involvement, enthesitis, dactylitis), US (synovitis count (by Grey Scale), Power Doppler (PD)+ synovitis), thickening and hypoechogenicity at entheses, PD+ enthesitis, entheses with structural components); biological (high sensitive C-reactive protein (hsCRP), Erythrocyte Sedimentation Rate (ESR).

US examination included 798 joints and 3078 entheses (bilateral shoulders, acromioclavicular joints, elbows, wrists, hips, knees, ankles; entheses at the projection of these joints (total number = 54). US enthesal findings were fixed according to consensus-based US definition and scoring for enthesitis in spondyloarthritis and PsA (OMERACT US)¹.

Results: In all 57 patients: male - 25 (43.9%), mean age 43.4±10.3(SD) years (y), PsA duration was 7 (3;10) y, Ps duration 10 (8; 22) y; 53 (41.1%) had axial involvement, 42 (73.7%) dactylitis, 8 (14%) clinical enthesitis, and 56 (98.2 %) skin psoriasis, Psoriasis Activity and Severity Index score 6.4 (2;14.4), Disease Activity in PsA score 18.1 (10.2;26.1), hsCRP 10.1(2.4;21.4), ESR 20 (11.3;31.5). Synovitis count increased with age noticeably ($r=0.508$, $p<0.01$), and weak correlation of PD+ synovitis ($r=0.262$, $p=0.049$) and age was found. The enthesal thickening and hypoechogenicity and structural findings increased with age respectively ($r=0.345$, $p=0.009$; $r=0.337$, $p=0.01$). There was no correlation between PD+ enthesitis and age. The association between PD+ enthesitis and blood biomarkers of inflammation (hs-CRP ($r=0.364$, $p=0.008$); ESR ($p=0.358$, $p=0.008$) was found.

Conclusion: Our study found significant relationship between age and US synovitis. Association between age and US enthesal involvement was noted. Only PD+ enthesitis was not related with age in comparison with other US enthesal findings. The presence of PD US signal at enthesitis in association with increased inflammatory blood biomarkers can be evaluated as the sign of disease activity regardless of age and not as age-related lesion in PsA patients.

References:

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SAT0416 ENTHERSITIS AND CLINICAL RESPONSE IN PSORIATIC ARTHRITIS: REAL-LIFE DATA

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Background: Psoriatic arthritis (PsA) is an inflammatory arthritis that is characterized by a broad spectrum of clinical conditions, including axial skeletal involvement, enthesitis, dactylitis, uveitis and arthritis. Among those, enthesitis, the inflammation of the junction where the tendon, ligament or joint capsule inserts into the bone, is assigned to be the hallmark, affecting 35–50% of patients. Several clinical methods have been developed to measure it, including The Maastricht AS Enthesitis Score (MASES) index, which tests 13 entheses and the Spondyloarthritis Research Consortium of Canada (SPARCC) index that assesses 16.

Objectives: To assess the relationship between enthesitis and clinical response in psoriatic arthritis.

Methods: Retrospective study including all the patients with PsA meeting the CASPAR criteria, beginning first-line biologic therapy at our centre. Demographic and clinical data including age, gender, body mass index (BMI), smoking status, physical examination findings such as presence of enthesitis, dactylitis, chronic back pain, tender and swollen joint counts (TJC/ SJC), ESR, CRP, DAS 28 4vESR, BASDAI, BASFI, BASMI, ASDAS, HAQ, patient VAS score, MASES and SPARCC were collected from the Portuguese database Reumapt. Statistical analysis was performed with SPSS. Continuous variables were analysed through Spearman correlations.

Results: We included 119 patients with PsA (60 female), of which 14.9% were active smokers. The mean age of patients was 46.3 ± 1.03 years. The median disease duration was 6.8 (0.3-33.8) years and the mean BMI was 26.8 ± 0.5 Kg/m². Enthesitis, dactylitis, inflammatory back pain, peripheral arthritis, ungual dystrophy, and psoriasis were present in 53 (45.7%), 45 (38.8%), 76 (65.5%), 109 (94%), 45 (38.8%), 104 (89.7%) patients, respectively.

At baseline, mean (SD) disease activity parameters were: DAS 28 4vESR 4.9 (0.2), ESR 33.2 (2.3) mm/h; CRP 2.35 (0.3) mg/dL, HAQ 1.3 (0.1), BASDAI 6.6 (0.2), ASDAS 3.9 (0.1), BASMI 3.7 (0.2), BASFI 5.8 (0.3), MASES 1.9 (0.3), SPARCC 2.3 (0.3). Median (min-max) values of TJC, SJC and patient VAS score at baseline were 4 (0-28), 3 (0-19), 76 (0-100), respectively.

