consistently predicted improvement in fatigue response at Wks 16, 52, and 104. A one-unit increase in BL BASDAI score (i.e. worsening) was a significant factor for achieving FACIT-F response at Wk 104 (P=0.02).

Conclusions: SEC provided sustained improvements in fatigue for up to 156 wks in both TNF-naïve and TNF-IR pts with AS. Fatigue response was generally higher in TNF-naïve pts.

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Disclosure of Interest: T. Kvien Consultant for: AbbVie, Biogen, BMS, Boehringer Ingelheim, Celltrion, Eli Lilly, Epirus, Janssen, Merck-Serono, MSD, Mundipharma, Novartis, Oktal, Orion Pharma, Hospira/Pfizer, Roche, Sandoz and UCB, Speakers bureau: AbbVie, Biogen, BMS, Boehringer Ingelheim, Celltrion, Eli Lilly, Epirus, Janssen, Merck-Serono, MSD, Mundipharma, Novartis, Oktal, Orion Pharma, Hospira/Pfizer, Roche, Sandoz and UCB, A. Deodhar Grant/research support from: Eli Lilly, Janssen, Novartis, Pfizer, UCB, Abbvie, Amgen, GSK, L. Gossec Grant/research support from: BMS, Lippy, Pfizer, Consultant for: Abbvie, BMS, Celgene, Janssen, MSD, Novartis, Pfizer, Roche and UCB, P. Conaghan Consultant for: Abbvie, BMS, Lilly, Novartis, Pfizer, Roche, Speakers bureau: Abbvie, BMS, Lilly, Novartis, Pfizer, Roche, V. Strand Consultant for: AbbVie, Amgen, BMS, Celgene, Celltrion, CORRONA, Genentech/Roche, GSK, Janssen, Lilly, Merck, Novartis, Pfizer, Regeneron, Samsung, Sanofi, and UCB, M. Østergaard Consultant for: Abbvie, BMS, Boehringer-Ingelheim, Celgene, Eli-Lilly, Janssen, Merck, Novartis, Orion, Pfizer, Regeneron, Roche, UCB, Speakers bureau: Abbvie, BMS, Boehringer-Ingelheim, Celgene, Eli-Lilly, Janssen, Merck, Novartis, Orion, Pfizer, Regeneron, Roche, UCB, N. Williams Employee of: RTI Health Solutions, B. Porter Shareholder of: Novartis, Employee of: Novartis, K. Gandhi Shareholder of: Novartis, Employee of: Novartis, S. Jugl Shareholder of: Novartis, Employee of: Novartis

DOI: 10.1136/annrheumdis-2017-eular.1839

THU0394 RHEUMATOLOGISTS USE DIFFERENT CUT OFFS FOR DISEASE ACTIVITY IN REAL LIFE – THE EXPERIENCE WITH GOLIMUMAB IN ANKYLOSING SPONDYLITIS – A SUBANALYSIS FROM THE NON-INTERVENTIONAL GO-NICE TRIAL

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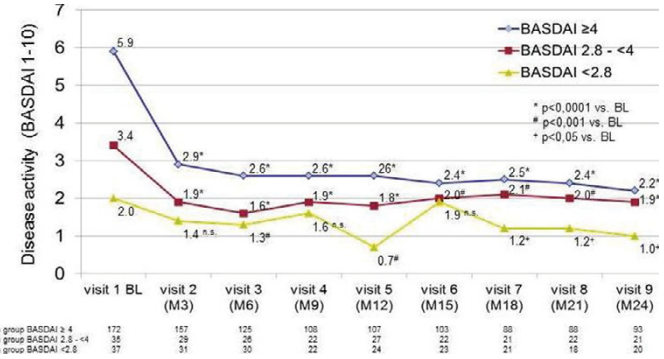
Background: International recommendations for the management of axial spondyloarthritis including ankylosing spondylitis (AS) suggest a BASDAI level of disease activity of ≥4 to indicate treatment with biologics. Other cut-offs have rarely been studied so far.

Objectives: Therefore, we were interested to learn about the level of disease activity used in daily routine to start anti-TNF therapy.

Methods: In a posthoc subanalysis of the non-interventional, prospective, study GO-NICE that has been performed in a real life setting in Germany we used data from biologic naïve patients with established AS to study the initial BASDAI values before the start of therapy with Golimumab 50mg SC once monthly. Established standardized outcome measures were used.

Results: Out of a total of 543 AS-patients (pts.) documented in 126 German centers, 244 biologic-naïve pts. were eligible. A total of 134 pts. (54.9%) completed the 24 month observational period. The majority of pts. (70.5%), had a BASDAI ≥4 (group (gr.).1), while 14.3% had a BASDAI of ≥2.8 - <4 (gr.2) and 15.1% even had a BASDAI <2.8 (gr.3, Table). The patient demographics did not differ much between these 3 groups, the proportion of males was numerically somewhat lower in gr.1. The proportion of pts. with an elevated CRP was highest in gr.2 at BL. The BASDAI in gr.1,2 and 3 was initially 5.9±1.3, 3.4±0.4 and 2.0±0.8, dropped significantly to 2.2*±2.0, 1.9*±1.2 and 1.0±1.2 within 3 months (*p<0.0001 vs. BL), and decreased significantly (p<0.005) to 2.2±1.7, 1.9±1.7 and 1.4±1.0 at month 24, respectively (fig.).The BASDAI 50% improvement was 68.8%, 44.8%, and 45.2% at month 3, and increased to 84.9%, 61.9%, and 55.0% at month 24, respectively.

