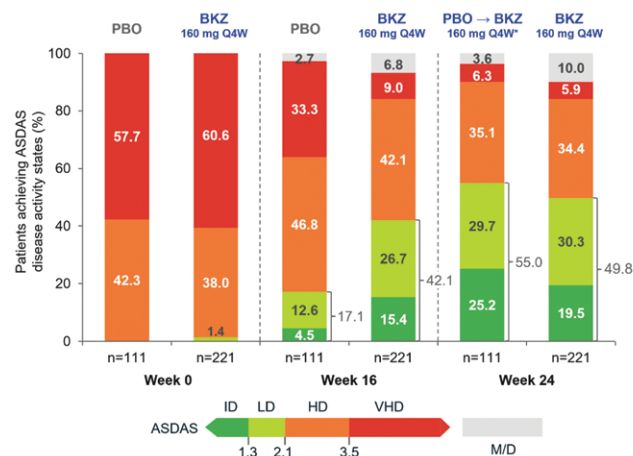


Figure. ASDAS states over time



Randomised set. Data reported as observed case. *At Wk 16, pts on PBO switched to BKZ.

Abbreviations: AS: ankylosing spondylitis; ASAS20/40: Assessment of SpondyloArthritis international Society 20/40% response; ASAS PR: ASAS partial remission; ASDAS-CRP: Ankylosing Spondylitis Disease Activity Score C-reactive protein; ASDAS-MI: ASDAS major improvement; ASQoL: Ankylosing Spondylitis Quality of Life; BASDAI: Bath Ankylosing Spondylitis Disease Activity Index; BASFI: Bath Ankylosing Spondylitis Functional Index; BASMI: Bath Ankylosing Spondylitis Metrology Index; BKZ: bimekizumab; BL: baseline; CIB: change from baseline; HD: high disease; HLA-B27: human leukocyte antigen B27; hs-CRP: high sensitivity-CRP; IBD: inflammatory bowel disease; ID: inactive disease; IL: interleukin; LD: low disease; MACE: Major Adverse Cardiovascular Event; MASES: Maastricht Ankylosing Spondylitis Enthesitis Score; M/D: missing data; MI: multiple imputation; MRI: magnetic resonance imaging; n: number; NRI: non-responder imputation; OC: observed case; PBO: placebo; Pts: patients; Q4W: every four weeks; SAEs: serious adverse events; SD: standard deviation; SE: standard error; SPARRC: Spondyloarthritis Research Consortium of Canada; SJ: Sacroiliac Joints; SF-36 PCS: Short Form-36 Physical Component Summary; TNFi: tumour necrosis factor inhibitor; VHD: very high disease; Wks: weeks; yr: year.

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OP0020

SEX DIFFERENCES IN EFFECTIVENESS OF FIRST-LINE TUMOR NECROSIS FACTOR INHIBITORS IN AXIAL SPONDYLOARTHRITIS; RESULTS FROM FIFTEEN COUNTRIES IN THE EUROSPA RESEARCH COLLABORATION NETWORK

P. Hellamand¹, M. G. H. Van de Sande², L. Midtbøll Ørnberg³, T. Klausch⁴, M. Nurmohamed⁵, R. Van Vollenhoven^{6,7}, D. Nordström⁸, A. M. Hokkanen⁹, M. J. Santos¹⁰, E. Vieira-Sousa¹¹, A. G. Loft^{12,13}, B. Gllintborg³, M. Østergaard^{3,14}, U. Lindström¹⁵, J. K. Wallman¹⁶, B. Michelsen^{3,17,18}, A. Ciurea¹⁹, M.

