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Short report

Comparative effectiveness of faecal microbiota transplant by route of administration

N.D. Gundacker [a,*], A. Tamhane [a], J.B. Walker [b], C.D. Morrow [c], J.M. Rodriguez [a]

[a] Division of Infectious Diseases, University of Alabama at Birmingham, Birmingham, AL, USA
[b] Department of Medicine, University of Alabama at Birmingham, Birmingham, AL, USA
[c] Department of Cell, Developmental and Integrative Biology, University of Alabama at Birmingham, Birmingham, AL, USA

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SUMMARY

The optimal route of delivery for faecal microbiota transplant (FMT) is unknown. This observational single-centre study analysed the two-week cure rates for all patients who received FMT from 2013 to 2016 according to route of delivery. Overall, nasogastric delivery of FMT was less effective than lower endoscopic delivery. When patients were stratified by illness severity, nasogastric delivery achieved similar cure rates in healthier individuals, whereas lower endoscopic delivery was preferred for relatively ill individuals. Nasogastric delivery may be less effective than lower endoscopic delivery; however, when taking the cost, preparation and potential risk into account, this difference may not be clinically significant for patients with mild disease.

Background

Clostridium difficile infection (CDI) is currently the most common hospital-acquired infection in the USA with over 450,000 cases and 29,000 deaths annually [1,2]. Recurrent disease occurs in 20–30% of cases and is historically very difficult to treat. Faecal microbiota transplant (FMT) has revolutionized CDI treatment and is associated with success rates from 70% to 85% with a single administration of FMT [3–5]. The optimal route of FMT delivery remains undetermined; however, some studies have suggested that colonoscopy is the superior technique [6,7].

Despite FMT's high cure rate, some individuals will fail their first procedure, thus requiring repeated treatments. Several studies have suggested that patient characteristics and increasing comorbidities may contribute to this initial failure rate [6,7]. This single-centre observational study compared two-week cure rates of two common delivery methods of FMT: nasogastric tube (NGT) delivery and lower endoscopic delivery. The goal was to determine overall initial efficacy of each delivery route and to determine which patients would gain the greatest benefit from different delivery methods.

Methods

In this observational prospective follow-up study, all patients receiving FMT for CDI via NGT or lower endoscopy at the University of Alabama at Birmingham (UAB) from 2013 to 2016 were included in the analysis. The study was approved by the

* Corresponding author. Address: Division of Infectious Diseases, University of Alabama at Birmingham, 1900 University Blvd, THT 229, Birmingham, AL 35294-0006, USA.
E-mail address: ngundacker@uabmc.edu (N.D. Gundacker).

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Table I
Characteristics associated with cure in patients receiving faecal microbiota transplant at University of Alabama at Birmingham, 2013–2016

Characteristic	Total *N*=50	Cure[a] (*N*=41)	Relapse[a] (*N*=9)	Univariate analysis[b]		Multi-variate analysis[c]	
	N	*N* (%)[d]	*N* (%)[d]	Unadjusted RR (95% CI)	*P*-value	Adjusted RR (95% CI)	*P*-value
Route							
NGT	32	23 (71.9)	9 (28.1)	0.72 (0.58–0.89)	**0.002**	0.73 (0.59–0.90)	**0.004**
Lower endoscopic	18	18 (100.0)	0 (0.0)	Ref		Ref	
Age (years)							
≤59	20	18 (90.0)	2 (22.2)	1.17 (0.92–1.50)	0.20	1.00 (0.77–1.31)	0.98
≥60	30	23 (76.7)	7 (77.8)	Ref		Ref	
Sex							
Female	39	33 (80.5)	6 (66.7)	1.16 (0.79–1.71)	0.44	1.19 (0.85–1.67)	0.31
Male	11	8 (19.5)	3 (33.3)	Ref		Ref	
Ethnicity							
White	42	36 (90.0)	6 (66.7)	1.50 (0.78–2.88)	0.22	–	–
Black	7	4 (10.0)	3 (33.3)	Ref			
BMI (kg/m^2)							
Mean (SD)	50	26.4 (7.6)	29.5 (6.9)	0.98 (0.95–1.01)[e]	0.18[e]	–	–
Malignancy							
Yes	4	4 (10.5)	0 (0)	1.21 (1.05–1.39)	**0.01**	–	–
No	41	34 (89.5)	7 (100)	Ref			
Immunosuppression							
No	30	26 (63.4)	4 (44.4)	1.16 (0.87–1.54)	0.96	1.09 (0.80–1.47)	0.47
Yes	20	15 (36.6)	5 (55.6)	Ref		Ref	
CDI classification							
Mild/moderate	38	32 (78.1)	6 (66.7)	1.13 (0.79–1.60)	0.52	1.09 (0.86–1.39)	0.59
Severe	9	8 (19.5)	1 (11.1)	Ref[f]		Ref[f]	
Complicated	3	1 (2.4)	2 (22.2)				
Number of CDI episodes							
≤5	39	32 (78.0)	7 (77.8)	1.00 (0.73–1.37)	0.99	–	–
>5	11	9 (22.0)	2 (22.2)	Ref			
CCI							
≤5	29	27 (65.8)	2 (22.2)	1.40 (1.02–1.92)	**0.04**	1.26 (0.94–1.70)	0.13
>5	21	14 (34.2)	7 (77.8)	Ref		Ref	
Stratified by CCI							
≤5 (*N*=29)							
NGT	–	14 (87.5)	2 (12.5)	0.88 (0.41–1.86)	0.73	0.90 (0.76–1.07)[g]	0.23
Lower endoscopic	–	13 (100)	0 (0.0)	Ref		Ref	
>5 (*N*=21)							
NGT	–	9 (56.3)	7 (43.8)	0.56 (0.19–1.68)	0.30	0.62 (0.37–1.04)[g]	0.07
Lower endoscopic	–	5 (100)	0 (0.0)	Ref		Ref	

BMI, body mass index; CCI, Charlson Comorbidity Index; CDI, *Clostridium difficile* infection; CI, confidence interval; FMT, faecal microbiota transplant; Ref, reference category; NGT, nasogastric tube; RR, risk ratio; SD, standard deviation.
Bold typeface indicates statistical significance at 0.05 level.
Missing data: ethnicity=1 (upper=1); malignancy=5 (upper=4, lower=1), white blood cells=13 (upper=11, lower=2); albumin=14 (upper=11, lower=3); lactic acid=28 (upper=18, lower=10).
[a] A patient was classified as 'cured' if there was no diarrhoea or a marked reduction in stool frequency at two weeks; otherwise, they were classified as 'relapsed'.
[b] Risk ratios calculated by log binomial regression model except for route and malignancy, where modified Poisson method was used due to zero cell frequency.
[c] Risk ratios calculated by modified Poisson regression method. Characteristics with no estimates shown were not included in the multi-variate model.
[d] Row percentage.
[e] Per 1 unit increase.
[f] Severe and complicated categories combined.
[g] Adjusted for age, sex, CDI and immunosuppression.

UAB's Institutional Review Board. At UAB, CDI was diagnosed if both a GDH and toxin assay were positive. Outside referrals were diagnosed using a variety of methods. FMT was performed in patients with two or more recurrences, or patients with severe disease refractory to standard therapy. Patients received a number of treatments prior to FMT including metronidazole, vancomycin, vancomycin tapers and fidaxomicin. In total, 50 patients were identified and entered into a