The non-rheumatology led GCA pathway was associated with higher glucocorticoid burden. In this cohort, 23/55 (41.8%) patients who were found not to have GCA received more than 21 days of high dose steroids (40–60mg Prednisolone) whilst awaiting rheumatology review. 4 patients whose final diagnosis was not GCA received high dose steroids for more than 30 days (max 109 days).

Conclusions: 1. Availability of a rheumatology-led GCA pathway leads to improved care for patients with suspected GCA
2. Easy access for referral of patients with headache as assessed by the non-specialist can lead to over-use of the pathway and inappropriate referrals
3. Non-rheumatology-led GCA pathway can lead to a high glucocorticoid burden, especially in an elderly demographic with other comorbidities

Disclosure of Interest: None declared

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Spondyloarthritis - treatment

THU0345 REAL-LIFE EFFECTIVENESS OF TNF INHIBITORS IN AXIAL SPONDYLARTHROSIS: ARE CHANGING NATIONAL POLICIES ON CHOICE OF TNF INHIBITOR REFLECTED IN RESPONSE TO TREATMENT?

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Background: Tumour necrosis factor inhibitors (TNFi) have revolutionized treatment of axial spondylarthritis (axSpA). The five different available TNFi have not been compared directly, and whether effectiveness differs between agents is unknown. In Norway national authorities consider the different TNFi equivalent, and since 2009 the least expensive drug following an annual national tender has been the drug-of-choice in the publicly funded healthcare system. This has led to variations across different years in drug use where choice of TNFi has been predominantly based on national price policy and not clinical characteristics.

Objectives: Comparing response to TNFi during the first year of treatment of axSpA in biologics-naïve patients over years with highly varying uptake of different TNFi.

Methods: We included the 981 biologics-naïve patients with axSpA from the NOR-DMARD register who started their first TNFi from 2009 through 2015. The preferred drugs in national recommendations were: 2009 adalimumab, 2010 golimumab, 2011 etanercept, 2012 etanercept, 2013 golimumab, 2014 certolizumab, 2015 certolizumab/biosimilar infliximab (CT-P13). We compared the estimated change in Ankylosing Spondylitis Disease Activity Score (ASDAS) between treatment years at 3, 6 and 12 months after treatment start using a mixed model with subject-specific random intercept, adjusting for baseline disease activity, age, sex and treatment centre.

Results: Demographics, drug uptake and baseline characteristics for each year 2009–2015 are listed in table 1. The preferred drug was started in 57–91% of patients. There was a trend towards lower ASDAS and disease duration over time. There were no differences in treatment effectiveness between the years, regardless of the substantial differences in type of TNFi used (figure).

Conclusions: Real-life data do not show differences in response to TNFi despite large annual variation in type of TNFi prescribed, indicating similar effectiveness of the available TNFi in patients with axSpA. This supports the practice of selecting drug based on cost and feasibility of use, as is the current practice in Norway. Further adoption of this principle can provide access to TNFi treatment to more patients, as it reduces costs and healthcare resources are limited.

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Abstract THU0345 – Table 1. Demographics and baseline characteristics

	2009	2010	2011	2012	2013	2014	2015	p-value
N	110	104	200	124	148	192	103	
Age (years), mean (SD)	42.3 (11.2)	40.3 (11.5)	41.7 (13.0)	40.0 (12.0)	40.9 (12.7)	41.6 (11.8)	41.6 (12.3)	0.76
Proportion male	66.1%	61.2%	50.8%	55.6%	52.7%	54.7%	57.3%	0.19
Years since diagnosis, median (IQR)	4.51 (0.77, 14.69)	3.79 (0.61, 12.74)	2.63 (0.47, 12.88)	1.70 (0.56, 11.08)	0.76 (0.22, 6.78)	0.60 (0.19, 3.44)	1.41 (0.18, 10.76)	<0.001
ASDAS, mean (SD)	3.26 (0.84)	3.20 (0.92)	3.10 (0.94)	2.96 (1.01)	3.02 (0.87)	2.87 (0.89)	2.71 (1.01)	<0.001
Adalimumab	90.9%	29.8%	22.0%	14.5%	24.3%	12.0%	0.0%	<0.001
Certolizumab	0.0%	1.9%	0.0%	0.8%	12.8%	77.1%	49.5%	
Etanercept	7.3%	8.7%	63.5%	69.4%	4.7%	2.6%	1.9%	
Golimumab	0.0%	58.7%	11.0%	11.3%	57.4%	2.6%	4.9%	
Infliximab	1.8%	1.0%	3.5%	4.0%	0.7%	0.5%	0.0%	
Biosimilar infliximab	0.0%	0.0%	0.0%	0.0%	0.0%	5.2%	43.7%	

