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ROLE OF FECAL MICROBIOTA TRANSPLANT IN SEVERE ULCERATIVE COLITIS

Original Research

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ABSTRACT

Background: Ulcerative colitis is a chronic inflammatory bowel disease characterized by cycles of relapse and remission. Conventional therapies primarily target immune-mediated inflammation but often fall short in long-term disease control due to side effects, loss of response, and high costs. Fecal microbiota transplantation (FMT), a non-immunosuppressive approach aimed at restoring gut microbial balance, has shown promise in recurrent *Clostridioides difficile* infections. Its role in ulcerative colitis management, however, remains under investigation.

Objective: To compare the frequency of clinical remission with versus without fecal microbiota transplantation in the treatment of ulcerative colitis.

Methods: This randomized controlled trial was conducted at the Department of Gastroenterology, AIMC/Jinnah Hospital, Lahore, over six months from September 2021 to March 2022. A total of 180 patients diagnosed with active ulcerative colitis and meeting the inclusion criteria were enrolled and randomized into two groups. Group A received FMT via enema (50 g donor stool in 50 mL infusion) once weekly for six weeks. Group B received a placebo enema (50 mL sterile water) on the same schedule. Clinical remission was defined as a total Mayo score ≤2, assessed via endoscopy before and after the treatment period. Data were analyzed using SPSS v.25.

Results: The mean age was 38.81 ± 14.77 years in the FMT group and 37.74 ± 14.29 years in the control group. In the FMT group, 47 patients (52.2%) were male; in the control group, 68 (75.6%) were male. Baseline Mayo scores were similar (8.09 ± 1.50 vs. 7.94 ± 1.44; p = 0.510). After six weeks, the mean Mayo score was significantly lower in the FMT group (4.63 ± 2.40) than in controls (5.48 ± 2.18) (p = 0.015). Clinical remission was achieved in 32 (35.6%) patients in the FMT group and 17 (18.9%) in the control group (p = 0.012).

Conclusion: FMT was associated with a significantly higher clinical remission rate compared to standard treatment and may serve as a reliable adjunctive therapy for managing active ulcerative colitis.

Keywords: Colitis, Ulcerative; Enema; Fecal Microbiota Transplantation; Intestinal Microbiota; Mayo Score; Remission Induction; Treatment Outcome.

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INTRODUCTION

Ulcerative colitis (UC) is a chronic, relapsing inflammatory condition of the colon characterized by a range of clinical symptoms, including loose stools, bloody diarrhea, abdominal pain, unintended weight loss, joint discomfort, and anemia (1,2). As a form of inflammatory bowel disease (IBD), it significantly impairs patients' quality of life and poses substantial long-term health risks if not properly managed. Gastrointestinal diseases such as cirrhosis with esophageal varices have similarly been studied for their diagnostic and therapeutic challenges, highlighting the broader burden of GI pathologies on patient outcomes (3). While a variety of pharmacological and surgical interventions exist, including immunosuppressants and biologics, not all patients respond adequately to these therapies, and many experience adverse effects. Consequently, there remains an ongoing search for more targeted and safer treatment strategies. A growing body of evidence indicates that alterations in the gut microbiota, also known as microbial dysbiosis, play a pivotal role in the pathogenesis of UC by promoting chronic intestinal inflammation. Emerging studies have increasingly highlighted that restoring microbial balance could be key in managing UC more effectively (4). Fecal microbiota transplantation (FMT)—the process of transferring stool from a healthy donor to a patient's gastrointestinal tract—has gained attention as a non-immunosuppressive therapeutic approach that directly targets the underlying microbial imbalances (5). Unlike antibiotics, probiotics, or prebiotics, which often have limited and transient effects, FMT provides a complete and functional microbial ecosystem, potentially correcting dysbiosis and improving mucosal immunity (6).

