0.89) lower compared to males and the difference in probability for having CII was 9.4 percentage points (RD, 0.094; 95% CI, 0.069 to 0.12). The survival analysis included 28,608 axSpA patients with available data on retention rates. The TNFi 6/12/24-month retention rates were significantly lower in females (81%/69%/58%) compared to males (89%/81%/72%), see Figure 1.

Table 1.

	Female	Male
	Mean (SD), Median [IQR] or percentages	Mean (SD), Median [IQR] or percentages
Age (years)	42.0 (12.1)	41.4 (12.3)
Fulfilment of mNYC	66%	80%
Disease duration (years)	2.0 [1.0, 7.0]	3.0 [1.0, 9.0]
TNFi start year		
Start 1999-2009	7.2%	9.8%
Start 2010-2013	26%	27%
Start 2014-2016	37%	36%
Start 2017-2020	30%	27%
BASDAI, mm	59 (20)	54 (21)
BASFI, mm	48 (25)	46 (24)
ASDAS, units	3.5 (0.9)	3.5 (1.0)
CRP (mg/L)	6.7 [2.5, 16.0]	11.9 [4.0, 25.0]
SJC (0-28)	0 [0, 0]	0 [0, 0]
TJC (0-28)	0 [0, 2]	0 [0, 1]
VAS pain, mm	63 (22)	59 (24)
VAS fatigue, mm	65 (25)	59 (26)

mNYC, modified New York criteria; TNFi, tumor necrosis factor inhibitor; BASDAI, Bath Ankylosing Spondylitis Disease Activity Indexf; BASFI, Bath Ankylosing Spondylitis Functional Index; ASDAS, Ankylosing Spondylitis Disease Activity Score; CRP, C-reactive protein; SJC, swollen joint count; TJC, tender joint count; VAS, visual analogue scale.

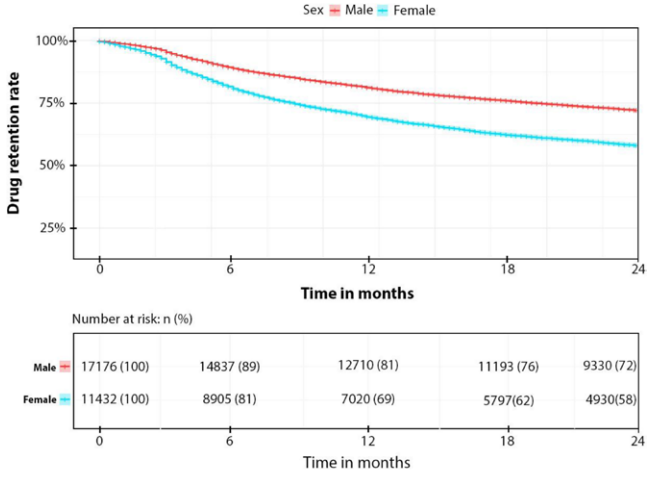

Figure. Sex differences in 24-month retention rates in first-line tumor necrosis factor inhibitors in patients with axial spondyloarthritis in EuroSpA (Kaplan-Meier, log-rank test; p<0.001).

Conclusion: Treatment efficacy and retention rates are lower among female patients with axSpA initiating their first TNFi. Females presented with lower C-reactive protein levels and higher scores on patient reported outcomes at baseline, reflecting differences in disease expression. Recognizing these sex differences is of relevance for customized patient care and may improve patient education.

