

Use of frozen material for fecal transplant successfully treats *C. difficile* infection

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A pilot study by Massachusetts General Hospital (MGH) investigators may lead to greater availability and acceptability of an unusual treatment for a serious medical problem – use of fecal material from healthy donors to treat recurrent diarrhea caused by the *Clostridium difficile* (*C. difficile*) bacteria. In their paper being published online in the journal *Clinical Infectious Diseases*, the researchers report that use of prescreened frozen fecal material from donors unrelated to patients was as successful in curing recurrent *C. difficile* infection as was the use of fresh material reported in previous studies of what is called Fecal Microbiota Transplant (FMT).

"We found that delivery of a frozen, stored inoculum through a nasogastric tube is safe, acceptable to patients and as successful as delivery by colonoscopy – which requires a preparatory 'clean out,' sedation or anesthesia, and is quite costly," says Elizabeth Hohmann, MD, of the MGH Infectious Diseases Division, senior author of the report. "Without this treatment option, patients with recurrent *C. difficile* may have chronic diarrhea – limiting their quality of life and their ability to maintain weight – and need to live on chronic antibiotic treatment, which is both expensive and can have other side effects."

C. difficile infection has become an increasingly serious problem, causing around 250,000 infections requiring hospitalization and 14,000 deaths each year in the U.S. Hohmann notes that from two to five patients test positive for the infection at MGH every day. In patients with recurrent or treatment-resistant infection, long-term treatment with

vancomycin or other antibiotics has had limited success, with symptoms recurring up to 30 percent of the time. In fact, antibiotic treatment has the potential of making matters worse, as it kills off the beneficial normal intestinal microbes that can keep pathologic species like *C. difficile* in check.

FMT probably treats *C. difficile* by restoring the normal balance of intestinal microbes. Previous animal and human FMT studies using fresh fecal material have had success rates of around 90 percent, but the MGH researchers note that recruiting and screening potential donors can be time-consuming and costly. Banking a supply of frozen, prescreened donor stool could significantly increase the availability of FMT, and the current study was designed to test the feasibility and effectiveness of such an approach, along with comparing two routes for delivery of the donor material.

Stool samples were donated by exceptionally healthy adults who received comprehensive screening for infectious diseases. Donors also were asked to refrain from eating any common allergens, such as nuts or eggs, in the days before donation. The donated fecal material was filtered, diluted, screened and frozen; stored for at least four weeks to allow retesting donors for any hidden infections; and prior to administration, thawed and kept refrigerated.

The study enrolled 20 patients – three of whom were children – who either had three or more episodes of mild to moderate *C. difficile* infection for which antibiotic treatment failed or had two episodes serious enough to require hospitalization. Participants were randomly divided into two groups – 10 who received donor material by standard colonoscopy and 10 who received it through a nasogastric tube (NGT) passed into the stomach. A single administration was successful in curing 14 of the 20 participants – 8 in the colonoscopy group and 6 in the NGT group, a difference not considered significant in such a small study.

Among those whose infections did not resolve, a single participant declined additional treatment. The other 5 received a second administration, which cured the infection in 4, for an overall success rate of 90 percent, similar to that of the previous studies. Participants who received the second infusion were allowed to choose the route of administration, and all chose to receive it via NGT.

Subsequently the researchers discovered that the participant who declined a second infusion was self-administering fecal enemas, using unprocessed material from his roommate, a practice Hohmann notes could be hazardous. "We certainly don't recommend 'home brew' FMT, since it's very important to screen donors properly. In addition, while some people may be comfortable using stool from a spouse or other intimate partner, many older patients might not have such a donor who is healthy enough to donate safely."

The research team also reports treating an additional 11 patients with frozen donor samples via NGT, achieving a 91 percent success rate, and they currently are investigating what may be an even more acceptable means of administration – via a capsule that would remain undigested until it reaches the small intestine.

"It's been very gratifying to be able to help these patients, some of whom have been sick for a year or two," Hohmann explains. "They have told us this has been life changing for them and that they have gotten themselves back to normal. There aren't many things in medicine that have a success rate of more than 90 percent. Insurers may not want to pay for this, but it is very effective, makes patients better quite quickly and saves money overall. While it may never become a first-line treatment, we are starting to consider using it more and more often," she adds.

Fast Facts:

1. A significant cause of life-threatening diarrhea, *Clostridium difficile* is responsible for 250,000 infections requiring hospitalization and 14,000 deaths in the U.S. each year. Relapsing infections are a serious problem.
2. This initial feasibility study found that using frozen stool from healthy, unrelated donors was safe and effective in treating a small group of patients with relapsing *C. difficile* infections, with an overall cure rate of 90 percent.
3. The treatment, known as fecal microbiota transplantation, appeared to be equally effective whether given via a colonoscope or a nasogastric tube.

Provided by Infectious Diseases Society of America

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