adalimumab (ADA), a TNF inhibitor, as monotherapy in biologic-naïve active PsA pts with active plaque psoriasis (defined as having at least one psoriatic plaque of ≥ 2 cm diameter or nail changes consistent with psoriasis or documented history of plaque psoriasis).

Objectives: To report the pre-specified skin outcomes from the EXCEED study in the subset of pts with at least 3% body surface area (BSA) affected with psoriasis at baseline.

Methods: Head-to-head, phase-3b, randomised, double-blind, active-controlled, multicentre, parallel-group trial: pts were randomised to receive SEC 300 mg subcutaneous at baseline, Week 1-4, followed by dosing every 4 weeks (q4w) until Week 48 or ADA 40 mg subcutaneous at baseline followed by same dosing q2w until Week 50. The primary endpoint was superiority of SEC vs. ADA on ACR20 response at Week 52. Pre-specified outcomes included the proportion of pts achieving a combined ACR50 and PASI 100 response, PASI 100 response, and absolute PASI score ≤ 3 . Missing data was handled using multiple imputation.

Results: 853 pts were randomised to receive SEC (n=426) or ADA (n=427). At baseline, there were 215 and 202 pts having at least 3% BSA affected with psoriasis in the SEC and ADA groups, respectively. A higher proportion of patients achieved simultaneous improvement in ACR50 and PASI 100 response with SEC vs. ADA (30.7% vs. 19.2%; $P=0.0087$ [Figure]). Higher efficacy was demonstrated for SEC vs. ADA for PASI 100 responses and for the proportion of pts achieving absolute PASI score ≤ 3 (Table).

Conclusion: In this pre-specified analysis, SEC provided higher responses compared to ADA in achievement of simultaneous improvement of joint and skin disease (combined ACR50 and PASI 100 response) and in skin specific endpoints (PASI 100 and PASI score ≤ 3) at Week 52.

References:

- [1] Coates LC and Helliwell PS. *Clinical Med*. 2017;17:65–70.
- [2] Langley RG et al. *N Engl J Med*. 2014;371:326–38.

Figure. Combined ACR50 and PASI 100 Response through Week 52

Table. Skin Specific Outcomes at Week 52

Endpoints, data is presented as % response	SEC 300 mg (N = 215)	ADA 40 mg (N = 202)	P-value (unadjusted)
PASI 100	46.0	29.7	0.0007
Absolute PASI score ≤ 3	79.2	65.0	0.0015

P value vs. adalimumab; Unadjusted P values are presented

N, number of patients in psoriasis subset

Multiple imputation was used for handling missing data

ADA, adalimumab; BSA, body surface area; PASI, psoriasis area severity index; SEC, secukinumab

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FRI0341

RISK FACTORS FOR AXIAL INVOLVEMENT IN EARLY PSORIATIC ARTHRITIS

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Background: Axial Involvement in psoriatic arthritis (PsA) is quite common [1]. Predictors of axial involvement at early-stage of disease haven't been sufficiently studied.

Objectives: To identify predictors of axial involvement in PsA patients (pts) at early-stage of disease.

