This report is based on research conducted by the Vanderbilt University Evidence-based Practice Center (EPC) under contract to the Agency for Healthcare Research and Quality (AHRQ), Rockville, MD (Contract No. HHSA 290-2007-10065-I). The findings and conclusions in this document are those of the authors, who are responsible for its content, and do not necessarily represent the views of AHRQ. No statement in this report should be construed as an official position of AHRQ or of the U.S. Department of Health and Human Services.

Evidence Report/Technology Assessment
Number 187

Treatment of Overactive Bladder in Women

Prepared for:
Agency for Healthcare Research and Quality
U.S. Department of Health and Human Services
540 Gaither Road
Rockville, MD 20850
www.ahrq.gov

Contract No. 290-2007-10065-I

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AHRQ Publication No. 09-E017
August 2009

Suggested Citation:
Hartmann KE, McPheeters ML, Biller DH, Ward RM, McKoy JN, Jerome RN, Micucci SR, Meints L, Fisher JA, Scott TA, Slaughter JC, Blume JD. Treatment of Overactive Bladder in Women. Evidence Report/Technology Assessment No. 187 (Prepared by the Vanderbilt Evidence-based Practice Center under Contract No. 290-2007-10065-I). AHRQ Publication No. 09-E017. Rockville, MD: Agency for Healthcare Research and Quality. August 2009.

No investigators have any affiliations or financial involvement (e.g., employment, consultancies, honoraria, stock options, expert testimony, grants or patents received or pending, or royalties) that conflict with material presented in this report.

Preface

The Agency for Healthcare Research and Quality (AHRQ), through its Evidence-Based Practice Centers (EPCs), sponsors the development of evidence reports and technology assessments to assist public- and private-sector organizations in their efforts to improve the quality of health care in the United States. This report was requested by the American Urological Association in preparation for clinical guideline development. These reports and assessments provide organizations with comprehensive, science-based information on common, costly medical conditions and new health care technologies. The EPCs systematically review the relevant scientific literature on topics assigned to them by AHRQ and conduct additional analyses when appropriate prior to developing their reports and assessments.

To bring the broadest range of experts into the development of evidence reports and health technology assessments, AHRQ encourages the EPCs to form partnerships and enter into collaborations with other medical and research organizations. The EPCs work with these partner organizations to ensure that the evidence reports and technology assessments they produce will become building blocks for health care quality improvement projects throughout the Nation. The reports undergo peer review prior to their release.

AHRQ expects that the EPC evidence reports and technology assessments will inform individual health plans, providers, and purchasers as well as the health care system as a whole by providing important information to help improve health care quality.

We welcome comments on this evidence report. 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 e-mail to **epc@ahrq.gov.**

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Acknowledgments

We are indebted to a tireless group of colleagues who made this report possible. Each step of systematic reviews draws on the skills and attention of an entire team.

Dr. Shilpa Amin has been an insightful task order officer who brought special considerations and decisions into focus. She was patient with our many questions, created a strong link with our project partner, and provided practical advice as we tackled challenges.

Ms. Rachel Bazan was our energetic student worker. She spent hours helping to track and file documents, always positive, and always ready to ensure that the project investigators had what they needed to do their work.

Dr. Liana Castel served as a quality grader and brought to the project her expertise in study design and analytic methods. We thank her for her thoughtful attention to the process of quality grading and willingness to help. Her comments on approaches to study reporting, particularly as they related to the implications of loss to followup and drop out, were especially valued.

Ms. Allison Glasser provided research assistance on this report, including combing papers for specific data points requested by the investigators and formatting summary and evidence tables. We appreciate her eagerness to learn and employ systematic review methods and her commitment to ensuring that tables were formatted exactly to specification. Ms. Glasser demonstrated great flexibility under pressure filling many needs.

Dr. Mark Hartmann brought his extraordinary attention to detail – and his commitment to perfection – to completion of the evidence tables. He spent many, many hours checking and rechecking tables both for formatting and for content. His ability to point out inconsistencies and enhance uniformity was key to ensuring smooth development of the evidence tables.

Ms. Sarah McLellan was a source of energy for all as she enthusiastically went about formatting evidence tables and completing and organizing appendices. We are grateful to lean on such detail oriented and focused research staff with a gift for encouraging others.

Ms. Toye Spencer oversaw the completion and formatting of the summary tables, and other critical elements of the report as a whole. She transferred data from investigator-developed spreadsheets into more tables than we imagined – and made sure that formatting was consistent, keeping track of the innumerable sets of changes that came her way.

Ms. Rachel Walden is a key member of the library science staff – her support of Ms. Jerome, including her creative insights and detailed approach to literature searching was invaluable. Her thoughtful attention to detail in reviewing abstracts and articles for inclusion in the review was a generous gift to the project and to the EPC as a whole.

Structured Abstract

Objectives: The Vanderbilt Evidence-based Practice Center systematically reviewed evidence on treatment of overactive bladder (OAB), urge urinary incontinence, and related symptoms. We focused on prevalence and incidence, treatment outcomes, comparisons of treatments, modifiers of outcomes, and costs.

Data: We searched PubMed, MEDLINE®, EMBASE, and CINAHL.

Review Methods: We included studies published in English from January 1966 to October 2008. We excluded studies with fewer than 50 participants, fewer than 75 percent women, or lack of relevance to OAB. Of 232 included publications, 20 were good quality, 145 were fair, and 67 poor. We calculated weighted averages of outcome effects and conducted a mixed-effects meta-analysis to investigate outcomes of pharmacologic treatments across studies.

Results: OAB affects more than 10 to 15 percent of adult women, with 5 to 10 percent experiencing urge urinary incontinence (UUI) monthly or more often. Six available medications are effective in short term studies: estimates from meta-analysis models suggest extended release forms (taken once a day) reduce UUI by 1.78 (95 percent confidence interval (CI): 1.61, 1.94) episodes per day, and voids by 2.24 (95 percent CI: 2.03, 2.46) per day. Immediate release forms (taken twice or more a day) reduce UUI by 1.46 (95 percent CI: 1.28, 1.64), and voids by 2.17 (95 percent CI: 1.81, 2.54). As context, placebo reduces UUI episodes by 1.08 (95 percent CI: 0.86, 1.30), and voids by 1.48 (95 percent CI: 1.19, 1.71) per day. No one drug was definitively superior to others, including comparison of newer more selective agents to older antimuscarinics.

Current evidence is insufficient to guide choice of other therapies including sacral neuromodulation, instillation of oxybutynin, and injections of botulinum toxin. Acupuncture was the sole complementary and alternative medicine treatment, among reflexology and hypnosis, with early evidence of benefit. The strength of the evidence is insufficient to fully inform choice of these treatments. Select behavioral interventions were associated with symptom improvements comparable to medications. Limited evidence suggests no clear benefit from adding behavioral interventions at the time of initiation of pharmacologic treatment.

Conclusions: OAB and associated symptoms are common. Treatment effects are modest. Quality of life and treatment satisfaction measures suggest such improvements can be important to women. The amount of high quality literature available is meager for helping guide women's choices. Gaps include weak or absent data about long-term followup, poorly characterized and potentially concerning harms, information about best choices to minimize side effects, and study of how combinations of approaches may best be used. This is problematic since the condition is chronic and a single treatment modality is unlikely to fully resolve symptoms for most women.

Contents

Tables

Figures

Appendixes

Appendixes and Evidence Tables for this report are provided electronically at
http://www.ahrq.gov/downloads/pub/evidence/pdf/bladder/bladder.pdf**.**

Executive Summary

Introduction

Importance of Overactive Bladder Treatment

At minimum, 11 to 16 million women in the United States cope on a daily basis with symptoms that include sudden strong urges to urinate, difficulty delaying voids, frequent trips to the bathroom, and in many cases involuntary loss of urine when urgency strikes.[1-4] They may wear pads for accidents, plan ahead for access to bathrooms, and modify their social and work lives to accommodate their symptoms. Some are very distressed by the symptoms whether mild or severe, and others find mechanisms to adapt, reporting little trouble with symptoms or interference with normal routines. Others report their symptoms negatively influence quality of life factors as varied as self-esteem, self-assessment of attractiveness, and sexual function. Many women believe that some amount of urinary incontinence is inevitable with aging. The majority of women with these symptoms do not talk with their health care providers concerning their bladder dysfunction, and providers may not systematically inquire. As a result, a small minority receive treatment.

Popular wisdom encourages self-management of symptoms of OAB through reduction of fluid intake, cutting back on caffeine, modifying voiding habits, and taking note of what individual factors influence severity of symptoms.

For this review, we operationally defined OAB as "idiopathic urinary urgency and frequency with or without associated urge urinary incontinence in adult females, not related to neurogenic conditions or as a result of (stress incontinence) surgery." The report is focused on treatments that are prescribed or provided by a healthcare practitioner and have been formally investigated including:

- Pharmacologic treatments, including prescription medications, both pills and patches
- Surgeries and procedures, such as sacral neuromodulation and botulinum injections
- Behavioral interventions, such as behavior modification programs and bladder training
- Complementary and alternative medicine, such as acupuncture and reflexology

OAB management is usually individualized to address the component symptom(s) that the patient finds most bothersome. Where possible, we have tried to address treatments with respect to the primary component symptoms of OAB: urge urinary incontinence, urgency, and frequency, so that the women, their health care providers, payors, policy-makers, and others have a detailed picture of the expected outcomes of available treatments.

Key Questions

In preparing this report, we have answered the following key questions:

KQ1. What is the prevalence and incidence of overactive bladder as estimated in representative populations?

KQ2. Among women with overactive bladder, what are the short and long-term outcomes of the following treatment approaches, or combinations of treatment approaches?

a. Pharmacologic treatments
b. Procedural and surgical treatments
c. Behavioral and physical therapy treatments
d. Complementary and alternative medicine treatments

KQ3. Where direct comparisons have been made between or among treatment modalities of interest, which modalities achieve superior outcomes with respect to benefits, short and long-term risks, and quality of life?

KQ4. Are the short and long term outcomes of these treatment approaches modified by clinical presentation, physical exam findings, urodynamic findings, menopausal status, age or other factors?

KQ5. What are the costs associated with these treatment approaches?

Methods

Literature search. We employed multi-term search strategies to retrieve research about treatment of overactive bladder in women, including exploration of three databases: PubMed, MEDLINE®, EMBASE, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL). We also hand-searched the reference lists of relevant articles to identify additional studies. Controlled vocabulary terms served as the foundation of our searches in each database, complemented by additional keyword phrases to represent the myriad ways in which overactive bladder is referred to in the clinical literature. We also employed indexing terms within each of the databases to exclude undesired publication types (e.g., reviews, case reports, CME handouts) and items published in languages other than English. We excluded studies that (1) were published in languages other than English; (2) did not report information pertinent to the key questions; (3) had fewer than 50 participants [at enrollment]; (4) were not original studies; and (5) provided data only for stress or mixed urinary incontinence.

Study selection. Two reviewers separately evaluated abstracts for inclusion or exclusion. If one reviewer concluded the abstract should be included for full review of the article, it was retained. For the full article review, two reviewers read each article and decided whether it met our inclusion criteria. Discordance was resolved by third-party adjudication.

Quality assessment. The research team used a quality assessment approach that ensured capture of key points most relevant to this literature. Quality was assessed by two reviewers independently, who resolved differences through discussion, review of the publications and coming to consensus with the team.

Data extraction. All team members shared the task of entering information into the evidence tables. After initial data extraction, another member of the team reviewed the article and checked all table entries for accuracy, completeness, and consistency. The two abstractors reconciled disagreements concerning the information reported in the evidence tables.

Evidence synthesis. The information included in tables reflects those outcomes most consistently reported in the literature: urge incontinence episodes and number of voids per day. (Studies with weekly or other metrics that could be converted to daily metric are included.) When common measures were available across studies using roughly comparable assessments (i.e., index questions, time intervals, etc.), we compiled tables to summarize outcomes of treatments. Measures of quality of life, interference with daily activities, degree of distress from symptoms, and satisfaction with the outcomes of treatment were also common and helpful metrics in this literature.

For behavioral, surgical, and complementary and alternative treatments, we produced evidence tables, summary tables of common outcomes where possible, and provided analysis in text form. For pharmacologic treatment, we produced similar summary tables and conducted a limited meta-analysis.

Conduct of meta-analysis. Descriptive statistics were computed and examined for homogeneity among studies. Studies that reported weekly rates for UUI (urinary urge incontinence) episodes and voids were standardized to daily rates. When only ranges of continuous variables were reported (instead of standard deviations), we estimated the standard deviations by dividing the range by four.[5] Study results were combined and summarized using two meta-analysis techniques, weighted averages and fixed effects regression models.[6] Minimum variance weighted averages of the mean daily decrease in UUI and voids per arm were computed using weights that were inversely proportional to their standard errors. To borrow strength across arms, we used fixed effect regression models with robust standard errors (to account for the clustering by study), and weighted the study arms inversely proportional to their standard errors of the mean. Each arm was treated as a fixed effect, and study was not included in the model except in the sense that the clustering was addressed by the robust standard errors. Fixed effects models were also adjusted for mean age and proportion of women in each arm.

Literature search yield. As a result of the search, 2,559 non-duplicate articles were identified. Two hundred thirty-two articles were included in the review, representing one hundred seventy-nine distinct studies, with 75 articles pertaining to KQ1, 150 to KQ2, 34 to KQ3, 32 to KQ4, and 5 to KQ5. Reasons and process for exclusions are described in the full report.

Conflict of interest. We used a two-step process to describe the contribution of industry-sponsored research to the evidence base. The first step was to calculate the proportion of publications that explicitly state the source of the funding for research, and the second step was to calculate the proportion supported by industry *among those that report funding source*. These counts are important because several studies have shown that industry-sponsored research tends to produce results that are favorable to the drug manufacturer even when the research is conducted in academic medical centers.[7-9]

Results

KQ1. Prevalence and incidence of overactive bladder

Content of the literature. We identified 75 publications,[2-4, 10-81] from 60 distinct study populations. Fifteen studies were conducted in United States populations; 24 in European populations; 13 Asian; and 8 in other countries. Thirty-eight of these studies (63 percent) appeared in print after the 2002 International Continence Society (ICS) revised definitions and 37 percent of these reported specifically about incidence or prevalence of OAB. One study prior to the standardized definitions used fully comparable definitions and the term “overactive bladder”. The strength of the evidence for understanding prevalence of OAB is moderate and for understanding incidence is weak.

Prevalence estimates. A total of 15 studies provided information specifically about OAB prevalence in adult women. These studies included a total of 64,528 women in 16 distinct populations. Estimates of prevalence ranged from 7.7 to 31.3 percent. Across all studies the

average prevalence of OAB was 16.1 percent. Excluding the highest and lowest estimates, an estimated 15.1 percent of women meet criteria for OAB, with 8.2 percent of those surveyed, having OAB with a component of urge incontinence. Combined estimates from the two populations from the United States are similar 15.1 percent with OAB and 11.0 percent with a component of urge incontinence.

A larger number of studies (n=48) examined urge urinary incontinence as the primary prevalence estimate of interest. Twenty-eight appeared after the ICS 2002 standardization of definitions. Across populations, prevalence of urge incontinence ranged from 1.5 to 22.0 percent. Average urge incontinence prevalence was 9.7 percent in the United States, 10.6 percent in Europe, and 9.6 percent in Asia.

Incidence and resolution. Ten studies provided incidence data and two reported on resolution of symptoms. Estimates for annual incidence of OAB ranged from 2.6 to 143 cases per thousand, with higher estimates in the oldest population groups. A proportion of cases, 23 percent to 35 percent, resolve over a year's time; however the majority of women have symptoms for years. No studies evaluated lifetime natural history.

KQ2: Outcomes of Treatment for Overactive Bladder

Pharmacologic treatment.

Content of the literature. We identified 13 randomized controlled trials (RCTs) of oxybutynin for treatment of OAB. A total of 22 study arms compared oxybutynin at varied doses, formulations, and intervals. These studies included five placebo arms. Most participants were recruited from specialty populations with seven studies performed in the United States,[82-88] three in Europe,[89-91] and one each in Japan,[92] Taiwan,[93] and South Korea.[94] These studies included a total of 2,575 women in treatment arms, and 383 women in the placebo arms.

For tolterodine there were 19 RCTs, including 29 drug arms and 13 placebo arms. Most were multinational studies conducted at centers in Europe, the United States, Australia, and Asia. A total of 6,564 women were in the treatment arms, with 3,109 women in the placebo arms.

Two RCTs compared fesoterodine at 4 and 8 mg to placebo for reducing symptoms of OAB and met criteria for inclusion in the systematic review.[95, 96] These studies included a total of 1,017 women in the treatment arms, and a total of 518 women in the placebo arms.

Three RCTs investigated solifenacin compared to placebo for reducing symptoms of OAB.[97-99] These studies included a total of 1,541 women in the solifenacin treatment arms, and a total of 638 women in the placebo arms.

Four RCTs provided data on the effectiveness of darifenacin.[82, 100-102] These four studies included at total of 690 women in the darifenacin treatment arms and a total of 304 women in the placebo arms.

Five RCTs evaluated trospium for reduction of symptoms of OAB. Four trials compared trospium to placebo, and one compared trospium to oxybutynin. Four were conducted in the United States,[103-106] and the fifth at multiple centers in Europe and Asia.[90] These studies included a total of 1,309 women in the trospium treatment arms, and a total of 1,130 women in the placebo arms.[103-106]

Three studies assessed the role of oral estrogen therapy in different doses and formulations in the alleviation of OAB symptoms.[107-109] All studies were performed in Europe and Scandinavia with a total of 514 women. Two were RCTs and one was a prospective cohort. After review and analysis of all 110 studies, of which four were good quality, 75 fair and 31 poor, including 68

RCTs, the strength of the evidence for managing OAB with pharmacologic treatment is weak to moderate for short term outcomes and weak for long term outcomes and harms.

Outcomes of treatment. All pharmacologic treatments were effective at improving one or more OAB symptoms when compared to placebo. Reductions ranged from 0.9 to 4.6 in incontinence episodes per day across all drug treatments and from 0.7 to 4.2 in voids per day. Study by study, extended release formulations achieved modestly better effects than immediate release, statistical significance varied. No one drug was definitively superior to others by preponderance of evidence, including more recently approved drugs. As estimated by meta-analysis, extended release forms (taken once a day) reduce UUI by 1.78 (95 percent CI: 1.61, 1.94) episodes per day, and voids by 2.24 (95 percent CI: 2.03, 2.46) per day. Immediate release forms (taken twice or more a day) reduce UUI episodes by 1.46 (95 percent CI: 1.28, 1.64) per day, and voids by 2.17 (95 percent CI: 1.81, 2.54) per day. Of note, placebo reduces UUI episodes by 1.08 (95 percent CI: 0.86, 1.30), and voids by 1.48 (95 percent CI: 1.19, 1.71) per day. Even in the context of small to moderate affect on symptoms, pharmacologic treatments were generally associated with increased quality of life and reductions in measures of impact or distress, compared to baseline and to placebo.

Table 1 below provides estimates of treatment effects for pharmacologic treatments represented by more than one trial arm. Some drugs and doses of drugs are not reported because the publications with trial arms for that treatment did not provide sufficient information to estimate variance in meta-analysis models.

Table 1. Estimates of mean reductions in incontinent episodes and voids per day

Drug	Decrease in Incontinent Episodes per Day			Decrease in Voids per Day		
	Estimate	95% CI		Estimate	95% CI	
Single drug estimates						
Placebo	1.08	0.86	1.30	1.48	1.19	1.71
Oxybutynin IR	1.49	1.18	1.80	2.18	1.75	2.61
Oxybutynin ER	*	*	*	*	*	*
Tolterodine IR	1.45	1.24	1.66	2.19	1.76	2.61
Tolterodine ER	1.75	1.65	1.85	2.48	1.94	3.02
Fesoterodine	2.03	1.74	2.31	1.84	1.64	2.03
Darifenacin	*	*	*	*	*	*
Solifenacin	1.46	1.32	1.59	2.19	1.94	3.02
Trospium IR	*	*	*	*	*	*
Trospium ER	2.45	2.19	2.70	2.68	2.38	2.98
Combined comparison of extended versus immediate release formulations						
Placebo	1.08	0.86	1.30	1.48	1.19	1.71
Extended Release	1.78	1.61	1.94	2.24	2.03	2.46
Immediate Release	1.46	1.28	1.64	2.17	1.81	2.54

*Estimates could not be calculated for these formulations because publications did not include adequate data on variance for weighting of the raw data.

Since baseline episodes of UUI per day ranged from 1.6 to 5.3, and voids per day from 7.2 to 13.7, these reductions (Table 1) reflect modest margins of benefit from baseline above placebo. Data was not consistently provided across studies to estimate the proportion of women who became symptom free.

Procedural and surgical treatment.

Content of the literature. We identified 18 studies about surgical treatments and procedures for OAB. Eleven were of sacral neuromodulation, one of peripheral neuromodulation, and one of electromagnetic therapy. Three studied bladder instillation or injection of drugs; one was on bladder distention; and one about bladder transection. This literature included 13 case series studies: nine prospective[110-118] and three retrospective.[119-121] One study had both retrospective and prospective components.[122] Given consideration of 18 studies, of which 11 were fair quality and seven poor, including five RCTs, the strength of the evidence for managing OAB with procedural and surgical treatment is weak for all aspects of understanding outcomes of care.

One study was a prospective cohort that compared outcomes among participants receiving sacral neuromodulation to participants who had lead placement without activation of electrical stimulation.[123] Four studies were RCTs: one looked at sacral neuromodulation versus medical therapy,[124] one evaluated transcutaneous electromagnetic stimulation versus sham,[125] and two evaluated instillation of a drug into the bladder versus placebo – one using oxybutynin[126] and one using resiniferatoxin.[127]

Outcomes of treatment. Among the trials of procedures and surgery, one study demonstrated a statistically significant benefit of sacral neuromodulation over usual care for the reduction of episodes of incontinence per day (average reduction of 7.1 compared to 2.1 increase among subjects who had failed medical management).[124] One trial demonstrated benefit of instillation of oxybutynin compared to sterile water in the reduction of voids per day (average reduction of 6.8 compared to 2.4)[126] and another reported benefits from botulinum toxin treatment which is compatible with the findings of a recent Cochrane Collaboration literature review and meta-analysis.[128]

Behavioral interventions.

Content of the literature. We identified nine studies that included only behavioral approaches; no two studies compared the same set of approaches. They included assessment of bladder training, multicomponent behavioral training, with or without biofeedback, pelvic muscle exercises or training, vaginal electrical stimulation, and caffeine reduction. The literature base included three retrospective case series.[129-131] All three were conducted in community-based clinical settings.

One prospective cohort study compared three approaches to providing bladder training: self-administered, coaching, and cognitive strategies.[132] Five studies were RCTs. One compared bladder training to a "control" condition.[133] One compared bladder training to pelvic muscle exercises.[134] One included three arms: pelvic floor muscle training, pelvic floor muscle training assisted with biofeedback, and vaginal electrical stimulation.[93] Another compared three different approaches to multicomponent behavioral training: biofeedback, verbal feedback and self-administered.[135] A last study compared bladder training to bladder training with caffeine reduction.[136] After review and analysis of 29 studies, of which 14 were fair quality and 15 poor, including 17 RCTs, the strength of the evidence for managing OAB with behavioral approaches treatment is moderate to weak for short term outcomes and weak for long term outcomes and harms.

Outcomes of treatment. No two studies could be combined to produce summary data. Overall, behavioral approaches can be effective in reducing episodes of incontinence and daily voids. Multicomponent approaches are most effective, and they perform relatively equivalently to pharmacologic treatment. Generally speaking, improvements were modest, with decreases in

incontinence episodes of up to 1.9 per day, and reductions in voids per day of up to about four. The addition of caffeine reduction reduced frequency, but made no difference in reduction of incontinence episodes. There is no evidence that behavioral approaches enhance the effectiveness of pharmacologic therapy for reducing episodes of incontinence or voiding, although they may improve patient satisfaction and quality of life measures.

Complementary and alternative therapies.

Content of the literature. We identified three studies that used complementary and alternative medicine therapies to treat OAB: a fair quality trial of acupuncture,[137] a fair quality trial of foot reflexology,[138] and a poor quality prospective case series of hypnotherapy.[139] There is weak to no evidence for complementary and alternative approaches to managing OAB.

Outcomes of treatment. The small trial of acupuncture has intriguing results related to decreased frequency of voiding and reduced symptoms of urgency which are associated with changes in cystometrics related to improved bladder capacity that are logical intermediates of the improvement in symptoms. Women felt they were improved as measured by scales that capture bother and quality of life. Evidence is insufficient to support definitive choice of acupuncture but offers preliminary information that promises modest improvements similar to those reported in many pharmacologic trials.

Reflexology is represented by a small trial with unmasking of participants that could have biased the results. No evidence supports choice of this modality. Likewise, hypnotherapy is not supported by the scant information provided by one case series with little detail, patient reported outcomes, or statistical assessment. Given the scope of placebo effects demonstrated in other well-conducted studies of OAB treatment, it is difficult to know whether to attribute any effect to hypnotherapy.

Conflict of interest. Changing trends in editorial standards have resulted in more complete reporting of funding source and author conflict of interest over the period in which the OAB literature was developing. Sources of funding were not reported for the majority of publications that appeared in the 1980s; and no publications in that decade reported on author conflict of interest. In the 1990s through the end of 2008, nine (56 percent) studies of procedural treatments (including sacral neuromodulation and bladder instillation or injection) reported source of funding, and six of the nine studies (67 percent) were industry sponsored. The other three were institutionally funded. Among studies of medications, 89 (77 percent) reported source of funding and among those, 82 (92 percent) were industry sponsored. Among studies that had a behavioral component, 13 (68 percent) reported on funding source and four had industry support. Author conflict of interest was poorly reported until the current decade, with fewer than half of all publications providing information. Within papers that did report conflict of interest, more than half of the authors (272 of 407) indicated that they had a financial relationship with one or more companies relevant to the research.

KQ3: Comparisons of Treatments

Comparisons between pharmacologic treatments.

Content of the literature. Twelve RCTs included direct comparisons of pharmacologic approaches. Specific comparisons have been made in the literature for the following pairs of drugs to identify differences in reduction in urge urinary incontinence or voids per day:

- Oxybutynin ER to Tolterodine ER[84]
- Oxybutynin ER to Tolterodine IR[83]

- Oxybutynin IR to Tolterodine IR[89, 91, 94]
- Oxybutynin IR to Darifenacin[82]
- Oxybutynin IR to Trospium IR[90]
- Oxybutynin TDS to Tolterodine ER[88]
- Tolterodine ER to Tolterodine IR[140, 141]
- Tolterodine ER to Solifenacin[99]
- Tolterodine ER to Fesoterodine[96]
- Tolterodine IR to Solifenacin[97]

Outcomes of treatment. In the majority of comparisons, neither drug was reported more effective at reducing either incontinence episodes or voids per day with a few exceptions. Both oxybutynin and tolterodine in their extended release forms demonstrated superiority in reducing urge incontinence episodes over tolterodine immediate release.[83, 140, 142] Oxybutynin extended release was more effective at reducing voids per day than tolterodine in immediate[83] or extended release formulations.[84]

Comparisons between procedural and pharmaceutical treatments.

Content of the literature. One RCT compared sacral neuromodulation to medical therapy. In this study, 98 participants were randomized to immediate sacral nerve stimulation or delayed sacral nerve stimulation. The delay group continued unspecified medical management for a six month period before having the procedure.

Outcomes of treatment. This study, which randomized after successful test stimulation, found a reduction in daily urge incontinence episodes from 9.7 to 2.6 in the sacral neuromodulation group, compared to an increase of 9.3 to 11.3 in the medical management group at 6 months ($p<0.01$) for patients with refractory OAB.124 At 18 months, 76 percent of participants receiving sacral neuromodulation reported that they were completely dry or had experienced a reduction in symptoms of 50 percent or greater. Note that the comparison is not ideal, as subjects continuing to receive medical therapy had already failed medical management.

Comparisons between behavioral and pharmacologic treatments.

Content of the literature. Seven studies (nine papers) included behavioral and pharmacologic arms in direct comparisons.[93, 143-150] This literature included one prospective cohort study,[147] and six RCTs.[93, 143-146, 148-150]

The behavioral approaches examined included bladder training,[151 146-150] multicomponent behavioral approaches,[143-145] and electrical stimulation.[93]

One study reported significantly greater reductions in incontinence episodes with multicomponent behavioral modification compared to oxybutynin,[143] but no studies found a difference in reductions in voids per day. In the same study that found greater reductions in incontinence with behavioral treatment, participants reported higher satisfaction with behavioral compared to pharmacologic interventions.

Comparison of combined behavioral and pharmacologic treatment to pharmacologic alone.

Content of the literature. Six studies examined the effect of adding a behavioral intervention to drug compared to drug alone.[150-155] In all but one study, the drug was tolterodine. The literature included five RCTs[150-152, 154, 155] and one randomized open-label trial.[153]

Outcomes of treatment. No added benefit for reducing incontinence episodes or voids per day was found by adding behavioral treatments to pharmacologic approaches for reduction in

incontinence. Two studies associated the addition of behavioral modification with reductions in voids per day, but two reported no difference.

KQ4: Modifiers of Treatments

Age. Eight publications examined the relationship of age to response to pharmacologic treatment.[83, 102, 156-161] Tolterodine was the focus of four of these studies;[156-158, 160] and one compared oxybutynin to tolterodine.[83] The largest study of tolterodine using clinically adjusted doses, was from an open-label clinical cohort of 2,250 patients from 462 urology practices in Germany. Participants on average were taking 2 mg per day and age did not predict response.[157] No studies reported lack of efficacy for reducing UUI, voids per day, or symptom distress among older participants. While effect was in some cases reduced, it was not the case that age predicted worse treatment response. Older individuals do benefit from treatment.

Prior treatment. Eight publications investigated whether prior treatment with antimuscarinics predicted treatment response.[85, 86, 102, 162-165] In two placebo-controlled trials of oxybutynin transdermal system[85] and tolterodine IR,[162] participants who had previously been on medication for OAB had comparable outcomes to those who were treatment naïve. The tolterodine study specifically commented on prior treatment failures, noting improvements among those who had failed prior treatments that were above placebo but not statistically significant; few participants were in this category making conclusions difficult to reach.[162]

Baseline severity. Two studies contrasted those with UUI at baseline to those without. In an open-label study of 3,824 participants with nine months of treatment, urgency, frequency, nocturia, and OAB scales were similarly improved regardless of UUI baseline status.[166] In the other, open-label, study of solifenacin, with the exception of nocturia, the point estimates for improvement in individual OAB indicators were better in the group with UUI at baseline though not in each instance statistically significantly better than among those without UUI.[167]

Severity of UUI, grouped as severe for those with 21 or more episodes per week, did not prevent tolterodine from having an effect above placebo, and both severe and non-severe groups had a high percentage reduction in incontinence episodes per day: a decrease of 67.6 percent among those with severe UUI and 71.4 percent among those with mild to moderate UUI.[168] In another study, those with severe baseline symptoms were less likely than others be symptom free at 12 weeks.[157] Cure rates were reported to be comparable when comparing participants with UUI to those with MUI.[169]

Urodynamic findings. Five publications related baseline urodynamic findings to outcomes of treatment.[89, 170-173] Three did not identify urodynamic findings that predicted poor response or non-response to treatment. Both women with and without detrusor instability had comparable benefits from treatment.[171] Classification of participants as having detrusor overactivity or sensory urgency based on urodynamics was not statistically significant as an effect modifier or predictor of treatment outcomes.[170] The third study to group participants by urodynamic findings had group sizes (n = 6, 25, 36, 40) too small to make definitive assessments but suggested in the two larger groups that those with low volume and high pressure profiles had comparable results to those with low volume and low pressure profiles. Among women with proven detrusor instability, those with detrusor activity in response to provocations like washing hands or running water, were less likely to improve,[172] and women who reported coital incontinence were more likely to be non-responders to treatment.[173]

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BMI. A single trial of tolterodine ER, tolterodine IR, and placebo (n=1,235) reported that women who were above the mean for BMI (> 27kg/m^2) were more likely to have UUI at baseline but achieved comparable results after 12 weeks of treatment.

Gender. Authors frequently reported that men, especially older men, fared less well in resolution of symptoms of OAB.[85, 106, 156, 157, 174] This evidence review was focused on outcomes of treatment among women. However, in order to retain landmark studies we included a number of studies that enrolled men as long as the proportion of women in the study was 75 percent or more. This means that treatment effects may be attenuated when men are included.

KQ5: Costs of Treatments

Content of the literature. We identified five studies on financial costs related to OAB that met criteria for inclusion.[175-179] All studies included assessment of direct medical costs, and two included costs due to lost productivity. One study additionally assessed financial implications for pain and suffering.

Costs of treatment. Total direct health care costs for women with OAB in 2000 were estimated at $6.9 billion, of which $1.1 billion were for pharmacologic treatment and $550 million for surgical treatment. The rest was estimated for "consequences" costs, which would include things like falls, longer hospital length of stay and skin conditions. Medication costs for OAB with the two most commonly used drugs (oxybutynin and tolterodine) ranged from $56 to $360 over a twelve month period for newly diagnosed patients. However, total health care costs were highest for patients who take oxybutynin, relative to tolterodine in any formulation, with costs lowest for patients on tolterodine ER. Explanations for this were not apparent.

Discussion

The study of OAB as a syndrome is entering its second decade. As is typical of advancing areas of research, publications based on case series are giving way to observational cohorts. Trials, beyond those required for FDA approval of indication for OAB, are appearing in the literature and health services researchers are investigating population-level factors such as cost of care and risk of rare but serious side effects of treatments.

The 2002 ICS standardization of terminology[180] was associated with a productive trend toward greater attention to and clarity of operational definitions in research. Documentation of inclusion and exclusion criteria, baseline characteristics, and change in symptom profiles have

become more detailed and nuanced in the last five to seven years. Improved clarity about research definitions for conducting the study and analyzing data was the case even when authors departed from ICS definitions. Simultaneously important research gains have been made in crafting, refining, and validating questionnaire and interview instruments for classifying symptoms, assessing severity of symptoms, describing impact of OAB on quality of life, and measuring satisfaction with outcomes. Despite this momentum the overall content of the current literature is fair to poor with a preponderance of study designs that do not provide strong evidence.

We find a concerning lack of high-quality evidence to inform clinical decision-making for millions of women in the United States. Medications can provide symptom relief which is often not complete, but valued by women who struggle with OAB. Well-conducted trials of greater duration and sophistication, separate from drug development and marketing efforts, are crucial. Because benefits of current treatments are modest, opportunities exist to study how to gain synergy from combinations of types of treatments. We must note that lack of evidence of benefits is not equivalent to evidence of no benefit. A number of treatments that are potentially promising warrant continued investigation. Cross-cutting concerns about the quality of research must be addressed to achieve literature that can be meaningfully synthesized. Current literature does not permit definitive conclusions about relative benefit, harm, or costs to achieve similar results. Given how common and concerning OAB is, a priority on promoting high-quality research in the United States is imperative. Women and their care providers deserve better information to guide their choices.

Evidence Report

Chapter 1. Introduction

Importance of Overactive Bladder Treatment

At minimum, 11 to 16 million women in the United States cope on a daily basis with symptoms that include sudden strong urges to urinate, difficulty delaying voids, frequent trips to the bathroom, and in many cases involuntary loss of urine when urgency strikes.[1] They may wear pads for accidents, plan ahead for access to bathrooms, and modify their social and work lives to accommodate their symptoms. Some women are very distressed by the symptoms whether mild or severe, and some find mechanisms to adapt, reporting little trouble with symptoms or interference with normal routines. Others report their symptoms negatively influence factors as varied as self-esteem, self-assessment of attractiveness, and sexual function. Many women believe that some amount of incontinence is inevitable with aging and the majority of women with these symptoms do not talk with their health care providers about their concerns with bladder function. As a result, a small minority receive treatment.

Defining OAB

Overactive bladder syndrome, referred to as OAB in this report, is formally defined as:

- urgency, which is the complaint of sudden need to void;
- with or without urge incontinence, involuntary loss of urine with urgency symptoms;
- usually with frequency, which is the individual's perception that she voids too often during the day, and is often defined as more than eight voids during waking hours;
- usually with nocturia, which is awakening from sleep to empty the bladder.

This operational definition was formally standardized as part of a consensus process of experts, in 2002 by the International Continence Society (ICS) as part of an effort to promote healthcare professionals' and researchers' use of common terminology in the care and study of women with OAB. Components of the syndrome have had varied, and at times conflicting, nomenclature that include detrusor (bladder muscle) instability; detrusor dysfunction; detrusor dysynergia; detrusor overactivity, and irritable bladder. In each case, these terms shared a causal model that hypothesizes that mistimed or poorly regulated bladder contractions create the sensation of sudden need to void with or without leakage. However clinical study of bladder muscle function using urodynamic testing to measure characteristics like bladder capacity, pattern and timing of bladder contractions, and bladder volume at which women first experienced the urge to void, did not reveal uniform test results among women who had identical complaints. Lacking a reliable biologic marker to define and describe the severity of the condition with objective tests of the bladder itself, clinicians, researchers, pharmaceutical companies, and others came to conceptualize the symptoms of OAB, which often appeared in combination, as a syndrome.

Syndromes are medical conditions defined by the symptoms, which are the sensations (urgency), changes (frequency), or events (incontinence episodes) experienced by the individual. A syndrome is not defined by a known biologic cause. The pathophysiology of OAB is incompletely characterized and the syndrome is a diagnosis of exclusion reached when other causes of the symptoms, like urinary tract infection, urethral inflammation, or neurologic causes of incontinence are ruled out as the cause. OAB symptoms may be life long, relapsing and

remitting; or may completely resolve; which manifestations of the syndrome a woman has may also vary over time. However followup studies that track women who have OAB find that on average it is a chronic condition that women experience for a year or more at a time, and may have into the indefinite future.

Little is known about causes and most physiology and clinical research aimed at understanding etiology is now focused at the descriptive and hypothesis development and testing phase of investigation. The most promising theories postulate abnormalities in control of bladder function resulting from aberrations in neurologic signals from the bladder (sensation) and in central and peripheral nervous system regulation.

OAB and Awareness of the General Public

Prior to the mid-1990s research and clinical care focused on describing and managing frank incontinence. The term "overactive bladder" was introduced into the lexicon in the mid-1990s by Pharmacia (acquired by Pfizer in 2002) to describe the frequent urge to urinate as part of its advanced marketing campaign of Detrol (tolterodine). The company framed this as an opportunity to "destigmatize" a range of symptoms encompassing urgency, frequent voiding, and urge incontinence, so that patients would not be afraid to speak with their doctors about the problem.[181] The construct – and subsequent marketing success – of OAB medications revolved around encouraging women to reflect on how their symptoms influenced their quality of life and the degree to which the symptoms caused inconvenience, emotional distress, withdrawal from activities, or sexual problems.

As a result, a broader spectrum of women, extending beyond those with incontinence, became candidates for treatment. This included those who were inconvenienced by or worried about frequent urination or who engaged in what has been referred to as "defensive voiding", emptying the bladder in an attempt to extend the interval between symptoms or to reduce the amount of urine that leaks with incontinence, and "toilet mapping," being aware of where bathrooms are and canvassing new locations to be sure the options are known. The group of those encouraged to consider treatment also came to include women who perceive they urinate more than "normal" and women whose jobs or lifestyles do not accommodate frequent, strong urges to urinate. Early advertisements featured school crossing guards and jurors who could not readily take a break. Momentum toward a very broad definition in marketing was a factor in the updated consensus definition of OAB by the ICS in 2002, so that the biomedical community would have an opportunity to formally standardize the definition with specificity.

Marketing of drug and the drug indication to physicians occurred through the usual channels, such as paid educational trips, speaking engagements, outsourcing drug studies, etc.[182, 183] Nearly simultaneously, as a result of less restrictive rules about direct to consumer marketing, women were reached directly through the power of television and print media in new ways.[184] Use of "buzz drivers," or people paid to promote the drug during news broadcasts or celebrity interviews came into play as new marketing techniques.[185] By 2006, the first drug to specifically target the broader definition of OAB hit the blockbuster mark of $1 billion in sales for the year.[186] Two drugs, tolterodine tartrate and oxybutynin, were the only drugs approved in the United States specifically for OAB until 2004 when trospium, darifenacin, and solifenacin were introduced.[187] Fesoterodine, a metabolite of tolterodine was approved in October 2008. Oxybutynin is now available in a transdermal formulation. Thus over roughly a decade – a very short time window in clinical medicine – both the condition of OAB and pharmaceutical treatments for OAB became part of the consciousness of the public and the general medical community alike.

Treatment Options

Popular wisdom encourages self-management of symptoms of OAB through reduction of fluid intake, cutting back on caffeine, modifying voiding habits, and taking note of what factors like phase of the menstrual cycle, food choices, or contraceptives may influence severity of symptoms in order to adapt or reduce the impact of OAB. Over-the-counter remedies like cranberry capsules and herbal preparations are reported to promote bladder health, reduce bladder irritation, or reduce the urgency associated with bladder infections while also taking antibiotics, have crossed-over into use by women who have the symptoms without an infection. While perhaps quite common, these strategies are not well-reflected in the scientific literature.

This report is focused on those treatments that have been formally investigated including:

- Pharmacologic treatments, including prescription medications, both pills and patches
- Surgeries and procedures, such as sacral neuromodulation and botulinum injections
- Behavioral interventions, such as behavior modification programs and bladder training
- Complementary and alternative medicine, such as acupuncture and reflexology

Note that when initiated, treatment should be prompted by distress over symptoms and their influence on quality of life. The symptoms are not *de facto* harmful, though consequences such as sleep interruption or risks of falls and fractures from rushing to the toilet may be harmful.[188, 189] As a result OAB management is usually individualized to address the component symptom(s) that the individual finds most bothersome. Where possible we have tried to address treatments with respect to the primary component symptoms of OAB: urgency, frequency (daytime and nighttime), and urge urinary incontinence, so that the women, their health care providers, payors, policy-makers and others have a detailed picture of the expected outcomes of available treatments.

This Evidence Report

Scope of the Report

Evidence reviews of therapeutics seek to identify and systematically summarize objective information about the evidence related to:

- Effectiveness of specific, well-defined treatments
- Relative benefit of one treatment over another
- Common side effects and serious risks of a treatment
- Whether individual characteristics help predict who will benefit or be harmed
- Degree to which individuals find the treatment acceptable or satisfactory
- Costs of care or risk-benefit assessments

Key Questions

For this review, we operationally defined OAB as "idiopathic urinary urgency and frequency with or without associated incontinence in adult females, not related to neurogenic conditions or as a result of (incontinence) surgery." This review is restricted to OAB, rather than exclusively mixed incontinence, stress incontinence, painful bladder syndrome, and other lower urinary tract symptoms (LUTS).

We have synthesized evidence in the published literature to address these key questions:

KQ1. What is the prevalence and incidence of overactive bladder as estimated in representative populations?

KQ2. Among women with overactive bladder, what are the short and long-term outcomes of the following treatments, or combinations of treatment approaches:

a. Pharmacologic treatments
b. Surgical and procedural treatments
c. Behavioral and physical therapy treatments
d. Complementary and alternative medicine treatments

KQ3. Where direct comparisons have been made between or among treatment modalities of interest, which modalities achieve superior outcomes with respect to benefits, short and long-term risks, and quality of life?

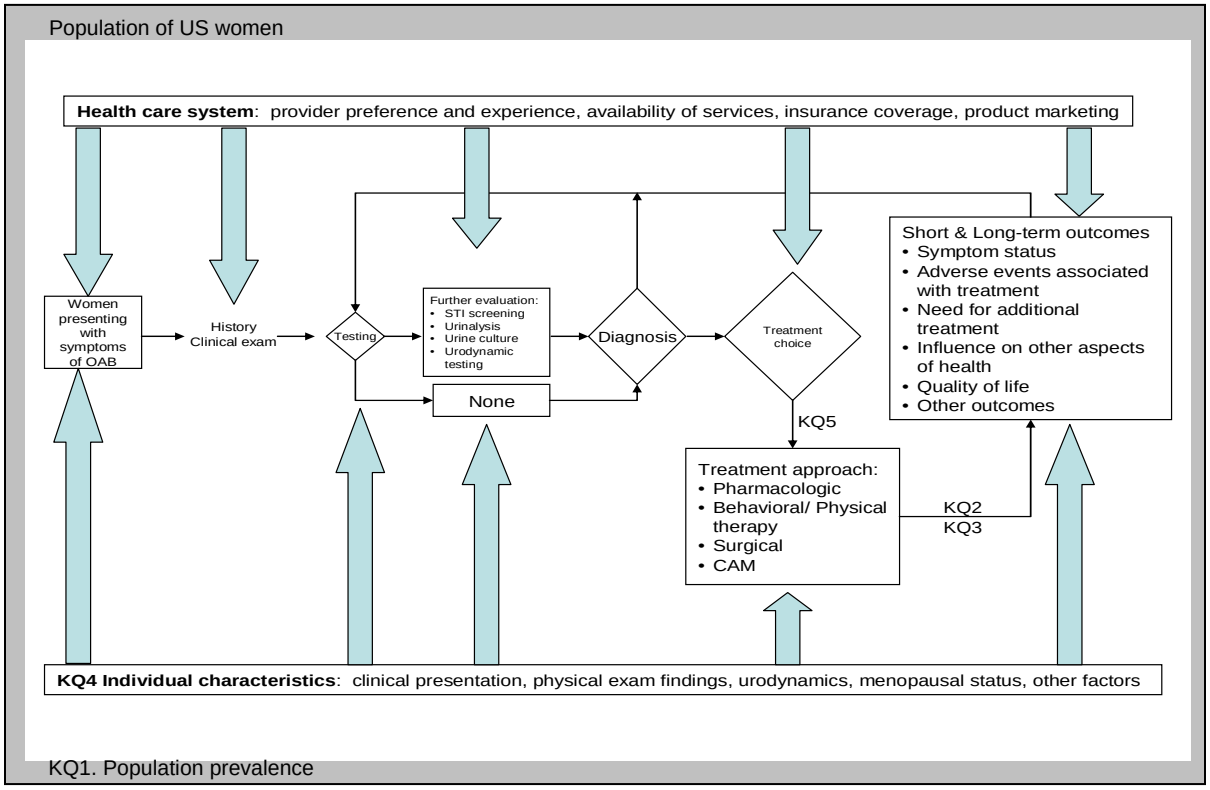
KQ4. Are the short and long term outcomes of these treatment approaches modified by clinical presentation, physical exam findings, urodynamic findings, menopausal status, age, or other factors?

KQ5. What are the costs associated with these treatment approaches?

Analytic Framework for the Treatment of OAB Women

The analytic framework in Figure 1 summarizes the conceptual model used to guide this systematic review by focusing the key questions on critical health care-related pathways and decision points. We recognize a number of other factors like provider prescribing preferences and types of testing performed for a patient presenting with symptoms are part of this pathway. However little literature was available to inform other nodes in the process of care.

Figure 1. Analytic framework for the treatment of OAB in women



Organization of this Evidence Report

Chapter 2 describes our methods including our search strategy, inclusion and exclusion criteria, approach to review of abstracts, to review of full publications, and for extraction of data into evidence tables, compiling evidence, and when possible conducting meta-analysis. We also describe the approach to grading of the quality of the literature and to describing the strength of the literature.

Chapter 3 presents the results of the evidence report by key question, synthesizing the findings across treatment type. We report the number and type of studies identified and we differentiate between total numbers of publications and unique studies to bring into focus the number of duplicate publications in this literature in which multiple publications are derived from the same study population. We emphasize the effect of treatment on the core symptom complex of OAB. Chapter 4 discusses the results in Chapter 3 and enlarges on methodologic considerations relevant to each key question. We also outline the current state of the literature and challenges for future research on OAB.

We have prioritized reporting on clinically relevant commonalities for United States care settings, being aware of the fact that primary care generalists and specialists alike are called upon to evaluate and treat OAB patients. We placed greatest value on the studies, and the content within studies, that is most likely to be applicable to help guide patient care, such as treatment selection, as well as inform anticipatory guidance about likely magnitude of treatment effects and risk of both nuisance side effects and serious harms.

Technical Expert Panel (TEP)

We identified technical experts on the topic of OAB in the fields of urology, urogynecology, gynecology, primary care, nursing, and patient advocacy to provide assistance during the project. The TEP (see Appendix E) was expected to contribute to AHRQ's broader goals of (1) creating and maintaining science partnerships as well as public-private partnerships and (2) meeting the needs of an array of potential customers and users of its products. Thus, the TEP was both an additional resource and a sounding board during the project. The TEP included twelve members serving as technical or clinical experts, including an AUA representative. To ensure robust, scientifically relevant work, we called on the TEP to provide reactions to work in progress and advice on substantive issues or possibly overlooked areas of research. TEP members participated in conference calls and discussions through e-mail to:

- Refine the analytic framework and key questions at the beginning of the project;
- Discuss the preliminary assessment of the literature, including inclusion/exclusion criteria;
- Provide input on the information and categories included in evidence tables;
- Develop a hierarchy of participant characteristics and outcomes to systematically assess;
- Advise about the clinical availability, use, and most common doses for therapeutics.

Because of their extensive knowledge of the literature, including numerous articles authored by TEP members themselves, and their active involvement in professional societies and as practitioners in the field, we also asked TEP members to participate in the external peer review of the draft report.

Uses of This Report

This evidence report addresses the key questions outlined above using methods described in Chapter 2 to conduct a systematic review of published literature including a meta-analysis of effects of pharmacologic treatment. We anticipate that the report will be of value to all urologic and women's health care providers, including AUA (our partner), the American College of Obstetrician Gynecologists, the American Urogynecologic Society, the American Academy of Family Physicians, American Academy of Nurse Practitioners, and other clinical groups who care for women from menarche through the remainder of their lives, such as the American Geriatrics Society. In addition, this review will be of use to the National Institutes of Health, Centers for Disease Control and Prevention, Centers for Medicare & Medicaid Services, and the Health Resources and Services Administration – all of which have offices or bureaus devoted to women's health issues. This report can bring practitioners up to date about the current state of evidence, and it provides an assessment of the quality of studies that aim to determine the outcomes of therapeutic options for the management of OAB. It will be of interest to individual women and the general public because of the high prevalence of OAB and the recurring need for women and their health care providers to make the best possible decisions among numerous options. We also anticipate it will be of use to private sector organizations concerned with women's health, such as Our Bodies Ourselves, the National Women's Health Network, the National Association for Continence, the Society of Urodynamic and Female Urology (SUFU), and the Simon Foundation for Continence.

Researchers can obtain a concise analysis of the current state of knowledge in this field. They will be poised to pursue further investigations that are needed to understand the prevalence and natural history of OAB, to clarify risk factors, develop prevention strategies, develop new treatment options, and optimize the effectiveness and safety of clinical care for those with OAB.

Chapter 2. Methods

In this chapter, we document the procedures that the Vanderbilt Evidence-based Practice Center used to develop this comprehensive evidence report on the treatment of OAB in women. We first describe our strategy for identifying articles relevant to our five key questions, our inclusion/exclusion criteria, and the process we used to abstract relevant information from the eligible articles and generate our evidence tables. We also discuss our criteria for grading the quality of individual articles and for rating the strength of the evidence as a whole. Finally, we describe the peer review process.

Literature Review Methods

Inclusion and Exclusion Criteria

Our inclusion/exclusion criteria were developed in consultation with the TEP, to capture the literature most tightly related to the key questions. Criteria are summarized below.

Table 1. Inclusion and Exclusion Criteria

Category	Criteria
Study population	Adult, community-dwelling females
Publication languages	English only
Admissible evidence (study design and other criteria)	Admissible designs Randomized controlled trials, cohorts with comparison, case-control, and case series Other criteria Original research studies that provide sufficient detail regarding methods and results to enable use and aggregation of the data and results Patient populations must include women with overactive bladder Studies must have relevant population ≥ 50 participants Studies must address one or more of the following for overactive bladder: Treatment modality Symptom management approach Short- and long-term outcomes and quality of life Prevalence and/or incidence Relevant outcomes must be able to be abstracted from data in the papers

We excluded studies that (1) were not published in English; (2) did not report information pertinent to the key questions; (3) had fewer than 50 female participants [at enrollment]; (4) had less than 75 percent female participants or failed to report results by gender; and (5) were not original studies.

For this review, the relevant population for all key questions was women with overactive bladder, defined as "idiopathic urinary urgency and frequency with or without associated urge urinary incontinence, not related to neurogenic conditions or as a result of (incontinence) surgery." The same inclusion/exclusion criteria were applied to identify papers for treatment-related key questions. We applied additional restrictions for inclusion and exclusion of incidence and prevalence publications for KQ1. To inform this question about the epidemiology of OAB and/or its component symptoms, we required that the study methods specify a population base *a*

Appendixes and Evidence Tables for this report are provided electronically at
http://www.ahrq.gov/downloads/pub/evidence/pdf/bladder/bladder.pdf

priori from which a sample of individuals was drawn as a representative selection to estimate the true proportion of prevalent and incident cases of OAB in the larger population. Additional information is provided in the results for KQ1. For KQ5, we required that publications provide data on direct costs in United States dollars for treatments reviewed in this report.

Treatment studies that included at least 75 percent women were included. This level was selected with expert input to avoid restricting to studies with only female participants as a large proportion of this literature includes both men and women, and to establish a threshold below which the difference in underlying processes (e.g., BPH in men) might substantially influence treatment effects. Studies with lower proportions of women were included if they presented results separately for women; or indicated that an interaction with gender was tested and found not to exist; or gender was controlled in the analysis. Publications about incontinence that did not distinguish between, or present results by urge, stress, and/or mixed incontinence were excluded.

Literature Search and Retrieval Process

Databases. We employed multi-term search strategies to retrieve research about treatment of overactive bladder in women, including exploration of three databases: PubMed, MEDLINE®, EMBASE, and the Cumulative Index to Nursing and Allied Health Literature (CINAHL). We also hand-searched the reference lists of relevant articles to identify additional studies for review.

Search terms. Controlled vocabulary terms served as the foundation of our search in each database, complemented by additional keyword phrases to represent the myriad ways in which overactive bladder is referred to in the clinical literature. We also employed indexing terms within each of the databases to exclude undesired publication types (e.g., reviews, case reports, CME handouts) and items published in languages other than English.

Tables 2 to 4 outline our search terms and the yield from each database. Our searches were executed between April and October, 2008, and were not limited by date. From PubMed, we identified 2,400 items for further review; EMBASE yielded 318 items, including 310 already identified in PubMed and 8 unique items; CINAHL yielded 264 citations, including 240 duplicates with PubMed and 24 new articles for review.

Table 2. PubMed search strategies (last updated October 1, 2008)

	Search terms	Search results
#1	("Urinary Bladder, Overactive"[Mh] OR "overactive bladder" OR "urge incontinence" OR urinary incontinence, urge[mh] OR "detrusor instability" OR "overactive detrusor" OR "urinary urgency" OR "urinary frequency" OR "irritable bladder" OR “detrusor overactivity”) AND "female"[MeSH Terms] AND "humans"[MeSH Terms] AND English[lang]	2,886
#2	#1 AND editorial[pt]	10
#3	#1 AND letter[pt]	30
#4	#1 AND case reports[pt]	164
#5	#1 AND review[pt]	299
#6	#1 AND practice guideline[pt]	2
#7	#1 NOT (#2 OR #3 OR #4 OR #5 OR #6)	2,400*†

***** Approximately 250 of these citations represent pediatric literature (due to variability in indexing for this topic, we were unable to exclude pediatric literature at the search strategy level).

† Numbers do not total due to exclusions in more than one category; 5 items were indexed as both letters and case reports and 14 items were indexed as both reviews and case reports

Table 3. EMBASE search (OVID) (last updated October 1, 2008)

	Search Terms	Search Results
#1	*overactive bladder/ or *urinary urgency/ or *urge incontinence/ or *urinary frequency/ or *detrusor dyssynergia/ or *bladder irritation/	1624
#2	limit 1 to (human and female and english language and (adult <18 to 64 years> or aged <65+ years>))	363
#3	#2 and review.pt.	12
#4	#2 and conference paper.pt.	4
#5	#2 and editorial.pt.	1
#6	#2 and letter.pt.	0
#7	#2 and note.pt.	3
#8	#2 and short survey.pt.	4
#9	#2 and case report/	18
#10	#2 and practice guideline/	4
#11	#2 and "systematic review"/	1
#12	#2 and meta analysis/	1
#13	#2 not (3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12)	318*†

* Overlap with PubMed: 310 citations; 8 new citations retrieved for inclusion.
† Numbers do not total due to exclusions in more than one category: 1 item was indexed as both a case report and review; 1 item was indexed as both a case report and a note; and 1 item was indexed as both a review and a systematic review.

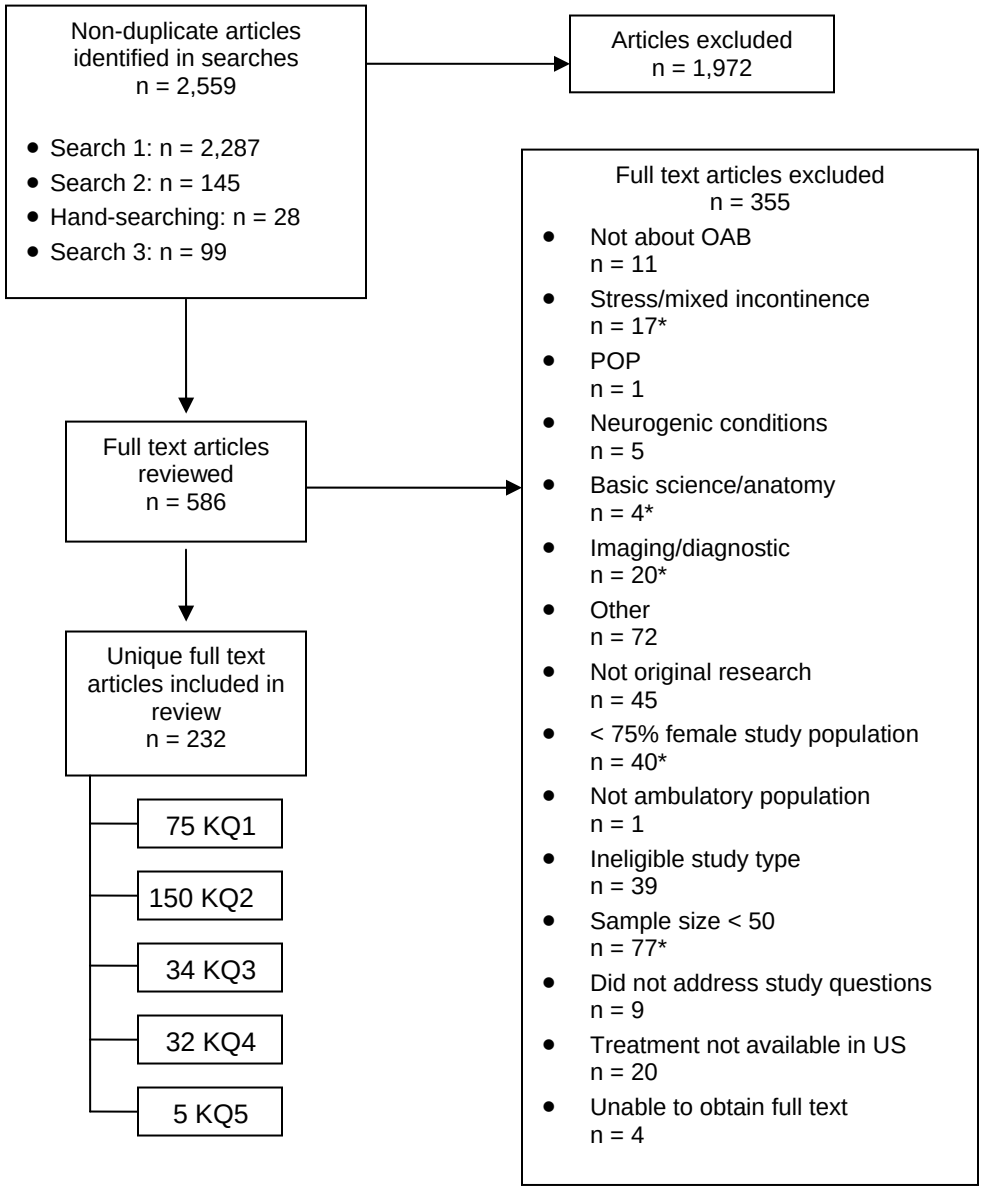
Table 4. CINAHL search (EBSCO) (last updated October 1, 2008)

	Search Terms	Search Results
#1	(MH “Urge Incontinence”) or (MH “Overactive Bladder”) or “overactive bladder” or “urge incontinence” or “urge urinary incontinence” or “detrusor instability” or “overactive detrusor” or “urinary urgency” or “urinary frequency” or “detrusor overactivity” and (MH “Adult+”) and (ZL “ENGLISH”) and (PT “Journal Article”)	305
#2	#1 and case reports	18
#3	#1 and review	6
#4	#1 and CE material	5
#5	#1 and abstract/commentary	7
#6	#1 and consumer literature	5
#7	1 not (2 or 3 or 4 or 5 or 6)	264*

* Overlap with PubMed: 240 citations; 24 new citations retrieved for inclusion.

Yield of literature searches. Figure 2 presents the yield and results from our searches. Beginning with a yield of 2,559 articles, we retained 232 articles covering 221 studies that we determined were relevant to answer our key questions and met our inclusion/exclusion criteria.

Figure 2. Disposition of articles for the treatment of overactive bladder (OAB)



KQ = key question
*The number of articles addressing each key question and those excluded exceed the total number of articles in each category because some of articles fit into multiple exclusion categories or addressed more than one key question. The excluded papers focused exclusively on populations of individuals with movement disorders, spinal cord injuries, or multiple sclerosis, for example. As a result, they did not meet the criteria for an “idiopathic” syndrome which was a requirement of the report.

Article selection process. Once we identified articles through the electronic database searches, review articles, and bibliographies, we examined abstracts of articles to determine whether studies met our criteria. Two reviewers separately evaluated the abstracts for inclusion or exclusion, using an Abstract Review Form (Appendix B). If one reviewer concluded that the article could be eligible for the review based on the abstract, we retained it. The group included three physicians (KH, DB, RW), and two senior health services researchers (MM, SM).

Of the entire group of 2,559 articles, 586 required full text review. For the full article review, two reviewers read each article and decided whether it met our inclusion criteria, using a Full Text Inclusion/Exclusion form. Reasons for article exclusion are listed in Appendix D.

Literature Synthesis

Development of Evidence Tables and Data Abstraction Process

The staff members and clinical experts who conducted this review jointly developed the evidence tables. We designed the tables to provide sufficient information to enable readers to understand the studies and to determine their quality; we gave particular emphasis to essential information related to our KQs. We based the format of our evidence tables on successful designs used for prior systematic reviews.

The team was trained to abstract by abstracting several articles into evidence tables and then reconvening as a group to discuss the utility of the table design. We repeated this process through several iterations until we decided that the tables included the appropriate categories for gathering the information contained in the articles. A priori, with the technical expert panel, a hierarchy of baseline characteristics and outcome measures was developed: UUI episodes, urgency, incontinence, voids, nocturia, QoL, urodynamic measures, and adverse events. All team members shared the task of initially entering information into the evidence tables. Another member of the team also reviewed the articles and edited all initial table entries for accuracy, completeness, and consistency. The two abstractors reconciled disagreements concerning the information reported in the evidence tables. The full research team met regularly during the article abstraction period and discussed global issues related to the data abstraction process. In addition to outcomes related to treatment effectiveness, we abstracted all data available on harms. Harms encompasses the full range of specific negative effects, including the narrower definition of adverse events.

The final evidence tables are presented in their entirety in Appendix C. Studies are presented in the evidence tables alphabetically by the last name of the first author. When possible, studies resulting from the same study population were grouped into a single evidence table. A list of abbreviations and acronyms used in the tables appears at the beginning of that appendix.

Synthesis of the Evidence

A series of spreadsheets was created to support systematic tabulation and assessment of study characteristics including key study population characteristics, number of participants by group, treatment received, length of followup, age of participants by group, outcomes measured and outcomes. This allowed us to identify common threads in reporting across publications.

Within the pharmaceutical treatment studies all unique trial arms were entered into a spreadsheet with exact values to two-decimal points as available for baseline measures, followup measures, difference from baseline, and for the related statistical indicators of precision (such as

standard deviations, standard errors, or confidence bounds). This was done to facilitate calculation of weighted averages and to support meta-analysis.

Conduct of meta-analysis. Descriptive statistics were computed and examined for homogeneity among studies. Studies that reported weekly rates for UUIs and voids were standardized to daily rates. When only ranges of continuous variables were reported (instead of standard deviations), we estimated the standard deviations by dividing the range by four.[5] Study results were combined and summarized using two meta-analysis techniques, weighted averages and fixed effects regression models.[6] In particular, minimum variance weighted averages of the mean daily decrease in UUI and voids per arm were computed using weights that were inversely proportional to their standard errors. To borrow strength across arms, we used fixed effect regression models with robust standard errors (to account for the clustering by study) and weighted the study arms inversely proportional to their standard errors of the mean. Each arm was treated as a fixed effect and study was not included in the model except in the sense that the clustering was addressed by the robust standard errors. Fixed effects models were also adjusted for mean age and proportion of women in each arm. We used STATA 10.0 and R statistical packages for computations.

Summary tables within this report. Each of the pharmacologic agents in this report is available in a least one dose form for clinical use. As part of the process of Food and Drug Administration (FDA) approval each has been determined superior to placebo for at least one facet of the syndrome, e.g., urge urinary incontinence, frequency of urination, symptoms of urgency, or nocturia. The experience of having overactive bladder is a constellation of these self-reported events, symptoms, and the impact that they have on an individual's life. Thus measures of quality of life, interference with daily activities, degree of distress from symptoms, and satisfaction with the outcomes of treatment are also common and helpful metrics in this literature. Where common measures are available across studies using roughly comparable assessments (i.e., similar index questions, time intervals, etc), we have compiled tables to summarize outcomes of treatments.

Given the content of the literature, this means that the majority of the information included in tables is for the outcomes of number of urge incontinence episodes per day and number of voids per day. (Studies with weekly or other metrics that could be converted to daily metric are included.) Because momentum in drug development within related classes of drugs has been toward daily dosing, the pharmacologic treatments are arranged from highest dose at lowest frequency of administration (daily) to lower doses and greater administration frequency (twice or more daily). Placebo arms from the same trials in which the drugs were evaluated are included within the table, or for areas in which the literature is large, in companion placebo outcome tables. The number of weeks of treatment and timing of followup outcome assessment were the same in these trials. The weeks of treatment column is therefore comparable to weeks at evaluation of outcomes.

Summary tables include data from distinct clinical trial arms in which the drug and dose or other type of treatment were evaluated for the related outcome. As a result, a single study may contribute more than one treatment arm as well as a placebo arm to the summary tables. For pharmacologic treatment we included only study arms in which no dose adjustment was allowed. Because many studies are dose finding with multiple drug arms or are direct comparisons of pharmacologic agents, there are more drug arms than placebo arms for virtually all drugs and treatment types.

Quality Rating of the Individual Studies

Rating the quality of individual articles. We developed our approach to assessing the quality of individual articles based on our prior experience with conducting systematic reviews.

Internal validity. The criteria for assessing internal validity were as follows:

Randomized allocation to treatment. This assessment combines randomization and method of randomization into a single criterion with a three-point scale.

Rationale: By randomly assigning groups to the intervention of interest, other factors that may confound the results are equally distributed between groups (assuming a large enough sample size). This equal distribution minimizes the chances of over- or underestimation of treatment effect based on unequal distribution of confounding factors.

If randomized, we also evaluated the study for randomization methods, using the rationale described in Matchar and colleagues, 2001.[190]

Rationale: "Pseudo-randomization" methods may be susceptible to bias, as demonstrated by evidence of unequal distribution of subject characteristics[191] and larger effect sizes compared with studies using more rigorous methods.[192] In addition, methods of allocation concealment are also important in preventing bias (e.g., use of prepared sealed envelopes).

We combined these elements into a single operational definition, as described below:

Operational definition: Criterion met if randomization methods were not susceptible to bias, such as computer-generated numbers in sealed sequentially numbered envelopes (+). Criterion not met by studies that either used methods more prone to bias, such as alternate medical record numbers, or did not describe randomization methods or methods of allocation concealment (-). Criterion not applicable if treatment was not randomly allocated (NA).

Masking.

Rationale: Masking, also known as blinding, refers to the concealment of treatment allocation from the care provider, the assessor, and the patient.[193] In certain trials, particularly surgical trials, masking the patient or the surgeon from the treatment allocation can be challenging or impossible. Similarly, masking the assessor assigned to record immediate post-procedural outcomes such as wound healing can also be difficult. Nevertheless, when possible, masking prevents expectations from influencing findings.

Operational definition: Criterion was met if assessors and participants were masked to treatment or group (+). Criterion was not met if either care provider, assessor, or patient were not masked (-). Criterion not applicable if treatment was not randomly allocated.

Adequate description of patients and control selection criteria.

Rationale: Patient characteristics that might affect outcomes (such as severity of symptoms, duration of symptoms, failure of prior treatment, or medical comorbidities) are likely to differ between two interventions. If these differences are not characterized, then erroneous conclusions may be drawn.

Operational definition: Criterion met if (a) inclusion and exclusion criteria for participation in the study were well described.

We expected that the study population should be adequately described to make clear the potential for confounding in the analysis. We expected the study authors to adequately describe the study population such that it could theoretically be reproducible by another investigator. We expected comparable methods to be used to identify and screen participants across exposure or treatment groups.

Description of loss to followup.

Rationale: Failing to account for patients lost to followup may lead to erroneous conclusions, especially if the loss to followup is related to either the underlying disease or the intervention (e.g., patients seeking care elsewhere because of continuing symptoms or unacceptable side effects of treatment).

Operational definition: Criterion met for adequate followup (+) if (a) loss to followup was explicitly reported and (b) no more than 20 percent of any study arm was lost to followup. Those studies with less than 10 percent lost to followup were given an extra (+). Studies with greater than 20 percent lost to followup were considered inadequate for this measure (-).

Description of dropout rates.

Rationale: Dropout rates may reflect differences in clinically important variables, such as side effects or treatment response. Failure to account for dropouts may result in erroneous conclusions similar to those seen with failure to account for loss to followup.

Operational definition: Criterion met if (a) patients dropping out of the study prior to completion were reported and (b) no more than 10 percent in any study arm left the study for reasons related to the study intervention or withdrawal of consent.

Power calculation provided.

Rationale: Many studies, especially case series, lack sufficient power to detect clinically important differences in outcomes or patient characteristics.

Operational Definition: Criterion met if a power calculation (pre or post) was provided.

Recognition and description of statistical issues.

Rationale: Use of inappropriate tests may lead to misleading conclusions. For example, variables such as number of voids per day or costs are often not normally distributed; use of means instead of medians when data may be affected by outlying observations can be misleading.

Operational definition: Criterion met if (a) appropriate statistical tests were used (e.g., nonparametric methods for variables with nonnormal distributions, or survival analysis techniques to account for loss to followup and dropouts) and (b) potential study limitations regarding design and analysis were discussed. Criterion not met if (a) inappropriate statistical tests were used or (b) study limitations were not discussed. An intention-to-treat (ITT) analysis was required of clinical trials.

External validity. The criteria for assessing external validity were as follows:

Baseline characteristics: We created a composite score for adequacy of the description of baseline characteristics. At minimum, we expected age and baseline OAB status to be presented. If either of these were omitted, criteria were not met. If the authors provided additional information above and beyond age and OAB status at baseline on any of the following, they were awarded an additional +: race/ethnicity, BMI, parity, menopausal status, prior treatment/surgery, duration of symptoms.

Required elements:

Description of age of study population.

Rationale: The outcomes of many interventions are affected by patient age. Age is especially important in studies related to reproductive health in women and associated with rates of overactive bladder.

Operational definition: Criterion met if summary statistics of subject age were given by comparison group. Criterion not met if summary statistics were not given.

Baseline OAB status.

Rationale: The baseline level of severity of OAB could affect the likelihood of successful treatment. Furthermore, definitions of OAB are not consistent across studies and may include different combinations of urgency, frequency, and incontinence that could affect interpretation of the outcomes. Therefore, we sought to determine whether studies defined OAB status by ICS or other criteria, by UUI alone or by combinations of UUI, urgency and frequency.

Operational definition: Criterion met if symptoms of OAB were presented by study group.

Length of followup.

Rationale: Outcome measures may vary depending on when they are obtained. Description of when outcomes were measured facilitates comparison between studies. We considered three months to be a minimally acceptable period of followup for observing effectiveness of treatment for OAB.

Operational definition: Criterion met if the study followed participants for at least three months, with an extra point provided for greater than or equal to six months.

Adequate description of methods used for outcome measurement.

Rationale: Comparison between studies requires common methods of measurement, which in turn requires adequate description of the methods used to assess comparability.

Operational definition: Criterion met if (a) methods used to measure outcomes were adequately described or referenced (e.g., 2002 ICS; QoL scales), (b) definitions were given (e.g., description of outcomes classified as "adverse events"), or (c) outcomes were unambiguous (e.g., reduction in number of voids per day). Criterion not met if (a), (b), or (c) was not present.

Adequate description of validity and reliability of outcome measurement.

Rationale: Measurements of outcomes are only useful if changes in the outcome being measured are reflected in changes in the measurement (validity) and if these changes are reasonably consistent between the same observer measuring at different times or between different observers (reliability). For example, changes in a scale to assess menstrual blood flow should correlate with some other physiological measure of menstrual blood loss, and this correlation should be consistent when different women apply the same scale.

Operational definition: Criterion met if (a) a description of the methods used to assess validity and reliability of at least one outcome measure was provided, (b) a reference to another article documenting validity and reliability was provided, or (c) only unambiguous outcomes were included as primary outcomes. Criterion not met if (a), (b), or (c) was not present.

Adequate description of the intervention provided to subjects.

Rationale: The ability to replicate study results is dependent on adequate description of methods. Additionally, readers should be aware of aspects of clinical care that might influence outcomes.

Operational definition: Criterion met if (a) a detailed description of the therapy (dose, dosing schedule, protocols for behavioral interventions, and route of administration for medications and/or techniques for invasive therapies) was provided; (b) a reference to another publication describing the procedure was provided; or (c) statistical adjustment was made for likely sources of variation in clinical care (e.g., site where care was given, type of specialist providing care, individual provider, dose and timing).

Criterion not met if (a), (b), or (c) was not provided.

Table 5. Scoring algorithm for quality rating of individual studies

Definition and Scoring Algorithm	Rating
Score Algorithm for Internal Validity Quality Rating	
• No negative scores, lowest loss-to-followup score, and lowest dropout rate	Good internal validity
• One negative score or intermediate loss-to-followup	Fair internal validity
• High loss-to-followup score, or high dropout rate ***OR***	Poor internal validity
• Two negative scores ***OR***	
• One negative score and intermediate loss-to-followup score	
Score Algorithm for External Validity Quality Rating	
• No negative scores	Good external validity
• One or two negative scores	Fair external validity
• Three or more negative scores	Poor external validity
Score Algorithm for Overall Quality Rating	
• Good internal validity and good external validity	Good overall
• Fair internal validity and fair external validity ***OR***	Fair overall
• Good internal validity and fair external validity ***OR***	
• Good internal validity and poor external validity ***OR***	
• Fair internal validity and good external validity ***OR***	
• Poor internal validity and good external validity	
• Poor internal validity and poor external validity ***OR***	Poor overall
• Fair internal validity and poor external validity ***OR***	
• Poor internal validity and fair external validity	

Strength of Available Evidence

Our scheme follows the criteria applied in earlier systematic reviews of systems for rating the strength of a body of evidence.[194, 195] That system includes three domains: quality of the research, quantity of studies (including number of studies and adequacy of the sample size), and consistency of findings. Two senior investigators assigned grades by consensus.

We graded the body of literature for each key question and present those ratings as part of the discussion in Chapter 4. The possible grades were:

I. Strong: The evidence is from studies of strong design; results are both clinically important and consistent with minor exceptions at most; results are free from serious doubts about generalizability, bias, or flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

II. Moderate: The evidence is from studies of strong design, but some uncertainty remains because of inconsistencies or concern about generalizability, bias, research design flaws, or adequate sample size. Alternatively, the evidence is consistent but derives from studies of weaker design.

III. Weak: The evidence is from a limited number of studies of weaker design. Studies with strong design either have not been done or are inconclusive.

IV. No evidence: No published literature.

External Peer Review

As is customary for all systematic evidence reviews done for AHRQ, this report was reviewed by a wide array of individual outside experts in the field, including our TEP, and from relevant professional societies and public organizations. AHRQ also requested review from its own staff. The Scientific Resource Center sent 11 invitations for peer review. Reviewers included clinicians (e.g., urologists, urogynecologists, gynecologists, geriatricians, family medicine physicians, and nurse practitioners), representatives of federal agencies, advocacy groups, and potential users of the report.

The Scientific Resource Center charged peer reviewers with commenting on the content, structure, and format of the evidence report, providing additional relevant citations, and pointing out issues related to how we had conceptualized and defined the topic and KQs. We also asked reviewers to complete a peer review checklist. The Scientific Resource Center received eight responses in addition to comments from AHRQ staff. The individuals listed in Appendix E gave us permission to acknowledge their review of the draft. We compiled all comments and addressed each one individually, revising the text as appropriate.

Chapter 3. Results

KQ1. Prevalence and Incidence of Overactive Bladder

To understand the epidemiology of OAB and associated symptoms (frequency, urgency, and urge incontinence), we sought publications that provided estimates of prevalence, which is the proportion of the population with the condition, or those that examined the proportion with onset of new symptoms over time, which is termed incidence. The strongest estimates come from a well-specified population-base that allows sampling to generate a representative group.

We applied operational criteria to select those studies best suited to estimate prevalence and incidence. The key criterion for inclusion was that the study authors specified a population base *a priori* from which a sample of individuals was drawn as a representative selection of individuals to estimate the true proportion in the larger population. The population was required to be clearly defined and capable of being enumerated such as the population of a region, the participants in a health plan or individuals on voter registration roles. This "roster" defines the sampling frame from which stratified samples are drawn. Often the research team has an explicit statistical goal of randomly selecting participants with aggregate characteristics (range of age, race/ethnicity, income level, etc.) that approximate the entire population of a city, region, or country. Common approaches include random digit dialing within a specific geographical region, or mailings of questionnaires to a sample of individuals who are in a pool of registered voters, registered residents, or on the patient panels of a national health systems or large healthcare organizations. Outside the United States, household canvassing and administered interviews were also common.

The characteristic of being able to define a sampling frame from which participants were subsequently drawn was a required characteristic for inclusion in the prevalence and incidence summary. Other approaches to the study of large groups, such as enrolling individuals who are presenting for clinical care, or who have just had a health event like childbirth or surgery, can be informative, however, such studies do not by virtue of their design, generate participant pools who are representative of a larger population. They represent those with access to care, who have sought care for a problem visit, chronic condition, or preventive care, or who have a medical condition or experience in common. Such designs may also reflect characteristics of the site of care at which the cohort was recruited, such as a high proportion of indigent patients or specialty referral patients. For this reason, cohort studies and clinical samples, without a population-based sampling frame were excluded in order to emphasize the broadest picture of the epidemiology and natural history of OAB is as possible.

Prevalence of Overactive Bladder

Using this approach, we identified 75 publications,[2-4, 10-81] from 60 distinct study populations. Detailed summaries for all studies are included in Appendix C and a summary is provided in Table 6.

Appendixes and Evidence Tables for this report are provided electronically at
http://www.ahrq.gov/downloads/pub/evidence/pdf/bladder/bladder.pdf

Table 6. Study characteristics of the prevalence and incidence literature

Study Characteristic	Population Studied				
	US (n=15)	**European** (n=24)	**Asian** (n=13)	**Other** (n=8)	**Total** (n=60)
Publications after 2002 ICS Definitions					
Distinct populations	(n=13)	(n=11)	(n=7)	(n=7)	(n=38)
Prevalence Only	10	7	7	6	30
Incidence Only	2	--	--	--	2
Both	1	4	--	1	6
Assessment Method					
Mailed	3	7	2	--	12
Telephone	2	2	1	3	8
Administered	6	1	4	3	14
Other	2	1	--	1	4
Conditions Assessed*					
Urge Incontinence	11	7	5	5	28
Overactive Bladder	2	4	5	3	14
Urgency	4	3	4	3	14
Frequency	3	3	5	3	14
Funding Source					
National (NIH, MRC, etc.)	8	4	1	--	13
Foundation/Other	--	2	--	1	3
Industry	4	3	1	2	10
Not Reported	1	2	5	4	12
Publications before 2002 ICS Definitions					
Distinct populations	(n=2)	(n=13)	(n=6)	(n=1)	(n=22)
Prevalence Only	--	13	6	1	20
Incidence Only	--	--	--	--	--
Both	2	--	--	--	2
Assessment Method					
Mailed	--	8	2	1	11
Telephone	1	2	2	--	5
Administered	1	2	2	--	5
Other	--	1	--	--	1
Conditions Assessed*					
Urge Incontinence	2	11	6	1	20
Overactive Bladder	--	1	--	--	1
Urgency	--	3	2	--	5
Frequency	--	3	2	--	5
Funding Source					
National (NIH, MRC, etc.)	2	3	--	--	5
Foundation/Other	--	1	1	1	3
Industry	--	4	1	--	5
Not Reported	--	5	4	--	9

* Inclusive: Total is greater than number of studies because some publications report multiple conditions.

Fifteen studies were conducted in United States populations; 24 in European populations; 13, Asian; and 8 other countries. Thirty-eight of these studies appeared in print after the 2002 International Continence Society revised definitions and 37 percent of these reported specifically about incidence or prevalence of OAB. One study prior to the consensus definitions used fully comparable definitions and the term “overactive bladder”.

A total of 15 studies provided information about OAB prevalence (Table 7). These studies included a total of 64,528 women in 16 distinct populations. The majority of respondents completed questionnaires returned by mail. The highest estimates of OAB prevalence was 31.3 percent in a telephone questionnaire study conducted in Korea in which the average age of participants was 59 years; the lowest was 7.7 percent in a mailed questionnaire conducted in the United Kingdom among women of nearly identical average age. Across all studies the weighted average prevalence of OAB was 13.7 percent. Excluding the highest and lowest estimates, an estimated 14.8 percent of women meet criteria for OAB, with 8.0 percent of those surveyed having OAB with a component of urge incontinence. Combined estimates from the two United States populations are similar: 14.7 percent with OAB and 11.3 percent with a component of urge incontinence.

No clear pattern of higher or lower estimates for prevalence of OAB was associated with survey response rates. The direction of bias is therefore difficult to estimate: researchers have noted both that those with symptoms may be more likely to be interested in the topic and to respond and that the social stigma or embarrassment associated with bladder control symptoms may prompt under-response. In each case in which the authors addressed non-response, they report the demographic characteristics of those who did not respond were similar to those who did with the exception of several authors who noted modest under-representation of the very oldest residents.

Age and prevalence of OAB. The relationship between OAB and age was fairly uniform across studies with a trend to increase with age.2, 3, 12-14, 38, 42 As discussed below, this increase appears to be more notable for OAB than UUI. Because OAB criteria can be met with urgency combined with incontinence, frequency, or nocturia, the “amplification” of age effects for OAB risk may in part be related to well-documented increases in stress urinary incontinence and therefore also mixed stress and urge incontinence with age. Prevalence of OAB for women in their 20s was in the range of 4.6 to 5.9 percent 2, 3, 11, 13 while uniformly double digits, 11.7 to 19 percent 2, 3, 11, 13 for women older than 60. Several researchers noted a threshold effect such that prevalence was not statistically different until an inflection in the 60s or 70s.12, 14, 38, 42 Few data were provided, however discussion materials often noted that all component symptoms: urgency, frequency, nocturia, and urge and mixed incontinence, increased with age therefore contributing to the rise in OAB.

Table 7. Prevalence of OAB

Author, Year Country	Respondents Response*	Measurement	Age of Respondents† Mean, Range	OAB Prevalence (%)
Lawrence et al.[2, 3, 13] 2008 US	4,103 34.0%	Mailed EPIQ	56.5 ± 15.8 (25, 84)	**Any: 13.3** Wet: 12.7
Wagner et al.[4, 42] 2002 US	2,735 83.9%	Telephone	54.2 (18, ≥ 75)	**Any: 16.9** Wet: 9.3
Herschorn et al.[12] 2007 Canada	518 NR	Telephone	44.5 ± 17.2 (18, 90)	**Any: 14.7** Wet: 7.1
Irwin et al.[18] 2006 Europe & Canada	9,000^ 33.0%	Telephone	(18, ≥ 70)	**Any: 12.8** Wet: 6.3
Corcos et al.[38] 2004 Canada	1,683 53.7%	Telephone	50.9 (35, ≥ 75)	**Any: 21.3** Wet: 6.5
McGrother et al.[26] 2006 UK	12,570 65.3%	Mailed	59.5 ± 13.0 (40, 98)	**Any: 7.7**
Dallosso et al.[39] 2004 UK	12,568 30.2%	Mailed	Median: 61	**Any: 15.9**
Van Der Vaart et al.[48] 2002 Netherlands	933 67.0%	Mailed UDI	34.2 ± 3.2 (20, 45)	**Any: 11.9**
Choo et al.[14] 2007 Korea	1,005 NR	Telephone	59.4 ± 11.6 (40, 89)	**Any: 31.3** Wet: 15.0
Yu et al.[30] 2006 Taiwan	925 33.5%	Administered	49.9 (30, 79)	**Any: 18.3**
Homma et al.[31] 2005 Japan	2,380 45.0%	Mailed	61 (41, 100)	**Any: 11.0** Wet: 7.0
Song et al. [29, 33, 34] 2005 China	4,684 77.2%	Mailed BFLUTS	40.4 ± 11.1	**Any: 8.0** Wet: 5.6
Chen et al. [41, 47] 2003 Taiwan	1,247 78.7%	Administered Bristol	43.2 ± 15.1 (20, ≥ 65)	**Any: 18.6** Wet: 9.1
Teloken et al.[23] 2006 Brazil	449 NR	Written	(15, 55)	**Any: 23.2**
Milsom et al.[51] 2001 Europe	9,728 NR	Telephone	(40, ≥ 75)	**Any: 17.4**
	Total: 64,528 Weighted average: 49.5%			Weighted averages: Any: 13.7 Any (without extremes): 14.8 Wet: 8.0

* Proportion of eligible sample who responded to survey and had responses included in analysis.
^Exact number of women not reported.
† Data provided is that included by the authors. Hierarchy was to provide mean if no indication of skew; median if author provided only median or data to show that median better captured a skewed distribution, and then range. Range was only provided when other options were not available. Complete information for each study is included in evidence tables; OAB-wet indicates OAB with incontinence.

Prevalence of Urge Urinary Incontinence

A larger number of studies (n=48) examined urge urinary incontinence as the primary prevalence estimate of interest. Twenty-six distinct study populations, with 36 publications, appeared after the ICS 2002 consensus definitions.[2, 3, 10-14, 17-19, 21, 25, 27, 29, 31-38, 70, 72, 75, 80] These are presented here in greater detail because the definitions used are more similar to those that define "OAB-wet" and therefore are more likely to have comparability in the measures. Across all these populations, prevalence of urge incontinence ranged from a low of 1.5 percent in a large European study of all adult women from ages 18 to 70, [18] up to a high estimate of 22.0 percent in a United States mall-based consumer survey[36] and 26.4 percent among a household sample of Jordanian women age 50 to 65.[35] Each of the latter had somewhat ambiguous survey items. Average urge incontinence prevalence by region was:

United States: 9.7 percent among 37,596 respondents from nine populations2-4, 10, 11, 13, 17, 19, 25, 27, 32, 36, 40, 42, 72

Europe: 10.6 percent among 68,051 respondents from seven studies including nine countries18, 37, 43, 45, 48, 75, 81

Asia: 9.6 percent among 14,537 respondents from five populations in three countries14, 21, 29, 31, 33, 34, 41, 47, 80

Other: 12.5 percent among 6,219 respondents in five populations from five countries12, 35, 38, 49, 70

Though more than half of studies did not report the frequency of urge incontinence episodes required to meet the case definition (e.g., weekly, monthly), or used nonspecific terms such as "mostly" and "sometimes" in definition, these estimates are concordant with the range of estimates for the prevalence of OAB with urge incontinence features, suggesting that the measurement instruments captured similar features. These estimates are consistent with the AHRQ report on the Prevention of Fecal and Urinary Incontinence in Adults, which reported prevalence of UUI in community dwelling adults as increasing "from 5 percent in younger women to 10 percent in women 45-64 (32 studies), and to 12 percent in women older than 65 years (28 studies)".[196]

In the nine studies in which the interval of occurrence required to meet the definition of urge incontinence was specified, there was not a clear pattern of relationship between length of the interval and proportion of women classified as having urge incontinence.[10, 17, 27, 31, 34, 37, 38, 72, 80] Overall the average prevalence of UUI across these nine studies was 8.9 percent. The two studies that required weekly symptoms reported a prevalence of 7.0 and 6.5 percent (in populations which had an average age of 61, and an age range from 35 to 75 without a mean reported, respectively).[21, 31, 38] The average across six studies that reflect a wide age range and required at least monthly episodes was 9.4 percent, and the sole study reporting any urge incontinence within the year was 7.9 percent with an average respondent age of 51.[72] This lack of a pattern associated with the operational definition of frequency of urge incontinence episodes may result from variation in the methods of measurement or characteristics of the respondents that obscures any trend, or, more likely given large population-based samples, similarity in estimates may reflect that most women who are affected have fairly frequent symptoms and are detected and properly classified regardless of interval definition required.

Other Measures

Urgency symptoms. Individually, the symptoms of urgency and frequency are common. The range of prevalence for urgency symptoms (in post ICS studies) was from 8.0 percent in a young population of pre-menopausal Indian women,50 to the highest estimate of 45.4 percent among an even younger population of European women (mean age 34).48 Despite this wide range, which may reflect varied operational definitions used by researchers, nine of ten estimates for the prevalence of urgency are 10 percent or above.12, 14, 18, 34, 38, 47, 48, 50, 73

Frequency. Thirteen studies with fourteen groups reported on frequency. Most defined frequency as more than eight voids per day (or more). The range of estimates for women with daily frequency was 5.2 percent among Thai women ages 20 to 59,20 to 34 percent among Danish women ages 20 to 45,48 and 49 percent among Japanese women with an average age of 61.31 The average proportion of women with frequent voiding across study groups was 16.0 percent, with five estimates between 5 and 15 percent,12, 18, 20, 45, 50 and four estimates between 15 and 25 percent.14, 34, 38, 47

Age as a predictor of UUI. The relationship between urge urinary incontinence and increasing age was less consistent across studies than that for OAB and age, with some authors reporting nearly identical prevalence across all age brackets and no statistical trend15, 53 and others noting increases parallel to OAB,11, 12, 14, 42 more modest increases64 or threshold ages as in OAB which are inflection points at which prevalence was meaningfully increased, typically among the oldest age strata: >60,11 >65,42 >70,55 and >75.38 In aggregate, the trend was less pronounced or not apparent for a strong and continuous influence of age on prevalence of UUI. Thresholds in older age seem more likely with risk being similar across wide ranges of younger ages. We must also note that such effects may not be results of age per se but of comorbidities and medication use that change with age.

Other predictors. Other factors noted across studies were the influence of race and ethnicity in United States populations. Three studies (one of high quality and two of fair quality), several with more than one related publication, documented statistical association showing black women were more likely than white to have urge urinary incontinence (while noting higher risk of mixed and stress among white women compared to black).11, 17, 25, 197 Another high quality United States study found no difference with adjusted estimates of prevalence of 3.5 percent among black women and 3.6 percent among white women.10

Incidence of Overactive Bladder and Urge Urinary Incontinence

Ten studies provide incidence data. Three investigated the occurrence of new OAB symptoms over varied periods of time.[22, 26, 39] Seven investigated the onset of urge urinary incontinence.[15, 17, 49, 64, 74, 77, 81] Two provide information about resolution of symptoms among those with symptoms at baseline.[64, 77]

Estimates for annual incidence of OAB ranged from 2.6 to 143 cases per thousand. The lowest estimates came from a population-based estimate using the national health services database of the United Kingdom and including all adults; the highest is from the top age bracket ($\geq$ 80 year) in another UK study.[39] In that study, by decade beginning at 40, the annual incidence was 78, 65, 100, 117 and 143 per 1,000; the remaining report had participants with a mean of 59 years and an estimate of 54 new cases per 1,000 women per year.[39]

The largest study to address urge urinary incontinence was conducted in the United States within the Nurses Health Study. They report followup from 64,650 respondents with two-year data. In each five year age bracket from 35 to 55 years of age, the annual incidence among those without symptoms at baseline was 4 per 1,000 with the exception of the 46 to 50 category at 5

per 1,000.15 A separate analysis within the Nurses Health Study, using supplemental data collection to gather additional details, reported two-year incidence of urge incontinence of 14 per 1,000, which annualized to approximately 7 new cases per 1,000 women per year.69, 74 A six state urban sample that recruited 16,065 women and followed a subset of 3,032 for five years, reported 5-year incidence of urge incontinence of 15.9 percent or 3 cases per thousand per year.17 Work in Finland in a much smaller population sample of adults who were in their 50s and 60s at baseline and followed into 60s and 70s report the equivalent of 1.1 case per 1,000 per year, and if mortality is taken into account, 1.7 cases per year. A single study in Southern Australia, reports estimates that are meaningfully higher than these. Defining urge incontinence as that which occurs at least occasionally, and without providing a specific definition of how urge was queried, they report annual incidence of 226 cases per thousand. Of note the entire study population was 70 or older and no information about adjustment for competing morbidity is provided.49

A study of 2,025 women older than 65 who lived in rural Iowa provides additional information. This interview-based study was conducted prior to ICS consensus definitions, the research team used the index item “How often do you have difficulty holding your urine until you can get to a toilet?”, classifying those who answered “never” and “hardly ever” as free of urge incontinence. Estimated 3-year incidence of urge incontinence, over two rounds of followup was 20.4 and 24 percent, which annualizes to 6.8 to 8.0 per 1,000 among older women.[64]

The authors also report on remission: among those with UUI, 31.7 to 34.9 percent had resolution of their symptoms over the 3-year followup windows.64 Other research in a single United States county, among women 60 and older, found annual incidence of 17 per 1000, with 22.7 percent of women with urge incontinence symptoms reporting resolution within a year.77

KQ2: Outcomes of Treatment of OAB

This section presents results of our literature search and findings about outcomes of pharmacologic treatments for OAB. We review the basic mechanism of action of the family of medications classified as antimuscarinic agents. Six specific agents are available to United States practitioners: oxybutynin, tolterodine, fesoterodine, solifenacin, darifenacin, and trospium. Because a number of the studies are dose ranging and safety studies, we have included doses and preparations that may not be available. We also summarize studies of estrogen treatment for OAB. Each pharmacologic agent is presented individually with a thorough description of the content of the literature followed by the findings from trials and information from cohorts and case series, when those studies provided additional information beyond that provided by trials. Side effect and harms of treatment are reviewed together at the end of this section.

Pharmacologic Treatments

Pharmacologic treatments for OAB include antimuscarinic agents which have differing affinities for multiple subtypes of muscarinic receptors found both in the bladder as well as throughout the body. These agents generally bind to muscarinic receptors on the bladder muscle blocking the input required for contraction of the muscle. In short, such drugs prevent or decrease the intensity of involuntary bladder contractions.

Because muscarinic receptors are present throughout the body, nonselective agents affect other processes explaining the occurrence of side effects such as dry mouth (reduced action on salivation), constipation (slowing gut contractions), dry eyes (affecting tear ducts), and altered cognition (affecting central nervous system). In an attempt to decrease the effect on other organs

and improve tolerability, the development of agents purported to be more specific in targeting subtypes of muscarinic receptors found in the bladder has been undertaken.

Medication is often initiated with the lowest dose of an agent and adjusted to the desired clinical effect while minimizing adverse effects. The two most frequently prescribed pharmacologic treatments for OAB in the United States are oxybutynin and tolterodine. Oxybutynin is available in an oral immediate-release (IR) and an extended-release (ER) form, a transdermal patch, and a topical gel, approved by the FDA in January 2009. Tolterodine is also available in both immediate and extended-release pills. Fesoterodine was approved by the FDA in October 2008. Fesoterodine is a first order metabolite of tolterodine with similar selectivity. Newer agents available in the United States include solifenacin, darifenacin, and trospium, which is available in both immediate and extended-release formulations.

We reviewed 110 studies,[82-96, 98-109, 140-172, 174, 198-255] of which four were good quality, 75 fair and 31 poor. This section of the report presents summary data for each pharmacologic treatment, including varied doses, intervals, and delivery mechanism. Direct comparisons across or among types of treatment (including pharmacologic, behavioral and procedural, and others) are presented in KQ3. Additional information is also provided in that section about comparisons across extended release versus immediate release. Detailed information on all studies relating to pharmacologic treatment of OAB can be found in evidence tables in Appendix C.

The summary tables included here compile unique arms of randomized trials that did not allow dose adjustment within the arm. Each drug and dose combination, as well as the related placebo arms, is presented here if data for the outcome in the summary table was provided in the publication. When necessary, weekly or monthly measures were converted to daily in order to allow ready assessment of the baseline similarity, outcomes, and effect size across studies. Each of these pharmacologic agents has been shown to be statistically superior to placebo for some facet of OAB symptoms. Complete details of measurement approach and statistical comparisons are available in Appendix C; comparisons among doses of the same drug are discussed in this section, and direct comparisons between or among drugs are presented with KQ3.

Treatment with oxybutynin.

Content of the literature. We identified 13 randomized controlled studies of oxybutynin for treatment of OAB. A total of 22 study arms compared oxybutynin at various doses and intervals, and included five placebo arms (Tables 8 and 9). Most participants were recruited from non-primary care populations with seven studies performed in the United States,[82-88] three in Europe,[89-91] and one each in Japan,[92] Taiwan,[93] and South Korea.[94] These studies included a total of 2,575 women in treatment arms, and 383 women in the placebo arms. Participants had an average age of 59.3 and 60.9, in the treatment and placebo groups, respectively.

Outcomes of treatment. Baseline numbers of incontinence episodes per day in the oxybutynin treatment groups ranged from 1.0 to 7.2, and in the placebo arms from 0.0 to 3.0. Because many trials were drug to drug comparisons, this difference in range does not reflect marked differences between placebo and comparison groups within studies, rather the higher severity of symptoms in the drug to drug comparison studies which were more likely to include more individuals with multiple urge incontinence episodes per day. Study participants using oral oxybutynin achieved a reduction in mean episodes of urge urinary incontinence of between 0.0 and 4.6 over the course of placebo-controlled studies that ranged in followup from 2 to 52 weeks. Of the formulations studied, 10 mg per day appeared to achieve the greatest reduction with a range of 2.9 to 7.2

(Tables 8 and 9). However, all estimates in this section of the report should be assessed with reference to the placebo arms, in which participants also reported reductions in incontinence

episodes. In oxybutynin trials, in the placebo arms, reduction in UUI episodes ranged from 0 to 1.4.

Oxybutynin was also associated with a decrease in voids per day in both oral and transdermal formulations. Baseline voids per day in drug and placebo arms were similar (7.2 to 11.7 overall). Voids per day were lowered by 1.8 to 2.3 in the transdermal arms, 0.7 to 4.2 in oral oxybutynin IR, 3.4 to 4.1 in oral oxybutynin ER and 0.8 to 1.7 in the placebo arms.

Meta-analysis was possible for immediate release but not extended release. Immediate release reduced UUI by 1.49 episodes per day (95 percent CI: 1.18, 1.80); and voids by 2.18 episodes per day (95 percent CI: 1.75, 2.61).

Table 8. RCT arms for oxybutynin chloride effect on urge incontinence

Author Year	N (% Women)	Mean age	Episodes per day baseline	Episodes per day on treatment	Decrease in episodes per day	Weeks treated
Oxybutynin 10 mg once a day						
Sand et al.[83] 2004	147 (100.0)	58.4	3.6	0.9	2.7	12
Diokno et al.[84] 2003	339 (100.0)	60.0	5.3	1.5	3.8	12
Oxybutynin 5 mg twice a day						
Halaska et al.[90] 2003	66 (87.0)	52.2	2.1	1.1	1.0	52
Lee et al.[94] 2002	90 (79.0)	52.0	2.4	1.0	1.4	8
Oxybutynin 5 mg three times a day						
Zinner et al.[82] 2005	13 (93.4)	59.9	2.9	1.4	1.6	2
Abrams et al.[91] 1998	117 (74.5)	58.0	2.6	0.9	1.7	12
Oxybutynin 2.5 mg two or three times a day						
Wang et al.[93] 2006	23 (NR)	NR	1.0	1.0	0.0	12
Davila et al.[87] 2001	36 (97.0)	63.0	7.2	2.6	4.6	6
Transdermal Oxybutynin 3.9 mg (or cm^2)						
Homma and Koyama[92] 2006	164 (81)	62.7	2.9	0.9	1.0	8
Transdermal Oxybutynin 3.9 mg (or cm^2)						
Dmochowski et al.[88] 2003	121 (90.1)	63.1	4.7	1.9	2.8	12

Table 8. RCT arms for oxybutynin chloride effect on urge incontinence (continued)

Author Year	N (% Women)	Mean age	Episodes per day baseline	Episodes per day on treatment	Decrease in episodes per day	Weeks treated
Oral Placebo						
Wang et al.[93] 2006	23 (NR)	NR	0.0	0.0	0.0	12
Abrams et al.[91] 1998	56 (75.4)	58.0	3.3	2.4	0.9	12
Transdermal Placebo						
Homma et al.[92] 2006	161 (72.7)	62.9	3.0	1.6	1.4	8

Table 9. RCT arms for oxybutynin chloride effect on voids per day

Author Year	N (% Women)	Mean age	Voids per day baseline	Voids per day on treatment	Decrease in voids per day	Weeks treated
Oxybutynin 10 mg once a day						
Sand et al.[83] 2004	147 (100.0)	58.4	13.1	9.7	3.4	12
Diokno et al.[84] 2003	339 (100.0)	60.0	13.6	9.5	4.1	12
Oxybutynin 5 mg twice a day						
Halaska et al.[90] 2003	66 (87.0)	52.2	12.5	8.3	4.2	52
Lee et al.[94] 2002	90 (79.0)	52.2	12.4	10.6	1.8	8
Oxybutynin 5 mg three times a day						
Abrams et al.[91] 1998	117 (74.5)	58.0	10.7	8.4	2.3	12
Giannitsas et al.[89] 2004	6 (100.0)	53.0	7.2	6.1	1.1	6
Giannitsas et al.[89] 2004	25 (100.0)	57.0	8.0	7.3	0.7	6
Giannitsas et al.[89] 2004	36 (100.0)	57.0	8.3	7.5	0.8	6
Giannitsas et al.[89] 2004	40 (100.0)	54.0	9.3	8.3	1.0	6
Zinner et al.[82] 2005	13 (93.4)	59.9	10.4	9.2	1.2	2
Transdermal Oxybutynin 3.9 mg patch						
Dmochowski et al.[88] 2003	121 (90.1)	63.1	12.4	10.4	2.0	12
Transdermal Oxybutynin 3.9 mg patch						
Dmochowski et al.[85] 2002	123 (94.4)	59.4	12.3	10.0	2.3	12

Table 9. RCT arms for oxybutynin chloride effect on voids per day (continued)

Author Year	N (% Women)	Mean age	Voids per day baseline	Voids per day on treatment	Decrease in voids per day	Weeks treated
Oral Placebo						
Abrams et al.[91] 1998	56 (75.4)	58.0	11.7	10.1	1.6	12
Zinner et al.[82] 2005	15 (93.4)	59.9	10.4	9.6	0.8	2
Transdermal Placebo						
Dmochowski et al.[85] 2002	130 (89.4)	62.7	NR	NR	1.7	12

Quality of life outcomes in these studies were measured with several validated tools, including the Kings Health Questionnaire, Incontinence Inventory Questionnaire (IIQ), and Urinary Distress Inventory (UDI) (Table 18). In all studies, statistically significant improvements were observed relative to baseline, and in drug groups compared to placebo.[85, 86, 88, 92, 93] The MATRIX study assessed HRQoL in patients treated with transdermal oxybutynin.[245, 246] This patient population included 2,508 women with an average age of 62.5 years, and followed patients for a minimum of six months. Sand and colleagues used the KHQ and the PPBC to assess general quality of life improvement, and reported improvement in nine of ten domains versus baseline ($p<0.001$).[245] A second paper by Sand and colleagues employed the Beck-Depression Inventory (BDI-II) and the KHQ, and demonstrated improvement in embarrassment scores, effect on sex life, and relationships with partners, all $p<0.001$. The BDI-II also showed improvement in interest in sex from baseline to study end ($p<0.001$).[246]

Treatment with tolterodine.

Content of the literature. We included 20 RCTs[83, 84, 86, 88, 89, 91, 94, 96, 97, 99, 140, 141, 154, 162, 168, 209, 223, 233, 240, 241] and 11 prospective cohort studies[157, 160, 166, 169, 172, 212, 224, 227, 232, 239, 243] of tolterodine. Among the RCTs were 30 tolterodine arms and 14 placebo arms (Tables 10 and 11). Most were multinational studies conducted at centers in Europe, the United States, Australia, and Asia. A total of 6,746 women were in the treatment arms, with 3,298 women in the placebo arms. The average ages were 58.1 and 59.9, respectively.

Outcomes. At baseline, women reported between 1.6 and 5.0 episodes of urge urinary incontinence per day. Treatment with 4 mg of drug once a day reduced episodes of urge in continence an average of 0.9 to 3.7 episodes each day, compared to a reduction of 1.3 to 2.4 for 2 mg taken twice a day. These doses and intervals are common in clinical practice; other doses and intervals also are included in Tables 10 and 11. Overall, reductions in urge urinary incontinence episodes on active therapy ranged from 0.9 to 3.7, compared to reductions in the placebo arms of 0.6 to 2.1.

With respect to frequency of voiding, tolterodine was associated with 0.9 to 3.6 fewer voids per day in study populations that had baseline voiding frequencies of 7.2 to 13.7. The range of response for placebo was 0.4 to 2.2 fewer voids per day, in study populations that had baseline voiding frequencies of 10.3 to 12.3 per day. Reductions differed by treatment dosage and timing, with a reduction of 1.7 to 3.6 with 4 mg once daily, 0.9 to 1.1 for 4 mg twice daily, and 1.4 to 3.3 for 2 mg twice daily.

Estimates were developed in the meta-analysis for decreases in UUI episodes and voids per day in tolterodine immediate release and tolterodine extended release formulations. Tolterodine immediate release reduced UUI by 1.45 episodes per day (95 percent CI: 1.24, 1.66) and voids

per day by 2.19 (95 percent CI: 1.76, 2.61). Tolterodine extended release reduced UUI by 1.75 episodes per day (95 percent CI: 1.65, 1.85) and voids per day by 2.48 (95 percent CI: 1.94, 3.02). The aggregate effect of placebo across all available study arms was a decrease in UUI episodes per day of 1.08 (95 percent CI: 0.86, 1.30) and voids by 1.48 (95 percent CI: 1.19, 1.71) per day.

Two RCTs included urodynamic parameters to assess intermediate effects of tolterodine treatment.[221, 238] In a dose-finding study, tolterodine 2 mg twice a day demonstrated statistically significant increase in the volume at first contraction (p=0.03), and an in increase in maximal cystometric capacity following four weeks of treatment compared to baseline urodynamic parameters.[221] In contrast, mean volume at first contraction was significantly increased after two weeks of treatment compared to baseline (p=0.046), but no improved outcome effect was seen for maximum cystometric capacity, bladder compliance, or number of detrusor contractions.[238]

Table 10. RCT arms for tolterodine tartrate effect on urge incontinence

Author Year	N (% Women)	Mean age	Episodes per day baseline	Episodes per day on treatment	Decrease in episodes per day	Weeks treated
Tolterodine 4 mg once a day						
Rogers et al.[241] 2008	182 (100)	49.0	2.5	NR	1.8	12
Chapple et al.[99] 2007	297 (87.1)	56.9	NR	NR	0.9	4
Chapple et al.[96] 2007	253 (78.0)	57.7	3.8	2.1	1.7	12
Robinson et al.[240] 2007	53 (100)	NR	2.3	0.7	1.7	8
Landis et al.[168] 2004	321 (81.6)	60.9	1.6	0.5	1.1	12
Landis et al.[168] 2004	284 (83.6)	60.0	4.7	1.6	3.3	12
Millard et al.[154] 2004	205 (75.4)	53.6	3.2	1.1	2.2	12
Millard et al.[154] 2004	191 (75.4)	53.6	3.2	1.0	2.3	24
Diokno et al.[84] 2003	357 (100)	60.0	5.3	1.6	3.7	12
Tolterodine 4 mg once a day						
Dmochowski et al.[88] 2003	123 (95.1)	62.9	5.0	1.9	3.1	12
Swift et al.[140] 2003	417 (100)	59.0	3.2	1.5	1.7	12
Van Kerrebroeck et al.[141] 2001	507 (82.0)	60.0	3.2	1.5	1.2	12

Table 10. RCT arms for tolterodine tartrate effect on urge incontinence (continued)

Tolterodine 2 mg twice a day						
Sand et al.[83] 2004	161 (100)	58.8	3.6	1.2	2.4	12
Chapple et al.[97] 2003	279 (72.9)	58.1	2.3	0.9	1.4	12
Swift et al.[140] 2003	408 (100)	59.0	3.3	1.8	1.4	12
Lee et al.[94] 2002	97 (74.0)	52.0	2.6	0.4	2.2	8
Jacquetin[162] 2001	103 (81.6)	58.0	3.2	1.9	1.3	4
Van Kerrebroeck et al.[141] 2001	514 (79)	60.0	3.3	1.8	1.5	12
Millard et al.[233] 1999	116 (77.0)	60.2	3.6	1.9	1.7	12
Abrams et al.[91] 1998	118 (77.1)	55.0	2.9	1.6	1.3	12
Tolterodine 2 mg three times a day						
Chancellor et al.[209] 2000	514 (80.0)	60.0	3.3	1.8	1.5	12
Tolterodine 1 mg twice a day						
Jacquetin et al.[162] 2001	97 (76.3)	53.0	3.7	2.6	1.1	4
Millard et al.[233] 1999	114 (78.0)	60.1	3.9	2.2	1.7	12
Placebo						
Chapple et al.[96] 2007	252 (81.0)	56.0	3.7	2.6	1.1	12
Landis et al.[168] 2004	171 (78.5)	60.6	1.6	1.0	0.6	12
Landis et al.[168] 2004	210 (84.8)	61.8	4.5	3.2	1.3	12

Table 10. RCT arms for tolterodine tartrate effect on urge incontinence (continued)

Author Year	N (% Women)	Mean age	Episodes per day baseline	Episodes per day on treatment	Decrease in episodes per day	Weeks treated
Placebo						
Rogers et al.[241] 2008	189 (100)	47.0	2.2	NR	1.4	12
Robinson et al.[240] 2007	59 (100)	NR	2.9	2.2	0.7	8
Chapple et al.[97] 2003	267 (76.3)	57.7	2.0	1.4	0.6	12
Dmochowski et al.[88] 2003	117 (93.2)	64.5	5.0	2.9	2.1	12
Swift et al.[140] 2003	410 (100)	60.0	3.4	2.4	1.0	12
Van Kerrebroeck et al.[141] 2001	507 (81.0)	61.0	3.3	2.3	1.0	12

Table 11. RCT arms for tolterodine tartrate effect on voids per day

Author Year	N (% Women)	Mean age	Voids per day baseline	Voids per day on treatment	Decrease in voids per day	Weeks treated
Tolterodine 4 mg once a day						
Rogers et al.[241] 2008	182 (100)	49.0	13.0	NR	3.3	12
Chapple et al.[96] 2007	253 (78.0)	57.7	11.5	9.8	1.7	12
Chapple et al.[99] 2007	267 (87.1)	56.9	NR	NR	1.5	4
Robinson et al.[240] 2007	53 (100)	NR	13.2	10.6	2.6	8
Landis et al.[168] 2004	321 (81.6)	60.9	9.6	NR	1.2	12
Landis et al.[168] 2004	171 (78.5)	60.6	10.3	NR	0.9	12
Millard et al.[154] 2004	191 (75.4)	53.6	12.8	9.2	3.6	24
Millard et al.[154] 2004	205 (75.4)	53.6	12.8	9.4	3.4	12
Diokno et al.[84] 2003	357 (100)	60.0	13.7	10.2	3.6	12
Dmochowski et al.[88] 2003	123 (95.1)	62.9	12.1	9.9	2.2	12

Table 11. RCT arms for tolterodine tartrate effect on voids per day (continued)

Author Year	N (% Women)	Mean age	Voids per day baseline	Voids per day on treatment	Decrease in voids per day	Weeks treated
Tolterodine 4 mg once a day						
Swift et al.[140] 2003	417 (100)	59.0	10.8	9.0	1.8	12
Van Kerrebroeck et al.[141] 2001	507 (82.2)	60.0	10.9	7.4	3.5	12
Tolterodine 4 mg twice a day						
Giannitsas et al.[89] 2004	6 (100)	53.0	7.2	6.3	0.9	6
Giannitsas et al.[89] 2004	25 (100)	57.0	8.0	7.0	1.0	6
Giannitsas et al.[89] 2004	36 (100)	57.0	8.3	7.2	1.1	6
Giannitsas et al.[89] 2004	40 (100)	54.0	8.5	7.6	0.9	6
Tolterodine 2 mg twice a day						
Sand et al.[83] 2004	161 (100)	58.8	13.1	10.2	2.9	12
Chapple et al.[97] 2003	279 (72.9)	58.1	12.1	9.9	2.2	12
Swift et al.[140] 2003	408 (100)	59.0	11.1	9.3	1.8	12
Lee et al.[94] 2002	97 (74.0)	52.0	12.2	9.6	2.6	8
Tolterodine 2 mg twice a day (continued)						
Jacquetin et al.[162] 2001	103 (81.6)	58.0	10.8	9.4	1.4	4
Van Kerrebroeck et al.[141] 2001	514 (79)	60.0	11.1	7.8	3.3	12
Millard et al.[233] 1999	116 (77.0)	60.2	11.2	8.9	2.3	12
Abrams et al.[91] 1998	118 (77.1)	55.0	11.5	8.8	2.7	12
Tolterodine 2 mg three times a day						
Chancellor et al.[209] 2000	514 (80.0)	60.0	11.1	9.4	1.7	12
Tolterodine 1 mg twice a day						
Jacquetin et al.[162] 2001	97 (76.3)	53.0	10.7	9.3	1.4	4
Millard et al.[233] 1999	114 (78.0)	60.1	11.5	9.2	2.3	12

Table 11. RCT arms for tolterodine tartrate effect on voids per day (continued)

Author Year	N (% Women)	Mean age	Voids per day baseline	Voids per day on treatment	Decrease in voids per day	Weeks treated
Placebo						
Rogers et al.[241] 2008	189 (100)	47.0	12.5	NR	2.3	12
Chapple et al.[96] 2007	252 (81.0)	56.0	11.5	11.1	1.0	12
Robinson et al.[240] 2007	59 (100)	NR	11.9	10.1	1.8	8
Landis et al.[168] 2004	210 (84.8)	61.8	11.1	NR	0.4	12
Landis et al.[168] 2004	284 (83.6)	60.0	10.7	NR	1.9	12
Chapple et al.[97] 2003	267 (76.3)	57.7	12.2	11.0	1.2	12
Dmochowski et al.[88] 2003	117 (93.2)	64.5	12.3	10.9	1.4	12
Swift et al.[140] 2003	410 (100)	60.0	11.2	9.9	1.3	12
Van Kerrebroeck et al.[141] 2001	507 (81.0)	61.0	11.3	9.1	2.2	12

Findings from cohort studies and case series were compatible with these results. Twelve such studies demonstrated improvement in urinary urgency, frequency, and urge incontinence with tolterodine treatment.[142, 157, 160, 166, 169, 172, 212, 224, 227, 232, 239, 243, 247]

Twelve studies including RCTs, prospective cohorts and extension studies evaluated the effect of tolterodine on patient reported outcomes, including quality of life in at least one arm.[86, 88, 91, 99, 142, 158, 160, 174, 223, 240, 241, 247] Participants in tolterodine arms consistently reported greater changes in quality of life, including on various domains of the Kings Health Questionnaire, IIQ, and UDI-6 when compared to placebo that were similar to those experienced by participants of oxybutynin arms in the studies.

One study evaluated the impact of treatment with tolterodine ER 4 mg once daily on emotional and sexual health. Sexual Quality of Life Questionnaire- Female (SQoL-F), Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire (PISQ), and the Hospital Anxiety and Depression scale (HAD) were used to assess patient reported outcomes. Treatment with tolterodine resulted in improved scores versus placebo in SQoL-F; PISQ- total score, and HAD anxiety ($p=0.004$, $p=0.009$, $p=0.03$ respectively).[241]

One study stratified outcomes by treatment in patients with prolapse and found no significant difference in changes in quality of life between those with anterior vaginal wall prolapse and those without.[243] Another study stratified patients by those with urge incontinence and those with OAB syndrome without incontinence, and found similar bother and severity scores in each group in an open label study of tolterodine ER.[159]

Most outcomes were equivalent in studies comparing tolterodine IR versus ER; however, in two RCTs, extended release tolterodine resulted in a greater reduction in incontinence episodes per day, $p=0.036$ and $p=0.05$, respectively.[140, 141] Other outcome parameters including voids per

day and pads per day showed a similar reduction compared to placebo with no statistical difference seen between the two formulations.

Treatment with fesoterodine.

Content of the literature. Two randomized controlled trials compared fesoterodine at 4 and 8 mg to placebo for reducing symptoms of OAB in this literature that met criteria for inclusion in the systematic review (Table 12).[95, 96] These studies included a total of 1,017 women with a mean age of 57.7 in the treatment arms, and a total of 518 women with a mean age of 57.5 in the placebo arms. Both studies reported outcome data at 12 weeks of treatment. One study included a tolterodine 4 mg arm, discussed in KQ3.[96] There is one paper included which is a post hoc analysis of this study population[96] assessing treatment effect on health-related quality of life.[142]

Outcomes. At baseline, women in the treatment arms reported between 2.2 and 3.2 episodes of urge urinary incontinence per day. Treatment with drug resulted in reductions of 1.95 and 3.2 episodes per day. In the placebo arms at baseline, participants had an average of 3.7 episodes of urge incontinence per day. UUI in the placebo group was reduced by 1.14 to 1.48 episodes per day after 12 weeks of treatment.[95, 96]

At baseline, women in the treatment arms reported between 11.6 and 12.9 voids per day. Treatment with drug resulted in reductions of 1.4 to 1.9 voids per day. Women in the placebo arms reported between 12.0 to 12.2 voids per day at baseline, and reported a reduction of voids per day ranging from 0.7 to 0.95.[95, 96]

In the meta-analysis, fesoterodine decreased UUI per day by 2.03 (95 percent CI: 1.74, 2.31) episodes and voids per day by 1.84 (95 percent CI: 1.64, 2.03) episodes. placebo reduces UUI episodes by 1.08 (95 percent CI: 0.86, 1.30), and voids by 1.48 (95 percent CI: 1.19, 1.71) per day. The aggregate effect of placebo across all available study arms was a decrease in UUI episodes per day of 1.08 (95 percent CI: 0.86, 1.30) and voids by 1.48 (95 percent CI: 1.19, 1.71) per day.

The post hoc analysis of fesoterodine arms showed significant improvement in HRQoL as assessed by KHQ and ICIQ-SF in both fesoterodine 8 mg arm and the tolterodine ER 4 mg arm versus placebo, but there was no significant difference between arms. The fesoterodine arm showed significant improvement in eight of nine domains (non significant in General Health domain). A subset of patients who reported incontinence at baseline showed similar improvements versus baseline; however, no significant difference was seen between arms as well as between subsets of those reporting incontinence at baseline versus those without.[142]

Table 12. RCT arms for fesoterodine fumarate effect on urge incontinence and voids

Author Year	N (% Women)	Mean age	Episodes per day baseline	Episodes per day on treatment	Decrease in episodes per day	Weeks treated
Episodes of urge incontinence						
Fesoterodine 8 mg once a day						
Chapple et al.[96] 2007	252 (81.0)	55.6	3.7	1.5	2.2	12
Nitti et al.[95] 2007	267 (78.0)	59.0	3.9	0.7	3.2	12
Fesoterodine 4 mg once a day						
Chapple et al.[96] 2007	231 (82.0)	57.1	3.8	1.9	2.0	12
Nitti et al.[95] 2007	267 (76.0)	59.0	3.9	1.3	2.6	12
Voids per day						
Fesoterodine 8 mg once a day						
Chapple et al.[96] 2007	252 (81.0)	55.6	11.9	10.0	1.9	12
Nitti et al.[95] 2007	267 (78.0)	59.0	12.0	10.1	1.9	12
Fesoterodine 4 mg once a day						
Chapple, et al.[96] 2007	231 (82.0)	57.1	11.6	9.8	1.8	12
Nitti et al.[95] 2007	267 (76.0)	59.0	12.9	11.5	1.4	12

Treatment with solifenacin.

Content of the literature. Three RCTs investigated solifenacin compared to placebo for reducing symptoms of OAB (Table 13).[97-99] These studies included at total of 1,541 women, with a mean age of 58.2 years in the solifenacin treatment arms, and a total of 638 women with a mean age of 59.3 in the placebo arms. Two were conducted at multiple centers across Europe, and the other in Japan at academic health centers. One of these trials compared solifenacin to tolterodine, without a placebo arm, and is described in KQ3.[99, 211] A newly published RCT performed at multiple centers in the United States comparing solifenacin at various doses to placebo over twelve weeks focused on outcomes of urgency and "warning time" showing significant decrease in urgency episodes per day ($p<0.001$), and an increase of 31.5 seconds in median warning time ($p=0.008$).[222] Voids per day and UUI episodes per day were significantly reduced compared to placebo (both $p<0.001$).[222]

Outcomes. The first study compared solifenacin 5 mg and 10 mg daily to placebo and propiverine 10 mg.[98] Women in the two solifenacin arms (713 women with a mean age of 60.2) had an average decrease in the number of UUI episodes per of 1.45 and 1.52 at 12 weeks compared to a reduction in the placebo arm of 0.89 ($p<0.001$ for comparisons of both dosages to placebo).[98] Participants had a significant decrease in the number of voids per day of 1.9 to 2.9 ($p<0.001$ for both doses)

The second study also studied 5 mg and 10 mg doses, compared to placebo. Women in the two solifenacin arms, 5 mg and 10 mg, (531 women with a mean age of 57.1) experienced reductions in number of UUI episodes per day of 1.4 and 0.9, respectively at 12 weeks. The placebo arm (267 women with a mean age of 57.7) demonstrated a reduction in urge urinary incontinence episodes per day of 0.6.[97]

Solifenacin was associated with a decrease of 1.46 episodes of UUI per day (95 percent CI: 1.32, 1.59) and of 2.19 voids per day (95 percent CI: 1.94, 3.02) in the meta-analysis.

Quality of life was assessed in four studies of solifenacin.[98, 99, 218, 225] Quality of life measures improved significantly in the solifenacin arms[218] including when compared to placebo.[98, 225] Significant improvement in quality of life was maintained upon sub- analysis for African Americans and Hispanics.[205, 229] Perception of bladder condition was better in one solifenacin arm that was compared to tolterodine[99] (p=0.006).

Two prospective case series with multiple publications evaluated solifenacin in the treatment of OAB.[205, 218, 220, 229] One study included 1,280 women with a mean age of 56.4 years.[220] Participants had a 66 percent reduction in incontinence episodes per day (from 2.66 to 0.93), a 23 percent reduction in voids per day (12.16 to 9.18), a 63 percent reduction in urgency episodes per day (5.76 to 2.28), and a 32 percent reduction in nocturia episodes (1.95 to 1.25) as assessed by urinary diary at one-year followup.

A dose ranging study evaluating treatment with solifenacin 5 and 10 mg daily after washout from tolterodine 4 mg ER, darifenacin or trospium found significant improvement in UUI episodes per day and voids per day over a 12 week treatment period after 14 day washout period ($p<0.001$). Patient reported outcomes assessed by the PPBC and OAB-q questionnaires indicated significant subjective improvement ($p<0.001$ in all domains).[208]

Another prospective randomized trial compared Solifenacin 5 and 10 mg daily to placebo. This study used the PPIUS (Patient Perception of Intensity of Urgency Scale) to assess treatment effect on urgency, and demonstrated that Solifenacin at the two doses demonstrated significant improvement in severe urgency episodes over placebo ($p<0.001$). In addition, patient reported outcomes of urgency bother, patient PBC score, and treatment satisfaction were significantly reduced compared to placebo ($p<0.001$).[206]

Table 13. RCT arms for solifenacin succinate effect on urge incontinence and voids

Author Year	N (% Women)	Mean age	Episodes per day baseline	Episodes per day on treatment	Decrease in episodes per day	Weeks treated
Episodes of urge incontinence						
Solifenacin 10 mg once a day						
Yamaguchi et al.[98] 2007	349 (85.7)	59.9	1.9	0.4	1.5	12

Table 13. RCT arms for solifenacin succinate effect on urge incontinence and voids (continued)

Author Year	N (% Women)	Mean age	Episodes per day baseline	Episodes per day on treatment	Decrease in episodes per day	Weeks treated
Episodes of urge incontinence						
Solifenacin 10 mg once a day						
Chapple et al.[97] 2003	263 (80.0)	56.9	1.9	1.0	0.9	12
Solifenacin 5 mg once a day						
Yamaguchi et al.[98] 2007	364 (83.0)	60.4	2.0	0.4	1.5	12
Chapple et al.[99] 2007	297 (87.5)	56.6	NR	NR	NR	4
Chapple et al.[97] 2003	268 (71.2)	57.2	2.1	0.8	1.4	12
Placebo						
Yamaguchi et al.[98] 2007	371 (84.3)	60.8	1.7	0.8	0.9	12
Chapple et al.[97] 2003	267 (76.3)	57.7	2.0	1.4	0.6	12
Voids per day						
Solifenacin 10 mg once a day						
Chapple et al.[97] 2003	263 (80.0)	56.9	12.1	10.2	1.9	12
Solifenacin 5 mg once a day						
Chapple et al.[99] 2007	297 (87.5)	56.6	NR	NR	1.7	4
Chapple et al.[97] 2003	268 (71.2)	57.2	12.3	9.7	2.6	12
Placebo						
Chapple et al.[97] 2003	267 (76.3)	57.7	12.2	11.0	1.2	12

Treatment with darifenacin.

Content of the literature. Five RCTs provided data on the effectiveness of darifenacin.[82, 100-102, 210] Three compared 15 and 30 mg daily relative to placebo (Tables 14 and 15).[82, 100, 101] These three studies included a total of 690 women, with a mean age of 57.6 years in the darifenacin treatment arms and a total of 304 women with a mean age of 57.6 in the placebo arms. Two of the three were conducted in the United States in a non-primary care population.[82, 101] The other was performed at multiple centers in Europe including community-based ambulatory populations, and also included a 7.5 mg arm.[100] The fourth study compared only darifenacin 7.5 mg to placebo and included 269 women with mean age of 57.5 in the treatment arm, and 129 women with an average of 58.5 in the placebo arm. This was a dose change study without report of outcomes by dosage.[102] A fifth RCT also compared darifenacin 7.5 mg to placebo in a multinational, multicenter trial. This was a dose changing study without reporting of outcome by dosage. The treatment arm included 206 women with an average age of 72 years and a placebo

arm including 100 women with an average age of 73 years.[210] One of these studies[82] also compared darifenacin to oxybutynin; the darifenacin arm is presented in Tables 14 and 15, but the comparison is described in the chapter on KQ3.

Outcomes. Baseline urge urinary incontinence episodes per day in the darifenacin arms ranged from 2.0 to 2.9. Urge urinary incontinence episodes per day on treatment ranged from 0.8 to 1.6, for a decrease in episodes of UUI per day ranging from 1.2 to 1.8. This is compared to an average reduction in the placebo groups of 0.8 to 1.0, with similar baseline measures of 2.3 to 3.0.

At baseline, participants reported an average of 10.3 to 11.0 voids per day. The treatment groups reported reductions ranging from 1.1 to 2.2 per day, compared to 0.8 to 1.8 in the placebo group. Study followup ranged from 2 to 12 weeks. Daily episodes of the symptom of urinary urgency also were reported to be reduced after treatment with darifenacin (range of reduction: 1.4 to 3.0 compared to 0.6 to 1.2 in placebo). The one study that reported reduction in urgency on a weekly basis, however, found no significant difference between treatment and placebo.[101]

Because of a lack of uniform information provided in the studies on variance measures, we could not use meta-analysis techniques to estimate effects of darifenacin on UUI or voids per day.

In the first dose-adjustment trial, urge urinary incontinence episodes were not reported, but voiding frequency was significantly reduced in the treatment arm versus placebo, p=0.001.[102] In the second dose changing trial changes in urge urinary incontinence episodes per week were not statistically different between the two arms (p=0.328), but reductions in voids per day were statistically greater in the treatment arm versus placebo (p=0.006). This study also assessed urgency episodes per day, but found no statistically significant difference in effect (p=0.174).[210]

Three studies assessed quality of life (QoL) with validated questionnaires using Visual Analog Scale (VAS), OAB-q, King's Health Questionnaire (KHQ), and ICIQ. The arms using 15 and 30 mg showed statistically significant improvement versus placebo, p=0.045 and p=0.011, respectively.[100] Zinner evaluated 15 mg versus placebo and showed significant improvement in quality of life questionnaires, OAB-q (p<0.001), ICIQ (p<0.001) and KHQ (p<0.05).[101] Chapple demonstrated improvement in all domains of the OAB-q versus placebo (p<0.001).[210] A single prospective cohort study evaluated the efficacy and tolerability of darifenacin.[219] This prospective, non-comparative, open-label extension study was conducted in multiple countries in Europe, Australia, and North America.[102] The authors stratified results by age. All outcome parameters were similar between groups showing similar reductions in voids per day, urgency episodes per day, and severity of urgency in those over and under 65 years old.[219] A second paper describing the open labeled extension study of those patients[219] demonstrated significant improvement from baseline in eight of nine domains (p<0.001) in health related quality of life outcomes as measured by the KHQ at 24 months. Significant reductions were confirmed in the subgroup of subjects 65 years old and greater. The only domain that did not show improvement was the General Health Perceptions.[217]

Table 14. RCT arms for darifenacin effect on urge incontinence

Author Year	N (% Women)	Mean age	Episodes per day baseline	Episodes per day on treatment	Decrease in episodes per day	Weeks treated
Darifenacin 30 mg once a day						
Hill et al.[100] 2006	96 (86.0)	54.0	2.7	1.1	1.6	12
Zinner et al.[82] 2005	15 (93.4)	59.9	2.9	1.3	1.7	2
Darifenacin 15 mg once a day						
Hill et al.[100] 2006	93 (86.0)	55.1	2.5	1.0	1.5	12
Zinner et al.[101] 2006	185 (86.4)	59.1	2.7	0.9	1.8	12
Zinner et al.[101] 2006	185 (86.4)	59.1	2.7	1.4	1.3	2
Zinner et al.[82] 2005	17 (93.4)	59.9	2.9	1.6	1.4	2
Darifenacin 7.5 mg once a day						
Hill et al.[100] 2006	99 (87.0)	56.1	2.0	0.8	1.2	12
Placebo						
Hill et al.[100] 2006	101 (83.0)	53.7	2.3	1.5	0.8	12
Zinner et al.[101] 2006	188 (88.0)	59.1	3.0	2.0	1.0	2
Zinner et al.[82] 2005	15 (93.4)	59.9	2.9	2.1	0.8	2

Table 15. RCT arms for darifenacin effect on voids per day

Author Year	N (% Women)	Mean age	Voids per day baseline	Voids per day on treatment	Decrease in voids per day	Weeks treated
Darifenacin 7.5 mg once a day						
Hill et al.[100] 2006	99 (87.0)	56.1	10.3	8.6	1.7	12
Darifenacin 15 mg once a day						
Hill et al.[100] 2006	93 (86.0)	55.1	11.0	9.1	1.9	12
Zinner et al.[101] 2006	185 (86.4)	59.1	11.0	8.8	2.2	12
Zinner et al.[82] 2005	17 (93.4)	59.9	10.4	9.3	1.1	2

Table 15. RCT arms for darifenacin effect on voids per day (continued)

Author Year	N (% Women)	Mean age	Voids per day baseline	Voids per day on treatment	Decrease in voids per day	Weeks treated
Darifenacin 30 mg once a day						
Hill et al.[100] 2006	96 (86.0)	54.0	10.4	8.2	2.2	12
Zinner et al.[82] 2005	15 (93.4)	59.9	10.4	8.9	1.6	2
Placebo						
Zinner et al.[101] 2006	188 (88.0)	59.1	11.2	9.4	1.8	12
Hill et al.[100] 2006	101 (83.0)	53.7	10.1	9.0	1.1	12
Zinner et al.[82] 2005	15 (93.4)	59.9	10.4	9.6	0.8	2

Treatment with trospium chloride.

Content of the literature. Five RCTs evaluated trospium for reduction of symptoms of OAB. Four trials compared trospium to placebo, and one compared trospium to oxybutynin (5 mg twice daily) (Table 16). Four were conducted in the United States,[103, 104 , 105, 106] and the fifth at multiple centers in Europe and Asia (Tables 16 and 17).[90] These studies included a total of 1,309 women, with a mean age of 59.8 years in the trospium treatment arms, and a total of 1,130 women with a mean age of 60.1 in the placebo arms.[103-106] One trial included a comparison to oxybutynin (5 mg twice a day).[90] The trospium arm is included in Tables 16 and 17; and the drug to drug comparison in noted in KQ3.

Outcomes. Reductions in numbers of urge urinary incontinence episodes per day at 12 weeks ranged from 1.8 to 2.5 relative to reductions in the placebo arms of 1.3 to 1.9. Reduction in voids per day on treatment ranged from 2.4 to 3.5 at 12 weeks, compared to placebo at 1.3 to 2.1

Meta-analysis could be used to estimate effects of trospium extended release only. This formulation reduced UUI episodes per day by 2.45 (95 percent CI: 2.19, 2.70) and voids per day by 2.68 (95 percent CI: 2.38, 2.98) episodes. The aggregate effect of placebo across all available study arms was a decrease in UUI episodes per day of 1.08 (95 percent CI: 0.86, 1.30) and voids by 1.48 (95 percent CI: 1.19, 1.71) per day.

Three studies evaluated urgency severity using the Indevus Urgency Severity Scale (IUSS). All three studies found statistically significant improvements in severity of urgency at trial end in the trospium arms versus placebo: $p=0.0004$, $p\leq0.001$, and $p<0.0001$ respectively.[103-105]

Table 16. RCT arms for trospium chloride effect on urge incontinence

Author Year	N (% Women)	Mean age	Episodes per day baseline	Episodes per day on treatment	Decrease in episodes per day	Weeks treated
Trospium 60 mg once a day						
Dmochowski et al.[105] 2008	267 (82.1)	61.2	4.0	1.6	2.4	12
Trospium 60 mg once a day						
Staskin et al.[103] 2007	263 (85.2)	59.6	4.1	1.6	2.5	12
Staskin et al.[103] 2007	263 (85.2)	59.6	4.1	1.8	2.4	4
Trospium 20 mg twice a day						
Rudy et al.[104, 242] 2006	323 (81.8)	61.1	2.9	1.0	1.9	12
Halaska et al.[90] 2003	200 (85.0)	54.2	1.5	0.5	1.0	52
Zinner et al.[106] 2004	256 (77.9)	63.0	3.0	1.2	1.8	12
Placebo						
Dmochowski et al.[105] 2008	276 (87.7)	58.4	4.0	2.4	1.6	12
Staskin et al.[103] 2007	273 (84.5)	59.3	4.1	2.2	1.9	12
Rudy et al.[104, 242] 2006	325 (81.2)	61.0	2.9	1.6	1.3	12
Zinner et al.[106] 2004	256 (71.6)	61.5	4.3	2.4	1.9	12
Staskin et al.[103] 2007	273 (84.5)	59.3	4.1	2.4	1.8	4

Table 17. RCT arms for trospium chloride effect on voids per day

Author Year	N (% Women)	Mean age	Voids per day baseline	Voids per day on treatment	Decrease in voids per day	Weeks treated
Trospium 60 mg once a day						
Dmochowski et al.[105] 2008	267 (82.1)	61.2	12.8	10.3	2.5	12
Staskin et al.[103] 2007	263 (85.2)	59.6	11.9	8.8	3.1	12
Staskin et al.[103] 2007	263 (85.2)	59.6	11.9	9.2	2.7	4

Table 17. RCT arms for trospium chloride effect on voids per day (continued)

Author Year	N (% Women)	Mean age	Voids per day baseline	Voids per day on treatment	Decrease in voids per day	Weeks treated
Trospium 20 mg twice a day						
Rudy et al.[104, 242] 2006	323 (81.8)	61.1	12.9	10.3	2.7	12
Trospium 20 mg twice a day						
Zinner et al.[106] 2004	256 (77.9)	63.0	12.7	10.3	2.4	12
Halaska et al.[90] 2003	200 (85.0)	54.2	11.4	7.9	3.5	52
Placebo						
Dmochowski et al.[105] 2008	276 (87.7)	58.4	12.9	11.1	1.8	12
Staskin et al.[103] 2007	273 (84.5)	59.3	11.8	9.7	2.1	12
Staskin et al.[103] 2007	273 (84.5)	59.3	11.8	10.1	1.7	4
Rudy et al.[104, 242] 2006	325 (81.2)	61.0	13.2	11.4	1.8	12
Zinner et al.[106] 2004	256 (71.6)	61.5	12.9	11.6	1.3	12

Quality of life was addressed in three studies using the OAB-SCS validated questionnaire[103, 104] and the IIQ in one.[106] Only one of the studies using the OAB-SCS reported statistically significant improvement in quality of life compared to placebo, $p<0.05$.[103]

Treatment with estrogen.

Content of the literature. Three studies assessed the role of hormonal therapy in different doses and formulations in the alleviation of OAB symptoms.[107-109] All studies were performed in Europe and Scandinavia. They included a total of 508 women with a mean age of 62.4 years. Three were RCTs and one was a case series.

Outcomes. One RCT compared oral estriol 3 mg per day to placebo at academic centers in England. They found that estriol was not significantly superior to placebo at improving symptoms or objective measures for all patients at one or three months.[107]

The second RCT compared an estradiol releasing vaginal ring to an estriol vaginal pessary in a community population in Denmark, and found both equal in improvement of UUI episodes, urgency, and nocturia. In each arm, 58 percent of participants had decreased UUI at 24 weeks; 51 and 56 percent had decreased urgency, respectively.[108] This is difficult to interpret in the absence of a placebo comparison.

A recently published RCT compared tolterodine 2 mg twice daily with and without CEE (conjugated equine estrogens) vaginal cream 0.625 mg twice weekly. Voids per day decreased significantly in the CEE arm ($p=0.001$), but did not show significant difference in UUI events per day. Subjective assessment with UDI-6 and IIQ-7 showed significant improvement in the tolterodine with CEE arm ($p=0.001$).[247]

One case series found oral HRT significantly improved frequency at six-month followup where dosage was not associated with outcome. Hormone replacement therapy in the form of

estriol significantly decreased frequency in the OAB arm at six weeks.[109] Outcomes were assessed with a five-point unvalidated rating system and no helpful comparison group.

Table 18. Effect on quality of life and satisfaction for pharmacologic treatment

Author Year	Comparison Groups, N	Outcomes
Oxybutynin		
Dmochowski et al.[85] 2002	**G1:** Oxybutynin TDS 1.3 mg **G2:** Oxybutynin TDS 2.6 mg **G3:** Oxybutynin TDS 3.9 mg **G4:** Placebo	• Participants in the treatment arm had significantly improved scores on the IIQ relative to placebo (p=0.033) • UDI scores showed greater improvement for treated patients compared to those on placebo (p=0.027)
Dmochowski et al.[88] 2003	**G1:** Oxybutynin TDS 3.9 mg **G2:** Tolterodine ER 4 mg **G3:** Placebo	• Compared to those receiving placebo, participants in both the oxybutynin and tolterodine groups had significantly greater improvement in the travel domain of the IIQ (p<0.05 for both) and on the irritative symptoms domain of the UDI (p<0.02 for both)
Homma et al.[92] 2006	**G1:** Oxybutynin TDS 26 cm^2 **G2:** Oxybutynin TDS 39 cm^2 **G3:** Oxybutynin TDS 52 cm^2 **G4:** Placebo	• Participants in the treatment arm had statistically significant improvements across all domains of the KHQ compared to placebo (p<0.05 for all comparisons)
Sand et al.[245, 246] 2006, 2007	**G1:** Oxybutynin TDS **G2:** Educational intervention	• Participants in the oxybutynin arm showed improvement in nine of ten domains on the KHQ and the PPBC vs. baseline (p<0.001), • Participants in the oxybutynin arm also showed improvement in embarrassment scores, effect on sex life, and relationships with partners (p<0.001) on BDI-II and KHQ • Oxybutynin also improved in interest in sex from baseline on BDI-II (p<0.001)
Sussman et al.[86] 2002	**G1:** Tolterodine ER 2 mg **G2:** Tolterodine ER 4 mg **G3:** Oxybutynin ER 5 mg **G4:** Oxybutynin ER 10 mg	• Patients on tolterodine ER reported greater improvements after 8 weeks of treatment in bladder condition compared to tolterodine IR, oxybutynin ER or oxybutynin IR, on a validated 6-point Likert scale (all comparisons p<0.01).
Wang et al.[93] 2006	**G1:** Electrical Stimulation **G2:** Oxybutynin 2.5 mg **G3:** Placebo	• Statistically significant differences were seen on the overall score and the incontinence impact domain of the KHQ between the ES group and oxybutynin (p<0.001 and p=0.038, respectively) and between the ES group and placebo (p=0.006 and p=0.012) • The difference between oxybutynin and placebo was also significant for the overall score only (p<0.001)

Table 18. Effect on quality of life and satisfaction for pharmacologic treatment (continued)

Author Year	Comparison Groups, N	Outcomes
Tolterodine		
Abrams et al.[91] 1998	**G1:** Tolterodine 2 mg **G2:** Oxybutynin 5 mg **G3:** Placebo	• After 12 weeks, 50% of patients on tolterodine, 49% on oxybutynin and 47% on placebo reported a perceived improvement in symptoms
Chapple et al.[142] 2008	**G1:** Tolterodine ER 4 mg **G2:** Fesoterodine 8 mg **G3:** Placebo	• Significant improvement in HRQoL as assessed by KHQ and ICIQ-SF in both fesoterodine 8 mg arm and the tolterodine ER 4 mg arm vs. placebo, but no significant difference between arms • Fesoterodine arm showed significant improvement in eight of nine domains (non significant in General Health domain) • Subset of patients who reported incontinence at baseline showed similar improvements versus baseline; however, no significant difference was seen between arms as well as between subsets of those reporting incontinence at baseline versus those without
Elinoff et al.[160] 2006	**G1:** Tolterodine ER 4 mg	• After 12 weeks of treatment, improvement in bladder condition was noted on the PPBC by 78.8% of the intent to treat population, 86.2% of those bothered by urgency, 78.5% with nocturnal frequency and 74.6% of those with urge urinary incontinence • All patients reported significant decreases in OAB symptoms. Median percentage change for those with urge urinary incontinence was -86.1 (95% CI: -91.7, -80.0)
Freeman et al.[174] 2003	**G1:** Tolterodine ER 4 mg **G2:** Placebo	• Significantly more participants in the tolterodine group reported “much benefit” and bladder symptom improvement than in the placebo group (43% vs. 24%; p<0.001 and 62% vs. 48%; p<0.001, respectively) • Participants in the tolterodine ER group had greater improvement in self reported urgency compared with placebo (46.6% vs. 26.6%; p=0.001)
Kelleher et al.[223] 2001	**G1:** Tolterodine ER 4 mg **G2:** Placebo	• Participants on tolterodine had significant improvements in several domains of the KHQ relative to placebo: incontinence impact, role limitations, physical limitations, sleep and energy, severity (coping), symptom severity, all at p<0.05 • No significant differences were observed for social limitations, personal relationships, etc. • A significantly higher proportion of patients on receiving placebo compared to tolterodine reported improvement in their bladder condition (58% vs. 43%; p=0.001)

Table 18. Effect on quality of life and satisfaction for pharmacologic treatment (continued)

Author Year	Comparison Groups, N	Outcomes
Tolterodine		
Robinson et al.[240] 2007	**G1:** Tamsulosin OCAS 0.25 mg **G2:** Tamsulosin OCAS 0.5 mg **G3:** Tamsulosin OCAS 1.0 mg **G4:** Tamsulosin OCAS 1.5 mg **G5:** Tolterodine ER **G6:** Placebo	• No significant improvements were seen on the KHQ in either the tolterodine or tamsulosin groups
Rogers et al.[241] 2008	**G1:** Tolterodine ER 4 mg **G2:** Placebo	• Treatment group had improvements in sexual and emotional health versus placebo. SQoL-F; PISQ-total score, and HAD anxiety; p=0.004, p=0.009, p=0.03 respectively
Tseng et al.[247] 2009	**G1:** Tolterodine 2 mg **G2:** Tolterodine 2 mg + vaginal CEE	• Both groups had improvements over baseline on the UDI-6 and IIQ-7
Zinner et al.[158] 2002	**G1:** Tolterodine ER 4 mg **G3:** Placebo **G3:** Tolterodine ER 4 mg **G4:** Placebo	• After 12 weeks, 69.8% of older (≥65) participants considered the treatment beneficial, compared to 46.9% on placebo (p<0.001) • In the younger group, 78.3% of treated patients considered the treatment beneficial, compared to 58.3% placebo (p<0.001)
Solifenacin		
Chapple et al.[99, 211] 2007	**G1:** Solifenacin 5 mg **G2:** Tolterodine ER 4 mg	• Significant change was seen on PPBC in solifenacin group compared to tolterodine group at 4 weeks (-1.51 vs. -1.33; p=0.006)
Garely et al.[218] 2006	**G1:** Solifenacin 5 mg or 10 mg (flexible dosing)	• Significant change was seen on the PPBC scale from baseline to study end (4.4 vs. 2.9; p<0.001) • Participants reported improvement on all subscales of the OAB-q (mean changes, 14.7 to 29.6; all p<0.001) • Using the VAS, participants reported significant reductions in degree of bother associated with urgency, urge urinary incontinence, frequency and/or nocturia (all p<0.001)
Kelleher et al.[225] 2005	**G1:** Solifenacin 5 mg **G2:** Solifenacin 10 mg **G3:** Placebo	• Patients in the solifenacin arms had significantly greater improvement in nine of ten domains of the KHQ (except personal relationships) after 12 weeks (p<0.05)
Yamaguchi et al.[98] 2007	**G1:** Solifenacin 5 mg **G2:** Solifenacin 10 mg **G3:** Propiverine 20 mg **G4:** Placebo	• Solifenacin and propiverine were both associated with significant improvements in QoL as measured by the KHQ when compared to placebo (p<0.05 on all subscales) • Greater improvements were reported on the severity domain in the solifenacin 10 mg group compared to placebo (p<0.05)

Table 18. Effect on quality of life and satisfaction for pharmacologic treatment (continued)

Author Year	Comparison Groups, N	Outcomes
Trospium		
Rudy et al.[104] 2006	**G1:** Trospium 20 mg **G2:** Placebo	• Participants in the trospium arm had significantly greater reduction in the OAB-SCS score compared to placebo (-8.4 vs. -4.6; p<0.0001)
Staskin et al.[103] 2007	**G1:** Trospium 60 mg **G2:** Placebo	• Using the OAB-SCS, the study demonstrated significant improvement of quality of life in the treatment group relative to placebo at 12 weeks (-11.2 vs. -7.8; p<0.001)
Zinner et al.[106] 2004	**G1:** Trospium 20 mg **G2:** Placebo	• Participants in the trospium arm had a reduction of their IIQ score of 59 compared to 36 in the placebo group (p≤0.05)
Darifenacin		
Hill et al.[100] 2006	**G1:** Darifenacin 7.5 mg **G2:** Darifenacin 15 mg **G3:** Darifenacin 30 mg **G4:** Placebo	• VAS was used to assess changes in severity of urgency before and after treatment • Although changes were significant in pre-post measures in G2 and G3, no statistical comparisons are reported between groups
Chapple et al.[210] 2007	**G1:** Darifenacin 7.5/15 mg **G2:** Placebo	• Participants in darifenacin arm showed statistically significant improvement in all domains of the OAB-q versus placebo (p<0.001)
Dwyer et al.[217]	**G1:** Darifenacin 7.5/15 mg	• Improvement in patient reported outcomes from baseline as measured by KHQ (eight of nine domains, p<0.001) at 24 months
Steers et al.[102] 2005	**G1:** Darifenacin 7.5 mg **G2:** Placebo	• Participants in the darifenacin arm reported significantly greater reduction in the severity of urgency episodes (p<0.05), by validated 100 mm VAS
Zinner et al.[101] 2006	**G1:** Darifenacin 15 mg **G2:** Placebo	• Participants in the darifenacin arm had a significantly greater change in OAB-q score after 12 weeks of treatment (26.4 vs. 19.1; p<0.001) • Changes were also significantly greater in the treatment group for incontinence impact (-24.7 vs. -17.8; p=0.022) and severity measures (-24.3 vs. -15.6; p<0.001) by ICIQ KHQ

Harms of Pharmacologic Treatments

Proportions of individuals reporting harms in RCTs of pharmacologic treatments ranged from 9.7 to 63.6 percent of study participants; however, harms were generally mild in nature, and withdrawals due to adverse events did not exceed 17 percent in any study (Table 19). The risk of occurrence of harms reported in treatment arms often overlapped those observed with placebo.

Dry mouth was the most commonly reported harm, ranging from 5.9 percent to 88 percent in studies of oxybutynin IR, compared to 1.6 to 21 percent in placebo arms. Studies of transdermal oxybutynin had the lowest reported estimates of dry mouth (2.6 to 9.6 percent). Impaired urination, not defined by the authors, was reported in studies of oxybutynin and tolterodine. It

was highest in two studies of oxybutynin IR (14 to 29 percent), compared to 3.2 to 4.0 percent in two studies of oxybutynin ER, no events to 9.0 percent in six studies of tolterodine IR and 1.0 percent in one study of tolterodine ER. Urinary tract infections were reported by up to 11 percent of participants in eight placebo arms. Immediate release formulations of oxybutynin and tolterodine both had reports of up to about 18 percent of participants experiencing a UTI, compared to up to 12 percent in studies of oxybutynin ER and 4.1 percent in studies of tolterodine ER. Between 0 and 32 percent of participants in treatment arms reported constipation; again, the highest rate was reported in an oxybutynin IR arm. Darifenacin had the second highest proportion of participants reporting constipation (18.5 to 27.8 percent). Up to seven percent of participants in placebo arms also reported constipation.

Cardiac events, including new abnormalities on EKG, were very rare and reported in only a few studies. The highest reported rate of cardiac events was five percent in tolterodine ER. Generally, however, less than one percent of participants experienced any cardiac event, mostly tachycardia and arrhythmias in treatment arms, with events also occurring in placebo arms (0 to 0.9 percent).

Table 19. Side effects and harms of pharmacologic treatment

Range (Number of studies reporting)	Placebo	Oxybutynin IR	Oxybutynin ER	Oxybutynin TDS	Tolterodine IR	Tolterodine ER	Trospium	Darifenacin	Solifenacin	Fesoterodine
Cardiac events*	0-0.9 (3)	0.2-1.2 (3)	NR	0.8 (1)	0 (1)	0-5 (2)	0.1 (1)	0.5 (1)	0.3 (1)	3.3-3.9 (1)
Constipation	0-7 (19)	0-32 (10)	6.4-8.6 (5)	3.3-5.4 (2)	2.6-10.4 (12)	2.5-10.2 (11)	7-10.9 (5)	18.5-27.8 (5)	6.4-18.9 (9)	3.3-14 (2)
Diarrhea	2-5.4 (4)	2-5 (2)	7.9-14 (3)	NR	3-3.4 (2)	2-6.8 (4)	1-3.1 (3)	NR	NR	NR
Dizziness	0-3.8 (5)	1.6-38 (6)	3.8-11 (5)	4 (1)	1.7-4.3 (4)	1.4-2.5 (5)	NR	0 (1)	1.2 (1)	1-1.5 (1)
Dry mouth	1.6-21 (23)	5.9-88 (15)	14-68 (9)	2.6-9.6 (3)	10-50 (15)	7.3-39 (13)	8.7-33 (5)	20.4-59.1 (5)	17.9-34.1 (9)	21.7-99 (2)
Dyspepsia	0.9-5 (4)	3-27 (5)	5.3-11 (3)	NR	3-9 (7)	2.7-3 (3)	5 (1)	5.2-8.7 (2)	NR	NR
Fatigue	<1-1.6 (3)	15 (1)	1.6-18 (2)	NR	1-3.6 (2)	2-3.4 (2)	NR	NR	NR	<1 (1)
Headache	0-5 (12)	1.2-22 (7)	5.6-12 (6)	NR	3-10.4 (10)	3-7 (9)	1-5.5 (4)	3.8-8.1 (4)	3.4-3.6 (4)	2.4-12 (2)
Impaired urination	0 (2)	14-29 (2)	3.2-4 (2)	NR	0-9 (6)	1 (1)	NR	NR	NR	NR
Insomnia	2-2.2 (2)	2 (1)	0.5-1.8 (3)	NR	0.5-1.8 (4)	0.8-1.7 (3)	4 (1)	NR	0.8 (1)	NR
Nausea	2-11 (4)	2-17 (7)	3.2-5 (3)	4.6 (1)	1.6-7 (6)	1-2.7 (4)	2 (1)	NR	1.8 (1)	<1-1.4 (1)
Respiratory events	0-14 (5)	3-13 (2)	6 (1)	NR	10-16 (2)	4 (1)	6.4 (1)	0.3-5.6 (2)	3.1-4.6 (3)	NR
Somnolence	0-2 (4)	3-40 (3)	1-4.3 (4)	1.6 (1)	1.6-2.7 (4)	2.3-3 (3)	NR	NR	NR	NR
Urinary tract infections	0-11 (8)	<1-18 (3)	5.1-12 (2)	2.4 (1)	3-19 (4)	2.7-4.1 (6)	4.9-12 (2)	1.1-4.8 (3)	3.4-3.6 (2)	10-15 (1)
Vision changes	0-7.7 (12)	1.2-22 (8)	2.2-3.3 (4)	2.3 (1)	0.6-7.5 (6)	<1-6 (6)	3 (1)	0-3.5 (2)	0.7-6.9 (9)	2.2-4.2 (1)
Any adverse event	17.5-48.9 (6)	57 (1)	51 (1)	NR	53 (1)	9.7-74 (6)	26.8-59.6 (2)	47.9-63.6 (2)	59.4 (2)	50-69 (2)
Withdrawals due to adverse events	0-6 (11)	16-17 (2)	6.2-13 (4)	10.7 (1)	1.9-15 (6)	2.8-6.3 (5)	7.3-8.8 (1)	3.2 (1)	3.7-9.7 (4)	6-9 (1)

* Includes new abnormal EKG, tachycardia, other arrhythmias, palpitations, and other cardiac events as grouped together in the literature.

Procedural and Surgical Treatments of OAB

We reviewed 18 studies, of which 11were fair quality and 7 poor. This section presents the results of our literature search and findings about outcomes of procedural and surgical treatments for OAB. These treatments include sacral neuromodulation, peripheral neuromodulation, electromagnetic nerve stimulation, injection or instillation of drugs into the bladder, bladder distention and bladder transection. No studies regarding augmentation cystoplasty or detrusor myomectomy met our search criteria. Detailed information on all studies relating to surgical management of OAB can be found in evidence tables in Appendix C.

Sacral neuromodulation. Stimulation of the sacral nerve roots is a technique in which an electrical stimulus directly stimulates the S3 sacral nerve root.[256] The technique has evolved over time, but typically it is performed as a staged procedure. The first stage involves a "test" stimulation using a percutaneous needle to stimulate the S3 nerve root. If there is a favorable response during the trial period, then long-term stimulation can be provided by implanting an implantable pulse generator surgically. The implantable pulse generator is usually placed in the fatty tissues overlying the buttocks, although abdominal placement was used with some of the earlier studies. Recent evolutions in this technique now permit a permanent lead to be used for the test stimulation. If the test is unsuccessful, the lead can be removed, but if it is successful, this lead is attached to the permanent implantable pulse generator. This has the advantage of ensuring that stimulation is provided in the exact location as during the test period. (Previously, a new lead was placed at the time of the implantable pulse generator placement.) The mechanism by which neuromodulation acts to improve symptoms is not completely understood. The technique is used for urinary urgency, frequency, and urge incontinence refractory to other treatment modalities.[256] It is also used for urinary retention. Given these seemingly contradictory applications, it is thought that the electrical stimulation affects the afferent nerves (which perceive bladder sensation), thus allowing them to appropriately transmit bladder sensations.

Peripheral neuromodulation. Other techniques for neuromodulation involve stimulating the S3 nerve fibers more peripherally, at the posterior tibial nerve or cutaneous stimulation of the pudendal nerve via an anal or vaginal probe.[257] For the posterior tibial nerve stimulation, a needle is placed percutaneously near the ankle and is attached to an external electrical device. Instead of implanting an implantable pulse generator, the patient returns for periodic sessions, often weekly for a series of treatments. Small case series suggest that posterior tibial nerve stimulation may improve OAB symptoms.[258-260] There were no studies involving this technique which met our search criteria. One study evaluating neuromodulation of the pudendal nerve with anal and/or vaginal probes met our search criteria. Similarly, this is performed on an outpatient basis with weekly treatment sessions.

For the purposes of this report, sacral neuromodulation will refer to techniques that directly stimulate the S3 nerve root. Peripheral neuromodulation will refer to nerve stimulation peripherally, such as the use of an anal or vaginal probe to stimulate the pudendal nerve. These approaches are reviewed in the same section of this text.

Electromagnetic sacral nerve stimulation. Electromagnetic stimulation is yet another modality to modulate the neurologic control of the bladder. Most treatments involve large, powerful magnets which require a dedicated facility as the magnets are not portable.[261] The study included in this review evaluated the use of a smaller, portable electromagnetic system.

Bladder instillation/injection of a drug. Another approach to treating urinary frequency, urgency, and urge incontinence is to instill or inject a drug into the bladder. Numerous drugs

have been administered using this approach. Two categories of intravesical drugs are included in this review, antimuscarinic agents and neurotoxins. By instilling or injecting the drug directly into the bladder, systemic adverse effects are theoretically avoided.

Two neurotoxins discussed in this review are resiniferatoxin and botulinum toxin. Botulinum toxin is a neuromuscular blocking agent which prevents nerve conduction. Typically botulinum toxin-A is used and can be injected directly into the wall of the bladder under cystoscopic guidance as a treatment for refractory OAB.[262-264] It is not FDA approved for this indication at the time of the writing of this document. Concerns with this approach are the risk of urinary tract infections and urinary retention and that the ideal dosing has not yet been determined. Additionally, the effects of botulinum toxin are temporary and multiple courses of treatment would be anticipated. An RCT comparing botulinum toxin A to placebo for women with refractory urge incontinence found that incontinence episodes decreased from over 20 episodes per three day diary to less than 5 episodes per three day diary among those receiving botulinum toxin A, while those taking placebo had no difference in the number of incontinence episodes. Using a Patient Global Impression of Improvement score, approximately 60% of the women who received botulinum toxin A had a clinical response, and this response lasted six times longer than that achieved with placebo. The study was stopped early due to increased postvoid residuals in 43% of women receiving botulinum toxin A and a high rate of urinary tract infections among those with elevated postvoid residuals.[265] Resiniferatoxin is a neurotoxin in the same category as capsaicin; these do not have FDA approval for the treatment of OAB. These agents block transmission along the C-fibers, nerve fibers involved in transmitting noxious stimuli.[127] It has been hypothesized that inhibition of these fibers may be a treatment for overactive bladder.

A review of RCTs evaluating the use of intravesical botulinum toxin for OAB was published by the Cochrane Collaboration in 2007.[128] Eight studies met their search criteria: five were published abstracts and three were full papers. Only one of the eight studies exclusively dealt with idiopathic OAB, the definition we used for our literature search. The remaining seven studies in the Cochrane review included subjects with neurogenic OAB.

The findings from the Cochrane review were that botulinum toxin injections were more effective than placebo, with fewer incontinence (unspecified type) episodes per day at 2 to 24 weeks and fewer incontinence episodes compared to baseline. Improvements following treatment were also seen in incontinence specific and overall quality of life. Urodynamic changes were also seen, including decreased pressure during a detrusor contraction and increased bladder capacity following treatment with botulinum toxin. The postvoid residual, the amount of urine left in the bladder after voiding, was also elevated. The numerical data were not provided by the author. Adverse events included cases of urinary retention requiring intermittent self catheterization following treatment. Of the patients requiring catheterization, 25 percent had a lower urinary tract infection.

In the Cochrane Collaboration, the limited number of studies, their small size and heterogeneous population highlight the need for more research regarding treatment with botulinum toxin.[128] One study compared botulinum toxin to bladder instillations with resiniferatoxin and found lower rates of incontinence, increased bladder capacity and lower detrusor pressure during uninhibited bladder contractions at 6 to 18 months with the botulinum toxin treatment. The optimal dose or long term effects of elevated postvoid residuals has not been determined.

Bladder distention and bladder transection. Two treatments that are no longer in common practice, prolonged bladder distention and bladder transection, are also included in this review. The bladder distention study describes distending the bladder to maximum capacity at a pressure equal to systolic blood pressure for four hours.[118] Bladder transection involves cutting the

bladder wall and detrusor muscle. Both have significant morbidity and have been abandoned by most practitioners.

Outcomes of procedural and surgical treatments.

Content of the literature. We identified 18 studies reporting on surgical treatments and procedures for OAB (clinical trials reported in Table 20).[110-127]

Eleven were of sacral neuromodulation, one of peripheral neuromodulation and one of electromagnetic sacral nerve stimulation. Three studied bladder instillation or injection of drugs, one was of bladder distention and one was of bladder transection.

Six of the 11 studies on sacral neuromodulation come from a family of papers financially supported by one company.[110, 111, 114, 115, 123, 124] The patient population for this family of studies included an RCT to evaluate sacral neuromodulation versus medical therapy for six months.[124] The other studies involved similar inclusion and exclusion criteria, but varied in regards to the number of centers involved in recruitment (between 12 and 17 centers) and timing for enrollment. Given this, it is not possible to determine the degree of subject duplication.

Table 20. Outcomes of clinical trials of procedures

Author Year Design	Groups	N	Per day baseline	Per day on treatment	Decrease in episodes per day	Weeks at evaluation
Episodes of urge incontinence per day						
Rios et al.[127] 2007	**G1:** Resiniferatoxin	34	3.1	2.7	0.4*	4
	G2: Placebo	24	5.8	4.2	1.6*	4
Schmidt et al.[124] 1999	**G1:** SNM	34	9.7	2.6	7.1^	24
	G2: Usual care	42	9.3	11.3	+2.0^	24
Voids per day						
O'Reilly et al.[125] 2008	**G1:** Trans-sacral magnetic stimulation	33	10.0	9.0	1.0*	12
	G2: Sham treatment	30	9.0	9.0	0.0*	12
Rios et al.[127] 2007	**G1:** Resiniferatoxin	34	9.7	9.0	0.7*	4
	G2: Placebo	24	9.9	9.2	0.7*	4
Enzelsberger et al.[126] 1995	**G1:** Oxybutynin instillation	26	12.6	5.8	6.8^	4
	G2: Sterile water instillation	26	12.8	10.4	2.4^	4

* Not significant differences between groups; ^ = p <0.01

This literature included 13 case series studies, which we operationally defined as descriptive analyses of a sequence of participants having the same type of procedure without a comparison to another type of surgery or treatment. Three of these studies are *retrospective* case series of a particular surgical treatment: two report on sacral neuromodulation[119, 120] and one on bladder transection.[121] Nine studies are *prospective* case series: six report on sacral neuromodulation,[110-115] one on peripheral nerve stimulation with anal and/or vaginal probes,[116] one on botulinum-A toxin injections[117] and one on prolonged bladder distention.[118] One case series had both a retrospective arm as well as a prospective arm; this study looked at sacral neuromodulation.[122]

One study is a prospective cohort that compared outcomes among subjects receiving sacral neuromodulation and subjects receiving a control surgery for sacral neuromodulation, but without active electrical stimulation.[123]

Four studies were RCTs: one looked at sacral neuromodulation versus medical therapy,[124] one evaluated transcutaneous electromagnetic stimulation versus sham,[125] and two evaluated instillation of a drug into the bladder versus placebo – one using oxybutynin[126] and one using resiniferatoxin.[127]

The majority of the studies were conducted in Europe, six of which included involvement from Canada and the United States (there is subject duplication among these six studies). One study was conducted in the United States only. Two studies were performed in Australia and one in Brazil. Two of the studies involved national registries, one from Switzerland and one from Italy. Five studies specified that they occurred in an academic setting, three in a specialty setting and the remainder did not specify the clinical setting for the study.

The quality of the studies varied widely. Of the four randomized controlled trials, three had an appropriate control group, the fourth compared sacral neuromodulation to continued medical treatment among subjects who had already failed medical management for refractory OAB.124 This does not adequately control for the placebo effect, which is quite prominent among these treatments. It is challenging to create an appropriate control group when evaluating sacral neuromodulation. This is illustrated by a cohort study in which surgical controls received sacral neuromodulation, but no electrical stimulation was applied. Given that subjects feel the electrical stimulation, they would be aware that this has been de-activated following the test stimulation.[123] Of the 11 studies on sacral neuromodulation, seven did not restrict the study population to OAB. Although sacral neuromodulation may be used to treat urinary retention, grouping these studies in such a fashion severely limited our ability to analyze the results. We restricted our discussion to the OAB findings in these papers. Case series studies are limited by the lack of a control group.

Outcomes assessed. Half of the studies reported on urge urinary incontinence outcomes (usually incontinence episodes per day as measured by a bladder diary, but also pad counts, pad weight, severity of incontinence or other measures). Nearly two-thirds of the studies reported some measure of urinary frequency, such as voids per day. Nearly all of the studies reported on a subjective measure of symptoms (such as percent cured, perceived severity, QoL). A third of the studies reported on urodynamic outcomes, such as the bladder volume at which there was a normal desire to void, and bladder capacity.

The majority (78 percent) of the studies, reported data on adverse effects or harms. Six studies reported on problems with constipation or gastrointestinal symptoms,[111, 114, 116, 119, 120, 126] eight reported the presence of pain, six reported on infection and nearly half of the sacral neuromodulation studies reported the presence of lead migration. Other adverse effects were reported in 72 percent of studies.

Outcomes of sacral neuromodulation and peripheral neuromodulation.

The one RCT comparing sacral neuromodulation to medical therapy found a reduction in daily incontinence episodes from 9.7 to 2.6 in the intervention group, compared to an increase of 9.3 to 11.3 in the medical management group at six months ($p<0.01$).[124] Of note, all subjects receiving medical therapy had already failed medical management; no benefit from continued medical therapy would be expected. The remaining six case series that reported on change in UUI had decreases in mean incontinence episodes per day of 51 percent to 80 percent[111, 114, 115, 119, 122] and from a median of five down to zero incontinence episodes a day.[112] Length of followup in these studies ranged for six months to five years.

Pad use per day also decreased with sacral neuromodulation. Most studies started with a baseline of five or more pads used daily. One RCT reported an 82 percent decrease in pad use from 6.2 to 1.1 pads daily, six months following initiation of sacral neuromodulation.[124] Three case series evaluating sacral neuromodulation also found significant decreases in pad use ranging from 49 to 84 percent fewer mean pads[111, 114, 115] and a 75 percent decrease in median pad use.[112] Length of followup on these studies ranged from six months to five years.

Some of the studies tried to characterize the severity of incontinence episodes. One RCT and two case series found a 64 percent to 92 percent decrease in the number of moderate to heavy urge urinary incontinence episodes at six months to five years of followup.[111, 115, 124] The RCT reported the highest rate of decreased heavy incontinence episodes with a mean baseline in the neuromodulation group of 3.4 per day, reduced to 0.3 per day six months after treatment. In comparison, those with refractory OAB receiving usual therapy experienced an increase in mean heavy episodes per day from 2.6 to 3.9.[124]

Improvement in episodes of urinary urgency without incontinence is difficult to measure as it is a more elusive symptom. Nonetheless, on a 3 point scale, (1=mild, 2=moderate, 3=severe), 69 percent of participants in one study reported improvement,[114] with a second study showing no change in experience of urgency.[115]

Reduction in urinary frequency of between 31 and 45 percent is seen consistently across studies of sacral neuromodulation, regardless of study design. The majority of studies of sacral neuromodulation reported urinary frequency as the mean number of voids in 24 hours as recorded by a bladder diary. Six studies reported mean voids per day, one of which was a prospective cohort study comparing subjects with sacral neuromodulation and controls who had sacral neuromodulation placed, but did not receive active electrical stimulation.[123] At six months, those receiving sacral neuromodulation had a 45 percent decrease in the number of voids per day; no change was seen in the controls. Similar results were seen in the other studies, which found 31 to 40 percent fewer voids per day with sacral neuromodulation, regardless of whether they were prospective or retrospective case series studies.[114, 115, 119] One study reported its results as a 40 percent decrease in the median number of voids per day.[112] Another study reported the results from an Italian national registry; they did not have baseline information regarding the number of voids in the registry prior to treatment, but 42 percent of subjects had fewer than 8 voids daily after treatment.[122] The 31 to 45 percent decrease in mean (and median) voids per day seen across the studies was present at six months and up to two years following initiation of the sacral neuromodulation.[112, 114, 115, 119, 123] The longest followup data was available from a prospective case series which found a 33 percent decrease in mean voids per day at one year which was reduced to a 23 percent decrease in mean voids per day at five years.[115]

Some studies also looked at the mean voided volume as a measure of treating urinary frequency. One cohort study and two case series found that sacral neuromodulation increased the mean voided volume between 1.7 to 1.9 fold, an increase of 78 mL to 108 mL per void.[114, 115, 123]

Peripheral neuromodulation and electromagnetic stimulation were clinically ineffective in changing voiding frequency. One prospective case series found a 12 percent decrease in the mean voids per 24 hours was seen six weeks following 12 sessions of peripheral neuromodulation with an anal and/or vaginal probe.[116] No decrease in mean voids per day was seen with electromagnetic stimulation of the sacral nerves.[125]

Neither sacral neuromodulation nor peripheral neuromodulation with an anal and/or vaginal probe had a clinically relevant impact on nocturia rates, which were very low in these studies at baseline. Both treatment approaches reduced already low rates by approximately 30 percent.[116, 119]

Several of the studies comment on clinical "cures" or "improvements", but lack definitions for these criteria. Moreover, several of the case series on sacral neuromodulation include diverse patient populations which may include urinary retention or pelvic pain in addition to patients with symptoms of overactive bladder. The clinical endpoints for improvement in urinary retention are very different from those for urinary urgency and frequency.

Studies evaluating improvements following sacral neuromodulation describe cure rates of 26 to 65 percent (cure was defined as "completely dry" at six to twelve months).[111, 122, 124] One study looked at improvements following the initial test stimulation and found 39 percent had greater than a 90 percent improvement in urinary frequency and/or urgency.[113] As would be expected, higher rates are seen for classifications of "success" or "improvement" as compared to "cure."

Compared to these rates, peripheral neuromodulation only had an 8.1 percent cure rate, with 31 percent reporting no change.[116]

Several studies evaluated QoL, either with the KHQ, a VAS or other validated QoL questionnaire (Table 21). Two studies evaluated the impact of sacral neuromodulation on QoL and found the treatment beneficial.[122, 123] There was no improvement in QoL with electromagnetic stimulation.

Table 21. Effect on quality of life and satisfaction of procedural treatments

Author, Year Study Type	Comparison Groups, N	Outcomes
Hassouna et al.[123] 2000 Cohort	**G1:** Neuromodulation (25) **G2:** Control (25)	• At six months, the neuromodulation group reported greater improvement in quality of life compared to controls ($p<0.0001$) • SF-36 scores[266] were significantly higher ($p<0.01$) for sacral neuromodulation participants relative to controls on physical function, role physical, bodily pain, vitality, social function and mental health domains
O'Reilly et al.[125] 2008 RCT	**G1:** Electromagnetic sacral nerve stimulation (33) **G2:** Sham (30)	• No significant differences were observed by group for the KHQ domain(s) or the Australian Quality of Life Questionnaire domain(s) after Bonferroni correction for multiple testing
Rios et al.[127] 2007 RCT	**G1:** Single dose 100 ml 50 nM resiniferatoxin (34) **G2:** Placebo (24)	• No differences were reported from baseline to post-treatment QoL scores by the KHQ for general health perception, social limitations or personal relationships. • Incontinence impact decreased a similar amount in both groups following intervention ($p<0.05$ pre-post). Emotions, sleep/energy and symptom severity scores decreased more for G1 following the intervention (no between group testing) • Role limitations decreased for G2 ($p<0.05$) but not G1 following the intervention
Schmid et al.[117] 2006 Prospective case series	Botulinum Toxin (100)	• 90% of patients experienced improvement in at least one category of the KHQ at three months, with a waning of benefit by nine months.
Spinelli et al.[122] 2001 Case series	**G1:** Sacral neuromodulation retrospective cases (93) **G2:** SNM prospective cases (103)	• In a validated QoL questionnaire[267] completed by 54% of prospective participants, all reported significant increases in life quality at all time points.

The evaluation of overactive bladder with urodynamics provides objective data, but the clinical relevance of this information is not always clear. Urodynamic parameters may indicate changes in bladder function, but unless symptoms were also evaluated, they do not necessarily carry over into improvements in clinical outcomes.

During bladder filling, known as cystometry, the first sensation of bladder filling can be measured. This is known to be one of the more variable urodynamic measurements.[268] The bladder volume at first sensation increased by 80 mL after sacral neuromodulation in one case series [110] and by 36 mL after peripheral neuromodulation with an anal/vaginal probe.[116] Both of these studies also looked for changes in bladder capacity and found this increased 1.4 fold for sacral neuromodulation and found no difference for peripheral neuromodulation.[110, 116]

By their very nature, surgical and procedural treatments are likely to have a higher incidence of adverse events than conservative and medical treatments for OAB. In the early studies of sacral neuromodulation, there was an average of 1.1 to 1.7 adverse events per participant.[115, 124] Advances in technology, such as the use of tined leads, have decrease this rate and the more recent studies report 0.1 to 0.5 events per participant.[112, 119] None of the studies exclusively used the newer technology. Of the adverse events, pain, lead migration or problems with the lead, infection and explantation of the device were the most common adverse events. From the test stimulation phase, pain at the needle site was 0.5 percent in a study employing newer technology[112] and 7 percent in a study with older technology.[113] When the implantation phase is included, pain rates and uncomfortable stimulation responses were seen in 3.9 to 43 percent of subjects, with studies employing new techniques at the lower end of this spectrum.[112, 114, 115, 120, 122, 124] The one RCT found a pain rate of 19.1 percent, but this was compared to medical management, not a sham procedure.[124] Pain at the implantable pulse generator implantation site was typically reported separately and occurred 15.4 to 27 percent of the time.[114, 115, 120, 124] Problems with the lead or lead migration occurred between 3.3 and 11 percent of the time.[114, 115, 120, 122, 124] This may be less common with the new tined leads, as one study had lead migration only with the older non-tined leads[112] and another found a lower loss of efficacy, 12.3 percent, with the tined leads compared to the non-tined leads, 31.7 percent.[119] Infection occurred in 1.9 to 6.1 percent of participants, sometimes requiring hospitalization for intravenous antibiotics or removal of the device.[114, 119, 120, 122, 124] Two papers noted a 0.5 to 1.7 percent risk of neuropraxia or nerve injury.[114, 120] There was a high rate of needing surgical revision, with most studies showing 33 to 48.3 percent of subjects required a return to the operating room.[114, 120, 124] Lower rates were documented in a study using newer technology, 7 percent,[112] and in a national registry, 9.7 percent.[122] One study looked at return to the operating room rates at five years and found that that there was a 67 percent risk of return (numbers based on the population enrolled).[115] However, at five years, many of the subjects were returning for new implantable pulse generator batteries, an expected development over time, thus this is not truly an adverse event. Unfortunately, the number of surgeries which were to replace implantable pulse generator batteries was not reported. Of the surgical adverse events, a significant proportion included explantations of the device. This occurred in 3.9 percent of subjects in the national registry;[122] higher rates were seen in the remaining studies, 9.8 to 14 percent.[111, 115, 120]

Adverse events following peripheral neuromodulation with an anal and/or vaginal probe led to a 19 percent dropout rate, with 29 percent of the dropouts attributed to pain. The other most common complaint was bowel irritation.[116] Currently, techniques of peripheral neuromodulation with an anal/vaginal probe are not routinely used.

