At the end of 12 months, compared to 1000mg, CD19 count was higher in 500mg group (p=0.25). Percentage of patients achieving EULAR moderate or no response was higher in 500mg group (37 vs. 29%, p=0.205), both complete and incomplete B cell depletion, but patients achieving good response was same in both groups (14.8% vs. 18.5%, p = 0.25). (Figure 1).

Figure 1. EULAR Response at 12 months

Conclusion: Low dose bRTX is effective in DMARD refractory RA patients with similar improvements as regular dose, although CD19 depletion was less in low dose group. A larger study to establish radiographic regression with CD19 depletion and disease activity score can help in further strengthening the use of lower dose bRTX in RA leading to significant economic advantage.

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SUSTAINABLE LOW DISEASE ACTIVITY IN PATIENTS WITH RHEUMATOID ARTHRITIS: REAL-WORLD EXPERIENCE WITH TOCILIZUMAB
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Background: Sustainability, the ability of drugs to maintain remission or low disease activity (LDA) in patients with rheumatoid arthritis (RA), plays a crucial role for the prevention of structural damage to joints and thus, preserving patients’ functional capacity, health-related quality of life and general sense of well-being. Therefore, studying the sustainable effectiveness of tocilizumab (TCZ) as a monotherapy or combined with methotrexate (MTX) is important (1).

Objectives: We aimed to examine to what extend TCZ, alone or combined with MTX, could achieve and further sustain LDA in patients with long-standing RA in the light of current, strictly index-based defined LDA and to compare the two versions of DAS28 in patients in real clinical practice

Methods: 85 RA patients treated with TCZ for at least eighteen months were consecutively enrolled in the present single-center, retrospective cohort study. All participants met the 1987 ACR classification criteria and attended the rheumatology department of University Hospital "St. Marina" Varna in an outpatient setting. Patients receiving pre-filled syringe contained 162 mg TCZ once weekly subcutaneously. Real-world data were extracted and analyzed from patient’s full medical file. For each visit, disease activity score 28 with ESR and CRP (DAS28-ESR and DAS28-CRP) and simple disease activity index (SDAI) were calculated simultaneously according to generally adopted formulas. A twelve-month result was determined for sustained LDA at each of the patient’s three visits (at 6-month intervals), according to DAS28 and SDAI. Descriptive statistics, Chi square test, Cochran`s Q test, kappa statistic were used, a binary logistics model was compiled to study the impact. Significance level of p < 0.05.

Results: Two hundred fifty-five patient visits were analyzed. The mean durations of RA and treatment with TCZ were 12.6 (±6) years and 3.64 (±0.7) years, respectively. The mean age of patients was 60.3 years (37-87 years), 80% were women, 24.7% were obese, 65.9% have concomitant hypertension. 61.2% of patients are treated with combination therapy TCZ with MTX.

Of all patients, these with a sustained 12-month LDA were 41.2%, 28.2% and 23.5% depending on the studied index (DAS28-ESR, SDAI, or DAS28-CRP, respectively).

A 12-month SDAI LDA was found in a significantly small proportion of patients (28.2%, p = 0.001). The DAS28 ESR determined a proportion similar to SDAI (23.5%, p = 0.05), while according to the DAS28 CRP, patients with a sustained 12-month LDA were significantly more (41.2% p = 0.005). A moderate level of agreement was found between the assessments of SDAI and the two variants of DAS28 when determining 12-month results of Tocilizumab treatment (DAS28-ESR k = 0.511, p = 0.001 and DAS28-CRP k = 0.618, p < 0.001). No relationship was found between the combination of TCZ with MTX and the patients’ chance of a sustained 12-month LDA, regardless of which index the result was measured.

Patients with hypertension were significantly less likely to have sustained 12-month LDA according to SDAI and DAS 28 ESR (OR 0.135, 95% CI 0.048-0.386; OR 0.313, 95% CI 0.110-0.882, respectively), but not according to DAS28 CRP.

Conclusion: Sustained 12-month LDA with TCZ in patients with long-term RA remains uncommon in daily clinical practice. Co-administration of MTX is not associated with an increased likelihood of achieving a sustained LDA in the analysis of long-term responses. Patients with concomitant hypertension are less likely to be in a sustained 12-month LDA, according to SDAI and DAS28-ESR. The results according to DAS28 ESR, but not according to DAS28/CRP are comparable to those of SDAI when measuring long-term results of treatment with TCZ.

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AB0225 TUMOR NECROSIS FACTOR ALPHA (TNF-α) INHIBITORS IN PATIENTS WITH REFRACTORY RHEUMATOID ARTHRITIS: REASONS FOR WITHDRAWAL
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Background: Refractory rheumatoid arthritis (RRA) is a subtype of rheumatoid arthritis (RA), in which the sequential administration of optimal methotrexate doses in combination with glucocorticoids, and at least - two biologic disease-modifying antirheumatic drugs (bDMARDs) with different mechanisms of action during 18-24 months does not lead to a significant decrease in the inflammatory activity of RA.

Objectives: to determine the reasons for the withdrawal of TNF-α inhibitors in patients with RRA.

Methods: The retrospective study included data of 95 RRA patients (80 females, 15 males), aged 23 to 80 years (mean age 57 years), treated with TNF-α inhibitors. Mean RA duration was 11.9±7.6 years. All patients were divided into 6 groups depending on the number of the lines of therapy received. A total of 154 cases of TNF-α were studied.

