

Conclusion: Therapy with TNF alpha inhibitor golimumab for 24 months in AS patients with coxitis was accompanied with statistically significant improvement of clinical scores with primary endpoint achieved (mean BASFI change -2.5 at 12 months), improvement of MRI and US findings without obvious structural progression measured with BASRI-hip score compared to baseline.

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POS0904 FACTORS ASSOCIATED WITH SWITCHING FROM ONE ANTI-TNF AGENT TO ANOTHER ANTI-TNF, OR IL17 AGENT IN PATIENT WITH ANKYLOSING SPONDYLITIS

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Background: A recent study examining Commercial Claims Insurance database found that many patients with ankylosing spondylitis (AS) do not remain on their initial TNF inhibitor two years after initiation, particularly women and those taking opioids.

Objectives: To examine factors associated with switching from one TNF inhibitor (i)agent to either another TNFi, IL-17i or JAKi over time (at <2years and >2 years) in a longitudinal cohort of AS patients.

Methods: Patients enrolled in the Prospective Study of Outcomes in AS (PSOAS), an observational longitudinal study of predictors of AS severity operative since 2002-2020 including over 1250 patients meeting modified New York criteria. Data collected included age, gender, ethnicity, HLA-B27 status, disease activity (BASDAI or ASDAS), erythrocyte sedimentation rate (ESR), C-reactive protein (CRP), disease severity (functional (BASFI) or radiographic (mSASSS)), comorbidities, smoking, exercise, disease duration, depression (either by self report or by the Center for Epidemiologic Studies Depression Scale (CES-D) and other medication usage (NSAIDs, including the NSAID index, nonbiologic DMARDs, opioids, anti-depressants, anxiolytics and hypnotics). Logistic regression models were built to identify clinical and sociodemographic characteristics associated with medication switching to another TNFi, IL-17i, or other biologic therapy (another TNFi, IL-17i, or JAKi) within 2 years and after 2 years of initiation).

Results: Of those patients in PSOAS who had at least two years of follow-up, 496 were prescribed anti-TNF, 34 anti-IL-17 and 3 anti-JAK agents. According to the multinomial logistic regression analysis, patients who switched from their original TNFi to another TNFi, IL-17i or JAKi within two years after initiating their original TNFi were more likely to be older, have higher baseline subjective disease activity (BASDAI), less radiographic severity by mSASSS, exercise > 120 minutes/week and less likely to be currently smoking. Patients who switched after two years were less likely to be depressed, had shorter disease duration, had greater subjective disease activity, were more likely to be exercising > 120 minutes/week, and had more comorbidities.

Conclusion: Different factors were encountered in AS patients who switched from their initial TNFi to another TNFi, IL-17i or JAKi within 2 years versus after 2 years of treatment.

Table 1. Factors Associated With Switching From One TNFi To A Second TNFi or IL-17i or JAKi Before or After Two Years Based On Multinomial Logistic Regression Model (N=496 Patients)

Variable	Switched within 2 years vs. not switched	p-value	Switched after 2 years vs. not switched	p-value
Gender (Male vs. Female)	0.99 (0.637, 1.549)	0.98	0.95 (0.528, 1.719)	0.87
HLA-B27_(+ vs. -)	0.99 (0.639, 1.523)	0.95	0.66 (0.365, 1.192)	0.17
Depression (CESD _≥ 16 or self-report)(Yes vs. No)	0.99 (0.676, 1.445)	0.95	0.35 (0.182, 0.672)	0.002
Disease duration at baseline (≥20 vs. <20 years)	0.72 (0.485, 1.062)	0.10	0.27 (0.146, 0.491)	<0.001
Age at baseline (≥40 vs. <40) (years)	2.00 (1.291, 3.101)	0.002	1.23 (0.693, 2.193)	0.48
CRP (≥0.8 vs. <0.8)	1.94 (1.230, 3.056)	0.004	0.90 (0.454, 1.789)	0.77
BASFI (≥40 vs. <40)	1.34 (0.852, 2.118)	0.20	0.87 (0.450, 1.688)	0.68
BASDAI (≥4 vs. <4)	1.73 (1.064, 2.797)	0.03	2.31 (1.202, 4.427)	0.01
NSAID index (≥50 vs. <50)	1.32 (0.822, 2.128)	0.25	0.83 (0.437, 1.586)	0.58
NSAIDs used (Yes vs. No)	0.84 (0.534, 1.309)	0.43	0.85 (0.479, 1.510)	0.58
Exercise (≥120 vs. <120) (minutes/week)	1.95 (1.396, 2.731)	<0.001	1.66 (1.057, 2.613)	0.03
ASDAS (≥3 vs. <3)	0.78 (0.454, 1.356)	0.39	1.07 (0.478, 2.399)	0.87
Number of comorbidities (≥2 vs. <2)	1.40 (0.997, 1.951)	0.05	1.63 (1.029, 2.575)	0.04
mSASSS (≥4, vs. <4)	0.63 (0.421, 0.957)	0.03	0.81 (0.474, 1.392)	0.03
Current smoker (Yes vs No)	0.69 (0.385, 1.225)	<0.001	0.79 (0.297, 2.076)	0.20

