Effective Health Care Program

Comparative Effectiveness Review
Number 54

Drug Therapy for Psoriatic Arthritis in Adults: Update of a 2007 Report

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Prepared by:
RTI International–University of North Carolina Evidence-based Practice Center
Research Triangle Park, NC

Investigators:
Katrina E. Donahue, M.D., M.P.H.
Dan Jonas, M.D., M.P.H.
Richard A. Hansen, Ph.D.
Robert Roubey, M.D.
Beth Jonas, M.D., M.P.H.
Linda J. Lux, M.P.A.
Gerald Gartlehner, M.D., M.P.H.
Elizabeth Harden, M.P.H.
Andrea Yuen, B.S.
Patricia Thieda, M.A.
Laura C. Morgan, M.A.
Karen Crotty, Ph.D.
Megan Van Noord, M.S.L.S.

Errata: Tables 2, 3, and 4 have been corrected

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

This report may be used, in whole or in part, as the basis for the development of clinical practice guidelines and other quality enhancement tools, or as a basis for reimbursement and coverage policies. AHRQ or U.S. Department of Health and Human Services endorsement of such derivative products may not be stated or implied.

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Preface

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

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

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

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

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

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

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

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

Stephanie Chang, M.D., M.P.H.
Director, EPC Program
Agency for Healthcare Research and Quality

Carmen Kelly, Pharm.D., R.Ph.
EPC Program Task Order Officer
Agency for Healthcare Research and Quality

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Technical Expert Panel

Teresa J. Brady, Ph.D.
Patient Representative

Jeffrey R. Curtis, M.D., M.P.H.
Assistant Professor
Division of Clinical Immunology and Rheumatology
Associate Director
Center for Education and Research on Therapeutics of MSK Disorders
University of Alabama at Birmingham
Birmingham, AL

Marion McDonagh, Pharm.D.
Assistant Professor
Informatics and Clinical Epidemiology
Oregon Health & Science University
Portland, OR

Christopher T. Ritchlin, M.D., M.P.H.
Internal Medicine, Rheumatology
School of Medicine and Dentistry
University of Rochester
Rochester, NY

Peer Reviewers

Marion McDonagh, Pharm.D.
Assistant Professor
Informatics and Clinical Epidemiology
Oregon Health & Science University
Portland OR

Christopher T. Ritchlin, M.D., M.P.H.
Internal Medicine, Rheumatology
School of Medicine and Dentistry
University of Rochester
Rochester, NY

Drug Therapy for Psoriatic Arthritis in Adults: Update of a 2007 Report

Structured Abstract

Objectives. To compare the benefits and harms of corticosteroids and oral and biologic disease-modifying antirheumatic drugs (DMARDs) for adults with psoriatic arthritis (PsA).

Data Sources. English language articles from 1980 to February 2011 identified through PubMed, Embase, Cochrane Library and International Pharmaceutical Abstracts; unpublished literature including dossiers from pharmaceutical companies.

Methods. Two people independently selected relevant head-to-head trials of any sample size, observational studies with at least 100 participants, and relevant good- or fair-quality meta-analyses that compared benefits or harms of 14 drug therapies. Observational studies were included only for harms. For biologic DMARDs, placebo-controlled, double-blind randomized controlled trials (RCTs) also were included. We required trials and observational studies to be at least 12 weeks in duration. Literature was synthesized qualitatively within and between the two main drug classes (oral and biologic DMARDs).

Results. No head-to-head controlled trials meeting inclusion criteria existed for any drugs in this review for treating patients with PsA. The available evidence was limited to two head-to-head cohort studies and placebo-controlled trials. For oral DMARDs, including sulfasalazine and methotrexate, the sparse data available involved placebo comparisons. For biologic DMARDs, evidence supported the efficacy of adalimumab, etanercept, golimumab, and infliximab for the treatment of PsA when compared with placebo. Qualitatively, these biologic DMARDs appeared to achieve similar improvements in disease activity, functional capacity, and health-related quality of life (American College of Rheumatology 20 percent improvement from baseline to endpoint, Health Assessment Questionnaire, and Short Form 36 Physical Component scores) in these trials. No difference in treatment response was found between the combination of an anti-tumor necrosis factor (TNF) (adalimumab, etanercept, or infliximab) with methotrexate compared with anti-TNF only. Evidence was insufficient to draw conclusions about the comparative harms for oral DMARDs. Among biologics, low evidence indicated that etanercept had a lower rate of withdrawals due to adverse events compared with infliximab. Compared with placebo, adalimumab and etanercept had more injection site reactions and adalimumab had few events of aggravated psoriasis. No comparative evidence was identified for subgroups.

Conclusions. Overall, the data are quite limited and the evidence is insufficient to draw firm conclusions on comparative efficacy, effectiveness, and harms of either oral or biologic DMARDs for PsA. This report's findings did not reveal any differences with current standard of care. Head-to-head (RCTs) are needed to establish the comparative efficacy and safety of different treatments with and without corticosteroids, oral DMARDs, and biologic DMARDs, to determine the best therapy to prevent or minimize debilitating joint damage and optimize quality of life for people with PsA.

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Executive Summary

Background

Psoriatic arthritis (PsA) is among the most disabling forms of arthritis, even though it affects fewer people than other types of arthritis. PsA has a highly variable presentation, which generally involves pain and inflammation in joints and progressive joint involvement and damage. The condition is associated with the skin disease psoriasis, but not all people with psoriasis will develop PsA. Additionally, PsA may predate the development of skin disease, leading to some diagnostic uncertainty. Among people with psoriasis, the prevalence of arthritis varies from 6 percent to 42 percent. In the general population, the prevalence of PsA is estimated to be 0.3 percent to 1 percent. Based on estimates from the 2000 U.S. Census, 520,000 people ages 18 or older in the United States have PsA.

Treatment of patients with PsA aims to control pain and inflammation and, ultimately, to slow the progression of joint destruction and disability. Available therapies for PsA include corticosteroids, oral disease-modifying antirheumatic drugs or DMARDs (hydroxychloroquine, leflunomide, methotrexate [MTX], and sulfasalazine), and biologic DMARDs. Five biologics (adalimumab, certolizumab pegol, etanercept, golimumab, and infliximab) are also classified as antitumor necrosis factor (anti-TNF) drugs. The U.S. Food and Drug Administration (FDA) has approved adalimumab, etanercept, golimumab, and infliximab for use in patients with PsA. This report also reviews evidence for abatacept, anakinra, certolizumab, rituximab, and tocilizumab, which are approved for rheumatoid arthritis (RA).

Historically, few trials have been conducted with patients having PsA, with only minimal research before biologic agents were introduced; management options tended to be adapted from RA trial evidence. Similar to RA trials, many questions remain about the risks of these agents across a spectrum of adverse events from relatively minor side effects such as injection-site reactions to severe and possibly life-threatening problems such as severe infections or infusion reactions.

Experts have not arrived at a consensus about the comparative effectiveness of corticosteroids, oral DMARDs, and biologic DMARDs for treating PsA. More importantly, it is unclear how the effectiveness and safety of different types of combination therapy compare. In addition, there is debate about how early in the disease process combination therapy should be initiated and whether patients will respond to a biologic agent if they have previously failed a different biologic agent. Finally, very little is known about the benefits or risks of these drugs in different patient subgroups, including ethnic minorities, the elderly, pregnant women, and patients with other comorbidities.

Objectives

This report summarizes the evidence on the comparative efficacy, effectiveness, and harms of corticosteroids, oral DMARDs, and biologic DMARDs in the treatment of patients with PsA. This report updates a previous version published in 2007. The Key Questions (KQs) are as follows:

KQ 1: For patients with PsA, do drug therapies differ in their ability to reduce disease activity, to slow or limit the progression of radiographic joint damage, or to maintain remission?

KQ 2: For patients with PsA, do drug therapies differ in their ability to improve patient-reported symptoms, functional capacity, or quality of life?

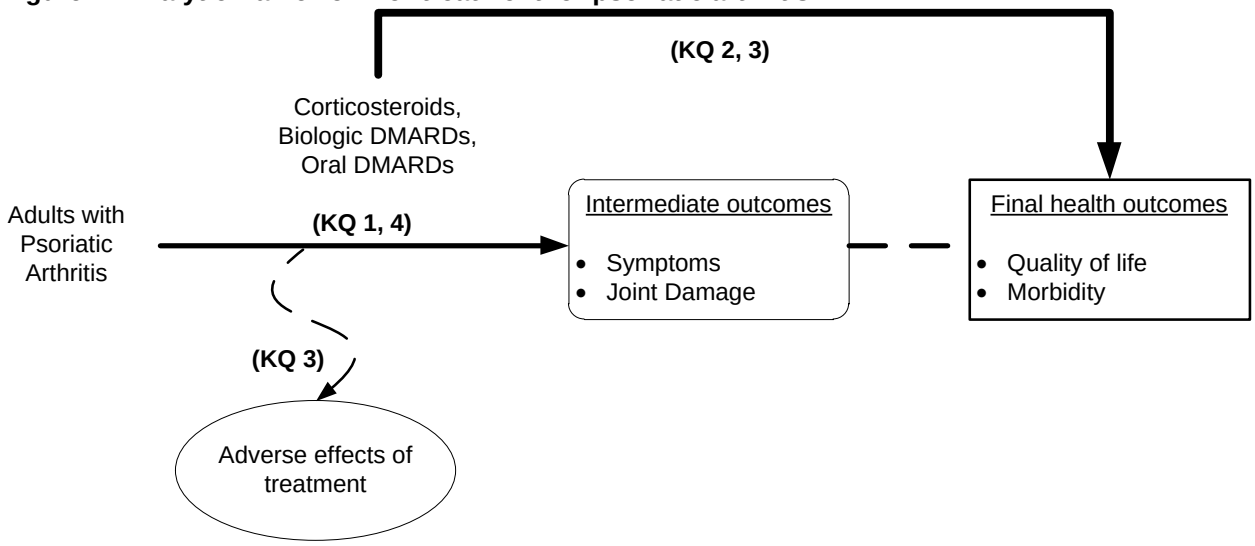
KQ 3: For patients with PsA, do drug therapies differ in harms, tolerability, patient adherence, or adverse effects?

KQ 4: What are the comparative benefits and harms of drug therapies for PsA in subgroups of patients based on stage of disease, prior therapy, demographics, concomitant therapies, or comorbidities?

Analytic Framework

Figure A lays out the analytic framework that guided the research.

Figure A. Analytic framework for treatment for psoriatic arthritis



DMARDS = disease-modifying antirheumatic drugs; KQ = Key Question

Methods

A Technical Expert Panel was employed for the finalization of the KQs and review of the planned analysis strategy. Our KQs and protocol were posted on the AHRQ Web site for public review and comment. Two reviewers performed an external peer review; one a leading expert in psoriatic arthritis and one a faculty member in clinical epidemiology and informatics as well the project director for the Oregon Health and Science University's Drug Effectiveness Review Project reports. The report was also posted for public review. We compiled all comments and addressed each one individually, revising the text as appropriate.

We searched MEDLINE®, Embase, the Cochrane Library, and the International Pharmaceutical Abstracts to identify relevant articles. We limited the electronic searches to "human" and "English language." For this update, the searches went up to January 2011. Hand searches were conducted on the Center for Drug Evaluation and Research (CDER) database of the FDA and unpublished literature, including dossiers from pharmaceutical companies.

Study eligibility (inclusion and exclusion) criteria were designed with respect to study design or duration, patient population, interventions, outcomes, and comparisons for each KQ. For efficacy and effectiveness, we focused on head-to-head trials and prospective cohort studies

comparing one drug with another. For biologic DMARDs, we also included placebo-controlled, double-blind RCTs. For harms and tolerability, as well as for efficacy and effectiveness in subgroups, we included head-to-head trials, high-quality systematic reviews, and observational studies. We included studies with sample sizes of at least 100 and duration of at least 3 months. We included only studies that used doses within the recommended dosing range or that used doses that could be considered equivalent to recommended doses.

Two individuals independently reviewed abstracts identified by searches. If both reviewers agreed that a study did not meet eligibility criteria, we excluded it. We obtained the full text of all remaining articles. Two individuals again independently reviewed the full text of all remaining articles to determine whether they should be included.

We designed and used a structured data abstraction form to ensure consistency of appraisal for each included study. Trained reviewers abstracted data from each study. A senior reviewer evaluated the completeness of each data abstraction.

We rated the quality of individual studies using the predefined criteria based on those developed by the U.S. Preventive Services Task Force (ratings: good, fair, poor)[1] and the National Health Service Centre for Reviews and Dissemination.[2] Two independent reviewers assigned quality ratings. They resolved any disagreements by discussion and consensus or by consulting with a third reviewer. We gave a good-quality rating to studies that met all criteria. We gave a poor-quality rating to studies that had a fatal flaw (defined as a methodological shortcoming that leads to a very high risk of bias) in one or more categories and excluded them from our analyses.

We synthesized the literature qualitatively. We graded the strength of evidence as high, moderate, low, or insufficient based on methods guidance for the EPC program.[3,4] We graded strength of evidence for the outcomes determined to be most important: measures of disease activity (e.g., ACR 20/50/70,[a] DAS), radiographic changes, functional capacity, quality of life, withdrawals due to adverse events, and specific adverse events if data were available (e.g., injection-site reactions, infections, malignancy).

Results

We identified 3,868 citations from our searches. We included 24 published articles reporting on 16 studies: 0 head-to-head randomized controlled trials, 0 head-to-head nonrandomized controlled trials, 10 placebo-controlled trials, 3 meta-analyses or systematic reviews, and 3 observational studies. Our findings included studies rated good or fair for internal validity. Most studies were of fair quality.

Our major findings are presented in this section by type of drug comparison and important outcomes (both benefits and harms as described in KQ 1, KQ 2, and KQ 3) (Table A). No comparative evidence was identified for KQ 4.

[a]American College of Rheumatology measure of disease activity: response scores based on 20, 50, or 70 percent criteria for improvement

Table A. Summary of findings

Key Comparisons	Efficacy and Effectiveness Strength of Evidence Grade	Harms Strength of Evidence Grade
Oral DMARDs		
Leflunomide	No head-to-head studies met inclusion criteria; unable to draw conclusions on the comparative efficacy of leflunomide and other treatments. INSUFFICIENT Compared with placebo in one study, leflunomide produced better improvement in health-related quality of life and statistically significant, but not clinically significant, improvement in disease activity and functional capacity. LOW	No head-to-head studies met inclusion criteria; unable to draw conclusions on the comparative harms of leflunomide and other treatments. INSUFFICIENT Current evidence was limited to placebo-controlled trials. Compared with placebo, leflunomide led to higher rates of withdrawals because of adverse events, diarrhea, and clinically significant increases in alanine aminotransferase. INSUFFICIENT
Methotrexate	No head-to-head studies met inclusion criteria; unable to draw conclusions on the comparative efficacy of MTX and other treatments. INSUFFICIENT Current evidence was limited to placebo-controlled trials. Compared with placebo in one fair study, MTX resulted in greater improvement in physician assessment of disease activity than placebo. LOW	No head-to-head studies met inclusion criteria; unable to draw conclusions on the comparative harms of MTX and other treatments. INSUFFICIENT
Sulfasalazine	No head-to-head studies met inclusion criteria; unable to draw conclusions on the comparative efficacy of sulfasalazine and other treatments. INSUFFICIENT Current evidence was limited to placebo-controlled trials. Compared with placebo in one good systematic review study, sulfasalazine reduced disease activity. MODERATE	No head-to-head studies met inclusion criteria; unable to draw conclusions on the comparative harms of sulfasalazine and other treatments. INSUFFICIENT
Biologic DMARDs		
Biologic DMARD + Oral DMARD vs. Biologic DMARD or Oral DMARD	The current evidence was limited to two cohort studies. Compared to anti-TNF monotherapy (adalimumab, etanercept, or infliximab), MTX plus anti-TNF produced similar disease activity response rates. LOW One systematic review of TNF inhibitors found that both TNF inhibitors and sulfasalazine are effective (similar withdrawals due to lack of efficacy); however, the data were insufficient to determine if the effect reached MCID. INSUFFICIENT	No head-to-head evidence met inclusion criteria; unable to draw conclusions on the comparative harms of biologic DMARD + oral DMARD and other treatments. INSUFFICIENT

Table A. Summary of findings (continued)

Key Comparisons	Efficacy and Effectiveness Strength of Evidence Grade	Harms Strength of Evidence Grade
Biologic	No head-to-head trials met inclusion criteria; unable to draw conclusions on the comparative efficacy of biologics and other treatments. INSUFFICIENT Compared with placebo, adalimumab, etanercept, golimumab, and infliximab led to greater improvement in disease activity, functional capacity[a] and health-related quality of life.[b] LOW to MODERATE[c]	Etanercept had a lower rate of withdrawals because of adverse events than infliximab in a prospective cohort study. LOW Additional evidence was limited to placebo-controlled trials, where adverse events were not the primary outcome. Overall adverse event profiles appeared to be similar for biologic DMARDs and placebo. However, compared with placebo, we noted the following: adalimumab and etanercept had more injection-site reactions and adalimumab had fewer events of aggravated psoriasis than placebo LOW Golimumab was associated with more malignancies than placebo in one RCT INSUFFICIENT

ACR 20 = American College of Rheumatology 20 percent improvement from baseline to endpoint; ADA = adalimumab; DMARD =, disease-modifying antirheumatic drug; ETN = etanercept; INF = infliximab; LEF = leflunomide, MCID = minimal clinically important difference; MTX = methotrexate; PCS = physical component score; SF-36 = Medical Outcomes Study Short Form 36; SSZ = sulfasalazine; TNF = tumor necrosis factor

[a]Of seven studies reporting outcomes for the Health Assessment Questionnaire (HAQ), the magnitude of benefit in functional capacity compared with placebo reached the MCID (HAQ change of ≥ 0.22) for all but one study of adalimumab (which found a between-group difference of 0.2).[7] The magnitude of benefit for functional capacity (between-group difference for improvement in HAQ) ranged from 0.2 to 0.3 for adalimumab, 0.5 to 1.1 for etanercept, 0.34 to 0.4 for golimumab, and 0.4 to 0.6 for infliximab.

[b]The magnitude of benefit in quality of life reached the MCID for the SF-36 PCS for all five studies that reported the PCS and ranged from 2.9 to 7.9 for adalimumab, 8.6 for etanercept, 5.9 to 7.2 for golimumab, and 6.4 to 8 for infliximab.

[c]Low for golimumab and moderate for adalimumab, etanercept, and infliximab.

Overall, the data are quite limited and the evidence is insufficient to draw firm conclusions on comparative efficacy, effectiveness, and harms of either oral or biologic DMARDs in this condition. Table B gives a range for effect sizes for commonly reported measures, including the American College of Rheumatology 20 percent improvement from baseline to endpoint (ACR 20), the Health Assessment Questionnaire (HAQ), and Medical Outcomes Study Short Form 36 Physical Component Score (SF-36 PCS). For the oral DMARDs, including sulfasalazine and methotrexate, sparse data are available.

Table B. Comparison of effect sizes* from placebo-controlled trials for ACR 20, HAQ, and SF-36 PCS by drug

Drug	Studies/Participants	ACR 20 (% of Subjects Achieving)	HAQ (Mean Improvement)	SF-36 PCS (Mean Improvement)
Oral DMARDs				
Leflunomide	1 RCT/ 190	36	0.14	NR
Methotrexate	1 RCT/ 37	NR	NR	NR
Sulfasalazine	1 SER/ 1,022	NR	NR	NR
Biologic DMARDS				
Adalimumab	2 RCTs/ 415	39 to 57	0.2 to 0.3	2.9 to 7.9
Etanercept	3 RCTs/ 633	59 to 65	0.5 to 1.1	8.6
Golimumab	1 RCT/ 405	45 to 51	0.34 to 0.4	5.9 to 7.2
Infliximab	2RCTs,1SER/ 673	58 to 62	0.4 to 0.6	6.4 to 8

ACR 20 = American College of Rheumatology 20 percent improvement from baseline to endpoint; HAQ = Health Assessment Questionnaire; PCS = physical component score; SF-36 = Medical Outcomes Study Short Form 36; RCT = Randomized controlled trial; SER = systematic evidence review

*Effect sizes represent the range of point estimates from individual studies for the absolute difference between drug and placebo. Minimally Clinically Important Differences (MCIDs): ACR 20 is 20% minimal improvement;ACR 50/70 considered more clinically significant; HAQ >=0.22 change, SF36 PCS>= 2 standard error of the mean (SEM).

Discussion

No head-to-head controlled trials meeting inclusion criteria existed for any drugs in this review for treating patients with PsA. Two cohort studies with low strength of evidence indicated that the combination of an anti-tumor necrosis factor (TNF) (adalimumab, etanercept, or infliximab) with methotrexate (MTX) only was not different in treatment response[5,6] than treatment with anti-TNF only.

For the oral DMARDs, including sulfasalazine and methotrexate, the sparse data available involved placebo comparisons. For biologic DMARDs, evidence supported the efficacy of adalimumab, etanercept, golimumab, and infliximab for the treatment of PsA when compared to placebo.[7-17] Qualitatively, these biologic DMARDs appeared to achieve similar ACR 20, HAQ, and SF-36 PCS scores in these trials (Table B). However, findings should be interpreted cautiously given these were not head-to-head trials. Evidence was insufficient to draw firm conclusions about the comparative efficacy, effectiveness, functional status, health-related quality of life, or tolerability of abatacept, adalimumab, anakinra, certolizumab, golimumab, etanercept, infliximab, rituximab, and tocilizumab for treating PsA.

Information generally was insufficient for the comparative harms, tolerability, adverse events, and adherence for patients with PsA. The available studies included two relatively small prospective cohort studies and placebo-controlled studies; no head-to-head studies meeting inclusion criteria have been published.

In terms of applicability to populations, the studies were generally multicenter involving adults with diagnosed PsA. Prior medications tried before these studies were variable, but in general patients had failed a DMARD prior to starting any of the biologic agents. It is also important to note that the diagnostic criteria for PsA before the 2006 publication of the ClASsification of Psoriatic Arthritis (CASPAR) criteria were not validated, which could lead to enrollment of patients that were not explicitly defined.

This report's findings did not reveal any differences with current standard of care. However the current available evidence for PsA was limited. Several areas need further research to help clinicians and researchers arrive at stronger conclusions on the comparative efficacy, effectiveness, quality of life, and harms of medications for PsA. For this condition, the available evidence was limited to two head-to-head cohort studies and placebo-controlled trials. Head-to-head randomized controlled trials are needed to establish the comparative efficacy and safety of different treatments with and without corticosteroids, oral DMARDs, and biologic DMARDs to determine the best therapy to prevent or minimize debilitating joint damage and optimize quality of life for people with PsA. Furthermore, head-to-head RCTs are needed to determine the comparative effectiveness and safety of biologic DMARDs for treating PsA. More generally, the issues of effectiveness, subgroups, and use in ordinary clinical settings warrant attention for PsA.

Abbreviations

ACR	American College of Rheumatology
AHRQ	Agency for Healthcare Research and Quality
CASPAR	ClASsification of Psoriatic Arthritis
DMARD	disease-modifying antirheumatic drug
FDA	U.S. Food and Drug administration
HAQ	Health Assessment Questionnaire
MTX	methotrexate
PsA	psoriatic arthritis
RCT	randomized controlled trial
SF-36 PCS	Short Form 36 Physical Functioning Scale

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Introduction

Background

Arthritis and other rheumatic conditions constitute the leading cause of disability among United States (U.S.) adults,[1] with more than 46 million Americans reporting doctor-diagnosed arthritis.[2] Noninflammatory arthritic conditions (e.g., osteoarthritis) are most common, but inflammatory arthritides such as spondyloarthropathies (e.g., ankylosing spondylitis, psoriatic arthritis [PsA]), and reactive arthritis) and rheumatoid arthritis (RA) can be equally or more disabling.

Among patients with arthritis, the burden of disease is evidenced by decreased quality of life,[3-6] decreased employment rates,[7, 8] and increased direct and indirect costs.[9-12] In 2003, arthritis and other rheumatic conditions cost the United States $127.8 billion ($80.8 billion in medical care expenditures and $47.0 billion in lost earnings).[13]

Costs associated with PsA are not as well studied as costs associated with other arthritic conditions, although they are believed to be just slightly lower than those associated with RA.[11] Indirect costs are believed to increase over time because as the disease progresses so does the loss of function and inability to work. Based on 1997 estimates for psoriasis and PsA, annual direct costs are approximately $650 million.[14] Of these costs, hospitalizations accounted for $31 million, outpatient physician visits for $87 million, photochemotherapy for $27 million, dermatologic prescription drugs for $148 million, and over-the-counter medications for $357 million.[14, 15] These estimates do not include indirect costs, and the specific direct costs of PsA are not known.

Causes and Diagnosis

Psoriasis, a skin disease, affects 2.2 percent of U.S. adults; approximately 6 percent to 42 percent of patients with psoriasis develop PsA.[16] Approximately 520,000 adults in the United States have PsA.[17] PsA can develop at any age but most often appears between 30 and 50 years of age. Unlike RA, PsA appears to affect men slightly more often than women.

Clinically PsA is a multifaceted disease and may have skin presentations that help with its diagnosis. The presentation is highly variable. Patients with PsA can have moderate to severe involvement of skin and joints, and this combination can have profound effects on function and quality of life. In most cases, the psoriasis predates the onset of the PsA, although arthritis has been described as the initial manifestation of psoriatic disease. Common presentations include a symmetric small-joint polyarthritis (RA-like) and an axial arthritis with involvement of the sacroiliac joints, axial skeleton (spine), and large joints. In all cases, symptoms include pain and stiffness in the affected joint, enthesial areas (where tendons insert into bone) with joint line tenderness, swelling, and often loss of range of motion. Pitting of the fingernails often correlates with the extent and severity of the disease. Dactylitis—swelling of a whole digit—is a characteristic clinical finding, and inflammatory eye disease (iritis, uveitis) may occur. More than one-third of patients with PsA will develop dactylitis and enthesopathy (a disease process at the site where muscle tendons or ligaments insert into bones or joints).

The etiology and pathogenesis of psoriasis and PsA are not completely understood, but genetic, immunologic, and environmental factors are all likely to play a role.[18] Several

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classification systems have been proposed for the diagnosis of PsA,[19] but which one best represents true PsA remains unclear.

Table 1 presents the CASPAR (ClASsification of Psoriatic ARthritis) as an example of one classification.[20]

Table 1. CASPAR criteria for the diagnosis of psoriatic arthritis

Inflammatory articular disease (joint, spine, or enthesial areas) with ≥ 3 points from the following:
1. Evidence of current psoriasis, a personal history of psoriasis, or a family history of psoriasis
2. Typical psoriatic nail dystrophy, including onycholysis, pitting, or hyperkeratosis
3. Negative test result for the presence of rheumatoid factor
4. Current dactylitis or history of dactylitis
5. Radiographic evidence of juxtaarticular new bone formation

Source: Taylor W, Gladman D, Helliwell P, Marchesoni A, Mease P, Mielants H. Classification criteria for psoriatic arthritis: development of new criteria from a large international study. Arthritis Rheum. 2006 Aug;54(8):2665-73.[20]

Treatment of Psoriatic Arthritis

Treatment of patients with PsA is aimed primarily at controlling pain and inflammation and, ultimately, at slowing or arresting the progression of joint destruction. Historically, few trials have been conducted in patients with PsA, with only minimal research before biologic agents were introduced; management options tended to be adapted from RA trial evidence. Like in RA trials, many questions remain about the risks of these agents across a spectrum of adverse events from relatively minor side effects such as injection-site reactions to severe and possibly life-threatening problems such as severe infections or infusion reactions. Unlike RA, there is no diagnostic marker for PsA, which can lead to misdiagnosis. Additionally, studies performed before the CASPAR criteria were used included patients that are not explicitly defined.

Corticosteroids

Corticosteroids—sometimes referred to as glucocorticoids or steroids—are used for many inflammatory and autoimmune conditions. As a class, corticosteroids have been used since the discovery of cortisone in the 1940s. Commonly used oral corticosteroids include methylprednisolone, prednisone, and prednisolone.

Corticosteroids are a synthetic form of cortisol, a hormone produced by the adrenal glands. They produce their anti-inflammatory and immunosuppressive response by interacting with steroid-specific receptors in the cytoplasm of cells, thereby inhibiting the movement of inflammatory cells into the site of inflammation, inhibiting neutrophil function, and inhibiting prostaglandin production. When used to treat PsA, corticosteroids are most often given as a joint injection rather than orally. Although they can be very effective in controlling joint inflammation, oral steroids are generally avoided in treating PsA, because a flare of skin disease has been described when steroids are tapered or withdrawn.

Oral Disease-Modifying Antirheumatic Drugs (DMARDs)

Oral DMARDs such as methotrexate (MTX), sulfasalazine, hydroxychloroquine, and leflunomide modify the course of inflammatory conditions, presumably through their effects on the immune system. Most of the oral DMARDs have been used in clinical practice for more than 20 years. MTX was developed in the 1940s as a treatment for leukemia but was not approved for the treatment of arthritis until 1988. Sulfasalazine also has been available since the 1940s; it is a

combination salicylate (acetylsalicylic acid) and antibiotic (sulfapyearidine) that originally was used to treat patients with inflammatory bowel disease. Hydroxychloroquine, approved in the 1950s for the treatment of malaria, is believed to work in treating arthritis by interfering with antigen presentation and the activation of immune response by increasing the pH within macrophage phagolysosomes. Additionally, hydroxychloroquine possibly inhibits toll-like receptors that mediate proinflammatory cytokine production. Only leflunomide, an isoxazole immunomodulatory agent, was specifically developed for treating inflammatory arthritis; the U.S. Food and Drug Administration (FDA) approved its use in 1998.

Oral DMARDs are not members of a single drug family. They are classified together, however, because they all are slow acting with the aim of improving symptoms, reducing or preventing joint damage, and preserving structure and function in patients with inflammatory disease. All the oral DMARDs covered in this review can be given orally, although MTX can also be injected (subcutaneous [SQ] or intramuscular [IM]).

Biologic DMARDs

Biologic DMARDs—commonly referred to as biological response modifiers or simply biologics—are a relatively new category of DMARDs that differ from oral DMARDs in that they target specific components of the immune system. FDA approved the first of the biologics (infliximab) in 1998; this report covers eight additional agents approved since that time: etanercept (1998), anakinra (2001), adalimumab (2002), abatacept (2005), rituximab (2006), certolizumab pegol (2008), golimumab (2009), and tocilizumab (2010). Of the nine agents, all are currently FDA approved for treating RA, but only adalimumab, etanercept, golimumab, and infliximab are approved for treating PsA. Even though anakinra, abatacept, certolixumab pegol, rituximab, and tocilizumab are not FDA approved for PsA, this report reviews the evidence for all of these agents.

The biologic DMARDs work by selectively blocking mechanisms involved in the inflammatory and immune response. Adalimumab, certolizumab pegol, etanercept, golimumab, and infliximab are known as tumor necrosis factor (TNF) inhibitors (i.e., drugs that block specific proinflammatory mediators known as cytokines). They produce their primary effect by blocking TNF from interacting with cell surface TNF receptors. Adalimumab, golimumab, and infliximab are monoclonal antibodies. Adalimumab is a fully human monoclonal antibody that binds specifically to TNF, blocking its interaction with both the p55 and p75 cell surface TNF receptor. Golimumab is also a human monoclonal antibody that binds to TNF alpha with high affinity. Infliximab is a chimeric (i.e., made from human and mouse proteins) monoclonal antibody that binds specifically to human TNF-alpha. Certolizumab pegol is a pegylated humanized antibody fragment of tumor necrosis factor monoclonal antibody. The drug binds to the TNF alpha-receptor and blocks TNF alpha activity. It only possesses the Fab fragment and lacks the Fc region. Hence, it does not induce antibody-dependant cell-mediated apoptosis or toxicity. Etanercept is not a monoclonal antibody, but rather a TNF-soluble receptor protein. More specifically, it is a soluble dimeric form of the p75 TNF receptor linked to the Fc portion of human immunoglobulin G1 (IgG1). Etanercept exerts its action by binding circulating TNF and preventing it from interacting with a cell surface receptor. It does not form neutralizaing antibodies or mediate cell lysis in the presence or absence of complement.

Interleukin-1 (IL-1), another naturally occurring cytokine, has both immune and proinflammatory actions. Anakinra is a human recombinant protein that competitively blocks the IL-1 receptor, thus blocking various inflammatory and immunological responses.

