

SAT0438 PSORIATIC ARTHRITIS AND NODAL OSTEOARTHRITIS CAN BE DIFFERENTIATED USING HAND RADIOGRAPHS: A NOVEL METHOD

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Background: One of the difficulties of rheumatology practice is the differentiation of Psoriatic Arthritis (PsA) and Nodal Osteoarthritis (NOA) in some patients with distal interphalangeal joint involvement. MRI and ultrasound imaging, have recently been demonstrated as inconclusive in some cases (1,2). This differentiation is critical, as treatment for these debilitating conditions is completely different.

Objectives: To establish a scoring system of radiographic joint and soft tissue features to differentiate PsA from NOA.

Methods: We devised a scoring system for hand radiographs of interphalangeal joints, soft tissue and bone features, allocated major and minor weighting. The scoring system was then tested in a single blind analysis of hand radiographs from 48 patients with PsA, 50 with NOA and 1 with RA (incorrectly classified as PsA at study entry) seen between 2008 and 2016. Anonymised patient images were assessed by a Musculoskeletal (MSK) Radiologist, blind to clinical information. Radiological diagnosis was then compared with clinical diagnosis. We taught the method to 2 rheumatology and 1 radiology trainees over 1 hour, who then independently assessed the same radiographs.

Results: The MSK radiologist reported normal hand radiographs in 5 patient sets. Of the remaining 94 patient sets, the scoring system correctly allocated 100% of images into PsA, NOA or RA. Notably, 2 patients with NOA who subsequently developed PsA several years later, and 1 patient with seropositive RA, initially misclassified as PsA, were correctly identified by the MSK radiologist.

Trainees using the system also achieved good agreement, after removing radiographs assessed as normal; Rheumatology trainees: 88% and 67% correct; Radiology trainee: 70% correct.

Conclusions: This initial single-centre study shows our novel radiological scoring system is effective at differentiating patients with PsA from NOA. Radiographs provide an accurate, time-efficient (for both clinician and patient) and inexpensive test. We also show that trainees can learn this scoring system with moderate accuracy after a short educational programme. We are currently carrying out a detailed analysis of the scoring system to optimise accuracy and ease of use by non-radiologists.

References:

- McGonagle D, Hermann KG, Tan AL. Differentiation between osteoarthritis and psoriatic arthritis: implications for pathogenesis and treatment in the biologic therapy era. *Rheumatology*. 2015;54:29–38.
- Yumusakhuyulu Y, Kasapoglu-Gunal E, Murat S et al. A preliminary study showing that ultrasonography cannot differentiate between psoriatic arthritis and nodal osteoarthritis based on enthesopathy scores. *Rheumatology*. 2016; 55:1703–4.

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SAT0439 INTEGRATED SAFETY SUMMARY OF TOFACITINIB IN PSORIATIC ARTHRITIS CLINICAL STUDIES

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Background: Tofacitinib is an oral Janus kinase inhibitor under investigation for psoriatic arthritis (PsA).

Objectives: To describe the safety profile of tofacitinib from integrated Phase (P)3 and long-term extension (LTE) studies.

Methods: Data were analysed for patients (pts) who received ≥ 1 dose of tofacitinib 5 or 10 mg BID or placebo (PBO), integrated across 2 P3 studies (OPAL Broaden [12 months; NCT01877668]; OPAL Beyond [6 months; NCT01882439]) and 1 LTE study (OPAL Balance [ongoing, database not locked; NCT01976364]). Common adverse events (AEs; occurring in $\geq 2\%$ of tofacitinib pts in any group) were analysed in the PBO-controlled portion (Months 0–3) of the P3 studies (Cohort 1 [C1]). Serious AEs (SAEs) and discontinuations due to AEs were analysed over 12 months in pts randomised to tofacitinib 5 or 10 mg BID in P3 studies (Cohort 2a [C2a]); pts randomised to PBO were excluded from this analysis. Deaths and AEs of special interest (serious infections [SI], herpes zoster [HZ], opportunistic infections [OI] including HZ, major adverse cardiac events [MACE], malignancies, non-melanoma skin cancer [NMSC]) were evaluated in all tofacitinib-treated pts in the P3 and LTE studies (Cohort 3 [C3]). Incidence rates (IR; pts with events/100 pt-years [PY] and 95% confidence intervals) are reported. Laboratory results will be reported in future publications.