Methods: 95 patients (pts) (M/F=47/48) with early PsA fulfilling the CASPAR criteria were included. All pts had peripheral arthritis for ≤ 2 years; no inflammatory back pain (IBP) pts were specifically selected. Mean (Me) age 36.5 ± 10.7 yrs, disease duration 12.2 ± 10.3 mo. Pts underwent standard clinical examination of PsA activity. Me disease activity indexes DAS=4.0 $\pm$ 1.4, DAS28=4.2 $\pm$ 1.1, BASDAI=4.5 $\pm$ 1.6; Me pts global disease activity VAS 56.9 $\pm$ 17.1. All patients were evaluated for the presence of IBP by ASAS criteria, underwent sacroiliac joints (SIJs) X-ray (pelvic radiographs) and HLA B27 antigen status study. MRI of SIJs was performed in 79 pts, regardless of IBP presence, on Signa Ovation 0.35T. Radiographic sacroiliitis (R-SI) was identified according to New York criteria (unilateral grade ≥ 3 or bilateral grade ≥ 2). Bone marrow edema/osteitis on MRI (STIR) was considered active MRI sacroiliitis (MRI-SI). X-ray and MRI results were evaluated by an independent reader. IBP was observed in 63 (66.3%) cases, MRI-SI in 28 of 79 (35.4%) examined cases, R-SI in 29 (30.5%) cases. Skin lesion severity was evaluated as body surface area (BSA) affected: minor at $< 3\%$, mild at 3-10%, severe at $> 10\%$. Pts were split into 2 groups (gr.): those with axial involvement (axPsA), that is with IBP and/or R-SI and/or MRI-SI; and those without axial involvement (having only peripheral PsA [pPsA]). The axPsA gr. included 65 (68.4%) cases, the pPsA gr. 30 (31.6%) cases. Multi-dimensional step-by-step discriminant analysis was used to identify a group of features that are more typical for the axPsA patients.

ROC Curve

1 - Specificity

Diagonal segments are produced by ties.

Results: The following features proved to be the most informative: male sex ($p = 0.300$), presence of HLA B27 ($p = 0.107$), mild or high DAS ($p = 0.098$), skin lesion severity $BSA > 3\%$ ($p = 0.118$), and $CRP > 5 \text{ mg/L}$ (0.038). Sensitivity of model 79.0%, specificity of model 57.7%. Area under ROC curve 0.756; 95% CI (0.642-0.869).

Conclusion: It is a combination of features – male sex, HLA-B27 positivity, mild or high activity of peripheral arthritis according to DAS, $CRP > 5 \text{ mg/L}$, and $BSA > 3\%$ – that constitutes a clinical predictor for the development of axial involvement in early psoriatic arthritis.

References:

[1] V. Chandran et al. *Curr Opin Rheumatol*. 2019;31:329-34

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FRI0342

POST-EFFORT SYNOVIAL AND ENTHESIC RESPONSE IN PATIENTS WITH PSORIATIC ARTHRITIS IN REMISSION OF LOW DISEASE ACTIVITY

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Background: Synovial inflammation is part of the pathophysiological process of PsOA although it is considered secondary to enthesitis. It is of interest to assess the synovial joint, peritendinous and enthesic response of patients with PsOA in remission under controlled mechanical stress.

Objectives: Our aim is to present our observational experience in patients with APso in remission or low activity of the disease exposed to controlled manual physical efforts adapted to the own grasping capacity of each subject.

Methods: Before-after study of a consecutive cohort of patients with PsOA (CASPAR criteria), of at least two years evolution and $DAPSA \leq 14$ at present. Patients with positive rheumatoid factor, patients with exclusively axial forms and patients on biological therapy at the beginning of the study were excluded. All patients underwent controlled basal ultrasound and post-dynamometric exercise (CAMRY EH101-17) of the dominant hand which included the carpus, MCFs, IFPs and IFDs of the 2nd to 5th fingers. The ultrasound findings were scored according to EULAR recommendations in grey scale (GS) and power Doppler (PD) for synovitis, enthesitis and tenosynovitis (maximum scores 71 and 87, respectively). For statistical analysis, comparisons were made with the results of their baseline and post-exercise ultrasound scores between subjects diagnosed with PsOA and controls. The Student's T test was used for related and unrelated data according to correspondence.

