Objectives: To explore the frequency of flares in patients with PsA, and to assess the validity of patient-defined flares against PsA disease activity.

Methods: ReFlap (NCT03119805, ref) was a longitudinal study in 14 countries of consecutive adult patients with definite PsA and more than 2 years of disease duration. Patients were seen twice in the context of usual care, around 4 months apart. The proportion of flares was computed at the second visit according to a patient-reported question: "At this time, are you having a flare of your psoriatic arthritis, if this means the symptoms are worse than usual?" and a symmetrical physician question. These definitions were compared with a change in disease activity defined as transition to a more active disease category based on the Disease Activity in Psoriatic Arthritis (DAPSA) categories. Agreement was calculated using prevalence-adjusted kappas. Validity of patient-reported flares was assessed by comparing patients who flared with patients who did not flare at the second visit using clinical and patient-reported variables. Finally, for patients flaring, effect sizes corresponding to a patient transition to flare state were calculated by standardized response means (SRMs) for continuous outcomes, with p values based on McNemar test or rank signed test. There was no imputation of missing data.

Results: Overall, 222 patients were analysed: 127 (58.8%) were male, mean age was 53.5±12.3 years, mean disease duration was 10.8±8.3 years; 66.3% received a biologic and 13.8% oral glucocorticoids. Disease activity was moderate: 35.9% had no current psoriasis skin lesions, mean tender joint count (TJC, 0-68) was 3.0±7.5, mean swollen joint count (SJC, 0-66) was 1.6±6.6, and mean DAPSA was 11.5±14.0. At 4.5±2.2 months follow-up, the proportion of patient-reported flares was 27.0% (n=60), compared to 17.6% (n=39) physician-reported flares; there was a worsening in DAPSA category in 40.1% (n=89) patients. Agreements between definitions were moderate (range of kappas, 0.32-0.59). Patients in flare had significantly more active disease than patients not in flare using all outcomes (all p<0.001 except skin lesions, p=0.01, perhaps due to the fact that the majority of patients were included in rheumatology departments and had mild skin involvement at visit 1). Finally, among patients self-describing as in flare (N=60), all outcomes were worse than at the first visit; changes from the first visit were most notable for patient global (SRM 1.22), pain (0.92), physician global (0.85), DAPSA (0.83) and PsAID12 (0.80).

Conclusion: Patient-reported flares occurred in 27% of these PsA patients at 4 months follow-up, which was more than the proportion of physician-reported flares but less than the proportion of patients showing worsening of DAPSA category. Patient flares were associated with more active disease for all PsA manifestations; and at the patient-level, to a clear worsening in disease activity. A single question for flares is feasible, easy to understand for patients and not time consuming. These findings provide preliminary validation of the notion of patient-reported flares.

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FRI0438

TREATMENT UTILISATION PATTERNS OF ADVANCED THERAPIES IN PSORIATIC ARTHRITIS

Leslie Harrold^{1,2}, Pankaj Patel³, Patrick Zueger³, Jacqueline O'Brien¹, Heather J. Litman¹, Hua Feng¹, Robert Mclean¹. ¹Corrona LLC, Waltham, United States of America; ²University of Massachusetts Medical School, Worcester, MA, United States of America; ³AbbVie, North Chicago, United States of America

Background: Psoriatic arthritis (PsA) is a chronic inflammatory arthropathy typically associated with psoriasis. Little is known regarding the pattern of advanced therapy use, such as biologics and targeted synthetic disease-modifying antirheumatic drugs (tsDMARDs), and how the characteristics of patients with PsA initiating these therapies differ by line of therapy.

Objectives: To characterise the prescribing frequency of medication classes and compare characteristics across line of therapy groups among patients with PsA who initiated a biologic/tsDMARD.

