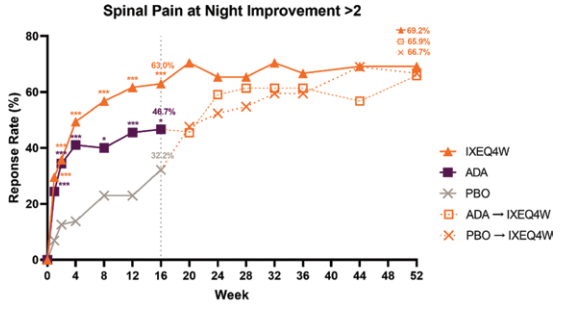
Lilly Corporate Center, Indianapolis, United States of America; [5]Royal Berkshire Hospital, Department of Rheumatology, Reading, United Kingdom; [6]Chung Shan Medical University Hospital, Department of Allergy, Immunology and Rheumatology, Taichung, Taiwan, Republic of China; [7]Chung Shan Medical University, Institute of Medicine, Taichung, Taiwan, Republic of China; [8]China Medical University, Graduate Institute of Integrated Medicine, Taichung, Taiwan, Republic of China

Background: Ixekizumab (IXE), a monoclonal antibody that selectively targets interleukin IL-17A, has shown efficacy in patients with radiographic axial spondyloarthritis (r-axSpA). Spinal pain, in particular spinal pain at night (SP-N), is a major contributor to the patient burden of r-axSpA.
Objectives: To assess SP-N improvement in patients up to week (W) 52 and to determine the association of SP-N improvement in patients treated with IXE with other patient-reported outcomes (PROs) at W16 and with reaching ASDAS LDA at W52.
Methods: The Phase III COAST-V (NCT02696785) trial investigated the efficacy of IXE in 341 patients with r-axSpA and were biological disease-modifying anti-rheumatic drug (bDMARD)-naïve. Patients were randomised to IXE every 2W (IXEQ2W), IXE every 4W (IXEQ4W), adalimumab (ADA) or placebo (PBO) up to W16. Only approved dose IXEQ4W data are presented here. SP-N was measured at each visit using a numeric rating scale (NRS) (0-10). A clinically relevant improvement in SP-N was defined as >2 point improvement from baseline. Differences in baseline variables between those achieving versus not achieving >2 improvement in SP-N were tested using Fisher's exact test (binary variables) and analysis of variance (ANOVA; continuous variables). Associations of SP-N improvement with PROs (BASFI, Fatigue Severity NRS, Jenkins Sleep Evaluation Questionnaire (JSEQ), SF-36 PCS) at W16, and ASDAS LDA at W52 were tested using analysis of covariance (ANCOVA; continuous variables) and logistic regression (binary variables). Missing values were imputed using non-responder imputation, and modified baseline observation carried forward.
Results: A greater proportion of patients achieved >2 improvement in SP-N with IXE treatment compared to PBO at W16 (63.0% vs. 32.2%, p <0.001) and improvement was sustained up to W52 (Figure 1). Of the 81 patients originally randomised to IXE, those achieving >2 improvement in SP-N (63%) at W16 were younger, more frequently positive for HLA-B27 and had higher disease activity at baseline compared to those that did not achieve >2 improvement (Table 1). Achieving >2 improvement in SP-N was associated with improvement in PROs including BASFI, Fatigue Severity, JSEQ and SF-36 PCS at W16 and with achieving ASDAS<2.1 at W52 compared to those not achieving >2 improvement in SP-N (Table 1).

Table 1. Baseline demographics, clinical characteristics, and PROs of IXE treated patients achieving vs. not achieving >2 improvement in SP-N at W16.

Achieved >2 Improvement in SP-N at W16	Yes (n=51)		No (n=30)	
Baseline Characteristics				
Age, yrs	38.6 (11.4)*		44.9 (12.4)	
Positive for HLA-B27, n (%)	50.0 (98.0)*		25.0 (83.3)	
CRP (mg/L)	14.9 (14.9)*		7.6 (8.4)	
ASDAS	3.9 (0.8)*		3.5 (0.6)	
Spinal Pain at Night	7.4 (1.3)*		6.4 (1.4)	
PROs	**Baseline**	**W16 CFB**	**Baseline**	**W16 CFB**
BASFI	6.1 (1.9)	-3.4 (2.2)***	6.0 (1.6)	-0.7 (1.5)
Fatigue Severity NRS	6.9 (1.7)	-3.5 (2.6)***	6.3 (1.6)	-0.7 (2.0)
JSEQ	7.1 (5.4)	-3.2 (4.2)***	7.2 (5.2)	-0.1 (2.7)
SF-36 PCS	32.8 (7.7)	10.9 (7.7)***	36.1 (6.7)	2.0 (6.5)
ASDAS <2.1 at W52 Response, n (%)	34 (66.7)**		9 (33.3)	