The FMT procedure involves three essential steps: meticulous donor screening, preparation of donor stool, and its delivery to the recipient's gut via various routes (6,7). Appropriate donors are typically adults between 18 and 60 years of age with a body mass index ranging from 18 to 30 kg/m² and free of infectious or metabolic disorders (7–9). Some studies suggest that using multiple donors enhances the microbial diversity of the transplanted material, which may improve clinical outcomes (10,11). Despite promising evidence in treating recurrent *Clostridium difficile* infections, the role of FMT in UC remains a topic of ongoing investigation, with mixed findings reported across clinical trials. For instance, one trial showed a significantly higher remission rate with FMT compared to control (24% vs. 5%, $p<0.05$) (12), while another found no statistically significant difference (30.4% vs. 20%, $p>0.05$) (13). These inconsistencies underscore the need for further investigation into its efficacy and clinical utility in UC management. Given the absence of prior local studies evaluating FMT in the context of UC, this study was undertaken to determine the impact of fecal microbiota transplantation on clinical remission in patients with ulcerative colitis within the local population. The findings aim to contribute meaningful data to the regional medical literature and assess whether FMT can be considered a viable adjunctive therapy for UC in this setting.

METHODS

This randomized controlled trial was conducted at the Department of Gastroenterology, Jinnah Hospital, Lahore, after obtaining formal approval from the Institutional Ethical Review Committee (ERC). The study period spanned from September 2021 to March 2022. A total sample size of 180 patients, with 90 individuals allocated to each group, was calculated using a 5% level of significance and 90% power. The sample size calculation was based on previously reported remission rates of 24% in the fecal microbiota transplantation (FMT) group and 5% in the control group (14). Patients were recruited using a non-probability consecutive sampling technique, ensuring the inclusion of all eligible individuals who met the predefined selection criteria. Participants included patients aged between 16 and 75 years of either gender, diagnosed with ulcerative colitis. The diagnosis was based on clinical presentation and confirmed by endoscopic evidence of inflammatory bowel disease affecting the colon, accompanied by a Mayo endoscopic score of ≥4. The Mayo scoring system, ranging from 0 to 12, was used to assess disease severity before and after treatment. Patients were excluded if they had conditions likely to interfere with gut microbiota, such as recent antibiotic or probiotic use (within the past month), ongoing use of medications like antacids, H2-receptor blockers, proton pump inhibitors, anticoagulants, antiplatelets, or anti-inflammatory drugs during the preceding month. Additional exclusions included individuals with hepatic encephalopathy, sepsis, corrosive intake, or positive *Helicobacter pylori* infection. Similarly, potential donors were excluded if they had any diagnosed illnesses or recent antibiotic or probiotic usage, as such factors could alter gut microbial composition.

