bind the soluble TNF. To date, very few data are available concerning the use of biosimilar drugs in a real-life setting. Results from DANBIO registry suggested a lower retention rate in RA patients switchers from Etanercept originator (ETA) to biosimilar (SB4) versus the historic ETA cohort and higher in comparison with historic SB4 patients (1).

Objectives: To compare the efficacy of ETA versus SB4 in a cohort of RA patients in a real life setting.

Methods: In this monocentric case-control prospective study, we consecutively enrolled RA patients starting ETA or SB4 treatment from 2015. RA diagnosis was made according with ACR/EULAR 2010 criteria (2). Data were collected and entered into a standardized, computerized, electronically filled-in form. We included patient demographics, date of diagnosis, comorbidities and previous and concomitant medications. The clinical evaluation included the count of swollen and tender joints and the patient's and physician's global disease assessment based on a visual analogue scale (VAS; range, 0 to 100 mm). Disease activity was measured according to the disease activity score in 28 joints (DAS28ESR) (3). The patients were asked to fill in the Health Assessment Questionnaire (HAQ). All the patients were evaluated at the beginning of treatment (T0) and after 4 (T1) and 12 months (T2). Clinical response to treatment was evaluated by using EULAR criteria (4).

Results: We evaluated 35 RA patients treated with SB4 (M/F 2/33; median age 63 years, IQR 21; median disease duration 108 months, IQR 138) and 40 with ETA (M/F 5/35; median age 60.5 years, IQR 20; median disease duration 102 months, IQR 141). Biologic drug was prescribed as first-line biological treatment in 71.4% of SB4 cohort and in 80.0% of ETA. At T0 no significant differences were observed among the two groups in terms of DAS28ESR [SB4 median 4.6 (IQR 1.8), ETA 4.3 (IQR 1.9), $p=ns$] and HAQ [SB4: median 1 (IQR 1.05), ETA median 1 (IQR 0.85), $p=ns$]. In both groups we observed a significant reduction of DAS28 values at T1 (SB4 $p=0.01$; ETA $p<0.0001$) and T2 (SB4 $p=0.0007$; ETA $p=0.0002$; Figure 1A). When evaluating the remission rate (DAS28ESR<2.6) at T1, we observed a significant higher rate in ETA (53.8%) versus SB4 (26.7%; $p=0.0002$; Figure 1B). No differences were found after 12 months of treatment.

Figure 1

Conclusion: The results of our study confirmed in a real-life setting the efficacy of SB4 in RA patients, as demonstrated by the significant reduction of DAS28ESR values after 4 and 12 months of treatment, similarly to ETA. Nonetheless, ETA seems to be able to induce a remission status earlier than SB4.

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AB0390

CORRELATION BETWEEN TNF-BLOCKERS BIOAVAILABILITY AND FCGR2A H131R POLYMORPHISM IN TUNISIAN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Rheumatoid arthritis (RA)'s prognosis drastically improved with the introduction of TNF-blockers. However, reasons behind therapeutic failure in some patients remain unclear. Several factors might influence pharmacokinetics of these drugs by reducing their half-life and, consequently, their effectiveness. Considering Fc-containing biologics like infliximab (IFX) and adalimumab (ADL), Fc gamma receptors (FcγRs) polymorphism would be an interesting genetic candidate to focus on.

Objectives: The aim of our study was to determine the influence of low affinity allele FcγRIIA-131R on ADL and IFX bioavailability.

Methods: We enrolled RA patients treated with IFX and ADL for over six months. Blood samples were collected for each patient immediately prior to drug administration. Quantitative measurements of the residual drug concentration (DC) was carried out by a commercial enzyme-linked immunosorbent assay (ELISA) kit (Promonitor®). Then, we identified patients with DC above therapeutic cut-off (DC+) for each biologic. EULAR criteria were considered to determine treatment outcome. FcγRIIA H131R polymorphism was genotyped using PCR-SSP.

Results: Twenty-nine patients were included (13 treated with ADL and 16 with IFX). We identified 31.3% and 23.1% non-responders among patients treated with IFX and ADL respectively. Patients with DC+ were more frequent in ADL group (76.9%) than IFX group (43.75%).

For IFX, DC+ was significantly correlated with the presence of FcγRIIA 131-R ($p=0.033$). In fact, none of the HH-genotyped patients had DC+. Furthermore, an association between FcγRIIA 131-R allele and poor response to IFX was noted ($p=0.059$) while all HH-genotyped patients responded to IFX. For ADL, no correlation was found with both of residual DC and response to treatment.

Conclusion: The presence of FcγRIIA-131 R allele might be a predictive factor of non-responsiveness to TNF-blockers. It also appears to be associated to a higher residual DC. That might be explained by a reduced biologic clearance due to a lower binding affinity to Fc portion compared to wild allele FcγRIIA-131H. Therefore, FcγR polymorphism assessment in RA patients would be a decision-making parameter to consider, as part of the personalized medicine approach.

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AB0392

ASSOCIATION BETWEEN FCGR2A R131H, FCGR2A NA1/NA2 AND FCGR2B V158F POLYMORPHISM AND RESPONSIVENESS TO BIOLOGICS IN RHEUMATOID ARTHRITIS TUNISIAN PATIENTS

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Background: Even though biologics have been used for several years in treatment of rheumatoid arthritis (RA), little is known about factors that modify their pharmacokinetics and therefore their efficacy. Polymorphisms (SNPs) in receptors for constant region Fc of IgG (FcγR) might influence the therapeutic outcome of molecules that incorporate an Fc fragment in