Results: Of the 651 and 327 pts randomized to receive UPA and ADA, 126 (19%) and 77 (24%), were considered NR and switched to ADA and UPA respectively. NR demographics were consistent with the overall randomized population. Of the switched pts, ~90% remained in the study through 6 mo ps. Patients switched to ADA (UPA-NR) achieved 59%/26%/12% improvements in ACR20/50/70 responses, and 35% achieved DAS28(CRP) ≤ 3.2 at 6 mos ps (**Table**). Patients switched to UPA (ADA-NR) achieved 75%/49%/24% improvements in ACR20/50/70, and 54% achieved DAS28(CRP) ≤ 3.2 at 6 mo- consistent with data observed in a phase 3 study of UPA in bDMARD-IR RA pts.⁴ The proportion (95% CI) of pts with infection and serious infection through 6 mos ps appeared consistent with those observed for ADA and UPA during comparable periods (ADA, switched from UPA: infection: 34.1 [26.43, 42.77], serious infection: 1.6 [0.44, 5.60]; UPA, switched from ADA: infection: 40.3 [30.02, 51.42], serious infection: 3.9 [1.33, 10.84]

Conclusion: Data from this blinded, controlled study indicate that pts with initial non-response to either UPA or ADA can benefit from switching to the other therapy. No additional safety concerns were observed. These are the first data to demonstrate effectiveness of a TNF inhibitor following failure of a JAK inhibitor.

REFERENCES:

- [1] Smolen, et al. *Ann Rheum Dis*, 2017;76:1113-36.
- [2] Singh, et al. *Arthritis Rheumatol*, 2016;68:1-26.
- [3] Fleischmann, et al. *Arthritis Rheumatol*, 2018;70(Suppl 10).
- [4] Genovese, et al. *Lancet*, 2018;391:2513-24.

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OP0030

RANDOMIZED CONTROLLED 24-WEEK TRIAL EVALUATING THE SAFETY AND EFFICACY OF BLINDED TAPERING VERSUS CONTINUATION OF LONG-TERM PREDNISONE (5 MG/D) IN PATIENTS WITH RHEUMATOID ARTHRITIS WHO ACHIEVED LOW DISEASE ACTIVITY OR REMISSION ON TOCILIZUMAB

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Background: Guidelines recommend low-dose, short-term glucocorticoid (GC) treatment for rheumatoid arthritis (RA).^{1,2} Long-term use, especially at prednisone-equivalent doses >5 mg/d, should be avoided,² but many patients (pts) with early established RA receive long-term GCs, often ≥ 5 mg/d.³

Objectives: Compare GC tapering vs continuation to maintain disease control in RA pts with chronic GC exposure receiving tocilizumab (TCZ) in a randomized controlled trial.

Methods: Before randomization pts had to receive TCZ $\pm$ conventional synthetic (cs)DMARDs and GC (prednisone-equivalent dose 5-15 mg/d) for ≥ 24 wks. At randomization pts had to be in at least low disease activity (LDA: DAS28-ESR ≤ 3.2) and receiving stable concomitant therapy (prednisone 5 mg/d [GC5mg]) and TCZ $\pm$ csDMARDs for ≥ 4 wks. Pts were randomized to continue blinded GC5mg for 24 wks or undergo blinded taper (GCTaper, from 4 mg/d with 1-mg reduction every 4 wks to 0 mg/d at wks 16-24) while receiving stable TCZ and csDMARD doses. Pts with RA flare (DAS28-ESR >3.2 and increase >0.6 vs baseline) received open-label rescue GC5mg for 2 wks and continued blinded treatment. Primary outcome was mean change in DAS28-ESR at wk 24. Key secondary outcome was treatment success—DAS28-ESR ≤ 3.2 at wk 24 and no RA flare during 24 wks and no adrenal insufficiency necessitating replacement therapy.

Results: 259 pts were randomized to GCTaper (n=131) or GC5mg (n=128); 114 and 112, respectively, completed 24 wks. Mean baseline DAS28-ESR was 1.9. Mean RA duration was 9.2 y. For the primary endpoint, the between-arm difference was 0.6 DAS28-ESR units (95% CI, 0.3, 0.9; $p<0.001$, ANCOVA) favoring GC5mg (Figure). Results were consistent for key subgroups (DAS28-ESR between-arm difference 0.5 [95% CI -0.1, 1.0] for TCZ monotherapy, 0.7 [0.4-1.0] for TCZ + csDMARDs, 0.6 [0.2-1.0] for baseline DAS28 <2 , and 0.6 [0.2-1.0] for baseline DAS28 ≥ 2). Most pts in both arms achieved treatment success (65% GCTaper vs 77% GC5mg; relative risk, 0.83 [0.71-0.97]; $p=0.021$, Cochran-Mantel-Haenszel test); 11% of GC5mg pts and 26% of GCTaper pts experienced RA flare. One GC5mg pt and no GCTaper pts discontinued blinded treatment due to insufficient flare control. Serious adverse events (no deaths) were reported for 5% of GC5mg vs 3% of GCTaper pts. No pts had symptomatic adrenal insufficiency.

