

The Efficacy of Biofeedback Treatment in Patients with Fecal Incontinence

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ABSTRACT

Background: The initial treatment for fecal incontinence (FI) includes supportive treatment and medical treatment. If the initial treatment fails, biofeedback therapy (BFT) is recommended. However, there are limited and conflicting results in the literature supporting the beneficial effect of BFT for FI. The aim of the study is to analyze the efficacy of BFT in 126 patients who have FI due to several causes.

Methods: The data of 126 patients (88 females (69.8%) and 38 males (30.2%)) were collected retrospectively. Colonoscopy, anorectal manometry (ARM), and 3D-Endoanal ultrasonography (EAUS) were performed for all patients before applying BFT. In addition, all patients received toilet training instruction and training in Kegel and other pelvic floor strengthening exercises from an experienced nurse, before BFT.

Results: The median age of participants was 54 years (range 18-75 years). While 80 patients (63.5%) had clinical and manometric benefit from BFT, 46 patients (36.5%) did not respond to BFT. According to the EAUS and ARM findings, BFT was beneficial in patients who had partial external sphincter failure, and was unsuccessful in patients who had both internal and external sphincter failure, both internal and external sphincter tears, and external sphincter tear rates of more than 25%. After BFT, significant increases in squeeze pressures were observed, with this increase being higher in the positive-response group.

Conclusion: The results suggest that BFT is effective in the treatment of FI for specific patient populations.

Keywords: Fecal incontinence, biofeedback therapy, anorectal diseases

INTRODUCTION

Functional anorectal disorders are common throughout different populations and are characterized by specific symptoms. The 3 major functional anorectal diseases defined according to the Roma IV criteria are defecation disorders (DD), fecal incontinence (FI), and anorectal pain disorders.^{1,2} FI describes involuntary solid or liquid fecal loss, while anal incontinence describes involuntary solid or liquid fecal or flatus loss. The degree of incontinence may vary from flatus to full discharge of the intestinal contents.³

Generally, FI has significant social and economic burdens and significantly decreases the quality of life.⁴⁻⁶ FI may affect people of any age, with prevalence ranging from 1.6% to 15%, depending on age and the presence of medical comorbidities. Bor et al. have shown that the frequency of FI in individuals between 55 and 74 years of age in Turkey is 5.2%, and it is 13.2% in individuals over the age of 75. The prevalence can be up to 50% for

residents of elderly care homes. Although the true prevalence of FI in the general population is high, it is suggested that FI is generally underreported by patients.^{1,3,5}

Approximately 80% of patients have more than 1 underlying pathologic abnormality. It is more frequently caused due to complex sensory and motor defects of the sphincter, rectum, and pelvic floor.⁷ Damage to the perineum during vaginal deliveries, disruption of the anal sphincter structure after anal dilation, and anorectal surgeries like hemorrhoidectomy, sphincterotomy, or fistulectomy are the main known causes of FI.^{7,8}

The initial treatment for FI includes supportive treatment and medical treatment.^{2,3} If initial treatment fails, biofeedback therapy (BFT) is recommended, after researching the functional and structural abnormalities causing the FI.^{1,9,10} However, there are limited and conflicting results in the literature that support the beneficial effect of BFT for FI.

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This study aimed to analyze the efficacy of BFT in 126 patients who have FI due to several causes.

MATERIALS AND METHODS

Patients

Although BFT was initially planned for 149 patients with FI, 23 or those patients were excluded from the study because they did not continue the BFT sessions. The data from 126 patients with FI who underwent BFT from January 2013 to January 2018 (88 females (69.8%) and 38 males (30.2%)) were collected retrospectively. The data were retrieved from medical records in the digital database of the motility laboratory in the gastroenterology department of the hospital where the study was performed.

None of the patients in the study population responded to conservative treatment modalities,¹⁻⁴ including (a) Avoiding the intake of foods which worsen symptoms, like incompletely digested sugars (e.g., fructose, lactose); (b) Maintaining a food and symptom diary to identify factors that cause diarrhea and incontinence; (c) Receiving a dietary supplement with a bulking agent to improve stool consistency; and (d) Obtaining a regular defecation program. Anorectal examination, colonoscopy, anorectal manometry (ARM), and 3D-Endoanal ultrasonography (EAUS) were performed for all patients before applying BFT. The degrees of tear rates of internal or external sphincters tears were determined via EAUS. The exclusion criteria were age less than 18 years, chronic diarrhea, duration of complaints less than 6 months, non-compliance with BFT procedures, pregnancy, external sphincter tear rates of more than 50% on EAUS, active intestinal disease, and dyssynergic defecation disorder accompanied by constipation and FI. Dyssynergic defecation disorder (impaired coordination of the abdominal and pelvic floor muscles during the discharge of feces) is seen in most patients with constipation accompanied by FI. The main problem in these patients is disruption of the stool discharge, resulting in distal stool accumulation in the

rectum. This situation causes FI (it causes overflow incontinence and rectal sensation disturbances in the patient). These patients were treated with a different method of BFT, which is why they were not included in the present study.

