Implementation of the OMERACT Psoriatic Arthritis Magnetic Resonance Imaging Scoring System in a randomized phase IIb study of abatacept in psoriatic arthritis

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Abstract

Objectives. To investigate if the OMERACT PsA MRI Scoring System (PsAMRIS), including a novel total inflammation score, shows sensitivity to change with an agent (abatacept) known to impact clinical outcomes in PsA.

Methods. We performed a post hoc analysis of a randomized phase IIb study of abatacept in patients with PsA and inadequate DMARD response. Participants received one of three abatacept dosing regimens [ABA3, ABA10 or ABA30/10 mg/kg (30 mg/kg switched to 10 mg/kg after two doses)] or placebo until day 169, then ABA10 through day 365. MRIs at baseline and days 85, 169 and 365 were centrally evaluated by two readers blinded to chronological order and treatment arm. Synovitis, osteitis, tenosynovitis, periarticular inflammation, bone erosions, joint space narrowing and bone proliferation were assessed using the PsAMRIS. A novel total inflammation score was tested.

Results. MRIs for 123 patients were included. On day 169, ABA10 and ABA30/10 significantly reduced MRI synovitis and tenosynovitis, respectively, vs placebo [differences \(-0.966 (P = 0.039)\) and \(-1.652 (P = 0.014)\), respectively]. Synovitis in the placebo group increased non-significantly from baseline to day 169, total inflammation and tenosynovitis decreased non-significantly and all measures improved significantly after a switch to ABA10 \([-1.019, -0.940, -2.275 (P < 0.05)\), respectively, day 365 vs day 169]. Structural outcomes changed minimally across groups.

Conclusion. Adults with PsA receiving ABA10 and ABA30/10 mg/kg demonstrated significant resolution of inflammatory components of disease, confirmed by MRI, with synovitis and tenosynovitis improvements consistent with previously reported clinical responses for these doses. Results indicate that a reduction in OMERACT PsAMRIS inflammation scores may provide proof of tissue-level efficacy in PsA clinical trials.

Registration. ClinicalTrials.gov (https://clinicaltrials.gov), NCT00534313.

Key words: MRI, DMARDs, spondylarthropathies (including psoriatic arthritis), hand, foot, inflammation
Introduction

PsA is an inflammatory arthritis that occurs in up to one-third of patients with psoriasis and is usually diagnosed years after the appearance of psoriatic skin disease [1, 2]. Abatacept is indicated for the treatment of adults with active PsA based on phase II and III research that showed abatacept was associated with significantly higher 20% improvement in ACR criteria (ACR20) response rates compared with placebo [3–6]. As a naïve T cell activation inhibitor, abatacept exerts therapeutic benefit via competitive binding to CD80 or CD86, thereby decreasing serum levels of cytokines and inflammatory proteins implicated in the pathogenesis of PsA [7].

There have been very few studies utilizing the tissue sensitivity of MRI in PsA. The multidose, randomized phase IIb study of abatacept in patients with PsA with inadequate response to DMARDs (IM101-158; NCT00534313 [6]) used MRI assessments of hand or foot joint inflammation and damage as exploratory efficacy outcome measures, applying an MRI scoring method that was developed for RA and modified for PsA. The international OMERACT MRI in Arthritis Working Group subsequently developed and validated the PsA MRI Scoring System (PsAMRIS), incorporating features characteristic of PsA, such as periarticular inflammation (including enthesitis) and tenosynovitis [8–10]. The PsAMRIS was formulated for assessing PsA pathology in the MCP, PIP and DIP joints [11]. The application of the PsAMRIS to the hand has previously shown moderate to high intrarater and interrater agreement and has proved sensitive to change in small observational cohorts [6, 10–12]. The PsAMRIS then demonstrated reliability and responsiveness at the hand or foot level in a subsequent pilot study using a subset of IM101-158 MRI data (image sets from 20 patients chosen for hands and 20 for feet, acquired at baseline and 6 months) [9].

