155

SCIENTIFIC LETTERS

Effectiveness and safety of switching to adalimumab biosimilar ABP 501 in Crohn's disease: the extrapolation concept

Keywords: Amgevita. Amjevita. Inflammatory bowel disease.

Dear Editor,

We sincerely thank Viscido et al. (1) for their appropriate and sharable comments on our recent study on adalimumab biosimilar ABP 501 in Crohn's disease (CD) (2). The use of a biosimilar in inflammatory disorders is one of the current main topics, given the great opportunity to save resources that can be invested in innovative drugs and the ethical problems that non-medical switching can generate (3).

We completely agree with Viscido et al. (1) that the process of authorization of biosimilars by regulatory agencies is highly regulated (4). However, we would like to underline the fact that the use of biosimilar of adalimumab in CD is now widespread in the clinical practice, without randomized controlled trials in CD (for example for ABP 501). This is a noteworthy fact, that the concept of extrapolation is unique to biosimilars.

Like Viscido et al. (1), we conclude that the use of biosimilars approved by regulatory agencies is desirable in both naive and experienced patients. However, we would also like to underline that studies about their efficacy and safety in inflammatory bowel diseases are equally desirable. Finally, the doctor must be the last decision maker about the therapy in the patient, whilst taking into account a conscientious use of resources. For example, patients with unstable disease in which a change of therapy is expected should maintain the drug currently in use.

Davide Giuseppe Ribaldone[1], Marta Vernero[2] and Marco Astegiano[3]
[1]Department of Medical Sciences. University of Turin. Turin, Italy.
[2]First Department of Internal Medicine. IRCCS Policlinico San Matteo. University of Pavia. Pavia, Italy. [3]Department of General and Specialist Medicine. Gastroenterologia-U. Città della Salute e della Scienza di Torino. Turin, Italy

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