



# Prevalence and Predictors of Functional Evacuation Disorder in Patients with Chronic Constipation

Manas Kumar Behera<sup>1</sup> Debakanta Mishra<sup>2</sup> Manoj Kumar Sahu<sup>2</sup> Ayaskanta Singh<sup>2</sup>  
Girish Kumar Pati<sup>2</sup> Shobhit Agarwal<sup>2</sup> Jimmy Narayan<sup>2</sup>

<sup>1</sup>Department of Hepatology, SCB Medical College and Hospital, Cuttack, Odisha, India

<sup>2</sup>Department of Gastroenterology, IMS and SUM Hospital, Bhubaneswar, Odisha, India

Address for correspondence Jimmy Narayan, MD, DM, Department of Gastroenterology, IMS and SUM Hospital, Bhubaneswar, Odisha, India (e-mail: jimmynarayan@live.com).

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## Abstract

**Background** Functional evacuation disorder (FED) is the second most common cause of functional constipation (FC) after constipation-predominant irritable bowel syndrome. However, the data on FED is relatively scanty in our region. Hence, the present study was performed to evaluate the demographics of FED and to find out the predictors of FED in patients with chronic constipation.

**Methods** A total of 134 patients with chronic constipation diagnosed according to the Rome IV criteria who were referred for high-resolution anorectal manometry (HRAM) were retrospectively enrolled in the present study. All FC patients who underwent HRAM were asked to fill a questionnaire and underwent anorectal manometry and were submitted to the balloon expulsion test (BET).

**Results** The mean age of patients was  $43.09 \pm 9.32$  years old, with a total of 76 (54%) males. The most common symptom was straining during defecation (87%) followed by incomplete evacuation (86%). The prevalence of FED, diagnosed by HRAM and by the BET was 39%. Patients with FED had a significantly higher percentage of straining and sensation of anorectal blockade compared with those without FED (96 versus 82%;  $p < 0.01$ ; 81 versus 44%;  $p < 0.001$ , respectively). On the multivariate regression analysis, straining  $> 30$  minutes (odds ratio [OR] = 3.63;  $p = 0.03$ ), maximum squeeze pressure (OR = 1.05;  $p < 0.001$ ), and balloon volume at maximal sensation (OR = 1.06;  $p < 0.001$ ) were found to be significant independent predictors of FED.

**Conclusion** Prolonged straining and sensation of anorectal blockade were significant indicators of FED in patients with chronic constipation.

## Keywords

- ▶ chronic constipation
- ▶ functional evacuation disorder
- ▶ anorectal manometry
- ▶ gender

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## Introduction

Chronic constipation is a common gastrointestinal problem, affecting between 11 and 20% of the adult population. The prevalence of constipation increases with advanced age with a significant female predominance.<sup>1,2</sup> Although constipation is not a deadly and debilitating disorder, it has a high impact on quality of life, requiring frequent medical attention in most patients.<sup>2-5</sup> Chronic constipation can be either primary or secondary to other neurological, metabolic, and endocrine diseases.<sup>6</sup> Primary constipation is categorized into three types: slow-transit constipation, fecal evacuation disorder (FED), and constipation-predominant irritable bowel syndrome (IBS) with normal transit.<sup>7</sup>

Among all types of functional constipation, FED, or dys-synergic defecation, is the second most common type of primary constipation. The coordination of abdominal muscles, anal sphincters and pelvic floor muscles is required for effective rectal emptying. Fecal evacuation disorder results when no coordination between these components occurs during defecation, resulting in inadequate propulsive force, paradoxical contraction, and/or inadequate relaxation of pelvic floor muscles.<sup>7</sup> The exact etiology of FED remains unclear; however, excessive straining during defecation may lead to this disorder.<sup>8</sup>

There are various investigation modalities available for the diagnosis of FED among patients with chronic constipation. Although there is no gold standard investigation to diagnose FED,<sup>9</sup> high-resolution anorectal manometry (HRAM), along with the balloon expulsion test (BET) and conventional or magnetic resonance imaging (MRI) defecography are the mainstay for the diagnosis of this pathophysiologic subtype of constipation.<sup>10,11</sup> High-resolution anorectal manometry is a simple and useful procedure, but not widely available in all tertiary care centers, as defecography. Although the BET is relatively simple and widely available, it alone cannot diagnose FED.<sup>12</sup> Hence, we need to identify the clinical parameters that can predict FED in patients with chronic constipation; therefore, these patients can be referred to specialized centers where HRAM with the BET are available. Even though FED is more common in females when compared with males according to western data,<sup>13,14</sup> there are few studies from India assessing FED among female patients, probably due to the lack of access to healthcare facilities.

