Two-Year Efficacy and Safety of Infliximab Treatment in Patients with Active Psoriatic Arthritis: Findings of the Infliximab Multinational Psoriatic Arthritis Controlled Trial (IMPACT)

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ABSTRACT. ***Objective.*** To investigate longterm efficacy/safety of infliximab over 2 years in patients with active psoriatic arthritis (PsA).

Methods. Initially, 104 patients were randomized to receive blinded infusions of infliximab 5 mg/kg or placebo at Weeks 0, 2, 6, and 14. At Week 16, all patients received infliximab 5 mg/kg every 8 weeks through Week 46. Seventy-eight of the 87 patients completing the first year continued into the open-label longterm extension and received infliximab 5 mg/kg at Weeks 54, 62, 70, 78, 86, and 94. The primary efficacy endpoint for the study extension was the proportion of patients with at least 20% improvement in the American College of Rheumatology response criteria (ACR20) at Week 98. Radiographic progression was assessed by the PsA-modified van der Heijde-Sharp score in patients with radiographs available at baseline and Week 98 (n = 43).

Results. At Week 98, 62% (48/78) of infliximab-treated patients achieved an ACR20 response; 45% (35/78) and 35% (27/78) of patients achieved ACR50 and ACR70 responses, respectively. Among patients with baseline Psoriasis Area and Severity Index scores ≥ 2.5, 64% (16/25) achieved > 75% improvement from baseline to Week 98. The average estimated annual radiographic progression with infliximab treatment was significantly reduced versus the estimated baseline rate of progression. No new safety issues were observed during the second year of the study.

Conclusion. Therapy with infliximab 5 mg/kg through Week 94 produced sustained improvement in joint and skin symptoms, inhibited radiographic progression, and continued to exhibit a favorable benefit-risk ratio in this population with treatment-refractory PsA. (First Release Mar 15 2008; J Rheumatol 2008;35:869–76)

Key Indexing Terms:
INFLIXIMAB PSORIATIC ARTHRITIS PSORIASIS TUMOR NECROSIS FACTOR-α

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Patients with psoriatic arthritis (PsA), a chronic inflammatory arthropathy occurring in association with psoriasis, may endure substantial morbidity; unfavorable outcomes can include the development of deformities, radiographic joint damage, and greatly impaired functional status[1-4]. Based on evidence indicating that proinflammatory cytokines, in particular tumor necrosis factor-α (TNF-α), serve a key role in the inflammatory responses associated with both psoriasis and PsA[5-10], biologic agents targeting TNF-α have been evaluated in the treatment of PsA and demonstrated significant efficacy in improving arthritic and psoriatic components of the disease[11-13]. With new anti-TNF agents available for treatment of this potentially debilitating condition, there is a need to better understand the longterm benefits and risks of anti-TNF therapy in PsA.

The Infliximab Multinational PsA Controlled Trial (IMPACT) study was a double-blind, randomized, controlled clinical trial that evaluated the efficacy and safety of infliximab using multiple assessments of skin and joint disease activity in patients with active PsA who had failed prior treatment with at least one disease modifying antirheumatic drug (DMARD). Results through the first year of this study, which have been reported[14], showed that therapy with infliximab 5 mg/kg significantly improved the signs and symptoms of arthritis, psoriasis, dactylitis, and enthesitis in patients with active PsA resistant to DMARD therapy, and that these benefits were sustained through 50 weeks with continued infliximab treatment. Radiographic benefits of infliximab were also sustained through 1 year of study treatment[15]. A longterm, open-label extension stage of this study was subsequently conducted to assess the efficacy and safety of infliximab over 2 years in this patient population. A subset of patients completing 2 years of the IMPACT study had hand and feet radiographic data available, thus allowing for assessment of the extent of radiographic damage. Results of this study extension are reported here.

MATERIALS AND METHODS

Patients. One hundred four adult (at least 18 years of age) patients with an established diagnosis of PsA of 6 months' duration or longer were initially recruited into our study. Details of patient eligibility criteria have been described[14]. Briefly, patients were required to have active peripheral polyarticular joint involvement and to have failed prior treatment with 1 or more DMARD. Patients who completed the first year of the study were eligible to continue with the second year of the study.