There were statistically significant positive correlations (0-12 months) between Δ MASES and Δ DAS 28 4vESR ($p=0.02$, $\rho=0.432$), Δ patient VAS score ($p=0.027$, $\rho=0.307$), Δ HAQ ($p=0.02$, $\rho=0.411$), Δ BASDAI ($p=0.025$, $\rho=0.326$), Δ BASFI ($p=0.037$, $\rho=0.315$), Δ ASDAS ($p=0.023$, $\rho=0.331$). Correlations

between Δ SPARCC and Δ DAS 28 4vESR ($p=0.023$, $\rho=0.332$), Δ patient VAS score ($p=0.003$, $\rho=0.402$), Δ HAQ ($p=0.012$, $\rho=0.440$), Δ BASDAI ($p=0.011$, $\rho=0.368$), Δ BASFI ($p=0.001$, $\rho=0.445$), Δ ASDAS ($p=0.002$, $\rho=0.437$), Δ CDAI ($p=0.039$, $\rho=0.320$) and Δ SDAI ($p=0.039$, $\rho=0.319$), were also significant. However, there weren't strong correlations between Δ MASES neither Δ SPARCC and PsARC response at 12 months.

Conclusion: Our results suggest that enthesitis is correlated with clinical response in PsA, supporting the idea that it is a major determinant of disease activity. It should be given more importance, namely by incorporating it in daily clinical practice, due to its major role, both in establishing an early diagnosis and in assessing treatment response.

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SAT0417 TILDRAKIZUMAB EFFICACY ON PSORIASIS IN PATIENTS WITH PSORIATIC ARTHRITIS—A 52-WEEK ANALYSIS FROM A PHASE 2 STUDY

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Background: Tildrakizumab (TIL)—a high-affinity anti-interleukin-23p19 monoclonal antibody—is approved in the US, EU, and Australia to treat moderate to severe plaque psoriasis.¹ A randomised, double-blind, multidose, placebo-controlled, phase 2b study (NCT02980692) evaluating the efficacy and safety of TIL for the treatment of psoriatic arthritis (PsA) was recently completed.

Objectives: To evaluate the proportion with 75%/90%/100% improvement in Psoriasis Area and Severity Index (PASI 75/90/100) among patients (pts) with PsA and measurable psoriasis ($\geq 3\%$ of the body surface area [BSA] affected at baseline) over 52 weeks of treatment.

Methods: Pts ≥ 18 years old with PsA² and ≥ 3 tender and ≥ 3 swollen joints, stratified by prior anti-TNF use and baseline body weight (≤ 90 kg and >90 kg), were randomised 1:1:1:1 to receive TIL 200 mg every 4 weeks (Q4W) to week 52 (W52), TIL 200 mg every 12 weeks (Q12W) to W52, TIL 100 mg Q12W to W52, TIL 20 mg Q12W to W24→TIL 200 mg Q12W to W52, or placebo (PBO) Q4W to W24→TIL 200 mg Q12W to W52. PASI 75/90/100 were prespecified endpoints and were assessed by an independent assessor. Pts who received ≥ 1 dose of study drug were analysed. Safety assessments included treatment-emergent adverse event (TEAE) monitoring.

Results: Overall, 391/500 pts screened met inclusion criteria; 235 (60.1%) had $\geq 3\%$ BSA involvement at baseline (41–55/treatment arm). Demographics and baseline disease characteristics were generally consistent across treatment arms. Mean (standard deviation [SD]) age was 48.8 (12.6) years, average body mass index was 29.7, 96.7% of pts were White, and 23.3% were anti-tumour necrosis factor (TNF)-experienced. At baseline, the mean (SD) PASI score was 6.8 (8.2) and mean (SD) BSA affected was 10.5% (14.3%) overall. Among pts with baseline BSA $\geq 3\%$, TIL treatment significantly increased the proportion of PASI 75/90/100 responders vs PBO at W24; the proportion of responders continued to increase thereafter and was sustained through W52 (Figure). Similarly, in pts switching from PBO→TIL 200 mg Q12W or escalating from TIL 20→200 mg Q12W after W24, PASI 75/90/100 response rates increased through W36 and remained stable through W52. From W0→W24/W25→W52, 50.4%/39.9% pts experienced a TEAE. The most frequent TEAEs were nasopharyngitis (pooled TIL arms 5.4%/4.2% vs PBO 6.3%/3.8%) and upper respiratory tract infection (pooled TIL arms 3.8%/4.2% vs PBO 1.3%/0.0%). One pt (0.3%) discontinued before 24 weeks due to hypertension. There were no deaths or major adverse cardiac events during W0→W24 or W25→W52.

