New hope for patients after vedolizumab found effective to treat chronic pouchitis

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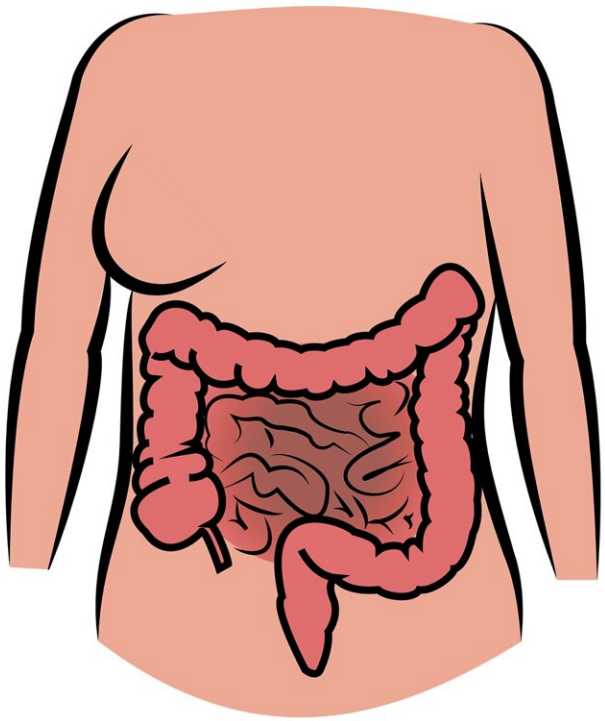

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A new study led by Oxford researchers has found vedolizumab can induce remission in patients who have chronic pouchitis after surgery for ulcerative colitis.

Twelve percent of people with ulcerative colitis need surgery to have their colon removed (colectomy). Most of those have an ileo-anal pouch surgically constructed from their small bowel, which means that they don't have to live with a stoma bag. Sadly, after surgery there is a risk of inflammation developing in the lining of the pouch, a condition known as pouchitis. Antibiotics are the first line treatment to reduce the inflammation, but one fifth will go on to develop chronic, antibiotic-refractory pouchitis.

Simon Travis, Professor of Clinical Gastroenterology at the Kennedy Institute, University of Oxford, and the Translational Gastroenterology Unit, John Radcliffe Hospital, ran an international randomized trial to evaluate the effect of vedolizumab on chronic pouchitis, sponsored by Takeda.

Professor Travis explained, "Vedolizumab is widely used for treating ulcerative colitis and this study shows that it is effective for pouchitis that recurs rapidly or persists in spite of antibiotics. Vedolizumab has become the first treatment in Europe licensed for pouchitis that does not respond to antibiotics. That's a game changer for these patients."

Published in the *New England Journal of Medicine* (*NEJM*), the trial randomized 102 adults who had developed chronic pouchitis after colectomy. Half the patients were assigned to receive 300mg of vedolizumab, the other half a placebo, administered at day 1, and weeks 2, 6, 14, 22 and 30. Both groups also received ciprofloxacin from weeks one to four.

The study team measured remission at week 14, based on the modified Pouchitis Disease Activity Index (mPDAI) that includes symptoms and endoscopy. Those patients receiving vedolizumab were three times more likely to achieve remission ay week 14 than those receiving placebo. A significant difference was found in key secondary endpoints, such as

remission at week 34, remission defined by the full PDAI (which includes histology), sustained remission (at both week 14 and week 34) and quality of life.

Professor Travis commented, "It's an awful thing for patients to get pouchitis after suffering such severe ulcerative colitis that they need surgery, which they thought would solve their bowel condition. The EARNEST trial of vedolizumab is really encouraging, because the treatment clearly works. In subsequent research we have shown that vedolizumab significantly improves mucosal healing in pouchitis. Vedolizumab is available for treatment of ulcerative colitis and Crohn's disease in the UK, Europe and around the world."

More information: Simon Travis et al, Vedolizumab for the Treatment of Chronic Pouchitis, *New England Journal of Medicine* (2023). DOI: 10.1056/NEJMoa2208450

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