J. Nissen²⁰, C. Codreanu²¹, C. Mogosan²¹, G. Macfarlane²², G. T. Jones²², K. Laas²³, Z. Rotar^{24,25}, M. Tomsic^{24,25}, I. Castrejon²⁶, M. Pombo-Suarez²⁷, B. Gudbjornsson^{28,29}, A. J. Geirsson³⁰, E. Kristianslund³¹, J. Vencovsky³², L. Nekvindova^{33,34}, S. Gulle³⁵, B. Zengin³⁵, M. L. Hetland^{3,14}, I. Van der Horst-Bruinsma³⁶, on behalf of EuroSpA Research Collaboration Network.

¹Amsterdam University Medical Centers, Vrije Universiteit Amsterdam, Department of Clinical Immunology and Rheumatology, Amsterdam, Netherlands; ²Amsterdam University Medical Centers, Academic Medical Center, Department of Clinical Immunology and Rheumatology, Amsterdam, Netherlands; ³Rigshospitalet, Copenhagen Center for Arthritis Research (COPECARE), Center for Rheumatology and Spine Diseases, Centre for Head and Orthopaedics, Glostrup, Denmark; ⁴Amsterdam University Medical Centers, Vrije Universiteit Amsterdam, Department of Epidemiology and Data Science, Amsterdam Public Health Research Institute, Amsterdam, Netherlands; ⁵Reade and Amsterdam UMC, Amsterdam Rheumatology immunology Center, Amsterdam, Netherlands; ⁶Amsterdam UMC, Department of Rheumatology and Clinical Immunology, Amsterdam, Netherlands; ⁷Amsterdam UMC, Amsterdam Rheumatology and immunology Center, Amsterdam, Netherlands; ⁸Helsinki University Hospital and University of Helsinki, Departments of Medicine and Rheumatology, Helsinki, Finland; ⁹Päijät-Häme Central Hospital, Department of Rheumatology, Lahti, Finland; ¹⁰Hospital Garcia de Orta, Serviço de Reumatologia, Almada, Portugal; ¹¹CHULN, Instituto de Medicina Molecular, Faculdade de Medicina da Universidade de Lisboa, Department of Rheumatology, Lisboa, Portugal; ¹²Aarhus University Hospital, Department of Rheumatology, Aarhus, Denmark; ¹³Aarhus University, Department of Clinical Medicine, Aarhus, Denmark; ¹⁴University of Copenhagen, Department of Clinical Medicine, Copenhagen, Denmark; ¹⁵Sahlgrenska Academy at University of Gothenburg, Rheumatology and Inflammation Research, Gothenburg, Sweden; ¹⁶Skåne University Hospital, Lund University, Department of Clinical Sciences Lund, Rheumatology, Lund, Sweden; ¹⁷Diakonhjemmet hospital, Division of Rheumatology and Research, Oslo, Norway; ¹⁸Hospital of Southern Norway Trust, Division of Rheumatology, Department of Medicine, Kristiansand, Norway; ¹⁹University Hospital Zurich, University of Zurich, Department of Rheumatology, Zurich, Switzerland; ²⁰Geneva University Hospital, Department of Rheumatology, Geneva, Switzerland; ²¹University of Medicine and Pharmacy, Center for Rheumatic Diseases, Bucharest, Romania; ²²University of Aberdeen, Aberdeen Centre for Arthritis and Musculoskeletal Health (Epidemiology Group), Aberdeen, United Kingdom; ²³East-Tallinn Central Hospital, Department of Rheumatology, Tallinn, Estonia; ²⁴University Medical Centre Ljubljana, Department of Rheumatology, Ljubljana, Slovenia; ²⁵University of Ljubljana, Faculty of Medicine, Ljubljana, Slovenia; ²⁶Hospital General Universitario Gregorio Marañón, Department of Rheumatology, Madrid, Spain; ²⁷Hospital Clínico Universitario, Rheumatology Service, Santiago de Compostela, Spain; ²⁸Landspítali, University Hospital, Centre for Rheumatology Research, Reykjavik, Iceland; ²⁹University of Iceland, Faculty of Medicine, Reykjavik, Iceland; ³⁰University Hospital, Department of Rheumatology, Reykjavik, Iceland; ³¹Diakonhjemmet Hospital, Division of Rheumatology and Research, Oslo, Norway; ³²Charles University, Institute of Rheumatology and Department of Rheumatology, 1st Medical Faculty, Prague, Czech Republic; ³³Ltd., Institute of Biostatistics and analyses, Brno, Czech Republic; ³⁴Charles university, First Faculty of Medicine, Prague, Czech Republic; ³⁵Dokuz Eylül University Faculty of Medicine, Department of Rheumatology, Izmir, Turkey; ³⁶Radboud University Medical Centre, Department of Rheumatology, Nijmegen, Netherlands