Outcomes of bladder instillation/injection of drugs. An RCT of resiniferatoxin bladder instillations versus placebo found no improvement in the number of urge urinary incontinence episodes per day with either arm.[127] However, bladder instillations with oxybutynin did decrease

mean voids per day. In an RCT evaluating bladder instillations with oxybutynin versus a placebo with sterile water, those receiving oxybutynin had a 47 percent decrease compared to a 16 percent decrease in mean voids per day with the placebo at two weeks following completion of treatment.[126] This decrease is similar to that seen with sacral neuromodulation. In a prospective case series evaluating the use of botulinum-A toxin injected into the detrusor muscle of the bladder wall, 74 percent of the subjects had 8 or fewer voids per day four weeks following treatment. All subjects had greater than 8 voids per day at the start of the study.[117] In an RCT of bladder instillations with resiniferatoxin versus placebo, there was no difference in the mean voids per day four weeks following treatment.[127] Bladder instillations with oxybutynin decreased nocturia 65 percent from 5 to 1.8 episodes per night.[126] Following injection of botulinum-A toxin into the bladder, 66 percent had no urgency at 12 weeks and 80 percent reported no urge incontinence.[117] No difference was seen compared to baseline or placebo in an RCT evaluating resiniferatoxin bladder instillations.[127]

Two studies looked at what volume the normal desire to void occurred, finding this increased 1.6 fold (55 mL increase) for instillation of oxybutynin into the bladder[126] and 1.7 fold (83 mL) for botulinum-A toxin bladder injections.[117] Theoretically these increases would result in less urinary frequency, and possibly less urgency. Similar changes were also seen in terms of bladder capacity after treatment, with bladder instillations of oxybutynin increasing capacity 1.5 fold (105 mL)[126] and 1.6 fold (135 mL) with botulinum-A toxin injections.[117]

A potential adverse effect of intravesical oxybutynin or botulinum-A toxin is impairment of the bladder's ability to empty.[265] The goal of treatment with these agents is to provide a dose large enough to decrease the symptoms of OAB, without impairing the ability to void when physiologically necessary. An objective measurement that can serve as a proxy for this parameter is a postvoid residual, the volume of urine that remains in the bladder after voiding; however the clinical importance of an increased postvoid residual in the absence of symptomatic urinary retention is not clear. The mean postvoid residual following treatment with intravesical oxybutynin increased twofold to a mean of 40 mL (range 10 to 50 mL) and for botulinum-A toxin, increased fourfold to a mean of 75 ± 10 mL.[117, 126] Both treatments seem to have similar effects on bladder capacity, but the risk of urinary retention may be higher with use of botulinum-A toxin.[117, 126] Currently, oxybutynin and resiniferatoxin instillations are not routinely used for the treatment of OAB.

For instilled/injected bladder drugs, there were small benefits seen in the emotions, sleep/energy and symptoms severity subscales of the KHQ for subjects receiving the treatment compared to placebo. Incontinence impact scores improved a similar amount for both resiniferatoxin and placebo ($p<0.05$). Emotions, sleep/energy and symptom severity scores decreased more for resiniferatoxin following the intervention ($p<0.05$).[127] Ninety percent of subjects receiving botulinum A toxin had an improvement in QoL scores at 3 months; this effect was waning at 9 months.[117]

Outcomes of bladder distention and transection. Bladder distention and transection are treatment methods no longer in routine use. Following bladder distention, 18 percent were symptom free at 18 months with 52 percent unchanged.[118] The study on bladder transection reports 65 percent were cured at two to five years and 16 percent were unchanged, but provides no information about the criteria for these categories.[121] Prolonged bladder distention had a 4 percent rate of bladder rupture.[118] Bladder transection was associated with a 14 percent rate of vesicoureteral reflux on urodynamics, the clinical significance of which was not determined, and 1 percent rate of a persistent urine leak requiring reoperation. The authors also noted "minor chest and urinary tract infections" but the rates of these adverse events were not reported.[121]

Behavioral Treatments

This section presents the results of our literature search and findings about outcomes of behavioral techniques to reduce overactive bladder in women. Behavioral treatment options for OAB have been used for managing urinary incontinence for more than 50 years, although large-scale and well-designed studies on them are fairly uncommon. We reviewed 27 studies, of which 14 were fair quality and 13 poor.

Behavioral techniques include the use of bladder training, pelvic floor muscle exercises (PME), biofeedback, dietary changes, and multicomponent approaches that combine bladder training with PME and/or biofeedback. Detailed information on all studies related to behavioral techniques for OAB can be found in evidence tables in Appendix C.

Bladder training. Bladder training was introduced in the 1960s (Jeffcoate and Francis), and modified by Frewen in the 1970s. It involves education, a strict schedule of daytime voiding with progressive increases in time between voids, urgency suppression techniques, and positive reinforcement. Frewen recommended that women be treated initially on an inpatient basis, and the training was often combined with antimuscarinic medication or sedatives to manage extreme urgency. Inpatient bladder training is no longer standard practice, and the technique has been modified to be administered on an outpatient basis, with the use of patient education and bladder diaries. Although the underlying mechanism for bladder training in OAB is not well understood, it is thought to reverse dysfunctional habits, increase bladder capacity and provide techniques for handling feelings of urgency.

Pelvic muscle exercises. Training the pelvic floor muscles were originally suggested for patients with stress incontinence, the idea being that patients could learn to contract the periurethral muscles to occlude the urethra during activities that caused leakage. However, it may also be useful in inhibiting detrusor contractions. PME can be implemented alone or with additional techniques such as biofeedback to help patients identify and contract the appropriate muscles.

Multicomponent approaches. Although both bladder training and PME can and are administered alone, they may also be combined with or without biofeedback for a multicomponent approach to reducing incontinence.

Tools for behavioral training. Behavioral training can be administered with written materials, verbal feedback, coaching in person or on the phone, in groups, or using other strategies, such as cognitive approaches or biofeedback for increasing the potential for success. Behavioral approaches can also be combined with medications such as antimuscarinics. Various combinations of approaches are examined in the literature and are described in this review.

For the purposes of this report, we will use the term "bladder training" to refer to bladder training alone (i.e., without PME without biofeedback). "Behavioral training" will refer to a multicomponent approach that includes bladder training. We indicate when biofeedback is used in conjunction with other behavioral techniques.

Behavioral treatments.

Content of the literature. We identified 29 papers from 27 studies that included arms with outcomes of behavioral interventions. We have divided the studies into three primary categories: those that compare only behavioral approaches, those that compare behavioral approaches to pharmaceutical ones directly and those that measure the effect of adding a behavioral approach to a pharmaceutical one (combination approaches). The first category is presented here and the second two are covered in KQ3.

Nine studies met criteria and included only behavioral arms. Among these, two studies focused on comparing delivery mechanisms or approaches and provide insight into techniques for teaching and encouraging participants in behavioral management.[132, 135]

Four additional studies (represented in six papers) with multiple arms, including pharmacologic ones, provided data that allowed the comparison of behavioral management to placebo[93, 143-145] or to another behavioral intervention.[148, 201] These are counted in the direct comparisons section, and therefore are not represented in the counts below, but relevant outcomes are described here as well as the direct comparisons section, and they appear in tables in both sections. All three of these are RCTs.

The literature base of studies that had only behavioral arms included three retrospective case series, which we have operationally defined as a sequence of participants having the same intervention without a comparison to another type of intervention. One examined bladder training alone,[129] one examined pelvic muscle exercises[130] and the third reported on a series of participants who were provided either bladder training or biofeedback, but presented results only for the two groups combined.[131] All three were conducted in community-based clinical settings.

One was a prospective cohort study comparing three bladder training approaches: self-administered, coaching and cognitive strategies.[132]

Five studies were randomized controlled trials. One compared bladder training to a "control" condition.[133] One compared bladder training to pelvic muscle exercises.[134] One included the following three arms: pelvic floor muscle training, pelvic floor muscle training assisted with biofeedback, and electrical stimulation.[93] One compared three different approaches to multicomponent behavioral training: biofeedback, verbal feedback and self-administered using an instruction booklet.[135] One compared bladder training to bladder training with an additional caffeine reduction component.[136]

Three of the studies were conducted in the United States, four in Europe, one in Australia and one in Taiwan. Four were conducted at academic medical centers; five were in community settings, of which two included an inpatient component.

Outcomes measured. For each type of intervention, we combed the publications for the outcomes and complications summarized in the analytic framework presented in Chapter 1.

Five studies reported a change in numbers of episodes of incontinence,[93, 134-136, 143] although the time period varied, and three of these calculated a percent reduction in incontinence episodes.[135, 136, 143] Three of the studies measured incontinence episodes over the course of a week,[134, 135, 143] two did so over 24 hours.[93, 136] One study reported that a significant decrease in frequency of voiding was observed, but did not provide data that could be included in this table.[132]

Five studies presented the outcome of cure or improvement in incontinence (using various definitions)[129-131, 133, 269] with three defining cure as complete resolution of incontinence.[129, 131, 133]

One study presented data on episodes of urgency separate from incontinence.[136]

Changes in frequency were reported in three studies.[131, 136, 145] Two specified voids per day as an outcome.[136, 145] In addition, Jarvis and colleagues[133] reported on the numbers of women indicating that they had nocturnal and diurnal frequency before and after treatment. One study

recorded frequency over a three-day period[132] and reported a statistically significant effect, but did not report numbers of episodes, and one reported time between voids.[131] One reported that cure included achieving a minimum of three to four hours between voids[129] and was therefore related to frequency but not summarized as effect on frequency.

Other patient-reported outcomes in this literature included reports of resolution or improvement and changes in severity, quality of life, and satisfaction.

Five of the studies provided some patient-reported outcome, with four reporting on perceived improvement.[130, 131, 134, 135] Three provided some report on severity;[130, 135, 143] four measured bother;[132, 134, 135, 143] two measured impact or interference with daily activity;[134, 135] one assessed changes in quality of life overall;[134] and three reported on patient satisfaction.[134, 135, 143]

Outcomes of behavioral treatment.

UUI episodes. Lack of consistency in study design, interventions or comparison groups makes it impossible to provide consistent summary results across studies. Although each intervention was associated with reductions in incontinence episodes, no behavioral approach performed better than any other in any study in this category on incontinence outcomes over any time period greater than 12 weeks. Trials are summarized in Table 22.

Table 22. Outcomes of behavioral treatment trials

Author Year	Groups	N	Per day baseline	Per day on treatment	Decrease in episodes	Weeks at evaluation
Episodes of incontinence per day						
Arruda et al.[201] 2008	**G1:** Oxybutynin	22	2.0	1.0	1.0	12
	G2: Functional electrostimulation	21	1.9	1.1	0.8	12
	G3: Pelvic floor training	21	2.3	1.1	1.2	12
Wang et al.[93] 2006	**G1:** Electrical stimulation	25	1.0	0.5	0.5	12
	G2: Oxybutynin 2.5 mg 3x/day	26	0.0	0.0	0.0	12
	G3: Placebo	23	1.0	1.0	0.0	12
Bryant et al.[136] 2002	**G1:** Bladder training + caffeine reduction	48	2.8	1.2	1.6*	4
	G2: Bladder training	47	3.1	1.4	1.7*	4
Burgio et al.[135] 2002	**G1:** Multicomponent via biofeedback	73	2.2	0.9	1.3*	10
	G2: Multicomponent via verbal	74	2.5	0.9	1.6*	10
	G3: Self-administered	75	2.2	1.0	1.2*	10
Burgio et al.[143] 1998	**G1:** Multicomponent	65	2.3	0.4	1.9^	10
	G2: Oxybutynin (range of doses)	67	2.3	0.8	1.5^	10
	G3: Placebo	65	2.2	1.2	1.0^	10

Table 22. Outcomes of behavioral treatment trials (continued)

Author Year	Groups	N	Per day baseline	Per day on treatment	Decrease in episodes	Weeks at evaluation
Episodes of incontinence per day (continued)						
Wyman et al.[134] 1998	**G1:** Bladder Training	68	2.0	0.9	1.1†	12
	G2: Pelvic muscle exercise	64	3.0	1.7	1.3†	12
	G3: Combination therapy	61	2.3	0.8	1.5†	12
Voids per day						
Arruda et al.[201] 2008	**G1:** Oxybutynin	22	7.7	6.4	1.3	12*
	G2: Functional electrostimulation	21	8.6	7.9	0.7	12*
	G3: Pelvic floor training	21	6.8	7.1	0.3^	12*
Wang et al.[93] 2006	**G1:** Electrical Stimulation	25	12.8	7.8	5.0^	12
	G2: Oxybutynin 2.5 mg 3x/day	26	11.5	7.4	4.1^	12
	G3: Placebo	23	11.5	10.0	1.5^	12
Bryant et al.[136] 2002	**G1:** Bladder training + caffeine reduction	48	11.1	6.8	4.3^	4
	G2: Bladder Training	47	11.2	7.9	3.3^	4
Goode et al.[145] 2002	**G1:** Multicomponent behavioral ± biofeedback	65	10.0	8.2	1.8	10
	G2: Oxybutynin (range of doses)	67	10.9	8.8	2.1	10
	G3: Placebo + bladder diary	65	10.0	9.7	0.3	10

* Not significant differences between groups. ^p<0.05 † Significant comparisons BT vs. CT and PME vs. CT

One study evaluated the ability of biofeedback to improve outcomes associated with multicomponent behavioral therapy,[135] relative to providing the training with verbal feedback. The intervention included multicomponent behavioral training with either biofeedback or verbal feedback, compared to a self-help booklet. Multicomponent behavioral training combined bladder training techniques (e.g., relaxation approaches in the presence of urge, extending time between voids) with pelvic muscle exercises. The interventions took place over an eight-week period with four visits, followed by a two-week bladder diary. Reductions (mean: 58.6 to 69.4 percent) in episodes of incontinence were seen in all groups, with median percentage reductions ranging from 70.4 (IQR: -29.4, 100) to 82.8 (IQR: 0, 100). The wide IQR makes this finding somewhat difficult to interpret, and overall there were no by-group differences (p=0.23), Nonetheless, patients' perceptions of treatment benefit differed (see section below on patient-reported outcomes) with patients in the self-administered training significantly less satisfied (p=0.001).

Burgio et al [135] also compared their multicomponent behavioral approach to oxybutynin and placebo (study described in KQ3) and observed reductions in incontinence episodes of 81 percent among those in the behavioral group relative to 39 percent in the placebo arm.

Wyman and colleagues attempted to separate the role of pelvic muscle strengthening from bladder drill, and assess the potential for a combined impact. Combining the approaches provided the greatest reduction in incontinence episodes immediately after the 12 week intervention (p=0.050), but the difference did not persist at three months (p=0.587).[134]

Only one study in this body of literature included vaginal electrical stimulation.[269] In this study of pelvic floor muscle training with or without biofeedback compared to electrical stimulation, about half of women reported subjective improvement or cure in OAB when treated with electrical stimulation or biofeedback assisted pelvic floor muscle exercises, compared to 38 percent of women instructed in pelvic floor muscle exercises and told to perform them at home.[269]

Frequency outcomes. Number of voids per day was a common, objective measure of treatment effectiveness for behavioral interventions – particularly as a key element of the training is generally encouraging patients to extend time between voiding progressively, with a goal of reaching three to four hours between voids. Bryant found greater reduction in frequency when a caffeine reduction component was added to bladder training (reduction of 4.3 versus 3.3; p=0.037).[136] Women who simultaneously reduced caffeine intake had a 35 percent decrease in number of voids per day compared to 25 percent for those using bladder training alone. In the study described above of multicomponent behavioral intervention compared to placebo (and oxybutynin), frequency of micturition was reduced significantly in the behavioral arm, but not the placebo arm with a reduction of 1.8 micturitions per day.

Urodynamic outcomes. Three studies examined urodynamic measures pre- and post-treatment.[131, 133, 135] In all of the studies, increased bladder capacity was seen along with changes in incontinence and frequency measures.

Pelvic muscle strength. Wang and colleagues[269] found that biofeedback associated pelvic floor muscle exercises resulted in greater change in muscle strength than electrical stimulation, but the clinical significance of the change was not examined.

Patient reported outcomes. The nature of OAB is such that while specific morbidities and mortality are not primary outcomes, the interference that OAB creates in patients' lives, along with embarrassment and stigma, is often the concern that results in treatment seeking. Therefore, characteristics that make up and affect quality of life are of concern for studies of women with OAB, and are the focus of the results presented below. Four studies presented data on patient-reported outcomes other than urgency and frequency or cure/improvement.[130, 132, 134, 135]

Wyman[134] examined the potential impact of combining pelvic muscle exercises with bladder training in an RCT of 204 women, of whom 59 had detrusor instability (results for the 145 women with SUI are not reported here as they are not relevant to this report). Although both impact (measured by the IIQ-R) and quality of life (measured by the UDI) were most improved in the combination group, relative to pelvic muscle exercises alone immediately after treatment, those effects were not sustained three months later. The combination group also had greater perceived improvement immediately after treatment, but again, no differences by group were sustained.

In the Burgio study[135] comparing biofeedback to verbal feedback and a pamphlet to teach multicomponent behavioral training, both biofeedback and verbal feedback performed equally well on all measures of patient perceptions of improvement, with verbal feedback better than the self-help booklet on five measures (accidents are smaller, p<0.006; comfortable with treatment, p=0.01; description of progress, p<0.001; satisfaction with progress, p<0.001; and restriction of

activities, p=0.002). The biofeedback group performed better on three measures (description of progress, p<0.001; satisfaction with progress, p=0.03 and restriction of activities, p=0.002). The biofeedback and verbal feedback groups saw no significant differences. All three groups had significantly improved quality of life scores (per Hopkins Symptom Checklist and Incontinence Impact Questionnaire), with no by-group differences. Similarly, Wang and colleagues[269] found that biofeedback produced greater change in the overall Kings Health Questionnaire score among the group with biofeedback assisted pelvic floor muscle training relative to those who received PFMT without biofeedback or those who received electrical stimulation. Quality of life and satisfaction outcomes are summarized in Table 23.

Table 23. Effects on quality of life and satisfaction of behavioral treatments

Author Year	Comparison Groups	Outcomes
Burgio et al.[135] 2002 RCT	**G1:** Behavioral training with biofeedback **G2:** Behavioral training with verbal feedback **G3:** Self-administered behavioral training	• 86% of those who received behavioral training with verbal feedback were completed satisfied relative to 75% of those receiving biofeedback and 56% in the self-administered group • Significantly more participants in the verbal feedback (89%) and biofeedback (79%) groups reported smaller accidents than in the self-administered group (68%) (p=0.02) • Almost all participants in the verbal (100%) and biofeedback (98%) groups were "comfortable enough" to continue treatment indefinitely, relative to self-administered (89%) (p=0.009)
Dorey et al.[130] 2006 Case Series	**G1:** Pelvic muscle exercises	• 64 of 75 reported pelvic muscle exercises were useful • Severity of UUI at discharge was reported to be severe in four (6%) and moderate in 12 (18%) participants, relative to 32 (37%) and 40 (46%) at baseline, respectively
Dowd et al.[132] 2003 Cohort	**G1:** Bladder health information **G2:** Bladder health information + cognitive strategies (CS) **G3:** Bladder health information + CS + coaching	• Persons in G1 and G3 saw modest gains in UFICQ scores over time; G2 did not. Significant group-by-type of UI interaction: G1 and G3 with urge had more improvement than participants with stress or other UI (F=3.61; p=0.037)
Wang et al.[269] 2004 RCT	**G1:** Pelvic floor muscle training (PFMT) **G2:** Biofeedback assisted PFMT **G3:** Electrical Stimulation (ES)	• Significantly greater changes on the KHQ were observed for both biofeedback assisted PFMT and ES compared to PFMT alone (p=0.003), but not between biofeedback assisted PFMT and ES • Significantly greater changes were observed for ES compared to both other interventions on two specific domains of the KHQ: emotions and severity
Wyman et al.[134] 1998 RCT	**G1:** Bladder training (BT) **G2:** Pelvic muscle exercise (PME) **G3:** Combination therapy (CT)	• Immediately after treatment, the combination group showed significantly more improvement in quality of life measures on the UDI (p=0.054) but the improvement was not sustained at three months (p=0.126) • Changes in life impact as measured by the IIQ-R was greatest in the combination group immediately after treatment (p=0.03), but not at three months (p=0.85) • Satisfaction levels were highest among the combination group immediately after treatment (82% very satisfied, relative to 73% in the PME group and 64% in the BT group); however, differences were not statistically significant (p=0.096)

Complementary and Alternative Therapies

Complementary and alternative therapies span a broad range of which only a small subset of modalities were used in studies of OAB. Acupuncture is an ancient Chinese medical system based on the balance of subtle energy flows (chi) in which imbalance of energy flows can result in disease. Acupuncture therapy aims to manipulate these energies through the insertion of fine needles at key, highly specific points related to chi flow to specific organs for varying periods of time. Foot reflexology is a variation of acupressure that postulates all body organs have corresponding external "reflex points on the foot" and the manipulation of these points can enhance the flow of energy to the reference organ. Specific areas of the sole of the foot are treated for specific medical conditions or symptoms. Hypnotherapy involves direct suggestion of symptom removal through therapeutic relaxation. Treatment of OAB is aimed at reduction of the component symptoms of urgency, frequency, and UUI.

We identified three publications that used complementary and alternative medicine therapies to treat OAB: a fair quality trial of acupuncture,[137] a fair quality trial of foot reflexology,[138] and a poor quality prospective case series of hypnotherapy.[139] See complete evidence tables in Appendix C.

Acupuncture. The acupuncture trial was conducted in Oregon at an academic teaching center and was notable for incorporating sham acupuncture treatment as the comparison group.[137] Among 85 women randomized, 74 (87 percent) completed all four weekly treatment sessions and had complete outcome data at two to four weeks after treatment. Outcomes included comparison of baseline and post-treatment three-day voiding diaries as well as cystometrics, measurements of post-void residuals, the Urinary Distress Inventory, and the Incontinence Impact Questionnaire.

Episodes of urge urinary incontinence were statistically equivalent across groups at completion of four weeks of treatment. Number of voids per day were reduced 14 percent in the acupuncture group compared to 4 percent in the sham treatment group ($p=0.03$). This equated to a reduction of 1.4 voids per day among those receiving acupuncture. The experience of symptoms of urgency was reduced 30 versus 3 percent, with those treated having 1.6 fewer distinct episodes of awareness of urgency per day ($p<0.02$).

Some measures, including functional bladder capacity and cystometric maximum capacity, were modestly improved in the treatment group ($p<0.05$); others, including volume at urge to void and detrusor contractions during cystometry, were comparable across groups with no apparent trends. Scores improved meaningfully on both validated instruments that evaluate distress and impact on quality of life, with statistical significance.[137] No subjects withdrew for adverse events and treatment was well tolerated.

Reflexology. The study of foot reflexology was conducted in an academic center in Hong Kong. They incorporated sham reflexology in the form of a nonspecific foot massage without deep pressure. Among 120 women randomized, 97 (81 percent) completed all treatments and the assessment at three weeks. The reflexology group had three of 60 drop out; the sham group had six of 60 drop out. Losses were related to various competing demands, including four individuals who reported fear of SARS which was a threat during the study period in Hong Kong, with five losses to followup for other personal or medical reasons. There were no withdrawals because of discomfort or complications of treatment. Outcomes included comparisons of baseline and followup 24-hour voiding diaries and the King's Health Questionnaire.

At completion, number of urge incontinence episodes, urgency episodes, and nocturnal voids were equivalent across groups. Daytime voids were reduced by 1.9 voids in the reflexology treatment group compared to 0.55 in the sham massage group (p=0.03). Quality of life measures did not differ. The authors note that their participants may have been unmasked by their familiarity with what to expect from reflexology treatments: as 88.9 percent of those in the reflexology group and 67.4 percent of those in the sham massage group believed that they had received "true" reflexology. This difference in unblinding could bias the findings.

Hypnotherapy. The hypnotherapy study was conducted in a UK academic setting and followed 63 women who were prospectively enrolled, had urodynamics, received 12 weeks of weekly hypnotherapy, and had followup urodynamic evaluation. Descriptive information is provided with little statistical analysis.[139]

Ten of 63 participants discontinued hypnotherapy before completing all sessions. Of those completing all sessions, 29 were reported to be entirely free of OAB symptoms with 14 "considerably improved". Of 44 women who had repeated urodynamics, 22 initially classified as having unstable bladder "converted to stability", other improvements in cystometrics were also reported. This case series lacks masking of assessors and does not provide key patient reported outcomes.

In summary, a well-conducted small trial of acupuncture has intriguing results related to decreased frequency of voiding and reduced symptoms of urgency which are associated with changes in cystometrics related to improved bladder capacity that are logical intermediates of the improvement in symptoms. Women in the study felt they were improved as measured by scales that capture bother and quality of life. This evidence is insufficient to support definitive choice of acupuncture but offers preliminary information that promises modest improvements that are similar to those reported in many pharmacologic trials.

Reflexology is represented by a small trial with unmasking of participants that could have biased the results. There is not evidence to support choice of this modality. Likewise, hypnotherapy is not supported by the scant information provided by one case series with little detail, patient reported outcomes, or statistical assessment. Given the scope of placebo effects demonstrated in other well-conducted studies of OAB treatment, it is difficult to know whether to attribute any effect to hypnotherapy.

KQ 3: Comparisons of Treatments

Direct comparisons of treatments are made between entire approaches to management of OAB (e.g., pharmacologic to behavioral) or within approaches (e.g., drug to drug). In this section we present the results of any direct comparisons of either type, beginning with comparisons within the pharmacologic approach, followed by procedures compared to medical therapy or one another, and finally any comparison involving behavioral approaches. This third group comprises three distinct subgroups: behavioral compared directly to pharmacologic; combination pharmacologic plus behavioral compared to pharmacologic alone, and combination behavioral plus pharmacologic compared to behavioral alone.

Comparisons between pharmacologic treatments

All trial arms for RCTs of pharmacologic treatment for OAB are presented in evidence tables in Appendix C. Specific comparisons have been made in the literature for the following pairs of drugs that describe differences in reduction in urge urinary incontinence or voids per day:

- Oxybutynin ER to Tolterodine ER[84]
- Oxybutynin ER to Tolterodine IR[83]

- Oxybutynin IR to Tolterodine IR[89, 91, 94]
- Oxybutynin IR to Darifenacin[82]
- Oxybutynin IR to Trospium IR[90]
- Oxybutynin TDS to Tolterodine ER[88]
- Tolterodine ER to Tolterodine IR[140, 141]
- Tolterodine ER to Solifenacin[99]
- Tolterodine ER to Fesoterodine[96, 142]
- Tolterodine IR to Solifenacin[97]

These studies are generally powered simplistically only to assess non-inferiority; studies would need to be much larger for full assessment of comparability at robust power for small differences between pharmacologic agents. Nonetheless, in the majority of comparisons, neither drug was reported more effective at reducing either urge urinary incontinence episodes or voids per day with a few exceptions (Tables 24 and 25).

Both oxybutynin and tolterodine in their extended release forms demonstrated superiority in reducing incontinence episodes over tolterodine immediate release.[83, 140] In the OBJECT trial, oxybutynin 10 mg ER was compared to tolterodine 2 mg IR twice a day.[83] At the end of 12 weeks, women taking oxybutynin reduced their episodes per week of urge urinary incontinence from 25.2 to 6.2, compared to a change from 25.1 to 8.5 in the tolterodine arm. The difference of 2.4 episodes per week between groups was statistically significant. However, upon stratifying by age group, the difference was maintained only among those age 64 and younger. Two studies compared the effectiveness of tolterodine 4 mg once per day to tolterodine 2 mg, taken twice per day, and found that the extended release formulation resulted in significantly greater reductions in incontinence episodes.[140, 141]

Sand and colleagues found that voids per week diminished from 91.7 to 68.0 in the oxybutynin 10 mg extended release arm, compared to 91.6 to 71.2 in the tolterodine 2 mg immediate release twice a day arm (p=0.024).[83] However, as with the difference observed for incontinence episodes, upon stratifying by age, the difference was maintained only among those 64 years and younger. Diokno and colleagues (2003)[84] observed greater reductions in voids per week (p=0.05) in women taking oxybutynin 10 mg ER compared to those taking tolterodine 4 mg ER in the OPERA trial. Both studies provided treatment for 12 weeks, and data were obtained via bladder diaries. Harms were rare in both studies, although Diokno and colleagues report significantly higher rates of dry mouth with oxybutynin (p=0.02).

No other comparisons yielded statistically significant differences in terms of our primary outcomes.

Table 24. Direct comparisons of pharmaceutical treatments on urge incontinence

	Oxybutynin, ER	Oxybutynin, IR	Tolterodine, ER	Tolterodine, IR	Solifenacin	Darifenacin	Trospium, ER	Trospium, IR	Fesoterodine	Oxybutynin TDS
Oxybutynin, ER										
Oxybutynin, IR										
Tolterodine, ER	=									
Tolterodine, IR	O>T^	=	ER>IR*							
Solifenacin			=	=						
Darifenacin		=								
Trospium, ER										
Trospium, IR		=								
Fesoterodine, IR			=							
Oxybutynin, TDS			=							

Equivalence assigned if shown to be statistically insignificant or outcomes similar and no significance testing.
^Oxybutynin ER superior for this outcome to Tolterodine IR[83]
*Tolterodine ER superior for this outcome to Tolterodine IR[140]

Table 25. Direct comparisons of pharmaceutical treatments on voids per day

	Oxybutynin, ER	Oxybutynin, IR	Tolterodine, ER	Tolterodine, IR	Solifenacin	Darifenacin	Trospium, ER	Trospium, IR	Fesoterodine	Oxybutynin TDS
Oxybutynin, ER										
Oxybutynin, IR										
Tolterodine, ER	O>T*									
Tolterodine, IR	O>T^	=	=							
Solifenacin			=	=						
Darifenacin		=								
Trospium, ER										
Trospium, IR		=								
Fesoterodine			=							
Oxybutynin TDS			=							

Equivalence assigned if shown to be statistically insignificant or outcomes similar and no significance testing.
*Oxybutynin ER superior for this outcome to Tolterodine ER[84]
^Oxybutynin ER superior for this outcome to Tolterodine IR[83]

Comparisons between procedural and pharmacologic treatments

The only procedure to be compared to another treatment modality was sacral neuromodulation, which was compared to medical therapy in one RCT. In this study, 98 participants refractory to medical therapy were randomized to immediate sacral nerve stimulation or delayed sacral nerve stimulation. The delay group continued unspecified medical management for a six month period before having the procedure. The study found a reduction in daily urge urinary incontinence episodes from 9.7 to 2.6 in the sacral neuromodulation group, compared to an increase from 9.3 to 11.3 in the medical management group at six months ($p<0.01$).[124] At 18 months, 76 percent of patients reported that they were completely dry or had experienced a reduction in symptoms of 50 percent or greater. It is important to note that those receiving medical therapy knew they were awaiting treatment with a modality that they were invested in believing was superior to their current level of symptom management. The differences in risk between sacral neuromodulation and medical management are important. Six patients had permanent explantation: three for pain, two for infection, and three for change in bowel function.

Comparisons between behavioral and pharmacologic treatments

Nine studies, with 11 publications, included behavioral and pharmaceutical arms in direct comparison to one another.[93, 143-150, 201, 254]

The literature base included one prospective cohort study,[147] and eight RCTs.[93, 133, 143-146, 148, 150]

Three of the studies were conducted in Europe, two were in the United States, two were in Asia (Taiwan and Korea), one in Brazil, and one in New Zealand. Seven were conducted at academic medical centers; two were in community settings.

The behavioral approaches examined included bladder training,[146-150, 254] multicomponent behavioral approaches,[143-145] pelvic floor training,[201], and electrical stimulation (Table 26).[93]

Table 26. Direct comparisons between pharmacologic and behavioral interventions

Author Year Design	Groups	N	Episodes per day baseline	Episodes per day on treatment	Decrease in episodes per day	Weeks treated
Urge incontinence per day						
Arruda et al.[201] 2008	**G1:** Oxybutynin 5 mg b.i.d.	22	2.0	1.0	1.0	12*
	G2: Electrical stimulation	21	1.9	1.1	0.8	12*
	G3: Pelvic floor training	21	2.3	1.1	1.2	12*
Lauti et al.[254] 2008	**G1:** Oxybutynin	21	2.2	0.8	1.4	12*
	G2: Bladder retraining	16	1.0	0.1	0.9	12*
	G3: Combination	19	1.8	0.6	1.2	12*

Table 26. Direct comparisons between pharmacologic and behavioral interventions (continued)

Author Year Design	Groups	N	Episodes per day baseline	Episodes per day on treatment	Decrease in episodes per day	Weeks treated
Urge incontinence per day						
Burgio et al.[143] 1998	**G1:** Multicomponent behavioral ± biofeedback	65	2.3	0.4	1.9^	10
	G2: Oxybutynin (range of doses)	67	2.3	0.8	1.5^	10
	G3: Placebo	65	2.2	1.2	1.0^	10
Wang et al.[93] 2006	**G1:** Electrical stimulation	25	1.0	0.5	0.5*	12
	G2: Oxybutynin (2.5 mg 3x/day)	26	0.0	0.0	0.0*	12
	G3: Placebo	23	1.0	1.0	0.0*	12
Voids per day						
Arruda et al.[201] 2008	**G1:** Oxybutynin (5 mg b.i.d.)	22	7.7	6.4	1.3	12*
	G2: Electrical stimulation	21	8.6	7.9	0.7	12*
	G3: Pelvic floor training	21	6.8	7.1	0.3^	12
Lauti et al.[254] 2008	**G1:** Oxybutynin	21	7.8	6.7	1.1	12*
	G2: Bladder retraining	16	8.0	6.3	1.3	12*
	G3: Combination	19	8.4	6.7	1.7	12*
Song et al.[150] 2006 RCT	**G1:** Bladder training	46	10.9	8.1	2.8*^	12
	G2: Tolterodine (2 mg qd)	47	11.6	8.1	3.5*	12
	G3: Tolterodine + bladder training	46	11.9	7.9	4.0^	12
Wang et al.[93] 2006	**G1:** Electrical stimulation	25	12.8	7.8	5.0^	12
	G2: Oxybutynin (2.5 mg 3x/day)	26	11.5	7.4	4.1^	12
	G3: Placebo	23	11.5	10.0	1.5^	12
Goode et al.[145] 2002 RCT	**G1:** Multicomponent behavioral ± biofeedback	65	10.0	8.2	1.8†	10
	G2: Oxybutynin (range of doses)	67	10.9	8.8	2.1†	10
	G3: Placebo	65	10.0	9.7	0.3†	10

* Not significant differences between groups; ^p‹0.05; †significance not reported.

Episodes of Incontinence. Two RCTs considered urge urinary incontinence episodes as a primary outcome.[93, 143] One compared multicomponent behavioral interventions to pharmacologic interventions[143] and reported on changes in incontinence episodes. This study was a three-arm study in which multicomponent behavioral treatment was compared to pharmacologic treatment and to placebo. The behavioral arm had a significantly higher percent reduction in episodes of incontinence at the ten-week followup ($p<0.001$) (80.7 percent compared to 68.5 percent for pharmacologic and 39.4 percent for placebo). In a pilot study comparing oxybutynin to bladder retraining, no difference was observed in effectiveness by group.[254]The authors calculated that to observe a difference between these arms in a full-scale study would require 165 women in each arm, rather than the approximately 20 in the pilot. This study also had a combination therapy arm. Two studies examined the effects of electrical stimulation with different comparison groups.[93, 201] One[93] found no difference in reduction of incontinence comparing electrical stimulation to oxybutynin or to placebo either within or by groups. The other[201] showed no difference in effectiveness between three groups: electrical stimulation, oxybutynin (5 mg b.i.d.) or pelvic floor exercises.

Cure. Three studies reported on numbers of patients who achieved "cure" or resolution of UUI, without further definition.146, 147, 149 The results were inconsistent, the studies were of poor quality, and all were conducted prior to the ICS definition of OAB. The behavioral intervention in Jarvis, 1981149, was inpatient bladder drill, which is not a current treatment approach.149 Diokno (1995) is a report on a series of patients who chose their own treatment modality.147 Only Colombo (1995) in this series was an RCT.146 Bladder training was provided over a six-week period on an outpatient basis; although cure rates at the end of treatment were essentially the same, after six months, those who had received bladder training maintained a higher cure rate (96 percent of those initially cured in the bladder training group versus 57 percent in the oxybutynin group). However, the numbers reported in this study were quite small (only 53 in all groups at six months followup).

Frequency. Of the six studies that provided data on voids per day, all found that both pharmacologic and behavioral approaches could reduce frequency, but that there was no difference between the two approaches.93, 145, 148, 150, 201, 254 Goode and colleagues conducted a secondary analysis of the original Burgio and colleagues 1998 study. They used structural equation modeling to determine that changes in voiding frequency were not mediating factors associated with decreases in incontinence.145

Similarly, both bladder training approaches (either multicomponent or bladder drill) and pharmacologic treatment were associated with urodynamic changes, including increased maximum cystometric capacity overall and at first and strong desire to void. These changes were statistically significant, and large enough to be clinically relevant as well. However, Goode and colleagues[145] examined the potential role of urodynamic changes to mediate the perceived effects of behavioral and pharmacologic treatment on incontinence and found, once again, that they did not seem to be associated with observed reductions in incontinence.[145]

Patient reported outcomes. Burgio and colleagues used the Hopkins Symptom checklist to consider psychological changes potentially associated with improvement in continence.144 Behavioral management and individually titrated oxybutynin were both associated with improvement in psychological status overall (including the placebo condition) and on a range of subscales, but psychological changes measured on the Hopkins Symptom checklist did not correlate with changes in rates of incontinence episodes. Satisfaction was highest among patients who received behavioral management (77.6 versus 54.7 percent with oxybutynin); interestingly, satisfaction on placebo was not substantially different than that on drug (43.1 percent). A very high proportion of the women receiving multicomponent behavioral training felt that they were

"comfortable enough" to continue with the approach (96.5 percent) relative to those on drug (54.7 percent) or placebo (43.1 percent).

Comparisons of combined behavioral and pharmacologic treatment to pharmacologic treatment alone

Seven studies examined the effect of adding a behavioral intervention to drug compared to drug alone, one of which was a feasibility study.[150-155, 254] In all but two studies, the drug was tolterodine. The literature included six RCTs [143, 150, 151, 154, 155] and two randomized open-label trial (Table 27).[153, 254]

Two of the studies were conducted in the United States, one was in Canada, one was in multiple Scandinavian countries, one in Korea, one in New Zealand, and one did not specify, but indicated that it took place internationally in multiple sites. The two United States studies, the Korean one, and the one in New Zealand were conducted at academic medical centers.

Burgio and colleagues (2008) provided multicomponent behavioral treatment as an adjunct to pharmacologic treatment compared to pharmacologic treatment alone[152] to examine the potential for behavioral management to aid patients in ceasing medication use and staying off. The primary endpoint of interest was a combined effect of a 70 percent reduction in incontinence plus no medication use or other therapy for incontinence. This study examined outcomes at 10 weeks, immediately after treatment, and at 8 months after a period of no treatment to examine persistent effects. During the post-treatment period, participants could request a return to medication. The participants in the behavioral group reported a greater reduction in episodes of incontinence than those in the oxybutynin group at 10 weeks; however the difference did not persist to 8 months (ability to discontinue drugs was 41 percent in both groups at 8 months). The two groups also experienced similar percentage reductions in episodes of urge incontinence (20.4 percent in the behavioral group versus 18.5 percent in tolterodine alone). The behavioral group did report statistically significantly greater satisfaction or quality of life.

Table 27. Comparisons of pharmaceuticals with and without behavioral interventions

Author Year	Groups	N	Episodes per day baseline	Episodes per day on treatment	Decrease in episodes per day	Weeks treated
Episodes of urge incontinence per day						
Burgio et al.[152] 2008	**G1:** Tolterodine ER 4 mg+ behavioral	153	3.3	0.4	2.9†	10
	G2: Tolterodine	154	3.3	0.7	2.6†	10
Chancellor et al.[153] 2008	**G1:** Darifenacin (ranges 7-15 mg qd) + behavioral	190	2.8	1.5	1.3*	12
	G2: Darifenacin	205	3.0	1.0	1.0*	12

Table 27. Comparisons of pharmaceuticals with and without behavioral interventions (continued)

Author Year	Groups	N	Episodes per day baseline	Episodes per day on treatment	Decrease in episodes per day	Weeks treated
Episodes of urge incontinence per day						
Lauti et al.[254] 2008	**G1:** Oxybutynin	21	7.8	6.7	1.1	12*
	G2: Bladder retraining	16	8.0	6.3	1.3	12*
	G3: Combination	19	8.4	6.7	1.7	12*
Millard et al.[154] 2004	**G1:** Tolterodine 2 mg b.i.d. with PFME	227	3.4	1.3	2.1*	12
	G2: Tolterodine	253	3.2	1.1	2.1*	12
Mattiasson et al.[151] 2003	**G1:** Tolterodine 2 mg b.i.d. + BT	244	2.0	0.3	1.7*	24
	G2: Tolterodine	257	2.3	0.3	2.0*	24
Voids per day						
Burgio et al.[152] 2008	**G1:** Tolterodine ER 4 mg + behavioral	153	NR	NR	0.5†	10
	G2: Tolterodine	154	NR	NR	0.04†	10
Song et al.[150] 2006	**G1:** Tolterodine 2 mg b.i.d. + BT	46	11.9	7.9	4.0^*	12
	G2: BT	46	10.9	8.1	2.8^	12
	G3: Tolterodine	47	11.6	8.1	3.5*	12
Herschorn et al.[155] 2004	**G1:** Tolterodine + behavioral information	39	NR	NR	1.8†	16
	G2: Tolterodine	45	NR	NR	2.2†	16
Millard et al.[154] 2004	**G1:** Tolterodine 2 mg b.i.d. + PFME	227	11.9	9.2	2.7†	12
	G2: Tolterodine	253	12.8	9.4	3.4†	12
Mattiasson et al. [151] 2003	**G1:** Tolterodine 2 mg b.i.d.+ BT	244	10.3	6.9	3.4†	24
	G2: Tolterodine	257	10.6	8.0	2.6†	24

* Not significant differences between groups. ^p<0.05; † significance not reported; ↑increase in episodes per day.

Three additional studies compared the effectiveness of combinations of drug and behavioral approaches to drug alone in changing episodes of incontinence as well as episodes of urgency per day.[151, 153, 154] Differences between the groups were small and non-significant, although there were significant decreases within all groups. Episodes of urgency decreased in all groups as well, with decreases ranging from approximately 1.9 to 2.7 episodes per day, but again there were no differences between the study groups.

Two studies found that adding behavioral training to tolterodine was associated with further reductions in frequency compared to tolterodine alone;[151, 152] two found no significant effect of

adding behavioral training.[150, 155] However, the type of the training provided differed dramatically – for example, the intervention provided by Herschorn[155] was purely informational, while Burgio[152] provided a multicomponent system that included biofeedback and pelvic floor muscle exercises. Per one study,[154] addition of pelvic floor exercises alone in addition to tolterodine immediate release (2 mg b.i.d.) did not confer added reductions in frequency.

In those studies that measured quality of life and participant satisfaction, improvements were significantly greater among those patients receiving combination therapy compared to those receiving pharmacologic therapy alone (Table 28).

Table 28. Effect on quality of life and satisfaction of combination treatment

Author Year	Comparison Groups, N	Quality of Life and Patient Satisfaction Outcomes
Burgio et al.[152] 2008	**G1:** Tolterodine ER 4 mg plus behavioral training **G2:** Tolterodine ER 4 mg	• 53% of participants in the combination group were completely satisfied at 10 weeks, compared to 40% in the drug only group (difference of 13, range 1–25) • At 8 months, 33% of the combination group were completely satisfied compared to 30% in the drug only group • OAB-q bother scores decreased by 36.7 at 10 weeks and 30.4 at 8 months in the combination group relative to 30.9 and 20.4 in the drug only group The difference was statistically significant (p<0.0001) • Health related quality of life improved in both groups with only small differences between groups
Chancellor et al.[153] 2008	**G1:** Darifenacin (7.5-15 mg qd) **G2:** Darifenacin + behavioral modification	• Improvement in total OAB-q scores and OAB-SAT-q at 12 wks, no difference between groups (numbers not provided)
Song et al.[150] 2006	**G1:** BT **G2:** Tolterodine 2 mg b.i.d. **G3:**Tolterodine 2 mg b.i.d. + BT	• More participants in combination treatment group (71%) had improved satisfaction scores at completion compared to the drug group (63%) or the bladder training group (54%) (difference not significant) • Urgency scores were reduced by 60% in the combination group, relative to 62% in the drug group and 45% in the bladder training group. The difference between drug and combination was not statistically significant, but differences between bladder training and combination and between bladder training and drug were at p<0.05

Comparisons of combined behavioral and pharmacologic treatment to behavioral treatment alone

Three studies measured the effect of adding a pharmaceutical approach to a behavioral one. All three of these studies used bladder training as the behavioral technique.

Ghei and colleagues[253] describe a series of cases in which patients chose management approaches that could include either bladder training alone, or bladder training in addition to an antimuscarinic agent. Only 52 of 708 patients chose the bladder training alone, and although they experienced greater reduction in frequency (p<0.0001), those in the combination group had greater reductions in incontinence episodes (p=0.024).

A retrospective chart review of 92 patients treated with bladder retraining drill, among whom 36 also received antimuscarinics, was reported by Fantl et al.[252] The outcome of cure, in this

clinical populations with 6 months to 6 years of followup, was defined as no further episodes of incontinence and voiding every 3 to 5 hours with no associated symptoms. Cure was achieved in 83.3 percent of patients using bladder training with antimuscarinics and 78.6 percent of patients using bladder training alone; this difference was not significant ($p>0.6$).

In a double-blind, placebo-controlled RCT, patients were randomized to receive placebo or oxybutynin 2.5 mg twice a day in addition to bladder training.[255] The patients taking oxybutynin had a greater reduction in daytime frequency when compared to the patients taking placebo ($p<0.05$). There were no differences between groups in the change in incontinence episodes.

Finally, Burgio and colleagues[251] provided the opportunity to patients in their trial of biofeedback-assisted therapy versus oxybutynin[143] whose treatment was not completely successful from the patient perspective to receive combined pharmacologic and behavioral management. Of the 35 individuals who met criteria and agreed to move onto combined treatment, eight crossed from behavioral alone to combination, and 27 went from pharmacologic alone to combined. Both groups experienced significant reductions in incontinence over the effect of the initial treatment. The behavioral to combined group went from 58 percent reduction at the end of single therapy to 89 percent reduction after combined therapy for an additional eight weeks. The pharmacologic to combined group also improved from 73 percent reduction to 84 percent reduction in incontinence episodes.

KQ 4. Modifiers of Treatment Outcomes

This section includes information related to how individual characteristics may influence likelihood of responding to treatment and outcomes of treatment. We included publications that explicitly presented stratification by a baseline characteristic that can be determined in a clinical setting and that presented statistical analysis related to interpreting the influence of the characteristic on treatment effects as they relate to outcomes. Detailed analyses of personality characteristics or psychometrics that require specialized expertise or survey instruments unlikely to be used by those providing care for women with OAB are not reviewed here.

Identified Modifiers

Age. Eight publications examined the relationship of age to response to pharmacologic treatment.[83, 102, 156-161]

Tolterodine was the focus of four of these studies;[156-158, 160] and one compared oxybutynin to tolterodine.[83] The largest study of symptom-related outcomes was an open label clinical cohort with 2,250 patients from 462 urology practices in Germany. The mean dose received was 3.8 ± 1.2 mg, with a median of 2 mg. Average age of those treated was 61 ± 14 years with range not provided. Increasing age was associated with being more likely to have incontinence episodes which were not strictly required to be urge incontinence. In multivariable regression models, with age as a continuous variable, each year of increasing age was associated with small absolute reductions in global efficacy (OR for global efficacy 0.986; 95 percent CI: 0.98, 0.99 per year of age). Global efficacy was defined as eight or fewer voids a day, fewer than two urge episodes, and no incontinence episodes per day.[157]

The largest RCT evaluated age effects among 1,015 participants and found that tolterodine drug was superior to placebo among patients aged younger than 65 compared to those 65 and older. They reported that treatment effects on incontinence episodes per week, voids per day, and subjective reports of experience of urgency and the ability to hold urine, were comparable across age groups at 12 weeks. A side-light of interest was that placebo effect was more pronounced for

reduction of voids per day in the younger group ($p<0.045$); however change from baseline in the treatment arm was comparable regardless of age.[158]

The IMPACT trial enrolled 896 individuals with urge incontinence from primary care settings and conducted an open-label evaluation of tolterodine extended release 4 mg once daily.[160, 239] All parameters, including UUI, urgency, frequency, and nocturnal frequency, were improved at 12 weeks for both those younger than 65 and those older. However, decreases in frequency were less pronounced among the older group who experienced on average a 22.2 percent reduction in daytime frequency (95 percent CI: -26.7, -15.2) and 28.6 percent decrease in nighttime frequency (95 percent CI: -35.7, -20.0); while younger participants had a 33 percent decrease in daytime frequency (95 percent CI: -36.0,-30.3) and a 50 percent decrease in nighttime frequency (95 percent CI: -53.8, 40.0). The most common treatment-related adverse events among those younger than 65 were dry mouth (11.4 percent), constipation (2.7 percent), and dry eyes (1.0 percent); among those who were older dry mouth (6.6 percent), constipation (4.4 percent) and headache (2.2 percent) were most common. Retention (<1 percent) occurred only among those older than 75 and none of four individuals with this complication required catheterization. Statistical comparisons for harms by age were not provided.[160]

A prescription-event monitoring study, conducted in the United Kingdom to assess population impact of tolterodine (range 1 to 4 mg) entering the prescription drug market, monitored more than 14,500 patients who filled prescriptions over a minimum of six months.[156] Average age was 63 ± 16. Analysis of risks of rare adverse events (fewer than 40 events in the full population) found the upper quartile of age, those over 74, had greater risk of rare events including hallucination, heart palpitations, and tachycardia. Those under 50 had the lowest risk of cardiac events. No note was made of whether more common side effects varied with age.

A small comparative study of oxybutynin (10 mg once daily) and tolterodine (2 mg twice daily) (n=315) found an advantage for oxybutynin extended release over tolterodine twice daily for decreasing urge incontinence, urgency, and frequency, among those 64 and younger. This effect was not apparent in older age groups in which both were comparably effective.[83]

Other pharmacologic treatments. A single placebo controlled RCT of trospium (20 mg twice a day) evaluated whether CNS adverse effects, specifically daytime drowsiness, varied with age. Using the Stanford Sleepiness Scale, they found fewer than 1.5 percent of those on trospium (and 2.5 percent of those on placebo) experienced a clinically relevant three or more point increase. Using continuous scores, neither age grouping as <65 and older or <75 and older revealed meaningful differences. Average changes in scores across groups were most often improvements of less than half a point, generally less than a quarter point.[161] Darifenacin has been studied among those age 65 and older in a two-year, open-label extension of 716 participants, that documented comparable effectiveness among older and younger participants with respect to sustained or improved treatment response over time as defined by a global response score, and individual measures that included incontinence episodes, voiding frequency, urgency, and OAB-related nocturnal waking.[159] All statistical testing for these outcomes across time points through 24 months had $p<0.088$ for the comparisons with baseline status.[159] A trial that allowed dose adjustment of darifenacin over the course of the study found the mean age of those requiring dose adjustments "for additional efficacy" was equal to those who did not change dose.[102]

Though some studies reported reduced efficacy for specific endpoints among older participants in their study populations, none reported complete lack of benefit among older populations.

Prior treatment. Seven publications investigated whether prior treatment with antimuscarinics predicted treatment response.[85, 86, 102, 162-165] In three placebo-controlled trials of oxybutynin patch,[85], and tolterodine IR,[162] participants who had previously been on

antimuscarinics had comparable outcomes to those who were treatment naïve. The tolterodine study specifically commented on prior treatment failures, noting improvements in those who had failed prior treatments that were above placebo but not statistically significant; few participants were in this category.[162]

In two drug-to-drug comparison trials, outcomes, including UUI, total incontinence episodes, and "perceived improvement of bladder condition," were likewise reported to be comparable for treatment naïve and previously treated participants. These studies investigated oxybutynin ER (5 mg and 10 mg) and tolterodine ER (2 mg and 4 mg);[86] and oxybutynin ER (10 mg) and tolterodine ER (4 mg).[164] A nine-month open label study of tolterodine 2 mg twice daily found that 89 percent of individuals previously unable to tolerate oxybutynin, tolerated tolterodine well.[163] One study included participants who had not been on medications as well as those switching from oxybutynin immediate release to extended release. In a subanalysis of those switching from immediate to extended release, the total proportions continent at 12 weeks is similar to that presented for the whole study population; no statistical test related to this comparison is provided. Some who had been on IR dosing regimens had worsening of symptoms on comparable total doses of ER.[165] This study was small (n=256 spread across 16 centers without placebo comparisons) which hinders interpretation. In a trial that allowed dose adjustments, prior treatment was associated with higher rates of dose increase.[102]

Baseline severity.

Presence, type, and severity of incontinence. Two studies contrasted those with UUI at baseline to participants without UUI. In an open-label study of tolterodine 3,824 participants with nine months of treatment, urge, frequency, nocturia, and OAB scales were similarly improved regardless of UUI baseline status.[166] The VOLT study of solifenacin was an open label study of flexible dosing.[167] Participants who had UUI at baseline and reported it was their most bothersome symptom, reported improvements in urgency, UUI, frequency, and nocturia, from "moderate to severe" to "very minor to some minor." With the exception of nocturia, the point estimates for improvement in individual measures were better in the group with UUI at baseline, although not always statistically significantly better.[167] Severity of UUI was not significantly associated with improvement in UUI. Subjects with severe UUI (defined as >20 episodes per week) had 67.6 percent decrease in UUI episodes, compared with 71.4 percent in subjects with less severe UUI.[168]

The response of those with UUI (n=552) was compared to those with urge-predominant mixed urinary incontinence (n=171) in a 16-week single blind trial of tolterodine that allowed dose adjustments from 1 mg twice daily to 2 mg twice daily. The authors reported cure rates were comparable: 44 percent of those with UUI achieved "dryness" and 39 percent of those with mixed urinary incontinence; 24.0 and 23.5 percent respectively had normalized voiding frequency (<8 voids per 24 hours).[169] Other studies included participants with urge-dominant mixed urinary incontinence, or failed to specifically address inclusion or exclusion of those with mixed urinary incontinence, and did not report assessing trial data for differential treatment effects.

Specific symptoms and outcomes. A single study of transdermal oxybutynin and tolterodine ER 4 mg reported on ability to improve frequency in the lowest quartile of frequency, which was those with <10 voids a day at baseline, and found that neither drug had a significant effect in that subgroup compared to placebo.[88] The IMPACT trial, an open label trial of tolterodine ER in primary care practices, documented improvements among all groups of participants whether the most bothersome symptom was daytime frequency, nocturnal frequency, urge urinary incontinence, or urgency. Statistical testing was not provided to determine if specific groups were more likely to benefit; the data presented suggests similar improvements in self-reported

improvement, symptom bother, coping, health-related quality of life, and AUA symptom index scores across all groups.[239]

Other authors used severity scales or single questionnaire items to group participants and to conduct sub-analyses by severity. In the German open-label, observational study of tolterodine 2 mg twice daily, patients with greater baseline symptom severity experienced greater magnitude of improvements. This trend was for global efficacy; individual component symptoms varied across groups and were not statistically significant. Overall, those with severe baseline symptoms were less likely than others be symptom free at 12 weeks.[157] In the ACET study among those whose self-reported symptom scores were graded as moderate to severe, those on tolterodine ER achieved greater magnitude of improvements on a global improvement scale than those on oxybutynin ER; comparison across moderate-to-severe to less affected participants was not provided.[86]

Urodynamic findings. Four publications related baseline urodynamic findings to outcomes of treatment.[89, 170, 171, 173] Three of these studies did not identify urodynamic findings that predicted poor response or non-response to treatment. The finding of detrusor overactivity compared to its absence was not associated with outcomes in a case series of 365 women treated with bladder retraining and oxybutynin 2.5 mg twice a day. Both women with and without detrusor instability had comparable benefits from treatment, as measured by voids per day and incontinence episodes.[171] Likewise in an RCT of duloxetine (an SSRI) versus placebo which showed treatment benefits for OAB with and without UUI, the classification of participants as having detrusor overactivity or sensory urgency based on urodynamic findings was not statistically significant as an effect modifier or predictor of treatment outcomes.[170] The third study to group participants by urodynamic finding had group sizes (n = 6, 25, 36, 40) too small to make definitive assessments but suggested in the two larger groups that those with low volume and high pressure profiles had comparable results to those with low volume and low pressure profiles. The last case series, reporting on 111 women with OAB based on symptoms and urodynamic diagnosis of detrusor overactivity, found that those women who had involuntary detrusor contractions with provocative maneuvers like coughing, washing hands in cold water, and the sound of running water, were less likely to respond to treatment, which was not operationally defined by the authors, with tolterodine 4 mg a day than those who did not respond to provocation (p=0.0008).[172]

A last study conducted urodynamics among 1,133 women of whom 132 met the criteria for detrusor overactivity "conforming" to the definitions of the ICS; the researchers then compared treatment outcomes among women with and without coital incontinence. Among women with DO treated with tolterodine ER 4 mg daily for 12 weeks, those women with coital incontinence at orgasm were more likely to be non-responders to treatment ("unimproved by self-report") for their OAB (41.2 percent) than those without coital incontinence (17.0 percent), (p=0.23).[173]

Other candidate modifiers.

Race and ethnicity. The VOLT study, an open label trial of solifenacin has resulted in two publications addressing race and ethnicity. The authors report these analyses were motivated by lack of literature that explicitly addresses whether minority groups achieve comparable outcomes to the overall study group; the publications focused on Hispanic and black participants in VOLT. They provide detailed symptom and outcome profiles and report that outcomes were similar to the larger cohort. However direct statistical comparison is not provided by race/ethnicity.[205, 229]

A single three-arm trial of tolterodine ER 4 mg, tolterodine IR 2 mg twice daily, and placebo (n=1,235) reported that women who were above the mean for BMI (> 27kg/m^2) were more likely to have UUI at baseline but achieve comparable reductions in number of incontinence episodes, to those with lower BMI after 12 weeks of treatment.[140]

Anterior vaginal wall prolapse. Anterior vaginal wall prolapse was the sole pelvic organ prolapse measure that we identified in the literature about treatment outcomes. Anterior vaginal wall prolapse was defined as descent to at least 1 cm proximal to the hymen (POP-Q measurement ≥ stage IIa). Women with such prolapse in this clinical case series of women treated with 4 mg of tolterodine extended release formula once daily were more likely to show no improvement at 12 weeks (39.2 percent) compared to those without prolapse (14.1 percent) using a three-point scale of no change, improved, and cured (p=0.0002).[243]

Gender. Authors frequently reported that men, especially older men, fared less well in resolution of symptoms of OAB.[85, 106, 156, 157, 174] This evidence review was focused on outcomes of treatment among women. However, in order to retain landmark studies we included a number of studies that enrolled men as long as the proportion of women in the study was 75 percent or more. This means that treatment effects may be attenuated when men are included.

KQ5. Costs of Overactive Bladder Treatment

This section presents the results of our literature search and findings about financial costs associated with treatment for overactive bladder. Direct medical costs, indirect medical costs, and lost productivity for individuals with OAB are significant issues, in part because these women may be at greater risk for comorbidities such as falls and fractures, urinary tract infections, depression, and skin conditions.[188, 189] OAB symptoms can interfere substantially with work and other activities,[250] affecting productivity. Nonetheless, the proportion of individuals with OAB who seek medical treatment for OAB has been estimated to be extremely low with possibly as few as 4 percent of individuals with symptoms seeking treatment.[24] Therefore, estimates of costs of care for OAB are likely a reflection of care provided to only a small proportion of a group that may be able to benefit from effective treatment.

Although several studies have estimated the cost of illness of urinary incontinence, few studies in the United States have estimated the cost of illness of OAB, and even fewer have focused on treatment costs, as specified for this review. In particular it is difficult to estimate costs related to OAB because it is a symptom-based syndrome with significant inter- and intra-individual variation in etiology and in symptoms. To answer the question of costs related to the treatments reviewed in this systematic review, we restricted our analysis to studies that included direct costs of treatment for OAB in the United States.

Detailed information on all studies related to financial costs associated with management of OAB can be found in Appendix C. Studies analyzed costs for at least one of the following cost categories:

- **Direct costs.** Depending on the bundle of treatment for OAB, costs may include PCP services, specialist care, skilled nursing facilities, home health care, and/or surgery. Direct costs include diagnostic costs, radiology costs, laboratory costs, treatment costs, and costs related to the consequences of OAB.
- **Indirect Costs.** Indirect medical costs include lost productivity and an informal caregiver's time.

Financial Costs

Content of the literature. We identified five studies on financial costs related to OAB that met criteria for inclusion.[175-179] All studies included assessment of direct medical costs related to OAB, and two included costs due to lost productivity. One study additionally assessed financial implications for pain and suffering. Two additional studies do not meet criteria for measuring direct costs of treatment, but provide context related to health care utilization.[24, 250]

The literature base included three analyses of administrative-claims databases: one using Medicare data; one using a large, private health plan affiliated with Ingenix; one using seven plans administered by UnitedHealth Group. These studies analyzed claims for ICD-9 codes they selected as indicative of OAB; some ICD-9 codes were unique to specific studies.

One study was a national telephone survey of community-dwelling adults[179] that was designed to measure prevalence in the community. A followup survey was sent to a selected set of age and sex-matched cases (with OAB) and controls to estimate treatment use, medication, routine care, OAB related consequences and work productivity.

One focused on community-dwelling adults, one on persons younger than 65 years of age who filled prescriptions for drug treatment of OAB, one on persons of any age with prescription-drug benefit who filled prescriptions for drug treatment of OAB, and one on persons who had failed tolterodine ER and sought alternative drug therapy. Each of the studies used a different definition of OAB (Table 29). Because Jensen's study[177] represents the Medicare population in 1994 to 1995 and is therefore likely substantially out of date, we do not summarize the data here. Data are available in the evidence table (Appendix C).

Table 29. Study definitions used for cost determination

Author Year	Population	Definition of Costs	Definition of OAB (ICD-9 Codes)
Hu et al.[179] 2003	National telephone survey of community-dwelling adults	**Direct:** Routine care Diagnostic costs Treatment costs Consequences of OAB **Indirect:** Lost productivity Informal caregiver's time	Self report in the NOBLE study
Hall et al.[176] 2001	Claims database of seven plans affiliated with UnitedHealth Group	Physician office visits Pharmacy claims Laboratory claims Radiology claims Outpatient hospitalizations Inpatient hospitalizations ER visits	(788.30, 788.31, 788.33, 788.34, 788.35, 788.36, 788.37, 788.39, 788.40, 788.41, 788.42, 788.43)
Nitz et al.[178] 2005	Claims database associated with Ingenix	Hospital ER Physician outpatient visits Laboratory Other non-pharmacy	(595.3, 596.51, 597.81, 788.30, 788.31, 788.33, 788.34, 788.36, 788.39, 788.4, 788.41, 788.43)
Jensen et al.[177] 2003	Medicare-claims database	Hospital inpatient care Outpatient care Physician services Laboratory and x-ray services Skilled nursing facility care Home health care services	(596.51, 596.59, 788.30, 788.31, 788.33, 788.41, 788.43)
Varadharajan et al.[175] 2005	PharMetrics Patient-Centric database	Pharmacy claims Outpatient medical care Laboratory/diagnostic costs Inpatient costs and days in hospital	(596.5x [excluding 596.53, 596.54], 788.3x, 788.41, 788.43)

Costs of treatment. Only Varadharajan and colleagues provided expenditures on medications for OAB, comparing sets of matched patients who used either tolterodine or oxybutynin in their extended release form, or who used tolterodine ER compared to oxybutynin in its immediate release formulation. They did not provide estimates by gender. Costs of drug ranged from an average low of $56 over 12 months for oxybutynin immediate release to a high of $360 for extended release tolterodine. The extended release formulation of oxybutynin had intermediate costs at $317. Tolterodine extended release was significantly more expensive over the course of treatment than both oxybutynin ER and oxybutynin IR ($p<0.001$). These differences in part reflect higher number of prescriptions filled in the extended release groups over the study period compared to the immediate release group ($p<0.0001$). Nonetheless, total healthcare costs, including those specifically related to OAB, were highest for users of oxybutynin immediate release compared to the extended release formulations ($p<0.0001$).

Three studies examined total medical costs (not just treatment costs) for persons who filled prescriptions for OAB drug treatment (Table 30). These studies calculated the total healthcare costs for persons with OAB, per person per year by drug (PPPY). No studies did so by surgical or behavioral approach and only Varadharajan presented data for women only.[175]

Table 30. Total cost differences in annual medical care among persons filling prescriptions for OAB drug treatment

Author Year	Groups	Cost Outcomes			
	Type of prescription filled	Average PPPY Total Costs before treatment ($), Unadjusted, Mean $ cost ± SD	Average PPPY Total Costs after treatment initiation ($), Unadjusted, Mean $ ± SD	Statistical significance	Reference standard
Nitz et al.[178] 2005	**G1:** Oxybutynin IR **G2:** Oxybutynin ER **G3:** Tolterodine ER	**G1:** 4956 ± 14396 **G2:** 4146 ± 8695 **G3:** 3349 ± 6715	**G1:** 7083 ± 39420 **G2:** 5980 ± 13263 **G3:** 5074 ± 11007	G1/G3: *P*<0.05 G1/G2: NS G2/G3: NS	NR
Hall et al.[176] 2001	**G1:** Tolterodine **G2:** Oxybutynin **G3:** Flavoxate or other OAB medication **G4:** No drug treatment for OAB	**G1:** 5004 **G2:** 5688 **G3:** 5352 **G4:** 2928	**G1:** 7020 **G2:** 7116 **G3:** 7380 **G4:** 5040	NR	NR
Varadharajan et al.[175] 2005 (women only)	**G1:** Tolterodine ER* **G2:** Oxybutynin ER **G3:** Tolterodine ER* **G4:** Oxybutynin IR	NR	**G1:** 8303 ± 18802 **G2:** 8862 ± 18684 **G3:** 9975 ± 42860 **G4:** 10521 ± 22602	G1vG2: p=0.0109 G3vG4: p=0.3612	2004 US dollars

PPPY = per person per year; *Separate groups matched according to G2 and G4

In their followup survey of individuals with OAB, Hu and colleagues[179] collected data on a range of health care utilization measures, including pharmacologic and surgical treatment for OAB. They used several sources of cost data, including the Red Book, to assign the annual costs of treatment for OAB in the United States in 2000. Pharmacologic treatment costs for women in 2000 were estimated at approximately $1.2 billion for women overall, with approximately equal

costs across age groups. OAB surgical costs among women in 2000 were estimated at approximately $550 million.[179] Overall health care costs, including lost productivity for the nation were $7.4 billion for women (approximately $3.1 billion for those under 65).

This body of literature is particularly challenged by the varying methodology for identifying and defining patients with OAB. In part, this variability is a reflection of the overall literature on OAB, which also uses varying definitions. Most problematic for definitional purposes is whether and when authors included incontinence in any of its forms.

None of the cost papers qualifying for inclusion used data beyond 2002, when the ICS definition of OAB was put into place.

Chapter 4. Discussion

This chapter summarizes the strength of the evidence to address our key questions and then presents methodologic considerations and a discussion of the findings for each of our five key questions. We conclude with a discussion of the status of research, limitations of the current literature, and our recommendations for future research priorities.

Strength of Evidence

We have summarized the quality of individual studies in categories of good, fair, or poor (with grading explained in Chapter 2) for each key question or sub-question within the summaries below and the information is included on the evidence table for each study in Appendix C. The strength of the evidence for each question or sub-question is a broad assessment of the totality of the literature available to provide evidence on a specific question or sub-question.

To reiterate the strength grades, the levels of strength of evidence are as follows:

I. **Strong:** The evidence is from studies of strong design; results are both clinically important and consistent with minor exceptions at most; results are free from serious doubts about generalizability, bias, or flaws in research design. Studies with negative results have sufficiently large samples to have adequate statistical power.

II. **Moderate:** The evidence is from studies of strong design, but some uncertainty remains because of inconsistencies or concern about generalizability, bias, research design flaws, or adequate sample size. Alternatively, the evidence is consistent but derives from studies of weaker design.

III. **Weak:** The evidence is from a limited number of studies of weaker design. Studies with strong design either have not been done or are inconclusive.

IV. **No evidence:** No published literature.

As a global assessment of this literature, no treatments reach the level of strong evidence. For the majority of interventions, strength hovers between moderate and weak because of crucial study design and reporting flaws. When there is no evidence we have noted that.

Principal Findings and Considerations

KQ1: Prevalence and Incidence of OAB

Methodologic issues. Data related to prevalence and incidence of OAB and urge urinary incontinence is notably coherent given the immense technical challenges to comparability. Response rates vary widely across studies with no clear patterns relating type of questionnaire (phone, mailed, administered) or population to completeness of response. Most research teams documented exhausting conventional options for improving response rates and many presented thoughtful analyses of non-response. While estimates, especially of self-reported symptom complexes, are very sensitive to the operational definitions used, these measures were able to be compared when the authors provided information about details like wording of survey items and the required frequency of an event to meet criterion definitions. With some exceptions, such information provided sufficient context to provide a global and United States picture of OAB and urge incontinence.

Appendixes and Evidence Tables for this report are provided electronically at
http://www.ahrq.gov/downloads/pub/evidence/pdf/bladder/bladder.pdf

Publications that appeared after the ICS consensus definitions had more similar results, even when they used operational definitions that differed from ICS. In general, greater detail was provided in the publications after the ICS standardization to support comparisons across studies. We found no evidence that studies supported by pharmaceutical companies returned higher estimates for similar measures, with the exception of a single United States publication reporting on a cluster of consumer surveys done in malls. The estimates from those surveys were high enough to be considered outliers and the operational definitions used to derive the estimates were not provided in order to determine how their results compared to others.[36] There was no readily apparent relationship between method of administration (e.g., mailed survey, administered, or other methods) and findings which is reassuring.

Summary of prevalence and incidence findings. Overactive bladder and urge urinary incontinence occur in women of all ages around the world. The type of healthcare system appears not to clearly relate to the proportion of women affected at any point in time, suggesting that universal access to care such as in the United Kingdom and Canada versus more socioeconomically correlated access in the United States, is not the driver of whether or not women currently report symptoms. Several factors work in synergy to determine whether a woman with OAB symptoms is counted among prevalent OAB cases: degree of bother of symptoms, which varies widely; individual decision to seek care, which is shown to be a low proportion of those affected (13 percent of nurses in the Nurses Health Study); availability of care; and the degree to which an individual woman is distressed by the symptoms or interprets them as a normal part of aging.

Conservatively estimated more than 10 to 15 percent of adult, community-dwelling women in the United States meet criteria for OAB and as many as 5 to 10 percent have urinary incontinence associated with urgency. OAB and continence status are not static; both OAB and urge incontinence can resolve, though the data suggest most women are affected for multiple years at minimum if they develop symptoms.[64, 77] How often resolution is related to treatment, individual behavioral change, or the natural history of the condition is completely undocumented. Evidence to describe the relationship of UUI or OAB with age is varied. The preponderance of the literature suggests that OAB risk is more directly associated with increasing age than urge incontinence. For both conditions the relationship may be complex, such that rates of increase in the proportion of women who are symptomatic are relatively consistent until a threshold age. The most probable threshold ages at which rates plateau are well past the average age of menopause and reported to fall between 60 and 75 years of age.

Because of the population-based design of these reports, often details like recent urinary tract infections or childbirth were not able to be taken into account, though future researchers could incorporate self-reported status in inclusion and exclusion for the studies as some of the strongest publications in this literature did. Likewise, future research on incidence and regression of symptoms would do well to attempt to account for intercurrent diagnosis and whether or not an individual has received treatment.

The epidemiology of OAB and urge incontinence lead us to conclude, as have others, that the conditions are common, occur across the lifespan, and that providers of all types – primary care, specialists, and advanced practice nurses and health educators – will be called on to advise patients and provide care.[196] Opportunities for detection and treatment in clinical settings should be frequent and attention should be addressed to the degree to which patients find the symptoms distressing including impact of self-image, quality of life, and sexual function.

KQ2: Outcomes of Treatments for OAB

Pharmacologic treatments.

Methodologic consideration for pharmacologic treatment studies. The content of this literature is predominantly of fair to poor quality and strength of the evidence is at best moderate, and improved only by the consistency with which medications for OAB are shown to have modest advantage over placebo. The duration of followup during the masked portion of trials is short, rarely longer than 12 weeks. Given the longevity of treatment likely to be used by patients this is concerning and limits the generalizability to clinical practice. No investigators were able to determine whether or not there is a time period after which individuals can discontinue treatment and still retain some or all of the benefits of treatment reduction. Statistical and methodologic concerns are addressed in detail in the Future Research Section of this chapter. After review and analysis of 110 studies, of which four were good quality, 75 fair and 31 poor, with 68 RCTs, the strength of the evidence for managing OAB with pharmacologic treatment is weak to moderate for short term outcomes and weak for long term outcomes and harms.

Findings from pharmacologic treatment studies. All pharmacologic treatments were effective at improving one or more OAB symptoms when compared to placebo. Reductions ranged from 0.9 to 4.6 in urge urinary incontinence episodes per day across all drug treatments and from 0.7 to 4.2 in voids per day. Study by study, extended release formulations achieved better effects than immediate release, although statistical significance varied. No one drug was definitively superior to others by preponderance of evidence, including comparison of newer selective agents to older antimuscarinics. As estimated by meta-analysis extended release forms (taken once a day) reduce UUI by 1.78 (95 percent CI: 1.61, 1.94) episodes per day, and voids by 2.24 (95 percent CI: 2.03, 2.46) per day. Immediate release forms (taken twice or more a day) reduce UUI by 1.46 (95 percent CI: 1.28, 1.64), and voids by 2.17 (95 percent CI: 1.81, 2.54). Of note, placebo reduces UUI by 1.08 (95 percent CI: 0.86, 1.30), and voids by 1.48 (95 percent CI: 1.19, 1.71). Even in the context of small to moderate affect on symptoms, pharmacologic treatments were generally associated with increased quality of life and reductions in measures of impact or distress, compared to baseline and to placebo.

Findings reported in this review are consistent with three prior reviews.[196, 270, 271] The most recent found: (1) antimuscarinics are efficacious compared to placebo, (2) mean decrease in UUI episodes per day ranged from 0.4 to 1.1, (3) mean decrease in the number of voids per day ranged from 0.5 to 1.3, (4) every treatment, with two exceptions, was associated with greater risk of adverse events compared to placebo, and (5) improvements were seen in quality of life.[271] This review added an additional 28 studies and incorporated evidence from study designs other than randomized clinical trials.

Table 31 below provides estimates of treatment effects for pharmacologic treatments represented by more than one trial arm. Some drugs and doses of drugs are not reported because the publications with trial arms for that treatment did not provide sufficient information to estimate variance in meta-analysis models. The models required that we have some estimate of the variance of the effect size such as standard deviation, standard error, or confidence bound, in order to achieve appropriate estimates.

Table 31. Estimates of mean reductions in incontinent episodes and voids per day

Drug	Decrease in Incontinent Episodes per Day			Decrease in Voids per Day		
	Estimate	95% CI		Estimate	95% CI	
Single drug estimates						
Placebo	1.08	0.86	1.30	1.48	1.19	1.71
Oxybutynin IR	1.49	1.18	1.80	2.18	1.75	2.61
Oxybutynin ER	*	*	*	*	*	*
Tolterodine IR	1.45	1.24	1.66	2.19	1.76	2.61
Tolterodine ER	1.75	1.65	1.85	2.48	1.94	3.02
Fesoterodine	2.03	1.74	2.31	1.84	1.64	2.03
Darifenacin	*	*	*	*	*	*
Solifenacin	1.46	1.32	1.59	2.19	1.94	3.02
Trospium IR	*	*	*	*	*	*
Trospium ER	2.45	2.19	2.70	2.68	2.38	2.98
Combined comparison of extended versus immediate release formulations						
Placebo	1.08	0.86	1.30	1.48	1.19	1.71
Extended Release	1.78	1.61	1.94	2.24	2.03	2.46
Immediate Release	1.46	1.28	1.64	2.17	1.81	2.54

*Estimates could not be calculated for these formulations because authors did not provide adequate data on variance for weighting of the raw data

Since baseline episodes of UUI per day ranged from 1.6 to 5.3, and voids per day from 7.2 to 13.7, these reductions (Table 31) reflect modest margins of benefit from baseline above placebo. Data was not consistently provided across studies to estimate the proportion of women who became symptom free.

Procedural and surgical treatments.

Methodologic consideration for procedural and surgical treatment studies. Studies in this treatment domain are of limited quality and predominantly case series in specialized treatment settings. Sacral neuromodulation has not had properly masked randomized clinical trials,[193] and botulinum toxin injections are promising but based on a small number of studies that identified urinary retention as a distinct risk factor that is self-resolving but troublesome.[193] Other procedures found no benefits or are no longer used in practice. Given consideration of 18 studies, of which 11 were fair quality and seven poor, with five RCTs, the strength of the evidence for managing OAB with procedural and surgical treatment is weak for all aspects of understanding outcomes of care.

Findings from procedural and surgical treatment studies. Among the trials of procedures and surgery, one demonstrated a statistically significant benefit of sacral neuromodulation over usual care for the reduction of episodes of urge urinary incontinence per day (average reduction of 7.1 compared to 2.1 increase with usual care) among subjects with OAB known to be refractory to medical therapy.[124] Enthusiasm is tempered primarily by reports from multiple case series that harms are not rare with these treatment approaches. Data that reflects newer sacral neuromodulation techniques in this refractory population are lacking.

Surgical and procedural treatments for OAB are not first line management due to the cost and risks of these types of procedures. Sacral neuromodulation decreases the number of urge incontinence episodes by at least 50 percent among patients refractory to conservative therapies. Moreover, the number of moderate-heavy incontinence episodes also decreases. These results persist even at five years. Sacral neuromodulation seems to have less of a benefit for urinary urgency (mixed results found in our review) and frequency (31 to 45 percent decrease), with benefits in frequency tapering off over time (23 percent reduction in daily voids at 5 years). These benefits come with a relatively high rate of adverse events. Early studies using older

technology had more than one adverse event per subject, on average;[115, 124] studies employing newer technology report lower rate, with events in 11 to 53 percent of subjects.[112, 119] Nearly 40 percent describe pain or an unpleasant stimulation, 7 to 48 percent returned to the operating room (this increased to 67 percent at five years, but includes the need to change the implantable pulse generator battery) and between 2 to 6 percent have an infection (often requiring hospitalization, intravenous antibiotics or explantation). The overall explantation rate hovers around 10 percent.

Our review included only one study on peripheral neuromodulation, using an anal and/or vaginal probe. Benefits in frequency were unlikely to be clinically significant (decrease from 9 to 8 voids daily) and there was a high dropout rate due to pain and effects on the bowels. Other forms of peripheral neuromodulation such as posterior tibial stimulation were not reviewed.

Electromagnetic stimulation with a portable unit was not found to be beneficial for OAB.

Of the drugs injected or instilled into the bladder, botulinum toxin and oxybutynin had the greatest benefit. One trial demonstrated benefit of instillation of oxybutynin compared to sterile water in the reduction of voids per day (average reduction of 6.8 compared to 2.4).[126] A trial we identified and the recent review by the Cochrane Collaboration found that small trials suggest benefit though researchers continue to evaluate means to decrease the risk of undesired side effects like urinary retention with botulinum toxin. Both botulinum toxin and instilled oxybutynin increase the postvoid residuals and the long term effects of higher residuals in terms of bladder infection and other risks is not known. Although evidence for these approaches is promising, the strength of the literature is inadequate to recommend any of these approaches for broader use in general practice. As of the date of the report, neither treatment is FDA approved for OAB.

Resiniferatoxin injection was not beneficial in the study reviewed. Older treatment modalities such as prolonged bladder distention or bladder transection are no longer commonly used due to the morbidity of these procedures. The reviewed studies also lacked rigorous methods for evaluating treatment benefit.

Behavioral treatments.

Methodologic considerations in behavioral treatment studies. Most of the literature addressing behavioral interventions (with or without comparison to pharmacologic intervention) was of fair or poor quality. In general, studies of behavioral approaches rarely included a true and comparable placebo arm. Although it is well recognized that there are inherent challenges to developing placebos for behavioral techniques, a reasonably strong evidence base on means of doing so suggests that it is possible. Burgio and colleagues[143] worked to mitigate this issue by maintaining similar visit schedules and through the use of bladder diaries in all groups, which was considered adequate masking for quality grading purposes. Particularly in older studies (prior to 2002), the behavioral approach often is not fully described; and inconsistency in the language used to identify different approaches requires the reader to examine the manuscripts very carefully – multiple studies may have called their approach by the same name, but in fact be studying quite different interventions.

To mitigate against such confusion, we have attempted in this report to always describe the intervention along with the first description of results from a given study. Studies conducted prior to the ICS definition of OAB in 2002 tended to examine more limited approaches to bladder training, while later studies focused more on multicomponent approaches and delivery of the training in different ways. Prior treatment attempts are rarely documented in this work, which may make it difficult to compare treatment groups across studies. Finally, this body of literature includes very few studies that included similar combinations of intervention and comparator making it almost impossible to summarize across them. After review and analysis of 29 studies, of which 14 were fair quality and 15 poor, including 17 RCTs, the strength of the evidence for

managing OAB with behavioral approaches treatment is moderate to weak for short term outcomes and weak for long term outcomes and harms.

Findings from behavioral treatment studies. Conclusions about the effectiveness of behavioral techniques for addressing the symptoms of overactive bladder are based on a total of 29 papers (27 studies) that encompass behavioral to behavioral comparisons as well as studies of combining behavioral approaches with pharmacologic treatment, and the reverse, combining pharmacologic approaches with behavioral ones. No two studies could be combined to produce summary data. Overall, behavioral approaches can be effective in reducing episodes of incontinence and daily voids. Multicomponent approaches are most effective, and they perform relatively equivalent to pharmacologic treatment. Generally speaking, reductions in symptoms were modest, with potential decreases in incontinence episodes of up to 1.9 per day, and reductions of up to about four voids per day. The addition of caffeine reduction to behavioral modification reduced frequency, but made no difference in reduction of incontinence episodes. There is no evidence the behavioral approaches enhance the effectiveness of pharmacologic therapy to reduce episodes of incontinence; and like pharmacologic approaches, there is no evidence for long term effectiveness beyond the period during which the intervention is being provided in the health care setting.

Complementary and alternative medicine treatments.

Findings from complementary and alternative therapy studies. We identified three studies that used complementary and alternative medicine therapies to treat OAB: a fair quality trial of acupuncture,[137] a fair quality trial of foot reflexology,[138] and a poor quality prospective case series of hypnotherapy. There is weak to no evidence for complementary and alternative approaches to managing OAB.

Outcomes of treatment. The small trial of acupuncture has intriguing results related to decreased frequency of voiding and reduced symptoms of urgency which are associated with changes in cystometrics related to improved bladder capacity that are logical intermediates of the improvement in symptoms. Women felt they were improved as measured by scales that capture bother and quality of life. Evidence is insufficient to support definitive choice of acupuncture but offers preliminary information that promises modest improvements similar to those reported in many pharmacologic trials.

Reflexology is represented by a small trial with unmasking of participants that could have biased the results. No evidence supports choice of this modality. Likewise, hypnotherapy is not supported by the scant information provided by one case series with little detail, patient reported outcomes, or statistical assessment. Given the scope of placebo effects demonstrated in other well-conducted studies of OAB treatment, it is difficult to know whether to attribute any effect to hypnotherapy.

KQ3: Comparisons of Treatments

Methodologic issues in studies that compare treatments. Evidence for direct comparisons of treatments was based on 19 studies: 12 were fair and 7 poor. Of these, 14 were RCTS. Evidence is currently weak to absent for choosing one therapy over another.

Pharmacologic. A number of pharmaceutical agents have been studied in direct comparison. Nine of these comparisons explicitly examined outcomes for urge urinary incontinence episodes and voids per day. Fewer report on the symptom of urgency. Five of these studies are comparability studies in which a new drug aimed to establish equivalence to oxybutynin, the first drug FDA approved for OAB. One study tested the hypothesis of whether the ER formulation of tolterodine was superior to the IR formulation and the remaining studies were “challenges” of newer drugs to tolterodine, which was the second drug to receive FDA approval. In this context

lack of statistical differences between active drugs is somewhat uninformative as trials were often powered for the comparison of the drugs individually to placebo and in many cases statistical testing of the outcomes of drug-to-drug comparison are not provided. Where studies reported being powered to detect differences between drugs, the postulated differences were unlikely and/or the withdrawals from protocol prevented meaningful effectiveness analysis beyond ITT. In a health services context, ideal comparisons would be of extended durations, since OAB is a chronic condition, and would report on all primary outcomes of relevance including differences in medication adherence, satisfaction with treatment, and quality of life.

Procedures. Participants in these studies were often not exclusively those with OAB. Strict application of inclusion criteria for this review would have eliminated virtually all studies of procedures for this reason. Studies of OAB included those with urinary retention and at times neurologic conditions as the indication. Masking, though challenging, was approximated by insertion of leads for sacral neuromodulation without activation; however given that a test period is done to establish efficacy before implantation of the permanent device, individuals may have been aware of their status and assessment of unmasking is not provided. Developing sham procedure methods may be of special importance in this area.

Behavioral. Variations in the behavioral approaches used and methods for teaching them, as well as differences in the duration and intensity of treatment make comparisons challenging. As a category the methods were generally strong with the continued challenge of developing attention control comparison methods and documenting testing of the degree to which individuals believed they knew their treatment status.

Findings of direct comparisons of treatments.

Pharmacologic. Among 14 pharmacologic RCTs that made ten unique comparisons among pharmacologic agents, the majority did not report statistical tests that showed one drug to be superior to another. The exceptions were from three RCTs. Both oxybutynin and tolterodine in extended release form were superior to tolterodine in immediate release forms.[83, 140] One trial reported oxybutynin ER superior to tolterodine ER for reducing voids per day.[84] Given heterogeneity of participant populations and study designs, this limited number of studies is insufficient for any drug to be considered definitively superior.

Procedures. For procedures, sacral neuromodulation was compared to wait list participants on medications. It is important to note that failure of prior medical management was a criteria for entry into the study; those waiting had worsening of many symptoms. This is in contradistinction to improvements noted in virtually all other comparison groups and likely reflects bias from the knowledge that they were awaiting what they considered more definitive treatment for severe OAB. No conclusions can be reached with this data and future research should address the differences in risk profile of sacral neuromodulation versus medications.[124]

Behavioral. Seven studies compared behavioral to pharmacologic treatments. One study in this group reported significant reductions in incontinence episodes with a multi-component intervention;[143] no study found differences in reductions in voids per day. Participants in one study who were queried reported a preference for behavioral treatment over pharmacologic.[143] Adding behavioral treatments to pharmacologic treatments did not improve outcomes for incontinence episodes or voids per day above pharmacologic treatment alone.

KQ4: Modifiers of Treatment Outcomes

Methodologic issues for study of modifiers. Individual characteristics of participants in OAB studies were highly varied on characteristics that are plausibly related to treatment outcomes such as: age, menopausal status, prior treatment, prior refractory symptoms during treatment, prior incontinence or gynecologic surgeries, severity of OAB at baseline, and presence

and type of incontinence. Higher quality studies reported on these characteristics and either found them comparable across trial arms or adjusted for baseline differences in their analyses. However, few studies indicated *a priori* goals of conducting sub-analyses in order to better understand treatment response. Among publications that did report on predictors of treatment response, the majority were under-powered to detect differences so the resulting claims of comparability are of limited value from an individual study. We found cross-cutting similarities for several of these characteristics such as age, severity, and prior treatment and have compiled those to present the limited picture that is coming into view. Overall this treatment literature is at an early stage of development in which the primary objective has been documenting superiority of the treatment to placebo. Population-based cohorts, such as the few provided by national and payor databases and larger clinical trials designed explicitly to more closely examine treatment response patterns and long-term effectiveness and tolerability will be required to have definitive information that can be used clinically with confidence.

Findings about modifiers of treatment outcomes. Advancing age was associated with more severe symptoms at baseline and with potentially observed attenuated treatment effects. Nonetheless, the majority of studies that reported on the effect of age in relationship to treatment outcomes found significant improvements in the older groups when active treatment was compared to placebo. No studies reported lack of efficacy among older participants. Older individuals do benefit from treatment. Race and ethnicity were not associated with outcomes in two analyses addressing this topic.

Presence of UUI, or urge-dominant mixed urinary incontinence, was not associated with treatment failure. Neither was severity of symptoms; in some cases those with the most severe symptoms, including more severe UUI, achieved the greatest treatment gains but were less likely to be symptom free.

Urodynamic findings do not provide consistent information about likelihood of treatment benefit or failure. A single study noted, among women who all had documented detrusor overactivity at enrollment, that those who had detrusor response to provocative maneuvers such as running water and washing hands were more likely to fail treatment. Further investigation of this finding from a small study would be intriguing as would examining the overall self-reported relationship between cues, urgency, UUI and treatment response. Another small study reported that anterior vaginal wall prolapse was a strong predictor of non-response to treatment. It is important to note that while these factors were associated with lower likelihood of treatment response, the majority of those treated with these characteristics did see improvement in symptoms.

Gender, while not a focus of this report, is important in interpreting findings with caution. Multiple research teams noted outcomes were not as favorable in men as in women. This likely reflects different pathophysiology behind the symptoms. Because some studies in this report included men (up to 25 percent of participants), results should be viewed in light of this potential bias.

KQ5: Costs of OAB Treatment

Methodologic considerations about cost studies. Studies that use administrative data are limited in their ability to adjust by clinical comorbidities and concomitant conditions, although they benefit from large enough numbers to provide a reasonable global estimate. Conversely studies that survey patients on their own health and health care may obtain more detailed information, but suffer from recall bias on the part of the respondents. None of the studies reports on their funding source; nor do they provide any information on investigator conflict of interest.

Findings about costs of treatment. Total direct health care costs for women with OAB in 2000 were estimated at $6.9 billion, of which $1.1 billion was for pharmacologic treatment and $550 million for surgical treatment. The rest was estimated for "consequences" costs, which would include things like falls, longer hospital LOS and skin conditions. Medication costs for OAB with the two most commonly used drugs (oxybutynin and tolterodine) range from $56 to $360 over a twelve month period for newly diagnosed patients. However, overall health care costs were highest for patients who take oxybutynin, relative to tolterodine in any formulation, with costs lowest for patients on tolterodine ER. No study adequately determines why the observed differences exist, in particular whether they are actually a reflection of the differences in the populations who are prescribed the various medications. The one study that measures baseline costs found that patients whose incident OAB prescription was for tolterodine ER had lower costs in the six months prior to prescription than did patients whose incident prescription was either oxybutynin ER or oxybutynin IR. None of the studies conducted a cost effectiveness analysis, although cost-utility analyses have been conducted in Europe (which would be difficult given the low effectiveness of any of the drugs, and short followup of almost all efficacy studies). Nor does any study specifically assess the effect of medication on peripheral outcomes of OAB such as falls.

In studies of adherence and persistence, most of which are conducted in managed care populations, fewer than half of patients ever refill their prescriptions for OAB medications. Average quit time is about a month; among those who persist, adherence is best among patients taking extended release versus immediate release formulations. Even in this group, adherence is low; the highest medication possession ratio noted in the studies we identified was about 36 percent.[272-275]

Future Research

State of the Literature

The study of OAB as a syndrome is entering its second decade. As is typical of advancing areas of research, publications based on case series are giving way to observational cohorts. Trials, beyond those required for FDA approval of indication for OAB, are appearing in the literature and health services researchers are investigating population-level factors such as cost of care and risk of rare but serious side effects of treatments.

The 2002 ICS standardization of terminology[180] was associated with a productive trend toward greater attention to and clarity of operational definitions in research. Documentation of inclusion and exclusion criteria, baseline characteristics, and change in symptom profiles have become more detailed and nuanced in the last five to seven years. Improved clarity about research definitions for conducting the study and analyzing data was the case even when authors departed from ICS definitions. Simultaneously important research gains have been made in crafting, refining, and validating questionnaire and interview instruments for classifying symptoms, assessing severity of symptoms, describing impact of OAB on quality of life, and measuring satisfaction with outcomes.

Concerning deficits. As a body of literature, a number of concerning deficits were common. Fewer than seven percent of included studies met criteria for good quality. For example, for clinical trials, this meant that publications lacked one or more of the following:

- Any description of randomization method
- Masking of participants *and* assessors to treatment assignment
- Description of participant and selection process sufficient to understand generalizability

- Details of intervention provided to subjects sufficient to replicate
- Followup of treatment effects for 12 weeks or longer
- Loss to followup less than 10 percent
- Drop out less than 10 percent
- Power calculations (preferably for two-sided tests)
- Use of appropriate statistical comparisons and tests
- Clear description of methods used to measure outcomes
- Description of validity or reliability of outcome measures for primary outcomes

Each of these criteria is fundamental to the conduct and reporting of research of sufficient quality to build knowledge and inform care. The treatment literature is currently hindered by critical flaws that must be eliminated. These include use of data from only those who completed the whole treatment course and not intention-to-treat analyses. Likewise authors frequently noted covariates that were associated with either baseline severity or outcomes and did not adjust for these factors in analysis or conduct stratified analyses. This was often the case because the size of the study would not support modeling or sub-analyses. Conclusions often over-reached findings in ways that in some instances were blatantly biased in favor of a newer treatment.

The large magnitude of placebo effect in OAB studies deserves special note. The fact of robust placebo response implies that uncontrolled studies will be notably biased. Indeed in this literature observational studies, with rare exceptions, overestimated treatment benefits when compared to trials. High quality trials and innovations in masking treatment group (especially for procedural and behavioral studies) will be essential to firmly establishing treatment effects.

Conflict of Interest. Trends in increasing transparency about sources of funding and potential conflicts of interest have been steadily positive over the past two decades (Table 32). However, a fundamental mismatch exists between the initial research needed to obtain regulatory approval and broader, longer term research needs to assess a wider range of questions about outcomes of care in typical practice settings. For a condition as common as OAB, the funding and conflict of interest picture that emerges suggests a research area that is urgently in need of additional sources of independent funding for the next wave of clinical effectiveness research.

Table 32. Funding sources and conflict of interest by decade of publication

	Source of funding for the research						Reporting of conflict of conflict of interest					
	Publications reporting research funding source, (%)			Industry funded among those reporting funding source, (%)			Publications reporting on author conflict of interest, (%)			Authors with COI for publications reporting COI, (%)*		
Study Focus	1980s	1990s	2000s	1980s	1990s	2000s	1980s	1990s	2000s	1980s	1990s	2000s
Surgical or procedural treatments (n =18)	0/2 (0)	1/4 (25)	8/12 (75)	---	1/1 (100)	5/8 (63)	0/2 (0)	1/4 (25)	6/12 (50)	---	5/7 (71)	32/64 (50)
Medications (n=119)	1/3 (33)	11/17 (65)	78/99 (79)	0/1 (0)	9/11 (82)	73/78 (94)	0/3 (0)	0/17 (0)	50/99 (50)	---	---	228/329 (69)
Behavioral interventions (n = 25)	1/6 (17)	3/5 (60)	10/14 (71)	0/1 (0)	1/3 (33)	3/10 (30)	0/6 (0)	0/5 (0)	1/14 (7)	---	---	7/7 (100)
Complementary and alternative medical treatments (n=3)	0/1 (0)	---	1/2 (50)	---	---	0/1 (0)	0/1 (0)	---	0/2 (0)	---	---	---

* Data presented is the total number of authors reporting they had a conflict of interest (numerator) over the total number of authors in those publications that reported on their individual conflict of interest status (denominator). All other data in the table is the number of publications with the characteristic over the number of publications of that type in the respective decades.

Future Research Directions

Momentum in the direction of higher quality and more informative research will follow from attention to:

- Reporting greater information about key characteristics of populations studied in order to allow assessment of comparability of study populations and applicability of findings. This also facilitates understanding of candidate confounders and variations in findings across studies and study types.
- Conducting studies of sufficient size to conduct hypothesis testing or assess treatment effects. Small studies preclude meaningful descriptive analysis of modifiers and appropriate adjustment of confounders. Inclusion of small numbers of men in much larger studies was a recurrent example of a modifier of treatment outcomes that was noted or ignored without sufficient study size to meaningfully interpret.
- Continuing the expansion of standardized nomenclature and use of validated measures. The current literature is challenging to synthesize and interpret because outcomes measured are varied, not cross-cutting, and measured on different time scales (e.g., episodes per day, per week or per other unit of time). Use of validated measures is improving but measures are perhaps too numerous to help bring results into focus.

Networks of researchers or those working in common areas would benefit from a rigorous, evidence-based consensus process to prioritize tools to use across studies to improve comparability of measures of outcomes like severity and quality of life.

Content priorities. Well-conducted larger studies with study populations that reflect the severity of conditions seen in both primary care and specialty practice settings are critical. It is imperative that the time window of followup be extended. The literature suggests that treatment effects can be achieved in the early weeks of treatment with pharmacologic, procedural, behavioral, and complementary and alternative therapies. However this does not mean that the duration of study should be truncated. To the degree that long-term efficacy and effectiveness is poorly documented, the resolution or worsening of side effects is poorly characterized, and satisfaction and continuation of treatment is not assessed over extended periods of time, the literature is not relevant for informing care for this chronic condition.

Each area that was a focus of this report would benefit from continued study of:

- Etiology and natural history of disease, risk factors and potential preventive measures
- Novel treatments
- Properly powered investigations of direct comparisons of existing treatments
- Longer term investigation of benefits and side effects of treatment
- Continued study of combinations of treatments
- Further investigation of complementary and alternative treatments
- Investigation of predictors of both good and poor treatment responses across treatment modalities.
- Selection of treatment options after prior treatment failure

Conclusions

We find a concerning lack of high-quality evidence to inform clinical decision-making for millions of women in the United States. Both medical and behavioral interventions can provide symptom relief which is often not complete, but valued by women who struggle with OAB. Well-conducted trials of greater duration and sophistication, separate from drug development and marketing efforts, are crucial. Because benefits of current treatments are modest, because drug side effects can be bothersome, opportunities exist to study how to gain synergy from combinations of types of treatments. We must note that lack of evidence of benefit is not equivalent to evidence of no benefit. A number of treatments that are potentially promising warrant continued investigation. Cross-cutting concerns about the quality of research must be addressed to achieve literature that can be meaningfully synthesized. Current literature does not permit definitive conclusions about relative benefit, harm, or costs to achieve similar results. Given how common and concerning OAB is, a priority on promoting high-quality research in the United States is imperative. Women and their care providers deserve better information to guide their choices.

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List of Acronyms/Abbreviations

±	plus or minus
≤	less than or equal to
≥	greater than or equal to
AE	adverse events
AHCPR	Agency for Health Care Policy and Research
AHRQ	Agency for Healthcare Research and Quality
AUC	area under the curve
AUM	ambulatory urodynamic monitoring
avg.	average
BAPFMT	biofeedback-assisted pelvic floor muscle training
BFQ	Bladder Function Questionnaire
b.i.d.	twice a day
BL	baseline
BM	bowel movements
BMI	body mass index
BOO	bladder outlet obstruction
BPH	benign prostatic hyperplasia
bpm	beats per minute
BRD	bladder retraining drill
BT	bladder training
CEE	Conjugated equine estrogens
CHF	Congestive heart failure
CI	confidence interval(s)
cm	centimeter
cmH2O	centimeters of water
CR	controlled release
CS	cognitive strategies
CT	combination therapy
CUBS	Compromised urinary bladder syndrome
d	day
d/t	drug treatment
DI	Detrusor instability
dL	deciliter
DM	Diabetes mellitus
DO	detrusor overactivity
Dx	diagnosis
EKG	electrocardiogram
ER	extended release
ES	electrical stimulation (electrostimulation)
etc.	et cetera
EtOH	Ethanol (alcohol)
F	F-distribution
G	group
GI	gastrointestinal
GII	global impression of improvement
GSI	genuine stress incontinence
GU	genitourinary
HAD	Hospital Anxiety and Depression Scale
H_2O	water
hr(s)	hour(s)
HRQoL	Health related quality of life
HRT	hormone replacement therapy

Hx	history
Hz	hertz
IBD	irritable bowel disease
IC	interstitial cystitis
ICIQ	International Consultation on Incontinence Modular Questionnaire
ICIQ-SF	International Consultation on Incontinence Questionnaire-Short Form
IIQ	Incontinence Impact Questionnaire
IIQ-R	Incontinence Impact Questionnaire-Revised
IMPACT	Improvement in Patients: Assessing symptomatic control with tolterodine
IQR	interquartile range
IR	immediate release
ITT	intention to treat
IUSS	Indevus Urgency Severity Scale
KQ	key question
kg/m^2	kilograms per meter squared
KHQ	King's Health Questionnaire
L	liter
LCB	low-compliance bladder
LOCF	last observation carried forward
LOS	length of stay
LS	least square
Ltd	limited
LTFU	Loss to followup
LUT	Lower urinary tract
LUTS	Lower urinary tract syndrome
mg	milligram
min	minute(s)
mL	milliliter
mL/s	milliliters per second
mm	millimeter
MMSE	Mini Mental Status Exam
mo(s)	month(s)
MUI	Mixed urinary incontinence
MVV	Mean volume voided
n, N	number
ng	nanogram
NIH	National Institutes of Health
NR	not reported
NS	Not significant
OAB	Overactive bladder
OAB-q	OAB questionnaire
OAB-SCS	OAB-Symptom Composite Score
OCAS	oral controlled absorption system
P, p	p value
PFME	pelvic floor muscle exercises
PFMT	pelvic floor muscle training
PGA	patient-reported goal achievement
PISQ	Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire
PME	pelvic muscle exercises
PNN50	measure of heart rate variability
P.O.	per oral (by mouth)
PPBC	Patient perception of bladder condition

PPBCS	Patient perception of bladder condition scale
PPIUS	Patient Perception of Intensity of Urgency Scale
PPPY	per person per year
PRO	Patient reported outcome(s)
Pt	patient
PVR	post-void residual
qAM	every morning
qd	every day
qid	four times per day
QoL	quality of life
QTcB	QT interval correct for heart rate using Bazett's formula
RCT	randomized controlled trial
RTX	resiniferatoxin
s	second
SCL-90-R	Symptom Checklist-90-Revised
SD	standard deviation
SE	standard error
SF	Sexual function
sec	second
SNM	sacroneuromodulation
SQoL-F	Sexual Quality of Life Questionnaire-Female
subj.	subjects
SUI	Stress urinary incontinence
Sx	symptoms
t.i.d.	three times a day
TDS	transdermal delivery system
UDI	Urogenital Distress Inventory
UDS	urodynamics
UFICQ	Urinary Frequency and Incontinence Questionnaire
UI	urinary incontinence
US	United States
UTI	urinary tract infection
UUDI	Urge Urogenital Distress Inventory
UUI	Urge urinary incontinence
VAS	visual analog scale
vs., v	versus
w/	with
wk(s)	week(s)
x	times
yr(s)	year(s)

APPENDIX A. Exact Search Strings

PubMed search strategies (last updated October 1, 2008)

	Search terms	Search results
#1	("Urinary Bladder, Overactive"[Mh] OR "overactive bladder" OR "urge incontinence" OR urinary incontinence, urge[mh] OR "detrusor instability" OR "overactive detrusor" OR "urinary urgency" OR "urinary frequency" OR "irritable bladder" OR "detrusor overactivity") AND "female"[MeSH Terms] AND "humans"[MeSH Terms] AND English[lang]	2886
#2	#1 AND editorial[pt]	10
#3	#1 AND letter[pt]	30
#4	#1 AND case reports[pt]	164
#5	#1 AND review[pt]	299
#6	#1 AND practice guideline[pt]	2
#7	#1 NOT (#2 OR #3 OR #4 OR #5 OR #6)	2400*†

***** Approximately 250 of these citations represent pediatric literature (due to variability in indexing for this topic, we were unable to exclude pediatric literature at the search strategy level).

† Numbers do not total due to exclusions in more than one category; 5 items were indexed as both letters and case reports and 14 items were indexed as both reviews and case reports

EMBASE search (OVID) (last updated October 1, 2008)

	Search Terms	Search Results
#1	*overactive bladder/ or *urinary urgency/ or *urge incontinence/ or *urinary frequency/ or *detrusor dyssynergia/ or *bladder irritation/	1624
#2	limit 1 to (human and female and english language and (adult <18 to 64 years> or aged <65+ years>))	363
#3	#2 and review.pt.	12
#4	#2 and conference paper.pt.	4
#5	#2 and editorial.pt.	1
#6	#2 and letter.pt.	0
#7	#2 and note.pt.	3
#8	#2 and short survey.pt.	4
#9	#2 and case report/	18
#10	#2 and practice guideline/	4
#11	#2 and "systematic review"/	1
#12	#2 and meta analysis/	1
#13	#2 not (3 or 4 or 5 or 6 or 7 or 8 or 9 or 10 or 11 or 12)	318*†

* Overlap with PubMed: 310 citations; 8 new citations retrieved for inclusion.
† Numbers do not total due to exclusions in more than one category: 1 item was indexed as both a case report and review; 1 item was indexed as both a case report and a note; and 1 item was indexed as both a review and a systematic review.

CINAHL search (EBSCO) (last updated October 1, 2008)

	Search Terms	Search Results
#1	(MH "Urge Incontinence") or (MH "Overactive Bladder") or "overactive bladder" or "urge incontinence" or "urge urinary incontinence" or "detrusor instability" or "overactive detrusor" or "urinary urgency" or "urinary frequency" or "detrusor overactivity") and (MH "Adult+") and (ZL "ENGLISH") and (PT "Journal Article")	305
#2	#1 and case reports	18
#3	#1 and review	6
#4	#1 and CE material	5
#5	#1 and abstract/commentary	7
#6	#1 and consumer literature	5
#7	1 not (2 or 3 or 4 or 5 or 6)	264*

* Overlap with PubMed: 240 citations; 24 new citations retrieved for inclusion.

APPENDIX B. Sample Data Abstract Forms

Systematic Review of the Etiology and Treatment of Overactive Bladder in Women
Abstract Review Form

First Author, Year: _____

Reference #_____ Abstractor Initials: ___ ___ ___

Primary Inclusion/Exclusion Criteria			
1. Applies to SER topic (If not, select at least one of the following reasons): a. ___Not OAB (including post-operative/iatrogenic) b. ___Stress or mixed incontinence c. ___Isolated nocturia d. ___Interstitial cystitis/painful bladder syndrome e. ___Pelvic organ prolapse f. ___Neurogenic conditions g. ___Basic science or anatomy only h. ___Imaging/diagnostic study only i. ___Other _____	Yes	No	Cannot Determine
2. Original research (exclude editorials, commentaries, letters to editor, reviews, etc)	Yes	No	Cannot Determine
3. Study published in English	Yes	No	
4. Adult female study population (or includes women)	Yes	No	Cannot Determine
5. Ambulatory population (exclude if exclusively institutionalized or home-bound)	Yes	No	
6. Eligible Study type a. ___RCT b. ___Cohorts with comparison c. ___Case-control d. ___Case series e. ___Incidence/prevalence in representative populations f. ___Cost of treatment in US populations (monetary & non-monetary)	Yes	No	Cannot Determine
7. Eligible study size Record N if < 50 relevant subjects enrolled:_____	Yes	No	Cannot Determine

OAB is operationalized as idiopathic urinary urgency and frequency

Retain for:

_____BACKGROUND/DISCUSSION

_____REVIEW OF REFERENCES

_____Other_____

COMMENTS:

Systematic Review of the Treatment Alternatives of Overactive Bladder in Women
Full-text Review Form

First Author, Year: _____

Reference #_____ Abstractor Initials: ___ ___ ___

OAB is operationalized as idiopathic urinary urgency and frequency

Primary Inclusion/Exclusion Criteria		
8. Applies to SER topic (If not, select at least one of the following reasons): a. ___Not OAB (including post-operative/iatrogenic) b. ___Stress or mixed incontinence c. ___Isolated nocturia d. ___Interstitial cystitis/painful bladder syndrome e. ___Pelvic organ prolapse f. ___Neurogenic conditions g. ___Basic science or anatomy only h. ___Imaging/diagnostic study only i. ___Other _____	Yes	No
9. Original research (exclude editorials, commentaries, letters to editor, reviews, etc)	Yes	No
10. Study published in English	Yes	No
11. Adult female study population (or reports data by gender) If No, % female_____	Yes	No
12. Ambulatory population (exclude if exclusively institutionalized or home-bound)	Yes	No
13. Eligible Study type g. ___RCT /CCT h. ___Cohorts with comparison i. ___Case-control j. ___Case series k. ___Incidence/Prevalence study (survey-based) l. ___Cost benefit/utility/effectiveness study	Yes	No
14. Eligible study size Record N if < 50 relevant subjects enrolled:_____	Yes	No
15. Does study address one of the following: a. ___Treatment of OAB b. ___Incidence/prevalence of OAB c. ___Monetary costs of treatment d. ___Non-monetary costs/harms of treatment	Yes	No

EXCLUDE IF AN ITEM IN A GRAY BOX IS SELECTED

Content Inventory
1. _____Treatment of women with symptoms of OAB a. _____Pharmacologic b. _____Surgical i. _____Botox ii. _____Central neuromodulation _____Sacral iii. _____Peripheral neuromodulation _____Tibial _____Pudendal iv. _____Augmentation cystoplasty v. _____Other_____ c. _____Behavioral/Physical Therapy d. _____Complementary and alternative therapies e. _____Other_____
2. Modification of outcomes by: a. _____Age b. _____Body habitus/BMI c. _____Clinical presentation, physical exam findings, urodynamic findings, symptom cluster d. _____Diabetes e. _____Functional status f. _____Hormone replacement therapy g. _____Menopausal status h. _____Parity/post-partum/route-of-delivery i. _____Prior treatment j. _____Race/ethnicity k. _____Smoking l. _____Hysterectomy m. _____Other factors_____ **Length of follow-up**:_____

Retain for:

_____BACKGROUND/DISCUSSION

_____REVIEW OF REFERENCES

_____Other_____

COMMENTS:

Evidence Table

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author:	**Design:**	**Inclusion criteria:**	**Incontinence:**	Outcomes:	
	Intervention:	**Exclusion criteria:**	**Urgency:**	Modifiers	
Country and setting:	**Groups:**		**Frequency:**		
Enrollment period:	**N at enrollment:**				
Funding:	**N at follow-up:**				
Author industry relationship disclosures:	**Age, yrs ± SD:**				
	Race/ethnicity, mean ± SD:				
	Women, N (%):				
	Parity mean ± SD:				

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Aaron et al., 2002 **Country:** India **Study period:** NR **Funding:** Department of Community Health and Development, Christian Medical College **Author industry relationship disclosures:** NR	**Design:** Cross-sectional administered questionnaire **Base population:** Permanent residents of the Kaniambadi rural development block of Vellore district in Tamil Nadu **Sampling frame:** Residents of 7 representative villages as enumerated by census; menopausal participant selected then matched to premenopausal control in same age strata **N sampled:** NR **N screened:** NR **N eligible:** Menopausal: 100 Pre-menopausal: 100 **N respondents:** NR **N included:** Menopausal: 100 Pre-menopausal: 100 **Age, mean ± SD:** Menopausal: 46.6 ± 2.2 Pre-menopausal: 45.4 ± 2.3 **Race/ethnicity:** NR	**Inclusion criteria:** • women • age 40 to 49 **Exclusion criteria:** • hysterectomy **Effective response:** NR	**Urgency**: NR **Frequency**: NR	**Prevalence of urgency, %:** Menopausal: 18 Pre-menopausal: 8 **Prevalence of frequency, %:** Menopausal: 17 Pre-menopausal: 11	Overall quality: Poor Internal validity score: 2, - External Validity Score: 2, - Sampling Method Described: + N sampled provided: - N eligible provided: - N included respondents: + Response Rate:* NR Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: - Required frequency defined*: -

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Bogren et al., 1997 **Country:** Sweden **Study period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cross sectional mailed questionnaire **Base population:** Primary healthcare district in southwest Sweden **Sampling frame:** All residents **N screened:** Total: 458 Women: 225 **N eligible:** Total: 458 Women: 225 **N respondents:** Total: 419 Women: 216 **N included:** Total: 419 Women: 216 **Age, %:** 65: 100 **Race/ethnicity:** NR	**Inclusion criteria:** • adults • 65 years old **Exclusion criteria:** NR **Effective response, %:** 96^	**UUI:** NR	**Prevalence UUI, %:** 18.5	Overall quality: Poor Internal validity score: 5, ++ External Validity Score: 1,- Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 96 Inclusion (Exclusion) Specified: + Age of population described: 0? Operational definition provided*: - Required frequency defined*: -

^Data presented for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Bortolotti et al., 2000 **Country:** Italy **Study period:** March 1997 to October 1997 **Funding:** Pharmacia & Upjohn Italia **Author industry relationship disclosures:** At least 2 of 12 Pharmacia & Upjohn (2)	**Design:** Cross-sectional telephone questionnaire **Base population:** Registered participants in primary care networks in six areas of Italy **Sampling frame:** NR **N sampled:** NR **N screened:** NR **N eligible:** NR **N respondents:** Women: 2,767 **N included:** Women: 2,767 **Age, %:^** 40-50: 22.6 51-60: 30.4 61-70: 19.8 > 70: 27.2 **Race/ethnicity:** NR	**Inclusion criteria:** • adults • women age ≥ 40 • men age ≥ 50 **Exclusion criteria:** NR **Effective response, %:** NR (“practically 100%”)	**Incontinence:** Loss of urine at least once in prior year **UUI**: NR **SUI**: NR **MUI**: NR	**Prevalence of UUI, %:*** 1.4 **Prevalence of MUI, %:*** 2.7	Overall quality: Poor Internal validity score: 2, - External Validity Score: 3, + Sampling Method Described: + N sampled provided: - N eligible provided: - N included respondents: + Response Rate:* NR Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: - Required frequency defined*: +

^Data presented for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Brieger et al., 1997 Yip and Chung, 2003 **Country:** Territory of Hong Kong **Study period:** May 1996 to November 1996 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cross-sectional telephone questionnaire **Base population:** Chinese women in Hong Kong **Sampling frame:** Multistage random sample of more than 1.7 million residential telephone listings in Hong Kong **N screened:** 3,509 **N eligible:** NR **N respondents:** 1,500 **N included:** 1,500 **Age, mean ± SD:** 45 ± 15 **Race/ethnicity, %:** Chinese: 100 **BMI, mean ± SD:** 22.4 ± 2.8 **Parity, %:** 83	**Inclusion criteria:** • women • oldest of eligibles in household • ethnic Chinese **Exclusion criteria:** NR **Effective response, %:** 43	**UUI:** NR **MUI:** NR **Detrusor dysfunction:** One or more of the following: UUI, urgency, frequency, or nocturia, in the absence of SUI **Urgency:** NR **Frequency:** NR	**Prevalence of UUI, %:** 0.7 **Prevalence of MUI, %:** 4.7 **Prevalence of detrusor dysfunction, %:** 2.4 **Prevalence of urgency, %:** 4.3 **Prevalence of frequency, %:** 4.2	Overall quality: Poor Internal validity score: 4, + External Validity Score: 1, - Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 43 Inclusion (Exclusion) Specified: + Age of population described: - Operational definition provided*: - Required frequency defined*: -

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Brieger et al., 1996 **Country:** Territory of Hong Kong **Study period:** NR **Funding:** NR **Author industry relationship disclosures: NR**	**Design:** Cross sectional telephone questionnaire (Kings College Urodynamics Questionnaire) **Base population:** Chinese women in Hong Kong **Sampling frame:** Multistage random sample of more than 1.7 million residential telephone listings in Hong Kong **N screened:** 3,248 **N eligible:** NR **N respondents:** NR **N included:** 819 **Age, mean ± SD:** 41.5 ± 16 **Race/ethnicity:** NR **Parity, %:** 66.9	**Inclusion criteria:** • women • age between 10 and 90 • oldest of eligibles in household **Exclusion criteria:** NR **Effective response, %:** 25.2	**UI:** Involuntary loss of urine that is socially or hygienically unacceptable **UUI:** NR **Frequency:** NR	**Prevalence of urgency and/or UUI, %:** 14.7 **Prevalence of frequency, %**: 18.8	Overall quality: Poor Internal validity score: 3, - External Validity Score: 2, - Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 25.2 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: - Required frequency defined*: -

^Data presented for women only.
Prevalence also reported by age.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Chen, Lin, Hu et al., 2003 Chen, Chen, Hu et al., 2003 **Country:** Taiwan **Study period:** 1999 **Funding:** National Science Council in Taiwan **Author industry relationship disclosures:** NR	**Design:** Cross-sectional administered questionnaire (Bristol) **Base population:** Female residents of Dali **Sampling frame:** 3% random sample based on national census records to achieve nationally representative age strata **N sampled:** 1,584 **N screened:** NR **N eligible:** NR **N respondents:** 1,253 **N included:** 1,247 **Age, mean ± SD:** 43.2 ± 15.1 **Race/ethnicity:** NR **BMI, mean ± SD:** 23.1 ± 3.3 **Parity, %** 86.5	**Inclusion criteria:** • women • age ≥ 20 **Exclusion criteria:** NR **Effective response, %:** 78.7	**UUI:** Involuntary loss of urine preceded by the urge to void or relatively uncontrollable voiding with little or no warning, without requirement for "bother" or perceived social or hygienic problem. **OAB:** Frequency and urgency, or nocturia, with or without UUI **Urgency:** Per ICS 2002 **Frequency:** Per ICS 2002 **Strict definitions**:* Above with requirement for "bother" and/or perceived social or hygienic problem	**Prevalence of UUI, %:** 9.1 **Prevalence of UUI-strict, %:** 1.5 **Prevalence of MUI, %:** 17.1 **Prevalence of MUI by age, %:** 20-30: 10.0 >30-40: 16.2 >40-50: 23.1 >50-65: 20.2 > 65: 16.6 *P* < 0.05 **Prevalence of MUI-strict, %:** 1.8 **Prevalence of MUI-strict by age, %:** 20-30: 0.8 >30-40: 0.5 >40-50: 3.5 >50-65: 3.7 > 65: 2.1 *P* < 0.05 **Prevalence of OAB, %** 18.6 **Prevalence of OAB by age, %** 20-30: 11.7 >30-40: 13.3 >40-50: 20.7 >50-65: 20.2 > 65: 39.3 *P* < 0.05 **Prevalence of OAB-strict, %** 2.5 **Prevalence of OAB-strict by age, %** 20-30: 0.9 >30-40: 0.5 >40-50: 1.5 >50-65: 4.8 > 65: 9.7 *P* < 0.05	Overall quality: Fair Internal validity score: 4+ External Validity score: 3, + Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 78.7 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Chen, Lin, Hu et al., 2003 Chen, Chen, Hu et al., 2003 (continued)				**Prevalence of urgency, %:** 12.6 **Prevalence of urgency-strict, %:** 1.7 **Prevalence of frequency, %:** 21.1 **Prevalence of frequency-strict, %:** 2.3	

* Authors provide the strict definition and term it “meeting the criteria of the ICS” in the publication.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Choo et al., 2007 **Country:** Korea **Study period:** 2000 **Funding:** Korean Continence Society-Johnson & Johnson Medical **Author industry relationship disclosures:** NR	**Design:** Cross-sectional telephone questionnaire **Base population:** Representative cross section of Korean population stratified by age, sex, and region **Sampling frame:** Random selection of telephone numbers **N sampled/ screened:** 14,559 **N eligible:** Total: 2,005 Women: 1,005 **Age, mean ± SD:^** 59.4 ± 11.6 **Age, median:^** 59.0 **Age, n (%):^** 40-49: 254 (25.3) 50-59: 252 (25.1) 60-69: 246 (24.5) ≥ 70: 253 (25.2) **Race/ethnicity:** NR	**Inclusion criteria:** • adults • age 40 to 89 • community-dwelling **Exclusion criteria:** None **Effective response:** NA	**Urgency:** "Do you have to rush to the toilet?" **Frequency:** "How often do you pass urine on average?" **UUI:** "When you have an urge to urinate, do you loose urine before you could reach the bathroom?" **OAB:** Per ICS **OAB-dry**: Per ICS urge + freq; or urge + nocturia; or urge + freq + nocturia, without UUI **OAB-wet**: Any combination with UUI	**Prevalence of UUI by age, %:** All: 19.2 40-49: 13.0 50-59: 15.1 60-69: 24.4 ≥ 70: 24.5 **Prevalence of OAB-wet by age, %:** All: 15.0 40-49: 10.2 50-59: 11.9 60-69: 19.5 ≥ 70: 18.6 **Prevalence of OAB-dry by age, %:** All: 16.3 40-49: 16.9 50-59: 15.5 60-69: 14.2 ≥ 70: 18.6 **Prevalence of urgency by age, %:** All: 32.5 40-49: 29.1 50-59: 28.6 60-69: 35.0 ≥ 70: 37.5 **Prevalence of frequency by age, %:** All: 17.7 40-49: 16.5 50-59: 14.7 60-69: 17.1 ≥ 70: 22.5	Overall quality: Fair Internal validity score: 3,- External Validity Score: 3,+ Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: - Response Rate:* NR Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

^Data presented for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Corcos and Schick, 2004 **Country:** Canada **Study period:** Spring 2002 **Funding:** Pfizer Novartis **Author industry relationship disclosures:** NR	**Design:** Cross-sectional telephone questionnaire **Base population:** Canada **Sampling frame:** Stratified random sample of census areas in four census metropolitan areas by gender from the telephone registry **N sampled:** Total: 7,487 **N screened:** NR **N eligible:** NR **N respondents:** Total: 3,249 Women: 1,683 **N included:** Total: 3,249 Women: 1,683 **Age, %:^** 35-44: 35.6 45-54: 28.1 55-64: 17.0 65-74: 11.9 ≥ 75: 6.8 **Race/ethnicity:** NR	**Inclusion criteria:** • adults • age ≥ 35 **Exclusion criteria:** NR **Effective response, %:** 53.7	**OAB-wet (UUI):** Urgency with urinary leaks **OAB-dry (urgency):** "Urgency with need to urinate that runs the risk of urine loss" at least weekly; or half the time or more it is "difficult to postpone urination" and they engage in bathroom seeking behavior. **OAB:** NR **Frequency:** ≥ 9 voids per day	**Prevalence of OAB-wet, %:** 6.5 **Prevalence of OAB, %:** 21.3 **Prevalence of OAB by age, %:** 35-44: 17.9 45-54: 21.1 55-64: 26.8 65-74: 24.0 ≥ 75: 21.4 **Prevalence of urgency, %:** 23.3 **Prevalence of frequency, %:** 15.5	Overall quality: Fair Internal validity score: 4, + External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 53.7 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

^Data presented for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Dallosso et al., 2004 **Country:** UK **Study period:** October 1998 to December 1998* Follow-up 1999 **Funding:** Medical Research Council **Author industry relationship disclosures:** NR	**Design:** Cross-sectional mailed questionnaire with repeated measures mailed food frequency (FFQ) questionnaire **Base population:** Patients registered in any of 108 general practices in Leicestershire **Sampling frame:** Random sample Leicestershire Health Authority registry **N sampled:** 20,247 **N screened:** NR **N eligible:** 19,241 **N respondents:** Baseline: 12,568 FFQ: 7,046 Follow-up FFQ: 5,816 **N included:** 5,816 **Age, median:** 61 **Race/ethnicity:** NR	**Inclusion criteria:** • women • age ≥ 40 • community dwelling **Exclusion criteria:** NR **Effective response, %:** 30.2	**OAB:** Urge leakage at least several times a month and/or very strong or overwhelming urgency	**Annual incidence of OAB, %:** 8.8 **Incidence of OAB by age, %:** 40-49: 7.8 50-59: 6.5 60-69: 10.0 70-79: 11.7 ≥ 80: 14.3 **Baseline prevalence of OAB, %:** 15.9 **Baseline prevalence of OAB by age, %:** 40-49: 12.1 50-59: 15.4 60-69: 16.8 70-79: 18.5 ≥ 80: 26.1	Overall quality: Fair Internal validity score: 4, + External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 30.2 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: +

*Initial mailing in October with two reminders sent in four week intervals

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Dooley et al., 2008* Minassian et al., 2008 **Country:** US **Study period:** 2001 to 2004* 2001 to 2002 **Funding:** NR*, NR **Author industry relationship disclosures:** NR*, NR	**Design:** Cross-sectional administered questionnaire **Base Population:** NHANES a probability sample of the US non-institutionalized civilian population **Sampling frame:** NHANES participants **N sampled:** 21,161* 11,039 **N screened:** NA **N eligible:** 4,541* 2,875 **N participants:** 4,229* 2,577 **Age, %:*** 20-39: 36.3 40-59: 28.0 ≥ 60: 35.7 **Age, mean ± SD:** 50.8 ± 20.1 **Race/ethnicity, %:*** White: 57.9 Black: 20.5 Hispanic: 21.5 **Race/ethnicity, %:** White: 55 Black: 18 Hispanic: 24 Other: 3 **BMI, kg/m^2 n:*** ≤ 25.0: 1,361 25.0-29.9: 1,320 30.0-39.9: 1,238 ≥ 40.0: 310 **BMI, mean ± SD:** 28.6 ± 6.8	**Inclusion criteria:** • women • age 20 or older • completed the standardized interview and examination • answered the questions about incontinence **Exclusion criteria:** • ethnicity classified as "other"* **Effective response:** NA	**UUI:** in past 12 months, "leaked or lost control of even a small amount of urine with an urge or pressure to urinate and you could not get to a toilet fast enough" **SUI:** In past 12 months, "leaked or lost control of even a small amount of urine with an activity like coughing, lifting, or exercise." **MUI:** affirmative response to both SUI and UUI. **Severity of incontinence:** Mild: few times a year Moderate: few times a month Severe: daily or few times a week	**Prevalence of UUI, %:*** 7.9 **Prevalence of UUI, %:** 8.8 **Prevalence of UUI by Age, %:*** 20-39: 4.6 40-59: 8.7 ≥ 60: 11.7 **Severity of UUI, %** Mild: 41 Moderate: 31 Severe: 57 **Prevalence of MUI, %:*** 17.0 **Prevalence of MUI, %:** 13.0 **Prevalence of MUI by Age, %:*** 20-39: 7.7 40-59: 18.6 ≥ 60: 28.7 **Severity of MUI, %** Mild: 13 Moderate: 31 Severe: 57	Overall quality: Fair Internal validity score: 4, + External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* NR Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: +

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Ege et al., 2008 **Country:** Turkey **Study period:** May 2006 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cross-sectional administered questionnaire **Base population:** Female residents of Konya **Sampling frame:** All postpartum women registered in seven health centers in the metropolitan area **N sampled:** 2,200 **N screened:** NR **N eligible:** NR **N respondents:** 1,749 **N included:** 1,749 **Age, mean ± SD:** 26.8 ± 5.1 **Race/ethnicity:** NR **BMI, mean ± SD:** 25.9 ± 3.8	**Inclusion criteria:** • women • within 12 months postpartum **Exclusion criteria:** • pregnant again at time of interview **Effective response, %:** 79.5	**UUI**: NR **SUI**: NR **MUI**: NR	**Prevalence of UUI postpartum, %:** 2.0 **Prevalence of MUI postpartum, %:** 9.3	Overall quality: Poor Internal validity score: 4, + External Validity Score: 1, - Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 79.5 Inclusion (Exclusion) Specified: + Age of population described: - Operational definition provided*: - Required frequency defined*: -

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Espino et al., 2003 **Country:** US **Study period:** Fall 1993 to Spring 1994 **Funding:** NIH **Author industry relationship disclosures:** NR	**Design:** Cross-sectional administered in-home interview **Base population:** Mexican-Americans, age ≥ 65 residing in southwestern states (AZ, CA, CO, NM, TX) **Sampling frame:** Representative probability sample from the Hispanic EPESE* **N screened:** NR **N eligible:** NR **N respondents:** 1,755 **N included:** 1,589 **Age, mean ± SD:** 73.3 ± 6.2 **Race/ethnicity, %:** Hispanic: 100 **BMI:** NR for total N	**Inclusion criteria:** • women • age ≥ 65 • community dwelling • Mexican-American **Exclusion criteria:** • individuals with indwelling catheters **Effective response, %:** 90.5	**UUI:** Feeling need to urinate before loosing urine **MUI:** UUI and leaking urine during sneezing, coughing, vomiting, lifting, laughing or straining	**Prevalence of UUI, %:** 5.0 **Frequency of UUI, %:** Hardly ever: 17.7 Some of the time: 59.5 Most of the time: 13.9 All of the time: 8.9 **Volume of urine loss UUI, %:** Small: 50.0 Moderate: 39.5 Large: 10.5 **Wear protection all the time UUI, %:** 10.1 **UUI Inhibits social activity, %:** 16.7 **Prevalence of MUI, %:** 6.3 **Frequency of MUI, %:** Hardly ever: 12.0 Some of the time: 60.0 Most of the time: 18.0 All of the time: 10.0 **Volume of urine loss MUI, %:** Small: 59.2 Moderate: 31.6 Large: 9.2 **Wear protection all the time MUI, %:** 16.0 **MUI Inhibits social activity, %:** 21.0	Overall quality: Fair Internal validity score: 3, + External Validity Score: 3, + Sampling Method Described: + N sampled provided: - N eligible provided: - N included respondents: + Response Rate:* 90.5 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Eva et al., 2003 **Country:** Sweden **Study period:** 1997 **Funding:** County of Östergötland (Folkshalsoanslaget); Linköping University Hospital **Author -industry relationship disclosures:** NR	**Design:** Cross-sectional mailed questionnaire **Base population:** Women in Östergötland born in 1937 or 1957 **Sampling frame:** 39% random sample of the base **N screened:** 2,000 **N eligible:** NR **N respondents:** 1,336 **N included:** 1,317 **Age, n (%):** 40-yr olds: 643 (48.8) 60-yr olds: 674 (51.2) **Race/ethnicity:** NR	**Inclusion criteria:** • women • born in designated years **Exclusion criteria:** NR **Effective response, %:** 65.9	**UUI:** Urge to void before leaking	**Prevalence of UUI, %:** **40-yr olds:** Sometimes: 11.3 Mostly: 2.1 **60-yr olds:** Sometimes: 15.1 Mostly: 5.2 **Prevalence of daytime voids, Number %:** **40-yr olds:** 8-10: 4.2 > 10: 2.1 **60-yr olds:** 8-10: 7.8 > 10: 2.1	Overall quality: Fair Internal validity score: 4, + External Validity Score: 3, + Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 65.9 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Fenner et al., 2008 **Country:** US **Study period:** Summer 2002 to Fall 2004 **Funding:** NIH **Author industry relationship disclosures:** 2 of 7: Johnson & Johnson (1) Novartis (1) Novasys (1)	**Design:** Cross-sectional telephone questionnaire **Base population:** Residents of 3 Michigan counties **Sampling frame:** Telephone listings from commercial survey sampling group **N sampled:** 12,541 **N screened:** 9,199 **N eligible:** 3,692 **N respondents:** 2,814 **Age, %:** 35-44: 40.6 45-54: 37.7 55-64: 21.7 **Race/ethnicity, n (%):** Black: 1,922 (68.3) White: 892 (31.7) **Vaginally Parous, %:** 69.3	**Inclusion criteria:** • black or white women • age 35 to 64 • community dwelling **Exclusion criteria:** • pregnancy in last 12 months **Effective response, %:** 69	**Incontinence:** Losing urine ≥ 12 times in 12 months **UUI:** based on at least one factor from urge component of factor analysis and no stress factors **SUI:** based on at least one factor from stress component of factor analysis	**Prevalence of UUI, %**: 3.6 **Prevalence of UUI by race/ethnicity, %**: Black: 3.5 White: 3.6 **Prevalence of MUI, %:** 6.0 **Prevalence of MUI by race/ethnicity, %**: Black: 4.1 White: 7.1	Overall quality: Good Internal validity score: 5, ++ External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 69 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: +

Estimates of proportions of population with different types of UI use weights “constructed based on age, race and geographic location to adjust for the oversampling and for survey nonresponse.” Estimates of the prevalence of UUI and MUI are computed by multiplying the overall prevalence of UI (reported at the top of page 1457) by the proportions of types of UI (reported in Table 4 on page 1459). For example, overall prevalence of UUI is 0.265x13.6%=3.6%

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Fitzgerald et al., 2006^ Thom et al., 2006 * Huang et al., 2006† **Country:** US **Study period:** NR **Funding:** NIH **Author industry relationship disclosures:** 4 of 7^ Allergan (2) Eli Lilly (1) Novartis (1) Pfizer (3) Q-med(1) Watson (1) Yamanouchi (4)	**Design:** Cross-sectional Written questionnaire and in-person interview follow-up **Base population:** Members of Kaiser Permanente Northern Care California **Sampling frame:** Random sampling of women by age and race strata to achieve equal strata size for age and fixed ratios by race/ethnicity **N screened:** 10,230* **N screened:** 8,835* **N eligible:** 3,240 estimated **N respondents:** 2,109* **N included:** 2,109 1,348† **Age, mean ± SD:** 56 ± 9 Asian: 53.2 ± 7.4† White: 56.0 ± 9.1† **Race/ethnicity, %:** White: 48 Black: 18 Latina: 17 Asian: 16 **Race/ethnicity, %:**† White: 74 Asian: 26	**Inclusion criteria:** • women • age 40 to 69 • members since age 18 • ≥ 50% births with Kaiser **Exclusion criteria:** • race/ethnicity other than White or Asian† **Effective response, %:** 65.1	**Urgency:** Strong urge or pressure to urinate without actually leaking, at least monthly **Frequency:** ≥ 7 voids/day; NR† **UUI:** NR, at least weekly; At least weekly incontinence with only or predominantly urge episodes in the last 7 days† **UUI only:*** NR, at least weekly **MUI:** NR, at least weekly **MUI, predominantly urge:*** NR, at least weekly **MUI, equal stress and urge:*** NR, at least weekly	**Prevalence of UUI, %:** 10 **Prevalence of UUI, %:**† Asian: 7.3 White: 9.5 *P*=.04 **Prevalence of UUI only, age-adjusted, by race/ethnicity, % (95%CI):*** White: 4.8 (3.9, 5.7) Hispanic: 5.8 (4.8, 6.8) Black: 7.6 (6.5, 8.8) Asian-American: 3.0 (2.3, 3.8) *P* = 0.027 **Prevalence of MUI, %:** 5 **Prevalence of MUI, predominantly urge, by race/ethnicity, % (95%CI):*** White: 4.0 (3.1, 4.8) Hispanic: 4.2 (3.3, 5.0) Black: 6.0 (5.0, 7.1) Asian-American: 4.4 (3.5, 5.2) *P* = NS **Prevalence of MUI, predominantly urge, by race/ethnicity, % (95%CI):*** White: 3.3 (2.5, 4.1) Hispanic: 5.3 (4.3, 6.3) Black: 1.9 (1.3, 2.5) Asian-American: 3.2 (2.5, 4.0) *P* = NS	Overall quality: Good Internal validity score: 5, ++ External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 65.1 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: +

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Fitzgerald et al., 2006^ Thom et al., 2006 * Huang et al., 2006† (continued)	**BMI, mean ± SD:** NR for total N Asian: 25.8 ± 4.8† White: 28.0 ± 6.7† **Parity, %:** Total: 80 White: 80.8† Asian: 79.3†			**Prevalence of urgency, %:** 34 **Prevalence of frequency, %:** 24% **Prevalence of daily frequency, %:†** Asian: 7.8 White: 13.0 **Prevalence of weekly frequency, %:†** Asian: 10.6 White: 17.8 *P*<.01	

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Hannestad et al., 2000 Rortveit et al., 2003* **Country:** Norway **Study period:** 1995 to 1997 **Funding:** National Health Screening Service of Norway; National Institute of Public Health; Norwegian University of Science and Technology; Research Council of Norway **Author industry relationship disclosures:** NR	**Design:** cross-sectional mailed questionnaire (EPINCONT) **Base population:** Nord-Trøndelag County **Sampling frame:** All female residents of county; All women with vital records linkage* **N sampled:** 47,313 **N screened:** NR **N eligible:^** 34,755 Birth substudy:* 15,307 **N respondents:^** 27,936 Birth substudy:* 15,307 **N included:** 27,936 Birth substudy:* 15,307 **Age, %:** 20-24: 6.7 25-29: 7.6 30-34: 8.9 35-39: 9.7 40-44: 10.5 45-49: 10.7 50-54: 9.9 55-59: 7.3 60-64: 6.6 65-69: 6.6 70-74: 6.4 75-79: 5.1 80-84: 2.7 85-89:1.0 ≥ 90: 0.2	**Inclusion criteria:** • women • age ≥ 20 • community dwelling Birth substudy: • no births, only cesareans, or only vaginal births of singletons* **Exclusion criteria:** NR; Birth substudy:* • more than four children (no women had more than four cesareans) • births prior to 1967 (start of compulsory birth registration) • age ≥ 65 (birth records not consistently accurate) **Effective response, %:** 80.4%	**UUI:** Any loss of urine with sudden and strong urge to go to the toilet **SUI:** Any loss of urine with coughing, sneezing, laughing, lifting, etc. **MUI**: Both UUI and SUI	**Prevalence of UUI, %:**** 2.7 **Prevalence of UUI by age, %:**** 20-24: 1.3 25-29: 1.9 30-34: 1.8 35-39: 1.5 40-44: 1.9 45-49: 2.0 50-54: 2.1 55-59: 2.5 60-64: 2.6 65-69: 4.4 70-74: 4.8 75-79: 6.4 80-84: 7.4 85-89: 8.0 ≥ 90: 4.8 **Prevalence of UUI, by birth type, %:*** None: 1.6 Cesarean: 2.2 Vaginal: 1.8 *P* = NS **Prevalence of MUI, %:**** 8.8 **Prevalence of MUI by age, %:**** 20-24: 3.4 25-29: 4.0 30-34: 4.9 35-39: 6.1 40-44: 6.9 45-49: 7.7 50-54: 10.9 55-59: 10.2 60-64: 12.1 65-69: 70-74: 75-79: 80-84: 85-89: ≥ 90: **Prevalence of MUI, by birth type, %:*** None: 3.1 Cesarean: 5.5 Vaginal: 6.8	Overall quality: Fair Internal validity score: 5, ++ External Validity Score: 3, + Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 80.4 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Hannestad et al., 2000 Rortveit et al., 2003* (continued)	**Age, birth substudy, %:*** 20-24: 12.1 25-29: 13.0 30-34: 14.0 35-39: 15.4 40-44: 16.9 45-49: 16.5 50-54: 8.7 55-59: 2.2 60-64: 1.2 **Race/ethnicity**: NR BMI birth sub-study kg/m^2, %:* < 25.0: 54.2 25.5-29.0: 32.9 ≥ 30: 12.9			***P* vaginal compared to none:*** ***P* < 0.05** ***P* vaginal compared to cesarean:*** ***P* = NS**	

^ Data presented for women only; for each type of incontinence severity increased with age.
** Prevalence is calculated by multiplying the prevalence of incontinence by the reported proportion of each type of incontinence

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Herschorn et al., 2008 **Country:** Canada **Study period:** October 2002 **Funding:** Janssen-Ortho Canada **Author industry relationship disclosures:** 3 of 4 Astellas (1) Gynecare (1) Janssen-Ortho (3) Pfizer (2) Purdue (1) Triton (2)	**Design:** Cross-sectional telephone questionnaire in English or French **Base population:** Representative cross section of Canadian population stratified by age, sex, province, and census division **Sampling frame: Modified random-digit dialing** **N sampled:** NA **N screened:** 2,500 **N eligible:** Total: 1,000 Women: 518 **Age, mean ± SD:^** 44.5 ± 17.2 **Age, %:^** 18-40: 42.8 41-64: 45.8 ≥ 65: 11.4 **Race/ethnicity**: NR	**Inclusion criteria:** • adults • age 18 or older • community dwelling **Exclusion criteria:** • institutionalized men and women **Effective response: NR**	**OAB:** Per ICS **Urgency:** Per ICS Frequency: Per ICS UUI: Per ICS	Prevalence of UUI, %: Total (any): 9.3 ≤ 1x/wk: 5.0 2-3x/wk: 1.4 ~1x/day: 1.0 Several x/day: 0.8 All the time: 0.6 **Prevalence of UUI by age, %: 18-40: 4.6 41-64: 10.7 ≥ 65: 22.4** **Prevalence of OAB, %: 14.7** **Prevalence of OAB by age, %: 18-40: 12.8 41-64: 13.7 ≥ 65: 27.5** **Prevalence of urgency,** %: Total (any): 14.1 ≤ 1x/wk: 4.4 2-3x/wk: 2.9 ~1x/day: 3.7 Several x/day: 2.0 All the time: 1.2 **Prevalence of urgency by age, %: 18-40: 13.3 41-64: 14.2 ≥ 65: 19.0** Prevalence of frequency, %: 14.9 **Prevalence of frequency by age, %: 18-40: 15.1 41-64: 13.3 ≥ 65: 22.4**	Overall quality: Poor Internal validity score: 2, - External Validity Score: 3, + Sampling Method Described: + N sampled provided: - N eligible provided: + N included respondents: - Response Rate:* NR Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

^Data presented for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Herzog et al., 1990 **Country:** US **Study period:** 1983 to 1986* **Funding:** NIH **Author industry relationship disclosures:** NR	**Design:** Baseline with follow-up telephone questionnaire **Base population:** Residents of Washtenaw County **Sampling frame:** Multistage stratified random sample of households **N screened:** Total: 13,912 **N eligible:** Total: 2,968 Women: NR N respondents**:** 1,956 N included:^ Baseline: 1,154 One-Yr: 1,056 Two-Yrs: 776 **Age, %:** NR **Race/ethnicity**: NR	**Inclusion criteria:** • adults • age ≥ 60 **Exclusion criteria:** NR **Effective response, %:** Total: 65.9	UUI: Urine loss preceded by urge to void or uncontrollable voiding with little or no warning SUI: Urine loss at times of exertion such as sneezing, lifting, bending MUI: Both UUI and SUI	**Annual incidence of UUI, %:** **Baseline to Yr1: 1.7** **Yr1 to Yr2: 1.5** **Annual incidence of MUI, %:** **Baseline to Yr1: 9.8** **Yr1 to Yr2: 5.4** **Annual remission of UUI, %:** **Baseline to Yr1: 22.7** **Yr1 to Yr2: 24.0** **Annual remission of MUI, %:** **Baseline to Yr1: 4.8** **Yr1 to Yr2: 8.6** **Baseline prevalence of UUI, %:** **2.8** **Baseline prevalence of MUI, %:** **21.2**	Overall quality: Fair Internal validity score: 5, ++ External Validity Score: 3, + Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 65.9 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

*Baseline was in 1983 and 1984 with one year and two year follow-up from those dates.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Homma et al., 2005 Homma et al., 2006 **Country:** Japan **Study period:** November 2002 to March 2003 **Funding:** NR **Author industry relationship disclosures:** None	**Design:** Cross-sectional mailed questionnaire **Base population:** Population of Japan age ≥ 40 **Sampling frame:** Two-stage random sample of households **N sampled:** 10,096 **N screened:** NA **N returned:** 4,605 **N participants:** Total: 4,570 Women: 2,380 **Age, mean (range):^** 61 (41,100) **Race/ethnicity:** NR	**Inclusion criteria:** • adults • age ≥ 40 **Exclusion criteria:** NR **Effective response, %:** Total: 45 Women: NR	**OAB:** ≥8 voids per day and ≥1 episode of urgency/week **UUI:** ICS definition **Frequency:** ≥ 8 voids per day **Frequency:** ≥ 11 voids per day **Urgency:** ICS definition per day or week	**Prevalence of UUI , %:** 7 **Prevalence of OAB, %:** 11 **Prevalence of UUI and OAB by age:** Prevalence of both types increase with age. *P*=NS **Prevalence of urgency ≥ 1/day, %:** 7 **Prevalence of urgency ≥ 1/wk, %:** 13 **Prevalence of frequency ≥ 8/day, %:** 49 **Prevalence of frequency ≥ 11/day, %:** 10	Overall quality: Fair Internal validity score: 4, + External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 45 Inclusion (Exclusion) Specified: + Age of population described: Operational definition provided*: + Required frequency defined*: +

^Data presented for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Hording et al., 1986 **Country:** Denmark **Study period:** April 1981 to July 1982 **Funding:** The Legacy of Emmy Lange, née Kramp, Rahbek Foundation **Author industry relationship disclosures:** NR	**Design:** Cross-sectional administered questionnaire **Base population:** Female residents of the Glostrup area of Copenhagen county born in 1936 **Sampling frame:** All women born in 1936 and living in the Glostrup area **N sampled:** 613 **N screened:** NR **N respondents:** 528 **N included:** 515 **Age:** 45 **Race/ethnicity:** NR **Parity, %:** 93	**Inclusion criteria:** • Women • Age 45 **Exclusion criteria:** NR **Effective response, %:** 85	**UUI:** Involuntary loss of urine following a pathologically strong desire to void **SUI:** Urine loss accompanying coughing, laughing, sneezing, running, or jumping with a full bladder or during sexual intercourse **MUI:** Mixture of UUI and SUI	**Prevalence of UUI, %:** 5.4 **Prevalence of MUI, %:** 3.1	Overall quality: Fair Internal validity score: 4, + External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: 1 N eligible provided: +-N included respondents: + Response Rate:* 85 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: Required frequency defined*: -

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Hsieh et al., 2006 **Country:** Taiwan **Study period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cross-sectional administered questionnaire **Base population:** Female residents of Taiwan **Sampling frame:** Three stage random sample: township, block, individual to obtain nationally representative sample **N sampled:** NR **N screened:** NR **N eligible:** 4,546 **N respondents:** 3,537 **N included:** 3,519 **Age, %:** 20-29: 27.1 30-39: 29.8 40-49: 26.5 50-59: 16.6 **Race/ethnicity:** NR	**Inclusion criteria:** • women • age 20 to 59 **Exclusion criteria:** NR **Effective response, %:** 77.4	**Frequency:** "void too often during the day"	**Prevalence of frequency, %:** 5.2 **Prevalence of frequency, voids per day, %:** 8-15: 2.4 16-23: 1.9 24-31: 0.05 ≥ 32: 0.7 **Prevalence of frequency by age, %:** 20-29: 4.7 30-39: 5.8 40-49: 5.2 50-59: 5.9 *P* = 0.33	Overall quality: Poor Internal validity score: 4, + External Validity Score: 2, - Sampling Method Described: + N sampled provided: - N eligible provided: + N included respondents: + Response Rate:* 77.4 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: - Required frequency defined*: -

3537 was described by authors as 77.8% response rate. Therefore 'N" whom they considered eligible would be 4546, so effective response rate is 3519/4546 = 77.4%

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Iosif and Bekassy, 1984 **Country:** Sweden **Study period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cross-sectional mailed questionnaire **Base population:** Malmöhus County, Sweden **Sampling frame:** Approximately 3,000 female residents born in 1921 **N sampled:** 1,200 **N screened:** NA **N eligible:** NA **N respondents:** 902 **Age:** NR **Race/ethnicity:** NR	**Inclusion criteria:** • women • born in 1921 **Exclusion criteria:** NR **Effective response, %:** 75	**UUI:** "do you usually get such a very strong urge that you cannot hold back until you reach a toilet?" **MUI:** Combination of urge and stress ("involuntary loss of urine when cough, laugh," etc) incontinence	**Prevalence UUI, %:** 8.0 **Prevalence MUI, %:** 9.5	Overall quality: Fair Internal validity score: 4, + External Validity Score: 2 - Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 75 Inclusion (Exclusion) Specified: + Age of population described: - Operational definition provided*: + Required frequency defined*: -

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Irwin et al., 2006 **Country:** Canada, Germany, Italy, Sweden, UK **Study period:** April 2005 to December 2005 **Funding:** Pfizer **Author industry relationship disclosures:** 10 of 11 Astellas (5) Bayer (1) Boehringer-Ingelheim (1) Diagnostic Ultrasound (1) Ferring (1) Janssen-Ortho (1) Lilly (2) Novartis (3) Paladin (1) Pfizer (10) Plethora (1) Schwarz-Pharma (1) Tena (1) UCB (1) Yamanouchi (1)	**Design:** Cross-sectional telephone questionnaire (EPIC) **Base population:** Residents of Canada, Germany, Italy, Sweden, UK **Sampling frame:** Two-step random sampling of households and individuals via residential telephone **N screened:** 58,139 **N eligible:** NR **N respondents:** 19,165 **N included:** Total: 19,165 Women: NR **Age, %:^** 18-29: 13.6 30-34: 7.5 35-39: 10.2 40-44: 11.7 45-49: 10.5 50-54: 9.7 55-59: 9.2 60-64: 7.0 ≥ 70: 12.5 **Race/ethnicity, %:** White: 95.6	**Inclusion criteria:** • adults • age ≥ 18 • most recent birthday in household **Exclusion criteria:** NR **Effective response, %:** 33	**Urgency:** Per ICS 2002 **Frequency:** Per ICS 2002 **UUI:** Per ICS 2002 **MUI:** Per ICS 2002	**Prevalence of UUI, % (95% CI):** 1.5 (1.2, 1.7) **Prevalence of UUI by age, % (95% CI):** ≤ 39: 1.0 (0.6, 1.3) 40-59: 1.1 (0.7, 1.5) ≥ 60: 2.5 (1.9, 3.0) **Prevalence of MUI, % (95% CI):** 2.4 (2.1, 2.7) **Prevalence of MUI by age, % (95% CI):** ≤ 39: 1.0 (0.6, 1.3) 40-59: 2.4 (1.9, 3.0) ≥ 60: 4.1 (3.4, 4.8) **Prevalence of urgency, % (95% CI):** 12.8 (12.2, 13.5) **Prevalence of urgency by age, % (95% CI):** ≤ 39: 9.7 (8.8, 10.7) 40-59: 11.2 (10.1, 12.3) ≥ 60: 18.3 (16.9, 19.6) **Prevalence of frequency, % (95% CI):** 7.4 (6.9, 7.9) **Prevalence of frequency by age, % (95% CI):** ≤ 39: 7.9 (7.0, 8.8) 40-59: 5.8 (5.0, 6.6) ≥ 60: 8.4 (7.5, 9.4)	Overall quality: Fair Internal validity score: 4, + External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 33 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: - Required frequency defined*: -

^Data presented for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Ju, et al. 1991 **Country:** Singapore **Study period:** July 1989 to November 1989 **Funding:** National University of Singapore **Author industry relationship disclosures:** NR	**Design:** Cross-sectional administered questionnaire, with follow-up interview if incontinent **Base population:** Elderly residents of a postal district in Telok Blangah Housing Estate **Sampling frame:** All elderly people in Ministry of Home Affairs registry for study district **N sampled:** 1,511 **N eligible:** 1,143 **N respondents:** 919 **N included:** Total: 919 Women: 484 **Age:** NR by gender **Race/ethnicity:** NR by gender	**Inclusion criteria:** • Adults • Age ≥ 65 **Exclusion criteria:** NR **Effective response, %:** 80.4	**Incontinence:** Leakage of urine two or more times in the past month **UUI:** Urine loss because of inability to delay voiding following an urge to micturition **SUI:** Urine loss associated with increases in intra-abdominal pressure (physical exertion, straining, coughing, or laughing) **MUI:** NR	**Prevalence of UUI, %:** 3.3 **Prevalence of UUI, %:** 0.8	Overall quality: Fair Internal validity score: 4, + External Validity Score: 4,++ Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 82 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

^Data presented is for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Kay et al., 1999 **Country:** Denmark **Study period:** NR **Funding:** Gammelgårds Grant, Synthélabo Scandinavia **Author industry relationship disclosures:** NR	**Design:** Cross-sectional mailed questionnaire (DAN-PPS) **Base population:** Population of Herlev municipality **Sampling frame:** Gender and age stratified random sample of adults in age range **N sampled:** Total: 500 Women: 250 **N screened:** NA **N eligible:** NR **N respondents:** All: 368 Women: 158 **Age, n:^** 40-49: 33 50-59: 40 60-69: 28 70-79: 36 80-89: 21 **Age, mean:^** 62.5 **Age, median (range):^** 61 (41, 89) **Race/ethnicity:** NR	**Inclusion criteria:** • adults • age 40 to 89 **Exclusion criteria:** NR **Effective response, %:** All: 74 Women: 63	All measures are for two week window **UUI:** NR **Urgency:** NR **Frequency:** NR	**Prevalence of UUI, % (95% CI):** 25.3 (18.9, 33.0) **Prevalence of urgency, % (95% CI):** 67.1 (59.1, 74.2) **Prevalence of frequency, % (95% CI):** 42.2 (34.7, 50.5)	Overall quality: Fair Internal validity score: 4, + External Validity Score: 3,+ Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 63 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: - Required frequency defined*: +

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Kim et al., 2006 **Country:** US **Study period:** 2000 **Funding:** Pfizer **Author industry relationship disclosures:** 5 of 5 Pfizer (5)	**Design:** Database linkage study **Base population:** US population **Sampling frame:** National Ambulatory Medical Care Survey, National Hospital Ambulatory Medical Care Survey, National Hospital Discharge Survey data for 2000 **N sampled:** NR **N screened:** NR **N eligible:** NR **N respondents:** NR **N included:** NR **Age:** NR	**Inclusion criteria:** • adults • age ≥ 18 • first three coded diagnoses per care episode **Exclusion criteria:** NR **Effective response:** NA	**OAB visits:** ICD-9: 788.31, 788.41 and 788.33 **Frequency:** coded indication for visit. **Urge incontinence**: Coded indication for visit. **Prevalence:** expressed as number of adults with visit type per 10,000 adult population weighted for gender based on 2000 census.	**National annual OAB visits:** 1.4 million (1.1, 1.8) **Prevalence of visits for UUI:** 16 per 10,000 adults **Prevalence of visits for MUI:** 5 per 10,000 adults **Prevalence of visits for any OAB symptom:** Women: 81/10,000 Men: 56/10,000 **Prevalence of visits for frequency:** 48 per 10,000 adults	Overall quality: Fair Internal validity score: (+) External Validity Score: 2, - Sampling Method Described: + N sampled provided: NA N eligible provided: NA N included respondents: NA Response Rate:* NA Inclusion (Exclusion) Specified: + Age of population described: - Operational definition provided*: + Required frequency defined*: -

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Koyama et al., 1998 **Country:** Japan **Study period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cross-sectional mailed questionnaire **Base population:** Residents of the selected farming village or suburban town **Sampling frame:** Distribution to all residents, 970 in village; 1,508 in suburb **N sampled:** Village: 970 Suburb: 1,508 **N screened:** NA **N eligible:** NA **N respondents:** Village: 937 Suburb: 934 Women: 1,120 **Age, %:** 60-69*: 31.7 70-79: 47.9 ≥ 80: 20.4 **Race/ethnicity:** NR	**Inclusion criteria:** • adults • age > 65 • community dwelling **Exclusion criteria:** NR **Effective response, %:** Village: 98.4 Suburb: 65.0	**Incontinence:** "even a small amount of urinary leakage at a time when there was no intention of urinating." **UUI:** Not specified, however "urgency" subtype presented	**Prevalence of UUI, %:** Women: 5.3**	Overall quality: Poor Internal validity score: 4, + External Validity Score: 2, - Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* >65 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: - Required frequency defined*: -

*Age range as presented "60-69" however, inclusion says all participants >65 years old?!
**Denominator for total community dwelling in Table 1 = 1120 women, Table 3 = 59 with urgency as "nature of urinary incontinence"
^Data presented for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Kuh et al., 1999 **Country:** UK **Study period:** 1993 to 1994 **Funding:** Medical Research Council **Author industry relationship disclosures:** None	**Design:** Cross-sectional mailed questionnaire **Base population:** Women in the UK **Sampling frame:** Members of the Medical Research Council National Survey of Health and Development a nationally representative birth cohort begun in March 1946 **N sampled:** 1,486 **N screened:** NR **N eligible:** 1,486 **N respondents:** 1,378 **N included:** 1,333 **Age, %:** 48: 100% **Race/ethnicity:** NR **BMI kg/m^2, %:** < 20: 7.2 20.1-25.0: 55.9 25.1-30.0: 25.0 > 30.0: 12.0 **Vaginally parous, %:** 81.7	**Inclusion criteria:** • women • born in March 1946 • members of cohort **Exclusion criteria:** NR **Effective response, %:** 89.7	**UUI**: Urgent and strong desire to pass urine which is difficult to control and ever any loss of urine before getting to toilet **SUI**: Loss of urine when you cough, sneeze, laugh, run, or exercise **MUI**: Both UUI and SUI	**Prevalence of UUI, %:** 22 **Prevalence of MUI, %:** 20	Overall quality: Fair Internal validity score: 5, ++ External Validity Score: 3, + Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 89.7 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Lara and Nacey, 1994 **Country:** New Zealand **Study period:** NR **Funding:** Wellington Medical Research Foundation **Author industry relationship disclosures:** NR	**Design:** Cross-sectional mailed questionnaire **Base population:** Female residents of three areas of central Wellington **Sampling frame:** Random sample of the electoral roll **N sampled:** 1,028 **N screened:** NA **N eligible:** NA **N respondents:** 556 **Age, mean (range):** Maoris: 39.1 (18, 95) Pacific Islanders: 34.9 (18, 79) Europeans: 47 (18, 90) **Race/ethnicity, %:** Maoris: 25.7 Pacific Islanders: 21.9 Europeans: 52.3	**Inclusion criteria:** • women on electoral roll **Exclusion criteria:** NR **Effective response, %:** 54	**Incontinence definition:** "any involuntary loss of urine" **UUI:** "sudden involuntary loss" **MUI:** Elements of UUI and stress ("loss with increased intraabdominal pressure")	**Prevalence of UUI, %:** 9.2 **Prevalence of MUI, %:** 7.4	Overall quality: Fair Internal validity score: 4, + External Validity Score: 2, - Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 54 Inclusion (Exclusion) Specified: - Age of population described: + Operational definition provided*: + Required frequency defined*: -

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Link et al., 2007 Hall et al., 2008 **Country:** US **Study period:** 2002 to 2005 **Funding:** NIH **Author industry relationship disclosures:** NR	**Design:** Cross-sectional administered questionnaire **Base population:** Residents of 16/17 Boston residential planning districts* **Sampling frame:** Two-stage random sample stratified to achieve gender and race/ethnicity representation **N screened:** 24,063 households* 9,066 individuals* **N eligible:** 8,702* **N respondents:** 5,506* **N included:** Total: 5,506 Women: 3,205* **Age, %:^** 30-39: 24.7* 40-49: 26.2* 50-59: 24.3* 60-79: 24.7* **Race/ethnicity, n (%):^** Black: 1,070* (33.4) White: 1,024* (32.0) Hispanic: 1,111* (34.7)	**Inclusion criteria:** • adults • age 30 to 79 • community dwelling **Exclusion criteria:** NR **Effective response, %**: 57.3*	**Frequency:** Needed to urinate again < 2hrs after urinating (fairly often, usually, almost always) and/or frequent urination during the day (fairly often, usually, almost always) and/or on average 8 or more urinations per day **Urgency:** Difficulty postponing urination (fairly often, usually, almost always) and/or strong urge or pressure to urinate immediately with little or no warning (fairly often, usually, almost always) and/or strong urge to urinate immediately whether or not they urinated or leaked urine (several times, many times per day) † **Cluster analysis groupings:** Four symptomatic clusters emerged which cannot be readily mapped to clinically useful tool/descriptors.	**Prevalence of urgency, %:** 14.2 **Prevalence of frequency, %:** 36.9	Overall quality: Fair Internal validity score: 5, ++ External Validity Score: 3, + Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 57.3 Inclusion (Exclusion) Specified: + Age of population described:+ Operational definition provided*: + Required frequency defined*: -

^Data presented for women only.
† Groupings may have etiologic or other research utility see publication for details.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Liu and Andrews, 2002 **Country:** Australia **Study period:** 1992 to 1994 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Repeated measures telephone questionnaire **Base population:** Residents of Southern Australia **Sampling frame:** Random sample, stratified by age from the State Electoral Data Base for South Australia **N sampled:** 4,184* **N screened:** NR **N eligible:** 2,272 **N respondents:** 2,087 **N included:** 2,087 **Age:** "sample size of more than 190 in each gender and age group [70-74, 75-79,80-84,≥85]" **Race/ethnicity:** NR	**Inclusion criteria:** • adults • age ≥ 70 **Exclusion criteria:** NR **Effective response, %:** 49.9	**UUI**: NR, "at least occasionally" **SUI**: NR, "at least occasionally" **Mixed:** Both UUI and SUI, "at least occasionally"	**Annual Incidence of UUI, %:** 22.6 **Two-Year Incidence of UUI, %:** 37.5 **Prevalence of UUI by year, %:**** Yr 1: 18.2 Yr 2: 16.1 Yr 3: 21.2 **Prevalence of MUI by year, %:**** Yr 1: 23.2 Yr 2: 26.5 Yr 3: 26.8	Overall quality: Fair Internal validity score: 4, + External Validity Score: 2, - Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 49.9 Inclusion (Exclusion) Specified: + Age of population described:- Operational definition provided*: + Required frequency defined*: -

^Data presented for women only.
* Study also included 151 individuals identified within households sampled
** Prevalence for UUI and MUI is calculated by multiplying the prevalence of the combined UUI and MUI (reported in Table 1) by the relevant proportions from Table 3, e.g. 41.4 * 0.384/(0.384+0.495)=18.2

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Lukacz et al., 2006 Lawrence et al., 2007^ Lawrence et al., 2008† **Country:** US **Study period:** April 2004 to January 2005 **Funding:** NIH NIH; Kaiser Permanente Direct Community Benefit Funds^† **Author industry relationship disclosures:** † 2 of 5 Astellas (1) Novartis (1) Pfizer (2) Watson (1)	**Design:** Cross-sectional mailed questionnaire (EPIQ*) **Base population:** Kaiser Permanente Southern California members **Sampling frame:** Age-stratified random sample of 950,000 female members in age range in April 2004 **N sampled:** 12,200 **N eligible:** 12,200 **N respondents:** 4,458 **N included:** 4,103 3,962^ **Age, mean ± SD:** 56.5 ± 15.8 56.6 ± 15.8^ **Race/ethnicity, %:** White: 61.0 Hispanic: 19.4 Black: 9.7 Asian/Pacific: 7.9 Other: 2.1 **Race/ethnicity, %:^** White: 61.7 Hispanic: 19.2 Black: 9.6 Asian/Pacific: 8.2 Other/unknown: 1.3 **BMI, mean ± SD:** 27.4 ± 6.3 27.8 ± 6.2^ **Parity, %:** 80.8	**Inclusion criteria:** • women • age 25 to 84 • address on record with HMO **Exclusion criteria:** • insufficient data to categorize **Effective response, %:** 33.6 32.5^	**OAB:** Per EPIQ* **OAB-any:** Includes urgency and frequency, with or without incontinence **OAB-wet:** Includes urgency and frequency, with incontinence **SUI:** Per EPIQ*	**Prevalence of OAB-any, % (95% CI):** 13.3 (12.2, 14.4) **Prevalence of OAB-any by age, %:†** 25-39: 5.9 40-54: 10.9 55-69:14.8 70-84: 19.0 *P*<0.01 **Prevalence of OAB, %:^** All: 13.4 Nondiabetic: 12.5 Diabetic: 21.4 *P*<0.0001 for diabetic vs. non **Prevalence of OAB by parity, % (95% CI):** Nulliparous: 9 (7, 11) Cesarean: 9 (7, 13) Vaginal: 15 (14, 16) *P*<0.05 both comparisons to vaginal **Prevalence of OAB-wet, % (95% CI):** † 12.7 (11.7, 13.9) **Prevalence of mixed OAB-wet and SUI, % (95% CI):** † 8.3 (7.5, 9.2)	Overall quality: Fair Internal validity score: 5, ++ External Validity Score: 3, + Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 34 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Lukacz et al., 2006 Lawrence et al., 2007^ Lawrence et al., 2008† (continued)	**Vaginally Parous, %:^** 71.6				

**12,200 mailed, 4458 returned, 3962 evaluable = effective response of 3962/12,200 = 32.5%

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: MacDiarmid and Rosenberg, 2005 **Country:** US **Study period:** September 2004 **Funding:** Ortho-McNeil **Author industry relationship disclosures:** 2 of 2 GlaxoSmithKline (1) Lilly (1) Novartis (1) Odyssey (1) Ortho-McNeil (2) Pfizer (2) Reliant (1) Watson (1) Yamanouchi (1)	**Design:** E-mailed invitation to online questionnaire **Base population:** Adult members of a multi-million-member online panel **Sampling frame:** Random electronic mailing **N eligible:** 2,951 **N respondents:** 2,951 **Age:** NR for total N **Race/ethnicity:** NR for total N **BMI:** NR for total N **Parity:** NR for total N	**Inclusion criteria:** • women • age ≥ 30 **Exclusion criteria:** NR **Effective response**: NR	**UUI:** ICS definition **MUI:** ICS definition	**Prevalence of UUI, %:** 9.2* **Prevalence of MUI, %:** 13.2*	Overall quality: Poor Internal validity score: 2, - External Validity Score: 2, - Sampling Method Described: + N sampled provided: - N eligible provided: + N included respondents: + Response Rate:* NR Inclusion (Exclusion) Specified: + Age of population described: - Operational definition provided*: + Required frequency defined*: -

*Calculated from reported frequencies: 271/2,951 and 389/2,951

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: McGrother et al., 2006^ Donaldson et al., 2006* **Country:** UK **Study period:** Baseline questionnaires mailed in 1998* **Funding:** Medical Research Council **Author industry relationship disclosures:** None	**Design:** Repeated measures mailed questionnaires at baseline and 1, 2*, and 3*-year follow-up **Base population:** Leicestershire Health Authority (108 general practices) **Sampling frame:** Random sample from 20,247 women on registers at baseline **N eligible:** 19,241 **N respondents:** Baseline: 12,750 Follow-up: NR Year 1: NR Year 2: NR Year 3: NR **Age, mean ± SD:** 59.5 ± 13.0* **Race/ethnicity, %:** White: 85.5* **BMI kg/m^2, %:^** < 20: 3.2 > 20-25: 38.7 > 25-30: 38.6 > 30: 19.5 **Parity, %:** 87.2*	**Inclusion criteria:** • women • age ≥ 40 • community dwelling **Exclusion criteria:** NR^; • very elderly people in residential care;* **Effective Response, %:** Baseline: 65.3 Follow-up: 79.7^ Year 1: 76.4* Year 2: 71.2* Year 3: 67.0*	**OAB:** "a strong desire to pass urine resulting in leakage *or* urgency occurring monthly or more." (exclusive of SUI)^ Very strong or overwhelming urgency and UUI several times a month or more* **UUI:** strong desire to pass urine resulting in leakage before reaching toilet (exclusive of SUI) **MUI:^** Not explicitly defined	**Annual incidence of MUI, %:^** 4.5 **Annual incidence of OAB, %:^** 5.4 **Year 1 Incidence of OAB, %:*** 6.9 **Year 1 Incidence OAB by age, %:*** 40-49: 6.7 50-59: 6.5 60-69: 7.0 70-79: 6.9 80+: 9.5 **Year 1 Remission of OAB, %:*** 38.8 **Year 1 Remission OAB by age, %:*** 40-49: 36.3 50-59: 32.9 60-69: 45.4 70-79: 39.7 80+: 45.9 **Year 2 Incidence of OAB, %:*** 6.0 **Year 2 Remission of OAB, %:*** 38.9 **Year 3 Incidence of OAB, %:*** 6.8 **Year 3 Remission of OAB, %:*** 36.9 **Baseline prevalence of MUI, %:^** 12.7 **Baseline prevalence of OAB, %:^** 7.7	Overall quality: Fair Internal validity score: 4, + External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: - Response Rate:* + Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: +

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
McGrother et al., 2006^ Donaldson et al., 2006* (continued)				**Baseline prevalence of OAB by age, %:*** 40-49: 11.4 50-59: 14.060-69: 12.5 70-79: 12.1 80+: 15.5	

Prevalence, year 1 incidence and remission are reported by age in Table 2 on page 712; urgency is defined in Table 1, but the threshold is only given for “When you need to pass urine, how strong is the urge usually?”

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Milsom et al., 2001 **Country:** France, Germany, Italy, Spain, Sweden, UK **Study period:** NR **Funding:** Pharmacia Corporation **Author industry relationship disclosures:** NR	**Design:** Cross-sectional telephone questionnaire, except Spain where in-person interviews were done **Base population:** Residents of France, Germany, Italy, Spain, Sweden, UK **Sampling frame:** Stratified random sample to obtain nationally representative respondents from telephone listings (or voter roles in Spain) **N sampled:** NR **N screened:** NR **N eligible:** NR **N respondents:** Total: 16,776 Women: 9,728 **Age, %:** 40-44: 17.4 45-49: 14.8 50-54: 13.2 55-59: 12.2 60-64: 11.1 65-69: 10.9 70-74: 8.9 ≥ 75: 11.5 **Race/ethnicity:** NR	**Inclusion criteria:** • adults • age ≥ 40 **Exclusion criteria:** • voiding symptoms suggestive of stress incontinence, prostatic obstruction, or urinary tract infection **Effective response:** NR	**Frequency:** > 8 voids/day **Urgency:** "Strong urge to go to toilet with no advance warning; have to hurry to toilet in time to urinate, have to keep running to toilet to urinate" **UUI:** "unable to get to bathroom in time; have wetting accidents at night when asleep; sudden and uncontrolled loss of urine; leak urine during the day without being able to control it" **OAB:** Frequency, urgency, and urge urinary incontinence alone or in any combination	**Prevalence of OAB, %:** 17.4 **Prevalence of OAB by age, %:** 40-44: 8.7 45-49: 10.6 50-54: 11.9 55-59: 16.9 60-64: 16.9 65-69: 17.5 70-74: 22.1 75+: 31.3	Overall quality: Poor Internal validity score: 2, - External Validity Score: 3, + Sampling Method Described: + N sampled provided: - N eligible provided: - N included respondents: + Response Rate:* NR Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

^Data presented for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Møller et al., 2000 **Country:** Denmark **Study period:** June 1996 **Funding:** Coloplast A/S Pharmacia A/S Four Danish foundations **Author industry relationship disclosures:** NR	**Design:** Cross sectional mailed questionnaire **Base population:** Residents of Denmark **Sampling frame:** Random sampling of Danish Civil Registry System in age and urban vs. rural strata **N screened:** 4,000 **N eligible:** NR **N respondents:** 3,204 **N included:** 2,860 **Age, %:** 40: 21.5 45: 20.3 50: 20.0 55: 19.2 60: 18.9 **Race/ethnicity:** NR	**Inclusion criteria:** • women • age 40, 45, 50, 55, or 60 **Exclusion criteria:** NR **Effective response, %:** 71.7	**UUI:** Do you leak urine if suddenly you need to void? **Urgency:** Do you rush to the toilet because of a sudden desire to void? **Daytime frequency:** Number of episodes exceeds 10 voids daily.*	**Prevalence UUI, weekly or more, %:** 7.2 (95% CI : 6.2,8.2) **Prevalence of urgency, weekly or more, %:** 7.1 (95% CI: 6.1,8.1) **Prevalence of daytime frequency, %:** 3.6 (95% CI: 2.9,4.3)	Overall quality: Fair Internal validity score: 4, + External Validity Score: 3, + Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 71.7 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: Required frequency defined*: -

^Data presented for women only.
*More than 10 voids per day is categorized as “often” (and reported in Table III).

