Biosimilar switching not suitable for all patients

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The results of a study presented today at the European League Against Rheumatism Annual Congress (EULAR 2016) showed that when antibodies develop in response to the biological treatment Remicade (infliximab), they also cross-react with the biosimilar of infliximab (CT-P13: Inflectra or Remsima). These findings suggest that antibody-positive patients being treated with Remicade should not be switched to treatment with the biosimilar, since these antibodies will interact with the new drug and potentially lead to a loss of response. ,

Biosimilars are similar to biotechnologically created proteins, but have been approved after the patent for the original branded product has lapsed. Unlike chemically-created generic drugs, the biosimilar molecule is not identical to the original product; it is highly similar. Over the past decade, several biosimilars have been introduced into medicine with the goal of reducing treatment costs and increasing accessibility to therapy for patients. The first infliximab biosimilar in Europe is marketed under two brand names: Inflectra (made by Hospira) and Remsima (made by Mundipharma).

Biopharmaceuticals (or 'biologics'), such as infliximab, have revolutionised the treatment of many rheumatic diseases. However, some patients generate an immune response to such drugs, with the resultant antibodies potentially limiting their clinical efficacy and safety.3 Infliximab is a TNF-α inhibitor which, in the European Union, is approved as an effective treatment of various inflammatory rheumatic diseases, including rheumatoid arthritis, ankylosing spondylitis and

psoriatic arthritis.

"While most studies show there are no significant differences in clinical response between a biosimilar and the original product, some physicians and patient advocacy groups have expressed concern about how interchangeable they really are, and whether it is safe to switch from the brand name version to the biosimilar," said lead author Dr Daniel Nagore of Progenika Biopharma, Derio, Spain.

"Our results have shown that all the antibodies that developed in patients being treated with Remicade cross-reacted with the biosimilar. The presence of these anti-infliximab antibodies is likely to enhance clearance of the drug from the body, potentially leading to a loss of response, as well as increasing the risk of side effects. Therefore, in patients where biological infliximab is ineffective due to the presence of circulating antibodies, switching to its biosimilar will lead to the same problems," Dr Nagore concluded.

The study included 250 rheumatoid arthritis and spondyloarthritis patients undergoing Remicade treatment who had never been previously treated with the biosimilar, and 77 control patients. Using assays to assess concentrations of anti-infliximab antibodies, half (50.4%) of the Remicade-treated patients tested positive for anti-infliximab antibodies, and 100% of those who tested positive for anti-infliximab antibodies also exhibited antibody reactivity against the biosimilar.

These results are aligned with previous infliximab antibody data among patients with inflammatory bowel diseases being treated with Remicade. Further studies are now planned with biosimilar-treated patients to better assess the potentially different immune responses associated with biologics.

Provided by European League Against Rheumatism