Methods: This observational study included patients with PsA in the US Corrona PsA/SpA Registry who initiated a biologic/tsDMARD between 31 March 2013 and 31 October 2018. Patients were grouped by line of therapy at time of drug initiation: 1st, 2nd, 3rd, or 4th-or-higher. For each group, frequencies of medication classes were calculated, and proportions (categorical variables) and means with standard deviations (continuous variables) were determined for patient demographic, clinical and disease activity characteristics, patient-reported outcome measures, history of medication use, and concomitant medication use at the time of therapy initiation. Comparisons across groups were made with chi-square tests and one-way analysis of variance.

Results: Data from 1516 initiators (396 (26%), 453 (30%), 333 (22%), 334 (22%) in the 1st, 2nd, 3rd, or 4th-or-higher line groups, respectively) were examined. Mean age was 53.1 years, mean time since PsA diagnosis was 8.1 years and mean time from PsA diagnosis to 1st line therapy initiation was 5.2 years. TNFi therapy was commonly initiated earlier, while initiation of the other classes as a proportion of total line-specific initiations increased in later lines of therapy (TNFi: 77%, 61%, 41%, and 30%; tsDMARDs: 16%, 18%, 19%, and 22%; IL-17: 4%, 12%, 25%, and 34%; non-TNFi/non-IL-17: 3%, 8%, 14%, and 14% for the 1st, 2nd, 3rd, and 4th-or-higher lines of therapy, respectively). Among all initiators, 72% had a history of methotrexate (MTX) use and 35% had concomitant MTX use at drug initiation. Most patients had moderate to high disease activity at therapy initiation based on the proportion of patients reporting minimal disease activity (20%) (Table); 30% had enthesitis and 15% had dactylitis. Across therapy lines, statistically significant differences in minimal disease activity, HAQ, fatigue, pain and morning stiffness (P<0.05) were seen. Generally, scores were lower for those receiving 1st line therapy relative to the 4th-or-higher line group; fatigue scores ranged from 45.1 to 56.8, pain scores ranged from 46.6 to 58.2, and the percentage of patients with morning stiffness ≥30 minutes ranged from 72% to 80%.

Conclusion: Patients with PsA who initiated biologic/tsDMARD therapies in a large, national US based registry frequently exhibited significant disease activity, as demonstrated by patient-reported outcome measures and validated disease activity measures. On average, disease activity was worse in later lines of therapy. Enthesitis and dactylitis were highly prevalent in this population. TNFi was the most common 1st line therapy while newer agents such as IL-17 inhibitors were most commonly initiated as 4th line therapy or higher. In light of the newly published guidelines, it appears that rheumatologists are treating in a manner aligned with the guidelines based on the characteristics of patients observed across the different lines of therapy.

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Employee of: AbbVie, Patrick Zueger Shareholder of: AbbVie, Employee of: AbbVie, Jacqueline O'Brien Employee of: Corrona, Heather J. Litman: None declared, Hua Feng Employee of: Corrona, Robert McLean: None declared

Variable	Line of Therapy					P-value*
	All (n=1516)	1 st (n=396)	2 nd (n=453)	3 rd (n=333)	4 th -or-Higher (n=334)	
Minimal Disease Activity, n (%)	235 (20.3)	73 (23.9)	83 (23.2)	44 (17.4)	35 (14.4)	0.01
Tender Joint Count ≥6, mean±SD	4.5±5.8	4.2±5.3	4.3±6.0	4.8±6.2	4.7±5.7	0.21
Swollen Joint Count ≥6, mean±SD	2.5±3.6	3.0±4.0	2.5±3.7	2.3±3.5	2.3±3.1	0.01
Enthesitis category ≥0, n (%)	380 (30.1)	96 (27.7)	102 (26.4)	96 (35.8)	86 (33.1)	0.03
Dactylitis category ≥0, n (%)	190 (15.1)	70 (20.2)	49 (12.7)	34 (12.7)	37 (14.2)	0.02
HAQ ≥1, n (%)	483 (39.1)	108 (32.3)	146 (38.2)	104 (39.7)	125 (48.8)	0.001
Body surface area ≤3% affected by psoriasis, n (%)	790 (64.2)	215 (64.8)	239 (62.9)	165 (62.7)	171 (67.1)	0.69
Patient reported fatigue 0-100, mean±SD	50.7±28.2	45.1±28.7	49.7±29.4	53.4±25.8	56.8±26.4	<0.001
Patient overall pain 0-100, mean±SD	51.5±28.2	46.6±29.0	49.2±28.6	54.8±26.4	58.2±27.0	<0.001
Morning stiffness ≥30 min, n (%)	950 (77.2)	241 (72.2)	293 (77.1)	212 (80.9)	204 (80.0)	0.046

HAQ, Health Assessment Questionnaire; SD, standard deviation.

