Treatment Update on
Fecal Microbiota Transplantation

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Disclosure

I serve as a paid medical monitor for Rebiotix
Objectives

• The “scope” of the problem
• Diagnostic criteria
• Microbiota primer
• Literature review
• Fecal microbiota transplantation protocol
• Future microbiota treatments
• Alternative uses
Abbreviations

• FMT - Fecal Microbiota Transplantation
• ASD - Autism Spectrum Disorder
• CDI - *C. difficile* infection
• MS - Multiple Sclerosis
• UC - Ulcerative Colitis
“All disease begins in the gut”

- Hippocrates
Far more could be done to stop the deadly bacteria C. diff

By Peter Eisler, USA TODAY

Little-known fecal transplant cures woman's bacterial infection

By William Hudson, CNN

updated 11:38 AM EDT, Thu September 27, 2012
The “Scope” of the Problem

• In 2010, the yearly incidence of CDI was estimated at 500,000

• Doubling of CDI diagnoses from 31/100,000 to 61/100,000 between 1996 to 2003

• Most common cause of nosocomial diarrhea

• 30-40% of all CDI cases are community acquired
The “Scope” of the Problem

- Mortality rate between 15-20,000 annually
- 400% increase in CDI deaths between 2000 and 2007
- 90% of deaths occur in patients > 65 years
- Half of all CDI occur < 65 years old
The “Scope” of the Problem

- Total additional health care utilization estimated up to $3.2 BILLION per year in the United States!!
PPI Risk

• 2 Meta analyses of pooled data from 23 and 39 studies noted an independent association between PPI use and increased risk of CDI

• Gut microbiome of PPI users versus nonusers reported changes in 20% of bacterial taxa which were consistent with changes known to predispose to CDI
Hypervirulent Strains

- NAP1/BI/027 strain
- 10x toxin A and 23x toxin B
- Binary toxin - more severe diarrheal illness
- Montreal, Pittsburgh, and Atlanta outbreaks
Pseudomembranes
Animal to Person Transmission

• C diff has been isolated from all mammals, some birds including poultry
• Associated with antimicrobial therapy in animals
• Outbreaks reported in vet hospitals
Hypervirulent Strains

- Ribotype 078
- Toxin A, B, Binary toxin
- Found in meat products
- 3rd most commonly isolated strain in community acquired disease
- Found in rural areas where pig farms were located
<table>
<thead>
<tr>
<th>Severity</th>
<th>SHEA/IDSA 2010</th>
<th>ACG 2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mild to Moderate</td>
<td>WBC &lt; 15K</td>
<td>Mild diarrhea</td>
</tr>
<tr>
<td></td>
<td>Cr &lt; 1.5 times premorbid level</td>
<td></td>
</tr>
<tr>
<td>Severe</td>
<td>WBC &gt; 15K or Cr &gt; 1.5 times premorbid level</td>
<td>Albumin &lt; 3 + WBC &gt; 15K or abdominal tenderness</td>
</tr>
<tr>
<td>Severe and Complicated</td>
<td>Hypotension or shock</td>
<td>ICU admission</td>
</tr>
<tr>
<td></td>
<td>Ileus</td>
<td>Hypotension</td>
</tr>
<tr>
<td></td>
<td>Megacolon</td>
<td>Fever &gt; 38.5 C</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Hypotension</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Mental status changes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Weiss</td>
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<tr>
<td></td>
<td></td>
<td>Megacolon</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Lactate &gt; 2.2</td>
</tr>
<tr>
<td></td>
<td></td>
<td>End organ failure</td>
</tr>
<tr>
<td>Severity</td>
<td>Criteria</td>
<td>Treatment</td>
</tr>
<tr>
<td>--------------------------------</td>
<td>--------------------------------------------------------------------------</td>
<td>----------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>Mild-to-moderate disease</td>
<td>Diarrhea plus any additional signs or symptoms not meeting severe or complicated criteria</td>
<td>Metronidazole 500mg orally three times a day for 10 days. If unable to take metronidazole, vancomycin 125mg orally four times a day for 10 days</td>
</tr>
<tr>
<td>Severe disease</td>
<td>Serum albumin &lt;3g/dl plus ONE of the following:</td>
<td>Vancomycin 125mg orally four times a day for 10 days</td>
</tr>
<tr>
<td></td>
<td>WBC ≥15,000 cells/mm³, Abdominal tenderness</td>
<td></td>
</tr>
<tr>
<td>Severe and complicated disease</td>
<td>Any of the following attributable to CDI:</td>
<td>Vancomycin 500mg orally four times a day and metronidazole 500mg IV every 8h, and vancomycin per rectum (vancomycin 500mg in 500ml saline as enema) four times a day</td>
</tr>
<tr>
<td></td>
<td>Admission to intensive care unit for CDI</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hypotension with or without required use of vasopressors</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Fever ≥38.5°C</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ileus or significant abdominal distention</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Mental status changes</td>
<td></td>
</tr>
<tr>
<td></td>
<td>WBC ≥35,000 cells/mm³ or &lt;2,000 cells/mm³</td>
<td></td>
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<tr>
<td></td>
<td>Serum lactate levels &gt;2.2mmol/l</td>
<td></td>
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<tr>
<td></td>
<td>End organ failure (mechanical ventilation, renal failure, etc.)</td>
<td></td>
</tr>
<tr>
<td>Recurrent CDI</td>
<td>Recurrent CDI within 8 weeks of completion of therapy</td>
<td>Repeat metronidazole or vancomycin pulse regimen</td>
</tr>
</tbody>
</table>