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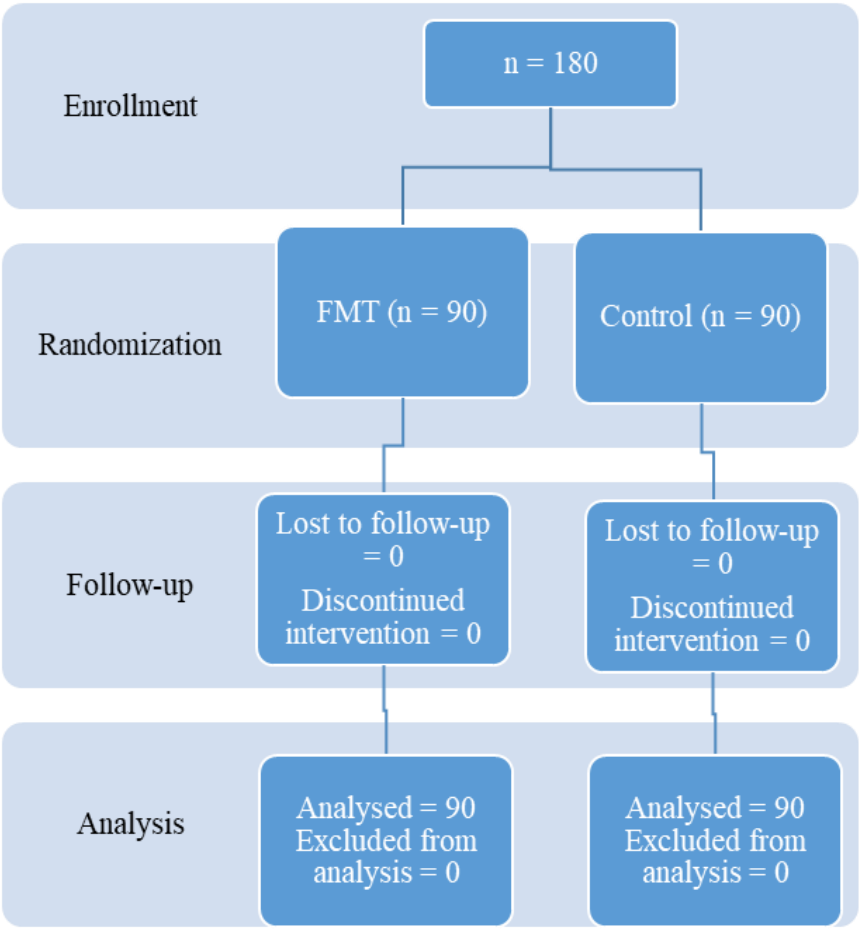
Written informed consent was obtained from all participants prior to enrollment. Baseline demographic and clinical data were documented. Patients were randomly assigned to either Group A (intervention group) or Group B (control group) through a simple lottery method to ensure allocation concealment. In Group A, patients received fecal microbiota transplantation via rectal enema, consisting of 50 grams of stool dissolved in 50 mL of saline, administered once weekly for a total of six weeks. The donor stool was freshly prepared under sterile conditions following standard protocols. In contrast, patients in Group B received a placebo treatment in the form of a 50 mL water enema once weekly for six weeks. All endoscopic evaluations were performed by the principal investigator under the supervision of a consultant gastroenterologist with a minimum of four years of clinical and procedural experience. The primary outcome was clinical remission, defined as a total Mayo score of ≤2 on follow-up endoscopy performed at the end of the six-week intervention period. Mayo scores were recorded at baseline and reassessed at six weeks. Data were entered and analyzed using SPSS version 25. Frequencies and percentages were calculated for categorical variables, while mean and standard deviation were used for continuous variables. The chi-square test was applied to compare remission rates between the two groups, and a p-value ≤0.05 was considered statistically significant.



RESULTS

The mean age of patients in the FMT group was 38.81 ± 14.77 years, while in the control group it was 37.74 ± 14.29 years. Gender distribution in the FMT group included 47 males (52.2%) and 43 females (47.8%), compared to 68 males (75.6%) and 22 females (24.4%) in the control group. The average BMI was slightly lower in the FMT group (26.96 ± 3.58 kg/m²) than in the control group (28.23 ± 4.19 kg/m²). The mean duration of ulcerative colitis at presentation was 8.58 ± 4.18 weeks for the FMT group and 9.22 ± 4.67 weeks for the control group. In the FMT group, 21 patients (23.3%) were diabetic, 9 (10%) had hypertension, and 6 (6.7%) were current smokers, while in the control group, 22 (24.4%) were diabetic, 13 (14.4%) hypertensive, and 23 (25.6%) smokers. At baseline, the mean Mayo score was comparable between the two groups (8.09 ± 1.50 in FMT vs 7.94 ± 1.44 in control; p = 0.510). After six weeks of

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treatment, a greater reduction in Mayo score was observed in the FMT group (mean 4.63 ± 2.40) compared to the control group (mean 5.48 ± 2.18), and this difference was statistically significant (p = 0.015). Clinical remission, defined as a total Mayo score ≤2, was achieved in 32 patients (35.6%) in the FMT group versus 17 patients (18.9%) in the control group (p = 0.012), indicating a significantly higher remission rate with FMT therapy. Stratified analysis by age showed that in patients aged 16–40 years, remission was significantly more frequent in the FMT group (40.8%) compared to the control group (20.8%) (p = 0.028), whereas in patients aged 41–75 years, the difference was not statistically significant (29.3% vs 16.2%, p = 0.172). Among males, the remission rate was higher in the FMT group (31.9%) compared to the control group (20.6%), though this difference was not statistically significant (p = 0.169). However, a significant difference was noted among females (39.5% in FMT vs 13.6% in control; p = 0.046).

