Table. Clinical, Functional, and Structural Outcomes Through 24 Weeks Among Adalimumab- and Placebo-treated Patients Having Severe* or Mild-to-Moderate* Psoriasis at Baseline Relative to the Overall Study Population.

n (%)	ADA 40 mg eow				PBO eow			
	Severe Ps (N=17)	Mild-to-Moderate Ps (N=66)	Mild-to-Moderate Ps (N=83)	Total study population (N=151)	Severe Ps (N=20)	Mild-to-Moderate Ps (N=60)	Mild-to-Moderate Ps (N=80)	Total study population (N=162)
MDA	5 (29)	29 (44)	34 (41)	53 (35)	3 (15)	6 (10)	9 (11)	11 (7)
DAPSA <4	4 (24)	19 (29)	23 (28)	33 (22)	1 (5)	1 (2)	2 (3)	4 (2)
DAPSA <4, <14	4 (24)	19 (29)	14 (17)	33 (22)	3 (15)	5 (8)	8 (10)	14 (9)
HAQ-DI <0.25	6 (35)	29 (44)	35 (42)	70 (46)	4 (20)	12 (20)	16 (20)	33 (20)
ΔHAQ-DI ≥0.22	12 (75)	43 (80)	55 (79)	99 (79)	5 (31)	16 (38)	21 (36)	52 (42)
ΔmTSS ≤0*	14 (82)	46 (70)	60 (72)	120 (79)	11 (55)	33 (55)	44 (55)	93 (57)
ΔmTSS ≤0.5*	16 (94)	54 (82)	70 (84)	132 (87)	12 (60)	41 (68)	53 (66)	111 (69)
PASI50*	14 (82)	42 (64)	56 (68)	N/A	3 (15)	8 (13)	11 (14)	N/A
PASI75*	8 (47)	35 (53)	43 (52)	N/A	1 (5)	3 (5)	4 (5)	N/A
PASI90*	7 (41)	24 (36)	31 (37)	N/A	1 (5)	2 (3)	3 (4)	N/A

All analyses are non-responder imputation, unless otherwise noted.
 *Severe psoriasis defined as PASI ≥12 AND BSA ≥10%; mild-to-moderate psoriasis defined as PASI <12 AND BSA <10%; imputation using ranks of total Sharp score and 75th percentile; *PASI responses were only collected for patients with psoriasis involving >3% BSA at baseline; ADA: adalimumab; eow: every other week; PBO: placebo; Psoriasis: Minimal disease activity; DAPSA: disease activity index for psoriatic arthritis; HAQ-DI: health assessment questionnaire disability index; ΔHAQ-DI: change from baseline in HAQ-DI; ΔmTSS: change from baseline in modified total Sharp score.

Methods: Pts with baseline PASI and BSA available from ADEPT, a phase 3, randomized, double-blind, PBO-controlled trial of ADA 40 mg every other week, were included in this post hoc analysis.² Pts were sub-grouped based on baseline PsO severity (severe PsO: PASI ≥12 OR BSA ≥10%; mild-to-moderate PsO: PASI <12 AND BSA <10%), relative to overall study population. Clinical outcomes at wk 24 were assessed by attainment of minimal disease activity (MDA), remission and low disease activity (LDA) by disease activity index for psoriatic arthritis (DAPSA), and PASI50/75/90; function and structural progression were assessed by the % of pts experiencing HAQ-DI normative values (≤0.25) and improvement from baseline ≥0.22 (MCID), and the % of pts having change from baseline in mTSS ≤0 and ≤0.5 in the modified total Sharp score (mTSS) respectively. A logistic model with treatment group baseline PASI/BSA and PASI/BSA by treatment interaction was fit for each outcome variable. *P*-values for interaction term and baseline BSA/PASI were calculated. Non-responder imputation was used for missing clinical and functional endpoints. 75th percentiles were imputed for missing radiographic data. Treatment-emergent adverse events (TEAEs) were monitored throughout.

Results: Of the 163 pts enrolled in the study with baseline PASI and BSA, only 23% (n=37; ADA: 17; PBO: 20) were classified as having severe PsO and had similar characteristics to those with mild-to-moderate PsO, except for numerically higher physician's global assessment, dactylitis, and enthesitis scores. Following 24 wks of treatment, 41% of ADA-treated pts achieved MDA and 45% achieved DAPSA LDA or better, a finding consistent irrespective of baseline PsO severity (Table). 72% of ADA-treated pts with baseline PsO did not exhibit any structural progression by mTSS (≤0) through 24 wks as compared to 55% receiving PBO. Logistic regression analyses confirmed limited role that PsO severity played across examined outcomes. DAPSA remission was more likely at wk 24 among pts with higher baseline PASI scores, and this effect was less apparent with ADA treatment. TEAEs appeared comparable between ADA and PBO groups; fewer infectious AEs occurred in the ADA severe PsO group vs the mild-to-moderate PsO group.

