A comparison of clinical examination and ultrasound enthesitis indices in patients with psoriatic arthritis, adjusted for concomitant fibromyalgia

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Abstract

Objectives: To: (a) determine the extent of ultrasound (US)-detected peripheral enthesitis in a cohort of patients with psoriatic arthritis (PsA); (b) compare this with three clinical examination (CE) enthesitis indices; and (c) determine the effect of concurrent fibromyalgia on the evaluation of enthesitis.

Methods: A prospective single-centre cross-sectional study of consecutive outpatients with established PsA undergoing clinical examination for enthesitis and US examination for inflammatory and structural lesions of enthesitis. Multivariable analyses tested for association between US scores, CE enthesitis indices and influence of concurrent fibromyalgia.

Results: A total of 106 patients were assessed. Of these, 91/106 (85.8%) had CE enthesitis and 105/106 (99.1%) had ⩾1 US feature of enthesitis. There was a moderate correlation between US entheseal inflammation and both the Leeds Enthesitis Index (LEI) (Spearman rank, $r = 0.36$) and Spondyloarthritis Research Consortium of Canada Enthesitis Index (SPARCC) ($r = 0.44$). US entheseal damage did not correlate with CE enthesitis indices. Twenty-eight (26.4%) patients were classified as having concurrent fibromyalgia, in whom multivariable regression analyses demonstrated no correlation between US scores and CE enthesitis indices. PsA patients without fibromyalgia demonstrated a statistically significant association between both LEI ($r = 0.48$, $p < 0.0001$) and SPARCC ($r = 0.62$, $p < 0.0001$) and US entheseal inflammation.

Conclusion: There is a moderate association between US entheseal inflammation, but not damage, and CE enthesitis indices in patients with PsA. The presence of concurrent fibromyalgia is linked with higher CE enthesitis scores, without an increase in US inflammation, suggesting that CE enthesitis indices should be used/interpreted with caution in these patients. Imaging, including US, should be the preferred modality to detect enthesitis in PsA patients with concurrent fibromyalgia.

Keywords: enthesitis, fibromyalgia, musculoskeletal ultrasound, psoriatic arthritis

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Introduction

Enthesitis is a hallmark clinical and pathological feature of psoriatic arthritis (PsA).[1] Prior studies estimate the point prevalence of enthesitis in PsA cohorts to be 10–50%.[2,3] In patients with PsA, enthesitis is associated with higher disease activity,[4] greater pain, sleep disturbance,[5] and poorer quality of life.[6] Enthesitis has become an important outcome in clinical trials, although the optimal method to assess enthesitis is unclear.

Conventionally, enthesitis has been ascertained by clinical examination, defined as tenderness at the entheseal site. Several clinical examination (CE) enthesitis tools have been developed. The Leeds Enthesitis Index (LEI) was developed

specifically for PsA, while others were developed for ankylosing spondylitis (Maastricht Ankylosing Spondylitis Enthesitis Score; MASES), or spondyloarthritis in general (Spondyloarthritis Research Consortium of Canada Enthesitis Index; SPARCC). Although CE enthesitis scores have been shown to correlate with global disease activity measures, all have limitations.[7] It is not clear whether tenderness always denotes soft-tissue inflammation, whether tenderness occurs from structural damage, or whether the absence of tenderness excludes enthesitis.[8]

While clinical examination is not always able to identify specific disease characteristics, ultrasound (US) allows accurate visualisation of both features of structural damage and inflammation.[9,10] Several US enthesitis scoring systems have been developed; however, each incorporates different elementary lesions, and therefore comparisons across studies are problematic.[11] In 2014 an Outcome Measures in Rheumatology (OMERACT) task force defined elementary lesions of US enthesitis, and in 2018 the group produced a standardised definition of US-detected enthesitis in spondyloarthritis and psoriatic arthritis.[12,13]

The optimal way to determine the presence and extent of enthesitis in patients with PsA remains to be determined. A tool with high sensitivity and specificity is needed to translate clinical trial results.

The objectives of this study were to: (a) determine the extent of US-detected peripheral enthesitis in a cohort of patients with PsA; (b) compare this with three CE enthesitis indices; and (c) determine the effect of concurrent fibromyalgia on the evaluation of enthesitis.

Methods
A prospective single-centre cross-sectional study was performed. Unselected consecutive patients with PsA (according to classification criteria for psoriatic arthritis) were recruited from a dedicated PsA outpatient clinic at a large university hospital. Patients with a prior diagnosis of another co-existing inflammatory arthritis were excluded. Clinical assessment, examination and US were completed at one time point.