Patients with active ulcerative colitis, perianal disease, or bacterial or parasitic infections were excluded while the disease was active. Patients were included in the study if their incontinence persisted after their active illness passed.

According to weekly incontinence counts, patients were divided into 3 groups: those with incontinence 2 or fewer times per week, those with incontinence 3 to 5 times per week, and those with incontinence more than 5 times per week or daily.

Patients were also grouped according to the degree of tear rates of the external sphincter on EAUS, as 10-25%, and more than 25%.

Anorectal Physiological Tests

Conventional ARM was performed using an 8-channel (Dentsleeve International, Mui Scientific) water perfusion system. The catheter was connected to calibrated pressure transducers, and the data coming from the pressure transducers were recorded digitally.^{11,12} All standard procedures were performed by an experienced nurse. Anal resting pressure, anal maximum squeezing pressure, anal pressure while coughing, and the recto-anal inhibitor reflex were recorded. Rectal sensation was evaluated by inflating a rectal balloon and measuring the first sensation, desire to defecate, and maximum tolerable volumes.

With conventional ARM, the average resting pressure is measured with sensors inside the rectum. The main source of the resting pressure is the internal sphincter. Therefore, resting pressure provides information about internal sphincter function. Mean anal squeeze pressure is measured with sensors in the anal canal (by asking the patient to squeeze the anal canal). The anal squeeze pressure provides information about external sphincter function.

BFT

Before undergoing BFT, all patients received toilet training. In order to prevent urge or overflow incontinence, an attempt was made to encourage regular defecation habits 2 to 3 times per day (usually at the same time of day)

MAIN POINTS

- BFT is effective in the treatment of FI, especially in those without spinal cord injury and those with normal external sphincter functions, and in those without tears in the external sphincter or with less than 25% tears.
- BFT has a high response rate, with no side effects.
- BFT should be planned as a second-line treatment method in appropriate patients who do not respond to conservative treatments.

for all patients in the study. The patients were instructed by a nurse who was experienced in Kegel and other exercises to strengthen the pelvic floor muscles, and were also given visual and written documents to allow them perform these exercises at home.

In this study, an electromyography (EMG)-BFT technique was applied. While the patient was lying in the left lateral decubitus position, surface EMG probes were adhered to the skin on the bilateral anal canal. The patients watched the manometric tracings on a computer monitor from surface EMG probes around the bilateral anal canal. Patients with BFT tried to control the sphincter and pelvic floor muscles with visual feedback on the monitor, and were taught to fulfill the commands given by the nurse. The patients received at least 6 sessions of BFT, applied under the supervision of a motility nurse. BFT was discontinued in patients who showed no reduction in the number of daily or weekly incontinence episodes by the end of their sixth session. The treatment was extended to 10 to 15 sessions for patients who responded to the first 6 sessions. Each BFT session was conducted for 30 to 45 minutes. After the final BFT session, clinical and manometric reevaluations were performed. FT was considered to be successful in patients who became asymptomatic and in whom the anorectal manometric findings were ameliorated.

Ethical approval for this study was obtained from by the local ethics committee (Study No. 29620911/929) of Turkey Yuksek Ihtisas Training and Research Hospital, Ankara, Turkey.

Statistical Analysis

Statistical analyses were performed with the SPSS 20.0 (SPSS, Chicago, Illinois, USA) statistical package for Windows. Continuous variables were compared using the Student's *t*-test or the Mann-Whitney *U*-test, depending on the normality of distribution. The categorical variables were compared by the Pearson's or Fisher's exact chi-square tests. The Wilcoxon signed-rank test and paired samples test were used, depending on normality of distribution, for comparing 2 related samples to assess whether their population mean ranks differed. A receiver operator characteristic (ROC) curve was built to determine the predictive value of anal squeeze pressures before BFT, for treatment response. Binary logistic regression analysis was performed to detect independent predictive factors for successful BFT. Any value of $P < .05$ was considered statistically significant.

RESULTS

The study included 88 females (69.8%) and 38 males (30.2%). The median age was 54 years (with a range of 18-75 years). The initial demographic and clinical features, the ARM and EAUS findings, and the BFT results of the patients are shown in Table 1.

The patients had a history of incontinence for a median of 36 (min-max: 6-444) months. Of those, 43.6% experienced incontinence more than 5 times per week or daily, while 31% experienced incontinence 3 to 5 times per week, and 25.4% experienced incontinence 2 or fewer times per week. Of the patients, 26 had diabetes mellitus, and 13 had spinal cord injury history. Twenty-three patients had undergone previous anorectal surgery. Of these patients, 12 had undergone operations due to distal rectal carcinoma. Of the female patients, 74 had given birth by the normal vaginal route. Twenty-three female patients had difficult deliveries, and fifteen had perineum tears during delivery.

