Figure 1A

Figure 1B

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EFFECTIVENESS AND SAFETY OF ORIGINAL AND BIOSIMILAR ETANERCEPT IN bDMARD-NAÏVE PATIENTS IN A REAL-WORLD COHORT OF PORTUGAL

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Background: The patent expiration of the original etanercept in Europe has facilitated the development of biosimilar products. Non-significant differences in efficacy and safety were noted in clinical trials which are not expected to influence clinical performance. Nonetheless, daily practice data should be gathered to support the claim for biosimilarity.

Objectives: To compare the effectiveness and safety of original and biosimilar etanercept, in biological-Disease Modifying Antirheumatic Drug (bDMARD)-naïve patients.

Methods: A retrospective multicenter non-interventional study, using data collected prospectively from Reuma.pt (The Rheumatic Diseases Portuguese Register) was done, including patients with: age ≥ 18 years old; diagnosis of Rheumatoid Arthritis (RA), Psoriatic Arthritis (PsA) or Spondyloarthritis (SpA) (axial or peripheral); active disease who initiated treatment with etanercept as first line of biological treatment after 2010. Kaplan-Meier was used to calculate the persistence rate in treatment. Disease activity at baseline and follow-up data at 6, 12, 18 and 24 months of treatment was compared using the chi-square for categorical variables and t-student or Mann-Whitney tests for continuous variables. Reasons for discontinuing therapy were summarized using descriptive statistics. Statistical significance was assumed for 2-sided p-values >0.05 .

Results: We included 1694 patients (413 on biosimilar and 1280 on original etanercept) 864 with RA, 335 with PsA and 494 with SpA. The population's baseline characteristics were not significantly different among both groups, except concomitant treatment in RA (higher use of conventional DMARDs in biosimilar group and higher use of NSAIDs in original group) and in SpA patients (higher use of corticosteroids in original group).

At baseline, a higher joint count was found in patients treated with original etanercept with a statistical difference for swollen ($p=0.03$) and tender ($p=0.01$) joints count (SJC and TJC, respectively) in RA and in TJC in SpA patients ($p=0.02$). In RA patients, CDAI and SDAI were higher in patients who started original ($p=0.03$; $p=0.04$, respectively). Pain measured by visual analogic scale was higher in SpA patients treated with biosimilar ($p=0.03$).

The 3-year PR was not significantly different between both treatment groups in RA, PsA and SpA (Figure1). In RA, PR in biosimilar was 72.6%, with a median time-on-drug (TOD) of 28.3 months; for original etanercept PR was 63.6%, with a median TOD of 27.4 months ($p=0.566$). In PsA patients, the PR for biosimilar was 70.6%, with a median TOD of 27.6 months, and in original drug 67.0%, with a median TOD of 28.1 months ($p=0.743$). In SpA patients, the PR were 78.4% for biosimilar (median TOD of 27.4 months) and 71.5% for original treatment (median TOD of 28.0 months ($p=0.816$)).

Figure 1. Drug survival in biosimilar and original etanercept in Rheumatoid Arthritis, Psoriatic Arthritis and Spondyloarthritis

In RA patients, we did not find differences between the two treatment groups for the proportion of patients in remission or low disease activity by CDAI ≤ 10 , SDAI ≤ 11 or DAS28 < 3.2 at 6, 12, 18 and 24 months of treatment. For PsA, no differences were found in the same timelines for DAPSA ≤ 14 , DAS28 < 3.2 , BASDAI < 4 , ASDAS < 2.1 or PsARC response. Also, in SpA patients, no differences were found in BASDAI < 4 , BASFI < 4 , ASDAS < 2.1 , ASDAS response and BASDAI response in all the timelines with the exception of BASDAI response at 18 months, which was achieved in fewer patients in biosimilar therapy ($p=0.02$). Overall, 535 (31.6%) patients stopped etanercept (428 patients on original and 107 patients on biosimilar). Discontinuations due to inefficacy were the most frequent, but there were no significant differences between both groups as for adverse events. Discontinuations due to "other reasons" were higher for the original group, both in RA ($p=0.01$) and in SpA ($p=0.04$).

Conclusion: Biosimilar and original used as first-line biological treatment showed similar effectiveness and safety in our long-term cohort of patients with RA, PsA, and SpA

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