Results: Nineteen patients and controls were included, of which 73.7% were male. Mean age: 42.2 SD 6.6 and 42.21 SD 8.28, respectively. Basal DAPSA among patients: 7.26 SD 4.53. Mean traction strength of patients and controls: 23.8 SD 7.3 and 26.1 SD 6.9 kg, respectively ($P=0.336$). In the group of patients, the post exercise DAPSA had a mean of 7.52 SD 4.62 ($P=0.021$, with respect to the basal DAPSA). The mean total GS score in the patient group was 3.94 SD 2.36 and 7.31 SD 3.3, pre- and post-exercise, respectively ($P<0.001$). The mean total score in the PD study was 0.73 SD 0.73 and 2.57 SD 1.16, respectively ($P<0.001$). In patients with PsOA there were no detectable enthesic changes. In the control group, no ultrasound changes were statistically significant, although the score for tenosynovitis ranged from 0.1 SD 0.31 to 0.42 SD 0.6 ($P=0.055$).

Conclusion: Patients with APso in clinical remission or low disease activity develop ultrasound changes after controlled exercise. These changes are appreciable in the joint synovium and tendon but not at an enthesic level. Although these changes are also detectable in a healthy population, their prevalence is much lower. Our interpretation is that control of the disease correlates with an absence of enthesic inflammatory activity although synovial susceptibility remains less evident. This reinforces the idea that PsOA is an inflammatory enthesitis with associated arthritis and not its opposite.

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FRI0343

EFFICACY AND SAFETY OF FILGOTINIB, A SELECTIVE JANUS KINASE 1 INHIBITOR, IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS: SUBGROUP ANALYSES FROM A RANDOMIZED, PLACEBO-CONTROLLED, PHASE 2 TRIAL (EQUATOR)

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Background: Treatment with the oral selective Janus kinase 1 inhibitor filgotinib was associated with rapid and significant improvements in multiple domains of active psoriatic arthritis versus placebo in the 16-week Phase 2, multicenter, double-blind, randomized EQUATOR trial (NCT03101670).¹ A significantly greater proportion of patients receiving filgotinib, versus placebo, achieved the primary endpoint of 20% improvement in American College of Rheumatology (ACR) 20 response at Week 16 (80% vs 33%, respectively).¹

Objectives: The aim of this predefined analysis was to evaluate the consistency of the response to filgotinib across predefined relevant subpopulations participating in the EQUATOR trial.

Methods: In EQUATOR, patients with active psoriatic arthritis were treated with filgotinib 200 mg ($n=65$) or placebo ($n=66$) once daily for 16 weeks. Key clinical endpoints, including ACR20 and ACR50 (50% improvement) response rates, Psoriatic Arthritis Disease Activity Score (PASDAS), and Disease Activity Index for Psoriatic Arthritis (DAPSA) were evaluated according to the following baseline characteristics: sex, body mass index, disease duration, baseline disease severity, concurrent use of disease-modifying antirheumatic drug(s), and prior exposure to tumor necrosis factor inhibitor(s). For PASDAS and DAPSA scores, statistical analysis of changes from baseline was performed using analysis of covariance with factors for treatment, randomization stratification, subgroup, and an interaction between treatment and subgroup. Least-squares (LS) mean difference between treatment arms and the corresponding 95% confidence intervals (CI) were calculated. For ACR20 and ACR50 response rates, statistical analysis used the point estimate and corresponding 95% CI, based on the Newcombe method.

Results: Sixty patients (92%) in the filgotinib group and 64 (97%) in the placebo group completed the study. The total number of patients in each subpopulation ranged from 18 to 104 (Figure 1). Differences in the proportions of patients achieving ACR20 consistently favored filgotinib, compared with placebo, across all subgroups (Figure 1); all differences reached statistical significance. Similarly, differences in the proportions of ACR50 responders and LS mean treatment differences for PASDAS and DAPSA consistently favored filgotinib, reaching statistical significance in most subgroups. No clinically relevant differences in the effect of filgotinib were observed across subgroups. Filgotinib was generally well tolerated and no new safety signals were identified.

Figure 1. Effect of filgotinib on ACR20 response across subgroups.

ACR20, 20% improvement in American College of Rheumatology response criteria; BMI, body mass index; DMARD, disease-modifying antirheumatic drug; PASDAS, Psoriatic Arthritis Disease Activity Score; TNF, tumor necrosis factor