CDI, *Clostridium difficile* infection; FMT, fecal microbiota transplant; IV, intravenous; WBC, white blood cell.
<table>
<thead>
<tr>
<th>Antibiotic</th>
<th>Cost per dose</th>
<th>Regimen</th>
<th>Cost per 10-day regimen</th>
</tr>
</thead>
<tbody>
<tr>
<td>Metronidazole 500 mg</td>
<td>$0.73</td>
<td>500 mg three times a day</td>
<td>$22.00</td>
</tr>
<tr>
<td>Vancomycin 125 mg pills</td>
<td>$17.00</td>
<td>125 mg four times a day</td>
<td>$680.00</td>
</tr>
<tr>
<td>Vancomycin 125 mg IV compounded for oral</td>
<td>$2.50–$10.00</td>
<td>125 mg four times a day</td>
<td>$100.00–$400.00</td>
</tr>
<tr>
<td>Fidaxomicin 200 mg</td>
<td>$140.00</td>
<td>200 mg twice a day</td>
<td>$2,800.00</td>
</tr>
</tbody>
</table>

IV, intravenous.
Vancomycin IV form can be compounded for oral use as well as used for enema therapy.
FMT Definition

The instillation of stool from a healthy person to a sick person
Early History of FMT

4th century: Ge Hong described use of human fecal suspension by mouth for food poisoning or severe diarrhea

“Zghou Hou Bei Ji Fang” (Handy Therapy for Emergencies)

16th century: Li Shizhen detailed prescriptions of fermented fecal solution, fresh fecal suspension, dry feces or infant feces for abdominal diseases with diarrhea, abdominal pain, fever, vomiting and constipation. Fecal suspension was called “yellow soup”

“Ben Cao Gang Mu” (Compendium of Materia Medica)

17th century: veterinary medicine:

- **transfaunation** (transfer of cecal contents or fresh feces) from healthy horses to treat horses with chronic diarrhea

- **rumen transfaunation** to refaunate cows that have been off-feed because of mastitis or other illness
Beware the yellow soup!!
Later History of FMT

- **1983:** FMT enema (*Schwann, et al.* 65 y.o woman with CDI. “Prompt normalization” of symptoms within 24 hrs)
- **1991:** NG tube (*Aas, Gessert, Bakken*)
- **2000:** colonoscopy (*Persky, Brandt*)
- **2010:** self-administered enemas (*Silverman, Davis, Pillai*)
Understanding the Human Microbiota

Culture: 5-20%

Culture-independent Methods

- Bacterial 16S rRNA
- Sanger full-length pyrosequencing
- DNA fingerprinting
- DGGE
- TRFLP
- RISA
- DNA microarrays
- FISH
- qPCR
Vertical Heterogeneity
Vertical Heterogeneity

Vertical Heterogeneity

- 2 predominant phyla
  - Bacteroidetes 16%
  - Firmicutes 76%
- 4,000 species and $10^{14}$ bacterial cells
- Bacteria comprise 60% of dry weight of feces
Microbiota in CDI

Decreased Diversity of the Fecal Microbiome in Recurrent C. difficile

- Patients with recurrent C. difficile have decreased phylogenetic richness
- Bacteroidetes and Firmicutes are reduced in patients with recurrent C. difficile not in patients with just one episode of C. difficile infection