The objective of this study was to determine whether the OMERACT PsAMRIS shows sensitivity to change with an agent known to impact clinical outcomes in PsA. We conducted a retrospective analysis of all the MRI data from the phase IIb study of abatacept in PsA (IM101-158), both from the initial placebo-controlled period (baseline–month 6) and the open-label extension (month 6–month 12), using the PsAMRIS, and also including a novel score for total MRI inflammation. Using such a score has the advantage of providing comprehensive information from individual inflammatory components in a more succinct form as one composite measure of MRI inflammation.

Methods

Study design

The design of the clinical trial has been published previously [6] and is summarized briefly here. This was a 6-month, multicentre, randomized, double-blind, multiple dose-level, placebo-controlled study. Patients with PsA were randomized 1:1:1:1 to placebo or one of three abatacept regimens [3, 10 or 30/10 mg/kg (30 mg/kg on days 1 and 15, followed by the weight-tiered dose of 10 mg/kg)]. Treatments were administered as 30-min i.v. infusions on days 1, 15 and 29 and every 28 days thereafter. Patients who completed the 6-month double-blind period were given the weight-tiered abatacept dose of 10 mg/kg, administered monthly starting on day 169 for the duration of the 18-month open-label period. The study design is shown in Supplementary Fig. S1, available at Rheumatology online.

Ethics

The study was conducted in accordance with the Declaration of Helsinki [13] and the International Conference on Harmonization Good Clinical Practice Guidelines [14]. The study protocol and patient enrolment materials were approved by local ethics committees and regulatory agencies in each participating country prior to initiation of the study.

Patients

Adult patients who met the criteria of the Classification of PsA Study Group [15] and had active arthritis (defined as the presence of three or more swollen joints and three or more tender joints), active plaque psoriasis (with at least one qualifying target lesion ≥2 cm in diameter) and a disease duration of ≥3 months were eligible for enrolment in the study. Patients were required to have had an inadequate response to DMARDs including, but not limited to, MTX or anti-TNF agents.

Study assessments and endpoints

Patient demographics and disease characteristics were recorded by treatment line. The primary endpoint of the original study was an ACR20 response (defined as an improvement of ≥20% in the ACR core criteria) on day 169. Other clinical assessments were secondary outcomes and various MRI parameters of joint involvement were exploratory outcomes. The current post hoc analysis focused mainly on changes in MRI evidence of inflammation based on the PsAMRIS, as described in the next section.

Design of the MRI analysis

The MRI acquisition protocol included imaging of joints in a single hand or single foot at baseline and on days 85, 169 and 365; sequences included axial T1 weighted (T1w), coronal and sagittal T2 weighted (T2w), coronal short tau inversion recovery (STIR), axial T1w post-contrast (T1w+i) and coronal three-dimensional T1w+ images. The selection of the hand or foot to be imaged followed these rules: hand or foot most affected by PsA; hand or foot with no surgical interventions previously performed; no plan at study entry for surgical intervention on the selected hand or foot for the duration of the study; if both hands and both feet were asymptomatic,
the investigator chose a foot to be imaged; and the hand or foot chosen at baseline was imaged throughout the study. In this analysis, MRI scans were centrally evaluated by two readers blinded to treatment, clinical information and chronology of acquisitions.

Readers undertook training and calibration on the image set at a 2-day face-to-face meeting prior to formal reading. Hands were scored based on the second–fifth MCP joint region, second–fifth PIP joint region and second–fifth MCP joint region [8, 16, 17]. MRIs of the feet were scored based on the first–fifth MTP joint region and first IP joint region [9]. Scores, according to the OMERACT PsAMRIS, were based on the following components: synovitis, scored 0–3 at each joint; tenosynovitis, scored 0–3 at each joint; bone marrow oedema, scored 0–3 for the proximal side and 0–3 for the distal side of each joint; periarticular inflammation, scored 0 or 1 for the palmar side and 0 or 1 for the dorsal side of each joint; bone erosions, scored 0–10 for the proximal side and 0–10 for the distal side of each joint; joint space narrowing, scored 0–4 for each joint space; and bone proliferation, scored 0 or 1 for each joint [8, 9, 16]. Additionally, the total inflammation score was defined as the sum of synovitis + tenosynovitis + bone marrow oedema + periarticular inflammation. As twice as many joints were measured in the hand vs in the foot, foot scores were doubled before selecting adjudication cases to normalize them to hand scores, so that the selection was not biased towards the hands. Additional details of scoring methods are shown in Supplementary Table S1, available at Rheumatology online. For each component, the total score for each reader was computed as the sum of individual joint scores. The change from baseline in total score was computed and the largest discrepancies between readers for day 169 change were adjudicated in a consensus session in which the images for all time points were reviewed and final scores were determined by agreement between the readers. In total, 71 components (the 10 most discrepant results for each of seven features, including a ‘tie’ for one feature where patients 10 and 11 had the same discrepancy) among 52 patients were adjudicated. For statistical analysis of treatment effects, the average of the two readers’ total scores was used unless consensus scores were available.

