Conclusions: Over 2 years, a numerically lower rate of progression was seen in secukinumab-treated pts vs a control cohort of biologic-naïve AS pts. Further research is needed to understand the impact of IL-17A inhibition with secukinumab on spinal disease progression in AS pts; SURPASS (NCT03259074), an ongoing H2H study powered to compare differences in spinal radiographic progression with secukinumab vs biosimilar adalimumab, will help answer these questions.

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SAT0260

ELIGIBILITY CRITERIA FOR TNFI THERAPY IN AXSPA: GOING BEYOND BASDAI

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Background: A BASDAI ≥ 4 has been often required to start TNFi therapy in patients with axSpA. However, this cut-off of high disease activity (HDA) is largely arbitrary. Unlike BASDAI, ASDAS incorporates objective measures (e.g. CRP) and has a validated definition of HDA (≥ 2.1). It has thus been suggested that ASDAS could also be used to guide treatment decisions, but evidence to support this is still scarce.

Objectives: To compare the impact of applying the ASDAS and BASDAI definitions of HDA in selecting patients for TNFi-treatment in daily clinical practice

Methods: Patients from Reuma.pt (Rheumatic Diseases Portuguese Register), with diagnosis of axSpA according to their rheumatologists (both treated and not treated with their first TNFi), with complete baseline BASDAI and ASDAS data, and complete 6 month of follow-up (i.e. baseline, 3 and 6 months visits available) were included. Four subgroups [cross-tabulation between ASDAS (≥ 2.1) and BASDAI (≥ 4) definitions of HDA], were compared according to baseline demographic and clinical characteristics in the 'eligible population' (i.e. irrespective of TNFi-treatment). In addition, for patients starting TNFi and with complete follow-up BASDAI/ASDAS data ('efficacy population'), the subgroups were also compared according to different response criteria (see table 1), at 3 and 6 months.

Results: In total, 466 patients were included (59% males and 66% HLA-B27 positive). The large majority (n=382; 82%) fulfilled the definition of HDA according to both BASDAI and ASDAS at baseline (i.e. BASDAI ≥ 4 and ASDAS ≥ 2.1). The frequency of ASDAS ≥ 2.1 , if BASDAI < 4 , was much higher than the opposite condition (i.e. ASDAS < 2.1 , if BASDAI ≥ 4) (70% vs 0.5%). Compared to patients fulfilling both definitions, those who were ASDAS ≥ 2.1 only, were more likely to be male (82.5% vs 54%), HLA-B27 positive (79% vs 54%), to show higher levels of CRP (2.6 $\pm$ 2.5 vs 2.2 $\pm$ 2.8 mg/dL) and lower BASFI (3.1 $\pm$ 2.6 vs 5.6 $\pm$ 2.3). In the 'efficacy population' (n=296), better responses were observed among patients with ASDAS ≥ 2.1 only, especially for the most 'stringent' outcomes [e.g. ASDAS inactive disease (ASDAS ID): 59% and 50%, at 3 and 6 months respectively], compared to patients fulfilling both definitions (ASDAS ID: 26% and 25% at 3 and 6 months respectively) (table 1).

Abstract SAT0260 – Table 1. TNFi response criteria across subgroups according to BASDAI/ASDAS category ('efficacy population')

Variables	Overall (N= 296) *	ASDAS ≥ 2.1		ASDAS < 2.1		p-value **
		BASDAI ≥ 4 (N=256)	BASDAI < 4 (N=34)	BASDAI ≥ 4 (N=1)	BASDAI < 4 (N=5)	
Outcomes - 3 months, n (%)						
ASAS20	159 (59)	142 (60)	15 (56)	0 (0)	2 (40)	0.48
ASAS40	127 (47)	111 (46)	14 (52)	0 (0)	2 (40)	0.74
ASAS PR	73 (26)	56 (22)	14 (56)	0 (0)	3 (60)	<0.01
BASDAI50	184 (62)	160 (63)	21 (62)	0 (0)	3 (60)	0.64
ASDAS CII	207 (70)	179 (70)	26 (77)	0 (0)	2 (40)	0.16
ASDAS MI	123 (42)	111 (43)	12 (35)	0 (0)	0 (0)	0.16
ASDAS ID	90 (30)	66 (26)	20 (59)	0 (0)	4 (80)	<0.01
Outcomes - 6 months, n (%)						
ASAS20	160 (61)	139 (61)	18 (62)	0 (0)	3 (60)	0.67
ASAS40	124 (46)	104 (45)	17 (57)	0 (0)	3 (60)	0.43
ASAS PR	74 (27)	57 (24)	13 (48)	0 (0)	4 (80)	<0.01
BASDAI50	188 (64)	167 (65)	18 (53)	0 (0)	3 (60)	0.29
ASDAS CII	216 (73)	190 (74)	25 (74)	0 (0)	1 (20)	0.02
ASDAS MI	128 (43)	117 (46)	11 (32)	0 (0)	0 (0)	0.08
ASDAS ID	84 (28)	63 (25)	17 (50)	0 (0)	4 (80)	<0.01

