FECAL MICROBIAL TRANSPLANTATION FOR IBD PATIENTS

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Author: Analina Bayag, BSN, RNII, CGRN

EBP Mentors: Amanda Davis, MPH, RD, CHES, Rebecca Harper, Emily Brennan MLIS

ASK THE QUESTION

Clinical Question: IN CHILDREN WITH INFLAMMATORY BOWEL DISEASE (IBD), CAN FECAL MICROBIAL TRANSPLANTATION BE AN OPTION AS A TREATMENT?

Objective: TO DEVELOP A PROCESS THAT MAY BE AN ALTERNATIVE TREATMENT FOR IBD PATIENTS, ESPECIALLY THE ONES WHO ARE ALLERGIC TO TRADITIONAL INFLAMMATORY BOWEL DISEASE (IBD) THERAPY.

Background: TRADITIONAL IBD THERAPY HAVE SIGNIFICANT SIDE EFFECTS AND CAN POSE A LIFE THREATENING REACTION ESPECIALLY FOR PATIENTS WHO MAY BE ALLERGIC TO THE MEDICINE. BECAUSE OF THESE, WE WOULD LIKE TO PURSUE THE ALTERNATIVE TREATMENT.

SEARCH FOR EVIDENCE

Databases searched: PubMed

Search strategy: Fecal Microbiota Transplantation (FMT) AND Inflammatory Bowel Disease

CRITICALLY APPRIASE THE EVIDENCE

Fecal Microbiota Transplantation as an alternative therapy for IBD is a fairly new concept, but there’s a trend emerging. There are limited studies available in pediatrics. But, the limited studies available showed a very positive outcome of remission.
<table>
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<th>Author/Date/Journal</th>
<th>Purpose of Study</th>
<th>Study Design</th>
<th>Sample and Setting</th>
<th>Outcomes</th>
<th>Design Limitations</th>
<th>Lower Quality Rating if:</th>
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<tbody>
<tr>
<td>American Journal of Gastroenterology 2015 Richard Kellermayer, MD, PhD et al</td>
<td>To evaluate whether FMT is an effective treatment for patients with UC and facilitates the withdrawal of conventional therapies</td>
<td>This is a prospective observational study that shows that FMT can alter patient microbiota colonic mucosa</td>
<td>3 immunotherapy (Infliximab, 6 mercaptopurine, and steroid, respectively)-dependent pediatric (14-16 years old) UC patients received a tapering course (22-30 treatments) of FMT delivered by means of colonoscopy an enemas during a 6-12 week period A single donor (37yo man) for all 3 patients</td>
<td>All patients were in endoscopic and histologic remission 2 weeks after the last FMT The FMT series appeared to induce a transient engraftment of the donor Microbiome There is an increased abundance of Coprococcus and Lachnospiraceae which may have delivered beneficial effects to the colonic epithelium of the UC patients This report describes high intensity FMT as a strategy to reset the intestinal microbiota in pediatric IBD. Serial FMT in Pediatric UC may induce beneficial changes in patient microbiota and colonic mucosa.</td>
<td>Non-Experimental/Observational Studies (case-control, cohort, cross sectional, longitudinal, descriptive, epidemiologic, case study/series, QI, survey) ☐ Insufficient sample size ☐ Sample not representative of patients in the population as a whole ☐ Variables (confounders, exposures, predictors) were not described ☐ Outcome criteria not objective or were not applied in blind fashion ☐ Insufficient follow-up, if applicable ☐ For prognostic study, sample not defined at common point in course of disease/condition ☐ For diagnostic study, gold standard not applied to all patients ☐ For diagnostic study, no independent, blind comparison between index test and gold standard ☐ Studies inconsistent (When there are differences in the direction of the effect, populations, interventions or outcomes between studies) ☐ Studies are indirect (Your PICO question is quite different from the available evidence in regard to population, intervention, comparison, or outcome) ☐ Studies are imprecise (When studies include few patients and few events and thus have wide confidence intervals and the results are uncertain) ☐ Publication Bias (e.g. pharmaceutical company sponsors)</td>
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<td>Gastroenterology Research &amp; Practice 2015 Wei Yao et al</td>
<td>To determine the effect of FMT on quality of life in patients with Inflammatory Bowel Disease (IBD)</td>
<td>This is a prospective observational study</td>
<td>Total 14 IBD adult patients 11 UC (Ulcerative Colitis) 3 CD (Crohn’s Disease) Were treated with FMT via Colonoscopy or</td>
<td>One patient was excluded due to intolerance. Two patients had moderate degree of fever post FMT but spontaneously normalized within 24 hours. Minor discomfort, but no serious adverse events were</td>
<td>Study Limitations = ☐ None Non-Experimental/Observational Studies (case-control, cohort, cross sectional, longitudinal, descriptive, epidemiologic, case study/series, QI, survey) ☐ Insufficient sample size ☐ Sample not representative of patients in the population as a whole ☐ Variables (confounders, exposures, predictors) were not described</td>
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<td>Gastroenterology 2015 Paul Moayyedi et al</td>
<td>To evaluate whether FMT is an effective treatment for patients with ulcerative colitis</td>
<td>RCT</td>
<td>Total 75 adult patients n=38 Received FMT 50 ml via enema from healthy anonymous donors n=37 Placebo 50 ml water enema Once weekly X 6 weeks Patients &amp; Clinicians &amp; Investigators are blinded to the groups</td>
<td>70 patients completed the trial (3 dropped off from placebo &amp; 2 from FMT) 9 patients w/ FMT 24% 2 with Placebo 5% Were in remission @ 7 weeks No significant difference in adverse events FMT induces remission in a significantly greater percentage of patients with active UC</td>
<td>Study Limitations = None RCT &amp; Quasi-Experimental Studies Insufficient sample size Lack of randomization Lack of blinding Stopped early for benefit Lack of allocation concealment Selective reporting of measures Large losses to F/U</td>
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**APPLY THE EVIDENCE**

- Outcome criteria not objective or were not applied in blind fashion
- Insufficient follow-up, if applicable
- For prognostic study, sample not defined at common point in course of disease/condition
- For diagnostic study, gold standard not applied to all patients
- For diagnostic study, no independent, blind comparison between index test and gold standard

**Level of evidence for studies as a whole:**

- High
- Moderate
- Low
- Very Low
Practice Recommendation: Fecal Microbiota Transplant (FMT) should be considered for pediatric patients with Inflammatory Bowel Disease

Weak Recommendation, Low quality evidence

EVALUATE THE EVIDENCE

Outcome & Process Measures: TBD

Implementation Plan: Meet with Dr. Scott Curry to discuss developing FMT protocol in MUSC

REFERENCES