Our study was conducted at 9 centers in Europe, the United States, and Canada. Institutional review boards at each participating site approved the protocol. All patients provided written informed consent prior to participating in the longterm extension portion of the study.

Study design. The study design included 3 stages (Figure 1). As described[14], patients were randomly assigned to receive placebo (n = 52) or infliximab 5 mg/kg (n = 52) by intravenous infusion at Weeks 0, 2, 6, and 14 in stage I. In stage II, all patients received infliximab 5 mg/kg and treatment continued every 8 weeks through Week 46. The open-label, longterm extension stage (stage III) from Week 54 to Week 98 was a continuation of open-label treatment with infliximab 5 mg/kg, with infusions given at Weeks 54, 62, 70, 78, 86, and 94.

Study agent. Infliximab (Remicade®, Centocor, Inc., Malvern, PA, USA) was supplied in 20 ml vials containing 100 mg of lyophilized concentrate. Each infusion was administered over 2 h using an infusion set with an in-line, sterile, nonpyrogenic, low protein-binding filter (pore size of 1.2 μm) through a peripheral venous access site.

Concomitant medications. Patients were allowed concomitant therapy with stable doses of the following DMARD given as monotherapy: methotrexate (MTX), leflunomide, sulfasalazine, hydroxychloroquine, intramuscular gold, penicillamine, or azathioprine. Concomitant therapy with oral corticosteroids (10 mg prednisone equivalent/day or less) and nonsteroidal antiinflammatory drugs (NSAID) was permitted if doses were stable for at least 2 weeks prior to screening. During the open-label study extension, patients were permitted to lower the dose of concomitant DMARD, NSAID, or corticosteroids, or even to discontinue their use, if clinically indicated and approved by the treating physician.

Standard topical treatments for psoriatic lesions were permitted, provided they remained stable during stage I of the study, but psoralen plus ultraviolet A was not permitted throughout the study. Patients who received any previous treatment with a monoclonal antibody or fusion protein were ineligible.

Study procedures and evaluations. The primary efficacy assessment was the achievement of at least 20% improvement according to the American College of Rheumatology criteria (ACR20) for determining improvement in rheumatoid arthritis (RA)[16] at Week 98. Assessment of skin involvement was made using the Psoriasis Area and Severity Index (PASI)[17], which was scored at baseline and at Weeks 16, 50, and 98. For the PASI score, lesions were rated on the basis of erythema, scaling, thickness, and anatomic location (head, trunk, upper extremities, or lower extremities), with the involved area of each anatomical part factored into the overall value. The maximum possible PASI score is 72. Patients with a baseline PASI score of 2.5 or higher were included in the efficacy evaluation of the skin.

Additional response evaluations included the following: erythrocyte sedimentation rate; degree of tenderness in 68 joints and of swelling in 66 joints (0–3 grading scale); and number of digits, out of a possible 20, with dactylitis (0–3 grading scale). Patients were also evaluated using the PsA Response Criteria (PsARC)[18] and the disease activity score (DAS28)[19,20], and were assessed for the presence or absence of enthesitis.

Patients' assessments of pain and overall disease activity, and physicians' assessments of patient disease activity, were made using 0- to 10-cm visual analog scales; the 20-question Health Assessment Questionnaires (HAQ)[21] was also administered.

Radiographs of the hands and feet were obtained at baseline and Weeks 50 and 98. Original radiographs were sent to Bio-Imaging Technologies, Inc. for digitization. Digitized images for each patient were stored as a set (baseline and Weeks 50 and 98) in a random and blinded manner. Two central, independent, trained radiograph readers, both blinded to treatment arm and radiograph sequence, analyzed the digitized images. Bone erosion, joint space narrowing (JSN), and total radiographic scores were determined using a PsA-modified van der Heijde-Sharp (vdH-S) scoring method[22,23] that included, in addition to the joints scored in RA, the second through fifth distal interphalangeal joints of each hand to address the joint involvement considered characteristic of PsA. Erosions (on a scale of 0–5 for hands and 0–10 for feet) and JSN (on a scale of 0–4) were graded separately in 40 joints in both hands and 12 joints in both feet. The total PsA-modified vdH-S score (hands and feet combined) ranged from 0 to 528, with higher scores indicating more articular damage. In addition, the PsA-characteristic features of pencil-in-cup deformity and gross osteolysis were assessed. Radiographic damage was measured by comparing the average estimated annual radiographic progression before and during our study, and by assessing if the change in the modified vdH-S score from baseline to Week 98 was greater than the smallest detectable change (SDC) based on the limits of agreement[24]. In addition, no radiographic worsening at Week 98 was defined as a change from baseline in the modified vdH-S score that was 0.5 or less. Radiographic findings at Week 50 have been described[15].

