Conclusion: These newly developed and preliminary validated msk-US activity and damage scores could be used in patients with PsA in the context of observational and controlled trials.

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OP0224

CONTINUOUS COMPOSITE MEASURES FOR ROUTINE CARE IN PSORIATIC ARTHRITIS: THRESHOLDS OF MEANING AND CLINICALLY IMPORTANT DIFFERENCE ESTIMATES FOR THE 3 AND 4 VAS SCALES FROM A UK MULTICENTRE STUDY

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Background: There is a recognised need for a continuous composite measure of disease activity for the assessment of Psoriatic Arthritis (PsA) in routine clinical settings to allow objective assessment of response and implementation of treat to target.¹ Longer multidimensional measures are considered less feasible in routine care and a number of shorter measures have been proposed including, the Disease Activity Score for Psoriatic Arthritis (DAPSA), Disease Activity Score 28 (DAS28), the 3 Visual Analogue Scale (VAS) (comprising physician global VAS, patient global VAS and patient skin VAS) or 4 VAS (comprising physician global VAS, patient pain VAS, joint VAS and patient skin VAS). Testing of these measures in clinical trial datasets has been suggested but thresholds of meaning have not been established.²

Objectives: To estimate clinically relevant thresholds of disease activity and improvement for composite measures for routine clinical practice in PsA.

Methods: Clinical and patient reported outcome measures were assessed in patients fulfilling CASPAR criteria for PsA at three consecutive follow up visits in a UK multicentre observational study. Participants underwent clinical assessment and completed patient reported measures including health anchor questions. Estimates for Minimal Detectable Change (MDC) were derived using $1.96 \times 2 \times \text{Standard Error of the Mean (SEM)}$. Minimal Clinically Important Difference (MCID) for improvement were derived using the health anchor method and two distribution methods (Table 1). Thresholds for low, moderate and high disease activity were triangulated from established cut-off values for the patient global VAS, PASDAS and DAPSA.

Table 1. Minimal Clinically Important Difference (MCID) and Minimal detectable change (MDC)

	ANCHOR (MEDIAN)	DISTRIBUTION#1	DISTRIBUTION #2	MDC
CPDAI	0.5	1.49	1.5	4.16
GRACE	0.26	0.6	0.77	2.18
PASDAS	1.22	0.64	0.76	1.58
DAS28	0.2	0.85	0.62	1.46
3VAS	1.13	1.16	0.91	3.12
4VAS	1.11	0.96	0.94	2.45
DAPSA	7.25	9.09	10.40	35.63

Disease Activity Score for Psoriatic Arthritis (DAPSA); Psoriatic Arthritis Disease Activity Score (PASDAS); Composite Psoriatic Arthritis Disease Activity Index (CPDAI); Disease Activity Score 28 (DAS28). Distribution #1: Baseline standard deviation (sd) * $\sqrt{1 - \text{Cronbach's alpha}}$ Distribution #2: 0.5 * baseline sd/Minimal detectable change (MDC): $1.96 \times 2 \times \text{SEM}$ where SEM = baseline sd / $\sqrt{1 - \text{ICC}}$

Results: 139 subjects were recruited (59 male, 80 female, mean (range) age (years) 52.7 (19 – 83), mean (range) duration of psoriasis (years) 21.9 (2 – 71), mean (range) duration of psoriatic arthritis (years) 6.1 (0 – 41). Cut-off values for low, moderate and high disease activity were 1.3, 2.4, and 4.8 for the 3 VAS and 1.6, 2.8 and 5.0 for the 4 VAS (Figure 1). Estimates for the MCID and MDC for the continuous composite measures and are reported in Table 1.

Conclusion: We report estimates of clinically relevant improvements for continuous composite measures in PsA and estimates of low, moderate and high disease activity for the 3 and 4 VAS scales. The thresholds of meaning can now be tested in independent observational and clinical trial datasets.

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Figure 1: Thresholds of Meaning for the 3 and 4 VAS

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OP0225

DEPRESSIVE SYMPTOMS IN PSA: A CROSS-SECTIONAL ANALYSIS FROM THE NATIONAL GERMAN RABBIT-SPA REGISTRY

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Background: Psoriatic arthritis (PsA) is a chronic inflammatory disease affecting the musculoskeletal system as well as skin and nails. The prevalence of depression in psoriasis and PsA is high and ranges from 7-40% [1]. Persistent depressive mood may influence disease activity outcome in PsA, especially patient-reported outcomes.