Figure. PASI 75/90/100 response rates up to week 52 across treatments and time points

Response rates were calculated in patients with BSA $\geq 3\%$ at baseline. Black symbols and corresponding p-values were analysed using nonresponse imputation for missing responses. Error bars represent two-sided 95% CI based on the normal approximation for binomial proportions. P-values are based on Cochran-Mantel-Haenszel test (with prior anti-TNF use and baseline body weight as stratification factors) for nonresponse imputation. * $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$ vs placebo. BSA, body surface area; CI, confidence interval; PASI, Psoriasis Area and Severity Index; Q4W, every 4 weeks; Q12W, every 12 weeks; TIL, Itrixolizumab; TNF, tumour necrosis factor.

Conclusion: PASI75/90/100 response rates progressively improved with treatment; PASI 75 responses were significantly improved vs placebo as early as W4 (TIL 200mg Q12W), and all response rates were significantly improved vs placebo at W24. Response rates continued to improve through W36 and were sustained through W52. These results demonstrate TIL significantly reduced psoriasis disease activity and was generally well tolerated in a mixed population of anti-TNF-naïve and -experienced patients with PsA and BSA $\geq 3\%$ through W52.

References:

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SAT0418

EFFECT OF TOFACITINIB TREATMENT ON ACTIVE MRI SACROILIITIS AND DISEASE ACTIVITY REDUCTION IN PSORIATIC ARTHRITIS PATIENTS. DATA FROM CLINICAL PRACTICE

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Background: Axial involvement in psoriatic arthritis (PsA) is quite common. Tofacitinib (TOFA) is an oral Janus kinase inhibitor. There is no data on the use of TOFA in PsA patients (pts) with axial involvement, nor is there any data on its effect on active MRI sacroiliitis (MRI-SI). There are only preliminary results of a randomized clinical trial on TOFA efficacy on active SI in AS (1).

Objectives: To study the effect of TOFA therapy on active MRI-SI in PsA pts.

Methods: 40 pts (F/M – 23/17) with active PsA fulfilling the CASPAR criteria were examined. No patients with inflammatory back pain (IBP) were specifically selected. Median (Me) age 41.0 [35.0; 50.0] yrs, Me PsA duration 6.0 [3.0; 10.0] yrs. Pts underwent a standard clinical examination of PsA activity: Me tender joint count 19 [12; 24], swollen joint count 11 [8; 16], patient's global disease activity measured by Visual Analogue Scale (VAS) 70 [50; 80], patient's pain VAS 65 [50; 75], Me activity indexes: DAPSA 44.2 [37.8; 55.3], BASDAI 6.0 [4.2; 7.0], ASDAS 3.8 [2.8; 4.4]. Me CRP 21.3 [3.2; 72.3] mg/L, ESR 28 [12; 52] mm/h. Enthesitis was observed in 65.9% of pts, dactylitis in 53.7% of pts. Apart from a standard clinical examination, all 40 pts underwent sacroiliac joint (SIJ) MRI on scanner Siemens General Electric 1.5 TESLA. Bone marrow edema/osteitis on MRI (STIR) with one lesion on two consecutive slices or at least two lesions on a single slice, was considered active MRI-SI. MRI results were evaluated by 2 independent readers (radiologist and rheumatologist). TOFA was given in 5 mg tablets bds over a period of 6 months, after which 35 patients underwent SIJ MRI. Me [Q25; Q75], Pierson- χ^2 tests were performed. All $p < 0.05$ were considered to indicate statistical significance.

