Real-World Usage of Biologic Disease-Modifying Anti-Rheumatic Drugs in Patients with Axial Spondyloarthritis in Germany

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Objective

The objective was to reveal characteristics of patients with axial spondyloarthritis (axSpA), including comorbidities and biologic disease-modifying anti-rheumatic drugs (bDMARD) history, in relation to bDMARD initiation and dosing in real-world clinical practice in Germany (year 2017–2021).

Background

- For axSpA, more treatment options have become available, including bDMARDs, i.e., tumour necrosis factor (TNF) and interleukin (IL)-17A inhibitors, and targeted synthetic DMARDs such as Janus kinase (JAK) inhibitors.¹
- Examining real-world treatment patterns is important for patients and healthcare providers.

Methods

- This study utilised German Allgemeine Ortskrankenkasse (AOK) Plus claims data. Patients with axSpA (aged ≥18 years on cohort entry date) with newly initiated bDMARD treatment between 2018-2021 were identified.
- Patient characteristics were screened from 2017 onwards (covariate assessment window). bDMARD history was assessed during a pre-defined look back window. Patients were followed up for a maximum of 12 months. See Figure 1 for study period definitions for an example patient.
- Given the variability in prescribing recommendations for secukinumab, for patients initiating secukinumab, dosing was reported for the total cohort and stratified by bDMARD history and by psoriasis and psoriatic arthritis diagnosis (PSO/PsA).
- Starting (week 0-5 from cohort entry date) and maintenance dose (after week 5) of secukinumab were estimated based on the interval between the first two dispensations within the corresponding phase and the total amount of drug dispensed.

Results

Patient characteristics (Table 1)

- This study identified 1,402 patients with axSpA (mean age: 48.7 years; females: 47.5%) initiating a new bDMARD, of which 236 (16.8%) were bDMARDexperienced.
- Adalimumab (44.2%), secukinumab (16.1%) and etanercept (16.1%) were the most frequently indexed bDMARDs.
- The proportion of bDMARD-experienced patients varied across bDMARDs and
- was the highest amongst certolizumab pegol initiators (43.5%). The proportion of additional diagnoses varied across bDMARDs initiators.
- Rheumatologists were the most frequently observed prescribers (42.4%).
- 32.5% and 24.0% of patients had additional diagnoses of PSO and PsA, respectively. Most frequent comorbidities included hypertension (47.6%) and depression (27.5%).

Secukinumab dosing (Figure 2a and b)

- Amongst 226 secukinumab initiators, starting and maintenance dose data were available for 159 and 203 patients, respectively.
- Among all patients with axSpA, regardless of PSO/PsA diagnosis, who initiated secukinumab, 48.4% of patients received 300 mg as starting dose, while 63.1% of patients received 300 mg at maintenance.
- A similar pattern was observed regardless of bDMARD history.
- The proportions of axSpA patients with and without PSO/PsA receiving 300 mg at maintenance were 76.7% and 39.2%, respectively, irrespective of starting dose.
- The proportions of axSpA patients with and without PSO/PsA receiving 150 mg at maintenance were 23.3% and 60.8%, respectively, irrespective of starting dose.

Limitations

- Diagnoses and treatments were identified using ICD-10 and ATC codes, which are subject to potential miscoding and risk of information bias.
- Data is limited to dispensation information. The patients' drug consumption behavior and dosing for patients lost to follow up remained unknown.
- Subgroup analyses were limited by sample size, and results based on groups
- with n<10 were not presented. The findings may not be generalisable to countries outside Germany or the EU.
- Data does not reflect all potential medical interventions, such as participation in clinical trials or other interventions which do not qualify for medical claims.

Conclusions

This study characterised patients with axSpA treated with bDMARDs and suggests that biologic experience and additional diagnoses seem to be associated with the type of bDMARD treatment.

While secukinumab dosing patterns did not seem to be associated with biologic experience, having a PSO/PsA diagnosis seems to be associated with receiving a 300 mg maintenance dose.

Future studies are warranted to identify patient outcomes associated with treatment patterns, including persistence, which can assist in tailoring therapies to patient needs.

