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.

References:

[1] Baeten. NEJM 2015;373:2534–48.
[2] Kvien. ARD 2016;75(Suppl2):823.

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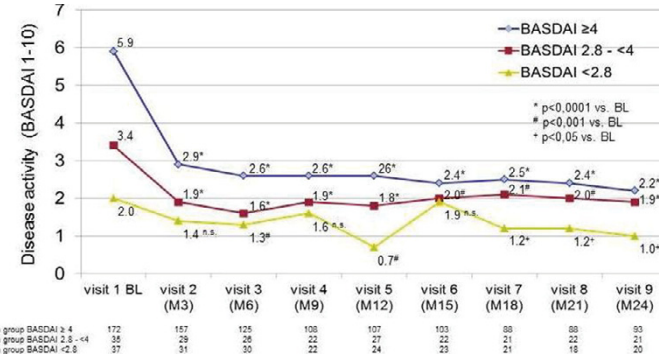
Background: International recommendations for the management of axial spondyloarthritis including ankylosing spondylitis (AS) suggest a BASDAI level of disease activity of ≥4 to indicate treatment with biologics. Other cut-offs have rarely been studied so far.

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%)

Characteristics	AS; n=108	PsA; n=239
Age (Mean±SD)	46.9±12.7	53.4±11.9
Male (%)	62.0	42.7
CRP (mg/L) (Mean±SD)	14.8±22.5	11.8±18.0
Previous NSAID exposure (%)	61.1	24.7
Previous cDMARD exposure (%)	39.8	72.8
Previous bDMARD exposure (%)	68.5	72.8
Lack of efficacy of prev. bDMARD (%)	82.4	85.1

other studies in the phase III program of secukinumab[1,2]. Major difference is represented by the high number of biological-experienced patients and comorbidities. Potential differences between these real world results and previously obtained phase III results will have to be discussed to assess their impact on patients.

References:
[1] McInnes IB et al. Lancet. 2015;386(9999):1137–46.
[2] Baeten D et al. Lancet. 2013;382(9906):1705–13.

Disclosure of Interest: U. Kiltz Grant/research support from: AbbVie, Chugai, MSD, Novartis, Pfizer, Roche, UCB, Consultant for: AbbVie, Chugai, MSD, Novartis, Pfizer, Roche, UCB, C. Legeler: None declared, M. Maier-Peuschel Employee of: Novartis, J. Veit Employee of: Novartis, C. Mann Employee of: Novartis, H.-P. Tony Grant/research support from: AbbVie, Astra-Zeneca, BMS, Chugai, Janssen, Lilly, MSD, Novartis, Pfizer, Roche, Sanofi, Consultant for: AbbVie, Astra-Zeneca, BMS, Chugai, Janssen, Lilly, MSD, Novartis, Pfizer, Roche, Sanofi

DOI: 10.1136/annrheumdis-2017-eular.6164

THU0396 EFFICACY OF SWITCHING BDMARDS IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS: RESULTS FROM A SYSTEMATIC LITERATURE REVIEW

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Background: bDMARDs (TNF or IL-17 inhibitors) have been shown to be efficacious in patients with axial spondyloarhritis (axSpA). However, approximately 30–50% of patients who receive a first bDMARD do not respond well. Current practice in these patients is switching to another bDMARD but the scientific evidence for this attitude is sparse.

Objectives: To evaluate the efficacy of switching bDMARDs in patients with axSpA.

Methods: A systematic literature review until February 2016 was performed using Medline, EMBASE and Cochrane databases. Furthermore, abstracts from the previous EULAR and ACR meetings were reviewed. The research question was formulated according to the PICOS method: Population (axSpA patients); Intervention (bDMARD); Outcome (clinical response); and Setting (longitudinal studies with follow-up ≥12 weeks of follow up including data from ≥50 patients). Data was extracted using a form developed for this specific purpose. The quality of the studies was assessed based on CEBM Oxford. Clinical response in patients who switched to a second bDMARD was determined and compared with the one achieved after receiving the first bDMARD (a TNFi in all cases). Results are shown as median (range) and relative frequencies (%).

Results: In total, 7 studies out of 1506 retrieved citations were included. All studies included patients with ankylosing spondylitis (AS). The study design was prospective observational (n=3), retrospective observational (n=2), open-label trial (n=1) and post-hoc analysis from two RCTs (n=1). The level of evidence for all the studies was 4. In these studies, a total of in 4678 patients received a first bDMARD and 1198 patients switched to a second bDMARD (a TNFi in all cases except in 51 patients that switched to secukinumab). Baseline characteristics of patients included in the studies were: 41 (38–44) years old, 67% (64–74) males, 78% (74–89) HLA-B27+ and BASDAI before switching 6.2 (5.3–6.5). The most frequent reason to switch bDMARD was inefficacy, followed by intolerance/adverse events. Median (range) time to assess response after switching was 6 (3–12) months. The criteria to define clinical response were heterogeneous. BASDAI50 was employed in four studies and the percentage of patients who achieved this response after the first and the second bDMARD for each study was: (63% vs 41%), (50% vs 28%), (54% vs 37%), (72% vs 56%), respectively. The response for the other three studies was based on different definitions, being as follows: BASDAI <4 (83% vs 78%), ASAS20 response (67% vs 48%) and retention rate after one year (65% vs 60%). The reason to switch bDMARD (intolerance or inefficacy) was not found as a significant predictor of treatment response in most of the studies. In addition, two studies reported data (n=137 and 11 patients) to evaluate the efficacy of switching to a third bDMARD (TNFi in both cases). The percentage of patients who responded (BASDAI50) to the third TNFi was 30% and 52%, respectively.