Conclusions: The most interesting observation of this real life study and posthoc analysis is certainly that almost a third of the pts. were included in the study who did not reach the recommended BASDAI cut-off of ≥4. Furthermore the data show that the patients with a BASDAI 2.8 - <4 seem to have significant benefit of anti-TNF treatment, while this was not really the case with in pts. with a BASDAI <2.8. This finding should lead to a reevaluation of the established BASDAI cut-off of ≥4. Future studies should also evaluate the performance of an ASDAS cut-off.



It seems likely that especially pts. with elevated CRP levels and a BASDAI <4 will benefit from this new strategy. We think that in light of the rather weak correlation of pain and "objective" parameters of inflammation such as CRP and MRI the here reported observation does make some sense. Regarding the treatment with golimumab no new safety signals were detected.

Disclosure of Interest: J. Braun Consultant for: AbbVie (Abbott), Amgen, Biogen, Boehringer Ingelheim, BMS, Celgene, Celltrion, Centocor, Chugai, EBEWE Pharma, Epirus, Hospira, Janssen, Medac, MSD (Schering-Plough), Mundipharma, Novartis, Pfizer (Wyeth), Roche, Sanofi-Aventis and UCB, X. Baraliakos Consultant for: AbbVie, Bristol-Myers Squibb, Celgene, Janssen, Novartis, Pfizer, Roche, MSD and UCB, U. Kiltz Consultant for: AbbVie, Chugai, Janssen, MSD, Novartis, Pfizer, Roche and UCB, K. Krüger Consultant for: AbbVie, BMS, Celgene, Janssen Biologics, MSD, Pfizer, Roche, and Sanofi-Aventis, G. Burmester Consultant for: AbbVie, BMS, MSD, Pfizer, Roche, and UCB, S. Wassenberg Consultant for: AbbVie, Chugai, Janssen Biologics, MSD, Novartis, Pfizer, Roche, and USB, M. Thomas Employee of: MSD Sharp & Dohme GmbH

DOI: 10.1136/annrheumdis-2017-eular.5759

THU0395 HIGH NUMBER OF PREVIOUS BIOLOGIC USE AND COMORBIDITIES IN FIRST REAL WORLD SECUKINUMAB STUDY IN PSA AND AS – NON-INTERVENTIONAL, AQUILA STUDY IN GERMANY

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Background: Secukinumab has been shown to significantly improve symptoms of psoriatic arthritis (PsA)[1] and ankylosing spondylitis (AS)[2] in numerous phase III studies. Still, as randomized, controlled, clinical trials often limit their patients to a very strict and selected group, further data on real world evidence is necessary to assess efficacy in a broader patient group.

Objectives: To evaluate baseline characteristics regarding demographics, disease activity and comorbidities in patients with active PsA or AS in daily practice treated with secukinumab in Germany.

Methods: AQUILA, a non-interventional, multi-center, 52-week study enrolling 2000 patients with active PsA or AS. Patients are documented as treated in clinical practice. Here, we will report the baseline characteristics of a subgroup of 347 patients who have been enrolled in the study. At baseline patient's health status, selected comorbidities and disease history was assessed using routine parameters (among others: CRP, joint count, BASDAI). Furthermore, overall disease activity and quality of life has been documented using ASAS-HI (AS) and PsAID-12 item (PsA).

Results: 108 AS- and 239 PsA-patients were included, majority of AS patients were male, in PsA the majority was female. Previous bDMARD exposure was high in both groups, percentage of NSAID and cDMARD exposure varied (Tab). For PsA patients elevated CRP (Tab) and a high number of tender (8.4) and swollen joints (4.4) was reported. Assessed comorbidities included coronary heart disease (9.7%), stroke (2.5%), heart failure (2.9%) and depression (13.4%). Effect of PsA on patient's life at baseline was reported via PsAID-12 item with a mean score of 5.0 (±2.2). AS patients enrolled in this trial had a high disease activity with a mean BASDAI of 5.5 (±2.0) and elevated CRP (Table). Considered comorbidities were coronary heart disease (4.6%), stroke (0%), heart failure (0.9%) and depression (12%). Patient's impairments due to AS were assessed at baseline with the ASAS-HI, reporting a mean score of 8.1 (±3.6).

Conclusions: The baseline characteristics of the population are comparable with

Abstract THU0394 – Table 1. Demographics and baseline characteristics

	BASDAI ≥4 (n=172)	BASDAI 2.8–<4 (n=35)	BASDAI <2.8 (n=37)	Total AS patients (n=244)
Mean age [years] ± SD (range)	41.9±12.5 (18–72)	44.7±11.6 (20–69)	39.1±12.5 (23–69)	41.9±12.4 (18–72)
Proportion males n (%)	117 (68.0%)	29 (82.9%)	27 (73.0%)	173 (70.9%)
Mean time since first diagnosis [years] ± SD	8.8±9.5	10.1±10.2	8.7±9.0	9.0±9.5
Mean C-reactive protein (CRP) [mg/l] ± SD (range)	18.4±52.8 (0.3–660.0)	27.7±74.1 (0.3–426.0)	18.3±17.8 (1.0–60.6)	19.7±52.7 (0.3–660.0)
Above normal range yes, no, n (%)	75 (45.2%), 91 (54.8%)	21 (65.6%), 11 (34.4%)	18 (51.4%), 17 (48.6%)	114 (48.9%), 119 (51.1%)