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SAT0161

SUSTAINED MODERATE DISEASE ACTIVITY (sMDA) IN RHEUMATOID ARTHRITIS PATIENTS ON BIOLOGIC THERAPIES IS ASSOCIATED WITH 5 YEARS FUNCTIONAL LIMITATION AND SERIOUS ADVERSE EVENTS DEVELOPMENT; EVIDENCE TO SUPPORT TREAT-TO-TARGET APPROACH FOR PATIENTS IN sMDA AND ESPECIALLY THOSE IN HIGH sMDA

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Background: Registry data have shown that treatment with biologic disease modifying antirheumatic drugs (bDMARDs) induces remission or low disease activity in up to 50% of Rheumatoid Arthritis (RA) patients, yet 30-50% of patients remain in moderate disease activity (MDA) with limited data on their long-term prognosis¹.

Objectives: To assess the long-term outcome of RA patients with sustained MDA on bDMARDs, in clinical practice.

Methods: We analyzed data from the Hellenic Registry of Biologic Therapies. Disease activity, function, treatments of patients starting a bDMARD are recorded prospectively every 3-6 months. Herein, we included patients with at least 5 years of follow-up, irrespective of treatment switches. If DAS28-ESR was at the same disease activity range for at least 50% of the follow-up time, patients were assigned to one of 3 main groups: sustained remission or low disease activity (sRLDA) with DAS $\leq$ 3.2, sustained moderate disease activity (sMDA) with 3.2<DAS $\leq$ 5.1 and sustained high disease activity (sHDA) with DAS>5.1. Patients in sMDA were further divided into subgroups *low* and *high* sMDA (50% of follow-up has DAS lower or greater than 4.2 respectively). Function at 5 years based on Health Assessment Questionnaire (HAQ) was the primary outcome, while cumulative serious adverse events (SAEs) and bDMARDs switches were also analyzed.

Results: Out of 527 patients with available data, 90 (17%), 295 (56%) and 142 (27%) were assigned to sRLDA, sMDA and sHDA groups respectively. At baseline, sMDA patients were older, more often women, had received more csDMARDs and had higher DAS, HAQ and EuroQol status compared to sRLDA group. During follow-up, sMDA patients had more bDMARDs switches as compared to sRLDA (mean $\pm$ sd: 1.82 $\pm$ 1.03 vs 1.26 $\pm$ 0.53, $p<0.0001$). Notably, patients in sMDA had significant improvement in HAQ at 5 years compared to baseline ($p<0.0001$), yet they presented significantly higher HAQ compared to sRLDA group (mean $\pm$ sd: 0.55 $\pm$ 0.47 vs 0.30 $\pm$ 0.31, $p<0.0001$). Trajectories of longitudinal HAQ for groups sRLDA, sMDA and sHDA, were clearly differentiated during treatment course (Figure 1). Clusters sRLDA, sMDA and sHDA also displayed differential 5 years outcomes ($p<0.0001$) regarding SAEs (Figure 1). Interestingly, within sMDA patients, the *low* sMDA patient subgroup

had better long-term outcome ($p<0.05$) concerning both HAQ at 5 years and cumulative SAEs as compared to patients in *high* sMDA subgroup

Figure 1. Differential long term outcomes of patient clusters, sRLDA, sMDA and sHDA

Conclusion: In clinical practice 56% of RA patients on bDMARDs have sustained MDA in spite of bDMARDs switches, presenting 5 years worse functional status and more SAEs compared to patients in sRLDA. These data support the treat-to-target approach for patients in sMDA and especially those with high sMDA.

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A POOLED ANALYSIS OF 1-YEAR CLINICAL OUTCOMES AMONG 6-MONTH RESPONDERS AND NON-RESPONDERS FROM THREE RANDOMISED CONTROLLED STUDIES OF TNF INHIBITOR BIOSIMILARS IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: SB4, SB2, and SB5 are biosimilars of etanercept, infliximab, and adalimumab. Phase III randomised, double-blind studies were conducted to compare efficacy and safety between biosimilars and reference products.

Objectives: Assess and compare 1-year outcomes among 6-month responders and non-responders.

Methods: Patients who had 6-month data from each phase III study were pooled and categorised, based on their disease status at 6 months (week 24 for etanercept and adalimumab and week 30 for infliximab) and 1 year (week 52 for etanercept and adalimumab and week 54 for infliximab).

Responders included patients who achieved an ACR20 response or low disease activity (including remission) by DAS28, SDAI, or CDAI at 6 months. Those who did not or dropped out were considered non-responders.

Primary outcome was the proportion of responders who maintained responses from 6 months to 1 year or non-responders at 6 months who achieved responses at 1 year.

Results: Data from 1461 patients were included in the analysis. For all treatments combined, 81.1% of ACR20 responders, 69.6%, 77.8%, and 77.0% of responders with DAS28, SDAI, and CDAI low disease activity (LDA) at 6 months maintained their responses at 1 year, and 33.9%, 18.8%, 26.7%, and 24.9% of 6-month non-responders achieved responses at 1 year, respectively. The proportions of patients maintaining or achieving an ACR20 response or DAS28, SDAI, and CDAI LDA at 1 year were similar across different treatment groups (Table 1).