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Muller, 2005 **Country:** US **Study period:** October 2000 to December 2000 **Funding:** Pfizer **Author industry relationship disclosures:** NR	**Design:** Cross sectional administered questionnaire (NS) **Base population:** US population **Sampling frame:** Unspecified sampling of shoppers in retail malls of 20 major urban areas **N sampled:** NR **N screened:** NR **N eligible:** NR **N respondents:** NR **N included:** Total: 1,001 Women: NR **Age:** NR **Race/ethnicity:** NR	**Inclusion criteria:** • adults • age 30 to 70 • community dwelling **Exclusion criteria:** NR **Effective response:** NR	**Definitions:** NR	**Prevalence of "sudden urge to urinate", %:** 13 **Prevalence of "both urge and leakage", %:** 22	Overall quality: Poor Internal validity score: 1, - External Validity Score: 1,- Sampling Method Described:+ N sampled provided: - N eligible provided: - N included respondents: - Response Rate:* NR Inclusion (Exclusion) Specified: + Age of population described: - Operational definition provided*: - Required frequency defined*: - -

Note: This is a report from the Executive Director of The National Association for Continence presenting for academic audiences consumer research done as part of pre- or post-marketing research by for profit entities. The Association assisted with formation and scope of questions included in the questionnaire.
^Data presented for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Nuotio et al., 2002 **Country:** Finland **Study period:** 1979 to 1989 **Funding:** Medical Research Fund of Tampere University Hospital, the Academy of Finland, and the Uulo Arhio Foundation **Author industry relationship disclosures:** NR	**Design:** Cross-sectional administered questionnaire with similar follow-up questionnaire 10 years later **Base population:** Elderly residents of Tampere, Finland **Sampling frame:** Age and gender stratified random sample; part of the European Longitudinal Study on Aging (ELSA) **N sampled:** 1,494 **N screened:** NR **N eligible:** Baseline: 1,309 Follow-up: 518 **N included:** Total: 1,052 Women: 528 Follow-up: 435 Women: 260 **Age, mean:^** 73.2 **Race/ethnicity:** NR	**Inclusion criteria:** • Adults • Age ≥ 60 **Exclusion criteria:** NR **Effective response, %:** Baseline: 82 Follow-up: 84	**Urgency:** "Do you ever have trouble getting to the lavatory in time?" **UUI:** Urgency and urinary leakage, regardless of the frequency of urine loss	**Prevalence of urgency, %:** 8 **Prevalence of UUI, %:** 6	Overall quality: Fair Internal validity score: 4, + External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 82 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*:

^Data presented is for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Nygaard and Lemke, 1996 **Country:** US **Study period:** 1981 to 1988 **Funding:** NIH **Author industry relationship disclosures:** NR	**Design:** Repeated measures, in-person interviews **Base population:** Residents of two counties in rural Iowa **Sampling frame:** Age stratified random sample of women with address on record **N sampled:** NR **N screened:** NA **N eligible:** NR **N respondents:** 2025 **Age, %:** 65-69: 25.6 70-74: 25.9 75-79: 23.0 80-84: 15.9 85-89: 7.5 ≥ 90: 2.1 **Race/ethnicity, %:** Non-Hispanic white: 61.7 Hispanic: 19.2 Black: 9.6 Asian-Pacific Islander: 8.2 Other/unknown: 1.3 **BMI, mean:** 25.4	**Inclusion criteria:** • women • age ≥ 65 • living in community **Exclusion criteria:** NR **Effective response, %:** 80	**UUI:** "How often do you have difficulty holding your urine until you can get to a toilet?" For prevalence, incidence, and remission never and hardly ever = negative response	**3-year incidence of UUI (first follow-up), %:** 20.4 **3-year remission of UUI (first follow-up), %:** 31.7 **3-year incidence of UUI (second follow-up), %:** 24.0* **3-year remission of UUI (second follow-up), %:** 34.9* **Baseline prevalence of UUI, %:** Total ever: 55 Positive response: 36.3 **Baseline prevalence of UUI by how often, %:** Hardly ever: 18.6 Some of the time: 27.8 Most of the time: 6.7 All of the time: 1.6	Overall quality: Fair Internal validity score: 3, + External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: - N eligible provided: - N included respondents: + Response Rate:* 80 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: +

*3-year incidence and remission in the second follow-up are calculated from those women without UUI at baseline. Effective response rate is reported on page 1050, but the number sampled is not reported.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Odeyemi et al., 2006 **Country:** UK **Study period:** 1987 to 2004 **Funding:** Allergan **Author industry relationship disclosures:** 1 of 6: Allergan (1)	**Design:** Healthcare database **Base population:** Residents of the UK receiving care in one of 350 general practices selected to be representative of the National Health Service **Sampling frame:** General Practice Research Database (4.6% representative sample with longitudinal data) **N sampled:** NR **N screened:** NA **N eligible:** 68,910 **Age:** NR for total N **Race/ethnicity:** NR for total N	**Inclusion criteria:** • adults • in GPRD sample **Exclusion criteria:** UTI within two weeks before or after visit meeting OAB criteria, renal dysfunction, diuretics use **Effective response:** NR	**OAB-related symptoms:** Oxford Medical Index System and Read Clinical Classification codes for urgency, frequency, urge, urgency incontinence, nocturia, unstable bladder or irritable bladder	**Annual incidence of OAB-related symptoms (95% CI):** 2.60/1,000 (2.57, 2.63) **Prevalence of OAB-related symptoms:** 3.64/1,000	Overall quality: Fair Internal validity score: (+) External Validity Score: 2, - Sampling Method Described: + N sampled provided: NA N eligible provided: NA N included respondents: NA Response Rate:* NA Inclusion (Exclusion) Specified: + Age of population described: - Operational definition provided*: + Required frequency defined*: -

^Data presented for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Perry et al., 2000 **Country:** UK **Study period:** October 1996 to June 1997 **Funding:** Medical Research Council **Author industry relationship disclosures:** NR	**Design:** Cross-sectional mailed questionnaire **Base population:** Patients registered in any of 108 general practices in Leicestershire **Sampling frame:** Random sample Leicestershire Health Authority registry **N sampled:** 15,904 **N screened:** NR **N eligible:** Total: 14,600 Women: 7,659 **N respondents:** Total: 10,226 Women: NR **N included:** Total: 10,116 Women: 5,544 **Age, %:^** 40-49: 25.1 50-59: 24.8 60-69: 21.8 70-79: 17.9 ≥ 80: 10.4 **Race/ethnicity:** NR	**Inclusion criteria:** • adults • age ≥ 40 • community dwelling **Exclusion criteria:** NR **Effective response, %:^** 72.4	**Incontinence:** Loss of urine several times a month or more **Urgency:** Experienced an overwhelming urge to pass urine or had difficulty holding urine most of the time or overwhelming **Frequency:** Voiding hourly or more often	**Prevalence of urgency, %:** 8.8 **Prevalence of frequency, %:** 9.1	Overall quality: Good Internal validity score: 5, ++ External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 72.4 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: +

^Data presented is for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Rohr et al., 2004 **Country:** Denmark **Study period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cross-sectional telephone questionnaire **Base population:** Female residents of central Odense **Sampling frame:** Central Person Register listing of residents in postal district 5000 **N sampled:** 498 **N screened:** 498 **N eligible:** 421 **N respondents:** 223 **N included:** 223 **Age, median (range):** 82 (75, 96) **Race/ethnicity:** NR	**Inclusion criteria:** • women • age ≥ 70 **Exclusion criteria:** • need for proxy respondent **Effective response, %:** 53	**UUI**: Such a strong urge that it was impossible to get to the toilet in time **SUI**: Involuntary loss of urine in connection with physical exertion in the past month **MUI**: Both UUI and SUI	**Prevalence of UUI, % (95% CI):** 16 (10.9, 20.5) **Prevalence of MUI, % (95% CI):** 13 (8.2, 16.9)	Overall quality: Good Internal validity score: 5, ++ External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 53 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: +

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Schulman et al., 1997 **Country:** Belgium **Study period:** November 1994 to February 1995 **Funding:** NR **Author industry relationship disclosures:** 1 of 3 Marrion Merrell Dow (1)	**Design:** Cross sectional written questionnaire in home **Base population:** Residents of Belgium **Sampling frame:** Two stage, random sampling, stratified by region, gender, age, and profession for nationally representative sample. **N screened:** 8,000 **N eligible:** NR **N respondents:** 5,920 **N included:** Total: 5,269 Women: 2,770 **Age, %:** 30-34: 13.3 35-49: 34.0 50-64: 28.0 ≥ 65: 24.7 **Race/ethnicity:** NR	**Inclusion criteria:** • adults • age 30 and older • community dwelling **Exclusion criteria:** NR **Effective response, %:** NR	**UUI:** Arriving too late at the toilet	**Prevalence of UUI, %:** 2.7	Overall quality: Poor Internal validity score: 3, - External Validity Score: 2, - Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* NR Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: - Required frequency defined*: -

^Data presented for women only.
The total number of UUI cases is 0.026*5,269=137, of which 55% (see page 317) are women. The prevalence of UUI can then be calculated as 137*0.55/2,770=75/2,770=2.7%

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Shakhatreh, 2005 **Country:** Jordan **Study period:** July 2003 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cross-sectional administered questionnaire **Base population:** Female residents of Southern Jordan in this age group **Sampling frame:** 68 census blocks selected from among 228 to achieve representative sample; household and then individuals randomly selected within blocks **N sampled:** Households: 810 **N screened:** NR **N eligible:** Women: 190* **N respondents:** 182 **N included:** 182 **Age, %:** 50-54: 38.9 55-59: 23.9 60-65: 37.2 **Race/ethnicity:** NR **BMI kg/m^2, %:** 18.5-24: 20 25-29: 32 ≥ 30: 48 **Parity, %:** 95.8	**Inclusion criteria:** • women • age 50 to 65 • community dwelling **Exclusion criteria:** NR **Effective response, %:** 96*	**UUI:** Inability to postpone urination with strong urge to void **SUI:** Involuntary leakage of urine on exertion as in coughing, sneezing, laughing, bending over, or with exercise as in jumping **MUI:** Combination of UUI and SUI	**Prevalence of UUI, %:** 26.4 **Prevalence of MUI, %:** 18.1	Overall quality: Fair Internal validity score: 5, ++ External Validity Score: 3, + Sampling Method Described:+ N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 96 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

* Authors report 96% of eligible women participated and 182 = respondents.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Simeonova et al., 1999 **Country:** Sweden **Study period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cross-sectional mailed questionnaire **Base population:** Female residents of the Central [primary care] District of Götenberg **Sampling frame:** Every fourth female resident (other detail NR) **N sampled:** 2,911 **N screened:** NR **N eligible:** NR **N respondents:** 2,248 **N included:** 2,176 **Age, %:** 20-29: 22.0 30-39: 18.2 40-49: 14.8 50-59: 12.6 60-69: 10.2 70-79: 12.0 ≥ 80: 10.2 **Race/ethnicity:** NR	**Inclusion criteria:** • women • age ≥ 20 **Exclusion criteria:** NR **Effective response, %:** 74.8	**Incontinence:** involuntary loss of urine at least 1x/wk, considered by women to be hygienic or social problem **UUI**: incontinence preceded by urge to void or uncontrollable voiding with little or no warning **SUI:** Incontinence precipitated by coughing, sneezing, or physical exertion **Mixed:** Both UUI and SUI	**Prevalence of UUI, %:** 5.1 **Prevalence of UUI by age, %:** 20-29: 0.8 30-39: 1.5 40-49: 4.4 50-59: 4.9 60-69: 7.7 70-79: 10.0 ≥ 80: 13.7 *P* < 0.01 for increase with age **Prevalence of MUI, %:** 3.9 **Prevalence of MUI by age, %:** 20-29: 1.1 30-39: 1.5 40-49: 2.5 50-59: 4.9 60-69: 5.5 70-79: 6.7 ≥ 80: 10.0 *P* < 0.01 for increase with age	Overall quality: Fair Internal validity score: 4, + External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 74.8 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: +

*Urge and mixed incontinence prevalence (overall and by age) computed from proportions of types of incontinence estimated from Figure 3.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Siracusano et al., 2003 **Country:** Italy **Study period:** NR **Funding:** Associazione Progetto Continenza **Author industry relationship disclosures:** NR	**Design:** Cross-sectional mailed questionnaire **Base population:** Female residents of Trieste **Sampling frame:** NR **N sampled:** 10,000 **N screened:** NR **N eligible:** NR **N respondents:** 3,557 **N included:** 2,900 **Age:** NR for respondents **Race/ethnicity:** NR	**Inclusion criteria:** • women • age 18 to 49 **Exclusion criteria:** NR **Effective response, %:** 29	**UUI**: NR	**Prevalence of UUI, %:** 8.7*	Overall quality: Poor Internal validity score: 2, - External Validity Score: 1, - Sampling Method Described: - N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 29% Inclusion (Exclusion) Specified: + Age of population described:- Operational definition provided*: - Required frequency defined*: -

* Calculated: 43.5% of 581 women with incontinence had urge incontinence (Table 2) and denominator is 2900.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Song et al., 2005 Zhang et al., 2005 Zhang et al., 2006* **Country:** China **Study period:** April 2002 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cross-sectional mailed questionnaire (BFLUTS) **Base population:** Residents of Fuzhou, China **Sampling frame:** Random sample (3%) of national census records for the city **N sampled:** 6,066 **N screened:** NA **N eligible:** 4,745 **N respondents:** 4,684 **Age, mean ± SD:** 40.0 ± 11.1 **Race/ethnicity:** Han Chinese: 100 **BMI, mean ± SD:** 21.9 ± 3.0 **Vaginally Parous, %:** 79.8	**Inclusion criteria:** • women • age ≥ 20 **Exclusion criteria:** NR **Effective response, %:** 77.2	**Incontinence:** Any involuntary loss of urine in last month **UUI:** incontinence preceded by a sudden urge to void or uncontrollable voiding with little or no warning **MUI:** Symptoms of stress and urge incontinence **OAB:** OAB-wet or OAB-dry **OAB-wet*:** Urge incontinence with any combination of at least one of the following: urgency, frequency, nocturia, or mixed incontinence **OAB-dry*:** Urgency with either or both frequency and nocturia **Frequency:** ≥ 8 voids a day	**Prevalence of UUI, %:** 10.0 **Prevalence of MUI, %:** 7.7 **UUI and MUI Prevalence increases with age** *P*<0.01 **Prevalence of OAB-wet*, %:** 5.6 **Prevalence of OAB-dry*, %:** 2.4 **Overall prevalence of OAB, %:** 8.0 **Prevalence of urgency, %:** 10.2 **Prevalence of frequency, %:** 16.4	Overall quality: Good Internal validity score: 5, ++ External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 77.2 Inclusion (Exclusion) Specified: + Age of population described:+ Operational definition provided*: + Required frequency defined*: +

Note: differences between UUI and OAB-wet prevalence result from differences in operational definitions used in Zhang et al., 2006.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Stewart et al., 2003 Wagner et al., 2002 **Country:** US **Study period:** November 2000 to January 2001 **Funding:** Pharmacia **Author industry relationship disclosures:** 2 of 8 Pharmacia (2)	**Design:** Cross sectional telephone questionnaire **Base population:** US adults who are English speaking **Sampling frame:** Nationwide random sample by telephone to achieve representative sample by age, sex, and region **N sampled:** 17,231 **N screened:** 11,740 **N eligible:** 6,201 **N respondents:** 6,201 **N included:** Total: 5,204 Women: 2,735 **Age, %:^** < 25: 11.2 25-34: 15.3 35-44: 22.2 45-54: 16.5 55-64: 14.1 65-75: 11.1 > 75: 8.6 **Race/ethnicity, %:^** White: 81.7 Black: 9.1 Hispanic: 4.2 Other: 3.8 **BMI:^** < 22.0: 25.3 22.0-23.9: 15.7 24.0-25.9: 15.9 26.0-29.9: 19.3 ≥ 30: 23.8	**Inclusion criteria:** • adults • age 18 or older • English speaking • residential phone • most recent birthday among eligibles **Exclusion criteria:** NR **Effective response, %:** 83.9	**OAB-wet:** Per ICS 2002 **OAB-dry:** Per ICS 2002	**Prevalence of OAB-wet, %:** 9.3 **Prevalence of OAB-dry, %**: 7.6	Overall quality: Fair Internal validity score: 5, ++ External Validity Score: 3, + Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 83.9 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

^Data presented for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Teloken et al., 2006 **Country:** Brazil **Study period:** November 2003 to August 2004 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cross sectional, written questionnaire (King's Health Questionnaire) **Base population:** Residents of Porto Alegre, Brazil **Sampling frame:** NR ("population based") **N screened:** NR **N eligible:** NR **N respondents:** 913 **N included:** Total: 848 Women: 449 **Age, %:** < 25: 59.3 26-35: 21.4 36-45: 13.2 46-55: 6.1 **Race/ethnicity, %:** White: 90.8 Black: 3.9 Other: 5.3 **Parity, %:^** 39.9	**Inclusion criteria:** • individuals • ages 15 to 55 **Exclusion criteria:** • current pregnancy • UTI • Diabetes • SUI • diuretic use • urinary tract or gynecologic cancer • renal stones • previous urogenital tract surgery **Effective response, %:** NR	**OAB:** Per ICS 2002	**Prevalence of OAB, %**: 23.2	Overall quality: Poor Internal validity score: 1, - External Validity Score: 2, - Sampling Method Described: - N sampled provided: - N eligible provided: - N included respondents: + Response Rate:* NR Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

^Data presented for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Tikkinen et al., 2008 **Country:** Finland **Study period:** November 2003 to February 2004 **Funding:** Competitive Research Funding of the Pirkanmaa Hospital District; Pfizer **Author industry relationship disclosures:** 1 of 6 Astellas (1) Orion (1)	**Design:** Cross-sectional mailed questionnaire (DAN-PSS; AUA-SI) **Base population:** Women in Finland **Sampling frame:** Random sample with over-sampling in younger age strata from Finish Population Registry to achieve representative sample with good precision of estimates for all ages **N sampled:** 3,000 **N screened:** NR **N eligible:** 2,989 **N respondents:** 2,002 **N included:** 1,728 **Age, mean ± SD:** 42.3 ± 15.6 **Race/ethnicity:** NR **Parity, %:** 64	**Inclusion criteria:** • women • age 18 to 79 **Exclusion criteria:** • pregnant or postpartum women • those reporting current UTI **Effective response, %:** 57.6	**Urgency**: An imperative (strong) urge to urinate, often or always	**Age-standardized prevalence of urgency, % (95% CI):** 10.2 (8.5, 11.9)	Overall quality: Good Internal validity score: 5, ++ External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 57.6 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: +

Prevalence of urgency by age in Figure 2 (no data).

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Danforth et al., 2007* Townsend et al., 2008 **Country:** US **Study period:** Baseline 2000 Follow-up 2002 **Funding:** NIH **Author industry relationship disclosures:** None	**Design:** Repeated measures mailed questionnaires at two time points, with supplement to some individuals with incident 1x/wk incontinence at follow-up **Base population:** Nurses Health Study (NHS) participants **Sampling frame:** Members of the NHS cohort **N sampled/ screened:** 121,700 Supplement: 1,939 **N respondents:** 77,696 Supplement: 1,753 **N eligible:** 35,754 Supplement: 1,601 **Age, mean:** 65.3 **Race/ethnicity**: White: 96.5 Black: 1.6 Hispanic: 0.9 Asian: 0.8 Other: 0.2 **BMI kg/m^2, %:** < 21: 12.6 21-24: 36.3 25-29: 33.9 ≥ 30: 17.1 **Parity, %:** 94.0	**Inclusion criteria:** • women • NHS participants returning both baseline and follow-up • community dwelling **Exclusion criteria:** • missing data on BMI or UI • prevalent UI 1x/mo at baseline • history of major neurologic conditions • significant functional limitations **Effective response, %:** 46.0 Supplement: 82.6	**Frequent incontinence:** Leaking ≥ 1x/wk **UUI:** Frequent incontinence with a sudden feeling of bladder fullness or when a toilet was inaccessible **SUI:** Frequent incontinence with coughing or sneezing, lifting things, laughing, or doing exercise **MUI:** Reporting UUI and SUI symptoms equally	**2-year incidence of UUI , %:**** 1.4 **2-year incidence of MUI, %:**** 1.9	Overall quality: Fair Internal validity score: 3, + External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: - Response Rate:* 46 Inclusion (Exclusion) Specified: + Age of population described:+ Operational definition provided*: + Required frequency defined*: +

* Incidence of UUI and MUI from Danforth et al., 2007 is 1.4% and 1.8%, respectively.
** Incidence calculated as incidence of frequent UI (1x/wk) times estimated proportion with each type of UI, e.g. (2,416/35,754)*(342/1,601) = 1.4%

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Townsend et al., 2007 **Country:** US **Study period:** Baseline 2001 Follow-up 2003 **Funding:** NIH **Author industry relationship disclosures:** NR	**Design:** Repeated measures mailed questionnaires at two time points, with supplemental questionnaire if ≥ 1x/wk incontinence at follow-up **Base population:** Nurses Health Study (NHS) participants **Sampling frame:** Members of the NHSII cohort **N sampled/ screened:** 115,713 **N respondents:** Baseline: 85,994 Follow-up: 70,712 **N eligible:** Total: 64,650 **Age, mean:** 46.4 **Age, %:** 36-40: 13.2 41-45: 29.1 46-50: 34.8 51-55: 22.9 **Race/ethnicity**: "Largely Caucasian" **BMI kg/m^2, %:** ≥ 25: 50.3 **Parity, %:** 79.0	**Inclusion criteria:** • women • age 35 to 54 at baseline • NHS participants returning both baseline and follow-up **Exclusion criteria:** • missing data • unclear continence status at baseline **Response, %:** Baseline: 74 Follow-up: 61 **Effective response, %:** Total: 57	**Incontinence:** "During last 12 months, how often have you leaked or lost control of your urine?" (required ≥ 1x/wk) **UUI:** Predominance of urge symptoms in the Medical Epidemiological and Social Aspects of Aging questionnaire, per Diokno (1995) **SUI:** Predominance of stress symptoms **MUI:** Equal predominance of UUI and SUI symptoms	**2-year incidence of UUI , %:** 0.4 **2-year incidence of UUI by age, %:** 36-40: 0.4 41-45: 0.4 46-50: 0.5 51-55: 0.4 **2-year incidence of MUI, %:** 0.6 **2-year incidence of MUI by age, %:** 36-40: 0.3 41-45: 0.6 46-50: 0.7 51-55: 0.9	Overall quality: Fair Internal validity score: 5, ++ External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 61 Inclusion (Exclusion) Specified: + Age of population described:+ Operational definition provided*: + Required frequency defined*: +

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Tseng et al., 2000 **Country:** Taiwan **Study period:** March 1997 to April 1997 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cross-sectional administered questionnaire **Base population:** Residents of Tungkang Town **Sampling frame:** Random sample stratified to obtain age and gender representation by city region **N sampled:** NR **N screened:** NR **N eligible:** NR **N respondents:** NR **N included:** Total: 504 Women: 256 **Age, %:** 65-70: 43.1 71-75: 28.1 76-80: 18.4 > 80: 12.1 **Race/ethnicity:** NR **BMI, %:** "Overweight": 47.3*	**Inclusion criteria:** • adults • age ≥ 65 **Exclusion criteria:** NR **Effective response, %:** 80 (per authors cannot calculate)	**UI**: "ever experienced inappropriate loss of urine" **UUI**: Because of inability to delay voiding following micturition urge **SUI**: Loss associated with physical exertion (coughing, sneezing, lifting, or other physical activity) **MUI:** Features of UUI and SUI	**Prevalence of UUI, % :** 6.6 **Prevalence of MUI, %:** 6.3	Overall quality: Poor Internal validity score: 2, - External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: - N eligible provided: - N included respondents: + Response Rate:* NR Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: +

^ Data presented for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Ueda et al., 2000 **Country:** Japan **Study period:** NR **Funding:** LACADIA Health and Welfare Foundation; Social Department Foundation for Senior Citizens **Author industry relationship disclosures:** NR	**Design:** Cross-sectional mailed questionnaire **Base population:** Residents of Shiga Prefecture **Sampling frame:** Random sample of individuals in seven towns **N sampled:** 3,500 **N screened:** NR **N eligible:** NR **N respondents:** 1,836 **N included:** Total: 1,786 Women: 968 **Age, %:^** 40-49: 26.4 50-59: 28.8 60-69: 29.4 ≥ 70: 15.4 **Race/ethnicity:** NR **BMI:** NR	**Inclusion criteria:** • adults • age 40 to 80 • community-dwelling **Exclusion criteria:** NR **Effective response, %:** 51.0	**Incontinence:** involuntary loss of urine within prior year **UUI:** Often have difficulty holding urine until able to get to toilet **SUI:** Leak when cough, sneeze, or laugh? **MUI:** Both UUI and SUI	**Prevalence of UUI, %:** 6.9 **Prevalence of UUI by age, %:** 40-49: 5.1 50-59: 4.3 60-69: 8.8 ≥ 70: 11.4 **Prevalence of MUI, %:** 12.9 **Prevalence of MUI by age, %:** 40-49: 14.5 50-59: 14.3 60-69: 6.3 ≥ 70: 20.1	Overall quality: Fair Internal validity score: 4, + External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 51 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: +

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: van der Vaart et al., 2002 **Country:** Netherlands **Study period:** 1999 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cross-sectional mailed questionnaire (UDI) **Base population:** Female residents of the Central Netherlands **Sampling frame:** Random sample of women from the population registry office of a suburban area **N sampled:** 1,393 **N screened:** NR **N eligible:** NR **N respondents:** 1,029 **N included:** 933 **Age, mean ± SD:** 34.2 ± 3.2 **Race/ethnicity:** NR **BMI, mean ± SD:** 23.6 ± 4.2	**Inclusion criteria:** • women • age 20 to 45 **Exclusion criteria:** NR **Effective response, %:** 67	**UUI:** Urine loss related to feeling of urgency **OAB:** Per ICS **Urgency:** Per ICS **Frequency:** Per ICS	**Prevalence of UUI, %:** 15.3 **Prevalence of OAB, %:** 11.9 **Prevalence of urgency, %:** 45.4 **Prevalence of frequency, %:** 34.0	Overall quality: Fair Internal validity score: 4, + External Validity Score: 3, + Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 67% Inclusion (Exclusion) Specified: + Age of population described:+ Operational definition provided*: + Required frequency defined*: -

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Waetjen et al., 2007 **Country:** US **Study period:** 1995 to 2001 **Funding:** NIH, Univ. of California Davis Health Systems Research Award **Author industry relationship disclosures:** None	**Design:** Repeated measures administered questionnaire and follow-up visits **Base population:** Women in six states near seven urban study centers **Sampling frame:** Random digit dialing, snowballing, and list sampling based on study center **N sampled:** 16,065 **N screened:** 16,065 **N eligible:** NR **N respondents:** 16.065 baseline 3,302 included in follow-up based on per center quotas **Age, mean ± SD:** 45.8 ± 2.7 **Race/ethnicity, %:** Caucasian: 47.0 Black: 28.3 Chinese: 7.6 Japanese: 8.5 Hispanic: 8.7 **BMI, mean ± SD:** 28.2 ± 7.2 **Parity, mean ± SD:** 2.0 ± 1.4	**Inclusion criteria:** • women • age 42 to 52 • self-identified as member of one of five race/ethnic groups **Exclusion criteria:** • inability to speak English, Spanish, Japanese, or Cantonese • no menstrual period in prior 3 months • hysterectomy and/or oophorectomy prior to study • current use of hormones including birth control pills **Effective response, %:** NR	**UUI:** at least monthly leakage when "urge to void and can't reach the toilet fast enough." **SUI:** at least monthly leakage "with coughing, laughing, sneezing, jogging, jumping, or picking up an object from the floor." **MUI:** Affirmative answers to both UUI and SUI at least monthly	**5-year incidence of UUI, %:** 15.9 **5-year incidence of MUI, %:** 11.9 **Baseline prevalence of UUI, %:** 7.6 **Baseline prevalence of MUI, %:** 12.4	Overall quality: Fair Internal validity score: 3, - External Validity Score: 3, ++ Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* NR Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: +

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Wesnes et al., 2007 **Country:** Norway **Study period:** 1999 to 2006 **Funding:** Research Council of Norway **Author industry relationship disclosures:** NR	**Design:** Cross-sectional mailed questionnaire **Base population:** Pregnant women in Norway **Sampling frame:** Women receiving prenatal care in one of 52 maternity units **N screened:** NR **N eligible:** NR **N respondents:** 46,262 **N included:** 43,279 **Age, mean (range):** 29.5 (14, 47) **Race/ethnicity:** NR **Pre-pregnancy BMI, mean (range):** 24.1 (13, 59) **Parity, %:** 53.8	**Inclusion criteria:** • pregnant women • read and write Norwegian • completion of questionnaire by 30-week visit **Exclusion criteria:** • participated in prior pregnancy **Effective response, %:** 45	**UUI:** Per ICS 2002 **MUI:** Per ICS 2002	**Prevalence of UUI, before pregnancy, %:** 3.8 **Prevalence of UUI during pregnancy, %:** 4.8 **Prevalence of MUI, before pregnancy, %:** 5.5 **Prevalence of MUI during pregnancy, %:** 16.4	Overall quality: Fair Internal validity score: 3, + External Validity Score: 3, + Sampling Method Described: + N sampled provided: - N eligible provided: - N included respondents: + Response Rate:* 45 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Yarnell et al., 1981 **Country:** UK **Study period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cross-sectional administered questionnaire **Base population:** Female residents of South Wales **Sampling frame:** Random sample of electoral role from base population of 38,000 **N sampled:** 1,140 **N screened:** NR **N eligible:** 1,060 **N respondents:** 1,022 **N included:** 1,000 **Age, %:** 17-24: 12 23-34: 21 35-44: 15 45-54: 19 55-64: 15 65-74: 11 ≥ 75: 7 **Race/ethnicity:** NR **BMI:** NR	**Inclusion criteria:** • women • age ≥ 18 **Exclusion criteria:** NR **Effective response, %:** 94.3	**UUI**: Ever (12 months) have to rush to the toilet to pass water and ever loose water before reaching toilet **SUI**: Ever (12 months) loose urine when you cough, laugh, sneeze, etc. **MUI:** Both UUI and MUI	**Prevalence of UUI, %:** 9.2 **Prevalence of UUI by age, %:** 17-24: 9 23-34: 5 35-44: 10 45-54: 9 55-64: 10 65-74:13 ≥75: 14 **Prevalence of MUI, %:** 13.5 **Prevalence of MUI by age, %:** 17-24: 4 23-34: 8 35-44: 16 45-54: 16 55-64: 15 65-74: 13 ≥ 75: 28	Overall quality: Good Internal validity score: 5, ++ External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 94.3 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: +

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence^	Quality Rating
Author: Yu et al., 2006 **Country:** Taiwan **Study period:** February 2003 to February 2005 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cross-sectional administered questionnaire **Base population:** Residents of Matsu **Sampling frame:** 100% of residents **N sampled:** 5,456 **N screened:** NR **N eligible:** NR **N respondents:** 1,921 **N included:** Total: 1,827 Women: 925 **Age, %:^** 30-39: 22.6 40-49: 34.5 50-59: 19.4 60-69: 12.8 70-79: 10.8 **Race/ethnicity:** NR **BMI kg/m^2, %:^** < 24.0: 70.9 24.0-26.9: 20.5 ≥ 27.0: 8.5 **Parity, %:** 89.4	**Inclusion criteria:** • adults • age ≥ 30 in 2000 **Exclusion criteria:** NR **Effective response, %:** 33.5	**UUI:** Urine loss associated with an urge to void **OAB:** Per ICS 2002	**Prevalence of OAB, %:** 18.3 **Prevalence of OAB by age, %:** 30-39: 14.4 40-49: 14.7 50-59: 19.6 60-69: 25.4 70-79: 31.0 *P* = 0.001 for trend	Overall quality: Fair Internal validity score: 4, + External Validity Score: 3, + Sampling Method Described: + N sampled provided: + N eligible provided: - N included respondents: + Response Rate:* 33.5 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

^Data presented for women only.

Evidence Table 1. KQ 1 Prevalence and Incidence of OAB (continued)

Study Description	Study Design and Sampling	Inclusion/ Exclusion Criteria	Study Definitions	Incidence/ Prevalence	Quality Rating
Author: Zhu et al., 2008 **Country:** China **Study period:** April 2005 to July 2005 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cross-sectional administered questionnaire (Chinese ICIQ) **Base population:** Female residents of Beijing **Sampling frame:** 1.0% of female Beijing residents age ≥ 20 (2000 national census data) **N sampled:** 5,300 **N included:** 5,221 **Age, mean:** 46.4 **Race/ethnicity:** NR	**Inclusion criteria:** • Age ≥ 20 **Exclusion criteria:** NR **Effective response, %:** 98.5	**Incontinence:** Any leakage or involuntary loss of urine within the last month. **SUI:** A leak or loss of urine caused by sneezing, coughing, exercising, lifting, or physical activity. **UUI:** An urge to urinate but being unable to reach the toilet before leaking or having a strong sudden urge to go to the toilet to urinate with no advance warning. **MUI:** Experiencing at least one stress and one urge symptom.	**Prevalence of UUI, %**: 2.8 **Prevalence of UUI by menopausal status, %**: Premenopause: 1.9 Menopause: 4.0 **Prevalence of MUI, %:** 12.4 **Prevalence of MUI by menopausal status, %**: Premenopause: 6.0 Menopause: 20.4	Overall quality: Good Internal validity score: 4, + External Validity Score: 4, ++ Sampling Method Described: + N sampled provided: + N eligible provided: + N included respondents: + Response Rate:* 98.5 Inclusion (Exclusion) Specified: + Age of population described: + Operational definition provided*: + Required frequency defined*: -

Mean age and prevalence of UUI and MUI by menopausal status calculated from results reported.
Prevalence of UUI and MUI by age groups in Figure 3 on page 567 (no results reported).

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Abrams et al., 1998 **Country and setting:** UK, Ireland, Sweden, Academic medical center **Enrollment period:** July 1995 to July 1996 **Funding:** Pharmacia Upjohn **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Tolterodine vs. Oxybutynin vs. Placebo x 12 wks **Groups:** **G1:** Tolterodine 2 mg b.i.d. (dose could be reduced to 1.0 mg b.i.d.) **G2:** Oxybutynin 5 mg t.i.d. (dose could be reduced to 2.5 mg t.i.d.) **G3:** Placebo **N at enrollment:** **G1:** 118 **G2:** 118 **G3:** 57 **N at follow-up:** **G1:** 118 **G2:** 117 **G3:** 56 **Women, n (%):** **G1:** 91 (77.1) **G2:** 88 (74.5) **G3:** 43 (75.4) **Age, mean (range):** **G1:** 55 (19-80) **G2:** 58 (21-80) **G3:** 58 (26-78)	**Inclusion criteria:** • Age ≥ 18 • UDS confirmed bladder overactivity • ≥ 8 voids/day • ≥ 1 episode UUI/ day **Exclusion criteria:** • SUI • Detrusor hyperreflexia • Hepatic, renal, hematological disorders • Symptomatic or recurrent UTI • BOO • Bladder retraining • Electrical stimulation therapy • Indwelling catheter • CIC • Pregnant/ nursing • Women without reliable BC	**Incontinence episodes, n (%):** **G1:** 93 (79) **G2:** 88 (75) **G3:** 40 (70) **Incontinence episodes/day, mean (range):** **G1:** 2.9 (0.1-24.0) **G2:** 2.6 (0.1-24.0) **G3:** 3.3 (0.1-23.5) **Voids/day, mean (range):** **G1:** 11.5 (6.3-37.0) **G2:** 10.7 (5.3-27.7) **G3:** 11.7 (6.9-34.4) **≥ 8 voids/day, n (%):** **G1:** 112 (95) **G2:** 109 (92) **G3:** 53 (93) **Voided volume (mL), mean (range):** **G1:** 166 (55-426) **G2:** 176 (57-423) **G3:** 157 (59-276) **Previous OAB therapy, n (%):** **G1:** 61 (52) **G2:** 71 (60) **G3:** 43 (75)	**Incontinence episodes/day, mean change ± SD:** **G1:** -1.3 ± 3.2 **G2:** -1.7 ± 3.1 **G3:** -0.9 ± 1.5 **G1/G3:** *P* = 0.22 **G2/G3:** *P* = 0.023 **Voids/day, mean change ± SD:** **G1:** -2.7 ± 3.8 **G2:** -2.3 ± 2.7 **G3:** -1.6 ± 3.6 **G1/G3:** *P* = 0.002 **G2/G3:** *P* = 0.068 **Voided volume (mL), mean change ± SD:** **G1:** 38 ± 54 **G2:** 47 ± 58 **G3:** 6 ± 42 **G1/G3:** *P* < 0.001 **G2/G3:** *P* < 0.001 **Subjective improvement in bladder symptoms, %:** **G1:** 50 **G2:** 49 **G3:** 47 **Dose reductions, n (%):** **G1:** 9 (8) **G2:** 38 (32) **G3:** 1 (2) **G2/G1:** *P* < 0.001 **G2/G3:** *P* < 0.001	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: + Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Abrams et al., 1998 (continued)				**Dry mouth, n (%):** **G1:** 59 (50) **G2:** 102 (86) **G3:** 12 (21) **G1/G3:** *P* < 0.001 **G2/G1:** *P* < 0.001 **G2/G3:** *P* < 0.001 **Dyspepsia, n (%):** **G1:** 11 (9) **G2:** 27 (23) **G3:** 3 (5) **Nausea, n (%):** **G1:** 4 (3) **G2:** 7 (6) **G3:** 6 (11) **Upper respiratory infection, n (%):** **G1:** 12 (10) **G2:** 3 (3) **G3:** 8 (14) **Adverse events reported, N:** **G1:** 302 **G2:** 412 **G3:** 117 **Patients with ≥ 1 AE, n (%):** **G1:** 105 (89) **G2:** 114 (97) **G3:** 46 (81) **G2/G1:** *P* = 0.023 **G2/G3:** *P* < 0.001 **Discontinued due to AEs, n (%):** **G1:** 10 (8) **G2:** 20 (17) **G3:** 1 (2)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Abrams et al., 2006 **Country and setting:** UK, 8 sites **Enrollment period:** NR **Funding:** Pfizer **Author industry relationship disclosures:** 2 of 6 Pfizer (2)	**Design:** Crossover RCT **Intervention:** 8 weeks consisting of 2-week run-in period followed by two-week treatment period, 2 week washout, and additional 2 week treatment. **Groups:** **G1:** Propiverine 20 mg qd **G2:** Propiverine 15 mg t.i.d. **G3:** Oxybutynin 5 mg t.i.d. **G4:** Placebo **N at enrollment:** Total: 77 **G1:** 38 **G2:** 42 **G3:** 41 **G4:** 24 **N at follow-up:** Safety Analysis: 77 AUM parameter analysis: 69 **Women, n (%)*:** 59 (76.6) **Age, range:** 47-56 **Race/ethnicity:** NR **Weight, range (kg):** 74-81	**Inclusion criteria:** • Age ≥ 18 • Clinical diagnosis of idiopathic OAB with detrusor overactivity • Two or more of the following during 2-week run-in period: urinary frequency (≥ 7 voids/ day), UUI (≥ 1 episode/week requiring change of clothing or pad), urinary urgency (≥ 7 episodes preceding week) **Exclusion criteria:** • Hepatic, renal or cardiac abnormalities • SUI • Untreated narrow-angle glaucoma • Urinary or gastric retention • BOO > 40 (Abrams-Griffiths number) • Indwelling catheter • Recent urogenital surgery • Use of investigational drugs in 30 days preceding the study	**Duration of OAB since diagnosis (years), range:** 5-15 f	**IDC number, all activities, mean difference (SE):** **G2/G1:** -1.3 (1.4)* **G3/G1:** -3.8 (1.4) *P* ≤ 0.01 **G3/G2:** -2.6 (1.4)* **IDC number, with concurrent symptoms, mean difference (SE):** **G2/G1:** -0.9 (0.7)* **G3/G1:** -1.7 (0.7) *P* ≤ 0.05 **G3/G2:** -0.8 (0.7)* **IDC duration (sec), all activities, mean difference (SE):** **G2/G1:** -133.6 (88.0)* **G3/G1:** -244 (91.3) *P* ≤ 0.01 **G3/G2:** -110.4 (88.9)* **IDC duration (sec), with concurrent symptoms, mean difference (SE):** **G2/G1:** -54.3 (48.0)* **G3/G1:** 108.1 (50.0) *P* ≤ 0.05 **G3/G2:** 53.7 (49.0)* **AUC detrusor pressure vs time (cmH_20 * s), all activities, mean difference (SE):** **G2/G1:** -0.1 (0.5)* **G3/G1:** -0.3 (0.5)* **G3/G2:** -0.2 (0.5)*	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: ++ Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: -, NR Baseline OAB status: NR Baseline characteristics: - Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

^ gender accounted for in mixed-effects statistical model; * *P* = NS

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Abrams et al., 2006 (continued)				**AUC detrusor pressure vs. time (cmH_20 * s), with concurrent symptoms, mean difference (SE):** **G2/G1:** -0.2 (0.8)* **G3/G1:** -1.3 (0.8)* **G3/G2:** -1.1 (0.8)* **IDC max amplitude (cmH_20), all activities, mean difference (SE):** **G2/G1:** -3.8 (8.2)* **G3/G1:** -16.8 (8.5)* **G3/G2:** 12.7 (8.3)* **IDC max amplitude (cmH_20), with concurrent symptoms, mean difference (SE):** **G2/G1:** -5.0 (7.6)* **G3/G1:** -15.8 (7.9) *P* ≤ 0.05 **G3/G2:** -10.7 (7.7)* **Salivary flow rate, mean difference (SE):** **G2/G1:** 0.0 (0.7)* **G3/G1:** -0.6 (0.1) *P* < 0.0001 **G3/G2:** -0.6 (0.1) *P* < 0.0001 **Visual near point, mean difference (SE):** **G2/G1:** 1.6 (1.2)* **G3/G1:** 0.6 (1.2)* **G3/G2:** -1.0 (1.2)* **Heart rate, mean difference (SE):** **G2/G1:** 2.7 (1.4) *P* < 0.05 **G3/G1:** -5.1 (1.4) *P* < 0.0001 **G3/G2:** -7.8 (1.4) *P* < 0.0001	

^ gender accounted for in mixed-effects statistical model; * *P* = NS

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Abrams et al., 2006 (continued)				**PNN50, mean difference (SE):** **G2/G1:** -3.6 (1.8) *P* < 0.05 **G3/G1:** 6.2 (1.8) *P* < 0.0001 **G3/G2:** 9.9 (1.8) *P* < 0.0001 **St. George's index, mean difference (SE):** **G2/G1:** -3.5 (1.9) *P* < 0.05 **G3/G1:** 3.4 (1.9) *P* < 0.05 **G3/G2:** 6.9 (1.9) *P* < 0.0001 **Dry mouth, n (%):** **G1:** 13 (34) **G2:** 22 (52) **G3:** 34 (83) **G4:** 4 (17) **Abnormal vision, n (%):** **G1:** 9 (24) **G2:** 14 (33) **G3:** 9 (22) **G4:** 0 **Constipation, n (%):** **G1:** 6 (16) **G2:** 10 (24) **G3:** 4 (10) **G4:** 0 **Headache, n (%):** **G1:** 1 (3) **G2:** 3 (7) **G3:** 6 (15) **G4:** 0	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Anderson et al., 1999 **Country and setting:** US, multi-center **Enrollment period:** NR **Funding:** Oros Oxybutynin Study group Alza Corp **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Oxybutynin CR vs. Oxybutynin IR 1 wk washout period prior to initiation of study **Groups:** **G1:** Oxybutynin 5, 10, 15, 20, 25, or 30 mg CR qd **G2:** Oxybutynin 5 mg IR daily to qid **N at enrollment:** **G1:** 53 **G2:** 52 **N at follow-up:** **G1:** 46 **G2:** 47 **Age, yrs ± SD:** **G1:** 59.2 ± 10.6 **G2:** 59.6 ± 10.0 **Race/ethnicity:** NR **Women, N (%):** **G1:** 50 (94) **G2:** 47 (90)	**Inclusion criteria:** • Community dwelling • Symptoms of urge incontinence or mixed incontinence with primary urge symptoms • ≥6 episodes UUI/ wk when not taking medications • Previous favorable response with oxybutynin **Exclusion criteria:** • Myasthenia gravis • Narrowing of GI tract • glaucoma • Pregnant/ lactating • Positive urine drug screen • Receiving meds other than oxybutynin, hyoscamine, or propantheline which was considered effective in UUI treatment • At risk for complete urinary retention caused by anticholinergic treatment • Prostate surgery in last 9 mos • BOO • PVR>100	**UUI episodes/ week, mean ± SD:** **G1:** 27.4 ± 24.0 **G2:** 23.4 ± 16.3 **Total incontinence episodes, mean ± SD:** **G1:** 29.3 ± 24.2 **G2:** 26.3 ± 18.5 **Voids/ week, mean ± SD:** **G1:** 48.3 ± 18.4 **G2:** 51.5 ± 19.4 **Voided volume/ void (mL), mean ± SD:** **G1:** 134.2 ± 82 **G2:** 161.2 ± 92 **PVR/ void (mL), mean ± SD:** **G1:** 15.4 ± 21 **G2:** 18.0 ± 24 **Total bladder volume/ void (mL), mean ± SD:** **G1:** 149.7 ± 90 **G2:** 179.2 ± 95	**UUI episodes/ week, mean:** **G1:** 4.8 **G2:** 3.1 *P* = 0.6 **Total incontinence episodes, mean:** **G1:** 6 **G2:** 3.8 *P* = 0.7 **Percentage reduction in UUI episodes/ week (%):** **G1:** 84 **G2:** 88 *P* = 0.7 **No UUI episodes/ week, %:** **G1:** 52 **G2:** 51 *P* = 0.7 **Totally continent, %:** **G1:** 41 **G2:** 41 *P* = 0.9 **Voided volume/ void (mL), mean ± SD:** **G1:** 176.6 ± 138 **G2:** 194.5 ± 152 *P* = 0.1 **PVR/ void (mL), mean ± SD:** **G1:** 33.5 ± 77 **G2:** 36.1 ± 59 *P* = 0.2 **Total bladder volume/ void (mL), mean ± SD:** **G1:** 210.1 ± 148 **G2:** 230.6 ± 176 *P* = 0.9 **≥1 anticholinergic event, n (%):** **G1:** 46 (87) **G2:** 49 (94)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: + Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Anderson et al., 1999 (continued)				**Dry Mouth, n (%):** **G1:** 36 (68) **G2:** 45 (87) *P* = 0.04 **Moderate-severe dry mouth, n (%):** **G1:** 13 (25) **G2:** 24 (46) *P* = 0.03 **Somnolence, n (%):** **G1:** 20 (38) **G2:** 21 (40) *P* = 0.8 **Blurred vision, n (%):** **G1:** 15 (28) **G2:** 9 (17) *P* = 0.3 **Constipation, n (%):** **G1:** 16 (30) **G2:** 16 (31) *P* = 1.0 **Dizziness, n (%):** **G1:** 15 (28) **G2:** 20 (38) *P* = 0.3 **Impaired urination, n (%):** **G1:** 13 (25) **G2:** 15 (29) *P* = 0.7 **Nervousness, n (%):** **G1:** 13 (25) **G2:** 12 (23) *P* = 1.0 **Nausea, n (%):** **G1:** 10 (19) **G2:** 9 (17) *P* = 1.0	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Anderson et al., 2006 [See evidence table for Diokno et al. 2003] **Country and setting:** US, Multicenter **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** 1 of 6 ALZA Corp (1)	**Design:** RCT **Intervention:** Extended release antimuscarinic medications in women with or without prior antimuscarinic treatment for OAB **Groups:** **G1:** Prior antimuscarinic **G1a:** Oxybutynin ER 10 mg po daily **G1b:** Tolterodine ER 4mg po daily **G2:** No prior anticholinergic treatment **G2a:** Oxybutynin ER 10 mg po daily **G2b:** Tolterodine ER 4mg po daily **Ga:** Oxybutynin ER 10 mg po daily **Gb:** Tolterodine ER 4mg po daily **N at enrollment:** Total: 790 **G1:** 373 **G1a:** 180 **G1b:** 193 **G2:** 417 **G2a:** 211 **G2b:** 206 **N at follow-up, 12 weeks:** **G1:** 341 **G1a:** 165 **G1b:** 176 **G2:** 355 **G2a:** 174 **G2b:** 181	**Inclusion criteria:** • Women • Age ≥ 18 • Mean of 21-60 UUI episodes per week and mean of ≥ 10 voids per 24 hr **Exclusion criteria:** NR	**UUI episodes/ wk, mean ± SD:** **G1a:** 36.8 ± 16.4 **G1b:** 37.4 ± 14.0 **G2a:** 37.5 ± 14.0 **G2b:** 36.2 ± 13.9 **Incontinence episodes/wk, mean ± SD:** **G1a:** 41.5 ±19.0 **G1b:** 43.0 ± 18.0 **G2a:** 45.0 ±19.4 **G2b:** 41.9 ± 17.9 **Voids/week, mean ± SD:** **G1a:** 92.8 ± 23.7 **G1b:** 94.6 ± 25.2 **G2a:** 96.5 ± 27.1 **G2b:** 97.9 ± 24.2	**UUI episodes/wk, mean ± SD:** **G1a:** 11.4 ± 17.9 **G1b:** 13.3 ± 15.1 **G2a:** 10.2 ± 13.7 **G2b:** 9.3 ± 13.3 **G1a/G1b:** *P* = 0.3 **UUI episodes/wk, completed wk 12, mean ± SD:** **G1a:** 9.9 ± 14.1 **G1b:** 12.9 ± 14.9 *P* = 0.049 **No UUI, 12 wk, %:** **G1a:** 25.2 **G1b:** 16.4 **G2a:** 29.4 **G2b:** 26.4 **G1a/G1b:** *P* = 0.046 **G2a/G2b:** *P* = 0.495 **Incontinence episodes/wk, mean ± SD:** **G1a:** 12.7 ± 18.7 **G1b:** 16.5 ± 19.8 **G2a:** 11.9 ± 15.1 **G2b:** 11.3 ± 16.0 **G1a/G1b:** *P* = 0.09 for LOCF (*P* = 0.012 if completed wk 12) **G2a/G2b:** *P* = 0.886 **Voids/week, mean ± SD:** **G1a:** 68.4 ± 17.2 **G1b:** 72.8 ± 25.4 **G2a:** 64.8 ± 22.0 **G2b:** 69.4 ± 21.3 **G1a/G1b:** *P* = 0.05 for LOCF (*P* = 0.026 wk 12) **G2a/G2b:** *P* = 0.035 for LOCF (*P* = 0.026 wk 12)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Anderson et al., 2006 (continued)	**Women, %:** 100 **Age, mean ± SD:** **G1a:** 62.6 ± 12.9 **G1b:** 62 ± 12.6 **G2a:** 57.5 ± 13.4 **G2b:** 58.8 ± 12.4 **Race/ethnicity, %:** **White:** **G1a:** 87 **G1b:** 88 **G2a:** 82 **G2b:** 84 **Black:** **G1a:** 7 **G1b:** 9 **G2a:** 9 **G2b:** 8.7 **Asian:** **G1a:** 0.6 **G1b:** 0 **G2a:** 0 **G2b:** 1 **Hispanic:** **G1a:** 5.6 **G1b:** 3.1 **G2a:** 8.1 **G2b:** 6.3 **Other** **G1a:** 0 **G1b:** 0.5 **G2a:** 0.9 **G2b:** 0			**Dry mouth, %** **G1a:** 32 **G1b:** 19 **G2a:** 27.5 **G2b:** 25.2 **G1a/G1b:** *P* = 0.004 **G2a/G2b:** *P* = 0.6 **Constipation, %:** **G1a:** 7.8 **G1b:** 5.2 **G2a:** 5.2 **G2b:** 10.2 **Diarrhea, %:** **G1a:** 7.8 **G1b:** 5.7 **G2a:** 8.1 **G2b:** 6.8 **Headache, %:** **G1a:** 4.4 **G1b:** 5.2 **G2a:** 6.6 **G2b:** 6.8 **Discontinued due to AE, n (%):** **G1a:** 7 (3.9) **G1b:** 6 (3.1) **G2a:** 13 (6.2) **G2b:** 13 (6.3) **Withdrew, %:** **G1:** 3.5 **G2:** 6.2	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Appell, Abrams et al., 2001 **Country and setting:** Multinational, Multicenter **Enrollment period:** NR **Funding:** Pharmacia **Author industry relationship disclosures:** NR	**Design:** Open-label extension study (after 12-wk RCT and 1 wk washout) **Intervention:** Tolterodine 2 mg b.i.d. with option for patients to self-lower their dosage to 1 mg b.i.d. **Groups:** NA **N at enrollment:** 854 **N at follow-up, n (%):** 594 (70) **Age, yrs, mean (range):** 59.5 (19-89) **Race/ethnicity:** NR **Women, %:** 76 **Previous drug therapy for OAB, n (%):** 472 (55) **Previous lower urinary tract surgery, n (%):** 291 (34)	**Inclusion criteria:** • ≥18 years old • Cystometric evidence of detrusor overactivity (phasic detrusor contraction with amplitude 10+ cm H2O) • ≥ 8 voids/day • ≥ 1 urinary incontinence episode/day **Exclusion criteria:** • SUI • Hepatic or renal disease • Recurrent or symptomatic UTIs • Interstitial cystitis • Hematuria secondary to malignant disease • Contraindication to anti-muscarinic therapy • Serious AE on oxybutynin • Clinically significant voiding difficulty w/ treatment of urinary retention • Treatment in 14 days prior to baseline visit • Initiation of antimuscarinic or any drug for UI during study • Electro-stimulation or bladder training • Indwelling or intermittent catheter • Total voided volume >3L/day	**Detrusor instability, %:** 93.7 **UUI episodes, n (%):** 724 (85) **Symptom duration > 5 yrs, n (%):** 412 (48) **Urgency, n (%):** 841 (98) **Severe/very severe problems, n (%):** 384 (45) **UUI episodes/ day, mean (range):** 3.5 (0.1-24.0) **Voids/day, mean (range):** 11.4 (5.3-37.0) **Voided volume (mL), mean (range):** 159 (25-423) **Adverse events at end of 12-wk RCT, n (%):** Any: 358 (76) ANS: 203 (43) CNS: 59 (12) GI: 125 (26) Respiratory: 68 (14) Urinary: 50 (11) Dry mouth: 187 (39) UTI: 26 (5) Headache: 49 (10) Constipation: 31 (7) Abdominal pain: 36 (8) URI: 28 (6)	**UUI episodes/day, 3 mos, mean (range):** 1.3 (0.0-24.0) **UUI episodes/day, mean change (95% CI):** -2.1 (-2.4, -1.9) *P* = 0.0001 **UUI episodes/day, 3 mos, mean (range):** 1.5 (0.0-24.0) **UUI episodes/day, mean change (95% CI):** -2.0 (-2.2, -1.7) *P* = 0.0001 **UUI episodes/day, median % change:** -76 **Voids/day, 3 mos, mean (range)** 8.8 (2.0-23.4) **Voids/day, 3 months, mean change (95% CI):** -2.6 (-2.8, -2.3) *P* = 0.0001 **Voids/day, 9 mos, mean (range):** 8.9 (1.9-31.6) **Voids/day, 9 months, mean change (95% CI):** -2.5 (-2.9, -2.4) *P* = 0.0001 **Voids/day, 9 mos, median % change:** -22	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Appell, Abrams et al., 2001 (continued)				**Voided volume (mL), 3 mos, mean (range):** 201 (33-444) **Voided volume (mL), 3 mos, mean change (95% CI):** 41 (36, 45) *P* = 0.0001 **Voided volume (mL), 9 mos, mean (range):** 199 (34-514) **Voided volume (mL), 9 mos, mean change (95% CI):** 40 (35, 45) *P* = 0.0001 **Voided volume (mL), 9 mos, median % change:** 22 **Improvement, 9 mos, %:** 65 **Any adverse event, n (%):** 652 (76) **ANS, n (%):** 268 (31) **General, n (%):** 219 (26) **CNS/PNS, n (%):** 82 (10) **GI, n (%)** 201 (24) **Respiratory, n (%):** 139 (16) **Urinary, n (%):** 165 (19) **Dry mouth, n (%):** 236 (28)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Appell, Abrams et al., 2001 (continued)				**Mild dry mouth, %:** **19** **Moderate dry mouth, %:** 7 **Severe dry mouth, %:** 2 **UTI, n (%):** 106 (12) **Headache, n (%):** 57 (7) **Constipation, n (%):** 57 (7) **Abdominal pain, n (%):** 50 (6) **Upper respiratory tract infection, n (%):** 45 (5) **Serious adverse events, n:** 72 **Discontinued due to AE, n (%):** 73 (9) **Reduced dosage to 1 mg b.i.d., n (%):** 108 (13)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Appell, Sand et al., 2001 **Country and setting:** US, 37 sites **Enrollment period:** March 2000 to October 2000 **Funding:** ALZA Corp **Author industry relationship disclosures:** 12 of 12 ALZA (12) Pharmacia (9)	**Design:** RCT stratified by UUI severity (mild ≤ 21/wk, or moderate >21/wk) **Intervention:** Oxybuynin ER vs Tolterodine **Groups:** **G1:** Oxybutynin ER 10 mg **G2:** Tolterodine 4mg (2mg b.i.d.) **N at enrollment:** **G1:** 185 **G2:** 193 **N at follow-up:** **G1:** 160 **G2:** 172 **Women, %:** **G1:** 82 **G2:** 85 **Age, mean ± SD:** **G1:** 58.6 ± 13.4 **G2:** 59.6 ± 13.2 **Race/ethnicity, %:** **White:** **G1:** 87.6 **G2:** 86.0 **Black:** **G1:** 5.4 **G2:** 6.7 **Hispanic:** **G1:** 3.8 **G2:** 5.2 **Asian:** **G1:** 2.2 **G2:** 1.6 **Other:** **G1:** 1.1 **G2:** 0.5 **Follow-up:** 12 week	**Inclusion criteria:** • 7-50 urge urinary incontinence episodes per week • ≥ 10 voids/day • Majority of leakage urge-related **Exclusion criteria:** • Non-OAB cause for incontinence • Delivered baby < 6 mos prior • PVR >150 mL • Significant medical comorbidities • Decreased hepatic function • Renal impairment • Myasthenia gravis • Gastroparesis • Hematuria • Narrow-angle glaucoma • POP to hymen • Known allergy • Pregnant or lactating	**UUI episodes/ week, mean ± SD:** **G1:** 25.5 ± 14.6 **G2:** 24.6 ± 15.1 *P* = 0.36 **Incontinence episodes/week, mean ± SD:** **G1:** 28.4 ± 17.8 **G2:** 28.0 ± 18.3 *P* = 0.62 **Voids/week, mean ± SD:** **G1:** 92.9 ± 23.0 **G2:** 91.8 ± 20.0 *P* = 0.77 **Received antimuscarinic med before study, n (%):** **G1:** 75 (40.5) **G2:** 73 (37.8)	**UUI episodes/ week, mean ± SD (95% CI):** **G1:** 6.1 ± 9.7 (4.4, 7.3) **G2:** 7.8 ± 11.1 (6.7, 9.5) *P* = 0.03 **Incontinence episodes/week, mean ± SD (95% CI):** **G1:** 7.1 ± 12.0 (5.2, 8.6) **G2:** 9.3 ± 13.4 (8.0, 11.3) *P* = 0.02 **Voids/week, mean ± SD (95% CI):** **G1:** 67.1 ± 22.1 (64.6, 70.0) **G2:** 71.5 ± 20.5 (69.1, 74.2) *P* = 0.02 **Discontinuation due to AE, n (%):** **G1:** 14 (7.6) **G2:** 15 (7.8) *P* > 0.99 **Dry mouth, n (%):** **G1:** 52 (28.1) **G2:** 64 (33.2) **Constipation, n (%):** **G1:** 13 (7) **G2:** 12 (6.2) **Impaired urination/ retention, n (%):** **G1:** 6 (3.2) **G2:** 6 (3.1) *P* ≥ 0.99 **Blurred vision, n (%):** **G1:** 4 (2.2) **G2:** 2 (1.0) *P* = 0.44 **Dizziness, n (%):** **G1:** 9 (4.9) **G2:** 8 (4.1) *P* = 0.81	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Appell, Sand et al., 2001 (continued)				**Somnolence, n (%):** **G1:** 8 (4.3) **G2:** 3 (1.6) *P* = 0.13 **Asthenia, n (%):** **G1:** 3 (1.6) **G2:** 7 (3.6) *P* = 0.34 **Insomnia, n (%):** **G1:** 1 (0.5) **G2:** 3 (1.6) *P* = 0.62 **Headache, n (%):** **G1:** 15 (8.1) **G2:** 17 (8.8) *P* = 0.86 **Dyspepsia, n (%):** **G1:** 11 (5.9) **G2:** 10 (5.2) *P* = 0.82 **Nausea, n (%):** **G1:** 6 (3.2) **G2:** 3 (1.6) *P* = 0.33 **Vomiting, n (%):** **G1:** 3 (1.6) **G2:** 3 (1.6) *P* > 0.99	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Arruda et al., 2008 **Country and setting:** Brazil, community **Enrollment period:** August 2001 to September 2005 **Funding:** NR **Author industry relationship disclosures:** None	**Design:** RCT **Intervention:** Oxybutynin vs. functional electrostimulation vs. pelvic floor training **Groups:** **G1:** Oxybutynin 5 mg b.i.d. **G2:** Ambulatory stimulation applied vaginally **G3:** Pelvic floor exercises with a therapist and at home **N Screened:** 81 **N at enrollment:** **G1**: 22 **G2:** 21 **G3:** 21 **N at follow-up:** **G1**: 22 **G2:** 21 **G3:** 21 **Age, range:** 35-80 **Race/ethnicity:** NR **Women, %:** 100 **Length of follow up:** 12 weeks	**Inclusion criteria:** • Community-dwelling • Dx of OAB and DO • Capable of completing a bladder diary and performing a pelvic muscle floor contraction • For those with MUI, urge was predominant **Exclusion criteria:** • Hx of psychiatric or neurologic illness • Persistent UTI • Inability to comply with regular follow-up visits • Current pregnancy • Postvoid residual volume > 100 ml • Contraindications to anticholinergic therapy • Cardiac pacemaker • Type III SUI • Uncontrolled metabolic conditions or indwelling catheterization • Using medications including anticholinergic drugs, calcium antagonists, beta agonists, dopamine agonists, striated muscle relaxants or estrogens • Any uterine prolapsed	**UUI episodes/ week, mean ± SD:** **G1:** 13.8 ± 11.6 **G2:** 13.5 ± 15.6 **G3:** 16.4 ± 17.2 **Nocturia episodes/week, mean ± SD:** **G1:** 1.7 ± 1.5 **G2:** 1.9 ± 1.9 **G3:** 1.4 ± 1.2 **Pads/day, mean ± SD:** **G1:** 2.6 ± 2.7 **G2:** 2.3 ± 2.4 **G3:** 2.7 ± 1.5 **Voids/day, mean ± SD:** **G1:** 7.7 ± 2.6 **G2:** 8.6 ± 3.4 **G3:** 6.8 ± 2.2 **Residual volume mean mL ± SD:** **G1:** 3.2 ± 6.3 **G2:** 1.0 ± 2.6 **G3:** 1.8 ± 3.3 **Volume, first desire to void, mean mL ± SD:** **G1:** 117.7 ± 68.9 **G2:** 102.4 ± 51.1 **G3:** 86.7 ± 38.9 **Maximal cystometric capacity, mean mL ± SD:** **G1:** 410.4 ± 194.1 **G2:** 350.0 ± 212.9 **G3:** 424.0 ± 149.0	**UUI episodes/ week, mean ± SD:** **G1:** 7.0 ± 10.6 **G2:** 7.9 ± 13.7 **G3:** 7.8 ± 15.3 **G1/BL:** *P* = 0.007 **G2/BL:** *P* = 0.039 **G3/BL:** *P* = 0.035 **Urgency resolved, n (%):** **G1:** 14 (63.6) **G2:** 11 (52.4) **G3:** 12 (57.1) *P* = 0.754 **Satisfied, n (%):** **G1:** 17 (77.3) **G2:** 11 (52.4) **G3:** 16 (76.2) *P* = 0.142 **Nocturia episodes/week, mean ± SD:** **G1:** 0.9 ± 0.8 **G2:** 1.2 ± 1.3 **G3:** 1.0 ± 1.1 **G1/BL:** *P* = 0.003 **G2/BL:** *P* = 0.036 **G3/BL:** *P* = 0.086 **Pads/day, mean ± SD:** **G1:** 0.9 ± 1.5 **G2:** 0.9 ± 1.7 **G3:** 0.8 ± 1.3 **G1/BL:** *P* < 0.001 **G2/BL:** *P* = 0.004 **G3/BL:** *P* < 0.001 **Voids/day, mean ± SD:** **G1:** 6.4 ± 1.6 **G2:** 7.9 ± 2.3 **G3:** 7.1 ± 2.1 **G1/BL:** *P* = 0.014 **G2/BL:** *P* = 0.291 **G3/BL:** *P* = 0.441 **Residual volume, mean mL ± SD:** **G1:** 4.7 ± 9.4 **G2:** 1.1 ± 2.5 **G3:** 2.1 ± 3.5 **G1/BL:** *P* = 0.425 **G2/BL:** *P* = 0.760 **G3/BL:** *P* = 0.297	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Method and blinding: - Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: + Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: + Measurement methods: - Measurement reliability: - Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Arruda et al., 2008 (continued)			**Involuntary detrusor contraction volume mean mL ± SD:** **G1:** 189.5 ± 114.1 **G2:** 220.0 ± 127.2 **G3:** 239.3 ± 163.0 **Involuntary detrusor contraction maximal pressure (mm H_20):** **G1:** 39.4 ± 26.1 **G2:** 43.7 ± 22.9 **G3:** 34.2 ± 19.8	**Volume first desire to void, mean mL ± SD:** **G1:** 157.3 ± 63.8 **G2:** 123.8 ± 59.0 **G3:** 137.6 ± 76.7 **G1/BL:** *P* = 0.019 **G2/BL:** *P* = 0.091 **G3/BL:** *P* = 0.017 **Maximal cystometric capacity mean mL ± SD:** **G1:** 517.3 ± 191.7 **G2:** 436.6 ± 178.7 **G3:** 489.0 ± 141.3 **G1/BL:** *P* = 0.001 **G2/BL:** *P* = 0.017 **G3/BL:** *P* = 0.113 **Involuntary detrusor contraction volume (mL):** **G1:** 188.6 ± 183.2 **G2:** 73.3 ± 112.4 **G3:** 114.3 ± 154.2 **G1/BL:** *P* = 0.986 **G2/BL:** *P* = 0.001 **G3/BL:** *P* = 0.044 **Involuntary detrusor contraction maximal pressure, mm H_20 ± SD:** **G1:** 19.6 ± 20.9 **G2:** 22.4 ± 30.1 **G3:** 17.2 ± 25.5 **G1/BL:** *P* < 0.001 **G2/BL:** *P* = 0.002 **G3/BL:** *P* = 0.027 **Normal urodynamic evaluation, n (%):** **G1:** 8 (36.4) **G2:** 12 (57.1) **G3:** 11 (52.4) *P* = 0.358 **Persistent improvement at 1 year:** **G1:** 10/17 **G2:** 4/11 **G3:** 9/16	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Arruda et al., 2008 (continued)				**Dry mouth, n (%):** **G1:** 16 (72.7) **G2:** 0 **G3:** 0 **Difficulty voiding, n (%):** **G1:** 2 (9.1) **G2:** 0 **G3:** 0 **Dizziness, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0 **Blurred vision, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0 **Constipation, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0 **Dry mouth, n (%):** **G1:** 16 (72.7) **G2:** 0 **G3:** 0 **Difficulty voiding, n (%):** **G1:** 2 (9.1) **G2:** 0 **G3:** 0 **Dizziness, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0 **Blurred vision, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0 **Constipation, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Barkin et al., 2004 **Country and setting:** Canada, Community **Enrollment period:** NR **Funding:** Purdue Pharma **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Oxybutynin CR versus Oxybutynin IR 3 week washout period followed by 2 weeks of dose titration plus 4 weeks stable dose period **Groups:** **G1:** Oxybutynin CR 15 mg daily **Final titration dose, n (%):** 5 mg: 3 (6) 10mg: 10 (19) ≥ 15mg: 40 (75) **G2:** Oxybutynin IR 5 mg t.i.d. **Final titration dose, n (%):** 5 mg: 6 (15) 10mg: 14 (34) ≥ 15mg: 21 (51) **N at enrollment:** **G1:** 65 **G2:** 60 **N at follow-up:** **G1:** 53 **G2:** 41 **Women, n (%):** **G1:** 48 (91) **G2:** 37 (90) **Age, yrs ± SD:** **G1:** 58.0 ± 12.4 **G2:** 60.6 ± 14.8 **Race/ethnicity:** NR	**Inclusion criteria:** • Age ≥ 18 • ≥ 7 UUI/week during washout period • ≥ 8 voids/day during washout period **Exclusion criteria:** • PVR> 100mL • Unstable dosage of any drug with anticholinergic or diuretic/ antidiuretic side effects • Allergy or previous life threatening side effects with anticholinergic/ antispasmodic meds • SUI • Conditions contraindicating anticholinergic therapy • Daily fluid intake > 3 liters • Hepatic/ renal disease • IC/ painful bladder syndrome • Urinary retention • Hematuria • UTI • Recurrent UTI • Indwelling catheter • Bladder training within 14 days of screening • Drug/ alcohol abuse • Untreated psychiatric disease effecting completion of bladder diary	**Purdue Urgency Questionnaire, frequency, mean score ± SD:** **G1:** 3.3 ± 1.1 **G2:** 3.2 ± 0.9 **Purdue Urgency Questionnaire, severity, mean score ± SD:** **G1:** 3.8 ± 1.1 **G2:** 3.7 ± 1.1 **Incontinence episodes/week, mean ± SD:** **G1:** 24.3 ± 19.0 **G2:** 23.0 ± 17.7 **Pads/day, mean:** **G1:** 2.3 **G2:** 2.4 **Voids/day, mean ± SD:** **G1:** 11.4 ± 2.9 **G2:** 11.0 ± 3.1 **Voided volume (mL), mean ± SD:** **G1:** 177 ± 77 **G2:** 221 ± 137 **Fluid intake (cups/day), mean:** **G1:** 6.8 **G2:** 6.6 **IIQ, mean score ± SD:** **G1:** 2.6 ± 0.8 **G2:** 2.3 ± 0.8 **UDI, mean score ± SD:** **G1:** 2.6 ± 0.6 **G2:** 2.5 ± 0.4	**Purdue Urgency Questionnaire, frequency, mean ± SD:** **G1:** 2.3 ± 1.2 **G2:** 1.9 ± 0.9 **G1/G2:** *P* = 0.116 **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **Purdue Urgency Questionnaire, severity, mean ± SD:** **G1:** 2.3 ± 1.0 **G2:** 2.3 ± 1.3 **G1/G2:** *P* = 0.255 **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **Incontinence episodes/ week, mean ± SD:** **G1:** 10.4 ± 18.8 **G2:** 6.1 ± 8.8 **G1/G2:** *P* = 0.404 **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **Pads/day, mean:** **G1:** 1.7 **G2:** 1.9 **G1/G2:** *P* = NS **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **Voids/day, mean ± SD:** **G1:** 9.6 ± 2.6 **G2:** 8.6 ± 2.8 **G1/G2:** *P* = 0.286 **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **Voided volume (mL), mean ± SD:** **G1:** 202 ± 80 **G2:** 261 ± 119 **G1/G2:** *P* = 0.533 **G1/BL:** *P* = 0.064 **G2/BL:** *P* = 0.077	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Barkin et al., 2004 (continued)		• Untreated constipation • BOO • Pregnant or breast feeding • Women using reliable method of birth control		**Fluid intake (cups/day), mean:** **G1:** 7.0 **G2:** 7.7 **G1/G2:** *P* = NS **G1/BL:** *P* = NS **G2/BL:** *P* = 0.032 **IIQ score, mean ± SD:** **G1:** 1.9 ± 1.7 **G2:** 1.6 ± 0.6 **G1/G2:** *P* = NS **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **UDI scores, mean ± SD:** **G1: 2.0 ± 0.6** **G2: 1.8 ± 0.5** **G1/G2:** *P* = NS **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **Dry mouth, overall, n (%):** **G1:** 44 (68) **G2:** 43 (72) **Dry mouth, moderate/ severe, n (%):** **G1:** 25 (38) **G2:** 27 (45) **Dry throat, n (%):** **G1:** 23 (35) **G2:** 24 (40) **Dry skin, n (%):** **G1:** 11 (17) **G2:** 7 (12) **Diarrhea, n (%):** **G1:** 9 (14) **G2:** 3 (5) **Headache, n (%):** **G1:** 8 (12) **G2:** 13 (22) **UTI, n (%):** **G1:** 8 (12) **G2:** 11 (18) **Dizziness, n (%):** **G1:** 7 (11) **G2:** 11 (18)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Barkin et al., 2004 (continued)				**Dyspepsia, n (%):** **G1:** 7 (11) **G2:** 10 (17) **Rhinitis, n (%):** **G1:** 7 (11) **G2:** 9 (15) **Abdominal pain, n (%):** **G1:** 6 (9) **G2:** 6 (10) **Asthenia, n (%):** **G1:** 5 (18) **G2:** 9 (15) **Constipation, n (%):** **G1:** 5 (8) **G2:** 6 (10) **Taste perversion, n (%):** **G1:** 5 (8) **G2:** 7 (12) **Cough increased, n (%):** **G1:** 4 (6) **G2:** 8 (13) **Dysphagia, n (%):** **G1:** 4 (6) **G2:** 8 (13) **Dry eyes, n (%):** **G1:** 2 (3) **G2:** 9 (15) **Nausea, n (%):** **G1:** 3 (5) **G2:** 10 (17) **Discontinued due to AEs, n (%):** **G1:** 11 (17) **G2:** 12 (20)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Bemelmans et al., 2000 **Country and setting:** Netherlands, Primary Care **Enrollment period:** May 1995 to September 1997 **Funding:** Byk Nederland (Distributor Oxybutynin) **Author industry relationship disclosures:** NR	**Design:** Prospective case series **Intervention:** Oxybutynin Run in study with all subjects enrolled in G1 with assessment at 2 wks treatment with diary followed by movement to G2 if effect was unsatisfactory or capable of improvement Tx x 4 more wks followed by voiding diary. **Groups:** **G1:** Responders to oxybutynin 2.5 mg t.i.d. **G2:** Non responders to oxybutynin 2.5 mg t.i.d. increased to xybutynin 5 mg t.i.d. **N at enrollment:** Total: 416 **G1:** 320 **G2:** 96 **N at follow-up:** 350 **Women, N (%):** 346 (83.2) **Age, mean (range):** 61.3 (16.4-91.5) **Race/ethnicity:** NR	**Inclusion criteria:** • Complaint of involuntary urine loss • Score of ≥ 14 on symptom score questionnaire indicating UUI (determined by unvalidated questionnaire) **Exclusion criteria:** • Age ≤ 15 • Concurrent use of bladder medication • Urinary retention • Hematuria • UTI • SUI	**Incontinence episodes/day, mean ± SD:** **G1:** 5.6 ± 3.5 **G2:** 7.2 ± 3.9 **Voids/day, mean ± SD:** **G1:** 9.6 ± 3.5 **G2:** 11.1 ± 3.9	**Incontinence episodes/day, mean ± SD:** **G1:** 1.5 ± 1.5 **G2:** 2.3 ± 2.3 **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **Voids/day, mean ± SD:** **G1:** 5.8 ± 2.3 **G2:** 6.8 ± 2.9 **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **Side effects, n (%):** **G1:** 83 (26) **G2:** 40 (42) **Severity of side effects, %:** Mild: 72 Severe: 21 Extremely severe: 4 **Side effects, %:** Dry mouth: 23 Blurred vision: 11 Nausea/ vomiting: 6 Dizziness: 6 Headache: 6 Anorexia: 3 Constipation: 3 Drowsiness: 3 Tachycardia: 1 Urinary retention: <1 Allergic Reaction: <1 **Discontinued due to AEs, n (%):** 66 (16)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: - Measurement methods: + Measurement reliability: - Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Boone et al., 2002 **Country and setting:** US, Multicenter (86.0% of physicians in private-practice) **Enrollment period:** NR **Funding:** Alza Pharmaceuticals **Author industry relationship disclosures:** NR	**Design:** Prospective observational **Intervention:** Non-specific/non-specified pharmacologic therapy **Groups:** **G1:** persons who started drug therapy (any) at baseline and continued therapy for ≥ 3 mos **G2:** persons who started drug therapy (any) at baseline but did not continue for 3 mos **G3:** persons who did not start drug therapy at baseline but were receiving it at 3 mos **G4:** persons who did not start drug therapy at baseline and were not receiving therapy at 3 mos **G5:** persons who were on drugs at 3 mos and 6 mos **G6:** persons who were on drugs at 3 mos and not at 6 mos **G7:** persons who were on not drugs at 3 mos and on drug at 6 mos **G8:** persons on no drugs at 3 mos and 6 mos **N at enrollment:** Total: 213	**Inclusion criteria:** • Age ≥ 18 • Fluent in English • US resident • Urgency and ≥ 1 incontinence episodes/day • ≥ 8 voids/day • ≥ 3 nocturia episodes/day **Exclusion criteria:** • Neurogenic condition causing incontinence • Persistent or recurrent UTI • History of interstitial cystitis • Bladder cancer • Previous bladder augmentation surgery • Spinal injury • Alzheimer's disease • Other dementia • Obstruction of urinary tract • Primary diagnosis of SUI • Enrolled in another study involving medication • Pharmacologic treatment for OAB during previous year	**Incontinence episodes/day, mean ± SD:** Total: 2.2 ± 3.4 **G1-G2:** 2.34 **G3-G4:** 2.09 **Duration of symptoms (yrs), mean ± SD:** Total: 8.1 ± 10.3 **G1-G2:** 8.5 ± 12.0 **G3-G4:** 7.8 ± 9.1 **Symptom severity, n (%):** Mild: **G1-G2:** 11 (22.0) **G3-G4:** 18 (25) Moderate **G1-G2:** 26 (52.0) **G3-G4:** 43 (59.7) Severe **G1-G2:** 13 (26.0) **G3-G4:** 11 (15.3) **Symptom severity worsening, n (%):** **G1-G2:** 28 (56.0) **G3-G4:** 37 (51.4) **U-UDI score, mean ± SD:** **G1-G2:** 1.99 ± 0.79 **G3-G4:** 1.99 ± 0.88 **Non-drug interventions, mean ± SD:** **G1-G2:** 0.40 ± 0.49 **G3-G4:** 0.47 ± 0.65 **Pads/week, mean ± SD:** **G1-G2:** 0.30 ± 1.34 **G3-G4:** 0.17 ± 0.56	**Improvement in OAB sx, 3 mos, n (%):** **G1:** 30 (76.9) **G2:** 7 (63.6) **G3:** 10 (52.6) **G4:** 19 (35.8) **G1-G2/G3-G4:** *P* < 0.001 **Moderate to great improvement in OAB sx, n (%):** **G1-G2:** 26 (52.0) **G3-G4:** 21 (29.2) **G1-G2/G3-G4:** *P* = 0.014 **Pads/week, 3 mos, mean % change:** **G1-G2:** -25.4 **G3-G4:** 135.2 **Physician visits, mean:** **G1:** 0.15 **G2:** 0.64 **G3:** 1.16 **G4:** 0.26 **G1-G2/G3-G4:** *P* = 0.096 **Patients pre-scribed nondrug intervention(s), 3 mos, n (%):** **G1-G2:** 5 (10.0) **G3-G4:** 16 (22.2) **G1-G2/G3-G4:** *P* = 0.092 **Patients with improvement in OAB sx, 4-6 mos, n (%):** **G5:** 35 (81.4) **G6:** 1 (12.5) **G7:** 2 (28.6) **G8:** 12 (28.6) **Pads/week, 4-6 mo, % change:** **G5:** 23 **G6:** 25 **G7:** 0 **G8:** 16	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: NR Baseline characteristics: - Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: -

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Boone et al., 2002 (continued)	**N at follow-up:** **G1:** 39 **G2:** 11 **G3:** 19 **G4:** 53 **G5:** 43 **G6:** 8 **G7:** 7 **G8:** 42 **Women, n (%):** **G1-G2:** 40 (80) **G3-G4:** 64 (88.9) **Age, mean ± SD:** **G1-G2:** 62.3 ± 11.9 **G3-G4:** 60.3 ± 16.4 **Race/ethnicity, n (%):** White: 94 (77.7) Black: 17 (14.0) Hispanic: 7 (5.8) Asian: 2 (1.7) Other: 1 (0.8)			**Physician visits, 4-6 mo, mean:** **G5:** 0.16 **G6:** 0.38 **G7:** 0.43 **G8:** 0.05 **Predictors of OAB symptom improvement, OR (95 %CI):** Rx at baseline: 4.3 (1.8-9.9) Incontinence episodes/day: 3.2 (1.2-8.4)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Burgio et al., 1998 **Country and setting:** US, academic health center outpatient geriatric medicine clinic **Enrollment period:** July 1989 to August 1995 **Funding:** National Institutes on Aging **Author industry relationship disclosures:** NR	**Design:** RCT, placebo controlled Computer-generated random numbers using a block size of 6, w/ prior stratification by type and severity of incontinence **Intervention:** Biofeedback-assisted behavioral vs. drug treatment (oxybutynin chloride; possible range of doses 2.5 mg/d-5.0 mg t.i.d.) vs. placebo All patients had 4 visits over an 8-week period. Patients in G1 had biofeedback added to behavioral training in absence of 50% improvement by session 3. **Groups:** **G1:** Behavioral ± biofeedback **G2:** Pharmacologic **G3:** Placebo **N at enrollment:** 468 screened 271 not eligible 197 randomized **G1:** 65 **G2:** 67 **G3:** 65 **N at follow-up:** **G1:** 61 **G2:** 55 **G3:** 53	**Inclusion criteria:** • Community-dwelling women at least age 55 • Ambulatory • At least 2 urge accidents per week by baseline bladder diary • Urge incontinence as predominant pattern • Urodynamic evidence of bladder dysfunction **Exclusion criteria:** • Continual leakage • Postvoid residual urine volume >200mL • Uterine prolapse past the introitus • Narrow-angle glaucoma • Unstable angina • Decompensated congestive heart failure • Hx of malignant arrhythmias • MMSE <20 (Dementia)	**Duration of symptoms, mean yrs ± SD:** **G1:** 9.4 ± 10.8 **G2:** 9.8 ± 11.9 **G3:** 12.7 ± 15.9 **Restricted activity, (%):** **G1:** 30.8 **G2:** 32.8 **G3:** 38.5 **UUI only, %:** **G1:** 49.2 **G2:** 49.3 **G3:** 47.7 **Accidents per week, mean ± SD:** **G1:** 15.8 ± 14.5 **G2:** 15.9 ± 14.1 **G3:** 15.4 ± 13.4 *P* = .98 **Severity classification, %:** Mild (<5 accidents/wk) **G1:** 18.5 **G2:** 17.9 **G3:** 18.5 Moderate (5-10 accidents/wk) **G1:** 29.2 **G2:** 29.9 **G3:** 27.7 Severe (>10 accidents/wk) **G1:** 52.3 **G2:** 52.2 **G3:** 53.8 **Previous treatment with surgery, %:** **G1:** 20.0 **G2:** 26.9 **G3:** 29.2	**Accidents per week, mean ± SD:** **G1:** 2.8 ± 4.7 **G2:** 5.7 ± 9.8 **G3:** 8.2 ± 11.6 *P* = .005 **Percent reduction, mean ± SD:** **G1:** 80.7 ± 24.8 **G2:** 68.5 ± 37.2 **G3:** 39.4 ± 80.0 *P* < 0.001 **Percent reduction, range:** **G1:** -0.9 – 100 **G2:** -85.7 – 100 **G3:** -400.0 - 100 **Patient perceptions of progress in treatment, %:** Much better **G1:** 74.1 **G2:** 50.9 **G3:** 226.9 Better: **G1:** 25.9 **G2:** 30.9 **G3:** 38.5 About the same: **G1:** 0.0 **G2:** 16.4 **G3:** 28.8 Worse: **G1:** 0.0 **G2:** 1.8 **G3:** 5.8 **Estimate of % improvement, mean ± SD:** **G1:** 81.6 ± 18.6 **G2:** 66.4 ± 35.4 **G3:** 45.1 ± 36.6 **Having fewer accidents, %:** **G1:** 100.0 **G2:** 87.3 **G3:** 67.3	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al., 1998 (continued)	**Women, %:** 100 **Age, yrs ± SD:** **G1:** 67.3 ± 7.6 **G2:** 68.2 ± 7.5 **G3:** 67.6 ± 7.6 **Race/ethnicity,:** NR **Parity mean ± SD:** **G1:** 2.8 ± 2.0 **G2:** 2.1 ± 1.4 **G3:** 2.7 ± 1.8 **P < 0.05**		**Previous treatment with medication, %:** **G1:** 27.7 **G2:** 35.8 **G3:** 30.8 **Using estrogen, %:** **G1:** 32.3 **G2:** 38.8 **G3:** 35.4 **Using diuretics, %:** **G1:** 20.0 **G2:** 14.9 **G3:** 12.3	**Accidents are smaller, %:** **G1:** 87.3 **G2:** 78.8 **G3:** 54.0 **Able to wear less protection, %:** **G1:** 76.0 **G2:** 56.0 **G3:** 334.1 **Comfortable enough with treatment to continue indefinitely, %:** **G1:** 96.5 **G2:** 54.7 **G3:** 43.1 **Patient satisfaction with progress, %:** Completely satisfied: **G1:** 77.6 **G2:** 54.7 **G3:** 43.1 Somewhat satisfied: **G1:** 22.4 **G2:** 40.0 **G3:** 34.0 Not at all satisfied: **G1:** 0.0 **G2:** 10.9 **G3:** 38.0 **Wish to receive another form of treatment, %:** **G1:** 14.0 **G2:** 75.5 **G3:** 75.5 *P* < 0.001 for all comparisons **Adverse effects, p compared to placebo G3:** **Dry mouth, %:** **G1:** 34.9 **G2:** 96.9 **G3:** 54.8 *P* < 0.001	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al., 1998 (continued)				**Inability to void, %:** **G1:** 6.3 **G2:** 21.5 **G3:** 3.2 *P* = 0.002 **Constipation, %:** **G1:** 22.2 **G2:** 38.5 **G3:** 37.1 *P* = 0.10 **Blurred vision, %:** **G1:** 9.5 **G2:** 15.4 **G3:** 9.7 *P* = 0.50 **Confusion, %:** **G1:** 6.3 **G2:** 7.7 **G3:** 11.3 *P* = 0.59	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Burgio et al. 2000 [See Burgio et al., 1998] **Country and setting:** US, University based **Enrollment period:** two weeks after completion of Burgio et al. 1998 **Funding:** National Institute on Aging **Author industry relationship disclosures:** NR	**Design:** Modified crossover of RCT **Intervention:** Participants whose treatment was not completely successful were given the opportunity to switch or use combined treatment; further reductions in incontinence were measured. **Groups:** Treatment Changes: **G1:** Previous oxybutynin to behavioral modification alone **G2:** Previous behavior alone to 2.5 mg oxybutynin t.i.d. + behavioral therapy **G3:** Previous oxybutynin alone to 2.5 mg oxybutynin t.i.d. + behavioral therapy **G4:** Placebo to behavioral **G5:** Placebo to oxybutynin **N at enrollment** **G1:** 19 **G2:** 8 **G3:** 27 **G4:** 34 **G5:** 10 **N at follow-up:** **G1:** 18 **G2:** 8 **G3:** 26 **G4:** NR **G5:** NR	**Inclusion criteria:** • Community-dwelling women at least age 55 • Ambulatory • At least 2 urge accidents per week by baseline bladder diary • Urge incontinence as predominant pattern • Urodynamic evidence of bladder dysfunction • Not completely dry or satisfied with previous, 8-wk treatment **Exclusion criteria:** • Continual leakage • Postvoid residual urine volume >200mL • Uterine prolapse past the introitus • Narrow-angle glaucoma • Unstable angina • Decompensated congestive heart failure • Hx of malignant arrhythmias • MMSE <20 (Dementia)	**Incontinence, after previous study (at baseline), mean % reduction:** **G1:** 59.1 **G2:** 57.5 **G3:** 72.7 **G4:** 22.9 **G5:** 44.8	**Incontinence, final mean % reduction:** **G1:** 77.1, *P* = 0.109 **G2:** 88.5, *P* = 0.034 **G3:** 84.3 *P* = 0.001 **G4:** 63.9 *P* = 0.002 **G5:** 76.5 *P* = 0.012 **Note:** 29.2 of G3 declined to continue with drug therapy once they received behavioral modification. Numbers were too low to compare across groups.	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Burgio et al., 2001 [See Burgio et al,. 1998] **Country and setting:** US, University based **Enrollment period:** [See Burgio et al,. 1998] **Funding:** NIH **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Psychological distress associated with pharmacologic treatment vs. behavioral vs. placebo **Groups:** G1: Behavioral training with biofeedback, 4 visits G2: Oxybutynin 2.5 mg po t.i.d., up to a max of 5 mg t.i.d. G3: Placebo **N at enrollment:** 197 women **N treated:** 169 **N at follow-up:** 155 (completed both pre and post-treatment psychological assessment) **Age yrs, mean ± SD:** 67.5 ± 7.2 **Women, %:** 100 **Race/ethnicity, %:** White: 97 African American: 3	**Inclusion criteria:** • ≥ 55 yrs old • Ambulatory • UUI ≥2x/wk (2 wk bladder diary), persisting x 3 mo • Predominant UUI (vs. other forms incontinence) • Urodynamic evidence of bladder dysfunction (DI or maximal capacity ≤350 mL) • **Exclusion criteria:** • Contraindication to oxybutynin or behavioral treatment • Continual leakage • PVR > 200 mL • Uterine prolapse beyond the introitus • Decompensated CHF • Hx of malignant arrhythmias • Impaired mental status (MMSE <20)	**SCL-90-R scores ± SD:** Somatization G1: 56.0 (10.6) G2: 51.4 (10.8) G3: 52.4 (11.1) Obsessive-Compulsive: G1: 56.5 (10.7) G2: 56.6 (11.4) G3: 57.7 (10.0) Interpersonal Sensitivity G1: 53.8 (11.0) G2: 51.4 (11.9) G3: 50.4 (12.0) Depression G1: 54.7 (10.0) G2: 52.5 (9.7) G3: 51.0 (11.9) Anxiety G1: 48.7 (13.9) G2: 46.8 (12.0) G3: 47.2 (12.8) Hostility G1: 49.3 (10.7) G2: 45.9 (10.1) G3: 48.3 (10.4) Phobia G1: 47.5 (10.2) G2: 46.7 (10.3) G3: 45.7 (8.5) Paranoid Ideation G1: 48.6 (12.4) G2: 49.3 (11.1) G3: 46.1 (12.8) Psychoticism G1: 54.1 (10.7) G2: 52.1 (10.3) G3: 50.5 (11.2) Global Severity G1: 54.2 (11.1) G2: 52.5 (10.3) G3: 52.4 (11.2)	**Reduction in incontinence episodes:** G1: 83.3% G2: 74.4% G3: 41.4% P<0.001 **SCL-90-R scores ± SD:** Somatization G1: 51.8 (11.4) G2: 51.2 (9.8) G3: 49.8 (13.0) Obsessive-Compulsive: G1: 53.8 (13.9) G2: 53.9 (10.9) G3: 55.4 (11.0) Interpersonal Sensitivity G1: 49.5 (12.0) G2: 48.9 (11.2) G3: 49.2 (11.3) Depression G1: 51.5 (11.5) G2: 50.6 (10.7) G3: 51.4 (11.2) Anxiety G1: 46.1 (14.6) G2: 44.5 (12.3) G3: 45.8 (12.9) Hostility G1: 44.9 (10.8) G2: 44.6 (10.5) G3: 47.3 (11.2) Phobia G1: 47.1 (11.2) G2: 45.0 (8.3) G3: 45.1 (8.5) Paranoid Ideation G1: 45.8 (10.9) G2: 47.2 (11.6) G3: 47.2 (12.0) Psychoticism G1: 49.2 (11.7) G2: 50.4 (9.7) G3: 49.6 (10.3) Global Severity G1: 50.8 (12.8) G2: 50.4 (10.0) G3: 51.4 (10.9)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Methods and blinding: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al., 2001 (continued)			155 participants were compared to the 42 who did not complete intervention and psychological assessment, higher scores (greater distress) on 6 of 10 SCL-90-R scales (somatization, obsessive/compulsive, depression, hostility, paranoid ideation, global severity index), all p values <0.05 Normal range, score 0-63 >75% in normal range (including dropouts) on 9 of 10 scales Highest impairment rate: 33% scored abnormal for obsessive-compulsive	**Correlations between reduction of incontinence and changes in psychological symptoms** Somatization G1: 0.28* G2: -0.09 G3: 0.17 Obsessive-Compulsive G1: 0.01 G2: -0.14 G3: 0.02 Interpersonal Sensitivity G1: -0.09 G2: 0.04 G3: 0.13 Depression G1:-0.04 G2: 0.03 G3: 0.07 Anxiety G1: -0.10 G2: -0.01 G3: 0.34* Hostility G1: -0.10 G2: 0.09 G3: 0.11 Phobic anxiety G1:-0.21 G2: -0.17 G3: 0.02 Paranoid Ideation G1: 0.14 G2: -0.04 G3: -0.06 Psychoticism G1: -0.01 G2: -0.01 G3: 0.13 ***P=0.001	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al., 2001 (continued)				Global Severity Index G1: 0.01 G2: 0.06 G3: 0.45*** *p<0.05	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Burgio et al., 2008 **Country and setting:** US, Academic medical centers **Enrollment period:** July 2004 to January 2006 **Funding:** NIH Pfizer **Author industry relationship disclosures:** 20 of 29 Allergan (3) Alza (1) Astellas Pharma (7) Bionovo (1) Bristol-Meyers Squibb (1) Dynogen (1) Elan (1) Ethicon (2) GSK (4) Johnson & Johnson (3) Lilly (7) Medtronic (1) Merck (1) Novartis (6) Ortho-McNeil (3) Pfizer (>10) Procter & Gamble (3) Q-Med (1) Renessa (1) Sanofi (1) Solace (1) Watson (1)	**Design:** RCT **Intervention:** Pharmacologic vs. pharmacologic plus behavioral interventions for 10 wks (Stage 1), followed by no drug therapy (Stage 2) with assessments at 10 wks and 8 mos* **Groups:** **G1:** Tolterodine tartrate (ER capsules), 4 mg/d plus behavioral training: pelvic floor muscle control and exercises, behavioral strategies to diminish urgency, suppress bladder contractions and prevent both stress and urge incontinence; delayed voiding; fluid management; handout with hints **G2:** Tolterodine tartrate (ER capsules), 4 mg/d **N at enrollment:** 4043 screened 2612 not eligible 870 declined 561 consented 254 excluded 307 randomized **G1:** 153 **G2:** 154	**Inclusion criteria:** • Women • Community-dwelling • UUI only, or urge-predominant • ≥ 7 episodes of incontinence in a 7-day bladder diary • Persistent incontinence for at least 3 mos • No current use of antimuscarinics or other medications that could affect UI • No evidence of neurogenic etiology **Exclusion criteria:** • Age < 21 • Pregnant, planning a pregnancy in next 8 mos, or not using birth control • < 6 mos postpartum or termination after 20 wks gestation • Unable to contract pelvic floor muscles during evaluation • Behavioral therapy of > 2 mos in past 2 yrs • Continual leakage or always damp • Hypersensitive to study drug • Systemic disease that affects bladder function	**UUI, 7-13 episodes/week, n (%):** **G1:** 2 (1.3) **G2:** 2 (1.3) **UUI, ≥ 14 episodes/week, n (%):** **G1:** 2 (1.3) **G2:** 4 (2.6) **MUI, 7-13 episodes/week, n (%):** **G1:** 46 (29.9) **G2:** 46 (30.1) **MUI, ≥ 14 episodes/week, n (%):** **G1:** 104 (67.5) **G2:** 101 (66.0) **Adjusted incontinence episodes/week, mean:** **G1:** 23.1 **G2:** 23.2 **Previous non-surgical treatment for incontinence, n (%):** **G1:** 19 (12) **G2:** 22 (14)	**Success, n (%):** **G1:** 43 (28) **G2:** 41 (27) **Failure, n (%):** **G1:** 75 (49) **G2:** 78 (51) **Success rate, 8 months, lifetable analysis, % (95% CI):** **G1:** 41 (32, 50) **G2:** 41 (33, 50) **G1/G2:** 0 (-12, 12) **Success rate, 8 months, complete cases, % (95% CI):** **G1:** 36 (27, 45) **G2:** 34 (25, 43) **G1/G2:** 2 (-10, 14) **Success rate, 8 mos, assuming missings were failures, % (95% CI):** **G1:** 28 (21, 35) **G2:** 27 (20, 34) **G1/G2:** 1 (-9, 11) **Adjusted incontinence episodes/week, after Stage 1, mean:** **G1:** 2.7 **G2:** 4.7 **Adjusted incontinence episodes/week, after Stage 1, mean change:** **G1:** -20.4 **G2:** -18.5 **G1/G2:** -1.9 (-5.9, 2.0)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to followup: - Drop-out rates: ++ Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al., 2008 (continued)	**N at follow-up:** **G1:** 153 Completed treatment: 107 Outcome known at 8 mos: 119 **G2:** 154 Completed treatment: 101 Outcome known at 8 mos: 118 **Age, mean ± SD:** **G1:** 55.8 ± 14.2 **G2:** 58.0 ± 13.5 **Women, %:** 100 **Race/ethnicity, n (%):** **Hispanic:** **G1:** 13 (9) **G2:** 17 (11) **NH White:** **G1:** 105 (69) **G2:** 85 (56) **NH Black:** **G1:** 22 (14) **G2:** 35 (23) **Other:** **G1:** 13 (9) **G2:** 15 (10) **BMI, kg/m^2 ± SD:** **G1:** 33.2 ± 9.5 **G2:** 32.3 ± 7.6	• Currently using catheter to empty bladder • Postvoid residual volume > 150mL • Treatment for prolapse with pessary < 3 mos • Incontinence, vaginal, bladder or prolapse surgery in the past 6 mos • Urethral diverticulum • Previous augmentation cystoplasty or artificial sphincter • Neuromodulation for pelvic indications • Using anticholinergic agents, cholinergic agonists, tricyclic antidepressants, or duloxetine in ≤ 4 wks • Using diuretics with dosage change past 3 mos • Uncontrolled medical problem • History of bladder or pelvic cancer or pelvic radiation therapy • Glaucoma • Gastric retention • Non-ambulatory • Participation in other intervention trial that might influence outcome		**Achieved 70% reduction in incontinence episodes, per bladder diary, 10 weeks (%):** **G1:** 69 **G2:** 58 **G1/G2:** 11 (-0.3, 22.1) **Totally dry, per bladder diary, 10 weeks (%):** **G1:** 21 **G2:** 17 **Voids/day, mean change:** **G1:** 0.5 **G2:** -0.4 **G1/G2:** 0.9 (0.3, 1.5) **Symptom Distress Scores:** **G1/G2:** *P* < 0.0001 **Symptom Bother Scores (OAB-q), Stage 1, mean change:** **G1:** -36.7 **G2:** -30.4 **G1/G2:** *P* < 0.0001 **Symptom Bother Scores (OAB-q), Stage 2, mean change:** **G1:** -30.9 **G2:** -20.4 **G1/G2:** *P* < 0.0001 **Patient completely satisfied, Stage 1, %:** **G1:** 53 **G2:** 40 **G1/G2:** 13 (1, 25)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al., 2008 (continued)				**Patient completely satisfied, 8 months, %:** **G1:** 33 **G2:** 20 **G1/G2:** 13 (2, 24) **Patient better or much better, Stage 1, %:** **G1:** 90 **G2:** 77 **G1/G2:** 13 (4, 22) **Patient better or much better, 8 months, %:** **G1:** 69 **G2:** 43 **G1/G2:** 26 (14 , 38) **Persistence in perceived improvement, 8 mos, women with improvement at Stage 1:** **G1:** 72 **G2:** 54 **G1/G2:** 17 (4, 30) **Harms:** **G1:** 3 participants 1: blurred vision, syncope, night sweats, stomach cramping and weakness 2: 2 episodes of small-bowel obstruction and an allergic reaction (pruritus and rash) 3: tachycardia during stage 2 **G2:** 3 participants 1: small bowel obstruction 2: peripheral edema 3: renal cell carcinoma diagnosis during stage 2	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Capo et al. 2008 **Country and setting:** US, 207 centers **Enrollment period:** NR **Funding:** Astellas Pharma US, Inc., and GlaxoSmithKline **Author industry relationship disclosures:** 5 of 5 Astellas (4) Boehringer Mannheim Pharmaceuticals (1) Cephalon Inc. (1) GlaxoSmithKline (3) Reliant Pharmaceuticals (1) Schering Plough Corporation (1) Abbott (1) Akros (1) AstraZenica (1) Johnson & Johnson (1) Lilly (1) Manking (1) Merck (1) Novartis (1) NovoNordisk (1) Pfizer Inc. (1) Solvay (1) Takeda & TAP (1) Pri Med (1) Lucente (1)	**Design:** RCT **Intervention:** 12-wk treatment with 5 mg solifenacin succinate. Dosage could be increased at wk 4 and wk 8 to 10 mg, maintained or decreased in response to pt perceived efficacy and tolerability **Groups:** **G1:** Hispanic subgroup of G2 **G2:** full study population including G1 **N at enrollment:** **G1:** 94 **G2:** 2205 **N at follow-up, range:** **G1:** 47-80 **G2:** 1254-2005 **Age, yrs ± SD:** **G1:** 51.8 ± 12.8 **G2:** 59.7 ± 14.4 **Weight in lbs, mean ± SD:** **G1:** 171.1±36.4 **G2:** 182.2±47.0 **Race/ethnicity, n (%):** **Hispanic:** **G1:** 94 (100) **G2:** 94 (4.3) **White:** **G2:** 1761 (79.9) **Black:** **G2:** 274 (12.4) **Asian:** **G2:** 59 (2.7) **Other:** **G2:** 17 (0.8) **Women, N (%):** **G1:** 74 (78.7) **G2:** 1813 (82.2)	**Inclusion criteria:** • ≥ 18 yrs of age • OAB symptoms ≥3 mos • Toilet without difficulty • Washout of other OAB meds ≥ 7 days • Non-drug treatment of OAB if established ≥ 4 wks prior to study and continued **Exclusion criteria:** • SUI • Stress predominant MUI • UTI or chronic inflammation clinically significant outflow • Obstruction due to BPH • Narrow-angle glaucoma • Urinary or gastric retention • Severe renal or hepatic impairment • Chronic severe constipation or gastrointestinal obstructive disease • Bladder cancer • Women not using a reliable contraceptive • Hypersensitivity to the study medication, any of its components, or to anticholinergic medication	**Urge incontinence, n (%):** **G1:** 63 (67.0) **G2:** 1586 (71.9) **Urinary urgency, n %:** **G1:** 88 (93.6) **G2:** 2007 (91.0) **Frequency, n, (%):** **G1:** 86 (91.5) **G2:** 1969 (89.3) **Nocturia, n (%):** **G1:** 79 (84.0) **G2:** 1792 (81.3) **Patient perception of bladder condition, mean score:** **G1:** 4.0 **G2:** 4.0 **Most bothersome OAB symptom-frequency, n %:** **G1:** 38 (40.4) **G2:** 619 (28.1) **Most bothersome OAB symptom-urinary urgency, n %:** **G1:** 22 (23.4) **G2:** 508 (23.0) **Most bothersome OAB symptom-urge incontinence, n %:** **G1:** 17 (18.1) **G2:** 602 (27.3) **Most bothersome OAB symptom-nocturia, n %:** **G1:** 12 (12.8 **G2:** 337 (15.3)	**Increased dosage 5 mg/day, n (%)-Wk 4:** **G1:** 46 (48.9) **Increased dosage 10 mg/day, n (%)-Wk 4:** **G1:** 37 (39.4) **Discontinued, n Wk 4:** **G1:** 1 **Increased dosage 5 mg/day, n (%)-Wk 8:** **G1:** 31 (33.0) **Increased dosage 10 mg/day, n (%)-Wk 8:** **G1:** 39 (41.5) **Discontinued-Wk 8, n:** 1 **Returned to 5 mg/day-Wk 8, n:** 5 **Increased dosage to 10 mg/day-Wk 8, n:** 12 **Patient Perception of Bladder, mean Wk 4:** **G1:** 3.3* **G2:** 3.3* **Patient Perception of Bladder, mean Wk 8:** **G1:** 2.8* **G2:** 2.8*	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: NR Baseline characteristics: - Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Capo et al., 2008 (continued)	**Parity :** NR		**Most bothersome OAB symptom-none specified, n %:** **G1:** 5 (5.3) **G2:** 139 (6.3)	**Patient Perception of Bladder, mean Wk 12:** **G1:** 3.0* **G2:** 2.9* *P <0.001 vs.baseline **Symptom bother from VAS, Change from Baseline, mean scores (mm), (95% CI) p-value:** **Urinary urgency:** **G1:** -39.2 (-45.9, -32.5) P < 0.001 **G2:** -39.5 (-41.0, -38.1) P < 0.001 **Urge Incontinence:** **G1:** -37.7 (-46.0, -29.4) P < 0.001 **G2:** -40.1 (-41.8, -38.4) P < 0.001 **Frequency:** **G1:** -40.0 (-46.9, -33.2) P < 0.001 **G2:** -41.8 (-43.3, -40.3) P < 0.0001 **Nocturia:** **G1:** -43.2 (-50.4, -36.1) P < 0.001 **G2:** -36.9 (-38.4, -35.4) p < 0.001 **OAB-q subscales, change from baseline, mean (95% CI) p-value:**	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Capo et al., 2008 (continued)				**Symptom bother:** **G1:** -29.1 (-34.8, -23.4) *P* < 0.001, **G2:** -29.6 (-30.7, -28.6) *P* < 0.001 **Coping:** **G1:** 24.0 (18.0, 30.1) *P* < 0.001 **G2:** 27.4 (26.2, 28.5) *P* < 0.001 **Concern:** **G1:** 25.8 (19.5, 32.2) *P* < 0.001 **G2:** 29.6 (28.4, 30.8) *P* < 0.001 **Sleep:** **G1:** 25.7 (19.4, 32.0) *P* < 0.001 **G2:** 27.3 (26.1, 28.5) *P* < 0.001 **Social Interaction** **G1:** 15.9 (11.5, 20.3) *P* < 0.001 **G2:** 14.7 (13.7, 15.6) *P* < 0.001 **Overall Health-related QoL:** **G1:** 23.2 (18.0, 28.5) *P* < 0.001 **G2:** 25.4 (24.4, 26.4) *P* < 0.001 **Any Adverse Event, n (%):** **G1:** 48 (51.4) **G2:** 1321 (59.4) **Dry mouth, n (%):** **G1:** 17 (18.1) **G2:** 477 (21.4)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Capo et al., 2008 (continued)				**Constipation, n (%):** **G1:** 12 (12.8) **G2:** 295 (13.3) **Headache, n (%):** **G1:** 3 (3.2) **G2:** 76 (3.4) **Dizziness, n (%):** **G1:** 2 (2.1) **G2:** 27 (1.2) **Blurred vision, n (%):** **G1:** 4 (4.3) **G2:** 57 (2.6) **Palpitations, n (%):** **G1:** 2 (2.1) **G2:** 6 (0.3) **Upper respiratory tract infection, n (%):** **G1:** 3 (3.2) **G2:** 68 (3.1) **UTI, n (%):** **G1:** 3 (3.2) **G2:** 76 (3.4) **Bronchitis, n (%):** **G1:** 3 (3.2) **G2:** 31 (1.4) **Nasopharyngitis, n (%):** **G1:** 2 (2.1) **G2:** 50 (2.3) **Influenza, n (%):** **G1:** 2 (2.1) **G2:** 11 (0.5) **Insomnia, n (%):** **G1:** 2 (2.1) **G2:** 17 (0.8) **Depression, n (%):** **G1:** 2 (2.1) **G2:** 19 (0.9) **Hypertension, n (%):** **G1:** 2 (2.1) **G2:** 16 (0.7)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Cardozo et al., 1993 **Country and setting:** UK, Denmark, Germany, Netherlands, 4 centers **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Oral oestriol vs. placebo **Groups:** **G1:** 3 mg oral estradiol 3mg qd x 12 wks **G2:** placebo x 12 wks **N at enrollment:** **G1:** 34 **G2:** 30 **N at follow-up:** **G1:** 31 **G2:** 25 **Women, %:** 100 **Age, mean ± SD:** **G1:** 58.9 ± 10.4 **G2:** 60.2 ± 9.8 **Race/ethnicity:** NR **Height (cm), mean ± SD:** **G1:** 161.9 ± 7.1 **G2:** 162.9 ± 6.6 **Weight (kg), mean ± SD:** **G1:** 70.9 ± 11.6 **G2:** 69.1 ± 12.6	**Inclusion criteria:** • Women • Ambulant • Postmenopausal • Sensory and/or motor urge incontinence (confirmed by urodynamics) **Exclusion criteria:** • Symptoms present for > 3 years before menopause • Voiding difficulty • Pelvic anatomical defect requiring surgery • Neurological disease • Recent estrogen usage (< 6 mos) • Medication use that could affect bladder or urethral function • Contraindication to estrogen	**Daytime incontinence episodes/day, mean ± SD:** **G1:** 3.4 ± 4.2 **G2:** 3.2 ± 4.7 **Nocturnal incontinence episodes/day, mean ± SD:** **G1:** 1.6 ± 6.0 **G2:** 1.0 ± 2.3 **Daytime voids/ day, mean ± SD:** **G1:** 10.2 ± 5.0 **G2:** 10.6 ± 5.4 **Nocturia s/day, mean ± SD:** **G1:** 2.0 ± 1.4 **G2:** 2.6 ± 2.2 **Diurnal frequency, %:** **G1:** 26 **G2:** 20 **Nocturia, %:** **G1:** 25 **G2:** 20 **Urgency, %:** **G1:** 29 **G2:** 25 **Dysuria, %:** **G1:** 9 **G2:** 4 **SUI, %:** **G1:** 11 **G2:** 10 **UUI, %:** **G1:** 25 **G2:** 23 **Urgency severity, mean score ± SD:** **G1:** 2.6 ± 0.5 **G2:** 2.5 ± 0.8 **Nocturia severity mean score ± SD:** **G1:** 1.6 ± 0.8 **G2:** 1.7 ± 1.1	**Daytime incontinence episodes/day, 1 mo, mean ± SD:** **G1:** 3.0 ± 3.5 **G2:** 2.1 ± 2.6 **Daytime incontinence episodes/day, 3 mos, mean ± SD:** **G1:** 2.7 ± 3.5 **G2:** 1.3 ± 2.3 **Nocturnal incontinence episodes/day, 1 mo, mean ± SD:** **G1:** 0.6 ± 1.2 **G2:** 0.7 ± 2.0 **Nocturnal incontinence episodes/day, 3 mos, mean ± SD:** **G1:** 0.3 ± 0.7 **G2:** 0.3 ± 0.8 **Daytime voids/ day, 1 mo, mean ± SD:** **G1:** 8.9 ± 3.0 **G2:** 10.6 ± 5.4 **Daytime voids/ day, 3 mos, mean ± SD:** **G1:** 8.6 ± 3.4 **G2:** 7.2 ± 2.2 **G1/BL:** $P < 0.05$ **G2/BL:** $P < 0.01$ **Nocturia episodes/day, 1 mo, mean ± SD:** **G1:** 2.0 ± 1.6 **G2:** 1.5 ± 1.2 **Nocturia episodes/day, 3 mos, mean ± SD:** **G1:** 1.5 ± 1.1 **G2:** 1.4 ± 1.3 **G2/BL:** $P < 0.05$ **Diurnal frequency, cure %:** **G1:** 6 **G2:** 9	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: ++ Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Cardozo et al., 1993 (continued)			**Bladder volume (mL), first desire to void, mean ± SD:** **G1:** 161 ± 74 **G2:** 163 ± 86 **Detrusor pressure (cm H_2O), mean ± SD:** **G1:** 17 ± 12 **G2:** 17 ± 17 **Max cystometric capacity (mL), mean ± SD:** **G1:** 328 ± 125 **G2:** 322 ± 113 **Max pressure (cm H_2O), mean ± SD:** **G1:** 31 ± 27 **G2:** 21 ± 79	**Nocturia, cure %:** **G1:** 10 **G2:** 8 *P* < 0.01 **Urgency, cure %:** **G1:** 7 **G2:** 9 *P* < 0.01 **Dysuria, cure %:** **G1:** 5 **G2:** 4 **SUI, cure %:** **G1:** 6 **G2:** 6 **UUI, cure %:** **G1:** 11 **G2:** 7 *P* < 0.01 **Urgency severity, 1 mo, mean score ± SD:** **G1:** 1.8 ± 0.8 **G2:** 1.6 ± 1.0 **Urgency severity, 3 mos, mean score ± SD:** **G1:** 1.5 ± 1.1 **G2:** 1.4 ± 1.1 **G1/BL:** *P* < 0.01 **G2/BL:** *P* < 0.01 **Nocturia severity, 1 mo, mean score ± SD:** **G1:** 1.3 ± 0.8 **G2:** 1.3 ± 1.0 **Nocturia severity, 3 mos, mean score ± SD:** **G1:** 1.0 ± 0.8 **G2:** 1.0 ± 1.1 **G1/BL:** *P* < 0.01 **Bladder volume (mL), first desire to void, 3 mos, mean ± SD:** **G1:** 206 ± 142 **G2:** 202 ± 142 **G1/BL:** *P* < 0.05	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Cardozo et al., 1993 (continued)				**Detrusor pressure (cm H_2O), 3 months, mean ± SD:** **G1:** 17 ± 15 **G2:** 22 ± 39 **Max cystometric capacity (mL), mean ± SD:** **G1:** 333 ± 163 **G2:** 365 ± 136 **Max pressure (cm H_2O), mean ± SD:** **G1:** 25 ± 20 **G2:** 32 ± 65 **G1/BL:** $P < 0.05$	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Cardozo et al., 2004 [See evidence table for Kelleher et al., 2005] **Country and setting:** 84 centers in Denmark, UK, Czech Republic, Australia, Netherlands, Russia, US **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Solifenacin 5 mg vs. solifenacin 10 mg vs. placebo, 12 weeks once daily therapy **Groups:** **G1:** Solifenacin 5 mg qd **G2:** Solifenacin 10 mg qd **G3:** Placebo **N at enrollment:** 911 **N treated:** **G1:** 299 **G2:** 307 **G3:** 301 **N at follow-up, first visit:** **G1:** 286 **G2:** 290 **G3:** 281 **N at follow-up, study completion:** **G1:** 277 **G2:** 283 **G3:** 270 **Women, n (%):** **G1:** 237 (82.9) **G2:** 238 (82.1) **G3:** 227 (80.8) **Age, mean ± SD (range):** **G1:** 55.4 ± 13.8 (19-85) **G2:** 55.9 ± 14.2 (18-83) **G3:** 56.1 ± 13.3 (18-82) **Race/ethnicity, n (%):** **White:** **G1:** 280 (97.9) **G2:** 281 (96.9) **G3:** 274 (97.5)	**Inclusion criteria:** • Age ≥ 18 • Symptoms of OAB (including urinary frequency with urgency and/or UUI) for ≥3 months • ≥ 8 voids/day • ≥ 3 episodes urinary incontinence during 3-day diary period **Exclusion criteria:** • BOO • PVR volume >200 mL • Stress predominant MUI • Neurological cause for detrusor overactivity • UTI or bladder stones • Previous pelvic irradiation • Malignant disease of pelvic organs • Contraindication to antimuscarinic medication • Narrow-angle glaucoma • Urinary or gastric retention • Non drug treatment for OAB 2 wks before study • Diabetic neuropathy • Drugs to treat incontinence • Drugs with cholinergic or anticholinergic side-effects	**UUI, n (%):** 405 (47) **Urinary incontinence, n (%):** 491 (57) **Voids/day, range:** 12.05-12.31 **Duration of symptoms (months), median (range):** **G1:** 27.0, 4-383) **G2:** 28.0, 4-314) **G3:** 29.0, 5-327) **Prior drug therapy, n (%):** **G1:** 101 (35.3) **G2:** 94 (32.5) **G3:** 95 (33.8) **Any other non-drug therapy, n (%):** **G1:** 64 (22.4) **G2:** 77 (26.6) **G3:** 94 (33.5)	**UUI episodes/day, mean change (% change):** **G1:** -1.3 (-62.7) **G2:** -1.21 (-57.1) **G3:** -0.91 (-42.5) **G1/BL:** *P* = 0.014* **G2/BL:** *P* = 0.042* **Urgency episodes/day, mean change (95% CI for difference):** **G1:** -2.84 (-1.44, -0.28) **G2:** -2.90 (-1.49, -0.35) **G3:** -1.98 **G1/G3:** *P* = 0.003 **G2/G3:** *P* = 0.002 **Incontinence episodes/day, mean change (% change):** **G1:** -1.63 (-60.7) **G2:** -1.57 (-51.9) **G3:** -1.25 (-27.9) **G1/BL:** *P* = 0.002* **G2/BL:** *P* = 0.016* **Incontinent patients with no incontinence at end of study, %:** **G1:** 50.3 **G2:** 49.7 **Voids/day, mean change (95% CI for difference):** **G1:** -2.37 (-1.27, -0.29) **G2:** -2.81 (-1.71, -0.72) **G3:** -1.59 **G1/G3:** *P* = 0.0018 **G2/G3:** *P* = 0.0001	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: - Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Cardozo et al., 2004 (continued)	**Black:** **G1:** 2 (0.7) **G2:** 2 (0.7**)** **G3:** 3 (1.1) **Asian:** **G1:** 4 (1.4) **G2:** 6 (2.1) **G3: 2** (0.7) **Other:** **G1:** 0 **G2:** 1(0.3) **G3:** 2 (0.7) **Weight (kg), mean ± SD:** **G1:** 74.1 ± 15.0 **G2:** 74.6 ± 15.4 **G3:** 74.1 ± 14.4	• Participation in a clinical trial within 30 days • Childbearing potential, pregnant or nursing or not using reliable contraceptive methods		**Nocturia episodes/day, mean change (95% CI for difference):** **G1:** -0.58 **G2:** -0.71 (-0.38, -0.01) *P* = 0.005 **G3:** -0.52 **G1/G3:** *P* = 0.48 **G2/G3:** *P* = 0.036 **KHQ, general health perception, mean change:** **G1:** -5.8 **G2:** -4.5 **G3:** -2.3 **KHQ, inconti-nence impact, mean change:** **G1:** -27.0 **G2:** -30.3 **G3:** -20.1 **G1/BL:** *P* < 0.01 **G2/BL:** *P* < 0.001 **KHQ, role limitations, mean change:** **G1:** -21.9 **G2:** -24.4 **G3:** -15.9 **G1/BL:** *P* < 0.01 **G2/BL:** *P* < 0.001 **KHQ, physical limitations, mean change:** **G1:** -19.2 **G2:** -22.3 **G3:** -15.4 **G2/BL:** *P* < 0.001 **KHQ, social limitations, mean change:** **G1:** -12.1 **G2:** -11.7 **G3:** -9.0	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Cardozo et al., 2004 (continued)				**KHQ, personal relationships, mean change:** **G1:** -8.5 **G2:** -8.3 **G3:** -9.4 **KHQ, emotions, mean change:** **G1:** -16.4 **G2:** -16.6 **G3:** -12.2 **G1/BL:** *P* < 0.05 **G2/BL:** *P* < 0.05 **KHQ, sleep/ energy, mean change:** **G1:** -15.4 **G2:** -15.9 **G3:** -11.4 **G1/BL:** *P* < 0.05 **G2/BL:** *P* < 0.05 **KHQ, severity measures, mean change:** **G1:** -9.6 **G2:** -11.8 **G3:** -7.2 **G2/BL:** *P* < 0.01 **KHQ, symptom severity, mean change:** **G1:** -3.4 **G2:** -3.4 **G3:** -2.4 **G1/BL:** *P* < 0.01 **G2/BL:** *P* < 0.01 **Voided volume (mL), mean change (95% CI for difference):** **G1:** 30.8 (12.4-27.2) **G2:** 36.0 (17.7-33.0) **G3:** 10.67 **G1/G3:** *P* = 0.0001 **G2/G3:** *P* = 0.0001 **Dry mouth, n (%):** **G1:** 23 (7.7) **G2:** 71 (23.1) **G3:** 7 (2.3)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Cardozo et al., 2004 (continued)				**Dry mouth, mild, n (%):** **G1:** 18 (6.0) **G2:** 55 (17.9) **G3:** 5 (1.7) **Dry mouth, moderate, n (%):** **G1:** 5 (1.7) **G2:** 15 (5.2) **G3:** 1 (0.3) **Dry mouth, severe, n (%):** **G1:** 0 **G2:** 0 **G3:** 1 (0.3) **Constipation, n (%):** **G1:** 11 (3.7) **G2:** 28 (9.1) **G3:** 6 (2.0) **Constipation, mild, n (%):** **G1:** 9 (3.0) **G2:** 16 (5.2) **G3:** 5 (1.7) **Constipation, moderate, n (%):** **G1:** 5 (1.7) **G2:** 15 (5.2) **G3:** 1 (0.3) **Constipation, severe, n (%):** **G1:** 0 **G2:** 2 (0.7) **G3:** 0 **Blurred vision, n (%):** **G1:** 12 (4.0) **G2:** 18 (5.9) **G3:** 7 (2.3) **Blurred vision, mild, n (%):** **G1:** 7(2.3) **G2:** 14 (4.6) **G3:** 6 (2.0) **Blurred vision, moderate, n (%):** **G1:** 4 (1.3) **G2:** 4 (1.3) **G3:** 1 (0.3)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Cardozo et al., 2004 (continued)				**Blurred vision, severe, n (%):** **G1:** 1 (0.3) **G2:** 0 **G3:** 0 **Discontinued due to AEs, n (%):** **G1:** 7 (2.3) **G2:** 12 (3.9) **G3:** 10 (3.3)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Cardozo et al., 2008 **Country and setting:** Europe, Community **Enrollment period:** April 2004 to October 2005 **Funding:** Astellas Pharma Europe Ltd **Author industry relationship disclosures:** 9 of 9 Apogepha (1) Astellas (9) BARD (1) Bayer-Schering (1) Boston Scientific (1) Cook (1) Gynecare (1) J&J (1) Lilly (3) Merckle Recordati (1) Organon (1) Pfizer (3) Plethora (1) Recordati (1) Sanofi-Aventis (1) UCB (1)	**Design:** Multicenter randomized double blind placebo-controlled 2 week run in **Intervention:** Solifenacin 5 or 10 mg daily (pts requesting dose increase to 10 mg at 8 weeks were randomized in a 1:1 ratio to 5 mg or 10 mg) **Groups:** **G1:** Solifenacin 5 or 10 mg daily **G2:** Placebo **N at enrollment:** **G1:** 640 **G2:** 223 **N at follow-up:** **G1:** 505 **G2:** 223 **Women, %:** **G1:** 89.1 **G2:** 85.7 **Age, mean:** **G1:** 57.7 **G2:** 57.9 **Race/ethnicity, %:** **White:** **G1:** 98.4 **G2:** 99.1 **Black:** **G1:** 0.4 **G2:** 0.4 **Asian:** **G1:** 0.8 **G2:** 0 **Other:** **G1:** 0.4 **G2:** 0.4 **Follow-up:** 16 weeks	**Inclusion criteria:** • Age ≥ 18 • Male or female • OAB symptoms of urgency, frequency, urge incontinence ≥ 3 months • ≥ 3 episodes of urgency with or without incontinence in last 3 days • Mean of ≥ 8 voids/day **Exclusion criteria:** • Clinically significant BOO • PVR > 200 mL • UTI • Bladder stones • IC • Previous irradiation • Malignant pelvic disease • Sexually active women practicing an unreliable method of birth control • Pregnancy/ lactation • Conditions contraindicating anticholinergic medication	**UUI episodes/ day, mean:** **G1:** 1.63 **G2:** 2.01 **Severe urgency episodes (PPIUS 3+4)/day, mean:** **G1:** 5.11 **G2:** 5.54 **Urgency episodes (PPIUS 1-4)/day, mean:** **G1:** 10.72 **G2:** 10.81 **Maximum urgency intensity (PPIUS)/day, mean:** **G1:** 3.53 **G2:** 3.59 **Incontinence episodes/day, mean:** **G1:** 1.58 **G2:** 1.96 **Voids/day, mean:** **G1:** 11.10 **G2:** 11.14 **PPBC score, mean:** **G1:** 5 **G2:** 5 **Urgency bother score, VAS (mm), mean:** **G1:** 68 **G2:** 69 **Treatment satisfaction score, VAS (mm), mean:** **G1:** 29 **G2:** 29	**UUI episodes/day, mean change ± SD:** **G1:** -1.7 ± 2.2 (N=326) **G2:** -1.3 ± 2.0 (N=158) *P* = 0.0002 **Severe urgency episodes (PPIUS 3+4)/day, mean ± SD:** **G1:** -2.6 ± NR (N=503) **G2:** -1.8 ± NR (N= 216) *P* < 0.0001 **Urgency episodes (PPIUS 1-4)/day, mean ± SD:** **G1:** -2.3 ± 3.0 (N=503) **G2:** -1.6 ± 3.3 (N=216) *P* = 0.0006 **Maximum urgency intensity (PPIUS)/day, mean change ± SD:** **G1:** -0.8 ± 0.9 (N=503) **G2:** -0.6 ± 0.9 (N=216) *P* = 0.0006 **Incontinence episodes/day, mean change ± SD:** **G1:** -1.7 ± 2.2 (N=329) **G2:** -1.4 ± 2.0 (N=158) *P* = 0.0003 **Voids/day, mean change ± SD:** **G1:** -2.1 ± 2.6 (N= 502) **G2:** -1.3 ± 2.7 (N= 216) *P* < 0.0001	Quality: Overall quality score: good INTERNAL VALIDITY: good Randomization: + Method and blinding: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Cardozo et al., 2008				**PPBC score, median % change:** **G1:** -33 **G2:** -20 *P* < 0.0001 **Urgency bother score, VAS (mm), median % change:** **G1:** -59 **G2:** -35 P < 0.0001 **Treatment satisfaction score, VAS (mm), median % change:** **G1:** 66 **G2:** 34 *P* < 0.0001 **Withdrawn due to AEs, n:** **G1:** 17 **G2:** 6 **Dry mouth, %:** **G1:** 15.8 **G2:** 2.7 *P* < 0.001 **Constipation, %:** **G1:** 6.9 **G2:** 2.2 *P* = NS **Blurred Vision, %:** **G1:** 0.8 **G2:** 0.9 *P* = NS	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Chancellor et al., 2000 **Country and setting:** 167 centers in Europe, North America, Australia **Enrollment period:** NR **Funding:** Pharmacia & Upjohn **Author industry relationship disclosures:** NR	**Design:** randomized, double-blind, placebo-controlled, parallel-group **Intervention:** tolterodine vs. placebo **Groups:** **G1:** tolterodine 2 mg b.i.d. x 12 wks **G2:** placebo x 12 wks **N at enrollment:** **G1:** 514 **G2:** 508 **N at follow-up:** **G1:** 514 **G2:** 508 **Age, mean yrs (range):** **G1:** 60 (22-92) **G2:** 61 (21-93) **Women, N (%):** 818 (80%) **Race/ethnicity:** NR	**Inclusion criteria:** • ≥18 years • ≥5 incontinence episodes/wk • Average ≥8 voids/24 hr • OAB symptoms ≥6 mos **Exclusion criteria:** • Stress incontinence • Total daily urine volume >3L • Contra-indications to antimuscarinic therapy • Hepatic/renal disorders • Symptomatic or history of recurrent UTI • BOO • Haematuria • Interstitial cystitis • Receiving bladder training, electro-stimulation therapy • Indwelling or intermittent catheter • Pregnant or nursing • Women not using reliable contraception • Concomitant treatment for OAB (other than ERT for at least 2 mos) • Use of agents or drugs with potential to inhibit cytochrome P4503A4 isoform	**Previous drug therapy for OAB, %:** **G1:** 54 **G2:** 52 **Good efficacy response, %:** **G1:** 62 **G2:** 59 **Incontinence episodes/week, mean (range):** **G1:** 23.2 (0-168) **G2:** 23.3 (0-168) **≥5 incontinence episodes/week, n (%):** **G1:** 494 (97) **G2:** 498 (97) **Voids/day, mean (range):** **G1:** 11.1 (2-48.6) **G2:** 11.3 (2-37.4) **≥8 voids/day, n (%):** **G1:** 469 (91) **G2:** 467 (92) **Voided volume (mL), mean (range):** **G1:** 137 (38-283) **G2:** 136 (21-374) **Pads/day, mean (range):** **G1:** 1.4 (0-25) **G2:** 1.5 (0-22)	**Incontinence episodes/week, mean change ± SD:** **G1:** -10.6 ± 16.9 **G2:** -6.9 ± 15.4 *P* = 0.0005* **Voids/day, mean change ± SD:** **G1:** -1.7 ± 3.3 **G2:** -1.2 ± 2.9 *P* = 0.0079* **Voided volume (mL), mean change ± SD:** **G1:** +29 ± 47 **G2:** +14 ± 41 *P* = 0.0001* **Pads/day, mean change ± SD:** **G1:** -0.5 ± 1.8 **G2:** -0.2 ± 1.4 *P* = 0.0035* **Improvement, n (%):** **G1:** 313 (61) **G2:** 218 (43) **No change, n (%):** **G1:** 158 (31) **G2:** 225 (44) **Deterioration, n (%):** **G1:** 43 (8) **G2:** 65 (13) **Mild dry mouth, n (%):** **G1:** 93 (18) **G2:** 31 (6) **Moderate dry mouth, n (%):** **G1:** 50 (10) **G2:** 8 (2) **Severe dry mouth, n (%):** **G1:** 12 (2) **G2:** 0	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chancellor et al., 2000 (continued)				**Constipation, n (%):** **G1:** 35 (7) **G2:** 22 (4) **Headache, n (%):** **G1:** 19 (4) **G2:** 23 (5)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Chancellor, Kianifard, et al., 2008 **Country and setting:** US **Enrollment period:** May 2005 to February 2006 **Funding:** NR **Author industry relationship disclosures:** 6 of 7 Genaera (1) Novartis (6)	**Design:** Randomized open-label **Intervention:** Behavioral modification in addition to darifenacin (allowed to increase dose from darifenacin 7.5 mg to 15 mg daily after 2 weeks) **Groups:*** **G1:** Darifenacin **G2:** Darifenacin and behavioral modification **N at enrollment:** **G1:** 190 **G2:** 205 **N at follow-up, 12 weeks:** **G1:** 173 **G2:** 175 **Age, mean ± SD:** **G1:** 57.4 ± 13.1 **G2:** 58.4 ± 14.6 **Race/ethnicity: White:** **G1:** 90 **G2:** 88.3 **Other (non-white):** **G1:** 10 **G2:** 11.7 **Women, %:** **G1:** 90 **G2:** 88.3	**Inclusion criteria:** • ≥ 8 voids/ day • ≥ 2 UUI episodes/ day • ≥ 2 episodes of urgency/day **Exclusion criteria:** • Any drug with bladder effects for 2 weeks prior to study participation • Participation in any formal bladder-training program within 30 days of screening • Predominant SUI • Bladder or neurologic condition that could affect bladder function or in which use of anticholinergics was contra-indicated	**UUI episodes/ day, mean ± SD:** **G1:** 2.78 ± 2.57 **G2:** 3.00 ± 2.56 **UUI episodes/ day, median:** **G1:** 2.33 **G2:** 2.58 **Mean UUI episodes/day, total population, n (%):** 0 episodes: **G1:** 36 (19.1) **G2:** 29 (14.2) 1-6 episodes: **G1:** 138 (73.0) **G2:** 155 (76.0) 7-13 episodes: **G1:** 15 (7.9) **G2:** 20 (9.8) ≥14 episodes **G1:** 0 (0.0) **G2:** 0 (0.0) **Mean UUI episodes/day, age ≥ 65, n (%)** 0 episodes **G1:** 9 (17.0) **G2:** 8 (9.9) 1-6 episodes **G1:** 40 (75.5) **G2:** 63 (77.8) 7-13 episodes **G1:** 4 (7.5) **G2:** 10 (12.3) **Urgency episodes/day, mean ± SD:** **G1:** 10.88 ± 3.80 **G2:** 10.58 ± 4.00 **Urgency episodes/day, median:** **G1:** 10.67 **G2:** 10.33 **Voids/day, mean ± SD:** **G1:** 11.92 ± 3.03 **G2:** 11.75 ± 3.37	**UUI episodes/day mean change ± SD:** **G1:** -1.89 ± 2.29 **G2:** -2.10 ± 2.32 **G1/G2:** *P* = 0.268 **UUI episodes/day median change (95% CI):** **G1:** -1.33 (-2.00, -1.00) **G2:** -2.00 (-2.00, -1.33) **Urgency episodes/day mean change ± SD:** **G1:** -2.87 ± 3.59 **G2:** -2.68 ± 3.54 **G1/G2:** *P* = 0.882 **Urgency episodes/day median change (95% CI):** **G1:** -2.33 (-3.00, -1.67) **G2:** -2.67 (-3.00, -2.00) **Voids/day, mean change ± SD:** **G1:** -2.96 ± 2.91 **G2:** -2.82 ± 2.87 **G1/G2:** *P* = 0.681 **Voids/day, median change (95% CI):** **G1:** -2.67 (-3.33, -2.00) **G2:** -2.67 (-3.00, -2.33) **Nocturia episodes/day, mean change ± SD:** **G1:** -0.65 ± 1.26 **G2:** -0.67 ± 1.21 **G1/G2:** *P* = 0.315	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chancellor, Kianifard, et al., 2008 (continued)			**Voids/day, median:** **G1:** 11.33 **G2:** 11.33 **Nocturia episodes/day, mean ± SD:** **G1:** 1.77 ± 1.43 **G2:** 1.87 ± 1.35 **Nocturia episodes/day, median:** **G1:** 1.67 **G2:** 1.67 **Pads used/day, mean ± SD:** **G1:** 1.12 ±1.93 **G2:** 0.99 ± 1.67 **Pads used/day, median:** **G1:** 0 **G2:** 0	**Nocturia episodes/day, median change (95% CI):** **G1:** -0.67 (-0.67, -0.33) **G2:** -0.67 (-0.67, -0.33) **Pads used/day mean change ± SD:** **G1:** -0.72 ±1.54 **G2:** -0.61 ± 1.28 **G1/G2:** *P* = 0.978 **Pads used/day median change (95% CI):** **G1:** 0 (0,0) **G2:** 0 (0,0) **Side effects, %:** Constipation: 18.5 Dry mouth 25 UTI: 4.8 Headache: 3.8 **Discontinued due to adverse event(s), n (%)** **G1:** 6 (3.2) **G2:** 21 (10.25) **Discontinued due to constipation, %:** 2 **Discontinued due to dry mouth, %:** 1.8	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Chancellor, Zinner et al., 2008 **Country and setting:** USA, multicenter **Enrollment period:** NR **Funding:** Astellas Pharma US, Glaxo-SmithKline **Author industry relationship disclosures:** 12 of 12 Abbot (1) AEterna Zentaris (1) Akros (1) Allergan (3) American Medical Systems (2) Amgen (1) Astellas (10) AstraZeneca (1) Bard (1) Bayer (1) Boehringer Ingelheim (3) Cephalon (1) Coloplast (1) Cook (1) CooperSurgical (1) Eli Lilly (2) Ferring GSK (6) Gynecare (1) Indevus (2) J&J (1) Mankind (1) Medtronic (1) Merck (1) Novartis (3) Novo Nordisk (1) Ortho-McNeil (1)	**Design:** Prospective cohort, open label, flexible-dose, 14 day washout **Intervention:** Solifenacin 5-10 mg daily **Groups:** **G1:** Solifenacin 5-10 mg daily **N at enrollment:** **G1:** 440 **N at follow-up (%):** **G1:** 390 (88.4) **Age, mean ± SD:** **G1:** 61.4 ± 13.8 **Race/ethnicity, n (%):** White: **G1:** 392 (88.9) **Women, N (%):** **G1:** 389 (88.2) **BMI, kg/m^2 ± SD:** **G1:** 30.1 ± 7.1	**Inclusion criteria:** • Age ≥ 18 • OAB symptoms > 3 months • Treatment with tolterodine ER 4 mg, solifenacin, darifenacin, or trospium x ≥ 4 weeks • Desired change in therapy • ≥ 3 mean UUI episodes/day **Exclusion criteria:** • Treatment < 4 weeks with tolterodine, solifenacin, darifenacin, or trospium • SUI • MUI with primary stress • UTI • Chronic bladder inflammation • Bladder cancer • Severe constipation • Elevated PVR • Neurological deficit • Renal/ hepatic disease • Narrow angle glaucoma • Urinary retention • Gastric retention • Hypersensitivity to drugs • BOO • Women of childbearing age/ lactation	**Urgency episodes/day, mean change:** **G1:** 6.9 ± 4.4 **Incontinence episodes/day, mean ± SD:** **G1:** 3.8 ± 3.6 **Voids/day, mean ± SD:** **G1:** 11.3 ± 3.8 **Nocturia episodes/day, mean ± SD:** **G1:** 1.9 ± 1.2 **PPBC score, mean:** **G1:** 4.2 **OAB-q score, mean:** Symptom bother: 57.3 Coping: 52.2 Concern: 51.3 Sleep: 50.6 Social Interaction: 77.7 Total score: 56.7	**Urgency episodes/day, mean change ± SD (95% CI):** **G1:** -4.2 ± 4.2 (-4.6, -3.8) **G1/BL:** *P* < 0.001 **Incontinence episodes/day, mean change ± SD (95% CI):** **G1:** -2.6 ± 3.2 (-3.0, -2.3) **G1/BL:** P < 0.001 **Voids/day, mean change ± SD (95% CI):** **G1:** -2.3 ± 3.2 (-2.6, -2.0) **G1/BL:** P< 0.001 **Nocturia episodes/day, mean change ± SD (95% CI):** **G1:** -0.8 ± 1.0 (-0.9,-0.6) **G1/BL:** P < 0.001 **PPBC score, mean change (95% CI):** **G1:** -1.2 (-1.3, -1.0) **G1/BL:** *P* < 0.001 **OAB-q score, mean:** Symptom bother: 27.8 Coping: 80.1 Concern: 81.1 Sleep: 75.1 Social Interaction: 92.7 Total score: 81.9 **G1/BL:** *P* < 0.001 all domains and total score **Dry Mouth, n (%):** **G1:** 77 (17.5) **Constipation, n (%):** **G1:** 51 (11.6)	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: - Method and blinding: NA Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chancellor, Zinner, et al., 2008 (continued) **Author industry relationship disclosures:** Pfizer (7) Pharmacia (1) Pri Med (1) Reliant (1) Solvay (1) Sanofi-Aventis (1) Schering-Plough (1) Takeda (1) TAP (1) Watson (1)				**Blurred vision, n (%):** **G1:** 10 (2.3) **UTI, n (%):** **G1:** 19 (4.3) **Headache, n (%):** **G1:** 13 (2.9) **URI, n (%):** **G1:** 11 (2.5)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Chapple et al., 2004 **Country and setting:** 98 centers – United States, United Kingdom, Poland, Russia, New Zealand, Belgium, Netherlands **Enrollment period:** NR **Funding:** Yamanouchi Pharmaceutical Co., Ltd, Tokyo, Japan **Author industry relationship disclosures:** NR	**Design:** RCT, double-blind placebo controlled, with 2-wk placebo run-in period **Intervention:** Tolterodine vs. solifenacin vs. placebo **Groups:** **G1:** Tolterodine 2 mg b.i.d. **G2:** Solifenacin 5 mg qd **G3:** Solifenacin 10 mg qd **G4:** Placebo qd **N at enrollment:** **G1:** 279 **G2:** 269 **G3:** 266 **G4:** 267 **N at follow-up:** **G1:** 250 **G2:** 266 **G3:** 264 **G4:** 253 **Female, n (%)** **G1:** 200 (80.0) **G2:** 188 (71.2) **G3: 194 (72.9)** **G4:** 193 (76.3) **Age, yrs ± SD:** **G1: 56.9 +/-12.8** **G2:** 58.1± 13.4 **G3:** 57.2 ±13.4 **G4:** 57.8 ± 13.7 **<65 years of age, n (%)** **G1:** 169 (63.5) **G2:** 172 (65.2) **G3:** 172 (68.8) **G4:** 168 (66.4) **≥65 years of age, n (%)** **G1:** 97 (36.5) **G2:** 92 (34.8) **G3:** 78 (31.2) **G4:** 85 (33.6)	**Inclusion criteria:** • Age ≥ 18 • Symptoms of OAB (including urinary frequency with urgency and/or UI) for ≥ 3 months • ≥ 8 voids per 24 hr • ≥ 3 episodes UUI during 3-day diary period **Exclusion criteria:** • Clinically significant BOO • Postvoid residual volume >200 mL • Stress predominant factor • Neurological cause for detrusor overactivity • UTI or bladder stones • Previous pelvic irradiation • Malignant disease of pelvic organs • Contraindication to antimuscarinic medication (including narrow-angle glaucoma, urinary or gastric retention) • Non pharma-cological treatment for OAB 2 wks before study • Diabetic neuropathy • Use of drugs intended to treat incontinence	**UUI only, n (%):** **G1:** 142 (56.8) **G2:** 162 (61.4) **G3:** 172 (64.7) **G4:** 177(70.0) **MUI, n (%):** **G1:** 90 (36.0) **G2:** 81 (30.7) **G3:** 79 (29.7) **G4:** 59(23.3) **No incontinence, n (%):** **G1:** 18 (7.2) **G2:** 20 (7.6) **G3:** 15 (5.6) **G4:** 17 (6.7) **UUI episodes/ day, mean ± SD:** **G1:** 2.33 ± 2.50 **G2:** 2.14 ± 2.44 **G3:** 1.86 ± 1.54 **G4:** 2.02 ± 2.50 **Urgency episodes/day, mean ± SD:** **G1:** 5.77 ± 4.89 **G2:** 5.82 ± 4.45 **G3:** 5.45 ± 3.87 **G4:** 5.30 ± 3.92 **Incontinence episodes/day, mean ± SD:** **G1:** 2.64 ± 2.55 **G2:** 2.59 ± 2.88 **G3:** 2.32 ± 1.94 **G4:** 2.71 ± 2.83 **Voids/day, mean ± SD:** **G1:** 12.08 ± 3.86 **G2:** 12.32 ± 3.95 **G3:** 12.08 ± 3.43 **G4:** 12.20 ± 4.11 **Voided volume (mL), mean ± SD:** **G1:** 149.6 ± 54.6 **G2:** 147.2 ± 51.2 **G3:** 147.0 ± 50.3 **G4:** 143.8 ± 53.6	**UUI episodes/day, mean change ± SD:** **G1:** -0.91 (2.01) **G2:** -1.41 (1.74) **G3:** -1.36 (2.13) **G4:** -0.62 (1.96) **G1/G4:** *P* = 0.239 **G2/G4:** *P* = 0.002 **G3/G4:** *P* = 0.0028 **UUI episodes/day, mean % change:** **G1:** -58 **G2:** -65 **G3:** -63 **G4:** -40 **UUI episodes/day, estimated difference vs. tolterodine (95% CI):** **G2:** -0.487 (-0.988, 0.014) **G3:** -0.436 (-0.921, 0.048) **Urgency episodes/day, mean change ± SD:** **G1:** -2.05 ± 3.58 **G2:** -2.85 ± 3.74 **G3: -**3.07 ± 3.90 **G4:** -1.41 ± 3.67 **G1/G4:** *P* = 0.0511 **G2/G4:** *P* < 0.001 **G3/G4:** *P* < 0.001 **Urgency episodes/day, mean % change:** **G1:** -38 **G2:** -55 **G3:** -52 **G4:** -33	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: ++ Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2004 (continued)	**<75 years of age, n (%)** **G1:** 236 (88.7) **G2:** 241 (91.3) **G3:** 233 (93.2) **G4:** 225 (88.9) **≥75 years of age, n (%)** **G1:** 30 (11.3) **G2:** 23 (8.7) **G3:** 17 (16.8) **G4:** 28 (11.1) **Weight, mean kg ± SD** **G1:** 74.8 +/-14.8 **G2:** 74.6±14.3 **G3:** 75.5±14.2 **G4:** 72.6±14.4 **Race/ethnicity, n (%):** **White** **G1:** 261(98.1) **G2:** 260 (98.5) **G3:** 247(98.8) **G4:** 248 (98.0) **Black** **G1:** 2 (0.8) **G2:** 0 **G3:** 1 (0.4) **G4:** 1 (0.4) **Asian** **G1:** 2 (0.8) **G2:** 0 **G3:** 2(0.8) **G4:** 1 (0.4) **Other** **G1:** 1 (0.4) **G2:** 4 (1.5) **G3:** 0 **G4:** 3 (1.2)	• Use of drugs with cholinergic or anticholinergic side-effects • Participation in a clinical trial within 30 days • Childbearing potential, pregnant or nursing or not using reliable contraceptive methods	**Time from start of symptoms (months), mean ± SD:** **G1:** 57.4 ± 60.5 **G2:** 72.6 ± 105.4 **G3:** 62.9 ± 82.5 **G4:** 61.0 ± 83.9 **Prior drug therapy, n (%):** **G1:** 93 (34.9) **G2:** 106 (40.1) **G3:** 77 (30.8) **G4:** 83 (32.8) **Any non drug therapy, n (%):** **G1:** 92 (34.6) **G2:** 92 (34.8) **G3:** 88 (35.2) **G4:** 76 (30.0)	**Urgency episodes/day, estimated difference vs. tolterodine (95% CI):** **G2:** -0.791 (-14.34, -0.148) **G3:** -1.015 (-1.659, -0.370) **Incontinence episodes/day, mean change ± SD:** **G1:** -1.42 ± 1.82 **G2:** -1.45 ± 2.24 **G3:** -1.14 ± 2.15 **G4:** -0.76 ± 2.26 **G1/G4:** *P* = 0.1122 **G2/G4:** *P* = 0.008 **G3/G4:** *P* = 0.0038 **Incontinence episodes/24 h Δ from baseline, %:** **G1:** -59 **G2:** -47 **G3:** -59 **G4:** -29 **Incontinence episodes/day, estimated difference vs. tolterodine (95% CI):** **G2:** -0.276 (-0.761, 0.208) **G3:** -0.316 (-0.786, 0.154) **Voids/day, mean change ± SD:** **G1:** -1.88 ± 3.00 **G2:** -2.19 ± 2.87 **G3:** -2.61 ± 3.24 **G4:** -1.20 ± 3.26 **G1/G4:** *P* = 0.0145 **G2/G4:** *P* = 0.003 **G3/G4:** *P* < 0.001	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2004 (continued)				**Voids/day, mean % change:** **G1:** -15 **G2:** -20 **G3:** -17 **G4:** -18 **Voids/day, estimated difference vs. tolterodine (95% CI):** **G2:** -0.312 (-0.844, 0.219) **G3:** -0.737 (-1.269, -0.204) **Voided volume (mL), mean change ± SD:** **G1:** 24.4 ± 49.2 **G2:** 32.9 ± 47.7 **G3:** 39.2 ± 50.4 **G4:** 07.4 ± 36.3 **G1/G4:** $P < 0.001$ **G2/G4:** $P < 0.001$ **G3/G4:** $P < 0.001$ **Voided volume (mL), mean % change:** **G1:** 20 **G2:** 25 **G3:** 29 **G4:** 9 **Voided volume (mL), estimated difference vs. tolterodine (95% CI):** **G2:** 8.4 (0.496, 16.34) **G3:** 14.8 (6.855, 22.72) **Discontinued due to AEs, n (%):** **G1:** 5 (1.9) **G2:** 9 (3.2) **G3:** 7 (2.6) **G4:** 10 (3.7) **Dry mouth, n (%):** **G1:** 49 (18.6) **G2:** 39 (14.0) **G3:** 57 (21.3) **G4:** 13 (4.9)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2004 (continued)				**Constipation, n (%):** **G1:** 7 (2.6) **G2:** 20 (7.2) **G2:** 21 (7.8) **G4:** 5 (1.9) **Blurred Vision, n (%):** **G1:** 4 (1.5) **G2:** 10 (3.6) **G3:** 15 (5.6) **G4:** 7 (2.6)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Chapple et al., 2005* Chapple, Fianu-Jonsson et al., 2007† **Country and setting:** European, Multicenter **Enrollment period:** May 2003 to October 2004 **Funding:** Yamanouchi (now Astellas) **Author industry relationship disclosures:** NR* 1 of 9† Astellas (1) Novartis (1) Pfizer (1) Schwartz (1) UCB (1)	**Design:** RCT **Intervention:** Solifenacin 5 mg vs. tolterodine ER 4 mg **Groups:** **G1:** Solifenacin 5mg **G2:** Tolterodine ER 4mg **G1a:** G1 who elected not to increase dose at 4 weeks **G2a:** G2 who elected not to increase dose at 4 weeks **N at enrollment:** **G1:** 578 **G2:** 599 **N at follow-up:** **G1a:** 297 **G2a:** 267 **Age, mean:** **G1:** 56.5 **G2:** 56.4 **G1a:** 56.5 **G2a:** 56.9 **Race/ethnicity, %:** **White:** **G1:** 99.3 **G2:** 99.5 **G1a:** 99.3 **G2a:** 99.3 **Women, %:** **G1:** 85.3 **G2:** 88.3 **G1a:** 87.5 **G2a:** 87.1	**Inclusion criteria:** • Age ≥ 18 • OAB symptoms for ≥ 3 months • Outpatient treatment • ≥ 8 voids/day • ≥ 1 incontinence episode/day or ≥ 1 urgency episode/day **Exclusion criteria:** NR	**UUI episodes/ day, mean ± SD:*** **G1:** 2.31 ± 2.35 **G2:** 2.12 ± 2.14 **UUI episodes/ day, mean:†** **G1a:** 1.97 **G2a:** 1.66 **Urgency episodes/day, mean ± SD:*** **G1:** 6.01 ± 4.66 **G2:** 5.84 ± 4.12 **Urgency episodes/day, mean:†** **G1a:** 5.67 **G2a:** 5.30 **Incontinence episodes/day, mean ± SD:*** **G1:** 2.77 ± 2.65 **G2:** 2.55 ± 2.37 **Incontinence episodes/day, mean:†** **G1a:** 2.32 **G2a:** 2.01 **Voids/day, mean ± SD:*** **G1:** 11.78 ± 3.58 **G2:** 11.66 ± 3.25 **Voids/day, mean:†** **G1:** 11.10 **G2:** 11.36 **Nocturia, episodes/day, mean ± SD:*** **G1:** 2.02 ± 1.33 **G2:** 1.92 ± 1.22 **Nocturia, episodes/day, mean:†** **G1a:** 1.83 **G2a:** 1.84	**UUI episodes/day, 4 wks, mean change:†** **G1:** -1.22 **G2:** -0.91 *P* = NS **UUI episodes/day, 12 wks, mean change:*** **G1:** -1.42 **G2:** -0.83 *P* = 0.001 **UUI episodes/day, 12 wks, mean change:†** **G1a:** -1.46 **G2a:** -1.03 **Urgency episodes/day, 4 wks, mean change:†** **G1:** -1.98 **G2:** -1.67 *P* = NS **Urgency episodes/day, 12 wks, mean change:*** **G1:** -2.85 **G2:** -2.42 *P* = 0.035 **Urgency episodes/day, 12 wks, mean change:†** **G1a:** -3.08 **G2a:** -2.62 **Incontinence episodes/day, 4 wks, mean change:†** **G1:** -1.30 **G2:** -0.90 *P* = 0.0181	Quality: Overall quality score: good INTERNAL VALIDITY: good Randomization: + Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2005* Chapple et al., 2007† (continued)				**Incontinence episodes/day, 12 wks, mean change:*** **G1:** -1.60 **G2:** -1.11 *P* = 0.006 **Incontinence episodes/day, 12 wks, mean change:†** **G1a:** -1.56 **G2a:** -1.23 **Voids/day, 4 wks, mean change:†** **G1:** -1.71 **G2:** -1.47 *P* = NS **Voids/day, 12 wks, mean change:*** **G1:** -2.45 **G2:** -2.24 *P* = 0.004 for non-inferiority **Voids/day, 12 wks, mean change:†** **G1a:** -2.47 **G2a:** -2.49 **Nocturia, episodes/day, 4 wks, mean change:†** **G1:** -0.51 **G2:** -0.44 *P* = NS **Nocturia, episodes/day, 12 wks, mean change:*** **G1:** -0.71 **G2:** -0.63 *P* = NS **Nocturia episodes/day, 12 wks, mean change:†** **G1a:** -0.72 **G2a:** -0.69	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2005* Chapple et al., 2007† (continued)				**Perception of bladder condition, 4 wks, mean change:†** **G1:** -0.96 **G2:** -0.88 *P* = NS **Perception of bladder condition, 12 wks, mean change:*** **G1:** -1.51 **G2:** -1.33 *P* < 0.0061 **Perception of bladder condition, 12 wks, mean change:†** **G1a:** -1.72 **G2a:** -1.62 **Pad use, 4 wks, mean change:†** **G1:** -1.21 **G2:** -0.80 *P* = 0.0089 **Pad use, 12 wks, mean change:*** **G1:** -1.72 **G2:** -1.19 *P* < 0.0023 **Pad use, 12 wks, mean change:†** **G1a:** -1.55 **G2a:** -1.40 **Dry rate, 4 wks, mean % change:†** **G1:** 39 **G2:** 34 *P* = NS **Dry rate, 12 wks, mean % change:†** **G1a:** 65.4 **G2a:** 58.3 *P* = NS	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2005* Chapple et al., 2007† (continued)				**Voided volume (mL), 12 wks, mean change:*** **G1:** 38 **G2:** 31 *P* = 0.010 **Voided volume (mL), 12 wks, mean change:†** **G1a:** 39.95 **G2a:** 37.84 **Dry mouth, mild, %:*†** **G1:** 17.5 **G2:** 14.8 **G1a:** 6.5 **G2a:** 5.0 **Dry mouth, moderate, %:*†** **G1:** 10.8 **G2:** 7.7 **G1a:** 10.4 **G2a:** 7.0 **Dry mouth, severe, %:*†** **G1:** 1.7 **G2:** 1.5 **G1a:** 0.7 **G2a:** 2.1 **Constipation, mild, %:*†** **G1:** 3.2 **G2:** 1.3 **G1a:** 2.0 **G2a:** 1.0 **Constipation, moderate, %:*†** **G1:** 2.7 **G2:** 1.0 **G1a:** 1.7 **G2a:** 1.4 **Constipation, severe, %:*†** **G1:** 0.5 **G2:** 0.2 **G1a:** 0.3 **G2a:** 0.0	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2005* Chapple et al., 2007† (continued)				**Blurred vision, mild, %:*†** **G1:** 0.7 **G2:** 0.7 **G1a:** 0.3 **G2a:** 0.7 **Blurred vision, moderate, %:*†** **G1:** 0.0 **G2:** 1.0 **G1a:** 0.0 **G2a:** 1.7 **Blurred vision, severe, %:*†** **G1:** 0.0 **G2:** 0.0 **G1a:** 0.0 **G2a:** 0.0	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Chapple, Van Kerrebroeck et al., 2007 **Country and setting:** Multicenter study in Europe, Africa, and Oceania (academic and private), 150 sites in 19 countries **Enrollment period:** NR **Funding:** Schwarz BioSciences GmbH, Pfizer Inc. **Author conflicts of interest:** 9 of 9: Astellas (Yamanouchi) (2) Eli-Lilly (1) Ferring (1) GlaxoSmithKline (1) Novartis (3) Pfizer (5) Schwarz (4) UCB (1)	**Design:** RCT **Intervention:** Fesoterodine (8 mg or 4 mg) vs. tolterodine ER 4 mg **Groups:** **G1:** Tolterodine ER 4mg **G2:** Fesoterodine 8mg **G3:** Fesoterodine 4mg **G4:** Placebo **N at enrollment:** **G1:** 290 **G2:** 288 **G3:** 272 **G4:** 285 **N at follow-up:** **G1:** 253 **G2:** 252 **G3:** 231 **G4:** 252 **Age, mean ± SD:** **G1:** 57.7 ± 14.6 **G2:** 55.6 ± 14.1 **G3:** 57.1 ± 13.2 **G4:** 56.0 ± 13.7 **Women, %:** **G1:** 78 **G2:** 82 **G3:** 81 **G4:** 81 **Race/ethnicity, %:** **White:** **G1:** 98 **G2:** 98 **G3:** 96 **G4:** 98 **Black:** **G1:** 0 **G2:** 1 **G3:** 0 **G4:** <1 **Asian:** **G1:** 2 **G2:** 1 **G3:** 2 **G4:** 2	**Inclusion criteria:** • OAB symptoms with urinary urgency for ≥ 6 mos • Age ≥ 18 • ≥ 8 voids per day • ≥ 6 urgency episodes or ≥ 3 UUI episodes/day • At least moderate problems recorded via a Likert scale • Negative pregnancy test • Adequate contraception **Exclusion criteria:** • SUI • Bladder stones • Interstitial cystitis • Urothelial tumors • Grade III or higher pelvic prolapse • BOO • Polyuria (>3L/d) • UTIs • PVR urine volume >100mL • Use of antimuscarinic ≤ 2 weeks • Treatment with electrostimulation ≤ 4 weeks • Neurological disease • Clinically relevant cardiac arrhythmia • Unstable angina • QTcB interval > 500ms	**UUI episodes/ day, mean ± SD:** **G1:** 3.8 ± 3.1 **G2:** 3.7 ± 3.0 **G3:** 3.8 ± 3.1 **G4:** 3.7 ± 3.1 **Urgency episodes/day mean ± SD:** **G1:** 11.0 ± 3.4 **G2:** 11.5 ± 4.2 **G3:** 11.0 ± 3.4 **G4:** 11.4 ± 4.0 **Incontinence, %:** **G1:** 79 **G2:** 81 **G3:** 75 **G4:** 76 **Continent days/ wk, mean ± SD:** **G1:** 0.6 ± 1.3 **G2:** 0.6 ± 1.3 **G3:** 0.8 ± 1.6 **G4:** 0.8 ± 1.5 **Voids/day, mean ± SD:** **G1:** 11.5 ± 2.9 **G2:** 11.9 ± 3.8 **G3:** 11.6 ± 3.2 **G4:** 12.0 ± 3.7 **Daytime voids/ day, mean ± SD:** **G1:** 2.0 ± 1.2 **G2:** 2.0 ± 1.6 **G3:** 1.9 ± 1.3 **G4:** 1.8 ± 1.2 **Duration of OAB symptoms (yrs), mean ± SD:** **G1:** 8.7 ± 10.1 **G2:** 7.6 ± 8.4 **G3:** 9.0 ± 11.2 **G4:** 7.9 ± 9.6 **Previous drug treatment, n (%):** **G1:** 135 (47) **G2:** 118 (41) **G3:** 102 (38) **G4:** 112 (40)	**UUI episodes/day, LS mean change (SE):** **G1:** -1.74 (0.16) **G2:** -2.22 (0.16) **G3:** -1.95 (0.17) **G4:** -1.14 (0.16) **G1/G4:** *P* = 0.008 **G2/G4:** *P* < 0.001 **G3/G4:** *P* = 0.001 **UUI episodes/day, median % change:** **G1:** -70.0 **G2:** -87.5 **G3:** -80.0 **G4:** -50.0 **G1/G4:** *P* = 0.105 **G2/G4:** *P* < 0.001 **G3/G4:** *P* = 0.001 **Urgency episodes/day mean change (SE):** **G1:** -2.03 (0.19) **G2:** -2.36 (0.20) **G3:** -1.88 (0.20) **G4:** -1.07 (0.19) **G1/G4:** *P* < 0.001 **G2/G4:** *P* < 0.001 **G3/G4:** *P* = 0.003 **Urgency episodes/day median change, %:** **G1:** -16.0 **G2:** -19.1 **G3:** -17.6 **G4:** -11.1 **G1/G4:** *P* = 0.004 **G2/G4:** *P* < 0.001 **G3/G4:** *P* = 0.002 **Continent days/wk mean change (SE):** **G1:** 2.48 (0.20) **G2:** 3.32 (0.19) **G3:** 2.84 (0.21) **G4:** 2.07 (0.20) **G1/G4:** *P* = 0.139 **G2/G4:** *P* < 0.001 **G3/G4:** *P* = 0.007	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple, Van Kerrebroeck et al., 2007 (continued)	**Other:** **G1:** <1 **G2:** 0 **G3:** 3 **G4:** <1 **BMI, kg/m^2 ± SD:** **G1:** 27.5 ± 5.2 **G2:** 27.1 ± 5.2 **G3:** 27.5 ± 5.5 **G4:** 27.2 ± 5.2		**Voided volume (mL), mean ± SD:** **G1:** 154.3 ± 52.9 **G2:** 153.9 ± 56.9 **G3:** 160.0 ± 59.5 **G4:** 150.2 ± 52.0	**Voids/day, LS mean change (SE):** **G1:** -1.73 (0.16) **G2:** -1.88 (0.16) **G3:** -1.76 (0.17) **G4:** -0.95 (0.16) **G1/G4:** *P* = 0.001 **G2/G4:** *P* < 0.001 **G3/G4:** *P* < 0.001 **Voids/day, median % change:** **G1:** -13.8 **G2:** -18.6 **G3:** -16.7 **G4:** -11.1 **G1/G4:** *P* = 0.005 **G2/G4:** *P* < 0.001 **G3/G4:** *P* < 0.001 **Daytime voids/ day, LS mean change (SE):** **G1:** -0.40 (0.06) **G2:** -0.39 (0.06) **G3:** -0.39 (0.06) **G4:** -0.32 (0.06) **Daytime voids/ day, median % change:** **G1:** -25.0 **G2:** -23.1 **G3:** -28.6 **G4:** -26.8 **Treatment Response, % yes:** **G1:** 72 **G2:** 79 **G3:** 75 **G4:** 53 **G1/G4:** *P* < 0.001 **G2/G4:** *P* < 0.001 **G3/G4:** *P* < 0.001	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple, Van Kerrebroeck et al., 2007 (continued)				**Maximum voided volume, mean change (SE):** **G1:** 23.64 (3.31) **G2:** 33.62 (3.35) **G3:**27.72 (3.41) **G4:** 9.37 (3.33) **G1/G4:** (*P* = 0.003) **G2/G4:** (*P* <0.001) **G3/G4:** (*P* = 0.001) **Adverse events, n (%):** **G1:** 144 (50) **G2:** 167 (58) **G3:** 135 (50) **G4:** 107 (38) **Dry mouth, n (%):** **G1:** 49 (16.9) **G2:** 97 (33.8) **G3:** 59 (21.7) **G4:** 20 (7.1) **Constipation, n (%):** **G1:** 8 (2.8) **G2:** 13 (4.5) **G3:** 9 (3.3) **G4:** 4 (1.4) **Headache, n (%):** **G1:** 14 (4.8) **G2:** 7 (2.4) **G3:** 12 (4.4) **G4:** 14 (4.9) **Dry eye, n (%):** **G1:** 1 (<1) **G2:** 12 (4.2) **G3:** 6 (2.2) **G4:** 0 **Nasopharyngitis, n (%):** **G1:** 10 (3.4) **G2:** 5 (1.7) **G3:** 8 (2.9) **G4:** 7 (2.5) **Fatigue, n (%):** **G1:** 10 (3.4) **G2:** 1 (<1) **G3:** 1 (<1) **G4:** 1 (<1)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple, Van Kerrebroeck et al., 2007 (continued)				**Influenza, n (%):** **G1:** 2 (<1) **G2:** 2 (<1) **G3:** 9 (3.3) **G4:** 6 (2.1) **Dry throat, n (%):** **G1:** 3 (1) **G2:** 8 (2.8) **G3:** 1 (<1) **G4:** 0 **Dizziness, n (%):** **G1:** 4 (1.4) **G2:** 3 (1.0) **G3:** 4 (1.5) **G4:** 7 (2.5) **Alanine aminotransferase, n (%):** **G1:** 0 **G2:** 6 (2.1) **G3:** 2 (<1) **G4:** 1 (<1) **Nausea, n (%):** **G1:** 6 (2.1) **G2:** 4 (1.4) **G3:** 1 (<1) **G4:** 1 (<1) **Mean change in heart rate (bpm):** **G1:** 2.89 **G2:** 3.9 **G3:** 3.3 **G4:** 0.8	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Chapple, DuBeau et al., 2007 **Country and setting:** US, Poland, South Africa, Hungary, Sweden, United Kingdom, Germany; 73 centers **Enrollment period:** NR **Funding:** Novartis **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Darifenacin 7.5 mg qd versus placebo x 12 weeks, with optional up-titration offered (to 15 mg qd) after 2 weeks of treatment **Groups:** **G1:** Darifenacin **G2:** Placebo **N at enrollment:** **G1:** 266 **G2:** 133 **N at follow-up (%):** **G1:** 244 (91.7) **G2:** 117 (87.3) **Age, mean ± SD (range):** **G1:** 72 ± 5 (64-89) **G2:** 73 ± 5 (64-87) **Women, n (%):** **G1:** 206 (77.4) **G2:** 100 (75.2) **Race/ethnicity:** NR **Follow-up:** 12 weeks	**Inclusion criteria:** • Age ≥ 65 • OAB sx for ≥ 6 months • Capable of independent toileting • Able to complete the diary independently • Completed at least 5 days of the 7-day diary during the baseline period • ≥ 1 UUI episodes/day • ≥ 10 micturitions/ day **Exclusion criteria:** • Treatment w/ drugs known to effect urinary bladder function or the external urethral sphincter • Total urinary volume ≥ 3L • Mean voided volume > 300 ml • Clinically significant SUI or BOO • PVR > 100mL by ultrasound • Women with marked cystocele or other clinically significant Stage 3 or Stage 4 pelvic prolapsed • Participated in a bladder-training program or received electrical stimulation therapy w/in 3 mos of screening • Serious or intermittent UTI	**UUI episodes/ week, median (range):** **G1:** 19.8 (4.0-142.0) **G2:** 21.0 (7.0-155.4) **Urgency episodes/day, median (range):** **G1:** 7.6 (1.0-24.4) **G2:** 7.4 (1.3-22.2) **Voids/day, median (range):** **G1:** 11.8 (7.1-25.1) **G2:** 12.0 (7.6-27.6)	**UUI episodes/ week, median change (% change):** **G1:** -14.0 (-88.6) **G2:** -13.0 (-77.9) **UUI episodes/ week, median change (95% CI):** **G1/G2:** -1.0 (-2.83, 1) *P* = 0.328 **Urgency episodes/day, median change (% change):** **G1:** -3.3 (-69.6) **G2:** -3.1 (-55.5) **Urgency episodes/day, median change (% change):** **G1/G2:** -0.5 (-1.2, 0.2) *P* = 0.174 **Voids/day, median change (% change):** **G1:** -3.0 (-25.3) **G2:** -2.2 (-18.5) **Voids/day, median change (95% CI):** **G1/G2:** -0.7 (-1.1, -0.2) *P* = 0.006 **OAB-q, total score, mean change:** **G1:** 22.9 **G2:** 16.8 *P* < 0.001 **OAB-q, symptom severity score, mean change:** **G1:** -27.9 **G2:** -20.7 *P* < 0.001	Quality: Overall quality score: good INTERNAL VALIDITY: good Randomization: + Method and blinding: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: + Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple, DuBeau et al., 2007 (continued)		• Clinically significant congenital or acquired disorder of the urinary tract • Any urinary bladder dysfunction other than OAB • Hx of chronic pain syndrome of the lower urinary tract **Other significant medical conditions that made participant unfit (cognitive impairment, uncontrolled severe HTN, uncontrolled severe heart failure, recent MI, uncontrolled thyroid disease**		**OAB-q, coping score, mean change:** **G1:** 27.4 **G2:** 19.2 *P* < 0.001 **OAB-q, concern score, mean change:** **G1:** 26.5 **G2:** 18.6 *P* < 0.001 **OAB-q, sleep score, mean change:** **G1:** 21.1 **G2:** 16.8 *P* = 0.015 **OAB-q, social score, mean change:** **G1:** 12.5 **G2:** 10.4 *P* = 0.047 **PVR (mL), wk 12, mean change (95% CI) :** **G1:** 11.9 (1.7, 22.1) **G2:** 17.3 (-18.1, 52.8) *P* = NS **Adverse Event, n (%)** **G1:** 149 (56.0) **G2:** 60 (45.1) **AEs attributed to treatment, n (%)** **G1:** 99 (37.2) **G2:** 24 (18.0) **Dry mouth, n (%)** **G1:** 59 (22.2) **G2:** 5 (3.8) **Constipation, n (%)** **G1:** 41 (15.4) **G2:** 11 (8.3) **Discontinued due to AEs, n (%)** **G1:** 4 (1.6) **G2:** 1 (0.8)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Chapple et al., 2008 **Country and setting:** European, multicenter (academic and private) **Enrollment period:** NR **Funding:** Pfizer, Schwarz BioSciences **Author industry relationship disclosures:** 4 of 5 Pfizer (4)	**Design:** Multicenter randomized placebo-controlled **Intervention:** Tolterodine 4 mg ER vs. fesoterodine 8 mg **Groups:** **G1:** Tolterodine ER 4mg **G2:** Fesoterodine 8mg **G3:** Placebo **N at enrollment:** **G1:** 290 **G2:** 287 **G3:** 283 **Age, mean ± SD:** Total: 57 ± 14 **Race/ethnicity, %:** **White:** Total: >95 **Women, %:** Total: 80 **Follow-up:** 12 weeks	**Inclusion criteria:** • Age ≥ 18 • OAB sx w/ urinary urgency for ≥6 mos • ≥ 8 voids/day • ≥ 6 urgency episodes or ≥ 3 UUI episodes/day • At least moderate problems recorded via a Likert scale • Negative pregnancy test • Adequate contraception throughout trial **Exclusion criteria:** • LUT pathology: SI, bladder stones, interstitial cystitis, urothelial tumors • Grade III or higher pelvic prolapsed • Bladder-outlet obstruction • Polyuria (>3L/d) • Symptomatic or recurrent UTIs • PVR urine volume >100 mL • Antimuscarinic agent w/in 2 wks • Electrostimulation for bladder training in prior 4 wks • Active UTI • Underlying neurological dz • Clinically relevant cardiac arrhythmia • Unstable angina • QTcB interval > 500ms	**Time since first diagnosis or onset of OAB (years), mean:** Total: 8-9 **Incontinent at BL, n:** **G1:** 213 **G2:** 217 **G3:** 203	**KHQ severity score, mean change:** **G1:** -12.6 **G2:** -14.0 **G3:** -9.0 **G1/G3:** $P < 0.05$ **G2/G3:** $P < 0.05$ **KHQ severity score, patients incontinent at BL, mean change:** **G1:** -14.9 **G2:** -15.8 **G3:** -10.8 **G1/G3:** $P < 0.05$ **G2/G3:** $P < 0.05$ **KHQ emotions score, mean change:** **G1:** -16.3 **G2:** -17.4 **G3:** -10.1 **G1/G3:** $P < 0.05$ **G2/G3:** $P < 0.05$ **KHQ emotions score, patients incontinent at BL, mean change:** **G1:** -17.3 **G2:** -18.6 **G3:** -11.3 **G1/G3:** $P < 0.05$ **G2/G3:** $P < 0.05$ **KHQ role limitations score, mean change:** **G1:** -22.1 **G2:** -21.7 **G3:** -11.8 **G1/G3:** $P < 0.05$ **G2/G3:** $P < 0.05$	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Method and blinding: + Pt selection criteria: + Loss to followup: NR Drop-out rates: NR Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2008 (continued)				**KHQ role limitations score, patients incontinent at BL, mean change:** **G1:** -23.2 **G2:** -23.7 **G3:** -12.4 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05 **KHQ physical limitations score, mean change:** **G1:** -19.7 **G2:** -21.7 **G3:** -11.4 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05 **KHQ Physical limitations score, patients incontinent at BL, mean change:** **G1:** -20.5 **G2:** -23.3 **G3:** -11.1 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05 **KHQ social limitations score, mean change:** **G1:** -14.1 **G2:** -15.4 **G3:** -8.7 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05 **KHQ social limitations score, patients incontinent at BL, mean change:** **G1:** -15.7 **G2:** -16.2 **G3:** -9.5 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2008 (continued)				**KHQ sleep/energy score, mean change:** **G1:** -11.7**G2:** -13.6 **G3:** -9.6 **G1/G3:** *P* = NS **G2/G3:** *P* < 0.05 **KHQ sleep/energy score, patients incontinent at BL, mean change:** **G1:** -12.5 **G2:** -15.3 **G3:** -10.4 **G1/G3:** *P* = NS **G2/G3:** *P* < 0.05 **KHQ personal relationship score, mean change:** **G1:** -10.4 **G2:** -11.9 **G3:** -6.2 **G1/G3:** *P* = NS **G2/G3:** *P* < 0.05 **KHQ personal relationship score, patients incontinent at BL, mean change:** **G1:** -12.7 **G2:** -12.3 **G3:** -6.8 **G1/G3:** *P* < 0.05 **G2/G3:** *P* = NS **KHQ incontinence impact score, mean change:** **G1:** -23.3 **G2:** -24.6 **G3:** -16.1 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2008 (continued)				**KHQ incontinence impact score, patients incontinent at BL, mean change:** **G1:** -23.8 **G2:** -26.5 **G3:** -17.7 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05 **KHQ general health score, mean change:** **G1:** -4.3 **G2:** -4.0 **G3:** -3.8 **G1/G3:** *P* = NS **G2/G3:** *P* = NS **KHQ general health score, patients incontinent at BL, mean change:** **G1:** -4.3 **G2:** -4.5 **G3:** -5.5 **G1/G3:** *P* = NS **G2/G3:** *P* = NS **ICIQ-SF total score, mean:** **G1:** -3.95 **G2:** -4.41 **G3:** -2.55 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05 **ICIQ-SF total score, patients incontinent at BL, mean:** **G1:** -4.56 **G2:** -5.29 **G3:** -3.12 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2008 (continued)				**Major improvement in severity of bladder-related problems, %:** **G1:** 34 **G2:** 39 **G3:** 25 **G1/G3:** *P* = 0.01 **G2/G3:** *P* = 0.01 **Dry mouth, n (%):** **G1:** 49 (17) **G2:** 97 (34) **G3:** 20 (7) **Constipation, n (%):** **G1:** 8 (3) **G2:** 13 (5) **G3:** 4 (1) **Nasopharyngitis, n (%):** **G1:** 10 (3) **G2:** 5 (2) **G3:** 7 (3) **Dry eye, n (%):** **G1:** 1 (1) **G2:** 12 (4) **G3:** 0 (0) **Nausea, n (%):** **G1:** 6 (2) **G2:** 4 (1) **G3:** 1 (1) **Fatigue, n (%):** **G1:** 10 (3) **G2:** 1 (1) **G3:** 1 (1) **Dry throat, n (%):** **G1:** 3 (1) **G2:** 8 (3) **G3:** 0 (0)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Choo et al., 2008 **Country and setting:** Korea, Academic hospital **Enrollment period:** July 2005 to March 2006 **Funding:** NR **Author industry relationship disclosures:** None	**Design:** Prospective cohort **Intervention:** Tolterodine ER 4 mg qd x 12 wks **Groups:** NA **N at enrollment:** 60 **N at follow-up:** 56 **Women, %:** 100 **Age, mean ± SD:** 54.8 ± 11.5 **Race/ethnicity:** NR	**Inclusion criteria:** • Age ≥ 18 • OAB for ≥ 3 mos • ≥ 8 frequency episodes/d and ≥ 2 urgency episodes/d **Exclusion criteria:** • Total 24-h micturition volume > 3L • PVR > 30% of voided volume or ≥ 150 mL • Stress UI • Hx of urinary retention • Active UTI • Indwelling catheter • Intermittent self-catheterisation • Neurological dz • Any condition for which antimuscarinic agents are contraindicated	**UUI episodes/ day, mean ± SD:** 1.4 ± 2.7 **UUI episodes/ day, mean ± SD:** PGA < 80%: 2.4 ± 3.4 PGA ≥ 80%: 2.9 ± 4.1 **Urgency episodes/day, mean ± SD:** 9.6 ± 6.8 **Urgency episodes/day, mean ± SD:** PGA < 60%: 12.6 ± 7.7 PGA ≥ 60%: 7.1 ± 4.9 *P* < 0.01 **Total of all urgency scales/ day, mean ± SD:** 94.4 ± 43.0 **Voids/day, mean ± SD:** 12.6 ± 5.3 **Voids/day, mean ± SD:** PGA < 60%: 14.9 ± 6.2 PGA ≥ 60%: 10.5 ± 2.9 *P* < 0.01 **Nocturia episodes/day, mean ± SD:** 1.6 ± 0.9 **Nocturia episodes/day, mean ± SD:** PGA < 50%: 1.9 ± 0.8 PGA ≥ 50%: 1.6 ± 0.7	**UUI episodes /day, 12 wks, mean ± SD:** 0.4 ± 0.9 *P* < 0.01 **UUI severity, 12 wks, median % change (95% CI):** -71 (-76.8, -39.2) **UUI, PGA median rate, % (95% CI):** 80 (34.2, 80.0) **UUI episodes /day, 12 wks, mean change ± SD:** PGA < 80%: -0.9 ± 1.6 PGA ≥ 80%: -2.8 ± 4.3 **UUI, PPBC, mean change ± SD:** PGA < 80%: -1.6 ± 1.1 PGA ≥ 80%: -2.2 ± 1.5 **UUI, GII, %:** PGA < 80%: No: 1 (11.1) Little: 5 (55.6) Much: 3 (33.3) PGA ≥ 80%: No: 0 (0) Little: 4 (40.0) Much: 6 (60.0) **UUI, continue treatment, n (%):** PGA < 80%: 5 (55.6) PGA ≥ 80%: 8 (80.0) **Urgency episodes /day, 12 wks, mean ± SD:** 5.4 ± 4.5 *P* < 0.01 **Urgency severity, 12 wks, median % change (95% CI):** -55 (-60.4, -40.1)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Methods and blinding: - Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Choo et al., 2008 (continued)			**Most troublesome symptoms, n (%):** UUI: 9 (16.1) Urgency: 6 (10.7) Frequency: 28 (50) Nocturia: 10 (17.9) Tenesmus: 3 (5.4) **Voided volume, (mL), mean ± SD:** 157.0 ± 70.3	**Total of all urgency scales/ day, 12 wks, mean ± SD:** 66.3 ± 31.2 *P* < 0.01 **Urgency, PGA median rate, %** (95% CI): 60 (46.2, 64.9) **Urgency episodes /day, 12 wks, mean change ± SD:** PGA < 60%: -4.2 ± 6.8 PGA ≥ 60%: -4.3 ± 4.7 *P* < 0.01 **Urgency, PPBC, mean change ± SD:** PGA < 60%: -1.5 ± 1.0 PGA ≥ 60%: -2.3 ± 1.1 *P* < 0.01 **Urgency, GII, %:** PGA < 60%: No: 4 (16.0) Little: 15 (60.0) Much: 6 (24.0) *P* < 0.01 PGA ≥ 60%: No: 0 (0) Little: 7 (22.6) Much: 24 (77.4) *P* < 0.01 **Urgency, pts want to continue treatment, n (%):** PGA < 60%: 16 (64.0) PGA ≥ 60%: 25 (80.6) **Voids/day, 12 wks, mean ± SD:** 9.9 ± 4.2 *P* < 0.01	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Choo et al., 2008 (continued)				**Frequency severity, 12 wks, median % change (95% CI):** -45 (-54.4, -36.2) **Frequency, PGA median rate, % (95% CI):** 60 (46.9, 63.6) **Voids/day, 12 wks, mean change ± SD:** PGA < 60%: -2.6 ± 2.9 PGA ≥ 60%: -2.7 ± 2.2 *P* < 0.01 **Frequency, PPBC, mean change ± SD:** PGA < 60%: -1.4 ± 1.1 PGA ≥ 60%: -2.4 ± 1.0 *P* < 0.01 **Frequency, GII, %:** PGA < 60%: No: 4 (14.8) Little: 16 (59.3) Much: 7 (25.9) *P* < 0.01 PGA ≥ 60%: No: 0 (0) Little: 6 (20.7) Much: 23 (79.3) *P* < 0.01 **Frequency, continue treatment, n (%):** PGA < 60%: 18 (66.7) PGA ≥ 60%: 23 (79.3) **Nocturia episodes /day, 12 wks, mean ± SD:** 0.9 ± 0.8 *P* < 0.01	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Choo et al., 2008 (continued)				**Nocturia severity, 12 wks, median % change (95% CI):** -52 (-59.7, -40.2) **Nocturia, PGA median rate, % (95% CI):** 50 (39.4, 57.6) **Nocturia episodes /day, 12 wks, mean change ± SD:** PGA < 50%: -0.6 ± 1.1 PGA ≥ 50%: -1.4 ± 0.9 **Nocturia, PPBC, mean change ± SD:** PGA < 50%: -1.3 ± 0.9 PGA ≥ 50%: -2.3 ± 1.1 *P* < 0.01 **Nocturia, GII, %:** PGA < 50%: No: 4 (20.0) Little: 13 (65.0) Much: 3 (15.0) *P* < 0.01 PGA ≥ 50%: No: 0 (0) Little: 6 (20.7) Much: 23 (79.3) *P* < 0.01 **Nocturia, pts want to continue treatment, n (%):** PGA < 50%: 9 (45.0) PGA ≥ 50%: 26 (89.7) *P* < 0.01 **Nocturia severity, 12 wks, median % change (95% CI):** -52 (-59.7, -40.2)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Choo et al., 2008 (continued)				**Tenesmus severity, 12 wks, median % change (95% CI):** -26 (-50.4, -16.9) **Tenesmus, PGA median rate, %** (95% CI)**:** 30 (25.4, 52.2) **Tenesmus, PPBC, mean change ± SD:** PGA < 30%: -1.4 ± 0.9 PGA ≥ 30%: -2.1 ± 1.1 **Tenesmus, GII, %:** PGA < 30%: No: 2 (15.4) Little: 9 (69.2) Much: 2 (15.4) *P* < 0.01 PGA ≥ 30%: No: 0 (0) Little: 5 (31.3) Much: 11 (68.8) *P* < 0.01 **Tenesmus, pts want to continue treatment, n (%):** PGA < 30%: 8 (61.5) PGA ≥ 30%: 14 (87.5) **Most troublesome symptom severity, median % change:** UUI: -64.5 Urgency: -32 Frequency: -42.5 Nocturia: -56.5 **Voided volume (mL), 12 wks, mean ± SD:** 189.3 ± 111.5 *P* = 0.05 **Dry mouth, n (%):** 13 (21.7)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Choo et al., 2008 (continued)				**Constipation/ indigestion, n (%):** 6 (10) **Headache, n (%):** 3 (5) **UTI, n (%):** 2 (3.3) **Peripheral oedema, n (%):** 1 (1.7)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Colombo et al., 1995 **Country and setting:** Italy; Setting **Enrollment period:** May 1990 to March 1993 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT, Computer generated random assignment **Intervention:** Oxybutynin vs. Bladder training for 6 weeks **Groups:** **G1:** Oxybutynin, 3 daily doses of 5 mg each for 6 weeks (dose reduced to half if substantial AEs) **G2:** Bladder training **N at enrollment:** **G1:** 42 **G2:** 39 **N at 6 wk follow-up:** **G1:** 38 **G2:** 37 **N at 6 mo follow-up:** **G1:** 28 **G2:** 27 **Age, yrs ± SD:** **G1:** 48 (31 – 65) **G2:** 49 (24 – 65) **Race/ethnicity:** NR **Women, N (%):** **G1:** 42 (100) **G2:** 39 (100) **Postmenopausal n (%):** **G1:** 16 (38) **G2:** 20 (51)	**Inclusion criteria:** • Socially embarrassing (severe) urinary urge incontinence • On cystometry: detrusor instability, or low-compliance bladder (LCB), or sensory bladder **Exclusion criteria:** • Stable bladder at cystometry • Neurologic disease • Detrusor hyperreflexia • Age greater than 65 y • Coexisting genuine SUI • Genital prolapse • Postvoid residual volume >50mL • Previous gynecologic or urogynecologic surgery • Prior use of any drug to treat UUI • Urethral diverticula • Fistulas • Urinary tract neoplasia • Cystitis • Bladder stones • Previous pelvic radiotherapy	**Detrusor instability, n (%):** **G1:** 14 (37) **G2:** 13 (35) **Low compliance bladder, n (%):** **G1:** 9 (24) **G2:** 8 (22) **Sensory bladder, n (%):** **G1:** 15 (39) **G2:** 16 (43) **Daily UUI episodes, range 9 – 17** **Diurnal frequency, n (%):** **G1:** 32 (84) **G2:** 29 (78) **Nocturia, n (%):** **G1:** 11 (29) **G2:** 18 (49) **Volume at first desire (mL):** **G1:** 120 ± 59 **G2:** 134 ± 61 **Volume at very strong desire (mL):** **G1:** 317 ± 92 **G2:** 332 ± 87	**Clinically cured overall, n (%):** **G1:** 28 (74) **G2:** 27 (73) **Cured among DI, (%):** **G1:** 13 (93) **G2:** 8 (62) *P* = 0.07 **Cured among LCB:** **G1:** 6 (67) **G2:** 6 (75) *P* = 0.56 **Cured among sensory bladder:** **G1:** 9 (60) **G2:** 13 (81) *P* = 0.18 **Cured among 18 G1 patients requiring dosage halving:** 12 (67%) **Diurnal frequency resolved, n (%):** **G1:** 18 (56) **G2:** 20 (69) **Nocturia resolved n (%):** **G1:** 3 (27) **G2:** 11 (61) **Volume at first desire (mL), mean ± SD:** **G1:** 179 ± 32 *P* = .0009 **G2:** 178 ± 49 *P* = .001 **Volume at very strong desire (mL) mean ± SD:** **G1:** 408 ± 76 *P* = .00001 **G2:** 403 ± 69 *P* = .0002 **Patients still cured at 6 mos,n:** **G1:** 16 **G2:** 26	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to followup: ++ Drop-out rates: + Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: - Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Colombo et al., 1995 (continued)				**Patients still cured at 6 mos among DI, n:** **G1:** 8 **G2:** 8 **Patients still cured at 6 mos among LCB, n:** **G1:** 4 **G2:** 6 **Patients still cured at 6 mos among sensory bladder, n:** **G1:** 4 **G2:** 12 **Treatment discontinued in 6 cases:** **G1:** 4 (3 cases of severe dry mouth, 1 case of previously unknown glaucoma) **G2:** 2 (treatment was time consuming) **Other adverse effects** **G1:** 18 (47%) with AE requiring halving of dosage: -dry mouth (n=15) -constipation (n=6) -nausea (n=5) -dizziness (n=2) - decrease in visual acuity (n=1) - tachycardia (n=1)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Davila, et al., 2001 **Country and setting:** US, Specialty treatment centers **Enrollment period:** 6 weeks **Funding:** Watson Laboratories, Inc **Author industry relationship disclosures:** 2 of 3 Pharmadigm (1) Watson Laboratories (2)	**Design:** RCT **Intervention:** Transdermal Oxybutynin vs. Oral Oxybutynin 2 week washout **Groups:** **G1:** Transdermal OXY 1.3mg/day **G2:** OXY 2.5mg b.i.d./t.i.d. **N at enrollment:** **G1:** 38 **G2:** 38 **N at follow-up:** **G1:** 38 **G2:** 36 **Women, n (%):** **G1:** 33 (87) **G2:** 37 (97) **Age, mean ± SD:** **G1:** 64 ± 15 **G2:** 63 ± 13 **Race/ethnicity, n, (%):** White: 72 (95) Black: 4 (5)	**Inclusion criteria:** • Age ≥ 18 • History of UUI or MUI with predominant urge symptoms • ≥ 3 episodes UI/ day with ≥ 30% increase in UUI episodes/ day during 2 week washout • Diagnosis of motor urge incontinence • Improvement during ≥ 6 wks with oral oxybutynin • UDS confirmed motor urge incontinence **Exclusion criteria:** • Allergy to oxybutynin • Intolerability of transdermal system • Pregnancy or breastfeeding • Overflow incontinence secondary to underactive or non-contractile detrusor • BOO • Impaired bladder compliance including tonic increase in pressure> 15 cmH_2O during filling cystometry • Medical conditions or drug therapies that could cause incontinence	**Incontinence episodes/day, mean ± SD:** **G1:** 7.2 ± 4.5 **G2:** 7.2 ± 4.1 **Bladder volume (mL), first contraction, mean ± SD:** **G1:** 165 ± 158 **G2:** 267 ± 187 **Max cystometric capacity (mL), mean ± SD:** **G1:** 244 ± 168 **G2:** 342 ± 167	**Incontinence episodes/day, mean ± SD:** **G1:** 2.4 ± 2.4 **G2:** 2.6 ± 3.3 **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **G1/G2:** *P* = NS **Patient assess-ment of efficacy, VAS score, mean change ± SD:** **G1: 5.8 ± 4.2** **G2: 6.0 ± 3.3** **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **G1/G2:** *P* = 0.9 **Bladder volume (mL), first contraction, mean ± SD:** **G1:** 229 ± 189 **G2:** 302 ± 198 **G1/BL:** *P* = 0.0055 **G2/BL:** *P* = 0.1428 **G1/G2:** *P* = 0.57 **Max cystometric capacity (mL), mean ± SD:** **G1:** 297 ± 176 **G2:** 387 ± 162 **G1/BL:** *P* = 0.0011 **G2/BL:** *P* = 0.0538 **G1/G2:** *P* = NR **Dry mouth, n (%):** **G1:** 15 (39) **G2:** 31 (82) **Constipation, n (%):** **G1:** 8 (21) **G2:** 19 (50) **Somnolence, n (%):** **G1:** 7 (18) **G2:** 14 (37) **Nausea, n (%):** **G1:** 3 (8) **G2:** 10 (26)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Davila et al. 2001 (continued)		• Medical conditions that could be worsened by oxybutynin		**Dizziness, n (%):** **G1:** 6 (16) **G2:** 10 (26) **Blurred vision, n (%):** **G1:** 7 (18) **G2:** 9 (24) **Urinary retention, n (%):** **G1:** 9 (24) **G2:** 13 (34) **Impaired vision, n (%):** **G1:** 9 (24) **G2:** 9 (24) **Palpitation, n (%):** **G1:** 3 (8) **G2:** 5 (13) **Dry mouth by unvalidated questionnaire, %:** **G1:** 38 **G2:** 94 *P* < 0.001	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Diokno et al., 1995 **Country and setting:** US, private clinic **Enrollment period:** January 1992 to December 1992 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cohorts with comparison; (Series of patients self selected into two groups) **Intervention:** Bladder training vs. anticholinergic or antispasmodic **Groups:** **G1:** Bladder training **G2:** oxybutynin 2.5-5.0 mg b.i.d. or t.i.d. **N at enrollment:** **G1:** 39 **G2:** 33 **N at follow-up:** **G1:** 26 **G2:** 28 **Age, mean (range):** 64 (20-93) **Race/ethnicity:** NR **Women, N (%):** 72 (100)	**Inclusion criteria:** • Incontinent by AHCPR guidelines* • Incontinence persisted after treatment for transient incontinence **Exclusion criteria:** • Post-void residual of more than 150 mL	**UUI, n (%):** **G1:** 27 (49) **G2:** 28 (51) **MUI with predominant urge, n (%):** **G1:** 12 (71) **G2:** 5 (29)	**Continent, n (%):** **G1:** 1 (4) **G2:** 1 (4) **Improved, n (%):** **G1:** 22 (85) **G2:** 19 (68) **No Change, n (%):** **G1:** 3 (11) **G2:** 8 (28)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: - Loss to followup: - Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: poor Age: -, NR Baseline OAB status: NR Baseline characteristics: - Length of followup: ++ Measurement methods: - Measurement reliability: - Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Diokno et al., 2002 **Country and setting:** US, Community-dwelling **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** 1 of 7 ALZA Corp (1)	**Design:** Multicenter, open-label, prospective cohort with 12 mos follow-up **Intervention:** Oxybutynin chloride ER **Groups:** NA **N at enrollment:** 1,067 **N at follow-up:** 493 **Women, n (%):** 904 (84.7) **Age, mean ± SD:** 64 ± 14.4 **Age, n (%):** < 40: 65 (6.1) 40-65: 415 (38.9) >65-74: 313 (29.3) ≥ 75: 274 (25.7) **Race/ethnicity, n (%):** White: 950 (89.0) Black: 82 (7.7) Hispanic: 28(2.6) Asian: 2 (0.2) Native American: 5 (0.5) **Follow-up:** 12 months	**Inclusion criteria:** • Community-dwelling • Urge or mixed incontinence • Age ≥ 18 • Generally in good health **Exclusion criteria:** • UTI • Prostatitis • Urinary tract obstruction • Bladder tumor • Bladder stone • Prostate cancer • Contraindication to study drug • Current drug or alcohol abuse • Pregnant or breastfeeding • Pre-existing severe GI narrowing • Taken an investigational drug ≤ 1 mo • Known allergy or hypersensitivity to oxybutynin chloride • Not able to swallow medication whole	**Incontinence impact, mean score ± SD:** 1.4 ± 0.72 **Sleep impact, mean score ± SD:** 3.3 ± 1.67 **Bother score, estimated from figure, mean:** 72	**Incontinence impact, end of dose adjustment, mean change ± SD:** -0.5 ± 0.70 *P* < 0.001 **Incontinence impact, 90 days, mean change ± SD:** -0.6 ± 0.76 *P* < 0.001 **Incontinence impact, final measure, mean change ± SD:** -0.5 ± 0.77 *P* < 0.001 **Sleep impact, end of dose adjust-ment, mean change ± SD:** -1.0 ± 1.73 *P* < 0.001 **Sleep impact, 90 days, mean change ± SD:** -1.2 ± 1.82 *P* < 0.001 **Sleep impact, final measure, mean change ± SD:** -1.1 ± 1.81 *P* < 0.001 **Bother score, end of dose adjust-ment, estimated from figure, mean:** 44 *P* < 0.001 **Bother score, 90 days, estimated from figure, mean:** 42 *P* < 0.001	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: NR Baseline characteristics: - Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Diokno et al., 2002 (continued)				**Bother score, 12 mos, estimated from figure, mean:** 39 *P* < 0.001 **Headache, %:** 1-90 days: 6.2 91-180 days: 0.6 181-270 days: 0.4 271-364 days: 0.4 Total: 7.6 **Dizziness, %:** 1-90 days: 5.0 91-180 days: 0.4 181-270 days: 0.2 271-364 days: 0 Total: 5.6 **Blurred vision, %:** 1-90 days: 2.8 91-180 days: 0.4 181-270 days: 0.1 271-364 days: 0 Total: 3.3 **Somnolence, %:** 1-90 days: 2.8 91-180 days: 0 181-270 days: 0.2 271-364 days: 0 Total: 3.0 **Confusion, %:** 1-90 days: 1.1 91-180 days: 0.1 181-270 days: 0.2 271-364 days: 0 Total: 1.4 **Discontinued due to AEs, n (%):** 256 (24) **Discontinued due to lack of efficacy, n (%):** 108 (10.1) **Discontinued due to administrative reasons, n (%):** 90 (8.4)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Diokno et al., 2003* Chu et al., 2005† **Country and setting:** US, Academic medical center **Enrollment period:** November 2000 to October 2001 **Funding:** ALZA Corporation, Ortho-McNeil Pharmaceuticals **Author industry relationship disclosures:** 5 of 7* ALZA (1) Indevus (1) Ortho-McNeil (4) Pharmacia (1) Watson (1) NR†	**Design:** RCT **Intervention:** Oxybutynin ER vs Tolterodine ER 12 week treatment period **Groups:** **G1:** Oxybutynin ER 10 mg daily **G2:** Tolterodine ER 4mg daily **N at enrollment:** **G1:** 391 **G2:** 399 **N at follow-up:** **G1:** 339 **G2:** 357 **Age, mean (range) :** **G1:** 60 (23-92) **G2:** 60 (18-85) **Race/ethnicity, N (%):** **White:** **G1:** 329 (84) **G2:** 342 (86) **Black:** **G1:** 32 (8) **G2:** 35 (9) **Hispanic:** **G1:** 27 (7) **G2:** 19 (5) **Other:** **G1:** 3 (1) **G2:** 3 (1) **Women, N (%):** **G1:** 391 (100) **G2:** 399 (100)	**Inclusion criteria:** • Age ≥ 18 • ≥ 21 episodes UUI/ week • ≥ 10 voids/ day • Urge > non-urge incontinence **Exclusion criteria:** • Treatable GU conditions causing incontinence • PVR > 150 mL by ultrasound x 2 • Risk of developing complete urinary retention • Medical problems worsened by anticholinergic effects • Hematuria • Uncontrolled narrow angle glaucoma • Obstructive uropathy • Reduced GI motility • Hypersensitivity to medications	**UUI episodes/ wk, mean ± SD:** **G1:** 37.2 ± 15.2 **G2:** 36.9 ± 14.1 **Total incontinence episodes/wk, mean ± SD:** **G1:** 43.3 ± 19.3 **G2:** 42.6 ± 18.2 **Voids/wk, mean ± SD:** **G1:** 94.8 ± 25.4 **G2:** 96.2 ± 24.5	**UUI episodes/wk, mean:** **G1:** 10.8 **G2:** 11.2 *P* = 0.28 **Incontinence episodes/wk, mean:** **G1:** 12.3 **G2:** 13.8 *P* = 0.08 **Voids/wk, mean:** **G1:** 66.4 **G2:** 71.1 *P* = 0.03 **UUI episodes/wk, % reduction ± SD:** **G1:** 72.0 ± 34.0 **G2:** 70.2 ± 33.2 *P* = 0.13 **Incontinent episodes/wk, % reduction ± SD:** **G1:** 72.8 ± 31.0 **G2:** 69.1 ± 34.9 *P* = 0.08 **Voids/wk, % reduction ± SD:** **G1:** 27.7 ± 19.7 **G2:** 24.9 ± 18.9 *P* = 0.05 **Total dryness, %:** **G1:** 23 **G2:** 16.8 *P* = 0.03 **No UUI episodes, %:** **G1:** 26.7 **G2:** 20.9 *P* = 0.06 **Dry mouth, any degree, n (%):** **G1:** 116 (29.7) **G2:** 89 (22.3) *P* = 0.02 **Dry Mouth, mild, n (%):** **G1:** 87 (22.3) **G2:** 69 (17.3)	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: - Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Diokno et al., 2003* Chu et al., 2005† (continued)				**Dry mouth, moderate-severe, n (%):** **G1:** 29 (7.4) **G2:** 20 (5.0) **Constipation, n (%):** **G1:** 25 (6.4) **G2:** 31 (7.8) **Diarrhea, n (%):** **G1:** 31 (7.9) **G2:** 25 (6.3) **Headache, n (%):** **G1:** 22 (5.6) **G2:** 24 (6.0) **UTI, n (%):** **G1:** 20 (5.1) **G2:** 13 (3.3) **CNS AE, n (%):†** **G1:** 35 (9.0) **G2:** 33 (8.3) **Dizziness, n (%):†** **G1:** 15 (3.8) **G2:** 10 (2.5) **Dizziness, mild,** %:†** **G1:** 1.8 **G2:** 1.5 **Dizziness, moderate,** %:†** **G1:** 0.8 **G2:** 0.3 **Somnolence, n (%):†** **G1:** 4 (1.0) **G2:** 9 (2.3) **Somnolence, mild,** %:†** **G1:** 0.5 **G2:** 1.5 **Somnolence, moderate,** %:†** **G1:** 0.3 **G2:** 0.5 **Insomnia, n (%):†** **G1:** 7 (1.8) **G2:** 3 (0.8)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Diokno et al., 2003* Chu et al., 2005† (continued)				**Insomnia, mild** %:†** **G1:** 0.8 **G2:** 0 **Insomnia, moderate,** %:†** **G1:** 0.5 **G2:** 0 **Depression, n (%):†** **G1:** 5 (1.3) **G2:** 3 (0.8) **Hypertonia, n (%):†** **G1:** 2 (0.5) **G2:** 4 (1.0) **Hypertonia, mild,** %:†** **G1:** 0 **G2:** 0 **Hypertonia, moderate,** %:†** **G1:** 0.3 **G2:** 0 **Anxiety, mild,** %:†** **G1:** 0.5 **G2:** 0 **Anxiety, moderate,** %:†** **G1:** 0.3 **G2:** 0 **Nervousness, mild,** %:†** **G1:** 0 **G2:** 0 **Nervousness, moderate,** %:†** **G1:** 0.3 **G2:** 0 **Tremor, mild,** %:†** **G1:** 0.3 **G2:** 0.3 **Tremor, moderate,** %:†** **G1:** 0 **G2:** 0	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Diokno et al., 2003* Chu et al., 2005† (continued)				**Confusion, mild,** %:†** **G1:** 0.3 **G2:** 0.3 **Confusion, moderate,** %:†** **G1:** 0 **G2:** 0	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Dmochowski et al., 2002 **Country and setting:** US, Community **Enrollment period:** NR 2 week washout 12 week treatment period **Funding:** NR **Author industry relationship disclosures:** 7 of 7 Abbot (1) Alza (3) Amgen (1) AstraZeneca (1) Bayer (1) Bioform (1) Genyx (1) Glaxo (1) Interneuron (2) Lilly (2) Merck (1) Otsulta (1) Pharmacia (3) Pfizer (1) Praecis (2) Roche (1) Seprecor (1) Surx (1) Synthelabo (1) Vivus (1) Watson (7) Yamanouchi (1)	**Design:** RCT Followed by: 12 week open label dose titration **Intervention:** Oxybutynin TDS vs. placebo **Groups:** **G1:** OXY TDS 1.3 mg **G2:** OXY TDS 2.6 mg **G3:** OXY TDS 3.9 mg **G4:** placebo **N at enrollment:** **G1:** 130 **G2:** 133 **G3:** 125 **G4:** 132 **N at follow-up:** **G1:** 128 **G2:** 131 **G3:** 123 **G4:** 130 **Women, N (%):** **G1:** 120 (92.3) **G2:** 123 (92.5) **G3:** 114 (91.2) **G4:** 121 (91.7) **Age, mean ± SD:** **G1:** 61.5 ± 11.8 **G2:** 61.9 ± 13.5 **G3:** 59.4 ± 14.5 **G4:** 62.7 ± 13.1 **Race/ethnicity, n (%):** **White:** **G1:** 119 (91.5) **G2:** 118 (88.7) **G3:** 118 (94.4) **G4:** 118 (89.4) **Black:** **G1:** 7 (5.4) **G2:** 10 (7.5) **G3:** 3 (2.4) **G4:** 11 (8.3)	**Inclusion criteria:** • Age ≥ 18 • History of OAB • ≥ 10 episodes UUI either pure urge or predominant urge on 7 day voiding diary • ≥ 56 voids/ 7 day diary • Average recorded urinary volume of ≤ 350 mL **Exclusion criteria:** • Incontinence related to chronic illness • Concomitant medications • History of lower urinary tract surgery in ≤ 6 mos • IC • Urethral syndrome • Painful bladder syndrome • Overflow urinary incontinence • Alcohol/drug abuse • Known hypersensitivity to oxybutynin, similar compounds or transdermal systems • Active skin disorder • Narrow angle glaucoma • Excessive caffeine intake > 5 cups/day	**Incontinence episodes/week, median:** **G1:** 31.0 **G2:** 30.0 **G3:** 31.0 **G4:** 30.0 **Voids/day, mean ± SD:** **G1:** 12.4 ± 2.9 **G2:** 12.1 ± 3.3 **G3:** 12.3 ± 3.3 **Voided volume (mL), mean:** **G1:** 175 **G2:** 165 **G3:** 156 **G4:** 170 **Open Label: Incontinence episodes/week, open label, median:** **G1:** 30.0 **G2:** 29.0 **G3:** 37.0 **G4:** NA **Prior years incontinent, years, mean ± SD:** **G1:** 9.1 ± 10.3 **G2:** 8.9 ± 8.8 **G3:** 9.9 ± 9.8 **G4:** 9.1 ± 9.1 **IIQ (QoL), total score, mean:** **G1:** 167 **G2:** 161 **G3:** 144 **G4:** 160 **Prior anticholinergic treatment, n, (%):** **G1: 30 (23.1)** **G2: 28 (21.1)** **G3: 28 (22.4)** **G4: 27 (20.5**	**Incontinence episodes/ week, median change:** **G1:** -16.0 **G2:** -14.0 **G3:** -19.0 **G4:** -14.5 **G3/G4:** *P* < 0.0165 **Voids/day, mean change ± SD:** **G1:** -1.8 ± 2.6 **G2:** -1.8 ± 2.4 **G3:** -2.3 ± 2.5 **G4:** -1.7 ± 3.0 **G3/G4:** *P* = 0.0457 **Voided volume, mL, mean increase ± SD:** **G1:** -2 **G2:** 19 **G3:** 24 **G4:** 6 **G3/G4:** *P* = 0.0063 **G2/G4:** *P* = 0.0157 **Open Label: Incontinence episodes/week, median change:** **G1:** -18.0 **G2:** -17.0 **G3:** -19.0 **G4:** NA **IIQ (QoL), total score, mean change:** **G1:** 119 **G2:** 104 **G3:** 89 **G4:** 113 **G3/G4:** *P* = 0.0327 **UDI (QoL), total score, mean ± SD:** **G1:** NR **G2:** NR **G3:** 78.8 ± 51.9 **G4:** 94.7 ± 50.0 **G3/G4:** *P* = 0.0266	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Dmochowski et al., 2002 (continued)	**Other:** **G1:** 4 (3.1) **G2:** 5 (3.8) **G3:** 4 (3.2) **G4:** 3 (2.3)			**Dry mouth, n (%):** **G1:** 6 (4.6) **G2:** 9 (6.8) **G3:** 12 (9.6) **G4:** 11 (8.3) **Dizziness, n (%):** **G1:** 2 (1.5) **G2:** 4 (3.0) **G3:** 5 (4.0) **G4:** 5 (3.8) **Dysuria, n (%):** **G1:** 1 (0.8) **G2:** 3 (2.3) **G3:** 3 (2.4) **G4:** 0 (0) **Somnolence, n (%):** **G1:** 1 (0.8) **G2:** 0 (0) **G3:** 2 (1.6) **G4:** 1 (0.8) **Nausea, n (%):** **G1:** 6 (4.6) **G2:** 5 (3.8) **G3:** 2 (1.6) **G4:** 7 (5.3) **Constipation, (%):** **G1:** 7 (5.4) **G2:** 3 (2.3) **G3:** 1 (0.8) **G4:** 4 (3.0) **Palpitations, n (%):** **G1:** 1 (0.8) **G2:** 0 (0) **G3:** 1 (0.8) **G4:** 0 (0) **Vision abnormal, n (%):** **G1:** 3 (2.3) **G2:** 2 (1.5) **G3:** 0 (0) **G4:** 2 (1.5) **Localized application site reactions, n (%):** **G1:** 32 (26.4) **G2:** 7 (5.7) **G3:** 8 (6.9)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Dmochowski et al., 2002 (continued)				**Application site erythema, n (%):** **G1:** 23 (19) **G2:** 29 (23.6) **G3:** 14 (12.0) **Application site erythema, mild, double blind period, n (%):** **G1:** 79 (31.5) **G2:** 29 (36.2) **G3:** NA **Application site erythema, moderate, double blind period, n (%):** **G1:** 46 (18.3) **G2:** 46 (18.1) **G3:** NA **Application site erythema, severe, double blind period, n (%):** **G1:** 6 (2.4) **G2:** 8 (3.1) **G3:** NA **Application site erythema, mild, open label, n (%):** **G1:** 18 (34.6) **G2:** 58 (38.4) **G3:** 87 (43.9) **Application site erythema, moderate, open label, n (%):** **G1:** 7(13.5) **G2:** 23 (15.2) **G3:** 24 (12.1) **Application site erythema, severe, open label, n (%):** **G1:** 0 (0) **G2:** 2 (1.3) **G3:** 0 (0)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Dmochowski et al., 2003 **Country and setting:** US, Community **Enrollment period:** **NR** 2 week washout 12 week treatment period **Funding:** Watson Pharma **Author industry relationship disclosures:** 6 of 6 Watson Pharma (6)	**Design:** RCT **Intervention:** Oxybutynin TDS vs. Tolterodine ER vs. placebo, 2 week washout plus 12 weeks treatment period; drug/placebo applied transdermally twice weekly to the abdomen and oral capsule ingested once daily **Groups:** **G1:** OXY TDS 3.9 mg/day **G2:** Tolterodine ER 4 mg daily **G3:** placebo **N at enrollment:** **G1:** 121 **G2:** 123 **G3:** 117 **Total:** 361 **N at follow-up:** **G1:** NR **G2:** NR **G3:** NR **Total:** 320 (89%) **Age, mean yrs ± SD:** **G1:** 63.1 ± 12.0 **G2:** 62.9 ± 13.5 **G3:** 64.5 ± 12.3 **Race/ethnicity, n (%):** **White:** **G1:** 111 (91.7) **G2:** 120 (97.6) **G3:** 110 (94.0) **Black:** **G1:** 8 (6.6) **G2:** 1(0.8) **G3:** 4 (3.4)	**Inclusion criteria:** • ≥ 18yo men and women • Current pharmacological treatment for OAB with beneficial response • ≥4 episodes UUI episodes either pure urge or predominant urge on 3 day voiding diary • ≥ 24 voids/ 3 day diary • Average recorded urinary volume of ≤350 mL **Exclusion criteria:** • History of lower urinary tract surgery in previous 6 months • IC • Urethral syndrome • Painful bladder syndrome • Overflow urinary incontinence	**Incontinence episodes/ day, mean ± SD:** **G1:** 4.7 ± 2.9 **G2:** 5.0 ± 2.9 **G3:** 5.0 ± 3.2 **Incontinence episodes/day, median:** **G1:** 4 **G2:** 4 **G3:** 4 **Voids/day, mean ± SD:** **G1:** 12.4 ± 2.9 **G2:** 12.1 ± 3.3 **G3:** 12.3 ± 3.3 **Voids/day, median:** **G1:** 12 **G2:** 12 **G3:** 12 **Voided volume (mL), mean ± SD:** **G1:** 165 ± 62 **G2:** 165 ± 61 **G3:** 175 ± 68 **Voided volume, mL, median:** **G1:** 160 **G2:** 150 **G3:** 171 **Global assessment of disease, QOL, mean ± SD:** **G1:** 65 ± 19 **G2:** 63 ± 20 **G3:** 65 ± 20 **IIQ (QOL), travel domain, mean ± SD:** **G1:** 49 ± 28 **G2:** 47 ± 29 **G3:** 43 ± 29	**Incontinence episodes/ day, mean ± SD:** **G1:** 1.9 ± 2.7 **G2:** 1.9 ± 3.0 **G3:** 2.9 ± 3.8 **G1/G3:** *P* = 0.0137 **G2/G3:** *P* = 0.0011 **G1/G2:** *P* = 0.5878 **Incontinence episodes/day, mean change ± SD:** **G1:** 2.9 ± 3.0 **G2:** 3.2 ± 2.8 **G3:** 2.1 ± 3.0 **Incontinence episodes/day, median** **G1:** 1 **G2:** 1 **G3:** 2 **Incontinence episodes/day, median change** **G1:** 3 **G2:** 3 **G3:** 2 **Voids/day, mean ± SD:** **G1:** 10.4 ± 3.2 **G2:** 9.9 ± 3.1 **G3:** 10.9 ± 3.8 **G1/G3:** *P* = 0.101 **G2/G3:** *P* = 0.0025 **G1/G2:** *P* = 0.276 **Voids/day, mean change ± SD:** **G1:** -1.9 ± 2.7 **G2:** -2.2 ± 2.6 **G3:** -1 ± 1.4 **Voids/day, median:** **G1:** 10 **G2:** 10 **G3:** 10	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Dmochowski et al., 2003 (continued)	**Other:** **G1:** 2 (1.6) **G2:** 2 (1.6) **G3:** 3 (2.6) **Women, N (%):** **G1:** 109 (90.1) **G2:** 117 (95.1) **G3:** 109 (93.2) **Prior antimuscarinic treatment, Tolterodine, n, (%):** **G1:** 57 (47) **G2:** 60 (49) **G3:** 54 (46) **Prior antimuscarinic treatment, Oxybutynin, n, (%):** **G1:**61 (51) **G2:** 59 (48) **G3:** 59 (50) **Prior antimuscarinic treatment, Other, n, (%):** **G1:** 7 (6) **G2:** 6 (5) **G3:** 6 (5)		**UDI (QOL), irritative symptoms, mean ± SD:** **G1:** 62 ± 20 **G2:** 66 ± 18 **G3:** 63 ± 20	**Voids/day, median change:** **G1:** 2 **G2:** 2 **G3:** 1 **Voided volume, (mL), mean ± SD:** **G1:** 198 ± 84 **G2:** 193 ± 75 **G3:** 182 ± 84 **G1/G3:** *P* = 0.0010 **G2/G3:** *P* = 0.0017 **G1/G2:** *P* = 0.7690 **Voided volume (mL), mean change ± SD:** **G1:** 32 ± 55 **G2:** 29 ± 57 **G3:** 9 ± 63 **Voided volume (mL), median:** **G1:** 188 **G2:** 189 **G3:** 165 **Voided volume (mL), median change:** **G1:** 24 **G2:** 29 **G3:** 5.5 **Global assessment of disease, QOL, change ± SD:** **G1:** 30 ± 30 **G2:** 33 ± 28 **G3:** 21 ± 31 **G1/G3:** *P* = 0.0106 **G2/G3:** *P* = 0.001 **G1/G2:** *P* = 0.1861	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Dmochowski et al., 2003 (continued)				**IIQ (QOL) travel domain, change ± SD:** **G1:** 23 ± 25 **G2:** 22 ± 29 **G3:** 11 ± 30 **G1/G3:** *P* = 0.0018 **G2/G3:** *P* = 0.0045 **UDI (QOL), irritative symptoms, change ± SD:** **G1:** 25 ± 26 **G2:** 28 ± 26 **G3:** 18 ± 24 **G1/G3:** *P* = 0.0156 **G2/G3:** *P* = 0.0010 **Treatment compliance with assigned dosage regimen: 92%:** **Frequency decreased to a greater extent for patients with > 14 micturations per day at baseline** **G1: -2.9/day, *P* = 0.0036 (data for other groups not reported)** **Adverse effects:** **Dry mouth, %:** **G1:** 4.1 **G2:** 7.3 **G3:** 1.7 **G1/G3:** *P* = 0.2678 **G2/G3:** *P* = 0.0379 **Constipation, (%):** **G1:** 3.3 **G2:** 5.7 **G3:** NR	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Dmochowski et al., 2003 (continued)				**Mild systemic adverse effects, n (%):** **G1:** 15 (12.4) **G2:** 13 (10.6) **G3:** 6 (5.1) **Moderate systemic adverse effects, n (%)** **G1:** 7 (5.8) **G2:** 13 (10.6) **G3:** 7 (6.0) **Severe systemic adverse effects, n (%)** **G1:** 1 (0.8) **G2:** 3 (2.4) **G3:** 1 (0.9)**Mild localized application site reactions, n (%):** **G1:** 9 (7.4) **G2:** 2 (1.6) **G3:** 5 (4.3) **Moderate localized application site reactions, n (%):** **G1:** 17 (14.0) **G2:** 4 (3.3) **G3:** 2 (1.7) **Severe localized application site reactions, n (%):** **G1:** 6 (5.0) **G2:** 1 (0.8) **G3:** 1 (0.9) **Treatment discontinuation due to adverse effects, n (%):** **G1:** 13 (10.7) (12 due to application site reactions, 1 due to hot flushes) **G2:** 2 (1.6) (1 due to fatigue and 1 due to dizziness) **G3:** NR	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Dmochowski et al., 2003 (continued)				**Postvoid residual>150 mL at end of treatment:** **G1:** 4 **G2:** 4 **G3:** 3 No reports of symptomatic urinary retention **Withdraw due to** AEs: **23**	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Dmochowski et al., 2007 **Country and setting:** International, multicenter **Enrollment period:** NR **Funding:** Pfizer Inc. **Author industry relationship disclosures:** 5 of 5 Astellas (2) Esprit (1) Lilly (1) Merck (1) Novartis (2) Ortho-McNeil (1) Pfizer (5) Watson (1)	**Design:** RCT (subanalysis) **Intervention:** Tolterodine ER vs. placebo **Groups:** **G1:** Tolterodine ER 4mg po qAM **G2:** Placebo qAM **N at enrollment:** Total: 1015 **G1:** 507 **G2:** 508 **N at follow-up:** **G1:** 507 **G2:** 507 **Age, yrs (range):** **G1:** 60 (20-89) **G2:** 61 (22-93) **Race/ethnicity, %:** **White:** **G1:** 95 **G2:** 94 **Black:** **G1:** 3 **G2:** 4 **Other:** **G1:** 1 **G2:** 2 **Women, %:** 81 **Follow-up:** 12 wks	**Inclusion criteria:** • Age ≥18 • ≥ 8 voids/day and ≥ 5 episodes/wk UUI x 6 mos **Exclusion criteria:** • Hepatic, renal disease • UTI, recurrent UTIs • SUI • BOO • Indwelling catheter • Self catheterization • Taking anticholinergic medication • Mean voided volume > 200 mL or total daily voided volume > 3000 mL	**UUI episodes/ wk, mean ± SD:** **G1:** 22.1 ± 22.3 **G2:** 23.3 ± 20.7 **UUI episodes/ wk, 24:00-06:00, mean ± SD:** **G1:** 3.5 ± 5.0 **G2:** 3.9 ± 5.0 **UUI episodes/ wk, 06:00-12:00, mean ± SD:** **G1:** 6.9 ± 8.1 **G2:** 6.7 ± 6.7 **UUI episodes/ wk, 12:00-18:00, mean ± SD:** **G1:** 6.9 ± 8.2 **G2:** 7.2 ± 6.9 **UUI episodes/ wk, 18:00-24:00, mean ± SD:** **G1:** 5.3 ± 8.1 **G2:** 5.5 ± 5.8 **Voids/day, mean ± SD:** **G1:** 10.9 ± 4.2 **G2:** 11.3 ± 3.8 **Voids/day, 24:00-06:00, mean ± SD:** **G1:** 1.7 ± 1.0 **G2:** 1.8 ± 1.1 **Voids/day, 06:00-12:00, mean ± SD:** **G1:** 3.3 ± 1.4 **G2:** 3.4 ± 1.3 **Voids/day, 12:00-18:00, mean ± SD:** **G1:** 3.1 ± 1.4 **G2:** 3.2 ± 1.3 **Voids/day, 18:00-24:00, mean ± SD:** **G1:** 2.8 ± 1.3 **G2:** 2.9 ± 1.1	**UUI episodes/wk, mean change ± SD:** **G1:** -11.8 ± 17.8 **G2:** -6.9 ± 15.4 P ≤ 0.001 Benefit ratio 1.71 **UUI episodes/wk, 24:00-06:00, mean change ± SD:** **G1:** -1.6 ± 4.0 **G2:** -1.0 ± 3.5 *P* ≤ 0.001 Benefit ratio 1.53 **UUI episodes/wk, 06:00-12:00, mean change ± SD:** **G1:** -3.7 ± 7.1 **G2:** -2.0 ± 5.4 *P* ≤ 0.001 Benefit ratio 1.82 **UUI episodes/wk, 12:00-18:00, mean change ± SD:** **G1:** -3.9 ± 7.1 **G2:** -2.2 ± 5.7 *P* ≤ 0.001 Benefit ratio 1.82 **UUI episodes/wk, 18:00-24:00, mean change ± SD:** **G1:** -3.0 ± 6.9 **G2:** -1.6 ± 4.5 *P* ≤ 0.001 Benefit ratio 1.89 **Voids/day, mean change ± SD:** **G1:** -1.8 ± 3.4 **G2:** -1.2 ± 2.9 *P* ≤ 0.001 Benefit ratio 1.46 **Voids/day, 24:00-06:00, mean change ± SD:** **G1:** -0.22 ± 0.7 **G2:** -0.17 ± 0.8 *P* ≤ 0.05 Benefit ratio 1.29	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Dmochowski et al., 2007 (continued)			**Voided volume (mL), mean ± SD:** **G1:** 141 ± 43 **G2:** 136 ± 42 **Voided volume (mL), 24:00-06:00, mean ± SD:** **G1:** 201± 99 **G2:** 190 ± 96 **Voided volume (mL), 06:00-12:00, mean ± SD:** **G1:** 141 ± 52 **G2:** 139 ± 55 **Voided volume (mL), 12:00-18:00, mean ± SD:** **G1:** 126 ± 49 **G2:** 119 ± 45 **Voided volume (mL), 18:00-24:00, mean ± SD:** **G1:** 129 ± 50 **G2:** 123 ± 47	**Voids/day, 06:00-12:00, mean change ± SD:** **G1:** -0.57 ± 1.2 **G2:** -0.35 ± 1.0 *P* ≤ 0.001 Benefit ratio 1.60 **Voids/day, 12:00-18:00, mean change ± SD:** **G1:** -0.55 ± 1.2 **G2:** -0.39 ± 1.0 *P* ≤ 0.001 Benefit ratio 1.42 **Voids/day, 18:00-24:00, mean change ± SD:** **G1:** -0.43 ± 1.1 **G2:** -0.30 ± 0.8 *P* ≤ 0.002 Benefit ratio 1.43 **Voided volume (mL), mean change ± SD:** **G1:** 34.1 ± 50.5 **G2:** 14. 0± 41.3 *P* ≤ 0.001 Benefit ratio 2.44 **Voided volume (mL), 24:00-06:00, mean change ± SD:** **G1:** 33.8± 105.5 **G2:** 16.7 ± 87.7 *P* ≤ 0.002 Benefit ratio 2.03 **Voided volume (mL), 06:00-12:00, mean change ± SD:** **G1:** 38.2 ± 63.9 **G2:** 15.5± 58.6 *P* ≤ 0.001 Benefit ratio 2.47 **Voided volume (mL), 12:00-18:00, mean change ± SD:** **G1:** 31.5 ± 59.4 **G2:** 12.4 ± 42.4 *P* ≤ 0.001 Benefit ratio 2.55	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Dmochowski et al., 2007 (continued)				**Voided volume (mL), 18:00-24:00, mean change ± SD:** **G1:** 29.2 ± 55.0 **G2:** 12.0 ± 49.6 *P* ≤ 0.001 Benefit ratio 2.44	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Dmochowski et al., 2008 **Country and setting:** US, 62 sites **Enrollment period:** September 2005 to June 2006 **Funding:** Esprit Pharma and Indevus Pharmaceuticals Inc. **Author industry relationship disclosures:** 4 of 4 Allergan (4) Astellas (3) Eli Lilly (1) Esprit Pharma (4) GSK (2) Indevus (4) Medtronics (1) Novartis (3) Ortho (2) Pfizer (2) Schwarz Pharma (1) Watson (4)	**Design:** RCT **Intervention:** Trospium vs. placebo **Groups:** **G1:** Trospium 60 mg qd **G2:** Placebo **N at enrollment:** **G1:** 280 **G2:** 284 **N at follow-up:** **G1:** 267 **G2:** 276 **Women, n (%):** **G1:** 230 (82.1) **G2:** 249 (87.7) **Age, mean (SE):** **G1:** 61.2 (0.7) **G2:** 58.4 (0.7) **Race/ethnicity, n (%):** **White:** **G1:** 245 (87.5) **G2:** 234 (82.4) **Black:** **G1:** 18 (16.4) **G2:** 28 (9.9) **Hispanic:** **G1:** 12 (4.3) **G2:** 14 (4.9) **Asian:** **G1:** 2 (0.7) **G2:** 3 (1.1) **Other:** **G1:** 3 (1.1) **G2:** 5 (1.8)	**Inclusion criteria:** • Age ≥ 18 • Symptoms of OAB ≥ 6 mos duration • Urinary frequency (mean of ≥ 10 toilet voids per day) • Urgency (1 or more episodes of severe urgency associated with a toilet void) • UUI (a mean of 1 or more UUI episodes per day) **Exclusion criteria:** • Total voided volumes > 3000 mL/day • Mean voided volume > 250 mL • Predominantly SUI • Insensate, or overflow incontinence • Neurogenic bladder • Indwelling or intermittent catheterization • Renal disease (serum creatinine >1.5 mg/dL) • Uninvestigated hematuria • UTI • History of > 3 UTIs in the previous 12 mos • Urinary retention (PVR > 100 mL) • Cancer • Interstitial cystitis	**UUI episodes/ day, mean (SE):** **G1:** 4.0 (0.2) **G2:** 4.0 (0.2) **Urgency severity, mean (SE):** **G1:** 1.82 (0.03) **G2:** 1.83 (0.03) **Voids/day, mean (SE):** **G1:**12.8 (0.2) **G2:** 12.9 (0.2) **Prior anticholinergic use for OAB, mean (SE):** **G1:** 142 (50.7) **G2:** 156 (54.9) **Voided volume (mL), mean (SE):** **G1:** 149.1 (2.9) **G2:** 151.8 (2.8)	**UUI episodes/day, 12 wks, mean change (SE):** **G1:** -2.4 (0.2) **G2:** -1.6 (0.2) **G1/BL:** *P* ≤ 0.001 **Urgency severity, 12 wks, mean change (SE):** **G1:** -0.28 (0.03) **G2:** -0.13 (0.03) **G1/BL:** *P* ≤ 0.001 **Voids/day, 12 wks, mean change (SE):** **G1:** -2.5 (0.2) **G2:** -1.8 (0.2) **G1/BL:** *P* ≤ 0.001 **Voided volume (mL), 12 wks, mean change (SE):** **G1:** 31.5 (3.4) **G2:** 17.8 (3.3) **G1/BL:** *P* ≤ 0.01 **Treatment emergent AE, n (%):** **G1:** 154 (55) **G2:** 130 (45.8) **Mild to Moderate AEs, %:** **G1:** 87% **G2:** 91.5% **Dry mouth, n (%):** **G1:** 36 (12.9) **G2:** 12 (4.6) **Constipation, n (%):** **G1:** 21 (7.5) **G2:** 5 (1.8) **Headache, n (%):** **G1:** 5 (1.8) **G2:** 6 (2.1)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Dmochowski et al., 2008 (continued)		• PSA > greater than 4 ng/mL • Prostate cancer, or chronic prostatitis			