Statistical methods. All 87 patients who completed the first year of the study

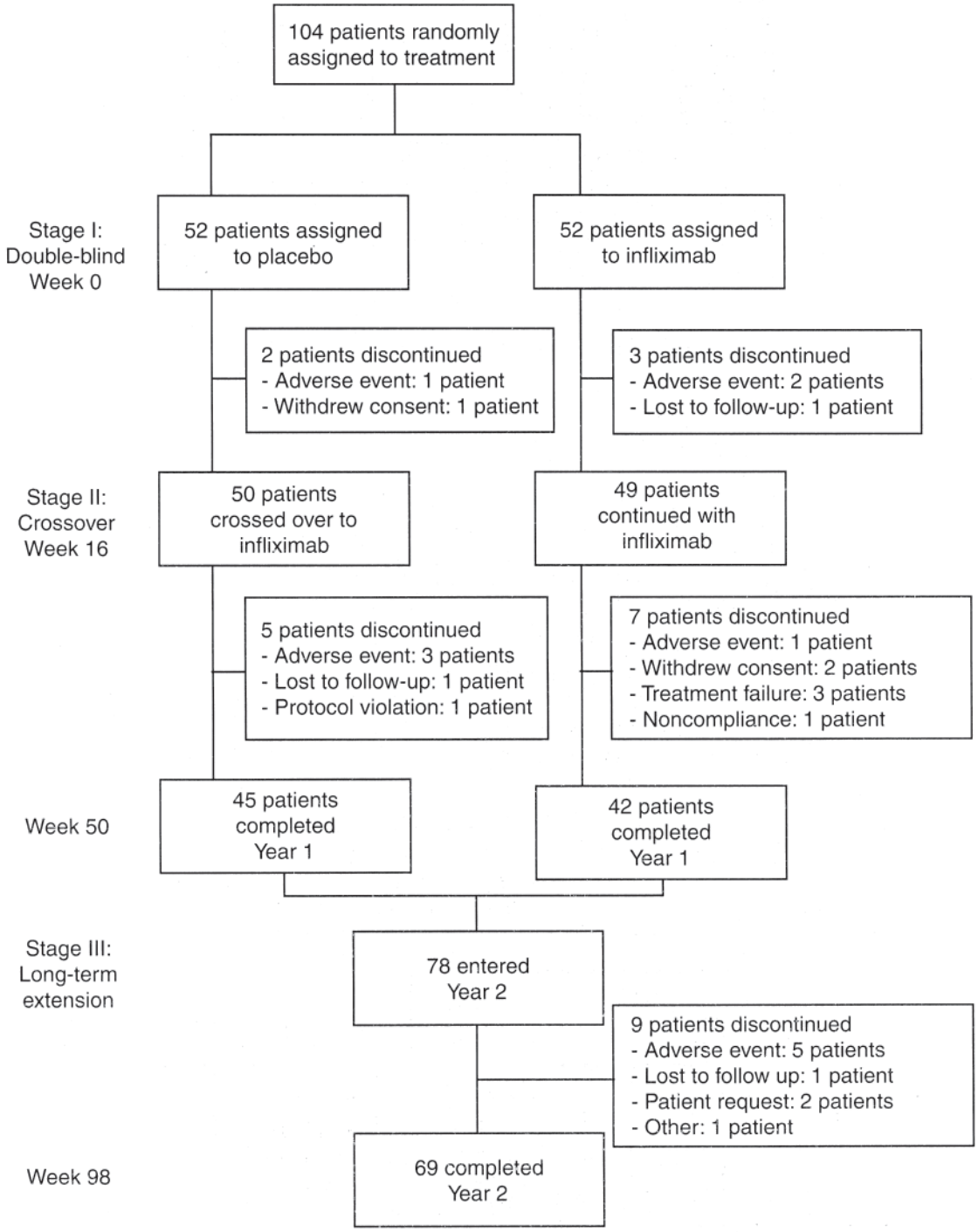

Figure 1. Study design and patient disposition. Patients initially assigned to the infliximab group received infusions of placebo at Weeks 16 and 18 in order to maintain the blind.