ACG 2012
Microbiota in CDI
This is Your Normal Gut Microbiota
This is Your Gut Microbiota after Recurrent C diff and Vancomycin Tapers
So Does FMT REALLY Work???
<table>
<thead>
<tr>
<th>Author</th>
<th>Year</th>
<th># cases</th>
<th>UGI</th>
<th>LGI</th>
<th>Cure (%)</th>
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<tbody>
<tr>
<td>Eiseman, et al</td>
<td>1958</td>
<td>4</td>
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<tr>
<td>Collins</td>
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<td>12</td>
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<td>12</td>
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<td>Fenton et al</td>
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<td>Lund-Tønnesen, et al</td>
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<td>Jorup-Rönström, et al</td>
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<td>-</td>
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<td>Louie, et al</td>
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<td>Nieuwdorp, et al</td>
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<td>You, et al</td>
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<td>Helleman, et al</td>
<td>2009</td>
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<td>1</td>
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<td>MacConnachie, et al</td>
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<td>15</td>
<td>-</td>
<td>100</td>
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<td>Khoruts, et al</td>
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<td>1</td>
<td>-</td>
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<td>Silverman, et al</td>
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<td>-</td>
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<td>Yoon, Brandt</td>
<td>2010</td>
<td>12</td>
<td>-</td>
<td>12</td>
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<td>Rohlke, et al</td>
<td>2010</td>
<td>12</td>
<td>-</td>
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<tr>
<td>Garborg</td>
<td>2010</td>
<td>40</td>
<td>38</td>
<td>-</td>
<td>83</td>
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<tr>
<td>Mellow</td>
<td>2010</td>
<td>13</td>
<td>-</td>
<td>13</td>
<td>92</td>
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<tr>
<td>Russell, et al</td>
<td>2010</td>
<td>1</td>
<td>1</td>
<td>-</td>
<td>100</td>
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<tr>
<td>Hamilton, et al</td>
<td>2012</td>
<td>43</td>
<td>-</td>
<td>43</td>
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<tr>
<td>Mattila, et al</td>
<td>2012</td>
<td>70</td>
<td>-</td>
<td>70</td>
<td>100</td>
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<tr>
<td>Total</td>
<td></td>
<td>434</td>
<td>81</td>
<td>6</td>
<td>347</td>
</tr>
<tr>
<td>Cure (%)</td>
<td></td>
<td>97</td>
<td></td>
<td></td>
<td>~93</td>
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</table>
FMT in Recurrent *C. difficile*  
(317 patients, 27 case series, 8 countries)

<table>
<thead>
<tr>
<th>Route</th>
<th>Resolution (92%)</th>
<th>Relapse (4%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>colonoscope (62)</td>
<td>55/62 (88.7)</td>
<td>3/55 (5.4)</td>
</tr>
<tr>
<td>enema, rectal tube (156)</td>
<td>149/156 (95.5)</td>
<td>5/149 (3.3)</td>
</tr>
<tr>
<td>EGD, NG tube (72)</td>
<td>55/72 (76.4)</td>
<td>2/55 (3.6)</td>
</tr>
<tr>
<td>&gt;1 method (21)</td>
<td>19/21 (90.5)</td>
<td>1/19 (5.3)</td>
</tr>
</tbody>
</table>

Re-Rx resolution rate (87.5%)

<table>
<thead>
<tr>
<th>Donor</th>
<th>Resolution (93.3%)</th>
<th>Relapse (3.6%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>related</td>
<td>195/209 (93.3)</td>
<td>7/195 (3.6)</td>
</tr>
<tr>
<td>- family member</td>
<td>34/39 (87.2)</td>
<td>2/24 (8.3)</td>
</tr>
<tr>
<td>- spouse/partner</td>
<td>23/24 (90.5)</td>
<td>2/15 (13.3)</td>
</tr>
<tr>
<td>unrelated</td>
<td>21/25 (84.0)</td>
<td>0/21 (0.0)</td>
</tr>
<tr>
<td>male</td>
<td>12/14 (85.7)</td>
<td>0/12 (0.0)</td>
</tr>
<tr>
<td>female</td>
<td>12/12 (100.0)</td>
<td>1/12 (8.3)</td>
</tr>
</tbody>
</table>

Gough, Shaikh, Manges. CID, 2012
# FMT in Recurrent *C. difficile*

(317 patients, 27 case series, 8 countries)

