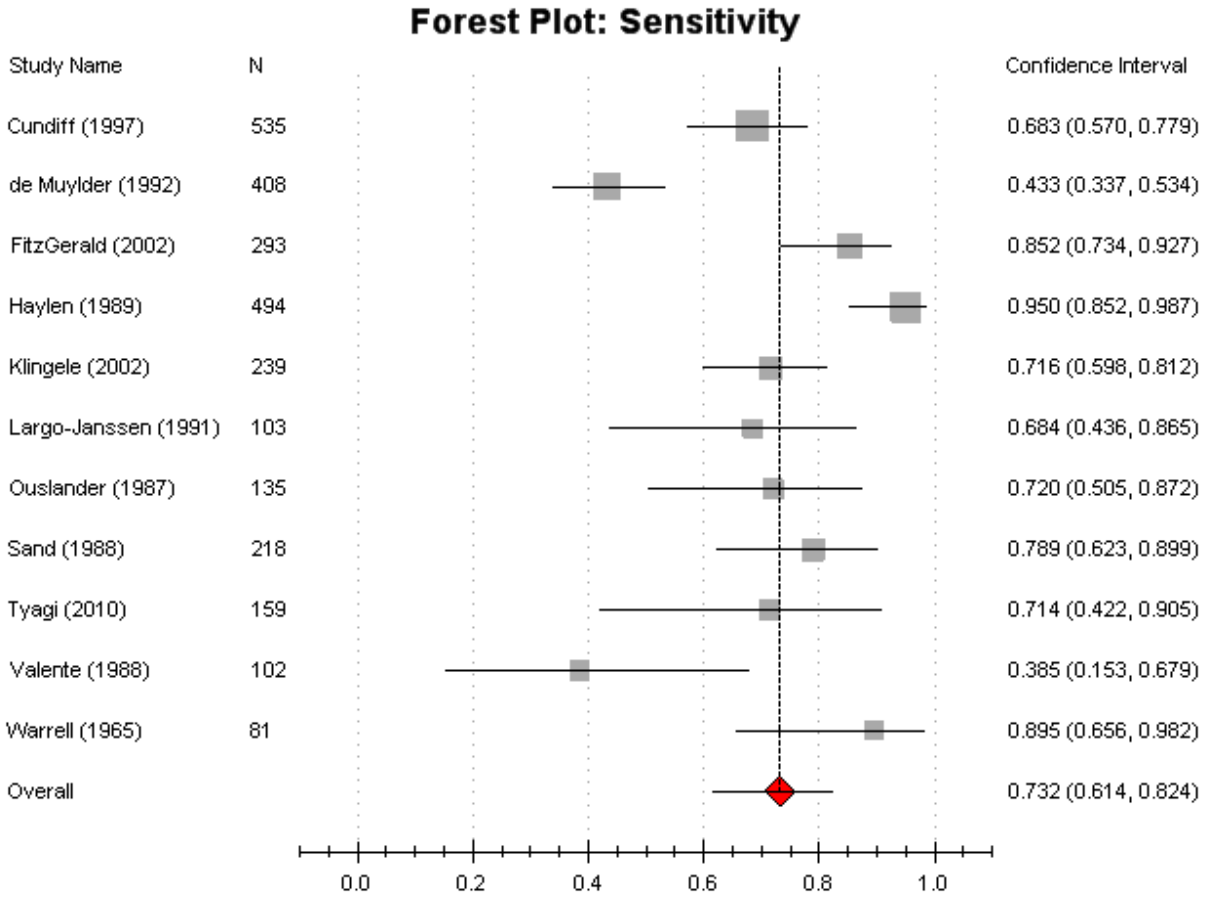
Appendix Table F13. Pooled diagnostic value of urgency symptoms with or without UI compared to multichannel urodynamics ("gold standard") for pure detrusor overactivity[72-74,97,103,105]

	Estimate	Lower 95% CI	Upper 95% CI	Tau^2	I^2	Q-statistic	Degree of freedom	P-value
Specificity	0.31	0.24	0.39	0.14	0.84	25.01	5.00	0.00
Sensitivity	0.86	0.83	0.89	0.00	-0.46	2.74	5.00	0.74
Positive predictive value	0.27	0.17	0.40	0.45	0.93	58.88	5.00	0.00
Negative predictive value	0.86	0.76	0.93	0.47	0.77	17.05	5.00	0.00
Accuracy	0.45	0.38	0.52	0.09	0.84	24.71	5.00	0.00
Diagnostic odds ratio	2.26	1.68	3.04	0.00	-0.26	3.18	5.00	0.67
Positive likelihood ratio	1.21	1.11	1.32	0.00	0.46	7.35	5.00	0.20
Negative likelihood ratio	0.52	0.41	0.67	0.00	-0.69	2.37	5.00	0.80

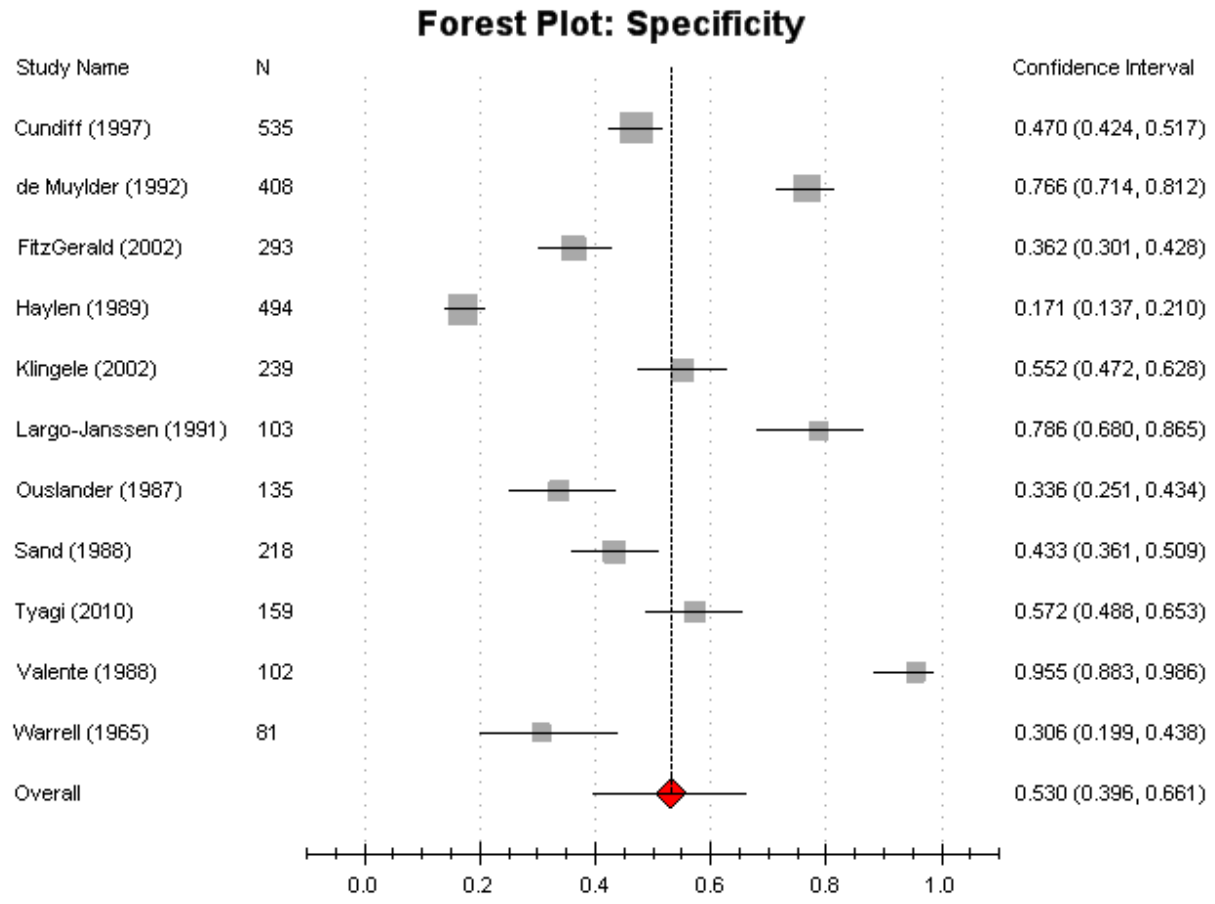
Appendix Table F14. Diagnostic value of mixed symptoms compared to multichannel urodynamics ("gold standard") for mixed UI

Reference	True positive	False negative	True negative	False positive	Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio
Cundiff, 1997[75]	56	26	213	240	0.68	0.47	1.29	0.67
De Muylder, 1992[88]	45	59	233	71	0.43	0.77	1.85	0.74
FitzGerald, 2002[82]	52	9	84	148	0.85	0.36	1.34	0.41
Haylen, 1989[93]	57	3	74	360	0.95	0.17	1.15	0.29
Klingele, 2002[99]	53	21	91	74	0.72	0.55	1.60	0.51
Lagro-Janssen, 1991[90]	13	6	66	18	0.68	0.79	3.20	0.40
Ouslander, 1987[91]	18	7	37	73	0.72	0.34	1.08	0.83
Sand, 1988[83]	30	8	78	102	0.79	0.43	1.39	0.49
Tyagi, 2010[102]	10	4	83	62	0.71	0.57	1.67	0.50
Valente, 1988[85]	5	8	85	4	0.39	0.96	8.56	0.64
Warrell, 1965[98]	17	2	19	43	0.90	0.31	1.29	0.34

Appendix Figure F12. Sensitivity of mixed symptoms compared to multichannel urodynamics ("gold standard") for mixed UI[75,82,83,85,88,90,91,93,98,99,102]



Appendix Figure F13. Specificity of mixed symptoms compared to multichannel urodynamics ("gold standard") for mixed UI[75,82,83,85,88,90,91,93,98,99,102]



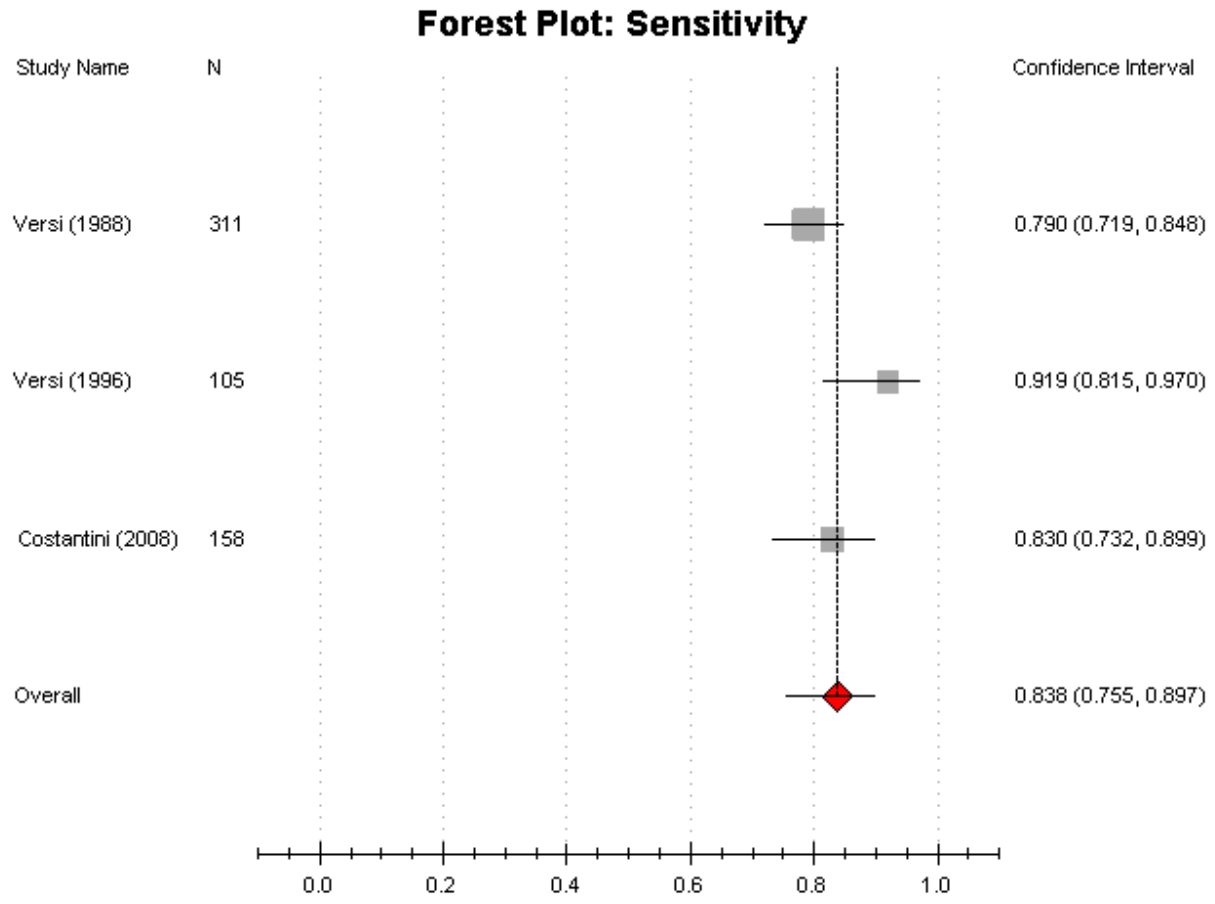
Appendix Table F15. Pooled Diagnostic value of mixed symptoms compared to multichannel urodynamics ("gold standard") for mixed UI[75,82,83,85,88,90,91,93,98,99,102]

	Estimate	Lower 95% CI	Upper 95% CI	Tau^2	I^2	Q-statistic	Degree of freedom	P-value
Specificity	0.53	0.40	0.66	0.80	0.97	327.20	10.00	0.00
Sensitivity	0.73	0.61	0.82	0.63	0.85	58.61	10.00	0.00
Positive predictive value	0.26	0.20	0.34	0.30	0.88	76.99	10.00	0.00
Negative predictive value	0.89	0.85	0.92	0.21	0.72	31.88	10.00	0.00
Accuracy	0.56	0.46	0.66	0.43	0.96	241.00	10.00	0.00
Diagnostic odds ratio	2.90	2.18	3.86	0.05	0.32	13.29	10.00	0.21
Positive likelihood ratio	1.45	1.27	1.67	0.04	0.80	45.18	10.00	0.00
Negative likelihood ratio	0.61	0.52	0.71	0.01	0.25	11.97	10.00	0.29

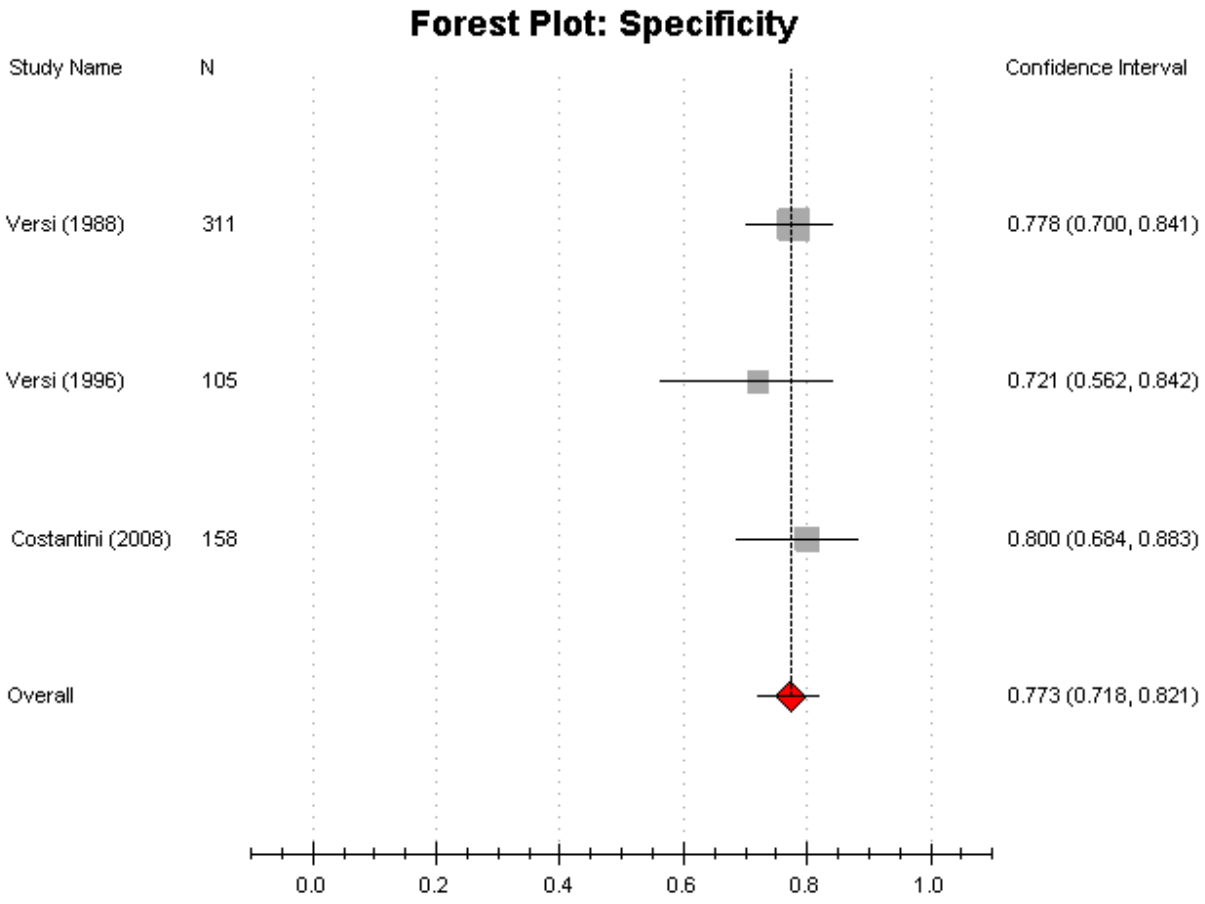
Appendix Table F16. Diagnostic value of pad test compared to multichannel urodynamics ("gold standard") for stress UI

Reference	True positives [false negatives]	False positives [true negatives]	Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio
1 hour pad test vs. UD						
Versi, 1988[80]	20 [19]	144 [128]	0.51	0.47	0.97	1.01
Costantini, 2008[77]	53 [8]	34 [63]	0.87	0.65	2.48	0.2
Pad test vs. UD						
Versi, 1988[80]	132 [35]	32 [112]	0.79	0.78	3.56	0.27
Versi, 1996[70]	57 [5]	12 [31]	0.92	0.72	3.29	0.11
Costantini, 2008[77]	73 [15]	14 [56]	0.83	0.80	4.15	0.21

Appendix Figure F14. Sensitivity of pad test compared to multichannel urodynamics ("gold standard") for any stress UI[70,77,80]



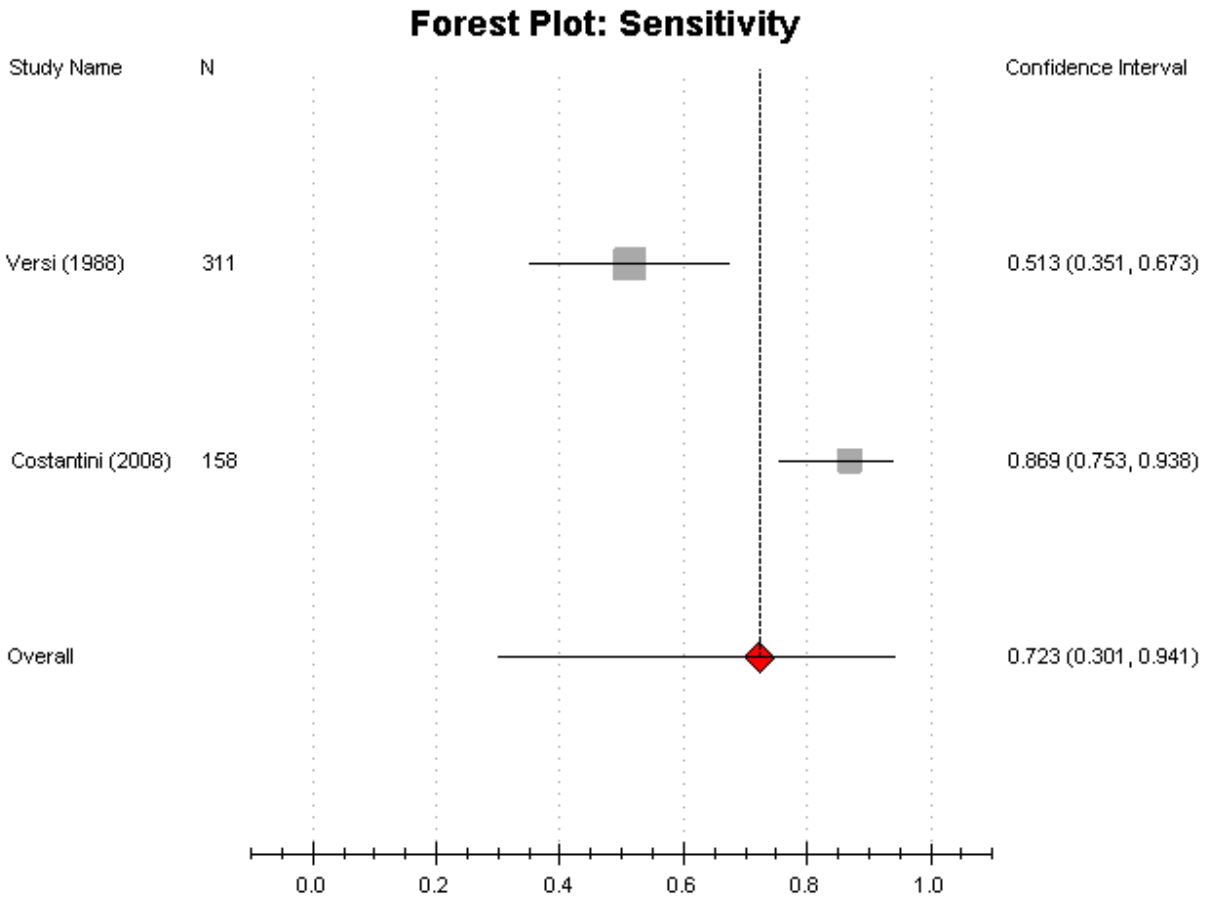
Appendix Figure F15. Specificity of pad test compared to multichannel urodynamics ("gold standard") for any stress UI[70,77,80]



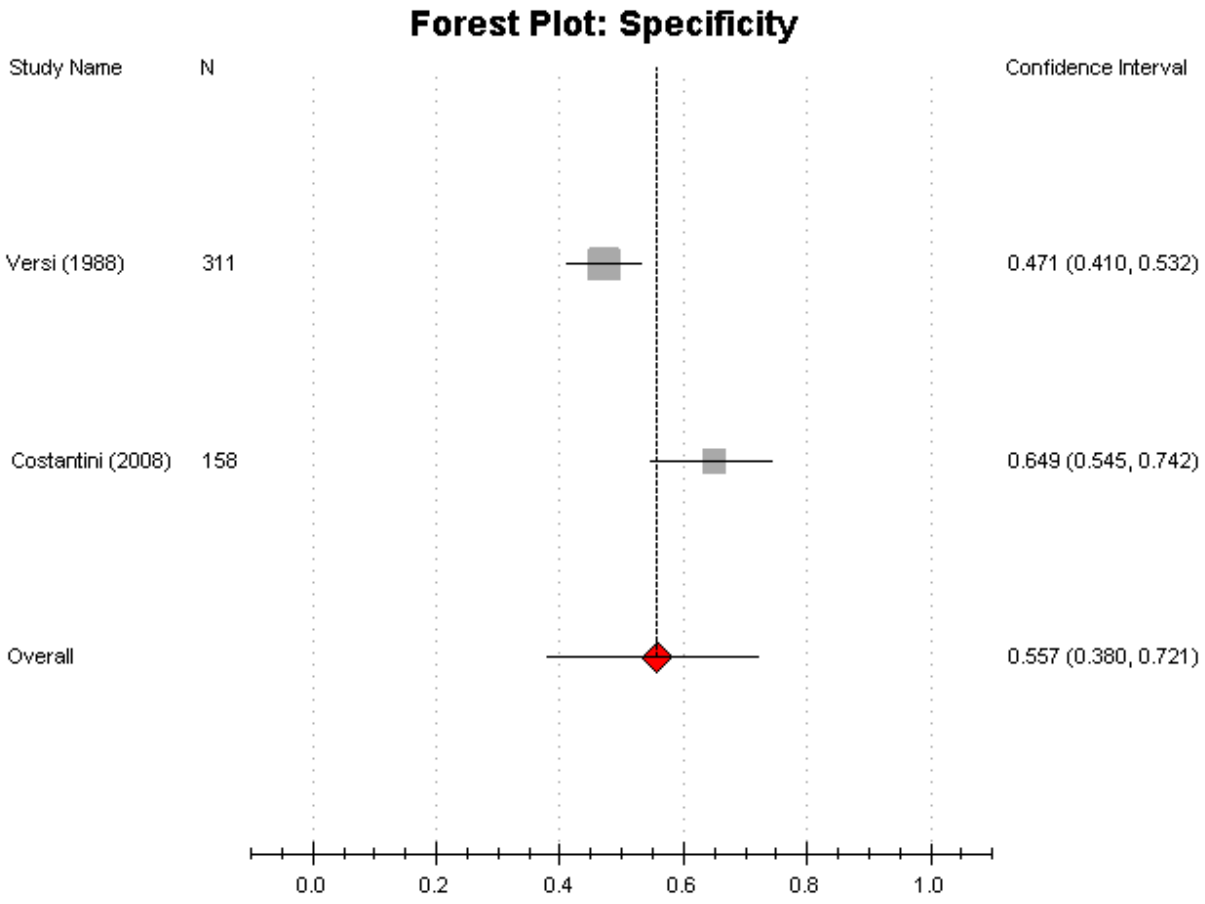
Appendix Table 17. Pooled Diagnostic value of pad test compared to multichannel urodynamics ("gold standard") for any stress UI[70,77,80]

	Estimate	95% CI	Tau-sq	I^2	Q-statistic	Degree of freedom	P-value
Specificity	0.773	0.718; 0.821	0.000	-0.032	0.969	2.000	0.616
Sensitivity	0.838	0.755; 0.897	0.123	0.796	4.908	2.000	0.086
Positive predictive value	0.818	0.772; 0.857	0.000	-1.088	0.479	2.000	0.787
Negative predictive value	0.781	0.726; 0.828	0.000	0.396	1.655	2.000	0.437
Accuracy	0.802	0.767; 0.833	0.000	0.397	1.660	2.000	0.436
Diagnostic odds ratio	16.343	10.761; 24.821	0.000	0.450	1.819	2.000	0.403
Positive likelihood ratio	3.624	2.875; 4.568	0.000	-1.138	0.468	2.000	0.791
Negative likelihood ratio	0.216	0.146; 0.319	0.057	0.736	3.782	2.000	0.151

Appendix Figure F16. Sensitivity of pad test compared to multichannel urodynamics ("gold standard") for any detrusor overactivity[77,80]



Appendix Figure F17. Specificity of pad test compared to multichannel urodynamics ("gold standard") for any detrusor overactivity[77,80]



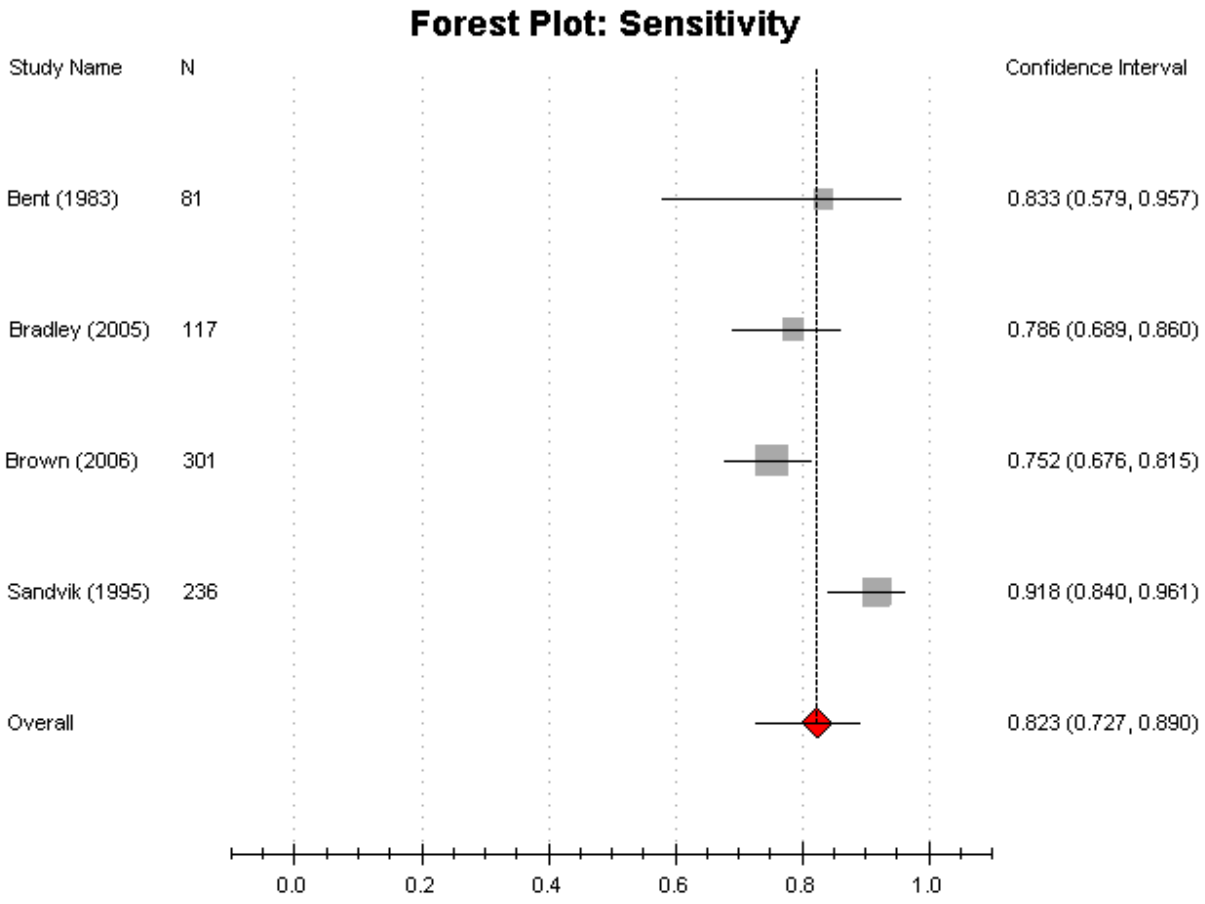
Appendix Table F18. Pooled diagnostic value of pad test compared to multichannel urodynamics ("gold standard") for any detrusor overactivity[77,80]

	Estimate	95% CI	Tau-sq	Q statistics	Degree of freedom	P-value
Specificity	0.557	0.380; 0.721	0.240	8.987	1.000	0.003
Sensitivity	0.723	0.301; 0.941	1.569	13.728	1.000	0.000
Positive predictive value	0.318	0.042; 0.833	2.871	55.565	1.000	0.000
Negative predictive value	0.876	0.825; 0.914	0.000	0.121	1.000	0.728
Accuracy	0.611	0.345; 0.824	0.596	27.306	1.000	0.000
Diagnostic odds ratio	3.342	0.268; 41.640	3.160	21.616	1.000	0.000
Positive likelihood ratio	1.555	0.619; 3.904	0.417	17.943	1.000	0.000
Negative likelihood ratio	0.469	0.095; 2.325	1.263	18.387	1.000	0.000

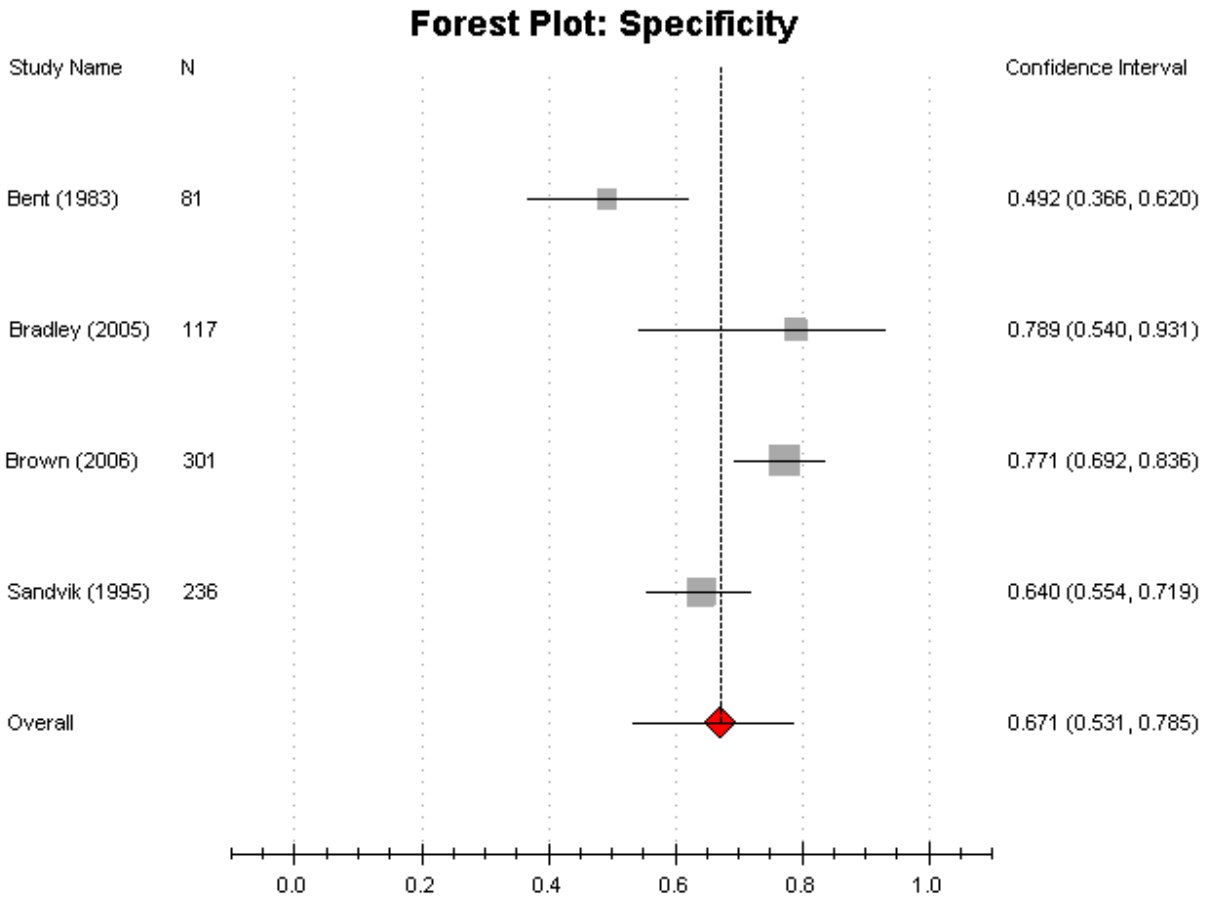
Appendix Table F19. Diagnostic value of symptoms compared to clinical diagnosis ("gold standard") for different types of urinary incontinence

Type of UI	Reference	True positives [false negatives]	False positives [true negatives]	Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio
Urgency UI	Bent, 1983[87]	15 [3]	32 [31]	0.83	0.49	1.64	0.34
Urgency UI	Bradley, 2005[81]	77 [21]	4 [15]	0.79	0.79	3.76	0.27
Urgency UI	Brown, 2006[76]	121 [40]	32 [108]	0.75	0.77	3.29	0.32
Urgency UI	Sandvik, 1995[71]	89 [8]	50 [89]	0.92	0.64	2.55	0.13
Urgency	Bent, 1983[87]	16 [2]	37 [26]	0.89	0.41	1.51	0.27
Stress UI	Bent, 1983[87]	20 [1]	22 [38]	0.95	0.63	2.60	0.08
Stress UI	Bradley, 2005[81]	75 [13]	8 [21]	0.85	0.71	2.93	0.21
Stress UI	Brown, 2006[76]	149 [25]	51 [76]	0.86	0.60	2.13	0.24
Stress UI	Sandvik, 1995[71]	179 [4]	26 [27]	0.98	0.51	1.99	0.04
Stress UI	Fischer-Rasmussen[121]	68[62]	12[70]	0.52	0.85	3.6	0.6
Mixed UI	Bradley, 2005[81]	50 [22]	78 [13]	0.70	0.86	5.00	0.35
Mixed UI	Brown, 2006[76]	15 [27]	47 [212]	0.36	0.82	1.97	0.79
Mixed UI	Sandvik, 1995[71]	47 [9]	61 [119]	0.84	0.66	2.48	0.24

Appendix Figure F18. Sensitivity of urgency UI symptoms compared to clinical diagnosis ("gold standard") for any detrusor overactivity (Bradley et al uses a composite diagnostic score)[71,76,81,87]



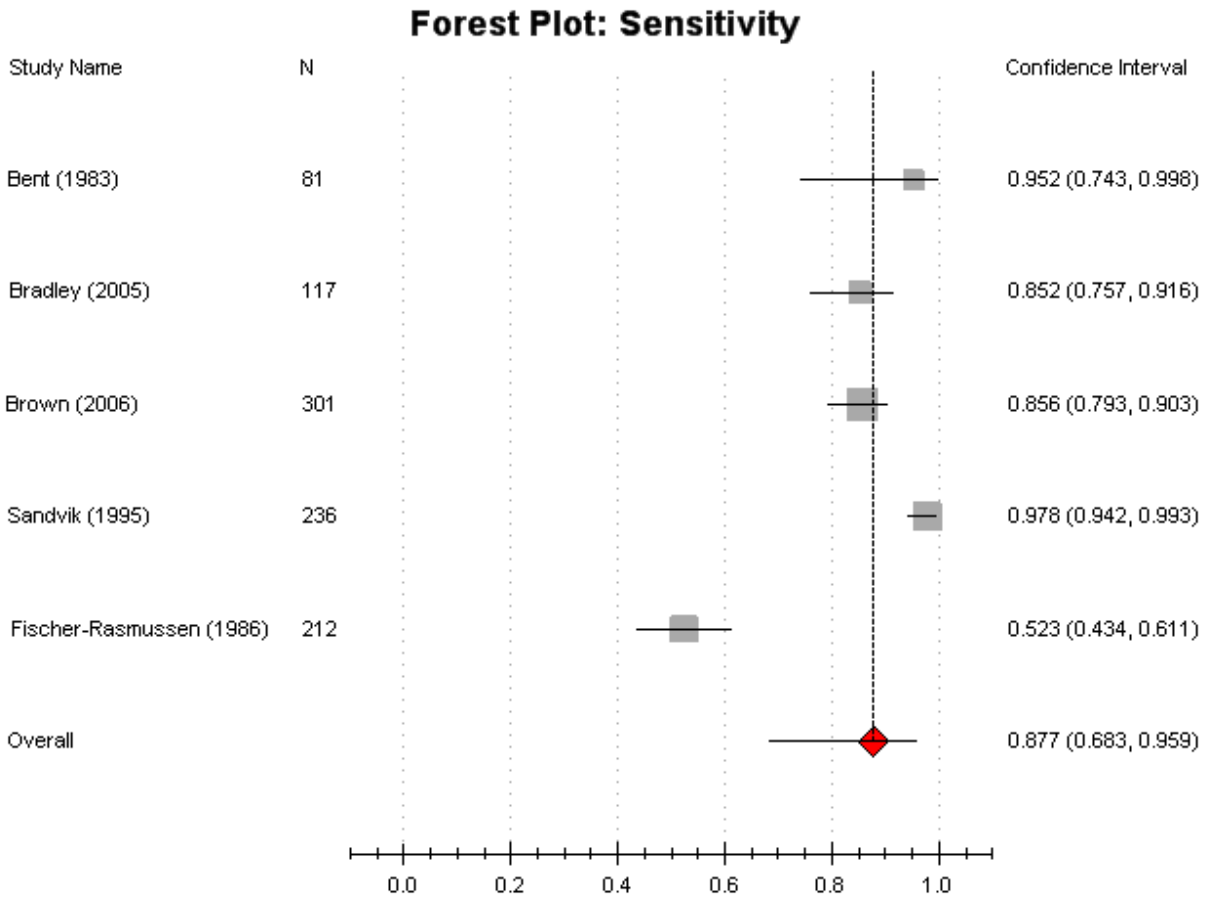
Appendix Figure F19. Specificity of urgency UI symptoms compared to clinical diagnosis ("gold standard") for any detrusor overactivity (Bradley et al uses a composite diagnostic scores)[71,76,81,87]



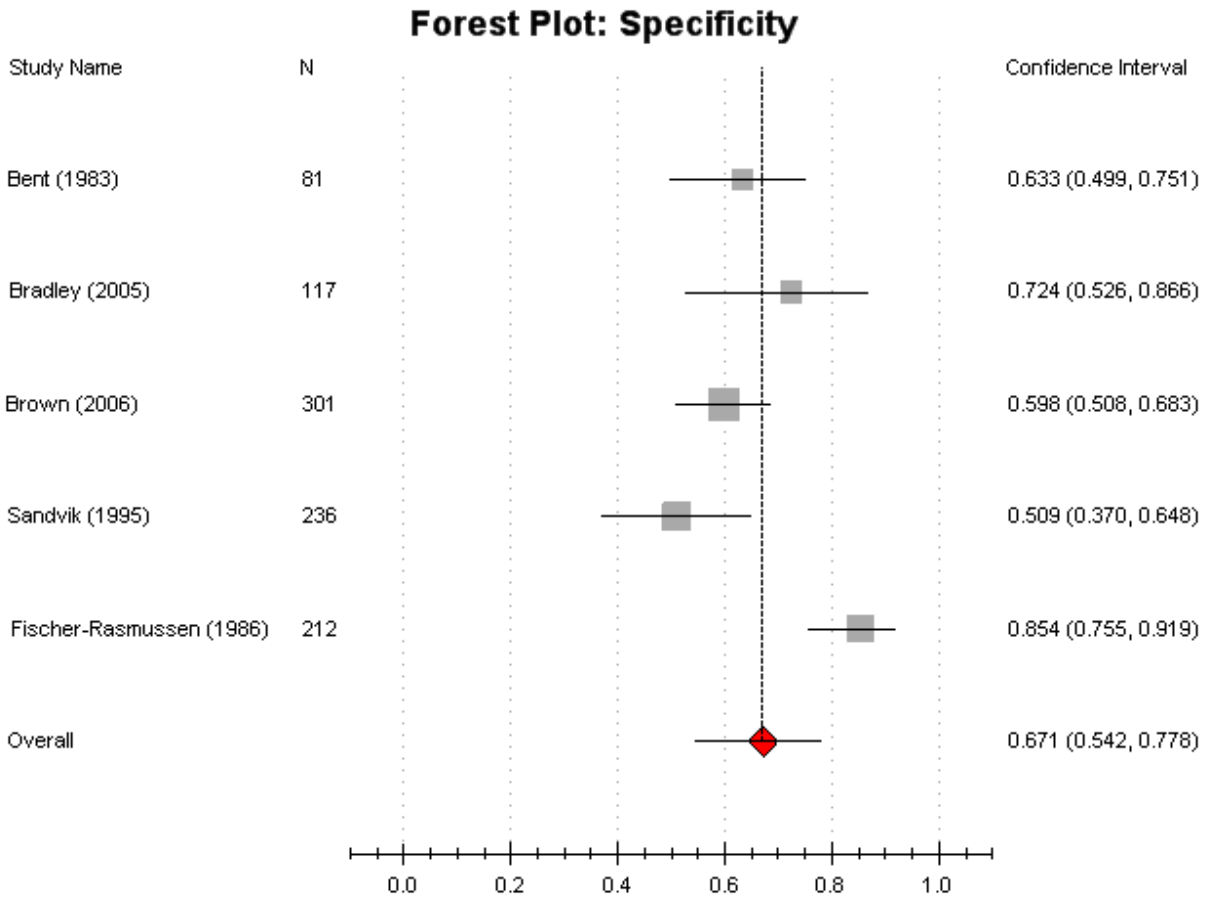
Appendix Table F20. Pooled Diagnostic value of urgency UI symptoms compared to clinical diagnosis ("gold standard") for any detrusor overactivity[71,76,81,87]

	Estimate	95% CI	Tau-sq	I^2	Q statistic	Degree of freedom	P-value
Specificity	0.671	0.531; 0.785	0.271	0.880	16.715	3.000	0.001
Sensitivity	0.823	0.727; 0.890	0.209	0.804	10.221	3.000	0.017
Positive predictive value	0.724	0.479; 0.882	1.040	0.961	51.159	3.000	0.000
Negative predictive value	0.786	0.543; 0.919	1.168	0.943	34.992	3.000	0.000
Accuracy	0.727	0.646; 0.796	0.114	0.858	14.083	3.000	0.003
Diagnostic odds ratio	11.684	7.321; 18.648	0.044	0.452	3.651	3.000	0.302
Positive likelihood ratio	2.516	1.808; 3.502	0.073	0.807	10.374	3.000	0.016
Negative likelihood ratio	0.257	0.176; 0.375	0.071	0.675	6.156	3.000	0.104

Appendix Figure F20. Sensitivity of stress UI symptoms compared to clinical diagnosis ("gold standard") for any stress UI[71,76,81,87,121]



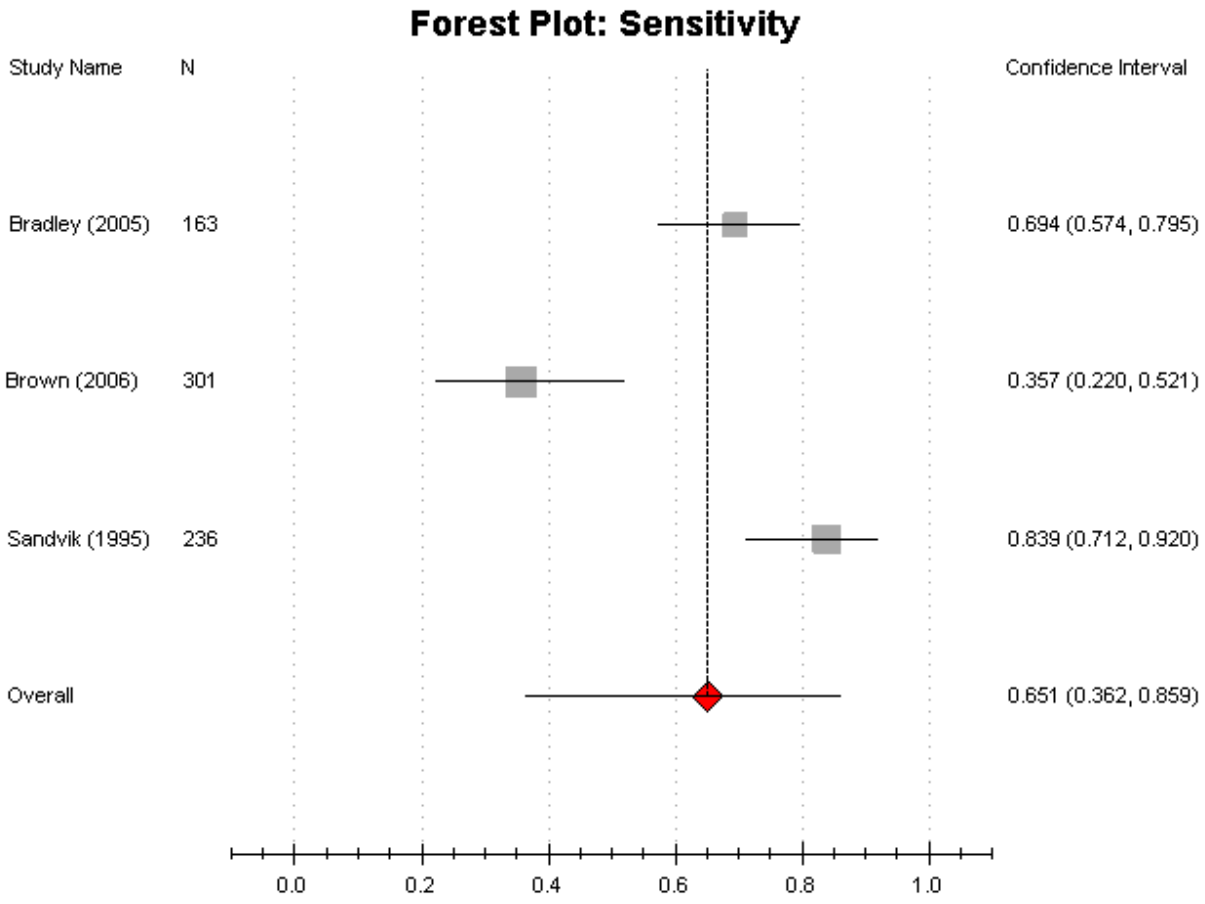
Appendix Figure F21. Specificity of stress UI symptoms compared to clinical diagnosis ("gold standard") for any stress UI[71,76,81,87,121]



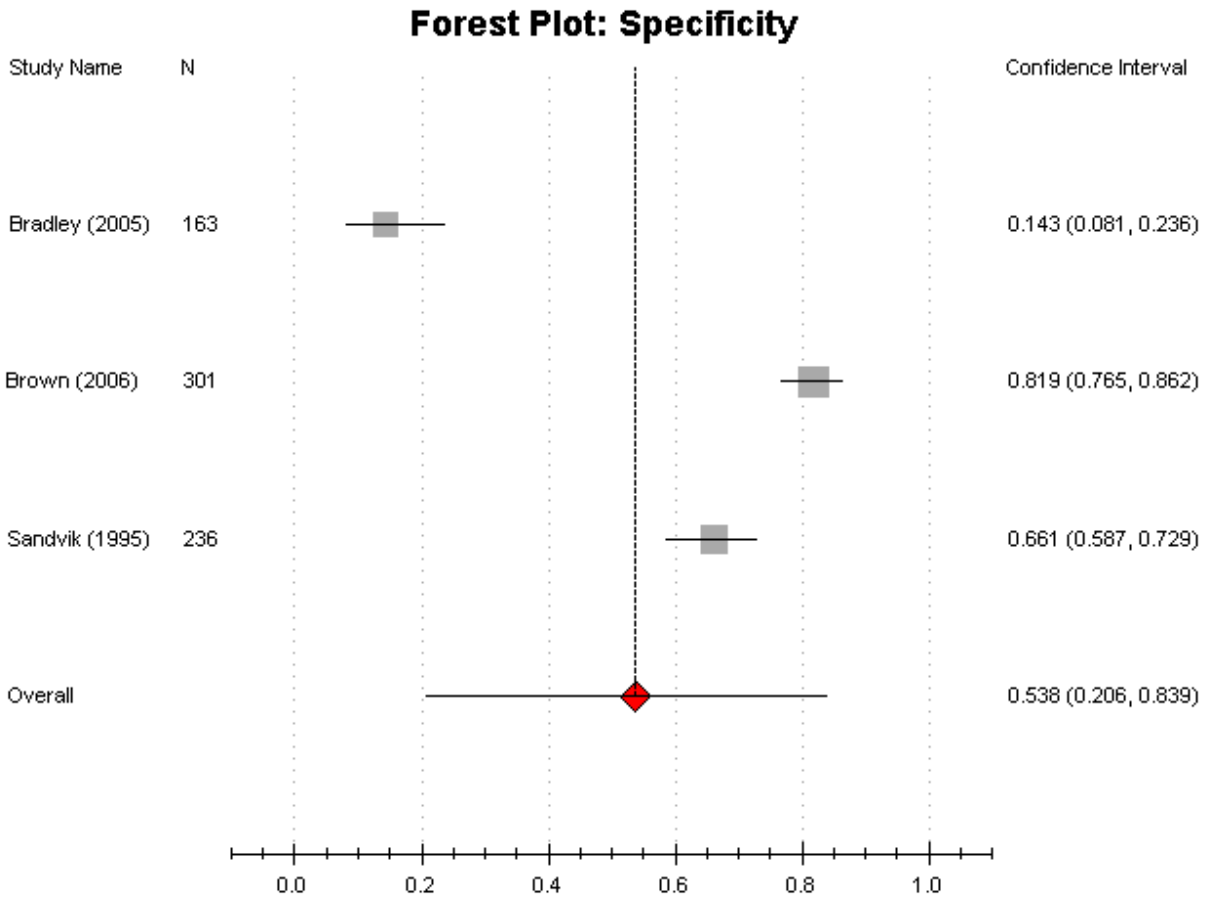
Appendix Table F21. Pooled diagnostic value of stress UI symptoms compared to clinical diagnosis ("gold standard") for any stress UI[71,76,81,87,121]

	Estimate	Lower (95% CI)	Upper (95% CI)	Tau-sq	I^2	Q-statistic	Degree of freedom	P-value
Specificity	0.67	0.54	0.78	0.30	0.85	20.10	4	0
Sensitivity	0.88	0.68	0.96	1.64	0.96	79.62	4	0
Positive predictive value	0.80	0.66	0.89	0.56	0.92	39.59	4	0
Negative predictive value	0.75	0.58	0.87	0.58	0.89	27.54	4	0
Accuracy	0.77	0.68	0.84	0.23	0.91	32.37	4	0
Diagnostic odds ratio	13.65	6.91	26.97	0.34	0.72	10.69	4	0.03
Positive likelihood ratio	2.35	1.97	2.81	0.01	0.44	5.39	4	0.25
Negative likelihood ratio	0.19	0.09	0.41	0.61	0.93	44.83	4	0

Appendix Figure F22. Sensitivity of mixed symptoms compared to clinical diagnosis ("gold standard") for mixed UI[71,76,81]



Appendix Figure F23. Specificity of mixed symptoms compared to clinical diagnosis ("gold standard") for mixed UI[71,76,81]



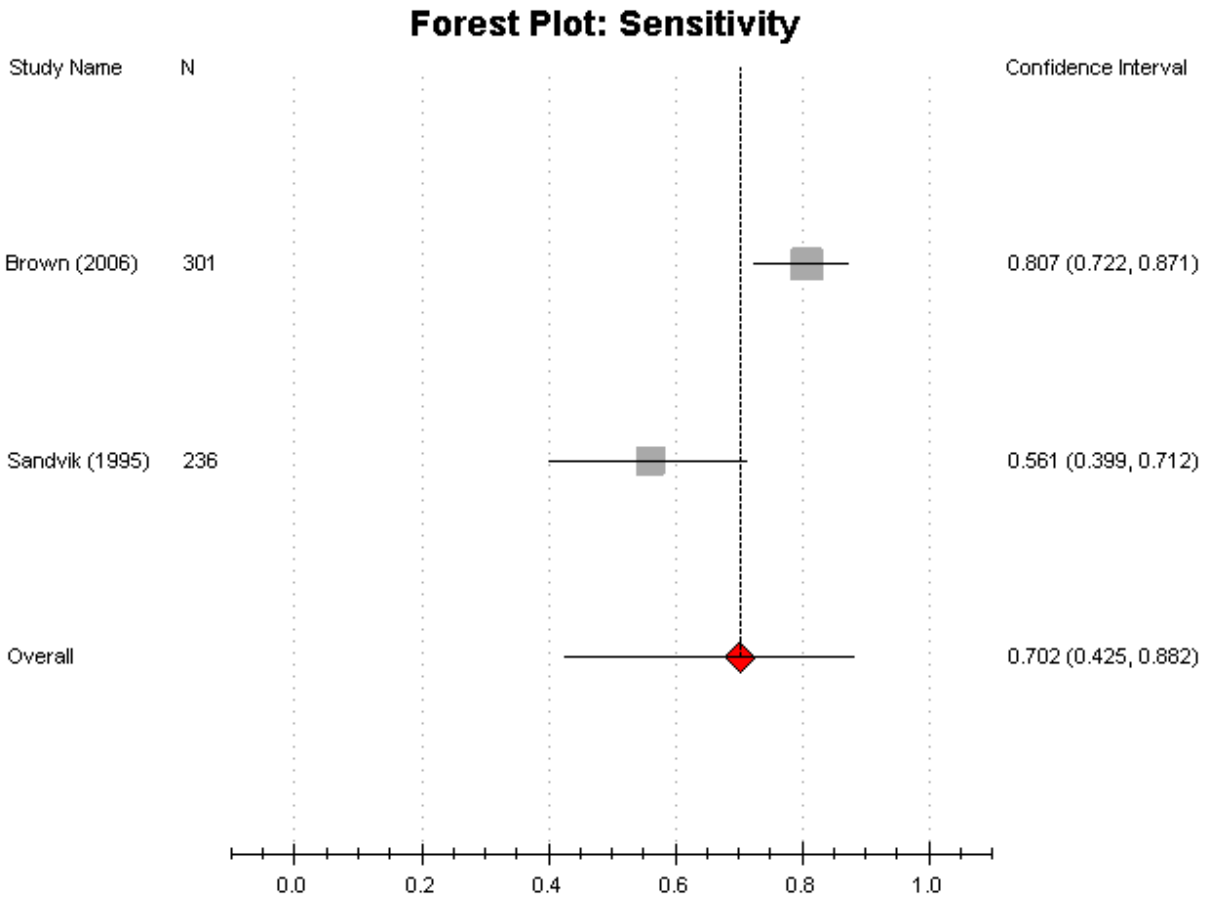
Appendix Table F22. Diagnostic value of mixed symptoms compared to clinical diagnosis ("gold standard") for mixed UI[71,76,81]

	Estimate	95% CI	Tau-sq	I^2	Q-statistic	Degree of freedom	P-value
Specificity	0.538	0.206; 0.839	1.707	0.989	94.201	2.000	0.000
Sensitivity	0.651	0.362; 0.859	1.003	0.956	22.724	2.000	0.000
Positive predictive value	0.363	0.269; 0.469	0.101	0.841	6.293	2.000	0.043
Negative predictive value	0.799	0.428; 0.955	2.092	0.980	50.001	2.000	0.000
Accuracy	0.625	0.400; 0.807	0.635	0.984	62.148	2.000	0.000
Diagnostic odds ratio	2.131	0.347; 13.073	2.423	0.971	35.002	2.000	0.000
Positive likelihood ratio	1.567	0.684; 3.587	0.509	0.983	59.879	2.000	0.000
Negative likelihood ratio	0.743	0.284; 1.947	0.657	0.959	24.565	2.000	0.000

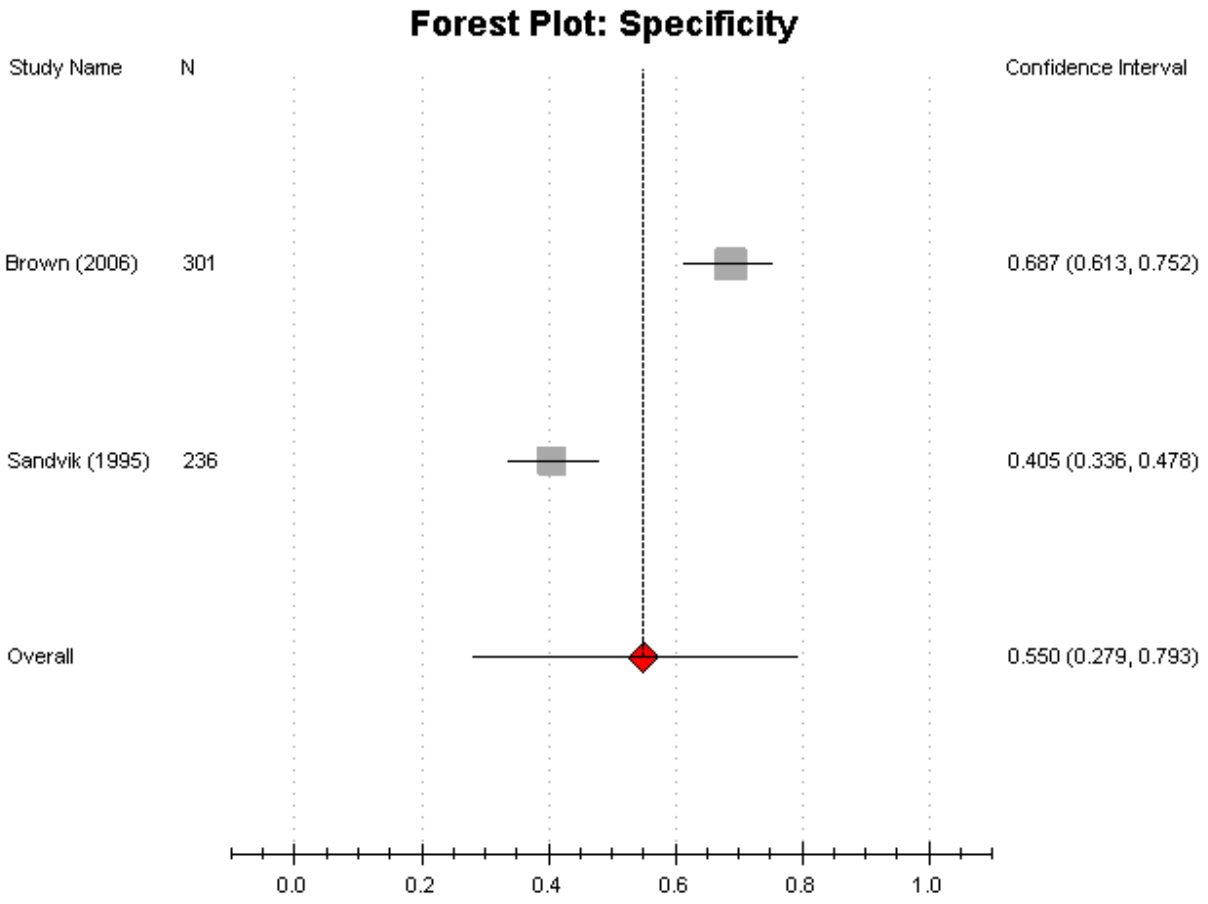
Appendix Table F23. Diagnostic value of urgency UI symptoms compared to clinical diagnosis for detrusor overactivity

Reference	True positives [false negatives]	False positives [true negatives]	Sensitivity	Specificity	Positive likelihood ratio	Negative likelihood ratio
Brown, 2006[76]	96 [23]	57 [125]	0.81	0.69	0.63	0.84
Sandvik, 1995[71]	23 [18]	116 [79]	0.56	0.41	0.17	0.81

Appendix Figure F24. Sensitivity of urgency UI symptoms compared to clinical diagnosis for pure detrusor overactivity[71,76]



Appendix Figure F25. Specificity of urgency UI symptoms compared to clinical diagnosis for pure detrusor overactivity[71,76]



Appendix Table F24. Pooled diagnostic value of urgency UI symptoms compared to clinical diagnosis for detrusor overactivity[71,76]

	Estimate	95% CI	Tau-sq	Q- statistic	Degree of freedom	P-value
Specificity	0.550	0.279; 0.793	0.660	29.206	1.000	0.000
Sensitivity	0.702	0.425; 0.882	0.624	9.163	1.000	0.002
Positive predictive value	0.368	0.067; 0.825	2.248	57.170	1.000	0.000
Negative predictive value	0.832	0.780; 0.874	0.000	0.382	1.000	0.537
Accuracy	0.592	0.291; 0.837	0.814	48.453	1.000	0.000
Diagnostic odds ratio	2.847	0.284; 28.566	2.669	27.721	1.000	0.000
Positive likelihood ratio	1.565	0.585; 4.190	0.487	27.556	1.000	0.000
Negative likelihood ratio	0.552	0.147; 2.069	0.871	23.833	1.000	0.000

Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT)[180]

Outcome	Predictor of effect	Fesoterodine daily dose	Control treatment	Daily dose of control treatment	Events/ randomized to active	Events/ randomized to control	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat	Attributable events/1000 treated
Discontinued	Patients with DO and urgency	4mg	Fesoterodine-extended release	8mg	4/25	6/28	0.75 (0.24; 2.35)	-0.05 (-0.26; 0.15)		
Discontinued	Patients with DO and urgency	4mg	Fesoterodine-extended release	12mg	4/25	4/22	0.88 (0.25; 3.11)	-0.02 (-0.24; 0.19)		
Discontinued	Patients with DO and urgency	4mg	Placebo		4/25	7/24	0.55 (0.18; 1.64)	-0.13 (-0.36; 0.10)		
Discontinued	Patients with DO and urgency	8mg	Placebo		6/28	7/24	0.73 (0.29; 1.89)	-0.08 (-0.31; 0.16)		
Discontinued	Patients with DO and urgency	12mg	Placebo		22/22	7/24	3.26 (1.79; 5.95)	0.71 (0.52; 0.90)	1	708
Discontinued	Patients with DO and urgency	8mg	Fesoterodine-extended release	12mg	6/28	4/22	1.18 (0.38; 3.67)	0.03 (-0.19; 0.25)		
Discontinued	Patients with no DO	4mg	Fesoterodine-extended release	8mg	1/18	3/19	0.35 (0.04; 3.08)	-0.10 (-0.30; 0.09)		
Discontinued	Patients with no DO	4mg	Fesoterodine-extended release	12mg	1/18	1/16	0.89 (0.06; 13.08)	-0.01 (-0.17; 0.15)		
Discontinued	Patients with no DO	4mg	Placebo		1/18	1/19	1.06 (0.07; 15.64)	0.00 (-0.14; 0.15)		
Discontinued	Patients with no DO	8mg	Placebo		3/19	1/19	3.00 (0.34; 26.33)	0.11 (-0.09; 0.30)		
Discontinued	Patients with no DO	12mg	Placebo		1/16	1/19	1.19 (0.08; 17.51)	0.01 (-0.15; 0.17)		

Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT)[180] (continued)

Outcome	Predictor of effect	Fesoterodine daily dose	Control treatment	Daily dose of control treatment	Events/ randomized to active	Events/ randomized to control	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat	Attributable events/1000 treated
Discontinued	Patients with no DO	8mg	Fesoterodine-extended release	12mg	3/19	1/16	2.53 (0.29; 21.98)	0.10 (-0.11; 0.30)		
Any adverse effects	Patients with DO and urgency	4mg	Fesoterodine-extended release	8mg	22/25	25/28	0.99 (0.81; 1.20)	-0.01 (-0.18; 0.16)		
Any adverse effects	Patients with DO and urgency	4mg	Fesoterodine-extended release	12mg	22/25	20/22	0.97 (0.80; 1.18)	-0.03 (-0.20; 0.15)		
Any adverse effects	Patients with DO and urgency	4mg	Placebo		22/25	16/24	1.32 (0.96; 1.81)	0.21 (-0.01; 0.44)		
Any adverse effects	Patients with DO and urgency	8mg	Placebo		25/28	16/24	1.34 (0.98; 1.83)	0.23 (0.01; 0.45)	4	226
Any adverse effects	Patients with DO and urgency	12mg	Placebo		20/22	16/24	1.36 (1.00; 1.86)	0.24 (0.02; 0.47)	4	242
Any adverse effects	Patients with DO and urgency	8mg	Fesoterodine-extended release	12mg	25/28	20/22	0.98 (0.82; 1.18)	-0.02 (-0.18; 0.15)		
Any adverse effects	Patients with DO and urgency	4mg	Fesoterodine-extended release	8mg	11/25	17/28	0.72 (0.43; 1.24)	-0.17 (-0.43; 0.10)		
Any adverse effects	Patients with DO and urgency	4mg	Fesoterodine-extended release	12mg	11/25	14/22	0.69 (0.40; 1.19)	-0.20 (-0.48; 0.08)		
Any adverse effects	Patients with DO and urgency	4mg	Placebo		11/25	3/24	3.52 (1.12; 11.09)	0.32 (0.08; 0.55)	3	315
Dry mouth	Patients with DO and urgency	8mg	Placebo		17/28	3/24	4.86 (1.62; 14.59)	0.48 (0.26; 0.71)	2	482
Dry mouth	Patients with DO and urgency	12mg	Placebo		14/22	3/24	5.09 (1.69; 15.36)	0.51 (0.27; 0.75)	2	511

Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT)[180] (continued)

Outcome	Predictor of effect	Fesoterodine daily dose	Control treatment	Daily dose of control treatment	Events/ randomized to active	Events/ randomized to control	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat	Attributable events/1000 treated
Dry mouth	Patients with DO and urgency	8mg	Fesoterodine-extended release	12mg	17/28	14/22	0.95 (0.62; 1.47)	-0.03 (-0.30; 0.24)		
Headache	Patients with DO and urgency	4mg	Fesoterodine-extended release	8mg	5/25	7/28	0.80 (0.29; 2.20)	-0.05 (-0.27; 0.17)		
Headache	Patients with DO and urgency	4mg	Fesoterodine-extended release	12mg	5/25	4/22	1.10 (0.34; 3.59)	0.02 (-0.21; 0.24)		
Headache	Patients with DO and urgency	4mg	Placebo		5/25	5/24	0.96 (0.32; 2.90)	-0.01 (-0.23; 0.22)		
Headache	Patients with DO and urgency	8mg	Placebo		7/28	5/24	1.20 (0.44; 3.29)	0.04 (-0.19; 0.27)		
Headache	Patients with DO and urgency	12mg	Placebo		4/22	5/24	0.87 (0.27; 2.84)	-0.03 (-0.26; 0.20)		
Headache	Patients with DO and urgency	8mg	Fesoterodine-extended release	12mg	7/28	4/22	1.38 (0.46; 4.11)	0.07 (-0.16; 0.30)		
Influenza-like symptoms	Patients with DO and urgency	4mg	Fesoterodine-extended release	8mg	6/25	3/28	2.24 (0.62; 8.03)	0.13 (-0.07; 0.34)		
Influenza-like symptoms	Patients with DO and urgency	4mg	Fesoterodine-extended release	12mg	6/25	3/22	1.76 (0.50; 6.22)	0.10 (-0.12; 0.32)		
Influenza-like symptoms	Patients with DO and urgency	4mg	Placebo		6/25	2/24	2.88 (0.64; 12.90)	0.16 (-0.04; 0.36)		
Influenza-like symptoms	Patients with DO and urgency	8mg	Placebo		3/28	2/24	1.29 (0.23; 7.07)	0.02 (-0.14; 0.18)		
Influenza-like symptoms	Patients with DO and urgency	12mg	Placebo		3/22	2/24	1.64 (0.30; 8.90)	0.05 (-0.13; 0.23)		

Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT)[180] (continued)

Outcome	Predictor of effect	Fesoterodine daily dose	Control treatment	Daily dose of control treatment	Events/ randomized to active	Events/ randomized to control	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat	Attributable events/1000 treated
Influenza-like symptoms	Patients with DO and urgency	8mg	Fesoterodine-extended release	12mg	3/28	3/22	0.79 (0.18; 3.52)	-0.03 (-0.21; 0.15)		
Dizziness	Patients with DO and urgency	4mg	Fesoterodine-extended release	8mg	0/25	1/28	0.37 (0.02; 8.73)	-0.04 (-0.13; 0.06)		
Dizziness	Patients with DO and urgency	4mg	Fesoterodine-extended release	12mg	0/25	2/22	0.18 (0.01; 3.50)	-0.09 (-0.23; 0.05)		
Dizziness	Patients with DO and urgency	4mg	Placebo		0/25	2/24	0.19 (0.01; 3.81)	-0.08 (-0.21; 0.05)		
Dizziness	Patients with DO and urgency	8mg	Placebo		1/28	2/24	0.43 (0.04; 4.44)	-0.05 (-0.18; 0.08)		
Dizziness	Patients with DO and urgency	12mg	Placebo		2/22	2/24	1.09 (0.17; 7.10)	0.01 (-0.16; 0.17)		
Dizziness	Patients with DO and urgency	8mg	Fesoterodine-extended release	12mg	1/28	2/22	0.39 (0.04; 4.06)	-0.06 (-0.19; 0.08)		
Nausea	Patients with DO and urgency	4mg	Fesoterodine-extended release	8mg	2/25	3/28	0.75 (0.14; 4.11)	-0.03 (-0.18; 0.13)		
Nausea	Patients with DO and urgency	4mg	Fesoterodine-extended release	12mg	2/25	3/22	0.59 (0.11; 3.20)	-0.06 (-0.23; 0.12)		
Nausea	Patients with DO and urgency	4mg	Placebo		2/25	3/24	0.64 (0.12; 3.50)	-0.05 (-0.21; 0.12)		
Nausea	Patients with DO and urgency	8mg	Placebo		3/28	3/24	0.86 (0.19; 3.86)	-0.02 (-0.19; 0.16)		
Nausea	Patients with DO and urgency	12mg	Placebo		3/22	3/24	1.09 (0.25; 4.85)	0.01 (-0.18; 0.21)		

Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT)[180] (continued)

Outcome	Predictor of effect	Fesoterodine daily dose	Control treatment	Daily dose of control treatment	Events/ randomized to active	Events/ randomized to control	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat	Attributable events/1000 treated
Nausea	Patients with DO and urgency	8mg	Fesoterodine-extended release	12mg	3/28	3/22	0.79 (0.18; 3.52)	-0.03 (-0.21; 0.15)		
Constipation	Patients with DO and urgency	4mg	Fesoterodine-extended release	8mg	1/25	5/28	0.22 (0.03; 1.79)	-0.14 (-0.30; 0.02)		
Constipation	Patients with DO and urgency	4mg	Fesoterodine-extended release	12mg	1/25	4/22	0.22 (0.03; 1.82)	-0.14 (-0.32; 0.04)		
Constipation	Patients with DO and urgency	4mg	Placebo		1/25	0/24	2.88 (0.12; 67.53)	0.04 (-0.07; 0.15)		
Constipation	Patients with DO and urgency	8mg	Placebo		5/28	0/24	9.48 (0.55; 163.15)	0.18 (0.03; 0.33)	6	179
Constipation	Patients with DO and urgency	12mg	Placebo		4/22	0/24	9.78 (0.56; 171.91)	0.18 (0.01; 0.35)	5	182
Constipation	Patients with DO and urgency	8mg	Fesoterodine-extended release	12mg	5/28	4/22	0.98 (0.30; 3.23)	0.00 (-0.22; 0.21)		
Abdominal pain	Patients with DO and urgency	4mg	Fesoterodine-extended release	8mg	2/25	2/28	1.12 (0.17; 7.37)	0.01 (-0.13; 0.15)		
Abdominal pain	Patients with DO and urgency	4mg	Fesoterodine-extended release	12mg	2/25	3/22	0.59 (0.11; 3.20)	-0.06 (-0.23; 0.12)		
Abdominal pain	Patients with DO and urgency	4mg	Placebo		2/25	0/24	4.81 (0.24; 95.25)	0.08 (-0.05; 0.21)		
Abdominal pain	Patients with DO and urgency	8mg	Placebo		2/28	0/24	4.31 (0.22; 85.62)	0.07 (-0.04; 0.19)		
Abdominal pain	Patients with DO and urgency	12mg	Placebo		3/22	0/24	7.61 (0.42; 139.47)	0.14 (-0.02; 0.29)		

Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT)[180] (continued)

Outcome	Predictor of effect	Fesoterodine daily dose	Control treatment	Daily dose of control treatment	Events/ randomized to active	Events/ randomized to control	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat	Attributable events/1000 treated
Abdominal pain	Patients with DO and urgency	8mg	Fesoterodine-extended release	12mg	2/28	3/22	0.52 (0.10; 2.87)	-0.06 (-0.24; 0.11)		
Diarrhea	Patients with DO and urgency	4mg	Fesoterodine-extended release	8mg	4/25	0/28	10.04 (0.57; 177.65)	0.16 (0.01; 0.31)	6	160
Diarrhea	Patients with DO and urgency	4mg	Fesoterodine-extended release	12mg	4/25	1/22	3.52 (0.42; 29.18)	0.11 (-0.05; 0.28)		
Diarrhea	Patients with DO and urgency	4mg	Placebo		4/25	0/24	8.65 (0.49; 152.58)	0.16 (0.00; 0.32)	6	160
Diarrhea	Patients with DO and urgency	8mg	Placebo		0/28	0/24	0.00 (0.00; 0.00)	0.00 (-0.07; 0.07)		
Diarrhea	Patients with DO and urgency	12mg	Placebo		1/22	0/24	3.26 (0.14; 76.10)	0.05 (-0.07; 0.16)		
Diarrhea	Patients with DO and urgency	8mg	Fesoterodine-extended release	12mg	0/28	1/22	0.26 (0.01; 6.19)	-0.05 (-0.16; 0.07)		
Any adverse events	Patients with no DO	4mg	Fesoterodine-extended release	8mg	14/18	14/19	1.06 (0.73; 1.52)	0.04 (-0.23; 0.32)		
Any adverse events	Patients with no DO	4mg	Fesoterodine-extended release	12mg	14/18	13/16	0.96 (0.68; 1.35)	-0.03 (-0.31; 0.24)		
Any adverse events	Patients with no DO	4mg	Placebo		14/18	17/19	0.87 (0.65; 1.16)	-0.12 (-0.35; 0.12)		
Any adverse events	Patients with no DO	8mg	Placebo		14/19	17/19	0.82 (0.60; 1.12)	-0.16 (-0.40; 0.08)		
Any adverse events	Patients with no DO	12mg	Placebo		13/16	17/19	0.91 (0.69; 1.20)	-0.08 (-0.32; 0.15)		
Any adverse events	Patients with no DO	8mg	Fesoterodine-extended release	12mg	14/19	13/16	0.91 (0.63; 1.30)	-0.08 (-0.35; 0.20)		

Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT)[180] (continued)

Outcome	Predictor of effect	Fesoterodine daily dose	Control treatment	Daily dose of control treatment	Events/ randomized to active	Events/ randomized to control	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat	Attributable events/1000 treated
Dry mouth	Patients with no DO	4mg	Fesoterodine-extended release	8mg	8/18	8/19	1.06 (0.50; 2.21)	0.02 (-0.30; 0.34)		
Dry mouth	Patients with no DO	4mg	Fesoterodine-extended release	12mg	8/18	10/16	0.71 (0.37; 1.35)	-0.18 (-0.51; 0.15)		
Dry mouth	Patients with no DO	4mg	Placebo		8/18	4/19	2.11 (0.77; 5.81)	0.23 (-0.06; 0.53)		
Dry mouth	Patients with no DO	8mg	Placebo		8/19	4/19	2.00 (0.72; 5.53)	0.21 (-0.08; 0.50)		
Dry mouth	Patients with no DO	12mg	Placebo		10/16	4/19	2.97 (1.15; 7.68)	0.41 (0.11; 0.71)	2	414
Dry mouth	Patients with no DO	8mg	Fesoterodine-extended release	12mg	8/19	10/16	0.67 (0.35; 1.29)	-0.20 (-0.53; 0.12)		
Headache	Patients with no DO	4mg	Fesoterodine-extended release	8mg	3/18	0/19	7.37 (0.41; 133.37)	0.17 (-0.02; 0.35)		
Headache	Patients with no DO	4mg	Fesoterodine-extended release	12mg	3/18	3/16	0.89 (0.21; 3.80)	-0.02 (-0.28; 0.24)		
Headache	Patients with no DO	4mg	Placebo		3/18	3/19	1.06 (0.24; 4.57)	0.01 (-0.23; 0.25)		
Headache	Patients with no DO	8mg	Placebo		0/19	3/19	0.14 (0.01; 2.59)	-0.16 (-0.34; 0.02)		
Headache	Patients with no DO	12mg	Placebo		3/16	3/19	1.19 (0.28; 5.09)	0.03 (-0.22; 0.28)		
Headache	Patients with no DO	8mg	Fesoterodine-extended release	12mg	0/19	3/16	0.12 (0.01; 2.19)	-0.19 (-0.39; 0.02)		
Influenza-like symptoms	Patients with no DO	4mg	Fesoterodine-extended release	8mg	2/18	2/19	1.06 (0.17; 6.72)	0.01 (-0.19; 0.21)		
Influenza-like symptoms	Patients with no DO	4mg	Fesoterodine-extended release	12mg	2/18	1/16	1.78 (0.18; 17.80)	0.05 (-0.14; 0.24)		

Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT)[180] (continued)

Outcome	Predictor of effect	Fesoterodine daily dose	Control treatment	Daily dose of control treatment	Events/ randomized to active	Events/ randomized to control	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat	Attributable events/1000 treated
Influenza-like symptoms	Patients with no DO	4mg	Placebo		2/18	3/19	0.70 (0.13; 3.73)	-0.05 (-0.27; 0.17)		
Influenza-like symptoms	Patients with no DO	8mg	Placebo		2/19	3/19	0.67 (0.13; 3.55)	-0.05 (-0.27; 0.16)		
Influenza-like symptoms	Patients with no DO	12mg	Placebo		1/16	3/19	0.40 (0.05; 3.44)	-0.10 (-0.30; 0.11)		
Influenza-like symptoms	Patients with no DO	8mg	Fesoterodine-extended release	12mg	2/19	1/16	1.68 (0.17; 16.91)	0.04 (-0.14; 0.22)		
Dizziness	Patients with no DO	4mg	Fesoterodine-extended release	8mg	2/18	0/19	5.26 (0.27; 102.66)	0.11 (-0.06; 0.28)		
Dizziness	Patients with no DO	4mg	Fesoterodine-extended release	12mg	2/18	3/16	0.59 (0.11; 3.11)	-0.08 (-0.32; 0.16)		
Dizziness	Patients with no DO	4mg	Placebo		2/18	2/19	1.06 (0.17; 6.72)	0.01 (-0.19; 0.21)		
Dizziness	Patients with no DO	8mg	Placebo		0/19	2/19	0.20 (0.01; 3.91)	-0.11 (-0.27; 0.06)		
Dizziness	Patients with no DO	12mg	Placebo		3/16	2/19	1.78 (0.34; 9.38)	0.08 (-0.15; 0.32)		
Dizziness	Patients with no DO	8mg	Fesoterodine-extended release	12mg	0/19	3/16	0.12 (0.01; 2.19)	-0.19 (-0.39; 0.02)		
Nausea	Patients with no DO	4mg	Fesoterodine-extended release	8mg	4/18	3/19	1.41 (0.36; 5.43)	0.06 (-0.19; 0.32)		
Nausea	Patients with no DO	4mg	Fesoterodine-extended release	12mg	4/18	4/16	0.89 (0.26; 2.98)	-0.03 (-0.31; 0.26)		
Nausea	Patients with no DO	4mg	Placebo		4/18	5/19	0.84 (0.27; 2.66)	-0.04 (-0.32; 0.23)		
Nausea	Patients with no DO	8mg	Placebo		3/19	5/19	0.60 (0.17; 2.16)	-0.11 (-0.36; 0.15)		
Nausea	Patients with no DO	12mg	Placebo		4/16	5/19	0.95 (0.31; 2.95)	-0.01 (-0.30; 0.28)		

Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT)[180] (continued)

Outcome	Predictor of effect	Fesoterodine daily dose	Control treatment	Daily dose of control treatment	Events/ randomized to active	Events/ randomized to control	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat	Attributable events/1000 treated
Nausea	Patients with no DO	8mg	Fesoterodine-extended release	12mg	3/19	4/16	0.63 (0.17; 2.41)	-0.09 (-0.36; 0.18)		
Constipation	Patients with no DO	4mg	Fesoterodine-extended release	8mg	1/18	2/19	0.53 (0.05; 5.33)	-0.05 (-0.22; 0.12)		
Constipation	Patients with no DO	4mg	Fesoterodine-extended release	12mg	1/18	3/16	0.30 (0.03; 2.57)	-0.13 (-0.35; 0.09)		
Constipation	Patients with no DO	4mg	Placebo		1/18	2/19	0.53 0.05; 5.33)	-0.05 (-0.22; 0.12)		
Constipation	Patients with no DO	8mg	Placebo		2/19	2/19	1.00 (0.16; 6.38)	0.00 (-0.20; 0.20)		
Constipation	Patients with no DO	12mg	Placebo		3/16	2/19	1.78 (0.34; 9.38)	0.08 (-0.15; 0.32)		
Constipation	Patients with no DO	8mg	Fesoterodine-extended release	12mg	2/19	3/16	0.56 (0.11; 2.96)	-0.08 (-0.32; 0.15)		
Abdominal pain	Patients with no DO	4mg	Fesoterodine-extended release	8mg	0/18	2/19	0.21 (0.01; 4.11)	-0.11 (-0.27; 0.06)		
Abdominal pain	Patients with no DO	4mg	Fesoterodine-extended release	12mg	0/18	3/16	0.13 (0.01; 2.30)	-0.19 (-0.39; 0.02)		
Abdominal pain	Patients with no DO	4mg	Placebo		0/18	2/19	0.21 (0.01; 4.11)	-0.11 (-0.27; 0.06)		
Abdominal pain	Patients with no DO	8mg	Placebo		2/19	2/19	1.00 (0.16; 6.38)	0.00 (-0.20; 0.20)		
Abdominal pain	Patients with no DO	12mg	Placebo		3/16	2/19	1.78 (0.34; 9.38)	0.08 (-0.15; 0.32)		
Abdominal pain	Patients with no DO	8mg	Fesoterodine-extended release	12mg	2/19	3/16	0.56 (0.11; 2.96)	-0.08 (-0.32; 0.15)		
Diarrhea	Patients with no DO	4mg	Fesoterodine-extended release	8mg	1/18	1/19	1.06 (0.07; 15.64)	0.00 (-0.14; 0.15)		

Appendix Table F25. Clinical outcomes after fesoterodine in patients with an overactive bladder and urgency UI by the urodynamic finding of detrusor overactivity (DO) (results from individual RCT)[180] (continued)

Outcome	Predictor of effect	Fesoterodine daily dose	Control treatment	Daily dose of control treatment	Events/ randomized to active	Events/ randomized to control	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat	Attributable events/1000 treated
Diarrhea	Patients with no DO	4mg	Fesoterodine-extended release	12mg	1/18	2/16	0.44 (0.04; 4.45)	-0.07 (-0.26; 0.12)		
Diarrhea	Patients with no DO	4mg	Placebo		1/18	2/19	0.53 (0.05; 5.33)	-0.05 (-0.22; 0.12)		
Diarrhea	Patients with no DO	8mg	Placebo		1/19	2/19	0.50 (0.05; 5.06)	-0.05 (-0.22; 0.12)		
Diarrhea	Patients with no DO	12mg	Placebo		2/16	2/19	1.19 (0.19; 7.50)	0.02 (-0.19; 0.23)		
Diarrhea	Patients with no DO	8mg	Fesoterodine-extended release	12mg	1/19	2/16	0.42 (0.04; 4.23)	-0.07 (-0.26; 0.12)		

DO=detrusor overactivity

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Weight loss	Auwad, 2008[181]	Effects of moderate weight loss in obese women with urodynamically stress UI	64	100	100	Weight reduction program low calorie diet + exercise with a target loss of 5-10%	2 years	Obese women with urodynamic stress UI, 52.5 years old	Weight loss was associated with a significant reduction in pad test loss and significant improvement in quality of life.
Weight loss	Wing, 2010[182]	To examine the relationship between magnitude of weight loss and changes in urinary incontinence frequency.	338	100	100	Patients were randomly assigned to a 6 month weight loss program followed immediately by a 12-month weight maintenance program or to a structured education program. These groups were combined to examine the effects of the magnitude of weight loss on changes in urinary incontinence	18 months	Program to Reduce Incontinence by Diet and Exercise (PRIDE) trial: Women aged 30 years or older, having a body mass index (BMI) of 25–50, and reporting at least 10 urinary incontinent episodes (including both stress and urge incontinent episodes) on a 7-day voiding diary at baseline.	The adjusted odds (adjusted for treatment group, use of incontinence behavioral treatment booklet, clinic, age, alcohol use, smoking status, race, number of live births, and amount of calories burned) of at least 70% reduction in number of incontinent episodes per week reported in voiding diary in those who had more than 10% weight loss: At 6 months: Total UI: OR=3.8 (95% CI=1.5-9.6); Stress UI: OR=1.6 (95% CI=0.6-3.9); and Urge UI: OR=4.5 (95% CI=1.4-14.1). At 18 months: Total UI: OR=3.3 (95% CI=1.7-6.4); Stress UI:OR=2.3 (95% CI=1.0-5.1); and Urge UI: OR=4.0 (95% CI=2.1-7.9)

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Pelvic floor muscle training	Hines, 2007[183]	To assess factors predictive of high adherence to a behavioral intervention to prevent UI	359, but data used for instru-ment-develop-ment project reported in the article were from partici-pants in the treatment arm only (n=164)	100	100	Pelvic floor muscle training and bladder training	1 year	359 community-dwelling, post-menopausal women, aged 55 to 80 years old	Women incorporated PFMT into their lives using either a routine or ad hoc approach (Routine approach=Doing PME at set times of the day or linking with a daily routine that occurs at a set time; ad hoc approach=Doing PME when they think of it or by linking with a sporadic cue or situation). Those using a routine approach at 3 months were 12 times more likely to adhere (odds ratio=12.4, CI=4.0-38.8,p<0.001) at a high level at 3 months and significantly more likely to maintain that level 12 months post-intervention (OR=2.7,CI=1.2-6.0,p<0.014). High adherence to PFMT was operationally defined as an adherence score of 5 to 7 (reporting adherence of >=1 1 set of PFMT each day).

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Pelvic floor muscle training	Sugaya, 2003[184]	Effects of the device to promote adherence to pelvic floor muscle exercise in women with stress UI	46	100	100	Device with a chime to sound three times a day when exercise sessions were scheduled and set a rhythm for the muscle contractions vs. pelvic floor muscle exercise alone	8 weeks	women with stress UI	Quality of life category was delighted, pleased, or mostly satisfied in 15% patients from the control group and 48% from the device groups
Pelvic floor muscle training	Brubaker, 2008[185]	Effectiveness of nonmedical pelvic floor muscle training class on UI	102	100	99	Pelvic fitness and education class taught by a lay instructor	11 weeks, 1 year of followup	Adult women with urgency or urge UI 57.9 year, 11% after surgery for UI or prolapse	The training improved quality of life and sexual function improvements in after vs. before UDI-SF scores. Achievement of self selected goal- 71% at 11 weeks, 67% at 1 year
Pelvic floor muscle training	Wang, 2000[186]	Efficacy of bladder-sphincter-biofeedback in women with detrusor instability who failed to respond to oxybutynin treatment	31	100	100	Bladder sphincter biofeedback vs. pelvic floor muscle training	5 months	Women with urge syndrome 44,.3 years who failed previous Oxybutynin treatment	Continence 12.5% in biofeedback and 13.33% in exercise group. Improvement 87.5% in biofeedback and 86.67% in exercise group. 140 significant differences were found.

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Pelvic floor muscle training	Wang, 2000[186]	Efficacy of bladder-sphincter-biofeedback as a secondary treatment for those women with detrusor instability who failed to respond to oxybutynin chloride	31	100	100	Bladder-sphincter-biofeedback training group or control pelvic floor exercise group	Not reported	women with detrusor instability who failed to respond to oxybutynin chloride	The cure rate or improvement rate of subjective changes (urgency, and frequency and episodes of urge incontinence) did not significantly differ
Medical device	Bellin, 1998[187]	Efficacy of CapSure (Re/Stor) continence shield for stress UI in females	100	100	100	CapSure (Re/Stor) continence shield : no control	12 weeks	Women 40-69 years old (mean 54) with pure stress moderate UI and no urgency or urge UI	Continence - 82%, negative pad stress test - 91%; no UI episodes in diary - 48%, Bothersome vaginal or urethral irritation - 12%, positive urine culture - 1.56
Medical device	Crivellaro, 2010[188]	To examine effects of the Adjustable Continence Therapy on female UI	60	100	100	Adjustable Continence Therapy implantation that involves two silicone balloons sited on either side of the proximal urethra under the bladder neck, each attached to a titanium port buried in the labia allowing post operative titration of the balloons.	Once	Adult women with stress urinary incontinence resulting from intrinsic sphincteric deficiency	82% were significantly improved, 8% were moderately improved and 10% remained unchanged. Post-operative complications necessitating device removal included migration seen in 8% of patients and urethral erosion in 3.5% of patients
Medical device	Morris, 2003[189]	Efficacy of contiform incontinence device in women with stress UI and no prolapse	59	100	100	Contiform incontinence device no control	3 weeks	Women, 42-53 years old, with urodynamic mild to severe stress UI and no prolapse	Continence - 20%, withdrawal - 31%, acute bacterial cystitis - 5%, small degree of fracture of the curvature of device - 22%

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Medical device	Allen, 2008[190]	Efficacy of contiform intravaginal device for stress UI	73	100		Contiform intravaginal device, no control	4 weeks	Women 41-54 years old with predominant stress UI and no prolapse	Continence - 54%, withdrawal, 29%, residual volume >100 ml - 5.4%
Medical device	Sander, 2008[191]	The effect of a vaginal device (Continence Guard) on urine leakage and quality of life in women with stress UI	55	100	100	Continence Guard	12 weeks	Women with stress incontinence	Completion -74.5%; subjective cure 20% and improvement in 49%. Score of the Incontinence Impact Questionnaire showed highly significant improvement
Medical device	Hahn, 1996[192]	Effectiveness of vaginal device for the treatment of female stress UI	90			Conveen Continence Guard	4 weeks	90 women with stress incontinence (mean age 47.5 years, range 31-65).	Continence - 46% Improvement - 29% ; objective improvement - 75%; Failure- 25% 72% of the women considered the product to function satisfactorily and 60% expressed a wish to continue with the treatment; local discomfort - 62%
Medical device	Nilsson, 2000[193]	Efficacy of the conveen continence guard (a disposable vaginal device) in the treatment of complicated female stress incontinence	28			Decreases from baseline in RR, QRS and QT intervals for patients receiving duloxetine Conveen continence guard (a disposable vaginal device)	3 weeks	Women, with a urodynamically proven stress UI	Completion rate 68%; continence or improved incontinence 58%; objective improvement 55%

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Medical device	Pieper, 1993[194]	The efficacy of external urine-collection device for women with UI	7			External urine-collection device	5 days	Black women with UI, 21-35 years old	1 woman had vulvar irritation and redness; all were satisfied with the device
Medical device	Versi, 1998[195]	Efficacy of external urethral device in women with genuine stress urinary incontinence	14			FemAssist- non-invasive supple silicone domed cap that fits over the external urethral meatus	3-4 weeks	Women with symptoms of urinary incontinence and a videourodynamic diagnosis of genuine stress incontinence; mean age was 55 years	>50% improvement on their IIQ - 50% ; improvement in UDI -21.4% UDI.
Medical device	Versi, 1998[196]	Efficacy of external urethral device in women with genuine stress UI	131			FemAssist- non-invasive supple silicone domed cap that fits over the external urethral meatus	4 weeks	Ambulatory women with symptoms of UI	Withdrawal -27%; >50% improvement on the Incontinence Impact Questionnaire 59%; in the Urogenital Distress Inventory-33%
Medical device	Sirls, 2002[197]	Efficacy of FemSoft urethral insert for female stress urinary incontinence	150			FemSoft urethral insert no control	48-96 weeks	women with mean age of 53.5 years, stable stress urinary incontinence, mixed UI with predominant stress UI	Continence -93% at 48 months, withdrawal rate - 41%. Adverse effects: urinary tract infection - 31.3%, mild trauma - 6.7%, hematuria - 3.3%. Significant improvement in quality of life.
Medical device	Macaulay, 2007[198]	The effects of Non-Invasive Continence Management System (NICMS) on women with UI	80			Non-Invasive Continence Management System (NICMS)	15 months	Women over 18 years of age with UI	Overall satisfaction 34%; among wheel chair users 21%

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Medical device	Donnelly, 2004[199]	Predictors of successful fit and continuous use of pessaries	239			Pessaries	2 weeks, 48 weeks	Women with stress or mixed UI, 57.4 years old	Successful fit- 89.1%, Discontinuation-45%; Reason for discontinuation %: Persistent UI-58%; Discomfort using pessary-33%; Frequent pessary expulsion-18%; Women with pulmonary disease and those who used diuretics were more likely to use pessaries
Medical device	Brincat, 2004[200]	Predictors of discontinuation of pessaries use	136			Pessaries: dishes with and without floor, rings with and without floor, pessary rings with floor	96 weeks	Women with UI	Reason for pessary discontinuation and % sexually active women and women with prolapse used pessaries during study period more often
Medical device	Maito, 2006[201]	Predictors of continuous use of pessaries	120			Pessary	24 weeks	Women with UI and/or pelvic floor organ prolapse, 61 years of age	Successful fit - 86% Discontinuation - 11% Predictors of unsuccessful fit - history of prolapse, procedure or hysterectomy. Predictors of discontinuation- severe posterior prolapse; Improved stress UI- 94%
Medical device	Sulak, 1993[202]	Effectiveness of pessaries in women with pelvic relaxation.	107			Pessary Gelhorn	3 years	Women with symptomatic pelvic relaxation, 65.5 years	Discontinuation 46%

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Medical device	Clemons, 2004[203]	Patient satisfaction and UI after pessary use	100			Pessary ring with floor, Gellhorn (Milex)		Women with systematic pelvic organ prolapse. Stage II or greater; 71 years old	Successful fit-73% Improved stress UI-45% Improved urge UI - 21%. De novo urge UI - 6% Dissatisfaction 18% was associated with stress UI (OR 17.1; 95% CI, 1.9, 206)
Medical device	Farrell, 2007[204]	Effectiveness of a new self-positioning women's pessary	32			Pessary Uresta/ EastMed Inc	48 weeks	Women with 41, 50 years old	Satisfaction with pessary - 66% Discontinuation - 34% Continence -47% (among stress UI), 36% (among urge UI) Improved UI- 53% No significant predictions for successful fitting were found
Medical device	Nguyen, 2005[205]	Predictors of successful pessary fitting and continence pessary use	130			Pessary: Milex products, PelX/Des Chutes medical products	4 years	Women with pelvic relaxation 66-69 years old	Successful fit- 74% Reasons for unsuccessful fit % Prolapse repair 29% Cystocele repair 21% Stress UI 69% Discontinuation among successfully fitted/ 50 %

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Medical device	Staskin, 1996[206]	Efficacy of urethral insert for female stress or mixed UI	135			Reliance urinary control insert no control	12 weeks	Women with mean age of 52.6 years of age with pure stress or mixed UI	Continence - 80%, improvement with >80& decrease in urine loss - 95%, adverse events - 13%, bacteriuria - 8%, withdrawal, - 37%
Medical device	Kocjancic, 2008[207]	Effectiveness of adjustable device for the treatment of recurrent stress UI	49			The Adjustable Continence Therapy (ACT®)	1 year	Women with stress UI who previously failed anti-incontinence surgery	Continence -53%; improvement in UI - 16%; failure- 12%; migrations -12% and urethral or portal erosions -4%
Medical device	Brubaker, 1999[208]	The efficacy and safety of an external urethral barrier for mild/moderate stress UI in adult women.	411			Urethral barrier device	12 weeks	Women with mild to moderate stress 41 or mixed 41	Withdrawal – 16% comfortable use - 90% Positive urine culture - 4.1% Trace of blood in urine - 21% Bacterial vaginosis - 16%
Medical device	Moore, 1999[209]	The efficacy and user acceptability of the urethral occlusive device (FemAssist*) for incontinence	97			Urethral occlusive device (FemAssist*)	1 month	Women with UI 65 years of age with UI, 37% with severe UI	Discontinuation rate 41%; Continence 47%; >50% reduction in UI- 33% Response did not differ by baseline severity of UI or type of UI (stress, urge or mixed incontinence)
Medical device	Sand, 1999[210]	Efficacy of reliance urinary control insert in women with stress UI	63			Uromed Corp, Needham, MA - reliance urinary control insert-no control	48 weeks	Women with mean age of 55 years old, predominant stress UI	Continence - 79%, urinary tract infection - 29%, gross hematuria - 22%, improved physical functioning and quality of life

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Medical device	Aboseif, 2009[211]	Efficacy of adjustable continence device in women with recurrent stress UI	162			Uromedica, Plymouth, Minnesota - adjustable continence device. No control	48 weeks	women 67.4 years old with recurrent stress UI after 6 months of prior conservative or surgical therapy	Continence - 52%, improvement >50% reduction on stress pad test - 80%, complications - 24.4%, most common adverse effect port erosion - 7.5%
Stimulation	Indrekvam, 2001[212]	Effectiveness of home managed electrical stimulation in women with stress or mixed UI	3,198			Home managed 2 main types of vaginal/anal electro stimulators, Vitacon Norway AS and Conmax Sports Enterprises	2 years	Women with urge stress, or mixed UI	Discontinuation of treatment - 12% Continence, doctor assessment - 7%, continence patient self report - 4%. Compliers, doctor assessment - 14%, patient self report - 8%. Continence or much better, doctor assessment - 43%, patient self report - 31%. OR of treatment effect assessed by women : Increasing frequency of leakage - 0.82 (0.69;0.96), increasing amount of leakage - 0.77 (0.62;0.95), increasing discomfort with treatment - 0.77 (0.7;0.84)

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Stimulation	Galloway, 2000[213]	Effects of extracorporeal magnetic innervation for stress 111 in women	111			Extracorporeal magnetic innervation (ExMI) therapy using Neocontrol chair, 20 minutes, 2 times/ week; 5-50h2	6 weeks, 6 month of followup	Women with stress UI, 55 years old	Countenance - 28% No pad or <1 pad per day- 53% Reduced pad use- 70% In women with recurrent after therapy stress UI or hysterectomy countenance rate was 18% and + improvement - 40%
Stimulation	Bergstrom, 2000[214]	Efficacy of manual acupuncture could influence urge- or mixed-type incontinence among elderly women who failed previous treatments	15			Manual acupuncture	12 times, 3 months of followup	Elderly women with stress or mixed UI who failed previous treatments	Improvement rate 80%
Stimulation	Nuhoglu, 2006[215]	Efficacy of Stoller afferent nerve stimulation (SANS) in women with overactive bladder who failed anticholinergic treatment	35			Stoller afferent nerve stimulation (SANS)	10 weeks	With overactive bladder who failed therapy with oxybutynin	54% (n=19) women were continent at the end of the treatment but only 23% at followup
Stimulation	van Kerrebroeck, 2004[216]	Efficacy of copolymer system on female UI	42			Nonanimal stabilized hyaluronic acid/dextranomer copolymer injected transurethrally into the urethra via the Implacer TM device	1 year	Women not previously treated by invasive therapy and with urodynamically verified SUI	Satisfaction rate at 3 months -71%, at 9 months- 60%; failure 43%

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Stimulation	van Kerrebroeck, 2004[217]	Effects of the novel system (NASHA/Dx copolymer insertion using the Implacer) on female UI	42			Nonanimal stabilized hyaluronic acid/dextranomer (NASHA/Dx) copolymer for transurethral injection	12 months	Therapy-naive female patients with stress UI	Improvement - 76%; improvement by at least one category on the 6-point patient perception scale - 69%; Treatment-related AEs-36%.
Stimulation	Chapple, 2005[218]	Efficacy of non-endoscopic injection of nonanimal stabilized hyaluronic acid/dexranomer (NASHA/Dx) gel and Implacer device on female stress UI	142			Zuidex TM system for injection of bulking agent NASHA/Dx gel and Implacer TM device	8 weeks, 12 months	Women with stress UI for >12 months 55.7 years old, who failed prior nonsurgical treatments and were not treated with invasive methods.	Reduction in provocation test leakage 750% vs. baseline - 77% at 1 year Continuance- 62% at 1 year Improvement of quality of life - 67% Adverse effects: Urinary retention - 29/142 Urinary tract infection - 17/142 Micturition urgency - 17/142 Injection sit reaction- 11/142 Vaginal discomfort- 10/142 Injection in injection site- 3 serious/142

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Evidence-based self-management tool	Tannenbaum, 2010[219]	To develop and evaluate an evidence -based self-management urinary incontinence risk factor modification tool designed specifically for older women.	103	100	100	Self-management tool developed using evidence from a systematic review on risk factor modification for incontinence and input from focus groups of health care experts and incontinent women. Six risk factors were incorporated into a self-management tool with associated strategies for change and self-monitoring: 1) weak pelvic floor muscles, high caffeine intake (>400mg/day), high body mass index, vision and hearing impairment, smoking and constipation	3 months without intervention and 3 months with intervention	English and French speaking incontinent women 50 years of age and older who reported experiencing urinary incontinence at least twice a week for a period lasting at least 3 months during the prior 2 years were recruited via community-advertising. MMSE scores >24/30	Self-Efficacy Index (max score 150): Coefficient (mean change) = 8.7 with 95% highest posterior density interval (CI)=3.6-13.7. UDI-6 (max score 100): Coefficient (mean change)=-7.3 with 95% highest posterior density interval (CI) =-12.3- -2.1. IIQ-7 (max score 100):Coefficient (mean change) =-0.5 with 95% highest posterior density interval (CI) =-5.4-4.9

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Adjustable continence therapy	Crivellaro, 2010[188]	The Adjustable Continence Therapy is a minimally invasive treatment for females with Stress Urinary incontinence resulting from Intrinsic Sphincteric Deficiency (ISD). This study represents the term results of the first series of patients	60	100	100	Adjustable Continence Therapy implantation that involves two silicone balloons sited on either side of the proximal urethra under the bladder neck, each attached to a titanium port buried in the labia allowing post operative titration of the balloons	Once	Women with stress UI	82% were significantly improved, 8% were moderately improved and 10% remained unchanged. Post-operative complications necessitating device removal included migration seen in 8% of patients and urethral erosion in 3.5% of patients
Percutaneous tibial nerve stimulation	Vandoninck, 2003[220]	To determine the safety and efficacy of percutaneous peripheral afferent nerve stimulation for treatment of refractive overactive bladder and/or pelvic floor dysfunction.	53	90.20	Not reported	Percutaneous Tibial Nerve Stimulation: 12 sessions	12 weeks	Patients older than 18 years with documented urgency, frequency, and/or pelvic floor dysfunction resulting in a mean frequency of at least 10 voids/day and/or 3 voids/night. In all these patients, all traditional therapy had failed.	Dependent on baseline conditions, treatment with the percutaneous device in the acute treatment phase (12 weeks) resulted in at least a 25% reduction or improvement in daytime frequency for 55.2% of patients having 10 or greater voids per day ($p<0.05$), an average 25% reduction or improvement in mean daytime voiding frequency ($p<0.05$), an average 22% reduction or improvement in

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
									mean 24-hour voiding frequency ($p<0.05$) and an average 70% reduction, that is "mean daytime frequency defined as the mean number of voids greater than 10 per patient per day" ($p<0.05$). Overall, treatment with the device resulted in an average 21% reduction or improvement in mean nighttime voiding frequency ($p<0.05$). Overall, patients had a 35% reduction or improvement in daytime and night time urge incontinence or leak episodes during the 12-week treatment ($p<0.05$). 71% patients were classified by the investigators as treatment successes after 12 weeks (success was defined as patients who had at least a 25% in daytime and/or nighttime frequency).

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Percutaneous tibial nerve stimulation	Vandoninck, 2003[221]	To evaluate urodynamic changes after percutaneous tibial nerve stimulation (PTNS) for the treatment of complaints related to overactive bladder syndrome and to search for urodynamic-based predictive factors	90	74.44	75	Percutaneous Tibial Nerve Stimulation: 12 sessions	Not reported	Patients with overactive bladder syndrome (defined as urgency, frequency, and/or urge incontinence) were enrolled. For urgency and urge incontinence, International Continence Society definitions were used. Urinary frequency was defined as eight voids or more per 24 hours.	The objective success rate was 56% (leakages/24 hours). Subjective success rate was 64%. Subjects without detrusor instabilities at baseline were 1.7 times more prone to respond to PTNS (odds ratio, 1.75; 95% confidence interval [CI], 0.67-4.6). The more the bladder overactivity was pronounced, the less these patients were found to respond to PTNS, the area under the receiver operating curve was 0.644 (95% CI, 0.48-0.804).

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Percutaneous tibial nerve stimulation	Govier, 2001[222]	To evaluate the effect of posterior tibial nerve stimulation for the treatment of urge incontinence	35	71.43	100	Percutaneous Tibial Nerve Stimulation: 12 sessions	Not reported	Patients with symptoms of urge incontinence	A total of 24 patients (69%) showed a reduction in incontinence episodes (primary outcome measure) of more than 50%; of these 24 patients, 16 had no leakage episodes. 22 patients (63%) reported a subjective success. Severity of incontinence and number of pads used, decreased more than 50% in 19 (54%) and 20 patients (57%), respectively.

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Percutaneous tibial nerve stimulation	Woolridge, 2009[223]	To evaluate the application of percutaneous tibial nerve stimulation, a minimally invasive neuromodulation therapy	53	98.11	79.25	Percutaneous Tibial Nerve Stimulation: 12 sessions of 30 minutes duration each	12 weeks	Patients with chronic OAB symptoms referred to a community-based, nurse practitioner-led continence practice; older than 18 years with documented urgency, frequency, and/or pelvic floor dysfunction resulting in a mean frequency of at least 10 voids/day and/or 3 voids/night.	Patients experienced a statistically significant average decrease in daytime voids of 27.9% from baseline (p <0.0001). Patients experienced an average 63.5% decrease in nighttime voids from baseline (p <0.0001). Thirty-seven of the 42 patients reporting incontinence at baseline (88%) improved with 59.5% (25 of 42) patients cured (such as reporting no incontinence episodes during the period of review for the study).

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Percutaneous tibial nerve stimulation	Vandoninck, 2004[224]	To determine urodynamic changes and predictive factors in patients with voiding dysfunction who underwent 12 percutaneous tibial nerve stimulations	39	69.23	Not reported	Percutaneous Tibial Nerve Stimulation: 12 sessions of 30 minutes duration each	12 weeks	Patients with idiopathic non-obstructive voiding dysfunction; symptoms existed for a minimum of 6 months	In 13 out of 23 patients, more than 50% decrement in 24 hour total catheterized volume was obtained. Another eight subjects noticed a reduction of their 24 hour residual volume with more than 25%. Side effects: diarrhea, headaches, calf cramps, and low back pain were reported; one patient did not complete the treatment because of aggravating pre-existing heart rhythm problems. However, these adverse effects were considered not to be related to PTNS.

Appendix Table F26. Clinical outcomes after nonpharmacological treatments in nonrandomized studies (continued)

Intervention	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
PFMT and electrical stimulation	Surwit, 2009[225]	The hypothesis of the study is that adding percutaneous tibial nerve neuromodulation with pelvic floor muscle rehabilitation is safe, and more successful than either therapy alone for the treatment of urge incontinence	256	100	100	Eight traditional PFMR (Pelvic Floor Muscle Rehabilitation) twice a week with biofeedback, PFMT exercises, and electrical stimulation at 100 Hz, and then an additional 8 weekly electrical stimulations at 10 Hz, utilizing the Hollister Evadri bladder control system equipment.	8 weeks	Patients with both urge incontinence and mixed (urge and stress incontinence) were eligible for this prospective clinical trial	935 achieved a totally dry status and an OAB-V8 score of less than 8, three months after the completion of their treatment (The criteria for successful treatment was an absence of incontinent episodes (dry) and an OAB-V8 score less than 8, indicating no OAB). The remaining 7% patients had a median improvement in UI episodes of 84%. No patient improved less than 70%, and all felt that the treatment had significantly improved their quality of life. The urge continence patients had a 94% dry rate at three months, while the mixed incontinence patients had a 91% dry rate. There were no adverse side events.

Appendix Table F27. Pharmacological treatments for female UI

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Abrams, 1998[226] Study: RCT Sample: 293	Men and women aged ≥18 years having urodynamically confirmed bladder overactivity, an increased frequency of micturition (≥8 micturitions/24h) and urge incontinence (≥1 incontinent episode/24h) and /or urgency during a 2-week washout/run-in period	Clinically significant stress incontinence; detrusor hyper-reflexia; hepatic, renal or hematological disorders; symptomatic or recurrent urinary tract infection; bladder outlet obstruction; those receiving bladder training, electro stimulation therapy; those with an indwelling catheter or who were on intermittent catheterization; pregnant or nursing women; or women of childbearing age who were not using reliable contraception	tolterodine	oxybutynin	Pharmacia and Upjohn AB, Uppsala. Sweden	Not reported
Abrams, 2006[227] 1032 Study Group. UK N: 77	Men and women (aged >18 years) with a clinical diagnosis of idiopathic OAB with detrusor overactivity and two or more of the following OAB symptoms during the 2-week run-in period were enrolled: urinary frequency(7 or more micturitions/day), urgency incontinence (one or more episodes necessitating a change of clothing or pad), or urinary urgency(7 or more episodes preceding micturition/week)	Clinically significant hepatic, renal, or cardiac abnormalities; stress incontinence; evidence of untreated narrow angle glaucoma; urinary and gastric retention; bladder outlet obstruction >40 (Abrams-Griffiths number); indwelling catheter; recent urogenital surgery; and use of investigational drugs in the 30 days preceding the study	Propiverine 20 mg once daily or propiverine 15 mg three times daily or oxybutynin 5 mg three times daily	Placebo	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Abrams, 2008[50] Pooled Country: not reported N: 1,059	Pooled analysis of three RCTs: Women and men, age >18 years with reported symptoms of OAB for >6 months, 5–50 episodes of UI per week during the treatment-free or placebo run-in periods, together with an increased frequency of micturition (a mean of at least 8 voids per day) and urgency (a mean of at least one episode per day)	The presence of clinically significant stress UI (i.e., >1 episode of stress UI per week), BOO and/or a postvoid residual urine volume of >200 mL (as measured by pelvic ultrasound); contraindications to antimuscarinic therapy (e.g. uncontrolled narrow-angle glaucoma, urinary retention, gastric retention).	Darifenacin 7.5 mg and 15 mg once daily	Placebo	ACUMED® provided editorial and project management services for this manuscript. Funding for this was provided by Novartis Pharma AG.	Paul Abrams is a consultant to Novartis Pharma AG and Jasper Huels, Erhard Quebe- Fehling, Mohamed A. Omar and Michael Steel are all employees of Novartis Pharma AG.
Altan-Yaycioglu, 2005[228]RCT Turkey N: 52	Women with urodynamic diagnosis of overactive bladder	History of ocular disease or surgery; dry eyes, ocular surface disorders, glaucoma, or issues that could affect visual acuity or accommodation (such as cataract, macular degeneration, or history of ocular surgery)	2 mg tolterodine bid	5 mg oxybutynin tid	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Appell, 1997[229] Pooled Country: not reported N: 1120	Pooled analysis of 4 RCTS: men and women with detrusor overactivity (phasic detrusor contraction with an amplitude 2 10 cm H, O); and 4) urinary frequency (an average of 28 micturitions/24 hours) and urge incontinence (an average of ≥1 incontinence episode/24 hours) or urinary frequency.	Clinically significant stress incontinence; hepatic or renal disease; recurrent urinary tract infections (UTIs); interstitial cystitis; uninvestigated hematuria or hematuria secondary to malignant disease; indwelling catheter or intermittent catheterization; treatment with any investigational drug in the 2 months prior to entry; previous treatment with Tolterodine; electro stimulation therapy or bladder training within 14 days prior to entry or initiation during the study; treatment with any anti-cholinergic drug or any drug for urinary incontinence within 14 days prior to the baseline visit or initiation during the study; unstable dosage of any treatment with anticholinergic side effects of initiation of such treatment during the study; previously demonstrated serious side effects on oxybutynin; an average total voided volume >3,000ml/24 hours; and clinically significant voiding difficulty with risk of urinary retention.	Tolterodine 2 mg twice daily; tolterodine 1 mg twice daily; oxybutynin (5 mg three times daily)	Placebo	Not reported	Not reported
Appell, 2001[230]The OBJECT (Overactive Bladder: Judging Effective Control and Treatment) US N: 378	Participants with overactive bladder who had between 7 and 50 episodes of urge incontinence per week and 10 or more voids per 24 hours were included. Those with mixed stress and urge incontinence were eligible if the majority of the leakage accidents were related to urge incontinence.	Urinary tract infection, interstitial cystitis, urinary tract obstruction, urethral diverticulum, bladder tumor, bladder stone, prostate cancer were excluded, as were those who had delivered a baby or undergone pelvic, vaginal, bladder, or prostate surgery less than 6 months before study enrollment; participants with a post-void residual urine volume of more than 150ml at the time of screening; those at considerable risk of developing complete urinary retention	10 mg/d of extended-release oxybutynin	2 mg twice daily of tolterodine	AlZA Corporation, Mountain View, California	Dr Appell is an adviser, investigator, and speaker for ALZA Corporation and a speaker and investigator for Pharmacia Corporation. Dr Sand is an adviser, investigator, and speaker for ALZA Corporation and an investigator for

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
		if placed on an anti-muscarinic agent; those with clinically important medical problems or other organ abnormalities or pathologies for whom administration of extended-release oxybutynin or Tolterodine would present undue risk (medically uncontrolled cardiovascular, pulmonary, gastrointestinal, renal, endocrine, neurological, autoimmune, hematological, urological, or psychiatric disorders; severely reduced hepatic function or renal impairment); subjects with hematuria, or a positive urine culture; those with narrow-angle glaucoma; obstructive uropathy; myasthenia gravis; pelvic organ prolapse to the hymenal ring; gastrointestinal conditions such as partial or complete obstruction, preexisting severe gastrointestinal narrowing (pathologic or iatrogenic), decreased gastrointestinal motility (paralytic ileus, intestinal atony, chronic and severe constipation), or risk of gastric retention; those who had taken an investigational drug within the previous month; those with known allergies or hypersensitivities to oxybutynin chloride, tolterodine tartrate, or components of the respective drugs; current alcohol or other drug abuse; women who were pregnant or breastfeeding; those who were not capable of following the study schedule or directions; and those who were not able to swallow the medication without chewing, crushing, biting, dividing, or dissolving the capsule.				Pharmacia Corporation

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Armstrong, 2005[231] RCT NR N: 790	Post hoc analysis of the OPERA study: Women 18 years and older, with urinary urge incontinence (21–60 episodes/week), urinary urgency, and frequency (on average at least 10 voids per day); may have a history of prior treatment with an antimuscarinic drug for overactive bladder	Treatable genitourinary conditions that could cause incontinence, 2 postvoid residual urine volumes greater than 150 ml at the time of screening, significant risk of developing complete urinary retention, clinically significant medical condition that could put the patient at undue risk from anti-cholinergic effects, hematuria, uncontrolled narrow-angle glaucoma, obstructive uropathy, reduced gastrointestinal motility, or known hypersensitivity to the study medications.	Extended release oxybutynin 10 mg once daily	Extended release tolterodine 4 mg once daily	Not reported	Not reported
Armstrong, 2007[232] Pooled USA N: 1168	OBJECT and OPERA trials: men and women 18 years of age and older with a diagnosis of overactive bladder with 7–50 episodes of urge UI/week in the OBJECT study and 21–60 episodes/week in the OPERA study	Reported previously	Extended-release oxybutynin 10 mg qd	Extended-release tolterodine 4 mg qd; Immediate-release tolterodine 2 mg bid	This report was supported by Ortho Women's Health and Urology Division of Ortho Pharmaceutical, Inc.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Barkin, 2004[233] UROMAX Study Group. Canada N: 125	Men and women with UI (≥7 episode/week) and frequency (≥8 micturitions/day)	Postvoid residual volume >100 mL; unstable dosage of any drug with anticholinergic or diuretic/antidiuretic side effects; allergy or previous life-threatening side effects with anticholinergic/antispasmodic medications; primary diagnosis of stress UI; conditions contraindicating anticholinergic therapy; daily fluid intake >3L; hepatic/renal disease; diagnosed painful bladder syndrome; uninvestigated voiding difficulty with risk of urinary retention, uninvestigated hematuria, hematuria secondary to malignant disease; urinary tract infection (UTI) or history of recurrent UTI (>3 UTIs/year); indwelling catheter or bladder training within 14 days of screening; drug/alcohol abuse; untreated psychiatric conditions affecting completion of voiding diaries; chronic untreated constipation; bladder outlet obstruction; pregnancy or breastfeeding; failure to use reliable contraception in women of childbearing potential.	CR oxybutynin 15 mg every morning	IR oxybutynin 5 mg t.i.d.	Purdue Pharma	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Bent, 2008[234] RCT USA N: 588	Women, 19-85 years old with ≥4 incontinence episodes/week (at least one SUI and at least one UUI episode) for a minimum of three consecutive months prior to study entry	Treatment of UI by a specialist (a urologist, urogynecologist, gynecologist whose practice emphasized incontinence, continence nurse or advisor, or physiotherapist) within the past 5 years; an active urinary tract infection; the use of medication for UI within 3 months; any previous use of duloxetine; surgery within 6 months; pelvic organ prolapse greater than ICS Stage II; any non-pharmacological intervention (e.g., electrical stimulation, bladder training, continence devices) within 3 months; pelvic floor muscle training that had not been stable for 3 months or would not remain stable during the trial; and a major neurological lesion affecting lower urinary tract function.	Duloxetine 40 mg twice daily	Placebo	Eli Lilly and Company; Boehringer Ingelheim GmbH	Not reported
Birns, 2000[235] Study: The Oxybutynin CR Clinical Trial Study Sample: 130	Outpatients of either sex, aged 18-76 years, with voiding problems which were currently stabilized on and tolerant to treatment with the referent drug, were recruited.	Patients with any medical condition for which anticholinergic medication is contraindicated or with a history of myasthenia gravis, glaucoma or functional or organic gastrointestinal obstructive disorders; patients with symptomatic UTIs, clinically significant BOO or symptoms of only nocturnal enuresis; female patients who were pregnant, lactating, or of child-bearing age and using adequate contraceptive measures.	oxybutynin - controlled release	oxybutynin	Funded by Leiras Oy and Pharmacia & UpJohn	NR

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Blom, 1995[236] RCT The Netherlands N: 19	19 ambulant elderly women (52 years and older) with confirmed urge incontinence.	History of breast and endometrial cancer, thromboembolic disorders, severe hypertension, cardiac failure, diabetes mellitus, peptic ulceration.	1. Estradiol transdermal therapeutic system (0.05mg estradiol/day). 2. Estradiol transdermal therapeutic system (0.05mg estradiol/day) combined with naproxen 250mg tablets twice daily.	Placebo	CIBA, Isando, South Africa supplied Estraderm TTS and PHARMATEZ Pharmaceuticals. Lyndhurst, Johannesburg, South Africa supplied naproxen tablets	Not reported
Bodeker, 2010[237] Study: Post-hoc J6 N: 1,658	Men and women 18 years of age or older with urinary frequency (8 or more micturitions every 24 hours) plus urge incontinence (5 or more episodes per week)	Subjects with a total daily urine volume of 2.8L or more, a mean micturition volume of more than 250mL, and/or a clinically significant bladder outlet obstruction (i.e., post void residual urine volume of more than 100mL); those with indwelling catheter or intermittent self-catheterization; urinary tract infection at the screening visit; interstitial cystitis and/or hematuria; contraindications to anticholinerigc therapy (e.g., untreated narrow-angle glaucoma, mechanical gastrointestinal stenosis, myasthenia gravis syndrome), tachycardiac arrhythmia, severe psychiatric illnesses, hypersensitivity to trospium or oxybutynin or one of the vehicle ingredients; participation in a bladder training or electro stimulation program, or in another study within the past 30 days.	Trospium chloride	Oxybutynin chloride	Dr. R .Pfleger GmbH (Bamberg, Germany) sponsored the parent study and the post hoc analysis	Rolf-Hasso Bodekar is paid consultant to Dr.R.Pfleger GmbH. Claudia Neumeister is Project Manager Clinical Research of Dr.R.Pfleger GmbH. Helmut Madersbacher and Michael Zellner declare that they have no competing interests to disclose

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Brubaker, 2008[238] Pelvic Floor Disorders Network. USA N: 43	Women at least 21 years with refractory urge incontinence, detrusor overactivity incontinence and 6 or greater urge incontinence episodes in 3 days	Not reported	BoNT-A (200 U)	Placebo	Grants from the National Institute of Child Health and Human Development	Not reported
Brunton, 2010[239] Study: RCT Sample: 17822	52 multicenter studies with data from 17822 patients. All patients were at least 18 years of age	NR	duloxetine	Placebo	Sponsored/supported by Eli Lilly and Company and Boehringer Ingelheim, GmbH	Fujun Wnag, S.Beth Edwards, Antonio Crucitti, Melissa Ossana, Daniel Walker and Michael Robinson own stock in and are employees of Eli Lilly and Company. Stephen Brunton has acted as consultant for Eli Lilly and Company, Novo Nordisk and Amylin Pharmaceuticals, Inc.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Bump, 2003[108] Duloxetine Urinary Incontinence Study Group. USA N: 553	The Duloxetine Urinary Incontinence Study Group: Women aged 18–65 years with urinary incontinence of at least 3 months' duration. The case definition included a predominant symptom of stress urinary incontinence with a weekly incontinent episode frequency of at least four; the lack of predominant symptoms of enuresis or urge urinary incontinence; diurnal and nocturnal frequencies less than eight and less than three, respectively, on screening history; negative funnel infusion cystometry with a first sensation greater than 100ml and a bladder capacity of at least 400ml; and a positive fixed volume cough stress test and stress pad test (greater than 2g).	Prolapse stage II or greater; had a postvoid residual volume of 50 mL or more; were using any pharmacologic agent or device for urinary incontinence; had adopted or changed behavioral management for urinary incontinence within 3 months; or had a history of prior continence surgery.	Duloxetine 20 mg per day (20 mg once daily), duloxetine 40 mg per day (20 mg twice daily), duloxetine 80 mg per day (40 mg twice daily)	Placebo	This work was sponsored by Eli Lilly and Company. Dr. Bump and Dr. Yalcin are full-time employees of Eli Lilly and Company and hold stock and stock options in the company.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Bump, 2008[240] Pooled Europe N: 3939	Women were >18 years with a clinical diagnosis of predominant SUI (an incontinence episode frequency, IEF of >7/week) identified with an identical, validated clinical algorithm that required a retrograde-filling bladder capacity of 400 mL and a positive cough-stress test and stress pad test. For study 4, the major diagnostic criteria were age >18 years and predominant SUI symptoms with an IEF >4/week and urine leakage most often associated with activity. Cohort B included 2,515 patients from not published RCT with predominant SUI that was defined as twice as many SUI episodes as urge UI episodes on the S/UIQ.	Not reported	Duloxetine 40-mg twice daily	Placebo	The studies and these analyses were sponsored by Eli Lilly and Company and by Boehringer Ingelheim GmbH.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Burgio, 2001[241] RCT NR N: 197	Older, community-dwelling women at least 55 years of age, ambulatory, with predominant urge incontinence (the number of urge accidents had to exceed the number of stress and other accidents) at least twice per week and persisting for at least 3 months.	Continual leakage, postvoid residual urine volume greater than 200 ml, uterine prolapse past the introitus, narrow-angle glaucoma, unstable angina, decompensated congestive heart failure, history of malignant arrhythmias, or impaired mental status (MMSE score below 20).	Four clinic visits at 2-week intervals; biofeedback-assisted behavioral treatment implemented by nurse specialist, or drug treatment with oxybutynin chloride 2.5 mg of oxybutynin chloride three times a day	Placebo; self-monitoring (bladder diary), and therapist contact	Supported by Grants AG 08010	Not reported
Burgio, 2000[242] RCT analysis USA N: 197	Older, community dwelling women with urge incontinence at least twice per week (the number of urge accidents had to exceed the number of stress accidents) and persisting for at least 3 months; urodynamic evidence of bladder dysfunction (detrusor instability during filling or provocation or maximal cystometric capacity of 350ml or less).	Continual leakage, postvoid residual urine volume >200ml, uterine prolapse past the introitus, narrow-angle glaucoma, unstable angina, decompensated congestive heart failure, history of malignancy arrhythmias, or impaired mental status (MMSE score <20).	Oxybutynin chloride individually titrated from 2.5 mg to 15 mg daily	2.5 to 5mg t.i.d./Placebo	Supported by Grants AG 08010	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Burgio, 1998[243]RCT USA N: 197	Adults with at least 2 urge accidents per week on the 2-week baseline bladder diary, and urge incontinence had to be the predominant pattern (the number of urge accidents had to exceed the number of stress accidents). Also, there had to be urodynamic evidence of bladder dysfunction (detrusor instability filling or provocation or maximal cystometric capacity of ≤350ml).	Continual leakage, postvoid residual urine volume >200 mL, uterine prolapse past the introitus, narrow-angle glaucoma, unstable angina, decompensated congestive heart failure, history of malignant arrhythmias, or impaired mental status (MMSE score <20).	Oxybutynin chloride, possible range of doses, 2.5 mg daily to 5.0 mg 3 times daily	Behavioral Training: biofeedback-assisted PFMT/ placebo	Grants AG08010	Not reported
Burgio, 2008[244] Fitzgerald, 2008[245] Zimmern, 2010[246] Urinary Incontinence Treatment Network. USA N: 307	The BE-DRI (Behavior Enhances Drug Reduction of Incontinence) trial: at least 7 episodes of incontinence in the diary, persistent incontinence for at least 3 months, no current use of antimuscarinic or other medications that could affect UI, and no evidence that incontinence was secondary to neurologic or other systemic diseases.	Age <21 years; pregnancy, plan to become pregnant in the next 8 months, or declining medically acceptable birth control; <6 months postpartum delivery or other termination after 20 weeks of gestation; inability to contract pelvic floor muscles during evaluation; participated in a formal behavioral therapy program of >2 months in the past 2 years; reported continual leakage or always being damp; hypersensitive to study drug (extended-release tolterodine); systemic disease known to affect bladder function (e.g., Parkinson's disease, multiple sclerosis, spina bifida, or spinal cord injury or trauma); currently using catheter to empty bladder; postvoid residual volume >150ml; treatment for pelvic organ prolapsed with pessary <3 months; incontinence, vaginal, bladder, or prolapse surgery in the	Tolterodine tartrate (extended-release capsules), 4 mg/day + behavioral intervention: teaching pelvic floor muscle control and exercises; behavioral strategies to diminish urgency, suppress bladder contractions, and prevent both stress and urge	Tolterodine tartrate (extended-release capsules), 4 mg/day	Grant support by the National Institute of Diabetes and Digestive and Kidney diseases. Additional support, including provision of study drugs and funding, was contributed by Pfizer	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
		past 6 months; urethral diverticulum, current or repaired; previous augmentation cystoplasty or artificial sphincter; neuromodulation for pelvic indications; currently using anticholinergic agents, cholinergic agonists, tricyclic antidepressants, or duloxetine-must have discontinued use for ≥4 weeks; currently using diuretics with dosage change in past 3 months; uncontrolled medical problem (e.g., poorly controlled diabetes or decompensated congestive heart failure); history of bladder or pelvic cancer or pelvic radiation therapy; glaucoma, with or without ophthalmologist clearance; gastric retention (by medical history); non-ambulatory (may use assisted device); and participation in another intervention trial that might influence the results of the trial.				

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Burgio, 2010[247] Study: RCT Sample: 64	Community dwelling women with urgency predominant incontinence. Incontinence for 3 or more months, no formal behavioral therapy, an average of 2 or more urgency incontinence episodes per week on bladder diary, number of urge incontinence episodes exceeding other types and cystometric evidence of bladder dysfunction (detrusor overactivity or reduced bladder capacity)	NR	Pelvic Floor Muscle training +Urge suppression techniques +Oxybutynin	Oxybutynin	Supported by a grant from the Department of Veterans Affairs, Veterans Health Administration, Rehabilitation Research and Development Service, and the Female Veterans Project, Birmingham/Atlanta Geriatric Research Education and Clinical Center, Birmingham VA Medical Center	Kathryn Burgio has financial interest and/or other relationship with Pfizer and Astellas; Patricia Goode has financial interest and/or other relationship with Pfizer; Holly Richter has financial interest and/or other relationship with Xanodyne, Pfizer and Astellas; Theodore Johnson has financial interest and/or other relationship with Aventis, Yamanouchi, Ortho McNeil, Boehringer Ingelheim, Johnson & Johnson and Pfizer
But, 2010[248] Study: SOLIDAIR Sample: 77	Women with OAB symptoms	NR	solifenacin	darifenacin	Funded by a research grant from Astellas, Europe	NR

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Cardozo, 2010[249] Study: RCT followed by open-label Sample: 2758	Women aged >=18 years with SUI, defined by either urodynamic evaluation within 12 months before study entry without intervening continence surgery or significant change in symptoms, or by episodes of SUI confirmed by question 1 of the validated Stress/Urge Incontinence Questionnaire(S/UIQ). In addition, eligible patients had at least twice as many SUI episodes as urge incontinence episodes as defined by question 2 of the S/UIQ and an average of >=7 incontinence episodes	Pregnancy; alcohol abuse; active or chronically recurring urinary tract infection; presence of ureteric, bladder, urethral or rectal fistula; uncorrected congenital abnormality leading to incomplete emptying or advanced pelvic organ prolapse(stage III or IV by ICS POP-Q criteria); active or chronic hepatitis A, B or C; previous urinary incontinence surgery; or any other condition that, in the opinion of the investigator, precludes evaluation of response to duloxetine hydrochloride. Patients were not allowed to be on a medication regimen that included diuretics where dose and/or frequency were unstable, nor did they allow taking other medications that were demonstrated to be effective for SUI. Subjects who regularly performed pelvic floor muscle exercises could not change their exercise regimen during the course of the study and subjects who did not perform pelvic floor exercises were not permitted to start during the study	duloxetine	Placebo	Sponsored by Eli Lilly and Company and by Boehringer Ingelheim GmbH	L.C. has disclosed being in receipt of funding for research, lecturing, and/or advice/consultancies from Astellas, Pfizer, UCB Pharma, Plethora, cook, Organon, Bioxell, and Sanofi-Aventis. R.L. is a member of European and German advisory boards and speaker in Lilly-sponsored congresses or training sessions. S.V., A.B., M.M., L.V. and Y.D.Z. are employed by Eli Lilly and Company and potentially own stock and/or hold stock options in the company
Cardozo, 2006[250] Pooled NR N: 3,298	Men and women at least 18 years of age with a mean of >8 micturitions/day; >1 incontinence episode/day; >1 urgency episode/day	Reported previously	Solifenacin 5 mg; solifenacin 10mg	Placebo	Grant from Yamanouchi Pharmaceutical Co., Ltd., Tokyo, Japan.	Not reported
Cardozo, 2004[251] RCT Performed in 14 tertiary urogynecological or urological centers in	Women aged 18–75 years with severe stress urinary incontinence defined with both urodynamic and severity criteria. Pure urodynamic stress incontinence was defined	Not reported	Duloxetine (40 mg twice daily for 4 weeks, escalating to 60 mg twice daily for another 4 weeks)	Placebo	This work was sponsored by Eli Lilly and Company and Boehringer Ingelheim.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Australia, Canada, the Netherlands, and the United Kingdom N: 109	as a predominant complaint of stress urinary incontinence and the finding of urodynamic stress incontinence without detrusor overactivity and with normal compliance on an urodynamic study within 6 months of enrollment. All urodynamic diagnoses conformed to the standards of the International Incontinence Society. Severity criteria included both 1) that the subject have at least 14 incontinence episodes per week and 2) that she had scheduled her continence surgery after having discussed all other reasonable options for stress urinary incontinence with her physician. Intrinsic sphincteric deficiency was defined as urodynamic stress incontinence with a maximum straining urethral axis less than 20^{o}, maximum urethral closure pressure less than 20cm H_2O, or Valsalva leak-point pressure less than 60 cm H_2O.					