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Drutz et al., 1999 **Country and setting:** 25 centers United States and Canada **Enrollment period:** NR **Funding:** Pharmacia & Upjohn AB, Uppsala, Sweden **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Tolterodine vs. oxybutynin vs. placebo **Groups:** 2 wk washout/run-in period **G1:** Tolterodine 2 mg b.i.d. x 12 wks **G2:** Oxybutynin 5 mg t.i.d. x 12 wks **G3:** placebo **N at enrollment:** **G1:** 109 **G2:** 112 **G3:** 56 **N at follow-up:** Protocol correct **G1:** 70 **G2:** 41 **G3:** 36 **Age, mean range:** **G1:** 63.0 (31-88) **G2:** 66.3 (23-91) **G3:** 62.1 (26-87) **Women, %:** **G1:** 81 **G2:** 91 **G3:** 80	**Inclusion criteria:** • Age≥18 yrs • Provided written informed consent • Post-menopausal • Surgically sterile • Adequate contraception • Detrusor overactivity on subtracted cystometry • Urinary frequency (58 voids on average per 24 hrs) and either urge incontinence (51 incontinence episode on average per 24 hrs **Exclusion criteria:** • SUI • Hepatic or renal disease • Recurrent UTIs • Interstitial cystitis • Hematuria or hematuria secondary to malignant disease • Indwelling catheter or intermittent catheterization • Treatment with investigational drug in ≤ 2 mos • Treatment with tolterodine or electro-stimulation therapy or BT ≤ 14 days	**Duration of symptoms >5 years (%):** **G1:** 47 (43) **G2:** 41 (37) **G3:** 25 (45) **Instability hyperreflexia (%):** **G1:** 101:8 (93:7) **G2:** 100:8 (89:7) **G3:** 53:3 (95:5) **Urgency (%):** **G1:** 104 (95) **G2:** 111 (99) **G3:** 55 (98) **Previous drug therapy for urge incontinence, (%):** **G1:** 49 (45) **G2:** 50 (45) **G3:** 31 (55) **Good response to previous drug therapy, n (%):** **G1:** 20 (41) **G2:** 20 (40) **G3:** 12 (39) **Previous surgery affecting the lower urinary tract (%):** **G1:** 29 (27) **G2:** 50 (45)* **G3:** 19 (34) **Patients with incontinence episodes, n (%):** **G1:** 90 (83) **G2:** 103 (92) **G3:** 50 (89) **Incontinence episodes/day, mean (range):** **G1:** 3.7 (0.1-19.9) **G2:** 3.4 (0.1-13.4) **G3:** 3.5 (0.1-14.9)	**Incontinence episodes/day, mean change ± SD:** **G1:** -1.7 ± 2.0 **G2:** -1.7 ± 1.7 **G3:** -1.0 ± 2.2 **G1/G3:** *P* = 0.063 **Mean difference (SEM):** **G1/G2:** 0.0 (0.4) (95% CI) **G1/G2:** -0.7 to 0.7 **Voids/day, mean change ± SD:** **G1:** -2.0 ± (2.5) **G2:** -2.0 ± (2.3) **G3:** -1.1 ± (2.9) **G1/G3:** *P* = 0.036 **Mean difference (SEM):** **G1/G2:** 0.0 (0.4) (95% CI) **G1/G2:** -0.8 to 0.8 **Voided volume (mL), mean change ± SD:** **G1:** 34 ± 41 **G2:** 50 ± 43 **G3:** 12 ± 41 **G1/G3:** *P* = 0.0075 **Mean difference (SEM):** **G1/G2:** NA (95% CI) **G1/G2:** NA	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Drutz et al., 1999 (continued)	**Race/ethnicity, %:** **Caucasian:** **G1:** 87 **G2:** 94 **G3:** 93 **BMI, mean kg/m^2 (range):** **G1:** 29.0 (18.3-56.2) **G2:** 28.0 (16.0-51.4) **G3:** 29.1 (17.2-52.8)	• Treatment with anticholinergic drug, or any drug for urinary urge • Incontinence ≤ 14 days • Unstable dosage of any anticholinergic • Serious adverse effects on oxybutynin • Average total voided volume/24 hours of >3000 mL • Clinically significant voiding difficulty with risk of urinary retention (such as residual volume >200 mL or urine flow rate <10 mL/s)	**Patients with ≥ 8 voids/day, n (%):** **G1:** 108 (99) **G2:** 110 (98) **G3:** 55 (98) **Voids/day, mean (range):** **G1:** 11.6 (7.7-22.0) **G2:** 11.5 (7.1-31.4) **G3:** 11.6 (6.6-21.9) **Volume voided/void, mean mL (range):** **G1:** 155 (48–290) **G2:** 149 (42–315) **G3:** 160 (33–371) ***P*** <0.05 vs. placebo and tolterodine treatment groups.		

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Dwyer et al., 2008 **Country and setting:** Multinational, multicenter (academic and private) **Enrollment period:** NR **Funding:** Novartis Pharma AG **Author industry relationship disclosures:** 6 of 7 Allergan (1) Amgen (1) AMS (1) Astellas (1) Bayer (1) GSK (1) Hospira Australia (1) Novartis (5) Ocean Spray (1) Ono (1) Pfizer (2) Spectrum (1) Sunumoto (1)	**Design:** Multicenter open label extension **Intervention:** Darifenacin 7.5 mg or 15 mg (all pts received 7.5 mg dose for 2 weeks followed by individual dose adjustments) **Groups:** **G1:** Darifenacin continuation group 7.5 or 15 mg daily **N at enrollment:** **G1**: 303 **N at follow-up:** **G1**: 300 **Women, N (%):** **G1:** 262 (86.5) **Age, mean (range):** **G1:** 57.1 (22-89) **Race/ethnicity:** NR **Follow-up:** 12 weeks followed by 2 year extension	**Inclusion criteria:** • Successful completion of one of 2 previous, 12-wk feeder studies with no major protocol violation • "wet OAB" (urgency, frequency, and incontinence) x 6 months • Adequate contraception if of childbearing potential • Able to complete patient diaries independently • Capable of independent toileting **Exclusion criteria:** • Certain concomitant medications (see previous studies) • Max darifenacin dose of 7.5 mg qd for patients taking potent inhibitors of CYP450 3A4 and pts w/ moderate hepatic impairment (Child Pugh B) • Other active management strategies of OAB (bladder training)	**Incontinence episodes/week, mean ± SD:** **G1**: 20.8 ± 13.6 **Incontinence episodes/week, median:** **G1**: 17.0 **KHQ incontinence impact score, mean:** **G1:** 78.56 **KHQ severity score, mean:** **G1**: 52.56 **KHQ role limitations score, mean:** **G1:** 62.72 **KHQ physical limitations score, mean:** **G1:** 62.67 **KHQ social limitations score, mean:** **G1:** 34.28 **KHQ emotions score, mean:** **G1:** 43.85 **KHQ sleep/ energy score, mean:** **G1:** 52.50 **KHQ personal relationship score, mean:** **G1:** 26.94 **KHQ general health score, mean:** **G1:** 27.25	**Incontinence episodes/week, median % change:** **G1**: -83.3 *P* < 0.001 **KHQ incontinence impact score, mean change:** **G1:** -25.25 *P* < 0.001 **KHQ severity score, mean change:** **G1:** -13.53 *P* < 0.001 **KHQ role limitations score, mean change:** **G1:** -26.77 *P* < 0.001 **KHQ physical limitations score, mean change:** **G1:** -26.35 *P* < 0.001 **KHQ social limitations score, mean change:** **G1:** -15.51 *P* < 0.001 **KHQ emotions score, mean change:** **G1:** -12.79 *P* < 0.001 **KHQ sleep/energy score, mean change:** **G1:** -11.59 *P* < 0.002 **KHQ personal relationship score, mean change:** **G1:** -8.68 *P* < 0.001	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Method and blinding: - Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Dwyer et al., 2008 (continued)				**KHQ general health score, mean change:** **G1:** 2.05 *P* = NS	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Elinoff et al., 2006^ Roberts et al., 2006 **Country and setting:** US, 82 Primary care & Ob-Gyn offices **Enrollment period:** NR **Funding:** Pfizer **Author industry relationship disclosures:** 6 of 6 Pfizer (6) Astellas (1) Novartis (1)	**Design:** Open-label, single-arm cohort **Intervention:** Tolterodine ER 4 mg qd for 12 wks **Groups:** NA **N at enrollment:** 896 **N at follow-up:** 758 **Age, yrs ± SD:** 56 ± 15 **Race/ethnicity, n (%):** White: 691 (80) Black: 94 (11) Asian: 22 (3) Other: 53 (6) **Women, N (%):** 708 (82) **Parity:** NR	**Inclusion criteria:** • Age ≥ 18 • OAB symptoms for ≥3 mos • ≥ 8 voids/day • 2+ episodes of urgency or UUI in a 3-d period • 3+ on the OAB Bother Rating Scale **Exclusion criteria:** • Stress, functional, or overflow incontinence • Acute UTI • Clinically significant LUT pathology • Indwelling catheter • Intermittent self-catherization • Use of anticholinergics, antimuscarinics for OAB, drugs to treat UUI, potent cytochrome P450 3A4 inhibitors, or investigational drugs	**Duration of OAB (yrs), mean ± SD:** 6 ± 8 **Duration on study drug (days), mean ± SD:** 80 ± 19 **Daytime voids/ day, mean ± SD:** 9.3 ± 2.8 **Nocturia episodes/day, mean ± SD:** 3.0 ± 1.7 **UUI episodes/ day, mean ± SD:** 2.7 ± 3.2 **Urgency episodes/day, mean ± SD:** 5.0 ± 3.8 **OAB-q scores:** Symptom bother: 60.0 Coping: 50.0 Concern: 51.4 Sleep: 44.4 Social Interaction: 84.0 Total HRQL: 55.2 **AUA-SI:** Total: 18 Irritative: 10 Obstructive: 8 **Most bothersome symptom, n (%)** Daytime frequency: 256 (30) Nocturnal frequency: 241 (28) UUI: 206 (24) Urgency: 154 (18)	**UUI episodes/day, week 12, mean % change (95% CI):^** -86.1 (-91.7, -80.0)* **UUI episodes/day, week 12, UUI most bothersome, mean % change (95% CI):^** -80.0 (-85.7, -69.2)* **Urgency episodes/day, week 12, mean % change (95% CI):^** -75.0 (-80.0, -71.4)* **Urgency episodes/day, week 12, urgency most bothersome, mean % change (95% CI):^** -78.4 (-83.3, -72.2)* **Nocturia episodes/day, week 12, mean % change (95% CI):^** -37.5 (-40.0, -33.3)* **Nocturia episodes/day, week 12, nocturia most bothersome, mean % change (95% CI):^** -40.0 (-42.9, -33.3)*	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Elinoff et al., 2006 Roberts et al., 2006 (continued)				**Daytime voids/ day, week 12, mean % change (95% CI):^** -29.0 (-31.0, -27.3)* **Daytime voids/ day, week 12, daytime voids most bothersome, mean % change (95% CI):^** -30.4 (-33.3, -27.3)* **OAB-q scores, 12 weeks, median change (95% CI):*** Symptom bother: -37.5 (-37.5 , -35.0) Coping: 32.5 (30.0, 35.0) Concern: 34.3 (31.4, 37.1) Sleep: 28.0 (28.0, 32.0) Social Interaction: 12.0 (12.0, 16.0) Total HRQL: 28.9 (27.2, 31.2) **AUA-SI, Median change from baseline to 12 wks (95% CI):*** Total: -9 (-9, -8) Irritative: -5 (-5, -5) Obstructive: -4 (-4, -3) *P < 0.0001 vs. baseline **All-cause AE, %:** 51 **Discontinued treatment, n %:** 15 (7)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Elinoff et al., 2006 Roberts et al., 2006 (continued)				**Trt-related AE, %:** 23 Dry mouth, %: 10.0 Constipation, %: 3.7 Headache, %: 3.0 UTI, %: 2.7	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Fantl et al.,1981 **Country and setting:** US, University **Enrollment period:** N/A **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Retrospective chart review **Intervention:** Bladder retraining drill (BRD) and anticholinergics when BRD not satisfactory **Groups:** **G1:** Detrusor muscle contraction approximately 5 seconds after a cough **G2:** Detrusor muscle contracts spontaneously without prior provocation **G3:** Both cough contraction and spontaneous contraction **N at enrollment:** **G1:** 39 **G2:** 4 **G3:** 49 **N at follow-up:** NA **Women, %:** 100 **Age, mean ± SD:** 42.7 ± 10:3 **Race/ethnicity:** NR **Parity, mean:** 3.5	**Inclusion criteria:** • Cystometric tracings showed a rise of 15 cm water or more in intravesical pressure when recorded independently and calculated by subtraction from intra-abdominal transrectal pressures **Exclusion criteria:** • Neuropathic conditions • UTI	**Urgency and frequency, n (%):** 72 (78.2) **Urinary incontinence, n (%):** 65 (70.6) **Sensation of incomplete voiding, n (%)** 59 (64.1) **Nocturia, n (%):** 66 (71.7) **Dysuria, n (%):** 3 (3.2) **MUI, n (%):** 6 (6.5) **Enuresis in childhood, n (%):** 5 (5.4) **Previously operated on for similar urologic symptoms, n (%):** 34 (36.9)	**Cured, n (%):** **G1:** 32 (82.1) **G2:** 1 (25) **G3:** 41 (83.7) **Cured by BRD alone, n (%):** 44 (78.6) **Cured by BRD + anticholinergics, n (%):*** 30 (83.5)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: NR Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: NA Measurement methods: + Measurement reliability: - Intervention description: -

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Garely et al., 2006 **Country and setting:** US, 207 centers **Enrollment period:** June 2004 to April 2005 **Funding:** Astellas Pharma US, Inc. and GlaxoSmithKline **Author industry relationship disclosures:** 2 of 5 Astellas (2)	**Design:** Phase IIIb trial **Intervention:** Treatment with 5 mg solifenacin succinate. Dosage could be increased to 10 mg, maintained or decreased in response to pt perceived efficacy and tolerability **N at enrollment:** 2,205 **N at follow-up**: 1,743 **Women, N (%):** 1813 (82.2) **Age, mean ± SD:** 59.7 ± 14.4 **Race/ethnicity, n (%):** White: 1,761 (79.9) Black: 274 (12.4) Other: 170 (7.7) **Weight, mean ± SD:** 182.2 ± 47.0 **Follow-up:** 12 weeks	**Inclusion criteria:** • ≥ 18 yrs • OAB symptoms ≥ 3 months • Toilet without difficulty • Other OAB meds with washout period ≥ 7 days • Non-drug treatment of OAB if established ≥ 4 wks prior to study and continued **Exclusion criteria:** • SUI • Stress predominant MUI • UTI or chronic inflammation • Outflow obstruction due to benign prostatic hyperplasia • Uncontrolled narrow-angle glaucoma • Urinary or gastric retention • Severe renal or hepatic impairment • Chronic severe constipation or diagnosed gastrointestinal obstructive disease • Bladder cancer • Pregnant or not using reliable method of birth control	**UUI, physician assessment, n (%):** 1,586 (71.9) **Urgency, physician assessment, n (%):** 2,007 (91.0) **Frequency, physician assessment, n (%):** 1,969 (89.3) **Nocturia, physician assessment, n (%):** 1,792 (81.3) **Perception of bladder condition, mean:** 4.4 **Most bother-some OAB symptom, n (%):** Frequency: 619 (28.1) UUI: 602 (27.3) Urgency: 508 (23.0) Nocturia: 337 (15.3) None: 139 (6.3) **Duration of OAB, n (%):** 3 mo to 1 year: 349 (15.8) > 1 to 5 years: 1,124 (51.0) > 5 years: 732 (33.2)	**Flexible drug admin dose, wk 4, n (%):** Remained at 5 mg/d: 941 (45.3) 5 mg/d to 10 mg/d: 1,076 (51.8) Discontinued: 60 (2.9) **Flexible drug admin dose, wk 8, n (%):** Remained at 5 mg/d: 782 (43.3) 5 mg/d to 10 mg/d: 166 (17.6) Remained at 10 mg/d: 1,018 (56.4) 10 mg/d to 5 mg/d: 491 (8.5) Discontinued: 4 (0.2) **Perception of bladder condition, wk 4, mean:** 3.3 *P* < 0.001 **Perception of bladder condition, wk 12 early termi-nation, mean:** 2.9 *P* < 0.001 **Perception of bladder condition, endpoint, mean:** 2.9 *P* < 0.001 **Urgency bother, VAS score (mm), mean (n):** 29.1 (1,781) **UUI bother, VAS score (mm), mean (n):** 24.0 (1,504)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Garely et al., 2006 (continued)		• Known hypersensitivity to study medication, its components, or to anticholinergic medication		**Frequency bother, VAS score (mm), mean (n):** 28.3 (1,751) **Nocturia bother, VAS score mean mm (n):** 28.3 (1,659) **OAB-q symptom severity subscale, mean change (95% CI):** -29.6 (-30.7, -28.6) *P* < 0.001 **OAB-q coping subscale, mean change (95% CI):** 27.4 (26.2, 28.5) *P* < 0.001 **OAB-q concern subscale, mean change (95% CI):** 29.6 (28.4, 30.8) *P* < 0.001 **OAB-q sleep subscale, mean change (95% CI):** 27.3 (26.1, 28.5) *P* < 0.001 **OAB-q social interaction subscale, mean change (95% CI):** 14.7 (13.7, 15.6) *P* < 0.001 **OAB-q overall health-related QoL subscale, mean change (95% CI):** 25.4 (24.4, 26.4) *P* < 0.001 **Adverse events, n (%):** 1,321 (59.4) **Any treatment-related AE, n (%):** 928 (41.7)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Garely et al., 2006 (continued)				**Dry mouth, n (%):** Mild: 352 (15.8) Moderate: 100 (4.5) Severe: 25 (1.1) **Constipation, n (%):** Mild: 190 (8.5) Moderate: 85 (3.8) Severe: 20 (0.9) **Headache, n (%):** 76 (3.4) **Blurred vision, n (%):** Mild: 41 (1.8) Moderate: 15 (0.7) Severe: 1 (0) **Dry eye, n (%):** 29 (1.3)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Garely et al., 2007* Mallett et al., 2007^ **Country and setting:** US, multicenter (207 sites) **Enrollment period:** NR **Funding:** Astellas Pharma US Glaxo-SmithKline **Author industry relationship disclosures:** 4 of 4* Astellas (4) Pfizer (1) Novartis (1) 4 of 4^ Astellas (3) GlaxoSmthKline (2) Novartis (1) Watson (1) Yamanouchi (1)	**Design:** Prospective case series **Intervention:** Flexibly dosed, once daily solifenacin (started on 5 mg/d; option of increasing to 10 mg/d at week 4; option to maintain 10 mg dose or decrease to 5 mg at wk 8); for 12 weeks of treatment **10 mg dose, %:** 4 wks: **G1:** 55 8 wks: **G1:** 59 (8% went back to 5mg; 19% increased to 10 mg) **Groups:** **G1:** Urge incontinence as most bothersome symptom **G2:** Black participants **G3:** Full study population **N at enrollment:** **G1:**582 **G2:** 274 **G3:** 2205 **Age, mean yrs ± SD:** **G1:** 60.9 ± 13.1 **G2:** 54.7 ± 13.6 **G3:** 59.7 ± 14.4 **Race/ethnicity, n (%):** **White:** **G1:** 493 (84.7) **G3:** 1761 (79.9) **African American:** **G1:** 62 (10.7) **G3:** 274 (12.4)	**Inclusion criteria:** • Age ≥ 18 • Symptoms of OAB for ≥ 3 mos • Ambulatory • Able to use the toilet without difficulty • Urgency, UUI, frequency or nocturia ≥ 3 mos **Exclusion criteria:** • Previous use of solifenacin	**UUI, n (%):** **G1:** 582 (100%) **G2:** NR **G3:** 1596 (71.9%) **Urgency, n (%):** **G1:** 534 (91.8) **G2:** NR **G3:** 2007 (91.0) **Frequency, n (%):** **G1:** 488 (83.8) **G2:** NR **G3:** 1969 (89.3) **Nocturia, n (%):** **G1:** 438 (75.3) **G2:** NR **G3:** 1792 (81.3) **Most bothersome OAB symptom** **Urgency, n (%):** **G2:** 48 (17.5) **G3:** 508 (23.0) **UUI, n (%):** **G1:** 582 (100) **G2:** 63 (23.0) **G3:** 602 (27.3) **Frequency, n (%):** **G2:** 106 (38.7) **G3:** 619 (28.1) **Nocturia, n (%):** **G2:** 34 (12.4) **G3:** 337 (15.3) **None specified, n (%):** **G2:** 23 (8.4) **G3:** 139 (6.3) **OAB for 3 mos -1 yr, n (%):** **G1:** 57 (9.8) **G3:** 349 (15.8%) **OAB for 1-5 yrs, n (%):** **G1:** 294 (50.5) **G3:** 1124 (51.0) **OAB for >5 yrs:** **G1:** 231 (39.7) **G3:** 732 (33.2)	**Patient perception of bladder condition scale, 4 wks, mean:** **G1:** 3.3* **G2:** 3.1* **G3:** 3.3* **Patient Perception of Bladder Condition Scale, 8 wks, mean:** **G1:** 3.0* **G2:** 2.7* **G3:** 2.9* **Patient Perception of Bladder Condition Scale, 12 wks or early termination, mean:** **G1:** 2.9* **G2:** 2.6* **G3:** 2.9* **Symptom severity, mean VAS, wk 4:** Urinary urgency: **G1:** 40.9 **G2:** 39.7 **G3:** 40.6 UUI: **G1:** 36.9 **G2:** 29.9 **G3:** 32.8 Frequency: **G1:** 34.5 **G2:** 39.3 **G3:** 39.9 Nocturia: **G1:** 30.4 **G2:** 35.4 **G3:** 38.2	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: - Loss to followup: NR Drop-out rates: + Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Garely et al., 2007* Mallett et al., 2007^ (continued)	**Other:** **G1:** 27 (4.6) **G3:** 170 (7.7) **Women, n (%):** **G1:** 536 (92.1) **G2:** 213 (77.7) **G3:** 1813 (82.2) **Weight (lbs), mean ± SD (range):** **G2:** 198 ± 51.6 (100-400) **G3:** 182.2 ± 47.0 (80-413)		**Perception of bladder condition scale (mean):** **G1:** 4.6 **G2:** 4.2 **G3:** 4.4 **Symptom severity, mean VAS:** Urinary urgency: **G1:** 72.3 **G2:** 70.8 **G3:** 68.7 UUI: **G1:** 78.5 **G2:** 70.8 **G3:** 64.1 Frequency: **G1:** 65.7 **G2:** 70.8 **G3:** 70.6 Nocturia: **G1:** 57.9 **G2:** 66.5 **G3:** 65.2 **OAB-q, symptom severity, mean (SE):** **G1:** 63.1 (0.84) **G2:** 59.4 (NR) **G3:** 56.9 (NR) **OAB-q, coping, mean (SE):** **G1:** 48.9 (1.18) **G2:** 46.5 (NR) **G3:** 53.1 (NR) **OAB-q, concern, mean (SE) :** **G1:** 43.1 (1.12) **G2:** 46.6 (NR) **G3:** 50.8 (NR) **OAB-q, sleep, mean (SE):** **G1:** 55.2 (1.22) **G2:** 43.8 (NR) **G3:** 49.2 (NR) **OAB-q, social, mean (SE):** **G1:** 73.6 (1.14) **G2:** 68.9 (NR) **G3:** 76.0 (NR)	**Symptom severity, mean VAS, wk 8:** Urinary urgency: **G1:** 31.1 **G2:** 29.4 **G3:** 30.0 UUI: **G1:** 28.9 **G2:** 22.1 **G3:** 24.5 Frequency: **G1:** 24.9 **G2:** 27.0 **G3:** 28.6 Nocturia: **G1:** 25.4 **G2:** 36.4 **G3:** 29.0 **Symptom severity, mean VAS, wk 12 (or early termination):** Urinary urgency: **G1:** 27.5 **G2:** 25.3 **G3:** 28.0 UUI: **G1:** 24.3 **G2:** 20.0 **G3:** 22.7 Frequency: **G1:** 21.6 **G2:** 24.5 **G3:** 27.4 Nocturia: **G1:** 22.0 **G2:** 21.4 **G3:** 27.2	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Garely et al., 2007* Mallett et al., 2007^ **(**continued)			**OAB-q, HRQoL, mean (SE):** **G1:** 53.4 (1.01) **G2:** 50.5 (NR) **G3: 56.3 (NR)**	**Symptom severity, VAS, mean change from baseline (95% CI) p-value:** Urinary urgency*: **G1:** -43.1 (-45.8, -40.4) p < 0.001 **G2:** -43.0 (-47.6, -38.5) **G3:** -39.5 (-41.0, -38.1) p < 0.001 UUI*: **G1:** -51.7 (-54.5, -49.0) p < 0.001 **G2:** -42.3 (-47.8, -36.8) **G3:** -40.1 (-41.8, -38.4) p < 0.001 Frequency*: **G1:** -42.0 (-45.0, -39.0) p < 0.001 **G2:** -44.2 (-48.8, -39.6) **G3:** -41.8 (-43.3, -40.3) p < 0.001 Nocturia*: **G1:** -34.4 (-37.3, -31.5) p < 0.001 **G2:** -42.6 (-47.5, -37.8) **G3:** -36.9 (-38.4, -35.4) p < 0.001 **OAB-q, symptom severity, mean change (± SE or 95% CI)*:** **G1:** -35.9 ± 1.08 **G2:** -33.6 (-37.0, -30.3) **G3:** -29.6 (-30.7, -28.6) **OAB-q, coping, mean change (± SE or 95% CI)*:** **G1:** 32.5 ± 1.16 **G2:** 32.9 (29.3, 36.6) **G3:** 27.4 (26.2, 28.5)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Garely et al., 2007* Mallett et al., 2007^ **(**continued)				**OAB-q, concern, mean change (± SE or 95% CI)*:** **G1:** 37.0 ± 1.21 **G2:** 34.0 (30.4, 37.6) **G3:** 29.6 (28.4, 30.8) **OAB-q, sleep, mean change (± SE or 95% CI)*:** **G1:** 26.0 ± 1.19 **G2:** 33.8 (29.7, 37.9) **G3:** 27.3 (26.1, 28.5) UUI*: **G1:** -51.7 (-54.5, -49.0) p < 0.001 **G2:** -42.3 (-47.8, -36.8) **G3:** -40.1 (-41.8, -38.4) p < 0.001 Frequency*: **G1:** -42.0 (-45.0, -39.0) p < 0.001 **G2:** -44.2 (-48.8, -39.6) **G3:** -41.8 (-43.3, -40.3) p < 0.001 Nocturia*: **G1:** -34.4 (-37.3, -31.5) p < 0.001 **G2:** -42.6 (-47.5, -37.8) **G3:** -36.9 (-38.4, -35.4) p < 0.001 **OAB-q, symptom severity, mean change (± SE or 95% CI)*:** **G1:** -35.9 ± 1.08 **G2:** -33.6 (-37.0, -30.3) **G3:** -29.6 (-30.7, -28.6) **OAB-q, coping, mean change (± SE or 95% CI)*:** **G1:** 32.5 ± 1.16 **G2:** 32.9 (29.3, 36.6) **G3:** 27.4 (26.2, 28.5)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Garely et al., 2007* Mallett et al., 2007^ **(**continued)				**OAB-q, concern, mean change (± SE or 95% CI)*:** **G1:** 37.0 ± 1.21 **G2:** 34.0 (30.4, 37.6) **G3:** 29.6 (28.4, 30.8) **OAB-q, sleep, mean change (± SE or 95% CI)*:** **G1:** 26.0 ± 1.19 **G2:** 33.8 (29.7, 37.9) **G3:** 27.3 (26.1, 28.5) **OAB-q, social, mean change (± SE or 95% CI)*:** **G1:** 17.7 ± 1.03 **G2:** 20.1 (16.7, 23.5) **G3:** 14.7 (13.7, 15.6) **OAB-q, HRQoL, mean change (± SE or 95% CI)*:** **G1:** 29.6 ± 1.02 **G2:** 30.8 (27.5, 34.1) **G3:** 25.4 (24.4, 26.4) **Side effects, n (%):** **G1:** 357 (61.3) **G2:** 128 (46.4) **G3:** 1321 (59.4) **Dry mouth, n (%):** **G1:** 104 (17.9) **G2:** 36 (13.0) **G3:** 477 (21.4) **Constipation, n (%):** **G1:** 85 (14.6) **G2:** 19 (6.9) **G3:** 295 (13.3) **Nausea, n (%):** **G1:** NR **G2:** 7 (2.5) **G3:** 39 (1.8)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Garely et al., 2007* Mallett et al., 2007^ **(**continued)				**Headache, n (%):** **G1:** 21 (3.6) **G2:** 9 (3.3) **G3:** 76 (3.4) **Blurred vision, n (%):** **G1:** 20 (3.4) **G2:** 7 (2.5) **G3:** 57 (2.6) **Upper respiratory tract infection, n (%):** **G1:** 27 (4.6) **G2:** 7 (2.5) **G3:** 69 (3.10) **UTI, n (%)** **G1:** 21 (3.6%) **G2:** NR **G3:** NR **Rash, n (%):** **G1:** NR **G2:** 6 (2.2) **G3:** 22 (0.99) **Nasopharyngitis, n (%)** **G1:** 13 (2.2%) **G2:** NR **G3:** NR **Cough, n (%)** **G1:** 12 (2.1%) **G2:** NR **G3:** NR **Withdrew, n (%):** **G1:** NR **G2:** 21 (7.6) **G3:** 216 (9.7)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Ghei et al., 2006 **Country and setting:** UK, Primary care **Enrollment period:** NR Duration 16 weeks **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Observational cohort **Intervention:** Bladder retraining vs. Bladder retraining + antimuscarinic (oxybutynin IR/ ER, tolterodine IR/ER, or imipramine combined with either oxybutynin or tolterodine as combination therapy) **Groups:** **G1:** Bladder retraining alone **G2:** Antimus-carinic therapy+ bladder retraining **N at enrollment:** **G1:** 52 **G2:** 656 **N at Follow-up:** **G1:** 46 **G2:** 501 **Women, n (%):** **G1:** 45 (86) **G2:** 618 (94) **Age, mean ± SD:** **G1:** 52 ± 14 **G2:** 54 ± 23 **Race/ethnicity:** NR	**Inclusion criteria:** • Frequency • Urgency with or without UUI **Exclusion criteria:** • SUI • Symptoms of BOO	**Incontinence episodes/day, mean ± SD:** **G1:** 0.47 ± 1.2 **G2:** 1.12 ± 1.7 *P* < 0.001 **Voids/day, mean ± SD:** **G1:** 14 ± 6 **G2:** 11 ± 6 *P* = 0.001	**Incontinence episodes/day, mean change difference (95% CI):** **G2/G1:** -0.60 (-0.93, -0.27) *P* = 0.024 **Voids/day, mean change difference (95% CI):** **G2/G1:** 2.35 (1.4, 3.3) *P* < 0.001 **Nocturia episodes/day, mean change difference (95% CI):** **G2/G1:** 0.57 (0.15, 0.99) **Attendance visits, n (%)** Failed follow-up: **G1:** 6 (12) **G2:** 155 (23) 1 follow-up visit: **G1:** 10 (19) **G2:** 15 (2) 2 follow-up visits: **G1:** 18 (35) **G2:** 86 (13) 3 follow-up visits: **G1:** 9 (17) **G2:** 225 (35) 4 follow-up visits: **G1:** 9 (17) **G2:** 175 (27)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: NR Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: + Measurement methods: + Measurement reliability: - Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Giannitsas et al., 2004 **Country and setting:** Greece, Specialty treatment center **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Randomized for which drug to receive first two-way crossover, table of random numbers **Intervention:** Oxybutynin 15 mg t.i.d. vs. Tolterodine 4mg b.i.d.; 6 weeks treatment with 3-4 weeks washout **Groups:** **G1:** Oxybutynin 15 mg t.i.d. **G2:** Tolterodine 4mg b.i.d. **Stratified by UDS findings:** **a:** high volume (> 250mL); low pressure (< 25cmH_2O) **b:** high volume (≥ 250mL); high pressure (> 25cmH_2O) **C**: low volume (< 250mL); low pressure (< 25cmH_2O) **d**: low volume (< 250mL); high pressure (> 25cmH_2O) **N at enrollment:** Total: 128 **N at follow-up:** Total: 107 **Ga**: 6 **Gb:** 25 **Gc:** 36 **Gd:** 40 **Women, %:** 100	**Inclusion criteria:** • Age ≥ 18 • DO on urodynamics **Exclusion criteria:** • Symptomatic or recurrent UTI • BOO • Neurologic disease • History of previous pelvic surgery • Narrow angle glaucoma • SUI • History of anticholinergic side effects • Interstitial cystitis • Child-bearing age without BC	**Voids/day, mean ± SD:** Total: 8.5 ± 2.63 **Ga:** 7.2 ± NR **Gb:** 8.0 ± 2.40 **Gc:** 8.3 ± 2.31 **Gd:** 9.3 ± 2.91 **Volume (mL)/day, mean ± SD:** Total: 1568.5 ± 398.64 **Ga:** 1756 ± NR **Gb:** 1594.6 ± 326.12 **Gc:** 1678.8 ± 402.15 **Gd:** 1420.5 ± 384.96 **Voided volume (mL), mean ± SD:** Total: 196.1 ± 60.19 **Ga:** 253 ± NR **Gb:** 213.5 ± 53.57 **Gc:** 209.8 ± 57.43 **Gd:** 163.4 ± 51.97 **Bladder volume (mL), first desire void, mean ± SD:** Total: 105.6 ± 39.38 **Ga:** 109 ± NR **Gb:** 128.0 ± 41.78 **Gc:** 94.3± 35.40 **Gd:** 101.1 ± 38.14 **Bladder volume (mL), first contraction, mean ± SD:** Total: 172 ± 98.4 **Ga:** 258 ± NR **Gb:** 303.3 ± 60.51 **Gc:** 111.9 ± 48.11 **Gd:** 124.4 ± 56.66	**Voids/day, mean ± SD:** **G1:** 7.7 ± 1.87 **G2:** 7.6 ± 2.18 **G1a:** 6.1 ± NR **G2a:** 6.3 ± NR **G1b:** 7.3 ± 1.69 **G2b:** 7.0 ± 1.87 **G1c:** 7.5 ± 1.41 **G2c:** 7.2 ± 1.58 **G1d:** 8.3 ± 2.23 **G2d:** 8.4 ± 2.53 **Volume (mL)/day, mean ± SD:** **G1:** 1764.4 ± 333.03 **G2:** 1670.7 ± 338.6 **G1a:** 1862 ± NR **G2a:** 1720 ± NR **G1b:** 1715.6 ± 292.54 **G2b:** 1665.8 ± 251.19 **G1c:** 1847.9 ± 333.81 **G2c:** 1808.1 ± 317.59 **G1d:** 1694.7 ± 331.33 **G2d:** 1550.3 ± 373.65 **Voided volume (mL), mean ± SD:** **G1:** 239.9 ± 64.98 **G2:** 236.7 ± 63.03 **G1a:** 321 ± NR **G2a:** 286 ± NR **G1b:** 243.3 ± 59.56 **G2b:** 248.3 ± 53.91 **G1c:** 252.9 ± 55.75 **G2c:** 258.6 ± 60.63 **G1d:** 217.6 ± 67.07 **G2d:** 203.1 ± 55.43	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: NA Pt selection criteria: + Loss to followup: ++ Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Giannitsas et al., 2004 (continued)	**Age, mean ± SD:** Total: 56 ±16.3 **Ga:** 53 ± 17.2 **Gb:** 57 ± 16.2 **Gc:** 57 ± 16.3 **Gd:** 54 ± 16.6 **Weight (kg), mean ± SD:** Total: 63 ± 5.6 **Ga:** 63 ± 5.6 **Gb:** 70 ± 9.1 **Gc:** 67 ± 8.8 **Gd: 69 ± 7.5**		**Pressure (cmH_20), first contraction, mean ± SD:** Total: 34.8 ± 21.97 **Ga:** 17.4 ± NR **Gb:** 37.7 ± 14.03 **Gc:** 18.5 ± 4.60 **Gd:** 50.3 ± 25.14 **Overactivity index, mean ± SD:** Total: 36.8 ± 31.36 **Ga:** 15.3 ± NR **Gb:** 24.8 ± 19.66 **Gc:** 26.3 ± 16.14 **Gd:** 57.0 ± 38.85 **Cystometric capacity (mL), mean ± SD:** Total: 362.8 ± 119.10 **Ga:** 403 ± NR **Gb:** 410.0 ± 97.78 **Gc:** 357.6 ± 127.52 **Gd:** 331.4 ± 114.17	**Bladder volume (mL), first desire void, mean ± SD:** **G1:** 129.0 ± 30.14 **G2:** 117.9 ± 27.62 **G1a:** 144 ± NR **G2a:** 140 ± NR **G1b:** 153.5 ± 25.72 **G2b:** 132.0 ± 31.01 **G1c:** 120.8 ± 25.07 **G2c:** 113.2 ± 23.16 **G1d:** 119.4 ± 29.43 **G2d:** 110.1 ± 26.15 **G1/BL:** $P < 0.05$ **G2/BL:** $P < 0.05$ **Bladder volume (mL), first contraction, mean ± SD:** **G1:** 212.9 ± 106.10 **G2:** 206.9 ± 103.56 **G1a:** 382 ± NR **G2a:** 364 ± NR **G1b:** 355.28 ± 74.79 **G1c:** 142.4 ± 43.51 **G2c:** 144.6 ± 48.43 **G1d:** 173.3 ± 57.37 **G2d:** 162.7 ± 53.87 **G1d/BL:** $P < 0.01$ **G2d/BL:** $P < 0.01$	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Giannitsas et al., 2004 (continued)				**Pressure (cmH_20), first contraction, mean ± SD:** **G1:** 30.9 ± 22.63 **G2:** 30.9 ± 19.01 **G1a:** 14.0 ± NR **G2a:** 17.4 ± NR **G1b:** 35.6 ± 12.86 **G2b:** 29.6 ± 13.56 **G1c:** 17.2 ± 6.80 **G2c:** 17.9 ± 6.69 **G1d:** 42.9 ± 28.91 **G2d:** 44.1 ± 20.75 **Overactivity index, mean ± SD:** **G1:** 24.4 ± 22.61 **G2:** 24.7 ± 23.46 **G1a:** 7.0 ± NR **G2a:** 9.5 ± NR **G1b:** 14.1 ± 12.09 **G2b:** 14.1 ± 12.71 **G1c:** 18.3 ± 15.89 **G2c:** 16.9 ± 16.84 **G1d:** 38.9 ± 26.50 **G2d:** 40.7 ± 26.58 **Cystometric capacity (mL), mean ± SD:** **G1:** 419.3 ± 120.86 **G2:** 415.63 ± 114.06 **G1a:** 465 ± NR **G2a:** 453 ± NR **G1b:** 449.6 ± 106.23 **G2b:** 459.4 ± 101.17 **G1c:** 409.9 ± 130.22 **G2c:** 411.05 ± 132.49 **G1d:** 401.8 ± 118.34 **G2d:** 386.7 ± 96.53 **Dry mouth, n (%):** **G1:** 52 (40.6) **G2:** 20 (15.6)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Giannitsas et al., 2004 (continued)				**Constipation, n (%):** **G1:** 11 (10.3) **G2:** 3 (2.8) **Discontinued due to AEs, n:** Dry mouth: 12 Palpitations: 1	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Gleason et al. 1999 **Country and setting:** US, Community **Enrollment period:** NR 12 week follow up **Funding:** Alza Corporation **Author industry relationship disclosures:** NR	**Design:** Multicenter Open label Single treatment **Intervention:** Oxybutynin ER **Groups:** **G1:** Oxybutynin ER 5- 30 mg/ day (dose adjustment period) **N at enrollment:** **G1:** 256 **N at follow-up:** **G1:** 219 37 missing data 20 from AEs 4 dc'd lack of effectiveness, included in analysis **Age, yrs ± SD:** NR 38.8% were 65+ **Race/ethnicity, n (%):** **White:** **G1:** 235 (91.8) **Women, N (%):** **G1:** 234 (91.4)	**Inclusion criteria:** • ≥ adult men and women • Idiopathic urge incontinence • Mixed incontinence with clinically significant urge component Exclusion criteria: • Uncontrolled medical condition • PVR > 100 mL • Significant bacteruria • Significant pyuria	**UUI episodes/ week, mean ± SD:** **G1:** 18.8 ± 1.2 **Total incontinent episodes/ week, mean ± SD:** **G1:** 22.2 ± 1.3 **Voids/ week, mean ± SD:** **G1:** 81.1 ± 1.8 **PVR, mL, mean ± SD:** **G1:** 17.4 ± 1.3 **Voided volume, mL, ± SD:** **G1:** 121 ± 79.1	**UUI episodes/ week, mean ± SD:** **G1:** 2.8 ± 0.6 *P* < 0.001 **Total incontinent episodes/ week, mean ± SD:** **G1:** 4.0 ± 0.7 *P* < 0.001 **Voids/ week, mean ± SD:** **G1:** 66.8 ± 1.4 **Reduction Voids/week, mean ± SD:** **G1:** 14.3 ± 1.3 **95%CI:** 11.7-16.8 **PVR, mL, mean ± SD:** **G1:** 21.0 ± 2.2 *P* = NR **Voided volume, mL, ± SD:** **G1:** 113.4 ± 84.6 *P* = NR **Participants free UUI episodes, %:** 55.7 **Dry Mouth, n (%):** **G1:** 128 (58.6) **Discontinuation d/t AE, n (%):** 20 (7.8) **Nausea (%):** 2.3 **Dry Mouth (%):** 1.6 **Somnolence (%):** 1.2 **Urinary retention, n (%):** 2 (0.8) **Increased PVR, n, (%):** 1 (0.4)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: + Drop-out rates: ++ Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Goode et al., 2002 **Country and setting:** US, academic health center outpatient geriatric medicine clinic **Enrollment period:** July 1989 to August 1995 **Funding:** National Institutes on Aging **Author industry relationship disclosures:** NR	**Design:** RCT, placebo controlled Computer-generated random numbers using a block size of 6, w/ prior stratification by type and severity of incontinence **Intervention:** Biofeedback-assisted behavioral vs. drug treatment (oxybutynin chloride; possible range of doses 2.5 mg/d-5.0 mg t.i.d.) vs. placebo All patients had 4 visits over an 8-week period. Patients in G1 had biofeedback added to behavioral training in absence of 50% improvement by session 3. **Groups:** **G1:** Behavioral ± biofeedback **G2:** Pharmacologic **G3:** Placebo **N at enrollment:** 468 screened 271 not eligible 197 randomized 105 had pre and post treatment urodynamics **G1:** 33 **G2:** 35 **G3:** 37 **N at follow-up:** NA	**Inclusion criteria:** • Community-dwelling women at least age 55 • Ambulatory • At least 2 urge accidents per week by baseline bladder diary • Urge incontinence as predominant pattern • Urodynamic evidence of bladder dysfunction **Exclusion criteria:** • Continual leakage • Postvoid residual urine volume >200mL • Uterine prolapse past the introitus • Narrow-angle glaucoma • Unstable angina • Decompensated congestive heart failure • History of malignant arrhythmias • MMSE <20 (Dementia)	**Voids per day, mean ± SD:** **G1:** 10.0 **G2:** 10.9 **G3:** 10.0 **Cystometric volume (mL), first desire to void, mean ± SD:** **G1:** 97.1 ± 50.7 **G2:** 101.1 ± 62.1 **G3:** 124.6 ± 73.7 **Cystometric volume (mL), strong desire to void mean ± SD:** **G1:** 188.5 ± 93.1 **G2:** 212.1 ± 86.7 **G3:** 222.3 ± 87.0 **Cystometric volume (mL), bladder capacity, mean ± SD:** **G1:** 288.3 ± 117.0 **G2:** 308.7 ± 93.7 **G3:** 328.9 ± 107.6	**Voids per day, mean ± SD:** **G1:** 8.2 **G2:** 8.8 **G3:** 9.7 **DI on UDS, n (%):** +Baseline DI/ +DI post-treatment: **G1:** 7 (21.2) **G2:** 1 (2.9) **G3:** 5 (13.5) +Baseline DI/ -DI post-treatment: **G1:** 1 (3.0) **G2:** 7 (20.0) **G3:** 7 (18.9) -Baseline DI/ +DI post-treatment: **G1:** 3 (9.1) **G2:** 3 (8.6) **G3:** 3 (8.1) -Baseline DI/-DI post-treatment: **G1:** 22 (66.7) **G2:** 24 (68.6) **G3:** 22 (59.5) **Cystometric volume (mL), first desire to void, mean ± SD:** **G1:** 115.9 ± 64.9 **G2:** 145.6 ± 74.0 **G3:** 133.5 ± 59.6 **Cystometric volume (mL), strong desire to void mean ± SD:** **G1:** 228.9 ± 106.4 **G2:** 282.0 ± 93.2 **G3:** 230.1 ± 78.8**Cystometric volume (mL), bladder capacity, mean ± SD:** **G1:** 305.6 ± 117.9 **G2:** 377.6 ± 92.1 **G3:** 323.0 ± 109.0	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Goode et al., 2002 (continued)	**Age, yrs ± SD:** **G1:** 65.3 ± 4.5 **G2:** 67.9 ± 7.9 **G3:** 67.6 ± 7.7 **Race/ethnicity, %:** Black: 2 White: 98 **Women: 100%** **Parity mean ± SD:** **G1:** 3.1 ± 1.7 **G2:** 2.1 ± 1.3 **G3:** 2.3 ± 1.5			**Cystometric, volume (mL), first desire to void, mean change:** **G1:** 18.8 **G2:** 44.4 **G3:** 8.9 *P* = 0.149 **Cystometric, volume (mL), strong desire to void, mean change:** **G1:** 40.5 **G2:** 69.9 **G3:** 7.8 *P* = 0.018 **Cystometric, volume (mL), bladder capacity, mean change:** **G1:** 17.3 **G2:** 68.9 **G3:** -6.0 *P* = 0.000 **Standardized estimates of direct and mediated effects of treatment:** **G1/G3:** Total effect: 0.28* Direct effect: 0.23 Mediated Effect: 0.05 **G2/G3:** Total Effect: 0.34* Direct Effect: 0.30* Mediated Effect: 0.04 *$P < 0.01$	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Haab et al., 2005 **Country and setting:** Multinational, Community **Enrollment period:** NR 52 week open enrollment **Funding:** Yamanouchi **Author industry relationship disclosures:** 1 of 4 Yamanouchi (1)	**Design:** Cohort open-label extension **Intervention:** Solifenacin 5mg for 4 weeks, then pt-selected dose of either 5 or 10 mg daily for remainder of study **Groups:** NA **N at enrollment:** 1,637 **N at follow-up:** 1,329 **Women, n (%):** 1,280 (78) **Age, mean ± SD:** 56.4 ± 13.5 **Race/ethnicity, n (%):** **Black:** 8 (0.5) **White:** 1,602 (98.1) **Asian** 13 (0.8) **Other:** 10 (0.6) **Weight (kg), mean ± SD:** 74.5 ± 14.6 **Height (cm), mean ± SD:** 165.3 ± 8.4	**Inclusion criteria:** • Age ≥ 18 • Symptoms of OAB ≥ 3 months • ≥ 8 voids per day • ≥ 1 urgency episode / day • ≥ 1 UUI episodes / day • Completed treatment in previous RCT ≤ 14 days prior to extension study entry **Exclusion criteria:** • BOO • PVR > 200 mL • Persistent or recurrent UTI • Bladder stones • IC • Previous pelvic radiation • Previous or current pelvic organ malignancy • Narrow angle glaucoma • Gastric retention • Urinary retention • Pregnant/nursing • Non-reliable BC in childbearing woman	**Urgency episodes/day, mean ± SD:** 5.76 ± 4.46 **Incontinence episodes/day, mean ± SD:** 2.66 ± 2.51 **Voids/day, mean ± SD:** 12.16 ± 3.79 **Nocturia episodes/day, mean ± SD:** 1.95 ± 1.22 **Voided volume (mL), mean ± SD:** 147.6 ± 53.8	**Urgency episodes/day, mean ± SD (% change):** 2.28 ± 3.59 (-63) **Incontinence episodes/day, mean ± SD (% change):** 0.93 ± 2.06 (-66) **Voids/day, mean ± SD (% change):** 9.18 ± 3.33 (-23) **Nocturia episodes/day, mean ± SD (% change):** 1.25 ± 1.26 (-32) **Voided volume (mL), mean ± SD (% change):** 187.4 ± 75.4 (31) **Dry mouth, n (%):** 339 (20.7) **Constipation, n (%):** 157 (9.6) **Blurred vision, n (%):** 113 (6.9) **Discontinuation rate due to AE, %:** 4.7	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: + Drop-out rates: ++ Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Haab et al., 2006 [See evidence table for Hill et al., 2007] **Country and setting:** France, Denmark, Sweden, Australia, Canada, US **Enrollment period:** NR **Funding:** Novartis Pharma AG (educational grant) **Author industry relationship disclosures:** 8 of 9 Astellas (1) Novartis (8) Pfizer (1)	**Design:** 2-year, non-comparative, open-label extension study **Intervention:** Darifenacin following 2 feeder studies of darifenacin 3.75/7.5/15 mg qd or placebo x 12 wks **Groups:** NA **N at enrollment:** 719 **N at follow-up (%):** 475 (66.3) **Women, n (%):** 609 (85.1) **Age, mean (range):** 57.3 (19-89) **Age ≥ 65, %:** 29.9 **Race/ethnicity:** NR **Received treatment ≥ 365 days, n (%):** 532 (74.3)	**Inclusion criteria:** • Successful completion of one of two previous, 12-wk feeder studies with no major protocol violation **Exclusion criteria:** NR	**Urgency episodes/day, median (IQR):** 8.1 (5.7-10.3) **Urgency severity, VAS score, median (IQR):** 54.7 (43.7-66.1) **Incontinence episodes/week, median (IQR):** 16.8 (10.0-27.0) **Significant leaks/week, median (IQR):** 7.0 (2.3-14.0) **Voids/day, median (IQR):** 10.1 (8.9-12.1) **Nocturia episodes/week, median (IQR):** 11.0 (7.0-16.0) **Voided volume (mL), median (IQR):** 163 (121-217) **Primary diagnosis, n (%)** Idiopathic: 674 (94.1) Neurogenic: 42 (5.9) **Previous OAB drug treatment, n (%):** 163 (22.8)	**Urgency episodes/day, median change (median % change):** -3.9 (-56.4) *P* < 0.001 **Urgency severity, median change (median % change):** -15.4 (-28.8) *P* < 0.001 **Incontinence episodes/week, median change (median % change):** -11.0 (-84.4) *P* < 0.001 **Significant leaks/week, median change (median % change):** -4.7 (-100.0) *P* < 0.001 **Incontinence episodes, responders, reduction, %:** ≥ 50%: 77.2 ≥ 70%: 62.3 ≥ 90%: 43.8 **Voids/day, median change (median % change):** -1.4 (-13.9) *P* < 0.001 **Nocturia episodes/week, median change (median % change):** -1.5 (-14.3) *P* < 0.001 **Increased dose to 15 mg at 2 wks and maintained, n (%):** 363 (50.7)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Haab et al., 2006 (continued)				**Remained on 7.5 mg dose, n (%):** 182 (25.4) **Dose adjusted at other times, n (%):** 171 (23.9) **Compliance, ≥ 80% of doses, %:** >85 **Voided volume (mL), median change (median % change):** 19.0 (11.9) *P* < 0.001 **Adverse events, all causality, n (%):** Any: 572 (79.9) Serious: 84 (11.7) Dry mouth: 167 (23.3) Constipation: 150 (20.9) UTI: 82 (11.5) Respiratory d/o: 76 (10.6) Dyspepsia: 65 (9.1) Accidental injury: 57 (8.0) 'Flu' syndrome: 49 (6.8) HA: 42 (5.9) HTN: 39 (5.4) Arthritis: 36 (5.0) Bronchitis: 34 (4.7) Arthralgia: 33 (4.6) Back pain: 30 (4.2) Increased cough: 26 (3.6) Arthrosis: 25 (3.5) Pain: 23 (3.2) Sinusitis: 22 (3.1)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Haab et al., 2006 (continued)				**Adverse events, treatment related, n (%):** Any: 343 (47.9) Serious: 1 (0.1) Dry mouth: 166 (23.2) Constipation: 142 (19.8) UTI: 8 (1.1) Respiratory d/o: 2 (0.3) Dyspepsia: 36 (5.2) Accidental injury: 1 (0.1) 'Flu' syndrome: 0 HA: 14 (2.0) HTN: 3 (0.4) Arthritis: 1 (0.1) Bronchitis: 0 Arthralgia: 1 (0.1) Back pain: 4 (0.6) Increased cough: 1 (0.1) Arthrosis: 0 Pain: 1 (0.1) Sinusitis: 1 (0.1) **Days of bowel motions, mean change*:** -0.04 **Days of hard or lumpy bowel motions, mean change:*** 0.13 **Days of straining, mean change:*** 0.22	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Haab et al., 2006 (continued)				**Days of incomplete bowel openings:*** 0.39 **Days on which patient felt life was affected by bowel habits:*** 0.17 **Extent to which life affected by bowel habits in previous 2 wks, mean score:*** 0.31	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Halaska et al., 2003 **Country and setting:** Europe and Asia, Academic medical center **Enrollment period:** May 1996 to May 1999 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Randomized controlled double blind crossover **Intervention:** Trospium vs. Oxybutynin **Groups:** **G1:** Trospium 20 mg b.i.d. **G2:** Oxybutynin 5 mg b.i.d. **N at enrollment:** **G1:** 268 **G2:** 90 **N at follow-up:** **G1:** 200 **G2:** 66 **Women, n (%):** **G1:** 228 (85) **G2:** 78 (87) **Age, mean (range):** **G1:** 54.2 (19, 89) **G2:** 52.2 (19, 85) **Weight (kg), mean (range):** **G1:** 72.3 (50-120) **G2:** 70.4 (50-90) **Height (cm), mean (range):** **G1:** 164.8 (144-185) **G2:** 165.5 (145-183) **Smokers, n (%):** **G1:** 38 (14) **G2:** 10 (11) **Previous illness, n (%):** **G1:** 184 (69) **G2:** 66 (73) **Previous medication, n (%):** **G1:** 101 (38) **G2:** 46 (51)	**Inclusion criteria:** • Age ≥ 18 yrs • Urge syndrome • Urge incontinence • UUI as one component of MUI • UUI due to neurologic condition (detrusor hyperreflexia) **Exclusion criteria:** • Absolute tachycardia • Closed angle glaucoma • Myasthenia gravis • Arteriosclerosis of cerebral vessels • SUI • Heart or renal failure • Frequency from diuretics • BOO • Acute UTI • Hiatus hernia with reflux esophagitis • Stenosis of GI tract • Megacolon • Colonic ulceration • Allergy to study medications • Anticholinergics, TCAs, alpha blockers, beta sympatho-mimetics ≤ 7 days • Urological or gynecologic surgery ≤ 3 mos • Pregnant or lactating • In another study	**Urgency episodes/day, mean:** **G1:** 10.2 **G2:** 11.0 **Incontinence episodes/ day, mean:** **G1:** 1.5 **G2:** 2.1 **Voids/day, mean:** **G1:** 11.4 **G2:** 12.5 **Max cystometric capacity (mL), mean:** **G1:** 205 **G2:** 205	**Urgency episodes/day, mean:** **G1:** 6.7 **G2:** 7.4 **Incontinence episodes/ day, mean:** **G1:** 0.5 **G2:** 1.1 **Voids/day, mean:** **G1:** 7.9 **G2:** 8.3 **Max cystometric capacity (mL), 26 wks, mean change:** **G1:** 92.0 **G2:** 117.0 **G1/BL:** *P* ≤ 0.001 **G2/BL:** *P* ≤ 0.001 **Max cystometric capacity (mL), 52 wks, mean change:** **G1:** 115.0 **G2:** 119.4 **G1/BL:** *P* ≤ 0.001 **G2/BL:** *P* ≤ 0.001 **Bladder volume (mL), first contraction, 26 wks, mean change:** **G1:** 63.5 **G2:** 61.2 **Bladder volume (mL), first contraction, 52 wks, mean change:** **G1:** 46.1 **G2:** 36.7 **Bladder volume (mL), first sensation, 26 wks, mean change:** **G1:** 73.6 **G2:** 76.93	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Halaska et al., 2003 (continued)				**Bladder volume (mL), first sensation, 26 wks, mean change:** **G1:** 78.6 **G2:** 70.2 **Abnormal EKG, n (%):** **G1:** 4 (0.1) **G2:** 2 (0.2) **Any adverse event, n (%):** **G1:** 10 (3.7) **G2:** 6 (6.7) **Poor efficacy, n (%):** **G1:** 8 (3) **G2:** 2 (2.2) **Poor compliance, n (%):** **G1:** 15 (15.6) **G2:** 6 (6.7) **Abdominal pain, n (%):** **G1:** 5 (2) **G2:** 0 (0) **Constipation, n (%):** **G1:** 18 (7) **G2:** 4 (4) **Diarrhea, n (%):** **G1:** 2 (1) **G2:** 2 (2) **Dyspepsia, n (%):** **G1:** 13 (5) **G2:** 3 (3) **Dysphagia, n (%):** **G1:** 9 (3) **G2:** 3 (3) **Dry mouth, n (%):** **G1:** 87 (33) **G2:** 45 (50) *P* < 0.001 **Nausea, n (%):** **G1:** 6 (2) **G2:** 2 (2)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Halaska et al., 2003 (continued)				**UTI, n (%):** **G1:** 33 (12) **G2:** 10 (11) **Headache, n (%):** **G1:** 11 (4) **G2:** 8 (9) **Visual disturbances, n (%):** **G1:** 9 (3) **G2:** 5 (6) **Virus infection, n (%):** **G1:** 9 (3) **G2:** 4 (4) **Abnormal EKG, n (%):** **G1:** 4 (0.1) **G2:** 2 (0.2) **Sleeplessness, n (%):** **G1:** 10 (4) **G2:** 2 (2)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Herschorn et al., 2004 **Country and setting:** Canada, Family medicine and urology clinics **Enrollment period:** June 2000 to December 2001 **Funding:** Pharmacia Pfizer Canada **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Health education with tolterodine vs. tolterodine alone **Groups:** **G1:** Health education with tolterodine **G2:** tolterodine alone **N at enrollment:** **G1:** 39 **G2:** 45 **N at follow-up, 5 weeks:** **G1:** 37 **G2:** 40 **N at follow-up, 10 weeks:** **G1:** 35 **G2:** 32 **N at follow-up, 16 weeks:** **G1:** 34 **G2:** 31 **Age, yrs ± SD:** **G1:** 65.7 ± 14.5 **G2:** 63.1 ± 15.7 **Race/ethnicity:** NR **Women, %:** **G1:** 92.3 **G2:** 84.4 **Parity:** NR	**Inclusion criteria:** • Age ≥ 50 • Symptoms of OAB • Attend investigators' practice • Normal cognitive function • Able to read English **Exclusion criteria:** • Enrollment in another clinical trial • Interstitial cystitis • UTI • Already taking tolterodine	**OAB duration (yrs), mean ± SD:** **G1:** 8.7 ± 11.0 **G2:** 8.7 ± 10.8 **Mild bladder problems, n (%):** **G1:** 13 (33.3) **G2:** 13 (28.9) **Moderate bladder problems, n (%):** **G1:** 19 (48.7) **G2:** 28 (62.2) **Severe bladder problems, n (%):** **G1:** 7 (18.0) **G2:** 4 (8.9) **Obtained prescription, n (%):** **G1:** 38 (97.4) **G2:** 37 (82.2) *P* < 0.05 **Intends to fill prescription, (%):** **G1:** 0 (0) **G2:** 6 (7.5)	**Incontinence episodes/week, mean change ± SD:** **G1:** -7.72 ± 21.16 **G2:** -10.24 ± 19.56† **Voids/day, mean change ± SD:** **G1:** -1.82 ± 3.41 **G2:** -2.18 ± 4.89 *P* = NR **Nocturia episodes/day, mean change ± SD:** **G1:** -0.44 ± 1.13† **G2:** -0.07 ± 0.91 **No change in bladder problem severity, n (%):** **G1:** 14 (42.4) **G2:** 20 (66.7) **Improved bladder problem severity, n (%):** **G1:** 15 (45.4)† **G2:** 6 (20) **Worsened bladder problem severity, n (%):** **G1:** 4 (12.1) **G2:** 4 (13.3) **Compliance, 10 weeks, %:** **G1:** 41 **G2:** 38 *P* > 0.05 **Compliance, 16 weeks, %:** **G1:** 39 **G2:** 31 *P* > 0.05 **Continued or started non-drug OAB treatment, 16 weeks, %:** **G1:** 82 **G2:** 53 *P* > 0.05	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: + Loss to followup: - Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: NR Baseline characteristics: - Length of followup: ++ Measurement methods: + Measurement reliability: - Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Herschorn et al., 2004 (continued)				**Stopped non-drug OAB treatments, %:** **G1:** 12.8 **G2:** 28.9	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Hill et al., 2006 **Country and setting:** Multinational-European; Community; 62 centers **Enrollment period:** NR **Funding:** Pfizer Novartis Thomson ACUMED **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Darifenacin vs. placebo **Groups:** **G1:** Darifenacin 7.5 mg daily **G2:** Darifenacin 15 mg daily **G3:** Darifenacin 30 mg daily **G4:** placebo **N at enrollment:** **G1:** 108 **G2:** 107 **G3:** 115 **G4:** 109 **N at follow-up:** **G1:** 99 **G2:** 93 **G3:** 96 **G4:** 101 Total 50 (11.4%) discontinued study- AE and withdrawal of consent **Age, mean (range):** **G1:** 56.1 (23-88) **G2:** 55.1 (24-82) **G3:** 54.0 (23-79) **G4:** 53.7 (21-85) **Race/ethnicity:** NR **Women, N (%):** **G1:** 94 (87) **G2:** 92 (86) **G3:** 99 (86) **G4:** 90 (83) **Parity :** NR **Previous drug therapy, n (%):** **G1:** 21 (19.4) **G2:** 22 (20.6) **G3:** 33 (28.7) **G4:** 24 (22.0)	**Inclusion criteria:** • Male and female • Age ≥18 • ≥ 10 episodes UUI over 14 days • ≥ 8 voids/ day • ≥ 1 episode of urinary urgency • Symptoms OAB ≥ 6 months **Exclusion criteria:** • SUI • > 2 UTI/ year • BOO • PVR> 200 • IC • Bladder stones • Severe constipation • History of intermittent UTI • Urogenital surgery within previous 6 months • Cystoscopy within previous 30 days • Indwelling catheter • CIC • Clinically significant systemic disease • Bladder training • CI to antimuscarinic therapy • Pregnant/ lactating • Concomitant treatment with anticholinergic/ antispasmodics, opioids, HRT, drugs that inhibit cytochrome P450, 2D6, and 3A4 isoenzymes	**Urgency episodes/day, median (95% CI):** **G1:** 8.5 (7.0, 8.7) **G2:** 8.6 (7.8, 9.4) **G3:** 8.4 (7.8, 8.8) **G4:** 8.1 (7.4, 8.7) **Severity of urgency, visual analog scale (0=mild, 100= severe), (range):** **G1:** 53.2 (50.1-56.5 **G2:** 55.8 (51.5-59.8) **G3:** 53.5 (50.0-57.9) **G4:** 53.5 (51.2-57.0) **Incontinence episodes/week, median (95% CI):** **G1:** 13.7 (11.8, 17.8) **G2:** 17.3 (13.5, 21.5) **G3:** 19.1 (15.8, 22.8) **G4:** 16.1 (14.0, 19.4) **Voids/day, median (95% CI):** **G1:** 10.3 (9.8, 10.9) **G2:** 11.0 (10.4, 12.1) **G3:** 10.4 (9.8, 11.4) **G4:** 10.1 (9.8, 10.8) **Number OAB-related nocturnal awakenings/ week, median (95 %CI):** **G1:** 12.4 (10.2, 12.9) **G2:** 11.7 (9.8, 14.5) **G3:** 12.4 (10.5, 14.0) **G4:** 10.4 (9.2, 12.9)	**Urgency episodes/ day, median change (%):** **G1:** -1.8 (-29.2) **G2:** -2.3 (-26.9) **G3:** -3.0 (-33.1) **G4:** -1.2 (-15.7) **G1/G4:** *P* = 0.196 **G2/G4:** *P* = 0.013 **G3/G4:** *P* < 0.001 **Severity of urgency, visual analog scale (0=mild, 100= severe), median change (range):** **G1:** -7.0 (-14.2) **G2:** -7.0 (-11.6) **G3:** -9.4 (-19.9) **G4:** -3.9 (-8.0) **G1/G4:** *P* = 0.177 **G2/G4:** *P* = 0.045 **G3/G4:** *P* = 0.011 **Incontinence episodes/wk, median change (%):** **G1:** -8.1 (-68.7) **G2:** -10.4 (-76.5) **G3:** -11.4 (-77.3) **G4:** -5.9 (-46.0) **G1/G4:** *P* = 0.007 **G2/G4:** *P* < 0.001 **G3/G4:** *P* < 0.001 **Leaks/week, median change (%):** **G1:** -4.3 (-67.0) **G2:** -5.3 (-76.7) **G3:** -6.0 (-73.7) **G4:** -2.4 (-43.2) **G1/G4:** *P* = 0.012 **G2/G4:** *P* < 0.001 **G3/G4:** *P* < 0.001	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Hill et al., 2006 (continued)			**Voided volume (mL), median (95 %CI):** **G1:** 162 (153, 181) **G2:** 157 (143, 173) **G3:** 156 (144, 168) **G4:** 162 (149, 174)	**Patients achieving ≥7 consecutive days "dry", (%):** **G1:** NR **G2:** 28 **G3:** 30 **G4:** 17 **G2/G4:** *P* = 0.29 **G3/G4:** *P* = 0.011 **Voids/day, median change (%):** **G1:** -1.7 (-16.7) **G2:** -1.9 (-17.9) **G3:** -2.2 (-21.2) **G4:** -1.1 (-9.6) **G1/G4:** *P* = 0.06 **G2/G4:** *P* = 0.033 **G3/G4:** *P* < 0.001 **Number OAB-related nocturnal awakenings/ week, median change (%):** **G1:** -1.9 (-22.1) **G2:** -1.7 (-22.7) **G3:** -2.0 (-19.2) **G4:** -0.4 (-3.6) **G1/G4:** *P* = 0.028 **G2/G4:** *P* = 0.022 **G3/G4:** *P* = 0.008 **Voided volume (mL), median change (%):** **G1:** 17 (10.3) **G2:** 24 (15.6) **G3:** 44 (26.0) **G4:** 7 (4.1) **G1/G4:** *P* = 0.079 **G2/G4:** *P* = 0.001 **G3/G4:** *P* < 0.001 **Dry mouth, n (%):** **G1:** 25 (23.1) **G2:** 43 (40.2) **G3:** 68 (59.1) **G4:** 6 (5.5)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Hill et al., 2006 (continued)				**Constipation, n (%):** **G1:** 17 (15.7) **G2:** 27 (25.2) **G3:** 32 (27.8) **G4:** 5 (4.6) **Dyspepsia, n (%):** **G1:** 4 (3.7) **G2:** 9 (8.4) **G3:** 10 (8.7) **G4:** 1 (0.9) **Headache, n (%):** **G1:** 7 (6.5) **G2:** 7 (6.5) **G3:** 7 (6.1) **G4:** 2 (1.8) **Respiratory tract infection, n (%):** **G1:** 4 (3.7) **G2:** 6 (5.6) **G3:** 1 (0.9) **G4:** 6 (5.5) **Urinary tract disorder, n (%):** **G1:** 0 (0) **G2:** 6 (5.6) **G3:** 1 (0.9) **G4:** 0 **UTI, n (%):** **G1:** 3 (2.8) **G2:** 3 (2.8) **G3:** 5 (4.3) **G4:** 2 (1.8) **Flu syndrome, n (%):** **G1:** 3 (2.8) **G2:** 2 (1.9) **G3:** 0 **G4:** 5 (4.6) **Back pain, n (%):** **G1:** 3 (2.8) **G2:** 1 (0.9) **G3:** 5 (4.3) **G4:** 3 (2.8) **Abdominal pain, n (%):** **G1:** 1 (0.9) **G2:** 3 (2.8) **G3:** 4 (3.5) **G4:** 1 (0.9)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Hill et al., 2006 (continued)				**Abnormal vision, n (%):** **G1:** 2 (1.9) **G2:** 0 **G3:** 4 (3.5) **G4:** 0	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Hill et al., 2007 [See evidence table for Haab et al., 2006] **Country and setting:** France, Denmark, Sweden, Australia, Canada, US, Multicenter **Enrollment period:** NR **Funding:** Novartis Pharma AG (educational grant) **Author industry relationship disclosures:** NR	**Design:** 2-yr, non-comparative, open-label extension study **Intervention:** Darifenacin following 2 feeder studies of darifenacin 3.75/7.5/15 mg qd or placebo x 12 wks **Groups:** NA **N at enrollment:** 214 **N at follow-up (%):** 137 (64.0) **Patient years of exposure:** 308 **Women, n (%):** 172 (80.4) **Age, n (%):** 65-74 years: 166 (77.6) 75-89 years: 48 (22.4) **Race/ethnicity:** NR **Menopausal, n (%):** 13 (6.1)	**Inclusion criteria:** • Age ≥ 65 • Successful completion of one of 2 previous, 12-wk feeder studies with no major protocol violation **Exclusion criteria:** NR	**Urgency episodes/day, median:** 8.1 **Urgency severity, median VAS score:** 51.8 **Incontinence episodes/week, median:** 18.7 **Voids/day, median:** 10.1 **Voided volume (mL), median:** 156 **Concomitant drug treatment, n (%):** 210 (98.1)	**Urgency episodes/day, median change (median % change):** -3.7 (-52.0) *P* < 0.05 **Urgency severity, VAS score, median change (median % change):** -12.6 (-23.3) *P* < 0.05 **Incontinence episodes/week, median change (median % change):** -11.0 (-83.7) *P* < 0.05 **Significant leaks/ week, median change (median % change):** -4.9 (-100.0) *P* < 0.05 **Incontinence episodes, responders, % reduction, %:** ≥ 50%: 74.1 ≥ 70%: 60.0 ≥ 90%: 44.4 **Voids/day, median change (median % change):** -1.2 (-12.4) *P* < 0.05 **Normalization of voiding frequency (< 8 voids/day) after darifenacin treatment, %:** 3 months: 34 2 years: 33.8	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Hill et al., 2007 (continued)				**Nocturia episodes/week, median change (median % change):** -1.4 (-10.9) **G1/BL:** *P* < 0.05 **Increased dose to 15 mg at 2 wks and maintained, n (%):** 110 (51.4) **Remained on 7.5 mg dose, n (%):** 55 (25.7) **Dose adjusted at other times, n (%):** 49 (22.9) **Compliance, ≥ 80% of doses, n (%):** 214 (84) **Voided volume (mL), median change (median % change):** 11.1 (6.3) **Dry mouth, n (%):** 50 (23.4) **Constipation, n (%):** 48 (22.4) **CVD, %:** 1.4 **Peripheral/CNS, %:** 3.3	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Homma and Koyama, 2006 **Country and setting:** Japan, Community **Enrollment period:** NR 9 weeks 1 week wash out 8 week treatment **Funding:** Sanyko Company **Author industry relationship disclosures:** 1 of 2 Sanyko (1)	**Design:** RCT **Intervention:** Oxybutynin Transdermal (TDS) patch vs placebo **Groups:** **G1:** OXY TDS 26 cm^2 **G2:** OXY TDS 39 cm^2 **G3:** OXY TDS 52 cm^2 **G4:** placebo **N at enrollment:** **G1:** 160 **G2:** 164 **G3:** 152 **G4:** 161 **N at follow-up:** **G1:** 160 **G2:** 164 **G3:** 152 **G4:** 161 **Women, n (%):** **G1:** 122 (76.3) **G2:** 132 (80.5) **G3:** 119 (78.3) **G4:** 117 (72.7) **Age, mean ± SD:** **G1:** 63.5 ± 11.5 **G2:** 62.7 ± 12.4 **G3:** 62.0 ± 13.6 **G4:** 62.9 ± 12.3 **Race/ethnicity:** NR	**Inclusion criteria:** • Adult with OAB syndrome • ≥ 1 episodes UUI per day • ≥ 8 voids per day **Exclusion criteria:** NR	**Incontinence episodes/week, mean ± SD:** **G1:** 21.1 ± 13.9 **G2:** 20.8 ± 14.6 **G3:** 20.4 ± 14.1 **G4:** 21.1 ± 16.6 **KHQ, general health, mean ± SD:** **G1:** 36.9 ± 21.0 **G2:** 38.6 ± 20.3 **G3:** 36.0 ± 21.4 **G4:** 36.0 ± 20.5 **KHQ, incontinence impact, mean ± SD:** **G1:** 54.6 ± 27.1 **G2:** 54.9 ± 26.7 **G3:** 57.1 ± 27.4 **G4:** 54.0 ± 25.5 **KHQ, role limitation, mean ± SD:** **G1:** 42.5 ± 24.6 **G2:** 40.7 ± 24.5 **G3:** 41.8 ± 26.5 **G4:** 43.0 ± 25.1 **KHQ, physical limitation, mean ± SD:** **G1:** 48.6 ± 26.0 **G2:** 45.8 ± 26.0 **G3:** 48.9 ± 29.6 **G4:** 46.9 ± 26.2 **KHQ, social limitation, mean ± SD:** **G1:** 27.4 ± 23.7 **G2:** 25.2 ± 24.3 **G3:** 26.1 ± 24.5 **G4:** 26.3 ± 25.7 **KHQ, personal relationship, mean ± SD:** **G1:** 17.9 ± 21.6 **G2:** 13.2 ± 20.7 **G3:** 16.4 ± 23.4 **G4:** 17.0 ± 24.7	**Incontinence episodes/week, mean ± SD:** **G1:** 10.3 ± 17.8 **G2:** 6.3 ± 10.4 **G3:** 8.9 ± 15.8 **G4:** 11.0 ± 15.4 **G2/G4:** $P = 0.014$ **KHQ domain, general health, mean ± SD:** **G1:** 33.4 ± 20.3 **G2:** 30.9 ± 22.2 **G3:** 33.9 ± 21.6 **G4:** 33.0 ± 22.7 **G2/G4:** $P < 0.05$ **KHQ domain, incontinence impact, mean ± SD:** **G1:** 34.6 ± 23.2 **G2:** 32.7 ± 23.6 **G3:** 34.0 ± 24.4 **G4:** 39.7 ± 26.0 **G2/G4:** $P < 0.05$ **KHQ domain, role limitation, mean ± SD:** **G1:** 24.8 ± 22.0 **G2:** 22.0 ± 20.3 **G3:** 26.5 ± 24.7 **G4:** 31.9 ± 24.1 **G2/G4:** $P < 0.05$ **KHQ domain, physical limitation, mean ± SD:** **G1:** 29.7 ± 25.6 **G2:** 26.6 ± 22.8 **G3:** 29.7 ± 27.3 **G4:** 36.5 ± 27.5 **G2/G4:** $P < 0.05$ **KHQ domain, social limitation, mean ± SD:** **G1:** 16.3 ± 21.3 **G2:** 13.2 ± 17.1 **G3:** 18.4 ± 22.8 **G4:** 21.6 ± 24.2 **G2/G4:** $P < 0.05$	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: NA Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Homma and Koyama, 2006 (continued)			**KHQ, emotions, mean ± SD:** **G1:** 45.3 ± 28.9 **G2:** 46.5 ± 27.3 **G3:** 46.1 ± 28.1 **G4:** 46.2 ± 26.2 **KHQ, sleep/ energy, mean ± SD:** **G1:** 32.0 ± 25.4 **G2:** 35.3 ± 24.9 **G3:** 33.4 ± 28.5 **G4:** 32.5 ± 26.3	**KHQ domain, personal relationship, mean ± SD:** **G1:** 10.4 ± 17.3 **G2:** 8.4 ± 16.8 **G3:** 11.6 ± 22.1 **G4:** 12.0 ± 20.2 **G2/G4:** $P < 0.05$ **KHQ domain, emotions, mean ± SD:** **G1:** 28.2 ± 25.8 **G2:** 24.9 ± 21.6 **G3:** 29.3 ± 26.7 **G4:** 35.2 ± 28.4 **G2/G4:** $P < 0.05$ **KHQ domain, sleep/ energy, mean ± SD:** **G1:** 18.2 ± 19.2 **G2:** 17.9 ± 18.9 **G3:** 21.1 ± 22.8 **G4:** 26.0 ± 25.6 **G2/G4:** $P < 0.05$	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Jacquetin and Wyndaele, 2001 **Country and setting:** France (22 centers) and Belgium (10 centers) **Enrollment period:** NR **Funding:** Pharmacia **Author industry relationship disclosures:** NR	**Design:** Double-blind, placebo-controlled, parallel-group, multicenter phase III study w/ 2-wk washout period **Intervention:** Tolterodine vs placebo for 4 weeks **Groups:** **G1:** Tolterodine 2mg b.i.d. **G2:** Tolterodine 1 mg b.i.d. **G3:** placebo (frequency NR) **N at enrollment:** NR **N at follow-up:** **G1:** 103 **G2:** 97 **G3:** 51 **Women, n (%):** **G1:** 84 (82) **G2:** 74 (76) **G3:** 41 (80) **Age, mean (range):** **G1:** 58 (21-88) **G2:** 53 (18-85) **G3:** 56 (19-89) **Race/ethnicity:** NR **BMI, kg/m^2 (range):** **G1:** 26.4 (17.7-39.7) **G2:** 25.5 (16.7-46.3) **G3:** 24.8 (17.6-36.9)	**Inclusion criteria:** • Age ≥ 18 • UDS-verified detrusor overactivity • ≥ 1 UUI episode/ day • ≥ 8 voids/day **Exclusion criteria:** • SI • Hepatic or renal dz • +UTI or recurrent UTIs • Interstitial cystitis • Hematuria • Clinically significant voiding difficulty • Pts receiving bladder training, electrostimulation therapy • Indwelling catheter • Intermittent cath • Pregnant or nursing • Women of childbearing age w/o reliable contraception	**UUI, n (%)** **G1:** 75 (73) **G2:** 75 (77) **G3:** 39 (76) **UUI episodes/ day, mean (range):** **G1:** 3.2 (0.1-24.0) **G2:** 2.7 (0.1-24.0) **G3:** 2.4 (0.1-8.4) **Voids/day, mean (range):** **G1:** 10.8 (6.2-34.7) **G2:** 10.7 (4.9-26.4) **G3:** 11.7 (6.3-26.3) **≥ 8 voids/day, n (%):** **G1:** 96 (93) **G2:** 89 (92) **G3:** 49 (96) **Urinary symptoms > 5 years, n (%):** **G1:** 46 (45) **G2:** 42 (43) **G3:** 17 (33) **Previous lower urinary tract surgery, n (%):** **G1:** 36 (35) **G2:** 29 (30) **G3:** 16 (31) **Previous drug therapy for OAB, n (%):** **G1:** 66 (64) **G2:** 59 (61) **G3:** 36 (71) **Previous poor efficacy response, n (%):** **G1:** 50 (76) **G2:** 45 (76) **G3:** 26 (72)	**UUI episodes/ day, mean change ± SD:** **G1:** -1.3 ± 1.8 **G2:** -1.1 ± 2.2 **G3:** -0.4 ± 1.9 **G1/G3:** *P* = 0.0089 **G2/G3:** *P* = 0.045 **Voids/day, mean change ± SD:** **G1:** -1.4 ± 4.3 **G2:** -1.4 ± 2.8 **G3:** -1.2 ± 2.7 **G1/G3:** *P* = NS **G2/G3:** *P* = NS **Good efficacy response in current study, previous poor efficacy response, n/N (%)** **G1:** 20/39 (51) **G2:** 18/37 (49) **G3:** 7/19 (37) **G1/G3:** *P* = NS **G2/G3:** *P* = NS **Voided volume (mL), mean change ± SD:** **G1:** 19 ± 46 **G2:** 20 ± 42 **G3:** 7 ± 40 **G1/G3:** *P* = 0.056 **G2/G3:** *P* = 0.055 **Dry mouth, n (%):** **G1:** 35 (34) **G2:** 20 (21) **G3:** 3 (6) **G1/G2:** *P* < 0.05 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05 **Abdominal pain, n (%):** **G1:** 4 (4) **G2:** 6 (6) **G3:** 2 (4) **Constipation, n (%):** **G1:** 2 (2) **G2:** 4 (4) **G3:** 2 (4)	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: - Masking: + Pt selection criteria: + Loss to followup: NR Drop-out rates: ++ Power calculation: + Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Jacquetin and Wyndaele, 2001 (continued)			**Voided volume (mL), mean (range):** **G1:** 158 (43-382) **G2:** 150 (46-320) **G3:** 148 (23-284)	**Headache, n (%):** **G1:** 3 (3) **G2:** 3 (3) **G3:** 2 (4) **Total AEs reported, n:** **G1:** 84 **G2:** 78 **G3:** 26 **Any AE, n (%):** **G1:** 55 (53) **G2:** 39 (40) **G3:** 16 (31) **G1/G3:** $P < 0.05$ **Discontinued due to AEs, n (%):*** **G1:** 2 (2) **G2:** 3 (3) **G3:** 1 (2)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Jarvis et al., 1981 **Country and setting:** UK, Academic medical center **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Inpatient bladder drill vs outpatient drug therapy **Groups:** **G1:** inpatient bladder drill **G2:** flavoxate hydrochloride 200 mg tds and imipramine 25 mg tds x 4 wks **N at enrollment:** **G1:** 25 **G2:** 25 **N at follow-up:** **G1:** 25 **G2:** 25 **Women, %:** 100 **Age, mean ± SD (range):** **G1:** 47 ± 15.4 (17-78) **G2:** 46 ± 12.8 (17-65)	**Inclusion criteria:** • Women • UDS-diagnosed detrusor instability **Exclusion criteria:** • DM • Neurological abnormalities • UTIs • Taking a drug suspected of affecting lower urinary tract function • Genuine stres incontinence	**UUI, n**: **G1:** 25 **G2:** 25 **SUI, n:** **G1:** 19 **G2:** 17 **Urgency, n:** **G1:** 25 **G2:** 25 **Frequency, n:** **G1:** 25 **G2:** 25 **Nocturia, n:** **G1:** 21 **G2:** 19 **Duration of symptoms (years), mean ± SD (range):** **G1:** 4.3 ± 2.7 (1-15) **G2:** 5.4 ± 3.2 (1-20) **Bladder volume (mL), first sensation, mean:** **G1:** 87 **G2:** 79 **Max cystometric capacity (mL), mean:** **G1:** 381 **G2:** 353	**UUI, n:** **G1:** 4 **G2:** 11 **SUI, n:** **G1:** 1 **G2:** 9 **Urgency, n:** **G1:** 4 **G2:** 11 **Frequency, n:** **G1:** 6 **G2:** 12 **Nocturia, n:** **G1:** 4 **G2:** 13 **Continent, n (%):** **G1:** 21 (84) **G2:** 14 (56) *P* < 0.05 **Symptom-free, n (%):** **G1:** 19 (76) **G2:** 12 (48) *P* < 0.05 **Bladder volume (mL), first sensation, mean:** **G1:** 152 **G2:** 140 **Max cystometric capacity (mL), mean:** **G1:** 470 **G2:** 446 **Adverse events, drug therapy, n:*** Dizziness: 8 Headache: 6 Dry mouth: 6 Nausea: 4 Drowsiness: 2 Vomiting: 1 **Discontinued due to AEs, n:** Dizziness: 1 Headache: 1 Vomiting: 1	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: - Loss to followup: ++ Drop-out rates: ++ Power calculation: - Statistical issues: - EXTERNAL VALIDITY: poor Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: - Measurement reliability: - Intervention description: -

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Jonas et al., 1997 **Country and setting:** Austria, Germany, Sweden, Academic medical center **Enrollment period:** NR 1-2 week washout-run in to total 4 weeks efficacy/ tolerability **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Tolterodine 1 mg b.i.d. vs tolterodine 2 mg b.i.d. vs placebo **Groups:** **G1:** Tolterodine 1 mg b.i.d. **G2:** Tolterodine 2mg b.i.d. **G3:** placebo **N at enrollment:** **G1:** 99 **G2:** 99 **G3:** 44 **N at follow-up:** **G1:** 98 **G2:** 99 **G3:** 44 **Women, n (%):** **G1:** 73 (74) **G2:** 76 (77) **G3:** 33 (75) **Age, mean (range):** **G1:** 59 (21, 81) **G2:** 57 (20, 83) **G3:** 57 (23, 92) **Race/ethnicity:** NR	**Inclusion criteria:** • Age ≥18 • Detrusor overactivity (phasic activity of amplitude of ≥ 10 cm H20 or 1 strong detrusor contraction that caused end of infusion) • ≥ 8 voids/ day and ≥ 1 incontinence episode/ day, urinary urgency, or both **Exclusion criteria:** • SUI • Hepatic disease • Renal disease • Any condition contraindicating anticholinergic activity • Indwelling catheter • Recurrent UTI • IC • Uninvestigated hematuria • Voiding difficulty at risk for urinary retention • Patients on anticholinergic therapy • Electrostimulation therapy or bladder training within 14 days prior to enrollment	**Urinary incontinence, n (%):** **G1:** 79 (80) **G2:** 83 (84) **G3:** 38 (86) **Voids/day, mean (range):** **G1:** 11.7 (0.0, 25.9) **G2:** 11.2 (4.1, 23.4) **G3:** 12.2 (7.3, 22.0) **≥ 8 voids/day, n (%):** **G1:** 94 (95) **G2:** 91 (92) **G3:** 42 (96) **Volume (mL), first contraction, mean ± SD:** **G1:** 142 ± 102 **G2:** 141 ± 102 **G3:** 140 ± 86 **Maximal height of wave (cmH_2O), mean ± SD:** **G1:** 41 ± 34 **G2:** 52 ± 43 **G3:** 47 ± 34 **Max cystometric capacity (mL), mean ± SD:** **G1:** 276 ± 142 **G2:** 272 ± 136 **G3:** 264 ± 116 **Postvoid residual volume (mL), mean ± SD:** **G1:** 25 ± 45 **G2:** 28 ± 47 **G3:** 38 ± 53 **DO ≥ 10 cmH_2O, n (%):** **G1:** 99(100) **G2:** 97 (98) **G3:** 44 (100)	**Volume (mL), first contraction, mean ± SD:** **G1:** 210 ± 163 **G2:** 230 ± 160 **G3:** 181 ± 142 **G1/G3:** *P* = 0.22 **G2/G3:** *P* = 0.030 **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **G3/BL:** *P* = 0.11 **Maximal height of wave (cmH_2O), mean ± SD:** **G1:** 35 ± 36 **G2:** 37 ± 38 **G3:** 40 ± 36 **G1/G3:** *P* = 0.97 **G2/G3:** *P* = 0.17 **G1/BL:** *P* = 0.007 **G2/BL:** *P* < 0.001 **G3/BL:** *P* = 0.11 **Max cystometric capacity (mL), mean ± SD:** **G1:** 294 ± 151 **G2:** 316 ± 156 **G3:** 268 ± 135 **G1/G3:** *P* = 0.43 **G2/G3:** *P* = 0.034 **G1/BL:** *P* = 0.36 **G2/BL:** *P* < 0.001 **G3/BL:** *P* = 0.80 **Postvoid residual volume (mL), mean ± SD:** **G1:** 35 ± 52 **G2:** 46 ± 70 **G3:** 41 ± 62 **G1/G3:** *P* = 0.034 **G2/G3:** *P* = 0.042 **G1/BL:** *P* = 0.063 **G2/BL:** *P* = 0.0076 **G3/BL:** *P* = 0.99 **Dry mouth, n (%):** **G1:** 8 (8) **G2:** 10 (10) **G3:** 1 (2) **Dry mouth, mild, n (%):** **G1:** 5 (5) **G2:** 7 (7) **G3:** 1 (2)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: NR Drop-out rates: + Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Jonas et al., 1997 (continued)				**Dry mouth, moderate, n (%):** **G1:** 3 (3) **G2:** 2 (2) **G3:** 0 (0) **Dry mouth, severe, n (%):** **G1:** 0 (0) **G2:** 1 (1) **G3:** 0 (0) **UTI, n (%):** **G1:** 5 (5) **G2:** 2 (2) **G3:** 2 (5) **Accomodation abnormal, n (%):** **G1:** 3 (3) **G2:** 5 (5) **G3:** NA **Constipation, n (%):** **G1:** 2 (2) **G2:** 3 (3) **G3:** 2 (5) **Headache, n (%):** **G1:** 3 (3) **G2:** 3 (3) **G3:** 1 (2)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Karram et al., 2009 **Country and setting:** USA, multicenter (61 sites) **Enrollment period:** NR **Funding:** Astellas Pharma US, Glaxo-SmithKline **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Solifenacin 5 or 10 mg daily **Groups:** **G1:** solifenacin 5 mg daily (with dose adjustment at weeks 4 and 8) **G2:** placebo **N at enrollment:** **G1**: 372 **G2:** 367 **N at follow-up (%):** **G1**: 357 **G2:** 350 **Age, mean:** Total: 57 **Race/ethnicity, %:** White: Total: 83.5 **Women, %:** Total: 84.2	**Inclusion criteria:** • Age ≥ 18 • OAB symptoms • ≥ 1 Urgency episode/day with or without leakage • >8 voids/day • ± nocturia **Exclusion criteria:** • SUI • MUI with primary stress • UTI • Chronic bladder inflammation • Bladder stones • Bladder cancer • Severe constipation • Narrow angle glaucoma • Urinary retention • Gastric retention • Hypersensitivity to drugs • BOO	**Urgency episodes/day, mean ± SD:** **G1:** 6.15 ± 3.92 **G2:** 6.03 ± 3.90 **Warning time (sec), mean ± SD:** **G1:** 136.4 ± 224.2 **G2:** 161.6 ± 333.9 **Incontinence episodes/ day, mean ± SD:** **G1:** 2.82 ± 2.70 **G2:** 2.56 ± 2.72 **Voids/day, mean ± SD** **G1:** 11.65 ± 3.72 **G2:** 11.70 ± 3.62	**Urgency episodes/day, mean ± SD:** **G1:** 2.24 ± 3.04 **G2:** 3.30 ± 3.84 **Urgency episodes/day, mean change ± SD:** **G1:** -3.91 ± 3.54 **G2:** -2.73 ± 3.84 *P* < 0.0001 **Warning time (sec), mean change ± SD:** **G1:** 186.4 ± 600.7 **G2:** 54.7 ± 393.5 *P* = 0.008 **Incontinence episodes/day, mean ± SD:** **G1:** 0.72 ± 1.45 **G2:** 1.32 ± 2.65 **Incontinence episodes, mean change ± SD:** **G1:** -2.10 ± 2.39 **G2:** -1.24 ± 2.30 *P* < 0.0001 **Voids/day, mean ± SD:** **G1:** 8.98 ± 3.26 **G2:** 9.76 ± 3.50 **Voids/day, mean change ± SD:** **G1:** -2.67 ± 3.31 **G2:** -1.94 ± 3.30 *P* = 0.0014 **Dry Mouth, %:** **G1:** 25.3 **G2:** 9.0 **Constipation, %:** **G1:** 14.8 **G2:** 9.3 **Blurred vision, %:** **G1:** 3.8 **G2:** 1.1	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Method and blinding: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Karram et al., 2009 (continued)				**Headache, %:** **G1:** 4.6 **G2:** 5.2 **Dizziness, %:** **G1:** 3.2 **G2:** 1.9 **Fatigue, %:** **G1:** 2.7 **G2:** 1.1	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Kelleher, Reese et al., 2002* Kelleher, Kreder, et al., 2002 [See evidence table for Van Kerrebroeck, et al., 2001] **Country and setting:** Multinational: Europe North America Australia/New Zealand Russia/Ukraine, Community **Enrollment period:** NR 12 week 12 month† **Funding:** Pharmacia Corporation **Author industry relationship disclosures:** NR	**Design:** Randomized placebo-controlled double blind parallel-group; Open label uncontrolled non-randomized extension† **Intervention:** Tolterodine ER vs placebo **Groups:** **G1:** Tolterodine ER 4mg daily **G2:** placebo **G3:** Tolterodine IR 2mg b.i.d.* **N at enrollment:** **G1:** 507 **G2:** 508 **G3:** 514 **N at follow-up:** **G1:** 450 **G2:** 440 **G3:** 447 **Women, n (%):** Total: 827 (81.5) **G1:** 417 (82.2) **G2:** 410 (80.7)* **G3:** 408 (79.4)* **Age, mean ± SD:** **G1:** 60.3 ± 14.4 **G2:** 61.1 ± 13.9 **G3:** 60.0 ± 14.3* **Race/ethnicity:** NR **Extension:†** Tolterodine ER 4mg daily **Groups:†** **G4:** KHQ **G5:** SF-36 **N at enrollment:†** Total: 1077	**Inclusion criteria:** • Age ≥ 18 • ≥ 8 voids/day on 7 day voiding diary • ≥ 5 UUI episodes/ week • OAB symptoms for at least 6 months **Exclusion criteria:** NR	NR	**Patient rating of bladder condition, improvement, %:** **G1:** 43 **G2:** 58 *P* = 0.001 **Patient rating of bladder condition, deterioration, %:** **G1:** 13 **G2:** 7 *P* = 0.004 **KHQ, inconti-nence impact, mean change ± SD:** **G1:** -15.68 ± 29.36 **G2:** -8.86 ± 26.65 *P* = 0.001 **KHQ, inconti-nence impact, 12 months, mean change (SE):†** **G4:** -23.1 (1.1) *P* = 0.002 **KHQ, role limitations, mean change ± SD:** **G1:** -17.93 ± 30.58 **G2:** -10.26 ± 29.20 *P* = 0.001 **KHQ, role limitations, 12 months, mean change (SE):†** **G4:** -23.8 (1.1) *P* = 0.002 **KHQ, physical limitations, mean change ± SD:** **G1:** -15.60 ± 29.98 **G2:** -8.73 ± 27.90 *P* = 0.001	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: NR Baseline characteristics: - Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Kelleher, Reese et al., 2002 Kelleher, Kreder, et al., 2002 (continued)	**N at follow-up:**† **G4:** 838 **G5:** 961 **Women, n (%):**† **G4:** 678 (80.9) **G5:** 793 (82.5) **Age, yrs ± SD:**† **G4:** 61.1 ± 13.5 **G5:** 60.2 ± 13.7 **Race/ethnicity, n, (%):**† **White:** **G4:** 800 (95.5) **G5:** 927 (96.5) **Black:** **G4:** 28 (3.3) **G5:** 25 (2.5) **Asian or Pacific:** **G4:** 6 (0.7) **G5:** 6 (0.6) **Mixed:** **G4:** 4 (0.5) **G5:** 4 (0.4)			**KHQ, physical limitations, 12 months, mean change (SE):**† **G4:** -19.9 (1.1) *P* = 0.002 **KHQ, social limitations, mean change ± SD:** **G1:** -8.49 ± 23.24 **G2:** -6.25 ± 22.76 *P* = 0.062 **KHQ, social limitations, 12 months, mean change (SE):**† **G4:** -11.5 (0.8) *P* = 0.002 **KHQ, personal relationships, mean change ± SD:** **G1:** -5.66 ± 26.74 **G2:** -3.44 ± 23.15 *P* = 0.446 **KHQ, personal relationships, 12 months, mean change (SE):**† **G4:** -8.4 (1.2) *P* = 0.002 **KHQ, emotions, mean change ± SD:** **G1:** -9.31 ± 24.85 **G2:** -6.52 ± 23.98 *P* = 0.106 **KHQ, emotions, 12 months, mean change (SE):**† **G4:** -13.8 (0.9) *P* = 0.002 **KHQ, sleep and energy, mean change ± SD:** **G1:** -9.82 ± 24.45 **G2:** -5.08 ± 21.06 *P* = 0.006	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Kelleher, Reese et al., 2002 Kelleher, Kreder, et al., 2002 (continued)				**KHQ, sleep and energy, 12 months, mean change (SE):†** **G4:** -11.7 (0.8) *P* = 0.002 **KHQ, severity (coping) measures, mean change ± SD:** **G1:** -11.98 ± 22.04 **G2:** -6.12 ± 20.39 *P* = 0.001 **KHQ, severity (coping) measures, 12 months, mean change (SE):†** **G4:** -13.8 (0.8) *P* = 0.002 **KHQ, general health perception, mean change ± SD:** **G1:** -0.41 ± 17.55 **G2:** -0.12 ± 17.49 *P* = 0.900 **KHQ, general health perception, 12 months, mean change ± SD:†** **G4:** -0.1 (0.6) *P* = 0.8302 **KHQ, symptom severity, mean change ± SD:** **G1:** -2.90 ± 4.10 **G2:** -1.42 ± 3.99 *P* = 0.001 **KHQ, symptom severity, 12 months, mean change (SE):†** **G4:** -11.7 (0.5) *P* = 0.002	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Kelleher, Reese et al., 2002 Kelleher, Kreder, et al., 2002 (continued)				**SF-36, physical summary, mean change ± SD:** **G1:** 0.97 ± 7.34 **G2:** 0.72 ± 6.57 *P* = 0.451 **SF-36, mental summary, mean change ± SD:** **G1:** 0.67 ± 8.63 **G2:** 0.10 ± 8.43 *P* = 0.684	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Kelleher et al., 2005 [See evidence table for Chapple et al., 2004 and Cardozo et al. 2004] **Country and setting:** Multinational, multicenter **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** 1 of 5 Pfizer (1) Yamanouchi (1) Lilly (1) Novartis (1) Q Med (1)	**Design:** Pooled analysis from the 40-wk open-label extension studies of 2 12-wk multinational, multicentre, double-blind RCTs **Intervention:** Solifenacin 5 mg vs solifenacin 10 mg vs placebo **Groups:** **G1:** solifenacin 5 mg qd **G2:** solifenacin 10 mg qd **G2:** placebo qd **N at enrollment:** 1637 **N at follow-up:** 1347	**Inclusion criteria:** [See evidence table for Chapple et al., 2004 and Cardozo et al. 2004] **Exclusion criteria:** [See evidence table for Chapple et al., 2004 and Cardozo et al. 2004]	[See evidence table for Chapple et al., 2004 and Cardozo et al. 2004]	**KHQ, general health perception, 12 weeks, mean change:** **G1:** -4.3 **G2:** -4.0 **G3:** -2.3 **G1/G3:** *P* < 0.001 **G2/G3:** *P* = 0.031 **KHQ, incontinence impact, 12 weeks, mean change:** **G1:** -24.7 **G2:** -27.3 **G3:** -18.2 **G1/G3:** *P* < 0.001 **G2/G3:** *P* < 0.001 **KHQ, role limitations, 12 weeks, mean change:** **G1:** -20.6 **G2:** -22.7 **G3:** -15.4 **G1/G3:** *P* < 0.001 **G2/G3:** *P* < 0.001 **KHQ, physical limitations, 12 weeks, mean change:** **G1:** -17.7 **G2:** -20.3 **G3:** -13.7 **G1/G3:** *P* = 0.002 **G2/G3:** *P* < 0.001 **KHQ, social limitations, 12 weeks, mean change:** **G1:** -11.3 **G2:** -11.7 **G3:** -7.8 **G1/G3:** *P* = 0.003 **G2/G3:** *P* = 0.015	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: - Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Kelleher et al., 2005 (continued)				**KHQ, personal relationships, 12 weeks, mean change:** **G1:** -8.7 **G2:** -9.3 **G3:** -9.7 **G1/G3:** *P* = 0.650 **G2/G3:** *P* = 0.747 **KHQ, emotions, 12 weeks, mean change:** **G1:** -16.0 **G2:** -17.7 **G3:** -12.3 **G1/G3:** *P* < 0.001 **G2/G3:** *P* < 0.001 **KHQ, sleep/ energy, 12 weeks, mean change:** **G1:** -13.8 **G2:** -14.4 **G3:** -10.0 **G1/G3:** *P* = 0.002 **G2/G3:** *P* = 0.001 **KHQ, severity measures, 12 weeks, mean change:** **G1:** -10.5 **G2:** -13.2 **G3:** -7.3 **G1/G3:** *P* < 0.001 **G2/G3:** *P* < 0.001 **KHQ, symptom severity, 12 weeks, mean change:** **G1:** -3.4 **G2:** -3.6 **G3:** -2.6 **G1/G3:** *P* < 0.001 **G2/G3:** *P* < 0.001 **KHQ, general health perception, 40 weeks, mean change:** **G1:** -6.0 **G2:** -7.1 **G3:** -7.8	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Kelleher et al., 2005 (continued)				**KHQ, incontinence impact, 40 weeks, mean change:** **G1:** -33.5 **G2:** -35.3 **G3:** -32.9 **KHQ, role limitations, 40 weeks, mean change:** **G1:** -29.1 **G2:** -28.9 **G3:** -30.8 **KHQ, physical limitations, 40 weeks, mean change:** **G1:** -25.7 **G2:** -27.0 **G3:** -26.0 **KHQ, social limitations, 40 weeks, mean change:** **G1:** -15.6 **G2:** -18.1 **G3:** -15.7 **KHQ, personal relationships, 40 weeks, mean change:** **G1:** -14.1 **G2:** -15.0 **G3:** -13.2 **KHQ, emotions, 40 weeks, mean change:** **G1:** -22.2 **G2:** -24.8 **G3:** -21.0 **KHQ, sleep/ energy, 40 weeks, mean change:** **G1:** -17.9 **G2:** -19.5 **G3:** -18.8	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Kelleher et al., 2005 (continued)				**KHQ, severity measures, 40 weeks, mean change:** **G1:** -15.3 **G2:** -17.2 **G3:** -14.7 **KHQ, symptom severity, 40 weeks, mean change:** **G1:** -4.4 **G2:** -4.7 **G3:** -4.7	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Koonings et al., 1991 **Country and setting:** US, Academic medical center **Enrollment period:** January 1986 to October 1987 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cohort **Intervention:** Oxybutynin chloride 5 mg t.i.d. x 4 wks **Groups:** NA **N at enrollment:** 126 **N at follow-up:** 114 **Women, %:** 100 **Age, mean (range):** 39 (21-74) **Race/ethnicity:** NR **Menopausal, n:** 44 **Parity, mean (range):** 2 (0-12)	**Inclusion criteria:** • Confirmed diagnosis of detrusor instability • Uninhibited detrusor contraction > 15 cm H_2O on standing provocative urethra cystometry **Exclusion criteria:** • Urethritis (on urethroscopy) • Cystitis (on cystoscopy) • Neurologic findings on screening test of S2-S4 lower voiding center • MUI • Glaucoma	**Uninhibited detrusor contraction starting prior to urethral pressure change, n (%):** 73 (64%) **Urethral pressure drop (≥ 20 cmH_2O) prior to detrusor contraction, n (%):** 41 (6)	**Good response, n (%):** 66 (58) **Poor response, n (%):** 48 (42) **Response, women with uninhibited detrusor contraction starting prior to urethral pressure, n (%):** Good: 61 (81) Poor: 5 (12) *P* < 0.01 **Response, women with urethral pressure drop (≥ 20 cmH_2O) prior to detrusor contraction, n (%):** Good: 12 (16) Poor: 36 (88) *P* < 0.01	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: ++ Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Kreder et al., 2002 [See evidence table for Van Kerrebroeck, et al., 2001] **Country and setting:** Multinational; open label extension x 12 months **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Prospective case series Open label, uncontrolled, non-randomized extension study of Phase III **Intervention:** Tolterodine ER 4 mg daily **Groups:** Tolterodine ER 4 mg daily **N at enrollment:** 1077 **N at follow-up (%):** 759 (70.6) **Age, mean (range):** 60.3 (19.6-93.2) **Race/ethnicity:** NR **Women, N (%):** 883 (82)	**Inclusion criteria:** [See evidence table for Van Kerrebroeck, et al., 2001] **Exclusion criteria:** [See evidence table for Van Kerrebroeck, et al., 2001]	**Frequency ≥ 8 voids/day, n (%):** 1041 (96.7) **UUI episodes/ day ≥ 5, n (%):** 1056 (98.1) **Voided volume ≤ 200 mL, n (%):** 1032 (95.8) **Incontinence episodes/week, n (range):** 21.6 (0.0-168.0) **Voids/day, n (range):** 10.9 (2.3-48.6) **Voided volume (mL), mean (range):** 137.7 (21.1-373.5) **Previous treatment for OAB, n (%):** 591 (54.9) **Previous treatment for OAB with poor efficacy, n (%):** 231 (39.1)	**Incontinence episodes/week, 3 months, mean change ± SD:** -13.4 ± 19.3 *P* = 0.297 **Incontinence episodes/week, 12 months, mean change ± SD:** -12.5 ± 19.9 *P* = 0.5888 **Voids/day, 3 months, mean change ± SD:** -2.4 ± 3.2 *P* = 0.0077 **Voids/day, 12 months, mean change ± SD:** -2.3 ± 3.4 *P* = 0.0661 **Voided volume (mL), 3 months, mean change ± SD:** 42.9 ± 55.6 *P* = 0.6319 **Voided volume (mL), 12 months, mean change ± SD:** 43.2 ± 60.3 *P* = 0.6426 **Dry mouth, n (%):** 139 (12.9) **Constipation, n (%):** 35 (3.3) **Dyspepsia, n (%):** 24 (2.2) **Upper Respiratory Tract Infection, n (%):** 43 (4.0) **Bronchitis, n (%):** 28 (2.6) **UTI, n (%):** 44 (4.1)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Kreder et al., 2002 (continued)				**Cystitis, n (%):** 23 (2.1) **Headache, n (%):** 26 (2.4) **Back pain, n (%):** 35 (3.3) **Flu-like illness, n (%):** 28 (2.6) **Serious adverse events related to tolterodine, n:** Urinary retention: 1 Aggravated MS: 1 Med error: 1 **Withdrawal due to AEs (N= 107), n (%):** Dry Mouth: 19 (1.8) Headache: 9 (0.8) Abd pain: 9 (0.8) Dizziness: 7 (0.7) UTI: 7 (0.7) Dyspepsia: 6 (0.6) Constipation: 6 (0.6) Xerophthalmia: 5 (0.5) Voiding disorder: 5 (0.5)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Kreder et al., 2003 **Country and setting:** US and Canada, Community **Enrollment period:** NR 16 week follow up **Funding:** Pharmacia Corporation **Author industry relationship disclosures:** NR	**Design:** Subgroup analysis of multicenter, single blind cohort **Intervention:** Tolterodine 1-2 mg b.i.d. **Groups:** **G1:** MUI with primary urge **G2:** UUI **N at enrollment:** **G1:** 171 **G2:** 552 **N at follow-up:** **G1:** 170 **G2:** 551 **Women, n (%):** **G1:** 165 (96.5) **G2:** 464 (84) **Age, median (range):** **G1:** 62 (21, 88) **G2:** 65 (20, 88) **Race/ethnicity:** NR	**Inclusion criteria:** • Age ≥ 65 • History, PE, UDS consistent with urge incontinence • ≥ 4 episodes UI on 5 day voiding diary • ≥ 8 voids/day • Either urgency or ≥ 1 UI episodes / day **Exclusion criteria:** • MUI with predominate stress component • Contraindications to antimuscarinic therapy • Hepatic/renal disease • Symptomatic or recurrent UTI • Hematuria • IC • Voiding difficulty with risk of retention • Concurrent bladder training • Electrostimulation therapy • Indwelling catheter • CIC • Women with reproduction potential • Pregnant/ nursing • Concomitant anticholinergic meds/ treatment	**Incontinence episodes/day, median (range):** **G1:** 3 (1, 19) **G2:** 3 (1, 15) **≥ 2 nocturia episodes/day, n (%):** **G1:** 100 (58.5) **G2:** 334 (60.5) **Using pads, n (%):** **G1:** 122 (71) **G2:** 342 (62) **Voided volume (mL), median (range):** **G1:** 169 (62, 506) **G2:** 164 (31, 524) **Duration of symptoms > 5 years, n (%):** **G1:** 91 (53) **G2:** 259 (47) **Previous drug therapy for OAB, n (%):** **G1:** 85 (50) **G2:** 275 (50)	**Incontinence episodes/day, median % change:** **G1:** -67 **G2:** -75 *P* = NS **Cure rate, achieved dryness, n (%):** **G1:** 66 (39) **G2:** 243 (44) *P* = NS **Voids/day, median % change:** **G1:** -15 **G2:** -17 *P* = NS **Cure rate, ≤ 8 voids/day dryness, n (%):** **G1:** 40 (23.5) **G2:** 130 (24) *P* = NS **Nocturia episodes/day, median % change:** **G1:** -50 **G2:** -33 *P* = NS **Cure rate, achieving ≤ 2 nocturnal voiding episodes/day, n (%):** **G1:** 83 (83) **G2:** 254 (76) *P* = NS **Cure rate, achieved no pad usage, n (%):** **G1:** 26 (21) **G2:** 93 (27) *P* = NS	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Kreder et al., 2003 (continued)				**Voided volume (mL), median change (range):** **G1:** 26.5 (-261, 195) **G2:** 27 (-345, 389) **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Landis et al., 2004 [See evidence table for van Kerrebroeck et al., 2001] **Country and setting:** Multinational, Community **Enrollment period:** NR 12 weeks **Funding:** Pharmacia **Author industry relationship disclosures:** 2 of 4 ALZA (1) Bristol-Myers Squibb (1) Pharmacia (2)	**Design:** RCT **Intervention:** Tolterodine ER vs placebo 1 week run-in period with 12 weeks treatment **Groups:** **G1:** Tolterodine ER 4 mg daily **G2:** placebo **Stratified:** **a:** 5-20 UUI episodes/week **b:** ≥ 21 UUI episodes/week **N at enrollment:** **G1:** 492 **G1a:** 321 **G1b:** 171 **G2:** 494 **G2a:** 284 **G2b:** 210 **N at follow-up:** **G1a:** 321 **G1b:** 171 **G2a:** 284 **G2b:** 210 **Women, N (%):** **G1a:** 262 (81.6) **G1b:** 143 (83.6) **G2a:** 223 (78.5) **G2b:** 178 (84.8) **Age, mean ± SD:** **G1a:** 60.86 ± 14.45 **G1b:** 60.04 ± 14.10 **G2a:** 60.61 ± 13.59 **G2b:** 61.84 ± 13.85 **Race/ethnicity:** NR	**Inclusion criteria:** • Age ≥ 18 • ≥ 5 UUI episodes/ week • ≥ 8 voids/day • Symptoms of OAB x 5 months **Exclusion criteria:** NR	**UUI episodes/ week, median (range):** **G1:** 16 (5-168) **G1a:** 11 (5-20) **G1b:** 34 (21-168) **G2:** 18 (5-168) **G2a:** 11 (5-20) **G2b:** 31.5 (21-168) **Voids/day, median (range):** **G1a:** 9.57 (2.57-34.85) **G1b:** 10.71 (2.28-51.28) **G2a:** 10.28 (2.28-28.42) **G2b:** 11.14 (2-37.42) **Voided volume (mL), median (range):** **G1a:** 142.72 (36.19-338) **G1b:** 135.12 (51.45-270.52) **G2a:** 136.25 (32.51-237.5) **G2b:** 126.94 (21.16-373.46) **Number prior Tx for OAB, n (%):** **G1a:** 162 (50.6) **G1b:** 100 (58.5) **G2a:** 139 (49.1) **G2b:** 117 (55.7) **Number prior Tx for OAB w/ good efficacy, n (%):** **G1a:** 85 (52.8) **G1b:** 63 (63.0) **G2a:** 84 (60.4) **G2b:** 68 (58.6)	**UUI episodes/ week, median change:** **G1:** -9.0 **G1a:** -6.0 **G1b:** -21 **G2:** -5.0 **G2a:** -4.0 **G2b:** -9.5 **G1/G2:** *P* < 0.0001 **G1a/G2a:** *P* < 0.0001 **G1b/G2b:** *P* < 0.0001 **UUI episodes/ week, median % change:** **G1a:** -71.42 **G1b:** -67.56 **G2a:** -38.46 **G2b:** -29.81 **G1a/G2a:** *P* = 0.0264 (adjusted) **G1b/G2b:** *P* = 0.0221 (adjusted) **Voids/day, median change:** **G1a:** -1.22 **G1b:** -1.9 **G2a:** -0.85 **G2b:** -0.4 **G1a/G2a:** *P* < 0.04 **G1b/G2b:** *P* < 0.02 **Voided volume (mL), median change:** **G1a:** 24.0 **G1b:** 27.0 **G2a:** 4.0 **G2b:** 2.9 **G1a/G2a:** *P* < 0.0001 **G1a/G2a:** *P* < 0.0001	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Lauti et al., 2008 **Country and setting:** New Zealand, Academic **Enrollment period:** February 2003 to July 2003 **Funding:** University of Otago **Author industry relationship disclosures:** None	**Design:** RCT pilot study, unmasked **Intervention:** Oxybutynin vs. bladder retraining vs. combination therapy **Groups:** **G1:** Oxybutynin 2.5 mg/day (daily dose could be increased by 2.5 mg every 5 days to a maximum of 15 mg/day) **G2:** Bladder retraining **G3:** Combination therapy **N screened:** 120 **N at enrollment:** **G1**: 21 **G2:** 16 **G3:** 19 **N at 3 month follow-up:** **G1**: 18 **G2:** 16 **G3:** 12 **N at 12 month follow-up:** **G1**: 16 **G2:** 14 **G3:** 12 **Age, mean ± SD:** **G1:** 53.8 ± 14.8 **G2:** 63.9 ± 17.2 **G3:** 47.6 ± 16.3 **Race/ethnicity:** NR **Women, %:** Total: 100 **Parrous, %:** **G1:** 81 **G2:** 62.5 **G3:** 73.7	**Inclusion criteria:** • Age > 18 • Predominant UUI **Exclusion criteria:** • Predominant SUI • Contraindications to anticholinergic drugs • Current UTI • Neurological disease • Psychiatric disorder • Untreated co-existing pelvic organ prolapse below the hymenal ring • Obstructed voiding • Functional-reversible cause of incontinence • Inability to toilet independently • Limited fluency of written/spoken English • Current or recent use of any of the trial interventions	**Urgency episodes/day, mean ± SD:** **G1:** 3.8 ± 2.7 **G2:** 3.1 ± 2.2 **G3:** 3.5 ± 2.0 **Incontinence episodes/day, mean ± SD:** **G1:** 2.2 ± 1.5 **G2:** 1.0 ± 1.1 **G3:** 1.8 ± 1.6 **Nocturia episodes/day, mean ± SD:** **G1:** 1.1 ± 1.0 **G2:** 1.4 ± 1.0 **G3:** 0.8 ± 0.7 **Voids per day, mean ± SD:** **G1:** 7.8 ± 2.8 **G2:** 8.0 ± 1.7 **G3:** 8.4 ± 2.5 **OAB-q total HRQL, mean ± SD:** **G1:** 73.1 ± 17.4 **G2:** 69.5 ± 24.6 **G3:** 71.6 ± 21.5 **OAB-q severity, mean ± SD:** **G1:** 47.0 ± 16.2 **G2:** 42.3 ± 17.7 **G3:** 45.9 ± 18.7 **OAB-q coping, mean ± SD:** **G1:** 72.0 ± 21.6 **G2:** 66.2 ± 31.7 **G3:** 73.8 ± 26.2 **OAB-q concern, mean ± SD:** **G1:** 68.2 ± 19.0 **G2:** 68.8 ± 27.6 **G3:** 63.8 ± 29.2 **OAB-q sleep, mean ± SD:** **G1:** 63.1 ± 28.7 **G2:** 59.8 ± 29.9 **G3:** 55.1 ± 27.6	**Urgency episodes/day, 3 mos, mean ± SD:** **G1:** 2.2 ± 1.8 **G2:** 1.5 ± 2.1 **G3:** 1.7 ± 1.8 **Urgency episodes/day, 12 mos, mean ± SD:** **G1:** 2.3 ± 2.5 **G2:** 1.9 ± 2.1 **G3:** 2.0 ± 1.1 **Incontinence episodes/day, 3 mos, mean ± SD:** **G1:** 0.8 ± 0.8 **G2:** 0.1 ± 0.3 **G3:** 0.6 ± 0.8 **Incontinence episodes/day, 12 mos, mean ± SD:** **G1:** 0.9 ± 0.0 **G2:** 0.9 ± 1.0 **G3:** 0.8 ± 0.7 **Nocturia episodes/day, 3 mos, mean ± SD:** **G1:** 1.0 ± 0.5 **G2:** 0.8 ± 0.7 **G3:** 0.6 ± 0.5 **Nocturia episodes/day, 12 mos, mean ± SD:** **G1:** 1.0 ± 0.9 **G2:** 1.2 ± 0.6 **G3:** 0.7 ± 0.7 **Voids/day, 3 mos, mean ± SD:** **G1:** 6.7 ± 1.8 **G2:** 6.3 ± 1.6 **G3:** 6.7 ± 2.2 **Voids/day, 12 mos, mean ± SD:** **G1:** 7.2 ± 1.1 **G2:** 6.8 ± 1.4 **G3:** 7.6 ± 1.5	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Method and blinding: - Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Lauti et al., 2008 (continued)			**OAB-q social, mean ± SD:** **G1:** 92.5 ± 14.6 **G2:** 85.4 ± 19.9 **G3:** 92.8 ± 18.6 **SF-12 quality of life, physical, mean ± SD:** **G1:** 49.0 ± 9.6 **G2:** 41.7 ± 11.5 **G3:** 46.2 ± 10.6 **SF-12 quality of life, mental, mean ± SD:** **G1:** 49.1 ± 9.3 **G2:** 53.1 ± 8.8 **G3:** 46.3 ± 8.3	**OAB-q total HRQL, 3 mos, mean ± SD:** **G1:** 82.3 ± 16.1 **G2:** 89.6 ± 9.4 **G3:** 91.8 ± 7.4 **OAB-q total HRQL, 12 mos, mean ± SD:** **G1:** 87.9 ± 11.6 **G2:** 81.6 ± 19.3 **G3:** 88.9 ± 9.9 **OAB-q severity, 3 mos, mean ± SD:** **G1:** 37.2 ± 22.0 **G2:** 16.8 ± 12.0 **G3:** 21.6 ± 10.9 **OAB-q severity, 12 mos, mean ± SD:** **G1:** 24.6 ± 10.6 **G2:** 33.1 ± 16.6 **G3:** 21.9 ± 14.8 **OAB-q coping, 3 mos, mean ± SD:** **G1:** 79.2 ± 22.1 **G2:** 91.6 ± 9.5 **G3:** 92.7 ± 9.4 **OAB-q coping, 12 mos, mean ± SD:** **G1:** 89.2 ± 13.7 **G2:** 81.5 ± 23.7 **G3:** 90.5 ± 10.0 **OAB-q concern, 3 mos, mean ± SD:** **G1:** 78.6 ± 18.0 **G2:** 87.7 ± 14.5 **G3:** 90.2 ± 12.4 **OAB-q concern, 12 mos, mean ± SD:** **G1:** 85.3 ± 15.5 **G2:** 81.7 ± 19.7 **G3:** 85.2 ± 13.4 **OAB-q sleep, 3 mos mean ± SD:** **G1:** 77.7 ± 24.9 **G2:** 81.3 ± 14.6 **G3:** 85.0 ± 19.6	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Lauti et al., 2008 (continued)				**OAB-q sleep, 12 mos, mean ± SD:** **G1:** 79.9 ± 18.3 **G2:** 72.0 ± 24.5 **G3:** 83.2 ± 18.4 **OAB-q social, 3 mos, mean ± SD:** **G1:** 96.4 ± 9.7 **G2:** 95.6 ± 7.0 **G3:** 98.9 ± 1.9 **OAB-q social, 12 mos, mean ± SD:** **G1:** 97.3 ± 7.1 **G2:** 91.9 ± 14.2 **G3:** 97.3 ± 6.9 **SF-12 quality of life, physical** **G1:** 50.6 ± 8.0 **G2:** 42.1 ± 12.7 **G3:** 48.4 ± 10.8 **SF-12 quality of life, physical, 12 mos, mean ± SD:** **G1:** 50.0 ± 7.3 **G2:** 45.1 ± 13.9 **G3:** 45.3 ± 13.4 **SF-12 quality of life, mental, 3 mos, mean ± SD:** **G1:** 50.4 ± 9.6 **G2:** 51.2 ± 9.5 **G3:** 46.7 ± 7.6 **SF-12 quality of life, mental, 12 mos, mean ± SD:** **G1:** 49.6 ± 7.5 **G2:** 50.1 ± 10.7 **G3:** 50.6 ± 8.4 **Dry mouth, n (%):** **G1:** 3 (21) **G2:** 5 (46) **G3:** 5 (42) **Headaches, n (%):** **G1:** 6 (43) **G2:** 1 (11) **G3:** 7 (58) **Dizziness, n (%):** **G1:** 4 (29) **G2:** 2 (20) **G3:** 3 (25)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Lauti et al., 2008 (continued)				**Constipation, n (%):** **G1:** 3 (21) **G2:** 3 (27) **G3:** 3 (27) **Fatigue, n (%):** **G1:** 9 (64) **G2:** 5 (46) **G3:** 7 (64)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Layton et al., 2001 **Country and setting:** England, Community **Enrollment period:** November 1998 to May 1999 **Funding:** Pharmacia Upjohn **Author industry relationship disclosures:** NR	**Design:** Prospective observational cohort **Intervention:** Tolterodine prescription event monitoring in UK **Groups:** NA **N at enrollment:** 35,295 had commenced treatment 26,991 green forms mailed out 14,526 returned forms Response rate: 53.8% **Age, mean ± SD:** 62.7 ± 16.4 **Women, N (%):** 9965 (68.6) **Parity:** NR	**Inclusion criteria:** • Patients prescribed tolterodine in general practice in UK **Exclusion criteria:** • None		**Dry mouth, n:** 250 **Unspecified adverse effects, n:** 168 **Headache, n:** 123 **Constipation, n:** 78 **General malaise, n:** 78 **Hallucinations, n:** 23 **Palpitations/tachy cardia, n:** 42 **Other cardiac arrhythmias, n:** 29 **Chest pains, n:** 87	Quality: Overall quality score: good INTERNAL VALIDITY: good Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: NA Drop-out rates: NA Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: NR Baseline characteristics: + Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: -