Values represent mean (SD) unless otherwise stated. *p<0.05, **p<0.01, ***p<0.001 versus those not achieving >2 improvement in SP-N.HLA-B27; Human Leukocyte antigen-B27, CRP; C-reactive protein, ASDAS; Ankylosing Spondylitis Disease Activity Score, CFB; change from baseline, BASFI; Bath Ankylosing Spondylitis Functional Index, NRS; Numeric Rating Score, JSEQ; Jenkins Sleep Evaluation Questionnaire, SF-36 PCS; Short-Form 36 physical component score.



Footnote: ADA; Adalimumab (reference arm), PBO; Placebo, IXE; Ixekizumab

W0-16; IXEQ4W: N=81, ADA: N=90, PBO: N=87,

Pts initially randomised to IXE remained on the same regimen up to W52. Pts on PBO or ADA were re-randomised to IXEQ2W or IXEQ4W at W16. Only approved dose IXEQ4W data are presented here.

W16-52; IXEQ4W: N=78, ADA→IXEQ4W: N=44, PBO→IXEQ4W: N=42.

**p <0.05, ***p<0.001 versus PBO (Logistic regression analysis with treatment, geographic region, and baseline CRP status as factors).*

Figure 1. Patients achieving meaningful spinal pain at night improvement through W52.

Conclusion: IXE improved SP-N for patients with r-axSpA not previously treated with bDMARDs. Improvements in SP-N were associated with improvements in disease activity, function, fatigue and quality of life.
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POS0932 UPTAKE OF NEWER BIOLOGIC AND TARGETED SYNTHETIC DMARDS IN PSORIATIC ARTHRITIS, RESULTS FROM FOUR NORDIC BIOLOGIC REGISTRIES

B. Glintborg[1,2], D. DI Giuseppe[3], J. K. Wallman[4], D. Nordström[5], B. Gudbjornsson[6,7], M. L. Hetland[1,2], J. Askling[8], G. Gröndal[6,7], T. Sokka-Isler[9,10], S. Aarrestad Provan[11], U. Lindström[12]. *[1]University Hospital of Copenhagen Rigshospitalet, DANBIO and Copenhagen Center for Arthritis Research (COPECARE), Glostrup, Denmark; [2]University of Copenhagen, Department of Clinical Medicine, Faculty of Health and Medical Sciences, Copenhagen, Denmark; [3]Karolinska Institutet, Department of Medicine Solna, Stockholm, Sweden; [4]Lund University, Skåne University Hospital, Lund, Department of Clinical Sciences Lund, Rheumatology, Lund, Sweden; [5]Helsinki University Hospital and University of Helsinki, ROB-FIN, Helsinki, Finland; [6]Landspitali University Hospital, Centre for Rheumatology Research (ICEBIO), Reykjavik, Iceland; [7]University of Iceland, The Faculty of Medicine, Reykjavik, Iceland; [8]Karolinska Institutet, Clinical Epidemiology Division, Department of Medicine Solna, Stockholm, Sweden; [9]Jyväskylä Central Hospital, Rheumatology, Jyväskylä, Finland; [10]Faculty of Health Sciences, UEF, Kuopio, Finland; [11]Diakonhjemmet Hospital, Division of Rheumatology and Research, Oslo, Norway; [12]Sahlgrenska Academy at University of Gothenburg, Department of Rheumatology and Inflammation Research, Gothenburg, Sweden*