p-values for between-year differences.

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THU0346 CONCOMITANT FIBROMYALGIA IN AXIAL SPONDYLOARTRITIS HAS A NEGATIVE IMPACT ON TNF ALPHA BLOCKERS TREATMENT EFFECT IN REAL LIFE

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Background: Coexisting fibromyalgia (FM) in axial spondyloarthritis (axSpA) can represent therapeutic challenges, particularly when evaluating the treatment effect of biologics (i.e. TNF alpha blockers (TNFb)). Indeed, since FM patients often report high levels of pain and disability there is the risk of classifying such patients as refractory to TNFb (ie, as not reaching a significant improvement in disease activity).

Objectives: To evaluate the impact of concomitant FM on the TNFb treatment effect in axSpA.

Methods: Design: Prospective observational national study with 2 visits 3 months apart (baseline and 12 weeks after TNFb initiation) (Predict-SpA study ClinicalTrials.gov: NCT03039088). **Patients:** axSpA patients (diagnosis according to treating rheumatologist) initiating a TNFb. **Data collection:** the FIRST questionnaire (Fibromyalgia Rapid Screen Test) which screens for FM, patients and disease characteristics and effectiveness measures (e.g. ASAS response components). **Statistical analysis:** FM positive screening was defined by a FIRST score $\geq 5/6$; the primary efficacy outcome was the ASAS 40. Non-responder imputation and baseline observation carried forward imputation (for binary and continuous outcome variables, respectively) was performed. Impact of FM on the TNFb treatment effect was evaluated by multivariable logistic regression, with ASAS 40 as the dependent variable and FM as the independent variable; were also included in the model other factors previously reported in the literature as associated with treatment efficacy (i.e. X-ray and MRI sacroiliitis, abnormal CRP ($>6\text{mg/L}$), HLA B-27, smoking status, previous TNFb exposure, age <40 and male gender).

Results: Among the 527 patients enrolled in the study, 508 patients were analysed. Mean age was 41.4 (± 11.6), 237 (46.7%) were women, with a 6.1 $\pm$ 8.5 mean disease duration. Among them, 192 (37.8%) were screened as FM by the FIRST questionnaire. Overall efficacy of the TNFb was good (ASAS40, 201/508 (39.6%)) though 50 patients (9.8%) patients discontinued the TNFb before the follow-up visit and were considered as non-responders.

Patients with FM presented less frequently an ASAS 40 response (87/192 (45.3%) vs 171/316 (54.1%)), for the FM vs non-FM groups according to the FIRST definition. Presence of FM was independently associated with poorer ASAS40 response (adjusted odds ratio, OR = 0.5 [95% CI 0.3 – 0.8]) while X-ray sacroiliitis (1.8 [1.2 – 2.8]), abnormal CRP (1.6 [1.0 – 2.4]) and absence of previous exposure to TNFb (1.7 [1.1 – 2.6]) were found to be associated with an ASAS40 response.

Conclusions: This study 1) confirms the “conventional” predisposing factors of TNFb treatment response such as X-ray sacroiliitis, abnormal CRP and absence of previous exposure to TNFb; and 2) suggests that concomitant FM influences treatment response. FM deserves to be screened in axSpA, in particular in case of a decision to initiate a TNFb therapy.

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THU0347 IMPACT OF OBESITY ON THE RESPONSE TO TUMOUR NECROSIS FACTOR INHIBITORS IN AXIAL SPONDYLOARTHRITIS

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Background: Few studies have investigated the impact of obesity on response to tumour necrosis factor inhibitors (TNFi) in patients with axial spondyloarthritis (axSpA).