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Lee et al., 2002 **Country and setting:** South Korea, University **Enrollment period:** NR **Funding:** Pharmacia Corp **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Tolterodine 2mg b.i.d. vs Oxybutynin 5mg b.i.d. **Groups:** **G1:** Tolterodine 2mg b.i.d. **G2:** Oxybutynin 5mg b.i.d. **N at enrollment:** **G1:** 112 **G2:** 116 **N at follow-up:** **G1:** 97 **G2:** 90 **Women, n (%):** **G1:** 84 (74) **G2:** 92 (79) **Age, mean (range):** **G1:** 52 (27, 82) **G2:** 52 (20, 86) **Race/ethnicity (%):** **Asian:** **G1:** 100 **G2:** 100 **BMI, kg/m^2 (range):** **G1:** 23 (17, 32.5) **G2:** 23.5 (16, 38) **Previous drug therapy: N (%)** **G1:** 36 (32) **G2:** 26 (22)	**Inclusion criteria:** • Age ≥ 18 • OAB symptoms > 6 mos • ≥ 8 voids/day, with or without incontinence (measured by diary) **Exclusion criteria:** • SUI • Women not using reliable contraception • Pregnant or nursing • Prior treatment with anticholinergic < 2 wks • Renal or hepatic disease • Narrow angle glaucoma • Urinary retention • Gastric retention • Hypersensitivity to drugs • UTI • IC • Hematuria • BOO • Concomitant bladder training, e-stim treatment • Indwelling catheter • CIC • Concomitant treatment for OAB ≤ 2 mos	**Incontinence episodes/day, mean (range):** **G1:** 2.6 (0.3, 9.3) **G2:** 2.4 (3.0, 14.7) **Patients with incontinence episodes, n (%):** **G1:** 46 (41) **G2:** 42 (36) **Voids/day, mean (range):** **G1:** 12.2 (8.0, 23.7) **G2:** 12.4 (7.7, 29.7)	**Incontinence episodes/day, mean change ± SD (% change):** **G1:** -2.2 ± 2.3 (-85) **G2:** -1.4 ± 1.8 (-58) **G1/BL:** *P* = 0.0001 **G1/BL:** *P* = 0.0001 **G1/G2:** *P* = 0.10 **Voids/ day, mean change ± SD (% change):** **G1:** -2.6 ± 2.9 (-21) **G2:** -1.8 ± 4.2 (-15) **G1/BL:** *P* = 0.0001 **G1/BL:** *P* = 0.0001 **G1/G2:** *P* = 0.14 **Benefit of Tx, %:** **G1:** 45 **G2:** 46 **G1/G2:** *P* = NS **Patients reporting adverse events, n (%):** **G1:** 62 (55) **G2:** 94 (82) **Discontinued due to AEs, n (%):** **G1:** 11 **G2:** 18 **Dry mouth, n (%):** **G1:** 39 (35) **G2:** 72 (63) **G1/G2:** *P* = 0.001 **Dry mouth, mild, n (%):** **G1:** 29 (26) **G2:** 40 (35) **Dry mouth, moderate, n (%):** **G1:** 9 (8) **G2:** 26 (23)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Lee et al., 2002 (continued)				**Dry mouth, severe, n (%):** **G1:** 1 (1) **G2:** 6 (5) **Voiding disorder, n (%):** **G1:** 10 (9) **G2:** 16 (14) **Dyspepsia, n (%):** **G1:** 8 (7) **G2:** 6 (5) **Abdominal pain, n (%):** **G1:** 6 (5) **G2:** 6 (5) **Headache, n (%):** **G1:** 4 (4) **G2:** 6 (5)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Leung et al., 2002 **Country and setting:** Hong Kong, Academic, uro-gynecology centers **Enrollment period:** April 2000 to December 2000 **Funding:** Pharmacia Limited **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** oral tolterodine 2 mg vs. oxybutynin 5 mg b.i.d. for 10 weeks **Groups:** **G1:** tolterodine 2 mg **G2:** oxybutynin 5 mg b.i.d. **N at enrollment:** **G1:** 53 **G2:** 53 **N at follow-up:** **G1:** 44 **G2:** 45 **Women, %:** 100 **Age, median (IQR):** **G1:** 51 (44, 67) **G2:** 49 (43, 57) **Race/ethnicity, %:** Hong Kong Chinese: 100 **Menopausal, %:** **G1:** 66.0 **G2:** 45.3 **G1/G2:** *P* = 0.073	**Inclusion criteria:** • UDS-confirmed detrusor instability • Age ≥ 18 • Diagnosis of OAB (phasic detrusor contraction with an amplitude ≥ 15 cmH_2O by ICS criteria • ≥ 8 voids/day • ≥ 1 incontinent episodes/day **Exclusion criteria:** • Genuine SUI • Voiding difficulty (max flow rate < 10mL/s with a residual volume of > 200mL) • Recurrent or acute UTIs • Intermittent or indwelling catheter • Hematuria or bladder cancer • Currently on treatment for OAB or on anticholinergic medications • Psychiatric disease or cognitive impairment (by history or MMSE) • Cardiac, hepatic, renal, or hematologic disorder • Contraindications for antimuscarinic agents • Pregnant or lactating • Women not using reliable contraception	**Overall severity, VAS score, wk 0, median (IQR):** **G1:** 5.2 (5.0,7.85) **G2:** 5.7 (5.0, 8.0) **Peak flow rate (mL/s), median (IQR)** **G1:** 13.1 (10.0, 17.4) **G2:** 13.9 (11.2, 21.2) **Max cystometric capacity (mL), median (IQR):** **G1:** 333 (263.3, 400.8) **G2:** 373 (293, 416.8)	**Overall severity, VAS score, wk 4, median (IQR):** **G1:** 5.0 (5.0, 7.0) **G2:** 5.0 (3.0, 6.0) **Overall severity, VAS score, wk 10, median (IQR):** **G1:** 5.0 (3.5, 6.0) **G2:** 5.0 (4.0, 6.0) *P* < 0.005 for change with duration of treatment, *P* < 0.005 for linear pattern **Perceived change in symptoms, double-sided VAS score, wk 4, median (IQR):** **G1:** 1.0 (0.0, 2.5) **G2:** 2.0 (0.0, 3.0) **Perceived change in symptoms, double-sided VAS score, wk 10, median (IQR):** **G1:** 1.0 (0.0, 2.0) **G2:** 2.0 (0.0, 3.0) **G1/G2:** *P* = 0.053 ITT analysis **G1/G2:** *P* = 0.047 per-protocol analysis **Urinary pad weight (g), ITT analysis, median change (IQR):** **G1:** -5.0 (-54.75, 0) **G2:** 0.0 (-4.5, -0.75) **G1/G2:** *P* = 0.019	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Leung et al., 2002 (continued)				**Urinary pad weight (g), per-protocol analysis, median change (IQR):** **G1:** -5.0 (-54.75, 0) **G2:** 0.0 (-5.0, 0) **G1/G2:** *P* = 0.031 **Drug compliance, %:** **G1:** 75 **G2:** 87.5 **Significance of variables, change with duration of treatment, ITT analysis:** XQ overall dryness: *P* < 0.001 XQ uncomfortable: *P* < 0.001 XQ sleep: *P* = 0.020 XQ speak: *P* = 0.042 XQ swallow: *P* = 0.002 XQ liquid: *P* = 0.005 XQ dentures: *P* = 0.361 Diary frequency: *P* < 0.001 Diary urgency episodes: *P* = 0.109 Diary incontinence episodes: *P* = 0.203 Diary pad use: *P* = 0.593	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Leung et al., 2002 (continued)				**Significance of variables, between groups, ITT analysis:** XQ overall dryness: *P* = 0.062 XQ uncomfortable: *P* = 0.285 XQ sleep: *P* = 0.626 XQ speak: *P* = 0.652 XQ swallow: *P* = 0.197 XQ liquid: *P* = 0.451 XQ dentures: *P* = 0.480 Diary frequency: *P* = 0.965 Diary urgency episodes: *P* = 0.672 Diary incontinence episodes: *P* = 0.993 Diary pad use: *P* = 0.665 **Drug compliance rate (IQR):** **G1:** 75.0 (8.9, 98.8) **G2:** 87.5 (11.4, 99.3) **Withdrawal rate, %:** **G1:** 17.0 **G2:** 15.1 **Side effects, %:** **G1:** 60.4 **G2:** 49.1	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Lose et al., 2000 **Country and setting:** Denmark, 26 clinics in the Dept of Obstetrics & Gynaecology Outpatient Clinic **Enrollment period:** September 1994 to April 1996 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT parallel group with active control, sequential numbers **Intervention:** oestradiol-releasing vaginal ring vs. oestriol vaginal pessaries (DANUGA study) **Groups:** **G1:** 7.5 mg oestradiol per 24 h oestradiol-releasing vaginal ring x 12 wks **G2:** 1-0.5 mg oestriol vaginal pessaries per day x 3 wks followed by 1 every 2 days for 21 wks **N at enrollment:** **G1:** 134 **G2:** 117 **N at follow-up:** **G1:** 129 **G2:** 114 **Age, yrs ± SD:** **G1:** 65.6±9.5 **G2:** 66.8 ± 9.1 **Race/ethnicity:** NR **Women, N (%):** **G1:** 134 (100) **G2:** 117 (100) **Height (cm) mean ± SD:** **G1:** 164 ± 5.9 **G2:** 164 ± 6.4 **Body weight (kg) mean ± SD:** **G1:** 69.8 ± 12.7 **G2:** 68.1 ± 12.4	**Inclusion criteria:** • Women who reported at least one bothersome lower urinary tract symptom appearing at least two years after spontaneous or surgical postmenopause **Exclusion criteria:** • known or suspected oestrogen-dependent neoplasia or mammary, ovarian endometrioid) or corpus uteri malignancies • vaginal bleeding of unknown origin • clinically significant liver disease • acute or intermittent porphyria, uterovaginal prolapse of grade II or III • sex hormone treatment within the last 6 mos • previous participation in clinical trials within 3 mos prior to inclusion	**Persistence of symptoms (months), mean ± SD:** **G1:** 74 ± 88 **G2:** 80 ± 101 **Urgency %:** **G1:** 84 **G2:** 91 **Frequency %:** **G1:** 75 **G2:** 73 **Urge Incontinence %:** **G1:** 66 **G2:** 64 **Stress Incontinence %:** **G1:** 67 **G2:** 58 **Nocturia %:** **G1:** 60 **G2:** 66 **Dysuria %:** **G1:** 25 **G2:** 23 **Mucusal atrophy, n (%):** **G1:** 127 (95) **G2:** 115 (98) **Vaginal pH, mean:** **G1:** 6.0 **G2:** 6.0 **Urinary symptoms measured by VAS, mean:** **G1:** 21.1 **G2:** 23.2 **Concimitant medication n (%):** **G1:** 54 (41) **G2:** 50 (42)	**Responder rate, 24 weeks, %:** Urgency : **G1:** 51 **G2:** 56 Frequency : **G1:** 61 **G2:** 58 UUI: **G1:** 58 **G2:** 58 SUI: **G1:** 53 **G2:** 59 Nocturia: **G1:** 51 **G2:** 54 Dysuria: **G1:** 76 **G2:** 63 **G1/G2:** *P* = 0.282 Vaginal dryness: **G1:** 77 **G2:** 89 Dyspareunia: **G1:** 75 **G2:** 78	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: + Masking: - Pt selection criteria: + Loss to followup: ++ Drop-out rates: + Power calculation: + Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: - Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Lose et al., 2000 (continued)		• signs of vaginal irritation other than atrophy derived or signs of vaginal ulceration		**Symptom free rate, 24 weeks, %:** Urgency : **G1:** 27 **G2:** 33 Frequency : **G1:** 34 **G2:** 44 **G1/G2:** *P* = 0.203 UUI: **G1:** 33 **G2:** 34 SUI: **G1:** 34 **G2:** 41 Nocturia : **G1:** 31 **G2:** 35 Dysuria : **G1:** 67 **G2:** 52 **G1/G2:** *P* = 0.244 Vaginal dryness: **G1:** 57 **G2:** 83 **G1/G2:** *P* = 0.019 Dyspareunia : **G1:** 61 **G2:** 71 **Vaginal pH at 24 weeks, mean:** **G1:** 4.8 **G2:** 4.8 **Subjective judgement of administration form, %:** **Excellent:** **G1:** 60 **G2:** 14 **Good:** **G1:** 27 **G2:** 34 **Acceptable:** **G1:** 6 **G2:** 48 **Bad:** **G1:** 2 **G2:** 3	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Lose et al., 2000 (continued)				**Unacceptable:** **G1:** 3 **G2:** 2 *P* = 0.0001 **At least 1 adverse events, n (%):** 49 (19.5) difference between groups = NS **Vaginal discomfort, n :** **G1:** 6 **G2:** 13 **Leukorrhea, n :** **G1:** 7 **G2:** 7 **Vaginal itching, n:** **G1:** 1 **G2:** 4 **Breast pain, n:** **G1:** 2 **G2:** 3 **Vaginal haemorrhage, n:** **G1:** 2 **G2:** 2 **Weight increase, n:** **G1:** 2 **G2:** 3 **Breast discharge, n:** **G1:** 1 **G2:** 3 **Abdominal pain, n:** **G1:** 2 **G2:** 0 **Nausea, n:** **G1:** 2 **G2:** 0 **Headache, n:** **G1:** 1 **G2:** 1 **Pruritus, n:** **G1:** 1 **G2:** 1	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Lose et al., 2000 (continued)				**Flushing, n:** **G1:** 1 **G2:** 0 **Urinary urgency, n:** **G1:** 1 **G2:** 0 **Change in body smell, n:** **G1:** 0 **G2:** 1 **Malaise, n:** **G1:** 0 **G2:** 1 **Hypertrichosis, n:** **G1:** 0 **G2:** 1**Stranguria, n:** **G1:** 1 **G2:** 0 **Oedema, n:** **G1:** 1 **G2:** 0 **Palpitation, n:** **G1:** 1 **G2:** 0 **Increased sweating, n:** **G1:** 1 **G2:** 0 **Uterine discomfort, n:** **G1:** 0 **G2:** 1 **Amnesia, n:** **G1:** 0 **G2:** 1 **Pelvic inflammation, n:** **G1:** 1 **G2:** 0	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Macaulay et al., 1987 **Country and setting:** UK, Specialty treatment center **Enrollment period:** NR **Funding:** Wellcome Trust, trustees of St. George's Hospital **Author industry relationship disclosures:** NR	**Design:** RCT (randomization not specified) **Intervention:** Brief eclectic psychotherapy, bladder training or medication **Groups:** **G1:** psycho-therapy **G2:** bladder drill **G3:** Propan-theline **N at enrollment:** **G1:** 19 **G2:** 16 **G3:** 15 **N at follow-up:** **G1:** 18 **G2:** 15 **G3:** 14 **Women, %:** 100 **Age:** NR **Race/ethnicity:** NR **Follow-up:** 3 months	**Inclusion criteria:** • Previous completion of survey on psych conditions w/ OAB • Detrusor instability on UDS or sensory urgency **Exclusion criteria:** NR	**Detrusor instability, n:** **G1:** 10 **G2:** 8 **G3:** 8 **Sensory urgency, n:** **G1:** 9 **G2:** 8 **G3:** 7 **Voids/day, mean:** **G1:** NR **G2:** NR **G3:** 10.8 **Bladder capacity (mL), mean:** **G1:** 393 **G2:** NR **G3:** 323 **Bladder volume (mL), first sensation, mean:** **G1:** 107 **G2:** 110 **G3:** 70 **Detrusor pressure rise (cm H_2O), mean:** **G1:** NR **G2:** 45.5 **G3:** NR	**Voids/day, mean:** **G1:** NR **G2:** NR **G3:** 8.3 **G3/BL:** $P < 0.005$ **Bladder capacity (mL), mean:** **G1:** 414 **G2:** NR **G3:** 368 **G1/BL:** P = NS **G3/BL:** P = NS **Bladder volume (mL), first sensation, mean:** **G1:** 142 **G2:** 150 **G3:** 137 **G1/BL:** P = NS **G2/BL:** $P < 0.05$ **G3/BL:** $P = 0.06$ **Detrusor pressure rise (cm H_2O), mean:** **G1:** NR **G2:** 29.5 **G3:** NR **G2/BL:** $P < 0.05$	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: - Loss to followup: ++ Drop-out rates: ++ Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: -, NR Baseline OAB status: NR Baseline characteristics: - Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Malone-Lee et al., 2003 **Country and setting:** UK, Hospital **Enrollment period:** 1993-1999 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Prospective observational **Intervention:** Oxybutynin 2.5mg b.i.d. and bladder retraining **Groups:** **G1:** urinary frequency and urgency w/ detrusor instability **G2:** urinary frequency and urgency w/o detrusor instability **N at enrollment:** **G1:** 266 **G2:** 86 **N at follow-up:** Total: 347 **G1:** NR **G2:** NR **Age, mean (range):** **G1:** 54.8 (20, 90) **G2:** 51.8 (21, 88) **Race/ethnicity:** NR	**Inclusion criteria:** • Women • Age ≥ 18 • ≥ 8 voids/day **Exclusion criteria:** • Neurological disease • Significant stress incontinence • Symptomatic UTI • Interstitial cystitis	**Incontinence episodes/day, median (95% CI):** **G1:** 2 (0, 7) **G2:** 2 (0, 6.3) **Voids/day median (95% CI):** **G1:** 14 (8, 24) **G2:** 12 (8, 22)	**Incontinence episodes/day, median change (95% CI):** **G1:** 0 (2, 6) **G2:** 0 (2, 6) **G1/G2:** *P* = 0.73 **Voids/day, median change (95% CI):** **G1:** -5 (1.9-14) **G2:** -5 (1-12.3) **G1/G2:** *P* = 0.61 **Dry mouth, n (%):** **G1:** 219 (84) **G2:** 69 (70) **Constipation, n (%):** **G1:** 84 (32) **G2:** 19 (22) **Heartburn, n (%):** **G1:** 71 (27) **G2:** 20 (23) **Dry skin, n (%):** **G1:** 46 (18) **G2:** 4 (5) **G1/G2:** *P* = 0.01 **Headache, n (%):** **G1:** 25 (10) **G2:** 3 (3.5) **Dry eyes, n (%):** **G1:** 12 (5) **G2:** 1 (1)	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: ++ Drop-out rates: NR Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Mattiason et al., 2003 **Country and setting:** Sweden, Denmark, Norway (Tolterodine Scandinavian Study Group) **Enrollment period:** October 1999 to December 2000 **Funding:** Pharmacia Corp **Author industry relationship disclosures:** NR	**Design:** RCT, single-blinded (balanced blocks of 4, computerized randomization list) **Intervention:** Pharmacologic ± behavioral therapy; Tolterodine 2mg b.i.d. ± bladder training (BT); Tolterodine dosage could be decreased to 1mg po b.i.d. during the first 2 wks if intolerable SE; BT taught with a written handout **Groups:** **G1:** Tolterodine + BT x 24 wks **G2:** Tolterodine x 24 wks **N at enrollment:** Total: 505 **N at follow-up:** **G1:** 244 **G2:** 257 **N Completed treatment:** **G1:** 77% **G2:** 79% Total: 74% **Women, n (%)** **G1:** 177 (73) **G2:** 201 (78) **Age, median (range):** **G1:** 62 (19, 86) **G2:** 63 (22, 86) **Race/ethnicity:** NR **Follow-up:** 24 weeks	**Inclusion criteria:** • Age ≥ 18 • ≥ 8 voids/day and urinary urgency (± UUI) as determined by 1 wk bladder diary • With or without UUI • Women of reproductive age had to be using reliable birth control **Exclusion criteria:** • Contraindication to antimuscarinic therapy • Use of electrostimulation therapy or BT within prior 3 mo • Indwelling catheter or intermittent catheterization • Pregnancy or lactation • Use of anticholinergic agents or concomitant treatment for OAB (estrogen permitted)	**Urgency episodes/day, mean (range):** **G1:** 6.0 (0, 23.0) **G2:** 6.6 (0, 34.3) **Incontinence episodes/day, mean (range):** **G1:** 2 (0.3, 20.3) **G2:** 2.3 (0.3, 16.3) **Voids/day, mean (range):** **G1:** 10.3 (7.3, 27.6) **G2:** 10.6 (7.7, 24.6) **Duration of symptoms > 5 years, n (%):** **G1:** 120 (49) **G2:** 124 (48) **Previous drug therapy for OAB, n (%):** **G1:** 40 (160 **G2:** 35 (14) **Previous surgery affecting lower urinary tract, n (%):** **G1:** 28 (11.5) **G2:** 30 (12) **Symptoms caused at least moderate problems, %:** **G1:** 92 **G2:** 93	**Urgency episodes/day, median % change (IQR):** **G1:** -38 (-76.7, -14.1) **G2:** -38 (-68.7, -8.0) **G1/G2:** *P* = 0.75 **Incontinence episodes/day, median IQR% change; n=301:** **G1:** -87 (-100, -20) **G2:** -81 (-100, -41.8) **G1/G2:** *P* = 0.28 **Voids/day, median % change (IQR):** **G1:** -33 (-42.3, 21.3) **G2:** -25 (-38.8, -13.0) **G1/G2:** *P* < 0.001 **Voided volume (mL), median % change (IQR):** **G1:** 31.5 (13.3, 56.2) **G2:** 20 (3.1, 45.4) **G1/G2:** *P* < 0.001 **Symptoms are "minor or less", %:** **G1:** 66.5 **G2:** 61.5 **Overall improvement in symptoms, %:** **G1:** 76 **G2:** 71 **Worsening of symptoms, %:** **G1:** 3 **G2:** 5 **Dry mouth, n (%):** **G1:** 76 (31) **G2:** 90 (35)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Mattiason et al., 2003 (continued)				**Headache, n (%):** **G1:** 15 (6) **G2:** 21 (8)**Constipation, n (%):** **G1:** 7 (3) **G2:** 14 (5) **≥ 1 SE, n (%):** **G1:** 158 (65) **G2:** 177 (69) **G1/G2:** *P* = NS **Withdrawal due to, %:** AE: 15 **Withdrawal due to lack of efficacy:** 3 **Withdrawal of consent :** 2 **Protocol violations:** 1 **Completed treatment:** **G1:** 77% **G2:** 79%	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Messelink, 1999 **Country and setting:** NR **Enrollment period:** NR **Funding:** Pharmacia & Upjohn **Author industry relationship disclosures:** NR	**Design:** Compilation of findings from four Phase II and eight Phase III studies with open label follow-up; not all trials have been previously published* **Intervention:** Tolterodine 2mg b.i.d. **Groups:** **G1:** tolterodine 2mg b.i.d. previously in 4 week placebo controlled trial; continued for 12 months open label **G2:** tolterodine 2mg b.i.d. previously in 12 week placebo controlled trial continued for 9 months open label **N at enrollment:** **G1:** 135 **G2:** 121 **N at follow-up:** **G1:** 135 **G2:** 121 **Age, yrs (range):** **G1:** 60 (18, 92) **G2:** 61 (18, 88) **Race/ethnicity:** NR **Women, %:** **G1:** 68 **G2:** 76 **Parity:** NR	**Inclusion criteria:** • Participants in prior trials (details NR) • Proceeded into long term open label study **Exclusion criteria:** • NR	**Incontinence episodes/day, mean:** **G1:** 2.9 **G2:** 3.5 **Voids/day, mean:** **G1:** 10.9 **G2:** 11.4 **Voided volume (mL), mean:** **G1:** 159 **G2:** 159	**Incontinence episodes/day, 3 months, mean:** **G1:** ND **G2:** 1.4 **Incontinence episodes/day, 6 months, mean:** **G1:** 1.4 **G2:** ND **Incontinence episodes/day, 9 months, mean:** **G1:** ND **G2:** 1.5 **Incontinence episodes/day, 12 months, mean:** **G1:** 1.6 **G2:** ND **Voids/day, 3 months, mean:** **G1:** ND **G2:** 8.8 **Voids/day, 6 months, mean:** **G1:** 8.6 **G2:** ND **Voids/day, 9 months, mean:** **G1:** ND **G2:** 8.9 **Voids/day, 12 months, mean:** **G1:** 8.6 **G2:** ND **Voided volume (mL), 3 months, mean:** **G1:** ND **G2:** 201 **Voided volume, (mL), 6 months, mean:** **G1:** 193 **G2:** ND	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: + Loss to followup: NR Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Messelink, 1999 (continued)				**Voided volume (mL), 9 months, mean:** **G1:** ND **G2:** 199 **Voided volume (mL), 12 months, mean:** **G1:** 190 **G2:** ND	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Michel et al., 2002 **Country and setting:** Germany, Community **Enrollment period:** NR 12 week follow up **Funding:** Pharmacia GmbH **Author industry relationship disclosures:** 1 of 4 Pharmacia(1) Sanofi-Synthelabo(1)	**Design:** Open-label observational post-marketing surveillance **Intervention:** Tolterodine **Groups:** Tolterodine Median dose: 2 mg daily **Dose (mg), mean ± SD:** 3.81 ± 1.16 **N at enrollment:** 2,250 **N at follow-up:** 1,979 **Women, n (%):** 1,730 (76.9) **Age, mean ± SD:** 61.1 ± 13.8 **Race/ethnicity:** NR **BMI, kg/m^2 ± SD:** 73.2 ± 11.3	**Inclusion criteria:** • Physician medical judgement **Exclusion criteria:** NR	**Urgency episodes/day, mean ± SD:** 8.4 ± 5.1 **Incontinence episodes/day, mean ± SD:** 3.4 ± 4.2 **Voids/day, mean ± SD:** 12.4 ± 4.3	**Urgency episodes/day, mean ± SD:** 2.0 ± 3.0 *P* = NR **Incontinence episodes/day, mean ± SD:** 0.8 ± 2.0 *P* = NR **Voids/day, mean ± SD:** 7.7 ± 2.7 *P* = NR **Urgency, successful treatment, OR (95% CI):** Gender, M/F: 0.764 (0.583, 1.001) *P* = 0.0508 Age, years: 0.981 (0.973, 0.990) *P* < 0.001 Frequency, BL episodes/day: 1.038 (0.997- 1.080) *P* = 0.0724 Urgency, BL episodes/day: 0.851 (0.823, 0.880) *P* < 0.001 Incontinence, BL episodes/day: 0.979 (0.950, 1.000) *P* = 0.1735 Tolterodine dose, mg/day: 0.913 (0.830, 1.005) *P* = 0.0623	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: - Loss to followup: + Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Michel et al., 2002 (continued)				**Incontinence, successful treatment, OR (95% CI):** Gender, M/F: 1.453 (1.062, 1.990) *P* = 0.0196 Age, years: 0.978 (0.968, 0.987) *P* < 0.001 Frequency, BL episodes/day: 1.034 (0.993, 1.076) *P* = 0.1036 Urgency, BL episodes/day: 1.053 (1.018, 1.088) *P* = 0.0027 Incontinence, BL baseline episodes/day: 0.744 (0.716, 0.774) *P* < 0.001 Tolterodine dose, mg/day: 0.866 (0.784, 0.956) *P* = 0.0043	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Michel et al., 2002 (continued)				**Frequency, successful treatment, OR (95% CI):** Gender, M/F: 0.745 (0.552, 1.004) *P* = 0.0532 Age, years: 0.981 (0.971, 0.991) *P* = 0.001 Frequency, BL episodes/day: 0.735 (0.701, 0.771) *P* < 0.001 Urgency, BL episodes/day: 1.008 (0.975, 1.041) *P* = 0.6526 Incontinence, BL episodes/day: 0.969 (0.937, 1.002) *P* = 0.0644 Tolterodine dose, mg/day: 1.070 (0.957, 1.196) *P* = 0.2335	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Michel et al., 2002 (continued)				**Effect on Global efficacy, OR (95% CI):** Gender, M/F: 0.656 (0.526, 0.818) *P* = 0.0002 Age, years: 0.986 (0.980, 0.993) *P* < 0.001 Frequency, BL epsidoes/day: 1.002 (0.972, 1.033) *P* = 0.8896 Urgency, BL episodes/day: 1.009 (0.984, 1.033) *P* = 0.4906 Incontinence, BL episodes/day: 0.963 (0.939, 0.987) *P* < 0.0026Tolterodine dose, mg/day: 1.000 (0.926, 1.080) *P* = 0.9971	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Michel et al., 2002 (continued)				**Effect on global tolerability of Tolterodine, OR (95% CI):** Gender, M/F: 0.993 (0.790, 1.249) *P* = 0.9519 Age, years: 0.995 (0.988, 1.002) *P* = 0.1915 Frequency, BL episodes/day: 1.002 (0.971, 1.034) *P* = 0.8995 Urgency, BL episodes/day: 1.022 (0.997, 1.048) *P* = 0.08 Incontinence, BL episodes/day: 0.990 (0.965, 1.016) *P* < 0.459 Tolterodine dose, mg/day: 1.114 (1.028, 1.206) *P* = 0.008589	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Michel et al., 2007* Michel et al., 2005 **Country and setting:** Germany, NR **Enrollment period:** November 2001 to June 2003 **Funding:** Pharmacia (became Pfizer before publication) **Author industry relationship disclosures:** 5 of 5* 4SC (1) Astellas (1) Boehringer Ingelheim (2) Eli Lilly (2) Pfizer (4) Theravance (1) Anformed (1)	**Design:** Retrospective cohort, open label **Intervention:** Tolterodine ER **Groups:** **G1:** Incontinent **G2:** Continent **N at enrollment:** Total: 3,824 **G1:** 2,571 **G2:** 1,253 **N at follow-up:** Total: 3,416 **Women, %:** Total: 75.8 **G1:** 81.7 **G2:** 62.6 *P* < 0.001 **Age, mean ± SD:** Total: 64.8 ± 13.3 **G1:** 66.3 ± 12.6 **G2:** 61.4 ± 14.1 *P* < 0.001 **Race/ethnicity:** NR **Follow-up:** 9 months	**Inclusion criteria:** NR **Exclusion criteria:** NR	**Urgency episodes/day, mean ± SD:** Total: 7.9 ± 5.2 **G1:** 8.0 ± 5.2 **G2:** 7.7 ± 5.2 *P* = 0.1937 **Incontinence episodes/day, mean ± SD:** **G1:** 4.8 ± 3.7 **G2:** NA **Voids/day, mean ± SD:** Total: 14.0 ± 4.6 **G1:** 14.1 ± 4.6 **G2:** 13.5 ± 4.4 *P* < 0.001 **Daytime voids/ day, mean ± SD:** Total: 10.7 ± 3.7 **G1:** 10.8 ± 3.7 **G2:** 10.4 ± 3.4 *P* = 0.0128 **Frequency ≥ 8 voids/day, %:** **G1:** 95.7 **G2:** 95.2 **Nocturia episodes/day, mean ± SD:** Total: 3.4 ± 1.7 **G1:** 3.5 ± 1.8 **G2:** 3.2 ± 1.6 *P* < 0.001 **Pad use/day, mean ± SD:** **G1:** 3.4 ± 2.8 **G2:** 0.1 ± 0.6 *P* < 0.001 **Duration of symptoms (mos), mean ± SD:** **G1:** 50 ± 53 **G2:** 40 ± 46 *P* < 0.001	**Incontinence episodes/day, mean change ± SD:** **G1:** -3.8 ± 3.5 **G2:** NA **Urgency episodes/day, mean ± SD:** Total: 1.6 ± 2.8 **No urgency, %:** **G1:** 53.4 **G2:** 63.2 **Voids/day, mean ± SD:** Total: 7.5 ± 3.0 **Daytime voids/ day, mean ± SD:** Total: 6.2 ± 2.3 **Frequency ≥ 8 voids/day, %:** **G1:** 43.7 **G2:** 39.1 **Nocturia episodes/day, mean ± SD:** Total: 1.4 ± 1.1 **Pad use/day, mean change ± SD:** **G1:** -2.4 ± 2.5 **Limitation of daily activities, score change ± SD:** **G1:** 4.49 ± 2.65 **G2:** 4.10 ± 2.51 **Limitations in daily life caused by bladder prob-lems, score ± SD:** **G1:** 7.59 ± 1.65 **G2:** 6.66 ± 1.69 *P* < 0.001 **Total adverse events, n (%):** Total: 496 (13.0) **Dry mouth, n (%):** 299 (7.8)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: - Loss to followup: NR Drop-out rates: NA Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Michel et al., 2007* Michel et al., 2005 (continued)			**Previous treatment, %:** **G1:** 50.8 **G2:** 44.8 *P* = 0.0007	**Withdrew:** 11% **Unable to tolerate medication:** 2.8% **Administrative reasons:** 2.6% **Lack of efficacy :** 2.4% **Patient request:** 1.2%	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Michel et al,, 2008 **Country and setting:** Germany, 50% of office-based urologists **Enrollment period:** September 2004 to November 2005 **Funding:** Astellas Pharma GmbH **Author industry relationship disclosures:** 3 of 4 Astellas (3) Bayer (1) Boehringer (1) Elbion (1) Eli Lilly (1) Pfizer (1)	**Design:** Case series **Intervention:** Solifenacin 5-10 mg qd x 12 wks (initial dose could be adjusted at first and second follow-up visits) **Groups:** NA **N at enrollment:** 4,450 **N at follow-up:** 4,146 **Age, mean ± SD:** 63.6 ± 13.1 **Weight (kg), mean ± SD:** 75.5 ± 12.3 **Height (cm), mean ± SD:** 167 ± 7 **Race/ethnicity:** "the vast majority of OAB patients in Germany are Caucasian" **Women, %:** 83.5 **Follow-up:** 12 weeks	**Inclusion criteria:** • Age ≥ 18 **Exclusion criteria:** NR	**Duration of OAB (years), mean ± SD:** 2.9 ± 3.7 **Duration of OAB (years), median (range):** 1.5 (0-34.6) **Previous OAB drug treatment, %:** Herbal drugs: 28 Oxybutynin: 23 Trospium chloride: 20 Tolterodine: 13 Topical estrogens: 12 No treatment: 30 **Previous non-pharma OAB treatment, %:** Absorbent products: 51 Pelvic floor exercises: 41 Bladder training: 22 No treatment: 30 **Initial solifenacin dose, %:** 5 mg: 93.4 10 mg: 6.1 **Final solifenacin dose, %:** 5 mg: 78.7 10 mg: 20.8 **Heart rate (beats/min), mean ± SD:** 75.2 ± 8.2 **Blood pressure (mm Hg), mean ± SD:** 137 ± 15 / 82 ± 7	**Mult regression analysis of the presence of trt-emergent AEs, OR (95% CI):** Male sex: 0.840 (0.559,1.265) *P* = 0.4042 Age: NA *P* = 0.0019 Age 41-50: 1.144 (0.363, 3.608) *P* = 0.8180 Age 51-60: 1.773 (0.614, 5.119) *P* = 0.2900 Age 61-70: 1.941 (0.682, 5.524) *P* = 0.2137 Age 71-80: 1.816 (0.627, 5.262) *P* = 0.2715 Age > 80: 3.902 (1.327, 11.472) *P* = 0.0133 BMI (kg/m^2): NA *P* = 0.9052 Comedication present: 1.768 (1.219, 2.564) *P* = 0.0027 CHD/MI present: 0.997 (0.667, 1.491) *P* = 0.9892 CHF present: 1.243 (0.774, 1.997) *P* = 0.3684 Diabetes mellitus present: 1.083 (0.762, 1.541) *P* = 0.6557 **Heart rate (beats/ min), mean ± SD:** 74.5 ± 7.6 **Blood pressure (mm Hg), mean ± SD:** 134 ± 13 / 81 ± 8 **Treatment-emergent AEs, n (%):** 215 (4.8)	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: NA Method and blinding: NA Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: NR Baseline characteristics: + Length of followup: ++ Measurement methods: + Measurement reliability: - Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Michel et al., 2008 (continued)				**Leukocyturia, n (%):** 48 (1.1) **Dry mouth, n (%):** 31 (0.7) **Haematuria, n (%):** 26 (0.6) **Constipation, n (%):** 20 (0.4) **Proteinuria, n (%):** 17 (0.4) **UTI, n (%):** 15 (0.3) **Nausea, n (%):** 14 (0.3) **Nitrate present in urine, n (%):** 13 (0.3) **Bacteriuria, n (%):** 9 (0.2) **Glycosuria, n (%):** 7 (0.2) **Discontinued dt AEs, n (%):** 62 (1.4)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Millard et al., 1999 **Country and setting:** Australia & US, Academic medical centers **Enrollment period:** NR **Funding:** Pharmacia and Upjohn AB **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Tolterodine 1 mg vs. tolterodine 2 mg vs. placebo **Groups:** **G1:** tolterodine 1 mg x 12 wks **G2:** tolterodine 2 mg x 12 wks **G3:** placebo x 12 wks **N at enrollment:** **G1:** 129 **G2:** 123 **G3:** 64 **N at follow-up:** **G1:** 114 **G2:** 116 **G3:** 61 **Women, %:** **G1:** 78 **G2:** 77 **G3:** 66 **Age, mean (range):** **G1:** 60.1 (24-89) **G2:** 60.2 (24-83) **G2:** 60.5 (25-84) **BMI, kg/m^2 (range):** **G1:** 28.0 (17.2-47.2) **G2:** 27.3 (16.6-51.4) **G2:** 26.8 (19.9-47.1)	**Inclusion criteria:** • Age ≥ 18 • Cystometrically proved DO • Average urinary frequency ≥8 voids/day • UI (≥ 1 incontinence episodes/day) and/or urinary urgency • Adequate contraception **Exclusion criteria:** • SUI • Voiding difficulty (max flow rate < 10 mL/second with post-void residual volume > 200 mL) • Recurrent UTI • Interstitial cystitis • Hematuria • Bladder cancer • Intermittent catheterization or indwelling catheter • Hepatic or renal disease • Narrow angle glaucoma • Electro-stimulation for bladder training • Started primarily anticholinergic drug ≤ 14 days • Unstable dose of any treatment with anticholinergic side effects • Average total voided volume >3 L/24 h	**Urgency, %:** **G1:** 100 **G2:** 100 **G3:** 98 **Incontinence, %:** **G1:** 88 **G2:** 90 **G3:** 86 **Incontinence episodes/day, mean ± SD:** **G1:** 3.9 ± 4.0 **G2:** 3.6 ± 4.0 **G3:** 3.5 ± 3.2 **Incontinence episodes/day, mean (range):** **G1:** 3.9 (0.1-24.0) **G2:** 3.6 (0.3-24.0) **G3:** 3.5 (0.1-18.4) **≥ 8 voids/day, %:** **G1:** 99 **G2:** 98 **G3:** 98 **Voids/day, mean ± SD:** **G1:** 11.5 ± 3.7 **G2:** 11.2 ± 3.1 **G3:** 11.3 ± 3.4 **Voids/day, mean (range):** **G1:** 11.5 (7.0-26.3) **G2:** 11.2 (6.3-22.0) **G3:** 11.3 (7.1-21.7) **Duration of symptoms > 5 yrs, %:** **G1:** 44 **G2:** 49 **G3:** 47 **Detrusor instability, %:** **G1:** 87 **G2:** 88 **G3:** 91	**Incontinence episodes/day, mean change ± SD (mean % change):** **G1:** -1.7 ± 2.8 (-43) **G2:** -1.7 ± 2.5 (-50) **G3:** -1.3 ± 2.5 **G1/G3:** *P* = 0.27 **G2/G3:** *P* < 0.19 **Voids/day, mean change ± SD:** **G1:** -2.3 ± 3.0 (-20) **G2:** -2.3 ± 2.1 (-25) **G3:** -1.4 ± 2.3 **G1/G3:** *P* = 0.0029 **G2/G3:** *P* = 0.045 **Patients achieving normalized voiding frequency, %:** **G1:** 26 **G2:** 43 **G3:** 26 **G2/G3:** *P* = 0.012 **G2/G1:** *P* = 0.022 **Complete cure, %:** **G1:** 19 **G2:** 11 **G3:** 10 **Compliance (12 of 14 wks), %:** **G1:** 87 **G2:** 89 **Perceived improvement, %:** **G1:** 41 **G2:** 59 **G3:** 38 **G2/G3:** *P* = 0.015 **G2/G1:** *P* = 0.018	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: + Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Millard et al., 1999 (continued)		• Treatment with any investigational drug during or 2 mos before study	**Hyper reflexia, %:** **G1:** 13 **G2:** 12 **G3:** 9 **Severe problems, patient perception, %:** **G1:** 42 **G2:** 50 **G3:** 36 **Previous therapy for UI, %:** **G1:** 50 **G2:** 47 **G3:** 48 **Previous therapy for UI, good efficacy response, %:** **G1:** 39 **G2:** 48 **G3:** 45 **Previous lower urinary tract surgery, %:** **G1:** 35 **G2:** 33 **G3:** 30 **Voided volume (mL), mean ± SD:** **G1:** 151 ± 56 **G2:** 155 ± 52 **G3:** 158 ± 53 **Voided volume (mL), mean (range):** **G1:** 151 (34-334) **G2:** 155 (32-304) **G3:** 158 (47-299) **Bladder volume (mL), initial contraction, mean (range):** **G1:** 167 (4-600) **G2:** 188 (7-520) **G3:** 212 (6-600)	**Voided volume (mL), mean change ± SD:** **G1:** 27 ± 41 **G2:** 36 ± 50 **G3:** 10 ± 47 **G1/G3:** *P* = 0.0059 **G2/G3:** *P* < 0.0001 **Minor noncholinergic and cholinergic AEs, %:** **G1:** 74 **G2:** 73 **G3:** 78 **AEs per patient, mean:** **G1:** 1.9 **G2:** 2.2 **G3:** 2.0 **Autonomic nervous system disorders, %:** **G1:** 29 **G2:** 43 **G3:** 17 **Dry mouth, %:** **G1:** 24 **G2:** 39 **G3:** 13 **Dry mouth, severe, %:** **G1:** 1 **G2:** 2 **G3:** 2 **Dry eyes, %:** **G1:** 2 **G2:** 6 **G3:** 2 **Serious AEs, n (%):** **G1:** 5 (4) **G2:** 7 (5) **G3:** 5 (4) **G3:** 2	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Millard et al., 1999 (continued)			**Post voiding residual volume (mL), mean (range):** **G1:** 28 (0-180) **G2:** 25 (0-178) **G3:** 33 (0-200) **Max flow rate, (mL/sec), mean (range):** **G1:** 18 (2-56) **G2:** 20 (3-70) **G3:** 19 (5-57) **Detrusor overactivity ≥ 10 cm, %:** **G1:** 98 **G2:** 98 **G3:** 98 **Max wave height (cm), mean (range):** **G1:** 44 (2-144) **G2:** 45 (2-165) **G3:** 52 (4-188)	**Severe AEs possibly indicating cardiac dysfunction, %:** **G1:** 0 **G2:** 2 **Nonserious cardiac AEs, %:** **G1:** 3 **G2:** 3 **G3:** 6 **Discontinued due to AEs, n (%):** **G1:** 2 (2) **G2:** 8 (6) **G3:** 0	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Millard, 2004 **Country and setting:** International, Multicenter study, 54 sites **Enrollment period:** NR **Funding:** Pharmacia Corp **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Tolterodine ± simplified pelvic-floor exercise regimen for 24 weeks **Groups:** **G1:** tolterodine 2 mg b.i.d. and simple pelvic floor muscle exercise (PFME) program **G2:** tolterodine 2 mg b.i.d. daily **N at enrollment:** **G1:** 227 **G2:** 253 **N at follow-up, 12 weeks, n (%):** **G1:** 181 (79.7) **G2:** 205 (81.0) **N at follow-up, 24 weeks, n (%):** **G1:** 164 (72.2) **G2:** 190 (75.1) **Women, n (%):** **G1:** 169 (75.4) **G2:** 190 (75.4) **Age, mean ± SD:** **G1:** 53.6 ± 16.9 **G2:** 53.2 ± 17.4 **Race/ethnicity:** **Asian:** **G1:** 176 (78.6) **G2:** 203 (80.6) **White/mixed:** **G1:** 48 (21.4) **G2:** 49 (19.4)	**Inclusion criteria:** • Age 18-90 • ≥ 8 voids/day • Urgency • ≥ 1 UI episode/d • sx for ≥ 6 months **Exclusion criteria:** • Symptomatic SI • Significant PVR volume • Neuropathy • Glaucoma • UTI • + urine cytology • Use of concomitant anticholinergic therapy w/in 14 days of randomization	**Urgency episodes/day, mean ± SD:** **G1:** 4.2 ± 3.6 **G2:** 4.1 ± 4.0 **Urgency episodes/day, median (IQR):** **G1:** 3.6 (1.3-6.0) **G2:** 3.0 (1.3-6.0) **Incontinence episodes/day, mean ± SD:** **G1:** 3.44 ± 3.4 **G2:** 3.21 ± 3.4 **Incontinence episodes/day, median (IQR):** **G1:** 2.3 (1.3-4.0) **G2:** 2.9 (1.3-3.7) **Voids/day, mean ± SD:** **G1:** 11.87 ± 4.3 **G2:** 12.78 ± 5.6 **Voids/day, median (IQR):** **G1:** 10.7 (9.0-13.7) **G2:** 11.3 (9.0-15.0) **Voided volume (mL), mean ± SD:** **G1:** 146.1 ± 67.7 **G2:** 146.0 ± 83.3 **Voided volume (mL), median (IQR):** **G1:** 137 (98-186) **G2:** 132 (99-189) **Duration of symptoms, n (%):** ≤ 5 years: **G1:** 166 (74.1) **G2:** 173 (68.7) > 5 years: **G1:** 56 (25) **G2:** 78 (31)	**Urgency episodes/day, wk 12, mean change ± SD (% change):** **G1:** -1.9 ± 4.0 (-64.5) **G2:** -2.2 ± 3.6 (-69.8) **G1/BL:** *P* = 0.001 **G1/BL:** *P* = 0.001 **G1/G2:** *P* = NS **Urgency episodes/day, wk 12, median change:** **G1:** -1.6 **G2:** -1.3 **G1/G2:** *P* = 0.7658 **Urgency episodes/day, wk 24, mean change ± SD (% change):** **G1:** -2.2 ± 3.6 (-78.7) **G2:** -2.7 ± 3.5 (-83) **G1/BL:** *P* = 0.001 **G1/BL:** *P* = 0.001 **G1/G2:** *P* = NS **Urgency episodes/day, wk 24, median change:** **G1:** -1.9 **G2:** -2.0 **G1/G2:** *P* = 0.3029 **Incontinence episodes/day, wk 12, mean change ± SD:** **G1:** -2.15 ± 3.0 **G2:** -2.15 ± 2.7 **G1/BL:** *P* = 0.001 **G1/BL:** *P* = 0.001 **G1/G2:** *P* = 0.2215	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: + Loss to followup: ++ Drop-out rates: - Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Millard, 2004 (continued)			**Previous UT surgery, n (%):** **G1:** 44 (19.6) **G2:** 43 (17.1) **Prev antichol-inergics, n (%):** **G1:** 19 (8.5) **G2:** 14 (5.6) **Prev UUI drug, n (%):** **G1:** 101 (45.1) **G2:** 91 (36.1) **Patient sub-jective rating of UI symptoms as "severe" or "many severe", %:** **G1:** 54.0 **G2:** 56.8	**Incontinence episodes/day, wk 12, median change:** **G1:** -1.6 **G2:** -1.6 **G1/G2:** *P* = 0.8251 **Incontinence episodes/day, wk 24, mean change ± SD (% change):** **G1:** -2.23 ± 3.0 (-64) **G2:** -2.26 ± 3.0 (-70) **G1/BL:** *P* = 0.001 **G1/BL:** *P* = 0.001 **G1/G2:** *P* = NS **Incontinence episodes/day, wk 24, median change:** **G1:** -1.6 **G2:** -1.6 **G1/G2:** *P* = 0.8341 **Voids/day, wk 12, mean change ± SD (% change):** **G1:** -2.68 ± 3.8 (-22) **G2:** -3.42 ± 4.6 (-26) **G1/BL:** *P* = 0.001 **G1/BL:** *P* = 0.001 **G1/G2:** *P* = 0.9478 **Voids/day, wk 24, mean change ± SD (% change):** **G1:** -2.58 ± 5.0 (-22) **G2:** -3.58 ± 5.2 (-26) **G1/BL:** *P* = 0.001 **G1/BL:** *P* = 0.001 **G1/G2:** *P* = 0.3549	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Millard, 2004 (continued)				**Voided volume (mL), wk 12, median change (% change):** **G1:** 20.4 (17.2) **G2:** 17.5 (15.8) **Voided volume (mL), wk 12, median change (% change):** **G1:** 21.1 (18.1) **G2:** 19.1 (15.4) **Patient subjective report of improvement in bladder condition, wk 12, %:** **G1:** 82.6 **G2:** 83.9 **Patient subjective report of improvement in bladder condition, wk 24, %:** **G1:** 81.7 **G2:** 85.9 **Adverse events, n (%):** **G1:** 22 (9.7) **G2:** 23 (9.1) **Mild dry mouth, %:** **G1:** 18.1 **G2:** 21.3 **Moderate dry mouth, %:** **G1:** 7.5 **G2:** 5.1 **Severe dry mouth, %:** **G1:** 4.0 **G2:** 3.2 **Headache, %:** 6 **Constipation, %:** 4.8 **Nausea, %:** 2.7	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Millard, 2004 (continued)				**Dry eyes, %:** 2.5 **Dizziness, %:** 2.4	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Minassian et al., 2007 **Country and setting:** Canada, Tertiary care center **Enrollment period:** February 2003 to December 2005 **Funding:** Janssen-Ortho Inc. **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Oxybutynin XL vs oxybutynin IR **Groups:** **G1:** oxybutynin XL 5 mg qd after 4 weeks non responders to oxybutynin XL 10 mg qd **G2:** oxybutynin IR 2.5 mg t.i.d. after 4 weeks non responders to oxybutynin 5 mg t.i.d. **N at enrollment:** **G1:** 39 **G2:** 33 **N at follow-up:** **G1:** 35 **G2:** 27 **Age, mean ± SD:** **G1:** 75 ± 6 **G2:** 73 ± 5 **Women, %:** **G1:** 100 **G2:** 100 **Race/ethnicity:** NR **Height, cm ± SD:** **G1:** 158 ± 6 **G2:** 159 ± 5 **Weight, kg ± SD:** **G1:** 73 ± 14 **G2:** 76 ± 14 **BMI, kg/m^2 ± SD:** **G1:** 29 ± 5 **G2:** 30 ± 5 **Parous, %:** **G1:** 85 **G2:** 88	**Inclusion criteria:** • Symptoms of OAB (ICS) • Female • Age > 65 • Community-dwelling • OAB main presenting symptom, 2-week washout if on anticholinergic medication **Exclusion criteria:** • Bedridden • Permanent indwelling catheter • MMSE score <24 • Glaucoma • Gastric retention or bowel obstruction • History of allergy to anticholinergic medications • Taking tricyclic antidepressants or anticho-linesterase inhibitors • Post-void residual bladder volume >100 mL • History of neurologic disorder	**UUI, %:** **G1:** 95 **G2:** 94 **SUI, %:** **G1:** 67 **G2:** 52 **Urgency, %:** **G1:** 100 **G2:** 97 **Incontinence episodes/day, median (IQR):** **G1:** 2 (0, 4) **G2:** 1 (0, 3) **Frequency episodes/day, median (IQR):** **G1:** 9 (7, 11) **G2:** 10 (8, 12) **Voids/day, median (IQR):** **G1:** 13 (10, 16) **G2:** 14 (11, 16) **Nocturia episodes/day, median (IQR):** **G1:** 2 (2, 3) **G2:** 3 (2, 4) **Pads/day, median (IQR):** **G1:** 1 (0, 3) **G2:** 1 (0, 3) **Mini-mental state exam, median score (IQR):** **G1:** 29 (29, 30) **G2:** 30 (28, 30) **U-IIQ, activities score ± SD:** **G1:** 2.7 ± 0.9 **G2:** 3.1 ± 1.1 **U-IIQ, travel score ± SD:** **G1:** 2.4 ± 1.3 **G2:** 2.8 ± 1.6	**Incontinence episodes/day, 12 wks, median (IQR):** **G1:** 1 (0, 2) **G2:** 0 (0, 1) *P* = 0.05 **Frequency episodes/day, wk 1-12, median change (IQR):** **G1:** -1.4 (-3.3, 0.4) **G2:** -1.3 (-4.1, 0.3) *P* = 0.65 **Voids/day, wk 12, median (IQR):** **G1:** 11 (9, 13) **G2:** 11 (9, 14) *P* = 0.35 **Pads/day, 12 wks, median (IQR):** **G1:** 0 (0, 2) **G2:** 0 (0, 1) *P* = 0.53 **U-IIQ, activities score ± SD:** **G1:** 2.2 ± 1.0 **G2:** 2.1 ± 1.2 *P* = 0.73 **U-IIQ, travel score ± SD:** **G1:** 2.0 ± 1.1 **G2:** 1.9 ± 1.2 *P* = 0.79 **U-IIQ, physical activities score ± SD:** **G1:** 2.3 ± 1.3 **G2:** 1.9 ± 1.2 *P* = 0.45 **U-IIQ, feelings score ± SD:** **G1:** 2.0 ± 1.1 **G2:** 1.9 ± 1.3 **U-IIQ, relationships score ± SD:** **G1:** 1.4 ± 0.9 **G2:** 1.5 ± 1.0	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Minassian et al., 2007 (continued)			**U-IIQ, physical activities score ± SD:** **G1:** 2.4 ± 1.2 **G2:** 2.6 ± 1.5 **U-IIQ, feelings score ± SD:** **G1:** 2.5 ± 1.2 **G2:** 2.7 ± 1.5 **U-IIQ, relationships score ± SD:** **G1:** 1.7 ± 0.6 **G2:** 2.0 ± 1.4 **U-UDI, mean score ± SD:** **G1:** 2.9 ± 0.6 **G2:** 2.7 ± 0.8 **Voided volume (mL), median (IQR):** **G1:** 142 (109, 192) **G2:** 138 (108, 165) **Postvoid residual volume (mL), median (IQR):** **G1:** 0 (0, 23) **G2:** 0 (0, 22) **Urine culture positive, %** **G1:** 8 **G2:** 9 **Previous prolapse/ incontinence surgery, %:** **G1:** 13 **G2:** 49 **Positive cough test, lying, %:** **G1:** 26 **G2:** 15	**U-UDI, mean score ± SD:** **G1:** 2.1 ± 1.0 **G2:** 1.7 ± 1.0 *P* = 0.10 **Voided volume (mL), 12 wks, median (IQR):** **G1:** 164 (129, 187) **G2:** 161 (114, 109) *P* = 0.78 **Postvoid residual volume (mL), 12 wks, median (IQR):** **G1:** 0 (0, 29) **G2:** 4 (0, 87) *P* = 0.33 **Remained on med, 12 wks, %:** **G1:** 70 **G2:** 61 *P* = 0.42 **Experienced side effects, %:** **G1:** 51 **G2:** 57 **Dry mouth, n:** **G1:** 14 **G2:** 16 **Gastro-intestinal, n:** **G1:** 6 **G2:** 2	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Minassian et al., 2007 (continued)			**Positive cough test, standing, %:** **G1:** 33 **G2:** 15		

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Molander et al., 1991 **Country and setting:** Sweden, Academic hospital **Enrollment period:** NA **Funding:** Goteborg Medical Society, University of Goteborg **Author industry relationship disclosures:** NR	**Design:** Case series **Intervention:** 3mg estriol qd for 1 mo, then 1-2 mg estriol qd for 2 mos **Groups:** **G1:** Intervention among SUI **G2:** Intervention among UUI **G3:** Intervention among MUI **N at enrollment:** **G1:** 91 **G2:** 113 **G3:** 142 **N at follow-up:** **G1:** 55 **G2:** 69 **G3:** 82 **Women, %:** 100 **Age, mean (SE):** **G1:** 70.1 (1.9) **G2:** 73.5 (1.2) **G3:** 72.6 (1.3) **Race/ethnicity:** NR **Parity, mean (SE):** **G1:** 2.0 (0.2) **G2:** 1.7 (0.1) **G3:** 1.9 (0.1) **Menopausal age, mean (SE):** **G1:** 49.6 (0.4) **G2:** 49.1 (0.4) **G3:** 48.8 (0.5)	**Inclusion criteria:** • Self-reported UI (with UUI defined as involuntary urine loss preceded by the urge to void or uncontrollable voiding with little or no warning; SUI definded as involuntary urinary loss precipitated by coughing, sneezing, or physical exertion; and MUI defined as a combination of UUI+SUI) **Exclusion criteria:** NR	**Total leakage/48 hours (mL), mean (SEM):** **G1:** 25.2 (6.1) **G2:** 44.4 (9.8) **G3:** 65.1 (11.5) **Max single leakage/48 hours, mean (SE):** **G1:** 14.0 (3.1) **G2:** 21.7 (3.6) **G3:** 31.5 (3.1) **Voids/day, mean (SE):** **G1:** 6.9 (0.3) **G2:** 8.4 (0.3) **G3:** 7.6 (0.3) **Total voided volume/day (mL), mean (SE):** **G1:** 1405 (68) **G2:** 1515 (71) **G3:** 1497 (68) **Max voided volume (mL)/day, mean (SE):** **G1:** 401 (22) **G2:** 396 (23) **G3:** 383 (18)	**Total leakage/48 hours (mL), mean (SEM):** **G1:** 19.7+/-6.1 **G2:** 37.3+/-11.9 **G3:** 26.2+/-6.8 **G3/BL:** $P < 0.01$ **Max single leakage/48 hours, mean (SE):** **G1:** 11.3 (3.1) **G2:** 19.2 (4.6) **G3:** 16.1 (4.2) **G3/BL:** $P < 0.05$ **Voids/day, mean (SE):** **G1:** 7.1 (0.4) **G2:** 7.9 (0.4) **G3:** 7.4 (0.4) **G2/BL:** $P < 0.05$ **Total voided volume/day (mL), mean (SE):** **G1:** 1539 (67) **G2:** 1481 (74) **G3:** 1483 (88) **Max voided volume (mL)/day, mean (SE):** **G1:** 438 (24) **G2:** 399 (27) **G3:** 392 (26)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: + Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Moore et al., 1990 Moore and Sutherst, 1990* **Country and setting:** UK, academic health center **Enrollment period:** NR **Funding:** Tillots Laboratories NR* **Author industry relationship disclosures:** NR	**Design:** RCT with crossover **Intervention:** oxybutynin hydrochloride vs placebo **Groups:** **G1:**oxybutynin hydrochloride 3 mg t.i.d. **G2:**placebo **N at enrollment:** 53 **N at follow-up:** **G1:** 27 **G2:** 22 **Age, mean ± SD:** **G1:** 46.0 ± 11.7 **G2:** 46.4 ± 12.4 **Race/ethnicity:** NR **Parity, mean:** **G1:** 2.3 **G2:** 2.2	**Inclusion criteria:** • UDS-defined idiopathic detrusor instability • Involuntary detrusor contractions > 30 cm H2O during filling phase of cystometry **Exclusion criteria:** • Neurological disorder • Urologic disorder • Age > 75 years • Genuine SI • Low-compliance bladder • Bacterial or interstitial cystitis • Previous treatment with oxybutynin	**Voids/day, mean ± SD:** **G1:** 11.1 ± 7.9 **G2:** 12.1 ± 5.7 **Volume at first desire to void mean mL ± SD:** **G1:** 94.2 ± 66 **G2:** 107.4 ± 101 **Max detrusor filling pressure mean cm H2O, ±SD:** **G1:** 55.3 ± 23 **G2:** 59.2 ± 26 **Max cystometric capacity (mL)** **G1:** 275 ± 164 **G2:** 290 ± 168 **Residual urine volume mean mL ± SD:** **G1:** 23.1 ± 34.2 **G2:** 22.7 ± 34.0 **Duration of OAB, mean yrs ± SD):** **G1:** 7.5 ± 7.9 **G2:** 8.9 ± 9.0	**Change in volume at first desire to void, period 1, mean mL ± SD (95% CI)** **G1:** 70.0 ± 103 **G2:** 7.7 ± 76 **G1/G2:** *P* = 0.02 95% CI: (10, 113) **Change in maximum detrusor filling pressure, mean ± SD:** **G1:**-16.9 ± 19.5 **G2:**1.0 ± 28.7 **G1/G2:** *P* = 0.02 95% CI: (-32.5, -3.2) **Change in maximum cystometric capacity, mean ± SD:** **G1:**104.0 ± 131 **G2:**7.0 ± 103 **G1/G2:** *P* = 0.006 95% CI: (29, 165) **Change in residual urine Volume, period 1:** **G1:** 22.4 (79.3) **G2:** 7.7 (45.7) *P* = 0.42 **Change in residual urine Volume, period 2:** **G1:** 10.0 ± 27.1 **G2:** 25.7 ± 55.6 *P* = 0.33 **Dry mouth on oxybutynin, %:** 88 **Dry mouth on placebo, %:** 33 **Mouth ulcers on oxybutynin, %:** 16	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Moore et al., 1990 Moore and Sutherst, 1990 (continued)				**Mouth ulcers on placebo, %:** 0 **Constipation on oxybutynin, %** 12.5 **Constipation on placebo, %** 0 **Drowsiness on oxybutynin, %:** 12.5 **Drowsiness on placebo, %:** 7 **Nausea on oxybutynin, %:** 8.3 **Nausea on placebo, %:** 2.3 **Initial hesitancy on oxybutynin, %:** 4.2 **Initial hesitancy on placebo, %:** 2.3 **Dizziness on oxybutynin, %:** 4.2 **Dizziness on placebo, %:** 7.0 **Metallic taste on oxybutynin, %:** 2.4 **Metallic taste on placebo, %:** 2.3 **Crown Crisp Experimental Index, >50% improvement:*** **Free floating anxiety:** 6.4	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Moore et al., 1990 Moore and Sutherst, 1990 (continued)				**Phobic anxiety:** **5.3Obsessionalism:** 6.2 **Somatic complaints:** 6.2 **Depression:** 4.0 **Hysteria:** 2.6 **Total:** 30.7 **Crown Crisp Experimental Index, <49% improvement:*** **Free floating anxiety:** 8.8 **Phobic anxiety:** 6.8 **Obsessionalism:** 8.1 **Somatic complaints:** 8.9	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Nitti et al.,2007 **Country and setting:** US, 83 center **Enrollment period:** October 2003 to February 2005 **Funding:** Schwarz BioSciences GmbH and Pfizer, Inc **Author industry relationship disclosures:** 9 of 9 Allergan (3) Astellas (3) Gynecare (1) Novartis (2) Pfizer (5) Boston Scientific (1) Espirit (4) Ortho (1) Watson (1) Indevus (1) GlaxoSmithKline (1) Schwarz Biosciences (3)	**Design:** RCT **Intervention:** Placebo, Fesoteorine 4 or 8 mg, bladder diary before randomization, 2, 8, 12 wks **Groups:** **G1:** Placebo **G2:** Fesoterodine 4 mg/d **G3:** Fesoterodine 8 mg/d **N at enrollment:** Total: 836 **G1:** 274 **G2:** 283 **G3:** 279 **N at follow-up:** **G1:** 266 **G2:** 267 **G3:** 267 **Age, mean (range):** Total: 59 (21, 91) **G1:** 59 (24, 88) **G2:** 59 (21, 85) **G3:** 59 (23, 91) **Women, %:** Total: 76 **G1:** 74 **G2:** 76 **G3:** 78 **Race/ethnicity:** **White:** Total: 82% **G1:** 80% **G2:** 82% **G3:** 84% **Black:** **G1:** 10% **G2:** 9% **G3:** 8% **Asian:** **G1:** 2% **G2:** 1% **G3:** 1%	**Inclusion criteria:** • Age ≥ 18 • Urinary frequency ≥8 voids/day • Urgency ≥ 6 for 3 days or UUI ≥ 3 episodes/3 day diary • At least moderate bladder problems on a Likert scale **Exclusion criteria:** • Pregnant • Women of reproductive age not on adequate contraception • Lower urinary tract pathology (SUI, urolithiasis, interstitial cystitis, urothelial tumors, ≥ grade 3 pelvic organ prolapse, BOO, postvoid residual > 100 mL, polyuria >3 L/24 h, rec UTI) • Current antimuscarinic • Neurogenic cause for OAB • Arrhythmia • Unstable angina or corrected QT interval > 500 ms • Electrostimulation or bladder training in past 4 weeks or currently	**UUI episodes/ day, mean ± SD:** **G1:** 3.7 ± 3.3 (n=205) **G2:** 3.9 ± 3.5 (n=228) **G3:** 3.9 ± 3.3 (n=218) **Urgency episodes/day, mean ± SD:** **G1:** 11.4 ± 3.8 **G2:** 12.5 ± 4.1 **G3:** 11.6 ± 3.7 **Incontinence, n (%):** **G1:** 205 (77) **G2:** 228 (85) **G3:** 218 (82) **Continent days/ wk, mean ± SD:** **G1:** 0.6 ± 1.3 **G2:** 0.7 ± 1.5 **G3:** 0.7 ± 1.4 **Voids/day, mean ± SD:** **G1:** 12.2 ± 3.7 **G2:** 12.9 ± 3.9 **G3:** 12.0 ± 3.3 **Daytime voids/ day, mean ± SD:** **G1:**10.2 ± 3.3 **G2:** 10.7 ± 3.4 **G3:** 10.1 ± 2.9 **Nocturia episodes/day, mean ± SD:** **G1:** 2.0 ± 1.3 **G2:** 2.2 ± 1.6 **G3:** 1.9 ± 1.4 **Voided volume (mL), mean ± SD:** **G1:** 159 ± 69 **G2:** 152 ± 60 **G3:** 156 ± 58	**UUI episodes/day, LS mean change (SE):** **G1:** -0.96 (0.17) **G2:** -1.65 (0.16)* **G3:** -2.28 (0.16)* **UUI episodes/day, median % change:** **G1:** -40.0 (n=205) **G2:** -67.4* (n=228) **G3:** -81.8* (n=218) **Urgency episodes/day, LS mean change (SE):** **G1:** -0.79 (0.20) **G2:** -1.91 (0.20) **G3:** -2.30 (0.20) **Urgency episodes/day, median % change:** **G1:**-3.3 **G2:** -16.3* **G3:** -18.4* **Continent days/ wk, LS mean change (SE):** **G1:** 1.31 (0.20) **G2:** 2.33 (0.19)* **G3:** 2.80 (0.19)* **Voids/day, LS mean change (SE):** **G1:** -1.08 (0.18) **G2:** -1.61 (0.18)* **G3:** -2.09 (0.18)* **Voids/day, mean % change:** **G1:** -6.9 **G2:** -14.9* **G3:** -16.0* **Daytime voids/ day, LS mean change (SE):** **G1:** -0.69 (0.16) **G2:** -1.04 (0.16) (*P* = 0.107) **G3:** -1.54 (0.16)*	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Nitti et al., 2007 (continued)			**Years since OAB diagnosis, mean ± SD:** **G1:** 9.8 ± 10.3 **G2:** 9.1 ± 10.3 **G3:** 10.1 ± 11.5 **Previous tolterodine use, n (%):** **G1:** 90 (33) **G2:** 88 (31) **G3:** 95 (34) **Previous oxybutynin use, n (%):** **G1:** 101 (37) **G2:** 94 (33) **G3:** 97 (35) **Previous trospium chloride use, n (%):** **G1:** 7 (2.6) **G2:** 6 (2.1) **G3:** 3 (1.1)	**Daytime voids/ median % change:** **G1:** -5.9 **G2:** -11.1 (*P* = 0.008) **G3:** -15.6* **Nocturia episodes/day, LS mean change (SE):** **G1:** -0.39 (0.07) **G2:** -0.58 (0.17) (*P* = 0.042) **G3:** -0.55 (0.17) (*P* = 0.09) **Nocturia episodes/day, median % change:** **G1:** -25.0 **G2:** -33.3 (*P* = 0.013) **G3:** -25.0 (*P* = 0.267) **Treatment response, n (% yes)** **G1:** 266 (45) **G2:** 267 (64)* **G3:** 267 (74)* **Voided volume (mL), LS mean change (SE):** **G1:** 8.38 (4.06) **G2:** 16.5 (4.00) (*P* = 0.15) **G3:** 33.6 (4.04)* **Side effects, n (%):** **G1:** 149 (55) **G2:** 171 (61) **G3:** 193 (69) **Dry mouth, n (%):** **G1:** 19 (7) **G2:** 45 (16) **G3:** 99 (36) **Constipation, n (%):** **G1:** 7 (3) **G2:** 14 (5) **G3:** 21 (8)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Nitti et al., 2007 (continued)				**UTI, n (%):** **G1:** 11 (4) **G2:** 10 (4) **G3:** 15 (5) **Headache, n (%):** **G1:** 9 (3) **G2:** 12 (4) **G3:** 8 (3) **Withdrew, %:** Total: 19 **G1:** 41 **G2:** 58 **G3:** 56 **Withdrew due to AE, %:** **G1:** 4 **G2:** 6 **G3:** 9 *P < 0.001	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Preik et al., 2004 [See evidence table for Anderson et al. 1999] **Country and setting:** Germany & US, Multiple academic hospitals **Enrollment period:** NR **Funding:** ALZA Corporation **Author industry relationship disclosures:** 4 of 5 ALZA Corp (2) Ditropan XL (1) Janssen-Cilag GmbH (1) Johnson and Johnson (1) Ortho-McNeil (1)	**Design:** RCT **Intervention:** Oxybutynin **Groups:** daily dose increased in 5 mg increments each 4-7 days until reaching the minimum effective dose, maximum tolerated dose, or maximum allowable dose. Once participant reached titrated dose, maintained for 1 week confirmation period and 1 week maintenance period. **G1:** Controlled-release oxybutynin (OROS-O) **G2:** Immediate release oxybutynin (IR-O) **N at enrollment:** 105 **N at follow-up:** Total: 93 **G1:** 46 **G2:** 47 **Women, n (%):** **G1:** 50 (94.3) **G2:** 47 (90.4) **Age, mean (SE):** **G1:** 59.2 (10.6) **G2:** 59.6 (10.0) **Race/ethnicity:** NR **Weight (kg), mean (SE):** **G1:** 78.0 (18.3) **G2:** 80 (20.2)	**Inclusion criteria:** • Community-dwelling men & women age 40-75 • Urge or mixed UI • ≥ 6 UUI episodes per week recorded on the run-in diary after washout of anticholinergic • Previous response to anticholinergic • Urge predominant SUI **Exclusion criteria:** • Known treatable GU disorders that could cause incontinence • Men who had had prostate surgery < 9 mos before study enrollment or with a PSA level of >10 ng/mL • PVR of > 100mL • Estimated Cr clearance of < 50 mL/min • Glaucoma or untreated anterior chamber angles • Hgb < 100g/L • Known hypersensitivity to oxybutynin • History of drug or alcohol abuse • Positive urine drug screen • Pregnant or breastfeeding • Myasthenia gravis	**UUI episodes/ wk, mean (SE):** **G1:** 27.6 (24.0) **G2:** 23.4 (16.3) **Duration of incontinence, n (%):** 1-5 years: **G1:** 26 (49) **G2:** 22 (42) > 5 years: **G1:** 23 (43) **G2:** 22 (42)	**Dose-titration endpoint, MED, n/N (%):** **G1:** 29/46 (63) **G2:** 26/47 (55) **Dry mouth, MED, n/N (%):** **G1:** 3/29 (10) **G2:** 7/26 (27) **Dose-titration endpoint, MTD, n/N (%):** **G1:** 11/46 (24) **G2:** 19/47 (41) **Dry mouth, MTD, n/N (%):** **G1:** 7/11 (64) **G2:** 13/19 (68) **Dose-titration endpoint, MAD, n/N (%):** **G1:** 6/46 (13) **G2:** 2/47 (4) **Dry mouth, MAD, n/N (%):** **G1:** 1/6 (17) **G2:** 1/2 (50)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Rentzhog et al., 1993 **Country and setting:** Sweden & UK, 17 academic hospitals **Enrollment period:** NR **Funding:** Pharmacia & Upjohn AB **Author industry relationship disclosures:** NR	**Design:** RCT, double blind, placebo controlled **Intervention:** tolterodine vs placebo **Groups:** **G1:** tolterodine 1mg/d **G2:** tolterodine 2 mg/d **G3:** tolterodine 4mg/d **G4:** tolterodine 8mg/d **G5:** placebo **N at enrollment:** **G1:** 21 **G2:** 16 **G3:** 14 **G4:** 16 **G5:** 13 **N at follow-up:** **G1:** 17 **G2:** 15 **G3:** 11 **G4:** 11 **G5:** 10 **Women, n:** **G1:** 14 **G2:** 10 **G3:** 12 **G4:** 15 **G5:** 10 **Age, mean:** **G1:** 56 **G2:** 59 **G3:** 56 **G4:** 58 **G5:**58 **Race/ethnicity:** NR **Body weight, kg, mean:** **G1:** 73 **G2:** 76 **G3:** 72 **G4:** 76 **G5:** 73	**Inclusion criteria:** • age 18-75 • urinary urgency, 8+ micturitions/d, and/or UI (1+ episode/d) • UDS-confirmed detrusor instabililty (phasic increase in detrusor pressure in the presence of typical sx) • max urinary flow rate of >15 mL/s • sterile or clinically insignificant bacteriuria • normal routine laboratory tests **Exclusion criteria:** • antimuscarinic agents or drugs w/ antimuscarinic side effects • other drugs for UI (except estrogens) • clinically significant cardiac, hepatic, renal, or heme disorders • contraindications to antimuscarinic agents • pregnant or lactating • women not using reliable contraception	**Frequency of micturitions/d:** **G1:** 10.3 **G2:** 11.2 **G3:** 12.8 **G4:** 10.2 **G5:** 10.2 **Incontinence episodes/d:** **G1:** 2.1 **G2:** 1.7 **G3:** 1.8 **G4:** 2.7 **G5:** 4.1 **Previous drug therapy:** **G1:** 9 **G2:** 10 **G3:** 9 **G4:** 9 **G5:** 4 **Frequency, n:** **G1:** 7 **G2:** 7 **G3:** 4 **G4:** 5 **G5:** 4 **Leakage, n:** **G1:** 2 **G2:** - **G3:** 2 **G4:** 1 **G5:** 3 **Leakage and frequency, n:** **G1:** 11 **G2:** 9 **G3:** 7 **G4:** 9 **G5:** 6 **Volume at first contraction (mL), mean mL ± SD** **G1:** 243 ± 220 **G2:** 274 ± 129 **G3:** 171 ± 109 **G4:** 297 ± 123 **G5:** 295 ± 16723 (	**Volume at first contraction (mL), mean change (% change):** **G1:** 74 (63) **G2:** 17 (17) **G3:** 89 (114) **G4:** 115 (119) **G5:** -23 (-4) Linear regression of change: *P* = 0.0459 **Residual urinary volume (mL), mean change (% change):** **G1:** 6 (2) **G2:** 10 (57) **G3:** 30 (122) **G4:** 143 (225) **G5:** 4 (126) Linear regression of change: *P* = 0.0003 **Max cystometric capacity (mL), mean change (% change):** **G1:** 15 (20) **G2:** -25 (5) **G3:** 2 (10) **G4:** 76 (30) **G5:** -17 (3) Linear regression of change: *P* = 0.0921 **Bladder compliance (mL/cmH2O), mean change (% change):** **G1:** -29 (-9) **G2:** 10 (164) **G3:** 2 (72) **G4:** 18 (355) **G5:** -6 (11) Linear regression of change: *P* = 0.1646	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Methods and blinding: + Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rentzhog et al.,1993 (continued)			**Residual urinary volume, mean mL ± SD:** **G1:** 24 ± 31 **G2:** 51 ± 94 **G3:** 25 ± 18 **G4:** 52 ± 130 **G5:** 26 ± 35 **Max cystometric capacity, mean mL ± SD:** **G1:** 381 ± 200 **G2:** 397 ± 197 **G3:** 284 ± 195 **G4:** 335 ± 145) **G5:** 377 ± 181) **Bladder compliance, mean mL/cmH2O ± SD:** **G1:** 65 ± 105 **G2:** 50 ± 44 **G3:** 36 ± 43 **G4:** 44 ± 46 **G5:** 44 ± 28 **# detrusor contractions >10 cmH20, mean ± SD:** **G1:** 4.1 ± 3.3 **G2:** 2.3 ± 1.8 **G3:** 3.4 ± 2.5 **G4:** 3.3 ± 2.7 **G5:** 3.1 ± 3.0	**Detrusor contractions >10 cmH_20, mean change (% change):** **G1:** -1.6 (-34) **G2:** -1.2 (-38) **G3:** -2.0 (-33) **G4:** -0.3 (-32) **G5:** 0.0 (48) Linear regression of change: *P* = 0.7284 **Max urinary flow (mL/s), mean change (% change):** **G1:** 1.2 (9) **G2:** 1.3 (18) **G3:** -2.4 (-3) **G4:** -0.3 (-32) **G5:** -2.0 (28) Linear regression of change: *P* = 0.3072 **Volume at normal desire to void (mL), mean change (% change):** **G1:** -1 (2) **G2:** -18 (1) **G3:** 32 (25) **G4:** 66 (45) **G5:** -18 (15) Linear regression of change: *P* = 0.0492 **Patients reporting 1+ adverse event, n:** **G1:** 8 **G2:** 6 **G3:** 7 **G4:** 12 **G5:** 6	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rentzhog et al.,1993 (continued)			**Max urinary flow, mean mL/s ± SD:** **G1:** 21.0 ± 7.5 **G2:** 2.33 ± 9.9 **G3:** 19.2 ± 9.8 **G4:** 20.5 ± 8.2 **G5:** -2.0 ± 28 **Volume at normal desire to void, mean mL ± SD:** **G1:** 235 ± 128 **G2:** 273 ± 121 **G3:** 143 ± 83 **G4:** 211 ± 128 **G5:** 255 ± 157 **Concomitant dz, n:** **G1:** 11 **G2:** 11 **G3:** 7 **G4:** 11 **G5:** 9	**Total AE reported:** **G1:** 10 **G2:** 14 **G3:** 10 **G4:** 25 **G5:** 10 **Dry mouth** **G1:** 2 **G2:** 2 **G3:** 5 **G4:** 9 **G5:** 2 **Constipation** **G1:** 1 **G2:** 3 **G3:** 1 **G4:** 2 **G5:** 0 **Abnormal vision** **G1:** 0 **G2:** 3 **G3:** 1 **G4:** 1 **G5:** 1 **Urinary retention** **G1:**0 **G2:** 0 **G3:** 0 **G4:** 1 **G5:** 0 **Other** **G1:** 7 **G2:** 6 **G3:** 3 **G4:** 12 **G5:** 7	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Robinson et al., 2007 **Country and setting:** 12 countries in Europe, 39 study sites **Enrollment period:** July 2002 to December 2002 **Funding:** Astellas **Author industry relationship disclosures:** 2 of 4 Astellas (2)	**Design:** RCT **Intervention:** tamsulosin OCAS (0.25, 0.5, 1.0, 1.5 mg) qd vs tolterodine ER qd vs placebo qd **Groups:** **G1:** 0.25 mg tamsulosin OCAS qd **G2:** 0.5 mg tamsulosin OCAS qd **G3:** 1.0 mg tamsulosin OCAS qd **G4:** 1.5 mg tamsulosin OCAS qd **G5:** tolterodine ER qd **G6:** placebo qd **N at enrollment:** **G1:** 58 **G2:** 65 **G2:** 63 **G4:** 60 **G5:** 61 **G6:** 61 **N at follow-up:** **G1:** 52 **G2:** 61 **G3:** 55 **G4:** 46 **G5:** 53 **G6:** 59 **Women, %**: 100 **Age, range:** 18-70 **Race/ethnicity:** NR	**Inclusion criteria:** • Symptoms of OAB ≥ 3 months **Exclusion criteria:** • SUI or MUI where stress symptoms predominant and neurogenic	**Urgency episodes/day, mean:** **G1:** 5.83 **G2:** 5.58 **G3:** 5.82 **G4:** 6.28 **G5:** 6.78 **G6:** 5.58 **Incontinence episodes/day, mean:** **G1:** 3.22 **G2:** 2.17 **G3:** 3.33 **G4:** 2.98 **G5:** 2.33 **G6:** 2.90 **Voids/day, mean:** **G1:** 12.20 **G2:** 11.09 **G3:** 12.96 **G4:** 12.46 **G5:** 13.22 **G6:** 11.90 **Nocturia episodes/day, mean:** **G1:** 1.97 **G2:** 1.76 **G3:** 1.82 **G4:** 2.10 **G5:** 2.34 **G6:** 1.87 **Voided volume (mL), mean:** **G1:** 135.5 **G2:** 148.6 **G3:** 135.1 **G4:** 131.4 **G5:** 148.9 **G6:** 145.5	**Urgency episodes/day, mean change:** **G1:** -1.51 **G2:** -1.66 **G3:** -1.83 **G4:** -1.91 **G5:** -2.49 **G6:** -1.86 **G4/G6:** *P* = 0.901 **G5/G6:** *P* = 0.632 **Incontinence episodes/day, mean change:** **G1:** -1.40 **G2:** -0.93 **G3:** 0.02 **G4:** -0.66 **G5:** -1.66 **G6:** -0.66 **G4/G6:** *P* = 0.945 **G5/G6:** *P* = 0.025 **Voids/day, mean change:** **G1:** -1.60 **G2:** -1.01 **G3:** -1.38 **G4:** -1.18 **G5:** -2.59 **G6:** -1.81 **G4/G6:** *P* = 0.189 **G5/G6:** *P* = 0.353 **Nocturia episodes/day, mean change:** **G1:** -0.35 **G2:** -0.36 **G3:** -0.33 **G4:** -0.34 **G5:** -0.74 **G6:** -0.41 **G4/G6:** *P* = 0.495 **G5/G6:** *P* = 0.353	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: - Drop-out rates: NR Power calculation: + Statistical issues: + EXTERNAL VALIDITY: fair Age: -, NR Baseline OAB status: + Baseline characteristics: - Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Robinson et al., 2007 (continued)				**Void volume (mL), mean change:** **G1:** 13.9 **G2:** 9.7 **G3:** 12.6 **G4:** 12.9 **G5:** 24.3 **G6:** 11.4 **G4/G6:** *P* = 0.992 **G5/G6:** *P* = 0.092	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Rogers et al., 2008 **Country and setting:** USA, multicenter (54 outpatient sites) **Enrollment period:** NR **Funding:** Pfizer **Author industry relationship disclosures:** 7 of 7 Bayer (1) Boeringer Ingelheim(1) Duramed (1) J&J (1) P&G (1) Novartis (1) Novo-Nordisk (1) Pfizer (7) Wyeth (1)	**Design:** Multicenter randomized placebo-controlled double-blind **Intervention:** Tolterodine 4 mg ER vs placebo within 4 hours of bedtime **Groups:** **G1:** Tolterodine 4mg ER daily **G2:** Placebo **N at enrollment:** **G1**: 202 **G2:** 211 **N at follow-up:** **G1**: 163 **G2:** 167 **Women, %:** Total: 100 **Age, yrs ± SD:** **G1:** 49 ± 12 **G2:** 47 ± 12 **Race/ethnicity, n (%):** **White:** **G1:** 139 (69) **G2:** 138 (66) **Black:** **G1:** 37 (18) **G2:** 45 (21) **Asian:** **G1:** 3 (2) **G2:** 4 (2) **Other:** **G1:** 22 (11) **G2:** 23 (11) **Parrous, %:** **G1:** 86 **G2:** 91 **Follow-up:** 12 weeks **Premenopausal, n (%):** **G1:** 71 (35) **G2:** 95 (45)	**Inclusion criteria:** • Age ≥ 18 • Women • ≥ 0.6 UUI episodes/day • ≥ 8 voids/day • ≥ 3 OAB voids/ day (urgency-associated voids) • "some moderate problems" on PPBC • OAB symptoms ≥ 3 months • Stable, sexually active relationship with man ≥ 6 months **Exclusion criteria:** • POP Stage 3 or greater • History of lower urinary tract surgery • Lifelong sexual dysfunction unrelated to lifelong UUI • Predominate SUI	**UUI episodes/ day, mean ± SD:** **G1:** 2.5 ± 2.1 **G2:** 2.2 ± 1.8 **Voids/ day, mean ± SD:** **G1:** 13.0 ± 4.1 **G2:** 12.5 ± 3.9 **OAB voids/ day, mean ± SD:** **G1:** 10.6 ± 4.4 **G2:** 9.9 ± 4.2 **Pads/ day, mean ± SD:** **G1:** 2.9 ± 2.7 **G2:** 2.9 ± 3.1 **SQOL-F total score, mean± SD:** **G1:** 69.6 ± 23.1 **G2:** 69.2 ± 23.0 **PISQ total score, mean ± SD:** **G1:** 88.7 ± 13.9 **G2:** 88.9 ± 14.2 **PISQ Behavioral/ emotive score, mean ± SD:** **G1:** 38.0 ± 8.9 **G2:** 38.0 ± 9.0 **PISQ Physical score, mean ± SD:** **G1:** 31.7 ± 5.9 **G2:** 31.8 ± 6.0 **PISQ partner related score, mean ± SD:** **G1:** 19.0 ± 2.8 **G2:** 19.0 ± 2.5 **HAD Anxiety score, mean ± SD:** **G1:** 8.3 ± 4.0 **G2:** 8.2 ± 4.0 **HAD Depression score, mean ± SD:** **G1:** 5.1 ± 3.3 **G2:** 5.4 ± 3.4	**UUI episodes/day, mean change (SE):** **G1:** 1.8 (0.1) **G2:** 1.4 (0.1) *P* = 0.0029 (*P* = 0.0525 when a single statistical outlier is excluded) **UUI episodes/day, median % change:** **G1:** -100.0 **G2:** -82.5 *P* = 0.0003 **No UUI events, week 12, %:** **G1:** 57 **G2:** 42 *P* < 0.004 **OAB voids/day, mean change (SE):** **G1:** -4.7 (0.3) **G2:** -3.0 (0.3) *P* < 0.0001 **Pads/day, mean change (SE):** **G1:** -1.5 (0.1) **G2:** -1.0 (0.1) *P* = 0.0024 **Voids/day, mean change (SE):** **G1:** -3.3 (0.2) **G2:** -2.3 (0.2) *P* = 0.0006 **SQOL-F score, mean change (SE):** **G1:** 6.4 (1.2) **G2:** 1.5 (1.2) *P* = 0.004 **PISQ total score, mean change (SE):** **G1:** 4.9 (0.7) **G2:** 2.3 (0.7) *P* = 0.009	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: + Method and blinding: + Pt selection criteria: + Loss to followup: - Drop-out rates: + Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rogers et al., 2008 (continued)	**Perimenopausal, n (%):** **G1:** 18 (9) **G2:** 16 (8) **Postmeno-pausal, n (%):** **G1:** 112 (56) **G2:** 99 (47)			**PISQ behavioral/ emotive score, mean change (SE):** **G1:** 1.6 (0.4) **G2:** 0.5 (0.4) *P* = NS **PISQ physical score, mean change (SE):** **G1:** 2.6 (0.3) **G2:** 1.6 (0.3) *P* ≤ 0.01 **PISQ partner related score, mean change (SE):** **G1:** 0.6 (0.1) **G2:** 0.3 (0.1) *P* = NS **HAD anxiety score, mean change (SE):** **G1:** -1.9 (0.3) **G2:** -1.1 (0.3) *P* = 0.03 **HAD depression score, mean change (SE):** **G1:** -1.2 (0.2) **G2:** -0.8 (0.2) *P* = NS **Subjects with adverse events, n (%):** **G1:** 114 (57) **G2:** 111 (53) **Withdrawn due to AEs, n (%):** **G1:** 9 (5) **G2:** 6 (3) **Dry mouth, n (%):** **G1:** 26 (13) **G2:** 19 (9) **Constipation, n (%):** **G1:** 7 (4) **G2:** 8 (4)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rogers et al., 2008 (continued)				**Nasopharyngitis, n (%):** **G1:** 9 (5) **G2:** 10 (5) **Sinusitis, n (%):** **G1:** 8 (4) **G2:** 9 (4) **URI, n (%):** **G1:** 9 (4) **G2:** 9 (5) **UTI, n (%):** **G1:** 12 (6) **G2:** 5 (2) **Headache, n (%):** **G1:** 7 (4) **G2:** 6 (3) **Depression, n (%):** **G1:** 5 (3) **G2:** 0 (0) **Insomnia, n (%):** **G1:** 5 (3) **G2:** 0 (0)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Rudy et al., 2006 Rudy et al., 2006* Staskin and Harnett, 2004† **Country and setting:** US, 52 sites **Enrollment period:** NR **Funding:** Indevus NR† **Author industry relationship disclosures:** 5 of 5 **Indevus (5)** NR†	**Design:** RCT **Intervention:** Trospium chloride vs placebo x 12 wks **Groups:** **G1:** trospium chloride 20 mg b.i.d. **G2:** matching placebo **N at enrollment:** **G1:** 329 **G2:** 329 **N at follow-up:** **G1:** 323 **G2:** 325 **Age, mean (SE):** **G1:** 61.1 (0.69) **G2:** 61.0 (0.70) **Women, N (%):** **G1:** 269 (81.8) **G2:** 267 (81.2) **Race/ethnicity, n (%):** **Black:** **G1:** 26 (7.9) **G2:** 21 (6.4) **White:** **G1:** 284 (86.3) **G2:** 300 (91.2) **Hispanic:** **G1:** 13 (4.0) **G2:** 5 (1.5) **Asian:** **G1:** 5 (1.5) **G2:** 3 (0.9) **Parity:** NR	**Inclusion criteria:** • Age ≥18 • ≥ 6 mos of OAB sx • ≥10 voids/day • Sx of urgency • ≥ 7 UUI episodes/wk **Exclusion criteria:** • Predominantly SUI, insensate UI, or overflow UI • Neurogenic bladder d/o's • Significant renal dz • Uninvestigated hematuria • UTI at washout or more than 2x during the prior 12 mos • PVR >100mL • Use of any anticholinergic drug or other drug therapy for OAB w/in 21 days before randomization • Bladder surgery w/in 6 mos before randomization • Cancer • Interstitial cystitis • PSA >10ng/mL • Diuretic use • Estrogen therapy • Nonmedical bladder therapy not part of a stable, long-term program (ie, timed voids and straight caths; Kegels were allowed) • Pregnancy	**UUI episodes/ day, median:** **G1:** 2.86 **G2:** 2.86 *P* = 0.9849 **Urgency severity score associated with toilet voids, median:** **G1:** 1.79 **G2:** 1.75 *P* = 0.4100 **Voids/day, mean:** **G1:** 12.94 **G2:** 13.17 *P* = 0.3169 **Nocturia episodes/day, median:** **G1:** 2.00 **G2:** 2.00 *P = 0.9048* **Nocturnal urgency severity score associated with toilet voids, mean:** **G1:** 2.03 **G2:** 2.01 *P* = 0.6863 **OAB-SCS, median:** **G1:** 36.56 **G2:** 36.88 *P* = 0.7176 **Stanford Sleepiness Scale, mean** **G1:** 1.98 **G2:** 1.94 **Stanford Sleepiness Scale, age group < 65 years:** **G1:** 1.99 **G2:** 2.09	**UUI episodes/day, day 1, median change:** **G1:** -1.00 **G2:** -0.57 *P* = 0.042 **UUI episodes/day, day 2, median change:** **G1:** -1.29 **G2:** -0.86 *P* = 0.0022 **UUI episodes/day, day 3, median change:** **G1:** -1.57 **G2:** -0.86 *P* < 0.0001 **UUI episodes/day, day 4, median change:** **G1:** -1.57 **G2:** -1.00 *P* < 0.0001 **UUI episodes/day, day 5, median change:** **G1:** -1.57 **G2:** -1.00 *P* < 0.0001 **UUI episodes/day, day 6, median change:** **G1:** -1.71 **G2:** -1.00 *P* < 0.0001 **UUI episodes/day, day 7, median change:** **G1:** -1.71 **G2:** -1.00 *P* < 0.0001	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: + Measurement methods: + Measurement reliability: - Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)		• Contraindication to antimuscarinic therapy	**Stanford Sleepiness Scale, age group > 65 years:** **G1:** 1.96 **G2:** 1.71	**UUI episodes/day, week 1, median change:*** **G1:** -1.43 **G2:** -0.86 *P* < 0.0001	
			Stanford Sleepiness Scale, age group < 75 years: **G1:** 2 **G2:** 1.97	**UUI episodes/day, week 4, median change:*** **G1:** -1.71 **G2:** -1.14 *P* < 0.0001	
			Stanford Sleepiness Scale, age group >75 years: **G1:** 1.86 **G2:** 1.79	**UUI episodes/day, week 12, median change:*** **G1:** -1.86 **G2:** -1.29 *P* < 0.0001	
			Voided volume (mL), mean: **G1:** 154.80 ± NR **G2:** 154.64 ± NR *P* = 0.9667	**Urgency severity score, day 1, mean change:** **G1:** 0.00 **G2:** 0.02 *P* = 0.47	
			Prior OAB medications, n (%): **G1:** 162 (49.2) **G2:** 169 (51.4)	**Urgency severity score, day 2, mean change:** **G1:** -0.08 **G2:** -0.03 *P* = 0.13	
			Prior hx of pelvic-floor training, n (%): **G1:** 62 (18.8) **G2:** 76 (23.1)	**Urgency severity score, day 3, mean change:** **G1:** -0.11 **G2:** -0.04 *P* = 0.015	
			Currently practice undergarment change d/t incontinence, n (%): **G1:** 227 (69.0) **G2:** 239 (72.6)	**Urgency severity score, day 4, mean change:** **G1:** -0.12 **G2:** -0.05 *P* = 0.031	
				Urgency severity score, day 5, mean change: **G1:** -0.13 **G2:** -0.05 *P* = 0.021	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)				**Urgency severity score, day 6, mean change:** **G1:** -0.08 **G2:** 0.04 *P* < 0.0001 **Urgency severity score, day 7, mean change:** **G1:** -0.09 **G2:** 0.03 *P* < 0.0001 **Urgency severity score, week 1, mean change:*** **G1:** -0.09 **G2:** -0.01 *P* = 0.0023 **Urgency severity score, week 4, mean change:*** **G1:** -0.19 **G2:** -0.04 *P* < 0.0001 **Urgency severity score, week 12, mean change:*** **G1:** -0.21 **G2:** -0.02 *P* < 0.0001 **Voids/day, day 1, mean change:** **G1:** -0.66 **G2:** -0.35 *P* = 0.14 **Voids/day, day 2, mean change:** **G1:** -1.11 **G2:** -0.75 *P* = 0.09 **Voids/day, day 3, mean change:** **G1:** -1.30 **G2:** -0.77 *P* = 0.012 **Voids/day, day 4, mean change:** **G1:** -1.33 **G2:** -0.95 *P* = 0.086	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)				**Voids/day, day 5, mean change:** **G1:** -1.73 **G2:** -1.12 *P* = 0.0037 **Voids/day, day 6, mean change:** **G1:** -1.80 **G2:** -1.28 *P* = 0.017 **Voids/day, day 7, mean change:** **G1:** -1.99 **G2:** -1.44 *P* = 0.011 **Voids/day, week 1, mean change:*** **G1:** -1.42 **G2:** -0.96 *P* = 0.0039 **Voids/day, week 4, mean change:*** **G1:** -2.34 **G2:** -1.55 *P* < 0.0001 **Voids/day, week 12, mean change:*** **G1:** -2.67 **G2:** -1.76 *P* < 0.0001 **Nocturia episodes/day, week 1, median change:*** **G1:** -0.29 **G2:** -0.29 *P* = 0.8454 **Nocturia episodes/day, week 4, median change:*** **G1:** -0.43 **G2:** -0.29 *P* = 0.0299 **Nocturia episodes/day, week 12, median change:*** **G1:** -0.57 **G2:** -0.29 *P* = 0.0026	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)				**Nocturnal urgency severity score, week 1, mean change:*** **G1:** -0.05 **G2:** 0.03 *P* = 0.0442 **Nocturnal urgency severity score, week 4, mean change:*** **G1:** -0.13 **G2:** =0.01 *P* = 0.0062 **Nocturnal urgency severity score, week 12, mean change:*** **G1:** -0.17 **G2:** 0.01 *P* = 0.0005 **OAB-SCS, day 1, median change:** **G1:** -2.50 **G2:** -0.14 *P* = 0.014 **OAB-SCS, day 2 median change:** **G1:** -3.86 **G2:** -2.14 *P* = 0.015 **OAB-SCS, day 3, median change:** **G1:** -4.71 **G2:** -2.71 *P* = 0.0019 **OAB-SCS, day 4, median change:** **G1:** -4.86 **G2:** -3.36 *P* = 0.011 **OAB-SCS, day 5, median change:** **G1:** -6.43 **G2:** -3.36 *P* < 0.0001 **OAB-SCS, day 6, median change:** **G1:** -5.43 **G2:** -2.93 *P* < 0.0001	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)				**OAB-SCS, day 7, median change:** **G1:** -6.29 **G2:** -3.00 *P* < 0.0001 **OAB-SCS, week 1, median change:*** **G1:** -4.71 **G2:** -2.29 *P* < 0.0001 **OAB-SCS, week 4, median change:*** **G1:** -8.14 **G2:** -3.86 *P* < 0.0001 **OAB-SCS, week 12, median change:*** **G1:** -8.43 **G2:** -4.62 *P* < 0.0001 **Stanford Sleepiness Scale, week 1, mean change:**† **G1:** -0.2 **G2:** -0.12 **Stanford Sleepiness Scale, week 4, mean change:**† **G1:** -0.17 **G2:** -0.14 **Stanford Sleepiness Scale, week 12, mean change:**† **G1:** -0.16 **G2:** -0.11 **Stanford Sleepiness Scale, including T-max time point values only (G1=93, G2=97), week 1, mean change:**† **G1:** -0.42 **G2:** -0.2	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)				**Stanford Sleepiness Scale, including T-max time point values only (G1=144, G2=148), week 4, mean change:†** **G1:** -0.2 **G2:** -0.19 **Stanford Sleepiness Scale, including T-max time point values only (G1=182, G2=179), week 12, mean change:†** **G1:** -0.17 **G2:** -0.18 **Mean Stanford Sleepiness Scale, age group < 65 years, week 1, mean change:†** **G1:** -0.27 **G2:** -0.19 **Mean Stanford Sleepiness Scale, age group < 65 years, week 4, mean change:†** **G1:** -0.14 **G2:** -0.27 **Mean Stanford Sleepiness Scale, age group < 65 years, week 12, mean change:†** **G1:** -0.14 **G2:** -0.22 **Mean Stanford Sleepiness Scale, age group >65 years, week 1, mean change:†** **G1:** -0.04 **G2:** -0.03	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)				**Mean Stanford Sleepiness Scale, age group >65 years, week 4, mean change:**† **G1:** -0.23 **G2:** 0.03 **Mean Stanford Sleepiness Scale, age group >65 years, week 12, mean change:**† **G1:** -0.22 **G2:** 0.03 **Mean Stanford Sleepiness Scale, age group < 75 years, change from baseline to week 1:**† **G1:** -0.21 **G2:** -0.14 **Mean Stanford Sleepiness Scale, age group < 75 years, change from baseline to week 4:**† **G1:** 0.14 **G2:** -0.16 **Mean Stanford Sleepiness Scale, age group < 75 years, week 12, mean change:**† **G1:** 0.15 **G2:** -0.14 **Mean Stanford Sleepiness Scale, age group > 75 years, change from baseline to week 1:**† **G1:** -0.02 **G2:** 0	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)				**Mean Stanford Sleepiness Scale, age group > 75 years, change from baseline to week 4:**† **G1:** -0.49 **G2:** -0.09 **Mean Stanford Sleepiness Scale, age group > 75 years, week 12, mean change:**† **G1:** -0.33 **G2:** 0.02 **Clinically significant increase (≥ 3 points) from baseline to week 12 in SSS score, n (%):**† **G1:** 5 (1.5) **G2:** 8 (2.5) **Voided volume (mL), week 1, mean change:*** **G1:** 29.23 **G2:** 6.05 *P* < 0.0001 **Voided volume (mL), week 4, mean change:*** **G1:** 39.50 **G2:** 9.45 *P* < 0.0001 **Voided volume (mL), week 12, mean change:*** **G1:** 35.59 **G2:** 9.44 *P* < 0.0001 **Adverse events Any, n (%)** **G1:** 196 (59.6) **G2:** 153 (46.5) **Dry mouth:** **G1:** 65 (19.8) **G2:** 17 (5.2)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)				**Constipation:** **G1:** 36 (10.9) **G2:** 19 (5.8) **Headache not otherwise specified:** **G1:** 18 (5.5) **G2:** 15 (4.6) **UTI not otherwise specified:** **G1:** 16 (4.9) **G2:** 8 (2.4) **Nasopharyngitis:** **G1:** 13 (4.0) **G2:** 12 (3.6) **Cough:** **G1:** 8 (2.4) **G2:** 1 (0.3) **Diarrhea:** **G1:** 7 (2.1) **G2:** 13 (4.0) **AEs leading to treatment discontinuation, %:** **G1:** 7.3 **G2:** 4.6 **Most common AEs leading to discontinuation:** **Constipation:** **G1:** 1.8% **G2:** 0.6% **Dry mouth:** **G1:** 1.5% **G2:** 0.0% **At least one CNS event:** **G1:** 5.8% **G2:** 5.2% **Somnolence** **G1:** 0.3% **G2:** 0.6% **Sedation:** **G1:** 0 **G2:** 0.3%	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Salvatore et al., 2005 **Country and setting:** UK, Urogynecology specialty **Enrollment period:** 1 year with phone questionnaire at 2 years **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Prospective randomized phone questionnaire **Intervention:** Oxybutynin with incremental increase in dosage to 5mg t.i.d. over 6 weeks at 14 day intervals **Groups:** **G1:** Oxybutynin 2.5 mg b.i.d. **G2:** Oxybutynin 5 mg at night **N at enrollment:** **G1:** 42 **G2:** 44 **N at follow-up:** **G1:** 27 **G2:** 39 **Women, %:** 100 **Age, yrs ± SD:** **G1:** 59.2 ± 12.6 **G2:** 53.3 ± 14.4 **Race/ethnicity:** NR	**Inclusion criteria:** • Women • Video-urodynamic diagnosis of DO or low bladder capacity • DO- ≥ 1 contractions on filling cystometry associated with urgency • Low bladder compliance = linear detrusor pressure rise during filling cystometry > 15 cmH2O at 500mL associated with urgency or leakage • **Exclusion criteria:** NR	**Stopped treatment, n (%)** **G1:** 16 (59.3) **G2:** 28 (71.8)	**SUI episdes/day, mean ± SD:** **G1:** 0.85 ± 0.78 **G2:** 1.27 ± 1.17 *P* = 0.04 **Nocturia episodes/ day, mean ± SD:** **G1:** 1.21 ± 1.17 **G2:** 2.04 ± 1.45 *P* = 0.01 **Oxybutynin compliance, 2 yrs, n (%) :** **G1:** 11 (40.7) **G2:** 11 (28.2) **Time on drug, n:** 1 month: **G1:** 6 **G2:** 12 1-2 months: **G1:** 6 **G2:** 11 1-2 months: **G1:** 2 **G2:** 3 3-4 months: **G1:** 2 **G2:** 2 **Duration of treatment:** **G1:** NR **G2:** NR *P* = 0.08 **General perception of improvement:** *P* = 0.58 **Max dose of oxybutynin reached:** *P* = 0.31 **Present dose of oxybutynin:** *P* = 0.45 **Present overall severity of symptom:** *P* = 0.12	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: NA Pt selection criteria: - Loss to followup: - Drop-out rates: NR Power calculation: + Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: NR Baseline characteristics: - Length of followup: ++ Measurement methods: + Measurement reliability: - Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Salvatore et al., 2005 (continued)				**Daytime frequency:** *P* = 0.78 **Urgency:** *P* = 0.78 **Urge incontinence:** *P* = 0.18 **Pad usage:** *P* = 0.24 **Side effects, n:** **G1:** 3 **G2:** 4 **Dry Mouth, n:** **G1:** 1 **G2:** 4 **Dry Throat, n:** **G1:** 2 **G2:** 0 **Dry nose, n:** **G1:** 0 **G2:** 1 **Dry eyes, n:** **G1:** 0 **G2:** 1 **Nausea, n:** **G1:** 0 **G2:** 4 **Tachycardia, n:** **G1:** 0 **G2:** 1 **Dizziness, n:** **G1:** 0 **G2:** 2 **Constipation, n:** **G1:** 0 **G2:** 0 **Headache. N:** **G1:** 0 **G2:** 1	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Salvatore et al., 2007 **Country and setting:** Italy, Urogynecology outpatient clinic **Enrollment period:** January 2004 to October 2005 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cohort **Intervention:** Tolterodine SR 4 mg qd **Groups:** **G1:** vaginal profile stage 0a or Ia **G2:** anterior prolapse ≥ stage IIa **N at enrollment:** **G1:** 184 **G2:** 51 **N at follow-up:** NR **Women, %:** 100 **Age, median (range):** **G1:** 59 (20, 85) **G2:** 59 (35, 82) **Race/ethnicity:** NR **Parity, mean (range):** **G1:** 2 (0-6) **G2:** 2 (0-6) **Menopausal, n (%):** **G1:** 132 (72) **G2:** 7 (18)	**Inclusion criteria:** • Women • Urodynamically proven OAB who had no prolapse or pure anterior vaginal prolapse • Proven detrusor overactivity **Exclusion criteria:** • All symptoms or signs related to voiding difficulties • Prolapse	**Previous surgery, n (%):** **G1:** 52 (28) **G2:** 11 (22) **HRT, n (%)** **G1:** 35 (26) **G2:** 7 (18)	**Improvement in condition or cured, n (%):** **G1:** 158 (85.9) **G2:** 31 (60.8)* *P* = 0.0002	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: NR Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: poor Age: + Baseline OAB status: NR Baseline characteristics: - Length of followup: + Measurement methods: - Measurement reliability: - Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Salvatore et al., 2008 **Country and setting:** Italy, academic health center **Enrollment period:** January 2005 to August 2005 **Funding:** NR **Author industry relationship disclosures:** None	**Design:** prospective cohort **Intervention:** tolterodine ER 4 mg qd for 12 wks **Groups:** **G1:** Involuntary detrusor contractions during filling **G2:** Involuntary detrusor contractions after p **N at enrollment:** 111 **N at follow-up:** 109 **G1:** 84 **G2:** 25 **Age, mean yrs:** **G1:** 54.5 **G2:** 52 **BMI** **G1:** 25.5 (19-36) **G2:** 25 (18-38)	**Inclusion criteria:** • UDS+ detrusor overactivity **Exclusion criteria:** • UTI • DM • neurological dz • genital prolapse >/= POP-Q stage II • previous anti-incontinence or prolapse surgery • previous trt w/ antimuscarinics **Indications, N:**	**Menopause, n(%)** **G1:** 53 (63) **G2:** 16 (64) **HRT, n(%)** **G1:** 13 (24.5) **G2:** 6 (37.5) **Reported in relation to urodynamic findings** 1. women who experienced involuntary detrusor contractions during the filling phase spontaneously N=84 2. women who experienced involuntary detrusor contractions after provocative maneuvers such as listening to running water or washing hands in cold water N=25	**Non-response to trt, proportion (%):** **G1:** 12/84 (14) **G2:** 12/25 (48) G1<G2 (*P* = 0.0008)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: - Loss to followup: ++ Drop-out rates: ++ Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: - Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Sand et al., 2004 **Country and setting:** US, Specialty clinic **Enrollment period:** Subanalysis of OBJECT trial, women only **Funding:** ALZA Corp **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** 10mg ER Oxybutynin daily vs 4mg Tolterodine (2mg b.i.d.) **Groups:** **G1:** 10mg ER Oxybutynin daily x 12 wks **G2:** 4mg Tolterodine (2mg b.i.d.) x 12 wks **Stratified by age:** **a:** Age ≤ 64 **b:** Age 65-74 **c:** Age ≥ 75 **N at enrollment:** **G1:** 152 **G2:** 163 **N at follow-up:** **G1:** 132 **G2:** 146 **Women, %:** 100 **Age, yrs ± SD:** **G1:** 58.4 **G2:** 58.8 **Race/ethnicity:** NR	**Inclusion criteria:** • ≥ 7 and ≤ 50 UUI episodes/week • ≥ 10 voids/day • MUI included if predominant UUI **Exclusion criteria:** • UTI • IC • Urethral diverticulum • Bladder tumor • Bladder stone • Delivery within 6 mos • Pelvic, bladder, vaginal surgery in ≤ 6 mos • PVR ≥ 150 mL • Cardiovascular, renal, pulmonary, gastrointestinal, endocrine, neurologic, autoimmune, hematological, urological, psychiatric, or hepatic disease • Hematuria • Positive urine culture • Narrow angle glaucoma • Obstructive uropathy • Myasthenia gravis • POP to hymenal ring • Gastrointestinal obstruction • Decreased GI motility • GI narrowing • GI retention	**UUI episodes/ week, mean:** **G1:** 25.2 **G2:** 25.1 **Incontinence episodes/week, mean:** **G1:** 28.1 **G2:** 28.9 **Voids/week, mean:** **G1:** 91.7 **G2:** 91.6 **Naïve to anti-cholinergics, %:** **G1:** 60.5 **G2:** 60.7	**UUI episodes/ week, %:** **G1:** 6.2 **G2:** 8.5 **G1a:** 5.0 **G2a:** 8.4 **G1b:** 5.5 **G2b:** 7.5 **G1c:** 8.5 **G2c:** 11.1 **G1/G2:** *P* = 0.038 **G1a/G2a:** *P* = 0.005 **G1b/G2b:** *P* = 0.337 **G1c/G2c:** *P* = 0.568 **Incontinence episodes/week, mean:** **G1:** 7.3 **G2:** 10.1 **G1a:** 5.8 **G2a:** 10.0 **G1b:** 6.1 **G2b:** 9.2 **G1c:** 10.5 **G2c:** 12.5 **G1/G2:** *P* = 0.030 **G1a/G2a:** *P* = 0.005 **G1b/G2b:** *P* = 0.164 **G1c/G2c:** *P* = 0.714 **Voids/week, mean:** **G1:** 68.0 **G2:** 71.2 **G1a:** 63.7 **G2a:** 71.2 **G1b:** 73.8 **G2b:** 71.9 **G1c:** 66.8 **G2c:** 65.5 **G1/G2:** *P* = 0.272 **G1a/G2a:** *P* = 0.024 **G1b/G2b:** *P* = 0.706 **G1c/G2c:** *P* = 0.838	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Sand et al., 2004 (continued)		• Investigational drugs within 1 month of screening • Hypersensitivity to drugs • Current drug/ EtOH abuse • Pregnant • Breastfeeding • Inability to follow protocol		**Dry mouth, %:** **G1:** 28.3 **G2:** 33.7 **Constipation, %:** **G1:** 8.6 **G2:** 6.7 **Retention, %:** **G1:** 4.0 **G2:** 1.2 **Blurred vision, %:** **G1:** 2.6 **G2:** 0.6 **Dizziness, %:** **G1:** 3.9 **G2:** 4.3 **Insomnia, %:** **G1:** 0.7 **G2:** 1.8 **Somnolence, %:** **G1:** 3.3 **G2:** 1.8 **Nervousness, %:** **G1:** 0 **G2:** 1.2 **Headache, %:** **G1:** 9.2 **G2:** 10.4 **Dyspepsia, %:** **G1:** 5.3 **G2:** 6.1 **Nausea, %:** **G1:** 3.3 **G2:** 1.8 **Vomiting, %:** **G1:** 2.0 **G2:** 1.8	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Sand et al., 2006 [See evidence table for Sand et al., 2007] **Country and setting:** US, 327 centers **Enrollment period:** NR **Funding:** Watson Laboratories, Inc **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Oxybutynin transdermal system 3.9 mg/day, twice weekly patch for up to 6 months with "standard instruction" or with "educational intervention". Evaluate changes in HRQoL using Kings Health Questionnaire (KHQ) and Beck Depression Inventory II (BDI-II) **Groups:** **G1:** Standard instructions **G2:** Educational intervention (educational booklet, OAB newsletters, dosing reminders, calendar reminders, bladder diary) **N at enrollment:** Total: 2878 **G1:** **G2:**1596 **N at follow-up:** NR **Age, mean yrs ± SD:** 62.5 ± 14.8 **Women, %:** 87.2	**Inclusion criteria:** • ≥18 years old • UUI, urinary urgency or frequency • Willing to discontinue all prescription and OTC medications for OAB • Capable of completing QOL questionnaires without assistance • Negative pregnancy test & medically acceptable contraceptive **Exclusion criteria:** • Contra-indications to oxybutynin • Reversible etiologies for OAB • Prior treatment with Oxytrol • Long-term care facilities and nursing homes	**History of OAB, years, %:** <1 yr: 12.0% 1-2 yr: 18.5% 2-4 yr: 23.1% ≥ 4 yr: 46.4% **Sexually active:** Yes: 1500 (59.2%) No: 1034 (40.8%) **Coital incontinence, n (%):** Omitted or NA: 1924 (77.2) A little: 324 (13) Moderately: 137 (5.5) A lot: 108 (4.3) Total with incontinence: 569 (22.8%) **KHQ, embarrassed by bladder problems:** Yes: (1845/2571) 71.8% **OAB affects sex life:** 586 (39% of 1500 who answered; 23.1% of total population) **OAB affects relationship with partner:** Yes: 622 (37.3% of 1666 who answered, 24.4% of total population)	**Coital incontinence, n (%):** Omitted or NA: 1831 (80.7) A little: 260 (11.5) Moderately: 116 (5.1) A lot: 62 (2.7) Total with incontinence: 438 (19.3%) **Coital incontinence, n (%):** Improved: 277 (12.6%) Worsened: 165 (7.5%) *P* < 0.0001 **Embarrassed by OAB:** Improved: 828 (35.5%) Worsened: 251 (11.1%) *P* < 0.0001 **Effect of OAB on sex life:** Improved: 429 (19.1%) Worsened 251 (11.1%) *P* < 0.0001 **Effect of OAB on relationship with partners:** Improved: 444 (19.6%) Worsened: 271 (11.9%) *P* < 0.0001 **Interest in sex:** Improved: 472 (23.4%) Worsented: 246 (12.2%) *P* < 0.0001	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Sand et al., 2006 (continued)	**Race/ethnicity, %:** White: 83.6 African American: 9.9 Hispanic: 4.8 Asian: 1.2 Other: 0.5 **Follow-up:** 6 months		**Decreased interest in sex:** Total: 1219 (52.1%) Less interest: 589 (25.2%) Much less interest: 228 (9.7%) Complete loss of interest: 402 (17.2%)	**Improvement in all KHQ domains and BDI-II summary scores** (P < 0.0001) No difference between G1 and G2 in baseline sexual symptoms or improvement	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Sand et al., 2007 **Country and setting:** US, Multicenter, 327 sites (141 Urology 141, 96 Primary care, 43 Ob-Gyn, 17 Geriatric Med) **Enrollment period:** NR **Funding:** Watson Laboratiories, Inc **Author industry relationship disclosures:** 7 of 7 Allergan (1) Astellas (1) Esprit (1) GlaxoSmithKline (2) GSK (1) GTx (1) Indevus-Esprit (1) Lilly (1) Novartis (3) Ortho-McNeil (1) Ortho Urology (1) Pfizer (4) Sanofi (1) USB (1) Watson (6)	**Design:** RCT, open-label (case series for drug, RCT for educational materials) **Intervention:** Oxybutynin transdermal system 3.9 mg/day, twice weekly patch for up to 6 months with "standard instruction" or with "educational intervention". Evaluate changes in HRQoL using KHQ **Groups:** **G1:** Standard instructions **G2:** Educational intervention (educational booklet, OAB newsletters, dosing reminders, calendar reminders, bladder diary) **N at enrollment:** Total: 2,878 **G1:** 1,282 **G2:** 1,596 **Women, %:** 87.2 **Age, yrs ± SD:** 62.5 ± 14.8 **Race/ethnicity, %:** White: 83.6 African American: 9.9 Hispanic: 4.8 Asian: 1.2 Other: 0.5 **Follow-up:** 6 months	**Inclusion criteria:** • Age ≥18 • UUI, urinary urgency or frequency • Willing to discontinue all prescription and OTC medications for OAB • Capable of completing QOL questionnaires without assistance • Negative pregnancy test & medically acceptable contraceptive **Exclusion criteria:** • Contraindications to oxybutynin • Reversible etiologies for OAB • Prior treatment with Oxytrol • Long-term care facilities and nursing homes	**KHQ, UUI severity item score, %:** A lot: 38.1 Moderately: 31.3 A little: 20.5 Omitted, N/A: 10.1 **KHQ, urgency severity item score, %:** A lot: 49.2 Moderately: 30.3 A little: 14.8 Omitted, N/A: 5.6 **KHQ, frequency severity item score, %:** A lot: 59.3 Moderately: 32.5 A little: 7.2 Omitted, N/A:1.0 **KHQ, nocturia severity item score, %:** A lot: 47.3 Moderately: 33.5 A little: 16.7 Omitted, N/A: 2.4 **History of OAB, years, %:** <1 year: 12.0 1-2 years: 18.5 2-4 years: 23.1 ≥ 4 years: 46.4 **OAB Severity:** No problem: 1.8 Very minor: 4.6 Minor: 15.5 Moderate: 33.0 Severe: 28.4 Many severe problems: 16.7 **Previous OAB treatments, n (%):** 0: 43.4 1: 38.7 2: 13.1 3: 2.9 4: 1.9	**KHQ, UUI severity item score, %:** A lot: 21.3 Moderately: 29.5 A little: 31.6 Omitted, N/A: 17.7 **KHQ, urgency severity item score, %:** A lot: 27.3 Moderately: 33.8 A little: 27.3 Omitted, N/A: 11.5 **KHQ, frequency severity item score, %:** A lot: 33.5 Moderately: 45.2 A little: 18.7 Omitted, N/A: 2.6 **KHQ, nocturia severity item score, %:** A lot: 27.5 Moderately: 35.4 A little: 31.3 Omitted, N/A: 5.7 **KHQ, general health perception, mean ± SD (% improvement):** -1.2 ± 17.4 (-4.3) **KHQ, incontinence Impact, mean ± SD (% improvement):** -13.5 ± 29.5 (-19.5) **KHQ, symptom severity, mean ± SD (% improvement):** -12.4 ± 24.8 (-22.2)***	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Sand et al., 2007 (continued)			**KHQ, general health perception, mean ± SD:** 28.2 ± 19.8 **KHQ, incontinence Impact, mean ± SD:** 69.3 ± 27.4 **KHQ, symptom severity, mean ± SD:** 55.9 ± 20.5* **KHQ, role limitations, mean ± SD:** 45.1 ± 31.0 **KHQ, physical limitations, mean ± SD:** 46.7 ± 31.6 **KHQ, social limitations, mean ± SD:** 25.6 ± 28.3 **KHQ, emotions, mean ± SD:** 30.0 ± 29.2 **KHQ, personal relationships, mean ± SD:** 20.6 ± 29.5*** **KHQ, sleep/ energy, mean ± SD:** 54.2 ± 27.3 **KHQ, severity (coping) measures, mean ± SD:** 47.9 ± 26.4	**KHQ, role limitations, mean ± SD (% improvement):** -13.3 ± 29.2 (-29.5) **KHQ, physical limitations, mean ± SD (% improvement):** -11.7 ± 29.9 (-25.1) **KHQ, social limitations, mean ± SD (% improvement):** -6.7 ± 23.7 (-26.2) **KHQ, emotions, mean ± SD (% improvement):** -8.8 ± 25.4 (-29.3) **KHQ, personal relationships, mean ± SD (% improvement):** -6.0 ± 23.5 (-29.1)*** **KHQ, sleep/energy, mean ± SD (% improvement):** -11.2 ± 24.1 (-20.7) **KHQ, severity (coping) measures, mean ± SD (% improvement):** -8.6 ± 21.3 (-18.0) **Side effects, application site, %:** Total: 14.0 Pruritis: 4.9 Erythema: 4.6 Dermatitis: 4.4 Irritation: 3.2 Other: 2.0 **Side effects, %:** Rash: 3.0 Dry mouth: 2.6 Pruritis: 2.6 Skin irritation: 2.1	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Sand et al., 2007 (continued)				**Withdrew due to AEs, %:** 21.3 Withdrew: 1452 (50.5%) Adverse events 21.3% Withdrawn consent: 7.5% Requirement for alternative therapy 7.4% Loss to follow-up 7.2% Noncompliance 5.6% Administrative decision 0.7% Ineligible: 0.4% Death 0.1% No reason given 0.3%	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Song et al., 2006 **Country and setting:** Korea, Medical Center **Enrollment period:** May 2001 to April 2002 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** bladder training (BT) vs. Tolterodine vs. BT + Tolterodine **Groups:** **G1:** BT x 12 wks **G2:** Tolterodine 2 mg b.i.d. x 12 wks **G3:**Tolterodine 2 mg b.i.d. + BT x 12 wks **N at enrollment:** **G1:** 46 **G2:** 47 **G3:** 46 **N at follow-up:** **G1:** 26 **G2:** 32 **G3:** 31 **Women, %:** 100 **Age, mean ± SD:** **G1:** 45.73 ± 12.68 **G2:** 48.41 ± 9.38 **G3:** 45.42 ± 9.54 **Race/ethnicity, %:** Korean: 100	**Inclusion criteria:** • Age ≥ 18 • ≥ 8 voids/day • Urge with or without incontinence • Symptom duration ≥ 3 months • No prior history of treatment for OAB **Exclusion criteria:** • Active urinary tract infection • Clinically significant SUI • Bladder outlet obstruction • Interstitial cystitis • Glaucoma • Megacolon • Maximal urine flow rate of < 10 mL/sec • Postvoid residual volume > 30% of the total amount voided on uroflowmetry	**Voids/day, mean ± SD:** **G1:** 10.93 ± 2.14 **G2:** 11.63 ± 2.57 **G3:** 11.90 ± 1.51 **Nocturia episodes/day, mean ± SD:** **G1:** 1.45 ± 1.14 **G2:** 1.72 ± 1.04 **G3:** 1.96 ± 1.49 **Urgency, mean score ± SD:** **G1:** 2.58 ± 1.30 **G2:** 2.81 ± 0.74 **G3:** 3.00 ± 1.10 **Maximum flow rate (mL/s), mean ± SD:** **G1:** 20.35 ± 8.44 **G2:** 22.56 ± 4.94 **G3:** 21.19 ± 4.96 **Residual urine (mL), mean ± SD:** **G1:** 9.08 ± 22.56 **G2:** 7.59 ± 12.39 **G3:** 6.42 ± 10.16 **Symptom duration (years), mean ± SD:** **G1:** 6.44 ± 6.84 **G2:** 4.54 ± 5.15 **G3:** 4.10 ± 3.99	**Voids/day, mean (% decrease)** **G1:** 8.1 (25.9%)* **G2:** 8.1 (30.2%)* **G3:** 7.9 (33.5%)* **G3/G1:** *P* < 0.05 **Nocturia episodes/day, mean (% reduction):** **G1:** 0.6 (56.1%)* **G2:** 0.6 (65.4%)* **G3:** 0.6 (66.3%)* **Urgency, mean score (% reduction):** **G1:** 1.4 (44.8%)* **G2:** 1.1 (62.2%)* **G3:** 1.2 (60.2%)* **G3/G1:** *P* = 0.021 **G2/G1:** *P* = 0.017 **G2/G3:** *P* = NS **Satisfaction, mean score (% improved):** **G1:** 1.5 (53.9) **G2:** 1.4 (63.0) **G3:** 1.3 (71.0) **Dry mouth, n (%):** **G1:** 0 (0.0) **G2:** 7 (21.9) **G3:** 9 (28.9) **Hesitancy, n (%)** **G1:** 0 (0.0) **G2:** 3 (9.4) **G3:** 2 (6.5) **Decreased appetite/constipation, n (%):** **G1:** 0 (0.0) **G2:** 2 (6.3) **G3:** 2 (6.5) **Headache, n (%):** **G1:** 0 (0.0) **G2:** 1 (3.1) **G3:** 0 (0.0)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: + Loss to followup: - Drop-out rates: + Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Staskin et al., 2007 **Country and setting:** US, Multicenter **Enrollment period:** August 2005 to May 2006 **Funding:** Esprit Pharma, Indevus Pharmaceuticals **Author industry relationship disclosures:** 4 of 4 Allergan (3) Astellas (3) Eli Lilly (1) Esprit (4) GlaxoSmithKline (2) Indevus (3) Medtronics (1) Novartis (3) Ortho (1) Pfizer (2) Schwartz (1) Watson (4)	**Design:** RCT **Intervention:** Trospium chloride ER **Groups:** **G1:** trospium chloride ER 60mg qd **G2:** placebo **N at enrollment:** **G1:** 298 **G2:** 303 **N at follow-up:** **G1:** 263 **G2:** 273 **Women, n (%):** **G1:** 254 (85.2) **G2:** 256 (84.5) **Age, mean (SE):** **G1:** 59.6 (0.77) **G2:** 59.3 (0.70) **Race/ethnicity, %:** **White:** **G1:** 86.6 **G2:** 85.5 **Black:** **G1:** 8.7 **G2:** 9.9 **Hispanic:** **G1:** 3.0 **G2:** 2.3 **Asian:** **G1:** 1.0 **G2:** 1.3 **Other** **G1:** 0.7 **G2:** 1.0	**Inclusion criteria:** • Age ≥18 • OAB symptoms for ≥ 6 mos • ≥ 1 "severe" urgency severity rating per 3 days, measured Indevus Urgency Severity Scale • ≥ 30 voids per 3 days • ≥ 1 UUI episodes/day • Average total volume voided < 3L per day and < 250 per void **Exclusion criteria:** • SUI • Insensate incontinence or overflow incontinence • Neurogenic bladder • Significant renal disease • Hematuria • Current UTI • ≥ 3 UTIs during previous year • Significant bladder outlet obstruction • Indwelling catheter • Active IBD • Interstitial cystitis • Bladder cancer • PSA > 4 ng/ml • Prostate cancer or chronic prostatitis • Undergoing or likely to undergo bladder retraining or drill program • Diuretic estrogen use outside of a long-term stable program •	**Prior OAB medications, n (%):** **G1:** 159 (53.4) **G2:** 151 (49.8)	**UUI episodes/day, wk 1, mean change ± SD:** **G1:** -1.86 ± 0.13 **G2:** -1.24 ± 0.14 *P* = .0003 **UUI episodes/day, wk 4, mean change ± SD:** **G1:** -2.36 ± 0.17 **G2:** -1.75 ± 0.15 *P* = 0.0051 **UUI episodes/day, wk 12, mean change ± SD:** **G1:** -2.48 ± 0.17 **G2:** -1.93 ± 0.16 *P* = 0.0022 **UUI episodes/wk, wk 1, mean change ± SD:** **G1:** -13.03 ± 0.91 **G2:** -8.66 ± 0.95 *P* = 0.0003 **UUI episodes/wk, wk 4, mean change ± SD:** **G1:** -16.50 ± 1.17 **G2:** -12.24 ± 1.07 *P* = 0.0054 **UUI episodes/wk, wk 12, mean change ± SD:** **G1:** -17.34 ± 1.18 **G2:** -13.49 ± 1.09 *P* = 0.0024 **Urgency-associated voids/day, wk 1, mean change ± SD:** **G1:** -1.90 ± 0.16 **G2:** -1.34 ± 0.16 *P* = 0.0033	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: - Loss to followup: + Drop-out rates: + Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Staskin et al., 2007 (continued)				**Urgency-associated voids/day, wk 4, mean change ± SD:** **G1:** -2.66 ± 0.17 **G2:** -1.71 ± 0.18 *P* = 0.0003 **Urgency-associated voids/day, wk 12, mean change ± SD:** **G1:** -3.11 ± 0.17 **G2:** -2.12 ± 0.19 *P* < 0.0001 **Voids/day, wk 1, mean change ± SD:** **G1:** -1.66 ± 0.14 **G2:** -1.24 ± 0.13 *P* = 0.0092 **Voids/day, wk 4, mean change ± SD:** **G1:** -2.44 ± 0.15 **G2:** -1.58 ± 0.15 *P* < 0.001 **Voids/day, wk 12, mean change ± SD:** **G1:** -2.81 ± 0.15 **G2:** -1.99 ± 0.16 *P* < 0.001 **Urgency severity score/void, wk 1, mean change ± SD:** **G1:** -0.21 ± 0.02 **G2:** -0.10 ± 0.02 *P* = 0.0002 **Urgency severity score/void, wk 4, mean change ± SD:** **G1:** -0.26 ± 0.03 **G2:** -0.13 ± 0.03 *P* = 0.0008	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Staskin et al., 2007 (continued)				**Urgency severity score/void, wk 12, mean change ± SD:** **G1:** -0.32 ± 0.03 **G2:** -0.18 ± 0.03 *P* = 0.0004 **OAB-SCS, wk 1, mean change ± SD:** **G1:** -6.96 ± 0.51 **G2:** -4.81 ± 0.55 *P* = 0.0002 **OAB-SCS, wk 4, mean change ± SD:** **G1:** -9.67 ± 0.56 **G2:** -6.13 ± 0.64 *P* < 0.0001 **OAB-SCS, wk 12, mean change ± SD:** **G1:** -11.20 ± 0.55 **G2:** -7.80 ± 0.67 *P* < 0.0001 **Voided volume (mL), wk 1, mean change ± SD:** **G1:** 21.61 ± 2.76 **G2:** 12.07 ± 2.11 *P* = 0.0036 **Voided volume (mL), wk 4, mean change ± SD:** **G1:** 30.00 ± 3.14 **G2:** 17.24 ± 2.47 *P* = 0.0007 **Voided volume (mL), wk 12, mean change ± SD:** **G1:** 29.77 ± 3.16 **G2:** 18.89 ± 2.79 *P* = 0.0039 **Subjects who achieved normalization, %:** **G1:** 20.5 **G2:** 11.3 *P* < 0.01	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Staskin et al., 2007 (continued)				**At least 1 treatment emergent AE, n (%):** **G1:** 80 (26.8) **G2:** 53 (17.5) **Dry mouth, n (%):** **G1:** 26 (8.7) **G2:** 9 (3.0) **Constipation, n (%):** **G1:** 28 (9.4) **G2:** 4 (1.3) **Headache, n (%):** **G1:** 3 (1.0) **G2:** 8 (2.6)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Steers et al., 2005 **Country and setting:** US (49) and Canada (15), Multicenter **Enrollment period:** NR **Funding:** Pfizer **Author industry relationship disclosures:** 3 of 4 Pfizer (3)	**Design:** RCT **Intervention:** Darifenacin CR vs. placebo **Groups:** **G1:** Darifenacin CR 7.5-15 mg qd **G2:** Placebo **G3:** Increased dose at 2 wks **G4:** No increased dose at 2 wks **N at enrollment:** **G1:** 269 **G2:** 129 **N at follow-up:** **G1:** 261 **G2:** 123 **Women, N (%):** **G1:** 227 (84.7) **G2:** 106 (83.5) **Age, yrs (range):** **G1:** 57.5 (27-89) **G2:** 58.5 (22-86) **Aged < 65 years, n (%)** **G1:** 183 (68.3) **G2:** 81 (63.8) **Race/ethnicity:** NR	**Inclusion criteria:** • Age ≥ 18 • OAB symptoms for ≥ 6 mos • Capable of independent toileting • ≥ 5 episodes of UI per wk • ≥ 8 voids/day • Strong desire to void ≥ 1 times per day • Adequate method of contraception **Exclusion criteria:** • BPH on a non-stable dose of finasteride for < 6mos • Contra-indications to anticholinergic medication • Clinically significant SUI • BOO • PVR of > 200 mL • Pregnant or breastfeeding • GU conditions that could cause urinary symptoms • Fecal impaction or severe constipation (< 3 BM/wk) • Urogenital surgery in past 6 mos • Bladder biopsy in last 30 days • Indwelling catheter • Intermittent self-catherization • Intention to start a bladder-training program during study	**Urgency episodes/day, median (IQR):** **G1:** 8.3 (6.4, 10.6) **G2:** 8.0 (5.6, 10.3) **Severity of urgency, VAS score, median (IQR):** **G1:** 53 (41-66) **G2:** 53 (39-66) **Incontinence episodes/wk, median (IQR):** **G1:** 16.3 (9.1, 29.6) **G2:** 14.0 (9.0, 26.0) **Significant leaks/week, median (IQR):** **G1:** 7.0 (2.0, 13.1) **G2:** 5.3 (1.0, 11.2) **Voids/day, median (IQR):** **G1:** 9.9 (8.6, 11.9) **G2:** 10.4 (8.3, 11.6) **Nocturia episodes/week, median (IQR):** **G1:** 12.0 (7.0-16) **G2:** 11.2 (6.1-16) **Voided volume (mL), median (IQR):** **G1:** 175 (125, 253) **G2:** 177 (120, 229) **Idiopathic OAB, n (%):** **G1:** 253 (94.4) **G2:** 123 (96.8)	**Urgency episodes/day, median change (%):** **G1:** -2.3 (-28.2) **G2:** -0.9 (-11.0) **G1/G2:** *P* < 0.001 **Severity of urgency, VAS score, median change (%):** **G1:** -9.1 (-16.8) **G2:** -3.2 (-5.6) **G1/G2:** *P* < 0.05 **Significant leaks/week, median change (%):** **G1:** -3.0 (-67.3) **G2:** -1.8 (-42.9) **G1/G2:** *P* < 0.01 **Voids/day, median change (%):** **G1:** -1.9 (-18.9) **G2:** -1.0 (-10.0) **G1/G2:** *P* < 0.001 **Nocturia episodes/week, median change (%):** **G1:** -2.0 (-18.0) **G2:** -1.0 (-12.5) **G1/G2:** *P* = NS **Voided volume (mL), median change (%):** **G1:** 19 (10.5) **G2:** 7 (5.4) **G1/G2:** *P* < 0.05 **Constipation, n (%):** **G3:** 24 (22.2) **G4:** 32 (20.0) **Dry Mouth, n (%):** **G3:** 22 (20.4) **G4:** 28 (17.5) **Headache, n (%):** **G3:** 5 (4.6) **G4:** 13 (8.1)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Steers et al., 2005 (continued)		• Concomitant use anticholinergics, antispasmodics, opioids, other drugs known to cause constipation, HRT (unless taken for ≥ 2 months), and P450 3A4 inhibitors	**Previous drug therapy for frequency, enuresis, or incontinence, n (%):** **G1:** 62 (23.1) **G2:** 32 (25.2)		

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Steers et al., 2007 **Country and setting:** Australia, Canada, US; multicenter, 30 centers **Enrollment period:** July 2001 to September 2003 **Funding:** Eli Lilly, Boehringer Ingelheim GmbH. **Author industry relationship disclosures:** 7 of 7 Eli Lilly (7)	**Design:** RCT, placebo-controlled, double-blind, stratified by urodynamic observation **Intervention:** duloxetine vs placebo **Groups:** **G1:** placebo x 2 wks, duloxetine 40 mg b.i.d. x 4 wks, duloxetine 60 mg b.i.d. x 8 wks **G2:** placebo b.i.d. x 14 wks **N at enrollment:** **G1:** 153 **G2:** 153 **N at follow-up, N (%):** **G1:** 90 (59) **G2:** 120 (78) **Age, mean ± SD:** **G1:** 56.0 ± 14.8 **G2:** 53.3 ± 14.1 **Women, N (%):** 306 (100) **BMI, mean kg/m2 ± SD:** **G1:** 29.2 (7.4) **G2: 30.2 (7.8)**	**Inclusion criteria:** • women • >18 yoa • predominant symptoms of OAB ≥ 3 months defined as bothersome urinary urgency and/or urge, abnormal voiding frequency (≤2 h mean daytime voiding interval) • UDS observation of either detrusor OA or urgency that limited bladder capacity to <400mL **Exclusion criteria:** • -SUI • PVR >100 mL • Mean 24 h total volume voided of ≥ 3L • Urine culture • ≥4 UTIs in past yr • Regular use of meds for OAB w/in 4wks of enrollment • Previous use of duloxetine • Continence surgery ≤ 6 mos • Any major surgery ≤ 3 mos • Pelvic organ prolapse > ICS Stage II • Non-pharm intervention ≤ 3 mos	**Incontinence episodes, all assessable pts, mean:** **G1:** 1.70 **G2:** 1.44 **Urinary incontinence episode (wet OAB):** **G1:** 2.34 **G2:** 2.07 **Pads/week, mean:** **G1:** 7.81 **G2:** 7.05 **Voids/day, mean:** **G1:** 10.76 **G2:** 10.49 **Daytime voiding interval, mean:** **G1:** 113.58 **G2:** 119.63 **Nocturia episodes/day, mean:** **G1:** 1.47 **G2:** 1.63 **Voided volume (mL), mean:** **G1:** 175.41 **G2:** 183.40 **QoL Instrument score, mean ± SD:** I-QOL: **G1:** 56.65 ± 24.80 **G2:** 57.11 ± 23.3 U-IIQ: **G1:** 2.44 ± 1.18 **G2:** 2.39 ± 1.15 U-UDI: **G1:** 3.18 ± 0.58 **G2:** 3.15 ± 0.71 **Bladder compliance (mL/cmH_20)** **G1:** 71.8 ± 85.7 **G2:** 79.3 ± 91.0	**Incontinence episodes, all assessable pts, mean change:** **G1:** -0.74 **G2:** -0.14 *P* = 0.006 **Incontinuence episodes, wet OAB pts, mean change:** **G1:** -1.03 **G2:** -0.24 *P* = 0.032 **Pads/week, mean change:** **G1:** -1.41 **G2:** -0.53 *P* = 0.143 **Voids/day, mean change:** **G1:** -1.81 **G2:** -0.62 *P* < 0.001 **Daytime voiding interval, mean change:** **G1:** 29.46 **G2:** 6.51 *P* < 0.001 **Nocturia episodes/day, mean change:** **G1:** 0.05 **G2:** -0.18 *P* = 0.004 **Voided volume (mL), mean change:** **G1:** 8.85 **G2:** 5.07 *P* = 0.171 **Condition improved, 80 mg/day, %:** **G1:** 59.9 **G2:** 42.9 *P* = 0.005	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: - Drop-out rates: ++ Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Steers et al., 2007 (continued)		• Pelvic-floor-muscle training that had not been stable for 3 mos or would not remain stable during the trial	**SUI:** **G1:** 0 **G2:** 0 **Maximum cystometric capacity mL** **G1:** 318.3 ± 152.4 **G2:** 330.4 ± 135.4 **Volume threshold for first detrusor contraction mL** **G1:** 226.4 ± 141.8 **G2:** 250.6 ± 146.0 **Moderate or severe bladder condition from PGI-I Scale (%):** **G1:** 84.9 **G2:** 88.8 **I-QOL total score, mean ± SD:** **G1:** 56.6 (24.9) **G2:** 57.0 (23.2) **UIE , mean ± SD:** **G1:** 1.55 (2.08) **G2:** 1.41 (2.00) **VE24 , mean ± SD:** **G1:** 10.8 (3.3) **G2:** 10.6 (3.6) **Symptom of bothersome urgency, %:** **G1:** 99.3 **G2:** 99.3 **Symptoms of urge UI, %:** **G1:** 88.2 **G2:** 88.9 **Symptoms of SUI:** **G1:** 42.5 **G2:** 50.3 **Urodynamic** DOA **G1:** 42.5 **G2:** 41.8	**Condition improved, 120 mg/day, %:** **G1:** 61.6 **G2:** 42.1 *P* = 0.008 **Condition improved, overall, %:** **G1:** 53.4 **G2:** 41.9 *P* = 0.052 **Headache:** **G1:** 13 (8.5) **G2:** 8 (5.2) *P* = 0.336 **Diarrhea:** **G1:** 10 (6.5) **G2:** 5 (3.3) *P* = 0.289 **Cough:** **G1:** 7 (4.6) **G2:** 6 (3.9) p>0.999 **Change in QOL Instrument score, mean ±:** **I-QOL** **G1:** 8.37 ± 15.89 **G2:** 4.87 ± 15.27 G1>G2 (*P* = .035) **U-IIQ** **G1:** -0.44 ± 0.76 **G2:** -0.22 ± 0.87 *P* = 0.018 **U-UDI** **G1:** -0.26± 0.67 **G2:** -0.19 ± 0.59 *P* = 0.440 **Bladder compliance (mL/cmH20)** **G1:** 16.5 ±131.3 **G2:** 1.0 ± 120.8 *P* = 0.655 **Maximum cystometric capacity mL** **G1:** 22.1 ± 116.4 **G2:** 23.8 ± 108.5 *P* = 0.619	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Steers et al., 2007 (continued)			**Sensory urgency:** **G1:** 57.5 **G2:** 58.2 **Previous continence surgery, %:** **G1:** 13.1 **G2:** 11.8 **Current pelvic-floor muscle training, %:** **G1:** 9.2 **G2:** 11.8 **Previous behavioral therapy, %:** **G1:** 3.3 **G2:** 2.6 **Previous tolterodine therapy, %:** **G1:** 10.5 **G2:** 7.2 **Previous oxybutynin therapy, %:** **G1:** 13.0 **G2:** 9.2	**Volume threshold for first detrusor contraction mL** **G1:** 90.0 ± 200.6 G2 : 13.9 ± 112.8 *P* = 0.254 **PGI-I score** Better 4 wks (80 mg/day) **G1:** 59.9 **G2:** 42.9 *P* = 0.005 **TEAEs reported, %** **G1:** 79.1 **G2:** 55.6 *P* < 0.001 **Appetite decreased** **G1:** 6 (3.9) **G2:** 0 G1>G2, *P* = 0.030 **Arthralgia** **G1:** 6 (3.9) **G2:** 3 (2.0) *P* = 0.501 **Somnolence:** **G1:** 6 (3.9) **G2:** 0 *P* = 0.30 **Sweating increased:** **G1:** 6 (3.9) **G2:** 2 (1.3) *P* = 0.283 **UTI:** **G1:** 6 (3.9) **G2:** 6 (3.9) p>0.999 **Anorgasmia** **G1:** 5 (3.3) **G2:** 0 G1>G2, *P* = 0.060 **Anxiety:** **G1:** 5 (3.3) **G2:** 0 G1>G2, *P* = 0.060	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Steers et al., 2007 (continued)				**Tremor:** **G1:** 5 (3.3) **G2:** 0 **G1>G2, *P* =** 0.060 **Upper respiratory infection:** **G1:** 5 (3.3) **G2:** 4 (2.6) *P* > 0.999 **Vomiting:** **G1:** 5 (3.3) **G2:** 3 (2.0) *P* = 0.723 **Abdominal pain:** **G1:** 4 (2.6) **G2:** 1 (0.7) *P* = 0.371 **Back pain:** **G1:** 4 (2.6) **G2:** 1 (0.7) *P* = 0.371 Note: mean change consistent at 4 wks (duloxetine 80 mg/d) and 8 wks (duloxetine 120 mg/d) **Change in I-QOL total score, mean ± SD:** **Discontinuation due to TEAEs, %** **G1:** 28.1 **G2:** 5.2 *P* < 0.001 **Treatment emergent adverse events, n (%):** **Nausea:** **G1:** 47 (30.7) **G2:** 7 (4.6) G1>G2, *P* < 0.001 **Dry mouth:** **G1:** 25 (16.3) **G2:** 2 (1.3) G1>G2, *P* < 0.001	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Steers et al., 2007 (continued)				**Dizziness:** **G1:** 22 (14.4) **G2:** 1 (0.07) G1>G2, *P* < 0.001 **Constipation:** **G1:** 21 (13.7) **G2:** 5 (3.3) G1>G2, *P* = 0.002 **Insomnia:** **G1:** 20 (13.1) **G2:** 5 (3.3) G1>G2, *P* = 0.003 **Fatigue:** **G1:** 16 (10.5) **G2:** 3 (2.0) G1>G2, *P* = 0.003	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Sussman and Garely, 2002 **Country and setting:** US, 2 sites **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Multicenter RCT **Intervention:** Tolterodine ER vs. Oxybutynin ER **Groups:** **G1:** Tolterodine ER 2 mg qd x 8 wks **G2:** Tolterodine ER 4 mg qd x 8 wks **G3:** Oxybutynin ER 5 mg qd x 8 wks **G4:** Oxybutynin ER 10 mg qd x 8 wks **N at enrollment:** **G1:** 333 **G2:** 336 **G3:** 313 **G4:** 307 **N at follow-up:** **G1:** 313 (86) **G2:** 316 (88) **G3:** 286 (81) **G4:** 285 (79) **Age, yrs ± SD:** **G1:** 63.8 ± 15.7 **G2:** 63.4 ± 16.6 **G3:** 59.8 ± 16.5 **G4:** 63.2 ± 15.9 **Women, N (%):** **G1:** 243 (73) **G2:** 254 (76) **G3:** 245 (78) **G4:** 222 (72) **Race/ethnicity, n (%):** **White:** **G1:** 278 (84) **G2:** 296 (88) **G3:** 256 (82) **G4:** 247 (81) **Black:** **G1:** 28 (8) **G2:** 23 (7) **G3:** 41 (13) **G4:** 42 (14)	**Inclusion criteria:** • 18+ years old • OAB (urinary frequency + urgency) w/ or w/o UI **Exclusion criteria:** • Pure SI • Urinary retention • Gastric retention • Uncontrolled narrow-angle glaucoma • Significant hepatic or renal dysfunction • Symptomatic or recurrent UTI • Electrostimulation • Bladder training • Pelvic floor exercise w/in 1 wk of first study visit or expected to start during study • Indwelling catheter • Intermittent self-cath • Contraindication to antimuscarinic trt • Estrogen therapy started less than 2 mos prior to first visit • Any trt for UI w/in 1 wk of first visit • Use of anticholinergic drug or potent inhibitors of cytochrome P450 3A4 • Pregnant • Lactating	**Presence of UI, n (%):** **G1:** 195 (59) **G2:** 214 (64) **G3:** 199 (64) **G4:** 195 (64) **Duration of sx, n (%):** < 6 months: **G1:** 38 (11) **G2:** 48 (14) **G3:** 62 (20) **G4:** 43 (14) 6 months to 5 years: **G1:** 226 (68) **G2:** 224 (67) **G3:** 183 (59) **G4:** 205 (67) > 5 years: **G1:** 68 (20) **G2:** 64 (19) **G3:** 67 (21) **G4:** 59 (19) **Severity of bladder condition, %** No problems: **G1:** 1.3 **G2:** 0.3 **G3:** 1.0 **G4:** 0.7 Some very minor problems: **G1:** 6 **G2:** 5 **G3:** 5 **G4:** 5 Some minor problems: **G1:** 18 **G2:** 16 **G3:** 21 **G4:** 15 Moderate problems **G1:** 45 **G2:** 50 **G3:** 41 **G4:** 47	**Improvement in bladder condition, 8 wks, overall, %:** **G1:** 60 **G2:** 70 **G3:** 59 **G4:** 60 **G2/G3:** *P* < 0.01 **G2/G4:** *P* < 0.01 **Improvement in bladder condition, 8 wks, moderate or severe bladder condition, %:** **G2:** 77 **G4:** 65 **G2/G4:** *P* < 0.01 **Improvement in bladder condition, 8 wks, treatment naïve, %:** **G1:** 60 **G2:** 69 **G3:** 60 **G4:** 61 *P* = 0.11 for improvement rates *P* > 0.05 for overall difference btw trt arms **Improvement in bladder condition, 8 wks, treatment experienced, %:** **G1:** 57 **G2:** 75 **G3:** 59 **G4:** 54 *P* = 0.11 for improvement rates *P* > 0.05 for overall difference btw trt arms **Withdrawal due to AE, (%):** **G2:** 6 **G4:** 13 *P* = 0.001	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Sussman and Garely, 2002 (continued)	**Hispanic:** **G1:** 19 (6) **G2:** 15 (5) **G3:** 15 (5) **G4:** 16 (5) **Other, n (%):** **G1:** 8 (2) **G2:** 2 (<1) **G3:** 1 (<1) **G4:** 2 (<1) **Parity:** NR	• Childbearing potential w/o adequate contraception	Severe problems: **G1:** 26 **G2:** 21 **G3:** 23 **G4:** 25 Many severe problems: **G1:** 4 **G2:** 7 **G3:** 8 **G4:** 8	**Mean change in severity of dry mouth (visual analogue scale):** **G1:** 2.3 **G2:** 6.0 **G3:** 6.3 **G4:** 11.3 G1 vs **G2:** *P* = NS G3 vs **G4:** *P* = 0.05 G2 vs **G4:** *P* = 0.03	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Swift et al., 2003 **Country and setting:** Europe (167 centers), North America (74 centers), Australia and New Zealand (4 centers), University **Enrollment period:** February 1999 to October 1999 **Funding:** Pharmacia Corp **Author industry relationship disclosures:** NR	**Design:** RCT double blind placebo-controlled double dummy, random permuted blocks of 6 **Intervention:** Tolterodine ER vs. Tolterodine IR **Groups:** **G1:** Tolterodine ER 4 mg daily **G2:** Tolterodine IR 2 mg b.i.d. **G3:** placebo **N at enrollment:** **G1:** 417 **G2:** 408 **G3:** 410 **N at follow-up:** Total: 1092 **Women, %:** 100 **Age, yrs ± SD:** **G1:** 59 ± 14 **G2:** 59 ± 14 **G3:** 60 ± 14 **Race/ethnicity, n (%):** **White:** **G1:** 396 (95) **G2:** 389 (95) **G3:** 383 (93) **Black:** **G1:** 15 (4) **G2:** 12 (3) **G3:** 20 (5) **Asian/Pacific:** **G1:** 5 (1) **G2:** 4 (1) **G3:** 2 (1) **Mixed:** **G1:** 0 **G2:** 3 (1) **G3:** 5 (1) **Unknown:** **G1:** 1 (<1) **G2:** 0 **G3:** 0	**Inclusion criteria:** • Women • Age ≥ 18 • ≥ 8 voids/day • > 5 UUI/ week • Symptoms x ≥ 6 months (per voiding diary) **Exclusion criteria:** • SUI • Total daily urine volume > 3 liters • Hepatic/ renal disease • UTI • IC • Hematuria • BOO • Current e-stim • Current bladder training • Indwelling catheter • CIC • Pregnant/ nursing • Childbearing age without BC • Anticholinergic meds • Meds inhibit cytochromep450	**Incontinence episodes/week, mean ± SD:** **G1:** 22.1 ± 22.5 **G2:** 22.9 ± 21.9 **G3:** 23.9 ± 21.2 **Pads/day, mean ± SD:** **G1:** 1.6 ± 2.1 **G2:** 1.5 ± 2.0 **G3:** 1.7 ± 2.4 **Voids/day, mean ± SD:** **G1:** 10.8 ± 4.2 **G2:** 11.1 ± 3.7 **G3:** 11.2 ± 3.9 **Voided volume (mL), mean ± SD:** **G1:** 141.2 ± 43.1 **G2:** 137.2 ± 41.2 **G3:** 135.7 ± 43.2 **Previous drug therapy: n (%):** **G1:** 235 (56) **G2:** 222 (54) **G3:** 225 (55)	**Incontinence episodes/week, mean ± SD:** **G1:** 10.3 ± 17.2 **G2:** 12.8 ± 19.8 **G3:** 16.7 ± 19.7 **G1/G3:** *P* = 0.001 **G2/G3:** *P* = 0.001 **Pads/day, mean ± SD:** **G1:** 1.0 ± 1.8 **G2:** 1.0 ± 1.5 **G3:** 1.5 ± 2.2 **G1/G3:** *P* = 0.001 **G2/G3:** *P* = 0.001 **Voids/day, mean ± SD:** **G1:** 9.0 ± 3.2 **G2:** 9.3 ± 4.0 **G3:** 9.9 ± 3.8 **G1/G3:** *P* = 0.001 **G2/G3:** *P* = 0.005 **Voided volume (mL), mean ± SD:** **G1:** 179.1 ± 66.6 **G2:** 169.7 ± 65.6 **G3:** 149.0 ± 56.3 **G1/G3:** *P* = 0.001 **G2/G3:** *P* = 0.001 **Clinical effect-tiveness*, dry mouth:** **G1:** 0.53 **G2:** 0.39 **G3:** 0.30 **Dry mouth, n (%):** **G1:** 105 (25.3) **G2:** 127 (31.2) **G3:** 33 (8.0) **G1/G3:** *P* < 0.01 **G2/G3:** *P* < 0.01 **Abdominal pain, n (%):** **G1:** 18 (4.3) **G2:** 12 (2.9) **G3:** 7 (1.7) **G1/G3:** *P* = 0.03 **Constipation, n (%):** **G1:** 27 (6.5) **G2:** 27 (6.6) **G3:** 14 (3.4)	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: + Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Swift et al., 2003 (continued)	**BMI, kg/m^2 ± SD:** **G1:** 28.8 ± 13.8 **G2:** 29.0 ± 11.0 **G3:** 28.8 ± 6.7			**Dyspepsia, n (%):** **G1:** 11 (2.7) **G2:** 14 (3.4) **G3:** 6 (1.5) **Nausea, n (%):** **G1:** 7 (1.7) **G2:** 9 (2.2) **G3:** 9 (2.2) **Diarrhea, n (%):** **G1:** 10 (2.4) **G2:** 14 (3.4) **G3:** 9 (2.2) **Flatulence, n (%):** **G1:** 8 (1.9) **G2:** 11 (2.7) **G3:** 6 (1.5) **Xerophthalmia, n (%):** **G1:** 16 (3.9) **G2:** 8 (2.0) **G3:** 8 (2.0) **Abnormal vision, n (%):** **G1:** 5 (1.2) **G2:** 4 (1.0) **G3:** 2 (0.5) **Headache, n (%):** **G1:** 29 (7.0) **G2:** 14 (3.4) **G3:** 19 (4.6) **UTI, n (%):** **G1:** 15 (3.6) **G2:** 11 (2.7) **G3:** 19 (4.6) **Insomnia, n (%):** **G1:** 7 (1.7) **G2:** 2 (0.5) **G3:** 9 (2.2) **Somnolence, n (%):** **G1:** 12 (2.9) **G2:** 11 (2.7) **G3:** 8 (2.0) **Dizziness, n (%):** **G1:** 7 (1.7) **G2:** 7 (1.7) **G3:** 4 (1.0)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Swift et al., 2003 (continued)				**Hypertension, n (%):** **G1:** 6 (1.4) **G2:** 4 (1.0) **G3:** 4 (1.0) **Sinusitis, n (%):** **G1:** 8 (1.9) **G2:** 2 (0.5) **G3:** 3 (0.7) **Arthritis, n (%):** **G1:** 1 (0.2) **G2:** 5 (1.2) **G3:** 1 (0.2) **Dry skin, n (%):** **G1:** 2 (0.5) **G2:** 5 (1.2) **G3:** 1 (0.2)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics*	Outcomes	Quality Rating
Author: Szonyi et al., 1995 **Country and setting:** UK **Enrollment period:** NR **Funding:** Smith & Nephew Pharmaceuticals Ltd **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Oxybutynin plus bladder training vs placebo plus bladder training **Groups:** **G1:** Oxybutynin 2.5 mg b.i.d. with dose titration on days 29 and 43 plus bladder training **G2:** placebo + bladder training **N at enrollment:** **G1:** 30 **G2:** 30 **N at follow-up:** **G1:**16 **G2:** 23 **Women, n (%):** 56 (93) **Age, mean ± SD:** 82.2 ± 6.06 **Race/ethnicity:** NR **Weight (kg), mean ± SD:** 67.4 ± 14.92	**Inclusion criteria:** • Age > 70 • Frequency, urgency and UUI • Mobile • Able to keep diary **Exclusion criteria:** • UTI • Hepatic or renal disease • Glaucoma • Uncontrolled diabetes • Taking imipramine or propantheline		**Voids/2 weeks, median change (95% CI):** **G1/G2:** 577 (-27.0, 6.0) *P* = 0.0025 **Nocturia episodes/2 weeks, median change (95% CI):** **G1/G2:** -6 (-5, 7.0) **Daytime incontinence episodes/2 weeks, median change (95% CI):** **G1 vs. G2:** -9.5 (-11.0, 3.0) **Nocturia episodes/2 weeks, median change (95% CI):** **G1/G2:** -1.0 (-3.0, 2.0) **Patient assess-ment of benefit, %:** 29 days: **G1:** 86 **G2:** 55 *P* = 0.02 43 days: **G1:** 71 **G2:** 59 *P* = 0.41 57 days: **G1:** 79 **G2:** 55 *P* = 0.09 **Patient response, 29 days, n:** Cure: **G1:** 1 **G2:** 0 Significant improvement: **G1:** 15 **G2:** 8 Marginal improvement: **G1:** 7 **G2:** 8	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics*	Outcomes	Quality Rating
Szonyi et al., 1995 (continued)				No change: **G1:** 5 **G2:** 13 **Patient response, 57 days, n:** Cure: **G1:** 4 **G2:** 3 Significant improvement: **G1:** 14 **G2:** 8 Marginal improvement: **G1:** 3 **G2:** 4 No change: **G1:** 7 **G2:** 14 **Dry mouth, %:** **G1:** 93 **G2:** 86 **Blurred vision, %:** **G1:** 50 **G2:** 59 **Heartburn, %:** **G1:** 57 **G2:** 45 **Constipation, %:** **G1:** 50 **G2:** 45 **Dry skin, %:** **G1:** 50 **G2:** 59 **Poor compliance (< 75% of tablets), %:** **G1:** 20 **G2:** 20	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Tseng et al., 2009 **Country and setting:** Taiwan, University **Enrollment period:** January 2005 to November 2005 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Prospective cohort randomized **Intervention:** Tolterodine 2 mg b.i.d. vs. tolterodine 2 mg b.i.d. + conjugated equine estrogen 0.625 mg twice per week **Groups:** **G1:** tolterodine 2 mg b.i.d. **G2:** tolterodine 2 mg b.i.d. + conjugated equine estrogen 0.625 mg twice per week **N at enrollment:** **G1**: 40 **G2:** 40 **N at follow-up:** **G1**: 40 **G2:** 40 **Age, mean ± SD:** **G1:** 64.5 ± 7.4 **G2:** 66.2 ± 6.8 **Race/ethnicity:** NR **Women, N (%):** **G1:** 40 (100) **G2:** 40 (100) **BMI, kg/m^2 ± SD:** **G1:** 24.5 ± 3.9 **G2:** 25.3 ± 3.8 **Previous antimuscarinic Rx, n (%):** **G1:** 5 (12.5) **G2:** 6 (15) **Prior hysteric-tomy, n (%):** **G1:** 12 (30) **G2:** 14 (35)	**Inclusion criteria:** • Age ≥ 18 • OAB symptoms • Amenorrheic **Exclusion criteria:** • Advanced POP > Stage 2 • Women with storage and voiding dysfunction undiagnosed • Severe constipation • Elevated PVR • Neurological deficit • Renal/ hepatic disease • Narrow angle glaucoma • Urinary retention • Gastric retention • Hypersensitivity to drugs • BOO • Cardiac conduction disorders • Myasthenia gravis • History of CVA • History of VTE • Gallbladder disease • Known or suspected breast carcinoma • Undiagnosed genital bleeding • HRT within 3 months of study enrollment	**UUI episodes/ day, mean ± SD:** **G1:** 1.8 ± 0.7 **G2:** 2.1 ± 1.1 **Urgency episodes/ day, mean ± SD:** **G1:** 4.5 ± 0.8 **G2:** 4.3 ± 0.7 **Nocturia episodes/ day, mean ± SD:** **G1:** 3.5 ± 0.8 **G2:** 3.3 ± 0.8 **Voids/day, mean ± SD:** **G1:** 14.1 ± 1.3 **G2:** 14.8 ± 1.5 **UDI-6 score, mean ± SD:** **G1:** 9.5 ± 3.9 **G2:** 8.6 ± 3.8 **IIQ-7 score, mean ± SD:** **G1:** 10.2 ± 4.5 **G2:** 9.4 ± 3.6 **Voided volume (mL), mean ± SD:** **G1:** 108.5 ± 14.0 **G2:** 115.8 ± 15.1	**UUI episodes/day, mean ± SD:** **G1:** 1.5 ± 0.5 **G2:** 1.5 ± 0.5 *P* = NS **Urgency episodes/ day, mean ± SD:** **G1:** 3.5 ± 0.5 **G2:** 3.3 ± 0.6 **Nocturia episodes/ day, mean ± SD:** **G1:** 2.9 ± 0.6 **G2:** 2.6 ± 0.7 **Voids/day, mean ± SD:** **G1:** 6.4 ± 1.9 **G2:** 5.8 ± 0.9 *P* = 0.001 **UDI-6 score, mean ± SD:** **G1:** 7.2 ± 2.9 **G2:** 6.9 ± 2.7 *P* < 0.001 **IIQ-7 score, mean ± SD:** **G1:** 6.5 ± 2.7 **G2:** 6.1 ± 2.5 *P* < 0.001 **Voided volume (mL), mean ± SD:** **G1:** 134.5 ± 15.8 **G2:** 141.9 ± 16.1 *P* = 0.007 **Adverse events:** None	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: + Method and blinding: - Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Van Kerrebroeck et al., 2001 Freeman et al., 2003* **Country and setting:** North America (74 centers), Australasia (4 centers), Europe (89 centers) **Enrollment period:** NR **Funding:** Pharmacia Corporation **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Tolterodine ER vs Tolterodine IR vs placebo **Groups:** **G1:** tolterodine ER 4 mg qd **G2:** tolterodine IR 2 mg b.i.d. **G3:** placebo **N at enrollment:** **G1:** 507 **G2:** 514 **G3:** 508 **N at follow-up:** **Total:** 1442 **G1:** 398 **G3:** 374 **Women, n (%):** **G1:** 417 (82) **G2:** 408 (79) **G3:** 410 (81) **Age, mean (range):** **G1:** 60 (20, 89) **G2:** 60 (22, 92) **G3:** 61 (22, 93) **Race/ethnicity, %:*** **White:** **G1:** 95.7 **G3:** 94.7 **Black:** **G1:** 3.0 **G3:** 3.5 **Asian/Pacific Islander:** **G1:** 1.0 **G3:** 0.8 **Other:** **G1:** 0.3 **G3:** 1.1	**Inclusion criteria:** • Age ≥ 18 • Urinary frequency (≥ 8 voids/day) **Exclusion criteria:** • SUI • Total daily urine volume > 3 L • Contra-indications to antimuscarinic treatment • Hepatic or renal disease • UITs • Interstitial cystitis • Hematuria • BOO • Current electrostimula-tion or bladder training therapy • Indwelling catheter or intermittent self-catheterization • Pregnant or nursing • Women not using reliable contraception • Being treated for OAB with other anticholinergic drugs or drugs that inhibit cytochrome P450 3A4 isoenzymes • Estrogen therapy < 2 months • Treatment w/ investigational drug < 2 months	**Incontinence episodes/week, mean (range):** **G1:** 22.1 (0, 168.0) **G2:** 23.2 (0, 168.0) **G3:** 23.3 (0, 168.0) **≥ 5 incontinence episodes/week, n (%):** **G1:** 492 (97) **G2:** 498 (97) **G3:** 494 (97) **Pads/day, mean (range):** **G1:** 1.4 (0-18) **G2:** 1.4 (0-25) **G3:** 1.5 (0-22) **Voids/day, mean (range):** **G1:** 10.9 (2.3, 51.3) **G2:** 11.1 (2.0, 48.6) **G3:** 11.3 (2.0, 37.4) **≥ 8 voids/day, n (%):** **G1:** 458 (90) **G2:** 469 (91) **G3:** 467 (92) **Previous drug therapy, n (%):** **G1:** 270 (53) **G2:** 276 (54) **G3:** 263 (52) **Poor efficacy, %:** **G1:** 43 **G2:** 38.4 **G3:** 40.7 **Able to finish tasks before visiting a toilet, %:*** **G1:** 5 **G3:** 6	**Urgency, subject-tive assessment, 12 wks, n (%):*** Improvement: **G1:** 173 (44) **G3:** 118 (32) **G1/G3:** *P* < 0.001 No change: **G1:** 201 (51) **G3:** 212 (57) Deterioration: **G1:** 22 (6) **G3:** 44 (12) **G1/G3:** *P* < 0.002 **Urgency, improve-ment, 12 wks, women only, %:*** **G1:** 46.6 **G3:** 26.6 **G1/G3:** *P* = 0.001 OR 1.81 (95% CI: 1.31, 2.49) **Not able to hold urine, 12 wks, %:*** **G1:** 58 **G3:** 32 **G1/G3:** *P* < 0.001 **Incontinence episodes/week, mean change ± SD (%)** **G1:** -11.8 ± 17.8 **G2:** -10.6 ± 16.9 **G3:** -6.9 ± 15.4 **G1/G3:** *P* = 0.00001 **G2/G3:** *P* = 0.0005 **G1/G2:** *P* < 0.05 **Incontinence episodes/week, median % change:** **G1:** -71 **G2:** -60 **G3:** -30 **G1/G2:** *P* < 0.05	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Van Kerrebroeck et al., 2001 Freeman et al., 2003* (continued)			**Voided volume (mL), mean (range):** **G1:** 141 (36, 338) **G2:** 137 (38, 283) **G3:** 136 (31, 374)	**Pads/day, mean ± SD:** **G1:** -0.5 ± 1.4 **G2:** -0.5 ± 18 **G3:** -0.2 ± 1.4 **G1/G3:** *P* = 0.0145 **G2/G3:** *P* = 0.0035 **Voids/day, mean ± SD:** **G1:** -3.5 ± 4.9 **G2:** -3.3 ± 4.4 **G3:** -2.2 ± 4.0 **G1/G3:** *P* = 0.00001 **G2/G3:** *P* = 0.0002 **Voluntary voids/ day, mean ± SD:** **G1:** -1.8 ± 3.4 **G2:** -1.7 ± 3.3 **G3:** -1.2 ± 2.9 G1 vs G3 **G1/G3:** *P* = 0.00047 **G2/G3:** *P* = 0.0079 **Bladder symptoms, improvement, 12 wks, women only, %:*** **G1:** 62.8 **G3:** 48.4 **G1/G3:** *P* = 0.001 OR 1.78 (95% CI: 0.34, 2.37) **Treatment benefit, 12 wks, n (%):*** **Much benefit:** **G1:** 172 (43.2) **G3:** 88 (23.5) **G1/G3:** *P* < 0.001 Little benefit **G1:** 138 (34.7) **G3:** 118 (31.6) No benefit **G1:** 88 (22.1) **G3:** 168 (44.9)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Van Kerrebroeck et al., 2001 Freeman et al., 2003* (continued)				**Able to finish tasks before visiting a toilet, 12 wks, %:*** **G1:** 33 **G3:** 18 **G1/G3:** *P* < 0.001**Voided volume (mL), mean change ± SD:** **G1:** +34 ± 51 **G2:** +29 ± 47 **G3:** +14 ± 41 **G1/G3:** *P* = 0.00001 **G2/G3:** *P* = 0.0001 **Discontinued due to AEs, n (%):** **G1:** 27 (5) **G2:** 28 (5) **G3:** 33 (6) **Reported serious adverse events, n:** **G1:** 7 **G2:** 12 **G3:** 18 **Parasympathetic Dry mouth, n (%):** **G1:** 118 (23) **G2:** 156 (30) **G3:** 39 (8) **Xerophthalmia, n (%):** **G1:** 17 (3) **G2:** 12 (2) **G3:** 10 (2) **Abnormal vision, n (%):** **G1:** 6 (1) **G2:** 4 (1) **G3:** 2 (0.5) **Dry skin, n (%):** **G1:** 2 (0.5) **G2:** 6 (1) **G3:** 1 (0.5)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Van Kerrebroeck et al., 2001 Freeman et al., 2003* (continued)				**Gastrointestinal Constipation, n (%):** **G1:** 30 (6) **G2:** 35 (7) **G3:** 22 (4) **Dyspepsia, n (%):** **G1:** 15 (3) **G2:** 16 (3) **G3:** 7 (1) **Abdominal pain, n (%):** **G1:** 19 (4) **G2:** 13 (3) **G3:** 8 (2) **Diarrhea, n (%):** **G1:** 10 (2) **G2:** 16 (3) **G3:** 11 (2) **Flatulence, n (%):** **G1:** 10 (2) **G2:** 14 (3) **G3:** 9 (2) **Nausea, n (%):** **G1:** 7 (1) **G2:** 10 (2) **G3:** 10 (2) **Headache, n (%):** **G1:** 32 (6) **G2:** 19 (4) **G3:** 23 (5) **Somnolence, n (%):** **G1:** 14 (3) **G2:** 13 (3) **G3:** 9 (2) **Dizziness, n (%):** **G1:** 11 (2) **G2:** 9 (2) **G3:** 5 (1) **Fatigue, n (%):** **G1:** 11 (2) **G2:** 6 (1) **G3:** 4 (1) **Insomnia, n (%):** **G1:** 7 (1) **G2:** 2 (0.5) **G3:** 9 (2)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Van Kerrebroeck et al., 2001 Freeman et al., 2003* (continued)				**Urinary tract infection, n (%):** **G1:** 16 (3) **G2:** 13 (3) **G3:** 20 (4) **Dysuria, n (%):** **G1:** 5 (1) **G2:** 8 (2) **G3:** 1 (0.5) **Peripheral edema, n (%):** **G1:** 7 (1) **G2:** 7 (1) **G3:** 4 (1)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Versi et al., 2000 **Country and setting:** US, 20 Academic health centers **Enrollment period:** NR **Funding:** ALZA Corp **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Oxybutynin CR vs Oxybutynin IR Doses were increased/ decreased in 5 mg/d increments until optimal dose identified. Once identified the dose was maintained for 1 wk and urinary diary completed **Groups:** **G1:** Oxybutynin CR 5-20 mg/d **G2:** Oxybutynin IR 5-20 mg/d **N at enrollment:** **G1:** 111 **G2:** 115 **N at follow-up:** **G1:** 107 **G2:** 106 **Age, yrs ± SD:** **G1:** 58.8 **G2:** 59.6 **Race/ethnicity, %:** **White:** **G1:** 86.5 **G2:** 90.4 **Black:** **G1:** 5.4 **G2:** 3.5 **Hispanic** **G1:** 5.4 **G2: 5.2** **Asian:** **G1:** 0.9 **G2:** 0 **Native American** **G1:** 0 **G2:** 0.9	**Inclusion criteria:** • Known to be responsive to anticholinergic trt • 7-45 UI episodes per wk • Adult • Community-dwelling • 4+ days of incontinence/wk **Exclusion criteria:** • Clinically significant medical problems • PVR>100mL • Contraindication to oxybutynin	**UUI episodes/ week, mean:** **G1:** 18.6 **G2:** 19.8 **Incontinence episodes/week, mean:** **G1:** 20.2 **G2:** 22.4	**UUI episodes/ week, mean (%):** **G1:** 2.9 (83) **G2:** 4.4 (76) P value for change from baseline: **G1:** $P < 0.001$ **G2:** $P < 0.001$ $P = 0.36$ for % reduction **Incontinence episodes/week, mean (%):** **G1:** 3.5 (81) **G2:** 5.4 (75) P value for change from baseline: **G1:** $P < 0.001$ **G2:** $P < 0.001$ $P = 0.85$ for % reduction **Rates for Dry Mouth (%):** **G1:** 47.7 **G2:** 59.1 $P = 0.09$ **Pts reporting any dry mouth, cumulative %:** Dose of 5mg/day: **G1:** 18.9 **G2:** 35.7 Dose of 10mg/day: **G1:** 39.5 **G2:** 61.2 Dose of 15 mg/day: **G1:** 56.8 **G2:** 74.1 Dose of 20 mg/day: **G1:** 80.1 **G2:** 82.7 **G1/G2:** $P = 0.003$ for all comparisons	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Versi et al., 2000 (continued)	**Other** **G1:** 2 **G2:** 0 **Weight, mean kg:** **G1:** 78.0 **G2:** 79.0 **Height, mean cm:** **G1:** 163.7 **G2:** 165.1 **Women, %:** **G1:** 88.3 **G2:** 90.4 **Parity mean ± SD:** NR				

