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FRI0411

COMPARABLE CLINICAL RESPONSES BUT HIGHER TREATMENT ADHERENCE OF SECUKINUMAB COMPARED TO TNF INHIBITORS IN SPONDYLOARTHRITIS PATIENTS: LONG TERM PROSPECTIVE OBSERVATIONAL STUDY IN A TERTIARY HOSPITAL OF GREECE

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Background: Data regarding effectiveness and persistence to therapy with anti-IL17 agent secukinumab (SEC) in spondyloarthritis (SpA) patients of real world clinical practice are very limited.

Objectives: To assess characteristics of SpA patients starting therapy with SEC versus tumor necrosis factor inhibitors (TNFis) in routine clinical care and compare clinical responses and treatment retention at 2 years.

Methods: All patients starting a bDMARD in the Rheumatology Department of the University Hospital of Heraklion, Crete, are included in a prospective observational study after their written informed consent. Data concerning disease activity at pre-specified time-points, drugs, comorbidities and any adverse events are recorded. For the present study we analyzed all consecutive patients with axial (AxSpA) or peripheral SpA (pSpA) starting or switching bDMARD therapy, either a TNFi or SEC from 1/2015 till 12/2018. We excluded patients with IBD-related SpA, patients starting ustekinumab (or apremilast) and patients switching from a bio-originator to a biosimilar TNFi. We compared disease activity scores improvement at 6 months using linear regression analysis and treatment retention using Kaplan-Meier survival curves with log-rank test and Cox regression. Inverse propensity score weighting (IPW) was used to adjust for the potential confounding of gender, age, disease duration, previous bDMARDs and csDMARDs number, diagnosis (AxSpA vs pSpA), presence of peripheral arthritis and co-therapy with csDMARDs.

Results: A total of 239 patients with SpA started/switched bDMARD (SEC:69, TNFis:170). SEC was the $\geq 3^{\text{rd}}$ bDMARD in 63% of patients compared to 17% of TNFis ($p<0.001$). Patients' characteristics at baseline were comparable except for disease duration (median (IQR): 5 (1.5-11) years in SEC vs. 0.9 (0.2-4.6) in TNFis, $p<0.001$). AxSpA was the diagnosis in 78% patients starting SEC and 79% starting TNFis while peripheral arthritis was slightly more common with SEC (81% vs 76% in TNFis). Monotherapy tended to be more common with SEC compared to TNFis (52% vs 42%, $p=0.16$). Baseline disease activity regarding both axial and peripheral arthritis was comparable in the two groups. Unadjusted 2-year treatment retention was similar in the two groups, both overall (SEC: 63%, TNFi: 56%, $p=0.18$) and due to failure or adverse events. However, when we selected only patients on 1st or 2nd bDMARD (SEC:26, TNFis:131), 2-year survival of SEC was higher than that of TNFis (95% vs. 57%, $p=0.027$). Similarly, SEC tended to have higher survival than TNFis in patients with pSpA ($p=0.11$). After IPW, SEC administration was an independent predictor for higher bDMARD retention overall [HR (95%CI)=0.48(0.33-0.69), $p<0.001$] and specifically due to dis-

continuation for failure [HR=0.58 (0.38-0.88), $p=0.011$] and for adverse events [HR=0.21 (0.08-0.62), $p=0.004$].

Mean BASDAI and ASDAS improvements at 6 months were similar in patients with AxSpA receiving SEC or TNFis [Mean(SD) δ BASDAI: 1.6 (2.5) vs 1.4(2.5) respectively ($p=0.78$) and δ ASDAS: 0.7 (1.4) vs 1.0 (1.5), $p=0.44$]. Similarly, in patients with peripheral arthritis, δ DAS28 at 6 months was comparable in the two groups ($p=0.88$). Adjusted linear regression with IPW provided similar results to the unadjusted analyses in both axial and peripheral disease.

Conclusion: In SpA patients of real-world, administration of SEC results in similar clinical responses but higher treatment adherence compared to TNFis, especially if Secukinumab is the 1st or 2nd bDMARD. Larger number of patients and longer follow-up is needed to confirm these data.

Disclosure of Interests: None declared

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FRI0412

SPINAL AND SACROILIAC JOINTS INFLAMMATION IN PATIENTS WITH RADIOGRAPHIC AXIAL SPONDYLOARTHRITIS TREATED WITH NETAKIMAB – 16-WEEKS RESULTS OF MULTICENTER, RANDOMIZED, DOUBLE-BLIND, PLACEBO-CONTROLLED PHASE III ASTERA STUDY

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Background: Efficacy and safety of netakimab (NTK), a humanized anti-interleukin 17A antibody, have been previously established in two phase 2 clinical trials in patients with radiographic axial spondyloarthritis (r-axSpA)¹ and psoriasis². ASTERA is a randomized, double-blind, placebo (PBO)-controlled phase III trial, aimed to demonstrate efficacy and safety of NTK in subjects with r-axSpA (NCT03447704).

Objectives: To evaluate the effect of NTK on inflammation in spine and sacroiliac joints (SIJ) at Week (Wk) 16 in ongoing ASTERA study in patients with active r-axSpA.

Methods: 228 eligible adults with active r-axSpA were randomized into 2 study arms (1:1) to receive 120 mg of NTK or PBO, administered as SC injections at Wk 0, 1, 2 and then q2wk through Wk 16. After Wk 16 all patients will start to receive NTK up to week 52. Inflammation in spine and SIJ was assessed with magnetic resonance imaging (MRI) at baseline and Wk 16. The following scoring methods were used: the Berlin spine score (derived from Ankylosing Spondylitis Spine MRI Activity (ASspi-MRI-a) Score for spine assessment and the SPARCC score for SIJ assessment. All images were evaluated by central reader, blinded to treatment.

Results: Both arms were comparable in the Berlin spine score (4.18 ± 4.58 in NTK arm vs. 4.19 ± 4.32 in PBO arm) and the SPARCC score (5.67 ± 8.33 in NTK arm vs. 5.23 ± 7.86 in PBO arm) at baseline ($p \geq 0.05$). Data analysis at Wk16 revealed that NTK arm achieved significant decline in bone marrow edema in direct comparison with PBO arm: by Wk 16 the mean change from baseline in the Berlin spine score was -2.16 ± 2.87 in NTK arm vs. -0.30 ± 1.55 in PBO arm ($p<0.0001$) and the mean change from baseline in the SPARCC score was -3.80 ± 6.68 in NTK arm vs. -1.82 ± 4.12 in PBO arm ($p<0.01$).

Conclusion: the treatment with NTK at a dose 120 mg leads to improvement in spine and SIJ inflammation in patients with active r-axSpA by Wk16, as compared with PBO.

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