CE enthesitis was assessed by two blinded independent examiners (DJ, JE), after undergoing formal education and training in clinical enthesitis indices. Each patient completed the following patient-reported outcome measure (PROM) questionnaires: Health Assessment Questionnaire–Disability Index (HAQ-DI), patient global assessment, patient pain assessment, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Psoriatic Arthritis Impact of Disease (PsAID)-12 and Fibromyalgia Survey Questionnaire (FSQ). Those with a positive FSQ score, as defined by the 2016 revisions to the 2010/2011 American College of Rheumatology (ACR) fibromyalgia diagnostic criteria, were classified as having concurrent fibromyalgia.[14] Recent non-steroidal anti-inflammatory drug (NSAID) use and physical activity was recorded. Other clinical assessments included body mass index (BMI), 66 swollen joint count, 68 tender joint count, Psoriasis Area and Severity Index, modified Nail Psoriasis Severity Index and dactylitis count. Pertinent blood results, including erythrosedimentation rate (ESR), C-reactive protein (CRP) and human leukocyte antigen-B27 (HLA-B27) genotype, were recorded from the electronic patient record. The validated disease activity measures Disease Activity in Psoriatic Arthritis (DAPSA) and Minimal Disease Activity (MDA) were calculated.

Each patient underwent dynamic B-mode and power Doppler US assessment of 20 peripheral entheseal sites by a rheumatology fellow (MS) with specific training in entheseal US. The examined sites were: plantar fascia calcaneal insertion, Achilles insertion, patella ligament at superior and inferior insertion sites, quadriceps insertion, medial femoral condyle, greater trochanter, lateral humeral epicondyle, medial humeral epicondyle and supraspinatus insertion. MS was blinded to the clinical characteristics, clinical assessments and questionnaire findings of the patients. US was completed using a single device (GE Logiq-8 machine) with a linear (5–14 MHz) transducer. US at each site, including positioning, was carried out as per current European League Against Rheumatism (EULAR) US guidelines.[15] Doppler parameters were: Doppler frequency of 10 MHz, and pulse repetition frequency of 500 Hz. Each US site was scored for the presence (1) or absence (0) of each of the elementary lesions of US enthesitis (inflammatory components; hypoechogenicity, increased thickness of the tendon insertion, and Doppler activity; structural components; calcification, enthesophyte, erosion) as defined by the OMERACT group.[12,13]

Statistical analysis

Statistical analyses were performed using STATA v12.1 (2011; Texas, USA) including descriptive statistics, inter-rater reliability of CE enthesitis indices, Spearman rank correlation coefficients (r), univariable and multivariable negative binomial regression models. The threshold for statistical significance was set at $p < 0.05$.

Study ethics

The study was performed with ethical approval by Coventry and Warwickshire Research Ethics Committee (reference: 18/WM/0138), written consent from participants, and in accordance with the Declaration of Helsinki.

Results

A total of 106 patients were enrolled. They were predominantly women ($n = 58$, 54.7%), with a median age of 53.0 years and disease duration of 7.0 years. Eighty-one (76.4%) were taking at least one conventional synthetic or biological disease-modifying antirheumatic drug (DMARD), and 32 (30.2%) patients were classified as being in minimal disease activity (Table 1).

CE enthesitis, defined as a score of >0 in $\geqslant 1$ of the three CE enthesitis indices, was identified in 91 (85.8%) patients. There was high intraclass correlation coefficient between the two examiners for CE enthesitis indices; LEI (0.96), SPARCC (0.98) and MASES (0.97). There was a strong correlation between LEI and SPARCC scores (Spearman rank correlation coefficient, $r = 0.8$), and a moderate correlation between MASES and the two other CE enthesitis indices (with LEI $r = 0.63$; with SPARCC $r = 0.7$).

One hundred and five (99.1%) patients had $\geqslant 1$ elementary US enthesis lesion at one of the 20 peripheral entheseal sites. The median US inflammation score was 4.5 [interquartile range (IQR) 2, 9] and the damage score was 8 (IQR 5, 13). US features of inflammation were most common at the quadriceps insertion and at the lateral humeral epicondyle. Power Doppler was seen in 40/106 (37.8%) patients at 72/2120 (3.4%) total sites, most commonly at the lateral humeral epicondyle (22/212), the quadriceps insertion (14/212) and at the patella ligament insertion at the inferior pole of the patella (12/212). US features of damage were most

frequent at the quadriceps insertion, Achilles insertion and at the lateral humeral epicondyle.