Summary



1,402 bDMARD initiators with axSpA

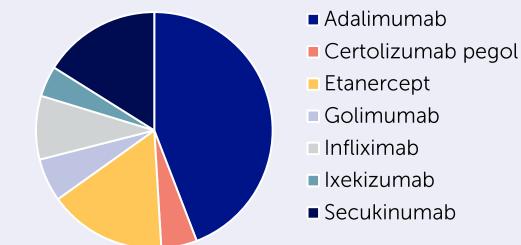
Patient characteristics





Bio-experienced: Bio-naïve: 83.2% 16.8% Proportion of bDMARDexperienced patients varied

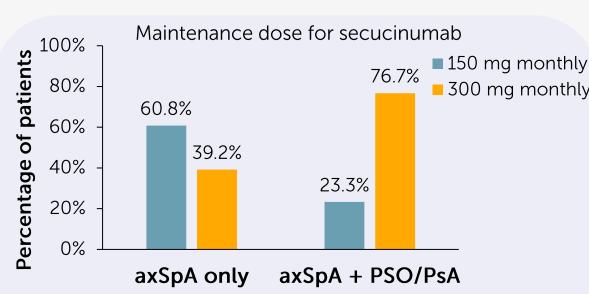
across bDMARDs



Etanercept Golimumab Infliximab Ixekizumab

There was variation in the type of bDMARDs prescribed

Dosing patterns



Among patients with PSO/PsA, most received a 300 mg maintenance dose

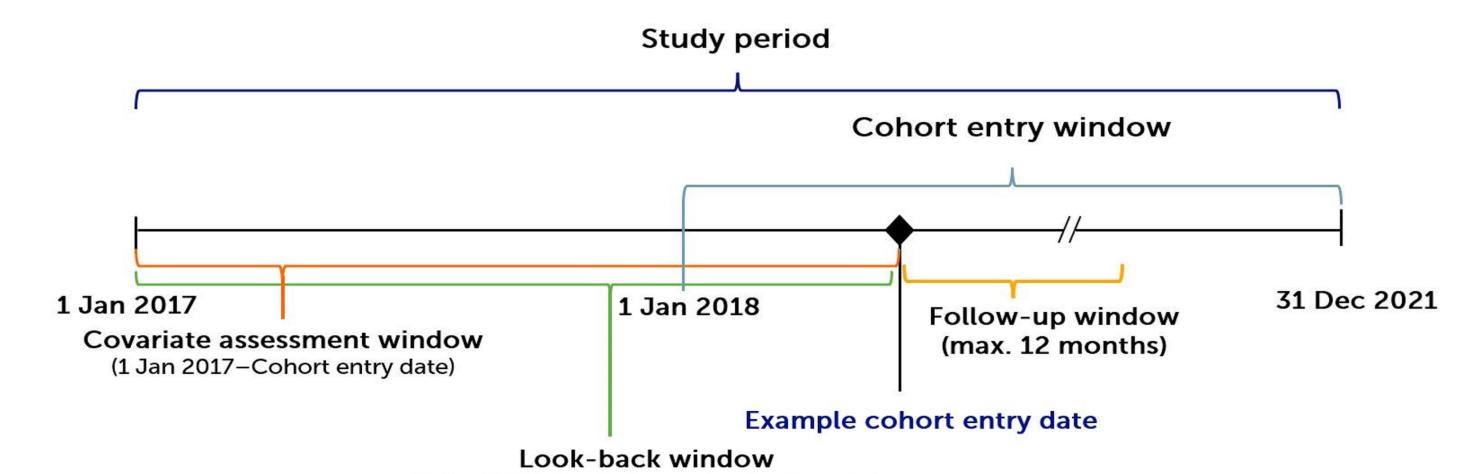
Conclusion



Biologic experience and additional diagnoses seem to be associated with the type of bDMARD treatment. Secukinumab dosing seems to be associated with PSO/PsA diagnosis.

