Switching from originator infliximab to biosimilar CT-P13 as maintenance therapy: Do we have sufficient data in Crohn's disease?

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Dear Editor,

in a recent trial the authors[1] evaluated, after switching from infliximab originator to infliximab biosimilar (CT-P13), the efficacy as maintenance therapy in several inflammatory diseases. Due to its health and economic involvements this is an issue of actual debate in literature.[2-4]

The authors calculated that 394 patients were required in the per protocol set to exclude a difference in favour of infliximab originator of more than 15%. For the originator the risk difference of disease worsening, after 52 weeks of follow up, was -4·4% (95% CI -12·7 to 3·9).

The presumption of the study should be that, being involved patients with a diagnosis of CD, ulcerative colitis, spondyloarthritis, rheumatoid arthritis, psoriatic arthritis or chronic plaque psoriasis on stable treatment with infliximab originator, the conclusions should be extended to all individual pathologies. The case of Crohn's disease (CD), however, is paradigmatic. Among the 175 patients affected by CD the risk difference of disease worsening was -14.3% (95% CI -29.3 to 0.7), close to the threshold of 15% definite clinically significant. The authors themselves highlighted that the study was not powered to show non-inferiority in individual diseases. Furthermore, with a difference so close to the threshold it could be useful to report in the main text not only this data from the per protocol analysis, but also from the more stringent intention to treat analysis.

In conclusion, data from this trial help us in the management of patients with inflammatory diseases treated by infliximab but, at least for CD, these results do not definitively resolve the issue of the equivalence between originator and CT-P13 in the individual diseases.

We declare no competing interests.

References

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