Hence, the present retrospective study was conducted with the aims of assessing the prevalence of FED among patients with chronic constipation, of evaluating the clinical and manometric predictors of FED among chronic constipation patients, and of characterizing and comparing the anorectal pressures in patients with or without FED.

## Material and Methods

### Study Design

All patients referred to the gastrointestinal and motility laboratory of the IMS and SUM Hospital for evaluation of chronic constipation from August 2016 to September 2019 were retrospectively analyzed. Clinical, laboratory, and ano-

rectal manometry data were extracted from the case records. Detailed clinical history including duration of illness, Bristol stool chart, presence of incomplete evacuation, straining, sensation of anorectal obstruction, manual evacuation, and mucus in stool were recorded. All patients, whose age ranged from 18 to 70 years old and presented with chronic constipation for > 6 months defined according to the ROME IV criteria were included in the study.<sup>15</sup> All patients had undergone either full-length colonoscopy or sigmoidoscopy including digital rectal examination. Secondary causes of constipation, such as mechanical obstruction, drugs, anatomical abnormalities of the pelvic floor or of the anorectum, uncontrolled diabetes mellitus, and thyroid diseases were excluded from the study. Informed consent was obtained from all patients.

### Anorectal Manometry

Each patient underwent HRAM using a water perfusion manometry system (Sandhill Scientific inc., Highland Ranch, CO, USA) according to the standard technique.<sup>16,17</sup> A 12-lumen manometry catheter with balloon was used. The patients were placed in the left lateral position and the manometry catheter was pushed deep inside the rectum. The catheter was afterwards pulled down slowly to be stationed at the high-pressure zone of the sphincter. The lengths of the sphincter zone and resting sphincter pressure were estimated from an average of the length and pressure data obtained. Then, the patients were told to squeeze the anal sphincter twice to measure the maximum squeeze pressure. Subsequently, the patients were asked to bear down to calculate the maximum residual anal sphincter pressure and the maximum intrarectal pressure. Then, the maximum intrarectal pressure was divided by the minimum anal sphincter pressure to derive the defecation index. A value  $\leq 1.4$  in this index indicates FED, since a defecation index  $> 1.5$  is required for normal defecation.<sup>18</sup> The ARM signal was analyzed using BioVIEW Software (Sandhill Scientific, Highlands Ranch, CO, USA).

The balloon was inflated with progressive increments of air volume (20 ml each time). The patients were asked to intimate the feeling of the balloon for the first time, when they felt urge to defecate, and the maximum tolerable limit of balloon volume. The rectoanal inhibitory reflex (RAIR) was evaluated during the inflation of the balloon. If there was a lowering of the resting anal sphincter pressure during the inflation of the balloon, then RAIR was considered to be present.

### Balloon Expulsion Test

This test provides an assessment of the ability of an individual to expel a simulated stool. A latex balloon tied to the tip of a thin catheter was placed inside the rectum and filled with 50 mL of warm water. The patient was asked to expel this while in the left lateral or sitting position. If the patient was unable to expel the balloon within 1 minute, the BET was considered abnormal.<sup>18</sup>

### Statistics

The data was analyzed on IBM SPSS Statistics for Windows, version 20.0 (IBM Corp. Armonk, NY, USA). Continuous

variables are presented as mean  $\pm$  standard deviation (SD), and categorical variables as the number of patients and percentages in parentheses. Continuous data were analyzed using the independent *t*-test or the Mann-Whitney U test when applicable, and the chi-squared test with Yate's correction (whenever applicable) was used for categorical variables. A stepwise logistic regression analysis was used for univariate and multivariate analysis. *P*-values  $< 0.05$  were considered statistically significant.

## Result

### Baseline Clinical and Demographic Data

A total of 134 patients with chronic constipation who had undergone anorectal manometry over a period of 6 years were enrolled in the study. The baseline clinical and anorectal manometry parameters in patients with chronic constipation are depicted in **Table 1**. The mean age of the patients was  $43.09 \pm 9.32$  years old; males constituted 54% of the study population. The median duration of constipation was 98 months, ranging from 14 to 146 months, suggesting longer duration of symptoms. Straining was the most common symptom (87%), followed by incomplete evacuation (86%), mucus in stool (62%), sensation of anorectal blockage (56%), and manual digital evacuation (43%). The median number of stools per week was 12, ranging from 4 to 19. The mean resting anal pressure and the maximal squeezing pressure were  $62.44 \pm 18.07$  mmHg and  $133.29 \pm 31.08$  mmHg, respectively. During balloon inflation, balloon volume at first sensation, urge, and discomfort were 50 (20–60) ml, 100 (70–140) ml, and 190 (140–300) ml, respectively, in patients with chronic constipation.

