

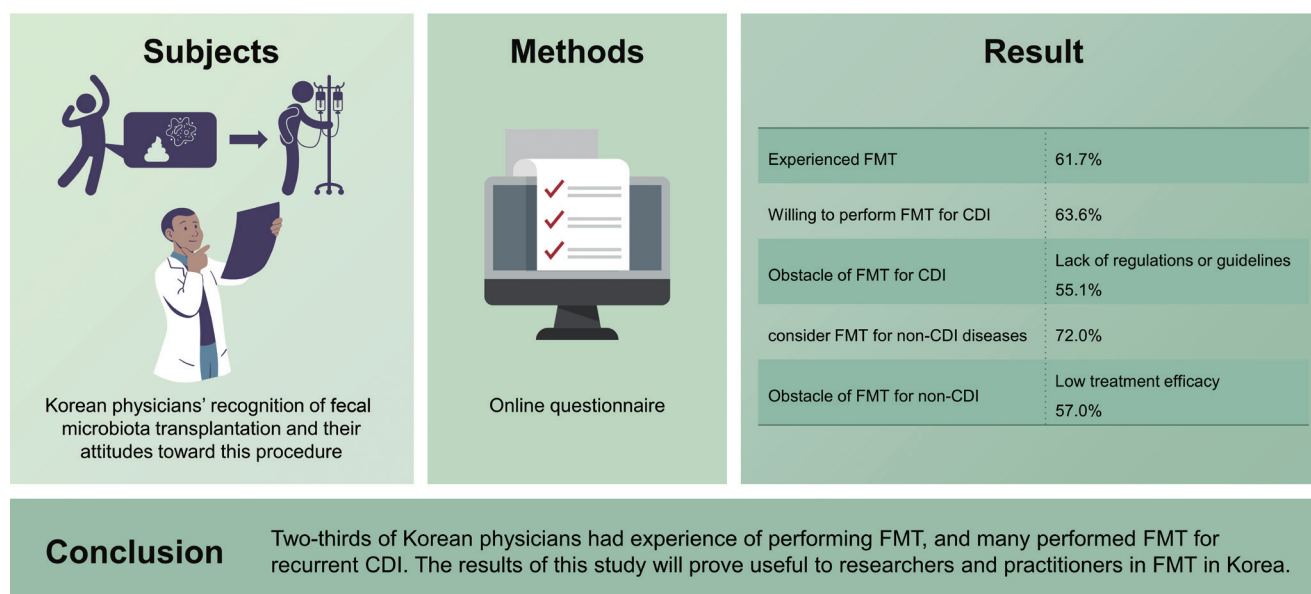


Recognition and attitudes of Korean physicians toward fecal microbiota transplantation: a survey study

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Background/Aims: Fecal microbiota transplantation (FMT) represents a treatment option for recurrent *Clostridioides difficile* infection (CDI). Recently, FMT has been investigated in various clinical settings other than CDI. This study examined Korean physicians' recognition of FMT and their attitudes toward this procedure

Methods: An online questionnaire included questions on indications for FMT, the FMT process, physicians' attitudes toward FMT for the treatment of CDI and non-CDI diseases, and possible concerns.

Results: Finally, 107 physicians responded to this survey: 66 (61.7%) had experience of performing FMT, and 86 (80.4%) replied that they were willing to perform FMT for CDI. Two-thirds of physicians (63.6%, n = 68) would perform FMT for recurrent CDI on patients who had at least three recurrences. The most common obstacle to performing FMT for the treatment of CDI was the lack of regulations or guidelines (55.1%, n = 59). Seventy-seven (72.0%) physicians would consider FMT for non-CDI diseases when conventional treatment had failed. The most common obstacle for FMT for the treatment of non-CDI diseases was low treatment efficacy (57.0%, n = 61).

Conclusions: Two-thirds of Korean physicians had experience of performing FMT, and many performed FMT for recurrent CDI. The results of this study will prove useful to researchers and practitioners in FMT in Korea.