were eligible to enter the study extension. All these patients received infliximab starting at Week 0 (infliximab patients) or 16 (placebo/infliximab patients) of the study. This analysis describes the 78 patients who elected to continue into the study extension. In addition, only a subset (n = 43) of these patients had radiographic data available at both baseline and Week 98. Since a limited cohort of patients in this open-label phase was evaluated, no statistical hypothesis testing was performed on the longterm extension data. Summary statistics were used to summarize continuous data. Response data were summarized using frequencies and percentages. The primary efficacy endpoint was the proportion of patients achieving an ACR20 response at Week 98. For the purpose of this analysis, the Week 98 data are summarized for all patients combined, since all patients had a relatively long exposure to infliximab by Year 2, i.e., 82 weeks for placebo/infliximab patients and 98 weeks for infliximab patients, and any earlier treatment group differences would have been washed out by Week 98. Treatment failures, i.e., patients who initiated systemic or intraarticular corticosteroid treatment, added anoth-

er DMARD, increased the baseline dose of concomitant DMARD, or withdrew before completing the intended treatment period, were analyzed as nonresponders for ACR20 analyses from that point onward. Sensitivity analyses comparing results for the completers versus those patients unaccounted for were not conducted. A similar approach was employed for the additional measures of clinical efficacy presented in Table 2. Note that for continuous variables, patients who withdrew had their last observation carried forward as the endpoint observation.

The average estimated annual progression rates of radiographic damage during the first and second years of our study were calculated by dividing the changes from baseline and Week 50, respectively, in the modified vdH-S score by 50 and 48 weeks of followup, respectively, and multiplying by 52 weeks in a year[25,26]. The estimated average annual progression rate of radiographic damage for the 2-year period was calculated as the average of the first and second years. The average estimated annual progression rate of radiographic damage prior to infliximab treatment was calculated by dividing the modified vdH-S score at Week 0 by PsA symptom duration (yrs) under the assumption that the modified vdH-S score at the time of PsA symptom onset was 0. To assess the effect of infliximab treatment in preventing structural damage, the change from baseline in the total modified vdH-S score at Week 98 was determined in the 43 patients who had evaluable radiographic data at both baseline and Week 98. Two additional radiographic endpoints, i.e., proportions of patients with radiographic progression and with no radiographic worsening at Week 98, were determined.

RESULTS

Baseline characteristics, patient disposition, and concomitant therapy. Eighty-seven of the 104 enrolled patients completed the first year of our study, and 78 of these patients entered the longterm trial extension. Of these, 69 (88%) patients completed the study through Week 98 (Figure 1). Baseline characteristics for the 78 patients who participated in the study extension (Table 1) are similar to those of the overall study population[14]. Moreover, baseline characteristics were consistent between the overall study extension population (n = 78) and the subset of 43 patients with evaluable radiographs. Baseline use of concomitant medications is also summarized in Table 1. The majority of patients did not receive either a new treatment or increased doses of concomitant treatment with MTX, DMARD, or NSAID. Five patients began treatment with corticosteroids during the second year of the study; all these patients were regarded as treatment failures from the time they began corticosteroid therapy through the end of the study. No new trends were observed in the use of concomitant medications during the second year of the study.

Efficacy. Articular manifestations: As reported, a significantly higher proportion of infliximab-treated patients achieved the original primary endpoint of an ACR20 response at Week 16 (65%, 34/52) than did placebo-treated patients (10%, 5/52) ($p < 0.01$) during the double-blind portion of the study[14]. After 2 years of study participation, 62% (48/78) of the patients who entered the longterm study extension achieved an ACR20 response at Week 98. In addition, 45% (35/78) of infliximab-treated patients achieved an ACR50 response, and 35% (27/78) achieved an ACR70 response at Week 98. As shown in Figure 2, the response to infliximab therapy achieved within the first 16 weeks of the study was maintained through the Week 98 visit.