* axSpA patients treated with TNFi, with complete 6 months of follow-up and data for BASDAI/ASDAS at every time-point ** comparison between subgroups according to BASDAI/ASDAS category of disease activity (ANOVA for continuous variables and Chi2 for categorical variables). ASDAS CII, ASDAS clinically important improvement. ASDAS MI, ASDAS major improvement. ASDAS ID, ASDAS inactive disease.

Conclusions: Our results show that the ASDAS-HDA definition (ASDAS ≥ 2.1) is more inclusive than the BASDAI-HDA definition (≥ 4) in selecting axSpA patients for TNFi treatment. Importantly, the additionally 'captured' patients respond better and have higher likelihood of predictors thereof. These results support the use of ASDAS ≥ 2.1 as a selection criterion for treatment decisions.

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SAT0261

CERTOLIZUMAB PEGOL SERUM LEVELS ≥ 20 MG/L ARE ASSOCIATED WITH TREATMENT RESPONSE IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS. DATA FROM THE NOR-DMARD STUDY

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Background: Measurement of serum drug levels can help clinicians tailor treatment with TNF-inhibitors. An association between certolizumab pegol (CP) serum levels and response has previously been found in patients (pts) with rheumatoid arthritis. ¹ Data for pts with axial spondyloarthritis (axSpA) are lacking.

Objectives: To examine the association between serum CP levels and treatment response in pts with axSpA and to identify a therapeutic target level.

Methods: Patients with a clinical diagnosis of axSpA starting standard treatment with CP included in the NOR-DMARD study with biobank sample at 3 months follow-up, were included in the present analyses. Serum drug levels (non-trough) were analysed with an in-house immunofluorometric assay automated on the AutoDELTA immunoassay platform. Associations between CP level and improvement in ASDAS-CRP and response (defined as ASDAS clinically important improvement (CII)) were assessed by multivariable linear and logistic regression (adjusting for age, sex and prior bDMARD (Y/N)), respectively.

Results: Median serum drug level at 3 month follow up was 35.0 mg/L (IQR 21.3–45.3) in 116 pts. Response data were available in 110/116 patients. Serum CP level ≥ 20 mg/L was associated with improvement in ASDAS at 3 months ($\beta=0.55$, (95% CI 0.12–1.98), $p=0.01$). Serum CP level ≥ 20 mg/L was associated with ASDAS CII at 3 months (OR 3.4 (95% CI 1.0–11.1, $p=0.045$)). Only 18.2% of pts with CP level <20 mg/L achieved ASDAS CII at 3 months, while 53.2% of pts with CP level 20–40 mg/L and 36.6% with ≥ 40 mg/L were responders.

Conclusions: Serum CP level was associated with clinical response after 3 months of treatment in pts with axSpA. We suggest 20 mg/L as a lower target level for non-trough samples. No additional benefit of having a certolizumab level over 40 mg/L was observed. These results suggest that a therapeutic level of 20–40 mg/L can be implemented in clinical practice for non-trough serum samples in pts with axSpA.

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SAT0262

3-YEAR FOLLOW-UP OF A DOSE TAPERING PROTOCOL OF ANTI-TNF THERAPY IN A COHORT OF PATIENTS WITH SPONDYLOARTHRITIS (SPA) IN CLINICAL REMISSION UNDER CONDITIONS OF CLINICAL PRACTICE

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Background: The dose tapering of biological therapy in patients in clinical remission is a strategy used in recent years in Rheumatology, consists in the reduction of the dose administered or in the extension of the interval between two doses, some studies suggest the possibility that patients with sustained remission could obtain the same benefit with a lower dose.

