

Frozen stool pills may make fecal transplants simpler and safer, study finds

October 13 2014, by Karen Kaplan, Los Angeles Times

Would you swallow frozen stool in a pill? What if you were infected by a stubborn strain of *Clostridium difficile* and suffering from diarrhea bad enough to send you to a hospital?

Researchers are embracing the concept of treating repeat *C. difficile* infections with fecal transplants.

The idea is that a healthy person's stool contains the right mix of gut bacteria to keep the gastrointestinal tract running smoothly. By transplanting a sample from that microbiome into a person whose gut has been colonized by *C. difficile*, the recipient can get his or her GI tract back in working order.

Americans spend an estimated \$3.2 billion a year battling *C. difficile*, and the bacterium is involved in about 14,000 American deaths each year, according to the Centers for Disease Control and Prevention. Cases appear to be rising as antibiotic-resistant bacteria become more prevalent, so doctors are becoming more open-minded about unconventional treatments.

Several studies have demonstrated that the transplants really work. In a report published last year in the *New England Journal of Medicine*, researchers reported that CDI patients who got fecal transplants (in addition to bowel cleansing and the antibiotic vancomycin) fared far better than those who didn't. Of the 16 patients in the [fecal transplant](#) group, 13 infections cleared up after one treatment and two of the

remaining three patients got better after a second treatment [?] an overall cure rate of 94 percent. That compares with a 31 percent cure rate for CDI patients treated with the antibiotic alone and a 23 percent cure rate for patients who took the antibiotic and had a bowel cleansing.

In that study, patients received their transplants [?] a mixture of fresh stool and lightly salted water [?] through a nasal tube that delivered the solution directly into the small intestine. Patients had no chance to smell or taste the tested remedy.

Later that year, another research group presented preliminary results of a trial of fresh stool pills. In that study, fecal donors were relatives of the patients, and their stool was compacted into gelatin capsules. When the researchers presented their results at a meeting of infectious disease experts, they claimed success in 31 of the 32 patients they had treated.

Now a team from Massachusetts General Hospital, Boston Children's Hospital, Harvard Medical School and Tel Aviv University in Israel has gone a step further, as detailed in a study published online by the *Journal of the American Medical Association*.

Obtaining fresh stool samples isn't practical for patients who need treatment right away. Among other logistical hurdles, screening potential donors and their stool can take days or weeks. So they tested frozen stool pills that could be made in advance and stored until needed, like traditional medications.

The researchers collected [stool samples](#) from four healthy donors who hadn't taken antibiotics for at least six months. Their blood was screened for HIV, hepatitis A, B and C, and a bacterium that causes syphilis. In addition, their feces were tested for various intestinal pathogens. Four weeks after their donations, they were screened again for HIV and hepatitis B and C to be sure nothing was missed the first time around.

The donated stool was placed in a blender and mixed with saline, and then strained to remove large particles. The remaining "slurry" was concentrated and packed into capsules that contained about 1.6 grams of fecal matter apiece. Then the pills were kept frozen at 112 degrees below zero.

A total of 20 patients received the pills between July 2013 and January 2014. The patients, whose ages ranged from 11 to 89, had suffered at least three bouts of mild to moderate CDI or had at least two episodes that were severe enough to send them to a hospital. Before they tried the frozen pills, they were having diarrhea up to 30 times a day.

The volunteers swallowed 15 pills a day for two days in a row. For 14 of the 20 patients, that was enough to stop the diarrhea and keep it away for about eight weeks, though one patient relapsed.

The six patients who were still sick took another round of 30 pills about a week later. After that, symptoms were resolved for five of them.

Overall, the researchers reported, the pills led to "clinical resolution of [diarrhea](#)" in 90 percent of the patients. On average, it took four days for the pills to work. That's twice as long as in other studies that tested fecal transplants administered through nasal tubes or with a colonoscope.

The pills caused only mild side effects — cramping and bloating — in six patients, and all symptoms were resolved within three days. None of the 20 patients threw up after taking the [pills](#), according to the JAMA study.

Though the researchers described the results as preliminary, they said they could help make fecal transplants "accessible to a wider population of patients, in addition to potentially making the procedure safer."

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Citation: Frozen stool pills may make fecal transplants simpler and safer, study finds (2014, October 13) retrieved 19 November 2023 from <https://medicalxpress.com/news/2014-10-frozen-stool-pills-fecal-transplants.html>

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