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AB0209

SERIOUS INFECTIOUS COMPLICATIONS IN PATIENTS WITH RHEUMATOID ARTHRITIS TREATED WITH BIOLOGICS

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Objectives: To study infectious complications of therapy with biologics, analyze the frequency of withdrawal of bDMARDs due to infectious complications.

Methods: The ambispective analysis included data on 505 cases of prescribing biologics with different mechanism of action in 188 patients with rheumatoid arthritis (160 women, 28 men).

Results: Patients in the study group received from 2 to 5 bDMARDs, median (25% -75%) 2 (2-3). Biologics were discontinued 326 times, of which due to the development of serious adverse reactions - 70 times, of which due to the development of infectious complications - 16 times (5% of all cases of discontinuations, 29% of all serious adverse reactions). During treatment with the first bDMARD, infectious complications that required discontinuation of the drug developed in 5.3% of cases (N = 10), with the second bDMARD - in 5.2% of cases (N = 4), no statistical differences were found between these groups. On the background of treatment with the third bDMARD, infectious complications led to the withdrawal of treatment in 14.3% of cases (N = 1), in the fourth - 0%, and in the fifth - 33.4% of cases (N = 1). There was no correlation between the number of sequentially prescribed biologics and the incidence of infectious complications. Most often, serious infections developed during treatment with drugs of the TNF- α inhibitor group (infliximab, etanercept, adalimumab, golimumab, certolizumab pegol) and tofacitinib. Out of 16 cases of infectious complications, 5 were associated with tuberculosis infection.

Conclusion: Infectious complications make up a significant proportion (29%) of all serious adverse reactions leading to the discontinuations of biologics in patients with rheumatoid arthritis. The frequency of discontinuation of bDMARDs due to infectious complications was about 5% and did not change during treatment with both the first and second biologics. It is necessary to remain alert about tuberculosis infection and examine patients before prescribing and during treatment with bDMARDs.

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AB0210

COMPARISON OF EFFICACY AND SAFETY OF BIOSIMILAR RITUXIMAB AND ORIGINATOR RITUXIMAB IN REAL CLINICAL PRACTICE

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Background: Due to the expiration of many originator biologics patents, their biosimilars (BS) have appeared and were put into clinical practice. The introduction of such drugs reduces the cost of treatment and thereby increases its availability. BS rituximab (RTX) Acellbia was developed by the Russian company "BIOCAD". Its effectiveness and safety have been proven in two clinical trials. It was licensed in Russia for the treatment of rheumatoid arthritis (RA) in 2017.

Objectives: To compare efficacy and safety of BSRTX and originator RTX (ORTX) in real clinical practice.

Methods: RA patients fulfilling the EULAR/ACR 2010 criteria and followed-up at the V. A. Nasonova Research Institute of Rheumatology were included. All of them had previously received methotrexate without effect. They were divided into 4 groups. The first and second groups included patients who had not previously received biologics. Treatment with BSRTX was started in the first group, ORTX was administered in the second group. The third and fourth groups included patients who received ORTX with significant improvement. Patients of the third group were switched to BSRTX, in the fourth group treatment with ORTX was continued. ORTX and BSRTX were administered twice 500 mg over 2 weeks. The indication for repeated administration of ORTX and BSRTX was an exacerbation of RA. Patients were examined before the first or regular administration of ORTX or BSRTX and before the planned repeat course of treatment with these drugs. RA activity was evaluated with the DAS28. Adverse events (AE) were recorded. Data were tested for normality using the Kolmogorov-Smirnov test. Continuous variables are presented as mean $\pm$ SD if they obey normal distribution, and as median [quartile interval] if they were not consistent with normal distribution. Mann-Whitney U test was used for comparison between groups.

Results: 127 patients with RA were included. 66 patients had not previously received biologics. BSRTX was started in 35 of them and ORTX - in 31. 61 patients already received ORTHX with clinical improvement. 31 of them were switched to BSRTX, and 30 continued therapy with ORTX. The median interval between the baseline examination and the assessment before the second treatment course in the BSRTX group was 6 [5; 13] months, in the ORTX group - 7 [7; 11] months. In group 1 median DAS28 during follow-up decreased from 5,8 [5,2; 6,9] to 3,9 [3,1; 4,5], in group 2 - from 5,7 [5,2; 6,0] to 4,1 [3,8; 4,6], respectively. These changes were comparable in both groups. The mean duration of the interval between infusion of BSRTX or ORTX and repeated examination - 11,3 $\pm$ 8,2 and 10,1 $\pm$ 4,8 months, respectively. These differences are not significant. In group 3 median DAS28 at the baseline examination was 5,1 [3,9; 5,9], at the second one - 4,3 [3,8; 5,3], in group 4 - 4,6 [3,7; 5,4] and 4,2 [3,5; 5,2] respectively. These values did not differ significantly. The frequency and nature of adverse events during treatment with ORTX and BSRTX did not significantly differ. We did not observe serious AE and unexpected AE.

Conclusion: The results of the present study show that efficacy and safety of BSRTX and ORTX were comparable when they were used as the first biologics and when switching from ORTX to BSRTX. BSRTX can be used in routine clinical practice for the treatment of RA. Disclosure of Interests:

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