

FMT -An Effective Treatment for Gastrointestinal Diseases

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Abstract

FMT involves restoration of the colonic microflora by introducing healthy bacterial flora through infusion of stool, e.g. by colonoscopy, endoscopy, sigmoidoscopy, enema, orogastric tube or orally in the form of a capsule containing freeze dried material, obtained from a healthy donor.

Keywords: Faecal microbial transplantation, colonic microflora, bacterial flora, donor

Introduction

Faecal microbiota transplantation (FMT) also known as a stool transplant is the process of transplantation of fecal bacteria from a healthy individual into a recipient. FMT involves restoration of the colonic micro flora by introducing healthy bacterial flora through infusion of stool, e.g. by colonoscopy, endoscopy, sigmoidoscopy, enema, orogastric tube or orally in the form of a capsule containing freeze dried material, obtained from a healthy donor. A limited number of studies have shown it to be an effective treatment for patients suffering from *Clostridium difficile* infection, which can range from diarrhea to pseudomembranous colitis. Due to an epidemic of *C. difficile*, FMT has gained increasing prominence, with some experts calling for it to become first-line therapy for *C. difficile*. In 2013 a randomized, controlled trial of FMT from healthy donors showed it to be highly effective in treating recurrent *C. difficile* in adults and more effective than vancomycin alone. FMT has also had promising results with many gastrointestinal or auto-immune diseases, including constipation, Irritable Bowel Syndrome, Crohn's Disease, Ulcerative Colitis, multiple sclerosis and Parkinson's. It has also been used around the world to treat other conditions, although more research in other areas is needed. The Food and Drug Administration (FDA) has regulated human faeces as an experimental drug since 2013, the FDA announced it was classifying fecal matter as both an Investigational New Drug (IND) and a Biologic, and that only physicians currently in possession of an approved IND application would be allowed to continue performing fecal transplant.

Purpose: The purpose of fecal transplant is to replace good bacteria that has been killed or suppressed, usually by the use of antibiotics, causing bad bacteria, specifically *C. difficile colitis*, to over-populate the colon. *C. difficile* is a very serious infection, and the incidence is on the rise throughout the world. The communicable disease control (CDC) reports that approximately 347,000 people in the U.S. alone were diagnosed with this infection in 2012. Of those, at least 14,000 died. Some estimates place that number in the 30,000 to 50,000 range, if the U.S. used the same cause of death reporting

methods as most of the rest of the world. FMT is performed as a treatment for recurrent *C. difficile colitis*. *C. difficile colitis*, a complication of antibiotic therapy, may be associated with diarrhea, abdominal cramping and sometimes fever. Over the age of 65 and/or have chronic illnesses, there may be at higher risk for having more severe infection. The initial infection is treated with an antibiotic that specifically targets the *C. difficile*. Antibiotics used for the treatment of this infection include metronidazole, vancomycin and fidaxomicin. In 30 percent of treated individuals, the infection returns within a few days or weeks after finishing the antibiotic course. The recurrences are treated with another round of antibiotic therapy. However, in those individuals who continue to have recurrent *C. difficile colitis*, fecal transplantation is an option. A recent study published in 2013 in the *New England Journal of Medicine* showed that fecal transplantation is more effective than oral vancomycin in preventing further recurrences in individuals who have already had recurrent *C. difficile colitis*. fecal transplantation is currently not routinely performed for indications other than recurrent *C. difficile colitis*. More research studies are still needed to determine if fecal transplantation should be performed for other clinical indications. Fecal transplantation for other clinical indications should be considered experimental, and performed only as part of a research study where safety is closely monitored.

Requirements: Donors should not have had any antibiotic exposure in the past six months, immunocompromised, have had any tattooing or body piercing in past six months, have any history of drug use, have any history of high-risk sexual behaviour, have any history of incarceration, have recently traveled to endemic areas and have any chronic GI disorders, such as inflammatory bowel disease. And the potential donor will need to be screened by their physician for infectious pathogens such as Hepatitis A, B, and C, HIV, RPR, Ova and parasites.

Procedure: FMT is usually performed by colonoscopy and less commonly by nasoduodenal tube. During colonoscopy the colonoscope is advanced through the entire colon. As the

colonoscope is withdrawn, the donor stool is delivered through the colonoscopy into the colon.

Before the procedure, any antibiotic therapy should be stopped within two days before the procedure, a liquid diet followed by an enema or laxative preparation the night before scheduled procedure, any allergies and medical history should be verified. Fecal transplant was first documented in 4th century China, known as “yellow soup”.

It has been used for over 100 years in veterinary medicine, and has been used regularly for decades in many countries as the first line of defense, or treatment of choice, for *C. difficile*. It is customary in many areas of the world for a newborn infant to receive a tiny amount of the mother’s stool by mouth, thought to provide immediate population of good bacteria in the baby’s colon, thereby jump-starting the baby’s immune system. Fecal transplant has been used in the U.S., sporadically since the 1950’s, without much regulation. It has gained popularity in the U.S. in the past few years, although experts estimate that total number of treatments to date in the U.S. remains below 500 patients. This has resulted in more and more physicians beginning to perform fecal transplant, but there are still only limited numbers serving the large population needing the treatment. There are also many patients who do not have a donor to assist them. And there are many patients who have never even heard of this treatment, even though the success rate for treatment of recurrent *C. difficile*. is estimated to be well over 90%.

Side effects: *There is no serious side effect reported from FMT.* FMT is a low-cost, low-risk, highly effective treatment. The Fecal Transplant Foundation was created to raise awareness of this life saving treatment and to help patients and physicians.

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