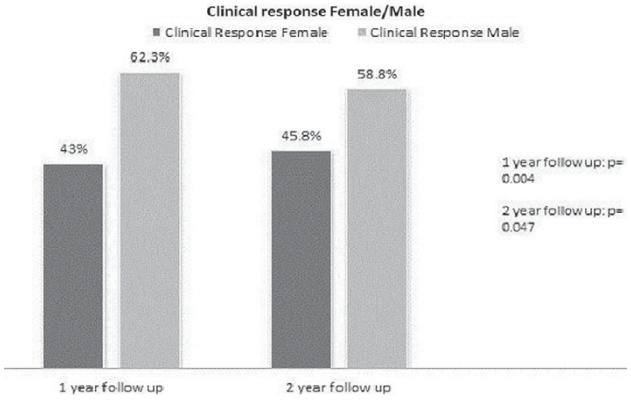
Results: In total, 312 consecutive AS patients, 34% female, were included with a mean follow-up of 18.9 months. Most patients (172, 55%) showed significant improvement after start of TNFi of whom 86 patients (28%) had a clinically important (ASDAS decrease >1.1) and 86 (26.9%) a major clinical improvement (ASDAS decrease >2.2). BMI was significantly correlated with age at diagnosis (p=0.016; 95% CI: 0.07 – 0.65): an increase of BMI with three points delayed the AS diagnosis with one year. At baseline, smoking and gender were not correlated with the ASDAS, but BASDAI and BASMI were both inversely related to BMI. Male gender was significantly associated with a higher chance at clinical response (improvement of the BASDAI with 50% or a 2 point decrease) to TNFi (p=0.041). At one year follow-up the clinical improvement of males versus females was respectively 62% vs. 43% and at two year follow-up 59% vs. 46%. Males also showed a significantly higher ASDAS improvement after one year of follow-up compared to females (p=0.015).



Conclusions: Significantly less females had a clinical response compared to males after one and two years of TNFi treatment. A higher BMI not only prolonged the time to AS diagnosis up to one year, but also negatively influenced the BASDAI and BASMI scores. Female gender and high body weight should be taken into consideration when the efficacy of TNFi is assessed, by stratifying for these factors in the analysis.

Disclosure of Interest: None declared

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THU0392 DO WE REALLY NEED DMARDS ADDITION TO ANKYLOSISNG SPONDYLITIS PATIENTS TREATED WITH TUMOR NECROSIS FACTOR ALPHA INHIBITORS?

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Background: The management of systemic inflammatory diseases, such as Rheumatoid arthritis (RA) and Ankylosing spondylitis (AS) has been revolutionized with the introduction of tumor necrosis factor alpha inhibitors (TNF-I). Significant reduction in disease activity and achievment of remission resulted in halting of joint damage and improved quality of life. Unfortunately, approximatly 15–30% of patients fail to reach desirable improvement or lose drug effectiveness with time. It may be explained by immunogenicity and production of human anti chimeric antibodies (HACA). Presence of HACA against TNF-I have been associated with low levels of the drug and lose of therapeutic response. The prevalence of HACA in RA is estimated between 20–40%, and in AS between 25–64%. The difference in the pathogenesis of RA and AS as well as diverce approach in using disease modifying anti-rheumatic drugs (DMARDs) may influence HACA production and TNF-I levels in these conditions.

Objectives: To compare the incidence of HACA and Infliximab, Etanercept, Adalimumab levels in patients with RA and AS with respect to concomitant DMARDs.

Methods: Patients' with RA and AS data treated with TNF-I for at least 3 months in whom tests for HACA and Infliximab, Etanercept, Adalimumab levels were available were extracted from patients' files. Data included: demographics, concomitant treatment, and disease activity scores (BASDAI for AS and DAS-28 for RA). Serum for assessment of drugs level (ELISA) and HACA (ADAb;Promonitor, Bridging, ELISA) was obtained before the next drug administration. Univariate comparison was done using Student t test for the continuous variables and Chi square test for the categorical variables (P <.05 was considered significant).

Results: Data on 53 patients with AS (mean age 47.9±11.9 years, 41.5. % female) and 29 patients with RA (mean age 54.8±8.1 years, 75, 9% female) were available: 22 RA patients were treated with Methotrexate and 7 with other DMARDs; no one AS patient was treated with concomitant DMARDs. High level of HACA was found in 22.6% AS patients and in 34.5% RA patients (p>0.05); 86.8% patients with AS reached theurapethic level of drug compared to 69% RA patients (p=0.027). Drugs levels were similar in AS and RA patients (Table). Low disease activity (DAS28-CRP<3.2) was registered in 62.1% RA patients and in 81.4% AS patients (BASDAI <4).

Conclusions: Despite significant difference in the use of concomitant DMARDs, patients with AS and RA had similar prevalence of HACA. Moreover, higher proportion of patients in AS group reached therapeutic level of TNF-I. The data supports the hypothesis, that immune responce to TNF-I may be different in AS and RA and, therefore, the addition of DMARDs to prevent development of HACA in patients with AS may be unnecessary.