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Cardozo, 2004[53] RCT NR N: 911	Men and women 18 years old or older with symptoms of OAB (including urinary frequency with urgency and/or urge incontinence) for 3 months or more with an average micturition frequency of >8 times/day, with >3 episodes of urgency and/or >3 episodes of UI during the 3-day micturition period.	Reported previously	Solifenacin 5 mg, solifenacin 10 mg	Placebo	Not reported	Not reported
Cartwright, 2011[252] Study: RCT Sample: 96	Adult women attending as new or followup patients between October 2006 and December 2007, with at least a 3-month history of OAB symptoms, with or without urgency urinary incontinence, were invited to participate. This included patients with mixed urinary incontinence symptoms, unless previous urodynamics had demonstrated isolated urodynamic stress incontinence	History of hypersensitivity to oxybutynin or a previous transdermal skin patch; pregnancy or breastfeeding, voiding difficulties (flow rate <15 mL/s, or post void residual >50mLs), current UTI, or one of a number of medical complaints contraindicating anticholinergic treatment as detailed in the Summary of Product Characteristics for the licensed drug Kentera, including narrow-angle glaucoma and myasthenia gravis. Participants could be naive to anticholinergic treatment, previous anticholinergic users or current anticholinergic users, provided that they discontinued other anticholinergic agents at study entry. Participants taking any contraindicated medication listed in the Summary of Product Characteristics, or any other medication for incontinence, including duloxetine, were also excluded.	Oxybutynin	Placebo	Unrestricted educational grant from UCB Pharma	Rufus Cartwright is a study investigator funded by UCB Pharma and has a financial relationship with a competitor of the mentioned product; Sushma Srikishna and Dudley Robinson were both funded by UCB Pharma and have a financial relationship with a competitor of the mentioned product; Linda Cardozo is a paid consultant for, and was funded by, UCB Pharma, and has a financial relationship with a competitor of the mentioned product.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Castro, 2008[253] Study: RCT Sample: 118	Women with proven urodynamic stress urinary incontinence and no detrusor overactivity; positive cough stress test; and >3g leakage measured by a pad test with a standardized bladder volume(200ml). All subjects had symptoms of SUI with an average of at least 3 stress incontinence episodes a week	Patients with chronic degenerative diseases that would affect muscular and nerve tissues, advanced genital prolapses, pregnancy, active or recurrent urinary tract infections, vulvovaginitis, continence surgery within one year, patients with cardiac pacemakers, patients with intrinsic sphincteric deficiencies identified by the Valsalva leak point pressure<=60cm H2O measurement in the sitting position with a volume of 250ml in the bladder and/or by the measurement of a urethral closure pressure<=20cm H2O in the sitting position at maximum cystometric capacity.	Pelvic Floor Muscle Training/ electrical stimulation/ vaginal cone	No treatment	NR	NR
Castro-Diaz, 2007[254] Duloxetine Dose Escalation Study Group. 64 study centers in 8 countries N: 516	Duloxetine Dose Escalation Study Group: women ≥18 years old with symptoms of predominant SUI using the validated Stress/Urge Incontinence Questionnaire (S/UIQ), with ≥7 SUI episodes per week and at least twice as many SUI episodes as urge UI episodes, urodynamic diagnosis of incontinence within the 6 months of study entry or an average daytime voiding interval >2 hours, a nocturnal voiding frequency ≤2 per day and a positive cough stress test.	Continence surgery within 6 months or pharmacological treatment for symptoms of overactive bladder within 14 days of visit 1, pelvic organ prolapse beyond the hymen and previous participation in a duloxetine clinical trial.	Duloxetine 40 mg BID for 8 weeks, duloxetine 40 mg daily for 2 weeks escalating to 40 mg BID for 6 weeks, duloxetine 20 mg BID for 2 weeks escalating to 40 mg BID for 6 weeks	Placebo	This study was sponsored and funded by Eli Lilly and Company and by Boehringer Ingelheim GmbH	Commercial or other associations that might pose a conflict of interest: Drs. Voss, Yalcin and Bump are full-time employees of Lilly Research Laboratories and Eli Lilly and Company.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Chancellor, 2001[255] RCT USA N: 36	Subjects were healthy men and women who were within 15% of ideal weight for height and had no clinically relevant abnormalities, as determined by medical history, physical examination, blood chemistry, complete blood count, urinalysis, and electrocardiography.	Clinically significant medical problems, glaucoma, obstructive uropathy, partial or complete obstruction or narrowing of the gastrointestinal tract, paralytic ileus, intestinal atony, colitis, or myasthenia gravis; male subject with hemoglobin levels <13 g/dL and female subjects with hemoglobin levels <11.5 g/dL; subjects using prescription medications (except for estrogen replacement or birth control) within 14 days before start of the study; known allergies to the study drugs; who had smoked tobacco within the past 3 months, or who drank ≥2 ounces of alcoholic beverages per day or >40 ounces of caffeine-containing beverages per day.	ER-oxybutynin 10mg, tolterodine 2mg, IR-oxybutynin 5mg	Placebo	This study was sponsored by ALZA Corporation, Mountain View, California.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Chancellor, 2008[256] The ABLE trial USA N: 395	Male and female patients >18 years old with symptoms of OAB for at least 6 months; >8 micturitions on average per day, >2 episodes of UUI on average per day and/or >2 episodes of urgency on average per day	Use of any drug that could affect bladder function within 2 weeks prior and during the study, participation in any formal bladder-training program within 30 days of screening, predominant stress urinary incontinence and any bladder or neurological condition that could affect urinary bladder function or in which use of anti-cholinergic drugs was contraindicated.	Darifenacin with voluntary up-titration from 7.5 mg once daily (qd) to 15 mg qd and Behavioral Modification Program: brochures on modification of diet and daily habits; training in a primary physician's office about pelvic muscle exercises and urgency control techniques including timed voiding, dietary modifications and Kegel-type exercises.	Darifenacin with voluntary up-titration from 7.5 mg once daily (qd) to 15 mg qd	Funding for this study was provided by Novartis Pharmaceuticals Corp., who was involved in study design, data collection and analysis.	Michael Chancellor has no potential conflicts of interest within International Journal of Clinical Practice guidelines for financial disclosure.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Chancellor, 2010[257] Study: Post-hoc A4,T3 N: 1,156	Male or female patients aged ≥18 years with OAB for ≥6 months; required to have urinary frequency (an average of ≥10 toilet voids per day); symptoms of urgency (at least 1 "severe" urgency severity rating associated with a toilet void per 3 days, as measured by the Indevus Urgency Severity Scale [IUSS]); and an average of ≥1 urge urinary incontinence (UUI) episode per day, as recorded in a baseline 3-day patient urinary diary	Total void volume of >3000mL per day, stress incontinence, insensate continence; history of neurogenic bladder; significant renal disease; urinary tract infections; and bladder obstructions	Trospium chloride XR	Placebo	Not reported	Dr. Oefelein-Director: Allergan; Dr. Chancellor-Consultant, Speaker honorarium, trial participant: Allergan
Chapple, 2005[258] RCT USA N: 65	Men and women aged 18–75 years with cystometric evidence of detrusor overactivity within the previous 6 months, either idiopathic or neurogenic (secondary to a neurological lesion present for >12 months), with >2 associated symptoms (average of >7 micturitions/day, >7 episodes of urgency/week, >1 urge incontinence episode/week necessitating change of clothing or pads).	Previous bladder surgery for detrusor overactivity; prostatectomy in the last 6 months; bladder stones; treatment with diuretics, antimuscarinic, tricyclic antidepressants or digoxin within the previous 2 weeks; stress and mixed incontinence, unless detrusor overactivity was the principal urodynamic observation and the patient was experiencing normal recommended limits, contraindiciations to anticholinergics (e.g. untreated or narrow angle glaucoma, bladder outlet obstruction).	Darifenacin immediate release (IR) 2.5 mg three times a day ; darifenacin controlled release (CR) 15 mg once daily (q.d.); darifenacin CR 30 mg q.d.	Oxybutynin 2.5 mg t.i.d.; oxybutynin 5 mg t.i.d.; oxybutynin 5 mg t.i.d.	Pfizer Inc	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Chapple, 2007[259] RCT Belgium, Bulgaria, Czech Republic, Estonia, France, Germany, Hungary, Italy, the Netherlands, Poland, Romania, Russia, Spain, Sweden, Ukraine, the United Kingdom, South Africa, Australia, and New Zealand N: 1,135	Men and women with OAB symptoms with urinary urgency for >6 months and >3 UUI episodes per 24 hours (symptoms were recorded in a 3-day diary).	Pregnancy ;non adequate contraception throughout the trial; lower urinary tract pathology that could, in the investigator's opinion, be responsible for urgency or incontinence (e.g., genuine stress incontinence, bladder stones, interstitial cystitis urothelial tumors), pelvic prolapse of grade III or higher, clinically relevant bladder outlet obstruction, polyuria (>3 l per 24 hours), symptomatic or recurrent urinary tract infections, or postvoid residual (PVR) urine volume >100 ml; currently receiving treatment, were treated within 2 weeks of screening visit with antimuscarinic agents, were treated within the past 4 weeks with electro stimulation for bladder training, or had an active urinary tract infection or an underlying neurological disease responsible for their OAB; cardiac arrhythmia and/or unstable angina or a QT interval >500 ms.	Tolterodine ER 4 mg, fesoterodine 4 mg, fesoterodine 8 mg	Placebo	Schwarz BioSciences GmbH and Pfizer Inc	Professor Chapple is a consultant/ investigator/speaker for Astellas (Yamanouchi), Pfizer Inc, Novartis, and Schwarz BioSciences GmbH, and has acted as a consultant for UCB. Professor Van Kerrebroeck is an investigator and lecturer for Astellas

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Chapple, 2008[260] RCT analysis Country: not reported N: 1,135	Men and women aged ≥18 years with OAB syndrome for ≥ 6 months; urinary frequency (≥8 voids/24 hours), and urinary urgency (≥6 episodes during the 3-day diary period) or UUI (≥3 episodes during the 3-day diary period, and at least moderate bladder problems on a six-point Likert scale.	The presence of lower urinary tract pathology that could, in the investigator's opinion, be responsible for urgency or UI (e.g. significant stress UI, urolithiasis, interstitial cystitis, urothelial tumors); pelvic organ prolapse grade >III; clinically relevant BOO; a postvoid residual urine volume of >100 mL; polyuria (>3 L/24 hours); symptomatic or recurrent UTIs; current treatment with antimuscarinic agents; a neurogenic cause for OAB; clinically relevant arrhythmia, unstable angina, or a QT interval of >500 ms; and current treatment, or treatment within the past 4 weeks, with electro stimulation or bladder training.	Fesoterodine 8 mg, tolterodine ER 4 mg	Placebo	Schwarz BioSciences GmbH and Pfizer Inc.	Philip E. Van Kerrebroeck and Christopher R. Chapple are Study Investigators funded by the Sponsor, and Joseph T. Wang and Marina Brodsky are Employees of the Sponsor.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Chapple, 2007[261] RCT USA, Poland, South Africa, Hungary, Sweden, UK and Germany N: 400	Men and women >65 years of age with OAB for at least 6 month with >1 urge UI/day and >10 micturitions/day	Dependent toileting, dependent diary completion, taking drugs that can affect bladder function or external urethral sphincter, total daily volume >3000ml, mean volume/micturition >300ml, clinically significant stress UI or bladder outlet obstruction (postvoid residual volume >100ml); marked cystocele, stage 3 or 4 pelvic prolapse; participation in bladder training program or electrical stimulation therapy within 3 months of screening; intermittent urinary tract infection, clinically significant congenital or acquired disorder of the urinary tract, chronic pain syndrome or other clinically significant medical conditions including cognitive impairment, uncontrolled severe hypertension, uncontrolled severe heart failure, recent myocardial infarction, or uncontrolled thyroid disease.	Darifenacin (7.5 mg once daily for 2 weeks, then optional titration to 15 mg daily)	Placebo	Not reported	Not reported
Chapple, 2005[262] Pooled Country: not reported N: 1,059	Men and women aged ≥18 years with symptoms of OAB for ≥6 months, and capable of independent toileting, with 5–50 episodes of incontinence per week during the run-in period, and a high voiding frequency (a mean of ≥8 voids/24 hours) and urgency (a mean of ≥1 episode/24 hours); women of childbearing potential required to use an adequate method of contraception throughout	Initiation of a bladder training; pregnancy and lactation; clinically significant stress incontinence (i.e.>1 episode of stress incontinence per week), BOO and/or a postvoid residual urine volume of > 200 mL (as measured by pelvic ultrasonography); clinically important medical problems that would interfere with the patient's participation in the study; patients with interstitial cystitis, severe constipation (two or fewer bowel movements per week), hematuria or intermittent UTI; cystocele or other clinically significant pelvic prolapsed; patients with an indwelling catheter and those who practiced intermittent	Darifenacin 7.5 mg or 15 mg/day	Placebo	The studies were funded by Pfizer Inc.	All authors are investigators in the study and/or have acted as consultants to Pfizer or Novartis.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
	the study; those taking hormone–replacement therapy had to have received such therapy for ≥2 months before entering the study; men taking finasteride for BPH had to be on a stable dose for ≥2 months; those receiving long-term therapy with diuretics, antihypertensive medications, benzodiazepines or antihistamines had to be taking a stable dose before study recruitment, with no plans to change treatment during the study; and patients on bladder training program were not to modify or discontinue their training during the course of the study.	self-catheterization; urogenital surgery in the previous 6 months; patients with contraindications to antimuscarinic therapy (e.g., uncontrolled narrow-angle glaucoma, urinary retention, gastric retention); history of alcohol/drug abuse; and known hypersensitivity to study medication.				
Chapple, 2007[60,61,263] U.S. Food and Drug Administration[60] STAR study group Country: not reported N: 1,177	The STAR study :men and women aged at least 18 years who had OAB symptoms (including urinary frequency, urgency or urgency incontinence) for 3 months or more; with an average of >8 micturitions/day; >1 incontinence episode/day, or an average of >1 urgency episode/day.	Stress incontinence or mixed incontinence where stress was predominant (mixed incontinence was allowed otherwise) and patients with a neurological cause of abnormal detrusor activity.	Solifenacin 5 mg	Tolterodine ER 4 mg	Grant from Yamanouchi Pharmaceutical Co, Ltd (now Astellas Pharma Inc). Tokyo, Japan.	Professor Chapple is a consultant, investigator, and speaker for Astellas Pharma Inc (Yamanouchi), Pfizer, Novartis, and Schwarz, and has acted as a consultant to UCB.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Chapple, 2006[264] Study: RCT Sample: 3032	Outpatient men and women, at least 18 years of age, with symptoms of OAB. During a baseline 3-day micturition diary period, patients were required to report a mean of ≥8 micturitions per 24 h ,and either a mean of ≥1 incontinence episode per 24 h or a mean of ≥1 urgency episode per 24 h.	Patients with at least one on-treatment efficacy assessment	solifenacin 5mg or 10mg	placebo	Funded by an educational grant from Astellas.	Christopher Chapple is an investigator/ consultant for Pfizer, Astellas, Schwarz Pharma, Novartis and UCB Pharma. Linda Cardozo receives money for consultancy and/or advisory work, or research or lecturing from Astellas, Lilly/Boehringer Ingelheim, UCB Pharma, Pfizer, Gynecare, Plethora and Cook. William D. Steers is an investigator/ consultant for Sanofi, Pfizer, Lilly and Astellas. Fred E. Govier has nothing to disclose
Chapple, 2004[265] Study: RCT Sample: 225	Men and women aged 18-80 years were eligible to enter the study if they had idiopathic detrusor overactivity (defined in this study as phasic contractions of ≥10 cmH20, assessed by filling cystometry) within 6 months of study initiation; a mean of ≥8 voids/24h for 3 days and ≥3 episodes of incontinence or urgency during the 3-day urinary diary period before randomization	Neurogenic detrusor overactivity, significant outlet obstruction, urinary retention, urodynamic stress incontinence, bladder stones, UTI, interstitial cystitis, previous or current malignant disease of the pelvic organs, previous pelvic radiation, and diabetic neuropathy; those taking concomitant anticholinergic medications, or had known or suspected hypersensitivity to anticholinergic medications or lactose; pregnant or lactating women and those not taking approved contraception methods	Solifenacin	Tolterodine and placebo	NR	NR

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Chapple, 2004[266] Study: RCT Sample: 728	NR	NR	fesoterodine	Placebo	NR	NR
Chapple, 2004[54] Study: RCT Sample: 1081	Men and women aged>=18 years with symptomatic OAB(including urgency, urge incontinence, or frequency) for >=3 months. After run-in period patients had to have had an average frequency of >=8 voids/24 hours and have experienced at least 3 episodes of urgency and/or three episodes of incontinence during the 3-day voiding diary period.	Significant BOO, a postvoid residual volume of >200mL, incontinence for which stress was determined to be the predominant factor, presence of a neurological cause for detrusor muscle overactivity, evidence of UTI or bladder stones, previous pelvic irradiation, or previous or current malignant disease of the pelvic organs, any medical condition contraindicating the use of antimuscarinic medication (including narrow-angle glaucoma and urinary or gastric retention), nonpharmacological treatment for OAB including electro stimulation therapy or start of a bladder training program during the 2 weeks before or during the study, diabetic neuropathy, use of drugs intended to treat incontinence, use of any drugs with cholinergic or anticholinergic side-effects, and participation in a clinical trial within 30 days before the study entry; pregnant or nursing women, women of child-bearing potential intending to become pregnant during the study or who were not going to use reliable contraceptive methods.	solifenacin 5mg and 10mg	Tolterodine 2mg twice daily or placebo	Yamanouchi Pharma Co., Ltd, Tokyo,Japan	NR

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Chompootaweep, 1998[267] RCT Thailand N: 40	40 postmenopausal women with urogenital symptoms related to estrogen deficiency.	Thromboembolic disorders, severe liver diseases, estrogen-dependent tumors, high blood pressure (diastolic >100mm/Hg), those who had received oral estrogen in the 3 months before the study.	Combined contraceptive intravaginal 1 pill/week at bedtime with 250mg levonorgestrel +30mg ethinyl estradiol.	Intravaginal conjugated estrogen cream (1g=0.625mg conjugated equine estrogens) at bedtime, 3/week in week 1, 2/week in week 2, and then 1/week for 6 weeks	Grant from the Rhatchada-Pisakessompoj Fund, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Choo, 2008[268] Study: H5 Sample: 357	Men and women aged ≥18 years with symptoms of OAB for ≥3months; average frequency of ≥8 voids per 24h and experienced at least three episodes of urgency or three episodes of urgency incontinence during the 3-day voiding diary period	Clinically significant bladder outlet obstruction, a PVR volume of >200ml, incontinence for which stress was determined to be the predominant factor, presence of a neurological cause for detrusor muscle overactivity, evidence of urinary tract infection or bladder stones, previous pelvic irradiation, or previous or current malignant disease in the pelvic organs, any medical condition contraindicating the use of antimuscarinic medication(including narrow angle glaucoma and urinary or gastric retention), non-pharmacological treatment for OAB including electro stimulation therapy or start of a bladder training program during the 2 weeks before or during the study, diabetic neuropathy, use of drugs intended to treat incontinence, use of any drugs with cholinergic or anitcholinergic side effects and participation in a clinical trial within 30 days before study entry; women of child-bearing potential who were pregnant or nursing, intending to become pregnant during the study, or who were not using reliable contraceptive methods.	solifenacin 5mg/10mg	tolterodine 4mg	Research grant from Astellas Pharma Inc., Tokyo, Japan	NR

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Chu, 2009[269] Study: RCT Sample: 672	Men and women aged ≥18 years with a diagnosis of OAB made by an investigator based on symptoms (urinary frequency, urgency, or urge incontinence); had to record a mean of >=8 micturitions per 24 hours plus a mean of ≥1 incontinence episode per 24hours and/or a mean of ≥1 urgency episode per 24 hours	Stress urinary incontinence or mixed urinary incontinence in which stress was predominant (mixed incontinence was otherwise allowed), a neurologic cause of detrusor overactivity, urinary retention, grade III/IV prolapse with cystocele, and recurrent or active urinary tract infection; patients with abnormal findings on 12-lead ECG or abnormal laboratory findings. Women of childbearing potential were required to have a negative serum pregnancy test at screening and to use a medically acceptable form of contraception during study participation	Solifenacin	Placebo	Funded and sponsored by Astellas Pharma Inc., Tokyo, Japan	No

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Corcos, 2006[270] Uromax Study Group Canada N: 237	Men and women (aged ≥18 years) with UUI	A screening postvoid residual urine volume of >100 mL; allergy/serious side-effects with anticholinergic medications; primary diagnosis of stress UI; conditions contraindicating anticholinergic therapy; hepatic/renal disease; interstitial cystitis, hematuria secondary to malignancy; recurrent UTI (more than three/year); indwelling catheter/bladder training within 14 days of screening; drug/alcohol abuse; untreated psychiatric conditions affecting participation; pregnant/nursing women; and women of childbearing potential not using reliable contraception. A urine sample was collected and analyzed at the first study visit. Confirmed UTI at study entry was treated, and initiation of the washout/baseline period followed confirmation of absence of bacteria. Use of pharmacotherapy for UUI was terminated at or before the baseline evaluation (if applicable).	Daily dose of 5, 10, and 15 mg controlled-release oxybutynin	Daily dose of 5, 10 and 15 mg controlled-release oxybutynin	Purdue Pharma	J. Corcos, A. Patrick, C. Andreou and R. Casey are study investigators funded by sponsor; P. Miceli is a paid consultant/writer; and A. Darke, J. Reiz and Z. Harsanyi are sponsor employees.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Davila, 2001[271] Transdermal Oxybutynin Study Group. N: 76	Men or women 18 years or older with a history of urge or mixed urinary incontinence with a predominance of urge symptoms, previously diagnosed with motor urge urinary incontinence and had symptomatic improvement during a minimum of 6 weeks of oral oxybutynin; a minimum of 3 incontinent episodes daily, and a greater than 30% increase after 2 week washout from current treatment.	Allergy to oxybutynin, intolerability of transdermal system, current pregnancy or lactation, overflow incontinence secondary to underactive or non-contractile detrusor or outlet obstruction, impaired bladder compliance, including tonic increase in pressure greater than 15 cm. water during filling cystometry, or current medical conditions or pharmacological therapies that could contribute to or cause urinary incontinence; medical conditions that could be worsened by oxybutynin.	Transdermal system with 1.3 mg. oxybutynin daily + oral placebo	Oral capsules with 2.5 mg. oxybutynin + transdermal placebo	Watson Laboratories, Inc.	Not reported
Dessole, 2004[272] RCT Italy N: 88	88 postmenopausal women with incontinence confirmed by the direct visualization of loss of urine from the urethra during the standard stress test and by urodynamic investigation.	Estrogen treatment, anatomical lesions of the urogenital tract, detrusor over activity and abnormal maximal cystometric capacity; presence of severe systemic disorders, thromboembolic diseases, biliary lithiasis, previous breast or uterine cancer, abnormal uterine bleeding, and body mass index of 25 kg/m^2 or higher.	Intravaginal estriol ovules: 1 ovule/day (1mg) for 2 weeks and then 2 ovules/ week for 6 months.	Placebo: vaginal suppositories	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Diokno, 2003[273] Chu, 2005[274] Anderson, 2006[275] OPERA (Overactive bladder: Performance of Extended Release Agents) trial USA N: 790	OPERA (Overactive bladder: Performance of Extended Release Agents):Women with OAB, aged 18 years and older, who documented 21 to 60 UUI episodes per week and an average of 10 or more voids per 24 hours; predominant urge UI; with or without history of prior treatment with an anticholinergic drug for OAB.	Treatable genitourinary conditions that could cause incontinence, 2 postvoid residual urine volumes shown by ultrasonography to exceed 150 mL; pronounced risk of developing complete urinary retention, clinically important medical problems that would put a participant at undue risk of anticholinergic effects, hematuria, uncontrolled narrow-angle glaucoma, obstructive uropathy, reduced gastrointestinal motility, and known hypersensitivity to the study medications.	Extended-release formulations of oxybutynin at 10 mg/d	Tolterodine at 4 mg/d	ALZA Corporation, Mountain View, California, and Ortho-McNeil Pharmaceutical, Raritan, NJ	Dr. Diokno is a medical consultant for Ortho-McNeil Pharmaceutical. Dr. Appell is on the Medical Advisory Board of Ortho-McNeil Pharmaceutical, Watson Pharmaceuticals, Inc, and Indevus Pharmaceuticals, Inc. Dr. Sand is an investigator/advisor for Pharmacia Corporation. Dr. Dmochowski is a consultant for Ortho-McNeil Pharmaceutical. Dr. Kell is a full-time employee of ALZA Corporation, a subsidiary of Johnson & Johnson; she owns Johnson & Johnson stock and has Johnson & Johnson stock options.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Dmochowski, 2002[276] Transdermal Oxybutynin Study Group. USA N: 520	Male and Female patients at least 18 years old with a history of overactive bladder, with or without neurological disease, 10 or more urge urinary incontinent episodes/week, with either pure urge or a predominance of urge episodes, 56 or more voids and an average recorded voided volume of 350 ml. or less.	Incontinence related to chronic illness, anatomical weakness/abnormalities or concomitant medications, lower urinary tract surgery in the previous 6 months; a diagnosis of interstitial cystitis, urethral syndrome, painful bladder syndrome and overflow urinary incontinence; alcohol/drug abuse within the previous year; known hypersensitivity to oxybutynin, similar compounds or transdermal medications; active skin disorder; narrow-angle glaucoma or shallow anterior chamber evident on physical examination; prostate specific antigen greater than 4ng./ml. or a history of biopsy positive prostate cancer in men, and excessive consumption of caffeine, defined as greater than 5 cups of caffeine–containing beverages daily.	1.3, 2.6, or 3.9 mg Oxybutynin twice weekly to the abdomen	Placebo twice weekly to the abdomen	Not reported	All authors have financial interest and/or other relationships with Watson Pharmaceuticals; Roger R. Dmochowski has financial interest and/or other relationship with Lilly, Surx, Alza, Pharmacia, Bioform, and Genyx; Norman ZInner has financial interest and/or other relationship with Bayer, Lilly, Abbott, Praecis, Pharmacia, Interneuron, Alza, Amgen, AstraZeneca, and Roche; Marc Gittelman has financial interest and/or other relationship with Alza, Interneuron, Yamanouchi, Merck, Pfizer, Seprecor, Otsulta, Glaxo, Pharmacia, Praecis, Synthelabo, and Vivus; Sydney Lyttle has financial interest and/or other relationship with PPD Development.
Dmochowski, 2008[48] RCT USA	Men and women aged 18 years or older with OAB of 6 months' or longer	Total voided volumes greater than 3000 mL/day or a mean volume voided/void greater than 250 mL;	Trospium chloride 60 mg once daily	Placebo	Esprit Pharma and Indevus Pharmaceuticals	Dr. Dmochowski has acted as a consultant for Esprit Pharma,

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
N: 564	duration with symptoms of urinary frequency (a mean of 10 or more toilet voids per day), urgency (1 or more episodes of severe urgency associated with a toilet void), and UUI (a mean of 1 or more UUI episodes per day).	predominantly stress, insensate, or overflow incontinence; history of neurogenic bladder, indwelling or intermittent catheterization, significant renal disease (defined as serum creatinine greater than 1.5 mg/dL), uninvestigated hematuria or urinary tract infection during screening, or a history of more than 3 urinary tract infections in the previous 12 months; other bladder pathologies, including clinically significant retention (defined as postvoid residual urine volume greater than 100 mL), cancer, and interstitial cystitis; prostate specific antigen level greater than 4 ng/mL, prostate cancer, or chronic prostatitis.			Inc.	Indevus Pharmaceuticals Inc, Allergan, Novartis, Pfizer, and Watson; Dr Sand has acted as a consultant for Esprit Pharma, Indevus Pharmaceuticals Inc, Ortho, Allergan, Watson, GSK, Astellas, and Schwarz Pharma. In addition, Dr Sand has also been an investigator in clinical trials for Esprit Pharma, Indevus Pharmaceuticals Inc, Ortho, Allergan, Watson, and Astellas, and has participated in meetings for Esprit Pharma, Indevus Pharmaceuticals Inc, Ortho, Allergan, Watson, GSK, and Astellas; Dr Zinner has acted as a consultant for Esprit Pharma, Indevus Pharmaceuticals Inc, Novartis, Watson, Eli Lilly, GSK, Allergan, Astellas, and Medtronic. In addition, Dr Zinner has also been an investigator on clinical trials for Esprit Pharma, Indevus

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
						Pharmaceuticals Inc, Novartis, Watson, GSK, Allergan, and Astellas, and has participated in meetings for Esprit Pharma, Indevus Pharmaceuticals Inc., Eli Lilly, and Astellas; Dr. Staskin has acted as a consultant for Esprit Pharma, Indevus Pharmaceuticals Inc, Ortho-McNeil, Novartis, Watson, Pfizer, and Astellas.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Dmochowski, 2005[277] Pooled USA N: 241	Pooled analysis of RCTs: men and women with urge or mixed urinary incontinence with a predominance of urge symptoms with >10 urge incontinence episodes/week and 56 or more micturitions (>8 micturitions per day). For study 2 patients had to have a beneficial response to previous anticholinergic OAB treatment, at least 4 incontinence episodes, 24 or more voids, and a mean void volume of 350 mL or less over 3 days.	Postvoid residual (PVR) volume >250 mL; Abnormal physical, laboratory, or ECG examination; Lower urinary tract surgery within preceding 6 months; An active dermatologic disorder; Known narrow–angle glaucoma; Shallow anterior chamber, evident on physical examination (study 1 only); Hypersensitivity to oxybutynin or other anticholinergic medications; Hypersensitivity to transdermal drug delivery systems; History of overflow incontinence caused by underactive or acontractile detrusor or outlet obstruction; A prostate-specific antigen level >4 ng/mL; A history of biopsy-positive prostate cancer; Failure to complete urinary diary during washout period; Recent (within 1 year) alcohol and/or drug abuse; Inability to maintain nonpharmacologic urinary; incontinence management program during study; Consumption of 5 or more cups of caffeinated beverages per day; Use of medications that affect detrusor activity; Use of medications that interfere with oxybutynin or tolterodine (study 2 only).	3 dosages of oxybutynin-TDS 1.3 mg/d , 2.6 mg/d , or 3.9 mg/d for 12-week (double-blind)+ 12-week (open-label)+ 28-week (open-label extension)	Placebo	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Dmochowski, 2003[278] Transdermal Oxybutynin Study Group. USA N: 361	Men and women at least 18 years of age taking current pharmacologic treatment for OAB with beneficial response to the pre-study treatment; four or more urge urinary incontinent episodes, with pure urge or a predominance of urge episodes, 24 or more voids, and an average recorded urinary void volume of 350 mL or less.	History of lower urinary tract surgery in the previous 6 months and a diagnosis of interstitial cystitis, urethral syndrome, painful bladder syndrome, and overflow urinary incontinence.	Transdermal oxybutynin 3.9 mg/day or oral tolterodine 4 mg/day	Placebo	Watson Pharma	R.R. Dmochowski, P.K. Sand, N.R. Zinner, M.C. Gittelman, and G.W. Davila are study investigators funded by, and members of the medical advisory board, the sponsor. S.W. Sanders is an employee of the sponsor.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Dmochowski, 2003[279] Duloxetine Urinary Incontinence Study Group Canada and the United States N: 683	Non-pregnant women 18 years and older with a clinical diagnosis of bothersome SUI at least 3 months in duration, with predominant symptom of SUI with 7 or greater stress incontinent episodes weekly; daytime voiding frequency less than 8 times daily, nocturnal frequency less than 3 times daily and no predominant urge incontinence symptoms. After filling a positive cough stress test and stress pad test were required. This clinical algorithm has been demonstrated to predict urodynamic stress incontinence with 92% accuracy.	Inability to tolerate retrograde bladder filling to 400 ml or who had a first sensation of bladder filling at less than 100 ml; treatment with other antidepressants.	80 mg duloxetine daily	Placebo	Supported by Eli Lilly and Co.	Roger Dmochowski has financial interest and/or other relationship with Lilly Pharmaceuticals, Watson Pharmaceuticals, Ortho McNeil and Indevus Pharmaceuticals; John Miklos, Ilker Yalcin and Richard Bump have financial interest and/or other relationship with Eli Lilly; Peggy Norton has Financial interest and/or other relationship with Eli Lilly, Pharmacia and Pfizer; Norman Zinner has Financial interest and/or other relationship with Lilly, Watson, Kyowa and Schwarz Pharmaceuticals.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Dmochowski, 2007[280] RCT USA N: 1015	Post hoc analysis of RCT: men and women aged ≥18 years and reported symptoms of urinary frequency (≥ 8 voids/24 hours) and UUI (≥5 episodes/week) for ≥6 months.	Significant hepatic or renal disease, current or recurring UTI, stress UI, clinically relevant BOO, indwelling catheter or intermittent self-catheterization, and any condition for which antimuscarinic treatment was contraindicated; taking any anticholinergic drug or treatment for OAB and those who showed a mean of 200 mL/void or total daily of 3000 mL.	Tolterodine-ER (4 mg once daily)	Placebo	Pfizer Inc	Dr. Dmochowski is an advisor to Pfizer. Dr Kreder is a speaker for Astellas, Lilly, Merck, Novartis, and Pfizer; serves as a paid consultant to Astellas, Lilly, and Pfizer; receives research support from Lilly, Merck, and Pfizer; and holds stock options from Merck. Dr MacDiarmid is a speaker for Pfizer, Ortho-McNeil, Esprit, Astellas, Watson, and Novartis; he is a paid consultant to Pfizer, Ortho-McNeil, Esprit, Astellas, and Watson. Martin Carlsson and Zhonghong Guan are employees of Pfizer Inc.
Dmochowski, 2010[281] Study: RCT K6 N: 313	Men and women 18 to 85 years old with symptoms of idiopathic OAB with UUI for 6 or more months who were not adequately treated with anticholinerigc therapy (defined as inadequate response or intolerable side effects) were included in the study following informed consent. At baseline patients were required to	If patients used CIC (clean intermittent catheterization), had a history or evidence of pelvic or urological abnormalities, or diseases affecting bladder function, had been treated for 2 or more UTIs within 6 months, or had 24-hour total urine volume voided greater than 3, 000ml or PVR urine volume greater than 200ml at screening	Onabotulinumtoxin A	Placebo	Supported by Allergen, Inc.	Roger Dmochowski has financial interest and/or other relationship with Allergen, Pfizer, Astellas, and Contura; Christopher Chapple has financial interest and/or other relationship with Pfizer, Allergen, Astellas, Novartis, Ono, and Recordati; Victor Nitti has financial interest

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
	have 8 or more UUI episodes a week, with no more than 1 incontinence-free day, and an average of 8 or more micturitions daily.					and/or other relationship with Allergen, Astellas, Coloplast, Ethicon, Medtronic, Pfizer, Serenity, Uroplasty and Watson; Michael Chancellor, Catherine Thompson, Grace Daniell, Jihao Zhou and Cornelia Haag-Molkenteller have financial interest and/or other relationship with Allergen; and Karel Everaert has financial interest and/or other relationship with Allergen and Medtronic

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Dorschner, 2000[282] RCT Country: Not reported N: 107	Men and women older than 60 years of age with urgency, urge incontinence, or mixed urge-stress incontinence, >1 episode of UI/day and micturition volume <300ml/micturition	Acute urinary tract infections, mechanical or functional bladder-emptying disorders, residual urine >20% of voided volume by ultrasound, micturition volume >300ml in uroflow, renal insufficiency, concomitant medications interfering with the drug studied (neurotropic/ musculotropic spasmolytics, centrally acting muscle relaxants, psychopharmacological agents or drugs for the treatment of Parkinson's disease, anti-arrhythmic), serious life threatening cardiovascular diseases (myocardial infarction within the previous 3 months, unstable coronary heart disease, implanted cardiac pace-maker, decompensated myocardial insufficiency, tachycardia or bradycardia at rest, second-or third-degree atrio-ventricular block, complete bundle branch interventricular heart block, chronic atrial fibrillation and ventricular extrasystoles Lown IVb in the pre-study ECG monitoring.	Propiverine (15 mg t.i.d.)	Placebo	Grant provided by Apogepha	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Drutz, 1999[283] RCT United States and Canada N: 277	Age ≥18 years; all female patients were to be postmenopausal, surgically sterile, or using an adequate contraceptive method before and during the study; evidence of detrusor overactivity on subtracted cystometry (phasic detrusor contraction with an amplitude ≥10cmH_2O), along with urinary frequency (≥8 micturitions on average per 24 hours) and either urge incontinence (≥1 incontinence episode on average per 24 hours), as confirmed by micturition diaries during the run-in period, and/or urinary urgency.	Clinically significant stress incontinence as determined by the investigator during a cough stress test maneuver; hepatic or renal disease; any disease which the investigator thought made the patient unsuitable for inclusion; recurrent urinary tract infections; interstitial cystitis; uninvestigated hematuria or hematuria secondary to malignant disease; indwelling catheter or intermittent catheterization; treatment with any investigational drug in the 2 months prior to entry; previous treatment with tolterodine; electro-stimulation therapy or bladder training within 14 days prior to entry or initiation during the study; treatment with any anticholinergic drug, or any drug for urinary urge incontinence within 14 days prior to the baseline visit or initiation during the study; unstable dosage of any treatment with anticholinergic adverse effects or initiation of such treatment during the study; previously demonstrated serious adverse effects on oxybutynin average total voided volume/24 hours of >3000 ml; or clinically significant voiding difficulty with risk of urinary retention (such as residual volume >200 ml or urine flow rate <10ml/s).	Tolterodine 2mg b.i.d. or oxybutynin 5mg t.i.d.	Placebo	The study was funded by Pharmacia & Upjohn AB, Uppsala, Sweden	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
DuBeau, 2005[284] RCT analysis Europe (Denmark, Finland, Ireland, Norway, Sweden, and United Kingdom) N: 854	Exploratory analysis of RCT: women aged >18 years with urge-predominant mixed incontinence (>5 episodes of urge UI per week), urinary frequency (mean > voids per 24 hours), and urgency (strong and sudden need to urinate), together with stress incontinence symptoms.	Any contraindication to antimuscarinic therapy (narrow angle glaucoma, urinary retention, gastric retention, allergy, or hypersensitivity); treatment within 2 weeks of randomization with any anticholinergic drug, or any drug for UI (excluding stable doses of estrogen and a-adrenergic agonists); interstitial cystitis, uninvestigated hematuria, bladder outlet obstruction, indwelling or intermittent catheterization; urinary tract infection during the run-in period or greater than three times in the last year; hepatic or renal dysfunction; use of inhibitors of cytochrome P450 3A4 isoenzymes; 24-hour urine volume >3L; significant renal or hepatic dysfunction; pregnancy, lactation, or childbearing potential without use of adequate contraception; and behavioral therapy for UI within 4 weeks of initial study visit.	Tolterodine 4 mg once daily	Placebo	Pfizer	Not reported
Duckett, 2007[285] Obs USA N: 222	Women with a diagnosis of urodynamic stress incontinence, with mixed USI and detrusor overactivity (DOA) if they were predominantly complaining of moderate/severe stress incontinence	Women not assessed with cystometry and women who declined drug therapy were excluded from further analysis.	Duloxetine 40 mg twice a day	None	Not reported	Not reported
Enzelsberger, 1995[286] RCT Austria N: 52	52 women complaining of frequency (more than five times per 12 hours), nocturia (more than twice per night) and urgency.	Women with urodynamically assessed genuine stress incontinence and with neurologic disorders.	Oxybutynin	Placebo	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Flynn, 2009[287] RCT Country: Not reported N: 22	Overactive bladder refractory to anticholinergic medications (at least 1 anticholinergic medication and behavioral modifications must have failed), multiple daily incontinence episodes and a 24-hour pad weight of 100 gm or greater; subjects with coexisting severe OAB and mild stress incontinence were allowed to enter the study; demonstrate willingness and ability to perform self-catheterization, and have negative urine culture.	Low leak point pressures, increased post-void residual volume or neurological etiologies; gross fecal incontinence or an absent detrusor contraction on pressure flow.	Cystoscopic administration of botulinum-A toxin 200 U and 300 U	Placebo	Supported by National Institutes of Health National Institute on Aging Grant #R21 AG25490-01.	Cindy L. Amundsen has financial interest and/or other relationship with Pfizer; George D. Webster has financial interest and/or other relationship with Lifetech and AMS.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Foote, 2005[288] Pooled Country: Not reported N: 317	Men and women with symptoms of OAB for at least 6 months and capable of visiting a toilet unaided with 5–50 episodes of incontinence per week, along with elevated micturition frequency (mean 8 voids/24 hours) and urgency (mean 1 episode/ 24 hours).	Clinically significant stress incontinence (i.e. 1 episode of stress incontinence per week); bladder outlet obstruction and/or post-void residual urine volume >200 ml; concomitant medical problems that would interfere with the patient's participation in the study; severe constipation (2 bowel movements per week); haematuria, intermittent urinary tract infection, cystocele or other clinically significant pelvic prolapse; use of an indwelling catheter or intermittent self-catheterization; urogenital surgery in the previous 6 months; contra-indications to antimuscarinic therapy (e.g,. uncontrolled narrow-angle glaucoma, urinary retention or gastric retention); and a history of alcohol/drug abuse or known hypersensitivity to study medications; treatment with potent cytochrome P450 (CYP) 3A4 inhibitors (e.g., ketoconazole), opioids (or other drugs that could cause significant constipation), non-study antimuscarinic agents or other drugs with significant anticholinergic effects (e.g. tricyclic antidepressants); concomitant treatment with CYP2D6 inhibitors such as cimetidine, fluoxetine and paroxetine; initiation of bladder-training program was not permitted during the study.	Darifenacin 7.5 mg or 15 mg once daily	Placebo	The studies were funded by Pfizer Inc. Preparation of the manuscript was supported by an educational grant from Novartis Pharma AG.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Franzen, 2010[289] RCT 72	Women ≥18 years of age with urgency/urge incontinence presenting to the gynecology/urology outpatient clinics; had symptoms for at least 3 months, had increased frequency of micturition (at least 8 micturitions per 24 hours), had a mean volume of urine voided per micturition of not more than 200ml, and had a total urine volume per 24 hours of less than 3,000ml during a 48-hour bladder diary.	Persistent urinary tract infection, post-void volume greater than 150ml, history of neurological disease or dementia, pregnancy, contraindications to anticholinergic therapy, and cardiac pacemaker; if they had used tolterodine or any other anticholinergic drugs in order to treat urgency/urge incontinence during the last 2 months or had received electrical stimulation treatment within the last 3 years.	Electrical stimulation	Tolterodine	Not reported	None
Freeman, 2003[290] RCT analysis N: 1015	Tolterodine Study Group (secondary analysis): men and women at least 18 years old with urinary frequency (eight or more micturitions per 24 hours) and urge incontinence (five or more episodes per week) irrespective of whether they had received prior antimuscarinic therapy and the outcome of that treatment.	Stress incontinence, total daily urine volume greater than 3 L, any contraindications to antimuscarinic treatment, significant hepatic or renal disease, symptomatic or recurrent urinary tract infections, interstitial cystitis, hematuria or bladder outlet obstruction, electro-stimulation or bladder training, indwelling catheter, or intermittent self-catheterization; pregnancy or nursing; any treatment for overactive bladder, including use of anticholinergic drugs or drugs that inhibit cytochrome P450 3A4 isoenzymes, within 14 days preceding randomization.	Tolterodine extended release 4 mg	Placebo	Pharmacia Corporation, Peapack, New Jersey	Investigator fees were paid by Pharmacia into the research funds of the authors and used to employ research staff, fund research, and purchase equipment. None of the authors own stock in Pharmacia or hold stock options.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Gahimer, 2007[291] Duloxetine exposures integrated safety database USA N: 23983	Reported previously for 64 pooled studies	Not reported	Duloxetine 20-120mg/day	None	Eli Lilly	Not reported
Ghei, 2005 [292] RCT Country: Not reported N: 20	Men and women 18 to 80 years old with urodynamic detrusor overactivity unresponsive to oral antimuscarinic agents willing to use intermittent self-catheterization.	Known bladder malignancies, previous bladder surgery, active urinary tract infections, known major drug allergies, prostatic cancer, major urethral access problems and children; anticholinergics during the study period were not permitted.	Botulinum toxin B (5,000 IU diluted up to 20 ml) intravesically	Placebo	Not reported	The trial was independent of industry sponsorship and involvement.
Ghoniem, 2005[293] Duloxetine/ Pelvic Floor Muscle Training Clinical Trial Group. Subjects were enrolled at 16 tertiary continence centers in the Netherlands, United Kingdom and United States. N: 201	Women 18 to 75 years old with SUI; urodynamic stress incontinence and no detrusor overactivity on studies within 6 months before entry (36 subjects) or a positive cough stress test and normal micturition frequency (less than 8 voids daily) at entry (165 subjects). All subjects had predominant symptoms of SUI with an average of at least 2 stress incontinent episodes daily.	Advanced pelvic organ prolapse, active or recurrent urinary tract infections, and continence surgery within 1 year, current device or pharmaceutical incontinence treatment, prior hip fracture or replacement and any prior formal PFMT with a continence nurse or physical therapist.	40 mg duloxetine twice daily plus imitation PFMT (duloxetine only), duloxetine plus PFMT (combined treatment), placebo plus PFMT (PFMT only). PFMT groups received 30 minutes of instruction and feedback initially and 15 minutes of re-instruction	Placebo plus imitation PFMT (no active treatment)	Supported by Eli Lilly and Company and Boehringer Ingelheim.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Goode, 2002[294] RCT USA N: 105	To be included, patients had to average at least two urge accidents per week documented in the 2-week bladder diary, and urge incontinence had to be the predominant pattern (the number of urge accidents had to exceed the number of stress and other accidents). Also, there had to be urodynamic evidence of bladder dysfunction (DI during filling or provocation or bladder capacity of 350 mL or less).	Patients were excluded if they had continual leakage, postvoid residual urine volume greater than 200 mL, uterine prolapse past the introitus, narrow-angle glaucoma, unstable angina pectoralis, decompensated congestive heart failure, history of malignant arrhythmias, or impaired mental status (Mini-Mental State Examination (MMSE) score <20).	Behavioral treatment	Oxybutynin treatment 2.5mg three times a day, placebo	Grants AG 08010 and K00431 from the National Institute on Aging to Dr.Burgio	Not reported
Goode, 2004[295] RCT analysis USA N: 197	Subjects were community-dwelling women aged ≥55 years who were recruited to a university based continence clinic through professional referrals and advertising. They had urge incontinence or mixed incontinence with urge as the predominant pattern. All patients were ambulatory and not demented. They had urodynamic evidence of bladder dysfunction, either detrusor overactivity (DO) or a maximal cystometric capacity ≥350 mL.	Not reported	Behavioral therapy	Oxybutynin 2.5mg/day to 5mg t.i.d. or Placebo	NIH Grant	Patricia S. Goode has been a paid consultant to Alza, Eli Lilly, Pharmcia, and Yamanouchi

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Gupta, 1999[296] RCT Scotland N: 13	To be included in the study, sub subjects must have been at least 40 years of age, within 20% of the Metropolitan Life Insurance Table ideal weight for height value, normotensive with no clinically significant postural hypotension, and using a birth control method if premenopausal.	Volunteers were excluded for known sensitivity to any anti cholinergic drug; recent (or planned) medication usage other than estrogen replacement therapy (ERT) or birth control pills; recent alcohol, caffeine, or investigational drug use; history of drug abuse; a positive urine drug screen; or recent smoking.	Three 5 mg OROS® oxybutynin chlo ride tab lets at 0700 every day for 4 days	IR oxybutynin 5 mg administered at 0700, 1500, and 2300 every day for 4 days	Not reported	Not reported
Gupta, 1999[297] Pooled Country; Not reported N: 187	Women and men with urge urinary incontinence or mixed urinary incontinence with clinically significant urge components who were known to be responsive to anticholinergic treatment of urinary incontinence but who might have discontinued such treatment because of side effects. Patients were allowed to enroll if they had at least six urge urinary incontinence episodes per week (based on off-medication run-in patient urinary diary results) and could distinguish between urge and non-urge episodes.	Not reported	Oxybutynin XL (Ditropan XL) 5 to 30mg once daily	Oxybutynin - immediate release 5mg once/twice/ thrice or four times a day	Not reported	Not reported
Gousse, 2010[298] Study: RCT Sample: 60	Patients with refractory idiopathic overactive bladder symptoms	NR	Botulinum toxin Type A	Botulinum toxin Type A	Funded by Allergan Inc., USA	NR

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Haab, 2006[299] RCT analysis Country: Not reported N: 719	Successful completion of previous 12-week darifenacin studies without major protocol violation; few concomitant medications, a maximum darifenacin dose of 7.5 mg for patients taking potent inhibitors of cytochrome P450 3A4 and patients with moderate hepatic impairment (Child Pugh B); adequate contraception ; ability to complete patient diaries independently; capable of independent toileting.	Reported previously	Patients received darifenacin CR 7.5 mg irrespective of previous study treatment, for the first 2 weeks of the extension followed by self-selected individualized dosing: patients were permitted to increase their dose to 15 mg or decreased from 15 to 7.5 mg.	None, all patients received darifenacin	Funded by Pfizer, Inc. and Novartis Pharma AG. Preparation of this manuscript was supported by an educational grant from Novartis Pharma AG and editorial and project management services were provided by ACUMED®.	F. Haab is a consultant for Novartis and Astellas and is a study investigator funded by sponsor; J. Corcos, P. Siami and P. Dwyer are study investigators funded by sponsor; J. Corcos is also a member of the board of sponsor; M. Steel, F. Kawakami and K. Lheritier are employees of sponsor; W. Steers is a paid consultant to sponsor and is a study investigator funded by sponsor.
Haab, 2005[300] RCT analysis Country: Not reported N: 1633	Solifenacin Study Group: Patients completing treatment in the two previous RCTs <14 days prior to extension-study; with symptoms of OAB (including urinary frequency, urgency, or urge incontinence) for >3 months, with >8 micturitions /day, either >1 urgency episode or >1 incontinence episode/day.	Clinically significant outflow obstruction, postvoid residual urine >200 ml, persistent or recurrent urinary tract infection, bladder stones, chronic interstitial cystitis, previous pelvic irradiation or previous or current malignant disease of the pelvic organs, and any medical condition contraindicating the use of anticholinergic medication (including narrow-angle glaucoma and urinary or gastric retention); pregnancy or nursing, or intention to become pregnant during the study, or unreliable method of contraception.	Solifenacin 5 mg daily for 4 weeks, after which a flexible dosing regimen based on patient satisfaction (5 mg or 10 mg)	No control	Grant from Yamanouchi Pharmaceutical Co., Ltd., Tokyo, Japan.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Haab, 2004[301] RCT N: 561	Men and women 19–88 years old , 85% females with symptoms of OAB for at least 6 months with urge incontinence (5-50 episodes per week); frequency of micturition (a mean of >8 voids per 24 hours); and urgency (a strong desire to void at least once per day). Those who did not benefit from other antimuscarinic agents or participated in previous double-blind studies of darifenacin were eligible for inclusion in the intervening period was >4 months.	Contraindications to the use of antimuscarinic drugs (e.g. uncontrolled narrow-angle glaucoma, urinary or gastric retention), clinically significant stress incontinence (more than one episode per week), clinically significant bladder outlet obstruction and/or a post-void residual volume >200 ml, genitourinary conditions that could cause urinary symptoms, recent urogenital surgery, or hepatic disease; bladder training program while in the study; known hypersensitivity to the study medication.	Darifenacin controlled-release tablets 3.75 mg ; 7.5 mg or 15 mg/day	Placebo	The study was funded by Pfizer Inc. Preparation of the manuscript was supported by an educational grant from Novartis PharmaAG. Editorial and project management services were provided by Thomson ACUMED1	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Halaska, 2003[302] RCT Austria, Bulgaria, Czechoslovakia, Germany, Russia and Spain N: 358	Men and women >18 years of age with urge syndrome (undue frequency of micturition, nocturia, overwhelming urge, wetting), urge incontinence, urge incontinence as one component of mixed incontinence, or urge incontinence due to a neurological condition (detrusor hyperreflexia) as confirmed using urodynamic measurements.	Absolute tachycardia; closed-angle glaucoma; myasthenia gravis; severe arteriosclerosis of the cerebral vessels; stress incontinence; undue frequency of micturition due to heart failure, renal failure or diuretic therapy; Bladder outlet obstruction; Acute urinary tract infection at the beginning of the trial; Hiatus hernia in combination with reflux oesophagitis; stenoses in the gastrointestinal tract; megacolon; colonic ulceration; allergy or intolerance towards atropine, OXY, TCI or other constituents of the trial medication; concurrent medication with anticholinergics, tricyclic or tetracyclic antidepressants, a-blockers or b-sympathomimetics within the last 7 days before starting the trial; urological or gynecological operations within the last 3 months before starting the trial; serious illnesses or conditions which would preclude participation in any clinical trial (malignant neoplasms, alcoholism, drug misuse); pregnancy or lactation; participation in any other study.	Trospium chloride (20 mg twice daily) or	Oxybutynin (5 mg twice daily).	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Herschorn, 2004[303] RCT Country: Not reported N: 138	Male and female adults older than 50 years of age with OAB symptoms (urinary urgency, frequency >8 micuritions/day, nocturia >2/night) with or without urge UI who would benefit from tolterodine administration (according to physician's opinion).	Stress UI only, abnormal cognitive function, non English speakers; interstitial cystitis, acute urinary tract infections, taking investigational drug.	Tolterodine combined with an education intervention: printed information and an explanation about OAB, medication use, and behavioral treatments (kegel exercise, bladder stretching, fluid regulation). Previously trained nurse or physician provided education.	Tolterodine alone	Pharmacia Corporation and Pfizer	Not reported
Herschorn, 2010[304] Study: VECTOR Sample: 132	18 years old or older with OAB symptoms (more than 1 urgency episode per 24 hours and 8 micturitions or greater per 24 hours)	Significant stress incontinence, active urinary tract infection or another significant lower urinary tract pathology, clinically significant outflow obstruction, urinary retention and the use of concomitant tricyclic antidepressants, α-blockers, 5α-reductase inhibitors or anti-Parkinson's disease agents	solifenacin 5mg	oxybutynin IR5mg thrice daily	NR	Sender Herschorn has financial interest and/or other relationship with Astellas, Pfizer, Allergan, American Medical Systems, Jonhson &Johnson and Coloplast; Lynn Stothers has financial interest and/or other relationship with Astellas Canada, Merck, Urodynamix, Allergan, UBC; Kevin Carlson has financial interest and/or other relationship with Astellas Canada, Pfizer Canada, GlaxoSmithKline,

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
						American Medical Systems, BR Capital Inc. and Health Education United Partnership Inc.; Blair Egerdie has financial interest and/or other relationship with Astellas Canada, Amgen, bayer, Protox Therapeutics and Pfizer; Jerzy Gajewski has financial interest and/or other relationship with Astellas Canada, Allergan, Pfizer, Sanofi-Aventis, Johnson & Johnson and Medtronic; Peter Pomerville has financial interest and/or other relationship with Astellas Canada, Aeterna Zentralis, American Medical Systems, Amgen, AstraZeneca, Dendreon, Eli Lilly, Ferring, Pfizer, Protox Therapeutics, Spectrum Uromedica, Bioniche Inc., Sanofi-Aventis, GlaxoSmithKline, Schering Plough, Amgen, and Abbott; Jane Schulz has financial interest and/or other relationship with

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
						Astellas, Gynecare, Pfizer and Triton; Sidney Radomski has financial interest and/or other relationship with Astellas Canada, Pfizer, Bayer and Lilly; Harold Drutz has financial interest and/or other relationship with Astellas, Lilly, Pfizer, Calldion, Gynecare, Troton and Watson; Jack Barkin has financial interest and/or other relationship with Astellas, GlaxoSmithKline, Merck, AstraZeneca and Pfizer; Fran Paradiso-Hardy has financial interest and/or other relationship with Astellas Pharma Canada

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Herschorn, 2008[305] Study: RCT Sample: 617	≥18 years of age; mean of ≥8 micturitions per 24 hours and ≥3 episodes of urgency or urgency urinary incontinence (UUI) in a 3-day bladder diary before randomization; experienced OAB symptoms for ≥3 months and at least moderate problems associated with their most bothersome OAB symptom, as reported on the OAB Bother Rating Scale	If received any drug used to treat UUI or OAB within 14 days before the study treatment period	tolterodine-ER	Placebo	Funded by Pfizer Inc	Sender Herschorn has served as an advisory board member for Pfizer Inc. and as a study investigator sponsored by Pfizer Inc., Astellas Pharma Inc., Johnson & Johnson, Sanofi Aventis, and Allergan Inc. John Heesakkers has no conflict of interest to declare. David Castro-Diaz has served as a study investigator sponsored by Pfizer Inc. Joseph Wang, marina Brodsky and Zhonghong Guan are employed by Pfizer Inc.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Hill, 2006[44] Darifenacin Study Group. Country: Not reported N: 439	Male and female patients, aged >18 years, with urge incontinence (>10 episodes over 14 days), high micturition frequency (mean of >8 eight voids per day), and urinary urgency (a strong desire to void on average at least once per day) for at least 6 months, regardless of previous antimuscarinic treatment.	Clinically significant stress incontinence, bladder outlet obstruction or a postvoid residual urinary volume >200 ml; local pathology that could cause urinary symptoms (e.g., interstitial cystitis, bladder stones, severe constipation (≤2 bowel movements per week), history of intermittent urinary tract infections; those who had undergone urogenital surgery within the previous 6 months, or cystoscopy in the previous 30 days; patients with indwelling catheter or using intermittent self-catheterization; presence of clinically significant systemic disease; patients who intended to start a bladder-training program during the study, or had contraindications to antimuscarinic therapy; pregnant and lactating women; no concomitant treatment with drugs (including drugs with significant anticholinergic effects), opioids, hormone replacement therapy (unless taken for >2 months), and drugs known to be significant inhibitors of cytochrome P450 2D6 or 3A4 isoenzymes (cimetidine, fluoxetine, ketoconazole, itraconazole, etc.).	Oral Darifenacin (Novartis Pharma AG, Basel, Switzerland) once-daily 7.5, 15, 30 mg	Placebo	The study was funded by Pfizer Inc.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Ho, 2010[306] Study: RCT L6 N: 75	1) male or female aged ≥18 years; 2) informed consent had been obtained; 3) the patient was willing and able to complete the micturition diary correctly; 4) the OAB symptoms, including urinary frequency, urgency, or urge incontinence, had persisted for ≥3 months; 5) the patient must have experienced frequency, defined as ≥8 micturitions per 24 hours	1) pregnant and lactating women or those who intended to become pregnant during the study; 2) clinically significant bladder outflow obstruction (such as men with benign prostatic hyperplasia or women with bladder outlet obstruction); 3) significant post-void residual (PVR) volume (>200mL); 4) genuine stress incontinence; 5) evidence of symptomatic urinary tract infection, chronic inflammation, bladder stones, previous pelvic radiation therapy, or previous or current malignant disease of the pelvic organs; 6) patients with any medical condition that contraindicated the use of antimuscarinic medication; 7) uncontrolled narrow angle glaucoma, urinary or gastric retention, or any other medical condition that, in opinion if the investigator, contraindicated the use of antimuscarinic	Solifenacin	Tolterodine	NR	NR

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Holtedahl, 2000[307] RCT analysis Norway N: 87	Women 50-74 years of age reporting two or more leakage episodes per month.	Reported previously	Oestriol and pelvic floor exercise (PFE) for all patients, plus bladder training and maximal electrical stimulation in patients with urge, vaginal long-term electrical stimulation in patients with stress, and all elements in patients with mixed incontinence.	Oestriol and pelvic floor exercise (PFE) for all patients, plus bladder training and maximal electrical stimulation in patients with urge, vaginal long-term electrical stimulation in patients with stress, and all elements in patients with mixed incontinence.	The Norwegian Medical Association Fund no. 1, Odd Berg Medical Research Fund, Finnmark County Research Fund, Medicon A/S, Organon A/S, Coloplast A/S, SABA Mo¨lnlycke A/S, and LIC Hygiene A/S.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Holtedahl, 1998[308] RCT Norway N: 90	Women, 50-74 years of age with regular incontinence (>2 leakage episodes per month) diagnosed during gynecological examinations, with positive pad test, or self reported in 48 hour chart.	Cardiac pacemaker, dementia, medical conditions that would prevent following the protocol.	Local estrogen in vagitories or jelly plus physiotherapy and electro-stimulation	Usual care	Financial and material (pads, estriol) support from The Norwegian Medical Association Fund no. 1, Odd Berg Medical Research Fund, Finnmark County Research Fund, Medicon A/S, Organon A/S, Coloplast A/S, SABA Mo¨ lnlycke A/S, LIC Hygiene A/S.	Not reported
Homma, 2006[309] RCT analysis Japan N: 637	Adult patients with OAB syndrome and having experienced urge incontinence one or more times a day on average with urinations eight or more times a day during the preceding week.	22 patients were excluded from FAS for the following reasons: (1) non-OAB patients (n =8), (2) not treated (n = 2), (3) no efficacy data after randomization (n =11), (4) duplicated enrollment (n =1).	Three sizes of oxybutynin transdermal patch (26, 39, and 52 cm2) were used	Placebo	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Homma, 2004[310] RCT Japan and Korea N: 293	Men and women aged ≥20 years were eligible for inclusion if they had symptoms of OAB for ≥6 months and urinary urgency, urinary frequency (≥8 micturitions/ 24 hours), urge incontinence (≥5 episodes/week) as assessed by micturition diaries during the wash-out/run-in period. Patients were recruited solely on the basis of their OAB symptoms, irrespective of whether they had received prior antimuscarinic treatment and irrespective of their response to such therapy.	Demonstrable stress incontinence, total daily urine volume >3 l, average volume voided/ micturition >200 ml, significant hepatic or renal disease, any contraindication for anticholinergic treatment (e.g., uncontrolled narrow-angled glaucoma, urinary retention, or gastric retention), symptomatic or recurrent urinary tract infection, interstitial cystitis, hematuria or bladder outlet obstruction, an indwelling catheter or intermittent self-catheterization, electro-stimulation or bladder training within 14 days before randomization or expected to commence during the study period.	Tolterodine ER 4 mg once daily	Oxybutynin 3 mg three times daily, placebo	Not reported	Not reported
Homma, 2003[311] Japanese and Korean Tolterodine Study Group Korea and Japan N: 608	Men and women aged >20 years with symptoms of urinary urgency, urinary frequency (> 8 voids/24 hours), urge incontinence (>5 episodes/ week) and symptoms of OAB for >6 months were eligible for inclusion. Patients were recruited based solely on their symptoms of OAB, irrespective of whether they had received previous antimuscarinic treatment and irrespective of their response to such therapy.	Demonstrable stress incontinence; total daily urine volume of >3 L; average volume voided/ void of >200 mL; significant hepatic or renal disease; any contraindication to anticholinergic treatment, e.g. uncontrolled narrow-angled glaucoma, urinary retention or gastric retention; symptomatic or recurrent UTI; interstitial cystitis; haematuria or BOO; an indwelling catheter or intermittent self-catheterization; and electro-stimulation or bladder training within 14 days before randomization or expected to commence during the study period; pregnant or nursing women and women of childbearing potential not using reliable contraception.	Tolterodine 4mg capsules once daily	Oxybutynin 3mg tablets three times daily, placebo	This study was supported by a grant from Pharmacia Corporation.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Hurley, 2006[312] Viktrup, 2007[313] Pooled The four studies were conducted at 186 sites in Africa, Australia, Europe, North America, and South America N: 2,188	1,913 women with SUI who participated in four controlled clinical trials of duloxetine vs. placebo. All had predominant SUI were enrolled using a clinical algorithm validated to be 90.2% predictive for urodynamic SUI.	Subjects who received lower doses of duloxetine (20 or 40 day, n = 275) in the phase 2 trial. Active substance abuse disorder within the 5 years prior to study entry. Regular consumption of 21 or more alcoholic drinks per week. Use of monoamine oxidase inhibitors (MAOIs) or antidepressants within 14 days prior to study entry. A current diagnosis of a voiding abnormality or significant diseases of the genito-urinary tract. A history of urogenital cancer. Symptomatic arrhythmia despite antiarrhythmic medication. Uncontrolled angina, or a significant abnormality on electrocardiogram (ECG) at screening. Any active cardiac ischemic condition, including myocardial infarction within 6 months prior to study entry. Uncontrolled or poorly controlled hypertension. An active seizure disorder. Unstable diabetes mellitus. A spinal cord lesion, multiple sclerosis, or neurological abnormality that affected the lower urinary tract. A history of severe allergies requiring emergency medical treatment or multiple adverse drug reactions. Active or chronic hepatitis A, B, or C.	Duloxetine (80 mg per day).All subjects were given the option to continue taking duloxetine in open-label extensions of these studies. Those randomized to duloxetine 80 mg per day in the phase 2 studies were dose escalated over the first 2 weeks from 20 mg twice daily for the first week to 30 mg twice daily for the second week before taking 40 mg twice daily. At the end of the active-treatment phase, subjects had their duloxetine dose tapered over 2 weeks (30 mg twice daily for the first week and 20 mg twice daily for the second week) before duloxetine was discontinued.	Placebo	This work was sponsored by Eli Lilly and Company and Boehringer Ingelheim.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Ishiko, 2001[314] RCT Japan N: 73	73 women with postmenopausal stress incontinence.	Urge or mixed incontinence	Combination of estriol (1 mg/day) and pelvic floor muscle exercise or Pelvic floor muscle exercise alone.	Pelvic floor muscle exercise	Not reported	Not reported
Jackson, 1999[315] RCT UK N: 67	Postmenopausal women with symptoms of urinary incontinence. If genuine stress incontinence was diagnosed, and the woman was more than 12 months post-menopausal and had not taken hormone replacement therapy in the previous 12 months, she was fully informed about her options for treatment as well as being offered recruitment to the clinical trial.	History of cancer of the endometrium, liver, or breast; endometrial thickness >4mm	Post oestradiol valerate 2mg/day	Placebo	Industry + grant	Not reported
Jacquetin, 2001[316] RCT Belgium and France N: 251	Male and female patients aged ≥18 years were eligible for inclusion in the study if they had urodynamically proven overactive bladder, and symptoms of urgency and/or urge incontinence (≥1 incontinence episode/24 hours) with increased frequency of micturition (≥8 micturitions/24 hours) irrespective of prior treatment or treatment failure.	Significant stress incontinence; hepatic or renal disease; symptomatic or recurrent urinary tract infection (UTI); interstitial cystitis; haematuria; clinically significant voiding difficulty; patients receiving bladder training, electro-stimulation therapy or having an indwelling catheter or on intermittent catheterization; pregnant or nursing women, or women of childbearing age who were not using reliable contraception.	Tolterodine 1 or 2mg twice daily	Placebo	Pharmacia Corporation	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Johnson, 2005[317] RCT analysis USA N: 131	To be included in the study, participants had to report at least two accidents per week and to demonstrate the ability to complete an interpretable bladder diary that confirmed this frequency of urine loss. Urge incontinence had to be the predominant pattern (urge accidents exceeded the number of stress and other accidents), with urodynamic evidence of bladder dysfunction. Two-channel supine water cystometry was performed to demonstrate detrusor instability (defined as urodynamic observation of involuntary detrusor contractions during the filling phase) or sensory urgency (defined as bladder capacity of less than 350 mL) for inclusion in the study.	Participants with continual leakage, elevated postvoid residual urine volume (4200 mL), narrow angle glaucoma, uterine prolapse past the vaginal introitus, unstable angina pectoris, decompensated congestive heart failure, or impaired mental status (MMSE score 20) were excluded.	Behavioral training, drug treatment (oxybutynin IR titrated from 2.5 mg per day to 5.0 mg three times a day)	Placebo	Supported by grant from the National Institute on Aging. Dr. Johnson received additional support from the Emory University Center for Health in Aging. The John A. Hartford Foundation Southeast Center of Excellence in Geriatric Medicine and the Birmingham/ Alabama VA GRECC provided infrastructural support that enabled this inter-institutional collaboration.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Jonas, 1997[318] The International Study Group Country: Not reported N: 242	Men or women >18 years and presenting with detrusor overactivity, defined as the existence of any phasic detrusor contraction with an amplitude of >10 cmH_20 or the existence of one strong detrusor contraction that caused the end of the infusion, with frequency (> 8 micturitions/24 hours) in combination with urge incontinence (>1 incontinence episode/24 hours), urinary urgency, or both.	Significant stress incontinence hepatic disease, defined as twice the upper limit of the reference range for liver function tests, renal disease, defined as twice the upper limit of the reference range for creatinine, any condition contraindicating anticholinergic therapy, recurrent urinary tract infections (UTIs), interstitial cystitis, uninvestigated hematuria, or clinically significant voiding difficulty with risk of urinary retention; any anticholinergic treatment; using an indwelling catheter, history of electro-stimulation therapy or bladder training (last 14 days prior to the inclusion visit).Concomitant treatment with anticholinergic drugs or treatment with any agent for urinary urge incontinence (with the exception of any estrogen treatment started at more than 2 months prior to entry) was not permitted in the 14 days prior to entry or during the study.	Tolterodine 1 or 2 mg b.i.d	Placebo	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Junemann, 2006[319] Study: RCT Sample: 988	Patients with overactive bladder who met all of the following inclusion criteria were allowed to participate in the study: female and male patients >=18 years, voluntarily signed informed consent, at least 2 incontinence episodes within 3 days, and at least 10 micturitions within 24h	Stress incontinence; intermittent catheterization; neurogenic detrusor under- and overactivity; postvoid residual urine >=100ml; acute urinary tract infections; electro stimulation therapy, bladder training if performed within 4 weeks before run-in period of this study; anomalies of the lower genitourinary tract (e.g.ectopic ureters, fistulas, urethral stenosis); pre-existing medical contraindications for anticholinergics (e.g. obstruction of the bowel, toxic megacolone, severe colitis ulcerosa, bladder or intestinal atony, significant degree of bladder outflow obstruction where urinary retention could be anticipated, pollakisuria of cardiac or renal genesis, tachyarrhythmia, narrow-angle glaucoma, myasthenia gravis); cardiac insufficiency(New York Heart Association stage III/IV); multiple sclerosis; evidence of severe renal, hepatic or metabolic disorders; history of drug or alcohol abuse; concomitant medications known to have a potential to interfere with the study medication; pregnant or breastfeeding women, or women of childbearing potential without using any reliable contraceptive method	Propiverine hydrochloride IR	Propiverine hydro-chloride ER and placebo	Funded by Apogepha Arzneimittel GmbH	NR

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Junemann, 2000[320] Study: RCT Sample: 234	Patients with urge - syndrome (motor urge, sensory urge and combined motor urge and stress incontinence). Patients medical history and a urodynamic measurement (minimum one unstable detrusor contraction of 10 cm H2O or first desire to void at a bladder filling of <150ml) verified the diagnosis of urge-syndrome	NR	trospium hydrochloride	tolterodine and placebo	NR	NR
Junemann, 2005[321] RCT 31 centers in Europe (Bosnia, Czech Republic, Germany, Poland, Slovenia, United Kingdom). N: 201	Men and women aged >18 years with overactive bladder, defined as at least one unstable detrusor contraction at a minimum of 10 cmH2O combined with an increased frequency of micturition (>8 micturitions/24 hours); sensoric urge incontinence, defined as at least one incontinence episode/24 hours combined with increased frequency of micturition (>8 micturitions/24 hours).	Maximum cystometric bladder capacity 300 ml; post void residual >50 ml; acute urinary tract infection (>106 bacteria/ml urine); electro-stimulation therapy, bladder training if performed <4 weeks before run-in period of this study; intermittent catheterization; anomalies of the lower genitourinary tract (e.g. ectopic ureters, fistulas, urethral stenosis, etc.); operations of the lower urinary tract within the last 4 weeks; pre-existing medical contraindication for anticholinergics.	15 mg propiverine twice daily	2mg tolterodine twice daily	APOGEPHA Arzneimittel GmbH.	Not reported
Kaplan, 2010[322] Study: RCT Sample: 2417	Subjects with OAB symptoms for >=months and recorded micturitions and >=1 urgency urinary incontinence episode per 24h in 3-day baseline diaries	NR	Fesoterodine	Tolterodine/ Placebo	Sponsored by Pfizer Inc.	NR

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Karademir, 2005[323] RCT Turkey N: 43	A total of 43 patients (5 males, 38 females; mean age 41.7 years; range 21-69 years) with a >6-month history of overactive bladder symptoms and who had detrusor overactivity findings on urodynamic studies (UDS).	Urinary tract obstruction, urinary retention, a neurologic or metabolic disorder; any kind of intervention for urinary incontinence.	Stoller afferent neurostimulation (SANS) with low-dose anticholinergic (oxybutynin hydrochloride)	Stoller afferent neurostimulation (SANS)	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Karram, 2009[324] Toglia, 2009[325] Study: VENUS Sample: 739	This study, that is, the VENUS study enrolled patients aged>=18 years with OAB (at least 1 urgency episode with or without incontinence and >=8 micturitions per 24 hours) for >=3 months	Presence of stress or stress-predominant mixed urinary incontinence, chronic inflammation or cystitis, and clinically significant bladder outlet obstruction	Solifenacin	Placebo	Research grant from Astellas Pharma US, Inc. and GlaxoSmithKline	Marc Toglia discloses conflict of interest with Astellas Pharma US, Inc. and Ethicon Women's Health. Scott R. Serels discloses conflicts of interest with Astellas Pharma US, Inc., GlaxoSmithKline, and Takeda. Mickey Karram discloses conflict of interest with Allergan, Astellas Pharma US, Inc., Cooper, and Ehticon. Indrani Nandy discloses conflict of interest with GlaxoSmithKline. Masakazu Andoh discloses no conflict of interest. Raafat Seifeldin discloses conflict of interest with AStellas Pharma US, Inc.Sergio Forero-Schwanhaeuser discloses conflict of interest with GlaxoSmithKline

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Kelleher, 2006[326] RCT USA N: 3032	Pooled analysis of 4 RCTs: men and women at least 18 years of age with either MUI or UUI based on their history and the results of a cough test; a mean of ≥8 micturitions per 24 hours in addition to a mean of ≥1 incontinence episode per 24 hours or a mean of ≥1 urgency episode per 24 hours during the baseline 3-day micturition diary period.	Predominant stress UI.	5 mg solifenacin once daily, 10 mg solifenacin once daily	Placebo	Not reported	Not reported
Kelleher, 2002[327] RCT USA N: 1015	Male and female patients aged 18 years or older with urinary frequency (average of ≥8 micturitions/24 hours over a 7-day period), urge incontinence (≥5 episodes/week), and symptoms of OAB for at least 6 months.	Other types of bladder dysfunction, with diseases that may have affected urinary output.	Tolterodine extended-release (ER) 4 mg once/day, or tolterodine immediate-release (IR) 2 mg twice daily	Placebo	Pharmacia Corporation	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Kelleher, 2008[328] Study: pooled analysis E4,X3 N: 1,971	Men and women aged ≥18 years with OAB syndrome for ≥6 months; patients had to report at least moderate problems related to their bladder condition on a six-point Likert scale	Presence of lower urinary tract pathology that could, in the investigator's opinion, be responsible for urgency or UI (e.g. significant stress UI, interstitial cystitis, urothelial tumors); pelvic organ prolapse grade ≥III; clinically relevant BOO; a post void residual urine volume of >100mL; polyuria (>3L/24h); symptomatic or recurrent UTI; current treatment with antimuscarinic agents; a neurogenic cause of OAB; clinically relevant arrhythmia, unstable angina, or a QTcB interval of >500ms; and current treatment, or treatment within the past 4 weeks, with electro stimulation or bladder training	Fesoterodine	Tolterodine/ Placebo	Funded by Schwarz BioSciences GmbH and Pfizer Inc	Con J.Kelleher is an Advisor to Astellas and Novartis and a Lecturer for Pfizer. Andrea Tubaro is a paid Consultant and study investigator funded by the sponsor. Joseph is an employee of the sponsor
Khullar, 2004[329] RCT UK N: 854	Women 18 years or older with urge-predominant mixed incontinence, including urge incontinence (five or more episodes per week), urinary frequency (eight or more micturitions on average in 24 hours), and urgency in combination with stress incontinence irrespective of the use of previous antimuscarinic treatment.	Pure stress urinary incontinence; predominant stress urinary incontinence; a total daily urine volume greater than 3 L; suspected or documented hepatic or renal dysfunction; symptomatic urinary tract infection; interstitial cystitis, uninvestigated hematuria, or clinically significant bladder obstruction; any contraindication to antimuscarinic treatment; and any nonsurgical treatment for incontinence within 4 weeks of the first study visit; treatment within 2 weeks before randomization with any drug for incontinence (except estrogen therapy started more than 2 months before the first visit); agonist or potent inhibitors of cytochrome P450 3A4 isoenzymes; pregnancy, lactation, or inadequate contraception.	Tolterodine tartrate extended-release (ER) 4 mg	Placebo	Pfizer Inc	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Khullar, 2008[330] Pooled USA N: 1674	Pooled analysis of two RCTs: men and women 18 years of age or older with OAB syndrome for 6 or more months; urinary frequency (8 or more micturitions per 24 hours) and urinary urgency (6 or more episodes during the 3-day diary period) or UUI (3 or more episodes during the 3-day diary period).	Presence of lower urinary tract pathology that could, in the investigator's opinion, be responsible for urgency or incontinence (for example, significant stress incontinence, urolithiasis, interstitial cystitis, urothelial tumors); pelvic organ prolapse grade III or higher; clinically relevant bladder outlet obstruction; postvoid residual urine volume greater than 100mL; polyuria (more than 3L/24 hours); symptomatic or recurrent urinary tract infections; current treatment with antimuscarinic agents; a neurogenic cause of OAB symptoms; clinically relevant arrhythmia, unstable angina, or a QTcB interval greater than 500 ms; current treatment, or treatment within the past 4 weeks, with electro-stimulation or bladder training during the past 4 weeks.	Fesoterodine 4 mg, or fesoterodine 8 mg	Placebo	Schwarz BioSciences GmbH and Pfizer Inc	Dr. Vik Khullar has been a consultant and investigator in clinical trials by Pfizer Inc. Drs. Eric Rovner and Roger Dmochowski have served as consultants and investigators on clinical trials sponsored by Pfizer Inc. Dr. Victor Nitti has been a consultant and lecturer sponsored by Pfizer Inc. Joseph Wang and Dr. Zhonghong Guan are employed by Pfizer Inc.
Kinchen, 2005[331] RCT Country: Not reported N: 451	Ambulatory women with symptoms of SUI 18 years of age or older, >1 episode per week of urinary incontinence due to activities such as coughing, sneezing, lifting, and exercising. Women had to have experienced stress symptoms for >3 months but may have predominant symptoms of urge incontinence	Pregnancy, breastfeeding, having an active urinary tract infection, participation in a previous trial of duloxetine, or having conditions such as arrhythmias, poorly controlled or uncontrolled hypertension, liver disease, seizure disorders, or an unstable cardiac condition.	Duloxetine (40 mg b.i.d.) but dose adjustment was allowed	Placebo	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Kreder, 2003[332] RCT analysis Country: Not reported N: 994	Age >18 years with OAB, diagnosed by a physician assessment based on self-reported symptoms with urinary frequency (>8 voids/24 hours) and either urgency or UI (>1 incontinence episode/24 hours).	Predominating stress UI; contraindications to antimuscarinic therapy; significant hepatic or renal disease; symptomatic UTI or history of recurrent UTI; haematuria or interstitial cystitis; significant voiding difficulty with risk of urinary retention; and bladder training, electro stimulation therapy, or having an indwelling catheter or an intermittent catheterization, women with reproductive potential; pregnancy or nursing; concomitant treatment for OAB (other than estrogen-replacement therapy started at least 2 months before study commencement) and use of anticholinergic agents.	Tolterodine 1 mg twice daily for 4 weeks, after which the dose could be increased to 2 mg twice daily (and subsequently reduced to 1 mg if necessary), based on the patient's response	None. Outcomes were compared among patients with urge UI vs. mixed UI	Pharmacia Corporation.	Not reported
Lackner, 2008[333] RCT USA N: 50	Nursing home resident for at least 3 months; aged ≥65; not residing in a subacute, transitional care, or rehabilitation unit of the nursing home; not enrolled in hospice; bladder incontinence (Minimum Data Set 2.0 score of 1–4); 12 no indwelling catheter; able to swallow medication intact and obtained permission from potential participants or their designated proxies for chart review by the NP; Mini-Mental State Examination score of 5–23; Global Deterioration Scale score of 3–6; ≥1 symptom or sign of urge	Terminal illness; bed-bound; non-communicative; delirium (Confusion Assessment Method feature 1 (acute onset) and 2 (inattention) plus feature 3 (disorganized thinking) or 4 (altered level of consciousness)); Lewy body dementia; history of ≥3 urinary tract infections in previous year or current infection; postvoid residual urine volume ≥150 mL (bladder ultrasound); urethral diverticulum; bladder tumor or stone; severe pelvic organ prolapse or vaginitis; genitourinary surgery within past 6 months; hepatic disease; severe cardiovascular disease; myasthenia gravis; spinal cord injury; bowel movement <every 3 days; history of gastrointestinal obstruction or decreased motility; current drug therapy for urinary incontinence; current use of acetylcholinesterase	Extended release oxybutynin 5mg once daily	Placebo	Funded by a research grant from Ortho-McNeil Pharmaceutical, Raritan, New Jersey. ALZA Corporation, Mountain View, California, supplied oxybutynin extended-release (Ditropan XL) 5-mg tablets and matching placebo tablets.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
	urinary incontinence (≥4 micturitions or wet checks or requests to toilet within an 8-hour period of prompted voiding schedule on 2 consecutive days (8:00 a.m. to 4:00 p.m.); nocturia or nocturnal enuresis 42 times per night; staff observation that incontinence occurs on way to toilet or resident reports urgency; or medical record documentation of detrusor overactivity or urgency); Medication adherence rate ≥80% during the week before screening.	inhibitor or bisphosphonate; investigational drug, systemic or ophthalmic cholinomimetic drug, diphenhydramine, or gastrointestinal antispasmodic within 2 weeks before trial.				
Landis, 2004[334] RCT 159 centers in North America, Europe and Australia/New Zealand. N: 1529	Men and women 18 years old or older with urinary frequency (8 micturitions or greater per 24 hours), urge incontinence (5 episodes or greater a week) and symptoms of overactive bladder for 6 months; severe incontinence defined as 21 episodes or greater per week at baseline irrespective of prior antimuscarinic treatment and response to such treatment.	Reported previously	4 mg tolterodine ER once daily	Placebo	Pharmacia Corporation, Peapack, New Jersey	J. Richard Landis has financial interest and/or other relationship with Alza Pharmaceuticals, Pharmacia and Bristol-Myers Squibb; Eboo Versi has financial interest and/or other relationship with Pharmacia.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Lee, 2002[335] RCT South Korea N: 228	Male and female subjects aged ≥18 years with symptoms of overactive bladder for ≥6 months were eligible for enrolment in the study. Symptoms, as measured by micturition diaries, were defined as urinary urgency and frequency (≥8 micturitions on average per 24 hours), with or without urge incontinence. Patients were enrolled exclusively on the basis of symptoms (i.e. urodynamics was not performed), irrespective of whether they had received prior antimuscarinic therapy.	(i) significant stress incontinence; (ii) women of childbearing age who were not using reliable contraception; (iii) pregnant or nursing women; (iv) treatment with any drug with known anticholinergic side-effects in the in the 2 weeks prior to the study; (v) significant renal or hepatic disease; (vi) any contraindication to antimuscarinic therapy (e.g. narrow-angle glaucoma, urinary or gastric retention, known hypersensitivity to tolterodine or oxybutynin); (vii) symptomatic acute or recurrent urinary tract infection; (viii) interstitial cystitis or hematuria; (ix) bladder outlet obstruction; and (x) patients receiving bladder training, electro-stimulation therapy or having an indwelling catheter or on intermittent catheterization.	Tolterodine 2mg bid	Oxybutynin 5mg bid	Grant from Pharmacia	Not reported
Lee, 2010[336] Study: Propiverine study on overactive bladder including urgency data N: 264	Men and women ages ≥18 years who had self-reported symptoms of OAB for ≥3months; average urinary frequency of ≥10 voids/24h and urgency of two or more episodes/24h defined as 'moderate to severe' in the Indevus Urgency Severity Scale(IUSS) during the 3-day voiding diary period before randomization	Clinically significant stress urinary incontinence (more than one episode per week); genitourinary conditions that could cause OAB symptoms, such as UTI; and contraindications to the use of antimuscarinic drugs	Propiverine hydrochloride 60 mg/d	Placebo	Sponsored by Jeil Pharmaceutical Co. Ltd., Seoul, Korea	NR

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Lehtoranta, 2002[337] RCT Finland N: 9	Female or male patients aged 18–75 years were recruited to the study. They had to have a history of urgency or urge incontinence and cystometrically proven detrusor hyperreflexia or instability according to the ICS criteria (International Continence Society).	Stress incontinence and pure nocturnal enuresis were excluded.	OXYBUTYNIN 5mg/30ml three times daily	PLACEBO 30ml of sterile saline	Not reported	Not reported
Leung, 2002[338] RCT Hong Kong Chinese N: 106	(i) age ≥18 years; (ii) a diagnosis of overactive bladder confirmed by urodynamic test (phasic detrusor contraction with an amplitude ≥15cmH_2O) in accordance with ICS criteria; (iii) urinary frequency (an average of ≥8 voids/24 hours), urgency or urge incontinence (an average of ≥1 incontinence episode/24 hours); and (iv) willing to give written informed consent.	(i) a diagnosis of genuine stress incontinence; (ii) clinically significant voiding difficulty (maximum flow rate <10 mL/s with a residual volume of >200 mL); (iii) recurrent or acute UTIs; (iv) require intermittent catheterization or an indwelling catheter; (v) uninvestigated haematuria or bladder cancer; (vi) currently on treatment for an overactive bladder or on anticholinergic medications; (vii) presence of psychiatric disease or cognitive impairment, as shown by their history or an abnormal Mini Mental State Examination; (viii) clinically significant cardiac, hepatic, renal or hematological disorders, as shown by their history; (ix) the presence of contraindications for antimuscarinic agents; (x) pregnant or lactating women and women of childbearing age who were not using reliable contraception.	Tolterodine 2mg twice daily	Oxybutynin 5mg twice daily	Financial Assistance from Pharmacia Limited	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Lin, 2008[339] RCT Taiwan N: 121	Non-pregnant women 20 years of age and older with predominant symptoms of SUI during the last 3 months with an average of ≥1 incontinent episode/day, positive cough stress test after filling the bladder, daytime voiding frequency ≤8 voids daily, nocturnal frequency ≤ 2 voids daily and no predominant urge incontinence symptoms.	Inability to tolerate retrograde bladder filling to 400 mL or who had a first sensation of bladder filling at ≤100 mL. Concomitant medications including urinary continence promoting drugs, antidepressants, drugs for obesity (including over the counter appetite suppressants and diet pills), and illicit drugs.	80 mg duloxetine (40 mg twice daily)	Placebo	This study was supported by Eli Lilly and Company and Boehringer Ingelheim.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Lipton, 2005[340] RCT Country: Not reported N: 129	Male and female volunteers 65 years or older with a score of 10 or less on the Short Orientation Memory and Concentration Test,12 which is a short version of the Blessed Information-Memory Concentration (no clinical dementia).	A diagnosis of clinical dementia, depression or any other medical, psychological or social condition that would impair participation in the study, clinically significant or unstable hematological, renal, hepatic or cardiac disease, or the use of cimetidine, psychotropic drugs, anticholinergic drugs, antihistamines or other drugs known to affect cognitive function; severe drug allergy or contraindications to antimuscarinic therapy (e.g., narrow angle glaucoma, significant urinary outflow obstruction or obstructive bowel disease); treatment with another investigational drug within the previous 3 months.	Darifenacin controlled release (3.75, 7.5 or 15 mg once daily), darifenacin immediate-release (5 mg 3 times daily)	Placebo	Supported by Pfizer, Inc. and an educational grant from Novartis Pharma AG.	Not reported
Lose, 2000[341] RCT Denmark N: 254	251 women reporting at least one bothersome lower urinary tract symptom after spontaneous or surgical post menopause.	Known or suspected estrogen-dependent neoplasia or mammary, ovarian (endometroid) or corpus uteri malignancies, vaginal bleeding, clinically significant liver diseases, acute or intermittent porphyria, uterovaginal prolapse II-III, sex hormone treatment within the last 6 months, vaginal irritation other than atrophy derived or signs of vaginal ulceration; participation in clinical trials within last 3 months prior to inclusion.	1. Oestradiol-releasing ring, 7.5mg oestradiol.	Oestriol pessaries 0.5 mg every second day	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
MacDiarmid, 2005[342] Pooled USA N: 420	Men and women with UUI or mixed incontinence with a predominating urge component; with at least 6 (studies 1 and 3) or 7 (study 2) UUI episodes weekly when unmedicated; with known response to oxybutynin in study 1 or to anticholinergic medications in study 2.	Reported previously	ER oxybutynin was then initiated at 5 mg daily and adjusted in 5 mg increments at intervals of approximately 1 week until continence achieved	None	Grant from ortho-McNeil Pharmaceutical, Inc.	Not reported
Madersbacher, 1999[343] RCT USA N: 366	History of urgency or urge incontinence, a maximum cystometric bladder capacity of ≤300 ml, age ≥18years and body weight ≥45kg.	Detrusor hyperreflexia, postoperative (bladder) incontinence, intravesical obstruction, a postvoid residual urine (PVR) of >15% of the maximal cystometric bladder capacity, acute UTIs, angina pectoris, glaucoma, megacolon, clinically relevant cardiac, renal or hepatic dysfunctions, tachy/dysrhythmias, frequency or nocturia due to heart or renal insufficiency, or overt cerebral sclerosis.	Propiverine 15mg three times a day	Oxybutynin 5mg twice a day, placebo three times a day	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Malhotra, 2010[344] Study: RCT Sample: 261	Healthy subjects aged 45-65 years with a body mass index between 19 and 32kg/m2(inclusive); had no clinically relevant abnormal findings on the physical examination, ECG, blood pressure, pulse rate, medical history, or clinical laboratory results at the eligibility assessment visit and were characterized as extensive metabolizers for CYP2D6	Medical history of any serious disease of the internal organs or of the central nervous system; a history or presence of urinary retention, obstructive disturbance of bladder emptying, micturition disturbance, nocturia, or pollakiuria, for example, prostatic hyperplasia, or urethral stricture; a history of ischemic heart disease or a positive diagnostic cardiac stress test within 12 weeks before the start of the trial; a supine systolic blood pressure of<100mg or>160mmHg or a supine diastolic blood pressure of >95mmHg; a supine pulse rate of <50bpm or >100bpm; and any clinically relevant changes in ECG such as second-or third-degree AV block, or prolongation of the QRS interval to >110ms, the PR interval to >240ms, or QTc(Bazett's correction, machine read) to >480ms	fesoterodine 4mg/28mg	Placebo/Moxifloxacin	Funded bySchwarz BioSciences GmbH and Pifizer Inc.	Bimal Malhotra and Kuan Gandelman are employees of Pfizer Inc., New York, NY, USA.Nolan Wood was an employee of Pfizer Inc., Sandwich, Kent, and UK at the time the study was conducted. Richard Sachse is an employee of Schwarz BioSciences, Monheim, Germany
Malone-Lee, 2009[345] RCT UK N: 307	Male and female subjects aged ≥18 years with urinary frequency (defined as an average of ≥8 voids/24 hours, measured over a 7-day period) and urgency (with or without UUI), symptoms of OAB for ≥6 months before randomization, with no significant stress UI and adequate contraception.	Mean volume voided of >300 mL/void or a mean total volume of urine >3000 mL/24 hours; significant hepatic or renal disease, symptomatic UTI, diagnosed interstitial cystitis, un-investigated hematuria, or clinically significant BOO; anticholinergic drugs or other treatments for OAB in the 14 days before randomization; known hypersensitivity to tolterodine-ER or any of its recipients; oral cytochrome P450 3A4 inhibitors (e.g. macrolide antibiotics), and electro-stimulation or bladder retraining in the 3 months before randomization.	Tolterodine-ER (4 mg capsule od)	Placebo	Pharmacia (now Pfizer Ltd)	James Malone-Lee has received travel expenses for attending professional conferences from Pharmacia & Upjohn and Pfizer Inc, and has served as a consultant and received research funds from Pfizer Inc.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Malone-Lee, 2001[346] RCT United Kingdom, France, and the Republic of Ireland N: 177	Older men and women (age ≥65 years) with symptoms of urinary urgency, increased frequency of micturition (≥8 micturitions/24 hours), and/or urge incontinence (≥1 episode/24 hours).	Significant stress incontinence, urinary outflow obstruction, urinary retention (as determined by palpation after voiding), symptomatic urinary infection, interstitial cystitis, unexplained hematuria, use of urinary catheterization or electro-stimulation, hepatic and renal disease with biochemical markers twice the upper limit of the normal reference range, concomitant antimuscarinic medication, previous treatment with tolterodine, and exposure to any other investigational drug in the preceding 2 months.	Tolterodine 1 mg or 2 mg twice daily	Placebo	Pharmacia & Upjohn AB	Not reported
Mattiasson, 2009[65] U.S. Food and Drug Administration, [64] Study: SOLAR Sample: 643	Men or women aged >=18 years with OAB symptoms were eligible if they gave written informed consent, were capable of completing a simplified bladder training regimen correctly, and were willing and able to complete a voiding diary correctly	Patients should not have received non-drug treatment for OAB, including electro stimulation therapy and pelvic floor exercises, in the 4 weeks before starting the study, or during the study except for those randomized to receive bladder training instructions. Patients were also excluded if they had received cognitive bladder training in the previous 6 months, or if they intended to commence bladder training other than the study regimen during the study.	Simplified Bladder training + Solifenacin	solifenacin 5mg or 10mg	Research Grant from Astellas Pharma Europe Ltd.	Anders Mattiason: Astellas, Ferring: Pfizer; Alberto Masala: Astellas, Angelini Group; Richard Morton and John Bolodeoku:employees of Astellas

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Mattiasson, 2003[347] Study: RCT Tolterodine Scandinavian Study Group N: 501	Men and women aged ≥18 years with symptoms of urinary frequency (≥8 micturitions/24h on average) and urgency (a strong and sudden desire to urinate), with or with no urge incontinence. Women of child-bearing potential were required to be using a reliable birth control method to enter the study	Any contraindication to antimuscarinic therapy; use of electro stimulation therapy or behavioral therapy within the previous 3 months; patients with an indwelling catheter or on intermittent catheterization; pregnancy and lactation; and use of anticholinerigc agents or concomitant treatment for an overactive bladder (other than estrogen replacement therapy started at least 2 months before study commencement)	Tolterodine + Simplified Bladder training	Tolterodine	Supported by Pharmacia Corporation	NR
Milani, 1993[348] RCT Milan N: 50	Women over 18 years of age with motor or sensory urgency	Severe illness, overt neurological diseases, acute or chronic urinary tract infections or obstructive diseases, pregnancy, taking concomitant medication which could affect urinary symptoms, continence or bladder function.	Flavoxate was 1 200 mg (400 mg t.i.d.)	Oxybutynin 15 mg (5 mg t.i.d.)	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Millard, 1999[349] RCT Sweden N: 316	Male and female patients 18 years old or older with cystometrically proved detrusor overactivity (idiopathic instability or detrusor hyperreflexia, or uninhibited phasic detrusor contractions with an amplitude of 10 cm. water or greater) and average urinary frequency of 8 or more voids per 24 hours; urge incontinence (an average of 1 or more incontinence episodes per 24 hours on the frequency volume chart) and/or urinary urgency.	Inadequate contraception; demonstrable stress incontinence (fluid escaping from the external urethral orifice during coughing when the bladder was stable), clinically significant voiding difficulty (maximum flow rate less than 10 ml. per second with post-void residual volume greater than 200 ml.), proved recurrent urinary tract infection, interstitial cystitis, uninvestigated hematuria or any bladder cancer; catheterization, indwelling catheterization , hepatic or renal disease, or narrow angle glaucoma, electro-stimulation therapy or bladder training, any primarily anticholinergic drug initiated 14 days before or at any time during the study, an unstable dose of any treatment with anticholinergic side effects; average total voided volume of greater than 3,000 ml/24 hours, or treatment with any investigational drug during or 2 months before the study.	1 or 2 mg. tolterodine twice daily	Placebo	Pharmacia and Upjohn AB	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Millard, 2004[350] Duloxetine UI Study Group Country: Not reported N: 458	Duloxetine UI Study Group: Women aged ≥18 years with a clinical diagnosis of troublesome SUI of at least 3 months' duration with the predominant symptom of SUI with ≥7 incontinent episodes per week. An 'episode' was defined as an easily noticed leakage of urine that wet a pad or clothing and occurred with a physical stress such as coughing, sneezing or exercising. Patients also needed to report a diurnal frequency of <9 per day, nocturnal frequency of and the absence of predominant symptoms of urge incontinence. In addition, objective testing was used to confirm normal bladder capacity and the sign of SUI. With the patient supine the bladder was filled with saline at 100 mL/min with no pressure measurements; positive cough-stress test (visualization of urine leakage concurrent with a cough) and a positive stress pad test (leakage of >2.0 g) (clinical algorithm has a sensitivity of 92% for urodynamic stress incontinence).	Inability to tolerate filling to 400 mL were excluded, as were those who experienced a first sensation of bladder filling at <100 mL, or who had no sensation at any time during the filling.	Duloxetine 40 mg twice daily	Placebo	Sponsored by Eli Lilly and Company and Boehringer Ingelheim.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Moore, 1990[351] Study: RCT Sample: 53	Patients with involuntary detrusor contractions >30cm H2O during the filling phase of cystometry	Those with neurological and other urological disorders; patients with coexistent genuine stress incontinence, low compliance bladder, bacterial or interstitial cystitis, age greater than 75 years or previous treatment with oxybutynin	oxybutynin hydrochloride	Placebo	Tillots Laboratories provided oxybutynin and placebo tablets	NR
Naglie, 2002[352] RCT USA N: 86	Men and women 65 years or older with a history, physical exam and urodynamic findings consistent with urge incontinence, and at least 4 documented episodes of urinary incontinence on a 5-day voiding record.	An indwelling or condom catheter, or intermittent catheterization; a clinical history of stress urinary incontinence; a history of >2 urinary tract infections per year; insulin dependent diabetes; spinal cord pathology; symptomatic orthostatic hypotension, congestive heart failure or ventricular arrhythmia; taking any calcium channel blocker; cognitive impairment; evidence of prostate or bladder cancer; cystoscopic or urodynamic evidence of outlet obstruction; post-void residual urine volume >100 cc or >trivial urinary leakage occurring with coughing/straining in the sitting or standing position; unable to complete a 5-day voiding record during the run-in period.	30 mg. nimodipine twice daily	Placebo	Research grant from the Physicians' Services Incorporated	Not reported
NCT00269750[57] Study: RCT N: 105	Men and women, age 40 to 75, with urge or mixed UI provided that stress UI was not the predominant manifestation of mixed UI. Patients who were currently taking immediate-release oxybutynin (Ditropan), hyoscyamine (Levsin Cystospaz), or propantheline (Pro-Banthine), or who had taken Ditropan® in the	NR	oxybutynin chloride	oxybutynin chloride IR	Alza Corporation	NR

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
	past for urge or mixed UI. Patients who had taken and discontinued Ditropan® for urge or mixed UI should not have discontinued due to failure of efficacy; patients who had at least six urge UI episodes per week recorded on the Run-in Diary after washout of anticholinergic medications. Patients who were able to differentiate incontinent episodes associated with urgency from incontinent episodes not associated with urgency when recording incontinent episodes in the diary. The Run-in Diary after washout of all anticholinergic medications must have demonstrated that the number of urge incontinent episodes per week was greater than the number of incontinent episodes not associated with urgency per week.					

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
NCT00168454[55] Study: RCT N: 313	Must be between 18-85 years old; must have been diagnosed by his/her doctor with overactive bladder at least 6 months ago; must weigh at least 50 kg (110 lbs); must be willing and able to record information regarding bladder function into a diary (provided); and must be willing and able to complete the entire course of the study	Cannot currently be catheterizing as a way to control incontinence and must not have used botulinum toxin type A or any other botulinum toxin previously for any condition	Botulinum toxin Type A	Placebo	Sponsored by Allergan, Inc.	Principal Investigators are not employed by the organization sponsoring the study.
NCT00444925[58] Study: RCT N: 1712	Adult overactive bladder (OAB) patients who present with OAB symptoms, including urinary frequency ≥ 8 per day and urgency urinary incontinence ≥1 per day	Patients with conditions that would contraindicate for fesoterodine use, e.g, hypersensitivity to the active substance (fesoterodine) or to peanut or soya, urinary retention, and gastric retention; patients with significant hepatic and renal disease or other significant unstable diseases; and OAB symptoms caused by neurological conditions, known pathologies of urinary tract, etc.	Fesoterodine	Tolterodine/ Placebo	Sponsored by Pfizer Inc.	Principal Investigators are not employed by the organization sponsoring the study.
NCT00536484[59] Study: RCT N: 883	Adults 18 Years and older; # Overactive bladder symptoms for greater than or equal to 3 months; # Mean urinary frequency of greater than or equal to 8 micturitions per 24 hours in bladder diary; and Mean number of Urgency episodes greater than or equal to 3 per 24 hours in bladder diary.	Known etiology of OAB (e.g., neurogenic, local urinary tract pathology); Previous history of acute urinary retention requiring catheterization or severe voiding difficulties in the judgment of the investigator, prior to baseline; and Unable to follow the study procedures, including completion of self-administered bladder diary and patient reported outcome questionnaires.	Fesoterodine	Placebo	Sponsored by Pfizer Inc.	Principal Investigators are not employed by the organization sponsoring the study.
NCT00178191[56] Study: RCT N: 28	Adults 21 Years and older; subjects must have completed a routine	Children (< 21 years old), pregnant women and prisoners; History of carcinoma of the bladder; # Absence	Botulinum toxin Type A	Placebo	Sponsored by University of Rochester,	Principal Investigators are not employed by the organization

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
	evaluation of incontinence (urodynamics, bladder diaries, and pad weights) through the urogynecology clinic at SMH within 3 months of the screening visit; symptoms of urge incontinence associated with leakage on bladder diary; 24-hour pad weight >100 cc's (volume requiring multiple daily diaper changes); absence of a bladder infection or other condition that could explain urinary leakage; Absence of stress incontinence or a cough leak point pressure > 100 cm H2O on cystometry (this correlates with mild stress incontinence); failed anticholinergic therapy; willingness and ability to perform intermittent clean catheterization (due to the risk of prolonged urinary retention from Botox); the ability and willingness to return for surveillance evaluations; a negative urine pregnancy test if at risk for pregnancy; and competent to give signed consent and complete all of the study measures.	of a measurable detrusor contraction on a pressure flow micturition study; A foreign body in the bladder or other correctable etiology for the UUI; Prior documented resistance to Botox; Gross fecal incontinence (due to confounding effects on pad weights and counts); Known allergy to lidocaine or related compounds (used for local analgesia); Known allergy to or inability to take both Bactrim DS or Ciprofloxacin (used for urinary tract infection prophylaxis); Current use of an aminoglycoside or preparing for general anesthesia within 1 week (risk of synergetic effects); and known neurologic conditions such as Parkinson's disease, myasthenia gravis, multiple sclerosis, autonomic dysfunction, Lambert-Eaton syndrome, Amyotrophic Lateral Sclerosis or other neurologic disorder that may impact urinary function or the effect of Botox.			New York, USA	sponsoring the study.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Nitti, 2007[353] RCT USA N: 836	Men and women 18 years or older with OAB syndrome for 6 months or greater, including urinary frequency (8 micturitions or greater per 24 hours) and urinary urgency (6 episodes or greater during the 3-day diary period) or UUI (3 episodes or greater during the 3-day diary period).The amended inclusion criterion required 3 or greater UUI episodes in 3-day diary; at least moderate bladder problems on a Likert scale that was almost identical to the patient perception of bladder condition.	Positive pregnancy test and non adequate contraception throughout the trial; lower urinary tract pathology that could in the opinion of the investigator be responsible for urgency or incontinence, such as significant stress incontinence, urolithiasis, interstitial cystitis or urothelial tumors; pelvic organ prolapse grade III or greater; clinically relevant bladder outlet obstruction; PVR volume greater than 100 ml; polyuria (greater than 3 l/24 hours); symptomatic or recurrent urinary tract infections; current treatment with antimuscarinic agents; a neurogenic cause of OAB; clinically relevant arrhythmia, unstable angina or a corrected QT interval (Bazett's formula) of greater than 500 milliseconds; or current treatment or treatment within the last 4 weeks with electro-stimulation or bladder training.	4 mg fesoterodine or 8 mg fesoterodine once daily	Placebo	Not reported	Not reported
Norton, 1994[354] RCT USA N: 93	Women 18-86 years old with at least 4 episodes of urge UI/week, detrusor instability, negative urine culture, and post-void residual volume <100ml.	Stress UI, contraindication to terodiline, concomitant use of medications affecting bladder function (diuretics, calcium antagonists), pregnancy, neurologic disease, abnormal biochemical profiles.	Terodiline, 25 mg twice daily	Placebo	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Norton, 2002[355] Sahai, 2006[356] Duloxetine Urinary Incontinence Study Group. USA N: 553	Women aged 18 to 65 years with a predominant symptom of stress urinary incontinence for at least 3 months with ≥4 incontinent episodes per week (easily noticeable leakage of urine that wets a pad or clothing and occurs with a physical stress such as coughing, sneezing, or exercising); urinary diurnal frequency ≤7 per day, nocturnal frequency ≤2 per day; both a positive cough stress test (CST, visualization of urine leakage concurrent with a cough) and SPT (leakage of >2.0 g).	Predominant symptoms of enuresis or urge incontinence, and no previous continence or prolapse surgical procedure, inability to tolerate the filling, who had a first sensation of bladder filling at <100 mL, or who had no sensation at any time during the filling.	Duloxetine at one of three doses (20 mg/d, n = 138 women; 40 mg/d, n = 137 women; or 80 mg/d, n = 140 women)	Placebo	Supported by Eli Lilly and Company.	Not reported
, 1993[357] the Elderly American Multicenter Study Group USA N: 98	Terodiline in the Elderly American Multicenter Study Group: women, age 60 or older, with symptoms of urge incontinence and self-reported frequency of incontinence >4/week and detrusor instability with involuntary bladder contractions on dual-channel water cystometry; non predominant stress UI.	Predominant stress UI; Mini Mental State score <26, clinically significant urologic, gynecologic diseases, or neurologic diseases, potentially reversible causes of UI; contraindication for anticholinergic medication (glaucoma, inflammatory bowel disease, unstable cardiovascular condition)	Terodiline 25mg twice/day	Placebo	Forest Laboratories	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Ozdedeli, 2010[358] Study: RCT Sample: 35	35 female patients who presented to the University Departments of Urology and Physical Medicine and Rehabilitation for urge incontinence and had overactive bladder or mixed incontinence with predominantly overactive bladder symptoms	History of pelvic surgery, a neurological deficit or peripheral neuropathy that may cause neurogenic bladder, presence of a medical condition that may preclude anticholinergic drug use, pregnancy or suspicion of pregnancy, cardiac pacemaker, genitourinary infection or hemorrhage, deterioration in cognitive or intellectual functions, anatomical abnormality that hinders the use of vaginal probe, and post-voiding residual volume >100mL	trospium hydrochloride	electrical stimulation	Not reported	Not reported
Peters, 2009[359] MacDiarmid, 2010[360]The Overactive Bladder Innovative Therapy USA N: 100	The Overactive Bladder Innovative Therapy trial : ambulatory men and women with OAB symptoms, with or without a history of previous anticholinergic drug use, with at least 8 voids per 24 hours	OAB pharmacotherapy within the previous month, primary complaint of stress urinary incontinence, demonstrated sensitivity to tolterodine or its ingredients, pacemakers or implantable defibrillators, excessive bleeding, urinary or gastric retention, nerve damage or neuropathy, uncontrolled narrow angle glaucoma, positive urinalysis for infection or pregnancy, or current pregnancy or planning to become pregnant during the trial.	Weekly percutaneous 30-minute tibial nerve stimulation	4 mg daily extended-release tolterodine with a subsequent decrease to 2 mg daily if intolerability was experienced	Supported by Uroplasty Inc.	Kenneth Peters has financial interest and/or relationship with Medtronic Inc., Advanced Bionics, Boston Scientific, Allergean, Pfizer, Celegene and Trillium Therapeutics; Scott MacDiarmid has financial interest and/or other relationship with Watson, Pfizer, Astellas, Allergan, Novartis and Uroplasty; Leslie S. Wooldridge has financial and /or relationship with Astellas, Uroplasty and Watson; Eric Rovner has financial and/or relationship with Novartis, Astellas, Allergan, Contura, Solace, Tengion and Pfizer; Steven Siegel has financial and/or

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
						relationship with Medtronic, American Medical Systems, Uroplasty, Uromedica, North Central Section of the American Urological Association, and Society for Urodynamics and Female Urology; Susan B. Tate has financial and/or relationship with C.R. Bard; Peter Rosenblatt has financial and/or relationship with Pfizer; Brian A. Feagins has financial and/or relationship with Medtronic, American Medical Systems, Novartis, Astellas, Uroplasty and Boston Scientific.
Pontari, 2010[361] Study: RCT Sample: 20	Female gender, age 18 years or older, with symptoms of urinary frequency of at least 8 voids per day for at least 6 months	Stress incontinence, total daily volume greater than 3 L, significant hepatic or renal disease, symptomatic or recurrent urinary tract infections, concomitant sacral neurostimulation therapy, claustrophobia with magnetic resonance imaging, bladder outlet obstruction, self-catheterization, post-void residual volume greater than 100 ml, women who pregnant or nursing, or women of child bearing potential not using reliable contraceptive methods, or any neurological condition which may contribute to bladder dysfunction such as multiple sclerosis.	tolterodine	placebo	Supported by an educational grant form Pfizer	Michel Pontari has financial interest and/or relationship with Pfizer, Sanofi and Endo Pharmaceuticals

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Rentzhog, 1998[362] Study: RCT Sample: 81	Men and women aged 18-75 years; presence of symptoms of urinary urgency, increased frequency of micturition (at least 8 micturitions per 24 hours) and/or urge incontinence (at least one episode of incontinence per 24 hours) during a 1-week pre-study run-in period. All eligible patients should have had urodynamically confirmed detrusor instability (defined as a phasic increase in detrusor pressure in the presence of typical symptoms) and a maximum urinary flow rate (Q max)of >=15mL/s (patients with a lower Qmax were eligible for inclusion provided there was no evidence of clinically significant bladder outlet obstruction), either sterile urine or clinically insignificant bacteriuria, and normal routine laboratory tests	Stress incontinence or detrusor hyperreflexia; clinically significant cardiac, hepatic, renal or hematological disorders; patients with contraindications to antimuscarinic agents; and pregnant or lactating women and women of childbearing age who were not using reliable contraception.	tolterodine	Placebo	Pharmacia and Upjohn AB, Uppsala. Sweden	NR
Richter, 2010[363] Study: ATLAS Sample: 446	Women at least 18 years old with symptoms of stress only or stress-predominant mixed-incontinence symptoms.	NR	behavioral therapy	pessary or pessary+behavioral therapy	Grants from the Eunice Kennedy Shriver National Institute of Child Health and Human Development; National	Dr.Burgio is a consultant for Pfizer (New York) and on the advisory board for Astellas (Deerfield, IL). Dr. Brubaker is a Research Consultant for Pfizer (New York, NY) and a Research Investigator for

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
					Institute of Diabetes and Digestive and Kidney Diseases, and National Institutes of Health Office of Research on Women's Health	Allergan (Irvine, CA). Dr.Zyczynski has performed contract research for Johnson and Johnson (New Brunswick, NJ). Dr. Lukacz is a consultant for Pfizer (New York, NY), Medtronic (Minneapolis, MN) and Watson Pharmaceuticals (Corona, CA). She has served on the speaker's bureau for Novartis (Basel, Switzerland) and Proctor and Gamble (Cinncinati, Ohio). She has been a consultant and proctor for Intuitive Surgical Corporation (Sunnyvale, CA), and she has been an editor First Consult. Dr.Schaffer is on the Speaker's bureau and National Advisory Board of Astellas/ GlaxoSmithKline (Deerfield, IL; Philadelphia, PA) and on the Specialty Surgeons Advisory Board of Cadence Pharmaceuticals (San Diego, CA)

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Rios, 2007[364]RCT USA N: 58	Women clinically diagnosed with urgency incontinence and proven urodynamic DO for at least 6 months prior to the study	The use of anticholinergics or tricyclic antidepressants in the last 2 months, neurologic conditions, urinary tract infection, pelvic prolapses (greater than grade 2), history of pelvic radiation or bladder tumor, poor bladder wall compliance, and detrusor underactivity.	Single intravesical dose of 100 ml of resiniferatoxin 50 nM	Single intravesical dose of 100 ml placebo	Departments of Urology of the Federal University of Saõ Paulo, Paulista School of Medicine and Hospital do Servidor Pu´blico Estadual de Saõ Paulo.	Not reported
Robinson, 2007[365] Study: The Tamsulosin Study Group Sample: 364	Women aged 18-75 years with symptoms of OAB (urinary urgency and frequency, with or without urge incontinence) for >=3 months; patients must have recorded a mean of at least eight voids/24h in the previous 3 days and one or more of the following during the 3-day period)at least 3 episodes of urinary urge incontinence; or ii) at least three episodes of urgency	Stress incontinence or mixed incontinence where stress symptoms were predominant and women with neurogenic DOA	tolterodine	Placebo	Funded by Astellas	Gerben Terpstra and John Bolodeoku are both employees of the sponsor
Rogers, 2009[366] Rogers, 2008[367] Study: C Sample: 413	Women ≥18 years with OAB symptoms for>=3 months; mean of >=8 micturitions per 24 hours, including ≥0.6 UUI episodes and ≥3 OAB micturitions (i.e. micturitions associated with at least a moderate degree of urgency), in a 5-day bladder diary at baseline; subjects also	One subject in the tolterodine group with an extreme increase in the number of UUI episodes per 24 hours from baseline to week 12 was identified as an influential outlier and was excluded from all efficacy analyses	tolterodine-ER	Placebo	Funded by Pfizer Inc.	Zhanna Jumadilova, Franklin Sun, Jon Morrow and Zhonghong Guan have disclosed that they are employed by Pfizer Inc. Rebecca Rogers has disclosed that she received speaker honoraria and research funding support from Pfizer

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
	reported being in a stable, sexually active relationship (self-defined) for ≥6 months and having at least some moderate problems related to their bladder condition on the Patient Perception of Bladder Condition. Heterosexual.					Inc., and has served a consultant for Pfizer Inc. She has also disclosed that she serves on the advisory board for American Medical Systems. Gloria Bachmann has disclosed that she has served as a consultant and received research funding support from Astellas Pharma Inc., Wyeth, and other pharmaceutical companies. Harriett Scraper has disclosed that she has received speaker honoraria from Pfizer Inc., Astellas Pharma, Inc., and Watson Inc. All peer reviewers receive honoraria from CMRO for their review work. Peer reviewer 1 has disclosed that he/she is on the speakers' bureau of Watson Pharmaceuticals. Reviewer 2 has no relevant financial relationships

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Rogers, 2009[368] RCT USA N: 202	Sexually active women (≥18 years) reported OAB symptoms for ≥3 months, mean of ≥8 micturitions per 24 hour, including ≥0.6 UUI episodes and ≥3 OAB micturitions (i.e., micturitions associated with at least a moderate degree of urgency), in 5-day bladder diaries at baseline; reported being in a stable sexually active relationship (self-defined) with a male partner for ≥6 months; and indicated at least "some moderate problems" related to their bladder condition on the Patient Perception of Bladder Condition questionnaire.	Reported previously. Women who did not complete active treatment in the original study, women who were randomized to placebo were excluded from the analysis.	Tolterodine extended release 4 mg/day	Placebo for 12 weeks, none for 24 weeks	Pfizer Inc	Gloria Bachmann: Grant/Research Support: Astellas, Wyeth, Bayer, Duramed, Pfizer, Boehringer-Ingelheim, Roche, Merck, QuatRx, Bionovo, Glaxo Smith Kline, Femme Pharma, Hormos, Covance, Novartis, Johnson & Johnson, Boston Scientific, Novonordisk

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Rogers, 2008[367] RCT USA N: 413	Women (aged ≥18 years) with a mean of greater than or equal to eight micturitions, ≥0.6 UUI episodes, and greater than or equal to three OAB micturitions (i.e., micturitions associated with moderate or severe urgency or UUI) per 24 hours with at least "some moderate problems" on the Patient Perception of Bladder Condition Questionnaire ; with OAB symptoms for ≥3 months and to have been in a stable, sexually active relationship (self-defined) with a male partner for ≥6 months.	Stage ≥3 pelvic organ prolapse, history of lower urinary tract surgery, lifelong sexual dysfunction unrelated to lifelong UUI, or predominant stress UI.	Tolterodine ER (4 mg)	Placebo	Pfizer Inc	Not reported
Rudy, 2006[369] RCT USA N: 658	Female and male patients were 18 years or older with OAB symptoms for at least 6 months; a minimal urinary frequency average of >10 toilet voids/day, symptoms of urgency (i.e., at least one "mild," "moderate," or "severe" urgency severity rating under the "degree of urgency," associated with "toilet void" events); >7 urge urinary incontinence episodes/week.	Predominately stress, insensate, or overflow UI; neurogenic bladder disorders, significant renal disease, uninvestigated hematuria, and urinary tract infection at washout or more than twice during the prior year; significant bladder outlet obstruction defined as a postvoid residual volume >100 mL and in the clinical judgment of the investigator; using any anticholinergic drug or other drug therapy for OAB within 21 days before randomization, history of bladder surgery.	Trospium chloride 20 mg twice daily	Placebo	Indevus Pharma-ceuticals	D. Rudy, K. Cline, R. Harris, K. Goldberg, and R. Dmochowski are study investigators funded by the sponsor

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Rudy, 2006[36] RCT analysis USA N: 658	Men and women ≥18 years old with OAB symptoms for ≥6 months, a minimum urinary frequency of 70 toilet voids per 7 days (i.e. mean ≥10 voids/day), and symptoms of urgency; with at least seven UUI episodes/week.	Predominately stress, insensate, or overflow; neurogenic bladder disorders, significant renal disease, uninvestigated haematuria, >2 UTIs during the previous year; significant BOO, concurrent anticholinergic drug use or other drug therapy for OAB within 21 days before randomization, bladder surgery within 6 months, cancer, interstitial cystitis, men with PSA levels of ≥10 ng/mL, diuretic use, estrogen therapy, and non-pharmacological bladder therapy that were not part of a stable, long-term program.	Trospium chloride 20 mg twice daily	Placebo	Indevus Pharma-ceuticals	Not reported
Rufford, 2003[370] RCT England N: 40	Postmenopausal women (>1 year at menopause) with the 'urge syndrome'; with estradiol <150pmol/l in women after hysterectomy with no contraindication for estrogen therapy.	Medication treatment of urge syndrome, diuretics, HRT, history of diabetes, endometrial thickness >4mm urinary tract infection, pelvic masses and urogenital prolapse.	25mg 17 beta-estradiol implant subcutaneous tissue.	Placebo	Educational grant from Organon	Not reported
Salvatore, 2005[371] RCT UK N: 96	Over a period of 1 year women with urinary symptoms referred to the Urogynecology Department of the King's College Hospital in London were recruited into this study after approval of our Ethical Committee. We only included those who had a videourodynamic diagnosis of detrusor overactivity or low bladder compliance and who signed an informed consent.	Not reported	Oxybutynin 2.5 mg twice a day We instructed all our patients, orally and with written information, to increase oxybutynin to a maximum dose of 5 mg three times a day over a period of 6 weeks .	Oxybutynin 5 mg nocte We instructed all our patients, orally and with written information, to increase oxybutynin to a maximum dose of 5 mg three times a day over a period of 6 weeks.	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Sand, 2009[372] Pooled USA N: 1971	Men and women ≥18 years of age who reported OAB symptoms for ≥6 months and demonstrated urinary frequency (≥8 micturitions per 24 hours) and either urinary urgency (≥6 total episodes) or UUI (≥3 total episodes) in 3-day bladder diaries at least moderate bladder problems on a six-point Likert scale: "My bladder causes me no problems (0), very minor problems (1), minor problems (2), moderate problems (3), severe problems (4), or very severe problems (5)."	Lower urinary tract pathology that could (in the investigator's opinion) be responsible for urgency or incontinence, significant pelvic prolapse (grade III or higher), clinically relevant bladder outlet obstruction, polyuria (>3 L/24 hours), symptomatic or recurrent urinary tract infections, postvoid residual volume >100 mL, and recent treatment with an antimuscarinic agent.	Fesoterodine 4 or 8 mg, or tolterodine extended release (ER) 4 mg	Placebo	Schwarz Bio-Sciences GmbH and Pfizer Inc.	Peter Sand is an advisor for Astellas, Allergan, American Medical Systems, Boston Scientific, Coloplast, Glaxo-SmithKline, Ortho McNeil, Pfizer Inc, and Watson Pharma; an investigator for Allergan, Boston Scientific, Ortho McNeil, Pfizer Inc, and Watson Pharma and a speaker for Allergan, Astellas, GlaxoSmithKline, Ortho McNeil, and Watson Pharma. Jon Morrow and Tamara Bavendam are employees of Pfizer Inc. Dana Creanga is a consultant for Pfizer Inc. Victor Nitti is an investigator for Schwarz Pharma, a consultant and lecturer for Pfizer Inc and Novartis, a consultant and investigator for Allergan, a consultant for Astellas, an advisor for Watson Pharma, Serenity Pharmaceuticals, and Coloplast Corp, and a lecturer for American Medical Systems.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Sand, 2004[373] RCT USA N: 276	Participants with overactive bladder who had ≥7 and ≤50 urge incontinence episodes/ week and ≥10 voids/24 hours were included.	Those with mixed stress and urge incontinence were eligible if the majority of the leakage accidents were related to urge incontinence. Participants with other causes of incontinence (e.g. urinary tract infection, interstitial cystitis, urinary tract obstruction, urethral diverticulum, bladder tumor, bladder stone) were excluded, as were those who had delivered a baby or undergone pelvic, vaginal or bladder surgery fewer than 6 months before study enrollment. Participants with a postvoid residual (pVR) urine volume of >150 ml at the time of screening were also excluded. In addition, those with clinically significant medical problems, or other organ abnormalities or pathologies for whom the administration of extended-release oxybutynin chloride or tolterodine tartrate would present an undue risk (medically uncontrolled cardiovascular, pulmonary, gastrointestinal, renal, endocrine, neurological, autoimmune, hematological, urological or psychiatric disorders, significantly reduced hepatic function or renal impairment) were excluded. Participants with hematuria or a positive urine culture, those with uncontrolled narrow-angle glaucoma, obstructive uropathy, myasthenia gravis, pelvic organ prolapse to the hymeneal ring, gastrointestinal conditions such as partial or complete obstruction, pre-existing severe gastrointestinal narrowing (pathologic	ER Oxybutynin Chloride	Tolterodine Tartrate	ALZA Corporation, Mountain View, California	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
		or iatrogenic), decreased gastrointestinal motility (paralytic ileus, intestinal atony, chronic and severe constipation), or those at risk of gastric retention, were excluded. Subjects were recruited regardless of whether or not they had received prior treatment and regardless of their response to prior anticholinergic therapy. Any medications used for the treatment of overactive bladder, or medications with anticholinergic activity used to treat other conditions, had to be discontinued at screening. Participants who had taken an investigational drug within the last month or had known allergies or hypersensitivities to oxybutynin chloride, tolterodine tartrate, or components of the respective tablets were excluded. Participants with current drug or alcohol abuse, female participants who were pregnant or breastfeeding, and participants who were not capable of following the study schedule or directions were excluded. Those who were not able to swallow the medication without chewing, crushing, biting, dividing or dissolving the capsule were also excluded.				
Sand, 2009[374] Dmochowski, 2010[375] Pooled Country not reported N: 989	Subgroup analysis of women aged ≥18 years with OAB of ≥6 months' duration with urinary urgency (≥1 severe urgency severity rating on the validated Indevus urgency severity scale); urinary frequency	Predominantly stress, insensate, or overflow incontinence (as determined by investigators), demonstrable renal or urinary disorders including neurogenic bladder disorders, significant renal disease, uninvestigated hematuria, current or a history of ≥3 episodes of urinary tract infection in the preceding year,	Trospium ER (60-mg capsules)	Placebo	Allergan, Inc. and Endo Pharma-ceuticals (formerly Indevus Pharma-ceuticals Inc.).	Peter K. Sand, MD, serves as an advisor and speaker for Allergan, Inc., Astellas Pharma US, Inc., Pfizer, Ortho-McNeil, Colplast, and Watson Pharmaceuticals. Dr.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
	(average ≥10 voids/day, occurring at any time of the 24-hour period); and pure urge or mixed urinary incontinence with predominant UUI, with an average of ≥1 UUI episode/day.	bladder outlet obstruction, interstitial cystitis, or bladder cancer; subjects requiring long-term diuretic or estrogen therapy.				Sand has received grants from Allergan, Inc., Astellas Pharma US, Inc., Boston Scientific, Pfizer, Ortho-McNeil, Watson Pharmaceuticals, and Antares Pharma. Roger R. Dmochowski, MD, has financial relationships with Allergan, Inc., Pfizer, Watson Pharmaceuticals, Novartis, and Astellas Pharma US, Inc. David R. Staskin, MD, serves as a consultant and lecturer for Allergan, Inc., Pfizer, Watson Pharmaceuticals, and Astellas Pharma US, Inc. Norman R. Zinner, MD, serves as a consultant, speaker, and/or for a clinical trial for Allergan, Inc., Actelion, Watson Pharmaceuticals, Pfizer, Novartis, Ferring Pharmaceuticals, and GlaxoSmithKline. Rodney A. Appell, MD (deceased) was on the advisory board for Pfizer, Boston

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
						Scientific, and Astellas Pharma US, Inc. Dr. Appell held stock in American Medical Systems. Dr. Appell served as an investigator for Allergan, Inc., Astellas Pharma US, Inc., Watson Pharmaceuticals, American Medical Systems, Boston Scientific, Solace Technology, Bulkamid, and Novasys Medical.
Sand, 2006[376] Sand, 2007[377] The Multicenter Assessment of Transdermal Therapy in Overactive Bladder with Oxybutynin trial USA N: 2592	At least 18 years of age; have 1 or more symptoms of OAB (urge urinary incontinence, urgency, and/or frequency); be willing to discontinue any over-the-counter and/or prescription treatment for OAB for the duration of the study; be capable of completing Quality of Life Questionnaires without assistance; be willing and able to comply with the protocol; and for females of childbearing potential, have a negative urine pregnancy test and have used a medically acceptable contraceptive method.	Urinary retention or uncontrolled narrow-angle glaucoma or risk for these conditions; demonstrated hypersensitivity to oxybutynin or other components of the product; had 1 or more treatable conditions that might cause urinary incontinence or urgency (i.e., urinary tract infection, prostatitis, bladder tumor, bladder stone, prostate cancer); had received an investigational product within 30 days prior to participation in this study; had been previously treated with transdermal oxybutynin; resided in long-term care facilities or nursing homes; or were judged by the investigator to be unsuitable for enrollment into the study.	Transdermal oxybutynin 3.9 mg plus behavioral intervention of enhanced patient education	Transdermal oxybutynin alone	Supported by Watson Laboratories (Morriston, NJ)	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Schagen van Leeuwen, 2008[378] RCT Germany, France, The Netherlands, Spain, Sweden, Switzerland and South-Africa N: 265	Community-dwelling women of ≥65 years with symptoms of SUI or S-MUI for ≥3 consecutive months and ≥7 incontinence episodes per week as determined by the stress/urge incontinence questionnaire S/UIQ; predominant stress UI with ≥50% of incontinence episodes had to be due to stress UI; post-void residual ≤100mL.	Language or significant cognitive barriers (modified mini-mental state exam [3MS] score <80; >>4 urinary tract infections in the preceding year or a positive urine culture at visit 1, any nonpharmacological intervention (surgery, bulking agents, initiation of pelvic floor muscle training) for incontinence or prolapse within 3 months before study entry or throughout the study, increased suicidal risk (score ≥2 on question 9 of the Beck depression inventory [BDI-II]), history of syncopal episodes, or hepatic dysfunction, defined as serum glutamate–pyruvate–transaminase (alanine aminotransferase) or glutamate–oxaloacetate–transaminase (aspartate aminotransferase) ≥3 times upper limit of normal (ULN) or bilirubin ≥1.5 times ULN.	Duloxetine 20 mg twice daily	Placebo	Funding was provided by Eli Lilly and Company, and Boehringer Ingelheim, GmbH	Not reported
Staskin, 2006[39] Pooled Country not reported N: 3298	Pooled analysis of 4 RCTs of men and women over 18 years with OAB (mean of ≥8 voids/24 hours, plus ≥1 incontinence episode or ≥1 urgency episode/24 hours)	Women with a history of stress-predominant UI, positive cough-provocation test; no baseline assessment or no episodes of the individual diary symptom during the baseline diary screening period.	Solifenacin 5mg; Solifenacin 10mg;	Placebo	Yamanouchi Pharma Inc.	D. Staskin is a consultant for Pfizer, Ortho- McNeil, Indevus, Watson, Astellas and Novartis; A. Te is an investigator for Sanofi- Aventis, Pfizer and NIH, and is a consultant for Sanofi-Aventis, Glaxo and Astellas. Source of funding: Astellas.
Staskin, 2007[47] Trospium Study Group. USA N: 601	Not reported	Not reported	Trospium chloride 60 mg/day	Placebo	Esprit Pharma and Indevus Pharmaceuticals	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Staskin, 2004[379] RCT USA N: 658	Not reported	Not reported	Trospium chloride 20-mg twice daily	Placebo	Not reported	Not reported
Staskin, 2009[33] RCT US N: 789	Men and women with OAB who were 18 years or older; urge or mixed UI with a predominance of urge UI episodes as well as a mean of 8 or more urinary voids per day and 4 or more urge UI episodes per day on a baseline 3-day bladder diary regardless of whether symptoms were of neurological origin. The bladder diary was to be independently completed by the patient. Patients needed to have a mean voided volume of 350 ml or less during a 2-day urine collection period and a PVR of 250 ml or less on ultra-sonography or catheterization.	Potential participants were excluded from study based on criteria designed to rule out incontinence related to chronic illness, anatomical abnormality and concomitant medication.	OTG (oxybutynin chloride)	Placebo	Laboratory assessments were performed at Mayo Laboratory for Clinical Trials, Rochester, Minnesota	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Staskin, 2009[380] Study: Post-hoc A4,T3 N: 1165	Adult men and women with OAB of ≥6 months' duration with urgency and an average of ≥1UUI episode/day and ≥10 toilet voids/day, as assessed using 3 -day bladder diaries	NR	Trospium chloride	Placebo	Supported by Allergen, Inc. and Indevus Pharmaceuticals Inc.	Dr. Staskin has been an advisor and speaker for Allergen, Astellas Pharma, Pfizer and Watson. Professor Cardozo has received funding as a speaker, consultant or researcher from Astellas, Bioxell,Pfizer, Recordati, Rottapharm and Allergan within the last year
Staskin, 2009 [52] Study: pooled analysis Sample: 1165	Adults with OAB of ≥6 months' duration with urinary urgency (>=1 severe urgency severity rating/3 days on the validated Indevus Urgency Severity Scale [IUSS]), frequency (mean ≥10 voids/day), and UUI (mean of ≥1 UUI episode/day), as assessed using the 3-day bladder diaries. Subjects undergoing current pharmacological therapy for OAB eligible after a 7-day washout period prior to 3-day bladder diary data collection.	A mean total volume voided of >3000 ml/day; a mean voided volume of >250 ml/void; predominantly stress, insensate, or overflow incontinence; interstitial cystitis; bladder or prostate cancer; and a history of neurogenic bladder; clinically significant renal disease (defined as screening serum creatinine values >1.5mg/dl), urinary tract infection or clinically significant urinary retention (defined as postvoid residual urine volume >100ml); subjects who and been treated with or received trospium chloride in previous trials.	Trospium XR 60 mg once daily	Placebo	Supported by Allergan, Inc. and Endo Pharma-ceuticals Inc. (formerly Indevus Pharma-ceuticals, Inc.) Editorial support funded by Allergan, Inc.	David R. Staskin is a consultant and speaker for Allergan, Astellas, Pfizer, and Watson. Matt T. Resenberg receives grant/research support from Ortho-McNeil and Sanofi-Synthelabo and serves as a consultant for Ortho-McNeil, Sanofi-Sythelabo, Pfizer, GlaxoSmithKline, Endo Pharmaceuticals (formerly Indevus Pharmaceuticals), Lilly, and Novartis. He is also on the Speakers' Bureau for Ortho-McNeil, Endo Pharmaceuticals,

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
						GlaxoSmithKline, Pfizer, Lilly and AstraZeneca. Peter K.Sand is an advisor and speaker for Allergan, Astellas, Pfizer, Ortho, Colplast, and Watson. He has received grants from Allergan, Astellas, Boston Scientific, Pfizer, Ortho-McNeil, Watson, and Antares. Norman R.Zinner is a consultant, clinical trial investigator , and/or speaker for Allergan, Watson, Pfizer, Novartis, Ferring, GlaxoSmithKline and Astellas. Roger R. Dmochowski is a consultant for Allergan, Astellas, Novartis, Pfizer, and Watson.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Steers, 2005[45] RCT Canada, USA N: 395	Patients aged >18 years with symptoms of OAB for at least 6 months, capable of independent toileting. Irrespective of response to previous treatments patients had to have urge incontinence (>5 episodes per week), voiding frequency (>8 voids per day), and urgency (a strong desire to void at least once per day). Adequate method of contraception throughout the study for young women.	Contraindications to anticholinergic therapy (e.g., uncontrolled narrow-angle glaucoma, urinary retention or gastric retention); clinically significant stress incontinence, BOO and/or a postvoid residual urinary volume (PVR) of >200 mL ; pregnancy and lactation; genitourinary conditions that could cause urinary symptoms; fecal impaction or severe constipation (two or fewer bowel movements per week); urogenital surgery within the previous 6 months; bladder biopsy in the previous 30 days; indwelling catheter and intermittent self-catheterization; clinically significant disease; bladder-training program during the study; concomitant treatment with anticholinergic or antispasmodic drugs (including drugs with significant anticholinergic effects, e.g., imipramine), opioids and other drugs known to cause significant constipation, hormone replacement therapy (unless taken for >2 months), and drugs known to be potent cytochrome P450 3A4 inhibitors (e.g., ketoconazole).	Darifenacin controlled-release tablets 7.5 mg	Placebo	This study was funded by Pfizer Inc.	Jacques Corcos is a member of the board of Sponsor; Georg Kralidis is an employee of Sponsor; Jenelle Foote is a study investigator funded by Sponsor.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Steers, 2007[381] Duloxetine OAB Study Group. Australia, Canada, USA N: 306	Duloxetine OAB Study Group: women aged ≥18 years and to be identified as having predominant symptoms of OAB for ≥3 consecutive months before study entry; no SUI, including a negative cough stress. The case definition for OAB: bothersome urinary urgency or urge UI+ abnormal voiding frequency (≥2 hours mean daytime voiding interval, VI) documented by ≥2 days of recording of a screening urinary diary + urodynamic testing detected DOA or sensory urgency(urgent desire to void during the testing session in the absence of a DOA, with a maximum cystometric capacity (MCC) of □400 mL, both with no SUI, including a negative cough stress test at MCC after the urethral catheter was removed.	A postvoid residual urine volume (PVR) of >100 mL; a mean 24-hour total voided volume of < 3 L, documented on a 2-day frequency-volume chart (FVC); a positive urine culture (>100 000 colony-forming units/mL) or four or more UTIs during the year before enrolment; the regular use of medications for OAB symptoms within a month of enrolment; any previous use of duloxetine; continence surgery within 6 months or any major surgery within 3 months of enrolment; pelvic organ prolapse greater than ICS Stage II; any nonpharmacological intervention (e.g., electrical stimulation, bladder training, continence devices) within 3 months of enrolment; and pelvic floor muscle training 3 months before the study.	Duloxetine (40-mg twice daily). After 4 weeks, the dose of duloxetine was increased to 60-mg twice daily	Placebo	Eli Lilly and Company and by Boehringer Ingelheim GmbH.	William D. Steers and Sender Herschorn are paid consultants and study investigators funded by the sponsor. Karl J. Kreder, Kate Moore and Kris Strohbehn are study investigators funded by the sponsor. Ilker Yalcin and Richard C. Bump are employees of Eli Lilly and company. Sponsored by Eli Lilly and Company and by Boehringer Ingelheim GmbH.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Swift, 2003[382] Tolterodine Study Group 167 centers in Europe (n=89), North America (n=74), Australia and New Zealand (n=4) N: 1235	The Tolterodine Study Group: age 18 years or more with urinary frequency (58 micturitions/24 hours) and urge incontinence (55 incontinence episodes/week), having had these symptoms of overactive bladder for 6 months or more whether or not they were treatment naïve, and irrespective of response to prior antimuscarinic therapy.	Demonstrable stress incontinence, total daily urine volume >3 L, any contraindications to antimuscarinic treatment, significant hepatic or renal disease (with biochemical markers twice the upper limit of the normal reference range), symptomatic or recurrent urinary tract infections (diagnosed by urinalysis), interstitial cystitis (diagnosed by clinical suspicion), hematuria or bladder outlet obstruction, current electro-stimulation or bladder training therapy, an indwelling catheter or intermittent self-catheterization; pregnant or nursing women; women of child-bearing potential not using reliable contraceptive methods; other treatments for overactive bladder, such as anticholinergic drugs, or drugs that inhibit cytochrome P450 3A4 isoenzymes were not permitted; treatment with an investigational drug in the 2 months prior to study entry was prohibited.	Tolterodine ER 4 mg capsules once daily, tolterodine IR tablets 2 mg twice daily	Placebo	This study was sponsored by a grant from Pharmacia Corporation.	Not reported
Szonyi, 1995[383] RCT Country not reported N: 60	Outpatients of either sex aged over 70 with symptoms of urinary frequency, urgency and urge incontinence were recruited. Patients had to be mobile, able to attend an outpatient department, able to keep a diary chart and willing to give consent.	Urinary infections at the time of recruitment, patients with severe hepatic or renal disease, glaucoma, or uncontrolled diabetes. Patients on concomitant anticholinergic therapy with imipramine were excluded.	Oxybutynin 2.5 mg twice daily	Placebo	Funded by Smith and Nephew Pharmaceuticals Ltd.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Takei, 2005[384] Japanese Tolterodine Study Group. Japan N: 293	Eligible Japanese patients completing 12 weeks' treatment in a randomized, double-blind trial 20 continued with 12 months' open-label treatment with tolterodine ER 4 mg once daily, irrespective of (and without unblinding) the treatment received during the double blind study (tolterodine ER 4 mg capsules once daily [Detrol capsule, Detrusitol, Pharmacia Corporation, Peapack, NJ], oxybutynin 3 mg tablets three times daily [Pollakisu, Aventis Pharma Ltd, Tokyo, Japan] or placebo).	Demonstrable stress incontinence, total daily urine volume >3 L, average volume voided/micturition >200 mL, significant hepatic or renal disease, any contraindication for anticholinergic treatment, symptomatic or recurrent urinary tract infection, interstitial cystitis, hematuria or bladder outlet obstruction, indwelling catheter or intermittent self-catheterization, electro-stimulation or bladder training within 14 days before randomization or expected to commence during the study. Patients who were poorly compliant (missed >25% of prescribed medication), had an ongoing serious adverse event and pregnant or nursing women and women of childbearing potential not using reliable contraception were also excluded.	Tolterodine ER	Oxybutynin, Placebo	Pfizer Japan Inc	Not reported
Tapp, 1990[385] RCT Country not reported N: 37	Postmenopausal women, with a mean age of 61 years (SD 13, range 41-87)	Not reported	Oxybutynin 5mg four times daily	Placebo	Support from Tillots Laboratories	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Tincello, 2000[386] RCT UK N: 67	Urodynamically confirmed diagnosis of idiopathic detrusor instability.	All patients were screened for UTI using commercially available reagent test-strips before cystometry, and those with positive results were deferred until appropriate treatment had been given. All patients had a urinary flow rate and residual volume measured. Fluid-filled rectal and vesical pressure catheters were used and cystometry performed with the patient either sitting or recumbent. Warm saline (37^{o}C) was used as the filling fluid, at 50-75 mL/min. At cystometric capacity, provocation tests were conducted with the patient standing, which consisted of three strong coughs, jumping on the spot, and hearing running water. The ICS criteria were used for diagnosis. Patients with a residual volume of ≥100mL and those with a maximum flow rate of <15mL/s were excluded.	Oxybutynin with salivary stimulant pastilles	Oxybutynin only	Drugs were supplied by Lorex Synthelabo and Thames Laboratories, Consolidated Chemicals, Wrexham, UK	Not reported
Thuroff, 1991[387] Study: RCT N: 169	15 years old and older complaining of symptoms of frequency, urgency and/or incontinence, in whom cystometry findings were related to detrusor hyperactivity, whether idiopathic (unstable detrusor) or neurogenic (detrusor hyperreflexia) in origin.	Pregnancy, congestive heart failure, severe renal/liver disease, myasthenia gravis, unable to swallow/uncooperative patient, hiatal hernia/reflux esophagitis, gastrointestinal tract obstruction, urinary tract obstruction, residual urine greater than 50ml, untreated urinary tract infection and hyperreflexia without urge	oxybutynin chloride	propantheline and placebo	Pharmcia Leo Therapeutics, Helsingborg, Sweden provided the pharmaceutical preparations used in this study	NR

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Toglia, 2010[388] Study: Post-hoc Karram, 2009[324] VENUS N: 739	Patients aged ≥18 years with OAB symptoms for ≥3 months	Reported previously-18995887	Solifenacin	Placebo	Supported by Astellas Pharma US, Inc. and GlaxoSmithkline	Dr. Toglia is a consultant and speaker for Astellas; Dr. Ostergard is a consultant and speaker for Astellas, GlaxoSmithKline, Novartis, Pfizer and Watson. Dr. Fakhoury is an employee of Astellas. Mr. Andoh and Dr. Hussain were employees of Astellas at the time the study was conducted and have no other conflicts of interest to disclose
U.S. Food and Drug Administration[62] Cardozo, 2008[63] Study: SUNRISE N: 865	Male of female aged ≥18 years, from whom written consent had been obtained, and who were willing and able to complete a voiding diary correctly; symptoms of OAB (including urinary frequency, urgency or urgency incontinence) for ≥3 months and three or more episodes of urgency with or without incontinence in the last 3 days	NR	Solifenacin	Placebo	Research grant from Astellas Pharma Europe Ltd.	Linda Cardozo:Astellas, Lilly, UCB Pharma, Pfizer, Gynecare, Plethora, Cook, Organon; Elke Heβdörfer:Astellas, Pfizer, Bayer-Schering, Snaofi Aventis, Apogepha, Merckle Recordati, Lilly; Rodolfo Milani:Astellas, BARD, Recordati; Pedro Arano: Astellas; Luc Dewilde:Astellas; Mark Slack:Astellas, Pfizer, Lilly, Johnson & Johnson, Boston Scientific; Ted Drogendijk, Mark Wright and John Bolodeoku:employees of Astellas

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
U.S. Food and Drug Administration, 2004[389] Study: RCT Sample: 509	Male or female, 18 years and older, with symptoms of overactive bladder for at least 6 months prior to enrollment	NR	trospium chloride	Placebo	Indevus Pharmaceuticals, Inc.	NR
U.S. Food and Drug Administration, 2004[35] Study: RCT Sample: 509	Male or female, 18 years and older, with symptoms of overactive bladder for at least 6 months prior to enrollment	NR	trospium chloride	Placebo	Indevus Pharmaceuticals, Inc.	NR
U.S. Food and Drug Administration, 2004[43] Study: RCT Sample: 680	Male and female subjects, aged 18 years and older with symptoms of overactive bladder for at least 6 months. Subjects must exhibit all of the following symptoms of overactive bladder during the run-in period: 1) incontinence 2) frequency of micturition -at least 8 times per 24 hours, on average, over the run-in period 3) urgency -at least once per 24 hours, on average, over the run-in period		darifenacin	Placebo	NR	NR

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
U.S. Food and Drug Administration, 2004[390] Study: RCT N: 562	Male and female subjects, aged 18 years and older with symptoms of overactive bladder for at least 6 months. Subjects must exhibit all of the following symptoms of overactive bladder during the run-in period: 1) incontinence 2) frequency of micturition -at least 8 times per 24 hours, on average, over the run-in period 3) urgency -at least once per 24 hours, on average, over the run-in period		darifenacin	Placebo	NR	NR
U.S. Food and Drug Administration, 2007[40] Study: RCT N: 601	Patients currently undergoing OAB therapy at the time of enrollment were required to undergo 7-day wash-out period, followed by 3-day baseline urinary diary collection, prior to randomization. Patients not under OAB therapy could begin treatment after 3-days of baseline diary collection	NR	trospium chloride ER	Placebo	Indevus Pharma-ceuticals, Inc.	NR

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
U.S. Food and Drug Administration, 2007[46] Study: RCT N: 564	Patients currently undergoing OAB therapy at the time of enrollment were required to undergo 7-day wash-out period, followed by 3-day baseline urinary diary collection, prior to randomization. Patients not under OAB therapy could begin treatment after 3-days of baseline diary collection	NR	trospium chloride ER	Placebo	Indevus Pharmaceuticals, Inc.	NR
U.S. Food and Drug Administration, 1998[41] Anderson, 1999[391,392] Study: RCT OROS Oxybutynin Study Group N: 134	Female patients aged 40 years and older with urge urinary incontinence. Non-pregnant women determined to be in good health; patients with mixed urinary incontinence, provided that symptoms and/or signs of stress incontinence are not the predominant manifestation of UI and UUI episodes associated with urgency can be differentiated from urge incontinence episodes not associated with urgency; normotensive, with or without hypertensive medication; no postural hypotension; patients who successfully completed the screening urinary diary for 7 days	Patients with known genitourinary conditions that may cause incontinence; those receiving any drugs that are considered effective in the treatment of incontinence less than the equivalent of 5 times the half-life of the drug and patients who have been treated with anticholinergic agents for urge UI and were found to be refractory to these agents	Oxybutynin as OROS-O5mg to 30mg/day based on achieved continence	Oxybutynin IR 5mg to 20mg/day based on achieved continence	Alza Corporation Mountain View, California	M. Preik is an employee of Jansen-Cilag GmbH, Germany. A Albercht and M O'Connell are employees of ALZA Corp., USA. R. Anderson is a stakeholder of Johnson and Johnson stock, is a member of the national advisory board for Ditropan Xl, and also acts on behalf of the Speaker's Bureau of Ortho-McNeil.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Van Kerrebroeck, 2004[393] Duloxetine Urinary Incontinence Study Group. 46 study centers in Belgium, Canada, Denmark, France, Germany, the Netherlands, Sweden and the United Kingdom N: 494	Women aged 24–83 years with predominant symptoms of stress urinary incontinence (according to clinical algorithm that was 100% predictive of urodynamic stress urinary incontinence), with >7 weekly incontinence episode, without predominant symptoms of urge incontinence, normal diurnal and nocturnal frequencies, a bladder capacity >400 mL and both a positive cough stress test and positive stress pad test.	Inability to tolerate the filling to 400 mL or who experienced a first sensation of bladder filling <100 mL.	Duloxetine 40 mg BD	Placebo	Funded by Eli Lilly and Boehringer Ingelheim.	Dr Yalcin and Dr Bump are both full-time employees of Eli Lilly and hold stock and stock options in the company.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Van Kerrebroeck, 2001[394] Tolterodine Study Group. 167 centers in Australasia (n 54), Europe (n 589), and North America (n 574). N: 1529	Men and women with urinary frequency (eight or more micturitions every 24 hours) and urge incontinence (five or more episodes per week) irrespective of whether they had received prior treatment and irrespective of their response to prior antimuscarinic therapy.	Demonstrable stress incontinence, total daily urine volume greater than 3 L, any contraindications to antimuscarinic treatment, significant hepatic or renal disease (biochemical markers twice the upper limit of the normal reference range), symptomatic or recurrent urinary tract infections, interstitial cystitis, hematuria or bladder outlet obstruction, current electro-stimulation or bladder training therapy, and indwelling catheter or intermittent self-catheterization, pregnancy, breastfeeding, unreliable contraceptive methods; other treatments for an overactive bladder such as anticholinergic drugs or drugs that inhibit cytochrome P450 3A4 isoenzymes; treatment with an investigational drug in the 2 months before study entry.	Tolterodine ER 4 mg once daily	Placebo	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Vardy, 2009[395] Study: RCT VIBRANT Sample: 768	Eligible patients (aged ≥18 years) were required to have OAB symptoms for ≥3 months (≥8 micturitions and ≥1 urgency episode, with or without incontinence, per 24 hours) and a PPBC score ≥3	Significant stress or stress-predominant mixed incontinence, recurrent urinary tract infection (UTI; ≥3 episodes within the past 3 months) or evidence of UTI at baseline, evidence of chronic urologic inflammation/interstitial cystitis or urinary/gastric retention.	Solifenacin	Placebo	Research grant from Astellas Pharma U.S. Inc. and Glaxo-Smithkline	Dr. Vardy is a consultant for Astellas Pharma US, Inc. and a speaker for Wyeth and BARD Urologic. Dr. Mitcheson is a study investigator for Pfizer, Novartis, Eli Lilly, Watson, and Antares; he is a speaker for GlaxoSmithKline. Dr. Forero-Schwanhaeuser is an employee of GlaxoSmithKline, and Drs. Marshall and He are employees of Astellas Pharma US Inc. Editorial support, including writing assistance, was provided by Linda A. Golstein, PhD, a medical writer at Envision Scientific Solutions and was funded by Astellas Pharma Global Development Inc. and GlaxoSmithkline
Vella, 2008[396] CT UK N: 228	Women with a diagnosis of urodynamic stress incontinence (USI) or mixed USI and detrusor overactivity.	Concurrent prolapse or contraindications to drug therapy	148 Duloxetine: 40 mg bid (140 women). 80 women received an escalating dose; initially 20 mg bid escalating to 40 mg bid after 2 weeks	None	Not reported	Jonathan Duckett has received funding to attend conferences from the makers of duloxetine.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Versi, 2000[42] Gleason, 1999[397] U.S. Food and Drug Administration, 1998[41] The Ditropan XL Study Group United States N: 226	Patients were included only if they had previously responded to treatment with anticholinerigc medications or to a trial of oxybutynin before enrollment.	Patients with clinically significant medical problems, a postvoid residual urine volume over 100 mL, or other conditions in which oxybutynin is contraindicated were excluded.	Controlled-release oxybutynin tablets containing 5 mg oxybutynin or a placebo were placed in identical hard gelatin capsules and packaged in cards that provided total doses of 5, 10, 15, and 20 mg.	Immediate-release oxybutynin tablets containing 5 mg oxybutynin or a placebo were placed in identical hard gelatin capsules and packaged in cards that provided total doses of 5, 10, 15, and 20 mg.	Grant from ALZA Corporation	Not reported
Von Holst, 2000[398] RCT Germany N: 186	Hysterectomised women age 40-65 years, with postmenopausal complaints, normal gynecological history and examination, serum estradiol <30pg/ml and follicle stimulating hormone >30IU/ml.	Use of sex hormones taken orally within the last 28 days; locally-applied sex hormones within the last 21 days or injectable sex hormones within the last 6 months.	7-day-Estradiol patch (1.5mg estradiol/week or 50mg estradiol/24 hours). All patients received active drug therapy (7-days). Estradiol patch) for a further 3 months (three cycles).	Placebo once-weekly	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Waetjen, 2005[399] RCT USA N: 417	Postmenopausal women age 60-80 years, with a uterus and at least 5 years after menopause, with normal bone mineral density for age (z score not below –2.0 at the lumbar spine).	Use of estrogen or progestin within 3 months of randomization or having unexplained uterine bleeding, endometrial hyperplasia or an endometrium 5mm or more in double-wall thickness, abnormal mammogram, breast cancer, a history of metabolic disease, cancer, coronary disease, cerebrovascular disease, uncontrolled hypertension, uncontrolled thyroid disease, liver disease, fasting triglycerides more than 300 mg/dL, or fasting glucose more than 180 mg/dL.	14mg of transdermal E2 per day.	Placebo	Grant from Berlex laboratories inc, Montville, NJ; Grant IND No. 98188 from the U.S. Food and Drug administration	Dr. Pinkerton is on the Berlex speaker's bureau
Wagg, 2006[400] Study: pooled analysis Sample: 1045	Mean of ≥8 micturitions/24 hours and at least I of the following:1)a mean of ≥1 incontinence episode/24 hours; or 2)a mean of ≥1 urgency episode/24 hours	existing urinary tract dysfunction including postvoid residual volume of >150 or >200mL (depending on the trial), stress incontinence or mixed urinary incontinence with stress urinary incontinence predominating, neurologic dysfunction or injury affecting detrusor function or other lower urinary tract function, absolute urinary retention, grade III/IV prolapse with cystocele, recurrent or active urinary tract infection, bladder stones, current or previous bladder neoplasm, or history of interstitial cystitis. To discontinue any drug for treatment of urinary incontinence. Use of anticholinergic or antimuscarinic agents only allowed only if receiving a stable dose. Electro-stimulation, biofeedback, or bladder-training therapy not allowed during the study and not permitted during the 2 to 4 weeks immediately before the trials.	solifenacin 5 or 10 mg	placebo	Yamanouchi Pharma Co., Ltd, Tokyo, Japan	Dr. Wagg has received consultancy, lecture, and writing fees relating to OAB from Yamanouchi. Dr. Sieber is a member of the speaker's bureau for Yamanouchi and was also a principal investigator. Professor Wyndaele has no financial involvement with Yamanouchi

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Wang, 2006[401] RCT Taiwan N: 74	Age: 16 to 80 years; OAB for more than 6 months. No patients had taken anticholinergics or tricyclic antidepressants and none had been treated with pelvic floor muscle training, bladder training, or pelvic prolapse repair.	Pregnancy, neurologic disorders, diabetes mellitus, demand cardiac pacemaker or intrauterine device use, genital prolapse greater than Stage II of the International Continence Society grading system, a postvoid residual urine volume greater than 100 mL, overt urinary stress incontinence, a history of anti-incontinence surgery, and urinary tract infection.	Electrical stimulation (ES)	Oxybutynin, placebo	Grant from National Science Council, Taiwan.	Not reported
Wang, 2009[402] RCT Taiwan N: 73	Women with OAB for more than 6 months, and the symptom of urgency three times or more per day.	Treatment with anticholinergics or tricyclic antidepressants; treatment with pelvic floor or bladder training and pelvic prolapse repair, participation in prior trials; pregnancy, neurologic disorders, diabetes mellitus, demand cardiac pacemaker or intrauterine device use, genital prolapse greater than the International Continence Society (ICS) grading system stage II, overt urinary stress incontinence, a history of anti-incontinence surgery, urinary tract infection and patients receiving any OAB treatment during the 14-day washout/run-in period preceding randomization.	Vaginal electric stimulation (20 minutes per session, twice a week) or oxybutynin (2.5 mg) three times per day	Placebo three times per day	Grant from the National Science Council, Taiwan (NSC95-2314-B-182-062).	Not reported
Mazur, 1995[403] RCT Country not reported N: 185	Men and women with urge urinary incontinence or urgency	Neurogenic bladder dysfunctions, urinary tract infections, gastrointestinal obstructions, cardiovascular diseases, potential pregnancy.	Propiverine hydrochloride 60 mg/d	Propiverine hydrochloride 15, or 45 mg/d	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Weil, 1998[404] RCT Country not reported N: 105	Women with a history of mild to moderate stress urinary incontinence, age between 18 and 70 years old, stress urinary incontinence was proven during urodynamic filling cystometry (up to 75% of bladder capacity)	Body weight deviating >45% from the Broca Index, arterial hypertension, urinary tract infections, positive urine cytology, with motor urge incontinence, a bladder compliance of <20 ml/cmH20, detrusor activity while coughing or >50 ml of residual urine after voiding; patients who had undergone extensive pelvic surgery or surgery to correct urinary incontinence; patients with vaginal descent grade III, or who had undergone pelvic irradiation; patients taking diuretics, adrenergic agonists or antagonists, other drugs which act on smooth muscle, or other drugs used to control urinary incontinence; patients using other treatments for urinary incontinence; patients with significant renal, hepatic, or hematological disease, a history of cardiac disease, pheochromocytoma, thyrotoxicosis, uncontrolled diabetes mellitus, seizures, mental impairment or a history of cerebrovascular accident; and pregnant or breast feeding women. Patients who were unlikely to be compliant with protocol requirements were also excluded.	Oral midodrine (5, 7.5 and 10 mg/day)	Placebo	Not reported	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Wein, 2007[405] RCT analysis Australia, Europe and North America N: 1005	Men and women aged ≥18 years with symptoms of urinary frequency (≥8 voids/24 hours) and urgency UI (≥5 episodes/ week) for ≥6 months.	Stress UI, as determined by the investigator and confirmed by a cough provocation test; significant hepatic or renal disease, current or recurring UTI, clinically relevant BOO (defined by investigator's judgment based on a patient's history), indwelling catheter or intermittent self-catheterization, and any condition for which antimuscarinic treatment was contraindicated; anticholinergic drug or treatment for OAB during the 14-day washout/run-in period preceding randomization, and those with a mean micturition volume of 200 mL or total daily volume of 3 L on bladder diaries.	Tolterodine-ER (4 mg)	Placebo	Not reported	Alan J. Wein is a consultant to Astellas, Novartis, Pfizer and Indevus; Vik Khullar is a speaker and investigator for Pfizer on tolterodine; Joseph T. Wang and Zhonghong Guan are employees of Pfizer Inc.
Weinstein, 2006[406] DESIRE (Duloxetine Efficacy and Safety for Incontinence in Racial and Ethnic populations). USA N: 3983	DESIRE Study Group: women >18 years old with stress urinary incontinence (>1 episode/week) or stress predominant mixed incontinence (frequency of stress at least twice higher than urge)	Prior treatment with monoamine oxidase inhibitors and duloxetine; depression; diabetic peripheral neuropathic pain	Duloxetine 40 mg twice daily	Not controlled trial	Funded by Eli Lilly and Boehringer Ingelheim.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Wiseman, 1991[407] RCT UK N: 37	Men and women over 70 mobile and able to use a toilet or commode independently, able to understand and complete a bladder diary chart properly, and able to give informed consent with symptoms of urinary frequency and urge incontinence caused by detrusor instability.	Urinary infections during the previous four weeks; women with bladder neck prolapse; and patients with severe liver or renal disease, uncontrolled diabetes mellitus, glaucoma, or other contraindications to antimuscarinic treatment; taking other antimuscarinic drugs, calcium channel blockers, and non-steroidal anti-inflammatory drugs as these all affect the bladder.	Terodiline 25 mg +bladder retraining	placebo+ bladder retraining	Not reported	Not reported
Yalcin, 2006[408] Pooled USA N: 1133	1133 women with SUI who were enrolled in two double-blind, controlled, randomized studies of duloxetine versus placebo having predominant SUI that was diagnosed using a clinical algorithm demonstrated to be 90.2% predictive of urodynamic stress.	Reported previously in individual studies	Duloxetine 80mg/day	Placebo	This study was sponsored by Eli Lilly and Company and Boehringer Ingelheim.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Yalcin, 2004[409] the Duloxetine UI Study Group one phase 2 study in the US, and 3 phase 3 studies in 16 countries in Africa, Australia, Europe, and North and South America N: 1913	Women with SUI of at least 3 months' duration predominant symptom of SUI with a weekly IEF >4 in phase 2 and IEF >7 in the 3 phase 3 studies, where an episode was defined as an easily noticeable leakage of urine that wet a pad or clothing, and that occurred with a physical stress such as coughing, sneezing, or exercising; the lack of predominant symptoms of enuresis or urge urinary incontinence, daytime frequency mL per minute, without pressure measurements; a positive cough stress test (visualization of urine leakage concurrent with a cough) and a positive stress pad test (leakage of >2.0 g).	Inability to tolerate filling to 400 mL a first sensation of bladder filling <100 mL, or who had no sensation at any time during the filling; previous continence surgery.	All phase 3 studies included only duloxetine 40 mg bid as an active treatment. The phase 2 study included 3 duloxetine treatment groups (20 mg qd, 20 mg bid, and 40 mg bid); however, data from subjects taking duloxetine doses <40 mg bid were not included in the analyses to avoid any potential confounding effects of lower efficacy (duloxetine 40 mg bid has been demonstrated to be the optimum dose). Subgroup analysis was performed within each treatment group based on baseline incontinence severity.	Placebo	This work was sponsored by Eli Lilly and Company	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Yamaguchi, 2007[410] Study: RCT N: 1593	Men and women aged ≥20 years and with symptoms of OAB reported for ≥6 months were eligible for screening and study enrolment. To be eligible for randomization after the 2-week placebo run-in period, patients had to report a mean number of voids/24 hr of ≥8, ≥3 episodes of urgency and/or ≥3 episodes of urgency incontinence during a 3-day voiding - diary period.	Significant BOO, an assessment based on measuring the postvoid residual urine volume(PVR); patients with a PVR of ≥100mL; presence of BOO symptoms assessed by investigators(who were all urologists); urinary retention, demonstrable stress incontinence, bladder stones, UTI, interstitial cystitis, previous or current malignant disease of the pelvic organs; those taking concomitant anticholinergic medications; known hypersensitivity to anticholinergic medications or lactose.	solifenacin 5mg or 10mg	Propiverine or placebo	Funded and sponsored by Astellas Pharma Inc.(formerly Yamanouchi Pharma-ceutical Co. Ltd), Tokyo, Japan	Osamu Yamaguchi and Eji Marui are consultants to Atellas Pharma
Zellner, 2009[411] Study: RCT N: 1659	Male or female outpatients aged ≥18 years with urinary frequency ≥8 micturitions per day) and urge incontinence (≥5 episodes per week), as verified in the micturition diary.	Patients were excluded if they did not complete the micturition diary correctly for 7 consecutive days to confirm that they met the inclusion criteria and to establish baseline symptoms and urgency severity before the entrance visit. Based on this diary, patients with a total daily urine volume ≥2.8 L (determined by total daily urine for 2 days, divided by 2), a mean micturition volume of >250 mL, and/or a clinically significant bladder outlet obstruction (ie, postvoid residual urine volume of >100 mL, determined via sonography) were also excluded as were those with an indwelling catheter or intermittent self-catheterization. Those with other significant medical problems or urogenital conditions, including urinary tract infection at the screening visit (or before or at the entrance visit), interstitial cystitis and/or hematuria (as determined via	Oxybutynin Hydrochloride	Trospium Chloride	Dr. R. Pfleger GmbH (Bamberg, Germany) sponsored this study. Petra Schwantes, PhD, Biomedical Services, assisted with the writing of this article; she received compensation from the sponsor.	Petra Schwantes, PhD, Biomedical Services, assisted with the writing of this article; she received compensation from the sponsor. The authors have indicated that they have no other conflicts of interest regarding the content of this article.