Statistical analyses

To evaluate the changes in the OMERACT PsAMRIS scores between treatment groups at each time point, the change from baseline was analysed using a linear mixed-effects model, with treatment, visit and treatment-by-visit interaction as fixed effects and baseline MRI value as a fixed covariate. The adjusted mean change from baseline (95% CI) per treatment and adjusted mean differences between the abatacept and placebo groups (unadjusted P-values) at each time point were reported. To evaluate the adjusted mean change from baseline per treatment group over time, raw MRI values were modelled using a similar linear mixed-effects algorithm. Comparisons between follow-up and baseline scans in each treatment group were performed. Tukey-adjusted P-values for multiple comparisons were reported. No imputation of missing data was done. To account for missing values, the parameter estimations were based on the assumption that data were missing at random and the restricted maximum likelihood method was used. Correlations between clinical and MRI assessments (baseline and change from baseline) were measured with Spearman’s coefficients. Kruskal–Wallis global P-values were provided for baseline PsAMRIS parameters across treatment groups.

Subanalyses of changes in PsAMRIS parameters focused on hand images only, hand images of MCP + PIP excluding DIP joints only, and foot images only were performed by calculating the corresponding change in scores from baseline.

Results

Demographics and baseline characteristics

Table 1 shows the demographics and baseline clinical and MRI characteristics for the 123 patients who provided data usable for this analysis (71 hand cases and 52 foot cases). At baseline, OMERACT PsAMRIS assessments did not differ significantly, although PsAMRIS parameters of inflammation were numerically lower in the placebo vs active groups (total inflammation was 6.93 in the placebo group compared with 11.60, 14.54 and 11.64 in the abatacept 30/10, 10 and 3 mg/kg groups, respectively; P = 0.11). Representative MRI images of changes over time are shown for hand joints (Fig. 1) and foot joints (Fig. 2).

Changes from baseline to day 169 (placebo-controlled period) and day 365

At day 169, four parameters showed statistically significant changes (improvement) from baseline based on the least square mean change in the abatacept 30/10 mg/kg group: total inflammation [−3.03 (95% CI −4.90, −1.15)], synovitis [−0.82 (−1.44, −0.19)], bone marrow oedema [−1.16 (−1.82, −0.50)] and periarticular inflammation [−0.53 (−0.91, −0.15)]. Additionally, two parameters showed significant changes from baseline based on the least square mean change in the abatacept 10 mg/kg group: total inflammation [−3.12 (−5.14, −1.10)] and tenosynovitis [−1.71 (−2.63, −0.80)] (Fig. 3, left). The structural outcomes, joint space narrowing and bone erosion, remained stable within each treatment group, showing little change from baseline to days 85, 169 and 365. Supplementary Fig. S2 (available at Rheumatology online) shows changes over time in PsAMRIS variables for each treatment group, adjusted for baseline, and Supplementary Table S2 (available at Rheumatology online) shows the difference vs placebo in the change from baseline in all PsAMRIS parameters for all active treatments at days 85, 169 and 365. The day 169 improvements from baseline in severity of synovitis and
Changes from day 169 to 365 were investigated. Patients originally randomized to placebo switched at day 169 to abatacept 10 mg/kg and showed statistically significant improvements in total inflammation (\(C_0^2.28; P = 0.04\)), synovitis (\(C_0^1.02; P = 0.03\)) and tenosynovitis (\(C_0^0.94; P = 0.02\)) from day 169 to 365 (Fig. 3, right).