The immunosuppressant agent abatacept produces its immune response by interfering with T lymphocyte activation. Abatacept is a soluble fusion protein that consists of the extracellular domain of human cytotoxic T lymphocyte-associated antigen (CTLA-4) and the modified Fc portion of IgG1.

Rituximab, a chimeric murine/human monoclonal antibody, works by binding to the CD20 antigen found on the surface of B lymphocytes. Thus, it in effect removes circulating B cells from the pre-B cell stage through the activated B cells. B cells are believed to play a role in autoimmune and inflammatory processes.

Interleukin-6 (IL-6) is a naturally occurring cytokine involved in regulating immune responses and inflammation. Tocilizumab is a monoclonal antibody that inhibits IL-6 receptors, blocking the action of IL-6 and leading to a reduction in cytokine and inflammatory response.

Tables 2 through 4 provide detailed information (names, manufacturers, and available dosage forms) on agents used in the treatment of RA that we have included in this review. Also presented are routs of administration, labeled uses, and usual (recommended) adult doses and frequency for PsA.

Table 2. Pharmaceutical treatments for psoriatic arthritis: corticosteroids

Generic Name	Manufacturer U.S. Trade Name(s)*	How Supplied	Usual Adult Dose
Methyl-prednisolone	Multiple Medrol®, Depo-Medrol®, Solu-Medrol®	Acetate - Injectable IM—20, 40, and 80 mg/ml Sodium succinate - Injectable: IM—40, 125, and 500 mg, 1 and 2 g vials Oral: Tabs—2, 4, 8, 16, and 32 mg	Acetate: IM—10 to 80 mg every 1 to 2 weeks Intra-articular, intralesional—4 to 80 mg every 1 to 5 weeks Sodium succinate: IM—10 to 80 mg daily IV—10 to 40 mg every 4 to 6 hours; up to 30 mg/kg every 4 to 6 hours Oral: 2 to 60 mg in 1 to 4 divided doses to start, followed by gradual reduction
Prednisone	Multiple Deltasone®, Sterapred®, LiquiPred®	Oral Solution—1 and 5 mg/ml Tabs—1, 2.5, 5, 10, 20, and 50 mg	Use lowest effective dose (5-60 mg/day)
Prednisolone	Multiple Orapred®, Pediapred®, Prelone®, Delta-Cortef®, Econopred®	Oral Solution/Syrup—5, 15, and 20 mg/5 ml Oral Tabs—5 and 15 mg	Use lowest effective dose (5 to 7.5 mg/day)

IM = intramuscular; IV = intravenous; kg = kilogram; mg = milligram; ml = milliliter

*Listed trade names are limited to commonly prescribed U.S. products when multiple trade names are available.

Table 3. Pharmaceutical treatments for psoriatic arthritis: oral DMARDs

Generic Name	Manufacturer U.S. Trade Name(s)*	How Supplied	Usual Adult Dose
Hydroxy-chloroquine[b]	Multiple Plaquenil®	Oral Tabs—200 mg	200 to 400[a] mg/day in 1 or 2 divided doses
Leflunomide[b]	Multiple Arava®	Oral Tabs—10 and 20 mg	10 to 20 mg/day in a single dose
Methotrexate[b]	Multiple Trexall®, Folex®, Rheumatrex®	Injectable—25 mg/ml, 20 mg and 1 g vials Oral Tabs—2.5, 5, 7.5, 10, and 15 mg	IM, SQ, oral—7.5 to 20 mg/week in a single dose
Sulfasalazine[b]	Multiple Azulfidine®, EN-tabs®, Sulfazine®	Oral Suspension—250 mg/5 ml Oral Tabs—500 mg	500 to 3,000 mg/day in 2 to 4 divided doses

g = gram; IM = intramuscular; mg = milligram; ml = milliliter
*Listed trade names are limited to commonly prescribed U.S. products when multiple trade names are available.
[a]Initial dose is 400 to 600 mg/day for 4 to 12 weeks.
[b]Dosed according to the RA dosing recommendations.

Table 4. Pharmaceutical treatments for psoriatic arthritis: biologic DMARDs

Generic Name	Manufacturer U.S. Trade Name(s)*	Injectable Supply	Usual Adult Dose
Biologic DMARDs			
Abatacept[a]	Bristol Myers Squibb Orencia®	250 mg vial	IV—Dosed according to body weight (<60 kg=500 mg; 60-100 kg=750 mg; >100 kg=1,000 mg); dose repeated at 2 weeks and 4 weeks after initial dose, and every 4 weeks thereafter SQ—May give weight-based IV loading dose, then 125 mg SQ once weekly
Adalimumab	Abbott Humira®	40 mg/0.8 ml, 20 mg/0.4 ml prefilled syringe	SQ—40 mg every other week alone or in combination with other DMARDs
Anakinra[a]	Amgen Kineret®	100 mg/0.67 ml syringe	SQ—100 mg/day; dose should be decreased to 100 mg every other day in renal insufficiency
Certolizumab Pegol[a]	UCB Cimzia®	200 mg powder for reconstitution, 200 mg/ml solution	SQ—Initial dose of 400 mg (as 2 SQ injections of 200 mg), repeat dose 2 and 4 weeks after initial dose; maintenance dose is 200 mg every other week (may consider maintenance dose of 400 every 4 weeks)
Etanercept	Amgen Pfizer Immunex Enbrel®	50 mg/ml in 25 mg or 50 mg single use prefilled syringe	SQ—50 mg once weekly with or without MTX
Golimumab	Centocor Ortho Biotech Simponi®	50 mg/0.5 ml syringe	SQ—50 mg once per month, alone or in combination with MTX

Table 4. Pharmaceutical treatments for psoriatic arthritis: biologic DMARDs (continued)

Generic Name	Manufacturer U.S. Trade Name(s)*	Injectable Supply	Usual Adult Dose
Infliximab	Centocor Ortho Biotech Remicade®	100 mg in a 20 ml vial	IV—5 mg/kg at 0, 2, and 6 weeks followed by maintenance every 8 weeks thereafter; may be given with or without MTX
Rituximab[a]	Biogen Idec / Genentech Rituxan®	100 mg/10 ml and 500 mg/50 ml vial	IV—1,000 mg IV infusion separated by 2 weeks (one course) every 24 weeks or based on clinical evaluation, but not sooner than every 16 weeks
Tocilizumab[a]	Genentech / Roche Actemra®, RoActemra®	80 mg/4 ml, 200 mg/10 ml, 400 mg/20 ml vial	IV—4 mg/kg every 4 weeks; increase to 8 mg/kg every 4 weeks based on clinical response

kg = kilogram; mg = milligram; ml = milliliter; MTX = methotrexate; IV = intravenously; SQ = subcutaneously
*Listed trade names are limited to commonly prescribed U.S. products w hen multiple trade names are available.
[a]Dosed according to the RA dosing recommendations.

Treatment Strategies

The first line of treatment of PsA is nonsteroidal anti-inflammatory drugs (NSAIDs), although in most cases DMARDs are necessary. MTX is particularly useful because it treats the psoriasis in addition to the arthropathy. Corticosteroids may be used to control inflammation, but they do not have much of a role in chronic disease management in psoriatic disease. The tapering or withdrawal of steroids in PsA has been associated with severe flares of skin disease. When chronic disease continues to be active despite the use of MTX, biologics are indicated. Biologics most often are given in combination with oral DMARDs (e.g., MTX).[21]

Historically, few PsA trials have been conducted, and management has been adapted from RA trial data. Since the introduction of biologic therapy, however, dedicated PsA trials have demonstrated efficacy in this distinct disease. Detailed and comparative examination of the efficacy, effectiveness, and harms of treatments for PsA is needed.

Scope and Key Questions

The purpose of this review is to compare the efficacy, effectiveness, and harms of corticosteroids, oral DMARDS, and biologic DMARDs in the treatment of patients' PsA. We address the following four Key Questions (KQs):

- KQ 1: For patients with PsA, do drug therapies differ in their ability to reduce disease activity, to slow or limit progression of radiographic joint damage, or to maintain remission?
- KQ 2: For patients with PsA, do drug therapies differ in their ability to improve patient-reported symptoms, functional capacity, or quality of life?
- KQ 3: For patients with PsA, do drug therapies differ in harms, tolerability, adherence, or adverse effects?
- KQ 4: What are the comparative benefits and harms of drug therapies for PsA in subgroups of patients based on stage of disease, history of prior therapy, demographics, concomitant therapies, or comorbidities?

Appendix A presents our search strategy; Appendix B contains our review criteria and abstraction forms; Appendix C lists our full bibliography and the source retrieved from; Appendix D lists excluded studies; Appendix E presents evidence tables; Appendix F presents the criteria for assessing the quality of individual studies; Appendix G describes clinical assessment scales commonly used in arthritis trials; Appendix H presents the poor quality studies; and Appendix I contains our strength of evidence tables.

Methods

In this chapter, we document the procedures that the RTI International–University of North Carolina Evidence-based Practice Center (RTI–UNC EPC) used to develop this comparative effectiveness review (CER) on pharmacologic treatments for psoriatic arthritis. We briefly describe the topic development process below. We then document our literature search and retrieval process and describe methods of abstracting relevant information from the eligible articles to generate evidence tables. We also document our criteria for rating the quality of individual studies and for grading the strength of the evidence as a whole.

Topic Development

This report is an update of a CER completed in 2007.[22] The topic of the original report and the preliminary Key Questions (KQs) arose through a public process involving the public, the Scientific Resource Center (SRC, at www.effectivehealthcare.ahrq.gov/aboutUs/index.cfm#RC) for the Agency for Healthcare Research and Quality's (AHRQ's) Effective Health Care program (www.effectivehealthcare.ahrq.gov), and various stakeholder groups (www.effectivehealthcare.ahrq.gov/aboutUs/index.cfm#SG). Investigators from the RTI–UNC EPC then refined the original questions, in consultation with AHRQ, the SRC, and the Technical Expert Panel (TEP) during multiple conference calls, into the KQs used for the original report. For this update, the KQs were again refined into the final set of KQs listed in the introduction. No substantive changes to the KQs were made for this update other than adding new medications that have been approved since the previous report. The protocol for the project was posted on the AHRQ Web site (http://www.effectivehealthcare.ahrq.gov). The original report included both rheumatoid arthritis (RA) and psoriatic arthritis (PsA). When updating the material, the decision was made to divide the material into two separate reports, one for RA and one for PsA. This report includes only the information related to patients with PsA. This report is intended to replace the original report; it includes the information from the original report as well as the new information we identified.

Literature Search

To identify articles relevant to each KQ, we searched MEDLINE®, Embase, the Cochrane Library, and the International Pharmaceutical Abstracts. The full search strategy is presented in Appendix A. We conducted this review at the same time as a review on RA; that is, we conducted the literature searches and review processes in parallel, shown in AppendixA. We used either Medical Subject Headings (MeSH or MH) as search terms when available or key words when appropriate. We combined terms for selected indications (PsA and RA), drug interactions, and adverse events with a list of included medications. We included the following medications: corticosteroids (methylprednisolone, prednisone, and prednisolone), four oral disease-modifying antirheumatic drugs (DMARDs) (methotrexate [MTX], leflunomide, sulfasalazine, and hydroxychloroquine), and nine biologic DMARDs (abatacept, adalimumab, anakinra, certolizumab pegol, etanercept, golimumab, infliximab, rituximab, and tocilizumab). We limited the electronic searches to "human" and "English language." For the original report, sources were searched from 1980 to September 2006. For this update, sources were searched from June 2006 to January 2011. We overlapped the update search with the original search to account for delays in indexing. We used the National Library of Medicine (NLM) publication type tags to identify reviews, randomized controlled trials (RCTs), and meta-analyses. We

manually searched reference lists of pertinent review articles and letters to the editor to supplement searches for the original report. We used the Scopus abstract and citation database to supplement searches for this update. We imported all citations into an electronic database (EndNote X.0.2). Additionally, we hand-searched the Center for Drug Evaluation and Research (CDER) database to identify unpublished research submitted to the U.S. Food and Drug Administration (FDA). The SRC contacted pharmaceutical manufacturers and invited them to submit dossiers, including citations. We received dossiers from five pharmaceutical companies (Abbott, Amgen, Bristol-Myers Squibb, Centocor, and Genentech) for the original report. We received dossiers from three pharmaceutical companies (Abbott, Amgen, and Centocor) for this update. The SRC also searched the following for potentially relevant unpublished and ongoing literature: FDA Web site; Health Canada; Authorized Medicines for EU; ClinicalTrial.gov; Current Controlled Trials; Clinical Study Results; WHO Clinical Trials; Conference Papers Index; Scopus; NIH RePORTER; HSRPROJ; Hayes, Inc. Health Technology Assessment; and the New York Academy of Medicine's Grey Literature Index.

Study Selection

We developed eligibility (inclusion and exclusion) criteria with respect to study design or duration, patient population, interventions, outcomes, and comparisons as described in Table 5 below. For efficacy and effectiveness, we focused on head-to-head trials and prospective observational studies comparing one drug with another. For biologic DMARDs, we also included placebo-controlled, double-blind RCTs. For safety and tolerability, as well as for efficacy and effectiveness in subgroups, we included head-to-head trials, high-quality systematic reviews, and prospective and retrospective observational studies.

For this review, results from well-conducted, valid head-to-head trials provide the strongest evidence to compare drugs with respect to efficacy, effectiveness, and harms. We defined head-to-head trials as those comparing one drug of interest with another. RCTs or prospective cohort studies of at least 3 months' duration and an adult study population were eligible for inclusion. For harms (i.e., evidence pertaining to tolerability, adverse effects, and adverse events), we examined data from both experimental and prospective and retrospective observational studies. We included RCTs (no sample size limit) and observational studies (with sample sizes $\geq$ 100 patients) that lasted at least 3 months and reported an outcome of interest.

Because equipotency among the reviewed drugs is not well established, we assumed that comparisons made within the recommended dosing ranges in the Introduction chapterare appropriate. Dose comparisons made outside the recommended daily dosing range are not in our report.

Table 5. Outcome measures and study eligibility criteria

Key Questions and Outcomes of Interest	Study Eligibility Criteria
KQ 1 /KQ 2:[a] **Efficacy/effectiveness** **KQ 1:** Disease activity[b] Radiographic joint damage Remission **KQ 2:** Functional capacity Quality of life Patient-reported symptoms	**Study Design** • Head-to-head double-blind RCTs • High-quality systematic reviews • Prospective, controlled observational studies **Minimum Study Duration** • RCT—3 months • Observational—3 months **Study Population** • Ages 19 or older • Patients with PsA **Sample Size** • RCT no limit • Observational N ≥ 100
KQ 3: **Harms, tolerability, adherence, adverse effects**	**Study Design** • Head-to-head double-blind RCTs • High-quality systematic reviews • Observational studies, prospective and retrospective **Minimum Study Duration** • RCT—3 months • Observational—3 months **Study Population** • Ages 19 or older • Patients with PsA **Sample Size** • RCT no limit • Observational N ≥ 100
KQ 4: **Benefits and harms in subgroups based on stage, history of prior therapy, demographics, concomitant therapies, comorbidities**	**Study Design** • Head-to-head double-blind RCTs • High-quality systematic reviews • Observational studies **Minimum Study Duration** • RCT—3 months • Observational—3 months **Study Population** • Ages 19 or older • Patients with PsA **Sample Size** • RCT no limit • Observational N ≥ 100

KQ = Key Question; PsA = psoriatic arthritis; RCT = randomized controlled trial

[a]We divided the assessment of efficacy/effectiveness into two KQs based on two groups of outcomes: those addressing disease activity, radiographic measures, and remission (KQ 1) and those addressing functional capacity, quality of life, and other patient-reported symptoms (KQ 2). We did this to group measures that are based on more objective measures under KQ 1 and those that are based more on subjective patient-reported outcomes under KQ 2.

[b]Disease activity reflects the overall PsA activity. Measures of disease activity, such as the Psoriasis Area and Severity Index (PASI), the Psoriatic Arthritis Response Criteria (PsARC), or the American College of Rheumatology 20 percent response (ACR 20), include assessment of some or all of the following: the number of swollen and tender joints, the patient's global assessment of his/her disease activity, the physician's global assessment of the patient's disease activity, patient's pain score, patient's physical function score, acute phase reactants (C-reactive protein), scaling, erythema, induration, severity, and affected body surface area. Appendix G provides additional details about these measures.

Two individuals independently reviewed abstracts. If both reviewers agreed that a study did not meet eligibility criteria, we excluded it. We obtained the full text of all remaining articles and used the same eligibility criteria to determine which, if any, to exclude at this stage. We did not include studies that met eligibility criteria but were reported as an abstract only. Appendix C lists our full bibliography and their source database. Appendix D summarizes reasons for excluding studies that were reviewed as full-text articles but did not meet eligibility criteria.

We reviewed studies that reported health outcomes for efficacy or effectiveness. For example, these outcomes included clinical response to treatment, remission, functional capacity, and quality of life. In addition, we included radiographic outcomes as intermediate outcome measures. For harms, we looked for both total adverse events and specific adverse events ranging in severity (e.g., serious infections, malignancies, hepatotoxicity, hematological adverse events, infusion and injection reactions, nausea), withdrawals attributable to adverse events, and drug interactions. We included systematic reviews and meta-analyses in our evidence report if we found them to be relevant for a KQ and of good or fair methodological quality. We did not abstract individual studies if they had been used in a systematic review or meta-analysis of good quality. However, we reviewed them to determine whether any other outcomes of interest were reported.

Data Extraction

We designed and used a structured data abstraction form to ensure consistency of appraisal for each study. Trained reviewers abstracted data from each study. A senior reviewer read each abstracted article and evaluated the completeness of the data abstraction.

We abstracted the following data from included articles: study design, eligibility criteria, intervention (drugs, dose, and duration), additional medications allowed, methods of outcome assessment, population characteristics (such as age, sex, race or ethnicity, or mean disease duration), sample size, loss to followup, withdrawals because of adverse events, results, and adverse events reported. We recorded intention-to-treat results if available. All data abstraction employed SRS 4.0, Mobius Analytics™. Evidence tables containing all abstracted data of included studies are presented in Appendix E.

Quality Assessment

To assess the quality (internal validity) of trials, we used predefined criteria based on those developed by the U.S. Preventive Services Task Force (ratings: good, fair, poor)[23] and the National Health Service Centre for Reviews and Dissemination.[24] Elements of quality assessment included randomization and allocation concealment, similarity of compared groups at baseline, use of ITT analysis (i.e., all patients were analyzed as randomized), adequacy of blinding, and overall and differential loss to followup.

In general terms, a "good" study has a low risk of bias and results are considered to be valid. A "fair" study is susceptible to some risk of bias but probably not sufficient to invalidate its results. The fair-quality category is likely to be broad, so studies with this rating will vary in their strengths and weaknesses. A "poor" rating indicates significant risk of bias (stemming from, e.g., serious errors in design, analysis reporting a large amount of missing information, or discrepancies in reporting) that may invalidate the study's results.

To assess the quality of observational studies, we used criteria outlined by Deeks et al.[25] Items assessed included selection of cases or cohorts and controls, adjustment for confounders, methods of outcomes assessment, length of followup, and statistical analysis. To assess the

quality of systematic reviews and meta-analyses, we assessed the following: whether the review was based on a clear question, clear reporting of inclusion criteria, methods used for identifying literature (the search strategy), whether two reviewers independently reviewed publications to determine eligibility, whether authors used a standard method of critical appraisal (or quality rating or validity assessment), assessment of heterogeneity, assessment of publication bias, and statistical analysis. Systematic reviews were categorized as good when all criteria were met.

Two independent reviewers assigned quality ratings. They resolved any disagreements by discussion and consensus or by consulting with a third reviewer. Appendix G details the predefined criteria used for evaluating the quality of all included studies. Studies that met all criteria were rated good quality. Studies that had a fatal flaw (defined as a methodological shortcoming that leads to a very high risk of bias) in one or more categories were rated poor quality and excluded from our analyses.

Applicability Assessment

Using the parameters for evaluation in guidance provided by AHRQ's Methods Guide for Comparative Effectiveness Reviews,[26] we evaluated the applicability of the included studies. Applicability is similar to generalizability or external validity of the studies included in the evidence base. We evaluated applicability using a qualitative assessment of the population, intervention/treatment, comparator, outcomes measured, timing of followup, and setting. We specifically considered whether populations enrolled in these trials or studies differed from target populations as laid out in Chapter 1, whether studied interventions are comparable with those in routine use, whether comparators reflect best alternatives, whether measured outcomes reflect the most important clinical outcomes, whether followup was sufficient, and whether study settings were representative of most settings.

Grading Strength of Evidence

We evaluated the strength of evidence based on methods guidance for the EPC program.[26, 27] For this report, we graded the strength of evidence for the outcomes determined to be most important: measures of disease activity (e.g., Psoriasis Area and Severity Index-PASI, Disease Activity Score-DAS, Psoriasis Arthritis Response Criteria-PsARC), radiographic changes, functional capacity, quality of life, withdrawals due to adverse events, and specific adverse events if data were available (e.g., injection-site reactions, infections, malignancy). Because no head-to-head trials were identified, we graded the strength of evidence for each of the included medications compared with placebo. The strength of evidence for each outcome or comparison that we graded incorporates scores on four domains: risk of bias, consistency, directness, and precision; it can also reflect ratings for other domains that can be factored in when relevant (e.g., dose-response relationships).

As described in Owens et al.,[27] the evaluation of risk of bias includes assessment of study design and aggregate quality of studies. We judged good quality studies to result in evidence with low risk of bias. We graded evidence as consistent when effect sizes across studies were in the same direction. When the evidence linked the interventions directly to health outcomes, we graded the evidence as being direct. We graded evidence as being precise when results had a low degree of uncertainty. A precise estimate is an estimate that would allow a clinically useful conclusion. An imprecise estimate is one for which the confidence interval is wide enough to include clinically distinct conclusions.[27]

We dually evaluated the overall strength of evidence for each major outcome based on a qualitative assessment of strength of evidence for each domain and reconciled all disagreements. The levels of strength of evidence are shown in Table 6.

Table 6. Strength of evidence grades and their definitions

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

Source: Owens DK, Lohr KN, Atkins D, et al. AHRQ series paper 5: grading the strength of a body of evidence when comparing medical interventions—agency for healthcare research and quality and the effective health-care program. J Clin Epidemiol. 2010 May;63(5):513-23.[27]

Data Synthesis

Throughout this CER we synthesized the literature qualitatively because there were too few studies for each of the comparisons of interest to justify combining them in quantitative analyses. We constructed tables showing the study characteristics, quality ratings, and main results for all included studies.

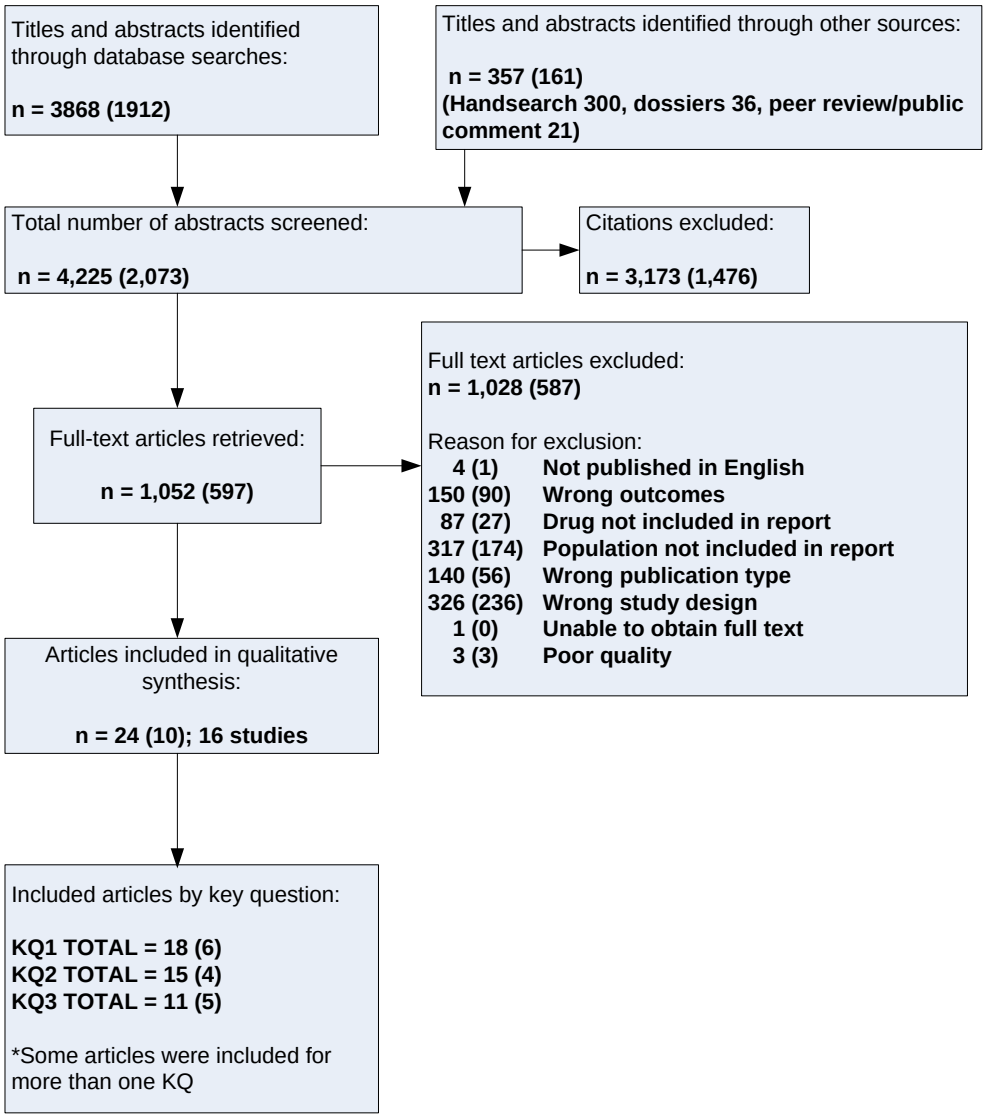
Peer Review

This CER underwent external peer review from individuals who were experts in rheumatology and from various stakeholder and user communities (listed in the Front Matter). The SRC oversaw the peer-review process. Peer reviewers were charged 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. Our peer reviewers, also Technical Expert Panel members, gave us permission to acknowledge their review of the draft. We compiled all comments and addressed each one individually, revising the text as appropriate. AHRQ and the SRC also requested review from its own staff.

Results

Figure 1 documents the results of the literature search (AppendixA).We included 24 published articles reporting on 16 studies: 0 head-to-head randomized controlled trials (RCTs), 0 head-to-head nonrandomized controlled trials, 10 placebo-controlled trials, 3 meta-analyses or systematic reviews, and 3 observational studies. Our findings include studies rated good or fair for internal validity. Most studies were of fair quality; we designate in the text only those of good quality. Evidence tables for included studies can be found in Appendix E.

Figure 1. Disposition of articles (PRISMA figure)*



KQ = Key Question; n = number of studies; PRIMSA = Preferred Reporting Items for Systematic Reviews and Meta-Analyses
*The first number listed includes all references identified in both the original and update reports. The number in parentheses indicates references identified in the update report only.
Note: Number of included articles differs from number of included studies because some studies have multiple publications.

We included articles based on eligibility criteria or methodological criteria (quality rating) as explained in the Methods chapter.

Of the 16 included studies, 8 (50 percent) were supported by pharmaceutical companies; 4 (25 percent) were funded by governmental or independent funds; 3 (19 percent) were supported by a combination of pharmaceutical and government funding; and 1 did not report the funding source (6 percent).

This chapter is organized by Key Question (KQ). When comparative evidence is available, we discuss it before presenting placebo controlled trials. Generally, the chapter is organized by oral DMARD comparisons followed by biologic DMARD comparisons.

Across all KQs, we have included head-to-head studies, observational studies, and systematic reviews. When comparative evidence is available, we discuss it before presenting placebo-controlled trials. Table 7 gives the numbers of trials or studies for drug class comparisons; when some groupings have important subcomparisons, we note these. We do not, however, offer an exhaustive list of all possible comparisons among corticosteroids, oral DMARDs, and biologic DMARDs simply because of the sheer number of potential combinations of drugs within classes and across classes, which cannot be clearly and concisely presented here.

Table 7. Number of trials or studies by drug comparison and study design for psoriatic arthritis

Drug Comparison	Number of Studies; Study Design
Oral DMARDs vs. placebo	1 SR, 2 RCTs
Biologic DMARDs vs. placebo	1 SR, 8 RCTs
Oral DMARDs vs. Oral DMARDs	0
Biologic DMARDs vs. biologic DMARDs	1 OS
Biologic DMARDs vs. oral DMARDs	0
Biologic DMARDs + oral DMARDs vs. biologic DMARDs	2 OS
Biologic DMARDs + oral DMARDs vs. oral DMARDs	1 SR

DMARD = disease modifying anti-rheumatic drug; vs. = versus; SR = systematic review; RCT = randomized controlled trial; OS = observational study

Table 8 lists abbreviations and full names of diagnostic scales and health status or quality-of-life instruments encountered in these studies, as well information about clinical significance when available. For further details about such instruments and scales, see Appendix G**.**

Table 8. Disease activity, radiographic progression, functional capacity, and quality-of-life measures

Abbreviated Name	Complete Name of Measure or Instrument	Range of Scores	Improvement Denoted by	Clinically Significant Improvement
ACR-N	American College of Rheumatology percent improvement from baseline to endpoint	0 to 100 percent	Increase	--
ACR 20/50/70*	American College of Rheumatology response scores based on 20, 50, or 70 percent criteria for improvement	0 to 100 percent	Increase	ACR 20 is 20% minimal improvement ;ACR 50/70 considered more clinically significant[28]
ASHI	Arthritis-Specific Health Index (Medical Outcomes Study Short Form SF-36 Arthritis-specific Health Index)	0 to 100	Increase	--

Table 8. Disease activity, radiographic progression, functional capacity, and quality-of-life measures (continued)

Abbreviated Name	Complete Name of Measure or Instrument	Range of Scores	Improvement Denoted by	Clinically Significant Improvement
DAS*	Disease Activity Score	0 to 10	Decrease	DAS <1.6 correlates with remission[28, 29]
DAS 28	Disease Activity Score Short Form	0 to10	Decrease	DAS28 <2.6 correlates with remission [28,30]
DLQI	Dermatology Life Quality Index	0 to 30	Decrease	--
EQ-5D*	EuroQol EQ-5D Quality of Life Questionnaire	0 to 1	Increase	--
EULAR response	European League Against Rheumatism response	N/A	N/A	--
HAQ* (D-HAQ)	Health Assessment Questionnaire (Dutch Version)	0 to 3	Decrease	HAQ >= 0.22 change[31]
HAQ-DI	Disability Index of the Heath Assessment Questionnaire	0 to 3	Decrease	--
PASI*	Psoriasis Area and Severity Index	0 to 72	Decrease	Improvement needs to be at least 50% (used to be 75% but has since been lowered[32]
PsARC*	Psoriatic Arthritis Response Criteria	0 to 100 percent	Increase	Has not been assessed to be clinically significant[33]
SF-36*	Medical Outcomes Study Short Form 36 Health Survey	0 to 100	Increase	SF36 physical or mental component two standard error of the mean (SEM)[34-37]
SHS*	Sharp/van der Heijde Method (SHS) for Scoring Radiographs (SHS is frequently modified by individual authors to meet study requirements and needs; there is no standard modified SHS)	Erosion: 0 to 160 for hands; 0 to 120 for feet Joint space narrowing: 0 to 168 Total: 0 to 448	Decrease	Changes in joint damage around the level of 5 units of the Sharp/van der Heijde method as minimal clinically important[38]

* These key scales are defined in Appendix G.

-- Less commonly used measures for which there is sparse data regarding what constitutes a clinically significant improvement.

KQ 1: Reductions in Disease Activity, Limitations of Disease Progression, and Maintenance of Remission

KQ 1 concerned three main topics. Specifically, "for patients with psoriatic arthritis, do drug therapies differ in their ability to reduce disease activity, to slow or limit progression of radiographic joint damage, or to maintain remission?" We use the term *disease activity* to refer to condition-specific measures such as the Psoriasis Area and Severity Index (PASI), the Psoriatic Arthritis Response Criteria (PsARC), or the American College of Rheumatology (ACR) response. Strength of evidence is presented, and additional tables provide selected study-specific information on outcomes, broken out by primary outcomes and radiologic outcomes. Evidence Tables in Appendix E document details about all these studies.

