



Perception of fecal microbiota transplantation in patients with ulcerative colitis in Korea: a KASID multicenter study



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Aim	Results
 <p>Our study aimed to investigate patient perceptions of fecal microbiota transplantation (FMT)</p>	<p>Unawareness of FMT 51.4%</p>
<p>Methods</p> <p>Prospective, multicenter study</p>  <p>210 Patients with ulcerative colitis (UC) ≥ 19 years</p> <ul style="list-style-type: none"> • 22 questions on FMT • Changes in perceptions of FMT before and after education 	<p>Willingness to undergo FMT</p> <p>27.1% → 46.7% (Before education) (After education)</p> <p>43.1% → 92.3% (Non-severe cases) (Severe cases)</p>
	<p>Preferred fecal donor The one recommended by a physician (41%)</p>
	<p>Preferred method Oral capsule (30.4%)</p>
	<p>National medical policy Influenced choice of FMT treatment (50%)</p>
<p>Conclusion</p>	<p>Education can increase preference for FMT in patients with UC. When patients have severe disease symptoms or their quality of life decreases their willingness to undergo FMT increases. Moreover, national medical policies may influence patient choices regarding FMT.</p>

Background/Aims: Fecal microbiota transplantation (FMT) is a promising therapy for inducing and maintaining remission in patients with ulcerative colitis (UC). However, FMT has not been approved for UC treatment in Korea. Our study aimed to investigate patient perceptions of FMT under the national medical policy.

Methods: This was a prospective, multicenter study. Patients with UC ≥ 19 years of age were included. Patients were surveyed using 22 questions on FMT. Changes in perceptions of FMT before and after education were also compared.

Results: A total of 210 patients with UC were enrolled. We found that 51.4% of the patients were unaware that FMT was an alternative treatment option for UC. After reading the educational materials on FMT, more patients were willing to undergo this procedure (27.1% vs. 46.7%; $p < 0.001$). The preferred fecal donor was the one recommended by a physician (41.0%), and the preferred transplantation method was the oral capsule (30.4%). A large proportion of patients (50.0%) reported that the national medical policy influenced their choice of FMT treatment. When patients felt severe disease activity, their willingness to undergo FMT increased (92.3% vs. 43.1%; $p = 0.001$).

Conclusions: Education can increase preference for FMT in patients with UC. When patients have severe disease symptoms or their quality of life decreases their willingness to undergo FMT increases. Moreover, national medical policies may influence patient choices regarding FMT.

Keywords: Ulcerative colitis; Fecal microbiota transplantation; Education; National medical policy; Severity

INTRODUCTION

Fecal microbiota transplantation (FMT) has gained increasing importance for treating recurrent or refractory *Clostridioides difficile* infections (CDI). Although immunomodulators, biological agents, and small-molecule drugs are mainly used to treat inflammatory bowel diseases (IBD) such as ulcerative colitis (UC) and Crohn's disease [1-5], FMT is a promising therapy for inducing and maintaining remission in patients with UC [6,7]. In Korea, FMT first began in 2013 for patients with CDI but was not approved for treating UC. The reimbursement of FMT is not covered by the national health insurance.

In several randomized controlled trials (RCTs) [8-11] and a meta-analysis of RCTs conducted on 140 patients with UC [12], FMT significantly increased the clinical remission rate. Even when steroid dependence was observed in patients with UC using classical treatments or biological agents, long-term use of FMT showed a good clinical response ($> 90\%$) and endoscopic remission (up to 80%) [13].

Many studies have investigated the perception of FMT in Western countries [14-18]. Recently, a survey on physicians' perceptions of FMT was conducted in South Korea [19]. In this study, most of the 107 physicians who responded to the survey had experience performing FMT; the most common indication for FMT was CDI. In Korea, FMT as a new therapeutic option for patients with UC remains in its infancy. Therefore, we investigated the recognition of FMT in patients with UC and their attitudes toward this procedure for UC treatment. Their preference for FMT was also assessed after receiving ed-

ucational materials under the national medical policy.