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OP0021

TREATMENT WITH NON-STEROIDAL ANTI-INFLAMMATORY DRUGS IS ASSOCIATED WITH RETARDATION OF RADIOGRAPHIC SPINAL PROGRESSION IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS: 10-YEAR RESULTS FROM THE GERMAN SPONDYLOARTHRITIS INCEPTION COHORT

M. Torgutalp[1], V. Rios Rodriguez[1], A. Dilbaryan[2], F. Proft[1], M. Protopopov[1], M. Verba[1], J. Rademacher[1], H. Haibel[1], J. Sieper[1], M. Rudwaleit[3], D. Poddubnyy[1]. *[1]Charité – Universitätsmedizin Berlin, corporate member of Freie Universität Berlin and Humboldt-Universität zu Berlin, Department of Gastroenterology, Infectious Diseases, and Rheumatology (including Nutrition Medicine), Berlin, Germany*; *[2]Moscow City Clinical Hospital, Department of Internal Medicine, Moscow, Russian Federation*; *[3]University of Bielefeld, Department of Internal Medicine and Rheumatology, Bielefeld, Germany*

Background: There are conflicting data regarding effect of nonsteroidal anti-inflammatory drugs (NSAID) on radiographic spinal progression in axial spondyloarthritis (axSpA). The analysis of the first 2-year of the GErman SPondyloarthritis Inception Cohort (GESPIC) showed that higher NSAID intake may retard new bone formation in r-axSpA. It remained, however, unclear, whether cyclooxygenase-2 selective inhibitors (COX2i) might have a stronger effect than non-selective (NS) ones and if the effect could be observed also in nr-axSpA.

Objectives: To investigate the effect of NSAIDs (COX2i and NS) intake on radiographic spinal progression in patients with r-axSpA and nr-axSpA.

Methods: Based on availability of at least two sets of spinal radiographs during 10-year follow-up, 243 patients with early axSpA (130 and 113 nr- and r-axSpA, respectively) from GESPIC were included in this analysis. The patients contributed a total of 540 2-year radiographic intervals. Radiographs were scored by 3 trained and calibrated readers according to modified Stoke Ankylosing Spondylitis Spine Score (mSASSS). Final mSASSS was calculated as a mean of 3 readers, and progression was defined as absolute mSASSS change score over 2 years. NSAID type, daily dose, and frequency of intake were recorded at visits. The ASAS index of NSAID intake (0-100) counting both dose and duration of intake was calculated for intervals. The association between NSAID intake

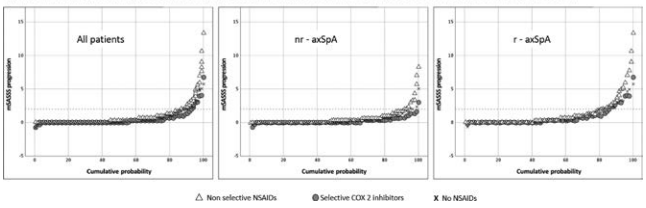
(NSAID type and NSAID score) and radiographic spinal progression over 2 years was analysed using longitudinal generalized estimated equations (GEE).
Results: At baseline, 161 (66.3%) patients were treated with NSAIDs. While 289 (53.5%) and 128 (23.7%) 2-year radiographic intervals were covered by NS and COX-2i respectively, 123 (22.8%) intervals were not covered by NSAID. The significant association between higher NSAID intake and retardation of radiographic spinal progression was found in adjusted multivariable longitudinal GEE analysis. This effect was mostly attributable to patients with r-axSpA (Table 1). mSASSS progression was numerically lower in patients taking COX2i (irrespectively of dose) as compared to patients treated with NS-NSAIDs; in stratified analysis, however, there was no clear dose-dependency (as reflected by NSAID index) in both groups (Figure 1, Table 1).