Keywords: Fecal microbiota transplantation; *Clostridioides difficile* infection; Surveys and questionnaires

INTRODUCTION

Fecal microbiota transplantation (FMT) has been established as an effective treatment option for recurrent or refractory *Clostridioides difficile* infection (CDI) [1]. The clinical manifestations of CDI may differ between countries; for example, the incidence of CDI is lower in Asia-Pacific countries than in Western countries [2,3]. The incidence of community-associated CDI is reported to be up to 50% in Western countries [4]. By contrast, its proportion in Korea is reported to be less than 5% [2,5].

Because FMT provides a rapid resolution of CDI and is associated with a lower recurrence compared with conventional treatment [6], it is recommended for recurrent or refractory CDI [1,7,8]. The process of FMT includes patients selection (= FMT indication), donor screening, stool processing, and fecal microbiota administration. Despite its high efficacy for the treatment of CDI, physicians as well as patients are rather reluctant to pursue FMT as a treatment option for non-CDI diseases [9,10]. Nevertheless, with growing evidence of the relationship between dysbiosis of the gut microbiota and various diseases, including gastrointestinal and metabolic diseases, FMT has been investigated in a number of clinical settings other than CDI [11-14].

The first FMT procedure in Korea was reported in 2013 and it has since been performed in several academic centers [15-18]. In this nationwide survey, we investigated physicians' recognition of FMT and their attitudes toward this

procedure for treatment of both CDI and non-CDI diseases.

METHODS

A nationwide online survey was conducted that contained 20 questions in six categories. The survey focused on demographic characteristics of physicians' experience of FMT, and their attitude toward FMT for the treatment of CDI and non-CDI diseases. The perception of safety of FMT and stool banks was investigated. The perception of safety of FMT was compared with that of a blood transfusion. Overall safety of FMT was investigated using a 5-point scale. Details of the questionnaire are presented in Appendix 1. The anonymous survey was conducted online by Survey Monkey (<https://www.surveymonkey.com>). The email invitation to participate was sent three times to members of the Korean Society of Neurogastroenterology and Motility, the Korean Association for the Study of Intestinal Diseases, and the Korean Society of Gastroenterology. Responses were collected from May to October 2019. Ethical approval for the study was obtained from Bucheon St. Mary's Hospital (IRB approval number: HC22QASI0028). Informed consent was waived by the board.

Table 1. Demographic characteristics of responders

Characteristic	Total (n = 107)
Age, yr	
< 40	16 (15)
40–49	59 (55.1)
50–59	27 (22.2)
≥ 60	5 (4.7)
Male sex	83 (77.6)
Practice setting	
Academic hospital	92 (76)
Community hospital or primary clinic	15 (14)
Number of previous FMT	
0	42 (39.3)
< 5	31 (29.0)
5–10	8 (7.5)
11–20	10 (9.3)
21–30	5 (4.7)
> 30	11 (10.3)

Values are presented as number (%).
FMT, fecal microbiota transplantation.

RESULTS

In total, 107 physicians responded to this survey (response rate: 11.7%, 107/917). The response rate of physicians in the academic hospital and the primary clinic or community hospital was 30.3% (92/304) and 2.4% (15/613), respectively. Demographic characteristics of responders are presented in Table 1 (males: 77.6%, 83/117). All responders were gastroenterologists. Most responders worked as professors in university-affiliated hospitals, and 60.7% had FMT experience. Details of their experience of FMT are presented in Table 2. Indications for FMT experience were CDI, inflammatory bowel disease (IBD), irritable bowel syndrome (IBS), and graft-versus-host disease. FMT was mostly performed for the treatment of CDI (92.3%). Mostly fresh stool was chosen for FMT. Frozen stool from non-profit stool banks was the second most used fecal product. The reasons for lack of FMT experience were investigated: 35.7% physicians (15/42) chose lack of previous FMT experience.