Subgroup analyses
Changes in hands and feet were evaluated separately (Supplementary Fig. S3, available at Rheumatology online). Results showed that the change from baseline in foot synovitis at day 169 was significantly different (improved) for abatacept 3 mg/kg vs placebo (\(-1.69; P = 0.02\)) and the change in hand tenosynovitis at day 169 was significantly different (improved) for abatacept 10 mg/kg vs placebo (\(-2.33; P = 0.01\)).

Supplementary Fig. S4 (available at Rheumatology online) shows the adjusted mean change from baseline in the hand. In summary, significant decreases were seen at day 169 for total inflammation and tenosynovitis in the 10 mg/kg group. Periarticular inflammation decreased at days 85 and 169 in the 30/10 mg/kg group. Results were somewhat inconsistent across treatment groups, time points and joint collections (all joints, MCP + PIP, etc.), likely reflecting the small sample size and limited statistical power. Significant changes were more often seen for all joints and MCP + PIP joints. During the open-label period...
In terms of construct validity, at baseline several PsAMRIS variables were weakly correlated with the 28-joint DAS (DAS28) score, including tenosynovitis and total inflammation [correlation coefficients were both 0.2 (\(P = 0.02\))] (Supplementary Fig. S5, available at Rheumatology online). Supplementary Fig. S6 (available at Rheumatology online) shows correlations between changes in clinical and MRI variables from baseline to day 169. For instance, the change in total inflammation had a moderate positive correlation (\(P < 0.05\)) with the change in DAS28 score, tender joints and CRP (correlation coefficient 0.38 for all). Additionally, the change in swollen joints was moderately correlated with the change in tenosynovitis (correlation coefficient 0.38).

**Discussion**

In this blinded retrospective analysis of MRIs from a randomized placebo-controlled phase IIb study of...
patients with PsA using the dedicated OMERACT PsAMRIS, 6 months of abatacept 30/10 mg/kg and abatacept 10 mg/kg statistically significantly reduced (improved) levels of synovitis and tenosynovitis in the hands and feet compared with placebo. This finding was consistent with the clinical response at day 169 for these two doses, as seen in the initial publication of this study [6]. To the best of our knowledge, this is the largest study of MRIs of the hands and feet from a global, multicentre, randomized clinical trial in PsA.

In the primary study, assessment of three abatacept dosing regimens compared with placebo in patients with PsA showed that patients receiving 10 mg/kg as a maintenance dose achieved the greatest improvements in the signs and symptoms of arthritis, physical function and quality of life [6]. The results from the current tissue-level imaging analysis confirmed the clinical outcomes. The inflammatory components of the PsAMRIS for the placebo participants were stable or deteriorated during the 6 months of the double-blind period before a

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**Fig. 2** MRIs demonstrating improvement over time in foot MTP joints in the (A) axial and (B) coronal planes

Images are axial T1-w pre- and post-contrast MRI scans (A) and coronal pre-contrast short tau inversion recovery (STIR) and post-contrast T1-w scans (B). Baseline [day 1] images show synovitis [in MTPs 1 (mild)–4; thin arrows], flexor tenosynovitis [in MTPs 2 and 3; thick arrows] and bone marrow oedema [in MTPs 2 and 4; arrowheads], with marked improvement at day 169. The two readers scored the change in total inflammation score [the sum of synovitis + tenosynovitis + bone marrow oedema + periarticular inflammation] for this patient as improvements of 16 and 15, respectively.
significant improvement was seen when the participants were switched to abatacept 10 mg/kg. Structural damage outcomes were generally stable and with limited change for all groups during the 1-year observation period.