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
		urinalysis), contraindications to anticholinergic therapy (eg, untreated narrow-angle glaucoma, mechanical gastrointestinal stenosis, myasthenia gravis syndrome), tachycardiac arrhythmia, severe psychiatric illnesses, or hypersensitivity to trospium chloride or oxybutynin or 1 of the vehicle ingredients, were also excluded. Patients who had participated in a bladder-training program, or in another study within 30 days before screening, were also prohibited, as were those undergoing electro stimulation programs. Further reasons for exclusion were alcohol and/or drug abuse, pregnancy, breastfeeding, and insufficient contraception among women of childbearing age.				
Zinner, 2005[412] RCT US N: 76	Males and non-pregnant (nor breastfeeding) females aged 18–85 years with urge incontinence (>4 significant incontinent episodes per week, where significant was defined as leakage that would normally require a change of clothing or absorbent pad) and urinary frequency (≥8 voids per day, on average).	Neurogenic bladder or stress incontinence, contraindications to antimuscarinic therapy, previous bladder or prostate surgery, bladder stones (as demonstrated by pelvic x-ray or ultrasound), acute or chronic urinary tract infection, significant urinary outflow obstruction, and clinically significant concomitant disease; Patients intending to start or modify either an existing bladder training program or existing treatment with thyroid or estrogen hormone replacement therapy; those who had received treatment with drugs that affect bladder function/urine production in the previous 2 weeks.	Darifenacin controlled-release tablets 15 mg and 30 mg once/daily	Oxybutynin 5 mg three times daily, Placebo	Industry +Grant	Disclosure

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Zinner, 2008[413] CT Country not reported N: 500	Men and women (>18 years of age) with OAB symptoms [an average of > 8 micturitions/ 24 hours; >1 urgency episode/24 hours, with or without urgency urinary incontinence; >2 scores on the Patient Perception of Bladder Condition (PPBC) questionnaire; naive to darifenacin, dissatisfaction with previous oxybutynin ER or tolterodine ER administration after at least 1 week of taking these medications.	Mean daily urinary volume >3000 ml or a mean volume micturition of >300 ml (in micturition diary); clinically predominant and bothersome stress urinary incontinence, urinary retention, clinically significant bladder outlet obstruction, an indwelling catheter or intermittent self-catheterization; significant medical problems or urogenital conditions, including neurogenic bladder, cystocele or distal pelvic organ prolapse, frequent urinary tract infections (>3 over the preceding year) or urogenital surgery in the previous year or unexplained hematuria at screening; bladder-training program or any electro-stimulation therapy within 2 weeks prior to screening; pregnancy or inadequate contraception. Concomitant treatment with anticholinergics, antispasmodics, serotonin-noradrenalin-reuptake-inhibitors; cholinergic agonists, cholinesterase inhibitors (e.g. bethanecol, donepezil and rivastigmine), potent inhibitors of cytochrome CYP3A4 (e.g., ketoconazole, itraconazole, ritonavir, nelfinavir, clarithromycin and nefazadone), potent P-glycoprotein inhibitors (e.g. cyclosporine and verapamil), drugs with significant anticholinergic side effects (e.g. tricyclic antidepressants, selective-serotonin-reuptake-inhibitors and first generation antihistamines) or any other investigational drug.	Darifenacin 7.5 mg once daily (qd) for the first 2 weeks with voluntary up-titration to darifenacin 15 mg if the patient required additional efficacy, and treatment was well tolerated	Placebo	Funding for this study and for the editorial and project management services of ACUMED in the preparation of this manuscript were provided by Novartis Pharma AG.	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Zinner, 2006[414] RCT Country not reported N: 445	Men and women aged >18 years with a history of OAB for >6 months and on average >1 urge incontinence episodes/day; >8 micturitions/day; >4 urgency episodes/day and mean warning time of <15 minutes during 12 consecutive hours.	Stress urinary incontinence; marked cystocele or pelvic prolapse; those taking the following drugs in the 2 weeks prior to the screening visit: anticholinergic/antispasmodic drugs, or those with anticholinergic effects, cholinergic agonists, potent cytochrome P450 3A4 inhibitors, opioids and drugs that cause significant constipation; those who have contraindications to anticholinergic drugs, clinically significant bladder outlet obstruction, have the intention to start a bladder training program and an indwelling catheter or intermittent self-catheterization.	Darifenacin 15 mg controlled release qd	Placebo	This study was funded by Novartis Pharma AG	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Zinner, 2004[37] Trospium Study Group. USA N: 523	The Trospium Study Group: male and female 18 years or older with OAB symptoms for at least 6 months; with urinary urgency, a minimum voiding frequency of 70 voids per week with at least 7 urge incontinence episodes per week.	Predominantly stress UI , insensate or overflow in nature; with neurogenic bladder disorders, significant renal disease, uninvestigated hematuria and urinary tract infection at washout or more than twice during the prior year; significant bladder outlet obstruction (post-void residual volume >100 ml); concurrent use of any anticholinergic drug or other drug therapy for overactive bladder within 21 days before randomization, history of bladder surgery within 6 months before randomization, bladder cancer or interstitial cystitis were excluded from study; diuretic use, estrogen therapy and nonmedical bladder therapy that was not part of a stable, long-term program.	20 mg trospium twice daily	Placebo	Indevus Corporation	Not reported
Zinner, 2002[415] RCT Europe, United States, Canada, Australia, and New Zealand N: 1015	Men and women aged 18 and older with urinary frequency (>8 micturitions/24 hours), urge incontinence (>5 episodes per week), symptoms of overactive bladder for 6 months or more, and ability and willingness to complete micturition charts.	Stress incontinence; total daily urine greater than 3 L; significant hepatic or renal disease; symptomatic or recurrent urinary tract infections; interstitial cystitis, hematuria, or clinically relevant bladder obstruction; bladder training or electro-stimulation within 14 days before randomization; and indwelling catheter or intermittent self-catheterization, pregnancy and breastfeeding; unreliable contraceptive methods; Treatments for overactive bladder (excluding estrogen treatment started more than 2 months before randomization), anticholinergic drugs, or potent inhibitors of cytochrome P450 3A4 isoenzymes.	Tolterodine ER 4 mg once daily	Placebo	Pharmacia Corporation	Not reported

Appendix Table F27. Pharmacological treatments for female UI (continued)

Reference study, sample	Inclusion criteria	Exclusion criteria	Active	Control	Sponsorship	Conflict of interest
Zinner, 2005[416] Pooled USA N: 1157	Symptoms of urgency, an average of 10 or greater toilet voids daily and an average of 1 or greater UUI episode daily.	Reported previously	20 mg trospium chloride twice daily	Placebo	Indevus, Lilly, Pfizer, Watson, Bayer and Glaxo Smith Kline	Not reported

NR = Not reported

Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI

Reference	Study	Masking of the treatment status	Intention to treat	Allocation concealment	Adequacy of randomization	Sample size justification
Abrams, 2006[227]	1032 Study Group.	Double blind	Yes	Unclear	Adequate	No
Abrams, 1998[226]	RCT	Double-blind	Yes	NR	Adequate	Yes
Abrams, 2008[50]	Pooled	Double blind	Yes	Previously reported	Adequate	No
Altan-Yaycioglu, 2005[228]	RCT	Single blind	Not stated	Unclear	Adequate	No
Anderson, 1999[391] U.S. Food and Drug Administration, 1998[41]	OROS Oxybutynin Study Group	Double blind	No	Not reported	Adequate	No
Appell, 1997[229]	Pooled	Double blind	Yes	Unclear	Adequate	No
Appell, 2001[230]	OBJECT (Overactive Bladder: Judging Effective Control and Treatment)	Double blind	Yes	Unclear	Adequate	No
Armstrong, 2005[231]	RCT	Double blind	No	Previously reported	Previously reported	Previously reported
Armstrong, 2007[232]	Pooled	Double blind	Yes	Previously reported	Adequate	Previously reported
Rios, 2007[364]	RCT	Double blind	Yes	Unclear	No	Yes
Barkin, 2004[233]	UROMAX Study Group.	Double blind	Yes	Unclear	Adequate	No
Bent, 2008[234]	RCT	Double blind	Yes	Adequate	Adequate	Yes
Birns, 2000[235]	The Oxybutynin CR Clinical Trial Study	Double-blind	Yes	Adequate	Adequate	Yes
Blom, 1995[236]	RCT	Single blind	No	NR	NR	No
Bodeker, 2010[237]	Post-hoc	Double blind	Reported previously[417]	Reported previously[417]	Adequate	Previously reported
Brubaker, 2008[238]	Pelvic Floor Disorders Network.	Double blind	Not stated	Unclear	Adequate	Yes
Brunton, 2010[239]	RCT	Double-Blind	NR	NR	Adequate	NR
Bump, 2003[108]	Duloxetine Urinary Incontinence Study Group.	Double blind	No	Previously reported	Adequate	Yes
Bump, 2008[240]	Pooled	Combination	Not stated	Previously reported	Previously reported	No
Burgio, 2001[241]	RCT	Double blind	No	Unclear	Not reported	No
Burgio, 2000[242]	RCT analysis	Double blind	Not reported	Not reported	Not reported	No

Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI (continued)

Reference	Study	Masking of the treatment status	Intention to treat	Allocation concealment	Adequacy of randomization	Sample size justification
Burgio, 1998[243]	RCT	Double blind	Yes	Unclear	No	No
Burgio, 2008[244]	Urinary Incontinence Treatment Network	Open label	Yes	Unclear	Not reported	Yes
Burgio, 2010[247]	RCT	Open-label	Yes	NR	Not-adequate	Yes
But, 2010[248]	SOLIDAIR	Open-Label	Yes	NR	Not-adequate	NR
Cardozo, 2006[250]	Pooled	Double blind	No	Previously reported	Adequate	Previously reported
Cardozo, 2004[251]	RCT	Double blind	Yes	Adequate	Adequate	Yes
Cardozo, 2004[53]	RCT	Double blind	No	Previously reported	Adequate	Yes
Cardozo, 2010[249]	RCT followed by open-label	Double blind	Yes	Adequate	Adequate	Yes
Cardozo, 2008[63]	SUNRISE	Double blind	Yes	NR	Adequate	Yes
Cartwright, 2011[252]	RCT	Not reported	Yes	Adequate	Adequate	Yes
Castro, 2008[253]	RCT	Single blind	No	NR	Not Adequate	Yes
Castro-Diaz, 2007[254]	Duloxetine Dose Escalation Study Group.	Double blind	Yes	Unclear	Adequate	Yes
Chancellor, 2001[255]	RCT	Double blind	No	Not reported	Adequate	No
Chancellor, 2008[256]	The ABLE trial	Open label	Yes	Adequate	Adequate	Yes
Chancellor, 2010[257]	Post-hoc	Double blind	NR	Unclear	NR	NR
Chapple, 2005[258]	RCT	Double blind	No	Adequate	Adequate	Yes
Chapple, 2007[259]	RCT	Double blind	No	Adequate	Adequate	No
Chapple, 2008[260]	RCT analysis	Double blind	No	Adequate	Previously reported	No
Chapple, 2007[261]	RCT	Double blind	Yes	Unclear	Adequate	Yes
Chapple, 2005[262]	Pooled	Double blind	Yes	Previously reported	Previously reported	No
Chapple, 2004[265]	RCT	Double-blind	Yes	NR	Adequate	Yes
Chapple, 2004[266]	RCT	Double-blind	No	NR	NR	NR
Chapple, 2007[261]	RCT	Double blind	Yes	Unclear	Adequate	Yes
Chapple, 2007[263]	STAR study group	Double blind	Yes	Adequate	Adequate	Previously reported
Chapple, 2005[61]	The STAR study group.	Double blind	Yes	Adequate	Adequate	Yes
Chapple, 2006[264]	RCT	Single-blind	No	NR	Not adequate	Yes
Chapple, 2004[54]	RCT	Double blind	NR	NR	Adequate	Yes

Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI (continued)

Reference	Study	Masking of the treatment status	Intention to treat	Allocation concealment	Adequacy of randomization	Sample size justification
Chompootaweep, 1998[267]	RCT	NR	NR	Unclear	Adequate	No
Choo, 2008[268]	RCT	Double blind	No	NR	Adequate	No
Chu, 2009[269]	RCT	Double blind	No	Adequate	Adequate	Yes
Corcos, 2006[270]	Uromax Study Group	Double blind	Yes	NR	Adequate	Yes
Davilla, 2001[271]	Transdermal Oxybutynin Study Group.	Double blind	Not stated	Unclear	Adequate	Yes
Dessole, 2004[272]	RCT	Double blind	Yes	Adequate	Adequate	Yes
Diokno, 2003[273] Anderson, 2006[275] Chu, 2005[274]	OPERA (Overactive bladder: Performance of Extended Release Agents) trial	Double blind	Yes	Unclear	Adequate	No
Dmochowski, 2002[276]	Transdermal Oxybutynin Study Group.	Double blind	No	Unclear	Adequate	Yes
Dmochowski, 2008[48]	RCT	Double blind	Not stated	Unclear	Adequate	No
Dmochowski, 2005[277]	Transdermal Oxybutynin Study Group.	Double blind	Yes	Previously reported	Previously reported	Previously reported
Dmochowski, 2003[278]	Transdermal Oxybutynin Study Group.	Double blind	Yes	Unclear	Adequate	Yes
Dmochowski, 2003[279]	Duloxetine Urinary Incontinence Study Group	Double blind	Yes	Adequate	Adequate	Yes
Dmochowski, 2007[280]	RCT	Double blind	Yes	Previously reported	Previously reported	Previously reported
Dmochowski, 2010[375]	RCT	Double blind	Yes	Reported previously	Adequate	Yes
Dmochowski, 2010[281]	RCT	Double blind	Yes	Unclear	Adequate	Yes
Dorschner, 2000[282]	RCT	Double blind	No	Unclear	Adequate	No
Drutz, 1999[283]	RCT	Double blind	No	NR	Adequate	Yes
DuBeau, 2005[284]	RCT analysis	Double blind	No	Adequate	Adequate	Yes
Duckett, 2007[285]	Observational study	Open label	No	Not relevant	Not relevant	No

Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI (continued)

Reference	Study	Masking of the treatment status	Intention to treat	Allocation concealment	Adequacy of randomization	Sample size justification
Enzelsberger, 1995[286]	RCT	Open label	Not reported	Adequate	Adequate	No
Fitzgerald, 2008[245]	Urinary Incontinence Treatment Network.	Open label	Yes	Unclear	Not reported	Yes
Flynn, 2009[287]	RCT	Double blind	Yes	Adequate	Adequate	Yes
Foote, 2005[288]	Pooled	Double blind	Yes	Unclear	Adequate	No
Franzen, 2010[289]	RCT	Open label	Yes	Adequate	Adequate	Yes
Freeman, 2003[290]	RCT analysis	Double blind	No	Adequate	No	Previously reported
Gahimer, 2007[291]	The duloxetine exposures integrated safety database	Open label	Yes	Previously reported	Not relevant	No
Ghei, 2005[292]	RCT	Double blind	Yes	Adequate	Not reported	Yes
Ghoniem, 2005[293]	Duloxetine/Pelvic Floor Muscle Training Clinical Trial Group.	Double blind	Yes	Adequate	Adequate	Yes
Gleason, 1999[397]	Ditropan XL Study Group, non RCT	Open label	No	Not relevant	Not relevant	No
Goode, 2002[294]	RCT	Double blind	No	NR	Adequate	No
Goode, 2004[295]	RCT analysis	Double blind	No	Not reported	Not reported	No
Gupta, 1999[296]	RCT	Open label	No	Not reported	Not reported	No
Gupta, 1999[297]	Pooled	Double blind	Not reported	Not reported	Not reported	No
Gousse, 2010[298]	RCT	NR	NR	NR	Adequate	NR
Haab, 2006[299]	RCT analysis	Open label	Yes	Not relevant	Not relevant	No
Haab, 2005[300]	RCT analysis	Open label	Yes	Previously reported	Previously reported	Previously reported
Haab, 2004[301]	RCT	Double blind	Yes	Adequate	Adequate	Yes
Halaska, 2003[302]	RCT	Double blind	Yes	Unclear	Adequate	No
Herschorn, 2004[303]	RCT	Open label	Yes	Adequate	No	No
Herschorn, 2010[304]	VECTOR	Double-blind	Yes	NR	Adequate	Yes
Herschorn, 2008[305]	RCT	Double blind	Yes	NR	Adequate	Yes
Hill, 2006[44]	Darifenacin Study Group.	Double blind	Yes	Unclear	Adequate	Yes
Ho, 2010[306]	RCT	Open label	Yes	Unclear	Adequate	NR
Holtedahl, 2000[307]	RCT analysis	NR	Yes	Not adequate	Adequate	Reported previously

Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI (continued)

Reference	Study	Masking of the treatment status	Intention to treat	Allocation concealment	Adequacy of randomization	Sample size justification
Holtedahl, 1998[308]	RCT	Not reported	No	Unclear	Adequate	Yes
Homma, 2006[309]	RCT analysis	Double blind	No	Not reported	Adequate	No
Homma, 2004[310]	RCT	Double blind	Yes	Not reported	No	No
Homma, 2003[311]	Japanese and Korean Tolterodine Study Group	Double blind	Yes	Not reported	Adequate	Yes
Hurley, 2006[312] Viktrup, 2007[313]	Duloxetine Urinary Incontinence Study Group	Double blind	No	Previously reported	Not reported	Pooled analysis
Ishiko, 2001[314]	RCT	Open label	No	Unclear	Adequate	No
Jackson, 1999[315]	RCT	Double blind	Not reported	Not reported	Adequate	Yes
Jacquetin, 2001[316]	RCT	Double blind	Yes	Unclear	No	Yes
Johnson, 2005[317]	RCT analysis	Double blind	Not reported	Adequate	Adequate	Yes
Jonas, 1997[318]	International Study Group	Double blind	Not stated	Unclear	Adequate	No
Junemann, 2000[320]	RCT	Double blind	No	NR	NR	NR
Junemann, 2005[321]	RCT	Double blind	Yes	Unclear	Not reported	No
Junemann, 2006[319]	RCT	Double blind	No	NR	NR	NR
Kaplan, 2010[322]	RCT	Double blind	NR	NR	NR	Yes
Karademir, 2005[323]	RCT	Open label	No	Not reported	Adequate	No
Karram, 2009[324]	VENUS	Double blind	No	NR	Adequate	Yes
Kelleher, 2006[326]	RCT	Double blind	No	Previously reported	Previously reported	No
Kelleher, 2002[327]	RCT	Double blind	Yes	Unclear	Adequate	No
Kelleher, 2008[328]	Pooled analysis	Double blind	NR	Unclear	Adequate	NR
van Kerrebroeck, 2004[393]	Duloxetine Urinary Incontinence Study Group.	Double blind	Yes	Adequate	No	Yes
Van Kerrebroeck, 2001[394]	Tolterodine Study Group.	Double blind	Yes	Unclear	Adequate	No
Khullar, 2004[329]	RCT	Double blind	Yes	Adequate	Adequate	Yes
Khullar, 2008[330]	Pooled	Double blind	Yes	Previously reported	Previously reported	Previously reported
Kinchen, 2005[331]	RCT	Double blind	Yes	Adequate	Adequate	Yes
Kreder, 2003[332]	RCT analysis	Single blind	No	Unclear	Adequate	No

Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI (continued)

Reference	Study	Masking of the treatment status	Intention to treat	Allocation concealment	Adequacy of randomization	Sample size justification
Lackner, 2008[333]	RCT	Double blind	Yes	All study personnel were blinded to group assignment until data collection was complete.	Adequate	Yes
Landis, 2004[334]	RCT	Double blind	No	Previously reported	No	Previously reported
Lee, 2002[335]	RCT	Double blind	Yes	Not reported	Adequate	No
Lee, 2010[336]	Propiverine study on overactive bladder including urgency data	Double blind	No	Not adequate	Adequate	Yes
Lehtoranta, 2002[337]	RCT	Double blind	Yes	Not reported	Not reported	No
Leung, 2002[338]	RCT	Open label	Yes	Not reported	Adequate	Yes
Lin, 2008[339]	RCT	Double blind	Yes	Adequate	No	Yes
Lipton, 2005[340]	RCT	Double blind	No	Unclear	Not reported	Yes
Lose, 2000[341]	RCT	Open label	Yes	Unclear	Adequate	Yes
MacDiarmid, 2005[342]	Pooled	2 Double blind and one open label	Yes	Previously reported	Previously reported	Previously reported
Madersbacher, 1999[343]	RCT	Double blind	Yes	Not reported	Adequate	No
Malhotra, 2010[344]	RCT	Double blind	Yes	NR	Not adequate	Yes
Malone-Lee, 2009[345]	RCT	Double blind	No	Unclear	Adequate	Yes
Malone-Lee, 2009[346]	RCT	Double blind	Yes	Adequate	No	No
Mattiasson, 2009[65]	SOLAR	Single blind	Yes	NR	Adequate	Yes
Mattiasson, 2003[347]	RCT Tolterodine Scandinavian Study Group	Single blind	Yes	Adequate	Adequate	Yes
Milani, 1993[348]	RCT	Double blind	No	Unclear	Not relevant	No
Millard, 1999[349]	RCT	Double blind	Yes	Unclear	No	Yes
Millard, 2004[350]	Duloxetine UI Study Group	Double blind	Yes	Adequate	No	Yes
Moore, 1990[351]	RCT	Double blind	No	Adequate	Adequate	NR
Naglie, 2002[352]	RCT	Double blind	Yes	Unclear	Adequate	Yes
NCT00269750, 2005 [57]	RCT	Double-blind	NR	NR	NR	NR

Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI (continued)

Reference	Study	Masking of the treatment status	Intention to treat	Allocation concealment	Adequacy of randomization	Sample size justification
NCT00168454, 2008 [55]	RCT	Double-blind	NR	NR	NR	NR
NCT00444925, [58]	RCT	Double-blind	NR	NR	NR	NR
NCT00536484, [59]	RCT	Double-blind	NR	NR	NR	NR
NCT00178191, [56]	RCT	Double-blind	NR	NR	NR	NR
Nitti C, 2007[353]	RCT	Double blind	No	Adequate	Adequate	No
Norton, 1994[354]	RCT	Double blind	Yes	Not adequate	Adequate	Yes
Norton, 2002[355] Sahai, 2006[356]	Duloxetine Urinary Incontinence Study Group.	Double blind	Yes	Adequate	Adequate	Yes
1993[357]	Elderly American Multicenter Study Group	Double blind	Yes	Unclear	Adequate	Yes
Ozdedeli, 2010[358]	RCT	Open-label	No	Not adequate	Adequate	NR
Peters, 2009[359]	Overactive Bladder Innovative Therapy	Open label	No	Unclear	Adequate	Yes
Pontari, 2010[361]	RCT	Double blind	Yes	NR	Not adequate	No
Preik, 2004[392]	RCT	Double blind	No	Not reported	Adequate	No
Rentzhog, 1998[362]	RCT	Double blind	No	NR	Adequate	Yes
Richter, 2010[363]	ATLAS	Open label	Yes	Not adequate	Adequate	Yes
Robinson, 2007[365]	The Tamsulosin Study Group	Double blind	No	Adequate	Adequate	Yes
Rogers, 2009[366]	RCT	Double blind	No	NR	Adequate	NR
Rogers, 2009[368]	RCT	Open label	No	Previously reported	Previously reported	Previously reported
Rogers, 2008[367]	RCT	Double blind	No	Unclear	Adequate	Yes
Rudy, 2006[369]	RCT	Double blind	Yes	Unclear	Adequate	Yes
Rudy, 2006[36]	RCT analysis	Double blind	Yes	Unclear	Adequate	Yes
Rufford, 2003[370]	RCT	Double blind	No	Adequate	Adequate	Yes
Salvatore, 2005[371]	RCT	Open label	No	Not reported	Not reported	Yes
Sand, 2009[372]	Pooled	Double blind	No	Previously reported	Adequate	No
Sand, 2004[373]	RCT	Double blind	Yes	Not reported	Adequate	No
Sand, 2009[374]	Pooled	Double blind	Yes	Unclear	Adequate	Previously reported
Sand, 2006[376] Sand, 2007[377]	Multicenter Assessment of Transdermal Therapy in Overactive Bladder with Oxybutynin trial	Open label	Yes	Not adequate	Adequate	Yes

Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI (continued)

Reference	Study	Masking of the treatment status	Intention to treat	Allocation concealment	Adequacy of randomization	Sample size justification
Schagen van Leeuwen, 2008[378]	RCT	Double blind	Yes	Unclear	Adequate	Yes
Staskin, 2006[39]	Pooled	Double blind	No	Previously reported	Not reported	Previously reported
Staskin, 2007[47]	Trospium Study Group	Double blind	Yes	Adequate	Adequate	Yes
Staskin, 2004[379]	RCT	Double blind	Yes	Unclear	Adequate	Yes
Staskin, 2009[33]	RCT	Double blind	Yes	Not reported	Adequate	Yes
Staskin, 2009[380]	Post-hoc	Double blind	Yes	Reported previously	Adequate	NR
Staskin, 2009[52]	RCT	Double-blind	Yes	NR	Adequate	Yes
Staskin, 2009[52]	Pooled analysis of individual patient data	Not reported	Yes	Not reported	Adequate	Not reported
Steers, 2005[45]	RCT	Double blind	No	Unclear	Adequate	Yes
Steers, 2007[381]	Duloxetine OAB Study Group	Double blind	Yes	Unclear	Adequate	Yes
Swift, 2003[382]	Tolterodine Study Group	Double blind	Yes	Unclear	Adequate	No
Szonyi, 1995[383]	RCT	Double blind	No	Not reported	Adequate	Yes
Takei, 2005[384]	Japanese Tolterodine Study Group.	Combination	Yes	Not reported	Adequate	No
Tapp, 1990[385]	RCT	Double blind	No	Adequate	Adequate	Yes
Tincello, 2000[386]	RCT	Open label	Not reported	Adequate	Not adequate	Yes
Thuroff, 1991[387]	RCT	Double blind	No	Adequate	Adequate	NR
Toglia, 2009[325]	VENUS	Double blind	No	NR	Adequate	Yes
Toglia, 2010[388]	Post-hoc VENUS	Double blind	NR	Unclear	Not adequate	Previously reported
U.S. Food and Drug Administration, 2004[389]	RCT	Double-blind	NR	NR	NR	NR
U.S. Food and Drug Administration, 2004[35]	RCT	Double-blind	NR	NR	NR	NR
U.S. Food and Drug Administration, 2004[43]	RCT	Double-blind	Yes	NR	NR	NR
U.S. Food and Drug Administration, [62]	SUNRISE	Double-blind	Yes	NR	Adequate	Yes

Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI (continued)

Reference	Study	Masking of the treatment status	Intention to treat	Allocation concealment	Adequacy of randomization	Sample size justification
U.S. Food and Drug Administration, 2004[390]	RCT	Double-blind	Yes	NR	NR	NR
U.S. Food and Drug Administration, 1998[41]	RCT	Double-blind	NR	NR	NR	Yes
U.S. Food and Drug Administration, [64]	SOLAR	Single blind	Yes	NR	Adequate	Yes
U.S. Food and Drug Administration, 2007[40]	RCT	12 weeks double-blind followed by 9 months open-label	Yes	NR	Adequate	Yes
U.S. Food and Drug Administration, 2007[46]	RCT	12 weeks double-blind followed by 9 months open-label	Yes	NR	Adequate	Yes
U.S. Food and Drug Administration, [60]	STAR	Double-blind	NR	NR	Adequate	NR
Vardy, 2009[395]	VIBRANT	Double-blind	No	Not reported	Adequate	Yes
Vella, 2008[396]	Not RCT	Open label	No	Not relevant	Not relevant	No
Versi, 2000[42]	Ditropan XL Study Group	Double blind	Not reported	Adequate	No	No
von Holst[398]	RCT	Double blind	Yes	Unclear	Adequate	Yes
Waetjen, 2005[399]	RCT	Double blind	Yes	Adequate	Adequate	Yes
Wagg, 2006[400]	pooled analysis	4 double-blind studies and one open-label	NR	NR	NR	NR
Wang, 2006[401]	RCT	Single blind	No	Not adequate	Adequate	Yes
Wang, 2009[402]	RCT	Double blind	Yes	Adequate	Adequate	Yes
Mazur, 1995[403]	RCT	Open label	No	Unclear	Not reported	No
Weil, 1998[404]	RCT	Double blind	Yes	Unclear	No	No
Wein, 2007[405]	RCT analysis	Double blind	Yes	Previously reported	Adequate	No
Weinstein, 2006[406]	DESIRE (Duloxetine Efficacy and Safety for Incontinence in Racial and Ethnic populations).	Open label	Yes	Not relevant	Not adequate	No
Wiseman, 1991[407]	RCT	Double blind	No	Unclear	Adequate	Yes
Yalcin, 2006[408]	Pooled	Double blind	Yes	Previously reported	Previously reported	Previously reported

Appendix Table F28. Quality of the studies that examined pharmacological treatments for UI (continued)

Reference	Study	Masking of the treatment status	Intention to treat	Allocation concealment	Adequacy of randomization	Sample size justification
Yalcin, 2004[409]	Duloxetine UI Study Group	Double blind	Yes	Previously reported	Adequate	Pooled analysis
Yamaguchi, 2007[410]	RCT	Double blind	No	NR	Adequate	Yes
Zellner, 2009[411]	RCT	Double blind	Yes	Not adequate	Adequate	Yes
Zinner, 2005[412]	RCT	Double blind	No	Unclear	Adequate	Yes
Zinner, 2008[413]	RCT	Open label	No	Not relevant	Not reported	Yes
Zinner, 2006[414]	RCT	Double blind	Yes	Unclear	Adequate	Yes
Zinner, 2004[37]	Trospium Study Group.	Double blind	Yes	Unclear	Adequate	No
Zinner, 2002[415]	RCT	Double blind	Yes	Adequate	Adequate	Yes
Zinner, 2005[416]	Pooled	Double blind	Yes	Previously reported	Adequate	No

NR = Not reported

Table F29. Effects from local estrogen therapy compared to no active treatment

Treatments	Reference Studies	Subjects	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1,000 treated (95% CI)	Evidence
Continence							
Estrogen in tablets or jelly	1[308]	80	20.68 (1.23;346.46)	0.22 (0.08; 0.36)	5 (3; 12)	222 (83; 361)	Insufficient
Estradiol implant	1[370]	40	Not Significant				Insufficient
Improvement							
Estrogen in tablets or jelly	1[308]	80	4.28 (1.54; 11.87)	0.30 (0.12; 0.48)	3 (2; 9)	298 (117; 478)	Insufficient
Intravaginal estriol ovules	1[272]	88	4.29 (2.11; 8.71)	0.52 (0.35; 0.70)	2 (1; 3)	523 (348; 698)	Insufficient
Transdermal E2	1[399]	417	Stress 0.53 (0.36; 0.79) – Not significant in urgency UI	-0.13 (-0.21; -0.05)	-8 (-19 ;-5)	-128 (-205; -52)	Insufficient

Appendix Table F30. Continence after topical estrogen treatment compared to no active treatment (individual RCTs)

Reference N	Active	Definition of continence	Randomized active/ control	Active events/rate	Control events/rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1,000 treated (95% CI)
Holtedahl, 1998[308] 80	Local estrogen in tablets or jelly plus physiotherapy and electro stimulation	Number of cured: no reported leakage and no wet episodes	36/44	8/22	0/0	20.68 (1.23; 346.46)	0.22 (0.08; 0.36)	5 (3; 12)	222 (83; 361)
Rufford, 2003[370] 40	25 mg 17 beta-estradiol implant	Urgency, % of cured	20/20	3/15	2/10	1.50 (0.28; 8.04)	0.05 (-0.15; 0.25)		
Rufford, 2003[370] 40	25 mg 17 beta-estradiol implant	Stress incontinence, % cured	20/20	4/20	3/15	1.33 (0.34; 5.21)	0.05 (-0.18; 0.28)		
Rufford, 2003[370] 40	25 mg 17 beta-estradiol implant	Dysuria, % of cured	20/20	4/20	3/15	1.33 (0.34; 5.21)	0.05 (-0.18; 0.28)		
Rufford, 2003[370] 40	25 mg 17 beta-estradiol implant	Urge incontinence, % of cured	20/20	7/35	6/30	1.17 (0.48; 2.86)	0.05 (-0.24; 0.34)		

Appendix Table F31. Improvement in incontinence after topical estrogen treatment compared to no active treatment (individual RCTs)

Reference N	Active	Definition of outcome	Randomized active/ control	Active events/rate	Control events/rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1,000 treated (95% CI)
Holtedahl, 1998[308] 80	Local estrogen in tablets or jelly	Number of improved: reduction in frequency amount, or wet episodes	36/44	14/39	4/9	4.28 (1.54; 11.87)	0.30 (0.12; 0.48)	3 (2; 9)	298 (117; 478)
Dessole, 2004[272] 88	Intravaginal estriol ovules: 1 ovule (1 mg) once daily for 2 weeks and then 2 ovules once weekly for 6 months.	Rate of cured and improved	44/44	30/68	7/16	4.29 (2.11; 8.71)	0.52 (0.35; 0.70)	2 (1; 3)	523 (348; 698)
Waetjen, 2005[399] 417	14 mg of transdermal E2 per day for 4 months	Improved incontinence: the number of incontinence episodes per week decreased by 2 or more, 4 months	208/209	52/25	74/35	0.71 (0.52; 0.95)	-0.10 (-0.19; -0.02)		
Waetjen, 2005[399] 417	14 mg of transdermal E2 per day for 4 months	Improved incontinence: the number of incontinence episodes per week decreased by 2 or more, 2 years	208/209	57/27	80/38	0.72 (0.54; 0.95)	-0.11 (-0.20; -0.02)	-9 (-52; -5)	-109 (-198; -19)

Appendix Table F31. Improvement in incontinence after topical estrogen treatment compared to no active treatment (individual RCTs) (continued)

Reference N	Active	Definition of outcome	Randomized active/ control	Active events/rate	Control events/rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1,000 treated (95% CI)
Waetjen, 2005[399] 417	14 mg of transdermal E2 per day for 4 months	Improved stress incontinence: the number of incontinence episodes per week decreased by 2 or more, 4 months	208/209	30/14	57/27	0.53 (0.36; 0.79)	-0.13 (-0.21; -0.05)	-8 (-19; -5)	-128 (-205 ;-52)
Waetjen, 2005[399] 417	14 mg of transdermal E2 per day for 4 months	Improved stress incontinence: the number of incontinence episodes per week decreased by 2 or more, 2 years	208/209	37/18	61/29	0.61 (0.43; 0.87)	-0.11 (-0.19; -0.03)	-9 (-30; -5)	-114 (-195; -33)
Waetjen, 2005[399] 417	14 mg of transdermal E2 per day for 4 months	Improved urge incontinence: the number of incontinence episodes per week decreased by 2 or more, 4 months	208/209	25/12	26/13	0.97 (0.58; 1.62)	0.00 (-0.07; 0.06)		
Waetjen, 2005[399] 417	14 mg of transdermal E2 per day for 4 months	Improved urge incontinence: the number of incontinence episodes per week decreased by 2 or more, 2 years	208/209	27/13	35/17	0.78 (0.49; 1.23)	-0.04 (-0.11; 0.03)		

Appendix Table F32. Clinical outcomes after topical estrogen therapy compared to no treatment (individual RCTs)

Reference sample	Active	Definition of outcome	Randomized active/ control	Active events/rate	Control events/rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1,000 treated (95% CI)
Waetjen, 2005[399] 417/0	14 mg of transdermal E2 per day for 4 months	Worsened urge incontinence: the number of incontinence episodes per week increased by 2 or more.	208/209	5/2	21/10	0.24 (0.09; 0.62)	-0.08 (-0.12; -0.03)	-13 (-33; -8)	-76 (-122; -31)
Waetjen, 2005[399] 417/0	for 2 years	Worsened urge incontinence: the number of incontinence episodes per week increased by 2 or more.	208/209	27/13	38/18	0.71 (0.45; 1.12)	-0.05 (-0.12; 0.02)		
Waetjen, 2005[399] 417/0	for 2 years	Worsened incontinence	208/209	35/17	35/17	1.00 (0.66; 1.54)	0.00 (-0.07; 0.07)		
Waetjen, 2005[399] 417/0	for 2 years	Worsened stress incontinence	208/209	20/10	19/9	1.06 (0.58; 1.92)	0.01 (-0.05; 0.06)		
Waetjen, 2005[399] 417/0	for 4 months	Unchanged stress incontinence	208/209	136/66	124/59	1.10 (0.95; 1.28)	0.06 (-0.03; 0.15)		
Waetjen, 2005[399] 417/0	for 4 months	Unchanged urge incontinence	208/209	178/86	162/77	1.10 (1.01; 1.21)	0.08 (0.01; 0.15)	12 (6; 152)	81 (7; 155)
Waetjen, 2005[399] 417/0	for 4 months	Unchanged incontinence	208/209	106/51	95/46	1.12 (0.92; 1.37)	0.06 (-0.04; 0.15)		
Waetjen, 2005[399] 417/0	for 2 years	Unchanged urge incontinence	208/209	154/74	136/65	1.14 (1.00; 1.29)	0.09 (0.00; 0.18)	11 (6; 568)	90 (2; 178)
Waetjen, 2005[399] 417/0	for 2 years	Unchanged stress incontinence	208/209	151/73	129/62	1.18 (1.03; 1.35)	0.11 (0.02; 0.20)	9 (5; 52)	109 (19; 198)

Appendix Table F32. Clinical outcomes after topical estrogen therapy compared to no treatment (individual RCTs) (continued)

Reference sample	Active	Definition of outcome	Randomized active/ control	Active events/rate	Control events/rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1,000 treated (95% CI)
Waetjen, 2005[399] 417/0	for 2 years	Unchanged incontinence	208/209	116/56	94/45	1.24 (1.02; 1.50)	0.11 (0.01; 0.20)	9 (5; 80)	108 (13; 203)
Waetjen, 2005[399] 417/0	for 4 months	Worsened incontinence	208/209	50/24	40/19	1.26 (0.87; 1.82)	0.05 (-0.03; 0.13)		
Waetjen, 2005[399] 417/0	for 4 months	Worsened stress incontinence	208/209	42/20	28/14	1.51 (0.97; 2.34)	0.07 (0.00; 0.14)		
Waetjen, 2005[399] 417/0	for 2 years	New developed incontinence at 2 years	208/209	81/39	77/37	1.06 (0.83; 1.35)	0.02 (-0.07; 0.11)		
Dessole, 2004[272] 88/0	Intravaginal estriol ovules: 1 ovule (1 mg) once daily for 2 weeks and then 2 ovules once weekly for 6 months.	Subjective complaints of stress urinary incontinence.	44/44	14/32	37/84	0.38 (0.24; 0.59)	-0.52 (-0.70; -0.35)	-2 (-3; -1)	-523 (-698; -348)
Holtedahl, 1998[308] 80/0	Local estrogen in tablets or jelly	Worse incontinence: self reported worsening of severity or impact	36/44	4/11	13/30	0.38 (0.13; 1.05)	-0.18 (-0.35; -0.01)	-5 (-67; -3)	-184 (-354; -15)
Holtedahl, 1998[308] 80/0	Local estrogen in tablets or jelly	Unchanged incontinence: no changes in frequency, amount, or wet episodes	36/44	10/28	27/61	0.45 (0.25; 0.81)	-0.34 (-0.54; -0.13)	-3 (-8; -2)	-336 (-541; -131)

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Adherence to the drugs	Yeaw, 2009[418]	To assess variations in adherence and persistence for anti-muscarinic medications (overactive bladder)	7,722	78.20%	NR	Retrospective analysis	1 year	PharMetrics Patient-Centric Database, a nationally representative database of more than 64 million individual members enrolled in 100 U.S. health plans. Patients were included in the analysis if they initiated a retail or mail-order prescription drug of interest between January 1 and December 31, 2005.	At 6 months post-index, with the application of a 60-day refill grace period, persistence rate (A patient was considered persistent until an excessive gap in days supplied occurred; refill gaps of 30, 60, and 90 days were used to calculated persistence for all cohorts) for OAB medications was 28% and at 1-year it was 18%. Mean (SD) patient adherence calculated as a continuation measure of PDC over a 12-month followup period was 35% (32%) for OAB medications.
Drug fesoterodine	Michel, 2008[419]	To review the preclinical and clinical data on fesoterodine	NR	NR	NR	2, 4, 8, or 12mg/day of fesoterodine	NA	20 phase 1, three phase II and two phase III studies	4 and 8mg once daily doses were consistently superior to placebo in improving the symptoms of overactive bladder syndrome, with 8mg/day having significantly greater effects than 4mg/day

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Drug fesoterodine	Cole, 2004[420]	NR	728	NR	NR	4, 8 and 12mg fesoterodine once daily	12 weeks	Phase II clinical trial in 728 patients with OAB at sites in Europe, Israel and South Africa	Dropout rates due to adverse events were 4% in the placebo group, 6%, 2% and 12% in the 4mg, 8mg and 12mg groups, respectively. Dry mouth was reported in 9%, 25%, 26% and 34% of patients in placebo and fesoterodine 4-, 8-, and 12-mg groups, respectively
Drug fesoterodine	Kelleher, 2008[421]	To present an overview of the components and construction of an economic model using the costs and outcomes associated with fesoterodine	NR	NR	NR	Fesoterodine 4mg daily and fesoterodine 8mg daily	12 weeks	NR	The QALS (Quality-adjusted life year) gained were 0.0111 for tolterodine 4mg/d, 0.0115 for solifenacin, 0.0124 for fesoterodine 4mg/d and 0.0143 for fesoterodine 8mg/d. Fesoterodine may result in fewer overall costs and greater QALYs gained than treatment with tolterodine and solifenacin for the management of patients with OAB and incontinence

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Drug tolterodine	Kelleher, 2002[422]	To evaluate the long-term effects of tolterodine on the health-related quality of life (HRQoL) of patients diagnosed with overactive bladder with incontinence	1077	82.00%	NR	Tolterodine 4mg once daily	12 weeks of RCT followed by 12 months of open - label	Participants of 12 weeks RCT continued a one-year open-label, uncontrolled, nonrandomized study at 138 research centers and clinics. They were eligible if they had an average of 8 or more micturitions per 24 hours over a 7-day period and at least 5 urge incontinence episodes per week	Mean changes in the KHQ scores from rollover (start of open-label study) and month 12: in PT (placebo-treated group: incontinence impact=-12.7 (1.8) and in TT (tolterodine-treated) group=-5.9 (1.2); role limitations in PT=-11.6 (1.8) and in TT=-4.1 (1.2); physical limitations in PT=-10.1 (1.7) and in TT=-2.9 (1.2) severity (coping) measures in PT=-5.1 (1.3) and in TT= -2.1 (0.9) and symptom severity in PT=-6.6 (0.9) and in TT=-0.8 (0.6)

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Drug tolterodine	Siami, 2002[423]	To assess the speed of onset of therapeutic benefit with tolterodine extended-release 4mg	1138	73.46%	NR	Tolterodine extended-release 4mg once daily	12 weeks	The Speed of Onset of Therapeutic Assessment Trial (STAT). Men and women aged ≥18 years with a diagnosis of OAB, with symptoms of urinary frequency (≥8 micturitions/24 hours) and urgency with or without urge incontinence. Patients were categorized into drug-naïve and previously treated (that is those receiving pharmacologic treatment other than tolterodine for OAB)	72% of the maximum effect on urge incontinence was observed in both groups; and 84.7% of drug-naïve patients and 83.6% of previously treated patients perceived a benefit from benefit. Dry mouth was reported in 15.5% of drug naïve patients and 15.5% of previously treated patients also. In drug - naive group:10.8% had mild dry mouth, 3.1% had moderate and 1.6% had severe and in previously treated patients 11.85 had mild dry mouth, 3% had moderate and 0.7% had severe dry mouth

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Drug tolterodine	Kreder, 2002[424]	To examine the long-term safety, tolerability and efficacy of tolterodine extended-release in patients who had completed 12 weeks of treatment in a randomized, double-blind study comparing tolterodine ER4mg once daily, tolterodine immediate-release 2mg twice daily and placebo	1077	82%	NR	Tolterodine extended-release 4mg once daily	12 month open-label after 12 weeks RCT	Men and women aged ≥18 years with urinary frequency (≥8 micturitions/24 hours; urge incontinence (≥5 incontinence episodes per week) and urgency; and symptoms of overactive bladder for ≥6 months	A total of 75% of patients had an improvement in their bladder condition and 51% had an improvement in their urgency. 139 (12.9%) reported dry mouth, 35 (3.3%) had constipation, 24 (2.2%) had dyspepsia, 43 (4%) had upper respiratory tract infection, 28 (2.6%) had bronchitis, 44 (4.1%) had UTI, 23 (2.1%) had cystitis, 26 (2.4%) had headache
Duloxetine	Wernick, 2007[425]	The cardiovascular safety profile of the SNRI duloxetine through evaluation of cardiovascular-related parameters and adverse events	Data from 42 placebo-controlled clinical trials of 8,504 patients			Duloxetine 40-80mg vs. placebo	Varied	Adults with major depressive disorder (15 studies), diabetic peripheral neuropathic pain (3 studies), fibromyalgia (2 studies), generalized anxiety disorder (3 studies) and lower urinary tract disorders (19 studies, all related to incontinence).	Duloxetine resulted in decrease from baseline in RR, QRS and QT intervals but not clinically significant

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Duloxetine	Michel, 2009[426]	To evaluate the safety and tolerability of duloxetine in the treatment of female stress incontinence in women greater than 18 years of age	5879	100	100	20mg duloxetine daily	Not reported	Female patients with stress incontinence and greater than 18 years of age	Adverse events occurred at a rate of 9.1& in the duloxetine group and 5.7% in the control group
Estrogen combined with tolterodine	Serati, 2009[427]	To compare the efficacy of antimuscarinic alone versus antimuscarinic combination with local estrogens for OAB; to verify whether risk factors for lower antimuscarinic efficacy can be overcome by the concomitant use of local estrogens	236	100	Not reported	Subjects in group 1 were prescribed only tolterodine ER 4mg once daily to be taken at night for at least 12 weeks; subjects in group 2 were prescribed both tolterodine ER 4mg and concomitant estrogen cream application once daily to be taken at night for at least 12 weeks	12 weeks	Postmenopausal (women were considered postmenopausal if they were >40 years old and reported absence of menses for at least 12 months) women with symptomatic urodynamically proven detrusor overactivity	The efficacy of the therapy was 80.6% in the tolterodine group and 82% in the tolterodine and estrogen group. 62.8% were cured, 17.8% showed improvement, and 19.4% were nonresponders in the tolterodine alone; and 62% were cured, 20% showed improvement, and 18% were nonresponders in the tolterodine and estrogen group
Antimuscarinic drugs and bladder training vs. bladder training alone	Ghei, 2006[428]	Cooperative effectiveness of antimuscarinic drugs and bladder training vs. bladder training alone in adults with urge UI	664 women and 44 men	93.8	100	Oxybutynin, tolterodine, or imipramine combined with antimuscarinic drugs and bladder	16 weeks	Adults with mean 54 years and overactive bladder and no significant stress UI	Antimuscarinic drugs were more effective reducing UI

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Solifenacin VOLT (VESIcare Open-Label Trial)	Garely, 2006[429]	VOLT study: perceptions of improvements in symptom bother and health-related quality of life with solifenacin succinate 5- and 10-rag treatments in patients with OAB	2,225	82.2	100	Solifenacin succinate 5- and 10-rag	12 weeks	VOLT (VESIcare Open-Label Trial):adult (aged >18 years) men and women (82.2%) with OAB (urgency, urge UI, frequency, and/or nocturia for ≥3 months)	Some improvement-73%;improvement in UI-60%; Treatment-emergent adverse events -59%; 10% discontinued treatment due to adverse events
Solifenacin VOLT (VESIcare Open-Label Trial)	Garely, 2006[429]	VOLT study: OAB patients' perceptions of improvements in symptom bother and quality of life after solifenacin under conditions reflecting day- to-day practice.	582	92.1	100	Flexibly dosed, once-daily solifenacin	12 weeks	VOLT (VESIcare Open-Label Trial): Adults who had OAB symptoms and urge UI for 3 months or longer	80% of patients achieved improvement in their PPBC score. (61.3%) experienced an adverse event during treatment. Adverse Event: Dry mouth 104 (17.9)
Solifenacin VOLT (VESIcare Open-Label Trial)	Capo, 2008[430]	To report patient satisfaction with treatment, as measured by symptom bother and HRQoL, in a subgroup of Hispanics participating in an open-label study of solifenacin succinate	94	74	63	Solifenacin 5m/d with a dosing option of 5 or 10mg/d at weeks 4 and 8	12 weeks	This is a subset analyses of Hispanic patients enrolled in the VOLT study. Ambulatory men and women 18 years of age and older with symptoms of OAB for at least 3 months and able to use the toilet without difficulty	Over 72% of patients experienced PPBC score improvement. Hispanics receiving solifenacin for OAB reported improvement from baseline in symptom bother and HTQoL

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Solifenacin VOLT (VESIcare Open-Label Trial)	Sand, 2009[431]	To determine the efficacy of solifenacin to improve subjects' MBS (Most Bothersome Symptom) based on PRO (Patient-Reported-Outcome) measures	2225	74.56%	26.16%	Solifenacin 5m/d with a dosing option of 5 or 10mg/d at weeks 4 and 8	12 weeks	VOLT is a study in adults with OAB symptoms for >=3 months	The UUI group showed the largest VAS(Visual Analogue Scale), OAB-q, and PPBC improvements. 90.7% of patients whose MBS was UUI showed improved VAS score; 94% of patients whose MBS was UUI showed improved VAS:UUI score; 88.8% of patients whose MBS was UUI showed improved VAS: daytime urinary frequency, and 86.6% of patients whose MBS was UUI showed improvement in VAS: Nocturia score

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Solifenacin VOLT (VESIcare Open-Label Trial)	Mallett, 2007[432]	To present patient-reported outcomes, as measured by symptom bother and HRQoL, in black patients participating in an open-label study of solifenacin succinate	274 black and 2205 white patients	81.73%	26.83%	Solifenacin 5mg or 10mg once daily according to an individualized flexible-dosing regimen	12 weeks	VOLT study: Men and women aged 18 years or older with symptoms of OAB for 3 months or longer; ambulatory who were able to use the toilet without difficulty and who had not received solifenacin	86.5% of black patients with urinary urgency found it bothersome after solifenacin treatment than at baseline; 87.9% found urge incontinence less bothersome. 46.4% of black subjects experienced an adverse event ; of these 30.1% had at least one treatment-related adverse event; 13% had dry mouth, 6.9% had constipation, 2.5% had blurred vision, 2.5% had nausea, and 2.2% had rash. A total of 7.6% black subjects discontinued treatment due to an adverse event.

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Solifenacin VERSUS study	Chancellor, 2008[433]	To assess the efficacy, tolerability, and effects on HRQL of solifenacin in patients with residual urgency after ≥4 weeks of treatment with tolterodine extended release 4mg	441	88.2	69.39%	Solifenacin 5m/d with dose adjustment at weeks 4 and 8	12 weeks	VERSUS study: patients ages >18 years who had symptoms of OAB for ≥3 months, had been treated with tolterodine ER 4mg for ≥4 weeks and wished to switch therapy because of a lack of sufficient subjective improvement in urgency.	A mean decrease of 3.4 urgency episodes/24 hours (95% CI,-3.8 to -3.0; p<0.001); a mean improvement of 1.2 points (95% CI, -1.3 to -1.1; p<0.001) in PPBC score; changes in all OAB-q scales and domains (symptom bother, coping, concern, sleep, social interaction, and total HRQL) were also statistically significant(p<0.0001). Treatment emergent AEs such as dry mouth (77[17.5%]), constipation (51[11.6%]), and blurred vision (10[2.3%]).

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Solifenacin VERSUS study	Swift, 2009[434]	To evaluate the effects of solifenacin in OAB patients with high symptom bother, this post hoc analysis focuses on the VERSUS 'severe cohort', as defined by patients with scores ≥5 on the PPBC scale at baseline (on tolterodine ER mg/d) who remained severe at post-washout (when the patients were receiving no drug)	440, but 116 were from the severe cohort	88.8	Not reported	Solifenacin 5m/d with dose adjustment at weeks 4 and 8	12 weeks	VERSUS study: Men and women ages >18 years with symptoms of OAB for ≥3 months who were ambulatory and able to use the toilet without difficulty and who had received tolterodine ER 4mg/d for ≥4 weeks but wished to switch therapy because of lack of sufficient subjective improvement in urgency	In the severe OAB cohort, the mean number of urgency episodes/24 hours decreased by 3.95(97% CI: -4.81, -3.08; p<0.0001)
Solifenacin VERSUS study	Zinner, 2009[435]	To assess changes in health-related quality of life, medical care resource utilization, work, and activity impairment, and health utility among elderly patients with OAB who continued to have urgency symptoms with	441	88	Not reported	Solifenacin 5mg/d with dosing adjustments allowed at week 4 (to 10mg/d) and at week 8 (back to 5mg/d for patients whose dose was increased to 10mg/d at week 4)	12 weeks	Patients who have been treated with tolterodine 4mg/d for ≥4 weeks immediately preceding study entry without sufficient improvement in urgency episodes	Subgroup analysis included 108 patients 65 to 74 years of age and 86 patients ≥75 years of age. Patients in both groups experienced significant improvement in HRQoL (p<0.001), as well as significant reduction in non protocol-related office visits (p<0.001) and activity management (p<0.025). A significant reduction in the use of

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
		tolterodine and were willing to try solifenacin							pads/diapers was reported for patients 65 to 74 years of age ($p<0.018$), and patients in this age group who were working reported significantly less impairment related to OAB while working during solifenacin treatment than during tolterodine treatment ($p<0.042$). No significant differences in HUI2/3 scores were observed in either of the elderly groups. Solifenacin was found to improve symptom bother, HRQoL, work productivity, activity participation, and reduced medical care resource utilization in the elderly subjects with OAB who continued to have urgency symptoms with tolterodine and were willing to try solifenacin

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Solifenacin VERSUS study	Zinner, 2008[436]	To evaluate the health outcomes, in terms of medical resource use, work and activity impairment, and health utility, of these patients	441	88.2	Not reported	Solifenacin 5m/day with dose adjustment at weeks 4 and 8	12 weeks	Men and women aged >=18 years with symptoms of OAB for >=3 months who were ambulatory and bale to use the toilet without difficulty and who had been treated with tolterodine ER 4mg/d for at least 4 weeks immediately preceding study entry, but failed to achieve satisfactory improvement in urgency episodes	3.9% discontinued treatment due to adverse events. Patients who were working reported a reduction in percent of work time missed (0.2% vs. 2.1%; p=0.0017), a reduction in percent of impairment while working (11.3% vs. 22.9%; p<0.0001), and a reduction in percent of overall work impairment (11.9% vs. 24.0%; p<0.0001), while a larger group of patients reported a reduction in percent of activity impairment (18.4% vs. 31.6%; p<0.0001)
Treatments for overactive bladder	Sexton, 2009[437]	To assess the impact of OAB on work productivity among employed men and women under the age 65 in the United States	5696	52.92%	7.86%	OAB	NA	Cross-sectional survey of working (full-or part-time) men and women aged 40 to 65 years. This study is part of a study conducted in the US, UK and Sweden. This study focused only on US participants.	Work limitations questionnaire total score, mean (SD): men and continent OAB group=9.3 (14.3) and women and continent group=10.8 (15.6); men and incontinent group=12.5 (16.7) and women and incontinent group=12.6 (16.7); men and no/minimal symptoms=0.6 (4.2) and women and no/minimal

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
									symptoms=1.0 (5.3) The regression coefficient in men: urgency with fear of leaking vs. urinary - specific work impairment scores (higher scores indicate greater impairment)=2.232 and in women=0.960; UUI and urinary-specific work impairment scores in men=0.832 and in women=0.941; SUI and urinary-specific impairment scores in men=1.189 and in women=1.312 and nocturnal enuresis and urinary-specific impairment scores in men=1.318 and in women=1.025

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Treatments for overactive bladder	Irwin, 2006[438]	To determine the impact of overactive bladder symptoms on issues related to employment, social interactions, and emotional well-being in a population aged 40-64 years	1272	50.80%	NR	OAB	NA	Cross-sectional survey of 11,521 individuals aged 40-64 years and 1,272 of them had OAB	Of those with OAB, approx. 32% reported that having these symptoms made them feel depressed and 28% reported feeling very stressed. 36.4% of OAB with incontinence patients reported emotional stress as compared to 19.6% of patients with OAB and no incontinence. 39.8% of OAB with incontinence patients reported depression as compared to 23.3% patients with OAB and no incontinence. Overall, 76% of individuals reporting OAB symptoms stated that this condition interfered with or made it more difficult to perform daily activities
Treatments for overactive bladder	Wu, 2005[439]	To assess the indirect work loss costs to employers as the result of employees with overactive bladder	21,087	NR	NR	OAB	NA	There were two samples: Sample1 was used to analyze OAB employees' work loss patterns and costs and sample2 was used to assess OAB employees' time	Employees with OAB had 2.2 excess days of work loss absenteeism to medically related absenteeism and 3.4 excess days attributable to disability compared with control subjects ($p<0.01$ for both comparisons).Multivariate regression analysis revealed that

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
								to disability and related risk factors. Individual enrollees in both samples were active employees, 18 to 64 years, with at least one diagnostic code to identify OAB	employees with AOB had 4.4 more days of work loss per year than control subjects(p<0.05).The average annual indirect work loss cost of an employee with OAB was $1220 from an employer's prospective, which was 1.7 times the indirect work loss cost of a control employee (i.e., $715) (p<0.01). Multivariate regression analysis showed that OAB imposes an indirect work loss cost burden of $391 per OAB employee per year from an employers' perspective (p<0.05). Kaplan - Meier analysis showed that employees with OAB had significantly shorter times to disability than did their non-OAB controls
Treatments for overactive bladder	Pelletier, 2009[440]	To evaluate adherence with overactive bladder pharmacotherapy and compare costs between patients receiving pharmacotherapy versus	86,734	78%	NR	OAB therapy	1 year	Anonymous, patient-level data were obtained from the PharMetrics Patient-Centric Database (Watertown, MA) which contains	14.4% of the aggregate OAB therapy cohort (43, 576) reached a PDC (proportion of days covered) of 80% or higher, with an average PDC of 32.4%. Following pharmacotherapy

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
		nonpharma-cological management						adjudicated medical and pharmaceutical claims for more than 90 US managed health care plans across the United States. Patients were 18 years or older and had at least 1 OAB diagnostic code or at least 1 prescription for an antimuscarinic OAB medication during a 24-month index window from January 1, 2005 through December 31, 2006. Subjects were required to have continuous health plan enrollment for a minimum of 6 months before and 12 months after the index date; during periods of continuous enrollment, all medical (inpatient and	initiation, OAB therapy subjects had significantly higher mean (median) total costs compared with nonpharmacological managed subjects ($9917 [$4598] vs. $9657 [$4299]; p<0.001). Nonpharmacologically managed subjects averaged $277 for OAB-related outpatient services compared with $176 for OAB therapy subjects (p<0.001), with 69% more OAB-related physician office visits and more than double the number of OAB-related laboratory tests among nonpharmacologically managed subjects contributing to this difference

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
								outpatient) and pharmacy (retail and mail order) claims are captured.	
Treatments for overactive bladder	Schabert, 2009[441]	To describe the challenges to improving management of overactive bladder outcomes and summarize research findings on critical success factors for supporting OAB treatment	5392	NR	NR	OAB therapy	NA	OAB Persistence Survey: respondents who had been prescribed one antimuscarinic or more for OAB over the prior 12 months	24.5% reported discontinuing one antimuscarinic prescription medication or more during the prior 12 months. Among these patients discontinuing medications, 45.4% reported unmet treatment expectations as the reason for discontinuation

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Treatments for overactive bladder	Bolge, 2006[442]	To examine the impact of overactive bladder on health care resource utilization, daily activities, work productivity, and health complications	441	76.40%	76.40%	Presence of OAB	NA	US National Health and Wellness Survey, 18, and internet population-based survey conducted annually by Consumer Health Sciences. It was administered to a representative sample of registered adult panelists aged 18 years or older in the United States. There were 2602 respondents who reported a history of OAB diagnosed by a physician and out of these 441 respondents were administered the survey for the study.	Of the 196 patients receiving prescription medication, 147 (75%) reported satisfaction with therapy. Of the 31 patients receiving behavioral therapy, 21 (67.7%) were satisfied with treatment. 63 of (48.8%) the 129 respondents taking Kegel exercises were satisfied with this treatment. Impairment in productivity was primarily attributed to lack of concentration (40%), followed by inability to complete tasks (5.4%). OAB reduced their daily activities but 27.6%. Successful treatment of OAB was associated with a significantly lower incidence of complications than unsuccessful treatment($p < 0.05$)

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Treatments for overactive bladder	Dmochowski, 2007[443]	To examine the effects of OAB on participants; treatment-seeking behaviors, patient satisfaction with oral OAB therapies, and desirable characteristics of new treatments	1228	100%	43%	Cross-sectional survey	NA	Women with symptoms of OAB , aged 40-65 years	87% of current users of OAB medications took their medication daily, with 70% taking it once daily. Only 32% were completely satisfied with their medications. Among respondents with OAB symptoms, 61% felt that less frequent dosing was 'very important' or 'extremely important. Among lapsed users of OAB medications, as compared with current users, significantly higher percentages indicated that it was extremely or very important to not feel nausea (79% vs. 59%), not have dry eyes (68% vs. 54%), not experience constipation as often(71% vs. 59%) and not have to take a high dose of medication (75% vs. 64%)

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Treatments for overactive bladder	Zhou, 2001[444]	To identify components of costs attributable to OAB, using medical claims data on insured patients with OAB between 18 and 64 years of age; to examine the demographic and health risk characteristics of patients with a primary or secondary diagnosis of OAB; and to suggest cost-effective treatment strategies for OAB	148,697	NR	NR	Presence of OAB	NA	Two cohorts were identified on the basis of whether individuals had received formal OAB treatment based on the ICD-9 codes for bladder disorders in the claims data. The OAB cohort consisted of 2385 persons with an outpatient claim, primary or secondary ICD-0 code specified for OAB; or persons with an inpatient claim, primary ICD-9 code specified for OAB. The non-OAB cohort included 146, 312 patients whose claims over the entire period showed none of the specified ICD-9 codes for OAB	The probability of hospital admission during the year was 20.65 among OAB patients compared with 7% among non-OAB patients. After adjustment for patient risk characteristics, total annual claims for a patient with OAB were 45% higher (p=0.0001), than for a patient without OAB. Annual inpatient claims were 23% higher but not significantly different form claims for a non-OAB patient. Much of the significance in cost for the OAB patients was due to age, sex, and the presence of non-OAB medical conditions.
Treatments for overactive bladder	Brubaker, 2010[445]	To identify predictors of self-reported discontinuation of overactive	5392	76%	NR	OAB therapy	1 year	OAB Medication Use Survey. Participants were representatives	Among 2838 respondents at phase3, 1194 had recently discontinued and 1644 were

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
		bladder medication using a three-phase survey						of the USA population identified from the Taylor Nelson Sofres (formerly National Family Opinion) household panel	persistent with medications at phase2. Among phase3 respondents who were persistent at phase2, 1040 continued to be persistent at phase3, 280 had discontinued between phases 2 and 3, and 261 had switched medication between phases 2 and 2; 63 had missing prescription at phase 3. Predictors of discontinuing at phase3 included smoking (OR:1.80; 95%CI=1.15-2.83, p=0.010), not knowing whether treating bladder problems requires multiple daily doses of medications (1.71, 1.10-2.67 ;p=0.018), believing (2.11, 1.34-3.33, p=0.001) or not knowing (1.76, 1.23-2.52, p=0.002) whether adverse effects of OAB medications are often severe, and being bothered ‘quite a bit or more’ by a sudden urge to urinate (1.54, 1.05-2.26; p=0.028). Respondents taking 2 or more medications

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
									were less likely to discontinue (OR: 0.45-0.58, p<0.05)
Treatments for overactive bladder	Benner, 2010[446]	To evaluate patient-reported reasons for discontinuing antimuscarinic prescription medications for OAB	5392	77.60%	26.80%	OAB therapy	1 year	Representative sample of households in the USA (260,000) that agreed to participate in surveys from the Taylor Nelson Sofres (formerly National Family Opinion)	Among the 5392 phase2 respondents, 1322 (24.5%) reported discontinuing one or more antimuscarinic prescription AOB medication during the previous 12 months. Most respondents (89%) reported discontinuing OAB medication primarily due to unmet treatment expectations (46.2%) and/or tolerability (21.1%); many respondents in this class switched to a new antimuscarinic agent. A smaller group (11%) indicated a general aversion to taking medication.

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Tolterodine	Coyne, 2008[447]	The IMPACT trial: Relationship between treatment-related improvements in overactive bladder (OAB) symptoms as recorded in bladder diaries and patient reported symptom bother, bladder-related problems and health-related quality of life (HRQL).	863	82		Tolterodine ER (4 mg once daily)	12 weeks	>18 years of age (82% women) and have frequency (>8 micturitions per 24 hours) and either urgency (strong, sudden desire to urinate) or urgency urinary incontinence (UUI) (>2 episodes per day as recorded in 3-day bladder diaries)	Tolterodine ER-related improvements in OAB symptoms (assessed by diary variables) and patients' perceptions of changes in symptom bother, bladder-related problems and HRQL (assessed by PPBC and OAB- were significantly correlated).
Tolterodine	Elinoff, 2006[448]	The IMPACT trial: the efficacy of tolterodine extended release (ER) for patients' most bothersome overactive bladder (OAB) symptom in a primary care setting	863			Tolterodine ER (4 mg q.d.)	12 weeks	>18 years of age (82% women) and have frequency (>8 micturitions per 24 hours) and either urgency (strong, sudden desire to urinate) or urgency urinary incontinence (UUI) (>2 episodes per day as recorded in 3-day bladder diaries)	Discontinuation due to adverse events-7%; improvement in bladder condition (1 point) - 78.8% and 74.6% of the UUI group; all-cause AE-51%; treatment-related adverse events -23%

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Tolterodine	Michel, 2007[449]	The association between symptoms of UI, bother, and patient satisfaction with treatment using tolterodine in overactive bladder	3,824			Tolterodine ER (4 mg q.d.)	9 months	Adults with OAB	Patient bother was the strongest individual predictor of patient treatment satisfaction in overactive bladder. Changes in episodes of the four symptoms of OAB were not associated with patient satisfaction
Tolterodine	Michel, 2004[450]	The impact of concomitant stress incontinence (SI) on the therapeutic effects of tolterodine in patients with OAB with and without concomitant SI.	2,250			2 mg tolterodine twice daily	12 weeks	Adults with OAB	Patients with concomitant III degree SI (but not I or II degree) have significantly less improvement
Tolterodine	Michel, 2002[451]	The association between patient age and gender and the therapeutic response to tolterodine in adults with OAB	2,251			2 mg tolterodine twice daily	12 weeks	Adults with OAB	Age (OR/yr. 0.978 (0.968–0.987)) and baseline Incontinence (OR 0.744 (0.716–0.774)) was negatively associated with treatment success. Increasing of tolterodine dose was associated with worse response (OR 0.866 (0.784–0.956)) and less tolerance (OR 1.114 (1.028–1.206)

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Tolterodine	Roberts, 2006[452]	The IMPACT trial: the effect of tolterodine extended release (ER) on patient- and clinician-reported outcomes in a primary care setting	863			Tolterodine ER (4 mg once daily)	12 weeks	Adults with overactive bladder (OAB) symptoms for ≥3 months and were at least moderately bothered by their most bothersome symptom	improvement in their overall bladder condition - 79%; Major improvement (improvement of two or more points) - 50.4% and 49.7% of the UUI group
Tolterodine	Sussman, 2007[453]	Timing of the efficacy of tolterodine extended release (ER) in patients with overactive bladder	698			Tolterodine ER (4 mg qd)	12 weeks	Adults (aged ≥18 years) with urinary frequency ≥8 micturitions/24 hours) and urgency (strong and sudden desire to urinate) with or without urgency urinary incontinence (UUI).	Patients with OAB experienced significant reductions in OAB symptoms as early as Day 5 of treatment with tolterodine ER

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Tolterodine vs. Oxybutynin	Lawrence, 2000[454]	Adherence to treatment with immediate-release (IR) oxybutynin and Tolterodine`	1531			Tolterodine, IR Oxybutynin	6 months	All patients age 18 years and over who began therapy with either Tolterodine or IR Oxybutynin during April or May 1998	The proportion of patients continuing therapy for 6 months was statistically superior for Tolterodine (32%) Compared with IR Oxybutynin 22% Oxybutynin was switched to another therapy more commonly than Tolterodine (19% and 14%, respectively) Patients discontinuing all therapy within 6 months Men: Tolterodine 33%; Oxybutynin 39 % Women: Tolterodine 67%; Oxybutynin 61% Only 35 (32%) of IR Oxybutynin recipients were fully adherent compared with 87 (53%) of Tolterodine recipients.

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Tolterodine vs. Oxybutynin	Shaya, 2005[455]	Predictions of persistence with Tolterodine or Oxybutynin in patients with over active bladder	3,054, 1,637, included in analysis	75		Tolterodine ER, Oxybutynin ER, Oxybutynin 1r 4 weeks		Adults, 75% women, 45% African-American 26% younger than 18, with prescriptions of Tolterodine or Oxybutynin for over active bladder.	Hazard ratio of non persistence adjusted for age, sex, race Oxybutynin 1R vs. Tolterodine ER 30 days 1.09 (0.88; 1.35) >30 days 1.13 (0.84; 1.51) Oxybutynin ER vs. Tolterodine ER <30 days 0.96 (0.6; 1.53) > 30 days 1.47 (1.01; 2.14) Age <18 vs. 18-39 1.56 (1.33; 1.82) > 40 vs. 18-39 0.85 (0.74, 0.97) African Americans vs. Whites 1.22 (1.09; 1.36)
Oxybutynin	Hussain, 1996[456]	Effect of oxybutynin on the QTc interval in elderly patients with UI	21		100	Oxybutynin	4 weeks	Elderly	No QTc interval prolongation or ventricular arrhythmias
Oxybutynin	Nilsson, 1997[457]	The efficacy and tolerability of controlled release vs. 5-mg conventional oxybutynin twice daily	17	100	100	10-mg Controlled Release Oxybutinin vs. a 5-mg Oxybutynin Tablet	9 weeks	women with urge UI	No difference in efficacy or safety of two formulations

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Oxybutynin	Bemelmans, 2000[458]	The efficacy of a low-dose oxybutynin (2.5 mg three times daily) in men and women with symptomatic urge incontinence	416			Oxybutynin (2.5 mg three times daily)	6 weeks	Men and women in primary care practice with symptomatic urge incontinence	Complete symptomatic cure -95%; side effects attributable to the use of oxybutynin - 30%; 10% had to stop the medication because of the severity of these side effects.
Oxybutynin	Radomski, 2004[459]	The efficacy of controlled-release (CR) oxybutynin tablet taken once-daily in patients with urinary urge incontinence	12			Oxybutynin (2.5-5 mg bid)	8 weeks	Men and women with urodynamically-confirmed detrusor instability, micturition frequency (≥8 voids/day) and/or urinary incontinence (≥2 incontinence periods/day)	CR oxybutynin (15 mg OD) was at least as effective as the patients' previous dose of IR oxybutynin (mean dose: 6.7 +/- 2.5 mg/day).

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Oxybutynin	Wang, 2002[460]	Risk of ventricular arrhythmia or sudden death after treatment with oxybutynin or other urinary antispasmodics	14,368, 67-75 4% women	70.5		Oxybutynin or flavoxate	Not specified	Adults who filled prescriptions for Oxybutynin or Flavoxate via Medicaid program.	Relative risk of ventricular arrhythmias adjusted for age gender time - varying exposure urinary antispasmodic use 1,23 (0.87-1.75) Concurrent antihistamine/ cytochrome inhibitor use 5.47/1.34- 22.26) Relative risk of sudden death adjusted for age gender, and full of exposure urinary antispasmodic use 0.7 (0.28-1.74) Concurrent antihistamine/ cytochrome inhibitor use 21.5 (5.23-88.32)
Oxybutynin	Diokno, 2002[461]	Long-term safety of Oxybutynin in adults with over active bladder	904 women and 163 men	84.7	100	Oxybutynin ER	12 weeks-1 year	Adults with urge or mixed UI, mean age 64 years	Discontinuations during 3 month - 25.5%, 1 year-53.8% Discontinuations due to adverse events 15.6% Dry mouth- 5.6% Lack of efficacy -4.9% Central nervous system at 91-180 days Headache-0.6% Dizziness- 0.4% Blurred vision-0.4% Somnolence 0.2% (181 day) Confusion 0.1%

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Oxybutynin MATRIX study	Pizzi, 2009[462]	To evaluate the impact of oxybutynin transdermal system (OXY-TDS) and subsequent treatment on productivity among working participants	2878 and 1112 were employed (that formed the study population)	92.2	53.51%	OXY-TDS 3.9mg/day, twice weekly patch applications	6 months	MATRIX study: Community - based; 2978 adults aged ≥18 years with symptoms of OAB	Participants experienced significant improvements in mean scores for all four WPQ (Work Productivity Questionnaire) scales (p<=0.0002) and the mean WPQ Index decreased from 8.2 to 5.5 (p<0.0001). The WPLS (Work Productivity Loss Score) decreased from 7.7% to 5.2% (p<0.0001)
Oxybutynin MATRIX study	Newman, 2008[463]	To evaluate the effectiveness of transdermal oxybutynin (OXY-TDS) in improving HRQoL in a community - based adult population	2878	87.2	NR	OXY-TDS 3.9mg/day, twice weekly patch applications	6 months	MATRIX study: community-based; men and women aged ≥18 years having at least one symptom of OAB, such as urge UI, urgency, and/or frequency	Among all participants, 16.5% discontinued OXY-TDS due to adverse events. Overall, this study found that OXY-TDS administered resulted in improvement in HRQoL, with the medication having its greatest effect on the impact of incontinence, severity of symptoms, and role limitations

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Darifenacin	Zinner, 2008[413]	To investigate patient -reported outcomes and clinical parameters during darifenacin treatment in OAB patients who expressed dissatisfaction with prior extended -release oxybutynin or tolterodine therapy	497	84.1	82.9	7.5mg darifenacin once daily with the possibility of up-titrating to 15mg after 2 weeks, for up to 12 weeks	12 weeks	Men and women (≥18 years of age) with OAB symptoms [an average of ≥8 micturitions/24 hours and ≥1 urgency episode/24 hours, with or without urgency urinary incontinence episodes] for at least 6 months prior to randomization, and with a baseline score of ≥2 on the Patient Perception of Bladder Condition questionnaire at screening. Patients were required to be naive to darifenacin treatment, to have received at least 1 week of treatment with oxybutynin ER or tolterodine ER within the year prior to this trial and to report that they were dissatisfied with	Darifenacin treatment resulted in statistically significant improvements in PPBC scores, micturition frequency, urgency and UUI episodes from baseline at 12 weeks. More than 85% of patients expressed satisfaction with darifenacin. The odds (and 95% CI) for improvement in PPBC amongst previous recipients of oxybutynin ER or tolterodine ER were 2.08 (1.48, 2.92) and 1.77(1.29, 2.43). The odds for reporting satisfaction (and 95%CI) were 4.35 (2.90, 6.53) amongst previous oxybutynin ER recipients and 5.23 (3.50, 7.80) for tolterodine ER recipients, representing an odd ratio (95% CI) of 0.83 (0.50, 1.40). 14.2 % discontinued in group who had prior treatment with oxybutynin and 10.4 % in group who had prior treatment with tolterodine. 58.4% had AEs, 20.1% dry mouth,

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
								the most recent of these treatments	14.1% constipation, 6.6% urinary tract infection, 3.6% headache, 3.2% nausea, 2.6% dyspepsia, 2.2% dry eye, and 2% upper respiratory tract infection. 40.1% of total patients reported ≥90% improvement in number of UUI episodes/week, 39.1% of patients in group that had prior treatment with oxybutynin reported ≥90% improvement, and 40.4% in group that had prior treatment with tolterodine reported ≥90% improvement.

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Fesoterodine	Wyndaele, 2009[464]	To evaluate the efficacy and tolerability of flexible -dose fesoterodine in subjects with overactive bladder who were dissatisfied with previous tolterodine treatment	516	77	50	Fesoterodine 4mg once daily for 4 weeks; thereafter, daily dosage maintained at 4mg or increased to 8mg	12 weeks	Men and women aged ≥18 years with self-reported OAB symptoms for ≥3 months with a mean micturition frequency of ≥8 micturitions per 24 hours and mean number of urgency episodes ≥3 per 24 hours in a 5-day bladder diary; they had to rate their bladder condition as causing at least 'some moderate problems' on the PPBC questionnaire at baseline; they were required to have been treated with tolterodine or tolterodine ER for OAB within 2 years of screening	Approximately 80% of subjects who responded to the TSQ (Treatment Satisfaction Question) at week 12 reported satisfaction with treatment; 38% reported being very satisfied. 8.5% of patients reported no problems on the PPBC scale; 38.9% patients reported 'Usually able to finish what I am doing' on the UPS (Urgency Perception Scale) scale. Significant improvements from baseline ($p<0.0001$) exceeding the minimally important difference (10 points) were observed in OAB-q Symptom Bother and Health-Related Quality of Life scales and all four HRQL domains.

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Botulinum-A toxin	Werner, 2005[465]	To investigate the efficacy and safety of botulinum -A toxin treatment for non-neurologic detrusor overactivity incontinence	26	100	100	100 units of botulinum -A toxin(BTX-A) injected into the detrusor at 30 sites	One day	Women with urge incontinence and urodynamically demonstrable detrusor overactivity incontinence who failed to respond to various antimuscarinic	53.8% women were dry after 4 weeks, 65% after 12 weeks, and 60% after 36 weeks. 2 women failed to respond. 15.4% showed subjective improvement in effect on life and 11.5% showed subjective improvement in urge incontinence after 36 weeks. Within the 51 followup visits, 30.8% patients had 9 urinary tract infections

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Role of urodynamics in evaluation of outcomes	Malone-Lee, 2009[345]	The place of urodynamics in the evaluation of patients with symptoms of the overactive bladder by comparing the response to antimuscarinic therapy in those with and with no urodynamically verified symptoms	356			Oxybutynin 2.5 mg twice daily and bladder retraining	6-8 weeks	Women ≥18 years with symptoms of overactive bladder and urgency, with or without urgency incontinence	Patients respond equally to antimuscarinic therapy independent of urodynamic results. Detrusor instability-no detrusor Change from baseline 0 (2-6) / 0 (2-6) Dry mouth 84% / 70% Constipation 32% / 22% Heartburn 27% / 23% Dry skin 18% / 5% Headache 10% / 3.5% Dry eyes / 5% / 1% 4 were excluded 76% had detrusor instability on cystometry
Adherence to antimus-carinic medication	Balkrishnan, 2006[466]	Relationship between adherence to antimuscarinic medication and health care services utilization.	275	76	100	Antimuscarinic medications; medications possessions score was calculated as the days of antimuscarinic prescriptions supply dispensed divided by the number of days between these prescription refills.	6 months or more	Enrollees in Medicare magnet care plan in the southern US, 16-24% men; 73-74 years old who dispensed antimuscarinic drugs every 6 months	Charlson index comorbidity, patient perception of quality of life, and total number of prescribed medications during the year before enrollment in Medicare where predictors of poor adherence to antimuscarinic drugs.

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Adherence to antimus-carinic medication	Yu, 2005[467]	Predictors of adherence to medications for over active bladder syndrome	2,496	80		Tolterodine, Oxybutynin, Oxybutynin ER	6-12 months	20% random sample of California Medicaid program 20-25% men, 63-64 years old who dispersed any OAB/UI medication	Discontinuation-16% Hazard ratios of drug persistence White race -insignificant Tolterodine vs. Oxybutynin 0.7(0.67; 0.81) Previous antipsychotics use 0.85; 0.83; 0.88) Hazard ratios of drug adherence; Tolterodine vs. Oxybutynin 1.75 (1.10; 2.78) Oxybutynin ER vs. Oxybutynin 2.25 (1.36; 3.75)

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Cost effectiveness	Perfetto, 2005[468]	1-year total healthcare costs for patients with overactive bladder	Simulation model			Tolterodine tartrate extended release capsules (tolterodine ER) versus extended release oxybutynin chloride (oxybutynin ER).			Tolterodine ER had lower monthly drug and medical management costs
Cost effectiveness	Hughes, 2004[469]	Cost-Effectiveness Analysis of Extended-Release Formulations of Oxybutynin and Tolterodine for the Management of Urge Incontinence	Simulation study			Oxy-IR 5mg tablets Oxy-XL 10mg tablets Tol-IR 2mg tablets Tol-ER 4mg tablets			The incremental cost per incontinent-free week for Oxy-IR (versus no treatment) ranged from £2.58 to £16.59. Oxy-XL and Tol-ER were more effective than Oxy-IR but at additional costs per incontinent-free week. Tol-IR did not appear to be a cost-effective option as it was less effective and more costly than the extended-release formulations
Cost effectiveness	O'Brien, 2001[470]	Cost-effectiveness of Tolterodine for Patients with urge incontinence who discontinue initial therapy with Oxybutynin	Simulation study with Markov model			Tolterodine in patients who discontinued Oxybutynin			The incremental cost per QALY was Can $9982 and appeared to be robust

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Cost effectiveness	Varadharajan, 2005[471]	Post treatment medical costs for patients with overactive bladder				Oxybutynin chloride immediate release (oxybutynin IR), oxybutynin chloride extended release (oxybutynin ER), or tolterodine extended-release tartrate capsules (tolterodine ER).			Costs for patients taking oxybutynin IR were 48% higher than costs for patients taking tolterodine ER (P = .026), and costs for patients taking oxybutynin ER were 191% higher than costs for patients taking tolterodine ER (P <.0001).
Cost effectiveness	Ko, 2006[472]	The cost-effectiveness of various antimuscarinic agents for the treatment of overactive bladder	Decision-analysis model			Darifenacin, solifenacin, trospium, immediate release oxybutynin, extended-release oxybutynin, transdermal oxybutynin, immediate-release tolterodine, and extended-release tolterodine			Expected costs for each patient with OAB ranged from $3373 when treated with solifenacin to $3769 when treated with immediate-release oxybutynin. The average cost/patient with continued and successful treatment was lowest for solifenacin ($6863). Solifenacin dominated all other antimuscarinic agents because they were associated with high costs and low effectiveness.

Appendix Table F33. Clinical outcomes after pharmacological treatments in nonrandomized studies (continued)

Treatment	Reference	Aim	Number	% Women	% with UI	Treatment	Duration	Population	Results
Cost effectiveness	Yu, 2005[467]	Cost effectiveness of antimuscarinic medications	2,496	80	Not reported	Tolterodine Oxybutynin extended-release Oxybutynin Other OAB drugs	6 months-12 months	20% random sample of the administrative files provided by the California Medicaid program (Medi-Cal) from January 1999 to April 2002 with chronic OAB/UI	Expected costs for each patient with OAB ranged from $3373 when treated with solifenacin to $3769 when treated with immediate-release oxybutynin. The average cost/patient with continued and successful treatment was lowest for solifenacin ($6863). Solifenacin

Appendix Table F34. Continence after duloxetine vs. placebo, random effects model

Reference	Active events/randomized	Control events/randomized	Relative risk (95% CI)	Weight	Absolute risk difference (95% CI)	Weight
Norton, 2002[355]	123/140	132/138	0.92 (0.86; 0.99)	98.96	-0.08 (-0.14; -0.01)	46.58
Millard, 2004[350]	16/227	14/231	1.16 (0.58; 2.33)	1.04	0.01 (-0.04; 0.06)	53.42
Pooled estimate			0.92 (0.86; 1.0)	100	-0.03 (-0.12; 0.06)	100
I squared			0.00%		79.30%	
p value for heterogeneity			0.507		0.028	

Appendix Table F35. Continence after different doses of duloxetine

Reference sample size	Outcome as reported	Daily dose mg/day	Events in active group/randomized to active	Events in control group/randomized to control	Relative risk (95% CI)	Absolute risk difference (95% CI)
Norton, 2002[355] 275	SPT ≤2G	20mg/day vs. 40mg/d	110/138	111/137	0.98 (0.88; 1.11)	-0.01 (-0.11; 0.08)
Norton, 2002[355] 275	Negative CST	20mg/day vs. 40mg/d	112/138	112/137	0.99 (0.89; 1.11)	-0.01 (-0.10; 0.09)
Norton, 2002[355] 275	Zero incontinent episodes of diary	20mg/day vs. 40mg/d	128/138	123/137	1.03 (0.96; 1.11)	0.03 (-0.04; 0.10)
Norton, 2002[355] 278	SPT ≤2G	20mg/day vs. 80mg/d	110/138	113/140	0.99 (0.88; 1.11)	-0.01 (-0.10; 0.08)
Norton, 2002[355] 278	Negative CST	20mg/day vs. 80mg/d	112/138	114/140	1.00 (0.89; 1.12)	0.00 (-0.09; 0.09)
Norton, 2002[355] 278	Zero incontinent episodes of diary	20mg/day vs. 80mg/d	128/138	123/140	1.06 (0.98; 1.14)	0.05 (-0.02; 0.12)
Norton, 2002[355] 277	SPT ≤2G	40mg/day vs. 80mg/d	111/137	113/140	1.00 (0.90; 1.13)	0.00 (-0.09; 0.10)
Norton, 2002[355] 277	Negative CST	40mg/day vs. 80mg/d	112/137	114/140	1.00 (0.90; 1.12)	0.00 (-0.09; 0.09)
Norton, 2002[355] 277	Zero incontinent episodes of diary	40mg/day vs. 80mg/d	123/137	123/140	1.02 (0.94; 1.11)	0.02 (-0.05; 0.09)

Appendix Table F36. Improvement in UI after duloxetine vs. placebo (random effects model)

Outcome	Reference	Active events/randomized	Control events/randomized	Relative risk (95% CI)	Weight	Absolute risk difference (95% CI)	Weight
Improvement in PGI rating	Schagen van Leeuwen, 2008[378]	18/131	14/134	1.32 (0.68; 2.53)	29.16	0.03 (-0.05; 0.11)	25.46
Improvement in PGI rating	Millard, 2004[350]	167/227	148/231	1.15 (1.01; 1.3)	45.4	0.10 (0.01; 0.18)	24.16
Improvement in PGI rating	Steers, 2007[381]	5/153	1/153	5 (0.59; 42.30)	6.39	0.03 (-0.01; 0.06)	35.95
Improvement in PGI rating	Cardozo, 2004[251]	17/55	4/54	4.17 (1.50; 11.60)	19.05	0.24 (0.09; 0.38)	14.43
Improvement in PGI rating: very much better, much better	Pooled estimate			1.68 (0.94; 3.00)	100	0.08 (0.01; 0.14)	100
I squared	I squared			62.10%		69.40%	
p value for heterogeneity	p value for heterogeneity			0.048		0.02	
Improvement in UI	Lin, 2008[339]	42/60	28/61	1.53 (1.11; 2.10)	12.7	0.24 (0.07; 0.41)	10.63
Improvement in UI	Yalcin, 2006[408]	198/433	152/425	1.28 (1.09; 1.51)	48.26	0.10 (;0.03; 0.17)	34.27
Improvement in UI	Cardozo, 2004[251]	4/55	1/54	3.93 (0.45; 34.02)	0.28	0.05 (-0.02; 0.13)	29.68
Improvement in UI	Millard, 2004[350]	135/227	100/231	1.37 (1.15; 1.65)	38.76	0.16 (0.07; 0.25)	25.42
Improvement in UI	Cardozo, 2010[249]	697/1378	431/1380	1.62 (1.47; 1.78)	37.29	0.19 (0.16; 0.23)	27.76
Improvement in UI: 50% or more reduction in urinary episode frequency	Pooled estimate			1.46 (1.28; 1.66)	100	0.14 (0.08; 0.21)	100
p value for heterogeneity	I squared			0.10		0.01	
I squared				49.20%		72.60%	

Appendix Table F37. Perceived treatment success after different doses of duloxetine

Reference sample size	Outcome	Subgroup	Daily dose	Events in active/ randomized	Events in control/ randomized	Relative Risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 Treated
Norton, 2002[355] 275	PGI-I score Percent in "very much" or "much better" categories	Baseline IEF ≥14	20 vs. 40mg/day	29/138	56/138	0.51 (0.35; 0.75)	-0.20 (-0.31; -0.09)	-5 (-11; -3)	-199 (-305; -92)
Norton, 2002[355] 275	Increase in avoidance/limiting domain of I-QOL score from baseline		20 vs. 40mg/day	4/138	14/138	0.28 (0.10; 0.84)	-0.07 (-0.13; -0.02)	-14 (-65; -8)	-73 (-131; -15)
Norton, 2002[355] 275	Increase in psychosocial domain of I-QOL score from baseline		20 vs. 40mg/day	4/138	10/138	0.40 (0.13; 1.24)	-0.04 (-0.10; 0.01)		
Norton, 2002[355] 275	Increase in social embarrassment domain of I-QOL score from baseline		20 vs. 40mg/day	5/138	16/138	0.31 (0.12; 0.82)	-0.08 (-0.14; -0.02)	-12 (-54; -7)	-81 (-143; -18)
Norton, 2002[355] 278	PGI-I score Percent in "very much" or "much better" categories		20 vs. 80mg/day	29/138	70/138	0.42 (0.29; 0.60)	-0.29 (-0.40; -0.18)	-3 (-5; -3)	-290 (-397; -183)
Norton, 2002[355] 278	Increase in avoidance/limiting domain of I-QOL score from baseline		20 vs. 80mg/day	4/138	20/138	0.20 (0.07; 0.58)	-0.11 (-0.18; -0.05)	-9 (-20; -6)	-114 (-178; -50)
Norton, 2002[355] 278	Increase in psychosocial domain of I-QOL score from baseline		20 vs. 80mg/day	4/138	16/138	0.25 (0.09; 0.74)	-0.09 (-0.14; -0.03)	-12 (-39; -7)	-85 (-145; -26)
Norton, 2002[355] 278	Increase in social embarrassment domain of I-QOL score from baseline		20 vs. 80mg/day	5/138	21/138	0.24 (0.09; 0.62)	-0.11 (-0.18; -0.05)	-9 (-21; -6)	-114 (-181; -47)
Norton, 2002[355] 277	PGI-I score Percent in "very much" or "much better" categories		40 vs. 80mg/day	56/137	70/137	0.82 (0.63; 1.06)	-0.09 (-0.21; 0.03)		

Appendix Table F37. Perceived treatment success after different doses of duloxetine (continued)

Reference sample size	Outcome	Sub-group	Daily dose	Events in active/ randomized	Events in control/ randomized	Relative Risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 Treated
Norton, 2002[355] 277	Increase in avoidance/limiting domain of I-QOL score from baseline		40 vs. 80mg/day	14/137	20/137	0.72 (0.38; 1.36)	-0.04 (-0.12; 0.04)		
Norton, 2002[355] 277	Increase in psychosocial domain of I-QOL score from baseline		40 vs. 80mg/day	10/137	16/137	0.64 (0.30; 1.36)	-0.04 (-0.11; 0.03)		
Norton, 2002[355] 277	Increase in social embarrassment domain of I-QOL score from baseline		40 vs. 80mg/day	16/137	21/137	0.78 (0.42; 1.43)	-0.03 (-0.11; 0.05)		
Duckett, 2007[285] 222	PGI-I score: very much better	in stress vs. mixed UI	60 vs. 40mg twice daily	10/123	8/123	1.01 (0.41; 2.45)	0.00 (-0.07; 0.07)		
Duckett, 2007[285] 222	PGI-I score: much better	in stress vs. mixed UI	60 vs. 40mg twice daily	22/123	11/123	1.61 (0.82; 3.16)	0.07 (-0.02; 0.16)		
Duckett, 2007[285] 222	PGI-I score: a little better	in stress vs. mixed UI	60 vs. 40mg twice daily	15/123	14/123	0.86 (0.44; 1.70)	-0.02 (-0.11; 0.07)		
Duckett, 2007[285] 222	PGI-I score: no change	in stress vs. mixed UI	60 vs. 40mg twice daily	21/123	10/123	1.69 (0.84; 3.42)	0.07 (-0.02; 0.16)		
Duckett, 2007[285] 222	PGI-I score: a little worse	in stress vs. mixed UI	60 vs. 40mg twice daily	1/123	3/123	0.27 (0.03; 2.54)	-0.02 (-0.06; 0.02)		
Duckett, 2007[285] 222	PGI-I score: much worse	in stress vs. mixed UI	60 vs. 40mg twice daily	1/123	3/123	0.27 (0.03; 2.54)	-0.02 (-0.06; 0.02)		
Duckett, 2007[285] 222	PGI-I score: very much worse	in stress vs. mixed UI	60 vs. 40mg twice daily	0/123	1/123	0.27 (0.01; 6.53)	-0.01 (-0.04; 0.02)		
Duckett, 2007[285] 222	PGI-I score: total	in stress vs. mixed UI	60 vs. 40mg twice daily	70/123	50/123	1.13 (0.88; 1.44)	0.06 (-0.07; 0.20)		
Bump, 2003[108] 277	Mixed urinary incontinence		40 vs. 0mg/day	85/137	88/137	0.99 (0.82; 1.18)	-0.01 (-0.12; 0.11)		

Appendix Table F37. Perceived treatment success after different doses of duloxetine (continued)

Reference sample size	Outcome	Sub-group	Daily dose	Events in active/ randomized	Events in control/ randomized	Relative Risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 Treated
Bump, 2003[108] 277	Stress urinary incontinence		40 vs. 80mg twice daily	79/137	91/137	0.89 (0.74; 1.07)	-0.07 (-0.19; 0.04)		

Appendix Table F38. Treatment failure after duloxetine vs. placebo (random effects model)

Change in PGI-I rating scale	Reference	Active events/randomized	Control events/randomized	Relative risk (95% CI)	Weight	Absolute risk difference (95% CI)	Weight
Deterioration very much worse	Schagen van Leeuwen, 2008[378]	0/131	1/134	0.34 (0.01; 8.29)	0.99	-0.01 (-0.03; 0.01)	30.27
Deterioration very much worse	Bent, 2008[234]	4/300	0/288	8.64 (0.47; 159.78)	1.19	0.01 (-0.00; 0.03)	35.81
Deterioration very much worse	Steers, 2007[381]	1/153	1/153	1 (0.06; 15.84)	1.32	0 (-0.02; 0.02)	32.56
Deterioration very much worse	Cardozo, 2004[251]	31/55	42/54	0.73 (0.55; 0.95)	96.5	-0.21 (-0.39; -0.04)	1.36
Deterioration very much worse	Pooled estimate			0.74 (0.54; 1.02)	100	0 (-0.02; 0.02)	100
Deterioration very much worse	I squared			0.70%		67.30%	
Deterioration very much worse	p value for heterogeneity			0.39		0.03	
Deterioration much worse	Schagen van Leeuwen, 2008[378]	1/131	1/134	1.02 (0.07; 16.18)	26.1	0 (-0.02; 0.02)	22.7
Deterioration much worse	Bent, 2008[234]	3/300	1/288	2.88 (0.30; 27.53)	39.06	0.01 (-0.01; 0.02)	57.04
Deterioration much worse	Steers, 2007[381]	1/153	2/153	0.5 (0.05; 5.46)	34.84	-0.01; -0.03; 0.02)	20.26
Deterioration much worse	Pooled estimate			1.19 (0.29; 4.90)	100	0.00 (-0.01; 0.01)	100
Deterioration much worse	I squared			0.00%		0.00%	
Deterioration much worse	p value for heterogeneity			0.575		0.591	
No change	Schagen van Leeuwen, 2008[378]	26/131	35/134	0.76 (0.49; 1.19)	17.76	-0.06 (-0.16; 0.04)	25.63
No change	Bent, 2008[234]	74/300	94/288	0.76 (0.58; 0.98)	53.17	-0.08 (-0.15; -0.01)	49.21
No change	Steers, 2007[381]	41/153	49/153	0.84 (0.59; 1.19)	29.07	-0.05 (-0.15; 0.05)	25.16
No change	Pooled estimate			0.78 (0.65; 0.94)	100	-0.07 (-0.12; -0.02)	100
No change	I squared			0.00%		0.00%	

Appendix Table F38. Treatment failure after duloxetine vs. placebo (random effects model) (continued)

Change in PGI-I rating scale	Reference	Active events/randomized	Control events/randomized	Relative risk (95% CI)	Weight	Absolute risk difference (95% CI)	Weight
No change	p value for heterogeneity			0.89		0.90	
Deterioration a little worse	Schagen van Leeuwen, 2008[378]	4/131	14/134	0.29 (0.10; 0.87)	28.82	-0.07 (-0.13; -0.01)	22.62
Deterioration a little worse	Bent, 2008[234]	8/300	10/288	0.77 (0.31; 1.91)	39.65	-0.01 (-0.04; 0.02)	47.04
Deterioration a little worse	Steers, 2007[381]	6/153	8/153	0.75 (0.27; 2.11)	31.53	-0.01 (-0.06; 0.03)	30.34
Deterioration a little worse	Pooled estimate			0.58 (0.32; 1.05)	100	-0.03 (-0.06; 0.01)	100
Deterioration a little worse	I squared			5.80%		48.80%	
Deterioration a little worse	p value for heterogeneity			0.35		0.14	

Appendix Table F39. Quality of life after duloxetine vs. placebo

Reference sample size	Dose	Outcome measure, MID	Randomized to active/control	Mean +/- standard deviation active	Mean +/- standard deviation control	Mean difference (95% CI)
Yalcin, 2006[408] 858	80mg daily	Increase in total I-QOL score from baseline; 2 to 5	433/425	10.5+/-14.0	6.4+/-12.6	4.1 (2.3; 5.90)
Yalcin, 2006[408] 858	80mg daily	Increase in avoidance/limiting domain of I-QOL score from baseline	433/425	10.8+/-10.8	7.2+/-13.9	3.6 (1.9; 5.30)
Yalcin, 2006[408] 858	80mg daily	Increase in psychosocial domain of I-QOL score from baseline	433/425	9.4+/-14.8	4.9+/-12.9	4.5 (2.6; 6.40)
Yalcin, 2006[408] 858	80mg daily	Increase in social embarrassment domain of I-QOL score from baseline	433/425	12.1+/-18.4	8.1+/-17.6	4.0 (1.6; 6.40)
Dmochowski, 2003[279] 683	40mg twice daily	Increase in I-QOL score from baseline	344/339	11.1+/-14.8	6.8+/-13.8	4.3 (2.2; 6.40)
Dmochowski, 2003[279] 683	40mg twice daily	Increase in I-QOL score from baseline for the avoidance/limiting behavior domain	344/339	11.1+/-15.8	7.1+/-14.8	4.0 (1.7; 6.30)
Dmochowski, 2003[279] 683	40mg twice daily	Increase in I-QOL score from baseline for psychosocial domain	344/339	10.2+/-15.5	5.7+/-14.6	4.5 (2.2; 6.80)
Dmochowski, 2003[279] 683	40mg twice daily	Increase in I-QOL score from baseline for social embarrassment domain	344/339	12.4+/-19.8	8.4+/-18.6	4.0 (1.1; 6.90)
Millard, 2004[350] 458	40mg twice daily	I-QOL Total score (0 worse to 100)	227/231	69.2+/-23.8	64.7+/-24.9	4.5 (0.0; 9.00)
Millard, 2004[350] 458	40mg twice daily	I-QOL Total score (0 worse to 100)	227/231	69.0+/-24.4	64.9+/-24.9	4.1 (-0.4; 8.60)
Millard, 2004[350] 458	40mg twice daily	avoidance/limiting behavior- I-QOL subscale	227/231	69.7+/-23.7	65.5+/-24.7	4.2 (-0.2; 8.60)
Millard, 2004[350] 458	40mg twice daily	psychosocial- I-QOL subscale	227/231	75.5+/-24.8	71.4+/-26.2	4.1 (-0.6; 8.80)
Millard, 2004[350] 458	40mg twice daily	social embarrassment- I-QOL subscale	227/231	57.1+/-27.8	51.5+/-29.7	5.6 (0.3; 10.90)
Steers, 2007[381] 306	40-60mg twice daily	I-QOL	153/153	65.0+/-23.8	62.0+/-25.3	3.0 (-2.5; 8.50)

Appendix Table F39. Quality of life after duloxetine vs. placebo (continued)

Reference sample size	Dose	Outcome measure, MID	Randomized to active/control	Mean +/- standard deviation active	Mean +/- standard deviation control	Mean difference (95% CI)
Cardozo, 2004[251] 109	40mg twice daily for 4 weeks, 60 mg twice daily for 4 weeks	Avoidance and Limiting Behavior, I -QOL Subscales	55/54	10.1+/-20.8	2.0+/-11.1	8.1 (1.9; 14.30)
Cardozo, 2004[251] 109	40mg twice daily for 4 weeks, 60 mg twice daily for 4 weeks	Psychosocial Impacts, I-QOL Subscales	55/54	10.6+/-18.7	2.1+/-9.6	8.5 (2.9; 14.10)
Cardozo, 2004[251] 109	40mg twice daily for 4 weeks, 60 mg twice daily for 4 weeks	Social Embarrassment, I-QOL Subscales	55/54	11.5+/-22.6	3.6+/-12.6	7.9 (1.0; 14.80)
Cardozo, 2004[251] 109	40mg twice daily for 4 weeks, 60 mg twice daily for 4 weeks	I-QOL total score	55/54	10.6+/-19.1	2.4+/-9.4	8.2 (2.6; 13.80)
Lin, 2008[339] 121	40mg twice daily	Mean change in I-QOL from baseline	60/61	13.6+/-0.0	13.3+/-0.0	0.3 (-4.8; 6.80)
Lin, 2008[339] 121	40mg twice daily	change from baseline in I-QOL avoidance and limiting behavior	60/61	12.7+/-0.0	12.8+/-0.0	-0.1 (-5.3; 6.50)
Lin, 2008[339] 121	40mg twice daily	change from baseline in I-QOL psychological impact subscale score	60/61	12.9+/-0.0	12.0+/-0.0	0.9 (-3.7; 7.90)
Lin, 2008[339] 121	40mg twice daily	change from baseline in I-QOL social embarrassment subscale score	60/61	16.4+/-0.0	16.5+/-0.0	-0.1 (-7.4; 6.80)
Viktrup, 2007[313] 1913	40mg twice daily	I-QOL mean % change, for patient's age <50	958/955	9.1+/-13.5	0.0+/-0.0	5.1 (-22.3; 32.50)
Viktrup, 2007[313] 1913	40mg twice daily	I-QOL mean % change, for patient's age ≥51	958/955	9.3+/-15.4	0.0+/-0.0	6.4 (-20.8; 33.60)

Appendix Table F40. Adverse effects after duloxetine vs. placebo, random effects model

Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Abnormal elevation in bilirubine	Millard, 2004[350]	1/227	9/231	0.11 (0.01; 0.89)	33.43	-0.04 (-0.06; -0.01)	40.86
Total bilirubin above ULN	Hurley, 2006[312]	4/958	8/955	0.50 (0.15; 1.65)	66.57	-0.00 (-0.01; 0.00)	59.14
	Pooled	5/1185	17/1186	0.30 (0.08 1.20)	100	-0.02 (-0.05; 0.01)	100
	P value/I squared			0.22 33.00%		0.03 78.90%	
Abnormal elevation in alanine aminotransferase	Millard, 2004[350]	4/227	2/231	2.04 (0.38; 11.00)	3.38	0.01 (-0.01; 0.03)	56.46
ALT above ULN	Hurley, 2006[312]	84/958	62/955	1.35 (0.99; 1.85)	96.62	0.02 (-0.00; 0.05)	43.54
	Pooled	88/1185	64/1186	1.37 (1.00; 1.87)	100	0.02 (-0.00; 0.03)	100
	P value/I squared			0.64 0.00%		0.39 0.00%	
Abnormal elevation in aspartate aminotransferase	Millard, 2004[350]	3/227	6/231	0.51 (0.13; 2.01)	28.62	-0.01 (-0.04; 0.01)	46.87
AST above ULN	Hurley, 2006[312]	60/958	42/955	1.42 (0.97; 2.09)	71.38	0.02 (-0.00; 0.04)	53.13
	Pooled	63/1185	48/1186	1.06 (0.43; 2.64)	100	0.00 (-0.03; 0.04)	100
	P value/I squared			0.16 50.00%		0.06 72.40%	
Anorexia	Millard, 2004[350]	15/227	0/231	31.54 (1.90; 524.06)	17.1	0.07 (0.03; 0.10)	19.84
Anorexia	Hurley, 2006[312]	37/958	2/955	18.44 (4.46; 76.3)	66.97	0.04 (0.02; 0.05)	59.74
Anorexia	Schagen van Leeuwen, 2008[378]	4/131	0/134	9.21 (0.5; 169.28)	15.93	0.03 (-0.00; 0.06)	20.42
	Pooled	56/1316	2/1320	18.10 (5.66; 57.85)	100	0.04 (0.02; 0.06)	100
	P value/I squared			0.84 0.00%		0.23 32.50%	
Anorgasmia	Hurley, 2006[312]	13/958	0/955	26.92 (1.60; 452.12)	51.14	0.01 (0.01; 0.02)	81.44
Anorgasmia	Steers, 2007[381]	5/153	0/153	11 (0.61; 197.22)	48.86	0.03 (0.00; 0.06)	18.56
	Pooled	18/1111	0/1108	17.38 (2.31; 130.72)	100	0.02 (0.00; 0.03)	100
	P value/I squared			0.66 0.00%		0.24 28.90%	
Anxiety	Hurley, 2006[312]	18/958	7/955	2.56 (1.08; 6.11)	70.6	0.01 (0.00; 0.02)	61.05
Anxiety	Kinchen, 2005[331]	9/224	2/227	4.56 (1.00; 20.87)	23.01	0.03 (0.00; 0.06)	20.6
Anxiety	Steers, 2007[381]	5/153	0/153	11 (0.61; 197.22)	6.39	0.03 (0.00; 0.06)	18.35
	Pooled	32/1335	9/1335	3.21 (1.55; 6.66)	100	0.02 (0.01; 0.03)	100
	P value/I squared			0.56 0.00%		0.22 33.50%	

Appendix Table F40. Adverse effects after duloxetine vs. placebo, random effects model (continued)

Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Appetite decreased	Hurley, 2006[312]	22/958	2/955	10.97 (2.59; 46.50)	34.81	0.02 (0.01; 0.03)	64.18
Appetite decreased	Kinchen, 2005[331]	10/224	2/227	5.07 (1.12; 22.87)	32	0.04 (0.01; 0.07)	7.18
Appetite decreased	Lin, 2008[339]	4/60	1/61	4.07 (0.47; 35.34)	15.54	0.05 (-0.02; 0.12)	1.26
Appetite decreased	Bent, 2008[234]	6/300	0/288	12.48 (0.71; 220.56)	8.81	0.02 (0.00; 0.04)	21.58
Appetite decreased	Steers, 2007[381]	6/153	0/153	13 (0.74 (23;.77)	8.84	0.04 (0.01; 0.07)	5.8
	Pooled	48/1695	5/1684	7.54 (3.21; 17.68)	100	0.02 (0.02; 0.03)	100
	P value/I squared			0.90 0.00%		0.64 0.00%	
Asthenia	Ghoniem, 2005[293]	6/104	0/97	12.13 (0.69; 212.55)	7.05	0.06 (0.10; 0.11)	4.14
Asthenia	Hurley, 2006[312]	7/958	0/955	14.95 (0.86; 261.45)	7.05	0.01 (0.00; 0.01)	50.11
Asthenia	Lin, 2008[339]	3/60	1/61	3.05 (0.33; 28.51)	11.56	0.03 (-0.03; 0.10)	2.44
Asthenia	Cardozo, 2010[249]	27/1378	6/1380	4.51 (1.87; 10.88)	74.34	0.02 (0.01; 0.02)	43.31
	Pooled	43/2500	7/2493	5.03 (2.35; 10.75)	100	0.01 (0.00; 0.02)	100
	P value/I squared			0.76 0.00%		0.08 55.10%	
Constipation	Ghoniem, 2005[293]	15/104	3/97	4.66 (1.39; 15.61)	2.95	0.11 (0.04; 0.19)	2.98
Constipation	Millard, 2004[350]	29/227	4/231	7.38 (2.64; 20.65)	4.07	0.11 (0.06; 0.16)	6.62
Constipation	Hurley, 2006[312]	105/958	22/955	4.76 (3.03; 7.47)	21.2	0.09 (0.07; 0.11)	15.57
Constipation	Kinchen, 2005[331]	20/224	5/227	4.05 (1.55; 10.61)	4.65	0.07 (0.03; 0.11)	7.7
Constipation	van Kerrebroeck, 2004[393]	35/247	10/247	3.5 (1.77; 6.91)	9.31	0.10 (0.05; 0.15)	5.96
Constipation	Norton, 2002[355]	6/140	1/138	5.91 (0.72; 48.49)	0.97	0.04 (-0.00; 0.07)	9.29
Constipation	Castro-Diaz, 2007[254]	16/136	6/120	2.35 (0.95; 5.82)	5.25	0.07 (0.00; 0.13)	3.72
Constipation	Lin, 2008[339]	10/60	0/61	21.34 (1.28; 356.28)	0.54	0.17 (0.07; 0.26)	1.9
Constipation	Schagen van Leeuwen, 2008[378]	14/131	1/134	14.32 (1.91; 107.35)	1.06	0.10 (0.05; 0.15)	5.15
Constipation	Dmochowski, 2003[279]	33/344	7/339	4.65 (2.08; 10.36)	6.7	0.08 (0.04; 0.11)	9.9
Constipation	Bent, 2008[234]	25/300	12/288	2 (1.02; 3.91)	9.62	0.04 (0.00; 0.08)	8.54
Constipation	Steers, 2007[381]	21/153	5/153	4.2 (1.63; 10.85)	4.78	0.11 (0.04; 0.17)	4.29
Constipation	Cardozo, 2010[249]	125/1378	31/1380	4.04 (2.75; 5.94)	28.89	0.07 (0.05; 0.09)	18.38
	Pooled	454/4402	107/4370	4.01 (3.26; 4.93)	100	0.08 (0.06; 0.09)	100
	P value/I squared			0.55 0.00%		0.10 35.10%	
Diarrhea	Hurley, 2006[312]	49/958	26/955	1.88 (1.18; 3.00)	48.74	0.02 (0.01; 0.04)	27.08
Diarrhea	Kinchen, 2005[331]	19/224	8/227	2.41 (1.08; 5.38)	16.4	0.05 (0.01; 0.09)	12.38
Diarrhea	Norton, 2002[355]	4/140	3/138	1.31 (0.30; 5.76)	4.86	0.01 (-0.03; 0.04)	15.23
Diarrhea	Castro-Diaz, 2007[254]	1/136	4/120	0.22 (0.03; 1.95)	2.24	-0.03 (-0.06; 0.01)	16

Appendix Table F40. Adverse effects after duloxetine vs. placebo, random effects model (continued)

Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Diarrhea	Dmochowski, 2003[279]	21/344	9/339	2.30 (1.07; 4.95)	18.1	0.03 (0.00; 0.07)	18.46
Diarrhea	Steers, 2007[381]	10/153	5/153	2 (0.70; 5.72)	9.65	0.03 (-0.02; 0.08)	10.84
	Pooled	104/1955	55/1932	1.91 (1.38; 2.65)	100	0.02 (0; 0.04)	100
	P value/I squared			0.47 0.00%		0.07 50.70%	
Dizziness	Ghoniem, 2005[293]	19/104	5/97	3.54 (1.38; 9.12)	5.03	0.13 (0.05; 0.22)	3.2
Dizziness	Millard, 2004[350]	25/227	6/231	4.24 (1.77; 10.14)	5.92	0.08 (0.04; 0.13)	7.79
Dizziness	Cardozo, 2004[251]	9/55	2/54	4.42 (1; 19.52)	2.04	0.13 (0.02; 0.24)	2.12
Dizziness	Hurley, 2006[312]	91/958	25/955	3.63 (2.35; 5.60)	23.95	0.07 0.05; 0.09)	13.78
Dizziness	Kinchen, 2005[331]	30/224	8/227	3.8 (1.78; 8.11)	7.84	0.10 (0.05; 0.15)	6.9
Dizziness	van Kerrebroeck, 2004[393]	30/247	8/247	3.75 (1.75; 8.02)	7.8	0.09 (0.04; 0.14)	7.65
Dizziness	Norton, 2002[355]	7/140	2/138	3.45 (0.73; 16.32)	1.86	0.04 (-0.01; 0.08)	8.66
Dizziness	Castro-Diaz, 2007[254]	14/136	1/120	12.35 (1.65; 92.55)	1.11	0.10 (0.04; 0.15)	6.43
Dizziness	Lin, 2008[339]	8/60	6/61	1.36 (0.50; 3.67)	4.53	0.04 (-0.08; 0.15)	2
Dizziness	Schagen van Leeuwen, 2008[378]	12/131	6/134	2.05 (0.79; 5.29)	4.99	0.05 (-0.01; 0.11)	5.48
Dizziness	Dmochowski, 2003[279]	26/344	8/339	3.20 (1.47; 6.97)	7.43	0.05 (0.02; 0.08)	10.77
Dizziness	Bent, 2008[234]	29/300	7/288	3.98 (1.77; 8.94)	6.87	0.07 (0.03; 0.11)	9.41
Dizziness	Cardozo, 2010[249]	68/1378	23/1380	2.96 (1.86; 4.72)	20.64	0.03 (0.02; 0.05)	15.8
	Pooled	368/4304	107/4271	3.33 (2.69; 4.11)	100	0.07 (0.045; 0.08)	100
	P value/I squared			0.86 0.00%		0.01 56.20%	
Dry mouth	Ghoniem, 2005[293]	19/104	3/97	5.91 (1.81; 19.34)	6.36	0.15 (0.07; 0.23)	5.12
Dry mouth	Millard, 2004[350]	28/227	4/231	7.12 (2.54; 19.98)	7.39	0.11 (0.06; 0.15)	7.97
Dry mouth	Cardozo, 2004[251]	12/55	0/54	24.55 (1.49; 404.63)	1.75	0.22 (0.11; 0.33)	3.53
Dry mouth	Kinchen, 2005[331]	26/224	5/227	5.27 (2.06; 13.48)	8.09	0.09 (0.05; 0.14)	7.95
Dry mouth	van Kerrebroeck, 2004[393]	48/247	6/247	8 (3.49; 18.35)	9	0.17 (0.12; 0.22)	7.35
Dry mouth	Norton, 2002[355]	7/140	1/138	6.9 (0.86; 55.35)	2.89	0.04 (0.00; 0.08)	8.6
Dry mouth	Castro-Diaz, 2007[254]	22/136	5/120	3.88 (1.52; 9.93)	8.09	0.12 (0.05; 0.19)	5.85
Dry mouth	Lin, 2008[339]	10/60	2/61	5.08 (1.16; 22.24)	4.83	0.13 (0.03; 0.24)	3.87
Dry mouth	Schagen van Leeuwen, 2008[378]	26/131	2/134	13.30 (3.22; 54.90)	5.09	0.18 (0.11; 0.26)	5.86
Dry mouth	Dmochowski, 2003[279]	42/344	3/339	13.80 (4.32; 44.08)	6.51	0.11 (0.08; 0.15)	8.84

Appendix Table F40. Adverse effects after duloxetine vs. placebo, random effects model (continued)

Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Dry mouth	Bent, 2008[234]	36/300	8/288	4.32 (2.04; 9.14)	9.72	0.09 (0.05; 0.13)	8.37
Dry mouth	Steers, 2007[381]	25/153	2/153	12.5 (3.01; 51.86)	5.07	0.15 (0.09; 0.21)	6.65
Dry mouth	Cardozo, 2010[249]	117/1378	47/1380	2.49 (1.79; 3.47)	13.56	0.05 (0.03; 0.07)	10.19
Dry mouth	Hurley, 2006[312]	128/958	14/955	9.11 (5.29; 15.71)	11.65	0.12 (0.10; 0.14)	9.86
	Pooled	546/4457	102/4424	6.26 (4.22; 9.28)	100	0.12 (0.09; 0.14)	100
	P value/I squared			0.00 58.20%		0 78.60%	
Fatigue	Millard, 2004[350]	23/227	8/231	2.93 (1.34; 6.40)	6.04	0.07 (0.02; 0.11)	8.93
Fatigue	Cardozo, 2004[251]	10/55	6/54	1.64 (0.64; 4.19)	4.2	0.07 (-0.06; 0.20)	2.52
Fatigue	Hurley, 2006[312]	122/958	36/955	3.38 (2.36; 4.85)	28.49	0.09 (0.07; 0.11)	11.92
Fatigue	Kinchen, 2005[331]	45/224	12/227	3.8 (2.07; 6.99)	9.98	0.15 (0.09; 0.21)	7.14
Fatigue	van Kerrebroeck, 2004[393]	34/247	11/247	3.09 (1.60; 5.96)	8.6	0.09 (0.04; 0.14)	8.36
Fatigue	Norton, 2002[355]	10/140	3/138	3.29 (0.92; 11.68)	2.3	0.05 (0.00; 0.10)	8.49
Fatigue	Lin, 2008[339]	5/60	0/61	11.18 (0.63; 197.86)	0.45	0.08 (0.01; 0.16)	5.6
Fatigue	Schagen van Leeuwen, 2008[378]	19/131	7/134	2.78 (1.21; 6.38)	5.35	0.09 (0.02; 0.160	5.98
Fatigue	Dmochowski, 2003[279]	51/344	13/339	3.87 (2.14; 6.98)	10.64	0.11 (0.07; 0.15)	9.35
Fatigue	Bent, 2008[234]	20/300	8/288	2.4 (1.07; 5.36)	5.74	0.04 (0.01; 0.07)	10.59
Fatigue	Steers, 2007[381]	16/153	3/153	5.33 (1.59; 17.93)	2.52	0.09 (0.03; 0.14)	7.96
Fatigue	Cardozo, 2010[249]	65/1378	21/1380	3.1 (1.91; 5.04)	15.68	0.03 (0.02; 0.05)	13.16
	Pooled	420/4217	128/4207	3.22 (2.66; 3.90)	100	0.08 (0.05; 0.10)	100
	P value/I squared			0.94 0.00%		0 73.70%	
Headache	Millard, 2004[350]	33/227	20/231	1.68 0.99; 2.84)	9.44	0.06 (0; 0.12)	4.8
Headache	Cardozo, 2004[251]	15/55	5/54	2.95 (1.15; 7.54)	2.94	0.18 (0.04; 0.32)	0.87
Headache	Hurley, 2006[312]	93/958	63/955	1.47 (1.08; 2)	27.54	0.03 (0.01; 0.06)	21.9
Headache	Kinchen, 2005[331]	28/224	14/227	2.03 (1.10; 3.75)	6.87	0.06 (0.01; 0.12)	5.69
Headache	van Kerrebroeck, 2004[393]	24/247	19/247	1.26 (0.71; 2.25)	7.84	0.02 (-0.03; 0.07)	6.51
Headache	Norton, 2002[355]	8/140	9/138	0.88 (0.35; 2.21)	3.05	-0.01 (-0.06; 0.05)	5.15
Headache	Castro-Diaz, 2007[254]	11/136	11/120	0.88 (0.40; 1.96)	4.07	-0.01 (-0.08; 0.06)	3.5
Headache	Dmochowski, 2003[279]	25/344	12/339	2.05 (1.05; 4.02)	5.75	0.04 (0.00; 0.07)	13.02
Headache	Steers, 2007[381]	13/153	8/153	1.63 (0.69; 3.81)	3.58	0.03 (-0.02; 0.09)	5.11
Headache	Cardozo, 2010[249]	109/1378	64/1380	1.71 (1.26; 2.30)	28.93	0.03 (0.02; 0.05)	33.46
	Pooled	359/3862	225/3844	1.58 (1.35; 1.86)	100	0.03 (0.02; 0.05)	100

Appendix Table F40. Adverse effects after duloxetine vs. placebo, random effects model (continued)

Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
	P value/I squared			0.57 0.00%		0.34 10.90%	
Hyperhidrosis	Lin, 2008[339]	5/60	0/61	11.18 (0.63; 197.86)	0.94	0.08 (0.01; 0.16)	3.1
Hyperhidrosis	Schagen van Leeuwen, 2008[378]	7/131	0/134	15.34 (0.89; 265.91)	0.95	0.05 (0.01; 0.09)	8.15
Hyperhidrosis	Cardozo, 2010[249]	45/1378	13/1380	3.47 (1.88; 6.40)	20.58	0.02 (0.01; 0.03)	22.23
Hyperhidrosis	Brunton, 2010[239]	189/10326	34/7496	4.04 (2.80; 5.81)	58.33	0.01 (0.01; 0.02)	25.17
Hyperhidrosis	Millard, 2004[350]	13/227	2/231	6.62 (1.51; 28.98)	3.54	0.05 (0.02; 0.08)	10.84
Hyperhidrosis	Kinchen, 2005[331]	15/224	1/227	15.20 (2.03; 114.11)	1.9	0.06 (0.03; 0.10)	10.34
Hyperhidrosis	Hurley, 2006[312]	43/958	8/955	5.36 (2.53; 11.34)	13.76	0.04 (0.02; 0.05)	20.17
	Pooled	317/13304	58/10484	4.34 (3.29; 5.73)	100	0.04 (0.02; 0.05)	100
	P value/I squared			0.69 0.00%		0 79.40%	
Insomnia	Ghoniem, 2005[293]	12/104	1/97	11.19 (1.48;84.47)	2.85	0.11 (0.04; 0.17)	7.07
Insomnia	Millard, 2004[350]	31/227	6/231	5.26 (2.24;12.36)	9.09	0.11 (0.06; 0.16)	8.3
Insomnia	Cardozo, 2004[251]	7/55	3/54	2.29 (0.63; 8.40)	5.6	0.07 (-0.04; 0.18)	4.37
Insomnia	Hurley, 2006[312]	121/958	18/955	6.70 (4.12; 10.91)	13.41	0.11 (0.09; 0.13)	10.24
Insomnia	Kinchen, 2005[331]	33/224	13/227	2.57 (1.39; 4.76)	11.81	0.09 (0.04; 0.15)	7.8
Insomnia	van Kerrebroeck, 2004[393]	31/247	3/247	10.33 (3.20; 33.36)	6.41	0.11 (0.07; 0.16)	8.76
Insomnia	Norton, 2002[355]	7/140	1/138	6.9 (0.86; 55.35)	2.71	0.04 (0.00; 0.08)	9.13
Insomnia	Castro-Diaz, 2007[254]	14/136	6/120	2.06 (0.82;5.19)	8.41	0.05 (-0.01; 0.12)	7.1
Insomnia	Dmochowski, 2003[279]	49/344	8/339	6.04 (2.90; 12.55)	10.42	0.12 (0.08; 0.16)	9.01
Insomnia	Bent, 2008[234]	7/300	7/288	0.96 (0.34; 2.70)	7.44	-0.00 (-0.03; 0.02)	10.13
Insomnia	Steers, 2007[381]	20/153	5/153	4 (1.54; 10.38)	8.14	0.10 (0.04; 0.16)	7.4
Insomnia	Cardozo, 2010[249]	63/1378	24/1380	2.63 (1.65; 4.18)	13.7	0.03 (0.02; 0.04)	10.69
	Pooled	395/4266	95/4229	3.76 (2.59; 5.47)	100	0.08 (0.05; 0.11)	100
	P value/I squared			0.01 55.20%		0 86.90%	
Nausea	Ghoniem, 2005[293]	40/104	5/97	7.46 (3.07; 18.13)	6.09	0.33 (0.23; 0.44)	5.49
Nausea	Millard, 2004[350]	57/227	9/231	6.45 (3.27; 12.71)	7.72	0.21 (0.15; 0.27)	7.51
Nausea	Cardozo, 2004[251]	25/55	7/54	3.51 (1.66; 7.42)	7.13	0.33 (0.17; 0.48)	3.48
Nausea	Hurley, 2006[312]	222/958	35/955	6.32 (4.48; 8.93)	10.74	0.20 (0.17; 0.22)	8.92
Nausea	Kinchen, 2005[331]	70/224	13/227	5.46 (3.11; 9.58)	8.76	0.26 (0.19; 0.32)	7.21
Nausea	van Kerrebroeck, 2004[393]	69/247	16/247	4.31 (2.58; 7.21)	9.21	0.22 (0.15; 0.28)	7.41
Nausea	Norton, 2002[355]	13/140	2/138	6.41 (1.47; 27.87)	3.22	0.08 (0.03; 0.13)	7.98

Appendix Table F40. Adverse effects after duloxetine vs. placebo, random effects model (continued)

Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Nausea	Castro-Diaz, 2007[254]	40/136	7/120	5.04 (2.35; 10.83)	7.01	0.24 (0.15; 0.32)	6.23
Nausea	Lin, 2008[339]	9/60	0/61	19.31 (1.15; 324.56)	1.08	0.15 (0.06; 0.24)	5.93
Nausea	Schagen van Leeuwen, 2008[378]	10/131	4/134	2.56 (0.82; 7.95)	4.6	0.05 (-0.01; 0.10)	7.9
Nausea	Dmochowski, 2003[279]	78/344	7/339	10.98 (5.14; 23.45)	7.06	0.21 (0.16; 0.25)	8.23
Nausea	Bent, 2008[234]	54/300	13/288	3.99 (2.23; 7.15)	8.57	0.13 (0.09; 0.19)	8.09
Nausea	Steers, 2007[381]	47/153	7/153	6.71 (3.13; 14.38)	7.03	0.26 (0.18; 0.34)	6.58
Nausea	Cardozo, 2010[249]	279/1378	113/1380	2.47 (2.01; 3.04)	11.78	0.12 (0.10; 0.15)	9.04
	Pooled	1013/4457	238/4424	5.02 (3.70; 6.82)	100	0.19 (0.15; 0.22)	100
	P value/I squared			0 70.40%		0 84.30%	
Sleep disorder	Schagen van Leeuwen, 2008[378]	4/131	1/134	4.09 (0.46; 36.12)	6.18	0.02 (-0.01; 0.06)	8.58
Somnolence	Ghoniem, 2005[293]	11/104	1/97	10.26 (1.35; 77.99)	6.84	0.10 (0.03; 0.16)	5.43
Somnolence	Millard, 2004[350]	19/227	0/231	39.68 (2.41; 653.35)	4.17	0.08 (0.05; 0.12)	8.13
Somnolence	Cardozo, 2004[251]	7/55	1/54	6.87 (0.88; 54.00)	6.69	0.11 (0.01; 0.20)	3.25
Somnolence	Hurley, 2006[312]	65/958	1/955	64.80 (9.01; 466.01)	7.12	0.07 (0.05; 0.08)	10.33
Somnolence	Kinchen, 2005[331]	23/224	4/227	5.83 (2.05; 16.58)	14.22	0.09 (0.04; 0.13)	7.38
Somnolence	van Kerrebroeck, 2004[393]	10/247	0/247	21 (1.24; 356.41)	4.1	0.04 (0.02; 0.07)	9.4
Somnolence	Castro-Diaz, 2007[254]	15/136	2/120	6.62 (1.55; 28.35)	10.42	0.09 (0.04; 0.15)	5.89
Somnolence	Lin, 2008[339]	9/60	0/61	19.31 (1.15; 324.56)	4.12	0.15 (0.06; 0.24)	3.32
Somnolence	Dmochowski, 2003[279]	30/344	1/339	29.56 (4.06; 215.57)	7.05	0.08 (0.05; 0.12)	8.87
Somnolence	Bent, 2008[234]	8/300	1/288	7.68 (0.97; 61.02)	6.64	0.02 (0.00; 0.04)	10.03
Somnolence	Steers, 2007[381]	6/153	0/153	13 (0.74; 228.77)	4.01	0.04 (0.01; 0.07)	8.57
Somnolence	Cardozo, 2010[249]	28/1378	12/1380	2.34 (1.19; 4.58)	18.45	0.01 (0.00; 0.02)	10.81
	Pooled	235/4317	24/4286	8.61 (4.58; 16.20)	100	0.06 (0.04; 0.08)	100
	P value/I squared			0.08 38.40%		0 85.20%	
Treatment associated adverse effects	Dmochowski, 2003[279]	255/344	170/339	1.48 (1.31; 1.68)	13.35	0.24 (0.17; 0.31)	13.9
Treatment associated adverse effects	Millard, 2004[350]	173/227	137/231	1.29 (1.13; 1.46)	12.63	0.169 0.085 0.253	11.46
Treatment associated adverse effects	van Kerrebroeck, 2004[393]	200/247	158/247	1.27 (1.13; 1.42)	14.93	0.17 (0.09; 0.25)	12.61

Appendix Table F40. Adverse effects after duloxetine vs. placebo, random effects model (continued)

Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Treatment associated adverse effects	Cardozo, 2004[251]	51/55	39/54	1.28 (1.07; 1.54)	7.98	0.21 (0.07; 0.34)	5.77
Treatment associated adverse effects	Kinchen, 2005[331]	198/224	159/227	1.26 (1.15; 1.39)	17.06	0.18 (0.11; 0.26)	13.44
Treatment associated adverse effects	Steers, 2007[381]	121/153	85/153	1.42 (1.21; 1.68)	9.27	0.24 (0.13; 0.34)	9.01
Treatment associated adverse effects	Lin, 2008[339]	48/60	27/61	1.81 (1.33; 2.46)	3.29	0.36 (0.20; 0.52)	4.49
Treatment associated adverse effects	Schagen van Leeuwen, 2008[378]	58/131	49/134	1.21 (0.90; 1.63)	3.59	0.08 (-0.04; 0.20)	7.32
Treatment associated adverse effects	Cardozo, 2010[249]	666/1378	460/1380	1.45 (1.32; 1.59)	17.88	0.15 (0.11; 0.19)	21.99
	Pooled	1769/2819	1283/2826	1.36 (1.28; 1.44)	100	0.19 (0.15; 0.22)	100
	P value/I squared			0.12 37.70%		0.07 44.60%	
Vomiting	Millard, 2004[350]	14/227	4/231	3.56 (1.19; 10.66)	7.65	0.04 (0.01; 0.08)	6.05
Vomiting	Cardozo, 2004[251]	7/55	1/54	6.87 (0.88; 54.00)	2.16	0.11 (0.01; 0.20)	0.85
Vomiting	Hurley, 2006[312]	46/958	15/955	3.06 (1.72; 5.44)	27.71	0.03 (0.02; 0.05)	29.24
Vomiting	Kinchen, 2005[331]	19/224	8/227	2.41 (1.08; 5.38)	14.17	0.05 (0.01; 0.09)	4.02
Vomiting	van Kerrebroeck, 2004[393]	16/247	5/247	3.2 (1.19; 8.60)	9.4	0.05 (0.01; 0.08)	6.1
Vomiting	Steers, 2007[381]	5/153	3/153	1.67 (0.41; 6.85)	4.6	0.01 (-0.02; 0.05)	5.98
Vomiting	Cardozo, 2010[249]	54/1378	19/1380	2.85 (1.70; 4.78)	34.31	0.03 (0.01; 0.04)	47.75
		161/3242	55/3247	2.9 (2.14; 3.93)	100	0.03 (0.02; 0.04)	100
				0.95 0.00%		0.40 2.90%	
Adverse effects	Bent, 2008[234]	5/300	5/288	0.96 (0.28; 3.28)	61.32	-0.00 (-0.02; 0.02)	57.85
	Steers, 2007[381]	6/153	1/153	6 (0.73; 49.25)	38.68	0.03 (-0.00; 0.07)	42.15
	Pooled	11/453	6/441	1.95 (0.34; 11.22)	100	0.01 (-0.02; 0.05)	100
	P value/I squared			0.14 53.90%		0.10 63.90%	

Appendix Table F41. Adverse effects after duloxetine treatments compared to placebo (pooled results from RCTs)

Outcome	Studies	Patients	Rate active/ control	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)	Bayesian odds ratio median (2.5; 97.5%)	Evidence
Total bilirubin above ULN	2[312,350]	2,371	0.4/1.4	0.30 (0.08; 1.20)	-0.02 (-0.05; 0.00)			0.26 (0.06; 0.90)	Low
ALT above ULN/ Abnormal elevation in alanine aminotransferase	2[312,350]	2,371	7.4/5.4	1.37 (1.00; 1.87)	0.015 (-0.001; 0.000)			1.38 (0.55; 3.34)	Low
AST above ULN/ Abnormal elevation in aspartate aminotransferase	2[312,350]	2,371	5.3/4.0	1.06 (0.43; 2.64)	0.00 (-0.03; 0.00)			1.06 (0.28; 2.76)	Low
Anorexia	3[312,350,378]	2,636	4.3/0.2	18.10 (5.66; 57.85)	0.04 (0.02; 24.39)	24 (17; 42)	41 (24; 58)	36.13 (9.10; 233.30)	Moderate
Anorgasmia	2[312,381]	2,219	1.6/0.0	17.38 (2.31; 130.72)	0.02 (0.00; 58.82)	59 (31; 333)	17 (3; 32)		Low
Anxiety	3[312,331,381]	2,670	2.4/0.7	3.21 (1.55; 6.66)	0.02 (0.01; 52.63)	53 (29; 200)	19 (5; 34)	4.11 (1.65; 11.50)	High
Appetite decreased	5[234,312,331,339,381]	3,379	2.8/0.3	7.54 (3.21; 17.68)	0.02 (0.02; 43.48)	43 (32; 67)	23 (15; 31)	11.44 (4.43; 35.72)	High
Asthenia	4[249,293,312,339]	4,993	1.7/0.3	5.03 (2.35; 10.75)	0.01 (0.00; 76.92)	77 (42; 333)	13 (3; 24)	7.47 (2.90; 23.90)	Moderate
Constipation	13[234,249,254,279, 293,312,331,339,350, 355,378,381,393]	8,772	10.3/2.4	4.01 (3.26; 4.93)	0.08 (0.06; 12.82)	13 (11; 16)	78 (64; 91)	4.67 (3.55; 6.17)	High
Diarrhea	6[254,279,312,331, 355,381]	3,887	5.3/2.9	1.91 (1.38; 2.65)	0.02 (0.00; 52.63)			1.80 (1.01; 2.95)	Moderate
Dizziness	13[234,249,251,254, 279,293,312,331, 339,350,355,378,393]	8,575	8.6/2.5	3.33 (2.69; 4.11)	0.07 (0.05; 14.93)	15 (12; 20)	67 (49; 84)	3.80 (2.89; 5.06)	High
Dry mouth	14[234,249,251,254, 279,293,312,331, 339,350,355,378, 381,393]	8,881	12.2/2.3	6.26 (4.22; 9.28)	0.12 (0.09; 8.70)	9 (7; 11)	115 (89; 141)	6.94 (5.07; 9.76)	High

Appendix Table F41. Adverse effects after duloxetine treatments compared to placebo (pooled results from RCTs) (continued)

Outcome	Studies	Patients	Rate active/ control	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)	Bayesian odds ratio median (2.5; 97.5%)	Evidence
Fatigue	12[234,249,251,279,312,331,339,350,355,378,381,393]	8,424	10.0/3.0	3.22 (2.66; 3.90)	0.08 (0.05; 12.99)	13 (10; 19)	77 (53; 100)	3.60 (2.75; 4.73)	High
Headache	10[249,251,254,279,312,331,350,355,381,393]	7,706	9.3/5.9	1.58 (1.35; 1.86)	0.03 (0.02; 30.30)	30 (22; 50)	33 (20; 46)	1.67 (1.28; 2.21)	High
Hyperhidrosis	7[239,249,312,331,339,350,378]	23,788	2.4/0.6	4.34 (3.29; 5.73)	0.04 (0.02; 28.57)	29 (20; 48)	35 (21; 49)	6.02 (3.85; 10.53)	High
Insomnia	12[234,249,251,254,279,293,312,331,350,355,381,393]	8,495	9.3/2.3	3.76 (2.59; 5.47)	0.08 (0.05; 13.16)	13 (10; 21)	76 (47; 105)	4.35 (3.01; 6.26)	High
Nausea	14[234,249,251,254,279,293,312,331,339,350,355,378,381,393]	8,881	22.7/5.4	5.02 (3.70; 6.82)	0.19 (0.15; 5.35)	5 (4; 7)	187 (149; 224)	6.25 (4.66; 8.50)	High
Somnolence	13[234,249,251,254,279,293,312,331,339,350,378,381,393]	8,603	5.4/0.6	8.61 (4.58; 16.20)	0.06 (0.04; 16.95)	17 (13; 26)	59 (39; 80)	11.84 (6.99; 21.58)	High
Treatment associated adverse effects	9[249,251,279,331,339,350,378,381,393]	5,646	62.7/45.4	1.36 (1.28; 1.44)	0.19 (0.15; 5.35)	5 (4; 7)	187 (150; 224)	2.53 (1.95; 3.44)	High
Vomiting	7[249,251,312,331,350,381,393]	6,489	5.0/1.7	2.90 (2.14; 3.93)	0.03 (0.02; 32.26)	32 (26; 45)	31 (22; 39)	3.21 (2.16; 4.95)	High
Adverse effects	2[234,381]	894	2.4/1.4	1.95 (0.34; 11.22)	0.01 (-0.02; 0.00)			1.94 (0.54; 8.21)	Low

Appendix Table F42. Outcomes after different doses of duloxetine

Outcome	Reference sample size	Daily dose mg/day	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Any TEAE mild	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg BID for 6 weeks	49/136	51/133	0.94 (0.69; 1.28)	-0.02 (-0.14; 0.09)		
Any TEAE mild	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg b.i.d. for 6 weeks	49/136	65/127	0.70 (0.53; 0.93)	-0.15 (-0.27; -0.03)	-7 (-30; -4)	-152 (-270; -33)
At least one adverse event	Norton, 2002[355] 275	20mg/day vs. 40mg/d	62/138	68/137	0.91 (0.70; 1.16)	-0.05 (-0.16; 0.07)		
At least one adverse event	Norton, 2002[355] 278	20mg/day vs. 80mg/d	62/138	73/140	0.86 (0.68; 1.10)	-0.07 (-0.19; 0.05)		
At least one adverse event	Norton, 2002[355] 277	40mg/day vs. 80mg/d	68/137	73/140	0.95 (0.76; 1.20)	-0.03 (-0.14; 0.09)		
Constipation	Norton, 2002[355] 275	20mg/day vs. 40mg/d	4/138	4/137	0.99 (0.25; 3.89)	0.00 (-0.04; 0.04)		
Constipation	Norton, 2002[355] 278	20mg/day vs. 80mg/d	4/138	6/140	0.68 (0.20; 2.34)	-0.01 (-0.06; 0.03)		
Constipation	Norton, 2002[355] 277	40mg/day vs. 80mg/d	4/137	6/140	0.68 (0.20; 2.36)	-0.01 (-0.06; 0.03)		
Constipation	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg BID for 6 weeks	16/136	18/133	0.87 (0.46; 1.63)	-0.02 (-0.10; 0.06)		
Constipation	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg b.i.d. for 6 weeks	16/136	6/127	2.49 (1.01; 6.17)	0.07 (0.00; 0.14)	14 (7; 205)	70 (5; 136)

Appendix Table F42. Outcomes after different doses of duloxetine (continued)

Outcome	Reference sample size	Daily dose mg/day	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Constipation	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	6/127	18/133	0.35 (0.14; 0.85)	-0.09 (-0.16; -0.02)	-11 (-52; -6)	-88 (-157; -19)
Constipation	Gahimer, 2007[291] 15,178	20-60mg/day vs. 20-120mg once/twice a day	48/826	1149/14352	0.73 (0.55; 0.96)	-0.02 (-0.04; -0.01)	-46 (-186; -26)	-21 (-39; -5)
Diarrhea	Norton, 2002[355] 275	20mg/day vs. 40mg/d	5/138	4/137	1.24 (0.34; 4.52)	0.01 (-0.03; 0.05)		
Diarrhea	Norton, 2002[355] 278	20mg/day vs. 80mg/d	5/138	4/140	1.27 (0.35; 4.62)	0.01 (-0.03; 0.05)		
Diarrhea	Norton, 2002[355] 277	40mg/day vs. 80mg/d	4/137	4/140	1.02 (0.26; 4.00)	0.00 (-0.04; 0.04)		
Diarrhea	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	1/136	0/133	2.93 (0.12; 71.39)	0.01 (-0.01; 0.03)		
Diarrhea	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg b.i.d. for 6 weeks	1/136	4/127	0.23 (0.03; 2.06)	-0.02 (-0.06; 0.01)		
Diarrhea	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	4/127	0/133	9.42 (0.51; 173.25)	0.03 (0.00; 0.07)		
Diarrhea	Gahimer, 2007[291] 15178	20-60mg/day vs. 20-120mg once/twice a day	11/826	502/14352	0.38 (0.21; 0.69)	-0.02 (-0.03; -0.01)	-46 (-75; -33)	-22 (-30; -13)
Dizziness	Norton, 2002[355] 275	20mg/day vs. 40mg/d	2/138	6/137	0.33 (0.07; 1.61)	-0.03 (-0.07; 0.01)		
Dizziness	Norton, 2002[355] 278	20mg/day vs. 80mg/d	2/138	7/140	0.29 (0.06; 1.37)	-0.04 (-0.08; 0.01)		
Dizziness	Norton, 2002[355] 277	40mg/day vs. 80mg/d	6/137	7/140	0.88 (0.30; 2.54)	-0.01 (-0.06; 0.04)		

Appendix Table F42. Outcomes after different doses of duloxetine (continued)

Outcome	Reference sample size	Daily dose mg/day	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Dizziness	Castro-Diaz, 2007[254] 2 69	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	14/136	4/133	3.42 (1.16; 10.13)	0.07 (0.01; 0.13)	14 (8; 71)	73 (14; 132)
Dizziness	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks	14/136	10/127	1.31 (0.60; 2.84)	0.02 (-0.05; 0.09)		
Dizziness	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	10/127	4/133	2.62 (0.84; 8.14)	0.05 (-0.01; 0.10)		
Dizziness	Gahimer, 2007[291] 15,178	20-60mg/day vs. 20-120mg once/twice a day	31/826	852/14,352	0.63 (0.44; 0.90)	-0.02 (-0.04; -0.01)	-46 (-120; -28)	-22 (-35; -8)
Dry mouth	Norton, 2002[355] 275	20mg/day vs. 40mg/d	4/138	5/137	0.79 (0.22; 2.89)	-0.01 (-0.05; 0.03)		
Dry mouth	Norton, 2002[355] 278	20mg/day vs. 80mg/d	4/138	7/140	0.58 (0.17; 1.94)	-0.02 (-0.07; 0.02)		
Dry mouth	Norton, 2002[355] 277	40mg/day vs.80mg/d	5/137	7/140	0.73 (0.24; 2.24)	-0.01 (-0.06; 0.03)		
Dry mouth	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	22/136	19/133	1.13 (0.64; 1.99)	0.02 (-0.07; 0.10)		
Dry mouth	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg b.i.d. for 6 weeks	22/136	15/127	1.37 (0.74; 2.52)	0.04 (-0.04; 0.13)		

Appendix Table F42. Outcomes after different doses of duloxetine (continued)

Outcome	Reference sample size	Daily dose mg/day	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Dry mouth	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	15/127	19/133	0.83 (0.44; 1.56)	-0.02 (-0.11; 0.06)		
Dry mouth	Gahimer, 2007[291] 15,178	20-60mg/day vs. 20-120mg once/twice a day	63/826	1559/14,352	0.70 (0.55; 0.89)	-0.03 (-0.05; -0.01)	-31 (-74; -20)	-32 (-51; -14)
Fatigue	Norton, 2002[355] 275	20mg/day vs. 40mg/d	1/138	8/137	0.12 (0.02; 0.98)	-0.05 (-0.09; -0.01)	-20 (-106; -11)	-51 (-93; -9)
Fatigue	Norton, 2002[355] 278	20mg/day vs. 80mg/d	1/138	10/140	0.10 (0.01; 0.78)	-0.06 (-0.11; -0.02)	-16 (-52; -9)	-64 (-109; -19)
Fatigue	Norton, 2002[355] 277	40mg/day vs. 80mg/d	8/137	10/140	0.82 (0.33; 2.01)	-0.01 (-0.07; 0.04)		
Fatigue	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	12/136	8/133	1.47 (0.62; 3.47)	0.03 (-0.03; 0.09)		
Fatigue	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks	12/136	6/127	1.87 (0.72; 4.83)	0.04 (-0.02; 0.10)		
Fatigue	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg BID for 2 weeks escalating to 40mg b.i.d. for 6 weeks	6/127	8/133	0.79 (0.28; 2.20)	-0.01 (-0.07; 0.04)		
Fatigue	Gahimer, 2007[291] 15,178	20-60mg/day vs. 20-120mg once/twice a day	41/826	1102/14,352	0.65 (0.48; 0.88)	-0.03 (-0.04; -0.01)	-37 (-85; -24)	-27 (-43; -12)
Headache	Norton, 2002[355] 275	20mg/day vs. 40mg/d	7/138	10/137	0.69 (0.27; 1.77)	-0.02 (-0.08; 0.03)		
Headache	Norton, 2002[355] 278	20mg/day vs. 80mg/d	7/138	8/140	0.89 (0.33; 2.38)	-0.01 (-0.06; 0.05)		
Headache	Norton, 2002[355] 277	40mg/day vs. 80mg/d	10/137	8/140	1.28 (0.52; 3.14)	0.02 (-0.04; 0.07)		

Appendix Table F42. Outcomes after different doses of duloxetine (continued)

Outcome	Reference sample size	Daily dose mg/day	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Headache	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	11/136	9/133	1.20 (0.51; 2.79)	0.01 (-0.05; 0.08)		
Headache	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg b.i.d. for 6 weeks	11/136	11/127	0.93 (0.42; 2.08)	-0.01 (-0.07; 0.06)		
Headache	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	11/127	9/133	1.28 (0.55; 2.98)	0.02 (-0.05; 0.08)		
Headache	Gahimer, 2007[291] 15,178	20-60mg/day vs. 20-120mg once/twice a day	68/826	1029/14352	1.15 (0.91; 1.45)	0.01 (-0.01; 0.03)		
Hyperhidrosis	Gahimer, 2007[291] 15,178	20-60mg/day vs. 20-120mg once/twice a day	54/826	549/14352	1.71 (1.30; 2.24)	0.03 (0.01; 0.04)	37 (23; 100)	27 (10; 44)
Insomnia	Norton, 2002[355] 275	20mg/day vs. 40mg/d	2/138	7/137	0.28 (0.06; 1.34)	-0.04 (-0.08; 0.01)		
Insomnia	Norton, 2002[355] 278	20mg/day vs. 80mg/d	2/138	7/140	0.29 (0.06; 1.37)	-0.04 (-0.08; 0.01)		
Insomnia	Norton, 2002[355] 277	40mg/day vs. 80mg/d	7/137	7/140	1.02 (0.37; 2.84)	0.00 (-0.05; 0.05)		
Insomnia	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	14/136	8/133	1.71 (0.74; 3.94)	0.04 (-0.02; 0.11)		
Insomnia	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg BID for 6 weeks	14/136	6/127	2.18 (0.86; 5.50)	0.06 (-0.01; 0.12)		

Appendix Table F42. Outcomes after different doses of duloxetine (continued)

Outcome	Reference sample size	Daily dose mg/day	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Insomnia	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	6/127	8/133	0.79 (0.28; 2.20)	-0.01 (-0.07; 0.04)		
Insomnia	Gahimer, 2007[291] 15,178	20-60mg/day vs. 20-120mg once/twice a day	59/826	1179/14352	0.87 (0.68; 1.12)	-0.01 (-0.03; 0.01)		
Nasopharyngitis	Norton, 2002[355] 275	20mg/day vs. 40mg/d	8/138	4/137	1.99 (0.61; 6.44)	0.03 (-0.02; 0.08)		
Nasopharyngitis	Norton, 2002[355] 278	20mg/day vs. 80mg/d	8/138	6/140	1.35 (0.48; 3.80)	0.02 (-0.04; 0.07)		
Nasopharyngitis	Norton, 2002[355] 277	40mg/day vs. 80mg/d	4/137	6/140	0.68 (0.20; 2.36)	-0.01 (-0.06; 0.03)		
Nausea	Norton, 2002[355] 275	20mg/day vs. 40mg/d	9/138	9/137	0.99 (0.41; 2.43)	0.00 (-0.06; 0.06)		
Nausea	Norton, 2002[355] 278	20mg/day vs. 80mg/d	9/138	13/140	0.70 (0.31; 1.59)	-0.03 (-0.09; 0.04)		
Nausea	Norton, 2002[355] 277	40mg/day vs. 80mg/d	9/137	13/140	0.71 (0.31; 1.60)	-0.03 (-0.09; 0.04)		
Nausea	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	40/136	22/133	1.78 (1.12; 2.82)	0.13 (0.03; 0.23)	8 (4; 34)	129 (30; 228)
Nausea	Castro-Diaz,2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg b.i.d. for 6 weeks	40/136	32/127	1.17 (0.78; 1.74)	0.04 (-0.07; 0.15)		
Nausea	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	32/127	22/133	1.52 (0.94; 2.47)	0.09 (-0.01; 0.18)		
Nausea	Gahimer, 2007[291] 15,178	20-60mg/day vs. 20-120mg once/twice a day	19/826	2204/14352	0.15 (0.10; 0.23)	-0.13 (-0.14; -0.12)	-8 (-8; -7)	-131 (-142; -119)

Appendix Table F42. Outcomes after different doses of duloxetine (continued)

Outcome	Reference sample size	Daily dose mg/day	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Nausea mild	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	56/136	78/133	0.70 (0.55; 0.90)	-0.17 (-0.29; -0.06)	-6 (-18; -3)	-175 (-292; -57)
Nausea mild	Castro-Diaz, 2007[254] 264	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg b.i.d. for 6 weeks	56/136	64/127	0.82 (0.63; 1.07)	-0.09 (-0.21; 0.03)		
Nausea moderate	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	48/127	43/133	1.17 (0.84; 1.63)	0.05 (-0.06; 0.17)		
Nausea severe	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	14/136	12/133	1.14 (0.55; 2.37)	0.01 (-0.06; 0.08)		
Nausea severe	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg b.i.d. for 6 weeks	14/136	15/127	0.87 (0.44; 1.73)	-0.02 (-0.09; 0.06)		
Nausea severe	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	15/127	12/133	1.31 (0.64; 2.69)	0.03 (-0.05; 0.10)		
Sinusitis	Norton, 2002[355] 275	20mg/day vs. 40mg/d	4/138	4/137	0.99 (0.25; 3.89)	0.00 (-0.04; 0.04)		
Sinusitis	Norton, 2002[355] 278	20mg/day vs. 80mg/d	4/138	4/140	1.01 (0.26; 3.98)	0.00 (-0.04; 0.04)		
Sinusitis	Norton, 2002[355] 277	40mg/day vs. 80mg/d	4/137	4/140	1.02 (0.26; 4.00)	0.00 (-0.04; 0.04)		

Appendix Table F42. Outcomes after different doses of duloxetine (continued)

Outcome	Reference sample size	Daily dose mg/day	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Somnolence	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	15/136	11/133	1.33 (0.64; 2.80)	0.03 (-0.04; 0.10)		
Somnolence	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg b.i.d. for 6 weeks	15/136	6/127	2.33 (0.93; 5.83)	0.06 (0.00; 0.13)		
Somnolence	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	6/127	11/133	0.57 (0.22; 1.50)	-0.04 (-0.10; 0.02)		
Somnolence	Gahimer, 2007[291] 15,178	20-60mg/day vs. 20-120mg once/twice a day	60/826	990/14352	1.05 (0.82; 1.35)	0.00 (-0.01; 0.02)		
TEAE moderate	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	65/136	64/133	0.99 (0.77; 1.27)	0.00 (-0.12; 0.12)		
TEAE moderate	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	42/127	64/133	0.69 (0.51; 0.93)	-0.15 (-0.27; -0.03)	-7 (-31; -4)	-151 (-268; -33)
TEAE severe	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	20/136	19/133	1.03 (0.58; 1.84)	0.00 (-0.08; 0.09)		
TEAE severe	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg b.i.d. for 6 weeks	20/136	20/127	0.93 (0.53; 1.65)	-0.01 (-0.10; 0.08)		