METHODS

Study design and patients

This prospective study was conducted between January 2021 and December 2022 at seven university hospitals in South Korea. Patients with UC who were ≥ 19 years of age and agreed to participate were enrolled. At the time of the survey, the patients' age, sex, education and economic levels, operation history, clinical classification according to the Montreal classification at diagnosis, and disease activity at diagnosis and during the survey were recorded. Informed consent was obtained from all the patients. The study protocol was in accordance with the Declaration of Helsinki and approved by the Institutional Review Board of each facility (approval number: SCHUH 2020-01-008-001, SMC 2021-12-039).

Survey instrument

The survey instrument was developed based on the opinions of the study group. Patients were surveyed using 22 questions on FMT. To investigate changes in the perception of FMT before and after providing educational material, three questions were asked before education, and 19 questions were asked after education. Educational materials on FMT included definitions, indications, donor selection and screening tests, efficacy for UC, and adverse events associated with FMT. The questionnaire details are presented

Table 1. Questionnaire results (n = 210)

Question	All responders
Before education about FMT	
1. Have you ever heard about FMT as a treatment option?	
Yes	87 (41.4)
No	108 (51.4)
Uncertain	15 (7.1)
2. Would you be willing to undergo FMT as a treatment for UC?	
Yes	57 (27.1)
No	26 (12.4)
Uncertain	127 (60.5)
3. If you hear about other patients who have had FMT as a treatment for UC and have had good results, would you be willing to undergo that treatment?	
Yes	130 (61.9)
No	11 (5.2)
Uncertain	69 (32.9)
After education about FMT	
4. After gaining knowledge about FMT, would you be willing to undergo fecal transplantation as a treatment for UC?	
Yes	98 (46.7)
No	22 (10.5)
Uncertain	90 (42.9)
5. If you decide to have a fecal transplant, who would you prefer as a fecal donor?	
Family	84 (40.2)
Spouse	11 (5.3)
Friend	0 (0.0)
Your choice	7 (3.3)
Anonymous	13 (6.2)
Physician's choice	86 (41.1)
Others	8 (3.9)
6. If you could only receive feces from a pre-screened, anonymous, healthy fecal donor, would you still be willing to undergo FMT?	
Yes	97 (46.2)
No	20 (9.5)
Uncertain	93 (44.3)
7. There are different infusion methods for FMT. Assuming they are equally effective, what is your favorite method?	
Enema	20 (9.5)
Colonoscopy	46 (21.9)
Freeze-dried capsule	63 (30.0)
Any method	35 (16.7)
Uncertain	46 (22.0)
8. Under what circumstances would you make the decision to undergo FMT?	
This treatment will be considered after FMT is determined to be safe.	67 (33.5)
If FMT is found to be effective, this treatment will be considered.	63 (31.5)

Table 1. Continued

Question	All responders
I want to try FMT because I'm worried about side effects with my current medications.	0 (0.0)
I would like to try FMT as it is less artificial than medication.	3 (1.5)
If my physician recommends FMT, I will consider this treatment.	31 (15.5)
If all medications fail, a preoperative fecal transplant will be considered.	28 (14.0)
If the dose or type of current medication can be reduced, a fecal transplant will be considered.	8 (4.0)
9. What are your main concerns about FMT?	
Infection after FMT	99 (48.3)
No treatment effect after FMT	53 (25.9)
FMT is disgusting	13 (6.3)
Uncertain	45 (19.5)
10. What are your main concerns regarding the safety of FMT?	
I'm concerned about the hygiene of the donated feces themselves.	38 (18.6)
I'm concerned that the feces being donated haven't been thoroughly screened for infectious diseases.	63 (30.1)
I'm worried that the injection method is not secure.	6 (2.9)
I'm worried that my UC will get worse after FMT.	64 (31.4)
I'm concerned that FMT will interfere with my current treatment for UC.	18 (8.8)
I don't have any specific concerns.	15 (7.4)
11. Regardless of its effectiveness, FMT is not yet approved as a treatment for UC in Korea. Would this medical policy affect your choice of undergoing FMT?	
Yes	105 (50.0)
No	28 (13.3)
Uncertain	77 (37.7)
12. How would you describe your current UC disease status?	
Asymptomatic	37 (17.8)
Mild	100 (48.1)
Moderate	47 (22.6)
Severe	13 (6.3)
Uncertain	11 (5.3)
13. Do you suffer from UC and find it difficult to lead a normal life?	
No	92 (43.8)
A little	93 (44.3)
A lot	25 (11.9)
14. Do you have any fears that your UC may get worse?	
No	26 (12.4)
A little	125 (59.5)
A lot	59 (28.1)
15. How do you feel about your current treatment medications?	
Highly satisfied	39 (18.6)
Satisfied	89 (42.4)
Moderately	74 (35.2)
Dissatisfied	7 (3.3)
Highly dissatisfied	1 (0.5)