Conclusion: Continued GC5mg provided better DAS28-ESR control than GC taper in RA pts in LDA or remission. The 0.6 DAS28-ESR unit between-arm difference should be interpreted in the context of approximately two-thirds of tapered pts experiencing treatment success and no tapered pts discontinuing due to lack of flare control. The taper schedule was safe regarding adrenal insufficiency. The results suggest that all pts achieving LDA or remission with TCZ and receiving long-term low-dose GC should be considered for GC tapering, ideally targeting discontinuation.

Figure. Primary Efficacy End Point: Change From Randomization to Week 24 in DAS28 ESR

REFERENCES:

- [1] Singh JA et al. *Arthritis Rheum*. 2016;68:1.
- [2] Smolen JS et al. *Ann Rheum Dis*. 2017;76:960.
- [3] Buttgerit F, Bijlsma JW. *Ann Rheum Dis*. 2017;76:1785.

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Spondyloarthritis on the move: Thrilling developments

OP0031

ARE THE MODIFIED NEW YORK AND ASAS AXIAL SPONDYLOARTHRITIS CRITERIA INTERCHANGEABLE IN THE CLASSIFICATION OF SPONDYLOARTHRITIS PATIENTS WITH RADIOGRAPHIC SACROILIITIS: COMPARISON IN 8 COHORTS?

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Background: Axial spondyloarthritis (axSpA) patients with radiographic sacroiliitis may be classified using the modified New York (mNY) criteria and the more recent ASAS criteria. In the mNY criteria these patients are referred to as ankylosing spondylitis (AS) patients and in the ASAS criteria as radiographic axSpA (r-axSpA) patients. In both the mNY and the ASAS r-axSpA classification sets the radiographic criterion is the same but the additionally required features differ (figure), for example patients with age at onset of back pain ≥ 45 cannot fulfil the ASAS criteria. This raises the question whether the two sets can be used interchangeably in the classification of axSpA patients with radiographic sacroiliitis.

Modified New York criteria for the classification of AS	ASAS criteria for the classification of radiographic axSpA
1. Low back pain and stiffness for at least 3 months, which improves with exercise and is not relieved by rest	1. Back pain 3 months
2. Limitation of lumbar spine motion in the sagittal and frontal planes	2. Age at onset ≥ 45 years
3. Decreased chest expansion, compared to age- and sex-matched controls	3. Sacroiliitis on imaging*
4a. Unilateral sacroiliitis grade 2 or 4	4. 2/3 SpA feature:
4b. Bilateral sacroiliitis grade 2 or 4	- Inflammatory back pain
	- Arthritis
	- Enthesitis
	- Uveitis
	- Dactylitis
	- Psoriasis
	- Crohn's/colitis
	- Good response to NSAIDs
	- Family history for SpA
	- HLA-B27 positive
	- Elevated CRP (or ESR)
Definite AS if sacroiliitis as described in 4a or 4b and any of the clinical symptoms (1-3).	*Definite radiographic sacroiliitis according to mNY criteria
	Definite r-axSpA if fulfilment of 1 and 2, sacroiliitis as described in 3 and at least one of the clinical SpA features as described in 4.

Figure 1. mNY and ASAS r-axSpA criteria for the classification of patients with axSpA and radiographic sacroiliitis.

Objectives: To investigate to what degree patients with axSpA and radiographic sacroiliitis who fulfil the mNY criteria also fulfil the ASAS criteria for r-axSpA and vice-versa.

Methods: Patients diagnosed with axSpA who had back pain longer than 3 months and definite radiographic sacroiliitis (i.e. common and mandatory features for both classification criteria sets (figure)) were selected from several cohorts (ASAS, Esperanza, GESPIC, OASIS, Reuma.pt, SCQM, SPACE, and UCSF). Subsequently we calculated how many patients fulfil the mNY criteria and/or the ASAS r-axSpA criteria. For the Esperanza and OASIS cohorts specific information on the individual items of the mNY criteria was unavailable, which restricted data analysis for these cohorts.

Results: Of the 3882 patients fulfilling the mNY criteria, 93% also fulfilled the ASAS r-axSpA criteria. Inversely, of the 3434 patients fulfilling the ASAS r-axSpA criteria, 96% also fulfilled the mNY criteria (table). In total, 89% (3607/4041) of patients with axSpA and radiographic sacroiliitis fulfilled both criteria sets; 7% only the mNY criteria; 3% only the ASAS criteria and 1% neither set.