Disclosure of Interest: None declared

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THU0393 SECUKINUMAB PROVIDES SUSTAINED REDUCTION IN FATIGUE IN PATIENTS WITH ANKYLOSING SPONDYLITIS THROUGH 3 YEARS: LONG-TERM RESULTS OF TWO RANDOMISED DOUBLE-BLIND PLACEBO-CONTROLLED PHASE 3 STUDIES

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Background: In patients (pts) with ankylosing spondylitis (AS), fatigue is a common symptom negatively affecting health-related quality of life (HRQoL) and social functioning. Secukinumab (SEC), a fully human anti–IL-17A mAb, rapidly improved signs and symptoms, physical functioning, and HRQoL in pts with AS.[1,2]

Objectives: To assess the long-term effects of SEC on fatigue in TNF inhibitor (TNF)-naïve and TNF inhibitor inadequate responder/intolerant (TNF-IR) AS pts in MEASURE 1 and MEASURE 2.

Methods: 371 and 219 pts were randomized to SEC or placebo (PBO) in MEASURE 1 (10 mg/kg IV followed by 150 or 75 mg SC) and MEASURE 2 (150 or 75 mg SC), respectively. At Week (Wk) 16, non-responder PBO pts were re-randomized to SEC 150 or 75 mg SC (in MEASURE 1, PBO pts achieving ASAS20 response at Wk 16 were switched to SEC at Wk 24). Fatigue was measured at baseline (BL) and Wks 4, 8, 12, 16, 24, 52, 104 and 156 using FACIT-F, which assesses fatigue in the previous 7 days using 13 questions graded on a 0–4 scale (higher scores=less fatigue). An increase from BL in FACIT-F score of ≥4 points (based on MCID) was used to define "response". Approximately 69% of pts were TNF-naïve and 31% were TNF-IR across both trials. Analyses were based on the full analysis set and subgroups stratified by prior TNF therapy. Correlations between BL characteristics and improvements in fatigue were investigated using a logistical regression model. Only data from the approved dose (SEC 150 mg) are presented.

Results: FACIT-F was 24.5–25.6 and 22.6–24.3 at BL across groups in MEASURE 1 and 2, respectively. Improvements in FACIT-F with SEC at Wk 16 were sustained through Wk 156 in MEASURE 1 and Wk 104 in MEASURE 2 (Table). Rapid and sustained fatigue responses were also seen in subgroups stratified by prior TNF use. In the overall population, LS mean changes (±SEM) from BL in FACIT-F scores were significantly greater with SEC vs PBO at Wk 16 in both MEASURE 1 (7.60±0.99 vs 3.34±1.00, *P*=0.002) and MEASURE 2 (8.10±1.09 vs 3.27±1.09, *P*=0.018); reductions in fatigue were sustained throughout the entire follow up in both trials (MEASURE 1 Wk 156: 9.81±0.95; MEASURE 2 Wk 104: 9.27±1.13). Similar results were reported in both TNF-naïve and TNF-IR pts. Correlational analyses based on pooled data from both trials did not identify any BL factors that

Table: FACIT-F responders in MEASURE 1 and MEASURE 2 with secukinumab 150 mg[a]

	Proportion of Patients with FACIT-F Response[b], % (n/m)			
	Week 16	Week 52	Week 104	Week 156
MEASURE 1[c]				
Overall (N=87)	66.7 (58/87)	73.6 (64/87)	72.2 (57/79)	75.6 (65/86)
TNF-naïve (N=70)	70.0 (49/70)	75.7 (53/70)	70.3 (45/64)	74.3 (52/70)
TNF-IR (N=17)	52.9 (9/17)	64.7 (11/17)	80.0 (12/15)	81.3 (13/16)
MEASURE 2				
Overall (N=72)	77.6 (52/67)	80.6 (50/62)	81.4 (48/59)	–
TNF-naïve (N=44)	86.0 (37/43)	90.0 (36/40)	84.6 (33/39)	–
TNF-IR (N=28)	62.5 (15/24)	63.6 (14/22)	75.0 (15/20)	–

[a]Observed data are shown; [b]Defined as improvement (increase in FACIT-F score) by ≥4.0 points from BL; [c]Data shown are from patients who entered the MEASURE 1 long-term extension study at Week 104 (NCT01863732)
m, number of patients with sufficient data for evaluation; N, number of patients randomized to SEC 150 mg
n, number of responders

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

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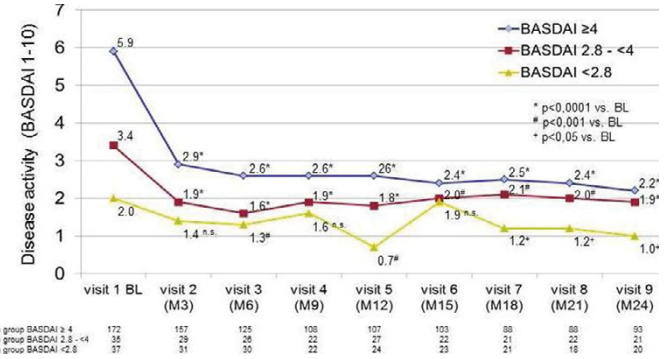
Background: International recommendations for the management of axial spondyloarthritis including ankylosing spondylitis (AS) suggest a BASDAI level of disease activity of ≥4 to indicate treatment with biologics. Other cut-offs have rarely been studied so far.

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

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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%)