Table 1. Continued

Question	All responders
16. If your UC worsens in the future, what is your next preferred treatment?	
New medicine	79 (37.6)
FMT	24 (11.4)
Uncertain	107 (51.0)
17. Please check all the things you have done individually to improve your UC. (You may select more than one)	
Fish oils (e.g., krill oil, omega-3, etc.)	34 (16.2)
Vitamins or dietary supplements (not recommended by your healthcare provider)	63 (30.0)
Herbal treatments (e.g., herbal medicine, acupuncture, etc.)	15 (7.1)
Exercise therapy (e.g., yoga, Pilates, etc.)	62 (29.5)
Diet (e.g., low-carb diet, low-fat diet, etc.)	82 (39.0)
Others	55 (26.2)
18. In the past 3 days, how many more defecations have you had than your average number of normal defecations per day?	
Normal number of stool	124 (59.1)
1–2 stools more than normal	57 (27.1)
3–4 stools more than normal	24 (11.4)
≥ 5 stools more than normal	5 (2.4)
19. What was the average amount of blood in your stool per day for the past 3 days?	
No blood seen	158 (75.2)
Streaks of blood with stool less than half the time	37 (17.6)
Obvious blood with stool most of the time	13 (6.2)
Blood alone passed	2 (1.0)
20. How was your average general body condition over the past 3 days?	
Very good	35 (16.7)
Above average	41 (19.5)
Fair	103 (49.0)
Slightly worse than average	28 (13.3)
Worst	3 (1.4)
21. What is your highest level of education?	
Middle school or less	17 (9.1)
High school	68 (36.4)
College	88 (47.1)
Graduate or higher	14 (7.5)
22. What is your household's approximate annual income? (Household annual income, not you)	
Less than \$20,000	11 (5.2)
\$20,000–\$50,000	38 (20.3)
\$50,000–\$70,000	29 (15.5)
\$70,000–\$100,000	41 (21.9)
More than \$100,000	27 (14.4)
Do not wish to disclose	41 (21.9)

Values are presented as number (%).

FMT, fecal microbiota transplantation; UC, ulcerative colitis

Table 2. Patient characteristics

Variable	UC (n = 210)
Age (yr)	44.6
Male	144 (68.6)
Education level	
Less than middle school	17 (9.1)
High school graduation	68 (36.4)
College degree	88 (47.1)
Postgraduate education	14 (7.5)
Household income	
Less than \$20,000	11 (5.2)
\$20,000–\$50,000	38 (20.3)
\$50,000–\$70,000	29 (15.5)
\$70,000–\$100,000	41 (21.9)
More than \$100,000	27 (14.4)
Do not wish to disclose	41 (21.9)
Previous surgery	19 (9.0)
Duration of disease (yr)	
< 2	131 (65.8)
2–5	35 (17.6)
> 5	33 (16.6)
Age at diagnosis, mean years	
A1 (< 17 years)	5 (2.4)
A2 (17–40 years)	111 (52.9)
A3 (> 40 years)	93 (44.3)
UC extent (at diagnosis)	
E1 (proctitis)	89 (42.4)
E2 (left-sided)	52 (25.6)
E3 (extensive)	62 (30.5)
Disease activity ^{a)} (at diagnosis)	
Clinical remission	11 (6.7)
Mild activity	62 (37.6)
Moderate activity	82 (49.7)
Severe activity	10 (6.1)
Disease activity ^{a)} (at survey)	
Clinical remission	142 (71.0)
Mild activity	33 (16.5)
Moderate activity	22 (11.0)
Severe activity	3 (1.5)
Concomitant medications (at survey)	
5-ASA	57 (27.1)
5-ASA + topical 5-ASA	55 (26.2)
Topical 5-ASA	32 (15.2)