Clinically meaningful improvements from baseline to Week 98 were also observed in the individual components of the ACR, including the HAQ, among the infliximab-treated patients who participated in the longterm extension (Table 2). In addition, efficacy observed through Week 50 in the PsARC, DAS28, and in the number of digits with dactylitis and

Table 1. Baseline characteristics of the study population.

Characteristic	Infliximab 5 mg/kg	
	Patients Who Entered the 2-year Study Extension, n = 78	Patients Who Completed Year 2 and Had Radiographs Available for Analysis, n = 43
Women, n (%)	32 (41.0)	16 (37.2)
Age, yrs	45.9 ± 10.3	45.1 ± 10.8
Symptom duration of PsA, yrs	11.0 ± 7.6	9.9 ± 7.0
Selected ACR components		
No. of swollen joints (0–66)	14.6 ± 8.1	15.4 ± 8.9
No. of tender joints (0–68)	21.5 ± 11.4	20.7 ± 11.1
C-reactive protein, mg/l	27.7 ± 35.7	30.5 ± 39.0
Health Assessment Questionnaire (0–3)	1.1 ± 0.6	1.0 ± 0.6
Annual estimated rate of progression (modified vdH-S points/yr)	5.98	5.74
Medication use at baseline, n (%)		
MTX	44 (56.4)	—
DMARD other than MTX	11 (15.3)	—
Corticosteroids	29 (37.1)	—
NSAID	70 (89.7)	—

Values are n (%) or mean ± standard error. ACR: American College of Rheumatology; MTX: methotrexate; DMARD: disease modifying antirheumatic drugs; NSAID: nonsteroidal antiinflammatory drugs. PsA: psoriatic arthritis; vdH-S: van der heijde-Sharp score.

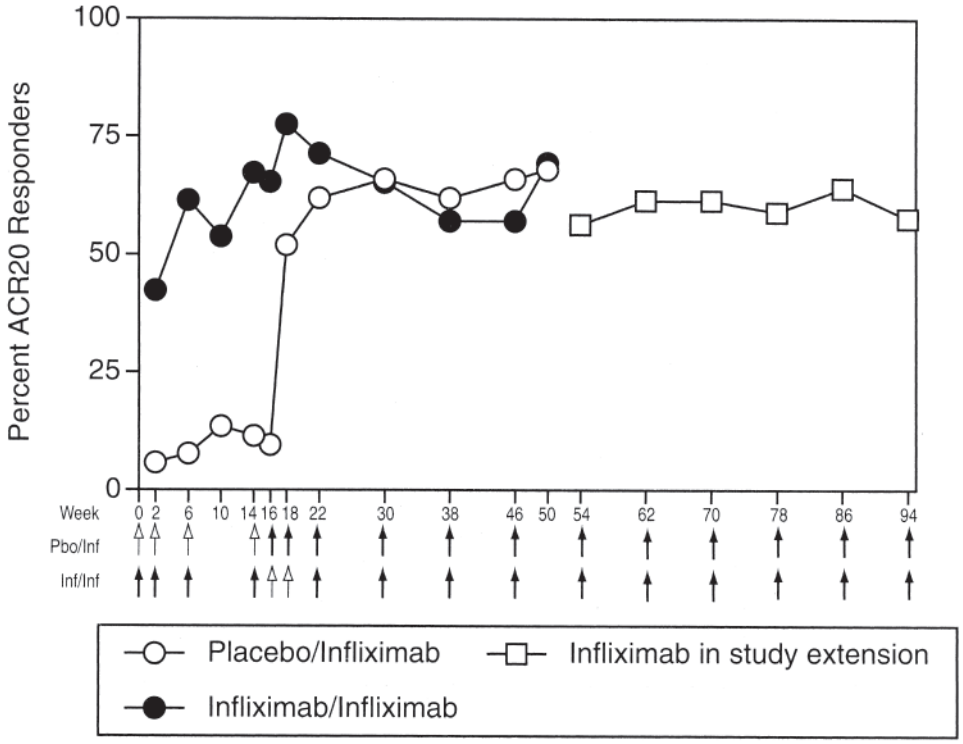

Figure 2. Percentages of patients achieving an ACR20 response through Week 98. Arrows indicate weeks at which infusions were administered: open arrows denote placebo infusions and filled arrows denote infusions of infliximab 5 mg/kg.

