Figure 1. Drug survival of initial TNFi in axSpA patients (p=0.56).

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THU0379

REDUCTION OF ANTERIOR UVEITIS FLARES IN PATIENTS WITH AXIAL SPONDYLOARTHRITIS FOLLOWING ONE YEAR OF TREATMENT WITH CERTOLIZUMAB PEGOL: 48-WEEK INTERIM RESULTS FROM A 96-WEEK OPEN-LABEL STUDY

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Background: Acute anterior uveitis (AAU), inflammation of the anterior uveal tract, is reported in up to 40% of patients (pts) with axial spondyloarthritis (axSpA).¹ AAU is associated with significant clinical burden; symptoms include blurred vision, photophobia and pain.² Previous studies have shown that TNF inhibitors (TNFi) can reduce AAU flare incidence in pts with radiographic axSpA,³⁻⁵ but few have focused on pts across the full axSpA spectrum.

Objectives: To analyse the impact of certolizumab pegol (CZP) treatment on AAU in pts with active radiographic and non-radiographic axSpA and a recent history of AAU.

Methods: C-VIEW (NCT03020992) is an ongoing multicentre, open-label, phase 4 study. Pts had active axSpA according to the ASAS classification, a history of recurrent AAU (≥ 2 AAU flares in total and ≥ 1 AAU flare in the year prior to study entry), were HLA-B27 positive, and were eligible for TNFi treatment (previous failure of ≥ 2 NSAIDs, biologic naïve or had failed ≤ 1 TNFi). Pts received CZP 400mg at Weeks (Wks) 0/2/4, then 200mg every two wks (Q2W) to Wk 96. The primary variable was incidence of AAU flares compared to historic rates. A pre-specified interim analysis compared AAU incidence in the 48 wks prior to CZP treatment with the 48 wks of treatment, using Poisson regression adjusted for possible within-pt correlations, with period (pre- and post-baseline) and axSpA disease duration as covariates. Incidence rates (IR) were calculated based on the number of cases/pts at risk over 48 wks. Observed data are reported.

Results: Of 115 enrolled pts, 89 initiated CZP treatment; 85 completed Wk 48. Baseline characteristics are shown in the Table. The 48-wk interim analysis revealed significantly fewer AAU flares/pt during CZP treatment vs before treatment (Figure; Poisson-adjusted IR: 0.2 vs 1.5, $p < 0.001$). The number of pts experiencing 1 and ≥ 2 AAU flares (64.0% and 31.5% respectively) substantially reduced during CZP treatment (12.4% and 2.2%). After 48 wks CZP treatment, disease activity improved substantially (mean $\pm$ SD Ankylosing Spondylitis Disease Activity Score [ASDAS]: 2.0 ± 0.9 ; Bath Ankylosing Spondylitis Disease Activity Index [BASDAI]: 3.3 ± 2.1), with 31.4% pts achieving ASAS partial remission and 29.1% ASDAS major improvement. No new safety signals were identified.

Table. Baseline characteristics

CZP 200 mg Q2W (N=89)	
Age (years), mean $\pm$ SD	46.5 $\pm$ 11.2
Male, n (%)	56 (62.9)
Racial group, n (%)	
Caucasian	87 (97.8)
Other	2 (2.2)
Diagnosis, n (%)	
Radiographic axSpA	76 (85.4)
Non-radiographic axSpA	13 (14.6)
Duration of axSpA (years), mean $\pm$ SD	8.6 $\pm$ 8.4
Time since onset of first uveitis flare (years), mean $\pm$ SD	9.9 $\pm$ 9.0
ASDAS, mean $\pm$ SD	3.5 $\pm$ 0.9
BASDAI, mean $\pm$ SD	6.5 $\pm$ 1.5

Conclusion: In this open-label study, AAU flare rate significantly reduced in axSpA pts with a history of recurrent AAU during the first 48 wks of CZP. Pts also experienced substantial improvements in axSpA disease activity.

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Figure: (A) Mean number of acute anterior uveitis flares experienced by patients in C-VIEW and (B) proportion of patients experiencing 1, 2 or ≥ 3 acute anterior uveitis flares

AAU: acute anterior uveitis; CZP: certolizumab pegol; Q2W: every 2 weeks; SD: standard deviation.

