EXPERT OPINION

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Efficacy of the new infliximab biosimilar CT-P13 induction therapy in Crohn's disease and ulcerative colitis – experiences from a single center

Klaudia Farkas, Mariann Rutka, Anita Bálint, Ferenc Nagy, Renáta Bor, Ágnes Milassin, Zoltán Szepes & Tamás Molnár†
University of Szeged, First Department of Medicine, Szeged, Hungary

Background: CT-P13 is the first biosimilar monoclonal antibody to infliximab (IFX); it has been approved for the same indications as its IFX counterpart in Hungary. The aim of this study was to assess the efficacy of CT-P13 induction therapy in patients with Crohn's disease (CD) and ulcerative colitis (UC).
Methods: Patients diagnosed with CD and UC, who were administered CT-P13, were prospectively enrolled. Disease activity was estimated at the start and after the induction therapy. In patients with UC, sigmoideoscopy was also performed at the end of the induction therapy.
Results: Eighteen CD and 21 UC patients were enrolled. Induction treatment was completed in 16 of the CD and 15 of the UC patients. In those with luminal CD, clinical response and remission was achieved in 6 (37.5%) and 8 (50%) of the patients at Week 8. In UC, clinical response and remission was achieved in 3 (20%) and 10 (66.7%) patients at Week 8. Mucosal healing was shown in 11 patients.
Conclusions: This was the first study to prospectively evaluate the outcome of CT-P13 induction therapy in CD and UC. Our results confirm that induction with CT-P13 is safe and effective.

Keywords: Crohn's disease, CT-P13, efficacy, infliximab biosimilar, ulcerative colitis

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1. Background

The introduction of chimeric anti-TNF-α infliximab (IFX) has led to a real revolution in the management of chronic inflammatory bowel diseases (IBD) in the last decade followed by the production of newer biological agents. However, the increasing use and the significant cost of biological therapy have led to the development of biosimilar products. The lower cost of biosimilars will eventually substitute long existing biologics thereby allowing for the treatment of more patients. Biosimilars are known to be highly similar with the same target, but are not identical to their reference biologics due to the structural complexity and manufacturing procedures of the originator drug. In Europe, European Medicines Agency (EMA) approved two available IFX biosimilars which include all of the indications – pediatric and adult Crohn's disease (CD) and ulcerative colitis (UC) – as the originator. In both cases, the approval was based on randomized clinical trials conducted in patients with rheumatoid arthritis [1], supplemented by a clinical and a pharmacokinetic study on ankylosing spondylitis [2].

CT-P13 is the first biosimilar monoclonal antibody to IFX with the same indications, approved in 2013 by the EU and in June 2014 in Hungary. Studies

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