Table 2. Continued

Variable	UC (n = 210)
5-ASA + AZA	16 (7.6)
No specific medication	9 (4.3)
5-ASA + steroid	8 (3.8)
5-ASA + topical 5-ASA + biologics	6 (2.9)
Biologics	6 (2.9)
5-ASA + steroid + AZA	4 (1.9)
5-ASA + topical 5-ASA + AZA	4 (1.9)
5-ASA + AZA + biologics	3 (1.4)
AZA	2 (1.0)
5-ASA + biologics	2 (1.0)
AZA + biologics	2 (1.0)
5-ASA + topical 5-ASA + steroid	1 (0.5)
5-ASA + topical 5-ASA + AZA + biologics	1 (0.5)
Steroid	1 (0.5)
Steroid + biologics	1 (0.5)

Values are presented as mean only or number (%).

UC, ulcerative colitis; 5-ASA, 5-aminosalicylic acid; AZA, azathioprine.

^{a)}Disease activity was assessed using the Mayo score. The Mayo score was classified into four categories: 0–2, clinical remission; 3–5, mild; 6–10, moderate; and 11–12, severe.

in Table 1. The survey focused on patients' perceptions of FMT. The willingness, preferred donor and method, concerns about FMT, and factors influencing the choice of FMT were investigated. The Korean version of the questionnaire and educational materials are provided in the Supplementary Material.

Statistical analysis

Quantitative variables are expressed as means, and qualitative variables are expressed as percentages. Continuous and categorical variables were compared using a two-tailed Student's t-test and chi-square test, respectively. Statistical significance was set at $p < 0.05$. Data management and statistical analyses were performed using the SPSS software (version 21.0; IBM Corp., Armonk, NY, USA).

RESULTS

Patient characteristics

A total of 210 patients participated in this study. The mean

age was 44.6 years, and males outnumbered females by 68.6%. Of the total, 170 patients had a high school or high-

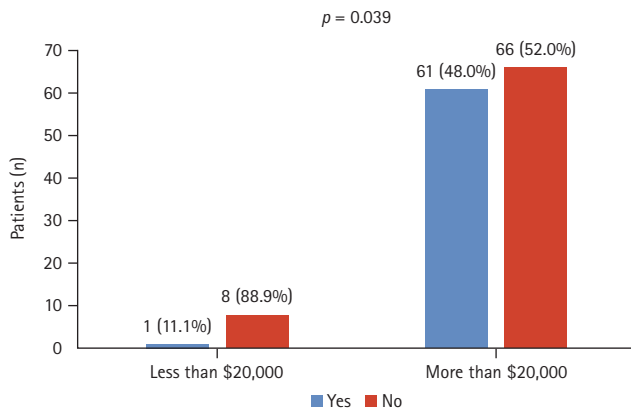


Figure 1. Fecal microbiota transplantation awareness by income level.

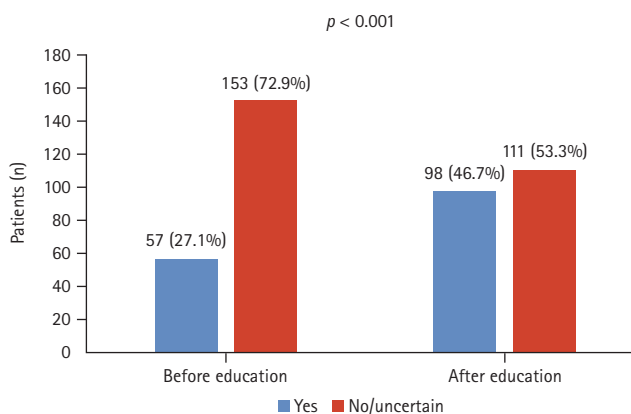
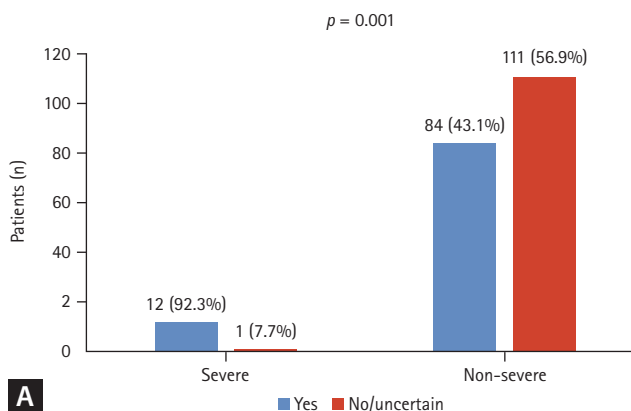


Figure 2. Attitude changes regarding undergoing fecal microbiota transplantation after education.



