AB0303

PRE dictors of Serious Infections in Patients with Rheumatoid Arthritis Receiving Targeted Therapy.

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Background: The problem of infectious complications in patients receiving bDMARDs deserves special attention. Serious infectious adverse events (SIAE) are a most important issue. To develop measures for their prevention it is necessary to know the predisposing factors.

Objectives: to detect predictors of serious infections among patients with rheumatoid arthritis receiving targeted therapy

Methods: The study includes patients with rheumatoid arthritis from the Moscow Unified Arthritis Registry (MUAR), receiving treatment with biologics or tofacitinib. Search for predictors was carried out in two steps. At first step we selected patient related predictors (confounders) that significantly correlate with risk of SIAE. At the second step in the Cox risk regression model by forward stepwise selection were added independent significant predictors of risk, which demonstrated significant correlation with development of serious infections. Then data about the treatment was added to the generated model: used targeted DMARDs, doses of glucocorticoids (GC), doses of methotrexate (MTX).

Results: Analysis includes 1052 treatment events in 772 patients. There were 44 serious infections. The mean age was 57.1 ± 12.8 years. The mean observation time was 3.5 years. Independent patient related predictors of SIAE risk were: the age RR - 1.12 per year (CI: 1.06-1.19), the onset of disease RR - 0.94 per year (CI: 0.90-0.98), the age at inclusion in the registry RR - 0.64 per year (CI: 0.59-0.69). The dose of MTX and the doses of GC positively correlate with SIAE risk. RR for MTX is 1.05 per mg (CI: 1.00-1.10), RR for GC - 1.11 per mg (CI: 1.04-1.236).

Conclusion: Higher doses of methotrexate and glucocorticoids are independent significant predictors of serious infections in RA patients receiving targeted DMARDs.

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AB0304

IMMUNOGENICITY OF BIOLOGIC DRUGS IN THE CLINICAL PRACTICE IN THE BULGARIAN POPULATION OF PATIENTS SUFFERING FROM RHEUMATOID ARTHRITIS

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Background: Biological drugs are protein derivatives that, as such, are highly immunogenic. In recent years there have been many conflicting opinions about the role of drug immunogenicity in clinical practice.

Objectives: To evaluate the drug immunogenicity of TNF-alpha blocking drugs (etanercept and adalimumab) used to treat patients with rheumatoid arthritis. To determine whether their presence can alter the effect of treatment and to evaluate their role in the clinical practice of rheumatologists.

Methods: 121 patients with rheumatoid arthritis, as well as 31 healthy controls, similar in sex and age, were examined. They were all monitored at 0, 6, 12 and 24 months from the start of TNF-alpha blocker treatment. Demographics, vital signs, markers of inflammation such as C-reactive protein (CRP), erythrocyte sedimentation rate (ESR) and disease activity indices were examined at each visit, respectively. Drug-induced neutralizing antibodies, as well as drug bioavailability in patients treated with adalimumab, were examined by ELISA.

Results: Drug-induced neutralizing antibodies to adalimumab were detected in 11.57% of patients at 6 months, in 17.64% of patients at 12 months, and 24.8% at 24 months. Drug-induced neutralizing antibodies to etanercept were not detected at 6 months, at 7.77% at 12 months, at 9.63% of patients at 24 months. Of the adalimumab patients who were having drug-induced antibodies, 92.59% had low drug bioavailability, while the remaining 7.41% of patients showed normal drug bioavailability despite the presence of drug-induced neutralizing antibodies. In terms of worsening of the disease activity, a positive correlation was found with the presence of drug antibodies - Pearson Correlation = 0.701, p = 0.001. Patients with poor clinical response and available drug antibodies receiving adalimumab were slightly more than those treated with etanercept at 12 and 24 months but the difference is non-significant-U = 0.527, p > 0.05 and U = 0.623, p > 0.05, respectively.

Conclusion: Presence of drug-induced neutralizing antibodies in patients treated with adalimumab and etanercept has been associated with poor clinical response and worsening of the patient’s condition. Testing of drug-induced neutralizing antibodies as well as the drug bioavailability of the drug used can be used as reliable biomarkers in clinical rheumatology.

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