### Clinical and Anorectal Manometry Findings, Classified according to Fecal Evacuation Disorder

Demographic and clinical findings of chronic constipation patients with or without FED are shown in **Table 2**. Fecal evacuation disorder, diagnosed by both abnormal ARM and

**Table 1** Baseline demographic, clinical, and anorectal manometry characteristics of patients with chronic constipation

	Total number of patients (n = 134)
Age (years old)	43.09 $\pm$ 9.32
Gender	Male = 73 (54%)
	Female = 63 (46%)
Duration (months)	98 (14–146)
Straining	118 (87%)
Incomplete evacuation	115(86%)
Manual evacuation	57 (43%)
Mucus in stool	83 (62%)
Sensation of anorectal blockage	75 (56%)
Stools per week	12 (4–19)
Sphincter Length (cm)	3 (2.2–3.4)
Basal pressure (mmHg)	62.44 $\pm$ 18.07
Squeeze pressure (mmHg)	133.29 $\pm$ 31.08
Balloon volume at first sensation (ml)	50 (20–60)
Balloon volume at urge (ml)	100 (70–140)
Balloon volume at discomfort (ml)	190 (140–300)

BET, was found in 52 (39%) chronic constipation patients. The FED patients had a significantly higher percentage of straining and sensation of anorectal blockage compared with those without FED (96 versus 82%, *p*  $< 0.01$ ; 81 versus 44%, *p*  $< 0.001$ , respectively). **Table 3** summarizes the anorectal manometry findings in patients with chronic constipation. The resting anal pressure ( $71.18 \pm 18.7$  versus  $57.98 \pm 16.08$  mmHg; *p*  $< 0.01$ ) and maximum squeeze pressure ( $160.53 \pm 26.60$  versus  $119.35 \pm 23.18$  mmHg; *p*  $< 0.01$ ) were significantly higher, and the sphincter length was

**Table 2** Demographic and clinical findings in chronic constipation patients with or without functional evacuation disorder

Parameters	No FED (n = 82)	FED (n = 52)	<i>p</i> -value
Age (years old)	43.38 $\pm$ 8.32	43.18 $\pm$ 10.61	0.9
Gender	Male	43 (52%)	0.32
	Female	39 (48%)	
Duration (months)	96 (52–146)	106 (34–136)	0.91
Straining	67 (82%)	50 (96%)	0.02
Straining > 30 minutes	28 (34%)	33 (64%)	0.01
Incomplete evacuation	69 (84%)	47 (91%)	0.29
Manual evacuation	34 (41%)	23 (44%)	0.45
Mucus in stool	53 (65%)	30 (58%)	0.74
Sensation of anorectal blockage/obstruction	36(44%)	42(81%)	0.001
Stools per week	7 (3–15)	15 (8–19)	0.01

Abbreviation: FED, fecal evacuation disorder.

**Table 3** Anorectal manometry findings in chronic constipation patients with or without functional evacuation disorder

	No FED (n = 88)	FED (n = 45)	p-value
Sphincter Length (cm)	3.03 ± 0.27	2.71 ± 0.25	0.01
Basal Pressure (mmHg)	57.98 ± 16.08	71.18 ± 18.7	0.001
Maximal Squeeze Pressure (mmHg)	119.35 ± 23.18	160.53 ± 26.60	0.001
Balloon volume at first sensation (ml)	40 (20–60)	40 (30–60)	0.11
Balloon volume at urge (ml)	100 (70–130)	100 (80–140)	0.08
Balloon volume at maximal sensation (ml)	180 (140–250)	250 (160–300)	0.001

Abbreviation: FED, fecal evacuation disorder.