Appendix Table F42. Outcomes after different doses of duloxetine (continued)

Outcome	Reference sample size	Daily dose mg/day	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
TEAE severe	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. D for 2 weeks escalating to 40mg b.i.d. for 6 weeks	20/127	19/133	1.10 (0.62; 1.97)	0.01 (-0.07; 0.10)		
Upper respiratory tract infection	Norton, 2002[355] 275	20mg/day vs.40mg/d	2/138	2/137	0.99 (0.14; 6.95)	0.00 (-0.03; 0.03)		
Upper respiratory tract infection	Norton, 2002[355] 278	20mg/day vs. 80mg/d	2/138	1/140	2.03 (0.19; 22.12)	0.01 (-0.02; 0.03)		
Upper respiratory tract infection	Norton, 2002[355] 277	40mg/day vs. 80mg/d	2/137	1/140	2.04 (0.19; 22.28)	0.01 (-0.02; 0.03)		
Adverse effects leading to discontinuation	Duckett, 2007[285]215	60mg/day vs. 40mg twice daily	21/67	74/148	0.63 (0.42; 0.93)	-0.19 (-0.32; -0.05)	-5 (-20; -3)	-187 (-324; -49)
Discontinuation due to any adverse event	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	22/136	10/133	2.15 (1.06; 4.37)	0.09 (0.01; 0.16)	12 (6; 98)	87 (10; 163)
Discontinuation due to any adverse event	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg b.i.d. for 6 weeks	22/136	15/127	1.37 (0.74; 2.52)	0.04 (-0.04; 0.13)		
Discontinuation due to any adverse event	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	15/127	10/133	1.57 (0.73; 3.37)	0.04 (-0.03; 0.11)		
Discontinuation due to asthenia	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	2/136	1/133	1.96 (0.18; 21.31)	0.01 (-0.02; 0.03)		

Appendix Table F42. Outcomes after different doses of duloxetine (continued)

Outcome	Reference sample size	Daily dose mg/day	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Discontinuation due to asthenia	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg b.i.d. for 6 weeks	2/136	0/127	4.67 (0.23; 96.38)	0.01 (-0.01; 0.04)		
Discontinuation due to asthenia	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	0/127	1/133	0.35 (0.01; 8.49)	-0.01 (-0.03; 0.01)		
Discontinuation	Norton, 2002[355] 275	20mg/day vs. 40mg/d	13/138	17/137	0.76 (0.38; 1.50)	-0.03 (-0.10; 0.04)		
Discontinuation	Norton, 2002[355] 278	20mg/day vs. 80mg/d	13/138	21/140	0.63 (0.33; 1.20)	-0.06 (-0.13; 0.02)		
Discontinuation	Norton, 2002[355] 277	40mg/day vs. 80mg/d	17/137	21/140	0.83 (0.46; 1.50)	-0.03 (-0.11; 0.05)		
Discontinuation due to dizziness	Norton, 2002[355] 275	20mg/day vs. 40mg/d	0/138	2/137	0.20 (0.01; 4.10)	-0.01 (-0.04; 0.01)		
Discontinuation due to dizziness	Norton, 2002[355] 278	20mg/day vs. 80mg/d	0/138	1/140	0.34 (0.01; 8.23)	-0.01 (-0.03; 0.01)		
Discontinuation due to dizziness	Norton, 2002[355] 277	40mg/day vs. 80mg/d	2/137	1/140	2.04 (0.19; 22.28)	0.01 (-0.02; 0.03)		
Discontinuation due to dizziness	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	2/136	0/133	4.89 (0.24; 100.92)	0.01 (-0.01; 0.04)		
Discontinuation due to dizziness	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg b.i.d. for 6 weeks	2/136	2/127	0.93 (0.13; 6.53)	0.00 (-0.03; 0.03)		
Discontinuation due to dizziness	Castro-Diaz, 2007[254]	100mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	2/127	0/133	5.23 (0.25; 107.98)	0.02 (-0.01; 0.04)		

Appendix Table F42. Outcomes after different doses of duloxetine (continued)

Outcome	Reference sample size	Daily dose mg/day	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Discontinuation due to fatigue	Castro-Diaz, 2007[254]	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	0/136	0/133	0.00 (0.00; 0.00)	0.00 (-0.01; 0.01)		
Discontinuation due to fatigue	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg b.i.d. D for 6 weeks	0/136	1/127	0.31 (0.01; 7.58)	-0.01 (-0.03; 0.01)		
Discontinuation due to fatigue	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	1/127	0/133	3.14 (0.13; 76.39)	0.01 (-0.01; 0.03)		
Discontinuation due to headache	Castro-Diaz, 2007[254] 275	20mg/day vs. 40mg/d	1/138	1/137	0.99 (0.06; 15.71)	0.00 (-0.02; 0.02)		
Discontinuation due to headache	Castro-Diaz, 2007[254] 278	20mg/day vs. 80mg/d	1/138	2/140	0.51 (0.05; 5.53)	-0.01 (-0.03; 0.02)		
Discontinuation due to headache	Castro-Diaz, 2007[254] 277	40mg/day vs. 80mg/d	1/137	2/140	0.51 (0.05; 5.57)	-0.01 (-0.03; 0.02)		
Discontinuation due to headache	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	3/136	0/133	6.85 (0.36; 131.29)	0.02 (-0.01; 0.05)		
Discontinuation due to headache	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg b.i.d. for 6 weeks	3/136	1/127	2.80 (0.30; 26.59)	0.01 (-0.01; 0.04)		

Appendix Table F42. Outcomes after different doses of duloxetine (continued)

Outcome	Reference sample size	Daily dose mg/day	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Discontinuation due to headache	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. D for 6 weeks	1/127	0/133	3.14 (0.13; 76.39)	0.01 (-0.01; 0.03)		
Discontinuation due to insomnia	Castro-Diaz, 2007[254] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. for 6 weeks	2/136	1/133	1.96 (0.18; 21.31)	0.01 (-0.02; 0.03)		
Discontinuation due to insomnia	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg b.i.d. for 6 weeks	2/136	1/127	1.87 (0.17; 20.35)	0.01 (-0.02; 0.03)		
Discontinuation due to insomnia	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. D for 6 weeks	1/127	1/133	1.05 (0.07; 16.56)	0.00 (-0.02; 0.02)		
Discontinuation due to menorhagia	Norton, 2002[355] 275	20mg/day vs. 40mg/d	2/138	0/137	4.96 (0.24; 102.46)	0.01 (-0.01; 0.04)		
Discontinuation due to menorhagia	Norton, 2002[355] 278	20mg/day vs. 80mg/d	2/138	0/140	5.07 (0.25; 104.69)	0.01 (-0.01; 0.04)		
Discontinuation due to menorhagia	Norton, 2002[355] 277	40mg/day vs. 80mg/d	0/137	0/140		0.00 (-0.01; 0.01)		
Discontinuation due to nausea	Norton, 2002[355] 275	20mg/day vs. 40mg/d	2/138	5/137	0.40 (0.08; 2.01)	-0.02 (-0.06; 0.02)		
Discontinuation due to nausea	Norton, 2002[355] 278	20mg/day vs. 80mg/d	2/138	6/140	0.34 (0.07; 1.65)	-0.03 (-0.07; 0.01)		
Discontinuation due to nausea	Norton, 2002[355] 277	40mg/day vs. 80mg/d	5/137	6/140	0.85 (0.27; 2.73)	-0.01 (-0.05; 0.04)		

Appendix Table F42. Outcomes after different doses of duloxetine (continued)

Outcome	Reference sample size	Daily dose mg/day	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Discontinuation due to nausea	Norton, 2002[355] 269	80mg/day vs. 20mg b.i.d. for 2 weeks escalating to 40mg b.i.d. D for 6 weeks	4/136	3/133	1.30 (0.30; 5.72)	0.01 (-0.03; 0.04)		
Discontinuation due to nausea	Castro-Diaz, 2007[254] 263	80mg/day vs. 40mg QD for 2 weeks escalating to 40mg b.i.d. for 6 weeks	4/136	2/127	1.87 (0.35; 10.02)	0.01 (-0.02; 0.05)		
Discontinuation due to nausea	Castro-Diaz, 2007[254] 260	100mg/day vs. 20mg b.i.d. D for 2 weeks escalating to 40mg b.i.d. for 6 weeks	2/127	3/133	0.70 (0.12; 4.11)	-0.01 (-0.04; 0.03)		
Discontinuation due to somnolence	Norton, 2002[355] 275	20mg/day vs. 40mg/d	1/138	0/137	2.98 (0.12; 72.48)	0.01 (-0.01; 0.03)		
Discontinuation due to somnolence	Norton, 2002[355] 278	20mg/day vs. 80mg/d	1/138	2/140	0.51 (0.05; 5.53)	-0.01 (-0.03; 0.02)		
Discontinuation due to somnolence	Norton, 2002[355] 277	40mg/day vs. 80mg/d	0/137	2/140	0.20 (0.01; 4.22)	-0.01 (-0.04; 0.01)		
Discontinuation due to lack of efficacy leading to discontinuation	Duckett, 2007[285] 215	60mg/day vs. 40mg twice daily	14/67	37/148	0.84 (0.49; 1.44)	-0.04 (-0.16; 0.08)		

Appendix Table F43. Adverse effects that result in discontinuation of the treatment after duloxetine vs. placebo, random effects models

Reference	Active events/ randomized	Control events/ randomized	Relative risk	Lower (95% CI)	Upper (95% CI)	Weight	Absolute risk difference	Lower (95% CI)	Upper (95% CI)	Weight
Anxiety										
	6/958	0/955	9.158	0.496	169.125	49.29	0.018	-0.001	0.037	16.45
	4/227	0/231	12.959	0.731	229.72	50.71	0.006	0.001	0.012	83.55
Pooled estimate			10.921	1.41	84.603	100	0.008	0	0.016	100
I squared			0.00%				21.20%			
p value for heterogeneity			0.868				0.26			
Asthenia										
	1/60	0/61	2.8	0.115	67.922	23.69	0.01	-0.017	0.036	12.41
	2/136	0/120	4.416	0.214	91.081	26.3	0.015	-0.01	0.04	14
	2/300	0/288	3.049	0.127	73.398	23.81	0.017	-0.028	0.061	4.42
	1/104	0/97	4.801	0.231	99.566	26.2	0.007	-0.005	0.018	69.18
Pooled estimate			3.71	0.786	17.516	100	0.009	-0.001	0.018	100
I squared			0.00%				0.00%			
p value for heterogeneity			0.994				0.926			
Constipation										
Hurley, 2006[312]	1/955	1/955	0.311	0.013	7.547	37.16	-0.01	-0.038	0.017	2.14
Constipation-discontinuation due to adverse event										
Ghoniem, 2005[293]	1/97	1/97	2.991	0.312	28.699	62.84	0.002	-0.002	0.006	97.86
Pooled estimate			1.29	0.151	11.001	100	0.002	-0.002	0.006	100
I squared			22.30%				0.00%			
p value for heterogeneity			0.257				0.385			
Dizziness										
Ghoniem, 2005[293]	2/104	0/97	4.667	0.227	95.996	6.33	0.019	-0.013	0.052	3.74
Millard, 2004[350]	5/227	0/231	11.193	0.623	201.255	6.93	0.022	0.001	0.043	9.08
Hurley, 2006[312]	20/958	2/955	9.969	2.337	42.531	27.48	0.019	0.009	0.028	43.41
van Kerrebroeck, 2004[393]	9/247	1/247	9	1.149	70.504	13.65	0.032	0.008	0.057	6.45
Norton, 2002[355]	1/140	0/138	2.957	0.122	71.977	5.68	0.007	-0.012	0.027	10.17
Castro-Diaz, 2007[254]	2/136	0/120	4.416	0.214	91.081	6.32	0.015	-0.01	0.04	6.2
Lin, 2008[339]	4/60	2/61	2.033	0.387	10.689	21	0.034	-0.043	0.111	0.66
Dmochowski, 2003[279]	5/344	1/339	4.927	0.579	41.954	12.61	0.012	-0.002	0.025	20.3
Pooled estimate			5.487	2.564	11.739	100	0.017	0.011	0.023	100
I squared			0.00%				0.00%			
p value for heterogeneity			0.914				0.821			

Appendix Table F43. Adverse effects that result in discontinuation of the treatment after duloxetine vs. placebo, random effects models (continued)

Reference	Active events/ randomized	Control events/ randomized	Relative risk	Lower (95% CI)	Upper (95% CI)	Weight	Absolute risk difference	Lower (95% CI)	Upper (95% CI)	Weight
Fatigue										
Hurley, 2006[312]	13/958	2/955	6.48	1.466	28.636	37.22	0.011	0.004	0.019	41.12
Castro-Diaz, 2007[254]	0/136	2/120	0.177	0.009	3.643	17.1	-0.017	-0.044	0.011	11.54
Bent, 2008[234]	4/300	0/288	8.869	1.13	69.624	27.67	0.023	0.005	0.041	20.97
Dmochowski, 2003[279]	9/344	1/339	8.641	0.467	159.784	18.01	0.013	-0.001	0.028	26.37
Pooled estimate			4.021	0.913	17.71	100	0.011	0.001	0.022	100
I squared			42.60%				48.30%			
p value for heterogeneity			0.156				0.121			
Insomnia										
Hurley, 2006[312]	16/958	2/955	10.267	0.575	183.248	8.47	0.048	0.003	0.093	1.91
van Kerrebroeck, 2004[393]	5/247	1/247	7.123	0.37	137.119	8.05	0.013	-0.004	0.03	13.25
Castro-Diaz, 2007[254]	2/136	1/120	7.975	1.839	34.589	32.69	0.015	0.006	0.023	51.81
Lin, 2008[339]	1/60	0/61	5	0.588	42.488	15.37	0.016	-0.003	0.035	10.37
Dmochowski, 2003[279]	7/344	1/339	1.765	0.162	19.218	12.34	0.006	-0.02	0.032	5.71
Ghoniem, 2005[293]	5/104	0/97	3.049	0.127	73.398	6.96	0.017	-0.028	0.061	1.92
Millard, 2004[350]	3/227	0/231	6.898	0.853	55.767	16.11	0.017	0.001	0.033	15.03
Pooled estimate			5.7	2.463	13.189	100	0.015	0.009	0.021	100
I squared			0.00%				0.00%			
p value for heterogeneity			0.959				0.85			
Nausea										
Ghoniem, 2005[293]	7/104	0/97	14	0.81	241.894	5.74	0.067	0.016	0.119	3.31
Millard, 2004[350]	7/227	0/231	15.263	0.877	265.685	5.71	0.031	0.007	0.055	12.96
Hurley, 2006[312]	48/958	3/955	15.95	4.985	51.03	34.44	0.047	0.033	0.061	27.18
van Kerrebroeck, 2004	13/247	2/247	6.5	1.482	28.503	21.32	0.045	0.015	0.075	8.83
Norton, 2002[355]	6/140	1/138	5.914	0.721	48.486	10.52	0.036	-0.001	0.072	6.26
Castro-Diaz, 2007[254]	4/136	0/120	7.949	0.432	146.134	5.5	0.029	-0.003	0.061	7.91
Lin, 2008[339]	2/60	0/61	5.082	0.249	103.691	5.12	0.033	-0.021	0.088	2.94
Dmochowski, 2003[279]	22/344	0/339	44.348	2.701	728.141	5.95	0.064	0.038	0.09	11.02
Bent, 2008[234]	7/300	0/288	14.402	0.826	251.018	5.7	0.023	0.005	0.042	19.61

Appendix Table F43. Adverse effects that result in discontinuation of the treatment after duloxetine vs. placebo, random effects models (continued)

Reference	Active events/ randomized	Control events/ randomized	Relative risk	Lower (95% CI)	Upper (95% CI)	Weight	Absolute risk difference	Lower (95% CI)	Upper (95% CI)	Weight
Pooled estimate			11.267	5.693	22.295	100	0.04	0.031	0.05	100
I squared			0.00%				16.40%			
p value for heterogeneity			0.958				0.297			
Somnolence										
Norton, 2002[355]	2/140	0/138	4.667	0.227	95.996	12.04	0.019	-0.013	0.052	2.74
Bent, 2008[234]	3/300	0/288	9.969	1.279	77.721	26.09	0.009	0.003	0.016	63.07
Lin, 2008[339]	2/60	0/61	4.929	0.239	101.744	12.01	0.014	-0.01	0.038	5.02
Dmochowski, 2003	7/344	1/339	5.082	0.249	103.691	12.1	0.033	-0.021	0.088	0.97
Hurley, 2006[312]	10/958	1/955	6.898	0.853	55.767	25.19	0.017	0.001	0.033	11.24
Ghoniem, 2005[293]	2/104	0/97	6.721	0.349	129.543	12.57	0.01	-0.003	0.023	16.96
Pooled estimate			6.684	2.341	19.081	100	0.011	0.006	0.017	100
I squared			0.00%				0.00%			
p value for heterogeneity			0.998				0.874			
Any adverse event										
Millard, 2004[350]	39/227	4/231	9.922	3.604	27.312	9.98	0.154	0.103	0.206	11.06
Cardozo, 2004[251]	18/55	3/54	5.891	1.841	18.851	9.37	0.272	0.133	0.41	7.66
Castro-Diaz, 2007[254]	22/136	7/120	5	0.241	103.616	3.8	0.008	-0.006	0.022	11.87
Bent, 2008[234]	47/300	9/288	2.957	1.299	6.731	10.72	0.099	0.03	0.169	10.45
Norton, 2002[355]	21/140	7/138	2.773	1.228	6.261	10.75	0.103	0.029	0.178	10.26
Lin, 2008[339]	16/60	4/61	4.067	1.443	11.46	9.88	0.201	0.073	0.329	8.07
Schagen van Leeuwen, 2008[378]	15/131	7/134	2.192	0.924	5.202	10.56	0.062	-0.004	0.129	10.57
Dmochowski, 2003[279]	83/344	14/339	5.842	3.384	10.086	11.66	0.2	0.15	0.25	11.12
Duckett, 2007[285]	21/67	74/148	0.627	0.425	0.925	12.08	-0.187	-0.324	-0.049	7.7
van Kerrebroeck, 2004[393]	2/247	0/247	5.013	2.503	10.041	11.19	0.125	0.08	0.171	11.24
Pooled estimate			3.434	1.691	6.974	100	0.105	0.041	0.169	100
I squared			87.40%				92.80%			
p value for heterogeneity			0.00%				0.00%			
Diarrhea										
Bent, 2008[234]	3/300	1/288	1.994	0.181	21.951	46.97	0.001	-0.003	0.005	93.23
Hurley, 2006[312]	2/958	1/955	2.88	0.301	27.527	53.03	0.007	-0.007	0.02	6.77
Pooled estimate			2.423	0.468	12.541	100	0.001	-0.002	0.005	100
I squared			0.00%				0.00%			

Appendix Table F43. Adverse effects that result in discontinuation of the treatment after duloxetine vs. placebo, random effects models (continued)

Reference	Active events/ randomized	Control events/ randomized	Relative risk	Lower (95% CI)	Upper (95% CI)	Weight	Absolute risk difference	Lower (95% CI)	Upper (95% CI)	Weight
p value for heterogeneity			0.827				0.43			
Headache										
Norton, 2002[355]	3/136	1/120	4.929	0.239	101.744	25.72	0.014	-0.01	0.038	22.85
Castro-Diaz, 2007[254]	4/300	0/288	2.647	0.279	25.11	46.58	0.014	-0.016	0.043	15
Bent, 2008[234]	3/136	1/120	8.641	0.467	159.784	27.7	0.013	-0.001	0.028	62.15
Pooled estimate			4.311	0.928	20.016	100	0.014	0.002	0.025	100
I squared			0.00%				0.00%			
p value for heterogeneity			0.816				0.998			

Appendix Table F44. Exploring clinical diversity in discontinuation rates due to adverse effects after duloxetine when compared to placebo

Reference	Country	Weeks of treatment	Age	Prior treatment	Concurrent medication	% Women	Inclusion of women with surgical risk factors for UI	Inclusion of those who failed prior treatments	Inclusion of minorities	Presence of mixed UI	Daily UI
Millard, 2004[350]	Poland, South Africa, Australia, Brazil, Argentina and Finland	12	53.7-52.6	Previous continence surgery including injections, 18.5% in active and 17.3% in control group	No response	100	No response	No response	Yes	No response	Yes
Cardozo, 2004[251]	Australia, Canada, the Netherlands, and the United Kingdom	8	54.5-52.4	Prior continence surgery in 16.4% duloxetine and 14.8% placebo women	Hormone replacement therapy in 47.3% duloxetine and 40.7% placebo group	100	No response	No response	Yes	No response	Yes
Castro-Diaz, 2007[254]	64 study centers in 8 countries	8	52.7-53.3	No response	No response	100	No response	No response	No response	No response	Yes
Bent, 2008[234]	USA	8	53.2-54.2	Antimuscarinic agents (either tolterodine or oxybutynin) were used by 7.8% of subjects	Antidepressant medications, including other SNRIs and selective serotonin reuptake inhibitors:19.4 % in placebo and 23.0% in active group	100	No	No	Yes	Yes	Yes
Norton, 2002[355]	USA	12	49.3-53.2	No response	No response	100	No	No response	Yes	No response	Yes

Appendix Table F44. Exploring clinical diversity in discontinuation rates due to adverse effects after duloxetine when compared to placebo (continued)

Reference	Country	Weeks of treatment	Age	Prior treatment	Concurrent medication	% Women	Inclusion of women with surgical risk factors for UI	Inclusion of those who failed prior treatments	Inclusion of minorities	Presence of mixed UI	Daily UI
Lin, 2008[339]	Taiwan	8	53-56	Previous surgery had 3 women in duloxetine and 5 in placebo group	Were not permitted	100	No response	No response	No response	No response	Yes
Schagen van Leeuwen, 2008[378]	Germany, France, The Netherlands, Spain, Sweden, Switzerland and South-Africa	12	70.63-71.1	Previous incontinence surgery 15.3% in placebo and 11.9% in duloxetine	Approximately 80% of patients reported concomitant drug therapies before and after randomization. Behavioral therapy 0.8% in placebo and 0.7% in duloxetine; Current PFMT 9.9% in placebo and 9.7% in duloxetine group	100	No	No response	Yes	Yes	Yes
Dmochowski, 2003[279]	Canada and the United States	12	52.3-53.3	% prior continence surgery, including injection 12.2% in duloxetine and 13.1% in placebo group % PFMT 16.9% in duloxetine and 18.0% in placebo group	No response	100	No response	No response	Yes	No response	Yes

Appendix Table F44. Exploring clinical diversity in discontinuation rates due to adverse effects after duloxetine when compared to placebo (continued)

Reference	Country	Weeks of treatment	Age	Prior treatment	Concurrent medication	% Women	Inclusion of women with surgical risk factors for UI	Inclusion of those who failed prior treatments	Inclusion of minorities	Presence of mixed UI	Daily UI
van Kerrebroeck, 2004[393]	Belgium, Canada, Denmark, France, Germany, The Netherlands, Sweden and the United Kingdom	12	52-54	Prior continence surgery in 7.7% in duloxetine and in 7.7% placebo group	No response	100	No response	No response	Yes	No response	Yes

Appendix Table F45. Exploring heterogeneity in discontinuation rates due to adverse effects after duloxetine compared to placebo (results from meta-regression)

Variable	Coefficient	Standard error	T statistic	P>t	Lower 95% CI	Upper 95% CI
Daily dose	0.01	0.004	1.83	0.11	-0.01	0.02
Constant	-.49	0.34	-1.47	0.19	-1.69	0.69
Conflict of interest	0.03	0.06	0.52	0.62	-0.17	0.23
Constant	0.08	0.10	0.78	0.46	-0.27	0.42
Adequacy of randomization	0.06	0.06	1.00	0.36	-0.16	0.28
Allocation concealment	0.08	0.07	1.20	0.28	-0.17	0.33
Constant	-0.12	0.18	-0.64	0.55	-0.80	0.57
Presence of mixed UI	-0.04	0.14	-0.26	0.81	-0.70	0.63
Inclusion of minorities	0.00	0.09	0.00	1.00	-0.43	0.43
Presence of those who failed prior treatments	0.06	0.14	0.45	0.68	-0.59	0.71
Presence of women with surgical risk factors for UI	-0.05	0.11	-0.42	0.70	-0.57	0.48
Constant	0.15	0.08	1.90	0.13	-0.21	0.50

Appendix Table F46. Exploring methodological diversity in discontinuation rates due to adverse effects after duloxetine compared to placebo

Reference	Masking	Intention to treat	Allocation concealment	Adequacy of randomization	Justification for sample size	Presence of conflict of interest
Millard, 2004[350]	Double blind	Yes	Adequate	No	Yes	No response
Cardozo, 2004[251]	Double blind	Yes	Adequate	Adequate	Yes	Yes
Castro-Diaz, 2007[254]	Double blind	Yes	Unclear	Adequate	Yes	Yes
Bent, 2008[234]	Double blind	Yes	Adequate	Adequate	Yes	Yes
Norton, 2002[355]	Double blind	Yes	Adequate	Adequate	Yes	No response
Lin, 2008[339]	Double blind	Yes	Adequate	No	Yes	Yes
Schagen van Leeuwen, 2008[378]	Double blind	Yes	Unclear	Adequate	Yes	No response
Dmochowski, 2003[279]	Double blind	Yes	Adequate	Adequate	Yes	Yes
van Kerrebroeck, 2004[393]	Double blind	Yes	Adequate	No	Yes	Yes

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Darifenacin	Adverse effects	Hill, 2006[44]	73/107	54/109	1.4(1.1;1.7)	20.83	0.187(0.06;0.32)	16.47
Darifenacin	Adverse effects	Zinner, 2006[414]	136/214	110/225	1.3(1.1;1.5)	26.51	0.147(0.06;0.24)	24.15
Darifenacin	Adverse effects	Chapple, 2007[261]	99/266	24/133	2.1(1.4;3.1)	10.96	0.192(0.10;0.28)	25.28
Darifenacin	Adverse effects	Hill, 2006[44]	62/108	54/109	1.2(0.9;1.5)	19.21	0.079(-0.05;0.21)	15.9
Darifenacin	Adverse effects	Hill, 2006[44]	92/115	54/109	1.6(1.3;2.0)	22.48	0.305(0.19;0.42)	18.2
	Pooled				1.4(1.2;1.7)	100	0.183(0.12;0.25)	100
	P value/I squared				0.071/54		0.132/44	
Darifenacin	Nausea	Lipton, 2005[340]	1/65	1/69	1.06 (0.07; 16.62)	29.5	0.001 (-0.04; 0.04)	19.08
Darifenacin	Nausea	Zinner, 2006[414]	3/214	2/225	1.58 (0.27; 9.35)	70.5	0.005 (-0.02; 0.03)	80.92
	Pooled				1.40 (0.32; 6.25)	100	0.004 (-0.01; 0.02)	100
	P value/I squared				0.813	0.00%	0.856	0.00%
Darifenacin	Serious adverse effects	Hill, 2006[44]	2/107	2/109	1.02 (0.15; 7.10)	41.31	0.000 (-0.04; 0.04)	29.35
Darifenacin	Serious adverse effects	Zinner, 2006[414]	2/214	5/225	0.42 (0.08; 2.15)	58.69	-0.013 (-0.04; 0.01)	70.65
	Pooled				0.61 (0.17; 2.11)	100	-0.009 (-0.03; 0.01)	
	P value/I squared				0.494	0.00%	0.545	0.00%
Darifenacin	Urinary tract infection	Hill, 2006[44]	3/107	2/109	1.53 (0.26; 8.96)	28.46	0.010 (-0.03; 0.05)	36.63
Darifenacin	Urinary tract infection	Zinner, 2006[414]	6/214	6/225	1.05 (0.34; 3.21)	71.54	0.001 (-0.03; 0.03)	63.37
	Pooled				1.17 (0.46; 3.01)	100	0.004 (-0.02; 0.03)	100
	P value/I squared				0.726	0.00%	0.747	0.00%
Darifenacin	Constipation	Hill, 2006[44]	17/108	5/109	3.43 (1.31; 8.97)	11.81	0.112 (0.03; 0.19)	12.17
Darifenacin	Constipation	Chapple, 2007[261]	41/266	11/133	1.86 (0.99; 3.51)	16.56	0.071 (0.01; 0.14)	13.21
Darifenacin	Constipation	Chapple, 2004[473]	2/53	11/164	0.56 (0.13; 2.46)	7.01	-0.029 (-0.09; 0.04)	13.19
Darifenacin	Constipation	Lipton, 2005[340]	8/65	6/69	1.42 (0.52; 3.86)	11.3	0.036 (-0.07; 0.14)	10.46
Darifenacin	Constipation	Hill, 2006[44]	27/107	5/109	5.50 (2.20; 13.75)	12.38	0.206 (0.12; 0.30)	11.33
Darifenacin	Constipation	Zinner, 2006[414]	9/214	8/225	1.18 (0.47; 3.01)	12.16	0.007 (-0.03; 0.04)	14.81
Darifenacin	Constipation	Chapple, 2004[473]	33/229	11/164	2.15 (1.12; 4.13)	16.24	0.077 (0.02; 0.14)	13.49
Darifenacin	Constipation	Hill, 2006[44]	32/115	5/109	6.07 (2.45; 15.00)	12.52	0.232 (0.14; 0.32)	11.35
	Pooled				2.29 (1.44; 3.65)	100	0.084 (0.03; 0.14)	100
	P value/I squared				0.032	54.50%	0	83.20%
Darifenacin	Treatment discontinuation	Chapple, 2004[473]	4/53	12/164	1.03 (0.35; 3.06)	14.52	0.002 (-0.08; 0.08)	40.1

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Darifenacin	Treatment discontinuation	Zinner, 2006[414]	29/214	37/225	0.82 (0.53; 1.29)	85.48	-0.029 (-0.10; 0.04)	59.9
	Pooled				0.85 (0.56; 1.29)	100	-0.016 (-0.07; 0.04)	100
	P value/I squared				0.709	0.00%	0.561	0.00%
Darifenacin	Treatment discontinuation due to adverse effects	Steers, 2005[45]	12/108	4/41	1.14 (0.39; 3.33)	11.61	0.014 (-0.10; 0.12)	1.72
Darifenacin	Treatment discontinuation due to adverse effects	Hill, 2006[44]	2/108	3/109	0.67 (0.12; 3.95)	4.92	-0.009 (-0.05; 0.03)	9.74
Darifenacin	Treatment discontinuation due to adverse effects	Chapple, 2007[261]	12/266	9/133	0.67 (0.29; 1.54)	16.75	-0.023 (-0.07; 0.03)	6.99
Darifenacin	Treatment discontinuation due to adverse effects	U.S. Food and Drug Administration, 2004 [43]	3/229	3/164	0.72 (0.15; 3.50)	5.98	-0.005 (-0.03; 0.02)	17.32
Darifenacin	Treatment discontinuation due to adverse effects	Chapple, 2004[473]	0/53	2/164	0.61 (0.03; 12.53)	1.79	-0.012 (-0.04; 0.02)	13.36
Darifenacin	Treatment discontinuation due to adverse effects	Steers, 2005[45]	6/160	4/41	0.38 (0.11; 1.30)	9.46	-0.060 (-0.16; 0.04)	2.18
Darifenacin	Treatment discontinuation due to adverse effects	Zinner, 2006[414]	17/214	10/225	1.79 (0.84; 3.82)	19.19	0.035 (-0.01; 0.08)	8.07
Darifenacin	Treatment discontinuation due to adverse effects	U.S. Food and Drug Administration, 2004 [43]	8/112	4/115	2.05 (0.64; 6.63)	10.07	0.037 (-0.02; 0.10)	5.32

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Darifenacin	Treatment discontinuation due to adverse effects	U.S. Food and Drug Administration, 2004 [43]	3/115	3/164	1.43 (0.29; 6.94)	6.02	0.008 (-0.03; 0.04)	11.42
Darifenacin	Treatment discontinuation due to adverse effects	Chapple, 2004[473]	3/229	2/164	1.07 (0.18; 6.36)	4.88	0.001 (-0.02; 0.02)	19.54
Darifenacin	Treatment discontinuation due to adverse effects	Hill, 2006[44]	13/115	3/109	4.11 (1.20; 14.02)	9.33	0.086 (0.02; 0.15)	4.34
	Pooled				1.16 (0.77; 1.75)	100	0.003 (-0.01; 0.02)	100
	P value/I squared				0.283	16.90%	0.184	27.30%
Darifenacin	Treatment discontinuation due to failure	Hill, 2006[44]	2/107	2/109	1.02 (0.15; 7.10)	26.72	0.000 (-0.04; 0.04)	11.42
Darifenacin	Treatment discontinuation due to failure	Zinner, 2006[414]	2/214	5/225	0.42 (0.08; 2.15)	37.96	-0.013 (-0.04; 0.01)	27.5
Darifenacin	Treatment discontinuation due to failure	U.S. Food and Drug Administration, 2004[43]	1/112	2/115	0.51 (0.05; 5.58)	17.69	-0.008 (-0.04; 0.02)	16.9
Darifenacin	Treatment discontinuation due to failure	U.S. Food and Drug Administration, 2004[43]	2/269	1/129	0.96 (0.09; 10.48)	17.62	0.000 (-0.02; 0.02)	44.18
	Pooled				0.64 (0.23; 1.74)	100	-0.005 (-0.02; 0.01)	100
	P value/I squared				0.892	0.00%	0.842	0.00%
Darifenacin	Dry mouth	Lipton, 2005[340]	5/74	2/69	2.33 (0.47; 11.62)	6.27	0.039 (-0.03; 0.11)	11.35
Darifenacin	Dry mouth	Hill, 2006[44]	25/108	6/109	4.21 (1.80; 9.84)	11.88	0.176 (0.09; 0.27)	10.89
Darifenacin	Dry mouth	Chapple, 2007[261]	59/266	5/133	5.90 (2.43; 14.35)	11.51	0.184 (0.13; 0.24)	11.55
Darifenacin	Dry mouth	Chapple, 2004[473]	7/53	14/164	1.55 (0.66; 3.63)	11.85	0.047 (-0.05; 0.15)	10.63
Darifenacin	Dry mouth	Lipton, 2005[340]	6/65	2/69	3.19 (0.67; 15.22)	6.49	0.063 (-0.02; 0.14)	11.11
Darifenacin	Dry mouth	Hill, 2006[44]	43/107	6/109	7.30 (3.24; 16.44)	12.26	0.347 (0.25; 0.45)	10.59
Darifenacin	Dry mouth	Zinner, 2006[414]	15/214	10/225	1.58 (0.72; 3.43)	12.59	0.026 (-0.02; 0.07)	11.8
Darifenacin	Dry mouth	Chapple, 2004[473]	43/229	14/164	2.20 (1.25; 3.89)	14.71	0.102 (0.04; 0.17)	11.42
Darifenacin	Dry mouth	Hill, 2006[44]	68/115	6/109	10.74 (4.86; 23.73)	12.45	0.536 (0.44; 0.64)	10.66

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
	Pooled				3.55 (2.16; 5.84)	100	0.165 (0.07; 0.26)	100
	P value/I squared				0.004	64.80%	0	93.30%
Darifenacin	Dyspepsia	Lipton, 2005[340]	1/74	1/69	0.93 (0.06; 14.62)	7.8	-0.001 (-0.04; 0.04)	15.59
Darifenacin	Dyspepsia	Hill, 2006[44]	4/108	1/109	4.04 (0.46; 35.54)	11.64	0.028 (-0.01; 0.07)	15.15
Darifenacin	Dyspepsia	Lipton, 2005[340]	4/71	1/69	3.89 (0.45; 33.91)	11.72	0.042 (-0.02; 0.10)	9.65
Darifenacin	Dyspepsia	Hill, 2006[44]	9/107	1/109	9.17 (1.18; 71.13)	12.83	0.075 (0.02; 0.13)	10.75
Darifenacin	Dyspepsia	Zinner, 2006[414]	9/214	2/225	4.73 (1.03; 21.65)	20.05	0.033 (0.00; 0.06)	18.85
Darifenacin	Dyspepsia	Chapple, 2004[473]	4/229	4/164	0.72 (0.18; 2.82)	23.02	-0.007 (-0.04; 0.02)	19.03
Darifenacin	Dyspepsia	Hill, 2006[44]	10/115	1/109	9.48 (1.23; 72.81)	12.93	0.078 (0.02; 0.13)	10.99
	Pooled				3.08 (1.36; 7.00)	100	0.030 (0.01; 0.05)	100
	P value/I squared				0.26	22.20%	0.034	56.10%
Darifenacin	Headache	Lipton, 2005[340]	1/74	0/69	2.80 (0.12; 67.60)	6.79	0.014 (-0.02; 0.05)	21.88
Darifenacin	Headache	Hill, 2006[44]	7/108	2/109	3.53 (0.75; 16.62)	28.69	0.046 (-0.01; 0.10)	10.92
Darifenacin	Headache	Lipton, 2005[340]	2/71	0/69	4.86 (0.24; 99.46)	7.55	0.028 (-0.02; 0.08)	14
Darifenacin	Headache	Hill, 2006[44]	7/107	2/109	3.57 (0.76; 16.78)	28.7	0.047 (-0.01; 0.10)	10.77
Darifenacin	Headache	Zinner, 2006[414]	7/214	2/225	3.68 (0.77; 17.52)	28.27	0.024 (0.00; 0.05)	42.43
	Pooled				3.61 (1.58; 8.28)	100	0.027 (0.01; 0.05)	100
	P value/I squared				1	0.00%	0.804	0.00%
Darifenacin	Improvement in UI	Hill, 2006[44]	28/108	15/109	1.88 (1.07; 3.32)	7.67	0.122 (0.02; 0.23)	32.43
Darifenacin	Improvement in UI	Chapple, 2007[261]	122/266	47/133	1.30 (1.00; 1.69)	35.39	0.105 (0.00; 0.21)	35.06
Darifenacin	Improvement in UI	Steers, 2005[45]	160/268	60/127	1.26 (1.03; 1.56)	56.93	0.125 (0.02; 0.23)	32.51
	Pooled				1.32 (1.12; 1.54)	100	0.112 (0.08; 0.15)	100
	P value/I squared				0.422	0.00%	0.961	0.00%
Fesoterodine	Abdominal pain	NCT00444925,[58]	10/685	4/337	1.23 (0.39; 3.89)	22.52	0.003 (-0.01; 0.02)	52.38
Fesoterodine	Abdominal pain	Chapple, 2004[266]	14/173	7/183	2.12 (0.88; 5.12)	38.32	0.043 (-0.01; 0.09)	23.45
Fesoterodine	Abdominal pain	Chapple, 2004[266]	15/186	7/183	2.11 (0.88; 5.05)	39.16	0.042 (-0.01; 0.09)	24.17
	Pooled				1.87 (1.08; 3.23)	100	0.022 (-0.01; 0.05)	100
	P value/I squared				0.721	0.00%	0.113	54.10%
Fesoterodine	Abnormal vision	Chapple, 2004[266]	0/186	2/183	0.20 (0.01; 4.07)	22.65	-0.011 (-0.03; 0.01)	36.7
Fesoterodine	Abnormal vision	Chapple, 2004[266]	0/173	2/183	0.21 (0.01; 4.37)	22.65	-0.011 (-0.03; 0.01)	35.8
Fesoterodine	Abnormal vision	Chapple, 2004[266]	2/186	2/183	0.98 (0.14; 6.91)	54.7	0.000 (-0.02; 0.02)	27.5
	Pooled				0.48 (0.11; 2.04)	100	-0.008 (-0.02; 0.00)	100
	P value/I squared				0.567	0.00%	0.697	0.00%
Fesoterodine	Adverse effects	Chapple, 2007[259]	135/272	107/285	1.32 (1.09; 1.60)	15.82	0.121 (0.04; 0.20)	14.75
Fesoterodine	Adverse effects	Nitti C, 2007[353]	171/283	149/274	1.11 (0.96; 1.28)	18.07	0.060 (-0.02; 0.14)	14.7
Fesoterodine	Adverse effects	NCT00444925,[58]	290/685	76/337	1.88 (1.51; 2.33)	14.68	0.198 (0.14; 0.26)	20.88
Fesoterodine	Adverse effects	NCT00536484,[59]	199/438	130/445	1.56 (1.30; 1.86)	16.5	0.162 (0.10; 0.23)	19.43
Fesoterodine	Adverse effects	Chapple, 2007[259]	167/288	107/285	1.54 (1.29; 1.85)	16.41	0.204 (0.12; 0.28)	15.12

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Fesoterodine	Adverse effects	Nitti C, 2007[353]	193/279	149/274	1.27 (1.11; 1.45)	18.52	0.148 (0.07; 0.23)	15.12
	Pooled				1.41 (1.22; 1.63)	100	0.153 (0.11; 0.19)	100
	P value/I squared				0.001	76.50%	0.094	46.80%
Fesoterodine	Back pain	Chapple, 2004[266]	6/186	5/183	1.18 (0.37; 3.80)	21.26	0.005 (-0.03; 0.04)	16.67
Fesoterodine	Back pain	NCT00444925,[58]	10/685	10/337	0.49 (0.21; 1.17)	38.69	-0.015 (-0.04; 0.01)	49.02
Fesoterodine	Back pain	Chapple, 2004[266]	7/173	5/183	1.48 (0.48; 4.58)	22.82	0.013 (-0.03; 0.05)	14.12
Fesoterodine	Back pain	Chapple, 2004[266]	4/186	5/183	0.79 (0.22; 2.89)	17.23	-0.006 (-0.04; 0.03)	20.2
	Pooled				0.83 (0.48; 1.42)	100	-0.006 (-0.02; 0.01)	100
	P value/I squared				0.429	0.00%	0.543	0.00%
Fesoterodine	Constipation	Chapple, 2004[266]	4/186	5/183	0.79 (0.22; 2.89)	5.73	-0.006 (-0.04; 0.03)	8.35
Fesoterodine	Constipation	Chapple, 2007[259]	9/272	4/285	2.36 (0.74; 7.57)	6.42	0.019 (-0.01; 0.04)	8.52
Fesoterodine	Constipation	Nitti C, 2007[353]	14/283	7/274	1.94 (0.79; 4.73)	8.1	0.024 (-0.01; 0.06)	8.35
Fesoterodine	Constipation	Dmochowski, 2010[474]	48/438	25/445	1.95 (1.23; 3.11)	11.08	0.053 (0.02; 0.09)	8.2
Fesoterodine	Constipation	Herschorn, 2010[475]	37/679	10/334	1.82 (0.92; 3.62)	9.54	0.025 (0.00; 0.05)	8.52
Fesoterodine	Constipation	Kaplan, 2010[322]	270/963	10/480	13.46 (7.23; 25.06)	10	0.260 (0.23; 0.29)	8.36
Fesoterodine	Constipation	NCT00444925,[58]	37/685	10/337	1.82 (0.92; 3.62)	9.54	0.024 (0.00; 0.05)	8.53
Fesoterodine	Constipation	NCT00536484,[59]	48/438	25/445	1.95 (1.23; 3.11)	11.08	0.053 (0.02; 0.09)	8.2
Fesoterodine	Constipation	Chapple, 2004[266]	5/173	5/183	1.06 (0.31; 3.59)	6.12	0.002 (-0.03; 0.04)	8.26
Fesoterodine	Constipation	Chapple, 2007[259]	13/288	4/285	3.22 (1.06; 9.75)	6.74	0.031 (0.00; 0.06)	8.46
Fesoterodine	Constipation	Nitti C, 2007[353]	21/279	7/274	2.95 (1.27; 6.82)	8.46	0.050 (0.01; 0.09)	8.21
Fesoterodine	Constipation	Chapple, 2004[266]	11/186	5/183	2.17 (0.77; 6.11)	7.17	0.032 (-0.01; 0.07)	8.03
	Pooled				2.33 (1.54; 3.54)	100	0.047 (0.01; 0.09)	100
	P value/I squared				0	70.80%	0	94.80%
Fesoterodine	Cough	Chapple, 2004[266]	6/186	7/183	0.84 (0.29; 2.46)	25.64	-0.006 (-0.04; 0.03)	8.89
Fesoterodine	Cough	NCT00444925,[58]	8/685	1/337	3.94 (0.49; 31.34)	12.44	0.009 (0.00; 0.02)	40.07
Fesoterodine	Cough	NCT00536484,[59]	9/438	2/445	4.57 (0.99; 21.04)	18.35	0.016 (0.00; 0.03)	30.58
Fesoterodine	Cough	Chapple, 2004[266]	2/173	7/183	0.30 (0.06; 1.44)	17.93	-0.027 (-0.06; 0.01)	11.56
Fesoterodine	Cough	Chapple, 2004[266]	6/186	7/183	0.84 (0.29; 2.46)	25.64	-0.006 (-0.04; 0.03)	8.89
	Pooled				1.16 (0.48; 2.78)	100	0.004 (-0.01; 0.02)	100
	P value/I squared				0.095	49.40%	0.151	40.50%
Fesoterodine	Diarrhea	Herschorn, 2010[475]	14/679	4/334	1.72 (0.57; 5.19)	30.45	0.009 (-0.01; 0.02)	36.36
Fesoterodine	Diarrhea	NCT00444925,[58]	14/685	4/337	1.72 (0.57; 5.19)	30.45	0.009 (-0.01; 0.02)	36.56
Fesoterodine	Diarrhea	NCT00536484,[59]	9/438	19/445	0.48 (0.22; 1.05)	39.11	-0.022 (-0.05; 0.00)	27.07
	Pooled				1.05 (0.42; 2.61)	100	0.000 (-0.02; 0.02)	100
	P value/I squared				0.078	60.90%	0.062	64.00%

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Fesoterodine	Treatment discontinuation	Chapple, 2007[259]	41/272	33/285	1.30 (0.85; 2.00)	11.01	0.035 (-0.02; 0.09)	5.95
Fesoterodine	Treatment discontinuation	Nitti C, 2007[353]	58/283	41/274	1.37 (0.95; 1.97)	15.18	0.055 (-0.01; 0.12)	4.83
Fesoterodine	Treatment discontinuation	Dmochowski, 2010[474]	56/438	60/445	0.95 (0.68; 1.33)	17.44	-0.007 (-0.05; 0.04)	9.12
Fesoterodine	Treatment discontinuation	Herschorn, 2010[475]	81/679	30/334	1.33 (0.89; 1.98)	12.69	0.029 (-0.01; 0.07)	11.38
Fesoterodine	Treatment discontinuation	NCT00444925,[58]	6/685	3/337	0.98 (0.25; 3.91)	1.06	0.000 (-0.01; 0.01)	48.14
Fesoterodine	Treatment discontinuation	NCT00536484,[59]	56/438	60/445	0.95 (0.68; 1.33)	17.44	-0.007 (-0.05; 0.04)	9.12
Fesoterodine	Treatment discontinuation	Chapple, 2007[259]	36/288	33/285	1.08 (0.69; 1.68)	10.24	0.009 (-0.04; 0.06)	6.62
Fesoterodine	Treatment discontinuation	Nitti C, 2007[353]	56/279	41/274	1.34 (0.93; 1.94)	14.94	0.051 (-0.01; 0.11)	4.83
	Pooled				1.16 (1.00; 1.33)	100	0.010 (-0.01; 0.02)	100
	P value/I squared				0.661	0.00%	0.306	15.70%
Fesoterodine	Treatment discontinuation due to adverse effects	Chapple, 2004[266]	11/186	7/183	1.55 (0.61; 3.90)	9.57	0.021 (-0.02; 0.07)	8.42
Fesoterodine	Treatment discontinuation due to adverse effects	Dmochowski, 2010[474]	34/438	21/445	1.65 (0.97; 2.79)	18.74	0.030 (0.00; 0.06)	12.15
Fesoterodine	Treatment discontinuation due to adverse effects	Herschorn, 2010[475]	44/679	6/334	3.61 (1.55; 8.38)	10.92	0.047 (0.02; 0.07)	15.77
Fesoterodine	Treatment discontinuation due to adverse effects	Kaplan, 2010[322]	48/963	10/480	2.39 (1.22; 4.69)	14.55	0.029 (0.01; 0.05)	17.97
Fesoterodine	Treatment discontinuation due to adverse effects	NCT00444925,[58]	44/685	6/337	3.61 (1.55; 8.38)	10.92	0.046 (0.02; 0.07)	15.86

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Fesoterodine	Treatment discontinuation due to adverse effects	NCT00536484,[59]	34/438	21/445	1.65 (0.97; 2.79)	18.74	0.030 (0.00; 0.06)	12.15
Fesoterodine	Treatment discontinuation due to adverse effects	Chapple, 2004[266]	3/173	7/183	0.45 (0.12; 1.73)	5.35	-0.021 (-0.06; 0.01)	11.4
Fesoterodine	Treatment discontinuation due to adverse effects	Chapple, 2004[266]	22/186	7/183	3.09 (1.35; 7.06)	11.23	0.080 (0.03; 0.13)	6.29
	Pooled				2.05 (1.47; 2.87)	100	0.032 (0.02; 0.05)	100
	P value/I squared				0.131	37.40%	0.027	55.60%
Fesoterodine	Treatment discontinuation due to failure	Dmochowski, 2010[474]	5/438	16/445	0.32 (0.12; 0.86)	25.28	-0.025 (-0.04; -0.01)	23.5
Fesoterodine	Treatment discontinuation due to failure	Herschorn, 2010[475]	13/679	5/334	1.28 (0.46; 3.56)	24.72	0.004 (-0.01; 0.02)	26.44
Fesoterodine	Treatment discontinuation due to failure	NCT00444925,[58]	13/685	5/337	1.28 (0.46; 3.56)	24.72	0.004 (-0.01; 0.02)	26.57
Fesoterodine	Treatment discontinuation due to failure	NCT00536484,[59]	5/438	16/445	0.32 (0.12; 0.86)	25.28	-0.025 (-0.04; -0.01)	23.5
	Pooled				0.63 (0.29; 1.39)	100	-0.009 (-0.03; 0.01)	100
	P value/I squared				0.062	59.00%		
Fesoterodine	Dizziness	Chapple, 2004[266]	7/186	5/183	1.38 (0.45; 4.26)	33.68	0.010 (-0.03; 0.05)	8.46
Fesoterodine	Dizziness	NCT00444925,[58]	8/685	3/337	1.31 (0.35; 4.91)	24.63	0.003 (-0.01; 0.02)	66.81
Fesoterodine	Dizziness	Chapple, 2004[266]	2/173	5/183	0.42 (0.08; 2.15)	16.23	-0.016 (-0.04; 0.01)	13.61
Fesoterodine	Dizziness	Chapple, 2004[266]	4/186	5/183	0.79 (0.22; 2.89)	25.46	-0.006 (-0.04; 0.03)	11.13
	Pooled				0.97 (0.51; 1.88)	100	0.000 (-0.01; 0.01)	100
	P value/I squared				0.644	0.00%	0.615	0.00%
Fesoterodine	Continence	Kaplan, 2010[322]	609/963	258/480	1.18 (1.07; 1.30)	54.44	0.095 (0.04; 0.15)	52.89
Fesoterodine	Continence	NCT00444925,[58]	396/685	138/337	1.41 (1.22; 1.63)	45.56	0.169 (0.10; 0.23)	47.11
	Pooled				1.28 (1.07; 1.53)	100	0.130 (0.06; 0.20)	100
	P value/I squared				0.038	76.70%	0.085	66.30%
Fesoterodine	Dry eye	Chapple, 2007[259]	6/272	0/285	13.62 (0.77; 240.60)	6.45	0.022 (0.00; 0.04)	14.34

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Fesoterodine	Dry eye	Nitti C, 2007[353]	2/283	0/274	4.84 (0.23; 100.39)	5.89	0.007 (-0.01; 0.02)	19.1
Fesoterodine	Dry eye	Dmochowski, 2010[474]	13/438	8/445	1.65 (0.69; 3.94)	25.71	0.012 (-0.01; 0.03)	13.46
Fesoterodine	Dry eye	NCT00444925,[58]	9/685	6/337	0.74 (0.27; 2.06)	23.03	-0.005 (-0.02; 0.01)	15.84
Fesoterodine	Dry eye	NCT00536484,[59]	13/438	8/445	1.65 (0.69; 3.94)	25.71	0.012 (-0.01; 0.03)	13.46
Fesoterodine	Dry eye	Chapple, 2007[259]	12/288	0/285	24.74 (1.47; 415.89)	6.64	0.042 (0.02; 0.07)	11.31
Fesoterodine	Dry eye	Nitti C, 2007[353]	9/279	0/274	18.66 (1.09; 319.06)	6.57	0.032 (0.01; 0.05)	12.48
	Pooled				2.35 (1.05; 5.25)	100	0.016 (0.01; 0.03)	100
	P value/I squared				0.082	46.50%	0.022	59.40%
Fesoterodine	Dry mouth	Chapple, 2004[266]	47/186	16/183	2.88 (1.69; 4.88)	6.48	0.164 (0.09; 0.24)	6.79
Fesoterodine	Dry mouth	Chapple, 2007[259]	59/272	20/285	3.09 (1.91; 4.99)	7.57	0.147 (0.09; 0.20)	8.25
Fesoterodine	Dry mouth	Nitti C, 2007[353]	45/283	19/274	2.29 (1.38; 3.82)	6.88	0.090 (0.04; 0.14)	8.71
Fesoterodine	Dry mouth	Dmochowski, 2010[474]	113/438	34/445	3.38 (2.36; 4.84)	11.32	0.182 (0.13; 0.23)	9.11
Fesoterodine	Dry mouth	Herschorn, 2010[475]	189/679	20/334	4.65 (2.99; 7.23)	8.54	0.218 (0.18; 0.26)	9.62
Fesoterodine	Dry mouth	Kaplan, 2010[322]	270/963	24/480	5.61 (3.75; 8.39)	9.74	0.230 (0.20; 0.27)	10.3
Fesoterodine	Dry mouth	NCT00444925,[58]	189/685	20/337	4.65 (2.99; 7.23)	8.54	0.217 (0.18; 0.26)	9.65
Fesoterodine	Dry mouth	NCT00536484,[59]	113/438	34/445	3.38 (2.36; 4.84)	11.32	0.182 (0.13; 0.23)	9.11
Fesoterodine	Dry mouth	Chapple, 2004[266]	45/173	16/183	2.98 (1.75; 5.06)	6.45	0.173 (0.10; 0.25)	6.58
Fesoterodine	Dry mouth	Chapple, 2007[259]	97/288	20/285	4.80 (3.05; 7.55)	8.25	0.267 (0.21; 0.33)	7.82
Fesoterodine	Dry mouth	Nitti C, 2007[353]	99/279	19/274	5.12 (3.23; 8.12)	8.01	0.285 (0.22; 0.35)	7.68
Fesoterodine	Dry mouth	Chapple, 2004[266]	63/186	16/183	3.87 (2.33; 6.45)	6.89	0.251 (0.17; 0.33)	6.4
	Pooled				3.82 (3.29; 4.45)	100	0.200 (0.17; 0.23)	100
	P value/I squared				0.183	26.60%	0	72.70%
Fesoterodine	Failure	Dmochowski, 2010[474]	14/438	29/445	0.49 (0.26; 0.92)	16.31	-0.033 (-0.06; -0.01)	31.89
Fesoterodine	Failure	Herschorn, 2010[475]	32/679	34/334	0.46 (0.29; 0.74)	29.42	-0.055 (-0.09; -0.02)	19.47
Fesoterodine	Failure	NCT00444925,[58]	49/685	36/337	0.67 (0.44; 1.01)	37.78	-0.035 (-0.07; 0.00)	17.41
Fesoterodine	Failure	NCT00536484,[59]	14/438	30/445	0.47 (0.26; 0.88)	16.49	-0.035 (-0.06; -0.01)	31.23
	Pooled				0.54 (0.42; 0.69)	100	-0.038 (-0.05; -0.02)	100
	P value/I squared				0.628	0.00%	0.807	0.00%
Fesoterodine	Fatigue	NCT00444925,[58]	12/685	0/337	12.32 (0.73; 207.42)	22.03	0.018 (0.01; 0.03)	68.42
Fesoterodine	Fatigue	NCT00536484,[59]	11/438	2/445	5.59 (1.25; 25.07)	77.97	0.021 (0.01; 0.04)	31.58
	Pooled				6.65 (1.77; 25.03)	100	0.018 (0.01; 0.03)	
	P value/I squared				0.628	0.00%	0.752	0.00%
Fesoterodine	Headache	Chapple, 2004[266]	32/186	29/183	1.09 (0.69; 1.72)	15.51	0.014 (-0.06; 0.09)	2.11

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Fesoterodine	Headache	Chapple, 2007[259]	12/272	14/285	0.90 (0.42; 1.91)	7.14	-0.005 (-0.04; 0.03)	8.22
Fesoterodine	Headache	Nitti C, 2007[353]	12/283	9/274	1.29 (0.55; 3.02)	5.8	0.010 (-0.02; 0.04)	9.63
Fesoterodine	Headache	Dmochowski, 2010[474]	19/438	15/445	1.29 (0.66; 2.50)	8.82	0.010 (-0.02; 0.04)	13.08
Fesoterodine	Headache	Herschorn, 2010[475]	38/679	8/334	2.34 (1.10; 4.95)	7.17	0.032 (0.01; 0.06)	14.19
Fesoterodine	Headache	NCT00444925,[58]	38/685	8/337	2.34 (1.10; 4.95)	7.16	0.032 (0.01; 0.06)	14.35
Fesoterodine	Headache	NCT00536484,[59]	19/438	15/445	1.29 (0.66; 2.50)	8.82	0.010 (-0.02; 0.04)	13.08
Fesoterodine	Headache	Chapple, 2004[266]	28/173	29/183	1.02 (0.64; 1.64)	14.76	0.003 (-0.07; 0.08)	2.09
Fesoterodine	Headache	Chapple, 2007[259]	7/288	14/285	0.50 (0.20; 1.21)	5.29	-0.025 (-0.06; 0.01)	10.01
Fesoterodine	Headache	Nitti C, 2007[353]	8/279	9/274	0.87 (0.34; 2.23)	4.84	-0.004 (-0.03; 0.03)	11.02
Fesoterodine	Headache	Chapple, 2004[266]	28/186	29/183	0.95 (0.59; 1.53)	14.68	-0.008 (-0.08; 0.07)	2.22
	Pooled				1.15 (0.92; 1.43)	100	0.009 (0.00; 0.02)	100
	P value/I squared				0.271	18.20%	0.205	25.10%
Fesoterodine	Improvement in UI	Dmochowski, 2010[474]	182/438	137/445	1.35 (1.13; 1.61)	31.57	0.108 (0.05; 0.17)	18.56
Fesoterodine	Improvement in UI	Herschorn, 2010[475]	293/679	113/334	1.28 (1.07; 1.52)	33.47	0.093 (0.03; 0.16)	18.59
Fesoterodine	Improvement in UI	NCT00444925,[58]	102/685	32/337	1.57 (1.08; 2.28)	7.12	0.054 (0.01; 0.10)	43.58
Fesoterodine	Improvement in UI	NCT00536484,[59]	161/438	130/445	1.26 (1.04; 1.52)	27.84	0.075 (0.01; 0.14)	19.27
	Pooled				1.31 (1.19; 1.45)	100	0.075 (0.05; 0.10)	100
	P value/I squared				0.74	0.00%	0.501	0.00%
Fesoterodine	Influenza-like symptoms	Chapple, 2004[266]	17/186	15/183	1.12 (0.57; 2.17)	40.53	0.009 (-0.05; 0.07)	27.49
Fesoterodine	Influenza-like symptoms	Chapple, 2004[266]	7/173	15/183	0.49 (0.21; 1.18)	29.75	-0.042 (-0.09; 0.01)	35.53
Fesoterodine	Influenza-like symptoms	Chapple, 2004[266]	7/186	15/183	0.46 (0.19; 1.10)	29.71	-0.044 (-0.09; 0.00)	36.98
	Pooled				0.67 (0.37; 1.22)	100	-0.029 (-0.06; 0.00)	100
	P value/I squared				0.183	41.20%	0.308	15.10%
Fesoterodine	Nasopharyngitis	Chapple, 2007[259]	8/272	7/285	1.20 (0.44; 3.26)	12.88	0.005 (-0.02; 0.03)	13.51
Fesoterodine	Nasopharyngitis	Nitti C, 2007[353]	10/283	7/274	1.38 (0.53; 3.58)	14.25	0.010 (-0.02; 0.04)	12.09
Fesoterodine	Nasopharyngitis	NCT00444925,[58]	13/685	10/337	0.64 (0.28; 1.44)	19.47	-0.011 (-0.03; 0.01)	22.68
Fesoterodine	Nasopharyngitis	Chapple, 2007[259]	5/288	7/285	0.71 (0.23; 2.20)	10	-0.007 (-0.03; 0.02)	17.82
Fesoterodine	Nasopharyngitis	Nitti C, 2007[353]	2/279	7/274	0.28 (0.06; 1.34)	5.28	-0.018 (-0.04; 0.00)	21.95
Fesoterodine	Nasopharyngitis	NCT00536484,[59]	19/438	25/445	0.77 (0.43; 1.38)	38.12	-0.013 (-0.04; 0.02)	11.94
	Pooled				0.80 (0.56; 1.15)	100	-0.007 (-0.02; 0.00)	100
	P value/I squared				0.553	0.00%	0.629	0.00%
Fesoterodine	Nausea	Chapple, 2004[266]	9/186	13/183	0.68 (0.30; 1.55)	17.86	-0.023 (-0.07; 0.03)	3.77

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Fesoterodine	Nausea	Chapple, 2007[259]	1/272	1/285	1.05 (0.07; 16.67)	2.03	0.000 (-0.01; 0.01)	21.32
Fesoterodine	Nausea	Nitti C, 2007[353]	3/283	6/274	0.48 (0.12; 1.92)	7.58	-0.011 (-0.03; 0.01)	12.43
Fesoterodine	Nausea	NCT00444925,[58]	12/685	6/337	0.98 (0.37; 2.60)	13.8	0.000 (-0.02; 0.02)	15.12
Fesoterodine	Nausea	NCT00536484,[59]	6/438	18/445	0.34 (0.14; 0.85)	15.21	-0.027 (-0.05; -0.01)	12.26
Fesoterodine	Nausea	Chapple, 2004[266]	3/173	13/183	0.24 (0.07; 0.84)	9.14	-0.054 (-0.10; -0.01)	4.77
Fesoterodine	Nausea	Chapple, 2007[259]	4/288	1/285	3.96 (0.45; 35.20)	3.2	0.010 (-0.01; 0.03)	16.75
Fesoterodine	Nausea	Nitti C, 2007[353]	7/279	6/274	1.15 (0.39; 3.37)	11.61	0.003 (-0.02; 0.03)	10.05
Fesoterodine	Nausea	Chapple, 2004[266]	11/186	13/183	0.83 (0.38; 1.81)	19.57	-0.012 (-0.06; 0.04)	3.51
	Pooled				0.67 (0.45; 1.01)	100	-0.006 (-0.02; 0.00)	100
	P value/I squared				0.31	14.90%	0.051	48.20%
Fesoterodine	Serious adverse effects	NCT00444925,[58]	15/685	8/337	0.92 (0.40; 2.15)	64.37	-0.002 (-0.02; 0.02)	37.71
Fesoterodine	Serious adverse effects	NCT00536484,[59]	5/438	7/445	0.73 (0.23; 2.27)	35.63	-0.004 (-0.02; 0.01)	62.29
	Pooled				0.85 (0.43; 1.67)	100	-0.003 (-0.02; 0.01)	100
	P value/I squared				0.741	0.00%	0.845	0.00%
Fesoterodine	Upper respiratory tract infection	NCT00444925,[58]	2/685	4/337	0.25 (0.05; 1.34)	31.3	-0.009 (-0.02; 0.00)	84.59
Fesoterodine	Upper respiratory tract infection	NCT00536484,[59]	21/438	23/445	0.93 (0.52; 1.65)	68.7	-0.004 (-0.03; 0.03)	15.41
	Pooled				0.61 (0.18; 2.05)	100	-0.008 (-0.02; 0.00)	100
	P value/I squared				0.146	52.80%	0.743	0.00%
Fesoterodine	Urinary tract infection	Herschorn, 2010[475]	15/679	2/334	3.69 (0.85; 16.04)	29.81	0.016 (0.00; 0.03)	36.48
Fesoterodine	Urinary tract infection	NCT00444925,[58]	15/685	2/337	3.69 (0.85; 16.04)	29.81	0.016 (0.00; 0.03)	36.7
Fesoterodine	Urinary tract infection	NCT00536484,[59]	8/438	12/445	0.68 (0.28; 1.64)	40.39	-0.009 (-0.03; 0.01)	26.82
	Pooled				1.86 (0.53; 6.50)	100	0.009 (-0.01; 0.02)	100
	P value/I squared				0.052	66.20%	0.086	59.30%
Oxybutynin	Adverse effects	Dmochowski, 2003[278]	7/121	13/117	0.52 (0.22; 1.26)	30.53	-0.053 (-0.12; 0.02)	34.84
Oxybutynin	Adverse effects	Homma, 2003[311]	30/244	4/122	3.75 (1.35; 10.40)	27.72	0.090 (0.04; 0.14)	36.04
Oxybutynin	Adverse effects	Madersbacher, 1999[343]	104/145	30/72	1.72 (1.29; 2.31)	41.75	0.301 (0.17; 0.44)	29.12
	Pooled				1.48 (0.61; 3.60)	100	0.101 (-0.05; 0.26)	100
	P value/I squared				0.011	78.10%	0	91.40%
Oxybutynin	Blurred vision	Szonyi, 1995[383]	14/28	17/29	0.85 (0.53; 1.38)	43.59	-0.086 (-0.34; 0.17)	3.4
Oxybutynin	Blurred vision	Homma, 2003[311]	8/244	0/122	8.54 (0.50; 146.65)	7.26	0.033 (0.01; 0.06)	60.42

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Oxybutynin	Blurred vision	Burgio, 1998[243]	10/67	6/65	1.62 (0.62; 4.19)	30.46	0.057 (-0.05; 0.17)	15.29
Oxybutynin	Blurred vision	Zinner, 2005[412]	1/19	0/19	3.00 (0.13; 69.31)	6.11	0.053 (-0.08; 0.19)	11.14
Oxybutynin	Blurred vision	Tapp, 1990[385]	8/37	1/33	7.14 (0.94; 54.07)	12.58	0.186 (0.04; 0.33)	9.76
	Pooled				1.73 (0.76; 3.95)	100	0.050 (0.00; 0.10)	100
	P value/I squared				0.118	45.60%	0.266	23.20%
Oxybutynin	Constipation	Moore, 1990[351]	6/48	0/43	11.67 (0.68; 201.30)	1.45	0.125 (0.03; 0.23)	7.13
Oxybutynin	Constipation	Dmochowski, 2002[276]	1/125	4/132	0.26 (0.03; 2.33)	2.48	-0.022 (-0.06; 0.01)	27.48
Oxybutynin	Constipation	Homma, 2003[311]	15/244	6/122	1.25 (0.50; 3.14)	13.66	0.012 (-0.04; 0.06)	19.48
Oxybutynin	Constipation	Staskin, 2009[33]	5/389	4/400	1.29 (0.35; 4.75)	6.84	0.003 (-0.01; 0.02)	38.24
Oxybutynin	Constipation	Burgio, 1998[243]	26/67	24/65	1.05 (0.68; 1.63)	57.22	0.019 (-0.15; 0.18)	2.92
Oxybutynin	Constipation	Zinner, 2005[412]	2/19	1/19	2.00 (0.20; 20.24)	2.2	0.053 (-0.12; 0.22)	2.75
Oxybutynin	Constipation	Tapp, 1990[385]	13/37	6/33	1.93 (0.83; 4.50)	16.15	0.170 (-0.03; 0.37)	1.99
	Pooled				1.22 (0.87; 1.72)	100	0.012 (-0.02; 0.04)	100
	P value/I squared				0.414	1.30%	0.087	45.70%
Oxybutynin	Treatment discontinuation	Szonyi, 1995[383]	8/28	5/29	1.66 (0.62; 4.46)	9.16	0.113 (-0.10; 0.33)	2.81
Oxybutynin	Treatment discontinuation	Madersbacher, 1999[343]	16/145	7/72	1.14 (0.49; 2.63)	12.65	0.013 (-0.07; 0.10)	18.08
Oxybutynin	Treatment discontinuation	Staskin, 2009[33]	43/389	45/400	0.98 (0.66; 1.46)	57.78	-0.002 (-0.05; 0.04)	68.23
Oxybutynin	Treatment discontinuation	Burgio, 1998[243]	10/67	9/65	1.08 (0.47; 2.48)	12.91	0.011 (-0.11; 0.13)	9.19
Oxybutynin	Treatment discontinuation	Zinner, 2005[412]	6/19	4/19	1.50 (0.50; 4.48)	7.5	0.105 (-0.17; 0.38)	1.7
	Pooled				1.10 (0.81; 1.48)	100	0.007 (-0.03; 0.04)	100
	P value/I squared				0.863	0.00%	0.811	0.00%
Oxybutynin	Treatment discontinuation due to adverse effects	Homma, 2003[311]	42/244	11/122	1.91 (1.02; 3.58)	42.87	0.082 (0.01; 0.15)	28.89
Oxybutynin	Treatment discontinuation due to adverse effects	Homma, 2004[310]	21/122	5/57	1.96 (0.78; 4.94)	19.79	0.084 (-0.02; 0.18)	20.69
Oxybutynin	Treatment discontinuation due to adverse effects	Staskin, 2009[33]	19/389	13/400	1.50 (0.75; 3.00)	35.27	0.016 (-0.01; 0.04)	42.43

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Oxybutynin	Treatment discontinuation due to adverse effects	Zinner, 2005[412]	4/19	0/19	9.00 (0.52; 156.41)	2.07	0.211 (0.02; 0.41)	7.99
Oxybutynin	Treatment discontinuation due to adverse effects	Thuroff, 1991[387]	2/63	0/52	4.14 (0.20; 84.38)	6.59	0.032 (-0.02; 0.09)	80.16
Oxybutynin	Treatment discontinuation due to adverse effects	Abrams, 1998[226]	20/118	7/57	1.38 (0.62; 3.07)	93.41	0.047 (-0.06; 0.16)	19.84
	Pooled				1.74 (1.21; 2.50)	100	0.046 (0.01; 0.08)	100
	P value/I squared				0.816	0.00%	0.182	33.90%
Oxybutynin	Dizziness	Moore, 1990[351]	2/48	3/43	0.60 (0.11; 3.41)	18.34	-0.028 (-0.12; 0.07)	1.62
Oxybutynin	Dizziness	Dmochowski, 2002[276]	5/125	5/132	1.06 (0.31; 3.56)	37.66	0.002 (-0.05; 0.05)	6.51
Oxybutynin	Dizziness	Homma, 2003[311]	6/244	2/122	1.50 (0.31; 7.32)	22.12	0.008 (-0.02; 0.04)	16.49
Oxybutynin	Dizziness	Staskin, 2009[33]	6/389	2/400	3.09 (0.63; 15.19)	21.88	0.010 (0.00; 0.02)	73.82
Oxybutynin	Dizziness	Zinner, 2005[412]	0/19	0/19	(Excluded) (0.00; 0.00)		0.000 (-0.10; 0.10)	1.56
	Pooled				1.30 (0.62; 2.74)	100	0.009 (0.00; 0.02)	100
	P value/I squared				0.564	0.00%	0.946	0.00%
Oxybutynin	Continence	Moore, 1990[351]	5/28	0/25	9.86 (0.57; 169.86)	0.69	0.179 (0.03; 0.33)	9.2
Oxybutynin	Continence	Staskin, 2009[33]	108/389	69/400	1.61 (1.23; 2.10)	78.38	0.105 (0.05; 0.16)	63.55
Oxybutynin	Continence	Burgio, 1998[243]	15/67	8/65	1.82 (0.83; 4.00)	9.07	0.101 (-0.03; 0.23)	13.03
Oxybutynin	Continence	Goode, 2004[295]	15/67	8/65	1.82 (0.83; 4.00)	9.07	0.101 (-0.03; 0.23)	13.03
Oxybutynin	Continence	Lehtoranta, 2002[337]	4/9	2/9	2.00 (0.48; 8.31)	2.77	0.222 (-0.20; 0.65)	1.19
	Pooled				1.68 (1.32; 2.13)	100	0.112 (0.07; 0.16)	100
	P value/I squared				0.787	0.00%	0.893	0.00%
Oxybutynin	Dry mouth	Dmochowski, 2002[276]	27/388	11/132	0.84 (0.43; 1.64)	9.91	-0.014 (-0.07; 0.04)	10.67
Oxybutynin	Dry mouth	Moore, 1990[351]	42/48	14/43	2.69 (1.73; 4.19)	11.56	0.549 (0.38; 0.72)	9.67
Oxybutynin	Dry mouth	Szonyi, 1995[383]	26/28	25/29	1.08 (0.90; 1.29)	12.94	0.067 (-0.09; 0.22)	9.8
Oxybutynin	Dry mouth	Homma, 2003[311]	131/244	12/122	5.46 (3.15; 9.46)	10.81	0.439 (0.36; 0.52)	10.51
Oxybutynin	Dry mouth	Homma, 2004[310]	75/122	3/57	11.68 (3.85; 35.45)	6.9	0.562 (0.46; 0.67)	10.34
Oxybutynin	Dry mouth	Staskin, 2009[33]	27/389	11/400	2.52 (1.27; 5.02)	9.8	0.042 (0.01; 0.07)	10.76
Oxybutynin	Dry mouth	Burgio, 1998[243]	65/67	36/65	1.75 (1.40; 2.19)	12.78	0.416 (0.29; 0.54)	10.12

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Oxybutynin	Dry mouth	Abrams, 1998[226]	102/118	12/57	4.11 (2.47; 6.82)	11.11	0.654 (0.53; 0.78)	10.17
Oxybutynin	Dry mouth	Zinner, 2005[412]	7/19	1/19	7.00 (0.95; 51.54)	3.34	0.316 (0.08; 0.56)	8.75
Oxybutynin	Dry mouth	Tapp, 1990[385]	29/37	10/33	2.59 (1.50; 4.46)	10.85	0.481 (0.28; 0.69)	9.21
	Pooled				2.58 (1.69; 3.93)	100	0.347 (0.19; 0.51)	100
	P value/I squared				0	88.70%	0	97.10%
Oxybutynin	Dry skin	Szonyi, 1995[383]	14/28	17/29	0.85 (0.53; 1.38)	46.25	-0.086 (-0.34; 0.17)	26.21
Oxybutynin	Dry skin	Homma, 2003[311]	4/244	1/122	2.00 (0.23; 17.70)	25.72	0.008 (-0.01; 0.03)	40.56
Oxybutynin	Dry skin	Tapp, 1990[385]	13/37	1/33	11.60 (1.60; 83.90)	28.03	0.321 (0.16; 0.49)	33.23
	Pooled				2.21 (0.44; 11.14)	100	0.087 (-0.13; 0.31)	100
	P value/I squared				0.035	70.10%	0.001	85.90%
Oxybutynin	Dyspepsia	Chancellor, 2001[255]	1/36	0/36	3.00 (0.13; 71.28)	5.66	0.028 (-0.05; 0.10)	32.67
Oxybutynin	Dyspepsia	Homma, 2003[311]	20/244	4/122	2.50 (0.87; 7.15)	51.4	0.049 (0.00; 0.10)	40.58
Oxybutynin	Dyspepsia	Abrams, 1998[226]	27/118	3/57	4.35 (1.38; 13.73)	42.94	0.176 (0.08; 0.27)	26.75
	Pooled				3.20 (1.51; 6.81)	100	0.076 (0.00; 0.15)	100
	P value/I squared				0.784	0.00%	0.037	69.80%
Oxybutynin	Dysuria	Dmochowski, 2002[276]	3/125	0/132	7.39 (0.39; 141.62)	46.77	0.024 (-0.01; 0.06)	29.95
Oxybutynin	Dysuria	Staskin, 2009[33]	1/389	1/400	1.03 (0.07; 16.38)	53.23	0.000 (-0.01; 0.01)	70.05
	Pooled				2.59 (0.34; 19.49)	100	0.007 (-0.01; 0.03)	100
	P value/I squared				0.34	0.00%	0.134	55.40%
Oxybutynin	Failure	Wang, 2006[401]	14/23	19/21	0.67 (0.47; 0.96)	47.59	-0.296 (-0.53; -0.06)	7.81
Oxybutynin	Failure	Homma, 2003[311]	12/244	10/122	0.60 (0.27; 1.35)	9.17	-0.033 (-0.09; 0.02)	30.74
Oxybutynin	Failure	Madersbacher, 1999[343]	28/145	23/72	0.60 (0.38; 0.97)	26.86	-0.126 (-0.25; 0.00)	18.01
Oxybutynin	Failure	Burgio, 1998[243]	1/67	3/65	0.32 (0.04; 3.03)	1.2	-0.031 (-0.09; 0.03)	30.17
Oxybutynin	Failure	Thuroff, 1991[387]	11/63	21/52	0.43 (0.23; 0.81)	15.17	-0.229 (-0.39; -0.07)	13.28
	Pooled				0.60 (0.47; 0.77)	100	-0.096 (-0.17; -0.02)	100
	P value/I squared				0.785	0.00%	0.028	63.20%
Oxybutynin	Headache	Chancellor, 2001[255]	6/36	4/36	1.50 (0.46; 4.87)	19.22	0.056 (-0.10; 0.22)	1.35
Oxybutynin	Headache	Homma, 2003[311]	11/244	8/122	0.69 (0.28; 1.67)	34.08	-0.020 (-0.07; 0.03)	13.13
Oxybutynin	Headache	Chancellor, 2001[255]	6/36	4/36	1.50 (0.46; 4.87)	19.22	0.056 (-0.10; 0.22)	1.35
Oxybutynin	Headache	Staskin, 2009[33]	6/389	11/400	0.56 (0.21; 1.50)	27.48	-0.012 (-0.03; 0.01)	84.17
	Pooled				0.88 (0.52; 1.47)	100	-0.011 (-0.03; 0.01)	100
	P value/I squared				0.444	0.00%	0.686	0.00%
Oxybutynin	Improvement in UI	Moore, 1990[351]	10/28	1/25	8.93 (1.23; 64.90)	1.9	0.317 (0.12; 0.51)	7.45

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Oxybutynin	Improvement in UI	Johnson, 2005[317]	4/46	1/38	3.30 (0.39; 28.33)	1.65	0.061 (-0.04; 0.16)	9.71
Oxybutynin	Improvement in UI	Szonyi, 1995[383]	22/28	16/29	1.42 (0.97; 2.08)	11.39	0.234 (0.00; 0.47)	6.47
Oxybutynin	Improvement in UI	Wang, 2006[401]	2/23	0/21	4.58 (0.23; 90.30)	0.91	0.087 (-0.05; 0.22)	8.8
Oxybutynin	Improvement in UI	Homma, 2003[311]	129/244	31/122	2.10 (1.51; 2.91)	11.99	0.277 (0.18; 0.38)	9.65
Oxybutynin	Improvement in UI	Homma, 2004[310]	20/122	26/57	0.36 (0.22; 0.59)	10.11	-0.292 (-0.44; -0.15)	8.62
Oxybutynin	Improvement in UI	Madersbacher, 1999[343]	116/145	43/72	1.34 (1.09; 1.65)	13.16	0.203 (0.07; 0.33)	8.96
Oxybutynin	Improvement in UI	Burgio, 1998[243]	37/67	20/65	1.80 (1.18; 2.74)	10.9	0.245 (0.08; 0.41)	8.17
Oxybutynin	Improvement in UI	Goode, 2002[294]	7/35	7/37	1.06 (0.41; 2.71)	5.78	0.011 (-0.17; 0.19)	7.7
Oxybutynin	Improvement in UI	Goode, 2004[295]	33/67	18/65	1.78 (1.12; 2.82)	10.45	0.216 (0.05; 0.38)	8.22
Oxybutynin	Improvement in UI	Thuroff, 1991[387]	26/63	15/52	1.43 (0.85; 2.40)	9.79	0.124 (-0.05; 0.30)	7.94
Oxybutynin	Improvement in UI	Abrams, 1998[226]	58/118	27/57	1.04 (0.75; 1.44)	11.96	0.018 (-0.14; 0.18)	8.31
	Pooled				1.36 (1.01; 1.82)	100	0.122 (0.03; 0.22)	100
	P value/I squared				0	75.90%	0	80.10%
Oxybutynin	Nausea	Moore, 1990[351]	4/48	1/43	3.58 (0.42; 30.83)	8.42	0.060 (-0.03; 0.15)	7.91
Oxybutynin	Nausea	Dmochowski, 2002[276]	2/125	7/132	0.30 (0.06; 1.43)	14.52	-0.037 (-0.08; 0.01)	18.56
Oxybutynin	Nausea	Chancellor, 2001[255]	1/36	1/36	1.00 (0.07; 15.38)	5.48	0.000 (-0.08; 0.08)	10.14
Oxybutynin	Nausea	Madersbacher, 1999[343]	14/145	6/72	1.16 (0.47; 2.89)	29.83	0.013 (-0.07; 0.09)	9.44
Oxybutynin	Nausea	Chancellor, 2001[255]	0/36	1/36	0.33 (0.01; 7.92)	4.16	-0.028 (-0.10; 0.05)	10.57
Oxybutynin	Nausea	Staskin, 2009[33]	1/389	2/400	0.51 (0.05; 5.65)	6.96	-0.002 (-0.01; 0.01)	31.29
Oxybutynin	Nausea	Abrams, 1998[226]	7/118	6/57	0.56 (0.20; 1.60)	25.49	-0.046 (-0.14; 0.04)	7.89
Oxybutynin	Nausea	Tapp, 1990[385]	7/37	0/33	13.42 (0.80; 226.31)	5.15	0.189 (0.06; 0.32)	4.2
	Pooled				0.88 (0.45; 1.72)	100	0.000 (-0.03; 0.03)	100
	P value/I squared				0.279	19.00%	0.057	48.80%
Oxybutynin	Retention	Homma, 2003[311]	8/244	0/122	8.54 (0.50; 146.65)	24.79	0.033 (0.01; 0.06)	40.48
Oxybutynin	Retention	Staskin, 2009[33]	0/389	1/400	0.34 (0.01; 8.39)	20.77	-0.002 (-0.01; 0.00)	45.15
Oxybutynin	Retention	Burgio, 1998[243]	14/67	2/65	6.79 (1.61; 28.71)	54.44	0.178 (0.07; 0.28)	14.37
	Pooled				3.87 (0.74; 20.21)	100	0.038 (-0.01; 0.09)	100
	P value/I squared				0.224	33.20%	0	88.70%
Oxybutynin	Serious adverse effects	Dmochowski, 2003[278]	1/121	3/117	0.32 (0.03; 3.06)	30.01	-0.017 (-0.05; 0.02)	32.74
Oxybutynin	Serious adverse effects	Homma, 2003[311]	20/244	0/122	20.58 (1.26; 337.49)	24.45	0.082 (0.05; 0.12)	31.85
Oxybutynin	Serious adverse effects	Staskin, 2009[33]	7/389	10/400	0.72 (0.28; 1.87)	45.54	-0.007 (-0.03; 0.01)	35.41

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
	Pooled				1.28 (0.19; 8.67)	100	0.018 (-0.04; 0.07)	100
	P value/I squared				0.055	65.60%	0	90.10%
Oxybutynin	Somnolence	Dmochowski, 2002[276]	2/125	1/132	2.11 (0.19; 23.00)	21.73	0.008 (-0.02; 0.04)	6.37
Oxybutynin	Somnolence	Homma, 2003[311]	4/244	4/122	0.50 (0.13; 1.97)	66.15	-0.016 (-0.05; 0.02)	3.57
Oxybutynin	Somnolence	Staskin, 2009[33]	1/389	0/400	3.09 (0.13; 75.49)	12.12	0.003 (0.00; 0.01)	90.06
	Pooled				0.85 (0.28; 2.60)	100	0.002 (0.00; 0.01)	100
	P value/I squared				0.415	0.00%	0.527	0.00%
Oxybutynin	Vision disorder	Dmochowski, 2002[276]	0/125	2/132	0.21 (0.01; 4.35)	4.51	-0.015 (-0.04; 0.01)	68.22
Oxybutynin	Vision disorder	Madersbacher, 1999[343]	26/145	10/72	1.29 (0.66; 2.53)	91.4	0.040 (-0.06; 0.14)	5.64
Oxybutynin	Vision disorder	Thuroff, 1991[387]	1/63	0/52	2.48 (0.10; 59.73)	4.09	0.016 (-0.03; 0.06)	26.13
	Pooled				1.22 (0.64; 2.32)	100	-0.004 (-0.03; 0.02)	100
	P value/I squared				0.47	0.00%	0.334	8.70%
Oxybutynin	Vomiting	Chancellor, 2001[255]	2/36	0/36	5.00 (0.25; 100.63)	23.29	0.056 (-0.03; 0.15)	17.46
Oxybutynin	Vomiting	Madersbacher, 1999[343]	2/145	2/72	0.50 (0.07; 3.45)	55.8	-0.014 (-0.06; 0.03)	58.1
Oxybutynin	Vomiting	Chancellor, 2001[255]	1/36	0/36	3.00 (0.13; 71.28)	20.91	0.028 (-0.05; 0.10)	24.45
	Pooled				1.24 (0.29; 5.27)	100	0.008 (-0.03; 0.05)	100
	P value/I squared				0.371	0.00%	0.305	15.80%
Propiverine	Adverse effects	Abrams, 2006[227]	30/38	12/24	1.58 (1.03; 2.43)	25.82	0.289 (0.05; 0.53)	11.2
Propiverine	Adverse effects	Lee, 2010[336]	32/176	10/88	1.60 (0.83; 3.10)	11.01	0.068 (-0.02; 0.16)	35.65
Propiverine	Adverse effects	Junemann, 2006[319]	117/391	30/202	2.02 (1.40; 2.90)	36.57	0.151 (0.08; 0.22)	41.52
Propiverine	Adverse effects	Abrams, 2006[227]	34/42	12/24	1.62 (1.06; 2.48)	26.6	0.310 (0.08; 0.54)	11.63
	Pooled				1.74 (1.40; 2.17)	100	0.155 (0.07; 0.25)	100
	P value/I squared				0.803	0.00%	0.101	51.80%
Propiverine	Blurred vision	Yamaguchi, 2007[410]	15/402	8/406	1.89 (0.81; 4.42)	67	0.018 (-0.01; 0.04)	49.98
Propiverine	Blurred vision	Junemann, 2006[319]	18/391	1/202	9.30 (1.25; 69.16)	33	0.041 (0.02; 0.06)	50.02
	Pooled				3.20 (0.74; 13.88)	100	0.029 (0.01; 0.05)	100
	P value/I squared				0.152	51.20%	0.156	50.40%
Propiverine	Constipation	Abrams, 2006[227]	6/38	0/24	8.33 (0.49; 141.53)	3.05	0.158 (0.03; 0.29)	7.75
Propiverine	Constipation	Yamaguchi, 2007[410]	45/402	16/406	2.84 (1.63; 4.94)	79.72	0.073 (0.04; 0.11)	26.56

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Propiverine	Constipation	Lee, 2010[336]	5/176	0/88	5.53 (0.31; 98.91)	2.94	0.028 (0.00; 0.06)	28.41
Propiverine	Constipation	Junemann, 2006[319]	13/391	2/202	3.36 (0.77; 14.74)	11.17	0.023 (0.00; 0.05)	30.42
Propiverine	Constipation	Abrams, 2006[227]	10/42	0/24	12.21 (0.75; 199.55)	3.13	0.238 (0.10; 0.38)	6.86
	Pooled				3.19 (1.95; 5.23)	100	0.063 (0.02; 0.10)	100
	P value/I squared				0.801	0.00%	0.002	76.10%
Propiverine	Treatment discontinuation	Yamaguchi, 2007[410]	36/402	34/406	1.07 (0.68; 1.67)	70.84	0.006 (-0.03; 0.05)	50.3
Propiverine	Treatment discontinuation	Junemann, 2006[319]	23/391	11/202	1.08 (0.54; 2.17)	29.16	0.004 (-0.04; 0.04)	49.7
	Pooled				1.07 (0.74; 1.56)	100	0.005 (-0.02; 0.03)	100
	P value/I squared				0.981	0.00%	0.959	0.00%
Propiverine	Treatment discontinuation due to adverse effects	Yamaguchi, 2007[410]	26/402	11/406	2.39 (1.20; 4.77)	89.7	0.038 (0.01; 0.07)	30.45
Propiverine	Treatment discontinuation due to adverse effects	Junemann, 2006[319]	11/391	1/202	5.68 (0.74; 43.71)	10.3	0.023 (0.00; 0.04)	69.55
	Pooled				2.61 (1.36; 5.02)	100	0.028 (0.01; 0.04)	100
	P value/I squared				0.43	0.00%	0.413	0.00%
Propiverine	Dizziness	Lee, 2010[336]	1/176	2/88	0.25 (0.02; 2.72)	47.45	-0.017 (-0.05; 0.02)	35.29
Propiverine	Dizziness	Junemann, 2006[319]	6/391	1/202	3.10 (0.38; 25.57)	52.55	0.010 (-0.01; 0.03)	64.71
	Pooled				0.94 (0.08; 11.03)	100	0.001 (-0.03; 0.03)	100
	P value/I squared				0.121	58.30%	0.141	53.80%
Propiverine	Continence	Junemann, 2006[319]	211/391	77/202	1.42 (1.16; 1.73)	86.85	0.158 (0.08; 0.24)	83.96
Propiverine	Continence	Dorschner, 2000[282]	24/49	15/49	1.60 (0.96; 2.66)	13.15	0.184 (-0.01; 0.37)	16.04
	Pooled				1.44 (1.20; 1.73)	100	0.163 (0.09; 0.24)	100
	P value/I squared				0.661	0.00%	0.812	0.00%
Propiverine	Dry mouth	Abrams, 2006[227]	13/38	4/24	2.05 (0.76; 5.57)	8.97	0.175 (-0.04; 0.39)	9.34
Propiverine	Dry mouth	Yamaguchi, 2007[410]	103/402	23/406	4.52 (2.94; 6.96)	48.14	0.200 (0.15; 0.25)	27.41
Propiverine	Dry mouth	Lee, 2010[336]	14/176	2/88	3.50 (0.81; 15.06)	4.19	0.057 (0.01; 0.11)	27.11
Propiverine	Dry mouth	Junemann, 2006[319]	85/391	13/202	3.38 (1.93; 5.90)	28.61	0.153 (0.10; 0.21)	26.81

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Propiverine	Dry mouth	Abrams, 2006[227]	22/42	4/24	3.14 (1.23; 8.05)	10.1	0.357 (0.15; 0.57)	9.33
	Pooled				3.70 (2.74; 4.98)	100	0.161 (0.08; 0.24)	100
	P value/I squared				0.663	0.00%	0	80.50%
Propiverine	Failure	Junemann, 2006[319]	63/391	59/202	0.55 (0.40; 0.75)	62.84	-0.131 (-0.20; -0.06)	56.33
Propiverine	Failure	Dorschner, 2000[282]	6/49	23/49	0.26 (0.12; 0.58)	37.16	-0.347 (-0.51; -0.18)	43.67
	Pooled				0.42 (0.21; 0.85)	100	-0.225 (-0.44; -0.02)	100
	P value/I squared				0.09	65.30%	0.02	81.50%
Propiverine	Headache	Abrams, 2006[227]	1/38	0/24	1.92 (0.08; 45.37)	16.44	0.026 (-0.06; 0.11)	6.64
Propiverine	Headache	Lee, 2010[336]	1/176	2/88	0.25 (0.02; 2.72)	28.4	-0.017 (-0.05; 0.02)	28.99
Propiverine	Headache	Junemann, 2006[319]	6/391	1/202	3.10 (0.38; 25.57)	35.99	0.010 (-0.01; 0.03)	59.69
Propiverine	Headache	Abrams, 2006[227]	3/42	0/24	4.07 (0.22; 75.60)	19.17	0.071 (-0.03; 0.17)	4.68
	Pooled				1.48 (0.41; 5.39)	100	0.006 (-0.02; 0.03)	100
	P value/I squared				0.378	2.90%	0.254	26.40%
Propiverine	Improvement in UI	Lee, 2010[336]	55/176	12/88	2.29 (1.30; 4.05)	14.38	0.176 (0.08; 0.28)	36.6
Propiverine	Improvement in UI	Junemann, 2006[319]	264/391	94/202	1.45 (1.23; 1.71)	73.52	0.210 (0.13; 0.29)	52.25
Propiverine	Improvement in UI	Dorschner, 2000[282]	19/49	11/49	1.73 (0.92; 3.24)	12.09	0.163 (-0.02; 0.34)	11.15
	Pooled				1.58 (1.26; 1.99)	100	0.192 (0.13; 0.25)	100
	P value/I squared				0.292	18.90%	0.829	0.00%
Solifenacin	Adverse effects	Chapple, 2004[265]	6/41	6/38	0.93 (0.33; 2.63)	5.76	-0.012 (-0.17; 0.15)	10.7
Solifenacin	Adverse effects	Chapple, 2004[265]	12/37	6/38	2.05 (0.86; 4.90)	7.55	0.166 (-0.02; 0.36)	8.41
Solifenacin	Adverse effects	Karram, 2009[324]	160/372	88/367	1.79 (1.45; 2.23)	22.68	0.190 (0.12; 0.26)	21.87
Solifenacin	Adverse effects	Toglia, 2009[325]	160/372	88/367	1.79 (1.45; 2.23)	22.68	0.190 (0.12; 0.26)	21.87
Solifenacin	Adverse effects	Chapple, 2004[265]	12/35	6/38	2.17 (0.91; 5.16)	7.59	0.185 (-0.01; 0.38)	8.1
Solifenacin	Adverse effects	Chu, 2009[269]	236/340	197/332	1.17 (1.04; 1.31)	25.09	0.101 (0.03; 0.17)	21.07
Solifenacin	Adverse effects	Chapple, 2004[265]	21/37	6/38	3.60 (1.64; 7.89)	8.67	0.410 (0.21; 0.61)	7.99
	Pooled				1.69 (1.27; 2.24)	100	0.165 (0.10; 0.23)	100
	P value/I squared				0	78.20%	0.021	59.60%
Solifenacin	Blurred vision	Chapple, 2004[265]	1/41	2/38	0.46 (0.04; 4.91)	0.88	-0.028 (-0.11; 0.06)	0.76
Solifenacin	Blurred vision	Chapple, 2004[265]	1/37	2/38	0.51 (0.05; 5.42)	0.88	-0.026 (-0.11; 0.06)	0.71
Solifenacin	Blurred vision	Chapple, 2004[54]	10/279	7/267	1.37 (0.53; 3.54)	5.41	0.010 (-0.02; 0.04)	4.69
Solifenacin	Blurred vision	Cardozo, 2006[250]	13/314	14/781	2.31 (1.10; 4.86)	8.86	0.023 (0.00; 0.05)	6
Solifenacin	Blurred vision	Staskin, 2006[39]	22/578	22/1216	2.10 (1.18; 3.77)	14.43	0.020 (0.00; 0.04)	8.36

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Solifenacin	Blurred vision	Yamaguchi, 2007[410]	7/400	8/406	0.89 (0.33; 2.43)	4.85	-0.002 (-0.02; 0.02)	7.81
Solifenacin	Blurred vision	Cardozo, 2008[63]	4/641	2/224	0.70 (0.13; 3.79)	1.71	-0.003 (-0.02; 0.01)	9.94
Solifenacin	Blurred vision	Karram, 2009[324]	14/372	4/367	3.45 (1.15; 10.39)	4.03	0.027 (0.01; 0.05)	6.58
Solifenacin	Blurred vision	Toglia, 2009[325]	15/372	4/367	3.70 (1.24; 11.04)	4.1	0.029 (0.01; 0.05)	6.4
Solifenacin	Blurred vision	Vardy, 2009[395]	4/386	5/382	0.79 (0.21; 2.93)	2.87	-0.003 (-0.02; 0.01)	9.25
Solifenacin	Blurred vision	Chapple, 2004[265]	5/35	2/38	2.71 (0.56; 13.10)	1.98	0.090 (-0.05; 0.23)	0.31
Solifenacin	Blurred vision	Chapple, 2004[54]	15/269	7/267	2.13 (0.88; 5.13)	6.31	0.030 (0.00; 0.06)	3.83
Solifenacin	Blurred vision	Cardozo, 2006[250]	36/778	14/781	2.58 (1.40; 4.75)	13.19	0.028 (0.01; 0.05)	8.29
Solifenacin	Blurred vision	Staskin, 2006[39]	59/1233	22/1216	2.65 (1.63; 4.29)	20.98	0.030 (0.02; 0.04)	9.78
Solifenacin	Blurred vision	Yamaguchi, 2007[410]	16/385	8/406	2.11 (0.91; 4.87)	6.99	0.022 (0.00; 0.05)	5.95
Solifenacin	Blurred vision	Chu, 2009[269]	3/340	0/332	6.84 (0.35; 131.83)	0.56	0.009 (0.00; 0.02)	11.01
Solifenacin	Blurred vision	Chapple, 2004[265]	5/37	2/38	2.57 (0.53; 12.42)	1.97	0.083 (-0.05; 0.21)	0.33
	Pooled				2.11 (1.70; 2.64)	100	0.015 (0.01; 0.02)	100
	P value/I squared				0.578	0.00%	0.014	48.10%
Solifenacin	Dry mouth	Chapple, 2004[265]	5/37	0/38	11.29 (0.65; 197.21)	0.9	0.135 (0.02; 0.25)	5.68
Solifenacin	Dry mouth	Cardozo, 2006[250]	35/314	35/781	2.49 (1.59; 3.90)	9.74	0.067 (0.03; 0.10)	8.53
Solifenacin	Dry mouth	Staskin, 2006[39]	63/578	51/1216	2.60 (1.82; 3.71)	10.74	0.067 (0.04; 0.10)	8.76
Solifenacin	Dry mouth	Yamaguchi, 2007[410]	67/400	23/406	2.96 (1.88; 4.65)	9.71	0.111 (0.07; 0.15)	8.39
Solifenacin	Dry mouth	Cardozo, 2008[63]	80/641	6/224	4.66 (2.06; 10.53)	6.21	0.098 (0.07; 0.13)	8.64
Solifenacin	Dry mouth	Karram, 2009[324]	94/372	33/367	2.81 (1.94; 4.07)	10.6	0.163 (0.11; 0.22)	8.08
Solifenacin	Dry mouth	Toglia, 2009[325]	93/372	33/367	2.78 (1.92; 4.03)	10.6	0.160 (0.11; 0.21)	8.08
Solifenacin	Dry mouth	Chapple, 2004[265]	5/35	0/38	11.92 (0.68; 207.96)	0.9	0.143 (0.02; 0.27)	5.49
Solifenacin	Dry mouth	Cardozo, 2006[250]	226/778	35/781	6.48 (4.61; 9.12)	10.89	0.246 (0.21; 0.28)	8.6
Solifenacin	Dry mouth	Staskin, 2006[39]	340/1233	51/1216	6.58 (4.95; 8.73)	11.46	0.234 (0.21; 0.26)	8.77
Solifenacin	Dry mouth	Yamaguchi, 2007[410]	130/385	23/406	5.96 (3.91; 9.08)	10.05	0.281 (0.23; 0.33)	8.1
Solifenacin	Dry mouth	Chapple, 2004[265]	14/37	0/38	29.76 (1.84; 481.47)	0.95	0.378 (0.22; 0.54)	4.35
Solifenacin	Dry mouth	Vardy, 2009[395]	51/386	9/382	5.61 (2.80; 11.23)	7.25	0.109 (0.07; 0.15)	8.55
	Pooled				4.10 (3.09; 5.43)	100	0.161 (0.12; 0.21)	100
	P value/I squared				0	73.80%	0	92.80%
Solifenacin	Dyspepsia	Chapple, 2004[265]	1/37	0/38	3.08 (0.13; 73.25)	8.98	0.027 (-0.04; 0.10)	8.41
Solifenacin	Dyspepsia	Chapple, 2004[265]	1/35	0/38	3.25 (0.14; 77.25)	8.98	0.029 (-0.05; 0.10)	7.85
Solifenacin	Dyspepsia	Chu, 2009[269]	16/340	3/332	5.21 (1.53; 17.71)	60.22	0.038 (0.01; 0.06)	33.06
Solifenacin	Dyspepsia	Chapple, 2004[265]	5/37	0/38	11.29 (0.65; 197.21)	11.02	0.135 (0.02; 0.25)	3.44
Solifenacin	Dyspepsia	Vardy, 2009[395]	5/386	0/382	10.89 (0.60; 196.20)	10.79	0.013 (0.00; 0.03)	47.24

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
	Pooled				5.62 (2.17; 14.52)	100	0.028 (0.01; 0.05)	100
	P value/I squared				0.952	0.00%	0.132	43.50%
Solifenacin	Failure	Chapple, 2004[54]	2/279	2/267	0.96 (0.14; 6.75)	1.21	0.000 (-0.02; 0.01)	26.24
Solifenacin	Failure	Cardozo, 2008[63]	298/641	147/224	0.71 (0.63; 0.80)	39.46	-0.191 (-0.27; -0.12)	24.27
Solifenacin	Failure	Toglia, 2009[325]	112/372	191/367	0.58 (0.48; 0.70)	34.39	-0.219 (-0.29; -0.15)	24.47
Solifenacin	Failure	Vardy, 2009[395]	53/386	115/382	0.46 (0.34; 0.61)	24.95	-0.164 (-0.22; -0.11)	25.02
	Pooled				0.59 (0.48; 0.74)	100	-0.141 (-0.27; -0.01)	100
	P value/I squared				0.03	66.50%	0	96.40%
Solifenacin	Fatigue	Karram, 2009[324]	10/372	4/367	2.47 (0.78; 7.79)	39.63	0.016 (0.00; 0.04)	24.58
Solifenacin	Fatigue	Toglia, 2009[325]	11/372	4/367	2.71 (0.87; 8.44)	40.71	0.019 (0.00; 0.04)	23.01
Solifenacin	Fatigue	Vardy, 2009[395]	5/386	2/382	2.47 (0.48; 12.67)	19.66	0.008 (-0.01; 0.02)	52.41
	Pooled				2.57 (1.24; 5.29)	100	0.012 (0.00; 0.02)	100
	P value/I squared				0.992	0.00%	0.617	0.00%
Solifenacin	Headache	Chapple, 2004[265]	0/41	1/38	0.31 (0.01; 7.38)	1.13	-0.026 (-0.10; 0.04)	2.57
Solifenacin	Headache	Chapple, 2004[265]	2/37	1/38	2.05 (0.19; 21.70)	2.05	0.028 (-0.06; 0.12)	1.53
Solifenacin	Headache	Karram, 2009[324]	17/372	19/367	2.17 (0.21; 22.91)	2.05	0.031 (-0.06; 0.12)	1.43
Solifenacin	Headache	Toglia, 2009[325]	19/372	18/367	2.05 (0.19; 21.70)	2.05	0.028 (-0.06; 0.12)	1.53
Solifenacin	Headache	Chapple, 2004[265]	2/35	1/38	0.88 (0.47; 1.67)	27.99	-0.006 (-0.04; 0.03)	12.57
Solifenacin	Headache	Chu, 2009[269]	16/340	24/332	1.04 (0.56; 1.95)	28.88	0.002 (-0.03; 0.03)	12.26
Solifenacin	Headache	Chapple, 2004[265]	2/37	1/38	0.59 (0.14; 2.47)	5.62	-0.005 (-0.02; 0.01)	58.66
Solifenacin	Headache	Vardy, 2009[395]	3/386	5/382	0.65 (0.35; 1.20)	30.22	-0.025 (-0.06; 0.01)	9.45
	Pooled				0.86 (0.61; 1.21)	100	-0.005 (-0.02; 0.01)	100
	P value/I squared				0.84	0.00%	0.845	0.00%
Solifenacin	Improvement in UI	Toglia, 2009[325]	260/372	206/367	1.25 (1.11; 1.39)	52.27	0.138 (0.07; 0.21)	49.62
Solifenacin	Improvement in UI	Vardy, 2009[395]	196/386	109/382	1.78 (1.48; 2.15)	47.73	0.222 (0.16; 0.29)	50.38
	Pooled				1.48 (1.04; 2.09)	100	0.180 (0.10; 0.26)	100
	P value/I squared				0.001	90.30%	0.085	66.40%
Solifenacin	Nausea	Chu, 2009[269]	19/340	13/332	0.66 (0.19; 2.32)	25.82	-0.005 (-0.02; 0.01)	70.68
Solifenacin	Nausea	Vardy, 2009[395]	4/386	6/382	1.43 (0.72; 2.84)	74.18	0.017 (-0.02; 0.05)	29.32
	Pooled				1.17 (0.60; 2.27)	100	0.001 (-0.02; 0.02)	100
	P value/I squared				0.292	10.10%	0.228	31.10%
Solifenacin	Urinary retention	Chu, 2009[269]	7/340	3/332	5.13 (0.26; 103.41)	16.69	0.054 (-0.03; 0.14)	4.25
Solifenacin	Urinary retention	Chapple, 2004[265]	2/37	0/38	2.28 (0.59; 8.74)	83.31	0.012 (-0.01; 0.03)	95.75
	Pooled				2.61 (0.77; 8.90)	100	0.013 (0.00; 0.03)	100
	P value/I squared				0.629	0.00%	0.345	0.00%
Solifenacin	Constipation	Chapple, 2004[265]	1/41	0/38	2.79 (0.12; 66.37)	0.74	0.024 (-0.04; 0.09)	5.1
Solifenacin	Constipation	Cardozo, 2006[250]	20/314	28/781	5.42 (0.27; 109.06)	0.82	0.057 (-0.03; 0.15)	3.59
Solifenacin	Constipation	Staskin, 2006[39]	31/578	35/1216	13.34 (0.78; 228.71)	0.91	0.162 (0.04; 0.29)	2.26

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Solifenacin	Constipation	Yamaguchi, 2007[410]	42/400	16/406	1.78 (1.02; 3.11)	8.81	0.028 (0.00; 0.06)	8.38
Solifenacin	Constipation	Cardozo, 2008[63]	35/641	5/224	3.91 (2.61; 5.85)	10.58	0.104 (0.08; 0.13)	8.59
Solifenacin	Constipation	Karram, 2009[324]	55/372	34/367	1.86 (1.16; 2.99)	9.77	0.025 (0.00; 0.05)	9.18
Solifenacin	Constipation	Toglia, 2009[325]	56/372	33/367	4.65 (3.26; 6.64)	11.11	0.105 (0.08; 0.13)	9.14
Solifenacin	Constipation	Chapple, 2004[265]	2/35	0/38	2.66 (1.52; 4.66)	8.8	0.066 (0.03; 0.10)	7.86
Solifenacin	Constipation	Cardozo, 2006[250]	109/778	28/781	4.75 (2.81; 8.01)	9.2	0.148 (0.10; 0.19)	7.1
Solifenacin	Constipation	Staskin, 2006[39]	165/1233	35/1216	2.45 (0.97; 6.17)	5.48	0.032 (0.01; 0.06)	8.72
Solifenacin	Constipation	Yamaguchi, 2007[410]	72/385	16/406	1.60 (1.07; 2.39)	10.58	0.055 (0.01; 0.10)	6.78
Solifenacin	Constipation	Chu, 2009[269]	26/340	7/332	1.67 (1.12; 2.51)	10.55	0.061 (0.01; 0.11)	6.78
Solifenacin	Constipation	Chapple, 2004[265]	6/37	0/38	4.38 (1.95; 9.83)	6.38	0.062 (0.03; 0.09)	8.35
Solifenacin	Constipation	Vardy, 2009[395]	31/386	7/382	3.63 (1.60; 8.24)	6.27	0.055 (0.02; 0.09)	8.17
	Pooled				2.80 (2.11; 3.70)	100	0.066 (0.05; 0.09)	100
	P value/I squared				0.001	64.20%	0	80.30%
Solifenacin	Death	Chapple, 2004[54]	0/279	0/267	2.98 (0.12; 72.77)	50.01	0.000 (-0.01; 0.01)	40.44
Solifenacin	Death	Cardozo, 2008[63]	1/641	0/224	1.05 (0.04; 25.72)	49.99	0.004 (-0.01; 0.01)	19.64
Solifenacin	Death	Chapple, 2004[54]	1/269	0/267	(Excluded) (0.00; 0.00)		0.002 (-0.01; 0.01)	39.92
	Pooled				1.77 (0.19; 16.96)	100	0.001 (0.00; 0.01)	100
	P value/I squared				0.652	0.00%	0.842	0.00%
Solifenacin	Treatment discontinuation	Chapple, 2004[265]	3/37	6/38	0.51 (0.14; 1.90)	2.07	-0.077 (-0.22; 0.07)	1.09
Solifenacin	Treatment discontinuation	Chapple, 2004[54]	28/279	32/267	1.27 (0.47; 3.41)	3.54	0.042 (-0.13; 0.22)	0.75
Solifenacin	Treatment discontinuation	Yamaguchi, 2007[410]	34/400	34/406	0.84 (0.52; 1.35)	12.91	-0.019 (-0.07; 0.03)	8.37
Solifenacin	Treatment discontinuation	Cardozo, 2008[63]	49/641	24/224	0.62 (0.36; 1.06)	10.83	-0.046 (-0.10; 0.01)	9.24
Solifenacin	Treatment discontinuation	Toglia, 2009[325]	9/372	18/367	1.02 (0.64; 1.60)	14.01	0.001 (-0.04; 0.04)	15.68
Solifenacin	Treatment discontinuation	Chapple, 2004[265]	7/35	6/38	0.99 (0.63; 1.58)	13.66	-0.001 (-0.04; 0.04)	15.54
Solifenacin	Treatment discontinuation	Chapple, 2004[54]	20/269	32/267	0.71 (0.45; 1.14)	13.57	-0.031 (-0.08; 0.02)	11.2
Solifenacin	Treatment discontinuation	Yamaguchi, 2007[410]	32/385	34/406	0.49 (0.23; 1.08)	5.43	-0.025 (-0.05; 0.00)	31.56

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Solifenacin	Treatment discontinuation	Chu, 2009[269]	70/340	58/332	1.18 (0.86; 1.61)	23.98	0.031 (-0.03; 0.09)	6.57
	Pooled				0.88 (0.73; 1.07)	100	-0.015 (-0.03; 0.00)	100
	P value/I squared				0.293	16.80%	0.529	0.00%
Solifenacin	Treatment discontinuation due to adverse effects	Chapple, 2004[54]	9/279	10/267	0.86 (0.36; 2.09)	5.11	-0.005 (-0.04; 0.03)	7.82
Solifenacin	Treatment discontinuation due to adverse effects	Cardozo, 2006[250]	14/314	40/781	0.70 (0.27; 1.80)	4.5	-0.011 (-0.04; 0.02)	8.18
Solifenacin	Treatment discontinuation due to adverse effects	Staskin, 2006[39]	4/159	19/430	0.87 (0.48; 1.58)	9.88	-0.007 (-0.03; 0.02)	8.9
Solifenacin	Treatment discontinuation due to adverse effects	Yamaguchi, 2007[410]	20/400	11/406	1.28 (0.86; 1.91)	16.95	0.014 (-0.01; 0.04)	10.6
Solifenacin	Treatment discontinuation due to adverse effects	Cardozo, 2008[63]	15/641	4/224	0.57 (0.20; 1.65)	3.68	-0.019 (-0.05; 0.01)	7.72
Solifenacin	Treatment discontinuation due to adverse effects	Karram, 2009[324]	24/372	17/367	1.55 (0.89; 2.71)	10.94	0.024 (-0.01; 0.06)	7.97
Solifenacin	Treatment discontinuation due to adverse effects	Toglia, 2009[325]	25/372	16/367	1.85 (0.90; 3.80)	7.23	0.023 (0.00; 0.05)	9.27
Solifenacin	Treatment discontinuation due to adverse effects	Chapple, 2004[54]	7/269	10/267	2.49 (1.25; 4.98)	7.78	0.040 (0.01; 0.07)	8.2

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Solifenacin	Treatment discontinuation due to adverse effects	Cardozo, 2006[250]	51/778	40/781	1.31 (0.44; 3.91)	3.5	0.006 (-0.02; 0.03)	11.65
Solifenacin	Treatment discontinuation due to adverse effects	Staskin, 2006[39]	31/452	19/430	1.39 (0.76; 2.55)	9.63	0.018 (-0.02; 0.05)	7.19
Solifenacin	Treatment discontinuation due to adverse effects	Yamaguchi, 2007[410]	26/385	11/406	1.54 (0.84; 2.84)	9.48	0.024 (-0.01; 0.06)	7.2
Solifenacin	Treatment discontinuation due to adverse effects	Chu, 2009[269]	37/340	18/332	2.01 (1.17; 3.45)	11.33	0.055 (0.01; 0.10)	5.3
	Pooled				1.36 (1.10; 1.68)	100	0.012 (0.00; 0.02)	100
	P value/I squared				0.246	20.10%	0.059	42.50%
Solifenacin	Treatment discontinuation due to failure	Cardozo, 2008[63]	11/641	6/224	0.50 (0.05; 5.44)	7.05	-0.004 (-0.02; 0.01)	41.35
Solifenacin	Treatment discontinuation due to failure	Toglia, 2009[325]	8/372	5/367	0.64 (0.24; 1.71)	41.82	-0.010 (-0.03; 0.01)	12.06
Solifenacin	Treatment discontinuation due to failure	Chapple, 2004[54]	1/269	2/267	1.58 (0.52; 4.78)	32.92	0.008 (-0.01; 0.03)	18.46
Solifenacin	Treatment discontinuation due to failure	Chu, 2009[269]	4/340	3/332	1.30 (0.29; 5.77)	18.22	0.003 (-0.01; 0.02)	28.13
	Pooled				0.96 (0.51; 1.82)	100	0.000 (-0.01; 0.01)	100
	P value/I squared				0.598	0.00%	0.623	0.00%
Solifenacin	Dizziness	Karram, 2009[324]	12/372	7/367	1.69 (0.67; 4.25)	33.62	0.013 (-0.01; 0.04)	34.2
Solifenacin	Dizziness	Toglia, 2009[325]	11/372	7/367	1.55 (0.61; 3.96)	32.5	0.010 (-0.01; 0.03)	36
Solifenacin	Dizziness	Chu, 2009[269]	10/340	8/332	1.22 (0.49; 3.06)	33.88	0.005 (-0.02; 0.03)	29.8
	Pooled				1.47 (0.86; 2.51)	100	0.010 (0.00; 0.02)	100
	P value/I squared				0.878	0.00%	0.896	0.00%
Solifenacin	Continence	Cardozo, 2006[250]	160/314	266/781	1.50 (1.29; 1.73)	23.09	0.169 (0.10; 0.23)	14.08
Solifenacin	Continence	Staskin, 2006[39]	49/159	122/430	1.53 (1.36; 1.72)	34.95	0.180 (0.13; 0.23)	15.75

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Solifenacin	Continence	Karram, 2009[324]	133/372	93/367	1.09 (0.82; 1.43)	6.4	0.024 (-0.06; 0.11)	12.11
Solifenacin	Continence	Cardozo, 2006[250]	405/778	266/781	1.44 (1.19; 1.73)	14.08	0.123 (0.06; 0.19)	14.32
Solifenacin	Continence	Staskin, 2006[39]	184/452	122/430	1.41 (1.13; 1.76)	9.96	0.104 (0.04; 0.17)	13.92
Solifenacin	Continence	Chu, 2009[269]	119/340	80/332	1.32 (0.88; 1.99)	2.95	0.030 (-0.01; 0.07)	16.16
Solifenacin	Continence	Vardy, 2009[395]	48/386	36/382	1.45 (1.14; 1.85)	8.56	0.109 (0.04; 0.18)	13.66
	Pooled				1.45 (1.35; 1.56)	100	0.107 (0.06; 0.16)	100
	P value/I squared				0.496	0.00%	0	78.60%
Tolterodine	Abdominal pain	Jacquetin, 2001[316]	6/97	2/51	1.58 (0.33; 7.54)	6.13	0.023 (-0.05; 0.09)	1.69
Tolterodine	Abdominal pain	Van Kerrebroeck, 2001[394]	19/507	8/508	2.38 (1.05; 5.39)	22.47	0.022 (0.00; 0.04)	15.81
Tolterodine	Abdominal pain	Van Kerrebroeck, 2001[394]	13/514	8/508	1.61 (0.67; 3.84)	19.71	0.010 (-0.01; 0.03)	18.74
Tolterodine	Abdominal pain	Malone-Lee, 2001[346]	6/73	5/74	1.22 (0.39; 3.81)	11.5	0.015 (-0.07; 0.10)	1.21
Tolterodine	Abdominal pain	Jacquetin, 2001[316]	4/103	2/51	0.99 (0.19; 5.23)	5.41	0.000 (-0.07; 0.07)	2.04
Tolterodine	Abdominal pain	Swift, 2003[382]	18/417	7/410	2.53 (1.07; 5.99)	20.16	0.026 (0.00; 0.05)	12.56
Tolterodine	Abdominal pain	Khullar, 2004[329]	12/569	2/285	3.01 (0.68; 13.34)	6.75	0.014 (0.00; 0.03)	21.83
Tolterodine	Abdominal pain	NCT00444925,[58]	4/690	4/337	0.49 (0.12; 1.94)	7.87	-0.006 (-0.02; 0.01)	26.11
	Pooled				1.72 (1.17; 2.54)	100	0.011 (0.00; 0.02)	100
	P value/I squared				0.549	0.00%	0.212	27.10%
Tolterodine	Abnormal vision	Rentzhog, 1998[362]	0/21	1/13	0.21 (0.01; 4.85)	7.71	-0.077 (-0.25; 0.10)	0.18
Tolterodine	Abnormal vision	Rentzhog, 1998[362]	3/16	1/13	2.44 (0.29; 20.75)	16.47	0.111 (-0.13; 0.35)	0.1
Tolterodine	Abnormal vision	Rentzhog, 1998[362]	1/14	1/13	0.93 (0.06; 13.37)	10.62	-0.005 (-0.20; 0.19)	0.14
Tolterodine	Abnormal vision	Van Kerrebroeck, 2001[394]	4/514	2/508	1.98 (0.36; 10.74)	26.35	0.004 (-0.01; 0.01)	63.53
Tolterodine	Abnormal vision	Swift, 2003[382]	5/417	2/410	2.46 (0.48; 12.60)	28.28	0.007 (-0.01; 0.02)	35.89
Tolterodine	Abnormal vision	Rentzhog, 1998[362]	1/16	1/13	0.81 (0.06; 11.77)	10.57	-0.014 (-0.20; 0.17)	0.16
	Pooled				1.54 (0.65; 3.67)	100	0.005 (0.00; 0.01)	100
	P value/I squared				0.78	0.00%	0.873	0.00%
Tolterodine	Adverse effects	Rentzhog, 1998[362]	8/21	6/13	0.83 (0.37; 1.84)	1.2	-0.081 (-0.42; 0.26)	0.89
Tolterodine	Adverse effects	Jonas, 1997[318]	31/99	17/44	0.81 (0.51; 1.30)	3.16	-0.073 (-0.24; 0.10)	3.44

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Tolterodine	Adverse effects	Rentzhog, 1998[362]	6/16	6/13	0.81 (0.34; 1.93)	1.04	-0.087 (-0.45; 0.27)	0.8
Tolterodine	Adverse effects	Rentzhog, 1998[362]	10/14	10/13	0.93 (0.60; 1.45)	3.5	-0.055 (-0.38; 0.27)	0.96
Tolterodine	Adverse effects	Abrams, 1998[226]	105/118	46/57	1.10 (0.96; 1.27)	15.24	0.083 (-0.03; 0.20)	6.88
Tolterodine	Adverse effects	Drutz, 1999[283]	85/109	42/56	1.04 (0.87; 1.25)	12.31	0.030 (-0.11; 0.17)	5.13
Tolterodine	Adverse effects	Jacquetin, 2001[316]	55/103	16/51	1.70 (1.09; 2.65)	3.52	0.220 (0.06; 0.38)	3.89
Tolterodine	Adverse effects	Chapple, 2004[265]	12/37	6/38	2.05 (0.86; 4.90)	1.03	0.166 (-0.02; 0.36)	2.79
Tolterodine	Adverse effects	Khullar, 2004[329]	221/569	96/285	1.15 (0.95; 1.40)	11.55	0.052 (-0.02; 0.12)	16.84
Tolterodine	Adverse effects	Chapple, 2007[259]	144/290	107/285	1.32 (1.09; 1.60)	11.77	0.121 (0.04; 0.20)	12.99
Tolterodine	Adverse effects	Rogers, 2008[367]	114/202	111/211	1.07 (0.90; 1.28)	12.64	0.038 (-0.06; 0.13)	9.71
Tolterodine	Adverse effects	Malone-Lee, 2009[345]	88/165	67/142	1.13 (0.90; 1.42)	9.69	0.062 (-0.05; 0.17)	7.44
Tolterodine	Adverse effects	Junemann, 2000[320]	25/76	12/79	2.17 (1.17; 3.99)	1.99	0.177 (0.05; 0.31)	5.53
Tolterodine	Adverse effects	NCT00444925,[58]	213/690	76/337	1.37 (1.09; 1.72)	9.58	0.083 (0.03; 0.14)	21.83
Tolterodine	Adverse effects	Rentzhog, 1998[362]	12/16	6/13	1.63 (0.85; 3.12)	1.77	0.288 (-0.06; 0.63)	0.88
	Pooled				1.17 (1.07; 1.28)	100	0.079 (0.05; 0.11)	100
	P value/I squared				0.111	32.20%	0.333	10.80%
Tolterodine	Autonomic nervous system	Jonas, 1997[318]	11/99	4/44	1.22 (0.41; 3.63)	7.95	0.020 (-0.09; 0.13)	22.51
Tolterodine	Autonomic nervous system	Jonas, 1997[318]	16/99	4/44	1.78 (0.63; 5.01)	8.76	0.071 (-0.04; 0.18)	21.39
Tolterodine	Autonomic nervous system disorders	Millard, 1999[349]	37/129	11/64	1.67 (0.91; 3.05)	25.92	0.115 (-0.01; 0.24)	19.88
Tolterodine	Autonomic nervous system disorders	Millard, 1999[349]	53/123	11/64	2.51 (1.41; 4.46)	28.49	0.259 (0.13; 0.39)	18.92
Tolterodine	Autonomic nervous system disorders	Drutz, 1999[283]	35/109	12/56	1.50 (0.85; 2.65)	28.88	0.107 (-0.03; 0.25)	17.3
	Pooled				1.78 (1.31; 2.42)	100	0.110 (0.03; 0.19)	100
	P value/I squared				0.696	0.00%	0.074	53.00%
Tolterodine	Blurred vision	Chapple, 2004[265]	0/37	2/38	0.21 (0.01; 4.14)	14.1	-0.053 (-0.14; 0.03)	7.45

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Tolterodine	Blurred vision	Chapple, 2004[54]	4/266	7/267	0.57 (0.17; 1.94)	85.9	-0.011 (-0.04; 0.01)	92.55
	Pooled				0.50 (0.16; 1.53)	100	-0.014 (-0.04; 0.01)	100
	P value/I squared				0.534	0.00%	0.358	0.00%
Tolterodine	Constipation	Rentzhog, 1998[362]	1/21	0/13	1.91 (0.08; 43.65)	0.46	0.048 (-0.10; 0.19)	0.17
Tolterodine	Constipation	Jonas, 1997[318]	2/99	2/44	0.44 (0.07; 3.05)	1.22	-0.025 (-0.09; 0.04)	0.76
Tolterodine	Constipation	Rentzhog, 1998[362]	3/16	0/13	5.77 (0.32; 102.44)	0.55	0.188 (-0.03; 0.40)	0.07
Tolterodine	Constipation	Malone-Lee, 2001[346]	5/61	2/74	3.03 (0.61; 15.09)	1.77	0.055 (-0.02; 0.13)	0.57
Tolterodine	Constipation	Jacquetin, 2001[316]	4/97	2/51	1.05 (0.20; 5.55)	1.64	0.002 (-0.06; 0.07)	0.79
Tolterodine	Constipation	Jonas, 1997[318]	3/99	2/44	0.67 (0.12; 3.85)	1.48	-0.015 (-0.09; 0.06)	0.7
Tolterodine	Constipation	Rentzhog, 1998[362]	1/14	0/13	2.80 (0.12; 63.20)	0.47	0.071 (-0.11; 0.25)	0.11
Tolterodine	Constipation	Van Kerrebroeck, 2001[394]	35/514	22/508	1.57 (0.94; 2.64)	16.89	0.025 (0.00; 0.05)	4.4
Tolterodine	Constipation	Van Kerrebroeck, 2001[394]	30/507	22/508	1.37 (0.80; 2.34)	15.82	0.016 (-0.01; 0.04)	4.71
Tolterodine	Constipation	Malone-Lee, 2001[346]	0/73	2/74	0.20 (0.01; 4.15)	0.5	-0.027 (-0.07; 0.02)	1.73
Tolterodine	Constipation	Jacquetin, 2001[316]	2/103	2/51	0.50 (0.07; 3.42)	1.22	-0.020 (-0.08; 0.04)	0.98
Tolterodine	Constipation	Swift, 2003[382]	27/417	14/410	1.90 (1.01; 3.56)	11.43	0.031 (0.00; 0.06)	4
Tolterodine	Constipation	Chapple, 2004[265]	1/37	0/38	3.08 (0.13; 73.25)	0.45	0.027 (-0.04; 0.10)	0.68
Tolterodine	Constipation	Khullar, 2004[329]	9/569	2/285	2.25 (0.49; 10.36)	1.95	0.009 (-0.01; 0.02)	17.4
Tolterodine	Constipation	DuBeau, 2005[284]	6/569	3/285	1.00 (0.25; 3.98)	2.39	0.000 (-0.02; 0.02)	16.43
Tolterodine	Constipation	Chapple, 2007[259]	8/290	4/285	1.97 (0.60; 6.46)	3.22	0.014 (-0.01; 0.04)	6.39
Tolterodine	Constipation	Rogers, 2008[367]	7/202	8/211	0.91 (0.34; 2.47)	4.59	-0.003 (-0.04; 0.03)	2.66
Tolterodine	Constipation	Herschorn, 2008[305]	11/410	3/207	1.85 (0.52; 6.56)	2.84	0.012 (-0.01; 0.04)	6.8
Tolterodine	Constipation	Herschorn, 2010[475]	28/684	10/334	1.37 (0.67; 2.78)	9.02	0.011 (-0.01; 0.04)	6.25
Tolterodine	Constipation	Kaplan, 2010[322]	29/974	10/480	1.43 (0.70; 2.91)	9.01	0.009 (-0.01; 0.03)	12.5
Tolterodine	Constipation	NCT00444925,[58]	28/690	10/337	1.37 (0.67; 2.78)	9.02	0.011 (-0.01; 0.03)	6.36
Tolterodine	Constipation	Rentzhog, 1998[362]	2/16	0/13	4.12 (0.22; 78.89)	0.52	0.125 (-0.07; 0.32)	0.09

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Tolterodine	Constipation	Chapple, 2004[54]	7/266	5/267	1.41 (0.45; 4.37)	3.53	0.008 (-0.02; 0.03)	5.46
	Pooled				1.45 (1.17; 1.79)	100	0.009 (0.00; 0.02)	100
	P value/I squared				0.982	0.00%	0.767	0.00%
Tolterodine	Diarrhea	Van Kerrebroeck, 2001[394]	16/514	11/508	1.44 (0.67; 3.07)	23.9	0.009 (-0.01; 0.03)	12.85
Tolterodine	Diarrhea	Van Kerrebroeck, 2001[394]	10/507	11/508	0.91 (0.39; 2.13)	19.11	-0.002 (-0.02; 0.02)	16.16
Tolterodine	Diarrhea	Malone-Lee, 2001[346]	4/73	5/74	0.81 (0.23; 2.90)	8.45	-0.013 (-0.09; 0.07)	0.83
Tolterodine	Diarrhea	Swift, 2003[382]	10/417	9/410	1.09 (0.45; 2.66)	17.32	0.002 (-0.02; 0.02)	11.89
Tolterodine	Diarrhea	Khullar, 2004[329]	10/569	3/285	1.67 (0.46; 6.02)	8.35	0.007 (-0.01; 0.02)	19.29
Tolterodine	Diarrhea	Herschorn, 2010[475]	15/684	4/334	1.83 (0.61; 5.47)	11.44	0.010 (-0.01; 0.03)	19.32
Tolterodine	Diarrhea	NCT00444925,[58]	15/690	4/337	1.83 (0.61; 5.48)	11.44	0.010 (-0.01; 0.03)	19.66
	Pooled				1.28 (0.89; 1.86)	100	0.006 (0.00; 0.01)	100
	P value/I squared				0.889	0.00%	0.941	0.00%
Tolterodine	Treatment discontinuation	Drutz, 1999[283]	14/109	8/56	0.90 (0.40; 2.01)	4.95	-0.014 (-0.13; 0.10)	0.46
Tolterodine	Treatment discontinuation	Van Kerrebroeck, 2001[394]	1/507	8/508	0.13 (0.02; 1.00)	0.75	-0.014 (-0.03; 0.00)	43.35
Tolterodine	Treatment discontinuation	Kelleher, 2002[327]	57/507	68/508	0.84 (0.60; 1.17)	29.63	-0.021 (-0.06; 0.02)	3.51
Tolterodine	Treatment discontinuation	Chapple, 2004[265]	5/37	6/38	0.86 (0.29; 2.56)	2.68	-0.023 (-0.18; 0.14)	0.22
Tolterodine	Treatment discontinuation	DuBeau, 2005[284]	29/569	18/285	0.81 (0.46; 1.43)	9.89	-0.012 (-0.05; 0.02)	5.1
Tolterodine	Treatment discontinuation	Chapple, 2007[259]	37/290	33/285	1.10 (0.71; 1.71)	16.65	0.012 (-0.04; 0.07)	2.01
Tolterodine	Treatment discontinuation	Robinson, 2007[365]	8/61	2/61	4.00 (0.89; 18.08)	1.42	0.098 (0.00; 0.19)	0.62
Tolterodine	Treatment discontinuation	Herschorn, 2010[475]	56/684	30/334	0.91 (0.60; 1.39)	17.95	-0.008 (-0.05; 0.03)	4.2
Tolterodine	Treatment discontinuation	NCT00444925,[58]	6/690	3/337	0.98 (0.25; 3.88)	1.69	0.000 (-0.01; 0.01)	38.56
Tolterodine	Treatment discontinuation	Chapple, 2004[54]	29/266	32/267	0.91 (0.57; 1.46)	14.4	-0.011 (-0.07; 0.04)	1.96
	Pooled				0.91 (0.76; 1.09)	100	-0.007 (-0.02; 0.00)	100
	P value/I squared				0.499	0.00%	0.504	0.00%

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Tolterodine	Treatment discontinuation due to adverse effects	Abrams, 1998[226]	10/118	7/57	0.69 (0.28; 1.72)	8.72	-0.038 (-0.14; 0.06)	1.07
Tolterodine	Treatment discontinuation due to adverse effects	Drutz, 1999[283]	7/109	4/56	0.90 (0.28; 2.94)	6.35	-0.007 (-0.09; 0.07)	1.54
Tolterodine	Treatment discontinuation due to adverse effects	Malone-Lee, 2001[346]	7/73	1/74	7.10 (0.90; 56.25)	2.68	0.082 (0.01; 0.16)	1.92
Tolterodine	Treatment discontinuation due to adverse effects	Jacquetin, 2001[316]	3/97	1/51	1.58 (0.17; 14.78)	2.35	0.011 (-0.04; 0.06)	3.56
Tolterodine	Treatment discontinuation due to adverse effects	Jacquetin, 2001[316]	2/103	1/51	0.99 (0.09; 10.67)	2.11	0.000 (-0.05; 0.05)	4.22
Tolterodine	Treatment discontinuation due to adverse effects	Chapple, 2004[54]	5/266	10/267	0.50 (0.17; 1.45)	7.33	-0.019 (-0.05; 0.01)	8.98
Tolterodine	Treatment discontinuation due to adverse effects	Khullar, 2004[329]	26/569	16/285	0.81 (0.44; 1.49)	12.51	-0.010 (-0.04; 0.02)	7.58
Tolterodine	Treatment discontinuation due to adverse effects	DuBeau, 2005[284]	26/569	16/285	0.81 (0.44; 1.49)	12.51	-0.010 (-0.04; 0.02)	7.58
Tolterodine	Treatment discontinuation due to adverse effects	Chapple, 2007[259]	9/290	6/285	1.47 (0.53; 4.09)	7.68	0.010 (-0.02; 0.04)	9.86
Tolterodine	Treatment discontinuation due to adverse effects	Herschorn, 2008[305]	12/410	2/207	3.03 (0.68; 13.41)	4.59	0.020 (0.00; 0.04)	12.46

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Tolterodine	Treatment discontinuation due to adverse effects	Herschorn, 2010[475]	28/684	6/334	2.28 (0.95; 5.45)	9.15	0.023 (0.00; 0.04)	12.76
Tolterodine	Treatment discontinuation due to adverse effects	Kaplan, 2010[322]	29/974	10/480	1.43 (0.70; 2.91)	11.09	0.009 (-0.01; 0.03)	15.38
Tolterodine	Treatment discontinuation due to adverse effects	NCT00444925,[58]	28/690	6/337	2.28 (0.95; 5.45)	9.15	0.023 (0.00; 0.04)	12.87
Tolterodine	Treatment discontinuation due to adverse effects	Rentzhog, 1998[362]	2/67	3/13	0.13 (0.02; 0.70)	3.77	-0.201 (-0.43; 0.03)	0.2
	Pooled				1.12 (0.78; 1.62)	100	0.008 (0.00; 0.02)	100
	P value/I squared				0.048	42.20%	0.114	32.70%
Tolterodine	Treatment discontinuation due to failure	Khullar, 2004[329]	3/569	2/285	0.75 (0.13; 4.47)	12.83	-0.002 (-0.01; 0.01)	29.08
Tolterodine	Treatment discontinuation due to failure	Herschorn, 2008[305]	3/410	9/207	0.17 (0.05; 0.62)	23.29	-0.036 (-0.07; -0.01)	7.68
Tolterodine	Treatment discontinuation due to failure	Herschorn, 2010[475]	5/684	5/334	0.49 (0.14; 1.68)	25.51	-0.008 (-0.02; 0.01)	22.07
Tolterodine	Treatment discontinuation due to failure	NCT00444925,[58]	5/690	5/337	0.49 (0.14; 1.68)	25.5	-0.008 (-0.02; 0.01)	22.32
Tolterodine	Treatment discontinuation due to failure	Chapple, 2004[54]	3/266	2/267	1.51 (0.25; 8.94)	12.87	0.004 (-0.01; 0.02)	18.84
	Pooled				0.47 (0.24; 0.90)	100	-0.006 (-0.02; 0.00)	100
	P value/I squared				0.364	7.50%	0.191	34.60%
Tolterodine	Dizziness	Van Kerrebroeck, 2001[394]	9/514	5/508	1.78 (0.60; 5.27)	15.05	0.008 (-0.01; 0.02)	17.93
Tolterodine	Dizziness	Van Kerrebroeck, 2001[394]	11/507	5/508	2.20 (0.77; 6.30)	16.08	0.012 (0.00; 0.03)	15.47

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Tolterodine	Dizziness	Malone-Lee, 2001[346]	4/73	7/74	0.58 (0.18; 1.90)	12.7	-0.040 (-0.12; 0.05)	0.51
Tolterodine	Dizziness	Swift, 2003[382]	7/417	4/410	1.72 (0.51; 5.83)	11.98	0.007 (-0.01; 0.02)	14.95
Tolterodine	Dizziness	Khullar, 2004[329]	6/569	3/285	1.00 (0.25; 3.98)	9.44	0.000 (-0.02; 0.02)	17.2
Tolterodine	Dizziness	Chapple, 2007[259]	4/290	7/285	0.56 (0.17; 1.90)	12.05	-0.011 (-0.03; 0.01)	7.21
Tolterodine	Dizziness	Herschorn, 2008[305]	5/410	5/207	0.51 (0.15; 1.72)	11.84	-0.012 (-0.04; 0.01)	6.59
Tolterodine	Dizziness	NCT00444925,[58]	10/690	3/337	1.63 (0.45; 5.88)	10.86	0.006 (-0.01; 0.02)	20.14
	Pooled				1.12 (0.73; 1.72)	100	0.004 (0.00; 0.01)	100
	P value/I squared				0.412	2.30%	0.515	0.00%
Tolterodine	Continence	Rogers, 2008[367]	115/202	89/211	1.35 (1.11; 1.65)	22.57	0.148 (0.05; 0.24)	
Tolterodine	Continence	Malone-Lee, 2009[345]	41/165	26/142	1.36 (0.88; 2.10)	6.99	0.065 (-0.03; 0.16)	17.05
Tolterodine	Continence	Kaplan, 2010[322]	566/974	258/480	1.08 (0.98; 1.19)	39.93	0.044 (-0.01; 0.10)	18.14
Tolterodine	Continence	NCT00444925,[58]	358/690	138/337	1.27 (1.09; 1.47)	30.52	0.109 (0.05; 0.17)	35.49
	Pooled				1.21 (1.07; 1.37)	100	0.085 (0.04; 0.13)	29.32
	P value/I squared				0.11	50.20%	0.209	34.00%
Tolterodine	Dry mouth	Rentzhog, 1998[362]	2/21	2/13	0.62 (0.10; 3.87)	0.92	-0.059 (-0.29; 0.17)	1.27
Tolterodine	Dry mouth	Rentzhog, 1998[362]	2/16	2/13	0.81 (0.13; 5.01)	0.94	-0.029 (-0.28; 0.23)	1.08
Tolterodine	Dry mouth	Rentzhog, 1998[362]	5/14	2/13	2.32 (0.54; 9.95)	1.44	0.203 (-0.12; 0.52)	0.71
Tolterodine	Dry mouth	Abrams, 1998[226]	59/118	12/57	2.38 (1.39; 4.05)	8.18	0.289 (0.15; 0.43)	3.01
Tolterodine	Dry mouth	Van Kerrebroeck, 2001[394]	118/507	39/508	3.03 (2.16; 4.26)	14.42	0.156 (0.11; 0.20)	9.47
Tolterodine	Dry mouth	Jacquetin, 2001[316]	35/103	3/51	5.78 (1.87; 17.89)	2.31	0.281 (0.17; 0.39)	4.1
Tolterodine	Dry mouth	Chapple, 2004[265]	9/37	0/38	19.50 (1.18; 323.41)	0.4	0.243 (0.10; 0.39)	2.91
Tolterodine	Dry mouth	Chapple, 2007[259]	49/290	20/285	2.41 (1.47; 3.95)	9.15	0.099 (0.05; 0.15)	8.57
Tolterodine	Dry mouth	Rogers, 2008[367]	26/202	19/211	1.43 (0.82; 2.50)	7.64	0.039 (-0.02; 0.10)	7.8
Tolterodine	Dry mouth	Herschorn, 2008[305]	89/410	21/207	2.14 (1.37; 3.34)	10.52	0.116 (0.06; 0.17)	8.08
Tolterodine	Dry mouth	Malone-Lee, 2009[345]	20/165	0/142	35.32 (2.16; 578.77)	0.4	0.121 (0.07; 0.17)	8.71
Tolterodine	Dry mouth	Herschorn, 2010[475]	112/684	20/334	2.74 (1.73; 4.32)	10.15	0.104 (0.07; 0.14)	10.06
Tolterodine	Dry mouth	Junemann, 2000[320]	21/76	5/79	4.37 (1.74; 10.99)	3.34	0.213 (0.10; 0.33)	4

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Tolterodine	Dry mouth	Kaplan, 2010[322]	127/974	24/480	2.61 (1.71; 3.98)	11.26	0.080 (0.05; 0.11)	10.89
Tolterodine	Dry mouth	NCT00444925,[58]	112/690	20/337	2.74 (1.73; 4.32)	10.15	0.103 (0.07; 0.14)	10.09
Tolterodine	Dry mouth	Rentzhog, 1998[362]	9/16	2/13	3.66 (0.95; 14.05)	1.67	0.409 (0.10; 0.72)	0.74
Tolterodine	Dry mouth	Chapple, 2004[54]	49/266	13/267	3.78 (2.10; 6.81)	7.1	0.136 (0.08; 0.19)	8.48
	Pooled				2.63 (2.20; 3.15)	100	0.127 (0.10; 0.15)	100
	P value/I squared				0.203	21.50%	0	63.70%
Tolterodine	Dry skin	Van Kerrebroeck, 2001[394]	2/507	1/508	2.00 (0.18; 22.03)	49.99	0.002 (-0.01; 0.01)	59.94
Tolterodine	Dry skin	Swift, 2003[382]	2/417	1/410	1.97 (0.18; 21.60)	50.01	0.002 (-0.01; 0.01)	40.06
	Pooled				1.99 (0.37; 10.81)	100	0.002 (0.00; 0.01)	100
	P value/I squared				0.991	0.00%	0.944	0.00%
Tolterodine	Dyspepsia	Abrams, 1998[226]	11/118	3/57	1.77 (0.51; 6.10)	11.3	0.041 (-0.04; 0.12)	1.42
Tolterodine	Dyspepsia	Van Kerrebroeck, 2001[394]	16/514	7/508	2.26 (0.94; 5.45)	20.56	0.017 (0.00; 0.04)	15.6
Tolterodine	Dyspepsia	Van Kerrebroeck, 2001[394]	15/507	7/508	2.15 (0.88; 5.22)	20.21	0.016 (0.00; 0.03)	15.82
Tolterodine	Dyspepsia	Malone-Lee, 2001[346]	6/73	9/74	0.68 (0.25; 1.80)	17.07	-0.039 (-0.14; 0.06)	0.92
Tolterodine	Dyspepsia	Swift, 2003[382]	11/417	6/410	1.80 (0.67; 4.83)	16.94	0.012 (-0.01; 0.03)	14.51
Tolterodine	Dyspepsia	Khullar, 2004[329]	7/569	2/285	1.75 (0.37; 8.39)	7.31	0.005 (-0.01; 0.02)	21.17
Tolterodine	Dyspepsia	Malone-Lee, 2009[345]	12/165	0/142	21.54 (1.29; 360.53)	2.35	0.073 (0.03; 0.11)	4.61
Tolterodine	Dyspepsia	NCT00444925,[58]	8/690	1/337	3.91 (0.49; 31.11)	4.26	0.009 (0.00; 0.02)	25.95
	Pooled				1.81 (1.17; 2.79)	100	0.014 (0.00; 0.02)	100
	P value/I squared				0.355	9.70%	0.107	40.80%
Tolterodine	Failure	Kelleher, 2002[327]	35/507	66/508	0.53 (0.36; 0.79)	18.08	-0.061 (-0.10; -0.02)	14.83
Tolterodine	Failure	Freeman, 2003[290]	88/398	168/374	0.49 (0.40; 0.61)	23.2	-0.228 (-0.29; -0.16)	11.75
Tolterodine	Failure	Herschorn, 2008[305]	16/410	19/207	0.43 (0.22; 0.81)	11.71	-0.053 (-0.10; -0.01)	14.11
Tolterodine	Failure	Rogers, 2009[366]	16/202	12/211	1.39 (0.68; 2.87)	10.22	0.022 (-0.03; 0.07)	13.56
Tolterodine	Failure	Herschorn, 2010[475]	64/684	34/334	0.92 (0.62; 1.36)	17.96	-0.008 (-0.05; 0.03)	14.58
Tolterodine	Failure	NCT00444925,[58]	59/690	36/337	0.80 (0.54; 1.19)	18	-0.021 (-0.06; 0.02)	14.58
4.0	Failure	Rogers, 2008[367]	0/202	1/211	0.35 (0.01; 8.50)	0.83	-0.005 (-0.02; 0.01)	16.6
	Pooled				0.66 (0.50; 0.89)	100	-0.045 (-0.09; -0.01)	100
	P value/I squared				0.011	63.80%	0	

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Tolterodine	Fatigue	Van Kerrebroeck, 2001[394]	11/507	4/508	2.76 (0.88; 8.60)	40.48	0.014 (0.00; 0.03)	25.66
Tolterodine	Fatigue	Chapple, 2007[259]	10/290	1/285	9.83 (1.27; 76.27)	12.48	0.031 (0.01; 0.05)	14.89
Tolterodine	Fatigue	Herschorn, 2008[305]	11/410	4/207	1.39 (0.45; 4.31)	40.89	0.008 (-0.02; 0.03)	12.74
Tolterodine	Fatigue	NCT00444925,[58]	4/690	0/337	4.40 (0.24; 81.53)	6.15	0.006 (0.00; 0.01)	46.71
	Pooled				2.51 (1.22; 5.18)	100	0.012 (0.00; 0.02)	100
	P value/I squared				0.404	0.00%	0.174	39.60%
Tolterodine	Flatulence	Van Kerrebroeck, 2001[394]	10/507	9/508	1.11 (0.46; 2.72)	58.06	0.002 (-0.02; 0.02)	52.59
Tolterodine	Flatulence	Swift, 2003[382]	8/417	6/410	1.31 (0.46; 3.75)	41.94	0.005 (-0.01; 0.02)	47.41
	Pooled				1.19 (0.60; 2.35)	100	0.003 (-0.01; 0.02)	100
	P value/I squared				0.816	0.00%	0.837	0.00%
Tolterodine	General body disorders	Jonas, 1997[318]	6/99	4/44	0.67 (0.20; 2.25)	19.24	-0.030 (-0.13; 0.07)	59.49
Tolterodine	General body disorders	Drutz, 1999[283]	40/109	15/56	1.37 (0.83; 2.26)	80.76	0.099 (-0.05; 0.25)	40.51
	Pooled				1.19 (0.68; 2.08)	100	0.022 (-0.10; 0.15)	100
	P value/I squared				0.282	13.60%	0.15	51.70%
Tolterodine	Headache	Jonas, 1997[318]	3/99	1/44	1.33 (0.14; 12.46)	0.9	0.008 (-0.05; 0.06)	2.21
Tolterodine	Headache	Malone-Lee, 2001[346]	5/61	2/74	3.03 (0.61; 15.09)	1.74	0.055 (-0.02; 0.13)	1.14
Tolterodine	Headache	Jonas, 1997[318]	3/99	1/44	1.33 (0.14; 12.46)	0.9	0.008 (-0.05; 0.06)	2.21
Tolterodine	Headache	Van Kerrebroeck, 2001[394]	19/514	23/508	0.82 (0.45; 1.48)	12.65	-0.008 (-0.03; 0.02)	9.81
Tolterodine	Headache	Van Kerrebroeck, 2001[394]	32/507	23/508	1.39 (0.83; 2.35)	16.47	0.018 (-0.01; 0.05)	7.83
Tolterodine	Headache	Malone-Lee, 2001[346]	7/73	2/74	3.55 (0.76; 16.51)	1.89	0.069 (-0.01; 0.15)	1.17
Tolterodine	Headache	Jacquetin, 2001[316]	3/97	2/51	0.79 (0.14; 4.57)	1.45	-0.008 (-0.07; 0.06)	1.71
Tolterodine	Headache	Jacquetin, 2001[316]	3/103	2/51	0.74 (0.13; 4.31)	1.45	-0.010 (-0.07; 0.05)	1.76
Tolterodine	Headache	Swift, 2003[382]	29/417	19/410	1.50 (0.86; 2.63)	14.17	0.023 (-0.01; 0.06)	6.22
Tolterodine	Headache	Chapple, 2004[265]	0/37	1/38	0.34 (0.01; 8.14)	0.45	-0.026 (-0.10; 0.04)	1.39
Tolterodine	Headache	Khullar, 2004[329]	22/569	8/285	1.38 (0.62; 3.06)	7.06	0.011 (-0.01; 0.04)	9.47
Tolterodine	Headache	DuBeau, 2005[284]	17/569	7/285	1.22 (0.51; 2.90)	5.94	0.005 (-0.02; 0.03)	10.93
Tolterodine	Headache	Chapple, 2007[259]	14/290	14/285	0.98 (0.48; 2.02)	8.58	-0.001 (-0.04; 0.03)	5.18
Tolterodine	Headache	Rogers, 2008[367]	7/202	6/211	1.22 (0.42; 3.56)	3.89	0.006 (-0.03; 0.04)	5.58