Cohort study using German **AOK claims** data

Figure 1. Study periods (example patient)



(1 Jan 2017 – Day before cohort entry date)

Table 1. Characteristics of patients with axSpA

Patient characteristics at cohort entry date	Total	Bio-naïve	Bio- experienced	TNF inhibitors					IL-17A Inhibitors	
				Adalimumab	Certolizumab pegol	Etanercept	Golimumab	Infliximab	lxekizumab	Secukinumab
Sample size, n (%)	1,402	1,166 (83.2)	236 (16.8)	619 (44.2)	69 (4.9)	225 (16.1)	82 (5.9)	122 (8.7)	59 (4.2)	226 (16.1)
Females, %	47.5	48.2	44.1	46.7	69.6	46.2	35.4	54.9	54.2	42.9
Age, mean (SD)	48.7 (13.7)	48.8 (13.9)	48.7 (13.2)	48.1 (13.3)	40.1 (12.5)	47.0 (13.1)	43.1 (13.5)	54.8 (15.4)	56.2 (12.3)	51.8 (12.5)
bDMARD experience, %	¦ 16.8	0.0	100.0	¦ 10.3	¦ 43.5	12.9	¦ 23.2	¦ 13.1	ł 27.1	¦ 27.4
Prescriber specialty, %										
Rheumatologist	42.4	38.9	60.2	37.5	58.0	66.7	51.2	nr	18.6	49.6
Dermatologist	15.2	15.9	11.9	16.8	i nr	4.4	nr	i nr	71.2	23.5
General practitioner	¦ 13.9	¦ 12.0	¦ 23.3	¦ 10.3	¦ 26.6	22.7	¦ 13.4	¦ nr	¦ nr	¦ 19.5
Other	¦ 34.5	33.0	42.0	¦ 35.4	¦ 36.2	26.2	¦ 45.1	¦ 59.8	17.0	¦ 27.0
Comorbidities and/or ad	ditional	diagnoses, %								
Allergy	21.1	22.0	17.0	21.3	18.8	26.2	15.9	19.7	nr	20.8
Asthma	13.9	14.6	10.6	13.7	14.5	15.6	nr	12.3	nr	15.0
IBD	¦ 21.9	¦ 22.4	¦ 19.5	¦ 27.6	¦ 18.8	¦ nr	¦ 20.7	¦ 78.7	¦ nr	¦ nr
Fibromyalgia	l 1.5	1.5	l nr	l nr	¦ nr	l nr	l nr	¦ nr	l nr	l nr
PSO	32.5	31.7	36.0	29.4	24.6	20.9	12.2	9.0	96.6	58.0
PsA	24.0	22.8	29.7	20.8	18.8	19.1	i nr	nr	66.1	44.3
Hidradenitis suppurativa	3.0	3.4	nr	6.3	i nr	nr	hr	i nr	nr	¦ nr
Enthesitis	¦ 1.7	¦ 2.1	¦ nr	¦ nr	¦ nr	hr	¦ nr	¦ nr	¦ nr	¦ nr
Uveitis	8.0	7.6	9.8	12.1	i nr	7.6	l nr	<u>l</u> nr	nr	i nr
Dactylitis	1.5	1.6	nr	i nr	! nr	l nr	i nr	i nr	nr	ị nr
Anxiety	26.0	27.4	19.5	26.8	29.0	24.9	12.2	24.6	23.7	30.5
Cardiovascular disease	¦ 19.5	¦ 19.6	¦ 18.6	¦ 18.6	¦ nr	15.1	¦ 13.4	¦ 32.8	¦ 28.8	¦ 22.6
Osteoporosis	¦ 19.5	11.7	10.6	11.0	l nr	9.3	¦ nr	17.2	20.3	¦ 11.5
Depression	27.5	28.5	22.5	28.0	29.0	26.2	14.6	30.3	30.5	29.2
Hyperlipidemia	25.1	24.6	27.5	24.2	15.9	19.1	22.0	27.9	33.9	33.6
Hypertension	47.6	47.2	49.6	47.3	33.3	40.9	36.6	57.4	59.3	54.9
Obesity	¦ 24.8	¦ 24.2	28.0	¦ 25.4	¦ 13.0	18.2	¦ 19.5	¦ 24.6	¦ 35.6	¦ 31.7
Liver disease	18.3	18.2	18.6	19.2	14.5	15.1	13.4	27.9	22.0	15.5

Data of patients with n<10 has not been reported and is presented as 'nr'.