A

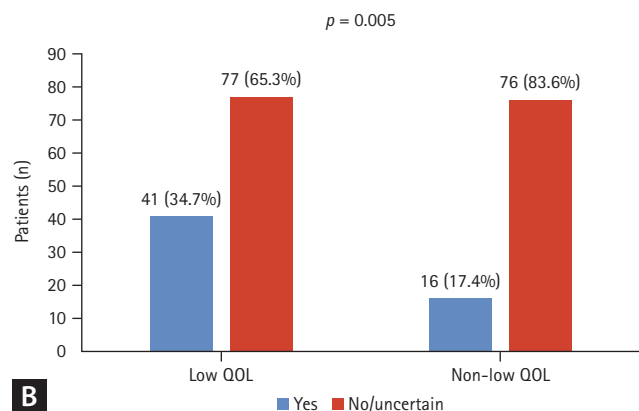
er education level, accounting for more than 90%. More than 50% of patients' households earned \geq \$50,000. One hundred sixteen (55.3%) people were diagnosed with UC under the age of 40. At the time of the survey, 142 (71.0%) patients were in clinical remission, and 55 (27.5%) had mild to moderate disease activity. The disease period was less than 2 years for 131 people (65.8%), 2–5 years for 35 people (17.6%), and $>$ 5 years for 33 people (16.6%). The patient characteristics are shown in Table 2.

Patient awareness and intention about FMT before education

Before education, 87 (41.4%) patients had heard of FMT, and 108 (51.4%) said they had not heard of it. The questionnaire asked, "What would you do if you heard from other patients that UC treatment was effective after FMT?" The number of patients willing to try it increased from 57 (27.1%) to 130 (61.9%) (Table 1). No significant correlation was observed between educational status and perceptions of FMT ($p > 0.05$). In contrast, there was a significant difference in awareness of FMT based on income, from one (11.1%) patient earning $<$ \$20,000 to 61 (48.0%) earning $>$ \$20,000 ($p = 0.039$; Fig. 1).

Attitude changes and factors related to attitude changes after education

The number of people who wanted to undergo FMT before and after receiving educational materials on FMT increased significantly from 57 (27.1%) to 98 (46.7%) ($p < 0.001$; Fig. 2). Currently, FMT is not recognized as a formal treatment for UC in Korea, and 105 respondents (50%) reported



B

Figure 3. Factors related to attitude changes after education. The willingness to undergo fecal microbiota transplantation according to disease severity (A) and quality of life (QOL) (B) perceived by the patient.

that it affected FMT treatment decisions. In response to the survey question, "How would you describe your current UC disease status?" 13 (6.3%) patients reported severe disease (Table 1).

Among patients who felt disease activity was severe, 12 of 13 patients (92.3%) showed a willingness to undergo FMT, whereas, in the group that did not, 84 of 195 patients (43.1%) showed an interest in FMT ($p = 0.001$). Disease duration was not associated with patients' willingness to undergo FMT. In the group that felt that it was challenging to live their daily lives because of UC, 41 of 118 people (34.7%) were willing to try FMT, and in the group that did not find it challenging, only 16 of 92 (17.4%) were interested in FMT ($p = 0.005$; Fig. 3).

Preferred donor and application method

The most preferred FMT donors were physician recommendations in 86 patients (41.1%), followed by family members in 84 patients (40.2%). Most patients wanted a physician's recommendation or family members as donors. Freeze-dried capsules were the most preferred method of administering FMT in 63 patients (30.0%), followed by colonoscopy in 46 patients (21.9%). If UC worsened, the preferred treatment was new drugs in 79 patients (37.6%) and FMT in 24 (11.4%). In the case of receiving feces from anonymous healthy stool donors selected through pre-testing, 97 (46.2%) were willing to undergo FMT (Table 1).

