AB0292

Efficacy and Safety of Two Biosimilar Etanercept After the Switch from Their Corresponding Originator in the Treatment of Patients with Autoimmune Arthritis: A Retrospective Analysis in a Real Life Setting

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Background: The available biosimilars of etanercept are as effective and well tolerated as their bio originator molecule in the naïve setting of chronic autoimmune arthritis. More data about the switching from the bio originator are needed.

Objectives: To compare the clinical outcomes of the treatment with etanercept biosimilars (SB4 and GP2015) naïve and after the switch from their corresponding originator in patients affected by autoimmune arthritis in a real life setting

Methods: We retrospectively analyzed the baseline characteristics and the retention rate in a cohort of patients who received at least a course of etanercept (originator or biosimilar) in our Rheumatology Units from January 2000 to January 2020. We stratified the study population according to biosimilar use. Descriptive data are presented by medians (interquartile range [IQR]) for continuous data or as numbers (percentages) for categorical data. Drug survival distribution curves were computed by the Kaplan-Meier method and compared by a stratified log-rank test. A Cox proportional hazards regression analysis stratified by indication, drug, age, disease duration, sex, treatment line, biosimilar use and prescription year was performed. P values ≤0.05 were considered statistically significant.

Results: 477 patients (65% female, median age 56 [46-75] years, median disease duration 97 [40.25-178.75] months) treated with etanercept were included in the analysis. 257 (53.9%) were affect by rheumatoid arthritis, 139 (29.1%) by psoriatic arthritis, and 81 (17%) by axial spondyl arthritis. 298 (62.5%) were treated with etanercept originator, 97 (20.3%) with SB4, and 82 (17.2%) with GP2015. Among the biosimilars 90/179 (50.3%) patients were naïve to etanercept treatment. Among the 89 switchers we observed 8 treatment discontinuations: one due to surgical infection complication, three due to disease flare, two due to subjective worsening and one due to remission. The overall 6- and 12-month retentions rate were 92.8% and 92.7%. The 6- and 12-month retention rate for etanercept, SB4 and GP2015 were 92.7%, 93.4% and 90.2%, and 82%, 74.5% and 88.1% respectively, without significant differences among the three groups (p=0.374). Patients switching from originator to biosimilars showed and overall higher treatment survival when compared to naïve (12-month retention rate 81.2% vs 70.8%, p=0.036). The Cox proportional hazard regression analysis highlighted that the only predictor significantly associated with an overall higher risk of treatment discontinuation was the year of prescription (HR 1.08, 95% CI 1.04 to 1.13, p=0.001).

Conclusion: In our retrospective study etanercept originator and its biosimilars (SB4 and GP2015) showed the same effectiveness. Patients switching from originator to biosimilars showed a significant higher retention rate when compared to naïve. The only predictor of treatment discontinuation highlighted by the Cox proportional hazard regression analysis was the year of treatment prescription.

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AB0294

Persistence with Abatacept Versus Tumor Necrosis Factor-Inhibitors for Rheumatoid Arthritis Complicated by Positive Anti-cycRular TNF- 1

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Background: Rheumatoid arthritis (RA) treatment usually begins with a non-biologic disease-modifying antirheumatic drug (DMARD), followed by a biologic DMARD (including abatacept or tumor necrosis factor-inhibitors [TNFis]) in non-responsive patients. Since, treatments are switched if disease activity does not improve, it is valuable to understand treatment persistence and switch patterns in RA patients with poor prognostic factors in a real-world setting.

Objectives: To assess 12-month treatment persistence in early-line abatacept versus TNFi treated patients with RA complicated by poor prognostic factors.

Methods: We performed a multi-center retrospective medical record review of adult RA patients with poor prognostic factors treated at 6 United States clinics. Patients were treated with abatacept or TNFi as the first biologic treatment at the clinic. Poor prognostic factors included positive anti-cyclic citrullinated peptide antibodies (ACPA+), positive rheumatoid factor antibodies (RF+), increased C-reactive protein levels, elevated erythrocyte sedimentation rate levels, or presence of joint erosions. TNFis included adalimumab, etanercept, infliximab (and their biosimilars), certolizumab pegol, or golimumab. Data were collected from first biologic treatment for ≥1 year. Patients with Crohn’s disease, ankylosing spondylitis, ulcerative colitis, psoriatic arthritis, or anal fistula were excluded. Demographic, disease, and treatment information (start, stop, reason for discontinuation) was abstracted. Treatment persistence (continuation of index treatment with gap ≤60 days) at 12 months and time to discontinuation were reported. Multivariate logistic and Cox regressions were used to compare 12-month persistence and risk of discontinuation between abatacept and TNFi, controlling for demographic and disease characteristics (American College of Rheumatology comorbidity index [ACR-CI], RA duration), baseline utilization, and clinic. Findings among a subgroup of ACPA+ and/or RF+ patients are reported.

Results: Data on 265 patients (100 abatacept, 165 TNFi) were collected, including 163 ACPA+ and/or RF+ patients (55 abatacept, 108 TNFi). Overall, abatacept patients were older than TNFi patients (67.0 vs. 60.3 years, p=0.001), but there were no statistically significant differences in gender, comorbidities, or duration of treatment at the clinic. At 12 months, 83.0% of abatacept patients were persistent vs. 66.1% of TNFi patients (p=0.003). Persistence was similar among ACPA+ and/or RF+ patients (83.6% vs. 64.8%, p=0.012). Median time to discontinuation was 1,423 days for abatacept vs. 690 days for TNFi (p=0.014) (961 days vs. 581 days among ACPA+ and/or RF+ patients, p=0.048) (Figures 1,2). In the adjusted analysis, risk of all-cause discontinuation was statistically significantly higher among TNFi than abatacept patients (17 (95% CI: 1.1-2.6), p=0.012). The odds of TNFi patients being persistent at 12 months was 51% lower than abatacept patients, although not statistically significant.