This study demonstrated several important characteristics of the OMERACT PsAMRIS. The inflammatory components including synovitis, tenosynovitis and bone marrow oedema were the most responsive, as expected. Although sums of scores of inflammatory components have previously been calculated per finger and per joint group [18], this study is the first to apply the PsAMRIS total inflammation score per hand and foot. This novel score showed similar patterns in the change from baseline as the synovitis and tenosynovitis scores. The advantage of using a total inflammation score is that it provides one value representing a comprehensive picture of the inflammatory activity in the investigated anatomical region. In RA, a total inflammation score was a predictor of successful tapering of therapy in patients in remission [19] and was shown to be sensitive to change in a randomized controlled trial [20]. Our results encourage further validation and use of the PsAMRIS, as the approach may be helpful in future clinical trials and in clinical practice in patients with PsA. The total inflammation score represents another step in the development of the PsAMRIS following the original hand system [8].

The analysis of hand scans separate from foot scans showed that abatacept 30/10 or 10 mg/kg treatment was associated with significant improvement from baseline in several PsAMRIS assessments and that this could be seen even in the smaller sample limited to hand scans. Expansion of the use of PsAMRIS criteria to scans of the foot (20 sets of scans) had been done on a small scale in the validation of the criteria [9]. In that work, abatacept treatment was found to be associated with significant improvement in synovitis in the MTP joints of the foot; this was mirrored in the present analysis, as synovitis of the foot was improved by abatacept therapy.

Limitations of this study include the small size of the cohorts (~30 patients/arm) and the lack of balance with respect to MRI scores between treatment arms—the abatacept 10 mg/kg group had numerically higher structural damage and inflammation scores at baseline than other groups, while the placebo group had numerically lower structural damage and inflammation scores at baseline than other groups. Additionally, there was a low level of MRI abnormalities at baseline; this has to be considered carefully in PsA trials where the extent and severity of inflammation may be less than in RA. The MRIs were acquired during the study period from 2007 to 2011 and thus the image quality did not always meet current expectations for image quality. Additionally, images were not optimally acquired for all pathologies, e.g. detection of erosions and erosion progression was reduced by the lack of T1w images in two planes, which were recommended in the original PsAMRIS and in European Society of Musculoskeletal Radiology guidelines.

All patients switched to abatacept 10 mg/kg after day 169. Error bars are standard errors. *Significant change from baseline to day 169 based on least squares mean and 95% CI. **Significant difference in change from day 169 to 365, based on an unadjusted $P$-value <0.05. $^a$Novel PsAMRIS defined as the sum of synovitis + tenosynovitis + bone marrow oedema + periarticular inflammation. Figure adapted from poster POS1040 from the EULAR European Congress of Rheumatology 2021, 2–5 June 2021, © the authors.
[8, 21]. The study design called for images to be taken of the foot if patients were asymptomatic in both hands and feet, which suggests lower disease activity and baseline scores in the feet, potentially limiting the ability to assess change in both inflammation and joint destruction in the feet. Although no comparison of hands and feet was performed, the potential heterogeneity caused by pooling data from the hands and feet should also be considered; if it had been feasible, both hands and both feet of each patient would ideally have been examined by MRI. However, the pooled approach was prespecified, and previous work suggests that responsiveness of the PsAMRIS to change in the foot is similar to that of the hand [9].

In conclusion, this post hoc analysis of a randomized placebo-controlled study found that abatacept (30/10 and 10 mg/kg doses) was associated with greater improvement from baseline in synovitis and tenosynovitis, respectively, compared with placebo, confirming the clinical outcomes. The greatest changes from baseline demonstrated by the OMERACT PsAMRIS following treatment with abatacept were in the inflammatory components. These findings add to previous research using the PsAMRIS method by applying this scoring system in a randomized controlled trial for the first time, as well as including a novel total inflammation score and broader application of the criteria to both foot and hand MRI scans. The results encourage further use of PsAMRIS scoring in observational cohorts and clinical trials for objective assessment of the influence of new drugs on joint inflammation and damage progression in PsA.

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Data availability statement

De-identified patient-level data can be made available upon request. Bristol Myers Squibb’s policy on data sharing may be found at https://www.bms.com/researchers-and-partners/independent-research/data-sharing-request-process.html.

Supplementary data

Supplementary data are available at *Rheumatology* online.

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