1407

Fecal Bacteriotherapy in Community Hospital: Satisfaction and Effectiveness from the Patient Perspective

Ravi Kamepalli, MD CWS & Laurie Schnipke, RN, BSN
Regional Infectious Diseases & Infusion Center, Lima, Ohio

Regional Infectious Diseases and Infusion Center
830 West High Street
Suite 255
Lima, Ohio 45801 USA
Phone 419-228-1535
Fax 419-227-1410
Website: http://www.nobadbugs.com

Abstract:
Background: While ongoing studies confirm the effectiveness of fecal Bacteriotherapy as a treatment option for recurrent Clostridium Difficile Infections, limited information has been collected regarding the patient's perception of the procedure and whether perceived benefits of the procedure outweigh the repugnance of the process. **Methods:** This study used retrospective quasi-experimental design examining patients' impressions of the short-term (2-10 days post procedure) and long-term (over 3 months) effectiveness of fecal Bacteriotherapy along with patient satisfaction with fecal Bacteriotherapy. Consecutive sampling methods of 34 patients who underwent fecal Bacteriotherapy from 2009 to 2012 resulted in 28 eligible respondents based on criteria of being 3 months post procedure and cognitively able to complete the questionnaire. Questionnaire developed in collaboration with gastrointestinal specialist and utilized 0-10 rating scale for questions regarding pain (0=no pain, 10 worst pain ever), nausea (0=no nausea, 10= severe nausea) and patient satisfaction (0=least satisfied/least likely, 10=most satisfied/very likely), dichotomous (Yes/No) questions for long-term results, and checklist questions for stool frequency. 28 questionnaires sent with 20 returned (71%). **Results:** Average age of respondent was 67 years (+/- 13.98) and female to male ratio 15:5. Short-term outcomes: Abdominal pain score averages dropped from 6.5 to 1.7; nausea average scores dropped from 4 to 1.2; and at 10 days post procedure, 100% respondents had less than 4 stools per day. Long-term outcomes: At 3 months or longer post procedure, 17 of 20 (85%) had no further episodes of diarrhea requiring physician or hospital visit; 17 of 20 (85%) had no further nausea requiring physician or hospital visit; 18 of 20 (90%) had no further abdominal cramping requiring physician or hospital visit. Patient satisfaction: Average satisfaction score with overall results of procedure was 9.6 (+/- 1.10) average satisfaction score in regards to cost associated with procedure was 9.6 (+/- 1.27); average satisfaction score regarding facility was 9.9 (+/- 0.31); and likelihood to recommend procedure to family/friend was 9.9 (+/- 0.45). **Conclusion:** Results of study suggests patients are very satisfied with fecal Bacteriotherapy as treatment for Clostridium Difficile colitis despite the procedure's anticipated repugnance. Patients also reported significant improvement in long-term and short-term symptomology.

Introduction

- Clostridium Difficile infections continue to be a challenge for medical professional to treat
  - Recurrent C Diff infections are cited in as many as 35% of patients treated successfully on initial occurrence
  - Limited number of approved medications available for treating C Diff
  - Resistant strains of C Diff complicate the treatment plan
- Emerging research is favorably supporting the effectiveness of fecal Bacteriotherapy as an alternative option treating C diff
- Many barriers to the widespread use of fecal Bacteriotherapy exist and prevent it from becoming a reimbursable procedure
  - Lack of standardized procedural protocol,
  - Insufficient widespread randomized clinical studies
  - FDA involvement in regulating donor stool
  - Non payment by government funded and private insurance providers for donor testing and procedure
- While fecal Bacteriotherapy will likely become a legitimate procedure with reimbursement with time, perceived patient repugnance by providers can also be viewed as a barrier
  - This study is an effort at examining how patients who have actually underwent the procedure feel about its effectiveness and whether they would recommend the procedure to others.
  - Currently limited data has been collected regarding fecal Bacteriotherapy from patient perspective

Methods

- At time of retrospective study via surveys, **34** patients had underwent Fecal Bacteriotherapy by Dr. Kamepalli since 2009
- By performing retrospective chart review, **28** of **34** patients were deemed appropriate for proposed survey (**inclusion criteria**)
  - Alive
  - 3 months post procedure
  - Cognitively able to answer survey questions
- **Outcomes** for the study included
  - **(1)** improved symptoms of diarrhea, nausea, and abdominal pain at short term interval (2-10 days following the procedure)
  - **(2)** improved symptoms of diarrhea, nausea and abdominal pain at long term interval (3-6 months)
  - **(3)** patient satisfaction on aspects of the procedure.
- 20 of 28 patients returned the surveys **(71%)**
- Average **age** of respondent **67** years old
- Ratio **female** to **male 15:5**
- Ratio of procedure done **inpatient** to **outpatient 3:17**

Copy of questionnaire

Severity of Symptoms

*****These are a few questions pertaining to period before the fecal Bacteriotherapy and the gastrointestinal symptoms you experienced…please circle answer:**

1. During the acute diarrheal phase when you were diagnosed with C Diff infection, how many stools a day were you having? **0-4** **5-10** **over 10**
2. During the acute phase when you were diagnosed with the C Diff infection, how severe was the abdominal pain or cramping you experienced?
   No pain 0….1….2….3….4….5….6….7….8….9….10 **Worst pain ever**
1. During the acute phase when you were diagnosed with the C Diff infection, how severe was the nausea you experienced?
   No nausea 0….1….2….3….4….5….6….7….8….9….10 **Worst nausea ever**

Short Term Results Post Fecal Bacteriotherapy

*****These questions are pertaining to the immediate (2-10 days) following the completion of the fecal Bacteriotherapy.**