Overview

A total of nine placebo-controlled randomized controlled trials (RCTs), two observational studies, and three systematic reviews or meta-analyses examined symptom response, radiographic joint damage, and remission. The main drug classes compared included oral disease-modifying antirheumatic drugs (DMARDs), biologic DMARDs (also referred to simply as biologics), and combined strategies. Overall strength of evidence is listed in Appendix I. When possible, we describe whether treatment effects reach minimal clinically important differences (MCIDs). In this section, achieving at least an ACR of 20 or above or a PASI of at least 50 percent improvement is considered minimally clinically important (Table 8).

Oral DMARD Versus Oral DMARD

We did not find any studies meeting our criteria for inclusion.

Oral DMARD Versus Placebo

Evidence from one 12-week study provides low strength of evidence that parenteral high-dose methotrexate (MTX) improves physician assessment of disease severity, compared with placebo (median change 1 vs. 0; P=0.001).[39] The MCID cannot be determined from this comparison.

One systematic review found that, compared with placebo, sulfasalazine improved patient outcomes (pooled index of variables in the OMERACT: 0.38 units; 95% CI, 0.21 to 0.54).[40] The MCID cannot be determined from this comparison.

Evidence from one 24-week trial provides low strength of evidence that leflunomide patients experienced improved disease activity compared with those in the placebo arm (PsARC primary outcome 58.9 percent vs. 29.7 percent, P<0.0001).[41, 42] The strength of evidence is low. Improvements in additional outcomes including ACR 20 did reach MCID, but the PASI did not.

Biologic DMARD + Oral DMARD Versus Biologic DMARD

We did not find any head-to-head controlled trials for any of the included drugs, but two observational cohort studies provide some evidence. One cohort study compared the combination of an anti-tumor necrosis factor (TNF) (adalimumab, etanercept, or infliximab) with MTX versus anti-TNF only and found no difference in treatment response.[43] Another cohort study compared adalimumab, etanercept, and infliximab and found no differences in efficacy among the groups.[44] The strength of evidence is low.

Biologic DMARD + Oral DMARD Versus Oral DMARD

A systematic review provided low strength of evidence of a comparison between TNF inhibitors (adalimumab, etanercept, and infliximab) compared with sulfasalazine and found that the TNF inhibitors were relatively effective and had the largest effect size (risk ratio: 0.25, 95% CI, 0.13 to 0.48), and sulfasalazine was moderately effective (risk ratio: 0.45, 95% CI, 0.23 to 0.89).[45] The MCID cannot be determined from this comparison.

Biologic DMARD Versus Placebo

The use of four biologics—adalimumab, etanercept, golimumab, and infliximab—provided low to moderate evidence of improved disease activity compared with placebo.[46-54] The magnitude of benefit for ACR 20 ranged from 39 percent to 57 percent for adalimumab, 59

percent to 65 percent for etanercept, 45 percent to 51 percent for golimumab, and 58 percent to 62 percent for infliximab.

Psoriatic Arthritis: Detailed Analysis

Oral DMARD Versus Oral DMARD

We did not find any studies meeting our criteria for inclusion. We did not identify any studies meeting our inclusion/exclusion criteria that examined the use of corticosteroids in the treatment of psoriatic arthritis (PsA). Because of the paucity of head-to-head trials, we additionally reviewed placebo-controlled trials to summarize the general efficacy of oral and biologic DMARDs. Summarizing the general efficacy, however, does not provide evidence on the comparative efficacy and tolerability of treatments for PsA.

Oral DMARD Versus Placebo

One systematic review examined the efficacy of oral DMARDs used in placebo-controlled trials.[40] The investigators used data from 13 RCTs that included 1,022 adults with PsA in a meta-analysis that focused on comparisons of sulfasalazine, auranofin, etretinate, fumaric acid, intramuscular injection of gold, azathioprine, efamol marine, and MTX with placebo (Table 9). Two drugs (MTX and sulfasalazine) are of interest for our report. The primary outcome measure included individual component variables validated by the Outcome Measures in Rheumatology Clinical Trials (OMERACT) to create a pooled index; components used include acute phase reactants, disability, pain, patient global assessment, physician global assessment, swollen joint count, tender joint count, and radiographic changes of joints in any trial of 1 year or longer. The primary outcome was change in a pooled disease index.

Methotrexate

One multicenter 12-week RCT (N=37),[39] included in the systematic review described above, compared MTX (weekly dose of 7.5 mg to 15 mg) with placebo. The study reported some improvement in PsA as measured by change in grip strength, morning stiffness, and patient assessment in the drug treatment group, but statistically significant improvement compared with placebo occurred only in physician assessment of disease severity (P=0.001); there were no differences between groups in joint swelling or pain/tenderness. Psoriatic skin lesions showed no significant changes in scaling, induration, or erythema from entry appearance, but surface area involvement improved significantly compared with placebo (P=0.039) in 14 of the MTX patients assessed (Table 9). The systematic review used this single study comparing MTX with placebo to calculate an overall improvement in the OMERACT index of 0.65 units (95% CI, 0.00 to 1.30).[40] The MCID cannot be determined.

Sulfasalazine

The investigators pooled six trials involving comparisons of sulfasalazine (average dose of 2 g/day to 3 g/day) with placebo (N=564). Sulfasalazine showed an improvement in the pooled index of 0.38 units (95% CI, 0.21 to 0.54).[40] The MCID cannot be determined.

Table 9. Disease activity of oral DMARD versus placebo

Study	Study Design N Duration	Study Population	Comparison (dose)	Results of Primary Outcome Measure	Quality Rating
Jones et al., 2000[40]	Systematic review and meta-analysis 1,022	Active PsA, concomitant MTX NR	SSZ vs. placebo (6 RCTs)	Change in pooled index: SSZ 0.38 units (95% CI, 0.21 to 0.54)	Good
Willkens et al.,1984[39]	RCT 37 12 weeks	Active PsA, MTX naive	MTX (7.5 mg-15 mg/week vs. placebo	Median change in physician assessment of disease severity: MTX, 1 vs. placebo, 0 (P=0.001)	Fair
Kaltwasser et al., 2004[41, 42]	RCT 190 24 weeks	Active PsA, failed at least one DMARD, concomitant MTX 0%	LEF (100 mg/day 3 days then 20 mg/day) vs. placebo	PsARC at week 24: LEF 58.9% vs. placebo 29.7% (P<0.0001)	Fair

CI = confidence interval; DMARD = disease-modifying antirheumatic drug; LEF = leflunomide; mg = milligram; MTX = methotrexate; NR = not reported; PsA = psoriatic arthritis; PsARC = Psoriatic Arthritis Response Scale; RCT = randomized controlled trial; SSZ = sulfasalazine; vs. = versus

Leflunomide

One trial (two publications) evaluated the efficacy of leflunomide against placebo in 190 patients over 24 weeks;[41, 42] PsA was defined as having at least three swollen joints and three tender or painful joints and psoriasis over at least 3 percent of the body surface area. In this study, almost 50 percent of the patients were DMARD naive. Patients who were not DMARD naive were required to discontinue all oral DMARDs as well as biologic agents and investigational drugs 28 days before baseline.

The leflunomide group had significantly greater improvements in measures of disease activity than the placebo group. These improvements included response rates on a modified ACR 20 (36.3 percent vs. 20 percent; P=0.014), the PsARC (achieved in 58.9 percent vs. 29.7 percent; P=0.0001), and the PASI (17.4 percent vs. 7.8 percent reached threshold; P=0.048). The ACR 20 did reach MCID, but the PASI did not.

Biologic DMARD + Oral DMARD Versus Biologic DMARD

One retrospective cohort (N=261) of anti-TNF naive patients with active PsA in Sweden compared patients taking MTX concomitant with anti-TNF (adalimumab—40 mg every other week; etanercept—25 mg twice a week; or infliximab—3 mg/kg at 0, 2, and 6 weeks and then every 8 weeks) versus anti-TNF alone.[43] Eligible patients had active PsA with high disease activity and/or unacceptably high steroid use. Over 12 months, there were no significant differences in European League Against Rheumatism response (EULAR) good or EULAR overall between patients taking MTX with anti-TNF compared with anti-TNF only, see Table 10.

Also in Table 10 is the second cohort study, conducted in Great Britain, that found no significant differences in EULAR response rates at six (P=0.679), 12 (P=0.904), and 18 (P=0.583) months between the three anti-TNF therapies of adalimumab, etanercept, and infliximab.[44] Furthermore, EULAR response rates for the whole anti-TNF cohort were similar in patients receiving anti-TNF agents in combination with MTX (78.1 percent at 6 months), another DMARD (73.3 percent), or anti-TNF monotherapy (79.5 percent).[44]

Table 10. Disease activity of biologic DMARD + oral DMARD versus biologic DMARD

Study	Study Design N Duration	Study Population	Comparison (Dose)	Results of Primary Outcome Measure	Quality Rating
Kristensen et al., 2008[43]*	Cohort 261 12 months	Active PsA, anti-TNF naïve, concomitant MTX 62%	ADA (40 mg every other week) or ETN (25 mg twice a week) or INF (3 mg/kg at 0, 2, 6 weeks, then every 8th week) + MTX (median—15 mg/week) vs. monotherapy with ADA, ETN, or INF	No difference in anti-TNF + MTX vs. anti-TNF only (data NR)	Fair
Saad et al., 2010[44]	Cohort 596 18 months	Patients with PsA, mean disease duration varied	ETN 25 mg twice weekly or 50 mg once weekly; ADA 40 mg every 2 weeks; INF 5 mg/kg administered at weeks 0, 2, 6, and 8 and then every 8 weeks	No difference in anti-TNF MTX vs. anti-TNF	Fair

ADA = adalimumab; DMARD = disease-modifying antirheumatic drug; ETN = etanercept; INF = infliximab; kg = kilogram; mg = milligram; MTX = methotrexate; NR = not reported; PsA = psoriatic arthritis; TNF = tumor necrosis factor; vs. = versus
*New study added since last review.

Biologic DMARD + Oral DMARD Versus Oral DMARD

One systematic review, as seen in Table 11, included an analysis of TNF inhibitors and sulfasalazine for the treatment of PsA and examined efficacy as defined by the number of patients that withdrew because of lack of effect.[45] The TNF inhibitors analysis included five studies with 882 patients and found that the risk ratio for efficacy was 0.25 (95% CI, 0.13 to 0.48). The analysis of sulfasalazine found that the risk ratio for efficacy was 0.45 (95% CI, 0.23 to 0.89). The MCID cannot be determined from this comparison.

Table 11. Disease activity of biologic DMARD + oral DMARD versus sulfasalazine

Study	Study Design N Duration	Study Population	Comparison (Dose)	Results of Primary Outcome Measure	Quality Rating
Ravindran et al., 2008[45]	Meta-analysis NR	Patients with PsA, mean disease duration varied	TNF inhibitors as a class vs. sulfasalazine	TNF inhibitors were relatively effective and sulfasalazine was moderately effective	Fair

DMARD = disease-modifying antirheumatic drug; NR = not reported; PsA = psoriatic arthritis; TNF = tumor necrosis factor; vs. = versus

Biologic DMARD Versus Placebo

Seven RCTs (11 articles) and 1 systematic review examined the efficacy of biologics against placebo in treating patients with PsA (Table 12).[46-56] Two trials were of adalimumab, 2 of etanercept, 3 of infliximab, and 1 of golimumab. All trials allowed patients to continue an oral DMARD, usually MTX. The systematic review examined etanercept and infliximab versus placebo.[55] All showed that the use of biologics led to significantly better outcomes than placebo.

Table 12. Disease activity in biologic DMARD versus placebo

Study	Study Design N Duration	Study Population	Comparison (Dose)	Results of Primary Outcome Measure	Quality Rating
Adalimumab vs. Placebo					
Genovese et al., 2007[56]*	RCT 102 12 weeks	Active PsA, failed at least one DMARD, concomitant MTX 46%	ADA (40 mg every other week) vs. placebo	ACR 20 at week 12: ADA 39% vs. placebo 16% (*P*=0.012)	Fair
Mease et al., 2005 ADEPT Trial[46]	RCT 313 24 weeks	Active PsA, failed at least one DMARD, concomitant MTX 51%	ADA (40 mg every other week) vs. placebo	ACR 20 at week 24: ADA 57% vs. placebo 15% (*P*<0.001) Mean change in the modified total Sharp score at week 24: ADA -0.2 vs. placebo 1.0 (*P*<0.001) Erosion scores (mean change): ADA 0.0 vs. placebo 0.6 Joint space narrowing scores (mean change): ADA -0.2 vs. placebo 0.4 (*P*<0.001 for both)	Fair
Etanercept vs. Placebo					
Woolacott et al., 2006[55]	Systematic review and meta-analysis 369	Adults with PsA, concomitant MTX 46% to 56%	ETN (25 mg twice a week) vs. placebo (two studies)	ACR 20 at week 12: ETN 65% vs. placebo NR (RR, 4.19 [95% CI, 2.74 to 6.42]	Good
Mease et al., 2000[47]	RCT 60 12 weeks	Active PsA, failed at least one DMARD, concomitant MTX use 47%	ETN (25 mg twice a week) vs. placebo	PsARC at week 12: ETN 87% vs. placebo 23% (*P*<0.0001)	Fair
Mease et al., 2004[48] Mease et al., 2004[49]	RCT 205 24 weeks (with additional 48 weeks open label)	Active PsA, failed at least one DMARD, concomitant MTX 47%	ETN (25 mg twice a week) vs. placebo	ACR 20 at week 24: ETN 59% vs. placebo 15% (*P*<0.001) Mean annualized rate of change over 1 year of treatment in modified Sharp score: ETN -0.03 unit vs. placebo 1.00 unit (*P*=0.0001)	Fair
Golimumab vs. Placebo					
Kavanaugh, 2009[54] GO-REVEAL*	RCT 405 14 weeks[a]	Active PsA, failed at least one DMARD or NSAID, concomitant MTX 35%	GOL (50 mg every 4 weeks), GOL (100 mg every 4 weeks) vs. placebo	ACR 20 at week 14: GOL 50 mg 51%, GOL 100 mg 45%, placebo 9% (*P*<0.001)	Good
Infliximab vs. Placebo					
Woolacott et al., 2006[55]	Systematic review and meta-analysis 369	Adults with PsA, concomitant MTX 46% to 56%	INF (5 mg/kg) vs. placebo (one study)	ACR 20 at weeks 14–16: INF 62% vs. placebo NR (RR, 5.75; 95% CI, 3.55 to 9.30)	Good

Table 12. Disease activity in biologic DMARD versus placebo (continued)

Study	Study Design N Duration	Study Population	Comparison (Dose)	Results of Primary Outcome Measure	Quality Rating
Antoni et al., 2005 IMPACT Study[50, 51]	RCT 104 50 weeks (16 blinded, 34 open-label)	Active PsA, failed at least one DMARD or NSAID, concomitant MTX 56%	INF (5 mg/kg at weeks 0, 2, 6, 14 then every 8 weeks) vs. placebo[b] 71% received a concomitant DMARD	ACR 20 at week 16: INF 65.4% vs. placebo 9.6% (*P*<0.001)	Fair
Antoni et al., 2005 IMPACT 2 Study[52, 53] Vander Heijde et al., 2007[57]*	RCT 200 54 weeks (at week 16, patients could enter early escape and be reassigned from placebo to INF if not improving; all placebo subjects crossed over to INF at week 24)	Active PsA, failed at least one DMARD, concomitant MTX 46%	INF (5 mg/kg at weeks 0, 2, 6, 14, 22) vs. placebo[c] 46% received concomitant MTX	ACR 20 at week 14: INF 58% vs. placebo 11% (*P*<0.001) Mean change in total Sharp/van der Heijde score at week 24: ADA -0.70 +/- 2.53 (SD) vs. placebo 0.82 +/- 2.62 (*P*<0.001)	Fair

ACR 20 = American College of Rheumatology 20 percent improvement from baseline to endpoint; ADA = adalimumab; ADEPT = Adalimumab Effectiveness in Psoriatic Arthritis Trial; DMARD = disease-modifying antirheumatic drug; ETN = , etanercept; GOL = golimumab; IMPACT = Infliximab Multinational Psoriatic Arthritis Controlled Trial; INF =, infliximab; kg = kilogram; mg = milligram; MTX = methotrexate; NR = not reported; PsA = psoriatic arthritis; PsARC = Psoriatic Arthritis Response Scale; RCT = randomized controlled trial; RR = relative risk

*New studies since last review.

[a]GO-REVEAL is planned to continue through 5 years; results have been published through week 24.

[b]INF 5 mg/kg or placebo at weeks 0, 2, 6, and 14, followed by open-label treatment with INF 5 mg/kg every 8 weeks.

[c]Placebo-treated patients with<10% improvement could cross over to INF 5 mg/kg at week 16. All remaining placebo patients crossed over to receive INF at weeks 24, 26, 30, 38, and 46. INF patients with<20% improvement received INF 10 mg/kg at weeks 38 and 46.

Adalimumab

Two RCTs examined the use of adalimumab (40 mg every other week) in patients suffering from moderate to severe PsA (defined as having at least three swollen joints and three tender or painful joints) who had an inadequate response or intolerance to nonsteroidal anti-inflammatory drug (NSAID) therapy[46] or previous oral DMARD therapy.[56] Patients were allowed to continue current MTX therapy as long as the dose had been stable for 4 weeks. In the first study,[46] the double-blind phase of the study lasted 24 weeks, but patients who failed to achieve at least a 20 percent decrease in both swollen and tender joint counts on two consecutive visits could receive rescue therapy with corticosteroids or oral DMARDs. A significantly higher percentage of the adalimumab group met ACR 20/50/70 response criteria than the placebo group (all $P<0.001$). According to the PsARC, 60 percent of the adalimumab group and 23 percent of the placebo group responded (P=NR). PASI 75 was achieved by 59 percent of the adalimumab group and 1 percent of the placebo group ($P<0.001$). At 24 weeks, the changes in the modified Sharp score, erosion score, and joint space narrowing score were significantly less in adalimumab-treated than placebo-treated patients ($P=0.001$). The second trial[56] randomized 102 patients for 12 weeks and

similarly found a higher percentage of patients meeting ACR 20 at week 12 compared with placebo (39 vs. 16 percent, P=0.012).[56]

Etanercept

Two RCTs examined the efficacy of etanercept (25 mg twice weekly by subcutaneous injections) in a total of 265 patients with active PsA who were not adequately responding to conventional DMARD therapies.[47, 48] In both studies, patients were allowed to continue MTX therapy as long as the dose had been stable for 4 weeks before entry into the study. One study lasted 12 weeks (N=60);[47] the other (N=205) was double-blinded for 24 weeks.[48] In both studies, the proportions of patients on etanercept meeting ACR 20 response criteria were significantly higher than those for patients on placebo. In the 12-week study, 87 percent of patients on etanercept and 23 percent of those on placebo achieved a PsARC response (P<0.0001).[47] The 24-week study had similar results at 12 weeks: 72 percent of patients on etanercept and 31 percent of those on placebo achieved a PsARC response (P=NR).[48] PASI 75 criteria were met by a greater proportion of patients in the etanercept groups than in the placebo groups in both studies. In the 12-week study, 26 percent of patients on etanercept met PASI 75 criteria versus zero patients on placebo (P=0.015); in the longer study, the figures were 23 percent on etanercept versus 3 percent on placebo (P<0.001). The longer study assessed the radiographic progression of disease at 24 weeks in 205 patients; the mean annualized change in the modified Sharp score was significantly lower in etanercept-treated patients (decrease of -0.03) than in placebo-treated patients (increase of 1.0; P=0.0001).[49]

A systematic review pooled the 12-week data from these two studies; the ACR 20 threshold for improvement was achieved by 65 percent of the etanercept groups (placebo NR), with a pooled relative risk of 4.19 (95% CI, 2.74 to 6.42) compared with placebo.[55] The ACR 50 and ACR 70 criteria were achieved by 45 percent and 12 percent of those treated with etanercept, respectively. In addition, the PsARC was reached by almost 85 percent, with a pooled relative risk of 2.6 (95% CI, 1.96 to 3.45) compared with placebo (placebo NR).[55]

Golimumab

One 14-week RCT of 405 patients with active PsA compared golimumab (50 mg ever 4 weeks or 100 mg every 4 weeks) with placebo.[54] At 14 weeks, all patients on either golimumab dose achieved a higher ACR 20 when compared with placebo (48 percent vs. 9 percent, P<0.001). Significantly greater improvements were also noted for those treated with golimumab for 75 percent improvement in the PASI (40 percent in the 50 mg group, 58 percent in the 100 mg group, and 3 percent in the placebo group; P<0.001).

Infliximab

Two RCTs (five articles) of infliximab compared with placebo included a total of 304 patients with active PsA who had not adequately responded to conventional DMARD therapies.[50-53, 57] In both studies, patients were allowed to continue MTX therapy as long as the dose had been stable for 4 weeks before study entry. One RCT (N=104) was double-blinded for 16 weeks.[50] The other RCT was double-blinded for 24 weeks (N=200 patients with cross-over allowed at week 16 for nonresponders); the primary outcomes were evaluated at 14 weeks and before any crossover.[52] Both studies had the same dosing regimen of 5 mg/kg of infliximab at weeks 0, 2, 6, and 14; the longer study had an additional infusion at week 22. In both studies, the percentages meeting ACR 20 response criteria were significantly greater for subjects treated with

infliximab than for those treated with placebo. In the shorter study, 75 percent of the patients on infliximab and 21 percent on placebo achieved a PsARC response ($P<0.001$). The longer study had similar results in patients achieving a PsARC response at 14 weeks: 77 percent of the patients on infliximab and 27 percent on placebo ($P<0.001$). PASI 75 was achieved by a greater proportion of patients in the infliximab groups than the placebo groups in both studies: for the 16-week study, 68 percent on infliximab versus zero on placebo ($P<0.01$) and, for the later study, 50 percent on infliximab versus 1 percent on placebo ($P<0.001$). Radiographic changes were also less at 24 weeks (Sharp/van der Heijde (-0.70+/-2.53 vs. 0.82+/-2.62, $P<0.001$).[57]

A systematic review described above in the etanercept studies[55] pooled the 14- and 16-week data from these two infliximab studies;[50, 52] the ACR 20 threshold for improvement was achieved by 62 percent of the etanercept groups (placebo NR), with a pooled relative risk of 5.75 (95% CI, 3.55 to 9.30) compared with placebo.[55] In addition, the PsARC was reached by almost 76 percent, with a pooled relative risk of 3.05 (95% CI, 2.29 to 4.08) compared with placebo (placebo NR).[55]

KQ 2: Functional Capacity and Quality of Life

KQ 2 specifically examined the issue of whether, for patients with psoriatic arthritis (PsA), drug therapies differed in their ability to improve patient-reported symptoms, functional capacity, or quality of life. Findings are organized as for KQ 1. Table 7 lists the abbreviated and full names of all instruments and scales referred to in this chapter. Functional capacity, functional status, and functional ability are three concepts often used interchangeably to refer to similar capabilities. Quality of life is a far broader construct comprising physical health; mental or emotional health; a variety of symptom states (e.g., pain, fatigue); and coping, spiritual, and other domains. For the purposes of this report, we divided outcomes into functional capacity and health-related quality of life. We use the terms *functional capacity, functional status,* or *functional ability* to refer to condition-specific measures, such as the Health Assessment Questionnaire (HAQ), developed to assess function in patients with PsA or other types of arthritis. We use *health-related quality of life* when referring to generic measures, such as the Medical Outcomes Study Short Form 36 Health Survey (SF-36), that have been developed to assess quality of life in both healthy people and those with different conditions; we also use health-related quality of life when referring to measures developed to assess quality of life for a specific condition or group of conditions, such as the Dermatology Life Quality Index (DLQI), a quality-of-life instrument for dermatologic diseases. We attempted to use terminology consistent with reporting from individual studies; if the authors used the term *functional ability* rather than *functional capacity,* we used the same term. Outcomes for functional capacity and health-related quality of life were often secondary outcomes in these studies; that is, studies were not all designed to detect a difference between groups for these types of outcomes.

Overview

A total of eight RCTs examined functional capacity or quality of life in patients being treated for PsA. Details are found in the Evidence Tables in Appendix E. Tables 12 and 13 provide information on comparisons made, quality-of-life outcomes, and quality ratings. Conclusions are limited because we found no good or fair quality head-to-head studies. The available studies are all placebo-controlled studies evaluating the efficacy of one oral disease-modifying antirheumatic drug (DMARD) or one biologic DMARD. In total, we found one study (two

articles) comparing an oral DMARD with placebo[41, 42] and seven studies comparing a biologic DMARD with placebo. Overall results and strength of evidence are described in Appendix H.

Small differences in outcome measures may be statistically significant, yet clinically unimportant. Therefore, in the text below, we describe whether treatment effects reach minimal clinically important differences (MCIDs) for the HAQ and SF-36, the two most commonly reported outcome measures in KQ2. For the HAQ, we considered a change of ≥0.22 to be an MCID.[31] For the SF-36, some have suggested an improvement of 3 to 5 for the MCID.[35, 58] We found no published PsA ranges but found some developed using data from clinical trials of RA patients that suggest slightly lower values, with ranges of 2.6 to 4.4 for the physical component score (PCS) and 2.2 to 4.7 for the mental component score (MCS).[34] We used these lower ranges to take a conservative approach on what might be an MCID.

Head-to-Head Evidence

We did not find any head-to-head studies meeting our inclusion/exclusion criteria.

Oral DMARD Versus Placebo

Evidence from one 24-week study provides a low strength of evidence that patients treated with leflunomide had statistically significant greater improvement in functional capacity (mean change in HAQ: -0.19 vs. -0.05; *P*=0.027) and quality-of-life outcomes (mean change in DLQI: -1.9 vs. -0.2; *P*=0.017) than those treated with placebo.[41, 42] However, the improvement in functional capacity did not reach the MCID (change of ≥0.22).

Biologic DMARD Versus Placebo

Evidence from seven studies comparing either adalimumab (two studies),[46, 56, 59] etanercept (two studies),[47-49, 60] golimumab (one study),[54] or infliximab (two studies)[50-53, 61] with placebo provides a low to moderate strength of evidence for the efficacy of each of these biologic DMARDs for improving functional capacity and quality of life. The magnitude of benefit in functional capacity reached the MCID (HAQ change of ≥0.22) for all but one study of adalimumab (which found a between-group difference of 0.2).[56] Overall, the magnitude of benefit for functional capacity (between-group difference for improvement in HAQ) ranged from 0.2 to 0.3 for adalimumab, 0.5 to 1.1 for etanercept, 0.34 to 0.4 for golimumab, and 0.4 to 0.6 for infliximab.

The magnitude of benefit in quality of life reached the MCID for the PCS for all five studies that reported the PCS and ranged from 2.9 to 7.9 for adalimumab, was 8.6 for etanercept, 5.9 to 7.2 for golimumab, and 6.4 to 8 for infliximab. The magnitude of benefit in quality of life reached the MCID for the MCS for two of the four studies that reported the MCS[48, 49, 52, 53, 60, 61] and ranged from 1.2 to 1.7 for adalimumab, was 2.8 for etanercept, and 3.5 to 5 for infliximab.

Detailed Analysis

Oral DMARD Versus Placebo

We did not identify any studies that examined the use of corticosteroids in the treatment of PsA or any head-to-head studies of oral DMARDs reporting outcomes relevant for this section. One study met inclusion criteria for this section. It compared leflunomide with placebo (Table 13).[41, 42]

Table 13. Oral DMARD versus placebo studies: functional capacity and health-related quality of life outcomes: leflunomide vs. placebo

Study	Study Design N Duration	Study Population	Comparison (Dose)	Results	Quality Rating
Kaltwasser et al., 2004[41, 42]	RCT 190 24 weeks	Active PsA, failed at least 1 DMARD	LEF (100 mg/day, 3 days then 20 mg/day) vs. placebo	Mean change in HAQ: -0.19 vs. -0.05; *P*=0.027 Mean change in DLQI: -1.9 vs. -0.2; *P*=0.017	Fair

DLQI = Dermatology Life Quality Index; DMARD = disease-modifying antirheumatic drug; HAQ = Health Assessment Questionnaire; LEF = leflunomide; PsA = psoriatic arthritis; RCT = randomized controlled trials

Leflunomide

One 24-week trial (two publications) evaluated the efficacy of leflunomide in PsA patients.[41, 42] The study randomized 190 subjects to leflunomide or placebo; PsA was defined as having at least three swollen joints and three tender or painful joints and psoriasis over at least 3 percent of the body surface area. Almost 50 percent of the patients were DMARD naive. Those who were not DMARD naïve were required to discontinue all oral DMARDs, biologic DMARDs, and investigational drugs 28 days before baseline measures were done. At 24 weeks, subjects treated with leflunomide had greater improvement in functional capacity and quality of life than those treated with placebo.

Biologic DMARD Versus Placebo

We did not identify any head-to-head studies of biologic DMARDs reporting outcomes relevant for this section. Seven studies (13 articles) compared one biologic DMARD with placebo (Table 14).[46-54, 56, 59-61]

Table 14. Biologic DMARD versus placebo studies: functional capacity and health-related quality-of-life outcomes

Study	Study Design N Duration	Study Population	Comparison (Dose)	Results	Quality Rating
Adalimumab vs. Placebo					
Genovese et al., 2007[56]*	RCT 102 12 weeks	Active PsA, failed at least one DMARD	ADA (40 mg every other week) vs. placebo	Mean change in HAQ (12 weeks): ADA -0.3 vs. placebo -0.1; *P*=0.010 Mean change in SF-36 PCS (12 weeks): ADA 5.7 vs. placebo 2.8, *P*=0.082 Mean change in SF- 36 MCS (12 weeks): ADA 1.1 vs. placebo -0.6, *P*=0.242 Mean change in DLQI (12 weeks): -3.4 vs. -1.7 (*P*=0.171)	Fair
Mease et al., 2005;[46] Gladman et al., 2007[59] ADEPT	RCT 313 24 weeks	Active PsA, failed at least one DMARD	ADA (40 mg every other week) vs. placebo 51% received concomitant MTX	Mean change in HAQ-DI at 24 weeks: ADA -0.4 vs. placebo -0.1, *P*<0.001 Mean change in SF-36 PCS at 24 weeks: ADA 9.3 vs. placebo 1.4, *P*<0.001 Mean change in SF-36 MCS at 24 weeks: ADA 1.8 vs. 0.6, *P*=0.288 Mean change in DLQI at 24 weeks: -6.1 vs. -0.7 (*P*<0.001)	Fair

Table 14. Biologic DMARD versus placebo studies: functional capacity and health-related quality-of-life outcomes (continued)

Study	Study Design N Duration	Study Population	Comparison (Dose)	Results	Quality Rating
Etanercept vs. Placebo					
Mease et al., 2000[47]	RCT 60 12 weeks	Active PsA, failed at least one DMARD	ETN (25 mg twice a week) vs. placebo 51% received concomitant MTX	Improvement in HAQ from baseline ETN 83% (change in median from 1.3 to 0.1) vs. placebo 3% (from 1.2 to 1.1) (*P*<0.0001)	Fair
Mease et al., 2004[48, 49, 60]	RCT 205 96 weeks (24 double-blinded, 24 blinded maintenance, 48 open label)[a]	Active PsA, failed at least one DMARD	ETN (25 mg twice a week) vs. placebo 41% received concomitant MTX	Improvement in HAQ from baseline to 24 weeks: ETN 54% vs. placebo 6% (*P*<0.0001); between-group difference in mean change in HAQ at week 24: 0.5 (*P*<0.0001) Mean HAQ-DI scores at start and end of the open-label extension: ETN 0.4 vs. placebo 1.0 at start ETN 0.4 vs. placebo-ETN 0.6 at end Mean change in SF-36 PCS at 24 weeks: ETN 9.3 vs. placebo 0.7 (*P*<0.001) Mean change in SF-36 MCS at 24 weeks: ETN 2.7 vs. -0.1 (*P*=0.062)	Fair
Golimumab vs. Placebo					
Kavanaugh et al., 2009[54] GO-REVEAL*	RCT 405 24 weeks[b] (at week 16, patients could be reassigned from placebo to golimumab if not improving)	Treatment resistant active PsA despite therapy with DMARDs or NSAIDs, multinational	GOL (50 mg every 4 weeks) vs. GOL (100 mg every 4 weeks) vs. placebo At week 16, patients with<10% improvement from baseline in both SJC and TJC entered early escape= dose escalation from placebo to 50 mg GOL every 4 weeks or from 50 mg GOL to 100 mg GOL every 4 weeks	Mean change in HAQ at 14 weeks was not reported. Mean change at 24 weeks, including the early escape phase: GOL (50 mg) 0.33 vs. GOL (100 mg) 0.39 vs. -0.01 placebo, *P*<0.001for either GOL group vs. placebo Mean change in SF-36 PCS at 14 weeks: GOL (50 mg) 6.53 vs. GOL (100 mg) 7.85 vs. 0.63 placebo, *P*<0.001 for either GOL group vs. placebo Mean change in SF-36 MCS: NR	Good
Antoni et al., 2005[50, 51] IMPACT study	RCT 104 50 weeks (16 blinded, 34 open label)	Active PsA, failed at least one DMARD	INF (5 mg/kg at weeks 0, 2, 6, 14 and then every 8 weeks) vs. placebo[c] All subjects received INF from week 16 to study completion 71% received a concomitant DMARD	Mean percentage improvement in HAQ at week 16: 49.8 vs. -1.6; *P*<0.001; between-group difference in mean change in HAQ at week 16: 0.6; *P*<0.001	Fair

Table 14. Biologic DMARD versus placebo studies: functional capacity and health-related quality-of-life outcomes (continued)

Study	Study Design N Duration	Study Population	Comparison (Dose)	Results	Quality Rating
Infliximab vs. Placebo					
Antoni et al., 2005[52, 53, 61] IMPACT2 study	RCT 200 54 weeks (at week 16, patients could enter early escape and be reassigned from placebo to INF if not improving; all placebo subjects crossed over to INF at week 24)	Active PsA, failed at least one DMARD or NSAID	INF (5 mg/kg at weeks 0, 2, 6, 14, 22) vs. placebo[d] All subjects received INF from week 24 to study completion 46% received concomitant MTX	Mean percentage improvement in HAQ, at week 14: 48.6% vs. -18.4%; *P*<0.001; between-group difference in mean change at weeks 14 and 24: 0.4 and 0.4, *P*<0.001 SF-36 PCS; change from baseline: to week 14: 9.1 vs. 1.1; *P*<0.001 to week 24: 7.7 vs. 1.3; *P*<0.001 SF36 MCS; change from baseline to week 14: 3.8 vs. -1.2; *P*=0.001 to week 24: 3.9 vs. 0.4; *P*=0.047 Improvement in employment status from unemployed at baseline to employed at week 14: 11.5% vs. 0%; *P*=0.084 From part-time to full-time employment: 30.0% vs. 10.0%; *P*=0.582 No significant difference in percentage of missed workdays in past 4 weeks at 14 weeks among patients who were employed full-time at baseline and week 14: 3.7% vs. 13%; *P*=0.138	Fair

ADA = adalimumab; DLQI = Dermatology Life Quality Index; DMARD = disease-modifying antirheumatic drug; ETN = etanercept; GO = golimumab; HAQ = Health Assessment Questionnaire; HAQ DI = Health Assessment Questionnaire Disability Index, INF = infliximab; LEF = leflunomide; MCS = mental component score; MTX = methotrexate; PCS = physical component score; PsA = psoriatic arthritis; SJC = Swollen Joint Count; TJC = Total Joint Count; vs. = versus

[*]New study since last update.