Concerns about FMT

In a survey on the most worrisome aspects of FMT, 99 patients (48.3%) answered that they were most worried about infection after FMT. Fifty-three patients (25.9%) were concerned it would not have a therapeutic effect. Safety and treatment efficacy were the most concerning aspects for patients with UC who chose FMT as a therapeutic option. The primary concern regarding the safety of FMT was that it would worsen UC, with 64 patients (31.4%) stating this, followed by 63 (30.1%) who were concerned that the donor stool may not be thoroughly screened for infectious diseases (Table 1).

DISCUSSION

This study aimed to investigate perceptions of FMT in patients with UC and to identify the association between atti-

tudes toward FMT and education, national medical policy, and disease severity. To the best of our knowledge, no survey has investigated the various factors related to attitude changes toward FMT.

Recently, FMT has been increasingly used as a CDI treatment and is recognized as a standard treatment, especially for recurrent CDI [20-22]. The effect of FMT on UC has also been confirmed in Western studies [8-13]. As a result, awareness among physicians and patients has increased and is being implemented in many cases. Nonetheless, a Western study reported that 53.5% of patients with CDI and UC were unaware of FMT [14]. Similarly, in our study, a large proportion of patients with UC (51.4%) were unaware of FMT as a therapeutic option. This shows that the awareness of FMT remains low among patients with UC in Korea. Significantly more patients were positive toward FMT after the educational materials were provided. Western studies have reported similar results [14,17]. This suggests that educational materials, including the current evidence, can change attitudes toward new therapeutic options. Physicians must cultivate patient treatment knowledge by providing information on therapeutic options. However, the latest American Gastroenterological Association guidelines suggest against using conventional FMT in patients with UC, except in the context of clinical trials [23]. Although our study showed that patient education can increase the preference for FMT in patients with UC, physicians should consider that FMT for UC can be used outside of a clinical trial when no comparable or satisfactory alternative treatment options are available. Further large, population-based, well-designed studies are needed to establish the long-term efficacy and safety of FMT for treating UC.

Notable results were observed regarding the disease activity and quality of life. Up to 93% of the patients who experienced severe disease activity were willing to receive FMT. Compared with the group who did not experience severe disease activity, the willingness to undergo FMT was significantly higher (92.3% vs. 43.1%, $p = 0.001$). Willingness to undergo FMT was significantly increased in patients who thought it challenging to live a normal life due to UC compared with those whose quality of life was not affected (34.7% vs. 17.4%, $p = 0.005$). This suggests that the desire for and acceptance of new therapeutic options such as FMT is higher in patients with higher disease severity and lower quality of life. In addition, 50% (105/210) of the respondents said that their decisions were affected because FMT

was not approved as a treatment option for IBD in Korea. This suggests that national medical policies may foster a reluctance to select appropriate therapeutic options.

Evidence regarding the donor type best suited for FMT in patients with UC is lacking. In our study, a similar number of patients preferred donor selection regardless of their physician's recommendation (41.1%) or that of family members (40.2%). Safety (e.g., worse UC and infection) and treatment efficacy of FMT in patients with UC were evaluated in our study. The future implementation of FMT in Korean patients with UC implies that shared decision-making will play an important role in donor and treatment selection.

Our study has several advantages. First, this was a multicenter prospective survey that enrolled 210 patients with UC. Therefore, the results may be generalizable. Second, this study is the first to investigate the factors related to attitude changes toward FMT. Third, this survey suggests that patients with UC are interested in FMT as a new therapeutic option and would like it to become available. However, this study has some limitations. First, an unvalidated questionnaire was used. Secondly, there were some missing values in the questionnaire, which made the study less reliable. Despite these limitations, our results suggest that many factors influence Korean patients with UC's perceptions of and attitudes toward FMT and can be changed through education.

In conclusion, FMT awareness remains low among patients with UC in Korea. The preference for FMT in patients with UC can be increased through patient education. Attitude changes concerning FMT were associated with disease severity as perceived by the patient and the national medical policy.

KEY MESSAGE

1. More than half of the surveyed patients were unaware that FMT was an alternative treatment option for UC.
2. Education can increase the preference for FMT in patients with UC.
3. Patient attitudes towards FMT were influenced by national medical policy, as well as the disease severity and quality of life perceived by the patients.

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Conflicts of interest

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