Conclusions: In patients with AS who do not respond to a first TNFi, switching to another bDMARD (either a TNFi or secukinumab) is efficacious in a considerable number of patients (30–50%). However, the clinical response after receiving a second bDMARD is lower to the one experienced after the first TNFi. Published data for switching to a third bDMARD is very limited.

Disclosure of Interest: None declared

DOI: 10.1136/annrheumdis-2017-eular.5717

THU0397 SECUKINUMAB PROVIDES SUSTAINED IMPROVEMENTS IN THE SIGNS AND SYMPTOMS OF ACTIVE ANKYLOSING SPONDYLITIS: 3-YEAR RESULTS FROM A PHASE 3 EXTENSION TRIAL (MEASURE 1)

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Background: Rapid and sustained improvements in the signs and symptoms of ankylosing spondylitis (AS) have been reported with secukinumab, a fully human anti–IL-17A mAb, over the first 2 years (yrs) in the Phase 3 MEASURE 1 trial.[1,2]

Objectives: To report efficacy and safety of secukinumab through 3 yrs in an extension trial (NCT01863732) to the core MEASURE 1 trial.

Methods: After the 2-yr core trial, patients (pts) receiving secukinumab 150 or 75mg s.c. were invited to enter a 3-yr extension trial. Efficacy results at Week (Wk) 156 are reported for pts who were originally randomised to secukinumab. Assessments at Wk 156 included ASAS20/40, BASDAI, BASDAI50, SF-36 PCS, ASAS partial remission (ASAS PR) and ASDAS-CRP. Binary and continuous variables used multiple imputation and MMRM estimates, respectively. Analyses by anti-TNF use (naïve/intolerant to or inadequate response [IR]) was pre-specified and reported as observed. Safety analyses included all pts who received ≥1 dose of secukinumab.

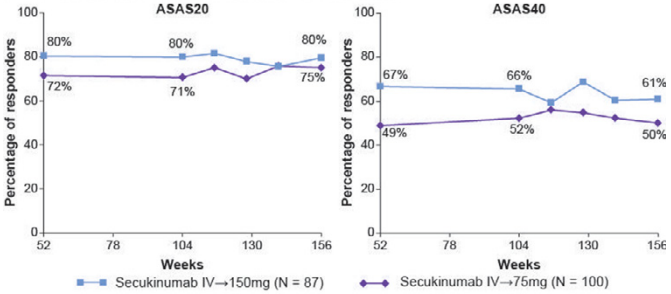
Results: A total of 290/371 pts (78%) completed the 2-yr core trial. Of these, 274 pts entered the extension trial, with 260 completing 156 wks (83/87 pts [95%] in IV→150mg; 95/100 pts [95%] in IV→75mg; 82/87 [94%] pts in placebo→secukinumab). At Wk 156, clinical improvements were sustained across all endpoints (Table, Figure). Similar trends were observed regardless of prior anti-TNF use (Table). Across the treatment period (secukinumab exposure [mean±SD]: 964.3±372.1 days), exposure-adjusted incidence rate with secukinumab for serious infections, Crohn's disease and malignant/unspecified tumours was 1.1, 0.5 and 0.5 per 100 pt-yrs, respectively.

Table 1. Summary of 156-wk efficacy results

	Observed data		Missing data considered[a]	
	Secukinumab IV→150mg (N=87)	Secukinumab IV→75mg (N=100)	Secukinumab IV→150mg (N=87)	Secukinumab IV→75mg (N=100)
ASAS, % response				
ASAS20/40	80/62[b]	76/50[b]	80/61	75/50
ASAS PR	27[b]	14[b]	27	14
BASDAI				
Baseline, mean±SD	6.1±1.5	6.0±1.5	6.1±1.5[#]	6.0±1.5[#]
Mean change from baseline[c]	–3.3±2.4[b]	–3.0±1.7[b]	–3.1±0.2	–2.9±0.2
	Secukinumab IV→150mg		Secukinumab IV→75mg	
Analysis by anti-TNF status[d]				
Anti-TNF-naïve[e]	N=70		N=76	
ASAS20/40, % response	80/61		76/48	
Anti-TNF-IR[e]	N=17		N=24	
ASAS20/40, % response	81/63		74/57	

[a]Missing data of binary variables were imputed and for continuous variables MMRM estimates are shown. [b]Evaluable data available in n=86 and n=98 pts in the secukinumab IV→150mg and IV→75mg groups, respectively. [c]Least squares mean±SE for MMRM estimates and mean±SD for observed data. [d]Observed data. [e]Evaluable data available in n=70 and 75 pts (naïve) and n=16 and 23 pts (IR) in the secukinumab IV→150mg and IV→75mg groups, respectively. [#]Observed data provided for reference. IV, pts received secukinumab 10mg/kg i.v. loading at baseline, Wks 2 and 4; N, number of pts in the extension trial.

Figure. ASAS20 and ASAS40 responses through Week 156



Data presented after multiple imputation through Week 156. ASAS20 and ASAS40 responses through Week 104 have been reported previously.[2] N, number of patients in the extension trial

Conclusions: Secukinumab provided sustained efficacy in signs/symptoms and physical function in pts with active AS over 3 yrs. Secukinumab was well tolerated with a favorable safety profile consistent with that reported previously.[1,2]

References:
[1] Baeten D, et al. N Engl J Med 2015;373:2534–48.
[2] Braun J, et al. Ann Rheum Dis 2016;doi: 10.1136/annrheumdis-2016-209730.