*P-values from chi-square tests (categorical variables) and one-way analysis of variance (continuous variables) across lines of therapy.

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FRI0439 **PERCEIVED INFLUENCE OF HEALTH STATUS ON SEXUAL ACTIVITY IN PATIENTS WITH PSORIATIC ARTHRITIS IS ASSOCIATED WITH MUSCULOSKELETAL MANIFESTATIONS BUT NOT WITH PSORIASIS SKIN MANIFESTATIONS**

Glenn Haugeberg¹, Brigitte Michelsen¹, Arthur Kavanaugh². ¹Sørlandet Hospital, Rheumatology, Kristiansand, Norway; ²UCSD Medical Center, Rheumatology, San Diego, United States of America

Background: Psoriatic arthritis (PsA) is a heterogeneous disease involving multiple domains including the musculoskeletal system and the skin. The disease may have a significant impact on various aspects of quality of life including sexuality.

Objectives: To explore the prevalence of self-reported problems with sexual activity in patients with PsA, and any associations with demographic and disease related variables as well as treatment.

Methods: PsA patients were consecutively recruited from a Norwegian rheumatology outpatient clinic. Data collection included information on demographics, measures of PsA disease activity (both skin and musculoskeletal manifestations), patient reported outcome measures and treatment. The perceived effect of health status on sexual activity was assessed using question 15 in the Health Related Quality of Life (HRQoL) instrument 15D. The question reads: My state of health: 1. Has no adverse effect on my sexual activity. 2. Has a slight effect on my sexual activity. 3. Has a considerable effect on my sexual activity. 4. Makes sexual activity almost impossible. 5. Makes sexual activity impossible. For analytical purposes the answers were dichotomized into "no/little negative effect" (answers 1 and 2) and "large negative effect" (answers 3-5). For group comparisons we used Chi-square test for categorical variables and student t-test for continuous variables. Adjusted logistic regression models were also applied.

Results: Among the 135 PsA patients assessed mean (SD) age was 52.1 (10.2) years and 51.1% were men. The majority of patients (111 patients, 82.2%) reported their state of health to have no/little effect on their sexual activity and 24 patients (17.8%) reported their state of health to have large negative effect on their sexual activity.

Patients with a large negative effect of their health status on sexual activity had significantly longer disease duration as well as higher DAPSA, MASES and fatigue score compared with the patients reporting no/little impact of their health status on sexual activity (table).

In adjusted logistic regression models with disease duration, DAPSA, MASES and fatigue in the model, only disease duration and MASES were independently associated with a large negative effect on sexual activity, this also when adjusting for age and sex.

Conclusion: Approximately 20% of the PsA patients reported their health status to have a large negative effect on their sexual activity. Only disease duration and measures reflecting musculoskeletal disease were found to have a negative effect on sexual activity among PsA patients; skin psoriasis did not have an impact.

