

Early introduction of biologic therapy improves Crohn's disease outcomes

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A large-scale study of medical claims data shows that introducing sophisticated biologic therapies early in the course of treatment for Crohn's disease improves response to medication and reduces the need for surgery.

There is no known cure for Crohn's disease, and traditional treatment is focused on a "step-up" strategy of managing inflammatory symptoms, starting with simpler and less costly oral medications such as aminosalicylates (5-ASAs) and corticosteroids, and escalating through a series of steps to more expensive biological therapies that target specific proteins in the immune system's [inflammatory response](#).

David Rubin, MD, associate professor of medicine and co-director of the University of Chicago Medicine's [Inflammatory Bowel Disease Center](#), studied a newer "top-down" strategy that reverses this order of treatment. He found that [patients](#) treated with biologic therapies earlier were significantly less likely to need [steroids](#), lose response to their biologic therapy, and require surgery related to their Crohn's disease. "We're essentially reversing the management strategy in Crohn's disease," Rubin said.

He emphasized that the medications often used first for patients with Crohn's are also the least effective and carry risks for side effects. "We've long discussed and debated that 5-ASAs don't work in the majority of Crohn's patients, and certainly don't change any outcomes," he said. "Steroids are ineffective long-term and are also dangerous

because they have significant side effects such as infections."

Crohn's is a disorder in which the body's immune system appears to have lost the ability to regulate itself and becomes overactive, causing progressive damage to the bowel structure and function. Patients often need [bowel surgery](#) to repair this damage. Researchers have made great progress finding genetic and environmental contributors to Crohn's disease, but the actual cause is unknown.

Rubin said that physicians have questioned the effectiveness of the step-up strategy because patients experience little relief while being treated with medications before they receive the biological therapies. During that time, they suffer from active disease, have low rates of remission and often appear to lose response to the biological therapies.

In recent years a treatment strategy that starts with the targeted biologic therapy as a first option has been explored in controlled clinical trials. The encouraging results suggested that such an approach results in higher remission rates. However, it was not clear whether this top-down approach would translate to the general population of patients with Crohn's disease, or whether such an approach would maintain the response to biologic therapy and decrease the need for surgery.

The Food and Drug Administration approved the first targeted biologic therapy for Crohn's disease in 1998 and the second two in 2007 and 2008. Rubin said physicians are hesitant to prescribe them earlier because they are expensive, must be administered through injections instead of pills and are typically saved until last. "Patients and doctors are nervous about immune suppressive therapies. The perception in the current treatment algorithm is that the therapies saved for last must also be the most dangerous," he said. "But that's the wrong thinking, and by delaying their prescription it may be a self-fulfilling prophecy because by then patients have suffered more damage to their bowels and are less

likely to respond favorably."

In the study, published in the journal *Inflammatory Bowel Diseases*, Rubin and his colleagues analyzed health insurance claims from a database that includes records from more than 94 commercial health plans throughout the United States. Patients eligible for the study had to be enrolled in the same health plan continuously for at least six months before the first claim related to Crohn's and stay enrolled for at least 12 months after the first claim for anti-TNF treatments.

Rubin then separated these patients into three groups: those who followed the traditional step-up therapy starting with 5-ASAs or [corticosteroids](#) before anti-TNF treatment, those who had immunosuppressive therapy (but not 5-ASAs) before anti-TNF treatment, and those who started anti-TNF treatment within 30 days of their first prescription for Crohn's disease.

In general, the group that started anti-TNF treatment early had significantly lower rates of continuous steroid use to treat flare-ups than the other groups, lower rates of escalation of dosage for their medications and needed fewer surgeries related to Crohn's disease. "This is the first time we did a large assessment of the top-down, early-TNF strategy using claims databases," Rubin said. "It gave us lots of detail and lots of information, much larger than with a controlled trial. We could look at hundreds of thousands of patients in order to get a big picture of how effective these approaches are in treating Crohn's. It's also the first time we were able to examine surgical outcomes associated with this strategy."

"Having a new class of therapies and having a culture change in GI takes a lot of discussions," he said. "This paper contributes to the discussion about how important this kind of [treatment](#) is because it changes the outcomes for people suffering from [Crohn's disease](#)."

Provided by University of Chicago Medical Center

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