POS0930

SECUKINUMAB IN PATIENTS WITH PSORIATIC ARTHRITIS AND AXIAL MANIFESTATIONS: PREDICTORS OF RESPONSE FROM THE DOUBLE-BLIND, RANDOMISED, PHASE 3B MAXIMISE TRIAL

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Background: Psoriatic arthritis (PsA) is a heterogeneous disease with variability of response to different therapeutic modalities.¹ Identifying potential demographic and disease characteristics as predictors of treatment response may define personalised treatment optimisation strategies.²⁻³

Objectives: This post-hoc exploratory analysis of the MAXIMISE trial⁴ investigated the differential treatment effect of demographics and baseline characteristics as predictive factors in biologic naïve patients with active PsA and symptoms of active spinal disease.

Methods: The full analysis set (FAS) comprised of all patients from the randomised set assigned to study treatment, fulfilling the predefined clinical criteria for active axial disease and for whom Assessment of SpondyloArthritis International Society (ASAS) 20 data were available at Week 12. The research hypothesis was that the odds ratio associated with the effect of treatment on ASAS20 responder status at Week 12 would be different depending on 12 pre-specified predictor variables. A logistic regression model was initially fitted to the FAS that included 12 pre-specified covariates. A second logistic regression model was then fitted to the FAS that allowed for all 12 pre-specified variables to interact with treatment.⁵ The log-likelihood of the two fitted models were compared using a likelihood ratio test at a pre-specified significance level of 20% (i.e. P -value ≤ 0.20) to test whether any of the predefined variables interacted with treatment. If the above test was statistically significant at the 20% level of statistical significance the variables of the second model were formally examined to determine whether the overall effect of treatment is not applicable. Three forest plots were produced, one for each treatment group. Hypothesis tests were employed to determine the strength of evidence for each individual variable.

Results: The likelihood ratio test provided evidence against the assumption that the overall effect of treatment is applicable to all patients (P -value = 0.08). Notably, the odds of being an ASAS20 responder if nail dystrophy is present at baseline were 3 times greater in the secukinumab 150mg group and 5 times greater in the 300mg group compared with placebo (interaction P -value = 0.029). Although males fare worse than females in the placebo group, in the secukinumab 150mg and 300mg treatment groups the odds of being a responder were similar to females (interaction P -value = 0.039). Current smokers were less likely to be ASAS20 responders compared to never smokers regardless of treatment group (interaction P -value = 0.589) (Figure 1). Age, CRP level, Berlin MRI spine/SIJ score, time since first axial signs, number of swollen joints, new bone formation and BMI did not show a differential treatment effect on ASAS20 responses.

Conclusion: Of the 12 baseline variables of a unique population of 473 PsA patients with active axial disease diagnosed by clinical criteria, our analyses showed evidence of a differential treatment effect most notably for nail dystrophy suggesting that the presence of nail dystrophy may predict a better response to secukinumab in PsA patients with axial manifestations.

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Figure 1. Forest plots of the adjusted odds ratio by treatment using interaction model. Disclosure of Interests:

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POS0931

RETENTION RATE AND TREATMENT RESPONSE OF BIOLOGICAL AGENTS IN ADVANCED SPINAL ANKYLOSIS AND BAMBOO SPINE: THE REAL LIFE DATA FROM THE HUR-BIO REGISTRY

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Background: Axial spondyloarthritis (axSpA) may lead to linear radiographic progression and progress to advanced spinal disease and finally to the bamboo spine (1).

Objectives: To assess the demographic, clinical, disease activity and retention rates of patients using biological disease-modifying antirheumatic drugs (bDMARD) with advanced spinal disease and bamboo spine in the Hacettepe University Rheumatology Biologic Registry (HUR-BIO) cohort.

Methods: In the HUR-BIO spondyloarthritis (SpA) registry were available 2952 patients. Of these, 774 patients with lumbar and cervical radiographs were included in the study. Advanced spinal ankylosis (99 patients) was defined as the presence of at least two intervertebral adjacent bridges at the lumbar and/or cervical spine level without bamboo spine. Bamboo spine (78 patients) was defined with a complete fusion of all lumbar and cervical spines. In addition, patients who diagnosed with axSpA for at least 10 years but no develop syndesmophytes on lumbar and cervical spine (92 patients) were used as a control group.

Results: Both the bamboo spine and advanced spinal disease had higher age, higher BMI, more smoking (ever) and hip involvement compared to the without syndesmophytes group. Acute phase reactants, Bath Ankylosing Spondylitis Disease Activity Index (BASDAI), Bath Ankylosing Spondylitis Functional Index (BASFI), Ankylosing spondylitis disease activity Score-CRP (ASDAS-CRP) parameters were similar at the beginning of bDMARD in all groups. BASFI was higher in the bamboo spine group than in the without syndesmophytes group at last visit (Table 1). There were no differences between all groups in terms of the retention rate of the first bDMARD (Log rank $p=0.86$) (Figure 1).

Conclusion: Data on the use of bDMARDs in SpA patients with bamboo spine are limited. This study showed that bDMARDs are an effective treatment option in SpA patients with bamboo spine with high disease activity. Similar drug retention rates were found compared to SpA patients with no syndesmophytes. Although the disease activity decreased similar rates in the groups, functional limitation continued in approximately half of the patients in bamboo spine patients.

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