<table>
<thead>
<tr>
<th>Diluent</th>
<th>Resolution (92%)</th>
<th>Relapse (4%)</th>
<th>Re-Rx (87.5%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>normal saline</td>
<td>169/196 (86.2%)</td>
<td>5/169 (3.0%)</td>
<td></td>
</tr>
<tr>
<td>water</td>
<td>64/65 (98.5%)</td>
<td>5/64 (7.8%)</td>
<td></td>
</tr>
<tr>
<td>other (milk)</td>
<td>31/35 (88.6%)</td>
<td>1/31 (3.2%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Volume</th>
<th>Resolution (92%)</th>
<th>Relapse (4%)</th>
<th>Re-Rx (87.5%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;200</td>
<td>32/40 (80.0%)</td>
<td>2/32 (6.2%)</td>
<td></td>
</tr>
<tr>
<td>200-500</td>
<td>98/114 (86.0%)</td>
<td>4/98 (4.1%)</td>
<td></td>
</tr>
<tr>
<td>&gt;500</td>
<td>107/110 (97.3%)</td>
<td>5/107 (4.7%)</td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Stool weight</th>
<th>Resolution (92%)</th>
<th>Relapse (4%)</th>
<th>Re-Rx (87.5%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>&lt;50 grams</td>
<td>53/64 (82.8%)</td>
<td>2/53 (3.8%)</td>
<td></td>
</tr>
<tr>
<td>&gt;50 grams</td>
<td>100/116 (86.2%)</td>
<td>1/100 (1.0%)</td>
<td></td>
</tr>
</tbody>
</table>

Gough, Shaikh, Manges. CID 2011

ACG 2012

Annual Scientific Meeting • October 22-24, 2012
Duodenal Infusion of Donor Feces for Recurrent Clostridium difficile

Els van Nood, M.D., Anne Vrieze, M.D., Max Nieuwdorp, M.D., Ph.D., Susana Fuentes, Ph.D., Erwin G. Zoetendal, Ph.D., Willem M. de Vos, Ph.D., Caroline E. Visser, M.D., Ph.D., Ed J. Kuijper, M.D., Ph.D., Joep F.W.M. Bartelsman, M.D., Jan G.P. Tijssen, Ph.D., Peter Speelman, M.D., Ph.D., Marcel G.W. Dijkgraaf, Ph.D., and Josbert J. Keller, M.D., Ph.D.
Modern FMT Landmark Study

- FMT via naso-duodenal infusion versus vancomycin versus vancomycin with bowel lavage
- Halted at interim analysis due to 81% versus 31% versus 23% success rate
- 2/3 treatment failures improved with pretreatment bringing overall success to 93.75%
Evidence Supporting FMT

- Aliment Pharmacol Ther 2011; 34: 409-415
- Literature review of 239 patients undergoing FMT ages 2-90
- 17/22 studies in fulminant or refractory CDI
- Effective in 145/166 (87%) of patients
- Small number of patients for IBD/IBS
0 adverse events reported
1 patient in 1 study developed IBS
Time to response 1-12 days
Followup to 13 years
4 studies confirmed decreased Bacteroides and Firmicutes pretreatment
Treatment Durability

- J Clin Gastroenterol Vol 44, 8, 9/2010
- 10 patients with FMT for CDI
- Fecal samples checked 4, 8, and 24 weeks after FMT
- Primer sets developed to target primer sets from Bacteroides, Clostridium coccoides and leptum, and established domains
- Comparisons to baseline samples were significantly similar
A, Dendrogram of the 16S-based T-RFLPs obtained from fecal material from the patient and the donor before and after fecal transplantation. B, Distribution of bacterial species in feces of the donor and the patient before and after fecal transplantation.

FMT Immuno-compromised

- 75 patients with solid organ transplant, AIDS, chemotherapy, IBD
- 89% efficacy
- No infectious complications
The Long-term Efficacy and Safety of Fecal Microbiota Transplant for Recurrent, Severe, and Complicated *Clostridium difficile* Infection in 146 Elderly Individuals

Manasi Agrawal, MD,* Olga C. Aroniadis, MD,* Lawrence J. Brandt, MD, MACG,* Colleen Kelly, MD, FACG,† Sarah Freeman, MD,† Christina Surawicz, MD, MACG,‡ Elizabeth Broussard, MD,‡ Neil Stollman, MD, FACG,§ Andrea Giovanelli, BS,§ Becky Smith, MD,|| Eugene Yen, MD,|| Apurva Trivedi, MD,¶ Levi Hubble, MD,¶ Dina Kao, MD,# Thomas Borody, MD, PhD, FACG,** Sarah Finlayson, BadvSc,** Arnab Ray, MD,†† and Robert Smith, MD †††
FMT Elderly CDI