Results: Prior to TOFA therapy, active MRI-SI was detected in 14 of 40 (35%) pts: bilateral in 9 pts, unilateral in 5 pts. At the end of 6 months therapy, active MRI-SI was detected in 4 of 35 (11.4%) pts observed: in 1 pt with baseline bilateral MRI-SI and in 2 pts with unilateral MRI-SI. 1 pt showed negative dynamics, that is, development of active MRI-SI (absent at baseline). The decrease in number

of active MRI-SI patients is statistically significant ($p = 0.017$; Pearson- χ^2). At baseline, inflammatory changes were detected in 23 of 80 (28.8%) SIJs, after 6 months of therapy they were found in 5 of 70 (7.1%) SIJs observed. Decrease in number of SIJs with active inflammation is statistically significant ($p = 0.001$; Pearson- χ^2). At baseline, Me BASDAI 6.0 [4.2; 7.0], Me ASDAS 3.8 [2.8; 4.4]. After 6 months of treatment, Me BASDAI 1.4 [0.6; 3.2], Me ASDAS 1.5 [1.0; 2.1] ($p = 0.001$ for both comparisons).

Conclusion: JAK inhibition using TOFA therapy shows high efficacy in reducing active MRI-SI and decreasing activity of axial involvement in PsA. More extensive studies are needed.

References:

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SAT0419

ASSOCIATION OF ACTIVE MRI SACROILIITIS WITH DACTYLITIS AND WORK PRODUCTIVITY IMPAIRMENT IN PSORIATIC ARTHRITIS PATIENTS. POSITIVE EFFECTS OF TOFACITINIB TREATMENT. DATA FROM CLINICAL PRACTICE

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Background: Psoriatic arthritis (PsA) is a heterogeneous disease with multiple manifestations and choosing among treatments can be a complex decision. Patients (pts) with axial involvement and pts having dactylitis are more likely to develop a severe disease (1, 2). Tofacitinib (TOFA), an oral Janus kinase inhibitor, showed efficacy in treating PsA pts with dactylitis (3). However, its efficacy in treating PsA pts with active sacroiliitis (SI) and dactylitis has not been studied.

Objectives: To study the effect of TOFA therapy in PsA pts having active SI on MRI (MRI-SI) and dactylitis.

Methods: 40 pts (M/F – 23/17) with active PsA fulfilling the CASPAR criteria were examined. Median (Me) age 41.0 [35.0; 50.0] yrs, Me PsA duration 6.0 [3.0; 10.0] yrs. A standard clinical examination of PsA activity was performed: Me tender joint count 19 [12; 24], swollen joint count 11 [8; 16], patient's global disease activity measured by Visual Analogue Scale (VAS) 70 [50; 80], patient's pain VAS 65 [50; 75], Me activity indexes: DAPSA 44.2 [37.8; 55.3], BASDAI 6.0 [4.2; 7.0], ASDAS 3.8 [2.8; 4.4]. CRP 21.3 [3.2; 72.3] mg/L, ESR 28 [12; 52] mm/h. Enthesitis was observed in 65.9% of pts with Me LEI index 1 [0; 1], dactylitis in 53.7% of pts, Me digits with dactylitis 1 [0; 2]. Apart from a standard clinical examination, MRI of sacroiliac joints (SIJs) was performed in all 40 pts using MRI scanner Siemens General Electric 1.5 TESLA. Bone marrow edema/osteitis on MRI (STIR) considered active MRI sacroiliitis (MRI-SI), was evaluated by 2 independent readers (radiologist and rheumatologist). TOFA was given in 5 mg tablets bds over a period of 6 months, after which 35 patients underwent SIJ MRI. Me [Q25; Q75], Pierson- χ^2 tests were performed. All $p < 0.05$ were considered to indicate statistical significance.

Results: Prior to TOFA therapy, MRI-SI was detected in 14 of 40 (35.0%) pts. At the end of 6 months therapy, MRI-SI was detected in 4 of 35 (11.4%) pts: in 3 pts with baseline SI; 1 pt showed negative dynamics, that is, development of active SI (absent at baseline). The decrease in number of active MRI-SI pts is statistically significant ($p = 0.017$; Pearson- χ^2). Significant differences between baseline symptoms in patients with MRI-SI ($n = 14$) and without it ($n = 26$) were defined by **number of digits with dactylitis:** 2 [0; 4] and 0 [0; 2] ($p = 0.047$), **by ESR:** 47 [26; 76] and 20 [6; 37] mm/h ($p = 0.025$), and **by WPAI overall work impairment due to health index:** 80 [60; 84]% and 20 [0; 60]% ($p = 0.033$), respectively; these parameters were higher in MRI-SI subgroup. After 6 months of therapy number of digits with dactylitis, ESR and WPAI indexes were significantly lower as compared with the baseline ones (Table 1).