Results: Infliximab (IFN) was most often prescribed as the first line of therapy - 40 prescriptions. The reasons for the withdrawal of INF as the first bDMARDs were: insufficient effectiveness (IE) - 20 cases (50% of appointments), administrative reasons (AdmR) - 13 cases (32.5% of appointments), adverse reactions (AR) - 6 cases (15% of appointments), remission - 1 case (2.5% of appointments). In the 2nd line of therapy, INF was prescribed in only 3 cases, the drug was canceled in all cases due to IE. In 3 lines of therapy, INF was prescribed in 4 cases, the reasons for withdrawal in these cases were IE (50%, 2 cases) and AR (50%, 2 cases).

Etanercept (ETC) was prescribed as the first line of therapy in 10 cases. The most common reason for withdrawal was IE in 5 cases (50% of appointments), AR - 4 cases (40%), AdmR - 1 case (10%). ETC was prescribed as a 2 line in 15 cases, the reasons for withdrawal then were: IE - 11 cases (73.3%), AR - 1 case (6.7%). AdmR - 3 cases (20%). ETC was prescribed as a 3-line therapy in 20 cases. The reasons for withdrawal were as follows: IE - 8 cases (40%), AR - 4 cases (20%), AdmR - 8 cases (40%). As a drug of 4 lines of therapy, ETC was prescribed 1 time and was canceled due to the development of AR. As the 5th line, ETC was appointed in 1 case and was canceled due to IE. ETC was assigned as line 6 in 1 case. The reason for the withdrawal was AR.

Adalimumab (ADA) was prescribed as the first line of therapy in 19 cases, the reasons for withdrawal were: IE - 14 cases (73.7%), AR - 2 cases (10.5%), AdmR - 3 (15.8%). On line 2, ADA made 20 appointments, the reasons for withdrawal were: IE - 13 (65%), AR - 3 (15%), AdmR - 4 (20%). ADA was prescribed as
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AB0027
SAFETY AND EFFECTIVENESS OF ADALIMUMAB REFERENCE PRODUCT AND BIOSIMILAR IN PATIENTS WITH INFLAMMATORY ARTHROPATHIES

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Background: Biological therapy revolutionized the treatment and prognosis of inflammatory arthropathies; however, its high cost has an economic impact on health system and limits its access. Biosimilars are products with similar molecular structure, equivalent efficacy, and comparable safety and immunogenicity, which arise as a necessity to reduce costs. Although, their long-term safety is still to be confirmed.

Objectives: Our aim is to compare the safety and effectiveness between adalimumab reference product and biosimilar in patients with inflammatory arthropathies.

Methods: Cohort study of 92 patients with arthritic spondylitis (AS), rheumatoid arthritis (RA) and psoriatic arthritis (PsA) in a specialized multicenter health institution in Colombia. Rate of incidence of non-serious ADRs were calculated as an annual incidence rate (AIR) and treatment failure (TF) was estimated among patients exposed to reference product and biosimilar. 95% confidence interval (CI) for the ratio is also calculated. AIR and TF Incidences in both groups were calculated using the Kaplan Meier curve.

Results: Between October 2019 and October of 2020, 92 patients started adalimumab, 64% (n = 59) reference product and 36% (n = 33) biosimilar (18 naïve and 15 switch). 41.3% of patients had a diagnosis of RA, 35% AS and 24% PsA. Additionally, 62% were women, with median age of 53 years (Interquartile Range (IQR): 41-62); disease evolution time of 9 years (IQR: 5-20); and treatment time of 0.8 years (IQR: 0.4-1.04). No statistically significant differences were found between the drug between diagnosis, drug evolution, time or disease activity. Of all patients 21 presented ADR; 11 with reference product (IR 0.18 per 100 person-years), and 10 with biosimilar (IR 0.30 per 100 person-years); IR ratio of 0.61 (95% CI 0.26-1.44; p-value = 0.36). From ADR reactions, 35% were infections, 13% skin disorders and 74% hepatobiliary disorders; all were classified as non-serious. 5 TF events were presented, 3 with reference product (IR 0.05 per 100 person-years) and 2 with biosimilar (IR 0.06 per 100 person-years); IR ratio of 0.83 (95% CI 0.09-10.04; p-value = 1.00). There were no statistically significant differences between reference product and biosimilar in time of ADR presentation (Log Rank Test 0.74; p = 0.39) or on TF (Log Rank Test 0.55; p = 0.45).

Conclusion: Results shown that analyzed biosimilar is a safe product with a similar rate of ADR and without differences in effectiveness evaluated by TF, although 95% CIs are imprecise. This suggests that use of biosimilars in a real-life setting could be safe and with similar effectiveness, which is correlated with other studies carried out in RA and is an appropriate measure to reduce treatment costs in patients with inflammatory arthropathy.

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AB0028
LONG-TERM EFFECTIVENESS, DRUG SURVIVAL OF BIOLOGIC THERAPIES IN PATIENTS WITH ACTIVE RHEUMATOID ARTHRITIS AND SPONDYLOARTHRITIS AND PREDICTIVE FACTORS OF DRUG DISCONTINUATION DUE TO DISEASE REMISSION

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