Results: C1 included 474 tofacitinib- and 236 PBO-treated pts; C2a included 474 tofacitinib-treated pts; and C3 included 783 tofacitinib-treated pts (exposure:

776 PY). Nasopharyngitis (5.9%) and headache (8.5%) were the most commonly reported AEs at Month 3 in pts receiving tofacitinib 5 and 10 mg BID, respectively (Table). In pts randomised to tofacitinib 5 or 10 mg BID, over 12 months (C2a), the IRs for SAEs were 7.92 (4.09, 13.84) and 8.11 (4.19, 14.17), respectively. Discontinuation due to AEs occurred in 11 (4.6%) and 11 (4.7%) pts randomised to tofacitinib 5 and 10 mg BID, respectively, with IRs of 7.16 (3.58, 12.82) and 7.31 (3.65, 13.08), respectively, over 12 months (C2a). Across all tofacitinib-treated pts in the P3 and LTE studies (C3), SIs occurred in 11 pts (1.4%; IR 1.40 [0.70, 2.50]). HZ was reported in 16 pts (2.0%; IR 2.05 [1.17, 3.33]) receiving tofacitinib. All 3 cases of multidermatomal HZ were adjudicated as OIs; these were the only OIs (0.4%; IR 0.38 [0.08, 1.11]). In C3, 2 deaths occurred (0.3%; IR 0.25 [0.03, 0.91]); all were considered unrelated to the study drug. MACE were reported in 3 pts (0.4%; IR 0.38 [0.08, 1.11]), malignancies (excluding NMSC) in 5 pts (0.6%; IR 0.63 [0.21, 1.48]) and NMSC in 4 pts (0.5%; IR 0.51 [0.14, 1.30]).

Table: Common adverse events ($\geq 2\%$ occurrence in any group, all causalities) at Month 3 in patients receiving tofacitinib 5 or 10 mg BID or placebo

Common Adverse Events, n (%)	Tofacitinib 5 mg BID (N=238)	Tofacitinib 10 mg BID (N=236)	Placebo (N=236)
Diarrhoea	8 (3.4)	9 (3.8)	1 (0.4)
Dyspepsia	5 (2.1)	2 (0.8)	2 (0.8)
Nausea	6 (2.5)	5 (2.1)	7 (3.0)
Fatigue	0	7 (3.0)	1 (0.4)
Bronchitis	6 (2.5)	4 (1.7)	0
Nasopharyngitis	14 (5.9)	13 (5.5)	6 (2.5)
Pharyngitis	1 (0.4)	7 (3.0)	3 (1.3)
Upper respiratory tract infection	12 (5.0)	11 (4.7)	11 (4.7)
Urinary tract infection	3 (1.3)	6 (2.5)	5 (2.1)
Headache	9 (3.8)	20 (8.5)	11 (4.7)
Dizziness	6 (2.5)	1 (0.4)	3 (1.3)
Acne	3 (1.3)	5 (2.1)	0
Hypertension	4 (1.7)	5 (2.1)	3 (1.3)

BID, twice daily; N, number of patients evaluable

Conclusions: Tofacitinib was well tolerated in pts with PsA, with a safety profile consistent to that seen in RA; no new risks were identified. Longer-term follow-up and larger pt populations will provide further information on the safety profile of tofacitinib in pts with PsA.

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SAT0440 DO DEPRESSION AND ANXIETY INFLUENCE THE CHANGE OF REMISSION IN PATIENTS WITH PSORIATIC ARTHRITIS? REAL LIFE DATA FROM THE NOR-DMARD STUDY

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Background: Depression and anxiety are frequent comorbidities in psoriatic arthritis (PsA). Still, the potential influence of depression/anxiety on achievement of remission remains unexplored.