Objectives: To assess the correlation of depressive symptoms with PsA-specific outcome parameters.

Methods: RABBIT-SpA is a prospective longitudinal cohort study including PsA patients enrolled at start of a new conventional treatment or b/tsDMARD treatment. In regularly provided follow-up questionnaires, physician- and patient-reported information on the disease course including the depression screening tool WHO-5 to assess mental health is collected. For the current analysis, the WHO-5 score was categorised into 4 groups using validated cut-offs: severe depressive symptoms <13, moderate depressive symptoms 13-28, mild depressive symptoms 29-50, well-being >50. Spearman correlation coefficient was calculated to analyse the relationship between the WHO-5 score and various PsA related outcome parameters.

Results: 936 PsA patients were included. Baseline characteristics are shown in Table 1. In 411 patients (43.9%) the WHO-5 score indicated well-being, 249

(26.6%) had mild depressive, 203 (21.7%) moderate depressive and 73 patients (7.8%) severe depressive symptoms. WHO-5 results correlated with patient reported skin involvement (DLQI: -0.25, patient assessment skin: -0.17), and the composite scores DAPSA (-0.33) and DAS28 (-0.28) as well as with patient reported pain (-0.43) and patient global disease assessment (-0.42). The highest correlation was found for physician assessed global health status (-0.51) and PSAID (-0.62). No significant correlation was found with CRP, swollen joint count and physician assessed skin involvement including body surface area (BSA).

Table 1. Baseline characteristics of patients included in the analysis stratified by WHO-5 categories.

Parameter	WHO-5 (<13) severe N=73	WHO-5 (13-28) moderate N=203	WHO-5 (29-50) mild N=249	WHO-5 (>50) well-being N=411	Total N=936
Age, mean (SD)	52.6 (11.4)	51 (11.3)	51.4 (12.5)	52.8 (12.7)	52 (12.2)
Female, n (%)	52 (71.2)	127 (62.6)	157 (63.1)	227 (55.2)	563 (60.1)
Disease duration, years, mean (SD)	8.3 (8.7)	6 (7.9)	6.2 (6.7)	6.4 (7.5)	6.4 (7.5)
Dactylitis, n (%)	14 (19.7)	31 (15.5)	46 (18.5)	77 (18.8)	168 (18.1)
Axial involvement, n (%)	14 (19.7)	54 (26.9)	49 (19.7)	71 (17.3)	188 (20.2)
Nail involvement, n (%)	34 (47.2)	85 (42.3)	106 (42.6)	158 (38.6)	383 (41.1)
BMI>=30, n (%)	37 (51.4)	75 (37.1)	98 (39.5)	125 (30.9)	335 (36.2)
CRP of >=5 mg/L, n (%)	33 (51.6)	84 (45.4)	99 (46.5)	138 (39.1)	354 (43.4)
BSA (0-100), mean (SD)	10.1 (18.3)	9.5 (16.8)	8.5 (14.9)	8.1 (14.6)	8.7 (15.5)
Physician assessed global health (NRS 0-10), mean (SD)	6.3 (1.5)	5.6 (1.8)	5.2 (1.7)	4.9 (1.9)	5.2 (1.9)
TJC68, mean (SD)	9.9 (7.1)	8.6 (7.6)	8.2 (7.6)	7.3 (8.2)	8 (7.8)
SJC66, mean (SD)	6 (5.2)	4.8 (4.9)	4.7 (4.4)	4.3 (3.8)	4.6 (4.4)
DAPSA, mean (SD)	29.3 (11.1)	25.1 (12.9)	23.4 (12.1)	18.9 (12.4)	22.3 (12.8)
DAS28-CRP, mean (SD)	4.1 (1)	3.8 (1.2)	3.7 (1.1)	3.2 (1.1)	3.6 (1.2)
Patient assessed global health (NRS 0-10), mean (SD)	7.9 (2.1)	6.6 (2.1)	5.9 (2)	4.8 (2.3)	5.7 (2.4)
Patient assessed pain (NRS 0-10), mean (SD)	7.8 (1.8)	6.4 (2.1)	5.8 (2)	4.6 (2.4)	5.5 (2.4)
DLQI (0-30), mean (SD)	8.5 (8.2)	7.8 (7.2)	5.4 (5.7)	4.1 (4.9)	5.6 (6.2)
PSAID (0-10), mean (SD)	6.9 (1.8)	5.5 (1.8)	4.4 (1.7)	3 (1.7)	4.2 (2.2)

Conclusion: The impact of depressive symptoms on outcome parameters used in rheumatology is increasingly being recognised. Interestingly, direct measures of inflammatory disease activity of joint and skin disease such as BSA, CRP, and swollen joint count were not correlated with depressive symptoms. The highest correlation was found for broader assessments like global health status and PSAID.