[a]Additional outcomes for the EuroQol EQ-5D Quality of Life questionnaire, EQ-5D , and for the open-label extension are provided in the Evidence Tables in Appendix E.

[b]GO-REVEAL is planned to continue through 5 years; results have been published through week 24.

[c]INF 5 mg/kg or placebo at weeks 0, 2, 6, and 14, followed by open-label treatment with INF 5 mg/kg every 8 weeks.

[d]Placebo-treated patients with<10% improvement could cross over to INF 5 mg/kg at week 16. All remaining placebo patients crossed over to receive INF at weeks 24, 26, 30, 38, and 46. INF patients with<20% improvement received INF 10 mg/kg at weeks 38 and 46.

Adalimumab

Two RCTs compared adalimumab (40 mg every other week) with placebo.[46, 56, 59] In both studies, patients were allowed to continue current MTX therapy as long as the dose had been stable. Both enrolled subjects who had an inadequate response or intolerance to previous treatments. Both studies found greater improvement in functional capacity for subjects treated with adalimumab than those treated with placebo. For health-related quality of life, several outcome measures were reported in both studies; results for each measure either statistically significantly favored adalimumab or were not statistically significantly different but point estimates favored adalimumab.

The Adalimumab Effectiveness in Psoriatic Arthritis Trial (ADEPT) included 313 patients suffering from moderate to severe PsA, which was defined as having at least three swollen joints

and three tender or painful joints, who had had an inadequate response or intolerance to NSAID therapy.[46, 59] The double-blind phase of the study was 24 weeks, but patients who failed to achieve at least a 20 percent decrease in both swollen and tender joint counts on two consecutive visits could receive rescue therapy with corticosteroids or DMARDs. Subjects treated with adalimumab had greater improvements in functional capacity and two quality-of-life measures (SF-36 PCS and DLQI) than those who received placebo.

The other RCTs enrolled 102 subjects with PsA and at least three swollen joints and three tender joints who were receiving concomitant DMARD therapy or had a history of DMARD therapy with an inadequate response.[56] Subjects treated with adalimumab had greater improvements in functional capacity than those who received placebo. Differences between groups for quality-of-life outcome measures were not statistically significantly different between groups, but there was a trend toward greater improvement in subjects treated with adalimumab.

Etanercept

Two studies (three articles) that examined the efficacy of etanercept included a total of 265 patients with active PsA who were not adequately responding to conventional DMARD therapies.[47-49] In both studies, patients were allowed to continue MTX therapy as long as it had been stable for 4 weeks prior to enrollment. One of these trials lasted 12 weeks (N=60);[47] the other was double-blinded for 24 weeks (N=205).[48] Both studies had the same dosing regimen of 25 mg of etanercept twice weekly by subcutaneous injections. Functional capacity improved significantly more with etanercept than with placebo in both studies. The longer study also had an additional 24-week blinded maintenance phase and a 48-week open-label extension during which all subjects received etanercept.[60] Subjects originally assigned to etanercept maintained or improved their HAQ-DI scores, SF-36 physical component summary scores, and EQ-5D scores from the double-blind period through the end of the open-label extension period. Subjects originally assigned to placebo demonstrated improvement in their HAQ-DI scores, SF-36 physical component summary scores, and EQ-5D scores during the open-label extension while receiving etanercept.

Golimumab

The "Golimumab-A Randomized Evaluation of Safety and Efficacy in Subjects with Psoriatic Arthritis Using a Human Anti-TNF Monoclonal Antibody" (GO-REVEAL) study randomized 405 subjects with active PsA to golimumab 50 mg every 4weeks, golimumab 100 mg every 4 weeks, or placebo.[54] The subjects maintained the treatment to which they were randomized for the first 14 weeks; at week 16, subjects with less than 10 percent improvement from baseline in both swollen joint count and tender joint count entered early escape, with dose escalation from placebo to 50 mg golimumab (every 4 weeks) or from 50 mg to 100 mg golimumab (every 4 weeks). Subjects in both golimumab groups had greater improvements in functional capacity and in quality of life (measured by the SF-36 PCS) than those in the placebo group.

Infliximab

Two studies, "Infliximab Multinational Psoriatic Arthritis Controlled Trial" (IMPACT) and IMPACT 2, randomized a total of 304 patients with active PsA who were not adequately responding to conventional DMARD therapies to infliximab or placebo.[50, 52] Both studies permitted patients to continue MTX therapy as long as it had been stable for 4 weeks before

enrollment. One trial was double-blinded for 16 weeks (N=104);[50] the other was double-blinded for 24 weeks (N=200), with crossover allowed at week 16 for nonresponders on the primary outcomes measured at the 14-week evaluation.[52] Both studies had the same dosing regimen of 5 mg/kg of infliximab at weeks 0, 2, 6, and 14; the longer study had an additional injection at week 22. Subjects treated with infliximab had significantly greater improvement in functional capacity than those treated with placebo in both studies. In IMPACT 2, subjects treated with infliximab had greater improvement in functional capacity and quality of life than those treated with placebo. Increases in the physical and mental component summary (PCS and MCS) scores and all eight scales of the SF-36 in the infliximab group were greater than those in the placebo group at week 14 ($P \leq 0.001$). These benefits were sustained through week 24. Compared with the placebo group, higher proportions of patients in the infliximab group improved employment status from unemployed at baseline to employed at week 14 and from part-time to full-time employment.

KQ 3: Harms, Tolerability, Adverse Effects, or Adherence

KQ 3 concerned the potential negative aspects of drug therapies for psoriatic arthritis (PsA) (i.e., harms, tolerability, and adverse effects), as well as patient adherence to treatments. Strength of evidence is presented and additional tables provide selected study-specific information on outcomes, broken out by overall tolerability, specific adverse events, and adherence. Evidence Tables in Appendix E document details about all of these studies.

Overview

A total of one systematic review and meta-analysis, eight randomized controlled trials (RCTs), and two observational studies compared tolerability, harms, and adherence in patients with PsA. The drugs examined in RCTs and the systematic review of RCTs included two oral disease-modifying antirheumatic drugs (DMARDs) (leflunomide and sulfasalazine) and four biologic DMARDs (adalimumab, etanercept, golimumab, and infliximab), all in comparison with placebo. Both prospective cohort studies included patients on adalimumab, etanercept, and infliximab (with or without methotrexate [MTX]), and all of these groups were compared with each other. Overall strength of evidence is insufficient (Appendix H), except for the assessment of withdrawals due to adverse events for the comparison of adalimumab, etanercept, and infliximab, and placebo comparisons of adalimumab and etanercept, which has a low strength of evidence.

Oral DMARDs Versus Placebo

The use of leflunomide versus placebo can increase the likelihood of diarrhea. It can also lead to clinically significant increases in alanine aminotransferase. The rates of adherence are similar for leflunomide and placebo. Withdrawals due to adverse events are higher with leflunomide than placebo based on a single study. Withdrawals due to adverse events with sulfasalazine are not statistically significantly greater than placebo based on a meta-analysis[45] of five trials. The strength of evidence is insufficient given the indirectness of the evidence.

Biologic DMARDs Versus Placebo

Seven placebo-controlled studies of biologics, including two each on adalimumab, etanercept, and infliximab, and one on golimumab, provide indirect evidence on harms. When the individual drugs were compared with placebo, the authors reported few differences in the rate

of adverse events. Exceptions to this finding were increased rates of injection-site reactions with the use of adalimumab and etanercept and increased rates of infections and malignancies with golimumab. Adalimumab-treated patients had fewer reports of aggravated psoriasis compared with placebo-treated patients. Based on data from two prospective cohort studies, etanercept had a statistically significantly lower risk of discontinuation because of adverse events than infliximab. Infusion reactions with infliximab largely contributed to this difference in withdrawal rates. No evidence addressed adherence. The strength of evidence is low for adalimumab and etanercept and insufficient for golimumab and infliximab based on placebo-controlled data and low for the observational evidence addressing withdrawals due to adverse events.

Psoriatic Arthritis: Detailed Analysis

One systematic review and meta-analysis, eight RCTs, and two observational studies compared tolerability, harms, and adherence in patients with PsA. Summary information on these studies is highlighted in Table 15, and full details are found in Evidence Tables in Appendix E.

Table 15. Studies assessing adverse events, discontinuation rates, and adherence in psoriatic arthritis

Study	Study Design Duration	Study Population	Drug	Results	Quality Rating
Oral DMARDs					
Kaltwasser et al., 2004[41]	RCT 190 24 weeks	Patients with active PsA	LEF	Differences in rates of withdrawals because of adverse events, diarrhea, and clinically significant increases in ALT (for all, *P*=NR). Compliance of ≥ 80% to<110%: LEF, 85%; placebo, 78%	Fair
Ravindran et al., 2008[45]*	Meta-analysis SFZ: five studies LEF: one study	Placebo-controlled RCTs of oral or biological DMARDs for patients with PsA	LEF, SFZ	Withdrawals due to adverse events vs. placebo: LEF: RR 3.86 (1.2-12.39) SFZ: RR 1.76 (0.98-3.14)	Fair
Biologic DMARDs					
Antoni et al., 2005[50] IMPACT study	RCT 104 16 weeks	Patients with active PsA despite background biologic or synthetic DMARD treatment	INF	No statistically significant differences in adverse events	Fair
Antoni et al., 2005[52] IMPACT2 study	RCT 200 24 weeks	Patients with active PsA despite background biologic or synthetic DMARD treatment	INF	No statistically significant differences in adverse events	Fair
Genovese et al., 2007[56]*	RCT 102 12 weeks	Patients with active PsA despite synthetic DMARD treatment	ADA	More adverse events for placebo (79.6%) than ADA (52.9%); *P* ≤ 0.01. Aggravation of psoriasis more common for placebo (16.3%) than ADA (3.9%); *P* ≤ 0.05	Fair
Kavanaugh et al., 2009[54] GO-REVEAL*	RCT 405 24 weeks	Patients with active PsA despite synthetic DMARD or NSAID treatment	GOL	Infections and malignancies more common with GOL than placebo (for all, *P*=NR)	Fair

Table 15. Studies assessing adverse events, discontinuation rates, and adherence in psoriatic arthritis (continued)

Study	Study Design Duration	Study Population	Drug	Results	Quality Rating
Kristensen et al., 2008[43]*	Prospective cohort 261 12 months	Patients with active PsA, biologic DMARD naïve	ADA, ETN, INF, MTX	Concomitant MTX associated with significantly fewer withdrawals due to adverse events HR, 0.25; 95% CI, 0.11 to 0.52; *P*<0.01). Compared with INF, ETN had lower risk of withdrawals due to adverse events (HR, 0.30; 95% CI, 0.11 to 0.80, *P*=0.02)	Fair
Mease et al., 2000[47]	RCT 60 12 weeks	Patients with active PsA despite background biologic or synthetic DMARD treatment	ETN	No statistically significant differences in adverse events except for ISRs. ETN 20% vs. placebo 3% (*P*=NS)	Fair
Mease et al., 2005[62]	RCT 313 24 weeks	Patients with active PsA despite background biologic or synthetic DMARD treatment	ADA	No statistically significant differences in adverse events except for ISRs. ADA 6.6% vs. placebo 3.1% (*P*=NR)	Fair
Mease et al., 2006[49]	RCT 205 72 weeks (24 blinded, 48 open label)	Patients with active PsA despite background biologic or synthetic DMARD treatment	ETN	No statistically significant differences in adverse events except for ISRs. ETN 20% vs. placebo 9% (*P*<0.001)	Fair
Ravindran et al., 2008[45]*	Meta-analysis TNF-inhibitors: five studies	Placebo-controlled RCTs of oral or biological DMARDs for patients with PsA	ADA, ETN, INF	Withdrawals due to adverse events vs. placebo: TNF Inhibitors: RR 2.2 (0.82-5.91)	Fair
Saad et al., 2009[63]*	Observational 566 3 years	Patients from the British Society for Rheumatology Biologics Register (BSRBR) with PsA	ADA, ETN, INF	Withdrawals due to adverse events: ADA 14.8%, ETN 12.3%, INF 23.5%. Hazard ratio for INF vs. ETN 3.1 (95% CI, 1.4 to 6.2)	Good

ADA = adalimumab; ALT = alanine aminotransferase; DMARD = disease-modifying antirheumatic drug; ETN = etanercept; GOL = golimumab; HR = hazard ratio, INF = infliximab; ISR = injection-site reaction; LEF = lefluonomide; MTX = methotrexate; NR = not reported; NS = not significant; NSAID = nonsteroidal anti-inflammatory drugs; PsA = psoriatic arthritis; RCT = randomized controlled trial; RR = relative risk; SFZ = sulfasalazine; TNF = tumor necrosis factor
*New studies added since last review.

Oral DMARDs

Overall Tolerability

We did not identify any studies meeting our inclusion/exclusion criteria that examined the use of corticosteroids in the treatment of PsA. One 24-week trial with 190 patients examined adverse events in the treatment of PsA using leflunomide versus placebo.[41] The overall rates of adverse events were the same in each group: 85.4 percent of both trial arms experienced an adverse event. In meta-analyses of placebo-controlled trials, withdrawals due to adverse events were not statistically significantly more common for suflasalazine than for placebo (five studies: RR, 1.76; 95% CI 0.98 to 3.14, *P*=0.06) but were statistically significantly more common for leflunomide than placebo based on one contributing study (RR, 3.86; 95% CI 1.20 to 12.39, *P*=0.02).[45]

Specific Adverse Events

One trial showed some differences in specific adverse events for leflunomide, in particular diarrhea (leflunomide, 24%; placebo, 13%; *P*=NR) and increases in alanine aminotransferase (leflunomide, 13%; placebo, 5%; *P*=NR).[41]

Adherence

This same trial also reported adherence in the treatment of PsA.[41] Over 24 weeks, treatment adherence of between 80 percent and 100 percent was reported by 85 percent of leflunomide patients and 78 percent of placebo patients (*P*=NR). Additionally, one patient was withdrawn by the investigator from the placebo group because of poor adherence.

Biologic DMARDs

Overall Tolerability

Based on a Swedish prospective cohort study that included patients treated with adalimumab, etanercept, and infliximab, severe adverse events occurred in 5 to 6 percent of patients per year.[43] Two anaphylactic infusion reactions occurred, both with infliximab. Other adverse event rates were similar. Concomitant MTX was associated with significantly fewer withdrawals due to adverse events (HR, 0.25; 95% CI, 0.11 to 0.52; *P*<0.01). Compared with infliximab, etanercept had a lower risk of withdrawal because of adverse events (HR, 0.30; 95% CI, 0.11 to 0.80; *P*=0.02).[43] Based on 3 years of data from another observational study of patients from the British Society for Rheumatology Biologics Register (BSRBR), withdrawals due to adverse events were 14.8% for ADA, 12.3% for etanercept, and 23.5% for infliximab. Differences were statistically significant for infliximab compared with etanercept (HR, 3.1; 95% CI, 1.4 to 6.2). The most common reason for discontinuation with infliximab was infusion reactions (n=12; 7.4%).[63] As a class for TNF inhibitors (including adalimumab, etanercept, and infliximab), withdrawals due to adverse events were not statistically significantly more common than with placebo (RR, 2.20; 95% CI, 0.82 to 5.91, *P*=0.12) in a meta-analysis of five studies.[45] In efficacy trials for patients with PsA, overall tolerability profiles appeared to be similar for biologic DMARDs (adalimumab, etanercept, and infliximab) and placebo.[41, 46, 47, 49, 50, 52, 54, 56] Injection-site reactions, dizziness, headaches, and upper respiratory tract infections were the most commonly reported individual adverse events. Of these, injection-site reactions appeared to occur more often in the active group than in the control group.

Specific Adverse Events

Adalimumab and etanercept used to treat PsA showed some differences in injection-site reactions. In a 24-week RCT examining adalimumab versus placebo, the adalimumab group experienced more injection-site reactions (6.6 percent) than the placebo group (3.1%; *P*=NR).[46] Two other studies comparing etanercept to placebo also showed higher rates of injection-site reactions in the active arms.[47, 49] A 12-week RCT reported injection-site reaction rates of 20 percent in the etanercept group and 3 percent in the placebo group; these results were not significant, probably owing to the small sample size (N=60).[47] In an RCT with 205 patients, however, the difference between these two groups was statistically different.[49] In the 24-week blinded portion of this study, injection-site reactions occurred in 36 percent of the etanercept patients and 9 percent of the placebo patients (*P*<0.001). Infusion reactions with infliximab

(n=12; 7.4%) were more common than injection-site reactions with adalimumab (n=1; 1.1%) or etanercept (n=2; 0.6%) in a 3-year observational study.[63]

Most studies reported no statistically significant differences in adverse events between active treatment and placebo. In the only RCT of golimumab, more infections and malignancies were reported in golimumab-treated patients than placebo-treated patients (*P*=NR).[54]

Adherence

No study specifically addressed adherence with biologic DMARDs in the treatment of PsA.

Discussion

This report provides a comprehensive review of the comparative efficacy, effectiveness, and harms of members of three main classes of drugs used to treat adult patients with psoriatic arthritis (PsA). These drugs include corticosteroids, oral disease-modifying antirheumatic drugs (DMARDs), and biologic DMARDs. The objective of this report is to evaluate the comparative efficacy, effectiveness, and harms of monotherapies, combination therapies, and different treatment strategies.

Table 16 summarizes our findings and the strength of evidence for the Key Questions (KQs) addressed by this report. In brief, the KQs addressed benefits of these drugs, alone or in combination, in terms of slowing or limiting the progression of radiographic joint damage and maintaining remission (KQ 1); reduction of patient-reported symptoms and improved functional capacity and quality of life (KQ 2); harms and risks of these drugs (KQ 3); and the benefits or harms in various patient subpopulations defined by sociodemographic characteristics or health states (KQ 4).

Table 16. Summary of findings

Key Comparisons	Efficacy and Effectiveness Strength of Evidence Grade	Harms Strength of Evidence Grade
	Oral DMARDs	
Leflunomide	No head-to-head studies met inclusion criteria; unable to draw conclusions on the comparative efficacy of leflunomide and other treatments. INSUFFICIENT Compared with placebo in one study, leflunomide produced better improvement in health-related quality of life and statistically significant, but not clinically significant, improvement in disease activity and functional capacity. LOW	No head-to-head studies met inclusion criteria; unable to draw conclusions on the comparative harms of leflunomide and other treatments. INSUFFICIENT Current evidence was limited to placebo-controlled trials. Compared with placebo, leflunomide led to higher rates of withdrawals because of adverse events, diarrhea, and clinically significant increases in alanine aminotransferase. INSUFFICIENT
Methotrexate	No head-to-head studies met inclusion criteria; unable to draw conclusions on the comparative efficacy of MTX and other treatments. INSUFFICIENT Current evidence was limited to placebo-controlled trials. Compared with placebo in one fair study, MTX resulted in greater improvement in physician assessment of disease activity than placebo. LOW	No head-to-head studies met inclusion criteria; unable to draw conclusions on the comparative harms of MTX and other treatments. INSUFFICIENT

Table 16. Summary of findings (continued)

Key Comparisons	Efficacy and Effectiveness Strength of Evidence Grade	Harms Strength of Evidence Grade
Sulfasalazine	No head-to-head studies met inclusion criteria; unable to draw conclusions on the comparative efficacy of sulfasalazine and other treatments. INSUFFICIENT Current evidence was limited to placebo-controlled trials. Compared with placebo in one good systematic review study, sulfasalazine reduced disease activity. MODERATE	No head-to-head studies met inclusion criteria; unable to draw conclusions on the comparative harms of sulfasalazine and other treatments. INSUFFICIENT
Biologic DMARDs		
Biologic DMARD + Oral DMARD vs. Biologic DMARD or Oral DMARD	The current evidence was limited to two cohort studies. Compared to anti-TNF monotherapy (adalimumab, etanercept, or infliximab), MTX plus anti-TNF produced similar disease activity response rates. LOW One systematic review of TNF inhibitors found that both TNF inhibitors and sulfasalazine are effective (similar withdrawals due to lack of efficacy); however, the data were insufficient to determine if the effect reached MCID. INSUFFICIENT	No head-to-head evidence met inclusion criteria; unable to draw conclusions on the comparative harms of biologic DMARD + oral DMARD and other treatments. INSUFFICIENT

Table 16. Summary of findings (continued)

Key Comparisons	Efficacy and Effectiveness Strength of Evidence Grade	Harms Strength of Evidence Grade
Biologic	No head-to-head trials met inclusion criteria; unable to draw conclusions on the comparative efficacy of biologics and other treatments. INSUFFICIENT Compared with placebo, adalimumab, etanercept, golimumab, and infliximab led to greater improvement in disease activity, functional capacity* and health-related quality of life.† LOW to MODERATE‡	Etanercept had a lower rate of withdrawals because of adverse events than infliximab in a prospective cohort study. LOW Additional evidence was limited to placebo-controlled trials, where adverse events were not the primary outcome. Overall adverse event profiles appeared to be similar for biologic DMARDs and placebo. However, compared with placebo, we noted the following: adalimumab and etanercept had more injection-site reactions and adalimumab had fewer events of aggravated psoriasis than placebo LOW Golimumab was associated with more malignancies than placebo in one RCT INSUFFICIENT

ADA = adalimumab; DMARD = disease-modifying antirheumatic drug; ETN = etanercept; INF = infliximab; LEF = leflunomide; MCID = minimal clinically important difference; MTX = methotrexate; PCS = physical component score; SF-36 = Medical Outcomes Study Short Form 36; SSZ = sulfasalazine; TNF = tumor necrosis factor
*Of seven studies reporting outcomes for the Health Assessment Questionnaire (HAQ), the magnitude of benefit in functional capacity compared with placebo reached the MCID (HAQ change of ≥ 0.22) for all but one study of adalimumab (which found a between-group difference of 0.2).[a] The magnitude of benefit for functional capacity (between-group difference for improvement in HAQ) ranged from 0.2 to 0.3 for adalimumab, 0.5 to 1.1 for etanercept, 0.34 to 0.4 for golimumab, and 0.4 to 0.6 for infliximab.
†The magntude of benefit in quality of life reached the MCID for the SF-36 PCS for all five studies that reported the PCS and ranged from 2.9 to 7.9 for adalimumab, 8.6 for etanercept, 5.9 to 7.2 for golimumab, and 6.4 to 8 for infliximab.
‡Low for golimumab and moderate for adalimumab, etanercept and infliximab.

Data are quite limited for PsA patients, and the evidence is insufficient to draw firm conclusions on comparative efficacy, effectiveness, and harms of either oral or biologic DMARDs in this condition.

Key Findings

No head-to-head controlled trials meeting inclusion criteria exist for any drugs in this review for treating patients with PsA. Two cohort studies with low evidence indicated that the combination of an anti-tumor necrosis factor (TNF) (adalimumab, etanercept, or infliximab) with methotrexate (MTX) only was not different in treatment response[43, 44] than treatment with anti-TNF only.

Table 17 gives a range for effect sizes for commonly reported measures, including American College of Rheumatology 20 percent improvement from baseline to endpoint (ACR 20), Health

[a]Genovese MC, Mease PJ, Thomson GT, et al. Safety and efficacy of adalimumab in treatment of patients with psoriatic arthritis who had failed disease modifying antirheumatic drug therapy. J Rheumatol 2007;34(5):1040-50.

Assessment Questionnaire (HAQ), and Short Form 36 Physical Component Score (SF-36 PCS). For the oral DMARDs, including sulfasalazine and methotrexate, sparse data are available. Parenteral high-dose MTX and sulfasalazine improved physician assessment of disease activity compared with placebo.[40] For both of these comparisons, minimally clinically important differences (MCIDs) cannot be determined. Additionally, patients taking leflunomide had higher response rates and better quality-of-life outcomes than those taking placebo, however these reached MCID by ACR 20, but not by the Psoriasis Area and Severity Index (PASI) or by the HAQ scales.[41, 42]

Table 17. Comparison of effect sizes* from placebo-controlled trials for ACR 20, HAQ, and SF-36 PCS by Drug

Drug	Studies/ Participants	ACR 20 (% of Subjects Achieving)	HAQ (Mean Improvement)	SF-36 PCS (Mean Improvement)
Oral DMARDs				
Leflunomide	1 RCT/ 190	36	0.14	NR
Methotrexate	1 RCT/ 37	NR	NR	NR
Sulfasalazine	1 SER/ 1,022	NR	NR	NR
Biologic DMARDS				
Adalimumab	2 RCTs/ 415	39 to 57	0.2 to 0.3	2.9 to 7.9
Etanercept	3 RCTs/ 633	59 to 65	0.5 to 1.1	8.6
Golimumab	1 RCT/ 405	45 to 51	0.34 to 0.4	5.9 to 7.2
Infliximab	2RCTs,1SER/ 673	58 to 62	0.4 to 0.6	6.4 to 8

ACR 20 = American College of Rheumatology 20 percent improvement from baseline to endpoint; HAQ = Health Assessment Questionnaire; PCS = physical component score; SF-36 = Medical Outcomes Study Short Form 36; RCT = Randomized controlled trial; SER = systematic evidence review

*Effect sizes represent the range of point estimates from individual studies for the absolute difference between drug and placebo.Minimally Clinically Important Differences (MCIDs): ACR 20 is 20% minimal improvement; ACR 50/70 considered more clinically significant; HAQ >=0.22 change, SF36 PCS>= 2 standard error of the mean (SEM).

Evidence supports the efficacy of adalimumab, etanercept, golimumab, and infliximab for the treatment of PsA.[46-56] However, evidence is insufficient to draw firm conclusions about the comparative efficacy, effectiveness, functional status, health-related quality of life, or tolerability of abatacept, adalimumab, anakinra, certolizumab, golimumab, etanercept, infliximab, rituximab, and tocilizumab for treating PsA.

As noted in Table 17, DMARDs, including adalimumab, etanercept, golimumab, and infliximab, appear to achieve similar ACR 20, HAQ, and SF-36 PCS scores when compared with placebo.

Information is generally insufficient to compare drugs for PsA with respect to harms, tolerability, adverse events, and adherence. The available studies include two relatively small prospective cohort studies and placebo-controlled studies; no head-to-head studies meeting inclusion criteria have been published.

In terms of applicability to patient subgroups, the studies are generally multicenter involving adults with diagnosed PsA. Prior medications tried before these studies were variable, but, in general, patients had failed a DMARD prior to starting any of the biologic agents. It is also important to note that the diagnostic criteria for PsA before the publication of the CASPAR criteria were not validated, which could lead to enrollment of patients that were not explicitly defined.

This report's findings did not reveal any differences with current standard of care. DMARDs are needed in most cases for PsA treatment. MTX is commonly used and useful treating psoriasis in addition to arthropathy. However, when chronic disease continues to be active despite use of

MTX, biologics are indicated and most often given in combination with oral DMARDs (e.g., MTX).[21] Comparative effectiveness remains lacking among and between oral and biologic DMARDs.

Future Research

We have identified several areas needing further research to help clinicians and researchers arrive at stronger conclusions on the comparative efficacy, effectiveness, quality of life, and harms of medications for PsA. For this condition, the available evidence is limited to two head-to-head cohort studies and placebo-controlled trials. The quality of studies on oral DMARDs is sparse and fraught with methodological issues. Head-to-head RCTs are required to establish the comparative efficacy and safety of different treatment strategies to determine the best therapy to prevent or minimize debilitating joint damage. Specifically, we need better studies that include head-to-head comparisons particularly between oral DMARDS and biologics versus DMARDS and with combination therapies of different types. Furthermore, head-to-head RCTs have to determine the comparative effectiveness and safety of biologic DMARDs for the treatment of PsA. More generally, the issues of effectiveness, subgroups, and use in ordinary clinical settings highlighted for RA warrant attention for PsA as well. Future studies should also include outcome measures for axial disease, enthesitis, and dactylitis along with more traditional joint counts. An organized effort to identify diagnostic markers and surrogate endpoints for PsA is also a major unmet need and will help better define and treat this population.