Attitudes toward FMT for the treatment of CDI are shown

Table 2. Experiences of fecal microbiota transplantation

Characteristic	Total (n = 107)	
	With FMT experience (n = 65)	Without FMT experience (n = 42)
Previous experience of FMT (you may select more than one option)		
<i>Clostridioides difficile</i> infection	60 (92.3)	NA
Ulcerative colitis	10 (15.4)	NA
Crohn's disease	4 (6.2)	NA
Irritable bowel syndrome	12 (18.5)	NA
Graft-versus-host-disease	3 (4.6)	NA
Source of fecal material (you may select more than one option)		
Fresh stool	35 (52.8)	
Frozen stool, collected by physicians and stored in hospital	10 (15.4)	
Frozen stool from non-profit stool bank	30 (46.2)	
Reasons for lack of FMT experience		
Lack of previous FMT experience	NA	15 (35.7)
Lack of FMT candidate (= patient)	NA	10 (23.8)
Unwillingness	NA	7 (16.7)
Difficulties for preparing fecal suspension	NA	5 (11.9)
Ethical problem	NA	2 (4.8)
Others	NA	3 (7.1)

Values are presented as number (%).
FMT, fecal microbiota transplantation; NA, not available.

in Table 3. About 80% of physicians responded that they performed FMT when indicated; 17 (15.9%) responded that they would transfer patients to specialized treatment centers when FMT was indicated for a patient. Except for four physicians (3.7%), most responders replied that FMT could

Table 3. Attitude toward fecal microbiota transplantation for the treatment of *Clostridioides difficile* infection

Characteristic	Total (n = 107)
Willingness to perform FMT for CDI	
Actively perform	48 (44.9)
Perform if clinically indicated	38 (35.5)
Transfer patients to dedicated center	17 (15.9)
FMT is not needed for treatment	4 (3.7)
Reasons for considering FMT for the treatment of CDI (select one or more)	
Favorable treatment efficacy	96 (89.7)
Proven safety	27 (25.2)
Cessation of anti-CDI antibiotics	32 (29.9)
Improvement of dysbiosis	55 (51.4)
Possible FMT indications for CDI (select one or more)	
Recurrent CDI	78 (72.9)
Refractory CDI	99 (92.5)
Severe CDI	32 (29.9)
Fulminant CDI	35 (32.7)
How many recurrences of CDI, will you perform FMT?	
1st recurrence	10 (9.3)
2nd recurrence	23 (21.5)
3rd recurrence	68 (63.6)
Don't know	6 (5.6)
Obstacles to FMT in the treatment of CDI (select one or more)	
Adverse event	25 (23.4)
Medicolegal problem	26 (24.3)
Lack of confidence in treatment efficacy	21 (19.6)
Aesthetically unappealing procedure	62 (57.9)
Difficulty in obtaining consent from the patient or the patient's family	27 (25.2)
Lack of guidelines or regulations	64 (59.8)

Values are presented as number (%). FMT, fecal microbiota transplantation; CDI, *C. difficile* infection.

be considered for the treatment of CDI. The most common reason for trying FMT was due to its favorable treatment efficacy (89.7%). Where there was a possible indication of refractory (defined as unresponsiveness after at least two weeks of conventional treatment) or recurrent CDI, FMT was considered by 92.5% and 72.9% of responders, respectively. About one-third of physicians considered that FMT could be considered in severe CDI or fulminant CDI. For recurrent CDI, 63.6% considered FMT in three or more cases of CDI recurrence. Where FMT was not used to treat CDI, the two major obstacles were lack of guidelines (59.8%) and the aesthetically unappealing nature of the FMT procedure.

Table 4. Attitude toward fecal microbiota transplantation for the treatment of diseases other than *Clostridioides difficile* infection

Characteristic	Total (n = 107)
Willingness to perform FMT for non-CDI diseases ^a	
Actively perform FMT	17 (15.9)
Perform FMT	60 (56.1)
Intermediate	16 (15.0)
FMT is not considered	14 (13.1)
Possible indication for FMT other than CDI (select one or more)	
Ulcerative colitis	45 (42.1)
Crohn's disease	23 (21.5)
Graft-versus-host disease	14 (13.1)
Irritable bowel syndrome	33 (30.8)
Obesity	15 (14.0)
Non-alcoholic steatohepatitis	6 (5.6)
Not indicated for other diseases than CDI	39 (36.4)
Obstacles for performing FMT in treating diseases other than CDI (select one or more)	
Low treatment efficacy	61 (57.0)
Transmission of infectious disease	43 (40.2)
Adverse events related to FMT procedure	42 (39.2)
Aggravation of underlying disease	21 (19.6)
Low patient compliance	22 (20.6)

Values are presented as number (%).