- 146 patients between 65 to 97 years old
- Recurrent, severe, and complicated disease
- Mean age 78.6 years old
- Primary cure rate 83%, Secondary cure rate 95%
- Major adverse event re-hospitalization for CDI
FMT Severe CDI

ORIGINAL ARTICLE

Long-term Follow-up Study of Fecal Microbiota Transplantation for Severe and/or Complicated Clostridium difficile Infection

A Multicenter Experience

Olga C. Aroniadis, MD,* Lawrence J. Brandt, MD,* Adam Greenberg, MD,* Thomas Borody, MD,† Colleen R. Kelly, MD,‡ Mark Mellow, MD,§ Christina Surawicz, MD,‖ Leslie Cagle, MD,¶ Leila Neshatian, MD,# Neil Stollman, MD,** Andrea Giovanelli, BS, PA-S,** Arnab Ray, MD,††† and Robert Smith, MD†††
FMT Severe CDI

- 17 patients (82% inpatient, 18% outpatient)
- 2/17 had early recurrence < 90 days: 88% primary cure rate
  - 94% secondary cure rate
- 1/17 had a late recurrence due to antibiotics
FMT Protocol

• Indications
  • 3 episodes of mild/moderate CDI
  • Failure of 6-8 weeks vancomycin taper
  • 2 hospitalizations
  • Moderate CDI not responding to vancomycin x 1 week
  • Severe/fulminant CDI with no response to standard therapy after 48 hours
FMT Protocol

- Absolute Donor Exclusion Criteria
  - Known HIV, Hep B, C or exposure
  - High risk sexual behavior
  - Illicit drug use, tattoo, or body piercing within 6 months
  - Incarceration
  - Travel to areas of the world with high risk for traveler’s diarrhea
FMT Protocol

- Absolute Donor Exclusion Criteria
  - Inflammatory bowel disease
  - Irritable bowel syndrome
  - History of GI malignancy or polyposis (?)
  - Antibiotics in 3 months
  - Immunosuppression or chemotherapy
FMT Protocol

• Relative Donor Exclusion Criteria
  • History of major GI surgery (bypass)
  • Metabolic syndrome
  • Autoimmunity
  • Atopy

• Chronic pain, fatigue, fibromyalgia
FMT Protocol

• Donor testing
  • Stool - culture, C. diff, crypto/giardia, ova and parasites
    • crypto/microsporidia optional
  • Serum - HIV 1/2, HepA IgM, HepB sAg, HCV, RPR (test recipient as well)
    • HTLV 1/2, CMV, EBV, H pylori IgG Ab optional
BYOB = Bring Your Own Blender!

Come to HOMER'S BBBQ. The extra B is for BYOBB.
Open Biome

- First Stool Bank in the Country opened in 2012
- Non profit based in Boston
- $485 dose
- $635 capsules
- 5000 patients over 800 institutions in 50 States and 6 countries
- Only 3% of donors pass screening protocol
  - $40 per donation!! Available in Boston for 60 days
Neurological conditions
Psychiatric conditions
Atopic and autoimmune conditions
Chronic pain syndromes
Medications, including antibiotics, antivirals, antifungals
HIV or viral hepatitis exposures
Gastrointestinal conditions
Metabolic conditions
BMI & waist circumference
Travel history to regions with high risk of acquiring infectious pathogens
Current communicable diseases
High risk sexual behaviors, use of illicit drugs, incarceration, or recent tattoos

Microbiome Characterization
16S rRNA microbiome characterization to evaluate diversity & representation from critical phylogenetic groups

Serologic Testing
HIV antibody, type 1 and 2
Hepatitis A
Hepatitis B
Hepatitis C
Treponema pallidum
HTLV 1 and 2
CBC with differential
Hepatic function panel

Stool Testing
Common enteric pathogens (e.g., Salmonella, Shigella, Campylobacter; Vibrio, E. coli Shiga toxin)
Clostridium difficile
Helicobacter pylori
Ova and parasites
Cryptosporidium
Giardia lamblia
Microsporidia
Cyclospora
Adenovirus
Norovirus
Rotavirus
VRE

Age (18-50)
FMT CAPSULE G3 microbiota preparation for oral administration

OpenBiome has developed and pilot launched orally administered capsules for FMT.