Correlation between CE enthesitis and US scores

There was a moderate correlation between both LEI ($r = 0.36$, $p = 0.002$) and SPARCC ($r = 0.44$, $p < 0.001$) and US inflammation scores. There was no correlation between MASES and US inflammation scores ($r = 0.05$, $p = 0.95$). There was no correlation between US damage scores and LEI ($r = 0.07$, $p = 0.55$), SPARCC ($r = 0.07$, $p = 0.38$) or MASES ($r = -0.12$, $p = 0.32$).

Univariable and multivariable regression analyses confirmed the association between US inflammation and both LEI and SPARCC, and also between US total scores and both LEI and SPARCC (Table 2). Increasing age, but not inflammatory markers or swollen joint count, was independently associated with US inflammation scores. Increasing age, male gender and PsA duration were each independently associated with US damage. Increasing age, female gender and tender joint count were independently associated with CE enthesitis scores. Increased BMI was independently associated with US damage; however, the association between increased BMI and US inflammation on univariable regression analysis was no longer significant on multivariable analysis.

When individual anatomical sites were analysed independently, at every site the presence of tenderness on physical examination was strongly associated with the presence of US inflammation [incidence risk ratio (IRR) 4.2 at Achilles insertion, up to 14.6 at the patella ligament insertion to tibial tuberosity; $p < 0.001$].

Effect of concurrent fibromyalgia

Twenty-eight (26.4%) patients were classified as having concurrent fibromyalgia using the 2016 ACR fibromyalgia diagnostic criteria. Concurrent fibromyalgia was more common in female patients (36.2 *versus* 14.6%, $p = 0.01$). PsA patients with fibromyalgia had higher mean tender joint counts (17.4 *versus* 3.3, $p < 0.0001$), higher PROM scores (HAQ 1.4 *versus* 0.53, $p < 0.0001$; PsAID-12 5.8 *versus* 2.8, $p < 0.0001$; BASDAI 6.1 *versus* 4.0, $p < 0.0001$; patient global visual analogue scale (VAS) 6.4 *versus* 3.2, $p < 0.0001$; patient

Table 1. Demographic characteristics, medications and clinical findings in the entire cohort (*n* = 106).

Age, years	53 (43, 61)
PsA disease duration, years	7 (2, 15)
PsC disease duration, years	20 (9.5, 30)
Women, *n* (%)	58 (54.7)
Ethnicity, *n* (%)	
Caucasian	101 (95.3)
Other	5 (4.7)
BMI	28.5 (24.9, 33.1)
HLA-B27 +ve, *n* (%)	8 (9.3)
CRP, mg/L	1 (1, 5)
ESR, mm	7 (5, 13)
NSAID use in past 3 days, *n* (%)	30 (28.3)
Current use csDMARD, *n* (%)	63 (59.4)
Current use bDMARD, *n* (%)	37 (34.9)
TJC	3 (0, 10)
SJC	0 (0, 1)
Dactylitis, *n* (%)	9 (8.5)
Clinical enthesitis at any site, *n* (%)	91 (85.8%)
Clinical enthesitis indices	
LEI	1 (0, 2)
SPARCC	3 (1, 6)
MASES	1 (0, 4)
Patient global VAS	4 (2, 6)
Patient pain VAS	4 (2, 6)
PASI	1.2 (0, 2.7)
mNPSI	3 (0, 9)
US enthesitis at any site, *n* (%)	105 (99.1)
Damage	104 (98.1)
Inflammation	98 (92.5)
US damage score	8 (5,13)
US Inflammation score	4.5 (2, 9)
DAPSA	16 (8, 26)
In MDA, *n* (%)	32 (30.2)
Concomitant fibromyalgia classification, *n* (%)	28 (26.4)
HAQ-DI	0.625 (0.125, 1.25)
PsAID-12	3.5 (1.7, 5.5)
BASDAI	4.7 (3.0, 6.4)

