OP0232

FEMALE VERSUS MALE BURDEN OF PSORIATIC ARTHRITIS IS HIGHER AND TREATMENT PERSISTENCE SHORTER AFTER USTEKINUMAB OR TUMOUR NECROSIS FACTOR INHIBITOR TREATMENT: 1-YEAR DATA FROM THE PSABIO STUDY

I. van der Horst-Bruinsma¹, M. Nurmohamed², A. Van Kuijk², S. Siebert³, P. Bergmans⁴, K. De Vlam⁵, E. Gremese⁶, B. Joven-Ibáñez⁷, T. Korotaeva⁸, W. Noel⁹, P. Sfikakis¹⁰, E. Theander¹¹, J. S. Smolen¹², L. Gossec^{13,14}.

¹Amsterdam University Medical Center, Location VUmc, Department of Rheumatology and Immunology, Amsterdam, Netherlands; ²Reade and VU University Medical Center, Department of Rheumatology, Amsterdam, Netherlands; ³University of Glasgow, Institute of Infection Immunity and Inflammation, Glasgow, United Kingdom; ⁴Janssen-Cilag BV, Biostatistics, Breda, Netherlands; ⁵University Hospitals Leuven, Division of Rheumatology, Leuven, Belgium; ⁶Catholic University of the Sacred Heart, Fondazione Policlinico A Gemelli IRCCS, Rome, Italy; ⁷University Hospital 12 de Octubre, Department of Rheumatology, Madrid, Spain; ⁸VA Nasonova Research Institute of Rheumatology, Department of Spondyloarthritis and Psoriatic Arthritis, Moscow, Russian Federation; ⁹Janssen Pharmaceutica NV, Medical Affairs, Beerse, Belgium; ¹⁰National and Kapodistrian University of Athens Medical School, First Department of Propaedeutic and Internal Medicine, Athens, Greece; ¹¹Janssen-Cilag AB, Medical Affairs, Solna, Sweden; ¹²Medical University of Vienna, Division of Rheumatology, Department of Medicine III, Vienna, Austria; ¹³Sorbonne University, INSERM, Pierre Louis Institute of Epidemiology and Public Health, Paris, France; ¹⁴Pitié-Salpêtrière Hospital, AP-HP, Department of Rheumatology, Paris, France

Background: Sex-related differences in biologic treatment of psoriatic arthritis (PsA) have been insufficiently studied in a real-world setting.

Objectives: To evaluate impact of sex on PsA, treatment effectiveness and persistence after 1 year of biologic treatment.

Methods: PsABio (NCT02627768) is a multinational, prospective real-world study in PsA with ustekinumab (UST) or TNF inhibitor (TNFi) as 1st/2nd/3rd-line biologic. Males and females were compared for disease activity and patient-reported outcomes. Descriptive statistics including 95% CI at baseline (BL) and 12 (±3) months (LOCF) follow-up are presented. Intra-sex comparisons between UST and TNFi cohorts were done by logistic regression analysis, with propensity score adjustment for imbalanced BL covariates and non-response imputation for stopping/switching biologic drugs.

Results: Among 494 females and 399 males, age and disease duration were similar. However, differences in disease characteristics at BL were considerable:

Table 1. Patient and disease characteristics at BL and 1-year by sex

	BL female	BL male	1-year LOCF female	1-year LOCF male
Biologic line, %				
1 st	46	55	N/A	N/A
2 nd	34	33		
3 rd	20	13		
Co-treatment, %				
MTX	37.4	34.3	N/A	N/A
Corticosteroids	34.6	32.1		
NSAIDs	59.9	64.4		
Antidepressant	7.9	2.5		
Comorbidities, %				
Cardiovascular	69.0	59.4	N/A	N/A
metabolic syndrome	40.1	31.7		
Obesity	35.2	23.7		
Anxiety/depression	12.6	7.5		
Smoking status, %				
Never	54.9	41.9	N/A	N/A
Past	16.8	26.6		
Current	22.7	24.3		
Unknown	5.7	7.3		
Joint counts, n				
Swollen 66	6.1 (5.4; 6.9)	5.6 (4.7; 6.4)	2.2 (1.7; 2.6)	1.3 (1.0; 1.6)
Tender 68	13.2 (12.0; 14.4)	10.0 (8.9; 11.1)	6.0 (5.2; 6.7)	3.6 (2.9; 4.3)
cDAPSA score, mean (95% CI)				
cDAPSA, %	32.5 (30.5; 34.4)	26.9 (24.9; 29.0)	15.9 (14.5; 17.2)	10.3 (9.0; 11.6)
Remission	1.0 (0.3; 2.6)	4.0 (2.1; 6.7)	17.8 (14.1; 22.0)	37.7 (32.4; 43.2)
Low	6.7 (4.4; 9.7)	15.0 (11.3; 19.4)	33.0 (28.3; 37.9)	36.5 (31.3; 42.0)
Moderate	38.9 (34.0; 44.0)	42.6 (37.2; 48.2)	34.3 (29.6; 39.2)	16.9 (13.0; 21.4)
High	53.4 (48.2; 58.4)	38.3 (33.0; 43.9)	14.9 (11.6; 18.9)	8.9 (6.0; 12.5)
MDA	2.3 (1.0; 4.3)	7.7 (5.1; 11.2)	27.5 (23.1; 32.1)	52.2 (46.6; 57.7)
VLDA	0.0	0.9 (0.2; 2.6)	6.2 (4.1; 9.0)	19.7 (15.6; 24.3)
HAQ-DI score	1.31 (1.25; 1.37)	0.93 (0.86; 1.00)	0.95 (0.89; 1.02)	0.53 (0.47; 0.59)
PsAID-12 score	6.1 (5.9; 6.3)	5.1 (4.9; 5.3)	4.0 (3.8; 4.3)	2.7 (2.4; 2.9)
EQ5D VAS score	48.6 (46.6; 50.5)	53.8 (51.6; 55.9)	59.2 (56.9; 61.4)	68.0 (65.5; 70.4)
Enthesitis	50.7 (45.9; 55.5)	48.1 (42.8; 53.3)	32.6 (28.3; 37.3)	18.0 (14.1; 22.3)
Dactylitis	15.6 (12.4; 19.3)	24.7 (20.4; 29.3)	5.7 (3.8; 8.3)	4.8 (2.9; 7.4)