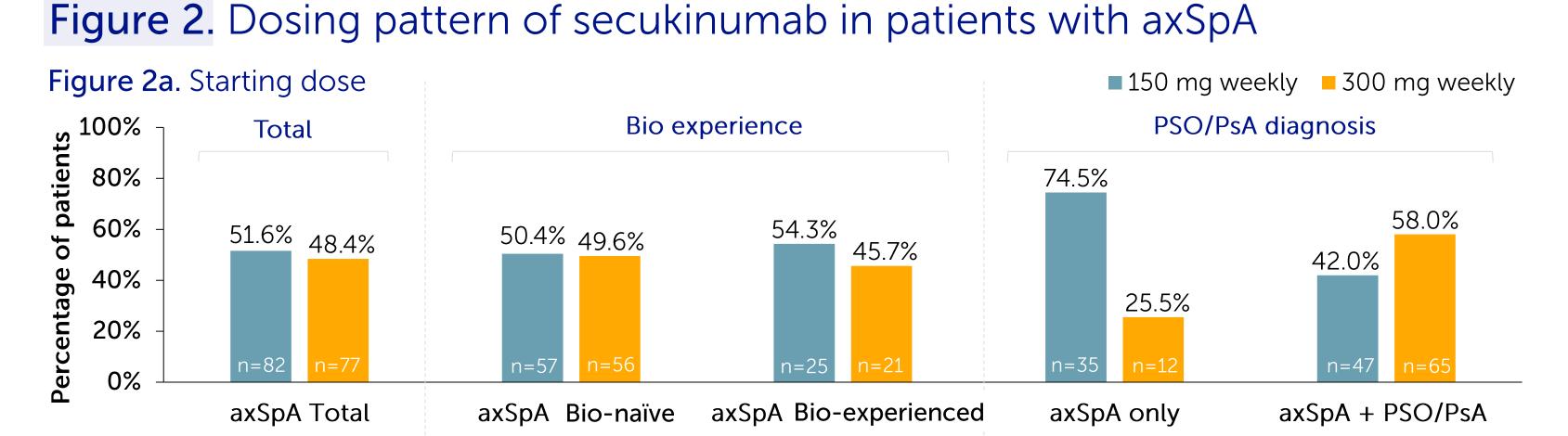


Figure 2b. Maintenance dose ■ 150 mg monthly ■ 300 mg monthly PSO/PsA diagnosis **Total** Bio experience 100% 76.7% 63.1% 63.0% 63.2% 60.8% 39.2% 36.9% 37.0% 36.8% 23.3% axSpA Bio-naïve axSpA + PSO/PsA axSpA Total axSpA Bio-experienced axSpA only

AOK: Allgemeine Ortskrankenkasse; ATC: Anatomical Therapeutic Chemical; axSpA: axial spondyloarthritis; bDMARD: biologic disease-modifying anti-rheumatic drug; EU: European Union; IBD: inflammatory bowel disease; ICD: International Classification of Diseases; IL: interleukin; JAK: Janus kinase; max.: maximum; PsA: psoriatic arthritis; PSO: psoriasis; SD: standard deviation; TNF: tumour necrosis factor.

Institutions: ¹UCB Pharma, Brussels, Belgium; ²Karolinska Institutet, Stockholm, Sweden; ³Quantify Research, Stockholm, Sweden; ⁴Cytel, Wismar, Germany; ⁵Cytel, Berlin, Germany; ⁶AOK PLUS, Dresden, Germany; ⁷Institut für Pharmakoökonomie und Arzneimittellogistik (IPAM), Wismar, Germany

References: ¹Fragoulis GE, et al. Rheumatology (Oxford). 2020;59(Suppl4):iv79-iv89. Author Disclosures: CA: Employee of Quantify Research, a contract research organization that provides consultancy services to the pharmaceutical industry, JB: Employee and stockholder of Quantify Research, ARD: Employee of Quantify Research, JS: Employee of UCB Pharma, SA: Employee of UCB Pharma, SW: Stockholder of UCB Pharma and GSK and was employee of UCB Pharma at the time of study conduct. Funding/Acknowledgement: This study was funded by UCB Pharma. Medical writing and editorial services were provided by Quantify Research and review management was provided by Costello Medical, both of which were funded by UCB Pharma. The authors acknowledge Celia Menckeberg, UCB Netherlands for publication coordination. Author Contributions: All authors contributed to study conception/design, acquisition/analysis/interpretation of data, drafting of the publication, and/or reviewing it critically. All authors provided final approval of the publication.

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