*p-values calculated based on multinomial logistic regression model when switching is defined as being prescribed a second TNFi or taking IL-17i or JAKi before or after 2 years from first TNFi initiation

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POS0905 ACHIEVEMENT OF PARTIAL REMISSION AND INACTIVE DISEASE IN UPADACITINIB-TREATED PATIENTS WITH ANKYLOSING SPONDYLITIS

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Background: Assessment of SpondyloArthritis international Society (ASAS) response criteria and AS Disease Activity Score (ASDAS) are both commonly used, rigorous composite indices consisting of components with relevance to patients. Clinically meaningful thresholds for these measures have been defined to reflect partial remission (PR), inactive disease (ID), and low disease activity (LDA).

Objectives: To study the association of ASAS PR and ordinal ASDAS disease categories (including ASDAS ID, which is the most stringent category of this composite score) in upadacitinib (UPA)-treated patients with AS.

Methods: In the SELECT-AXIS 1 (NCT03178487) study, biologic DMARD naïve-patients (pts; ≥18 y) with active AS and intolerance/contraindication or inadequate response to ≥2 NSAIDs were randomized 1:1 to UPA 15mg once daily (QD) or placebo (PBO).¹ At wk 14, pts entered an open-label extension (OLE) of UPA 15mg QD; pts randomized to PBO were switched to UPA. This post hoc analysis assessed the responsiveness of individual ASAS and ASDAS core components among pts who achieved ASAS PR. The association of ASAS PR with achievement of ASDAS ID (ASDAS <1.3), ASDAS LDA (ASDAS <2.1 but ≥1.3) or ASDAS high disease activity (HDA)/very HDA (VHDA) (ASDAS ≥2.1 for HDA/VHDA) was also assessed by measures including Youden index, distance to perfect point, and sensitivity/specificity

equality. These evaluations were performed in pts randomized to UPA from baseline (BL; continuous UPA, assessed at wk 14) and those who were randomized to PBO and switched to UPA upon entry in the OLE (PBO to UPA; re-baselined at wk 14 and assessed at wk 32, representing 18 wks of UPA exposure).

Results: At wk 14, for the continuous UPA group, 16 pts (19%) achieved ASAS PR. At wk 32, following 18 wks of UPA exposure for the PBO-to-UPA group, 28 pts (33%) achieved ASAS PR. Among both groups (continuous UPA and PBO-to-UPA), improvements were seen across all core components (Figure 1). Of the 44 total pts who achieved ASAS PR, 91% achieved either ASDAS ID or LDA. The majority of patients who achieved ASAS PR achieved ASDAS ID in the continuous UPA and PBO-to-UPA groups: 11/16 (69%) and 16/28 (57%), respectively. For the continuous UPA group, the remaining 5 pts who achieved ASAS PR also achieved ASDAS LDA (Table 1). ASAS PR was associated with ASDAS categories in the following manner: the highest rate of ASAS PR was achieved for ASDAS ID followed by ASDAS LDA followed by ASDAS HDA/VHDA. The cutoff of 1.3 (the upper threshold for ASDAS ID) was a better discrimination threshold for ASAS PR than the cutoff of 2.1 (the upper threshold for ASDAS LDA).

Conclusion: Nineteen percent of pts receiving UPA from BL achieved ASAS PR after 14 wks of treatment, with similar results seen in pts who were originally randomized to PBO and switched to UPA at wk 14. A consistent improvement was seen across all core components of ASAS among those who achieved ASAS PR with UPA treatment. The achievement of ASAS PR was most closely associated with the achievement of ASDAS ID, providing further clarity on the reduction of disease activity in AS pts treated with UPA.

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POS0906 PREVALENCE OF SLEEP DISTURBANCE IN PATIENTS WITH ANKYLOSING SPONDYLITIS WITHIN THE AUSTRALIAN CLINICAL SETTING (ASLEEP STUDY): A REAL-WORLD OBSERVATIONAL STUDY USING THE OPAL DATASET

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Background: Sleep disorders are more prevalent in patients with ankylosing spondylitis (AS) compared to the general population. Sleep disturbance in AS, in addition to pain and fatigue, can lead to impaired physical function and reduced quality of life.