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Wang et al., 2002 **Country and setting:** US, Health care database **Enrollment period:** January 1991 to June 1995 **Funding:** Pharmacia **Author industry relationship disclosures:** NR	**Design:** Healthcare database utilization claims analysis (retrospective cohort) **Intervention:** Urinary antispasmotics including flavoxate, oxybutynin, hyoscyamine and hyocyamine sulfate **Groups:** **G1:** Prescribed any urinary antispasmotic in interval **G2:** No prescriptions for urinary antispasmotic agents **N in database:** **G1:** 3,898 **G2:** 10,740 **N at follow-up:** NA **Women, %:** **G1:** 75.4 **G2:** 67.0 **Age, mean:** **G1:** 78.0 **G2:** 80.3 **Race/ethnicity, %:** **White:** **G1:** 82.9 **G2:** 82.5 **Black:** **G1:** 12.5 **G2:** 13.0 **Other:** **G1:** 4.6 **G2:** 4.5	**Inclusion criteria:** • New Jersey residents in Medicaid/ Medicare or Pharmacy Assistance for the Aged and Disabled with comprehensive prescription programs • Covered by programs from January 1990 to June 1995 • Age ≥ 65 • Diagnosis of urinary incontinence • Care utilization or prescription for any indication in the six months before and after the index date of the diagnosis of incontinence • **Exclusion criteria:** • No record of care utilization or prescriptions filled in the study interval	**Charlson comorbidity index, mean score:** **G1:** 1.8 **G2:** 2.6 *P* < 0.001 **Hospital days in prior 180 days, mean:** **G1:** 6.8 **G2:** 12.5 *P* < 0.001 **Physician visits in prior 180 days, mean:** **G1:** 7.3 **G2:** 5.4 *P* < 0.001 **Nursing home days in prior 180 days, mean:** **G1:** 17.0 **G2:** 36.8 *P* < 0.001 **SES: Medicaid, %:** **G1:** 51.5 **G2:** 65.7 *P* < 0.001 **SES: PAAD, %:** **G1:** 48.5 **G2:** 34.3 *P* < 0.001 **Dx of CVD, %:** **G1:** 18.2 **G2:** 25.2 *P* < 0.001 **Dx of CHF, %:** **G1:** 16.9 **G2:** 25.1 *P* < 0.001 **Dx of conduction disturbance, %:** **G1:** 3.0 **G2:** 3.9 *P* = 0.008	**Adjusted relative risk of ventricular arrhythmia, G1/G2 (95% CI):** Urinary antispasmodic use: 1.23 (0.87, 1.75) Nonsedating antihistamine use: 0.95 (0.23, 3.84) Cytochrome P450 3A4 inhibitor use: 1.12 (0.60, 2.08) Concurrent nonsedating antihistamine/ cytochrome inhibitor use: 5.47 (1.34, 22.26) **Adjusted relative risk of sudden death, G1/G2 (95% CI):** Urinary antispasmodic use: 0.70 (0.28, 1.74) Nonsedating antihistamine use: 1.43 (0.20, 10.35) Cytochrome P450 3A4 inhibitor use: 1.80 (0.86, 3.76) Concurrent nonsedating antihistamine/ cytochrome inhibitor use: 21.50 (5.23, 88.37)	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: NA Drop-out rates: NA Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: NR Baseline characteristics: - Length of followup: NA Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Wang et al., 2002 (continued)			**Dx of supra-ventricular dysrhythmia, %:** **G1:** 7.8 **G2:** 12.2 *P* < 0.001 **Dx of HTN, %:** **G1:** 44.8 **G2:** 43.8 *P* = 0.255 **Dx of Ischemic heart disease, %:** **G1:** 31.0 **G2:** 36.7 *P* < 0.001 **Dx of other CVD, %:** **G1:** 28.0 **G2:** 35.0 *P* < 0.001 **Dx of electrolyte abnormalities, %:** **G1:** 6.4 **G2:** 11.8 *P* < 0.001	**Incidence rate of ventricular arrhythmia with medication use, (95% CI):** Urinary antispasmodics: 1.08 (0.85, 1.37) Nonsedating antihistamines: 1.00 (0.50, 1.99) Cytochrome P450 3A4 inhibitors: 1.02 (0.77, 1.34) Concurrent nonsedating antihistamine/cytochrome inhibitor use: 3.45 (1.11, 10.69) **Incidence rate of sudden death with medication use, (95% CI):** Urinary antispasmodics: 0.69 (0.29, 1.66) Nonsedating antihistamines: 1.14 (0.16, 8.06) Cytochrome P450 3A4 inhibitors: 1.51 (0.76, 3.02) Concurrent nonsedating antihistamine/ cytochrome inhibitor use: 24.35 (6.09, 97.35)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Wang et al., 2006 **Country and setting:** Taiwan; Academic medical center **Enrollment period:** July 2004 to November 2005 **Funding:** National Science Council, Taiwan **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Electric Stimulation (ES) vs Oxybutynin vs Placebo for 12 weeks **Groups:** **G1:** ES: intravaginal electrode; biphasic symmetric pulsed current w/ a 10-Hz frequency, 400-millisecond pulse width, 10/5 duty cycle, and varying intensity, 20 min/session, twice weekly **G2:** Oxybutynin, 2.5 mg 3 times daily **G3:** Placebo pill 3 times daily **N at enrollment:** **G1:** 25 **G2:** 26 **G3:** 23 **N at follow-up:** **G1:** 24 **G2:** 23 **G3:** 21 **Age:** NR **Race/ethnicity:** NR	**Inclusion criteria:** • Female • OAB for ≥ 6 mos • Age 16-80 • Urgency ≥ 4 times per day **Exclusion criteria:** • Use of anticholinergics or TCAs • Previous treatment with pelvic-floor muscle training, bladder training • Pelvic prolapse repair • Pregnancy • Neurologic disorders • DM • Demand cardiac pacemaker • IUD use • Genital prolapse greater than ICS Stage II • PVR>100 mL • Overt SI • Anti-incontinence surgery • UTI	**UUI episodes/ day, median (range):** **G1:** 1 (0-2) **G2:** 0 (0-2) **G3:** 1 (0-2) **Urgency episodes/day, median (range):** **G1:** 11.4 (4.0-16.0) **G2:** 12.1 (5-18) **G3:** 9.8 (4.2-15.5) **Voids/day, median (range):** **G1:** 12.8 (8.8-16.0) **G2:** 11.5 (4.3-19.5) **G3:** 11.5 (6.5-22.8) **Nocturia episodes/day, median (range):** **G1:** 1.75 (0-6.5) **G2:** 0 (0-2.5) **G3:** 0.65 (0-3.1) **Pads/day, median (range):** **G1:** 1 (0-4.1) **G2:** 0 (0-3) **G3:** 1 (0-4) **Warning time (sec), median (range):** **G1:** 41.5 (8-105) **G2:** 44 (2-215) **G3:** 65 (26-265 **Max voided volume (mL), median (range):** **G1:** 340 (120-450) **G2:** 310 (130-800) **G3:** 350 (120-600)	**UUI episodes/day, median (range):** **G1:** 0.5 (0-2) **G2:** 0 (0-2) **G3:** 1 (0-2) **G1/BL:** *P* = 0.814 **G2/BL:** *P* = 0 083 **G3/BL:** *P* = 0.854 **G1-G3:** *P* = 0.413 **Urgency episodes/day median (range):** **G1:** 1.0 (0.0-12.3) **G2:** 6 (0.5-13) **G3:** 7.4 (3.9-13.4) **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **G3/BL:** *P* = 0.003 **G1-G3:** *P* < 0.001 **Voids/day, median (range):** **G1:** 7.8 (1.8-13.0) **G2:** 7.4 (2-14) **G3:** 10 (3.9-13.4) **G1/BL:** *P* < 0.001 **G2/BL:** *P* < 0.001 **G3/BL:** *P* = 0.070 **G1-G3:** *P* = 0.002 **Nocturia episodes/day, median (range):** **G1:** 0 (0-3.0) **G2:** 0 (0-2.5) **G3:** 1 (0-3.6) **G1/BL:** *P* = 0.001 **G2/BL:** *P* = 0.394 **G3/BL:** *P* = 0.176 **G1-G3:** *P* = 0.002 **Pads/day, median (range):** **G1:** 0 (0-2) **G2:** 0 (0-2.5) **G3:** 1 (0-3) **G1/BL:** *P* = 0.010 **G2/BL:** *P* = 0.662 **G3/BL:** *P* = 0.501 **G1-G3:** *P* = 0.012	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to followup: ++ Drop-out rates: + Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Wang et al., 2006 (continued)			**Total voided volume/day (mL), median (range):** **G1:** 2160 (1010-2950) **G2:** 2106 (1560-3153) **G3:** 2305 (1305-3300)	**Warning time (sec), median (range):** **G1:** 72 (32-633) **G2:** 54.5 (138-850) **G3:** 66.5 (26-219) **G1/BL:** *P* = 0.002 **G2/BL:** *P* = 0.001 **G3/BL:** *P* = 0.532 **G1-G3:** *P* < 0.001 **Max voided volume (mL), median (range):** **G1:** 355 (150-550) **G2:** 336.5 (138-850) **G3:** 340 (160-600) **G1/BL:** *P* = 0.018 **G2/BL:** *P* = 0.004 **G3/BL:** *P* = 0.979 **G1-G3:** *P* = 0.035 **Total voided volume/day (mL), median (range):** **G1:** 2270 (1210-3106) **G2:** 2100 (1619-3200) **G3:** 2305 (1351-3221) **G1/BL:** *P* = 0.024 **G2/BL:** *P* = 0.728 **G3/BL:** *P* = 0.627 **G1-G3:** *P* = 0.050	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Yamaguchi et al., 2007 **Country and setting:** Japan, 155 academic health centers **Enrollment period:** June 2003 to January 2004 **Funding:** Astellas Pharma Inc. **Author industry relationship disclosures:** 2 of 12 Astellas (2)	**Design:** RCT, double-blind, double-dummy, placebo controlled **Intervention:** solifenacin vs propiverine vs placebo **Groups:** **G1:** solifenacin 5 mg qd x 12 wks **G2:** solifenacin 10 mg qd x 12 wks **G3:** propiverine 20 mg qd x 12 wks **G4:** placebo qd x 12 wks **N at enrollment:** **G1:** 398 **G2:** 381 **G3:** 400 **G4:** 405 **N at follow-up:** **G1:** 364 **G2:** 349 **G3:** 364 **G4:** 371 **Women, n (%):** **G1:** 318 (83.0) **G2:** 318 (85.7) **G3:** 321 (83.6) **G4:** 333 (84.3) **Age, mean ± SD, (range):** **G1:** 60.4 ± 13.3 (20.0-89.0) **G2:** 59.9 ± 13.0 (20.0-86.0) **G3:** 59.6 ± 13.6 (23.0-94.0) **G4:** 60.8 ± 12.5 (28.0-90.0) **Age ≥ 65, N (%):** **G1:** 161 (42.0) **G2:** 157 (42.3) **G3:** 166 (43.2) **G4:** 163 (41.3)	**Inclusion criteria:** • Age ≥ 20 • OAB sx for ≥ 6 mos • ≥ 8 voids/day • ≥ 3 episodes of urgency or ≥ 3 episodes of urgency incontinence over 72 hours **Exclusion criteria:** • PVR >100 mL • Significant BOO • Urinary retention • SI • Bladder stones • UTI • Interstitial cystitis • Previous or current malignant dz of the pelvic organs • Previous pelvic radiation • Current trt w/ anticholinergic meds • Known or suspected hypersensitivity to anticholinergic meds or lactose	**UUI episodes/ day, mean ± SD:** **G1:** 1.95 ± 2.14 **G2:** 1.89 ± 1.91 **G3:** 1.82 ± 1.94 **G4:** 1.67 ± 1.95 **Urgency episodes, n:** **G1:** 383 **G2:** 371 **G3:** 384 **G4:** 395 **Urgency episodes/day, mean ± SD:** **G1:** 4.40 ± 3.38 **G2:** 4.47 ± 3.30 **G3:** 4.07 ± 3.19 **G4:** 4.04 ± 3.11 **Incontinent, n:** **G1:** 274 **G2:** 270 **G3:** 295 **G4:** 283 **Incontinence type, n (%):** Urge: **G1:** 235 (61.4) **G2:** 213 (57.4) **G3:** 218 (56.8) **G4:** 244 (61.8) Mixed: **G1:** 130 (33.9) **G2:** 143 (38.5) **G3:** 144 (37.5) **G4:** 135 (34.2) None: **G1:** 18 (4.7) **G2:** 15 (4.0) **G3:** 22 (5.7) **G4:** 16 (4.1) **Incontinence episodes/day, mean ± SD:** **G1:** 2.35 ± 2.45 **G2:** 2.19 ± 2.04 **G3:** 2.15 ± 2.31 **G4:** 1.99 ± 2.11	**UUI episodes/day, mean change ± SD:** **G1:** -1.45 ± 1.89 **G2:** -1.52 ± 1.77 **G3:** -1.19 ± 2.20 **G4:** -0.69 ± 2.00 **G1/G4:** *P* < 0.001 **G2/G4:** *P* < 0.001 **G3/G4:** *P* < 0.025 **Urgency free, n (%):** **G1:** 126 (32.9) **G2:** 138 (37.2) **G3:** 128 (33.3) **G4:** 82 (20.8) **Urgency episodes/day, mean change ± SD:** **G1:** -2.41 ± 2.88 **G2:** -2.78 ± 2.82 **G3:** -2.30 ± 3.08 **G4:** -1.28 ± 2.90 **G1/G4:** *P* < 0.001 **G2/G4:** *P* < 0.001 **G3/G4:** *P* < 0.001 **G2/G3:** *P* = 0.012 **Continent, n (%):** **G1:** 154 (56.2) **G2:** 161 (59.6) **G3:** 165 (55.9) **G4:** 105 (37.1) **Incontinence episodes/day, mean change ± SD:** **G1:** -1.59 ± 2.12 **G2:** -1.60 ± 1.81 **G3:** -1.25 ± 2.79 **G4:** -0.72 ± 1.95 **G1/G4:** *P* < 0.001 **G2/G4:** *P* < 0.001 **G3/G4:** *P* < 0.025	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Yamaguchi et al., 2007 (continued)	**Race/ethnicity:** NR **Weight (kg), mean ± SD (range):** **G1:** 56.3 ± 9.7 (30.5-123.0) **G2:** 57.1 ± 10.5 (35.0-117.4) **G3:** 56.6 ± 10.0 (33.0-103.0) **G4:** 56.2 ± 9.4 (36.0-90.0)		**Voids/day, mean ± SD** **G1:** 11.44 ± 2.94 **G2:** 11.15 ± 2.76 **G3:** 11.37 ± 2.71 **G4:** 11.25 ± 2.73 **≥ 8 voids/day, n:** **G1:** 383 **G2:** 371 **G3:** 384 **G4:** 395 **Nocturia episodes/day, mean ± SD:** **G1:** 1.91 ± 1.22 **G2:** 1.78 ± 1.04 **G3:** 1.95 ± 1.29 **G4:** 1.84 ± 1.10 **Duration of symptoms (years), n (%):** ≥ 0.5 to < 1: **G1:** 46 (12.0) **G2:** 36 (9.7) **G3:** 38 (9.9) **G4:** 39 (9.9) ≥ 1 to < 3: **G1:** 89 (23.2) **G2:** 97 (26.1) **G3:** 85 (22.1) **G4:** 81 (20.5) ≥ 3 to < 5: **G1:** 34 (8.9) **G2:** 45 (12.1) **G3:** 38 (9.9) **G4:** 40 (10.1) ≥ 5 to < 10: **G1:** 24 (6.3) **G2:** 23 (6.2) **G3:** 22 (5.7) **G4:** 37 (9.4) ≥ 10 **G1:** 23 (6.0) **G2:** 14 (3.8) **G3:** 20 (5.2) **G4:** 24 (6.1) Unknown: **G1:** 167 (43.6) **G2:** 36 (9.7) **G3:** 38 (9.9) **G4:** 39 (9.9)	**Voids/day, mean change ± SD:** **G1:** -1.93 ± 1.97 **G2:** -2.19 ± 2.09 **G3:** -1.87 ± 2.70 **G4:** -0.94 ± 2.29 **G1/G4:** *P* < 0.001 **G2/G4:** *P* < 0.001 **G3/G4:** *P* < 0.001 **G1/G3:** *P* = NS **G2/G3:** *P* = NS **≥ 8 voids/day, n (%):** **G1:** 109 (28.5) **G2:** 137 (36.9) **G3:** 101 (26.3) **G4:** 83 (21.0) **Nocturia episodes/day, mean change ± SD:** **G1:** -0.41 ± 0.96 **G2:** -0.46 ± 0.90 **G1:** -0.43 ± 1.21 **G4:** -0.30 ± 0.91 **G1/G4:** *P* = NS **G2/G4:** *P* < 0.025 **G3/G4:** *P* = NS **KHQ, general health:*** **G1/G4:** *P* < 0.05 **G3/G4:** *P* < 0.05 **KHQ, incontinence impact:*** **G1/G4:** *P* < 0.05 **G2/G4:** *P* < 0.05 **G3/G4:** *P* < 0.05 **KHQ, role limitations:*** **G1/G4:** *P* < 0.05 **G2/G4:** *P* < 0.05 **G3/G4:** *P* < 0.05 **KHQ, physical limitations:*** **G1/G4:** *P* < 0.05 **G2/G4:** *P* < 0.05 **G3/G4:** *P* < 0.05	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Yamaguchi et al., 2007 (continued)			**Volume voided, mean mL ± SD:** **G1:** 153.4 ± 52.91 **G2:** 154.4 ± 50.21 **G3:** 151.2 ± 49.38 **G4:** 152.8 ± 44.28	**KHQ, social limitations:*** **G1/G4:** *P* < 0.05 **G2/G4:** *P* < 0.05 **G3/G4:** *P* < 0.05 **KHQ, personal relationships:*** **G2/G4:** *P* < 0.05 **G3/G4:** *P* < 0.05 **KHQ, emotions:*** **G1/G4:** *P* < 0.05 **G2/G4:** *P* < 0.05 **G3/G4:** *P* < 0.05 **KHQ, sleep/ energy:*** **G1/G4:** *P* < 0.05 **G2/G4:** *P* < 0.05 **G3/G4:** *P* < 0.05 **KHQ, severity:*** **G1/G4:** *P* < 0.05 **G2/G4:** *P* < 0.05 **G3/G4:** *P* < 0.05 **G2/G3:** *P* < 0.05 **Voided volume (mL), mean change ± SD:** **G1:** 35.78 ± 43.49 **G2:** 43.59 ± 44.52 **G3:** 36.62 ± 37.99 **G4:** 11.67 ± 33.74 **G1/G4:** *P* < 0.001 **G2/G4:** *P* < 0.001 **G3/G4:** *P* < 0.001 **G2/G3:** *P* = 0.009 **Discontinued due to AEs, n (%):** **G1:** 20 (5.1) **G2:** 26 (6.8) **G3:** 26 (6.5) **G4:** 11 (2.7) **Dry mouth, n (%):** **G1:** 67 (16.9) **G2:** 130 (34.1) **G3:** 103 (25.8) **G4:** 23 (5.7) **G1/G3:** *P* = 0.003 **G2/G3:** *P* = 0.012	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Yamaguchi et al., 2007 (continued)				**Dry mouth, mild, n (%):** **G1:** 64 (16.2) **G2:** 124 (32.5) **G3:** 100 (25.0) **G4:** 23 (5.7) **Dry mouth, moderate, n (%):** **G1:** 3 (0..8) **G2:** 6 (1.6) **G3:** 3 (0.8) **G4:** 1 (0.2) **Constipation, n (%):** **G1:** 42 (10.6) **G2:** 72 (18.9) **G3:** 45 (11.3) **G4:** 16 (4.0) **G2/G3:** *P* = 0.004 **Blurred vision, n (%):** **G1:** 7 (1.8) **G2:** 14 (3.7) **G3:** 15 (3.8) **G4:** 8 (2.0)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Zinner et al., 2002 [See evidence table for Van Kerrebroeck et al., 2001] **Country and setting:** North America (74 centers), Australasia (4 centers), Europe (89 centers) **Enrollment period:** NR **Funding:** Pharmacia Corporation **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Tolterodine ER vs placebo **Groups:** **G1:** tolterodine ER 4 mg qd < 65 years of age **G2:** placebo < 65 years of age **G3:** tolterodine ER 4 mg qd ≥ 65 years of age **G4:** placebo ≥ 65 years of age **N at enrollment:** **G1:** 293 **G2:** 285 **G3:** 214 **G4:** 223 **N at follow-up:** **G1:** 257 **G2:** 246 **G3:** 193 **G4:** 194 **Women, n (%):** **G1:** 255 (87)** **G2:** 247 (87)** **G3:** 162 (76) **G4:** 163 (73) **Age, mean ± SD:** **G1:** 51 ± 10.5 **G2:** 51 ± 10 **G3:** 74 ± 6 **G2:** 74 ± 6 **Race/ethnicity:** NR	**Inclusion criteria:** • Age ≥ 18 • Urinary frequency (≥ 8 voids/day) **Exclusion criteria:** • Demonstrable SUI • Total daily urine volume > 3 L • Contra-indications to antimuscarinic treatment • Hepatic or renal disease • UTI • Interstitial cystitis • Hematuria • BOO • Current electrostimula-tion or bladder training therapy • Indwelling catheter or intermittent self-catheterization • Pregnant or nursing • Women not using reliable contraception • Being treated for OAB with other anticholinergic drugs or drugs that inhibit cytochrome P450 3A4 isoenzymes • Estrogen therapy < 2 months • Treatment w/ investigational drug < 2 months	**Not able to hold urine upon experiencing urgency, %:** **G1:** 24.9 **G2:** 29.1 **G3:** 33.6 **G4:** 34.5 **Able to complete tasks before toilet visit in response to urgency,%:** **G1:** 6.5 **G2:** 7.7 **G3:** 5.1 **G4:** 4.9 **Incontinence episodes/week, mean ± SD:** **G1:** 21.4 ± 22.1 **G2:** 23.2 ± 22.0 **G3:** 23.2 ± 22.7 **G4:** 23.4 ± 18.9 **Voids/day, mean ± SD:** **G1:** 11.0 ± 3.9 **G2:** 11.4 ± 4.2 **G3:** 10.8 ± 4.5 **G4:** 11.0 ± 3.2 **Voided volume (mL), mean ± SD:** **G1:** 140 ± 41 **G2:** 137 ± 45 **G3:** 141 ± 45 **G4:** 134 ± 39 **Previous drug therapy, n (%):** **G1:** 148 (50.5) **G2:** 146 (51.2) **G3:** 121 (56.5) **G4:** 117 (52.5) **Percentage with poor efficacy, %:** **G1:** 74 (50.0)** **G2:** 60 (41.1)** **G3:** 40 (33.1) **G4:** 46 (39.3)	**Not able to hold urine upon experiencing urgency, %:** **G1:** 11.3 **G2:** 21.1 **G3:** 15.9 **G4:** 25.6 **G1/G2:** *P* = 0.003 **G3/G4:** *P* = 0.007 No age-related difference **Able to complete tasks before toilet visit in response to urgency,%:** **G1:** 32.8 **G2:** 16.8 **G3:** 26.2 **G4:** 14.8 **G1/G2:** *P* = 0.001 **G3/G4:** *P* = 0.003 No age-related difference **Incontinence episodes/week, mean ± SD** **G1:** -12.0 ± 17.6 **G2:** -7.4 ± 15.6 **G3:** -11.5± 18.2 **G4:** -6.3 ± 15.0 **G1/G2:** *P* = 0.001 **G3/G4:** *P* < 0.001 No age-related difference **Voids/day, mean ± SD** **G1:** -2.0 ± 3.1 **G2:** -1.4 ± 3.1 **G3:** -1.4± 3.7 **G4:** -0.9 ± 2.6 **G1/G2:** *P* = 0.26 **G3/G4:** *P* = 0.92	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: NR Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Zinner et al., 2002 (continued)				**Perception of bladder condition, improved, %:** **G1:** 60.1 **G2:** 51.9 **G3:** 54.2 **G4:** 31.4 **G1/G2:** *P* < 0.05 **G3/G4:** *P* < 0.0001 **Perception of bladder condition, no change, %:** **G1:** 32.4 **G2:** 38.9 **G3:** 38.3 **G4:** 51.1 **G4/G2:** *P* < 0.0001 **Perception of bladder condition, deterioration, %:** **G1:** 7.2 **G2:** 9.1 **G3:** 7.5 **G4:** 17.5 **Treatment beneficial, %:** **G1:** 78.3 **G2:** 58.3 **G3:** 69.8 **G4:** 46.9 **G1/G2:** *P* = 0.001 **G3/G4:** *P* = 0.001 No age-related difference **Voided volume (mL), mean ± SD:** **G1:** 35 ± 53 **G2:** 13 ± 41 **G3:** 33± 47 **G4:** 16 ± 41 **G1/G2:** *P* < 0.001 **G3/G4:** *P* < 0.001 No age-related difference	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Zinner et al., 2002 (continued)				**Adverse events, %:** **G1:** 50.7 **G2:** 50.5 **G3:** 54.2 **G4:** 46.0 **Dry mouth, severe, %** **G1-G2:** 1.7 **G3-G4:** 1.9 **Dry mouth, moderate, %** **G1-G2:** 7.6 **G3-G4:** 6.5 **Dry mouth, mild, %** **G1-G2:** 13.4 **G3-G4:** 15.9 **No dry mouth, %** **G1-G2:** 77.3 **G3-G4:** 75.7	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Zinner et al., 2004 **Country and setting:** US, 51 sites **Enrollment period:** NR **Funding:** Indevus Corporation **Author industry relationship disclosures:** 4 of 5 Alza (1) Indevus (4) Kyowa (1) Lilly (2) Merck (1) Ortho-McNeil (1) Pfizer (2) Pharma (1) Pharmacia (1) Schwarz (1) Watson (2) Yamanouchi (1)	**Design:** RCT with 2 wk washout period **Intervention:** Trospium chloride vs placebo **Groups:** **G1:** Tropsium chloride 20 mg b.i.d. **G2:** placebo **N at enrollment:** **G1:** 262 **G2:** 261 **N at follow-up:** **G1:** 256 **G2:** 256 **Women, n (%):** **G1:** 203 (77.5) **G2:** 186 (71.3) **Age, mean ± SD:** **G1:** 63 ± 0.8 **G2:** 61.5 ± 0.8 **Race/ethnicity, n (%):** **White:** **G1:** 222 (84.7) **G2:** 225 (86.2) **Black:** **G1:** 26 (9.9) **G2:** 20 (7.7) **Hispanic:** **G1:** 10 (3.8) **G2:** 13 (5.0) **Other:** **G1:** 4 (1.6) **G2:** 3 (1.1)	**Inclusion criteria:** • Age ≥18 years • OAB symptoms ≥ 6 mos • Urinary urgency • ≥ 70 voids per week • ≥ 7 UUI episodes/week **Exclusion criteria:** • Stress predominant MUI • Insensate or overflow • Neurogenic bladder disorders • Significant renal disease • Hematuria hematuria and UTI at washout or ≥ twice in the prior year • BOO with PVR ≥ 100 mL • Concurrent use of any anticholinergic drug or other drug therapy for OAB within 21 days before randomization • Bladder surgery ≤ 6 mos • Bladder cancer • Interstitial cystitis • PSA ≥ 10 ng/mL • Diuretic use, estrogen therapy and nonmedical bladder therapy that was not part of a stable, long-term program.	**UUI episodes/ day, mean:** **G1:** 3.9 **G2:** 4.3 **Urgency episodes/day, mean:** **G1:** 11.29 **G2:** 11.72 **Urgency severity score, mean:** **G1:** 1.8 **G2:** 1.8 **Voids/day, mean:** **G1:** 12.7 **G2:** 12.9 **Daytime voids/ day, mean:** **G1:** 10.6 **G2:** 10.9 **Nocturia episodes/day, mean:** **G1:** 2.1 **G2:** 2.0 **Voided volume (mL), mean:** **G1:** 155.1 **G2:** 156.1 **IIQ, mean score (SE):** **G1:** 183.5 (5.6) **G2:** 195.4 (5.6) **IIQ,, women only, mean score (SE):** **G1:** 191.2 (6.3) **G2:** 201.9 (6.6) **Incontinence Impact Ques-tionnaire, travel subscale, score (SE):** **G1:** 52.4 (1.7) **G2:** 55.6 (1.7)	**UUI episodes/ day, week 1, mean % change:** **G1:** -40.1 **G2:** -27.5 **G1/G2:** *P* ≤ 0.001 **UUI episodes/ day, week 4, mean % change:** **G1:** -58.5 **G2:** -40.9 **G1/G2:** *P* ≤ 0.0001 **UUI episodes/ day, week 12, mean % change:** **G1:** -59.0 **G2:** -44.2 **G1/G2:** *P* ≤ 0.0001 **Urgency episodes/day, week 1, mean change:** **G1:** -1.13 **G2:** -1.08 **Urgency episodes/day, week 4, mean change:** **G1:** -2.10 **G2:** -1.00 **G1/G2:** *P* ≤ 0.0001 **Urgency episodes/day, week 12, mean change:** **G1:** -2.30 **G2:** -1.08 **G1/G2:** *P* ≤ 0.0001 **Urgency severity score, week 1, mean change:** **G1:** -0.11 **G2:** -0.01 **G1/G2:** *P* ≤ 0.01	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: + Masking: - Pt selection criteria: + Loss to followup: ++ Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Zinner et al., 2004 (continued)			**IIQ, social relationships, score (SE):** **G1:** 37.8 (1.5) **G2:** 40.3 (1.5) **IIQ, emotional health, mean score (SE):** **G1:** 47.1 (1.6) **G2:** 49.6 (1.6) **IIQ,, physical activity, mean score (SE):** **G1:** 46.1 (1.6) **G2:** 50.2 (1.6) **Prior OAB med, n (%):** **G1:** 135 (51.5) **G2:** 142 (54.5)	**Urgency severity score, week 4, mean change:** **G1:** -0.18 **G2:** -0.06 **G1/G2:** *P* ≤ 0.01 **Urgency severity score, week 12, mean change:** **G1:** -0.22 **G2:** -0.04 **G1/G2:** *P* ≤ 0.001 **Voids/day, week 1, mean change:** **G1:** -1.18 **G2:** -0.81 **G1/G2:** *P* ≤ 0.05 **Voids/day, week 4, mean change:** **G1:** -2.20 **G2:** -1.07 **G1/G2:** *P* ≤ 0.0001 **Voids/day, week 12, mean change:** **G1:** -2.37 **G2:** -1.29 **G1/G2:** *P* ≤ 0.0001 **Daytime voids/ day, week 1, mean change:** **G1:** -1.00 **G2:** -0.68 **G1/G2:** *P* ≤ 0.05 **Daytime voids/ day, week 4, mean change:** **G1:** -1.77 **G2:** -0.89 **G1/G2:** *P* ≤ 0.0001 **Daytime voids/ day, week 12, mean change:** **G1:** -1.90 **G2:** -0.98 **G1/G2:** *P* ≤ 0.0001	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Zinner et al., 2004 (continued)				**Nocturia episodes/day, week 1, mean change:** **G1:** -0.18 **G2:** -0.15 **Nocturia episodes/day, week 4, mean change:** **G1:** -0.43 **G2:** -0.17 **G1/G2:** *P* ≤ 0.001 **Nocturia episodes/day, week 12, mean change:** **G1:** -0.47 **G2:** -0.29 **G1/G2:** *P* ≤ 0.05 **Voided volume (mL), week 1, mean change:** **G1:** 19.9 **G2:** 6.6 **G1/G2:** *P* ≤ 0.0001 **Voided volume (mL), week 4, mean change:** **G1:** 30.0 **G2:** 8.5 **G1/G2:** *P* ≤ 0.0001 **Voided volume (mL), week 12, mean change:** **G1:** 32.1 **G2:** 7.7 **G1/G2:** *P* ≤ 0.0001 **IIQ, week 12, LS mean change (SE):** **G1:** -54.0 (5.6) **G2:** -36.0 (5.6) **G1/G2:** *P* ≤ 0.05	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Zinner et al., 2004 (continued)				**IIQ, women only, week 12, LS mean change (SE):** **G1:** -59.1 (6.6) **G2:** -35.7 (6.9) **G1/G2:** *P* ≤ 0.05 **IIQ, travel subscale, week 12, LS mean change (SE):** **G1:** -14.9 (1.7) **G2:** -9.9 (1.7) **G1/G2:** *P* < ≤ 0.05 **IIQ, social relationsips, week 12, LS mean change (SE):** **G1:** -10.8 (1.4) **G2:** -6.3 (1.4) **G1/G2:** *P* ≤ 0.05 **IIQ, emotional health, 12 weeks, LS mean change (SE):** **G1:** 14.1 (1.5) **G2:** -9.2 (1.5) **G1/G2:** *P* ≤ 0.05 **IIQ, physical activity, 12 weeks, LS mean change (SE):** **G1:** -13.5 (1.7) **G2:** -11.0 (1.7) **Dry mouth, n (%):** **G1:** 57 (21.8) **G2:** 17 (6.5) **Constipation, n (%):** **G1:** 25 (9.5) **G2:** 10 (3.8) **Headache, n (%):** **G1:** 17 (6.5) **G2:** 12 (4.6)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Zinner et al., 2004 (continued)				**Diarrhea, n (%):** **G1:** 8 (3.1) **G2:** 14 (5.4) **Abdominal pain, n (%):** **G1:** 8 (3.1) **G2:** 3 (1.1) **Discontinuation due to AE, %:** **G1:** 8.8 **G2:** 5.7	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Zinner et al., 2005 **Country and setting:** US, Specialty treatment center **Enrollment period:** NR **Funding:** Pfizer Novartis Pharma Thomson ACUMED **Author industry relationship disclosures:** NR	**Design:** Randomized double- blind placebo-controlled four way crossover **Intervention:** Darifenacin 15 mg qd vs darifenacin 30 mg qd vs. Oxybutynin vs. placebo **Groups:*** **G1:** Darifenacin 15mg daily **G2:** Darifenacin 30mg daily **G3:** Oxybutynin 5 mg t.i.d. **G4:** placebo **N at enrollment:** **G1-G4:** 76 **N included, tolerability:** **G1-G4:** 61 **N included, efficacy:** **G1-G4:** 58 **Women, n (%):** **G1-G4:** 71 (93.4) **Age, mean (range):** **G1-G4:** 59.9 (33-84) **Race/ethnicity:** NR **Weight (kg), mean (range):** **G1-G4:** 75.7 (42-157)	**Inclusion criteria:** • Age 18-85 • ≥ 4 UUI episodes/week • ≥ 8 voids/day (from 14 day run in placebo voiding diary) **Exclusion criteria:** • Neurogenic bladder • SUI • Contraindication to antimuscarinic treatment • UTI • Bladder symptoms • Bladder stones • BOO • Concomitant disease • Concurrent bladder training • Concurrent thyroid or HRT • Other bladder meds • Pregnant or breastfeeding	**Urgency episodes/day, mean ± SD:** **G1-G 4:** 9.3 ± 3.4 **Urgency severity, mean ± SD:** **G1-G4:** 2.0 ± 0.4 **Incontinence episodes/week, mean ± SD:** **G1-G4:** 20.4 ± 17.7 **Voids/ day, mean ± SD:** **G1-G4:** 10.4 ± 3.0	**Urgency episodes/day, mean:** **G1:** 7.95 **G2:** 7.59 **G3:** 8.12 **G4:** 8.71 **G1-G3/G4:** *P* < 0.05 **Urgency severity, mean:** **G1:** 1.93 **G2:** 1.84 **G3:** 1.89 **G4:** 2.03 **G1-G3/G4:** *P* < 0.05 **Incontinence episodes/week, mean:** **G1:** 10.93 **G2:** 8.82 **G3:** 9.45 **G4:** 14.64 **G1-G3/G4:** *P* < 0.05 **Voids/day, mean ± SD:** **G1:** 9.33 **G2:** 8.85 **G3:** 9.24 **G4:** 9.62 **G2/G4:** *P* < 0.05 **Dry mouth, (%):** **G1:** 13.1 **G2:** 34.4 **G3:** 36.1 **G4:** 4.9 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05 **G2/G4:** *P* < 0.05 **G3/G4:** *P* < 0.05 **Constipation, (%):** **G1:** 9.8 **G2:** 21.3 **G3:** 8.2 **G4:** 3.3 **G2/G3:** *P* < 0.05 **G2/G4:** *P* < 0.05	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: - Drop-out rates: NR Power calculation: + Statistical issues: + EXTERNAL VALIDITY: fair Age: -, NR Baseline OAB status: NR Baseline characteristics: - Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Zinner et al., 2005 (continued)				**Blurred vision, (%):** **G1:** 0 **G2:** 0 **G3:** 3.3 **G4:** 0 **Dizziness, (%):** **G1:** 0 **G2:** 0 **G3:** 1.6 **G4:** 0	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Zinner et al., 2006 **Country and setting:** NR, Multicenter **Enrollment period:** NR **Funding:** Novartis **Author industry relationship disclosures:** 5 of 6 Alza (1) Eli Lilly (2) Astellas (1) GSK (1) Indevus (1) Madaus (1) Novartis (5) Pfizer (2) Sanofi (1) Watson (2) Yamanouchi (1)	**Design:** RCT **Intervention:** Darifenacin 15 mg controlled release once daily vs. placebo **Groups:** **G1:** Darifenacin 15 mg controlled release once daily **G2:** Placebo **N at enrollment:** **G1:** 214 **G2:** 225 **N at follow-up:** **G1:** 185 **G2:** 188 **Women, n (%):** **G1:** 185 (86.4) **G2:** 198 (88.0) **Age, mean (range):** **G1:** 59.1 (20-93) **G2:** 59.1 (18-89) **Race/ethnicity:** NR	**Inclusion criteria:** • Adults • Age ≥18 • History of OAB for ≥ 6 mos • ≥ 1 urge incontinence episodes/day • ≥ 8 voids/day • ≥ 4 urgency episodes/day • Mean warning time of ≤ 15 min during 12 hrs **Exclusion criteria:** • SUI • Marked cystocele • Pelvic prolapse • Use of anticholinergics, antispasmodics, cholinergic agonists, potent cytochrome P450 3A4 inhibitors, or opioids 2 wks prior to screening visit • Contraindications to drugs that cause significant constipation, clinically significant bladder outlet obstruction • Intention to start bladder training program • In-dwelling catheter • Intermittent self-catheterization	**UUI episodes/ wk, median:** **G1:** 18.73* **G2:** 21.00^ **Urgency episodes/wk, median:** **G1:** 82.60* **G2:** 85.40^ **Warning time (min), mean:** **G1:** 4.38* **G2:** 4.74* **Warning time (min), median:** **G1:** 2.57* **G2:** 3.04* **Voids/day, median:** **G1:** 11.00* **G2:** 11.20^ **Duration of OAB (years), mean (range):** **G1:** 7.8 (0, 45) **G2:** 8.3 (0, 58) **Previous OAB therapy, n (%):** **G1:** 112 (52.3) **G2:** 124 (55.1) **Voided volume (mL), median:** **G1:** 153.50* **G2:** 144.62^	**UUI episodes/wk, wk 2, median change:** **G1:** -9.1 **G2:** -7.0 *P* < 0.01 **UUI episodes/wk, wk 6, median change:** **G1:** -11.2 **G2:** -8.4 *P* = 0.031 **UUI episodes/wk, wk 12, median change:** **G1:** -12.60 **G2:** -9.80 *P* = 0.035 **Urgency episodes/wk, wk 12, median change:** **G1:** -18.20 **G2:** -15.58 *P* = 0.18 **Urgency-free time, (min), median:** **G1:** 34.3 **G2:** 25.0 *P* = 0.003 **Warning time, median % change:** **G1:** 41.8 **G2:** 18.4 **Voids/day, wk 12, median change:** **G1:** -2.20 **G2:** -1.80 *P* = 0.176 **Voided volume (mL), wk 12, mean change:** **G1:** 22.62 **G2:** 11.31 *P* = 0.002	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Zinner et al., 2006 (continued)				**Total OAB-q score, wk 6, mean change:** **G1:** 24.5 **G2:** 18.7 *P* = 0.035 **Total OAB-q score, wk 12, mean change:** **G1:** 26.4**G2:** 19.1 *P* < 0.001 **Incontinence Impact, wk 12, mean change:** **G1:** -24.7 **G2:** -17.8 *P* = 0.022 **Severity measures, wk 12, mean change:** **G1:** -24.3 **G2:** -15.6 *P* < 0.001 **Adverse events, %:** **G1:** 63.6 **G2:** 48.9 **Discontinuation, n (%):** **G1:** 17 (7.9) **G2:** 9 (4) **Dry mouth and constipation, n (%):** **G1:** 29.0 (17.8) **G2:** 5.8 (4.9) **Discontinuation due to dry mouth, %:** **G1:** 2.3 **G2:** 0 **Discontinuation due to constipation, %:** **G1:** 2.3 **G2:** 0 **Headaches, %:** **G1:** 6.1 **G2:** 2.2	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Zinner et al., 2006 (continued)				**Cardiac AEs, %:** **G1:** 0.5 **G2:** 0.9	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Zinner et al. 2008 **Country and setting:** US, 89 sites **Enrollment period:** NR **Funding:** Astellas Pharma US, GlaxoSmithKline **Author industry relationship disclosures:** 5 of 5 Astellas (5) Esprit (2) Watson (3) Allergan (2) Medtronics (1) GlaxoSmithKline (3) Indevus (1)	**Design:** open label, non-comparative, flexible-dosing **Intervention:** solifenacin 5 or 10 mg qd for 12 wks after washout from tolterodine, with dose adjustments at wk 4 and wk 8 **Groups:** NA **N at enrollment:** 440 **N at follow-up:** 390 **Age, yrs ± SD:** 61.5 ± 13.69 **Age < 65, n (%):** 246 (55.9) **Age ≥ 65-74, n (%):** 108 (24.5) **Age ≥ 75, n (%):** 86 (19.5) **Race/ethnicity, n (%):** **Caucasian** 391 (88.9) **Black or African** 37 (8.4) **Asian** 1 (0.2) **Other** 11 (2.5) **Women, N (%):** 388 (88.2) **Women < 65 yrs, n (%):** 227 (58.5) **Women Age ≥ 65-74, n (%):** 92 (23.7) **Women Age ≥ 75, (%):** 69 (17.8)	**Inclusion criteria:** • Age ≥ 18 • Symptoms of OAB ≥ 3 mos • Ambulatory and able to use toilet without difficulty • Treated with tolterodine ER 4 mg/day at least 4 wks preceding study but failed to achieve satisfactory improvement in urgency episodes • ≥3 urgency episodes/24 hrs documented in 3-day voiding diary while receiving tolterodine ER 4 mg/d • Prior drug or other treatment for OAB with ≥ 4 wks washout before screening **Exclusion criteria:** • Prior treatment with darifenacin • SUI • Stress dominant MUI • UTI • Interstitial cystitis • Bladder stones • Outflow obstruction due to benign prostatic hyperplasia • Uncontrolled narrow-angle glaucoma • Urinary or gastric retention • Severe renal or hepatic impairment	**Urgency episodes/day, mean:** 6.03 **Voids/day, mean:** 10.59 **Incontinence episodes/day, mean:** 3.04 **Nocturia episodes/day, mean:** 1.83 **Nocturnal voids/day, mean:** 2.32 **Pads or diapers/ week, mean:** 10.7	**Urgency episodes/day, mean change (95% CI):** -3.41 (-3.79, -3.04)* **Voids/day, mean change (95% CI):** -1.57 (-1.86, -1.28)* **Incontinence episodes/day, mean change (95% CI):** -1.86 (-2.19, -1.53)* **Nocturia episodes/day, mean change (95% CI):** -0.72 (-0.84, -0.59)* **Nocturnal voids/day, mean change (95% CI):** -0.79 (-0.95, -0.62)* **Pads or diapers/ week, mean change:** 7.9 *P* = 0.0009 **Improvement in HRQL, mean (95% CI):** 21.1 (19.0, 23.1)* **Change in symptom bother score, mean (95% CI):^** -27.4 (-29.7, -25.1)* **Change in coping, score, mean (95% CI)^:** 23.1 (20.6, 25.6)* **Change in concern score, mean (95% CI)^:** 25.2 (22.8, 27.5)*	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: + Drop-out rates: NR Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Zinner et al. 2008 (continued)	**Height, mean cm ± SD:** 164.1 ± 8.39 **Weight, mean kg ± SD:** 81.1 ± 20.56 **BMI, mean kg/m^2 ± SD:** 30.1 ± 7.12	• Chronic severe constipation • Gastrointestinal obstructive disease • Bladder cancer • Pregnant or breast-feeding • Not using a reliable birth control method • Known hypersensitivity to solifenacin or to anticholinergic medicines • Participating in any clinical trial of any investigational drug within 30 days		**Change in sleep, score, mean (95% CI)^:** 21.9 (19.5, 24.3)* **Change in social interaction score, mean (95% CI)^:** 11.1 (9.4, 12.9)* **Change in % work time missed, mean ± SD†:** -1.84 ± 0.57 *P* = 0.0017 **Change in % impairment while working, mean ± SD†:** -11.64 ± 1.64 *P* < 0.0001 **Change in % overall work impairment, mean ± SD †:** -12.14 ± 1.79 P <0.0001 **Change in % activity impairment, mean ± SD†:** -13.21 ± 1.31 *P* < 0.001 **Change in office visits, mean ± SD:** -1.00 ± 0.08 *P* < 0.001 **Change in UTI, mean ± SD:** -0.12 ± 0.03 *P* < 0.001 **Change in skin rash episodes, mean ± SD:** -0.46 ± 0.34 *P* = 0.1801	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Zinner et al. 2008 (continued)				**Change in number of falls, mean ± SD:** 0.04 ± 0.07 *P* = 0.5561 **Change in number of pads/diapers/ wk, mean ± SD:** -2.79 ± 0.83 *P* = 0.0009	

Evidence Table 3. KQ2 Procedural and surgical treatments

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Enzelsberger et al. 1995 **Country and setting:** Austria, Academic gynecology/ urology outpatient clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Instillation of oxybutynin or sterile water into the bladder via a disposable catheter, administered over a period of 12 days **Groups:** **G1:** instillation of 20 mg oxybutynin in 40 mL sterile water **G2:** instillation of 40 mL sterile water **N at enrollment:** **G1:** 26 **G2:** 26 **N at follow-up:** **G1:** 23 **G2:** 20 **Women, %:** 100 **Age, median (range):** **G1:** 61 (55, 66) **G2:** 59 (56, 64) **Race/ethnicity:** NR **Weight (kg), median (range):** **G1:** 68 (58, 74) **G2:** 70 (59, 77)	**Inclusion criteria:** • Women • Presenting complaint of frequency (more than 5 times/ 12hr), nocturia (more than twice per night), and urgency • Confirmed idiopathic detrusor instability **Exclusion criteria:** • Urodynamically assessed genuine stress incontinence • Neurologic disorders	**Daytime voids /day, median (range):** **G1:** 7.5 (5, 15) **G2:** 8.2 (6, 12) **Nocturia episodes/day, median (range):** **G1:** 5.1 (3, 7) **G2:** 4.6 (3, 8) **Voided volume (mL), first desire to void, median (range):** **G1:** 95 (30, 140) **G2:** 90 (25, 170) **Cystometric capacity (mL), median (range):** **G1:** 205 (50, 340) **G2:** 195 (40, 260) **Max pressure rise during filling (cmH_20), median (range):** **G1:** 16 (10, 22) **G2:** 14 (9, 19) **Max contraction (cmH_2O), median (range):** **G1:** 32 (20, 44) **G2:** 29 (18, 42) **Peak flow rate (mL/s), median (range):** **G1:** 27 (15, 45) **G2:** 30 (17, 40) **Residual urinary volume (mL), median (range):** **G1:** 40 (10, 50) **G2:** 35 (12, 50) **Duration of symptoms (months), median (range):** **G1:** 7 (2, 9) **G2:** 8 (3, 9)	**Daytime voids/ day, median (range):** **G1:** 4.0 (2, 7) **G2:** 6.9 (5, 10) *P* < 0.05 **Nocturia episodes/day, median (range):** **G1:** 1.8 (1, 3) **G2:** 3.5 (3, 6) *P* < 0.05 **Voided volume (mL), first desire to void, median (range):** **G1:** 150 (80, 180) **G2:** 110 (30, 140) *P* < 0.05 **Cystometric capacity (mL), median (range:** **G1:** 310 (100, 390) **G2:** 207 (43, 240) *P* < 0.05 **Max pressure rise during filling (cmH_20), median (range):** **G1:** 8 (5, 10) **G2:** 11 (6, 12) *P* < 0.05 **Max contraction (cmH_2O), median (range):** **G1:** 14 (10, 20) **G2:** 24 (11, 42) *P* < 0.05 **Peak flow rate (mL/s), median (range):** **G1:** 22 (15, 40) **G2:** 32 (15, 45) **Residual urinary volume (mL), median (range):** **G1:** 81 (40, 140) **G2:** 38 (15, 60) *P* < 0.05	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Enzelsberger et al. 1995 (continued)			**Previous operations for UI, n:** **G1:** 11 **G2:** 10	**Dry mouth, n (%):** **G1:** 4 (17) **G2:** 2 (10) **Blurred vision, n (%):** **G1:** 2 (8) **G2:** 1 (5) **Nausea, n (%):** **G1:** 0 **G2:** 0 **Constipation, n (%):** **G1:** 2 (8) **G2:** 3 (15) **Dizziness, n (%):** **G1:** 3 (13) **G2:** 0 **Headache, n (%):** **G1:** 1 (4) **G2:** 1 (5) **UTI, n (%):** **G1:** 4 (17) **G2:** 2 (10)	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Fossberg et al., 1990 **Country and setting:** Norway, Denmark, Finland, Sweden, Academic medical center **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Prospective case series **Intervention:** Treatment with a stimulation device including an anal and a vaginal plug electrode; stimulation provided at cyclic sweep within 5-10 Hz, administered 12 times for 20 minutes each (frequency of treatment not indicated) **Groups:** NA **N at enrollment:** 91 **N at follow-up:** 74 **Women, %:** 88 **Age, mean (range):** 53 (20-78) **Race/ethnicity:** NR **Menopausal, %:** 50	**Inclusion criteria:** • Cystometrically proven detrusor instability, frequency and UUI **Exclusion criteria:** • UTI • Drugs affecting the lower urinary tract • Discontinued anticholinergic drugs < 6 weeks before study	**Voids/day, mean ± SD (range):** 9.1 ± 3.5 (4-20) **Nocturia episodes/day, mean ± SD (range):** 1.6 ± 1.1 (0-6) **Bladder volume (mL), mean ± SD (range):** 169 ± 68 (50-425) **Bladder volume (mL), first sensation, mean ± SD (range):** 139 ± 81 (33-300) **Max cystometric capacity (mL), mean ± SD (range):** 270 ± 155 (25-750) **Previously treated with drugs for UUI, %** 67	**Voids/day, before last treatment, mean ± SD (range):** 7.9 ± 2.9 (3-18) *P* = 0.001 **Voids/day, 6 weeks after last treatment, mean ± SD (range):** 8.0 ± 2.8 (3-19) *P* = 0.003 **Nocturia epsides/day, before last treatment, mean ± SD (range):** 1.2 ± 1.2 (0-6) *P* = 0.002 **Nocturia epsides/day, 6 weeks after last treatment, mean ± SD (range):** 1.1 ± 1.1 (0-4) *P* < 0.001 **Bladder volume (mL), before last treatment, mean ± SD (range):** 189 ± 82 (50-490) *P* = 0.002 **Bladder volume (mL), 6 weeks after last treatment, mean ± SD (range):** 194 ± 93 (50-500) *P* < 0.001 **Bladder volume (mL), first sensation, before last treatment, mean ± SD (range):** 164 ± 93 (35-410) *P* = 0.008	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Fossberg et al., 1990 (continued)				**Bladder volume (mL), first sensation, 6 weeks after last treatment, mean ± SD (range):** 175 ± 114 (25-470) *P* = 0.003 **Max cystometric capacity (mL), before last treatment, mean ± SD (range):** 307 ± 159 (50-725) *P* = 0.009 **Max cystometric capacity (mL), before last treatment, mean ± SD (range):** 299 ± 174 (25-690) *P* = 0.12 **Patient evaluation of effect, before last treatment, n:** Cured: 6 Improved: 45 Unchanged: 23 Worse: 0 *P* < 0.001 **Patient evaluation of effect, 6 weeks after last treatment, n:** Cured: 8 Improved: 32 Unchanged: 34 Worse: 0 *P* < 0.001 **Adverse effects, n:*** 11	

Data analysis indicated no differences between males and females in any data recorded

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Groenendijk et al. 2007 [See evidence table for Hassouna et al. 2000] **Country and setting:** US, Canada, and Europe;16 centers **Enrollment period:** NR **Funding:** Medtronic Inc. **Author conflict of interest:** Medtronic (6)	**Design:** Cohort **Intervention:** implantable Interstim system stimulating the nerve ramus in preoperatively tested sacral nerve foramen **Groups:** **G1:** urge incontinence and detrusor overactivity (DO) **G2:** urge incontinence without detrusor overactivity **N at enrollment:** **G1:** 67 **G2:** 44 **N at follow-up:** **G1:** 51 **G2:** 32 **Age:** NR **Race/ethnicity: NR** **Women, n:** **G1:** 59 **G2:** 40 **Follow-up:** 6 months	**Inclusion criteria:** • >16 years of age • refractory to standard medical therapy • Bladder capacity of at least 100mL • -Normal upper urinary tract **Exclusion criteria:** • Treatable etiologies for urinary/frequency symptoms • Neurologic conditions • -Primary stress incontinence • Pelvic pain symptoms	**First sensation of filling, mL ± SD:** Overall: 82.8 ± 64.7 **G1:** NR **G2:** 122.2 ±78.8 **Bladder volume at first detrusor contraction, mL ± SD:** Overall: 104.7 ± 111.0 **Bladder capacity, mL ± SD:** Overall: 254 ± 138 **G1:** NR **G2:** 313 ± 117 **Detrusor pressure at capacity, cm water ± SD:** Overall: 27.7 ± 21.6	**First sensation of filling, mL ± SD:** Overall: 167.4 ± 109.3, p<0.001 **G1:** NR **G2:** 192.4 ± 118.4 p=0.001 **Bladder volume at first detrusor contraction, mL ± SD:** Overall:133.7 ± 125.9, p =0.30 **Bladder capacity, mL ± SD:** Overall: 328 ± 148, p=0.001 **G1:** NR **G2:** 365 ± 115, p=0.02 **Detrusor pressure at capacity, cm water ± SD:** Overall: 17.7 ± 16.5 **DO at 6 months, n (%):** **G1:** -25 (49%) -stimulation was clinically successful in 19 (40%) -failed in 3 (6%) - 26 (51%) were negative for DO -stimulation was clinically successful in 20 (42%) - failed in 6 (12%) **G2:** -3 (9%)were positive for DO -stimulation was clinically successful in 2 (7%) - failed in 1 (4%) - 29 remained negative for DO -stimulation was successful in 23 (82%) -failed in 2 (7%)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: -, NR Baseline OAB status: + Baseline characteristics: - Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Hassouna et al., 2000 **Country and setting:** US, Canada, and Europe, 12centers **Enrollment period:** Ended June 1998 **Funding:** Medtronic Inc. **Author conflict of interest:** Medtronic	**Design:** Prospective cohort **Intervention:** implantable Interstim system stimulating the nerve ramus in preoperatively tested sacral nerve foramen **Groups:** G1: Neurostimulation G2: control **N at enrollment:** G1: 25 G2: 26 **N at follow-up:** 51 patients with urgency/ frequency **Age, mean yrs ± SD:** Total: 39.0 ±11.8 **Race/ethnicity:** NR **Women, %:** 90 **Follow-up:** 6 months	**Inclusion criteria:** • >16 years of age • refractory to standard medical therapy • Bladder capacity of at least 100mL • -Normal upper urinary tract **Exclusion criteria:** • Treatable etiologies for urinary/frequency symptoms • Neurologic conditions • -Primary stress incontinence • Pelvic pain symptoms	**Mean voids/day:** 16.0 ±8.2 **Mean mL voided/void:** G1: 118±74 G2: 124±66 **Mean max. voided volume:** 288 ±156 **Mean total voided volume/day**: 1693± 866 **Mean % indicating they felt empty:** 44 ±39 **Mean duration of urinary symptoms before enrollment:** 8.1 ± 9.2 years **Mean pelvic/ bladder discomfort (0 none-3 severe):** 2.1 ±0.8 **Degree urgency before voiding:** G1: 2.2±0.6 G2: 2.4±0.5	**Mean mL voided/void:** G1: 226±124 G2: 123±75 P< 0.001 **Degree urgency before voiding:** G1: 1.6±0.9 G2: 2.3±0.5 P = 0.01	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: + Loss to followup: NR Drop-out rates: NR Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Evidence Table 3. KQ2 Procedural and surgical treatments (continued)					
Study Description	**Study Design, Interventions, and Population**	**Inclusion/ Exclusion Criteria**	**Symptom Characteristics**	**Outcomes**	**Quality Rating**
Author: Janknegt et al., 2001 **Country and setting:** 15 investigators in US, Canada, and Europe **Enrollment period:** December 1993-September 1999 **Funding:** NR. **Author conflict of interest:** NR	**Design:** Prospective case series **Intervention:** implantable Interstim system stimulating the nerve ramus in preoperatively tested sacral nerve foramen **Groups:** NA **N at enrollment:** NA **N at follow-up:** 96 patients with urge incontinence **Age:** NR **Women, n (%):** 85 (89) **Race/ethnicity:** NR **Follow-up**: ≥12 months Mean follow-up 30.8 months (range 12-60)	**Inclusion criteria:** • age > 16 years • refractory to standard medical therapy for UUI • 100 mL bladder capacity with normal upper urinary tract **Exclusion criteria:** • neurological conditions • stress urinary incontinence • rimary pelvic pain	**Duration of symptoms, mean yrs ± SD:** 9.1± 7.0. **Leaking episodes/day:** 10.9 ±6.5 **Leak severity ranking:** 2.0 ±0.6 **Absorbent pad/diapers replaced/day:** 6.6 ±5.2 **Pads/diapers used daily, mean ± SD:** 7.1 ± 5.1 **Leaking episodes per day, mean ± SD:** 8.0± 4.8 **Heavy leaks per day, mean ± SD:** 4.7 ± 4.2	**Leaking episodes/day:** 4.2 ± 4.9 p<0.0001 **Completely dry, n (%):** 25 (26) **> 50% reduction in frequency of incontinent episodes, n (%):** 35 (36) **Leak severity ranking:** 1.7±0.6 P<0.0001 **Pads/diapers used daily mean ± SD:** 2.9 ± 3.8 P<0.0001 **Stopped using pads, n (%):** 30 (33) **Reduced pad use ≥ 50%, n (%):** 25 (28) **Heavy leaks per day, mean ± SD:** 2.8± 4.0 P<0.0001 **Eliminated both moderate and heavy leaking episodes, n (%):** 38 (43) **≥ 50% reduction in moderate/heavy leaking, n (%):** 18 (20) 11 patients explanted due to lack of efficacy	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: ++ Drop-out rates: + Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
				(n=9), chronic leg pain (n=1), or bowel dysfunction (n=1)	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Kessler et al., 2007 **Country and setting:** Switzerland, Swiss Registry database **Enrollment period:** July 2000 to December 2005 **Funding:** not described **Author conflict of interest:** Authors Kessler, Buchser, and Burkhard have consultancy agreements with Medtronic; author Zrehen is a Medtronic employee; Metronic Switzerland was assigned to monitor and maintain the Swiss Registry.	**Design:** Prospective case series **Intervention:** SNM testing and IPG implantation **Groups:** A portion of this series is composed of patients with urge incontinence (not further defined). **N at enrollment:** 209 evaluated: 181 female, 28 male. **N at follow-up:** 209: all evaluated were considered for adverse events of SNM testing 102 successful tests 91 had implantation of implantable pulse generator (IPG). 71 of these had urge incontinence. **Age, median:** 58 yrs **Race/ethnicity:** NR **Follow-up, mean:** 24 months for UUI	**Inclusion criteria:** • Tested for urge incontinence, nonobstructive chronic urinary retrention and chronic pain syndrome • Refractory to conventional therapies • Underwent urologic evaluation with medical history, physical exam, bladder and/or pain diary, urine analysis, urine culture and urodynamic studies before SNM. **Exclusion criteria:** NR	**Urge incontinence, n:** Female: 137 Male: 16 **Leakages per 24 hrs, median:** 5 **Pads used per 24 hrs, median:** 4 **Voids per 24 hrs, median:** 10 **Of 91 who underwent IPG implantation (11 of the 102 with successful testing refused implantation):** 71 urge incontinence; 13 nonobstructive chronic urinary retention and 7 chronic pelvic pain syndrome.	**Median follow-up was 24 months**. **Primary outcome:** subjective symptom improvement, changes in bladder/pain diary variables. SNM was considered successful in 64 of 91 implanted patients, including 50 with urge incontinence. This group at last follow-up had a median of 0 leakages per 24 hours, 1 pad use per 24 hours, 6 voids per 24 hours, and 80% subjective symptom improvement. **Secondary outcome:** **I**ncidence and treatment of adverse events due to SNM: Adverse events were reported in 12 of 209 patients who were initially tested, including lead migration in 9, wound infection in 2, and refractory pain at tined lead site in 1. These were not broken down separately for urge incontinence group.	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: ++ Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: - Measurement reliability: - Intervention description: +

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Kessler et al., 2007 (continued)				Adverse events with IPG implantation were reported in 10 of 91 patients, including lead migration (2) broken lead (1), wound infection at IPG site (2), pain at IPG site (3), IPG migration (1), and IPG malfunction after MIR (1). 6 of these patients required surgical revision. These were not broken down separately for urge incontinence group.	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Koldewijn et al. 1994 **Country and setting:** The Netherlands **Enrollment period:** June 1990 to August 1993 **Funding:** NR	**Design:** Prospective case series **Intervention:** percutaneous stimulation of the sacral root S3 on the left and right sides **Groups:** NA **N at enrollment:** NR **N at follow-up:** 100 **Age (mean):** 42 years **Women, n:** 86 **Race/ethnicity:** NR	**Inclusion criteria:** • failed previous treatment with medication, behavioral therapy, surgery, or combination therapy **Exclusion criteria:** • No other lower urinary tract conditions	Urge incontinence, n: 46 Incomplete bladder emptying, n: 23 Urgency and frequency, n: 13 Mixed incontinence, n: 10 Dysuria or pelvic pain, n: 5 Stress incontinence, n: 3 Detrusor overactivity, n: 52 Detrusor underactivity, n : 24 Urethral instability, n: 5 No abnormalities by UDS, n: 19 No neuro-physiological abnormalities, n: 18 Central neuro-physiological abnormality, n: 10 Peripheral neuro-physiological abnormaility, n: 16	**Perfect improvement** (>90%), n: 22 **Moderate improvement (50-90 %), n :** 8 **Slight improvement (10-50%), n :** 10 **No response, n:** 17 **Pain in the area of puncture during stimulation, n:** 7	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: NR Drop-out rates: NR Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: - Intervention description: +

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Korda et al., 1987 **Country and setting:** Australia **Enrollment period:** 1983 - 1984 **Funding:** NR	**Design:** Prospective case series **Intervention:** Bladder distention **Groups:** NA **N at enrollment:** 50 **N at follow-up:** 50 **Age:** NR **Race/ethnicity:** NR **Gender:** 100% F **Follow-up:** 3, 6 and 12 mo	**Inclusion criteria:** • Diagnosis with detrusor instability and failure to respond to anticholinergic treatment **Exclusion criteria:** NR	**NR**	**Extraperitoneal rupture:** 2 patients **At 3 mos:** Symptom free: 10 Improved: 25 Unchanged: 15 **At 12 mos:** Symptom free: 9 Improved: 15 Unchanged: 26	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: - Loss to followup: ++ Drop-out rates: + Power calculation: - Statistical issues: - EXTERNAL VALIDITY: poor Age: -, NR Baseline OAB status: NR Baseline characteristics: - Length of followup: ++ Measurement methods: - Measurement reliability: - Intervention description: +

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Evidence Table 3. KQ2 Procedural and surgical treatments (continued)					
Study Description	**Study Design, Interventions, and Population**	**Inclusion/ Exclusion Criteria**	**Symptom Characteristics**	**Outcomes**	**Quality Rating**
Author: Mundy 1983 **Country and setting:** UK **Enrollment period:** NR **Funding:** NR	**Design:** retrospective case series **Intervention:** bladder transection **Groups, N:** **G1:** 23; circumferential transection of the bladder wall just above the ureteric orifices **G2:** 81; transection of the posterior and posterolateral bladder wall from 1 cm lateral to the right ureteric orifice to 1 cm lateral on the left side ureteric orifice **N at enrollment:** 104 **Duration of follow-up:** at least 12 months (range 12-59 months; mean 35 months) **N at follow-up:** 104 at year 1, 82 at year 2, 49 at year 3, 25 at year 4, and 6 at year 5 **Age mean yrs (range):** 37 (19-81) **Women, n (%):** 91(87.5%) **Race/ethnicity:** NR No separate analysis by	**Inclusion criteria:** • urodynamically proven detrusor instability • frequency, urgency and urge incontinence for at least 3 years • failure to respond to standard conservative treatment (e.g. bladder drill, probanthine therapy, imipramine therapy, emepromium bromide therapy, hydrostatic bladder dilatation, oxybutynin) **Exclusion criteria:** NR	NR	**Initial post-operative evaluation (3-6 months after operation):** 74% cured, 14% improved; 12% failures; authors note same results at year 1 **At last evaluation (in patients followed for 2-5 years)**: 53 (65% still cured), 16 (19%) improved; 13 (16%) failures 9 participants with residual symptoms after operation later responded to other therapies **Among 68 patients with at least one postoperative urodynamic study:** 50 symptomatically cured; 14 of these reverted to stability and 26 showed a shift to the right of the urodynamic pattern 28 were failures or showed partial response; 8 were no longer unstable, and 14 remained the same as before their operation; authors note 6 with genuine stress incontinence were successfully managed by appropriate surgical treatment	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: - Loss to followup: ++ Drop-out rates: + Power calculation: - Statistical issues: - EXTERNAL VALIDITY: poor Age: + Baseline OAB status: NR Baseline characteristics: - Length of followup: ++ Measurement methods: - Measurement reliability: - Intervention description: -

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
	gender				

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Mundy 1983 (continued)				**Adverse events:** 1 patient developed persistent urine leak from her bladder requiring reoperation. • Urodynamic evidence of vesicoureteric reflux postoperatively that had not been observed pre-operatively in 14 patients; none were symptomatic or developed acute pyelonephritis	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Evidence Table 3. KQ2 Procedural and surgical treatments (continued)					
Study Description	**Study Design, Interventions, and Population**	**Inclusion/ Exclusion Criteria**	**Symptom Characteristics**	**Outcomes**	**Quality Rating**
Author: O'Reilly et al., 2008 **Country and setting:** Australia, Academic health centers **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Trans-sacral nerve (S3-S4) stimulation vs sham **Groups:** **G1:** transsacral nerve magnetic stimulator of the S3 and S4 nerve roots x 20 min/ day x 12 wk **G2:** sham x 20 min/day x 12 wk **N at enrollment:** **G1:** 33 **G2:** 30 **N at follow-up:** **G1:** 33 **G2:** 30 **Women, %:** 100 **Age, mean ± SD:** **G1:** 62.6 ± 13.45 **G2:** 59.8 ± 14.19	**Inclusion criteria:** • Women • Age ≥ 18 • Ability to give informed consent • Ability to comply w/ instructions to use the device • Ability to perform treatment over an 84-d period and attend for f/u • OAB symptoms for ≥ 6 mos • Unresponsive to behavioral measures or anticholinergic medication **Exclusion criteria:** • Pregnancy • Actively trying to conceive • Waking voiding frequency < 7 in 12 hrs • Nocturia < 2 • SUI symptoms • Benign or malignant bladder tumor • UTI • Previous irradiation or drug-induced cystitis • Symptomatic diverticulum • Vaginal infection • DM • Peripheral neuropathy • Cardiovascular disease • Cancer of the genital tract, urinary tract calculi • Cardiac arrhythmia	**Voids/day, mean ± SD** **G1:** 10 ± 3.2 **G2:** 9 ± 3.3 **Symptom impact, median VAS score (IQR):** **G1:** 80 (50-90) **G2:** 80 (70-90) **AQoL, overall mean score ± SD:** **G1:** 0.67 ± 0.22 **G2:** 0.67 ± 0.26 **AQoL, illness, median score (IQR):** **G1:** 0.42 (0.14-0.87) **G2:** 0.40 (0.17-0.87) **AQoL, independent living, median score (IQR):** **G1:** 1 (0.87-1) **G2:** 1 (0.88-1) **AQoL, social relationships, median score (IQR):** **G1:** 1 (0.90-1) **G2:** 0.97 (0.79-1) **AQoL, physical senses, median score (IQR):** **G1:** 0.94 (0.86-1) **G2:** 0.97 (0.92-1) **AQoL, psycho-logical well-being, median score (IQR):** **G1:** 0.85 (0.85-0.91) **G2:** 0.87 (0.85-0.93)	**Voids/day, mean ± SD:** **G1:** 9 ± 2.7 **G2:** 9 ± 3.2 **Symptom impact, median VAS score (IQR):** **G1:** 70 (40-90) **G2:** 75 (50-80) **AQoL, overall mean score ± SD:** **G1:** 0.69 ± 0.22 **G2:** 0.72 ± 0.25 **AQoL, illness, median score (IQR):** **G1:** 0.52 (0.19-0.81) **G2:** 0.42 (0.17-0.87) **AQoL, independent living, median score (IQR):** **G1:** 1 (0.9-1) **G2:** 1 (0.83-1) **AQoL, social relationships, median score (IQR):** **G1:** 0.94 (0.88-1) **G2:** 0.94 (0.86-1) **AQoL, physical senses, median score (IQR):** **G1:** 0.94 (0.86-1) **G2:** 0.94 (0.92-1) **AQoL, psycho-logical well-being, median score (IQR):** **G1:** 0.85 (0.83-0.93) **G2:** 0.90 (0.85-0.98) **KHQ, general health, median**	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: + Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: + Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
				score (IQR): **G1:** 25 (0-50) **G2:** 25 (0-50)	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
O'Reilly et al., 2008 (continued)			**KHQ, general health, median score (IQR):** **G1:** 25 (0-25) **G2:** 25 (25-50) **KHQ, incontinence Impact, median score (IQR):** **G1:** 100 (66.6-100) **G2:** 100 (66.6-100) **KHQ, role limitations, median score (IQR):** **G1:** 66.6 (50-83.3) **G2:** 58 (33.3-83.3) **KHQ, physical limitations, median score (IQR):** **G1:** 50 (16.6-83.3) **G2:** 50 (16.6-66.6) **KHQ, social limitations, median score (IQR):** **G1:** 30 (10-70) **G2:** 30 (10-60) **KHQ, personal relationships, median score (IQR):** **G1:** 16.6 (0-66.6) **G2:** 16.6 (0-50) **KHQ, emotions, median score (IQR):** **G1:** 66.6 (33-100) **G2:** 55.2 (22.2-88.8) **G2:** 50 (33.3-83.3)	**KHQ, incontinence Impact, median score (IQR):** **G1:** 100 (33.3-100) **G2:** 100 (33.3-100) **KHQ, role limitations, median score (IQR):** **G1:** 33.3 (16.6-83.3) **G2:** 33.3 (0-66.6) **KHQ, physical limitations, median score (IQR):** **G1:** 41.6 (16.6-83.3) **G2:** 50 (16.6-66.6) **KHQ, social limitations, median score (IQR):** **G1:** 25 (10-60) **G2:** 20 (10-30) **KHQ, personal relationships, median score (IQR):** **G1:** 0 (0-33.3) **G2:** 0 (0-33.3) **KHQ, emotions, median score (IQR):** **G1:** 44.4 (22.2-88.8) **G2:** 44.4 (22.2-77.7) **KHQ, sleep and energy, median score (IQR):** **G1:** 50 (33.3-66.6) **G2:** 50 (33.3-66.6) **KHQ, severity measures, median score (IQR):** **G1:** 53.3 (33.3-73.3) **G2:** 46.6 (40-66.6)	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
O'Reilly et al., 2008 (continued)			**KHQ, sleep and energy, median score (IQR):** **G1:** 66.6 (33.3-83.3)	**Voided volume (mL), median (IQR):** **G1:** 425 (250-550) **G2:** 375 (300-500)	
			KHQ, severity measures, median score (IQR): **G1:** 60 (46.6-76.6) **G2:** 50 (40-66.6)	**Total voided volume/ day (mL), mean ± SD:** **G1:** 1780 ± 630 **G2:** 1790 ± 710	
			Voided volume (mL), median (IQR): **G1:** 350 (250-500) **G2:** 400 (300-550)		
			Total voided volume/day (mL), mean ± SD: **G1:** 1850 ± 715 **G2:** 1800 ± 750		

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Evidence Table 3. KQ2 Procedural and surgical treatments (continued)					
Study Description	**Study Design, Interventions, and Population**	**Inclusion/ Exclusion Criteria**	**Symptom Characteristics**	**Outcomes**	**Quality Rating**
Author: Rios et al., 2007 **Country and setting:** Brazil, academic hospital **Enrollment period:** NR **Funding:** Departments of Urology of the Federal University of São Paulo, Paulista School of Medicine and Hospital do Servidor Público Estadual de São Paulo **Author industry relationship disclosures:** None	**Design:** RCT **Intervention:** intravesical resiniferatoxin (RTX) **Groups:** **G1:** single dose 100 ml 50 nM RTX **G2:** placebo **N at enrollment:** **G1:** 34 **G2:** 24 **N at follow-up:** **G1:** 33 **G2:** 23 **Women, %:** 100 **Age, mean ± SD:** 56 ± 12.09 **Race/ethnicity:** NR	**Inclusion criteria:** • Urinary frequency, daily urgency & UUI, nocturia for > 6 mos prior to study • Involuntary detrusor contractions on cystometrogram **Exclusion criteria:** • Use of anticholinergics or tricyclic antidepressants in last 2 mos • Neurologic conditions • UTI • Pelvic prolapse > grade 2 • History of pelvic radiation or bladder tumor • Poor bladder wall compliance • Detrusor underactivity	**Incontinence episodes/day, per-protocol analysis, mean ± SD:** **G1:** 3.11 ± 2.50 **G2:** 5.76 ± 3.39 *P* = 0.002 **Incontinence episodes/day, ITT analysis, mean ± SD:** **G1:** 3.00 ± 2.46 **G2:** 5.06 ± 3.37 *P* = 0.015 **Voids/day, per-protocol analysis, mean ± SD:** **G1:** 9.68 ± 2.92 **G2:** 9.94 ± 2.76 *P* = 0.756 **Voids/day, ITT analysis, mean ± SD:** **G1:** 9.66 ± 2.88 **G2:** 9.90 ± 2.58 *P* = 0.746 **Enuretic episodes/wk, per-protocol analysis, mean ± SD:** **G1:** 0.33 ± 0.53 **G2:** 0.59 ± 0.80 *P* = 0.340 **Enuretic episodes/wk, ITT analysis, mean ± SD:** **G1:** 0.36 ± 0.53 **G2:** 0.46 ± 0.72 *P* = 0.864 **Nocturia episodes/day, per-protocol analysis, mean ± SD:** **G1:** 2.22 ± 1.02	**Incontinence episodes/day, per-protocol analysis, mean ± SD:** **G1:** 2.68 ± 3.08 **G2:** 4.50 ± 3.83 *P* = 0.012 **Incontinence episodes/day, ITT analysis, mean ± SD:** **G1:** 2.72 ± 3.04 **G2:** 4.20 ± 3.57 *P* = 0.027 **Voids/day, per-protocol analysis, mean ± SD:** **G1:** 9.03 ± 2.77 **G2:** 9.10 ± 2.68 *P* = 0.814 **Voids/day, ITT analysis, mean ± SD:** **G1:** 9.03 ± 2.73 **G2:** 9.21 ± 2.53 *P* = 0.738 **Enuretic episoldes/wk, per-protocol analysis, mean ± SD:** **G1:** 0.15 ± 0.34 **G2:** 0.65 ± 1.06 *P* = 0.140 **Enuretic episodes/wk, ITT analysis, mean ± SD:** **G1:** 0.17 ± 0.36 **G2:** 0.52 ± 0.98 *P* = 0.321 **Nocturia episodes/day, per-protocol analysis, mean ± SD:** **G1:** 1.73 ± 1.14 **G2:** 1.82 ± 1.16 *P* = 0.794	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: - Loss to followup: ++ Drop-out rates: NR Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
			G2: 2.29 ± 1.26 *P* = 0.827		

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rios et al., 2007 (continued)			**Nocturia episodes/day, ITT analysis, mean ± SD:** **G1:** 2.21 ± 1.02 **G2:** 2.28 ± 1.19 *P* = 0.796 **KHQ, general health perception, mean score ± SD:** **G1:** 37.88 ± 14.14 **G2:** 42.70 ± 21.61 **KHQ, incontinence impact, mean score ± SD:** **G1:** 77.78 ± 28.46 **G2:** 83.33 ± 22.94 **KHQ, role limitations, mean score ± SD:** **G1:** 62.63 ± 36.33 **G2:** 70.00 ± 35.29 **KHQ, physical limitations, mean score ± SD:** **G1:** 59.60 ± 34.37 **G2:** 60.00 ± 31.71 **KHQ, social limitations, mean score ± SD:** **G1:** 27.44 ± 25.23 **G2:** 29.90 ± 28.64 **G2/G1:** *P* < 0.05 **KHQ, personal relationship, mean score ± SD:** **G1:** 34.92 ± 41.47 **G2:** 26.47 ± 34.89 **KHQ, emotions, mean score ± SD:** **G1:** 57.24 ± 35.59 **G2:** 66.11 ± 29.39	**Nocturia episodes/day, ITT analysis, mean ± SD:** **G1:** 1.77 ± 1.14 **G2:** 1.89 ± 1.12 *P* = 0.769 **KHQ, general health perception, mean score ± SD:** **G1:** 34.85 ± 13.89 **G2:** 43.75 ± 24.16 **KHQ, incontinence impact, mean score ± SD:** **G1:** 60.61 ± 33.80 **G2:** 65.00 ± 38.20 **G1/BL:** *P* < 0.05 **G2/BL:** *P* < 0.05 **KHQ, role limitations, mean score ± SD:** **G1:** 48.99 ± 35.09 **G2:** 49.12 ± 37.46 **G2/BL:** *P* < 0.05 **KHQ, physical limitations, mean score ± SD:** **G1:** 45.45 ± 36.39** **G2:** 44.17 ± 39.84 **KHQ, social limitations, mean score ± SD:** **G1:** 21.55 ± 25.30 **G2:** 38.50 ± 31.91 **KHQ, personal relationship, mean score ± SD:** **G1:** 27.08 ± 38.33 **G2:** 37.50 ± 41.51 **KHQ, emotions, mean score ± SD:** **G1:** 42.76 ± 35.80 **G2:** 54.45 ± 37.10 **G1/BL:** *P* < 0.05 **KHQ, sleep and energy, mean score ± SD:** **G1:** 28.79 ± 24.03 **G2:** 38.33 ± 31.11 **G1/BL:** *P* < 0.05	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rios et al., 2007 (continued)			**KHQ, sleep and energy, mean score ± SD:** **G1:** 43.43 ± 26.66 **G2:** 37.50 ± 24.71 **KHQ, symptom severity, mean score ± SD:** **G1:** 8.08 ± 7.59 **G2:** 10.88 ± 13.55 **Cystometric capacity, per-protocol analysis, mean ± SD:** **G1:** 112.94 ± 68.22 **G2:** 124.15 ± 76.05 *P* = 0.581 **Cystometric capacity, ITT analysis, mean ± SD:** **G1:** 114.62 ± 67.89 **G2:** 127.42 ± 72.99 *P* = 0.496 **Max cystometric capacity, per-protocol analysis, mean ± SD:** **G1:** 285.8 ± 183.20 **G2:** 246.50 ± 92.87 *P* = 0.306 **Max cystometric capacity, ITT analysis, mean ± SD:** **G1:** 287.47 ± 180.64 **G2:** 240.63 ± 85.77 *P* = 0.194	**KHQ, symptom severity, mean score ± SD:** **G1:** 13.94 ± 9.91 **G2:** 10.88 ± 11.80 **G1/BL:** *P* < 0.05 **Cystometric capacity, per-protocol analysis, mean ± SD:** **G1:** 144.70 ± 93.41 **G2:** 172.75 ± 117.83 *P* = 0.310 **Cystometric capacity, ITT analysis, mean ± SD:** **G1:** 145.44 ± 92.08 **G2:** 167.92 ± 109.93 *P* = 0.322 **Max cystometric capacity, per-protocol analysis, mean ± SD:** **G1:** 298.03 ± 161.48 **G2:** 270.50 ± 109.57 *P* = 0.402 **Max cystometric capacity, ITT analysis, mean ± SD:** **G1:** 299.26 ± 159.18 **G2:** 260.63 ± 102.37 *P* = 0.237 **Bladder volume, 1st involuntary contraction, per-protocol analysis, mean ± SD:** **G1:** 120.17 ± 68.98 **G2:** 140.83 ± 84.34 *P* = 0.093	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rios et al., 2007 (continued)			**Bladder volume, first involuntary contraction, per-protocol analysis, mean ± SD:** **G1:** 89.31 ± 44.58 **G2:** 125.56 ± 79.92 *P* = 0.263 **Bladder volume, 1st involuntary contraction, ITT analysis, mean ± SD:** **G1:** 103.82 ± 59.51 **G2:** 124.38 ± 73.01 *P* = 0.243 **Max detrusor voiding pressure, per-protocol analysis, mean ± SD:** **G1:** 35.90 ± 12.05 **G2:** 34.06 ± 12.86 *P* = 0.807 **Max detrusor voiding pressure, ITT, analysis, mean ± SD:** **G1:** 33.59 ± 12.59 **G2:** 35.00 ± 11.67 *P* = 0.666	**Bladder volume, 1st involuntary contraction, ITT analysis, mean ± SD:** **G1:** 121.83 ± 68.39 **G2:** 139.09 ± 79.83 *P* = 0.102 **Max detrusor voiding pressure, per-protocol analysis, mean ± SD:** **G1:** 33.83 ± 15.78 **G2:** 32.33 ± 12.29 *P* = 0.625 **Max detrusor voiding pressure, ITT analysis, mean ± SD:** **G1:** 33.33 ± 15.74 **G2:** 32.91 ± 11.50 *P* = 0.819	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Evidence Table 3. KQ2 Procedural and surgical treatments (continued)					
Study Description	**Study Design, Interventions, and Population**	**Inclusion/ Exclusion Criteria**	**Symptom Characteristics**	**Outcomes**	**Quality Rating**
Author: Schmid et al. 2006 **Country and setting:** Switzerland; 3 clinics **Enrollment period:** January 2003 to October 2004 **Funding:** International Institute for Research in Paraplegia; Swiss National Science Foundation **Author conflict of interest:** NR	**Design:** prospective case series **Intervention:** 1000 U Botox-A in 10 mL 0.9% normal saline injected into the detrusor muscle 1-2 mm under the urothelium layer at 30 sites on the inner surface of the bladder wall (approx. 0.3 mL each injection) **Groups:** NA **N at enrollment:** 100 **N at follow-up:** 100 at 1 month; 80 at 3 months; 20 at 9 months **Age:** mean 63 years (range 24-89) **Race/ethnicity:** NR **Follow-up:** patients followed 4, 12, and 36 weeks after treatment Mean follow-up: 20 weeks (range 4-36) No separate analysis by gender	**Inclusion criteria:** • OAB syndrome (ICS) • Urodynamically demonstrable nonneurogenic detrusor overactivity or hypersensitive bladder with premature filling sensation • ≥ 8 voids per 24 hours (with or without incontinence) • Not effectively treated with maximal doses of anticholinergics (or unable to tolerate those drugs) **Exclusion criteria:** • Renal dysfunction • Myasthenia gravis • Neurogenic bladder dysfunction • Serious illness • Pregnant or breastfeeding • Interstitial cystitis • Radiocystitis • Bladder tumor • Chronic pelvic pain syndrome • Prostate hyperplasia • Infravesical obstruction • PVR > 150 mL • Hypocontractile/ acontractile detrusor • Prior SUI surgery and de novo	**Maximal cystometric bladder capacity (mL; mean ± SD):** 246 ±15 **Detrusor compliance (mL/cm H2O; mean ± SD):** 24.5 ± 2.3 **Reflex volume (mL; mean ± SD):** 169 ±14 (n=54) **First desire to void (mL mean ± SD):** 125 ±13 **Urgency to void (mL; mean ± SD):** 214 ±16 **Postvoid residual (mL; mean ± SD):** 21 ±8 **Incontinence, n:** 84 **Voiding frequency/24 hrs, n:** 9-15 times: 37 16-23 times:41 >24 times: 24	**Voiding frequency/24 hrs:** 4-8 times: 69 8-15 time : 24 **Maximal cystometric bladder capacity (mL; mean ± SD):** 1 mo.: 381 ±19 3 mos.: 384 ±19 9 mos.: 325 ±55 **Detrusor compliance (mL/cm H2O; mean ± SD):** 1 mo.: 40.5 ±2.9 3 mos.: 45.1 ±2.9 9 mos.: 37.1 ±8.4 **Reflex volume (mL; mean ± SD):** 1 mo.: 229 ±25 (n=14) 3 mos.: 222 ±35 (n=14) 9 mos.: 195 ±57 (n=6) **First desire to void (mL mean ± SD):** 1 mo.: 212 ±16 3 mos.: 208 ±16 9 mos.: 178 ±40 **Urgency to void (mL; mean ± SD):** 1 mo.: 309 ±20 3 mos: 332 ±20 9 mos: 210 ±57 **Postvoid residual (mL; mean ± SD):** 1 mo: 75 ±10 3 mos: 85 ±10 9 mos: 14 ±28 • Urgency disappeared in 72 patients at the 4 week assessment and in 66% at the 12	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: + Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
		urge • Mixed incontinence		week followup	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Schmid et al., 2006 (continued)				• Incontinence disappeared in 74% at 4 week follow-up and 80% at 12 week followup • No improvement in 8 patients • 90% of patients experienced improvement in at least 1 quality of life category, increasing at 3 month follow-up and decreasing at 9 months **Adverse events**: • 4 patients developed temporary (4 week) urinary retention and postvoid residual > 400 mL at 1-2 weeks after injection, requiring temporary intermittent clean self-catheterization; PVR returned to baseline within 6-9 months • 15 patients reported mild difficulty in voiding during the first moth with PVR 150-200 mL; declined ICSC • 10 patients developed bladder infection successfully treated by antibiotics	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Evidence Table 3. KQ2 Procedural and surgical treatments (continued)					
Study Description	**Study Design, Interventions, and Population**	**Inclusion/ Exclusion Criteria**	**Symptom Characteristics**	**Outcomes**	**Quality Rating**
Author: Schmidt et al., 1999 **Country and setting:** 16 centers in US, Canada, and Europe **Enrollment period:** 1993- April 1997 **Funding:** Supported by Medtronics Inc. **Author conflict of interest:** Schmidt, Jonas, Oleson, Janknegt, Siegel: financial interest and/or other relationship with Medtronic Inc.	**Design:** randomized controlled trial **Intervention:** implantable Interstim system stimulating the nerve ramus in preoperatively tested sacral nerve foramen **Groups:** G1: implantation with immediate stimulation (n=34 for efficacy analysis) G2: control group receiving standard medical therapy for 6 months; allowed to cross over at 6 months if remained eligible for implantation (n=42 for efficacy analysis) **N at enrollment:** 155 **N randomized:** 98 (the remaining 57 did not respond to test stimulation so were not randomized) **N at follow-up:** 76 at 6 months **Age:** mean 46.6 ±13.0 (range 20.2 – 78.9) **Gender:** 125 F (80.6%), 30 M (19.4%)	**Inclusion criteria:** • age > 16 years • refractory to standard medical therapy • ≥ 100 mL bladder capacdity with normal upper urinary tract • good surgical candidate • able to complete study documentation and return for follow-up evaluation **Exclusion criteria:** • neurological conditions • stress urinary incontinence • primary pelvic pain	Duration of urinary symptoms before enrollment: mean 9.0±7.4 (range 0.6-35.4) Mean number of daily incontinence episodes: 8.9± 5.9 G1: 9.7 ± 6.3 G2: 9.3 ± 4.8 Mean leak severity rating: 1.9± 0.6 G1: 2.0 ± 0.7 G2: 1.8 ± 0.6 Mean absorbent pads/diapers replaced daily 4.8± 4.8 G1: 6.2 ± 5.0 G2: 5.0 ± 3.7 Mean heavy incontinence episodes per day: G1: 3.4 ±3.8 G2: 2.6 ±3.5 3-day diary data: 90.3% of patients had at least 1 moderate/heavy and 74.8% had at least 1 heavy incontinence episode **Previous treatment for urinary problems:** 153 (89.7%), including pharmacological in 144 (92.5%, nonsurgical in 55 (35.5%), and surgical in 88 (56.8%)	At 6 months: Mean number of daily incontinence episodes: G1: 2.6± 5.1 (p<0.0001) G2: 11.3 ± 5.9 (p=0.002) Mean leak severity rating: G1: 0.8 ± 0.9 (p<0.0001) G2: 2.0± 0.6 (p=0.006) Mean absorbent pads/diapers replaced daily G1: 1.1 ± 2.0 (p<0.0001) G2: 6.3 ± 3.6 (p=0.003) Mean heavy incontinence episodes per day: G1: 0.3 ±0.9 (P<0.0001) G2: 3.9 ±3.8 G1: 47% completely dry at 6 months; 3 patients had no reduction in incontinence after 6 months (one underwent device explantation and 2 had increased frequency of urination and incontinence)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: + Loss to followup: - Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
	Race/ethnicity: NR				

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Schmidt et al., 1999 (continued)				**Safety data (pooled for 157 patients):** adverse events requiring surgical repositioning or replacement of implant devices document in 51 (32.5%) 168 post-implant events reported by 83 patients, including pain at the neurostimulator site in 15.9%, pain at implant site in 19.1, and lead migration in 7.0% Infection or skin irritation led to device explantation in 2 patients and temporary explant in 2 patients No permanent injuries or nerve damage reported.	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Evidence Table 3. KQ2 Procedural and surgical treatments (continued)					
Study Description	**Study Design, Interventions, and Population**	**Inclusion/ Exclusion Criteria**	**Symptom Characteristics**	**Outcomes**	**Quality Rating**
Author: Siegel et al. 2000 **Country and setting:** US, Canada, and Europe, 12 centers in **Enrollment period:** 1993- 999 **Funding:** partially funded through restricted research grants from Medtronics Inc. **Author conflict of interest:** NR	**Design:** case series **Intervention:** implantable Interstim system stimulating the nerve ramus in preoperatively tested sacral nerve foramen **N at enrollment:** 219 undergoing stimulator placement (from pool of 581 patients evaluated)* **UUI:** urge incontinence (n=41) **Urgency/Frequency:** (n=29) **N at follow-up:** total=112; 23 additional patients had undergone device explantation and an additional 84 were not yet due for long-term follow-up **Age, mean (range):** 43 (17-81) **Women, %:** 78% **Race/ethnicity:** NR	**Inclusion criteria:** • patients who received implanted Interstim and were due for long-term follow-up **Exclusion criteria:** NA **Indications, N:** Urge incontinence: 41 Urgency/frequency: 29 Retention: 42	**UUI episodes/day, mean ± SD:** 11.6 ± 6.6 **Heavy episodes per day, mean ± SD:** 3.6 ±4.0 **Pads per day, mean ± SD:** 6.7 ±4.6 **Voids per day:** 17.7 ±8.6 **Average volume per void:** 132.5 ±93.6 **Average degree of urgency before voiding (scale 1 mild – 3 severe):** 2.2. ±0.7 **Void volume per void, mean mL ± SD:** 343 ± 167	**UUI episodes/day, mean ± SD:** 5.0 ±6.1 P<0.0001 **Heavy episodes per day, mean ± SD:** 1.3 ±3.5 P<0.0001 **Pads per day, mean ± SD:** 3.4 ±4.9 P<0.0001 **Voids per day:** 10.6 ±6.6 P < 0.0001 **Void volume per void, mean mL ± SD:** 225 ±162 P < 0.0001 Improvement in degree of urgency before voiding was present in 69% of patients Eliminated use of catheterization, %: 58	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: - Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Siegel et al. 2000 (continued)				**Adverse events:** Pain at neurostimulator site (15.4%), new pain (9.0%), suspected lead migration (8.4%), infection (6.1%), transient electric shock (5.5%), pain at lead site (5.4%), adverse change in bowel function (3.0%), technical problems (1.7%), suspected device problems (1.6%), change in menstrual cycle (1.0%), adverse change in voiding function (0.6%), persistent skin irritation (0.5%), suspected nerve injury (0.5%), device rejection (0.5%), other (9.5%) **Surgical revision rate:** 33% (73/219)	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Evidence Table 3. KQ2 Procedural and surgical treatments (continued)					
Study Description	**Study Design, Interventions, and Population**	**Inclusion/ Exclusion Criteria**	**Symptom Characteristics**	**Outcomes**	**Quality Rating**
Author: Spinelli et al., 2001 **Country and setting:** Italy, Registry **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Case series **Intervention:** sacral neuromodulation with Itrel II or Interstim stimulation system **Groups:** **G1:** retrospective cases **G2:** prospective cases **N at enrollment:** **G1:** 93 **G2:** 103 **N at follow-up:** **G1:** 65 **G2:** NR **Age, mean (range):** **G1:** 50.9 (17, 79) **G2:** 50.1 (17, 79) **Race/ethnicity:** NR **Women, %:** **G1:** 80.6 **G2:** 72.8 **Follow-up:** **G1:** median 40 months, range 28-73 months **G2:** 3, 6, 9, 12, 18 and 24 months	**Inclusion criteria:** • placement of a sacral neurostimulator **Exclusion criteria:** NR	**Incontinence episodes/day, mean ± SD:** **G2:** 5.4 ± 3.9 **Detrusor instability QoL index, mean:** **G2:** 33.1 **Urgency/ frequency QoL index, mean:** **G2:** 40 **Detrusor instability, n (%):** **G1:** 44 (47.3) **G2:** 42 (40.8) **Retention, n (%):** **G1:** 20 (21.5) **G2**: 25 (24.3) **Neurogenic retention, n (%):** **G1:** 0 **G2:** 10 (9.7) **Detrusor hyperreflexia, n (%):** **G1:** 8 (8.6) **G2:** 15 (14.6) **Urgency/frequency, n (%):** **G1:** 5 (5.6) **G2:** 5 (4.9) **Pelvic pain, n (%):** **G1:** 9 (9.7) **G2:** 4 (3.9) **Urethral instability, n (%):** **G1:** 4 (4.3) **G2:** 2 (1.9) **Interstitial cystitis, n (%):** **G1:** 3 (3.2) **G2:** 0 **Detrusor insta-**	**Mean incontinence episodes/ day, UUI patients (including detrusor or urethral instability), %:** Completely dry: **G1:** 39 < 1 episode: **G1:** 23 1-3 esisodes: **G1:** 23 > 3 episodes: **G1:** 15 **Incontinence episodes/day, 12 mo, mean ± SD:** **G2:** 1.1 ± 1.6 *P* < 0.001 **Completely dry, 3 months, %:** **G2:** 57 *P* = NR **Completely dry, 6 months, %:**: **G2:** 65 *P* < 0.001 **Completely dry, 9 months, %:** **G2:** 55 *P* < 0.003 **Completely dry, 12 months, %:** **G2:** 59 *P* < 0.001 **Completely dry, 18 months, %:** **G2:** 43 *P* < 0.04 **Mean voids/day, %:** < 8 voids: **G1:** 42 8-12 voids: **G1:** 42 >12 voids: **G1:** 18	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: - Loss to followup: + Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
			bility or urgency/ frequency, n (%): Total: 102 (52)		

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Spinelli et al., 2001 (continued)				**Detrusor instability QoL index, 3 months, mean:** **G2:** 74.7 *P* < 0.001 **Detrusor instability QoL index, 6 months, mean:** **G2:** 80.5 *P* < 0.001 **Detrusor instability QoL index, 12 months, mean:** **G2:** 69.6 *P* < 0.001 **Detrusor instability QoL index, 18 months, mean:** **G2:** 73.7 *P* = NR **Urgency/ frequency QoL index, 3 months, mean:** **G2:** 73 *P* = NR **Urgency/ frequency QoL index, 6 months, mean:** **G2:** 66 *P* = NS **Urgency/ frequency QoL index, 12 months, mean:**: **G2:** 69.5 *P* = NS **Not requiring catheterization (but baseline catheterization), 3 months, %:** **G2:** 67 *P* < 0.001	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Spinelli et al., 2001 (continued)				**Not requiring catheterization (but baseline catheterization), 6 months, %:** **G2:** 67 *P* < 0.001 **Not requiring catheterization (but baseline catheterization), 9 months, %:** **G2:** 50 *P* < 0.001 **Not requiring catheterization (but baseline catheterization), 12 months, %:** **G2:** 50 *P* < 0.003 **Any adverse events, %:** **G1:** NR **G2:** 15.5 **Pain at implant site or extension cable connector, %:** **G2:** 3.9 **Hematoma/wound problem, %:** **G2:** 1.9 **Surgical revision necessary, %:** **G2:** 9.7 **Lead fracture, %:** **G2:** 3.9 **Explant of stimulation system, %:** **G2:** 3.9 **Lead repositioning, %:** **G2:** 1.9 **Lead displacement, %:** **G1:** 6.5	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Spinelli et al., 2001 (continued)				**New lead required due to initial bad position, %: G1:** 3.2 **Explantation of pulse generator due to infection, %: G1:** 1 **Lead breakage, %: G1:** 1 **System removed due to treatment failure, %: G1:** 3.2	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Evidence Table 3. KQ2 Procedural and surgical treatments (continued)					
Study Description	**Study Design, Interventions, and Population**	**Inclusion/ Exclusion Criteria**	**Symptom Characteristics**	**Outcomes**	**Quality Rating**
Author: Sutherland et al. 2007 **Country and setting:** US continence and female urology clinic **Enrollment period:** December 1993 to December 2004 **Funding:** funded in part by Medtronic, Inc. **Author conflict of interest:** 3 authors received fees for educational speaking on OAB and incontinence from Pfizer, Indevus, Astellas, and Medtronic, and consulting fees from Medtronic	**Design:** retrospective case series **Intervention:** implantable pulse generator for sacral nerve stimulation (device made by Medtronic) **N at enrollment:** 234 patients underwent the procedure **N at follow-up:** 104 patients were consented **Age, mean yrs ± SD:** 50 ± 13.4 **Women, N:** 91 **Race/ethnicity:** NR **Gender:** **Mean follow-up** 22 months (range 3-162 months)	**Inclusion criteria:** • Undergoing SNS **Exclusion criteria:** NR	**Voids per 24 hrs, mean ± SD:** 12.4 ±5.1 **Nocturnal voids per 24 hrs, mean ± SD:** 2.3 ±1.8 **Leaks per 24 hrs, mean ± SD:** 5.0 ±4.7 **Pads used per 24 hrs, mean ± SD:** 2.3 ±2.6 **Duration of symptoms, mean mos (range):** 116-130 (9-600)	**Urge incontinence:** 96% experienced reduction in pad use after SNS therapy; 50% completely dry; 46% used fewer pads, and 4% had no change **Voids per 24 hrs, mean ± SD:** 8.5 ±5.0 voids/24 hr P < 0.0001 **Nocturnal voids per 24 hrs, mean ± SD:** 1.6 ±2.2 P = 0.0091 **Leaks per 24 hrs, mean ± SD:** 1.0 ±1.4 leaks/24 hr P < 0.0001 **Pads used per 24 hrs, mean ± SD:** 0.3 ±0.7 pads/24 hr P < 0.0001 **Subjective improvement**: >50%: 69% >80%: 50% >90%: 35% **Satisfaction:** - satisfied: 60.5% - equivocal: 23.3% - dissatisfied: 16.1% **Adverse events:** - infection: 13 events (4 severe requiring hospitalization for iv antibiotics) - hematoma: 2 events - discomfort at component: 28 events	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Method and blinding: NA Pt selection criteria: + Loss to followup: - Drop-out rates: NA Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Sutherland et al., 2007 (continued)				battery depletion: 5 events - bowel complaints: 4 events - pelvic pain: 1 event - high impedance: 2 events - malposition of component: 1 event - seizures: 2 events - herpes flare: 3 events	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Evidence Table 3. KQ2 Procedural and surgical treatments (continued)					
Study Description	**Study Design, Interventions, and Population**	**Inclusion/ Exclusion Criteria**	**Symptom Characteristics**	**Outcomes**	**Quality Rating**
Author: van Kerrebroeck et al., 2007 **Country and setting:** US, Canada, and Europe, 17 centers **Enrollment period:** NR **Funding:** Medtronic Inc. **Author conflict of interest:** authors have financial interest and/or other relationship with Medtronic and other pharma and device companies (AMS, Astellas, Pfizer, Advanced Bionics, Uroplasty, Uromedica, J&J, Novartis, UCB, Bayer, Boehringer, Allergan, BioXell SpA, Alza, Solvay Pharma, Lilly Icos, Sanofi-Synthelabo, Janssen-Ortho, Purde Pharma, Negma Lerad, Laserscope, QLT, Lumenis, Schwarz, Glaxo, Eli Lilly, Boston Scientific)	**Design:** Prospective case series **Intervention:** implantable Interstim system stimulating the nerve ramus in preoperatively tested sacral nerve foramen **N at enrollment:** 163; 152 with implants **N at follow-up,** 1 year 79 **Age mean ± SD:** 44.7 ± 11.2 **Women, n (%):** 141 (87) **Race/ethnicity:** NR	**Inclusion criteria:** • patients receiving Interstim for management of voiding dysfunction **Exclusion criteria:** NR	**UUI:** -average number of leaking episodes per day: 9.6 ±6.0 - number of heavy leaks per day: 2.6± 3.3 - number of pads per day: >5 **Frequency:** - average number of voids per day 19.3±7.0 - average voided volume (mL): 92.3±52.8 -degree of urgency/day: 2.3±0.6 Urinary frequency: 28 UUI: 87 Urinary retention: 31 *	**UUI:** -average number of leaking episodes per day: 4.7 ±4.9 at one year follow-up; maintained throughout follow-up with mean 3.9± 4.0 at 5 years - number of heavy leaks per day: 1.2± 2.7 at one year follow-up and 0.8± 1.7 at 5 year follow-up - number of pads per day: 1.8 at 5 years follow-up **Frequency:** - average number of voids per day 13.0±7.9 at year 1 and 14.8± 7.6 at year 5 - average voided volume (mL): 169.9±118.2 at year 1 and 165.2± 147.7 at year 5 -degree of urgency/day: 1.9±0.8 at year 1, 2.1±0.7 at year 5 Adverse events: -110 events required surgery in 60 patients - system explanted from 16 due to AE or lack of efficacy - 31 AEs were device related and 240 were therapy related - new pain or undesirable change in stimulation: 43 patients, 60 events Pain at PNE or implant site, INS:	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: ++ Drop-out rates: + Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
				30 patients, 40 events	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
van Kerrebroeck et al., 2007 (continued)				-infection at PNE or implant site: 12 patients, 14 events - pain at PNE or implant site, lead: 12 patients, 13 events - sensation of electric shock: 12 patients, 14 events - undesirable change in voiding function 11 patients, 12 events - lead migration: 13 patients, 14 events - technical problems during PNE/implant: 8 patients, 8 events - device problem: 16 patients, 19 events - Other: 51 patients, 77 events -surgical intervention required for adverse events in 60 patients (110 events), including device exchange in 36 patients, positioning of pulse generator in 12, reposition of lead and generator in 10, reposition lead in 10, permanent explant in 9, temporary explant in 2, other intervention in 2, bilateral implant in 1, and surgical wound care in 1	

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: van Voskuilen et al., 2006 **Country and setting:** Netherlands, academic medical center **Enrollment period:** 1990 to 2003 **Funding:** WAMU Foundation **Author industry relationship disclosures:** NR	**Design:** retrospective case series **Intervention:** sacral nerve stimulation with Itrel-I device (1990 – 1994), Itrel-II device (1994 – 1999), or Interstim device (1999-2003) **Groups:** NA **N at enrollment:** 190 **N at follow-up:** 149 **Women, n (%):** 122 (81.9) **Age, mean yrs ± SD:** 46.7 (10.0) **Race/ethnicity:** NR **Follow-up, mean mos ± SD:** 64.2 (38.5)	**Inclusion criteria:** • Receiving a neuromodulation system or revision surgery for urge incontinence or urgency-frequency (with or without pelvic pain complaints), or non-obstructive urinary retention **Exclusion criteria:** • Percutaneous tined lead procedure • Receiving bilateral stimulation	**Overactive bladder, n (%):** 107 (71.8) **Urinary retention, n (%):** 42 (28.2%) **Idiopathic urgency/frequency or retention, n (%):** 129 (86.6%) **Neurologic urgency/frequency or retention:** 42 (28.2%)	**Good result, n (%):** 89 (59.7) **Insufficient results, n (%):** 44 (29.5) **Reprogramming session at last visit, n (%):** 16 (10.7%) **Good result after reprogramming, n (%):** 11 (68.8) **Insufficient results after reprogramming, n (%):** 5 (31.3) **Adverse events, n:** 194 in 106 patients **Pain/undesirable change in stimulation, n:** 64 **Undesirable change in voiding function/loss of efficacy, n :** 42 **Pain at IPG implant site, n:** 41 **Adverse change in bowel function, n:** 15 **Suspected lead migration, n :** 10 **Suspected device problem (including lead breakage), n:** 6 **Infection, n:** 6	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: - Loss to followup: - Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: poor Age: + Baseline OAB status: NR Baseline characteristics: - Length of followup: ++ Measurement methods: - Measurement reliability: - Intervention description: +

Evidence Table 3. KQ2 Procedural and surgical treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
van Voskuilen et al. 2006 (continued)				**Technical problem, n:** 5 **Suspected neuropraxia, n** : 2 **Other, n:** 3 **Requiring at least one reoperation due to AE, %:** 48.3 **Life span of replaced IPGs, mean mos (range):** 73.7 (28-127) **IPG removed, n (%):** 21 (14.1)	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Arruda et al., 2008 **Country and setting:** Brazil, community **Enrollment period:** August 2001 to September 2005 **Funding:** NR **Author industry relationship disclosures:** None	**Design:** RCT **Intervention:** Oxybutynin vs. functional electrostimulation vs. pelvic floor training **Groups:** **G1:** Oxybutynin 5 mg b.i.d. **G2:** Ambulatory stimulation applied vaginally **G3:** Pelvic floor exercises with a therapist and at home **N Screened:** 81 **N at enrollment:** **G1:** 22 **G2:** 21 **G3:** 21 **N at follow-up:** **G1:** 22 **G2:** 21 **G3:** 21 **Age, range:** 35-80 **Race/ethnicity:** NR **Women, %:** 100 **Length of follow up:** 12 weeks	**Inclusion criteria:** • Community-dwelling • Dx of OAB and DO • Capable of completing a bladder diary and performing a pelvic muscle floor contraction • For those with MUI, urge was predominant **Exclusion criteria:** • Hx of psychiatric or neurologic illness • Persistent UTI • Inability to comply with regular follow-up visits • Current pregnancy • Postvoid residual volume > 100 mL • Contraindications to anticholinergic therapy • Cardiac pacemaker • Type III SUI • Uncontrolled metabolic conditions or indwelling catheterization • Using medications including anticholinergic drugs, calcium antagonists, beta agonists, dopamine agonists, striated muscle relaxants or estrogens • Any uterine prolapse	**UUI episodes/ week, mean ± SD:** **G1:** 13.8 ± 11.6 **G2:** 13.5 ± 15.6 **G3:** 16.4 ± 17.2 **Nocturia episodes/week, mean ± SD:** **G1:** 1.7 ± 1.5 **G2:** 1.9 ± 1.9 **G3:** 1.4 ± 1.2 **Pads/day, mean ± SD:** **G1:** 2.6 ± 2.7 **G2:** 2.3 ± 2.4 **G3:** 2.7 ± 1.5 **Voids/day, mean ± SD:** **G1:** 7.7 ± 2.6 **G2:** 8.6 ± 3.4 **G3:** 6.8 ± 2.2 **Residual volume mean mL ± SD:** **G1:** 3.2 ± 6.3 **G2:** 1.0 ± 2.6 **G3:** 1.8 ± 3.3 **Volume, first desire to void, mean mL ± SD:** **G1:** 117.7 ± 68.9 **G2:** 102.4 ± 51.1 **G3:** 86.7 ± 38.9 **Maximal cystometric capacity, mean mL ± SD:** **G1:** 410.4 ± 194.1 **G2:** 350.0 ± 212.9 **G3:** 424.0 ± 149.0 **Involuntary detrusor contraction volume mean mL ± SD:** **G1:** 189.5 ± 114.1 **G2:** 220.0 ± 127.2 **G3:** 239.3 ± 163.0	**UUI episodes/ week, mean ± SD:** **G1:** 7.0 ± 10.6 **G2:** 7.9 ± 13.7 **G3:** 7.8 ± 15.3 **G1/BL:** $P = 0.007$ **G2/BL:** $P = 0.039$ **G3/BL:** $P = 0.035$ **Urgency resolved, n (%):** **G1:** 14 (63.6) **G2:** 11 (52.4) **G3:** 12 (57.1) $P = 0.754$ **Satisfied, n (%):** **G1:** 17 (77.3) **G2:** 11 (52.4) **G3:** 16 (76.2) $P = 0.142$ **Nocturia episodes/week, mean ± SD:** **G1:** 0.9 ± 0.8 **G2:** 1.2 ± 1.3 **G3:** 1.0 ± 1.1 **G1/BL:** $P = 0.003$ **G2/BL:** $P = 0.036$ **G3/BL:** $P = 0.086$ **Pads/day, mean ± SD:** **G1:** 0.9 ± 1.5 **G2:** 0.9 ± 1.7 **G3:** 0.8 ± 1.3 **G1/BL:** $P < 0.001$ **G2/BL:** $P = 0.004$ **G3/BL:** $P < 0.001$ **Voids/day, mean ± SD:** **G1:** 6.4 ± 1.6 **G2:** 7.9 ± 2.3 **G3:** 7.1 ± 2.1 **G1/BL:** $P = 0.014$ **G2/BL:** $P = 0.291$ **G3/BL:** $P = 0.441$ **Residual volume, mean mL ± SD:** **G1:** 4.7 ± 9.4 **G2:** 1.1 ± 2.5 **G3:** 2.1 ± 3.5 **G1/BL:** $P = 0.425$ **G2/BL:** $P = 0.760$ **G3/BL:** $P = 0.297$	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Method and blinding: - Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: + Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: + Measurement methods: - Measurement reliability: - Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Arruda et al., 2008 (continued)			**Involuntary detrusor contraction maximal pressure (mm H_20 ± SD):** **G1:** 39.4 ± 26.1 **G2:** 43.7 ± 22.9 **G3:** 34.2 ± 19.8	**Volume first desire to void, mean mL ± SD:** **G1:** 157.3 ± 63.8 **G2:** 123.8 ± 59.0 **G3:** 137.6 ± 76.7 **G1/BL:** *P* = 0.019 **G2/BL:** *P* = 0.091 **G3/BL:** *P* = 0.017 **Maximal cystometric capacity mean mL ± SD:** **G1:** 517.3 ± 191.7 **G2:** 436.6 ± 178.7 **G3:** 489.0 ± 141.3 **G1/BL:** *P* = 0.001 **G2/BL:** *P* = 0.017 **G3/BL:** *P* = 0.113 **Involuntary detrusor contraction volume (mL):** **G1:** 188.6 ± 183.2 **G2:** 73.3 ± 112.4 **G3:** 114.3 ± 154.2 **G1/BL:** *P* = 0.986 **G2/BL:** *P* = 0.001 **G3/BL:** *P* = 0.044 **Involuntary detrusor contraction maximal pressure, mm H_20 ± SD:** **G1:** 19.6 ± 20.9 **G2:** 22.4 ± 30.1 **G3:** 17.2 ± 25.5 **G1/BL:** *P* < 0.001 **G2/BL:** *P* = 0.002 **G3/BL:** *P* = 0.027 **Normal urodynamic evaluation, n (%):** **G1:** 8 (36.4) **G2:** 12 (57.1) **G3:** 11 (52.4) *P* = 0.358 **Persistent improvement at 1 year:** **G1:** 10/17 **G2:** 4/11 **G3:** 9/16	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Arruda et al., 2008 (continued)				**Dry mouth, n (%):** **G1:** 16 (72.7) **G2:** 0 **G3:** 0 **Difficulty voiding, n (%):** **G1:** 2 (9.1) **G2:** 0 **G3:** 0 **Dizziness, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0 **Blurred vision, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0 **Constipation, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0 **Dry mouth, n (%):** **G1:** 16 (72.7) **G2:** 0 **G3:** 0 **Difficulty voiding, n (%):** **G1:** 2 (9.1) **G2:** 0 **G3:** 0 **Dizziness, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0 **Blurred vision, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0 **Constipation, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Bryant et al., 2002 **Country and setting:** Australia, Specialty treatment centers **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Bladder training plus an educational intervention to reduce caffeine intake to less than 100mg per day vs. bladder training alone **Groups:** **G1:** BT + caffeine reduction **G2:** BT **N at enrollment:** **G1:** 48 **G2:** 47 **N at follow-up:** **G1:** 36 **G2:** 39 **Age, yrs ± SD:** **G1:** 56 ± 18 **G2:** 58 ± 16 **Women, %:** **G1:** 94 **G2:** 87 **Weight in kg, mean ± SD:** **G1:** 69 ± 17 **G2:** 68 ± 20 **Race/ethnicity:** NR **Parity** NR	**Inclusion criteria:** • Adult • Symptoms of urinary urgency, frequency and/or urge incontinence • Routinely ingested ≥ 100mg caffeine/24 hrs **Exclusion criteria:** • Significant cognitive impairment • Pregnant • Symptoms of UTI	**Voids/24 hrs, mean ± SD:** **G1:** 11.4 ± 4.0 **G2:** 11.2 ± 3.5 **Urgency episodes/24 hrs, mean ± SD:** **G1:** 4.8 ± 3.5 **G2:** 4.6 ± 3.0 **Leakages/24 hrs, mean ± SD:** **G1:** 2.8 ± 3.2 **G2:** 3.1 ± 3.9 **Volume/void (mL) mean ± SD:** **G1:** 178 ± 78 **G2:** 177 ± 101 **Caffeine intake/day (mg) mean ± SD:** **G1:** 238.7 ± 121 **G2:** 272 ± 184 **Duration of urinary symptoms (yrs), mean ± SD:** **G1:** 13.7 ± 14.9 **G2:** 10.7 ± 15.5	**Leakages/24 hrs, mean ± SD:** **G1:** 1.2 ± 1.9 **G2:** 1.4 ± 1.7 **Mean reduction in leakages/24 hrs, %:** **G1:** 55 **G2:** 26 *P* = 0.219 **Voids/24 hrs, mean ± SD:** **G1:** 6.8 ± 2.0 **G2:** 7.9 ± 2.6 **Urgency episodes per 24 h, mean ± SD:** **G1:** 1.6 ± 1.9 **G2:** 3.2 ± 2.8 **Mean reduction in voids/24 hrs,%:** **G1:** 35 **G2:** 23 *P* = 0.037 **Mean reduction in urgency episodes/24 hrs, %:** **G1:** 61 **G2:** 12 *P* = 0.002	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to follow up: - Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of follow up: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Burgio et al., 1998 **Country and setting:** US, academic health center outpatient geriatric medicine clinic **Enrollment period:** July 1989 to August 1995 **Funding:** National Institutes on Aging **Author industry relationship disclosures:** NR	**Design:** RCT, placebo controlled Computer-generated random numbers using a block size of 6, w/ prior stratification by type and severity of incontinence **Intervention:** Biofeedback-assisted behavioral vs. drug treatment (oxybutynin chloride; possible range of doses 2.5 mg/d-5.0 mg t.i.d.) vs. placebo All patients had 4 visits over an 8-week period. Patients in G1 had biofeedback added to behavioral training in absence of 50% improvement by session 3. **Groups:** **G1:** Behavioral ± biofeedback **G2:** Pharmacologic **G3:** Placebo **N at enrollment:** 468 screened 271 not eligible 197 randomized **G1:** 65 **G2:** 67 **G3:** 65 **N at follow-up:** **G1:** 61 **G2:** 55 **G3:** 53	**Inclusion criteria:** • Community-dwelling women at least age 55 • Ambulatory • At least 2 urge accidents per week by baseline bladder diary • Urge incontinence as predominant pattern • Urodynamic evidence of bladder dysfunction **Exclusion criteria:** • Continual leakage • Postvoid residual urine volume >200mL • Uterine prolapse past the entroitus • Narrow-angle glaucoma • Unstable angina • Decompensated congestive heart failure • Hx of malignant arrhythmias • MMSE <20 (Dementia)	**Duration of symptoms, mean yrs ± SD:** **G1:** 9.4 ± 10.8 **G2:** 9.8 ± 11.9 **G3:** 12.7 ± 15.9 **Restricted activity, (%):** **G1:** 30.8 **G2:** 32.8 **G3:** 38.5 **Urge UUI only, %:** **G1:** 49.2 **G2:** 49.3 **G3:** 47.7 **Accidents per week, mean ± SD:** **G1:** 15.8 ± 14.5 **G2:** 15.9 ± 14.1 **G3:** 15.4 ± 13.4 *P* = .98 **Severity classification, %:** Mild (<5 accidents/wk) **G1:** 18.5 **G2:** 17.9 **G3:** 18.5 Moderate (5-10 accidents/wk) **G1:** 29.2 **G2:** 29.9 **G3:** 27.7 Severe (>10 accidents/wk) **G1:** 52.3 **G2:** 52.2 **G3:** 53.8 **Previous treatment with surgery, %:** **G1:** 20.0 **G2:** 26.9 **G3:** 29.2	**Accidents per week, mean ± SD:** **G1:** 2.8 ± 4.7 **G2:** 5.7 ± 9.8 **G3:** 8.2 ± 11.6 *P* = 0.005 **Percent reduction, mean ± SD:** **G1:** 80.7 ± 24.8 **G2:** 68.5 ± 37.2 **G3:** 39.4 ± 80.0 *P* < 0.001 **Percent reduction, range:** **G1:** -0.9 – 100 **G2:** -85.7 – 100 **G3:** -400.0 - 100 **Patient perceptions of progress in treatment** Much better **G1:** 74.1 **G2:** 50.9 **G3:** 226.9 Better **G1:** 25.9 **G2:** 30.9 **G3:** 38.5 About the same **G1:** 0.0 **G2:** 16.4 **G3:** 28.8 Worse **G1:** 0.0 **G2:** 1.8 **G3:** 5.8 **Estimate of % improvement, mean ± SD:** **G1:** 81.6 ± 18.6 **G2:** 66.4 ± 35.4 **G3:** 45.1 ± 36.6	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to follow up: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of follow up: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al., 1998 (continued)	**Women, %:** 100 **Age, yrs ± SD:** **G1:** 67.3 ± 7.6 **G2:** 68.2 ± 7.5 **G3:** 67.6 ± 7.6 **Race/ethnicity:** NR **Parity mean ± SD:** **G1:** 2.8 ± 2.0 **G2:** 2.1 ± 1.4 **G3:** 2.7 ± 1.8 ***P* < 0.05**		**Previous treatment with medication, %:** **G1:** 27.7 **G2:** 35.8 **G3:** 30.8 **Using estrogen, %:** **G1:** 32.3 **G2:** 38.8 **G3:** 35.4 **Using diuretics, %:** **G1:** 20.0 **G2:** 14.9 **G3:** 12.3	**Having fewer accidents, %:** **G1:** 100.0 **G2:** 87.3 **G3:** 67.3 **Accidents are smaller, %:** **G1:** 87.3 **G2:** 78.8 **G3:** 54.0 **Able to wear less protection, %:** **G1:** 76.0 **G2:** 56.0 **G3:** 334.1 **Comfortable enough with treatment to continue indefinitely, %:** **G1:** 96.5 **G2:** 54.7 **G3:** 43.1 **Patient satisfaction with progress, %:** Completely satisfied **G1:** 77.6 **G2:** 54.7 **G3:** 43.1 Somewhat satisfied **G1:** 22.4 **G2:** 40.0 **G3:** 34.0 Not at all satisfied **G1:** 0.0 **G2:** 10.9 **G3:** 38.0 Wish to receive another form of treatment, %: **G1:** 14.0 **G2:** 75.5 **G3:** 75.5 *P* < 0.001 for all comparisons	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al., 1998 (continued)				**Adverse effects, %, p compared to placebo G3:** **Dry mouth, %:** **G1:** 34.9 **G2:** 96.9 **G3:** 54.8 *P* < 0.001 **Inability to void, %:** **G1:** 6.3 **G2:** 21.5 **G3:** 3.2 *P* = 0.002 **Constipation, %:** **G1:** 22.2 **G2:** 38.5 **G3:** 37.1 *P* = 0.10 **Blurred vision, %:** **G1:** 9.5 **G2:** 15.4 **G3:** 9.7 *P* = 0.50 **Confusion, %:** **G1:** 6.3 **G2:** 7.7 **G3:** 11.3 *P* = 0.59	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Burgio et al.. 2000 [See Burgio et al., 1998] **Enrollment period:** Two weeks after completion of Burgio et al. 1998 **Funding:** National Institute on Aging, grants AG 08010 and K04 00431 **Author industry relationship disclosures:** NR	**Design:** Modified crossover of RCT **Intervention:** Participants whose treatment was not completely successful were given the opportunity to switch or use combined treatment; further reductions in incontinence were measured. **Groups:** Treatment Changes: **G1:** Previous oxybutynin to behavioral modification alone **G2:** Previous behavior alone to 2.5 mg oxybutynin t.i.d. + behavioral therapy **G3:** Previous oxybutynin alone to 2.5 mg oxybutynin t.i.d. + behavioral therapy **G4:** Placebo to behavioral **G5:** Placebo to oxybutynin **N at enrollment** **G1:** 19 **G2:** 8 **G3:** 27 **G4:** 34 **G5:** 10 **N at follow-up:** **G1:** 18 **G2:** 8 **G3:** 26 **G4:** NR **G5:** NR	**Inclusion criteria:** • Community-dwelling women at least age 55 • Ambulatory • At least 2 urge accidents per week by baseline bladder diary • Urge incontinence as predominant pattern • Urodynamic evidence of bladder dysfunction • Not completely dry or satisfied with previous, 8-wk treatment **Exclusion criteria:** • Continual leakage • Postvoid residual urine volume >200mL • Uterine prolapse past the introitus • Narrow-angle glaucoma • Unstable angina • Decompensated congestive heart failure • Hx of malignant arrhythmias • MMSE <20 (Dementia)	**% Reduction of incontinence after previous study (at baseline), mean:** **G1:** 59.1 **G2:** 57.5 **G3:** 72.7 **G4:** 22.9 **G5:** 44.8	**Final % Reduction of incontinence mean, p:** **G1:** 77.1, 0.109 **G2:** 88.5, 0.034 **G3:** 84.3, 0.001 **G4:** 63.9, .002 **G5:** 76.5, .012 **Note:** 29.2 of G3 declined to continue with drug therapy once they received behavioral modification. Numbers were too low to compare across groups.	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to follow up: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of follow up: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Burgio et al., 2001 [See Burgio et al,. 1998] **Country and setting:** US, University based **Enrollment period:** [See Burgio et al., 1998] **Funding:** NIH **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Psychological distress associated with pharmacologic treatment vs. behavioral vs. placebo **Groups:** **G1:** Behavioral training with biofeedback, 4 visits **G2:** Oxybutynin 2.5 mg po t.i.d., up to a max of 5 mg t.i.d. **G3:** Placebo **N at enrollment:** 197 women **N treated:** 169 **N at follow-up:** 155 (completed both pre and post-treatment psychological assessment) **Age yrs, mean ± SD:** 67.5 ± 7.2 **Women, %:** 100 **Race/ethnicity, %:** White: 97 African American: 3	**Inclusion criteria:** • ≥ 55 yrs old • ambulatory • UUI ≥2x/wk (2 wk bladder diary), persisting x 3 mos • Predominant UUI • Urodynamic evidence of bladder dysfunction (DI or maximal capacity ≤350 mL) **Exclusion criteria:** • contraindication to oxybutynin or behavioral treatment • Continual leakage • Post void residual > 200 mL • Uterine prolapse beyond the introitus • Decompensated CHF • Hx of malignant arrhythmias • Impaired mental status (MMSE <20)	**SCL-90-R scores mean (SD):** Somatization **G1:** 56.0 (10.6) **G2:** 51.4 (10.8) **G3:** 52.4 (11.1) Obsessive-Compulsive: **G1:** 56.5 (10.7) **G2:** 56.6 (11.4) **G3:** 57.7 (10.0) Interpersonal Sensitivity **G1:** 53.8 (11.0) **G2:** 51.4 (11.9) **G3:** 50.4 (12.0) Depression **G1:** 54.7 (10.0) **G2:** 52.5 (9.7) **G3:** 51.0 (11.9) Anxiety **G1:** 48.7 (13.9) **G2:** 46.8 (12.0) **G3:** 47.2 (12.8) Hostility **G1:** 49.3 (10.7) **G2:** 45.9 (10.1) **G3:** 48.3 (10.4) Phobia **G1:** 47.5 (10.2) **G2:** 46.7 (10.3) **G3:** 45.7 (8.5) Paranoid Ideation **G1:** 48.6 (12.4) **G2:** 49.3 (11.1) **G3:** 46.1 (12.8) Psychoticism **G1:** 54.1 (10.7) **G2:** 52.1 (10.3) **G3:** 50.5 (11.2) Global Severity **G1:** 54.2 (11.1) **G2:** 52.5 (10.3) **G3:** 52.4 (11.2)	**Reduced incontinence episodes:** **G1:** 83.3% **G2:** 74.4% **G3:** 41.4% *P* < 0.001 **SCL-90-R scores (SD):** Somatization **G1:** 51.8 (11.4) **G2:** 51.2 (9.8) **G3:** 49.8 (13.0) Obsessive-Compulsive: **G1:** 53.8 (13.9) **G2:** 53.9 (10.9) **G3:** 55.4 (11.0) Interpersonal sensitivity **G1:** 49.5 (12.0) **G2:** 48.9 (11.2) **G3:** 49.2 (11.3) Depression **G1:**51.5 (11.5) **G2:** 50.6 (10.7) **G3:** 51.4 (11.2) Anxiety **G1:** 46.1 (14.6) **G2:** 44.5 (12.3) **G3:** 45.8 (12.9) Hostility **G1:** 44.9 (10.8) **G2:** 44.6 (10.5) **G3:** 47.3 (11.2) Phobia **G1:** 47.1 (11.2) **G2:** 45.0 (8.3) **G3:** 45.1 (8.5) Paranoid ideation **G1:** 45.8 (10.9) **G2:** 47.2 (11.6) **G3:** 47.2 (12.0) Psychoticism **G1:** 49.2 (11.7) **G2:** 50.4 (9.7) **G3:** 49.6 (10.3) Global Severity **G1:** 50.8 (12.8) **G2:** 50.4 (10.0) **G3:** 51.4 (10.9)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to follow up: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of follow up: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al., 2001 (continued)			155 participants were compared to the 42 who did not complete intervention and psychological assessment, higher scores (greater distress) on 6 of 10 SCL-90-R scales (somatization, obsessive/compulsive, depression, hostility, paranoid ideation, global severity index), all p values <0.05 Normal range, score 0-63 >75% in normal range (including dropouts) on 9 of 10 scales Highest impairment rate: 33% scored abnormal for obsessive-compulsive	**Correlations between reduction of incontinence and changes in psychological symptoms:** Somatization **G1:** 0.28* **G2:** -0.09 **G3:** 0.17 Obsessive-Compulsive **G1:** 0.01 **G2:** -0.14 **G3:** 0.02 Interpersonal Sensitivity **G1:** -0.09 **G2:** 0.04 **G3:** 0.13 Depression **G1:** -0.04 **G2:** 0.03 **G3:** 0.07 Anxiety **G1:** -0.10 **G2:** -0.01 **G3:** 0.34* Hostility **G1:** -0.10 **G2:** 0.09 **G3:** 0.11 Phobic anxiety **G1:** -0.21 **G2:** -0.17 **G3:** 0.02 Paranoid Ideation **G1:** 0.14 **G2:** -0.04 **G3:** -0.06 Psychoticism **G1:** -0.01 **G2:** -0.01 **G3:** 0.13	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al., 2001 (continued)				Global Severity Index **G1:** 0.01 **G2:** 0.06 **G3:** 0.45*** *P < 0.05 ***P = 0.001	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Burgio et al., 2002 **Country and setting:** US, Academic medical center **Enrollment period:** April 1995 to March 2001 **Funding:** NIH **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Behavioral training with or without biofeedback for 8 wks compared to self-training, followed by 2 wks of post-treatment bladder diaries and a patient satisfaction questionnaire **Groups:** **G1:** Behavioral training with biofeedback **G2:** Behavioral training with verbal feedback **G3:** Self-administered behavioral training N at enrollment: **Evaluated: 474** **Excluded: 252** **Randomized: 222** **G1:** 73 **G2:** 74 **G3:** 75 N at follow-up: **G1:** 62 **G2:** 65 **G3:** 68 Women, %: **100** Age, mean ± SD: **G1:** 64.8 ± 7.1 **G2:** 65.8 ± 7.6 **G3:** 65.8 ± 8.5 **Race/ethnicity, n (%):** **Black:** **G1:** 11 (15.1) **G2:** 13 (17.6) **G3:** 11 (14.7)	**Inclusion criteria:*** Women Age ≥ 55 Community-dwelling Ambulatory Predominant urge incontinence ≥ 2x/wk for at least 3 mos Urodynamic evidence of bladder dysfunction **Exclusion criteria:** • Continual leakage • PVR ≥ 150mL • Severe uterine prolapse past uterine introitus • Decompensated congestive heart failure • MMSE score <24	**Incontinence episodes/week, mean ± SD:** **G1:** 15.1 ± 13.5 **G2:** 17.3 ± 16.3 **G3:** 15.4 ± 14.2 *P* = 0.62 **< 5 incontinence episodes/wk, n (%):** **G1:** 14 (19.2) **G2:** 14 (18.9) **G3:** 16 (21.3) 5-10 incontinence episodes/wk, n (%): **G1:** 20 (27.4) **G2:** 21 (28.4) **G3:** 21 (28.0) > 10 incontinence episodes/wk, n (%): **G1:** 39 (53.4) **G2:** 39 (52.7) **G3:** 38 (50.7) *P* > 0.99 **UUI, n (%):** **G1:** 50 (68.5) **G2:** 50 (67.6) **G3:** 50 (66.7) MUI, n (%): **G1:** 23 (31.5) **G2:** 24 (32.4) **G3:** 25 (33.3) *P* = 0.97 **Duration of symptoms (yrs), mean ± SD:** **G1:** 7.1 ± 7.8 **G2:** 6.6 ± 7.7 **G3:** 6.6 ± 8.7 **Previous treatment with medication, n (%):** **G1:** 16 (21.9) **G2:** 18 (24.3) **G3:** 21 (28.0)	**Incontinence episodes/week, mean ± SD:** **G1:** 6.1 ± 10.3 **G2:** 6.0 ± 10.7 **G3:** 6.7 ± 11.4 *P* = 0.78 **Incontinence episodes/week, % change, mean ± SD:** **G1:** -63.1 ± 42.7 **G2:** -69.4 ± 32.7 **G3:** -58.6 ± 38.8 *P* = 0.23 **Incontinence episodes/week, % change, median (IQR):** **G1:** -75.0 (-100, 120.0) **G2:** -82.8 (-100, 0) **G3:** -70.4 (-100, 29.4) **Fewer incontinence episodes, n (%):** **G1:** 51 (96.2) **G2:** 57 (100) **G3:** 58 (92.1) *P* = 0.09 **Smaller accidents, n (%):** **G1:** 42 (79.2) **G2:** 49 (89.1) **G3:** 42 (67.7) **G2/G3:** *P* = 0.006 **G1/G2/G3:** *P* = 0.02 **Able to wear less protection, n (%):** **G1:** 33 (71.7) **G2:** 40 (83.3) **G3:** 34 (70.8) *P* = .29 **Much better progress, n (%):** **G1:** 33 (62.3) **G2:** 36 (63.2) **G3:** 20 (30.8)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to follow up: + Drop-out rates: + Power calculation: + Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of follow up: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al., 2002 (continued)	**Parity, mean ± SD:** **G1:** 2.5 ± 1.7 **G2:** 3.0 ± 2.0 **G3:** 2.7 ± 2.0 **Using estrogen, n (%):** **G1:** 52 (72.2) **G2:** 51 (68.9) **G3: 44 (59.5)**		**Previous treatment with surgery, n (%):** **G1:** 16 (21.9) **G2:** 13 (17.6) **G3:** 12 (16.0) **Bladder capacity (mL), mean ± SD:** **G1:** 282 ± 117 **G2:** 238 ± 100 **G3:** 266 ± 105 *P* = 0.04	**Better progress, n (%):** **G1:** 18 (34.0) **G2:** 20 (35.1) **G3:** 36 (55.4) **No Progress, n (%):** **G1:** 2 (3.8) **G2:** 1 (1.8) **G3:** 8 (12.3) **Worse, n (%):** **G1:** 0 **G2:** 0 **G3:** 1 (1.5) **G2/G3:** *P* < 0.001 **G1/G3:** *P* < 0.001 **G1/G2/G3:** *P* < 0.001 **Comfortable enough to continue treatment indefinitely, n (%):** **G1:** 49 (98.0) **G2:** 54 (100) **G3:** 54 (88.5) **G2/G3:** *P* = 0.01 **G1/G2/G3:** *P* = 0.009 **Completely satisfied with progress, n (%):** **G1:** 39 (75.0) **G2:** 47 (85.5) **G3:** 34 (55.7) **Somewhat satisfied with progress, n (%):** **G1:** 12 (23.1) **G2:** 8 (14.5) **G3:** 24 (39.3) **Not at all satisfied with progress, n (%):** **G1:** 1 (1.9) **G2:** 0 **G3:** 3 (4.9) **G2/G3:** *P* < 0.001 **G1/G3:** *P* = 0.03 **G1/G2/G3:** *P* < 0.001	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al., 2002 (continued)				**Incontinence restricts activities-not at all, n (%):** Not at all: **G1:** 36 (69.2) **G2:** 43 (78.2) **G3:** 31 (50.8) **Incontinence restricts activities- some or all, n (%):** **G1:** 16 (30.8) **G2:** 12 (21.8) **G3:** 30 (49.2) **G2/G3:** *P* = 0.002 **G1/G3:** *P* = 0.047 **G1/G2/G3:** *P* = 0.007 **Not at all disturbed about incontinence, n (%)** **G1:** 26 (49.1) **G2:** 32 (59.3) **G3:** 23 (39.0) Somewhat disturbed about incontinence, n (%): **G1:** 26 (49.1) **G2:** 22 (40.7) **G3:** 32 (54.2) Extremely disturbed about incontinence, n (%): **G1:** 1 (1.9) **G2:** 0 **G3:** 4 (6.8) *P* = 0.18	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Burgio et al., 2008 **Country and setting:** US, Academic medical centers **Enrollment period:** July 2004 to January 2006 **Funding:** NIH Pfizer **Author industry relationship disclosures:** 20 of 29 Allergan (3) Alza (1) Astellas Pharma (7) Bionovo (1) Bristol-Meyers Squibb (1) Dynogen (1) Elan (1) Ethicon (2) GSK (4) Johnson & Johnson (3) Lilly (7) Medtronic (1) Merck (1) Novartis (6) Ortho-McNeil (3) Pfizer (>10) Procter & Gamble (3) Q-Med (1) Renessa (1) Sanofi (1) Solace (1) Watson (1)	**Design:** RCT **Intervention:** Pharmacologic vs. pharmacologic plus behavioral interventions for 10 wks (Stage 1), followed by no drug therapy (Stage 2) with assessments at 10 wks and 8 mos* **Groups:** **G1:** Tolterodine tartrate (ER capsules), 4 mg/d plus behavioral training: pelvic floor muscle control and exercises, behavioral strategies to diminish urgency, suppress bladder contractions and prevent both stress and urge incontinence; delayed voiding; fluid management; handout with hints **G2:** Tolterodine tartrate (ER capsules), 4 mg/d **N at enrollment:** 4043 screened 2612 not eligible 870 declined 561 consented 254 excluded 307 randomized **G1:** 153 **G2:** 154	**Inclusion criteria:** • Women • Community-dwelling • UUI only, or urge-predominant • ≥ 7 episodes of incontinence in a 7-day bladder diary • Persistent incontinence for at least 3 mos • No current use of antimuscarinics or other medications that could affect UI • No evidence of neurogenic etiology **Exclusion criteria:** • Age < 21 • Pregnant, planning a pregnancy in next 8 mos, or not using birth control • < 6 mos postpartum or termination after 20 wks gestation • Unable to contract pelvic floor muscles during evaluation • Behavioral therapy of > 2 mos in past 2 yrs • Continual leakage or always damp • Hypersensitive to study drug • Systemic disease that affects bladder function	**UUI, 7-13 episodes/week, n (%):** **G1:** 2 (1.3) **G2:** 2 (1.3) **UUI, ≥ 14 episodes/week, n (%):** **G1:** 2 (1.3) **G2:** 4 (2.6) **MUI, 7-13 episodes/week, n (%):** **G1:** 46 (29.9) **G2:** 46 (30.1) **MUI, ≥ 14 episodes/week, n (%):** **G1:** 104 (67.5) **G2:** 101 (66.0) **Adjusted incontinence episodes/week, mean:** **G1:** 23.1 **G2:** 23.2 **Previous non-surgical treatment for incontinence, n (%):** **G1:** 19 (12) **G2:** 22 (14)	**Success, n (%):** **G1:** 43 (28) **G2:** 41 (27) **Failure, n (%):** **G1:** 75 (49) **G2:** 78 (51) **Success rate, 8 months, lifetable analysis, % (95% CI):** **G1:** 41 (32, 50) **G2:** 41 (33, 50) **G1/G2:** 0 (-12, 12) **Success rate, 8 months, complete cases, % (95% CI):** **G1:** 36 (27, 45) **G2:** 34 (25, 43) **G1/G2:** 2 (-10, 14) **Success rate, 8 mos, assuming missings were failures, % (95% CI):** **G1:** 28 (21, 35) **G2:** 27 (20, 34) **G1/G2:** 1 (-9, 11) **Adjusted incontinence episodes/week, after Stage 1, mean:** **G1:** 2.7 **G2:** 4.7 **Adjusted incontinence episodes/week, after Stage 1, mean change:** **G1:** -20.4 **G2:** -18.5 **G1/G2:** -1.9 (-5.9, 2.0)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to followup: - Drop-out rates: ++ Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al., 2008 (continued)	**N at follow-up:** **G1:** 153 Completed treatment: 107 Outcome known at 8 mos: 119 **G2:** 154 Completed treatment: 101 Outcome known at 8 mos: 118 **Age, mean ± SD:** **G1:** 55.8 ± 14.2 **G2:** 58.0 ± 13.5 **Women, %:** 100 **Race/ethnicity, n (%):** **Hispanic:** **G1:** 13 (9) **G2:** 17 (11) **NH White:** **G1:** 105 (69) **G2:** 85 (56) **NH Black:** **G1:** 22 (14) **G2:** 35 (23) **Other:** **G1:** 13 (9) **G2:** 15 (10) **BMI, kg/m^2 ± SD:** **G1:** 33.2 ± 9.5 **G2:** 32.3 ± 7.6	• Currently using catheter to empty bladder • Postvoid residual volume > 150mL • Treatment for prolapse with pessary < 3 mos • Incontinence, vaginal, bladder or prolapse surgery in the past 6 mos • Urethral diverticulum • Previous augmentation cystoplasty or artificial sphincter • Neuromodulation for pelvic indications • Using anticholinergic agents, cholinergic agonists, tricyclic antidepressants, or duloxetine in ≤ 4 wks • Using diuretics with dosage change past 3 mos • Uncontrolled medical problem • History of bladder or pelvic cancer or pelvic radiation therapy • Glaucoma • Gastric retention • Non-ambulatory • Participation in other intervention trial that might influence outcome		**Achieved 70% reduction in incontinence episodes, per bladder diary, 10 weeks (%):** **G1:** 69 **G2:** 58 **G1/G2:** 11 (-0.3, 22.1) **Totally dry, per bladder diary, 10 weeks (%):** **G1:** 21 **G2:** 17 **Voids/day, mean change:** **G1:** 0.5 **G2:** -0.4 **G1/G2:** 0.9 (0.3, 1.5) **Symptom Distress Scores:** **G1/G2:** *P* < 0.0001 **Symptom Bother Scores (OAB-q), Stage 1, mean change:** **G1:** -36.7 **G2:** -30.4 **G1/G2:** *P* < 0.0001 **Symptom Bother Scores (OAB-q), Stage 2, mean change:** **G1:** -30.9 **G2:** -20.4 **G1/G2:** *P* < 0.0001 **Patient completely satisfied, Stage 1, %:** **G1:** 53 **G2:** 40 **G1/G2:** 13 (1, 25)	

Evidence Table 2. KQ 2 Pharmacologic Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al., 2008 (continued)				**Patient completely satisfied, 8 months, %:** **G1:** 33 **G2:** 20 **G1/G2:** 13 (2, 24) **Patient better or much better, Stage 1, %:** **G1:** 90 **G2:** 77 **G1/G2:** 13 (4, 22) **Patient better or much better, 8 months, %:** **G1:** 69 **G2:** 43 **G1/G2:** 26 (14 , 38) **Persistence in perceived improvement, 8 mos, women with improvement at Stage 1:** **G1:** 72 **G2:** 54 **G1/G2:** 17 (4, 30) **Harms:** **G1:** 3 participants 1: blurred vision, syncope, night sweats, stomach cramping and weakness 2: 2 episodes of small-bowel obstruction and an allergic reaction (pruritus and rash) 3: tachycardia during stage 2 **G2:** 3 participants 1: small bowel obstruction 2: peripheral edema 3: renal cell carcinoma diagnosis during stage 2	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Colombo et al., 1995 **Country and setting:** Italy; Setting **Enrollment period:** May 1990 to March 1993 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Oxybutynin vs. Bladder training for 6 weeks **Groups:** **G1:** Oxybutynin, 3 daily doses of 5 mg each for 6 weeks (dose reduced to half if substantial AEs) **G2:** Bladder training **N at enrollment:** **G1:** 42 **G2:** 39 **N at 6 wk follow-up:** **G1:** 38 **G2:** 37 **N at 6 mo follow-up:** **G1:** 28 **G2:** 27 **Age, yrs ± SD:** **G1:** 48 (31 – 65) **G2:** 49 (24 – 65) **Race/ethnicity, mean ± SD: Black:** NR **Women, N (%):** **G1:** 42 (100) **G2:** 39 (100) **Postmenopausal n (%):** **G1:** 16 (38) **G2:** 20 (51)	**Inclusion criteria:** • Socially embarrassing (severe) urinary urge incontinence • On cystometry: detrusor instability, or low-compliance bladder (LCB), or sensory bladder **Exclusion criteria:** • Stable bladder at cystometry • Neurologic disease • Detrusor hyperreflexia • Age greater than 65 yr • Coexisting genuine SUI • Genital prolapse • Postvoid residual volume >50mL • Previous gynecologic or urogynecologic surgery • Prior use of any drug to treat UUI • Urethral diverticula • Fistulas • Urinary tract neoplasia • Cystitis • Bladder stones • Previous pelvic radiotherapy	**Detrusor instability, n (%):** **G1:** 14 (37) **G2:** 13 (35) **Low compliance bladder, n (%):** **G1:** 9 (24) **G2:** 8 (22) **Sensory bladder, n (%):** **G1:** 15 (39) **G2:** 16 (43) **Daily UUI episodes, range 9 – 17** **Diurnal frequency, n (%):** **G1:** 32 (84) **G2:** 29 (78) **Nocturia, n (%):** **G1:** 11 (29) **G2:** 18 (49) **Volume at first desire (mL):** **G1:** 120 ± 59 **G2:** 134 ± 61 **Volume at very strong desire (mL):** **G1:** 317 ± 92 **G2:** 332 ± 87	**Clinically cured overall, n (%):** **G1:** 28 (74) **G2:** 27 (73) **Cured among DI, (%):** **G1:** 13 (93) **G2:** 8 (62) *P* = 0.07 **Cured among LCB:** **G1:** 6 (67) **G2:** 6 (75) *P* = 0.56 **Cured among sensory bladder:** **G1:** 9 (60) **G2:** 13 (81) *P* = 0.18 **Cured among 18 G1 patients requiring dosage halving:** 12 (67%) **Diurnal frequency resolved, n (%):** **G1:** 18 (56) **G2:** 20 (69) **Nocturia resolved n (%):** **G1:** 3 (27) **G2:** 11 (61) **Volume at first desire (mL), mean ± SD:** **G1:** 179 ± 32 *P* = .0009 **G2:** 178 ± 49 *P* = .001 **Volume at very strong desire (mL) mean ± SD:** **G1:** 408 ± 76 *P* = .00001 **G2:** 403 ± 69 *P* = .0002 **Patients still cured at 6 mos, n:** **G1:** 16 **G2:** 26	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to follow up: ++ Drop-out rates: + Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of follow up: - Measurement methods: + Measurement reliability: - Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Colombo et al., 1995 (continued)				**Patients still cured at 6 mos among DI, n:** **G1:** 8 **G2:** 8 **Patients still cured at 6 mos among LCB, n:** **G1:** 4 **G2:** 6 **Patients still cured at 6 mos among sensory bladder, n:** **G1:** 4 **G2:** 12 **Treatment discontinued in 6 cases:** **G1:** 4 (3 cases of severe dry mouth, 1 case of previously unknown glaucoma) **G2:** 2 (treatment was time consuming) **Other adverse effects** **G1:** 18 (47%) with AE requiring halving of dosage: -dry mouth (n=15) -constipation (n=6) -nausea (n=5) -dizziness (n=2) - decrease in visual acuity (n=1) - tachycardia (n=1)	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Diokno et al., 1995 **Country and setting:** US; private clinic **Enrollment period:** January 1992 to December 1992 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cohorts with comparison; (Series of patients self selected into two groups) **Intervention:** Bladder training vs. anticholinergic or antispasmodic **Groups:** **G1:** Bladder training **G2:** oxybutynin 2.5-5.0 mg b.i.d. or t.i.d. **N at enrollment:** **G1:** 39 **G2:** 33 **N at follow-up:** **G1:** 26 **G2:** 28 **Age, mean yrs (range):** 64 (20-93) **Race/ethnicity:** NR **Women, N (%):** **72 (100)** **Parity:** NR	**Inclusion criteria:** • Incontinent by AHCPR guidelines* • Incontinence persisted after treatment for transient incontinence **Exclusion criteria:** • Post-void residual of more than 150 mL	**UUI, n (%):** **G1:** 27 (49) **G2:** 28 (51) **MUI with predominant urge, n (%):** **G1:** 12 (71) **G2:** 5 (29)	**Continent, n (%):** **G1:** 1 (4) **G2:** 1 (4) **Improved, n (%):** **G1:** 22 (85) **G2:** 19 (68) **No Change, n (%):** **G1:** 3 (11) **G2:** 8 (28)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: - Loss to follow up: - Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: poor Age: -, NR Baseline OAB status: NR Baseline characteristics: - Length of follow up: ++ Measurement methods: - Measurement reliability: - Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes*	Quality Rating
Author: Dorey et al., 2006 **Country and setting:** UK, Urogynecology clinic **Enrollment period:** January 2002 to July 2004 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Retrospective review of cases **Intervention:** Physiotherapeutic treatment, avg. 3 sessions, including: PFME Urge suppression techniques Fluid advice Dietary advice **Groups:** NA **N at enrollment:** 87 **N at follow-up:** 66 13 (15%) excluded for SUI 7 (8%) LTFU 1 (1%) self-catherized **Women, n (%):** 87 (100) **Age, mean yrs (range):** 56 (29-79) **Race/ethnicity:** NR **BMI >30, %:** 20 **Parous, n (%):** 79 (91) **Prior pelvic surgery, n (%):** 60 (69) **Prior hysterectomy, n (%):** 30 (35)	**Inclusion criteria:** • Treated for UUI from Jan 2002 to Jul 2004 **Exclusion criteria:** • Severe stress urinary incontinence • Self-catherization	**Daily leakage, n (%):** 44 (67) **Strong pelvic floor muscles, %:** 75	**Significant improvement in UUI, n (%):** 55 (83) **Daily leakage, n (%):** 8 (12) **100 % improvement, n (%):** 8 (12) **≥80% improvement, n (%):** 24 (37) **50-75% improvement, n (%):** 31(48) **Slight improvement, n (%):** 6 (9) **No improvement, n (%):** 4 (6) **No UUI at discharge, n (%):** 5 (8) **Mild UUI at discharge, n (%):** 46 (69) **Moderate UUI at discharge, n (%):** 12 (18) **Severe UUI at discharge, n (%):** 4 (6)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: - Loss to follow up: NR Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of follow up: NA Measurement methods: - Measurement reliability: - Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes^	Quality Rating
Author: Dowd et. al., 2003 **Country and setting:** US, Community **Enrollment period:** NR **Funding:** Kidney Foundation of Ohio **Author industry relationship disclosures:** NR	**Design:** Cohorts with comparison, patients alternately assigned to 3 groups **Intervention:** **G1:** Pamphlet plus CS plus coaching **G2:** Pamphlet plus cognitive strategies (CS) via audiotape daily for 4 wks then 1x wk until 12 wks **G3:** Pamphlet on bladder health, etc. **Groups:** **G1:** Bladder health information + CS + coaching **G2:** Bladder health information + CS **G3:** Bladder health information **N at enrollment:** Total: 58 **N at follow-up:** **G1:** 18 **G2:** 18 **G3:** 14 **Women, n (%):** **G1:** 17 (94) **G2:** 18 (100) **G3:** 13 (93) *P* = 0.54 **Age, mean:** **G1:** 68.7 **G2:** 59.6 **G3:** 57.1 *P* = 0.03 **Race/ethnicity:** NR	**Inclusion criteria:** • Adults • Living independently • No major hearing problem, • Able to read and write English, • CUBS for 6 mos or more • MMSE score >20 • Negative urine screen **Exclusion criteria:** See inclusion criteria	**UUI, %:** **G1:** 26.7 **G2:** 31.6 **G3:** 33.3 **SUI or MUI, %:** **G1:** 73.3 **G2:** 68.4 **G3:** 66.7	**Comfort (UFIQC):** Persons in G1 and G3 saw modest gains over time; G2 did not. Significant group-by-type of UI interaction: G1 and G3 with urge had more improvement than participants with stress or other UI (F=3.61; *P* = .037) **Bladder Function (BFQ):** Significant change for all groups (F=13.31; *P* = 0.0001); No significant interactions by type of incontinence by significant main effect for urge	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to follow up: - Drop-out rates: ++ Power calculation: + Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: NR Baseline characteristics: - Length of follow up: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Fantl et al., 1981 **Country and setting:** US, University **Enrollment period:** N/A **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Retrospective chart review **Intervention:** Bladder retraining drill (BRD) and anticholinergics when BRD not satisfactory **Groups:** **G1:** Detrusor muscle contraction approximately 5 seconds after a cough **G2:** Detrusor muscle contracts spontaneously without prior provocation **G3:** Both cough contraction and spontaneous contraction **N at enrollment:** **G1:** 39 **G2:** 4 **G3:** 49 **N at follow-up:** NA **Women, %:** 100 **Age, mean ± SD:** 42.7 ± 10:3 **Race/ethnicity:** NR **Parity, mean:** 3.5	**Inclusion criteria:** • Cystometric tracings showed a rise of 15 cm water or more in intravesical pressure when recorded independently and calculated by subtraction from intra-abdominal transrectal pressures **Exclusion criteria:** • Neuropathic conditions • UTI	**Urgency and frequency, n (%):** 72 (78.2) **Urinary incontinence, n (%):** 65 (70.6) **Sensation of incomplete voiding, n (%)** 59 (64.1) **Nocturia, n (%):** 66 (71.7) **Dysuria, n (%):** 3 (3.2) **MUI, n (%):** 6 (6.5) **Enuresis in childhood, n (%):** 5 (5.4) **Previously operated on for similar urologic symptoms, n (%):** 34 (36.9)	**Cured, n (%):** **G1:** 32 (82.1) **G2:** 1 (25) **G3:** 41 (83.7) **Cured by BRD alone, n (%):** 44 (78.6) **Cured by BRD + anticholinergics, n (%):*** 30 (83.5)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to follow up: NR Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of follow up: NA Measurement methods: + Measurement reliability: - Intervention description: -

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Frewen, 1982 **Country and setting:** UK; Outpatient clinic **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Case series **Intervention:** Bladder training **Groups:** NA **N at enrollment:** 90 **N at follow-up:** 90 **Age, range:** 15-75 **Race/ethnicity:** NR **Women, N (%):** 90 (100) **Parity mean ± SD:** NR	**Inclusion criteria:** • Consecutive patients presenting with frequency, urgency and/or urge incontinence **Exclusion criteria:** • NR	**Urgency incontinence, n (%):** 63 (70) **Detrusor Instability, n (%):** NR (63) **Frequency, n:** 10 **Diurnal-nocturnal enuresis, n:** 20 **Duration of symptoms, yrs (range):** **stable:** 4-5 **unstable:** 12 **Results of cystometry in 82 patients, n:** **Unstable:** 40	**Cure, n (%):*** 78 (86.6) **Free from incontinence (but residual urgency), n (%):** 12 (13.4)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: - Loss to follow up: ++ Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: + Length of follow up: NA Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Ghei et al., 2006 **Country and setting:** UK, Primary care **Enrollment period:** NR Duration 16 weeks **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Observational cohort **Intervention:** Bladder retraining vs. Bladder retraining + antimuscarinic (oxybutynin IR/ ER, tolterodine IR/ER, or imipramine combined with either oxybutynin or tolterodine as combination therapy) **Groups:** **G1:** Bladder retraining alone **G2:** Antimuscarinic therapy+ bladder retraining **N at enrollment:** **G1:** 52 **G2:** 656 **N at follow-up:** **G1:** 46 **G2:** 501 **Women, n (%):** **G1:** 45 (86) **G2:** 618 (94) **Age, mean ± SD:** **G1:** 52 ± 14 **G2:** 54 ± 23 **Race/ethnicity:** NR	**Inclusion criteria:** • Frequency • Urgency with or without UUI **Exclusion criteria:** • SUI • Symptoms of BOO	**Incontinence episodes/day, mean ± SD:** **G1:** 0.47 ± 1.2 **G2:** 1.12 ± 1.7 *P* < 0.001 **Voids/day, mean ± SD:** **G1:** 14 ± 6 **G2:** 11 ± 6 *P* = 0.001	**Incontinence episodes/day, mean change difference (95% CI):** **G2/G1:** -0.60 (-0.93, -0.27) *P* = 0.024 **Voids/day, mean change difference (95% CI):** **G2/G1:** 2.35 (1.4, 3.3) *P* < 0.001 **Nocturia episodes/day, mean change difference (95% CI):** **G2/G1:** 0.57 (0.15, 0.99) **Attendance visits, n (%)** Failed follow-up: **G1:** 6 (12) **G2:** 155 (23) 1 follow-up visit: **G1:** 10 (19) **G2:** 15 (2) 2 follow-up visits: **G1:** 18 (35) **G2:** 86 (13) 3 follow-up visits: **G1:** 9 (17) **G2:** 225 (35) 4 follow-up visits: **G1:** 9 (17) **G2:** 175 (27)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to follow up: - Drop-out rates: NR Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: + Length of follow up: + Measurement methods: + Measurement reliability: - Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Goode et al., 2002 **Country and setting:** US; academic health center outpatient geriatric medicine clinic **Enrollment period:** July 1989 to August 1995 **Funding:** National Institutes on Aging **Author industry relationship disclosures:** NR	**Design:** RCT, placebo controlled Computer-generated random numbers using a block size of 6, w/ prior stratification by type and severity of incontinence **Intervention:** Biofeedback-assisted behavioral vs. drug treatment (oxybutynin chloride; possible range of doses 2.5 mg/d-5.0 mg t.i.d.) vs. placebo All patients had 4 visits over an 8-week period. Patients in G1 had biofeedback added to behavioral training in absence of 50% improvement by session 3. **Groups:** **G1:** Behavioral ± biofeedback **G2:** Pharmacologic **G3:** Placebo **N at enrollment:** 468 screened 271 not eligible 197 randomized 105 had pre and post treatment urodynamics **G1:** 33 **G2:** 35 **G3:** 37 **N at follow-up:** NA	**Inclusion criteria:** • Community-dwelling women at least age 55 • Ambulatory • At least 2 urge accidents per week by baseline bladder diary • Urge incontinence as predominant pattern • Urodynamic evidence of bladder dysfunction **Exclusion criteria:** • Continual leakage • Postvoid residual urine volume >200mL • Uterine prolapse past the introitus • Narrow-angle glaucoma • Unstable angina • Decompensated congestive heart failure • Hx of malignant arrhythmias • MMSE <20 (Dementia)	**Voids per day, mean ± SD:** **G1:** 10.0 **G2:** 10.9 **G3:** 10.0 **Cystometry at baseline:** **First desire to void, mL ± SD:** **G1:** 97.1 ± 50.7 **G2:** 101.1 ± 62.1 **G3:** 124.6 ± 73.7 **Strong desire to void, mL ± SD:** **G1:** 188.5 ± 93.1 **G2:** 212.1 ± 86.7 **G3:** 222.3 ± 87.0 **Bladder capacity, mL ± SD:** **G1:** 288.3 ± 117.0 **G2:** 308.7 ± 93.7 **G3:** 328.9 ± 107.6	**Voids per day, mean ± SD:** **G1:** 8.2 **G2:** 8.8 **G3:** 9.7 **DI on UDS, n (%)** +Baseline DI/+DI post-treatment **G1:** 7 (21.2) **G2:** 1 (2.9) **G3:** 5 (13.5) **DI on UDS, n (%)** +Baseline DI/-DI post-treatment **G1:** 1 (3.0) **G2:** 7 (20.0) **G3:** 7 (18.9) **DI on UDS, n (%)** -Baseline DI/+DI post-treatment **G1:** 3 (9.1) **G2:** 3 (8.6) **G3:** 3 (8.1) **DI on UDS, n (%)** -Baseline DI/-DI post-treatment **G1:** 22 (66.7) **G2:** 24 (68.6) **G3:** 22 (59.5) **Cystometry post-treatment:** **First desire to void, mL ± SD:** **G1:** 115.9 ± 64.9 **G2:** 145.6 ± 74.0 **G3:** 133.5 ± 59.6 **Strong desire to void, mL ± SD:** **G1:** 228.9 ± 106.4 **G2:** 282.0 ± 93.2 **G3:** 230.1 ± 78.8 **Bladder capacity, mL ± SD:** **G1:** 305.6 ± 117.9 **G2:** 377.6 ± 92.1 **G3:** 323.0 ± 109.0	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to follow up: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of follow up: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Goode et al., 2002 (continued)	**Age, yrs ± SD:** **G1:** 65.3 ± 4.5 **G2:** 67.9 ± 7.9 **G3:** 67.6 ± 7.7 **Race/ethnicity, %:** Black: 2 White: 98 **Women:** **100%** **Parity mean ± SD:** **G1:** 3.1 ± 1.7 **G2:** 2.1 ± 1.3 **G3:** 2.3 ± 1.5			**Cystometry change:** **First desire to void, mL:** **G1:** 18.8 **G2:** 44.4 **G3:** 8.9 *P* = 0.149 **Strong desire to void, mL:** **G1:** 40.5 **G2:** 69.9 **G3:** 7.8 *P* = 0.018 **Bladder capacity, mL:** **G1:** 17.3 **G2:** 68.9 **G3:** -6.0 *P* = 0.000 **Standardized estimates of direct and mediated effects of treatment:** **G1 v G3:** Total effect: 0.28* Direct effect: 0.23 Mediated Effect: 0.05 **G2 v G3:** Total Effect: 0.34* Direct Effect: 0.30* Mediated Effect: 0.04 *$P < 0.01$	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Herschorn et al., 2004 **Country and setting:** Canada; Family medicine and urology clinics **Enrollment period:** June 2000 to December 2001 **Funding:** Pharmacia Pfizer Canada **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Health education with tolterodine vs. tolterodine alone **Groups:** **G1:** Health education with tolterodine **G2:** Tolterodine alone **N at enrollment:** **G1:** 39 **G2:** 45 **N at follow-up, 5 weeks:** **G1:** 37 **G2:** 40 **N at follow-up, 10 weeks:** **G1:** 35 **G2:** 32 **N at follow-up, 16 weeks:** **G1:** 34 **G2:** 31 **Age, yrs ± SD:** **G1:** 65.7 ± 14.5 **G2:** 63.1 ± 15.7 **Race/ethnicity:** NR **Women, %:** **G1:** 92.3 **G2:** 84.4 **Parity:** NR	**Inclusion criteria:** • Age ≥ 50 • Symptoms of OAB • Attend investigators' practice • Normal cognitive function • Able to read English **Exclusion criteria:** • Enrollment in another clinical trial • Interstitial cystitis • UTI • Already taking tolterodine	**Duration of OAB, yrs ± SD:** **G1:** 8.7 ± 11.0 **G2:** 8.7 ± 10.8 **Mild bladder problems, n (%):** **G1:** 13 (33.3) **G2:** 13 (28.9) **Moderate bladder problems, n (%):** **G1:** 19 (48.7) **G2:** 28 (62.2) **Severe bladder problems, n (%):** **G1:** 7 (18.0) **G2:** 4 (8.9) **Obtained prescription, n (%):** **G1:** 38 (97.4) **G2:** 37 (82.2) *P* < 0.05 **Intends to fill prescription, (%):** **G1:** 0 (0) **G2:** 6 (7.5)	**Change in incontinence episodes/wk, mean ± SD:** **G1:** -7.72 ± 21.16 **G2:** -10.24 ± 19.56† **Change in voids/d, mean ± SD:** **G1:** -1.82 ± 3.41 **G2:** -2.18 ± 4.89 *P* = NR **Change in nocturnal voids, mean ± SD:** **G1:** -0.44 ± 1.13† **G2:** -0.07 ± 0.91 **No change in bladder problem severity, n (%):** **G1:** 14 (42.4) **G2:** 20 (66.7) **Improved bladder problem severity, n (%):** **G1:** 15 (45.4)† **G2:** 6 (20) **Worsened bladder problem severity, n (%):** **G1:** 4 (12.1) **G2:** 4 (13.3) **Compliance, 10 weeks, %:** **G1:** 41 **G2:** 38 *P* > 0.05 **Compliance, 16 weeks, %:** **G1:** 39 **G2:** 31 *P* > 0.05 **Continued or started non-drug OAB treatment, 16 weeks, %:** **G1:** 82 **G2:** 53 *P* > 0.05	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: + Loss to followup: - Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: NR Baseline characteristics: - Length of followup: ++ Measurement methods: + Measurement reliability: - Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Herschorn et al., 2004 (continued)				**Stopped non-drug OAB treatments, %:** **G1:** 12.8 **G2:** 28.9	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Jarvis et al., 1980 **Country and setting:** UK, Hospital **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Behavioral: 1) rationale explained 2) pt instructed to pass urine at specific intervals during the day 3) pt encouraged to maintain usual fluid intake and chart fluid balance 4) pt introduced to someone successfully treated by the drill **Groups:** **G1:** Bladder drill **G2:** Control (told they should now be able to hold urine 4 hrs and sent home) **N at enrollment:** **G1:** 30 **G2:** 30 **N at follow-up:** **G1:** 30 **G2:** 30 **Women, %:** 100 **Age, range:** 27-79 **Race/ethnicity:** NR	**Inclusion criteria:** • Women • Diagnosis of DI by pressure flow studies • Not taking medications known to affect urinary tract function **Exclusion criteria:** • Co-existing genuine SUI	**UUI, n:** **G1:** 30 **G2:** 30 **SUI, n:** **G1:** 21 **G2:** 21 **Urgency, n:** **G1:** 30 **G2:** 30 **Diurnal frequency, n:** **G1:** 30 **G2:** 30 **Nocturnal frequency, n:** **G1:** 27 **G2:** 25	**Continent and symptom-free:** **G1:** 27 **G2:** 7 *P* < 0.01 **UUI, n:** **G1:** 3 **G2:** 23 *P* < 0.01 **SUI, n:** **G1:** 3 **G2:** 16 *P* < 0.01 **Urgency, n:** **G1:** 4 **G2:** 23 *P* < 0.01 **Diurnal frequency, n:** **G1:** 5 **G2:** 23 *P* < 0.01 **Nocturnal frequency:** **G1:** 3 **G2:** 20 *P* < 0.01	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: - Loss to follow up: ++ Drop-out rates: ++ Power calculation: - Statistical issues: - EXTERNAL VALIDITY: poor Age: + Baseline OAB status: NR Baseline characteristics: - Length of follow up: ++ Measurement methods: - Measurement reliability: - Intervention description:-

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Jarvis et al., 1981 **Country and setting:** UK, Academic medical center **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Inpatient bladder drill vs. outpatient drug therapy **Groups:** **G1:** Inpatient bladder drill **G2:** Flavoxate hydrochloride 200 mg t.i.d. and imipramine 25 mg t.i.d. x 4 wks **N at enrollment:** **G1:** 25 **G2:** 25 **N at follow-up:** **G1:** 25 **G2:** 25 **Women, %:** 100 **Age, mean ± SD (range):** **G1:** 47 ± 15.4 (17-78) **G2:** 46 ± 12.8 (17-65)	**Inclusion criteria:** • Women • UDS-diagnosed detrusor instability **Exclusion criteria:** • DM • Neurological abnormalities • UTIs • Taking a drug suspected of affecting lower urinary tract function • Genuine stress incontinence	**UUI, n**: **G1:** 25 **G2:** 25 **SUI, n:** **G1:** 19 **G2:** 17 **Urgency, n:** **G1:** 25 **G2:** 25 **Frequency, n:** **G1:** 25 **G2:** 25 **Nocturia, n:** **G1:** 21 **G2:** 19 **Duration of symptoms (years), mean ± SD (range):** **G1:** 4.3 ± 2.7 (1-15) **G2:** 5.4 ± 3.2 (1-20) **Bladder volume (mL), first sensation, mean:** **G1:** 87 **G2:** 79 **Max cystometric capacity (mL), mean:** **G1:** 381 **G2:** 353	**UUI, n:** **G1:** 4 **G2:** 11 **SUI, n:** **G1:** 1 **G2:** 9 **Urgency, n:** **G1:** 4 **G2:** 11 **Frequency, n:** **G1:** 6 **G2:** 12 **Nocturia, n:** **G1:** 4 **G2:** 13 **Continent, n (%):** **G1:** 21 (84) **G2:** 14 (56) *P* < 0.05 **Symptom-free, n (%):** **G1:** 19 (76) **G2:** 12 (48) *P* < 0.05 **Bladder volume (mL), first sensation, mean:** **G1:** 152 **G2:** 140 **Max cystometric capacity (mL), mean:** **G1:** 470 **G2:** 446 **Adverse events, drug therapy, n:*** Dizziness: 8 Headache: 6 Dry mouth: 6 Nausea: 4 Drowsiness: 2 Vomiting: 1 **Discontinued due to AEs, n:** Dizziness: 1 Headache: 1 Vomiting: 1	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: + Loss to follow up: ++ Drop-out rates: - Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Lauti et al., 2008 **Country and setting:** New Zealand, Academic **Enrollment period:** February 2003 to July 2003 **Funding:** University of Otago **Author industry relationship disclosures:** None	**Design:** RCT pilot study, unmasked **Intervention:** Oxybutynin vs. bladder retraining vs. combination therapy **Groups:** **G1:** Oxybutynin 2.5 mg/day (daily dose could be increased by 2.5 mg every 5 days to a maximum of 15 mg/day) **G2:** Bladder retraining **G3:** Combination therapy **N screened:** 120 **N at enrollment:** **G1:** 21 **G2:** 16 **G3:** 19 **N at 3 month follow-up:** **G1:** 18 **G2:** 16 **G3:** 12 **N at 12 month follow-up:** **G1:** 16 **G2:** 14 **G3:** 12 **Age, mean ± SD:** **G1:** 53.8 ± 14.8 **G2:** 63.9 ± 17.2 **G3:** 47.6 ± 16.3 **Race/ethnicity:** NR **Women, %:** Total: 100 **Parous, %:** **G1:** 81 **G2:** 62.5 **G3:** 73.7	**Inclusion criteria:** • Age > 18 • Predominant UUI **Exclusion criteria:** • Predominant SUI • Contraindications to anticholinergic drugs • Current UTI • Neurological disease • Psychiatric disorder • Untreated co-existing pelvic organ prolapse below the hymenal ring • Obstructed voiding • Functional-reversible cause of incontinence • Inability to toilet independently • Limited fluency of written/spoken English • Current or recent use of any of the trial interventions	**Urgency episodes/day, mean ± SD:** **G1:** 3.8 ± 2.7 **G2:** 3.1 ± 2.2 **G3:** 3.5 ± 2.0 **Incontinence episodes/day, mean ± SD:** **G1:** 2.2 ± 1.5 **G2:** 1.0 ± 1.1 **G3:** 1.8 ± 1.6 **Nocturia episodes/day, mean ± SD:** **G1:** 1.1 ± 1.0 **G2:** 1.4 ± 1.0 **G3:** 0.8 ± 0.7 **Voids per day, mean ± SD:** **G1:** 7.8 ± 2.8 **G2:** 8.0 ± 1.7 **G3:** 8.4 ± 2.5 **OAB-q total HRQoL, mean ± SD:** **G1:** 73.1 ± 17.4 **G2:** 69.5 ± 24.6 **G3:** 71.6 ± 21.5 **OAB-q severity, mean ± SD:** **G1:** 47.0 ± 16.2 **G2:** 42.3 ± 17.7 **G3:** 45.9 ± 18.7 **OAB-q coping, mean ± SD:** **G1:** 72.0 ± 21.6 **G2:** 66.2 ± 31.7 **G3:** 73.8 ± 26.2 **OAB-q concern, mean ± SD:** **G1:** 68.2 ± 19.0 **G2:** 68.8 ± 27.6 **G3:** 63.8 ± 29.2 **OAB-q sleep, mean ± SD:** **G1:** 63.1 ± 28.7 **G2:** 59.8 ± 29.9 **G3:** 55.1 ± 27.6	**Urgency episodes/day, 3 mos, mean ± SD:** **G1:** 2.2 ± 1.8 **G2:** 1.5 ± 2.1 **G3:** 1.7 ± 1.8 **Urgency episodes/day, 12 mos, mean ± SD:** **G1:** 2.3 ± 2.5 **G2:** 1.9 ± 2.1 **G3:** 2.0 ± 1.1 **Incontinence episodes/day, 3 mos, mean ± SD:** **G1:** 0.8 ± 0.8 **G2:** 0.1 ± 0.3 **G3:** 0.6 ± 0.8 **Incontinence episodes/day, 12 mos, mean ± SD:** **G1:** 0.9 ± 0.0 **G2:** 0.9 ± 1.0 **G3:** 0.8 ± 0.7 **Nocturia episodes/day, 3 mos, mean ± SD:** **G1:** 1.0 ± 0.5 **G2:** 0.8 ± 0.7 **G3:** 0.6 ± 0.5 **Nocturia episodes/day, 12 mos, mean ± SD:** **G1:** 1.0 ± 0.9 **G2:** 1.2 ± 0.6 **G3:** 0.7 ± 0.7 **Voids/day, 3 mos, mean ± SD:** **G1:** 6.7 ± 1.8 **G2:** 6.3 ± 1.6 **G3:** 6.7 ± 2.2 **Voids/day, 12 mos, mean ± SD:** **G1:** 7.2 ± 1.1 **G2:** 6.8 ± 1.4 **G3:** 7.6 ± 1.5	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Method and blinding: - Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Lauti et al., 2008 (continued)			**OAB-q social, mean ± SD:** **G1:** 92.5 ± 14.6 **G2:** 85.4 ± 19.9 **G3:** 92.8 ± 18.6 **SF-12 quality of life, physical, mean ± SD:** **G1:** 49.0 ± 9.6 **G2:** 41.7 ± 11.5 **G3:** 46.2 ± 10.6 **SF-12 quality of life, mental, mean ± SD:** **G1:** 49.1 ± 9.3 **G2:** 53.1 ± 8.8 **G3:** 46.3 ± 8.3	**OAB-q total HRQoL, 3 mos, mean ± SD:** **G1:** 82.3 ± 16.1 **G2:** 89.6 ± 9.4 **G3:** 91.8 ± 7.4 **OAB-q total HRQoL, 12 mos, mean ± SD:** **G1:** 87.9 ± 11.6 **G2:** 81.6 ± 19.3 **G3:** 88.9 ± 9.9 **OAB-q severity, 3 mos, mean ± SD:** **G1:** 37.2 ± 22.0 **G2:** 16.8 ± 12.0 **G3:** 21.6 ± 10.9 **OAB-q severity, 12 mos, mean ± SD:** **G1:** 24.6 ± 10.6 **G2:** 33.1 ± 16.6 **G3:** 21.9 ± 14.8 **OAB-q coping, 3 mos, mean ± SD:** **G1:** 79.2 ± 22.1 **G2:** 91.6 ± 9.5 **G3:** 92.7 ± 9.4 **OAB-q coping, 12 mos, mean ± SD:** **G1:** 89.2 ± 13.7 **G2:** 81.5 ± 23.7 **G3:** 90.5 ± 10.0 **OAB-q concern, 3 mos, mean ± SD:** **G1:** 78.6 ± 18.0 **G2:** 87.7 ± 14.5 **G3:** 90.2 ± 12.4 **OAB-q concern, 12 mos, mean ± SD:** **G1:** 85.3 ± 15.5 **G2:** 81.7 ± 19.7 **G3:** 85.2 ± 13.4 **OAB-q sleep, 3 mos mean ± SD:** **G1:** 77.7 ± 24.9 **G2:** 81.3 ± 14.6 **G3:** 85.0 ± 19.6	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Lauti et al., 2008 (continued)				**OAB-q sleep, 12 mos, mean ± SD:** **G1:** 79.9 ± 18.3 **G2:** 72.0 ± 24.5 **G3:** 83.2 ± 18.4 **OAB-q social, 3 mos, mean ± SD:** **G1:** 96.4 ± 9.7 **G2:** 95.6 ± 7.0 **G3:** 98.9 ± 1.9 **OAB-q social, 12 mos, mean ± SD:** **G1:** 97.3 ± 7.1 **G2:** 91.9 ± 14.2 **G3:** 97.3 ± 6.9 **SF-12 quality of life, physical** **G1:** 50.6 ± 8.0 **G2:** 42.1 ± 12.7 **G3:** 48.4 ± 10.8 **SF-12 quality of life, physical, 12 mos, mean ± SD:** **G1:** 50.0 ± 7.3 **G2:** 45.1 ± 13.9 **G3:** 45.3 ± 13.4 **SF-12 quality of life, mental, 3 mos, mean ± SD:** **G1:** 50.4 ± 9.6 **G2:** 51.2 ± 9.5 **G3:** 46.7 ± 7.6 **SF-12 quality of life, mental, 12 mos, mean ± SD:** **G1:** 49.6 ± 7.5 **G2:** 50.1 ± 10.7 **G3:** 50.6 ± 8.4 **Dry mouth, n (%):** **G1:** 3 (21) **G2:** 5 (46) **G3:** 5 (42) **Headaches, n (%):** **G1:** 6 (43) **G2:** 1 (11) **G3:** 7 (58) **Dizziness, n (%):** **G1:** 4 (29) **G2:** 2 (20) **G3:** 3 (25)	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Lauti et al., 2008 (continued)				**Constipation, n (%):** **G1:** 3 (21) **G2:** 3 (27) **G3:** 3 (27) **Fatigue, n (%):** **G1:** 9 (64) **G2:** 5 (46) **G3:** 7 (64)	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Macaulay et al., 1987 **Country and setting:** UK, Specialty treatment center **Enrollment period:** NR **Funding:** Wellcome Trust, trustees of St. George's Hospital **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Brief eclectic psychotherapy, bladder training or medication **Groups:** **G1:** Psycho-therapy **G2:** Bladder drill **G3:** Propantheline **N at enrollment:** **G1:** 19 **G2:** 16 **G3:** 15 **N at follow-up:** **G1:** 18 **G2:** 15 **G3:** 14 **Women, %:** 100 **Age:** NR **Race/ethnicity:** NR **Follow-up:** 3 months	**Inclusion criteria:** • Previous completion of survey on psych conditions w/ OAB • Detrusor instability on UDS or sensory urgency **Exclusion criteria:** NR	**Detrusor instability, n:** **G1:** 10 **G2:** 8 **G3:** 8 **Sensory urgency, n:** **G1:** 9 **G2:** 8 **G3:** 7 **Voids/day, mean:** **G1:** NR **G2:** NR **G3:** 10.8 **Bladder capacity (mL), mean:** **G1:** 393 **G2:** NR **G3:** 323 **Bladder volume (mL), first sensation, mean:** **G1:** 107 **G2:** 110 **G3:** 70 **Detrusor pressure rise (cm H_2O), mean:** **G1:** NR **G2:** 45.5 **G3:** NR	**Voids/day, mean:** **G1:** NR **G2:** NR **G3:** 8.3 **G3/BL:** *P* < 0.005 **Bladder capacity (mL), mean:** **G1:** 414 **G2:** NR **G3:** 368 **G1/BL:** *P* = NS **G3/BL:** *P* = NS **Bladder volume (mL), first sensation, mean:** **G1:** 142 **G2:** 150 **G3:** 137 **G1/BL:** *P* = NS **G2/BL:** *P* < 0.05 **G3/BL:** *P* = 0.06 **Detrusor pressure rise (cm H_2O), mean:** **G1:** NR **G2:** 29.5 **G3:** NR **G2/BL:** *P* < 0.05	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: - Loss to follow up: ++ Drop-out rates: ++ Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: -, NR Baseline OAB status: NR Baseline characteristics: - Length of follow up: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Mattiason et al., 2003 **Country and setting:** Sweden, Denmark, Norway (Tolterodine Scandinavian Study Group) **Enrollment period:** October 1999 to December 2000 **Funding:** Pharmacia Corp **Author industry relationship disclosures:** NR	**Design:** RCT, single-blinded (balanced blocks of 4, computerized randomization list) **Intervention:** Tolterodine 2mg b.i.d. ± bladder training (BT); Tolterodine dosage could be decreased to 1 mg P.O. b.i.d. during the first 2 wks if intolerable SE; BT taught with a written handout **Groups:** **G1:** Tolterodine + BT x 24 wks **G2:** Tolterodine x 24 wks **N at enrollment:** Total: 505 **N at follow-up:** **G1:** 244 **G2:** 257 **N Completed treatment:** **G1:** 77% **G2:** 79% Total: 74% **Women, n (%)** **G1:** 177 (73) **G2:** 201 (78) **Age, median (range):** **G1:** 62 (19, 86) **G2:** 63 (22, 86) **Race/ethnicity:** NR **Follow-up:** 24 weeks	**Inclusion criteria:** • Age ≥ 18 • ≥ 8 voids/day and urinary urgency (± UUI) as determined by 1 wk bladder diary • With or without UUI • Women of reproductive age had to be using reliable birth control **Exclusion criteria:** • Contraindication to antimuscarinic therapy • Use of electrostimulation therapy or BT within prior 3 mo • Indwelling catheter or intermittent catheterization • Pregnancy or lactation • Use of anticholinergic agents or concomitant treatment for OAB (estrogen permitted)	**Urgency episodes/day, mean (range):** **G1:** 6.0 (0, 23.0) **G2:** 6.6 (0, 34.3) **Incontinence episodes/day, mean (range):** **G1:** 2 (0.3, 20.3) **G2:** 2.3 (0.3, 16.3) **Voids/day, mean (range):** **G1:** 10.3 (7.3, 27.6) **G2:** 10.6 (7.7, 24.6) **Duration of symptoms > 5 years, n (%):** **G1:** 120 (49) **G2:** 124 (48) **Previous drug therapy for OAB, n (%):** **G1:** 40 (160 **G2:** 35 (14) **Previous surgery affecting lower urinary tract, n (%):** **G1:** 28 (11.5) **G2:** 30 (12) **Symptoms caused at least moderate problems, %:** **G1:** 92 **G2:** 93	**Urgency episodes/day, median % change (IQR):** **G1:** -38 (-76.7, -14.1) **G2:** -38 (-68.7, -8.0) **G1/G2:** *P* = 0.75 **Incontinence episodes/day, median IQR% change; n=301:** **G1:** -87 (-100, -20) **G2:** -81 (-100, -41.8) **G1/G2:** *P* = 0.28 **Voids/day, median % change (IQR):** **G1:** -33 (-42.3, 21.3) **G2:** -25 (-38.8, -13.0) **G1/G2:** *P* < 0.001 **Voided volume (mL), median % change (IQR):** **G1:** 31.5 (13.3, 56.2) **G2:** 20 (3.1, 45.4) **G1/G2:** *P* <0.001 **Symptoms are "minor or less", %:** **G1:** 66.5 **G2:** 61.5 **Overall improvement in symptoms, %:** **G1:** 76 **G2:** 71 **Worsening of symptoms, %:** **G1:** 3 **G2:** 5 **Dry mouth, n (%):** **G1:** 76 (31) **G2:** 90 (35) **Headache, n (%):** **G1:** 15 (6) **G2:** 21 (8)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to follow up: - Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of follow up: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Mattiason et al., 2003 (continued)				**Constipation, n (%):** **G1:** 7 (3) **G2:** 14 (5) **≥ 1 SE, n (%):** **G1:** 158 (65) **G2:** 177 (69) **G1/G2:** *P* = NS **Withdrawal due to, %:** AE: 15 **Withdrawal due to lack of efficacy:** 3 **Withdrawal of consent :** 2 **Protocol violations:** 1 **Completed treatment:** **G1:** 77% **G2:** 79%	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)					
Study Description	**Study Design, Interventions, and Population**	**Inclusion/ Exclusion Criteria**	**Symptom Characteristics**	**Outcomes**	**Quality Rating**
Author: Millard et al., 1983 **Country and setting:** Australia, Hospital **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Report of hospital-based results **Intervention:** All patients initially hospitalized for 5-14 days then assigned to a Frewen-type bladder training program or biofeedback, each lasting 3 months. Adjunctive therapy* was used when patients did not show improvement. **Groups:** NR **N at enrollment:** 59 **N at follow-up:** 59 **Women, %:** 100 **N at follow-up:** 39 **Age, mean (range):** 49 (14-74) **Race/ethnicity:** NR	**Inclusion criteria*:** • Men, women or children with frequency, urgency, nocturia and urge incontinence **Exclusion criteria:** • Neurological lesions	**Frequency, n:** 59 **Nocturia, n:** 37 **UUI, n:** 42 **MUI, n:** 24 **Enuresis, n:** 12 **Giggle, n:** 9 **Urodynamic status, n:** Unstable bladder: 38 Unstable bladder & bladder neck incompetence: 6 Sensory urgency: 12 Sensory urgency & bladder neck incompetence: 3 **Duration of symptoms (years), mean:** 11.9	**Results, patients with unstable bladder, n:** Cure: 18 Significant improvement: 10 Minor improvement: 2 Failure: 8 **Results, patients with unstable bladder & bladder neck incompetence, n:** Cure: 0 Significant improvement: 3 Minor improvement: 1 Failure: 0 **Results, patients with sensory urgency, n:** Cure: 7 Significant improvement: 4 Minor improvement: 1 Failure: 0 **Results, patients with sensory urgency & bladder neck incompetence, n:** Cure: 0 Significant improvement: 0 Minor improvement: 0 Failure: 3 **Bladder Capacity (mL), by result, patients with unstable bladder, mean change:** Cure: 149 Significant improvement: 87 Minor	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: - Loss to follow up: ++ Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of follow up: + Measurement methods: - Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
				improvement: 95 Failure: 73	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Millard et al., 1983 (continued)				**Bladder Capacity (mL) by result, patients with sensory urgency, mean change:** Cure: 83 Significant improvement: 115 Minor improvement: 127 Failure: NA **Voiding frequency (hours), by result, patients with unstable bladder, initial/final:** Cure: 1.9/4.8 Significant improvement: 1.8/3.2 Minor improvement: 1.0/4.0 Failure: 1.4/3.3 **Voiding frequency (hours), by result, patients with sensory urgency, initial/final:** Cure: 1.7/3.8 Significant improvement: 1.0/3.4 Minor improvement: 3.3/4.0 Fail: NA	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)					
Study Description	**Study Design, Interventions, and Population**	**Inclusion/ Exclusion Criteria**	**Symptom Characteristics**	**Outcomes**	**Quality Rating**
Author: Sand et al., 2007 **Country and setting:** US, Multicenter, 327 sites (141 Urology 141, 96 Primary care, 43 Ob-Gyn, 17 Geriatric Med) **Enrollment period:** NR **Funding:** Watson Laboratories, Inc **Author industry relationship disclosures:** 7 of 7 Allergan (1) Astellas (1) Esprit (1) GlaxoSmithKline (2) GSK (1) GTx (1) Indevus-Esprit (1) Lilly (1) Novartis (3) Ortho-McNeil (1) Ortho Urology (1) Pfizer (4) Sanofi (1) USB (1) Watson (6)	**Design:** RCT, open-label (case series for drug, RCT for educational materials) **Intervention:** Oxybutynin transdermal system 3.9 mg/day, twice weekly patch for up to 6 months with "standard instruction" or with "educational intervention". **Groups:** **G1:** Standard instructions **G2:** Educational intervention (educational booklet, OAB newsletters, dosing reminders, calendar reminders, bladder diary) **N at enrollment:** Total: 2,878 **G1:** 1,282 **G2:** 1,596 **Women, %:** 87.2 **Age, yrs ± SD:** 62.5 ± 14.8 **Race/ethnicity, %:** White: 83.6 African American: 9.9 Hispanic: 4.8 Asian: 1.2 Other: 0.5 **Follow-up:** 6 months	**Inclusion criteria:** • Age ≥18 • UUI, urinary urgency or frequency • Willing to discontinue all prescription and OTC medications for OAB • Capable of completing QoL questionnaires without assistance • Negative pregnancy test & medically acceptable contraceptive **Exclusion criteria:** • Contraindications to oxybutynin • Reversible etiologies for OAB • Prior treatment with Oxytrol • Long-term care facilities and nursing homes	**KHQ, UUI severity item score, %:** A lot: 38.1 Moderately: 31.3 A little: 20.5 Omitted, N/A: 10.1 **KHQ, urgency severity item score, %:** A lot: 49.2 Moderately: 30.3 A little: 14.8 Omitted, N/A: 5.6 **KHQ, frequency severity item score, %:** A lot: 59.3 Moderately: 32.5 A little: 7.2 Omitted, N/A:1.0 **KHQ, nocturia severity item score, %:** A lot: 47.3 Moderately: 33.5 A little: 16.7 Omitted, N/A: 2.4 **History of OAB, years, %:** <1 year: 12.0 1-2 years: 18.5 2-4 years: 23.1 ≥ 4 years: 46.4 **OAB Severity:** No problem: 1.8 Very minor: 4.6 Minor: 15.5 Moderate: 33.0 Severe: 28.4 Many severe problems: 16.7 **Previous OAB treatments, n (%):** 0: 43.4 1: 38.7 2: 13.1 3: 2.9	**KHQ, UUI severity item score, %:** A lot: 21.3 Moderately: 29.5 A little: 31.6 Omitted, N/A: 17.7 **KHQ, urgency severity item score, %:** A lot: 27.3 Moderately: 33.8 A little: 27.3 Omitted, N/A: 11.5 **KHQ, frequency severity item score, %:** A lot: 33.5 Moderately: 45.2 A little: 18.7 Omitted, N/A: 2.6 **KHQ, nocturia severity item score, %:** A lot: 27.5 Moderately: 35.4 A little: 31.3 Omitted, N/A: 5.7 **KHQ, general health perception, mean ± SD (% improvement):** -1.2 ± 17.4 (-4.3) **KHQ, incontinence Impact, mean ± SD (% improvement):** -13.5 ± 29.5 (-19.5) **KHQ, symptom severity, mean ± SD (% improvement):** -12.4 ± 24.8 (-22.2)*** **KHQ, role limitations, mean ± SD (%**	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
			4: 1.9	**improvement):** -13.3 ± 29.2 (-29.5)	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Sand et al., 2007 (continued)			**KHQ, general health perception, mean ± SD:** 28.2 ± 19.8 **KHQ, incontinence Impact, mean ± SD:** 69.3 ± 27.4 **KHQ, symptom severity, mean ± SD:** 55.9 ± 20.5* **KHQ, role limitations, mean ± SD:** 45.1 ± 31.0 **KHQ, physical limitations, mean ± SD:** 46.7 ± 31.6 **KHQ, social limitations, mean ± SD:** 25.6 ± 28.3 **KHQ, emotions, mean ± SD:** 30.0 ± 29.2 **KHQ, personal relationships, mean ± SD:** 20.6 ± 29.5*** **KHQ, sleep/ energy, mean ± SD:** 54.2 ± 27.3 **KHQ, severity (coping) measures, mean ± SD:** 47.9 ± 26.4	**KHQ, physical limitations, mean ± SD (% improvement):** -11.7 ± 29.9 (-25.1) **KHQ, social limitations, mean ± SD (% improvement):** -6.7 ± 23.7 (-26.2) **KHQ, emotions, mean ± SD (% improvement):** -8.8 ± 25.4 (-29.3) **KHQ, personal relationships, mean ± SD (% improvement):** -6.0 ± 23.5 (-29.1)*** **KHQ, sleep/ energy, mean ± SD (% improvement):** -11.2 ± 24.1 (-20.7) **KHQ, severity (coping) measures, mean ± SD (% improvement):** -8.6 ± 21.3 (-18.0) **Side effects, application site, %:** Total: 14.0 Pruritis: 4.9 Erythema: 4.6 Dermatitis: 4.4 Irritation: 3.2 Other: 2.0 **Side effects, %:** Rash: 3.0 Dry mouth: 2.6 Pruritis: 2.6 Skin irritation: 2.1 **Withdrew due to AEs, %:** 21.3	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Sand et al., 2007 (continued)				**Withdrew:** 1452 (50.5%) **Adverse events, %:** 21.3 **Withdrawn consent, %:** 7.5 **Requirement for alternative therapy, %:** 7.4 **Loss to follow-up, %:** 7.2 **Noncompliance, %:** 5.6 **Administrative decision, %:** 0.7 **Ineligible, %:** 0.4 **Death, %:** 0.1 **No reason given, %:** 0.3	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Song, et al., 2006 **Country and setting:** Korea, Medical Center **Enrollment period:** May 2001 to April 2002 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Bladder training (BT) vs. Tolterodine vs. BT + Tolterodine **Groups:** **G1:** BT x 12 wks **G2:** Tolterodine 2 mg bid x 12 wks **G3**:Tolterodine 2 mg bid + BT x 12 wks **N at enrollment:** **G1:** 46 **G2:** 47 **G3:** 46 **N at follow-up:** **G1:** 26 **G2:** 32 **G3:** 31 **Women, %:** 100 **Age, mean ± SD:** **G1:** 45.73 ± 12.68 **G2:** 48.41 ± 9.38 **G3:** 45.42 ± 9.54 **Race/ethnicity, %:** Korean: 100	**Inclusion criteria:** • Age ≥ 18 • ≥ 8 voids/day • Urge with or without incontinence • Symptom duration ≥ 3 months • No prior history of treatment for OAB **Exclusion criteria:** • Active urinary tract infection • Clinically significant SUI • Bladder outlet obstruction • Interstitial cystitis • Glaucoma • Megacolon • Maximal urine flow rate of < 10 mL/sec • Postvoid residual volume > 30% of the total amount voided on uroflowmetry	**Voids/day, mean ± SD:** **G1:** 10.93 ± 2.14 **G2:** 11.63 ± 2.57 **G3:** 11.90 ± 1.51 **Nocturia episodes/day, mean ± SD:** **G1:** 1.45 ± 1.14 **G2:** 1.72 ± 1.04 **G3:** 1.96 ± 1.49 **Urgency, mean score ± SD:** **G1:** 2.58 ± 1.30 **G2:** 2.81 ± 0.74 **G3:** 3.00 ± 1.10 **Maximum flow rate (mL/s), mean ± SD:** **G1:** 20.35 ± 8.44 **G2:** 22.56 ± 4.94 **G3:** 21.19 ± 4.96 **Residual urine (mL), mean ± SD:** **G1:** 9.08 ± 22.56 **G2:** 7.59 ± 12.39 **G3:** 6.42 ± 10.16 **Symptom duration (years), mean ± SD:** **G1:** 6.44 ± 6.84 **G2:** 4.54 ± 5.15 **G3:** 4.10 ± 3.99	**Voids/day, mean (% decrease)** **G1:** 8.1 (25.9%)* **G2:** 8.1 (30.2%)* **G3:** 7.9 (33.5%)* **G3/G1:** P < 0.05 **Nocturia episodes/day, mean (% reduction):** **G1:** 0.6 (56.1%)* **G2:** 0.6 (65.4%)* **G3:** 0.6 (66.3%)* **Urgency, mean score (% reduction):** **G1:** 1.4 (44.8%)* **G2:** 1.1 (62.2%)* **G3:** 1.2 (60.2%)* **G3/G1:** *P* = 0.021 **G2/G1:** *P* = 0.017 **G2/G3:** *P* = NS **Satisfaction, mean score (% improved):** **G1:** 1.5 (53.9) **G2:** 1.4 (63.0) **G3:** 1.3 (71.0) **Dry mouth, n (%):** **G1:** 0 (0.0) **G2:** 7 (21.9) **G3:** 9 (28.9) **Hesitancy, n (%)** **G1:** 0 (0.0) **G2:** 3 (9.4) **G3:** 2 (6.5) **Decreased appetite/constipation, n (%):** **G1:** 0 (0.0) **G2:** 2 (6.3) **G3:** 2 (6.5) **Headache, n (%):** **G1:** 0 (0.0) **G2:** 1 (3.1) **G3:** 0 (0.0)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: + Loss to follow up: - Drop-out rates: + Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of follow up: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics*	Outcomes	Quality Rating

