line 3 in 8 cases, the reasons for withdrawal were: IE - 6 (75%), AR - 1 (12.5%), AdmR - 1 (12.5%). As a 4-line drug, ADA was prescribed in 4 cases and was canceled in all cases due to IE. On line 5, ADA was assigned 1 time and was discontinued due to IE.

Golimumab (GLM). He was appointed as the first line in 5 cases. The reasons for withdrawal were: IE - 1 case (20%), AdmR - 4 appointments (80%). As a 2-line drug, GLM was prescribed once and was canceled due to AdmR. The drug was not prescribed for the 3rd and 4th lines. As a 5-line therapy, it was prescribed once and was canceled due to IE.

When assessing the frequency of drug withdrawal due to IE or AR, no significant differences were found between the lines of therapy. Discontinuation rates were also not statistically different in the study groups.

Conclusion: The most common reason for the withdrawal of TNF- α in patients with RRA is IE. With an increase in the lines of TNF- α therapy, remission as a reason for withdrawal was not identified. As a result of the increase in the number of sequentially prescribed bDMARDs, the frequency of discontinuation of TNF- α in connection with IE did not decrease. A significant reason for cancellation is AdmR, to which we attributed the absence of the drug in the pharmacy network, financial reasons limiting the continuation o

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AB0226

EVALUATION OF RITUXIMAB EFFICACY WITH VARIOUS COMPOSITE MEASURES OF INFLAMMATORY ACTIVITY IN PATIENTS WITH RHEUMATOID ARTHRITIS

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Background: Disease modifying anti-rheumatic drugs (DMARD) can provide an unbalanced effect on individual components of the inflammatory process, which in some cases leads to an insufficiently correct assessment of the patient's status when using composite activity indices [1].

Objectives: To compare the results of the rituximab (RTX) efficacy assessment in patients with rheumatoid arthritis (RA) using different composite indices of disease activity.

Methods: Patients with active RA observed in 23 medical centers of the Russian Federation were included. They were randomized into 2 groups in a 2:1 ratio. In the main group methotrexate (MTX) was prescribed at 15 mg per week and RTX infusions 600 mg on days 1 and 15. Patients in the control group received MTX 15 mg per week and placebo on days 1 and 15. If after 15 weeks 20% reduction of tender joint count (TJC) and swollen joint count (SJC) was not achieved, another DMARD was prescribed.

Results: 159 RA patients (131 women and 18 men) were included. The mean age of patients was 51.4 $\pm$ 11.8 years, the median duration of RA – 2.8 [0.6; 5.8] years. At baseline DAS28, SDAI and CDAI in all cases assessed disease activity as high. 6 months after RTX administration DAS28 showed remission in 9%, low, moderate and high activity activity in 7%, 47% and 37% of cases, SDAI – in 7%, 12%, 34% and 47%, CDAI – in 7%, 11%, 30% and 52%, respectively. In the control group remission, low, moderate and high activity by DAS28 were revealed in 2%, 2%, 38% and 58%, by SDAI – in 2%, 4%, 35%, 59%, by CDAI – in 2%, 6%, 29%, 63% of patients respectively. After 6 months, in patients achieved the treatment target (remission or low activity) according to DAS28, SJC in 12 cases was 0, in 3 – 1 and in 1 – 2. TJC was 0 in 9 cases and in 7 patients ranged from 1 to 14. The level of C-reactive protein (CRP) in 14 cases was within the normal range and in 2 – increased. Erythrocyte sedimentation rate (ESR) was normal in all cases. SDAI after 6 months showed the target activity in 18 patients treated with RTX. In 12 of them the SJC was 0, in 4 – 1 and in 2 – 2. In 9 cases TJC was 0, in the rest patients it varied from 2 to 5. The level of CRP was normal in 15 patients, ESR – in all patients. CDAI met the target activity in 17 patients. In 12 of them, SJC was 0, in 3 – 1, in 2 – 2. The level of CRP was normal in 14, ESR – in all patients.

Conclusion: Assessment of RTX efficacy with DAS28, SDAI, and CDAI in RA provided comparable number of patients who achieved remission or low disease activity 6 months after administration of the drug. The groups of patients who reached this target level of activity by DAS28, SDAI, and CDAI did not have significant differences in the values of main measures characterizing residual inflammatory activity, including SJC, TJC, ESR, and CRP.

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AB0227

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 confirmed¹.

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 ankylosing spondylitis (AS), rheumatoid arthritis (RA) and psoriatic arthritis (PsA) in a specialized multicenter health institution in Colombia. Ratio of incidence rates (IR) for Adverse Drug Reactions (ADR) and therapeutic failure (TF) is estimated among patients exposed to reference product and biosimilar. 95% confidence interval (CI) for the ratio is also calculated. ADR 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 naive 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 according to the drug between diagnosis, evolution time, or disease activity. Of all patients 21 presented ADR; 11 events 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 7.4% hepatobiliary disorders; all were classified as non-serious ADR. 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 was no statistically significant 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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AB0228

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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