Objectives: To investigate the predictive value of baseline depression/anxiety on the likelihood of achieving remission in PsA, as well as the associations between

Abstract SAT0440 – Table 1

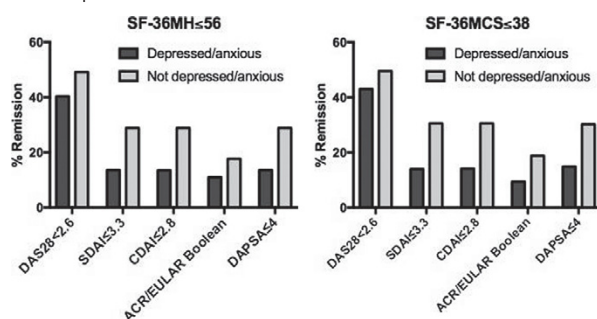
Months	Odds ratio (95% CI) for remission in patients with vs. without baseline depression/anxiety according to SF-36MH \leq 56				
	DAS28 \leq 2.6	SDAI \leq 3.3	CDAI \leq 2.8	ACR/EULAR Boolean	DAPSA \leq 4
3	0.61 (0.35–1.06), p=0.08	0.36 (0.17–0.76), p=0.007	0.48 (0.25–0.93), p=0.03	0.62 (0.29–1.30), p=0.20	0.37 (0.18–0.79), p=0.01
6	0.81 (0.44–1.51), p=0.51	0.38 (0.18–0.82), p=0.01	0.39 (0.19–0.81), p=0.01	0.61 (0.28–1.33), p=0.21	0.40 (0.19–0.84), p=0.02
Months	Odds ratio (95% CI) for remission in patients with vs. without baseline depression/anxiety according to SF-36MCS \leq 38				
	DAS28 \leq 2.6	SDAI \leq 3.3	CDAI \leq 2.8	ACR/EULAR Boolean	DAPSA \leq 4
3	0.68 (0.42–1.01), p=0.11	0.37 (0.20–0.69), p=0.002	0.45 (0.26–0.78), p=0.004	0.45 (0.23–0.88), p=0.02	0.42 (0.23–0.76), p=0.004
6	0.91 (0.54–1.56), p=0.74	0.42 (0.22–0.79), p=0.008	0.43 (0.24–0.78), p=0.005	0.51 (0.26–1.00), p=0.05	0.46 (0.25–0.86), p=0.02

baseline depression/anxiety and the components of the remission criteria at follow-up.

Methods: From the prospective multi-center observational NOR-DMARD study we included PsA patients starting first-time methotrexate/tumor necrosis factor inhibitors between year 2006 and 2012. The following criteria for depression/anxiety were assessed: 1) the Medical Outcomes Survey Short Form-36 (SF-36) Mental Health subscale (MH) \leq 56 and 2) SF-36 Mental Component Summary score (MCS) \leq 38.¹ The predictive value of baseline depression/anxiety on remission at 3 and 6 months was explored in prespecified logistic regression models adjusted for age, sex, disease duration and smoking, and the associations between baseline depression/anxiety and the components of the remission criteria at follow-up in prespecified multiple linear regression models adjusted for age, sex, disease duration and smoking.

Results: 805 PsA patients were included (mean (SD) age 48.0 (12.4) years, median (25th–75th percentile) disease duration 1.0 (0.07–6.8) years, 50.8% females, 28.6% current smokers). According to the SF-36MH \leq 56/SF-36MCS \leq 38 criteria 15.6/25.2% of the patients had depression/anxiety at baseline, respectively. Lower percentages of patients with vs. without baseline depression/anxiety achieved remission at 6 months (unadjusted analyses;figure). Patients with baseline depression/anxiety had consistently lower point estimates for achievement of remission at follow-up, but did not reach significance for all the analyses (adjusted analyses, table).

Baseline depression/anxiety was associated with increased patient's global assessment and joint pain at follow-up, but not with swollen joint count or levels of acute phase reactants.



Conclusions: Depression and anxiety may reduce likelihood of remission based on composite scores in PsA. These observations support a focus on depression and anxiety as comorbidities in a treat-to-target strategy and may also reflect that patient reported outcome measures are part of all these composite measures used to define remission.

References:

[1] Matcham et al. BMC Musculoskelet Disord. 2016;17:224.

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SAT0441 COMPARISON OF DIFFERENT REMISSION TARGETS IN PATIENTS WITH PSORIATIC ARTHRITIS AND EVALUATION OF THEIR PROGNOSTIC VALUE

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Background: Psoriatic arthritis (PsA) is a complex form of arthritis that develops in people with psoriasis. There is no agreement on the optimal criteria to identify remission in patients with PsA and some of them may miss skin lesions.