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Appendix A. Search Strings

2007 Search

Search	Most Recent Queries	Result
#2	Search ("Arthritis, Psoriatic"[MeSH] OR "Arthritis, Rheumatoid"[MeSH])	82356
#3	Search ("Arthritis, Psoriatic"[MeSH] OR "Arthritis, Rheumatoid"[MeSH]) Limits: All Adult: 19+ years, English, Publication Date from 1990, Humans	16462
#5	Search "Adrenal Cortex Hormones"[MeSH] OR corticosteroid*	190820
#6	Search #3 AND #5	686
#7	Search #3 AND #5 Limits: Editorial, Letter, Practice Guideline	18
#8	Search #6 NOT #7	668
#18	Search "Methotrexate"[MeSH] OR "leflunomide"[Substance Name] OR "Sulfasalazine"[MeSH] OR "Hydroxychloroquine"[MeSH]	28712
#28	Search "TNFR-Fc fusion protein"[Substance Name] OR etanercept OR "infliximab"[Substance Name] OR "adalimumab"[Substance Name] OR "cytotoxic T lymphocyte-associated antigen 4-immunoglobulin"[Substance Name] OR abatacept OR remicade OR enbrel OR humira OR "rituximab"[Substance Name] OR "interleukin 1 receptor antagonist protein"[Substance Name] OR anakinra	8701
#29	Search #3 AND #18	1365
#30	Search #3 AND #28	777
#31	Search #3 AND #18 Limits: Editorial, Letter, Practice Guideline	237
#32	Search #29 NOT #31	1128
#33	Search #3 AND #28 Limits: Editorial, Letter, Practice Guideline	178
#34	Search #30 NOT #33	599
#35	Search #8 OR #30 OR #34	1405

July 2009 Search

Search	Most Recent Queries	Result
#1	Search "Arthritis, Psoriatic"[MeSH] OR "Arthritis, Rheumatoid"[MeSH]	85528
#2	Search "Adrenal Cortex Hormones"[MeSH] OR corticosteroid*	239378
#3	Search "Methotrexate"[MeSH] OR "leflunomide"[Substance Name] OR "Sulfasalazine"[MeSH] OR "Hydroxychloroquine"[MeSH]	31900
#4	Search "TNFR-Fc fusion protein"[Substance Name] OR etanercept OR "infliximab"[Substance Name] OR "adalimumab"[Substance Name] OR "cytotoxic T lymphocyte-associated antigen 4-immunoglobulin"[Substance Name] OR abatacept OR remicade OR enbrel OR humira OR "rituximab"[Substance Name] OR "interleukin 1 receptor antagonist protein"[Substance Name] OR anakinra	15567
#5	Search ((("CDP870 "[Substance Name] OR certolizumab OR cimzia) OR "efalizumab "[Substance Name] OR raptiva) OR "alefacept "[Substance Name] OR amevive) OR "natalizumab "[Substance Name] OR tysabri	1127
#6	Search "golimumab "[Substance Name]	12
#7	Search #2 OR #3 OR #4 OR #5 OR #6	283303
#8	Search #7 AND #1	11283
#9	Search #7 AND #1 Limits: **Editorial, Letter, Practice Guideline**	1368
#10	Search #8 NOT #9	9915
#11	Search #8 NOT #9 Limits: **Humans, English, All Adult: 19+ years**	4079
#12	Search Limits: **Entrez Date from 2006/06/01, Humans, English, All Adult: 19+ years**	498212
#13	Search #11 AND #12	1027

August 2009 Search (for Tocilizumab)

Search	Most Recent Queries	Result
#1	Search "Arthritis, Psoriatic"[MeSH] OR "Arthritis, Rheumatoid"[MeSH]	85692
#2	Search actemra	4
#4	Search "tocilizumab "[Substance Name]	103
#5	Search #2 OR #4	104
#6	Search #5 AND #1	75
#7	Search #5 AND #1 Limits: **Editorial, Letter, Practice Guideline**	8
#8	Search #6 NOT #7	67
#9	Search #6 NOT #7 Limits: **Humans, English, All Adult: 19+ years**	14
#10	Search #9 Limits: **Entrez Date from 2006/06/01**	14

March 2010 Search

Search	Most Recent Queries	Result
#1	Search "Arthritis, Psoriatic"[MeSH] OR "Arthritis, Rheumatoid"[MeSH]	87507
#2	Search "Adrenal Cortex Hormones"[MeSH] OR corticosteroid*	244454
#3	Search "Methotrexate"[MeSH] OR "leflunomide"[Substance Name] OR "Sulfasalazine"[MeSH] OR "Hydroxychloroquine"[MeSH]	32512
#12	Search "TNFR-Fc fusion protein"[Substance Name] OR etanercept OR "infliximab"[Substance Name] OR "adalimumab"[Substance Name] OR "cytotoxic T lymphocyte-associated antigen 4-immunoglobulin" OR abatacept OR remicade OR enbrel OR humira OR "rituximab"[Substance Name] OR "interleukin 1 receptor antagonist protein"[Substance Name] OR anakinra	16979
#13	Search ((("CDP870 "[Substance Name] OR certolizumab OR cimzia) OR "efalizumab "[Substance Name] OR raptiva) OR "alefacept "[Substance Name] OR amevive) OR "natalizumab "[Substance Name] OR tysabri	1309
#14	Search actemra OR "tocilizumab"[Substance Name]	134
#15	Search "golimumab "[Substance Name]	32
#16	Search #2 OR #3 OR #12 OR #13 OR #14 OR #15	290354
#17	Search #16 AND #1	11855
#18	Search #17 Limits: Editorial, Letter, Practice Guideline	1450
#19	Search #17 NOT #18	10405
#20	Search #19 Limits: Humans, English, All Adult: 19+ years	4358
#21	Search "2009/05/01"[Entrez Date] : "3000"[Entrez Date] Limits: Humans, English, All Adult: 19+ years	89610
#22	Search #20 AND #21 Limits: Humans, English, All Adult: 19+ years Sort by: PublicationDate	176

August 2010 Search

Search	Most Recent Queries	Result
#1	Search "Arthritis, Psoriatic"[MeSH] OR "Arthritis, Rheumatoid"[MeSH]	89162
#2	Search "Adrenal Cortex Hormones"[MeSH] OR corticosteroid*	248455
#3	Search "Methotrexate"[MeSH] OR "leflunomide"[Substance Name] OR "Sulfasalazine"[MeSH] OR "Hydroxychloroquine"[MeSH]	33034
#4	Search "TNFR-Fc fusion protein"[Substance Name] OR etanercept OR "infliximab"[Substance Name] OR "adalimumab"[Substance Name] OR "cytotoxic T lymphocyte-associated antigen 4-immunoglobulin" OR abatacept OR remicade OR enbrel OR humira OR "rituximab"[Substance Name] OR "interleukin 1 receptor antagonist protein"[Substance Name] OR anakinra	18212
#5	Search ((("CDP870 "[Substance Name] OR certolizumab OR cimzia) OR "efalizumab "[Substance Name] OR raptiva) OR "alefacept "[Substance Name] OR amevive) OR "natalizumab "[Substance Name] OR tysabri	1468
#6	Search actemra OR "tocilizumab"[Substance Name]	250
#7	Search "golimumab "[Substance Name]	47
#8	Search #2 OR #3 OR #4 OR #5 OR #6 OR #7	296041
#9	Search #1 AND #8	12290
#10	Search #9 Limits: Editorial, Letter, Practice Guideline	1498
#11	Search #9 NOT #10	10792
#12	Search #11 Limits: Humans, English, All Adult: 19+ years	4578
#13	Search ((#12) AND "2010/01/01"[Entrez Date] : "3000"[Entrez Date]) AND "0"[Entrez Date] : "3000"[Entrez Date] Sort by: Author	125

January 2011 Search

Search	Most Recent Queries	Result
#1	Search "Arthritis, Psoriatic"[MeSH] OR "Arthritis, Rheumatoid"[MeSH]	90392
#2	Search "Adrenal Cortex Hormones"[MeSH] OR corticosteroid*	251312
#3	Search "Methotrexate"[MeSH] OR "leflunomide"[Substance Name] OR "Sulfasalazine"[MeSH] OR "Hydroxychloroquine"[MeSH]	33430
#4	Search "TNFR-Fc fusion protein"[Substance Name] OR etanercept OR "infliximab"[Substance Name] OR "adalimumab"[Substance Name] OR "cytotoxic T lymphocyte-associated antigen 4-immunoglobulin" OR abatacept OR remicade OR enbrel OR humira OR "rituximab"[Substance Name] OR "interleukin 1 receptor antagonist protein"[Substance Name] OR anakinra	19150
#5	Search ((("CDP870 "[Substance Name] OR certolizumab OR cimzia) OR "efalizumab "[Substance Name] OR raptiva) OR "alefacept "[Substance Name] OR amevive) OR "natalizumab "[Substance Name] OR tysabri	1583
#6	Search actemra OR "tocilizumab"[Substance Name]	305
#7	Search "golimumab "[Substance Name]	56
#8	Search #2 OR #3 OR #4 OR #5 OR #6 OR #7	300191
#9	Search #1 AND #8	12597
#10	Search #9 Limits: Editorial, Letter, Practice Guideline	1540
#11	Search #9 NOT #10	11057
#12	Search #11 Limits: Humans, English, All Adult: 19+ years	4714
#13	Search ((#12) AND "2010/05/01"[Entrez Date] : "3000"[Entrez Date]) AND "0"[Entrez Date] : "3000"[Entrez Date] Sort by: Author	116

Appendix B. Review and Abstraction Forms

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Previewing at Level 1

Reviewer Comments (Add a Comment)

Refid: 2161, P. Efthimiou, A. Kontzias, C. M. Ward and N. S. Ogden, Adult-onset Still's disease: can recent advances in our understanding of its pathogenesis lead to targeted therapy?, *Nat Clin Pract Rheumatol*, 3(6), 2007, p. 328-35
State: Excluded, Level: 1

Keywords:
Adrenal Cortex Hormones/therapeutic use

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Abstract
Adult-onset Still's disease is a rare systemic inflammatory disease of unknown etiology, characterized by daily high, spiking fevers, evanescent rash, and arthritis. There is no single diagnostic test for adult-onset Still's disease; rather, the diagnosis is based on clinical criteria and necessitates the exclusion of infections, neoplastic, and other 'autoimmune' diseases. Proinflammatory cytokines such as interleukin (IL)-1, IL-6, and IL-18, interferon-gamma, tumor necrosis factor, and macrophage colony-stimulating factor are elevated in patients with adult-onset Still's disease and are thought to have a major role in the pathogenesis of the disease. Treatment consists of nonsteroidal anti-inflammatory drugs, corticosteroids, immunosuppressants (methotrexate, gold, azathioprine, leflunomide, cyclosporin, and cyclophosphamide), intravenous immunoglobulin, and cytokine (tumor necrosis factor, IL-1 and IL-6) inhibitors. Recent advances in basic immunology have enhanced our ability to hinder the pathogenic mechanisms associated with adult-onset Still's disease and have led to a paradigm shift where targeted treatments have an increasingly important role.

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1. Original research (no review articles, editorials, letters to the editor) published in English after 1990 in adult patients with rheumatoid or psoriatic arthritis AND is not a case report or case series?

- ○ Yes
- ○ No
- ○ Cannot determine
- ○ No, but article will be used for background

Clear Selection

2. Study includes one or more of the following pharmaceutical interventions (check all that apply):

- ☐ Corticosteroids
- ☐ Oral DMARDs including methotrexate, leflunomide, sulfasalazine, cyclosporine, hydroxychloroquine
- ☐ Biologic DMARDs including anakinra, etanercept, infliximab, adalimumab, abatacept, certolizumab, golimumab, tocilizumab, rituximab
- ☐ Cannot determine
- ☐ Comparison is not of interest

3. Study compares-

- ○ Two of the included drugs
- ○ Biological DMARD (TNF) versus placebo
- ○ One of the included drugs versus placebo but is of interest because of specific outcome such as adverse events
- ○ Nothing of interest and article should not be included
- ○ Cannot determine

Clear Selection

4. Addresses one or more of the following key questions (check all that apply):

- ☐ KQ1 For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to reduce patient-reported symptoms, to slow or limit progression of radiographic joint damage, or to maintain remission (reduce the incidence flare-ups)?
- ☐ KQ2- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to improve functional capacity or quality of life?
- ☐ KQ3 For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in harms, tolerability, adherence, or adverse effects?
- ☐ KQ4 What are the comparative benefits and harms of drug therapies for rheumatoid arthritis and psoriatic arthritis in subgroups of patients based on stage of disease, history of prior therapy, demographics, concomitant therapies, or comorbidities?
- ☐ Cannot determine by the title or abstract
- ☐ None of the above

5. Study design is one of the following:

- ☐ RCT 3 months or longer

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Previewing at Level 2

Reviewer Comments (Add a Comment)

Refid: 2161, P. Efthimiou, A. Kontzias, C. M. Ward and N. S. Ogden, Adult-onset Stills disease: can recent advances in our understanding of its pathogenesis lead to targeted therapy?, *Nat Clin Pract Rheumatol*, 3(6), 2007, p. 328-35
State: Excluded, Level: 1

Save to finish later | Submit Data

1. Should the article be *excluded* for any of the following reasons?

- [ ] Study reported only in abstract
- [ ] Wrong outcome (i.e. pharmakinetic or intermediate outcomes)
- [ ] Wrong drug (not one of the following: corticosteroids, methotrexate, leflunomide, sulfasalazine, cyclosporine, hydroxychloroquine, anakinra, etanercept, infliximab, adalimumab, abatacept, certolizumab, golimumab, tocilizumab, rituximab)
- [ ] Wrong population (For example pediatric studies)
- [ ] Wrong publication type (e.g. letter or editorial)
- [ ] Wrong design (i.e. non-systematic meta-analysis or no comparison arm)
- [ ] RCT (n<100)
- [ ] Other? (Please explain!)
- [ ] Background article
- [ ] None of the above - should be included!

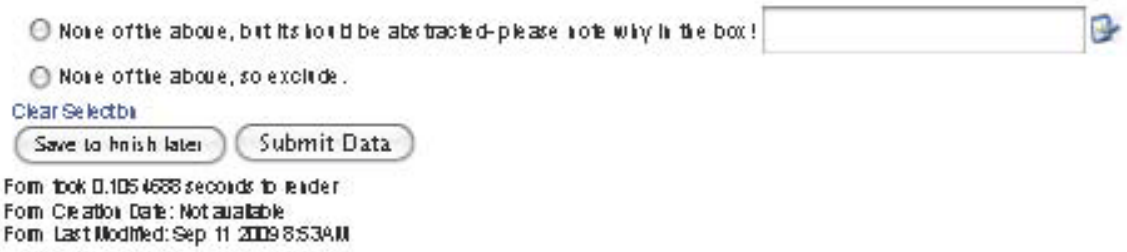
If the article has been excluded in the above question, the next two questions do not need to be answered.

2. Which of the following key questions are addressed by the article

- [ ] KQ1- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to reduce patient-reported symptoms, to slow or limit progression of radiographic joint damage, or to maintain remission (reduce the incidence flare-ups)?
- [ ] KQ2- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to improve functional capacity or quality of life?
- [ ] KQ3- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in harms, tolerability, adherence, or adverse effects?
- [ ] KQ4- What are the comparative benefits and harms of drug therapies for rheumatoid arthritis and psoriatic arthritis in subgroups of patients based on stage of disease, history of prior therapy, demographics, concomitant therapies, or comorbidities?
- [ ] None of the above

3. What is the study design?

- ( ) RCT > or equal to 100
- ( ) Observational > or equal to 100
- ( ) Meta-analysis or systematic review (i.e. Cochrane Review)


None of the above, but it should be abstracted-please note why in the box!
None of the above, so exclude.
Clear Selection
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Previewing at Level 3

Reviewer Comments (Add a Comment)

Refid: 2161, P. Efthimiou, A. Kontzias, C. M. Ward and N. S. Ogden, Adult-onset Stills disease: can recent advances in our understa
State: Excluded, Level: 1

Save to finish later | Submit Data

1. Author, Year, Study name if applicable (i.e. BeST):

Enlarge Shrink

2. Country and setting:

If more than a couple of countries are included just call it multinational. Settings include primary care, hospitals, uni

3. Source of funding

- [ ] Pharmaceutical company or other commercial source - please list name.
- [ ] Government or non-profit organization - please list name.
- [ ] Not reported

4. Condition being treated:

- [ ] Rheumatoid arthritis
- [ ] Psoriatic arthritis
- [ ] Other? Please explain

5. STUDY DESIGN

- ( ) Controlled Trials
- ( ) Observational

Clear Selection

6.
What is being compared?

- [ ] 1 Oral DMARD vs 1 Oral DMARD
- [ ] 1 Oral DMARD vs 1 BIOLOGIC
- [ ] 1 Oral DMARD vs 1 Corticosteroid
- [ ] 1 BIOLOGIC vs 1 BIOLOGIC
- [ ] 1 BIOLOGIC vs 1 Corticosteroid

- [ ] 1 BIOLOGIC vs Placebo
- [ ] Combination therapy vs Combination therapy
- [ ] SINGLE DRUG vs Combination therapy
- [ ] Strategy (Describe the strategy in detail for each arm in the 'Other' text box for numbers 8-12)

7. How many comparison arms does this study have?

- ( ) 2 ARMS
- ( ) 3 ARMS
- ( ) 4 ARMS
- ( ) 5 ARMS

Clear Selection

8. Check off the drug(s) studied for **ARM 1** and put dosage and frequency in the adjacent box

- [ ] Methylprednisolone
- [ ] Prednisone
- [ ] Prednisolone
- [ ] Methotrexate
- [ ] Leflunomide
- [ ] Sulfasalazine
- [ ] Hydroxychlorquine
- [ ] Etanercept
- [ ] Infliximab
- [ ] Adalimumab
- [ ] Anakinra
- [ ] Abatacept
- [ ] Rituximab
- [ ] Certolizumab
- [ ] Golimumab
- [ ] Tocilizumab
- [ ] Placebo
- [ ] Other (describe)

9. Check off the drug(s) studied for **ARM 2** and put dosage and frequency in the adjacent box

- [ ] Methylprednisolone
- [ ] Prednisone
- [ ] Prednisolone

- [ ] Methotrexate
- [ ] Leflunomide
- [ ] Sulfasalazine
- [ ] Hydroxychlorquine
- [ ] Etanercept
- [ ] Infliximab
- [ ] Adalimumab
- [ ] Anakinra
- [ ] Abatacept
- [ ] Rituximab
- [ ] Certolizumab
- [ ] Golimumab
- [ ] Tocilizumab
- [ ] Placebo
- [ ] Other (describe)

10. Check off the drug(s) studied for **ARM 3** and put dosage and frequency in the adjacent box

- [ ] Methylprednisolone
- [ ] Prednisone
- [ ] Prednisolone
- [ ] Methotrexate
- [ ] Leflunomide
- [ ] Sulfasalazine
- [ ] Hydroxychlorquine
- [ ] Etanercept
- [ ] Infliximab
- [ ] Adalimumab
- [ ] Anakinra
- [ ] Abatacept
- [ ] Rituximab
- [ ] Certolizumab

- [ ] Golimumab
- [ ] Tocilizumab
- [ ] Placebo
- [ ] Other (describe)

11. Check off the drug(s) studied for **ARM 4** and put dosage and frequency in the adjacent box

- [ ] Methylprednisolone
- [ ] Prednisone
- [ ] Prednisolone
- [ ] Methotrexate
- [ ] Leflunomide
- [ ] Sulfasalazine
- [ ] Hydroxychlorquine
- [ ] Etanercept
- [ ] Infliximab
- [ ] Adalimumab
- [ ] Anakinra
- [ ] Abatacept
- [ ] Rituximab
- [ ] Certolizumab
- [ ] Golimumab
- [ ] Tocilizumab
- [ ] Placebo
- [ ] Other (describe)

12. Check off the drug(s) studied for **ARM 5** and put dosage and frequency in the adjacent box

- [ ] Methylprednisolone
- [ ] Prednisone
- [ ] Prednisolone
- [ ] Methotrexate
- [ ] Leflunomide
- [ ] Sulfasalazine

- [ ] Hydroxychlorquine
- [ ] Etanercept
- [ ] Infliximab
- [ ] Adalimumab
- [ ] Anakinra
- [ ] Abatacept
- [ ] Rituximab
- [ ] Certolizumab
- [ ] Golimumab
- [ ] Tocilizumab
- [ ] Placebo
- [ ] Other (describe)

13. Research objective (*Please be brief and concise*):

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14. Overall study n =

Enlarge Shrink

15. Duration of study:

Enlarge Shrink

16. Inclusion criteria (check all that apply and list additional criteria in the text box)

- [ ] MTX Naive
- [ ] Early RA
- [ ] Treatment resistant

Additional inclusion criteria

17.

Exclusion criteria

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POPULATION CHARACTERISTICS

	ARM 1	ARM 2	
18. **Intervention/Treatment**			
19. # in group (n):			
20. Age (mean):			
21. Sex, female (%):			
22. Race, white (%):			
23. Race, black (%):			
24. Ethnicity, Latino (%):			
25. Disease duration (mean & SD):			
26. DMARD use (%):			
27. Corticosteroid use (%):			
28. MTX naive (%):			
29. Treatment resistant (%):			
30. Patients with early RA, three years or less, (%):			
31. Baseline DAS score:			
32. Tender joint count:			
33. Swollen joint count:			
34. Required treatment for latent TB:			
35. Other population characteristics?			

RESULTS: Outcome Measures and Health Outcomes
(Enter results for all time points and please specify units for all results)

	ARM 1	ARM 2	
36. ACR 20, %, (CI/SD/P value):			
37. ACR 50, %, (CI/SD/P value):			
38. ACR 70, %, (CI/SD/P value):			
39. PASI 20, %, (CI/SD/P value):			

40. PASI 50, %, (CI/SD/P value):

41. PASI 70, %, (CI/SD/P value):

42. HAQ, mean difference/absolute difference (CI/SD/P Value):

43. DAS, mean difference/absolute difference (CI/SD/P Value):

44. SF-36, mean difference/absolute difference (CI/SD/P Value):

45. PsARC, mean difference/absolute difference (CI/SD/P Value):

46. Radiographic measures, mean difference/absolute difference (CI/SD/P Value):

47. Quality of life scales (please name), mean difference/absolute difference (CI/SD/P Value):

48. Others, (please name); mean difference/absolute difference (CI/SD/P Value):

ATTRITION AND ADHERENCE

	ARM 1	ARM 2	
49. Overall attrition/withdrawal (n):			
50. Withdrawals due to adverse events (n):			
51. Withdrawals due to lack of efficacy (n):			
52. Adherent/compliant (n):			

53. Other attrition related comments?

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RESULTS: Adverse Events, n

	ARM 1	ARM 2	
54. Overall adverse events reported (n):			
55. Death (n):			
56. Lymphoma or leukemia (n):			
57. Skin cancer (basal cell or squamous cell) (n):			
58. Other cancer (specify) (n):			
59. Cardiovascular events (specify) (n):			
60. Hepatotoxicity/elevated liver enzymes (n):			
61. Tuberculosis (n):			
62. Pneumonia (n):			
63. Upper respiratory infection (n):			
64. Urinary tract infection (n):			
65. Other infections (specify) (n):			
66. Fractures (n):			
67. Infusion/injection site reactions (n):			
68. Skin rash (n):			
69. Demyelenation or multiple sclerosis (n):			
70. Progressive multifocal leukoencephalopathy (n):			
71. **Headache** (n):			
72. **Dizziness** (n):			
73. **Nausea or vomiting** (n):			
74. **Abdominal pain** (n):			
75. GI bleed or ulcer (n):			
76. Bowel obstruction (n):			
77. Other GI symptoms (specify) (n):			
78. Other AEs 1 (n):			
79. Other AEs 2 (n):			
80. Other AEs 3 (n):			

81. Other AEs 4 (n):

82. Any other AEs:

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83. Which Key Question(s) does this study address (check all that apply)?

- [ ] KQ1- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to reduce disease activity, t
- [ ] KQ2- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in their ability to improve functional capac
- [ ] KQ3- For patients with rheumatoid arthritis or psoriatic arthritis, do drug therapies differ in harms, tolerability, adherence, or adver
- [ ] KQ4- What are the comparative benefits and harms of drug therapies for rheumatoid arthritis and psoriatic arthritis in subgroups

Quality Review for Controlled Trials

84. Randomization adequate?

- ○ Yes
- ○ No
- ○ Not randomized
- ○ Method not reported

Clear Selection

85. Allocation concealment adequate?

- ○ Yes
- ○ No
- ○ Not randomized
- ○ Method not reported

Clear Selection

86. Groups similar at baseline?

- ○ Yes
- ○ No (what are the differences)
- ○ Not reported
- ○ Not applicable

Clear Selection

87. Outcome assessors blinded?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

88. Care provider blinded?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

89. Patient blinded?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

90. Overall attrition high (≥ 20%)?

- ○ Yes (please state how high) [ ]
- ○ No

Clear Selection

91. Differential attrition high (≥ 15%)?

- ○ Yes (please state difference) [ ]
- ○ No

Clear Selection

92. Were the outcome measures valid and reliable?

- ○ Yes
- ○ No
- ○ Not reported

Clear Selection

93. Were the outcome measures equally applied?

- ○ Yes
- ○ No
- ○ Not reported

Clear Selection

94. Was the statistical analysis based on intention-to-treat (ITT)?

- ○ Yes
- ○ No
- ○ Cannot tell
- ○ Not applicable

Clear Selection

95. Were there any post-randomization exclusions?

- ○ Yes (how many?) [ ]
- ○ No
- ○ Cannot tell

Clear Selection

96. Quality rating for efficacy/effectiveness

- ☐ Good
- ☐ Fair
- ☐ Poor

If poor, why? [ ]

Quality Review for Observational Studies

97. Were both groups selected from the same source population?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

98. Did both groups have the same risk of having the outcome of interest at baseline?

- ○ Yes
- ○ No
- ○ Not reported

Clear Selection

99. Were subjects in both groups recruited over the same time period?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

100. Were measurement methods adequate and equally applied to both groups?

- ○ Yes
- ○ No
- ○ Not reported

Clear Selection

101. Was an attempt made to blind the outcome assessors?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

102. Was the time of follow-up equal in both groups?

- ○ Yes
- ○ No
- ○ Not reported

Clear Selection

103. Overall attrition high (≥ 20%)?

- ○ Yes (please state how high) [ ]
- ○ No

Clear Selection

104. Differential attrition high (≥ 15%)?

- ○ Yes (please state difference) [ ]
- ○ No

Clear Selection

105. Was confounding accounted for either through study design or statistical analysis?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

106. Did the statistical analysis adjust for different lengths of follow-up?

- ○ Yes
- ○ No
- ○ Yes, but method not described
- ○ Not reported

Clear Selection

107. Was the length of follow-up adequate to assess the outcome of interest?

- ○ Yes
- ○ No
- ○ Not reported

Clear Selection

108. Quality rating for observational studies

- ☐ Good
- ☐ Fair
- ☐ Poor

Why?

109. Any other quality related comments?

Enlarge Shrink

Quality Review for Adverse Events

110. Methods of adverse effects assessment

- ☐ Patient reported
- ☐ Physical exam at study visits
- ☐ Lab evaluations
- ☐ Standardized scale (e.g. WHO, UKU-SES)
- ☐ other (please specify)

111. Adverse events pre-specified and defined?

- ○ Yes
- ○ No

Clear Selection

112. Measurement techniques non-biased and adequately described?

- ○ Yes
- ○ No

Clear Selection

113. Quality rating adverse events assessment:

- ○ Good
- ○ Fair
- ○ Poor

Clear Selection

114. First abstraction done by:

- ○ Karen Crotty
- ○ Katrina Donahue
- ○ Rick Hansen
- ○ Dan Jonas
- ○ Linda Lux
- ○ Robert Rowbey
- ○ Rachael Scheinman
- ○ Other (please write your name in the adjacent box):

Clear Selection

115. Second abstraction done by:

- ○ Karen Crotty
- ○ Katrina Donahue
- ○ Rick Hansen
- ○ Dan Jonas
- ○ Linda Lux
- ○ Robert Rowbey
- ○ Rachael Scheinman
- ○ Other (please write your name in the adjacent box):

Clear Selection

116. Study is already included in systematic review/meta-analysis and does not need to be put in an evidence table

- ○ Yes
- ○ No

Clear Selection

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Appendix C. Articles by Database Searched

Reference Source: PubMed

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Appendix D. Excluded Studies

Wrong Language

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Appendix E. Evidence Tables

Index of Studies Included by Key Question

Key Question 1

RCTs and other studies (Evidence Table 1)

Antoni, 2005 (IMPACT 2)[1]

Antoni, 2005 (IMPACT)[2]

Genovese, 2007[3]

Kaltwasser, 2004[4]

Kavanaugh, 2006 (IMPACT)[5] – found under Antoni, 2005

Kavanaugh, 2006 (IMPACT2)[6]

Kavanaugh, 2009[7]

Kristensen, 2008[8]

Mease, 2000[9]

Mease, 2004[10]

Mease, 2005 (ADEPT) [11]

Mease, 2006[12]–found under Mease 2004

Nash, 2006[13]–found under Kaltwasser 2004

Saad, 2010[14]

Van der Heijde, 2007[15]–found under Kavanaugh, 2006

Willkens, 1984[16]

Systematic Reviews and Meta-analyses (Evidence Table 2)

Jones, 2000[17]

Ravindran, 2008[18]

Woolacott, 2006[19]

Key Question 2

RCTs and other studies (Evidence Table 1)

Antoni, 2005 (IMPACT) [2]

Antoni, 2005 (IMPACT 2)[1]

Genovese, 2007[3]

Gladman, 2007(ADEPT) [20]

Kaltwasser, 2004[4]

Kavanaugh, 2006 [5] – found under Antoni, 2005

Kavanaugh, 2006[6]

Kavanaugh, 2006 [21]

Kavanaugh, 2009[7]

Kristensen, 2008[8]

Mease, 2000[9]

Mease, 2004[10]

Mease, 2005[22]

Mease, 2005 (ADEPT) [11]

Mease, 2006[12] – found under Mease 2004

Mease, 2010[23]

Nash, 2006[13] – found under Kaltwasser 2004

Saad, 2009[24]

Saad, 2010[14]

Van der Heijde, 2007[15] – found under Kavanaugh, 2006

Willkens, 1984[16]

Systematic Reviews and Meta-analyses (Evidence Table 2)

Ravindran, 2008

Key Question 3

RCTs and other studies (Evidence Table 1)

Antoni, 2005 (IMPACT 2)

Antoni, 2005 (IMPACT) [2]

Genovese, 2007[3]

Kaltwasser, 2004[4]

Kavanaugh, 2009[7]

Kristensen, 2008[8]

Mease, 2000[9]

Mease, 2005[22]

Mease, 2006 – found under Mease 2004

Saad, 2009[24]

Systematic Reviews and Meta-analyses (Evidence Table 2)

Ravindran, 2008[18]

Abbreviations

ACR	American College of Rheumatology
ADA	adalimumab
AEs	adverse events
AIDS	acquired immunodeficiency syndrome
AIMS	Arthritis Impact Measurement Scales
ANA	anakinra
ARA	American Rheumatism Association criteria (pre-1987)
AS	ankylosing spondylitis
ASHI	Arthritis-Specific Health Index (Medical Outcomes Study Short Form SF-36 Arthritis-specific Health Index)
AUC	area under the curve
BUD	budesonide
Ccs	corticosteroids
CFS	chronic fatigue syndrome
CHF	coronary heart failure
Cm	centimeters
Combo	combination therapy
CI	confidence interval
CHD	coronary heart disease
COPD	Chronic Obstructive Pulmonary Disease
CRP	C-reactive protein
CVD	cardiovascular disease
CXT	cyclophosamide
CYP	cyclosporine
Ds	days
DM	diabetes mellitus
DAS	Disease Activity Score
DMARD	disease modifying antirheumatic drug
D-HAQ	Dutch version of the Health Assessment Questionnaire (HAQ)
EQ-5D–	Quality of Life Questionnaire
ESR	erythrocyte sedimentation rate
ETA	etanercept
EULAR	European League against Rheumatism
EuroQol EQ-5D	European Quality of Life Questionnaire
EuroQOL VAS	European Quality of Life Visual Analogue Scale
GI	gastrointestinal
HAQ	Health Assessment Questionnaire
HAQ-DI	Disability Index of the Heath Assessment Questionnaire (HAQ)
HIV	Human immunodeficiency virus
HLA-DR4	Human immune-response, D-related antigen encoded by the D locus on chromosome 6
HR	hazard ratio
HRQOL	health related quality of life
ICD	International Classification of Diseases
INF	infliximab
ISRs	injection site reactions
ITT	intention to treat
JRA	juvenile rheumatoid arthritis
HCQ	hydroxychloroquine
JSN	joint space narrowing
LEF	leflunomide
MTX	methotrexate
Mg	milligrams
mSharp Scale	Modified Sharp Method for Scoring Radiographs
mos	months
MHAQ	Modified Health Assessment Questionnaire
NSAIDs	non-steroidal anti-inflammatory drugs
NSFHS	National Survey of Functional Health Status
NA	not applicable
NMSC	non-melanoma skin cancer
NR	not reported
NS	not significant

NYHA	New York Heart Association
OA	osteoarthritis
OR	odds ratio
OMERACT	Outcome Measures in Rheumatology Clinical Trials
PASI	Psoriasis Area and Severity Index
PNL	prednisolone
PRED	prednisone
PsA	psoriatic arthritis
PsARC	Psoriatic Arthritis Response Scale
Pt	patient
PY	person-year
QOL	quality of life
RCT	randomized controlled trial
RAI	Ritchie Articular Index
RA	rheumatoid arthritis
RDS	radiological damage score
RF	rheumatoid factor
RIT	rituximab
RR	risk ratio
SAEs	serious adverse events
SAARDs	slow-acting anti-rheumatic drugs
SCC	squamous cell carcinoma
SD	standard deviation
SF-36	Medical Outcomes Study Short Form 36 Health Survey
SJC	swollen joint count
SHS	Sharp/van der Heijde Method (SHS) for Scoring Radiographs
SIR	standardized incidence ratio
SLE	Systemic Lupus Erythematosus
SMR	standardized morbidity ratio
SSZ	sulfasalazine
SSTG	South Swedish Arthritis Treatment Group
TB	Tuberculosis
TIM	targeted immune modulator
TJC	tender joint count
TNF	tumor necrosis factor
Txt	treatment
URTI	upper respiratory tract infection
UTI	urinary tract infection
vs.	versus
yrs	years
w/	with
w/in	with in
w/o	with out