A p-value <0.05 indicates statistical significance.

significantly shorter ( $3.03 \pm 0.27$  cm versus  $2.71 \pm 0.25$  cm;  $p < 0.01$ ) in chronic constipation with FED patients than that of patients without chronic constipation with FED. In addition, FED patients had a significantly higher residual anal pressure ( $69.18 \pm 13.01$  versus  $40.98 \pm 8.52$  mmHg;  $p < 0.001$ ) and lower maximum intrarectal pressure ( $45.82 \pm 9.87$  versus  $64.85 \pm 12.95$  mmHg;  $p < 0.001$ ) compared with those without FED during simulated defecation. The median balloon volume at maximal sensation was higher in the FED subgroup compared with the non-FED subgroup (250 ml versus 180 ml;  $p < 0.001$ ); however, the balloon volume at the first sensation and at urge were similar in both subgroups.

#### Predictors of FED in Patients with Chronic Constipation

The clinical and anorectal manometry parameters predicting the presence of FED in chronic constipation patients are depicted in ►Table 4. On the univariate logistic regression analysis, an increased odds ratio (OR) for FED in chronic constipation patients was found for prolonged straining ( $\geq 30$  minutes; OR = 2.57;  $p = 0.01$ ), basal pressure (OR = 1.04;  $p = 0.001$ ), maximal squeeze pressure (OR = 1.06;  $p = 0.001$ ),

and balloon volume at discomfort (OR = 1.04;  $p = 0.001$ ). However, on the multivariate analysis, straining  $> 30$  minutes (OR = 3.63;  $p = 0.03$ ), maximum squeeze pressure (OR = 1.05;  $p < 0.001$ ), and balloon volume at maximal sensation (OR = 1.06;  $p < 0.001$ ) were found to be significant independent predictors of FED.

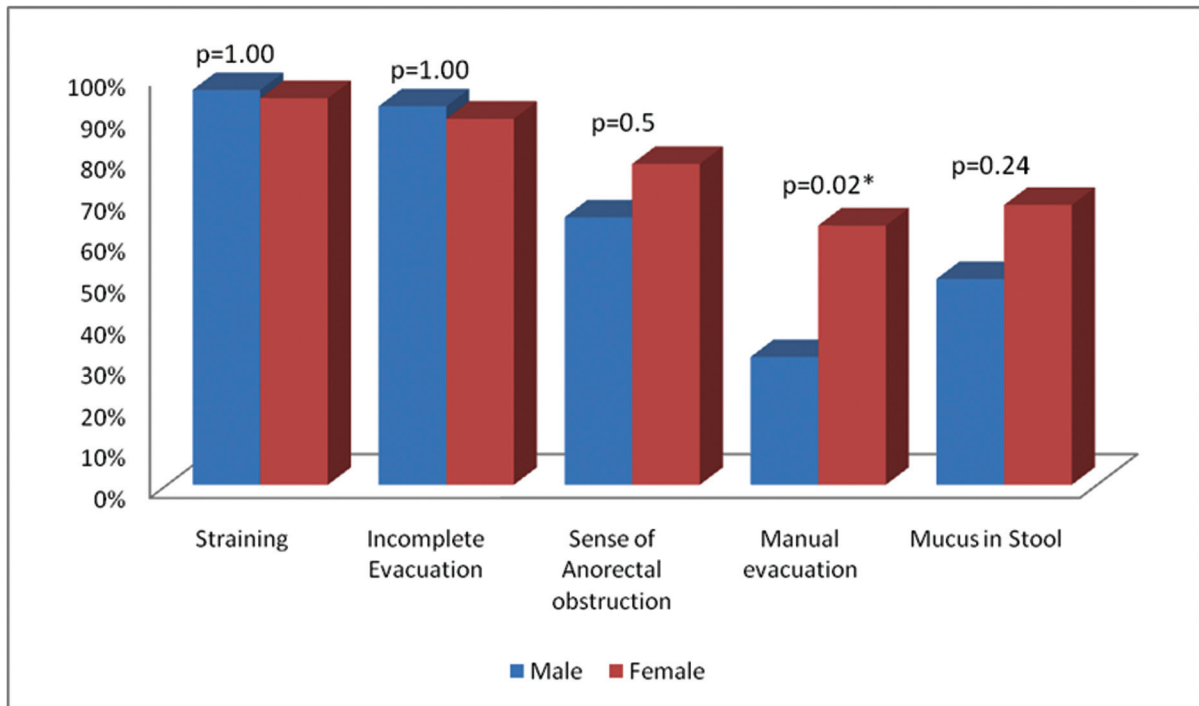
#### Relationship between Gender and FED