Background: The treatment landscape in psoriatic arthritis (PsA) is changing, including newer biologic and targeted synthetic disease-modifying antirheumatic drugs (b/tsDMARDs) with different modes of action becoming available. However, the most effective treatment strategy in routine care remains to be established.
Objectives: To explore the uptake and treatment patterns of newer b/tsDMARDs, namely JAK-inhibitors (JAKi; baricitinib, tofacitinib, upadacitinib), IL-17-inhibitors (ixekizumab, secukinumab), abatacept, apremilast, and ustekinumab in PsA patients from the Nordic countries. Furthermore, to describe patient characteristics and extra-musculoskeletal manifestations at treatment start (=baseline).
Methods: Observational cohort study, using prospectively collected routine care data from 4 Nordic rheumatology registries. Treatments (newer b/tsDMARDs with tumor-necrosis-factor inhibitors (TNFi) as the reference) initiated from January 2009 until December 2020 and corresponding baseline patient characteristics were identified. Linkage to national patient registries was used to identify previous extra-musculoskeletal manifestations (0-5 years). Country-level data were pooled for analyses. Uptake of each drug was explored as the cumulative number of treatment starts (a) overall, irrespective of previous b/tsDMARD experience, and (b) in b/tsDMARD-naïve patients. Each patient could contribute >1 treatment course.
Results: Overall, 13,364 unique patients contributing 24,325 treatment courses with either a newer b/tsDMARD (4,855, 20%) or a TNFi (19,470, 80%, whereof 10,897 were started year 2015-20) were identified. For the sub-group of 11,892 first b/tsDMARD treatment courses, 1,009 (8%) were a newer b/tsDMARD (10,883 were a TNFi, whereof 5,956 were started year 2015-20). Secukinumab dominated the newer b/tsDMARD uptake (1,848 new-starts, Figure 1). Ustekinumab-uptake increased over time both overall and in b/tsDMARD-naïve patients. In b/tsDMARD-naïve patients, apremilast had the fastest uptake (490 new-starts) (Figure 1). Use of JAKi was limited, especially in b/tsDMARD-naïve patients.

Table 1. Baseline characteristics upon treatment start

		Abata-cept	Apre-milast	Bari-citinib	Ixe-kizumab	Secuki-numab	Tofa-citinib	Upada-citinib	Uste-kinumab	Any TNFi
Cumulative uptake, n		362	935	106	342	1848	494	6	691	19470
Male gender, %		33	42	27	38	40	33	33	37	44
Age		54 (12)	53 (12)	55 (13)	52 (13)	51 (13)	54 (13)	52 (10)	50 (12)	49 (13)
b/tsDMARD treatment number, %	1	9	52	9	11	14	9	0	20	56
	2	19	15	12	26	25	18	17	19	25
	≥3	72	33	78	74	61	73	83	62	19
Disease duration, yrs		9 (8)	8 (8)	10 (8)	10 (8)	9 (9)	11 (10)	8 (8)	8 (9)	7 (8)
Pain, VAS (0-100)		63 (21)	61 (23)	64 (23)	64 (25)	63 (24)	66 (23)	75 (17)	64 (23)	59 (24)
DAS28		4.73 (1.34)	4.04 (1.35)	3.95 (1.36)	4.24 (1.19)	4.13 (1.36)	4.49 (1.33)	4.74 (0.88)	4.19 (1.32)	4.07 (1.29)
Uveitis, %*		3	2	3	1	2	3	0	2	2
IBD, %*		1	1	3	1	1	1	-	3	1

Numbers are mean (SD) unless otherwise statedIBD: inflammatory bowel disease, bDMARD: biologic DMARD, ts: targeted synthetic*0-5 years previously, available all study period for Iceland, Sweden, Finland until 31Dec2018, not available for Denmark

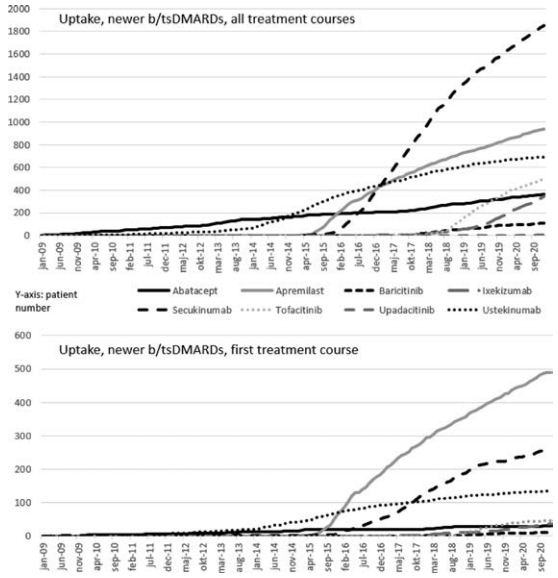

Figure 1.

Patients starting a newer b/tsDMARD tended to have longer disease duration and slightly higher disease activity at baseline (DAS28, patient-reported outcomes) than TNFi initiators (Table 1). Previous extra-musculoskeletal manifestations (uveitis, IBD) were rare, and with similar distributions across treatments (Table 1).

Conclusion: In this cross-country collaboration we were able to explore uptake of newer b/tsDMARDs. TNFi still dominates compared to newer b/tsDMARDs in routine care treatment of PsA. Newer b/tsDMARDs are mainly used in patients with several previous treatment failures, i.e. with longer disease duration and higher disease activity, indicating difficult to treat disease. Further studies are planned to explore real-world treatment patterns and outcomes.