Table 2. Summary of clinical efficacy measures at Weeks 50 and 98.

Efficacy Measures	Week 50 Infliximab, n = 78	Week 98 Infliximab, n = 78
Proportion of patients meeting criteria % (n)		
ACR20	73.1 (57)	61.5 (48)
ACR50	50.0 (39)	44.9 (35)
ACR70	39.7 (31)	34.6 (27)
Percentage improvement (mean ± SD unless otherwise noted) in ACR components and other measures		
Tender joint count	64.0 ± 42.9	50.8 ± 76.0
Swollen joint count	75.7 ± 36.1	58.9 ± 64.5
Patient pain assessment	56.1 ± 42.8	46.4 ± 44.6
Global disease assessment		
Patient	50.9 ± 53.1	40.3 ± 58.0
Physician	70.2 ± 30.3	54.8 ± 48.0
CRP	51.7 ± 57.1	16.1 ± 132.5
HAQ	48.8 ± 55.4	37.7 ± 71.8
DAS28	48.0 ± 25.8	42.4 ± 32.9
Enthesitis, n (%)	7 (9.0)	10 (12.8)
No. of digits with dactylitis, mean ± SD	0.32 ± 0.96	0.19 ± 0.72*
PsARC, n (%)	61 (78.2)	52 (66.7)

* At the end of Year 2, the mean (± SD) number of digits with dactylitis was 0.40 ± 1.81. ACR: American College of Rheumatology; CRP: C-reactive protein; HAQ: Health Assessment Questionnaire; DAS: Disease Activity Score; PsARC: Psoriatic Arthritis Response Criteria.

patients with enthesitis was generally maintained through Week 98 (Table 2).

Radiographic findings: The study protocol required that radiographs of the hands and feet be taken at baseline, Week 50 and *possibly* at Week 98. Therefore, not all patients had radiographs performed at Week 98. Among the 78 patients

who consented to enter the second year of the study, 43 had radiographs of both hands and feet at both baseline and Week 98. In the placebo group, 4 patients discontinued from the study with no Week 98 radiographs and 12 completed the study but had no radiographs at Week 98. In the infliximab group, 3 patients discontinued from the study with no Week 98 radiographs and 16 completed the study but had no radiographs at Week 98 (n = 14) or baseline (n = 2).

Among the 43 patients who had evaluable radiographs at baseline and Week 98, the mean (SD) and median total modified vdH-S scores at baseline were 36.13 (54.39) and 10.00, respectively, and at Week 98 were 37.35 (54.42) and 10.50, respectively. Mean (SD) and median changes from baseline to Week 98 in the total modified vdH-S score were 1.23 (8.67) and 0.00, respectively. At Week 98, 77% (33/43) of infliximab-treated patients had no worsening in radiographic progression, defined as a change from baseline in the modified vdH-S score that was 0.5 or less. In addition, only 9% (4/43) of patients had radiographic progression, defined as a change from baseline in the total modified vdH-S score greater than the SDC (SDC = 9.25). The PsA-characteristic radiographic features of gross osteolysis and pencil-in-cup deformity remained stable over the 2-year treatment period.

The mean (SD) estimated annual progression rate at baseline was 5.74 (15.94) modified vdH-S points. After 2 years of infliximab treatment, the mean (SD) estimated annual rate of progression had decreased to 0.65 (4.65) modified vdH-S points per year.

Dermatologic response: Note that since the protocol did not require the presence of psoriasis at the time of enrollment, some patients enrolled without psoriasis. In addition, 2 study sites did not perform baseline PASI assessments. As a result of these factors, 67 patients were evaluated for PASI at baseline, and only 46 of these patients also had PASI evaluations performed at the end of the second year of the study and thus had had both baseline and Week 98 PASI evaluations. In this subgroup of patients, the mean (SD) PASI scores were 5.7 (6.79) at baseline, 1.2 (1.73) at Week 50, and 1.5 (2.73) at Week 98 (Figure 3). Twenty-five of these patients had PASI scores of 2.5 or more at baseline and were therefore eligible for evaluation of PASI improvement. The percentages of patients with PASI improvement of at least 50%, 75%, and 90% at Week 50 were 80%, 60%, and 44%, and at Week 98 were 76%, 64%, and 48%, respectively.

