

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:

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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 CHANCE 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