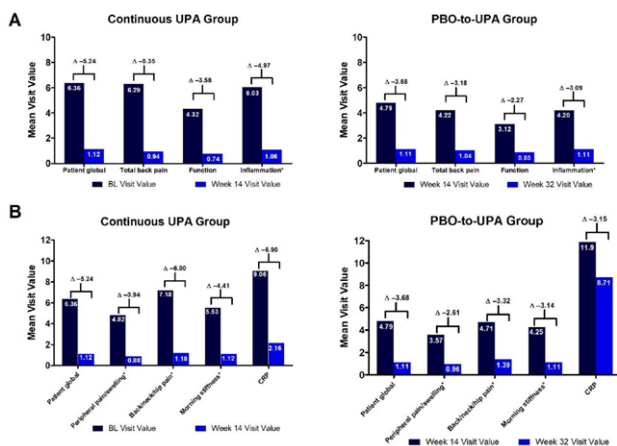
Objectives: The primary objective was to determine the prevalence of sleep disturbance in patients with AS in a real-world Australian cohort using the Insomnia Severity Index (ISI) and Multivariate Apnoea Prediction Index (MAPI). ISI score of ≥ 15 is considered clinical insomnia. MAPI values below 0.05 are suggestive of clinical apnoea.

Methods: Routinely collected, de-identified clinical data were sourced from the OPAL dataset. Patients aged between 18 and 95 years with a diagnosis of AS and who had completed at least one ISI or MAPI questionnaire between Jan-2019 and Sept-2020 were included. ISI and MAPI questionnaires were emailed to patients using OPAL's electronic patient reported outcome (ePRO) delivery method or completed in the clinic using a smart device and returned to the patient's file using a QR code. Disease activity was assessed using BASDAI collected at the same time as the sleep questionnaires. Age, sex and duration of symptoms were used to propensity match patients in the IL-17ai and TNFi group in a 1:2 ratio.

Results: 495 of the 5,323 patients identified with AS completed a questionnaire and were included in the analysis (n=395 TNFi, n=48 IL-17ai (secukinumab), n=52 other therapies). 142 were included in the propensity score matched population (n = 94 TNFi, and n = 48 IL-17ai). In the overall population the mean (SD) age was 48.3 (13.6), 55.4% were males, the mean (SD) BMI was 30.1 (19.6) at the index date and 4.8% reported depression. 51.7% had an optimal disease control (BASDAI <4). The mean (SD) ISI score was 8.6 (6.2). 48.1% reported no clinical significant insomnia, 32.7% reported subthreshold insomnia, 16% reported clinical insomnia (moderate severity) and 3.2% reported clinical insomnia (severe). The mean (SD) MAPI score was 0.4 (0.3). 292 patients (59.0%) had low risk of clinical apnoea, 134 patients (27.1%) had high risk of clinical apnoea and 69 patients 13.9% had not completed the MAPI questionnaire. In the propensity score matched population, the TNFi and IL-17ai groups had mean (SD) ISI scores of 9.1 (6.6) and 8.9 (5.9) at index, respectively (p = 0.83) and mean (SD) MAPI scores of 0.3 (0.2) and 0.4 (0.3) at index, respectively (p=0.046), however a higher percentage of overweight and obese patients were identified in the IL-17ai treatment group. Ordered logistic regression analysis of the relationship between demographics and ISI in the matched population found that patients with BASDAI ≥ 4 were seven times more likely to experience greater sleep disturbance (OR 7.29, 95%CI 2.37 to 22.46, p=0.001) than those with BASDAI <4.

Conclusion: In this real-world AS cohort, poor disease control was associated with sleep disturbance, despite bDMARD therapy. Little difference was observed between TNFi and IL-17ai treatment. Screening for sleep disturbance and fatigue in routine clinical care may provide a more holistic view of the burden of this disease.

Figure. Core ASAS (A) and ASDAS (B) Components Among Patients Who Achieved ASAS PR



*Inflammation based on mean of BASDAI question 5 and 6; peripheral pain/swelling based on BASDAI question 3; Back/neck/hip pain based on BASDAI question 2; duration of morning stiffness based on BASDAI question 6. ASAS, Assessment of SpondyloArthritis international Society response criteria; ASDAS, AS Disease Activity Score; PBO, placebo; PR, partial remission; UPA, upadacitinib.

Table 1. Association Between ASAS PR and ASDAS Clinical Thresholds (ID/LDA/HDA or VHDA)

	ASDAS ID (<1.3)	ASDAS LDA (1.3 to <2.1)	ASDAS HDA or VHDA (≥ 2.1)
Continuous UPA Group	n=15	n=31	n=39
ASAS PR Responders (n=16)	11	5	0
ASAS PR Non-responders (n=69)	4	26	39
PBO to UPA Group	n=25	n=35	n=25
ASAS PR Responders (n=28)	16	8	4
ASAS PR Non-responders (n=57)	9	27	21

P<0.001 for association of ASAS PR with the ordered ASDAS categories of ID-LDA-HDA, for both Continuous UPA Group and PBO to UPA Group. P-value calculated from Cochran-Armitage trend test for association of ordinal categories. ASAS, Assessment of SpondyloArthritis international Society response criteria; ASDAS, AS Disease Activity Score; HDA, high disease activity; ID, inactive disease; LDA, low disease activity; PBO, placebo; PR, partial remission; UPA, upadacitinib; VHDA, very high disease activity.

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