Unless otherwise stated data are presented as median (interquartile range). BASDAI, Bath Ankylosing Spondylitis Disease Activity Score; bDMARD, biological disease-modifying antirheumatic drug; BMI, body mass index; CRP, C-reactive protein; csDMARD, conventional synthetic disease-modifying antirheumatic drug; DAPSA, disease activity in psoriatic arthritis; ESR, erythrocyte sedimentation rate; HAQ-DI, Health Assessment Questionnaire – Disability Index; LEI, Leeds Enthesitis Index; MASES, Maastricht Ankylosing Spondylitis Enthesitis Score; MDA, minimal disease activity; mNPSI, modified nail psoriasis severity index; NSAID, non-steroidal anti-inflammatory drug; PASI, Psoriasis Area and Severity Index; PsA, psoriatic arthritis; PsAID-12, psoriatic arthritis impact of disease; PsC, psoriasis; SJC, swollen joint count; SPARCC, Spondyloarthritis Research Consortium of Canada Enthesitis Index; TJC, tender joint count; US, ultrasound; VAS, visual analogue scale.

pain VAS 6.8 *versus* 3.2, $p < 0.0001$) and higher CE enthesitis scores (LEI 2.7 *versus* 1.0, $p < 0.0001$; SPARCC 7.6 *versus* 2.4, $p < 0.0001$; MASES 5.7 *versus* 1.5, $p < 0.0001$). PsA cases with and without fibromyalgia were no different in terms of US inflammation scores (5.8 *versus* 5.6, $p = 0.84$), US damage scores (9.0 *versus* 8.9, $p = 0.94$), and US total scores (14.8 *versus* 14.5, $p = 0.87$).

When analyses were restricted to PsA cases without concurrent fibromyalgia ($n = 78$), US inflammation correlated closely with both LEI ($r = 0.48$, $p < 0.0001$) and SPARCC ($r = 0.62$, $p < 0.0001$). However, in PsA patients with fibromyalgia ($n = 28$), US inflammation no longer correlated with LEI ($r = 0.01$, $p = 0.98$) or SPARCC ($r = 0.13$, $p = 0.40$).

Discussion

Although most studies have found a higher prevalence of US enthesitis when compared with clinical examination, few studies have directly compared US and CE enthesitis indices in PsA.[16–19] Michelsen *et al*.[20] found no correlation between MASES and peripheral enthesitis examined by US. Husic *et al*.[16] found a weak correlation ($r = 0.3$) between the Madrid Sonography Enthesitis Index and LEI. In a small study by Kristensen *et al*.[21] a correlation was demonstrated between tendon thickness and hypoechogenicity, but not with other US features of enthesitis, with LEI ($r = 0.81$) and SPARCC ($r = 0.81$). Recently Macchioni *et al*.[22] found a low correlation between US findings and clinical enthesitis at six paired peripheral entheseal sites. The heterogeneity of US definitions and techniques used makes interpretation across previous studies difficult.[11]

Our study demonstrated high frequencies of both CE enthesitis and US enthesitis. We found moderate correlation between US inflammation at peripheral entheses and both SPARCC and LEI, but not MASES. We did not find a correlation between CE enthesitis scores and US damage scores, which supports the rationale to classify individual US elementary lesions of enthesitis as either relating to inflammation or structural damage. The OMERACT task force subgroup consensus definitions of US enthesitis and the 2017 EULAR standardised procedures for US imaging in rheumatology that were employed in this study should allow better comparisons across studies like this in the future.[12,15]

Table 2. Multivariable non-binomial regression analyses of clinical examination enthesitis indices and ultrasound scores.

	US inflammation		US damage	
	IRR (95% CI)	***p*-Value**	**IRR (95% CI)**	***p*-Value**
Entire cohort (*n* = 106)				
LEI	1.25 (1.08, 1.45)	0.003	Not associated	
SPARCC	1.15 (1.08, 1.22)	<0.001	Not associated	
MASES	Not associated		Not associated	
Age	1.02 (1.01, 1.04)	0.008	1.03 (1.02, 1.04)	<0.001
Female sex	Not associated		0.80 (0.64, 1.00)	0.05
PsA duration	Not associated		1.01 (1.00, 1.03)	0.015
PsA, no FMS (*n* = 78)				
LEI	1.38 (1.17, 1.62)	<0.001	Not associated	
SPARCC	1.29 (1.18, 1.41)	<0.001	Not associated	
MASES	Not associated		Not associated	
Age	1.02 (1.01, 1.04)	0.03	1.03 (1.02, 1.04)	<0.001
Female sex	Not associated		0.76 (0.61, 0.94)	0.011
PsA duration	Not associated		Not associated	
PsA with FMS (*n* = 28)				
LEI	Not associated		Not associated	
SPARCC	Not associated		Not associated	
MASES	Not associated		Not associated	
Age	1.03 (1.01, 1.05)	0.002	1.04 (1.01, 1.06)	<0.001
Female sex	Not associated		0.67 (0.49, 0.90)	0.009
PsA duration	Not associated		1.04 (1.01, 1.06)	0.002

