Efficacy of infliximab biosimilar CT-P13 induction therapy on mucosal healing in ulcerative colitis

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Abstract

Introduction. CT-P13 is the first biosimilar to infliximab that was approved for the same indications as its originator infliximab. No data is available on the effect of infliximab biosimilar on mucosal healing. The aim of this study was to evaluate the efficacy of CT-P13 induction therapy on mucosal healing in patients with ulcerative colitis (UC). Patients and methods. UC patients, who received CT-P13 therapy from its local introduction at three Hungarian and one Czech IBD centres, were prospectively enrolled. Sigmoidoscopy was performed after the end of the induction therapy at week 14. Mucosal healing was defined as Mayo endoscopic subscore 0 or 1. Complete mucosal healing was defined as Mayo endoscopic subscore 0. Trough level of CT-P13 was measured at week 14. Results. Sixty-three UC patients who underwent CT-P13 induction therapy were enrolled in the study. Indication of the therapy was acute, severe flare up and chronic, refractory activity in 24 and 39 patients. Cumulative clinical response and steroid-free remission at week 14 were achieved in 82.5% and 47.6% of the patients. Sigmoidoscopy revealed steroid-free mucosal healing in 47.6% of the patients, complete mucosal healing was present in 27%. Mayo endoscopic subscore decreased significantly at week 14 compared to baseline. Trough levels of infliximab correlated with mucosal healing. Conclusion. This was the first study examining the efficacy of CT-P13 induction therapy on mucosal healing in UC. Our results indicate that mucosal healing is achieved in two thirds of UC patients by the end of the induction treatment with CT-P13.

Key words: ulcerative colitis, infliximab, biosimilar, CT-P13, mucosal healing