Outcomes of Patients with Recurrent *Clostridioides difficile* Infection Treated with Fecal Microbiota Transplantation through the Microbiota Therapeutics Outcomes Program

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**ABSTRACT**

**Objectives:** Our previous randomized clinical trial (RCT) found limited effectiveness of a single fecal microbiota transplantation (FMT) by enema following treatment for acute recurrent *Clostridioides difficile* infection (rCDI). Other studies have shown improved outcomes primarily with multiple FMT given at a time other than acute recurrence. Through the Microbiota Therapeutics Outcomes Program (MTOP), we offer multiple FMT to patients with rCDI at a time distant from acute recurrence. MTOP records of patients with rCDI treated with FMT were reviewed to document clinical outcomes.

**Methods:** All patients enrolled in MTOP for rCDI between 2017-2019 were included. Records were reviewed to capture clinical outcomes, gender, rCDI history/risk factors, and comorbidities. Clinical outcomes were determined based on the most recent follow-up visit with failure defined as symptomatic, laboratory-confirmed CDI. Differences in results and FMT administration were compared between MTOP and our RCT.

**Results:** 32 patients with rCDI have received FMT through MTOP between 2017-2019. Of the 32, 26 [81.3% (95%CI 64.3-91.5%)] had successful outcomes as of their last follow-up visit (range 1-24m, median 6m) compared to 7 out of 16 [43.8% (95%CI 23.1%-66.9%)] at 3m in our RCT. Data for MTOP/RCT were: average age 62.1y/75.7y; %female 75.0%/68.8%; number of previous recurrences 3.0/4.4; previous vancomycin taper 100%/81.3%; Charlson comorbidity index 2.7/5.3; PPI 3.1%/43.8%; immunosuppression 12.5%/0%. FMT administration details are shown in the table.

**Conclusions:** FMT treatment of rCDI through MTOP is associated with 81.3% success, an increase compared to 43.8% in our RCT. Which of the differences in FMT administration between MTOP and our RCT is most responsible for this success requires further study.

**INTRODUCTION**

Our previous randomized clinical trial (RCT) (Hota et al, CID 2017 Feb 1;64(3):265-271) found limited effectiveness of a single fecal microbiota transplantation (FMT) by enema following treatment for acute recurrent *Clostridioides difficile* infection (rCDI). Other studies have shown improved outcomes primarily with multiple FMT given at a time other than acute recurrence. Through the Microbiota Therapeutics Outcomes Program (MTOP), we offer multiple FMT to patients with rCDI at a time distant from acute recurrence. MTOP records of patients with rCDI treated with FMT were reviewed to document clinical outcomes.

**METHOD**

All patients enrolled in MTOP for rCDI between 2017-2019 were included. Records were reviewed to capture clinical outcomes, gender, rCDI history/risk factors, and comorbidities. Clinical outcomes were determined based on the most recent follow-up visit with failure defined as symptomatic, laboratory-confirmed CDI. Differences in results and FMT administration were compared between MTOP and our RCT.

**RESULTS**

32 patients with rCDI have received FMT through MTOP between 2017-2019. Of the 32, 26 [81.3% (95%CI 64.3-91.5%)] had successful outcomes as of their last follow-up visit (range 1-24m, median 6m) compared to 7 out of 16 [43.8% (95%CI 23.1%-66.9%)] at 3m in our RCT. Data for MTOP/RCT were: average age 62.1y/75.7y; %female 75.0%/68.8%; number of previous recurrences 3.0/4.4; previous vancomycin taper 100%/81.3%; Charlson comorbidity index 2.7/5.3; PPI 3.1%/43.8%; immunosuppression 12.5%/0%. FMT administration details are shown in the table.

**DISCUSSION & CONCLUSION**

FMT treatment of rCDI through MTOP is associated with 81.3% success, an increase compared to 43.8% in our RCT. Which of the differences in FMT administration between MTOP and our RCT is most responsible for this success requires further study.