In patients with normal BMI, remission was achieved in 44.0% of FMT cases versus 27.3% in controls (p = 0.234, not significant), while in overweight or obese patients, the remission rate was significantly higher in the FMT group (32.3%) compared to control (16.2%) (p = 0.030). Among diabetics, FMT showed a numerically higher remission rate (38.1%) versus controls (27.3%), but the difference was not significant (p = 0.449). Among non-diabetics, however, remission was significantly more common in the FMT group (34.8%) than control (16.2%) (p = 0.013). Hypertensive patients did not demonstrate a statistically significant difference in remission rates (11.1% vs 23.1%, p = 0.616), whereas among non-hypertensives, the FMT group had significantly better outcomes (38.3% vs 18.2%, p = 0.005). Smoking status also influenced outcomes: smokers in the FMT group showed a high remission rate of 66.7%, compared to only 13.0% in the control group (p = 0.018), whereas among non-smokers, the difference was not statistically significant (33.3% vs 20.9%, p = 0.090). Duration of symptoms also had an impact—while remission rates in patients with ≤8 weeks of symptoms were not statistically different (34.6% in FMT vs 25.5% in control, p = 0.313), those with >8 weeks duration had significantly better outcomes with FMT (36.8% vs 10.3%, p = 0.007).

Table 1: Baseline parameters of enrolled patients (n = 180)

Age group	FMT	Control
n	90	90
Age (in years)	38.81 ± 14.77	37.74 ± 14.29
Gender		
Male	47 (52.2%)	68 (75.6%)
Female	43 (47.8%)	22 (24.4%)
BMI (kg/m2)	26.96 ± 3.58	28.23 ± 4.19
Duration of Ulcerative colitis (weeks)	8.58 ± 4.18	9.22 ± 4.67
Diabetes mellitus	21 (23.3%)	22 (24.4%)
Hypertension	9 (10%)	13 (14.4%)
Smoking	6 (6.7%)	23 (25.6%)

Table 2: Comparison of outcome of treatment during follow-up

Parameters	FMT	Control	p-value
n	90	90	
Pre-treatment Mayo score	8.09 ±1.50	7.94 ±1.44	0.510
Post-treatment Mayo score	4.63 ±2.40	5.48 ±2.18	0.015
Remission achieved	32 (35.6%)	17 (18.9%)	0.012

Table 3: Comparison of remission achieved in both trial groups when remission was checked for effect modifiers

Age group	FMT	Control	p value
16-40 years	20 (40.8%)	11 (20.8%)	0.028
41-75 years	12 (29.3%)	6 (16.2%)	0.172
Male	15 (31.9%)	14 (20.6%)	0.169
Female	17 (39.5%)	3 (13.6%)	0.046
Normal BMI	11 (44.0%)	6 (27.3%)	0.234
Overweight or obese	21 (32.3%)	11 (16.2%)	0.030

Age group	FMT	Control	p value
Diabetics	8 (38.1%)	6 (27.3%)	0.449
Non-diabetics	24 (34.8%)	11 (16.2%)	0.013
Hypertensive	1 (11.1%)	3 (23.1%)	0.616
Non-hypertensive	31 (38.3%)	14 (18.2%)	0.005
Smokers	4 (66.7%)	3 (13.0%)	0.018
Non-smokers	28 (33.3%)	14 (20.9%)	0.090
Duration of symptoms ≤8 weeks	18 (34.6%)	13 (25.5%)	0.313
Duration of symptoms >8 weeks	14 (36.8%)	4 (10.3%)	0.007