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THU0380

SECUKINUMAB IS FREQUENTLY PREFERRED IN MULTI ANTI-TNF RESISTANCE SPONDYLOARTHRITIS PATIENTS: HUR-BIO REAL LIFE RESULTS

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Background: Anti-TNF agents have been used for the last two decades. However, targeting interleukin-17 (secukinumab (SEC)) is a relatively novel treatment

option for spondyloarthritis (SpA). Therefore, SEC is frequently preferred after multi anti-TNF agents, in real life.

Objectives: The objective of this study was to assess the retention rate and response of SEC in anti-TNF naïve and anti-TNF resistance patients in real life experience.

Figure. Secukinumab survival in anti-TNF naïve, one anti-TNF failure and ≥ 2 anti-TNF failure patients

Methods: HUR-BIO is a monocentric database of biologics including 2886 SpA patients, since 2005. SEC is approved at May 2018 in Turkey and 147 patients have used SEC by January 2020. Demographic and clinical data were obtained from HUR-BIO registry. SpA patients were classified as ankylosing spondylitis (AS) and non-radiographic SpA (nrAxSpA). Response and retention rate of SEC were determined regarding to anti-TNF naïve vs anti-TNF resistance patients. Kaplan-Meier analysis was used to estimate SEC retention rates.

Results: In total, 147 axial SpA patients (96 (65.3%) AS and 51 (34.7%) nrAxSpA) were analyzed. Overall, 23/147 (15.7%) patients were anti-TNF naïve, 27 (18.4%) patients were 1 anti-TNF failure and 97 (65.9%) patients were ≥ 2 anti-TNF failure. Baseline characteristics of patients and the main causes of discontinuation of anti-TNF agents were shown in table. Median duration of SEC usage was 7.9 (min-max, 3.0-19.8) months in AS and 6.7 (min-max, 3.0-19.8) months in nrAxSpA group ($p=0.365$). SEC survival at 12 months was similar between AS and nrAxSpA patients (56% vs 52%, $p=0.315$) (not shown). SEC survival was similar among anti-TNF naïve, one anti-TNF failure and ≥ 2 anti-TNF failure patients (Figure). BASDAI 50 response was reached in 61.5% of anti-TNF naïve, 42.1% of one anti-TNF failure and 43.2% of ≥ 2 anti-TNF failure patients at the last control ($p=0.452$). Patients who used ≤ 1 anti-TNF agent had a higher drug survival rate (%69 vs %46, $p=0.027$) at 1 year, in comparison with patients who used > 1 anti-TNF agents before SEC (not shown).

Table. Baseline characteristics of patients and the main causes of discontinuation of anti-TNF agents

	Anti-TNF naïve, n=23	One anti-TNF failure, n=27	≥ 2 anti-TNF failure, n=97	p
Age, years, mean $\pm$ SD	46.0 $\pm$ 11.2	42.4 $\pm$ 8.4	44.3 $\pm$ 9.9	0.611
Female, n (%)	7 (30.4)	15 (55.6)	61 (62.9)	0.019
Disease duration, months, median (min-max)	72 (12-408)	102 (12-300)	120 (12-396)	0.054
Disease duration ≥ 5 years, n (%)	12 (52.2)	18 (66.7)	72 (74.2)	0.112
Secukinumab indications				<0.0001
-Anti-TNF inefficacy, n (%)	-	9 (33.4)	80 (82.5)	
-Anti-TNF adverse event, n (%)	-	10 (37.0)	16 (16.5)	
-Others, n (%)	-	8 (29.6)	1 (1.0)	
History of smoking, n (%)	14 (60.9)	17 (63.0)	54 (55.7)	0.754
History of uveitis, n (%)	5 (21.7)	7 (25.9)	10 (10.3)	0.081
Baseline BASDAI	54 (10-96)	54.5 (0-88)	60 (0-100)	0.307
Baseline BASFI	53 (10-78)	38 (0-94)	55 (0-100)	0.142
Baseline back pain VAS	55 (0-100)	50 (0-100)	70 (0-100)	0.113
ESR, mm/h, median (min-max)	21 (2-120)	24.5 (2-107)	20 (2-84)	0.621
CRP, mg/dL, median (min-max)	0.7 (0.1-8.4)	1.3 (0.1-10.4)	0.7 (0.1-30.8)	0.439
Syndesmophytes on X-ray, n (%)	8 (66.7)*	8 (47.1)	16 (22.9)*	0.019

