SESSION 3

Biosimilars: Where are we now?

HOW SHOULD CANADIAN IBD DOCS BE USING BIOSIMILARS?

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In the last two decades, the treatment of IBD has been revolutionized by the introduction of biologic therapies; however, their use is associated with high costs and access to these agents varies among countries. One possibility to reduce costs and increase access is the use of biosimilars. CT-P13 was the first biosimilar infliximab, approved by the European Medicines Agency (EMA) in 2013 and the U.S. Food and Drug Administration (FDA) in 2016. Data have quickly accumulated with this agent in IBD. Short- and long-term data from real-life IBD cohorts and an international, randomized, controlled trial in Crohn's disease demonstrated similar outcomes in terms of efficacy, safety, pharmacokinetics and immunogenicity compared to the originator product. Furthermore, one-way switching from the originator to biosimilar infliximab seems to be safe, and efficacy seems to be maintained after switching according to results from the NOR-SWITCH study and real-world trials from the UK and the Netherlands. Development and approval of additional biosimilars is underway, including a second infliximab biosimilar (SB2) and multiple adalimumab biosimilars. The real question for the near future is acceptability of non-medical switch and interchangeability. Biosimilars represent less expensive treatment choices. The price of available biosimilar infliximab is approximately 30% to 60% lower than the original product, which provides the potential for cost savings and/or increased access. The use of the biosimilar infliximab in IBD is increasing worldwide. Nonetheless, therapeutic algorithms and positioning of old and new biologics will become more complex with the advent of biosimilar era.

References

Jørgensen KK, Olsen IC, Goll GL, et al; NOR-SWITCH study group. Switching from originator infliximab to biosimilar CT-P13 compared with maintained treatment with originator infliximab (NOR-SWITCH): a 52-week, randomised, double-blind, non-inferiority trial. *Lancet*. 201;389(10086):2304–16.

Gonczi L, Gecse KB, Vegh Z, et al. Long-term Efficacy, Safety, and Immunogenicity of Biosimilar Infliximab After One Year in a Prospective Nationwide Cohort. *Inflamm Bowel Dis*. 2017;23(11):1908–15.

Komaki Y, Yamada A, Komaki F, et al. Systematic review with meta-analysis: the efficacy and safety of CT-P13, a biosimilar of anti-tumour necrosis factor-α agent (infliximab), in inflammatory bowel diseases. *Aliment Pharmacol Ther*. 2017;45(8):1043–57.