Q/ How effective and safe is fecal microbial transplant in preventing *C. difficile* recurrence?

**Evidence-based answer**

Fecal microbial transplant (FMT) is reasonably safe and effective. In patients who have had multiple *Clostridium difficile* infections (CDIs), fecal microbial transplant (FMT) results in a 65% to 80% cure rate with one treatment and 90% to 95% cure rate with repeated treatments compared with a 25% to 27% cure rate for antibiotics (strength of recommendation [SOR]: B, small open-label randomized controlled trials [RCTs]).

Fresh and frozen donor feces, administered by either nasogastric tube or colonoscopy, produce equal results (SOR B, RCTs).

FMT has an overall adverse event rate of 30%, primarily involving abdominal discomfort, but also, rarely, severe infections (0.7%) and death (0.1%) (SOR: B, systematic review not limited to RCTs).

**Evidence summary**

An open-label RCT enrolled 41 immunocompetent older adults who had relapsed CDI after at least one course of antibiotic therapy.1 Investigators randomized patients to 3 treatment groups:

- vancomycin therapy, bowel lavage (with 4 L nasogastric polyethylene glycol solution), and nasogastric-infused fresh donor feces;
- vancomycin with nasogastric bowel lavage without donor feces; or
- vancomycin alone.

Researchers defined cure as the absence of diarrhea or 3 negative stool samples (if patients continued to have persistent diarrhea) at 10 weeks without relapse.

Thirteen of 16 patients (81%) in the donor feces infusion group were cured with the first infusion. Two of the 3 remaining patients were cured after a second donor transplant. FMT produced higher total cure rates than those of vancomycin (94% vs 27%; *P*<.001; number needed to treat [NNT]=2). Bowel lavage had no effect on outcome.

FMT cures more patients than vancomycin alone

An open-label RCT of 39 patients compared healthy-donor, fresh FMT given via colonoscopy with vancomycin alone for recurrent CDIs.2 Researchers recruited immunocompetent adults who had recurrent CDIs after at least one course of vancomycin or metronidazole.

Patients in the treatment group received a short course of vancomycin, followed by bowel cleansing and fecal transplant via colonoscopy. Clinicians repeated the fecal transplant every 3 days until resolution for patients with pseudomembranous colitis. Patients in the control group were treated with vancomycin for at least 3 weeks. Researchers defined cure as the absence of diarrhea or 2 negative stool samples (if patients continued to have diarrhea) at 10 weeks without relapse.

Thirteen of 20 patients in the FMT group (65%) achieved cure after the first fecal infusion. The 7 remaining patients received multiple infusions; 5 were cured. Overall, FMT cured more patients than vancomy-
Fecal microbial transplant cures 65% to 80% of recurrent *Clostridium difficile* infections with one treatment compared with a 25% to 27% cure rate for antibiotics.

A third of patients suffer adverse effects, but serious harms are rare

A systematic review analyzed 50 trials (16 case series, 9 case reports, 4 RCTs, 21 unreported type; 1089 FMT-treated patients) for adverse effects of FMT. Most patients (831) had CDIs, 235 had inflammatory bowel disease, and 106 had both conditions. Donor screening tests for FMT included viral screenings (hepatitis A, B, and C; Epstein-Barr virus; human immunodeficiency virus; *Treponema pallidum*; and cytomegalovirus), stool tests for *C difficile* toxin, and routine bacterial culture for enteric pathogens (*Escherichia coli*, *Salmonella*, *Shigella*, *Yersinia*, *Campylobacter*), ova, and parasites.

Overall, 28.5% of patients receiving FMT experienced adverse events. Upper gastrointestinal (GI) administration resulted in more total adverse events than did lower GI delivery (43.6% vs 20.6%; *P* value not given), mostly abdominal discomfort. However, upper GI delivery was associated with fewer serious adverse events than was lower GI delivery (2% vs 6%; *P* value not given). FMT possibly or probably produced serious infections in 0.7% of patients, and there was one colonoscopy-associated death caused by aspiration (0.1% mortality).

Recommendations

Guidelines published by the American College of Gastroenterology in 2013 listed FMT as a treatment option for patients who have had 3 episodes of CDI and vancomycin therapy (based on moderate quality evidence).

References

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