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Tolterodine	Headache	Herschorn, 2008[305]	21/410	9/207	1.18 (0.55; 2.53)	7.7	0.008 (-0.03; 0.04)	5.22
Tolterodine	Headache	Malone-Lee, 2009[345]	13/165	0/142	23.26 (1.40; 387.80)	0.57	0.079 (0.04; 0.12)	3.63
Tolterodine	Headache	Herschorn, 2010[475]	23/684	8/334	1.40 (0.64; 3.11)	7.11	0.010 (-0.01; 0.03)	12.19
Tolterodine	Headache	NCT00444925,[58]	23/690	8/337	1.40 (0.64; 3.11)	7.11	0.010 (-0.01; 0.03)	12.36
	Pooled				1.27 (1.03; 1.57)	100	0.011 (0.00; 0.02)	100
	P value/I squared				0.828	0.00%	0.828	10.40%
Tolterodine	Improvement in UI	Kelleher, 2002[327]	294/507	218/508	1.35 (1.19; 1.53)	15.54	0.151 (0.09; 0.21)	12.9
Tolterodine	Improvement in UI	Freeman, 2003[290]	171/398	90/374	1.79 (1.44; 2.21)	12.12	0.189 (0.12; 0.25)	12.59
Tolterodine	Improvement in UI	Herschorn, 2008[305]	156/410	64/207	1.23 (0.97; 1.56)	11.17	0.071 (-0.01; 0.15)	11.6
Tolterodine	Improvement in UI	Sand, 2009[372]	140/227	167/430	1.59 (1.36; 1.86)	14.31	0.228 (0.15; 0.31)	11.62
Tolterodine	Improvement in UI	Rogers, 2009[366]	79/202	58/211	1.42 (1.08; 1.88)	9.77	0.116 (0.03; 0.21)	10.73
Tolterodine	Improvement in UI	Herschorn, 2010[475]	256/684	113/334	1.11 (0.93; 1.32)	13.45	0.036 (-0.03; 0.10)	12.79
Tolterodine	Improvement in UI	Kaplan, 2010[322]	654/974	287/480	1.12 (1.03; 1.22)	16.86	0.074 (0.02; 0.13)	13.46
Tolterodine	Improvement in UI	NCT00444925,[58]	79/690	32/337	1.21 (0.82; 1.78)	6.77	0.020 (-0.02; 0.06)	14.31
	Pooled				1.33 (1.17; 1.51)	100	0.108 (0.06; 0.16)	100
	P value/I squared				0	76.40%	0	82.90%
Tolterodine	Insomnia	Van Kerrebroeck, 2001[394]	7/507	9/508	0.78 (0.29; 2.08)	45.27	-0.004 (-0.02; 0.01)	38.98
Tolterodine	Insomnia	Swift, 2003[382]	7/417	9/410	0.77 (0.29; 2.03)	45.35	-0.005 (-0.02; 0.01)	33.55
Tolterodine	Insomnia	Rogers, 2008[367]	5/202	0/211	11.49 (0.64; 206.42)	9.38	0.025 (0.00; 0.05)	27.47
	Pooled				0.99 (0.39; 2.53)	100	0.004 (-0.01; 0.02)	100
	P value/I squared				0.204	37.00%	0.091	58.30%
Tolterodine	Nasopharyngitis	Chapple, 2007[259]	10/290	7/285	1.40 (0.54; 3.64)	15.42	0.010 (-0.02; 0.04)	15.71
Tolterodine	Nasopharyngitis	Chapple, 2008[260]	10/290	7/283	1.39 (0.54; 3.61)	15.42	0.010 (-0.02; 0.04)	15.62
Tolterodine	Nasopharyngitis	Rogers, 2008[367]	9/202	10/211	0.94 (0.39; 2.27)	18.06	-0.003 (-0.04; 0.04)	7.36
Tolterodine	Nasopharyngitis	Herschorn, 2008[305]	9/410	5/207	0.91 (0.31; 2.68)	11.97	-0.002 (-0.03; 0.02)	18.8
Tolterodine	Nasopharyngitis	Sand, 2009[372]	8/227	12/430	1.26 (0.52; 3.05)	18.04	0.007 (-0.02; 0.04)	14.68
Tolterodine	Nasopharyngitis	NCT00444925,[58]	13/690	10/337	0.64 (0.28; 1.43)	21.09	-0.011 (-0.03; 0.01)	27.84
	Pooled				1.03 (0.71; 1.49)	100	0.001 (-0.01; 0.01)	100
	P value/I squared				0.784	0.00%	0.805	0.00%
Tolterodine	Nausea	Abrams, 1998[226]	4/118	6/57	0.32 (0.10; 1.10)	10.58	-0.071 (-0.16; 0.02)	0.79

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Tolterodine	Nausea	Van Kerrebroeck, 2001[394]	10/514	10/508	0.99 (0.42; 2.35)	21.07	0.000 (-0.02; 0.02)	16.43
Tolterodine	Nausea	Van Kerrebroeck, 2001[394]	7/507	10/508	0.70 (0.27; 1.83)	17.29	-0.006 (-0.02; 0.01)	18.45
Tolterodine	Nausea	Malone-Lee, 2001[346]	3/73	2/74	1.52 (0.26; 8.84)	5.13	0.014 (-0.05; 0.07)	1.68
Tolterodine	Nausea	Swift, 2003[382]	7/417	9/410	0.77 (0.29; 2.03)	16.59	-0.005 (-0.02; 0.01)	13.93
Tolterodine	Nausea	Khullar, 2004[329]	7/569	5/285	0.70 (0.23; 2.19)	12.24	-0.005 (-0.02; 0.01)	15.33
Tolterodine	Nausea	Chapple, 2007[259]	6/290	1/285	5.90 (0.71; 48.67)	3.56	0.017 (0.00; 0.04)	15.28
Tolterodine	Nausea	NCT00444925,[58]	7/690	6/337	0.57 (0.19; 1.68)	13.54	-0.008 (-0.02; 0.01)	18.11
	Pooled				0.77 (0.52; 1.15)	100	-0.002 (-0.01; 0.01)	100
	P value/I squared				0.453	0.00%	0.311	15.10%
Tolterodine	Serious adverse effects	Millard, 1999[349]	5/129	1/64	2.48 (0.30; 20.79)	4.45	0.023 (-0.02; 0.07)	5.35
Tolterodine	Serious adverse effects	Van Kerrebroeck, 2001[394]	12/507	18/508	0.67 (0.33; 1.37)	38.84	-0.012 (-0.03; 0.01)	24.85
Tolterodine	Serious adverse effects	Malone-Lee, 2001[346]	2/61	1/74	2.43 (0.23; 26.12)	3.57	0.019 (-0.03; 0.07)	4.05
Tolterodine	Serious adverse effects	Drutz, 1999[283]	1/109	2/56	0.26 (0.02; 2.77)	3.56	-0.027 (-0.08; 0.03)	4.06
Tolterodine	Serious adverse effects	Van Kerrebroeck, 2001[394]	7/507	18/508	0.39 (0.16; 0.93)	26.95	-0.022 (-0.04; 0.00)	29.72
Tolterodine	Serious adverse effects	NCT00444925,[58]	9/690	8/337	0.55 (0.21; 1.41)	22.62	-0.011 (-0.03; 0.01)	31.97
	Pooled				0.59 (0.38; 0.93)	100	-0.012 (-0.02; 0.00)	100
	P value/I squared				0.466	0.00%	0.411	0.70%
Tolterodine	Somnolence	Van Kerrebroeck, 2001[394]	14/507	9/508	1.56 (0.68; 3.57)	49.83	0.010 (-0.01; 0.03)	25.93
Tolterodine	Somnolence	Swift, 2003[382]	12/417	8/410	1.48 (0.61; 3.57)	43.97	0.009 (-0.01; 0.03)	21.15
Tolterodine	Somnolence	Khullar, 2004[329]	1/569	2/285	0.25 (0.02; 2.75)	6.2	-0.005 (-0.02; 0.01)	52.91
	Pooled				1.36 (0.75; 2.47)	100	0.002 (-0.01; 0.01)	100
	P value/I squared				0.359	2.50%	0.237	30.60%
Tolterodine	urinary tract infection	Jonas, 1997[318]	2/99	2/44	0.44 (0.07; 3.05)	4.15	-0.025 (-0.09; 0.04)	1.39
Tolterodine	Urinary tract infection	Van Kerrebroeck, 2001[394]	13/514	20/508	0.64 (0.32; 1.28)	21.36	-0.014 (-0.04; 0.01)	10.45
Tolterodine	Urinary tract infection	Van Kerrebroeck, 2001[394]	16/507	20/508	0.80 (0.42; 1.53)	22.99	-0.008 (-0.03; 0.02)	9.71

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Tolterodine	Urinary tract infection	Swift, 2003[382]	15/417	19/410	0.78 (0.40; 1.51)	22.3	-0.010 (-0.04; 0.02)	7.35
Tolterodine	Urinary tract infection	Khullar, 2004[329]	2/569	2/285	0.50 (0.07; 3.54)	4.05	-0.004 (-0.01; 0.01)	23.99
Tolterodine	Urinary tract infection	Rogers, 2008[367]	12/202	5/211	2.51 (0.90; 6.99)	12.28	0.036 (0.00; 0.07)	3.98
Tolterodine	Urinary tract infection	Herschorn, 2010[475]	10/684	2/334	2.44 (0.54; 11.08)	6.44	0.009 (0.00; 0.02)	21.48
Tolterodine	Urinary tract infection	NCT00444925,[58]	10/690	2/337	2.44 (0.54; 11.08)	6.44	0.009 (0.00; 0.02)	21.66
	Pooled				0.97 (0.64; 1.45)	100	0.001 (-0.01; 0.01)	100
	P value/I squared				0.234	24.50%	0.166	32.90%
Tolterodine	Xerophthalmia	Van Kerrebroeck, 2001[394]	17/507	10/508	1.70 (0.79; 3.68)	54.12	0.014 (-0.01; 0.03)	57.01
Tolterodine	Xerophthalmia	Swift, 2003[382]	16/417	8/410	1.97 (0.85; 4.54)	45.88	0.019 (0.00; 0.04)	42.99
	Pooled				1.82 (1.03; 3.21)	100	0.016 (0.00; 0.03)	100
	P value/I squared				0.805	0.00%	0.745	0.00%
Trospium	Abdominal distension	Sand, 2009[374]	6/484	2/505	3.13 (0.64; 15.43)	66.69	0.008 (0.00; 0.02)	57.23
Trospium	Abdominal distention	Staskin, 2007[47]	3/298	1/303	3.05 (0.32; 29.16)	33.31	0.007 (-0.01; 0.02)	42.77
	Pooled				3.10 (0.84; 11.42)	100	0.008 (0.00; 0.02)	100
	P value/I squared				0.985	0.00%	0.849	0.00%
Trospium	Abdominal pain	Zinner, 2004[37]	8/262	3/261	2.66 (0.71; 9.90)	44.43	0.019 (-0.01; 0.04)	12.43
Trospium	Abdominal pain	Staskin, 2007[47]	3/298	2/303	1.53 (0.26; 9.06)	24.22	0.003 (-0.01; 0.02)	35.33
Trospium	Abdominal pain	Sand, 2009[374]	7/484	2/505	3.65 (0.76; 17.49)	31.35	0.011 (0.00; 0.02)	52.23
	Pooled				2.57 (1.07; 6.17)	100	0.009 (0.00; 0.02)	100
	P value/I squared				0.849	0.00%	0.533	0.00%
Trospium	Adverse effects	Rudy, 2006[369]	196/329	153/329	1.28 (1.11; 1.48)	29.01	0.131 (0.06; 0.21)	17.77
Trospium	Adverse effects	Junemann, 2000[320]	26/76	12/79	2.25 (1.23; 4.13)	6.29	0.190 (0.06; 0.32)	5.76
Trospium	Adverse effects	Staskin, 2007[47]	80/298	53/303	1.54 (1.13; 2.09)	16.44	0.094 (0.03; 0.16)	23.29
Trospium	Adverse effects	Dmochowski, 2008[48]	154/280	130/284	1.20 (1.02; 1.42)	27.34	0.092 (0.01; 0.17)	15.04
Trospium	Adverse effects	Sand, 2009[374]	138/484	83/505	1.74 (1.36; 2.21)	20.92	0.121 (0.07; 0.17)	38.15
	Pooled				1.43 (1.21; 1.69)	100	0.116 (0.08; 0.15)	100
	P value/I squared				0.042	59.70%	0.71	0.00%
Trospium	CNS disorders	Staskin, 2004[379]	19/327	17/326	1.11 (0.59; 2.11)	77.34	0.006 (-0.03; 0.04)	29.81

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Trospium	CNS disorders	Dmochowski, 2008[48]	5/280	6/284	0.85 (0.26; 2.74)	22.66	-0.003 (-0.03; 0.02)	70.19
	Pooled				1.05 (0.60; 1.83)	100	-0.001 (-0.02; 0.02)	100
	P value/I squared				0.685	0.00%	0.665	0.00%
Trospium	Constipation	Zinner, 2004[37]	25/262	10/261	2.49 (1.22; 5.08)	21.9	0.057 (0.02; 0.10)	13.43
Trospium	Constipation	Rudy, 2006[369]	36/329	19/329	1.90 (1.11; 3.23)	25.67	0.052 (0.01; 0.09)	13.69
Trospium	Constipation	Staskin, 2007[47]	28/298	4/303	7.12 (2.53; 20.04)	15.96	0.081 (0.05; 0.12)	19.23
Trospium	Constipation	Dmochowski, 2008[48]	21/280	5/284	4.26 (1.63; 11.14)	17.19	0.057 (0.02; 0.09)	20.47
Trospium	Constipation	Sand, 2009[374]	43/484	6/505	7.48 (3.21; 17.41)	19.28	0.077 (0.05; 0.10)	33.18
	Pooled				3.72 (2.09; 6.62)	100	0.068 (0.05; 0.08)	100
	P value/I squared				0.03	62.50%	0.716	0.00%
Trospium	Diarrhea	Zinner, 2004[37]	8/262	14/261	0.57 (0.24; 1.33)	53.1	-0.023 (-0.06; 0.01)	36.75
Trospium	Diarrhea	Rudy, 2006[369]	7/329	13/329	0.54 (0.22; 1.33)	46.9	-0.018 (-0.04; 0.01)	63.25
	Pooled				0.56 (0.30; 1.03)	100	-0.020 (-0.04; 0.00)	100
	P value/I squared				0.93	0.00%	0.825	0.00%
Trospium	Treatment discontinuation	U.S. Food and Drug Administration, 2007 [40]	37/280	36/284	1.04 (0.68; 1.60)	53.66	0.005 (-0.05; 0.06)	44.55
Trospium	Treatment discontinuation	U.S. Food and Drug Administration, 2007 [40]	35/298	30/303	1.19 (0.75; 1.88)	46.34	0.018 (-0.03; 0.07)	55.45
	Pooled				1.11 (0.81; 1.51)	100	0.013 (-0.02; 0.05)	100
	P value/I squared				0.687	0.00%	0.731	0.00%
Trospium	Treatment discontinuation due to adverse effects	Zinner, 2004[37]	23/262	15/261	1.53 (0.82; 2.86)	20.34	0.030 (-0.01; 0.08)	8.73
Trospium	Treatment discontinuation due to adverse effects	Rudy, 2006[369]	24/329	15/329	1.60 (0.86; 2.99)	20.39	0.027 (-0.01; 0.06)	13.26
Trospium	Treatment discontinuation due to adverse effects	Staskin, 2007[47]	12/298	11/303	1.11 (0.50; 2.47)	12.44	0.004 (-0.03; 0.04)	18.27

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Trospium	Treatment discontinuation due to adverse effects	Sand, 2009[374]	24/484	18/505	1.39 (0.77; 2.53)	22.37	0.014 (-0.01; 0.04)	27.08
Trospium	Treatment discontinuation due to adverse effects	U.S. Food and Drug Administration, 2007 [40]	18/280	8/284	2.28 (1.01; 5.16)	12.02	0.036 (0.00; 0.07)	14.39
Trospium	Treatment discontinuation due to adverse effects	U.S. Food and Drug Administration, 2007 [40]	12/298	11/303	1.11 (0.50; 2.47)	12.44	0.004 (-0.03; 0.04)	18.27
	Pooled				1.46 (1.10; 1.94)	100	0.017 (0.00; 0.03)	100
	P value/I squared				0.824	0.00%	0.657	0.00%
Trospium	Continence	Zinner, 2004[37]	55/262	29/261	1.89 (1.25; 2.86)	12.28	0.099 (0.04; 0.16)	23.9
Trospium	Continence	Staskin, 2007[47]	61/298	34/303	1.82 (1.24; 2.69)	14.12	0.092 (0.04; 0.15)	27.62
Trospium	Continence	Dmochowski, 2008[48]	95/280	58/284	1.66 (1.25; 2.20)	26.74	0.135 (0.06; 0.21)	17.61
Trospium	Continence	Sand, 2009[374]	163/484	103/505	1.65 (1.34; 2.04)	46.86	0.133 (0.08; 0.19)	30.87
	Pooled				1.71 (1.47; 1.97)	100	0.114 (0.08; 0.14)	100
	P value/I squared				0.925	0.00%	0.675	0.00%
Trospium	Dry eye	Staskin, 2007[47]	4/298	1/303	4.07 (0.46; 36.18)	47.1	0.010 (0.00; 0.03)	42.94
Trospium	Dry eye	Sand, 2009[374]	9/484	1/505	9.39 (1.19; 73.84)	52.9	0.017 (0.00; 0.03)	57.06
	Pooled				6.33 (1.41; 28.37)	100	0.014 (0.00; 0.02)	100
	P value/I squared				0.585	0.00%	0.51	0.00%
Trospium	Dry mouth	Zinner, 2004[37]	57/262	17/261	3.34 (2.00; 5.58)	22.05	0.152 (0.09; 0.21)	15.7
Trospium	Dry mouth	Rudy, 2006[369]	65/329	17/329	3.82 (2.29; 6.38)	22.24	0.146 (0.10; 0.20)	17.54
Trospium	Dry mouth	Junemann, 2000[320]	22/76	5/79	4.57 (1.83; 11.46)	6.9	0.226 (0.11; 0.34)	7.59
Trospium	Dry mouth	Staskin, 2007[47]	26/298	9/303	2.94 (1.40; 6.16)	10.6	0.058 (0.02; 0.10)	20.03
Trospium	Dry mouth	Dmochowski, 2008[48]	36/280	13/284	2.81 (1.52; 5.18)	15.52	0.083 (0.04; 0.13)	18.19
Trospium	Dry mouth	Sand, 2009[374]	55/484	19/505	3.02 (1.82; 5.01)	22.69	0.076 (0.04; 0.11)	20.95
	Pooled				3.30 (2.59; 4.20)	100	0.109 (0.07; 0.15)	100
	P value/I squared				0.937	0.00%	0.003	72.60%
Trospium	Dry skin	Staskin, 2007[47]	3/298	0/303	7.12 (0.37; 137.19)	34.42	0.010 (0.00; 0.02)	36.22
Trospium	Dry skin	Sand, 2009[374]	5/484	1/505	5.22 (0.61; 44.49)	65.58	0.008 (0.00; 0.02)	63.78
	Pooled				5.81 (1.02; 32.94)	100	0.009 (0.00; 0.02)	100
	P value/I squared				0.868	0.00%	0.836	0.00%

Appendix Table F47. Clinical outcomes after drugs vs. placebo (pooled with random effects models results from RCTs) (continued)

Drug	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Trospium	Dyspepsia	Staskin, 2007[47]	6/298	3/303	2.03 (0.51; 8.06)	45.54	0.010 (-0.01; 0.03)	29.31
Trospium	Dyspepsia	Sand, 2009[374]	6/484	4/505	1.57 (0.44; 5.51)	54.46	0.004 (-0.01; 0.02)	70.69
	Pooled				1.76 (0.70; 4.47)	100	0.006 (0.00; 0.02)	100
	P value/I squared				0.783	0.00%	0.626	0.00%
Trospium	Headache	Zinner, 2004[37]	17/262	12/261	1.41 (0.69; 2.90)	30.18	0.019 (-0.02; 0.06)	11.6
Trospium	Headache	Rudy, 2006[369]	18/329	15/329	1.20 (0.62; 2.34)	32.39	0.009 (-0.02; 0.04)	15.46
Trospium	Headache	Staskin, 2007[47]	3/298	8/303	0.38 (0.10; 1.42)	13.87	-0.016 (-0.04; 0.01)	31.94
Trospium	Headache	Sand, 2009[374]	7/484	14/505	0.52 (0.21; 1.28)	23.56	-0.013 (-0.03; 0.01)	41
	Pooled				0.88 (0.51; 1.55)	100	-0.007 (-0.02; 0.01)	100
	P value/I squared				0.159	42.20%	0.291	19.90%
Trospium	Improvement in UI	Staskin, 2004[379]	5/327	8/326	0.62 (0.21; 1.89)	21.8	-0.009 (-0.03; 0.01)	52.53
Trospium	Improvement in UI	Zinner, 2004[37]	186/262	141/261	1.31 (1.15; 1.51)	78.2	0.170 (0.09; 0.25)	47.47
	Pooled				1.12 (0.61; 2.04)	100	0.076 (-0.10; 0.25)	100
	P value/I squared				0.19	41.90%	0	94.20%
Trospium	Nausea	Staskin, 2007[47]	3/298	2/303	1.53 (0.26; 9.06)	56.36	0.003 (-0.01; 0.02)	37.72
Trospium	Nausea	Sand, 2009[374]	7/484	1/505	7.30 (0.90; 59.14)	43.64	0.012 (0.00; 0.02)	62.28
	Pooled				3.02 (0.66; 13.85)	100	0.009 (0.00; 0.02)	100
	P value/I squared				0.264	19.90%	0.338	0.00%
Trospium	Urinary tract infection	Rudy, 2006[369]	16/329	8/329	2.00 (0.87; 4.61)	54.52	0.024 (0.00; 0.05)	12.68
Trospium	Urinary tract infection	Staskin, 2007[47]	6/298	3/303	2.03 (0.51; 8.06)	20.05	0.010 (-0.01; 0.03)	27.38
Trospium	Urinary tract infection	Sand, 2009[374]	7/484	4/505	1.83 (0.54; 6.20)	25.44	0.007 (-0.01; 0.02)	59.94
	Pooled				1.96 (1.06; 3.63)	100	0.010 (0.00; 0.02)	100
	P value/I squared				0.991	0.00%	0.541	0.00%

Appendix Table F48. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported)

Diversity factor	Drug	Outcome	Contributing variable	Estimate	Coefficient	Standard error	P value
Study	Darifenacin	Constipation	Country	RR	-0.55	0.81	0.53
Study	Darifenacin	Constipation	Country	ARD	-0.01	0.04	0.71
Study	Darifenacin	Constipation	Intention to treat	RR	1.09	1.19	0.41
Study	Darifenacin	Constipation	Intention to treat	ARD	0.04	0.06	0.50
Treatment	Darifenacin	Constipation	Daily dose	RR	0.08	0.09	0.42
Treatment	Darifenacin	Constipation	Daily dose	ARD	0.00	0.00	0.43
Treatment	Darifenacin	Constipation	Weeks of treatment	RR	0.16	0.23	0.52
Treatment	Darifenacin	Constipation	Weeks of treatment	ARD	0.01	0.01	0.63
Women	Darifenacin	Constipation	% of women	RR	0.09	0.08	0.33
Women	Darifenacin	Constipation	% of women	ARD	0.00	0.00	0.47
Women	Darifenacin	Constipation	Daily UI	RR	2.19	2.37	0.41
Women	Darifenacin	Constipation	Daily UI	ARD	0.08	0.11	0.50
Women	Darifenacin	Constipation	Inclusion of minorities	RR	-2.19	2.37	0.41
Women	Darifenacin	Constipation	Inclusion of minorities	ARD	-0.08	0.11	0.50
Women	Darifenacin	Constipation	Inclusion of mixed UI	RR	-2.90	1.48	0.12
Women	Darifenacin	Constipation	Inclusion of mixed UI	ARD	-0.13	0.06	0.08
Women	Darifenacin	Constipation	Inclusion of prior failures	RR	1.20	0.83	0.22
Women	Darifenacin	Constipation	Inclusion of prior failures	ARD	0.04	0.04	0.41
Women	Darifenacin	Constipation	Inclusion of women with surgical risk factors for UI	RR	2.58	1.59	0.18
Women	Darifenacin	Constipation	Inclusion of women with surgical risk factors for UI	ARD	0.11	0.06	0.15
Women	Darifenacin	Constipation	Rate in placebo group	RR	-52.15	37.96	0.22
Women	Darifenacin	Constipation	Rate in placebo group	ARD	-1.62	1.86	0.42
Study	Darifenacin	Dry mouth	Adequate randomization	RR	1.59	1.32	0.28
Study	Darifenacin	Dry mouth	Adequate randomization	ARD	0.10	0.07	0.23
Study	Darifenacin	Dry mouth	Country	RR	0.33	1.26	0.81
Study	Darifenacin	Dry mouth	Country	ARD	0.00	0.07	0.96
Study	Darifenacin	Dry mouth	Intention to treat	RR	1.59	1.32	0.28
Study	Darifenacin	Dry mouth	Intention to treat	ARD	0.10	0.07	0.23
Treatment	Darifenacin	Dry mouth	Daily dose	RR	0.11	0.13	0.42
Treatment	Darifenacin	Dry mouth	Daily dose	ARD	0.01	0.01	0.24
Treatment	Darifenacin	Dry mouth	Weeks of treatment	RR	0.20	0.26	0.47
Treatment	Darifenacin	Dry mouth	Weeks of treatment	ARD	0.01	0.01	0.30
Women	Darifenacin	Dry mouth	% of women	RR	0.11	0.10	0.34
Women	Darifenacin	Dry mouth	% of women	ARD	0.01	0.01	0.24
Women	Darifenacin	Dry mouth	Daily UI	RR	3.19	2.63	0.28
Women	Darifenacin	Dry mouth	Daily UI	ARD	0.20	0.15	0.23

Appendix Table F48. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)

Diversity factor	Drug	Outcome	Contributing variable	Estimate	Coefficient	Standard error	P value
Women	Darifenacin	Dry mouth	Inclusion of minorities	RR	-3.19	2.63	0.28
Women	Darifenacin	Dry mouth	Inclusion of minorities	ARD	-0.20	0.15	0.23
Women	Darifenacin	Dry mouth	Inclusion of mixed UI*	RR	-4.70	1.73	0.04
Women	Darifenacin	Dry mouth	Inclusion of mixed UI*	ARD	-0.26	0.10	0.04
Women	Darifenacin	Dry mouth	Inclusion of prior failures	RR	1.06	1.27	0.44
Women	Darifenacin	Dry mouth	Inclusion of prior failures	ARD	0.09	0.07	0.26
Women	Darifenacin	Dry mouth	Inclusion of women with surgical risk factors for UI	RR	1.87	2.82	0.54
Women	Darifenacin	Dry mouth	Inclusion of women with surgical risk factors for UI	ARD	0.13	0.16	0.47
Women	Darifenacin	Dry mouth	Rate in placebo group	RR	-17.57	55.39	0.76
Women	Darifenacin	Dry mouth	Rate in placebo group	ARD	0.59	3.01	0.85
Study	Darifenacin	Dyspepsia	Adequate randomization	ARD	0.02	0.01	0.23
Study	Darifenacin	Dyspepsia	Intention to treat	ARD	0.02	0.01	0.23
Treatment	Darifenacin	Dyspepsia	Daily dose	ARD	0.00	0.00	0.87
Treatment	Darifenacin	Dyspepsia	Weeks of treatment	ARD	0.00	0.00	0.54
Women	Darifenacin	Dyspepsia	% of women	ARD	0.00	0.00	0.25
Women	Darifenacin	Dyspepsia	Daily UI	ARD	0.03	0.02	0.23
Women	Darifenacin	Dyspepsia	Inclusion of minorities	ARD	-0.03	0.02	0.23
Women	Darifenacin	Dyspepsia	Inclusion of mixed UI	ARD	-0.03	0.02	0.22
Women	Darifenacin	Dyspepsia	Inclusion of prior failures	ARD	0.02	0.01	0.23
Women	Darifenacin	Dyspepsia	Inclusion of women with surgical risk factors for UI	ARD	0.01	0.03	0.84
Women	Darifenacin	Dyspepsia	Rate in placebo group*	ARD	-3.54	1.30	0.04
Study	Darifenacin	Improvement in UI	Country	ARD	0.00	0.01	0.98
Study	Darifenacin	Improvement in UI	Intention to treat	ARD	-0.01	0.03	0.83
Treatment	Darifenacin	Improvement in UI	Daily dose	ARD	0.00	0.01	0.82
Women	Darifenacin	Improvement in UI	% of women	ARD	0.00	0.01	0.83
Women	Darifenacin	Improvement in UI	Inclusion of women with surgical risk factors for UI	ARD	-0.02	0.07	0.83
Treatment	Fesoterodine	Adverse effects	Daily dose	RR	0.05	0.07	0.54

Appendix Table F48. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)

Diversity factor	Drug	Outcome	Contributing variable	Estimate	Coefficient	Standard error	P value
Women	Fesoterodine	Adverse effects	% of women	RR	0.01	0.02	0.56
Women	Fesoterodine	Adverse effects	Inclusion of minorities	RR	-0.40	0.17	0.08
Women	Fesoterodine	Adverse effects	Inclusion of prior failures	RR	-0.40	0.17	0.08
Women	Fesoterodine	Adverse effects	Inclusion of women with surgical risk factors for UI	RR	0.40	0.17	0.08
Women	Fesoterodine	Adverse effects	Rate in placebo group*	RR	-1.81	0.42	0.01
Study	Fesoterodine	Adverse effects	Adequate randomization	RR	-0.20	0.08	0.08
Study	Fesoterodine	Adverse effects	Allocation concealment	RR	-0.20	0.08	0.08
Study	Fesoterodine	Adverse effects	Conflict of interest	RR	-0.01	0.26	0.97
Study	Fesoterodine	Adverse effects	Country	RR	0.27	0.20	0.26
Study	Fesoterodine	Adverse effects	Intention to treat	RR	0.40	0.17	0.08
Study	Fesoterodine	Adverse effects	Justification of sample size	RR	0.40	0.17	0.08
Study	Fesoterodine	Constipation	Adequate randomization	RR	-0.29	0.94	0.77
Study	Fesoterodine	Constipation	Adequate randomization	ARD	-0.01	0.02	0.51
Study	Fesoterodine	Constipation	Allocation concealment	RR	-0.60	1.01	0.57
Study	Fesoterodine	Constipation	Allocation concealment	ARD	-0.01	0.02	0.52
Study	Fesoterodine	Constipation	Conflict of interest	RR	-0.95	2.16	0.67
Study	Fesoterodine	Constipation	Conflict of interest	ARD	-0.02	0.04	0.61
Study	Fesoterodine	Constipation	Country	RR	0.73	1.17	0.54
Study	Fesoterodine	Constipation	Country	ARD	0.01	0.02	0.73
Study	Fesoterodine	Constipation	Intention to treat	RR	2.13	1.98	0.31
Study	Fesoterodine	Constipation	Intention to treat	ARD	0.06	0.04	0.14
Study	Fesoterodine	Constipation	Justification of sample size	RR	1.41	1.28	0.29
Study	Fesoterodine	Constipation	Justification of sample size	ARD	0.04	0.02	0.16
Treatment	Fesoterodine	Constipation	Daily dose	RR	-0.01	0.47	0.98
Treatment	Fesoterodine	Constipation	Daily dose	ARD	0.00	0.01	1.00
Women	Fesoterodine	Constipation	% of women	RR	-0.28	0.14	0.07
Women	Fesoterodine	Constipation	% of women*	ARD	-0.01	0.00	0.04
Women	Fesoterodine	Constipation	Inclusion of minorities	RR	-1.20	2.02	0.57
Women	Fesoterodine	Constipation	Inclusion of minorities	ARD	-.0275674 .0411983	-0.67	-0.12
Women	Fesoterodine	Constipation	Inclusion of mixed UI	RR	2.16	2.29	0.37
Women	Fesoterodine	Constipation	Inclusion of mixed UI	ARD	0.05	0.05	0.30

Appendix Table F48. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)

Diversity factor	Drug	Outcome	Contributing variable	Estimate	Coefficient	Standard error	P value
Women	Fesoterodine	Constipation	Inclusion of prior failures	RR	-0.88	2.07	0.68
Women	Fesoterodine	Constipation	Inclusion of prior failures	ARD	-0.03	0.04	0.48
Women	Fesoterodine	Constipation	Inclusion of women with surgical risk factors for UI	RR	0.83	2.07	0.70
Women	Fesoterodine	Constipation	Inclusion of women with surgical risk factors for UI	ARD	0.02	0.04	0.64
Women	Fesoterodine	Constipation	Rate in placebo group	RR	-73.31	75.60	0.36
Women	Fesoterodine	Constipation	Rate in placebo group	ARD	-0.49	1.62	0.77
Study	Fesoterodine	Discontinuation due to failure	Adequate randomization	ARD	0.01	0.01	0.33
Study	Fesoterodine	Discontinuation due to failure	Allocation concealment	ARD	0.00	0.01	1.00
Study	Fesoterodine	Discontinuation due to failure	Conflict of interest	ARD	0.00	0.02	1.00
Study	Fesoterodine	Discontinuation due to failure	Country	ARD	0.00	0.01	0.78
Study	Fesoterodine	Discontinuation due to failure	Justification of sample size	ARD	0.00	0.02	1.00
Women	Fesoterodine	Discontinuation due to failure	% of women	ARD	-0.01	0.00	0.20
Women	Fesoterodine	Discontinuation due to failure	Inclusion of minorities	ARD	0.00	0.02	1.00
Women	Fesoterodine	Discontinuation due to failure	Inclusion of prior failures	ARD	0.02	0.02	0.44
Women	Fesoterodine	Discontinuation due to failure	Inclusion of women with surgical risk factors for UI	ARD	0.02	0.02	0.41
Women	Fesoterodine	Discontinuation due to failure	Rate in placebo group	ARD	-1.36	0.44	0.09
Study	Fesoterodine	Dry eye	Adequate randomization	ARD	0.01	0.00	0.22
Study	Fesoterodine	Dry eye	Allocation concealment	ARD	0.01	0.01	0.18
Study	Fesoterodine	Dry eye	Conflict of interest	ARD	0.01	0.01	0.27
Study	Fesoterodine	Dry eye	Country	ARD	0.00	0.01	0.83
Study	Fesoterodine	Dry eye	Intention to treat	ARD	-0.02	0.01	0.17
Study	Fesoterodine	Dry eye	Justification of sample size	ARD	-0.01	0.01	0.29
Treatment	Fesoterodine	Dry eye	Daily dose	ARD	0.01	0.00	0.22
Women	Fesoterodine	Dry eye	% of women	ARD	0.00	0.00	0.35
Women	Fesoterodine	Dry eye	Inclusion of minorities	ARD	0.02	0.01	0.18
Women	Fesoterodine	Dry eye	Inclusion of prior failures	ARD	0.02	0.01	0.17
Women	Fesoterodine	Dry eye	Inclusion of women with surgical risk factors for UI	ARD	-0.02	0.01	0.18

Appendix Table F48. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)

Diversity factor	Drug	Outcome	Contributing variable	Estimate	Coefficient	Standard error	P value
Women	Fesoterodine	Dry eye	Rate in placebo group	ARD	-0.96	0.60	0.17
Study	Fesoterodine	Dry mouth	Adequate randomization	ARD	0.00	0.02	0.95
Study	Fesoterodine	Dry mouth	Allocation concealment	ARD	0.00	0.02	0.82
Study	Fesoterodine	Dry mouth	Conflict of interest	ARD	0.00	0.03	0.91
Study	Fesoterodine	Dry mouth	Country	ARD	0.00	0.02	0.95
Study	Fesoterodine	Dry mouth	Intention to treat	ARD	0.01	0.03	0.72
Study	Fesoterodine	Dry mouth	Justification of sample size	ARD	0.01	0.02	0.70
Treatment	Fesoterodine	Dry mouth	Daily dose	ARD	0.02	0.01	0.01
Women	Fesoterodine	Dry mouth	% of women	ARD	0.00	0.00	0.87
Women	Fesoterodine	Dry mouth	Inclusion of minorities	ARD	-0.01	0.03	0.82
Women	Fesoterodine	Dry mouth	Inclusion of mixed UI	ARD	0.01	0.04	0.89
Women	Fesoterodine	Dry mouth	Inclusion of prior failures	ARD	0.00	0.03	0.97
Women	Fesoterodine	Dry mouth	Inclusion of women with surgical risk factors for UI	ARD	0.02	0.03	0.65
Women	Fesoterodine	Dry mouth	Rate in placebo group	ARD	-0.91	1.33	0.51
Treatment	Oxybutynin	Adverse effects	Daily dose	RR	0.33	0.37	0.53
Treatment	Oxybutynin	Adverse effects	Daily dose	ARD	0.05	0.02	0.32
Treatment	Oxybutynin	Adverse effects	Weeks of treatment	RR	0.05	0.34	0.91
Treatment	Oxybutynin	Adverse effects	Weeks of treatment	ARD	-0.04	0.02	0.29
Women	Oxybutynin	Adverse effects	% of women	ARD	0.00	0.01	0.91
Women	Oxybutynin	Adverse effects	Daily UI	RR	0.40	2.76	0.91
Women	Oxybutynin	Adverse effects	Daily UI	ARD	-0.28	0.14	0.29
Women	Oxybutynin	Adverse effects	Inclusion of minorities	RR	-2.15	1.77	0.44
Women	Oxybutynin	Adverse effects	Inclusion of minorities	ARD	-0.24	0.18	0.41
Women	Oxybutynin	Adverse effects	Inclusion of mixed UI	RR	-1.08	0.89	0.44
Women	Oxybutynin	Adverse effects	Inclusion of mixed UI	ARD	-0.12	0.09	0.41
Women	Oxybutynin	Adverse effects	Rate in placebo group	RR	-2.58	7.43	0.79
Women	Oxybutynin	Adverse effects	Rate in placebo group	ARD	0.70	0.52	0.41
Study	Oxybutynin	Adverse effects	Country	RR	-1.28	0.56	0.26
Study	Oxybutynin	Adverse effects	Country	ARD	0.01	0.15	0.94

Appendix Table F48. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)

Diversity factor	Drug	Outcome	Contributing variable	Estimate	Coefficient	Standard error	P value
Study	Oxybutynin	Adverse effects	Justification of sample size	RR	0.20	1.38	0.91
Study	Oxybutynin	Adverse effects	Justification of sample size	ARD	-0.14	0.07	0.29
Study	Oxybutynin	Dry mouth	Adequate randomization	RR	-1.13	0.83	0.21
Study	Oxybutynin	Dry mouth	Adequate randomization	ARD	-0.06	0.06	0.38
Study	Oxybutynin	Dry mouth	Allocation concealment	RR	-0.81	1.35	0.57
Study	Oxybutynin	Dry mouth	Allocation concealment	ARD	0.10	0.10	0.33
Study	Oxybutynin	Dry mouth	Conflict of interest	RR	-0.16	2.81	0.96
Study	Oxybutynin	Dry mouth	Conflict of interest	ARD	-0.27	0.19	0.19
Study	Oxybutynin	Dry mouth	Country	RR	-0.56	0.96	0.58
Study	Oxybutynin	Dry mouth	Country	ARD	-0.03	0.07	0.67
Study	Oxybutynin	Dry mouth	Intention to treat	RR	1.15	1.03	0.30
Study	Oxybutynin	Dry mouth	Intention to treat	ARD	0.07	0.08	0.37
Study	Oxybutynin	Dry mouth	Justification of sample size	RR	-1.48	1.27	0.28
Study	Oxybutynin	Dry mouth	Justification of sample size	ARD	-0.12	0.09	0.24
Treatment	Oxybutynin	Dry mouth	Daily dose	RR	0.12	0.20	0.56
Treatment	Oxybutynin	Dry mouth	Daily dose	ARD	0.02	0.01	0.21
Treatment	Oxybutynin	Dry mouth	Weeks of treatment	RR	0.29	0.29	0.34
Treatment	Oxybutynin	Dry mouth	Weeks of treatment	ARD	-0.01	0.02	0.67
Women	Oxybutynin	Dry mouth	% of women*	RR	-0.18	0.07	0.03
Women	Oxybutynin	Dry mouth	% of women	ARD	-0.01	0.01	0.39
Women	Oxybutynin	Dry mouth	Daily UI	RR	-0.90	2.24	0.70
Women	Oxybutynin	Dry mouth	Daily UI	ARD	-0.11	0.16	0.52
Women	Oxybutynin	Dry mouth	Inclusion of minorities	RR	-2.81	2.58	0.31
Women	Oxybutynin	Dry mouth	Inclusion of minorities*	ARD	-0.43	0.12	0.01
Women	Oxybutynin	Dry mouth	Inclusion of mixed UI*	RR	-2.53	0.86	0.02
Women	Oxybutynin	Dry mouth	Inclusion of mixed UI	ARD	-0.14	0.08	0.09
Women	Oxybutynin	Dry mouth	Inclusion of prior failures	RR	0.45	1.75	0.80
Women	Oxybutynin	Dry mouth	Inclusion of prior failures	ARD	-0.09	0.13	0.48
Women	Oxybutynin	Dry mouth	Inclusion of women with surgical risk factors for UI	RR	-1.26	2.73	0.66
Women	Oxybutynin	Dry mouth	Inclusion of women with surgical risk factors for UI	ARD	0.24	0.19	0.24
Women	Oxybutynin	Dry mouth	Rate in placebo group	RR	-6.22	3.73	0.13
Women	Oxybutynin	Dry mouth	Rate in placebo group	ARD	-0.08	0.32	0.81
Study	Oxybutynin	Dry skin	Allocation concealment	RR	5.34	0.52	0.06

Appendix Table F48. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)

Diversity factor	Drug	Outcome	Contributing variable	Estimate	Coefficient	Standard error	P value
Study	Oxybutynin	Dry skin	Allocation concealment	RR	0.16	0.04	0.17
Study	Oxybutynin	Dry skin	Intention to treat	RR	-2.09	4.67	0.73
Study	Oxybutynin	Dry skin	Intention to treat	RR	-0.06	0.17	0.78
Treatment	Oxybutynin	Dry skin	Daily dose	RR	0.73	0.12	0.10
Treatment	Oxybutynin	Dry skin	Daily dose	RR	0.03	0.01	0.17
Treatment	Oxybutynin	Dry skin	Weeks of treatment	RR	-0.87	0.80	0.47
Treatment	Oxybutynin	Dry skin	Weeks of treatment	RR	-0.03	0.03	0.52
Women	Oxybutynin	Dry skin	% of women	RR	0.22	0.30	0.60
Women	Oxybutynin	Dry skin	% of women	RR	0.01	0.01	0.64
Women	Oxybutynin	Dry skin	Daily UI	RR	-4.18	9.34	0.73
Women	Oxybutynin	Dry skin	Daily UI	RR	-0.12	0.33	0.78
Women	Oxybutynin	Dry skin	Inclusion of mixed UI	RR	4.81	3.48	0.40
Women	Oxybutynin	Dry skin	Inclusion of mixed UI	RR	0.15	0.13	0.45
Women	Oxybutynin	Dry skin	Inclusion of prior failures	RR	-4.18	9.34	0.73
Women	Oxybutynin	Dry skin	Inclusion of prior failures	RR	-0.12	0.33	0.78
Women	Oxybutynin	Dry skin	Rate in placebo group	RR	-9.94	14.78	0.62
Women	Oxybutynin	Dry skin	Rate in placebo group	RR	-0.40	0.53	0.59
Study	Oxybutynin	Failure	Adequate randomization	ARD	-0.04	0.04	0.41
Study	Oxybutynin	Failure	Allocation concealment	ARD	-0.03	0.06	0.70
Study	Oxybutynin	Failure	Country	ARD	0.02	0.06	0.76
Study	Oxybutynin	Failure	Intention to treat	ARD	0.10	0.04	0.06
Study	Oxybutynin	Failure	Justification of sample size	ARD	-0.02	0.06	0.72
Study	Oxybutynin	Failure	Mask1	ARD	0.22	0.15	0.24
Treatment	Oxybutynin	Failure	Daily dose	ARD	-0.01	0.02	0.81
Treatment	Oxybutynin	Failure	Weeks of treatment	ARD	0.01	0.02	0.63
Women	Oxybutynin	Failure	% of women	ARD	0.00	0.00	0.47
Women	Oxybutynin	Failure	Daily UI	ARD	0.13	0.07	0.19
Women	Oxybutynin	Failure	Inclusion of mixed UI	ARD	0.03	0.06	0.68
Women	Oxybutynin	Failure	Inclusion of prior failures	ARD	0.08	0.07	0.33
Women	Oxybutynin	Failure	Inclusion of women with surgical risk factors for UI	ARD	0.11	0.07	0.22
Women	Oxybutynin	Failure	Rate in placebo group	ARD	-0.37	0.12	0.05
Study	Oxybutynin	Improvement in UI	Adequate randomization	RR	0.48	0.53	0.38
Study	Oxybutynin	Improvement in UI	Adequate randomization	ARD	0.04	0.04	0.30
Study	Oxybutynin	Improvement in UI	Allocation concealment	RR	1.03	0.66	0.15
Study	Oxybutynin	Improvement in UI	Allocation concealment	ARD	0.02	0.05	0.68

Appendix Table F48. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)

Diversity factor	Drug	Outcome	Contributing variable	Estimate	Coefficient	Standard error	P value
Study	Oxybutynin	Improvement in UI	Conflict of interest	RR	-0.52	2.34	0.83
Study	Oxybutynin	Improvement in UI	Conflict of interest	ARD	0.10	0.18	0.59
Study	Oxybutynin	Improvement in UI	Country	RR	-0.48	0.59	0.44
Study	Oxybutynin	Improvement in UI	Country	ARD	-0.01	0.05	0.88
Study	Oxybutynin	Improvement in UI	Intention to treat	RR	-0.79	0.64	0.25
Study	Oxybutynin	Improvement in UI	Intention to treat	ARD	-0.03	0.05	0.54
Study	Oxybutynin	Improvement in UI	Justification of sample size	RR	0.53	0.71	0.47
Study	Oxybutynin	Improvement in UI	Justification of sample size	ARD	0.03	0.05	0.62
Study	Oxybutynin	Improvement in UI	Mask1	RR	-2.50	2.75	0.39
Study	Oxybutynin	Improvement in UI	Mask1	ARD	0.04	0.18	0.84
Treatment	Oxybutynin	Improvement in UI	Daily dose*	RR	-0.33	0.14	0.04
Treatment	Oxybutynin	Improvement in UI	Daily dose	ARD	-0.01	0.01	0.59
Treatment	Oxybutynin	Improvement in UI	Weeks of treatment	RR	-0.19	0.21	0.39
Treatment	Oxybutynin	Improvement in UI	Weeks of treatment	ARD	-0.02	0.01	0.14
Women	Oxybutynin	Improvement in UI	% of women	RR	0.06	0.05	0.22
Women	Oxybutynin	Improvement in UI	% of women	ARD	0.01	0.00	0.20
Women	Oxybutynin	Improvement in UI	Daily UI	RR	-0.21	1.34	0.88
Women	Oxybutynin	Improvement in UI	Daily UI	ARD	-0.01	0.10	0.95
Women	Oxybutynin	Improvement in UI	Inclusion of mixed UI	RR	0.43	0.75	0.58
Women	Oxybutynin	Improvement in UI	Inclusion of mixed UI	ARD	0.03	0.06	0.58
Women	Oxybutynin	Improvement in UI	Inclusion of prior failures	RR	-1.21	1.06	0.28
Women	Oxybutynin	Improvement in UI	Inclusion of prior failures	ARD	-0.06	0.08	0.45
Women	Oxybutynin	Improvement in UI	Inclusion of women with surgical risk factors for UI	RR	-0.98	1.14	0.41
Women	Oxybutynin	Improvement in UI	Inclusion of women with surgical risk factors for UI	ARD	-0.03	0.08	0.75
Women	Oxybutynin	Improvement in UI	Rate in placebo group*	RR	-7.06	2.63	0.02
Women	Oxybutynin	Improvement in UI	Rate in placebo group	ARD	-0.11	0.26	0.67

Appendix Table F48. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)

Diversity factor	Drug	Outcome	Contributing variable	Estimate	Coefficient	Standard error	P value
Study	Propiverine	Constipation	Adequate randomization	ARD	0.04	0.04	0.44
Study	Propiverine	Constipation	Allocation concealment	ARD	0.07	0.09	0.48
Study	Propiverine	Constipation	Conflict of interest	ARD	-0.02	0.10	0.86
Study	Propiverine	Constipation	Country	ARD	-0.01	0.04	0.82
Study	Propiverine	Constipation	Intention to treat	ARD	0.08	0.03	0.06
Study	Propiverine	Constipation	Justification of sample size	ARD	-0.06	0.04	0.19
Treatment	Propiverine	Constipation	Daily dose	ARD	0.00	0.00	0.34
Treatment	Propiverine	Constipation	Weeks of treatment	ARD	-0.01	0.01	0.31
Women	Propiverine	Constipation	% of women	ARD	0.00	0.01	0.52
Women	Propiverine	Constipation	Daily UI	ARD	-0.07	0.08	0.42
Women	Propiverine	Constipation	Inclusion of minorities	ARD	-0.08	0.09	0.44
Women	Propiverine	Constipation	Inclusion of mixed UI	ARD	0.03	0.06	0.71
Women	Propiverine	Constipation	Rate in placebo group	ARD	-1.13	2.72	0.71
Study	Propiverine	Dry mouth	Adequate randomization	ARD	0.01	0.06	0.88
Study	Propiverine	Dry mouth	Allocation concealment	ARD	0.13	0.04	0.06
Study	Propiverine	Dry mouth	Conflict of interest	ARD	0.05	0.11	0.71
Study	Propiverine	Dry mouth	Country	ARD	0.01	0.04	0.85
Study	Propiverine	Dry mouth	Intention to treat	ARD	0.06	0.05	0.29
Study	Propiverine	Dry mouth	Justification of sample size	ARD	-0.06	0.05	0.32
Treatment	Propiverine	Dry mouth	Daily dose	ARD	0.01	0.01	0.25
Treatment	Propiverine	Dry mouth	Weeks of treatment	ARD	-0.01	0.01	0.38
Women	Propiverine	Dry mouth	% of women	ARD	0.00	0.01	0.75
Women	Propiverine	Dry mouth	Daily UI	ARD	0.02	0.10	0.84
Women	Propiverine	Dry mouth	Inclusion of minorities	ARD	-0.02	0.12	0.88
Women	Propiverine	Dry mouth	Inclusion of mixed UI	ARD	0.02	0.07	0.76
Women	Propiverine	Dry mouth	Rate in placebo group	ARD	1.39	0.69	0.14
Treatment	Solifenacin	Adverse effects	Daily dose	RR	0.13	0.05	0.05
Treatment	Solifenacin	Adverse effects	Daily dose	ARD	0.02	0.01	0.07
Treatment	Solifenacin	Adverse effects	Weeks of treatment	RR	-0.08	0.08	0.34
Treatment	Solifenacin	Adverse effects	Weeks of treatment	ARD	0.00	0.01	0.88
Women	Solifenacin	Adverse effects	% of women	RR	-0.03	0.03	0.36
Women	Solifenacin	Adverse effects	% of women	ARD	0.00	0.00	0.91
Women	Solifenacin	Adverse effects	Daily UI	RR	0.18	0.74	0.82
Women	Solifenacin	Adverse effects	Daily UI	ARD	-0.04	0.09	0.69

Appendix Table F48. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)

Diversity factor	Drug	Outcome	Contributing variable	Estimate	Coefficient	Standard error	P value
Women	Solifenacin	Adverse effects	Inclusion of mixed UI	RR	0.09	0.37	0.82
Women	Solifenacin	Adverse effects	Inclusion of mixed UI	ARD	-0.02	0.05	0.69
Women	Solifenacin	Adverse effects	Inclusion of prior failures	RR	-0.89	0.82	0.33
Women	Solifenacin	Adverse effects	Inclusion of prior failures	ARD	-0.08	0.11	0.48
Women	Solifenacin	Adverse effects	Inclusion of women with surgical risk factors for UI	RR	0.89	0.82	0.33
Women	Solifenacin	Adverse effects	Inclusion of women with surgical risk factors for UI	ARD	0.08	0.11	0.48
Women	Solifenacin	Adverse effects	Rate in placebo group	RR	-2.39	1.90	0.26
Women	Solifenacin	Adverse effects	Rate in placebo group	ARD	-0.19	0.27	0.52
Study	Solifenacin	Adverse effects	Allocation concealment	RR	-0.44	0.41	0.33
Study	Solifenacin	Adverse effects	Allocation concealment	ARD	-0.04	0.05	0.48
Study	Solifenacin	Adverse effects	Conflict of interest	RR	0.18	0.50	0.73
Study	Solifenacin	Adverse effects	Conflict of interest	ARD	0.04	0.06	0.51
Study	Solifenacin	Adverse effects	Country	RR	0.66	0.62	0.34
Study	Solifenacin	Adverse effects	Country	ARD	0.01	0.09	0.88
Study	Solifenacin	Adverse effects	Intention to treat	RR	0.33	0.31	0.34
Study	Solifenacin	Adverse effects	Intention to treat	ARD	0.01	0.05	0.88
Study	Solifenacin	Blurred vision	Adequate randomization	ARD	-0.01	0.00	0.22
Study	Solifenacin	Blurred vision	Allocation concealment	ARD	0.01	0.00	0.27
Study	Solifenacin	Blurred vision	Conflict of interest	ARD	0.00	0.01	0.62
Study	Solifenacin	Blurred vision	Country	ARD	0.00	0.00	0.39
Study	Solifenacin	Blurred vision	Intention to treat	ARD	-0.01	0.01	0.16
Study	Solifenacin	Blurred vision	Justification of sample size*	ARD	-0.02	0.01	0.02
Treatment	Solifenacin	Blurred vision	Daily dose	ARD	0.00	0.00	0.11
Treatment	Solifenacin	Blurred vision	Weeks of treatment	ARD	0.00	0.00	0.35
Women	Solifenacin	Blurred vision	% of women	ARD	0.00	0.00	0.39
Women	Solifenacin	Blurred vision	Daily UI	ARD	0.00	0.01	0.99
Women	Solifenacin	Blurred vision	Inclusion of minorities	ARD	0.00	0.01	0.73
Women	Solifenacin	Blurred vision	Inclusion of mixed UI	ARD	0.00	0.01	0.98
Women	Solifenacin	Blurred vision	Inclusion of prior failures	ARD	0.01	0.01	0.56

Appendix Table F48. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)

Diversity factor	Drug	Outcome	Contributing variable	Estimate	Coefficient	Standard error	P value
Women	Solifenacin	Blurred vision	Inclusion of women with surgical risk factors for UI	ARD	0.01	0.01	0.59
Women	Solifenacin	Blurred vision	Rate in placebo group	ARD	0.25	0.44	0.58
Study	Solifenacin	Constipation	Adequate randomization	RR	0.29	1.08	0.79
Study	Solifenacin	Constipation	Adequate randomization	ARD	0.00	0.01	0.96
Study	Solifenacin	Constipation	Allocation concealment	RR	-0.52	1.05	0.63
Study	Solifenacin	Constipation	Allocation concealment	ARD	0.00	0.01	0.85
Study	Solifenacin	Constipation	Conflict of interest	RR	-1.23	1.17	0.32
Study	Solifenacin	Constipation	Conflict of interest	ARD	0.01	0.02	0.75
Study	Solifenacin	Constipation	Country	RR	0.50	0.58	0.41
Study	Solifenacin	Constipation	Country	ARD	-0.01	0.01	0.31
Study	Solifenacin	Constipation	Intention to treat	RR	1.34	0.81	0.12
Study	Solifenacin	Constipation	Intention to treat	ARD	-0.01	0.01	0.45
Study	Solifenacin	Constipation	Justification of sample size	RR	1.00	1.66	0.56
Study	Solifenacin	Constipation	Justification of sample size	ARD	0.00	0.02	0.97
Treatment	Solifenacin	Constipation	Daily dose*	RR	0.61	0.11	0.00
Treatment	Solifenacin	Constipation	Daily dose	ARD	0.01	0.00	0.00
Treatment	Solifenacin	Constipation	Weeks of treatment*	RR	-0.48	0.19	0.03
Treatment	Solifenacin	Constipation	Weeks of treatment	ARD	0.00	0.00	0.76
Women	Solifenacin	Constipation	% of women	RR	-0.15	0.07	0.06
Women	Solifenacin	Constipation	% of women	ARD	0.00	0.00	0.97
Women	Solifenacin	Constipation	Daily UI	RR	1.56	1.79	0.40
Women	Solifenacin	Constipation	Daily UI	ARD	0.01	0.03	0.75
Women	Solifenacin	Constipation	Inclusion of minorities	RR	0.70	1.54	0.66
Women	Solifenacin	Constipation	Inclusion of minorities	ARD	-0.02	0.02	0.33
Women	Solifenacin	Constipation	Inclusion of mixed UI	RR	1.24	0.96	0.22
Women	Solifenacin	Constipation	Inclusion of mixed UI	ARD	0.01	0.01	0.49
Women	Solifenacin	Constipation	Inclusion of prior failures	RR	-0.84	1.84	0.66
Women	Solifenacin	Constipation	Inclusion of prior failures	ARD	0.00	0.03	0.87
Women	Solifenacin	Constipation	Inclusion of women with surgical risk factors for UI	RR	0.14	2.96	0.96
Women	Solifenacin	Constipation	Inclusion of women with surgical risk factors for UI	ARD	0.01	0.04	0.77
Women	Solifenacin	Constipation	Rate in placebo group	RR	-49.51	23.42	0.06
Women	Solifenacin	Constipation	Rate in placebo group	ARD	0.05	0.44	0.92

Appendix Table F48. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)

Diversity factor	Drug	Outcome	Contributing variable	Estimate	Coefficient	Standard error	P value
Study	Solifenacin	Dry mouth	Adequate randomization	RR	1.60	2.90	0.59
Study	Solifenacin	Dry mouth	Adequate randomization	ARD	0.01	0.03	0.84
Study	Solifenacin	Dry mouth	Allocation concealment	RR	-2.17	3.62	0.56
Study	Solifenacin	Dry mouth	Allocation concealment	ARD	0.00	0.04	0.91
Study	Solifenacin	Dry mouth	Conflict of interest	RR	-7.07	3.68	0.08
Study	Solifenacin	Dry mouth	Conflict of interest	ARD	-0.01	0.05	0.88
Study	Solifenacin	Dry mouth	Country	RR	2.66	1.33	0.07
Study	Solifenacin	Dry mouth	Country	ARD	0.00	0.02	0.88
Study	Solifenacin	Dry mouth	Intention to treat*	RR	5.01	1.74	0.02
Study	Solifenacin	Dry mouth	Intention to treat	ARD	0.00	0.03	0.88
Study	Solifenacin	Dry mouth	Justification of sample size	RR	3.99	4.43	0.39
Study	Solifenacin	Dry mouth	Justification of sample size	ARD	0.01	0.05	0.82
Treatment	Solifenacin	Dry mouth	Daily dose*	RR	1.58	0.28	0.00
Treatment	Solifenacin	Dry mouth	Daily dose*	ARD	0.03	0.00	0.00
Treatment	Solifenacin	Dry mouth	Weeks of treatment*	RR	-1.45	0.38	0.00
Treatment	Solifenacin	Dry mouth	Weeks of treatment*	ARD	-0.01	0.01	0.33
Women	Solifenacin	Dry mouth	% of women	RR	-0.49	0.16	0.01
Women	Solifenacin	Dry mouth	% of women	ARD	0.00	0.00	0.56
Women	Solifenacin	Dry mouth	Daily UI	RR	4.64	4.83	0.36
Women	Solifenacin	Dry mouth	Daily UI	ARD	0.02	0.06	0.68
Women	Solifenacin	Dry mouth	Inclusion of minorities	RR	5.73	3.90	0.17
Women	Solifenacin	Dry mouth	Inclusion of minorities	ARD	0.01	0.05	0.89
Women	Solifenacin	Dry mouth	Inclusion of mixed UI	RR	3.09	2.68	0.27
Women	Solifenacin	Dry mouth	Inclusion of mixed UI	ARD	0.02	0.03	0.60
Women	Solifenacin	Dry mouth	Inclusion of prior failures	RR	-3.32	5.78	0.58
Women	Solifenacin	Dry mouth	Inclusion of prior failures	ARD	-0.01	0.07	0.93
Women	Solifenacin	Dry mouth	Rate in placebo group*	RR	-160.12	55.51	0.02
Women	Solifenacin	Dry mouth	Rate in placebo group	ARD	-0.07	0.91	0.94
Study	Tolterodine	Dry mouth	Adequate randomization	ARD	-0.01	0.02	0.46
Study	Tolterodine	Dry mouth	Allocation concealment	ARD	-0.02	0.03	0.50
Study	Tolterodine	Dry mouth	Conflict of interest	ARD	-0.06	0.04	0.14
Study	Tolterodine	Dry mouth	Country	ARD	0.00	0.02	0.90
Study	Tolterodine	Dry mouth	Intention to treat	ARD	0.04	0.02	0.07
Study	Tolterodine	Dry mouth	Justification of sample size	ARD	0.00	0.03	0.97
Treatment	Tolterodine	Dry mouth	Daily dose	ARD	0.01	0.01	0.52

Appendix Table F48. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)

Diversity factor	Drug	Outcome	Contributing variable	Estimate	Coefficient	Standard error	P value
Treatment	Tolterodine	Dry mouth	Weeks of treatment	ARD	-0.01	0.01	0.06
Women	Tolterodine	Dry mouth	% of women	ARD	0.00	0.00	0.14
Women	Tolterodine	Dry mouth	Daily UI	ARD	-0.05	0.05	0.31
Women	Tolterodine	Dry mouth	Inclusion of minorities	ARD	-0.04	0.04	0.36
Women	Tolterodine	Dry mouth	Inclusion of mixed UI	ARD	0.00	0.03	0.87
Women	Tolterodine	Dry mouth	Inclusion of prior failures	ARD	0.01	0.03	0.65
Women	Tolterodine	Dry mouth	Inclusion of women with surgical risk factors for UI	ARD	0.07	0.05	0.21
Women	Tolterodine	Dry mouth	Rate in placebo group	ARD	0.16	0.45	0.73
Study	Tolterodine	Failure	Adequate randomization	RR	0.08	0.08	0.39
Study	Tolterodine	Failure	Adequate randomization	ARD	0.05	0.02	0.07
Study	Tolterodine	Failure	Allocation concealment	RR	-0.03	0.13	0.81
Study	Tolterodine	Failure	Allocation concealment	ARD	-0.04	0.03	0.22
Study	Tolterodine	Failure	Conflict of interest	RR	-0.07	0.16	0.67
Study	Tolterodine	Failure	Conflict of interest	ARD	-0.06	0.04	0.21
Study	Tolterodine	Failure	Country	RR	-0.12	0.09	0.23
Study	Tolterodine	Failure	Country	ARD	-0.03	0.03	0.34
Study	Tolterodine	Failure	Intention to treat	RR	-0.11	0.17	0.55
Study	Tolterodine	Failure	Intention to treat	ARD	0.01	0.04	0.87
Study	Tolterodine	Failure	Justification of sample size	RR	0.10	0.18	0.61
Study	Tolterodine	Failure	Justification of sample size	ARD	0.03	0.05	0.58
Treatment	Tolterodine	Failure	Daily dose	RR	0.06	0.16	0.71
Treatment	Tolterodine	Failure	Daily dose	ARD	0.02	0.05	0.75
Women	Tolterodine	Failure	% of women	RR	0.03	0.02	0.21
Women	Tolterodine	Failure	% of women	ARD	0.00	0.00	0.46
Women	Tolterodine	Failure	Daily UI	RR	-0.15	0.29	0.63
Women	Tolterodine	Failure	Daily UI	ARD	-0.04	0.07	0.61
Women	Tolterodine	Failure	Inclusion of minorities	RR	0.06	0.27	0.83
Women	Tolterodine	Failure	Inclusion of minorities	ARD	-0.01	0.07	0.90
Women	Tolterodine	Failure	Inclusion of mixed UI	RR	0.28	0.19	0.21
Women	Tolterodine	Failure	Inclusion of mixed UI	ARD	0.08	0.06	0.26
Women	Tolterodine	Failure	Inclusion of prior failures	RR	-0.21	0.23	0.41
Women	Tolterodine	Failure	Inclusion of prior failures	ARD	-0.08	0.06	0.22
Women	Tolterodine	Failure	Rate in placebo group	RR	-0.86	0.49	0.14
Women	Tolterodine	Failure	Rate in placebo group	ARD	-0.51	0.09	0.00

Appendix Table F48. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)

Diversity factor	Drug	Outcome	Contributing variable	Estimate	Coefficient	Standard error	P value
Study	Tolterodine	Improvement in UI	Adequate randomization	RR	-0.05	0.08	0.54
Study	Tolterodine	Improvement in UI	Adequate randomization	ARD	0.00	0.02	0.92
Study	Tolterodine	Improvement in UI	Allocation concealment	RR	0.10	0.10	0.36
Study	Tolterodine	Improvement in UI	Allocation concealment	ARD	0.02	0.03	0.53
Study	Tolterodine	Improvement in UI	Conflict of interest	RR	0.23	0.11	0.08
Study	Tolterodine	Improvement in UI	Conflict of interest	ARD	0.05	0.04	0.24
Study	Tolterodine	Improvement in UI	Country	RR	0.06	0.09	0.54
Study	Tolterodine	Improvement in UI	Country	ARD	0.01	0.03	0.81
Study	Tolterodine	Improvement in UI	Intention to treat	RR	-0.17	0.10	0.12
Study	Tolterodine	Improvement in UI	Intention to treat	ARD	-0.04	0.03	0.28
Study	Tolterodine	Improvement in UI	Justification of sample size	RR	-0.17	0.09	0.11
Study	Tolterodine	Improvement in UI	Justification of sample size	ARD	-0.06	0.03	0.07
Treatment	Tolterodine	Improvement in UI	Daily dose	RR	-0.08	0.16	0.63
Treatment	Tolterodine	Improvement in UI	Daily dose	ARD	-0.05	0.03	0.18
Women	Tolterodine	Improvement in UI	% of women	RR	0.01	0.01	0.11
Women	Tolterodine	Improvement in UI	% of women	ARD	0.00	0.00	0.15
Women	Tolterodine	Improvement in UI	Daily UI	RR	-0.17	0.18	0.39
Women	Tolterodine	Improvement in UI	Daily UI	ARD	-0.09	0.05	0.10
Women	Tolterodine	Improvement in UI	Inclusion of minorities	RR	0.20	0.18	0.30
Women	Tolterodine	Improvement in UI	Inclusion of minorities	ARD	0.05	0.05	0.41
Women	Tolterodine	Improvement in UI	Inclusion of mixed UI*	RR	-0.45	0.11	0.01
Women	Tolterodine	Improvement in UI	Inclusion of mixed UI*	ARD	-0.13	0.04	0.02
Women	Tolterodine	Improvement in UI	Inclusion of prior failures	RR	-0.02	0.14	0.88
Women	Tolterodine	Improvement in UI	Inclusion of prior failures	ARD	-0.02	0.04	0.70
Women	Tolterodine	Improvement in UI	Inclusion of women with surgical risk factors for UI	RR	-0.27	0.25	0.31
Women	Tolterodine	Improvement in UI	Inclusion of women with surgical risk factors for UI	ARD	-.1372185 .0723651	-1.90	

Appendix Table F48. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)

Diversity factor	Drug	Outcome	Contributing variable	Estimate	Coefficient	Standard error	P value
Women	Tolterodine	Improvement in UI	Rate in placebo group	RR	-0.53	0.65	0.45
Women	Tolterodine	Improvement in UI	Rate in placebo group	ARD	0.10	0.20	0.62
Treatment	Trospium	Adverse effects	Daily dose	RR	-0.01	0.02	0.70
Treatment	Trospium	Adverse effects	Weeks of treatment	RR	-0.09	0.04	0.13
Women	Trospium	Adverse effects	% of women	RR	-0.01	0.02	0.72
Women	Trospium	Adverse effects	Daily UI	RR	-0.83	0.40	0.13
Women	Trospium	Adverse effects	Inclusion of minorities	RR	-0.83	0.40	0.13
Women	Trospium	Adverse effects	Inclusion of mixed UI	RR	0.10	0.22	0.68
Women	Trospium	Adverse effects	Inclusion of prior failures	RR	-0.10	0.41	0.82
Women	Trospium	Adverse effects	Rate in placebo group*	RR	-1.59	0.45	0.04
Study	Trospium	Adverse effects	Adequate randomization	RR	-0.42	0.20	0.13
Study	Trospium	Adverse effects	Allocation concealment	RR	-0.01	0.25	0.97
Study	Trospium	Adverse effects	Conflict of interest	RR	-0.41	0.34	0.31
Study	Trospium	Adverse effects	Country	RR	-0.27	0.10	0.07
Study	Trospium	Adverse effects	Intention to treat	RR	-0.22	0.24	0.43
Study	Trospium	Adverse effects	Justification of sample size	RR	0.02	0.26	0.93
Study	Trospium	Constipation	Allocation concealment	RR	1.55	1.41	0.35
Study	Trospium	Constipation	Conflict of interest	RR	-0.25	2.71	0.93
Study	Trospium	Constipation	Country	RR	-1.78	1.31	0.27
Study	Trospium	Constipation	Intention to treat	RR	0.47	3.32	0.90
Study	Trospium	Constipation	Justification of sample size	RR	0.55	1.46	0.73
Treatment	Trospium	Constipation	Daily dose	RR	0.21	0.07	0.05
Women	Trospium	Constipation	% of women	RR	0.21	0.10	0.12
Women	Trospium	Constipation	Inclusion of mixed UI	RR	-1.87	1.41	0.28
Women	Trospium	Constipation	Inclusion of prior failures	RR	0.47	3.32	0.90
Women	Trospium	Constipation	Rate in placebo group	RR	-114.78	33.25	0.04
Study	Trospium	Dry mouth	Adequate randomization	ARD	-0.06	0.04	0.15
Study	Trospium	Dry mouth	Allocation concealment	ARD	-0.03	0.03	0.29
Study	Trospium	Dry mouth	Conflict of interest	ARD	-0.03	0.05	0.62
Study	Trospium	Dry mouth	Country	ARD	-0.01	0.03	0.77
Study	Trospium	Dry mouth	Intention to treat	ARD	-0.04	0.04	0.36

Appendix Table F48. Exploring statistical heterogeneity by treatment, clinical, or study characteristics with meta-regression (restricted maximum likelihood estimate of between-study variance, constant values not reported) (continued)

Diversity factor	Drug	Outcome	Contributing variable	Estimate	Coefficient	Standard error	P value
Study	Trospium	Dry mouth	Justification of sample size	ARD	-0.01	0.03	0.80
Treatment	Trospium	Dry mouth	Daily dose*	ARD	0.00	0.00	0.02
Treatment	Trospium	Dry mouth	Weeks of treatment	ARD	-0.01	0.01	0.15
Women	Trospium	Dry mouth	% of women	ARD	0.00	0.00	0.12
Women	Trospium	Dry mouth	Daily UI	ARD	-0.13	0.07	0.15
Women	Trospium	Dry mouth	Inclusion of minorities	ARD	-0.13	0.07	0.15
Women	Trospium	Dry mouth	Inclusion of mixed UI	ARD	0.04	0.02	0.14
Women	Trospium	Dry mouth	Inclusion of prior failures	ARD	-0.03	0.06	0.66
Women	Trospium	Dry mouth	Rate in placebo group*	ARD	3.28	0.85	0.02

*Significant at 95% C; ARD-absolute risk difference; RR-relative risk

Appendix Table F49. Severity and quality of life after oxybutynin (individual RCTs)

Reference	Active	Dose	Active N	Control N	Active Mean+/- Standard Deviation	Control Mean+/- Standard Deviation	Mean Difference (95% CI)
Anxiety							
Burgio, 2001[241]	Oxybutynin	2.5 to 5mg thrice daily	52	46	44.5+/-12.3	45.8+/-12.9	-1.3 (-6.3; 3.7)
Depression							
Burgio, 2001[241]	Oxybutynin	2.5 to 5mg thrice daily	52	46	50.6+/-10.7	51.4+/-11.2	-0.8 (-5.2; 3.6)
Emotions							
Homma, 2006[309]	Oxytrol	Transdermal patch 39cm^2	164	161	24.9+/-21.6	35.2+/-28.4	-10.3 (-15.8; -4.8)
Homma, 2004[310]	Oxybutynin IR	3mg thrice daily	122	57	26.7+/-27.9	37.1+/-30.7	-10.4 (-19.8; -1.0)
Homma, 2006[309]	Oxytrol	Transdermal patch 26cm^2	160	161	28.2+/-25.8	35.2+/-28.4	-7.0 (-12.9; -1.1)
Homma, 2006[309]	Oxytrol	Transdermal patch 52cm^2	152	161	29.3+/-26.7	35.2+/-28.4	-5.9 (-12.0; 0.2)
Estimate of percent improvement							
Burgio, 1998[243]	Oxybutynin	2.5-5mg thrice daily	67	65	66.4+/-35.4	45.1+/-36.6	21.3 (9.0; 33.6)
General health							
Homma, 2006[309]	Oxytrol	Transdermal patch 39cm^2	164	161	30.9+/-22.2	33.0+/-22.7	-2.1 (-7.0; 2.8)
Homma, 2006[309]	Oxytrol	Transdermal patch 26cm^2	160	161	33.4+/-20.3	33.0+/-22.7	0.4 (-4.3; 5.1)
Homma, 2006[309]	Oxytrol	Transdermal patch 52cm^2	152	161	33.9+/-21.6	33.0+/-22.7	0.9 (-4.0; 5.8)
General health perception							
Homma, 2004[310]	Oxybutynin IR	3mg thrice daily	122	57	34.6+/-20.9	32.9+/-21.2	1.7 (-4.9; 8.3)
Global severity							
Burgio, 2001[241]	Oxybutynin	2.5 to 5mg thrice daily	52	46	50.4+/-10.0	51.4+/-10.9	-1.0 (-5.2; 3.2)
Hostility							
Burgio, 2001[241]	Oxybutynin	2.5 to 5mg thrice daily	52	46	44.6+/-10.5	47.3+/-11.2	-2.7 (-7.0; 1.6)
Incontinence impact							
Homma, 2006[309]	Oxytrol	Transdermal patch 39cm^2	164	161	32.7+/-23.6	39.7+/-26.0	-7.0 (-12.4; -1.6)
Homma, 2004[310]	oxybutynin-IR	3mg thrice daily	122	57	33.9+/-29.4	46.2+/-28.0	-12.3 (-21.2; -3.4)
Homma, 2006[309]	Oxytrol	transdermal patch 52cm^2	152	161	34.0+/-24.4	39.7+/-26.0	-5.7 (-11.3; -0.1)
Homma, 2006[309]	Oxytrol	Transdermal patch 26cm2	160	161	34.6+/-23.2	39.7+/-26.0	-5.1 (-10.5; 0.3)
Interpersonal sensitivity							
Burgio, 2001[241]	Oxybutynin	2.5 to 5mg thrice daily	52	46	48.9+/-11.2	49.2+/-11.3	-0.3 (-4.8; 4.2)
Mean total UDI score							
Dmochowski, 2002[276]	Oxybutynin TDS	3.9mg	125	132	78.8+/-51.9	94.7+/-50.0	-15.9 (-28.4; -3.4)
Obsessive-compulsive							
Burgio, 2001[241]	Oxybutynin	2.5 to 5mg thrice daily	52	46	53.9+/-10.9	55.4+/-11.0	-1.5 (-5.8; 2.8)
Paranoid ideation							
Burgio, 2001[241]	Oxybutynin	2.5 to 5mg thrice daily	52	46	47.2+/-11.6	47.2+/-12.0	0.0 (-4.7; 4.7)

Appendix Table F49. Severity and quality of life after oxybutynin (individual RCTs) (continued)

Reference	Active	Dose	Active N	Control N	Active Mean+/- Standard Deviation	Control Mean+/- Standard Deviation	Mean Difference (95% CI)
Personal relationship							
Homma, 2006[309]	Oxytrol	Transdermal patch 39cm^2	164	161	8.4+/-16.8	12.0+/-20.2	-3.6 (-7.6; 0.4)
Homma, 2006[309]	Oxytrol	Transdermal patch 26cm^2	160	161	10.4+/-17.3	12.0+/-20.2	-1.6 (-5.7; 2.5)
Homma, 2006[309]	Oxytrol	Transdermal patch 52cm^2	152	161	11.6+/-22.1	12.0+/-20.2	-0.4 (-5.1; 4.3)
Homma, 2004[310]	oxybutynin-IR	3mg thrice daily	122	57	3.5+/-9.6	10.3+/-19.8	-6.8 (-12.2; -1.4)
Phobia							
Burgio, 2001[241]	Oxybutynin	2.5 to 5mg thrice daily	52	46	45.0+/-8.3	45.1+/-8.5	-0.1 (-3.4; 3.2)
Physical limitation							
Homma, 2006[309]	Oxytrol	Transdermal patch 39cm^2	164	161	26.6+/-22.8	36.5+/-27.5	-9.9 (-15.4; -4.4)
Homma, 2006[309]	Oxytrol	Transdermal patch 26cm^2	160	161	29.7+/-25.6	36.5+/-27.5	-6.8 (-12.6; -1.0)
Homma, 2006[309]	Oxytrol	Transdermal patch 52cm^2	152	161	29.7+/-27.3	36.5+/-27.5	-6.8 (-12.9; -0.7)
Homma, 2004[310]	oxybutynin-IR	3mg thrice daily	122	57	20.6+/-24.4	35.7+/-29.3	-15.1 (-23.9; -6.3)
Psychoticism							
Burgio, 2001[241]	Oxybutynin	2.5 to 5mg thrice daily	52	46	50.4+/-9.7	49.6+/-10.3	0.8 (-3.2; 4.8)
Role limitation							
Homma, 2006[309]	Oxytrol	Transdermal patch 39cm^2	164	161	22.0+/-20.3	31.9+/-24.1	-9.9 (-14.7; -5.1)
Homma, 2006[309]	Oxytrol	Transdermal patch 26cm^2	160	161	24.8+/-22.0	31.9+/-24.1	-7.1 (-12.1; -2.1)
Homma, 2006[309]	Oxytrol	Transdermal patch 52cm^2	152	161	26.5+/-24.7	31.9+/-24.1	-5.4 (-10.8; 0.0)
Homma, 2004[310]	Oxybutynin IR	3mg thrice daily	122	57	18.6+/-21.0	28.7+/-26.9	-10.1 (-18.0; -2.2)
Severity (coping) measure							
Homma, 2004[310]	oxybutynin IR	3mg thrice daily	122	57	19.4+/-18.9	29.7+/-21.5	-10.3 (-16.8; -3.8)
Sleep and energy							
Homma, 2004[310]	oxybutynin IR	3mg thrice daily	122	57	17.2+/-21.4	29.2+/-29.4	-12.0 (-20.5; -3.5)
Homma, 2006[309]	Oxytrol	Transdermal patch 39cm^2	164	161	17.9+/-18.9	26.0+/-25.6	-8.1 (-13.0; -3.2)
Homma, 2006[309]	Oxytrol	Transdermal patch 26cm^2	160	161	18.2+/-19.2	26.0+/-25.6	-7.8 (-12.7; -2.9)
Homma, 2006[309]	Oxytrol	Transdermal patch 52cm^2	152	161	21.1+/-22.8	26.0+/-25.6	-4.9 (-10.3; 0.5)
Social limitation							
Homma, 2006[309]	Oxytrol	Transdermal patch 39cm^2	164	161	13.2+/-17.1	21.6+/-24.2	-8.4 (-13.0; -3.8)
Homma, 2006[309]	Oxytrol	Transdermal patch 26cm^2	160	161	16.3+/-21.3	21.6+/-24.2	-5.3 (-10.3; -0.3)
Homma, 2006[309]	Oxytrol	Transdermal patch 52cm^2	152	161	18.4+/-22.8	21.6+/-24.2	-3.2 (-8.4; 2.0)
Homma, 2004[310]	oxybutynin-IR	3mg thrice daily	122	57	14.0+/-22.1	21.0+/-26.3	-7.0 (-14.9; 0.9)
Summarization							
Burgio, 2001[241]	Oxybutynin	2.5 to 5mg thrice daily	52	46	51.2+/-9.8	49.8+/-13.0	1.4 (-3.2; 6.0)
Symptom severity							
Homma, 2004[310]	oxybutynin-IR	3mg thrice daily	122	57	16.4+/-13.6	26.6+/-16.4	-10.2 (-15.1; -5.3)

Appendix Table F50. Domains of quality of life after oxybutynin treatments (individual RCTs)

Reference	Active	Control	Active N	Control N	Active Mean+/- Standard Deviation	Control Mean+/- Standard Deviation	Mean Difference (95%CI)
Personal relationship							
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 39cm^2	Oxybutynin transdermal patch 52cm^2	164	152	8.4+/-16.8	11.6+/-22.1	-3.2 (-7.6; 1.2)
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 26cm^2	Oxybutynin transdermal patch 39cm^2	160	164	10.4+/-17.3	8.4+/-16.8	2.0 (-1.7; 5.7)
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 26cm^2	Oxybutynin transdermal patch 52cm^2	160	152	10.4+/-17.3	11.6+/-22.1	-1.2 (-5.6; 3.2)
Social limitation							
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 39cm^2	Oxybutynin transdermal patch 52cm^2	164	152	13.2+/-17.1	18.4+/-22.8	-5.2 (-9.7; -0.7)
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 26cm^2	Oxybutynin transdermal patch 39cm^2	160	164	16.3+/-21.3	13.2+/-17.1	3.1 (-1.1; 7.3)
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 26cm^2	Oxybutynin transdermal patch 52cm^2	160	152	16.3+/-21.3	18.4+/-22.8	-2.1 (-7.0; 2.8)
Sleep/energy							
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 39cm^2	Oxybutynin transdermal patch 52cm^2	164	152	17.9+/-18.9	21.1+/-22.8	-3.2 (-7.8; 1.4)
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 26cm^2	Oxybutynin transdermal patch 39cm^2	160	164	18.2+/-19.2	17.9+/-18.9	0.3 (-3.8; 4.4)
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 26cm^2	Oxybutynin transdermal patch 52cm^2	160	152	18.2+/-19.2	21.1+/-22.8	-2.9 (-7.6; 1.8)
Role limitation							
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 39cm^2	Oxybutynin transdermal patch 52cm^2	164	152	22.0+/-20.3	26.5+/-24.7	-4.5 (-9.5; 0.5)
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 26cm^2	Oxybutynin transdermal patch 39cm^2	160	164	24.8+/-22.0	22.0+/-20.3	2.8 (-1.8; 7.4)
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 26cm^2	Oxybutynin transdermal patch 52cm^2	160	152	24.8+/-22.0	26.5+/-24.7	-1.7 (-6.9; 3.5)
Emotions							
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 39cm^2	Oxybutynin transdermal patch 52cm^2	164	152	24.9+/-21.6	29.3+/-26.7	-4.4 (-9.8; 1.0)
Physical limitation							
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 39cm^2	Oxybutynin transdermal patch 52cm^2	164	152	26.6+/-22.8	29.7+/-27.3	-3.1 (-8.7; 2.5)

Appendix Table F50. Domains of quality of life after oxybutynin treatments (individual RCTs) (continued)

Reference	Active	Control	Active N	Control N	Active Mean+/- Standard Deviation	Control Mean+/- Standard Deviation	Mean Difference (95%CI)
Emotions							
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 26cm^2	Oxybutynin transdermal patch 39cm^2	160	164	28.2+/-25.8	24.9+/-21.6	3.3 (-1.9; 8.5)
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 26cm^2	Oxybutynin transdermal patch 52cm^2	160	152	28.2+/-25.8	29.3+/-26.7	-1.1 (-6.9; 4.7)
Physical limitation							
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 26cm^2	Oxybutynin transdermal patch 39cm^2	160	164	29.7+/-25.6	26.6+/-22.8	3.1 (-2.2; 8.4)
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 26cm^2	Oxybutynin transdermal patch 52cm^2	160	152	29.7+/-25.6	29.7+/-27.3	0.0 (-5.9; 5.9)
General health							
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 39cm^2	Oxybutynin transdermal patch 52cm^2	164	152	30.9+/-22.2	33.9+/-21.6	-3.0 (-7.8; 1.8)
Incontinence impact							
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 39cm^2	Oxybutynin transdermal patch 52cm^2	164	152	32.7+/-23.6	34.0+/-24.4	-1.3 (-6.6; 4.0)
General health							
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 26cm^2	Oxybutynin transdermal patch 39cm^2	160	164	33.4+/-20.3	30.9+/-22.2	2.5 (-2.1; 7.1)
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 26cm^2	Oxybutynin transdermal patch 52cm^2	160	152	33.4+/-20.3	33.9+/-21.6	-0.5 (-5.2; 4.2)
Incontinence impact							
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 26cm^2	Oxybutynin transdermal patch 39cm^2	160	164	34.6+/-23.2	32.7+/-23.6	1.9 (-3.2; 7.0)
Homma, 2006[309]	Oxytrol-Oxybutynin transdermal patch 26cm^2	Oxybutynin transdermal patch 52cm^2	160	152	34.6+/-23.2	34.0+/-24.4	0.6 (-4.7; 5.9)
Mean reduction in IIQ score							
Dmochowski, 2002[276]	Oxybutynin TDS, 2.6mg	Oxybutynin TDS3.9mg	133	125	-85.1+/-72.7	-64.2+/-82.9	-20.9 (-40.0; -1.8)

Appendix Table F51. Clinical outcomes after oxybutynin treatments (individual RCTs)

Reference	Active drug	Dose	Control drug	Dose	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Continence										
Davila, 2001[271]	Oxybutynin transdermal	1.3mg	Oxybutynin-immediate release	5mg twice/thrice daily or 7.5mg thrice daily	8/38	10/38	0.80 (0.35; 1.81)	-0.05 (-0.24; 0.14)		
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	4/53	7/52	0.56 (0.17; 1.80)	-0.06 (-0.18; 0.06)		
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	4/53	5/52	0.78 (0.22; 2.76)	-0.02 (-0.13; 0.09)		
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	2/53	3/52	0.65 (0.11; 3.76)	-0.02 (-0.10; 0.06)		
Adverse events										
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	22/53	21/52	1.03 (0.65; 1.63)	0.01 (-0.18; 0.20)		
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	22/53	21/52	1.03 (0.65; 1.63)	0.01 (-0.18; 0.20)		
Continence										
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	6/53	4/52	1.47 (0.44; 4.92)	0.04 (-0.08; 0.15)		
Efficacy										
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	10mg/day	22/77	26/77	0.85 (0.53; 1.36)	-0.05 (-0.20; 0.09)		
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	10mg/day	27/77	28/77	0.96 (0.63; 1.47)	-0.01 (-0.16; 0.14)		
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	10mg/day	71/77	61/77	1.16 (1.02; 1.33)	0.13 (0.02; 0.24)	8 (4; 47)	130 (21; 238)
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	15mg/day	22/77	42/83	0.56 (0.37; 0.85)	-0.22 (-0.37; -0.07)	-5 (-14; -3)	-220 (-368; -73)
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	15mg/day	27/77	43/83	0.68 (0.47; 0.98)	-0.17 (-0.32; -0.02)	-6 (-62; -3)	-167 (-319; -16)

Appendix Table F51. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)

Reference	Active drug	Dose	Control drug	Dose	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	15mg/day	71/77	68/83	1.13 (1.00; 1.27)	0.10 (0.00; 0.20)	10 (5; 1567)	103 (1; 205)
Corcos, 2006[270]	Oxybutynin-controlled release	10mg/day	Oxybutynin-controlled release	15mg/day	26/77	42/83	0.67 (0.46; 0.97)	-0.17 (-0.32; -0.02)	-6 (-57; -3)	-168 (-319; -18)
Corcos, 2006[270]	Oxybutynin-controlled release	10mg/day	Oxybutynin-controlled release	15mg/day	28/77	43/83	0.70 (0.49; 1.01	-0.15 (-0.31; 0.00)	-6 (-408; -3)	-154 (-306; -2)
Corcos, 2006[270]	Oxybutynin-controlled release	10mg/day	Oxybutynin-controlled release	15mg/day	61/77	68/83	0.97 (0.83; 1.13)	-0.03 (-0.15; 0.10)		
Adverse effects										
Davila, 2001[271]	Oxybutynin transdermal	1.3mg	Oxybutynin-immediate release	5mg twice/thrice daily or 7.5mg thrice daily	25/38	13/38	1.92 (1.17; 3.16)	0.32 (0.10; 0.53)	3 (2; 10)	316 (102; 529)
Gupta, 1999[296]	OROS oxybutynin chloride	5mg once daily	Immediate-release oxybutynin-Ditropan	5mg thrice daily	6/13	12/13	0.50 (0.27; 0.92)	-0.46 (-0.77; -0.15)	-2 (-6; -1)	-462 (-769; -154)
Undefined										
Salvatore, 2005[371]	Oxybutynin	2.5 twice daily	Oxybutynin	5mg nocte	3/27	4/39	1.08 (0.26; 4.46)	0.01 (-0.14; 0.16)		
Adverse effects										
Davila, 2001[271]	Oxybutynin transdermal	1.3mg	Oxybutynin-immediate release	5mg twice/thrice daily or 7.5mg thrice daily	14/38	2/38	7.00 (1.71; 28.72)	0.32 (0.15; 0.48)	3(2; 7)	316 (147; 485)
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	46/53	49/52	0.92 (0.81; 1.04)	-0.07 (-0.19; 0.04)		
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	46/53	49/52	0.92 (0.81; 1.04)	-0.07 (-0.19; 0.04)		

Appendix Table F51. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)

Reference	Active drug	Dose	Control drug	Dose	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Discontinuation										
Preik, 2004[392]	OROS-oxybutynin controlled release	5-30mg/day	immediate-release oxybutynin	5-20mg/day	5/53	5/52	0.98 (0.30; 3.19)	0.00 (-0.11; 0.11)		
Withdrawal										
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	10mg/day	3/77	11/77	0.27 (0.08; 0.94)	-0.10 (-0.19; -0.01)	-10 (-69; -5)	-104 (-193; -15)
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	10mg/day	4/77	4/77	1.00 (0.26; 3.86)	0.00 (-0.07; 0.07)		
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	15mg/day	3/77	12/83	0.27 (0.08; 0.92)	-0.11 -0.19; -0.02)	-9 (-54; -5)	-106 (-193; -18)
Corcos, 2006[270]	Oxybutynin-controlled release	10mg/day	Oxybutynin-controlled release	15mg/day	11/77	12/83	0.99 (0.46; 2.11)	0.00 (-0.11; 0.11)		
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	15mg/day	4/77	2/83	2.16 (0.41; 11.44)	0.03 (-0.03; 0.09)		
Corcos, 2006[270]	Oxybutynin-controlled release	10mg/day	Oxybutynin-controlled release	15mg/day	4/77	2/83	2.16 (0.41; 11.44)	0.03 (-0.03; 0.09)		
Blurred vision										
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	10mg/day	1/77	1/77	1.00 (0.06; 15.70)	0.00 (-0.04; 0.04)		
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	15mg/day	1/77	1/83	1.08 (0.07; 16.94)	0.00 (-0.03; 0.04)		
Corcos, 2006[270]	Oxybutynin-controlled release	10mg/day	Oxybutynin-controlled release	15mg/day	1/77	1/83	1.08 (0.07; 16.94)	0.00 (-0.03; 0.04)		

Appendix Table F51. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)

Reference	Active drug	Dose	Control drug	Dose	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Davila, 2001[271]	Oxybutynin transdermal	1.3mg	Oxybutynin-immediate release	5mg twice/thrice daily or 7.5mg thrice daily	7/38	9/38	0.78 (0.32; 1.87)	-0.05 (-0.24; 0.13)		
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	15/53	9/52	1.64 (0.79; 3.40)	0.11 (-0.05; 0.27)		
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	15/53	9/52	1.64 (0.79; 3.40)	0.11 (-0.05; 0.27)		
Treatment compliance										
Salvatore, 2005[371]	Oxybutynin	2.5 twice daily	Oxybutynin	5mg nocte	11/27	11/39	1.44 (0.73; 2.84)	0.13 (-0.11; 0.36)		
Constipation										
Dmochowski, 2002[276]	Oxybutynin TDS	1.3mg	Oxybutynin TDS	2.6mg	7/130	3/133	2.39 (0.63; 9.03)	0.03 (-0.01; 0.08)		
Dmochowski, 2002[276]	Oxybutynin TDS	1.3mg	Oxybutynin TDS	3.9mg	7/130	1/125	6.73 (0.84; 53.92)	0.05 (0.00; 0.09)	22 (11; 249)	46 (4; 88)
Dmochowski, 2002[276]	Oxybutynin TDS	2.6mg	Oxybutynin TDS	3.9mg	3/133	1/125	2.82 (0.30; 26.75)	0.01 (-0.02; 0.04)		
Dmochowski, 2002[276]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	10mg/day	4/77	3/77	1.33 (0.31; 5.76)	0.01 (-0.05; 0.08)		
Dmochowski, 2002[276]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	15mg/day	4/77	4/83	1.08 (0.28; 4.16)	0.00 (-0.06; 0.07)		
Dmochowski, 2002[276]	Oxybutynin-controlled release	10mg/day	Oxybutynin-controlled release	15mg/day	3/77	4/83	0.81 (0.19; 3.50	-0.01 (-0.07; 0.05		
Dmochowski, 2002[276]	Oxybutynin transdermal	1.3mg	Oxybutynin-immediate release	5mg twice/thrice daily or 7.5mg thrice daily	8/38	19/38	0.42 (0.21; 0.84)	-0.29 (-0.49; -0.08)	-3 (-12; -2)	-289 (-495; -84)
Dmochowski, 2002[276]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	16/53	16/52	0.98 (0.55; 1.75)	-0.01 (-0.18; 0.17)		
Constipation										
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	16/53	16/52	0.98 (0.55; 1.75)	-0.01 (-0.18; 0.17)		

Appendix Table F51. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)

Reference	Active drug	Dose	Control drug	Dose	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Dizziness										
Dmochowski, 2002[276]	Oxybutynin TDS	1.3mg	Oxybutynin TDS	3.9mg	2/130	5/125	0.38 (0.08; 1.95)	-0.02 (-0.06; 0.02)		
Dmochowski, 2002[276]	Oxybutynin TDS	2.6mg	Oxybutynin TDS	3.9mg	4/133	5/125	0.75 (0.21; 2.74)	-0.01 (-0.05; 0.04)		
Salvatore, 2005[371]	Oxybutynin	2.5 twice daily	Oxybutynin	5mg nocte	0/27	2/39	0.29 (0.01; 5.73)	-0.05 (-0.14; 0.04)		
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	10mg/day	5/77	6/77	0.83 (0.27; 2.62)	-0.01 (-0.09; 0.07)		
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	15mg/day	5/77	6/83	0.90 (0.29; 2.82)	-0.01 (-0.09; 0.07)		
Corcos, 2006[270]	Oxybutynin-controlled release	10mg/day	Oxybutynin-controlled release	15mg/day	6/77	6/83	1.08 (0.36; 3.20)	0.01 (-0.08; 0.09)		
Davila, 2001[271]	Oxybutynin transdermal	1.3mg	Oxybutynin-immediate release	5mg twice/thrice daily or 7.5mg thrice daily	6/38	10/38	0.60 (0.24; 1.49)	-0.11 (-0.29; 0.08)		
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	15/53	20/52	0.74 (0.42; 1.27)	-0.10 (-0.28; 0.08)		
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	15/53	20/52	0.74 (0.42; 1.27)	-0.10 (-0.28; 0.08)		
Maximum dosage reached										
Davila, 2001[271]	Oxybutynin transdermal	1.3mg	Oxybutynin-immediate release	5mg twice/thrice daily or 7.5mg thrice daily	26/38	12/38	2.17 (1.29; 3.63)	0.37 (0.16; 0.58)	3 (2; 6)	368 (159; 577)
Dry eyes										
Salvatore, 2005[371]	Oxybutynin	2.5 twice daily	Oxybutynin	5mg nocte	0/27	1/39	0.48 (0.02; 11.27)	-0.03 (-0.10; 0.05)		
Worse dry mouth on completion of treatment										
Davila, 2001[271]	Oxybutynin transdermal	1.3mg	Oxybutynin-immediate release	5mg twice/thrice daily or 7.5mg thrice daily	2/38	13/38	0.15 (0.04; 0.64)	-0.29 (-0.46; -0.12)	-3 (-8; -2)	-289 (-456; -123)

Appendix Table F51. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)

Reference	Active drug	Dose	Control drug	Dose	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Dry mouth										
Gupta, 1999[296]	OROS oxybutynin chloride	5mg once daily	Immediate-release oxybutynin-Ditropan	5mg thrice daily	6/13	10/13	0.60 (0.31; 1.16)	-0.31 (-0.66; 0.05)		
Salvatore, 2005[371]	Oxybutynin	2.5 twice daily	Oxybutynin	5mg nocte	1/27	4/39	0.36 (0.04; 3.06)	-0.07 (-0.18; 0.05)		
Moderate to severe dry mouth										
Versi, 2000[42]	CR-Oxybutynin	5mg/day	IR-Oxybutynin	5mg/day	4/111	8/115	0.52 (0.16; 1.67)	-0.03 (-0.09; 0.02)		
Dry mouth										
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	10mg/day	43/77	52/77	0.83 (0.64; 1.06)	-0.12 (-0.27; 0.04)		
Severe dry mouth										
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	10mg/day	2/77	11/77	0.18 (0.04; 0.79)	-0.12 (-0.20; -0.03)	-9 (-32; -5)	-117 (-203; -31)
Dry mouth										
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	15mg/day	43/77	58/83	0.80 (0.63; 1.02)	-0.14 (-0.29; 0.01)		
Severe dry mouth										
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	15mg/day	2/77	4/83	0.54 (0.10; 2.86)	-0.02 (-0.08; 0.04)		
Dry mouth										
Corcos, 2006[270]	Oxybutynin-controlled release	10mg/day	Oxybutynin-controlled release	15mg/day	52/77	58/83	0.97 (0.78; 1.19)	-0.02 (-0.17; 0.12)		
Severe dry mouth										
Corcos, 2006[270]	Oxybutynin-controlled release	10mg/day	Oxybutynin-controlled release	15mg/day	11/77	4/83	2.96 (0.99; 8.92)	0.09 (0.00; 0.19)	11 (5; 254)	95 (4; 185)

Appendix Table F51. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)

Reference	Active drug	Dose	Control drug	Dose	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Dry mouth of any severity										
Preik, 2004[392]	OROS-oxybutynin controlled release	5-30mg/day	immediate-release oxybutynin	5-20mg/day	31/53	41/52	0.74 (0.57; 0.97)	-0.20 (-0.38; -0.03)	-5 (-33; -3)	-204 (-377; -31)
Moderate or severe dry mouth										
Preik, 2004[392]	OROS-oxybutynin controlled release	5-30mg/day	immediate-release oxybutynin	5-20mg/day	12/53	22/52	0.53 (0.29; 0.95)	-0.20 (-0.38; -0.03)	-5 (-37; -3)	-201 (-375; -27)
Dose titration endpoint-MTD-dry mouth										
Preik, 2004[392]	OROS-oxybutynin controlled release	5-30mg/day	immediate-release oxybutynin	5-20mg/day	7/53	13/52	0.53 (0.23; 1.22)	-0.12 (-0.27; 0.03)		
Dose titration endpoint-MED-dry mouth										
Preik, 2004[392]	OROS-oxybutynin controlled release	5-30mg/day	immediate-release oxybutynin	5-20mg/day	3/53	7/52	0.42 (0.11; 1.54)	-0.08 (-0.19; 0.03)		
Moderate dry mouth										
Preik, 2004[392]	OROS-oxybutynin controlled release	5-30mg/day	immediate-release oxybutynin	5-20mg/day	1/53	4/52	0.25 (0.03; 2.12)	-0.06 (-0.14; 0.02)		
Dose titration endpoint-MAD-dry mouth										
Preik, 2004[392]	OROS-oxybutynin controlled release	5-30mg/day	immediate-release oxybutynin	5-20mg/day	1/53	1/52	0.98 (0.06; 15.28)	0.00 (-0.05; 0.05)		
Moderate to severe dry mouth										
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	3/53	11/52	0.27 (0.08; 0.90)	-0.15 (-0.28; -0.03)	-6 (-36; -4)	-155 (-282; -28)
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	5/53	10/52	0.49 (0.18; 1.34)	-0.10 (-0.23; 0.03)		
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	7/53	10/52	0.69 (0.28; 1.67)	-0.06 (-0.20; 0.08)		

Appendix Table F51. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)

Reference	Active drug	Dose	Control drug	Dose	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	2/53	4/52	0.49 (0.09; 2.56)	-0.04 (-0.13; 0.05)		
Dry mouth										
Davila, 2001[271]	Oxybutynin transdermal	1.3mg	Oxybutynin-immediate release	5mg twice/thrice daily or 7.5mg thrice daily	15/38	31/38	0.48 (0.32; 0.74)	-0.42 (-0.62; -0.22)	-2 (-4; -2)	-421 (-619; -223)
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	36/53	45/52	0.78 (0.63; 0.97)	-0.19 (-0.34; -0.03)	-5 (-33; -3)	-186 (-342; -30)
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	36/53	45/52	0.78 (0.63; 0.97)	-0.19 (-0.34; -0.03)	-5 (-33; -3)	-186 (-342; -30)
Moderate to severe dry mouth										
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	13/53	24/52	0.53 (0.30; 0.93)	-0.22 (-0.39; -0.04)	-5 (-26; -3)	-216 (-395; -38)
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	13/53	24/52	0.53 (0.30; 0.93)	-0.22 (-0.39; -0.04)	-5 (-26; -3)	-216 (-395; -38)
Dry nose										
Salvatore, 2005[371]	Oxybutynin	2.5 twice daily	Oxybutynin	5mg nocte	0/27	1/39	0.48 (0.02; 11.27)	-0.03 (-0.10; 0.05)		
Dry throat										
Salvatore, 2005[371]	Oxybutynin	2.5 twice daily	Oxybutynin	5mg nocte	2/27	0/39	7.14 (0.36; 143.14)	0.07 (-0.04; 0.19)		
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	10mg/day	21/77	32/77	0.66 (0.42; 1.03)	-0.14 (-0.29; 0.01)		
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	15mg/day	21/77	24/83	0.94 (0.57; 1.55)	-0.02 (-0.16; 0.12)		
Corcos, 2006[270]	Oxybutynin-controlled release	10mg/day	Oxybutynin-controlled release	15mg/day	32/77	24/83	1.44 (0.94; 2.21)	0.13 (-0.02; 0.27)		
Dyspepsia										
Chancellor, 2001[255]	ER-oxybutynin	10mg/day	IR-oxybutynin	5mg/day	0/36	1/36	0.33 (0.01; 7.92)	-0.03 (-0.10; 0.05)		

Appendix Table F51. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)

Reference	Active drug	Dose	Control drug	Dose	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Dysuria										
Dmochowski, 2002[276]	Oxybutynin TDS	1.3mg	Oxybutynin TDS	2.6mg	1/130	3/133	0.34 (0.04; 3.24)	-0.01 (-0.04; 0.01)		
Dmochowski, 2002[276]	Oxybutynin TDS	1.3mg	Oxybutynin TDS	3.9mg	1/130	3/125	0.32 (0.03; 3.04)	-0.02 (-0.05; 0.01)		
Dmochowski, 2002[276]	Oxybutynin TDS	2.6mg	Oxybutynin TDS	3.9mg	3/133	3/125	0.94 (0.19; 4.57)	0.00 (-0.04; 0.04)		
Erythema absent										
Dmochowski, 2002[276]	Oxybutynin TDS	1.3mg	Oxybutynin TDS	2.6mg	120/130	108/133	1.14 (1.03; 1.25)	0.11 (0.03; 0.19)	9 (5; 33)	111 (30; 192)
Erythema-mild										
Dmochowski, 2002[276]	Oxybutynin TDS	1.3mg	Oxybutynin TDS	2.6mg	79/130	92/133	0.88 (0.73; 1.05)	-0.08 (-0.20; 0.03)		
Erythema-moderate										
Dmochowski, 2002[276]	Oxybutynin TDS	1.3mg	Oxybutynin TDS	2.6mg	46/130	46/133	1.02 (0.74; 1.42)	0.01 (-0.11; 0.12)		
Erythema-severe										
Dmochowski, 2002[276]	Oxybutynin TDS	1.3mg	Oxybutynin TDS	2.6mg	6/130	8/133	0.77 (0.27; 2.15)	-0.01 (-0.07; 0.04)		
Halitosis										
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	10mg/day	6/77	10/77	0.60 (0.23; 1.57)	-0.05 (-0.15; 0.04)		
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	15mg/day	6/77	8/83	0.81 (0.29; 2.22)	-0.02 (-0.11; 0.07)		
Corcos, 2006[270]	Oxybutynin-controlled release	10mg/day	Oxybutynin-controlled release	15mg/day	10/77	8/83	1.35 (0.56; 3.24)	0.03 (-0.06; 0.13)		
Headache										
Salvatore, 2005[371]	Oxybutynin	2.5 twice daily	Oxybutynin	5mg nocte	0/27	1/39	0.48 (0.02; 11.27)	-0.03 (-0.10; 0.05)		
Salvatore, 2005[371]	Oxybutynin	2.5 twice daily	Oxybutynin	5mg nocte	0/27	1/39	0.48 (0.02; 11.27)	-0.03 (-0.10; 0.05)		
Chancellor, 2001[255]	ER-oxybutynin	10mg/day	IR-oxybutynin	5mg/day	6/36	6/36	1.00 (0.36; 2.81)	0.00 (-0.17; 0.17)		

Appendix Table F51. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)

Reference	Active drug	Dose	Control drug	Dose	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Impaired urination										
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	13/53	15/52	0.85 (0.45; 1.61)	-0.04 (-0.21; 0.13)		
Nausea										
Dmochowski, 2002[276]	Oxybutynin TDS	1.3mg	Oxybutynin TDS	2.6mg	6/130	5/133	1.23 (0.38; 3.92)	0.01 (-0.04; 0.06)		
Dmochowski, 2002[276]	Oxybutynin TDS	1.3mg	Oxybutynin TDS	3.9mg	6/130	2/125	2.88 (0.59; 14.02)	0.03 (-0.01; 0.07)		
Dmochowski, 2002[276]	Oxybutynin TDS	2.6mg	Oxybutynin TDS	3.9mg	5/133	2/125	2.35 (0.46; 11.89)	0.02 (-0.02; 0.06)		
Salvatore, 2005[371]	Oxybutynin	2.5 twice daily	Oxybutynin	5mg nocte	0/27	4/39	0.16 (0.01; 2.83)	-0.10 (-0.21; 0.01)		
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	10mg/day	5/77	8/77	0.63 (0.21; 1.83)	-0.04 (-0.13; 0.05)		
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	15mg/day	5/77	7/83	0.77 (0.26; 2.32)	-0.02 (-0.10; 0.06)		
Chancellor, 2001[255]	ER-oxybutynin	10mg/day	IR-oxybutynin	5mg/day	0/36	1/36	0.33 (0.01; 7.92)	-0.03 (-0.10; 0.05)		
Corcos, 2006[270]	Oxybutynin-controlled release	10mg/day	Oxybutynin-controlled release	15mg/day	8/77	7/83	1.23 (0.47; 3.24)	0.02 (-0.07; 0.11)		
Davila, 2001[271]	Oxybutynin transdermal	1.3mg	Oxybutynin-immediate release	5mg twice/thrice daily or 7.5mg thrice daily	3/38	10/38	0.30 (0.09; 1.01)	-0.18 (-0.35; -0.02)	-5 (-50; -3)	-184 (-348; -20)
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	10/53	9/52	1.09 (0.48; 2.46)	0.02 (-0.13; 0.16)		
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	10/53	9/52	1.09 (0.48; 2.46)	0.02 (-0.13; 0.16)		
Nervousness										
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	13/53	12/52	1.06 (0.54; 2.11)	0.01 (-0.15; 0.18)		
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	13/53	12/52	1.06 (0.54; 2.11)	0.01 (-0.15; 0.18)		

Appendix Table F51. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)

Reference	Active drug	Dose	Control drug	Dose	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Palpitation										
Davila, 2001[271]	Oxybutynin transdermal	1.3mg	Oxybutynin-immediate release	5mg twice/thrice daily or 7.5mg thrice daily	3/38	5/38	0.60 (0.15; 2.34)	-0.05 (-0.19; 0.08)		
Dmochowski, 2002[276]	Oxybutynin TDS	1.3mg	Oxybutynin TDS	2.6mg	1/130	0/133	3.07 (0.13; 74.65)	0.01 (-0.01; 0.03)		
Dmochowski, 2002[276]	Oxybutynin TDS	1.3mg	Oxybutynin TDS	3.9mg	1/130	1/125	0.96 (0.06; 15.21)	0.00 (-0.02; 0.02)		
Dmochowski, 2002[276]	Oxybutynin TDS	2.6mg	Oxybutynin TDS	3.9mg	0/133	1/125	0.31 (0.01; 7.62)	-0.01 (-0.03; 0.01)		
Urinary retention										
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	10mg/day	2/77	8/77	0.25 (0.05; 1.14)	-0.08 (-0.15; 0.00)	-13 (-938; -6)	-78 (-155; -1)
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	15mg/day	2/77	6/83	0.36 (0.07; 1.73)	-0.05 (-0.11; 0.02)		
Corcos, 2006[270]	Oxybutynin-controlled release	10mg/day	Oxybutynin-controlled release	15mg/day	8/77	6/83	1.44 (0.52; 3.95)	0.03 (-0.06; 0.12)		
Davila, 2001[271]	Oxybutynin transdermal	1.3mg	Oxybutynin-immediate release	5mg twice/thrice daily or 7.5mg thrice daily	9/38	13/38	0.69 (0.34; 1.42)	-0.11 (-0.31; 0.10)		
Impaired urination										
Davila, 2001[271]	Oxybutynin transdermal	1.3mg	Oxybutynin-immediate release	5mg twice/thrice daily or 7.5mg thrice daily	9/38	9/38	1.00 (0.45; 2.24)	0.00 (-0.19; 0.19)		
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	13/53	15/52	0.85 (0.45; 1.61)	-0.04 (-0.21; 0.13)		
Somnolence										
Dmochowski, 2002[276]	Oxybutynin TDS	1.3mg	Oxybutynin TDS	2.6mg	1/130	0/133	3.07 (0.13; 74.65)	0.01 (-0.01; 0.03)		
Dmochowski, 2002[276]	Oxybutynin TDS	1.3mg	Oxybutynin TDS	3.9mg	1/130	2/125	0.48 (0.04; 5.24)	-0.01 (-0.03; 0.02)		

Appendix Table F51. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)

Reference	Active drug	Dose	Control drug	Dose	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Dmochowski, 2002[276]	Oxybutynin TDS	2.6mg	Oxybutynin TDS	3.9mg	0/133	2/125	0.19 (0.01; 3.88)	-0.02 (-0.04; 0.01)		
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	10mg/day	4/77	3/77	1.33 (0.31; 5.76)	0.01 (-0.05; 0.08)		
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	15mg/day	4/77	2/83	2.16 (0.41; 11.44)	0.03 (-0.03; 0.09)		
Corcos, 2006[270]	Oxybutynin-controlled release	10mg/day	Oxybutynin-controlled release	15mg/day	3/77	2/83	1.62 (0.28; 9.42)	0.01 (-0.04; 0.07)		
Davila, 2001[271]	Oxybutynin transdermal	1.3mg	Oxybutynin-immediate release	5mg twice/thrice daily or 7.5mg thrice daily	7/38	14/38	0.50 (0.23; 1.10)	-0.18 (-0.38; 0.01)		
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	20/53	21/52	0.93 (0.58; 1.51)	-0.03 (-0.21; 0.16)		
Anderson, 1999[391]	CR-oxybutynin	5 to 30mg once daily	IR-oxybutynin	5mg 1 to 4 times daily	20/53	21/52	0.93 (0.58; 1.51)	-0.03 (-0.21; 0.16)		
Tachycardia										
Salvatore, 2005[371]	Oxybutynin	2.5 twice daily	Oxybutynin	5mg nocte	0/27	1/39	0.48 (0.02; 11.27)	-0.03 (-0.10; 0.05)		
Urinary tract infection										
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	10mg/day	8/77	9/77	0.89 (0.36; 2.18)	-0.01 (-0.11; 0.09)		
Corcos, 2006[270]	Oxybutynin-controlled release	5mg/day	Oxybutynin-controlled release	15mg/day	8/77	13/83	0.66 (0.29; 1.51)	-0.05 (-0.16; 0.05)		
Corcos, 2006[270]	Oxybutynin-controlled release	10mg/day	Oxybutynin-controlled release	15mg/day	9/77	13/83	0.75 (0.34; 1.65)	-0.04 (-0.15; 0.07)		
Vasodilatation										
Chancellor, 2001[255]	ER-oxybutynin	10mg/day	IR-oxybutynin	5mg/day	0/36	0/36	0.00 (0.00; 0.00)	0.00 (-0.05; 0.05)		

Appendix Table F51. Clinical outcomes after oxybutynin treatments (individual RCTs) (continued)

Reference	Active drug	Dose	Control drug	Dose	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Vision abnormal										
Dmochowski, 2002[276]	Oxybutynin TDS	1.3mg	Oxybutynin TDS	2.6mg	3/130	2/133	1.53 (0.26; 9.03)	0.01 (-0.03; 0.04)		
Dmochowski, 2002[276]	Oxybutynin TDS	1.3mg	Oxybutynin TDS	3.9mg	3/130	0/125	6.73 (0.35; 129.03)	0.02 (-0.01; 0.05)		
Dmochowski, 2002[276]	Oxybutynin TDS	2.6mg	Oxybutynin TDS	3.9mg	2/133	0/125	4.70 (0.23; 96.98)	0.02 (-0.01; 0.04)		
Vomiting										
Chancellor, 2001[255]	ER-oxybutynin	10mg/day	IR-oxybutynin	5mg/day	1/36	2/36	0.50 (0.05; 5.27)	-0.03 (-0.12; 0.06)		

Appendix Table F52. Clinical outcomes after tolterodine vs. placebo in secondary data analyses

Outcome	Reference	Dose	Events/ randomized to Duloxetine	Events/ randomized to placebo	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to t (95% CI)	Attributable events (95% CI)
Improvement in incontinence								
Improved perceptions of bladder condition	Appell, 1997[229]	1mg twice daily	50/121	69/176	1.05 (0.80; 1.40)	0.02 (-0.09; 0.13)		
Improved perceptions of bladder condition	Appell, 1997[229]	2mg twice daily	246/474	69/176	1.32 (1.08; 1.62)	0.13 (0.04; 0.21)	8 (5; 24)	127 (42; 212)
Treatment response (primary and secondary efficacy endpoints)	Sand, 2009[372]	4mg daily	140/227	167/430	1.59 (1.36; 1.86)	0.23 (0.15; 0.31)	4 (3; 7)	228 (150; 307)
Perceived improvement in bladder symptoms	Freeman, 2003[290]	4mg once daily	247/398	180/374	1.19 (1.04; 1.37)	0.09 (0.02; 0.16)	11 (6; 48)	89 (21; 156)
Perceived improvement in bladder symptoms in females	Freeman, 2003[290]	4mg once daily	250/398	181/374	1.30 (1.14; 1.48)	0.14 (0.07; 0.21)	7 (5; 13)	144 (75; 214)
Global self-evaluation of treatment: “much benefit”	Freeman, 2003[290]	4mg once daily	171/398	90/374	1.53 (1.24; 1.88)	0.16 (0.09; 0.23)	6 (4; 12)	158 (86; 231)
Global self-evaluation of treatment: much benefit	Freeman, 2003[290]	4mg once daily	172/398	88/374	1.84 (1.48; 2.28)	0.20 (0.13; 0.26)	5 (4; 8)	197 (132; 262)
Treatment failure								
No change in urgency perception scale score	Freeman, 2003[290]	4mg once daily	203/398	212/374	0.90 (0.79; 1.03)	-0.06 (-0.13; 0.01)		
Decrease in urgency perception scale score	Freeman, 2003[290]	4mg once daily	22/398	44/374	0.47 (0.29; 0.77)	-0.06 (-0.10; -0.02)	-16 (-44; -10)	-62 (-102; -23)
Global self-evaluation of treatment: little benefit	Freeman, 2003[290]	4mg once daily	138/398	118/374	1.10 (0.90; 1.34)	0.03 (-0.04; 0.10)		
Global self-evaluation of treatment: no benefit	Freeman, 2003[290]	4mg once daily	88/398	168/374	0.49 (0.40; 0.61)	-0.23 (-0.29; -0.16)	-4 (-6; -3)	-228 (-293; -163)

Appendix Table F52. Clinical outcomes after tolterodine vs. placebo in secondary data analyses (continued)

Outcome	Reference	Dose	Events/ randomized to Duloxetine	Events/ randomized to placebo	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to t (95% CI)	Attributable events (95% CI)
Treatment discontinuation								
Withdrawal	Freeman, 2003[290]	4mg once daily	173/398	118/374	1.38 (1.14; 1.66)	0.12 (0.05; 0.19)	8 (5; 19)	119 (51; 187)
Withdrawal	Appell, 1997[229]	1mg twice daily	7/121	17/176	0.60 (0.26; 1.40)	-0.04 (-0.10; 0.02)		
Discontinued prematurely	Chapple, 2008 [260]	4mg daily	9/290	6/283	1.46 (0.53; 4.06)	0.01 (-0.02; 0.04)		
Withdrawal due to AE	Appell, 1997[229]	1mg twice daily	2/121	9/176	0.32 (0.07; 1.47)	-0.03 (-0.07; 0.01)		
Withdrawal due to AE	Appell, 1997[229]	2mg twice daily	38/474	9/176	1.57 (0.77; 3.18)	0.03 (-0.01; 0.07)		
Adverse effects								
Abdominal pain	Freeman, 2003[290]	4mg once daily	16/398	6/374	2.51 (0.99; 6.34)	0.02 (0.00; 0.05)	41 (21; 964)	24 (1; 47)
Adverse events	Appell, 1997[229]	1mg twice daily	94/121	164/176	0.83 (0.75; 0.92)	-0.15 (-0.24; -0.07)	-6 (-14; -4)	-155 (-238; -72)
Adverse events	Appell, 1997[229]	2mg twice daily	351/474	164/176	0.79 (0.74; 0.85)	-0.19 (-0.25; -0.14)	-5 (-7; -4)	-191 (-246; -137)
Autonomic nervous system disorder	Appell, 1997[229]	1mg twice daily	35/121	37/176	1.38 (0.92; 2.05)	0.08 (-0.02; 0.18)		
Autonomic nervous system disorder	Appell, 1997[229]	2mg twice daily	204/474	37/176	2.05 (1.51; 2.78)	0.22 (0.15; 0.30)	5 (3; 7)	220 (145; 295)
Back pain	Sand, 2009[372]	4mg daily	1/227	1/430	1.89 (0.12; 30.14)	0.00 (-0.01; 0.01)		
Cardiac dysfunction	Appell, 1997[229]	2mg twice daily	4/474	3/176	0.50 (0.11; 2.19)	-0.01 (-0.03; 0.01)		

Appendix Table F52. Clinical outcomes after tolterodine vs. placebo in secondary data analyses (continued)

Outcome	Reference	Dose	Events/ randomized to Duloxetine	Events/ randomized to placebo	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to t (95% CI)	Attributable events (95% CI)
Cardiovascular adverse events	Appell, 1997[229]	1mg twice daily	15/121	14/176	1.56 (0.78; 3.11)	0.04 (-0.03; 0.12)		
Cardiovascular adverse events	Appell, 1997[229]	2mg twice daily	20/474	14/176	0.53 (0.27; 1.03)	-0.04 (-0.08; 0.01)		
Constipation	Chapple, 2008 [260]	4mg daily	8/290	4/283	1.95 (0.59; 6.41)	0.01 (-0.01; 0.04)		
Constipation	Sand, 2009[372]	4mg daily	6/227	10/430	1.14 (0.42; 3.09)	0.00 (-0.02; 0.03)		
Constipation	Freeman, 2003[290]	4mg once daily	23/398	16/374	1.35 (0.73; 2.52)	0.02 (-0.02; 0.05)		
Cough	Sand, 2009[372]	4mg daily	5/227	3/430	3.16 (0.76; 13.09)	0.02 (-0.01; 0.04)		
Diarrhea	Sand, 2009[372]	4mg daily	3/227	10/430	0.57 (0.16; 2.04)	-0.01 (-0.03; 0.01)		
Diarrhea	Freeman, 2003[290]	4mg once daily	8/398	7/374	1.07 (0.39; 2.93)	0.00 (-0.02; 0.02)		
Dizziness	Sand, 2009[372]	4mg daily	4/227	9/430	0.84 (0.26; 2.70)	0.00 (-0.03; 0.02)		
Dose reduction in case of intolerance	Appell, 1997[229]	2mg twice daily	43/474	7/176	2.28 (1.05; 4.98)	0.05 (0.01; 0.09)	20 (11; 82)	51 (12; 90)
Dry eye	Chapple, 2008 [260]	4mg daily	1/290	0/283	2.93 (0.12; 71.57)	0.00 (-0.01; 0.01)		
Dry eye	Sand, 2009[372]	4mg daily	1/227	0/430	5.67 (0.23; 138.65)	0.00 (-0.01; 0.02)		
Dry mouth	Chapple, 2008 [260]	4mg daily	49/290	20/283	2.39 (1.46; 3.92)	0.10 (0.05; 0.15)	10 (7; 22)	98 (46; 151)
Dry mouth	Sand, 2009[372]	4mg daily	37/227	32/430	2.19 (1.40; 3.42)	0.09 (0.03; 0.14)	11 (7; 29)	89 (35; 143)
Dry mouth	Freeman, 2003[290]	4mg once daily	95/398	28/374	3.19 (2.14; 4.74)	0.16 (0.11; 0.21)	6 (5; 9)	164 (114; 213)

Appendix Table F52. Clinical outcomes after tolterodine vs. placebo in secondary data analyses (continued)

Outcome	Reference	Dose	Events/ randomized to Duloxetine	Events/ randomized to placebo	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to t (95% CI)	Attributable events (95% CI)
Dry throat	Chapple, 2008 [260]	4mg daily	3/290	0/283	6.83 (0.35; 131.66)	0.01 (0.00; 0.02)		
Dry throat	Sand, 2009[372]	4mg daily	2/227	0/430	9.45 (0.46; 196.04)	0.01 (-0.01; 0.02)		
Fatigue	Chapple, 2008 [260]	4mg daily	10/290	1/283	9.76 (1.26; 75.74)	0.03 (0.01; 0.05)	32 (19; 113)	31 (9; 53)
Fatigue	Sand, 2009[372]	4mg daily	7/227	2/430	6.63 (1.39; 31.65)	0.03 (0.00; 0.05)	38 (20; 358)	26 (3; 50)
Gastrointestinal disorder	Appell, 1997[229]	1mg twice daily	27/121	48/176	0.82 (0.54; 1.23)	-0.05 (-0.15; 0.05)		
Gastrointestinal disorder	Appell, 1997[229]	2mg twice daily	123/474	48/176	0.95 (0.72; 1.27)	-0.01 (-0.09; 0.06)		
Headache	Sand, 2009[372]	4mg daily	13/227	18/430	1.37 (0.68; 2.74)	0.02 (-0.02; 0.05)		
Headache	Freeman, 2003[290]	4mg once daily	23/398	14/374	1.54 (0.81; 2.95)	0.02 (-0.01; 0.05)		
Increased alanine aminotransferase	Chapple, 2008 [260]	4mg daily	0/290	1/283	0.33 (0.01; 7.95)	0.00 (-0.01; 0.01)		
Moderate or severe dry mouth	Appell, 1997[229]	1mg twice daily	5/121	11/176	0.66 (0.24; 1.85)	-0.02 (-0.07; 0.03)		
Moderate or severe dry mouth	[229]	2mg twice daily	81/474	11/176	2.73 (1.49; 5.01)	0.11 (0.06; 0.16)	9 (6; 17)	108 (59; 158)
Nasopharyngitis	Chapple, 2008 [260]	4mg daily	10/290	7/283	1.39 (0.54; 3.61)	0.01 (-0.02; 0.04)		
Nasopharyngitis	Sand, 2009[372]	4mg daily	8/227	12/430	1.26 (0.52; 3.04)	0.01 (-0.02; 0.04)		
Nausea	Chapple, 2008 [260]	4mg daily	6/290	1/283	5.86 (0.71; 48.33)	0.02 (0.00; 0.03)		
Nausea	Sand, 2009[372]	4mg daily	3/227	5/430	1.14 (0.27; 4.71)	0.00 (-0.02; 0.02)		

Appendix Table F52. Clinical outcomes after tolterodine vs. placebo in secondary data analyses (continued)

Outcome	Reference	Dose	Events/ randomized to Duloxetine	Events/ randomized to placebo	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to t (95% CI)	Attributable events (95% CI)
Nausea	Freeman, 2003[290]	4mg once daily	5/398	5/374	0.94 (0.27; 3.22)	0.00 (-0.02; 0.02)		
Palpitations	Appell, 1997[229]	1mg twice daily	8/121	4/176	2.91 (0.90; 9.45)	0.04 (-0.01; 0.09)		
Palpitations	Appell, 1997[229]	2mg twice daily	2/474	4/176	0.19 (0.03; 1.00)	-0.02 (-0.04; 0.00)		
Serious adverse events	Appell, 1997[229]	2mg twice daily	19/474	5/176	1.41 (0.53; 3.72)	0.01 (-0.02; 0.04)		
URI	Sand, 2009[372]	4mg daily	2/227	9/430	0.42 (0.09; 1.93)	-0.01 (-0.03; 0.01)		
Urinary tract infection	Freeman, 2003[290]	4mg once daily	7/398	12/374	0.55 (0.22; 1.38)	-0.01 (-0.04; 0.01)		
UTI	Sand, 2009[372]	4mg daily	4/227	17/430	0.45 (0.15; 1.31)	-0.02 (-0.05; 0.00)		
Dry mouth	Freeman, 2003[290]	4mg once daily	15/398	7/374	2.01 (0.83; 4.88)	0.02 (0.00; 0.04)		

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine

Outcome	Reference design	Active vs. control	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Improvement in UI	Appell, 1997[229] Pooled analysis	1mg twice daily vs. 2mg daily	50/121	246/474	0.80 (0.63; 1.00)	-0.11 (-0.20; -0.01)	-9 (-139; -5)	-106 (-204; -7)
Completed the study	Malone-Lee, 2006[346] RCT	1mg twice daily vs. 2mg twice daily	53/61	64/73	0.99 (0.87; 1.13)	-0.01 (-0.12; 0.11)		
Withdrew from study	Appell, 1997[229] Pooled analysis	1mg twice daily vs. 2mg daily	7/121	63/474	0.44 (0.20; 0.93)	-0.08 (-0.13; -0.02)	-13 (-43; -8)	-75 (-127; -23)
Withdrew from study	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg twice daily	27/507	28/514	0.98 (0.58; 1.63)	0.00 (-0.03; 0.03)		
Withdrew due to adverse events	Appell, 1997[229] Pooled analysis	1mg twice daily vs. 2mg daily	2/121	38/474	0.21 (0.05; 0.84)	-0.06 (-0.10; -0.03)	-16 (-33; -10)	-64 (-97; -30)
Withdrew due to adverse events	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	15/193	19/399	1.63 (0.85; 3.14)	0.03 (-0.01; 0.07)		
Withdrew due to adverse events	Malone-Lee, 2001[346] RCT	1mg twice daily vs. 2mg twice daily	4/61	7/73	0.68 (0.21; 2.23)	-0.03 (-0.12; 0.06)		
Withdrew due to adverse events	Jacquetin, 2001[316] RCT	1mg twice daily vs. 2mg twice daily	3/97	2/103	1.59 (0.27; 9.33)	0.01 (-0.03; 0.06)		
All adverse events	Jacquetin, 2001[316] RCT	1mg twice daily vs. 2mg twice daily	78/97	84/103	0.99 (0.86; 1.13)	-0.01 (-0.12; 0.10)		
All adverse events	Jacquetin, 2001[316] RCT	1mg twice daily vs. 2mg twice daily	39/97	55/103	0.75 (0.56; 1.02)	-0.13 (-0.27; 0.01)		

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

Outcome	Reference design	Active vs. control	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
All adverse events	Jonas, 1997[318] RCT	1mg twice daily vs. 2mg twice daily	34/99	43/99	0.79 (0.56; 1.13)	-0.09 (-0.23; 0.04)		
All adverse events	Jonas, 1997[318] RCT	1mg twice daily vs. 2mg twice daily	31/99	32/99	0.97 (0.64; 1.46)	-0.01 (-0.14; 0.12)		
At least one adverse event	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	152/193	254/399	1.24 (1.11; 1.37)	0.15 (0.08; 0.23)	7 (4; 13)	151 (76; 226)
At least one adverse event	Millard, 1999[349] RCT	1mg twice daily vs. 2mg twice daily	8/129	2/123	3.81 (0.83; 17.61)	0.05 (0.00; 0.09)		
At least one adverse event	Appell, 1997[229] Pooled analysis	1mg twice daily vs. 2mg daily	94/121	351/474	1.05 (0.94; 1.17)	0.04 (-0.05; 0.12)		
Adverse events of severe intensity	Malone-Lee, 2001[346] RCT	1mg twice daily vs. 2mg twice daily	5/61	6/73	1.00 (0.32; 3.11)	0.00 (-0.09; 0.09)		
Mild adverse events related to study medication	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	81/193	123/399	1.36 (1.09; 1.70)	0.11 (0.03; 0.19)	9 (5; 35)	111 (28; 194)
Mild adverse events not related to study medication	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	57/193	117/399	1.01 (0.77; 1.31)	0.00 (-0.08; 0.08)		
Moderate adverse events related to study medication	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	46/193	84/399	1.13 (0.83; 1.55)	0.03 (-0.04; 0.10)		

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

Outcome	Reference design	Active vs. control	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Moderate adverse events not related to study medication	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	35/193	40/399	1.81 (1.19; 2.75)	0.08 (0.02; 0.14)	12 (7; 52)	81 (19; 143)
Severe adverse events related to study medication	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	7/193	9/399	1.61 (0.61; 4.25)	0.01 (-0.02; 0.04)		
Severe adverse events not related to study medication	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	5/193	6/399	1.72 (0.53; 5.57)	0.01 (-0.01; 0.04)		
Serious adverse event	Malone-Lee, 2001[346] RCT	1mg twice daily vs. 2mg twice daily	2/61	1/73	2.39 (0.22; 25.76)	0.02 (-0.03; 0.07)		
Serious adverse event	Millard, 1999[349] RCT	1mg twice daily vs. 2mg twice daily	5/129	7/123	0.68 (0.22; 2.09)	-0.02 (-0.07; 0.03)		
Serious adverse event	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	7/507	12/514	0.59 (0.23; 1.49)	-0.01 (-0.03; 0.01)		
Abdominal pain	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	18/417	12/408	1.47 (0.72; 3.01)	0.01 (-0.01; 0.04)		
Abdominal pain	Jacquetin, 2007[316] RCT	1mg twice daily vs. 2mg twice daily	6/97	4/103	1.59 (0.46; 5.47)	0.02 (-0.04; 0.08)		
Abdominal pain	Malone-Lee, 2001[346] RCT	1mg twice daily vs. 2mg twice daily	3/61	6/73	0.60 (0.16; 2.29)	-0.03 (-0.12; 0.05)		

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

Outcome	Reference design	Active vs. control	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Abdominal pain	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	19/507	13/514	1.48 (0.74; 2.97)	0.01 (-0.01; 0.03)		
Abnormal accommodation	Malone-Lee, 2001[346] RCT	1mg twice daily vs. 2mg twice daily	0/61	3/73	0.17 (0.01; 3.24)	-0.04 (-0.09; 0.01)		
Abnormal accommodation	Jonas, 1997[318] RCT	1mg twice daily vs. 2mg twice daily	3/99	5/99	0.60 (0.15; 2.44)	-0.02 (-0.07; 0.03)		
Abnormal vision	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	5/417	4/408	1.22 (0.33; 4.52)	0.00 (-0.01; 0.02)		
Abnormal vision	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	6/507	4/514	1.52 (0.43; 5.36)	0.00 (-0.01; 0.02)		
Arthralgia	Takei, 2005[384] RCT	4mg/day vs. 4mg/day	1/80	11/74	0.08 (0.01; 0.64)	-0.14 (-0.22; -0.05)	-7 (-19; -5)	-136 (-221; -52)
Arthritis	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	1/417	5/408	0.20 (0.02; 1.67)	-0.01 (-0.02; 0.00)		
Autonomic nervous system	Jonas, 1997[318] RCT	1mg twice daily vs. 2mg twice daily	11/99	16/99	0.69 (0.34; 1.41)	-0.05 (-0.15; 0.04)		
Autonomic nervous system disorder	Appell, 1997[229] Pooled analysis	1mg twice daily vs. 2mg daily	35/121	204/474	0.67 (0.50; 0.91)	-0.14 (-0.23; -0.05)	-7 (-20; -4)	-141 (-233; -49)
Autonomic nervous system disorder	Millard, 1999[349] RCT	1mg twice daily vs. 2mg twice daily	37/129	53/123	0.67 (0.47; 0.93)	-0.14 (-0.26; -0.03)	-7 (-37; -4)	-144 (-261; -27)

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

Outcome	Reference design	Active vs. control	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Back pain	Takei, 2005[384] RCT	4mg/day vs. 4mg/day	3/80	11/74	0.25 (0.07; 0.87)	-0.11 (-0.20; -0.02)	-9 (-50; -5)	-111 (-202; -20)
Body disorder as a whole	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	61/193	85/399	1.48 (1.12; 1.96)	0.10 (0.03; 0.18)	10 (6; 38)	103 (26; 180)
Cardiovascular adverse events	Appell, 1997[229] Pooled analysis	1mg twice daily vs. 2mg daily	15/121	20/474	2.94 (1.55; 5.57)	0.08 (0.02; 0.14)	12 (7; 49)	82 (20; 143)
Constipation	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	27/417	27/408	0.98 (0.58; 1.64)	0.00 (-0.04; 0.03)		
Constipation	Jacquetin, 2001[316] RCT	1mg twice daily vs. 2mg twice daily	4/97	2/103	2.12 (0.40; 11.33)	0.02 (-0.03; 0.07)		
Constipation	Jonas, 1997[318] RCT	1mg twice daily vs. 2mg twice daily	2/99	3/99	0.67 (0.11; 3.90)	-0.01 (-0.05; 0.03)		
Constipation	Takei, 2005[384] RCT	4mg/day vs. 4mg/day	12/80	16/74	0.69 (0.35; 1.37)	-0.07 (-0.19; 0.06)		
Constipation	Malone-Lee, 2001[346] RCT	1mg twice daily vs. 2mg twice daily	5/61	0/73	13.13 (0.74; 232.79)	0.08 (0.01; 0.16)	12 (6; 114)	82 (9; 155)
Constipation	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	30/507	35/514	0.87 (0.54; 1.39)	-0.01 (-0.04; 0.02)		
Constipation	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	12/193	31/399	0.80 (0.42; 1.52)	-0.02 (-0.06; 0.03)		
Diarrhea	Malone-Lee, 2001[346] RCT	1mg twice daily vs. 2mg twice daily	8/61	4/73	2.39 (0.76; 7.57)	0.08 (-0.02; 0.18)		

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

Outcome	Reference design	Active vs. control	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Diarrhea	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	10/507	16/514	0.63 (0.29; 1.38)	-0.01 (-0.03; 0.01)		
Diarrhea	Armstrong, 2007[232] pooled analysis	2mg qd vs. 4mg qd	9/193	25/399	0.74 (0.35; 1.56)	-0.02 (-0.05; 0.02)		
Diarrhea	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	10/417	14/408	0.70 (0.31; 1.56)	-0.01 (-0.03; 0.01)		
Diarrhea	Takei, 2005[384] RCT	4mg/day vs. 4mg/day	6/80	12/74	0.46 (0.18; 1.17)	-0.09 (-0.19; 0.01)		
Digestive system	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	87/193	145/399	1.24 (1.01; 1.52)	0.09 (0.00; 0.17)	11 (6; 360)	87 (3; 172)
Dizziness	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	7/417	7/408	0.98 (0.35; 2.76)	0.00 (-0.02; 0.02)		
Dizziness	Malone-Lee, 2001[346] RCT	1mg twice daily vs. 2mg twice daily	5/61	4/73	1.50 (0.42; 5.33)	0.03 (-0.06; 0.11)		
Dizziness	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	11/507	9/514	1.24 (0.52; 2.96)	0.00 (-0.01; 0.02)		
Dry mouth	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	105/417	127/408	0.81 (0.65; 1.01)	-0.06 (-0.12; 0.00)		
Dry mouth	Jacquetin, 2001[316] RCT	1mg twice daily vs. 2mg twice daily	20/97	35/103	0.61 (0.38; 0.97)	-0.13 (-0.26; -0.01)	-7 (-85; -4)	-134 (-255; -12)

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

Outcome	Reference design	Active vs. control	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Dry mouth	Jonas, 1997[318] RCT	1mg twice daily vs. 2mg twice daily	8/99	10/99	0.80 (0.33; 1.94)	-0.02 (-0.10; 0.06)		
Dry mouth	Takei, 2005[384] RCT	4mg/day vs. 4mg/day	42/80	63/74	0.62 (0.49; 0.78)	-0.33 (-0.46; -0.19)	-3 (-5; -2)	-326 (-463; -190)
Dry mouth	Malone-Lee, 2001[346] RCT	1mg twice daily vs. 2mg twice daily	30/61	48/73	0.75 (0.55; 1.01)	-0.17 (-0.33; 0.00)		
Dry mouth	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	118/507	156/514	0.77 (0.62; 0.94)	-0.07 (-0.12; -0.02)	-14 (-60; -8)	-71 (-125; -17)
Dry mouth	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	64/193	89/399	1.49 (1.13; 1.95)	0.11 (0.03; 0.19)	9 (5; 33)	109 (31; 187)
Dry skin	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	2/417	5/408	0.39 (0.08; 2.01)	-0.01 (-0.02; 0.01)		
Dry skin	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	2/507	6/514	0.34 (0.07; 1.67)	-0.01 (-0.02; 0.00)		
Dyspepsia	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	11/417	14/408	0.77 (0.35; 1.67)	-0.01 (-0.03; 0.02)		
Dyspepsia	Malone-Lee, 2001[346] RCT	1mg twice daily vs. 2mg twice daily	2/61	6/73	0.40 (0.08; 1.91)	-0.05 (-0.13; 0.03)		
Dyspepsia	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	15/507	16/514	0.95 (0.47; 1.90)	0.00 (-0.02; 0.02)		

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

Outcome	Reference design	Active vs. control	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Dyspepsia	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	10/193	11/399	1.88 (0.81; 4.35)	0.02 (-0.01; 0.06)		
Dysuria	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	5/507	8/514	0.63 (0.21; 1.92)	-0.01 (-0.02; 0.01)		
Fatigue	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	11/507	6/514	1.86 (0.69; 4.99)	0.01 (-0.01; 0.03)		
Flatulence	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	8/417	11/408	0.71 (0.29; 1.75)	-0.01 (-0.03; 0.01)		
Flatulence	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	10/507	14/514	0.72 (0.32; 1.62)	-0.01 (-0.03; 0.01)		
Gastrointestinal	Jonas, 1997[318] RCT	1mg twice daily vs. 2mg twice daily	5/99	6/99	0.83 (0.26; 2.64)	-0.01 (-0.07; 0.05)		
Gastrointestinal disorder	Appell, 1997[229] Pooled analysis	1mg twice daily vs. 2mg daily	27/121	123/474	0.86 (0.60; 1.24)	-0.04 (-0.12; 0.05)		
General disorders	Jonas, 1997[318] RCT	1mg twice daily vs. 2mg twice daily	7/99	6/99	1.17 (0.41; 3.35)	0.01 (-0.06; 0.08)		
Headache	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	29/417	14/408	2.03 (1.09; 3.78)	0.04 (0.01; 0.07)	28 (15; 196)	35 (5; 65)
Headache	Jacquetin, 2001[316] RCT	1mg twice daily vs. 2mg twice daily	3/97	3/103	1.06 (0.22; 5.14)	0.00 (-0.05; 0.05)		

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

Outcome	Reference design	Active vs. control	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Headache	Jonas, 1997[318] RCT	1mg twice daily vs. 2mg twice daily	3/99	3/99	1.00 (0.21; 4.83)	0.00 (-0.05; 0.05)		
Headache	Takei, 2005[384] RCT	4mg/day vs. 4mg/day	6/80	10/74	0.56 (0.21; 1.45)	-0.06 (-0.16; 0.04)		
Headache	Malone-Lee, 2001[346] RCT	1mg twice daily vs. 2mg twice daily	5/61	7/73	0.85 (0.29; 2.56)	-0.01 (-0.11; 0.08)		
Headache	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	32/507	19/514	1.71 (0.98; 2.97)	0.03 (0.00; 0.05)		
Headache	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	18/193	24/399	1.55 (0.86; 2.79)	0.03 (-0.01; 0.08)		
Hypertension	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	6/417	4/408	1.47 (0.42; 5.16)	0.00 (-0.01; 0.02)		
Insomnia	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	7/417	2/408	3.42 (0.72; 16.39)	0.01 (0.00; 0.03)		
Insomnia	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	7/507	2/514	3.55 (0.74; 17.00)	0.01 (0.00; 0.02)		
Metabolic and nutritional system	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	17/193	21/399	1.67 (0.90; 3.10)	0.04 (-0.01; 0.08)		
Mild to-moderate intensity dry mouth	Jacquetin, 2001[316] RCT	1mg twice daily vs. 2mg twice daily	18/97	30/103	0.64 (0.38; 1.07)	-0.11 (-0.22; 0.01)		

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

Outcome	Reference design	Active vs. control	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Minor noncholinergic and cholinergic adverse events	Millard, 1999[349] RCT	1mg twice daily vs. 2mg twice daily	95/129	90/123	1.01 (0.87; 1.17)	0.00 (-0.10; 0.11)		
Moderate or severe dry mouth	Appell, 1997[229] Pooled analysis	1mg twice daily vs. 2mg daily	5/121	81/474	0.24 (0.10; 0.58)	-0.13 (-0.18; -0.08)	-8 (-12; -6)	-130 (-179; -81)
Nasopharyngitis	Takei, 2005[384] RCT	4mg/day vs. 4mg/day	6/80	50/74	0.11 (0.05; 0.24)	-0.60 (-0.72; -0.48)	-2 (-2; -1)	-601 (-722; -479)
Nausea	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	7/417	9/408	0.76 (0.29; 2.02)	-0.01 (-0.02; 0.01)		
Nausea	Malone-Lee, 2001[346] RCT	1mg twice daily vs. 2mg twice daily	2/61	3/73	0.80 (0.14; 4.62)	-0.01 (-0.07; 0.06)		
Nausea	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	7/507	10/514	0.71 (0.27; 1.85)	-0.01 (-0.02; 0.01)		
Pain	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	15/193	14/399	2.22 (1.09; 4.50)	0.04 (0.00; 0.08)	23 (12; 1303)	43 (1; 84)
Palpitations	Appell, 1997[229] Pooled analysis	1mg twice daily vs. 2mg daily	8/121	2/474	15.67 (3.37; 72.84)	0.06 (0.02; 0.11)	16 (9; 58)	62 (17; 107)
Peripheral edema	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	7/507	7/514	1.01 (0.36; 2.87)	0.00 (-0.01; 0.01)		
Peripheral edema	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	11/193	13/399	1.75 (0.80; 3.83)	0.02 (-0.01; 0.06)		
Psychiatric adverse events	Jonas, 1997[318] RCT	1mg twice daily vs. 2mg twice daily	1/99	1/99	1.00 (0.06; 15.76)	0.00 (-0.03; 0.03)		
Respiratory adverse events	Jonas, 1997[318] RCT	1mg twice daily vs. 2mg twice daily	1/99	3/99	0.33 (0.04; 3.15)	-0.02 (-0.06; 0.02)		

Appendix Table F53. Clinical outcomes after different doses and clinical formulations of tolterodine (continued)

Outcome	Reference design	Active vs. control	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Sinusitis	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	8/417	2/408	3.91 (0.84; 18.32)	0.01 (0.00; 0.03)		
Skin and appendages	Jonas, 1997[318] RCT	1mg twice daily vs. 2mg twice daily	1/99	1/99	1.00 (0.06; 15.76)	0.00 (-0.03; 0.03)		
Somnolence	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	12/417	11/408	1.07 (0.48; 2.39)	0.00 (-0.02; 0.02)		
Somnolence	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	14/507	13/514	1.09 (0.52; 2.30)	0.00 (-0.02; 0.02)		
Urinary AE	Jonas, 1997[318] RCT	1mg twice daily vs. 2mg twice daily	6/99	5/99	1.20 (0.38; 3.80)	0.01 (-0.05; 0.07)		
Urinary tract infection	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	15/417	11/408	1.33 (0.62; 2.87)	0.01 (-0.01; 0.03)		
Urinary tract infection	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	16/507	13/514	1.25 (0.61; 2.57)	0.01 (-0.01; 0.03)		
Urinary tract infection	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd	11/193	13/399	1.75 (0.80; 3.83)	0.02 (-0.01; 0.06)		
Urinary tract infection	Jonas, 1997[318] RCT	1mg twice daily vs. 2mg twice daily	5/99	2/99	2.50 (0.50; 12.58)	0.03 (-0.02; 0.08)		
Urogenital system adverse events	Armstrong, 2007[232] Pooled analysis	2mg qd vs. 4mg qd campaign	35/193	38/399	1.90 (1.24; 2.91)	0.09 (0.02; 0.15)	12 (7; 41)	86 (25; 148)
Xerophthalmia	Swift, 2003[382] RCT	4mg once daily vs. 2mg twice daily	16/417	8/408	1.96 (0.85; 4.52)	0.02 (0.00; 0.04)		
Xerophthalmia	Van Kerrebroeck, 2001[394] RCT	4mg once daily vs. 2mg once daily	17/507	12/514	1.44 (0.69; 2.98)	0.01 (-0.01; 0.03)		

Appendix Table F54. Clinical outcomes after tolterodine vs. placebo, the results from randomized controlled clinical trials pooled with random effects models

Drug	Outcome	Studies	Patients	Rate active/control	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)
Tolterodine	Continence	4[58,322,345,367]	3,404	53.2/43.7	1.2 (1.1; 1.4)	0.09 (0.04; 0.13)	12 (8; 25)
Tolterodine	Improvement in UI	8[290,305,327,366,372 58,322,475]	6,783	44.7/35.7	1.3 (1.2; 1.5)	0.11 (0.06; 0.16)	9 (6; 18)
Tolterodine	Treatment failure	7[58,290,305,327,366,367,475]	5,275	9.0/15.4	0.7 (0.5; 0.9)	-0.05 (-0.09; -0.01)	
Tolterodine	Adverse effects	12[58,226,259,265,283,316,318,320,329,345,362,367]	4,162	44.7/38.1	1.2 (1.1; 1.3)	0.08 (0.05; 0.11)	13 (9; 21)
Tolterodine	Serious adverse effects	5[58,283,346,349,394]	3,550	1.8/3.1	0.6 (0.4; 0.9)	-0.01 (-0.02; 0.00)	
Tolterodine	Discontinuation	10[54,58,259,265,283,284,327,365,394,475]	6,399	6.5/7.8	0.9 (0.8; 1.1)	-0.01 (-0.02; 0.00)	
Tolterodine	Discontinuation Adverse effects	13[54,58,226,259,283,284,305,316,322,329,346,362,475]	7,801	3.9/3.2	1.1 (0.8; 1.6)	0.01 (0.00; 0.02)	
Tolterodine	Discontinuation Treatment failure	5[54,58,305,329,475]	4,049	0.7/1.6	0.5 (0.2; 0.9)	-0.01 (-0.02; 0.00)	
Tolterodine	Autonomic nervous system disorders	3[283,318,349]	831	27.2/15.5	1.8 (1.3; 2.4)	0.11 (0.03; 0.19)	9 (5; 31)
Tolterodine	Blurred vision	2[54,265]	608	1.3/3.0	0.5 (0.2; 1.5)	-0.01 (-0.04; 0.01)	
Tolterodine	Constipation	15[54,58,259,265,284,305,316,318,322,329,346,362,367,382,394,475]	11,273	3.7/2.8	1.4 (1.2; 1.8)	0.01 (0.00; 0.02)	111 (67; 333)
Tolterodine	Diarrhea	6[58,329,346,382,394,475]	5,910	2.3/1.9	1.3 (0.9; 1.9)	0.01 (0.00; 0.01)	
Tolterodine	Dizziness	7[58,259,305,329,346,382,394]	6,084	1.6/1.5	1.1 (0.7; 1.7)	0.00 (0.00; 0.01)	
Tolterodine	Dry mouth	14[54,58,226,259,265,305,316,320,322,345,362,367,394,475]	7,637	18.4/6.7	2.6 (2.2; 3.2)	0.13 (0.10; 0.15)	8 (6; 10)
Tolterodine	Dry skin	2[382,394]	1,842	0.4/0.2	2.0 (0.4; 10.8)	0.00 (0.00; 0.01)	
Tolterodine	Dyspepsia	7[58,226,329,345,346,382,394]	5,374	2.8/1.5	1.8 (1.2; 2.8)	0.01 (0.00; 0.02)	71 (43; 250)
Tolterodine	Fatigue	4[58,259,305,394]	3,234	1.9/0.7	2.5 (1.2; 5.2)	0.01 (0.00; 0.02)	83 (45; 500)
Tolterodine	Flatulence	2[382,394]	1,842	1.9/1.6	1.2 (0.6; 2.4)	0.00 (-0.01; 0.02)	
Tolterodine	General body disorders	2[283,318]	308	22.3/18.6	1.2 (0.7; 2.1)	0.02 (-0.10; 0.15)	
Tolterodine	Headache	14[58,259,265,284,305,316,318,329,345,346,367,382,394,475]	9,474	4.4/3.5	1.3 (1.0; 1.6)	0.01 (0.00; 0.02)	91 (53; 500)
Tolterodine	Insomnia	3[367,382,394]	2,255	1.7/1.6	1.0 (0.4; 2.5)	0.00 (-0.01; 0.02)	
Tolterodine	Nasopharyngitis	6[58,259,260,305,367,372]	3,862	2.8/2.9	1.0 (0.7; 1.5)	0.00 (-0.01; 0.01)	
Tolterodine	Nausea	7[58,226,259,329,346,382,394]	5,642	1.6/2.0	0.8 (0.5; 1.1)	0.00 (-0.01; 0.01)	
Tolterodine	Somnolence	3[329,382,394]	2,696	1.8/1.6	1.4 (0.7; 2.5)	0.00 (-0.01; 0.01)	

Appendix Table F54. Clinical outcomes after tolterodine vs. placebo, the results from randomized controlled clinical trials pooled with random effects models (continued)

Drug	Outcome	Studies	Patients	Rate active/control	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)
Tolterodine	Urinary tract infection	7[58,318,329,367,382,394,475]	6,319	2.2/2.7	1.0 (0.6; 1.5)	0.00 (-0.01; 0.01)	
Tolterodine	Xerophthalmia	2[382,394]	1,842	3.6/2.0	1.8 (1.0; 3.2)	0.02 (0.00; 0.03)	63 (32; 1000)
Tolterodine	Abdominal pain	6[58,316,329,346,382,394]	5,194	2.8/1.7	1.7 (1.2; 2.5)	0.01 (0.00; 0.02)	91 (50; 1000)
Tolterodine	Abnormal vision	3[362,382,394]	1,968	1.4/0.8	1.5 (0.6; 3.7)	0.01 (0.00; 0.01)	