Conclusion: Prevalence of severe PsO in this population of PsA pts was consistent with previous observations.³ Treatment with ADA was associated with better PsA outcomes as compared to PBO irrespective of the degree of PsO severity at baseline.

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AB0766 EVOLUTION OF BONE MINERAL DENSITY IN PATIENTS WITH PSORIATIC ARTHROPATHY

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Background: Some studies indicate that psoriatic arthritis (PsA) patients have increased bone loss due to chronic inflammation, but data in the Spanish population is scarce.

Objectives: To study the evolution over time of bone mineral density (BMD) in patients with PsA and to investigate the factors related to these changes.

Methods: We included PsA patients with peripheral joint involvement. They were treated at the Doctor Peset University Hospital and a 3-year follow-up was carried out.

All patients underwent a bone densitometry and history of fracture was collected by conventional radiology at baseline and at 3 years. Phosphocalcic metabolism was also analyzed. We collected demographic and clinical variables [disease duration, DAS28, body mass index (BMI), smoking]. We considered 25OHD as deficient if <20 ng/ml, low bone mass as T or Z scale <-1 SD and osteoporosis as scale T <-2.5 DE or Z <-2 SD. Statistical analysis were performed with SPSS 22.0 program.

Results: We included 91 patients (67.2% women), with a mean age of 56.4 (SD 1.2) years. The mean of disease duration was 104.9 (SD 11.8) months. The BMI mean was 27.6 (SD 0.5) and 36.3% of patients were smokers. 25OHD mean was 27.7 (SD 1.3) ng/ml and 33.3% of patients had a deficient 25OHD. More than half of the patients (53.8%) had low bone mass and 14.3% had osteoporosis, measured by densitometry. Twelve patients had history of fractures [6 distal forearm, 5 vertebral fractures (VF) and 1 of femur]. Thirteen patients received antiresorptive treatment [9 bisphosphonates, 3 denosumab and 1 selective estrogen receptor modulator (SERM)], and 39.6% of patients received 25OHD supplements. We did not observe any significant correlation between the 25OHD values and the activity parameters of the PsA. However, we observed lower levels of 25OHD in obese patients. At 3 years, the BMD remained stable in the majority of patients (68.1%) receiving antiresorptive treatment, and it worsened in 2 patients despite treatment with bisphosphonates. We registered new fractures in 7 patients (4 VF, 1 femur fracture and two patients had more than one fracture). New fractures were not correlated with age, 25OHD deficiency or with previous osteoporotic treatment. We observed greater progression of BMD in patients exposed to tobacco.

Conclusion: More than half of patients with PsA have a low BMD (53.8%) and 33.3% deficient levels of 25OHD. Our study confirms results found in general population: classic risk factors, such as smoking, are related to BMI progression. It is important to evaluate BMD in these patients and intervene early.

Disclosure of Interests: None declared

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AB0767 MULTI-SYMPTOM IMPACT ON THE EQ-5D INDEX IN BIO-NAÏVE ACTIVE PSORIATIC ARTHRITIS PATIENTS: AN ANALYSIS THROUGH WEEK 24 OF THE GO-VIBRANT STUDY

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Background: Psoriatic arthritis (PsA) is a chronic inflammatory disease characterized by peripheral arthritis, axial inflammation, dactylitis, enthesitis and skin and nail psoriasis. The impact of skin and joint components of the disease on patient health-related quality of life has been described in

previous research (1,2) but the impact of other major clinical manifestations has not been similarly characterized.

Objectives: To quantify the impact of the major clinical manifestations of PsA on patient reported health related quality of life, as estimated by disease state preference (utility) derived from the EQ-5D index in a randomized clinical trial.

Methods: This analysis used data from a multicenter, randomized, double-blind, placebo-controlled trial of intravenous (IV) Golimumab in biologic naïve patients with active psoriatic arthritis (GO-VIBRANT study). Patient baseline characteristics of the GO-VIBRANT study population have been previously described (3). Core outcome measures recommended by OMERACT (Outcome Measures in Rheumatology Clinical Trials) and guideline on utility mapping by ISPOR (International Society for Pharmacoeconomics and Outcome Research) were used to guide initial attribute selection. Utility was derived from patient responses to the EQ-5D index, which assesses mobility, self-care, usual activities, pain/discomfort, and anxiety/depression, and was completed at weeks 0, 8, 14, and 24 in the trial (placebo-controlled period). EQ-5D index is used as a measure of overall health and is an outcome commonly used in health economic analyses. Multivariate analysis was performed using a Mixed-Effect Repeated Measures model based on observed data until week 24 in pooled patient population.