FMT, fecal microbiota transplantation; CDI, *C. difficile* infection.

^aFor diseases other than CDI where conventional treatment has failed and where FMT is being performed for a clinical trial, will you perform FMT.

dures itself (57.9%).

Attitudes toward FMT for the treatment of diseases other than CDI are presented in Table 4. About one-third of physicians thought that FMT was not indicated for diseases other than CDI. The most common and second most common indications for FMT were ulcerative colitis (42.1%) and IBS (30.8%), respectively. For Crohn's disease, 21.5% replied that FMT might be indicated; this response level was half that for ulcerative colitis. The most common obstacle

Table 5. Safety of fecal microbiota transplantation

Characteristic	Total (n = 107)
Safety for transfer of donor fecal microbiota to host	
Safer than a blood transfusion	11 (10.3)
More dangerous than a blood transfusion	52 (48.6)
Don't know	44 (41.1)
Overall safety of fecal microbiota transplantation	
Very dangerous	3 (2.8)
Dangerous	14 (13.1)
Intermediate	21 (19.6)
Safe	65 (60.7)
Very safe	4 (3.7)

Values are presented as number (%).

Table 6. Perception of stool bank

Characteristic	Total (n = 107)
Need for stool bank	
Essential	45 (42.1)
Frequently needed	52 (48.6)
Sometimes needed	6 (5.6)
Rarely needed	3 (2.8)
Never needed	1 (0.9)
Cautions for operation of stool bank (select one or more)	
Donor autonomy	55 (51.4)
Guarantee of anonymity for donors	28 (26.2)
Ownership of donated stool	24 (22.4)
Use of medical information for donated stool	32 (29.9)
Safety issue	95 (88.8)
No problems	3 (2.8)

Values are presented as number (%).

for FMT for the treatment of diseases other than CDI was its low treatment efficacy (57%). Regarding safety issues, transmission of infectious diseases and adverse events related to the FMT procedure were considered as obstacles in 40.2% and 39.2% of cases, respectively.

Table 5 indicates physicians' awareness of safety issues. The safety of FMT was compared with the safety of a blood transfusion. Almost 40% of physicians replied that they could not judge the safety of the FMT procedure compared with that of a blood transfusion; 11 physicians (10.3%) believed that FMT was safer than a blood transfusion, while about half considered that FMT was more dangerous than a blood transfusion. In terms of overall safety, 17 physicians (15.9%) thought that FMT was dangerous or very dangerous.

Table 6 shows physicians' attitudes toward a stool bank. About 90% responded that a stool bank was necessary to provide fecal material for FMT. Serious concerns regarding the operation of a stool bank involved safety issues (88.8%) and preservation of donor autonomy (51.4%).

DISCUSSION

In this survey, we investigated physicians' current recognition of FMT and attitudes toward this procedure for treatment of CDI and various other diseases. About 60% of physicians had experience in FMT, and most considered FMT favorably for the treatment of CDI, and more so than for non-CDI diseases.

In recent years, FMT has shown favorable treatment efficacy for the treatment of CDI and is recognized as the standard of care for recurrent CDI. We first investigated physicians' experience of performing FMT. About 60% of responders had previous FMT experience and CDI was the most common indication for previous FMT experience (92.3%). About half of respondents used frozen stool for FMT.

We also investigated the reasons for lack of FMT experience. Interestingly, the most common reason for not performing FMT was lack of previous FMT experience (35.7%). FMT procedures include donor screening, patient selection, fecal microbiota administration, and post-FMT care. In Western countries, the clinical characteristics of CDI may differ from those in Korea where community-acquired CDI is very low [2,5]. This means that CDI can be complicated be-

cause patients are elderly and often extremely ill. Our group reported the first experience of FMT in Korea and included older patients with multiple comorbidities [18]. In such cases, performing FMT is challenging.

