



# Endoscopic assessment and current topics of treatment of inflammatory bowel disease

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Biosimilars are defined as biologic products that are highly similar to reference products, notwithstanding minor differences in clinically inactive components, with no clinically meaningful differences between the biologic product and the reference product in terms of safety profile, purity, and potency. Due to the high cost of innovator biologics, as well as an increase in the number of these products reaching patent expiry, the development of a process for approving biosimilar products has become a crucial regulatory issue in the USA. Introducing competition to decrease the costs of biologics is an important component of an overall strategy to reduce healthcare costs worldwide. In 2014, total drug expenditure in the USA grew by 12% compared to the total expenditure in 2013, and it has grown by 7-9% in 2015. A major driver of this growth has been the use of biological medications; 14 of the top 15 medicinal products by total US expenditures administered in clinics were biological agents, at a cost to the US health system of nearly \$ 19 billion. Within hospitals, biologics represented nine of the top 15 expenditures in 2014, totaling \$ 4.5 billion. This economic argument justified the search for cheaper biosimilar products, but it is necessary to demonstrate

the therapeutic and safety equivalence. The establishment of regulatory processes for structurally complex drugs such as biosimilars is a longstanding challenge that has become increasingly urgent due to rapid technological advances and the expiration of innovator patents in this class. However, the variation among and between originator biologics and their biosimilars is an attribute of their molecular complexity and the manufacturing processes that contribute to their heterogeneity. Regulatory processes seek to quantify and understand these effects. Currently, the question of how similar a biosimilar must be to a reference drug to gain approval cannot be answered by any single standard set of methodologies. For this reason we welcome, in this issue, the paper of Biosimilar Monoclonal Antibodies: Considerations for Gastroenterologists, by Serra-Bonett and Faccin, which discusses the relevant aspects to take into account about the equivalence and extrapolation of biosimilar biologics in intestinal disorders.

Approximately 70% of patients with Crohn's disease undergo surgical resection for the treatment of medically refractory disease or its complications during their lifetime. The sickest cohort of Crohn's disease patients experiences

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rapid postoperative relapse at the anastomotic site, which can lead to repeated surgeries. In this issue Kotze, et al. present another article about of how to approach the postoperative endoscopic recurrence of Crohn's disease. They carefully review the risk factors that predispose to relapse, and the different diagnostic strategies to early identify these patients and how to treat them, making a sound comparative analysis of the debate about the therapeutic options for prevention of postoperative endoscopic recurrence.

Galiano reviews the role of video capsule endoscopy in different clinical situations of inflammatory bowel disease (IBD) concerning the suspicion of IBD; established IBD; unclassified IBD; ulcerative colitis (including ileorectal anastomosis), as well as complications related to the use of video capsule endoscopy in IBD. In this review there is also discussion about the

advantages of device-assisted enteroscopy in patients with suspected Crohn's disease in order to take mucosal biopsies for histological analysis, as well as its utility in the treatment of dilation of Crohn's disease-related stenoses less than 4 cm and non-inflammatory that is safe and effective.

Finally, Veitia, et al. reviews the importance of adhering to treatment, and the implementation of motivational communication as a tool for improving the dialogue and cooperation between healthcare providers and patients. They also discuss the factors associated to adherence and the role of a multidisciplinary team in order to achieve a better quality of life in IBD patients.

In conclusion, these topics are very helpful in order to improve the monitoring and to achieve the treatment goals in patients with IBD in order to obtain a good quality of life and to avoid complications, hospitalizations, and surgeries.