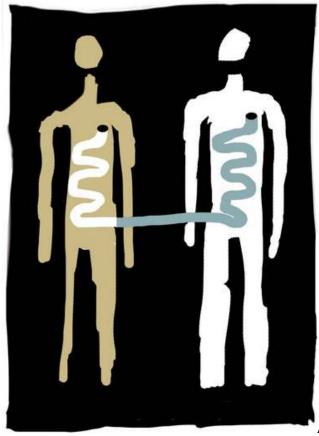


Fecal transplants being used to treat difficult C. diff cases

Diane Suchetka, The Plain Dealer 9-12 minutes



Andrea Levy, The Plain Dealer

CLEVELAND, Ohio -- For years, hospitals have struggled to help patients overcome the life-threatening gut infection

Clostridium difficile

, or C. diff, a stubborn bug that often won't respond to repeated rounds of antibiotics.

Now doctors are looking more and more to a treatment that has almost instant results in some of the sickest of patients.

The remedy operates on the premise that antibiotics wipe out beneficial bacteria that help people combat serious infections such as C. diff. And it puts that good bacteria back into their digestive tracts so they can overcome the disease.

The success rate is remarkable.

"Seventy-four percent of patients get better in three days," says <u>Dr. Lawrence Brandt</u>, a New York gastroenterologist who's been using the treatment since 1999. "But I've had patients who've felt better in three hours."

It's also less expensive than the most common treatment for recurrent C. diff, the heavy-duty antibiotic Vancomycin, which can cost patients about \$60 a pill, or \$1,200 for a 10-day course.

The only hitch: Many find the treatment repulsive.

It's called a fecal transplant, which means exactly what you think.

One reason people don't know about fecal transplants -- also called bacteriotherapy or human probiotic infusions -- is that access is not always easy.

Only about 15 doctors in the United States have made them an established part of their practices, says Dr. Colleen Kelly, a gastroenterologist who teaches at Brown University's medical school and has been performing fecal transplants for the past four years. None of the doctors on the list she keeps are from Ohio or any of the surrounding states.

There are a number of reasons why more physicians don't provide the treatment, says <u>Dr. Cliff</u> <u>McDonald</u>, a medical epidemiologist and senior adviser for science at the U.S. Centers for Disease Control's division of Healthcare Quality Promotion.

One, he says, is that it's so unappealing.

Transplants can be performed in a number of ways. Most often, doctors use a colonoscopy-like procedure, sedating a patient and depositing liquified, donated stool through a tube in the rectum. But sometimes they use a nasogastric tube, that goes through the nose, down the throat and into the gut. Other times, the stool is administered as an enema.

"And nobody in training teaches you how to do it," says Kelly, who practices at the <u>Women's Medicine</u> <u>Collaborative</u> in Providence, R.I. "My first one, I had no idea how to start."

Besides that, Kelly says, doctors can't always get the OK from the medical institution they're affiliated with.

"There's so much red tape. You have to bring it in front of so many people. And all it takes is one person saying, 'Hmm, I'm not comfortable with this.' "

But the big thing, McDonald says, is that no one has done a randomized, controlled trial.

Until now.

The doctor heading the new study is Kelly, who grew up in North Olmsted and graduated from the medical school at Ohio State University. She's working on it with Brandt, chief of gastroenterology at Montefiore Medical Center in New York, using a grant from the National Institutes of Health.

When the study is finished, sometime in 2014, about 50 patients will have undergone transplants, half using donor feces, and the other half, the control group, using their own. It's a double-blind study, so neither the patients nor the doctors will know who received which treatment.

"My real hope is that this study will provide the randomized, controlled, double-blind proof that people need," Kelly says. "And it will show that it is safe.

"So if [doctors] come up against a barrier at their hospital, they can say, 'Look, I have the science to prove it.' "

Researchers are recruiting patients for other fecal transplant studies in the United States and elsewhere. Some of those studies are looking into other uses for the procedure -- to treat <u>ulcerative colitis</u>, for example, or <u>inflammatory bowel disease</u> in children.

Shirley Kaiser hopes the study will help more people like her.

In August, Kaiser, who's 78 and lives in Harrison, in Ohio's southwest corner, drove 12 hours to the Mayo Clinic in Minnesota for a fecal transplant.

After eight years of severe C. diff-induced diarrhea, she couldn't believe how quickly she felt better.