Data are % (95% CI) unless indicated otherwise. Bold data are significantly different (non-overlapping 95% CI).

females had worse scores than males for cDAPSA, HAQ-DI, EQ5D VAS, PsAID-12, pain and comorbidities. At 1 year, similar improvements from BL were observed between sexes, but females remained in a worse health state than males (Table). Achievement of composite endpoints MDA (including VLDA) and cDAPSA LDA (including remission) was high overall (38.6% and 61.5%, respectively), but reached by >2-fold and 3-fold more males than females, respectively. HAQ-DI scores remained worse for females at 1 year (0.95) than for males at BL (0.93). Enthesitis resolution was achieved in 46% of females and 75% of males. No significant differences in effectiveness of UST vs TNFi were detected between sexes (Figure). Kaplan–Meier estimated drug persistence was significantly better in males than females (log-rank $p=0.0007$). There was no intra-sex difference between UST or TNFi in risk of stopping/switching in males or females.

Conclusion: These real-world data from PsABio on sex differences with biologic treatment suggest that females generally start biologics in a worse PsA state than males. Although treatment improvements were similar between sexes, females remained in worse health at 1 year, and stopped/switched biologic earlier. More comprehensive treatment before severe disease manifestations evolve may improve management in females.

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Proportion of females and males achieving treatment targets at 1 year

*Solid bar represents MDA and hashed bar represents VLDA.

*Solid bar represents cDAPSA LDA/remission (≤13) and hashed bar represents cDAPSA remission (≤4).

BL, baseline; cDAPSA, clinical Disease Activity in Psoriatic Arthritis; CI, confidence interval; EQ5D, EuroQoL 5-dimensional questionnaire; HAQ-DI, Health Assessment Questionnaire-Disability Index; LOCF, last observation carried forward; LDA, low disease activity; MDA, minimal disease activity; MTX, methotrexate; N/A, not available; NSAID, non-steroidal anti-inflammatory drugs; OR, odds ratio; PsAID-12, Psoriatic Arthritis Impact of Disease 12-item questionnaire; Rem, remission; TNFi, tumour necrosis factor inhibitor; UST, ustekinumab; VAS, visual analogue scale; VLDA, very low disease activity

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OP0233

EFFICACY AND SAFETY OF UPADACITINIB IN PATIENTS WITH PSORIATIC ARTHRITIS AND AXIAL INVOLVEMENT

A. Deodhar¹, R. Ranza², F. Ganz³, T. Gao⁴, J. Anderson⁴, A. Ostor⁵.

¹Oregon Health & Science University, Rheumatology, Portland, United States of America; ²Universidade Federal de Uberlândia, Rheumatology, Uberlândia, Brazil; ³AbbVie Inc., Rheumatology, Baar, Switzerland; ⁴AbbVie Inc., Rheumatology, North Chicago, United States of America; ⁵Cabrini Hospital, Monash University & Emeritus Research, Melbourne, Australia

Background: Patients (pts) with psoriatic arthritis (PsA) and axial involvement exhibit greater disease activity and quality of life impairments compared with those without axial involvement.

Objectives: To characterize PsA pts with and without axial involvement and compare efficacy of UPA vs placebo (PBO) in PsA pts with axial involvement.