Out of 52 FED patients, 30 were male and 22 were females. ►Figure 1 depicts the comparison of clinical features between male and female patients with FED. The percentage of straining, incomplete evacuation of stools, sensation of anorectal obstruction, and mucus in stools were similar in both male and female patients with FED. However, the percentage of manual digital evacuation of stools was significantly higher in females compared with males with FED. Comparison of anorectal manometric parameters between the male and female patients with FED is shown in ►Table 5. The sphincter length ( $2.8 \pm 0.22$  cm versus  $2.58 \pm 0.26$  cm), the maximal squeeze pressure ( $175.15 \pm 22.49$  versus  $159.32 \pm 21.72$  mmHg) were significantly higher in males compared with females with FED. The balloon volume at the first sensation, at urge, and at

**Table 4** Clinical and anorectal manometry parameters predicting functional evacuation disorder in patients with chronic constipation

	Univariate analysis			Multivariate analysis		
	OR	95%CI	p-value	OR	95%CI	p-value
Age (years old)	0.99	0.95–1.03	0.9			
Male versus Female	1.24	0.64–2.57	0.54			
Straining $> 30$ minutes versus straining $< 30$ minutes	2.57	1.19–5.55	0.01	3.63	1.08–12.18	0.03
Incomplete evacuation (yes or no)	1.93	0.15–6.27	0.26			
Sense of anorectal blockade (yes or no)	2.57	1.19–5.55	0.01	1.11	0.29–4.21	0.87
Basal pressure	1.04	1.02–1.06	0.001	1.02	0.97–1.06	0.32
Maximum squeezing pressure	1.06	1.04–1.08	0.001	1.05	1.02–1.09	0.001
Balloon volume at first sensation	1.02	0.99–1.06	0.11			
Balloon volume at urge	1.02	0.99–1.04	0.08			
Balloon volume at maximum sensation	1.04	1.02–1.05	0.001	1.06	1.02–1.09	0.001

Abbreviations: CI, confidence interval; OR, odds ratio.



**Fig. 1** Comparison of clinical symptoms of males and females with fecal evacuation disorder.

**Table 5** Anorectal manometry findings of male and female chronic constipation patients with functional evacuation disorder

	Male (n = 30)	Females (n = 22)	p-value
Sphincter Length (cm)	2.8 ± 0.22	2.58 ± 0.26	0.01*
Anal resting Pressure (mmHg)	65.58 ± 17.54	69.23 ± 22.34	0.49
Maximum squeezing pressure (mmHg)	175.15 ± 22.49	159.32 ± 21.72	0.02*
Balloon volume at first sensation (ml)	42 (30–60)	40 (30–60)	0.4
Balloon volume at urge (ml)	100 (80–130)	110 (80–140)	0.2
Balloon volume at maximum sensation (ml)	225 (160–300)	240 (140–300)	0.22

Abbreviation: FED, fecal evacuation disorder.  
A *p*-value <0.05 indicates statistical significance.

maximal sensation was similar among males and females with FED.

## Discussion

In the present study, we found that prolonged straining and sensation of anorectal obstruction was significantly higher in those with FED. Basal pressure, maximal squeeze pressure in anorectal manometry, and balloon volume at maximal sensation in the BET was also significantly elevated in FED patients. On the logistic regression analysis, straining > 30 minutes, maximum squeeze pressure in anorectal manometry, and balloon volume at maximal sensation in the BET were the factors significantly predicting FED in patients with chronic constipation.

The prevalence of FED among patients with chronic constipation is highly variable, ranging from 10 to 70% depending on different populations and their lifestyle. The

present study showed that ~ 39% of the patients presenting to tertiary care hospitals with constipation had FED, which is similar to the percentage observed in one study from India. Another prospective study from North India found a slightly higher proportion of FED (~47%) compared with our study.<sup>18</sup> However, a recently published retrospective study from China found a significantly higher percentage of FED (73%) compared with results from Indian studies.<sup>19</sup> A Turkish study of 82 functional constipation patients found FED in 25% of the patients by using colonic transit markers and the BET.<sup>20</sup> Another study from Thailand with 103 patients detected FED in 40% of the patients with chronic constipation, which is similar to what has been observed in our study.<sup>21</sup> This global variability in the prevalence of FED in patients may be attributed to the different population groups with differences in their dietary habits and lifestyle.

