

IBD patients may stay healthier when doctors monitor medications before they lose efficacy

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Adam S. Cheifetz, MD, Director of the Center for Inflammatory Bowel Disease who is also an Associate Professor of Medicine at Harvard Medical School. Credit: BIDMC

In patients with inflammatory bowel disease (IBD), the body attacks the lining of the digestive tract. Up to half of patients who benefit from the first-line anti-inflammatory drug infliximab eventually stop responding



to it. When that happens, doctors may begin to monitor patients' blood serum concentrations of the drug.

Now, a team led by gastroenterologists at the Center for Inflammatory Bowel Diseases at Beth Israel Deaconess Medical Center (BIDMC) and University of Pennsylvania, has shown that monitoring patients treated with infliximab prior to loss of patient response to the drug is associated with better long-term outcomes than monitoring the drug only after it loses efficacy. The team's retrospective study could set the stage for a change in the standard clinical approach to IBD. Their data were published in the October issue of the journal *Clinical Gastroenterology and Hepatology*.

"IBD can lead to serious complications and a high rate of surgery despite medical therapy," said Adam S. Cheifetz, MD, Director of the Center for Inflammatory Bowel Disease who is also an Associate Professor of Medicine at Harvard Medical School. "We demonstrated that proactive drug monitoring is associated with better clinical outcomes, including less treatment failure, serious infusion reactions, and less need for IBD-related surgery or hospitalization, when compared to reactive drug monitoring."

A chronic, life-long condition that can manifest as severe pain, diarrhea, lack of energy, rectal bleeding and weight loss, IBD - which includes Crohn's disease and ulcerative colitis - affects over 1.5 million Americans. Infliximab reduces symptoms and inflammation by targeting one of the proteins - called tumor necrosis factor (TNF) - that leads to inflammation in IBD.

Eventually, about half the patients who take the drug stop responding to it but not all for the same reasons. Some patients eventually develop antibodies against infliximab and need to switch medications. Previous research by Cheifetz and others suggested that monitoring drug levels



prior to loss of efficacy could improve treatment outcomes.

For this multicenter retrospective study, Cheifetz and colleagues analyzed the long-term outcomes of 264 patients with IBD on infliximab maintenance at either BIDMC or University of Pennsylvania hospitals, just under half of whom were monitored proactively. Of those, only 13 percent of patients experienced a treatment failure - defined as loss of response to infliximab or need for IBD-related surgery. In contrast, two-thirds - a full 66 percent - of the 134 patients undergoing reactive drug monitoring experienced treatment failure.

In addition, the probability and length of a hospital stay was much lower among patients being proactively monitored. Just seven percent of these patients had IBD-related hospitalizations, compared to a quarter of patients undergoing reactive monitoring. The total hospital stay was also much shorter among the proactively monitored patients; 37 days compared to 189 days for the reactive group.

"Prolonging infliximab's efficacy and avoiding surgery and hospitalization is very important for patients with IBD," said Cheifetz. "Proactive monitoring is the standard of care in my practice and that of [co-senior author] Mark Osterman, MD, and I think it would benefit the vast majority of patients on infliximab and similar biologic medications."

To follow up, Cheifetz and his colleagues will conduct a similar analysis comparing outcomes for reactive versus proactive monitoring of another <u>drug</u> used in the treatment of IBD, adalimumab.

"Large, prospective studies are needed to confirm these results," he said.

Provided by Beth Israel Deaconess Medical Center



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