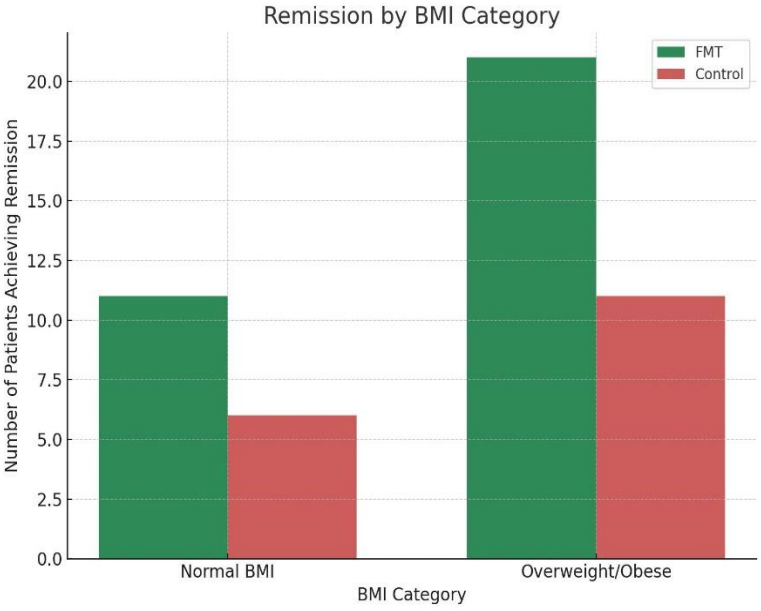

Figure 2 Remission of BMI Category

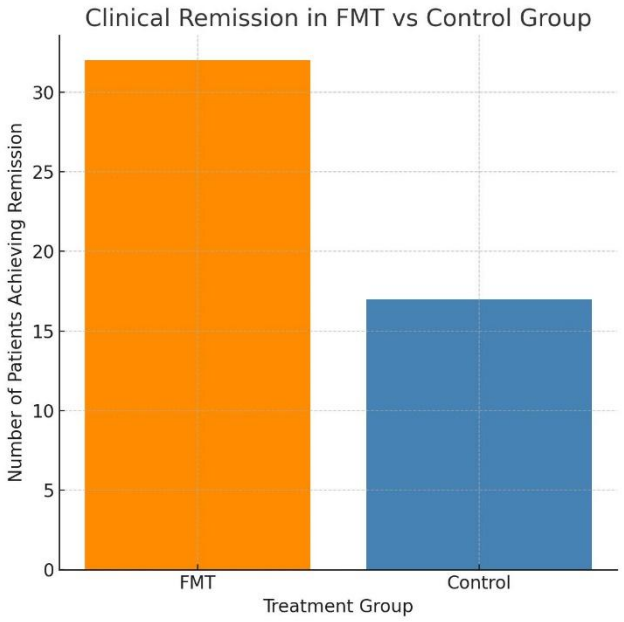

Figure 1 Clinical Remission in FMT vs Control Group

DISCUSSION

The present study explored the therapeutic potential of fecal microbiota transplantation (FMT) in achieving clinical remission among patients with ulcerative colitis. As a chronic inflammatory bowel disease, ulcerative colitis is characterized by fluctuating periods of flare-ups and remission. Although conventional treatment modalities primarily aim to suppress the aberrant immune response driving inflammation, concerns regarding long-term reliance on biologics have intensified due to associated risks such as serious infections, malignancy, high treatment costs, and diminishing therapeutic efficacy over time (15,16). FMT, the administration of processed fecal matter from healthy donors containing a complex mixture of microbiota and their functional ecosystems, has emerged as a promising non-immunosuppressive approach targeting gut dysbiosis directly (17,18). While its use is well-established for recurrent *Clostridioides difficile* infection, its application in ulcerative colitis remains under investigation with several unanswered questions surrounding its efficacy, safety, and standardization (19,20). In this study, the post-intervention reduction in Mayo score was significantly greater in the FMT group compared to the control group, indicating superior clinical remission outcomes with FMT. These findings align with previous studies that reported improved outcomes in FMT recipients; however, mixed results have also been observed in randomized controlled trials. In one such trial, the response rates to donor stool and autologous stool were comparable due to a pronounced placebo effect, which raises questions about the influence of psychological and procedural factors on perceived symptom relief. Additionally, other studies observed that dietary habits, particularly the intake of fermentable fiber, may play a modulatory role in shaping microbial