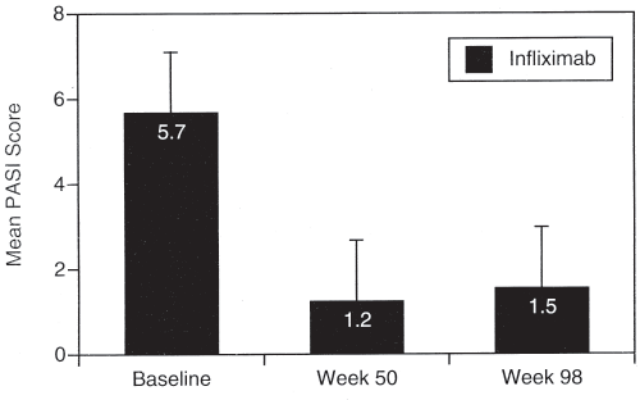

Figure 3. Psoriasis Area and Severity Index (PASI) scores (mean ± standard error) at baseline, Week 50, and Week 98 for the 46 patients with PASI evaluations at baseline and Week 98.

Adverse events. A summary of adverse events by treatment group during the longterm extension is provided in Table 3. The most frequently reported (i.e., those reported by > 5% of patients) treatment-emergent adverse events during Year 2 were: upper respiratory tract infection, 30 patients (38%); headache, diarrhea, pharyngitis, and psoriatic arthropathy, 7 patients each (9%); fatigue and abdominal pain, 6 patients each (8%); hypertension, antinuclear antibody positivity, nausea, alanine aminotransferase increased, 5 patients each (6%); and allergic reaction, dyspepsia, sinusitis, urinary tract infection, aspartate aminotransferase increased, arthralgia, arthritis aggravated, musculoskeletal pain, anxiety, depression, epistaxis, 4 patients each (5%). Most adverse events were mild to moderate in intensity.

Five patients discontinued study agent due to adverse events, all related to worsening of their PsA or psoriasis. One of these patients also had an infusion reaction that necessitated cessation of study therapy. Seven patients (9%) reported a total of 13 serious adverse events during the longterm study extension. The 13 events comprised 4 surgical procedures; 2 events of atrial fibrillation (occurring in the same patient); 2 infections (knee wound and bowel); 2 neoplasms (benign abdominal mucinous cystoma and nonresectable pancreatic ductal adenocarcinoma); and 1 event each of urinary incontinence, abdominal pain, and exacerbation of psoriasis. There were 2 additional neoplasms that were not reported as serious adverse events: 1 patient had a mild hemangioma and another had leukocythemia (literal term) that was incorrectly coded to the term of leukemia.

Infusion-associated adverse events were defined as reactions that occurred during or directly after infliximab infusion as determined by investigator. During the second year of the study, 4 patients experienced infusion-associated adverse events; all except 1 event were mild or moderate in intensity. One patient had a severe infusion reaction consisting of rash,

Table 3. Summary of adverse events through Week 98. All values n (%).

Adverse Event	Infliximab, n = 78
Adverse events	
All events	74 (94.9)
Treatment-related events	52 (66.7)
Influsion-associated adverse events	
All events	4 (5.1)
Treatment-related events	4 (5.1)
Serious adverse events	
All events	7 (8.9)
Treatment-related events	4 (5.1)

flushing, and cough that resulted in discontinuation from the study.

No patients reported lupus-like symptoms or tuberculosis during the longterm extension. In addition, no patients discontinued treatment due to abnormal laboratory test results.

