

Proactive monitoring of inflammatory bowel disease therapy could prolong effectiveness

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Proactive monitoring and dose adjustment of infliximab, a medication commonly used to treat inflammatory bowel disease (IBD), could improve a patient's chances of having a long-term successful response to therapy, a pilot observational study at Beth Israel Deaconess Medical Center concludes.

The study, published in the journals.lww.com/ibdjournal/Abstracting_of.99411.aspx target="_blank">*Inflammatory Bowel Diseases*, evaluated the levels of [infliximab](#), an antibody designed to bind to and block the effects of TNF-alpha, an inflammatory protein found in high levels in [patients](#) with IBD, such as Crohn's disease and ulcerative colitis, and numerous other inflammatory conditions such as [rheumatoid arthritis](#) and psoriasis. More commonly known as Remicade, infliximab is one of four anti-TNF agents used to treat these inflammatory diseases when they do not respond to or are intolerant of conventional therapies.

Infliximab has a good record of inducing and maintaining remission of IBD in patients with moderate to severe disease. But the therapy has not proven durable in treatment, primarily, researchers believe, because of the body's formation of antibodies to the medication. Only two-thirds of patients initially respond to infliximab and at one year less than half of the patients remain in remission. Additionally, it is estimated that 10 percent of patients on infliximab will lose response to the drug each year. This is significant because it is often prescribed with the expectation that patients will remain on it indefinitely.

Proactive therapeutic monitoring of a drug is common in other clinical scenarios, including solid organ transplant. In 2009, with that standard in mind, BIDMC attending physician Adam S. Cheifetz, MD began monitoring infliximab levels in his IBD patients with the goal of gradually adjusting their dosing regimens to hopefully improve long-term efficacy and decrease toxicity.

The pilot observational study of 48 patients found proactive monitoring of infliximab concentrations resulted in a significantly better chance of continuing on therapy than in patients who received the standard treatment and dosing regimen. The main reasons for this seemed to be less disease recurrence and fewer infusion reactions in the group that underwent proactive trough concentration monitoring. The authors hypothesize that maintaining a target infliximab concentration prevents the formation of antibodies to the therapy, which are implicated in loss of response to the drug and infusion reactions.

"Currently physicians are not routinely checking infliximab levels," said Cheifetz, Director of Center for Inflammatory Bowel Disease at BIDMC and an Associate Professor of Medicine at Harvard Medical School. "In our study, patients who did not have proactive monitoring were three times more likely to stop infliximab. Therefore, we are proposing that all patients have routine monitoring of IFX concentrations and adjustment of dose based on the level, even if clinically well."

Cheifetz noted "this would be a huge paradigm shift for patients on IFX. Instead of just weight based dosing with empiric dose escalation for symptoms, we propose monitoring the serum drug concentrations and adjusting the dose to achieve a drug concentration within the therapeutic range."

The next step, he said, is verifying this with prospective studies as well as creating a pathway or algorithm for a provider to follow when

prescribing IFX. This novel approach may have ramifications for other [inflammatory diseases](#) including rheumatoid arthritis and psoriasis, as well as for other biologic therapies (such as Humira) used to treat these conditions.

Provided by Beth Israel Deaconess Medical Center

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