(BASDAI 50), and Ankylosing Spondylitis Disease Activity Score (ASDAS) inactive disease and major improvement (Table 1). Response rates at W16 among IV GLM-treated pts were generally consistent through 1 year in both ED and LD subgroups; also in ED and LD subgroups, pts crossing over to IV GLM at W16 demonstrated response at W52 consistent with pts who started IV GLM at W0. At W16, improvements in enthesitis score were similar for pts with ED (mean change -2.9 for IV GLM vs 0.1 for PBO) and LD (mean change -2.5 for IV GLM vs 0.6 for PBO); improvements were maintained at W52 for ED and LD pts. Treatment-emergent adverse events and serious adverse events through 1 year were 46% and 3% for pts with ED compared with 61% and 2% for pts with LD, respectively.

Conclusion: While IV GLM provided clinically meaningful improvements in signs and symptoms of AS in pts regardless of disease duration, response generally appeared numerically better in pts with ED than in pts with LD. This supports the principle of prompt diagnosis and early treatment.

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Table 1. Efficacy Outcomes

	ED				LD			
	Week 16		Week 52		Week 16		Week 52	
	PBO (n=25)	IV GLM (n=35)	PBO→IV GLM (n=25)	IV GLM (n=35)	PBO (n=28)	IV GLM (n=24)	PBO→IV GLM (n=28)	IV GLM (n=24)
ASAS 20	32%	71%	68%	71%	21%	67%	68%	63%
ASAS 40	12%	46%	56%	60%	4%	42%	57%	42%
BASDAI 50	12%	40%	64%	60%	7%	33%	57%	42%
ASDAS inactive disease (score <1.3)	4%	17%	44%	37%	0%	8%	14%	4%
ASDAS major improvement (decrease ≥2.0)	n=24 4%	57%	n=24 54%	51%	0%	n=23 48%	46%	n=23 30%
ASDAS clinically important improvement (decrease ≥1.1)	n=24 29%	77%	n=24 75%	77%	18%	n=23 91%	61%	n=23 65%
Mean change from baseline (SD) in BASFI	n=23 -0.4 (2.0)	-2.3 (2.1)	n=23 -2.7 (2.7)	-2.8 (2.6)	n=27 -0.3 (1.8)	n=24 -2.2 (1.7)	n=27 -2.4 (2.2)	n=23 -2.3 (1.7)
Mean change from baseline (SD) in BASMI	n=23 -0.3 (0.7)	-0.4 (0.7)	n=23 -0.6 (0.7)	-0.3 (0.5)	n=27 0.01 (0.5)	n=21 -0.3 (0.6)	n=27 -0.4 (0.7)	n=20 -0.3 (0.7)
Mean change from baseline (SD) in enthesitis score	n=23 0.1 (3.6)	-2.9 (2.9)	n=23 -2.0 (4.4)	-3.2 (2.5)	n=27 -0.6 (3.4)	n=21 -2.5 (3.0)	n=27 -2.5 (3.1)	n=20 -3.5 (5.9)

SD=standard deviation

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POS0903

CLINICAL AND RADIOLOGICAL MANIFESTATIONS OF COXITIS IN PATIENTS WITH ANKYLOSING SPONDYLITIS (AS) TREATED WITH TNF-ALPHA INHIBITOR GOLIMUMAB: RESULTS OF A 24-MONTHS OBSERVATION (GO-COX STUDY)

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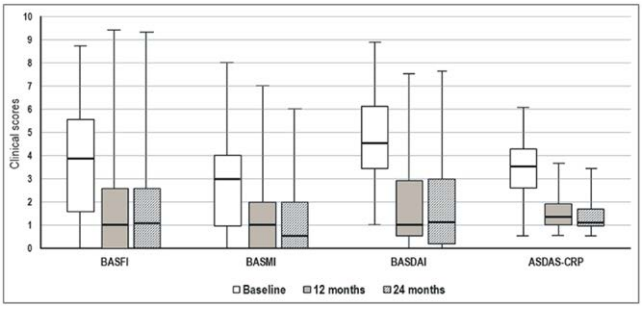
Background: Coxitis (hip joint inflammation) in AS is associated with worse BASFI scores due to hip joint involvement and more severe axial disease [1]. Radiological index of BASRI-hip, US and MRI findings may be used for evaluation of hip joint impairment [2, 3, 4]. Number of studies on coxitis in AS patients treated with biologics was limited at time of this study initiation.