DISCUSSION

PsA is a chronic, progressive disease, with measurable changes even at early onset that are associated with more radiological joint damage than was previously known[27]. We report that infliximab was an effective and, in general, well tolerated therapy in patients with PsA who participated in the IMPACT study for 2 years. Seventy-three percent of patients achieved at least 20% improvement in the ACR criteria at Week 50, and patients continued to experience improvement in their arthritis through the second year in the study extension (Week 98, 62% of patients with ACR20 response). Also at Week 98, more than 82% of patients showed articular improvement with a "moderate" or "good" DAS28 response. On average, DAS28 scores improved 48.0% and 42.4% from baseline at Weeks 50 and 98, respectively. Improved physical function, assessed using the HAQ, was apparent in infliximab-treated patients, with scores that approached "normal" levels of function in many patients by Week 50 (mean percentage improvement of 48.8% from mean baseline score of 1.1); at Week 98 there was a mean percentage improvement of 37.7% from baseline. Together, these Week 98 data represent maintenance of a clinically meaningful improvement from baseline. The findings are especially impressive considering that 69 of the 78 (88%) patients who entered the study extension at 1 year remained in the study through Year 2.

Previously reported findings of the IMPACT study indicate that the initial onset of patient improvement in articular and dermatologic measures was rapid and evident by 2 weeks after the first infusion of infliximab[14]. We have also reported that infliximab inhibits radiographic progression in patients with PsA through Week 50[15]. While the average (SD) estimated annual progression rate at baseline was 5.74 (15.94) modified vdH-S points, progression had decreased to 0.65 (4.65) modified vdH-S points per year after 2 years of infliximab treatment. In addition, through Week 98, 77% of infliximab-treated patients had no radiographic worsening (i.e., change in vdH-S score from baseline $\leq$ 0.5), also indicating that inhibition of radiographic progression was maintained through 2 years. Note that this decline in radiographic progression could be treatment related, but it is also possible that it may partially reflect "nonlinear" progression of damage in PsA, with more damage occurring in earlier disease stages, as suggested by Gladman, *et al*[26].

In addition to sustained benefits in joint symptoms, patients treated with infliximab showed rapid and sustained improvement in skin psoriasis. Summary data for PASI improvement (50%, 75%, and 90%) at Weeks 50 and 98 indicate that significant improvement was achieved during the first year of treatment and that comparable improvement was maintained through the second year.

Infliximab was generally well tolerated by all study participants during the IMPACT study extension. The observed adverse events during the second year of the study were similar to those reported during the first year[14]. The safety profile observed during the second year was also generally consistent with other reports from clinical trials evaluating anti-TNF treatment in other arthritides[28-30].

As discussed, findings from the present evaluation of infliximab in PsA indicated that a majority of patients experienced improvement in their disease after 2 years. The challenge for the future will be to identify patients most likely to be responders, resulting in more aggressive treatment and earlier intervention[31]. Of special concern are younger patients and those in early-stage PsA, as well as patients who are in progressive and rapid decline. Peak onset of PsA occurs between 30 and 55 years of age during the prime working years, and measurable and clinically significant decline generally follows within 10 years of early onset. Despite improvement with current DMARD treatment, PsA results in radiological damage in up to 47% of patients at a median interval of 2 years[27]. Thus, our observations indicating that there is a potential to change the structural damage aspect of PsA with infliximab therapy are especially salient.

Our radiographic findings are limited by the fact that fewer than half (41%, 43/104) of the patients who initially entered the IMPACT study and completed the longterm study had radiographs available for analysis at Week 98. In addition, during the second stage of the study, all patients received open-label infliximab 5 mg/kg, with no placebo control. It is important to note, however, that the radiographic findings of the current analysis of Week 98 data from the IMPACT trial are supportive of observations from the IMPACT 2 trial. The IMPACT 2 trial was a double-blind, placebo-controlled study of 200 patients with active PsA who received infliximab 5 mg/kg or placebo at Weeks 0, 2, and 6 and every 8 weeks thereafter through Week 54. In the IMPACT 2 trial, infliximab significantly inhibited radiographic progression in patients with PsA as early as 6 months after starting treatment, and the beneficial effect continued through 1 year of infliximab therapy[11].

Infliximab was generally well tolerated by study participants who completed the first year of the IMPACT study and continued into the second year extension. By Week 98, more than 82% of infliximab-treated patients showed articular improvement, with a "moderate" or "good" DAS28 response, 62% achieved an ACR20 response, and average estimated annual radiographic progression decreased significantly with infliximab treatment relative to baseline progression.

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