Results: Based on univariate analyses and evaluation of collinearity between variables, the following attributes were included in the multivariate models: age, gender, region, PsA disease duration, PASI score, enthesitis, dactylitis, tender joint count (TJC), swollen joint count (SJC), C-reactive protein (CRP mg/L) and Health Assessment Questionnaire-Disability Index (HAQ-DI). In the final model, PASI score ($\beta = -0.00126$, $p = 0.0006$), enthesitis ($\beta = -0.01237$, $p = 0.03$), TJC ($\beta = -0.00112$, $p < 0.0001$), CRP ($\beta = -0.00079$, $p < 0.0001$) and HAQ-DI ($\beta = -0.1664$, $p < 0.0001$) were all statistically significantly associated with the EQ-5D index. A sensitivity analysis among a subgroup of patients who had spondylitis with peripheral joint arthritis as their primary arthritic presentation of PsA showed that spinal pain ($\beta = 0.0101$, $p < 0.0001$), as measured by question #2 of the Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), was also statistically significantly associated with the EQ-5D index in the multivariate model.

Conclusion: Multiple PsA clinical manifestations including psoriasis, enthesitis, TJC, spinal pain, CRP, and physical function were statistically significantly associated with utility among PsA patients as derived from the EQ-5D index. These findings indicate that consideration of multiple clinical manifestations of PsA is warranted when evaluating the impact of PsA on patients.

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AB0768

BASILINE PAIN SEVERITY AS A PREDICTOR OF PAIN IMPROVEMENT FOLLOWING TREATMENT WITH TOFACITINIB IN PSORIATIC ARTHRITIS

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Background: Pain is a core domain of psoriatic arthritis (PsA).¹ Rapid, sustained pain reduction is a priority for patients (pts) and physicians when choosing treatment. Tofacitinib is an oral Janus kinase inhibitor for the treatment of PsA.

Objectives: This post hoc analysis aimed to estimate time to clinically meaningful pain improvement with tofacitinib.

Methods: Data were analysed from 2 Phase 3 studies of tofacitinib in pts with active PsA and an inadequate response to ≥ 1 conventional synthetic disease-modifying antirheumatic drug (csDMARD) (OPAL Broaden; NCT01877668; 12-month study), or to ≥ 1 tumour necrosis factor inhibitor (OPAL Beyond; NCT01882439; 6-month study). Pts treated with tofacitinib 5 mg twice daily (BID) and placebo (PBO) advanced to tofacitinib 5 mg BID at Month 3 (PBO-tofacitinib), in combination with csDMARDs, were included in this analysis. Current arthritis pain severity was reported by pts using a 100 mm visual analogue scale, where higher scores indicated greater severity of pain. Pain improvement was defined as the first post-baseline improvement of $\geq 30\%$ (meaningful change), $\geq 50\%$ (substantial change) or $\geq 70\%$ relative to baseline.² Time-to-event analyses were performed using a Kaplan-Meier (KM) method on pooled data. Descriptive analyses of the rate of improvements by study were performed.

Results: Overall, 354 pts were available for analysis. Rates of pain improvement over time with tofacitinib 5 mg BID were approximately the same in both studies (Figure). By Month 1, $\geq 40\%$ of pts experienced $\geq 30\%$ pain improvement, and by Month 2, approximately 55% of pts experienced $\geq 30\%$ pain improvement (Figure). KM analyses showed that pts receiving tofacitinib 5 mg BID achieved improvements in pain severity of 30–70% significantly faster compared with pts in the PBO-tofacitinib group (Table). The median time to $\geq 30\%$ pain improvement was 55 days in the tofacitinib 5 mg BID group and 106 days in the PBO-tofacitinib group (pts switched to tofacitinib 5 mg BID at Month 3; $p = 0.0132$). Similar trends between treatment groups were observed across other pain improvement thresholds.

Table. Median time (days) to clinically meaningful pain improvement by improvement threshold in pts with PsA

VAS pain improvement threshold	Median time (days) to pain improvement		Test of equality between groups Log-rank test, p value
	Tofacitinib 5 mg BID	PBO switching to tofacitinib 5 mg BID at Month 3	
$\geq 30\%$	55	106	0.0132
$\geq 50\%$	85	169	0.0068
$\geq 70\%$	184	337	0.0033

Derived using non-parametric KM (nonparametric) models for time to event
BID, twice daily; KM, Kaplan-Meier; PBO, placebo; PsA, psoriatic arthritis; pts, patients; VAS, visual analogue scale