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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 recruitement and had available BMI data as well as a baseline and follow-up visit at 1 year (±6mo) (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	BMI category		
	632	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	BMI category			P*
	496	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.
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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 ≥0.3mg/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	Golimumab 2 mg/kg
Patients randomized, n	103	105
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 ≤ 0.001
ASAS20/40, ≥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).