We investigated the willingness of physicians to perform FMT for the treatment of CDI; about 80% were willing to do so when clinically indicated. The two most common obstacles to performing FMT for CDI treatment were a lack of guidelines or regulations (59.8%) and FMT being aesthetically unappealing in nature (57.9%). However, multi-disciplinary national FMT guidelines have recently been published [8], and FMT is recommended for recurrent CDI after at least two recurrences. In the present survey, two-thirds of responders considered performing FMT to treat the third recurrence. The survey was completed before the development of Korean FMT guidelines, and FMT can now be performed as a 'New Health Technology' only for the treatment of CDI in Korea.

We also investigated physicians' attitudes toward FMT for diseases other than CDI. FMT is currently being tested in clinical trials for non-CDI diseases because the efficacy of FMT is lower than that of CDI in these diseases. Therefore, we questioned physicians' willingness to perform FMT for non-CDI diseases when conventional treatments have failed, which was a more conditional position. After CDI, ulcerative colitis and IBS were the most common possible indications for FMT. At the time of this survey, some randomized controlled trials for ulcerative colitis and IBS were published [19-21]. The most common obstacle to performing FMT for non-CDI diseases was low treatment efficacy. Although dysbiosis was proven in various diseases, the pathogenesis of IBS and IBD is multifactorial. In FMT trials for IBS, IBS-related symptoms did not improve after FMT even though dysbiosis improved [21].

Safety is a very important issue for FMT. Although FMT is widely performed in the USA, the Food and Drug Administration (FDA) has announced that fecal material used for FMT should be regulated as an 'investigational new drug' [22]. Physicians have raised concerns that the policy of the FDA could restrict FMT and argue that FMT should be managed in the same way as a blood transfusion rather than as a drug or as a solid organ transplantation [23]. We questioned the safety of FMT by comparing it to that of a blood transfusion. Except for those who did not choose either FMT or blood transfusion, 82.5% (52/63) of physicians thought that FMT was more dangerous than a blood transfusion. For

overall safety, 17 physicians (15.9%) thought that FMT was dangerous or very dangerous.

We investigated physicians' thoughts on stool banks, and about 90% of physicians agreed that they were necessary for FMT. FMT is an aesthetically unappealing procedure. Among the multiple steps, the handling and manufacturing of stool are the most unappealing. To counter these issues, nonprofit stool banks can help physicians by providing pre-screened and manufactured fecal material [24], and when frozen stool is used, the foul odor is less severe compared with that of fresh stool [25]. In their overall perception of stool banks, the aspect of greatest concern for physicians' was safety (89%). Although the FMT screening process is very strict and the qualification rate very low [26], transmission of pathogenic microorganisms is a major concern in FMT [27]. Recently, two universal stool banks have been established in Korea to provide stool product, which might help facilitate the FMT procedure.

Our study has several strengths. First, we included both CDI and non-CDI diseases in the survey, whereas similar previous surveys focused on CDI alone [9,28,29]. Given that FMT has recently been investigated for non-CDI diseases, it was logical to investigate physicians' attitudes toward FMT in both CDI and non-CDI diseases. Second, attitudes to safety were questioned in detail. Third, over 100 gastroenterologists, more than in previous studies, participated in this survey [9,28]. Nevertheless, there are some limitations that should be addressed. First, the survey was carried out before the coronavirus disease 2019 (COVID-19) pandemic. During the pandemic, a guideline was released that recommended that FMT might be best performed to a limited degree [30]. Thus, our survey does not represent the attitudes of the pandemic era toward FMT. Second, because the survey targeted only gastroenterologists, recognition of FMT and attitudes toward the procedure were not investigated among other physicians. Third, the response rate of 11.7% was low. FMT is mostly performed in dedicated academic centers. Physicians in the primary clinic or community hospital may not be interested in FMT. Certainly, the response rate differed among physicians in the academic centers.

In conclusion, this study was the first to investigate Korean gastroenterologists' recognition of FMT and their attitudes toward this procedure in for the treatment of CDI and non-CDI diseases. It is hoped that the results of this study will prove useful to researchers and practitioners in FMT in Korea.