Objectives: Evaluate the effectiveness of 3 year follow-up of a dose tapering in patients with SpA in maintained clinical remission and detect possible predictors of maintenance of the response.

Methods: Retrospective observational study, all patients with SpA were included, according to ASAS criteria, treated with anti-TNF, with dose tapering, from October 2014-December 2017. Clinical remission defined by BASDAI ≤ 2 and/or CRP ≤ 5 mg/L for at least 6 months, establishing dose tapering as lower doses or longer intervals (according to the guidelines of the Spanish Society of Rheumatology and Pharmacy). Those patients who relapsed (BASDAI >2 and/or CRP >5 mg/L) at any time during the study returned to the standard dose. Clinical and analytical parameters were collected (baseline and at the time of optimisation), as well as the survival of the drug and the efficacy parameters until the time of relapse and who continued in dose tapering.

Results: 149 patients with SpA in treatment with anti-TNF, 38/149 (25.5%) included in the dose tapering protocol, 84.4% men and the mean age 47.2 ± 10.6 years. The antecedents 25% uveitis, 6.3% psoriasis and 6.3% inflammatory bowel disease. Regarding the type of optimisation strategy, 32 patients (84.37%) followed the protocol for increasing the interval between doses, compared to the rest (15.62%) who used reduced doses. We found 27/38 patients (71.05%, CI: 55.2–83) maintained clinical remission with tapering, 9 (33.3%) infliximab, 7 (25.9%) golimumab, 6 (22.2%) etanercept and 5 (18.5%) adalimumab, at a time of drug follow-up of 57.9 ± 29.7 months. The demographic factors analysed sex, age, time of evolution and clinical remission, were not found as possible predictors of greater survival in the dose tapering.

	PATIENTS RELAPSE (n=11)			PATIENTS REMISSION (n=27)		
	Basal	Start tapering	Relapse	Basal	Start tapering	Last visit
BASDAI (0–10)	3.8 $\pm$ 2.4	2 $\pm$ 1.8	3.18 $\pm$ 2.27	4.4 $\pm$ 2.8	2.1 $\pm$ 2.5	1.5 $\pm$ 1.6
BASFI (0–10)	4.3 $\pm$ 2.8	2.8 $\pm$ 2.8	2.9 $\pm$ 2.37	3.7 $\pm$ 2.6	2.8 $\pm$ 3.1	2.0 $\pm$ 2.4
ESR (mm/1 st h)	17.1	9.3 $\pm$ 11.1	11.84	20.4	7.8 $\pm$ 6.1	8.4 $\pm$ 7.6
	$\pm$ 22.5		$\pm$ 11.29	$\pm$ 18.8		
CPR (mg/L)	10.9	9.7 $\pm$ 12.4	3.84 $\pm$ 4.54	14.6	3.7 $\pm$ 6.1	2.69 $\pm$ 3.0
	$\pm$ 12.2		$\pm$ 22.5			
n=38						
Age (years, mean $\pm$ SD)	47.2 $\pm$ 10.6					
Sex (%) Man/woman	84.4/15.6					
Time of evolution disease (years, mean $\pm$ SD)	12.2 $\pm$ 10.4					
Start biological therapy (months, mean $\pm$ SD)	22.84 $\pm$ 12.68					
	Start anti-TNF		Start tapering			
	4.2 $\pm$ 2.6		2.07 $\pm$ 1.96			
BASDAI (0–10)						
BASFI (0–10)	4 $\pm$ 2.7		2.8 $\pm$ 2.9			
CPR (mg/L)	13.1 $\pm$ 18.7		6.4 $\pm$ 9.7			
ESR (mm/1 st h)	19 $\pm$ 20.1		8.5 $\pm$ 8.5			

Conclusions: The monitoring of dose tapering of biological therapy in patients with SpA is possible and allows more than 70% of patients to maintain the clinical remission of the disease. However, a greater number of patients and longer follow-up are necessary for a solid conclusion. Additionally, our results do not show possible predictors of a longer survival in tapering protocol.

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