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics*	Outcomes	Quality Rating
Author: Szonyi et al., 1995 **Country and setting:** UK **Enrollment period:** NR **Funding:** Smith & Nephew Pharmaceuticals Ltd **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Oxybutynin + bladder training vs. placebo + bladder training **Groups:** **G1:** Oxybutynin 2.5 mg bid with dose titration on days 29 and 43 plus bladder training **G2:** Placebo + bladder training **N at enrollment:** **G1:** 30 **G2:** 30 **N at follow-up:** **G1:**16 **G2:** 23 **Women, n (%):** 56 (93) **Age, mean ± SD:** 82.2 ± 6.06 **Race/ethnicity:** NR **Weight (kg), mean ± SD:** 67.4 ± 14.92	**Inclusion criteria:** • Age > 70 • Frequency, urgency and UUI • Mobile • Able to keep diary **Exclusion criteria:** • UTI • Hepatic or renal disease • Glaucoma • Uncontrolled diabetes • Taking imipramine or propantheline		**Voids/2 weeks, median change (95% CI):** **G1/G2:** 577 (-27.0, 6.0) *P* = 0.0025 **Nocturia episodes/2 weeks, median change (95% CI):** **G1/G2:** -6 (-5, 7.0) **Daytime incontinence episodes/2 weeks, median change (95% CI):** **G1 vs. G2:** -9.5 (-11.0, 3.0) **Nocturia episodes/2 weeks, median change (95% CI):** **G1/G2:** -1.0 (-3.0, 2.0) **Patient assess-ment of benefit, %:** 29 days: **G1:** 86 **G2:** 55 *P* = 0.02 43 days: **G1:** 71 **G2:** 59 *P* = 0.41 57 days: **G1:** 79 **G2:** 55 *P* = 0.09 **Patient response, 29 days, n:** Cure: **G1:** 1 **G2:** 0 Significant improvement: **G1:** 15 **G2:** 8 Marginal improvement: **G1:** 7 **G2:** 8	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to follow up: - Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: + Length of follow up: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics*	Outcomes	Quality Rating
Szonyi et al., 1995 (continued)				**No change:** **G1:** 5 **G2:** 13 **Patient response, 57 days, n:** Cure: **G1:** 4 **G2:** 3 Significant improvement: **G1:** 14 **G2:** 8 Marginal improvement: **G1:** 3 **G2:** 4 No change: **G1:** 7 **G2:** 14 **Dry mouth, %:** **G1:** 93 **G2:** 86 **Blurred vision, %:** **G1:** 50 **G2:** 59 **Heartburn, %:** **G1:** 57 **G2:** 45 **Constipation, %:** **G1:** 50 **G2:** 45 **Dry skin, %:** **G1:** 50 **G2:** 59 **Poor compliance (< 75% of tablets), %:** **G1:** 20 **G2:** 20	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics*	Outcomes	Quality Rating

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Wang et al., 2004 **Country and setting:** Taiwan, NR **Enrollment period:** July 2001 to December 2002 **Funding:** National Science Council, Taiwan **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Pelvic floor muscle training (PFMT), biofeedback-assisted PFMT (BAPFMT), electrical stimulation (ES) **Groups:** **G1:** PFMT per PERFECT score **G2:** BAPFMT per PERFECT score **G3:** ES using biphasic symmetric probe current w/ 10-Hz freq, 400-microsec pulse width, 10/5 duty cycle, varying intensity **N at enrollment:** **G1:** 40 **G2:** 38 **G3:** 42 **N at follow-up:** **G1:** 34 **G2:** 34 **G3:** 35 **Women:** 100% **Age, mean ± SD:** **G1:** 50.09 ± 15.85 **G2:** 52.32 ± 12.68 **G3:** 55.74 ± 12.53 **Race/ethnicity:** NR **BMI, kg/m^2 ± SD:** **G1:** 22.69 ± 3.32 **G2:** 23.70 ± 3.90 **G3:** 23.93 ± 3.21 **Parity, mean ± SD:** **G1:** 2.47 ± 1.44	**Inclusion criteria:** • Female • Age 16-75 • OAB symptoms for > 6 months • Voids/day ≥ 8 • UUI/day ≥ 1 **Exclusion criteria:** • Anticholinergic medications • Tricyclic antidepressants • Treatment with pelvic-floor exercises • Treatment with bladder training • Repair of pelvic prolapse • Pregnancy • Deafness • Neurologic disorders • DM • Pacemaker or IUD use • Genital prolapse > stage II by ICS • Residual urine > 100 mL • UTI	**Incontinence episodes/day, mean ± SD:** **G1:** 0.86 ± 1.80 **G2:** 0.92 ± 1.77 **G3:** 2.09 ± 2.96 **Urine leakage during former pregnancy, no (%):** **G1:** 7 (20.59) **G2:** 3 (8.83) **G3:** 3 (8.57)	**UUI symptoms resolved, n (%):** **G1:** 10 (30.3) **G2:** 13 (38.24) **G3:** 14 (40) **UUI symptoms modified, n (%):** **G1:** 3 (6.06) **G2:** 4 (11.76) **G3:** 4 (11.43) **UUI symptoms unchanged, n (%):** **G1:** 21 (63.64) **G2:** 17 (50) **G3:** 17 (48.6) **Incontinence episodes/day, mean ± SD:** **G1:** 0.73±1.82 **G2:** 0.70±1.80 **G3:** 1.95±2.84 **G1/G2/G3:** *P* = 0.016 **OAB symptom improvement/ cure, %:** **G1:** 38.2 **G2:** 50.0 **G3:** 51.4 **G1/G2/G3:** *P* = 0.567 **Adherence to treatment, median % (range):** **G1:** 0.833 (0.25-1.00) **G2:** 0.791 (0.58-1.99) **G3:** 0.750 (0.54-1.00) **G1/G2/G3:** *P* = 0.356 **Compliance with home program (days), median (range):**	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to follow up: + Drop-out rates: - Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of follow up: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics*	Outcomes	Quality Rating
	G2: 2.91 ± 1.86 **G3:** 3.69 ± 1.75			**G1:** 8.5 (0-44) **G2:** 14.5 (0-44) **G1/G2:** *P* = 0.636	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics*	Outcomes	Quality Rating
Wang et al., 2004 (continued)	**Menopausal, n (%)** **G1:** 21 (61.76) **G2:** 17 (50) **G3:** 8 (22.86)			**KHQ, general health perception, mean change ± SD:** **G1:** 14.66 ± 24.57 **G2:** 12.10 ± 20.28 **G3:** 16.96 ± 24.58 **G1/G2/G3:** *P* = 0.376 **KHQ, inconti-nence impact, mean change ± SD:** **G1:** 6.03 ± 120.82 **G2:** 37.42 ± 37.11 **G3:** 47.03 ± 35.45 **G1/G2/G3:** *P* = 0.067 **KHQ, role limitation, mean change ± SD:** **G1:** 25.86 ± 26.57 **G2:** 30.64 ± 30.15 **G3:** 34.52 ± 31.73 **G1/G2/G3:** *P* = 0.376 **KHQ, physical limitation, mean change ± SD:** **G1:** 25.29 ± 26.58 **G2:** 33.33 ± 33.88 **G3:** 28.57 ± 28.99 **G1/G2/G3:** *P* = 0.693 **KHQ, social limitation, mean change ± SD:** **G1:** 17.05 ± 21.20 **G2:** 22.76 ± 29.20 **G3:** 20.84 ± 27.45 **G1/G2/G3:** *P* = 0.799 **KHQ, personal relationships, mean change ± SD:** **G1:** 2.30 ± 13.89 **G2:** 10.75 ± 26.37 **G3:** 3.57 ± 22.39 **G1/G2/G3:** *P* = 0.167	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics*	Outcomes	Quality Rating
Wang et al., 2004 (continued)				**KHQ, emotions, mean change ± SD:** **G1:** 19.31 ± 29.68 **G2:** 22.22 ± 27.82 **G3:** 46.83 ± 37.33 **G1/G2/G3:** *P* = 0.005 **G2/G3:** *P* = 0.003 **G1/G3:** *P* = 0.007 **G2/G1:** *P* = 0.751 **KHQ, sleep/ energy, mean change ± SD:** **G1:** 18.83 ± 26.18 **G2:** 26.88 ± 24.60 **G3:** 38.10 ± 39.51 **G1/G2/G3:** *P* = 0.249 **KHQ, severity measures, mean change ± SD:** **G1:** 14.71 ± 20.27 **G2:** 20.65 ± 31.19 **G3:** 31.23 ± 23.83 **G1/G2/G3:** *P* = 0.004 **G2/G3:** *P* = 0.029 **G1/G3:** *P* = 0.001 **G2/G1:** *P* = 0.587 **KHQ, total score, mean change ± SD:** **G1:** 50.27 ± 171.42 **G2:** 185.86 ± 176.57 **G3:** 180.08 ± 176.03 **G1/G2/G3:** *P* = 0.003 **G2/G3:** *P* = 0.952 **G1/G3:** *P* = 0.004 **G2/G1:** *P* = 0.003 **Pelvic muscle strength, scale of power:** **G2/G3:** *P* < 0.001 **G1/G3:** *P* < 0.001	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics*	Outcomes	Quality Rating
Wang et al., 2004 (continued)				**Times of fast contraction, mean ± SD:** **G1:** -5.82 ± 5.05 **G2:** -6.21 ± 4.56 **G3:** -3.03 ± 4.98 **G2/G3:** *P* = 0.007 **G1/G3:** *P* = 0.012 **Degree of vaginal pressure, mean change ± SD:** **G1:** -36.03 ± 21.79 **G2:** -38.35 ± 29.62 **G3:** -8.91 ± 12.83 **G2/G3:** *P* < 0.001 **G1/G3:** *P* < 0.01 **Vaginal pressure, mean % change (range):** **G1:** -78.95 (-522.22, -10.34) **G2:** -105.0 (-2450 to 79.55) **G3:** -12.63 (-138.46 to 50) **G1/G2/G3:** *P* < 0.001 **Vaginal pressure, mean change ± SD:** **G1:** -36.03 ± 21.79 **G2:** -38.35 ± 29.62 **G3:** -8.91 ± 12.83 **G2/G3:** *P* < 0.001 **G1/G3:** *P* < 0.001 **G2/G1:** *P* = NS	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics*	Outcomes	Quality Rating
Author: Wang et al., 2006 **Country and setting:** Taiwan; Academic medical center **Enrollment period:** July 2004 to November 2005 **Funding:** National Science Council, Taiwan **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Electric Stimulation (ES) vs. Oxybutynin vs. Placebo for 12 weeks **Groups:** **G1:** ES: intravaginal electrode; biphasic symmetric pulsed current w/ a 10-Hz frequency, 400-millisecond pulse width, 10/5 duty cycle, and varying intensity, 20 min/session, twice weekly **G2:** Oxybutynin, 2.5 mg t.i.d. **G3:** Placebo pill t.i.d. **N at enrollment:** **G1:** 25 **G2:** 26 **G3:** 23 **N at follow-up:** **G1:** 24 **G2:** 23 **G3:** 21 **Age:** NR **Race/ethnicity:** NR	**Inclusion criteria:** • Female • OAB for ≥ 6 mos • Age 16-80 • Urgency ≥ 4 times per day **Exclusion criteria:** • Use of anticholinergics or TCAs • Previous treatment with pelvic-floor muscle training, bladder training • Pelvic prolapse repair • Pregnancy • Neurologic disorders • DM • Demand cardiac pacemaker • IUD use • Genital prolapse greater than ICS Stage II • PVR>100 mL • Overt SI • Anti-incontinence surgery • UTI	**Warning time, s (range)** **G1:** 41.5 (8-105) **G2:** 44 (2-215) **G3:** 65 (26-265 **MVV, mL/void (range):** **G1:** 340 (120-450) **G2:** 310 (130-800) **G3:** 350 (120-600) **Daily voided volume, mL (range)** **G1:** 2160 (1010-2950) **G2:** 2106 (1560-3153) **G3:** 2305 (1305-3300) **Pads per day (range):** **G1:** 1 (0-4.1) **G2:** 0 (0-3) **G3:** 1 (0-4) **Urgency (subj):** **G1:** 11.4 (4.0-16.0) **G2:** 12.1 (5-18) **G3:** 9.8 (4.2-15.5) **Frequency (subj):** **G1:** 12.8 (8.8-16.0) **G2:** 11.5 (4.3-19.5) **G3:** 11.5 (6.5-22.8) **Nocturia (subj):** **G1:** 1.75 (0-6.5) **G2:** 0 (0-2.5) **G3:** 0.65 (0-3.1) **UI (subj):** **G1:** 1 (0-2) **G2:** 0 (0-2) **G3:** 1 (0-2)	**Warning time, s (range)** **G1:** 72 (32-633) **G2:** 54.5 (138-850) **G3:** 66.5 (26-219) *P*(G1-G3) < 0.001 **MVV, mL/micturition (range):** **G1:** 355 (150-550) **G2:** 336.5 (138-850) **G3:** 340 (160-600) *P*(G1-G3) = 0.035 **Voided volume/d, mL (range)** **G1:** 2270 (1210-3106) **G2:** 2100 (1619-3200) **G3:** 2305 (1351-3221) *P*(G1-G3) = 0.050 **Pad count, pad/d (range):** **G1:** 0 (0-2) **G2:** 0 (0-2.5) **G3:** 1 (0-3) *P*(G1-G3) = 0.012 **Urgency (subj)** **G1:** 1.0 (0.0-12.3) **G2:** 6 (0.5-13) **G3:** 7.4 (3.9-13.4) *P*(G1-G3) < 0.001 **Frequency (subj)** **G1:** 7.8 (1.8-13.0) **G2:** 7.4 (2-14) **G3:** 10 (3.9-13.4) *P*(G1-G3) = 0.002 **Nocturia (subj)** **G1:** 0 (0-3.0) **G2:** 0 (0-2.5) **G3:** 1 (0-3.6) *P*(G1-G3) = 0.002	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to followup: ++ Drop-out rates: + Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Wang et al., 2006 (continued)				**UI (subj)** **G1:** 0.5 (0-2) **G2:** 0 (0-2) **G3:** 1 (0-2) *P*(G1-G3) = 0.413 **P values before vs. after treatment** **Warning time, s (range):** **G1:** 0.002 **G2:** 0.001 **G3:** 0.532 **MVV, mL/void (range):** **G1:** 0.018 **G2:** 0.004 **G3:** 0.979 **Daily voided volume, mL (range):** **G1:** 0.024 **G2:** 0.728 **G3:** 0.627 **Pad per day (range):** **G1:** 0.010 **G2:** 0.662 **G3:** 0.501 **Urgency (subj):** **G1:** <0.001 **G2:** <0.001 **G3:** 0.003 **Frequency (subj):** **G1:** <0.001 **G2:** <0.001 **G3:** 0.070 **Nocturia (subj):** **G1:** 0.001 **G2:** 0.394 **G3:** 0.176 **UI (subj):** **G1:** 0.814 **G2:** 0 083 **G3:** 0.854	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Wyman et al. 1998 **Country and setting:** US, Academic medical center **Enrollment period:** NR **Funding:** NIH **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** 12-wk program of patient education, self-monitoring of voiding behaviors, compliance assessment, and positive-reinforcement techniques administered by trained RNs **Groups:** **G1:** Bladder Training (BT) **G2:** Pelvic muscle exercise (PME) **G3:** Combination therapy (CT) **N at enrollment:** Total: 204 **G1:** 68 **G2:** 69 **G3:** 67 **N at follow-up, 3 mos:** **G1:** 68 **G2:** 64 **G3:** 61 **Age, mean ± SD:** **G1:** 60 ± 10 **G2:** 62 ± 10 **G3:** 61 ± 9 **Race/ethnicity, n (%):** **White:** **G1:** 64 (94) **G2:** 62 (90) **G3:** 49 (91) **Parity (vaginal births), mean ± SD:** **G1:** 2.4 ± 1.7 **G2:** 2.6 ± 1.9 **G3:** 2.5 ± 1.7 *P* = 0.846	**Inclusion criteria:** • Age ≥ 45 • Community dwelling • Mentally intact • Able to toilet independently • Urine loss ≥1x/wk • Urodynamic evidence of GUI, DI or both **Exclusion criteria:** • Reversible cases of UI • Uncontrolled metabolic conditions • Residual urine volume after voiding > 100mL • UTI • Genitourinary fistula • Indwelling catheterization • Inability to correctly perform a pelvic muscle contraction on digital exam	**Stress urinary incontinence, n (%):** **G1:** 19 (28) **G2:** 35 (51) **G3:** 22 (33) *P* = 0.015 **Urge urinary incontinence, n (%):** **G1:** 8(12) **G2:** 6(9) **G3:** 10(15) **Mixed urinary incontinence, n (%):** **G1:** 41 (60) **G2:** 27 (39) **G3:** 35 (52) *P* = 0.044 **Genuine stress incontinence by urodynamics, n (%):** **G1:** 48 (71) **G2:** 48 (70) **G3:** 49 (73) **Detrusor Instability by urodynamics, n (%):** **G1:** 9 (13) **G2:** 10 (14) **G3:** 10 (15) **DI + GSI by urodynamics, n (%):** **G1:** 11 (16) **G2:** 11 (16) **G3:** 8 (12) **Incontinence episodes/wk, mean ± SD:** **G1:** 14.6 ± 11.2 **G2:** 16.8 ± 17.1 **G3:** 14.9 ± 13.8	**Incontinence episodes/wk, immediately after treatment, mean ± SD:** **G1:** 10.6 ± 16.3 **G2:** 9.6 ± 10.8 **G3:** 6.8 ± 10.7 *P* = 0.004 **G1/G2:** *P* = 0.796 **G1/G3:** *P* = 0.006 **G2/G3:** *P* = 0.003 **Incontinence episodes/wk, immediately after treatment, DI ± GSI subgroup, mean ± SD:** **G1:** 6.2 ± 9.1 **G2:** 11.9 ± 12.7 **G3:** 5.8 ± 9.5 **Incontinence episodes, % reduction, immediately after treatment, n (%):** 100%: **G1:** 12 (18) **G2:** 8 (13) **G3:** 19 (31) 75-99%: **G1:** 11 (16) **G2:** 8 (13) **G3:** 14 (23) 50-74%: **G1:** 12 (18) **G2:** 20 (31) **G3:** 10 (16) 0-49%: **G1:** 14 (21) **G2:** 13 (20) **G3:** 10 (16) None/worse: **G1:** 19 (28) **G2:** 15(23) **G3:** 8 (13) *P* = 0.050 **Incontinence episodes/wk, 3 mos, mean ± SD:** **G1:** 10.0 ± 12.0 **G2:** 9.4 ± 14.0 **G3:** 8.1 ± 12.4 *P* = 0.126	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: + Loss to follow up: ++ Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of follow up: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Wyman et al. 1998 (continued)	**BMI, kg/m^2 ± SD:** **G1:** 28.4 ± 6.6 **G2:** 27.6 ± 5.8 **G3:** 26.8 ± 5.6 *P* = 0.288		**Incontinence episodes/wk, DI ± GSI subgroup, mean ± SD:** **G1:** 14.3 ± 10.3 **G2:** 20.7 ± 22.4 **G3:** 16.2 ± 13.7 **Previous medical treatment for UI, n (%):** **G1:** 14 (21) **G2:** 14 (21) **G3:** 16 (24) **Previous surgical treatment for UI, n (%):** **G1:** 15 (22) **G2:** 14 (21) **G3:** 22 (33) **UDI QoL, mean ± SD:** **G1:** 130.1 ± 48.8 **G2:** 119.7 ± 49.9 **G3:** 118.9 ± 46.9 **UDI QoL, DI ± GSI subgroup, mean ± SD:** **G1:** 143.2 ± 54.0 **G2:** 133.2 ± 59.6 **G3:** 115.4 ± 42.5 **IIQ-R incontinence impact, mean ± SD:** **G1:** 93.7 ± 74.2 **G2:** 75.6 ± 67.1 **G3:** 84.6 ± 67.8 **IIQ-R incontinence impact, DI ± GSI subgroup, mean ± SD:** **G1:** 118.5 ± 84.4 **G2:** 93.7 ± 90.3 **G3:** 84.0 ± 66.9	**Incontinence episodes, % reduction, 3 mos, n (%):** 100%: **G1:** 10 (16) **G2:** 13 (20) **G3:** 16 (27) 75-99%: **G1:** 9 (15) **G2:** 12 (22) **G3:** 13 (22) 50-74%: **G1:** 9 (15) **G2:** 9 (14) **G3:** 6 (10) 0-49%: **G1:** 15 (24) **G2:** 12 (18) **G3:** 15 (25) None/worse: **G1:** 19 (31) **G2:** 17 (26) **G3:** 10 (17) *P* = 0.587 **UDI QoL, immediately after treatment, mean ± SD:** **G1:** 95.5 ± 54.4 **G2:** 90.8 ± 52.0 **G3:** 64.4 ± 48.6 **UDI QoL, immediately after treatment, DI ± GSI subgroup, mean ± SD:** **G1:** 86.8 ± 54.8 **G2:** 114.8 ± 70.3 **G3:** 67.6 ± 48.5 *P* = 0.054 **G1/G2:** *P* = 0.37 **G1/G3:** *P* = 0.956 **G2/G3:** *P* = 0.038 **UDI QoL, 3 months, mean ± SD:** **G1:** 91.7 ± 55.0 **G2:** 85.0 ± 52.4 **G3:** 72.8 ± 50.4 *P* = 0.203	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Wyman et al., 1998 (continued)				**IIQ-R incontinence impact, immediately after treatment, mean ± SD:** **G1:** 72.1 ± 75.2 **G2:** 56.8 ± 61.4 **G3:** 46.6 ± 65.3 **IIQ-R incontinence impact, immediately after treatment, DI ± GSI subgroup, mean ± SD:** **G1:** 81.2 ± 88.7 **G2:** 89.9 ± 79.4 **G3:** 31.8 ± 34.4 *P* = 0.0301 **G1/G2:** *P* = 0.357 **G1/G3:** *P* = 0.084 **G2/G3:** *P* = 0.009 **IIQ-R incontinence impact, 3 months, mean ± SD:** **G1:** 65.7 ± 80.2 **G2:** 59.3 ± 67.7 **G3:** 59.8 ± 83.9 *P* = 0.850 **Patient perception of improvement, immediately after treatment, n (%):** Much: **G1:** 25 (38) **G2:** 19 (30) **G3:** 32 (52) Some: **G1:** 18 (27) **G2:** 29 (46) **G3:** 23 (38) None: **G1:** 20 (30) **G2:** 13 (21) **G3:** 4 (7) Worse: **G1:** 3 (5) **G2:** 2 (3) **G3:** 2 (3) *P* = 0.011	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Wyman et al., 1998 (continued)				**Patient perception of improvement, 3 mos, n (%):** Much: **G1:** 21 (35) **G2:** 24 (37) **G3:** 31 (53) Some: **G1:** 16 (27) **G2:** 21 (33) **G3:** 13 (22) None: **G1:** 19 (32) **G2:** 16 (25) **G3:** 12 (21) Worse: **G1:** 4 (7) **G2:** 3 (5) **G3:** 2 (4) *P* = 0.414 **Patient satisfaction, immediately after treatment, n (%):** Very satisfied: **G1:** 42 (64) **G2:** 46 (73) **G3:** 50 (82) Slightly satisfied: **G1:** 6 (9) **G2:** 10 (16) **G3:** 7 (11) Neither **G1:** 12 (21) **G2:** 6 (10) **G3:** 3 (5) Dissatisfied: **G1:** 4 (6) **G2:** 1 (2) **G3:** 1 (2) **Patient satisfaction, 3 mos, n (%):** Very satisfied: **G1:** 36 (60) **G2:** 42 (66) **G3:** 45 (78) Slightly satisfied: **G1:** 11 (18) **G2:** 11 (17) **G3:** 6 (10)	

Evidence Table 4. KQ 2 Behavioral Treatment of OAB (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Wyman et al., 1998 (continued)				Neither: **G1:** 8 (13) **G2:** 10 (16) **G3:** 5 (9) Dissatisfied: **G1:** 5 (8) **G2:** 1 (2) **G3:** 2 (3) *P* = 0.310	

Evidence Table 5. KQ2 Complementary and Alternative Therapies

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Emmons and Otto, 2005 **Country and setting:** US, Academic medical center **Enrollment period:** July 2000 to October 2002 **Funding:** Supported in part by grants from the Oregon Health Science Foundation and the Public Health Service **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Acupuncture **Groups:** **G1:** acupuncture with needles placed at sites intended to address overactive bladder with UUI; administered for 20 minutes during 4 weekly sessions **G2:** acupuncture with needles placed at sites intended to support relaxation; administered for 20 minutes during 4 weekly sessions **N at enrollment:** **G1:** 44 **G2:** 41 **N at follow-up, 2-4 weeks:** **G1:** 38 **G2:** 36 **Women, %:** 100 **Age, mean ± SD:** **G1:** 53 ± 13 **G2:** 51 ± 12 **Race/ethnicity:** Minority, % **Parity, mean ± SD:** **G1:** 1.8 ± 1.6 **G2:** 1.8 ± 1.6 **Menopausal, n:** **G1:** 21 **G2:** 20	**Inclusion criteria:** • > 8 voids per day • Subjective urgency to void • Urge-associated incontinence ≥ twice during a 3 day period **Exclusion criteria:** • Current treatment with medications for OAB • Current treatment with acupuncture for other indications • Unable to walk • Unable to complete a 3-day voiding diary • Hematuria • Untreated UTI	**UUI episodes/3 days, mean ± SD:** **G1:** 16.2 ± 11.1 **G2:** 15.4 ± 10.2 *P* = 0.68 **Incontinence episodes/3 days, mean ± SD:** **G1:** 6.3 ± 7.3 **G2:** 8.9 ± 9.2 *P* = 0.09 **Voids/3 days, mean ± SD:** **G1:** 30.4 ± 7.8 **G2:** 32.7 ± 11.5 *P* = 0.40 **Urinary distress inventory score, mean ± SD:** **G1:** 8.4 ± 3.6 **G2:** 8.6 ± 5.5 *P* = 0.87 **Incontinence impact questionnaire score, mean ± SD:** **G1:** 8.9 ± 2.8 **G2:** 9.1 ± 2.6 *P* = 0.80 **Functional bladder capacity (mL), mean ± SD:** **G1:** 210 ± 88 **G2:** 199 ± 84 *P* = 0.50 **Cystometric max capacity (mL), mean ± SD:** **G1:** 371 ± 161 **G2:** 341 ± 126 *P* = 0.49 **Cystometric volume (mL), first urge to void, mean ± SD:** **G1:** 61 ±+/- 67 **G2:** 69 ±+/- 52 *P* = 0.84	**UUI episodes/3 days, mean ± SD (% change):** **G1:** 11.4 ± 8.8 (30) **G2:** 15.0 ± 9.4 (3) **G1/BL:** *P* < 0.003 **G1/G2:** *P* = 0.016 **Incontinence episodes/3 days, mean ± SD (% change):** **G1:** 2.6 ± 3.1 (59) **G2:** 5.3 ± 5.9 (40) **G1/BL:** *P* < 0.003 **G2/BL:** *P* < 0.003 **G1/G2:** *P* = 0.71 **Voids/3 days, mean ± SD (% change):** **G1:** 26.2 ± 7.1 (14) **G2:** 33.1 ± 16.1 (4) **G1/G2:** *P* = 0.03 **Urinary distress inventory score, mean ± SD (% change):** **G1:** 3.6 ± 3.2 (57) **G2:** 5.8 ± 4.8 (32) **G1/BL:** *P* < 0.003 **G2/BL:** *P* < 0.003 **G1/G2:** *P* = 0.05 **Incontinence impact questionnaire score, mean ± SD (% change):** **G1:** 4.3 ± 2.7 (52) **G2:** 7.0 ± 3.5 (23) **G1/BL:** *P* < 0.003 **G2/BL:** *P* < 0.003 **G1/G2:** *P* = 0.004 **Functional bladder capacity (mL), mean ± SD (% change):** **G1:** 236 ± 99 (12) **G2:** 196 ± 85 (-2) **G1/BL:** *P* < 0.03 **G1/G2:** *P* = 0.01	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: ++ Power calculation: + Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 5. KQ2 Complementary and Alternative Therapies (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Emmons and Otto, 2005 (continued)			**Cystometric volume (mL), strong urge to void, mean ± SD:** **G1:** 274 ± 144 **G2:** 241 ± 100 *P* = 0.26 **Detrusor contractions during cystometry, n:** **G1:** 7 **G2:** 11 *P* = 0.22 **Incontinence surgery, n:** **G1:** 8 **G2:** 6	**Cystometric max capacity (mL), mean ± SD (% change):** **G1:** 415 ± 205 (12) **G2:** 356 ± 193 (4) **G1/G2:** *P* = 0.049 **Cystometric volume (mL), first urge to void, mean ± SD (% change):** **G1:** 65 ± 80 (6) **G2:** 57 ± 75 (-19) **G1/G2:** *P* = 0.47 **Cystometric volume (mL), strong urge to void, mean ± SD (% change):** **G1:** 297 ± 167 (8) **G2:** 276 ± 156 (14) **G1/BL:** *P* < 0.03 **G2/BL:** *P* < 0.03 **G1/G2:** *P* = 0.75 **Detrusor contractions during cystometry, n (% change):** **G1:** 6 (3) **G2:** 10 (3) **G1/G2:** *P* = 0.98 **Bleeding/bruising from the needles, %:** 23 **Minor discomfort with needle placement, %:** 25	

Evidence Table 5. KQ2 Complementary and Alternative Therapies (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Freeman and Baxby, 1982 **Country and setting:** UK, Academic medical center **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Case series **Intervention:** 12 sessions of hypnotherapy **Groups:** NA **N at enrollment:** 63 **N at follow-up:** 44 **Women, %:** 100 **Age, mean ± SD:** 44.0 ± 15.6 **Race/ethnicity:** NR **Follow-up:** 3-14 months	**Inclusion criteria:** • Women • Detrusor instability by urodynamics • Normal cystoscopy • Normal neurological findings • No drugs that affect the detrusor **Exclusion criteria:** • Genuine stress incontinence • Flow rate < 15 ml/s • Voiding pressure > 70 cm H_2O	**Max cystometric capacity (mL), full study population, mean ± SD (range):** 410.0 ± 13.3 (120-650) **Max cystometric capacity (mL), urodynamic studies performed, mean ± SD:** 378 ± 126 **Height of unstable contraction (cm H_2O), full study population, mean ± SD (range):** 43.6 ± 22.1 (15-100) **Height of unstable contraction (cm H_2O), urodynamic studies performed, mean ± SD:** 57.5 ± 23.3 **Bladder volume (mL), first unstable contraction, full study population, mean ± SD (range):** 318.0 ± 14.4 (50-650) **Bladder volume (mL), first unstable contraction, urodynamic studies performed, mean ± SD:** 245 ± 159	**Max cystometric capacity (mL), mean ± SD:** 487 ± 117 **Max cystometric capacity (mL), mean change ± SD:** 92.3 ± 112.2 P < 0.001 **Height of unstable contraction (cm H_2O), mean ± SD:** 39.0 ± 13.2 **Height of unstable contraction difference (cm H_2O), mean change ± SD:** -18.5 ± 18.9 P < 0.01 **Bladder volume (mL), first unstable contraction, mean ± SD:** 337 ± 123 **Bladder volume (mL), first unstable contraction, mean change ± SD:** 92.2 ± 126 P < 0.02 **Symptom free, n:** 29 **Considerably improved symptoms, n:** 14 **No change in symptoms, n:** 7 **Relapse, n:** 1 year: 3 10 months: 1 8 months: 1 7 months: 1 2 months: 1	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: -, NR Baseline OAB status: NR Baseline characteristics: - Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 5. KQ2 Complementary and Alternative Therapies (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Mak et al., 2007 **Country and setting:** Hong Kong, China, Gynecological hospital **Enrollment period:** January 2003 to March 2003 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Foot reflexology vs nonspecific foot message **Groups:** **G1:** foot reflexology for 45 min **G2:** nonspecific foot massage for 45 min **N at enrollment:** **G1:** 60 **G2:** 60 **N at follow-up:** **G1:** 54 **G2:** 43 **Women, %:** 100 **Age, mean ± SD:** G1: 56.0 ± 13.4 G2: 56.4 ± 9.1 **Race/ethnicity:** NR **Menopausal, n (%):** **G1:** 33 (57.8) **G2:** 29 (67.4) *P* = 0.533 **BMI, kg/m^2, median (IQR):** **G1:** 24.2 (21.6, 27.4) **G2:** 24.7 (21.8, 26.7)	**Inclusion criteria:** • Majority of leakage related to UI • Taking antimuscarinics with required 3 week washout **Exclusion criteria:** • SUI • UTI • Interstitial cystitis • Urinary tract obstruction • Organic disease of bladder or urethra • Pregnant • Breast-feeding • Pelvic, vaginal, or bladder surgery within 6 mos • Heart disease • Abnormal EKG	**UUI episodes, median (IQR):** **G1:** 0.5 (0, 2) **G2:** 1.0 (0, 2) *P* = 0.86 **Urgency episodes, mean ± SD:** **G1:** 2.22 ± 1.42 **G2:** 2.14 ± 1.12 *P* = 0.75 **Voids/day, mean ± SD:** **G1:** 11.3 ± 4.68 **G2:** 10.23 ± 3.53 *P* = 0.22 **Daytime voids/ day, mean ± SD:** **G1:** 9.07 ± 4.59 **G2:** 8.09 ± 3.83 *P* = 0.26 **Nocturia episodes, median (IQR):** **G1:** 2 (1, 3) **G2:** 2 (1, 3) *P* = 0.94 **Perceived severity, median (IQR):** **G1:** 5.6 (3.9, 7.1) **G2:** 5.3 (3.1, 7.0) *P* = 0.18 **KHQ, general health, mean score ± SD:** **G1:** 56.0 ± 18.1 **G2:** 55.8 ± 17.1 *P* = 0.955 **KHQ, incontinence impact, mean score ± SD:** **G1:** 68.5 ± 30.6 **G2:** 69.7 ± 27.9 *P* = 0.836	**UUI episodes, median change (IQR):** **G1:** 0 (-1, 0) **G2:** 0 (-1, 0) **Urgency episodes, mean change ± SD:** **G1:** 0.27 ± 0.94 **G2:** 0.48 ± 1.12 *P* = 0.32 **Voids/day, mean change ± SD:** **G1:** 2.18 ± 2.80 **G2:** 1.04 ± 2.92 *P* = 0.055 **Daytime voids/ day, mean change ± SD:** **G1:** 1.90 ± 2.76 **G2:** 0.55 ± 3.21 *P* = 0.029 **Nocturia episodes, median change (IQR):** **G1:** -1 (-1, 0) **G2:** -1 (-1, 0)* *P* = 0.46 **Frequency, change from > 8 to ≤ 8 after treatment, n (%):** **G1:** 11 (20.3) **G2:** 7 (16.2) *P* = 0.482 **Perceived severity, median change (IQR):** **G1:** 1.5 (-0.65, 3.4) **G2:** 1.2 (-0.8, 3) *P* = 0.7 **Perceived change of bladder symptoms, median (IQR):** **G1:** 1.5 (0.5, 3) **G2:** 1.1 (0, 2) *P* = 0.172	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to followup: - Drop-out rates: + Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 5. KQ2 Complementary and Alternative Therapies (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Mak et al., 2007 (continued)			**KHQ, role limitations, mean score ± SD:** **G1:** 39.8 ± 33.7 **G2:** 41.4 ± 33.8 *P* = 0.811 **KHQ, physical limitations, mean score ± SD:** **G1:** 37.3 ± 35.0 **G2:** 54.2 ± 78.6 *P* = 0.160 **KHQ, social limitations, mean score ± SD:** **G1:** 28.6 ± 30.2 **G2:** 35.1 ± 30.5 *P* = 0.294 **KHQ, personal limitations, mean score ± SD:** **G1:** 17.2 ± 29.9 **G2:** 24.4 ± 31.5 *P* = 0.358 **KHQ, emotion, mean score ± SD:** **G1:** 36.2 ± 33.5 **G2:** 44.1 ± 35.9 *P* = 0.262 **KHQ, sleep/ energy, mean score ± SD:** **G1:** 36.1 ± 33.9 **G2:** 33.3 ± 29.9 *P* = 0.674 **KHQ, severity measures, mean score ± SD:** **G1:** 25.8 ± 21.1 **G2:** 25.5 ± 20.8 *P* = 0.959 **Peak flow rate, ml/s ± SD:** **G1:** 16.7 ± 9.75 **G2:** 18.5 ± 7.69	**KHQ, general health, mean change ± SD:** **G1:** -5.55 ± 19.8 **G2:** -5.23 ± 19.3 *P* = 0.936 **KHQ, inconti-nence impact, mean change ± SD:** **G1:** -9.87 ± 32.7 **G2:** -14.72 ± 33.5 *P* = 0.477 **KHQ, role limitations, mean change ± SD:** **G1:** -3.08 ± 31.0 **G2:** -2.32 ± 28.5 *P* = 0.902 **KHQ, physical limitations, mean change ± SD:** **G1:** -1.54 ± 27.9 **G2:** -12.8 ± 71.9 *P* = 0.337 **KHQ, social limitations, mean change ± SD:** **G1:** -0.51 ± 29.1 **G2:** -6.97 ± 27.6 *P* = 0.267 **KHQ, personal limitations, mean change ± SD:** **G1:** 2.15 ± 29.1 **G2:** -10.1 ± 29.8 *P* = 0.116 **KHQ, emotion, mean change ± SD:** **G1:** 1.44 ± 30.4 **G2:** -10.0 ± 31.6 *P* = 0.074 **KHQ, sleep/ energy, mean change ± SD:** **G1:** -5.8 ± 36.9 **G2:** -6.2 ± 36.2 *P* = 0.964	

Evidence Table 5. KQ2 Complementary and Alternative Therapies (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Mak et al., 2007 (continued)			**Max cystometric capacity, ml ± SD:** **G1:** 378.1 ± 89.0 **G2:** 347.8 ± 94.0 *P* = 0.11 **Duration of symptoms, median (IQR):** **G1:** 5 (3, 9) **G2:** 6 (3, 10) **Previous treatment for idiopathic detrusor overactivity, n (%):** **G1:** 27 (47.3) **G2:** 22 (44.9) **Previous continence surgery, n (%):** **G1:** 5 (8.8) **G2:** 7 (16.3)	**KHQ, severity measures, mean change ± SD:** **G1:** -0.37 ± 8.8 **G2:** -1.86 ± 21.3 *P* = 0.720 **Believed to have received intervention, %:** **G1:** 88.9 **G2:** 67.4 *P* = 0.012	

Evidence Table 6. KQ 3 Comparison of Treatments

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Abrams et al., 1998 **Country and setting:** UK, Ireland, Sweden, Academic medical center **Enrollment period:** July 1995 to July 1996 **Funding:** Pharmacia Upjohn **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Tolterodine vs. oxybutynin vs. placebo x 12 wks **Groups:** **G1:** Tolterodine 2mg bid (dose could be reduced to 1.5 mg b.i.d.) **G2:** Oxybutynin 5mg t.i.d. (dose could be reduced to 2.5 mg t.i.d.) **G3:** Placebo **N at enrollment:** **G1**: 118 **G2:** 118 **G3:** 57 **N at follow-up:** **G1**: 118 **G2:** 117 **G3:** 56 **Women, n (%):** **G1:** 91 (77.1) **G2:** 88 (74.5) **G3:** 43 (75.4) **Age, mean (range):** **G1:** 55 (19-80) **G2:** 58 (21-80) **G3:** 58 (26-78)	**Inclusion criteria:** • Age ≥ 18 • UDS confirmed bladder overactivity • ≥ 8 voids/day • ≥ 1 episode UUI/ day **Exclusion criteria:** • SUI • Detrusor hyperreflexia • Hepatic, renal, hematological disorders • Symptomatic or recurrent UTI • BOO • Bladder retraining • Electrical stimulation therapy • Indwelling catheter • Intermittent catherization • Pregnant/ nursing • Women without reliable BC	**Incontinence episodes, n (%):** **G1:** 93 (79) **G2:** 88 (75) **G3:** 40 (70) **Incontinence episodes/day, mean (range):** **G1:** 2.9 (0.1-24.0) **G2:** 2.6 (0.1-24.0) **G3:** 3.3 (0.1-23.5) **Voids/day, mean (range):** **G1:** 11.5 (6.3-37.0) **G2:** 10.7 (5.3-27.7) **G3:** 11.7 (6.9-34.4) **≥ 8 voids/day, n (%):** **G1:** 112 (95) **G2:** 109 (92) **G3:** 53 (93) **Voided volume (mL), mean (range):** **G1:** 166 (55-426) **G2:** 176 (57-423) **G3:** 157 (59-276) **Previous OAB therapy, n (%):** **G1:** 61 (52) **G2:** 71 (60) **G3:** 43 (75)	**Incontinence episodes/day, mean change ± SD:** **G1:** -1.3 ± 3.2 **G2:** -1.7 ± 3.1 **G3:** -0.9 ± 1.5 **G1/G3:** P = 0.22 **G2/G3:** P = 0.023 **Voids/day, mean change ± SD:** **G1:** -2.7 ± 3.8 **G2:** -2.3 ± 2.7 **G3:** -1.6 ± 3.6 **G1/G3:** P = 0.002 **G2/G3:** P = 0.068 **Voided volume (mL), mean change ± SD:** **G1:** 38 ± 54 **G2:** 47 ± 58 **G3:** 6 ± 42 **G1/G3:** P < 0.001 **G2/G3:** P < 0.001 **Subjective improvement in bladder symptoms, %:** **G1:** 50 **G2:** 49 **G3:** 47 **Dose reductions, n (%):** **G1:** 9 (8) **G2:** 38 (32) **G3:** 1 (2) **G2/G1:** P < 0.001 **G2/G3:** P < 0.001 **Dry mouth, n (%):** **G1:** 59 (50) **G2:** 102 (86) **G3:** 12 (21) **G1/G3:** P < 0.001 **G2/G1:** P < 0.001 **G2/G3:** P < 0.001 **Dyspepsia, n (%):** **G1:** 11 (9) **G2:** 27 (23) **G3:** 3 (5)	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: + Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Abrams et al., 1998 (continued)				**Nausea, n (%):** **G1:** 4 (3) **G2:** 7 (6) **G3:** 6 (11) **Upper respiratory infection, n (%):** **G1:** 12 (10) **G2:** 3 (3) **G3:** 8 (14) **Adverse events reported, N:** **G1:** 302 **G2:** 412 **G3:** 117 **Patients with ≥ 1 AE, n (%):** **G1:** 105 (89) **G2:** 114 (97) **G3:** 46 (81) **G2/G1:** P = 0.023 **G2/G3:** P < 0.001 **Discontinued due to AEs, n (%):** **G1:** 10 (8) **G2:** 20 (17) **G3:** 1 (2)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Arruda et al., 2008 **Country and setting:** Brazil, community **Enrollment period:** August 2001 to September 2005 **Funding:** NR **Author industry relationship disclosures:** None	**Design:** RCT **Intervention:** Oxybutynin vs. functional electrostimulation vs. pelvic floor training **Groups:** **G1:** Oxybutynin 5 mg b.i.d. **G2:** Ambulatory stimulation applied vaginally **G3:** Pelvic floor exercises with a therapist and at home **N Screened:** 81 **N at enrollment:** **G1**: 22 **G2:** 21 **G3:** 21 **N at follow-up:** **G1**: 22 **G2:** 21 **G3:** 21 **Age, range:** 35-80 **Race/ethnicity:** NR **Women, %:** 100 **Length of follow up:** 12 weeks	**Inclusion criteria:** • Community-dwelling • Dx of OAB and DO • Capable of completing a bladder diary and performing a pelvic muscle floor contraction • For those with MUI, urge was predominant **Exclusion criteria:** • Hx of psychiatric or neurologic illness • Persistent UTI • Inability to comply with regular follow-up visits • Current pregnancy • Postvoid residual volume > 100 ml • Contraindications to anticholinergic therapy • Cardiac pacemaker • Type III SUI • Uncontrolled metabolic conditions or indwelling catheterization • Using medications including anticholinergic drugs, calcium antagonists, beta agonists, dopamine agonists, striated muscle relaxants or estrogens • Any uterine prolapse	**UUI episodes/ week, mean ± SD:** **G1:** 13.8 ± 11.6 **G2:** 13.5 ± 15.6 **G3:** 16.4 ± 17.2 **Nocturia episodes/week, mean ± SD:** **G1:** 1.7 ± 1.5 **G2:** 1.9 ± 1.9 **G3:** 1.4 ± 1.2 **Pads/day, mean ± SD:** **G1:** 2.6 ± 2.7 **G2:** 2.3 ± 2.4 **G3:** 2.7 ± 1.5 **Voids/day, mean ± SD:** **G1:** 7.7 ± 2.6 **G2:** 8.6 ± 3.4 **G3:** 6.8 ± 2.2 **Residual volume mean mL ± SD:** **G1:** 3.2 ± 6.3 **G2:** 1.0 ± 2.6 **G3:** 1.8 ± 3.3 **Volume, first desire to void, mean mL ± SD:** **G1:** 117.7 ± 68.9 **G2:** 102.4 ± 51.1 **G3:** 86.7 ± 38.9 **Maximal cystometric capacity, mean mL ± SD:** **G1:** 410.4 ± 194.1 **G2:** 350.0 ± 212.9 **G3:** 424.0 ± 149.0	**UUI episodes/ week, mean ± SD:** **G1:** 7.0 ± 10.6 **G2:** 7.9 ± 13.7 **G3:** 7.8 ± 15.3 **G1/BL:** *P* = 0.007 **G2/BL:** *P* = 0.039 **G3/BL:** *P* = 0.035 **Urgency resolved, n (%):** **G1:** 14 (63.6) **G2:** 11 (52.4) **G3:** 12 (57.1) *P* = 0.754 **Satisfied, n (%):** **G1:** 17 (77.3) **G2:** 11 (52.4) **G3:** 16 (76.2) *P* = 0.142 **Nocturia episodes/week, mean ± SD:** **G1:** 0.9 ± 0.8 **G2:** 1.2 ± 1.3 **G3:** 1.0 ± 1.1 **G1/BL:** *P* = 0.003 **G2/BL:** *P* = 0.036 **G3/BL:** *P* = 0.086 **Pads/day, mean ± SD:** **G1:** 0.9 ± 1.5 **G2:** 0.9 ± 1.7 **G3:** 0.8 ± 1.3 **G1/BL:** *P* < 0.001 **G2/BL:** *P* = 0.004 **G3/BL:** *P* < 0.001 **Voids/day, mean ± SD:** **G1:** 6.4 ± 1.6 **G2:** 7.9 ± 2.3 **G3:** 7.1 ± 2.1 **G1/BL:** *P* = 0.014 **G2/BL:** *P* = 0.291 **G3/BL:** *P* = 0.441 **Residual volume, mean mL ± SD:** **G1:** 4.7 ± 9.4 **G2:** 1.1 ± 2.5 **G3:** 2.1 ± 3.5 **G1/BL:** *P* = 0.425 **G2/BL:** *P* = 0.760 **G3/BL:** *P* = 0.297	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Method and blinding: - Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: + Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: + Measurement methods: - Measurement reliability: - Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Arruda et al., 2008 (continued)			**Involuntary detrusor contraction volume mean mL ± SD:** **G1:** 189.5 ± 114.1 **G2:** 220.0 ± 127.2 **G3:** 239.3 ± 163.0 **Involuntary detrusor contraction maximal pressure (mm H_20):** **G1:** 39.4 ± 26.1 **G2:** 43.7 ± 22.9 **G3:** 34.2 ± 19.8	**Volume first desire to void, mean mL ± SD:** **G1:** 157.3 ± 63.8 **G2:** 123.8 ± 59.0 **G3:** 137.6 ± 76.7 **G1/BL:** *P* = 0.019 **G2/BL:** *P* = 0.091 **G3/BL:** *P* = 0.017 **Maximal cystometric capacity mean mL ± SD:** **G1:** 517.3 ± 191.7 **G2:** 436.6 ± 178.7 **G3:** 489.0 ± 141.3 **G1/BL:** *P* = 0.001 **G2/BL:** *P* = 0.017 **G3/BL:** *P* = 0.113 **Involuntary detrusor contraction volume (mL):** **G1:** 188.6 ± 183.2 **G2:** 73.3 ± 112.4 **G3:** 114.3 ± 154.2 **G1/BL:** *P* = 0.986 **G2/BL:** *P* = 0.001 **G3/BL:** *P* = 0.044 **Involuntary detrusor contraction maximal pressure, mm H_20 ± SD:** **G1:** 19.6 ± 20.9 **G2:** 22.4 ± 30.1 **G3:** 17.2 ± 25.5 **G1/BL:** *P* < 0.001 **G2/BL:** *P* = 0.002 **G3/BL:** *P* = 0.027 **Normal urodynamic evaluation, n (%):** **G1:** 8 (36.4) **G2:** 12 (57.1) **G3:** 11 (52.4) *P* = 0.358 **Persistent improvement at 1 year:** **G1:** 10/17 **G2:** 4/11 **G3:** 9/16	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Arruda et al., 2008 (continued)				**Dry mouth, n (%):** **G1:** 16 (72.7) **G2:** 0 **G3:** 0 **Difficulty voiding, n (%):** **G1:** 2 (9.1) **G2:** 0 **G3:** 0 **Dizziness, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0 **Blurred vision, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0 **Constipation, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0 **Dry mouth, n (%):** **G1:** 16 (72.7) **G2:** 0 **G3:** 0 **Difficulty voiding, n (%):** **G1:** 2 (9.1) **G2:** 0 **G3:** 0 **Dizziness, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0 **Blurred vision, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0 **Constipation, n (%):** **G1:** 1 (4.5) **G2:** 0 **G3:** 0	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Burgio et al. 1998 **Country and setting:** US; academic health center outpatient geriatric medicine clinic **Enrollment period:** July 1989 to August 1995 **Funding:** National Institutes on Aging **Author industry relationship disclosures:** NR	**Design:** RCT, placebo controlled Computer-generated random numbers using a block size of 6, w/ prior stratification by type and severity of incontinence **Intervention:** Biofeedback-assisted behavioral vs. drug treatment (oxybutynin chloride; possible range of doses 2.5 mg/d-5.0 mg t.i.d.) vs. placebo All patients had 4 visits over an 8-week period. Patients in G1 had biofeedback added to behavioral training in absence of 50% improvement by session 3. **Groups:** **G1:** Behavioral ± biofeedback **G2:** Pharmacologic **G3:** Placebo **N at enrollment:** 468 screened 271 not eligible 197 randomized **G1**: 65 **G2:** 67 **G3:** 65 **N at follow-up:** **G1**: 61 **G2:** 55 **G3:** 53	**Inclusion criteria:** • Community-dwelling women ≥ 55 years old • Ambulatory • ≥ 2 urge accidents per week by baseline bladder diary • Urge incontinence as predominant pattern • Urodynamic evidence of bladder dysfunction **Exclusion criteria:** • Continual leakage • Postvoid residual urine volume >200mL • Uterine prolapse past the introitus • Narrow-angle glaucoma • Unstable angina • Decompensated congestive heart failure • Hx of malignant arrhythmias • MMSE <20 (Dementia)	**Duration of symptoms, mean yrs ± SD:** **G1:** 9.4 ± 10.8 **G2:** 9.8 ± 11.9 **G3:** 12.7 ± 15.9 **Restricted activity, (%):** **G1:** 30.8 **G2:** 32.8 **G3:** 38.5 **Urge UUI only, %:** **G1:** 49.2 **G2:** 49.3 **G3:** 47.7 **Accidents per week, mean n ± SD:** **G1:** 15.8 ± 14.5 **G2:** 15.9 ± 14.1 **G3:** 15.4 ± 13.4 P=.98 **Severity classification, %:** Mild (<5 accidents/wk) **G1:** 18.5 **G2:** 17.9 **G3:** 18.5 Moderate (5-10 accidents/wk) **G1:** 29.2 **G2:** 29.9 **G3:** 27.7 Severe (>10 accidents/wk) **G1:** 52.3 **G2:** 52.2 **G3:** 53.8 **Previous treatment with surgery, %:** **G1:** 20.0 **G2:** 26.9 **G3:** 29.2	**Accidents per week, mean ± SD:** **G1:** 2.8 ± 4.7 **G2:** 5.7 ± 9.8 **G3:** 8.2 ± 11.6 P=.005 **Percent reduction, mean ± SD:** **G1:** 80.7 ± 24.8 **G2:** 68.5 ± 37.2 **G3:** 39.4 ± 80.0 P<0.001 **Percent reduction, range:** **G1:** -0.9 – 100 **G2:** -85.7 – 100 **G3:** -400.0 - 100 **Patient perceptions of progress in treatment** Progress, %: Much better **G1:** 74.1 **G2:** 50.9 **G3:** 226.9 Better **G1:** 25.9 **G2:** 30.9 **G3:** 38.5 About the same **G1:** 0.0 **G2:** 16.4 **G3:** 28.8 Worse **G1:** 0.0 **G2:** 1.8 **G3:** 5.8 Estimate of % improvement, mean ± SD: **G1:** 81.6 ± 18.6 **G2:** 66.4 ± 35.4 **G3:** 45.1 ± 36.6	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al. 1998 (continued)	**Women, %:** 100 **Age, yrs ± SD:** **G1:** 67.3 ± 7.6 **G2:** 68.2 ± 7.5 **G3:** 67.6 ± 7.6 **Race/ethnicity,:** NR **Parity mean ± SD:** **G1:** 2.8 ± 2.0 **G2:** 2.1 ± 1.4 **G3:** 2.7 ± 1.8		**Previous treatment with medication, %:** **G1:** 27.7 **G2:** 35.8 **G3:** 30.8 **Using estrogen, %:** **G1:** 32.3 **G2:** 38.8 **G3:** 35.4 **Using diuretics, %:** **G1:** 20.0 **G2:** 14.9 **G3:** 12.3	**Having fewer accidents, %:** **G1:** 100.0 **G2:** 87.3 **G3:** 67.3 **Accidents are smaller, %:** **G1:** 87.3 **G2:** 78.8 **G3:** 54.0 **Able to wear less protection, %:** **G1:** 76.0 **G2:** 56.0 **G3:** 334.1 **Comfortable enough with treatment to continue indefinitely, %:** **G1:** 96.5 **G2:** 54.7 **G3:** 43.1 **Patient satisfaction with progress, %:** Completely satisfied **G1:** 77.6 **G2:** 54.7 **G3:** 43.1 Somewhat satisfied **G1:** 22.4 **G2:** 40.0 **G3:** 34.0 Not at all satisfied **G1:** 0.0 **G2:** 10.9 **G3:** 38.0 Wish to receive another form of treatment, %: **G1:** 14.0 **G2:** 75.5 **G3:** 75.5 p<0.001 for all comparisons	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al. 1998 (continued)				**Adverse effects, %, p compared to placebo G3:** Dry mouth **G1:** 34.9 **G2:** 96.9 **G3:** 54.8 p<0.001 Inability to void **G1:** 6.3 **G2:** 21.5 **G3:** 3.2 p=0.002 Constipation **G1:** 22.2 **G2:** 38.5 **G3:** 37.1 p=0.10 Blurred vision **G1:** 9.5 **G2:** 15.4 **G3:** 9.7 p=0.50 Confusion **G1:** 6.3 **G2:** 7.7 **G3:** 11.3 p=0.59	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Burgio et al. 2000 [See Burgio et al., 1998] **Enrollment period:** two weeks after completion of Burgio et al. 1998, #2440 **Funding:** National Institute on Aging, grants AG 08010 and K04 00431 **Author industry relationship disclosures:** NR	**Design:** Modified crossover of RCT **Intervention:** Participants whose treatment was not completely successful were given the opportunity to switch or use combined treatment; further reductions in incontinence were measured. **Groups:** Treatment Changes: **G1:** Previous oxybutynin to behavioral modification alone **G2**: Previous behavior alone to 2.5 mg oxybutynin t.i.d. + behavioral therapy **G3:** Previous oxybutynin alone to 2.5 mg oxybutynin t.i.d. + behavioral therapy **G4:** Placebo to behavioral **G5:** Placebo to oxybutynin **N at enrollment** **G1:** 19 **G2:** 8 **G3**: 27 **G4:** 34 **G5:** 10 **N at follow-up:** **G1:** 18 **G2:** 8 **G3:** 26 **G4:** NR **G5:** NR	**Inclusion criteria:** • Community-dwelling women at least age 55 • Ambulatory • At least 2 urge accidents per week by baseline bladder diary • Urge incontinence as predominant pattern • Urodynamic evidence of bladder dysfunction • not completely dry or satisfied with previous, 8-wk treatment **Exclusion criteria:** • Continual leakage • Postvoid residual urine volume >200mL • Uterine prolapse past the introitus • Narrow-angle glaucoma • Unstable angina • Decompensated congestive heart failure • Hx of malignant arrhythmias • MMSE <20 (Dementia)	**% Reduction of incontinence after previous study (at baseline), mean:** **G1:** 59.1 **G2:** 57.5 **G3:** 72.7 **G4:** 22.9 **G5:** 44.8	**Final % Reduction of incontinence mean, p:** **G1:** 77.1, 0.109 **G2:** 88.5, 0.034 **G3:** 84.3, 0.001 **G4:** 63.9, .002 **G5:** 76.5, .012	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Note: 29.2 of G3 declined to continue with drug therapy once they received behavioral modification.

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Burgio et al., 2001 [See Burgio et al,. 1998] **Country and setting:** US, University based **Enrollment period:** [See Burgio et al,. 1998] **Funding:** NIH **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Psychological distress associated with pharmacologic treatment vs. behavioral vs. placebo **Groups:** **G1:** Behavioral training with biofeedback, 4 visits **G2:** Oxybutynin 2.5 mg P.O. t.i.d., up to a max of 5 mg t.i.d. **G3:** Placebo **N at enrollment:** 197 women **N treated:** 169 **N at follow-up:** 155 (completed both pre and post-treatment psychological assessment) **Age yrs, mean ± SD:** 67.5 ± 7.2 **Women, %:** 100 **Race/ethnicity, %:** White: 97 African American: 3	**Inclusion criteria:** • ≥ 55 yrs old • Ambulatory • UUI ≥2x/wk (2 wk bladder diary), persisting x 3 mo • Predominant UUI • UDS evidence of bladder dysfunction (DI or maximal capacity ≤350 mL) **Exclusion criteria:** • Contraindication to oxybutynin or behavioral treatment • Continual leakage • PVR > 200 mL • Uterine prolapse beyond the introitus • Decompensated CHF • Hx of malignant arrhythmias • Impaired mental status (MMSE <20)	**SCL-90-R scores ± SD:** Somatization **G1:** 56.0 (10.6) **G2:** 51.4 (10.8) **G3:** 52.4 (11.1) Obsessive-Compulsive: **G1:** 56.5 (10.7) **G2:** 56.6 (11.4) **G3:** 57.7 (10.0) Interpersonal Sensitivity **G1:** 53.8 (11.0) **G2:** 51.4 (11.9) **G3:** 50.4 (12.0) Depression **G1:** 54.7 (10.0) **G2:** 52.5 (9.7) **G3:** 51.0 (11.9) Anxiety **G1:** 48.7 (13.9) **G2:** 46.8 (12.0) **G3:** 47.2 (12.8) Hostility **G1:** 49.3 (10.7) **G2:** 45.9 (10.1) **G3:** 48.3 (10.4) Phobia **G1:** 47.5 (10.2) **G2:** 46.7 (10.3) **G3:** 45.7 (8.5) Paranoid Ideation **G1:** 48.6 (12.4) **G2:** 49.3 (11.1) **G3:** 46.1 (12.8) Psychoticism **G1:** 54.1 (10.7) **G2:** 52.1 (10.3) **G3:** 50.5 (11.2) Global Severity **G1:** 54.2 (11.1) **G2:** 52.5 (10.3) **G3:** 52.4 (11.2)	**Reduction in incontinence:** **G1:** 83.3% **G2:** 74.4% **G3:** 41.4% P<0.001 **SCL-90-R scores ± SD:** Somatization **G1:** 51.8 (11.4) **G2:** 51.2 (9.8) **G3:** 49.8 (13.0) Obsessive-Compulsive: **G1:** 53.8 (13.9) **G2:** 53.9 (10.9) **G3:** 55.4 (11.0) Interpersonal Sensitivity **G1:** 49.5 (12.0) **G2:** 48.9 (11.2) **G3:** 49.2 (11.3) Depression **G1:** 51.5 (11.5) **G2:** 50.6 (10.7) **G3:** 51.4 (11.2) Anxiety **G1:** 46.1 (14.6) **G2:** 44.5 (12.3) **G3:** 45.8 (12.9) Hostility **G1:** 44.9 (10.8) **G2:** 44.6 (10.5) **G3:** 47.3 (11.2) Phobia **G1:** 47.1 (11.2) **G2:** 45.0 (8.3) **G3:** 45.1 (8.5) Paranoid Ideation **G1:** 45.8 (10.9) **G2:** 47.2 (11.6) **G3:** 47.2 (12.0) Psychoticism **G1:** 49.2 (11.7) **G2:** 50.4 (9.7) **G3:** 49.6 (10.3) Global Severity **G1:** 50.8 (12.8) **G2:** 50.4 (10.0) **G3:** 51.4 (10.9)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al., 2001 (continued)			155 participants were compared to the 42 who did not complete intervention and psychological assessment, higher scores (greater distress) on 6 of 10 SCL-90-R scales (somatization, obsessive/compulsive, depression, hostility, paranoid ideation, global severity index), all p values <0.05 Normal range, score 0-63 >75% in normal range (including dropouts) on 9 of 10 scales Highest impairment rate: 33% scored abnormal for obsessive-compulsive	**Correlations between Reduction of Incontinence and Changes in Psychological Symptoms** Somatization **G1:** 0.28* **G2:** -0.09 **G3:** 0.17 Obsessive-Compulsive **G1:** 0.01 **G2:** -0.14 **G3:** 0.02 Interpersonal Sensitivity **G1:** -0.09 **G2:** 0.04 **G3:** 0.13 Depression **G1:**-0.04 **G2:** 0.03 **G3:** 0.07 Anxiety **G1:** -0.10 **G2:** -0.01 **G3:** 0.34* Hostility **G1:** -0.10 **G2:** 0.09 **G3:** 0.11 Phobic anxiety **G1:**-0.21 **G2:** -0.17 **G3:** 0.02 Paranoid Ideation **G1:** 0.14 **G2:** -0.04 **G3:** -0.06 Psychoticism **G1:** -0.01 **G2:** -0.01 **G3:** 0.13 Global Severity Index **G1:** 0.01 **G2:** 0.06 **G3:** 0.45*** *p<0.05 ***P=0.001	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Burgio et al., 2008 **Country and setting:** US, Academic medical centers **Enrollment period:** July 2004 to January 2006 **Funding:** NIH Pfizer **Author industry relationship disclosures:** 20 of 29 Allergan (3) Alza (1) Astellas Pharma (7) Bionovo (1) Bristol-Meyers Squibb (1) Dynogen (1) Elan (1) Ethicon (2) GSK (4) Johnson & Johnson (3) Lilly (7) Medtronic (1) Merck (1) Novartis (6) Ortho-McNeil (3) Pfizer (>10) Procter & Gamble (3) Q-Med (1) Renessa (1) Sanofi (1) Solace (1) Watson (1)	**Design:** RCT **Intervention:** Pharmacologic vs. pharmacologic plus behavioral interventions for 10 wks (Stage 1), followed by no drug therapy (Stage 2) with assessments at 10 wks and 8 mos* **Groups:** **G1:** tolterodine tartrate (ER capsules), 4 mg/d plus behavioral training: pelvic floor muscle control and exercises, behavioral strategies to diminish urgency, suppress bladder contractions and prevent both stress and urge incontinence; delayed voiding; fluid management; handout with hints **G2:** tolterodine tartrate (ER capsules), 4 mg/d **N at enrollment:** 4043 screened 2612 not eligible 870 declined 561 consented 254 excluded 307 randomized **G1:** 153 **G2:** 154	**Inclusion criteria:** • Women • Community-dwelling • UUI only, or urge-predominant incontinence • ≥ 7 episodes of incontinence in a 7-day bladder diary • Persistent incontinence for at least 3 mos • No antimuscarinics or other medications that could affect UI • No evidence of neurogenic etiology **Exclusion criteria:** • Age < 21 • Pregnant, or planning a pregnancy in next 8 mos, or not using birth control • < 6 mos postpartum or termination after 20 wks gestation • Unable to contract pelvic floor muscles • Behavioral therapy of > 2 mos in past 2 yrs • Continual leakage or always damp • Hypersensitive to study drug • Systemic disease that affects bladder function	**UUI, 7-13 episodes/week, n (%):** **G1:** 2 (1.3) **G2:** 2 (1.3) **UUI, ≥ 14 episodes/week, n (%):** **G1:** 2 (1.3) **G2:** 4 (2.6) **MUI, 7-13 episodes/week, n (%):** **G1**: 46 (29.9) **G2**: 46 (30.1) **MUI, ≥ 14 episodes/week, n (%):** **G1:** 104 (67.5) **G2:** 101 (66.0) **Adjusted incontinence episodes/week, mean:** **G1:** 23.1 **G2:** 23.2 **Previous non-surgical treatment for incontinence, n (%):** **G1:** 19 (12) **G2:** 22 (14)	**Success, n (%):** **G1:** 43 (28) **G2:** 41 (27) **Failure, n (%):** **G1:** 75 (49) **G2:** 78 (51) **8 month success rate, lifetable analysis, % (95% CI):** **G1:** 41 (32, 50) **G2:** 41 (33, 50) **G1/G2:** 0 (-12, 12) **8 mo success rate, complete cases, % (95% CI):** **G1:** 36 (27, 45) **G2:** 34 (25, 43) **G1/G2:** 2 (-10, 14) **8 mo success rate, assuming missings were failures, % (95% CI):** **G1:** 28 (21, 35) **G2:** 27 (20, 34) **G1/G2:** 1 (-9, 11) **Adjusted incontinence episodes/week, after Stage 1, mean:** **G1:** 2.7 **G2:** 4.7 **Adjusted incontinence episodes/week, after Stage 1, mean change:** **G1:** -20.4 **G2:** -18.5 **G1/G2:** -1.9 (-5.9, 2.0)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to followup: - Drop-out rates: ++ Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al., 2008 (continued)	**N at follow-up:** **G1:** 153 Completed treatment: 107 Outcome known at 8 mos: 119 **G2:** 154 Completed treatment: 101 Outcome known at 8 mos: 118 **Age, mean ± SD:** **G1:** 55.8 ± 14.2 **G2:** 58.0 ± 13.5 **Women, %:** 100 **Race/ethnicity, n (%):** **Hispanic:** **G1:** 13 (9) **G2:** 17 (11) **NH White:** **G1:** 105 (69) **G2:** 85 (56) **NH Black:** **G1:** 22 (14) **G2:** 35 (23) **Other:** **G1:** 13 (9) **G2:** 15 (10) **BMI, kg/m^2 ± SD:** **G1:** 33.2 ± 9.5 **G2:** 32.3 ± 7.6	• Currently using catheter to empty bladder • Postvoid residual volume > 150mL • Treatment for prolapse with pessary < 3 mos • Incontinence, vaginal, bladder or prolapse surgery in the past 6 mos • Urethral diverticulum • Previous augmentation cystoplasty or artificial sphincter • Neuromodulation for pelvic indications • Using anticholinergic agents, cholinergic agonists, tricyclic antidepressants, or duloxetine in ≤ 4 wks • Using diuretics with dosage change past 3 mos • Uncontrolled medical problem • History of bladder or pelvic cancer or pelvic radiation therapy • Glaucoma • Gastric retention • Non-ambulatory • Participation in other intervention trial that might influence outcome		**Achieved 70% reduction in incontinence episodes, 10 wks (%):** **G1:** 69 **G2:** 58 **G1/G2:** 11 (-0.3, 22.1) **Totally dry, per bladder diary, 10 wks (%):** **G1:** 21 **G2:** 17 **Voids/day, mean change:** **G1:** 0.5 **G2:** -0.4 **G1/G2:** 0.9 (0.3, 1.5) **Symptom Distress Scores:** **G1/G2:** P < 0.0001 **Symptom Bother Scores (OAB-q), Stage 1, mean change:** **G1:** -36.7 **G2:** -30.4 **G1/G2:** P < 0.0001 **Symptom Bother Scores (OAB-q), Stage 2, mean change:** **G1:** -30.9 **G2:** -20.4 **G1/G2:** P < 0.0001 **Patient completely satisfied, Stage 1, %:** **G1:** 53 **G2:** 40 **G1/G2:** 13 (1, 25)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Burgio et al., 2008 (continued)				**Patient completely satisfied, 8 months, %:** **G1:** 33 **G2:** 20 **G1/G2:** 13 (2, 24) **Patient better or much better, Stage 1, %:** **G1:** 90 **G2:** 77 **G1/G2:** 13 (4, 22) **Patient better or much better, 8 months, %:** **G1:** 69 **G2:** 43 **G1/G2:** 26 (14 , 38) **Persistence in perceived improvement, 8 months, women with improvement at Stage 1:** **G1:** 72 **G2:** 54 **G1/G2:** 17 (4, 30) **Harms:** **G1:** 3 participants 1: blurred vision, syncope, night sweats, stomach cramping and weakness 2: 2 episodes of small-bowel obstruction and an allergic reaction (pruritus and rash) 3: tachycardia during stage 2 **G2:** 3 participants 1: small bowel obstruction 2: peripheral edema 3: renal cell carcinoma diagnosis during stage 2	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Chancellor, Kianifard et al., 2008 **Country and setting:** US **Enrollment period:** May 2005 to February 2006 **Funding:** NR **Author industry relationship disclosures:** 6 of 7 Genaera (1) Novartis (6)	**Design:** Randomized open-label **Intervention:** Behavioral modification in addition to darifenacin (allowed to increase dose from darifenacin 7.5 mg to 15 mg daily after 2 weeks) **Groups:*** **G1:** Darifenacin **G2:** Darifenacin and behavioral modification **N at enrollment:** **G1:** 190 **G2:** 205 **N at follow-up, 12 weeks:** **G1:** 173 **G2:** 175 **Age, mean ± SD:** **G1:** 57.4 ± 13.1 **G2:** 58.4 ± 14.6 **Race/ethnicity: White:** **G1:** 90 **G2:** 88.3 **Other (non-white):** **G1:** 10 **G2:** 11.7 **Women, %:** **G1:** 90 **G2:** 88.3	**Inclusion criteria:** • ≥ 8 voids/ day • ≥ 2 UUI episodes/ day • ≥ 2 episodes of urgency/day **Exclusion criteria:** • Any drug with bladder effects for 2 weeks prior to study participation • Participation in any formal bladder-training program within 30 days of screening • Predominant SUI • Bladder or neurologic condition that could affect bladder function or in which use of anticholinergics was contra-indicated	**UUI episodes/ day, mean ± SD:** **G1:** 2.78 ± 2.57 **G2:** 3.00 ± 2.56 **UUI episodes/ day, median:** **G1:** 2.33 **G2:** 2.58 **Mean UUI episodes/day, total population, n (%):** 0 episodes: **G1:** 36 (19.1) **G2:** 29 (14.2) 1-6 episodes: **G1:** 138 (73.0) **G2:** 155 (76.0) 7-13 episodes: **G1:** 15 (7.9) **G2:** 20 (9.8) ≥14 episodes **G1:** 0 (0.0) **G2:** 0 (0.0) **Mean UUI episodes/day, age ≥ 65, n (%)** 0 episodes **G1:** 9 (17.0) **G2:** 8 (9.9) 1-6 episodes **G1:** 40 (75.5) **G2:** 63 (77.8) 7-13 episodes **G1:** 4 (7.5) **G2:** 10 (12.3) **Urgency episodes/day, mean ± SD:** **G1:** 10.88 ± 3.80 **G2:** 10.58 ± 4.00 **Urgency episodes/day, median:** **G1:** 10.67 **G2:** 10.33 **Voids/day, mean ± SD:** **G1:** 11.92 ± 3.03 **G2:** 11.75 ± 3.37	**UUI episodes/day mean change ± SD:** **G1:** -1.89 ± 2.29 **G2:** -2.10 ± 2.32 **G1/G2:** P = 0.268 **UUI episodes/day median change (95% CI):** **G1:** -1.33 (-2.00, -1.00) **G2:** -2.00 (-2.00, -1.33) **Urgency episodes/day mean change ± SD:** **G1:** -2.87 ± 3.59 **G2:** -2.68 ± 3.54 **G1/G2:** P = 0.882 **Urgency episodes/day median change (95% CI):** **G1:** -2.33 (-3.00, -1.67) **G2:** -2.67 (-3.00, -2.00) **Voids/day, mean change ± SD:** **G1:** -2.96 ± 2.91 **G2:** -2.82 ± 2.87 **G1/G2:** P = 0.681 **Voids/day, median change (95% CI):** **G1:** -2.67 (-3.33, -2.00) **G2:** -2.67 (-3.00, -2.33) **Nocturia episodes/day, mean change ± SD:** **G1:** -0.65 ± 1.26 **G2:** -0.67 ± 1.21 **G1/G2:** P = 0.315	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chancellor, Kianifard et al., 2008 (continued)			**Voids/day, median:** **G1:** 11.33 **G2:** 11.33 **Nocturia episodes/day, mean ± SD:** **G1:** 1.77 ± 1.43 **G2:** 1.87 ± 1.35 **Nocturia episodes/day, median:** **G1:** 1.67 **G2:** 1.67 **Pads used/day, mean ± SD:** **G1:** 1.12 ±1.93 **G2:** 0.99 ± 1.67 **Pads used/day, median:** **G1:** 0 **G2:** 0	**Nocturia episodes/day, median change (95% CI):** **G1:** -0.67 (-0.67, -0.33) **G2:** -0.67 (-0.67, -0.33) **Pads used/day mean change ± SD:** **G1:** -0.72 ±1.54 **G2:** -0.61 ± 1.28 **G1/G2:** P = 0.978 **Pads used/day median change (95% CI):** **G1:** 0 (0,0) **G2:** 0 (0,0) **Side effects, %:**** Constipation: 18.5 Dry mouth 25 UTI: 4.8 Headache: 3.8 **Discontinued due to adverse event(s), n (%)** **G1:** 6 (3.2) **G2:** 21 (10.25) **Discontinued due to constipation, %:** 2 **Discontinued due to dry mouth, %:** 1.8	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Chancellor, Zinner et al., 2008 **Country and setting:** USA, multicenter **Enrollment period:** NR **Funding:** Astellas Pharma US, Glaxo-SmithKline **Author industry relationship disclosures:** 12 of 12 Abbot (1) AEterna Zentaris (1) Akros (1) Allergan (3) American Medi-cal Systems (2) Amgen (1) Astellas (10) AstraZeneca (1) Bard (1) Bayer (1) Boehringer Ingelheim (3) Cephalon (1) Coloplast (1) Cook (1) CooperSurgical (1) Eli Lilly (2) Ferring GSK (6) Gynecare (1) Indevus (2) J&J (1) Mankind (1) Medtronic (1) Merck (1) Novartis (3) Novo Nordisk (1) Ortho-McNeil (1)	**Design:** Prospective cohort, open label, flexible-dose, 14 day washout **Intervention:** Solifenacin 5-10 mg daily **Groups:** **G1:** Solifenacin 5-10 mg daily **N at enrollment:** **G1:** 440 **N at follow-up (%):** **G1:** 390 (88.4) **Age, mean ± SD:** **G1:** 61.4 ± 13.8 **Race/ethnicity, n (%):** White: **G1:** 392 (88.9) **Women, N (%):** **G1:** 389 (88.2) **BMI, kg/m^2 ± SD:** **G1:** 30.1 ± 7.1	**Inclusion criteria:** • Age ≥ 18 • OAB symptoms > 3 months • Treatment with tolterodine ER 4 mg, solifenacin, darifenacin, or trospium x ≥ 4 weeks • Desired change in therapy • ≥ 3 mean UUI episodes/day **Exclusion criteria:** • Treatment < 4 weeks with tolterodine, solifenacin, darifenacin, or trospium • SUI • MUI with primary stress • UTI • Chronic bladder inflammation • Bladder cancer • Severe constipation • Elevated PVR • Neurological deficit • Renal/ hepatic disease • Narrow angle glaucoma • Urinary retention • Gastric retention • Hypersensitivity to drugs • BOO • Women of childbearing age/ lactation	**Urgency episodes/day, mean change:** **G1:** 6.9 ± 4.4 **Incontinence episodes/day, mean ± SD:** **G1:** 3.8 ± 3.6 **Voids/day, mean ± SD:** **G1:** 11.3 ± 3.8 **Nocturia episodes/day, mean ± SD:** **G1:** 1.9 ± 1.2 **PPBC score, mean:** **G1:** 4.2 **OAB-q score, mean:** Symptom bother: 57.3 Coping: 52.2 Concern: 51.3 Sleep: 50.6 Social Interaction: 77.7 Total score: 56.7	**Urgency episodes/day, mean change ± SD (95% CI):** **G1:** -4.2 ± 4.2 (-4.6, -3.8) **G1/BL:** *P* < 0.001 **Incontinence episodes/day, mean change ± SD (95% CI):** **G1:** -2.6 ± 3.2 (-3.0, -2.3) **G1/BL:** P < 0.001 **Voids/day, mean change ± SD (95% CI):** **G1:** -2.3 ± 3.2 (-2.6, -2.0) **G1/BL:** P< 0.001 **Nocturia episodes/day, mean change ± SD (95% CI):** **G1:** -0.8 ± 1.0 (-0.9,-0.6) **G1/BL:** P < 0.001 **PPBC score, mean change (95% CI):** **G1:** -1.2 (-1.3, -1.0) **G1/BL:** *P* < 0.001 **OAB-q score, mean:** Symptom bother: 27.8 Coping: 80.1 Concern: 81.1 Sleep: 75.1 Social Interaction: 92.7 Total score: 81.9 **G1/BL:** *P* < 0.001 all domains and total score **Dry Mouth, n (%):** **G1:** 77 (17.5) **Constipation, n (%):** **G1:** 51 (11.6)	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: - Method and blinding: NA Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chancellor, Zinner, et al., 2008 (continued) **Author industry relationship disclosures:** Pfizer (7) Pharmacia (1) Pri Med (1) Reliant (1) Solvay (1) Sanofi-Aventis (1) Schering-Plough (1) Takeda (1) TAP (1) Watson (1)				**Blurred vision, n (%):** **G1:** 10 (2.3) **UTI, n (%):** **G1:** 19 (4.3) **Headache, n (%):** **G1:** 13 (2.9) **URI, n (%):** **G1:** 11 (2.5)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Chapple et al. 2003 **Country and setting:** 98 centers – United States, United Kingdom, Poland, Russia, New Zealand, Belgium, Netherlands **Enrollment period:** NR **Funding:** Yamanouchi Pharmaceutical Co., Ltd, Tokyo, Japan **Author industry relationship disclosures:** Not reported	**Design:** RCT, double-blind placebo controlled, with 2-wk placebo run-in period **Intervention:** tolterodine vs. solifenacin vs. placebo **Groups:** **G1:** tolterodine 2 mg bid **G2:** solifenacin 5 mg qd **G3**: solifenacin 10 mg qd **G4**: placebo qd **N at enrollment:** **G1:** 279 **G2:** 269 **G3**: 266 **G4:** 267 **N at follow-up:** **G1:** 250 **G2:** 266 **G3**: 264 **G4:** 253 **Female, n (%)** **G1:** 200 (80.0) **G2:** 188 (71.2) **G3: 194 (72.9)** **G4**: 193 (76.3) **Age, yrs ± SD:** **G1: 56.9 +/-12.8** **G2:** 58.1± 13.4 **G3:** 57.2 ±13.4 **G4:** 57.8 ± 13.7 **<65 years of age, n (%)** **G1:** 169 (63.5) **G2:** 172 (65.2) **G3:** 172 (68.8) **G4**: 168 (66.4) **≥65 years of age, n (%)** **G1:** 97 (36.5) **G2:** 92 (34.8) **G3:** 78 (31.2) **G4**: 85 (33.6)	**Inclusion criteria:** • ≥ 18 years of age • symptoms of OAB (including urinary frequency with urgency and/or urge incontinence) for ≥3 months • ≥8 voids per 24 hr • ≥3 episodes urinary incontinence during 3-day diary period **Exclusion criteria:** • BOO • PVR >200 mL • stress predominant factor • neurological cause for detrusor overactivity • UTI or bladder stones • previous pelvic irradiation • malignant disease of pelvic organs • contraindication to antimuscarinic medication (including narrow-angle glaucoma, urinary or gastric retention) • non pharmacologic treatment for OAB 2 wks before study • diabetic neuropathy	**UI only, n (%)** **G1:** 142 (56.8) **G2:** 162 (61.4) **G3: 172 (64.7)** **G4**: 177(70.0) **Mixed SI/UI, n (%)** **G1:** 90 (36.0) **G2:** 81 (30.7) **G3: 79 (29.7)** **G4**: 59(23.3) **No incontinence, n (%)** **G1:** 18 (7.2) **G2:** 20 (7.6) **G3: 15 (5.6)** **G4**: 17 (6.7) **Urgency episodes/24 h, mean ± SD** **G1:** 5.77 ± 4.89 **G2:** 5.82 ± 4.45 **G3:** 5.45 ± 3.87 **G4**: 5.30 ± 3.92 **UI/24 h, mean ± SD** **G1:** 2.33 ± 2.50 **G2:** 2.14 ± 2.44 **G3:** 1.86 ± 1.54 **G4**: 2.02 ± 2.50 **Incontinence episodes/24 h, mean ± SD:** **G1:** 2.64 ± 2.55 **G2:** 2.59 ± 2.88 **G3:** 2.32 ± 1.94 **G4**: 2.71 ± 2.83 **# Voids/24 h, mean ± SD:** **G1:** 12.08± 3.86 **G2:** 12.32 ±3.95 **G3:** 12.08 ± 3.43 **G4: 12.20 ± 4.11** **Volume voided/void, mL, mean ± SD:** **G1:** 149.6 ± 54.6 **G2:** 147.2 ±51.2 **G3:** 147.0 ± 50.3 **G4:** 143.8 ± 53.6	**Urgency episodes/24 h mean Δ from baseline:** **G1:** -2.05 (3.58) **G2:** -2.85 (3.74) **G3: -3.07 (3.90)** **G4**: -1.41 (3.67) **Urgency episodes/24 h Δ from baseline, %:** **G1:** -38 **G2:** -55 **G3:** -52 **G4**: -33 **Urgency episodes estimated difference vs. tolterodine (95%CI)** **G1:** -0.791 (-14.34, -0.148) p<0.001 **G2:** -1.015 (-1.659, -0.370) p<0.001 **G3:** p=0.0511 **UI/24 h mean Δ from baseline:** **G1:** -0.91 (2.01) **G2:** -1.41 (1.74) **G3: -1.36 (2.13)** **G4**: -0.62 (1.96) **UI/24 h Δ from baseline, %:** **G1:** -58 **G2:** -65 **G3:** -63 **G4**: -40 **UI estimated difference vs. tolterodine (95%CI)** **G1:** -0.487 (-0.988, 0.014) p=0.002 **G2:** -0.436 (-0.921, 0.048) p=0.0028 **G3:** p=0.2390	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: ++ Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al. 2003 (continued)	**<75 years of age, n (%)** **G1:** 236 (88.7) **G2:** 241 (91.3) **G3:** 233 (93.2) **G4**: 225 (88.9) **≥75 years of age, n (%)** **G1:** 30 (11.3) **G2:** 23 (8.7) **G3:** 17 (16.8) **G4**: 28 (11.1) **Weight, mean kg ± SD** **G1:** 74.8 +/-14.8 **G2:** 74.6±14.3 **G3: 75.5±14.2** **G4**: 72.6±14.4 **Race, n (%)** **White** **G1:** 261(98.1) **G2:** 260 (98.5) **G3:** 247(98.8) **G4**: 248 (98.0) **Black** **G1:** 2 (0.8) **G2:** 0 **G3:** 1 (0.4) **G4**: 1 (0.4) **Asian** **G1:** 2 (0.8) **G2:** 0 **G3:** 2(0.8) **G4**: 1 (0.4) **Other** **G1:** 1 (0.4) **G2:** 4 (1.5) **G3:** 0 **G4**: 3 (1.2)	• use of drugs intended to treat incontinence • use of drugs with cholinergic or anticholinergic side-effects • participation in a clinical trial within 30 days • childbearing potential, pregnant or nursing or not using reliable contraceptive methods	**Time from start of symptoms, mean months (%)** **G1:** 57.4 (60.5) **G2:** 72.6 (105.4) **G3:** 62.9 (82.5) **G4**: 61.0 (83.9) **Prior drug therapy, n (%)** **G1:** 93 (34.9) **G2:** 106 (40.1) **G3:** 77 (30.8) **G4**: 83 (32.8) **Any non drug therapy, n (%)** **G1:** 92 (34.6) **G2:** 92 (34.8) **G3:** 88 (35.2) **G4:** 76 (30.0)	**Incontinence episodes/24 h mean Δ from baseline:** **G1:** -1.42 (1.82) **G2:** -1.45 (2.24) **G3:** -1.14 (2.15) **G4**: -0.76 (2.26) **Incontinence episodes/24 h Δ from baseline, %:** **G1:** -59 **G2:** -47 **G3:** -59 **G4**: -29 **Incontinence episodes estimated difference vs. tolterodine (95%CI)** **G1:** -0.276 (-0.761, 0.208) p=0.008 **G2:** -0.316 (-0.786, 0.154) p=0.0038 **G3:** p=0.1122 **Voids/24 h mean Δ from baseline:** **G1:** -1.88 (3.00) **G2:** -2.19 (2.87) **G3: -2.61 (3.24)** **G4**: -1.20 (3.26) **Voids/24 h Δ from baseline, %:** **G1:** -15 **G2:** -20 **G3:** -17 **G4**: -18 **Voids estimated difference vs. tolterodine (95%CI)** **G1:** -0.312 (-0.844, 0.219) p=0.003 **G2:** -0.737 (-1.269, -0.204) p<0.001 **G3:** p=0.0145	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al. 2003 (continued)				**Volume voided, mL mean Δ from baseline:** **G1:** 24.4 (49.2) **G2:** 32.9 (47.7) **G3: 39.2 (50.4)** **G4**: 07.4 (36.3) **Volume voided, mL Δ from baseline, %:** **G1:** 20 **G2:** 25 **G3:** 29 **G4**: 9 **Volume voided, mL estimated difference vs. tolterodine (95%CI)** **G1:** 8.4 (0.496, 16.34) p,0.001 **G2:** 14.8 (6.855, 22.72) p<0.001 **G3:** p<0.001 **Discontinued due to AEs, n (%):** **G1:** 5 (1.9) **G2:** 9 (3.2) **G3:** 7 (2.6) **G4:** 10 (3.7) **Dry mouth, n (%):** **G1:** 49 (18.6) **G2:** 39 (14.0) **G3:** 57 (21.3) **G4:** 13 (4.9) **Constipation, n (%):** **G1:** 7 (2.6) **G2:** 20 (7.2) **G2:** 21 (7.8) **G4**: 5 (1.9) **Blurred Vision, n (%):** **G1:** 4 (1.5) **G2:** 10 (3.6) **G3:** 15 (5.6) **G4:** 7 (2.6)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Chapple et al., 2005 Chapple et al., 2007† **Country and setting:** European, Multicenter **Enrollment period:** May 2003 to October 2004 **Funding:** Yamanouchi (now Astellas) **Author industry relationship disclosures:** NR* 1 of 9† Astellas (1) Novartis (1) Pfizer (1) Schwartz (1) UCB (1)	**Design:** RCT **Intervention:** Solifenacin 5mg vs. tolterodine ER 4mg **Groups:** **G1:** solifenacin 5mg **G2:** tolterodine ER 4mg **G1a:** G1 who elected not to increase dose at 4 weeks **G2a:** G2 who elected not to increase dose at 4 weeks **N at enrollment:** **G1:** 578 **G2:** 599 **N at follow-up:** **G1a:** 297 **G2a:** 267 **Age, mean:** **G1:** 56.5 **G2:** 56.4 **G1a:** 56.5 **G2a:** 56.9 **Race/ethnicity, %:** **White:** **G1:** 99.3 **G2:** 99.5 **G1a:** 99.3 **G2a:** 99.3 **Women, %:** **G1:** 85.3 **G2:** 88.3 **G1a:** 87.5 **G2a:** 87.1	**Inclusion criteria:** • Age ≥ 18 • OAB symptoms for ≥ 3 months • outpatient treatment • ≥ 8 voids/day • ≥ 1 incontinence episode/day or ≥ 1 urgency episode/day **Exclusion criteria:** NR	**UUI episodes/ day, mean ± SD:*** **G1:** 2.31 ± 2.35 **G2:** 2.12 ± 2.14 **UUI episodes/ day, mean:†** **G1a:** 1.97 **G2a:** 1.66 **Urgency episodes/day, mean ± SD:*** **G1:** 6.01 ± 4.66 **G2:** 5.84 ± 4.12 **Urgency episodes/day, mean:†** **G1a:** 5.67 **G2a:** 5.30 **Incontinence episodes/day, mean ± SD:*** **G1:** 2.77 ± 2.65 **G2:** 2.55 ± 2.37 **Incontinence episodes/day, mean:†** **G1a:** 2.32 **G2a:** 2.01 **Voids/day, mean ± SD:*** **G1:** 11.78 ± 3.58 **G2:** 11.66 ± 3.25 **Voids/day, mean:†** **G1:** 11.10 **G2:** 11.36 **Nocturia, episodes/day, mean ± SD:*** **G1:** 2.02 ± 1.33 **G2:** 1.92 ± 1.22 **Nocturia, episodes/day, mean:†** **G1a:** 1.83 **G2a:** 1.84	**UUI episodes/day, 4 wks, mean change:†** **G1:** -1.22 **G2:** -0.91 P = NS **UUI episodes/day, 12 wks, mean change:*** **G1:** -1.42 **G2:** -0.83 P = 0.001 **UUI episodes/day, 12 wks, mean change:†** **G1a:** -1.46 **G2a:** -1.03 **Urgency episodes/day, 4 wks, mean change:†** **G1:** -1.98 **G2:** -1.67 P = NS **Urgency episodes/day, 12 wks, mean change:*** **G1:** -2.85 **G2:** -2.42 P = 0.035 **Urgency episodes/day, 12 wks, mean change:†** **G1a:** -3.08 **G2a:** -2.62 **Incontinence episodes/day, 4 wks, mean change:†** **G1:** -1.30 **G2:** -0.90 P = 0.0181	Quality: Overall quality score: good INTERNAL VALIDITY: good Randomization: + Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2005* Chapple et al., 2007† (continued)				**Incontinence episodes/day, 12 wks, mean change:*** **G1:** -1.60 **G2:** -1.11 P = 0.006 **Incontinence episodes/day, 12 wks, mean change:†** **G1a:** -1.56 **G2a:** -1.23 **Voids/day, 4 wks, mean change:†** **G1:** -1.71 **G2:** -1.47 P = NS **Voids/day, 12 wks, mean change:*** **G1:** -2.45 **G2:** -2.24 P = 0.004 for non-inferiority **Voids/day, 12 wks, mean change:†** **G1a:** -2.47 **G2a:** -2.49 **Nocturia, episodes/day, 4 wks, mean change:†** **G1:** -0.51 **G2:** -0.44 P = NS **Nocturia, episodes/day, 12 wks, mean change:*** **G1:** -0.71 **G2:** -0.63 P = NS **Nocturia episodes/day, 12 wks, mean change:†** **G1a:** -0.72 **G2a:** -0.69	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2005* Chapple et al., 2007† (continued)				**Perception of bladder condition, 4 wks, mean change:†** **G1:** -0.96 **G2:** -0.88 P = NS **Perception of bladder condition, 12 wks, mean change:*** **G1:** -1.51 **G2:** -1.33 P < 0.0061 **Perception of bladder condition, 12 wks, mean change:†** **G1a:** -1.72 **G2a:** -1.62 **Pad use, 4 wks, mean change:†** **G1:** -1.21 **G2:** -0.80 P = 0.0089 **Pad use, 12 wks, mean change:*** **G1:** -1.72 **G2:** -1.19 P < 0.0023 **Pad use, 12 wks, mean change:†** **G1a:** -1.55 **G2a:** -1.40 **Dry rate, 4 wks, mean % change:†** **G1:** 39 **G2:** 34 P = NS **Dry rate, 12 wks, mean % change:†** **G1a:** 65.4 **G2a:** 58.3	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2005* Chapple et al., 2007† (continued)				**Voided volume (mL), 4 wks, mean change:†** **G1:** 28.51 **G2:** 24.29 P = NS **Voided volume (mL), 12 wks, mean change:*** **G1:** 38 **G2:** 31 P = 0.010 **Voided volume (mL), 12 wks, mean change:†** **G1a:** 39.95 **G2a:** 37.84 **Dry mouth, mild, %:*†** **G1:** 17.5 **G2:** 14.8 **G1a:** 6.5 **G2a:** 5.0 **Dry mouth, moderate, %:*†** **G1:** 10.8 **G2:** 7.7 **G1a:** 10.4 **G2a:** 7.0 **Dry mouth, severe, %:*†** **G1:** 1.7 **G2:** 1.5 **G1a:** 0.7 **G2a:** 2.1 **Constipation, mild, %:*†** **G1:** 3.2 **G2:** 1.3 **G1a:** 2.0 **G2a:** 1.0 **Constipation, moderate, %:*†** **G1:** 2.7 **G2:** 1.0 **G1a:** 1.7 **G2a:** 1.4	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2005* Chapple et al., 2007† (continued)				**Constipation, severe, %:*†** **G1:** 0.5 **G2:** 0.2 **G1a:** 0.3 **G2a:** 0.0 **Blurred vision, mild, %:*†** **G1:** 0.7 **G2:** 0.7 **G1a:** 0.3 **G2a:** 0.7 **Blurred vision, moderate, %:*†** **G1:** 0.0 **G2:** 1.0 **G1a:** 0.0 **G2a:** 1.7 **Blurred vision, severe, %:*†** **G1:** 0.0 **G2:** 0.0 **G1a:** 0.0 **G2a:** 0.0	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Chapple et al., 2008 **Country and setting:** European, multicenter (academic and private) **Enrollment period:** NR **Funding:** Pfizer, Schwarz BioSciences **Author industry relationship disclosures:** 4 of 5 Pfizer (4)	**Design:** Multicenter randomized placebo-controlled **Intervention:** Tolterodine 4 mg ER vs. fesoterodine 8 mg **Groups:** **G1:** Tolterodine ER 4mg **G2:** Fesoterodine 8mg **G3:** Placebo **N at enrollment:** **G1:** 290 **G2:** 287 **G3:** 283 **Age, mean ± SD:** Total: 57 ± 14 **Race/ethnicity, %:** **White:** Total: >95 **Women, %:** Total: 80 **Follow-up:** 12 weeks	**Inclusion criteria:** • Age ≥ 18 • OAB sx w/ urinary urgency for ≥6 mos • ≥ 8 voids/day • ≥ 6 urgency episodes or ≥ 3 UUI episodes/day • At least moderate problems recorded via a Likert scale • Negative pregnancy test • Adequate contraception throughout trial **Exclusion criteria:** • LUT pathology: SI, bladder stones, interstitial cystitis, urothelial tumors • Grade III or higher pelvic prolapsed • Bladder-outlet obstruction • Polyuria (>3L/d) • Symptomatic or recurrent UTIs • PVR urine volume >100 mL • Antimuscarinic agent w/in 2 wks • Electrostimulation for bladder training in prior 4 wks • Active UTI • Underlying neurological disease • Clinically relevant cardiac arrhythmia • Unstable angina • QTcB interval > 500ms	**Time since first diagnosis or onset of OAB (years), mean:** Total: 8-9 **Incontinent at BL, n:** **G1:** 213 **G2:** 217 **G3:** 203	**KHQ severity score, mean change:** **G1:** -12.6 **G2:** -14.0 **G3:** -9.0 **G1/G3:** $P < 0.05$ **G2/G3:** $P < 0.05$ **KHQ severity score, patients incontinent at BL, mean change:** **G1:** -14.9 **G2:** -15.8 **G3:** -10.8 **G1/G3:** $P < 0.05$ **G2/G3:** $P < 0.05$ **KHQ emotions score, mean change:** **G1:** -16.3 **G2:** -17.4 **G3:** -10.1 **G1/G3:** $P < 0.05$ **G2/G3:** $P < 0.05$ **KHQ emotions score, patients incontinent at BL, mean change:** **G1:** -17.3 **G2:** -18.6 **G3:** -11.3 **G1/G3:** $P < 0.05$ **G2/G3:** $P < 0.05$ **KHQ role limitations score, mean change:** **G1:** -22.1 **G2:** -21.7 **G3:** -11.8 **G1/G3:** $P < 0.05$ **G2/G3:** $P < 0.05$	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Method and blinding: + Pt selection criteria: + Loss to followup: NR Drop-out rates: NR Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2008 (continued)				**KHQ role limitations score, patients incontinent at BL, mean change:** **G1:** -23.2 **G2:** -23.7 **G3:** -12.4 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05 **KHQ physical limitations score, mean change:** **G1:** -19.7 **G2:** -21.7 **G3:** -11.4 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05 **KHQ Physical limitations score, patients incontinent at BL, mean change:** **G1:** -20.5 **G2:** -23.3 **G3:** -11.1 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05 **KHQ social limitations score, mean change:** **G1:** -14.1 **G2:** -15.4 **G3:** -8.7 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05 **KHQ social limitations score, patients incontinent at BL, mean change:** **G1:** -15.7 **G2:** -16.2 **G3:** -9.5 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2008 (continued)				**KHQ sleep/energy score, mean change:** **G1:** -11.7**G2:** -13.6 **G3:** -9.6 **G1/G3:** *P* = NS **G2/G3:** *P* < 0.05 **KHQ sleep/energy score, patients incontinent at BL, mean change:** **G1:** -12.5 **G2:** -15.3 **G3:** -10.4 **G1/G3:** *P* = NS **G2/G3:** *P* < 0.05 **KHQ personal relationship score, mean change:** **G1:** -10.4 **G2:** -11.9 **G3:** -6.2 **G1/G3:** *P* = NS **G2/G3:** *P* < 0.05 **KHQ personal relationship score, patients incontinent at BL, mean change:** **G1:** -12.7 **G2:** -12.3 **G3:** -6.8 **G1/G3:** *P* < 0.05 **G2/G3:** *P* = NS **KHQ incontinence impact score, mean change:** **G1:** -23.3 **G2:** -24.6 **G3:** -16.1 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2008 (continued)				**KHQ incontinence impact score, patients incontinent at BL, mean change:** **G1:** -23.8 **G2:** -26.5 **G3:** -17.7 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05 **KHQ general health score, mean change:** **G1:** -4.3 **G2:** -4.0 **G3:** -3.8 **G1/G3:** *P* = NS **G2/G3:** *P* = NS **KHQ general health score, patients incontinent at BL, mean change:** **G1:** -4.3 **G2:** -4.5 **G3:** -5.5 **G1/G3:** *P* = NS **G2/G3:** *P* = NS **ICIQ-SF total score, mean:** **G1:** -3.95 **G2:** -4.41 **G3:** -2.55 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05 **ICIQ-SF total score, patients incontinent at BL, mean:** **G1:** -4.56 **G2:** -5.29 **G3:** -3.12 **G1/G3:** *P* < 0.05 **G2/G3:** *P* < 0.05	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Chapple et al., 2008 (continued)				**Major improvement in severity of bladder-related problems, %:** **G1:** 34 **G2:** 39 **G3:** 25 **G1/G3:** *P* = 0.01 **G2/G3:** *P* = 0.01 **Dry mouth, n (%):** **G1:** 49 (17) **G2:** 97 (34) **G3:** 20 (7) **Constipation, n (%):** **G1:** 8 (3) **G2:** 13 (5) **G3:** 4 (1) **Nasopharyngitis, n (%):** **G1:** 10 (3) **G2:** 5 (2) **G3:** 7 (3) **Dry eye, n (%):** **G1:** 1 (1) **G2:** 12 (4) **G3:** 0 (0) **Nausea, n (%):** **G1:** 6 (2) **G2:** 4 (1) **G3:** 1 (1) **Fatigue, n (%):** **G1:** 10 (3) **G2:** 1 (1) **G3:** 1 (1) **Dry throat, n (%):** **G1:** 3 (1) **G2:** 8 (3) **G3:** 0 (0)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Colombo et al., 1995 **Country and setting:** Italy; Setting **Enrollment period:** May 1990 to March 1993 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT, Computer generated random assignment **Intervention:** Oxybutynin vs. Bladder training for 6 weeks **Groups:** **G1:** Oxybutynin, 3 daily doses of 5 mg each for 6 weeks (dose reduced to half if substantial AEs) **G2:** Bladder training **N at enrollment:** **G1**: 42 **G2:** 39 **N at 6 wk follow-up:** **G1**: 38 **G2:** 37 **N at 6 mo follow-up:** **G1**: 28 **G2:** 27 **Age, yrs ± SD:** **G1:** 48 (31 – 65) **G2:** 49 (24 – 65) **Race/ethnicity, mean ± SD: Black:** NR **Women, N (%):** **G1:** 42 (100) **G2:** 39 (100) **Postmenopausal n (%):** **G1:** 16 (38) **G2:** 20 (51)	**Inclusion criteria:** • Socially embarrassing (severe) urinary urge incontinence • On cystometry: detrusor instability, or LCB, or sensory bladder **Exclusion criteria:** • Stable bladder at cystometry • Neurologic disease • Detrusor hyperreflexia • Age greater than 65 y • Coexisting genuine SUI • Genital prolapse • Postvoid residual volume >50mL • Previous gynecologic or urogynecologic surgery • Prior use of any drug to treat UUI • Urethral diverticula • Fistulas • Urinary tract neoplasia • Cystitis • Bladder stones • Previous pelvic radiotherapy	**Detrusor instability, n (%):** **G1:** 14 (37) **G2:** 13 (35) **Low compliance bladder, n (%):** **G1:** 9 (24) **G2:** 8 (22) **Sensory bladder, n (%):** **G1:** 15 (39) **G2:** 16 (43) **Daily UUI episodes, range 9 – 17** **Diurnal frequency, n (%):** **G1:** 32 (84) **G2:** 29 (78) **Nocturia, n (%):** **G1:** 11 (29) **G2:** 18 (49) **Volume at first desire (mL):** **G1:** 120 ± 59 **G2:** 134 ± 61 **Volume at very strong desire (mL):** **G1:** 317 ± 92 **G2:** 332 ± 87	**Clinically cured overall, n (%):** **G1:** 28 (74) **G2:** 27 (73) **Cured among DI, (%):** **G1:** 13 (93) **G2:** 8 (62) P=0.07 **Cured among LCB:** **G1:** 6 (67) **G2:** 6 (75) P=0.56 **Cured among sensory bladder:** **G1:** 9 (60) **G2:** 13 (81) P=0.18 **Cured among 18 G1 patients requiring dosage halving:** 12 (67%) **Diurnal frequency resolved, n (%):** **G1:** 18 (56) **G2:** 20 (69) **Nocturia resolved n (%):** **G1:** 3 (27) **G2:** 11 (61) **Volume at first desire (mL), mean ± SD:** **G1:** 179 ± 32 P=.0009 **G2:** 178 ± 49 P=.001 **Volume at very strong desire (mL) mean ± SD:** **G1:** 408 ± 76 P=.00001 **G2:** 403 ± 69 P=.0002	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to followup: ++ Drop-out rates: + Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: - Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Colombo et al. 1995 (continued)				**Patients still cured at 6 mos, n:** **G1:** 16 **G2:** 26 **Patients still cured at 6 mos among DI, n:** **G1:** 8 **G2:** 8 **Patients still cured at 6 mos among LCB, n:** **G1:** 4 **G2:** 6 **Patients still cured at 6 mos among sensory bladder, n:** **G1:** 4 **G2:** 12 **Treatment discontinued in 6 cases:** **G1:** 4 (3 cases of severe dry mouth, 1 case of previously unknown glaucoma) **G2:** 2 (treatment was time consuming) **Other adverse effects** **G1:** 18 (47%) with AE requiring halving of dosage: -dry mouth (n=15) -constipation (n=6) -nausea (n=5) -dizziness (n=2) - decrease in visual acuity (n=1) - tachycardia (n=1)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Diokno et al. 1995 **Country and setting:** US; private clinic **Enrollment period:** January 1992 to December 1992 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cohorts with comparison; (Series of patients self selected into two groups) **Intervention:** Bladder training vs. anticholinergic or antispasmodic **Groups:** **G1:** Bladder training **G2:** oxybutynin 2.5-5.0 mg bid or t.i.d. **N at enrollment:** **G1**: 39 **G2:** 33 **N at follow-up:** **G1**: 26 **G2:** 28 **Age, mean yrs (range):** 64 (20-93) **Race/ethnicity:** NR **Women, N (%): 72 (100)** **Parity mean ± SD:** NR	**Inclusion criteria:** • Incontinent by AHCPR guidelines* • Incontinence persisted after treatment for transient incontinence **Exclusion criteria:** • Post-void residual of more than 150 mL	**UUI, n (%):** **G1:** 27 (49) **G2:** 28 (51) **MUI with predominant urge, n (%):** **G1:** 12 (71) **G2:** 5 (29)	**Continent, n (%):** **G1:** 1 (4) **G2:** 1 (4) **Improved, n (%):** **G1:** 22 (85) **G2:** 19 (68) **No Change, n (%):** **G1:** 3 (11) **G2:** 8 (28)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: - Loss to followup: - Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: poor Age: -, NR Baseline OAB status: NR Baseline characteristics: - Length of followup: ++ Measurement methods: - Measurement reliability: - Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Diokno et al., 2003* Chu et al., 2005† **Country and setting:** US, Academic medical center **Enrollment period:** November 2000 to October 2001 **Funding:** ALZA Corporation, Ortho-McNeil Pharmaceuticals **Author industry relationship disclosures:** 5 of 7* ALZA (1) Indevus (1) Ortho-McNeil (4) Pharmacia (1) Watson (1) NR†	**Design:** RCT **Intervention:** Oxybutynin ER vs. Tolterodine ER 12 week treatment period **Groups:** **G1:** Oxybutynin ER 10 mg daily **G2:** Tolterodine ER 4mg daily **N at enrollment:** **G1:** 391 **G2:** 399 **N at follow-up:** **G1**: 339 **G2:** 357 **Age, mean (range) :** **G1:** 60 (23-92) **G2:** 60 (18-85) **Race/ethnicity, N (%):** **White:** **G1:** 329 (84) **G2:** 342 (86) **Black:** **G1:** 32 (8) **G2:** 35 (9) **Hispanic:** **G1:** 27 (7) **G2:** 19 (5) **Other:** **G1:** 3 (1) **G2:** 3 (1) **Women, N (%):** **G1:** 391 (100) **G2:** 399 (100)	**Inclusion criteria:** • Age ≥ 18 • ≥ 21 episodes UUI/ week • ≥ 10 voids/ day • Urge > non-urge incontinence **Exclusion criteria:** • Treatable GU conditions causing incontinence • PVR > 150 mL by ultrasound x 2 • Risk of developing complete urinary retention • Medical problems worsened by anticholinergic effects • Hematuria • Uncontrolled narrow angle glaucoma • Obstructive uropathy • Reduced GI motility • Hypersensitivity to medications	**UUI episodes/ wk, mean ± SD:** **G1:** 37.2 ± 15.2 **G2:** 36.9 ± 14.1 **Total incontinence episodes/wk, mean ± SD:** **G1:** 43.3 ± 19.3 **G2:** 42.6 ± 18.2 **Voids/wk, mean ± SD:** **G1:** 94.8 ± 25.4 **G2:** 96.2 ± 24.5	**UUI episodes/wk, mean:** **G1:** 10.8 **G2:** 11.2 P = 0.28 **Incontinence episodes/wk, mean:** **G1:** 12.3 **G2:** 13.8 P = 0.08 **Voids/wk, mean:** **G1:** 66.4 **G2:** 71.1 P = 0.03 **UUI episodes/wk, % reduction ± SD:** **G1:** 72.0 ± 34.0 **G2:** 70.2 ± 33.2 P = 0.13 **Incontinent episodes/wk, % reduction ± SD:** **G1:** 72.8 ± 31.0 **G2:** 69.1 ± 34.9 P = 0.08 **Voids/wk, % reduction ± SD:** **G1:** 27.7 ± 19.7 **G2:** 24.9 ± 18.9 P = 0.05 **Total dryness, %:** **G1:** 23 **G2:** 16.8 P = 0.03 **No UUI episodes, %:** **G1:** 26.7 **G2:** 20.9 P = 0.06 **Dry mouth, any degree, n (%):** **G1:** 116 (29.7) **G2:** 89 (22.3) P = 0.02 **Dry Mouth, mild, n (%):** **G1:** 87 (22.3) **G2:** 69 (17.3)	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: - Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Diokno et al., 2003* Chu et al., 2005† (continued)				**Dry mouth, moderate-severe, n (%):** **G1:** 29 (7.4) **G2:** 20 (5.0) **Constipation, n (%):** **G1:** 25 (6.4) **G2:** 31 (7.8) **Diarrhea, n (%):** **G1:** 31 (7.9) **G2:** 25 (6.3) **Headache, n (%):** **G1:** 22 (5.6) **G2:** 24 (6.0) **UTI, n (%):** **G1:** 20 (5.1) **G2:** 13 (3.3) **CNS AE, n (%):†** **G1:** 35 (9.0) **G2:** 33 (8.3) **Dizziness, n (%):†** **G1:** 15 (3.8) **G2:** 10 (2.5) **Dizziness, mild,** %:†** **G1:** 1.8 **G2:** 1.5 **Dizziness, moderate,** %:†** **G1:** 0.8 **G2:** 0.3 **Somnolence, n (%):†** **G1:** 4 (1.0) **G2:** 9 (2.3) **Somnolence, mild,** %:†** **G1:** 0.5 **G2:** 1.5 **Somnolence, moderate,** %:†** **G1:** 0.3 **G2:** 0.5 **Insomnia, n (%):†** **G1:** 7 (1.8) **G2:** 3 (0.8)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Diokno et al., 2003* Chu et al., 2005† (continued)				**Insomnia, mild** %:†** **G1:** 0.8 **G2:** 0 **Insomnia, moderate,** %:†** **G1:** 0.5 **G2:** 0 **Depression, n (%):†** **G1:** 5 (1.3) **G2:** 3 (0.8) **Hypertonia, n (%):†** **G1:** 2 (0.5) **G2:** 4 (1.0) **Hypertonia, mild,** %:†** **G1:** 0 **G2:** 0 **Hypertonia, moderate,** %:†** **G1:** 0.3 **G2:** 0 **Anxiety, mild,** %:†** **G1:** 0.5 **G2:** 0 **Anxiety, moderate,** %:†** **G1:** 0.3 **G2:** 0 **Nervousness, mild,** %:†** **G1:** 0 **G2:** 0 **Nervousness, moderate,** %:†** **G1:** 0.3 **G2:** 0 **Tremor, mild,** %:†** **G1:** 0.3 **G2:** 0.3 **Tremor, moderate,** %:†** **G1:** 0 **G2:** 0	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Diokno et al., 2003* Chu et al., 2005† (continued)				**Confusion, mild,** %:†** **G1:** 0.3 **G2:** 0.3 **Confusion, moderate,** %:†** **G1:** 0 **G2:** 0	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Giannitsas et al., 2004 **Country and setting:** Greece, Specialty treatment center **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Randomized for which drug to receive first two-way crossover, table of random numbers **Intervention:** Oxybutynin 15 mg t.i.d. vs. Tolterodine 4mg bid; 6 weeks treatment with 3-4 weeks washout **Groups:** **G1:** Oxybutynin 15 mg t.id. **G2:** Tolterodine 4mg bid **Stratified by UDS findings:** **a:** high volume (> 250mL); low pressure (< 25cmH_2O) **b:** high volume (≥ 250mL); high pressure (> 25cmH_2O) **C**: low volume (< 250mL); low pressure (< 25cmH_2O) **d**: low volume (< 250mL); high pressure (> 25cmH_2O) **N at enrollment:** Total: 128 **N at follow-up:** Total: 107 **Ga**: 6 **Gb:** 25 **Gc:** 36 **Gd:** 40 **Women, %:** 100	**Inclusion criteria:** • Age ≥ 18 • DO on urodynamics **Exclusion criteria:** • Symptomatic or recurrent UTI • BOO • Neurologic disease • History of previous pelvic surgery • Narrow angle glaucoma • SUI • History of anticholinergic side effects • Interstitial cystitis • Child-bearing age without BC	**Voids/day, mean ± SD:** Total: 8.5 ± 2.63 **Ga:** 7.2 ± NR **Gb:** 8.0 ± 2.40 **Gc:** 8.3 ± 2.31 **Gd:** 9.3 ± 2.91 **Volume (mL)/day, mean ± SD:** Total: 1568.5 ± 398.64 **Ga:** 1756 ± NR **Gb:** 1594.6 ± 326.12 **Gc:** 1678.8 ± 402.15 **Gd:** 1420.5 ± 384.96 **Voided volume (mL), mean ± SD:** Total: 196.1 ± 60.19 **Ga:** 253 ± NR **Gb:** 213.5 ± 53.57 **Gc:** 209.8 ± 57.43 **Gd:** 163.4 ± 51.97 **Bladder volume (mL), first desire void, mean ± SD:** Total: 105.6 ± 39.38 **Ga:** 109 ± NR **Gb:** 128.0 ± 41.78 **Gc:** 94.3± 35.40 **Gd:** 101.1 ± 38.14 **Bladder volume (mL), first contraction, mean ± SD:** Total: 172 ± 98.4 **Ga:** 258 ± NR **Gb:** 303.3 ± 60.51 **Gc:** 111.9 ± 48.11 **Gd:** 124.4 ± 56.66	**Voids/day, mean ± SD:** **G1:** 7.7 ± 1.87 **G2:** 7.6 ± 2.18 **G1a:** 6.1 ± NR **G2a:** 6.3 ± NR **G1b:** 7.3 ± 1.69 **G2b:** 7.0 ± 1.87 **G1c:** 7.5 ± 1.41 **G2c:** 7.2 ± 1.58 **G1d:** 8.3 ± 2.23 **G2d:** 8.4 ± 2.53 **Volume (mL)/day, mean ± SD:** **G1:** 1764.4 ± 333.03 **G2:** 1670.7 ± 338.6 **G1a:** 1862 ± NR **G2a:** 1720 ± NR **G1b:** 1715.6 ± 292.54 **G2b:** 1665.8 ± 251.19 **G1c:** 1847.9 ± 333.81 **G2c:** 1808.1 ± 317.59 **G1d:** 1694.7 ± 331.33 **G2d:** 1550.3 ± 373.65 **Voided volume (mL), mean ± SD:** **G1:** 239.9 ± 64.98 **G2:** 236.7 ± 63.03 **G1a:** 321 ± NR **G2a:** 286 ± NR **G1b:** 243.3 ± 59.56 **G2b:** 248.3 ± 53.91 **G1c:** 252.9 ± 55.75 **G2c:** 258.6 ± 60.63 **G1d:** 217.6 ± 67.07 **G2d:** 203.1 ± 55.43	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: NA Pt selection criteria: + Loss to followup: ++ Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Giannitsas et al., 2004 (continued)	**Age, mean ± SD:** Total: 56 ±16.3 **Ga:** 53 ± 17.2 **Gb:** 57 ± 16.2 **Gc:** 57 ± 16.3 **Gd:** 54 ± 16.6 **Weight (kg), mean ± SD:** Total: 63 ± 5.6 **Ga:** 63 ± 5.6 **Gb:** 70 ± 9.1 **Gc:** 67 ± 8.8 **Gd:** 69 ± 7.5		**Pressure (cmH_20), first contraction, mean ± SD:** Total: 34.8 ± 21.97 **Ga:** 17.4 ± NR **Gb:** 37.7 ± 14.03 **Gc:** 18.5 ± 4.60 **Gd:** 50.3 ± 25.14 **Overactivity index, mean ± SD:** Total: 36.8 ± 31.36 **Ga:** 15.3 ± NR **Gb:** 24.8 ± 19.66 **Gc:** 26.3 ± 16.14 **Gd:** 57.0 ± 38.85 **Cystometric capacity (mL), mean ± SD:** Total: 362.8 ± 119.10 **Ga:** 403 ± NR **Gb:** 410.0 ± 97.78 **Gc:** 357.6 ± 127.52 **Gd:** 331.4 ± 114.17	**Bladder volume (mL), first desire void, mean ± SD:** **G1:** 129.0 ± 30.14 **G2:** 117.9 ± 27.62 **G1a:** 144 ± NR **G2a:** 140 ± NR **G1b:** 153.5 ± 25.72 **G2b:** 132.0 ± 31.01 **G1c:** 120.8 ± 25.07 **G2c:** 113.2 ± 23.16 **G1d:** 119.4 ± 29.43 **G2d:** 110.1 ± 26.15 **G1/BL:** P < 0.05 **G2/BL:** P < 0.05 **Bladder volume (mL), first contraction, mean ± SD:** **G1:** 212.9 ± 106.10 **G2:** 206.9 ± 103.56 **G1a:** 382 ± NR **G2a:** 364 ± NR **G1b:** 355.28 ± 74.79 **G1c:** 142.4 ± 43.51 **G2c:** 144.6 ± 48.43 **G1d:** 173.3 ± 57.37 **G2d:** 162.7 ± 53.87 **G1d/BL:** P < 0.01 **G2d/BL:** P < 0.01	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Giannitsas et al., 2004 (continued)				**Pressure (cmH_20), first contraction, mean ± SD:** **G1:** 30.9 ± 22.63 **G2:** 30.9 ± 19.01 **G1a:** 14.0 ± NR **G2a:** 17.4 ± NR **G1b:** 35.6 ± 12.86 **G2b:** 29.6 ± 13.56 **G1c:** 17.2 ± 6.80 **G2c:** 17.9 ± 6.69 **G1d:** 42.9 ± 28.91 **G2d:** 44.1 ± 20.75 **Overactivity index, mean ± SD:** **G1:** 24.4 ± 22.61 **G2:** 24.7 ± 23.46 **G1a:** 7.0 ± NR **G2a:** 9.5 ± NR **G1b:** 14.1 ± 12.09 **G2b:** 14.1 ± 12.71 **G1c:** 18.3 ± 15.89 **G2c:** 16.9 ± 16.84 **G1d:** 38.9 ± 26.50 **G2d:** 40.7 ± 26.58 **Cystometric capacity (mL), mean ± SD:** **G1:** 419.3 ± 120.86 **G2:** 415.63 ± 114.06 **G1a:** 465 ± NR **G2a:** 453 ± NR **G1b:** 449.6 ± 106.23 **G2b:** 459.4 ± 101.17 **G1c:** 409.9 ± 130.22 **G2c:** 411.05 ± 132.49 **G1d:** 401.8 ± 118.34 **G2d:** 386.7 ± 96.53 **Dry mouth, n (%):** **G1:** 52 (40.6) **G2:** 20 (15.6)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Giannitsas et al., 2004 (continued)				**Constipation, n (%):** **G1:** 11 (10.3) **G2:** 3 (2.8) **Discontinued due to AEs, n:** Dry mouth: 12 Palpitations: 1	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Goode et al., 2002 **Country and setting:** US; academic health center outpatient geriatric medicine clinic **Enrollment period:** July 1989 to August 1995 **Funding:** National Institutes on Aging **Author industry relationship disclosures:** NR	**Design:** RCT, placebo controlled Computer-generated random numbers using a block size of 6, w/ prior stratification by type and severity of incontinence **Intervention:** Biofeedback-assisted behavioral vs. drug treatment (oxybutynin chloride; possible range of doses 2.5 mg/d-5.0 mg t.i.d.) vs. placebo All patients had 4 visits over an 8-week period. Patients in G1 had biofeedback added to behavioral training in absence of 50% improvement by session 3. **Groups:** **G1:** Behavioral ± biofeedback **G2:** Pharmacologic **G3:** Placebo **N at enrollment:** 468 screened 271 not eligible 197 randomized 105 had pre and post treatment urodynamics **G1**: 33 **G2:** 35 **G3:** 37	**Inclusion criteria:** • Community-dwelling women at least age 55 • Ambulatory • At least 2 urge accidents per week by baseline bladder diary • Urge incontinence as predominant pattern • Urodynamic evidence of bladder dysfunction **Exclusion criteria:** • Continual leakage • Postvoid residual urine volume >200mL • Uterine prolapse past the introitus • Narrow-angle glaucoma • Unstable angina • Decompensated congestive heart failure • Hx of malignant arrhythmias • MMSE <20 (Dementia)	**Voids per day, mean n ± SD:** **G1:** 10.0 **G2:** 10.9 **G3:** 10.0 **<u>Cystometry at baseline, mL</u>** First desire to void **G1:** 97.1 ± 50.7 **G2:** 101.1 ± 62.1 G3: 124.6 ± 73.7 Strong desire to void **G1:** 188.5 ± 93.1 **G2:** 212.1 ± 86.7 **G3:** 222.3 ± 87.0 Bladder capacity **G1:** 288.3 ± 117.0 **G2:** 308.7 ± 93.7 **G3:** 328.9 ± 107.6	**Voids per day, mean n ± SD:** **G1:** 8.2 **G2:** 8.8 **G3:** 9.7 **DI on UDS, n (%)** +Baseline DI/+DI post-treatment **G1:** 7 (21.2) **G2:** 1 (2.9) **G3:** 5 (13.5) **DI on UDS, n (%)** +Baseline DI/-DI post-treatment **G1:** 1 (3.0) **G2:** 7 (20.0) **G3:** 7 (18.9) **DI on UDS, n (%)** -Baseline DI/+DI post-treatment **G1:** 3 (9.1) **G2:** 3 (8.6) **G3:** 3 (8.1) **DI on UDS, n (%)** -Baseline DI/-DI post-treatment **G1:** 22 (66.7) **G2:** 24 (68.6) **G3:** 22 (59.5) **Cystometry post-treatment, mL** First desire to void **G1:** 115.9 ± 64.9 **G2:** 145.6 ± 74.0 **G3:** 133.5 ± 59.6 Strong desire to void **G1:** 228.9 ± 106.4 **G2:** 282.0 ± 93.2 **G3:** 230.1 ± 78.8 Bladder capacity **G1:** 305.6 ± 117.9 **G2:** 377.6 ± 92.1 **G3:** 323.0 ± 109.0	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Goode et al., 2002 (continued)	**Age, yrs ± SD:** **G1:** 65.3 ± 4.5 **G2:** 67.9 ± 7.9 **G3:** 67.6 ± 7.7 **Race/ethnicity, %:** Black: 2 White: 98 **Women: 100%** **Parity mean ± SD:** **G1:** 3.1 ± 1.7 **G2:** 2.1 ± 1.3 **G3:** 2.3 ± 1.5			**Cystometry, change in mean volume by group** First desire to void **G1:** 18.8 **G2:** 44.4 **G3:** 8.9 P= 0.149 Strong desire to void **G1:** 40.5 **G2:** 69.9 **G3:** 7.8 P= 0.018 Bladder capacity **G1:** 17.3 **G2:** 68.9 **G3:** -6.0 P= 0.000 <u>Standardized Estimates of Direct and Mediated Effects of Treatment</u> G1 v G3 Total effect: 0.28* Direct effect: 0.23 Mediated Effect: 0.05 G2vG3 Total Effect: 0.34* Direct Effect: 0.30* Mediated Effect: 0.04 *P<0.01	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Halaska et al., 2003 **Country and setting:** Europe and Asia, Academic medical center **Enrollment period:** May 1996 to May 1999 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Randomized controlled double blind crossover **Intervention:** Trospium vs. Oxybutynin **Groups:** **G1:** Trospium 20 mg bid **G2:** Oxybutynin 5mg bid **N at enrollment:** **G1:** 268 **G2:** 90 **N at follow-up:** **G1:** 200 **G2:** 66 **Women, n (%):** **G1:** 228 (85) **G2:** 78 (87) **Age, mean (range):** **G1:** 54.2 (19, 89) **G2:** 52.2 (19, 85) **Weight (kg), mean (range):** **G1:** 72.3 (50-120) **G2:** 70.4 (50-90) **Height (cm), mean (range):** **G1:** 164.8 (144-185) **G2:** 165.5 (145-183) **Smokers, n (%):** **G1:** 38 (14) **G2:** 10 (11) **Previous illness, n (%):** **G1:** 184 (69) **G2:** 66 (73) **Previous medication, n (%):** **G1:** 101 (38) **G2:** 46 (51)	**Inclusion criteria:** • Age ≥ 18 yrs • Urge syndrome • Urge incontinence • UUI as one component of MUI • UUI due to neurologic condition (detrusor hyperreflexia) **Exclusion criteria:** • Absolute tachycardia • Closed angle glaucoma • Myasthenia gravis • Arteriosclerosis of cerebral vessels • SUI • Heart or renal failure • Frequency from diuretics • BOO • Acute UTI • Hiatus hernia with reflux esophagitis • Stenosis of GI tract • Megacolon • Colonic ulceration • Allergy to study medications • Anticholinergics, TCAs, alpha blockers, beta sympatho-mimetics ≤ 7 days • Urological or gynecologic surgery ≤ 3 mos • Pregnant or lactating • In another study	**Urgency episodes/day, mean:** **G1:** 10.2 **G2:** 11.0 **Incontinence episodes/ day, mean:** **G1:** 1.5 **G2:** 2.1 **Voids/day, mean:** **G1:** 11.4 **G2:** 12.5 **Max cystometric capacity (mL), mean:** **G1:** 205 **G2:** 205	**Urgency episodes/day, mean:** **G1:** 6.7 **G2:** 7.4 **Incontinence episodes/ day, mean:** **G1:** 0.5 **G2:** 1.1 **Voids/day, mean:** **G1:** 7.9 **G2:** 8.3 **Max cystometric capacity (mL), 26 wks, mean change:** **G1:** 92.0 **G2:** 117.0 **G1/BL:** P ≤ 0.001 **G2/BL:** P ≤ 0.001 **Max cystometric capacity (mL), 52 wks, mean change:** **G1:** 115.0 **G2:** 119.4 **G1/BL:** P ≤ 0.001 **G2/BL:** P ≤ 0.001 **Bladder volume (mL), first contraction, 26 wks, mean change:** **G1:** 63.5 **G2:** 61.2 **Bladder volume (mL), first contraction, 52 wks, mean change:** **G1:** 46.1 **G2:** 36.7 **Bladder volume (mL), first sensation, 26 wks, mean change:** **G1:** 73.6 **G2:** 76.93	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Halaska et al., 2003 (continued)				**Bladder volume (mL), first sensation, 26 wks, mean change:** **G1:** 78.6 **G2:** 70.2 **Abnormal EKG, n (%):** **G1:** 4 (0.1) **G2:** 2 (0.2) **Any adverse event, n (%):** **G1:** 10 (3.7) **G2:** 6 (6.7) **Poor efficacy, n (%):** **G1:** 8 (3) **G2:** 2 (2.2) **Poor compliance, n (%):** **G1:** 15 (15.6) **G2:** 6 (6.7) **Abdominal pain, n (%):** **G1:** 5 (2) **G2:** 0 (0) **Constipation, n (%):** **G1:** 18 (7) **G2:** 4 (4) **Diarrhea, n (%):** **G1:** 2 (1) **G2:** 2 (2) **Dyspepsia, n (%):** **G1:** 13 (5) **G2:** 3 (3) **Dysphagia, n (%):** **G1:** 9 (3) **G2:** 3 (3) **Dry mouth, n (%):** **G1:** 87 (33) **G2:** 45 (50) P < 0.001 **Nausea, n (%):** **G1:** 6 (2) **G2:** 2 (2)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Halaska et al., 2003 (continued)				**UTI, n (%):** **G1:** 33 (12) **G2:** 10 (11) **Headache, n (%):** **G1:** 11 (4) **G2:** 8 (9) **Visual disturbances, n (%):** **G1:** 9 (3) **G2:** 5 (6) **Virus infection, n (%):** **G1:** 9 (3) **G2:** 4 (4) **Abnormal EKG, n (%):** **G1:** 4 (0.1) **G2:** 2 (0.2) **Sleeplessness, n (%):** **G1:** 10 (4) **G2:** 2 (2)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Herschorn et al., 2004 **Country and setting:** Canada; Family medicine and urology clinics **Enrollment period:** June 2000 to December 2001 **Funding:** Pharmacia Pfizer Canada **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Health education with tolterodine vs. tolterodine alone **Groups:** **G1:** Health education with tolterodine **G2:** tolterodine alone **N at enrollment:** **G1**: 39 **G2:** 45 **N at follow-up, 5 weeks:** **G1**: 37 **G2:** 40 **N at follow-up, 10 weeks:** **G1**: 35 **G2:** 32 **N at follow-up, 16 weeks:** **G1**: 34 **G2:** 31 **Age, yrs ± SD:** **G1:** 65.7 ± 14.5 **G2:** 63.1 ± 15.7 **Race/ethnicity:** NR **Women, %:** **G1:** 92.3 **G2:** 84.4 **Parity:** NR	**Inclusion criteria:** • Age ≥ 50 • Symptoms of OAB^ • Attend investigators' practice • Normal cognitive function • Able to read English **Exclusion criteria:** • Enrollment in another clinical trial • Interstitial cystitis • UTI • Already taking tolterodine	**Duration of OAB, yrs ± SD:** **G1:** 8.7 ± 11.0 **G2:** 8.7 ± 10.8 **Mild bladder problems, n (%):** **G1:** 13 (33.3) **G2:** 13 (28.9) **Moderate bladder problems, n (%):** **G1:** 19 (48.7) **G2:** 28 (62.2) **Severe bladder problems, n (%):** **G1:** 7 (18.0) **G2:** 4 (8.9) **Obtained prescription, n (%):** **G1:** 38 (97.4) **G2:** 37 (82.2) P < 0.05 **Intends to fill prescription, (%):** **G1:** 0 (0) **G2:** 6 (7.5)	**Change in incontinence episodes/wk, mean ± SD:** **G1:** -7.72 ± 21.16 **G2:** -10.24 ± 19.56† **Change in voids/d, mean ± SD:** **G1:** -1.82 ± 3.41 **G2:** -2.18 ± 4.89 P = NR **Change in nocturnal voids, mean ± SD:** **G1:** -0.44 ± 1.13† **G2:** -0.07 ± 0.91 **No change in bladder problem severity, n (%):** **G1:** 14 (42.4) **G2:** 20 (66.7) **Improved bladder problem severity, n (%):** **G1:** 15 (45.4)† **G2:** 6 (20) **Worsened bladder problem severity, n (%):** **G1:** 4 (12.1) **G2:** 4 (13.3) **Compliance, 10 weeks, %:** **G1:** 41 **G2:** 38 P > 0.05 **Compliance, 16 weeks, %:** **G1:** 39 **G2:** 31 P > 0.05 **Continued or started non-drug OAB treatment, 16 weeks, %:** **G1:** 82 **G2:** 53 P > 0.05	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: + Loss to followup: - Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: NR Baseline characteristics: - Length of followup: ++ Measurement methods: + Measurement reliability: - Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Herschorn et al., 2004 (continued)				**Stopped non-drug OAB treatments, %:** **G1:** 12.8 **G2:** 28.9	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Jarvis et al., 1981 **Country and setting:** UK, Academic medical center **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Inpatient bladder drill vs. outpatient drug therapy **Groups:** **G1:** inpatient bladder drill **G2:** flavoxate hydrochloride 200 mg tds and imipramine 25 mg tds x 4 wks **N at enrollment:** **G1:** 25 **G2:** 25 **N at follow-up:** **G1:** 25 **G2:** 25 **Women, %:** 100 **Age, mean ± SD (range):** **G1:** 47 ± 15.4 (17-78) **G2:** 46 ± 12.8 (17-65)	**Inclusion criteria:** • Women • UDS-diagnosed detrusor instability **Exclusion criteria:** • DM • Neurological abnormalities • UTIs • Taking a drug suspected of affecting lower urinary tract function • Genuine stress incontinence	**UUI, n:** **G1:** 25 **G2:** 25 **SUI, n:** **G1:** 19 **G2:** 17 **Urgency, n:** **G1:** 25 **G2:** 25 **Frequency, n:** **G1:** 25 **G2:** 25 **Nocturia, n:** **G1:** 21 **G2:** 19 **Duration of symptoms (years), mean ± SD (range):** **G1:** 4.3 ± 2.7 (1-15) **G2:** 5.4 ± 3.2 (1-20) **Bladder volume (mL), first sensation, mean:** **G1:** 87 **G2:** 79 **Max cystometric capacity (mL), mean:** **G1:** 381 **G2:** 353	**UUI, n:** **G1:** 4 **G2:** 11 **SUI, n:** **G1:** 1 **G2:** 9 **Urgency, n:** **G1:** 4 **G2:** 11 **Frequency, n:** **G1:** 6 **G2:** 12 **Nocturia, n:** **G1:** 4 **G2:** 13 **Continent, n (%):** **G1:** 21 (84) **G2:** 14 (56) *P* < 0.05 **Symptom-free, n (%):** **G1:** 19 (76) **G2:** 12 (48) *P* < 0.05 **Bladder volume (mL), first sensation, mean:** **G1:** 152 **G2:** 140 **Max cystometric capacity (mL), mean:** **G1:** 470 **G2:** 446 **Adverse events, drug therapy, n:*** Dizziness: 8 Headache: 6 Dry mouth: 6 Nausea: 4 Drowsiness: 2 Vomiting: 1 **Discontinued due to AEs, n:** Dizziness: 1 Headache: 1 Vomiting: 1	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: + Loss to follow up: ++ Drop-out rates: - Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of follow up: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Lauti et al., 2008 **Country and setting:** New Zealand, Academic **Enrollment period:** February 2003 to July 2003 **Funding:** University of Otago **Author industry relationship disclosures:** None	**Design:** RCT pilot study, unmasked **Intervention:** Oxybutynin vs. bladder retraining vs. combination therapy **Groups:** **G1:** Oxybutynin 2.5 mg/day (daily dose could be increased by 2.5 mg every 5 days to a maximum of 15 mg/day) **G2:** Bladder retraining **G3:** Combination therapy **N screened:** 120 **N at enrollment:** **G1**: 21 **G2:** 16 **G3:** 19 **N at 3 month follow-up:** **G1**: 18 **G2:** 16 **G3:** 12 **N at 12 month follow-up:** **G1**: 16 **G2:** 14 **G3:** 12 **Age, mean ± SD:** **G1:** 53.8 ± 14.8 **G2:** 63.9 ± 17.2 **G3:** 47.6 ± 16.3 **Race/ethnicity:** NR **Women, %:** Total: 100 **Parous, %:** **G1:** 81 **G2:** 62.5 **G3:** 73.7	**Inclusion criteria:** • Age > 18 • Predominant UUI **Exclusion criteria:** • Predominant SUI • Contraindications to anticholinergic drugs • Current UTI • Neurological disease • Psychiatric disorder • Untreated co-existing pelvic organ prolapse below the hymenal ring • Obstructed voiding • Functional-reversible cause of incontinence • Inability to toilet independently • Limited fluency of written/spoken English • Current or recent use of any of the trial interventions	**Urgency episodes/day, mean ± SD:** **G1:** 3.8 ± 2.7 **G2:** 3.1 ± 2.2 **G3:** 3.5 ± 2.0 **Incontinence episodes/day, mean ± SD:** **G1:** 2.2 ± 1.5 **G2:** 1.0 ± 1.1 **G3:** 1.8 ± 1.6 **Nocturia episodes/day, mean ± SD:** **G1:** 1.1 ± 1.0 **G2:** 1.4 ± 1.0 **G3:** 0.8 ± 0.7 **Voids per day, mean ± SD:** **G1:** 7.8 ± 2.8 **G2:** 8.0 ± 1.7 **G3:** 8.4 ± 2.5 **OAB-q total HRQL, mean ± SD:** **G1:** 73.1 ± 17.4 **G2:** 69.5 ± 24.6 **G3:** 71.6 ± 21.5 **OAB-q severity, mean ± SD:** **G1:** 47.0 ± 16.2 **G2:** 42.3 ± 17.7 **G3:** 45.9 ± 18.7 **OAB-q coping, mean ± SD:** **G1:** 72.0 ± 21.6 **G2:** 66.2 ± 31.7 **G3:** 73.8 ± 26.2 **OAB-q concern, mean ± SD:** **G1:** 68.2 ± 19.0 **G2:** 68.8 ± 27.6 **G3:** 63.8 ± 29.2 **OAB-q sleep, mean ± SD:** **G1:** 63.1 ± 28.7 **G2:** 59.8 ± 29.9 **G3:** 55.1 ± 27.6	**Urgency episodes/day, 3 mos, mean ± SD:** **G1:** 2.2 ± 1.8 **G2:** 1.5 ± 2.1 **G3:** 1.7 ± 1.8 **Urgency episodes/day, 12 mos, mean ± SD:** **G1:** 2.3 ± 2.5 **G2:** 1.9 ± 2.1 **G3:** 2.0 ± 1.1 **Incontinence episodes/day, 3 mos, mean ± SD:** **G1:** 0.8 ± 0.8 **G2:** 0.1 ± 0.3 **G3:** 0.6 ± 0.8 **Incontinence episodes/day, 12 mos, mean ± SD:** **G1:** 0.9 ± 0.0 **G2:** 0.9 ± 1.0 **G3:** 0.8 ± 0.7 **Nocturia episodes/day, 3 mos, mean ± SD:** **G1:** 1.0 ± 0.5 **G2:** 0.8 ± 0.7 **G3:** 0.6 ± 0.5 **Nocturia episodes/day, 12 mos, mean ± SD:** **G1:** 1.0 ± 0.9 **G2:** 1.2 ± 0.6 **G3:** 0.7 ± 0.7 **Voids/day, 3 mos, mean ± SD:** **G1:** 6.7 ± 1.8 **G2:** 6.3 ± 1.6 **G3:** 6.7 ± 2.2 **Voids/day, 12 mos, mean ± SD:** **G1:** 7.2 ± 1.1 **G2:** 6.8 ± 1.4 **G3:** 7.6 ± 1.5	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Method and blinding: - Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Lauti et al., 2008 (continued)			**OAB-q social, mean ± SD:** **G1:** 92.5 ± 14.6 **G2:** 85.4 ± 19.9 **G3:** 92.8 ± 18.6 **SF-12 quality of life, physical, mean ± SD:** **G1:** 49.0 ± 9.6 **G2:** 41.7 ± 11.5 **G3:** 46.2 ± 10.6 **SF-12 quality of life, mental, mean ± SD:** **G1:** 49.1 ± 9.3 **G2:** 53.1 ± 8.8 **G3:** 46.3 ± 8.3	**OAB-q total HRQL, 3 mos, mean ± SD:** **G1:** 82.3 ± 16.1 **G2:** 89.6 ± 9.4 **G3:** 91.8 ± 7.4 **OAB-q total HRQL, 12 mos, mean ± SD:** **G1:** 87.9 ± 11.6 **G2:** 81.6 ± 19.3 **G3:** 88.9 ± 9.9 **OAB-q severity, 3 mos, mean ± SD:** **G1:** 37.2 ± 22.0 **G2:** 16.8 ± 12.0 **G3:** 21.6 ± 10.9 **OAB-q severity, 12 mos, mean ± SD:** **G1:** 24.6 ± 10.6 **G2:** 33.1 ± 16.6 **G3:** 21.9 ± 14.8 **OAB-q coping, 3 mos, mean ± SD:** **G1:** 79.2 ± 22.1 **G2:** 91.6 ± 9.5 **G3:** 92.7 ± 9.4 **OAB-q coping, 12 mos, mean ± SD:** **G1:** 89.2 ± 13.7 **G2:** 81.5 ± 23.7 **G3:** 90.5 ± 10.0 **OAB-q concern, 3 mos, mean ± SD:** **G1:** 78.6 ± 18.0 **G2:** 87.7 ± 14.5 **G3:** 90.2 ± 12.4 **OAB-q concern, 12 mos, mean ± SD:** **G1:** 85.3 ± 15.5 **G2:** 81.7 ± 19.7 **G3:** 85.2 ± 13.4 **OAB-q sleep, 3 mos mean ± SD:** **G1:** 77.7 ± 24.9 **G2:** 81.3 ± 14.6 **G3:** 85.0 ± 19.6	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Lauti et al., 2008 (continued)				**OAB-q sleep, 12 mos, mean ± SD:** **G1:** 79.9 ± 18.3 **G2:** 72.0 ± 24.5 **G3:** 83.2 ± 18.4 **OAB-q social, 3 mos, mean ± SD:** **G1:** 96.4 ± 9.7 **G2:** 95.6 ± 7.0 **G3:** 98.9 ± 1.9 **OAB-q social, 12 mos, mean ± SD:** **G1:** 97.3 ± 7.1 **G2:** 91.9 ± 14.2 **G3:** 97.3 ± 6.9 **SF-12 quality of life, physical** **G1:** 50.6 ± 8.0 **G2:** 42.1 ± 12.7 **G3:** 48.4 ± 10.8 **SF-12 quality of life, physical, 12 mos, mean ± SD:** **G1:** 50.0 ± 7.3 **G2:** 45.1 ± 13.9 **G3:** 45.3 ± 13.4 **SF-12 quality of life, mental, 3 mos, mean ± SD:** **G1:** 50.4 ± 9.6 **G2:** 51.2 ± 9.5 **G3:** 46.7 ± 7.6 **SF-12 quality of life, mental, 12 mos, mean ± SD:** **G1:** 49.6 ± 7.5 **G2:** 50.1 ± 10.7 **G3:** 50.6 ± 8.4 **Dry mouth, n (%):** **G1:** 3 (21) **G2:** 5 (46) **G3:** 5 (42) **Headaches, n (%):** **G1:** 6 (43) **G2:** 1 (11) **G3:** 7 (58) **Dizziness, n (%):** **G1:** 4 (29) **G2:** 2 (20) **G3:** 3 (25)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Lauti et al., 2008 (continued)				**Constipation, n (%):** **G1:** 3 (21) **G2:** 3 (27) **G3:** 3 (27) **Fatigue, n (%):** **G1:** 9 (64) **G2:** 5 (46) **G3:** 7 (64)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Lee et al., 2002 **Country and setting:** South Korea, University **Enrollment period:** NR **Funding:** Pharmacia Corp **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Tolterodine 2mg bid vs. Oxybutynin 5mg bid **Groups:** **G1:** Tolterodine 2mg bid **G2:** Oxybutynin 5mg bid **N at enrollment:** **G1**: 112 **G2:** 116 **N at follow-up:** **G1**: 97 **G2:** 90 **Women, n (%):** **G1:** 84 (74) **G2:** 92 (79) **Age, mean (range):** **G1:** 52 (27, 82) **G2:** 52 (20, 86) **Race/ethnicity (%):** **Asian:** **G1:** 100 **G2:** 100 **BMI, kg/m^2 (range):** **G1:** 23 (17, 32.5) **G2:** 23.5 (16, 38) **Previous drug therapy: N (%)** **G1:** 36 (32) **G2:** 26 (22)	**Inclusion criteria:** • Age ≥ 18 • OAB symptoms > 6 mos • ≥ 8 voids/day, with or without incontinence (measured by diary) **Exclusion criteria:** • SUI • Women not using reliable contraception • Pregnant or nursing • Prior treatment with anticholinergic < 2 wks • Renal or hepatic disease • Narrow angle glaucoma • Urinary retention • Gastric retention • Hypersensitivity to drugs • UTI • IC • Hematuria • BOO • Concomitant bladder training, e-stim treatment • Indwelling catheter • Intermittent catherization • Concomitant treatment for OAB ≤ 2 mos	**Incontinence episodes/day, mean (range):** **G1:** 2.6 (0.3, 9.3) **G2:** 2.4 (3.0, 14.7) **Patients with incontinence episodes, n (%):** **G1:** 46 (41) **G2:** 42 (36) **Voids/day, mean (range):** **G1:** 12.2 (8.0, 23.7) **G2:** 12.4 (7.7, 29.7)	**Incontinence episodes/day, mean change ± SD (% change):** **G1:** -2.2 ± 2.3 (-85) **G2:** -1.4 ± 1.8 (-58) **G1/BL:** *P* = 0.0001 **G1/BL:** *P* = 0.0001 **G1/G2:** *P* = 0.10 **Voids/ day, mean change ± SD (% change):** **G1:** -2.6 ± 2.9 (-21) **G2:** -1.8 ± 4.2 (-15) **G1/BL:** *P* = 0.0001 **G1/BL:** *P* = 0.0001 **G1/G2:** *P* = 0.14 **Benefit of Tx, %:** **G1:** 45 **G2:** 46 **G1/G2:** *P* = NS **Patients reporting adverse events, n (%):** **G1:** 62 (55) **G2:** 94 (82) **Discontinued due to AEs, n (%):** **G1:** 11 **G2:** 18 **Dry mouth, n (%):** **G1:** 39 (35) **G2:** 72 (63) **G1/G2:** *P* = 0.001 **Dry mouth, mild, n (%):** **G1:** 29 (26) **G2:** 40 (35) **Dry mouth, moderate, n (%):** **G1:** 9 (8) **G2:** 26 (23)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Lee et al., 2002 (continued)				**Dry mouth, severe, n (%):** **G1:** 1 (1) **G2:** 6 (5) **Voiding disorder, n (%):** **G1:** 10 (9) **G2:** 16 (14) **Dyspepsia, n (%):** **G1:** 8 (7) **G2:** 6 (5) **Abdominal pain, n (%):** **G1:** 6 (5) **G2:** 6 (5) **Headache, n (%):** **G1:** 4 (4) **G2:** 6 (5)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Macaulay et al., 1987 **Country and setting:** UK, Specialty treatment center **Enrollment period:** NR **Funding:** Wellcome Trust, trustees of St. George's Hospital **Author industry relationship disclosures:** NR	**Design:** RCT (randomization not specified) **Intervention:** Brief eclectic psychotherapy, bladder training or medication **Groups:** **G1:** psycho-therapy **G2:** bladder drill **G3:** propantheline **N at enrollment:** **G1:** 19 **G2:** 16 **G3:** 15 **N at follow-up:** **G1:** 18 **G2:** 15 **G3:** 14 **Women, %:** 100 **Age:** NR **Race/ethnicity:** NR **Follow-up:** 3 months	**Inclusion criteria:** • Previous completion of survey on psych conditions w/ OAB • Detrusor instability on UDS or sensory urgency **Exclusion criteria:** NR	**Detrusor instability, n:** **G1:** 10 **G2:** 8 **G3:** 8 **Sensory urgency, n:** **G1:** 9 **G2:** 8 **G3:** 7 **Voids/day, mean:** **G1:** NR **G2:** NR **G3:** 10.8 **Bladder capacity (mL), mean:** **G1:** 393 **G2:** NR **G3:** 323 **Bladder volume (mL), first sensation, mean:** **G1:** 107 **G2:** 110 **G3:** 70 **Detrusor pressure rise (cm H_2O), mean:** **G1:** NR **G2:** 45.5 **G3:** NR	**Voids/day, mean:** **G1:** NR **G2:** NR **G3:** 8.3 **G3/BL:** *P* < 0.005 **Bladder capacity (mL), mean:** **G1:** 414 **G2:** NR **G3:** 368 **G1/BL:** *P* = NS **G3/BL:** *P* = NS **Bladder volume (mL), first sensation, mean:** **G1:** 142 **G2:** 150 **G3:** 137 **G1/BL:** *P* = NS **G2/BL:** *P* < 0.05 **G3/BL:** *P* = 0.06 **Detrusor pressure rise (cm H_2O), mean:** **G1:** NR **G2:** 29.5 **G3:** NR **G2/BL:** *P* < 0.05	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: - Loss to followup: ++ Drop-out rates: ++ Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: -, NR Baseline OAB status: NR Baseline characteristics: - Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Mattiasson et al., 2003 **Country and setting:** Sweden, Denmark, Norway (Tolterodine Scandinavian Study Group) **Enrollment period:** October 1999 to December 2000 **Funding:** Pharmacia Corp **Author industry relationship disclosures:** NR	**Design:** RCT, single-blinded (balanced blocks of 4, computerized randomization list) **Intervention:** Pharmacologic ± behavioral therapy; Tolterodine 2mg b.i.d. ± BT; Tolterodine dosage could be decreased to 1mg P.O. b.i.d. during the first 2 wks if intolerable SE; BT taught with a written handout **Groups:** **G1:** Tolterodine + BT x 24 wks **G2:** Tolterodine x 24 wks **N at enrollment:** Total: 505 **N at follow-up:** **G1:** 244 **G2:** 257 **N Completed treatment:** **G1:** 77% **G2:** 79% Total: 74% **Women, n (%)** **G1:** 177 (73) **G2:** 201 (78) **Age, median (range):** **G1:** 62 (19, 86) **G2:** 63 (22, 86) **Race/ethnicity:** NR **Follow-up:** 24 weeks	**Inclusion criteria:** • Age ≥ 18 • ≥ 8 voids/day and urinary urgency (± UUI) as determined by 1 wk bladder diary • With or without UUI • Women of reproductive age had to be using reliable birth control **Exclusion criteria:** • Contraindication to antimuscarinic therapy • Use of electrostimulation therapy or BT within prior 3 mo • Indwelling catheter or intermittent catheterization • Pregnancy or lactation • Use of anticholinergic agents or concomitant treatment for OAB (estrogen permitted)	**Urgency episodes/day, mean (range):** **G1:** 6.0 (0, 23.0) **G2:** 6.6 (0, 34.3) **Incontinence episodes/day, mean (range):** **G1:** 2 (0.3, 20.3) **G2:** 2.3 (0.3, 16.3) **Voids/day, mean (range):** **G1:** 10.3 (7.3, 27.6) **G2:** 10.6 (7.7, 24.6) **Duration of symptoms > 5 years, n (%):** **G1:** 120 (49) **G2:** 124 (48) **Previous drug therapy for OAB, n (%):** **G1:** 40 (160 **G2:** 35 (14) **Previous surgery affecting lower urinary tract, n (%):** **G1:** 28 (11.5) **G2:** 30 (12) **Symptoms caused at least moderate problems, %:** **G1:** 92 **G2:** 93	**Urgency episodes/day, median % change (IQR):** **G1:** -38 (-76.7, -14.1) **G2:** -38 (-68.7, -8.0) **G1/G2:** *P* = 0.75 **Incontinence episodes/day, median IQR% change; n=301:** **G1:** -87 (-100, -20) **G2:** -81 (-100, -41.8) **G1/G2:** *P* = 0.28 **Voids/day, median % change (IQR):** **G1:** -33 (-42.3, 21.3) **G2:** -25 (-38.8, -13.0) **G1/G2:** *P* < 0.001 **Voided volume (mL), median % change (IQR):** **G1:** 31.5 (13.3, 56.2) **G2:** 20 (3.1, 45.4) **G1/G2:** *P* <0.001 **Symptoms are "minor or less", %:** **G1:** 66.5 **G2:** 61.5 **Overall improvement in symptoms, %:** **G1:** 76 **G2:** 71 **Worsening of symptoms, %:** **G1:** 3 **G2:** 5 **Dry mouth, n (%):** **G1:** 76 (31) **G2:** 90 (35) **Headache, n (%):** **G1:** 15 (6) **G2:** 21 (8)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Mattiasson et al., 2003 (continued)				**Constipation, n (%):** **G1:** 7 (3) **G2:** 14 (5) **≥ 1 SE, n (%):** **G1:** 158 (65) **G2:** 177 (69) **G1/G2:** *P* = NS **Withdrawal due to, %:** AE: 15 **Withdrawal due to lack of efficacy:** 3 **Withdrawal of consent :** 2 **Protocol violations:** 1 **Completed treatment:** **G1:** 77% **G2:** 79%	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Millard, 2004 **Country and setting:** International, Multicenter study, 54 sites **Enrollment period:** NR **Funding:** Pharmacia Corp **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Tolterodine ± simplified pelvic-floor exercise regimen for 24 weeks **Groups:** **G1:** tolterodine 2 mg b.i.d. and simple PFME program **G2:** tolterodine 2 mg b.i.d. daily **N at enrollment:** **G1:** 227 **G2:** 253 **N at follow-up, 12 weeks, n (%):** **G1:** 181 (79.7) **G2:** 205 (81.0) **N at follow-up, 24 weeks, n (%):** **G1:** 164 (72.2) **G2:** 190 (75.1) **Women, n (%):** **G1:** 169 (75.4%) **G2:** 190 (75.4%) **Age, mean ± SD:** **G1:** 53.6 ± 16.9 **G2:** 53.2 ± 17.4 **Race/ethnicity:** **Asian:** **G1:** 176 (78.6%) **G2:** 203 (80.6% **White/mixed:** **G1:** 48 (21.4%) **G2:** 49 (19.4%)	**Inclusion criteria:** • Age 18-90 • ≥ 8 voids/day • Urgency • ≥ 1 UI episode/d • Sx for ≥ 6 months **Exclusion criteria:** • Symptomatic SI • Significant PVR volume • Neuropathy • Glaucoma • UTI • + urine cytology • Use of concomitant anticholinergic therapy w/in 14 days of randomization	**Urgency episodes/day, mean ± SD:** **G1:** 4.2 ± 3.6 **G2:** 4.1 ± 4.0 **Urgency episodes/day, median (IQR):** **G1:** 3.6 (1.3, 6.0) **G2:** 3.0 (1.3, 6.0) **Incontinence episodes/day, mean ± SD:** **G1:** 3.44 ± (3.4) **G2:** 3.21 ± (3.4) **Incontinence episodes/day, median (IQR):** **G1:** 2.3 (1.3, 4.0) **G2:** 2.9 (1.3, 3.7) **Voids/day, mean ± SD:** **G1:** 11.87 ± 4.3 **G2:** 12.78 ± 5.6 **Voids/day, median (IQR):** **G1:** 10.7 (9.0, 13.7) **G2:** 11.3 (9.0, 15.0) **Voided volume (mL), mean ± SD:** **G1:** 146.1 ± 67.7 **G2:** 146.0 ± 83.3 **Voided volume (mL), median (IQR):** **G1:** 137 (98, 186) **G2:** 132 (99, 189) **Duration of symptoms, n (%):** ≤ 5 years: **G1:** 166 (74.1) **G2:** 173 (68.7) > 5 years: **G1:** 56 (25) **G2:** 78 (31)	**Urgency episodes/day, wk 12, mean change ± SD (% change):** **G1:** -1.9 ± 4.0 (-64.5) **G2:** -2.2 ± 3.6 (-69.8) **G1/BL:** P = 0.001 **G1/BL:** P = 0.001 **G1/G2:** P = NS **Urgency episodes/day, wk 12, median change:** **G1:** -1.6 **G2:** -1.3 **G1/G2:** P = 0.7658 **Urgency episodes/day, wk 24, mean change ± SD (% change):** **G1:** -2.2 ± 3.6 (-78.7) **G2:** -2.7 ± 3.5 (-83) **G1/BL:** P = 0.001 **G1/BL:** P = 0.001 **G1/G2:** P = NS **Urgency episodes/day, wk 24, median change:** **G1:** -1.9 **G2:** -2.0 **G1/G2:** P = 0.3029 **Incontinence episodes/day, wk 12, mean change ± SD:** **G1:** -2.15 ± 3.0 **G2:** -2.15 ± 2.7 **G1/BL:** P = 0.001 **G1/BL:** P = 0.001 **G1/G2:** P = 0.2215	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: + Loss to followup: ++ Drop-out rates: - Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Millard, 2004 (continued)			**Previous UT surgery, n (%):** **G1:** 44 (19.6) **G2:** 43 (17.1) **Prev antichol-inergics, n (%):** **G1:** 19 (8.5) **G2:** 14 (5.6) **Prev UUI drug, n (%):** **G1:** 101 (45.1) **G2:** 91 (36.1) **Patient sub-jective rating of UI symptoms as "severe" or "many severe", %:** **G1:** 54.0 **G2:** 56.8	**Incontinence episodes/day, wk 12, median change:** **G1:** -1.6 **G2:** -1.6 **G1/G2:** P = 0.8251 **Incontinence episodes/day, wk 24, mean change ± SD (% change):** **G1:** -2.23 ± 3.0 (-64) **G2:** -2.26 ± 3.0 (-70) **G1/BL:** P = 0.001 **G1/BL:** P = 0.001 **G1/G2:** P = NS **Incontinence episodes/day, wk 24, median change:** **G1:** -1.6 **G2:** -1.6 **G1/G2:** P = 0.8341 **Voids/day, wk 12, mean change ± SD (% change):** **G1:** -2.68 ± 3.8 (-22) **G2:** -3.42 ± 4.6 (-26) **G1/BL:** P = 0.001 **G1/BL:** P = 0.001 **G1/G2:** P = 0.9478 **Voids/day, wk 24, mean change ± SD (% change):** **G1:** -2.58 ± 5.0 (-22) **G2:** -3.58 ± 5.2 (-26) **G1/BL:** P = 0.001 **G1/BL:** P = 0.001 **G1/G2:** P = 0.3549	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Millard, 2004 (continued)				**Voided volume (mL), wk 12, median change (% change):** **G1:** 20.4 (17.2) **G2:** 17.5 (15.8) **Voided volume (mL), wk 12, median change (% change):** **G1:** 21.1 (18.1) **G2:** 19.1 (15.4) **Patient subjective report of improvement in bladder condition, wk 12, %:** **G1:** 82.6 **G2:** 83.9 **Patient subjective report of improvement in bladder condition, wk 24, %:** **G1:** 81.7 **G2:** 85.9 **Adverse events, n (%):** **G1:** 22 (9.7) **G2:** 23 (9.1) **Mild dry mouth, %:** **G1:** 18.1 **G2:** 21.3 **Moderate dry mouth, %:** **G1:** 7.5 **G2:** 5.1 **Severe dry mouth, %:** **G1:** 4.0 **G2:** 3.2 **Headache, %:** 6 **Constipation, %:** 4.8 **Nausea, %:** 2.7	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Millard, 2004 (continued)				**Dry eyes, %:** 2.5 **Dizziness, %:** 2.4	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Sand et al., 2004 **Country and setting:** US, Specialty clinic **Enrollment period:** Subanalysis of OBJECT trial, women only **Funding:** ALZA Corp **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** 10mg ER Oxybutynin daily vs. 4mg Tolterodine (2mg bid) **Groups:** **G1:** 10mg ER Oxybutynin daily x 12 wks **G2:** 4mg Tolterodine (2mg bid) x 12 wks **Stratified by age:** **a:** Age ≤ 64 **b:** Age 65-74 **c:** Age ≥ 75 **N at enrollment:** **G1**: 152 **G2:** 163 **N at follow-up:** **G1**: 132 **G2:** 146 **Women, %:** 100 **Age, yrs ± SD:** **G1:** 58.4 **G2:** 58.8 **Race/ethnicity:** NR	**Inclusion criteria:** • ≥ 7 and ≤ 50 UUI episodes/week • ≥ 10 voids/day • MUI included if predominant UUI **Exclusion criteria:** • UTI • IC • Urethral diverticulum • Bladder tumor • Bladder stone • Delivery within 6 mos • Pelvic, bladder, vaginal surgery in ≤ 6 mos • PVR ≥ 150 mL • Cardiovascular, renal, pulmonary, gastrointestinal, endocrine, neurologic, autoimmune, hematological, urological, psychiatric, or hepatic disease • Hematuria • Positive urine culture • Narrow angle glaucoma • Obstructive uropathy • Myasthenia gravis • POP to hymenal ring • GI obstruction • Decreased GI motility • GI narrowing • GI retention • Investigational drugs within 1 month of screening • Hypersensitivity to drugs	**UUI episodes/ week, mean:** **G1:** 25.2 **G2:** 25.1 **Incontinence episodes/week, mean:** **G1:** 28.1 **G2:** 28.9 **Voids/week, mean:** **G1:** 91.7 **G2:** 91.6 **Naïve to anti-cholinergics, %:** **G1:** 60.5 **G2:** 60.7	**UUI episodes/ week, %:** **G1:** 6.2 **G2**: 8.5 **G1a:** 5.0 **G2a:** 8.4 **G1b:** 5.5 **G2b:** 7.5 **G1c:** 8.5 **G2c:** 11.1 **G1/G2:** P = 0.038 **G1a/G2a:** P = 0.005 **G1b/G2b:** P = 0.337 **G1c/G2c:** P = 0.568 **Incontinence episodes/week, mean:** **G1:** 7.3 **G2**: 10.1 **G1a:** 5.8 **G2a:** 10.0 **G1b:** 6.1 **G2b:** 9.2 **G1c:** 10.5 **G2c:** 12.5 **G1/G2:** P = 0.030 **G1a/G2a:** P = 0.005 **G1b/G2b:** P = 0.164 **G1c/G2c:** P = 0.714 **Voids/week, mean:** **G1:** 68.0 **G2**: 71.2 **G1a:** 63.7 **G2a:** 71.2 **G1b:** 73.8 **G2b:** 71.9 **G1c:** 66.8 **G2c:** 65.5 **G1/G2:** P = 0.272 **G1a/G2a:** P = 0.024 **G1b/G2b:** P = 0.706 **G1c/G2c:** P = 0.838	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Sand et al., 2004 (continued)		• Current drug/ EtOH abuse • Pregnant • Breastfeeding • Inability to follow protocol		**Dry mouth, %:** **G1:** 28.3 **G2:** 33.7 **Constipation, %:** **G1:** 8.6 **G2:** 6.7 **Retention, %:** **G1:** 4.0 **G2:** 1.2 **Blurred vision, %:** **G1:** 2.6 **G2:** 0.6 **Dizziness, %:** **G1:** 3.9 **G2:** 4.3 **Insomnia, %:** **G1:** 0.7 **G2:** 1.8 **Somnolence, %:** **G1:** 3.3 **G2:** 1.8 **Nervousness, %:** **G1:** 0 **G2:** 1.2 **Headache, %:** **G1:** 9.2 **G2:** 10.4 **Dyspepsia, %:** **G1:** 5.3 **G2:** 6.1 **Nausea, %:** **G1:** 3.3 **G2:** 1.8 **Vomiting, %:** **G1:** 2.0 **G2:** 1.8	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Schmidt et al., 1999 **Country and setting:** 16 centers in US, Canada, and Europe **Enrollment period:** 1993- April 1997 **Funding:** Medtronics Inc. **Author conflict of interest:** Schmidt, Jonas, Oleson, Janknegt, Siegel: financial interest and/or other relationship with Medtronic Inc.	**Design:** randomized controlled trial **Intervention:** implantable Interstim system stimulating the nerve ramus in preoperatively tested sacral nerve foramen **Groups:** **G1:** implantation with immediate stimulation (n=34 for efficacy analysis) **G2:** control group receiving standard medical therapy for 6 months; allowed to cross over at 6 months if remained eligible for implantation (n=42 for efficacy analysis) **N at enrollment:** 155 **N randomized:** 98 (the remaining 57 did not respond to test stimulation so were not randomized) **N at follow-up:** 76 at 6 months **Age:** mean 46.6 ±13.0 (range 20.2 – 78.9) **Gender:** 125 F (80.6%), 30 M (19.4%) **Race/ethnicity:** NR	**Inclusion criteria:** • age > 16 years • refractory to standard medical therapy • ≥ 100 mL bladder capacity with normal upper urinary tract • good surgical candidate • able to complete study documentation and return for follow-up evaluation **Exclusion criteria:** • Neurological conditions • Stress urinary incontinence • Primary pelvic pain	Duration of urinary symptoms before enrollment: mean 9.0±7.4 (range 0.6-35.4) Mean number of daily incontinence episodes: 8.9± 5.9 **G1:** 9.7 ± 6.3 **G2:** 9.3 ± 4.8 Mean leak severity rating: 1.9± 0.6 **G1:** 2.0 ± 0.7 **G2:** 1.8 ± 0.6 Mean absorbent pads/diapers replaced daily 4.8± 4.8 **G1:** 6.2 ± 5.0 **G2:** 5.0 ± 3.7 Mean heavy incontinence episodes per day: **G1:** 3.4 ±3.8 **G2:** 2.6 ±3.5 3-day diary data: 90.3% of patients had at least 1 moderate/heavy and 74.8% had at least 1 heavy incontinence episode **Previous treatment for urinary problems:** 153 (89.7%), including pharmacological in 144 (92.5%, nonsurgical in 55 (35.5%), and surgical in 88 (56.8%)	At 6 months: Mean number of daily incontinence episodes: **G1:** 2.6± 5.1 (p<0.0001) **G2:** 11.3 ± 5.9 (p=0.002) Mean leak severity rating: **G1:** 0.8 ± 0.9 (p<0.0001) **G2:** 2.0± 0.6 (p=0.006) Mean absorbent pads/diapers replaced daily **G1:** 1.1 ± 2.0 (p<0.0001) **G2:** 6.3 ± 3.6 (p=0.003) Mean heavy incontinence episodes per day: **G1:** 0.3 ±0.9 (P<0.0001) **G2:** 3.9 ±3.8 **G1:** 47% completely dry at 6 months; 3 patients had no reduction in incontinence after 6 months (one underwent device explantation and 2 had increased frequency of urination and incontinence)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: + Loss to followup: - Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Schmidt et al., 1999 (continued)				**Safety data (pooled for 157 patients):** adverse events requiring surgical repositioning or replacement of implant devices document in 51 (32.5%) 168 post-implant events reported by 83 patients, including pain at the neurostimulator site in 15.9%, pain at implant site in 19.1, and lead migration in 7.0% Infection or skin irritation led to device explantation in 2 patients and temporary explant in 2 patients No permanent injuries or nerve damage reported.	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Song, et al., 2006 **Country and setting:** Korea, Medical Center **Enrollment period:** May 2001 to April 2002 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** bladder training (BT) vs. Tolterodine vs. BT + Tolterodine **Groups:** **G1:** BT x 12 wks **G2:** Tolterodine 2 mg bid x 12 wks **G3**:Tolterodine 2 mg bid + BT x 12 wks **N at enrollment:** **G1:** 46 **G2:** 47 **G3:** 46 **N at follow-up:** **G1:** 26 **G2:** 32 **G3:** 31 **Women, %:** 100 **Age, mean ± SD:** **G1:** 45.73 ± 12.68 **G2:** 48.41 ± 9.38 **G3:** 45.42 ± 9.54 **Race/ethnicity, %:** Korean: 100	**Inclusion criteria:** • Age ≥ 18 • ≥ 8 voids/day • Urge with or without incontinence • Symptom duration ≥ 3 months • No prior history of treatment for OAB **Exclusion criteria:** • Active urinary tract infection • Clinically significant SUI • Bladder outlet obstruction • Interstitial cystitis • Glaucoma • Megacolon • Maximal urine flow rate of < 10 mL/sec • Postvoid residual volume > 30% of the total amount voided on uroflowmetry	**Voids/day, mean ± SD:** **G1:** 10.93 ± 2.14 **G2:** 11.63 ± 2.57 **G3:** 11.90 ± 1.51 **Nocturia episodes/day, mean ± SD:** **G1:** 1.45 ± 1.14 **G2:** 1.72 ± 1.04 **G3:** 1.96 ± 1.49 **Urgency, mean score ± SD:** **G1:** 2.58 ± 1.30 **G2:** 2.81 ± 0.74 **G3:** 3.00 ± 1.10 **Maximum flow rate (mL/s), mean ± SD:** **G1:** 20.35 ± 8.44 **G2:** 22.56 ± 4.94 **G3:** 21.19 ± 4.96 **Residual urine (mL), mean ± SD:** **G1:** 9.08 ± 22.56 **G2:** 7.59 ± 12.39 **G3:** 6.42 ± 10.16 **Symptom duration (years), mean ± SD:** **G1:** 6.44 ± 6.84 **G2:** 4.54 ± 5.15 **G3:** 4.10 ± 3.99	**Voids/day, mean (% decrease)** **G1:** 8.1 (25.9%)* **G2:** 8.1 (30.2%)* **G3:** 7.9 (33.5%)* **G3/G1:** P < 0.05 **Nocturia episodes/day, mean (% reduction):** **G1:** 0.6 (56.1%)* **G2:** 0.6 (65.4%)* **G3:** 0.6 (66.3%)* **Urgency, mean score (% reduction):** **G1:** 1.4 (44.8%)* **G2:** 1.1 (62.2%)* **G3:** 1.2 (60.2%)* **G3/G1:** P = 0.021 **G2/G1:** P = 0.017 **G2/G3:** P = NS **Satisfaction, mean score (% improved):** **G1:** 1.5 (53.9) **G2:** 1.4 (63.0) **G3:** 1.3 (71.0) **Dry mouth, n (%):** **G1:** 0 (0.0) **G2:** 7 (21.9) **G3:** 9 (28.9) **Hesitancy, n (%)** **G1:** 0 (0.0) **G2:** 3 (9.4) **G3:** 2 (6.5) **Decreased appetite/constipation, n (%):** **G1:** 0 (0.0) **G2:** 2 (6.3) **G3:** 2 (6.5) **Headache, n (%):** **G1:** 0 (0.0) **G2:** 1 (3.1) **G3:** 0 (0.0)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: - Pt selection criteria: + Loss to followup: - Drop-out rates: + Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Swift et al., 2003 **Country and setting:** Europe (167 centers), North America (74 centers), Australia and New Zealand (4 centers), University **Enrollment period:** February 1999 to October 1999 **Funding:** Pharmacia Corp **Author industry relationship disclosures:** NR	**Design:** RCT double blind placebo-controlled double dummy, random permuted blocks of 6 **Intervention:** Tolterodine ER vs. Tolterodine IR **Groups:** **G1:** Tolterodine ER 4mg daily **G2:** Tolterodine IR 2 mg BID **G3**: placebo **N at enrollment:** **G1**: 417 **G2:** 408 **G3**: 410 **N at follow-up:** Total: 1092 **Women, %:** 100 **Age, yrs ± SD:** **G1:** 59 ± 14 **G2:** 59 ± 14 **G3:** 60 ± 14 **Race/ethnicity, n (%):** **White:** **G1:** 396 (95) **G2:** 389 (95) **G3:** 383 (93) **Black:** **G1:** 15 (4) **G2:** 12 (3) **G3:** 20 (5) **Asian/Pacific:** **G1:** 5 (1) **G2:** 4 (1) **G3:** 2 (1) **Mixed:** **G1:** 0 **G2:** 3 (1) **G3:** 5 (1) **Unknown:** **G1:** 1 (<1) **G2:** 0 **G3:** 0	**Inclusion criteria:** • Women • Age ≥ 18 • ≥ 8 voids/day • > 5 UUI/ week • Symptoms x ≥ 6 months (per voiding diary) **Exclusion criteria:** • SUI • Total daily urine volume > 3 liters • Hepatic/ renal disease • UTI • IC • Hematuria • BOO • Current e-stim • Current bladder training • Indwelling catheter • Intermittent catherization • Pregnant/ nursing • Childbearing age without BC • Anticholinergic meds • Meds inhibit cytochrome P450	**Incontinence episodes/week, mean ± SD:** **G1:** 22.1 ± 22.5 **G2:** 22.9 ± 21.9 **G3:** 23.9 ± 21.2 **Pads/day, mean ± SD:** **G1:** 1.6 ± 2.1 **G2:** 1.5 ± 2.0 **G3:** 1.7 ± 2.4 **Voids/day, mean ± SD:** **G1:** 10.8 ± 4.2 **G2:** 11.1 ± 3.7 **G3:** 11.2 ± 3.9 **Voided volume (mL), mean ± SD:** **G1:** 141.2 ± 43.1 **G2:** 137.2 ± 41.2 **G3:** 135.7 ± 43.2 **Previous drug therapy: n (%):** **G1:** 235 (56) **G2:** 222 (54) **G3:** 225 (55)	**Incontinence episodes/week, mean ± SD:** **G1:** 10.3 ± 17.2 **G2:** 12.8 ± 19.8 **G3:** 16.7 ± 19.7 **G1/G3:** P = 0.001 **G2/G3**: P = 0.001 **Pads/day, mean ± SD:** **G1:** 1.0 ± 1.8 **G2:** 1.0 ± 1.5 **G3:** 1.5 ± 2.2 **G1/G3:** P = 0.001 **G2/G3**: P = 0.001 **Voids/day, mean ± SD:** **G1:** 9.0 ± 3.2 **G2:** 9.3 ± 4.0 **G3:** 9.9 ± 3.8 **G1/G3:** P = 0.001 **G2/G3**: P = 0.005 **Voided volume (mL), mean ± SD:** **G1:** 179.1 ± 66.6 **G2:** 169.7 ± 65.6 **G3:** 149.0 ± 56.3 **G1/G3:** P = 0.001 **G2/G3**: P = 0.001 **Clinical effect-tiveness*, dry mouth:** **G1:** 0.53 **G2:** 0.39 **G3:** 0.30 **Dry mouth, n (%):** **G1:** 105 (25.3) **G2:** 127 (31.2) **G3:** 33 (8.0) **G1/G3:** P < 0.01 **G2/G3:** P < 0.01 **Abdominal pain, n (%):** **G1:** 18 (4.3) **G2:** 12 (2.9) **G3:** 7 (1.7) **G1/G3:** P = 0.03 **Flatulence, n (%):** **G1:** 8 (1.9) **G2:** 11 (2.7) **G3:** 6 (1.5)	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: + Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Swift et al., 2003 (continued)	**BMI, kg/m^2 ± SD:** **G1:** 28.8 ± 13.8 **G2:** 29.0 ± 11.0 **G3:** 28.8 ± 6.7			**Constipation, n (%):** **G1:** 27 (6.5) **G2:** 27 (6.6) **G3:** 14 (3.4) **Dyspepsia, n (%):** **G1:** 11 (2.7) **G2:** 14 (3.4) **G3:** 6 (1.5) **Nausea, n (%):** **G1:** 7 (1.7) **G2:** 9 (2.2) **G3:** 9 (2.2) **Diarrhea, n (%):** **G1:** 10 (2.4) **G2:** 14 (3.4) **G3:** 9 (2.2) **Xerophthalmia, n (%):** **G1:** 16 (3.9) **G2:** 8 (2.0) **G3:** 8 (2.0) **Abnormal vision, n (%):** **G1:** 5 (1.2) **G2:** 4 (1.0) **G3:** 2 (0.5) **Headache, n (%):** **G1:** 29 (7.0) **G2:** 14 (3.4) **G3:** 19 (4.6) **UTI, n (%):** **G1:** 15 (3.6) **G2:** 11 (2.7) **G3:** 19 (4.6) **Insomnia, n (%):** **G1:** 7 (1.7) **G2:** 2 (0.5) **G3:** 9 (2.2) **Somnolence, n (%):** **G1:** 12 (2.9) **G2:** 11 (2.7) **G3:** 8 (2.0) **Dizziness, n (%):** **G1:** 7 (1.7) **G2:** 7 (1.7) **G3:** 4 (1.0)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Swift et al., 2003 (continued)				**Hypertension, n (%):** **G1:** 6 (1.4) **G2:** 4 (1.0) **G3:** 4 (1.0) **Sinusitis, n (%):** **G1:** 8 (1.9) **G2:** 2 (0.5) **G3:** 3 (0.7) **Arthritis, n (%):** **G1:** 1 (0.2) **G2:** 5 (1.2) **G3:** 1 (0.2) **Dry skin, n (%):** **G1:** 2 (0.5) **G2:** 5 (1.2) **G3:** 1 (0.2)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Szonyi et al., 1995 **Country and setting:** UK **Enrollment period:** NR **Funding:** Smith & Nephew Pharmaceuticals Ltd **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Oxybutynin plus bladder training vs. placebo plus bladder training **Groups:** **G1:** Oxybutynin 2.5 mg bid with dose titration on days 29 and 43 plus bladder training **G2:** placebo + bladder training **N at enrollment:** **G1:** 30 **G2:** 30 **N at follow-up:** **G1:**16 **G2:** 23 **Women, n (%):** 56 (93) **Age, mean ± SD:** 82.2 ± 6.06 **Race/ethnicity:** NR **Weight (kg), mean ± SD:** 67.4 ± 14.92	**Inclusion criteria:** • Age > 70 • Frequency, urgency and UUI • Mobile • Able to keep diary **Exclusion criteria:** • UTI • Hepatic or renal disease • Glaucoma • Uncontrolled diabetes • Taking imipramine or propantheline		**Voids/2 weeks, median change (95% CI):** **G1/G2:** 577 (-27.0, 6.0) P = 0.0025 **Nocturia episodes/2 weeks, median change (95% CI):** **G1/G2:** -6 (-5, 7.0) **Daytime incontinence episodes/2 weeks, median change (95% CI):** **G1 vs. G2:** -9.5 (-11.0, 3.0) **Nocturia episodes/2 weeks, median change (95% CI):** **G1/G2:** -1.0 (-3.0, 2.0) **Patient assess-ment of benefit, %:** 29 days: **G1:** 86 **G2:** 55 P = 0.02 43 days: **G1:** 71 **G2:** 59 P = 0.41 57 days: **G1:** 79 **G2:** 55 P = 0.09 **Patient response, 29 days, n:** Cure: **G1:** 1 **G2:** 0 Significant improvement: **G1:** 15 **G2:** 8 Marginal improvement: **G1:** 7 **G2:** 8	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Szonyi et al., 1995 (continued)				No change: **G1:** 5 **G2:** 13 **Patient response, 57 days, n:** Cure: **G1:** 4 **G2:** 3 Significant improvement: **G1:** 14 **G2:** 8 Marginal improvement: **G1:** 3 **G2:** 4 No change: **G1:** 7 **G2:** 14 **Dry mouth, %:** **G1:** 93 **G2:** 86 **Blurred vision, %:** **G1:** 50 **G2:** 59 **Heartburn, %:** **G1:** 57 **G2:** 45 **Constipation, %:** **G1:** 50 **G2:** 45 **Dry skin, %:** **G1:** 50 **G2:** 59 **Poor compliance (< 75% of tablets), %:** **G1:** 20 **G2:** 20	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Tseng et al., 2009 **Country and setting:** Taiwan, University **Enrollment period:** January 2005 to November 2005 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Prospective cohort randomized **Intervention:** Tolterodine 2 mg b.i.d. vs. tolterodine 2 mg b.i.d. + conjugated equine estrogen 0.625 mg twice per week **Groups:** **G1:** tolterodine 2 mg b.i.d. **G2:** tolterodine 2 mg b.i.d. + conjugated equine estrogen 0.625 mg twice per week **N at enrollment:** **G1**: 40 **G2:** 40 **N at follow-up:** **G1**: 40 **G2:** 40 **Age, mean ± SD:** **G1:** 64.5 ± 7.4 **G2:** 66.2 ± 6.8 **Race/ethnicity:** NR **Women, N (%):** **G1:** 40 (100) **G2:** 40 (100) **BMI, kg/m^2 ± SD:** **G1:** 24.5 ± 3.9 **G2:** 25.3 ± 3.8 **Previous antimuscarinic Rx, n (%):** **G1:** 5 (12.5) **G2:** 6 (15) **Prior hysterectomy, n (%):** **G1:** 12 (30) **G2:** 14 (35)	**Inclusion criteria:** • Age ≥ 18 • OAB symptoms • Amenorrheic **Exclusion criteria:** • Advanced POP > Stage 2 • Women with storage and voiding dysfunction undiagnosed • Severe constipation • Elevated PVR • Neurological deficit • Renal/ hepatic disease • Narrow angle glaucoma • Urinary retention • Gastric retention • Hypersensitivity to drugs • BOO • Cardiac conduction disorders • Myasthenia gravis • History of CVA • History of VTE • Gallbladder disease • Known or suspected breast carcinoma • Undiagnosed genital bleeding • HRT within 3 months of study enrollment	**UUI episodes/ day, mean ± SD:** **G1:** 1.8 ± 0.7 **G2:** 2.1 ± 1.1 **Urgency episodes/ day, mean ± SD:** **G1:** 4.5 ± 0.8 **G2:** 4.3 ± 0.7 **Nocturia episodes/ day, mean ± SD:** **G1:** 3.5 ± 0.8 **G2:** 3.3 ± 0.8 **Voids/day, mean ± SD:** **G1:** 14.1 ± 1.3 **G2:** 14.8 ± 1.5 **UDI-6 score, mean ± SD:** **G1:** 9.5 ± 3.9 **G2:** 8.6 ± 3.8 **IIQ-7 score, mean ± SD:** **G1:** 10.2 ± 4.5 **G2:** 9.4 ± 3.6 **Voided volume (mL), mean ± SD:** **G1:** 108.5 ± 14.0 **G2:** 115.8 ± 15.1	**UUI episodes/day, mean ± SD:** **G1:** 1.5 ± 0.5 **G2:** 1.5 ± 0.5 *P* = NS **Urgency episodes/ day, mean ± SD:** **G1:** 3.5 ± 0.5 **G2:** 3.3 ± 0.6 **Nocturia episodes/ day, mean ± SD:** **G1:** 2.9 ± 0.6 **G2:** 2.6 ± 0.7 **Voids/day, mean ± SD:** **G1:** 6.4 ± 1.9 **G2:** 5.8 ± 0.9 *P* = 0.001 **UDI-6 score, mean ± SD:** **G1:** 7.2 ± 2.9 **G2:** 6.9 ± 2.7 *P* < 0.001 **IIQ-7 score, mean ± SD:** **G1:** 6.5 ± 2.7 **G2:** 6.1 ± 2.5 *P* < 0.001 **Voided volume (mL), mean ± SD:** **G1:** 134.5 ± 15.8 **G2:** 141.9 ± 16.1 *P* = 0.007 **Adverse events:** None	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: + Method and blinding: - Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Van Kerrebroeck et al., 2001 Freeman et al., 2003* **Country and setting:** North America (74 centers), Australasia (4 centers), Europe (89 centers) **Enrollment period:** NR **Funding:** Pharmacia Corporation **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Tolterodine ER vs. Tolterodine IR vs. placebo **Groups:** **G1:** tolterodine ER 4 mg t.i.d. **G2:** tolterodine IR 2 mg b.i.d. **G3:** placebo **N at enrollment:** **G1**: 507 **G2:** 514 **G3:** 508 **N at follow-up:** **Total:** 1442 **G1:** 398 **G3:** 374 **Women, n (%):** **G1:** 417 (82) **G2:** 408 (79) **G3:** 410 (81) **Age, mean (range):** **G1:** 60 (20, 89) **G2:** 60 (22, 92) **G3:** 61 (22, 93) **Race/ethnicity, %:*** **White:** **G1:** 95.7 **G3:** 94.7 **Black:** **G1:** 3.0 **G3:** 3.5 **Asian/Pacific Islander:** **G1:** 1.0 **G3:** 0.8 **Other:** **G1:** 0.3 **G3:** 1.1	**Inclusion criteria:** • Age ≥ 18 • Urinary frequency (≥ 8 voids/day) **Exclusion criteria:** • SUI • Total daily urine volume > 3 L • Contra-indications to antimuscarinic treatment • Hepatic or renal disease • UTIs • Interstitial cystitis • Hematuria • BOO • Current electrostimula-tion or bladder training therapy • Indwelling catheter or intermittent self-catheterization • Pregnant or nursing • Women not using reliable contraception • Being treated for OAB with other anticholinergic drugs or drugs that inhibit cytochrome P450 3A4 isoenzymes • Estrogen therapy < 2 months • Treatment w/ investigational drug < 2 months	**Incontinence episodes/week, mean (range):** **G1:** 22.1 (0, 168.0) **G2:** 23.2 (0, 168.0) **G3:** 23.3 (0, 168.0) **≥ 5 incontinence episodes/week, n (%):** **G1:** 492 (97) **G2:** 498 (97) **G3:** 494 (97) **Pads/day, mean (range):** **G1:** 1.4 (0-18) **G2:** 1.4 (0-25) **G3:** 1.5 (0-22) **Voids/day, mean (range):** **G1:** 10.9 (2.3, 51.3) **G2:** 11.1 (2.0, 48.6) **G3:** 11.3 (2.0, 37.4) **≥ 8 voids/day, n (%):** **G1:** 458 (90) **G2:** 469 (91) **G3:** 467 (92) **Previous drug therapy, n (%):** **G1:** 270 (53) **G2:** 276 (54) **G3:** 263 (52) **Poor efficacy, %:** **G1:** 43 **G2:** 38.4 **G3:** 40.7 **Able to finish tasks before visiting a toilet, %:*** **G1:** 5 **G3:** 6	**Urinary Urgency, subjective assessment, 12 wks, n (%):*** Improvement: **G1:** 173 (44) **G3:** 118 (32) **G1/G3:** P < 0.001 No change: **G1:** 201 (51) **G3:** 212 (57) Deterioration: **G1:** 22 (6) **G3:** 44 (12) **G1/G3:** P < 0.002 **Urinary urgency, improvement, 12 wks, women only, %:*** **G1:** 46.6 **G3:** 26.6 **G1/G3:** P = 0.001 OR 1.81 (95% CI: 1.31, 2.49) **Not able to hold urine, 12 wks, %:*** **G1:** 58 **G3:** 32 **G1/G3:** P < 0.001 **Incontinence episodes/week, mean change ± SD (%)** **G1:** -11.8 ± 17.8 **G2:** -10.6 ± 16.9 **G3:** -6.9 ± 15.4 **G1/G3:** P = 0.00001 **G2/G3:** P = 0.0005 **G1/G2:** P < 0.05 **Incontinence episodes/week, median % change:** **G1:** -71 **G2:** -60 **G3:** -30 **G1/G2:** P < 0.05	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Van Kerrebroeck et al., 2001 Freeman et al., 2003* (continued)			**Voided volume (mL), mean (range):** **G1:** 141 (36, 338) **G2:** 137 (38, 283) **G3:** 136 (31, 374)	**Pads/day, mean ± SD:** **G1:** -0.5 ± 1.4 **G2:** -0.5 ± 18 **G3:** -0.2 ± 1.4 **G1/G3:** P = 0.0145 **G2/G3:** P = 0.0035 **Voids/day, mean ± SD:** **G1:** -3.5 ± 4.9 **G2:** -3.3 ± 4.4 **G3:** -2.2 ± 4.0 **G1/G3:** P = 0.00001 **G2/G3:** P = 0.0002 **Voluntary voids/ day, mean ± SD:** **G1:** -1.8 ± 3.4 **G2:** -1.7 ± 3.3 **G3:** -1.2 ± 2.9 G1 vs. G3 **G1/G3:** P = 0.00047 **G2/G3:** P = 0.0079 **Bladder symptoms, improvement, 12 wks, women only, %:*** **G1:** 62.8 **G3:** 48.4 **G1/G3:** P = 0.001 OR 1.78 (95% CI: 0.34, 2.37) **Treatment benefit, 12 wks, n (%):*** **Much benefit:** **G1:** 172 (43.2) **G3:** 88 (23.5) **G1/G3:** P < 0.001 Little benefit **G1:** 138 (34.7) **G3:** 118 (31.6) No benefit **G1:** 88 (22.1) **G3:** 168 (44.9)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Van Kerrebroeck et al., 2001 Freeman et al., 2003* (continued)				**Able to finish tasks before visiting a toilet, 12 wks, %:*** **G1:** 33 **G3:** 18 **G1/G3:** P < 0.001 **Voided volume (mL), mean change ± SD:** **G1:** +34 ± 51 **G2:** +29 ± 47 **G3:** +14 ± 41 **G1/G3:** P = 0.00001 **G2/G3:** P = 0.0001 **Discontinued due to AEs, n (%):** **G1:** 27 (5) **G2:** 28 (5) **G3:** 33 (6) **Reported serious adverse events, n:** **G1:** 7 **G2:** 12 **G3:** 18 **Parasympathetic Dry mouth, n (%):** **G1:** 118 (23) **G2:** 156 (30) **G3:** 39 (8) **Xerophthalmia, n (%):** **G1:** 17 (3) **G2:** 12 (2) **G3:** 10 (2) **Abnormal vision, n (%):** **G1:** 6 (1) **G2:** 4 (1) **G3:** 2 (0.5) **Dry skin, n (%):** **G1:** 2 (0.5) **G2:** 6 (1) **G3:** 1 (0.5)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Van Kerrebroeck et al., 2001 Freeman et al., 2003* (continued)				**Gastrointestinal Constipation, n (%):** **G1:** 30 (6) **G2:** 35 (7) **G3:** 22 (4) **Dyspepsia, n (%):** **G1:** 15 (3) **G2:** 16 (3) **G3:** 7 (1) **Abdominal pain, n (%):** **G1:** 19 (4) **G2:** 13 (3) **G3:** 8 (2) **Diarrhea, n (%):** **G1:** 10 (2) **G2:** 16 (3) **G3:** 11 (2) **Flatulence, n (%):** **G1:** 10 (2) **G2:** 14 (3) **G3:** 9 (2) **Nausea, n (%):** **G1:** 7 (1) **G2:** 10 (2) **G3:** 10 (2) **Headache, n (%):** **G1:** 32 (6) **G2:** 19 (4) **G3:** 23 (5) **Somnolence, n (%):** **G1:** 14 (3) **G2:** 13 (3) **G3:** 9 (2) **Dizziness, n (%):** **G1:** 11 (2) **G2:** 9 (2) **G3:** 5 (1) **Fatigue, n (%):** **G1:** 11 (2) **G2:** 6 (1) **G3:** 4 (1) **Insomnia, n (%):** **G1:** 7 (1) **G2:** 2 (0.5) **G3:** 9 (2)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Van Kerrebroeck et al., 2001 Freeman et al., 2003* (continued)				**Urinary tract infection, n (%):** **G1:** 16 (3) **G2:** 13 (3) **G3:** 20 (4) **Dysuria, n (%):** **G1:** 5 (1) **G2:** 8 (2) **G3:** 1 (0.5) **Peripheral edema, n (%):** **G1:** 7 (1) **G2:** 7 (1) **G3:** 4 (1)	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Wang et al., 2006 **Country and setting:** Taiwan; Academic medical center **Enrollment period:** July 2004 to November 2005 **Funding:** National Science Council, Taiwan **Author industry relationship disclosures:** NR	**Design:** 12-wk RCT **Intervention:** Electric Stimulation (ES) vs. Oxybutynin vs. Placebo for 12 weeks **Groups:** **G1:** ES: intravaginal electrode; biphasic symmetric pulsed current w/ a 10-Hz frequency, 400-millisecond pulse width, 10/5 duty cycle, and varying intensity, 20 min/session, twice weekly **G2:** Oxybutynin, 2.5 mg 3 times daily **G3:** Placebo pill 3 times daily **N at enrollment:** **G1**: 25 **G2:** 26 **G3:** 23 **N at follow-up:** **G1**: 24 **G2:** 23 **G3:** 21 **Age:** NR **Race/ethnicity:** NR	**Inclusion criteria:** • Female • OAB for ≥ 6 mos • Age 16-80 • Urgency ≥ 4 times per day **Exclusion criteria:** • Use of anticholinergics or TCAs • Previous treatment with pelvic-floor muscle training, bladder training • Pelvic prolapse repair • Pregnancy • Neurologic disorders • DM • Demand cardiac pacemaker • IUD use • Genital prolapse greater than ICS Stage II • PVR>100 mL • Overt SI • Anti-incontinence surgery • UTI	**Warning time, s (range)** **G1:** 41.5 (8-105) **G2:** 44 (2-215) **G3:** 65 (26-265 **MVV, mL/void (range):** **G1:** 340 (120-450) **G2:** 310 (130-800) **G3:** 350 (120-600) **Daily voided volume, mL (range)** **G1:** 2160 (1010-2950) **G2:** 2106 (1560-3153) **G3:** 2305 (1305-3300) **Pads per day (range):** **G1:** 1 (0-4.1) **G2:** 0 (0-3) **G3:** 1 (0-4) **Urgency (subj):** **G1:** 11.4 (4.0-16.0) **G2:** 12.1 (5-18) **G3:** 9.8 (4.2-15.5) **Frequency (subj):** **G1:** 12.8 (8.8-16.0) **G2:** 11.5 (4.3-19.5) **G3:** 11.5 (6.5-22.8) **Nocturia (subj):** **G1:** 1.75 (0-6.5) **G2:** 0 (0-2.5) **G3:** 0.65 (0-3.1) **UI (subj):** **G1:** 1 (0-2) **G2:** 0 (0-2) **G3:** 1 (0-2)	**Warning time, s (range)** **G1:** 72 (32-633) **G2:** 54.5 (138-850) **G3:** 66.5 (26-219) p-value (among 3 groups): <0.001 **MVV, mL/micturition (range):** **G1:** 355 (150-550) **G2:** 336.5 (138-850) **G3:** 340 (160-600) p-value (among 3 groups): 0.035 **Voided volume/d, mL (range)** **G1:** 2270 (1210-3106) **G2:** 2100 (1619-3200) **G3:** 2305 (1351-3221) p-value (among 3 groups): 0.050 **Pad count, pad/d (range):** **G1:** 0 (0-2) **G2:** 0 (0-2.5) **G3:** 1 (0-3) p-value (among 3 groups): 0.012 **Urgency (subj)** **G1:** 1.0 (0.0-12.3) **G2:** 6 (0.5-13) **G3:** 7.4 (3.9-13.4) p-value (among 3 groups): <0.001 **Frequency (subj)** **G1:** 7.8 (1.8-13.0) **G2:** 7.4 (2-14) **G3:** 10 (3.9-13.4) p-value (among 3 groups): 0.002 **Nocturia (subj)** **G1:** 0 (0-3.0) **G2:** 0 (0-2.5) **G3:** 1 (0-3.6) p-value (among 3 groups): 0.002	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to followup: ++ Drop-out rates: + Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Wang et al., 2006 (continued)				**UI (subj)** **G1:** 0.5 (0-2) **G2:** 0 (0-2) **G3:** 1 (0-2) p-value (among 3 groups): 0.413 **P values before vs. after treatment** **Warning time, s (range):** **G1:** 0.002 **G2:** 0.001 **G3:** 0.532 **MVV, mL/void (range):** **G1:** 0.018 **G2:** 0.004 **G3:** 0.979 **Daily voided volume, mL (range):** **G1:** 0.024 **G2:** 0.728 **G3:** 0.627 **Pad per day (range):** **G1:** 0.010 **G2:** 0.662 **G3:** 0.501 **Urgency (subj):** **G1:** <0.001 **G2:** <0.001 **G3:** 0.003 **Frequency (subj):** **G1:** <0.001 **G2:** <0.001 **G3:** 0.070 **Nocturia (subj):** **G1:** 0.001 **G2:** 0.394 **G3:** 0.176 **UI (subj):** **G1:** 0.814 **G2:** 0 083 **G3:** 0.854	