KEY MESSAGE

1. The most common obstacle to performing fecal microbiota transplantation (FMT) for the treatment of *Clostridioides difficile* infection (CDI) was the lack of regulations or guidelines.
2. Two-thirds of physicians would perform FMT for recurrent CDI on patients who had at least three recurrences.
3. Three-fourth of physicians would consider FMT for non-CDI diseases when conventional treatment had failed.

Conflict of interest

No potential conflict of interest relevant to this article was reported.

Acknowledgments

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Appendix 1. Questionnaire

General information

1. What is your gender? male female

2. What is your present position?
 - Professor
 - Associate professor
 - Assistant professor
 - Clinical fellow
 - Doctor at a general hospital
 - Doctor at a primary clinic

3. What is your age?
 - ≤ 39 40–49 50–59 ≥ 60 years

4. Where is the location of your hospital (province)?

Experience of fecal microbiota transplantation (FMT)

5. How many cases of FMT have you performed in your hospital?
 - 0 1–4 5–10 11–20 21–30 > 30

6. Why have you not performed FMT?
 - Lack of previous FMT experience
 - No patients indicated for FMT
 - Unwillingness
 - Difficulties in preparing fecal suspension
 - Ethical issues
 - Other

7. What was the indication of previous cases of FMT (you may select more than one option)?
 - C. difficile* infection (CDI)
 - Ulcerative colitis
 - Crohn's disease
 - Graft versus host disease
 - Irritable bowel syndrome

8. What kind of fecal suspension have you used for FMT (you may select more than one option)?
 - Fresh stool
 - Frozen stool, in-house stool bank
 - Frozen stool, from nonprofit stool bank

Attitude toward FMT for the treatment of CDI

9. What are the possible indications of FMT for CDI treatment (you may select more than one option)?
 - Recurrent CDI
 - Refractory CDI (defined as unresponsiveness after at least two weeks of conventional treatment)

- Severe CDI
- Severe complicated CDI (fulminant CDI)

10. How actively do you perform FMT for CDI?

- Actively perform
- Perform albeit reluctantly
- Transfer patient to another hospital
- FMT is not needed for CDI

11. What are the reasons for considering FMT for the treatment of CDI (you may select more than one option)?

- Favorable treatment efficacy
- Proven safety
- Cessation of anti-CDI antibiotics
- Improvement of dysbiosis

12. For how many recurrences of CDI will you perform FMT?

- 1st recurrence
- 2nd recurrence
- 3rd recurrence
- Don't know

13. What are the obstacles to FMT in the treatment of CDI (you may select more than one option)?

- Adverse events
- Medicolegal issues
- Lack of confidence in treatment efficacy
- Aesthetically unappealing procedure
- Difficulty in obtaining consent from the patient or the patient's family
- Lack of guidelines or regulations

Attitude toward FMT for the treatment of diseases other than CDI

14. For diseases other than CDI where conventional treatment has failed and where FMT is being performed for a clinical trial, will you perform FMT?

- Actively perform FMT
- Perform FMT
- Intermediate
- FMT is not considered

15. What are the possible indications of FMT for diseases other than CDI (you may select more than one option)?

- Ulcerative colitis
- Crohn's disease
- Graft-versus-host disease
- Irritable bowel syndrome
- Obesity
- Nonalcoholic steatohepatitis
- FMT is not indicated for diseases other than CDI

16. What are the obstacles for performing FMT in treating diseases other than CDI (you may select more than one option)?

- Low treatment efficacy
- Transmission of infectious disease
- Adverse events related to FMT procedure
- Aggravation of underlying disease
- Low patient compliance
- Don't know

Safety of FMT

17. How do you judge the overall safety of FMT?

- Very dangerous
- Dangerous
- Intermediate
- Safe
- Very safe

18. Compared with a blood transfusion, how safe is the transfer of donor fecal microbiota to the patient?

- Safer than a blood transfusion
- More dangerous than a blood transfusion
- Don't know

Perception of stool bank

19. Is a stool bank for the provision of fecal material needed for FMT?

- Essential
- Frequently needed
- Sometimes needed
- Rarely needed
- Never needed

20. What needs to be considered for operation of a stool bank?

- Donor autonomy
- Guarantee of anonymity for donors
- Ownership of donated stool
- Use of medical information from donated stools
- Safety issues
- No problems