Objectives: To evaluate clinical changes measured by BASFI, BASMI, BASDAI, ASDAS-CRP and radiological changes in AS patients with coxitis (BASRI-hip, hip MRI [STIR- and T1-weighted sequences], hip US) after 12 and 24 months of treatment with TNF alpha inhibitor golimumab from baseline.

Methods: A non-interventional prospective cohort study. Bio-naïve patients with AS and coxitis were treated with golimumab according to daily clinical practice in 5 clinics across Russia and followed up for 24 months. 39 patients participated. This analysis includes data from 30 patients who completed the follow up. The whole cohort's data to be presented after consolidation of safety data. MRI and US data were collected for 12 months in up to 28 of 30 patients. The primary endpoint was mean change of BASFI which was expected to be -2.5 (± 2.12) from baseline at week 52 weeks (12 months) of therapy [5]. The power of the study was 90% with minimum sample size of 18 patients. Student's paired t-criteria, Wilcoxon signed rank test were used to compare quantitave and Chi-square test for qualitative variables.

Results: Majority of participants (66,7%; 20 out of 30) were male, with mean (SD) age of 33.2 (9.4) years, mean (SD) duration of AS was 36.2 (42.1) months, mean (SD) duration of coxitis was 36.9 (44.1) months. Baseline mean (SD) scores were: BASFI 3.9 (2.5), BASMI 3.1 (2.5), BASDAI 4.9 (2.0), ASDAS-CRP 3.5 (1.2). Changes of mean clinical scores from baseline after 12 and 24 months of treatment with golimumab were: ΔBASFI= -2.2 (p=0.0001), -2.1 (p=0.0000); ΔBASMI= -1.5 (p=0.0000), -1,8 (p=0.0000); ΔBASDAI= -3.0 (p=0.0000), -3.1 (p=0.0000); ΔASDAS-CRP= -2.0 (p=0.0000), -2.1 (p=0.0000), correspondingly (n=30). The clinical results (medians, interquartile ranges, min and max) are presented below.



Baseline mean (SD)/median BASRI-hip was 1.1 (0.8)/1.0 on the right and on the left. Changes of mean/median BASRI-hip score at 12 and 24 months compared to baseline were: 0.3/0.0 (n=25; p=0.2344) and 0.3/0.0 (n=25; p=0.1368) on the right; 0.4/0.0 (n=25; p=0.0352) and 0.4/1.0 (n=25; p=0.0735) on the left. Rates of patients with MRI and US findings are presented below.

Hip	MRI, paired analysis	Patients (%), n=27		Patients (%), n=23	
		Baseline	At 6 months	Baseline	At 12 months
Right	No findings	33.3	48.1	39.1	56.5
	Subchondral bone marrow edema (SBME)	37.0	11.1	34.8	8.7
	Joint effusion	74.1	25.9*	73.9	17.4*
	Enthesitis	33.3	11.1	34.8	21.7
	Fatty degeneration	37.0	55.6	34.8	52.2
Left	No findings	29.6	51.9	30.4	52.2
	SBME	18.5	3.7	8.7	4.3
	Joint effusion	63.0	22.2*	60.9	21.7
	Enthesitis	22.2	18.5	17.4	21.7
	Fatty degeneration	33.3	55.6	30.4	52.2
Hip	US, paired analysis	Patients (%), n=28		Patients (%), n=27	
		Baseline	At 6 months	Baseline	At 12 months
Right	No findings	14.3	50.0*	18.5	51.9*
	Joint effusion	46.4	25.0	51.9	11.1*
	Enthesitis	25.0	14.3	18.5	14.8
Left	No findings	14.3	50.0*	18.5	55.6*
	Joint effusion	42.9	28.6	48.1	25.9
	Enthesitis	17.9	17.9	11.1	18.5

*$p<0.05$

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), erythocyte 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 characterstics 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 TNFito 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 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 15 mg once daily (QD) or placebo (PBO).[1] At wk 14, pts entered an open-label extension (OLE) of UPA 15 mg 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