Objectives: To investigate the impact of different Body Mass Index (BMI) categories on TNFi response in a large cohort of patients with axSpA.

Methods: Patients within the Swiss Clinical Quality Management cohort were included if they fulfilled the ASAS criteria for axSpA, started a first TNFi after recruitment and had available BMI data as well as a baseline and follow-up visit at 1 year (± 6 mo) (N=632). Patients were categorized according to BMI: normal (BMI 18.5 to <25), overweight (BMI 25 to 30) and obese (BMI >30). We evaluated the proportion of patients achieving the 40% improvement ASAS criteria (ASAS40) as well as Ankylosing Spondylitis Disease Activity Score (ASDAS) improvement and status scores at 1 year. Patients having discontinued the TNFi were considered non-responders. We controlled for age, sex, HLA-B27, axSpA-type, BASDAI, BASMI, elevated CRP, current smoking and physical exercise in multiple adjusted logistic regression analyses.

Results: In comparison to normal weight and overweight patients, obese individuals were significantly older, had a longer symptom duration and higher BASFI and BASMI levels, while ASDAS levels were comparable between the 3 groups (Table 1). Data to calculate the ASAS40 response was available in 496 patients (78%). It was reached by 44%, 35% and 28% of patients with normal weight, overweight and obesity, respectively, ($p=0.02$; Table 2). A significantly lower odds ratio (OR) for achieving ASAS40 response was found in adjusted analyses in obese patients vs patients with normal BMI (OR 0.30, 95% confidence interval (CI) 0.11–0.73, $p=0.01$). Comparable results were found for the other outcomes assessed. The respective adjusted ASAS40 OR in overweight vs. normal weight patients was 0.69, 95% CI 0.38–1.24, $p=0.22$.

Table 1. Baseline characteristics at start TNFi

Parameter	N 632	BMI category		
		Normal (N=331)	Overweight (N=202)	Obese (N=99)
Male sex, %	632	54	74*	64
Age, years	632	37.0 (11.2)	40.6 (11.5)*	44.2 (10.9)*#
Symptom duration, years	627	11.8 (10.1)	13.0 (11.4)	15.8 (11.7)*#
HLA-B27 positive, %	579	81	77	72
BASDAI	552	5.3 (2.0)	5.7 (1.9)*	5.8 (1.8)*
ASDAS-CRP	520	3.4 (0.9)	3.5 (0.9)	3.6 (0.9)
Elevated CRP, %	587	55	49	59
BASFI	558	3.6 (2.4)	4.2 (2.4)*	4.9 (2.6)*
BASMI	541	2.0 (2.0)	2.2 (1.9)	3.0 (2.3)*

*P values <0.015 compared with patients with normal weight. #P values <0.015 compared with patients with overweight. Values are the mean (SD).

Table 2. Unadjusted response rates after 1 year of treatment with a first TNF inhibitor

Outcome	N 496	BMI category			P*
		Normal (N=258)	Overweight (N=162)	Obese (N=76)	
ASAS40	496	44	35	28	0.02
ASDAS improvement ≥ 1.1	425	60	46	38	0.002
ASDAS <2.1	472	56	39	31	<0.001
ASDAS improvement ≥ 2	425	26	24	14	0.14
ASDAS <1.3	472	30	15	10	<0.001

Values are the %. *Overall P value.

Conclusions: Obesity is associated with significantly lower response rates to TNFi in patients with axSpA.

Disclosure of Interest: None declared

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THU0348 SAFETY AND EFFICACY OF INTRAVENOUS GOLIMUMAB IN ADULT PATIENTS WITH ACTIVE ANKYLOSING SPONDYLITIS: RESULTS THROUGH WEEK 28

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Objectives: Subcutaneous (SC) golimumab (GLM) is currently approved for adult

patients (pts) with RA, PsA, and AS. The GO-ALIVE study was designed to evaluate the safety and efficacy of IV GLM in adult pts with active AS.