Adjusted for age, PsA duration, gender, ethnicity, BMI, B27 status, smoking status, PsC duration, DMARD use, prednisone use, NSAID use, diabetes, CRP, ESR, exercise, PROM, TJC, SJC, PASI, mNAPSI, dactylitis, DAPSA, MDA.
BMI, body mass index; CI, confidence interval; CRP, C-reactive protein; DAPSA, disease activity in psoriatic arthritis; DMARD, disease-modifying antirheumatic drug; ESR, erythrocyte sedimentation rate; FMS, ; IRR, incidence rate ratio; LEI, Leeds Enthesitis Index; MASES, Maastricht Ankylosing Spondylitis Enthesitis Score; MDA, minimal disease activity; mNAPSI, Modified Nail Psoriasis Severity Index; NSAID, non-steroidal anti-inflammatory drug; PROM, patient-reported outcome measure; PASI, Psoriasis Area and Severity Index; PsA, psoriatic arthritis; PsC, psoriasis; SJC, swollen joint count; SPARCC, Spondyloarthritis Research Consortium of Canada Enthesitis Index; TJC, tender joint count.

Even so, features of US enthesitis, including tendon thickening and hyoechogenicitiy, are not specific to PsA or spondyloarthritis in general. Less than half (40/98) of patients in our study with US inflammation had Doppler activity at an enthesis. Prior studies have demonstrated US enthesitis, including inflammatory lesions, are also common in patients with skin psoriasis alone, in patients with fibromyalgia, and in healthy controls.[22,23] Consistent with previous studies our results highlight the lack of specificity of US findings, demonstrating independent associations between

ultrasound scores and increasing age, male gender, disease duration, and BMI.[20]

CE enthesitis indices have been shown to be non-specific for enthesitis, especially when there is overlap with mechanical injury, adjacent synovial inflammation, or fibromyalgia.[9] In this study 26.4% of patients were classified as having concurrent fibromyalgia; similar to previous estimates in PsA cohorts.[24] Concurrent fibromyalgia worsens PsA outcomes and reduces quality of life.[25] Our study showed that those with fibromyalgia have higher disease activity measures, worse PROMs, and higher CE enthesitis indices scores, without an increase in objective measures of disease activity (CRP, ESR, swollen joint count, US enthesitis). To our knowledge this is the first study that compared US and CE enthesitis scores in PsA patients with and without concurrent fibromyalgia. The utility of elevated CE enthesitis scores in PsA cases with concurrent fibromyalgia is therefore put into doubt. Conversely, consideration of fibromyalgia should be given to patients with very high CE enthesitis scores.

The reliability and external validity of our results are improved by the large sample size in a clinical practice setting, adherence to standardised US technique and definitions, and a single sonographer performing all US assessments after detailed training. Multivariable regression models were used to adjust for concomitant treatments such as NSAIDs, csDMARDs and bDMARDs.

We acknowledge the limitations of this study. Due to the lack of an agreed scoring system, we devised a dichotomous score to calculate individual site and total US enthesitis scores. A grossly thickened tendon with confluent power Doppler signal was scored the same as a mildly thickened tendon with a few spots of power Doppler. Future studies utilising graded scores may permit a better test for correlation between US and CE enthesitis scores. While all entheseal sites included in LEI and SPARCC were examined by US, due to lack of a standardised imaging protocol for axial entheseal sites, the Achilles insertion was the only imaged entheseal site included in MASES. This, and the predominance of peripheral enthesitis in PsA patients, probably explains the lack of correlation with US inflammation and MASES. Most patients were already on treatments which may reduce the prevalence of enthesitis; although equally for US and clinical examination.

In conclusion, there is a moderate association between US entheseal inflammation and CE enthesitis indices in patients with PsA. US entheseal damage does not correlate with CE enthesitis indices. The presence of concurrent fibromyalgia is associated with higher CE enthesitis scores, without a difference in US entheseal inflammation, suggesting that CE enthesitis indices should be used/interpreted with caution in these patients. Imaging, including ultrasound, is preferred over clinical examination to detect enthesitis in PsA patients with concurrent fibromyalgia.

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