POSTER perspectives

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Ustekinumab Is Superior to TNF Inhibitor Treatment in Resolving Enthesitis in Psa Patients with Active Enthesitis-Results from the Enthesial Clearance in Psoriatic Arthritis Study

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Background/Purpose: IL-23 is considered to play an important role in the development of enthesitis. Ustekinumab (UST), a combined inhibitor of IL-12/IL-23 shows effcacy in psoriatic arthritis (PsA), while it has no therapeutic role in diseases driven by synovitis only such as rheumatoid arthritis. We therefore speculated that inhibition of IL-23 is particularly effective in enthesitis-driven PsA patients. To compare the efficacy of UST with tumor necrosis factor inhibitor (TNFi) treatment in clearing enthesitis in PsA patients.

Methods: ECLIPSA is a prospective, observational, open study. Patients with PsA with active enthesitis (at least one painful enthesis on SPARCC or MASES sites), were consecutively enrolled 1:1, receiving either standard doses of UST (arm 1) or TNFi (arm 2). At baseline the following parameters were assessed: age, gender, BMI, disease duration, previous DMARDs, use of corticosteroids, use of non-steroidal anti-inflammatories (NSAIDs), swollen and tender joint count, VAS-pain, VAS-global, NAPSI, PASI, MASES, SPARCC, LDI, BASDAI, BASFI, HAQ-DI, SF-36, FACIT-F, ESR and CRP. Primary endpoint was a SPARCC of 0 after 6 months. Patients were seen every 3 months and followed for a total of 6 months. In order to investigate the effects of study treatment over time we used 2×3 mixed design ANOVA models for both physician's and patient's reported outcomes. Furthermore, exploratory logistic regression was used to predict a SPARCC of 0 at month 6 from baseline PASI, tender joint count, swollen joint count, and FACIT while additionally accounting for age, gender, PsA duration and study treatment.

Results: 51 patients (UST=25; TNFi= 26) were screened and 47 patients (UST=23; TNFi= 24) were enrolled with 4 patients not presenting with active enthesitis at baseline. Mean ± SD age was 59.11 ± 12.16 years and mean ± SD disease duration was 6.4 ± 7.79 years. Mean± SD SPARCC at baseline was 4.9±2.7 in the UST group and 3.8±2.5 in the TNFi group. Other baseline characteristics were similar between both groups with exception of gender and mental component of the SF-36. In regards to the effect of study treatment (TNFi vs. UST) and time, the corresponding ANOVAs suggested an important interaction of both factors for measures of enthesitis (MASES and SPARCC), patient-reported disease activity (HAQ-DI), and skin activity (PASI), all $p \leq 0.03$ with superiority of UST. After 6 months, 17 out of 24 UST patients (70.8%) and 10 out of 26 TNFi patients (38.4%) reached the primary endpoint defined as clearence of enthesitis (SPARCC=0). Logistic regression predicting enthesitis-free state of disease according to SPARCC was significantly related to study treatment, with patients receiving UST being more likely to show no signs of enthesitis at month 6 (OR=0.034; p=0.005). Higher FACIT scores at baseline were also predictive of an enthesitis free-state (OR=0.864; p=0.024).

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Conclusion: These results show that UST is superior to TNFi in resolving the enthesitis component of disease in a population of PsA patients characterized by active enthesial disease. Based on these data more stratified treatment approaches can be designed in PsA patients, where enthesitis-driven patients are targeted by IL-23/IL-17 pathway inhibitors.

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