Objectives: To investigate the merits of different potential remission definitions using data from the PRESTA study.¹

Methods: Remission was investigated for disease activity index for PsA for 3 definitions: very low disease activity (VLDA), Disease Activity in PsA (DAPSA), and clinical (c)DAPSA. VLDA index was defined as 7/7 met criteria of the minimal disease activity (MDA) cut-off points: tender joint count (TJC) \leq 1, swollen joint count (SJC) \leq 1, psoriasis activity and severity index (PASI) \leq 1, patient global visual analog scale (Pt VAS) \leq 20mm, Pt pain VAS \leq 15mm, health assessment questionnaire (HAQ) \leq 0.5, tender entheses points \leq 1. DAPSA remission was defined as DAPSA \leq 4 (TJC, SJC, physician global VAS [cm], Pt VAS [cm], C-reactive protein [CRP]) and cDAPSA remission was defined as cDAPSA \leq 4 (DAPSA without CRP).

Results: At Week 24, the proportion of patients achieving remission was 9.6%, 31.0%, and 34.7% for VLDA, DAPSA, and cDAPSA remission, respectively. Discordance between VLDA and DAPSA or cDAPSA remission was 21.7% or 25.1%, respectively. Only 0.2% of the patients that achieved VLDA did not achieve DAPSA remission and 21.5% vice versa (Kappa coefficient 0.38) and 0.0% in the case of cDAPSA remission and 25.1% vice versa (Kappa coefficient 0.33). At the end of the study, residual levels of dactylitis and enthesitis appeared to be similar among all definitions (all \leq 3.0%); however, patients achieving DAPSA and cDAPSA remission had higher proportions of patients with PASI $>$ 1 than patients achieving VLDA remission (PASI 2–9: VLDA 0.0% vs DAPSA 46.4% vs cDAPSA 47.2%; PASI \geq 10: VLDA 0.0% vs DAPSA 5.8% vs cDAPSA 6.4%). Raised CRP values (upper limit of normal $>$ 8.99) were 7.8%, 4.8%, and 7.3% for VLDA, DAPSA, and cDAPSA, respectively.

Conclusions: VLDA remission is a more stringent target than DAPSA and cDAPSA remission, with the advantage of including a measurement for psoriasis. Therefore, VLDA is more useful than DAPSA or cDAPSA in assessing a remission state in patients with PsA and extended skin lesions. Measurement of CRP levels does not appear to provide further information on current disease activity level in these patients and exclusion of this laboratory marker should facilitate remission assessment in clinical practice.

References:

[1] Sterry W, et al. BMJ 2010;340:c147.

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SAT0442 FUNCTIONAL DISEASE STATUS AND HEALTHCARE COSTS IN PSORIATIC ARTHRITIS: A SIMILAR RELATIONSHIP TO THAT SEEN IN RHEUMATOID ARTHRITIS

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Background: The Health Assessment Questionnaire-Disability Index (HAQ-DI), an important, validated measure of functional status in patients with psoriatic arthritis (PsA), has been used as an intermediate variable in modelling of costs and quality-adjusted life-years. The relationship between HAQ-DI and costs has been well documented for rheumatoid arthritis (RA),^{1,2} but less so for PsA. The HAQ-DI study data in PsA patients from the British Society for Rheumatology Biologics Registers was mapped to resource use data in the Health Improvement Network dataset.³ A drawback of this approach relates to the HAQ-DI and resource use data being derived from separate patient cohorts.

Objectives: Estimate the HAQ-DI and cost relationship in PsA within a single cohort of patients.

Methods: Functional disease status, patient demographic, disease history and healthcare resource use data were extracted from a cohort of patients at the Royal National Hospital for Rheumatic Diseases. Resource data were available for primary and secondary care consultations, prescriptions, accident and emergency attendance, hospital admissions and tests, and collected for 6 months before and after HAQ-DI measurement. Medication costs were excluded from the modelling as it was not possible to specify which were PsA-related. Linear regression models were used to predict costs as a function of HAQ-DI and age at HAQ-DI