1. Starting approximately 2-3 days after completion of fecal Bacteriotherapy, how many stools did you have a day? **0-4** **5-10** **over 10**
2. Starting 2-3 days after fecal Bacteriotherapy, how severe was the abdominal pain or cramping you experienced?
   No pain 0….1….2….3….4….5….6….7….8….9….10 **Worst pain ever**
1. Starting 2-3 days after fecal Bacteriotherapy, how severe was the nausea you experienced?
   No nausea 0….1….2….3….4….5….6….7….8….9….10 **Worst nausea ever**
1. Approximately how many days did it take after the fecal Bacteriotherapy for normal bowel function to return? _____
2. At 7 days after the fecal Bacteriotherapy, how many stools were you having a day?
   0-4 **5-10** **over 10**
1. At 10 days after the fecal Bacteriotherapy, how many stools were you having a day?
   0-4 **5-10** **over 10**

Long Term Results Post Fecal Bacteriotherapy

*****These questions pertain to the long term gastrointestinal symptoms and events after the fecal Bacteriotherapy**

1. Within the 6 months following fecal Bacteriotherapy, did you experience any episodes of diarrhea requiring physician/ER visit or treatment for C diff (oral vancomycin/metronidazole/fidaxomicin)? **Yes/No**
2. Within the 6 months following the fecal Bacteriotherapy, have you had any persistent nausea requiring a physician/ER visit? **Yes/No**
3. Within the last 6 months following the fecal Bacteriotherapy, have you had any abdominal cramping requiring a physician/ER visit? **Yes/No**
4. Did you continue probiotics for at least 3 months after fecal Bacteriotherapy? **Yes/No**

Patient Satisfaction

*****10 denotes most satisfied or likely and 0 denotes least satisfied and unlikely**

1. How satisfied were you with the costs associated with the procedure?
   Unsatisfied 0….1….2….3….4….5….6….7….8….9….10 **Very Satisfied**
1. How satisfied were you with the facility where the procedure was performed?
   Unsatisfied 0….1….2….3….4….5….6….7….8….9….10 **Very Satisfied**
1. How satisfied were you with the results of the procedure?
   Unsatisfied 0….1….2….3….4….5….6….7….8….9….10 **Very Satisfied**
1. How likely would you be to recommend fecal Bacteriotherapy for friend/family member with C Diff?
   Unlikely 0….1….2….3….4….5….6….7….8….9….10 **Very Likely**

*****Optional Data Collection** ---**THIS IS NOT PART OF OFFICIAL SURVEY AND COMPLETELY OPTIONAL**

Regarding Cost of procedure

1. Did insurance/Medicare/Medicaid cover hospital costs? **Yes/No**
2. Did insurance/Medicare/Medicaid cover physician fees? **Yes/No**
3. Did you incur any out of pocket expenses specifically for the procedure? **Yes/No**
   How Much? _____

Results

(1) Short Term Results

Abdominal Pain: scale 0-10 with 0=no pain and 10=worst pain ever

- Average score **6.5** pre-procedure reduced to **1.7** at 2-10 days post procedure

Nausea: scale 0-10 with 0=no nausea and 10=severe nausea

- Average score of **4.0** pre-procedure reduced to **1.2** at 2-10 days post procedure

Stools per day: asked to estimate number of stool in a day: 0-4; 5-10; or over 10

- Prior to procedure **95%** having over 5 stools per day
- At 2-3 days post procedure, **84%** having less than 4
- At 7 days post procedure, **95%** having less than 4
- At 10 days post procedure, **100%** having less than 4 stools per day

(2) Long Term Result

- At 3-6 months post procedure, 17 of 20 **(85%)** had **no** further episodes of **diarrhea** requiring repeat physician /hospital visit or treatment for C diff.
- At 3-6 months post procedure, 17 of 20 **(85%)** had **no** further **nausea** episodes requiring physician/hospital visit
- At 3-6 months post procedure, 18 of 20 **(90%)** had **no** further **abdominal cramping/pain** requiring physician/hospital visit
- 19 of 20 **(95%)** of patient continued probiotics for at least 3 months post procedure

(3) Patient Satisfaction: 0-10 scale with 10=most satisfied/likely and 0=least satisfied/likely

- Average score **9.6** of **10** for satisfaction with cost associated with procedure
- Average score **9.9** of **10** for satisfaction with facility associated with procedure
- Average score of **9.6** of **10** for satisfaction with overall results of procedure
- Average score of **9.9** of **10** for likelihood of recommending procedure to friend/family member with C Diff

Discussion

- Despite it's perceived repugnance, patient satisfaction levels are exceedingly high regarding Fecal Bacteriotherapy and its effectiveness
- Short term and long term effects of the procedure show significant improvement in symptomology as reported by patients
- Fecal Bacteriotherapy has potential for being an effective and generally accepted tool in the arsenal against Clostridium difficile colitis

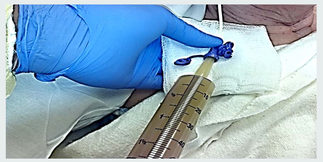
A little more about the procedure: What works for us…

Candidates for Fecal Bacteriotherapy: refractory, recurrent and fulminant Cdiff infection

Donor testing: stool for pathogens, serology for transmittable diseases. No antibiotics for preferably 6 months

Nasogastric Tube placement: small caliper NG placed into duodenum under fluoroscopy by interventional radiologist

Preparation of Affluent: See Pictures

Administration schedule: 120ml affluent instilled by MD then 60 ml every 8 hours usually for 48 hours (can be done with training at home by family member)

Follow up: NG removed after final instillation, probiotics continued for 6 months and no antibiotics for >6 months unless ok'd by Dr. Kamepalli.