INSIGHTS-JHR
INSIGHTS-JOURNAL OF HEALTH AND REHABILITATION

communities post-FMT. While baseline dietary fiber consumption was documented in a few trials, the lack of post-treatment dietary assessment limits understanding of its potential interaction with FMT outcomes (21,22). Adjunctive use of prebiotic fibers such as pectin has demonstrated an ability to sustain microbial diversity and enhance the benefits of FMT, suggesting that future protocols may benefit from integrating tailored dietary interventions alongside microbial therapy (23).

The mode of FMT delivery is another critical consideration. Enemas, colonoscopy, gastroscopy, and nasogastric routes have all been utilized in previous research, with variable outcomes. Although colonoscopic delivery has been preferred for *C. difficile* due to improved mucosal distribution, evidence remains inconclusive for ulcerative colitis, warranting further comparative trials to optimize delivery routes (24). Moreover, the inherent variability in the composition of donor stool—dependent on donor health, diet, and collection timing—poses a regulatory and scientific challenge. Even when sourced from the same donor, stool heterogeneity complicates efforts to standardize FMT as a therapeutic product. Concerns have also been raised regarding the transmission of drug-resistant organisms, such as extended-spectrum beta-lactamase (ESBL)-producing *E. coli*, particularly in immunocompromised individuals (25). Regulatory frameworks across the globe remain fragmented, reflecting ongoing debates over whether FMT should be classified as a drug, biologic, or tissue. While some countries have established clinical exemptions for FMT use in recurrent *C. difficile*, its application in other conditions typically requires ethical and regulatory approvals that vary by jurisdiction. Establishing a harmonized global standard remains essential for ensuring both patient safety and research advancement without impeding accessibility. A notable strength of this study lies in its randomized design and focus on a previously unexamined local population, thereby contributing region-specific evidence to the growing global literature on FMT in ulcerative colitis. The stratification of remission outcomes by age, gender, BMI, comorbidities, smoking status, and disease duration adds granularity to the analysis, offering potential insights into subgroups that may derive the greatest benefit. However, the study is limited by the lack of microbiological profiling of donor and recipient stool, absence of long-term follow-up to assess sustained remission, and failure to document adverse events, patient satisfaction, or quality of life measures. Furthermore, dietary intake before and after FMT, which could have influenced outcomes, was not monitored. In light of these findings, future research should prioritize integrating microbial sequencing, long-term safety assessments, and dietary interventions into FMT protocols. A focus on refining donor selection, optimizing delivery methods, and addressing regulatory inconsistencies is also warranted. With further validation, FMT holds the potential to serve as an effective, non-immunosuppressive alternative in the management of ulcerative colitis, particularly in cases resistant to conventional therapies.

CONCLUSION

This study demonstrated that fecal microbiota transplantation (FMT) offers a promising therapeutic approach for inducing clinical remission in patients with active ulcerative colitis. When compared to standard treatment, FMT was associated with a higher frequency of remission, highlighting its potential as a non-immunosuppressive, microbiota-targeted strategy. These findings contribute to the growing evidence supporting the integration of FMT into treatment protocols for ulcerative colitis, particularly in patients who may not respond adequately to conventional therapies.

AUTHOR CONTRIBUTION

Author	Contribution
Shehzad Aslam*	Substantial Contribution to study design, analysis, acquisition of Data Manuscript Writing Has given Final Approval of the version to be published
Attique Abou Bakr	Substantial Contribution to study design, acquisition and interpretation of Data Critical Review and Manuscript Writing Has given Final Approval of the version to be published
Muhammad Mobeen	Substantial Contribution to acquisition and interpretation of Data Has given Final Approval of the version to be published
Tayyab Shahzad	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published
Arooj Haider	Contributed to Data Collection and Analysis Has given Final Approval of the version to be published

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