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	Total (n=135)	No/little effect (n=111)	Large negative effect (n=24)	P-values
Age (SD) years	52.1 (10.2)	51.8 (10.3)	53.3 (10.3)	0.54
Men, n (%)	69 (51.1%)	58 (52.3%)	11 (45.8%)	0.57
BMI (SD) kg/m2	28.2 (4.4)	28.1 (4.2)	29.1 (5.0)	0.34
Smoking	21 (15.6%)	16 (14.4%)	5 (20.8%)	0.43
Disease duration (SD) years	8.7 (6.7)	8.1 (6.6)	11.6 (6.5)	0.02
68 Tender Joint Count	10.1 (11.1)	9.1 (10.2)	14.7 (13.8)	0.07
66 Swollen Joint Count	0.6 (1.1)	0.6 (1.1)	0.6 (0.9)	0.96
DAPSA	18.2 (14.2)	16.8 (13.3)	24.8 (16.6)	0.01
MASES	2.9 (3.1)	2.5 (2.9)	4.4 (3.5)	0.01
Fatigue (VAS 0-100)	45.1 (32.4)	42.2 (32.4)	58.1 (29.6)	0.03
Pain (VAS 0-100)	33.7 (23.1)	32.1 (22.8)	41.3 (23.5)	0.08
MHAQ	0.42 (0.40)	0.39 (0.34)	0.58 (0.58)	0.12
PASI skin score	2.5 (3.6)	2.4 (3.6)	3.1 (4.0)	0.38
Current Biologics	44 (32.6%)	36 (32.4%)	8 (34.8%)	0.83
Current DMARDs	79 (58.5%)	68 (61.3%)	11 (45.8%)	0.16

FRI0440 **THE EFFECT OF GUSELKUMAB ON PASDAS, GRACE INDEX, MCPDAI, AND DAPSA: RESULTS FROM A PHASE 2 STUDY IN PATIENTS WITH ACTIVE PSORIATIC ARTHRITIS**

Dafna D. Gladman¹, Philip Helliwell², Atul Deodhar³, Alice B. Gottlieb⁴, Wolf-Henning Boehncke⁵, Xie L. Xu⁶, Stephen Xu⁶, Yuhua Wang⁶, Elizabeth C. Hsia^{6,7}, Christopher T. Ritchlin⁸. ¹Centre for Prognosis Studies in The Rheumatic Diseases, Toronto, Canada; ²University of Leeds, Leeds, United Kingdom; ³Oregon Health and Science U, Portland, United States of America; ⁴Icahn School of Medicine at Mt Sinai, Dermatology, New York, United States of America; ⁵Geneva University Hospitals and Department of Pathology and Immunology, University of Geneva, Geneva, Switzerland; ⁶Janssen Research and Development, LLC, Spring House, United States of America; ⁷Univ of Penn Medical Center, Phila, United States of America; ⁸University of Rochester, Rochester, United States of America

Background: Psoriatic Arthritis Disease Activity Score (PASDAS), GRAppa Composite score (GRACE) Index, modified Composite Psoriatic Disease Activity Index (mCPDAI), and Disease Activity Index for Psoriatic Arthritis (DAPSA) are composite indices recently developed to assess disease activity in psoriatic arthritis (PsA).^{1,2}

Objectives: The effect of guselkumab (GUS) on these indices was evaluated in a phase 2 study in patients with active PsA.

Methods: Patients with ≥3 tender and ≥3 swollen joints, C-reactive protein ≥3 mg/L, and ≥3% body surface area (BSA) of plaque psoriasis despite treatment were randomized 2:1 to receive GUS 100 mg subcutaneously (N=100) or placebo (PBO, N=49) at Weeks 0, 4, and every 8 weeks thereafter through Week44. At Week16, patients with <5% improvement in both swollen and tender joint counts were eligible for early escape (EE) to open-label ustekinumab. All remaining PBO patients crossed-over to receive GUS 100 mg at Weeks 24, 28, 36, and 44 (PBO→GUS). The PsA composite indices through Week24 were analyzed using last-observation-carried-forward for missing data and data post EE. After Week24, observed data were used. Missing baseline data were excluded in the analyses.

Results: Baseline PASDAS, GRACE, mCPDAI, and DAPSA showed moderate to high disease activity (mean (SD): 6.53 (1.079), 6.08 (1.208), 7.6 (2.15), and 46.65 (20.391), respectively), and were generally comparable between PBO and GUS. At Week24, GUS significantly decreased PASDAS, GRACE, mCPDAI, and DAPSA scores (mean (SD) change from baseline: -2.50 (1.59), -2.73 (1.76), -3.8 (2.72),