FMT Capsule G3 is available in limited supply for clinical or research use. For more information about capsule formulation, clinical efficacy, administration, and ordering, please see our FMT Capsule G3 page.

Lower and Upper Delivery microbiota preparations

FMT LOWER DELIVERY microbiota preparation

A 250 mL microbiota preparation formulated for delivery via the lower gastrointestinal tract (e.g. by colonoscopy or enema)

FMT UPPER DELIVERY microbiota preparation

A 30 mL microbiota preparation formulated for delivery via the upper gastrointestinal tract (e.g. by nasogastric tube)
POOP PILLS!

FMT Capsule G3 Ingredients: Frozen human fecal microbiota filtered to 330 microns, theobroma oil, glycerol, hide bovine gelatin, sodium lauryl sulfate, colorants FD&C, titanium dioxide
Arnab’s Center for Fecal Excellence
FMT Selfie!
FMT in Action

3. Ileo-cecal Valve
4. Cecum
5. Transverse Colon
### Next Generation FMT

<table>
<thead>
<tr>
<th>Type</th>
<th>Phase</th>
<th>Agent</th>
<th>Sponsor</th>
<th>Clinicaltrials.gov Identifier</th>
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<td>SYN-004</td>
<td>Synthetic Biologics</td>
<td>NCT02563106</td>
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Nontoxigenic Spores

• Phase 2 RCT nontoxigenic C diff spores in oral liquid in 3 dosing regimens (VP20621 M3)

• Recurrence
  • Placebo 13/43 (30%)
  • M3 14/125 (11%)
    • Only 2 patients who became colonized with M3 experienced recurrence

JAMA 2015; 313(17): 1719-1727
Nontoxigenic Spores

- Theory is that they outcompete toxigenic strains of C. diff for metabolic resources
- Colonization appears transient
- Concerns for NTCD to get toxin genes from Toxigenic strains.
Fecal Spore Preparations

- SERES

- Encapsulated Spore fractions with 50 species from the Firmicutes phylum

- Prelim study with 30 patients with > 3 CDI episodes in the last year were treated with 2 doses of capsules - absence of recurrence was 87% in both groups

- Phase 2 interim data from 89 participants did not show benefit at 8 weeks
Rebiotix Punch CD2
Figure 2. Overall Success of RBX2660 in Patients Randomized to Receive at Least One Active Treatment

- At least 1 active treatment (Groups A and C): 89.2%
- 2 doses of placebo: 45.5%

P < 0.0001
Alternative Uses for FMT
FMT in UC

- 37 patients with mild to moderate UC
- Donor versus autologous arms
- Nasoduodenal infusion 3 weeks apart x 2
- Week 12: 30% in remission from donors versus 20% controls
FMT in UC

• 70 patients received enema or placebo enema q week x 6 weeks
• 9/38 in treatment arm were in remission (mayo < 2, end Mayo 0) at week 7.
• 7/9 received stool from single donor
• 5% of placebo in remission
FMT in UC

• Meta analysis - 25 studies with 2 RCT’s, 15 cohort studies, and 8 case reports with 234 patients reviewed

• 42% achieved clinical remission and 65% achieved clinical response
FMT in Autism

• 18 patients aged 7 to 17 with autism spectrum disorder and moderate to severe GI problems

• 14 days of vanco followed by bowel prep (Moviprep) followed by high dose microbiota treatment (oral versus rectal) followed by 7-8 weeks of daily oral therapy + PPI (Prilosec)

• Not randomized, placebo controlled, or blinded
FMT in Autism

- GI symptom rating scale - abdominal pain, indigestion, diarrhea, and constipation
  - 82% improvement from beginning to end of treatment
- Autism behaviors also improved along multiple behavioral scales
- Successful partial engraftment of donor microbiota at 8 weeks including *Bifidobacterium, Prevotella, and Desulfovibrio*
FMT in Multiple Sclerosis

• 2011 Borody et al. reported 3 wheelchair bound patients with MS treated with FMT for constipation

• Bowel symptoms resolved following FMT in all cases

• All 3 patients regained the ability walk unassisted, 2 patients with indwelling urinary catheters experienced restoration of urinary function
I Can Walk!
FMT - A Miracle?

IT'S A MIRACLE
THANK YOU!
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