Appendix Table F55. Clinical outcomes after darifenacin vs. placebo in pooled analyses of individual patient data from RCTs (high level of evidence)

Studies, reference	Dose, mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat 95% CI)	Attributable events (95% CI)
≥7 consecutive dry days							
Chapple, 2005[262]	7.5	19/337	15/388	1.46 (0.75; 2.82	0.018 (-0.013; 0.049)		
Chapple, 2005[262]	15	24/334	16/388	1.74 (0.94; 3.22	0.031 (-0.003; 0.065)		
≥3 dry days/week							
Chapple, 2005[262]	7.5	55/337	43/388	1.47 (1.02; 2.13	0.052 (0.002; 0.103)	19 (10; 486)	52 (2; 103)
Chapple, 2005[262]	15	61/334	48/388	1.48 (1.04; 2.09	0.059 (0.006; 0.112)	17 (9; 164)	59 (6; 112)
Reduction in incontinence episodes: ≥50%							
Chapple, 2005[262]	7.5	222/337	202/388	1.27 (1.12; 1.43	0.138 (0.067; 0.209)	7 (5; 15)	138 (67; 209)
Chapple, 2005[262]	15	234/334	217/388	1.25 (1.12; 1.40	0.141 (0.072; 0.211)	7 (5; 14)	141 (72; 211)
Reduction in incontinence episodes: ≥70%							
Chapple, 2005[262]	7.5	162/337	128/388	1.46 (1.22; 1.74	0.151 (0.080; 0.222)	7 (5; 13)	151 (80; 222)
Chapple, 2005[262]	15	190/334	151/388	1.46 (1.25; 1.71	0.180 (0.108; 0.252)	6 (4; 9)	180 (108; 252)
Reduction in incontinence episodes: ≥90%							
Chapple, 2005[262]	7.5	91/337	66/388	1.59 (1.20; 2.10	0.100 (0.040; 0.160)	10 (6; 25)	100 (40; 160)
Chapple, 2005[262]	15	94/334	66/388	1.65 (1.25; 2.19	0.111 (0.050; 0.172)	9 (6; 20)	111 (50; 172)
Incontinence impact							
Abrams, 2008[50]	7.5	52/337	30/388	2.00 (1.30; 3.05	0.077 (0.030; 0.124)	13 (8; 33)	77 (30; 124)
Abrams, 2008[50]	15	46/334	30/388	1.78 (1.15; 2.75	0.060 (0.015; 0.106)	17 (9; 67)	60 (15; 106)
Severity measures							
Abrams, 2008[50]	7.5	47/337	27/388	2.00 (1.28; 3.14	0.070 (0.025; 0.115)	14 (9; 40)	70 (25; 115)
Abrams, 2008[50]	15	46/334	27/388	1.98 (1.26; 3.11	0.068 (0.023; 0.113)	15 (9; 43)	68 (23; 113)
Role limitations							
Abrams, 2008[50]	7.5	65/337	46/388	1.63 (1.15; 2.30	0.074 (0.021; 0.127)	13 (8; 47)	74 (21; 127)
Abrams, 2008[50]	15	59/334	46/388	1.49 (1.04; 2.13	0.058 (0.006; 0.110)	17 (9; 165)	58 (6; 110)

Appendix Table F55. Clinical outcomes after darifenacin vs. placebo in pooled analyses of individual patient data from RCTs (high level of evidence) (continued)

Studies, reference	Dose, mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat 95% CI)	Attributable events (95% CI)
Social limitations							
Abrams, 2008[50]	7.5	57/337	42/388	1.56 (1.08; 2.26	0.061 (0.010; 0.111)	16 (9; 97)	61 (10; 111)
Abrams, 2008[50]	15	54/334	42/388	1.49 (1.03; 2.17	0.053 0.003; 0.104)	19 (10; 305)	53 (3; 104)
Physical limitations							
Abrams, 2008[50]	7.5	58/337	49/388	1.36 (0.96; 1.94	0.046 (-0.006; 0.098)		
Abrams, 2008[50]	15	53/334	49/388	1.26 (0.88; 1.80	0.032 (-0.019; 0.084)		
Emotions							
Abrams, 2008[50]	7.5	56/337	44/388	1.47 (1.02; 2.11	0.053 (0.002; 0.104)	19 (10; 493)	53 (2; 104)
Abrams, 2008[50]	15	53/334	44/388	1.40 (0.96; 2.03	0.045 (-0.005; 0.096)		
Personal relationships							
Abrams, 2008[50]	7.5	24/337	20/388	1.38 (0.78; 2.46	0.020 (-0.016; 0.055)		
Abrams, 2008[50]	15	23/334	20/388	1.34 (0.75; 2.39	0.017 (-0.018; 0.052)		
Sleep/energy							
Abrams, 2008[50]	7.5	46/337	37/388	1.43 (0.95; 2.15	0.041 (-0.006; 0.088)		
Abrams, 2008[50]	15	46/334	37/388	1.44 (0.96; 2.17	0.042 (-0.005; 0.089)		
General health perception							
Abrams, 2008[50]	7.5	24/337	19/388	1.45 (0.81; 2.61	0.022 (-0.013; 0.057)		
Abrams, 2008[50]	15	21/334	19/388	1.28 (0.70; 2.35	0.014 (-0.020; 0.048)		
≥1 adverse effect							
Chapple, 2005[262]	7.5	182/337	189/388	1.11 (0.96; 1.28	0.053 (-0.020; 0.126)		
Chapple, 2005[262]	15	219/334	189/388	1.35 (1.18; 1.53	0.169 (0.097; 0.240)	6 (4; 10)	169 (97; 240)
Adverse effects of any cause							
Foote, 2005[288]	15	76/110	56/110	1.36 (1.09; 1.69	0.182 (0.055; 0.309)	5 (3; 18)	182 (55; 309)
Foote, 2005[288]	7.5	52/97	56/110	1.05 (0.81; 1.37	0.027 (-0.109; 0.163)		
Discontinued							
Chapple, 2005[262]	7.5	19/337	31/388	0.71 (0.41; 1.23	-0.024 (-0.060; 0.013)		
Chapple, 2005[262]	15	43/334	31/388	1.61 (1.04; 2.50	0.049 (0.004; 0.094)	20 (11; 255)	49 (4; 94)

Appendix Table F55. Clinical outcomes after darifenacin vs. placebo in pooled analyses of individual patient data from RCTs (high level of evidence) (continued)

Studies, reference	Dose, mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat 95% CI)	Attributable events (95% CI)
Adverse effects leading to discontinuation							
Chapple, 2005[262]	7.5	5/337	10/388	0.58 (0.20; 1.67	-0.011 (-0.031; 0.009)		
Chapple, 2005[262]	15	17/334	10/388	1.97 (0.92; 4.25	0.025 (-0.003; 0.053)		
Foote, 2005[288]	15	10/110	6/110	1.67 (0.63; 4.43	0.036 (-0.032; 0.105)		
Foote, 2005[288]	7.5	1/97	6/110	0.19 (0.02; 1.54	-0.044 (-0.091; 0.003)		
Reduction in incontinence episodes: ≥30%							
Chapple, 2005[262]	7.5	259/337	248/388	1.20 (1.09; 1.32	0.129 (0.064; 0.195)	8 (5; 16)	129 (64; 195)
Chapple, 2005[262]	15	274/334	264/388	1.21 (1.11; 1.31	0.140 (0.078; 0.202)	7 (5; 13)	140 (78; 202)
Abdominal pain							
Chapple, 2005[262]	7.5	8/337	2/388	4.61 (0.98; 21.54	0.019 (0.001; 0.036)	54 (28; 1194)	19 (1; 36)
Chapple, 2005[262]	15	13/334	2/388	7.55 (1.72; 33.22	0.034 (0.012; 0.056)	30 (18; 84)	34 (12; 56)
Back pain							
Chapple, 2005[262]	7.5	8/337	12/388	0.77 (0.32; 1.86	-0.007 (-0.031; 0.016)		
Chapple, 2005[262]	15	5/334	12/388	0.48 (0.17; 1.36	-0.016 (-0.038; 0.006)		
Cardiovascular system (total)							
Foote, 2005[288]	7.5	3/97	0/110	7.93 (0.41; 151.59	0.031 (-0.008; 0.070)		
Foote, 2005[288]	15	1/110	0/110	3.00 (0.12; 72.85	0.009 (-0.016; 0.034)		
Constipation							
Chapple, 2005[262]	7.5	50/337	24/388	2.40 (1.51; 3.82	0.087 (0.042; 0.131)	12 (8; 24)	87 (42; 131)
Chapple, 2005[262]	15	71/334	24/388	3.44 (2.22; 5.33	0.151 (0.101; 0.201)	7 (5; 10)	151 (101; 201)
Foote, 2005[288]	7.5	18/97	7/110	2.92 (1.27; 6.68	0.122 (0.032; 0.212)	8 (5; 31)	122 (32; 212)
Foote, 2005[288]	15	26/110	7/110	3.71 (1.68; 8.20	0.173 (0.081; 0.264)	6 (4; 12)	173 (81; 264)
Dry mouth							
Chapple, 2005[262]	7.5	68/337	32/388	2.45 (1.65; 3.63	0.119 (0.068; 0.170)	8 (6; 15)	119 (68; 170)
Chapple, 2005[262]	15	118/334	32/388	4.28 (2.98; 6.15	0.271 (0.213; 0.329)	4 (3; 5)	271 (213; 329)
Foote, 2005[288]	7.5	20/97	5/110	4.54 (1.77; 11.63	0.161 (0.071; 0.250)	6 (4; 14)	161 (71; 250)
Foote, 2005[288]	15	34/110	5/110	6.80 (2.76; 16.74	0.264 (0.169; 0.358)	4 (3; 6)	264 (169; 358)
Dyspepsia							
Chapple, 2005[262]	7.5	9/337	10/388	1.04 (0.43; 2.52	0.001 (-0.022; 0.024)		

Appendix Table F55. Clinical outcomes after darifenacin vs. placebo in pooled analyses of individual patient data from RCTs (high level of evidence) (continued)

Studies, reference	Dose, mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat 95% CI)	Attributable events (95% CI)
Chapple, 2005[262]	15	28/334	10/388	3.25 (1.60; 6.60	0.058 (0.024; 0.092)	17 (11; 41)	58 (24; 92)
Foote, 2005[288]	7.5	2/97	1/110	2.27 (0.21; 24.63	0.012 (-0.022; 0.045)		
Foote, 2005[288]	15	8/110	1/110	8.00 (1.02; 62.89	0.064 (0.012; 0.115)	16 (9; 84)	64 (12; 115)
Headache							
Chapple, 2005[262]	7.5	15/337	21/388	0.82 (0.43; 1.57	-0.010 (-0.041; 0.022)		
Chapple, 2005[262]	15	17/334	21/388	0.94 (0.50; 1.75	-0.003 (-0.036; 0.029)		
Foote, 2005[288]	7.5	0/97	2/110	0.23 (0.01; 4.66	-0.018 (-0.049; 0.013)		
Foote, 2005[288]	15	0/110	2/110	0.20 (0.01; 4.12	-0.018 (-0.048; 0.012)		
Nervous system (total)							
Foote, 2005[288]	7.5	2/97	2/110	1.13 (0.16; 7.90	0.002 (-0.035; 0.040)		
Foote, 2005[288]	15	2/110	2/110	1.00 (0.14; 6.97	0.000 (-0.035; 0.035)		
Respiratory tract information							
Chapple, 2005[262]	7.5	9/337	26/388	0.40 (0.19; 0.84	-0.040 (-0.071; -0.010)	-25 (-99; -14)	-40 (-71; -10)
Chapple, 2005[262]	15	17/334	26/388	0.76 (0.42; 1.38	-0.016 (-0.050; 0.018)		
UTI							
Chapple, 2005[262]	7.5	16/337	10/388	1.84 (0.85; 4.00	0.022 (-0.006; 0.049)		
Chapple, 2005[262]	15	15/334	10/388	1.74 (0.79; 3.83	0.019 (-0.008; 0.046)		

Appendix Table F56. Dose response association between clinical outcomes and darifenacin in pooled analyses of individual patient data from RCTs (high level of evidence)

Studies, reference	Active dose, mg/day	Control dose mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat 95% CI)	Attributable events (95% CI)
≥1 adverse effect								
Chapple, 2005[262]	7.5	15	182/337	219/334	0.82 (0.73; 0.93	-0.116 (-0.189; -0.042)	-9 (-24; -5)	-116 (-189; -42)
Adverse effects of any cause								
Foote, 2005[288]	7.5	15	52/97	76/110	0.78 (0.62; 0.97	-0.155 (-0.286; -0.023)	-6 (-43; -3)	-155 (-286; -23)
Discontinued								
Chapple, 2005[262]	7.5	15	19/337	43/334	0.44 (0.26; 0.74	-0.072 (-0.116; -0.029)	-14 (-35; -9)	-72 (-116; -29)
Adverse effects leading to discontinuation								
Foote, 2005[288]	7.5	15	1/97	10/110	0.11 (0.01; 0.87	-0.081 (-0.138; -0.023)	-12 (-43; -7)	-81 (-138; -23)
Adverse effects leading to discontinuation								
Chapple, 2005[262]	7.5	15	5/337	17/334	0.29 (0.11; 0.78	-0.036 (-0.063; -0.009)	-28 (-109; -16)	-36 (-63; -9)
Incontinence impact								
Abrams, 2008[50]	7.5	15	52/337	46/334	1.12 (0.78; 1.62	0.017 (-0.037; 0.070)		
Severity measures								
Abrams, 2008[50]	7.5	15	47/337	46/334	1.01 (0.69; 1.48	0.002 (-0.051; 0.054)		
Role limitations								
Abrams, 2008[50]	7.5	15	65/337	59/334	1.09 (0.79; 1.50	0.016 (-0.042; 0.075)		
Social limitations								
Abrams, 2008[50]	7.5	15	57/337	54/334	1.05 (0.74; 1.47	0.007 (-0.049; 0.064)		
Physical limitations								
Abrams, 2008[50]	7.5	15	58/337	53/334	1.08 (0.77; 1.52	0.013 (-0.043; 0.070)		
Emotions								
Abrams, 2008[50]	7.5	15	56/337	53/334	1.05 (0.74; 1.48	0.007 (-0.048; 0.063)		

Appendix Table F56. Dose response association between clinical outcomes and darifenacin in pooled analyses of individual patient data from RCTs (high level of evidence) (continued)

Studies, reference	Active dose, mg/day	Control dose mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat 95% CI)	Attributable events (95% CI)
Personal relationships								
Abrams, 2008[50]	7.5	15	24/337	23/334	1.03 (0.60; 1.80)	0.002 (-0.036; 0.041)		
Sleep/energy								
Abrams, 2008[50]	7.5	15	46/337	46/334	0.99 (0.68; 1.45)	-0.001 (-0.053; 0.051)		
General health perception								
Abrams, 2008[50]	7.5	15	24/337	21/334	1.13 (0.64; 1.99)	0.008 (-0.029; 0.046)		
Dry mouth								
Chapple, 2005[262]	7.5	15	68/337	118/334	0.57 (0.44; 0.74)	-0.152 (-0.218; -0.085)	-7 (-12; -5)	-152 (-218; -85)
Foote, 2005[288]	7.5	15	20/97	34/110	0.67 (0.41; 1.08)	-0.103 (-0.221; 0.015)		
Abdominal pain								
Chapple, 2005[262]	7.5	15	8/337	13/334	0.61 (0.26; 1.45)	-0.015 (-0.042; 0.011)		
Back pain								
Chapple, 2005[262]	7.5	15	8/337	5/334	1.59 (0.52; 4.80)	0.009 (-0.012; 0.030)		
Cardiovascular system (total)								
Foote, 2005[288]	7.5	15	3/97	1/110	3.40 (0.36; 32.17)	0.022 (-0.017; 0.061)		
Constipation								
Chapple, 2005[262]	7.5	15	50/337	71/334	0.70 (0.50; 0.97)	-0.064 (-0.122; -0.006)	-16 (-161; -8)	-64 (-122; -6)
Foote, 2005[288]	7.5	15	18/97	26/110	0.79 (0.46; 1.34)	-0.051 (-0.162; 0.060)		
Dyspepsia								
Chapple, 2005[262]	7.5	15	9/337	28/334	0.32 (0.15; 0.66)	-0.057 (-0.091; -0.023)	-18 (-44; -11)	-57 (-91; -23)
Foote, 2005[288]	7.5	15	2/97	8/110	0.28 (0.06; 1.30)	-0.052 (-0.108; 0.004)		
Headache								
Chapple, 2005[262]	7.5	15	15/337	17/334	0.87 (0.44; 1.72)	-0.006 (-0.039; 0.026)		
Foote, 2005[288]	7.5	15	0/97	0/110	0.00 (0.00; 0.00)	0.000 (-0.019; 0.019)		

Appendix Table F56. Dose response association between clinical outcomes and darifenacin in pooled analyses of individual patient data from RCTs (high level of evidence) (continued)

Studies, reference	Active dose, mg/day	Control dose mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat 95% CI)	Attributable events (95% CI)
Nervous system (total)								
Foote, 2005[288]	7.5	15	2/97	2/110	1.13 (0.16; 7.90)	0.002 (-0.035; 0.040)		
Respiratory tract information								
Chapple, 2005[262]	7.5	15	9/337	17/334	0.52 (0.24; 1.16	-0.024 (-0.053; 0.005)		
UTI								
Chapple, 2005[262]	7.5	15	16/337	15/334	1.06 (0.53; 2.10)	0.003 (-0.029; 0.034)		

Appendix Table F57. Significant dose response association with clinical outcomes after darifenacin (individual RCTs)

Studies, reference	Active dose, mg/day	Control dose mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat 95% CI)	Attributable events (95% CI)
Adverse effects								
Hill, 2006[44]	7.5	30	62/108	92/115	0.72 (0.60; 0.86)	-0.23 (-0.34; -0.11)	-4 (-9; -3)	-226 (-344; -107)
Withdrawals: adverse effects								
Hill, 2006[44]	15	30	73/107	92/115	0.85 (0.73; 1.00)	-0.12 (-0.23; 0.00)	-8 (-314; -4)	-118 (-232; -3)
Hill, 2006[44]	7.5	30	2/108	13/115	0.16 (0.04; 0.71)	-0.09 (-0.16; -0.03)	-11 (-32; -6)	-95 (-158; -31)
Chancellor, 2008[256]	7	15	21/205	6/190	3.24(1.34; 7.86)	0.07(0.02; 0.12)	14(8; 44)	71(22; 119)
Withdrawals due to lack of response								
Hill, 2006[44]	7.5	15	1/108	2/107	0.50 (0.05; 5.38)	-0.01 (-0.04; 0.02)		
Hill, 2006[44]	7.5	30	1/108	1/115	1.06 (0.07; 16.81)	0.00 (-0.02; 0.03)		
Hill, 2006[44]	15	30	2/107	1/115	2.15 (0.20; 23.36)	0.01 (-0.02; 0.04)		
Constipation								
Steers, 2005[45]	7.5	15	32/108	24/160	1.98 (1.24; 3.16)	0.15 (0.04; 0.25)	7 (4; 23)	146 (44; 249)
Hill, 2006[44]	7.5	30	17/108	32/115	0.57 (0.33; 0.96)	-0.12 (-0.23; -0.01)	-8 (-72; -4)	-121 (-228; -14)
Chapple, 2004[473]	15	30	2/53	33/229	0.26 (0.06; 1.06)	-0.11 (-0.17; -0.04)	-9 (-26; -6)	-106 (-175; -38)
Chapple, 2004[473]	15	60	2/53	16/115	0.27 (0.06; 1.14)	-0.10 (-0.18; -0.02)	-10 (-50; -5)	-101 (-183; -20)
Dry mouth								
Steers, 2005[45]	7.5	15	28/108	22/160	1.89 (1.14; 3.12)	0.12 (0.02; 0.22)	8 (5; 43)	122 (23; 220)
Hill, 2006[44]	7.5	15	25/108	43/107	0.58 (0.38; 0.87)	-0.17 (-0.29; -0.05)	-6 (-21; -3)	-170 (-293; -48)
Hill, 2006[44]	7.5	30	25/108	68/115	0.39 (0.27; 0.57)	-0.36 (-0.48; -0.24)	-3 (-4; -2)	-360 (-480; -240)
Hill, 2006[44]	15	30	43/107	68/115	0.68 (0.52; 0.90)	-0.19 (-0.32; -0.06)	-5 (-17; -3)	-189 (-319; -60)
Chapple, 2004[473]	15	60	7/53	36/115	0.42 (0.20; 0.89)	-0.18 (-0.31; -0.06)	-6 (-18; -3)	-181 (-305; -57)
Chapple, 2004[473]	30	60	43/229	36/115	0.60 (0.41; 0.88)	-0.13 (-0.22; -0.03)	-8 (-38; -4)	-125 (-224; -27)
Dyspepsia								
Chapple, 2004[473]	30	60	4/229	9/115	0.22 (0.07; 0.71)	-0.06 (-0.11; -0.01)	-16 (-113; -9)	-61 (-113; -9)
Headache								
Steers, 2005[45]	7.5	15	13/108	5/160	3.85 (1.41; 10.49)	0.09 (0.02; 0.16)	11 (6; 45)	89 (22; 156)
Respiratory tract infection								
Hill, 2006[44]	15	30	6/107	1/115	6.45 (0.79; 52.69)	0.05 (0.00; 0.09)	21 (11; 1665)	47 (1; 94)

Appendix Table F57. Significant dose response association with clinical outcomes after darifenacin (individual RCTs) (continued)

Studies, reference	Active dose, mg/day	Control dose mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat 95% CI)	Attributable events (95% CI)
Urinary tract disorder								
Hill, 2006[44]	7.5	15	0/108	6/107	0.08 (0.00; 1.34)	-0.06 (-0.10; -0.01)	-18 (-106; -10)	-56 (-103; -9)

Appendix Table F58. Clinical outcomes after solifenacin vs. placebo, pooled individual patient data from RCTs (high level of evidence)

Outcome	Reference	Dose, mg/day	Number of subjects	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Complete continence	Cardozo, 2006[250]	5.00	1,095	1.50 (1.29; 1.73)	0.17 (0.10; 0.23)	6 (4; 10)	169 (104; 233)
Complete continence	Cardozo, 2006[250]	10.00	1,559	1.53 (1.36; 1.72)	0.18 (0.13; 0.23)	6 (4; 8)	180 (132; 228)
Complete continence	Staskin, 2006[39]	5.00	589	1.09 (0.82; 1.43)	0.02 (-0.06; 0.11)		
Complete continence	Staskin, 2006[39]	10.00	882	1.43 (1.19; 1.73)	0.12 (0.06; 0.19)	8 (5; 16)	123 (61; 186)
Discontinued treatment due to adverse effects	Cardozo, 2006[250]	5.00	1,095	0.87 (0.48; 1.58)	-0.01 (-0.03; 0.02)		
Discontinued treatment due to adverse effects	Cardozo, 2006[250]	10.00	1,559	1.28 (0.86; 1.91)	0.01 (-0.01; 0.04)		
Discontinued treatment due to adverse effects	Staskin, 2006[39]	5.00	589	0.57 (0.20; 1.65)	-0.02 (-0.05; 0.01)		
Discontinued treatment due to adverse effects	Staskin, 2006[39]	10.00	882	1.55 (0.89; 2.71)	0.02 (-0.01; 0.06)		
Blurred vision	Staskin, 2006[39]	5.00	1,794	2.10 (1.17; 3.77)	0.02 (0.00; 0.04)	50 (27; 375)	20 (3; 37)
Blurred vision	Staskin, 2006[39]	10.00	2,449	2.64 (1.63; 4.29)	0.03 (0.02; 0.04)	34 (23; 64)	30 (16; 44)
Blurred vision	Cardozo, 2006[250]	5.00	1,095	2.31 (1.10; 4.86)	0.02 (0.00; 0.05)		
Blurred vision	Cardozo, 2006[250]	10.00	1,559	2.58 (1.40; 4.75)	0.03 (0.01; 0.05)	35 (22; 92)	28 (11; 46)
Mild blurred vision	Cardozo, 2006[250]	5.00	1,150	1.94 (0.86; 4.37)	0.02 (-0.01; 0.04)		
Mild blurred vision	Cardozo, 2006[250]	10.00	1,643	2.01 (1.04; 3.88)	0.02 (0.00; 0.03)	63 (33; 833)	16 (1; 31)
Moderate blurred vision	Cardozo, 2006[250]	5.00	1,150	2.52 (0.36; 17.79)	0.00 (-0.01; 0.01)		
Moderate blurred vision	Cardozo, 2006[250]	10.00	1,643	4.01 (0.86; 18.85)	0.01 (0.00; 0.02)		
Severe blurred vision	Cardozo, 2006[250]	5.00	1,150	7.54 (0.31; 184.53)	0.00 (-0.00; 0.01)		
Severe blurred vision	Cardozo, 2006[250]	10.00	1,643	9.03 (0.49; 167.51)	0.01 (0.00; 0.01)		
Constipation	Staskin, 2006[39]	5.00	1,794	1.86 (1.16; 2.99)	0.03 (0.00; 0.05)	40 (22; 237)	25 (4; 45)
Constipation	Staskin, 2006[39]	10.00	2,449	4.65 (3.26; 6.64)	0.11 (0.08; 0.13)	10 (8; 12)	105 (84; 126)
Constipation	Cardozo, 2006[250]	5.00	1,095	1.78 (1.02; 3.11)	0.03 (-0.00; 0.06)		
Constipation	Cardozo, 2006[250]	10.00	1,559	3.91 (2.61; 5.85)	0.10 (0.08; 0.13)	10 (8; 13)	104 (77; 132)
Mild constipation	Cardozo, 2006[250]	5.00	1,150	1.99 (1.02; 3.86)	0.02 (-0.00; 0.05)		
Mild constipation	Cardozo, 2006[250]	10.00	1,643	2.69 (1.61; 4.52)	0.039 (0.020; 0.059)	26 (17; 51)	39 (20; 59)
Moderate constipation	Cardozo, 2006[250]	5.00	1,150	1.14 (0.40; 3.27)	0.00 (-0.01; 0.02)		
Moderate constipation	Cardozo, 2006[250]	10.00	1,643	4.84 (2.54; 9.19)	0.05 (0.03; 0.07)	20 (14; 31)	51 (33; 70)
Severe constipation	Cardozo, 2006[250]	5.00	1,150	7.54 (0.31; 184.53)	0.00 (-0.00; 0.01)		
Severe constipation	Cardozo, 2006[250]	10.00	1,643	23.08 (1.36; 391.08)	0.01 (0.01; 0.02)	75 (46; 192)	13 (5; 22)
Dry mouth	Staskin, 2006[39]	5.00	1,794	2.60 (1.82; 3.71)	0.07 (0.04; 0.10)	15 (11; 25)	67 (39; 95)
Dry mouth	Staskin, 2006[39]	10.00	2,449	6.57 (4.95; 8.73)	0.23 (0.21; 0.26)	4 (4; 5)	234 (206; 261)
Dry mouth	Cardozo, 2006[250]	5.00	1,095	2.49 (1.59; 3.90)	0.07 (0.03; 0.10)	15 (10; 35)	67 (29; 104)

Appendix Table F58. Clinical outcomes after solifenacin vs. placebo, pooled individual patient data from RCTs (high level of evidence) (continued)

Outcome	Reference	Dose, mg/day	Number of subjects	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Dry mouth	Cardozo, 2006[250]	10.00	1,559	6.48 (4.60; 9.12)	0.25 (0.21; 0.28)	4 (4; 5)	246 (211; 281)
Mild dry mouth	Cardozo, 2006[250]	5.00	1,150	2.92 (1.74; 4.91)	0.06 (0.03; 0.09)	17 (11; 39)	58 (25; 91)
Mild dry mouth	Cardozo, 2006[250]	10.00	1,643	6.18 (4.10; 9.33)	0.16 (0.13; 0.19)	6 (5; 8)	157 (128; 187)
Moderate dry mouth	Cardozo, 2006[250]	5.00	1,150	1.60 (0.63; 4.10)	0.01 (-0.01; 0.03)		
Moderate dry mouth	Cardozo, 2006[250]	10.00	1,643	6.30 (3.36; 11.81)	0.07 (0.05; 0.09)	14 (11; 20)	71 (50; 91)
Severe dry mouth	Cardozo, 2006[250]	5.00	1,150	0.84 (0.03; 20.50)	-0.00 (-0.01; 0.00)		
Severe dry mouth	Cardozo, 2006[250]	10.00	1,643	16.06 (2.13; 120.81)	0.02 (0.01; 0.03)	55 (36; 117)	18 (9; 28)

Appendix Table F59. Evidence of dose response association in clinical outcomes after solifenacin 5 vs.10mg/day (pooled individual patient data from RCTs)

Outcome	Reference	Number of subjects	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Continence	Staskin, 2006[39]	611	0.76 (0.58; 0.98)	-0.10 (-0.18; -0.01)	-10 (-71; -5)	-99 (-184; -14)
Continence	Cardozo, 2006[250]	1092	0.98 (0.86; 1.11)			
Discontinued treatment due to adverse effects	Cardozo, 2006[250]	1092	0.68 (0.38; 1.21)			
Discontinued treatment due to adverse effects	Staskin, 2006[39]	611	0.37 (0.13; 1.02)	-0.04 (-0.08; -0.01)	-23 (-103; -13)	-43 (-77; -10)
Dry mouth	Cardozo, 2006[250]	1092	0.38 (0.28; 0.53)	-0.18 (-0.23; -0.13)	-6 (-8; -4)	-179 (-226; -132)
Dry mouth	Staskin, 2006[39]	1811	0.40 (0.31; 0.51)	-0.17 (-0.20; -0.13)	-6 (-8; -5)	-167 (-202; -131)
Mild dry mouth	Cardozo, 2006[250]	1147	0.47 (0.32; 0.69)	-0.10 (-0.14; -0.06)	-10 (-17; -7)	-99 (-140; -58)
Moderate dry mouth	Cardozo, 2006[250]	1147	0.25 (0.12; 0.55)	-0.06 (-0.09; -0.04)	-16 (-26; -11)	-63 (-87; -38)
Severe dry mouth	Cardozo, 2006[250]	1147	0.08 (0.00; 1.26)	-0.02 (-0.03; -0.01)	-51 (-111; -33)	-20 (-30; -9)
Blurred vision	Cardozo, 2006[250]	1092	0.89 (0.48; 1.66)			
Blurred vision	Staskin, 2006[39]	1811	0.80 (0.49; 1.28)			
Mild blurred vision	Cardozo, 2006[250]	1147	0.96 (0.47; 1.98)			
Moderate blurred vision	Cardozo, 2006[250]	1147	0.63 (0.13; 2.94)			
Severe blurred vision	Cardozo, 2006[250]	1147	0.63 (0.07; 5.59)			
Constipation	Cardozo, 2006[250]	1092	0.45 (0.29; 0.72)	-0.08 (-0.11; -0.04)	-13 (-25; -9)	-76 (-113; -40)
Constipation	Staskin, 2006[39]	1811	0.40 (0.28; 0.58)	-0.08 (-0.11; -0.05)	-12 (-19; -9)	-80 (-107; -54)
Mild constipation	Cardozo, 2006[250]	1147	0.74 (0.42; 1.29)	-0.02 (-0.04; 0.01)		
Moderate constipation	Cardozo, 2006[250]	1147	0.24 (0.10; 0.59)	-0.05 (-0.07; -0.03)	-20 (-36; -14)	-49 (-71; -28)
Severe constipation	Cardozo, 2006[250]	1147	0.23 (0.03; 1.76)	-0.01 (-0.02; 0.00)		

Appendix Table F60. Results from VIBRANT trial[395]

Outcome	Dose	Relative risk 95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
BSW: benefit-much	5 -10mg daily	1.78 (1.48; 2.14)	0.222 (0.155; 0.290)	4 (3; 6)	222 (155; 290)
BSW: satisfaction-yes	5 -10mg daily	1.42 (1.26; 1.61)	0.207 (0.139; 0.275)	5 (4; 7)	207 (139; 275)
BSW: willingness to continue-yes	5 -10mg daily	1.39 (1.23; 1.57)	0.192 (0.123; 0.260)	5 (4; 8)	192 (123; 260)
PPBC score: None	5 -10mg daily	1.32 (0.88; 1.98)	0.030 (-0.014; 0.074)		
PPBC score: Very minor	5 -10mg daily	1.46 (1.10; 1.94)	0.079 (0.021; 0.136)	13 (7; 47)	79 (21; 136)
Discontinuation	10mg daily	0.84 (0.39; 1.81)	-0.011 (-0.057; 0.036)		
	5mg daily	0.63 (0.27; 1.46)	-0.031 (-0.089; 0.027)		
BSW: benefit-little	5 -10mg daily	0.88 (0.67; 1.15)	-0.028 (-0.087; 0.030)		
BSW: benefit-none	5 -10mg daily	0.46 (0.34; 0.61)	-0.164 (-0.221; -0.106)	-6 (-9; -5)	-164 (-221; -106)
BSW: satisfaction-no	5 -10mg daily	0.51 (0.39; 0.66)	-0.167 (-0.227; -0.106)	-6 (-9; -4)	-167 (-227; -106)
BSW: willingness to continue-no	5 -10mg daily	0.55 (0.43; 0.71)	-0.151 (-0.212; -0.090)	-7 (-11; -5)	-151 (-212; -90)
PPBC score: Severe	5 -10mg daily	0.42 (0.27; 0.64)	-0.095 (-0.140; -0.050)	-11 (-20; -7)	-95 (-140; -50)
PPBC score: Many severe	5 -10mg daily	0.78 (0.36; 1.69)	-0.008 (-0.033; 0.017)		
Dry mouth	5 -10mg daily	5.61 (2.80; 11.23)	0.109 (0.072; 0.146)	9 (7; 14)	109 (72; 146)
Constipation	5 -10mg daily	4.38 (1.95; 9.83)	0.062 (0.032; 0.092)	16 (11; 32)	62 (32; 92)
Dry eye	5 -10mg daily	5.94 (0.72; 49.09)	0.013 (0.000; 0.026)		
Dyspepsia	5 -10mg daily	10.89 (0.60; 196.20)	0.013 (0.001; 0.025)	77 (40; 1616)	13 (1; 25)
Fatigue	5 -10mg daily	2.47 (0.48; 12.67)	0.008 (-0.006; 0.021)		
Nausea	5 -10mg daily	0.66 (0.19; 2.32)	-0.005 (-0.021; 0.011)		
Blurred vision	5 -10mg daily	0.79 (0.21; 2.93)	-0.003 (-0.018; 0.013)		
Headache	5 -10mg daily	0.59 (0.14; 2.47)	-0.005 (-0.020; 0.009)		

Appendix Table F61. Clinical outcomes after fesoterodine vs. placebo, secondary data from post hoc and pooled analyses

Outcome	Reference daily dose mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Response to treatment	Sand, 2009[372] 4 mg/day	251/434	167/430	1.49 (1.29; 1.72)	0.190 (0.125; 0.255)	5 (4; 8)	190 (125; 255)
Response to treatment	Sand, 2009[372] 8 mg/day	291/452	167/430	1.66 (1.45; 1.90)	0.255 (0.192; 0.319)	4 (3; 5)	255 (192; 319)
Discontinuation	Sand, 2009[372] 8 mg/day	14/287	6/283	2.30 (0.90; 5.90)	0.028 (-0.002; 0.058)		
Discontinuation due to adverse effects	Khullar, 2008[330] 4 mg/day	27/554	19/554	1.42 (0.80; 2.53)	0.014 (-0.009; 0.038)		
Discontinuation due to adverse effects	Khullar, 2008[330] 8 mg/day	41/566	19/554	2.11 (1.24; 3.59)	0.038 (0.012; 0.064)	26 (16; 84)	38 (12; 64)
Back pain	Sand, 2009[372]mg/day	9/434	1/430	8.92 (1.13; 70.08)	0.018 (0.004; 0.033)	54 (31; 235)	18 (4; 33)
Back pain	Sand, 2009[372] 8 mg/day	4/421	1/430	4.09 (0.46; 36.40)	0.007 (-0.003; 0.018)		
Constipation	Sand, 2009[372] 4 mg/day	20/434	10/430	1.98 (0.94; 4.18)	0.023 (-0.002; 0.047)		
Constipation	Khullar, 2008[330] 4 mg/day	23/554	11/554	2.09 (1.03; 4.25)	0.022 (0.001; 0.042)	46 (24; 719)	22 (1; 42)
Constipation	Chapple, 2008[260] 8 mg/day	13/287	4/283	3.20 (1.06; 9.71)	0.031 (0.003; 0.059)	32 (17; 290)	31 (3; 59)
Constipation	Sand, 2009[372] 4 mg/day	24/421	10/430	2.45 (1.19; 5.06)	0.034 (0.007; 0.060)	30 (17; 135)	34 (7; 60)
Constipation	Khullar, 2008[330] 8 mg/day	34/566	11/554	3.03 (1.55; 5.91)	0.040 (0.017; 0.063)	25 (16; 57)	40 (17; 63)
Cough	Sand, 2009[372] 4 mg/day	7/434	3/430	2.31 (0.60; 8.88)	0.009 (-0.005; 0.023)		
Cough	Sand, 2009[372] 4 mg/day	5/421	3/430	1.70 (0.41; 7.08)	0.005 (-0.008; 0.018)		
Diarrhea	Sand, 2009[372] 4 mg/day	7/434	10/430	0.69 (0.27; 1.81)	-0.007 (-0.026; 0.011)		
Diarrhea	Sand, 2009[372] 4 mg/day	6/421	10/430	0.61 (0.22; 1.67)	-0.009 (-0.027; 0.009)		
Dizziness	Sand, 2009[372] 4 mg/day	4/434	9/430	0.44 (0.14; 1.42)	-0.012 (-0.028; 0.005)		
Dizziness	Sand, 2009[372] 4 mg/day	5/421	9/430	0.57 (0.19; 1.68)	-0.009 (-0.026; 0.008)		

Appendix Table F61. Clinical outcomes after fesoterodine vs. placebo, secondary data from post hoc and pooled analyses (continued)

Outcome	Reference daily dose mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Dry eye	Sand,2009[372] 4 mg/day	6/434	0/430	12.88 (0.73; 227.94)	0.014 (0.002; 0.026)		
Dry eye	Chapple, 2008[260] 8 mg/day	12/287	0/283	24.65 (1.47; 414.40)	0.042 (0.018; 0.066)	24 (15; 56)	42 (18; 66)
Dry eye	Sand, 2009[372] 4 mg/day	10/421	0/430	21.45 (1.26; 364.85)	0.024 (0.009; 0.039)	42 (26; 117)	24 (9; 39)
Dry mouth	Sand, 2009[372] 4 mg/day	89/434	32/430	2.76 (1.88; 4.03)	0.131 (0.085; 0.176)	8 (6; 12)	131 (85; 176)
Dry mouth	Khullar, 2008[330] 4 mg/day	104/554	39/554	2.67 (1.88; 3.78)	0.117 (0.078; 0.156)	9 (6; 13)	117 (78; 156)
Dry mouth	Chapple, 2008[260] 8 mg/day	97/287	20/283	4.78 (3.04; 7.52)	0.267 (0.205; 0.330)	4 (3; 5)	267 (205; 330)
Dry mouth	Sand, 2009[372] 4 mg/day	155/421	32/430	4.95 (3.47; 7.06)	0.294 (0.241; 0.346)	3 (3; 4)	294 (241; 346)
Dry mouth	Khullar, 2008[330] 8 mg/day	196/566	39/554	4.92 (3.56; 6.80)	0.276 (0.231; 0.321)	4 (3; 4)	276 (231; 321)
Dry throat	Sand, 2009[372] 4 mg/day	4/434	0/430	8.92 (0.48; 165.12)	0.009 (-0.001; 0.019)		
Dry throat	Khullar, 2008[330] 4 mg/day	5/554	2/554	2.50 (0.49; 12.83)	0.005 (-0.004; 0.015)		
Dry throat	Chapple, 2008[260] 8 mg/day	8/287	0/283	16.76 (0.97; 289.07)	0.028 (0.008; 0.048)	36 (21; 129)	28 (8; 48)
Dry throat	Sand, 2009[372] 4 mg/day	10/421	0/430	21.45 (1.26; 364.85)	0.024 (0.009; 0.039)	42 (26; 117)	24 (9; 39)
Dry throat	Khullar, 2008[330] 8 mg/day	13/566	2/554	6.36 (1.44; 28.06)	0.019 (0.006; 0.033)	52 (31; 165)	19 (6; 33)
Dyspepsia	Khullar, 2008[330] 4 mg/day	9/554	3/554	3.00 (0.82; 11.02)	0.011 (-0.001; 0.023)		
Dyspepsia	Khullar, 2008[330] 8 mg/day	13/566	3/554	4.24 (1.22; 14.80)	0.018 (0.004; 0.031)		
Fatigue	Sand, 2009[372] 4 mg/day	5/434	2/430	2.48 (0.48; 12.70)	0.007 (-0.005; 0.019)		
Fatigue	Chapple, 2008[260] 8 mg/day	1/287	1/283	0.99 (0.06; 15.69)	0.000 (-0.010; 0.010)		
Fatigue	Sand, 2009[372] 4 mg/day	1/421	2/430	0.51 (0.05; 5.61)	-0.002 (-0.010; 0.006)		

Appendix Table F61. Clinical outcomes after fesoterodine vs. placebo, secondary data from post hoc and pooled analyses (continued)

Outcome	Reference daily dose mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Headache	Sand, 2009[372] 4 mg/day	21/434	18/430	1.16 (0.62; 2.14)	0.007 (-0.021; 0.034)		
Headache	Khullar, 2008[330] 4 mg/day	24/554	23/554	1.04 (0.60; 1.83)	0.002 (-0.022; 0.026)		
Headache	Sand, 2009[372] 4 mg/day	13/421	18/430	0.74 (0.37; 1.49)	-0.011 (-0.036; 0.014)		
Headache	Khullar, 2008[330] 8 mg/day	15/566	23/554	0.64 (0.34; 1.21)	-0.015 (-0.036; 0.006)		
Increased alanine aminotransferase	Chapple, 2008[260] 8 mg/day	6/287	1/283	5.92 (0.72; 48.83)	0.017 (-0.001; 0.035)		
Lacrimal disorder	Khullar, 2008[330] 4 mg/day	8/554	0/554	17.00 (0.98; 293.82)	0.014 (0.004; 0.025)	69 (40; 255)	14 (4; 25)
Lacrimal disorder	Khullar, 2008[330] 8 mg/day	21/566	0/554	42.09 (2.56; 693.13)	0.037 (0.021; 0.053)	27 (19; 47)	37 (21; 53)
Mild-constipation	Khullar, 2008[330] 4 mg/day	8/554	1/554	8.00 (1.00; 63.75)	0.013 (0.002; 0.023)	79 (43; 478)	13 (2; 23)
Mild-constipation	Khullar, 2008[330] 4 mg/day	14/554	8/554	1.75 (0.74; 4.14)	0.011 (-0.006; 0.027)		
Mild-constipation	Khullar, 2008[330] 8 mg/day	14/566	1/554	13.70 (1.81; 103.86)	0.023 (0.010; 0.036)	44 (28; 104)	23 (10; 36)
Mild-constipation	Khullar, 2008[330] 8 mg/day	18/566	8/554	2.20 (0.97; 5.02)	0.017 (0.000; 0.035)		
Mild-dry mouth	Khullar, 2008[330] 4 mg/day	16/554	11/554	1.45 (0.68; 3.11)	0.009 (-0.009; 0.027)		
Mild-dry mouth	Khullar, 2008[330] 4 mg/day	84/554	27/554	3.11 (2.05; 4.72)	0.103 (0.068; 0.138)	10 (7; 15)	103 (68; 138)
Mild-dry mouth	Khullar, 2008[330] 8 mg/day	53/566	11/554	4.72 (2.49; 8.93)	0.074 (0.047; 0.100)	14 (10; 21)	74 (47; 100)
Mild-dry mouth	Khullar, 2008[330] 8 mg/day	126/566	27/554	4.57 (3.07; 6.81)	0.174 (0.135; 0.213)	6 (5; 7)	174 (135; 213)
Mild-headache	Khullar, 2008[330] 4 mg/day	6/554	3/554	2.00 (0.50; 7.96)	0.005 (-0.005; 0.016)		
Mild-headache	Khullar, 2008[330] 4 mg/day	15/554	19/554	0.79 (0.41; 1.54)	-0.007 (-0.028; 0.013)		

Appendix Table F61. Clinical outcomes after fesoterodine vs. placebo, secondary data from post hoc and pooled analyses (continued)

Outcome	Reference daily dose mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Mild-headache	Khullar, 2008[330] 8 mg/day	5/566	3/554	1.63 (0.39; 6.79)	0.003 (-0.006; 0.013)		
Mild-headache	Khullar, 2008[330] 8 mg/day	9/566	19/554	0.46 (0.21; 1.02)	-0.018 (-0.037; 0.000)		
Mild-urinary tract infection	Khullar, 2008[330] 4 mg/day	7/554	5/554	1.40 (0.45; 4.38)	0.004 (-0.009; 0.016)		
Mild-urinary tract infection	Khullar, 2008[330] 4 mg/day	11/554	12/554	0.92 (0.41; 2.06)	-0.002 (-0.019; 0.015)		
Mild-urinary tract infection	Khullar, 2008[330] 8 mg/day	8/566	5/554	1.57 (0.52; 4.76)	0.005 (-0.007; 0.018)		
Mild-urinary tract infection	Khullar, 2008[330] 8 mg/day	15/566	12/554	1.22 (0.58; 2.59)	0.005 (-0.013; 0.023)		
Nasopharyngitis	Sand, Morrow, 2009[372] 4 mg/day	14/434	12/430	1.16 (0.54; 2.47)	0.004 (-0.018; 0.027)		
Nasopharyngitis	Khullar, 2008[330] 4 mg/day	18/554	14/554	1.29 (0.65; 2.56)	0.007 (-0.012; 0.027)		
Nasopharyngitis	Chapple, 2008[260] 8 mg/day	5/287	7/283	0.70 (0.23; 2.19)	-0.007 (-0.031; 0.016)		
Nasopharyngitis	Sand, 2009[372] 4 mg/day	6/421	12/430	0.51 (0.19; 1.35)	-0.014 (-0.033; 0.006)		
Nasopharyngitis	Khullar, 2008[330] 8 mg/day	7/566	14/554	0.49 (0.20; 1.20)	-0.013 (-0.029; 0.003)		
Nausea	Sand, 2009[372] 4 mg/day	4/434	5/430	0.79 (0.21; 2.93)	-0.002 (-0.016; 0.011)		
Nausea	Chapple, 2008[260] 8 mg/day	4/287	1/283	3.94 (0.44; 35.07)	0.010 (-0.005; 0.026)		
Nausea	Sand, 2009[372] 4 mg/day	11/421	5/430	2.25 (0.79; 6.41)	0.015 (-0.004; 0.033)		
Severe-constipation	Khullar, 2008[330] 4 mg/day	1/554	2/554	0.50 (0.05; 5.50)	-0.002 (-0.008; 0.004)		
Severe-constipation	Khullar, 2008[330] 8 mg/day	2/566	2/554	0.98 (0.14; 6.92)	0.000 (-0.007; 0.007)		
Severe-dry mouth	Khullar, 2008[330] 4 mg/day	4/554	1/554	4.00 (0.45; 35.67)	0.005 (-0.002; 0.013)		

Appendix Table F61. Clinical outcomes after fesoterodine vs. placebo, secondary data from post hoc and pooled analyses (continued)

Outcome	Reference daily dose mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Severe-dry mouth	Khullar, 2008[330] 8 mg/day	17/566	1/554	16.64 (2.22; 124.61)	0.028 (0.014; 0.043)	35 (23; 73)	28 (14; 43)
Severe-headache	Khullar, 2008[330] 4 mg/day	3/554	1/554	3.00 (0.31; 28.75)	0.004 (-0.003; 0.011)		
Severe-headache	Khullar, 2008[330] 8 mg/day	1/566	1/554	0.98 (0.06; 15.61)	0.000 (-0.005; 0.005)		
Severe-urinary tract infection	Khullar, 2008[330] 4 mg/day	0/554	0/554	0.00 (0.00; 0.00)	0.000 (-0.004; 0.004)		
Severe-urinary tract infection	Khullar, 2008[330] 8 mg/day	1/566	0/554	2.94 (0.12; 71.93)	0.002 (-0.003; 0.007)		
Upper respiratory tract infection	Sand, 2009[372] 4 mg/day	12/434	9/430	1.32 (0.56; 3.10)	0.007 (-0.014; 0.027)		
Upper respiratory tract infection	Khullar,2008[330] 4 mg/day	14/554	12/554	1.17 (0.54; 2.50)	0.004 (-0.014; 0.021)		
Upper respiratory tract infection	Sand, 2009[372] 4 mg/day	8/421	9/430	0.91 (0.35; 2.33)	-0.002 (-0.021; 0.017)		
Upper respiratory tract infection	Khullar, 2008[330] 8 mg/day	10/566	12/554	0.82 (0.36; 1.87)	-0.004 (-0.020; 0.012)		
Urinary tract infection	Sand, 2009[372] 4 mg/day	18/434	17/430	1.05 (0.55; 2.01)	0.002 (-0.024; 0.028)		
Urinary tract infection	Khullar, 2008[330] 4 mg/day	18/554	17/554	1.06 (0.55; 2.03)	0.002 (-0.019; 0.022)		
Urinary tract infection	Sand, 2009[372] 4 mg/day	24/421	17/430	1.44 (0.79; 2.64)	0.017 (-0.011; 0.046)		
Urinary tract infection	Khullar, 2008[330] 8 mg/day	24/566	17/554	1.38 (0.75; 2.54)	0.012 (-0.010; 0.034)		

Appendix Table F62. Significant dose response effects of fesoterodine

Reference	Dose, mg/ day	Outcome	Relative risk 95% CI)	Absolute risk difference 95%CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Chapple, 2007[259]	8 vs.4	Any adverse event	1.17 (1.00; 1.36)	0.084 (0.001; 0.166)	12 (6; 836)	84 (1; 166)
Nitti, 2007[353]	8 vs.4	Any adverse event	1.14 (1.01; 1.29)	0.088 (0.009; 0.166)	11 (6;112)	88 (9; 166)
Nitti, 2007[353]	8 vs.4	Dry eye	4.56 (1.00; 20.94)	0.025 (0.002; 0.048)	40 (21; 439)	25 (2; 48)
Chapple, 2007[259]	8 vs.4	Dry mouth	1.55 (1.18; 2.05)	0.120 (0.047; 0.193)	8 (5; 21)	120 (47; 193)
Nitti, 2007[353]	8 vs.4	Dry mouth	2.23 (1.63; 3.05)	0.196 (0.125; 0.266)	5 (4; 8)	196 (125; 266)
Chapple, 2007[259]	8 vs.4	Dry throat	7.56 (0.95; 60.01)	0.024 (0.004; 0.044)	41 (23; 263)	24 (4; 44)
Nitti, 2007[353]	8 vs.4	Hyper-tension	0.07 (0.00; 1.18)	-0.025 (-0.044; -0.005)	-40 (-184; -23)	-25 (-44; -5)
Chapple, 2007[259]	8 vs.4	Influenza	0.21 (0.05; 0.96)	-0.026 (-0.049; -0.003)	-38 (-354; -20)	-26 (-49; -3)
Nitti, 2007[353]	8 vs.4	Naso-pharyngitis	0.20 (0.04; 0.92)	-0.028 (-0.052; -0.004)	-36 (-223; -19)	-28 (-52; -4)
Sand, 2009[372] 4 mg/day Pooled analysis	8 vs. 4	Dry mouth	1.67 (1.3; 42.09)	0.138 (0.080; 0.196)	7 (5; 13)	138 (80; 196)
Khullar, 2008[330] Pooled analysis	4 vs.8	Dry mouth-total	0.54 (0.44; 0.67)	-0.159 (-0.209; -0.108)	-6 (-9; -5)	-159 (-209; -108)
Khullar, 2008[330] Pooled analysis	4 vs.8	Lacrimal disorder	0.39 (0.17; 0.87)	-0.023 (-0.041; -0.004)	-44 (-239; -24)	-23 (-41; -4)
Khullar, 2008[330] Pooled analysis	4 vs.8	Moderate dry mouth	0.31 (0.18; 0.53)	-0.065 (-0.093; -0.037)	-15 (-27 -11)	-65 (-93; -37)
Khullar, 2008[330] Pooled analysis	4 vs.8	Mild dry mouth	0.68 (0.53; 0.87)	-0.071 (-0.116; -0.026)	-14 (-39 -9)	-71 (-116; -26)
Khullar, 2008[330] Pooled analysis	4 vs.8	Naso-pharyngitis	2.63 (1.11; 6.24)	0.020 (0.003; 0.037)	50 (27;360)	20 (3; 37)
Khullar, 2008[330] Pooled analysis	4 vs.8	Severe dry mouth	0.24 (0.08; 0.71)	-0.023 (-0.039; -0.007)	-44 (-141; -26)	-23 (-39; -7)
Sand, 2009[372] 4 mg/day Pooled analysis	8 vs. 4	Treatment response	1.11 (1.00; 1.24)	0.065 (0.001; 0.130)	15 (8; 727)	65 (1; 130)

Appendix Table F63. Clinical outcomes after fesoterodine vs. placebo

Reference	Mg/ day	Number of subjects	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable/1000 events (95% CI)
Any adverse events						
Cardozo, 2010[476]*	4	867	1.21 (1.07; 1.38)	0.100 (0.033; 0.166)	10 (6; 30)	100 (33; 166)
	8	882	1.39 (1.23; 1.57)	0.181 (0.117; 0.246)	6 (4; 9)	181 (117; 246)
Discontinuations						
Dmochowski, 2010[474]	4 to 8	883	0.95 (0.68; 1.33)	-0.007 (-0.052; 0.038)		
Herschorn, 2010[475]	4 to 8	1013	1.33 (0.89; 1.98)	0.029 (-0.010; 0.069)		
Adverse events leading to discontinuation						
Dmochowski, 2010[474]	4 to 8	883	1.64 (0.97; 2.79)	0.030 (-0.001; 0.062)		
Herschorn, 2010[475]	4 to 8	1013	3.61 (1.55; 8.38)	0.047 (0.023; 0.070)	21 (14; 43)	47 (23; 70)
Lack of efficacy leading to discontinuation						
Dmochowski, 2010[474]	4 to 8	883	0.32 (0.12; 0.86)	-0.025 (-0.044; -0.005)	-41 (-218; -22)	-25 (-44; -5)
Herschorn, 2010[475]	4 to 8	1013	1.28 (0.46; 3.56)	0.004 (-0.012; 0.021)		
Deterioration on the PPBC scale						
Dmochowski, 2010[474]	4 to 8	883	0.49 (0.26; 0.92)	-0.033 (-0.061; -0.005)	-30 (-201; -16)	-33 (-61; -5)
Deterioration on the UPS scale						
Dmochowski, 2010[474]	4 to 8	883	0.85 (0.51; 1.42)	-0.010 (-0.042; 0.022)		
Deterioration on the PPBC scale from baseline						
Herschorn, 2010[475]	4 to 8	1013	0.46 (0.29; 0.74)	-0.055 (-0.091; -0.019)	-18 (-54; -11)	-55 (-91; -19)
Deterioration on the UPS scale from baseline						
Herschorn, 2010[475]	4 to 8	1013	0.65 (0.36; 1.16)	-0.020 (-0.049; 0.009)		)
≥2-point improvement on the PPBC scale						
Dmochowski, 2010[474]	4 to 8	883	1.29 (1.06; 1.57)	0.080 (0.019; 0.141)	13 (7; 54)	80 (19; 141)
improvement on the UPS scale						
Dmochowski, 2010[474]	4 to 8	883	1.35 (1.13; 1.61)	0.108 (0.045; 0.171)	9 (6; 22)	108 (45; 171)
≥2-point improvement on the PPBC scale from baseline						
Herschorn, 2010[475]	4 to 8	1013	0.94 (0.80; 1.11)	-0.024 (-0.088; 0.040)		
improvement on the UPS scale from baseline						
Herschorn, 2010[475]	4 to 8	1013	1.28 (1.07; 1.52)	0.093 (0.030; 0.156)	11 (6; 33)	93 (30; 156)
UTI						
Herschorn, 2010[475]	4 to 8	1013	3.69 (0.85; 16.04)	0.016 (0.002; 0.030)	62 (33; 436)	16 (2; 30)
Cardozo, 2010[476]*	4	867	0.89 (0.43; 1.81)	-0.004 (-0.028; 0.020)		
	8	882	1.41 (0.74; 2.66)	0.014 (-0.012; 0.041)		

*pooled analysis

Appendix Table F64. Clinical outcomes after propiverine vs. placebo, individual RCTs

Reference	Dose, mg/day	Outcome	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Dorschner, 2000[282]	45	Urgency symptom free	15/49	7/49	2.14 (0.96; 4.79)	0.163 (0.001; 0.325)	6 (3; 806)	163 (1; 325)
		Incontinence symptom free	24/49	15/49	1.60 (0.96; 2.66)	0.184 (-0.007; 0.374)		
		Urgency improved	29/49	19/49	1.53 (1.00; 2.33)	0.204 (0.010; 0.398)	5 (3; 97)	204 (10; 398)
		Incontinence improved	19/49	11/49	1.73 (0.92; 3.24)	0.163 (-0.016; 0.343)		
		Incontinence unchanged	6/49	23/49	0.26 (0.12; 0.58)	-0.347 (-0.514; -0.180)	-3 (-6; -2)	-347 (-514; -180)
		Urgency unchanged	5/49	23/49	0.22 (0.09; 0.53)	-0.367 (-0.531; -0.204)	-3 (-5; -2)	-367 (-531; -204)
Abrams, 2006[227]	20	Patients with ≥1 AE	30/38	12/24	1.58 (1.02; 2.43)	0.289 (0.051; 0.528)	3 (2; 20)	289 (51; 528)
	45	Patients with ≥1 AE	34/42	12/24	1.62 (1.06; 2.48)	0.310 (0.077; 0.542)	3 (2; 13)	310 (77; 542)
	20	Patients with ≥1 AE*	30/38	12/24	1.58 (1.02; 2.43)	0.289 (0.051; 0.528)	3 (2; 20)	289 (51; 528)
	45	Patients with ≥1 AE*	34/42	12/24	1.62 (1.06; 2.48)	0.310 (0.077; 0.542)	3 (2; 13)	310 (77; 542)
	45	Abnormal vision	14/42	0/24	16.86 (1.05; 270.62)	0.333 (0.182; 0.485)	3 (2; 6)	333 (182; 485)
	20	Abnormal vision	9/38	0/24	12.18 (0.74; 200.11)	0.237 (0.091; 0.382)	4 (3; 11)	237 (91; 382)
	20	Abnormal vision*	9/38	0/24	12.18 (0.74; 200.11)	0.237 (0.091; 0.382)	4 (3; 11)	237 (91; 382)
	45	Abnormal vision*	14/42	0/24	16.86 (1.05; 270.62)	0.333 (0.182; 0.485)	3 (2; 6)	333 (182; 485)
	20	Constipation	6/38	0/24	8.33 (0.49; 141.53)	0.158 (0.029; 0.287)	6 (3; 35)	158 (29; 287)
	45	Constipation	10/42	0/24	12.21 (0.75; 199.55)	0.238 (0.098; 0.378)	4 (3; 10)	238 (98; 378)
	20	Constipation*	6/38	0/24	8.33 (0.49; 141.53)	0.158 (0.029; 0.287)	6 (3; 35)	158 (29; 287)
	45	Constipation*	10/42	0/24	12.21 (0.75; 199.55)	0.238 (0.098; 0.378)	4 (3; 10)	238 (98; 378)
	20	Dry mouth	13/38	4/24	2.05 (0.76; 5.56)	0.175 (-0.037; 0.388)		
	45	Dry mouth	22/42	4/24	3.14 (1.23; 8.05)	0.357 (0.145; 0.569)	3 (2; 7)	357 (145; 569)
	20	Dry mouth*	13/38	4/24	2.05 (0.76; 5.56)	0.175 (-0.037; 0.388)		
	45	Dry mouth*	22/42	4/24	3.14 (1.23; 8.05)	0.357 (0.145; 0.569)	3 (2; 7)	357 (145; 569)
	20	Headache	1/38	0/24	1.92 (0.08; 45.37)	0.026 (-0.055; 0.108)		
	45	Headache	3/42	0/24	4.07 (0.22; 75.60)	0.071 (-0.027; 0.170)		
	20	Headache*	1/38	0/24	1.92 (0.08; 45.37)	0.026 (-0.055; 0.108)		
	45	Headache*	3/42	0/24	4.07 (0.22; 75.60)	0.071 (-0.027; 0.170)		

* at followup

Appendix Table F65. Clinical outcomes after botulinum toxin vs. placebo, individual RCTs

Reference sample	Dose	Outcome	Active n/N	Control n/N	Relative risk	Lower 95% CI	Upper 95% CI	Absolute risk difference	Lower 95% CI	Upper 95% CI	Number needed to treat	Attributable events/1000 treated
Brubaker, 2008[238] 84	200U-single dose	>75% decreased number of incontinence episodes	18/28	0/15	20.41	1.32	316.75	0.643	0.448	0.837	2	643
Brubaker, 2008[238] 84	200U-single dose	Serious adverse events	3/28	2/15	0.80	0.15	4.29	-0.026	-0.233	0.180		
Brubaker, 2008[238] 84	200U-single dose	Unexpected adverse events	6/28	0/15	7.17	0.43	119.24	0.214	0.040	0.388	5	214
Brubaker, 2008[238] 84	200U-single dose	Treatment failure	6/28	11/15	0.29	0.14	0.63	-0.519	-0.790	-0.249	-2	-519
Brubaker, 2008[238] 84	200U-single dose	Urinary tract infection	12/28	3/15	2.14	0.71	6.43	0.229	-0.045	0.502		
Brubaker, 2008[238] 84	200U-single dose	Increase in post-void residual volume	12/28	0/15	13.79	0.87	217.93	0.429	0.229	0.628	2	429
Brubaker, 2008[238] 84	200U-single dose	Urinary tract infection without increased PVR	3/28	3/15	0.54	0.12	2.34	-0.093	-0.325	0.140		

Appendix Table F66. Quality of life after botulinum toxin vs. placebo, individual RCTs

Reference	Dose	Outcome	Active N	Control N	Active mean+/- standard deviation	Control mean+/- standard deviation	Mean difference	Lower 95% CI	Upper 95% CI
Ghei, 2005[292]	5000IU	KHQ score: emotional problems	10	10	5.3+/-2.02	7.0+/-2.42	-1.75	-3.70	0.20
Ghei, 2005[292]	5000IU	KHQ score: impact on life	10	10	1.5+/-0.81	2.5+/-0.81	-1	-1.71	-0.29
Ghei, 2005[292]	5000IU	KHQ score: incontinence impact	10	10	4.5+/-3.23	7.0+/-4.03	-2.5	-5.70	0.70
Ghei, 2005[292]	5000IU	KHQ score: incontinence severity measures	10	10	8.5+/-3.23	12.0+/-4.03	-3.5	-6.70	-0.30
Ghei, 2005[292]	5000IU	KHQ score: personal relationships	10	10	2.0+/-4.03	3.5+/-3.23	-1.5	-4.70	1.70
Ghei, 2005[292]	5000IU	KHQ score: physical/social limitations	10	10	5.0+/-2.42	7.5+/-4.03	-2.5	-5.42	0.42
Ghei, 2005[292]	5000IU	KHQ score: present health	10	10	1.0+/-0.81	1.5+/-0.81	-0.5	-1.21	0.21
Ghei, 2005[292]	5000IU	KHQ score: role limitations	10	10	2.5+/-1.61	3.5+/-1.61	-1	-2.41	0.41
Ghei, 2005[292]	5000IU	KHQ score: sleep/energy disturbances	10	10	3.5+/-1.61	5.0+/-0.81	-1.5	-2.62	-0.38

Appendix Table F67. Outcomes after intravesical 100ml of 50nM-single dose injection of resiniferatoxin vs. placebo, individual RCTs

Reference	Active N	Control N	Outcome	Active mean+/- standard deviation	Control mean+/- standard deviation	Mean difference	Lower 95% CI	Upper 95% CI
Rios, 2007[364]	34	24	General health perception	35.3+/-13.92	44.8+/-23.29	-9.50	-19.93	0.93
Rios, 2007[364]	34	24	Incontinence impact	61.8+/-33.97	66.7+/-36.78	-4.90	-23.53	13.73
Rios, 2007[364]	34	24	Role limitations	50.5+/-35.65	51.5+/-35.86	-0.96	-19.65	17.73
Rios, 2007[364]	34	24	Physical limitations	47.1+/-37.03	46.5+/-38.06	0.53	-19.14	20.20
Rios, 2007[364]	34	24	Social limitations	24.2+/-29.27	37.9+/-30.83	-13.74	-29.52	2.04
Rios, 2007[364]	34	24	Personal relationships	32.7+/-45.77	35.4+/-39.85	-2.75	-24.91	19.41
Rios, 2007[364]	34	24	Emotions	44.4+/-36.60	54.6+/-35.12	-10.19	-28.87	8.49
Rios, 2007[364]	34	24	Sleep and energy	28.9+/-23.68	38.2+/-31.27	-9.28	-24.11	5.55
Rios, 2007[364]	34	24	Symptom severity	15.5+/-10.05	10.1+/-10.98	5.39	-0.15	10.93

Reference	Active N	Control N	Outcome	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)
Rios, 2007[364]	34	24	Hypogastric pain	12/34	4/24	2.12 (0.78;5.78)	0.19 (-0.03;0.41)
Rios, 2007[364]	34	24	Dysuria	15/34	6/24	1.76 (0.80;3.89)	0.19 (-0.05;0.43)
Rios, 2007[364]	34	24	Minor hematuria	1/34	3/24	0.24 (0.03;2.13)	-0.10 (-0.24;0.05)

Appendix Table F68. Outcomes after nimodipine, 60mg/day, vs. placebo, individual RCT

Reference	Active N	Control N	Outcome	Active mean+/- standard deviation	Control mean+/- standard deviation	Mean difference	Lower 95% CI	Upper 95% CI
Naglie, 2002[352]	42	44	Mean IIQ scores(lower better)	15.0+/-13.29	19.4+/-14.82	-4.38	-10.69	1.93
Naglie, 2002[352]	42	44	AUA symptom scores (lower better)	11.4+/-5.62	13.8+/-6.46	-2.31	-6.26	1.64
Naglie, 2002[352]	42	44	Incontinent episodes	11.0+/-10.75	18.7+/-20.29	-7.71	-14.56	-0.86

Reference	Active N	Control N	Outcome	Active n/N	Control n/N	Relative Risk (95% CI)	Absolute Risk Difference (95% CI)
Naglie, 2002[352]	42	44	Withdrawals	6/42	4/44	1.57(0.48;5.18)	0.05(-0.08;0.19)

Appendix Table F69. Comparative effectiveness of local estrogen therapy

Active	Control	Reference studies	Subjects	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1,000 rreated (95% CI)	Evidence
Continence								
Estradiol-releasing ring, 7.5mg/day	Estradiol pessaries 0.5 mg every second day	1[341]	251	Urgency 77.79 (4.84; 1249.40)	0.33 (0.25; 0.41)	3 (2; 4)	328 (248; 409)	Insufficient
Estradiol-releasing ring, 7.5mg/day	Estradiol pessaries 0.5 mg every second day	1[341]	251	Stress 0.84 (0.61; 1.15)	-0.07 (-0.19; 0.05)			Insufficient
Improved incontinence								
Estradiol-releasing vaginal ring	Estradiol pessary	1[341]	232	2.69 1.60; 4.50)	0.26 (0.15; 0.37)	4 (3; 6)	262 (155; 369)	Insufficient

Appendix Table F70. Comparative effectiveness of estrogen topical treatments (individual RCTs)

Reference Sample	Active	Control	Definition of outcome	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1,000 treated (95% CI)
Continence										
Chom-pootaweep, 1998[267] 22/0	Combined contraceptive Intravaginal 1 pill/week at bedtime with 250 mg levonorgestrel +30 microg ethinyl estradiol	Intravaginal conjugated estrogen cream (1g = 0.625 mg conjugated equine estrogens) at bedtime	No urinary urgency	10/10	9/85	9/85	1.00 (0.67; 1.48)	0.00 (-0.32; 0.32)		
Lose, 2000[341] 251/0	Estradiol-releasing ring, 7.5 mg estradiol	Estradiol pessaries 0.5 mg every second day	No urge incontinence	134/117	44/33	0/34	77.79 (4.84; 1249.40)	0.33 (0.25; 0.41)	3 (2; 4)	328 (248; 409)
Lose, 2000[341] 251/0	Estradiol-releasing ring, 7.5 mg estradiol	Estradiol pessaries 0.5 mg every second day	No stress incontinence	134/117	46/34	48/41	0.84 (0.61; 1.15)	-0.07 (-0.19; 0.05)		
Improved incontinence										
Lose, 2000[341] 232/0	Estradiol-releasing vaginal ring	Estradiol pessary	Treatment perception: good	110/101	30/27	34/34	0.80 (0.52; 1.21)	-0.06 (-0.18; 0.05)		
Lose, 2000[341] 232/0	Estradiol-releasing vaginal ring	Estradiol Pessary	Treatment perception: excellent	110/101	66/60	14/14	2.69 (1.60; 4.50)	0.26 (0.15; 0.37)	4 (3; 6)	262 (155;369)
Lose, 2000[341] 232/0	Estradiol-releasing vaginal ring	Estradiol Pessary	Treatment perception: bad	110/101	2/2	3/3	0.61 (0.10; .59)	-0.01 (-0.05; 0.03)		
Lose, 2000[341] 232/0	Estradiol-releasing vaginal ring	Estradiol Pessary	Treatment perception: unacceptable	110/101	3/3	2/2	1.38 (0.23; 8.08)	0.01 (-0.03; 0.05)		

Appendix Table F71. Adverse effects of pharmacological treatments for UI when compared to each other

Reference	Active drug	Dose	Control drug	Dose	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)
Chapple, 2005[258]	Darifenacin IR	2.5 t.i.d.	Oxybutynin IR	2.5 t.i.d.	5/8	8/8	0.6(0.4; 1.1)	-0.38 (-0.73; -0.02)
Abrams, 1998[226]	Tolterodine	2mg twice daily	Oxybutynin	5mg thrice daily	105/118	114/118	0.9 (0.9; 1.0)	-0.08 (-0.14; -0.01)
Madersbacher, 1999[343]	Propiverine	15mg thrice daily	Oxybutynin	5mg twice daily	95/149	104/145	0.9 (0.8; 1.0)	-0.08 (-0.19; 0.03)
Drutz, 1999[283]	Oxybutynin	5mg thrice a day	Tolterodine	2mg twice a day	101/112	85/109	1.2(1.0; 1.3)	0.12 (0.03; 0.22)
Lee, 2002[335]	Oxybutynin	5mg twice daily	Tolterodine	2mg twice daily	94/116	62/112	1.5(1.2; 1.8)	0.26 (0.14; 0.37)
Leung, 2002[338]	Oxybutynin	5mg twice daily	Tolterodine	2mg twice daily	26/53	32/53	0.8(0.6; 1.2)	-0.11 (-0.30; 0.08)
Halaska, 2003[302]	Trospium	40mg/day	Oxybutynin	10mg/day	103/267	46/90	0.8(0.6; 1.0)	-0.13 (-0.24; -0.01)
Halaska, 2003[302]	Trospium	20mg twice daily	Oxybutynin	5mg twice daily	173/267	69/90	0.8(0.7; 1.0)	-0.12 (-0.22; -0.01)
Dmochowski, 2003[278]	Oxybutynin	3.9mg/day	Tolterodine LA	4mg/day	23/121	29/123	0.8(0.5; 1.3)	-0.05 (-0.15; 0.06)
Homma, 2003[311]	Oxybutynin	3mg thrice daily	Tolterodine ER	4mg/day	42/244	12/239	3.4(1.9; 6.3)	0.12 (0.07; 0.18)
Chapple, 2004[265]	Solifenacin	20mg once daily	Tolterodine	2mg twice daily	21/37	12/37	1.8(1.0; 3.0)	0.24 (0.02; 0.46)
Chapple, 2004[265]	Solifenacin	2.5mg once daily	Tolterodine	2mg twice daily	6/41	12/37	0.5(0.2; 1.1)	-0.18 (-0.36; 0.01)
Chapple, 2004[265]	Solifenacin	5mg once daily	Tolterodine	2mg twice daily	12/37	12/37	1.0(0.5; 1.9)	0.00 (-0.21; 0.21)
Chapple, 2004[265]	Solifenacin	10mg once daily	Tolterodine	2mg twice daily	12/35	12/37	1.1(0.6; 2.0)	0.02 (-0.20; 0.24)
Junemann, 2005[321]	Propiverine	15mg twice daily	Tolterodine	2mg twice daily	42/100	43/101	1.0(0.7; 1.4)	-0.01 (-0.14; 0.13)

Appendix Table F71. Adverse effects of pharmacological treatments for UI when compared to each other (continued)

Reference	Active drug	Dose	Control drug	Dose	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)
Armstrong, 2007[232]	Oxybutynin	10mg qd	Tolterodine ER	4mg qd	404/576	254/399	1.1(1.0; 1.2)	0.06 (0.00; 0.12)
Chapple, 2007[259]	Tolterodine	4mg daily	Fesoterodine	8mg daily	144/290	167/288	0.9(0.7; 1.0)	-0.08 (-0.16; 0.00)
Chapple, 2007[259]	Tolterodine	4mg daily	Fesoterodine	4mg daily	144/290	135/272	1.0(0.8; 1.2)	0.00 (-0.08; 0.08)
Herschorn, 2010[304]	Solifenacin	5mg once daily	Oxybutynin IR	5mg 3 times daily	49/68	59/64	0.8(0.7; 0.9)	-0.20 (-0.33; -0.08)
Junemann, 2000[320]	Trospium	20mg twice daily	Tolterodine	2mg twice daily	26/76	25/77	1.1(0.7; 1.6)	0.02 (-0.13; 0.17)
U.S. Food and Drug Administration , [60]	Solifenacin	5mgonce daily/5mg twice daily	Tolterodine ER	4mg once daily	282/593	265/607	1.1(1.0; 1.2)	0.04 (-0.02; 0.10)
NCT00444925, [58]	Fesoterodine	4 to 8mg once daily	Tolterodine ER	4 to 8mg once daily	290/685	213/690	1.4(1.2; 1.6)	0.11 (0.06; 0.17)

Appendix Table F72. Dry mouth after pharmacological treatments for UI when compared to each other

Reference	Active drug	Dose	Control drug	Dose	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)
Zinner, 2005[412]	Darifenacin ER	15mg/day	Oxybutynin	5 mg 3 times/day	0/19	7/19	0.1(0.0; 1.1)	-0.37 (-0.59; -0.15)
Abrams, 1998[226]	Oxybutynin	5mg thrice daily	Tolterodine	2mg twice daily	102/118	59/118	1.7(1.4; 2.1)	0.36 (0.26; 0.47)
Drutz, 1999[283]	Oxybutynin	5mg thrice a day	Tolterodine	2mg twice a day	77/112	33/109	2.3(1.7; 3.1)	0.38 (0.26; 0.51)
Appell, 2001[230]	Oxybutynin	10mg/day	Tolterodine LA	2mg twice daily	52/185	64/193	0.8(0.6; 1.2)	-0.05 (-0.14; 0.04)
Lee, 2002[335]	Oxybutynin	5mg twice daily	Tolterodine	2mg twice daily	72/116	39/112	1.8(1.3; 2.4)	0.27 (0.15; 0.40)
Halaska, 2003[302]	Trospium	40mg/day	Oxybutynin	10mg/day	87/267	45/90	0.7(0.5; 0.9)	-0.17 (-0.29; -0.06)
Halaska, 2003[302]	Trospium	20mg twice daily	Oxybutynin	5mg twice daily	87/267	45/90	0.7(0.5; 0.9)	-0.17 (-0.29; -0.06)
Diokno, 2003[273]	Oxybutynin	10mg/d	Tolterodine ER	4mg/d	116/391	89/399	1.3(1.0; 1.7)	0.07 (0.01; 0.13)
Homma, 2003[311]	Oxybutynin	3mg thrice daily	Tolterodine ER	4mg/day	131/244	80/239	1.6(1.3; 2.0)	0.20 (0.12; 0.29)
Chapple, 2004[265]	Solifenacin	2.5mg once daily	Tolterodine	2mg twice daily	0/41	9/37	0.0(0.0; 0.8)	-0.24 (-0.38; -0.10)
Chapple, 2004[265]	Solifenacin	5mg once daily	Tolterodine	2mg twice daily	5/37	9/37	0.6(0.2; 1.5)	-0.11 (-0.28; 0.07)
Chapple, 2004[265]	Solifenacin	10mg once daily	Tolterodine	2mg twice daily	5/35	9/37	0.6(0.2; 1.6)	-0.10 (-0.28; 0.08)
Chapple, 2004[265]	Solifenacin	20mg once daily	Tolterodine	2mg twice daily	14/37	9/37	1.6(0.8; 3.1)	0.14 (-0.07; 0.34)
Chapple, 2004[54]	Solifenacin	5mg daily	Tolterodine	2mg twice daily	39/279	49/266	0.8(0.5; 1.1)	-0.04 (-0.11; 0.02)
Chapple, 2004[54]	Solifenacin	10mg daily	Tolterodine	2mg twice daily	57/269	49/266	1.2(0.8; 1.6)	0.03 (-0.04; 0.10)

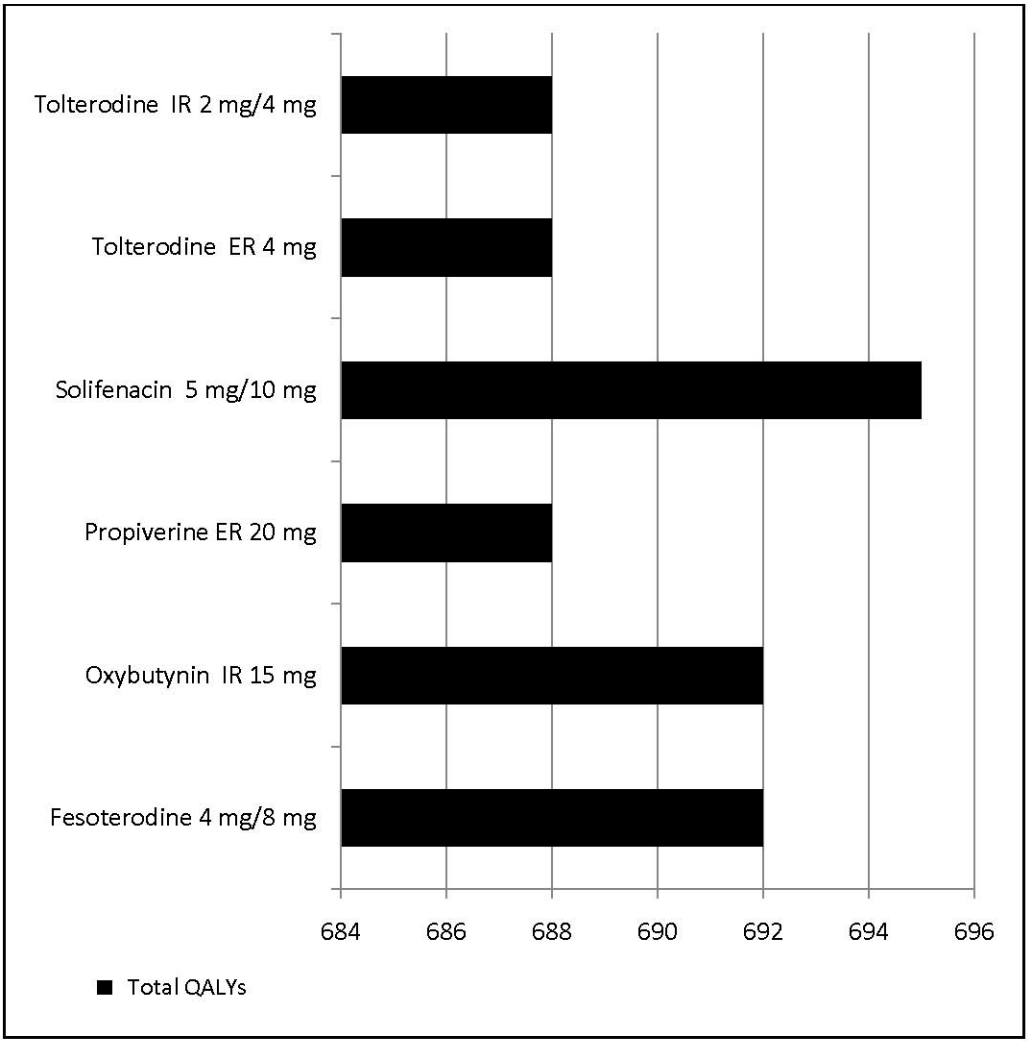
Appendix Table F72. Dry mouth after pharmacological treatments for UI when compared to each other (continued)

Reference	Active drug	Dose	Control drug	Dose	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)
Homma, 2004[310]	Oxybutynin	3mg thrice daily	Tolterodine ER	4mg/day	75/122	42/114	1.7(1.3; 2.2)	0.25 (0.12; 0.37)
Sand, 2004[373]	Oxybutynin	10mg/day	Tolterodine	2mg b.i.d.	43/152	55/163	0.8(0.6; 1.2)	-0.05 (-0.16; 0.05)
Chapple, 2005[258]	Darifenacin IR	2.5 t.i.d.	Oxybutynin IR	2.5 t.i.d.	4/8	8/8	0.5(0.3; 1.0)	-0.50 (-0.86; -0.14)
Zinner, 2005[412]	Darifenacin ER	30mg/day	Oxybutynin	5 mg 3 times/day	7/19	7/19	1.0(0.4; 2.3)	0.00 (-0.31; 0.31)
Armstrong, 2005[231]	Oxybutynin	10mg/day	Tolterodine ER	4mg daily	110/391	86/399	1.3(1.0; 1.7)	0.07 (0.01; 0.13)
Armstrong, 2007[232]	Oxybutynin	10mg qd	Tolterodine ER	2mg qd	169/576	64/193	0.9(0.7; 1.1)	-0.04 (-0.11; 0.04)
Armstrong, 2007[232]	Oxybutynin	10mg qd	Tolterodine ER	4mg qd	169/576	89/399	1.3(1.1; 1.6)	0.07 (0.02; 0.13)
Chapple, 2007[263]	Solifenacin	5mg daily	Tolterodine	4mg daily	82/578	69/599	1.2(0.9; 1.7)	0.03 (-0.01; 0.06)
Chapple, 2007[259]	Fesoterodine	8mg daily	Tolterodine	4mg daily	97/288	49/290	2.0(1.5; 2.7)	0.17 (0.10; 0.24)
Chapple, 2007[259]	Fesoterodine	4mg daily	Tolterodine	4mg daily	59/272	49/290	1.3(0.9; 1.8)	0.05 (-0.02; 0.11)
Yamaguchi, 2007[410]	Solifenacin	5mg daily	Propiverine	20mg daily	67/400	103/402	0.7(0.5; 0.9)	-0.09 (-0.14; -0.03)
Yamaguchi, 2007[410]	Solifenacin	10mg daily	Propiverine	20mg daily	130/385	103/402	1.3(1.1; 1.6)	0.08 (0.02; 0.15)
Chapple, 2008[260]	Fesoterodine	8mg daily	Tolterodine	4mg daily	97/287	49/290	2.0(1.5; 2.7)	0.17 (0.10; 0.24)
Choo, 2008[268]	Solifenacin	5mg once daily	Tolterodine IR	2mg twice daily	9/120	22/118	0.4(0.2; 0.8)	-0.11 (-0.20; -0.03)
Choo, 2008[268]	Solifenacin	10mg once daily	Tolterodine IR	2mg twice daily	23/119	22/118	1.0(0.6; 1.8)	0.01 (-0.09; 0.11)
Sand, 2009[372]	Fesoterodine	8mg daily	Tolterodine	4mg daily	155/452	37/227	2.1(1.5; 2.9)	0.18 (0.11; 0.24)

Appendix Table F72. Dry mouth after pharmacological treatments for UI when compared to each other (continued)

Reference	Active drug	Dose	Control drug	Dose	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)
Sand, 2009[372]	Fesoterodine	4mg daily	Tolterodine	4mg daily	89/434	37/227	1.3(0.9; 1.8)	0.04 (-0.02; 0.10)
Herschorn, 2010[475]	Fesoterodine	4-8mg once daily	Tolterodine ER	4mg once daily	189/679	112/684	1.7(1.4; 2.1)	0.11 (0.07; 0.16)
Herschorn, 2010[304]	Solifenacin	5mg once daily	Oxybutynin IR	5mg 3 times daily	24/68	53/64	0.4(0.3; 0.6)	-0.48 (-0.62; -0.33)
Junemann, 2000[320]	Trospium	20mg twice daily	Tolterodine	2mg twice daily	22/76	21/77	1.1(0.6; 1.8)	0.02 (-0.13; 0.16)
Kaplan, 2010[322]	Fesoterodine	4 to 8mg once daily	Tolterodine ER	4 mg once daily	270/963	127/974	2.2(1.8; 2.6)	0.15 (0.11; 0.19)
NCT00444925,[58]	Fesoterodine	4 to 8mg once daily	Tolterodine ER	4 to 8mg once daily	189/685	112/690	1.7(1.4; 2.1)	0.11 (0.07; 0.16)

Appendix Figure F26. Gain in quality adjusted life years per 1,000 treated patients[477]



Appendix Table F73. Constipation after pharmacological treatments for UI when compared to each other

Reference	Active drug	Dose	Control drug	Dose	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)
Zinner, 2005[412]	Darifenacin ER	15mg/day	Oxybutynin	5 mg 3 times/day	2/19	2/19	1.0(0.2; 6.4)	0.00 (-0.20; 0.20)
Halaska, 2003[302]	Trospium	40mg/day	Oxybutynin	10mg/day	18/267	4/90	1.5(0.5; 4.4)	0.02 (-0.03; 0.08)
Halaska, 2003[302]	Trospium	20mg twice daily	Oxybutynin	5mg twice daily	18/267	4/90	1.5(0.5; 4.4)	0.02 (-0.03; 0.08)
Chapple, 2004[265]	Solifenacin	2.5mg once daily	Tolterodine	2mg twice daily	1/41	1/37	0.9(0.1; 13.9)	0.00 (-0.07; 0.07)
Chapple, 2004[265]	Solifenacin	5mg once daily	Tolterodine	2mg twice daily	5/37	1/37	5.0(0.6; 40.8)	0.11 (-0.01; 0.23)
Chapple, 2004[265]	Solifenacin	10mg once daily	Tolterodine	2mg twice daily	2/35	1/37	2.1(0.2; 22.3)	0.03 (-0.06; 0.12)
Chapple, 2004[265]	Solifenacin	20mg once daily	Tolterodine	2mg twice daily	6/37	1/37	6.0(0.8; 47.4)	0.14 (0.01; 0.26)
Chapple, 2004[54]	Solifenacin	5mg daily	Tolterodine	2mg twice daily	20/279	7/266	2.7(1.2; 6.3)	0.05 (0.01; 0.08)
Chapple, 2004[54]	Solifenacin	10mg daily	Tolterodine	2mg twice daily	21/269	7/266	3.0(1.3; 6.9)	0.05 (0.01; 0.09)
Chapple, 2005[258]	Darifenacin ER	15mg daily	Oxybutynin IR	5mg t.i.d.	8/12	6/12	1.3(0.7; 2.7)	0.17 (-0.22; 0.56)
Chapple, 2005[258]	Darifenacin ER	30mg daily	Oxybutynin IR	5mg t.i.d.	10/13	2/12	4.6(1.3; 16.9)	0.60 (0.29; 0.91)
Chapple, 2005[258]	Darifenacin IR	2.5 t.i.d.	Oxybutynin IR	2.5 t.i.d.	1/8	1/8	1.0(0.1; 13.4)	0.00 (-0.32; 0.32)
Chapple, 2005[61]	Solifenacin	5-10mg od	Tolterodine	4mg once daily	3/578	1/599	3.1(0.3; 29.8)	0.00 (0.00; 0.01)
Zinner, 2005[412]	Darifenacin ER	30mg/day	Oxybutynin	5 mg 3 times/day	4/19	2/19	2.0(0.4; 9.6)	0.11 (-0.12; 0.33)
Armstrong, 2007[232]	Oxybutynin	10mg qd	Tolterodine ER	4mg qd	38/576	31/399	0.8(0.5; 1.3)	-0.01 (-0.04; 0.02)
Armstrong, 2007[232]	Oxybutynin	10mg qd	Tolterodine ER	2mg qd	38/576	12/193	1.1(0.6; 2.0)	0.00 (-0.04; 0.04)
Chapple, 2007[263]	Solifenacin	5mg daily	Tolterodine	4mg daily	12/578	7/599	1.8(0.7; 4.5)	0.01 (-0.01; 0.02)
Chapple, 2007[259]	Tolterodine	4mg daily	Fesoterodine	8mg daily	8/290	13/288	0.6(0.3; 1.5)	-0.02 (-0.05; 0.01)

Appendix Table F73. Constipation after pharmacological treatments for UI when compared to each other (continued)

Reference	Active drug	Dose	Control drug	Dose	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)
Chapple, 2007[259]	Tolterodine	4mg daily	Fesoterodine	4mg daily	8/290	9/272	0.8(0.3; 2.1)	-0.01 (-0.03; 0.02)
Yamaguchi, 2007[410]	Solifenacin	5mg daily	Propiverine	20mg daily	42/400	45/402	0.9(0.6; 1.4)	-0.01 (-0.05; 0.04)
Yamaguchi, 2007[410]	Solifenacin	10mg daily	Propiverine	20mg daily	72/385	45/402	1.7(1.2; 2.4)	0.08 (0.03; 0.12)
Chapple, 2008[260]	Tolterodine	4mg daily	Fesoterodine	8mg daily	8/290	13/287	0.6(0.3; 1.4)	-0.02 (-0.05; 0.01)
Choo, 2008[268]	Solifenacin	5mg once daily	Tolterodine IR	2mg twice daily	8/120	3/118	2.6(0.7; 9.6)	0.04 (-0.01; 0.09)
Choo, 2008[268]	Solifenacin	10mg once daily	Tolterodine IR	2mg twice daily	17/119	3/118	5.6(1.7; 18.7)	0.12 (0.05; 0.19)
Sand, 2009[372]	Tolterodine	4mg daily	Fesoterodine	8mg daily	6/227	24/452	0.5(0.2; 1.2)	-0.03 (-0.06; 0.00)
Sand, 2009[372]	Tolterodine	4mg daily	Fesoterodine	4mg daily	6/227	20/434	0.6(0.2; 1.4)	-0.02 (-0.05; 0.01)
Zellner, 2009[411]	Trospium	15mg to 30mg thrice daily	Oxybutynin	2.5mg to 5mg thrice daily	10/828	1/830	0.1(0.0; 0.8)	0.01 (0.003; 0.02)
Herschorn, 2010[475]	Tolterodine ER	4mg once daily	Fesoterodine	4-8mg once daily	28/684	37/679	0.8(0.5; 1.2)	-0.01 (-0.04; 0.01)
Kaplan, 2010[322]	Fesoterodine	4 to 8mg once daily	Tolterodine ER	4 mg once daily	270/963	29/974	9.4(6.5; 13.7)	0.25 (0.22; 0.28)
Milani, 1993[348]	Flavoxate	1200	Oxybutynin	5mg t.i.d.	1/50	2/50	0.5(0.0; 5.3)	-0.02 (-0.09; 0.05)
NCT00444925, [58]	Fesoterodine	4 to 8mg once daily	Tolterodine ER	4 to 8mg once daily	37/685	28/690	1.3(0.8; 2.1)	0.01 (-0.01; 0.04)

Appendix Table F74. Discontinuation due to adverse effects after pharmacological treatments for UI when compared to each other

Reference	Active drug	Dose	Control Drug	Dose	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)
Zinner, 2005[412]	Darifenacin ER	15mg/day	Oxybutynin	5 mg 3 times/day	0/19	4/19	0.1(0.0; 1.9)	-0.21 (-0.41; -0.02)
Appell, 1997[229]	Oxybutynin	5mg/day	Tolterodine	1mg/day	70/349	2/121	12.1(3.0; 48.7)	0.18 (0.14; 0.23)
Abrams, 1998[226]	Tolterodine	2mg twice daily	Oxybutynin	5mg thrice daily	20/118	10/118	2.0(1.0; 4.1)	0.08 (0.00; 0.17)
Drutz, 1999[283]	Oxybutynin	5mg thrice a day	Tolterodine	2mg twice a day	23/112	7/109	3.2(1.4; 7.1)	0.14 (0.05; 0.23)
Appell, 2001[230]	Oxybutynin	10mg/day	Tolterodine LA	2mg twice daily	14/185	15/193	1.0(0.5; 2.0)	0.00 (-0.06; 0.05)
Lee, 2002[335]	Oxybutynin	5mg twice daily	Tolterodine	2mg twice daily	18/116	11/112	1.6(0.8; 3.2)	0.06 (-0.03; 0.14)
Halaska, 2003[302]	Trospium	20mg twice daily	Oxybutynin	5mg twice daily	10/267	6/90	0.6(0.2; 1.5)	-0.03 (-0.09; 0.03)
Diokno, 2003[273]	Oxybutynin	10mg/d	Tolterodine ER	4mg/d	20/391	19/399	1.1(0.6; 2.0)	0.00 (-0.03; 0.03)
Chapple, 2004[54]	Solifenacin	5mg daily	Tolterodine	2mg twice daily	9/279	5/266	1.7(0.6; 5.1)	0.01 (-0.01; 0.04)
Chapple, 2004[54]	Solifenacin	10mg daily	Tolterodine	2mg twice daily	7/269	5/266	1.4(0.4; 4.3)	0.01 (-0.02; 0.03)
Homma, 2004[310]	Oxybutynin	3mg thrice daily	Tolterodine ER	4mg/day	21/122	6/114	3.3(1.4; 7.8)	0.12 (0.04; 0.20)
Sand, 2004[373]	Oxybutynin	10mg/day	Tolterodine	2mg b.i.d.	11/152	12/163	1.0(0.4; 2.2)	0.00 (-0.06; 0.06)
Chapple, 2005[258]	Darifenacin ER	15mg daily	Oxybutynin IR	5mg t.i.d.	1/12	0/12	3.0(0.1; 67.1)	0.08 (-0.12; 0.29)
Chapple, 2005[258]	Darifenacin ER	30mg daily	Oxybutynin IR	5mg t.i.d.	1/13	2/12	0.5(0.0; 4.5)	-0.09 (-0.35; 0.17)
Chapple, 2005[258]	Darifenacin IR	2.5 t.i.d.	Oxybutynin IR	2.5 t.i.d.	0/8	1/8	0.3(0.0; 7.1)	-0.13 (-0.41; 0.16)
Zinner, 2005[412]	Darifenacin ER	30mg/day	Oxybutynin	5 mg 3 times/day	1/19	4/19	0.3(0.0; 2.0)	-0.16 (-0.37; 0.05)
Armstrong, 2005[231]	Oxybutynin	10mg/day	Tolterodine ER	4mg daily	20/391	19/399	1.1(0.6; 2.0)	0.00 (-0.03; 0.03)
Armstrong, 2007[232]	Oxybutynin	10mg qd	Tolterodine ER	2mg qd	155/576	61/193	0.9(0.7; 1.1)	-0.05 (-0.12; 0.03)
Armstrong, 2007[232]	Oxybutynin	10mg qd	Tolterodine IR	2mg bid	35/576	15/193	0.8(0.4; 1.4)	-0.02 (-0.06; 0.03)

Appendix Table F74. Discontinuation due to adverse effects after pharmacological treatments for UI when compared to each other (continued)

Reference	Active drug	Dose	Control Drug	Dose	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)
Chapple, 2007[263]	Solifenacin	5mg daily	Tolterodine	4mg daily	4/578	7/599	0.6(0.2; 2.0)	0.00 (-0.02; 0.01)
Chapple, 2007[259]	Tolterodine	4mg daily	Fesoterodine	8mg daily	14/288	9/290	1.6(0.7; 3.6)	0.02 (-0.01; 0.05)
Chapple, 2007[259]	Tolterodine	4mg daily	Fesoterodine	4mg daily	7/272	9/290	0.8(0.3; 2.2)	-0.01 (-0.03; 0.02)
Yamaguchi, 2007[410]	Solifenacin	5mg daily	Propiverine	20mg daily	20/400	26/402	0.8(0.4; 1.4)	-0.01 (-0.05; 0.02)
Yamaguchi, 2007[410]	Solifenacin	10mg daily	Propiverine	20mg daily	26/385	26/402	1.0(0.6; 1.8)	0.00 (-0.03; 0.04)
Choo, 2008[268]	Solifenacin	5mg once daily	Tolterodine IR	2mg twice daily	5/120	2/118	2.5(0.5; 12.4)	0.02 (-0.02; 0.07)
Choo, 2008[268]	Solifenacin	10mg once daily	Tolterodine IR	2mg twice daily	7/119	2/118	3.5(0.7; 16.4)	0.04 (-0.01; 0.09)
Zellner, 2009[411]	Trospium	15mg to 30mg thrice daily	Oxybutynin	2.5mg to 5mg thrice daily	47/828	61/830	1.3(0.9; 1.9)	-0.017 (-0.04; 0.007)
Herschorn, 2010[475]	Tolterodine ER	4mg once daily	Fesoterodine	4-8mg once daily	44/679	28/684	1.6(1.0; 2.5)	0.02 (0.00; 0.05)
Herschorn, 2010[304]	Solifenacin	5mg once daily	Oxybutynin IR	5mg 3 times daily	7/68	7/64	0.9(0.3; 2.5)	-0.01 (-0.11; 0.10)
U.S. Food and Drug Administration, [60]	Solifenacin	5mgonce daily/5mg twice daily	Tolterodine ER	4mg once daily	25/593	23/607	1.1(0.6; 1.9)	0.00 (-0.02; 0.03)
Kaplan, 2010[322]	Fesoterodine	4 to 8mg once daily	Tolterodine ER	4 mg once daily	48/963	29/974	1.7(1.1; 2.6)	0.02 (0.00; 0.04)
But, 2010[248]	Solifenacin	NR	Darifenacin	NR	8/40	8/37	0.9(0.4; 2.2)	-0.02 (-0.20; 0.17)
NCT00444925, [58]	Fesoterodine	4 to 8mg once daily	Tolterodine ER	4 to 8mg once daily	44/685	28/690	1.6(1.0; 2.5)	0.02 (0.00; 0.05)

Appendix Table F75. Comparative effectiveness of drugs on continence

Reference	Active drug	Dose	Control drug	Dose	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)
Kaplan, 2010[322]	Fesoterodine	4 to 8mg once daily	Tolterodine ER	4 mg once daily	609/963	566/974	1.1(1.0; 1.2)	0.05 (0.01; 0.09)
NCT00444925[58]	Fesoterodine	4 to 8mg once daily	Tolterodine ER	4 to 8mg once daily	396/685	358/690	1.1(1.0; 1.2)	0.06 (0.01; 0.11)
Milani, 1993[348]	Flavoxate	1200	Oxybutynin	5mg t.i.d.	14/50	21/50	0.7(0.4; 1.2)	-0.14 (-0.32; 0.04)
Diokno, 2003[273]	Oxybutynin	10mg/d	Tolterodine	4mg/d	90/391	67/399	1.4(1.0; 1.8)	0.06 (0.01; 0.12)
Chapple, 2005[61]	Solifenacin	5-10mg od	Tolterodine	4mg once daily	341/578	294/599	1.2(1.1; 1.3)	0.10 (0.04; 0.16)
Halaska, 2003[302]	Trospium	20mg twice daily	Oxybutynin	5mg twice daily	60/267	11/90	1.8(1.0; 3.3)	0.10 (0.02; 0.19)

Appendix Table F76. Comparative effectiveness of oxybutynin vs. tolterodine (secondary data analyses using individual patient data from RCTs)

Outcomes	Reference	Oxybutynin dose	Tolterodine dose	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable effects/1000 treated (95% CI)
Improved perceptions of the bladder condition	Appell, 1997[229]	5mg three times daily	2mg twice daily	175/349	246/474	0.96 (0.84; 1.10)	-0.02 (-0.09; 0.05)		
Zero episodes of dry mouth	Armstrong, 2005[231]	10mg/day	4mg daily	281/391	313/399	0.92 (0.85; 0.99)	-0.07 (-0.13; -0.01)	-15 (-176; -8)	-66 (-126; -6)
Adverse events	Armstrong, 2007[232]	10mg qd	4mg qd	404/576	254/399	1.10 (1.01; 1.21)	0.07 (0.01; 0.13)	15 (8; 218)	65 (5; 125)
Adverse events	Appell, 1997[229]	5mg three times daily	2mg twice daily	262/349	351/474	1.01 (0.94; 1.10)	0.01 (-0.05; 0.07)		
Serious adverse events	Appell, 1997[229]	5mg three times daily	2mg twice daily	14/349	19/474	1.00 (0.51; 1.97)	0.00 (-0.03; 0.03)		
Serious adverse events	Appell, 1997[229]	5mg/day	2mg/day	14/349	19/474	1.00 (0.51; 1.97)	0.00 (-0.027; 0.027)		
Mild adverse events related to treatment	Armstrong, 2007[232]	10mg qd	2mg bid	217/576	81/193	0.90 (0.74; 1.09)	-0.043 (-0.12; 0.04)		
Moderate adverse events related to treatment	Armstrong, 2007[232]	10mg qd	4mg qd	103/576	40/399	1.78 (1.27; 2.51)	0.08 (0.04; 0.12)	13 (8; 28)	79 (36; 122)
Moderate adverse events related to treatment	Armstrong, 2007[232]	10mg qd	2mg bid	103/576	35/193	0.99 (0.70; 1.40)	-0.00 (-0.07; 0.06)		
Severe adverse events related to treatment	Armstrong, 2007[232]	10mg qd	2mg bid	25/576	5/193	1.68 (0.65; 4.32)	0.02 (-0.01; 0.05)		
Severe adverse events related to treatment	Armstrong, 2007[232]	10mg qd	4mg qd	25/576	6/399	2.89 (1.20; 6.97)	0.03 (0.01; 0.05)	35 (20; 127)	28 (8; 49)
Withdrawal	Appell, 1997[229]	5mg three times daily	2mg twice daily	94/349	63/474	2.03 (1.52; 2.70)	0.14 (0.08; 0.19)		
Withdrawal	Armstrong, 2005[231]	10mg/day	4mg daily	52/391	42/399	1.26 (0.86; 1.85)	0.03 (-0.02; 0.07)		
Patients with at least one adverse event leading to study drug discontinuation	Armstrong, 2007[232]	10mg qd	4mg qd	35/576	19/399	1.28 (0.74; 2.20)	0.01 (-0.02; 0.04)		

Appendix Table F76. Comparative effectiveness of oxybutynin vs. tolterodine (secondary data analyses using individual patient data from RCTs) (continued)

Outcomes	Reference	Oxybutynin dose	Tolterodine dose	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable effects/1000 treated (95% CI)
Patients with at least one adverse event leading to study drug discontinuation	Armstrong, 2007[232]	10mg qd	2mg bid	35/576	15/193	0.78 (0.44; 1.40)	-0.02 (-0.06; 0.03)		
Withdrawal due to adverse events	Appell, 1997[229]	5mg three times daily	2mg twice daily	70/349	38/474	2.50 (1.73; 3.62)	0.12 (0.07; 0.17)	8 (6; 14)	120 (72; 169)
Withdrawal due to adverse events	Armstrong, 2005[231]	10mg/day	4mg daily	52/391	42/399	1.26 (0.86; 1.85)	0.03 (-0.02; 0.07)		
Withdrawal due to adverse events	Armstrong, 2005[231]	10mg/day	4mg daily	20/391	19/399	1.07 (0.58; 1.98)	0.00 (-0.03; 0.03)		
Withdrawal due to dry mouth	Armstrong, 2005[231]	10mg/day	4mg daily	110/391	86/399	1.31 (1.02; 1.67)	0.07 (0.01; 0.13)	15 (8; 176)	66 (6; 126)
Dose reduction in case of intolerance	Appell, 1997[229]	5mg three times daily	2mg twice daily	112/349	43/474	3.54 (2.56; 4.89)	0.23 (0.18; 0.29)	4 (4; 6)	230 (175; 286)
Asthenia	Armstrong, 2007[232]	10mg qd	4mg qd	17/576	0/399	24.26 (1.46; 402.30)	0.03 (0.02; 0.04)	34 (23; 66)	30 (15; 44)
Autonomic nervous system disorder	Appell, 1997[229]	5mg three times daily	2mg twice daily	283/349	204/474	1.88 (1.68; 2.11)	0.38 (0.32; 0.44)	3 (2; 3)	381 (320; 441)
Autonomic nervous system disorder	Appell, 1997[229]	5mg/day	2mg/day	283/349	204/474	1.88 (1.68; 2.11)	0.38 (0.32; 0.44)	3 (2; 3)	381 (320; 441)
Autonomic nervous system disorder	Appell, 1997[229]	5mg/day	1mg/day	283/349	35/121	2.80 (2.11; 3.72)	0.52 (0.43; 0.61)	2 (2; 2)	52 (431; 612)
Discontinuation due to adverse effect on a body as a whole	Armstrong, 2007[232]	10mg qd	4mg qd	155/576	85/399	1.26 (1.00; 1.59)	0.06 (0.01; 0.11)	18 (9; 507)	5 6(2; 110)
Gastrointestinal disorders	Appell, 1997[229]	5mg three times daily	2mg twice daily	140/349	123/474	1.55 (1.27; 1.89)	0.14 (0.08; 0.21)	7 (5; 13)	142 (77; 206)
Dry mouth	Armstrong, 2007[232]	10mg qd	4mg qd	169/576	92/399	1.27 (1.02; 1.58)	0.06 (0.01; 0.12)	16 (8; 138)	63 (7; 118)
Dry mouth	Armstrong, 2007[232]	10mg qd	4mg qd	169/576	89/399	1.32 (1.05; 1.64)	0.07 (0.02; 0.13)	14 (8; 66)	70 (15; 126)
Dry mouth	Appell, 1997[229]	5mg/day	2mg/day	272/349	190/474	1.94 (1.72; 2.20)	0.379 (0.32; 0.44)	3 (2; 3)	379 (317; 440)
Dry mouth	Appell, 1997[229]	5mg/day	1mg/day	272/349	29/121	3.25 (2.36; 4.49)	0.54 (0.45; 0.63)	2 (2; 2)	540 (452; 627)

Appendix Table F76. Comparative effectiveness of oxybutynin vs. tolterodine (secondary data analyses using individual patient data from RCTs) (continued)

Outcomes	Reference	Oxybutynin dose	Tolterodine dose	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable effects/1000 treated (95% CI)
Dry mouth-onset at 1 month	Armstrong, 2005[231]	10mg/day	4mg daily	101/391	74/399	1.39 (1.07; 1.82)	0.07 (0.02; 0.13)	14 (8; 66)	73 (15; 131)
Dyspepsia	Appell, 1997[229]	5mg three times daily	2mg twice daily	38/349	28/474	1.84 (1.15; 2.94)	0.05 (0.01; 0.09)	20 (11; 92)	50 (11; 89)
Gastrointestinal disorders	Appell, 1997[229]	5mg/day	1mg/day	140/349	27/121	1.80 (1.26; 2.57)	0.178 (0.09; 0.27)	6 (4; 11)	178 (88; 268)
Moderate or severe dry mouth	Appell, 1997[229]	5mg three times daily	2mg twice daily	209/349	81/474	3.50 (2.82; 4.35)	0.428 (0.37; 0.49)	2 (2; 3)	428 (366; 490)
Nausea	Armstrong, 2007[232]	10mg qd	4mg qd	14/576	0/399	20.10 (1.20; 336.04)	0.02 (0.01; 0.04)	41 (27; 90)	24 (11; 38)
Pain	Armstrong, 2007[232]	10mg qd	4mg qd	22/576	0/399	31.20 (1.90; 512.77)	0.04 (0.02; 0.05)	26 (18; 45)	38 (22; 54)
Palpitations	Appell, 1997[229]	5mg three times daily	2mg twice daily	8/349	2/474	5.43 (1.16; 25.43)	0.02 (0.00; 0.04)	53 (28; 512)	19 (2; 35)
Rhinitis	Armstrong, 2007[232]	10mg qd	4mg qd	10/576	0/399	14.56 (0.86; 247.72)	0.02 (0.01; 0.03)	58 (35; 169)	17 (6; 29)
Severe dry mouth	Appell, 1997[229]	5mg/day	2mg/day	209/349	81/474	3.50 (2.82; 4.35)	0.43 (0.37; 0.49)	2 (2; 3)	428 (366; 490)
Severe dry mouth	Appell, 1997[229]	5mg/day	1mg/day	209/349	5/121	14.49 (6.12; 34.33)	0.56 (0.50; 0.62)	2 (2; 2)	558 (495; 620)
Symptoms associated with urinary emptying	Armstrong, 2007[232]	10mg qd	4mg qd	55/576	22/399	1.73 (1.07; 2.79)	0.04 (0.01; 0.07)	25 (14; 133)	40 (8; 73)
Urinary tract infection	Armstrong, 2007[232]	10mg qd	4mg qd	30/576	0/399	42.29 (2.59; 689.54)	0.05 (0.03; 0.07)	19 (14; 30)	52 (34; 71)
Urogenital system adverse effects	Armstrong, 2007[232]	10mg qd	4mg qd	92/576	38/399	1.68 (1.18; 2.39)	0.06 (0.02; 0.11)	16 (9; 44)	64 (23; 106)

Appendix Table F77. Comparative effectiveness of drugs on improved UI

Reference	Active drug	Dose	Control drug	Dose	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)
Sand, 2009[372]	Fesoterodine	8mg daily	Tolterodine	4mg daily	291/452	140/227	1.0(0.9; 1.2)	0.03 (-0.05; 0.10)
Abrams, 1998[226]	Oxybutynin	5mg thrice daily	Tolterodine	2mg twice daily	58/118	59/118		
Madersbacher, 1999[343]	Propiverine	15mg thrice daily	Oxybutynin	5mg twice daily	124/149	115/145	1.0(0.9; 1.2)	0.04 (-0.05; 0.13)
Lee, 2002[335]	Oxybutynin	5mg twice daily	Tolterodine	2mg twice daily	53/116	50/112	1.0(0.8; 1.4)	0.01 (-0.12; 0.14)
Homma, 2003[311]	Oxybutynin	3mg thrice daily	Tolterodine ER	4mg/day	129/244	100/239	1.3(1.0; 1.5)	0.11 (0.02; 0.20)
Chapple, 2005[61]	Solifenacin	5-10mg od	Tolterodine	4mg once daily	428/578	401/599	1.1(1.0; 1.2)	0.07 (0.02; 0.12)
Sand, 2009[372]	Fesoterodine	4mg daily	Tolterodine	4mg daily	251/434	140/227	0.9(0.8; 1.1)	-0.04 (-0.12; 0.04)
Zellner, 2009[411]	Trospium	15mg to 30mg thrice daily	Oxybutynin	2.5mg to 5mg thrice daily	368/828	374/830	1.0(0.9; 1.1)	-0.08 (-0.06; 0.04)
Herschorn, 2010[475]	Fesoterodine	4-8mg once daily	Tolterodine ER	4mg once daily	293/679	256/684	1.2(1.0; 1.3)	0.06 (0.01; 0.11)
Kaplan, 2010[322]	Fesoterodine	4 to 8mg once daily	Tolterodine ER	4 mg once daily	709/963	654/974	1.1(0.9; 1.2)	0.02 (0.02; 0.11)
Milani, 1993[348]	Flavoxate	1200	Oxybutynin	5mg t.i.d.	17/50	9/50	1.9(0.9; 3.8)	0.16 (-0.01; 0.33)
NCT00444925, [58]	Fesoterodine	4 to 8mg once daily	Tolterodine ER	4 to 8mg once daily	256/685	238/690	1.1(0.9; 1.2)	0.03 (-0.02; 0.08)

Appendix Table F78. Comparative effectiveness of tolterodine-ER 4mg/day vs. fesoterodine, evidence secondary data analysis

Outcome	Reference	Dose of Fesoterodine, mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)	Evidence
Discontinued prematurely	Chapple, 2008[260]	8	9/290	14/287	0.64 (0.28; 1.45)	-0.018 (-0.050; 0.014)			Insufficient
Treatment response	Sand, 2009[372]	8	140/227	291/452	0.96 (0.85; 1.08)	-0.027 (-0.104; 0.050)			Low
		4	140/227	251/434	1.07 (0.94; 1.21)	0.038 (-0.040; 0.117)			Low
Back pain	Sand, 2009[372]	8	1/227	4/452	0.50 (0.06; 4.43)	-0.004 (-0.017; 0.008)			Low
		4	1/227	9/434	0.21 (0.03; 1.67)	-0.016 (-0.032; 0.000)			Low
Constipation	Chapple, 2008[260]	8	8/290	13/287	0.61 (0.26; 1.45)	-0.018 (-0.048; 0.013)			Insufficient
	Sand, 2009[372]	8	6/227	24/452	0.50 (0.21; 1.20)	-0.027 (-0.056; 0.003)			Low
		4	6/227	20/434	0.57 (0.23; 1.41)	-0.020 (-0.048; 0.009)			Low
Cough	Sand, 2009[372]	8	5/227	5/452	1.99 (0.58; 6.81)	0.011 (-0.010; 0.032)			Low
		4	5/227	7/434	1.37 (0.44; 4.25)	0.006 (-0.017; 0.028)			Low
Diarrhea	Sand,2009[372]	8	3/227	6/452	1.00 (0.25; 3.94)	0.000 (-0.018; 0.018)			Low
		4	3/227	7/434	0.82 (0.21; 3.14)	-0.003 (-0.022; 0.016)			Low
Dizziness	Sand, 2009[372]	8	4/227	5/452	1.59 (0.43; 5.87)	0.007 (-0.013; 0.026)			Low
		4	4/227	4/434	1.91 (0.48; 7.57)	0.008 (-0.011; 0.028)			Low
Dry eye	Chapple, 2008[260]	8	1/290	12/287	0.08 (0.01; 0.63)	-0.038 (-0.062; -0.014)	-26 (-70; -16)	-38 (-62; -14)	Insufficient
	Sand, 2009[372]	8	1/227	10/452	0.20 (0.03; 1.55)	-0.018 (-0.034; -0.002)	-56 (-605; -30)	-18 (-34; -2)	Low
		4	1/227	6/434	0.32 (0.04; 2.63)	-0.009 (-0.023; 0.005)			Low

Appendix Table F78. Comparative effectiveness of tolterodine-ER 4mg/day vs. fesoterodine, evidence secondary data analysis (continued)

Outcome	Reference	Dose of Fesoterodine, mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)	Evidence
Dry mouth	Chapple, 2008[260]	8	49/290	97/287	0.50 (0.37; 0.68)	-0.169 (-0.239; -0.099)	-6 (-10; -4)	-169 (-239; -99)	Insufficient
	Sand, 2009[372]	8	37/227	155/452	0.48 (0.34; 0.66)	-0.180 (-0.245; -0.115)	-6 (-9; -4)	-180 (-245; -115)	Low
		4	37/227	89/434	0.79 (0.56; 1.13)	-0.042 (-0.103; 0.019)			Low
Dry throat	Chapple, 2008[260]	8	3/290	8/287	0.37 (0.10; 1.38)	-0.018 (-0.040; 0.005)			Insufficient
	Sand, 2009[372]	8	2/227	10/452	0.40 (0.09; 1.80)	-0.013 (-0.032; 0.005)			Low
		4	2/227	4/434	0.96 (0.18; 5.18)	0.000 (-0.016; 0.015)			Low
Fatigue	Chapple, 2008[260]	8	10/290	1/287	9.90 (1.28; 76.81)	0.031 (0.009; 0.053)	32 (19;112)	31 (9; 53)	Insufficient
	Sand, 2009[372]	8	7/227	1/452	13.94 (1.73; 112.60)	0.029 (0.006; 0.052)	35 (19; 175)	29 (6; 52)	Low
		4	7/227	5/434	2.68 (0.86; 8.34)	0.019 (-0.005; 0.044)			Low
Headache	Sand, 2009[372]	8	13/227	13/452	1.99 (0.94; 4.22)	0.029 (-0.005; 0.062)			Low
		4	13/227	21/434	1.18 (0.60; 2.32)	0.009 (-0.027; 0.045)			Low
Increased alanine aminotransferase	Chapple, 2008[260]	8	0/290	6/287	0.08 (0.00; 1.35)	-0.021 (-0.039; -0.003)	-48 (-232; -26)	-21 (-39; -3)	Insufficient
Nasopharyngitis	Chapple, 2008[260]	8	10/290	5/287	1.98 (0.69; 5.72)	0.017 (-0.009; 0.043)			Insufficient
	Sand, 2009[372]	8	8/227	6/452	2.65 (0.93; 7.56)	0.022 (-0.004; 0.048)			Low
		4	8/227	14/434	1.09 (0.47; 2.57)	0.003 (-0.026; 0.032)			Low
Nausea	Sand, 2009[372]	8	3/227	11/452	0.54 (0.15; 1.93)	-0.011 (-0.032; 0.009)			Low
		4	3/227	4/434	1.43 (0.32; 6.35)	0.004 (-0.013; 0.021)			Low
	Chapple, 2008[260]	8	6/290	4/287	1.48 (0.42; 5.21)	0.007 (-0.015; 0.028)			Insufficient

Appendix Table F78. Comparative effectiveness of tolterodine-ER 4mg/day vs. fesoterodine, evidence secondary data analysis (continued)

Outcome	Reference	Dose of Fesoterodine, mg/day	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)	Evidence
URI	Sand, 2009[372]	8	2/227	8/452	0.50 (0.11; 2.32)	-0.009 (-0.026; 0.008)			Low
		4	2/227	12/434	0.32 (0.07; 1.41)	-0.019 (-0.038; 0.001)			Low
UTI	Sand, 2009[372]	8	4/227	24/452	0.33 (0.12; 0.94)	-0.035 (-0.062; -0.009)	-28 (-116; -16)	-35 (-62; -9)	Low
		4	4/227	18/434	0.42 (0.15; 1.24)	-0.024 (-0.049; 0.002)			Low

Appendix Table F79. Improvement in UI after pharmacological treatments for UI

Active	Dose	Control	Dose	Studies	Patients	Rate in active group	Rate in control group	Relative risk (95% CI)	Absolute risk difference (95%CI)	Number needed to treat (95% CI)	Evidence
Fesoterodine	4-8mg once daily	Tolterodine-ER	4mg daily	4[58,322,372,475]	5,788	56	50	1.08 (1; 1.2)	0.045 (0.014; 0.076)	22 (13; 71)	High
Oxybutynin	10mg daily	Tolterodine	4mg/day	3[226,311,335]	947	50.3	44.7	1.11 (0.94; 1.31)	0.050 (-0.028; 0.128)		Moderate
Propiverine	15mg thrice daily	Oxybutynin	5mg twice daily	1[343]	294	83.0	79.0	1.05 (0.94; 1.17)	0.039 (-0.050; 0.128)		Insufficient
Solifenacin succinate	5-10mg once daily	Tolterodine	4mg once daily	1[61]	1,177	74.0	67.0	1.11 (1.03; 1.19)	0.071 (0.019; 0.123)	14 (52; 8)	Insufficient
Flavoxate hydrochloride	1200	Oxybutynin	5mg t.i.d.	1[348]	100	34.0	18.0	1.89 (0.93; 3.83)	0.160 (-0.009; 0.329)		Insufficient
Trospium Chloride	15mg to 30mg thrice daily	Oxybutynin Hydrochloride	2.5mg to 5mg thrice daily	1[411]	1,658	51	64	0.8 (0.5; 1.1)	-0.017 (-0.04; 0.007)		Insufficient

Appendix Table F80. Blurred vision after pharmacological treatments for UI when compared to each other

Reference	Active drug	Dose	Control drug	Dose	Active n/N	Control n/N	Relative risk (95% CI)	Absolute rRisk difference (95% CI)
Zinner, 2005[412]	Darifenacin ER	15mg/day	Oxybutynin	5 mg 3 times/day	0/19	1/19	0.3(0.01; 7.7)	-0.05 (-0.19; 0.08)
Chapple, 2004[265]	Solifenacin	2.5mg once daily	Tolterodine	2mg twice daily	1/41	0/37	2.7(0.1; 64.6)	0.02 (-0.04; 0.09)
Chapple, 2004[265]	Solifenacin	5mg once daily	Tolterodine	2mg twice daily	1/37	0/37	3.0(0.1; 71.3)	0.03 (-0.04; 0.10)
Chapple, 2004[265]	Solifenacin	10mg once daily	Tolterodine	2mg twice daily	5/35	0/37	11.6(0.7; 202.5)	**0.14 (0.02; 0.27)**
Chapple, 2004[265]	Solifenacin	20mg once daily	Tolterodine	2mg twice daily	5/37	0/37	11.0(0.6; 192.1)	**0.14 (0.02; 0.25)**
Chapple, 2004[54]	Solifenacin	5mg daily	Tolterodine	2mg twice daily	10/279	4/266	2.4(0.8; 7.5)	0.02 (-0.01; 0.05)
Chapple, 2004[54]	Solifenacin	10mg daily	Tolterodine	2mg twice daily	15/269	4/266	3.7(1.2; 11.0)	**0.04 (0.01; 0.07)**
Zinner, 2005[412]	Darifenacin ER	30mg/day	Oxybutynin	5 mg 3 times/day	0/19	1/19	0.3(0.0; 7.7)	-0.05 (-0.19; 0.08)
Chapple, 2007[263]	Solifenacin	5mg daily	Tolterodine	4mg daily	1/578	7/599	0.1(0.0; 1.2)	-0.01 (-0.02; 0.00)
Yamaguchi, 2007[410]	Solifenacin	5mg daily	Propiverine	20mg daily	7/400	15/402	0.5(0.2; 1.1)	-0.02 (-0.04; 0.00)
Yamaguchi, 2007[410]	Solifenacin	10mg daily	Propiverine	20mg daily	16/385	15/402	1.1(0.6; 2.2)	0.00 (-0.02; 0.03)
Milani, 1993[348]	Flavoxate	1200	Oxybutynin	5mg t.i.d.	1/50	2/50	0.5(0.0; 5.3)	-0.02 (-0.09; 0.05)
NCT00444925,[58]	Fesoterodine	4 to 8mg once daily	Tolterodine ER	4 to 8mg once daily	12/685	8/690	1.5(0.6; 3.7)	0.01 (-0.01; 0.02)
Armstrong, 2007[232]	Oxybutynin	10mg qd	Tolterodine ER	4mg qd	10/576	4/399	1.7(0.5; 5.5)	0.01 (-0.01; 0.02)

Bold - significant differences at 95%confidence level

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Aksac, 2003[478] Country: Turkey Aim: the effects of pelvic floor muscle exercises or biofeedback on female urinary stress incontinence	50 postmenopausal women with female urinary stress incontinence taking HRT	Not reported	Pelvic floor muscle exercise (contractions for 10 seconds and relaxation for 20 seconds, 10 times/session, 3 sessions/day) via digital palpation at home; pelvic floor muscle exercise (contractions for 10 seconds and relaxation for 20 seconds) via biofeedback	Usual care, hormone replacement therapy
Alewijnse, 2003[479] Country: The Netherlands Aim: the effectiveness of pelvic muscle floor exercise therapy supplemented with a health education program urinary incontinence among women.	129 community-dwelling women over 17 years old with urinary incontinence, ability to complete questionnaires in Dutch language.	Continence, neurological conditions, venereal disease, viral infections, using medication that may impact incontinence, pregnancy or 3 months after delivery, after surgical treatment for incontinence, and women with physical impairments. Severe prolapse	Bladder training with voiding frequency of ~7 voidings/day and pelvic floor muscle exercise: 10 slow twitch contractions (10-30 seconds) and 10 fast twitch contractions (2-3 seconds), 5 times/day, each contraction being followed by relaxation	Bladder training and pelvic floor muscle exercise
Amaro, 2005[480] Country: Brazil Aim: the effect of intravaginal electrical stimulation on pelvic floor muscle strength in women with mixed urinary incontinence.	40 women with mixed urinary incontinence and predominant urge incontinence.	Anticholinergic and tricyclic antidepressant medications, pelvic floor exercise, bladder training, vaginal prolapse more than II grade, urinary tract infection, metal implants, and neurological diseases	Intravaginal electrical stimulation with 3 20-minute sessions/week using 4Hz frequency.	Sham stimulation with inactive device

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Amaro, 2006[481] Country: Brazil Aim: the effects of intravaginal electrical stimulation in mixed urinary incontinence	40 women symptoms of predominant urge incontinence not taking anticholinergics or tricyclic antidepressants	Use of pelvic floor exercises or bladder training, vaginal prolapse >grade II, retention complaint or obstruction diagnosis during UDS, urinary infection, changes in cutaneous sensitivity, metal implants, and neurological diseases.	Effective intravaginal electrical stimulation using frequency of 4 Hz with 3 20-minute sessions/week	Sham intravaginal electrical stimulation using frequency of 4Hz with 3 20-minute sessions/week
Andersen, 2002[482] Country: USA Aim: the long-term effectiveness of Durasphere vs. Contigen in the treatment of female stress urinary incontinence caused by intrinsic sphincter deficiency	Adult women 21 years of age or older with stress UI caused by intrinsic sphincter deficiency for a period of at least 12 months; positive pad weight test; failure of previous non invasive treatments, post void residual <100 mL and abdominal leak point pressure	Urge primary incontinence, uncontrolled bladder instability, positive urine culture, previous urethral bulking treatments, medication affecting the evaluation of incontinence, pregnancy	Durasphere 4.5 mL injected submucosally between the bladder neck and external sphincter	Contigen 4.2 mL injected submucosally between the bladder neck and external sphincter
Appell, 2006[483] Country: USA Aim: the effects of transurethral radiofrequency energy collagen micro-remodeling on female stress urinary incontinence	173 women with stress urinary incontinence, bladder outlet hypermobility, and leak point pressure >60cm/H2O	Evidence of detrusor overactivity on cystometrogram, post-void residual bladder volumes >50cc, significant pelvic organ prolapse (POP-Q Stage IV) on physical examination, history of dry or wet overactive bladder, previous surgical or bulking agent therapy	Transurethral radiofrequency energy collagen micro-remodeling	Sham treatment probes lacked needle electrodes and sham treatment of radiofrequency generator
Arvonen, 2001[484] Country: Sweden Aim: the effects of pelvic floor muscle training with and without vaginal balls on females stress urinary incontinence	37 women ages 25-65 with stress urinary incontinence, understanding of spoken Swedish	Pregnancy, cysto/rectocele, prolapse, urinary tract infection, altered vaginal tissue, and medication affecting the functioning of the urinary tract or kidneys	Pelvic floor muscle training program with contractions/ relaxations for 5 seconds 10 times twice a day	Pelvic floor muscle training program with contractions/ relaxations for 20/20 seconds 10 times twice a day using weighted vaginal balls 50-100g.

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Aukee, 2002[485] Country: Finland Aim: the effec ts of electromyography-assisted biofeedback training and pelvic floor muscle training on female stress urinary incontinence	30 women with urodynamically tested stress incontinence ages 31 to 69 years without previous incontinence operations and an abdominal leak point pressure >90	Genital protrusion beyond the vaginal hymen, an inability to understand instructions for home training, pregnancy, and any severe disease such as malignancy in the abdominal region, multiple sclerosis, and insulin-dependent diabetes	Pelvic floor muscle exercise after verbal and written instructions for home practice of 20 minutes/day 5 times/week and individual EMG-assisted biofeedback device with vaginal probe and verbal control	Pelvic floor muscle exercise after verbal and written instructions for home practice of 20 minutes/day 5 times per week
Aukee, 2004[486] Country: Finland Aim: the effectiveness of pelvic floor training with home biofeedback device among women with stress urinary incontinence	35 women 21-70 years old with urodynamically confirmed stress incontinent (maximal urethral closure pressure >20cm/H2O and cough leak point pressure >90cm/H2O)	Previous incontinence operations, genital prolapse, inability to understand instructions for home training, pregnancy, severe diseases such as malignancies in the abdominal region, multiple sclerosis and diabetes mellitus requiring insulin	1. Home program with given verbal and written instructions for home practice and advise to practice for 20 minutes/day, 5 times/week. 2. Pelvic floor training by physiotherapist 5 times/12 weeks: 3-5 second contractions with 10 second intervals in supine	Home program with given verbal and written instructions for home practice
Bano, 2005[487] Country: UK Aim: the effects of porcine dermal implant (Permacol) and silicone injection (Macroplastique) on urodynamic stress incontinence in females	50 women with urodynamically proven stress incontinence	Not reported	Peri or transurethral porcine dermal implant injection (Permacol)	Transurethral silicone injection (Macroplastique)
Barroso, 2004[488] Country: Brazil Aim: the effects of transvaginal electrical stimulation on urinary incontinence	36 women (24 patients and 12 controls) with stress, urge, or mixed urinary incontinence	Prolapse or first degree urogenital prolapse, intrinsic sphincter deficiency, cardiac pacemaker; pregnancy, postmenopausal climacteric with symptoms and signs of urogenital atrophy (they could be included after 3 months of treatment with hormone-replacement therapy	Transvaginal electrical stimulation at home twice a day (20-minute sessions) with frequency of 20 (urge) or 50Hz (stress UI), a pulse width of 300ms, with asymmetrical biphasic pulses, an adjustable current intensity (0-100mA)	Placebo

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Berghmans,1996[489] Country: The Netherlands Aim: the effects of biofeedback and pelvic floor muscle exercise on female genuine stress incontinence.	40 women 18-70 years with mild or moderate stress incontinence (grade 1).	Use of medicine to counteract functional disabilities of the lower urinary tract, pronounced lesions of the pudendus nerve during clinical neurophysiological examination, positive sediment of urine culture, non-compliance in the diagnostic phase, neurogenic urinary incontinence	Pelvic floor muscle exercise 12 treatment sessions, 3 times/week with contractions 3-30 seconds 10-30 times beginning with 4 sets of 10 (5 quick and 5 sustained) and increased by 10 per set until 30 times/set. Biofeedback with EMG vaginal probe and visualization	Pelvic floor muscle exercise 12 treatment sessions, 3 times/week with contractions 3-30 seconds 10-30 times beginning with 4 sets of 10 (5 quick and 5 sustained) and increased by 10 per set until 30 times/set
Berghmans, 2002[490] Country: The Netherlands Aim: the effects of physiotherapy in women with proven bladder overactivity	98 patients older than 18 years with proven bladder overactivity defined as Detrusor Activity Index (DAI) ≥0.50, able to understand Dutch	Mechanical intravesical obstruction, urinary calculus, urinary tract infection, colpitis, pacemaker, pregnancy, physiotherapy within 3 months, uncontrolled diabetes mellitus	Pelvic floor exercises with contractions for >20 seconds controlled by physiotherapist palpation with relaxation period of 10 seconds. Bladder training to inhibit the sensation of urgency and to postpone voiding, voiding schedule with an interval >2 hours	Usual care

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Blowman, 1991[491] Country: UK Aim: To assess the efficacy of neuromuscular stimulation and pelvic floor exercises, compared with pelvic floor exercises only, in the treatment of genuine stress incontinence	Only patients diagnosed from bladder pressure studies as suffering from genuine stress incontinence were recruited. They all had maximum bladder volumes over 500ml and exhibited no detrusor contraction in lying or standing. All patients demonstrated cough-induced leakage when standing. They were referred to the physiotherapy department gynecology unit and gave informed written consent to take part in the trial.	Not reported	Neurotrophic stimulation	Placebo stimulation
Bo, 1997[492] Country: Norway Aim: Crossover RCT to examine the effect of voluntary pelvic floor muscle contraction and vaginal electrical stimulation on urethral pressure in women with genuine stress incontinence	12 women with genuine stress incontinence participated in pelvic floor exercise program with 8-12 contractions	Not reported	3 voluntary PFM contractions and 2 electrical stimulators Conmax 50Hz – pulse width 0.75ms, 0-90mA Medicon 50Hz - pulse width 0.5ms, 0-100mA	Electrical stimulation with Medicon 50 Hz - pulse width 0.5ms, 0-100mA

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Bo, 1999[493] Country: Norway Aim: the effects of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment on females genuine stress incontinence	107 women with clinically and urodynamically proved genuine stress incontinence >4g of leakage measured by pad test with standardized bladder volume.	Urinary incontinence other than genuine stress incontinence, involuntary detrusor contractions >10cm/H2O on cystometry, abnormal bladder function (residual urine >50ml and maximal uroflow <15ml/second), previous surgery for genuine stress incontinence, neurological or psychiatric disease, ongoing urinary tract infections, other diseases that could interfere with participation, use of concomitant treatments during the trial, and inability to understand instructions given in Norwegian	1. Pelvic floor exercise with 8-12 contractions 3 times/day and in groups with skilled physical therapists 1/week. 2. The electrical stimulation using vaginal intermittent stimulation with the MS 106 Twin at 50Hz 30 minutes/day. 3. The vaginal cones of 20, 40, and 70g for 20 minutes/day	The untreated control group offered the use of a continence guard
Bo, 2000[494] Country: Norway Aim: the effects of pelvic floor muscle exercise on female genuine stress incontinence	59 women with clinically and urodynamically proven genuine stress incontinence .4 grams of leakage measured by the pad test	Urinary incontinence other than GSI, involuntary detrusor contractions exceeding 10cm/H2O on cystometry, residual urine .50ml, maximal uroflow, 15ml/second, previous surgery for GSI, neurological or psychiatric disease, ongoing urinary tract infections	Pelvic floor muscle exercise with 8-12 maximum contractions in 3 series/day and 45 minutes/week group sessions	Untreated control group
Bo, 2005[495] Country: Norway Aim: Followup RCT to examine the effects of intensive exercise on stress urinary incontinence.	52 women with urodynamic stress urinary incontinence participated in the original RCT	Response rate 90.4%	Intensive pelvic floor exercise with 8-12 maximum contractions for 6-8 seconds 3 series/day under the supervision of physical therapist for 6 months	Home exercise groups

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Borawski, 2007[496] Country: USA Aim: the effects of percutaneous needle electrode technique or a surgical first stage lead placement on implantation of a pulse generator in older urge incontinent women	30 women >55 years with refractory urge incontinence after failure of medical, behavioral, and pelvic floor reeducation management	Not reported	Electrical stimulation with percutaneous needle electrode (22-G spinal needle) placement	Electrical stimulation with surgical first stage lead placement
Borello-France, 2006[497] Country: USA Aim: the effects of exercise position during pelvic-floor muscle exercises on females stress urinary incontinence	44 women 38 to 70 years old, ambulatory, with symptoms of stress urinary incontinence >1/week	Pregnancy, symptoms of urgency or urge urinary incontinence, prior treatments for stress urinary incontinence (collagen injection, medications affecting bladder tone, pessary, or surgery), practicing pelvic-floor muscle exercises, pacemaker, use of intrauterine device, medical history of pelvic cancer, severe endometriosis, neurologic or metabolic disorders likely to impair bladder or sphincter function	Pelvic floor muscle exercises with EMG biofeedback in the supine position only using maximum 30-60 repetitions of 3-12 second contractions twice daily	Pelvic floor muscle exercises with EMG biofeedback in both supine and upright positions, 1 set (3- and 12-second contractions) in each position with maximum 20 repetitions (2 sets of 10) of the 3-12 second contractions twice daily
Borello-France, 2008[498] Country: USA Aim: comparative effectiveness of maintenance exercise program either 1 or 4 times per week in women with stress UI	Women 38 to 70 years of age, not pregnant, ambulatory, and recorded at least one SUI episode and no urgency or urge urinary incontinence (UUI) in a 7-day bladder diary	A medical history that included pelvic cancer, severe endometriosis, use of an intrauterine device, or pacemaker; neurologic or metabolic disorders associated with bladder or sphincter dysfunction; previous medical/surgical treatments for SUI; or prior in	High-frequency (4 times per week) maintenance 2 times/day exercise program with 60 repetitions (3 sets of 20 repetitions) of a 3-second PFM contraction and 30 repetitions (3 sets of 10 repetitions) of a 12-second contraction per exercise session	Low-frequency (1 time/week) maintenance 2 times/day exercise program with 60 repetitions (3 sets of 20 repetitions) of a 3-second PFM contraction and 30 repetitions (3 sets of 10 repetitions) of a 12-second contraction per exercise

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Borrie, 2002[499] Country: Canada Aim: the effects of combined lifestyle and behavioral interventions led by nurses in the management of urinary incontinence	421 subjects 26 years of age or older with self reported urinary incontinence at least once per week, resided in the community, and communicated in English	Pregnancy, residency of long-term care institutions, dementia	Lifestyle modification sessions every 4 weeks led by trained "nurse continence advisers" with a physician with expertise in continence management	Usual care
Bower, 1998[500] Country: Australia Aim: the effects of surface neuromodulation on cystometric pressure and volume parameters in women with detrusor instability or sensory urgency.	48 women with proved detrusor instability or sensory urgency	Urinary tract infection, pregnancy, cardiac pacemaker, impaired cognition, neurogenic bladder dysfunction or cystocele beyond the introitus	Active transcutaneous electrical nerve stimulation with 10Hz. frequency and 200 microsecond pulse width (sacral placement)	1. Sham transcutaneous electrical nerve stimulation with sacral or suprapubic placement 2. Active transcutaneous electrical nerve stimulation with 150Hz. frequency and 200 microsecond pulse with (suprapubic placement)
Boyington, 2005[501] Country: USA Aim: the effects of computer-based system for continence health promotion that included self-management techniques for women with symptoms of involuntary urine loss, urinary frequency or urgency, or nocturia	Women 50 years or older who lived independently in the community with symptoms of UI, urinary frequency or urgency, or nocturia; minimum of 30 on the Telephone Interview for Cognitive Status-modified (TICS-m); Self-reported ability to read and write E	Toilet dependently; blood in their urine, recurrent urinary tract infections, persistent difficulty with bladder emptying as evidenced by straining or other efforts to drain the bladder completely, or symptomatic pelvic prolapse	computer-based system to promote continence health using health clinic visit metaphor that provided fact sheets, testimonials from women who improved with the adoption of behavioral techniques; the expert system advice on Bladder training, PFMT, fluid man	Alternate computer-based system simulating women's magazine with information about breast self-examination and tips for women traveling alone
Brown, 2006[502] Country: USA Aim: the effects of intensive lifestyle intervention or metformin on prevalence of urinary incontinence among overweight pre-diabetic women	2,191 women in the Diabetes Prevention Program RCT older than 25 years, body mass index ≥24kg/m2, a fasting plasma glucose level 95-125mg/dl, and a 2-hour post-challenge glucose level 140-199mg/dl	Exclusion criteria: Taking medications that could affect glucose tolerance or serious medical illness	Intensive lifestyle therapy to lose and maintain at least 7% of initial body weight through a low-fat diet and to engage in moderate-intensity physical activity for at least 150 minutes each week	Placebo twice daily.