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POS0933

IMPACT OF SACROILIAC JOINT STEROID INJECTION IN AXIAL SPA PATIENTS WITH BONE MARROW EDEMA ON DIFFERENT DISEASE OUTCOME MEASURES: A RANDOMIZED CONTROLLED TRIAL

S. Mahrous[1], A. Radwan[1], A. Khalifa[1], M. Ibraheem[2], F. Ali[3], A. Elsaman[1].
[1]*Sohag University Hospital, Rheumatology and Rehabilitation, Sohag, Egypt;* [2]*Sohag University Hospital, Radiology Department, Sohag, Egypt;* [3]*Minia University, Rheumatology and Rehabilitation, Minia, Egypt*

Background: Sacroiliac joint injection in axial spondyloarthritis (SpA) patients with steroid was controversial. A well designed randomized clinical trial testing its effect on different disease outcome measures particularly bone marrow edema was missing [1].

Objectives: To test the effect of steroid injection in the sacroiliac joint of axial SpA patients on different disease outcome measures.

Methods: N = 43 were registered. They were randomly assigned into 2 groups; Group I (23 cases) received sacroiliac joint injection lidocaine hydrochloride mixed with triamcinolone, whereas Group II (22 cases) received subcutaneous saline injections. All participants fulfilled the ASAS criteria for axial SPA and they all had bone marrow edema at baseline. Outcomes measures were: Visual Analogue Scale (VAS), ASDAS, BASFI, and SPARCC scores. Participants were assessed at baseline (before and after sacroiliac joint injection) and after 3 months.

Results: There was a significant difference between both groups regarding pain, spine mobility, SPARCC and ASDAS scores in favor of group I. Spine mobility showed the earliest improvement, followed by pain whilst SPARCC and ASDAS scores showed improvement after 3 months. Higher disease activity, younger age, and shorter disease duration all were associated with better outcomes. Bilateral hip involvement was a predictor of poor response

Conclusion: Sacroiliac joint injection of lidocaine and triamcinolone in axial SpA patients is effective in controlling pain, improving function, disease activity scores, and bone marrow edema with acceptable complications and relatively sustained effect.

REFERENCES:

[1] Elsaman, A., A. Hamed, and A. Radwan, *Ultrasound-guided epidural block in axial spondyloarthritis patients with limited spine mobility: a randomized controlled trial.* The Korean journal of pain, 2021. **34**(1): p. 114.

Table 1. Comparison between the two study groups

		Group I (N=24)	Group II (N=23)	P value*
Age		35.4±6.2	33.5±6.7	0.354
Sex	Male	17(77.3%)	16(76.2%)	1.000
	Female	5(22.7%)	5(23.8%)	
VAS	Before injection (0)	7.95±0.84	7.86±0.73	0.688
	After injection (1)	3.55±1.44	6.95±1.02	**<0.001**
	12 weeks later (2)	4.82±1.37	7.19±0.81	**<0.001**
	P value 0 vs 1**	**<0.001**	**0.003**	-
	P value 0 vs 2**	**<0.001**	**0.001**	-
	P value 1 vs 2**	**<0.001**	0.397	-
ASDAS	Before injection	2.69±0.44	2.60±0.37	0.451
	12 weeks later	1.51±0.44	2.40±0.46	**<0.001**
	P value **	**<0.001**	**0.022**	
BASFI	Before injection	61.91±9.70	62.95±11.71	0.752
	12 weeks later	57.50±8.13	61.24±0.53	0.199
	P value **	**<0.001**	0.081	-
SPARCC	Before injection	34.73±9.14	33.48±8.93	0.652
	12 weeks later	15.68±6.60	30.95±7.85	**<0.001**
	P value **	**<0.001**	**0.024**	-
Finger to floor	Before injection (0)	27.68±9.94	26.90±11.62	0.815
	After injection (1)	17.09±7.00	25.48±11.23	**0.005**
	12 weeks later (2)	19.64±7.83	26.76±11.79	**0.024**
	P value 0 vs 1**	**<0.001**	**0.001**	-
	P value 0 vs 2**	**<0.001**	0.791	-
	P value 1 vs 2**	**0.001**	0.072	-
Lateral bending	Before injection (0)	21.64±5.91	22.29±4.51	0.688
	After injection (1)	25.50±6.13	22.57±3.43	0.060
	12 weeks later (2)	24.55±4.95	22.24±2.95	0.071
	P value 0 vs 1**	**<0.001**	0.649	-
	P value 0 vs 2**	**0.003**	0.947	-
	P value 1 vs 2**	0.087	0.426	-

* p values were calculated using Independent t test, except for the sex, where Fisher Exact test was used.** p values for paired data was calculated using paired t test, to compare the baseline values (0) with either immediate post-injection (1) or 12 weeks later (2) values.