Table 1. The association between radiographic spinal progression (mSASSS change score) and NSAID intake in patients with axSpA in multivariable longitudinal GEE

	All axSpA β (95% CI)* (n=461)	nr-axSpA β (95% CI)* (n=244)	r-axSpA β (95% CI)* (n=217)
NSAID intake score, per 10 points	**-0.04 (-0.09, 0.00)**	-0.02 (-0.06, 0.02)	**-0.07 (-0.13, 0.00)**
NSAID type§			
NS inhibitors vs No NSAID	0.30(-0.07, 0.66)	0.25(-0.07, 0.57)	0.26(-0.40, 0.92)
COX2i vs No NSAID	0.17(-0.19, 0.54)	0.15(-0.15, 0.46)	0.18(-0.49, 0.85)
COX2i vs NS inhibitors	-0.12(-0.37, 0.12)	-0.10(-0.28, 0.09)	-0.08(-0.57, 0.40)
Analysis stratified according to NSAID type			
Non-selective NSAID intake score, per 10 points	-0.06(-0.12, 0.00)	-0.04(-0.09, 0.01)	-0.07(-0.17, 0.03)
COX2 selective NSAID intake score, per 10 points	-0.06(-0.13, 0.02)	-0.03(-0.07, 0.02)	-0.09(-0.18, 0.01)

axSpA: axial spondyloarthritis; COX2i, cyclooxygenase-2 selective inhibitors; n, number of current 2-year radiographic intervals in multivariable analyses; NS, non-selective COXi; NSAID, non-steroidal anti-inflammatory drugs. *All multivariable models were adjusted for sex, symptom duration at the beginning of the interval, time-averaged ASDAS the interval, classification as radiographic axSpA, smoking in the interval, mSASSS at the beginning of theinterval, and TNFi use in the interval. §NSAID intake score was added in this model.

Figure. Cumulative probability plots of mSASSS progression in patients receiving no NSAIDs, non-selective NSAIDs and selective COX2i.



Conclusion: Higher NSAID intake is associated with lower radiographic spinal progression, particularly in r-axSpA patients. COX2i might possess a stronger inhibitory effect on radiographic progression as compared to NS-NSAIDs.
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OP0022 DISEASE ACTIVITY-GUIDED TAPERING OF BIOLOGICS IN PATIENTS WITH INFLAMMATORY ARTHRITIS: A RANDOMISED, OPEN-LABEL, EQUIVALENCE TRIAL

L. Uhrenholt[1,2,3], R. Christensen[3,4], L. Dreyer[1,2], E. M. Hauge[5,6], A. Schlemmer[1,7], A. G. Loft[5,6], M. Nyhuus Bendix Rasch[5], H. C. Horn[8], K. Gade[1,8], P. C. Taylor[9], S. Kristensen[10,11]. [1]*Aalborg University Hospital, Department of Rheumatology, Aalborg, Denmark*; [2]*Aalborg University, Department of Clinical Medicine, Aalborg, Denmark*; [3]*The Parker Institue, Bispebjerg and Frederiksberg Hospital, Section for Biostatistics and Evidence-Based Research, Copenhagen, Denmark*; [4]*Odense University Hospital, Research Unit of Rheumatology, Department of Clinical Research, Odense, Denmark*; [5]*Aarhus University Hospital, Department of Rheumatology, Aarhus, Denmark*; [6]*Aarhus University, Department of Clinical Medicine, Aarhus, Denmark*; [7]*Randers Regional Hospital, Department of Rheumatology, Randers, Denmark*; [8]*Odense University Hospital, Department of Rheumatology, Odense, Denmark*; [9]*University of Oxford, Nuffield Department of Orthopaedics, Rheumatology and Musculoskeletal Sciences, Oxford, United Kingdom*; [10]*Aalborg University Hospital, Department of Rheumatology, Aalborg, Denmark*; [11]*Aalborg University, Department of Clinical Medicine, Aalborg, Denmark*

Background: Traditionally, biologics are maintained lifelong at standard dose in patients with inflammatory arthritis (IA) when sustained low disease activity (LDA) is reached. However, evidence of possible tapering is emerging but data on the optimal approach is lacking.
Objectives: The primary outcomes at 18 months follow-up are:

- *Superiority:* The proportion of patients reduced to ≤50% of their baseline biologic dose.
- *Equivalence:* Disease activity (rheumatoid arthritis [RA] and psoriatic arthritis [PsA]: Disease Activity Score28-C-Reactive Protein [DAS28-CRP] and axial spondyloarthritis [axSpA]: Ankylosing Spondylitis Disease Activity Score [ASDAS]).