* $p=0.007$

Conclusion: For SpA, SEC is a relatively new player in biological era. When SEC launched for new treatment option, it is preferred mostly (almost 2/3) in multi anti-TNF resistance patients. Moreover, those difficult patients' (usually female) treatment response and retention rate were not satisfactory than biological naïve patients.

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THU0381

MANAGEMENT OF CARDIOVASCULAR COMORBIDITY IN PSORIATIC ARTHRITIS IN THE ROUTINE CLINICAL PRACTICE: A COMPARATIVE STUDY OF METHOTREXATE OR APREMILAST AS MONOTHERAPY AND COMBINED

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Background: The presence of cardiovascular disease in psoriatic arthritis (PsA) is of particular concern, as it is considered the leading cause of mortality in PsA. Thus, it is essential to recognize those appropriate therapies that could target this comorbidity, reducing the risk of cardiovascular disease and metabolic alterations.

Objectives: To evaluate the efficacy of methotrexate (MTX) and apremilast as monotherapies or in combination, in the clinical manifestations of the disease and the reduction of cardiovascular risk factors in PsA.

Methods: Prospective longitudinal study in 30 PsA patients diagnosed according to CASPAR criteria: 10 patients were treated with MTX (12 $\pm$ 2.58 mg/week), 10 patients with apremilast (60 mg/day) and 10 were treated with combined therapy for 6 months, recruited in the routine clinical practice at the Reina Sofia Hospital of Cordoba and University Hospital of Jaen, Spain. Clinical and analytical parameters were collected at baseline and after 6 months of treatment: lipid profile (cholesterol, HDL, LDL, TG, ApoA and ApoB), glucose and insulin, body surface area (BSA) affected by psoriasis, number of tender and swollen joints, DAS28, DAPSA, VAS, CRP and ESR.

The presence of cardiometabolic risk factors such as metabolic syndrome (MetSyn) was evaluated according to National Cholesterol Education Program (NCEP) adult treatment panel III (ATP III) criteria, meeting 3 of the following characteristics: abdominal obesity (men (>102 cm); women (>88 cm), TG > 150 mg/dL, HDL (men (<40 mg/dL); women (<50 mg/dL), blood pressure $> 130/85$ mmHg, glucose levels > 110 mg/dL). Insulin resistance (HOMA-IR > 2.5), body mass index (BMI), ApoB/ApoA ratio, atherogenic index (AI) and SCORE (age, gender, cholesterol, HDL, smoking habit and diabetes) were also studied.

Results: Apremilast or MTX monotherapies caused a moderate reduction of the clinical inflammatory markers (CRP and ESR) and disease activity (VAS, DAPSA and DAS28) after 6 months of treatment. On the other hand, while apremilast significantly reduced the affected BSA, MTX had no significant effect. All those parameters were more significantly reduced after the combined treatment (MTX+apremilast).

Apremilast monotherapy significantly improved alterations in the lipid profile (reducing cholesterol and LDL levels, ApoB/ApoA ratio and AI), insulin resistance and decreased BMI, thus reducing the number of patients with MetSyn. MTX monotherapy treatment had no positive effect on these parameters. None of the treatments had significant effects on SCORE values.

The beneficial effects of apremilast on the lipid profile were mitigated after the combination with MTX. Nevertheless, the number of patients with MetSyn decreased even more after the combined therapy of MTX with apremilast compared to apremilast monotherapy.

Conclusion: 1) In patients with moderate disease activity, treatment with apremilast monotherapy might have some advantages compared to the MTX monotherapy, since it can decrease the percentage of BSA with psoriasis, the lipid profile alteration, IR and weight, thus improving the cardiovascular risk profile. 2) Combined therapy (MTX+ apremilast) can induce a deeper reduction in the disease activity compared to the monotherapies, maintaining, in turn, the positive effects of apremilast on the cardiovascular risk.

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