



Frequency and Characteristics of Infusion Reactions during Biosimilar Infliximab Treatment in Inflammatory Bowel Diseases: results from Central European nationwide cohort

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Abstract

Introduction. Safety data of the ‘real life’ use of an infliximab biosimilar, CT-P13 in inflammatory bowel disease (IBD) are still lacking. Our **aim** was to assess the frequency and characteristics of infusion reactions during CT-P13 therapy in 13 Hungarian and 1 Czech IBD centres. **Methods.** Clinical and safety data was registered at fixed appointments. Trough levels and anti-drug antibody (ADA) concentration were measured by ELISA. Association between demographic, clinical, laboratory parameters and infusion reaction rates were evaluated statistically. **Results.** Three hundred and eighty-four IBD patients were included. Twenty-eight Hungarian IBD patients (9.6%) developed infusion reaction during the treatment, 64.3% of them was previously exposed to anti TNF therapy. No infusion reaction occurred in the Czech population. CT-P13 therapy had to be stopped in 17 patients who developed infusion reaction and was switched to adalimumab in 12 patients. However in 39.3% of patients developing infusion reaction CT-P13 therapy was continued with the use of premedication. Cumulative ADA positivity rates were 8.7%, 19.3%, and 28.0% at weeks 0, 14, and 30. Previous anti-TNF-alpha exposure (30% vs. 3.1%, $p < 0.001$, OR 6.3 (2.7-14.6)) and ADA positivity (32.6% vs. 4.1%, $p < 0.001$, OR 19(5-73)) during the induction therapy were predictive factors for infusion reactions. **Conclusions.** Patients with previous exposure to anti-TNF-alpha and ADA positivity during the induction therapy were more likely to develop infusion reactions.