Methods: The BIODOPT trial was a randomised, open-label, equivalence trial (EudraCT 2017-001970-41). Eligible patients were adults with RA, PsA, or axSpA in LDA on stable biologic doses during ≥12 months. The randomisation ratio was 2:1 (tapering:continuation) stratified by diagnosis, centre, and repeated biologic failures. In the tapering group, the biologic dosing interval was prolonged by 25% every four months until flare or discontinuation. The continuation group was kept on their baseline biologic dosing interval; however, a small increase was allowed (as usual practise) if requested by the patient. The sample size calculation was based on a pre-defined equivalence margin of ±0.5 disease activity points (<half of the minimal important difference in DAS28-CRP [>1.2] or ASDAS [>1.1]) yielding a power of 87% for 180 enrolled patients. All analyses were based on the intention-to-treat population. Continuous outcomes were analysed with repeated-measures linear mixed-effects models with group, diagnosis, centre, repeated biologic failures, time point, and the interaction between group and time as fixed factors and the baseline value of the relevant variable as a covariate. Categorical outcomes were analysed using logistic regression with missing data imputed as trial failures.
Results: Between May, 2018, and March, 2020, 142 patients were enrolled of which 95 were randomised to tapering and 47 to continuation; inclusion was closed in April 2020 due to national implications of the coronavirus pandemic.
At 18 months, significantly more patients in the tapering group (35 patients [(37%]) achieved a significant reduction in their biologic dose (≥50%) compared to the continuation group (one patient [2%]), absolute risk difference (RD) 35%, 95%CI: 24% to 45%, p<0.0001, Table 1. Furthermore, disease activity at 18 months was within the equivalence margins of ±0.5, mean difference between groups 0.08, 95%CI: -0.12 to 0.29; Table 1 and Figure 1. Flares were more frequent in the tapering group (39 [41%] vs 10 [21%], RD 0.20, 95%CI: 0.04 to 0.35, p=0.011) but managed with rescue therapy (e.g. biologic dose escalation or glucocorticoids) as only one patient (1%) in the tapering group and three patients (6%) in the continuation group lost therapeutic response and were switched to another biological agent.

Table 1. Comparison at 18 months in the ITT population

Outcome	Tapering group N = 95	Continuation group N = 47	Group difference (95%CI)	p-value
Primary outcome:				
Biologics reduced to ≤50%, n (%)	35 (37%)	1 (2%)	0.35 (0.24 to 0.45)	<0.001
Disease activity, LSMeans (SE)	1.84 (0.15)	1.75 (0.16)	0.08 (-0.12 to 0.29)	0.428
Key secondary outcomes:				
Remission[1], n (%)	63 (66%)	33 (70%)	-0.04 (-0.20 to 0.12)	0.637
Low disease activity[2], n (%)	79 (83%)	41 (87%)	-0.04 (-0.16 to 0.08)	0.511
Flares[3], n (%)	39 (41%)	10 (21%)	0.20 (0.04 to 0.35)	0.011

N: number, CI: confidence interval, LSMeans: Least squares means, SE: Standard error. [1]: RA or PsA: DAS28-CRP <2.6. AxSpA: ASDAS <1.3. [2]: RA or PsA: DAS28-CRP <3.2. AxSpA: ASDAS <2.1. [3]: RA or PsA: ΔDAS28-CRP >1.2 or ΔDAS28-CRP >0.6 AND current DAS28-CRP ≥3.2. AxSpA: inflammatory back pain AND ΔASDAS ≥0.9 and/or ≥1 swollen joint.

Conclusion: Across IA conditions, a significant reduction of biologic dose is possible with disease activity-guided tapering while maintaining a similar disease activity state compared to continuation of biologic as usual care.
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