

**TITLE:** Long-term Follow-up Study of Fecal Microbiota Transplantation (FMT) for Inflammatory Bowel Disease (IBD)

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**BODY:**

**INTRODUCTION:** The role of intestinal dysbiosis in the pathogenesis of IBD is being increasingly appreciated. FMT restores fecal microbiome diversity in patients with *C. difficile* infection (CDI) and has resulted in impressive cure rates. It is possible that FMT can have a similar therapeutic benefit in IBD.

**METHODS:** A long-term follow-up study was performed to determine the efficacy of FMT for refractory IBD. 16 of 21 patients who had FMT at Montefiore Medical Center between 2010-2012 for the treatment of refractory IBD were successfully contacted and completed a questionnaire soliciting pre- and post-FMT data.

**RESULTS:** 56% of patients were men (avg age: 39 yrs; range: 20-75 yrs). Follow-up period between FMT and data collection ranged from 4.5 to 30 mos (avg: 14 mos). Patients had a diagnosis of IBD for an avg of 7.5 yrs (range: 1-33 yrs) before FMT. 14 (87%) had ulcerative colitis (UC) and 2 (13%) had Crohn's disease (CD). Initial FMT was by colonoscopy (n=15) or nasojejunal infusion (n=1) followed by self-administered fecal enemas (SAFE) in a tapered and then maintenance schedule. After FMT, 10 of 16 patients (63%) noted improved frequency of disease flares. 3 of these 10 patients did not have a flare during the follow-up period (avg: 21 mos; range 8-30 mos), while 7 patients had a reduction in the number of flares (pre FMT: 10.1 flares/yr; post-FMT: 2.8 flares/yr). No patient noted an increased number of flares after FMT. 9 patients (56%; 8 UC, 1 CD) reported decreased diarrhea (avg pre-FMT BMs/day: 8.2; avg post-FMT BMs/day: 3.6) while the remaining 7 patients (44%) had no change. Of 14 patients who had rectal bleeding (13 UC, 1 CD), resolution, decrease or no change in bleeding was reported in 4 (29%), 6 (43%), and 3 (21%) patients post-FMT, respectively; 1 patient (7%) noted increased bleeding post-FMT. Of 11 patients (69%) who reported abdominal pain, resolution, improvement or no change was seen in 5 (46%), 4 (36%) and 2 (18%) patients post-FMT, respectively. 12 patients (75%) reported weight loss prior to FMT and weight was maintained (n=8, 67%) or increased (n=4, 33%) in all after FMT. Of the 10 patients (63%) who were on oral steroids at the time of FMT, steroids were no longer required or required at decreased doses in 4 (40%) and 3 (30%) patients, respectively. TNF- $\alpha$  inhibitors were discontinued in 1 of 4 patients after FMT. Concomitant CDI was present in 4 UC patients who had the most improvement after FMT, and all were able to discontinue maintenance medications (steroids, n=3 and 6-MP, n=1). The only adverse event experienced after FMT was a transient worsening of abdominal distension in 3 patients (19%).

**CONCLUSIONS:** In this group of 16 patients with refractory IBD, FMT followed by SAFE resulted in improved symptoms and decreased medication requirements, especially in those with concomitant CDI.