Methods: In SELECT-PsA 1 (NCT03104400; N=1705, non-biologic DMARD IR) and SELECT-PsA 2 (NCT03104374; N=642, biologic DMARD IR), pts with active PsA (≥3 swollen and ≥3 tender joints), active or historical psoriasis, and on ≤2 non-biologic DMARDs were randomized to once daily UPA 15mg, UPA 30mg, adalimumab 40mg every other week (SELECT-PsA 1 only), or PBO. Efficacy was assessed in pts with axial involvement (diagnosed by investigators based on totality of information) pooled from the 2 studies. Assessments included change from BL in BASDAI, BASDAI Q2 (neck/back/hip pain) and Q3 (joint swelling/pain), and the AS Disease Activity Score (ASDAS-CRP), and percentage with BASDAI 50 response, ASDAS inactive disease (ID), ASDAS low disease activity (LDA), ASDAS major improvement (MI), and ASDAS clinically important improvement (CII). Uveitis and inflammatory bowel disease (IBD) adverse events were reviewed. Data on 24-week PBO-controlled period are presented.

Results: Prevalence of axial involvement was 31.3% in SELECT-PsA 1 and 34.2% in SELECT-PsA 2 (Table). Treatment with UPA 15mg and 30mg resulted in significantly greater improvements from BL in the BASDAI, BASDAI Q2 (neck/back/hip pain) and Q3 (joint swelling/pain) and ASDAS-CRP at weeks 12 and 24 vs PBO (Figure). Similarly, significantly higher percentages of pts on UPA 15mg and 30mg achieved BASDAI 50, ASDAS ID, LDA, MI, and CII at weeks 12 and 24 vs PBO (Figure). One pt on UPA 30mg had incident uveitis, and no IBD was reported on UPA.

Conclusion: PsA pts with axial involvement had higher BL disease burden compared with those without axial involvement. UPA was efficacious in treating axial symptoms in pts with psoriatic spondylitis.

REFERENCES:

[1] van der Heijde D, et al. *Lancet*. 2019;394(10214):2108-2117.

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Table 1. Demographics and Baseline Characteristics

Parameter, mean (SD)	SELECT-PsA 1			SELECT-PsA 2		
	With Psoriatic Spondylitis (n=534)	Without Psoriatic Spondylitis (n=1170)	P value*	With Psoriatic Spondylitis (n=219)	Without Psoriatic Spondylitis (n=421)	P value*
BMI (kg/m ²)	29.9 (6.5)	30.5 (6.9)	.0810	31.6 (8.0)	31.3 (6.9)	.6226
TJC68	21.6 (15.1)	19.2 (13.5)	.0022	27.5 (18.0)	23.3 (16.2)	.0027
SJC66	11.7 (9.4)	11.0 (7.9)	.1184	12.9 (9.2)	11.7 (8.7)	.0804
Physician's Global Assessment (NRS 0–10)	6.7 (1.6)	6.5 (1.7)	.0437	6.6 (1.8)	6.5 (1.7)	.1897
HAQ-DI	1.2 (0.6) n=531	1.1 (0.6) n=1164	.0170	1.2 (0.6) n=218	1.2 (0.7) n=416	.2049
Presence of dactylitis, n (%) [†]	188 (35.2)	328 (28.0)	.0028	69 (31.5)	100 (23.8)	.0348
Presence of enthesitis, n (%) [‡]	432 (80.9)	884 (75.6)	.0147	189 (86.3)	337 (80.0)	.0125
ASDAS-CRP	3.4 (0.9) n=530	3.1 (1.0) n=1161	<.0001	3.3 (1.0) n=217	3.2 (1.1) n=416	.1032
BASDAI	5.8 (2.0) n=530	5.3 (2.2) n=1161	<.0001	6.2 (2.2) n=217	5.8 (2.2) n=416	.0673
Morning Stiffness Duration (NRS 0–10; BASDAI Q6)	5.0 (3.0)	4.7 (3.0)	.0368	5.6 (3.2)	5.1 (3.0)	.0454
Patient's Assessment of Inflammatory Neck, Back, or Hip Pain (NRS 0–10; BASDAI Q2)	n=530	n=1161	<.0001	n=217	n=416	.0001

*Calculated by t-test for continuous variables and chi-square test for categorical values. Bolded if <0.05. Defined as [†]LDI>0 and [‡]total enthesitis count >0

Figure. Integrated Analysis of Efficacy in PsA Patients With Axial Involvement

ASDAS, ankylosing spondylitis disease activity score; BL, baseline; CII, clinically important improvement; ID, inactive disease; LDA, low disease activity; MI, major improvement; MMRM, mixed-effects model repeated measurement; NRI, non-responder imputation; QD, once daily; UPA, upadacitinib. *p<0.001, UPA vs placebo, nominal P values are presented and were not adjusted for multiple testing. MMRM analysis with unstructured variance-covariance matrix, including treatment, visit, treatment-by-visit interaction, study, and the stratification factor of current DMARD use (yes/no) as fixed factors and the continuous fixed covariates of baseline measurement. NRI analysis with nominal P-value constructed using the Mantel-Haenszel estimation adjusting for study and the main stratification factor of current DMARD use (yes/no). 95% CI for response rate calculated based on normal approximation to the binomial distribution.