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Conflicts of interest: none to declare.

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Key words: Anti-TNF – Biosimilar - CT-P13 – Infliximab - Ulcerative colitis

Ulcerative colitis (UC) is an inflammatory bowel disease (IBD) arising from an interaction between genetic and environmental factors.[1, 2]

In UC, the anti-tumor necrosis factor (TNF) infliximab, a chimeric IgG1 antibody, is approved to treat patients with steroid-refractory or steroid-dependent disease. The undoubted benefits of a better disease control are partly limited by the high cost of the infliximab originator (Remicade).

The biosimilar infliximab CT-P13 was approved for UC in Europe based on two randomised controlled trials in patients *naïve* to TNF inhibitors, comparing infliximab originator with CT-P13 in ankylosing spondylitis (PLANETAS, a phase 1 study) and rheumatoid arthritis (PLANETRA, a phase 3 study).[3] This extrapolation of indication has been debated in gastroenterology because the mechanisms of action for infliximab might differ between indications.[4]

To date a fair number of studies about switching from infliximab originator to infliximab biosimilar in UC have been available from open cohort studies in secondary or tertiary centres.[5-13]

A randomised, double-blind, parallel-group, multicentre, non-inferiority (non-inferiority margin of 15%) trial (NOR-SWITCH) was the first study to show that switching from an originator to a biosimilar TNF inhibitor was not inferior to continued treatment with the originator drug.[14] The authors calculated that 394 patients were required to exclude a difference in favour of infliximab originator. For the originator the risk difference of disease worsening was not statistically significant. The presumption of the study should be that, being involved patients with different immune-mediated disorders, the conclusions should be extended to all six relevant indications. Nevertheless, the authors highlighted that the study was not powered to show non-inferiority in individual diseases. So, also the data obtained by this study do not definitively resolve the issue of the equivalence between originator and CT-P13 in the individual diseases.

Tursi *et al.* recently published a prospective, observational, multicentre study performed in primary

IBD centres in Italy in which 29 adult outpatients with UC were treated with biosimilar infliximab CT-13 between 1st of May 2015 and 1st of October 2016 and a 12-month follow-up was performed (where available).[15] A group of patients was *naïve* to infliximab, another group switched Remicade to biosimilar infliximab CT-P13. The need of treatment discontinuation was left to the investigators' judgement, as well as concomitant medications including oral and topical aminosalicylates, steroids and immunosuppressants.

No adverse events were observed during follow-up, confirming the good safety profile of the drug.

The authors concluded that biosimilar IFX CT-P13 was effective in real life even when managed in primary IBD centres. They argued that their results were better, regarding clinical response, mucosal healing and clinical remission, than those reported in literature. However, it should be noted that the reported efficacy derives from a *per protocol* analysis: the data of 100% of clinical remission and of mucosal healing come from the only 6 (of 29 enrolled) patients that concluded the 12 months follow up. The data from an *intention to treat* analysis, when all the patients will have concluded the follow up, or at least more details on why other patients have stopped taking infliximab, will be of great clinical interest.

In conclusion, data from randomised clinical trials and from primary IBD centres are in the right direction to provide us more data on the equivalence between infliximab originator and the biosimilar infliximab CT-P13, but larger cohort and *intention to treat* analysis are needed to obtain the definitive answer.

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