Background: Evidence reveals sex differences in physiology, disease presentation and response to treatment in axial spondyloarthritis (axSpA). Pooled data from four randomized controlled trials demonstrated reduced treatment efficacy of a tumor necrosis factor inhibitor (TNFi) in females compared to males with ankylosing spondylitis¹. However, real-life evidence confirming these data in large cohorts is scarce. We sought to validate prior studies using data from a large multinational cohort based on real-life clinical practice.

Objectives: To investigate sex differences in treatment response and drug retention rates in clinical practice among patients with axSpA, treated with their first TNFi.

Methods: Data from biologic-naïve axSpA patients initiating a TNFi in the EuroSpA registries were pooled. In the primary analysis, propensity-score weighting was applied to assess the causal effect of sex on clinically important improvement (CII) according to ASDAS-CRP at 6 months. A generalized linear regression model was used to estimate the causal risk difference (RD) and relative risk (RR) of sex on CII. Possible covariates influencing the outcome were determined a priori and selected based on availability in the database (<20% missing). The final covariates included in the model were country, age and TNFi start year. In the secondary analysis, drug retention was assessed over 24 months of follow-up by Kaplan-Meier curves and log-rank test.

Results: In total, 6,451 axSpA patients with available data on ASDAS-CRP at baseline and 6 months were assessed for treatment response. Baseline characteristics are shown in the Table 1. In the adjusted analysis, the probability for females to have CII was 15% (RR, 0.85; 95% confidence interval [CI], 0.82 to

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)
Fulfillment 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 Index; 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.

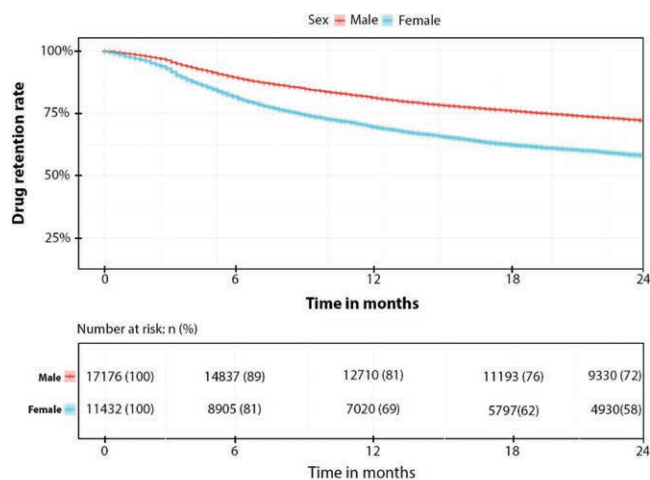


Figure. Sex differences in 24-month retention rates in first-line tumor necrosis factor inhibitors in patients with axial spondyloarthritis in EuroSpA (Kaplan-Meier, log-rank test; $p < 0.001$).

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. Torgutalp¹, V. Rios Rodriguez¹, A. Dilbaryan², F. Proft¹, M. Protopopov¹, M. Verba¹, J. Rademacher¹, H. Haibel¹, J. Sieper¹, M. Rudwaleit¹, D. Poddubnyy¹. ¹Charité – 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; ²Moscow City Clinical Hospital, Department of Internal Medicine, Moscow, Russian Federation; ³University 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