Evidence Table 1. Randomized controlled trials and observational studies

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Antoni et al., 2005;[2] Kavanaugh et al., 2006[5] IMPACT Study Country, Setting: Multinational, 9 clinical sites Funding: NIH; Centocor, Inc.; Schering-Plough Research Institute; Competence Network Research Objective: Efficacy and tolerability of INF for the articular and dermatologic manifestations of active PsA Study Design: RCT Overall N:	Inclusion Criteria: • Age ≥ 18 • Failure of 1 or more DMARD • Active peripheral polyarticular arthritis • MTX ≥ 15 mg/wk w/ folic acid supplementation • LEF, SSZ, HCQ, intramuscular gold, penicillamine, or azathioprine stable for 4 wks • Oral corticosteroids (dosage of 10 mg PRE equivalent/d or less) • NSAIDs stable for at least 2 wks Exclusion Criteria: • Monoclonal antibody or fusion protein • History of TB: positive tests for RF or latent TB investigational drug within 3 mos	Interventions: D1: Placebo D2: INF (5mg/kg at wks 0,2,6,14, then every 8 wks) N: D1: 52 D2: 52 Mean age, yrs: D1: 45.2 D2: 45.7 Sex, % female: D1: 42.3 D2: 42.3 Race, % white: NR	Mean disease duration, yrs: D1: 11 D2: 11.7 TJC, mean: D1: 20.4 D2: 23.7 SJC, mean: D1: 14.7 D2: 14.6 DMARD use, %: NR Corticosteroid use, %: NR MTX naive, %: NR Txt resistant, %: NR Pts with Early RA (≤3 yrs): NR Baseline DAS, mean:	• ACR50 Placebo 0/52 (0.0%) vs. INF 24/52 (46.2%) • ACR70 Placebo 0/52 (0.0%) vs. INF 15/52 (28.8%) • # of tender joints Placebo -23.6 vs. INF 55.2 • # of swollen joints Placebo -1.8 vs. INF 59.9 • DAS Placebo 2.8 vs. INF 45.5 *P* < 0.001 • HAQ Placebo -1.6 vs. INF 49.8 *P* < 0.001 • PsARC Placebo -12% vs. INF +86% *P* < 0.001 • ACR20 wk 16 Placebo 5/52 (9.6%) vs. INF 34/52 (65.4%) *P* < 0.001 • At 50 wks • Total modified vdH-S score, 85% and 84% in Placebo/INF and INF/INF groups had no worsening. • Change in erosion scores INF/INF 0.921, placebo/INF 0.536 (*P* = 0.780) • Change in JSN INF/INF -0.51, placebo/INF -0.47 (*P* = 0.211) • 16 wks-PsARC INF 75% vs. Placebo 21% (*P* < 0.001) • PASI75 INF 68% vs, placebo 0% (*P* < 0.001)	Overall: D1: 65 D2: 73 D3: 84 Headache: D1: 3 D2: 4 URTI: D1: 5 D2: 1	Overall Attrition Rate (%): 5 ITT Analysis: Yes Quality Rating: Fair

104 Study Duration: 50 wks (1-16 wks RCT 16-50 open, all treated with INF)	D1: 5.4 D2: 5.5 Concomitant MTX, %: 56

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)
Author, yr: Antoni, 2005{Antoni, 2005 #41}; Kavanaugh et al., 2006{Kavanaugh, 2006 #651}; van der Heijde et al., 2007{van der Heijde, 2007 #2401} IMPACT 2 Country, Setting: Multinational 36 sites in clinics Funding: Centocor Inc and Schering-Plough Research Objective: Efficacy, health related quality of life and physical function in pts with PsA Study Design: RCT	Inclusion Criteria: • Diagnosed with PsA • Diagnosed at least 6 mos before first infusion of study drug • Inadequate response to current or previous DMARDs or NSAIDs • Pts had to have active plaque psoriasis with at least 1 qualifying target lesion at least 2 cm in diameter • Negative test for RF in their serum • Stable doses of MTX, oral corticosteroids, NSAIDs Exclusion Criteria: • TNF α inhibitors; active or latent TB • Chronic or clinically significant infection, malignancy, or CHF	Interventions: D1: Placebo D2: INF (5 mg/kg at wks 0, 2, 6, 14, 22) N: D1: 100 D2: 100 Mean age, yrs: D1: 46.5 D2: 47.1 Sex, % female: D1: 49 D2: 29 Race, % white: NR	Mean disease duration, yrs: D1: 7.5 (7.8) D2: 8.4 (7.2) TJC, mean: D1: 25.1 D2: 24.6 SJC, mean: D1: 14.4 D2: 13.9 DMARD use, %: NR Corticosteroid use, %: D1: 10 D2: 15 MTX naive, %: NR Txt resistant, %: Overall: 100 Pts with Early RA (≤3 yrs): NR Baseline DAS, mean:	ACR mean difference/ absolute difference: ACR 20 At Week 14 D1: 11 D2: 58 p<0.001 At week 24 D1: 16 D2: 54 p<0.001 ACR 50 At week 14 D1: 3 D2: 36 p<0.001 At week 24 D1: 4 D2: 41 p<0.001 ACR 70 At week 14 D1: 1 D2: 15 p<0.001 At week 24 D1: 2 D2: 27 p<0.001 **PsARC** At week 14 D1: 27 D2: 77 p<0.001 At week 24	Overall: D1: 67 D2: 67 SAEs: D1: 6 D2: 9 Infusion or injection reaction: D1: 6 D2: 7 Dizziness: D1: 5 D2: 4 Headache: D1: 5 D2: 6 URTI: D1: 14 D2: 10 Attrition Rate: Overall

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)
Overall N: 200 Study Duration: 14 to 24 wks (pts with inadequate response entered early escape at wk 16)			NR Concomitant MTX, %: D1: 45 D2: 47 PASI: D1: 10.2 D2: 11.4	D1: 32 D2: 70 p<0.001 **PASI 50** At week 14 D1: 9 D2: 82 p<0.01 At week 24 D1: 8 D2: 75 p<0.01) **PASI 75** At week 14 D1: 2 D2: 64 p<0.01 At week 24 D1: 1 D2: 50 p<0.01 HAQ: At week 14 D1: 18.4 D2: 48.6 p<0.001 At week 24 D1: 19.4 D2: 46 p<0.001 DAS: NR SF-36: Physical	Wk 14: NR Wk 24: 7.5

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)
				At week 14 D1: 1.1 D2: 9.1 p<0.001 At week 24 D1: 1.3 D2: 7.7 p<0.001 Mental At week 14 D1: 1.2 D2: 3.8 *P* = 0.001 At week 24 D1: 0.4 D2: 3.9 p=0.047 Radiographic measures: Sharp/van der Heijde Total Score, change from baseline D1: 0.82 D2: -0.70 p<0.001 **Experienced additional Radiographic progression from baseline as measured by Total Score, % of patients** At week 24: D1: 12 D2: 3 p=0.017 Quality of life scales: Productivity VAS change from baseline, increase At week 14	

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)
				D1: 0.3 D2: 2.6 p<0.001 Median % change D1: 9.2 D2: 7.5 p<0.0001 Emotional impact on work or daily activities, %: To Week 14: D1: 88.0 to 84.4 D2: 85.0 to 52.5 p<0.001 Emotional effect on work or daily activities, %: To Week 14: D1: 47.0 to 55.2 D2: 57.0 to 41.4 p<0.01 Employment increase among those not employed, n (%): D1: 3/26 (11.5) D2: 0/32 (0) *P* = 0.084 Became employable D1: 6/20 (30) D2: 3/25 (12) p=0.157 **Median productivity, %** D1: 9.2 D2: 67.5 p<0.0001 **Improvement**	

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)
				At week 14 D1: 0 D2: 41 p<0.01 At week 24 D1: 0 D2: 39 p<0.01 **Missed workdays** At 14 weeks D1: 13 D2: 3.7 p=0.138	

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
Author, year, study name, if applicable Genovese et al., 2007[3] Country and setting 16 sites in Canada and United States Source of funding Abott Laboratories Research objective Determine safety and efficacy of ADA in pts with inadequate response to DMARDs Study design Controlled Trials Overall N 102 Duration of study 12 weeks double-blind Quality rating Fair	Inclusion Criteria • Treatment resistant, previous inadequate response to DMARD therapy • ≥ 18 yrs old • General good health determined by medical history, physical exam, laboratory profile, chest radiograph, and 12-lead electrocardio-gram • Pts required to have ≥ 3 swollen joints and ≥ 3 tender or painful joints • Active cutaneous lesion of chronic plague psoriasis or a documented history of chronic plaque psoriasis • Either currently receiving concomitant DMARD therapy or had a history of DMARD	Interventions, Dose D1: Placebo D2: ADA: 40 mg every other week Number in group D1: 49 D2: 51 Mean age, yrs (SD) D1: 47.7 (11.3) D2: 50.4 (11.0) Sex, % female D1: 49.0 D2: 43.1 Race, % white D1: 93.9 D2: 98.0 Race, % black NR Ethnicity, Latino NR	Mean disease duration, years (SD) D1: 7.2 yrs (7.0) D2: 7.5 yrs (7.0) Patients with early RA, three years or less, %: NR Treatment resistant, %: 100% inadequate response to previous DMARD treatment Tender Joint Count, mean (SD) D1: 29.3 (18.1) D2: 25.3 (18.3) Swollen Joint Count, mean (SD) D1: 18.4 (12.1) D2: 18.2 (10.9) Corticosteroid use, % At baseline" D1: 18.4 D2: 7.8 Previous Use D1: 30.6 D2: 9.6 DMARD use, %: At baseline D1: 67.3 D2: 64.7 Previous Use: 100% MTX naïve, %: D1: 20.4 D2: 19.6 Baseline DAS score	ACR mean difference/ absolute difference (95% CI): ACR 20: D1: 16 D2: 39 (5%-4%) *P* = 0.012 ACR 50: D1: 2 D2: 25 *P* = 0.001 ACR 70: D1: 0 D2: 14 *P* = 0.013 HAQ, mean difference/ absolute difference (CI/SD/*P* Value): D1: -0.1 ± 0.3 D2: -0.3 ± 0.5 *P* = 0.010 DAS, mean difference/absolute difference: NR SF-36, mean difference/absolute difference (CI/SD/P Value): PCS D1: 2.8 ± 7.1 (n = 45); D2: 5.7 ± 8.5 (n = 49); *P* = 0.082; MCS D1: -0.6 ± 7.8 (n = 45) D2: 1.1 ± 7.4 (n = 49) *P* = 0.242	Attrition/withdrawal, n: Overall D1: 5 D2: 1 Withdrawals due to adverse events, n: D1: 1 D2: 1 Withdrawals due to lack of efficacy, n: D1: 1 D2: 0 Adherent/compliant, n: D1: 46 D2: 50 **Overall adverse events reported, n:** D1: 39 D2: 27 *P* ≤ 0.01 Serious adverse events: Death, n: D1: 0 D2: 0 Congestive heart failure, n: D1: 0 D2: 0 Malignancies: Lymphoma or leukemia, n: D1: 0 D2: 0 Skin cancer (basal cell or squamous cell), n: D1: 0 D2: 0

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
	therapy with inadequate response • Evidence of previous TB infection were required to have documented history of treatment for latent TB or TB treatment initiated before first dose of study drug. Exclusion Criteria • History of previous anti-TNF therapy • Intravenous infusions or intraarticular injections of corticosteroids within 4 weeks of baseline • Topical psoriasis therapies within 2 weeks of baseline • Ultraviolent A (UVA) phototherapy within 2 weeks of baseline visit • Oral retinoids within 4 weeks		NR Required treatment for latent TB D1: 100% D2: 100%	Radiographic measures, mean difference/absolute difference: NR Quality of life scales, mean difference/absolute difference (CI/SD/*P* Value): Facit-F score (0-52) D1:: 2.3 ± 6.7 (n = 46) D2: 2.6 ± 7.1 *P* = 0.783 Others, (please name); mean difference/absolute difference (SD): Swollen Joint Count D1:-1.9 ± 11.5 D2:-5.7 ± 13.7 *P* = 0.140 Tender Joint Count D1:-6.2 ± 10.3 D2:-9.7 ± 17.3 *P* = 0.231	Other cancer, n: D1: 0 D2: 0 Respiratory events: Tuberculosis, n: D1: 0 D2: 0 Upper respiratory infection, n: D1: 4 D2: 7 Other infections (any), n: D1: 16 D2: 9 GI: Diarrhea: D1: 3 D2: 1 Other: Infusion/injection site reactions, n: D1: 6 D2: 6 Demyelenation or multiple sclerosis, n: D1: 0 D2: 0 HeD2che, n: D1: 3 D2: 0 Back pain, n: D1: 3 D2: 1 Psoriasis aggravated D1: 8

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
	• Alefacept or siplizumab within 12 weeks • Any biologic or investigational therapy within 6 weeks • Current use of or likely to need antiretroviral therapy • Persistent or severe infections or history of active TB, or active nonpsoriatic skin disease which may interfere with assessment of target lesions • Significant history of cardiac, renal, neurologic, psychiatric, endocrinologic, metabolic or hepatic disease • Neurologic symptoms suggestive of CNS demyelinating disease • History of malignancy other than carcinoma in				D2: 2 Aggravated Psoriatic Arthropathy At week 12 D1: 7 D2: 1 $P \leq 0.05$ Diverticulitis, n: D1: 0 D2: 1

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
	situ of cervix or adequately treated nonmetastatic squamous or basal cell skin carcinoma • Oral corticosteroids > equivalent of PRED 10mg/d, use of cyclosporine, tacrolimus • Long term (> 3 mths) treatment with MTX or other DMARDs • Unstable dose of MTX or other DMARDs during 4 wks preceding baseline visit • MTX dose > 30 mg/wk				

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
Author, year, study name, if applicable Gladman et al., 2007,[20] ADEPT This is a companion to ref ID 840 included in first report. Country and setting 50 multinational sites Source of funding Abbott Laboratories Research objective Evaluate effects of D2 on joint-related and skin-related functional impairment, HRQOL, fatigue and pain Study design Controlled Trials Overall N 315 Duration of study 24 Weeks Quality rating Fair Why?	Inclusion Criteria • Treatment resistant • Inadequate response or intolerance to NSAIDs • Age ≥ 18 • Moderate to severe PsA • Active psoriatic skin lesions or a documented history of psoriasis • MTX was allowed if it had been taken for at least 3 months previously, withdosage stable for at least 4 weeks prior to baseline. Exclusion Criteria • Cyclosporine, tacrolimus, DMARDs, or oral retinoid use within 4 weeks of baseline • Topical treatments for PsA within 2 wks other than medicated	Interventions, Dose D1: Placebo D2: 40 mg every other week Number in group D1: 162 D2: 151 Overall: 313 Mean age (years) D1: 49.2 yrs (11.1) D2: 48.6 yrs (12.5) Sex, % female D1: 45.1 D2: 43.7 Race, % white D1: 93.8 D2: 97.4 Race, % black NR Ethnicity, Latino NR	Mean disease duration, years (SD) D1: 9.2 yrs (8.7) D2: 9.8 yrs (8.3) Patients with early RA, three years or less, %: NR Treatment resistant, %: Inadequate response to previous NSAIDs D1: 100 D2: 100 Tender Joint Count, mean (SD) D1: 25.8 (18.0) D2: 23.9 (17.3) Swollen Joint Count, mean (SD) D1: 14.3 (11.1) D2: 14.3 (12.2) Corticosteroid use, % NR DMARD use, %: NR MTX naïve, %: NR Baseline DAS score NR Required treatment for latent TB NR HAQ DI (range 0-3) D1: 1.0 (0.7) D2: 1.0 (0.6)	ACR mean difference/ absolute difference (CI/SD/*P* Value): NR HAQ, mean difference/ absolute difference (CI/SD/*P* Value): At Week 12 D1: -0.1 (0.5) D2: -0.4 (0.5) *P* < 0.001 At Week 24 D1: -0.1 (0.4) D2: -0.4 (0.5) *P* < 0.001 DAS, mean difference/absolute difference (CI/SD/*P* Value): NR SF-36, mean difference/absolute difference (CI/SD/*P* Value): PCS at Week 12 D1: 1.4 (8.7) n = 151 D2: 9.3 (10.0) n = 136 *P* < 0.001 PCS at Week 24 D1: 1.4 (9.6) n = 152 D2: 9.3 (10.1) n = 140 *P* < 0.001 MCS at Week 12 D1: 1.2 (10.2) n = 151 D2: 1.6 (10.1) n = 136) *P* = 0.708 MCS at Week 24 D1: 0.6 (10.4) n = 152	Overall Overall attrition/withdrawal, n: D1: 13 D2: 13 Withdrawals due to adverse events, n: D1: 1 D2: 3 Withdrawals due to lack of efficacy, n: D1: 4 D2: 1 Adherent/compliant, n: D1: 149 D2: 140 Withdrew consent, n D1: 5 D2: 3 Protocol Violation D1: 1 D2: 0 Other attrition D1: 1 D2: 1 Abnormal lab value D1: 0 D2: 2 Administrative problems D1: 0 D2: 1 This data was extracted from companion study refid 840 included in original report.

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
	shampoos or low-potency topical steroids • Anti-TNF therapy • Concurrent treatment with MTX at dosages > 30mg/week and/or corticosteroids in a PRED-equivalent dosage of > 10 mg/day • History of TB • Central nervous system demyelinating disease • Listeriosis • Severe infection within 30 days or oral antibiotics within 14 days.		SF-36 PCS score D1: 33.3 (9.8) D2: 33.2 (9.9) n = 148 SF-36 MCS score D1: 46.6 (12.2) D2: 48.1 (10.2) n = 148 FACIT-fatigue (range 0-52) D1: 30.8 (12.2), n = 161 D2: 30.8 (12.1), n = 150 Patient's assessment of pain (0-100 mm VAS) D1: 48.8 (21.7) n = 161 D2: 51.1 (21.4) Patient's global assessment of disease activity (0-100 mm VAS): D1: 48.1 (21.2) D2: 47.1 (23.2) PASI (range 0-72) D1: 8.3 (7.3) n = 69 D2: 7.4 (6.1) n = 69 DLQI (range 0-30) D1: 10.3 (7.5) n = 68 D2: 8.6 (6.6) n = 66	D2: 1.8 (9.3) n = 140 *P* = 0.288 Radiographic measures, mean difference/absolute difference: NR Quality of life scales, mean difference/absolute difference: NR Physical Functioning, n (SD): At Week 12: D1: 3.9 (23.3) D2: 14.4 (22.1) *P* < 0.001 At Week 24: D1: 2.9(23.8 SD) D2: 15.8 (22.9 SD) *P* < 0.001 Role-physical, n (SD) At Week 12: D1: 7.2 (34.8) D2: 30.1 (41.9) *P* < 0.001 At Week 24: D1: 8.9 (43.4) D2: 30.0 (38.5) *P* < 0.001 Bodily pain, n (SD) At Week 12: D1: 3.0 (20.5) D2: 19.6 (23.4) *P* < 0.001 At Week 24: D1: 3.4 (18.9) D2: 21.8 (22.8) *P* < 0.001	

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
				General Health, n (SD) At Week 12: D1: 0.2 (16.7) D2: 12.4 (18.2) *P* < 0.001 At Week 24: D1: -0.1 (16.8) D2: 11.6 (19.4) *P* < 0.001	
				Vitality, n (SD) At Week 12: D1: 3.0 (17.2) D2: 13.7 (20.4) *P* < 0.001 At Week 24: D1: 1.7 (19.1) D2: 12.8 (21.0) *P* < 0.001	
				Social Functioning,, n (SD) At Week 12: D1: 4.4 (23.4) D2: 11.8 (25.7) *P* = 0.014 At Week 24: D1: 2.6 (25.4) D2: 11.8 (25.8) *P* = 0.003	
				Role-emotional, n (SD) At Week 12: D1: 4.4 (46.8 SD) D2: 5.7 (45.3 SD) *P* = 0.762 At Week 24: D1: 4.6 (48.5 SD) D2: 10.3 (40.3 SD) *P* = 0.255	
				Mental Health, n (SD) At Week 12: D1: 1.8 (15.0) D2: 5.1 (14.9)	

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
				P = 0.060 At Week 24: D1: 1.1 (14.9) D2: 4.5 (15.3) *P* = 0.045 FACIT-Fatigue, n (SD) At Week 12: D1: 0.6(8.4) D2: 6.5 (11.1) *P* < 0.001 At Week 24: D1: 0.1 (9.6 SD) D2: 7.1 (10.2 SD) *P* < 0.001 Pt's Assessment of Pain, n (SD) At Week 12: D1: 1.6 (24.0 SD) D2: -23.0(27.0 SD) *P* < 0.001 At Week 24: D1: 0.6 (24.1) D2: -24.0 (28.3) *P* < 0.001 Pt's global assessment of disease activity, n (SD): At Week 12: D1: 0.4 (23.1) D2: -19.6 (29.4) *P* < 0.001 Pt's global assessment of disease activity, n (SD) At Week 24: D1: 0.6 (24.5) D2: -21.1 (29.4) *P* < 0.001 DLQI, n (SD) At Week 12: D1: -0.4 (5.8) D2: -5.6 (5.6)	

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
				P < 0.001 At Week 24: D1: -0.7 (6.7) D2: -6.1 (6.3) *P* < 0.001 HAQ DI Patients achieving minimum clinically-important difference (MCID) ≥ -0.3, % (SD) At Week 12: D1: 26 D2: 51.4 *P* < 0.001 At Week 24: D1: 26.9 D2: 52.5, *P* < 0.001 HAQ DI Patients with complete resolution, %; At Week 12: D1: 14.3 D2: 33.8 *P* < 0.001 HAQ DI Patients with complete resolution, % At Week 24 D1: 13.1 D2: 34.0 *P* < 0.001 SF-36 PCS Patients achievingupper limit ofMCID ≥ 5 points, % At Week 12 (%): D1: 26.5 D2: 66.9 *P* < 0.001 At Week 24: D1: 30.1	

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
				D2: 61.7 *P* < 0.001 FACIT-Fatigue Patients achieving upper limit ofMCID ≥ 4 points, % At Week 12: D1: 30.4 D2: 60.7 *P* < 0.001 At Week 24 (%): D1: 31.5 D2: 61.9, *P* < 0.001 Dermatology Life Quality Index (DLQI)Patients achieving upper limit ofMCID ≥ -5 points, % At Week 12: D1: 21.7 D2: 54.8 *P* < 0.001 At Week 24: D1: 23.7 D2: 55.0 *P* = 0.001 DLQI Patients with complete resolution, % At Week 12 D1: 4.9 D2: 36.9 *P* < 0.001 At Week 24 D1: 5.0 D2: 43.6 *P* < 0.001	

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Kaltwasser et al., 2004[4] and Nash et al., 2006[13] Country, Setting: Multinational, multicenter (31) Funding: Aventis Research Objective: Efficacy and safety of LEF versus placebo in pts with PsA and psoriasis Study Design: RCT Overall: N: 190 (ITT = 186) Study Duration: 24 wks	Inclusion Criteria: • Age 18 to 70 • Diagnosed with PsA • NSAIDs or Css (prednisone dose of 10 mg/day or steroid equivalent administered orally) • Discontinue DMARDs, biologics and systemic antipsoriatic txt 28 days Exclusion Criteria: • Pregnant or lactating; leflunomide • Impaired renal or hepatic system • Nonpsoriatic inflammatory joint disease or arthritis onset < 16 yrs • RH factor +, rheumatoid nodules, serious infections, malignancy, or CVD, HIV, hepatitis B or C antigen positivity, guttate, pustular, or erythrodermic forms of psoriasis, body weight <45 kg • Impaired bone marrow function; history of drug or alcohol abuse	Interventions: D1: Placebo D2: LEF N: D1: 91 D2: 95 Mean age, yrs: Drug 1: 46.9 Drug 2: 48.6 Overall Sex, % female: D1: 37.4 D2: 42.1 Race, % white: D1: 95.6 D2: 97.9	Mean disease duration, yrs: D1: 10 D2: 11 TJC, mean: NR SJC, mean: NR DMARD use, %: D1: 49.5 D2: 61.1 Corticosteroid use, %: D1: 9.9 D2: 15.8 DMARD naive, %: D1: e 50.5 D2: 38.9 Txt resistant, %: NR Pts with Early RA (≤3 yrs): NR Baseline DAS,	• 56 of 95 leflunomide-treated pts (58.9%; 95% CI, 48.4-68.9) and 27 of 91 placebo-treated pts (29.7% (95% CI, 20.6-40.2)) were classified as responders by PsARC (P < 0.0001) Change in HAQ total score • Placebo (N:90) -0.05 ± 0.46 (P = 0.0267) • Leflunomide (N:94) -0.19 ± 0.51 Change in PASI score • Placebo (N:90) -0.6 ± 6.1 P = 0.0030 • Leflunomide (N:92) -2.1 ± 5.9 Change in DLQI total score • Placebo (N:89) -0.2 ± 5.1 P = 0.0173 • Leflunomide (N:90) -1.9 ± 5.1	Overall: D1: 76.1 D2: 85.4 SAEs: D1: 5.4 D2: 13.5 Serious Infections: D1: 0 D2: 0 Diarrhea: D1: 13.0 D2: 24.0 Headache: D1: 7.6 D2: 11.5 Nausea: D1: 8.7 D2: 9.4	Overall Attrition Rate (%): 47.9% ITT Analysis: Yes Quality Rating: Fair

								mean: NR Concomitant MTX, %: 0			

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
Author, year, study name, if applicable Kavanaugh et al., 2009,[7] GO-REVEAL Country and setting 58 investigational sites, multinational Source of funding Centocor Research and Development, Inc. and Schering-Plough Corporation Research objective Assess efficacy and safety of GOL in patients with active PsA Study design Controlled Trials Overall N 405 Duration of study 24 wks Quality rating Good	Inclusion Criteria • Treatment resistant active PsA despite therapy with DMARDs or NSAIDs • active PsA: ≥ 3 swollen and 3 tender joints, negative rheumatoid factor, at least 1 subset of PsA, presence of plaque psoriasis with lesion ≥ 2 cm in diameter; • MTX, NSAIDs, corticosteroids allowed in stable doses • Latent TB allowed if treated prior or concurrent to study Exclusion Criteria • Previous use of anti-TNF agents, RIT, natalizumab, or cytotoxic agents	Interventions, Dose D1: Placebo • At week 16, pts with < 10% improvement from baseline in both swollen and tender joint counts entered early escape = dose escalation from placebo to 50 mg GOL every four weeks D2: • GOL: 50 mg every 4 wks • At week 16, pts with <10% improvement from baseline in both swollen and tender joint counts entered early escape = dose escalation from 50 mg GOL to 100 mg GOL every four wks. D3: GOL: 100 mg every 4 wks D4: Randomized to placebo, crossed over to GOL 50 mg D5: Randomized to GOL 50, crossed over to 100 mg Number in group D1: 113 D2: 146 D3: 146 Mean age, years (SD) D1: 47.0 (10.6) D2: 45.7 (10.7)	Mean disease duration, years (SD) D1: 7.6 (7.9) D2: 7.2 (6.8) D3: 7.7 (7.8) Patients with early RA, three years or less, %: D1: 33 D2: 34 D3: 27 Treatment resistant, %: D1: 100 D2: 100 D3: 100 Tender Joint Count, mean (SD) D1: 21.9 (14.7) D2: 24.0 (17.1) D3: 22.5 (15.7) Swollen Joint Count, mean (SD) D1: 13.4 (9.8) D2: 14.1 (11.4) D3: 12.0 (8.4) Corticosteroid use, % D1: 17 D2: 13 D3: 18 DMARD use, %: MTX D1: 48 D2: 49 D3: 47 MTX naïve, %: D1: 33 D2: 34	ACR mean difference/ absolute difference (CI/SD/P Value): At week 14: ACR 20: D1: 9 D2: 51 D3: 45 *P* < 0.001 (D1 vs. D2 and D3) At week 24: ACR 20: D1: 12 D2: 52 D3: 61 *P* < 0.001 (D1 vs. D2 and D3) ACR 50 and ACR70 at weeks 14 and 24: Shown in figure only HAQ, mean difference/ absolute difference (CI/SD/P Value): D1: -0.01 (0.49) D2: 0.33 (0.55) D3: 0.39 (0.50) *P* < 0.001 (D1 vs. D2 and D3) DAS, mean difference/absolute difference (SD): At week 14: D1: -0.18 (0.78) D2: -1.38 (1.16) D3: -1.29 (1.16) *P* < 0.001 (D1 vs. D2 and D3)	Overall attrition/withdrawal, n: D1: 12 D2: 9 D3: 4 **Withdrawals due to adverse event, n:** D1: 5 D2: 2 D3: 4 **Withdrawals due to lack of efficacy, n:** D1: 2 D2: 1 D3: 0 **Adherent/compliant, n**: NR **Overall adverse events reported, n:** Through Week 24 D1: 67 D2: 99 D3: 95 Serious adverse events: SAEs: D1: 7 D2: 3 D3: 4 Prostate cancer, n: D1: NR D2: NR D3: 1 Respiratory events: Tuberculosis, n: Overall: 0

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
		D3: 48.2 (10.9) Sex, % female D1: 39 D2: 39 D3: 41 Race, % white D1: 97 D2: 97 D3: 97 Race, % black NR Ethnicity, Latino NR	D3: 27 Baseline DAS28-CRP score, mean (SD) D1: 4.3 (1.0) D2: 4.4 (1.1) D3: 4.3 (1.0) Required treatment for latent TB D1: 11 D2 & D3: 33	At week 24: D1: -0.12 (0.97) D2: -1.43 (1.34) D3: -1.56 (1.10) *P* < 0.001 (D1 vs. D2 and D3) DAS28-CRP No. EULAR response: At week 14: D1: 27 D2: 96 (*P* < 0.001) D3: 98 (*P* < 0.001) At week 24: D1: 27 D2: 94 (*P* < 0.001) D3: 114 (*P* < 0.001) SF-36, mean difference/absolute difference (CI/SD/P Value): D1: 0.63 (7.68) D2: 6.53 (8.88) D3: 7.85 (9.55) *P* < 0.001 (D1 vs. D2 and D3) Radiographic measures, mean difference/absolute difference: NR Quality of life scales, mean difference/absolute difference: NR **Morning stiffness, mean change (SD):** At week 14: D1: 23.4 (299.9) D2: -72.4 (201.3) (*P* < 0.001)	Pneumonia, n: D1: 2 D2: NR D3: NR Upper respiratory infection (n): D1: 7 D2: 17 D3: 13 Other infections, n: D1: Cellulits: 1, Urosepsis: 1 D2: Abscess: 1 D3: Sepsis/Cholecystitis: 1 Infusion/injection site reactions, n: D1: 3 D2: 4 D3: 6 GI: Nausea or vomiting, n: D1: 5 D2: 4 D3: 6 Headache, n: D1: 8 D2: 7 D3: 8 Dizziness: NR Nasopharyngitis, n: D1: 5 D2: 10 D3: 19 Back pain, n:

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
				D3: -86.3 (238.3), (P < 0.001) At week 24: D1: -20.4 (257.7) D2: -67.2(231.1) (P < 0.001) D3: -90.1 (234.5), (P < 0.001) PASI90, n: At week 14: D1: 0 D2: 22 (P < 0.001) D3: 26, (P < 0.001) At week 24: D1: 0 D2: 33 (P < 0.001) D3: 34, (P < 0.001)	D1: 5 D2: 6 D3: 7 Diarrhea, n: D1: 4 D2: 5 D3: 7 Cough, n: D1: 5 D2: 7 D3: 4 Elevated ALT levels, n: D1: 4 D2: 4 D3: 5 Injection-site erythema D1: 2 D2: 4 D3: 6 Markedly abnormal ALT levels: D1: 4 D2: 43 D3: 0 Markedly abnormal AST levels: D1: 3 D2: 2 D3: 0 Markedly abnormal total bilirubin levels: D1: 2 D2: 4 D3: 2 Antibodies to GOL: D1: NR