"As soon as I got up off that gurney," she says. "And the next morning, my daughter said. 'Mom, you even look better.'

When her C. diff was bad, it made her so weak she couldn't walk her dog a half a mile down the street without having to sit on the curb to rest.

She threw away soiled clothes.

And she spent entire days in her bedroom. It was close to the bathroom and some days she had to race there four or five times. On her worst day, she counted 37 trips.

She tried Vancomycin -- she only had to pay \$30 of the \$1,100 cost for a 10-day supply -- but as soon as she stopped taking it, her symptoms were back.

Her transplant turned all that around.

Since she's had it, she hasn't been sick once.

"To me, it's just a miracle that I found people that could do this," Kaiser says.

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She wants to spread the word, she says, because she knows how frightening C. diff is.

The bacterium lives in the colon and produces hard-to-kill spores that cause cramps, abdominal pain and severe diarrhea in about 500,000 people in the United States a year.

It can lead to blood poisoning.

It can damage colons so badly they have to be removed.

And it kills.

Every year in the United States, an estimated 14,000 to 30,000 people die from the disease. And it's said to contribute to 100,000 additional deaths.

There's a reason it's such a troublemaker.

Because its spores are so hardy, they survive on bed sheets, countertops, hospital curtains and other surfaces where people can pick them up months or years later.

Most of us have trillions of healthy micro-organisms in our gut to fight it off. But for many people, C. diff strikes after a round of antibiotics has killed off good micro-organisms, leaving the body with little natural ammunition to fight the disease.

Doctors know that getting that good bacteria back into the colon takes care of the problem.

Yogurt and over-the-counter probiotics don't work because they contain so few strains of bacteria and they're not the strains believed to squelch C. diff.

That leaves doctors with the fecal transplant.

For now, the treatment isn't regulated by the <u>U.S. Food and Drug Administration</u>. But that could change in the future.

And it doesn't usually cost patients much. Because insurance doesn't typically cover the doctor's fee to administer the treatment, many doctors don't charge for it. Insurance often pays for office visits, the colonoscopy-like procedure to administer it and testing of the donor for HIV, hepatitis and other diseases.

It's been used in veterinary medicine for decades.

But as the incidence of C. diff began increasing in recent years, more and more doctors adopted it for human use.

Australian gastroenterologist <u>Dr. Thomas Borody</u> performed his first in the mid-1980s. The story, as detailed in the magazine <u>The Scientist</u>, began when a woman came to him with an inflamed colon that wasn't getting better. Borody began researching alternative treatments and stumbled upon a paper published in 1958 that described four cases in which a similar condition was treated with feces from healthy donors.

"So I looked at the method and kind of made up the rest of it," Borody told the magazine.

Within days, the woman's colitis was gone.

And it never came back.

In more recent years, researchers have published documentation of human use dating back to 4th-century China. Then, a well-known traditional Chinese medical doctor described giving patients liquefied feces to drink as a treatment for severe diarrhea and food poisoning.

Now with more doctors offering the treatment, there's more documentation of how well it works.

Doctors who have tracked their cases, report that about 90 percent of patients get better after the first transplant; 95 percent after a second one.

And because it's so successful, the medical community is searching for ways to make it more palatable.

<u>Dr. Alexander Khoruts</u>, a gastroenterologist at the <u>University of Minnesota Medical Center</u>, is one of the researchers trying to isolate the good bacteria that cures C. diff so that a more palatable treatment, such as an easy-to-swallow capsule, can be developed.

"As long as it's done the way it's done now," Khoruts says, "it's never going to move beyond the fringe."

Others are looking into the effect that the trillions of bacteria and other micro-organisms in our guts have on diseases such as <u>Parkinson's</u>, <u>autism</u> and <u>obesity</u>.

A study in mice, for example, found that lean mice that received fecal transplants from obese mice became fat. And a small study in humans indicates they might respond in the same way.

As Khoruts says, it will be decades before we know exactly how all the microscopic organisms in our guts affect our health.

"We could say in the 19th and 20th centuries, the biggest achievements were in conquering infectious disease," he says.

But with all this sanitation and hygiene and anti-bacterial everything, he says, we may have unleashed a slew of other diseases.

"This is the big question right now," he says.

"This is why everybody is so excited about this new frontier."

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