Table 1. Percentage of patients fulfilling ASAS r-axSpA within subgroup fulfilling mNY criteria and vice-versa (per cohort and overall)

	ASAS within mNY subgroup	mNY within ASAS subgroup
ASAS	93% (3882/4182)	90% (3882/4302)
Esperanza	97% (106/109)	NA
GESPIC	95% (78/89)	93% (78/84)
OASIS	95% (202/211)	NA
Reuma.pt	93% (1156/1249)	95% (1156/1211)
SCQM	93% (1612/1768)	95% (1612/1693)
SPACE	100% (77/77)	84% (77/92)
UCSF	95% (129/288)	95% (129/288)
Total	93% (3607/3882)	96% (3300/3434)

The main difference between the two criteria sets was caused by reported age at onset of back pain. Out of 275 mNY+ patients not fulfilling the ASAS criteria (7% of all included patients), 265 (96%) cases were due to the age criterion and 10 (4%) due to the absence of SpA features. Of the 3434 ASAS+ patients, 90% fulfilled the mNY criteria because they had IBP, another 6% despite not having IBP fulfilled the mNY criteria due to a mobility restriction; and the remainder 4% had neither but fulfilled the ASAS criteria because of other SpA features.

Conclusion: AxSpA patients classified as AS according to mNY criteria and those classified as r-axSpA according to ASAS criteria are mostly the same: 93% of mNY positive patients also fulfil the ASAS r-axSpA criteria while 96% of ASAS r-axSpA positive patients also fulfil the mNY criteria. These findings support the interchangeable use of the terms r-axSpA and AS, which was also approved by a vote of ASAS members at the 2019 annual workshop in Amsterdam.

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OP0032

LOCALIZATION AND MORPHOLOGY OF MAGNETIC RESONANCE IMAGING FEATURES OF PATHOLOGIC CHANGES IN THE SACROILIAC JOINTS SUGGESTIVE OF AXIAL SPONDYLOARTHRITIS – A SYSTEMATIC COMPARISON OF PATIENTS AND CONTROLS WITH CHRONIC BACK PAIN

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Background: Bone marrow edema (BME), fat metaplasia (FL) and erosions have been identified as relevant for magnetic resonance imaging (MRI) changes in the sacroiliac joints (SIJ) of patients with axial spondyloarthritis (axSpA). However, a high prevalence of MRI changes has recently also been reported in subjects with no evidence of axSpA (1,2).

Objectives: To map the MRI lesions suspicious of axSpA in patients diagnosed with axSpA and compare them to those in patients with chronic back pain (cBP, non-SpA).

Methods: Consecutive patients with cBP < 45 years were included if they had at least one pathologic lesion of any type in the SIJ-MRI performed at the time point of cBP symptoms. AxSpA patients diagnosed by 2 experienced rheumatologists in consensus also had to fulfil ASAS classification criteria. Two experienced readers, blinded for diagnosis and patient's demographics, evaluated all MRIs independently. Lesions were only counted as positive if both readers were in agreement and mean values of both readers were calculated for the final analysis. Both the coronal (assessing the upper and lower sacral and iliac SIJ part) and axial (assessing the ventral, middle and retroauricular as well as the upper and lower sacral and iliac SIJ part) MRI orientations were analyzed for the localization of BME, FL, sclerosis and erosions. In addition, length and width were digitally measured for BME, FL and sclerosis, and signal intensity was measured electronically in each individual patient in comparison to the cerebrospinal fluid signal for BME and the subcutaneous fat for FL (no units).

Comparisons were calculated by Mann-Whitney-U-test for patients classified as positive by both readers for the respective lesions.

Results: A total of 200 consecutive patients (100 axSpA, 100 non-SpA), mean age 36.1 $\pm$ 11.3 and 40.3 $\pm$ 11.0 years, respectively, were analyzed. BME was found in 85% vs. 80% of patients, while 80% vs. 69% had FL, 54% vs. 40% had sclerosis and 64% vs. 12% had erosions, respectively. The largest surface area covered by BME in axSpA vs. non-SpA was found in the lower and dorsal SIJ: 60 $\pm$ 10.1 mm³ in the iliac and 47.3 $\pm$ 9.4 mm³ in the sacral part vs. the upper and ventral SIJ: 18.7 $\pm$ 3.4 mm³ in the sacral and 5.2 $\pm$ 0.1 mm³ in the iliac part.

Patients with axSpA showed a larger surface area covered by FL was found in the upper and anterior sacral SIJ (305.5 $\pm$ 56.3 mm³), whereas patients with non-SpA showed larger FL areas in the lower and posterior sacral SIJ (197.9 $\pm$ 1.2 mm³). Regarding sclerosis, the upper and anterior iliac part had more surface involvement in both SpA (139.3 $\pm$ 11.6 mm³) and non-SpA (81.8 $\pm$ 2.8 mm³) patients.