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
					D2: 5/114 D3: 7/143

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
Author, year, study name, if applicable Kristensen et al., 2008[8] Country and setting Sweden Source of funding NR Research objective Present efficacy and tolerability data and study impact of concomitant MTX, patterns of joint distribution, and other predictors for drug survival with TNF blocking agents Study design Observational Overall N 261 Duration of study 12 months Quality rating Fair	Inclusion Criteria • Diagnosis of PsA • Pts selected for anti-TNF therapy based on high disease activity and/or unacceptable steroid use • Only pts receiving first treatment course of biological therapy Exclusion Criteria NR	Interventions, Dose D1: concomitant MTX and anti-TNF • MTX: median dose = 15.0 mg/week, interquartile range (IQR) = 10.0-20.0 • ETN: 25 mg twice a wk • IFX: 3mg/kg wks 0,2, 6, and every eighth week, could be increased in steps of 100 mg to a maximum dose of 500 mg at 4-8 wk intervals,avg dose after 6 mos = 5 mg/kg every eighth wk ADA: 40 mg every other wkD2: • ETN: 25 mg twice a wk • IFX: 3 mg/kg wks 0, 2, 6, and every eighth week, could be increased in steps of 100 mg to a maximum dose of 500 mg at 4-8 wk intervals, avg dose after 6 mos = 5 mg/kg every eigth wk • ADA: 40 mg every other wk Number in group D1: 161 D2: 100	Median disease duration, years (IQR) D1: 7.9 (3.7-15.0) D2: 9.4 (4.2-17.8) *P* = 0.29 Patients with early RA, three years or less, %: NR Treatment resistant, %: NR Tender Joint Count, mean (SD) NR Swollen Joint Count, mean (SD) NR Corticosteroid use, % NR DMARD use, %: # of Previous DMARDs (IQR) D1: 2 (1.0-2.0) D2: 2 1.0-2.0) *P* = 0.20 MTX naïve, %: NR Baseline DAS28 score, median (IQR) D1: 4.93 calculated for subgroup, n = 125 (3.87-5.71) D2: 4.82 calculated for subgroup, n = 76 (3.83-5.46) *P* = 0.57 Required treatment for	ACR mean difference/ absolute difference: NR HAQ, mean difference/ absolute difference: NR DAS, mean difference/absolute difference: NR SF-36, mean difference/absolute difference: NR Radiographic measures, mean difference/absolute difference: NR Quality of life scales, mean difference/absolute difference: NR **EULAR overall response rates, (%):** At month 3 D1: 104 (78) D2: 67 (75) At month 6 D1: 82 (76) D2: 54 (81) At month 12 D1: 74 (69) D2: 27 (67) EULAR good response rates, %:	Attrition/withdrawal Withdrawals due to adverse events, HR (95% CI): D1: 0.24 (0.11-0.52) Sub-analyses ETN vs. IFX • Termination due to adverse events (HR 0.30 95% CI 0.11-0.80, *P* = 0.02) • Withdrawal due to failure (HR 0.55, 95% CI 0.25-1.20) Withdrawals due to lack of efficacy, HR (95% CI): D1: 1.39 (0.61-3.18) • In corresponding abstraction - no high attrition or differential attrition, although rates are unknown **Overall adverse events reported, n:** D1: 17 D2: 12 Serious adverse events: Death (n): D1: 1 D2: NR Cardiovascular events, n: D1: 3 D2: 2 Overall: Includes transient ischemic attack, two acute coronary syndromes, and two tachyarrhythmias. Septicaemia with E-coli bacteria: D1: 0 D2: 1

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
		Overall: 261 Mean age, years (SD) D1: 48.2 D2: 46.0 Overall, IQR range: D1: 38.6 - 53.9 IQR D2: 36.4 - 58.5 IQR; *P* = 0.99 Sex, % female D1: 47.8 D2: 55 *P* = 0.07 Race, % white NR Race, % black NR Ethnicity, Latino NR	latent TB NR Regular NSAID use % (n): D1: 60.9 (98) D2: 48.0 (48 *P* = 0.04 HAQ, median (IQR) D1:1.0 (0.63-1.38) D2: 1.0 (0.50-1.50) *P* = 0.67	At month 3 D1: 104 (51) D2: 67 (55) At month 6 D1: 82 (60) D2: 54 (59) At month 12 D1: 74 (54) D2: 27 (52) Lundex EULAR Overall, %: At month 3 D1: 74 D2: 68 At month 6 D1: 68 D2: 67 At month 12 D1: 55 D2: 45 Lundex EULAR Good, %: At month 3 D1: 48 D2: 50 At month 6 D1: 53 D2: 48 At month 12 D1: 43 D2: 35	Anaphylactic infusion reactions (occurred with IFX): D1: 0 D2: 2 Malignancies: Lymphoma or leukemia (n): D1: 1 D2: 1 Overall: Fatal non-Hodgkin's lymphoma (diffuse large B-cell lymphoma); Chronic lymphatic leukemia (CLL), with probable subclincial debut prior to anti TNF treatment Other infections: D1: 5 D2: 2 Overall: Designated as 'Infections' - mainly respiratory tract infections Other: Fractures, n: D1: 2 D2: 1 Overall: Three peripheral fractures and one cervical spinaql stenosis requiring surgery Other Adverse Events, n: D1: 3 D2: 3 Overall: Includes: severe vertigo, irritable bowl disease, benign stenosis of the esophagus, concrement in the

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events, %
					urinary tract, non-infectious pleuritis, severe dysplaisa of cervix uteri.

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Mease et al., 2000[9] Country, Setting: US, single center in Seattle Funding: Immunex Corp. Research Objective: To study the efficacy and safety of etanercept in pts with psoriatic arthritis and psoriasis Study Design: RCT Overall N: 60 Study Duration: 12 wks	Inclusion Criteria: • Age 18 to 70 • Diagnosed with PsA according to: > 3 swollen, tender, or painful joints • Inadequate response to NSAIDs • Hepatic transasminase concentrations no greater than 2x upper limit of normal • Hemoglobin 85 g/L or higher • Platelet count 125,000 per mL or more and serum creatinine 152-4 mmol/L or below • MTX < 25 mg/wk and stable for 4 wks • Corticosteriods if the dose < 10 mg/d of PRE, stable for at least 2 wks and maintained at a constant dose throughout study Exclusion Criteria: • Evidence of skin conditions other than psoriasis	Interventions: D1: Placebo D2: ETA (25mg 2x wkly) N: D1: 30 D2: 30 Mean age, yrs: D1: 43.5 D2: 46 Sex, % female: D1: 40 D2: 47 Race, % white: D1: 83 D2: 90	Mean disease duration, yrs: D1: 9.5 D2: 9 TJC, mean: NR SJC, mean: NR DMARD use, %: NR Corticosteroid use, %: D1: 40 D2: 20 MTX naive, %: NR Txt resistant, %: Overall 100 Pts with Early RA (≤3 yrs): NR Baseline DAS, mean: NR Concomitant MTX: D1: 47	• PsARC ETA 26 (87%) vs. Placebo 7 (23%) $P <$ 0.0001 95% CI, 44-83; ACR50 ETA 15 (50%) vs. Placebo 1 (3%) $P =$ 0.0001 95% CI, 28-66; • ACR70 ETA 4 (13%) vs. Placebo 0 (0%) $P = 0.0403$ 95% CI, 1-26; • HAQ ETA 0.1 (0,1) vs. Placebo 1.3 (0.9,1.6) $P < 0.001$ • •ACR20 was achieved by 73% ETA treated pts compared with 13% placebo treated pts ($P < 0.0001$) • Median % improvements in tender and swollen joint counts at 12 wks ETA 75% and 72% respectively vs. placebo 5% worsening and 19% improvement; disability according to HAQ significantly more improved in ETA than placebo (83% vs. 3%, $P < 0.0001$) • 26% of ETA vs. 0 of placebo pts achieved 75% improvement in PASI at 12 wks ($P = 0.0154$); similar differences between ETA and placebo also seen at 25% and 50% improvements in PASI scores	SAEs: D1: 0 D2: 3.3 Infusion or injection reaction: D1: 20 D2: 3 Headache: D1: 13 D2: 10 URTI: D1: 57 D2: 57	Overall Attrition Rate (%): 6.6% ITT Analysis: Yes Quality Rating: Fair

D2: 47

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Mease et al., 2004;[10] Mease et al., 2006[12] (2nd yr outcomes) Country, Setting: US, 17 sites Funding: Immunex Research Objective: Safety, efficacy, and effect on radiographic progression of ETA in pts with PsA Study Design: RCT Overall N: 205 Study Duration: 24 wks (with 48 wk open-label phase)	Inclusion Criteria: • Age 18 70 • Diagnosed with PsA ≥ 3 swollen and 3 tender joimts • Inadequate response to NSAID • At least one of PsA subtypes: distal interphalangeal joint involvement, polyarticular arthritis, arthritis mutilans, asymmetric peripheral arthritis, or ankylosing spondylitis-like arthritis • Stable plaque psoriasis with a qualifying lesion • MTX therapy (stable 2 mo ≤ 25 mg/wk) • Css (stable 4 wks ≤ 10 mg/d of prednisone) Exclusion Criteria: • Oral retinoids, topical vitamin A or D analog preparations, and anthralin	Interventions: D1: placebo D2: ETA (25 mg 2x wkly) N: D1: 104 D2: 101 Mean age, yrs: D1: 47.3 D2: 47.6 Sex, % female: D1: 55 D2: 43 Race, % white: D1: 91 D2: 90	Mean disease duration, yrs: D1: 9.2 D2: 9 TJC, mean: NR SJC, mean: NR DMARD use, %: NR Corticosteroid use, %: D1: 15 D2: 19 MTX naive, %: NR Txt resistant, %: NR Pts with Early RA (≤3 yrs): NR Baseline DAS, mean: NR Concomitant MTX	• At 12 wks, 59% of ETA pts met ACR20 criteria compared with 15% placebo pts ($P < 0.0001$) • 23% of ETA pts eligible for psoriasis evaluation achieved at least 75% improvement in psoriasis area and severity index, compared with 3% of placebo pts ($P = 0.001$) • 12 mos; the mean annualized rate of change over one yr of txt in modified Sharp score was –0.03 unit, compared with 1.00 unit in the placebo ($P = 0.0001$) • HAQ- improvement from baseline in ETA group 54% vs. 6% of placebo group ($P < 0.0001$) • 72% & 70% of ETA achieved PsARC at 12 and 24 wks, respectively, compared with 31% and 23% of placebo pts	SAEs: D1: 3.9 D2: 4 Infusion or injection reaction: D1: 9 D2: 36 Headache: D1: 5 D2: 8 URTI: D1: 23 D2: 21 UTI: D1: 6 D2: 6	Overall Attrition Rate (%): 19.5 ITT Analysis: Yes Quality Rating: Fair

Evidence Table 1. Randomized controlled trials and observational studies (continued)

									use, %: D1: 41 D2: 42 Sharp: D1: 18.3 D2: 25.89		

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events (%)	Analysis and Quality Rating
Author, yr: Mease et al., 2005[11] ADEPT Study Country, Setting: Multinational, multi-clinic (50) Funding: Abbott Laboratories Research Objective: Safety and efficacy of ADA compared with placebo in txt of active psoriatic arthritis Study Design: RCT Overall N: 313 Study Duration: 24 wks	Inclusion Criteria: • Age ≥ 18 • Moderate to severe PsA • Active psoriatic skin lesions or a documented history of psoriasis • Inadequate response or intolerance to NSAIDs • MTX ≥ 3 mos with stable dose 4 wks Exclusion Criteria: • CYP, tacrolimus, DMARDs, or oral retinoids (4 wks) • Topical txts for psoriasis within 2 wks, other than medicated shampoos or low-potency topical steroids • Anti-TNF • History of TB • Central nervous system demyelinating disease • Listeriosis, or severe infection within 30 ds or oral antibiotics within 14 ds	Interventions: D1: placebo D2: ADA (40mg every other wk) N: D1: 162 D2: 151 Mean age, yrs: D1: 49.2 D2: 48.6 Sex, % female: D1: 45.1 D2: 43.7 Race, % white: D1: 93.8 D2: 97.4	Mean disease duration, yrs: D1: 9.2 D2: 9.8 TJC, mean: D1: 25.8 D2: 23.9 SJC, mean: D1: 14.3 D2: 14.3 Mean number previous DMARDS: D1: 1.5 D2: 1.5 Corticosteroid use, %: NR **MTX naive, %:** NR **Txt resistant, %:** NR Pts with Early RA (≤3 yrs):	• PsARC ADA 60% wk. vs.placebo 23% • ACR50 ADA, 39% vs. placebo, 6% ($P < 0.001$) • ACR70 ADA, 23% vs. placebo, 1% ($P < 0.001$) • The PASI75 ADA 59% vs. placebo 1% ($P < 0.001$) (N:69 per group). • HAQ DI change placebo -0.1 ± 0.4 vs. ADA -0.4 ± 0.5 ($P < 0.001$) • ACR20 ADA 57% vs. placebo 15% (between-group difference 42%, 95% CI, 31-52%; $P < 0.001$). • Mmean change in modified total Sharp was -0.2 for ADA versus placebo ($P < 0.001$) • Erosion scores (mean change ADA 0.0 vs. placebo 0.6) and JSN scores (mean change ADA -0.2 vs. placebo 0.4) ($P < 0.001$ for both) • SF-36: SF-36 PCS; change in baseline to wk 12 for placebo vs ADA; 1.4 vs 9.3 ($P < 0.001$) • Change in baseline to wk 24; 1.4 vs 9.3 ($P < 0.001$) • SF-36 MCS • Change in baseline to wk 12; 1.2 vs 1.6 (P NS) • Change in baseline to wk 12; 0.6 vs 1.8 (P NS)	Infusion or injection reaction: D1: 3.1 D2: 6.6 Headache: D1: 8.6 D2: 6.0 URTI: D1: 14.8 D2: 12.6 UTI: NR	Overall Attrition Rate (%): 7.6 ITT Analysis: Yes Quality Rating: Fair.

								NR Baseline PASI (mean): D1: 8.3 D2: 7.4 Concomitant MTX use, %: D1: 50 D2: 51 Baseline HAQ: D1: 1.0 D2: 1.0			

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events
Author, year, study name, if applicable Mease et al., 2010[23] (*companion with Mease 2004, should be in same evidence Table) Country and setting Multicenter Source of funding Pharmaceutical company or other commercial source: Amgen Inc and Wyeth Pharmaceuticals Research objective To evaluate the effects of ETA treatment on patient-reported outcomes (PRO) in patients with psoriatic arthritis (PsA). Study design Controlled Trials Overall N 205 Duration of study 2 years (three phases: first 24 week double blind; 24 week blinded maintenance; 48 wk open label	Inclusion Criteria • 18 to 70 years of age • diagnosed with PsA with active arthritis • inadequate response to nonsteroidal antiinflammatory drug (NSAID) therapy at time of entry to study Exclusion Criteria • Pregnant or breastfeeding • Diabetes mellitus requiring insulin • Uncompensated congestive heart failure • Angina pectoris • Uncontrolled hypertension • Severe pulmonary disease requiring therapy • History of cancer other than resected cutaneous basal and squamous cell carcinoma or in situ cervical cancer.	Interventions, Dose D1: ETA: 25 mg twice weekly D2: Placebo Number in group 24 week double-blind D1: 101 D2: 104 48 week open-label D1: 88 D2: 81 Mean age (years) D1: NR D2: NR Overall: 47 Sex, % female D1: 43 D2: 55 Race, % white D1: NR D2: NR Overall: 90 Race, % black NR Ethnicity, Latino NR	Mean disease duration, years Overall: 6 to 7 years Patients with early RA, three years or less, %: NR Treatment resistant, % NR Tender Joint Count, mean NR Swollen Joint Count, mean NR Corticosteroid use, % NR DMARD use, %: NR MTX naïve, %: NR Baseline DAS score NR Required treatment for latent TB NR Other population characteristics NR	ACR: ACR 20 ACR Pain, mean (SE) At week 24 D1: 1.6 (0.1) D2: 2.8 (0.1) Start of open label D1: 1.4 (0.1) D2: 3.0 (0.1) Open-label at week 12 D1: 1.4 (0.1) D2: 1.9 (0.1) Open-label at week 24 D1: 1.5 (0.1) D2: 1.9 (0.1) Open-label at week 36 D1: 1.4 (0.1) D2: 1.7 (0.1) Open-label at week 48 D1: 1.3 (0.1) D2: 1.5 (0.1) Overall: ACR 20%: D1 vs D2: $P < 0.0001$) ACR Pain: D1 vs D2: $P < 0.001$ ACR 50: NR ACR 70: NR HAQ HAQ-DI, mean (SE) At week 24 D1: 0.5 (0.1) D2: 1.0 (0.1) Start of open label D1: 0.4 (0.1) D2: 1.0 (0.1)	Attrition/withdrawal: NR Overall adverse events NR Serious adverse events NR Malignancies NR Respiratory events NR Other infections NR GI NR Other NR

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events
extension) Quality rating NA Fair				Open-label at week 12 D1: 0.5 (0.1) D2: 0.7 (0.1) Open-label at week 24 D1: 0.4 (0.1) D2: 0.6 (0.1) Open-label at week 36 D1: 0.4 (0.1) D2: 0.6 (0.1) Open-label at week 48 D1: 0.4 (0.1) D2: 0.6 (0.1) Overall: *P* < 0.001 at week 4 and at week 12; *P* = NR beyond week 12, but Figure shows that both groups maintained improvement achieved up to that point and mean HAQ unchanged or almost unchanged beyond week 12 DAS NR SF-36 PCS, mean (SE) At week 24 D1: 45.1 (1.1) D2: 36.4 (1.0) Start of open label D1: 46.4 (1.2) D2: 36.8 (1.1) Open-label at week 12 D1: 46.7 (1.2) D2: 43.9 (1.2)	

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events
				Open-label at week 24 D1: 47.0 (1.3) D2: 44.4 (1.1) Open-label wk 36 D1: 46.0 (1.3) D2: 44.2 (1.2)/ Open-label at week 48 D1: 47.3 (1.2) D2: 44.1 (1.3) MCS, mean (SE) At week 24 D1: 53.6 (0.9) Start of open label D1: 53.7 (1.0) Open-label at week 12 D1: 52.8 (1.0) Open-label at week 24 D1: 51.6 (1.1) Open-label at week 36 D1: 53.6 (1.0) Open-label at week 48 D1: 53.5(1.0) MCS, mean (SE) At week 24: 48.4 (1.2) Start of open label: 49.1 (1.3) At week 12: 51.8 (1.2) At week 24: 49.8 (1.3) At week 36: 49.8 (1.3) At week 48: 50.8(1.3) DB Phase mean improvement in score, units At week 4 Overall: 5.8 vs. 0.5 *P* <	

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events
				0.001 At week 24: 9.3 vs. 0.7 *P* < 0.001) MCS change, units At week 24: 2.7 vs. -0.1 *P* = 0.062 Radiographic measures At 12 months Overall: radiographic disease progression inhibited in D1 vs.D2: *P* = 0.0001 Quality of life scales NR EQ5D VAS Mean change from baseline At 24 weeks D1: 14.3 D2: 2.1 *P* < 0.001	

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events
Author, year, study name, if applicable Saad et al., 2010[14] BSRBR Country and setting United Kingdom, multicenter Source of funding Pharmaceutical company or other commercial source: Abbott Laboratories, Amgen, Schering Plough, Wyeth Pharmaceuticals, Biovitrum Research objective To evaluate the risk-benefit profile of anti-TNF therapies in PsA and to study the predictors of treatment responses and disease remission Study design Observational Overall N 596 (PsA cohort only) Duration of study 1776.2 person	Inclusion Criteria • PsA diagnosis between 2002-2006, started ETN, INF, ADA as first biologic agent within 6 months of registration Exclusion Criteria NR	Interventions, dose D1: ETA: 25 mg twice weekly or 50 mg once weekly D2: INF: 5 mg/kg at weeks 0, 2, 6, and 8 then every 8 weeks D3: ADA: 40 mg every 2 weeks D4: RF-negative RA pts on oral DMARDs (control arm) Number in group D1: 333 D2: 171 D3: 92 D4: 1,115 Mean age, years D1: 45.8 D2: 44.8 D3: 47.0 D4: 59.4 Sex, % female D1: 51.1 D2: 55.0 D3: 53.3 D4: 73.5 Race, % white NR Race, % black NR Ethnicity, Latino NR	Mean disease duration, years D1: 12.8 (9.0) D2: 12.2 (8.0) D3: 11.4 (8.4) D4: 8.5 (9.7) Patients with early RA, three years or less, % NR Treatment resistant, % NR Tender Joint Count, mean (SD) D1: 13.5 (7.6) D2: 14.1 (8.1) D3: 12.1 (7.1) D4: 8.7 (7.1) Swollen Joint Count, mean (SD) D1: 8.8 (6.1) D2: 8.8 (6.4) D3: 9.7 (5.7) D4: 6.0 (5.4) Corticosteroid use, % NR DMARD use, %: D1: NR D2: NR D3: NR D4: 100 MTX naïve, %: NR Baseline DAS score (SD) D1: 6.1 (1.2) D2: 6.3 (1.1) D3: 6.0 (1.0)	ACR: NR HAQ: NR DAS (SD): At 6 months D1: 3.3 (1.4) D2: 3.9 (1.6) D3: 3.32 (1.37) Overall: 3.5 (1.5) At 12 months: D1: 3.2 (1.4) D2: 3.7 (1.7) D3:3.2 (1.5) Overall: 3.4 (1.5) 18 month D1: 3.3 (1.4) D2: 3.5 (1.6) D3: 3.2 (1.5) Overall: 3.3 (1.5) SF-36: NR Radiographic measures: NR Quality of life scales: NR Others: NR	Attrition/withdrawal: NR Overall adverse events: NR Serious adverse events: NR Malignancies: NR Respiratory events: NR Other infections: NR GI: NR Other: NR

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events
years Quality rating Fair			D4: 5.0 (1.4) Overall: PsA cohort: 6.2 (1.1) Required treatment for latent TB NR Other population characteristics NR		

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events
Author, year, study name, if applicable Willkens et al., 1984[16] Country and setting United States; multicenter Source of funding Government or non-profit organization: Supported by NIAMDD contract no. 6-2218, by Public Health Service Research Grant # RR-00064 from the Division of Research Resources, and an Arthritis Foundation Clinical Research Center grant to the University of Tennessee Center for Health Sciences. Research objective To evaluate the effectiveness, tolerability and safety of MTX Study design Controlled Trials Overall N	Inclusion Criteria • All participants were between the ages of 20 and 70 • Had an established diagnosis of PsA • MTX naïve • Unsuccessfully treated with antiinflammatory doses of aspirin or NSAIDs • If female, were not of childbearing potential Exclusion Criteria • Ultraviolet treatment within a month of starting treatment or during the trial • Pregnancy or nursing mothers • Conditions, medical or surgical, which would compromise the absorption, metabolism • Elevation of hepatic enzymes or serum bilirubin to a level of twice the upper limit of normal • Positive serologic test for hepatitis B associated	Interventions, Dose D1: MTX: 7.5 - 15 mg/wk (in doses of 2.5 mg every 12 hours for 3 consecutive doses each week, could be increased to 15 mg/week after 6 weeks. with 3 doses of 5.0 mg taken at 12-hour consecutive intervals) D2: Placebo Number in group D1: 16 D2: 21 Overall: 37 Mean age (years) D1: 44 D2: 47 Overall: NR Sex, % female D1: 62 D2: 56 Overall: 59% Race, % white D1: 81 D2: 88 Overall: 84 Race, % black D1: 5 D2: 0 Overall: 3 Ethnicity, Latino D1: 10 D2: 6 Overall: 8	Mean disease duration, years D1: 159 months D2: 103 months Overall: NR Patients with early RA, three years or less, %: NR Treatment resistant, % D1: Resistant to antiinflammatory does of NSAIDs or aspirin:100 D2: 100 Overall: 100 Tender Joint Count, mean NR Swollen Joint Count, mean NR Corticosteroid use, % NR DMARD use, % D1: 0 D2: 0 Overall: 0 MTX naïve, %: D1: 100 D2: 100 Overall: 100 Baseline DAS score NR Required treatment for latent TB NR Other population characteristics Severity of arthritis, Mild	ACR NR HAQ NR DAS NR SF-36 NR Radiographic measures NR Quality of life scales NR Others Mean grip strength on right, mm/Hg D1: 4 D2: -1 Overall: *P* = 0.167 Mean grip strength on left, mm/Hg D1: 9 D2: 0 Overall: 0.149 Morning stiffness, minutes D1: 45 D2: 30 Overall: *P* = 0.099 Physician assessment score, range 1 to 5 D1: 1 D2: 0 Overall: 0.001 Patient assessment score,	Attrition/withdrawal NR Overall adverse events NR Serious adverse events NR Malignancies NR Respiratory events NR Other infections NR GI: Gastrointestinal distress of stomatitis: D1: 3 D2: 0 Overall: 3 Other NR

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events
37 Duration of study 12 weeks Quality rating Fair	antigen • Significant renal disease • Regular or sporadic alcoholic beverage intake of more than 14 oz per week • Any other experimental drug, previous therapy with MTX or other cytotoxic drug • Preexisting bone marrow hypoplasia • Active infection except for minor self-limited infections • Recent major surgery • Insulin-dependent diabetes • mellitus • Overt obesity as determined by the investigator • Primary diagnosis of ankylosing spondylitis • Thrombocytopenia and/or leukopenia • History or prescence of a malignancy		D1: 5 D2: 2 Severity of arthritis, Moderate D1: 10 D2: 16 Severity of arthritis, Severe D1: 1 D2: 3 Severity of arthritis, Functional class 1: D1: 3 D2: 3 Severity of arthritis, Functional class 2: D1: 11 D2: 15 Severity of arthritis, Functional class 3: D1: 2 D2: 3 Severity of arthritis, Functional class 4: D1: 0 D2: 0	range 1 to 5 D1: 1 D2: 0 Overall: 0.087 Joint pain/tenderness count D1: 4 D2: 6 Overall: 0.559 Joint swelling count D1: 3 D2: 1 Overall: *P* = 0.635 Joint pain/tenderness score D1: 9 D2: 10 Overall: *P* = 0.870 Joint swelling score D1: 5 D2: 2 Overall: 0.390 Surface area, cm sq. D1: 114 D2: 0 Overall: 0.039 Scaling, scale of 0 to 3 D1: 1 D2: 0 Overall: 0.068 Induration, scale of 0 to 3 D1: 0 D2: 0 Overall: 0.950 Erythema, scale of 0 to 3	

Evidence Table 1. Randomized controlled trials and observational studies (continued)

Study Characteristics	Inclusion and Exclusion Criteria	Characteristics and Interventions	Baseline Disease and Treatment Characteristics	Health Outcomes	Adverse Events
				D1: 1 D2: 0 Overall: 0.271	

Evidence Table 2. Systematic reviews and meta-analyses

Study Characteristics	Characteristics of Included Stidies	Results	Adverse Events	Assessments, Study Appraisals, and Qulaity Rating
Author, year, country, funding: Jones, Crotty and Brooks, 2000[17] Multinational Cochrane **Study Design:** Systematic review. **Aims of the Review:** How do various treatments compare in terms of both efficacy and toxicity in the treatment of PsA?; To assess the effects of SSZ, auranofin, etretinate, fumaric acid, IMI gold, azathioprine, efamol marine and MTX, in PsA. **Number of Patients:** Twenty randomized trials were identified of which thirteen were included in the quantitative analysis with data from 1022 subjects.	**Studies included:** Published data only Carette et al. 1989; Clegg et al. 1996; Gupta et al. 1995; Hopkins et al. 1985; Levy et al. 1972; Peeters et al. 1992 Published/unpublished data Combe et al. 1996; Dougados et al. 1995; Farr et al. 1990; Fraser et al. 1993; McKendry et al. 1993; Palit et al. 1990; Willkens et al. 1984 **Characteristics of included studies:** At least two treatment groups, and the allocation to these must have been by formal randomization; in for quality assessment.; **Characteristics of included populations:** patients aged 20 years and over, with a clinical diagnosis of PsA. **Characteristics of**	Parenteral high dose MTX (data not available), SSZ, azathioprine and etretinate were the agents that achieved statistical significance in a global index of disease activity; SSZ (improvement in disease index 0.38 units (95% CI 0.21-0.54) and azathioprine (improvement in disease index 2.20 units (95% CI 1.06-3.33) and etretinate (improvement in disease index 0.84 units (95% CI 0.08-1.59) were statistically better than placebo.; In all trials the placebo group improved over baseline (pooled improvement 0.39 DI units, 95% CI 0.26-0.54).; One outstanding difference is the placebo group with PsA improves three times as much as the placebo RA group ($p<0.05$) Therefore, the results of uncontrolled trials are likely to be misleading in PsA	There was insufficient data to examine toxicity.	**Publication Bias Assessed**: Yes **Heterogeneity Assessed:** Yes **Standard Method of Study Appraisals:** Yes **Comprehensive Search Strategy:** Yes **Quality Rating:** Good

	interventions: All conservative therapeutic agents were eligible for inclusion in this review. Comparative trials without a placebo arm were not included.								

Evidence Table 2. Systematic reviews and meta-analyses (continued)

Study Characteristics, Quality Rating	Study Information	Study Characteristics	Results	Adverse Events
Author, Year: Ravindran et al., 2008[18] **Country and setting:** Study conducted in UK - components are multinational **Funding:** NR Aims of Review: Treatments for psoriatic arthritis (PsA) range from tumour necrosis factor (TNF) inhibitors evaluated in large randomised control trials (RCTs) and low-cost disease-modifying anti-rheumatic drugs (DMARDs) studied in less detail. We compared their efficacy and toxicity in a systematic review. **Quality Rating:** Fair	**Study design:** Systematic review and meta-analysis **Number of Patients:** 2039 **Studies Included:** 18	**Characteristics of Included Studies:** Placebo controlled RCTs **Characteristics of Included Populations** PsA patients **Characteristics of Interventions:** Current interventions	**Study Results:** • Efficacy - # of patients withdrawn for lack of efficacy • TNF inhibitors 5 studies n = 882 RR, 0.25 (95% CI, 0.13-0.48) *P* = 0.0001 • Sulfasalazine 5 studies, n = 434, RR (95% CI): 0.45 (0.23-0.89) *P* = 0.02 • Leflunomide 1 study, n = 190, RR (95% CI): 0.44 (0.23-0.83) *P* = 0.01 • All DMARDs 12 studies, n = 1081, RR (95% CI): 0.39 (0.27-0.57) *P* = 0.00001 • All treatment 18 studies, n = 2148, RR (95% CI): 0.35 (0.25-0.49) *P* = 0.00001	**Adverse Events:** • Toxicity - Withdrawals for adverse events • TNF inhibitors 5 studies, n = 882 RR (95% CI): 2.20 (0.82-5.91) *P* = 0.12 NNT/NNH = 0.25 • Sulfasalazine 5 studies, n = 434 RR (95% CI): 1.76 (0.98-3.14) *P* = 0.06 NNT/NNH = 0.93 • Leflunomide 1 study, n = 190 RR (95% CI): 3.86 (1.20-12.39) *P* = 0.02 NNT/NNH = 0.45 • All DMARDs 12 studies n = 1081, RR (95% CI): 2.32 (1.55-3.47) *P* = 0.0001 NNT/NNH = 0.86 • All treatment 18 studies, n = 2148, RR (95% CI): 2.33 (1.61-3.37) *P* = 0.00001 NNT/NNH = 0.62

Evidence Table 2. Systematic reviews and meta-analyses (continued)

Study Characteristics	Characteristics of Included Stidies	Results	Adverse Events	Assessments, Study Appraisals, and Qulaity Rating
Author, year, country, funding: Woolacott et al., 2006[19] Multi-national Health Technology Assessment **Study Design:** Systematic review **Aims of the Review:** to evaluate the clinical effectiveness, safety, tolerability and cost-effectiveness of etanercept and infliximab for the treatment of active and progressive psoriatic arthritis (PsA) in patients who have inadequate response to standard treatment, including disease-modifying antirheumatic drug (DMARD) therapy. **Number of Patients:** 265 patients were included in the etanercept trials and 104	**Studies included:** three trials of the efficacy of the interventions of interest (two for etanercept and one for infliximab), 23 studies of the adverse effects of the interventions and 14 trials of the efficacy of the DMARDs **Characteristics of included studies:** RCTs **Characteristics of included populations:** Adults with PsA **Characteristics of interventions:** INF and ETA	ETA 12 weeks, 65% of ACR 20 { RR 4.19 [95% CI 2.74 to 6.42]}, . ACR50 45% RR 10.84 (95% CI 4.47 to 26.28)] ACR 70 12%[RR 16.28 (95% CI 2.20 to 120.54)], (PsARC) 85%[RR 2.60 (95% CI 1.96 to 3.45)], INF- 16 weeks, ACR 20 65% [RR 6.80 (95% CI 2.89 to 16.01)], . Almost half achieved an ACR 50 [RR 49.00 (95% CI 3.06 to 785.06)] and over one-quarter achieved an ACR 70 [RR 31.00 (95% CI 1.90 to 504.86)] compared with none of the placebo group, . PsARC 75% [RR 3.55 (95% CI 2.05 to 6.13)]. The beneficial treatment effect on psoriasis was also statistically significant with a mean difference in percentage change from baseline in PASI of –5 (95% CI –6.8 to –3.3), as was the percentage improvement from baseline in HAQ score with infliximab compared with placebo [mean difference 51.4 (95% CI 48.08 to 54.72)], indicating a beneficial effect of infliximab on functional status.	Injection site reactions appear to be the most common adverse effects of etanercept. Overall, ETA appeared to be well tolerated in short-and long-term use, although much of the long-term data are not from patients with psoriastic arthritis. As identified in earlier reviews, the main areas of concern relate to uncommon but serious adverse events the significance of which is not readily discernible from the published reports of clinical trials. Overall, infusion reactions, the development of antibodies and infections appear to be the most common adverse effects of infliximab,	**Publication Bias Assessed**: Yes **Heterogeneity Assessed:** Yes **Standard Method of Study Appraisals:** Yes **Comprehensive Search Strategy:** Yes **Quality Rating:** Good

in the infliximab trial.

