Writing the Policy for Fecal Transplantation

Presented by
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What is Fecal Transplant

• Fecal transplant involves instilling stool from a healthy donor into the colon of a patient infected with C. difficile bacteria.
Indications

• To treat antibiotic–associated diarrhea, ulcerative colitis, and C. difficile associated diarrhea not responding to conventional treatment.
Risks Fecal Transplant

- Transmission of Infectious Organisms
- Allergic reaction to antigens in donor stool
- Enhanced colitis activity in patients with underlying IBD
- Perforation
- Blood Loss
Benefits of Fecal Transplant

• Documented success rate for FMT in the treatment of chronic or recurrent C. difficile disease is documented at over 90%.
Methods of Instillation

- Colonoscopy
- Nasogastric tube
- Enema
Process of Developing Policy for FMT

- Physician Champion
- Literature Review
- Present proposal to appropriate hospital Committees
- Present final proposal for approval
- Write and Implement Policy
Supportive Data for FMT

• C. difficile infection is an increasingly frequent cause of morbidity and mortality among elderly hospitalized patients.

• The initial treatment with antibiotic therapy results in 10% to 25% relapse in patients.

• Recurrence is usually treated with second course of antibiotics and up to 65% of those patients will suffer multiple relapses, despite maximal antibiotic therapy.
Primary Indications

• Recurrent or relapsing C. difficile Infection
• Moderate CDI not responding to standard therapy for at least a week
• Severe and fulminate C. difficile Colitis with no response to standard therapy after 48 hours
Recipient Exclusion Criteria

• Patients on major immunosuppressive or chemo agents

• Patients with decompensated liver cirrhosis, advanced HIV/AIDS, recent bone marrow transplant
Donor Exclusion Criteria

• HIV/AIDS, hepatitis B or C, known exposure to HIV or viral hepatitis within previous 12 months

• High risk sexual behavior, use of illicit drugs, tattoo or body piercing within 6 months

• Incarceration or history of incarceration
Donor Exclusion Criteria

- Major Immunosuppressive medication
- Known communicable disease, travel within the last 6 months to area of the world where diarrheal illness are endemic
- Hx of IBD/IBS, hx of G.I cancer, antibiotics within the preceding 3 months
Relative Exclusion Criteria

- History of major GI surgery
- Metabolic syndrome
- Systemic autoimmune, e.g., MS, connective tissue disease
- Atopic diseases, e.g., eczema, eosinophilic disorders of the GI tract
Donor Selection

- Spouse/Intimate partners
- Maternal line first degree relatives
- Volunteer donors
Donor Testing

• Stool for C. difficile, culture & sensitivity, ova & parasites
• Fecal Giardia antigen
• Fecal Cryptosporidium antigen
Donor Testing

- HIV type 1 and 2
- Hepatitis A IgM, and IgG
- Hepatitis B surface antigen, Hepatitis B Core antibody surface antigen, Hepatitis C antibody
- RPR and FTA -ABS
Donor Preparation

• Consider the use of a gentle osmotic laxative the night before procedure.
• Avoidance of any foods to which recipient may be allergic for 5 days prior to the procedure.
• Instructions to notify the practitioner if any symptoms of infection (fevers, *diarrhea*, *vomiting*) which occur between screening and time of donation.
Recipient Preparation

- Informed consent must be obtained for FMT procedure by the physician
- Large volume bowel prep the night prior to procedure. The severity of the patient’s illness may limit the ability to perform this step
Recipient Preparation

• Consider use of loperamide before the procedure to aid in ability to retain administered stool.

• If FMT is to be delivered by NGT, then a PPI must be given to the recipient the evening before and the morning of the procedure.
Preparation of Stool

• Use as soon as possible after passage, but certainly within 24 hours and preferable within 6 hours of passage. Stool should be kept in an airtight container and may be chilled but should not be frozen.

• Stool is prepared in the Microbiology Department under a hood
Preparation of Stool

• Universal precaution must be enforced. Those involved in mixing and/or handling the FMT material must wear a fluid-resistant gown, gloves, and mask with goggles or eye shield.

• A conventional household blender dedicated to the preparation of stool for FMT is used.
Preparation of Stool

• Stool specimen will be added to 250 ml to 300 ml of non-bacteriostatic normal saline and mixed in blender

• The suspension will be filtered twice with gauze pads, or urine strainer to remove as much particulate matter as possible

• The stool is homogenized, adding more diluent as necessary until it reaches a liquid consistency
FECAL MICROBIOTA PROCEDURE

• Set up is the same for colonoscopy or EGD
• 500 ml 0.9% Sodium Chloride
• 60 ml syringe/irrigation tubing and pump
• Stool suspension will be instilled into colon at the direction of the physician
• Stool suspension will be instilled via pump or manually, total 300ml to 500ml
Fecal Microbiota Procedure

- Via NGT x-ray is needed to confirm placement
- Total amount 50 ml to 70 ml, no more than 25 ml at a time
- Position patient 45 degree angle
- Patient should remain upright for 60 minutes post procedure
- Amount instilled and how patient tolerated procedure should be documented
Evaluation of Success

• Resolution of symptoms is the primary endpoint

• IDSA/SHEA guidelines do not recommend C. difficile testing in asymptomatic patients
Additional Information for Policy

• Who can perform procedure
• Different routes of instillation
• Specific locations where procedure may be performed
Barriers in Developing Policy

- Resistance from hospital committee members/Department
- Social stigma
- Lack of insurance coverage for donor testing
- Lack of an official FMT consent
- Time consuming
FYI

• Average cost for 10 day course of oral Vancomycin is approx. $680 and Fidaxomicin $2800

• Median cost per case of CDI is $8932 to 11,679

• Cost for FMT procedure estimated approx. $1590 and $3710

• Medicare $1590 and $1060
FYI

- C-difficile = $115
- Stool Culture = $159
- Giardia Antigen = $44
- Cryptosporidium = $66
- HIV Rapid 1&2 = $82
- O&P = $88
- Hepatitis Profile = $271
- RPR = $44
References


References

• Personal communication with Mary Reiner from Valley Hospital Laboratory Dept. 07/9/12