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Psoriatic arthritis - treatment

OP0226

TOWARDS DEVELOPMENT OF AN ULTRASOUND ENTHESITIS SCORE IN PSORIATIC ARTHRITIS: 24-WEEK RESULTS FROM THE PHASE III RANDOMISED ULTIMATE STUDY

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Background: Enthesitis is a key clinical domain and imaging hallmark of psoriatic arthritis (PsA). Ultrasound (US) is a highly sensitive tool for detecting synovitis and enthesitis in PsA. The Outcome Measures in Rheumatology Initiative (OMERACT) has developed an US definition and scoring system of enthesitis for clinical studies.¹ The ULTIMATE study (NCT02662985) is the first large double-blind (DB), placebo-controlled phase IIIb study designed to demonstrate a rapid and significant benefit of subcutaneous secukinumab vs. placebo on US detected synovitis in patients with PsA.²

Objectives: To report the enthesitis response to secukinumab over 24 weeks using two novel US composite enthesitis scores.

Methods: This was a 52-week study consisting of a 12-week DB, a 12-week open-label (OL) and a 6-month extension period.² Inclusion criteria required ≥1 clinical enthesitis as per SPARCC enthesitis index, but not US-assessed enthesitis.² Patients were randomised (1:1) to either weekly secukinumab (300 or 150 mg according to severity of skin psoriasis) or placebo followed by 4-weekly dosing thereafter. All placebo patients switched to OL secukinumab (placebo-secukinumab) at Week 12. Throughout the study, enthesitis was assessed with SPARCC and US. Six anatomical sites were assessed bilaterally with US: insertions of lateral epicondyle tendons, quadriceps, patellar ligaments (distal and proximal insertions), Achilles tendons and plantar fascia. Two exploratory global OMERACT-US enthesitis scores were tested: Definition 1 combining power Doppler (PD; 0–3) and Grey Scale (0–1) inflammation and Definition 2 rating PD only (0–3) across the six anatomical sites. Data were analysed with mixed-effect model repeated measures (MMRM) up to Week 12 and as observed from Week 12 to 24. The comparison of OMERACT-US enthesitis score within treatment groups was tested with paired and between treatment groups with unpaired t-tests.

Results: Of 166 patients enrolled, 93% completed 24 weeks of treatment (secukinumab, 95%; placebo-secukinumab, 92%). The average clinical enthesitis count at baseline was 4. Since the presence of PD was not a mandatory inclusion criterion, a higher proportion of patients met Global OMERACT-US enthesitis score with Definition 1 vs. Definition 2 (81% vs. 33%) at baseline (Table). Mean reduction from baseline to Week 24 in SPARCC enthesitis index was 3 each for initial secukinumab and placebo-secukinumab groups. Resolution of enthesitis (SPARCC) was 46% for initial secukinumab and 54% for placebo-secukinumab groups at Week 24. A comparable decrease in OMERACT-US enthesitis (Definition 1 and 2) score was observed from baseline to Week 24 for initial secukinumab and placebo-secukinumab groups (Figure).

Table 1. Distribution of US detected enthesitis at baseline according to OMERACT enthesitis score Definition 1 and 2

	Secukinumab		Placebo	
	Def 1 >0	Def 2 >0	Def 1 >0	Def 2 >0
N=	73	34	61	20
Anatomical sites, %				
Achilles tendon	49	12	45	2
Lateral epicondyle	49	21	46	21
Patellar ligament distal insertion	34	8	29	4
Patellar ligament proximal insertion	34	10	18	4
Plantar fascia	36	0	28	0
Quadriceps insertion	55	12	40	2

Proportion of patients is irrespective of the enthesitis site left or right side. N, total number of patients

Conclusion: A consistent clinical and US response on enthesitis was shown through 24 weeks across initial secukinumab and placebo switcher groups. While ULTIMATE has demonstrated the responsiveness of these global OMERACT-US enthesitis scores, further work is required to test these scores in PsA cohorts with inclusion criteria for both clinical and US enthesitis.

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