Defecation is a complex process, requiring the coordination of rectal muscles, pelvic floor muscles, and anal

sphincters. However, the mechanism of FED is not completely understood.<sup>22</sup> An inadequate increase in rectal pressure or an inappropriate decrement of anal pressure due to sensorimotor dysfunction may be the cause of FED.<sup>23</sup> Hence, anorectal manometry and the BET in properly selected patients can diagnose FED in patients with chronic constipation, as this subgroup of patients responds well to biofeedback rather than laxatives.<sup>24</sup> In our study, straining is one of predominant symptoms found, followed by incomplete evacuation; a similar clinical profile has been studied by Ghoshal et al. in India.<sup>25</sup> We also found that clinical parameters such as excessive straining during defecation ( $\geq 30$  minutes), sensation of anorectal obstruction, and higher number of stools per week point toward the presence FED in patients with chronic constipation. Hence, these patients should be referred for anorectal physiologic testing to be evaluated for FED. Observational studies from India by Ghosal et al. found that prolonged straining  $> 30$  minutes, incomplete evacuation, and  $> 3$  stools per week were more common in FED patients.<sup>25</sup> A previous study from the Mayo clinic, USA, with 194 patients found that the feeling of anorectal obstruction was the only symptom associated with dyssynergic defecation compared with normal transit constipation,<sup>26</sup> as has been observed in our study. Hence, chronic constipation patients complaining of a sensation of anorectal blockade should be always evaluated for FED by anorectal manometry.

Chronic constipation, especially FED, is an underreported entity in clinical practice due to lack of knowledge.<sup>13</sup> Females are found to be more prone to develop FED due to obstetric trauma after vaginal delivery. Moreover, females have less access to healthcare facilities in India due to various reasons. Hence, data is scarce regarding the relationship between gender and the presence of FED. A Western study has shown a higher prevalence of constipation in females;<sup>27</sup> however, in India, a higher prevalence has been noted in males due to their greater accessibility to the healthcare system in comparison to females.<sup>28</sup> However, in our study, males slightly outnumbered females. One study from Mumbai, India, a predominance of constipation in males of their study population, probably due to greater health-seeking behavior of males among the Indian population.<sup>29</sup> We have also found that females had symptoms similar to those of males, except for the manual evacuation of stools. The manometric findings suggest that the sphincter length was shorter and with lesser maximal squeeze pressure in females, similarly to previous studies<sup>24</sup> indicating that females are more prone to develop FED; however, they have a lower threshold for the urge to defecate, possibly due to sensory abnormalities related to obstetric injuries to the pudendal nerve and sphincter muscles.<sup>13</sup> Hence, all females with chronic constipation should be extensively evaluated for the presence of FED.

The scarcity of data on FED constitutes a great strength of our study; however there are some limitations. First, the present study is a retrospective study, so some data is missing, as expected. Second, we did not perform defecography due to its unavailability in our center. Third, we performed the BET only in the left lateral position, not in

the sitting position. Fourth, the colonic transit time was not assessed in our study, since few studies have shown a delayed colonic transit time in patients with FED.<sup>13</sup> Fifth, the obstructed defecation score to quantify the intensity of symptoms was not assessed in our study. Sixth, the number of patients included in the study was low; therefore, the relationship between gender and FED may have weak statistical significance. Despite these limitations, these are real-time data on patients with FED, and the present study elucidated clinical and manometric predictors of FED and compared the incidence of FED in males and females in terms of clinical and manometric findings. Also, this is the first study from eastern India to report the ARM data of FED patients.

In conclusion, the present study shows that  $\sim 40\%$  of the chronic constipation patients presenting to clinicians had FED, as evidenced by abnormal anorectal manometry and by the BET. The prolonged straining and sensation of anorectal blockade were higher in FED patients than in those who do not had FED. Also, prolonged straining was the only significant clinical independent predictor of FED. A large prospective study is needed in the future to validate our findings.

#### Data Availability Statement

All data are reported in the present manuscript.

#### Contribution of the Authors

Behera M. K.: Preparation and presentation of the published work through the creation of the initial draft, data collection, review of the literature, and development of the finalized manuscript; Mishra D.: Data collection, critical review, commentary, and revision of the manuscript; Sahu M. K.: Critical review, commentary, and revision of the manuscript; Singh A.: Data collection, critical review, and final revision of the manuscript; Pati G. K.: Data collection and final revision of the manuscript; Agarwal S.: Data collection, revision of the manuscript; Narayan J.: Design of the study, revision of the final draft, critical review, and commentary.

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#### Conflict of Interests

The authors have no conflict of interests to declare.

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