



AMERICAN COLLEGE OF GASTROENTEROLOGY

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Fecal Microbiota Transplants Effective Treatment for *C. difficile*

Long-Term Follow-Up of Potentially Life-Saving Procedure Provides Further Evidence of Efficacy

Washington, DC (October 31, 2011) – Growing evidence for the effectiveness of fecal microbiota transplants as a treatment for patients with recurrent bouts of *Clostridium difficile* (*C.difficile*) associated diarrhea is presented in three studies -- including a long-term follow-up of colonoscopic fecal microbiota transplant (FMT) for recurrent *C. difficile* Infection that included 77 patients from five different states-- unveiled today at the American College of Gastroenterology's (ACG) 76th Annual Scientific meeting in Washington, DC.

In a fourth study, investigators from the Centre for Digestive Diseases in Australia explored fecal bacterial transplantation as a treatment for Inflammatory Bowel Disease. While this is a new area of research, results of this study show success in treating three cases of IBD when the fecal transplant is done recurrently.

The first study, "***Long-term Follow-up of Colonoscopic Fecal Microbiota Transplant (FMT) for Recurrent C. difficile Infection (RCDI)***," included 77 patients from five different states (RI, NY, OK, CA,WA) who previously had a colonoscopic fecal microbiota transplant at least three months ago for recurrent *C. difficile* infection, and found that FMT was successful in 70 out of 77 patients (91 percent) who were on average elderly, debilitated and had undergone multiple failed treatments, including antibiotic and probiotic therapies. Additionally, in six of the remaining seven patients, a single two-week course of vancomycin or a two-week vancomycin course plus one further FMT resulted in cure (98 percent).

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“Many of these patients we followed up with had been ill for a long time, but once they underwent the fecal microbiota transplant their response to the treatment was quick and their symptoms improved on average in about six days,” said investigator Mark H. Mellow, MD, FACG, of INTERGRIS Baptist Medical Center in Oklahoma. The average duration of illness for these patients was 11 months, but after the procedure patients continued to improve and --without subsequent antibiotic treatment--did not have a recurrence of *C. difficile* infection during follow-up (on average, 17 months), according to Dr. Mellow and his team of co-investigators which included a leading pioneer of fecal microbiota transplantation, Lawrence J. Brandt, MD, MACG, of the Albert Einstein College of Medicine in New York.

Results from a meta-analysis by researchers at the University of Toledo Medical Center were also unveiled today, providing further evidence of the effectiveness of fecal microbiota transplantation.

“Fecal Bacteriotherapy Works for Clostridium difficile Infection –A Meta-Analysis,” reviewed the cases of 148 patients who had received fecal transplants for *C. difficile* infection. Follow-up ranged from 10 days to 62 months after the transplant, with an average follow-up of 1 year. Fecal transplant had an overall success rate of 85.4 percent, according to researchers, who also concluded that the procedure was a safe and effective treatment option for *C. difficile* infection.

Clostridium difficile is a bacterium that causes infection leading to diarrhea and is most often related to antibiotic use during medical treatment. A major cause of morbidity and increasing health care costs among hospitalized patients, *C. difficile* infections have dramatically increased in recent years, with 500,000 cases in the United States annually and approximately 15,000 deaths each year, according to the U.S. Centers for Disease Control & Prevention. Up to 25 percent of patients will have a recurrence of *C. difficile* infection, and a proportion will be refractory to antibiotics. *C. difficile* is especially dangerous for patients with weakened immune systems such as the elderly and those with Inflammatory Bowel Disease (IBD). Therapies for this difficult-to-treat subpopulation include antibiotics, probiotics, toxin-binding medications, active vaccination, intravenous immunoglobulin, and fecal microbiota transplant, for which the evidence has been mounting as an effective rescue for recurrent and refractory cases of *C. difficile* associated diarrhea.

“While the concept of fecal transplantation may sound unpleasant to some, patient acceptance of this treatment is growing, especially when they have been suffering for months with recurrent *C. difficile*,” said Dr. Mellow. “When we asked patients in our study about their choice of treatment if their infection recurred, 53 percent said fecal transplant would be their first choice for treatment.”

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In a related study also unveiled today, ***“Clostridium Difficile Infection in Ulcerative Colitis: Increased Risk of Colectomy and Postoperative Infectious Complications,”*** researchers from the University of Calgary found that patients with ulcerative colitis who were diagnosed with *C. difficile* were significantly less likely to respond to medical treatment and as a result require a colectomy when they diagnosed with *C. difficile* in the hospital or within 90 days of admission. In addition, patients with ulcerative colitis who had concomitant *C. difficile*, preoperatively were at a higher risk of infectious complications following a colectomy.

Researchers Explore Fecal Microbiota Transplantation in IBD

With the growing success of fecal transplantation for *C. Difficile*, researchers have started to explore the effectiveness of this procedure for other serious conditions, such as Inflammatory Bowel Disease (IBD). A second study, ***“Reversal of Inflammatory Bowel Disease (IBD) with Recurrent Fecal Microbiota Transplants (FMT),”*** reports successful treatment of severe mixed IBD using recurrent fecal microbiota transplants in three patient cases.

- In Case 1, a 19-year old female with an 11-year history of severe IBD and who presented with worsening symptoms including bloody diarrhea and inflamed, ulcerated mucosa, and was considering a colectomy, experienced symptom improvement within several days after receiving FMT. She underwent FMT initially via colonoscopy in July 2009 then by seven daily rectal FMT and 26 weekly FMT's. Follow-up colonoscopy revealed no gross inflammation or edema, with the patient remaining clinically well.
- In Case 2, a 23- year old male with a five-year history of steroid and anti-TNF α refractory ulcerative colitis presented with bloody diarrhea more than 20 times per day, anal fissures, severe abdominal pain and joint pain. Pre-FMT colonoscopy – showed severe disease of the left colon with marked cecal inflammation. He underwent daily rectal FMT for the first month, followed by infusions of lessening frequency until he reached 1 FMT/6 weeks. He reported resolution of bleeding 1-2 weeks post-FMT, and formed stool at 1 month post-FMT, resumed work, study activities and regained weight. Colonoscopy at one year showed no histological inflammation but occasional pseudopolyps in the cecum and ascending colon.

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- In Case 3, a 57-year old female with a nine- year history of 5-ASA antibiotics, probiotics and immunosuppressant refractory ulcerative proctitis in spite of treatment. After training in our clinic, she performed 69, initially daily, then weekly rectal FMT with virtually immediate resolution of diarrhea, bleeding and mucus. Follow-up colonoscopy showed no visible or histological inflammation and she has remained off all therapy for the last four years.

FMT may act as an antagonist to etiological infective agent(s) and aid in re-establishing depleted bacterial species, thereby reversing IBD, according to researchers from the Centre for Digestive Diseases in Australia.

Commenting on the cases of FMT in IBD, lead researcher Thomas Borody, MD, PhD, FACP, said, “the rapid response of FMT and lack of adverse effects make FMT a viable option for treatment-refractory patients and is certainly an added option for those facing colectomy.”

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About the American College of Gastroenterology

Founded in 1932, the American College of Gastroenterology (ACG) is an organization with an international membership of more than 12,000 individuals from 80 countries. The College is committed to serving the clinically oriented digestive disease specialist through its emphasis on scholarly practice, teaching and research. The mission of the College is to serve the evolving needs of physicians in the delivery of high quality, scientifically sound, humanistic, ethical, and cost-effective health care to gastroenterology patients. www.acg.gi.org View releases on other research breaking at the ACG meeting at www.acg.gi.org/media/press.asp [Follow ACG on Twitter](#)