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Brubaker, 1997[503] Country: USA Aim: the effects of transvaginal electrical stimulation for treatment of urinary incontinence in women	121 women >25 years of age with either urinary incontinence due to detrusor instability or genuine stress incontinence, or both (mixed incontinence) diagnosed with filling urethrocystometry	Urinary incontinence other than genuine stress incontinence, detrusor instability, or mixed incontinence; leakage episodes <3/week, inadequate genitourinary estrogen (minimum 3 months HRT), inadequate cognitive ability (investigator judgment), urinary tract infection, anatomic defect that precluded use of device, postvoid residual >100ml, implanted electric device, genitourinary surgery, drug treatment for urinary incontinence, anticipated geographic relocation during study.	The transvaginal electric stimulation for 20 minutes 2 times/day using frequency of 20Hz, a 2-second-4-second work-rest cycle with a range of stimulation intensities, from 0-100mA	Sham inactive device
Bryant, 2002[504] Country: Australia Aim: the effects of caffeine restriction on urinary incontinence symptoms	95 consecutive adult patients with urinary symptoms with routine intake of caffeine >100mg every 24 hours	Cognitive impairment, pregnancy, urinary tract infection	Education to reduce caffeine intake to <100mg/day plus bladder training	Bladder training: increasing intervals between voiding; increasing fluid intake to 2 L/day; urinary deferment techniques; ceasing "just in case" voiding
Burgio, 2002[505] Country: USA Aim: the effects of biofeedback as a part of complex behavioral training program for urge incontinence in community-dwelling older women	222 ambulatory, nondemented, community-dwelling women ages 55 to 92 years with urge incontinence or mixed incontinence >2 times/week for at least 3 months, and with urodynamic evidence of bladder dysfunction (detrusor instability during filling or provocation or maximal cystometric capacity of ≤400ml)	Continual leakage, postvoid residual urine volume >150ml, severe uterine prolapse past the vaginal introitus, decompensated congestive heart failure, or impaired mental status (Mini-Mental State Examination score <24)	Biofeedback-assisted behavioral training implemented by nurse practitioners. Abdominal pressure and sphincter responses were measured with 3-baloon probe inserted in rectum. Pelvic floor muscle exercise with 10 second contractions/10 second relaxation for 20-30 minutes	Self-administered behavioral treatment using a self-help booklet to advise pelvic floor exercise and bladder control

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Burns, 1990[506] Country: USA Aim: the effects of pelvic floor exercises or biofeedback on female stress urinary incontinence	128 women with stress or mixed urinary incontinence >3/week with Mini-Mental scores >23	Urinary tract infection	Kegel pelvic floor exercises 4 times/day. Biofeedback with vaginal EMG probe and visual control.	Usual care
Burns, 1993[507] Country: USA Aim: the effects of biofeedback and pelvic muscle exercise treatment on stress incontinence in older community-dwelling women	135 community-dwelling women older than 55 years with sphincteric incompetence, >3 urine losses/week, urodynamic incontinence, >23 scores in Mini-Mental State exam	Glycosuira, pyuria, residual urine >50cc, peak urine flow <15cc/second	Biofeedback using vaginal EMG probe, contraction for 10 seconds and relaxations for 10 seconds 10 times in each weekly session. Pelvic muscle exercise with 4 sets of 20 increasing by 10/set until maximum 200 sets/day	Usual care
But, 2003[508] Country: Slovenia Aim: the effects of functional magnetic stimulation in the treatment of women with urinary incontinence	55 women with urinary incontinence older than 18 years, not pregnant, and not physically or mentally disabled	Implanted electronic equipment (pacemakers), urolithiasis, bladder infection, tumor, recent urethral or continence surgery, use of anticholinergic drugs, beta-blocking agents, and diuretics	Functional magnetic stimulation with Pulsegen device, which produced a pulsating magnetic field of B = 10 microT intensity and a frequency of 10Hz	Placebo treatment with sham not active device
But, 2005[509] Country: Slovenia Aim: the effects of functional magnetic stimulation for treating women with mixed urinary incontinence	39 women with mixed urinary incontinence and predominant urge incontinence	Not reported	Functional magnetic stimulation applied continuously at 18.5Hz day and night	Sham inactive device

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
de Oliveira Camargo, 2009[510] Country: Brazil Aim: comparative effectiveness of individual vs. group pelvic floor muscle training	Women with confirmed urodynamic SUI, positive cough stress test, and less than 3 g of leakage as measured by a pad test with a standardized bladder volume (200 ml)	Detrusor overactivity, chronic neurological or muscular diseases, abnormal genital bleeding, uterine prolapse, advanced genital prolapse, active genitourinary tract infections, pregnancy, or vaginal atrophy, intrinsic sphincter deficiencies, Valsalva leak	Pelvic floor exercises in a group with two weekly sessions of 45 minutes each. In the orthostatic position, patients received oral instructions to perform ten contractions of 5 seconds with 5 seconds of recovery time, 20 contractions of 1 second with 1 second of recovery time	Individual pelvic floor exercises Following PERFECT assessment scheme with contractions in accordance with the endurance, power, and time that the patients could tolerate.
Cammu, 1998[511] Country: Belgium Aim: the effects of pelvic floor exercises and vaginal weight cones in the treatment on female genuine stress incontinence	60 ambulatory and fit white women with urodynamic urinary stress incontinence, and vaginal capacity permitting the use of a vaginal probe-EMG biofeedback-or cones post-partum period, and had neither a genital prolapse nor any other associated pathology	Not in abstract	Weekly session of pelvic floor exercises vaginal probe-EMG biofeedback using perineometer	Vaginal weight cones (20, 32, 45, 57, and 70 g) for 15 minutes, twice daily

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Castro, 2008[253] Country: Brazil Aim: To compare the effectiveness of pelvic floor exercises, electrical stimulation, vaginal cones, and no active treatment in women with urodynamic stress urinary incontinence.	Women with proven urodynamic stress urinary incontinence were enrolled at the Urogynecology and Reconstructive Pelvic Surgery	Patients with chronic degenerative diseases that would affect muscular and nerve tissues, advanced genital prolapses, pregnancy, active or recurrent urinary tract infections, vulvovaginitis, atrophic vaginitis, continence surgery within one year, and patients with cardiac pacemakers; patients with intrinsic sphincteric deficiencies identified by the Valsalva leak point pressure ≤60cm H20 measurement in the sitting position with a volume of 250 ml in the bladder and/or by the measurement of a urethral closure pressure ≤20cm H20 in the sitting position at maximum cystometric capacity.	Pelvic Floor Muscle Training	Electrical stimulation/weighted vaginal cone/no treatment
Chadha, 2000[512] Country: Australia Aim: the effects of national guidelines and local protocols in improving hospital care for women with UI	449 women with urinary incontinence from gynecology units in four district general hospitals across Scotland	Not reported	National evidence based guidelines adapted locally to protocols, which were disseminated at specific local educational meetings and implemented by placing a copy of the appropriate protocol in women's hospital case notes prior to consultation	Usual care

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Coleman, Country: USA Aim: the effect of Chronic Care Clinics on urinary incontinence in frail older adults	Frail older adults were those enrollees at high risk for hospitalization according to the Chronic Disease Score, the patients in the Group Health Cooperative of Puget Sound, a large Health Maintenance Organization located in western Washington State	Severe illness that precluded their participation in the study; moderate to severe dementia; residence in a nursing home, terminal illness	New model of primary care, Chronic Care Clinics: (1) An extended (30 minutes) visit to the patient's physician and team nurse dedicated to developing a shared treatment plan that emphasized the reduction of disability; (2) A session with the pharmacist	Usual care
Corcos, 2005[513] Country: Canada Aim: Noninferiority RCT to examine effects of collagen injection or surgery on female stress urinary incontinence	133 women older than 30 years with stress urinary incontinence lasted for >6 months	Contraindications to surgery or collagen injections (allergic reaction), associated conditions (e.g., severe medical disease or indication for hysterectomy) or pelvic prolapse (vault, cystocele, rectocele), neurogenic bladder or interstitial cystitis	Intraurethral collagen submucosal injection 4 injections at 1-month intervals	Surgery (needle bladder neck suspensions, Burch, and slings). The choice of technique was left to the surgeon
Demain, 2001[514] Country: USA Aim: comparative effectiveness of group versus individual management on physical symptoms and quality of life in female urinary incontinence	Women over 18 years of age with clinical symptoms of stress and/or urge incontinence (median duration of symptoms 3 years 7 months) presenting to physiotherapy	Pregnancy, recent pelvic surgery (3 months), history of pelvic malignancy, fecal incontinence, current urinary infection, grade III prolapse, diseases of central nervous system, acute mental illness and dementia, previous physiotherapy for incontinence	Three educational group sessions with 4-12 women. Women attended 3 1-hour sessions with educational and exercise components	One 45-minute individual treatment, instructions in pelvic floor muscle exercise
Demirturk, 2008[515] Country: Turkey Aim: comparative effectiveness of interferential current and biofeedback applications on incontinence severity in patients with urinary stress incontinence	Women with urodynamic stress UI and moderate intensity of incontinence as determined by a one-hour pad test referred Physical Therapy and Rehabilitation, Women's Health Unit	Urinary tract infections, detrusor over activity, cognitive problems and neoplasm	Interferential current with a frequency of 0–00 Hz 5 minutes per session, three times a week for a total of 5 sessions	Kegel exercises with biofeedback 5 minutes per session, three times a week for a total of 5 sessions

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Diokno, 2004[516] Country: USA Aim: the effects of behavioral modification program on incidence of urinary incontinence in older women	359 postmenopausal, continent women (0-5 days of incontinent episodes in the previous year) 55 years and older. At baseline 2 groups reported identical 39% absolute continence and zero UI days 61% of participants reported 1 to 5 UI episodes in year	Neurologic diseases, mini-mental scores <24, positive paper towel cough test, grade 4 uterine prolapse	1 2-hour classroom presentation on behavioral modification program: pelvic floor muscle training, bladder training, and individualized test of knowledge, adherence, and skills to reinforce the technique as needed	Usual care
Diokno, 2010[517] USA The effectiveness of behavioral modification program vs. standardized protocol taught to adult incontinent women	Adult incontinent ambulatory females from four Michigan counties in the U.S.	1) Women currently under incontinence treatment with medications or previous/current behavioral programs, 2) history of bladder cancer, stroke, multiple sclerosis, Parkinsonism, epilepsy or spinal cord tumor or trauma, 3) pregnancy, 4) MESA questionnaire of 725 or higher on urge score, 70% or higher on stress score, or urge percentage higher than stress percentage to eliminate those with total incontinence and those with urge predominant symptoms, respectively. Previously failed anti-incontinence surgery was not considered for exclusion	Group intervention	No intervention

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Dougherty, 2002[518] Country: USA Aim: the effects of behavioral management for continence on urinary incontinence in older rural women in their homes	218 women 55 years and older, who lived in a private residence in rural area; with involuntary urine loss >2/week of 1g/24 hours or more; without urinary tract infection	Bladder cancer or kidney disease, indwelling urinary catheter, residual urine >100cc, needed caregiver	Behavioral management for continence: Self-monitoring and bladder training to reduce caffeinated beverages to <2 cups/glasses, 1,500 <daily fluid intake <4000cc, no fluid consumption after 6 pm, daytime voiding interval <4 hours, and treatment of const	Usual care
Dowd, 1996[519] Country: USA Aim: the effects of hydration on the number of urinary incontinence episodes	58 women 50 years old and older with incontinence more than 6 months, independent in self-care, English speakers with >20 scores on Mini-Mental State	Exclusion criteria: not provided	1. Increase fluid intake by 500cc 2. Maintain fluid intake at baseline level	Decrease daily fluid intake by 300cc
Dowd, 2000[520] Country: USA Aim: the effects of cognitive strategies combined with educational programs in urinary incontinence	40 subjects >40 years of age, independent in self-care, with history of incontinence and/or frequency for at least 6 months, able to read and write English, and having hearing adequate for listening to an audiotape	Presence of urinary tract infections or severe neurological disorders	Education about bladder health, recorded incontinence and frequency episodes in a voiding diary, and listening to the audiotape daily	Education about bladder health and recorded incontinence and frequency episodes in the voiding diary

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Dumoulin, 2004[521] Country: Canada Aim: the effectiveness of multimodal supervised physiotherapy programs among women with persistent postnatal stress urinary incontinence	64 premenopausal women younger than 45 years presenting symptoms of stress urinary incontinence at least once per week 3 months or more after their last delivery	Current pregnancy, urinary incontinence before pregnancy, previous surgery for stress incontinence, moderate to severe urogenital prolapse, involuntary detrusor contraction on cystometry neurologic or psychiatric disease, or a major medical condition, taking medication that could interfere with their evaluation or treatment, inability to understand French or English instructions. Loss of followup: 2, plus 2 did not attend the final examination and were excluded from the analysis.	1. Pelvic floor rehabilitation: 15 minute electrical stimulation of the pelvic floor muscle; then 25 minute pelvic floor muscle exercise program with biofeedback, which included strengthening and motor relearning exercises and a home exercise 5 days/week. 2. Pelvic floor rehabilitation plus abdominal training: in addition to PFE 30 minutes of deep abdominal muscle training consisting of isolation, reeducation, and functional retraining of the transversus abdominis	Relaxation massage for the back and extremities by physiotherapist. They were asked not to exercise their pelvic floor muscles at home.
Elser, 1999[522] Country: USA Aim: the effects of pelvic floor muscle training, bladder training, or both, on urodynamic parameters in women with urinary incontinence	204 women 45 years or older, ambulatory, mentally intact with urodynamic genuine stress incontinence or detrusor instability, with or without stress incontinence, experiencing 1–100 episodes of incontinence per week as recorded on the qualifying 7-day diary	Reversible cause of incontinence, uncontrolled metabolic conditions (e.g., diabetes mellitus), postvoid residual of >100ml, persistent urinary tract infection, urinary tract fistula, or indwelling catheterization	Patient education, self-monitoring with treatment logs, compliance assessment, and positive reinforcement techniques administered by trained research nurses. Pelvic floor muscle training with10 fast (3 second) contractions and 40 sustained (10 second) contractions	Bladder training

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Emmons, 2005[523] Country: USA Aim: the effects of acupuncture on overactive bladder in women	85 women older than 18 years, with symptoms of overactive bladder with urge incontinence, >8 voids per day, subjective urgency to void, and urge-associated incontinence at least twice during a 3-day period of time	Pregnancy, taking medications for overactive bladder or receiving acupuncture treatments for any condition, unable to ambulate or unable to complete a 3-day voiding diary, and hematuria or untreated urinary tract infection	Acupuncture treatment expected to improve bladder symptoms	Placebo acupuncture treatment designed to promote relaxation
Engberg, 2002[524] Country: USA Aim: Cross-over RCT to examine the effects of prompted voiding in cognitively impaired homebound older adults	19 adults 60 years and older with urinary incontinence >2 episodes/week for >3 months who met Center for Medicare and Medicaid Services criteria for being homebound, residents in 2 large Medicare-approved home health agencies in a large metropolitan area	Terminal illness; postvoid residual volume >100ml; caregiver was unable or unwilling to provide toileting assistance, complete bladder diaries, or implement the PV protocol	Prompted voiding by caregivers to approach subjects hourly for perceived wet/dry status vs. objective wet checks, feedback and praising for correct response, toilet by request, positive feedback for appropriate toileting	Usual care with attention control (visits by the nurse practitioner every 1-2 weeks to provide social interaction)
Fantl, 1991[525] Country: USA Aim: the effects of bladder training on urinary incontinence in older women	131 noninstitutionalized women 55 years and older with clinical and urodynamic urinary incontinence >1 leakage/week; mentally intact (Mini-Mental State Examination score >23), capable of independent toileting	Uncontrolled diabetes, urinary tract infection, urinary obstruction, reversible cause of incontinence, permanent catheterization	Bladder training using 6 weekly visits included patient education; voiding schedule to have micturition from every 30-60 minutes to every 2.5-3 hours; and positive reinforcement	Usual care

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Felicissimo, 2010[526] Brazil The effectiveness of intensive supervised PFMT to unsupervised PFMT in the treatment of female stress UI	Women with confirmed urodynamic stress urinary incontinence with Valsalva leak point pressure more than 60 cm/h2O and no detrusor overactivity. All subjects had predominant symptoms of SUI with an average of at least three stress continence episodes per week.	Chronic neurological muscular diseases, abnormal genital bleeding, genital prolapse at stage ≥2 of POP-Q (Pelvic Organ Prolapse-Questionnaire), active genitourinary tract infections, pregnancy, and women who preferred surgery. Patients with intrinsic sphincter deficiencies as identified by Valsalva leak point pressure ≤60cm H2O measured in the sitting position with a volume of 250ml in the bladder were also excluded	Supervised Pelvic Floor Muscle Training	Unsupervised Pelvic Floor Muscle Training
Finazzi-Agro, 2005[527] Country: Italy Aim: comparative effectiveness of posterior tibial nerve stimulation performed weekly vs. 3 times per week in men and women with overactive bladder syndrome	Men and women with overactive bladder syndrome not responding to antimuscarinic therapy	Not reported	Posterior tibial nerve stimulation 3 times/week	Posterior tibial nerve stimulation 1 time/week

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Finazzi-Agro, 2010[528] Italy To evaluate the efficacy of percutaneous tibial nerve stimulation in female patients with detrusor overactivity incontinence	1) Urge incontinence and urodynamically diagnosed detrusor overactivity incontinence; 2) Unresponsive to behavioral and rehabilitation therapy or antimuscarinic; 3) Able to give written, informed consent; 4) 18 years of age or older; 5) Mentally competent and able to understand all study requirements; 6) Able to understand the procedures, advantages and possible side effects; 7) Willing and able to complete a 3-day voiding diary and I-QoL questionnaire; 8) Bladder capacity 100 ml or greater; 9) No signs of neurologic abnormalities at objective examination; no history of neurologic pathology; and no pharmacological treatment or pharmacological treatment unchanged for 30 days before beginning the study	1) Pregnancy or intention to become pregnant during the study; 2) Active urinary tract infection or recurrent urinary tract infections (more than 4 per year); 3) Presence of urinary fistula, bladder or kidney stones, interstitial cystitis, cystoscopic abnormalities that could be malignant; 4) Diabetes mellitus; and Cardiac pacemaker or implanted defibrillator	Percutaneous tibial nerve stimulation	Placebo
Fujishiro, 2000[529] Country: Japan Aim: the effects of magnetic stimulation of the sacral roots for the treatment of stress incontinence	62 women, 37 to 79 years old with stress incontinence, >1 episode of urinary leakage recorded in a 3-day voiding diary, and 2 gm or more urine loss on a 1-hour pad test	Urinary infection, interstitial cystitis and large uterine myoma, and other treatments for stress incontinence, including pelvic floor exercises, medical treatment and electrical stimulation	Magnetic stimulation of sacral roots with 15Hz. frequency, 50% intensity output for 5 seconds per minute for 30 minutes	Sham stimulation with inactive device

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Fujishiro, 2002[530] Country: Japan Aim: the effects of magnetic stimulation of the sacral roots for treating urinary frequency and urge incontinence	37 women 43 to 75 years old with the complaint of urinary frequency and/or urge incontinence, >8 voids daily and/or >1 episode of urge incontinence on a 3-day voiding diary, and mean of less than 250 ml. urine volume per void on a 3-day voiding diary	Neurological disorders suggesting neurogenic bladder dysfunction, apparent episode of stress incontinence, urinary infection, interstitial cystitis or large uterine myoma , other treatments for urinary frequency or urge incontinence, including pelvic floor exercises, medical treatment or electrical stimulation	Magnetic stimulation of sacral roots with 15Hz. frequency, 50% intensity output for 5 seconds per minute for 30 minutes	Sham stimulation with inactive device
Gallo, 1997[531] Country: USA Aim: comparative effectiveness of external cue to action, an audiocassette tape, to improve pelvic floor muscle exercise compliance in women with stress urinary incontinence	Women ages 20–80 with a history of self-reported stress urinary incontinence and objective genuine stress incontinence during a urodynamic evaluation	Pregnancy and psychological disorders that would make it difficult to follow pelvic floor exercise instruction	The audiotape reinforced pelvic floor exercise instruction with counted aloud 25 consecutive pelvic floor muscle exercise contractions for 10 seconds and then relaxing for 10 seconds; 45-minute appointment with the specialized on UI nurse investigator	45 minute appointment with the specialized on UI nurse investigator with detailed verbal instructions about pelvic floor muscle identification and contraction; proper pelvic floor muscle contraction by the patient measured using a biofeedback computer
Gameiro, 2010[532] Country: Brazil Aim: To compare the efficacy of the VWC (Vaginal Weight Cone) and assisted PFMT to treating UI in women.	To be eligible, patients had been referred by a gynecologist as having symptom of predominant SUI, and 50% also presented urge incontinence. None of the patients had a urodynamic diagnosis of SUI. None of the patients had taken anticholinergics or tricyclic antidepressants or had been treated using pelvic floor exercises or bladder training.	Anterior or posterior vaginal prolapse beyond grade II, urinary infection, neurological or demyelinating condition, and poor comprehension.	Assisted Pelvic Muscle Floor Training	Vaginal weight cone

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Ghoniem, 2009[533] Country: USA, Canada Aim: the effectiveness and safety of Macroplastique® as minimally invasive endoscopic treatment for female stress urinary incontinence primarily due to intrinsic sphincter deficiency	Women with a diagnosis of SUI primarily due to ISD that failed behavior modification (biofeedback) or exercise (Kegel)	Not viable mucosal lining, abnormal bladder capacity, urinary tract infection, uncontrolled detrusor overactivity, high post-void residual urine volume, high grade pelvic organ prolapse, confounding bladder pathology, pregnancy or morbid obesity	Transurethral injection of Macroplastique	Transurethral injection of Contigen®
Gilling, 2009[534] Country: New Zealand Aim: the efficacy of extracorporeal electromagnetic stimulation of the pelvic floor for treating female stress urinary incontinence	Women >20 years old; symptoms of SUI or mixed UI, genuine SUI confirmed by pad-testing and urodynamics, ambulatory and community-dwelling, neurologically normal, agree not to seek or use any other form of treatment for UI during the study, otherwise healthy	Previous incontinence or pelvic floor surgery, Grade 3 or 4 pelvic prolapse (ICS classification), pregnancy, drugs, e.g. diuretics, alga-adrenergic antagonists or other medication prescribed for bladder dysfunction, concurrent use of internal medical device	Electromagnetic stimulation 3 times/week using the NeoControl chair (Neotonus Inc., Marietta, GA, USA) with 10-minute stimulation at 10 Hz followed by a 3-minute rest and then a further 10-minute stimulation at 50 Hz. The intensity was adjusted to the maximum level	Sham stimulation with a thin deflective aluminum plate inserted in the chair, which prevented penetration of the magnetic field into the patient, and simulated the noise and sensation produced during active treatment sessions.
Glavind, 1996[535] Country: Denmark Aim: effects of biofeedback on continence rates in women with stress UI	Women with self reported incontinence when coughing, laughing, lifting and during physical exercise verified by a positive 1-hour pad-weighing test (>2 g) with a bladder volume of three-quarters of the cystometric capacity	Intravesical obstruction and detrusor instability, previous surgery for urinary incontinence	Physiotherapy 2-3 times with individual instruction combined with biofeedback four times. Biofeedback was performed with a vaginal surface electrode (Dantec 21L20, Skovlunde, Denmark) and a rectal catheter.	physiotherapy 2-3 times with individual instruction alone
Glavind, 1997[536] Country: Denmark Aim: the effects of vaginal sponge intended to support the urethra during aerobic exercise in women with stress urinary incontinence	Women 44-68 years with stress urinary incontinence lasting from 1 to 11 years, with daily episodes of incontinence.	intravesical obstruction and detrusor instability	half an hour of aerobic exercises on 2 consecutive days with the vaginal sponge intended to support the urethra	Half an hour of aerobic exercises on 2 consecutive days without the vaginal sponge

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Goode, 2003[294] Country: USA Aim: the effect of biofeedback-assisted behavioral training on urinary incontinence in older women	105 ambulatory, non demented, community-dwelling women 55 and older with self-reported urge incontinence at least twice per week for >3 months with urodynamic evidence of bladder dysfunction	Continual leakage, postvoid residual urine volume greater than 200ml, uterine prolapse past the introitus, narrow-angle glaucoma, unstable angina pectoralis, congestive heart failure, history of malignant arrhythmias, or impaired mental status	Four sessions (over 8 weeks) of biofeedback-assisted behavioral training by nurse practitioners	Placebo control condition, usual care
Goode, 2003 Country: USA Aim: whether pelvic floor electrical stimulation increases efficacy of behavioral training for community-dwelling women with stress incontinence	200 ambulatory, nondemented, community-dwelling women ages 40 to 78 years with urinary incontinence (at least 2 stress incontinence episodes per week on the 2-week baseline bladder diary) confirmed during urodynamic testing	Continual leakage, postvoid residual urine volume >150ml, severe uterine prolapse, congestive heart failure, hemoglobin A1C ≥9, or impaired mental status (Mini-Mental State Examination score <24)	Behavioral training (biofeedback-assisted pelvic floor muscle training, home exercises, bladder control strategies, and self-monitoring with bladder diaries). Anorectal biofeedback (~20 minutes) with 3-balloon probe to measure sphincter pressure	Control: self-administered behavioral training administered with a self-help booklet with suggestions for isolating the pelvic floor muscles, progressive home exercise, self monitoring, and bladder control strategies
Gorman,1995[537] Country: USA Aim: effectiveness of an expert system for disseminating knowledge to women with urinary incontinence	Ambulatory, alert, community dwelling women with urinary incontinence defined as accidental urine loss at least twice a week	Dependence on a urinary catheter; not successful completion of a mental competency test	1. The expert system-the Urinary Incontinence Consultation System-with the Agency for Health Care Policy and Research (AHCPR) patient guideline for urinary incontinence and research literature for behavioral treatments 2. The educational printed booklet	General health video
Hahn, 1991[538] Country: Sweden Aim: To compare the effect of two conservative methods and evaluate the long - term results	Women not previously operated upon, with pure stress urinary incontinence, consecutively referred for surgery	Not reported	Pelvic floor training	Intravaginal electrical stimulation

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Harvey, 2002[539] Country: Not reported Aim: To determine the comparative effectiveness of weighted cones versus biofeedback in women with urodynamic incontinence	Consecutive adult clinic patients with symptoms of mainly stress incontinence and confirmed urodynamic stress incontinence on urodynamics were approached	Age >65 year, detrusor overactivity, past treatment with cones/biofeedback/ electrical stimulation/surgery, POPQ >stage 3.	Biofeedback	Weighted vaginal cones
Hu, 1989[540] Country: USA Aim: the effects of behavior therapy program for urinary incontinence on women residents of nursing homes	143 women with confirmed stress incontinence in seven nursing homes with ability to recognize her own name.	Hospitalization, insufficient number of wet episodes per day (an average 0.18)	13-week behavior therapy program for urinary incontinence which included hourly checking and prompting of individuals to toilet, praising for successful toileting, and social reinforcement (additional personal service).	Control group received usual incontinence-related care
Huang, 2009[541] Country: USA Aim: the effects of an intensive behavioral weight reduction intervention on sexual function in overweight and obese women with urinary incontinence	The PRIDE study: at least 30 years old, have a BMI of 25 to 50 kg/m2 and self-report at least 10 episodes of incontinence weekly	Any condition that would prevent safely participating in an intensive diet and exercise program without medical supervision, medical therapy for incontinence, or weight loss in the previous month	Intensive lifestyle and behavior change program modeled after the Diabetes Prevention Program and Look AHEAD (Action for Health in Diabetes) trials designed to produce an average loss of 7% to 9% of initial body weight weekly 1-hour group sessions led by continent nurse	The structured education program: 1-hour group educational sessions at months 1, 2, 3, and 4, providing general information about weight loss, physical activity, healthy eating habits and health promotion
Hui, 2006[542] Country: China Aim: the effects of telemedicine vs. a conventional outpatient continence service (CS) in community-dwelling older women with urge or stress incontinence	Community-dwelling older women 60 years or over, with symptoms of urge or stress incontinence, and with one or more incontinence episodes in a week	Active urinary tract infection, a post-void residual volume by bladder ultrasound of more than 150 ml, third-degree uterine prolapse and treatment for urinary symptoms	The nurse specialist provided behavioral training to the group via videoconferencing, with the support of a female registered nurse who helped to run the TCP sessions. Each participant was encouraged to share her experiences with the nurse specialist	Face-to-face consultation the nurse specialist to give digital assessment feedback on pelvic floor contraction + booklet on urge and stress incontinence management

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Hung, 2010[543] Country: Taiwan Aim: To investigate the effect of treating SUI symptoms in women by retraining diaphragmatic, deep abdominal and PFM coordinated function.	Women aged 18-65 years and had at least one episode of SUI symptom during the previous month	Being pregnant or less than three months postpartum, having systemic neuromuscular disease, having had previous surgery or intensive PFMT for UI, having severe low back pain or pelvic pain, having had a radical hysterectomy or having ongoing urinary tract infections	Diaphragmatic, deep abdominal and pelvic floor retraining	Placebo (Self-monitored PFM exercises)
Janssen, 2001[544] Country: The Netherlands Aim: the effects of individual and group physiotherapy for urinary incontinence in women	530 women of all ages (mean 47.8 years) with stress, urge, or mixed incontinence	Neurological cause of incontinence, a tumor or infection in the pelvis, severe vaginal prolapse	Individual pelvic floor exercises 5 times/day and bladder training with delay voiding, training with 11 30-minute sessions	Group pelvic floor exercises 5 times/day and bladder training with delay voiding, training with 9 2-hour sessions
Jeyaseelan, 2000[545] Country: UK Aim: effects of electrical stimulation on women stress incontinence	Women with urodynamically proven stress incontinence	Neurological conditions diagnosed by consultant; Previous electrical stimulation for stress incontinence, prolapse; pregnancy; pacemakers and cardiomyopathy; abnormal urological/gynecological findings; urinary tract/vaginal infection; recent pelvic floor surgery	The electro stimulation technique described by Oldham (International Patent Publication WO98/47357) with a background low frequency (to target slow twitch fibers) and intermediate frequency with an initial doublet (to target fast twitch fibers).	Sham electrical stimulation consisted of one 250-μs impulse every minute for 60 minutes
Karademir, 2005[323] Country: Turkey Aim: the effects of Stoller afferent neurostimulation with and without a low-dose anticholinergic (oxybutynin hydrochloride) in patients with detrusor overactivity	43 patients with symptoms of detrusor overactivity confirmed urodynamically	Urinary tract obstruction, urinary retention, neurologic or metabolic disorder, other treatments for urinary incontinence	Stoller afferent neurostimulation with frequency 20Hz and amplitude 0.5-10mA	Stoller afferent neurostimulation with frequency 20Hz and amplitude 0.5-10mA combined with 5mg of oral oxybutynin hydrochloride

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Kim, 2009, [546] Country: Japan Aim: To determine the effects of exercise treatment on reducing urine leakage in Japanese elderly women with stress, urge, and mixed UI	Women aged 70 and older who reported urine leakage one or more times per month.	Not reported	Exercise treatment enhancing PFM and functional fitness	Placebo
Kim, 2001[547] Country: Korea Aim: the effects of continence efficacy intervention program on stress urinary incontinence in Japanese women	48 women 20-75 years old with stress or mixed urinary incontinence	Drug or surgery treatment for incontinence	Continence efficacy intervention program: common pelvic floor muscle education, audiovisual tape, calendar, counseling, schedule guideline, assessing self-care methods.	Conventional care
Kim, 2007[548] Country: Japan Aim: the effectiveness of pelvic floor muscle and fitness exercises in reducing urine leakage in elderly women with stress urinary incontinence	Women >70 years old with stress UI >1 per month	Stress UI <1/month; urge or mixed incontinence	Fitness exercises and 60-minute pelvic floor muscle exercise sessions two times per week; 10 fast contractions (3 seconds) and 10 sustained contractions (6–8 seconds) with 10-second relaxation periods between the contractions.	Not described (no active intervention)
Kim, 2008[549] Country: South Korea Aim: the effect of hand acupuncture treatment on the stress urinary incontinence in women	Women diagnosed with stress UI, never treated for UI including estrogen therapy or surgery	Stroke, dementia, Parkinson's disease, multiple sclerosis, spinal cord injury, communication problems, glycosuria or proteinuria	Active hand acupuncture points, ST27, CV4 or SP15	Inactive hand acupuncture points

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Kincade, 2007[550] Country: USA Aim: the efficacy of self-monitoring techniques to reduce urine loss and increase quality of life for women with urinary incontinence	Community-dwelling women 18 and older living in Wake, Nash, and surrounding counties in North Carolina with involuntary urine loss of >1 g in 24 hours	Involuntary urine loss of less than 1 g in 24 hours, positive urine test for bacteria, diagnosis of bladder cancer or kidney disease, prior treatment of UI with biofeedback, urinary catheter, available to participate for less than 1 year, post void residual	Self-monitoring group with training on self-monitoring techniques at the end of the second visit; individualized counseling about caffeine consumption, amount of and timing of fluid intake, voiding frequency, and constipation; teaching a simple pelvic floor exercise	Wait list group; teaching a simple pelvic floor muscle contraction technique (Quick Kegel)
Konstantinidou, 2007[551] Country: Greece Aim: comparative effectiveness of group pelvic floor muscle training under intensive supervision to that of individual home therapy in women with stress UI	Women over 18 years with a clinical and urodynamic diagnosis of SUI for more than 3 months, >7 incontinence episodes per week, daytime frequency of less than 8 micturition episodes, nocturia of less than 3 episodes, positive stress test (urine leakage)	Symptoms of urgency and urge incontinence (excluded by the incontinence-specific history and the absence of detrusor overactivity or increased bladder sensation during standard voiding cystometry), presence of any degree of pelvic organ prolapse	Common weekly session in subgroups of 5, written training instructions for the rest of the week, group instructions for home application of pelvic floor training. Individualized according to the strength and endurance of pelvic floor muscles training program	Group instructions for home application of pelvic floor training and individual followup in hospital every 4 weeks. Individualized according to the strength and endurance of pelvic floor muscles training program included 3 sets of fast contractions.
Kumari, 2008[552] Country: India Aim: effects of behavioral therapy for urinary incontinence in women	Adult women with urinary incontinence	Continuous urinary drainage catheter, those taking diuretics, diagnosed vesicovaginal fistula, multiple sclerosis, spinal injury, severe uterine prolapse, mental impairment, pregnant women, and women who had delivered a baby in last 6 months	Behavioral treatment with educational materials, pelvic floor exercises with at least 50 pelvic floor contraction exercises each day, bladder retraining, and maintenance of a voiding diary and exercise record	No active therapy
Lagro-Janssen, 1992[553] Country: The Netherlands Aim: the effects of pelvic floor exercises on stress incontinence and bladder training on urge incontinence	110 women with self-reported urinary incontinence confirmed with urodynamic as stress or urge	Not reported	Pelvic floor exercises alone (stress) or bladder training (urge) or its combination (mixed)	Usual care

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Lagro-Janssen, 1991[554] Country: The Netherlands Aim: the effects of pelvic floor exercise on urinary incontinence in women	66 women ages 20-65 years with genuine stress incontinence	Previously undergone an operation for incontinence; if they suffered from underlying neurological causes for incontinence, from diabetes mellitus or from urinary tract infection; or if there was a temporary cause for their incontinence (for example, pregnancy)	Instructions in pelvic floor exercises 5- 10 sessions of 10 pelvic muscle contractions for 6 seconds each day.	No therapy
Lamb, 2009[555] Country: UK Aim: To compare the effectiveness of group versus individual sessions of physiotherapy in terms of symptoms, quality of life, and costs, and to investigate the effect of patient preference on uptake and outcome of treatment	Women aged 18 years and over; able and willing to give informed written consent with an interpreter if necessary; clinical symptoms of stress and/or urge incontinence.	Pregnancy; recent pelvic surgery (less than three months); history of pelvic malignancy; current urinary infection; grade III and IV prolapse; disease of the central nervous system (e.g. multiple sclerosis, cerebrovascular accident) or acute mental illness and dementia; previous physiotherapy for incontinence within the last 12 months.	Group treatment Pelvic Muscle Floor Training	Individual treatment
Lappin, 2003[556] Country: USA Aim: Crossover, placebo controlled RCT to examine effects of pulsed electromagnetic fields on bladder control in patients with multiple sclerosis	145 patients 18-65 years old with clinically definite multiple sclerosis and light spasticity (>2 in 6 point scale) and bladder control problems	Changes in medication last 2 months, pregnancy, pacemaker, chronic diseases	Daily simulation with low frequency pulsed electromagnetic fields	Sham inactive device
Laycock, 2001[557] Country: UK Aim: the effects of vaginal cones, pressure biofeedback, and pelvic floor exercises on stress urinary incontinence in females	101 women 20-64 years old with symptoms of stress urinary incontinence	Moderate or severe urge urinary incontinence, moderate or severe genital prolapse, pregnancy or plans to become pregnant, use of medications that can affect the lower urinary tract, HRT for <3 months, neurological diseases	Pelvic floor exercise with maximum contraction for 1 second and rest for 4 seconds, 10 minutes/day combined with home pressure biofeedback using intra-vaginal perineometer	Pelvic floor exercise for 10 minutes/day

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Lee, 2001[558] Country: Canada Aim: the effects of periurethral autologous fat injection on female stress urinary incontinence	68 women with stress urinary incontinence determined by history, urinary leakage via the urethra with cough provocation	Detrusor instability on multichannel urodynamic, co-interventions, including hormone replacement, weight reduction, or Kegel exercises, other diagnoses causing incontinence, including bladder instability	Periurethral injections of autologous fat (30cc of fat from the anterior abdominal wall or buttock through a single 2-3mm) with 3 maximum injections depending on outcomes measures	Placebo (saline)
Liebergall-Wischnitzer, 2009[559] Country: Israel Aim: comparative effectiveness of circular muscle exercises (Paula method) or pelvic floor muscle exercise on stress UI in women	Women at least 1 g urinary leakage in a 1-hour clinic based pad test and with the ability to understand instructions in Hebrew or English	Pregnancy or breastfeeding; 12 weeks of delivery, 6 weeks of abortion, or 6 months of pelvic surgery; cardiac, respiratory, psychiatric, and neurological illnesses that limit physical activity; no demonstrated leakage of >1 g, grade three or higher uterine prolapse	The Paula method of circular muscle exercises. The Paula method was taught by three registered instructors to give weekly individual 45-minute sessions + recommendation to practice daily for 45 minutes at home	Pelvic floor muscle training taught by ten physiotherapists using a structured exercise program in groups of 1–10 people for 30 minutes once weekly for 4 weeks, followed by two more lessons 4 weeks apart each (overall six lessons)
Liebergall-Wischnitzer, 2005[560] Country: Israel Aim: the effects of circular muscle exercises on female urinary stress incontinence	59 women, mainly hospital employees with stress or mixed urinary incontinence with urine loss >1gin pad test	Pregnancy, severe cardiac or respiratory diseases, pelvic surgery within 6 months, grade 3 and 4 cystocele, previous pelvic radiation, active mucosal lesion in vagina or perineum	Paula method of circular muscle training 15-45 minutes/day with training sessions of 45 minutes/week	Pelvic floor muscle exercise 15 minutes with 30 minute lesson session/week
Lightner, 2001[561] Country: USA Aim: the effects of bulking agents on stress urinary incontinence due to intrinsic sphincter deficiency in women	355 women diagnosed with stress urinary incontinence due to intrinsic sphincter deficiency, abdominal leak point pressure of less than 90cm/H2O, who failed prior surgical and medical treatment	355 women diagnosed with stress urinary incontinence due to intrinsic sphincter deficiency, abdominal leak point pressure of less than 90cm/H2O, who failed prior surgical and medical treatment	Injection of bulking agent 1.0ml durasphere maximum 5 times with a minimum 7 day interval	Injection of bulking agent bovine collagen maximum 5 times with a minimum 7 day interval

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Lightner, 2009[562] Country: USA Aim: Comparative effectiveness of Zuidex using a non-cystoscopy mid-urethral injection technique vs. Contigen injected endoscopically at the bladder neck in the treatment of urinary stress incontinence secondary to intrinsic sphincter deficiency in adult women	Zuidex Study Group: adult women seeking treatment for stress UI with confirmed urodynamic stress incontinence with abdominal leak point pressures <100 cm H2O, positive pad testing (mean urinary leakage of >10 g during screening	Previous treatment with bulking agents of any type, pure predominant symptoms, mean voided volumes <200 ml on bladder diary, detrusor overactivity on filling cystometry, postvoid residual volumes >100 ml on 2 occasions, or stage III or IV pelvic floor prolapse	Non-cystoscopy mid-urethral injection of Zuidex	Endoscopical injection of Contigen
Luber, 1997[563] Country: USA Aim: the effects of functional electrical stimulation for stress incontinence in women	57 women with stress urinary incontinence who could adequately retain the vaginal probe and cooperate with the study protocol	Significant pelvic prolapse and detrusor instability, postvoid residual urine >100cc, extra urethral incontinence, history of vaginal intraepithelial neoplasia, urinary tract infection, and a fixed, immobile urethra	Functional electrical stimulation with 15-minute treatment session/day using pulse-width of 2msec scheduled for 2 seconds with 4 seconds rest, frequency of 50Hz, and power 10-100mA.	Sham stimulation with inactive device
MacDiarmid, 2010[360] Country: USA Aim: To assess the sustained effectiveness of PTNS therapy offered at individualized intervals during 1 year in subjects who finished an initial course of 12 consecutive weekly sessions.	Subjects in the OrBIT trial who finished an initial course of 12 consecutive weekly PTNS treatments were offered ongoing sessions of therapy for an additional 9 months to monitor improvement in frequency, nocturia, urgency, urge incontinence episodes and voided volume. Subjects were required to be OAB drug-free throughout the study.	Not reported	Percutaneous Tibial Nerve Stimulation	Percutaneous Tibial Nerve Stimulation

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Majumdar, 2010[564] UK To evaluate treatment outcomes based on baseline urodynamics vs. symptoms alone	Patients over 18 years of age referred from a primary care with UI and other lower urinary tract symptoms	Patients who were referred for undergoing surgery for significant prolapse (stage2 or more) or had previous consultation and were then referred for surgery for incontinence, cognitive difficulties (consent issue), neurological disorders, previous treatment for incontinence at tertiary level, recurrent dysuria or infection on urine culture	Urodynamics	Conservative treatment based on symptoms and bladder diary
Manganotti, 2007[565] Country: Italy Aim: the short and long-term effects of repetitive magnetic stimulation on the sacral roots	Women with stress UI, >1 episodes of stress UI in 3-day diary, >2g of urine loss in 1 hour pad test	Urinary tract infection, interstitial cystitis, large uterine myoma, severe cardiac or cerebrovascular disorders	Fifteen-Hz repetitive magnetic stimulation of the sacral roots (S2-S4) applied for 15 minutes 3 days a week for 2 weeks (6 times in all)	Sham stimulation
Manonai, 2006[566] Country: Thailand Aim: Cross-over RCT to examine the effect of a soy-rich diet on urogenital symptoms in peri- and postmenopausal women	42 healthy perimenopausal and postmenopausal women between 45-70 years old reported at least one type of urinary incontinence	Exclusion criteria: Presence or history of sex hormone dependent malignancies, liver or renal disorders, and pathology of urogenital tract	Self-selected diet with low-fat and low cholesterol foods and soy protein 25g in various forms of soy foods containing more than 50mg/day of isoflavones	Self-selected diet with low fat and low cholesterol foods
Mayer, 2007[567] Country: USA Aim: comparative effectiveness of soft-tissue augmentation of the urethral sphincter with calcium hydroxylapatite vs. glutaraldehyde cross-linked bovine collagen in female stress urinary incontinence due to intrinsic sphincter deficiency and without associated urethral hypermobility	Women age 18 years old or older, stress UI due to intrinsic sphincter deficiency without associated urethral hypermobility (straining urethral angle of 35° or less from horizontal), good bladder function and capacity (more than 250 mL without detrusor instability	Morbid obesity (more than 100 lb over ideal body weight) and a urethral length of less than 2.5 cm	Transurethral or periurethral soft-tissue augmentation of the urethral sphincter with calcium hydroxylapatite; up to 5 injections during 6 months	Transurethral or periurethral soft-tissue augmentation of the urethral sphincter with glutaraldehyde cross-linked bovine collagen; up to 5 injections during 6 months

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
McDowell, 2006[568] Country: Northern Ireland Aim: the effects of pelvic floor training and advice, electromyography biofeedback, and neuromuscular electrical stimulation on urinary incontinence in patients with multiple sclerosis	30 women >18 years with multiple sclerosis stabilized for the previous 3 months. Expanded Disability Status Scale score <7.5 with at least one of the following: any involuntary leakage of urine, voiding frequency >8/24 hours, nocturia, and/or reported voiding dysfunction such as hesitancy, straining, poor stream, and incomplete emptying demonstrated by uro-flowmetry.	MS relapse necessitating hospitalization 3 months prior to or during the study, symptomatic prolapse, presence of urinary tract infection, current or recent diagnosis of a serious medical condition (other than MS), severe cognitive impairment, contraindications to neuromuscular electrical stimulation.	Pelvic Floor Training and Advice: education with booklet about normal bladder control, lifestyle interventions (weight reduction, relieving constipation, cessation of smoking, caffeine reduction, fluid management, clothing, reducing emotional stress)	Pelvic Floor Training and Advice with EMG Biofeedback and neuromuscular electrical stimulation. Stimulation at clinic (weekly) initially for 5 min 30 minutes using pulse rate 40Hz, pulse width 250msec,with 5sec on and10 sec off or 10 Hz, 450msec, 10sec
McDowell, 1999[569] Country: USA Aim: Cross-over RCT to examine the effects of behavioral therapies of urinary incontinence in homebound older adults.	105 adults 60 years and older, homebound (Health Care Financing Administration, cognitively intact (Folstein Mini-Mental State Examination score >24), with urinary incontinence (>2 urinary accidents/week for at least 3 months), who understand and speak English	Folstein MMSE scores <24, severe pelvic prolapse, terminal illness, post-void residual >100ml unable to toilet independently, no caregiver willing and able to assist with toileting, <2 urinary accidents per week, unable to provide satisfactory self-report	Biofeedback-assisted pelvic floor muscle training by nurse practitioners skilled in behavioral therapies for urinary incontinence. Behavioral therapy: 8 weekly sessions at homes with biofeedback-assisted pelvic floor muscle exercises, urge and stress strategies, and bladder training	Usual care with attention control (visits by the nurse practitioner every 1-2 weeks to provide social interaction).
McFall, 2000[570] Country: USA Aim: the effects of group educational intervention for urinary incontinence in elderly women	145 women ages 65 or older with self reported urinary incontinence ≥3 months, residing in Oklahoma.	Severe prolapse of uterus, hematuria, diverticulum, fistula, unresolved urinary tract infection, two or more urinary tract infections within 3 months, urinary obstruction, overflow incontinence, a postvoid residual volume of urine (PVR) >100ml, and blood	Community-based intervention with 5 biweekly sessions of education and skill-building, for bladder training, managing the urge to urinate, and performing pelvic muscle exercises. Group support by registered nurses; occupational therapist, and public health professional	Usual care

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
McFall, 2000[571] Country: USA Aim: To report an assessment of a community-based intervention for UI and to summarize the outcomes of the intervention model related to incontinence and other urinary symptoms.	Most participants attended a community presentation prior to enrollment. Participants lived independently in a four-county region in central Oklahoma. The women were 65 years or older and had urinary incontinence for 3 months or more.	Severe prolapse of uterus, hematuria, diverticulum, fistula, unresolved urinary tract infection, two or more urinary tract infections within 3 months, urinary obstruction, overflow incontinence, a postvoid residual volume of urine (PVR) >100 ml, and blood glucose >300 mg/dl on two or more visits in a 3 month period. Functional or disability exclusions were being homebound because of frailty, severe hearing or vision problems, low literacy, and cognitive impairment.	Small group educational approach	Wait control
Miller, 1998[572] Country: USA Aim: the effects of intentionally contracting the pelvic floor muscles before and during a cough on mild and moderate female stress urinary incontinence.	27 women with self reported stress urinary incontinence and demonstrable urine loss during a deep cough with leakage occurring at least weekly and up to 5 times/day.	History of systemic neuromuscular disease, previous bladder surgery, active urinary tract infection, leakage that was delayed after coughing and categorized as detrusor instability, leakage that saturated a paper towel and/or pooled on the floor when coughing in the standing posture, inability to demonstrate any voluntary contraction of the pelvic floor muscles despite detailed instruction during the pelvic exam, and significant coexistent pelvic organ prolapse below the hymenal ring	Immediate intervention group taught intentionally contracting the pelvic floor muscles before and during a cough (Knack)	Wait-listed control group

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Moore, 2003[573] Country: Australia Aim: the effects of nurse continence advisors and urogynecologists in conservative management of urinary incontinence.	145 consecutive patients with stress and/or urge incontinence with idiopathic detrusor instability, sensory urgency, and mild or moderate leakage (urine loss in 1-hour pad test 2-9.9ml/hour or 10-50ml/hour).	Previous pelvic radiotherapy, proven recurrent bacterial cystitis, prolapse beyond the introitus, uterine enlargement or incomplete bladder emptying (postvoid residual >100ml).	2 nurse continence advisors/ patient and consulting urogynecologist for 25-35 minutes/week provided bladder training, gradual increase in fluid intake, individual deferment techniques, pelvic floor muscle exercise and examination, transvaginal electro stimulation	Outpatient regimen with 15-20 minute consultation with referral to physiotherapist and bladder training.
Morkved, 2002[574] Country: Norway Aim: the effects of individual pelvic floor muscle training with and without biofeedback in women with urodynamic stress incontinence.	103 women with symptoms of stress incontinence and >2g leakage measured by a pad test with standardized bladder volume.	involuntary detrusor contractions on cystometry, abnormal bladder function (residual urine >50ml), previous surgery for stress incontinence, neurologic or psychiatric disease, urinary tract infection, other diseases that could interfere with participation	Pelvic floor muscle training with 3 sets of 10 contractions 3 times/day, individually supervised by a physical therapist. At home, 3 sets of 10 high intensity (close to maximum) contractions per day with a biofeedback apparatus	Pelvic floor muscle training with 3 sets of 10 contractions 3 times/day, individually supervised by a physical therapist. At home, 3 sets of 10 high intensity (close to maximum) contractions per day without biofeedback
Du Moulin, 2007[575] Country: Netherlands Aim: effects of a specialized nurse in the care of community-dwelling women with urinary incontinence	Community-dwelling women aged 18 years who attended general practitioner clinic because of urinary incontinence	Urinary tract infection, PVR of 100 mL or more, delivery within 3 months preceding recruitment, bladder cancer, renal disease, or uterine prolapse past the introitus	The continence nurse and multidisciplinary team comprising a GP, urologist, physiotherapist	Standard care provided by the general practitioners
Nager, 2009[576] Country: USA Aim: association between successful incontinence pessary fitting or pessary size and specific pelvic organ prolapse measurements in women without advanced pelvic organ prolapse	Pelvic Floor Disorders Network (PFDN): women with stress urinary incontinence (SUI) and POPQ stage ≤2	Not reported	Incontinence pessary+ behavioral therapy including pelvic floor muscle training and exercise and bladder control strategies	Incontinence pessary

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Ng, 2008[577] Country: Taiwan Aim: the effect of nursing intervention to enhance the efficacy of a home-based pelvic floor muscle exercise (PFME) on mixed urinary incontinence in community-dwelling women	Women with mixed urinary incontinence interested in behavioral training and potentially available for telephone contact	no educational background, dependent in daily activities	A registered nurse monitoring via telephone checkups twice a week home based PFMT. Education about the pelvic anatomy, the function of the pelvic floor muscle, the bladder and urethra, the use of PFMT, and how to perform PFMT: 1 hour per session, twice weekly, for 4 weeks in total.	Home based PFMT. Education about the pelvic anatomy, the function of the pelvic floor muscle, the bladder and urethra, the use of PFMT, and how to perform PFMT:1 hour per session, twice weekly, for 4 weeks in total.
Nielsen, 1993[578] Country: Denmark Aim: Cross-over RCT to examine effects of urethral plug on female genuine urinary stress incontinence	40 women with genuine urinary stress incontinence	Not reported	Urethral plug as oval metal plate, a soft stalk, and 1 sphere along the stalk with fixed distances between the metal plate and the spheres. Inside the stalk is a removable semi-rigid guide pin to ease insertion.	Urethral plug as oval metal plate, a soft stalk, and 2 spheres along the stalk with fixed distances between the metal plate and the spheres. Inside the stalk is a removable semi-rigid guide pin to ease insertion.
Nygaard, 1995[579] Country: USA Aim: Crossover RCT to examine the effects of Hodge pessary with support, a super tampon on urinary incontinence during exercise.	20 female exercisers ages 33-73 with urinary incontinence during exercise and positive coughing test.	Prolapse of the uterus, stenotic vagina, or pelvic mass.	40-minute standardized aerobics session wearing a Hodge pessary with support 40-minute standardized aerobics sessions wearing a super tampon	40-minute standardized aerobics sessions with no mechanical device
Nygaard, 1996[580] Country: USA Aim: the effects of pelvic floor muscle exercises in combination with specially designed audiotape on stress, urge, and mixed urinary incontinence in women.	71 women non pregnant women >21 years old with urinary incontinence.	Genital prolapse past the vaginal introitus, parturition within the preceding 6 months, and deafness	Pelvic floor muscle exercises with 2 5-minute daily sessions, beginning with contractions for 4-8 seconds in combination with specially designed audiotape with 270 minutes of music and verbal instructions of technique tips, reminders, and exercise cues.	Pelvic floor muscle exercises with 2 5-minute daily sessions, beginning with contractions for 4-8 seconds.

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
O'Brien, 1991[581] Country: England Aim: the effects of pelvic floor exercises and bladder retraining supervised by non-specialist nurse on urinary incontinence in adults with regular urinary incontinence.	561 adults ages 35 years and older with regular urinary incontinence (two or more leaks in any one month).	Urinary tract infection.	Four sessions of pelvic floor exercises and bladder retraining supervised by non-specialist nurse.	Usual care
O'Brien, 1996[582] Country: UK Aim: Long term (followup of O'Brien, 1991[581]) effects of behavioral training on urinary incontinence in adult women	Female patients over 35 years from two large Somerset general practices with urinary incontinence two or more leaks in any one month	Reported previously	Nurse-led four sessions of pelvic floor exercises or bladder retraining depending on the dominant symptoms (stress or urge respectively)	Postponed treatment
Oldham, 2010[583] Country: Canada Aim: Evaluation of a self-contained, fully automated, disposable device (Femestin), with application similar to that of a tampon	Women with urinary incontinence were recruited via a process of self referral through ads placed in local newspapers and on local radio to reflect future practice	Not reported	Pelvic Floor Exercises obtained from Bladder and Bowel Foundation + Femestin device	Pelvic Floor Exercises obtained from Bladder and Bowel Foundation

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
O'Sullivan, 2003[584] Country: Australia Aim: the effect modification by baseline severity of any urinary incontinence on continence rates after nurse intervention in women with urodynamic UI	Women with urodynamically proven GSI, DI, or Sumild (2-9.9 g) to moderate (10-49.9 g) incontinence (as judged by weight gain on 1-hour pad testing)	Previous pelvic radiotherapy, proven recurrent bacterial cystitis, prolapse beyond the introitus, uterine enlargement of duration more than 12 weeks, or incomplete bladder emptying (residual >100 ml)	Nurse continence adviser with the first visit of 45 minutes with pelvic floor digital testing, verbal biofeedback , bladder training with individual deferment techniques; followup weekly visits of approximately 30 minutes with re-exam of pelvic floor muscle	Routine urogynecology outpatient therapy with a referral note to a physiotherapist (SUI) or educational videotape about bladder training (Urge UI) or anticholinergic therapy (DI)
Pages, 2001[585] Country: Germany Aim: the effects of intensive group physical therapy program with individual biofeedback training for female patients with urinary stress incontinence.	51 women, referred by gynecologists for nonoperative treatment of genuine stress incontinence of mild-to-moderate severity.	Not reported	Specific physical therapy program. Group therapy 5 times/week and home pelvic floor exercise with 50 contractions for 10 minutes 2 times/day. Recommendation of weight loss and aerobic sports.	Biofeedback training daily 90-minutes in group and individually for 15 minutes, 5 times/week; Intra vaginal pressure sensor and visual biofeedback in computer monitor
Peters, 2010[586] Country: USA Aim: To compare the efficacy of PTNS to a validated sham	Women and men ≥18 years of age; a score of ≥4 on the OAB-q short form for urgency; average urinary frequency of ≥10 voids per day; self-reported bladder symptoms ≥3 months; self-reported failed conservative care; discontinued all antimuscarinic for ≥2 weeks; capable of giving informed consent; ambulatory and able to use toilet independently without difficulty; and capable and willing to follow all study-related procedures	Pregnant or planning to become to pregnant during the study; neurogenic bladder; Botox use in bladder or pelvic floor muscles within the past one year; pacemakers or implantable defibrillators; current urinary tract infection; current vaginal infection; use of Interstim; use of Bion; current use of TENS in pelvic region, back or legs; previous PTNS treatment; use of investigational drug/device therapy within past 4 weeks; and participation in any clinical investigation involving or impacting gynecologic, urinary or renal function within past 4 weeks	Percutaneous tibial nerve stimulation	Placebo

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Peters, 2010[587] Country: USA Aim: To compare the efficacy of PTNS to a validated sham in subjects who have previously used OAB pharmacologic therapy	This analysis includes only those subjects who previously used OAB pharmacologic therapy prior to their participation in the study. Women and men ≥18 years of age; a score of ≥4 on the OAB-q short form for urgency; average urinary frequency of ≥10 voids per day; self-reported bladder symptoms ≥3 months; self-reported failed conservative care; discontinued all antimuscarinic for ≥2 weeks; capable of giving informed consent; ambulatory and able to use toilet independently without difficulty; and capable and willing to follow all study-related procedures.	Pregnant or planning to become to pregnant during the study; neurogenic bladder; botox use in bladder or pelvic floor muscles within the past one year; pacemakers or implantable defibrillators; current urinary tract infection; current vaginal infection; use of Interstim; use of Bion; current use of TENS in pelvic region, back or legs; previous PTNS treatment; use of investigational drug/device therapy within past 4 weeks; and participation in any clinical investigation involving or impacting gynecologic, urinary or renal function within past 4 weeks	Percutaneous Tibial nerve stimulation	Placebo
Ramsay, 1996[588] Country: Scotland Aim: comparative effectiveness of inpatient vs. outpatient behavioral treatment for urinary incontinence in women	Women with urgency, nocturia, urge incontinence and stress incontinence	Previous treatment for their incontinence, symptoms of hematuria, recurrent dysuria or voiding difficulty, or infection on urine culture	Bladder retraining and physiotherapy as an inpatient 5-day hospital stay	Bladder retraining and physiotherapy as an outpatient with two 2-hour sessions, 1 week apart.

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Richter, 2010[363] Country: USA Aim: To compare the effectiveness of a continence pessary to evidence-based behavioral therapy for stress incontinence and to assess whether combined pessary and behavioral therapy is superior to single modality therapy	ATLAS trial: Women at least 18 years old with symptoms of stress only or stress-predominant mixed-incontinence symptoms	Previously reported in Richter, 2007[589]	Behavioral therapy	Pessary + Behavioral therapy/Pessary alone
Robinson, 2003[590] Country: Canada Aim: the effects of new urethral device or the reliance insert on female urinary incontinence.	24 women 30-75 years old with mixed or stress urinary incontinence >2 episodes/week >2g urine loss on baseline pad weight test, with sound mental condition, willing to use >3 devices/week.	Overflow incontinence or neurogenic bladder, type III incontinence, kidney inflammatory diseases, urinary tract infection, use of anticoagulants or incontinence medications, allergy to antibiotics, diabetes mellitus type II, pregnancy, urethral mucosal abnormalities, prosthetic heart valve, HRT last 3 months, collagen injections or other urethral bulking agents last 3 months, detrusor contraction >20cm/H20.	Urethral device (NEAT) –sterile urethral insert with disposable applicator packaged with device.	Reliance insert sterile balloon type device
Sand, 1995[591] Country: USA Aim: the effects of transvaginal electrical stimulation in treating genuine stress incontinence.	52 community dwelling women with urodynamically proven genuine stress incontinence, who would comply with visits, not use/seek other treatment for incontinence.	Detrusor instability, pregnancy, pacemaker, prior pelvic floor stimulation, pelvic implanted devices, active vaginal lesions or infections, urinary tract infection, hypermenorrhea or menorrhaghia, urinary retention (>100ml), pelvic surgery in past 6 months	Active pelvic floor stimulator with gradually adjusted 60-80mA from 5 seconds on/1 second off for 15 minutes to 5 seconds on/5 seconds off for 30 minutes.	Sham inactive device

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Schreiner, 2010[592] Brazil To examine the efficacy of transcutaneous electrical tibial nerve stimulation (TTNS) to treat urge urinary incontinence (UUI) in older women	52 patients from the Urogynecology Section of the Gynecology Department in Sao Lucas Hospital of Pontificia Universidade Catolica do Rio Grande do Sul in the city of Porto Alegre with complaint of urge incontinence and age of 60 years or more.	Presence of urinary infection during the recruitment process, prior surgery for urinary incontinence, history of genito-urinary cancer, prior pelvic irradiation, pure stress urinary incontinence, genital prolapse above the second degree of Walker, and inability to perform the Kegel exercises.	Transcutaneous electrical tibial nerve stimulation + Bladder training	Bladder training
Schulz, 2004[593] Country: Canada Aim: the effects of periurethral and transurethral injections of bulking agents on stress urinary incontinence in females.	40 women ages 18-80 years old, with genuine stress incontinence for >12 months, or mixed incontinence with a minor and controlled urge component, who failed 3 months conservative treatments.	Other treatments for incontinence, urinary tract infection, bladder capacity <250ml or postvoid residual volume >100ml, neurogenic bladder, grade 3 cystoele, uterine prolapse or rectocele, radiation of urethra, pregnancy, life expectancy <15 months.	Periurethral route of injection of bulking agent-dextran copolymer	Transurethral route of injection of bulking agent-dextran copolymer
Seo, 2004[594] Country: South Korea Aim: the effects of vaginal cone with conventional FES-biofeedback therapy for female urinary incontinence.	120 patients, who required a non-surgical treatment for urinary incontinence.	Not reported	Pelvic floor exercise (5 second contraction and 10 second relaxation, 3-5 times for >5 minutes/day) and functional electrical stimulation biofeedback (35Hz-50Hz for 24 seconds); 2 training sessions/week.	Vaginal cone, 150g dumbbell-shaped made of fine ceramic material.
Sherman, 1997[595] Country: USA Aim: the effects of pelvic muscle exercises with urethral biofeedback on exercise-induced urinary incontinence in female soldiers.	39 female active duty soldiers with exercise-induced urinary incontinence (stress or mixed).	Not reported	Pelvic muscle exercises with contractions for 10 seconds and relaxation for 10 seconds 5 times/session, 20 minutes twice/day with urethral biofeedback using vaginal EMG probe.	Pelvic muscle exercises with contractions for 10 seconds and relaxation for 10 seconds 5 times/session 20 minutes twice/day alone.

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Smith, 1996[596] Country: USA Aim: the effects of intravaginal electrical stimulation on genuine stress urinary incontinence and detrusor instability in women.	57 women with urinary incontinence.	Type 3 stress urinary incontinence, pregnancy, urinary retention, vaginal prolapse, cardiac pacemaker, mixed incontinence with no major and minor components.	18 women with stress urinary incontinence: Electrical stimulation using frequency 12.5Hz.-50Hz and amplitude 5-10mA-80mA for 15 to 60 minutes 2/day 38 women with detrusor instability Anticholinergic therapy with Propantheline bromide in dose of 7.5 to 4	Kegel exercise
Spruijt, 2003[597] Country: The Netherlands Aim: the effects of intravaginal electrical stimulation of the pelvic floor for urinary incontinence in elderly women.	51 women ≥65 years of age, with symptoms of stress, urge or mixed urinary incontinence of >3 months' duration, and with urinary leakage >10cc/24hours.	Persistent urinary tract infection (positive urine culture after antibiotic treatment), recurrent urinary tract infection (within 4 weeks after treatment), bladder pathology or dysfunction because of fistula, tumor, pelvic irradiation, neurological or other chronic conditions (diabetes mellitus, Parkinson's disease), genital, pacemaker, and insufficient mental condition.	Intravaginal electrical stimulation of the pelvic floor using stimulator generated biphasic current pulses with duration of 1ms and a frequency of 50Hz (stress urinary incontinence) or 20Hz (urge urinary incontinence).	Kegel exercise program with verbal instructions on how to exercise at home.
Strasser, 2007[598] Country: Austria Aim: the effects of ultrasonography-guided injections of autologous cells or endoscopic injections of collagen on stress urinary incontinence.	63 females 36-84 years old with intrinsic sphincter insufficiency or stress urinary incontinence with only mild hypermobility of the urethra and the urinary bladder; good state of health who failed pelvic floor muscle exercises.	Urge incontinence and pronounced hypermobility of the urethra.	Transurethral ultrasonography-guided injections of autologous myoblasts and fibroblasts; regular training of the rhabdosphincter for 12 weeks and trans vaginal electrical stimulation for 4 weeks.	Conventional endoscopic injections of collagen; regular training of the rhabdosphincter for 12 weeks and trans vaginal electrical stimulation for 4 weeks

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Subak, 2002[599] Country: USA Aim: the effects of low-intensity behavioral therapy program on urinary incontinence in older women	Women 55 years and older with self reported urinary incontinence, members of health maintenance organization, living independently in the community and functionally capable of independent toileting.	Uncontrolled diabetes mellitus, urinary tract infection, history of urinary obstruction, overflow, functional incontinence, urinary tract anomalies	6 weekly 20-minute group instructional sessions on bladder training by nurse educators and followed individualized voiding schedules.	Usual care
Subak, 2005[600] Country: USA Aim: the effect of weight loss on urinary incontinence in overweight and obese women.	48 women 18 to 80 years old with body mass index between 25 and 45 kg/m2, urinary incontinence for at least 3 months and at least 4 incontinent episodes/week, the stable dose of other incontinence therapy .	Exclusion criteria: pregnancy, urinary tract infection, significant medical condition, pelvic cancer, neurological condition possibly associated with incontinence, interstitial cystitis or potential inability to complete the study.	Weight reduction intervention: 3-month standard low calorie liquid diet (800kcals/day or less), increased physical activity to 60 minutes/day, training by a nutritionist, exercise physiologist or behavioral therapist	Usual care
Subak, 2009[601] Country: USA Aim: effectiveness of weight loss on urinary incontinence in obese women	Women at least 30 years of age, a body-mass index of 25 to 50, >10 urinary-incontinence episodes/week, ability to walk unassisted for two blocks (approximately 270 m) without stopping	Pregnancy, urinary tract infection, significant medical condition, pelvic cancer, neurological condition possibly associated with incontinence, interstitial cystitis or potential inability to complete the study.	Intensive 6-month weight-loss program to produce an average loss of 7 to 9% of initial body weight that included diet, exercise, and behavior modification (AHEAD ,Action for Health in Diabetes) trial	Structured education program: four education sessions at months 1, 2, 3, and 4. During these 1-hour group sessions, which included 10 to 15 women, general information was presented about weight loss, physical activity, and healthful eating habits
Sung, 2000[602] Country: Korea Aim: the effects of pelvic floor muscle exercises on female genuine stress incontinence.	90 married women with urinary incontinence.	Not reported.	Functional electrical stimulation-biofeedback for 20 minutes/session with frequency 35Hz-50Hz and contractions of 32 seconds, 2 sessions/week Intensive pelvic floor muscle exercises	Control usual care

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Sung, 2000[603] Country: South Korea Aim: comparative effectiveness of pelvic floor muscle exercise and the functional electrical stimulation - biofeedback for female urinary incontinence	Married women diagnosed with genuine stress UI	Not reported	Intensive pelvic floor muscle exercise at home, videotape with instructions to perform exercise, weekly examination of accuracy and intensity of contractions	Functional electrical stimulation (FES)-biofeedback for 20 minutes/session, 2 sessions/week and weekly examination of accuracy and intensity of contractions. Pelvic electrical stimulation for 24 seconds at 35 and 50 Hz simultaneously followed by biofeedback
Swithinbank, 2005[604] Country: England Aim: Cross-over RCT to examine the effect of caffeine restriction and fluid manipulation in the treatment of patients with urodynamic stress incontinence.	69 women with urodynamically proven stress incontinence naive to surgery.	Urinary tract infection, hepatic, cardiac or renal disease and diabetes mellitus, use of antidepressants, anticholinergics or diuretics.	1. Increased decaffeinated fluids to 3 liters daily (20 cups) or decreased decaffeinated fluids to 750ml (5 cups) daily 2. Caffeine restriction and increased fluid intake to 2, 2,673ml/day 3. Caffeine restriction and decreased fluid intake to 872ml/day	Usual care
Tibaek, 2007[605] Country: Denmark Aim: the long term effect of pelvic floor muscle training in women with urinary incontinence after stroke	Women, diagnosed with first ever ischemic stroke according to the definition of World Health Organization and verified by CAT scan, stroke symptoms in at least one month; normal cognitive function (mini-mental state examination a.m. Folstein >25)	Urinary tract infection; symptoms of descensus urogenitale; chronic respiration diseases; psychiatric diseases; other neurological diseases; and do not speak Danish.	Systematic, controlled, intensive pelvic floor muscle training program by the specialist physiotherapist: group treatment with 6–8 patients/group for 1 hour/week, vaginal palpation 2-3 times and home exercises 1-2 times daily	Standard program of rehabilitation for patients with stroke without any specific treatment of urinary incontinence

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Theofrastous, 2002[606] Country: USA Aim: the efficacy of bladder training and pelvic muscle exercise with biofeedback-assisted instruction on urinary incontinence in women.	137 community-dwelling women 45 years and older diagnosed with genuine stress incontinence, (urine loss at least once per week), with urodynamic evidence of genuine stress incontinence, and mentally intact (Mini-Mental State Examination Score >23).	Reversible causes of urinary incontinence, uncontrolled metabolic conditions, residual urine volume after voiding >100ml, urinary tract infection, genitourinary fistula or indwelling catheterization, and inability to correctly perform a pelvic muscle contraction	Pelvic floor muscle training: 4 office biofeedback sessions and home exercise with two sets of 5 quick and 10 sustained contractions with 10-second rest periods increased to 5 quick and 20 sustained contractions 2/day for a total of 50 contractions per day	Bladder training
Thornburn, 1997[607] Country: UK Aim: the relationship between pad properties (absorption capacity, strike-through, and wetback) and wet comfort in women with light urinary incontinence	Women with light urinary incontinence who used disposable incontinence pads	Not reported	Pad A with the largest wetback	Pad B with the largest strike-through time; Pad F with the largest absorption capacity
Thyssen, 2001[608] Country: Denmark Aim: Crossover RCT to examine the effects of disposable intravaginal device on stress incontinence in women.	94 women with the predominant symptom of stress incontinence, 39 were recruited in Denmark, 28 in England, and 27 in Australia.	Major uterovaginal prolapse	Conveen Continence Guard, CCG made of hydrophilic polyurethane and requires soaking in water before being placed on a handle like applicator for insertion.	Contrelle Continence Tampon, CCT, Coloplastic made of hydrophobic polyurethane and supplied ready-assembled within an applicator, allowing insertion directly into the vagina with no manual contact

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Tibaek, 2004[609] Country: Denmark Aim: the effect of pelvic floor muscle training in women with urinary incontinence after ischemic stroke	Women diagnosed with first-ever ischemic stroke according to the definition of the World Health Organization and verified by CAT scan; stroke symptoms in at least 1 month; normal cognitive function (Mini-mental state examination a.m. Folstein >25)	Urinary tract infection; symptoms of descensus urogenitale; chronic respiration diseases; psychiatric diseases; other neurological diseases; and do not speak Danish	Systematic, controlled, intensive pelvic floor muscle training program in 12 consecutive weeks by the same specialist physiotherapist. Women received instructions how to perform strength PFM exercise with close to maximum contraction (6 s contraction/6 seconds relaxation	The normal, standard program of rehabilitation without any specific treatment of urinary incontinence
Tibaek, 2005[610] Country: Denmark Aim: the effect of pelvic floor muscle training in women with urinary incontinence after ischemic stroke.	26 women 40 and 85 years old with acute ischemic stroke verified by CAT scan lasting >24 hours; stroke symptoms in at least 1 month; normal cognitive function (mini-mental state examination >25); urinary incontinence related to stroke; independent walking	Urinary tract infection; symptom of vaginal prolapse; chronic respiratory diseases; psychiatric diseases; other neurological diseases; does not speak Danish.	Intensive pelvic floor muscle training 1-2 times/day by specialized physiotherapist: group information on incontinence and instruction in self-palpation of PFM, motivation and instruction in home exercises	Usual care
Tsai, 2009[611] Country: Taiwan Aim: comparative effectiveness of interpersonal support and digital vaginal palpation as part of the pelvic floor muscle exercise training compared to pelvic floor muscle exercise training with a printed handout instructions on stress urinary incontinence	Women who presented to the family medicine outpatient clinic without having urine leakage as their chief complaint but with transient UI	Severe uterine prolapse, past the vaginal introitus, heart failure; history of dementia (Mini-Mental State Examination (MMSE) score <24); prior knowledge of PFME prescribed by a physician, a nurse, a physical therapist, or any other health problems	Interpersonal support and digital vaginal palpation as part of the pelvic floor muscle exercise training. The researcher contacted the patients of experimental group by telephone once per week to inquire about any difficulties and/or improvements	Pelvic floor muscle exercise training with a printed handout instruction

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Wang, 2004[612] Country: Taiwan Aim: the efficacy of pelvic floor muscle training, biofeedback-assisted PFMT, and electrical stimulation in the management of overactive bladder.	120 women 16-75 years, symptoms of overactive bladder for more than 6 months, frequency of voiding eight times or more per day, and urge incontinence one time or more per day.	Pregnancy, deafness, neurologic disorders, diabetes mellitus, pacemaker or intrauterine device use, genital prolapse greater than Stage II of the International Continence Society grading system, residual urine >100ml, and urinary tract infection.	1. Pelvic floor muscle training with submaximal to maximal PFM contractions for 6 seconds 5 times and 10 fast contractions per session at least 3 times/day. 2. Biofeedback-assisted pelvic floor muscle training with an intravaginal electromyogram probe to contract or relax PFMs following the visual EMG signals.	Electrical stimulation in the management of overactive bladder with intravaginal electrode at the physiotherapy unit.
Wells, 1991[613] Country: USA Aim: the effects of pelvic muscle exercise or pharmacologic treatment of stress urinary incontinence in community-living elderly women	157 community-living women, ages 55 to 90 years.	Nursing home residency	Pelvic muscle exercises with contractions for 10 seconds and relaxation for 10 seconds, 90-160 times/day.	Phenylpropanolamine hydrochloride in a dose of 50mg /day, increasing to 50mg 2 times/ day
Williams, 2005[614] Country: England Aim: the effects of continence service provided by specially trained nurses delivering evidence-based interventions using predetermined care pathways in adults.	3,746 men and women ages 40 years and over living in private households reporting incontinence several times per month or more, or several times a year and reported significant impact of symptoms on quality of life.	Pregnancy, urinary fistula, pelvic malignancy, treatment for urinary symptoms.	Continence service that included advice on diet and fluids; bladder training; pelvic floor awareness and lifestyle advice.	Existing primary care including GP and continence advisory services in the area

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Williams, 2006[615] Country: Aim: the efficacy and cost-effectiveness of pelvic floor muscle therapies (PFMT) in women ≥40 years with urodynamic stress incontinence (USI) and mixed UI	Women ≥40 years were randomly sampled by household from the Family Health Service Authority registers of participating GP practices and invited if they had urodynamic diagnosis of USI or mixed UI and DO	Pregnant, had urinary fistula, pelvic malignancy, severe prolapse and those currently receiving treatment for urinary symptoms (e.g. on a waiting list for continence surgery).	Pelvic floor muscle therapies training by specially trained nurses, after an initial digital assessment and perineometry to develop individualized exercise regimen.	Standard care: leaflet with information about pelvic floor muscles and three steps in exercising these muscles
Wing, 2010[616] Country: USA Aim: To examine the longer term effects of a weight loss intervention on urinary incontinence.	Being at least 30 years old, having a BMI of 25 to 50 kg/m2, reporting at least 10 UI episodes on a 7-day voiding diary at baseline and agreeing not to initiate new treatments for incontinence or weight reduction during the trial.	Reported Previously in Subak, 2009[601]	Behavioral weight loss program	Structured education program
Wong, 2001[617] Country: China Aim: the efficacy of biofeedback in Chinese women with urinary stress incontinence	Chinese women with genuine stress incontinence	Second or third degree uterine prolapse, previous failure of pelvic floor muscle exercise, continence surgery, pad test with urine loss <2g, neurologic disease	Biofeedback from the abdominal muscle contractions during pelvic floor exercises with EMG attached over their abdominal muscles	Biofeedback from pelvic floor muscles during pelvic floor exercises
Wyman, 1997[618] Country: USA Aim: the effects of bladder training on quality of life in older women with urinary incontinence.	131 women 55 years and older, ambulatory, mentally intact, independent residents in the community with urodynamic stress urinary incontinence >1 episode/week.	Metabolic decompensation, urinary tract infection, outlet obstruction, fistula, reversible cause of urinary incontinence, permanent indwelling catheter.	Bladder training: patient education, progressive scheduled voiding regimen, positive reinforcement.	Usual care

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Wyman, 1998[619] Country: USA Aim: the efficacy of bladder training, pelvic muscle exercise with biofeedback-assisted instruction, and combination therapy, on urinary incontinence in women.	204 community-dwelling women age 45 years and older diagnosed with genuine stress incontinence, (urine loss at least once per week), with urodynamic evidence of genuine stress incontinence, and mentally intact (Mini-Mental State Examination Score >23).	Reversible causes of urinary incontinence, uncontrolled metabolic conditions, residual urine volume after voiding >100ml, urinary tract infection, genitourinary fistula or indwelling catheterization, and inability to correctly perform a pelvic muscle contraction	Structured 12-week program of patient education, self-monitoring of voiding behavior with daily treatment logs, compliance assessment, and positive reinforcement administered by trained registered nurses.	Bladder training
Yamanishi, 1997[620] Country: Japan Aim: CT to examine the effects of electrical pelvic stimulation in stress incontinence.	35 patients with stress incontinence.	Persistent urinary infection, uterine or rectal prolapse and cystocele, severe cardiac or cerebrovascular disorders including on-demand heart pacemakers, hepatic disorders and renal dysfunction. Anticholinergics, calcium antagonists, alpha or beta agonist	Electrical pelvic stimulation with 50Hz. square waves of 1msec. pulse duration and vaginal electrode in women and an anal electrode in men for 15 minutes 2 or 3 times daily	Sham electrical pelvic stimulation with inactive device
Yamanishi, 2000[621] Country: Japan Aim: the effects of electrical stimulation for urinary incontinence due to detrusor overactivity	68 patients with urinary incontinence due to detrusor overactivity urodynamically defined as involuntary detrusor contractions of more than 15cm/H2O during the filling phase.	Use of anticholinergics or tricyclic depressants, pelvic floor exercise, bladder training, or pelvic surgery before entry into the study.	Electrical stimulation 15 minutes twice daily for 4 weeks (vaginal electrode in women and an anal or surface electrode in men to provide alternating pulses of 10Hz square waves of 1-ms pulse duration and a maximum output current of 60mA).	Sham inactive device

Appendix Table F81. Randomized controlled clinical trials of nonpharmacological nonsurgical treatment for UI (continued)

Reference country aim of the Study	Inclusion criteria	Exclusion criteria	Active treatment	Control treatment
Yoon, 2003[622] Country: South Korea Aim: the effectiveness of bladder training versus pelvic muscle exercises in the treatment of urinary incontinence in women.	50 parous women 35–55 years old with urine loss of 1.0g or more on a 30 minute pad test and 14 voids or more during a period of 48 hours before the preliminary evaluation.	Urinary tract infection tested by urinalysis and urine culture, previous experience of surgery for urinary incontinence, HRT and other medication for urinary incontinence.	Bladder training with increased interval between voluntary voids ; Pelvic muscle exercise (30 contractions for 15 to 20 minutes/day) with immediate and simultaneous visual feedback of pelvic muscles during a 20 minute weekly biofeedback session	Usual care
Zanetti,2007[623] Country: Brazil Aim: comparative effectiveness of pelvic floor muscle exercises with or without physiotherapist supervision on female stress UI	Women with stress urinary incontinence confirmed by means of urodynamic testing	Topical hormone replacement therapy for less than three months, disorder affecting muscle or nerve tissues, or genital bleeding, pregnancy, urinary tract infection, vulvovaginitis, genital prolapse beyond the hymen, atrophic vaginitis or cardiac pacemaker	Supervised perineal exercises repeated in the orthostatic, sitting and supine positions under guidance from a physiotherapist (twice a week, for 45 minutes).	Unsupervised perineal exercises repeated in the orthostatic, sitting and supine positions performed at home with monthly assessment from a physiotherapist.
Clarke-O'Neill, 2002[624] Country: UK Aim: The Continence Product Evaluation Network: comparative survey of washable pants with integral pads for women with light incontinence	The Continence Product Evaluation Network: women 18 years of age and normally used an absorbent product (disposable or reusable) for light incontinence	Not reported	10 pants designed for light incontinence	Cross over evaluation
Tomlinson, 1999[625] Country: USA Aim: The effects of dietary caffeine and fluid intake on urinary incontinence in older rural women	The Behavioral Management for Continence (BMC):women 55 or older living in their own home in one of seven rural counties in northern Florida with involuntary urine loss at least twice a week and of 1 g per day or more	Diagnosis of bladder cancer or kidney disease; use of a urinary catheter; retention of 100 ml or more of urine; need for a caregiver but none was available; and availability for less than 6 months	The Behavioral Management for Continence: self-monitoring (2–4 weeks' duration); bladder training (6–8 weeks' duration); and pelvic muscle exercise with biofeedback (12 weeks' duration). The goal was appropriate intake of 1800–2400 ml/day of fluids	No active treatments; alternative resources within the community

Appendix Table F82. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI

Reference	Sponsorship	Conflict of Interest
Luber, 1997[563]	Contract grant sponsor: Kaiser Research Foundation; Contract grant number: 01-990-6571.	Not reported
Dougherty, 2002[518]	Contract grant sponsor: National Institute of Nursing Research, National Institutes of Health (Nursing model: Urinary incontinence for older, rural women); contract grant number: R01 NR 3139. Johnson & Johnson provided absorbent products for the project	Not reported
Hung, 2010[543]	Financial support from the National Science Council of the Republic of China under the grant No. NSC95-2314-B002-226-MY2	Not reported
Tibaek, 2004[609]	Financial support provided by The Foundation of Danish Physiotherapists Research, The Foundation of 1870, and Direktor Jacob Madsen og hustrus Fond.	Not reported
Tibaek, 2007[605]	Financial support provided by The Foundation of Danish Physiotherapists Research, The Foundation of 1870, and Direktor Jacob Madsen og hustrus Fond.	Not reported
Morkved, 2002[574]	Financial support was given by the Norwegian Industrial and Regional Development Fund, Norwegian National Insurance Administration, and by Trondheim Regional Hospital 2000, SINTEF Unimed, Trondheim and Vitacon, Trondheim, Norway	Not reported
Burns, 1993[507]	Funded by a cooperative agreement (UOI AG05260) from the National Institute on Aging and the National Center for Nursing Research	Not reported
Mayer, 2007[567]	Funded by BioForm Medical.	R. D. Mayer and K. Jacoby are study investigators partially funded by the sponsor, and are paid consultants to the sponsor. R. Dmochowski, R. A. Appell, P. K. Sand, I. Klimberg, C. W. Graham, J. A. Snyder, V. Nitti, and J. C. Winter are study investigators partially funded by the sponsor.
Oldham, 2010[583]	Funded by Femeda	Not reported
Kim, 2001[547]	Funded by Sasakawas' Health Science Foundations in Japan and the International Rotarian Scholarship in Japan	Not reported
Williams, 2005[614]	Funded by the Medical Research Council (UK) (G9410491). Nicola J Cooper was funded by University Hospitals of Leicester (UHL) NHS Trust. David A Turner was funded by Trent Institute for Health Services Research	None declared
Moore, 2003[573]	Funded by the Health Outcomes Unit of the New South Wales Department of Health of Australia.	Not reported
Borello-France, 2006[497]	Funded by the National Institutes of Health/National Institute on Aging grant R15AG15488 to Dr. Borello-France	Not reported

Appendix Table F82. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI (continued)

Reference	Sponsorship	Conflict of Interest
Bo, 1999[493]	Funded by the Norwegian Fund for Postgraduate studies in Physiotherapy and Norwegian Research Council. Coloplast AS provided the continence guards and Vitacon S provided the electrical stimulators and cones. They also gave financial support to seminars for the research group	None declared
Bo, 2000[494]	Funded by The Norwegian Fund for Postgraduate Studies in Physiotherapy and The Norwegian Research Council. In addition, Coloplast AS gave financial support to the study	Not reported
Borrie, 2002[499]	Funded by the Ontario Ministry of Health Assistive Devices Branch (grant no.M695A2), Parkwood Hospital, London, Ont., and the University of Western Ontario, London, Ont.	None
Peters, 2010[587]	Funded by Uroplasty, Inc.	Not reported
Lightner, 2001[561]	Funded through unrestricted, educational grants by Carbon Medical Technologies.	A. U. Khan and I. Klimberg received research funding from the sponsor of this study.
Jeyaseelan, 2000[545]	Funding for this project was provided by University of Manchester Medical Bequest Fund.	Not reported
Gorman, 1995[537]	Funding provided by Florida Nurses Foundation, Sigma Theta Tau, Alpha Theta Chapter, and Rural Women's Health Project (NR3139).	Not reported
Janssen, 2001[544]	Funding: Ziekenfondsraad;	None
Kincade, 2007[550]	Grant from National Institute of Nursing Research; Grant numbers: R01 NR05071, S1	Not reported
Elser, 1999[522]	Grant from National Institute on Aging/National Institutes of Health, Bethesda, MD, grant UO1AG05170-6	Not reported
Chadha, 2000[512]	Grant support for this study was provided by the Chief Scientist Office of the Scottish Office of Home and Health Department, which also funds the Health Services Research Unit, University of Aberdeen, Scotland.	Not reported
Williams, 2006[615]	Medical Research Council	None declared
Wyman, 1997[618]	National Institute of Aging, National Institute for Nursing Research (formerly National Center for Nursing Research), National Institutes of Health, Bethesda, Maryland, Grant Number AG05170.	
Wong, 2001[617]	None	Not reported
Zanetti, 2007[623]	None	None
Tsai, 2009[611]	None	None
Felicissimo, 2010[526]	None	None
Harvey, 2002[539]	Not supported by the Industry	Not reported
Demain, 2001[514]	Not reported	The physiotherapy clinical trialist is supported by the West Midlands NHS(E)
O'Brien, 1991[581]	Not reported	Not reported
Lagro-Janssen, 1991[554]	Not reported	Not reported
Smith, 1996[596]	Not reported	Not reported
Nielsen, 1993[578]	Not reported	Not reported
Nygaard, 1996[580]	Not reported	Not reported
O'Brien, 1996[582]	Not reported	Not reported
Berghmans, 1996[489]	Not reported	Not reported
Dowd, 1996[519]	Not reported	Not reported

Appendix Table F82. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI (continued)

Reference	Sponsorship	Conflict of Interest
Ramsay, 1996[588]	Not reported	Not reported
Glavind, 1996[535]	Not reported	Not reported
Bo, 1997[492]	Not reported	Not reported
Thornburn, 1997[607]	Not reported	Not reported
Brubaker, 1997[503]	Not reported	Not reported
Sherman, 1997[595]	Not reported	Not reported
Cammu, 1998[511]	Not reported	Not reported
Glavind, 1997[536]	Not reported	Not reported
Miller, 1998[572]	Not reported	Not reported
Bower, 1998[500]	Not reported	Not reported
Yamanishi, 2000[621]	Not reported	Not reported
McFall, 2000[571]	Not reported	Not reported
Pages, 2001[585]	Not reported	None
Clarke-O'Neill, 2002[624]	Not reported	Not reported
Thyseen, 2001[608]	Not reported	Not reported
Bryant, 2002[504]	Not reported	Not reported
Berghmans, 2002[490]	Not reported	Not reported
Aukee, 2002[485]	Not reported	Not reported
Yoon, 2003[622]	Not reported	Not reported
But, 2003[508]	Not reported	Not reported
Aksac, 2003[478]	Not reported	Not reported
O'Sullivan, 2003[584]	Not reported	Not reported
Robinson, 2003[590]	Not reported	Not reported
Diokno, 2004[516]	Not reported	Not reported
Bano, 2005[487]	Not reported	Not reported
Seo, 2004[594]	Not reported	Not reported
Schulz, 2004[593]	Not reported	Not reported
Amaro, 2005[480]	Not reported	Not reported
Swithinbank, 2005[604]	Not reported	Not reported
Finazzi Agro, 2005[527]	Not reported	Not reported
Karademir, 2005[323]	Not reported	Not reported
Amaro, 2006[481]	Not reported	Not reported
Andersen, 2002[482]	Not reported	Not reported
Borawski, 2007[496]	Not reported	None
Konstantinidou, 2007[551]	Not reported	None
Manganotti, 2007[565]	Not reported	Not reported
Du Moulin, 2007[575]	Not reported	Not reported
Demirturk, 2008[515]	Not reported	None
Castro, 2008[253]	Not reported	Not reported
Kumari, 2008[552]	Not reported	Not reported

Appendix Table F82. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI (continued)

Reference	Sponsorship	Conflict of Interest
Ghoniem, 2009[533]	Not reported	Gamal Ghoniem has financial interest and/or other relationship with Astellas, Coloplast, Uroplasty and Bulkamid; Jacques Corcos has financial interest and/or other relationship with Johnson & Johnson, Astellas, Purdue, Triton and Allergan; Craig Comiter has financial interest and/or other relationship with Coloplast and Astellas; O.Lenaine Westney has financial interest and/or other relationship with American Medical Systems; and Sender Herschorn has financial interest and/or other relationship with Pfizer, Astellas, Johnson & Johnson, Allergan and Lilly.
Gilling, 2009[534]	Not reported	None
de Oliveira Camargo, 2009[510]	Not reported	None
Gameiro, 2010[532]	Not reported	None
Blowman, 1991[491]	Not reported	Not reported
Majumdar, 2010[564]	Not Reported	None
Diokno, 2010[517]	Not Reported	NR
Liebergall-Wischnitzer, 2009[559]	Partially funded by The Hadassah Women's Health Research Fund and the Berman Family Foundation	None
Kim, 2009[546]	Research grant from the Ministry of Health and Welfare of Japan and a Grant-in-Aid for the Scientific Research B from the Japan Society for the Promotion of Science and Sanitary Products Research Foundation of the KAO Corporation	Not reported
Alewijnse, 2003[479]	Sponsored by a grant from Praeventiefonds/ZON (Netherlands Care Research); Grant number: 28-2505.	None
Ng, 2008[577]	Sponsored by a grant from The National Science Council in Taiwan (NSC-89-2314-B-040-046)	Not reported
Theofrastous, 2002[606]	Sponsored by National Institute on Aging; Contract grant number:UO1-AG-05170.	Not reported
Appell, 2006[483]	Sponsored by Novasys Medical, Inc. (Newark, CA)	None
McFall, 2000[570]	Supported by a co-operative agreement between the Centers for Disease Control & Prevention and the Oklahoma State Department of Health.	Not reported
Goode, 2003[626]	Supported by a grant 1R01DK49472 from the National Institutes of Health	Not reported
Sand, 1995[591]	Supported by a grant from Empi, Inc., St.Paul, Minnesota	Not reported
Gallo, 1997[531]	Supported by a grant from Incare Medical Products.	Not reported
Tibaek, 2005[610]	Supported by a grant from the Foundation of Danish Physiotherapists Research; Grant sponsor: The Foundation of 1870, Direkt r Jacob Madsen og hustrus Fond	Not reported
Wang, 2004[612]	Supported by a grant from the National Science Council, Taiwan (NSC90-2314-B-182-111).	Not reported

Appendix Table F82. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI (continued)

Reference	Sponsorship	Conflict of Interest
Tomlinson, 1999[625]	Supported by a research grant (R01 NR3139 Nursing Model: Urinary Continence for Older, Rural Women) from the National Institute of Nursing Research, National Institutes of Health (1992–1997). Johnson & Johnson Company (Milltown, NJ) donated the incontinence products	Not reported
Kim, 2007[548]	Supported by a Research Grant of the Ministry of Health and Welfare of Japan and a Grant-in-Aid for Scientific Research B of the Japan Society for the Promotion of Science.	None
Corcos, 2005[513]	Supported by a University-Industry grant from the Canadian Institute for Health Research (CIHR) in association with Bard Canada.	All authors are study investigators funded by CIHR and Bard.
Liebergall-Wischnitzer, 2005[560]	Supported by an Internal Grant for Paramedical Personnel at Hadassah and the Lillian Silverstein Fund	Not reported
Fantl, 1991[525]	Supported by Cooperative Agreement AG05170 with the National Institute on Aging and National Center on Nursing Research, Bethesda, Md	Not reported
Subak, 2002[599]	Supported by Direct Community Benefit Investment, Kaiser Foundation Research Institute	Not reported
Barroso, 2004[488]	Supported by Fundação de Amparo à Pesquisa do Rio Grande do Sul (FAPERGS) and the Fundo de Incentivo à Pesquisa (FIPE) of GPPG/HCPA	Not reported
Strasser, 2007[598]	Supported by FWF-grant P-12828 (Fonds zur Foerderung der wissenschaftlichen Forschung, Vienna; Institute for Biochemical Pharmacology, Medical University Innsbruck; Austria).	Michael Mitterberger is co-owner of IGOR, and Hannes Strasser and Rainer Marksteiner are founders and co-owners of Innovacell Biotechnologie. Both companies run certified facilities where the autologous cells were grown. Eva Margreiter, an employee of Innovacell, did most cell cultures.
Burgio, 2002[505]	Supported by grant AG RO1 08010 from the National Institute on Aging, National Institutes of Health, Bethesda, Md.	Not reported
Manonai, 2006[566]	Supported by grant from Thai Health Promotion Foundation	Not reported
But, 2005[509]	Supported by Grant L3-4476-0334-02/3.08 from the Ministry of Education, Science and Sport of the Republic of Slovenia	Not reported
Goode, 2002[294]	Supported by Grants AG 08010 and K04 00431 from the National Institute on Aging to Dr. Burgio.	Not reported

Appendix Table F82. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI (continued)

Reference	Sponsorship	Conflict of Interest
Richter, 2010[363]	Supported by grants from the Eunice Kennedy Shriver National Institute of Child Health and Human Development (U10 HD41261, U10 HD 41250, U10 HD54136, U10 HD41249, U10 HD41267, U10 HD41248, U10 HD41268, U10 HD41263, U10 HD54214, U10 HD54241, and U10 HD54215); National Institute of Diabetes and Digestive and Kidney Diseases, and National Institutes of Health Office of Research on Women's Health.	Dr. Burgio is a consultant for Pfizer (New York, NY) and on the advisory board for Astellas (Deerfield, IL). Dr. Brubaker is a Research Consultant for Pfizer (New York, NY) and a Research Investigator for Allergan (Irvine, CA). Dr. Zyczynski has performed contract research for Johnson & Johnson (New Brunswick, NJ). Dr. Lukacz is a consultant for Pfizer (New York, NY), Medtronic (Minneapolis, MN), and Watson Pharmaceuticals (Corona, CA). She has served on the speaker's bureau for Novartis (Basel, Switzerland) and Proctor&Gamble (Cincinnati, OH). She has been a consultant and proctor for Intuitive Surgical Corporation (Sunnyvale, CA) , and she has been an editor First Consult. Dr. Schaffer is on the Speaker's Bureau and National Advisory Board of Astellas/GlaxoSmithKline (Deerfield, IL; Philadelphia, PA) and on the Specialty Surgeons Advisory Board of Cadence Pharmaceuticals (San Diego, CA). The other authors did not report any potential conflicts of interest.
Nager, 2009[576]	Supported by grants from the Eunice Kennedy Shriver National Institute of Child Health and Human Development and the NIH Office of Research on Women's Health at National Institutes of Health (U10 HD54215, U10 HD41267, U10 HD41250, U10 HD41261, U10 HD54214, U10 HD54241, U10 HD54136, and U01 HD41249).	None
Subak, 2009[601]	Supported by grants from the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) (U01 DK067860, U01 DK067861, and U01 DK067862) and from the Office of Research on Women's Health.	Dr. Subak reports serving on an advisory board for Pfizer and receiving grant support from Pfizer; Dr. Grady, receiving grant support from Bionovo; Dr. Kusek, owning stock in Eli Lilly, Pfizer, and deCODE Genetics; and Dr. Burgio, serving on an advisory board for Pfizer, receiving grant support from Pfizer, and receiving advisory-board fees from Astellas and GlaxoSmithKline. No other potential conflict of interest relevant to this article was reported.

Appendix Table F82. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI (continued)

Reference	Sponsorship	Conflict of Interest
Wing, 2010[616]	Supported by Grants U01DK067860, U01DK067861 and U01 DK067862 from the National Institute of Diabetes and Digestive and Kidney Diseases, as well as by the Office of Research on Women's Health.	Delia Smith West has financial interest and/or other relationship with Jenny Craig, Inc.; Holly Richter has financial interest and/or other relationship with Xanodyne, University of California, San Francisco, Pfizer and American Geriatrics Society; and Kathryn Burgio has financial interest and/or other relationship with Pfizer, Astellas and Johnson & Johnson.
Huang, 2009[541]	Supported by GrantsU01 DK067860, U01 Dk067861 and U01 DK067862, and K24 Dk068389 and K24 Dk080775, from The National Institute of Diabetes and Digestive and Kidney Diseases, and the Office of Research on Women's Health, National Institutes of Health. Alison Huang was supported by Grant KL2RR024130 from the National Center for Research Resources, a component of the National Institutes of Health Clinical Translational Science Award for Medical Research	Alison Huang and Leslee Subak have financial interest and/or other relationship with Pfizer, Inc.
Arvonen, 2001[484]	Supported by Ipex Medical AB	Not reported
Engberg, 2002[524]	Supported by National Institute for Nursing Research grant No. R01 NR02874.	Not reported
Hahn, 1991[538]	Supported by Neurologiskt handikappades Riksförbund and the LIC hygien	Not reported
McDowell, 1999[569]	Supported by NINR RO1 NR02874.	Not reported
Lee, 2001[558]	Supported by Physicians Sources, Inc.	Not reported
Lightner, 2009[562]	Supported by Q-Med Ab, Inc., Uppsala, Sweden	Not reported
Subak, 2005[600]	Supported by research awards from Mount Zion Health Services,Inc. and the University of California, San Francisco Academic Senate, Committee on Research.	Leslee Subal is a Women's Reproductive Health Research Scholar supported by the National Institute of Child Health and Human Development, National Institutes of Health, Bethesda, Maryland (K12 HD01262–02). Leslee Subak has financial interest and/or other relationship with Yamanouchi.
Kim, 2008[549]	Supported by research funds from Chosun Nursing College, 2006	Not reported
Boyington, 2005[501]	Supported by research grant No. 1 K01 NR00125 (A Knowledge-Based System for Continence) from the National Institute for Nursing Research, National Institutes of Health (1999-2003).	Not reported
Laycock, 2001[557]	Supported by SSL-International (UK) and Cardio Design (Australia)	Not reported
Dumoulin, 2004[521]	Supported by the Canadian Institutes of Health Research and Laborie Medical Technologies Inc. through a Canadian Institutes of Health Research–Industry grant. C. Dumoulin was supported by studentships from the Canadian Institutes of Health Research and from the Fonds de la Recherche en Santé du Québec.	Not reported

Appendix Table F82. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI (continued)

Reference	Sponsorship	Conflict of Interest
Brown, 2006[502]	Supported by the following: The Diabetes Prevention Program National Institutes of Health/ National Institute of Diabetes and Digestive and Kidney Diseases, the National Institute of Child Health and Human Development, the National Institute on Aging, the Office of Research on Minority Health and Health Disparities, the Office of Women's Health, the Indian Health Service, the Centers for Disease Control and Prevention, the General Clinical Research Program, the National Center for Research Resources, the American Diabetes Association, Bristol-Myers Squibb, Lipha Pharmaceuticals, and Parke-Davis. LifeScan, Health O Meter, Hoechst Marion Roussel, Merck-Medco Managed Care, Merck, Nike Sports Marketing, Slim Fast Foods, and Quaker Oats donated materials, equipment, or medicines for concomitant conditions.	Not reported
Sung, 2000[602]	Supported by the Hallym Academy of Science, Hallym University in 1998	Not reported
Sung, 2000[603]	Supported by the Hallym Academy of Sciences, Hallym University in 1998	
Fujishiro, 2002[530]	Supported by the Life Science Foundation of Japan	Not reported
Fujishiro, 2000[529]	Supported by the Life Science Foundation of Japan.	Not reported
Wyman, 1998[619]	Supported by the National Institute of Aging/National Institutes of Health, Bethesda, Maryland, grant No. UOI AG05170	Not reported
Hu, 1989[540]	Supported by the National Institute on Aging and the National Center for Nursing Research, Bethesda, Md.	Not reported
Borello-France, 2008[498]	Supported by the National Institutes of Health, National Institute on Aging (grant R15 AG15488-03), and by a Magee-Women's Health Foundation grant	Not reported
Coleman, 1999[627]	Supported by the Robert Wood Johnson Foundation Chronic Care Initiative, Grant No. 024739	Dr Coleman was a Veteran's Affairs Robert Wood Johnson Clinical Scholar during his participation in this study
Dowd, 2000[520]	Supported by The University of Akron Faculty Grant 1355	Not reported

Appendix Table F82. Sponsorship and conflict of interest in studies of nonpharmacological treatments for UI (continued)

Reference	Sponsorship	Conflict of Interest
MacDiarmid, 2010[360]	Supported by Uroplasty, Inc.	MacDiarmid Scott has financial interest and/or other relationship with Uroplasty, Pfizer, Watson, Astellas and Allergan; Peters Kenneth has financial interest and/or other relationship with Medtronic, Advanced Bionics, Boston Scientific, Allergan, Pfizer, Celgene and Trillium Therapeutics; Wooldridge Leslie has financial interest and/or other relationship with Uroplasty, Astellas and Watson; Rovner Eric has financial interest and/or other relationship with Astellas; Leong Fah Che has financial interest and/or other relationship with Astellas; Siegel Steven has financial interest and/or other relationship with AMS, Medtronic, Uromedica, Uroplasty and QiG; Tate Susan has financial interest and/or other relationship with C.R. Bard; and Feagins Brian has financial interest and/or other relationship with Medtronic, AMS, Novartis, Allergan, Astellas, and Boston Scientific
Yamanishi, 1997[620]	Supported in part by grants from the National Research and Development for Medical and Welfare Apparatus under Industrial Science and Technology Frontier Program of the Agency of Industrial Science and Technology of the Ministry of International Trade and Industry and the New Energy and Industrial Technology Development Organization of Japan	Not reported
Lamb, 2009[555]	The trial was funded by the Physiotherapy Research Foundation	None
Hui, 2006[542]	The telemedicine equipment was supported by the SK Yee Medical Foundation	Not reported
Finazzi-Agro, 2010[528]	Supported by a grant from Uroplasty, Inc.	Enrico Finazzi-Agro has financial interest and/or other relationship with Astellas, Uroplasty and Bioniche.
Schreiner, 2010[592]	Not reported	None

Appendix Table 83. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI

Treatment	Reference sample length of treatment	Intention to treat allocation concealment justification of the sample Size	Randomization	Bias
Pelvic floor muscle training (PFMT) and/or other lifestyle interventions	Aksac, 2003[478] Sample: 50 8 weeks	Intention to treat: Intention to treat not stated Allocation concealment not adequate Sample size justified: No	Randomization: Randomization with choosing closed letters (patients had to pick up closed letters)	Randomization: Adequate
PFMT and/or other lifestyle interventions	Alewijnse, 2003[479] Sample: 129 14-22 weeks	Intention to treat: Yes Allocation concealment unclear Sample size justified: Yes	Randomization: Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Arvonen, 2001[484] Sample: 37 16 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Aukee, 2002[485] Sample: 30 12 weeks	Intention to treat: Yes Allocation concealment not reported Sample size justified: No	Randomization: Randomization with random numbers table with permuted blocks of four	Randomization: Adequate
PFMT and/or other lifestyle interventions	Aukee, 2004[486] Sample: 35 12 weeks	Intention to treat: Yes Allocation concealment unclear Sample size justified: No	Randomization: Randomization was performed by a random numbers table, in blocks of four	Randomization: Adequate
PFMT and/or other lifestyle interventions	Berghmans,1996[489] Sample: 40 12 weeks	Intention to treat: Yes Allocation concealment not adequate Sample size justified: No	Randomization: Computer generated randomization stratified by seriousness of incontinence (grade 1 and 2) and by referral (general practitioner or urologist) with permuted blocks of 4	Randomization: Adequate
PFMT and/or other lifestyle interventions	Bo, 2000[494] Sample: 59 24 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: Yes	Randomization: Computer generated randomization stratified by degree of leakage	Randomization: Adequate
PFMT and/or other lifestyle interventions	Bo, 2005[495] Sample: 52 24 weeks	Intention to treat: Yes Allocation concealment not reported Sample size justified: Yes	Randomization: Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Borello-France, 2006[497] Sample: 44 12 weeks	Intention to treat: Yes Allocation concealment not reported Sample size justified: No	Randomization: Block randomization schedule with a random number table	Randomization: Adequate
PFMT and/or other lifestyle interventions	Borrie, 2002[499] Sample: 421 24 weeks	Intention to treat: Yes Allocation concealment not adequate Sample size justified: No	Randomization: Computer generated randomization with random permuted blocks, block size of 4	Randomization: Adequate

Appendix Table 83. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)

Treatment	Reference sample length of treatment	Intention to treat allocation concealment justification of the sample Size	Randomization	Bias
PFMT and/or other lifestyle interventions	Boyington, 2005[501] Sample: 71 8 weeks	Intention to treat: Not stated Allocation concealment unclear Sample size justified: No	Randomization: Quasi-experimental trial with random assignment of participants to intervention and control groups. The minimization technique for balancing age (50-59 years, 60-69 years, and 70 years and older), ethnicity, and presence of the symptom of involuntary urine loss in the 2 groups	Randomization: Adequate
PFMT and/or other lifestyle interventions	Brown, 2006[502] Sample: 2191 2.9 years	Intention to treat: Yes Allocation concealment unclear Sample size justified: Yes	Randomization: Randomization was stratified by clinical center	Randomization: Adequate
PFMT and/or other lifestyle interventions	Bryant, 2002[504] Sample: 95 4 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: No	Randomization: Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Burgio, 2002[505] Sample: 222 8 weeks	Intention to treat: Yes Allocation concealment unclear Sample size justified: Yes	Randomization: stratified randomization; Randomization stratified by race, type, and severity of incontinence	Randomization: Adequate
PFMT and/or other lifestyle interventions	Burns,1990[506] Sample: 128 8 weeks	Intention to treat: Not stated Allocation concealment not reported Sample size justified: No	Randomization: Randomization with permuted blocks of 10.	Randomization: Adequate
PFMT and/or other lifestyle interventions	Burns, 1993[507] Sample: 135 24 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Adequate Adjustment for clinical site and study treatment, fluid intake, patient reported diagnosis of congestive heart failure, patient reported diagnosis of diabetes, body mass index, age, urge and stress scores from the medical, epidemiological and social aspects

Appendix Table 83. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)

Treatment	Reference sample length of treatment	Intention to treat allocation concealment justification of the sample Size	Randomization	Bias
PFMT and/or other lifestyle interventions	de Oliveira Camargo, 2009[510] Sample: 61 12 weeks	Intention to treat: Not stated Allocation concealment unclear Sample size justified: Yes	Randomization: computer-generated random number table	Randomization: Adequate
PFMT and/or other lifestyle interventions	Cammu,1998[511] Sample: 60 12 weeks	Intention to treat: Yes Allocation concealment not adequate Sample size justified: No	Randomization: Computerized randomization with random numbers tables	Randomization: Adequate
PFMT and/or other lifestyle interventions	Castro, 2008[253] Sample: 118	Intention to treat: Intention to treat not stated Adequate Sample size justified: No	Randomization: Not reported	Randomization No
PFMT and/or other lifestyle interventions	Chadha, 2000[512] Sample: 449 48 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: Yes	Randomization: Randomization stratified by hospital size and location. 2 x 2 balanced incomplete block controlled before and after study.	Randomization: Adequate
PFMT and/or other lifestyle interventions	Coleman,1999[627] Sample: 169 Length of treatment 48 weeks	Intention to treat: Modified intention-to-treat: patients with followup data were included in the followup analysis irrespective of level of exposure to the intervention Allocation concealment unclear Sample size justified: No	Randomization: Simple random numbers table; The unit of randomization was the physician practice	Randomization: Adequate Possible because the authors modified intention to treat analysis
PFMT and/or other lifestyle interventions	Demain, 2001[514] Sample: 44 12 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: No	Randomization: Stratified randomization using the method of minimization; Stratification by body mass index and age	Randomization: Adequate
Group intervention	Diokno, 2010[517] Sample: 44 6-8 weeks	Intention to treat: NR Allocation concealment NR Sample size justified: No	Randomization: NR	Randomization: Not adequate
PFMT and/or other lifestyle interventions	Diokno, 2004[516] Sample: 359 48 weeks	Intention to treat: Not stated Adequate Sample size justified: No	Randomization: Randomizations in blocks of 16 women to provide balanced recruitment between groups	Randomization: Adequate.
PFMT and/or other lifestyle interventions	Dougherty, 2002[518] Sample: 218 24 weeks	Intention to treat: Yes Allocation concealment unclear Sample size justified: No	Randomization: Randomization with minimization to balance by severity, age, bacteriuria ethnicity, and caregiver	Randomization: Adequate
PFMT and/or other lifestyle interventions	Dowd,1996[519] Sample: 58 5 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: No	Randomization: Not reported	Randomization Baseline data not provided but some differences at baseline reported.

Appendix Table 83. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)

Treatment	Reference sample length of treatment	Intention to treat allocation concealment justification of the sample Size	Randomization	Bias
PFMT and/or other lifestyle interventions	Dowd, 2000[520] Sample: 40 6 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Elser, 1999[522] Sample: 204 Length of treatment 12 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: Yes	Randomization: Randomization stratified by severity of urinary incontinence, urodynamic diagnosis, and treatment site randomization.	Randomization: Adequate
PFMT and/or other lifestyle interventions	Engberg, 2002[524] Sample: 19 8 weeks	Intention to treat: Yes Allocation concealment unclear Sample size justified: No	Randomization: Computer-generated stratified by cognitive ability, toileting skills, and severity of urinary incontinence randomization.	Randomization: Adequate
PFMT and/or other lifestyle interventions	Fantl,1991[525] Sample: 13 6 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: Yes	Randomization: Randomization stratified by urodynamic incontinence. Randomization stratified by urodynamic incontinence.	Randomization: Adequate
Supervised Pelvic Floor Muscle Training	Felicissimo, 2010[526] Sample: 62 8 weeks	Intention to treat: No Allocation concealment Adequate Sample size justified: Yes	Randomization: Computer generated random number generator	Randomization: Adequate
PFMT and/or other lifestyle interventions	Gallo,1997[531] Sample: 86 6 weeks	Intention to treat: Intention to treat not stated Allocation concealment not adequate Sample size justified: Yes	Randomization: Not reported	Randomization: States as adequate, baseline characteristics not reported.
PFMT and/or other lifestyle interventions	Gameiro, 2010[532] Sample: 103	Intention to treat: Intention to treat not stated Allocation concealment not reported Sample size justified: Yes	Randomization: Patients were systematically allocated, in a single-blind study, into two groups. The odd numbers were included in group 1 (n=51) and submitted to VWC associated to standardized general exercise; the even numbers were included in group G2 (n=52) and treated with assisted PFMT	Randomization Adequate
PFMT and/or other lifestyle interventions	Gilling, 2009[534] Sample: 70 6 weeks	Intention to treat: Yes Allocation concealment not adequate Sample size justified: Yes	Randomization: Random permuted blocks of 10	Randomization: Adequate
PFMT and/or other lifestyle interventions	Glavind,1997[536] Sample: 6 0.5 weeks	Intention to treat: Intention to treat not stated Allocation concealment not adequate Sample size justified: No	Randomization: Not reported	Randomization: Cross over trial

Appendix Table 83. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)

Treatment	Reference sample length of treatment	Intention to treat allocation concealment justification of the sample Size	Randomization	Bias
PFMT and/or other lifestyle interventions	Glavind,1996[535] Sample: 40 4 weeks	Intention to treat: No Allocation concealment not adequate Sample size justified: No	Randomization: Not reported	Randomization: Stated as adequate, no data provided
PFMT and/or other lifestyle interventions	Goode,2003[626] Sample: 200 8 weeks	Intention to treat: Yes Allocation concealment unclear Sample size justified: Yes	Randomization: Computer-generated stratified by types and severity of incontinence and race randomization with block size of 6.	Randomization: Adequate
PFMT and/or other lifestyle interventions	Goode, 2002[294] Sample: 105 8 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: No	Randomization: Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Gorman,1995[537] Sample: 60 6 weeks	Intention to treat: Not stated Allocation concealment unclear Sample size justified: No	Randomization: Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Hahn, 1991[538] Sample: 20	Intention to treat: Not reported Allocation concealment Not reported Sample size justified: Not reported	Randomization: Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Harvey, 2002[539] Sample: 44	Intention to treat: NR Allocation concealment NR Sample size justified: NR	Randomization: Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Hu, 1989[540] Sample: 143 12 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: Yes	Randomization: Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Huang, 2009[541] Sample: 338 24 weeks	Intention to treat: Not stated Reported previously Sample size justified: No	Randomization: Random permuted blocks; 2:1 ratio	Randomization: No, women in control group had slightly higher average Beck Depression Inventory score
PFMT and/or other lifestyle interventions	Hui, 2006[542] Sample: 32 8 weeks	Intention to treat: Not stated Allocation concealment unclear Sample size justified: No	Randomization: Randomization with a table of random numbers	Randomization: Adequate
PFMT and/or other lifestyle interventions	Hung, 2010[543] Sample: 70 Length of treatment 16 weeks	Intention to treat: No Allocation concealment Not adequate Sample size justified: Yes	Randomization: Block randomization with a maximum of 6 was used	Randomization Adequate
PFMT and/or other lifestyle interventions	Janssen, 2001[544] Sample: 530 12 weeks	Intention to treat: Yes Allocation concealment not adequate Sample size justified: No	Randomization: Randomization stratified by type, severity and duration of incontinence frequency sampling randomization	Randomization: Adequate

Appendix Table 83. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)

Treatment	Reference sample length of treatment	Intention to treat allocation concealment justification of the sample Size	Randomization	Bias
PFMT and/or other lifestyle interventions	Kim, 2009[546] Sample: 147	Intention to treat: NR Allocation concealment NR Sample size justified: NR	Randomization: NR	Randomization NR
PFMT and/or other lifestyle interventions	Kim, 2007[548] Sample: 70 12 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: Yes	Randomization: Computer-generated random numbers; randomization was repeated until there was no significant difference between the two groups	Randomization: Adequate unclear because the authors stated that "The participants were divided into two groups based on the frequency of urine leakage and functional fitness measurements"
PFMT and/or other lifestyle interventions	Kim, 2001[547] Sample: 48 12 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Randomization by the order of coming to the clinic.	Randomization: Adequate
PFMT and/or other lifestyle interventions	Kincade, 2007[550] Sample: 224 3 weeks	Intention to treat: Yes Allocation concealment unclear Sample size justified: Yes	Randomization: The minimization technique; to balance those in the two study groups on age (18–39, 40–64, 65+), estrogen status (pre menopausal/ hormone replacement versus post menopausal/no hormone replacement), severity of urine loss (<50 g vs. more than 50 g), and race	Randomization: Adequate
PFMT and/or other lifestyle interventions	Konstantinidou, 2007[551] Sample: 30 12 weeks	Intention to treat: No Allocation concealment not adequate Sample size justified: Yes	Randomization: Unclear consecutive order according to women hospital administration sequence; Not reported	Randomization: Adequate Unclear because described methods of treatment assignment was not random
PFMT and/or other lifestyle interventions	Kumari, 2008[552] Sample: 198 8 weeks	Intention to treat: Not stated Allocation concealment unclear Sample size justified: Yes	Randomization: Block randomization; Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Lagro-Janssen,1992[553] Sample: 110 12 weeks	Intention to treat: Not stated Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Lagro-Janssen,1991[554] Sample: 66 12 weeks	Intention to treat: Not stated Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Adequate

Appendix Table 83. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)

Treatment	Reference sample length of treatment	Intention to treat allocation concealment justification of the sample Size	Randomization	Bias
PFMT and/or other lifestyle interventions	Lamb, 2009[555] Sample: 174	Intention to treat: Yes Allocation concealment not adequate Sample size justified: Yes	Randomization: Randomized in a ratio of 2:1 (group: individual)	Randomization Adequate
PFMT and/or other lifestyle interventions	Liebergall-Wischnitzer, 2009[559] Sample: 245 12 weeks	Intention to treat: Yes Adequate: by a biostatistician and blinded research coordinator Sample size justified: Yes	Randomization: Randomization stratified with a table of random numbers, permuted blocks; block size of 4 and stratified by age (20–50 and 51–65) and place of residence (three towns).	Randomization: No, a significant difference in the prevalence of uterine prolapse
PFMT and/or other lifestyle interventions	Liebergall-Wischnitzer, 2005[560] Sample: 59 12 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: Yes	Randomization: Computer generated randomization with block of 4 stratified by age.	Randomization: Adequate
PFMT and/or other lifestyle interventions	MacDiarmid, 2010[360] Sample: 33	Intention to treat: Intention to treat not stated Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: NA
Urodynamics	Majumdar, 2010[564] Sample: 99 23–26 weeks	Intention to treat: Yes Allocation concealment Adequate Sample size justified: Yes	Randomization: Randomization was done with the help of a Clinical Trial Simulator, a web-based program	Randomization: NR
PFMT and/or other lifestyle interventions	Manonai, 2006[566] Sample: 42 Two 12-week diet periods and two 4-week washout periods.	Intention to treat: No Allocation concealment unclear Sample size justified: No	Randomization: Not reported	Randomization: Baseline data provided with no analysis for incontinence rate.
PFMT and/or other lifestyle interventions	McDowell, 2006[568] Sample: 30 24 weeks	Intention to treat: Yes Allocation concealment unclear Sample size justified: No	Randomization: Computer generated randomization list.	Randomization: Adequate
PFMT and/or other lifestyle interventions	McDowell,1999[569] Sample: 105 8 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: No	Randomization: Computer-generated stratified by cognitive ability, toileting skills, and severity of urinary incontinence randomization with permuted blocks.	Randomization: Adequate
PFMT and/or other lifestyle interventions	McFall, 2000[570] Sample: 145 Length of treatment 12 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: No	Randomization: Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Miller,1998[572] Sample: 27 1 week	Intention to treat: Not stated Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Baseline data is not reported

Appendix Table 83. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)

Treatment	Reference sample length of treatment	Intention to treat allocation concealment justification of the sample Size	Randomization	Bias
PFMT and/or other lifestyle interventions	Moore, 2003[573] Sample: 145 12 weeks	Intention to treat: Yes Allocation concealment not adequate Sample size justified: Yes	Randomization: Computer-generated randomization stratified with respect to mild and moderate leakage with permuted blocks of 20.	Randomization: Adequate
PFMT and/or other lifestyle interventions	Morkved, 2002[574] Sample: 103 24 weeks	Intention to treat: Yes Allocation concealment not adequate Sample size justified: Yes	Randomization: Centralized but no computerized randomization stratified by results of a pad test with standardized bladder volume (20g or less and more than 20g of leakage).	Randomization: Adequate
PFMT and/or other lifestyle interventions	Du Moulin, 2007[575] Sample: 38 24 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: Yes	Randomization: Random numbers table; general practitioners were randomized	Randomization No, mixed incontinence was more frequent in the intervention group, whereas stress incontinence was more frequent in the control group. Randomization did not provide balance between treatment groups
PFMT and/or other lifestyle interventions	Nager, 2009[576] Sample: 445 Not reported	Intention to treat: No Previously reported Sample size justified: No	Randomization: Previously reported; Randomization ignored in the article	Randomization: Adequate The outcome - pessary fitting reported in total sample not by randomization status.
PFMT and/or other lifestyle interventions	Ng, 2008[577] Sample: 88 12 weeks	Intention to treat: Not stated Allocation concealment unclear Sample size justified: Yes	Randomization: Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Nygaard,1996[580] Sample: 71 12 weeks	Intention to treat: Yes Allocation concealment not reported Sample size justified: Yes	Randomization: Randomization with random numbers table, in blocks of 4	Randomization: Baseline data is not reported
PFMT and/or other lifestyle interventions	O'Brien, 1991[581] Sample: 561 12 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: Yes	Randomization: Computer based randomization.	Randomization: Baseline data is not reported

Appendix Table 83. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)

Treatment	Reference sample length of treatment	Intention to treat allocation concealment justification of the sample Size	Randomization	Bias
PFMT and/or other lifestyle interventions	O'Brien,1996[582] Sample: 292 4 years of followup	Intention to treat: No Reported previously Sample size justified: No	Randomization: Not reported	Randomization Not relevant because the authors reported long term outcomes among all treated. The results reported ignoring randomization as non controlled study.
PFMT and/or other lifestyle interventions	O'Sullivan, 2003[584] Sample: 150 12 weeks	Intention to treat: Yes Adequate Sample size justified:	Randomization: Stratified randomization; randomization was stratified by mild and moderate incontinence	Randomization: Adequate The authors reported outcomes by baseline severity status pooling active and control groups because they did not differ after interventions
PFMT and/or other lifestyle interventions	Pages, 2001[585] Sample: 51 4 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: No	Randomization: Not reported	Randomization Baseline data is not reported
PFMT and/or other lifestyle interventions	Richter, 2010[363] Sample: 446	Intention to treat: Yes Adequate Sample size justified: Yes	Randomization: Previously reported	Randomization Adequate
PFMT and/or other lifestyle interventions	Sherman,1997[595] Sample: 39 8 weeks	Intention to treat: Not stated Allocation concealment not reported Sample size justified: No	Randomization: Randomization stratified by diagnosis of physical stress incontinence or mixed urge/stress incontinence.	Randomization: Adequate
PFMT and/or other lifestyle interventions	Subak, 2005[600] Sample: 48 12 weeks	Intention to treat: Yes Adequate Sample size justified: Yes	Randomization: Randomization was stratified by type of incontinence, with randomly permuted blocks of 4.	Randomization: Adequate
PFMT and/or other lifestyle interventions	Subak, 2009[601] Sample: 338 24 weeks	Intention to treat: Not stated Allocation concealment not adequate Sample size justified: Yes	Randomization: Randomization stratified random permuted blocks; 2:1 ratio with randomly permuted blocks of three or six, stratified according to clinical center	Randomization: Adequate
PFMT and/or other lifestyle interventions	Subak, 2002[599] Sample: 152 6 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: Yes	Randomization: Computer based randomization.	Randomization: Adequate

Appendix Table 83. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)

Treatment	Reference sample length of treatment	Intention to treat allocation concealment justification of the sample Size	Randomization	Bias
PFMT and/or other lifestyle interventions	Sung, 2000[603] Sample: 60 6 weeks	Intention to treat: Not stated Allocation concealment unclear Sample size justified: No	Randomization: The authors stated that they randomly selected patients for treatment. Unclear was it invitation for the study or treatment assignment	Randomization: Baseline data is not reported
PFMT and/or other lifestyle interventions	Swithinbank, 2005[604] Sample: 69 4 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: Yes	Randomization: Not reported	Randomization: Baseline data is not reported
PFMT and/or other lifestyle interventions	Tibaek, 2007[605] Sample: 24 12 weeks	Intention to treat: Not stated Reported previously Sample size justified: No	Randomization: Not reported	Randomization: Stated as adequate (no data provided)
PFMT and/or other lifestyle interventions	Theofrastous, 2002[606] Sample: 137 12 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: Yes	Randomization: Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Thornburn,1997[607] Sample: 20 1 week	Intention to treat: Not stated Allocation concealment unclear Sample size justified: No	Randomization: Not reported	Randomization Baseline data is not reported Unclear because baseline characteristics of women were not reported
PFMT and/or other lifestyle interventions	Tibaek, 2004[609] Sample: 26 12 weeks	Intention to treat: No Allocation concealment not adequate Sample size justified: No	Randomization: Simple random numbers table	Randomization: Adequate
PFMT and/or other lifestyle interventions	Tibaek, 2005[610] Sample: 26 12 weeks	Intention to treat: No Allocation concealment not adequate Sample size justified: No	Randomization: Randomization with a table of random numbers; Randomization with a table of random numbers	Randomization: Adequate
PFMT and/or other lifestyle interventions	Tsai, 2009[611] Sample: 108 12 weeks	Intention to treat: Not stated Allocation concealment unclear Sample size justified: Yes	Randomization: Random permuted blocks; block size 2	Randomization: Adequate
PFMT and/or other lifestyle interventions	Wang, 2004[612] Sample: 120 12 weeks	Intention to treat: No Adequate Sample size justified: Yes	Randomization: Central computer-generated randomization in blocks of 6.	Randomization: Adequate
PFMT and/or other lifestyle interventions	Wells,1991[613] Sample: 157 24 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Williams, 2005[614] Sample: 3746 24 weeks	Intention to treat: Yes Adequate Sample size justified: Yes	Randomization: Randomization by household, at a ratio of 4:1 in favor of the continence nurse practitioner.	Randomization: Adequate

Appendix Table 83. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)

Treatment	Reference sample length of treatment	Intention to treat allocation concealment justification of the sample Size	Randomization	Bias
PFMT and/or other lifestyle interventions	Williams, 2006[615] Sample: 238 12 weeks	Intention to treat: Yes Allocation concealment not adequate Sample size justified: Yes	Randomization: Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Wing, 2010[616] Sample: 338	Intention to treat: Yes Reported previously Sample size justified: Yes	Randomization: Randomly allocated in a 2:1 ratio	Randomization Adequate
PFMT and/or other lifestyle interventions	Wong, 2001[617] Sample: 38 4 weeks	Intention to treat: Not stated Allocation concealment unclear Sample size justified: No	Randomization: Permuted block randomization; blocks of 2	Randomization: Adequate
PFMT and/or other lifestyle interventions	Wyman,1997[618] Sample: 131 6 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: No	Randomization: Stratified by type of incontinence	Randomization: Adequate
PFMT and/or other lifestyle interventions	Wyman,1998[619] Sample: 204 12 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: Yes	Randomization: Stratified on the basis of their urodynamic diagnostic categorization (genuine stress incontinence or detrusor instability with or without genuine stress incontinence), baseline incontinence severity (1 to 9 incontinent episodes, 10 to 25 episodes, or 26 or greater episodes per week), and treatment site	Randomization: Adequate
PFMT and/or other lifestyle interventions	Yoon, 2003[622] Sample: 50 8 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Adequate
PFMT and/or other lifestyle interventions	Zanetti, 2007[623] Sample: 44 12 weeks	Intention to treat: Not stated Allocation concealment unclear Sample size justified: No	Randomization: Stratified randomized computer-generated random number table; Stratified by the satisfaction with the previous therapy	Randomization: Adequate
PFMT and/or other lifestyle interventions	Tomlinson,1999[625] Sample: 135 12 weeks	Intention to treat: No Allocation concealment unclear Sample size justified: No	Randomization: Not reported	Randomization: Adequate The results are reported after active treatment only

Appendix Table 83. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)

Treatment	Reference sample length of treatment	Intention to treat allocation concealment justification of the sample Size	Randomization	Bias
PFMT and/or other lifestyle interventions	Clarke-O'Neill, 2002[624] Sample: 72 1 week	Intention to treat: Yes Allocation concealment unclear Sample size justified: Yes	Randomization: Randomization using Latin squares; Not reported	Randomization Cross over trial differences in quality of life were calculated adjusting for baseline level, number of days practiced the intervention or in wait list group, age, hormone status, and race
Electro-stimulation	Finazzi Agro, 2005[527] Sample: 35 2-8 weeks	Intention to treat: Not stated Allocation concealment unclear Sample size justified: No	Randomization: Not reported	Randomization: Baseline data is not reported
Electro-stimulation	Amaro, 2005[480] Sample: 40 4 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: Yes	Randomization: Not reported	Randomization: Adequate
Electro-stimulation	Amaro, 2006[481] Sample: 40 7 weeks	Intention to treat: Not stated Allocation concealment not reported Sample size justified: Yes	Randomization: Not reported	Randomization: Adequate
Electro-stimulation	Barroso,2004[488] Sample: 36 12 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: Yes	Randomization: Randomization before the study by drawing lots	Randomization: Adequate
Electro-stimulation	Berghmans, 2002[490] Sample: 98 9 weeks	Intention to treat: Yes Allocation concealment not adequate Sample size justified: Yes	Randomization: Randomization using blocks of 4.	Randomization: Adequate
Electro-stimulation	Blowman, 1991[491] Sample: 14	Intention to treat: Not reported Sample size justified: Not reported	Randomization: Not reported	Randomization: Not reported
Electro-stimulation	Bo,1997[492] Sample: 12 1 day experiment	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization Baseline data is not reported
Electro-stimulation	Bo,1999[493] Sample: 122 24 weeks	Intention to treat: Yes Unclear Sample size justified: Yes	Randomization: Computer generated random numbers stratified by baseline leakage	Randomization: Adequate
Electro-stimulation	Borawski, 2007[496] Sample: 30 2 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: Yes	Randomization: Not reported	Randomization: No

Appendix Table 83. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)

Treatment	Reference sample length of treatment	Intention to treat allocation concealment justification of the sample Size	Randomization	Bias
Electro-stimulation	Borello-France, 2008[498] Sample: 28 24 weeks	Intention to treat: Not stated Allocation concealment unclear Sample size justified: No	Randomization: Randomization stratified random permuted blocks Four blocks with 12 assignments each stratified by age (within 5 years) and incontinence severity minimal (<5 urine leakage episodes per week), moderate (5–10 urine leakage episodes per week), or severe (>10 urine leakage episodes per week).	Randomization: Adequate
Electro-stimulation	Bower,1998[500] Sample: 48 Unclear	Intention to treat: No Allocation concealment not reported Sample size justified: Yes	Randomization: Not reported	Randomization: Adequate
Electro-stimulation	Brubaker,1997[503] Sample: 121 8 weeks	Intention to treat: No Allocation concealment unclear but centralized data manager blinded for treatment status analyzed the data. Sample size justified: No	Randomization: Computer generated randomization stratified by incontinence type.	Randomization: Adequate
Electro-stimulation	But, 2003[508] Sample: 55 Length of treatment 8 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Adequate
Electro-stimulation	But, 2005[509] Sample: 39 8 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Baseline data is not reported
Electro-stimulation	Demirturk, 2008[515] Sample: 41 5 weeks	Intention to treat: Not stated Allocation concealment unclear Sample size justified: No	Randomization by application order; Not reported	Randomization: Adequate
Electro-stimulation	Dumoulin, 2004[521] Sample: 64 8 weeks	Intention to treat: Not stated Adequate Sample size justified: Yes	Randomization: Stratified randomization by the results from pad test using a balanced block randomization schedule generated from a table of random numbers.	Randomization: Adequate
Electro-stimulation	Emmons, 2005[523] Sample: 85 4 weeks	Intention to treat: No Allocation concealment not adequate Sample size justified: Yes	Randomization: Computer-generated randomization with random numbers table.	Randomization: Adequate
Electro-stimulation	Fujishiro, 2000[529] Sample: 62 1 week	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Adequate

Appendix Table 83. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)

Treatment	Reference sample length of treatment	Intention to treat allocation concealment justification of the sample Size	Randomization	Bias
Electro-stimulation	Fujishiro, 2002[530] Sample: 37 1 week	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Adequate
Electro-stimulation	Jeyaseelan, 2000[545] Sample: 27 8 weeks	Intention to treat: Not stated Allocation concealment not adequate Sample size justified: Yes	Randomization: computer-generated table of random numbers	Randomization: Adequate
Electro-stimulation	Karademir, 2005[323] Sample: 43 8 weeks	Intention to treat: Not stated Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Baseline data reported for age only.
Electro-stimulation	Kim, 2008[549] Sample: 52 12 weeks	Intention to treat: Not stated Allocation concealment unclear Sample size justified: No	Randomization: Not reported	Randomization: Adequate
Electro-stimulation	Lappin, 2003[556] Sample: 145 10 weeks, 2 weeks washout period.	Intention to treat: No Adequate Sample size justified: No	Randomization: Central computer generated randomization.	Randomization: Adequate
Electrostimulation	Luber,1997[563] Sample: 57 12 weeks	Intention to treat: Not stated Allocation concealment not adequate Sample size justified: Yes	Randomization using the table of random numbers	Randomization: Adequate
Electro-stimulation	Manganotti, 2007[565] Sample: 20 2 weeks	Intention to treat: Not stated Allocation concealment unclear Sample size justified: No	Randomization: Not reported	Randomization: Baseline data is not reported
Electro-stimulation	Oldham, 2010[583] Sample: 128	Intention to treat: NR Randomly allocated by a computer-generated randomization list Sample size justified: Yes	Randomization: Not reported	Randomization NR
Electro-stimulation	Peters, 2010[587] Sample: 150	Intention to treat: Not reported Sample size justified: Yes	Randomization: Subjects were randomized 1:1 at the first intervention visit to PTNS or sham using a random block design stratified by investigational site	Randomization: Adequate
Electro-stimulation	Ramsay, [588] Sample: 74 1 week	Intention to treat: No Allocation concealment unclear Sample size justified: No	Randomization: computer-generated random number	Randomization: Adequate Multiple-imputation with missing data

Appendix Table 83. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)

Treatment	Reference sample length of treatment	Intention to treat allocation concealment justification of the sample Size	Randomization	Bias
Electro-stimulation	Sand, 1995[591] Sample: 52 15 weeks	Intention to treat: Yes Allocation concealment unclear Sample size justified: Yes	Randomization: Computer-generated random numbers with blocks at a 2:1 rate favoring active over placebo devices.	Randomization: Adequate
Electro-stimulation	Smith,1996[596] Sample: 57 16 weeks	Intention to treat: Intention to treat not stated Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Adequate
Electro-stimulation	Spruijt, 2003[597] Sample: 51 8 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: Yes	Randomization: Blocked randomization (Pocock).	Randomization: Adequate
Electro-stimulation	Sung, 2000[602] Sample: 90 6 weeks	Intention to treat: Yes Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Baseline data is not reported
Electro-stimulation	Yamanishi,1997[620] Sample: 35 4 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Adequate
Electro-stimulation	Yamanishi, 2000[621] Sample: 68 4 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Adequate
Bulking agents or medical devices	Appell, 2006[483] Sample: 173 48 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: Yes	Randomization: Computer generated randomization with ratio 2:1	Randomization: Adequate
Bulking agents or medical devices	Bano, 2005[487] Sample: 50 Length of treatment 6 months	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Adequate
Bulking agents or medical devices	Corcos, 2005[513] Sample: 133 48 weeks	Intention to treat: Yes Adequate Sample size justified: Yes	Randomization: Centralized randomization stratified by center with randomly distributed blocks 4 and 6 in size.	Randomization: Adequate
Bulking agents or medical devices	Ghoniem, 2009[533] Sample: 260 24 weeks	Intention to treat: Yes Allocation concealment unclear Sample size justified: Yes	Randomization: Not reported 1:1 ratio	Randomization: Adequate
Bulking agents or medical devices	Lee, 2001[558] Sample: 68 Duration of followup: 24 months	Intention to treat: No Allocation concealment not reported Sample size justified: Yes	Randomization: Computerized randomization with random number tables	Randomization: Adequate
Bulking agents or medical devices	Lightner, 2001[561] Sample: 355 48 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Baseline data is not reported

Appendix Table 83. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)

Treatment	Reference sample length of treatment	Intention to treat allocation concealment justification of the sample Size	Randomization	Bias
Bulking agents or medical devices	Lightner, 2009[562] Sample: 344 12 weeks	Intention to treat: Not stated Allocation concealment unclear Sample size justified: No	Randomization: Random permuted blocks; 2:1 allocation ratio of Zuidex to Contigen	Randomization: Adequate adjustment for age, race, partner status, parity, hysterectomy, oophorectomy, menopausal status, general health, depression symptoms, systemic estrogen use, SSRI use, clinical severity of incontinence, clinical type of incontinence, BMI and clinical site
Bulking agents or medical devices	Mayer, 2007[567] Sample: 296 24 weeks	Intention to treat: Yes Adequate - central computerized tables generated by Statistical Analysis Systems Sample size justified: Yes	Randomization: Random numbers tables generated by Statistical Analysis Systems	Randomization: Adequate Not relevant
Bulking agents or medical devices	Schulz, 2004[593] Sample: 40 Duration of followup: 12 months	Intention to treat: Yes Allocation concealment not reported Sample size justified: No	Randomization: Computer generated block randomization scheme.	Randomization: Adequate
Bulking agents or medical devices	Strasser, 2007[598] Sample: 63 48 weeks	Intention to treat: Yes Allocation concealment unclear Sample size justified: No	Randomization: Computer-generated randomization list with permuted blocks and ratio of 2:1.	Randomization: Adequate
Bulking agents or medical devices	Andersen, 2002[482] Sample: 52 Single injection	Intention to treat: No Allocation concealment unclear Sample size justified: No	Randomization: Not reported	Randomization: Adequate
Bulking agents or medical devices	Laycock, 2001[557] Sample: 101 12 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Permuted block randomization in ratio 2:2:1	Randomization: Baseline data is not reported
Bulking agents or medical devices	Nielsen, 1993[578] Sample: 40 2 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Baseline data is not reported
Bulking agents or medical devices	Nygaard, 1995[579] Sample: 20 Three exercise sessions	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Block randomization	Randomization: Baseline data is not reported

Appendix Table 83. Quality of randomized controlled clinical trials of nonpharmacological nonsurgical treatments for UI (continued)

Treatment	Reference sample length of treatment	Intention to treat allocation concealment justification of the sample Size	Randomization	Bias
Bulking agents or medical devices	Robinson, 2003[590] Sample: 24 Duration of followup: 4 months	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Adequate
Bulking agents or medical devices	Seo, 2004[594] Sample: 120 6 weeks	Intention to treat: Not stated Allocation concealment not reported Sample size justified: No	Randomization: Not reported	Randomization: Baseline data is not reported
Bulking agents or medical devices	Thyssen, 2001[608] Sample: 94 5 weeks	Intention to treat: No Allocation concealment not reported Sample size justified: No	Randomization: Block randomization;	Randomization: Baseline data is not reported
Percutaneous tibial nerve stimulation	Finazzi-Agro, 2010[528] Sample: 35	Intention to treat: No Allocation concealment Not reported Sample size justified: Yes	Randomization: Patients were randomly assigned to PTNS or a placebo group following a computer generated randomization list	Randomization: Adequate
Trans-cutaneous electrical tibial nerve stimulation + bladder training	Schreiner, 2010[592] Sample: 52 12 weeks	Intention to Treat: No Allocation Concealment: Not reported Justification of the Sample Size: No	Randomization: The patients were randomly divided into two groups through simple random number generator	Randomization: Not adequate

Appendix Table F84. Comparative effectiveness of nonpharmacological treatments on improvement of incontinence

Active	Control	Studies reference	Number of subjects	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events 95% CI)	Evidence
Continence service	Bladder training	1 study[588]	74	Not significant				Insufficient
Bladder training with audiotape about PFMT	Bladder training	1 study[520]	40	1.72 (1.10; 2.69)	0.38 (0.12; 0.64)	3 (2; 8)	378 (121; 636)	Insufficient
PFMT	Behavioral intervention	1 study[615]	238	Not significant				Insufficient
PFMT+ BT	PFMT	1 study[550]	224	Inconsistent across definitions benefit				Insufficient
Individual PFMT+ bladder training	Group	1 study[544]	530	Not significant				Insufficient
Circular muscle exercises (Paula method)	PFMT group	1 study[559]	240	1.26 (1.02; 1.57)	0.14 (0.01; 0.26)	7 (4; 69)	138 (15; 261)	Insufficient
PFMT+ EMG biofeedback	PFMT	3 studies[489,505,626]	322	Inconsistent across definition benefit				Low
PFMT	PFMT+ vaginal balls	1 study[484]	37	1.49 (0.74; 2.98)	0.19 (-0.13; 0.51)			Insufficient
PFMT	Vaginal cone	1 study[615]	238	Not significant				Insufficient
Physiotherapy + biofeedback	Physiotherapy	1 study[535]	40	Not significant				Insufficient
Group physiotherapy	Biofeedback	1 study[585]	40	Not significant				Insufficient
Vaginal cone therapy	Bladder training	1 study[615]	238	Not significant				Insufficient
Contrelle Continence Tampon, CCT	Conveen Continence device Guard, CCG	1 study[608]	94	Not significant				Insufficient
Durasphere	Contigen	1 study[482]	52	1.54 (0.99; 2.38)	0.27 (0.02; 0.52)	4 (2; 56)	269 (18; 521)	Insufficient

Appendix Table F84. Comparative effectiveness of nonpharmacological treatments on improvement of incontinence (continued)

Active	Control	Studies reference	Number of subjects	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events 95% CI)	Evidence
Urethral device (NEAT) packaged with device	Reliance Insert sterile balloon	1 study[590]	24	Not significant				Low
Durasphere	Bovine collagen	1 study[561]	364	Not significant				
Porcine dermal implant injection (Permacol)	Silicone injection (Macroplastique	1 study[487]	50	Not significant				Insufficient
Periurethral dextran copolymer	Transurethral agent-dextran copolymer	1 study[593]	40	Not significant				Insufficient
Calcium hydroxylapatite (CaHA	Bovine Dermal Collagen	1 study[567]	296	Not significant				Insufficient
Autologous myoblasts and fibroblasts	Collagen	1 study[598]	63	Not significant				Insufficient
Transurethral injection of Macroplastique	Transurethral injection of Contigen®	1 study[533]	247	Inconsistent across definitions benefit				
Zuidex Implacer	Contigen endoscopic guidance	1 study[562]	344	Inconsistent across definitions benefit				Insufficient

Appendix Table F85. Effectiveness of nonpharmacological treatments on stress UI in women (results from poorly reported randomized controlled clinical trials)

Reference	Aim	N	% Women	% With UI	Treatment	Duration	Population	Results
Hahn, 1991[628]	To evaluate the function of the pelvic floor and urethral sphincters before and after Contelle device	20	100	100	Pelvic floor training and electrical stimulation with Contelle device (the device was to used for 8-10 hours/night at maximally tolerable intensities)	6 months	Women with genuine stress incontinence	Very few reliable correlations between symptomatic improvement and urodynamic improvement were found

Appendix Table F85. Effectiveness of nonpharmacological treatments on stress UI in women (results from poorly reported randomized controlled clinical trials (continued)

Reference	Aim	N	% Women	% With UI	Treatment	Duration	Population	Results
Laycock, 1993[629]	To evaluate the effect of transcutaneous, pre-modulated interferential stimulation on the symptoms of female stress incontinence, by two prospective clinical trials	46 in first trial and 30 in second trial	100	100	Interferential pelvic floor therapy using an Endomed 433 (Enraf Nonius, Delft, Holland) for 15 minutes (on average ten sessions). Instructions: Pelvic Floor Exercises.	6 weeks	Women with urodynamically proven GSI and sterile urine. In the first trial, women were randomized into 2 groups: group 1 received a course of interferential stimulation and group 2 a course of PFMT and weighted vaginal cones therapy. In the second trial, women were randomized into active interferential stimulation and placebo groups.	There was no significant difference in severity of urinary incontinence between the two groups in trial 1 (p=0.4851). In trial 1: 43.5% of patients receiving IFT (n=23) were improved or cured (objectively measured), and 60.9% subjectively classified improved or cured. In trial 2: In the active IFT group: Pad test results showed: 6.7% worse, 6.7% no change, 60% improved, and 13.3% cured, and in the placebo group: 36.4% were worse, 0.7% showed no change, 45.5% improved, and 0% cured. For subjective assessment: in the active IFT group: 6.7% were worse, 60% showed no change, 33.3% improved, and 0% cured and in the placebo group: 54.5% were worse, 18.2% showed no change, 27.3% improved, and 0% cured. For difference in VAS score: in the active IFT group: 26.7% were worse, 0% no change, 73.3% improved, and 0% cured and in the placebo group: 36.4% were worse, 9.1% showed no change, 54.5% improved, and 0% cured
Borello-France, 2010[630]	To describe adherence to PFMT, barriers, and predictors of exercise	154	100	100	Either tolterodine tartrate extended release capsules 4 mg daily or tolterodine tartrate extended release	10 weeks	BE-DRI trial: Secondary data analysis. Community-dwelling women with pure or predominant UUI , recruited through the	At 12 months 42% (41) of total women had difficulty to find time to do all of the exercises; 56% (54) had difficulty remembering to exercise; 30% (28) perceived exercises did not help. During

Appendix Table F85. Effectiveness of nonpharmacological treatments on stress UI in women (results from poorly reported randomized controlled clinical trials (continued)

Reference	Aim	N	% Women	% With UI	Treatment	Duration	Population	Results
	adherence in women with urge-predominant UI.				capsules 4 mg daily combined with a behavioral intervention		investigators' clinical practices, study announcements, advertisements, and referrals, had post-void residual volume of less than 150 mL and the ability to contract their PFMs, had to show 7 or more episodes of UI on a 7-day baseline diary, and had to self-report persistent UI for at least 3 months, no current use of antimuscarinic or other medications that could affect UI, and no history of neurologic diseases or conditions (e.g., Parkinson disease, multiple sclerosis, spina bifida, spinal cord injury) or systemic diseases known to affect bladder function.	the intervention period: Adjusted regression coefficient: Total number of reported barriers to exercise adherence: -2.0 (95% CI=-3.1, -0.9) p-value=0.0007; Barrier: Difficult to find time to do all of the exercises: -7.7 (95% CI=-11.1, -4.4) p-value=<0.001; Barrier: Difficulty remembering to exercise: -7.5 (95% CI=-10.8, -4.2) p-value <0.001; Barrier: Perceived exercises do not help: 4.2 (95% CI=0.4, 8.0) p-value 0.03; Barrier: Other: -4.0 (95% CI=-8.1, -0.03) p-value=0.048. During the followup period: Adjusted Regression Coefficient: Barrier: Difficult to find time to do all of the exercises: -2.5 (95% CI= -4.7, -0.2) p-value=0.03. (Adjusted for age, education, race/ethnicity, Medical, Epidemiological, and Social Aspects of Aging Questionnaire (MESA) urge index, MESA stress index, volume of fluid intake pretreatment, and clinical site. Regression coefficient is the change in contractions per day per unit increase in total barriers or for endorsement of individual barrier versus no endorsement of that barrier)

Appendix Table F85. Effectiveness of nonpharmacological treatments on stress UI in women (results from poorly reported randomized controlled clinical trials (continued)

Reference	Aim	N	% Women	% With UI	Treatment	Duration	Population	Results
Griffiths, 2009[631]	To explore the concerns and expectations of women invited to attend group physiotherapy sessions for the management of female UI and whether the experience changed their views; and to gather recommenda-tions from women attending group sessions on the design and delivery of these sessions	22	100	100	Group treatment	3 weeks	Women who had participated in a randomized clinical trial comparing individual and group treatment, who had stress, urge or mixed incontinence and were recruited to one of five physiotherapy centers in the West Midlands of the UK. Of these women those who had expressed a preference for individual sessions, but were randomized to group sessions and attended at least one session were recruited for an interview study.	It is necessary to consider reducing embarrassment and uncertainty in women who attend group sessions run in physiotherapy departments for urinary incontinence prior to their attendance

Appendix Table F85. Effectiveness of nonpharmacological treatments on stress UI in women (results from poorly reported randomized controlled clinical trials (continued)

Reference	Aim	N	% Women	% With UI	Treatment	Duration	Population	Results
Engberg, 2009[632]	To examine the feasibility of recruiting women into a clinical trial designed to examine the efficacy of acupuncture in treating urge and mixed UI and the feasibility of performing the planned study procedures	11	100	100	Acupuncture: 12 treatments over 6 weeks. Control group was given sham acupuncture treatment	6 weeks	Women, aged 40 to 70 years of age, having urge or mixed urge and stress urinary accidents at least twice a week on average and have been incontinent for at least 3 months	Subjects randomized to true acupuncture group had a mean 67.47% (median=75.76%) reduction in daytime accidents/day at 4 weeks post acupuncture, whereas the mean reduction in daytime accidents was 16.67% (median=0%) at 4 weeks post-sham acupuncture. There were no significant group differences in changes in the scores on the quality-of-life measures. Subjects' perceptions about whether they had received the true or sham acupuncture were not significantly better than one would expect by chance.
MacDiarmid, 2010[633]	To examine percutaneous tibial nerve stimulation on U I (ORBIT trial)	100	90%	Not reported	Weekly 30 minute treatment	12 weeks followed by therapy at tapered intervals for 9 months	Ambulatory adults with AOB symptoms, with or without a history of previous anticholinergic drug use, with at least 8 voids per 24 hours documented by history and physical and voiding diary	Subjects received as low as 1.2 treatments monthly to sustain symptom improvement throughout 12 months. The response to PTNS therapy achieved following 12 weeks of treatment demonstrates excellent durability through 12 months of followup with 94% sustained improvement from 12 weeks. Analysis of number of treatments needed to sustain therapeutic effect appears acceptable

Appendix Table F85. Effectiveness of nonpharmacological treatments on stress UI in women (results from poorly reported randomized controlled clinical trials (continued)

Reference	Aim	N	% Women	% With UI	Treatment	Duration	Population	Results
Dunn, 2002[634]	To evaluate the short- and medium-term effectiveness of an intraurethral device (FemSoft Insert, Rochester Medical Corporation, Stewartville, Minnesota) in the treatment of exercise-induced incontinence in women	6	100%	100%	Urethral insert	3 months+	Female patients 18 years and older, having stress incontinence during exercise that required pads or clothing changes, being able to perform regular aerobic exercise, and having adequate manual dexterity and intelligence to use the device and complete the subject questionnaires.	This pilot study found that urethral insert is effective and feasible for unsupervised home use. After 3 months, mean satisfaction scores for ease of use were 2.09 for insertion and 1.18 for removal; for comfort, the scores were 2.18 for insertion, 2.05 while wearing, and 1.36 during removal (on a 5-point scale, 1 = very comfortable/satisfied, 5 = very uncomfortable/unsatisfied).
Borello-France, 2010[630]	To examine adherence to exercise therapy and barriers for adherence	154	100%	100%	Behavioral intention: Pelvic floor muscle training, bladder training, and individualized fluid management for those with excessive urine output (>70 oz per day)	10 week study with one-year followup	Adults with OAB	By end of one-year followup period, only 32% of women were exercising at least 5 to 6 days per week. The barriers to exercise adherence were: 42% had difficulty finding time to do all of the exercises; 56% had difficulty remembering to exercise, and 30% perceived exercises did not help.