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Appendix F. Criteria for Assessing the Quality of Individual Studies

Assessment of Internal Validity

To assess the internal validity of individual studies, the EPC adopted criteria for assessing the internal validity of individual studies from the U.S. Preventive Services Task Force and the NHS Centre for Reviews and Dissemination. To assess the quality of observational studies, we used criteria outlined by Deeks et al., 2003.[1]

For Controlled Trials:

Assessment of Internal Validity

1. Was the assignment to the treatment groups really random?

    Adequate approaches to sequence generation:

        Computer-generated random numbers

        Random numbers tables

    Inferior approaches to sequence generation:

        Use of alteration, case record numbers, birth dates or week days

    Not reported

2. Was the treatment allocation concealed?

    Adequate approaches to concealment of randomization:

        Centralized or pharmacy-controlled randomization

        Serially-numbered identical containers

        On-site computer-based system with a randomization sequence that is not readable until allocation

Other approaches sequence to clinicians and patients

Inferior approaches to concealment of randomization:

Use of alteration, case record numbers, birth dates or week days

Open random numbers lists

Serially numbered envelopes (even sealed opaque envelopes can be subject to manipulation)

Not reported

3. Were the groups similar at baseline in terms of prognostic factors?

4. Were the eligibility criteria specified?

5. Were outcome assessors blinded to the treatment allocation?

6. Was the care provider blinded?

7. Was the patient kept unaware of the treatment received?

8. Did the article include an intention-to-treat analysis or provide the data needed to calculate it (i.e., number assigned to each group, number of subjects who finished in each group, and their results)?

9. Did the study maintain comparable groups?

10. Did the article report attrition, crossovers, adherence, and contamination?

11. Is there important differential loss to followup or overall high loss to followup? (Give numbers in each group.)

Assessment of External Validity (Generalizability)

1. How similar is the population to the population to whom the intervention would be applied?

2. How many patients were recruited?

3. What were the exclusion criteria for recruitment? (Give numbers excluded at each step.)

4. What was the funding source and role of funder in the study?

5. Did the control group receive the standard of care?

6. What was the length of followup? (Give numbers at each stage of attrition.)

For Observational Studies:

Assessment of Internal Validity

1. Were both groups selected from the same source population?

2. Did both groups have the same risk of having the outcome of interest at baseline?

3. Were subjects in both groups recruited over the same time period?

4. Was there any obvious selection bias?

5. Were ascertainment methods adequate and equally applied to both groups?

6. Was an attempt made to blind the outcome assessors?

7. Was the time of followup equal in both groups?

8. Was overall attrition high ($\geq$ 20%)?

9. Was differential attrition high ($\geq$ 15%)?

10. Did the statistical analysis consider potential confounders or adjust for different lengths of followup?

11. Was the length of followup adequate to assess the outcome of interest?

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For Systematic Reviews and Meta-analyses:

1. Is the review based on a focused question of interest?

2. Did the search strategy employ a comprehensive, systematic, literature search?

3. Are eligibility criteria for studies clearly described?

4. Did at least 2 persons independently review studies?

5. Did authors use a standard method of critical appraisal before including studies?

6. Was publication bias assessed?

7. Was heterogeneity assessed and addressed?

8. Did statistical analysis maintain trials as the unit of analysis?

Appendix G. Clinical and Self-Reported Scales and Instruments Commonly Used in Studies of Drug Therapy for Rheumatoid Arthritis and Psoriatic Arthritis

Introduction

This appendix provides a brief overview of the various scales and self-reported measures that investigators used to assess outcomes in all the studies reviewed in this systematic review. The main outcome categories involve radiologic assessments of joint damage (erosion or narrowing) and various instruments that patients or subjects used to report on functional capacity or quality of life; the latter fall into two groups, one related to general health measures and one related to condition- or disease-specific instruments. General measures used in rheumatoid and psoriatic arthritis studies are described first; then the disease-specific measures used in rheumatoid and psoriatic arthritis studies are described separately. The new 2010 American College of Rheumatology ACR criteria are presented at the end of the document.

Radiographic Measures

Radiographic assessment of joint damage in hands (including wrists) or both hands and feet are critical to clinical trials in rheumatoid arthritis. The damage can be both joint space narrowing and erosions, and the underlying construct is sometimes referred to as radiographic progression (i.e., changes, whether positive or negative) as detected by radiography and interpretation. Several approaches exist, but the two commonly used are the Sharp Score (and variants) and the Larsen Score. These and other scoring methods have recently been reviewed by Boini and Guillemin;[1] additional citations or sources are given in the brief descriptions below.

Sharp Score and Sharp/van der Heijde Score

The Sharp Score is a means of evaluating joint damage in joints of the hands, including both erosion and joint space narrowing.[2] Although it has undergone modifications since its introduction, the version proposed in 1985 has become the standard approach. In this method, 17 joint areas in each hand are scored for erosions; 18 joint areas in each hand are scored for joint space narrowing. The score per single joint for erosions ranges from 0 to 5 and for joint space narrowing from 0 to 4. In both cases, a higher score is worse. Erosion scores range from 0 to 170 and joint space narrowing scores range from 0 to 144. Thus, the "total Sharp Score" is the sum of the erosion and joint space narrowing scores, or 0 to 314.

The Sharp/van der Heijde (SHS) method, introduced in 1989, overcame one drawback to the Sharp Score, namely its focus on only hands, given that feet can also be involved early in rheumatoid arthritis. Therefore, the SHS method was developed to take account of erosions and joint space narrowing in both hands and feet.[3-4] As with the Sharp Score, higher scores reflect worse damage. Erosion is assessed in 16 joints in each hand and 6 joints in each foot. Each joint is scored from 0 to 5 with a maximal erosion score of 160 in the hands and 120 in the feet. Joint space narrowing and subluxation are assessed in 15 joints in the hands and 6 joints in the feet. Each joint is scored from 0 to 4 with a maximal score of 120 in the hands and 48 in the feet. The

erosion and joint space narrowing scores are combined to give a total SHS score with a maximum of 448 (weighted toward hands because more joints are scored).

Numerous variants on the Sharp or SHS scores have been developed, differing subtly in terms of the numbers of joints measured and other details.[5] Generally, all the Sharp methods are very detailed assessments and the approach, although reliable and sensitive to change, is considered time-consuming and tedious. For a speedier approach, Larsen and colleagues developed a simpler approach.

Larsen Scale for Grading Radiographs

The Larsen Scale is an overall measure of joint damage, originally devised in the 1970s and updated most recently in the late 1990s.[6-10] It produces both a score for each joint (hands and feet) and an overall score that reflects measurement and extent of joint damage. Scores range from 0 ("normal conditions," i.e., intact bony outlines and normal joint space) to 5 ("mutilating abnormality," i.e., original bony outlines have been destroyed), so higher scores reflect greater damage. Scores can range from 0 to 250.

General Health Measures

Health Assessment Questionnaire

The Health Assessment Questionnaire (HAQ) is a widely used self-report measure of functional capacity; it is a dominant instrument in studies of patients with arthritis (particularly trials of drugs in patients with rheumatoid arthritis), but it is considered a generic (not disease-specific) instrument. Detailed information on its variations, scoring, etc., can be found at www.chcr.brown.edu/pcoc/EHAQDESCRSCORINGHAQ372.PDF (accessed for this purpose 1/18/2007) or www.hqlo.com/content/1/1/20 (accessed for this purpose 1/18/2007) and in the seminal reports by Fries et al.[11] and Ramey et al.[12]

The full, five-dimension HAQ consists of four domains: disability, discomfort and pain, toxicity, and dollar costs, plus death (obtained through other sources). More commonly, "the HAQ" as used in the literature refers to the shorter version encompassing the HAQ Disability Index (HAQ-DI), the HAQ pain measure, and a global patient outcome measure. The HAQ-DI is sometimes used alone.

The HAQ-DI, with the past week as the time frame, focuses on whether the respondent "is able to…" do the activity and covers eight categories in 20 items: dressing and grooming, arising, eating, walking, hygiene, reach, grip, and common daily activities. The four responses for the HAQ-DI questions are graded as follows: without any difficulty = 0; with some difficulty = 1; with much difficulty = 2; and unable to do = 3. The highest score for any component question in a category determines the category score. The HAQ-DI also asks about the use of aids and devices to help with various usual activities. Two composite scores can be calculated, one with and one without the aids/devices element; both range from 0 to 3.

The HAQ pain domain is measured on a doubly-anchored horizontal visual analog scale (VAS) of 15 cm in length; one end is labeled "no pain" (score of 0) and the other is labeled "very severe pain" (score of 100). Patients mark a spot on the VAS, and scores are calculated as the length from "no pain" in centimeters (cm) multiplied by 0.2 to yield a value that can range between 0 and 3.

With respect to interpretation, HAQ-DI scores of 0 to 1 are generally considered to represent mild to moderate disability, 1 to 2 moderate to severe disability, and 2 to 3 severe to very severe disability.

The HAQ global health status scale measures quality of life (essentially, as how the patient is feeling) with a 15 cm doubly-anchored horizontal VAS scored from 0 (very well) to 100 (very poor).

Medical Outcomes Study Short Form 36 Health Survey

The Medical Outcomes Study Short Form 36 Health Survey (SF-36) is an internationally known generic health survey instrument. Information can be found at www.sf-36.org/tools/sf36.shtml (accessed for this purpose 2/18/2007) and in a large number of articles documenting its psychometric properties.[13-19] It comprises 36 items in eight independent domains tapping functioning and well-being: physical functioning, role-physical, bodily pain, and general health in one grouping (physical health) and vitality, role-emotional, social functioning, and mental health in another grouping (mental health). The SF-36 provides a separate scale score for each domain (yielding a profile of health) and two summary scores, one for physical health and one for mental health. Each scale is scored from 0 to 100 where higher scores indicate better health and well-being.

A "version 2" of the SF-36 was introduced in the late 1990s to correct some drawbacks in formatting, wording, and other issues and to update the norm-based scoring with 1998 data. It can be fielded in two versions varying by recall period: 4-week recall (the usual approach) and 1-week recall (acute). More recently, it has been tested and used for computer adaptive testing according to item response theory principles.

EuroQol EQ-5D Quality of Life Questionnaire

A third generic quality-of-life instrument is the EuroQol EQ-5D Quality of Life Questionnaire, typically known just as the EQ-5D. More information can be found at http://www.euroqol.org/ (accessed for this purpose 1/18/2007) and in key descriptive articles,[20] one of which is about patients with rheumatoid arthritis.[21]

The EQ-5D covers health status in five domains (three questions each): mobility, self-care, usual activities, pain or discomfort, and anxiety or depression. It is intended for self-response but can be used in other administration modes. Each item can take one of three response levels – no problems, some moderate problems, extreme problems – identified as level 1, 2, or 3, respectively. This yields a profile of one level for each of the five domains; this is essentially a five-digit number, and no arithmetic properties attach to these values. Users can convert health states in the five-dimensional descriptive system into a weighted health state index by applying scores from EQ-5D "value sets" elicited from general population samples to the profile pattern (e.g., 1, 2, 3, 3, 1).

The EQ-5D also has a global health VAS scale (20 cm) scored from 0 to 100.

Rheumatoid Arthritis Measures

American College of Rheumatology 20/50/70

The American College of Rheumatology (ACR) criteria are concerned with *improvement* in counts of tender and swollen joints and several domains of health.[22] A principal aim of these

criteria is use in studies (particularly trials) of drugs for rheumatoid arthritis. More information can be found at www.rheumatology.org/publications/response/205070.asp and www.hopkins-arthritis.som.jhmi.edu/edu/acr/acr.html#remis_rheum (both accessed for this purpose 1/18/2007). Originally these latter involved patient assessment, physician assessment, erythrocyte sedimentation rate, pain scale, and functional questionnaire.

Today, based on work done in the mid 1990s,[23] values for clinical trial patients are defined as improvement in both tender and swollen joint counts and in three of the following: patient's assessment of pain; patient's global assessment of disease activity, patient's assessment of physical function (sometimes referred to as physical disability), the physician's global assessment of disease activity, and acute phase reactant (C-reactive protein, or CRP). The 20, 50, or 70 designations (sometimes called the ACR Success Criteria) refer to improvements in percentage terms to 20 percent, 50 percent, or 70 percent in the relevant dimensions. A physician's global assessment of 70 percent improvement is considered remission.

Thus, patients are said to meet ACR 20 criteria when they have at least 20 percent reductions in tender and swollen joint counts and in at least three of the domains. ACR 50 and ACR 70 criteria are defined in a manner similar to that for ACR 20, but with improvement of at least 50 percent and 70 percent in the individual measures, respectively. Table G-1 illustrates, in a study context, how a patient might be said to have an ACR 50 response.

Table G-1. Example of a patient with an ACR 50 response to treatment

Outcomes Measured	Baseline	Endpoint
Tender joints count *	12	6
Swollen joints count *	8	3
Patient's pain score*	60	20
Patient's physical function (disability) score	80	60
Physician's global activity score*	50	20
C-reactive protein*	3.6	1.4

* At least 50 percent improvement between baseline and endpoint measurements.

Ritchie Articular Index

This is a long-standing approach to doing a graded assessment of the tenderness of 26 joint regions, based on summation of joint responses after applying firm digital pressure.[24] Four grades can be used: 0, patient reported no tenderness; +1, patient complained of pain; +2, patient complained of pain and winced; and +3, patient complained of pain, winced, and withdrew. Thus, the index ranges from 0 to 3 for individual measures and 0 to 78 overall, with higher scores being worse tenderness.

Certain joints are treated as a single unit, such as the metacarpal-phalangeal and proximal interphalangeal joints of each hand and the metatarsal-phalangeal joints of each foot. For example, the maximum score for the five metacarpal-phalangeal joints of the right hand would be 3, not 15. No weights are used for different types of joints (e.g., by size), because the issue is one of measuring changes (improvements) in tenderness; this is especially relevant for rheumatoid arthritis.

Disease Activity Score

The Disease Activity Score (DAS) is an index of disease activity first developed in the mid 1980s. The history of its development and current definitions, scoring systems, and other details can be found at http://www.das-score.nl/www.das-score.nl/ (accessed for this purpose

1/19/2007) and in recent articles.[4,25] The DAS originally included the Ritchie Articular Index (see above), the 44 swollen joint count, the erythrocyte sedimentation rate, and a general health assessment on a VAS. A cut-off level of the DAS of 1.6 is considered to be equivalent with being in remission.

More recently, an index of RA disease activity using only 28 joints – the DAS 28 – has been developed, focusing on joint counts for both tenderness (TJC) and swelling (SJC). It also uses either the patient's or a physician's global assessment (PGA) of disease activity (on a 100 mm VAS) and the erythrocyte sedimentation rate (ESR) or C-reactive protein. The formula for calculating a DAS 28 score is as follows: = $(0.56 \times TJC^{1/2}) + (0.28 \times SJC^{1/2}) + (0.7 \times \ln [ESR]) + (0.014 \times PGA [\text{in mm}])$. Numerous formulas to calculate a variety of DAS and DAS 28 scores exist (see the website above), such as when a global patient assessment of health is unavailable.

The DAS 28 yields a score on a scale ranging from 0 to 10. A DAS 28 of 2.6 is considered to correspond to remission; a DAS 28 of 3.2 is a threshold for low disease activity; and a DAS 28 of more than 5.1 is considered high disease activity.

EULAR Response Criteria

The European League Against Rheumatism (EULAR) response criteria classify patients as good, moderate, or nonresponders based on both change in disease activity and current disease activity, using either the DAS or the DAS28 (see description above).[26] For example, to be classified as a good responder a patient must have relevant change in DAS (≥1.2) and low current disease activity (≤2.4), while a nonresponder must have ≤0.6 change in DAS and high disease activity (>3.7).[27]

The EULAR criteria have been validated in multiple clinical trials, and confirmed in an analysis of nine clinical trials that concluded a high level of agreement and equal validity between ACR and EULAR improvement classifications.[28] Good and moderate responders showed significantly more improvement in functional capacity and significantly less progression of joint damage than patients classified as nonresponders.[28]

Psoriatic Arthritis Measures

Psoriatic Arthritis Response Criteria

The psoriatic arthritis response criteria (PsARC) was initially designed for use in a clinical trial that compared sulphasalazine to placebo in the setting of the Veterans Administration.[29] It has since been used as the primary or secondary outcome in all the studies that examined biologics versus placebo in the treatment of PsA. The PsARC includes improvement in at least two of the following, one of which had to be a joint count, and no worsening of any measure: tender or swollen joint count improvement of at least 30%, patient global improvement by one point on a five-point Likert scale, or physician global improvement on the same scale.[29]

American College of Rheumatology 20

The ACR 20 (American College of Rheumatology 20 percent response) is the other outcome that is used as the primary outcome in clinical trials of biologics. The measurement is similar to that of the ACR 20 used for rheumatoid arthritis with modifications made that increased the number of joints tested from 68 tender and 66 swollen to 76 and 78, respectively, with the addition of distal interphalangeal joints of the feet and carpometacarpal joints of the hands.[29] The

outcomes from the ACR 20 are generally poorer when compared to the PsARC due to the variation in items measured; this is due in part to the need to see an improvement in tender *and* swollen joints in the ACR 20 versus an improvement in tender *or* swollen joint counts. An adaptation of the ACR 20 criteria as of 2010 are presented in Table G-2.

Table G-2. 2010 rheumatoid arthritis criteria

Target population (Who should be tested?) Patients who • have at least 1 joint with definite clinical synovitis (swelling) o Criteria aimed at classification of newly presenting patients; patients with erosive disease typical of RA with a history compatible with prior fulfillment of the 2010 criteria should be classified as having RA; patients with longstanding disease, including those whose disease is inactive (with or without treatment) who, based on retrospectively available data, have previously fulfilled the 2010 criteria should be classified as having RA • with the synovitis not better explained by another disease o Differential diagnoses vary among patients with different presentations, but may include conditions such as systemic lupus erythematosus, psoriatic arthritis, and gout. If it is unclear about the relevant differential diagnoses to consider, an expert rheumatologist should be consulted	
Classification criteria for RA Score-based algorithm: • Add score of categories: Joint involvement, serology, reactants, duration o Differential diagnoses vary among patients with different presentations, but may include conditions such as systemic lupus erythematosus, psoriatic arthritis, and gout. If it is unclear about the relevant differential diagnoses to consider, an expert rheumatologist should be consulted • Score of ≥6/10 needed for classification of a patient as having definite RA o Although patients with a score of <6/10 are not classifiable as having RA, their status can be reassessed and the criteria might be fulfilled cumulatively over time	**Score**
Joint involvement Joint involvement refers to any *swollen* or *tender* joint on examination, which may be confirmed by imaging evidence of synovitis; d Distal interphalangeal joints, first carpometacarpal joints, and first metatarsophalangeal joints are *excluded from assessment; c*ategories of joint distribution are classified according to the location and number of involved joints, with placement into the highest category possible based on the pattern of joint involvement	
1 large joint • "Large joints" refers to shoulders, elbows, hips, knees, and ankles	**0**
2-10 large joints	**1**
1-3 small joints (with or without involvement of large joints) • "Small joints" refers to the metacarpophalangeal joints, proximal interphalangeal joints,	**2**

second through fifth metatarsophalangeal joints, thumb interphalangeal joints, and wrists.	
4-10 small joints (with or without involvement of large joints)	**3**
>10 joints (at least 1 small joint) • In this category, at least 1 of the involved joints must be a small joint; the other joints can include any combination of large and additional small joints, as well as other joints not specifically listed elsewhere (e.g., temporomandibular, acromioclavicular, sternoclavicular, etc.)	**5**

Table G-2. 2010 rheumatoid arthritis criteria (continued)

Serology *(at least 1 test result is needed for classification)* (Cf. http://www.rheumatology.org/practice/clinical/classification/ra/ra_2010.asp#fn_08) • Negative refers to IU values that are less than or equal to the upper limit of normal (ULN) for the laboratory and assay; low-positive refers to IU values that are higher than the ULN but ≤3 times the ULN for the laboratory and assay; high-positive refers to IU values that are >3 times the ULN for the laboratory and assay; where rheumatoid factor (RF) information is only available as positive or negative, a positive result should be scored as low-positive for RF. ACPA = anti-citrullinated protein antibody	
Negative RF *and* negative ACPA	**0**
Low-positive RF *or* low-positive ACPA	**2**
High-positive RF *or* high-positive ACPA	**3**
Acute-phase reactants *(at least 1 test result is needed for classification)* • Normal/abnormal is determined by local laboratory standards. CRP = C-reactive protein; ESR = erythrocyte sedimentation rate	
Normal CRP *and* normal ESR	**0**
Abnormal CRP *or* abnormal ESR	**1**
Duration of symptoms • Duration of symptoms refers to patient self-report of the duration of signs or symptoms of synovitis (e.g., pain, swelling, tenderness) of joints that are clinically involved at the time of assessment, regardless of treatment status	
<6 weeks	**0**
≥6 weeks	**1**

Adapted from: 2010 Rheumatoid arthritis classification criteria: An American College of Rheumatology/European League Against Rheumatism collaborative initiative. Arthritis & Rheumatism. 2010 Sep; 62(9): 2569–2581.

The Psoriasis Area and Severity Index

The Psoriasis Area and Severity Index (PASI) was developed to measure the effect of treatments in clinical trials of psoriasis and is utilized to capture the psoriasis component found in psoriatic arthritis. The scale was originally published in 1978 in a trial of 27 patients suffering from severe chronic generalized psoriasis that were treated with Ro 10-9359, a retinoic acid derivative.[30] The PASI is a composite index of disease severity incorporating measures of scaling, erythema, and induration, and it is weighted by severity and affected body surface area. A PASI >12 defines severe, PASI 7-12 moderate, and PASI <7 mild psoriasis.

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Appendix H. Characteristics of Studies with Poor Internal Validity

Study	Design	Sample Size	Intervention	Reason for Exclusion
Atteno et al., 2010[1]	Open-label RCT	100	Adalimumab Etanercept Infliximab	No blinding; no ITT analysis; high risk of selection bias and measurement bias
Saad et al., 2010[2]	Observational	596	Adalimumab Etanercept Infliximab	High LTF
Virkki et al., 2010[3]	Observational	127	Etanercept Infliximab	High LTF; completers analysis

ITT = intention to treat; LTF = loss to followup; RCT = randomized controlled trial

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Appendix I. Strength of Evidence Tables

Table I-1. Strength of evidence for disease activity and radiographic progression

Number of Studies; # of Subjects	Risk of Bias Design/ Quality	Consistency	Directness	Precision	Results	Strength of Evidence
Oral DMARD vs. placebo						
Methotrexate vs. placebo 1 RCT; N=37	Medium 1 RCT/Fair	Unknown, single study	Direct	Precise	Greater improvement with physician assessment of disease activity with methotrexate than placebo	Low
Sulfasalazine vs. placebo 1 systematic review (including 6 RCTs); N=564	Low 1 Systematic review/Good	Consistent	Direct	Precise	Greater improvement in disease activity with sulfasalazine than placebo	Moderate
Leflunomide vs. placebo 1 RCT; N=190	Medium 1 RCT/Fair	Unknown, single study	Direct	Precise	Greater improvement in disease activity with leflunomide than placebo	Low
Biologic DMARD vs. placebo						
Adalimumab vs. placebo 2 RCTs; N=415	Medium 2 RCT/Fair	Consistent	Direct	Precise	Greater improvement in disease activity with adalimumab than placebo	Moderate
	Medium 1 RCT/Fair	Unknown, single study	Indirect	Precise	Less radiographic change for adalimumab than placebo	Low
Etanercept vs. placebo 1 systematic review, 2 RCTs; N=634	Low 1 Systematic review/Good; 2 RCTs /Fair	Consistent	Direct	Precise	Greater improvement in disease activity with etanercept than placebo	Moderate
	Medium				Less radiographic change for etanercept	

	1RCT/Fair	Unknown, single study	Indirect	Precise	than placebo	Low
Golimumab vs. placebo 1 RCT; N=405	Low 1 RCT/Good	Unknown, single study	Direct	Precise	Greater improvement in disease activity with golimumab than placebo	Low
Infliximab vs. placebo 1 systematic review, 2 RCTs; N=675	Low Systematic review/Good; 2 RCTs/Fair	Consistent	Direct	Precise	Greater improvement in disease activity with infliximab than placebo	Moderate
	Medium 1 RCT/Fair	Unknown, single study	Indirect	Precise	Less radiographic change for infliximab than placebo	Low
Oral DMARD vs. Oral DMARD						
No studies	n/a	n/a	n/a	n/a	n/a	Insufficient
Biologic DMARD vs. Biologic DMARD						
No studies	n/a	n/a	n/a	n/a	n/a	Insufficient
Biologic DMARD vs. Oral DMARD						
TNF inhibitors vs. sulfasalazine 1 systematic review; N=882	Low Systematic review/Fair	Unknown, single study	Direct	Precise	Greater improvement in disease activity with TNF inhibitors than sulfasalazine	Low

Table I-1. Strength of evidence for disease activity and radiographic progression (continued)

Number of Studies; **# of Subjects**	**Risk of Bias** **Design/ Quality**	**Consistency**	**Directness**	**Precision**	**Results**	**Strength of Evidence**
Biologic DMARD + Oral DMARD vs. Biologic DMARD						
Anti-TNF(ADA, ETN or INF) + MTX vs. Anti-TNF 2 cohort studies; N=857	Medium 2 Cohort/Fair	Consistent	Direct	Precise	No difference in disease activity	Low
Biologic DMARD + Oral DMARD vs. Oral DMARD						

No studies	n/a	n/a	n/a	n/a	n/a	Insufficient

ADA = adalimumab; DMARD = disease-modifying antirheumatic drug; INF = infliximab; MTX = methotrexate; N = total sample size; n/a = not applicable; RCT = randomized controlled trial; TNF = tumor necrosis factor; vs. = versus

Table I-2. Strength of evidence for functional capacity and quality of life outcomes

Number of Studies; # of Subjects	Risk of Bias Design/ Quality	Consistency	Directness	Precision	Results	Strength of Evidence
Oral DMARD vs. placebo						
Leflunomide vs. placebo 1 RCT; N=190	Medium RCT/Fair	Unknown, single study	Direct	Precise	Greater improvement in functional capacity[a] and quality of life with LEF than placebo	Low
Biologic DMARD vs. placebo						
Adalimumab vs. placebo 2 RCTs; N=415	Medium RCTs/ 2 Fair	Consistent	Direct	Precise	Greater improvement in functional capacity[b] with adalimumab	Moderate
		Inconsistent	Direct	Imprecise	For health-related quality of life, some results favored adalimumab[c]	Low
Etanercept vs. placebo 2 RCTs; N=265	Medium RCTs/2 Fair	Consistent	Direct	Precise	Greater improvement in functional capacity with etanercept	Moderate
		Unknown, single study[d]	Direct	Precise	Greater improvement in quality of life with etanercept	Low
Golimumab vs. placebo 1 RCT; N=405	Low RCT/Good	Unknown, single study	Direct	Precise	Greater improvement in functional capacity and quality of life with golimumab	Low
Infliximab vs. placebo 2 RCTs; N=304	Medium RCTs/2 Fair	Consistent	Direct	Precise	Greater improvement in functional capacity with infliximab	Moderate
		Unknown,	Direct	Imprecise	Greater improvement in quality of life with infliximab	Low

		single study[d]				
Oral DMARD vs. Oral DMARD						
No studies	n/a	n/a	n/a	n/a	n/a	Insufficient
Biologic DMARDs vs. Biologic DMARDs						
No studies	n/a	n/a	n/a	n/a	n/a	Insufficient
Biologic DMARDs vs. Oral DMARDs						
No studies	n/a	n/a	n/a	n/a	n/a	Insufficient
Biologic DMARDs + Oral DMARDs vs. Biologic DMARDs						
No studies	n/a	n/a	n/a	n/a	n/a	Insufficient
Biologic DMARDs + Oral DMARDs vs. Oral DMARDs						
No studies	n/a	n/a	n/a	n/a	n/a	Insufficient

[a]Difference was statistically significantly different, but did not reach the threshold for a clinically important difference.
[b]Difference in one of two studies was statistically significantly different (difference in improvement in HAQ of 0.2, $P = 0.01$), but did not reach the threshold for a clinically important difference of ≥ 0.22. In the other study, the difference was both clinically and statistically significant.
[c]Differences were statistically and clinically significant for the SF-36 PCS, but not for the MCS in both studies. Both studies reported results on the dermatology life quality index; one found a difference favoring adalimumab and the other found no statistically significant difference.
[d]Only one of the two trials reported a quality of life outcome.
N = number; n/a = not applicable; RCT = randomized controlled trial

Table I-3. Strength of evidence for adverse events

Number of Studies; # of Subjects	Risk of Bias Design/ Quality	Consistency	Directness	Precision	Results	Strength of Evidence
Biologic DMARD vs. Biologic DMARD						
ADA vs. ETN vs. INF 2 observational N=827	Medium 2 cohort/ 1 fair, 1 good	Consistent	Direct	Imprecise	ETN had lower risk of withdrawals due to AEs than INF. Concomitant MTX lowered withdrawals.	Low
Oral DMARD vs. placebo						
LEF vs. placebo 1 RCT N=143 1 meta-analysis (N=190)	Medium RCT and meta-analysis/ fair	Unknown, single study	Direct	Imprecise	Higher rates of diarrhea and increased ALT levels for LEF vs. placebo LEF had higher withdrawals due to AEs	Insufficient
SFZ vs. placebo 1 meta-analysis (N=434)	Medium meta-analysis/ fair	Consistent	Direct	Imprecise	SFZ had more withdrawals due to AEs than placebo, but not statistically significant	Insufficient
Biologic DMARD vs. placebo						
ADA vs. placebo 2 RCT N=415	Medium RCT/2 fair	Consistent	Direct	Imprecise	Infusion reactions with ADA; worsened psoriasis with placebo	Low
ETN vs. placebo 2 RCT N=265	Medium RCT/2 fair	Consistent	Direct	Imprecise	No difference in adverse events except for more ISRs with ETN	Low
GOL vs. placebo 1 RCT N=405	Medium RCT/1fair	Unknown, single study	Direct	Imprecise	More infections and malignancies for GOL than placebo	Insufficient
INF vs. placebo	Medium	Consistent	Direct	Imprecise	No differences in adverse events for INF and	Insufficient

2 RCT N=304	RCT/2 fair				placebo	
TNF Inhibitors vs. placebo 1 meta-analysis (N=882)	Medium meta-analysis/ fair	Consistent	Direct	Imprecise	TNF inhibitors as class had more withdrawals due to AEs than placebo, but not statistically significant	Insufficient

ADA = adalimumab; AE = adverse event; ALT = alanine aminotransferase; DMARD = disease-modifying antirheumatic drug; ETN = etanercept; GOL = golilumab; INF = infliximiab; ISR = injection site reaction; LEF = leflunomide; MTX = methotrexate; N = total sample size; RCT = randomized controlled trial; vs. = versus