Methods: GO-ALIVE is a Phase 3, multicenter, randomized, double-blind, placebo (PBO)-controlled trial. Pts (aged ≥ 18 yrs) had a diagnosis of definite AS (per modified New York criteria) and BASDAI ≥ 4 , total back pain visual analogue scale ≥ 4 , and CRP ≥ 0.3 mg/dL. Pts were randomized (1:1) to IV GLM 2mg/kg at weeks (wks) 0, 4, and every 8 wks or PBO at wks 0, 4, and 12, with crossover to GLM at wk16. Up to 20% of pts could have had a prior anti-TNF agent (other than GLM), and up to 10% of pts could have complete ankylosis of the spine. The primary endpoint was ASAS20 at wk16. Major secondary endpoints were ASAS40, BASDAI50, and change in BASFI score at wk16. Some of the other statistically-controlled assessments were BASMI, and ASAS partial remission. Pts were monitored for adverse events (AEs). Data through wk28 are reported here.

Results: 208 pts were randomized and received study agent (PBO: 103; GLM: 105). Baseline demographic and disease characteristics were similar between treatment groups. 78% of pts were male, mean age was 39 yrs; mean disease duration was 5.5 yrs, 89.9% were HLA-B27 positive, 5.8% had complete ankylosis of the spine, 14.4% used a prior anti-TNF. At wk16, significantly greater proportions of GLM pts vs PBO had ASAS20 (73.3% vs. 26.2%), ASAS40 (47.6% vs. 8.7%), and BASDAI 50 (41.0% vs. 14.6%) responses (all $p<0.001$; Table). Reductions in BASFI were also significantly greater with GLM. ASAS20 was significantly higher with GLM than PBO as early as wk2 (37.1% vs 19.4%; $p=0.005$). Responses in the GLM group were maintained through wk28. PBO pts who crossed over to GLM at wk16 had improvements in clinical response at wk20 that were maintained through wk28. Through wk16, 23.3% of PBO pts and 32.4% of GLM pts had ≥ 1 AE. Infections were the most common type of AE (PBO, 7.8%; GLM, 11.4%). Through wk28, 34.8% of all GLM-treated pts had ≥ 1 AE; nasopharyngitis (5.4%) was the most common. Two pts (1.0%) had SAEs (pancreatitis, n=1; pneumonia, n=1). Both were randomized to GLM. There were no opportunistic infections, malignancies, or deaths through wk28. The rate of infusion reactions was low (1.5%). 3 pts treated with GLM had 4 reactions; none was serious or severe.

Table. Efficacy at week 16.

	Placebo 103	Golimumab 2 mg/kg 105
Patients randomized, n		
Clinical efficacy		
ASAS20, n (%)	27 (26.2%)	77 (73.3%)*
ASAS40, n (%)	9 (8.7%)	50 (47.6%)*
BASDAI 50, n (%)	15 (14.6%)	43 (41.0%)*
Change from baseline in BASFI, n	98	105
mean (SD)	-0.5 (2.0)	-2.4 (2.1)*
ASAS partial remission, n (%)	4 (3.9%)	17 (16.2%)*
Change from baseline in BASMI (linear), n	96	100
mean (SD)	-0.1 (0.5)	-0.4 (0.6)*

* $p < 0.01$; ** $p \leq 0.001$

ASAS20/40, $\geq 20\%/40\%$ improvement in Assessment in Ankylosing Spondylitis (ASAS) International Working Group criteria; BASDAI, Bath Ankylosing Spondylitis Disease Activity Index; BASFI, Bath Ankylosing Spondylitis Functional Index; BASMI, Bath Ankylosing Spondylitis Metrology Index; SD, standard deviation

Conclusions: IV GLM 2mg/kg was efficacious in reducing the signs and symptoms of AS compared with PBO. GLM was well-tolerated through wk28; the safety profile was consistent with other anti-TNFs, including SC GLM.

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THU0349 METHOTREXATE REDUCES ADALIMUMAB IMMUNOGENICITY IN PATIENTS WITH SPONDYLOARTHRITIS: A RANDOMIZED CLINICAL TRIAL

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Background: TNF inhibitors are effective in treating spondyloarthritis (SpA).