Appendix Table F86. Subgroup analysis of continence with different nonpharmacological treatments by baseline type of UI (results from individual RCTs were pooled with random effects model)

Treatment	Type of UI	Reference pooled*	Relative risk	Lower 95% CI	Upper 95% CI	Absolute risk difference	Lower 95% CI	Upper 95% CI
PFMT	Not reported	Castro, 2008[253]	3.23	0.98	10.59	0.22	0.03	0.42
PFMT	Not reported	Hung, 2010[543]	5.00	0.62	40.64	0.11	-0.01	0.24
PFMT	Not reported	Pooled	3.59	1.28	10.09	0.15	0.04	0.25
PFMT	Mixed	Kim, 2009[546]	3.35	1.79	6.28	0.32	0.18	0.46
PFMT	Mixed	Burns, 1993[507]	6.35	0.82	49.32	0.14	0.02	0.26
PFMT	Mixed	Pooled	3.54	1.95	6.45	0.23	0.05	0.41
PFMT	Stress UI	Lagro-Janssen, 1991[554]	7.00	0.91	53.78	0.18	0.03	0.33
PFMT	Stress UI	Bo, 1999[493]	6.07	1.47	25.12	0.32	0.12	0.51
PFMT	Stress UI	Aksac, 2003[478]	16.24	1.07	246.51	0.75	0.53	0.98
PFMT	Stress UI	Kim, 2007[548]	6.33	2.06	19.49	0.46	0.27	0.65
PFMT	Stress UI	Pooled	6.85	3.15	14.87	0.42	0.19	0.65
PFMT+BT	Not reported	Diokno, 2004[516]	1.32	0.98	1.78	0.09	-0.01	0.19
PFMT+BT	Mixed	Lagro-Janssen, 1992[553]	10.37	1.37	78.28	0.17	0.06	0.28
PFMT+BT	Mixed	O'Brien, 1991[581]	15.49	2.13	112.49	0.08	0.05	0.11
PFMT+BT	Mixed	McFall, 2000[571]	1.69	0.97	2.93	0.14	0.00	0.29
PFMT+BT	Mixed	Kumari, 2008[552]	33.08	4.62	236.86	0.37	0.26	0.48
PFMT+BT	Mixed	Pooled	8.21	1.58	42.53	0.19	0.05	0.32
PFMT+BT	All	Pooled	3.79	1.55	9.27	0.17	0.06	0.27
PEM+EMG BFB	Mixed	Burns, 1993[507]	8.78	1.17	66.04	0.20	0.06	0.34
PEM+EMG BFB	Stress UI	Aksac, 2003[478]	17.29	1.14	261.69	0.80	0.59	1.01
PEM+EMG BFB	All	Pooled	11.17	2.21	56.44	0.49	-0.10	1.08
Continence service	Mixed	Moore, 2003[573]	1.32	0.90	1.91	0.12	-0.04	0.28
Continence service	Mixed	Williams, 2005[614]	1.47	1.26	1.72	0.09	0.06	0.12
Continence service	Mixed	Pooled	1.45	1.25	1.67	0.09	0.06	0.12
Continence service	Stress UI	Kim, 2009[546]	6.56	1.78	24.16	0.74	0.51	0.98
Continence service	All	Pooled	1.58	1.07	2.34	0.30	-0.01	0.60
Intravaginal electrical stimulation	Not reported	Yamanishi, 2000[621]	5.87	0.76	45.11	0.16	0.02	0.30
Intravaginal electrical stimulation	Not reported	Castro, 2008[253]	3.67	1.14	11.84	0.27	0.06	0.47

Appendix Table F86. Subgroup analysis of continence with different nonpharmacological treatments by baseline type of UI (results from individual RCTs were pooled with random effects model) (continued)

Treatment	Type of UI	Reference pooled*	Relative risk	Lower 95% CI	Upper 95% CI	Absolute risk difference	Lower 95% CI	Upper 95% CI
Intravaginal electrical stimulation	Not reported	Pooled	4.12	1.49	11.38	0.19	0.08	0.31
Intravaginal electrical stimulation	Mixed	Yamanishi, 1997[620]	3.33	0.17	64.33	0.10	-0.07	0.27
Intravaginal electrical stimulation	Stress UI	Sand, 1995[591]	1.70	0.40	7.33	0.08	-0.12	0.29
Intravaginal electrical stimulation	Stress UI	Luber, 1997[563]	1.20	0.27	5.30	0.03	-0.18	0.23
Intravaginal electrical stimulation	Stress UI	Bo, 1999[493]	3.50	0.79	15.58	0.16	-0.01	0.32
Intravaginal electrical stimulation	Stress UI	Blowman, 1991[491]	5.14	0.84	31.57	0.69	0.30	1.09
Intravaginal electrical stimulation	Stress UI	Pooled	2.30	1.06	4.97	0.18	-0.01	0.37
Intravaginal electrical stimulation	All	Pooled	2.86	1.57	5.23	0.16	0.06	0.26
Magnetic stimulation	Mixed	But, 2005[509]	1.08	0.71	1.62	0.05	-0.24	0.34
Magnetic stimulation	Stress UI	Fujishiro, 2000[529]	4.00	0.47	33.80	0.10	-0.04	0.23
Magnetic stimulation	Stress UI	Gilling, 2009[534]	2.00	0.54	7.37	0.09	-0.07	0.24
Magnetic stimulation	Stress UI	Pooled	2.42	0.79	7.35	0.09	-0.01	0.19
Magnetic stimulation	All	Pooled	1.22	0.78	1.88	0.09	-0.01	0.18
Vaginal Cone	Not reported	Castro, 2008[253]	3.33	1.01	11.05	0.23	0.03	0.44
Vaginal Cone	Stress UI	Bo, 1999[493]	2.21	0.44	11.17	0.08	-0.08	0.23
Vaginal Cone	All	Pooled	2.88	1.10	7.55	0.14	-0.01	0.29

PFMT- pelvic floor muscle exercise; BT- bladder training; BFB- biofeedback
* Der Simonian pooled estimate

Appendix Table F87. Clinical outcomes after pelvic floor muscle training compared to no active treatment (results from RCTs pooled with random effects models)

Outcome	Reference	Active events/ randomized	Control events/ randomized	Relative risk (95% CII)	Weight, %	Absolute risk difference (95% CI)	Weight %	Inclusion of mixed UI
Continence	Hung, 2010[543]	5/35	1/35	5.00 (0.62; 40.64)	6	0.11 (-0.01; 0.24)	12	Not reported
Continence	Kim, 2009[546]	34/74	10/73	3.35 (1.79; 6.28)	19	0.32 (0.18; 0.46)	12	Yes
Continence	Lagro-Janssen, 1991[554]	7/33	1/33	7.00 (0.91; 53.78)	6	0.18 (0.03; 0.33)	12	No
Continence	Burns, 1993[507]	7/43	1/39	6.35 (0.82; 49.32)	6	0.14 (0.02; 0.26)	13	Yes
Continence	Bo, 1999[493]	11/29	2/32	6.07 (1.47; 25.12)	10	0.32 (0.12; 0.51)	10	No
Continence	Aksac, 2003[478]	15/20	0/10	16.24 (1.07; 246.51)	4	0.75 (0.53; 0.97)	9	No
Continence	Williams, 2006[615]			1.59 (0.43; 5.87)				Yes
Continence	Kim, 2007[548]	19/35	3/35	6.33 (2.06; 19.49)	13	0.46 (0.27; 0.65)	10	No
Continence	Castro, 2008[253]	10/31	3/30	3.23 (0.98; 10.59)	12	0.22 (0.03; 0.42)	10	Not reported
Continence	Hung, 2010[543]	34/35	23/35	1.48 (1.16; 1.89)	23	0.31 (0.15; 0.48)	11	Not reported
Pooled		142/414	45/401	4.35 (2.83; 6.7)	100	0.30 (0.17; 0.42)	100	
Heterogeneity p value I squared				0.90	0	0	79.2	
Improved UI	Aksac, 2003[478]	5/20	2/10	1.25 (0.29; 5.35)	18	0.05 (-0.26; 0.36)	14	No
Improved UI	Castro, 2008[253]	12/31	2/30	5.81 (1.42; 23.79)	18	0.32 (0.13; 0.51)	17	Not reported
Improved UI	Burns, 1990[506]	21/38	0/40	45.21 (2.83; 720.96)	11	0.55 (0.39; 0.71)	17	Yes
Improved UI	Burns, 1993[507]	23/43	2/39	10.43 (2.63; 41.39)	18	0.48 (0.32; 0.65)	17	Yes
Improved UI	Hung, 2010[543]	25/35	21/35	1.19 (0.85; 1.68)	23	0.11 (-0.11; 0.34)	16	Not reported

Appendix Table F87. Clinical outcomes after pelvic floor muscle training compared to no active treatment (results from RCTs pooled with random effects models) (continued)

Outcome	Reference	Active events/ randomized	Control events/ randomized	Relative risk (95% CII)	Weight, %	Absolute risk difference (95% CI)	Weight %	Inclusion of mixed UI
Improved UI	Lagro-Janssen, 1991[554]	28/33	0/33	57.00 (3.62; 896.38)	11	0.85 (0.718; 0.98)	18	No
Pooled		114/200	27/187	5.44 (1.57; 18.83)	100	0.41 (0.17; 0.65)	100	
Heterogeneity p value I squared				0.00	80.00	0.00	90.00	
Treatment failure	Hung, 2010[543]	0/35	1/35	0.33 (0.01; 7.91)	12	-0.03 (-0.10; 0.05)	39	Not reported
Treatment failure	Bo, 2000[494]	1/29	12/30	0.09 (0.01; 0.62)	24	-0.37 (-0.55; -0.18)	32	
Treatment failure	Castro, 2008[253]	11/31	19/30	0.56 (0.32; 0.97)	64	-0.28 (-0.52; -0.04)	29	Not reported
Pooled		12/95	32/95	0.33 (0.102; 1.10)	100	-0.21 (-0.45; 0.02)	100	
Heterogeneity p value I squared				0.20	39.00	0.00	84.80	

Appendix Table F88. Quality of life after pelvic floor muscle training compared to no active treatment (individual RCTs)

Reference sample/men	Active	Definition of quality of life	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Bo, 2000[494] 59/0	8-12 maximum contractions in 3 series/day and 45 minutes/week group sessions	Dissatisfaction from spending the rest of the life with symptoms as now	29/30	1/4	11/38	0.09 (0.01; 0.68)	-0.33 (-0.52; -0.15)	-3 (-7; -2)	-332 (-517;-147)
Bo, 2000[494] 59/0	8-12 maximum contractions in 3 series/day and 45 minutes/week group sessions	Problem with pain in intercourse	29/30	3/11	10/33	0.31 (0.09; 1.01)	-0.23 (-0.43; -0.03)	-4 (-36; -2)	-230 (-432;-28)
Bo, 2000[494] 59/0	8-12 maximum contractions in 3 series/day and 45 minutes/week group sessions	Problem with sex-life spoiled by urinary symptoms	29/30	3/11	15/50	0.21 (0.07; 0.64)	-0.40 (-0.61; -0.19)	-3 (-5; -2)	-397 (-607;-186)
Bo, 2000[494] 59/0	8-12 maximum contractions in 3 series/day and 45 minutes/week group sessions	Sex-life spoiled by urinary symptoms	29/30	5/17	15/50	0.34 (0.14; 0.83)	-0.33 (-0.55; -0.10)	-3 (-10; -2)	-328 (-553;-102)
Bo, 2000[494] 59/0	8-12 maximum contractions in 3 series/day and 45 minutes/week group sessions	Overall interference with life	29/30	16/56	25/82	0.66 (0.46; 0.95)	-0.28 (-0.51; -0.06)	-4 (-18; -2)	-282 (-506;-57)
Lagro-Janssen, 1991[554] 66/0	5- 10 sessions of 10 pelvic muscle contractions held for 6 seconds daily	Improvement in psychological impact of urinary incontinence	33/33	23/70	0/0	47.00 (2.97; 742.97)	0.70 (0.54; 0.86)	1 (1; 2)	697 (536;857)
Lagro-Janssen, 1991[554] 66/0	5- 10 sessions of 10 pelvic muscle contractions held for 6 seconds daily	Improvement in restrictions of activities	33/33	25/75	2/6	12.50 (3.22; 48.56)	0.70 (0.53; 0.86)	1 (1; 2)	697 (530;864)

Appendix Table F89. Scoring of quality of life after pelvic floor muscle training compared to no active treatment (individual RCTs)

Reference	Active	Definition of quality of life	Randomized active/ control	Active mean standard deviation	Control mean standard deviation	Mean difference (95% CI)
Sung, 2000[602]	Intensive pelvic floor muscle exercises	Frequency of incontinence (0-5-very serious problem)	30/30	2.00/0.50	2.20/0.40	-0.20 (-0.43; 0.03)
Sung, 2000[602]	Intensive pelvic floor muscle exercises	Quantity of urine leakage	30/30	2.10/0.50	2.20/0.50	-0.10 (-0.35; 0.15)
Sung, 2000[602]	Intensive pelvic floor muscle exercises	Severity of incontinence	30/30	2.10/0.70	2.30/0.50	-0.20 (-0.51; 0.11)
Sung, 2000[602]	Intensive pelvic floor muscle exercises	Discomfort due to incontinence	30/30	2.00/0.70	2.20/0.60	-0.20 (-0.53; 0.13)
Sung, 2000[602]	Intensive pelvic floor muscle exercises	Wearing protection	30/30	1.40/0.60	1.50/0.60	-0.10 (-0.40; 0.20)
Sung, 2000[602]	Intensive pelvic floor muscle exercises	Discomfort due to wearing protection	30/30	1.20/0.40	1.30/0.50	-0.10 (-0.33; 0.13)
Sung, 2000[602]	Intensive pelvic floor muscle exercises	Avoidance of places and situations	30/30	1.40/0.70	1.50/0.80	-0.10 (-0.48; 0.28)
Bo, 2000[494]	8-12 maximum contractions in 3 series/day	Quality of Life Scale	29/30	90.10/10.23	85.20/12.05	4.90 (-0.80; 10.60)
Aksac, 2003[478]	Contractions for 10 seconds and relaxation for 20 seconds, 10 times/ session, 3 sessions/day	Visual analog scale based social activity index: 0=cannot undertake any social activity, 10-does not have any problem.	20/10	7.50/1.20	3.60/0.60	3.90 (3.26; 4.54)
Tibaek, 2004[609]	Pelvic floor muscle therapy	Total health perception	14/12	629.00/39.50	656.00/40.33	-27.00 (-57.80; 3.80)
Tibaek, 2004[609]	Pelvic floor muscle therapy	physical functioning (SF-36 0 worse to 100)	14/12	60.00/6.83	67.00/6.67	-7.00 (-12.20; -1.80)
Tibaek, 2004[609]	Pelvic floor muscle therapy	role limitation due to physical problems (SF-36 0 worse to 100)	14/12	75.00/8.33	88.00/14.50	-13.00 (-22.29; -3.71)
Tibaek, 2004[609]	Pelvic floor muscle therapy	Body pain (SF-36 0 worse to 100)	14/12	76.00/9.33	76.00/8.00	0.00 (-6.66; 6.66)
Tibaek, 2004[609]	Pelvic floor muscle therapy	General health perceptions (SF-36 0 worse to 100)	14/12	60.00/7.33	64.00/8.00	-4.00 (-9.94; 1.94)
Tibaek, 2004[609]	Pelvic floor muscle therapy	Vitality (SF-36 0 worse to 100)	14/12	55.00/5.50	83.00/4.83	-28.00 (-31.97; -24.03)
Tibaek, 2004[609]	Pelvic floor muscle therapy	Social functioning (SF-36 0 worse to 100)	14/12	100.00/2.00	100.00/0.00	0.00 (0.00; 0.00)

Appendix Table F89. Scoring of quality of life after pelvic floor muscle training compared to no active treatment (individual RCTs) (continued)

Reference	Active	Definition of quality of life	Randomized active/ control	Active mean standard deviation	Control mean standard deviation	Mean difference (95% CI)
Tibaek, 2004[609]	Pelvic floor muscle therapy	Role limitation due to mental problems (SF-36 0 worse to 100)	14/12	100.00/11.17	100.00/4.17	0.00 (-6.31; 6.31)
Tibaek, 2004[609]	Pelvic floor muscle therapy	Mental health (SF-36 0 worse to 100)	14/12	82.00/5.33	86.00/5.33	-4.00 (-8.11; 0.11)
Tibaek, 2004[609]	Pelvic floor muscle therapy	IIQ (0 best to 100) At followup: Total quality of life	14/12	29.00/10.83	18.00/18.67	11.00 (-0.99; 22.99)
Tibaek, 2004[609]	Pelvic floor muscle therapy	IIQ (0 best to 100) At followup: Physical activity	14/12	6.00/2.50	0.00/3.50	6.00 (3.63; 8.37)
Tibaek, 2004[609]	Pelvic floor muscle therapy	IIQ (0 best to 100) At followup: Travel	14/12	8.00/4.00	0.00/4.83	8.00 (4.55; 11.45)
Tibaek, 2004[609]	Pelvic floor muscle therapy	IIQ (0 best to 100) At followup: Social relationships	14/12	3.00/1.50	2.00/2.17	1.00 (-0.46; 2.46)
Tibaek, 2004[609]	Pelvic floor muscle therapy	IIQ (0 best to 100) At followup: Emotional health	14/12	8.00/3.17	13.00/2.83	-5.00 (-7.31; -2.69)
Tibaek, 2007[605] followup of Tibaek, 2004[609]	Pelvic floor muscle therapy	Physical functioning (SF-36 0 worse to 100)	12/12	60.00/7.33	70.00/9.00	-10.00 (-16.57; -3.43)
Tibaek, 2007[605] followup of Tibaek, 2004[609]	Pelvic floor muscle therapy	Role limitation due to physical problems (SF-36 0 worse to 100)	12/12	75.00/11.50	87.00/10.50	-12.00 (-20.81; -3.19)
Tibaek, 2007[605] followup of Tibaek, 2004[609]	Pelvic floor muscle therapy	General health perceptions (SF-36 0 worse to 100)	12/12	57.00/7.83	54.00/6.83	3.00 (-2.88; 8.88)
Tibaek, 2007[605] followup of Tibaek, 2004[609]	Pelvic floor muscle therapy	Vitality (SF-36 0 worse to 100)	12/12	52.00/5.83	70.00/6.33	-18.00 (-22.87; -13.13)

Appendix Table F89. Scoring of quality of life after pelvic floor muscle training compared to no active treatment (individual RCTs) (continued)

Reference	Active	Definition of quality of life	Randomized active/ control	Active mean standard deviation	Control mean standard deviation	Mean difference (95% CI)
Tibaek, 2007[605] followup of Tibaek, 2004[609]	Pelvic floor muscle therapy	Social functioning (SF-36 0 worse to 100)	12/12	100.00/5.67	100.00/1.67	0.00 (-3.34; 3.34)
Tibaek, 2007[605] followup of Tibaek, 2004[609]	Pelvic floor muscle therapy	Role limitation due to mental problems (SF-36 0 worse to 100)	12/12	100.00/5.67	100.00/0.00	0.00 (0.00; 0.00)
Tibaek, 2007[605] followup of Tibaek, 2004[609]	Pelvic floor muscle therapy	Mental health (SF-36 0 worse to 100)	12/12	82.00/4.67	84.00/2.67	-2.00 (-5.04; 1.04)
Tibaek, 2007[605] followup of Tibaek, 2004[609]	Pelvic floor muscle therapy	physical functioning at followup (SF-36 0 worse to 100)	12/12	60.00/7.00	65.00/8.33	-5.00 (-11.16; 1.16)
Tibaek, 2007[605] followup of Tibaek, 2004[609]	Pelvic floor muscle therapy	Role limitation due to physical problems at followup (SF-36 0 worse to 100)	12/12	75.00/11.50	75.00/12.50	0.00 (-9.61; 9.61)
Tibaek, 2007[605] followup of Tibaek, 2004[609]	Pelvic floor muscle therapy	IIQ (0 best to 100) At 6 month followup: Physical activity	12/12	0.00/3.00	6.00/1.83	-6.00 (-7.99; -4.01)
Tibaek, 2007[605] followup of Tibaek, 2004[609]	Pelvic floor muscle therapy	IIQ (0 best to 100) At 6 month followup: Travel	12/12	8.00/1.83	6.00/3.67	2.00 (-0.32; 4.32)

Appendix Table F89. Scoring of quality of life after pelvic floor muscle training compared to no active treatment (individual RCTs) (continued)

Reference	Active	Definition of quality of life	Randomized active/ control	Active mean standard deviation	Control mean standard deviation	Mean difference (95% CI)
Tibaek, 2007[605] followup of Tibaek, 2004[609]	Pelvic floor muscle therapy	IIQ (0 best to 100) At 6 month followup: Social relationships	12/12	0.00/0.33	3.00/1.50	-3.00 (-3.87; -2.13)
Tibaek, 2007[605] followup of Tibaek, 2004[609]	Pelvic floor muscle therapy	IIQ (0 best to 100) At 6 month followup: Emotional health	12/12	4.00/2.67	13.00/4.83	-9.00 (-12.12; -5.88)
Tibaek, 2007[605] followup of Tibaek, 2004[609]	Pelvic floor muscle therapy	IIQ (0 best to 100) At 6 month followup: Total quality of life	12/12	20.00/8.17	27.00/14.50	-7.00 (-16.42; 2.42)

Appendix Table F90. Clinical outcomes after vaginal cones compared to no active treatment (results from RCTs pooled with random effects models)

Outcome	Reference	Active events/ randomized	Control events/ randomized	Relative risk (95% CIl)	Weight, %	Absolute risk difference (95% CI)	Weight %	Inclusion of mixed UI
Continence	Bo, 1999[493]	4/29	2/32	2.21 (0.44; 11.17)	35	0.08 (-0.08; 0.23)	61	No
Continence	Castro, 2008[253]	9/27	3/30	3.33 (1.01; 11.05)	65	0.23 (0.03; 0.44)	39	Not reported
Pooled		13/56	5/62	2.88 (1.10; 7.55)	100	0.14 (-0.01; 0.29)	100	
Heterogeneity p value, I squared				0.69	0.00	0.23	31.20	
Improved UI-negative pad test	Castro, 2008[253]	11/27	2/30	6.11 (1.49; 25.13)		0.34 (0.14; 0.55)		Not reported
Improved UI-pad weight<2g	Castro, 2008[253]	11/27	3/30	4.07 (1.27; 13.07)		0.31 (0.09; 0.52)		Not reported
Improved UI-satisfied	Castro, 2008[253]	13/27	5/30	2.89 (1.19; 7.04)		0.32 (0.08; 0.55)		Not reported
Treatment discontinuation Treatment failure	Castro, 2008[253]	4/27	2/30	2.22 (0.44; 11.18)		0.08 (-0.08; 0.24)		Not reported
Treatment failure	Castro, 2008[253]	11/27	19/30	0.64 (0.38; 1.09)		-0.23 (-0.48; 0.03)		Not reported

Appendix Table F91. Scoring of quality of life after vaginal cones compared to no active treatment (results from individual RCT)

Reference	Active	Definition of quality of life	Randomized active/ control	Active mean standard deviation	Control mean standard deviation	Mean difference (95% CI)
Bo, 1999[493]	Vaginal cones of 20, 40, and 70g worn for 20 minutes/day	Change from baseline in leakage index	29/32	-0.30/0.53	0.10/0.58	-0.40 (-0.68; -0.12)
Bo, 1999[493]	Vaginal cones of 20, 40, and 70g worn for 20 minutes/day	Change from baseline in social activity index	29/32	0.10/1.06	-0.20/1.73	0.30 (-0.41; 1.01)

Appendix Table F92. Clinical outcomes after pelvic floor muscle training combined with biofeedback compared to no active treatment (results from RCTs pooled with random effects models)

Outcome	Reference	Active events/ randomized	Control events/ randomized	Relative risk (95% CII)	Weight, %	Absolute risk difference (95% CI)	Weight %	Inclusion of mixed UI
Continence	Burns, 1993[507]	9/40	1/39	8.78 (1.17; 66.04)	64	0.20 (0.06; 0.34)	51	Yes
Continence	Aksac, 2003[478]	16/20	0/10	17.29 (1.14; 261.69)	36	0.80 (0.59; 1.01)	49	No
Pooled		25/60	1/49	11.17 (2.21; 56.44)	100	0.49 (-0.10; 1.08)	100	
Heterogeneity p value I squared				0.70	0.00	0.00	95.30	
Improved UI	Aksac, 2003[478]	4/20	2/10	1.00 (0.22; 4.56)	25	0.00 (-0.30; 0.30)	20	No
Improved UI	Burns, 1990[506]	24/40	0/40	49.00 (3.08; 779.07)	15	0.60 (0.45; 0.75)	28	Yes
Improved UI	Burns, 1993[507]	24/40	2/39	11.70 (2.96; 46.20)	26	0.55 (0.38; 0.72)	27	Yes
Improved UI	Goode, 2002[294]	27/33	19/37	1.59 (1.12; 2.27)	35	0.31 (0.10; 0.51)	25	Yes
Pooled		80/133	23/126	3.93 (0.10; 15.49)	100	0.39 (0.17; 0.61)	100	
Heterogeneity p value I squared				0.00	78.00	0.00	80.30	

Appendix Table F93. Scoring of quality of life after pelvic floor muscle training with biofeedback using vaginal EMG probe compared to no active treatment (individual RCT)

Reference	Active	Definition of quality of life	Randomized active/ control	Active mean/standard deviation	Control mean standard deviation	Mean difference (95% CI)
Aksac, 2003[478]	Contractions for 10 seconds and relaxation for 20 seconds) via biofeedback (vaginal probe in EMG) 3 times/ week	Visual analog scale based social activity index: 0=cannot undertake any social activity, 10-does not have any problem	20/10	8.10/0.80	3.60/0.60	4.50 (3.99; 5.01)

Appendix Table F94. Continence after supervised pelvic floor muscle training when compared to no active treatment, individual RCTs

Reference sample/men	Active	Randomized active/control	Active events/rate	Control events/rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Bo, 1999[493] 61/0	Pelvic floor exercise with 8-12 contractions 3 times/day and in groups with skilled physical therapists 1/week	29/32	12/41	1/3	13.24 (1.83; 95.63)	0.38 (0.19; 0.57)	3 (2; 5)	383 (193; 572)

Appendix Table F95. Scoring of quality of life after supervised pelvic floor muscle training compared to no active treatment (individual RCTs)

Reference	Active	Definition of quality of life	Randomized active/ control	Active mean/ standard deviation	Control mean standard deviation	Mean difference (95% CI)
Bo, 1999[493]	Pelvic floor exercise with 8-12 contractions 3 times/day and in groups with skilled physical therapists 1/week	Change from baseline in leakage index	29/32	-0.90/0.51	0.10/0.58	-1.00 (-1.27; -0.73)
Bo, 1999[493]	Pelvic floor exercise with 8-12 contractions 3 times/day and in groups with skilled physical therapists 1/week	Change from baseline in Social activity index	29/32	0.60/1.02	-0.20/1.73	0.80 (0.09; 1.51)

Appendix Table F96. Clinical outcomes after electrical intravaginal stimulation compared to no active treatment (results from RCTs pooled with random effects models)

Outcome	Reference	Active events/ randomized	Control events/ randomized	Relative risk (95% CII)	Weight, %	Absolute risk difference (95% CI)	Weight %	Inclusion of mixed UI
Continence	Yamanishi, 1997[620]	2/20	0/13	3.33 (0.17; 64.33)	4	0.10 (-0.07; 0.27)	17	Yes
Continence	Luber, 1997[563]	3/20	3/24	1.20 (0.27; 5.30)	16	0.03 (-0.18; 0.23)	14	No
Continence	[491]	6/7	1/6	5.14 (0.84; 31.57)	11	0.69 (0.30; 1.09)	5	No
Continence	Sand, 1995[591]	7/35	2/17	1.70 (0.39; 7.33)	17	0.08 (-0.12; 0.28)	14	No
Continence	Bo, 1999[493]	7/32	2/32	3.50 (0.79; 15.58)	16	0.16 (-0.01; 0.32)	17	No
Continence	Yamanishi, 2000[621]	7/37	1/31	5.86 (0.76; 45.11)	9	0.16 (0.02; 0.30)	20	Not reported
Continence	Castro, 2008[253]	11/30	3/30	3.67 (1.14; 11.84)	26	0.27 (0.04; 0.47)	14	Not reported
Continence				4.38 (1.02; 18.84)				No
Pooled		43/188	12/159	2.86 (1.57; 5.23)	100	0.16 (0.06; 0.26)	100	
Heterogeneity p value, I squared				0.82	0.00	0.100	43.70	
Improved UI	Sand, 1995[591]	13/35	2/17	3.16 (0.80; 12.44)	9	0.25 (0.03; 0.48)	9	No
Improved UI	Brubaker, 1997[503]	21/60	10/61	2.14 (1.10; 4.14)	23	0.19 (0.03; 0.34)	16	Yes
Improved UI	Luber, 1997[563]	3/20	3/24	1.20 (0.27; 5.30)	8	0.03 (-0.18; 0.23)	10	No
Improved UI	Yamanishi, 1997[620]	3/20	0/13	4.67 (0.26; 83.55)	2	0.15 (-0.04; 0.34)	12	Yes
Improved UI	Bo, 1999[493]	3/32	1/32	3.00 (0.33; 27.33)	4	0.06 (-0.06; 0.18)	22	No
Improved UI	Yamanishi, 2000[621]	8/37	2/31	3.35 (0.77; 14.64)	8	0.15 (-0.01; 0.31)	15	Not reported
Improved UI	Amaro, 2006[481]	17/20	14/20	1.21 (0.86; 1.71)	38	0.15 (-0.11; 0.40)	7	Yes

Appendix Table F96. Clinical outcomes after electrical intravaginal stimulation compared to no active treatment (results from RCTs pooled with random effects models) (continued)

Outcome	Reference	Active events/ randomized	Control events/ randomized	Relative risk (95% CII)	Weight, %	Absolute risk difference (95% CI)	Weight %	Inclusion of mixed UI
Improved UI	Castro, 2008[253]	13/30	2/30	6.50 (1.60; 26.36)	9	0.37 (0.17; 0.57)	10	Not reported
Pooled		81/254	34/228	2.01 (1.28; 3.15)	100	0.16 (0.08; 0.23)	100	
Heterogeneity p value, I squared				0.19	30.00	0.239	23.800	
Treatment discontinuation	Jeyaseelan, 2000[545]	1/13	2/14	0.54 (0.06; 5.26)	46	-0.07 (-0.30; 0.17)	43	
Treatment discontinuation	Sand, 1995[591]	7/35	1/17	3.40 (0.45; 25.47)	54	0.14 (-0.03; 0.31)	57	No
Pooled		8/48	3/31	1.47 (0.24; 8.86)	100	0.05 (-0.15; 0.25)	100	
Heterogeneity p value, I squared				0.24	29.00	0.16	48.60	
Treatment failure		2/7	1/6	1.71 (0.20; 14.55)	6	0.12 (-0.33; 0.57)	35	No
Treatment failure	Castro, 2008[253]	12/30	19/30	0.63 (0.38; 1.06)	95	-0.23 (-0.48; 0.01)	65	Not reported
Pooled		14/37	20/36	0.67 (0.40; 1.10)	100	-0.11 (-0.44; 0.22)	100	
Heterogeneity p value, I squared				0.37	0.00	0.18	45.20	
Adherence	Sand, 1995[591]	28/35	15/17	0.91 (0.71; 1.15)		-0.08 (-0.29; 0.12)		No
Adverse effects	Sand, 1995[591]	1/35	2/17	0.24 (0.02; 2.49)		-0.09 (-0.25; 0.07)		No
Adverse effects	Sand, 1995[591]	3/35	1/17	1.46 (0.16; 12.99)		0.03 (-0.12; 0.17)		No
Adverse effects	Sand, 1995[591]	4/35	2/17	0.97 (0.20; 4.79)		-0.00 (-0.19; 0.18)		No
Adverse effects	Sand, 1995[591]	5/35	2/17	1.21 (0.26; 5.63)		0.03 (-0.17; 0.22)		No
Treatment discontinuation Adverse effects	Sand, 1995[591]	2/35	0/17	2.50 (0.13; 49.38)		0.06 (-0.06; 0.17)		No

Appendix Table F96. Clinical outcomes after electrical intravaginal stimulation compared to no active treatment (results from RCTs pooled with random effects models) (continued)

Outcome	Reference	Active events/ randomized	Control events/ randomized	Relative risk (95% CIl)	Weight, %	Absolute risk difference (95% CI)	Weight %	Inclusion of mixed UI
Treatment discontinuation	Castro, 2008[253]	1/30	2/30	0.50 (0.05; 5.22)		-0.03 (-0.14; 0.08)		Not reported
Treatment failure								

Appendix Table F97. Improvement in UI after nonpharmacological treatments compared to no active treatment

Treatment	Studies/ patients	Rate in active/ control	Relative risk (95% CI)	Absolute risk difference 95% CI)	Number needed to treat (95% CI)	Attributable Events (95% CI)	Bayesian odds ratio median (2.5%; 97.5%)	Level of evidence
Continence Service	2[582,614]/4038	62.6/53.5	1.33 (1.06; 1.68)	0.20 (-0.01; 0.41)				Low
Bladder Training	2[525,599]/283	61.4/19.2	3.22 (2.25; 4.60)	0.43 (0.28; 0.59)	2 (2; 4)	430 (275; 585)	8 (3; 20)	Low
Pelvic Floor Muscle Training	6[253,478,506,507,543,554]/510	56.9/14.7	5.44 (1.57; 18.83)	0.41 (0.17; 0.65)	2 (2; 6)	412 (174; 649)	14 (3; 69)	High
Pelvic Floor Muscle Training + Bladder Training	4[516,553,571,581]/1171	53.3/22.5	4.13 (1.58; 10.78)	0.39 (0.17; 0.60)	3 (2; 6)	387 (171; 603)	8 (2; 41)	High
Pelvic Floor Muscle Training with Biofeedback	4[294,478,506,507]/383	60.1/18.6	3.93 (1.00; 15.49)	0.39 (0.17; 0.61)	3 (2; 6)			High
Electrical Stimulation	8[253,481,493,503,563,591,620,621]/582	31.7/15.1	2.01 (1.28; 3.15)	0.16 (0.04; 0.23)	6 (4; 12)	156 (84; 228)	3 (2; 6)	High
Percutaneous Electrical Stimulation	3[528,586,587]/405	40/20	1.9(1.1;3.2)	0.31(0.04;0.58)	3(2;25)	308(40;577)	3.1(1.4:8.8)	Medium
Magnetic Stimulation	3[508,509,529]/153	46.8/21.2	2.30 (1.43; 3.71)	0.27 (0.11; 0.42)	4 (2; 9)	265 (112; 417)	4 (2; 12)	Moderate
Weight Loss	2[600,601]/386	42.8/20.8	2.17 (1.26; 3.76)	0.27 (0.06; 0.49)	4 (2; 18)	273 (57; 490)	3 (1; 10)	Moderate
Bulking Agents	2[483,558]/241		Not significant					Low

Appendix Table F98. Scoring of quality of life after electrical stimulation compared to no active treatment (results from individual RCTs)

Reference	Active	Definition of Quality of life	Randomized active/ control	Active mean/standard deviation	Control mean standard deviation	Mean difference (95% CI)
Yamanishi, 1997[620] 14 men	Electrical pelvic stimulation with 50 Hz. square waves of 1 ms. pulse duration using vaginal electrode in women for 15 minutes 2 or 3 times daily	Disturbance in daily activities: 0-not at all, 3-very disturbed	20/13	1.00/1.20	2.10/1.00	-1.10 (-1.86; -0.34)
Bo, 1999[493]	Electrical stimulation using vaginal intermittent stimulation with the MS 106 Twin at 50 Hz 30 minutes/day	Change from baseline in leakage index	32/32	-0.20/0.51	0.10/0.58	-0.30 (-0.57; -0.03)
Bo, 1999[493]	Electrical stimulation using vaginal intermittent stimulation with the MS 106 Twin at 50 Hz 30 minutes/day	Change from baseline in social activity index	32/32	0.60/1.02	-0.20/1.73	0.80 (0.10; 1.50)
Sung, 2000[602]	Functional electrical stimulation for 20 minutes/session with frequency 35Hz-50Hz	Frequency of incontinence (0/5-very serious problem)	30/30	1.70/1.00	2.20/0.40	-0.50 (-0.89; -0.11)
Sung, 2000[602]	Functional electrical stimulation for 20 minutes/session with frequency 35Hz	Quantity of urine leakage	30/30	1.80/0.90	2.20/0.50	-0.40 (-0.77; -0.03)
Sung, 2000[602]	Functional electrical stimulation for 20 minutes/session with frequency 35Hz	Severity of incontinence	30/30	1.80/0.80	2.30/0.50	-0.50 (-0.84; -0.16)
Sung, 2000[602]	Functional electrical stimulation for 20 minutes/session with frequency 35Hz	Discomfort due to incontinence	30/30	1.80/0.80	2.20/0.60	-0.40(-0.76; -0.04)
Sung, 2000[602]	Functional electrical stimulation for 20 minutes/session with frequency 35Hz	Wearing protection	30/30	1.60/1.10	1.50/0.60	0.10 (-0.35; 0.55)
Sung, 2000[602]	Functional electrical stimulation for 20 minutes/session with frequency 35Hz	Discomfort due to wearing protection	30/30	1.30/0.60	1.30/0.50	0.00 (-0.28; 0.28)
Sung, 2000[602]	Functional electrical stimulation for 20 minutes/session with frequency 35Hz-50Hz	Avoidance of places and situations	30/30	1.40/0.90	1.50/0.80	-0.10 (-0.53; 0.33)
Jeyaseelan, 2000[545]	Electrostimulation technique described by Oldham (International Patent Publication WO98/47357) with a background low frequency (to target slow twitch fibers) and intermediate frequency with an initial doublet (to target fast twitch fibers)	Change in incontinence impact questionnaire (IIQ)	13/14	-4.10/16.40	-9.10/17.10	5.00 (-7.64; 17.64)

Appendix Table F98. Scoring of quality of life after electrical stimulation compared to no active treatment (results from individual RCTs) (continued)

Reference	Active	Definition of Quality of life	Randomized active/ control	Active mean/standard deviation	Control mean standard deviation	Mean difference (95% CI)
Jeyaseelan, 2000[545]	Electrostimulation technique described by Oldham (International Patent Publication WO98/47357) with a background low frequency (to target slow twitch fibers) and intermediate frequency with an initial doublet (to target fast twitch fibers)	Change in Urogenital Distress Inventory (UDI)	13/14	-11.80/15.90	-3.30/8.30	-8.50 (-18.18; 1.18)

Appendix Table F99. Clinical outcomes after electrical stimulation compared to no active treatments (results from individual RCTs)

Reference sample/men	Active	Definition of improvement	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)
Amaro, 2006[481] 40/0	Effective Intravaginal electrical stimulation using frequency of 4 Hz with 3 20-minute sessions/week	Self reported urge incontinence	20/20	3/15	6/32	0.50 (0.14; 1.73)	-0.15 (-0.40; 0.10)
Amaro, 2005[480] 40/0	Intravaginal electrical stimulation with 3 20 minute sessions/week using 4 Hz frequency	Urge urinary incontinence at 1 month followup	20/20	3/15	6/32	0.50 (0.14; 1.73)	-0.15 (-0.40; 0.10)
Jeyaseelan, 2000[545] 27/0	New stimulation pattern by Oldham	Withdrawal of the treatment	13/14	1/8	2/14	0.54 (0.06; 5.26)	-0.07 (-0.30; 0.17)
Brubaker, 1997[503] 121/0	Transvaginal electric stimulation for 20 minutes 2 times/day using frequency of 20 Hz, a 2-second-4-second work-rest cycle with a range of stimulation intensities, from 0 to 100 mA	Final urodynamic diagnosis of Detrusor over activity	61/60	16/27	25/41	0.63 (0.38; 1.06)	-0.15 (-0.32; 0.01)

Appendix Table F100. Clinical outcomes after nonpharmacological treatments compared to no active treatment

Studies reference	Number of subjects	Pooled relative risk (95% CI)	Pooled absolute risk difference (95% CI)	Number needed to treat (95%CI)	Attributable events/1000 treated (95% CI)	Evidence
SEVERITY OF UI						
Continence service (1 study) Williams, 2005[614]	3,746	0.94 (0.89; 1.00)	-0.04 (-0.08; 0.00)	-25 (-452; -13)	-40 (-78; -2)	Insufficient
PFMT+BT (2 studies) Lagro-Janssen, 1992[553] McFall, 2000[570]	245	Significant reduction in severity and pad utilization				Low
DISCONTINUATION/ADHERENCE						
PFMT (1 study) Williams, 2006[615]	158	NS differences				Insufficient
PFMT+BT (1 study) Yang, 1995[635]	108	NS differences				Insufficient
Electrical stimulation (1 study) Jeyaseelan, 2000[545]	27	NS differences				Insufficient
Vaginal cones (1 study) Williams, 2006[615] adherence	159	0.63 (0.49; 0.80)	-0.30 (-0.44; -0.16)	-3 (-6; -2)	-297 (-438; -157)	Insufficient
Weight loss (1 study) Subak, 2009[601] Huang, 2009[541]	338	0.17 (0.06; 0.44)	-0.11 (-0.18; -0.05)	-9 (-22; -6)	-112 (-178; -46)	Insufficient
PREVALENCE OF UI						
PFMT (1 study) Williams, 2006[615]	158 NS differences in UI					Insufficient
PFMT+BT (1 study) Kumari, 2008[552]	164 Significant reduction in stress, urgency, but not mixed UI					Insufficient
Acupuncture (1 study) Emmons, 2005[523]	85	NS differences in UUI				Insufficient
Electrical stimulation (3 studies) Brubaker, 1997[503] Amaro, 2005[480] Amaro, 2006[481]	201	NS differences in UUI				Low

Appendix Table F100. Clinical outcomes after nonpharmacological treatments compared to no active treatment (continued)

Studies reference	Number of subjects	Pooled relative risk (95% CI)	Pooled absolute risk difference (95% CI)	Number needed to treat (95%CI)	Attributable events/1000 treated (95% CI)	Evidence
Vaginal cones (1 study) Williams, 2006[615]	159	NS differences				Insufficient
Weight loss (1 study) Brown, 2006[502]	1319 NS change in urgency UI	0.85 (0.73; 0.99)	-0.05 (-0.11; 0.00)	-18 (-329; -10)	-54 (-105; -3)	Insufficient
Diet high in soy protein (1 study) Manonai, 2006[566]	36 Significant increase in stress UI, NS changes in urgency UI					Insufficient
ADVERSE EFFECTS						
Macroplastique (1 study) Ghoniem, 2009[533]	240	NS differences				Insufficient

NS = Not significant

Appendix Table F101. Clinical outcomes after magnetic stimulation compared to no active treatment (results from RCTs pooled with random effects models)

Outcome	Reference	Active events/ randomized	Control events/ randomized	Relative risk (95% CII)	Weight, %	Absolute risk difference (95% CI)	Weight %	Inclusion of mixed UI
Continence	Fujishiro, 2000[529]	4/31	1/31	4.00 (0.47; 33.79)	4	0.10 (-0.04; 0.23)	51	No
Continence	Gilling, 2009[534]	6/35	3/35	2.00 (0.54; 7.37)	11	0.09 (-0.07; 0.24)	38	No
Continence	But, 2005[509]	17/23	11/16	1.08 (0.71; 1.62)	85	0.05 (-0.24; 0.34)	11	Yes
Pooled		27/89	15/82	1.22 (0.78; 1.88)	100	0.09 (-0.01; 0.18)	100	
Heterogeneity p value, I squared				0.35	4.00	0.96	0.00	
Improved UI	But, 2003[508]	7/30	1/22	5.13 (0.68; 38.77)	6	0.19 (0.01; 0.36)	46	Not reported
Improved UI	But, 2005[509]	11/26	3/13	1.83 (0.62; 5.45)	19	0.19 (-0.11; 0.49)	21	Yes
Improved UI	Fujishiro, 2000[529]	23/31	10/31	2.30 (1.33; 3.99)	75	0.42 (0.19; 0.64)	33	No
Pooled		41/87	14/66	2.30 (1.43; 3.71)	100	0.27 (0.11; 0.42)	100	
Heterogeneity p value, I squared				0.68	0.00	0.25	27.90	

Appendix Table F102. Pooled analysis of improvement in incontinence after magnetic stimulation when compared to no active treatment, random effects model

Reference	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk differences (95% CI)	Weight for relative risk	Weight for absolute risk differences
Fujishiro, 2000[529]	23/31	10/31	2.30 (1.33; 3.99)	0.42 (0.19; 0.64)	75.2	32.73
But, 2003[508]	7/30	1/22	5.13 (0.68; 38.77)	0.19 (0.01; 0.36)	5.58	45.92
But, 2005[509]	11/26	3/13	1.83 (0.62; 5.45)	0.19 (-0.11; 0.49)	19.22	21.35
Studies: 3	Patients: 153		2.30 (1.43; 3.71)	0.27 (0.11; 0.42)	100	100
I-squared (variation attributable to heterogeneity)			0	27.9		

Appendix Table F103. Scoring of quality of life after magnetic stimulation compared to no active treatment (results from RCTs)

Reference	Active	Definition of quality of life	Randomized active/ control	Active mean/ standard deviation	Control mean/ standard deviation	Mean difference (95% CI)
Manganotti, 2007[565]	Active magnetic stimulation	General health perception, 1 week (T2)	10/10	37.50/13.10	42.50/16.80	-5.00 (-18.20; 8.20)
Manganotti, 2007[565]	Active magnetic stimulation	Incontinence impact, 1 week (T2)	10/10	39.90/26.20	56.60/22.40	-16.70 (-38.06; 4.66)
Manganotti, 2007[565]	Active magnetic stimulation	Role limitation, 1 week (T2)	10/10	33.30/30.40	33.30/22.20	0.00 (-23.33; 23.33)
Manganotti, 2007[565]	Active magnetic stimulation	Physical limitation, 1 week (T2)	10/10	43.20/27.40	46.60/24.60	-3.40 (-26.22; 19.42)
Manganotti, 2007[565]	Active magnetic stimulation	Social limitation, 1 week (T2)	10/10	14.90/19.50	32.10/21.20	-17.20 (-35.05; 0.65)
Manganotti, 2007[565]	Active magnetic stimulation	Personal relationships, 1 week (T2)	10/10	6.60/11.60	31.60/39.60	-25.00 (-50.58; 0.58)
Manganotti, 2007[565]	Active magnetic stimulation	Emotions, 1 week (T2)	10/10	41.00/29.10	42.10/29.00	-1.10 (-26.56; 24.36)
Manganotti, 2007[565]	Active magnetic stimulation	Sleep/energy, 1 week (T2)	10/10	29.90/20.40	19.90/13.10	10.00 (-5.03; 25.03)
Manganotti, 2007[565]	Active magnetic stimulation	SEAPI-QMM, 1 week (T2)	10/10	1.70/0.80	1.80/0.60	-0.10 (-0.72; 0.52)
Manganotti, 2007[565]	Active magnetic stimulation	General health perception, 1 month (T3)	10/10	52.30/25.90	57.50/28.90	-5.20 (-29.25; 18.85)
Manganotti, 2007[565]	Active magnetic stimulation	Incontinence impact, 1 month (T3)	10/10	49.60/22.20	64.90/16.50	-15.30 (-32.44; 1.84)
Manganotti, 2007[565]	Active magnetic stimulation	Role limitation, 1 month (T3)	10/10	39.90/29.60	53.30/23.30	-13.40 (-36.75; 9.95)
Manganotti, 2007[565]	Active magnetic stimulation	Physical limitation, 1 month (T3)	10/10	47.90/28.80	58.20/26.30	-10.30 (-34.47; 13.87)
Manganotti, 2007[565]	Active magnetic stimulation	Social limitation, 1 month (T3)	10/10	27.20/33.00	44.40/28.60	-17.20 (-44.27; 9.87)
Manganotti, 2007[565]	Active magnetic stimulation	Personal relationships, 1 month (T3)	10/10	13.80/14.60	34.90/34.60	-21.10 (-44.38; 2.18)
Manganotti, 2007[565]	Active magnetic stimulation	Emotions, 1 month (T3)	10/10	46.30/30.90	48.80/35.10	-2.50 (-31.48; 26.48)
Manganotti, 2007[565]	Active magnetic stimulation	Sleep/energy, 1 month (T3)	10/10	29.90/17.20	33.30/13.60	-3.40 (-16.99; 10.19)
Manganotti, 2007[565]	Active magnetic stimulation	SEAPI-QMM, 1 month (T3)	10/10	2.30/0.80	2.10/0.30	0.20 (-0.33; 0.73)

Appendix Table F103. Scoring of quality of life after magnetic stimulation compared to no active treatment (results from RCTs) (continued)

Reference	Active	Definition of quality of life	Randomized active/ control	Active mean/ standard deviation	Control mean/ standard deviation	Mean difference (95% CI)
Gilling, 2009[534]	Electromagnetic stimulation	I-QOL score	35/35	71.20/3.30	67.30/4.40	3.90 (2.08; 5.72)
Gilling, 2009[534]	Electromagnetic stimulation	KHQ score	35/35	6.90/0.70	8.60/1.00	-1.70 (-2.10; -1.30)
Gilling, 2009[534]	Electromagnetic stimulation	I-QOL score at 6 months of followup	35/35	73.60/3.00	68.90/4.50	4.70 (2.91; 6.49)
Gilling, 2009[534]	Electromagnetic stimulation	KHQ score at 6 months of followup	35/35	7.70/0.70	8.50/1.00	-0.80 (-1.20; -0.40)

Appendix Table F104. Improvement in incontinence after injection of bulking agents when compared to no active treatment, results from individual RCTs

Reference sample	Active	Definition of outcomes	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)
Lee, 2001[558] 68	Periurethral injections of autologous fat with 3 max injections depending on outcomes measures	Cured or improved	35/33	6/17	6/18	0.94 (0.34; 2.63)	-0.01 (-0.19 ;0.17)
Appell, 2006[483] 173	Transurethral radiofrequency energy collagen micro-remodeling	Improvement >10 point I-QOL score	110/63	53/48	28/44	1.08 (0.77; 1.52)	0.04 (-0.12; 0.19)

Appendix Table F105. Scoring of quality of life after bulking agent when compared to no active treatment, results from individual RCT

Reference	Active	Definition of quality of life	Randomized active/ control	Active mean standard deviation	Control mean standard deviation	Mean difference (95% CI)
Lee, 2001[558]	Periurethral injections of autologous fat (30 cc of fat from the anterior abdominal wall or buttock through a single 2 to 3 mm) with 3 max injections depending on outcomes measures	Mean incontinence score	35/33	10.90/4.50	12.20/4.60	-1.30 (-3.46; 0.86)

Appendix Table F106. Clinical outcomes after bladder training compared to no active treatment (results from RCTs pooled with random effects models)

Outcome	Reference	Active events/ randomized	Control events/ randomized	Relative risk (95% CII)	Weight, %	Absolute risk difference (95% CI)	Weight %	Inclusion of mixed UI
Continence	Fantl, 1991[525]	8/65	2/66	4.06 (0.90; 18.41)		0.09 (0.00; 0.18)		Yes
Treatment failure	Fantl, 1991[525]	5/65	28/66	0.18 (0.07; 0.44)		-0.35 (-0.48; -0.21)		Yes
Improved UI	Subak, 2002[599]	39/77	11/75	3.41 (1.89; 6.15)	37	0.35 (0.22; 0.49)	52	Yes
Improved UI	Fantl, 1991[525]	49/65	16/66	3.11 (1.99; 4.87)	63	0.51 (0.36; 0.66)	48	Yes
Pooled		87/	27/	3.22 (2.25; 4.60)	100	0.43 (0.28; 0.59)	100	
Heterogeneity p value I squared				0.81	0.00	0.12	58	

Appendix Table F107. Scoring of quality of life after bladder training compared to no active treatment (individual RCT)

Reference	Active	Definition of quality of life	Randomized active/ control	Active mean/standard deviation	Control mean standard deviation	Mean difference (95% CI)
Wyman, 1997[618]	Bladder training: patient education, progressive scheduled voiding regimen, positive reinforcement	Self reported quality of life measures (Incontinence Impact Questionnaire (IIQ)	65/66	32.00/41.00	60.00/65.00	-28.00 (-46.58; -9.42)

Appendix Table F108. Clinical outcomes after percutaneous electrical stimulation compared to no active treatment (results from RCTs pooled with random effects models)

Outcome	Reference	Active events/ randomized	Control events/ randomized	Relative risk (95% CIl)	Weight, %	Absolute risk difference (95% CI)	Weight %	Inclusion of mixed UI
Improved UI	Peters, 2010[586]	39/110	23/110	1.70 (1.09; 2.64)	46.28	0.15 (0.03; 0.26)	34.31	Not reported
Improved UI	Peters, 2010[587]	29/73	18/77	1.70 (1.04; 2.78)	49.95	0.16 (0.02; 0.31)	35.63	
Improved UI	Finazzi-Agro, 2010[528]	12/18	0/17	23.7 (1.5;371.3)	3.77	0.67 (0.44; 0.89)	30.05	
Pooled		6880/201	41/204	1.9 (1.1; 3.2)	100	0.31 (0.04; 0.58)	100	
Heterogeneity p value, I squared		0.14/49%				0/89%		
Adverse effects	Peters, 2010[586]	6/110	0/110	13.00 (0.74; 228.00)		0.06 (0.01; 0.10)		Not reported

Appendix Table F109. Clinical outcomes after pelvic floor muscle training combined with bladder training compared to no active treatment (results from RCTs pooled with random effects models)

Outcome	Reference	Active events/ randomized	Control events/ randomized	Relative risk (95% CII)	Weight, %	Absolute risk difference (95% CI)	Weight %	Inclusion of mixed UI
Continence	Lagro-Janssen, 1992[553]	10/54	1/56	10.37 (1.37; 78.28)	12	0.17 (0.06; 0.28)	19	Yes
Continence	McFall,2000[571]	25/72	15/73	1.69 (0.97; 2.93)	30	0.14 (-0.00; 0.29)	17	Yes
Continence	Kumari, 2008[552]	30/78	1/86	33.08 (4.62; 236.86)	13	0.37 (0.26; 0.48)	19	Yes
Continence	O'Brien, 1991[581]	32/378	1/183	15.49 (2.13; 112.49)	13	0.08 (0.045; 0.11)	24	Yes
Continence	Diokno, 2004[516]	61/164	55/195	1.32 (0.98; 1.78)	32	0.09 (-0.01; 0.19)	20	Not reported
Pooled		158/746	72/593	3.79 (1.55; 9.27)	100	0.166 (0.06; 0.27)	100	
Heterogeneity p value I squared			<0.05	79		<0.05	85.2	
Improved UI	McFall,2000[571]	30/49	22/59	1.64 (1.10; 2.45)	28	0.24 (0.055; 0.42)	23	Yes
Improved UI	Lagro-Janssen, 1992[553]	40/54	2/56	20.74 (5.27; 81.63)	18	0.71 (0.58; 0.83)	25	Yes
Improved UI	Diokno, 2004[516]	92/164	80/195	1.37 (1.10; 1.70)	29	0.15 (0.05; 0.25)	26	Not reported
Improved UI	O'Brien, 1991[581]	182/378	7/183	12.59 (6.04; 26.22)	25	0.44 (0.39; 0.50)	27	Yes
Pooled		344/645	111/493	4.13 (1.58; 10.78)	100	0.39 (0.17; 0.60)	100	
Heterogeneity p value I squared				0.00	93.00	0.00	0.94	
Treatment failure	Lagro-Janssen, 1992[553]	1/54	2/56	0.52 (0.05; 5.55)	8	-0.02 (-0.08; 0.04)	87	Yes
Treatment failure	McFall, 2000[570]	10/49	15/59	0.80 (0.40; 1.62)	92	-0.05 (-0.21; 0.11)	13	Yes
Pooled		11/103	17/115	0.78 (0.39; 1.52)	100	-0.02 (-0.78; 0.04)	100	
Heterogeneity p value I squared				0.7	0	0.7	0	
Treatment discontinuation	McFall, 2000[570]	7/49	5/59	1.69 (0.57; 4.98)	38	0.06 (-0.06; 0.18)	40	Yes
Treatment discontinuation	Kumari, 2008[552]	9/78	10/86	0.99 (0.43; 2.31)	62	-0.00 (-0.10; 0.10)	60	Yes
Pooled		16/127	15/145	1.21 (0.62; 2.36)	100	0.02 (-0.05; 0.10)	100	
Heterogeneity p value I squared				0.45	0.00	0.46	0.00	

Appendix Table F110. Clinical outcomes after pelvic floor muscle training combined with bladder training when compared to no active treatment, individual RCTs

Reference sample/men	Active	Definition of outcome	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Lagro-Janssen, 1992[553] 110/0	PFMT alone (stress) or bladder training (urge) or its combination (mixed)	Self reported severe urinary incontinence	54/56	4/7	23/41	0.18 (0.07; 0.49)	-0.34 (-0.48; -0.19)	-3 (-5; -2)	-337 (-483; -190)
		Self reported deterioration in urinary incontinence	54/56	1/2	2/3	0.52 (0.05; 5.55)	-0.02 (-0.08; 0.04)		
McFall, 2000[570] 108/0	Community based small group educational intervention: PFMT + bladder training	Withdraw	49/59	7/14	5/8	1.69 (0.57; 4.98)	0.06 (-0.06; 0.18)		
		No reduction in number of incontinence episodes	49/59	10/20	15/25	0.80 (0.40; 1.62)	-0.05 (-0.21; 0.11)		
		Self reported bothersomeness of urinary incontinence	72/73	42/59	62/85	0.69 (0.55; 0.85)	-0.27 (-0.41; -0.13)	-4 (-8; -2)	-266 (-406; -126)
McFall, 2000[570] 145/0	Community-based intervention: bladder training, and PFMT	Use absorbent pads for urinary incontinence	72/73	39/54	56/77	0.71 (0.55; 0.90)	-0.23 (-0.38; -0.07)	-4 (-13; -3)	-225 (-376; -75)

Appendix Table F110. Clinical outcomes after pelvic floor muscle training combined with bladder training when compared to no active treatment, individual RCTs (continued)

Reference sample/men	Active	Definition of outcome	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Kumari, 2008[552] 164/0	Behavioral treatment with PFMT + bladder retraining	Death	78/86	2/3	1/1	2.21 (0.20; 23.85)	0.01 (-0.03; 0.06)		
		Stress incontinence 3 months after intervention	78/86	11/14	27/31	0.45 (0.24; 0.84)	-0.17 (-0.30; -0.05)	-6 (-21; -3)	-173 (-298; -48)
		Stress incontinence 6 months after intervention	78/86	9/12	22/26	0.45 (0.22; 0.92)	-0.14 (-0.26; -0.02)	-7 (-41; -4)	-140 (-257; -24)
		Stress incontinence	78/86	15/19	28/33	0.59 (0.34; 1.02)	-0.13 (-0.27; 0.00)	-8 (-873; -4)	-133 (-265; -1)
		Mixed incontinence 6 months after intervention	78/86	17/22	28/33	0.67 (0.40; 1.12)	-0.11 (-0.24; 0.03)		
		Mixed incontinence 3 months after intervention	78/86	23/30	32/37	0.79 (0.51; 1.23)	-0.08 (-0.22; 0.07)		
		Mixed incontinence	78/86	25/32	34/40	0.81 (0.54; 1.23)	-0.07 (-0.22; 0.07)		
		Urge incontinence 6 months after intervention	78/86	2/3	15/17	0.15 (0.03; 0.62)	-0.15 (-0.24; -0.06)	-7 (-16; -4)	-149 (-236; -61)
		Urge incontinence 3 months after intervention	78/86	6/8	19/22	0.35 (0.15; 0.83)	-0.14 (-0.25; -0.04)	-7 (-26; -4)	-144 (-250; -38)
		Urge incontinence	78/86	8/10	23/27	0.38 (0.18; 0.81)	-0.16 (-0.28; -0.05)	-6 (-20; -4)	-165 (-280; -50)

Appendix Table F111. Scoring of quality of life after pelvic floor muscle training combined with bladder training compared to no active treatment (individual RCT)

Reference	Active	Definition of quality of life	Randomized active/control	Active mean/standard deviation	Control mean/standard deviation	Mean difference (95% CI)
Kumari, 2008[552]	Behavioral treatment with PFMT+ bladder training	IIQ score	78/86	4.60/6.80	12.03/9.42	-7.43 (-9.93; -4.93)
Kumari, 2008[552]	Behavioral treatment with PFMT+ bladder training	IIQ score 6 month after intervention	78/86	2.57/8.16	9.54/10.88	-6.97 (-9.90; -4.04)

Appendix Table F112. Clinical outcomes after continence service compared to no active treatment (results from RCTs pooled with random effects models)

Outcome	Reference	Active events/ randomized	Control events/ randomized	Relative risk (95% CII)	Weight, %	Absolute risk difference (95% CI)	Weight %	Inclusion of mixed UI
Continence	Kim, 2001[547]	14/16	2/15	6.56 (1.78; 24.16)	8	0.72 (0.51; 0.98)	30	No
Continence	Moore, 2003[573]	37/74	27/71	1.31 (0.90; 1.91)	38	0.12 (-0.04; 0.28)	33	Yes
Continence	Williams, 2005[614]	828/2958	150/788	1.47 (1.26; 1.72)	54	0.09 (0.06; 0.12)	37	Yes
Pooled		879/3048	179/874	1.58 (1.07; 2.34)	100	0.30 (-0.01; 0.60)	100	
Heterogeneity p value I squared				0.07	63	0	93	
Improved UI	O'Brien, 1996[582]	56/61	102/168	3.11 (1.99; 4.87)	47	0.311 (0.21; 0.41)	47	Yes
Improved UI	Williams, 2005[614]	1834/2958	410/788	1.19 (1.11; 1.28)	53	0.100 (0.06; 0.14)	53	Yes
Pooled		1890/3019	512/956	1.33 (1.06; 1.68)	100	0.2 (-0.01; 0.41)	100	
Heterogeneity p value I squared				0.00	88.10	0.00	93.20	

Appendix Table F113. Improvement in urinary incontinence after interventions that were implemented by continence specialists when compared to no active treatment, individual RCTs

Reference sample/men	Active	Control	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
O'Brien, 1996[582] /0	Followup after nurse-led continence interventions	Postponed treatment	146 in cured patients	19/13					
			in those with improved UI	124/85					
			in those without improvement in UI	15/10					
	Adherence to PFMT for more than year	No adherence	61/168	56/92	102/61	1.51 (1.31; 1.74)	0.31 (0.21; 0.41)	3 (2; 5)	311 (210; 412)
Williams, 2005[614] 3746/1498	Continence service	Existing primary care	2958/788	1834/62	410/52	1.19 (1.11; 1.28)	0.10 (0.06; 0.14)	10 (7; 16)	100 (61; 139)

Appendix Table F114. Quality of life after interventions that were implemented by continence specialists when compared to no active treatment, individual RCTs

Reference sample/men	Active	Control	Definition of quality of life	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/ 1000 treated (95% CI)
Du Moulin, 2007[575] 101/0	Continence nurse and multi-disciplinary team	Standard care	No problem in pain/discomfort at 1 year of followup	50/51	19/38	5/10	3.88 (1.57; 9.58)	0.28 (0.12; 0.44)	4 (2; 8)	282 (125;439)
			No problem in usual activities at 1 year of followup	50/51	22/44	6/12	3.74 (1.66; 8.44)	0.32 (0.16; 0.49)	3 (2; 6)	322 (159;486)
			No problem in mobility at 1 year of followup	50/51	25/50	8/16	3.19 (1.59; 6.38)	0.34 (0.17; 0.51)	3 (2; 6)	343 (172;514)
			No problem in anxiety/depression at 1 year of followup	50/51	26/52	6/12	4.42 (1.99; 9.81)	0.40 (0.24; 0.57)	2 (2; 4)	402 (238;567)
			No problem in self-care at 1 year of followup	50/51	31/62	10/20	3.16 (1.74; 5.74)	0.42 (0.25; 0.60)	2 (2; 4)	424 (251;597)
Williams, 2005[614] 3746/1498	Continence service	Existing primary care	% satisfied with current urinary symptoms for rest of life	2958/788	1893/64	418/53	1.21 (1.12; 1.30)	0.11 (0.07; 0.15)	9 (7; 14)	110 (71;148)
Williams, 2005[614] 3,746/1,498			% of mild or no problem	2958/788	2337/79	552/70	1.13 (1.07; 1.18)	0.09 (0.05; 0.12)	11 (8; 8)	90 (54;125)

Appendix Table F115. Scoring of quality of life after interventions that were implemented by continence specialists when compared to no active treatment (individual RCTs)

Reference	Active	Control	Definition of quality of life	Randomized active/ control	Active mean/standard deviation	Control mean standard deviation	Mean difference (95% CI)
Du Moulin, 2007[575]	Continence nurse and multidisciplinary team	Standard care	IIQ (impact) mobility (0 to 100 worse)	50/51	21.00/25.30	17.60/20.40	3.40 (-5.57; 12.37)
			IIQ emotional (0 to 100 worse)	50/51	13.90/25.10	14.00/17.90	-0.10 (-8.62; 8.42)
			IIQ social (0 to 100 worse)	50/51	9.80/18.80	3.70/7.90	**6.10 (0.46; 11.74)**
			IIQ embarrassment (0 to 100 worse)	50/51	17.90/26.50	17.60/23.00	0.30 (-9.38; 9.98)
			IIQ physical (0 to 100 worse)	50/51	13.50/21.60	11.70/17.70	1.80 (-5.91; 9.51)
			1 year of followup IIQ (impact) mobility (0 to 100 worse)	50/51	18.40/25.00	14.70/18.40	3.70 (-4.87; 12.27)
			1 year of followup IIQ emotional (0 to 100 worse)	50/51	12.40/20.70	12.90/12.70	-0.50 (-7.21; 6.21)
			1 year of followup IIQ social (0 to 100 worse)	50/51	7.80/21.80	5.60/9.40	2.20 (-4.37; 8.77)
			1 year of followup IIQ embarrassment (0 to 100 worse)	50/51	15.40/26.60	13.30/16.30	2.10 (-6.52; 10.72)
			1 year of followup IIQ physical (0 to 100 worse)	50/51	10.40/19.50	9.30/12.40	1.10 (-5.29; 7.49)
			1 year of followup EQ-5D (0 worse to 100)	50/51	73.50/18.30	71.50/8.10	2.00 (-3.54; 7.54)
			Patient satisfaction (1 worse to 10)	50/51	8.20/1.20	7.40/1.10	**0.80 (0.35; 1.25)**
			Patient satisfaction (1 worse to 10) at 1 year of followup	50/51	8.70/1.00	7.50/1.00	**1.20 (0.81; 1.59)**
Chadha, 2000[512]	National evidence based guidelines	Pre-guidelines levels	Self-reported perception of urinary incontinence, scores	449/449	15.50/20.30	13.90/20.70	1.60 (-1.08; 4.28)
Kim, 2001[547]	Continence Efficacy Intervention Program	Conventional care	Improved scores (from 0 to 100)	16/17	37.80/23.90	23.60/18.90	14.20 (-0.56; 28.96)

Appendix Table F115. Scoring of quality of life after interventions that were implemented by continence specialists when compared to no active treatment (individual RCTs) (continued)

Reference	Active	Control	Definition of quality of life	Randomized active/ control	Active mean/standard deviation	Control mean standard deviation	Mean difference (95% CI)
Moore, 2003[573]	2 nurse continence advisors/patient and consulting urogynecologist	Outpatient regimen	Incontinence score	74/71	4.00/1.83	3.00/2.00	**1.00 (0.37; 1.63)**
			Quality of life Urogenital distress inventory	74/71	18.00/6.17	15.50/5.00	**2.50 (0.68; 4.32)**
			Short Urogenital distress inventory	74/71	8.00/1.50	6.00/2.50	**2.00 (1.33; 2.67)**
			Quality of life incontinence impact questionnaire	74/71	36.00/9.33	37.50/3.67	-1.50 (-3.79; 0.79)
			Short incontinence impact questionnaire 7	74/71	11.00/1.33	10.00/2.33	**1.00 (0.38; 1.62)**
Kim, 2001[547]	Continence Efficacy Intervention Program	Conventional care	Continence self-efficacy (16 worse 160)	16/15	140.20/14.60	107.70/34.70	**32.50 (13.54; 51.46)**
			Score of Improvement by subjective evaluation (0 to 100)	16/15	37.80/23.90	20.00/17.30	**17.80 (3.18; 32.42)**
Borrie, 2002[499], 120 men	Lifestyle modification by nurse continence advisers	Usual care	Control over urinary incontinence	210/211			**1.20 (0.70; 1.60)**
			Acceptance of urinary incontinence	210/211			**0.50 (0.00; 0.90)**
			Coping with urinary incontinence	210/211			**0.60 (0.30; 1.00)**
			Knowledge about incontinence	210/211			**2.30 (1.90; 2.70)**
			IIQ-short form	210/211			**3.10 (1.90; 4.30)**
			Change in bladder control	210/211			**1.70 (1.40; 1.90)**
			Change in amount leaked	210/211			**1.70 (1.50; 2.00)**
			Change in quality of life	210/211			**1.50 (1.20; 1.70)**

Bold = Significant differences at 95% confidence level

Appendix Table F116. Clinical outcomes after weight loss program compared to no active treatment (results from RCTs pooled with random effects models)

Outcome	Reference	Active events/ randomized	Control events/ randomized	Relative risk (95% CIl)	Weight, %	Absolute risk difference (95% CI)	Weight %	Inclusion of mixed UI
Continence	Subak, 2009[601]	16/226	4/112	1.98 (0.68; 5.79)		0.04 (-0.01; 0.08)		Yes
Improved UI	Subak, 2005[600]	14/24	4/24	3.50 (1.35; 9.11)	26	0.42 (0.17; 0.66)	37	Yes
Improved UI	Subak, 2009[601]	93/226	25/112	1.84 (1.26; 2.69)	74	0.19 (0.09; 0.29)	63	Yes
Pooled		107/250	28/136	2.17 (1.26; 3.76)	100	0.27 (0.06; 0.49)	100	
Heterogeneity p value, I squared				0.22	33.00	0.09	64.50	
Treatment discontinuation	Subak, 2009[601]	5/226	15/112	0.17 (0.06; 0.44)		-0.11 (-0.18; -0.05)		Yes
Treatment discontinuation	Huang, 2009[541]	5/226	15/112	0.17 (0.06; 0.44)		-0.11 (-0.18; -0.05)		Not reported

Appendix Table F117. Quality of life after intensive weight loss programs when compared to no active treatment (individual RCTs)

Reference sample	Active	Control	Definition of improvement	Randomized active/ control	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Subak, 2009[601] 313	Intensive 6-month weight-loss program (7 to 9% of initial body weight)	Structured education program	Incontinence somewhat or much less of a problem	219/94	1.40 (1.14; 1.71)	0.22 (0.10; 0.33)	5 (3; 10)	215 (100;331)
Huang, 2009[541]	Intensive lifestyle and behavior change program—an average loss of 7% to 9% of initial body weight	Structured education program	Odds ratio of frequency of sexual activity	226/112	1.34 (0.99; 1.81)			
Huang, 2009[541]	Intensive lifestyle and behavior change program—an average loss of 7% to 9% of initial body weight	Structured education program	Odds ratio of overall sexual satisfaction	226/112	1.28 (0.83; 1.99)			
Huang, 2009[541]	Intensive lifestyle and behavior change program—an average loss of 7% to 9% of initial body weight	Structured education program	Odds ratio of level of sexual desire	226/112	1.12 (0.79; 1.61)			

Appendix Table F118. Urinary incontinence, treatment failure and discontinuation after intensive weight loss programs when compared to no active treatment, individual RCTs

Reference sample/men	Active	Control	Definition of Outcome	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Subak, 2009[601] Huang, 2009[541] 338/0	Intensive 6-month weight-loss program (7 to 9% of initial body weight)	Structured education program	Discontinued the intervention	226/112	5/2	15/13	0.17 (0.06; 0.44)	-0.11 (-0.18; -0.05)	-9 (-22; -6)	-112 (-178; -46)
Brown, 2006[502] 1319/0	Intensive lifestyle therapy to lose and maintain at least 7% of initial body weight and physical activity for at least 150 minutes each week	Placebo twice daily.	Prevalence of stress incontinence after the treatment	659/660	206/31	242/37	0.85 (0.73; 0.99)	-0.05 (-0.11; 0.00)	-18 (-329; -10)	-54 (-105; -3)
			Prevalence of urge incontinence after the treatment	659/660	156/24	169/26	0.92 (0.77; 1.12)	-0.02 (-0.07; 0.03)		

Appendix Table F119. Urinary incontinence after a diet high in soy protein (individual RCT)

Reference	Active	Control	Definition of outcome	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Manonai, 2006[566]	Self-selected diet with low-fat and low-cholesterol foods and soy protein 25 g in various forms of soy foods containing more than 50 mg/day of isoflavones	Self-selected diet with low-fat and low-cholesterol foods	% of women reported stress incontinence after treatments	36/36	18/51	0/0	37.00 (2.31; 591.54)	0.50 (0.33; 0.67)	2 (2; 3)	500 (335; 665)
Manonai, 2006[566]	Self-selected diet with low-fat and low-cholesterol foods and soy protein 25 g in various forms of soy foods containing more than 50 mg/day of isoflavones	Self-selected diet with low-fat and low-cholesterol foods	% of women reported urge incontinence after treatments	36/36	6/17	8/22	0.75 (0.29; 1.94)	-0.06 (-0.24; 0.13)		

Appendix Table F120. UI after acupuncture compared to no active treatment (results from individual RCTs)

Reference sample	Active	Definition of incontinence	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)
Kim, 2005[523] 85	Acupuncture treatment expected to improve bladder symptoms	Proportion of subjects with detrusor contractions during cystometry	44/41	7/16	11/28	0.59 (0.25; 1.38)	-0.11 (-0.28; 0.06)

Appendix Table F121. Scoring of quality of life after acupuncture compared to no active treatment (results from individual RCTs)

Reference	Active	Definition of quality of life	Randomized active/ control	Active mean/ standard deviation	Control mean standard deviation	Mean difference (95% CI)
Emmons, 2005[523]	Acupuncture treatment expected to improve bladder symptoms	Urinary distress inventory score	44/41	3.60/3.20	5.80/4.80	-2.20 (-3.95; -0.45)
Emmons, 2005[523]	Acupuncture treatment expected to improve bladder symptoms	Incontinence impact questionnaire score	44/41	4.30/2.70	7.00/3.50	-2.70 (-4.04; -1.36)
Kim, 2008[549]	Hand acupuncture	How much inconvenience do you have due to urinary incontinence during daily life? (score 0 worse to 4)	25/27	1.70/0.66	1.70/0.08	0.00 (-0.26; 0.26)
Kim, 2008[549]	Hand acupuncture	for physical hobbies such as exercise and mountain climbing? (score 0 worse to 4)	25/27	1.70/0.59	1.80/0.07	-0.10 (-0.33; 0.13)
Kim, 2008[549]	Hand acupuncture	for social communities such as cinema and weddings (score 0 worse to 4)	25/27	1.80/0.70	1.30/0.09	0.50 (0.22; 0.78)
Kim, 2008[549]	Hand acupuncture	for keeping friendships (score 0 worse to 4)	25/27	1.90/0.64	1.70/0.08	0.20 (-0.05; 0.45)
Kim, 2008[549]	Hand acupuncture	for business with colleagues (score 0 worse to 4)	25/27	1.90/0.67	1.80/0.09	0.10 (-0.16; 0.36)
Kim, 2008[549]	Hand acupuncture	for sexual life (score 0 worse to 4)	25/27	1.80/0.70	1.40/0.09	0.40 (0.12; 0.68)
Kim, 2008[549]	Hand acupuncture	for making a new friends (score 0 worse to 4)	25/27	1.90/0.53	1.40/0.09	0.50 (0.29; 0.71)
Kim, 2008[549]	Hand acupuncture	financial loss (score 0 worse to 4)	25/27	1.50/0.51	1.60/0.09	-0.10 (-0.30; 0.10)
Kim, 2008[549]	Hand acupuncture	damage to your general health (score 0 worse to 4)	25/27	1.80/0.55	1.50/0.09	0.30 (0.08; 0.52)
Kim, 2008[549]	Hand acupuncture	easily angry or nervous (score 0 worse to 4)	25/27	1.80/0.57	1.50/0.09	0.30 (0.07; 0.53)
Kim, 2008[549]	Hand acupuncture	influence your general activity (score 0 worse to 4)	25/27	1.70/0.45	1.50/0.09	0.20 (0.02; 0.38)
Kim, 2008[549]	Hand acupuncture	useless person than before (score 0 worse to 4)	25/27	1.70/0.52	1.50/0.09	0.20 (-0.01; 0.41)

Appendix Table F122. Clinical outcomes after supervised PFMT combined with bladder training compared to self administered PFMT (results from RCTs pooled with random effects models)

Outcome	Reference	Active n/N	Control n/N	Rate active/control	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Continence	Bo, 2005[495]	13/21	4/26	60/17	4.02 (1.54; 10.53)	17.48	0.465 (0.215; 0.715)	18.61
Continence	de Oliveira Camargo, 2009[510]	14/30	16/30	47/53	0.88 (0.53; 1.46)	22.04	-0.067 (-0.319; 0.186)	24.66
Continence	Zanetti, 2007[623]	11/23	2/21	48/10	5.02 (1.26; 20.07)	11.75	0.383 (0.143; 0.623)	19.09
Continence	Burgio, 2002[505]	15/74	11/75	20/15	1.38 (0.68; 2.81)	25.95	0.056 (-0.066; 0.178)	18.48
Continence	Felicissimo, 2010[526]	11/31	11/31	37/35	1 (0.5; 1.9)	22.77	0 (-0.24; 0.24)	19.16
Pooled		64/179	44/183	36/24	1.6 (0.88; 2.9)	100	0.16 (-0.03; 0.35)	100
Heterogeneity P value, I squared,%					0.018	66.4%	0.003	75.1%
Improved UI	Zanetti, 2007[623]	15/23	5/21	67/24	2.74 (1.21; 6.23)	28.6	0.414 (0.147; 0.681)	24.5
Improved UI	Burgio, 2002[505]	36/74	20/75	49/27	1.82 (1.17; 2.84)	17.1	0.22 (0.068; 0.371)	16.59
Improved UI	Konstantinidou, 2007[551]	1/15	1/15	7/7	1 (0.07; 14.55)	2.65	0 (-0.179; 0.179)	22.52
Improved UI	de Oliveira Camargo, 2009[510]	18/30	20/30	60/67	0.9 (0.61; 1.33)	30.59	-0.067 (-0.31; 0.177)	18.03
Improved UI	Felicissimo, 2010[526]	11/31	11/31	37/35	1(0.51; 1.96)	21.06	0 (-0.24; 0.24)	18.36
Pooled		82/173	57/172	47/33	1.37 (0.87; 2.2)	100	0.11 (-0.05; 0.27)	100
Heterogeneity P value, I squared,%					0.05	57.9%	0.023	64.6%
Treatment failure	Konstantinidou, 2007[551]	4/15	7/15	27/47	0.86 (0.32; 2.30)	39.55	-0.056 (-0.405; 0.294)	26.35
Treatment failure	Bo, 2005[495]	1/21	7/26	5/27	0.18 (0.02; 1.33)	16.43	-0.222 (-0.415; -0.028)	44.5
Treatment failure	Aukee, 2004[486]	9/19	5/16	47/31	1.52 (0.64; 3.61)	44.03	0.161 (-0.158; 0.481)	29.15
Pooled		14/55	19/57	25/33	0.85 (0.34; 2.16)	100	-0.066 (-0.3; 0.167)	100
Heterogeneity P value, I squared,%					0.15	47.60%	0.126	51.70%
Treatment discontinuation	Tsai, 2009[611]	4/54	5/54	7/9	0.8 (0.23; 2.82)	49.05	-0.019 (-0.123; 0.086)	90.15
Treatment discontinuation	Konstantinidou, 2007[551]	3/15	5/15	20/33	0.79 (0.23; 2.7)	50.95	-0.063 (-0.379; 0.252)	9.85
Pooled		7/69	10/69	10/14	0.79 (0.33; 1.91)	100	-0.023 (-0.122; 0.076)	100
Heterogeneity P value, I squared,%					0.98	0.00%	0.791	0.00%

Appendix Table F123. Improvement in UI rates compared between nonpharmacological treatments

Active treatment	Control treatment	Studies	Patients	Rate active/ control, %	Relative risk (95% CI)	Absolute risk difference (95%CI)	Level of evidence
Pelvic floor muscle training+ bladder training	Bladder training	1[619]	272	21/15	1.40 (0.83; 2.36)	0.06 (-0.03; 0.15)	Insufficient
Supervised pelvic floor muscle training	Pelvic floor muscle training	4[505,510,551,623]	283	50/33	1.51 (0.85; 2.67)	0.14 (-0.05; 0.32)	Moderate
Pelvic floor muscle training	Electrical stimulation	4[253,538,596,597]	136	31/45	0.97 (0.62; 1.51)	-0.01 (-0.17; 0.16)	Moderate
Pelvic floor muscle training	Vaginal cone	4[253,532,594,615]	440	41/41	1.02 (0.91; 1.14)	0.01 (-0.08; 0.09)	Moderate

Appendix Table F124. Failure rates compared between nonpharmacological treatments

Active Treatment	Control treatment	Studies	Patients	Rate active/ control, %	Relative risk (95% CI)	Absolute risk difference (95% CI)	Level of evidence
Pelvic floor muscle training+ biofeedback	Pelvic floor muscle training	2[535,574]	143	1/6	0.32 (0.05; 1.98)	-0.04 (-0.11; 0.02)	Low
Supervised pelvic floor muscle training	Pelvic floor muscle training	3[486,495,551]	112	25/33	0.85 (0.34; 2.16)	-0.07 (-0.30; 0.17)	Low
Pelvic floor muscle training	Electrical stimulation	2[253,597]	98	31/43	1.41 (0.53; 3.78)	0.13 (-0.25; 0.51)	Low

Appendix Table F125. Quality of life after supervised vs. self-administered PFMT programs (individual RCTs)

Reference sample/men	Active	Definition of quality of life	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Ng, 2008[577] /0	A registered nurse monitoring via telephone checkups twice a week home based PFMT	Affect on family life	44/44			0.96 (0.50; 1.83)			
Ng, 2008[577] /0	A registered nurse monitoring via telephone checkups twice a week home based PFMT	Affect on holidays/ recreation	44/44			0.92 (0.57; 1.50)			
Ng, 2008[577] /0	A registered nurse monitoring via telephone checkups twice a week home based PFMT	Affect on interests/ hobbies	44/44			0.85 (0.53; 1.37)			
Ng, 2008[577] /0	A registered nurse monitoring via telephone checkups twice a week home based PFMT	Affect on social activities	44/44			0.79 (0.48; 1.30)			
Ng, 2008[577] /0	A registered nurse monitoring via telephone checkups twice a week home based PFMT	Worried about smell of urine	44/44			0.67 (0.44; 1.04)			
Ng, 2008[577] /0	A registered nurse monitoring via telephone checkups twice a week home based PFMT	Affect on sexual life	44/44			0.62 (0.34; 1.13)			
Ng, 2008[577] /0	A registered nurse monitoring via telephone checkups twice a week home based PFMT	Affect on sexual quality	44/44			0.52 (0.29; 0.95)			
Zanetti, 2007[623] 44/0	Supervised PMFT	Patient satisfaction	23/21	15/67	5/24	2.74 (1.20; 6.23)	0.41 (0.15; 0.68)	2 (1; 7)	414 (147;681)

Appendix Table F126. Scoring of quality of life after supervised vs. self-administered PFMT programs (individual RCTs)

Reference sample/men	Definition of quality of life	randomized active/control	Active mean/standard deviation	Control mean/standard deviation	Mean difference (95% CI)
de Oliveira Camargo, 2009[510] /0	Final general health (KHQ 0 best to 100)	30/30	39.20/21.50	37.50/20.50	1.70 (-8.93; 12.33)
de Oliveira Camargo, 2009[510] /0	Final incontinence impact (KHQ 0 best to 100)	30/30	20.00/25.70	13.30/24.10	6.70 (-5.91; 19.31)
de Oliveira Camargo, 2009[510] /0	Final physical activities limitations (KHQ 0 best to 100)	30/30	3.30/8.10	10.60/17.80	-7.30 (-14.30; -0.30)
de Oliveira Camargo, 2009[510] /0	Final physical limitations (KHQ 0 best to 100)	30/30	4.40/11.50	10.60/11.50	-6.20 (-12.02; -0.38)
de Oliveira Camargo, 2009[510] /0	Final social limitations (KHQ 0 best to 100)	30/30	0.70/2.80	3.70/10.20	-3.00 (-6.78; 0.78)
de Oliveira Camargo, 2009[510] /0	Final personal relationships (KHQ 0 best to 100)	30/30		2.30/7.80	
de Oliveira Camargo, 2009[510] /0	Final emotions (KHQ 0 best to 100)	30/30	5.60/19.30	4.80/11.60	0.80 (-7.26; 8.86)
de Oliveira Camargo, 2009[510] /0	Final sleep/disposition (KHQ 0 best to 100)	30/30	7.20/17.90	4.40/10.70	2.80 (-4.66; 10.26)
de Oliveira Camargo, 2009[510] /0	Final gravity (KHQ 0 best to 100)	30/30	15.30/20.30	14.40/20.30	0.90 (-9.37; 11.17)

Appendix Table F127. Continence and improvement in incontinence after complex group and individual pelvic floor muscle training programs, individual RCTs

Outcome	Reference	Active	Control	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Continence	Pages, 2001[585] 40/0	Specific physical therapy program: group therapy 5 times/week and home pelvic floor exercise with 50 contractions for 10 minutes 2 times/day; recommendation of weight loss and aerobic sports.	Biofeedback training daily 90-minutes in group and individually for 15 minutes, 5 times/week Intra vaginal pressure sensor and visual biofeedback in computer monitor	27/13	6/22	4/28	0.72 (0.25; 2.12)	-0.09 (-0.38; 0.21)		
Continence	Janssen, 2001[544] 530/0	Individual pelvic floor exercises 5 times/day and bladder training with delay voiding, training with 11 30-minute sessions.	Group pelvic floor exercises 5 times/day and bladder training with delay voiding, training with 9 2-hour sessions	126/404	25/20	53/13	1.51 (0.98; 2.33)	0.07 (-0.01; 0.14)		
				126/404	28/22	57/14	1.58 (1.05; 2.36)	0.08 (0.00; 0.16)	12 (6; 1003)	81 (1; 161)
Improvement in incontinence	Janssen, 2001[544] 530/0	Individual pelvic floor exercises 5 times/day and bladder training with delay voiding, training with 11 30-minute sessions.	Group pelvic floor exercises 5 times/day and bladder training with delay voiding, training with 9 2-hour sessions at 3 months	126/404	118/94	347/86	1.09 (1.03; 1.16)	0.08 (0.02; 0.13)	13 (8; 43)	78 (23; 132)
			at 9 months	126/404	107/85	315/78	1.09 (1.00; 1.19)	0.07 (0.00; 0.14)		

Appendix Table F127. Continence and improvement in incontinence after complex group and individual pelvic floor muscle training programs, individual RCTs (continued)

Outcome	Reference	Active	Control	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Improvement in incontinence	Pages, 2001 [585] 40/0	Specific physical therapy program: group therapy 5 times/week and home pelvic floor exercise with 50 contractions for 10 minutes 2 times/day; recommendation of weight loss and aerobic sports.	Biofeedback training daily 90-minutes in group and individually for 15 minutes, 5 times/week Intra vaginal pressure sensor and visual biofeedback in computer monitor	27/13	20/74	9/68	1.07 (0.70; 1.64)	0.05 (-0.25; 0.35)		

Appendix Table F128. Scoring of quality of life after PFMT with biofeedback using vaginal EMG probe when compared to PFMT (individual RCTs)

Reference sample/men	Active	Definition of quality of life	Randomized active/control	Active mean/standard deviation	Control mean/ standard deviation	Mean difference (95% CI)
Morkved, 2002[574] /0	PFMT with biofeedback	Leakage index	53/50	1.90/0.74	1.90/0.72	0.00 (-0.28; 0.28)
Morkved, 2002[574] /0	PFMT with biofeedback	Social activity index	53/50	9.50/0.74	9.40/1.08	0.10 (-0.26; 0.46)
Aukee, 2002[485] /0	Pelvic floor muscle exercise of and individual EMG-assisted biofeedback	Leakage index	15/15	34.90/10.40	38.10/10.50	-3.20 (-10.68; 4.28)
McDowell, 2006[568] /0	PFMT and Advice and EMG biofeedback	Incontinence Impact Questionnaire (IIQ) Scores: Total score	10/10	62.50/44.20	101.60/46.10	-39.10 (-78.68; 0.48)
McDowell, 2006[568] /0	PFMT and Advice and EMG biofeedback	Incontinence Impact Questionnaire (IIQ) Scores: Physical activity	10/10	32.90/37.10	35.60/25.70	-2.70 (-30.67; 25.27)
McDowell, 2006[568] /0	PFMT and advice and EMG Biofeedback	Incontinence Impact Questionnaire (IIQ) Scores: Emotional health	10/10	28.70/39.20	28.70/26.00	0.00 (-29.15; 29.15)
McDowell, 2006[568] /0	PFMT and advice and EMG biofeedback	Incontinence Impact Questionnaire (IIQ) Scores: Travel	10/10	32.90/37.10	46.40/28.00	-13.50 (-42.31; 15.31)
McDowell, 2006[568] /0	PFMT and advice and EMG biofeedback	Incontinence Impact Questionnaire (IIQ) Scores: Social relationships	10/10	28.80/39.30	14.90/12.40	13.90 (-11.64;3 9.44)
McDowell, 2006[568] /0	PFMT and advice and EMG biofeedback	Urogenital Distress Inventory (UDI) Scores: Total score	10/10	77.90/33.50	139.60/66.50	-61.70 (-107.85; -15.55)
McDowell, 2006[568] /0	PFMT and advice and EMG biofeedback	Urogenital Distress Inventory (UDI) Scores: Irritative symptoms	10/10	40.00/18.12	56.60/28.80	-16.60 (-37.69; 4.49)
McDowell, 2006[568] /0	PFMT and advice and EMG biofeedback	Urogenital Distress Inventory (UDI) Scores: Obstructive/discomfort	10/10	23.70/18.20	49.10/36.10	-25.40 (-50.46; -0.34)

Appendix Table F128. Scoring of quality of life after PFMT with biofeedback using vaginal EMG probe when compared to PFMT (individual RCTs) (continued)

Reference sample/men	Active	Definition of quality of life	Randomized active/control	Active mean/standard deviation	Control mean/ standard deviation	Mean difference (95% CI)
McDowell, 2006[568] /0	PFMT and advice and EMG biofeedback	Urogenital Distress Inventory (UDI) Scores: Stress symptoms	10/10	19.90/23.30	47.50/34.70	-27.60 (-53.51; -1.69)
McDowell, 2006[568] /0	PFMT and advice and EMG biofeedback	Incontinence Impact Questionnaire (IIQ) Scores: Total score	10/10	78.90/55.70	101.60/46.10	-22.70 (-67.51; 22.11)
McDowell, 2006[568] /0	PFMT and advice and EMG biofeedback	Incontinence Impact Questionnaire (IIQ) Scores: Physical activity	10/10	27.00/30.50	35.60/25.70	-8.60 (-33.32; 16.12)
McDowell, 2006[568] /0	PFMT and advice and EMG biofeedback	Incontinence Impact Questionnaire (IIQ) Scores: Emotional health	10/10	28.50/29.50	28.70/26.00	-0.20 (-24.57; 24.17)
McDowell, 2006[568] /0	PFMT and advice and EMG biofeedback	Incontinence Impact Questionnaire (IIQ) Scores: Travel	10/10	32.70/30.90	46.40/28.00	-13.70 (-39.54; 12.14)
McDowell, 2006[568] /0	PFMT and advice and EMG biofeedback	Incontinence Impact Questionnaire (IIQ) Scores: Social relationships	10/10	25.00/30.60	14.90/12.40	10.10 (-10.36; 30.56)
McDowell, 2006[568] /0	PFMT and advice and EMG biofeedback	Urogenital Distress Inventory (UDI) Scores: Total score	10/10	100.50/43.10	139.60/66.50	-39.10 (-88.22; 10.02)
McDowell, 2006[568] /0	PFMT and advice and EMG biofeedback	Urogenital Distress Inventory (UDI) Scores: Irritative symptoms	10/10	47.60/12.00	56.60/28.80	-9.00 (-28.34; 10.34)
McDowell, 2006[568] /0	PFMT and advice and EMG biofeedback	Urogenital Distress Inventory (UDI) Scores: Obstructive/discomfort	10/10	31.50/22.80	49.10/36.10	-17.60 (-44.06; 8.86)
McDowell, 2006[568] /0	PFMT and advice and EMG biofeedback	Urogenital Distress Inventory (UDI) Scores: Stress symptoms	10/10	23.20/26.20	47.50/34.70	-24.30 (-51.25; 2.65)
Wong, 2001[617] /0	Pelvic floor exercises with EMG	IIQ-7 (1 to 100 worse)	19/19	14.29	14.29	0.00
Sung, 2000[603] /0	Pelvic floor exercises with EMG	Discomfort due to incontinence (0 to 5 worse)	30/30	1.80/0.80	2.00/0.70	-0.20 (-0.58; 0.18)
Sung, 2000[603] /0	Pelvic floor exercises with EMG	Discomfort due to fluid intake restriction (0 to 5 worse)	30/30	1.40/0.70	1.10/0.30	0.30 (0.03; 0.57)

Appendix Table F128. Scoring of quality of life after PFMT with biofeedback using vaginal EMG probe when compared to PFMT (individual RCTs) (continued)

Reference sample/men	Active	Definition of quality of life	Randomized active/control	Active mean/standard deviation	Control mean/ standard deviation	Mean difference (95% CI)
Sung, 2000[603] /0	Pelvic floor exercises with EMG	Problems on daily tasks (0 to 5 worse)	30/30	1.40/0.70	1.10/0.30	0.30 (0.03; 0.57)
Sung, 2000[603] /0	Pelvic floor exercises with EMG	Avoidance of places & situations (0 to 5 worse)	30/30	1.40/0.90	1.40/0.70	0.00 (-0.41; 0.41)
Sung, 2000[603] /0	Pelvic floor exercises with EMG	Discomfort due to avoidance of places & situations (0 to 5 worse)	30/30	1.30/0.70	1.20/0.40	0.10 (-0.19; 0.39)
Sung, 2000[603] /0	Pelvic floor exercises with EMG	Interference in physical activity (0 to 5 worse)	30/30	1.60/0.80	1.30/0.40	0.30 (-0.02; 0.62)
Sung, 2000[603] /0	Pelvic floor exercises with EMG	Interference in relations with other people (0 to 5 worse)	30/30	1.20/0.70	1.10/0.30	0.10 (-0.17; 0.37)

Appendix Table F129. Clinical outcomes after pelvic floor muscle training with biofeedback using vaginal EMG probe when compared to pelvic floor muscle training, individual RCT

Reference sample	Active	Outcome	Randomized active/ control	Active events /rate, %	Control events/ rate, %	Relative risk (95%CI)	Absolute risk differences (95% CI)
Morkved, 2002[574] 103	Pelvic floor muscle training with biofeedback apparatus	Urinary incontinence is problematic	53/50	3/6	6/12	0.47(0.12;1.79)	-0.06(-0.17;0.05)
Morkved, 2002[574] 103	Pelvic floor muscle training with biofeedback apparatus	Urinary incontinence is minor problem	53/50	17/32	18/36	0.89(0.52;1.53)	-0.04(-0.22;0.14)
Morkved, 2002[574] 103	Pelvic floor muscle training with biofeedback apparatus	Urinary incontinence is moderate problem	53/50	8/15	5/10	1.51(0.53;4.31)	0.05(-0.08;0.18)

Appendix Table F130. Clinical outcomes after PFMT compared to electrical stimulation (results from RCTs pooled with random effects models)

Outcome	Reference	Active n/N	Control n/N	Rate active/control	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Continence	Castro, 2008[253]	10/31	11/30	32/37	0.88 (0.44; 1.76)	85.64	-0.044 (-0.282; 0.194)	43.26
Continence	Hahn, 1991[538]	1/10	1/10	10/10	1 (0.07; 13.87)	5.96	0 (-0.263; 0.263)	35.54
Continence	Smith, 1996[596]	1/9	2/9	11/22	0.5 (0.06; 4.58)	8.4	-0.111 (-0.452; 0.229)	21.2
Pooled		12/50	14/49	24/29	0.85 (0.45; 1.61)	100	-0.043 (-0.199; 0.114)	100
Heterogeneity P value, I squared,%							0.88	0.00%
Improved Urinary incontinence	Smith, 1996[596]	3/9	4/9	33/44	0.75 (0.23; 2.44)	14.09	-0.111 (-0.559; 0.336)	13.49
Improved Urinary incontinence	Spruijt, 2003[597]	4/25	7/12	36/29	1.19 (0.43; 3.29)	18.88	0.053 (-0.266; 0.373)	26.46
Improved Urinary incontinence	Castro, 2008[253]	12/31	13/30	39/43	0.89 (0.49; 1.63)	53.75	-0.046 (-0.293; 0.2)	44.41
Improved Urinary incontinence	Hahn, 1991[538]	4/10	3/10	40/30	1.33 (0.40; 4.49)	13.27	0.1 (-0.316; 0.516)	15.63
Pooled		23/75	27/61	31/45	0.97 (0.62; 1.51)	100	-0.006 (-0.17; 0.159)	100
Heterogeneity P value, I squared,%					0.88	0.00%	0.874	0.00%
Treatment failure	Castro, 2008[253]	11/31	12/30	35/40	0.89 (0.47; 1.69)	53.82	-0.045 (-0.288; 0.198)	54.03
Treatment failure	Spruijt, 2003[597]	7/25	6/12	55/25	2.43 (1.04; 5.66)	46.18	0.343 (0.018; 0.669)	45.97
Pooled		18/56	18/42	31/43	1.41 (0.53; 3.78)	100	0.133 (-0.246; 0.513)	100
Heterogeneity P value, I squared,%					0.06	71.00%	0.061	71.60%

Appendix Table F131. Clinical outcomes compared after different nonpharmacological treatments (results from individual RCTs)

Active	Control	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)
Bladder training	PFMT	Continence	Morkved, 2002[574]	28/53	21/50	1.26 (0.83; 1.90)	0.108 (-0.083; 0.300)	
Bladder training with audiotape	Bladder training	Improved UI	Dowd, 2000[520]	19/21	10/19	1.72 (1.10; 2.69)	0.378 (0.121; 0.636)	3 (2; 8)
Bladder training with audiotape	Bladder training	Improved UI	Dowd, 2000[520]	19/21	13/19	1.32 (0.95; 1.85)	0.221 (-0.023; 0.464)	
Cone	Bladder training	Continence	Williams, 2006[615]	0/80	0/79	0.88 (0.28; 2.76)		
Continence service	Bladder training	Continence	Ramsay, 1996[588]	19/35	23/39	0.92 (0.62; 1.37)	-0.047 (-0.273; 0.179)	
Continence service	Bladder training	Improved UI	Ramsay, 1996[588]	17/35	19/39	1.00 (0.62; 1.59)	-0.001 (-0.230; 0.227)	
Continence service	PFMT	Continence	Kim, 2001[547]	14/16	2/17	7.44 (2.00; 27.70)	0.757 (0.534; 0.980)	1 (1; 2)
Electrical stimulation	PFMT+ biofeedback	Treatment discontinuation	Demirturk, 208[515]	0/20	1/21	0.35 (0.02; 8.10)	-0.048 (-0.171; 0.076)	
Electrical stimulation	cone	Treatment discontinuation due to treatment failure	Castro, 2008[253]	1/30	4/27	0.23 (0.03; 1.89)	-0.115 (-0.263; 0.034)	
Electrical stimulation	cone	Continence	Castro, 2008[253]	13/30	11/27	1.06 (0.58; 1.96)	0.026 (-0.231; 0.282)	
Electrical stimulation	cone	Treatment failure	Castro, 2008[253]	12/30	11/27	0.98 (0.52; 1.85)	-0.007 (-0.263; 0.248)	
Electrical stimulation	cone	Improved UI	Castro, 2008[253]	13/30	11/27	1.06 (0.58; 1.96)	0.026 (-0.231; 0.282)	
Pessary	PFMT+ ring	Treatment discontinuation	Richter, 2010[363]	39/149	18/151	2.20 (1.32; 3.66)	0.143 (0.055; 0.230)	7 (4; 18)
Pessary	PFMT+ ring	Treatment discontinuation due to adverse effects	Richter, 2010[363]	1/149	0/151	3.04 (0.12; 74.03)	0.007 (-0.012; 0.025)	
Pessary	PFMT+ ring	Treatment discontinuation due to treatment failure	Richter, 2010[363]	6/149	4/151	1.52 (0.44; 5.28)	0.014 (-0.027; 0.054)	
Pessary	PFMT+ ring	Improved UI	Richter, 2010[363]	59/149	80/151	0.75 (0.58; 0.96)	-0.134 (-0.246; -0.022)	-7 (-45; -4)

Appendix Table F131. Clinical outcomes compared after different nonpharmacological treatments (results from individual RCTs) (continued)

Active	Control	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)
Pessary	PFMT+ ring	Improved UI	Richter, 2010[363]	94/149	118/151	0.81 (0.70; 0.94)	-0.151 (-0.252; -0.049)	-7 (-20; -4)
PFMT	Balls	Treatment failure	Arvonen, 2001[484]	1/19	1/18	0.95 (0.06; 14.04)	-0.003 (-0.149; 0.143)	
PFMT	Balls	Improved UI	Arvonen, 2001[484]	11/19	7/18	1.49 (0.74; 2.98)	0.190 (-0.126; 0.506)	
PFMT	Bladder training	Improved UI	Williams, 2006[615]	0/79	0/79	0.68 (0.35; 1.38)	0.000 (0.000; 0.000)	
PFMT	Bladder training	Improved UI	Williams, 2006[615]	0/79	0/79	0.77 (0.40; 1.47)	0.000 (0.000; 0.000)	
PFMT	Pessary	Treatment discontinuation	Richter, 2010[363]	22/146	39/149	0.58 (0.36; 0.92)	-0.111 (-0.202; -0.020)	-9 (-51; -5)
PFMT	Pessary	Treatment discontinuation due to adverse effects	Richter, 2010[363]	0/146	1/149	0.34 (0.01; 8.28)	-0.007 (-0.025; 0.012)	
PFMT	Pessary	Treatment discontinuation due to treatment failure	Richter, 2010[363]	2/146	1/149	2.04 (0.19; 22.27)	0.007 (-0.016; 0.030)	
PFMT	Pessary	Treatment failure	Richter, 2010[363]	6/146	6/149	1.02 (0.34; 3.09)	0.001 (-0.044; 0.046)	
PFMT	Pessary	Improved UI	Richter, 2010[363]	110/146	94/149	1.19 (1.02; 1.39)	0.123 (0.018; 0.227)	8 (4; 55)
PFMT	Pessary	Improved UI	Richter, 2010[363]	72/146	59/149	1.25 (0.96; 1.61)	0.097 (-0.016; 0.210)	
PFMT	Pessary	Improved UI	Richter, 2010[363]	71/146	49/149	1.48 (1.11; 1.96)	0.157 (0.047; 0.268)	6 (4; 21)
PFMT	PFMT+ ring	Treatment discontinuation	Richter, 2010[363]	22/146	18/151	1.26 (0.71; 2.26)	0.031 (-0.046; 0.109)	
PFMT	PFMT+ ring	Treatment discontinuation due to adverse effects	Richter, 2010[363]	0/146	0/151	0.00 (0.00; 0.00)	0.000 (-0.013; 0.013)	
PFMT	PFMT+ ring	Treatment discontinuation Treatment failure	Richter, 2010[363]	6/146	4/151	1.55 (0.45; 5.39)	0.015 (-0.027; 0.056)	
PFMT	PFMT+ ring	Improved UI	Richter, 2010[363]	72/146	80/151	0.93 (0.74; 1.16)	-0.037 (-0.150; 0.077)	

Appendix Table F131. Clinical outcomes compared after different nonpharmacological treatments (results from individual RCTs) (continued)

Active	Control	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)
PFMT+ biofeedback	Bladder training	Continence	Wyman, 1998[619]	8/69	12/68	0.66 (0.29; 1.51)	-0.061 (-0.178; 0.057)	
PFMT+ biofeedback	Bladder training	Continence	Wyman, 1998[619]	14/69	11/68	1.25 (0.61; 2.56)	0.041 (-0.088; 0.170)	
PFMT+ biofeedback	Bladder training	Continence 3 months	Wyman, 1998[619]	13/69	10/68	1.28 (0.60; 2.72)	0.041 (-0.084; 0.166)	
PFMT+ biofeedback	Bladder training	Treatment failure	Wyman, 1998[619]	13/69	14/68	0.92 (0.47; 1.80)	-0.017 (-0.151; 0.116)	
PFMT+ biofeedback	Bladder training	Improved UI	Wyman, 1998[619]	8/69	11/68	0.72 (0.31; 1.67)	-0.046 (-0.161; 0.070)	
PFMT+ biofeedback	Cone	Treatment discontinuation	Harvey, 2002[539]	12/19	18/25	0.88 (0.58; 1.34)	-0.088 (-0.368; 0.191)	
PFMT+ biofeedback	Cone	Continence UD	Harvey, 2002[539]	1/19	1/25	1.32 (0.09; 19.71)	0.013 (-0.114; 0.139)	
PFMT+ biofeedback	Cone	Continence (negative pad test)	Harvey, 2002[539]	2/19	2/25	1.32 (0.20; 8.51)	0.025 (-0.149; 0.199)	
PFMT+ bladder training	PFMT+ biofeedback	Adherence to treatment	Wyman, 1998[619]	39/67	44/69	0.91 (0.70; 1.20)	-0.056 (-0.219; 0.108)	
PFMT+ bladder training	PFMT+ biofeedback	Continence 3 months	Wyman, 1998[619]	16/67	13/69	1.27 (0.66; 2.43)	0.050 (-0.087; 0.188)	
PFMT+ bladder training	PFMT+ biofeedback	Continence	Wyman, 1998[619]	19/67	8/69	2.45 (1.15; 5.20)	0.168 (0.036; 0.299)	6 (3; 28)
PFMT+ bladder training	PFMT+ biofeedback	Treatment failure	Wyman, 1998[619]	4/67	13/69	0.32 (0.11; 0.92)	-0.129 (-0.237; -0.020)	-8 (-49; -4)
PFMT+ bladder training	PFMT+ biofeedback	Improved UI	Wyman, 1998[619]	10/67	20/69	0.51 (0.26; 1.02)	-0.141 (-0.277; -0.004)	-7 (-270; -4)
PFMT+ bladder training	PFMT+ biofeedback	Improved UI 3 months	Wyman, 1998[619]	6/67	9/69	0.69 (0.26; 1.82)	-0.041 (-0.146; 0.064)	
PFMT+ bladder training	PFMT+ biofeedback	Improved UI	Wyman, 1998[619]	32/67	19/69	1.73 (1.10; 2.74)	0.202 (0.043; 0.362)	5 (3; 23)
PFMT+ bladder training	PFMT+ biofeedback	Improved UI	Wyman, 1998[619]	14/67	8/69	1.80 (0.81; 4.01)	0.093 (-0.030; 0.216)	
PFMT+ electrical stimulation	PFMT	Improvement in ICIQ-UI score	Oldham, 2010[583]	32/64	16/64	2.00 (1.23; 3.26)	0.250 (0.088; 0.412)	4 (2; 11)
PFMT+ electrical stimulation	PFMT	Improvement in leak frequency	Oldham, 2010[583]	43/64	21/64	2.05 (1.39; 3.02)	0.344 (0.181; 0.506)	3 (2; 6)

Appendix Table F131. Clinical outcomes compared after different nonpharmacological treatments (results from individual RCTs) (continued)

Active	Control	Outcome	Reference	Active n/N	Control n/N	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)
PFMT+ electrical stimulation	PFMT	Improvement in terms of leak interference with life	Oldham, 2010[583]	32/64	21/64	1.52 (0.99; 2.34)	0.172 (0.004; 0.340)	6 (3; 261)
PFMT+ electrical stimulation	PFMT	Reduction in severity of symptoms: Condition mild or normal post treatment	Oldham, 2010[583]	54/64	45/64	1.20 (0.99; 1.45)	0.141 (-0.002; 0.284)	
PFMT+ reminder	PFMT+ Bladder training	Continence	Alenijnse, 2003[479]	17/52	21/51	0.79 (0.48; 1.32)	-0.085 (-0.271; 0.101)	
PFMT+ video tape	PFMT	"Routine" pelvic floor exercises, response=yes	Gallo, 1997[531]	41/43	22/43	1.86 (1.38; 2.51)	0.442 (0.280; 0.604)	2 (2; 4)
PFMT+ video tape	PFMT	Number of times per day patient performed pelvic floor exercises, response=two	Gallo, 1997[531]	34/43	4/43	8.50 (3.30; 21.89)	0.698 (0.548; 0.847)	1 (1; 2)
Face to face training	Telemedicine	Urinary incontinence	Hui, 2006[542]	2/27	4/31	0.57 (0.11; 2.89)	-0.055 (-0.209; 0.099)	
Weight loss	Education	≥70% improvement in weekly UI episodes: urge: 18 months	Wing, 2010[616]	106/226	38/112	1.38 (1.03; 1.85)	0.130 (0.021; 0.239)	8 (4; 49)
Weight loss	Education	≥70% improvement in weekly UI episodes: Total: 12 months	Wing, 2010[616]	104/226	35/112	1.47 (1.08; 2.01)	0.148 (0.040; 0.255)	7 (4; 25)
Weight loss	Education	≥70% improvement in weekly UI episodes: stress:12 months	Wing, 2010[616]	145/226	54/112	1.33 (1.07; 1.65)	0.159 (0.048; 0.271)	6 (4; 21)
Weight loss	Education	≥70% improvement in weekly UI episodes: urge: 12 months	Wing, 2010[616]	106/226	39/112	1.35 (1.01; 1.80)	0.121 (0.011; 0.230)	8 (4; 89)
Weight loss	Education	Reduction in weekly stress urinary incontinence episodes at 12 months	Wing, 2010[616]	147/226	53/112	1.37 (1.11; 1.71)	0.177 (0.066; 0.289)	6 (3; 15)

Appendix Table F132. Clinical outcomes after PFMT compared to vaginal cones (results from RCTs pooled with random effects models)

Outcome	Reference	Active n/N	Control n/N	Rate active/control	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Continence	Castro, 2008[253]	10/31	9/27	32/33	0.97 (0.46; 2.02)	16.99	-0.011 (-0.253; 0.232)	37.49
Continence	Williams, 2006[615]	0/79	0/80	0/0				
Continence	Gameiro, 2010[532]	26/52	34/51	50/67	0.75 (0.54; 1.05)	83.01	-0.167 (-0.354; 0.021)	62.51
Pooled		36/162	43/158	22/27	0.78 (0.58; 1.06)	100	-0.108 (-0.257; 0.04)	100
Heterogeneity P value, I squared,%					0.54	0.00%	0.319	0.00%
Improved Urinary incontinence	Seo, 2004[594]	55/60	53/60	92/88	1.04 (0.92; 1.17)	89.16	0.033 (-0.074; 0.141)	67.1
Improved Urinary incontinence	Castro, 2008[253]	12/31	11/27	39/41	0.95 (0.50; 1.79)	3.16	-0.02 (-0.273; 0.232)	12.09
Improved Urinary incontinence	Williams, 2006[615]	0/79	0/80					
Improved Urinary incontinence	Gameiro, 2010[532]	23/52	26/51	44/51	0.87 (0.58; 1.30)	7.69	-0.067 (-0.26; 0.125)	20.81
Pooled		0/222	0/218	0/0	1.02 (0.91; 1.14)	100	0.006 (-0.082; 0.094)	100
Heterogeneity P value, I squared,%					0.69	0.00%	0.653	0.00%

Appendix Table F133. Scoring of quality of life after PFMT with biofeedback vs. vaginal cones (individual RCTs)

Reference sample/men	Active	Control	Definition of quality of life	Randomized active/control	Active mean/standard deviation	Control mean standard deviation	Mean difference (95% CI)
Seo, 2004[594] /0	Pelvic floor exercise (5 second contraction and 10 second relaxation, 3-5 times for >5 minutes/day) and functional Electrical Stimulation Biofeedback (35Hz-50Hz for 24 seconds); 2 training sessions/week	Vaginal cone, 150-gram dumbbell-shaped made of fine ceramic material	Changes in sexual life	60/60	-0.19/0.12		
Seo, 2004[594] /0	Pelvic floor exercise (5 second contraction and 10 second relaxation, 3-5 times for >5 minutes/day) and functional Electrical Stimulation Biofeedback (35Hz-50Hz for 24 seconds); 2 training sessions/week	Vaginal cone, 150-gram dumbbell-shaped made of fine ceramic material	Changes in daily life	60/60	-0.27/0.11		
Seo, 2004[594] /0	Pelvic floor exercise (5 second contraction and 10 second relaxation, 3-5 times for >5 minutes/day) and functional Electrical Stimulation Biofeedback (35Hz-50Hz for 24 seconds); 2 training sessions/week	Vaginal cone, 150-gram dumbbell-shaped made of fine ceramic material	Changes in difficulty in personal relationships	60/60	-0.29/0.14		

Appendix Table F133. Scoring of quality of life after PFMT with biofeedback vs. vaginal cones (individual RCTs) (continued)

Reference sample/men	Active	Control	Definition of quality of life	Randomized active/control	Active mean/standard deviation	Control mean standard deviation	Mean difference (95% CI)
Seo, 2004[594] /0	Pelvic floor exercise (5 second contraction and 10 second relaxation, 3-5 times for >5 minutes/day) and functional Electrical Stimulation Biofeedback (35Hz-50Hz for 24 seconds); 2 training sessions/week	Vaginal cone, 150-gram dumbbell-shaped made of fine ceramic material	Changes in quality of life	60/60	-0.27/0.13		
Cammu, 1998[511] /0	Weekly session of pelvic floor exercises vaginal probe-EMG biofeedback using perineometer	Vaginal weight cones	Visual analogue scale (0–10)	30/30	2.60/2.10	2.90/2.40	-0.30 (-1.44;0.84)
Cammu, 1998[511] /0	Weekly session of pelvic floor exercises vaginal probe-EMG biofeedback using perineometer	Vaginal weight cones	Visual analogue scale (0–10)Severity of incontinence	30/30	2.10/2.10	3.40/3.30	-1.30 (-2.70;0.10)

Appendix Table F134. Comparative effectiveness of circular muscle exercises (Paula method) vs. PFMT (individual RCT)

Reference sample/men	Outcome	Randomized active/control	Active events/rate	Control events/rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Liebergall-Wischnitzer, 2009[559] 241/0	Improved (pad test <1g)	117/123	76/65	62/50	1.30 (1.04; 1.62)	0.15 (0.03; 0.27)	7 (4; 38)	150 (26; 273)
Liebergall-Wischnitzer, 2009[559] 241/0	Percent cured	117/123	60/51	42/34	1.50 (1.11; 2.03)	0.17 (0.05; 0.29)	6 (3; 21)	171 (48; 295)
Liebergall-Wischnitzer, 2009[559] 241/0	No feelings of bladder fullness	117/123	77/66	64/52	1.26 (1.02; 1.57)	0.14 (0.01; 0.26)	7 (4; 69)	138 (15; 261)

Appendix Table F135. Scoring of quality of life after circular muscle exercises (Paula method) vs. PFMT (individual RCTs)

Reference sample/men	Outcome	Randomized active/control	Active mean/standard deviation	Control mean standard deviation	Mean difference (95% CI)
Liebergall-Wischnitzer, 2009[559] /0	Mean I-QOL improvement	117/123	10.80/18.76	9.80/20.37	1.00 (-3.95; 5.95)
Liebergall-Wischnitzer, 2009[559] /0	I-QOL overall score	117/123	83.10/5.10	78.10/17.60	5.00 (1.76; 8.24)
Liebergall-Wischnitzer, 2005[560] /0	Change from baseline in quality of life-avoidance, limiting behaviors scores (8 items)	31/32	9.80/17.30	9.50/27.40	0.30 (-11.66; 11.06)
Liebergall-Wischnitzer, 2005[560] /0	Change from baseline in quality of life-avoidance, social embarrassment scores (5 items)	31/32	14.00/23.00	9.30/13.00	4.70 (-13.89; 4.49)

Appendix Table F136. Clinical outcomes after circular muscle exercises (Paula method) vs. PFMT (individual RCTs)

Reference sample/men	Outcome	Randomized active/control	Active events/rate	Control events/rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95%CI)
Liebergall-Wischnitzer, 2009[559] 240/0	Leakage annoyance often/very often	117/123	14/12	29/24	0.51 (0.28; 0.91)	-0.12 (-0.21; -0.02)	-9 (-48; -5)	-116 (-211 ;-21)
Liebergall-Wischnitzer, 2009[559] 240/0	Leakage amount moderate/very large	117/123	17/15	25/20	0.71 (0.41; 1.25)	-0.06 (-0.15; 0.04)		
Liebergall-Wischnitzer, 2009[559] 240/0	Feelings of bladder fullness	117/123	16/14	22/18	0.76 (0.42; 1.38)	-0.04 (-0.13; 0.05)		
Liebergall-Wischnitzer, 2009[559] 240/0	Leakage frequency monthly or once in several months	117/123	26/22	25/20	1.0 9 (0.67; 1.78)	0.02 (-0.08 ;0.12)		
Liebergall-Wischnitzer, 2009[559] 240/0	Daily-weekly	117/123	65/56	61/50	1.12 (0.88; 1.43)	0.06 (-0.07; 0.19)		

Appendix Table F137. Comparative effectiveness on quality of life after PFMT vs. active controls (individual RCTs)

Reference sample/men	Active	Control	Definitions of the outcomes	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Liebergall-Wischnitzer, 2009[559] 240/0	Circular muscle exercises (Paula method)	PFMT group	Leakage annoyance not at all/seldom/ sometime	117/123	81/69	59/48	1.44 (1.16; 1.80)	0.21 (0.09; 0.33)	5 (3; 11)	213 (91;334)
Morkved, 2002[574] 103/0	Pelvic floor muscle training with a biofeedback apparatus	Pelvic floor muscle training without biofeedback	Urinary incontinence is very problematic	53/50	1/2	3/6	0.31 (0.03; 2.92)	-0.04 (-0.12; 0.03)		
Sherman, 1997[595] 39/0	Pelvic muscle exercises with vaginal EMG probe.	Pelvic muscle	Best activity level	23/16	4/0	5/0	0.56 (0.18; 1.76)	-0.14 (-0.41; 0.14)		
Williams, 2006[615] /0	Pelvic floor muscle therapies	Vaginal cone therapy	Odds ratio of satisfaction with current urinary symptoms for rest of life	79/80			1.02 (0.54;1.95)			
Williams, 2006[615] /0	Pelvic floor muscle therapies	Behavioral intervention	Odds ratio of satisfaction with current urinary symptoms for rest of life	79/79			0.77 (0.40;1.47)			
Glavind, 1996[535] 40/0	Physiotherapy in combination with biofeedback	Physiotherapy	Acceptance of degree of incontinence	20/20	15/75	10/50	1.50 (0.90; 2.49)	0.25 (-0.04; 0.54)		

Appendix Table F138. Scoring of quality of life after PFMT (individual RCTs)

Reference sample/men	Active	Control	Definition of quality of life	Randomized active/control	Active mean/standard deviation	Control mean/standard deviation	Mean difference (95% CI)
Borello-France, 2008[498] /0	High-frequency (4 times per week)	Low-frequency (1 time per week)	Change in incontinence impact questionnaire score	22/22	-4.00/10.60	-6.00/27.00	2.00 (-10.12; 14.12)
Borello-France, 2008[498] /0	High-frequency (4 times per week)	Low-frequency (1 time per week)	Change in Brink score	22/22	0.00/0.97	0.00/1.00	0.00 (-0.58; 0.58)
Demain, 2001[514] /0	Three educational group sessions, PFMT	One 45-minute individual instruction in PFMT	Incontinence impact questionnaire score (0 to 100 worse)	22/22	14.30/22.73	7.10/28.72	7.20 (-8.10; 22.50)
Williams, 2006[615] /0	Pelvic floor muscle therapies	Vaginal cone therapy	Median (interquartile range) impact score	79/80			-0.46 (-3.09; 2.18)
Williams, 2006[615] /0	Pelvic floor muscle therapies	Primary behavioral intervention	Median (interquartile range) impact score	79/79			-0.02 (-2.78; 2.75)
Kincade, 2007[550] /0	Self-monitoring group with training on fluid intake, voiding frequency, and PFMT	Quick Kegel	Quality of life using Incontinence impact questionnaire with scores 0-400 (worse)	117/107	99.30/96.60	112.10/89.90	-12.80 (-37.22; 11.62)

Appendix Table F139. Continence after PFMT with personal reminders and self-help guides or different positions during exercise (individual RCTs)

Reference sample/men	Active	Control	Randomized active/control	Active events/rate	Control events/rate	Relative risk (95% CI)	Absolute risk differences (95% CI)
Alewijnse, 2003[479] 103/0	Pelvic floor muscle exercise with reminder and Self-Help Guide	Bladder training and pelvic floor muscle exercise	52/51	17/33	21/41	0.79 (0.48; 1.32)	-0.08 (-0.27; 0.10)
Borello-France, 2006[497] 44/0	Pelvic-floor muscle exercises with EMG biofeedback in the supine position only using max 30-60 repetitions of 3-12 second contractions twice daily	Pelvic-floor muscle exercises with EMG biofeedback in both supine and upright positions, 1 set (3- and 12-second contractions) in each position with max of 20 repetitions (2 sets of 10) of the 3-12 second contractions twice daily	22/22	13/59	13/59	1.00 (0.61; 1.64)	0.00 (-0.29; 0.29)

Appendix Table F140. Comparative effectiveness of medical devices (individual RCTs)

Reference sample	Active	Control	Definition of outcome	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/ 1000 treated (95% CI)
Williams, 2006[615] /0	Vaginal cone therapy	Primary behavioral intervention	Odds ratio of no symptoms (cure)	80/79			0.88 (0.28; 2.76)			
Williams, 2006[615] /0	Vaginal cone therapy	Primary behavioral intervention	Odds ratio of mild or no problem	80/79			0.88 (0.44; 1.77)			
Thyssen, 2001[608] 124/0	Contrelle Continence Tampon (CCT)	Conveen Continence disposable Intravaginal device guard, (CCG)	Subjectively continent	62/62	30/48	22/35	1.36 (0.89; 2.08)	0.13 (-0.04; 0.30)		
Thyssen, 2001[608] 188/0	Conveen Continence disposable Intravaginal device guard, (CCG)	Contrelle Continence Tampon (CCT)	Cured from stress urinary incontinence	94/94	34/36	45/48	0.76 (0.54; 1.06)	-0.12 (-0.26; 0.02)		
Nygaard, 1995[579] 40/0	Hodge pessary with support	40-minute standardized aerobics sessions wearing a super tampon	Continent during exercise	20/20	7/36	12/58	0.58 (0.29; 1.17)	-0.25 (-0.55; 0.05)		
Andersen, 2002[482] 52/0	Durasphere	Contigen®	Dry	26/26	10/38	3/12	3.33 (1.03; 10.74)	0.27 (0.05; 0.49)	4 (2; 22)	269 (46; 493)
Robinson, 2003[590] 24/0	Urethral device (NEAT) –sterile urethral insert with disposable applicator packaged with device.	Reliance Insert sterile balloon type device	Success as negative pad weight test	13/11	9/73	7/62	1.09 (0.61; 1.93)	0.06 (-0.32; 0.44)		

Appendix Table F140. Comparative effectiveness of medical devices (individual RCTs) (continued)

Reference sample	Active	Control	Definition of outcome	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/ 1000 treated (95% CI)
Improvement in incontinence										
Thyssen, 2001[608] 124/0	Contrelle Continence Tampon (CCT)	Conveen Continence disposable Intravaginal device guard (CCG)	Improvement in UI	62/62	22/35	25/40	0.88 (0.56; 1.38)	-0.05 (-0.22; 0.12)		
Thyssen, 2001[608] 188/0	Conveen Continence disposable Intravaginal device guard (CCG)	Contrelle Continence Tampon (CCT)	Self reported Improvement in stress urinary incontinence	94/94	38/40	34/36	1.12 (0.78; 1.61)	0.04 (-0.10; 0.18)		
Andersen, 2002[482] 52/0	Durasphere	Contigen®	Improvement of 1 or more continence grades	26/26	20/77	13/50	1.54 (0.99; 2.38)	0.27 (0.02; 0.52)	4 (2; 56)	269 (18; 521)
Seo, 2004[594] 120/0	Pelvic floor exercise (5 sec contraction and 10 sec relaxation, 3-5 times for >5 min/day) and functional Electrical Stimulation Biofeedback (35Hz-50Hz for 24 sec); 2 training sessions/week	Vaginal cone, 150-gram dumbbell-shaped made of fine ceramic material	Self reported improvement in urinary incontinence	60/60	55/92	53/88	1.04 (0.92; 1.17)	0.03 (-0.07; 0.14)		

Appendix Table F140. Comparative effectiveness of medical devices (individual RCTs) (continued)

Reference sample	Active	Control	Definition of outcome	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/ 1000 treated (95% CI)
Robinson, 2003[590] 24/0	Urethral device (NEAT) –sterile urethral insert with disposable applicator packaged with device.	Reliance Insert sterile balloon type device	Success as a 50% or greater reduction in urine loss	13/11	9/67	6/58	1.27 (0.66; 2.43)	0.15 (-0.24; 0.53)		

Appendix Table F141. Scoring of quality of life after medical devices compared to active controls (individual RCTs)

Reference sample	Active	Control	Definition of quality of life	Randomized active/control	Active mean/standard deviation	Control mean/standard deviation	Mean difference (95% CI)
Seo, 2004[594] /0	Pelvic floor exercise with Electrical Stimulation Biofeedback	Vaginal cone	Changes in scores Restriction in exercise due to incontinence	60/60	-0.59/0.18	-0.36/0.17	-0.23 (-0.29; -0.17)
Seo, 2004[594] /0	Pelvic floor exercise with Electrical Stimulation Biofeedback	Vaginal cone	Changes in scores Avoiding places due to urinary incontinence	60/60	-0.29/0.14	-0.13/0.15	-0.16 (-0.21; -0.11)
Andersen, 2002[482] /0	Durasphere	Contigen®	Change in continence grade	26/26	1.28/0.84	0.86/1.01	0.42 (-0.08; 0.92)
Williams, 2006[615] /0	Vaginal cone	Primary behavioral intervention	Median (interquartile range) impact score	80/79			-0.48 (-2.60; 1.66)

Appendix Table F142. Comparative effectiveness of medical devices on quality of life (individual RCT)

Reference sample	Active	Control	Definition of outcome	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Thyssen, 2001[608] 124/0	CCT	CCG	preference of the device	62/62	39/63	16/26	2.44 (1.53; 3.87)	0.37 (0.21; 0.53)	3 (2; 5)	371 (209;533)
Thyssen, 2001[608] 124/0	CCT	CCG	No bother from UI	62/62	54/87	45/72	1.20 (1.00; 1.44)	0.15 (0.01; 0.28)	7 (4; 160)	145 (6;284)
Williams, 2006[615] /0	Vaginal cone therapy	Behavioral intervention	OR of satisfaction with current urinary symptoms for rest of life	80/79			0.75 (0.40; 1.44)			

Appendix Table F143. Comparative comfort in using different pads for urinary incontinence (individual RCT)

Reference sample	Active	Control	Definition of outcome	Randomized active/control	Active events/rate	Control events/rate	Relative risk (95% CI)	Absolute risk differences (95% CI)
Thornburn, 1997[607] 514/0	Pad C	Pad F	Good wet comfort	258/255	116/45	128/50	0.90 (0.75; 1.08)	-0.05 (-0.14; 0.04)
Thornburn, 1997[607] 514/0	Pad A	Pad C	Good wet comfort	247/258	124/50	116/45	1.11 (0.93; 1.34)	0.05 (-0.04; 0.14)
Thornburn, 1997[607] 514/0	Pad A	Pad F	Good wet comfort	247/255	124/50	128/50	1.00 (0.84; 1.19)	0.00 (-0.09; 0.09)
Thornburn, 1997[607] 514/0	Pad C	Pad F	Good absorbency	258/255	134/52	153/60	0.87 (0.74; 1.01)	-0.08 (-0.17; 0.01)
Thornburn, 1997[607] 514/0	Pad A	Pad C	Good leakage performance	247/258	136/55	155/60	0.92 (0.79; 1.07)	-0.05 (-0.14; 0.04)
Thornburn, 1997[607] 514/0	Pad A	Pad F	Good leakage performance	247/255	136/55	153/60	0.92 (0.79; 1.07)	-0.05 (-0.14; 0.04)
Thornburn, 1997[607] 514/0	Pad A	Pad C	Good absorbency	247/258	143/58	134/52	1.11 (0.95; 1.31)	0.06 (-0.03; 0.15)
Thornburn, 1997[607] 514/0	Pad A	Pad F	Good absorbency	247/255	143/58	153/60	0.96 (0.83; 1.12)	-0.02 (-0.11; 0.07)
Thornburn, 1997[607] 514/0	Pad C	Pad F	Good leakage performance	258/255	155/60	153/60	1.00 (0.87; 1.15)	0.00 (-0.08; 0.09)

Appendix Table F144. Comparative effectiveness of bulking agents (individual RCTs)

Reference sample	Active	Control	Definition of outcome	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Continence										
Mayer, 2007[567] 296/0	Calcium hydroxylapatite (CaHA)	Bovine Dermal Collagen	Cure rate or Stamey grade 0 at 12 months	158/138	51/32	37/27	1.20 (0.84; 1.72)	0.05 (-0.05; 0.16)		
Bano, 2005[487] 50/0	Peri or transurethral porcine dermal implant injection (Permacol)	Transurethral silicone injection (Macroplastique	Urinary continence (negative pad test)	25/25	15/60	9/36	1.67 (0.90; 3.08)	0.24 (-0.03; 0.51)		
Schulz, 2004[593] 40/0	Periurethral route of injection of bulking agent-dextran copolymer	Transurethral route of injection of bulking agent-dextran copolymer	Objective urinary continence (dry in pad test)	20/20	1/5	3/15	0.33 (0.04; 2.94)	-0.10 (-0.28; 0.08)		
Ghoniem, 2009[533] 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	Number of Stamey grade dry	122/125	45/37	31/25	1.49 (1.01; 2.18)	0.12 (0.01; 0.24)	8 (4; 152)	121 (7; 235)
Ghoniem, 2009[533] 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	Patient assessment - dry	122/125	34/28	25/20	1.39 (0.89; 2.19)	0.08 (-0.03; 0.18)		
Ghoniem, 2009[533] 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	Physician assessment - dry	122/125	43/35	32/26	1.38 (0.94; 2.02)	0.10 (-0.02; 0.21)		
Strasser, 2007[598] 63/0	Transurethral ultra-sonography-guided injections of autologous myoblasts and fibroblasts	Conventional endoscopic injections of collagen	Continence	42/21	38/90	2/10	9.50 (2.53; 35.63)	0.81 (0.66; 0.96)	1 (1; 2)	810 (656; 963)
Lightner, 2009[562] 344/0	Zuidex Implacer	Contigen® endoscopic guidance	Dry rates	227/117	83/37	52/44	0.82 (0.63; 1.07)	-0.08 (-0.19; 0.03)		

Appendix Table F144. Comparative effectiveness of bulking agents (individual RCTs) (continued)

Reference sample	Active	Control	Definition of outcome	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Improvement in Incontinence										
Lightner, 2001[561] 364/0	Injection of bulking agent 1.0 mL Durasphere max 5 times with a minimum 7-day interval	Injection of bulking agent bovine collagen max 5 times with a minimum 7-day interval	Improvement of 1 or more continence grades	176/188	76/43	79/42	1.03 (0.81; 1.30)	0.01 (-0.09; 0.11)		
Bano, 2005[487] 50/0	Peri or transurethral porcine dermal implant injection (Permacol)	Transurethral silicone injection (Macroplastique)	Improvement in urinary incontinence (pad test)	25/25	15/60	10/40	1.50 (0.84; 2.67)	0.20 (-0.07 ;0.47)		
Bano, 2005[487] 50/0	Peri or transurethral porcine dermal implant injection (Permacol)	Transurethral silicone injection (Macroplastique)	Improved urinary incontinence scores (Stamey)	25/25	14/56	10/40	1.40 (0.77; 2.53)	0.16 (-0.11; 0.43)		
Bano, 2005[487] 50/0	Peri or transurethral porcine dermal implant injection (Permacol)	Transurethral silicone injection (Macroplastique)	Improved urinary incontinence scores (Kings College Hospital Quality of Health Questionnaire)	25/25	14/56	7/28	2.00 (0.98; 4.10)	0.28 (0.02; 0.54)	4 (2; 57)	280 (18; 542)
Schulz, 2004[593] 40/0	Periurethral route of injection of bulking agent-dextran copolymer	Transurethral route of injection of bulking agent-dextran copolymer	Subjective improvement in urinary incontinence	20/20	6/30	7/35	0.86 (0.35; 2.10)	-0.05 (-0.34; 0.24)		

Appendix Table F144. Comparative effectiveness of bulking agents (individual RCTs) (continued)

Reference sample	Active	Control	Definition of outcome	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Mayer, 2007[567] 296/0	Calcium hydroxylapatite (CaHA)	Bovine Dermal Collagen	Improved by one Stamey grade at 6 months	158/138	97/61	71/51	1.19 (0.97; 1.46)	0.10 (-0.01; 0.21)		
Mayer, 2007[567] 296/0	Calcium hydroxylapatite (CaHA)	Bovine Dermal Collagen	Improved by one Stamey grade at 12 months	158/138	83/53	57/41	1.27 (0.99; 1.63)	0.11 (0.00; 0.23)		
Mayer, 2007[567] 296/0	Calcium hydroxylapatite (CaHA)	Bovine Dermal Collagen	Improvement of two Stamey scale units or being dry	158/138	66/41	46/33	1.25 (0.92; 1.68)	0.08 (-0.03; 0.19)		
Mayer, 2007[567] 296/0	Calcium hydroxylapatite (CaHA)	Bovine Dermal Collagen	50% or more decline in 24-hour pad weight test at 12 months	158/138	81/51	54/39	1.31 (1.01; 1.70)	0.12 (0.01; 0.23)	8 (4; 116)	121 (9; 234)
Strasser, 2007[598] 63/0	Transurethral ultra-sonography-guided injections of autologous myoblasts and fibroblasts	Conventional endoscopic injections of collagen	Substantial improvement in urinary incontinence	42/21	3/7	1/5	1.50 (0.17; 13.56)	0.02 (-0.10 ;0.14)		
Strasser, 2007[598] 63/0	Transurethral ultra-sonography-guided injections of autologous myoblasts and fibroblasts	Conventional endoscopic injections of collagen	Slight improvement in urinary incontinence	42/21	1/2	6/29	0.08 (0.01; 0.65)	-0.26 (-0.46; -0.06)	-4 (-16; -2)	-262 (-461; -63)
Ghoniem, 2009[533] 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	Improvement of at least 1 Stamey grade at 12 months	122/125	75/61	60/48	1.28 (1.02; 1.61)	0.13 (0.01; 0.26)	7 (4; 85)	135 (12; 258)

Appendix Table F144. Comparative effectiveness of bulking agents (individual RCTs) (continued)

Reference sample	Active	Control	Definition of outcome	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Ghoniem, 2009[533] 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	Patient assessment - improved	122/125	45/37	39/31	1.18 (0.83; 1.68)	0.06 (-0.06; 0.17)		
Ghoniem, 2009[533] 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	Physician assessment - marked improvement	122/125	39/32	38/30	1.05 (0.73; 1.52)	0.02 (-0.10; 0.13)		
Ghoniem, 2009[533] 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	With a Stamey grade of 0 or dry outcome	122/125	45/37	31/25	1.49 (1.01; 2.18)	0.12 (0.01; 0.24)	8 (4; 152)	121 (7; 235)
Lightner, 2009[562] 344/0	Zuidex Implacer	Contigen® Endoscopic guidance	Reduction in urine leakage at least 50% on provocation tests	227/117	148/65	98/84	0.78 (0.69; 0.88)	-0.19 (-0.28; -0.09)	-5 (-11; -4)	-186 (-277; -94)
Lightner, 2009[562] 344/0	Zuidex Implacer	Contigen® Endoscopic guidance	Responder rate based on >50% reduction in incontinent episodes	227/117	122/54	78/67	0.81 (0.68 ;0.96)	-0.13 (-0.24; -0.02)	-8 (-46; -4)	-129 (-236; -22)
Lightner, 2009[562] 344/0	Zuidex Implacer	Contigen® Endoscopic guidance	One-grade improvement on Stamey score at 12 months	227/117	116/51	64/55	0.93 (0.76; 1.15)	-0.04 (-0.15; 0.08)		
Lightner, 2009[562] 344/0	Zuidex Implacer	Contigen® Endoscopic guidance	3 treatments needed for clinical effect	227/117	67/30	38/33	0.91 (0.65; 1.26)	-0.03 (-0.13; 0.07)		

Appendix Table F145. Quality of life scores after bulking agents (individual RCTs)

Reference sample/men	Active	Control	Definition of quality of life	Randomized active/control	Active mean/standard deviation	Control mean/standard deviation	Mean difference (95% CI)
Ghoniem, 2009[533] /0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	I-QOL improvement	122/125	28.70/20.70	26.40/24.00	2.30 (-3.29; 7.89)
Strasser, 2007[598] /0	Transurethral ultrasonography-guided injections of autologous myoblasts and fibroblasts	Conventional endoscopic injections of collagen	Quality of life score	42/21	108.00/0.67	64.00/17.33	44.00 (36.58; 51.42)

Appendix Table F146. Clinical outcomes after bulking agents (individual RCTs)

Reference sample	Active	Control	Definition of outcome	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Lightner, 2009[562] 344/0	Zuidex Implacer	Contigen® Endoscopic guidance	Withdraw due to adverse events	227/117	8/4	2/2	2.06 (0.44; 9.55)	0.02 (-0.02; 0.05)		
Lightner, 2009[562] 344/0	Zuidex Implacer	Contigen® Endoscopic guidance	Lack of effect	227/117	43/19	11/9	2.01 (1.08; 3.76)	0.10 (0.02; 0.17)	10 (6; 46)	9 5 (22; 169)
Lightner, 2009[562] 344/0	Zuidex Implacer	Contigen® Endoscopic guidance	Worsened incontinence at 12 months	227/117	32/14	8/7	2.06 (0.98; 4.33)	0.07 (0.01; 0.14)	14 (7; 121)	73 (8; 137)
Ghoniem, 2009[533] 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	Discontinued due to loss to followup	122/125	20/16	31/25	0.66 (0.40; 1.09)	-0.08 (-0.18; 0.02)		
Ghoniem, 2009[533] 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	Withdrew	122/125	8/7	4/3	2.05 (0.63; 6.63)	0.03 (-0.02; 0.09)		
Ghoniem, 2009[533] 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	Physician assessment - unchanged	122/125	6/5	10/8	0.61 (0.23; 1.64)	-0.03 (-0.09; 0.03)		
Ghoniem, 2009[533] 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	Patient assessment - unchanged	122/125	8/7	11/9	0.75 (0.31; 1.79)	-0.02 (-0.09 ;0.04)		
Ghoniem, 2009[533] 247/0	Transurethral injection of Macroplastique	Transurethral injection of Contigen®	Urge incontinence	122/125	6/5	5/4	1.23 (0.39; 3.92)	0.0 (-0.04; 0.06)		
Strasser, 2007[598] 63/0	Transurethral ultra-sonography-guided injections of autologous myoblasts and fibroblasts	Conventional endoscopic injections of collagen	Number of incontinent patients	42/21	4/10	19/90	0.11 (0.04; 0.27)	-0.81 (-0.96; -0.66)	-1 (-2; -1)	-810 (-963; -656)

Appendix Table F146. Clinical outcomes after bulking agents (individual RCTs) (continued)

Reference sample	Active	Control	Definition of outcome	Randomized active/ control	Active events/ rate	Control events/ rate	Relative risk (95% CI)	Absolute risk differences (95% CI)	Number needed to treat (95% CI)	Attributable events/1000 treated (95% CI)
Mayer, 2007[567] 296/0	Calcium hydroxylapatite (CaHA)	Bovine Dermal Collagen	Urge incontinence after treatment	158/138	7/5	12/9	0.51 (0.21; 1.26)	-0.04 (-0.10; 0.01)		
Lightner, 2001[561] 364/0	Injection of bulking agent 1.0 mL Durasphere max 5 times with a minimum 7-day interval	Injection of bulking agent bovine collagen max 5 times with a minimum 7-day interval	Incidence of urgency	176/188	43/25	22/12	2.09 (1.30; 3.34)	0.13 (0.05; 0.21)	8 (5; 20)	127 (49; 206)

Appendix Table F147. Comparative effectiveness of nonpharmacological treatments on continence (insufficient evidence)

Active	Control	Studies reference	Number of subjects	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events 95% CI)	Evidence
Continence service	Bladder training	1 study[588]	74	Not significant				Insufficient
Continence service	PFMT	1 study[547]	33	7.44 (2.00; 27.70)	0.76 (0.53; 0.98)	1 (1; 2)	757 (534; 980)	Insufficient
Continence service	Tele continence service	1 study[542]	58	Not significant				Insufficient
PFMT+ reminder	PFMT+ bladder training	1 study[479]	103	Not significant				Insufficient
PFMT in the supine position	PFMT in both supine and upright positions	1 study[497]	44	Not significant				Insufficient
Group physiotherapy	Biofeedback	1 study[585]	40	Not significant				Insufficient
Individual PFMT+BT	Group PFMT	1 study[544]	530	1.58 (1.05; 2.36)	0.08 (0.00; 0.16)	12 (6; 1003)	81 (1; 161)	Insufficient
Circular muscle exercises (Paula method)	PFMT	1 study[559]	245	1.50 (1.11; 2.03)	0.17 (0.05; 0.29)	6 (3; 21)	171 (48; 295)	Insufficient
PFMT	PFMT+ Balls	1 study[484]	37	0.11 (0.01; 1.83)	-0.22 (-0.43; -0.02)	-5 (-52; -2)	-222 (-425; -19)	Insufficient
Physiotherapy in combination with biofeedback	Physiotherapy	1 study[535]	40	3.67 (1.20; 11.19)	0.40 (0.13; 0.67)	3 (1; 8)	400 (132; 668)	Insufficient
Weekly posterior tibial nerve simulation	Posterior tibial nerve simulation three times per week	1 study[527]	35	Not significant				Insufficient
Vaginal cone	behavioral intervention	1 study[615]	238	Not significant				Insufficient
Conveen Continence device Guard, CCG	Contrelle Continence Tampon, CCT	1 study[608]	94	Not significant				Insufficient

Appendix Table F147. Comparative effectiveness of nonpharmacological treatments on continence (insufficient evidence) (continued)

Active	Control	Studies reference	Number of subjects	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events 95% CI)	Evidence
Hodge pessary with support	Super tampon	1 study[579]	40	Not significant				Insufficient
Durasphere	Contigen	1 study[482]	52	3.33 (1.03; 10.74)	0.27 (0.05; 0.49)	4 (2; 22)	269 (46; 493)	Insufficient
Urethral device (NEAT)	Reliance insert sterile balloon	1 study[590]	24	Not significant				Insufficient
Calcium hydroxylapatite (CaHA	Bovine Dermal Collagen	1 study[567]	296	Not significant				Insufficient
Peri or transurethral porcine dermal implant injection (Permacol)	Transurethral silicone injection (Macroplastique	[487]		Not significant				Insufficient
Periurethral route of injection of bulking agent-dextran copolymer	Transurethral route of injection of bulking agent-dextran copolymer	[593]		Not significant				Insufficient
Macroplastique	Contigen®	1 study[533]	247	1.49 (1.01; 2.18) NS for self reported continence	0.12 (0.01; 0.24)	8 (4; 152)	121 (7; 235)	Insufficient
Autologous myoblasts and fibroblasts	Collagen	1 study[598]	63	9.50 (2.53; 35.63)	0.81 (0.66; 0.96)	1 (1; 2)	810 (656; 963)	Insufficient
Zuidex Implacer	Contigen Endoscopic guidance	1 study[562]	344	Not significant				Insufficient

Appendix Table F148. Clinical outcomes after PFMT combined with bladder training compared to PFMT alone (results from RCTs pooled with random effects models)

Outcome	Reference	Active n/N	Control n/N	Rate active/control	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Continence	Berghmans, 1996[489]	5/20	3/20	25/15	1.67 (0.46; 6.06)	7.05	0.1 (-0.146; 0.346)	12.53
Continence	Glavind, 1996[535]	11/20	3/20	55/15	3.67 (1.20; 11.19)	8.95	0.4 (0.132; 0.668)	11.19
Continence	Morkved, 2002[574]	19/53	14/50	36/28	1.28 (0.72; 2.27)	21.85	0.078 (-0.101; 0.258)	17.73
Continence	Burgio, 2002[505]	15/73	11/75	20/15	1.40 (0.69; 2.84)	17.15	0.059 (-0.064; 0.181)	23.68
Continence UD	Goode, 2003[626]	18/66	25/67	28/38	0.73 (0.44; 1.21)	24.8	-0.1 (-0.258; 0.058)	19.82
Continence	Wang, 2004[612]	15/38	12/40	38/30	1.32 (0.71; 2.44)	20.2	0.095 (-0.116; 0.305)	15.05
Pooled		82/270	68/272	30/25	1.27 (0.88; 1.85)	100	0.079 (-0.031; 0.189)	100
Heterogeneity P value, I squared,%					0.147	38.80%	0.065	51.80%
Treatment failure	Morkved, 2002[574]	1/53	3/50	2/6	0.31 (0.03; 2.92)	66.52	-0.041 (-0.116; 0.034)	74.27
Treatment failure	Glavind, 1996[535]	0/20	1/20	0/5	0.33 (0.01; 7.72)	33.48	-0.05 (-0.178; 0.078)	25.73
Pooled		1/73	4/70	1/6	0.32 (0.05; 1.98)	100	-0.043 (-0.108; 0.022)	100
Heterogeneity P value, I squared,%					0.98	0.00%	0.907	0.00%

Appendix Table F149. Clinical outcomes after PFMT combined with bladder training compared to bladder training alone (results from RCTs pooled with random effects models

Outcome	Reference	Active n/N	Control n/N	Rate active/control	Relative risk (95% CI)	Weight, %	Absolute risk difference (95% CI)	Weight, %
Continence	Wyman, 1998[619]	16/67	10/68	24/15	1.62 (0.80; 3.32)	32.71	0.092 (-0.041; 0.224)	33.66
Continence	Elser, 1999[522]	10/68	17/68	15/25	0.59 (0.29; 1.19)	33.03	-0.103 (-0.236; 0.03)	33.56
Continence	Wyman, 1998[619]	18/67	11/68	27/16	1.66 (0.85; 3.25)	34.26	0.107 (-0.031; 0.244)	32.78
		44/202	38/204	22/19	1.17 (0.6; 2.28)		0.031 (-0.102; 0.164)	
					0.064	63.70%	0.053	66.00%
Improved UI	Wyman, 1998[619]	14/69	9/68	20/13	1.53 (0.71; 3.30)	46.39	0.071 (-0.054; 0.195)	52.52
Improved UI	Wyman, 1998[619]	14/67	11/68	21/16	1.29 (0.63; 2.64)	53.61	0.047 (-0.084; 0.178)	47.48
Pooled		28/136	20/136	21/15	1.40 (0.83; 2.36)	100	0.059 (-0.031; 0.15)	100
Heterogeneity P value, I squared,%					0.75	0.00%	0.8	0.00%

Appendix Table F150. Quality of life scoring after continence program vs. PFMT (individual RCT)

Reference sample/men	Active	Control	Outcome	Randomized active/control	Active mean/standard deviation	Control mean standard deviation	Mean difference (95% CI)
Kim, 2001[547] /0	Continence Efficacy Intervention Program	PFMT	Score of Improvement by subjective evaluation (0 to 100)	16/17	37.80/23.90	23.60/18.90	14.20 (-0.56;2 8.96)

Appendix Table F151. Nonsignificant differences in comparative effectiveness of oxybutynin when compared to nonpharmacological treatments (results from individual randomized controlled clinical trials)

Reference	Outcome	Active treatment	Control treatment	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)
Karademir, 2005[323]	Cured from urge incontinence	Stoller afferent neurostimulation with frequency 20 Hz and amplitude 0.5-10 mA	Stoller afferent neurostimulation with frequency 20 Hz and amplitude 0.5-10 mA combined with 5 mg of oral oxybutynin hydrochloride	3/21	3/23	1.10 (0.25; 4.84)	0.01 (-0.19; 0.22)
Karademir, 2005[323]	Decrease in symptoms of frequency	Stoller afferent neurostimulation with frequency 20 Hz and amplitude 0.5-10 mA	Stoller afferent neurostimulation with frequency 20 Hz and amplitude 0.5-10 mA combined with 5 mg of oral oxybutynin hydrochloride	8/21	10/22	0.84 (0.41; 1.71)	-0.07 (-0.37;0.22)
Karademir, 2005[323]	Decrease in symptoms of urgency	Stoller afferent neurostimulation with frequency 20 Hz and amplitude 0.5-10 mA	Stoller afferent neurostimulation with frequency 20 Hz and amplitude 0.5-10 mA combined with 5 mg of oral oxybutynin hydrochloride	10/21	13/22	0.81 (0.46; 1.42)	-0.12 (-0.41 ;0.18)
Karademir, 2005[323]	Decrease in symptoms of urge incontinence	Stoller afferent neurostimulation with frequency 20 Hz and amplitude 0.5-10 mA	Stoller afferent neurostimulation with frequency 20 Hz and amplitude 0.5-10 mA combined with 5 mg of oral oxybutynin hydrochloride	15/21	20/22	0.79 (0.58; 1.06)	-0.20 (-0.42; 0.03)
Burgio, 2010[247]	Completely satisfied with treatment progress	Pelvic Floor Muscle training + Urge suppression techniques + Oxybutynin	Oxybutynin	25/32	28/32	0.89 (0.71;1.12)	-0.09 (-0.28; 0.10)
Burgio, 2010[247]	Perceived improvement: much better	Pelvic Floor Muscle training + Urge suppression techniques + Oxybutynin	Oxybutynin	25/32	29/32	0.86 (0.70; 1.07)	-0.13 (-0.30;0.05)
Goode, 2002[294]	Self reported improvement in UI	Four sessions (over 8 weeks) of biofeedback-assisted behavioral training by nurse practitioners.	2.5 mg of oxybutynin chloride 3 times/day, dose adjustments from minimum 2.5 mg/ day to a maximum 5.0 mg 3 times/day	27/33	27/35	1.06 (0.83; 1.35)	0.05 (-0.15; 0.24)

Appendix Table F152. Comparative effectiveness of combined therapy with tolterodine ER, 4 mg daily and behavioral intervention with pelvic floor muscle training vs. tolterodine ER, 4 mg daily monotherapy. Urinary Incontinence Treatment Network: behavior enhances drug reduction of incontinence, (BE-DRI) randomized controlled clinical trial

Reference	Outcome	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Burgio, 2008[244]	Totally dry	32/154	26/153	1.22 (0.77; 1.95)	0.038 (-0.050; 0.125)		
Burgio, 2008[244]	At least 70% reduction in incontinence episodes	106/154	89/153	1.18 (1.00; 1.40)	0.107 (0.000; 0.214)		
Burgio, 2008[244]	Success as not receiving drugs or any other therapy for urge incontinence and a 70% or greater reduction in frequency of incontinence episodes	43/154	41/153	1.04 (0.72; 1.50)	0.011 (-0.088; 0.111)		
Burgio, 2008[244]	Completely satisfied with their progress at the end of stage 1	82/154	61/153	1.34 (1.05; 1.71)	0.134 (0.023; 0.244)	7 (43; 4)	134 (23;244)
Burgio, 2008[244]	Completely satisfied with their progress at 8 months	51/154	31/153	1.63 (1.11; 2.41)	0.129 (0.031 ;0.226)	8 (33; 4)	129 (31; 226)
Burgio, 2008[244]	Improvement with treatment as “better” or “much better” at stage 1	139/154	118/153	1.17 (1.06; 1.29)	0.131 (0.050 ;0.213)	8 (20; 5)	131 (50; 213)
Burgio, 2008[244]	Improvement with treatment as “better” or “much better” at 8 months	106/154	66/153	1.60 (1.29; 1.97)	0.257 (0.150; 0.364)	4 (7; 3)	257 (150; 364)
Zimmern, 2010[246]	Much better	63/154	46/153	1.36 (1.00; 1.85)	0.108 (0.002; 0.215)	9 (478; 5)	108 (2; 215)
Zimmern, 2010[246]	Blurriness	14/154	15/153	0.93 (0.46; 1.85)	-0.007 (-0.073; 0.058)		
Zimmern, 2010[246]	Confusion	14/154	16/153	0.8 (0.44; 1.72)	-0.014 (-0.080 ;0.053)		
Zimmern, 2010[246]	Constipation	63/154	64/153	0.98 (0.75; 1.28)	-0.009 (-0.119; 0.101)		
Zimmern, 2010[246]	Dry mouth	103/154	114/153	0.90 (0.78; 1.04)	-0.076 (-0.178; 0.025)		
Burgio, 2008[244]	Failure	75/154	49/153	1.52 (1.15; 2.02)	0.167 (0.059; 0.275)	6 (17; 4)	167 (59; 275)
Zimmern, 2010[246]	Much worse	0/154	0/153	0.00 (0.00; 0.00)	0.000 (-0.013; 0.013)		

Appendix Table F153 Comparative effectiveness of percutaneous tibial nerve stimulation versus extended-release tolterodine (results from overactive bladder innovative therapy trial)[359]

Outcome	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Subject assessment: cured	1/50	2/50	0.50 (0.05; 5.34)	-0.020 (-0.087; 0.047)		
Investigator assessment : cured	2/50	2/50	1.00 (0.15; 6.82)	0.000 (-0.077; 0.077)		
Subject assessment: improved	34/50	21/50	1.62 (1.11; 2.36)	0.260 (0.072; 0.448)	4 (2; 14)	260 (72; 448)
Subject assessment: cured or improved	35/50	23/50	1.52 (1.07; 2.16)	0.240 (0.052; 0.428)	4 (2; 19)	240 (52; 428)
Investigator assessment: improved	33/50	24/50	1.38 (0.97; 1.95)	0.180 (-0.011; 0.371)		
investigator assessment: cured or improved	35/50	26/50	1.35 (0.98; 1.86)	0.180 (-0.008 ;0.368)		
Withdrawn because treatment unsuccessful	0/50	3/50	0.14 (0.01; 2.70)	-0.060 (-0.134 ;0.014)		
Subject assessment no improvement/worsening	9/50	19/50	0.47 (0.24; 0.94)	-0.200 (-0.372; -0.028)	-5 (-35; -3)	-200 (-372; -28)
Investigator assessment no improvement/worsening	9/50	17/50	0.53 (0.26; 1.07)	-0.160 (-0.329; 0.009)		

Appendix Table F154. Nonsignificant differences in comparative effectiveness of flexible-dose solifenacin 5/10 mg with and without simplified bladder training in patients with overactive bladder syndrome (results from individual randomized controlled clinical trial)[65]

Outcome	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)
Mild adverse effects	66/323	71/320	0.92 (0.68; 1.24)	-0.018 (-0.081; 0.046)
Moderate adverse effects	68/323	66/320	1.02 (0.76; 1.38)	0.004 (-0.059; 0.067)
Serious adverse effects	6/323	6/320	0.99 (0.32; 3.04)	0.000 (-0.021; 0.021)
Severe adverse effects	16/323	12/320	1.32 (0.64; 2.75)	0.012 (-0.019; 0.044)
Treatment-related adverse effects	83/323	81/320	1.02 (0.78; 1.32)	0.004 (-0.064; 0.071)
Constipation	14/323	24/320	0.58 (0.30; 1.10)	-0.032 (-0.068; 0.005)
Dry mouth	52/323	45/320	1.14 (0.79; 1.65)	0.020 (-0.035; 0.076)
Dyspepsia	6/323	8/320	0.74 (0.26; 2.12)	-0.006 (-0.029; 0.016)
Eye disorders	15/323	14/320	1.06 (0.52; 2.16)	0.003 (-0.029; 0.035)
Gastrointestinal disorders	77/323	85/320	0.90 (0.69; 1.17)	-0.02 7(-0.094; 0.040)
General disorders and administration site	13/323	12/320	1.07 (0.50; 2.32)	0.003 (-0.027; 0.033)
Influenza and infections	52/323	45/320	1.14 (0.79; 1.65)	0.020 (-0.035; 0.076)
Musculoskeletal and connective tissue disorders	15/323	15/320	0.99 (0.49; 1.99)	0.000 (-0.033; 0.032)
Nervous system disorders	19/323	15/320	1.25 (0.65; 2.43)	0.012 (-0.023 ;0.047)
Psychiatric disorders	8/323	4/320	1.98 (0.60; 6.51)	0.012 (-0.009; 0.033)
Renal and urinary disorders	9/323	7/320	1.27 (0.48; 3.38)	0.006 (-0.018; 0.030)
Respiratory, thoracic, and mediastinal disorders	7/323	8/320	0.87 (0.32; 2.36)	-0.003 (-0.027 ;0.020)
Skin/subcutaneous disorders	11/323	5/320	2.18 (0.77; 6.20)	0.018 (-0.006; 0.042)

Appendix Table F155. Comparative effectiveness of intravaginal electrical stimulation and trospium hydrochloride in women with overactive bladder syndrome (results from individual randomized controlled clinical trial)[358]

Outcome	Active events/ randomized	Control events/ randomized	Relative risk (95% CI)	Absolute risk difference (95% CI)	Number needed to treat (95% CI)	Attributable events (95% CI)
Very satisfied or satisfied with the treatment	16/17	16/18	1.06 (0.87; 1.30)	0.05 (-0.13; 0.24)		
Experienced side-effects	8/17	5/18	1.69 (0.69; 4.16)	0.19 (-0.12; 0.51)		
Constipation	1/17	0/18	3.17 (0.14; 72.80)	0.06 (-0.09; 0.21)		
Hematuria secondary to nephrolithiasis	1/17	0/18	3.17 (0.14; 72.80)	0.06 (-0.09; 0.21)		
Urinary tract infection	1/17	2/18	0.53 (0.05; 5.32)	-0.05 (-0.24; 0.13)		
Vaginal discomfort	0/17	2/18	0.21 (0.01; 4.10)	-0.11 (-0.28; 0.06)		
Vaginal hemorrhage	0/17	1/18	0.35 (0.02; 8.09)	-0.06 (-0.20; 0.09)		
Xerostomia	5/17	0/18	11.61 (0.69; 195.26)	0.29 (0.07; 0.52)	3 (14; 2)	294 (69; 519)

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(Note that this set of references is different from those in the text of the report and the numbers are different.)

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