Background: The available biosimilars of etanercept are as effective and well tolerated as their bio originator molecule in the naïve treatment of chronic auto-immune 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 affected by rheumatoid arthritis, 139 (29.1%) by psoriatic arthritis, and 81 (17%) by axial spondylarthritis. 298 (62.5%) were affected by Crohn’s disease, ankylosing spondylitis, ulcerative colitis, psoriatic arthritis, or anil 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 proportional hazard regression analysis highlighted that the only predictor significantly associated with an overall higher treatment survival was the year of treatment prescription (HR 1.08, 95% CI 1.04 to 1.13; p=0.0001).

Conclusion: In our retrospective study etanercept etanercept and its biosimilars (SB4 and GP2015) showed the same effectiveness. Patients switching from originator to biosimilar showed an 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.

Disclosure of Interests: Francesco Girelli: None declared, Alarico Ariani: None declared, Andrea Becciolini: Speakers bureau Sanofi-Genzyme, UCSF and AbbVie, Lucia Gardelli: None declared, Maurizio Nizzoli: None declared

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