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Zinner et al., 2005 **Country and setting:** US, Specialty treatment center **Enrollment period:** NR **Funding:** Pfizer Novartis Pharma Thomson ACUMED **Author industry relationship disclosures:** NR	**Design:** Randomized double- blind placebo-controlled four way crossover **Intervention:** Darifenacin 15 mg qd vs. darifenacin 30 mg qd vs. Oxybutynin vs. placebo **Groups:*** **G1:** Darifenacin 15mg daily **G2:** Darifenacin 30mg daily **G3:** Oxybutynin 5 mg t.i.d. **G4:** placebo **N at enrollment:** **G1-G4:** 76 **N included, tolerability:** **G1-G4:** 61 **N included, efficacy:** **G1-G4:** 58 **Women, n (%):** **G1-G4:** 71 (93.4) **Age, mean (range):** **G1-G4:** 59.9 (33-84) **Race/ethnicity:** NR **Weight (kg), mean (range):** **G1-G4:** 75.7 (42-157)	**Inclusion criteria:** • Age 18-85 • ≥ 4 UUI episodes/week • ≥ 8 voids/day (from 14 day run in placebo voiding diary) **Exclusion criteria:** • Neurogenic bladder • SUI • Contraindication to antimuscarinic treatment • UTI • Bladder symptoms • Bladder stones • BOO • Concomitant disease • Concurrent bladder training • Concurrent thyroid or HRT • Other bladder meds • Pregnant or breastfeeding	**Urgency episodes/day, mean ± SD:** **G1-G 4:** 9.3 ± 3.4 **Urgency severity, mean ± SD:** **G1-G4:** 2.0 ± 0.4 **Incontinence episodes/week, mean ± SD:** **G1-G4:** 20.4 ± 17.7 **Voids/ day, mean ± SD:** **G1-G4:** 10.4 ± 3.0	**Urgency episodes/day, mean:** **G1:** 7.95 **G2:** 7.59 **G3:** 8.12 **G4:** 8.71 **G1-G3/G4:** P < 0.05 **Urgency severity, mean:** **G1:** 1.93 **G2:** 1.84 **G3:** 1.89 **G4:** 2.03 **G1-G3/G4:** P < 0.05 **Incontinence episodes/week, mean:** **G1:** 10.93 **G2:** 8.82 **G3:** 9.45 **G4:** 14.64 **G1-G3/G4:** P < 0.05 **Voids/day, mean ± SD:** **G1:** 9.33 **G2:** 8.85 **G3:** 9.24 **G4:** 9.62 **G2/G4:** P < 0.05 **Dry mouth, (%):** **G1:** 13.1 **G2:** 34.4 **G3:** 36.1 **G4:** 4.9 **G1/G3:** P < 0.05 **G2/G3:** P < 0.05 **G2/G4:** P < 0.05 **G3/G4:** P < 0.05 **Constipation, (%):** **G1:** 9.8 **G2:** 21.3 **G3:** 8.2 **G4:** 3.3 **G2/G3:** P < 0.05 **G2/G4:** P < 0.05	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: - Drop-out rates: NR Power calculation: + Statistical issues: + EXTERNAL VALIDITY: fair Age: -, NR Baseline OAB status: NR Baseline characteristics: - Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 6. KQ 3 Comparison of Treatments (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Zinner et al., 2005 (continued)				**Blurred vision, (%):** **G1:** 0 **G2:** 0 **G3:** 3.3 **G4:** 0 **Dizziness, (%):** **G1:** 0 **G2:** 0 **G3:** 1.6 **G4:** 0	

Evidence Table 7. KQ4 Modifiers of outcomes

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Anderson et al., 2006 [See evidence table for Diokno et al. 2003] **Country and setting:** US, Multicenter **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** 1 of 6 ALZA Corp (1)	**Design:** RCT **Intervention:** different extended release anticholinergic medications in women with or without prior anticholinergic treatment for OAB **Groups:** **G1:** Prior anticholinergic treatment **G1a:** ER oxybutynin 10 mg po daily **G1b:** ER tolterodine, 4mg po daily **G2:** No prior anticholinergic treatment **G2a:** ER oxybutynin 10 mg po daily **G2b:** ER tolterodine, 4mg po daily **Ga:** ER oxybutynin 10 mg po daily **Gb:** ER tolterodine, 4mg po daily **N at enrollment:** Total: 790 **G1:** 373 **G1a:** 180 **G1b:** 193 **G2:** 417 **G2a:** 211 **G2b:** 206 **N at follow-up, 12 weeks:** **G1:** 341 **G1a:** 165 **G1b:** 176 **G2:** 355 **G2a:** 174 **G2b:** 181	**Inclusion criteria:** • Women • Age ≥ 18 • Mean of 21-60 UUI episodes per week and mean of ≥ 10 voids per 24 hr **Exclusion criteria:** NR	**UUI episodes/ wk, mean ± SD:** **G1a:** 36.8 ± 16.4 **G1b:** 37.4 ± 14.0 **G2a:** 37.5 ± 14.0 **G2b:** 36.2 ± 13.9 **Incontinence episodes/wk, mean ± SD:** **G1a:** 41.5 ±19.0 **G1b:** 43.0 ± 18.0 **G2a:** 45.0 ±19.4 **G2b:** 41.9 ± 17.9 **Voids/week, mean** ± SD**:** **G1a:** 92.8 ± 23.7 **G1b:** 94.6 ± 25.2 **G2a:** 96.5 ± 27.1 **G2b:** 97.9 ± 24.2	**UUI episodes/wk, mean ± SD:** **G1a:** 11.4 ± 17.9 **G1b:** 13.3 ± 15.1 **G2a:** 10.2 ± 13.7 **G2b:** 9.3 ± 13.3 **G1a/G1b:** P = 0.3 **UUI episodes/wk, completed wk 12, mean ± SD:** **G1a:** 9.9 ± 14.1 **G1b:** 12.9 ± 14.9 P = 0.049 **No UUI, 12 wk, %:** **G1a:** 25.2 **G1b:** 16.4 **G2a:** 29.4 **G2b:** 26.4 G1a/G1b: P = 0.046 G2a/G2b: P = 0.495 **Incontinence episodes/wk, mean ± SD:** **G1a:** 12.7 ± 18.7 **G1b:** 16.5 ± 19.8 **G2a:** 11.9 ± 15.1 **G2b:** 11.3 ± 16.0 **G1a/G1b:** P = 0.09 (P = 0.012 if completed wk 12) **G2a/G2b:** P = 0.886 **Voids/week, mean** ± SD**:** **G1a:** 68.4 ± 17.2 **G1b:** 72.8 ± 25.4 **G2a:** 64.8 ± 22.0 **G2b:** 69.4 ± 21.3 G1a/G1b: P = 0.05 (P = 0.026 iwk 12) G2a/G2b: P = 0.035 (P = 0.026 wk 12) **Dry mouth, %** **G1a:** 32 **G1b:** 19 **G2a:** 27.5 **G2b:** 25.2 **G1a/G1b:** P = 0.004 **G2a/G2b:** P = 0.6	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Anderson et al., 2006 (continued)	**Women, %:** 100 **Age, mean ± SD:** **G1a:** 62.6 ± 12.9 **G1b:** 62 ± 12.6 **G2a:** 57.5 ± 13.4 **G2b:** 58.8 ± 12.4 **Race/ethnicity, %:** **White:** **G1a:** 87 **G1b:** 88 **G2a:** 82 **G2b:** 84 **Black:** **G1a:** 7 **G1b:** 9 **G2a:** 9 **G2b:** 8.7 **Asian:** **G1a:** 0.6 **G1b:** 0 **G2a:** 0 **G2b:** 1 **Hispanic:** **G1a:** 5.6 **G1b:** 3.1 **G2a:** 8.1 **G2b:** 6.3 **Other** **G1a:** 0 **G1b:** 0.5 **G2a:** 0.9 **G2b:** 0			**Constipation, %:** **G1a:** 7.8 **G1b:** 5.2 **G2a:** 5.2 **G2b:** 10.2 **Diarrhea, %:** **G1a:** 7.8 **G1b:** 5.7 **G2a:** 8.1 **G2b:** 6.8 **Headache, %:** **G1a:** 4.4 **G1b:** 5.2 **G2a:** 6.6 **G2b:** 6.8 **Discontinued d/t AE, n (%):** **G1a:** 7 (3.9) **G1b:** 6 (3.1) **G2a:** 13 (6.2) **G2b:** 13 (6.3) **Withdrew, %:** **G1:** 3.5 **G2:** 6.2	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Appell, Abrams et al., 2001 **Country and setting:** Multinational, Multicenter **Enrollment period:** NR **Funding:** Pharmacia **Author industry relationship disclosures:** NR	**Design:** Open-label extension study (after 12-wk RCT and 1 wk washout) **Intervention:** Tolterodine 2 mg BID with option for patients to self-lower their dosage to 1mg bid **Groups:** NA **N at enrollment:** 854 **N at follow-up, n (%):** 594 (70) **Age, yrs, mean (range):** 59.5 (19-89) **Race/ethnicity:** NR **Women, %:** 76 **Parity mean ± SD:** NR Previous drug therapy for OAB, n (%) 472 (55) Previous lower urinary tract surgery, n (%) 291 (34)	**Inclusion criteria:** • 18+ years old • Cystometric evidence of detrusor overactivity (phasic detrusor contraction with amplitude 10+ cm H2O • ≥ 8 voids/day • ≥ 1+ urinary incontinence episode/day **Exclusion criteria:** • SUI • Hepatic or renal disease • UTI • IC • Hematuria • Contraindication to antimuscarinic therapy • Previous serious AE on oxybutynin • Voiding difficulty w/ treatment of urinary retention • Treatment w/in 14 days prior to baseline visit • Initiation of antimuscarinic or any drug for UI during study • Electro-stimulation or bladder training • Indwelling or intermittent catheter • Total voided volume >3L/day	**Detrusor instability, %:** 93.7 **Urge incontinence episodes, n (%):** 724 (85) **Symptom duration > 5 yrs, n (%):** 412 (48) **Urgency, n (%):** 841 (98) **Severe/very severe problems, n (%):** 384 (45) **voids/day, mean (range):** 11.4 (5.3-37.0) **Urge incontinence episodes/day, mean (range):** 3.5 (0.1-24.0) **Volume voided mean mL (range):** 159 (25-423) **Adverse events at end of 12-wk RCT, n (%):** Any: 358 (76) ANS: 203 (43) CNS: 59 (12) GI: 125 (26) Respiratory: 68 (14) Urinary: 50 (11) Dry mouth: 187 (39) UTI: 26 (5) Headache: 49 (10) Constipation: 31 (7) Abdominal pain: 36 (8) URI: 28 (6)	**Voids/day, 3 mos, mean (range)** 8.8 (2.0-23.4) **Voids/day, 3 months, mean change (95% CI):** -2.6 (-2.8 to -2.3) P = 0.0001 **Voids/day, 9 mos, mean (range):** 8.9 (1.9-31.6) **Voids/day, 9 months, mean change (95% CI):** -2.5 (-2.9 to -2.4) P = 0.0001 **Void frequency, 9 mos, median change:** -22% **Urge incontinence episodes/day, 3 mos, mean (range):** 1.3 (0.0-24.0) **Urge incontinence episodes/day, mean change (95% CI):** -2.1 (-2.4 to -1.9) P = 0.0001 **Urge incontinence episodes/day, 3 mos, mean (range):** 1.5 (0.0-24.0) **Urge incontinence episodes/day, mean change (95% CI):** -2.0 (-2.2 to -1.7) P = 0.0001	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Appell, Abrams et al., 2001 (continued)				**Urge Incontinence episodes/day, median change, %:** -76% **Volume voided, 3 mos, mean mL (range):** 201 (33-444) **Volume voided, 3 mos, mean change mL (95% CI):** +41 (36-45) P = 0.0001 **Volume voided, 9 mos, mean change mL (range):** 199 (34-514) **Volume voided mean change mL (95% CI):** +40 (35-45) P = 0.0001 **Volume voided, 9 mos, median change, %:** +22% **Improvement, 9 mos, %:** 65 **Any adverse event, n (%):** 652 (76) **ANS, n (%):** 268 (31) **General, n (%):** 219 (26) **CNS/PNS, n (%):** 82 (10) **GI, n (%)** 201 (24) **Respiratory, n (%):** 139 (16) **Urinary, n (%):** 165 (19)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Appell, Abrams et al., 2001 (continued)				**Dry mouth, n (%):** 236 (28) **Mild dry mouth, %:** 19% **Moderate dry mouth, %:** 7% **Severe dry mouth, %:** 2% **UTI, n (%):** 106 (12) **Headache, n (%):** 57 (7) **Constipation, n (%):** 57 (7) **Abdominal pain, n (%):** 50 (6) **Upper respiratory tract infection, n (%):** 45 (5) **Serious adverse events, n:** 72 **Discontinued due to AE, n (%):** 73 (9) **Reduced dosage to 1 mg bid, n (%):** 108 (13%)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Capo et al. 2008 **Country and setting:** US, 207 centers **Enrollment period:** NR **Funding:** Astellas Pharma US, Inc., and GlaxoSmithKline **Author industry relationship disclosures:** 5/5 Astellas (4) Boehringer Mannheim Pharmaceuticals (1) Cephalon Inc. (1) GlaxoSmithKline (3) Reliant Pharmaceuticals (1) Schering Plough Corporation (1) Abbott (1) Akros (1) AstraZenica (1) Johnson & Johnson (1) Lilly (1) Manking (1) Merck (1) Novartis (1) NovoNordisk (1) Pfizer Inc. (1) Solvay (1) Takeda & TAP (1) Pri Med (1) Lucente (1)	**Design:** RCT **Intervention:** 12-wk treatment with 5 mg solifenacin succinate. Dosage could be increased at wk 4 and wk 8 to 10 mg, maintained or decreased in response to pt perceived efficacy and tolerability **Groups:** **G1:** Hispanic subgroup of G2 **G2:** full study population including G1 **N at enrollment:** **G1:** 94 **G2:** 2205 **N at follow-up, range:** **G1:** 47-80 **G2:** 1254-2005 **Age, yrs ± SD:** **G1:** 51.8 ± 12.8 **G2:** 59.7 ± 14.4 **Weight in lbs, mean ± SD:** **G1:** 171.1±36.4 **G2:** 182.2±47.0 **Race/ethnicity, n (%)** **G1**: Hispanic 94 (100) **G2:** White 1761 (79.9) Hispanic 94 (4.3) Black 274 (12.4) Asian 59 (2.7) Other 17 (0.8) **Women, N (%):** **G1:** 74 (78.7) **G2:** 1813 (82.2)	**Inclusion criteria:** • ≥ 18 yrs of age • OAB symptoms ≥3 mos • Toilet without difficulty • Washout of other OAB meds ≥ 7 days • Non-drug treatment of OAB if established ≥ 4 wks prior to study and continued **Exclusion criteria:** • SUI • Stress predominant MUI • UTI or chronic inflammation clinically significant outflow • Obstruction due to BPH • Narrow-angle glaucoma • Urinary or gastric retention • Severe renal or hepatic impairment • Chronic severe constipation or gastrointestinal obstructive disease • Bladder cancer • Women not using a reliable contraceptive • Hypersensitivity to the study medication, any of its components, or to anticholinergic medication	**Urge incontinence, n (%):** **G1:** 63 (67.0) **G2:** 1586 (71.9) **Urinary urgency, n %:** **G1:** 88 (93.6) **G2:** 2007 (91.0) **Frequency, n, (%):** **G1:** 86 (91.5) **G2:** 1969 (89.3) **Nocturia, n (%):** **G1:** 79 (84.0) **G2:** 1792 (81.3) **Patient perception of bladder condition, mean score:** **G1:** 4.0 **G2:** 4.0 **Most bothersome OAB symptom-frequency, n %:** **G1:** 38 (40.4) **G2:** 619 (28.1) **Most bothersome OAB symptom-urinary urgency, n %:** **G1:** 22 (23.4) **G2:** 508 (23.0) **Most bothersome OAB symptom-urge incontinence, n %:** **G1:** 17 (18.1) **G2:** 602 (27.3)	**Increased dosage 5 mg/day, n (%)-Wk 4:** **G1:** 46 (48.9) **Increased dosage 10 mg/day, n (%)-Wk 4:** **G1:** 37 (39.4) **Discontinued, n Wk 4:** **G1:** 1 **Increased dosage 5 mg/day, n (%)-Wk 8:** **G1:** 31 (33.0) **Increased dosage 10 mg/day, n (%)-Wk 8:** **G1:** 39 (41.5) **Discontinued-Wk 8, n:** 1 **Returned to 5 mg/day-Wk 8, n:** 5 **Increased dosage to 10 mg/day-Wk 8, n:** 12 **Patient Perception of Bladder, mean Wk 4:** **G1:** 3.3* **G2:** 3.3* **Patient Perception of Bladder, mean Wk 8:** **G1:** 2.8* **G2:** 2.8*	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: NR Baseline characteristics: - Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Capo et al. 2008 (continued)	**Parity :** NR		**Most bothersome OAB symptom-nocturia, n %:** **G1:** 12 (12.8 **G2:** 337 (15.3) **Most bothersome OAB symptom-none specified, n %:** **G1:** 5 (5.3) **G2:** 139 (6.3)	**Patient Perception of Bladder, mean Wk 12:** **G1:** 3.0* **G2:** 2.9* *P<0.001 vs BL **Symptom bother from VAS, change from Baseline, mean scores (mm), p-value, CI:** **Urinary urgency:** **G1:** -39.2 P<0.001, -45.9, -32.5 **G2:** -39.5 P<0.001, -41.0, -38.1 **Urge Incontinence:** **G1:** -37.7 P<0.001, -46.0, -29.4 **G2:** -40.1, P<0.001, -41.8, -38.4 **Frequency:** **G1:** -40.0 P<0.001, -46.9, -33.2 **G2:** -41.8 P<0.0001, -43.3, -40.3 **Nocturia:** **G1:** -43.2 P<0.001, -50.4, -36.1 **G2:** -36.9, -38.4, -35.4 **OAB-q subscales at end-point, change from baseline, mean, p-value, CI:** **Symptom bother:** **G1:** -29.1 P<0.001, -34.8, -23.4 **G2:** -29.6 P<0.001, -30.7, -28.6	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Capo et al. 2008 (continued)				**Coping:** **G1:** 24.0 P<0.001, 18.0, 30.1 **G2:** 27.4 P< 0.001 26.2, 28.5 **Concern:** **G1:** 25.8 P<0.001, 19.5, 32.2 **G2:** 29.6 P< 0.001, 28.4, 30.8 **Sleep:** **G1:** 25.7 P<0.001, 19.4, 32.0 **G2:** 27.3 P< 0.001, 26.1, 28.5 **Social Interaction** **G1:** 15.9 P<0.001, 11.5, 20.3 **G2:** 14.7 P< 0.001, 13.7, 15.6 **Overall Health-related QoL:** **G1:** 23.2 P<0.001, 18.0, 28.5 **G2:** 25.4 P< 0.001, 24.4, 26.4 **Any Adverse Event, n (%):** **G1:** 48 (51.4) **G2:** 1321 (59.4) **Dry mouth, n (%):** **G1:** 17 (18.1) **G2:** 477 (21.4) **Constipation, n (%):** **G1:** 12 (12.8) **G2:** 295 (13.3) **Headache, n (%):** **G1:** 3 (3.2) **G2:** 76 (3.4)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Capo et al. 2008 (continued)				**Dizziness, n (%):** **G1:** 2 (2.1) **G2:** 27 (1.2) **Blurred vision, n (%):** **G1:** 4 (4.3) **G2:** 57 (2.6) **Palpitations, n (%):** **G1:** 2 (2.1) **G2:** 6 (0.3) **Upper respiratory tract infection, n (%):** **G1:** 3 (3.2) **G2:** 68 (3.1) **UTI, n (%):** **G1:** 3 (3.2) **G2:** 76 (3.4) **Bronchitis, n (%):** **G1:** 3 (3.2) **G2:** 31 (1.4) **Nasopharyngitis, n (%):** **G1:** 2 (2.1) **G2:** 50 (2.3) **Influenza, n (%):** **G1:** 2 (2.1) **G2:** 11 (0.5) **Insomnia, n (%):** **G1:** 2 (2.1) **G2:** 17 (0.8) **Depression, n (%):** **G1:** 2 (2.1) **G2:** 19 (0.9) **Hypertension, n (%):** **G1:** 2 (2.1) **G2:** 16 (0.7)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Dmochowski et al., 2002 **Country and setting:** US, Community **Enrollment period:** NR 2 week washout 12 week treatment period **Funding:** NR **Author industry relationship disclosures:** 7 of 7 Abbot (1) Alza (3) Amgen (1) AstraZeneca (1) Bayer (1) Bioform (1) Genyx (1) Glaxo (1) Interneuron (2) Lilly (2) Merck (1) Otsulta (1) Pharmacia (3) Pfizer (1) Praecis (2) Roche (1) Seprecor (1) Surx (1) Synthelabo (1) Vivus (1) Watson (7) Yamanouchi (1)	**Design:** RCT Followed by: 12 week open label dose titration **Intervention:** Oxybutynin TDS vs placebo **Groups:** **G1:** OXY TDS 1.3 mg **G2:** OXY TDS 2.6 mg **G3:** OXY TDS 3.9 mg **G4:** placebo **N at enrollment:** **G1**: 130 **G2:** 133 **G3:** 125 **G4:** 132 **N at follow-up:** **G1**: 128 **G2:** 131 **G3:** 123 **G4:** 130 **Women, N (%):** **G1:** 120 (92.3) **G2:** 123 (92.5) **G3:** 114 (91.2) **G4:** 121 (91.7) **Age, mean ± SD:** **G1:** 61.5 ± 11.8 **G2:** 61.9 ± 13.5 **G3:** 59.4 ± 14.5 **G4:** 62.7 ± 13.1 **Race/ethnicity, n (%):** **White:** **G1:** 119 (91.5) **G2:** 118 (88.7) **G3:** 118 (94.4) **G4:** 118 (89.4) **Black:** **G1:** 7 (5.4) **G2:** 10 (7.5) **G3:** 3 (2.4) **G4:** 11 (8.3)	**Inclusion criteria:** • Age ≥ 18 • History of OAB • ≥ 10 episodes UUI either pure urge or predominant urge on 7 day voiding diary • ≥ 56 voids/ 7 day diary • Average recorded urinary volume of ≤ 350 mL **Exclusion criteria:** • Incontinence related to chronic illness • Concomitant medications • History of lower urinary tract surgery in ≤ 6 mos • IC • Urethral syndrome • Painful bladder syndrome • Overflow urinary incontinence • Alcohol/drug abuse • Known hypersensitivity to oxybutynin, similar compounds or transdermal systems • Active skin disorder • Narrow angle glaucoma • Excessive caffeine intake > 5 cups/day	**Incontinence episodes/week, median:** **G1:** 31.0 **G2:** 30.0 **G3:** 31.0 **G4:** 30.0 **Voids/day, mean ± SD:** **G1:** 12.4 ± 2.9 **G2:** 12.1 ± 3.3 **G3:** 12.3 ± 3.3 **Voided volume (mL), mean:** **G1:** 175 **G2:** 165 **G3:** 156 **G4:** 170 **Open Label: Incontinence episodes/week, open label, median:** **G1:** 30.0 **G2:** 29.0 **G3:** 37.0 **G4:** NA **Prior years incontinent, years, mean ± SD:** **G1:** 9.1 ± 10.3 **G2:** 8.9 ± 8.8 **G3:** 9.9 ± 9.8 **G4:** 9.1 ± 9.1 **IIQ (QoL), total score, mean:** **G1:** 167 **G2:** 161 **G3:** 144 **G4:** 160 **Prior anticholinergic treatment, n, (%):** **G1: 30 (23.1)** **G2: 28 (21.1)** **G3: 28 (22.4)** **G4: 27 (20.5**	**Incontinence episodes/ week, median change:** **G1:** -16.0 **G2:** -14.0 **G3:** -19.0 **G4:** -14.5 **G3/G4:** P < 0.0165 **Voids/day, mean change ± SD:** **G1:** -1.8 ± 2.6 **G2:** -1.8 ± 2.4 **G3:** -2.3 ± 2.5 **G4:** -1.7 ± 3.0 **G3/G4:** P = 0.0457 **Voided volume, mL, mean increase ± SD:** **G1:** -2 **G2:** 19 **G3:** 24 **G4:** 6 **G3/G4:** P = 0.0063 **G2/G4:** P = 0.0157 **Open Label: Incontinence episodes/week, median change:** **G1:** -18.0 **G2:** -17.0 **G3:** -19.0 **G4:** NA **IIQ (QoL), total score, mean change:** **G1:** 119 **G2:** 104 **G3:** 89 **G4:** 113 **G3/G4:** P = 0.0327 **UDI (QoL), total score, mean ± SD:** **G1:** NR **G2:** NR **G3:** 78.8 ± 51.9 **G4:** 94.7 ± 50.0 **G3/G4:** P = 0.0266	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Dmochowski et al., 2002 (continued)	**Other:** **G1:** 4 (3.1) **G2:** 5 (3.8) **G3:** 4 (3.2) **G4:** 3 (2.3)			**Dry mouth, n (%):** **G1:** 6 (4.6) **G2:** 9 (6.8) **G3:** 12 (9.6) **G4:** 11 (8.3) **Dizziness, n (%):** **G1:** 2 (1.5) **G2:** 4 (3.0) **G3:** 5 (4.0) **G4:** 5 (3.8) **Dysuria, n (%):** **G1:** 1 (0.8) **G2:** 3 (2.3) **G3:** 3 (2.4) **G4:** 0 (0) **Somnolence, n (%):** **G1:** 1 (0.8) **G2:** 0 (0) **G3:** 2 (1.6) **G4:** 1 (0.8) **Nausea, n (%):** **G1:** 6 (4.6) **G2:** 5 (3.8) **G3:** 2 (1.6) **G4:** 7 (5.3) **Constipation, (%):** **G1:** 7 (5.4) **G2:** 3 (2.3) **G3:** 1 (0.8) **G4:** 4 (3.0) **Palpitations, n (%):** **G1:** 1 (0.8) **G2:** 0 (0) **G3:** 1 (0.8) **G4:** 0 (0) **Vision abnormal, n (%):** **G1:** 3 (2.3) **G2:** 2 (1.5) **G3:** 0 (0) **G4:** 2 (1.5) **Localized application site reactions, n (%):** **G1:** 32 (26.4) **G2:** 7 (5.7) **G3:** 8 (6.9)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Dmochowski et al., 2002 (continued)				**Application site erythema, n (%):** **G1:** 23 (19) **G2:** 29 (23.6) **G3:** 14 (12.0) **Application site erythema, mild, double blind period, n (%):** **G1:** 79 (31.5) **G2:** 29 (36.2) **G3:** NA **Application site erythema, moderate, double blind period, n (%):** **G1:** 46 (18.3) **G2:** 46 (18.1) **G3:** NA **Application site erythema, severe, double blind period, n (%):** **G1:** 6 (2.4) **G2:** 8 (3.1) **G3:** NA **Application site erythema, mild, open label, n (%):** **G1:** 18 (34.6) **G2:** 58 (38.4) **G3:** 87 (43.9) **Application site erythema, moderate, open label, n (%):** **G1:** 7(13.5) **G2:** 23 (15.2) **G3:** 24 (12.1) **Application site erythema, severe, open label, n (%):** **G1:** 0 (0) **G2:** 2 (1.3) **G3:** 0 (0)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Dmochowski et al. 2003 **Country and setting:** US; Community **Enrollment period:** **NR** 2 week washout 12 week treatment period **Funding:** **Watson Pharma** **Author industry relationship disclosures:** 6 of 6 Watson Pharma	**Design:** RCT **Intervention:** Oxybutynin TDS vs Tolterodine ER vs placebo, 2 week washout plus 12 weeks treatment period; drug/placebo applied transdermally twice weekly to the abdomen and oral capsule ingested once daily **Groups:** **G1:** OXY TDS 3.9 mg/day **G2:** Tolterodine ER 4 mg daily **G3:** placebo **N at enrollment:** **G1**: 121 **G2:** 123 **G3:** 117 **Total:** 361 **N at follow-up:** **G1**: NR **G2:** NR **G3:** NR **Total:** 320 (89%) **Age, mean yrs ± SD:** **G1:** 63.1 ± 12.0 **G2:** 62.9 ± 13.5 **G3:** 64.5 ± 12.3 **Race/ethnicity, mean (%): White:** **G1:** 111 (91.7) **G2:** 120 (97.6) **G3:** 110 (94.0) **Race/ethnicity, mean (%): Black:** **G1:** 8 (6.6) **G2:** 1(0.8) **G3:** 4 (3.4)	**Inclusion criteria:** • ≥ 18yo men and women • Current pharmacological treatment for OAB with beneficial response • ≥4 episodes UUI episodes either pure urge or predominant urge on 3 day voiding diary • ≥ 24 voids/ 3 day diary • Average recorded urinary volume of ≤350 ml **Exclusion criteria:** • History of lower urinary tract surgery in previous 6 months • IC • Urethral syndrome • Painful bladder syndrome • Overflow urinary incontinence	**Incontinence episodes/ day, mean ± SD:** **G1:** 4.7 ± 2.9 **G2:** 5.0 ± 2.9 **G3:** 5.0± 3.2 **Incontinence episodes/day, median:** **G1:** 4 **G2:** 4 **G3:** 4 **Void frequency/ day, mean ± SD:** **G1:** 12.4 ± 2.9 **G2:** 12.1 ± 3.3 **G3:** 12.3 ± 3.3 **Void frequency/day, median:** **G1:** 12 **G2:** 12 **G3:** 12 **Voided volume, mL, mean ± SD:** **G1:** 165 ± 62 **G2:** 165 ± 61 **G3:** 175 ± 68 **Voided volume, mL, median:** **G1:** 160 **G2:** 150 **G3:** 171 **Global assessment of disease, QOL, baseline, (SD):** **G1:** 65 (19) **G2:** 63 (20) **G3:** 65 (20) **IIQ (QOL)- travel domain, baseline, (SD):** **G1:** 49 (28) **G2:** 47 (29) **G3:** 43 (29)	**Incontinence episodes/ day, mean ± SD:** **G1:** 1.9 ± 2.7 **G2:** 1.9 ± 3.0 **G3:** 2.9 ± 3.8 P=0.0137 G1 v G3 P=0.0011 G2 v G3 P=0.5878 G1 v G2 **Incontinence episodes/day, mean change±SD** **G1:** 2.9±3.0 **G2:** 3.2±2.8 **G3:** 2.1±3.0 **Incontinence episodes/day, median** **G1:** 1 **G2:** 1 **G3:** 2 **Incontinence episodes/day, median change** **G1:** 3 **G2:** 3 **G3:** 2 **Void frequency/ day, mean ± SD:** **G1:** 10.4 ± 3.2 **G2:** 9.9 ± 3.1 **G3:** 10.9 ± 3.8 P=0.101 G1 v G3 P= 0.0025 G2 v G3 P=0.276 G1 v G2 **Void frequency/day, mean change±SD:** **G1:** -1.9±2.7 **G2:** -2.2±2.6 **G3:** -1±1.4 **Void frequency/day, median:** **G1:** 10 **G2:** 10 **G3:** 10	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: - Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Dmochowski et al. 2003 (continued)	**Race/ethnicity, mean (%): Other:** **G1:** 2 (1.6) **G2:** 2 (1.6) **G3:** 3 (2.6) **Women, N (%):** **G1:** 109 (90.1) **G2:** 117 (95.1) **G3:** 109 (93.2) **Parity :** NR **Prior antimuscarinic treatment, Tolterodine, n, (%):** **G1:** 57 (47) **G2:** 60 (49) **G3:** 54 (46) **Prior antimuscarinic treatment, Oxybutynin, n, (%):** **G1:**61 (51) **G2:** 59 (48) **G3:** 59 (50) **Prior antimuscarinic treatment, Other, n, (%):** **G1:** 7 (6) **G2:** 6 (5) **G3:** 6 (5)		**UDI (QOL), irritative symptoms, baseline, (SD):** **G1:** 62 (20) **G2:** 66 (18) **G3:** 63 (20)	**Void frequency/day, median change:** **G1:** 2 **G2:** 2 **G3:** 1 **Voided volume, mL, mean ± SD:** **G1:** 198 ± 84 **G2:** 193 ± 75 **G3:** 182 ± 84 P=0.0010 G1 v G3 P=0.0017 G2 v G3 P=0.7690 G1 v G2 **Voided volume, mL, mean change±SD:** **G1:** 32±55 **G2:** 29±57 **G3:** 9±63 **Voided volume, mL, median:** **G1:** 188 **G2:** 189 **G3:** 165 **Voided volume, mL, median change:** **G1:** 24 **G2:** 29 **G3:** 5.5 **Global assessment of disease, QOL, change, (SD):** **G1:** 30 (30) **G2:** 33 (28) **G3:** 21 (31) P=0.0106 G1 v G3 P=0.001 G2 v G3 P=0.1861 G1 v G3 **IIQ (QOL)- travel domain, change, (%):** **G1:** 23 (25) **G2:** 22 (29) **G3:** 11 (30) P=0.0018 G1 v G3 P=0.0045 G2 v G3	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Dmochowski et al. 2003 (continued)				**UDI (QOL), irritative symptoms, change, (SD):** **G1**: 25 (26) **G2:** 28 (26) **G3:** 18 (24) P=0.0156 G1 v G3 P= 0.0010 G2 v G3 **Treatment compliance with assigned dosage regimen: 92%:** **Frequency decreased to a greater extent for patients with > 14 micturations per day at baseline G1: -2.9/day, p=0.0036 (data for other groups not reported)** **Adverse effects:** **Dry mouth, %:** **G1:** 4.1 **G2:** 7.3 **G3:** 1.7 P=0.2678 G1 v G3 P=0.0379 G2 v G3 **Constipation, (%):** **G1:** 3.3 **G2:** 5.7 **G3:** NR **Mild systemic adverse effects, n (%):** **G1: 15 (12.4)** **G2: 13 (10.6)** **G3: 6 (5.1)** **Moderate systemic adverse effects, n (%)** **G1: 7 (5.8)** **G2: 13 (10.6)** **G3: 7 (6.0)**	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Dmochowski et al. 2003 (continued)				**Severe systemic adverse effects, n (%)** G1: 1 (0.8) G2: 3 (2.4) G3: 1 (0.9) **Mild localized application site reactions, n (%):** **G1:** 9 (7.4) **G2:** 2 (1.6) **G3:** 5 (4.3) **Moderate localized application site reactions, n (%):** **G1:** 17 (14.0) **G2:** 4 (3.3) **G3:** 2 (1.7) **Severe localized application site reactions, n (%):** **G1:** 6 (5.0) **G2:** 1 (0.8) **G3:** 1 (0.9) **Treatment discontinuation due to adverse effects, n (%):** **G1**: 13 (10.7) (12 due to application site reactions, 1 due to hot flushes) **G2:** 2 (1.6) (1 due to fatigue and 1 due to dizziness) **G3:** NR **Postvoid residual>150 mL at end of treatment:** **G1:** 4 **G2:** 4 **G3:** 3 No reports of symptomatic urinary retention **Withdraw due to AEs:** 23	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Elinoff et al. 2006 Roberts et al. 2006 **Country and setting:** US; 82 Primary care & Ob-Gyn offices **Enrollment period:** NR **Funding:** Pfizer **Author industry relationship disclosures:** 6 of 6 Pfizer (6) Astellas (1) Novartis (1)	**Design:** Open-label, single-arm cohort **Intervention:** Tolterodine ER 4 mg qd for 12 wks **Groups:** NA **N at enrollment:** 896 **N at follow-up:** 758 **Age, yrs ± SD:** 56 ± 15 **Race/ethnicity, N (%):** White: 691 (80) Black: 94 (11) Asian: 22 (3) Other: 53 (6) **Women, N (%):** 708 (82) **Parity:** NR	**Inclusion criteria:** • 18+ years old • OAB symptoms for ≥3 mos • ≥ 8 voids/day • 2+ episodes of urgency or UUI in a 3-d period • 3+ on the OAB Bother Rating Scale **Exclusion criteria:** • Stress, functional, or overflow incontinence • Acute UTI • Clinically significant LUT pathology • Indwelling catheter • Intermittent self-cath • Use of anticholinergics, antimuscarinics for OAB, drugs to trt UUI, potent cytochrome P450 3A4 inhibitors, or investigational drugs	**Duration of OAB, yrs ± SD:** 6 (8) **Trt duration w/ study drug, days (SD):** 80 (19) **Daytime frequency episodes, #/d, mean ± SD:** 9.3 ± 2.8 **Nocturnal frequency episodes, #/d, mean ± SD:** 3.0 ± 1.7 **UUI episodes, #/d, mean ± SD:** 2.7 ± 3.2 **Urgency episodes, #/d, mean ± SD:** 5.0 ± 3.8 OAB-q scores Symptom bother: 60.0 Coping: 50.0 Concern: 51.4 Sleep: 44.4 Social Interaction: 84.0 Total HRQL: 55.2 AUA-SI Total: 18 Irritative: 10 Obstructive: 8 **Most bothersome symptom, n (%)** Daytime frequency: 256 (30) Nocturnal frequency: 241 (28) UUI: 206 (24) Urgency: 154 (18)	**Urgency, mean change% (95% CI). wk 12:^** -81.3 (-85.7, -73.3) **UUI episodes, mean change % (95% CI), wk 12:^** -80.0 (-85.7, -69.7) **Nighttime frequency, mean change % (95% CI), wk 12:^** -40.0 (-44.4, -33.3) **Daytime frequency, mean change % (95% CI), wk 12:^** -31.6 (-34.6, -28.1) **OAB-q scores, Median change from baseline to 12 wks (95% CI):** Symptom bother: -37.5 (-37.5 , -35.0) Coping: 32.5 (30.0, 35.0) Concern: 34.3 (31.4, 37.1) Sleep: 28.0 (28.0, 32.0) Social Interaction: 12.0 (12.0 to 16.0) Total HRQL: 28.9 (27.2 to 31.2)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: + Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Elinoff et al. 2006 Roberts et al. 2006 (continued)				AUA-SI, Median change from baseline to 12 wks (95% CI) *Total: -9 (-9 to -8) *Irritative: -5 (-5 to -5) *Obstructive: -4 (-4 to -3) *: p<0.001 **Urgency, mean change, wk 12 % (95% CI):** -75.0 (-80.0, -71.4) **Change from baseline to wk 12, UUI episodes, mean % (95% CI):** -86.1(-80.0, -71.4) **Nighttime frequency, mean change % (95% CI):** -37.5 (-40.0, -33.3) **Daytime frequency, mean change, wk 12 % (95% CI):** **-**29.0 (-31.0, -27.3) **All-cause AE:** 51% **Discontinued treatment, n %:** 15 (7) **Trt-related AE:** 23% Dry mouth, %: 10.0 Constipation, %: 3.7% Headache, %: 3.0% UTI, %: 2.7%	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Garely et al., 2007* Mallett et al., 2007^ **Country and setting:** US, multicenter (207 sites) **Enrollment period:** NR **Funding:** Astellas Pharma US Glaxo-SmithKline **Author industry relationship disclosures:** 4 of 4* Astellas (4) Pfizer (1) Novartis (1) 4 of 4^ Astellas (3) GlaxoSmthKline (2) Novartis (1) Watson (1) Yamanouchi (1)	**Design:** Prospective case series **Intervention:** Solifenacin qd (started on 5 mg/d; option of increasing to 10 mg/d at week 4; option to maintain 10 mg dose or decrease to 5 mg at wk 8); for 12 weeks of treatment **10 mg dose, n (%):** 4 wks: **G1:** 55% 8 wks: **G1:** 59% (8% went back to 5mg; 19% increased to 10 mg) **Groups:** **G1:** Urge incontinence as most bothersome symptom **G2:** Black participants **G3:** Full study population **N at enrollment:** **G1:**582 **G2:** 274 **G3:** 2205 **Age, mean yrs ± SD:** **G1:** 60.9 ± 13.1 **G2:** 54.7 ± 13.6 **G3:** 59.7 ± 14.4 **Race/ethnicity, n (%):** **White:** **G1:** 493 (84.7) **G3:** 1761 (79.9) **African American:** **G1:** 62 (10.7%) **G3:** 274 (12.4%)	**Inclusion criteria:** • -Age ≥ 18 • Symptoms of OAB for ≥ 3 mos • Ambulatory • Able to use the toilet without difficulty • Urgency, UUI, frequency or nocturia ≥ 3 mos **Exclusion criteria:** • Previous use of solifenacin	**UUI, n (%):** **G1:** 582 (100%) **G2:** NR **G3:** 1596 (71.9%) **Urgency, n (%):** **G1:** 534 (91.8) **G2:** NR **G3:** 2007 (91.0) **Frequency, n (%):** **G1:** 488 (83.8) **G2:** NR **G3:** 1969 (89.3) **Nocturia, n (%):** **G1:** 438 (75.3) **G2:** NR **G3:** 1792 (81.3) **Most bothersome OAB symptom** **Urgency, n (%):** **G2:** 48 (17.5) **G3:** 508 (23.0) **UUI, n (%):** **G1:** 582 (100) **G2:** 63 (23.0) **G3:** 602 (27.3) **Frequency, n (%):** **G2:** 106 (38.7) **G3:** 619 (28.1) **Nocturia, n (%):** **G2:** 34 (12.4) **G3:** 337 (15.3) **None specified, n (%):** **G2:** 23 (8.4) **G3:** 139 (6.3) **OAB for 3 mos -1 yr, n (%):** **G1:** 57 (9.8) **G3:** 349 (15.8%) **OAB for 1-5 yrs, n (%):** **G1:** 294 (50.5) **G3:** 1124 (51.0) **OAB for >5 yrs:** **G1:** 231 (39.7) **G3:** 732 (33.2)	**Patient perception of bladder condition scale, 4 wks, mean:** **G1:** 3.3* **G2:** 3.1* **G3:** 3.3* **Patient Perception of Bladder Condition Scale, 8 wks, mean:** **G1:** 3.0* **G2:** 2.7* **G3:** 2.9* **Patient Perception of Bladder Condition Scale, 12 wks or early termination, mean:** **G1:** 2.9* **G2:** 2.6* **G3:** 2.9* **Symptom severity, mean VAS, wk 4:** Urinary urgency: **G1:** 40.9 **G2:** 39.7 **G3:** 40.6 UUI: **G1:** 36.9 **G2:** 29.9 **G3:** 32.8 Frequency: **G1:** 34.5 **G2:** 39.3 **G3:** 39.9 Nocturia: **G1:** 30.4 **G2:** 35.4 **G3:** 38.2	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: - Loss to followup: NR Drop-out rates: + Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Garely et al., 2007* Mallett et al., 2007^ (continued)	**Other:** **G1:** 27 (4.6%) **G3:** 170 (7.7%) **Women, n (%):** **G1:** 536 (92.1) **G2:** 213 (77.7) **G3:** 1813 (82.2) **Weight (lbs), mean ± SD (range):** **G2:** 198 ± 51.6 (100-400) **G3:** 182.2 ± 47.0 (80-413)		**Perception of bladder condition scale (mean):** **G1:** 4.6 **G2:** 4.2 **G3:** 4.4 **Symptom severity, mean VAS:** Urinary urgency: **G1:** 72.3 **G2:** 70.8 **G3:** 68.7 UUI: **G1:** 78.5 **G2:** 70.8 **G3:** 64.1 Frequency: **G1:** 65.7 **G2:** 70.8 **G3:** 70.6 Nocturia: **G1:** 57.9 **G2:** 66.5 **G3:** 65.2 **OAB-q, symptom severity, mean ± SE:** **G1:** 63.1 ± 0.84 **G2:** 59.4 (NR) **G3:** 56.9 (NR) **OAB-q, coping, mean ± SE:** **G1:** 48.9 ± 1.18 **G2:** 46.5 (NR) **G3:** 53.1 (NR) **OAB-q, concern, mean ±SE :** **G1:** 43.1 ± 1.12 **G2:** 46.6 (NR) **G3:** 50.8 (NR) **OAB-q, sleep, mean ± SE:** **G1:** 55.2 ± 1.22 **G2:** 43.8 (NR) **G3:** 49.2 (NR) **OAB-q, social, mean ± SE:** **G1:** 73.6 ± 1.14 **G2:** 68.9 (NR) **G3:** 76.0 (NR)	**Symptom severity, mean VAS, wk 8:** Urinary urgency: **G1:** 31.1 **G2:** 29.4 **G3:** 30.0 UUI: **G1:** 28.9 **G2:** 22.1 **G3:** 24.5 Frequency: **G1:** 24.9 **G2:** 27.0 **G3:** 28.6 Nocturia: **G1:** 25.4 **G2:** 36.4 **G3:** 29.0 **Symptom severity, mean VAS, wk 12 (or early termination):** Urinary urgency: **G1:** 27.5 **G2:** 25.3 **G3:** 28.0 UUI: **G1:** 24.3 **G2:** 20.0 **G3:** 22.7 Frequency: **G1:** 21.6 **G2:** 24.5 **G3:** 27.4 Nocturia: **G1:** 22.0 **G2:** 21.4 **G3:** 27.2 **Symptom severity, VAS, mean change from baseline (95% CI):** Urinary urgency*: **G1:** -43.1 (-45.8, -40.4) **G2:** -43.0 (-47.6, -38.5) **G3:** -39.5 (-41.0, -38.1)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Garely et al., 2007* Mallett et al., 2007^ (continued)			**OAB-q, HRQoL, mean ± SE:** **G1:** 53.4 ± 1.01 **G2:** 50.5 (NR) **G3:** 56.3 (NR)	UUI*: **G1:** -51.7 (-54.5, -49.0) **G2:** -42.3 (-47.8, -36.8) **G3:** -40.1 (-41.8, -38.4) Frequency*: **G1:** -42.0 (-45.0, -39.0) **G2:** -44.2 (-48.8, -39.6) **G3:** -41.8 (-43.3, -40.3) Nocturia*: **G1:** -34.4 (-37.3, -31.5) **G2:** -42.6 (-47.5, -37.8) **G3:** -36.9 (-38.4, -35.4) **OAB-q, symptom severity, mean change (± SE or 95% CI)*:** **G1:** -35.9 ± 1.08 **G2:** -33.6 (-37.0, -30.3) **G3:** -29.6 (-30.7, -28.6) **OAB-q, coping, mean change (± SE or 95% CI)*:** **G1:** 32.5 ± 1.16 **G2:** 32.9 (29.3, 36.6) **G3:** 27.4 (26.2, 28.5) **OAB-q, concern, mean change (± SE or 95% CI)*:** **G1:** 37.0 ± 1.21 **G2:** 34.0 (30.4, 37.6) **G3:** 29.6 (28.4, 30.8) **OAB-q, sleep, mean change (± SE or 95% CI)*:** **G1:** 26.0 ± 1.19 **G2:** 33.8 (29.7, 37.9) **G3:** 27.3 (26.1, 28.5)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Garely et al., 2007* Mallett et al., 2007^ (continued)				**OAB-q, social, mean change ± SE (95% CI)*:** **G1:** 17.7 ± 1.03 **G2:** 20.1 (16.7, 23.5) **G3:** 14.7 (13.7, 15.6) **OAB-q, HRQoL, mean change (± SE or 95% CI)*:** **G1:** 29.6 ± 1.02 **G2:** 30.8 (27.5, 34.1) **G3:** 25.4 (24.4, 26.4) **Side effects, n (%):** **G1:** 357 (61.3) **G2:** 128 (46.4) **G3:** 1321 (59.4) **Dry mouth, n (%):** **G1:** 104 (17.9) **G2:** 36 (13.0) **G3:** 477 (21.4) **Constipation, n (%):** **G1:** 85 (14.6) **G2:** 19 (6.9) **G3:** 295 (13.3) **Nausea, n (%):** **G1:** NR **G2:** 7 (2.5) **G3:** 39 (1.8) **Headache, n (%):** **G1:** 21 (3.6) **G2:** 9 (3.3) **G3:** 76 (3.4) **Blurred vision, n (%):** **G1:** 20 (3.4) **G2:** 7 (2.5) **G3:** 57 (2.6)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Garely et al., 2007* Mallett et al., 2007^ (continued)				**Upper respiratory tract infection, n (%):** **G1:** 27 (4.6) **G2:** 7 (2.5) **G3:** 69 (3.10) **UTI, n (%)** **G1:** 21 (3.6%) **G2:** NR **G3:** NR **Rash, n (%):** **G1:** NR **G2:** 6 (2.2) **G3:** 22 (0.99) **Nasopharyngitis, n (%)** **G1:** 13 (2.2%) **G2:** NR **G3:** NR **Cough, n (%)** **G1:** 12 (2.1%) **G2:** NR **G3:** NR **Withdrew, n (%):** **G1:** NR **G2:** 21 (7.6) **G3:** 216 (9.7)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Giannitsas et al., 2004 **Country and setting:** Greece, Specialty treatment center **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Randomized for which drug to receive first two-way crossover, table of random numbers **Intervention:** Oxybutynin 15 mg tid vs Tolterodine 4mg bid; 6 weeks treatment with 3-4 weeks washout **Groups:** **G1:** Oxybutynin 15 mg tid **G2:** Tolterodine 4mg bid **Stratified by UDS findings:** **a:** high volume (> 250mL); low pressure (< 25cmH_2O) **b:** high volume (≥ 250mL); high pressure (> 25cmH_2O) **C**: low volume (< 250mL); low pressure (< 25cmH_2O) **d**: low volume (< 250mL); high pressure (> 25cmH_2O) **N at enrollment:** Total: 128 **N at follow-up:** Total: 107 **Ga**: 6 **Gb:** 25 **Gc:** 36 **Gd:** 40 **Women, %:** 100	**Inclusion criteria:** • Age ≥ 18 • DO on urodynamics **Exclusion criteria:** • Symptomatic or recurrent UTI • BOO • Neurologic disease • History of previous pelvic surgery • Narrow angle glaucoma • SUI • History of anticholinergic side effects • Interstitial cystitis • Child-bearing age without BC	**Voids/day, mean ± SD:** Total: 8.5 ± 2.63 **Ga:** 7.2 ± NR **Gb:** 8.0 ± 2.40 **Gc:** 8.3 ± 2.31 **Gd:** 9.3 ± 2.91 **Volume (mL)/day, mean ± SD:** Total: 1568.5 ± 398.64 **Ga:** 1756 ± NR **Gb:** 1594.6 ± 326.12 **Gc:** 1678.8 ± 402.15 **Gd:** 1420.5 ± 384.96 **Voided volume (mL), mean ± SD:** Total: 196.1 ± 60.19 **Ga:** 253 ± NR **Gb:** 213.5 ± 53.57 **Gc:** 209.8 ± 57.43 **Gd:** 163.4 ± 51.97 **Bladder volume (mL), first desire void, mean ± SD:** Total: 105.6 ± 39.38 **Ga:** 109 ± NR **Gb:** 128.0 ± 41.78 **Gc:** 94.3± 35.40 **Gd:** 101.1 ± 38.14 **Bladder volume (mL), first contraction, mean ± SD:** Total: 172 ± 98.4 **Ga:** 258 ± NR **Gb:** 303.3 ± 60.51 **Gc:** 111.9 ± 48.11 **Gd:** 124.4 ± 56.66	**Voids/day, mean ± SD:** **G1:** 7.7 ± 1.87 **G2:** 7.6 ± 2.18 **G1a:** 6.1 ± NR **G2a:** 6.3 ± NR **G1b:** 7.3 ± 1.69 **G2b:** 7.0 ± 1.87 **G1c:** 7.5 ± 1.41 **G2c:** 7.2 ± 1.58 **G1d:** 8.3 ± 2.23 **G2d:** 8.4 ± 2.53 **Volume (mL)/day, mean ± SD:** **G1:** 1764.4 ± 333.03 **G2:** 1670.7 ± 338.6 **G1a:** 1862 ± NR **G2a:** 1720 ± NR **G1b:** 1715.6 ± 292.54 **G2b:** 1665.8 ± 251.19 **G1c:** 1847.9 ± 333.81 **G2c:** 1808.1 ± 317.59 **G1d:** 1694.7 ± 331.33 **G2d:** 1550.3 ± 373.65 **Voided volume (mL), mean ± SD:** **G1:** 239.9 ± 64.98 **G2:** 236.7 ± 63.03 **G1a:** 321 ± NR **G2a:** 286 ± NR **G1b:** 243.3 ± 59.56 **G2b:** 248.3 ± 53.91 **G1c:** 252.9 ± 55.75 **G2c:** 258.6 ± 60.63 **G1d:** 217.6 ± 67.07 **G2d:** 203.1 ± 55.43	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: NA Pt selection criteria: + Loss to followup: ++ Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Giannitsas et al., 2004 (continued)	**Age, mean ± SD:** Total: 56 ±16.3 **Ga:** 53 ± 17.2 **Gb:** 57 ± 16.2 **Gc:** 57 ± 16.3 **Gd:** 54 ± 16.6 **Weight (kg), mean ± SD:** Total: 63 ± 5.6 **Ga:** 63 ± 5.6 **Gb:** 70 ± 9.1 **Gc:** 67 ± 8.8 Gd: **69 ± 7.5**		**Pressure (cmH_20), first contraction, mean ± SD:** Total: 34.8 ± 21.97 **Ga:** 17.4 ± NR **Gb:** 37.7 ± 14.03 **Gc:** 18.5 ± 4.60 **Gd:** 50.3 ± 25.14 **Overactivity index, mean ± SD:** Total: 36.8 ± 31.36 **Ga:** 15.3 ± NR **Gb:** 24.8 ± 19.66 **Gc:** 26.3 ± 16.14 **Gd:** 57.0 ± 38.85 **Cystometric capacity (mL), mean ± SD:** Total: 362.8 ± 119.10 **Ga:** 403 ± NR **Gb:** 410.0 ± 97.78 **Gc:** 357.6 ± 127.52 **Gd:** 331.4 ± 114.17	**Bladder volume (mL), first desire void, mean ± SD:** **G1:** 129.0 ± 30.14 **G2:** 117.9 ± 27.62 **G1a:** 144 ± NR **G2a:** 140 ± NR **G1b:** 153.5 ± 25.72 **G2b:** 132.0 ± 31.01 **G1c:** 120.8 ± 25.07 **G2c:** 113.2 ± 23.16 **G1d:** 119.4 ± 29.43 **G2d:** 110.1 ± 26.15 **G1/BL:** P < 0.05 **G2/BL:** P < 0.05 **Bladder volume (mL), first contraction, mean ± SD:** **G1:** 212.9 ± 106.10 **G2:** 206.9 ± 103.56 **G1a:** 382 ± NR **G2a:** 364 ± NR **G1b:** 355.28 ± 74.79 **G1c:** 142.4 ± 43.51 **G2c:** 144.6 ± 48.43 **G1d:** 173.3 ± 57.37 **G2d:** 162.7 ± 53.87 **G1d/BL:** P < 0.01 **G2d/BL:** P < 0.01 **Pressure (cmH_20), first contraction, mean ± SD:** **G1:** 30.9 ± 22.63 **G2:** 30.9 ± 19.01 **G1a:** 14.0 ± NR **G2a:** 17.4 ± NR **G1b:** 35.6 ± 12.86 **G2b:** 29.6 ± 13.56	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Giannitsas et al., 2004 (continued)				**Pressure (cmH_20), first contraction, mean ± SD:** **G1c:** 17.2 ± 6.80 **G2c:** 17.9 ± 6.69 **G1d:** 42.9 ± 28.91 **G2d:** 44.1 ± 20.75 **Overactivity index, mean ± SD:** **G1:** 24.4 ± 22.61 **G2:** 24.7 ± 23.46 **G1a:** 7.0 ± NR **G2a:** 9.5 ± NR **G1b:** 14.1 ± 12.09 **G2b:** 14.1 ± 12.71 **G1c:** 18.3 ± 15.89 **G2c:** 16.9 ± 16.84 **G1d:** 38.9 ± 26.50 **G2d:** 40.7 ± 26.58 **Cystometric capacity (mL), mean ± SD:** **G1:** 419.3 ± 120.86 **G2:** 415.63 ± 114.06 **G1a:** 465 ± NR **G2a:** 453 ± NR **G1b:** 449.6 ± 106.23 **G2b:** 459.4 ± 101.17 **G1c:** 409.9 ± 130.22 **G2c:** 411.05 ± 132.49 **G1d:** 401.8 ± 118.34 **G2d:** 386.7 ± 96.53 **Dry mouth, n (%):** **G1:** 52 (40.6) **G2:** 20 (15.6) **Constipation, n (%):** **G1:** 11 (10.3) **G2:** 3 (2.8) **Discontinued due to AEs, n:** Dry mouth: 12 Palpitations: 1	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Gleason et al. 1999 **Country and setting:** US, Community **Enrollment period:** NR 12 week follow up **Funding:** Alza Corporation **Author industry relationship disclosures:** NR	**Design:** Multicenter Open label Single treatment **Intervention:** Oxybutynin ER **Groups:** **G1:** Oxybutynin ER 5- 30 mg/ day (dose adjustment period) **N at enrollment:** **G1:** 256 **N at follow-up:** **G1:** 219 37 missing data 20 from AEs 4 dc'd lack of effectiveness, included in analysis **Age, yrs ± SD:** NR 38.8% were 65+ **Race/ethnicity, mean (%): white:** **G1:** 235 (91.8) **Women, N (%):** **G1:** 234 (91.4)	**Inclusion criteria:** • ≥ adult men and women • Idiopathic urge incontinence • Mixed incontinence with clinically significant urge component Exclusion criteria: • Uncontrolled medical condition • PVR > 100 ml • Significant bacteriuria • Significant pyuria	**UUI episodes/ week, mean ± SD:** **G1:** 18.8 ± 1.2 **Total incontinent episodes/ week, mean ± SD:** **G1:** 22.2 ± 1.3 **Voids/ week, mean ± SD:** **G1:** 81.1 ± 1.8 **PVR, ml, mean ± SD:** **G1:** 17.4 ± 1.3 **Voided volume, ml, ± SD:** **G1:** 121 ± 79.1	**UUI episodes/ week, mean ± SD:** **G1:** 2.8 ± 0.6 P<0.001 **Total incontinent episodes/ week, mean ± SD:** **G1:** 4.0 ± 0.7 P<0.001 **Voids/ week, mean ± SD:** **G1:** 66.8 ± 1.4 **Reduction Voids/week, mean ± SD:** **G1:** 14.3 ± 1.3 **95%CI:** 11.7-16.8 **PVR, ml, mean ± SD:** **G1:** 21.0 ± 2.2 P = NR **Voided volume, ml, ± SD:** **G1:** 113.4 ± 84.6 P = NR **Participants free UUI episodes, %:** 55.7 **Dry Mouth, n (%):** **G1:** 128 (58.6) **Discontinuation d/t AE, n (%):** 20 (7.8) **Nausea (%):** 2.3 **Dry Mouth (%):** 1.6 **Somnolence (%):** 1.2 **Urinary retention, n (%):** 2 (0.8) **Increased PVR, n, (%):** 1 (0.4)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: + Drop-out rates: ++ Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Hill et al., 2007 [See evidence table for Haab et al., 2006] **Country and setting:** France, Denmark, Sweden, Australia, Canada, US, Multicenter **Enrollment period:** NR **Funding:** Novartis Pharma AG (educational grant) **Author industry relationship disclosures:** NR	**Design:** 2-yr, non-comparative, open-label extension study **Intervention:** Darifenacin following 2 feeder studies of darifenacin 3.75/7.5/15 mg qd or placebo x 12 wks **Groups:** NA **N at enrollment:** 214 **N at follow-up (%):** 137 (64.0) **Patient years of exposure:** 308 **Women, n (%):** 172 (80.4) **Age, n (%):** 65-74 years: 166 (77.6) 75-89 years: 48 (22.4) **Race/ethnicity:** NR **Menopausal, n (%):** 13 (6.1)	**Inclusion criteria:** • Age ≥ 65 • Successful completion of one of 2 previous, 12-wk feeder studies with no major protocol violation **Exclusion criteria:** NR	**Urgency episodes/day, median:** 8.1 **Urgency severity, median VAS score:** 51.8 **Incontinence episodes/week, median:** 18.7 **Voids/day, median:** 10.1 **Voided volume (mL), median:** 156 Concomitant drug treatment, n (%): 210 (98.1)	**Urgency episodes/day, median change (median % change):** -3.7 (-52.0) P < 0.05 **Urgency severity, VAS score, median change (median % change):** -12.6 (-23.3) P < 0.05 **Incontinence episodes/week, median change (median % change):** -11.0 (-83.7) P < 0.05 **Significant leaks/ week, median change (median % change):** -4.9 (-100.0) P < 0.05 **Incontinence episodes, responders, % reduction, %:** ≥ 50%: 74.1 ≥ 70%: 60.0 ≥ 90%: 44.4 **Voids/day, median change (median % change):** -1.2 (-12.4) P < 0.05 **Normalization of voiding frequency (< 8 voids/day) after darifenacin treatment, %:** 3 months: 34 2 years: 33.8	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Hill et al., 2007 (continued)				**Nocturia episodes/week, median change (median % change):** -1.4 (-10.9) **G1/BL:** P < 0.05 **Increased dose to 15 mg at 2 wks and maintained, n (%):** 110 (51.4) **Remained on 7.5 mg dose, n (%):** 55 (25.7) **Had dose adjusted at other times, n (%):** 49 (22.9) **Compliance, ≥ 80% of doses, n (%):** 214 (84) **Voided volume (mL), median change (median % change):** 11.1 (6.3) **Dry mouth, n (%):** 50 (23.4) **Constipation, n (%):** 48 (22.4) **CVD, %:** 1.4 **Peripheral/CNS, %:** 3.3	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Jacquetin and Wyndaele, 2001 **Country and setting:** France (22 centers) and Belgium (10 centers) **Enrollment period:** NR **Funding:** Pharmacia **Author industry relationship disclosures:** NR	**Design:** Double-blind, placebo-controlled, parallel-group, multicenter phase III study w/ 2-wk washout period **Intervention:** Tolterodine vs placebo for 4 weeks **Groups:** **G1:** Tolterodine 2mg bid **G2:** Tolterodine 1 mg bid G3: placebo (frequency NR) **N at enrollment:** NR **N at follow-up:** **G1:** 103 **G2:** 97 **G3:** 51 **Women, n (%):** **G1:** 84 (82) **G2:** 74 (76) **G3:** 41 (80) **Age, mean (range):** **G1:** 58 (21-88) **G2:** 53 (18-85) **G3:** 56 (19-89) **Race/ethnicity:** NR **BMI, kg/m^2 (range):** **G1:** 26.4 (17.7-39.7) **G2:** 25.5 (16.7-46.3) **G3:** 24.8 (17.6-36.9)	**Inclusion criteria:** • Age ≥ 18 • UDS-verified detrusor overactivity • ≥ 1 UUI episode/ day • ≥ 8 voids/day **Exclusion criteria:** • SI • Hepatic or renal dz • +UTI or recurrent UTIs • Interstitial cystitis • Hematuria • Clinically significant voiding difficulty • Pts receiving bladder training, electrostimula-tion therapy • Indwelling catheter • Intermittent cath • Pregnant or nursing • Women of childbearing age w/o reliable contraception	**UUI, n (%)** **G1:** 75 (73) **G2:** 75 (77) **G3:** 39 (76) **UUI episodes/ day, mean (range):** **G1:** 3.2 (0.1-24.0) **G2:** 2.7 (0.1-24.0) **G3:** 2.4 (0.1-8.4) **Voids/day, mean (range):** **G1:** 10.8 (6.2-34.7) **G2:** 10.7 (4.9-26.4) **G3:** 11.7 (6.3-26.3) **≥ 8 voids/day, n (%):** **G1:** 96 (93) **G2:** 89 (92) **G3:** 49 (96) **Urinary symptoms > 5 years, n (%):** **G1:** 46 (45) **G2:** 42 (43) **G3:** 17 (33) **Previous lower urinary tract surgery, n (%):** **G1:** 36 (35) **G2:** 29 (30) **G3:** 16 (31) **Previous drug therapy for OAB, n (%):** **G1:** 66 (64) **G2:** 59 (61) **G3:** 36 (71) **Previous poor efficacy response, n (%):** **G1:** 50 (76) **G2:** 45 (76) **G3:** 26 (72)	**UUI episodes/ day, mean change ± SD:** **G1:** -1.3 ± 1.8 **G2:** -1.1 ± 2.2 **G3:** -0.4 ± 1.9 **G1/G3:** P = 0.0089 **G2/G3:** P = 0.045 **Voids/day, mean change ± SD:** **G1:** -1.4 ± 4.3 **G2:** -1.4 ± 2.8 **G3:** -1.2 ± 2.7 **G1/G3:** P = NS **G2/G3:** P = NS **Good efficacy response in current study, previous poor efficacy response, n/N (%)** **G1:** 20/39 (51) **G2:** 18/37 (49) **G3:** 7/19 (37) **G1/G3:** P = NS **G2/G3:** P = NS **Voided volume (mL), mean change ± SD:** **G1:** 19 ± 46 **G2:** 20 ± 42 **G3:** 7 ± 40 **G1/G3:** P = 0.056 **G2/G3:** P = 0.055 **Dry mouth, n (%):** **G1:** 35 (34) **G2:** 20 (21) **G3:** 3 (6) **G1/G2:** P < 0.05 **G1/G3:** P < 0.05 **G2/G3:** P < 0.05 **Abdominal pain, n (%):** **G1:** 4 (4) **G2:** 6 (6) **G3:** 2 (4) **Constipation, n (%):** **G1:** 2 (2) **G2:** 4 (4) **G3:** 2 (4)	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: - Masking: + Pt selection criteria: + Loss to followup: NR Drop-out rates: ++ Power calculation: + Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Jacquetin and Wyndaele, 2001 (continued)			**Voided volume (mL), mean (range):** **G1:** 158 (43-382) **G2:** 150 (46-320) **G3:** 148 (23-284)	**Headache, n (%):** **G1:** 3 (3) **G2:** 3 (3) **G3:** 2 (4) **Total AEs reported, n:** **G1:** 84 **G2:** 78 **G3:** 26 **Any AE, n (%):** **G1:** 55 (53) **G2:** 39 (40) **G3:** 16 (31) **G1/G3:** P < 0.05 **Discontinued due to AEs, n (%):*** **G1:** 2 (2) **G2:** 3 (3) **G3:** 1 (2)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Koonings et al., 1991 **Country and setting:** US **Enrollment period:** January 1986 to October 1987 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cohort **Intervention:** Oxybutynin chloride 5 mg tid x 4 wks **Groups:** NA **N at enrollment:** 126 **N at follow-up:** 114 **Women, %:** 100 **Age, mean (range):** 39 (21-74) **Race/ethnicity:** NR **Menopausal, n:** 44 **Parity, mean (range):** 2 (0-12)	**Inclusion criteria:** • Confirmed diagnosis of detrusor instability • Uninhibited detrusor contraction > 15 cm H_2O on standing provocative urethra cystometry **Exclusion criteria:** • Urethritis (on urethroscopy) • Cystitis (on cystoscopy) • Neurologic findings on screening test of S2-S4 lower voiding center • MUI • Glaucoma	**Uninhibited detrusor contraction starting prior to urethral pressure change, n (%):** 73 (64%) **Urethral pressure drop (≥ 20 cmH_2O) prior to detrusor contraction, n (%):** 41 (6)	**Good response, n (%):** 66 (58) **Poor response, n (%):** 48 (42) **Response, women with uninhibited detrusor contraction starting prior to urethral pressure, n (%):** Good: 61 (81) Poor: 5 (12) P < 0.01 **Response, women with urethral pressure drop (≥ 20 cmH_2O) prior to detrusor contraction, n (%):** Good: 12 (16) Poor: 36 (88) P < 0.01	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: ++ Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Kreder et al., 2003 **Country and setting:** US and Canada, Community **Enrollment period:** NR 16 week follow up **Funding:** Pharmacia Corporation **Author industry relationship disclosures:** NR	**Design:** Subgroup analysis of multicenter, single blind cohort **Intervention:** Tolterodine 1-2 mg bid **Groups:** **G1:** MUI with primary urge **G2:** UUI **N at enrollment:** **G1**: 171 **G2:** 552 **N at follow-up:** **G1**: 170 **G2:** 551 **Women, n (%):** **G1:** 165 (96.5) **G2:** 464 (84) **Age, median (range):** **G1:** 62 (21, 88) **G2:** 65 (20, 88) **Race/ethnicity:** NR	**Inclusion criteria:** • Age ≥ 65 • History, PE, UDS consistent with urge incontinence • ≥ 4 episodes UI on 5 day voiding diary • ≥ 8 voids/day • Either urgency or ≥ 1 UI episodes / day **Exclusion criteria:** • MUI with predominate stress component • Contraindications to antimuscarinic therapy • Hepatic/renal disease • Symptomatic or recurrent UTI • Hematuria • IC • Voiding difficulty with risk of retention • Concurrent bladder training • Electrostimulation therapy • Indwelling catheter • CIC • Women with reproduction potential • Pregnant/ nursing • Concomitant anticholinergic meds/ treatment	**Incontinence episodes/day, median (range):** **G1:** 3 (1, 19) **G2:** 3 (1, 15) **≥ 2 nocturia episodes/day, n (%):** **G1:** 100 (58.5) **G2:** 334 (60.5) **Using pads, n (%):** **G1:** 122 (71) **G2:** 342 (62) **Voided volume (mL), median (range):** **G1:** 169 (62, 506) **G2:** 164 (31, 524) **Duration of symptoms > 5 years, n (%):** **G1:** 91 (53) **G2:** 259 (47) **Previous drug therapy for OAB, n (%):** **G1:** 85 (50) **G2:** 275 (50)	**Incontinence episodes/day, median % change:** **G1:** -67 **G2:** -75 P = NS **Cure rate, dryness, n (%):** **G1:** 66 (39) **G2:** 243 (44) P = NS **Voids/day, median % change:** **G1:** -15 **G2:** -17 P = NS **≤ 8 voids/day dryness, n (%):** **G1:** 40 (23.5) **G2:** 130 (24) P = NS **Nocturia episodes/day, median % change:** **G1:** -50 **G2:** -33 P = NS **≤ 2 nocturnal voiding episodes/day, n (%):** **G1:** 83 (83) **G2:** 254 (76) P = NS **Achieved no pad usage, n (%):** **G1:** 26 (21) **G2:** 93 (27) P = NS **Voided volume (mL), median change (range):** **G1:** 26.5 (-261, 195) **G2:** 27 (-345, 389) **G1/BL:** P < 0.001 **G2/BL:** P < 0.001	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Landis et al., 2004 [See evidence table for van Kerrebroeck et al., 2001] **Country and setting:** Multinational, Community **Enrollment period:** NR 12 weeks **Funding:** Pharmacia **Author industry relationship disclosures:** 2 of 4 ALZA (1) Bristol-Myers Squibb (1) Pharmacia (2)	**Design:** RCT **Intervention:** Tolterodine ER vs placebo 1 week run-in period with 12 weeks treatment **Groups:** **G1:** Tolterodine ER 4 mg daily **G2:** placebo **Stratified:** **a:** 5-20 UUI episodes/week **b:** ≥ 21 UUI episodes/week **N at enrollment:** **G1**: 492 **G1a:** 321 **G1b:** 171 **G2:** 494 **G2a:** 284 **G2b:** 210 **N at follow-up:** **G1a:** 321 **G1b:** 171 **G2a:** 284 **G2b:** 210 **Women, N (%):** **G1a:** 262 (81.6) **G1b:** 143 (83.6) **G2a:** 223 (78.5) **G2b:** 178 (84.8) **Age, mean ± SD:** **G1a:** 60.86 ± 14.45 **G1b:** 60.04 ± 14.10 **G2a:** 60.61 ± 13.59 **G2b:** 61.84 ± 13.85 **Race/ethnicity:** NR	**Inclusion criteria:** • Age ≥ 18 • ≥ 5 UUI episodes/ week • ≥ 8 voids/day • Symptoms of OAB x 5 months **Exclusion criteria:** NR	**UUI episodes/ week, median (range):** **G1a:** 11 (5-20) **G1b:** 34 (21-168) **G2a:** 11 (5-20) **G2b:** 31.5 (21-168) **Voids/day, median (range):** **G1a:** 9.57 (2.57-34.85) **G1b:** 10.71 (2.28-51.28) **G2a:** 10.28 (2.28-28.42) **G2b:** 11.14 (2-37.42) **Voided volume (mL), median (range):** **G1a:** 142.72 (36.19-338) **G1b:** 135.12 (51.45-270.52) **G2a:** 136.25 (32.51-237.5) **G2b:** 126.94 (21.16-373.46) **Number prior Tx for OAB, n (%):** **G1a:** 162 (50.6) **G1b:** 100 (58.5) **G2a:** 139 (49.1) **G2b:** 117 (55.7) **Number prior Tx for OAB w/ good efficacy, n (%):** **G1a:** 85 (52.8) **G1b:** 63 (63.0) **G2a:** 84 (60.4) **G2b:** 68 (58.6)	**UUI episodes/ week, median % change:** **G1a:** -71.42 **G1b:** -67.56 **G2a:** -38.46 **G2b:** -29.81 **G1a/G2a:** P = 0.0264 **G1b/G2b:** P = 0.0221 **Voids/day, median change:** **G1a:** -1.22 **G1b:** -1.9 **G2a:** -0.85 **G2b:** -0.4 **G1a/G2a:** P < 0.04 **G1b/G2b:** P < 0.02 **Voided volume (mL), median change:** **G1a:** 24.0 **G1b:** 27.0 **G2a:** 4.0 **G2b:** 2.9 **G1a/G2a:** P < 0.0001 **G1a/G2a:** P < 0.0001	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Layton et al. 2001 **Country and setting:** England; Community **Enrollment period:** November 1998 to May 1999 **Funding:** **Pharmacia** **Upjohn** **Author industry relationship disclosures:** NR	**Design:** Prospective observational cohort **Intervention:** Tolterodine prescription event monitoring in UK **Groups:** NA **N at enrollment:** 35,295 had commenced treatment 26,991 green forms mailed out 14,526 returned forms Response rate: 53.8% **Age, yrs ± SD:** 62.7 ± 16.4 **Women, N (%):** 9965 (68.6) **Parity:** NR	**Inclusion criteria:** • Patients prescribed tolterodine in general practice in UK **Exclusion criteria:** • None		**Dry mouth, n:** 250 **Unspecified adverse effects, n:** 168 **Headache, n:** 123 **Constipation, n:** 78 **General malaise, n:** 78 **Hallucinations, n:** 23 **Palpitations/tachycardia, n:** 42 **Other cardiac arrhythmias, n:** 29 **Chest pains, n:** 87	Quality: Overall quality score: good INTERNAL VALIDITY: good Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: NA Drop-out rates: NA Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: NR Baseline characteristics: + Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: -

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Lee et al., 2002 **Country and setting:** South Korea, University **Enrollment period:** NR **Funding:** Pharmacia Corp **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Tolterodine 2mg bid vs Oxybutynin 5mg bid **Groups:** **G1:** Tolterodine 2mg bid **G2:** Oxybutynin 5mg bid **N at enrollment:** **G1**: 112 **G2:** 116 **N at follow-up:** **G1**: 97 **G2:** 90 **Women, n (%):** **G1:** 84 (74) **G2:** 92 (79) **Age, mean (range):** **G1:** 52 (27, 82) **G2:** 52 (20, 86) **Race/ethnicity (%):** **Asian:** **G1:** 100 **G2:** 100 **BMI, kg/m^2 (range):** **G1:** 23 (17, 32.5) **G2:** 23.5 (16, 38) **Previous drug therapy: N (%)** **G1:** 36 (32) **G2:** 26 (22)	**Inclusion criteria:** • Age ≥ 18 • OAB symptoms > 6 mos • ≥ 8 voids/day, with or without incontinence (measured by diary) **Exclusion criteria:** • SUI • Women not using reliable contraception • Pregnant or nursing • Prior treatment with anticholinergic < 2 wks • Renal or hepatic disease • Narrow angle glaucoma • Urinary retention • Gastric retention • Hypersensitivity to drugs • UTI • IC • Hematuria • BOO • Concomitant bladder training, e-stim treatment • Indwelling catheter • CIC • Concomitant treatment for OAB ≤ 2 mos	**Incontinence episodes/day, mean (range):** **G1:** 2.6 (0.3, 9.3) **G2:** 2.4 (3.0, 14.7) **Patients with incontinence episodes, n (%):** **G1:** 46 (41) **G2:** 42 (36) **Voids/day, mean (range):** **G1:** 12.2 (8.0, 23.7) **G2:** 12.4 (7.7, 29.7)	**Incontinence episodes/day, mean change ± SD (% change):** **G1:** -2.2 ± 2.3 (-85) **G2:** -1.4 ± 1.8 (-58) **G1/BL:** P = 0.0001 **G1/BL:** P = 0.0001 **G1/G2:** P = 0.10 **Voids/ day, mean change ± SD (% change):** **G1:** -2.6 ± 2.9 (-21) **G2:** -1.8 ± 4.2 (-15) **G1/BL:** P = 0.0001 **G1/BL:** P = 0.0001 **G1/G2:** P = 0.14 **Benefit of Tx, %:** **G1:** 45 **G2:** 46 **G1/G2:** P = NS **Patients reporting adverse events, n (%):** **G1:** 62 (55) **G2:** 94 (82) **Discontinued due to AEs, n (%):** **G1:** 11 **G2:** 18 **Dry mouth, n (%):** **G1:** 39 (35) **G2:** 72 (63) **G1/G2:** P = 0.001 **Dry mouth, mild, n (%):** **G1:** 29 (26) **G2:** 40 (35) **Dry mouth, moderate, n (%):** **G1:** 9 (8) **G2:** 26 (23)	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: + Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Lee et al., 2002 (continued)				**Dry mouth, severe, n (%):** **G1:** 1 (1) **G2:** 6 (5) **Voiding disorder, n (%):** **G1:** 10 (9) **G2:** 16 (14)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Malone-Lee et al., 2003 **Country and setting:** UK, Hospital **Enrollment period:** 1993-1999 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Prospective observational **Intervention:** Oxybutynin 2.5mg bid and bladder retraining **Groups:** **G1:** urinary frequency and urgency w/ detrusor instability **G2:** urinary frequency and urgency w/o detrusor instability **N at enrollment:** **G1:** 266 **G2:** 86 **N at follow-up:** Total: 347 **G1:** NR **G2:** NR **Age, mean (range):** **G1:** 54.8 (20, 90) **G2:** 51.8 (21, 88) **Race/ethnicity:** NR	**Inclusion criteria:** • Women • Age ≥ 18 • ≥ 8 voids/day **Exclusion criteria:** • Neurological disease • Significant stress incontinence • Symptomatic UTI • Interstitial cystitis	**Incontinence episodes/day, median (95% CI):** **G1:** 2 (0, 7) **G2:** 2 (0, 6.3) **Voids/day median (95% CI):** **G1:** 14 (8, 24) **G2:** 12 (8, 22)	**Incontinence episodes/day, median change (95% CI):** **G1:** 0 (2, 6) **G2:** 0 (2, 6) **G1/G2:** P = 0.73 **Voids/day, median change (95% CI):** **G1:** -5 (1.9-14) **G2:** -5 (1-12.3) **G1/G2:** P = 0.61 **Dry mouth, n (%):** **G1:** 219 (84) **G2:** 69 (70) **Constipation, n (%):** **G1:** 84 (32) **G2:** 19 (22) **Heartburn, n (%):** **G1:** 71 (27) **G2:** 20 (23) **Dry skin, n (%):** **G1:** 46 (18) **G2:** 4 (5) **G1/G2:** P = 0.01 **Headache, n (%):** **G1:** 25 (10) **G2:** 3 (3.5) **Dry eyes, n (%):** **G1:** 12 (5) **G2:** 1 (1)	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: ++ Drop-out rates: NR Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Michel et al., 2002 **Country and setting:** Germany, Community **Enrollment period:** NR 12 week follow up **Funding:** Pharmacia GmbH **Author industry relationship disclosures:** 1 of 4 Pharmacia(1) Sanofi-Synthelabo(1)	**Design:** Open-label observational post-marketing surveillance **Intervention:** Tolterodine **Groups:** Tolterodine Median dose: 2 mg daily **Dose (mg), mean ± SD:** 3.81 ± 1.16 **N at enrollment:** 2,250 **N at follow-up:** 1,979 **Women, n (%):** 1,730 (76.9) **Age, mean ± SD:** 61.1 ± 13.8 **Race/ethnicity:** NR **BMI, kg/m^2 ± SD:** 73.2 ± 11.3	**Inclusion criteria:** • Physician medical judgement **Exclusion criteria:** NR	**Urgency episodes/day, mean ± SD:** 8.4 ± 5.1 **Incontinence episodes/day, mean ± SD:** 3.4 ± 4.2 **Voids/day, mean ± SD:** 12.4 ± 4.3	**Urgency episodes/day, mean ± SD:** 2.0 ± 3.0 P = NR **Incontinence episodes/day, mean ± SD:** 0.8 ± 2.0 P = NR **Voids/day, mean ± SD:** 7.7 ± 2.7 P = NR **Urgency, successful treatment, OR (95% CI):** Gender, M/F: 0.764 (0.583, 1.001) P = 0.0508 Age, years: 0.981 (0.973, 0.990) P < 0.001 Frequency, BL episodes/day: 1.038 (0.997- 1.080) P = 0.0724 Urgency, BL episodes/day: 0.851 (0.823, 0.880) P < 0.001 Incontinence, BL episodes/day: 0.979 (0.950, 1.000) P = 0.1735 Tolterodine dose, mg/day: 0.913 (0.830, 1.005) P = 0.0623	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: - Loss to followup: + Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Michel et al., 2002 (continued)				**Incontinence, successful treatment, OR (95% CI):** Gender, M/F: 1.453 (1.062, 1.990) P = 0.0196 Age, years: 0.978 (0.968, 0.987) P < 0.001 Frequency, BL episodes/day: 1.034 (0.993, 1.076) P = 0.1036 Urgency, BL episodes/day: 1.053 (1.018, 1.088) P = 0.0027 Incontinence, BL baseline episodes/day: 0.744 (0.716, 0.774) P < 0.001 Tolterodine dose, mg/day: 0.866 (0.784, 0.956) P = 0.0043 **Frequency, successful treatment, OR (95% CI):** Gender, M/F: 0.745 (0.552, 1.004) P = 0.0532 Age, years: 0.981 (0.971, 0.991) P = 0.001 Frequency, BL episodes/day: 0.735 (0.701, 0.771) P < 0.001 Urgency, BL episodes/day: 1.008 (0.975, 1.041) P = 0.6526	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Michel et al., 2002 (continued)				Incontinence, BL episodes/day: 0.969 (0.937, 1.002) P = 0.0644 Tolterodine dose, mg/day: 1.070 (0.957, 1.196) P = 0.2335 **Effect on Global efficacy, OR (95% CI):** Gender, M/F: 0.656 (0.526, 0.818) P = 0.0002 Age, years: 0.986 (0.980, 0.993) P < 0.001 Frequency, BL epsidoes/day: 1.002 (0.972, 1.033) P = 0.8896 Urgency, BL episodes/day: 1.009 (0.984, 1.033) P = 0.4906 Incontinence, BL episodes/day: 0.963 (0.939, 0.987) P < 0.0026 Tolterodine dose, mg/day: 1.000 (0.926, 1.080) P = 0.9971 **Effect on global tolerability of Tolterodine, OR (95% CI):** Gender, M/F: 0.993 (0.790, 1.249) P = 0.9519 Age, years: 0.995 (0.988, 1.002) P = 0.1915 Frequency, BL episodes/day: 1.002 (0.971, 1.034) P = 0.8995	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Michel et al., 2002 (continued)				Urgency, BL episodes/day: 1.022 (0.997, 1.048) P = 0.0889 Incontinence, BL episodes/day: 0.990 (0.965, 1.016) P < 0.459 Tolterodine dose, mg/day: 1.114 (1.028, 1.206) P = 0.0085	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Michel et al., 2007* Michel et al., 2005 **Country and setting:** Germany, NR **Enrollment period:** November 2001 to June 2003 **Funding:** Pharmacia (became Pfizer before publication) **Author industry relationship disclosures:** 5/5* 4SC (1) Astellas (1) Boehringer Ingelheim (2) Eli Lilly (2) Pfizer (4) Theravance (1) Anformed (1)	**Design:** Retrospective cohort, open label **Intervention:** Tolterodine ER **Groups:** **G1:** Incontinent **G2:** Continent **N at enrollment:** Total: 3,824 **G1**: 2,571 **G2:** 1,253 **N at follow-up:** Total: 3,416 **Women, %:** Total: 75.8 **G1:** 81.7 **G2:** 62.6 P < 0.001 **Age, mean ± SD:** Total: 64.8 ± 13.3 **G1:** 66.3 ± 12.6 **G2:** 61.4 ± 14.1 P < 0.001 **Race/ethnicity:** NR **Follow-up:** 9 months	**Inclusion criteria:** NR **Exclusion criteria:** NR	**Urgency episodes/day, mean ± SD:** Total: 7.9 ± 5.2 **G1:** 8.0 ± 5.2 **G2:** 7.7 ± 5.2 P = 0.1937 **Incontinence episodes/day, mean ± SD:** **G1:** 4.8 ± 3.7 **G2:** NA **Voids/day, mean ± SD:** Total: 14.0 ± 4.6 **G1:** 14.1 ± 4.6 **G2:** 13.5 ± 4.4 P < 0.001 **Daytime voids/ day, mean ± SD:** Total: 10.7 ± 3.7 **G1:** 10.8 ± 3.7 **G2:** 10.4 ± 3.4 P = 0.0128 **Frequency ≥ 8 voids/day, %:** **G1:** 95.7 **G2:** 95.2 **Nocturia episodes/day, mean ± SD:** Total: 3.4 ± 1.7 **G1:** 3.5 ± 1.8 **G2:** 3.2 ± 1.6 P < 0.001 **Pad use/day, mean ± SD:** **G1:** 3.4 ± 2.8 **G2:** 0.1 ± 0.6 P < 0.001 **Duration of symptoms (mo), mean ± SD:** **G1:** 50 ± 53 **G2:** 40 ± 46 P < 0.001 **Previous treatment, %:** **G1:** 50.8 **G2:** 44.8 P = 0.0007	**Incontinence episodes/day, mean change ± SD:** **G1:** -3.8 ± 3.5 **G2:** NA **Urgency episodes/day, mean ± SD:** Total: 1.6 ± 2.8 **No urgency, %:** **G1:** 53.4 **G2:** 63.2 **Voids/day, mean ± SD:** Total: 7.5 ± 3.0 **Daytime voids/ day, mean ± SD:** Total: 6.2 ± 2.3 **Frequency ≥ 8 voids/day, %:** **G1:** 43.7 **G2:** 39.1 **Nocturia episodes/day, mean ± SD:** Total: 1.4 ± 1.1 **Pad use/day, mean change ± SD:** G1: -2.4 ± 2.5 **Limitation of daily activities, score change ± SD:** G1: 4.49 ± 2.65 G2: 4.10 ± 2.51 **Limitations in daily life caused by bladder prob-lems, score ± SD:** **G1:** 7.59 ± 1.65 **G2:** 6.66 ± 1.69 P < 0.001 **Total adverse events, n (%):** Total: 496 (13.0) **Dry mouth, n (%):** 299 (7.8)	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: - Loss to followup: NR Drop-out rates: NA Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Michel et al., 2007* Michel et al., 2005 (continued)				**Withdrew:** 11% **Unable to tolerate medication:** 2.8% **Administrative reasons:** 2.6% **Lack of efficacy :** 2.4% **Patient request:** 1.2%	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Moore et al., 1990 Moore and Sutherst 1990 **Country and setting:** UK, academic health center **Enrollment period:** NR **Funding:** Tillots Laboratories **Author industry relationship disclosures:** NR	**Design:** RCT with crossover **Intervention:** oxybutynin hydrochloride vs placebo **Groups:** **G1:**oxybutynin hydrochloride 3 mg tid **G2:**placebo **N at enrollment:** 53 **N at follow-up:** **G1:** 27 **G2:** 22 **Age, mean ± SD:** **G1:** 46.0 ± 11.7 **G2:** 46.4 ± 12.4 **Race/ethnicity:** NR **Parity, mean:** **G1:** 2.3 **G2:** 2.2	**Inclusion criteria:** • UDS-defined idiopathic detrusor instability • Involuntary detrusor contractions > 30 cm H2O during filling phase of cystometry **Exclusion criteria:** • Neurological disorder • Urologic disorder • Age > 75 years • Genuine SI • Low-compliance bladder • Bacterial or interstitial cystitis • Previous treatment with oxybutynin	**Voids/day, mean ± SD:** **G1:** 11.1 ± 7.9 **G2:** 12.1 ± 5.7 **Volume at first desire to void mean mL ± SD:** **G1:** 94.2 ± 66 **G2:** 107.4 ± 101 **Max detrusor filling pressure mean cm H2O, ±SD:** **G1:** 55.3 ± 23 **G2:** 59.2 ± 26 **Max cystometric capacity (mL)** **G1:** 275 ± 164 **G2:** 290 ± 168 **Residual urine volume mean mL ± SD:** **G1:** 23.1 ± 34.2 **G2:** 22.7 ± 34.0 **Duration of OAB, mean yrs ± SD):** **G1:** 7.5 ± 7.9 **G2:** 8.9 ± 9.0	**Change in volume at first desire to void, period 1, mean mL ± SD (95% CI)** **G1:** 70.0 ± 103 **G2:** 7.7 ± 76 **G1/G2:** P = 0.02 95% CI: (10, 113) **Change in maximum detrusor filling pressure, mean ± SD:** **G1:**-16.9 ± 19.5 **G2:**1.0 ± 28.7 **G1/G2:** P = 0.02 95% CI: (-32.5, -3.2) **Change in maximum cystometric capacity, mean ± SD:** **G1:**104.0 ± 131 **G2:**7.0 ± 103 **G1/G2:**p=0.006 95% CI: (29, 165) **Change in residual urine Volume, period 1:** **G1:** 22.4 (79.3) **G2:** 7.7 (45.7) P=0.42 **Change in residual urine Volume, period 2:** **G1:** 10.0 ± 27.1 **G2:** 25.7 ± 55.6 P = 0.33 **Dry mouth on oxybutynin, %:** 88 **Dry mouth on placebo, %:** 33 **Mouth ulcers on oxybutynin, %:** 16	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: - EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: ++ Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Moore et al., 1990 Moore and Sutherst 1990 (continued)				**Mouth ulcers on placebo, %:** 0 **Constipation on oxybutynin, %** 12.5 **Constipation on placebo, %** 0 **Drowsiness on oxybutynin, %:** 12.5 **Drowsiness on placebo, %:** 7 **Nausea on oxybutynin, %:** 8.3 **Nausea on placebo, %:** 2.3 **Initial hesitancy on oxybutynin, %:** 4.2 **Initial hesitancy on placebo, %:** 2.3 **Dizziness on oxybutynin, %:** 4.2 **Dizziness on placebo, %:** 7.0 **Metallic taste on oxybutynin, %:** 2.4 **Metallic taste on placebo, %:** 2.3 **Crown Crisp Experimental Index, >50% improvement:*** **Free floating anxiety:** 6.4	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Moore et al., 1990 Moore and Sutherst 1990 (continued)				**Phobic anxiety:** 5.3 **Obsessionalism:** 6.2 **Somatic complaints:** 6.2 **Depression:** 4.0 **Hysteria:** 2.6 **Total:** 30.7 **Crown Crisp Experimental Index, <49% improvement:*** **Free floating anxiety:** 8.8 **Phobic anxiety:** 6.8 **Obsessionalism:** 8.1 **Somatic complaints:** 8.9	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Rudy, et al. 2006 Rudy, et al. 2006 Staskin and Harnett, 2004 **Country and setting:** US; 52 sites **Enrollment period:** NR **Funding:** Indevus **Author industry relationship disclosures:** 5 of 5 Indevus (5)	**Design:** RCT **Intervention:** Trospium chloride vs placebo x 12 wks **Groups:** **G1:** trospium chloride 20 mg BID **G2:** matching placebo **N at enrollment:** **G1**: 329 **G2:** 329 **N at follow-up:** **G1**: 323 **G2:** 325 **Age, mean yrs ± SE:** **G1:** 61.1 ± 0.69 **G2:** 61.0 ± 0.70 **Women, N (%):** **G1:** 269 (81.8) **G2:** 267 (81.2) **Race/ethnicity, n (%):** **Black:** **G1:** 26 (7.9) **G2:** 21 (6.4) **White:** **G1:** 284 (86.3) **G2:** 300 (91.2) **Hispanic:** **G1:** 13 (4.0) **G2:** 5 (1.5) **Asian:** **G1:** 5 (1.5) **G2:** 3 (0.9) **Parity:** NR	**Inclusion criteria:** • 18+ years old • 6+ mos of OAB sx • 10+ voids/d • Sx of urgency • 7+ urge UIE/wk **Exclusion criteria:** • Predominantly SUI, insensate UI, or overflow UI • Neurogenic bladder d/o's • Significant renal dz • Uninvestigated hematuria • UTI at washout or more than 2x during the prior 12 mos • PVR>100mL • Use of any anticholinergic drug or other drug therapy for OAB w/in 21 days before randomization • Bladder surgery w/in 6 mos before randomization • Cancer • Interstitial cystitis • PSA>10ng/mL • Diuretic use • Estrogen therapy • Nonmedical bladder therapy not part of a stable, long-term program • Pregnancy • Contraindication to antimuscarinic therapy	**Daily voids, mean n:** **G1:** 12.94 **G2:** 13.17 P=0.3169 **Urgency severity score associated with toilet voids, median:** **G1:** 1.79 **G2:** 1.75 P=0.4100 **Volume voided in mL per void/24h, mean:** **G1:** 154.80 ± NR **G2:** 154.64 ± NR P=0.9667 **Median daily urge incontinence episodes:** **G1:** 2.86 **G2:** 2.86 P=0.9849 **Nocturnal voids/24 hr, median:** **G1:** 2.00 **G2:** 2.00 P=0.9048 **Nocturnal urgency severity score associated with toilet voids, mean:** **G1:** 2.03 **G2:** 2.01 P=0.6863 **OAB-SCS, median:** **G1:** 36.56 **G2:** 36.88 P=0.7176 **Stanford Sleepiness Scale, mean** **G1:** 1.98 **G2:** 1.94	**Change from baseline to day 1:** **Daily voids, mean:** **G1:** -0.66 **G2:** -0.35 P=0.14 **Urgency severity score associated with toilet voids, mean:** **G1:** 0.00 **G2:** 0.02 P=0.47 **Median daily urge incontinence episodes:** **G1:** -1.00 **G2:** -0.57 P=0.042 **OAB-SCS, median:** **G1:** -2.50 **G2:** -0.14 P=0.014 **Change from baseline to <u>day 2</u>:** **Daily voids, mean:** **G1:** -1.11 **G2:** -0.75 P=0.09 **Urgency severity score associated with toilet voids, mean:** **G1:** -0.08 **G2:** -0.03 P=0.13 **Median daily UI episodes:** **G1:** -1.29 **G2:** -0.86 P=0.0022 **OAB-SCS, median:** **G1:** -3.86 **G2:** -2.14 P=0.015	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: - Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: + Length of followup: + Measurement methods: + Measurement reliability: - Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)			**Stanford Sleepiness Scale, age group <65 years:** **G1:** 1.99 **G2:** 2.09 **Stanford Sleepiness Scale, age group >65 years:** **G1:** 1.96 **G2:** 1.71 **Stanford Sleepiness Scale, age group <75 years:** **G1:** 2 **G2:** 1.97 **Stanford Sleepiness Scale, age group >75 years:** **G1:** 1.86 **G2:** 1.79 **Prior OAB medications, n (%):** **G1:** 162 (49.2) **G2:** 169 (51.4) **Prior hx of pelvic-floor training, n (%):** **G1:** 62 (18.8) **G2:** 76 (23.1) **Currently practice undergarment change d/t incontinence, n (%):** **G1:** 227 (69.0) **G2:** 239 (72.6)	**Change from baseline to day 3:** **Daily voids, mean:** **G1:** -1.30 **G2:** -0.77 P=0.012 **Urgency severity score associated with toilet voids, mean:** **G1:** -0.11 **G2:** -0.04 P=0.015 **Median daily UI episodes:** **G1:** -1.57 **G2:** -0.86 P<0.0001 **OAB-SCS, median:** **G1:** -4.71 **G2:** -2.71 P=0.0019 **Change from baseline to day 4:** **Daily voids, mean:** **G1:** -1.33 **G2:** -0.95 P=0.086 **Urgency severity score associated with toilet voids, mean:** **G1:** -0.12 **G2:** -0.05 P=0.031 **Median daily UI episodes:** G1: -1.57 G2: -1.00 P<0.0001 **OAB-SCS, median:** G1: -4.86 G2: -3.36 P=0.011	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)				**Change from baseline to day 5:** **Daily voids, mean:** **G1:** -1.73 **G2:** -1.12 P=0.0037 **Urgency severity score associated with toilet voids, mean:** **G1:** -0.13 **G2:** -0.05 P=0.021 **Median daily UI episodes:** **G1:** -1.57 **G2:** -1.00 P<0.0001 **OAB-SCS, median:** **G1:** -6.43 **G2:** -3.36 P<0.0001 **Change from baseline to day 6:** **Daily voids, mean:** **G1:** -1.80 **G2:** -1.28 P=0.017 **Urgency severity score associated with toilet voids, mean:** **G1:** -0.08 **G2:** 0.04 P<0.0001 **Median daily UI episodes:** **G1:** -1.71 **G2:** -1.00 P<0.0001 **OAB-SCS, median:** **G1:** -5.43 **G2:** -2.93 P<0.0001	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)				**Change from baseline to week 1:** **Daily voids, mean:** **G1:** -1.42 **G2:** -0.96 P=0.0039 **Urgency severity score associated with toilet voids, mean:** **G1:** -0.09 **G2:** -0.01 P=0.0023 **Volume voided in mL per void/24h:** **G1:** 29.23 **G2:** 6.05 P<0.0001 **Median daily urge incontinence episodes:** **G1:** -1.43 **G2:** -0.86 P<0.0001 **Nocturnal voids/24 hr, median:** **G1:** -0.29 **G2:** -0.29 P=0.8454 **Nocturnal urgency severity score associated with toilet voids, mean:** **G1:** -0.05 G**2:** 0.03 P=0.0442 **OAB-SCS, median:** **G1:** -4.71 **G2:** -2.29 P<0.0001	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)				**Change from baseline to 4 weeks:** **Daily voids, mean:** **G1:** -2.34 **G2:** -1.55 P<0.0001 **Urgency severity score associated with toilet voids, mean:** **G1:** -0.19 **G2:** -0.04 P<0.0001 **Volume voided in mL per void/24h:** **G1:** 39.50 **G2:** 9.45 P<0.0001 **Median daily urge incontinence episodes:** **G1:** -1.71 **G2:** -1.14 P<0.0001 **Nocturnal voids/24 hr, median:** **G1:** -0.43 **G2:** -0.29 P=0.0299 **Nocturnal urgency severity score associated with toilet voids, mean:** **G1:** -0.13 **G2:** =0.01 P=0.0062 **OAB-SCS, median:** **G1:** -8.14 **G2:** -3.86 P<0.0001	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)				**Change from baseline to 12 weeks:** **Daily voids. mean:** **G1:** -2.67 **G2:** -1.76 P<0.0001 **Urgency severity score associated with toilet voids:** **G1:** -0.21 **G2:** -0.02 P<0.0001 **Volume voided in mL per void/24h:** **G1:** 35.59 **G2:** 9.44 P<0.0001 **Daily UI episodes, median:** **G1:** -1.86 **G2:** -1.29 P<0.0001 **Nocturnal voids/d, median:** **G1:** -0.57 **G2:** -0.29 P=0.0026 **Nocturnal urgency severity score, mean:** **G1:** -0.17 **G2:** 0.01 P=0.0005 **OAB-SCS, median:** **G1:** -8.43 **G2:** -4.62 P<0.0001 **Adverse events Any, n (%)** **G1:** 196 (59.6) **G2:**153 (46.5) **Dry mouth:** **G1:** 65 (19.8) **G2:** 17 (5.2) **Constipation:** **G1:** 36 (10.9) **G2:** 19 (5.8)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)				**Headache:** **G1:** 18 (5.5) **G2:** 15 (4.6) **UTI not otherwise specified:** **G1:** 16 (4.9) **G2:** 8 (2.4) **Nasopharyngitis:** **G1:** 13 (4.0) **G2:** 12 (3.6) **Cough:** **G1:** 8 (2.4) **G2:** 1 (0.3) **Diarrhea:** **G1:** 7 (2.1) **G2:** 13 (4.0) **AEs leading to treatment discontinuation, %:** **G1:** 7.3 **G2:** 4.6 **Most common AEs leading to discontinuation:** **Constipation:** **G1:** 1.8% **G2:** 0.6% **Dry mouth:** **G1:** 1.5% **G2:** 0.0% **Stanford Sleepiness Scale, change, wk 1:** **G1:** -0.2 **G2:** -0.12 **Stanford Sleepiness Scale, change wk 4:** **G1:** -0.17 **G2:** -0.14 **Stanford Sleepiness Scale, change, wk 12:** **G1:** -0.16 **G2:** -0.11	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)				**Stanford Sleepiness Scale including T-max time point values only (G1=93, G2=97), change BL to week 1:** **G1:** -0.42 **G2:** -0.2 **Stanford Sleepiness Scale including T-max time point values only (G1=144, G2=148), change BL to week 4:** **G1:** -0.2 **G2:** -0.19 **Stanford Sleepiness Scale including T-max time point values only (G1=182, G2=179), change BL to week 12:** **G1:** -0.17 **G2:** -0.18 **Mean Stanford Sleepiness Scale, age group <65 years, change BL to week 1:** **G1:** -0.27 **G2:** -0.19 **Mean Stanford Sleepiness Scale, age group >65 years, change BL to week 1:** **G1:** -0.04 **G2:** -0.03 **Mean Stanford Sleepiness Scale, age group <65 years, change BL to week 4:** **G1:** -0.14 **G2:** -0.27	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)				**Mean Stanford Sleepiness Scale, age group >65 years, change from baseline to week 4:** **G1:** -0.23 **G2:** 0.03 **Mean Stanford Sleepiness Scale, age group <65 years, change from baseline to week 12:** **G1:** -0.14 **G2:** -0.22 **Mean Stanford Sleepiness Scale, age group >65 years, change from baseline to week 12:** **G1:** -0.22 **G2:** 0.03 **Mean Stanford Sleepiness Scale, age group < 75 years, change from baseline to week 1:** **G1:** -0.21 **G2:** -0.14 **Mean Stanford Sleepiness Scale, age group > 75 years, change from baseline to week 1:** **G1:** -0.02 **G2:** 0 **Mean Stanford Sleepiness Scale, age group < 75 years, change from baseline to week 4:** **G1:** 0.14 **G2:** -0.16	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Rudy et al., 2006 Rudy et al., 2006 Staskin and Harnett, 2004 (continued)				**Mean Stanford Sleepiness Scale, age group > 75 years, change from baseline to week 4:** **G1:** -0.49 **G2:** -0.09 **Mean Stanford Sleepiness Scale, age group < 75 years, change from baseline to week 12:** **G1:** 0.15 **G2:** -0.14 **Mean Stanford Sleepiness Scale, age group > 75 years, change from baseline to week 12:** **G1**: -0.33 **G2:** 0.02 **At least one CNS event:** **G1:** 5.8% **G2:** 5.2% **Somnolence** **G1:** 0.3% **G2:** 0.6% **Sedation:** **G1:** 0 **G2:** 0.3% **Clinically significant increase (≥ 3 points) from baseline to week 12 in SSS score, n (%):** **G1:** 5 (1.5) **G2:** 8 (2.5)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Salvatore et al., 2007 **Country and setting:** Italy, Urogynecology outpatient clinic **Enrollment period:** January 2004 to October 2005 **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Cohort **Intervention:** Tolterodine SR 4 mg qd **Groups:** **G1:** vaginal profile stage 0a or Ia **G2:** anterior prolapse ≥ stage IIa **N at enrollment:** **G1:** 184 **G2:** 51 **N at follow-up:** NR **Women, %:** 100 **Age, median (range):** **G1:** 59 (20, 85) **G2:** 59 (35, 82) **Race/ethnicity:** NR **Parity, mean (range):** **G1:** 2 (0-6) G2: 2 (0-6) **Menopausal, n (%):** **G1:** 132 (72) **G2:** 7 (18)	**Inclusion criteria:** Women Urodynamically proven OAB who had no prolapse or pure anterior vaginal prolapse Proven detrusor overactivity **Exclusion criteria:** All symptoms or signs related to voiding difficulties Prolapse	**Previous surgery, n (%):** **G1:** 52 (28) **G2:** 11 (22) **HRT, n (%)** **G1:** 35 (26) **G2:** 7 (18)	**Improvement in condition or cured, n (%):** **G1:** 158 (85.9) **G2:** 31 (60.8)* P = 0.0002	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Masking: NA Pt selection criteria: + Loss to followup: NR Drop-out rates: NR Power calculation: - Statistical issues: - EXTERNAL VALIDITY: poor Age: + Baseline OAB status: NR Baseline characteristics: - Length of followup: + Measurement methods: - Measurement reliability: - Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Sand et al., 2004 **Country and setting:** US, Specialty clinic **Enrollment period:** Subanalysis of OBJECT trial, women only **Funding:** ALZA Corp **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** 10mg ER Oxybutynin daily vs 4mg Tolterodine (2mg bid) **Groups:** **G1:** 10mg ER Oxybutynin daily x 12 wks **G2:** 4mg Tolterodine (2mg bid) x 12 wks **Stratified by age:** **a:** Age ≤ 64 **b:** Age 65-74 **c:** Age ≥ 75 **N at enrollment:** **G1**: 152 **G2:** 163 **N at follow-up:** **G1**: 132 **G2:** 146 **Women, %:** 100 **Age, yrs ± SD:** **G1:** 58.4 **G2:** 58.8 **Race/ethnicity:** NR	**Inclusion criteria:** • ≥ 7 and ≤ 50 UUI episodes/week • ≥ 10 voids/day • MUI included if predominant UUI **Exclusion criteria:** • UTI • IC • Urethral diverticulum • Bladder tumor • Bladder stone • Delivery within 6 mos • Pelvic, bladder, vaginal surgery in ≤ 6 mos • PVR ≥ 150 mL • CV, renal, pulmonary, GI, endocrine, neurologic, autoimmune, hematological, urological, psychiatric, or hepatic disease • Hematuria • Positive urine culture • Narrow angle glaucoma • Obstructive uropathy • Myasthenia gravis • POP to hymenal ring • Gastrointestinal obstruction • Decreased GI motility • GI narrowing • GI retention • Investigational drugs within 1 month of screening • Hypersensitivity to drugs	**UUI episodes/ week, mean:** **G1:** 25.2 **G2:** 25.1 **Incontinence episodes/week, mean:** **G1:** 28.1 **G2:** 28.9 **Voids/week, mean:** **G1:** 91.7 **G2:** 91.6 **Naïve to anti-cholinergics, %:** **G1:** 60.5 **G2:** 60.7	**UUI episodes/ week, %:** **G1:** 6.2 **G2**: 8.5 **G1a:** 5.0 **G2a:** 8.4 **G1b:** 5.5 **G2b:** 7.5 **G1c:** 8.5 **G2c:** 11.1 **G1/G2:** P = 0.038 **G1a/G2a:** P = 0.005 **G1b/G2b:** P = 0.337 **G1c/G2c:** P = 0.568 **Incontinence episodes/week, mean:** **G1:** 7.3 **G2**: 10.1 **G1a:** 5.8 **G2a:** 10.0 **G1b:** 6.1 **G2b:** 9.2 **G1c:** 10.5 **G2c:** 12.5 **G1/G2:** P = 0.030 **G1a/G2a:** P = 0.005 **G1b/G2b:** P = 0.164 **G1c/G2c:** P = 0.714 **Voids/week, mean:** **G1:** 68.0 **G2**: 71.2 **G1a:** 63.7 **G2a:** 71.2 **G1b:** 73.8 **G2b:** 71.9 **G1c:** 66.8 **G2c:** 65.5 **G1/G2:** P = 0.272 **G1a/G2a:** P = 0.024 **G1b/G2b:** P = 0.706 **G1c/G2c:** P = 0.838	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Sand et al., 2004 (continued)		• Current drug/ EtOH abuse • Pregnant • Breastfeeding • Inability to follow protocol		**Dry mouth, %:** **G1:** 28.3 **G2:** 33.7 **Constipation, %:** **G1:** 8.6 **G2:** 6.7 **Retention, %:** **G1:** 4.0 **G2:** 1.2 **Blurred vision, %:** **G1:** 2.6 **G2:** 0.6 **Dizziness, %:** **G1:** 3.9 **G2:** 4.3 **Insomnia, %:** **G1:** 0.7 **G2:** 1.8 **Somnolence, %:** **G1:** 3.3 **G2:** 1.8 **Nervousness, %:** **G1:** 0 **G2:** 1.2 **Headache, %:** **G1:** 9.2 **G2:** 10.4 **Dyspepsia, %:** **G1:** 5.3 **G2:** 6.1 **Nausea, %:** **G1:** 3.3 **G2:** 1.8 **Vomiting, %:** **G1:** 2.0 **G2:** 1.8	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Serati et al, 2008 **Country and setting:** NR; Urogynecology unit **Enrollment period:** January 2005 to December 2006 **Funding:** NR **Author industry relationship disclosures:** None	**Design:** Prospective case series **Intervention:** Tolterodine ER 5 mg qd (prescribed to women with proven pure DO w/o SUI) **Groups:** **G1:** Coital incontinence at orgasm **G2:** Coital incontinence during penetration **G3:** DO + coital incontinence at orgasm (sub-group of G1) **G4:** DO w/o coital incontinence (controls) **N at enrollment:** **G1:** 49 **G2:** 83 **G3:** 34 **G4:** 53 **N at follow-up:** NR **Age, median (range):** **G1-G2:** 51 (22-70) **G3:** 50 (22-66) **G4:** 51 (19-68) **BMI (kg/m^2), median (range):** **G1-G2:** 24.1 (17-43) **G3:** 25.3 (17-43) **G4:** 26 (19-35) **Race/ethnicity:** NR **Postmenopausal, n (%):** **G1-G2:** 59 (44.7) **G3:** 14 (41.2) **G4:** 19 (35.8)	**Inclusion criteria:** • Sexually active women with UI **Exclusion criteria:** • Documented UTI • Previous anti-muscarinic trt • POP-Q ≥ Stage 2 • Refusal to answer questions about sex life	**Type of UI, n (%):** DO: **G1:** 34 (69.4) **G2:** 13 (15.7) *P* < 0.0001 SUI: **G1:** 5 (10.2) **G2:** 40 (48.2) MUI: **G1:** 0 **G2:** 11 (13.2) Inconclusive: **G1:** 10 (20.4) **G2:** 19 (22.9)	**Non-responders to trt, n (%):** **G3:** 14 (41.2) **G4:** 9 (17) *P* = 0.023	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: NA Method and blinding: NA Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: - Statistical issues: - EXTERNAL VALIDITY: fair Age: + Baseline OAB status: NR Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: - Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Serati et al, 2008 (continued)	**Parity, median (range):** **G1-G2:** 2 (0-5) **G3:** 2 (0-5) **G4:** 2 (0-4) **Nulliparous, n (%):** **G1-G2:** 7 (5.3) **G3:** NR **G4:** NR **Follow-up:** 12 weeks				

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Steers et al., 2007 **Country and setting:** Australia, Canada, US; multicenter, 30 centers **Enrollment period:** July 2001 to September 2003 **Funding:** Eli Lilly FVC - frequency volume chart DOA - detrusor overactivity SU - sensory urge PVR - postvoid residual urine BL - baseline PGI-I- Patient Global Impression of Improvement TEAEs= Treatment emergent adverse events	**Design:** RCT, placebo-controlled, double-blind, stratified by urodynamic observation (DOA **Intervention:** duloxetine vs placebo **Groups:** G1: placebo x 2 wks, duloxetine 40 mg bid x 4 wks, duloxetine 60 mg bid x bid 8 wks G2: placebo bid x 14 wks **N at enrollment:** G1: 153 G2: 153 **N at follow-up, N (%):** G1: 90 (59) G2: 120 (78) **Age, mean ± SD:** G1: 56.0 ± 14.8 G2: 53.3 ± 14.1 **Women, N (%):** 306 (100) **BMI, mean kg/m2 ± SD:** G1: 29.2 (7.4) **G2: 30.2 (7.8)**	**Inclusion criteria:** • women • >18 yoa • predominant symptoms of OAB ≥ 3 months defined as bothersome urinary urgency and/or urge, abnormal voiding frequency (≤2 h mean daytime voiding interval) • UDS observation of either detrusor OA or urgency that limited bladder capacity to <400mL **Exclusion criteria:** • -SUI • PVR >100 mL • Mean 24 h total volume voided of ≥ 3L • Urine culture • ≥4 UTIs in past yr • Regular use of meds for OAB w/in 4wks of enrollment • Previous use of duloxetine • Continence surgery ≤ 6 mos • Any major surgery ≤ 3 mos • Pelvic organ prolapse > ICS Stage II • Non-pharm intervention ≤ 3 mos • PFM training that had not been stable for 3 mos or would not remain stable during the trial	**Void per 24 hrs:** G1: 10.76 G2:: 10.49 **Daytime VI** G1: 113.58 G2: 119.63 **Urinary incontinence episodes(all assessable pts):** G1: 1.70 G2: 1.44 **Urinary incontinence episode (wet OAB):** G1: 2.34 G2: 2.07 **Continence pads/wk:** G1: 7.81 G2: 7.05 **Volume voided, mL:** G1: 175.41 G2: 183.40 **Nocturia episodes/d:** G1: 1.47 G2: 1.63 **Quality of Life Instrument score, mean ± SD:** **I-QOL** G1: 56.65 ± 24.80 G2: 57.11 ± 23.3 **U-IIQ:** G1: 2.44 ± 1.18 G2: 2.39 ± 1.15 **U-UDI:** G1: 3.18 ± 0.58 G2: 3.15 ± 0.71 **Bladder compliance (mL/cmH20)** G1: 71.8 ± 85.7 G2: 79.3 ± 91.0	**VE24** G1: -1.81 G2:: -0.62 G1vG2, P<0.001 **Daytime VI** G1: 29.46 G2: 6.51 G1vG2, P<0.001 **UIE (all assessable pts)** G1: -0.74 G2: -0.14 p=0.006 **UIE (wet OAB)** G1: -1.03 G2: -0.24 p=0.032 **Continence pads/wk:** G1: -1.41 G2: -0.53 P=0.143 **Volume voided, mL:** G1: 8.85 G2: 5.07 P=0.171 **Nocturia episodes/d:** G1: 0.05 G2: -0.18 p=0.004 **8/12 wks (120 mg/day)** G1: 61.6 G2: 42.1 p=0.008 **Overall:** G1: 53.4 G2: 41.9 G=0.052 **Headache:** G1: 13 (8.5) G2: 8 (5.2) p=0.336	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: - Drop-out rates: ++ Power calculation: + Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Steers et al., 2007 (continued)			**SUI:** G1: 0 G2: 0 **Maximum cystometric capacity mL** G1: 318.3 ± 152.4 G2: 330.4 ± 135.4 **Volume threshold for first detrusor contraction mL** G1: 226.4 ± 141.8 G2: 250.6 ± 146.0 **Moderate or severe bladder condition from PGI-I Scale (%):** G1: 84.9 G2: 88.8 **I-QOL total score, mean ± SD:** G1: 56.6 (24.9) G2: 57.0 (23.2) **UIE , mean ± SD:** G1: 1.55 (2.08) G2: 1.41 (2.00) **VE24 , mean ± SD:** G1: 10.8 (3.3) G2: 10.6 (3.6) **Symptom of bothersome urgency, %:** G1: 99.3 G2: 99.3 **Symptoms of urge UI, %:** G1: 88.2 G2: 88.9 **Symptoms of SUI:** G1: 42.5 G2: 50.3 **Urodynamic** DOA G1: 42.5 G2: 41.8	**Diarrhea:** G1: 10 (6.5) G2: 5 (3.3) p=0.289 **Cough:** G1: 7 (4.6) G2: 6 (3.9) p>0.999 **Change in QoL Instrument score, mean ± SD:** **I-QOL** G1: 8.37 ± 15.89 G2: 4.87 ± 15.27 G1>G2 (P=.035) **U-IIQ** G1: -0.44 ± 0.76 G2: -0.22 ± 0.87 P=0.018 **U-UDI** G1: -0.26± 0.67 G2: -0.19 ± 0.59 P=0.440 **Bladder compliance (mL/cmH20)** G1: 16.5 ±131.3 G2: 1.0 ± 120.8 P=0.655 **Maximum cystometric capacity mL** G1: 22.1 ± 116.4 G2: 23.8 ± 108.5 P=0.619 **Volume threshold for first detrusor contraction mL** G1: 90.0 ± 200.6 G2 : 13.9 ± 112.8 P=0.254 **PGI-I score** Better 4 wks (80 mg/day) G1: 59.9 G2: 42.9 p=0.005	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Steers et al., 2007 (continued)			**Sensory urgency:** G1: 57.5 G2: 58.2 **Previous continence surgery, %:** G1: 13.1 G2: 11.8 **Current pelvic-floor muscle training, %:** G1: 9.2 G2: 11.8 **Previous behavioral therapy, %:** G1: 3.3 G2: 2.6 **Previous tolterodine therapy, %:** G1: 10.5 G2: 7.2 **Previous oxybutynin therapy, %:** G1: 13.0 G2: 9.2	**TEAEs reported, %** G1: 79.1 G2: 55.6 P<0.001 **Appetite decreased** G1: 6 (3.9) G2: 0 G1>G2, p=0.030 **Arthralgia** G1: 6 (3.9) G2: 3 (2.0) p=0.501 **Somnolence:** G1: 6 (3.9) G2: 0 p=0.30 **Sweating increased:** G1: 6 (3.9) G2: 2 (1.3) p=0.283 **UTI:** G1: 6 (3.9) G2: 6 (3.9) p>0.999 **Anorgasmia** G1: 5 (3.3) G2: 0 G1>G2, p=0.060 **Anxiety:** G1: 5 (3.3) G2: 0 G1>G2, p=0.060 **Tremor:** G1: 5 (3.3) G2: 0 G1>G2, p=0.060 **Upper respiratory infection:** G1: 5 (3.3) G2: 4 (2.6) p>0.999 **Vomiting:** G1: 5 (3.3) G2: 3 (2.0) p=0.723	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Steers et al., 2007 (continued)				**Abdominal pain:** G1: 4 (2.6) G2: 1 (0.7) p=0.371 **Back pain:** G1: 4 (2.6) G2: 1 (0.7) p=0.371 Note: mean change consistent at 4 wks (duloxetine 80 mg/d) and 8 wks (duloxetine 120 mg/d) **Change in I-QOL total score, mean ± SD:** **Discontinuation due to TEAEs, %** G1: 28.1 G2: 5.2 p<0.001 **Treatment emergent adverse events, n (%):** **Nausea:** G1: 47 (30.7) G2: 7 (4.6) G1>G2, p<0.001 **Dry mouth:** G1: 25 (16.3) G2: 2 (1.3) G1>G2, p<0.001 **Dizziness:** G1: 22 (14.4) G2: 1 (0.07) G1>G2, p<0.001 **Constipation:** G1: 21 (13.7) G2: 5 (3.3) G1>G2, p=0.002 **Insomnia:** G1: 20 (13.1) G2: 5 (3.3) G1>G2, p=0.003 **Fatigue:** G1: 16 (10.5) G2: 3 (2.0) G1>G2, p=0.003	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Sussman and Garely, 2002 **Country and setting:** US; 2 sites **Enrollment period:** NR **Funding:** NR **Author industry relationship disclosures:** NR	**Design:** Multicenter RCT **Intervention:** Tolterodine ER vs. Oxybutynin ER **Groups:** **G1:** Tolterodine ER 2 mg qd x 8 wks **G2:** Tolterodine ER 4 mg qd x 8 wks **G3:** Oxybutynin ER 5 mg qd x 8 wks **G4:** Oxybutynin ER 10 mg qd x 8 wks **N at enrollment:** **G1**: 333 **G2:** 336 **G3:** 313 **G4:** 307 **N at follow-up:** **G1**: 313 (86) **G2:** 316 (88) **G3:** 286 (81) **G4:** 285 (79) **Age, yrs ± SD:** **G1:** 63.8 ± 15.7 **G2:** 63.4 ± 16.6 **G3:** 59.8 ± 16.5 **G4:** 63.2 ± 15.9 **Women, N (%):** **G1:** 243 (73) **G2:** 254 (76) **G3:** 245 (78) **G4:** 222 (72) **Race/ethnicity, n (%):** **White:** **G1:** 278 (84) **G2:** 296 (88) **G3:** 256 (82) **G4:** 247 (81) **Black:** **G1:** 28 (8) **G2:** 23 (7) **G3:** 41 (13) **G4:** 42 (14)	**Inclusion criteria:** • 18+ years old • OAB (urinary frequency + urgency) w/ or w/o UI **Exclusion criteria:** • Pure SUI • Urinary retention • Gastric retention • Uncontrolled narrow-angle glaucoma • Hepatic or renal dysfunction • Symptomatic or recurrent UTI • ES • BT • Pelvic floor exercise w/in 1 wk of first study visit or expected to start during study • Indwelling catheter • Intermittent self-catherization • Contraindication to antimuscarinic trt • Estrogen therapy started less than 2 mos prior to first visit • Any treatment for UI w/in 1 wk of first visit • Use of anticholinergic drug or potent inhibitors of cytochrome P450 3A4 • Pregnant • Lactating • Childbearing potential w/o adequate contraception	**Presence of UI, n (%):** **G1:** 195 (59) **G2:** 214 (64) G3: 199 (64) G4: 195 (64) **Duration of sx, n (%):** **<6 mos** **G1:** 38 (11) **G2:** 48 (14) **G3:** 62 (20) **G4:** 43 (14) **6mos-5yrs:** **G1:** 226 (68) **G2:** 224 (67) **G3:** 183 (59) **G4:** 205 (67) **>5yrs:** **G1:** 68 (20) **G2:** 64 (19) **G3:** 67 (21) **G4**: 59 (19) **Severity of bladder condition, %** **No problems:** **G1:** 1.3 **G2:** 0.3 **G3:** 1.0 **G4:** 0.7 **Some very minor problems:** **G1:** 6 **G2:** 5 **G3:** 5 **G4:** 5 **Some minor problems:** **G1:** 18 **G2:** 16 **G3:** 21 **G4:** 15 **Moderate problems** **G1:** 45 **G2:** 50 **G3:** 41 **G4:** 47	**Bladder Condition Questionnaire** **Improvement in bladder condition at 8 wks, %:** **Overall** **G1:** 60 **G2:** 70 **G3:** 59 **G4:** 60 G2 vs G3 p<0.01 G2 vs G4 p<0.01 **Pts with moderate or severe bladder condition:** **G2:** 77 **G4:** 65 G2 vs G4 p<0.01 **Treatment naive** **G1:** 60 **G2:** 69 **G3:** 60 **G4:** 61 p=0.11 for improvement rates p>0.05 for overall difference btw trt arms **Treatment experienced** **G1:** 57 **G2:** 75 **G3:** 59 **G4:** 54 p=0.11 for improvement rates p>0.05 for overall difference btw trt arms **Adverse Events** **Withdrawal d/t AE, (%):** **G2:** 6 **G4:** 13 P=0.001	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: - Pt selection criteria: + Loss to followup: - Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Sussman and Garely, 2002 (continued)	**Hispanic:** **G1:** 19 (6) **G2:** 15 (5) **G3:** 15 (5) **G4:** 16 (5) **Other, n (%):** **G1:** 8 (2) **G2:** 2 (<1) **G3:** 1 (<1) **G4:** 2 (<1) **Parity:** NR		**Severe problems:** **G1:** 26 **G2:** 21 **G3:** 23 **G4:** 25 **Many severe problems:** **G1:** 4 **G2:** 7 **G3:** 8 **G4:** 8	**Mean change in severity of dry mouth (visual analogue scale):** **G1:** 2.3 **G2:** 6.0 **G3:** 6.3 **G4:** 11.3 G1 vs G2: p=NS G3 vs G4: p=0.05 G2 vs G4: p=0.03	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Swift et al., 2003 **Country and setting:** Europe (167 centers), North America (74 centers), Australia and New Zealand (4 centers), University **Enrollment period:** February 1999 to October 1999 **Funding:** Pharmacia Corp **Author industry relationship disclosures:** NR	**Design:** RCT double blind placebo-controlled double dummy, random permuted blocks of 6 **Intervention:** Tolterodine ER vs. Tolterodine IR **Groups:** **G1:** Tolterodine ER 4mg daily **G2:** Tolterodine IR 2 mg BID **G3**: placebo **N at enrollment:** **G1**: 417 **G2:** 408 **G3**: 410 **N at follow-up:** Total: 1092 **Women, %:** 100 **Age, yrs ± SD:** **G1:** 59 ± 14 **G2:** 59 ± 14 **G3:** 60 ± 14 **Race/ethnicity, n (%):** **White:** **G1:** 396 (95) **G2:** 389 (95) **G3:** 383 (93) **Black:** **G1:** 15 (4) **G2:** 12 (3) **G3:** 20 (5) **Asian/Pacific:** **G1:** 5 (1) **G2:** 4 (1) **G3:** 2 (1) **Mixed:** **G1:** 0 **G2:** 3 (1) **G3:** 5 (1) **Unknown:** **G1:** 1 (<1) **G2:** 0 **G3:** 0	**Inclusion criteria:** • Women • Age ≥ 18 • ≥ 8 voids/day • > 5 UUI/ week • Symptoms x ≥ 6 months (per voiding diary) **Exclusion criteria:** • SUI • Total daily urine volume > 3 liters • Hepatic/ renal disease • UTI • IC • Hematuria • BOO • Current e-stim • Current bladder training • Indwelling catheter • CIC • Pregnant/ nursing • Childbearing age without BC • Anticholinergic meds • Meds inhibit cytochromep450	**Incontinence episodes/week, mean ± SD:** **G1:** 22.1 ± 22.5 **G2:** 22.9 ± 21.9 **G3:** 23.9 ± 21.2 **Pads/day, mean ± SD:** **G1:** 1.6 ± 2.1 **G2:** 1.5 ± 2.0 **G3:** 1.7 ± 2.4 **Voids/day, mean ± SD:** **G1:** 10.8 ± 4.2 **G2:** 11.1 ± 3.7 **G3:** 11.2 ± 3.9 **Voided volume (mL), mean ± SD:** **G1:** 141.2 ± 43.1 **G2:** 137.2 ± 41.2 **G3:** 135.7 ± 43.2 **Previous drug therapy: n (%):** **G1:** 235 (56) **G2:** 222 (54) **G3:** 225 (55)	**Incontinence episodes/week, mean ± SD:** **G1:** 10.3 ± 17.2 **G2:** 12.8 ± 19.8 **G3:** 16.7 ± 19.7 **G1/G3:** P = 0.001 **G2/G3**: P = 0.001 **Pads/day, mean ± SD:** **G1:** 1.0 ± 1.8 **G2:** 1.0 ± 1.5 **G3:** 1.5 ± 2.2 **G1/G3:** P = 0.001 **G2/G3**: P = 0.001 **Voids/day, mean ± SD:** **G1:** 9.0 ± 3.2 **G2:** 9.3 ± 4.0 **G3:** 9.9 ± 3.8 **G1/G3:** P = 0.001 **G2/G3**: P = 0.005 **Voided volume (mL), mean ± SD:** **G1:** 179.1 ± 66.6 **G2:** 169.7 ± 65.6 **G3:** 149.0 ± 56.3 **G1/G3:** P = 0.001 **G2/G3**: P = 0.001 **Clinical effect-tiveness*, dry mouth:** **G1:** 0.53 **G2:** 0.39 **G3:** 0.30 **Dry mouth, n (%):** **G1:** 105 (25.3) **G2:** 127 (31.2) **G3:** 33 (8.0) **G1/G3:** P < 0.01 **G2/G3:** P < 0.01 **Abdominal pain, n (%):** **G1:** 18 (4.3) **G2:** 12 (2.9) **G3:** 7 (1.7) **G1/G3:** P = 0.03	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: + Masking: + Pt selection criteria: + Loss to followup: ++ Drop-out rates: ++ Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Swift et al., 2003 (continued)	**BMI, kg/m^2 ± SD:** **G1:** 28.8 ± 13.8 **G2:** 29.0 ± 11.0 **G3:** 28.8 ± 6.7			**Constipation, n (%):** **G1:** 27 (6.5) **G2:** 27 (6.6) **G3:** 14 (3.4) **Dyspepsia, n (%):** **G1:** 11 (2.7) **G2:** 14 (3.4) **G3:** 6 (1.5) **Nausea, n (%):** **G1:** 7 (1.7) **G2:** 9 (2.2) **G3:** 9 (2.2) **Diarrhea, n (%):** **G1:** 10 (2.4) **G2:** 14 (3.4) **G3:** 9 (2.2) **Flatulence, n (%):** **G1:** 8 (1.9) **G2:** 11 (2.7) **G3:** 6 (1.5) **Xerophthalmia, n (%):** **G1:** 16 (3.9) **G2:** 8 (2.0) **G3:** 8 (2.0) **Abnormal vision, n (%):** **G1:** 5 (1.2) **G2:** 4 (1.0) **G3:** 2 (0.5) **Headache, n (%):** **G1:** 29 (7.0) **G2:** 14 (3.4) **G3:** 19 (4.6) **UTI, n (%):** **G1:** 15 (3.6) **G2:** 11 (2.7) **G3:** 19 (4.6) **Insomnia, n (%):** **G1:** 7 (1.7) **G2:** 2 (0.5) **G3:** 9 (2.2) **Somnolence, n (%):** **G1:** 12 (2.9) **G2:** 11 (2.7) **G3:** 8 (2.0)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Swift et al., 2003 (continued)				**Dizziness, n (%):** **G1:** 7 (1.7) **G2:** 7 (1.7) **G3:** 4 (1.0) **Hypertension, n (%):** **G1:** 6 (1.4) **G2:** 4 (1.0) **G3:** 4 (1.0) **Sinusitis, n (%):** **G1:** 8 (1.9) **G2:** 2 (0.5) **G3:** 3 (0.7) **Arthritis, n (%):** **G1:** 1 (0.2) **G2:** 5 (1.2) **G3:** 1 (0.2) **Dry skin, n (%):** **G1:** 2 (0.5) **G2:** 5 (1.2) **G3:** 1 (0.2)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Van Kerrebroeck et al., 2002 Freeman et al., 2003* **Country and setting:** North America (74 centers), Australasia (4 centers), Europe (89 centers) **Enrollment period:** NR **Funding:** Pharmacia Corporation **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Tolterodine ER vs Tolterodine IR vs placebo **Groups:** **G1:** tolterodine ER 4 mg sid **G2:** tolterodine IR 2 mg bid **G3:** placebo **N at enrollment:** **G1**: 507 **G2:** 514 **G3:** 508 **N at follow-up:** **Total:** 1442 **G1:** 398 **G3:** 374 **Women, n (%):** **G1:** 417 (82) **G2:** 408 (79) **G3:** 410 (81) **Age, mean (range):** **G1:** 60 (20, 89) **G2:** 60 (22, 92) **G3:** 61 (22, 93) **Race/ethnicity, %:*** **White:** **G1:** 95.7 **G3:** 94.7 **Black:** **G1:** 3.0 **G3:** 3.5 **Asian/Pacific Islander:** **G1:** 1.0 **G3:** 0.8 **Other:** **G1:** 0.3 **G3:** 1.1	**Inclusion criteria:** • Age ≥ 18 • Urinary frequency (≥ 8 voids/day) **Exclusion criteria:** • SUI • Total daily urine volume > 3 L • Contra-indications to antimuscarinic treatment • Hepatic or renal disease • UITs • Interstitial cystitis • Hematuria • BOO • Current electrostimula-tion or bladder training therapy • Indwelling catheter or intermittent self-catheterization • Pregnant or nursing • Women not using reliable contraception • Being treated for OAB with other anticholinergic drugs or drugs that inhibit cytochrome P450 3A4 isoenzymes • Estrogen therapy < 2 months • Treatment w/ investigational drug < 2 months	**Incontinence episodes/week, mean (range):** **G1:** 22.1 (0, 168.0) **G2:** 23.2 (0, 168.0) **G3:** 23.3 (0, 168.0) **≥ 5 incontinence episodes/week, n (%):** **G1:** 492 (97) **G2:** 498 (97) **G3:** 494 (97) **Pads/day, mean (range):** **G1:** 1.4 (0-18) **G2:** 1.4 (0-25) **G3:** 1.5 (0-22) **Voids/day, mean (range):** **G1:** 10.9 (2.3, 51.3) **G2:** 11.1 (2.0, 48.6) **G3:** 11.3 (2.0, 37.4) **≥ 8 voids/day, n (%):** **G1:** 458 (90) **G2:** 469 (91) **G3:** 467 (92) **Previous drug therapy, n (%):** **G1:** 270 (53) **G2:** 276 (54) **G3:** 263 (52) **Poor efficacy, %:** **G1:** 43 **G2:** 38.4 **G3:** 40.7 **Able to finish tasks before visiting a toilet, %:*** **G1:** 5 **G3:** 6	**Urinary Urgency, subjective assess-ment, 12 wks, n (%):*** Improvement: **G1:** 173 (44) **G3:** 118 (32) **G1/G3:** P < 0.001 No change: **G1:** 201 (51) **G3:** 212 (57) Deterioration: **G1:** 22 (6) **G3:** 44 (12) **G1/G3:** P < 0.002 **Urinary urgency, improvement, 12 wks, women only, %:*** **G1:** 46.6 **G3:** 26.6 **G1/G3:** P = 0.001 OR 1.81 (95% CI: 1.31, 2.49) **Not able to hold urine, 12 wks, %:*** **G1:** 58 **G3:** 32 **G1/G3:** P < 0.001 **Incontinence episodes/week, mean change ± SD (%)** **G1:** -11.8 ± 17.8 **G2:** -10.6 ± 16.9 **G3:** -6.9 ± 15.4 **G1/G3:** P = 0.00001 **G2/G3:** P = 0.0005 **G1/G2:** P < 0.05 **Incontinence episodes/week, median % change:** **G1:** -71 **G2:** -60 **G3:** -30 **G1/G2:** P < 0.05	Quality: Overall quality score: fair INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: - Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Van Kerrebroeck et al., 2002 Freeman et al., 2003* (continued)			**Voided volume (mL), mean (range):** **G1:** 141 (36, 338) **G2:** 137 (38, 283) **G3:** 136 (31, 374)	**Pads/day, mean ± SD:** **G1:** -0.5 ± 1.4 **G2:** -0.5 ± 18 **G3:** -0.2 ± 1.4 **G1/G3:** P = 0.0145 **G2/G3:** P = 0.0035 **Voids/day, mean ± SD:** **G1:** -3.5 ± 4.9 **G2:** -3.3 ± 4.4 **G3:** -2.2 ± 4.0 **G1/G3:** P = 0.00001 **G2/G3:** P = 0.0002 **Voluntary voids/ day, mean ± SD:** **G1:** -1.8 ± 3.4 **G2:** -1.7 ± 3.3 **G3:** -1.2 ± 2.9 G1 vs G3 **G1/G3:** P = 0.00047 **G2/G3:** P = 0.0079 **Bladder symptoms, improvement, 12 wks, women only, %:*** **G1:** 62.8 **G3:** 48.4 **G1/G3:** P = 0.001 OR 1.78 (95% CI: 0.34, 2.37) **Treatment benefit, 12 wks, n (%):*** **Much benefit:** **G1:** 172 (43.2) **G3:** 88 (23.5) **G1/G3:** P < 0.001 Little benefit **G1:** 138 (34.7) **G3:** 118 (31.6) No benefit **G1:** 88 (22.1) **G3:** 168 (44.9)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Van Kerrebroeck et al., 2002 Freeman et al., 2003* (continued)				**Able to finish tasks before visiting a toilet, 12 wks, %:*** **G1:** 33 **G3:** 18 **G1/G3:** P < 0.001 **Voided volume (mL), mean change ± SD:** **G1:** +34 ± 51 **G2:** +29 ± 47 **G3:** +14 ± 41 **G1/G3:** P = 0.00001 **G2/G3:** P = 0.0001 **Discontinued due to AEs, n (%):** **G1:** 27 (5) **G2:** 28 (5) **G3:** 33 (6) **Reported serious adverse events, n:** **G1:** 7 **G2:** 12 **G3:** 18 **Parasympathetic Dry mouth, n (%):** **G1:** 118 (23) **G2:** 156 (30) **G3:** 39 (8) **Xerophthalmia, n (%):** **G1:** 17 (3) **G2:** 12 (2) **G3:** 10 (2) **Abnormal vision, n (%):** **G1:** 6 (1) **G2:** 4 (1) **G3:** 2 (0.5) **Dry skin, n (%):** **G1:** 2 (0.5) **G2:** 6 (1) **G3:** 1 (0.5)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Van Kerrebroeck et al., 2002 Freeman et al., 2003* (continued)				**Gastrointestinal Constipation, n (%):** **G1:** 30 (6) **G2:** 35 (7) **G3:** 22 (4) **Dyspepsia, n (%):** **G1:** 15 (3) **G2:** 16 (3) **G3:** 7 (1) **Abdominal pain, n (%):** **G1:** 19 (4) **G2:** 13 (3) **G3:** 8 (2) **Diarrhea, n (%):** **G1:** 10 (2) **G2:** 16 (3) **G3:** 11 (2) **Flatulence, n (%):** **G1:** 10 (2) **G2:** 14 (3) **G3:** 9 (2) **Nausea, n (%):** **G1:** 7 (1) **G2:** 10 (2) **G3:** 10 (2) **Headache, n (%):** **G1:** 32 (6) **G2:** 19 (4) **G3:** 23 (5) **Somnolence, n (%):** **G1:** 14 (3) **G2:** 13 (3) **G3:** 9 (2) **Dizziness, n (%):** **G1:** 11 (2) **G2:** 9 (2) **G3:** 5 (1) **Fatigue, n (%):** **G1:** 11 (2) **G2:** 6 (1) **G3:** 4 (1) **Insomnia, n (%):** **G1:** 7 (1) **G2:** 2 (0.5) **G3:** 9 (2)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Van Kerrebroeck et al., 2002 Freeman et al., 2003* (continued)				**Urinary tract infection, n (%):** **G1:** 16 (3) **G2:** 13 (3) **G3:** 20 (4) **Dysuria, n (%):** **G1:** 5 (1) **G2:** 8 (2) **G3:** 1 (0.5) **Peripheral edema, n (%):** **G1:** 7 (1) **G2:** 7 (1) **G3:** 4 (1)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Zinner et al., 2002 [See evidence table for Van Kerrebroeck et al., 2001} **Country and setting:** North America (74 centers), Australasia (4 centers), Europe (89 centers) **Enrollment period:** NR **Funding:** Pharmacia Corporation **Author industry relationship disclosures:** NR	**Design:** RCT **Intervention:** Tolterodine ER vs. placebo **Groups:** **G1:** tolterodine ER 4 mg qd < 65 years of age **G2:** placebo < 65 years of age **G3:** tolterodine ER 4 mg qd ≥ 65 years of age **G4:** placebo ≥ 65 years of age **N at enrollment:** **G1**: 293 **G2:** 285 **G3:** 214 **G4:** 223 **N at follow-up:** **G1**: 257 **G2:** 246 **G3:** 193 **G4:** 194 **Women, n (%):** **G1:** 255 (87)** **G2:** 247 (87)** **G3:** 162 (76) **G4:** 163 (73) **Age, mean ± SD:** **G1:** 51 ± 10.5 **G2:** 51 ± 10 **G3:** 74 ± 6 **G2:** 74 ± 6 **Race/ethnicity:** NR	**Inclusion criteria:** • Age ≥ 18 • Urinary frequency (≥ 8 voids/day) **Exclusion criteria:** • Demonstrable SUI • Total daily urine volume > 3 L • Contra-indications to antimuscarinic treatment • Hepatic or renal disease • UTI • Interstitial cystitis • Hematuria • BOO • Current electrostimula-tion or bladder training therapy • Indwelling catheter or intermittent self-catheterization • Pregnant or nursing • Women not using reliable contraception • Being treated for OAB with other anticholinergic drugs or drugs that inhibit cytochrome P450 3A4 isoenzymes • Estrogen therapy < 2 months • Treatment w/ investigational drug < 2 months	**Not able to hold urine upon experiencing urgency, %:** **G1:** 24.9 **G2:** 29.1 **G3:** 33.6 **G4:** 34.5 **Able to complete tasks before toilet visit in response to urgency,%:** **G1:** 6.5 **G2:** 7.7 **G3:** 5.1 **G4:** 4.9 **Incontinence episodes/week, mean ± SD:** **G1:** 21.4 ± 22.1 **G2:** 23.2 ± 22.0 **G3:** 23.2 ± 22.7 **G4:** 23.4 ± 18.9 **Voids/day, mean ± SD:** **G1:** 11.0 ± 3.9 **G2:** 11.4 ± 4.2 **G3:** 10.8 ± 4.5 **G4:** 11.0 ± 3.2 **Voided volume (mL), mean ± SD:** **G1:** 140 ± 41 **G2:** 137 ± 45 **G3:** 141 ± 45 **G4:** 134 ± 39 **Previous drug therapy, n (%):** **G1:** 148 (50.5) **G2:** 146 (51.2) **G3:** 121 (56.5) **G4:** 117 (52.5) **Percentage with poor efficacy, %:** **G1:** 74 (50.0)** **G2:** 60 (41.1)** **G3:** 40 (33.1) **G4:** 46 (39.3)	**Not able to hold urine upon experiencing urgency, %:** **G1:** 11.3 **G2:** 21.1 **G3:** 15.9 **G4:** 25.6 **G1/G2:** P = 0.003 **G3/G4:** P = 0.007 No age-related difference **Able to complete tasks before toilet visit in response to urgency,%:** **G1:** 32.8 **G2:** 16.8 **G3:** 26.2 **G4:** 14.8 **G1/G2:** P = 0.001 **G3/G4:** P = 0.003 No age-related difference **Incontinence episodes/week, mean ± SD** **G1:** -12.0 ± 17.6 **G2:** -7.4 ± 15.6 **G3:** -11.5± 18.2 **G4:** -6.3 ± 15.0 **G1/G2:** P = 0.001 **G3/G4:** P < 0.001 No age-related difference **Voids/day, mean ± SD** **G1:** -2.0 ± 3.1 **G2:** -1.4 ± 3.1 **G3:** -1.4± 3.7 **G4:** -0.9 ± 2.6 **G1/G2:** P = 0.26 **G3/G4:** P = 0.92	Quality: Overall quality score: poor INTERNAL VALIDITY: poor Randomization: + Masking: + Pt selection criteria: + Loss to followup: + Drop-out rates: NR Power calculation: - Statistical issues: + EXTERNAL VALIDITY: fair Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: - Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Zinner et al., 2002 (continued)				**Perception of bladder condition, improved, %:** **G1:** 60.1 **G2:** 51.9 **G3:** 54.2 **G4:** 31.4 **G1/G2:** P < 0.05 **G3/G4:** P < 0.0001 **Perception of bladder condition, no change, %:** **G1:** 32.4 **G2:** 38.9 **G3:** 38.3 **G4:** 51.1 **G4/G2:** P < 0.0001 **Perception of bladder condition, deterioration, %:** **G1:** 7.2 **G2:** 9.1 **G3:** 7.5 **G4:** 17.5 **Treatment beneficial, %:** **G1:** 78.3 **G2:** 58.3 **G3:** 69.8 **G4:** 46.9 **G1/G2:** P = 0.001 **G3/G4:** P = 0.001 No age-related difference **Voided volume (mL), mean ± SD:** **G1:** 35 ± 53 **G2:** 13 ± 41 **G3:** 33± 47 **G4:** 16 ± 41 **G1/G2:** P < 0.001 **G3/G4:** P < 0.001 No age-related difference	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Zinner et al., 2002 (continued)				**Adverse events, %:** **G1:** 50.7 **G2:** 50.5 **G3:** 54.2 **G4:** 46.0 **Dry mouth, severe, %** **G1-G2:** 1.7 **G3-G4:** 1.9 **Dry mouth, moderate, %** **G1-G2:** 7.6 **G3-G4:** 6.5 **Dry mouth, mild, %** **G1-G2:** 13.4 **G3-G4:** 15.9 **No dry mouth, %** **G1-G2:** 77.3 **G3-G4:** 75.7	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Author: Zinner et al., 2004 **Country and setting:** US, 51 sites **Enrollment period:** NR **Funding:** Indevus Corporation **Author industry relationship disclosures:** 4 of 5 Alza (1) Indevus (4) Kyowa (1) Lilly (2) Merck (1) Ortho-McNeil (1) Pfizer (2) Pharma (1) Pharmacia (1) Schwarz (1) Watson (2) Yamanouchi (1)	**Design:** RCT with 2 wk washout period **Intervention:** Trospium chloride vs placebo **Groups:** **G1:** Tropsium chloride 20 mg bid **G2:** placebo **N at enrollment:** **G1**: 262 **G2:** 261 **N at follow-up:** **G1**: 256 **G2:** 256 **Women, n (%):** **G1:** 203 (77.5) **G2:** 186 (71.3) **Age, mean ± SD:** **G1:** 63 ± 0.8 **G2:** 61.5 ± 0.8 **Race/ethnicity, n (%):** **White:** **G1:** 222 (84.7) **G2:** 225 (86.2) **Black:** **G1:** 26 (9.9) **G2:** 20 (7.7) **Hispanic:** **G1:** 10 (3.8) **G2:** 13 (5.0) **Other:** **G1:** 4 (1.6) **G2:** 3 (1.1)	**Inclusion criteria:** • Age ≥18 years • OAB symptoms ≥ 6 mos • Urinary urgency • ≥ 70 voids per week • ≥ 7 UUI episodes/week **Exclusion criteria:** • Stress predominant MUI • Insensate or overflow • Neurogenic bladder disorders • Significant renal disease • Hematuria hematuria and UTI at washout or ≥ twice in the prior year • BOO with PVR ≥ 100 mL • Concurrent use of any anticholinergic drug or other drug therapy for OAB within 21 days before randomization • Bladder surgery ≤ 6 mos • Bladder cancer • Interstitial cystitis • PSA ≥ 10 ng/mL • Diuretic use, estrogen therapy and nonmedical bladder therapy that was not part of a stable, long-term program.	**UUI episodes/ day, mean:** **G1:** 3.9 **G2:** 4.3 **Urgency episodes/day, mean:** **G1:** 11.29 **G2:** 11.72 **Urgency severity score, mean:** **G1:** 1.8 **G2:** 1.8 **Voids/day, mean:** **G1:** 12.7 **G2:** 12.9 **Daytime voids/ day, mean:** **G1:** 10.6 **G2:** 10.9 **Nocturia episodes/day, mean:** **G1:** 2.1 **G2:** 2.0 **Voided volume (mL), mean:** **G1:** 155.1 **G2:** 156.1 **IIQ, mean score (SE):** **G1:** 183.5 (5.6) **G2:** 195.4 (5.6) **IIQ,, women only, mean score (SE):** **G1:** 191.2 (6.3) **G2:** 201.9 (6.6) **Incontinence Impact Ques-tionnaire, travel subscale, score (SE):** **G1:** 52.4 (1.7) **G2:** 55.6 (1.7)	**UUI episodes/ day, mean %change:** **G1:** 59.0 **G2:** 44.2 **G1/BL:** P < 0.0001 **Urgency episodes/day, mean change:** **G1:** -0.22 **G2:** -1.08 **G1/BL:** P < 0.001 **Urgency severity score, mean:** **G1:** 1.8 **G2:** 1.8 **Voids/day, mean change:** **G1:** -2.37 **G2:** -1.29 **G1/BL:** P < 0.0001 **Daytime voids/ day, mean change:** **G1:** -1.90 **G2:** -0.98 **G1/BL:** P < 0.0001 **Nocturia episodes/day, mean change:** **G1:** -0.47 **G2:** -0.29 **G1/BL:** P < 0.05 **Voided volume (mL), mean change:** **G1:** 32.1 **G2:** 7.7 **G1/BL:** P < 0.0001 **IIQ,, LS mean change (SE):** **G1:** -54.0 (5.6) **G2:** -36.0 (5.6) **G1/BL:** P ≤ 0.05	Quality: Overall quality score: fair INTERNAL VALIDITY: fair Randomization: + Masking: - Pt selection criteria: + Loss to followup: ++ Drop-out rates: + Power calculation: - Statistical issues: + EXTERNAL VALIDITY: good Age: + Baseline OAB status: + Baseline characteristics: ++ Length of followup: + Measurement methods: + Measurement reliability: + Intervention description: +

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Zinner et al., 2004 (continued)			**IIQ, social relationships, score (SE):** **G1:** 37.8 (1.5) **G2:** 40.3 (1.5) **IIQ, emotional health, mean score (SE):** **G1:** 47.1 (1.6) **G2:** 49.6 (1.6) **IIQ,, physical activity, mean score (SE):** **G1:** 46.1 (1.6) **G2:** 50.2 (1.6) **Prior OAB med, n (%):** **G1:** 135 (51.5) **G2:** 142 (54.5)	**IIQ, women only, LS mean change (SE):** **G1:** -59.1 (6.6) **G2:** -35.7 (6.9) **G1/BL:** P ≤ 0.05 **IIQ, travel subscale, LS mean change (SE):** **G1:** -14.9 (1.7) **G2:** -9.9 (1.7) **G1/BL:** P < ≤ 0.05 **IIQ, social relationsips, LS mean change (SE):** **G1:** -10.8 (1.4) **G2:** -6.3 (1.4) **G1/BL:** P ≤ 0.05 **IIQ, emotional health, LS mean change (SE):** **G1:** 14.1 (1.5) **G2:** -9.2 (1.5) **G1/BL:** P ≤ 0.05 **IIQ, physical activity, LS mean change (SE):** **G1:** -13.5 (1.7) **G2:** -11.0 (1.7) **Dry mouth, n (%):** **G1:** 57 (21.8) **G2:** 17 (6.5) **Constipation, n (%):** **G1:** 25 (9.5) **G2:** 10 (3.8) **Headache, n (%):** **G1:** 17 (6.5) **G2:** 12 (4.6)	

Evidence Table 7. KQ4 Modifiers of outcomes (continued)

Study Description	Study Design, Interventions, and Population	Inclusion/ Exclusion Criteria	Symptom Characteristics	Outcomes	Quality Rating
Zinner et al., 2004 (continued)				**Diarrhea, n (%):** **G1:** 8 (3.1) **G2:** 14 (5.4) **Abdominal pain, n (%):** **G1:** 8 (3.1) **G2:** 3 (1.1) **Discontinuation due to AE, %:** **G1:** 8.8 **G2:** 5.7	

Appendix D. List of Excluded Studies

Excluded Articles

Full Text Article Exclusion Criteria Codes for Database
X-1A: Not OAB (including post-operative/iatrogenic)
X-1B: Stress or mixed incontinence
X-1C: Isolated nocturia
X-1D: Interstitial cystitis/painful bladder syndrome
X-1E: Pelvic organ prolapse
X-1F: Neurogenic conditions
X-1G: Basic science or anatomy only
X-1H: Imaging/diagnostic study only
X-1I: Other (including questionnaire validation studies, coping strategies, etc.)
X-2: Not original research
X-4: Less than 75% of study population are adult females
X-5: Non-ambulatory population
X-6: Ineligible study type
X-7: N <50
X-8: Non- US cost study/general cost of incontinence (not specifically OAB)
X-9: Treatment not currently available in the US
X-10: Unable to obtain full text of manuscript

List of Excluded Studies

1. Terodiline and oxybutynin in detrusor instability. Drug Ther Bull. 1988 May 16;26(10):37-8. X-2
2. Effects of terodiline on urinary incontinence among older non-institutionalized women. Terodiline in the Elderly American Multicenter Study Group. J Am Geriatr Soc. 1993 Sep;41(9):915-22. X-9
3. Biofeedback, exercise for urge incontinence. Health News. 1999 Jan 5;5(1):7. X-2
4. Overactive bladder. Harv Womens Health Watch. 1999 Oct;7(2):6. X-2
5. Sacral nerve stimulation for the treatment of urinary urgency/frequency. Tecnologica MAP Suppl. 2000 Jun:12-5. X-2
6. Detrol LA and Diropan XL for overactive bladder. Med Lett Drugs Ther. 2001 Apr 2;43(1101):28. X-2
7. Incontinence: an overview. N2N: Nurse2Nurse. 2001 Feb;1(9):11-2, 14-5. X-2
8. Don't let elderly patients 'put up with' incontinence. Senior Care Management. 2002 Jun;5(6):87-8. X-10
9. Behavior therapy and urge incontinence. Mayo Clin Health Lett. 2003 May;21(5):4. X-2
10. Skin patch approved for treatment of overactive bladder. Mayo Clin Womens Healthsource. 2003 Aug;7(8):3. X-2
11. Overactive bladder. Relief for urgency, frequency and incontinence. Mayo Clin Womens Healthsource. 2004 Mar;8(3):1-2. X-2
12. Trospium chloride (Sanctura): another anticholinergic for overactive bladder. Med Lett Drugs Ther. 2004 Aug 2;46(1188):63-4. X-2
13. Innovations in overactive bladder treatment and the nursing home environment. Long-Term Care Interface. 2005;6:19-24. X-5
14. Design of the Behavior Enhances Drug Reduction of Incontinence (BE-DRI) study. Contemp Clin Trials. 2007 Jan;28(1):48-58. X-1I
15. Appropriate pharmacotherapy for nocturia in elderly patients reduces urinary frequency, thereby improving sleep and health-related quality of life. Drugs & Therapy Perspectives. 2008;24(2):15-18. X-1C
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23. Abrams P, Blaivas JG, Fowler CJ, et al. The role of neuromodulation in the management of urinary urge incontinence. BJU Int. 2003 Mar;91(4):355-9. X-2
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27. Abrams P and Swift S. Solifenacin is effective for the treatment of OAB dry patients: a pooled analysis. Eur Urol. 2005 Sep;48(3):483-7. X-2
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Appendix E. List of Peer Reviewers

We extend our appreciation to the members of the Technical Expert Panel (TEP) who provided advice and input during our research process. We identified technical experts on the topic of OAB in the fields of urology, urogynecology, gynecology, primary care, nursing, and patient advocacy to provide assistance during the project. The TEP was both an additional resource and a sounding board during the project. The TEP included twelve members serving as technical or clinical experts, including an AUA representative. To ensure robust, scientifically relevant work, we called on the TEP to provide reactions to work in progress and advice on substantive issues or possibly overlooked areas of research. TEP members are listed below (* also a peer reviewer):

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