According to the ARM findings, 47 patients had partial external sphincter failure (squeeze pressure >80 mmHg, but duration of anal canal contraction <3 s), 29 patients had both external and internal sphincter failure, 26 patients had external sphincter failure, 10 patients had partial external sphincter failure and internal sphincter failure, 3 patients had internal sphincter failure, and 11 patients were normal.

When the rectal capacity was evaluated by inflating a rectal balloon, it was found that 62 patients had normal rectal capacity, 53 patients had rectal hypersensitivity, and 11 patients had rectal hyposensitivity.

Outcomes of BFT

While 80 patients (63.5%) had clinical and manometric benefit from BFT, 46 patients (36.5%) did not respond to BFT. Those who benefited from BFT had an average of 12 sessions of BFT, while those who did not benefit had an average of 8.5 sessions.

According to the EAUS and ARM findings, BFT was beneficial in patients who had partial external sphincter failure, and was unsuccessful in patients who had both internal and external sphincter failure, both internal and external sphincter tears, and an external sphincter tear rate of more than 25%.

After BFT, significant increases in resting and squeeze pressures were observed, with this increase being higher

Table 1. Outcomes of Biofeedback Therapy

	Value, n (%)	Responders, n (%)	Non-responders, n (%)	P
Demographics				
Age, year, median (range)	54 (18-75)	54.5 (18-75)	53.5 (19-74)	.36
Male	38 (30.2)	25 (65.8)	13 (34.2)	.72
Female	88 (69.8)	55 (62.5)	33 (37.5)	
Incontinence history				
Duration of fecal incontinence, month, median (range)	36 (6-444)	60.79	68.22	.27
Grading of incontinence				
Less than 2 per week	32 (25.4%)	19 (59.4)	13 (40.6)	.1
3 to 5 per week	39 (31%)	30 (76.9)	9 (23.1)	
More than 5 per week or everyday	55 (43.6)	31 (54.4)	24 (43.6)	
Medical history				
Diabetes mellitus	26	18 (69.2)	8 (30.8)	.49
Previous incomplete spinal cord injury	13	3 (23.1)	10 (76.9)	.02
History of previous anorectal surgery				
Previous distal rectal surgery	12	6 (50)	6 (50)	.3
Hemorrhoidectomy	8	7 (87.5)	1 (12.5)	
Obstetric history				
Number of women who had a vaginal delivery	74	49 (66.2)	25 (33.8)	.44
Number of women who had a history of difficult vaginal delivery	23	15 (65.2)	8 (34.8)	.84
Number of women who had a history of pelvic trauma during vaginal delivery	15	8 (53.3)	7 (46.7)	.38
Anal tone in physical examination				
Normal	38 (30.2%)	28 (73.6)	10 (26.4)	.89
Decreased	88 (69.8%)	52 (59.1)	36 (40.9)	
Endoanal USG findings				
Normal	42	32 (76.2)	10 (23.8)	.36
Internal sphincter tears	3	2 (66.7)	1 (33.3)	.90
Atrophy in the internal sphincter	9	8 (88.9)	1 (11.1)	.10
External sphincter tears	26	17 (65.4)	9 (34.6)	.82
Atrophy in the external sphincter	6	2 (33.3)	4 (66.7)	.11
Defect in both internal and external sphincter	20	7 (35)	13 (65)	.004
External sphincter tear rate (%)				
10-25	25	19 (76)	6 (24)	.001
> 25	21	5 (23.8)	16 (76.2)	
Internal sphincter tear rate (%)				
10-25	12	7 (58.3)	5 (41.7)	.06
< 25	11	2 (18.2)	9 (81.8)	
Biofeedback number of sessions, median (range)		12 (12-15)	8 (7-15)	

(Continued)

	Value, n (%)	Responders, n (%)	Non-responders, n (%)	P
Anorectal manometry findings				
Normal	11	9 (81.8)	2 (18.2)	.18
İnternal sphincter failure	3	2 (66.7)	1 (33.3)	.90
External sphincter failure	26	12 (46.2)	14 (53.8)	.39
Partial external sphincter failure	47	38 (80.9)	9 (19.1)	.02
Internal and external sphincter failure	29	13 (44.8)	16 (55.2)	.017
Partial external sphincter and internal sphincter failure	10	6 (60)	4 (40)	.81
Rectal capacity				
Normal	62(49.2%)	43 (69.4)	19 (30.6)	.36
Decreased	11(8.7%)	7 (63.6)	4(36.4)	
Increased	53(42.1%)	30 (56.6)	23(43.4)	

P < .05.

in the success group (Table 2).The difference in squeeze pressure with BFT was significantly higher in the BFT-positive-response group, while the difference in resting pressure was comparable between BFT responders and non-responders (Table 3).

Binary logistic regression analysis revealed that squeeze pressure before BFT was an independent factor for BFT success (Table 4).

The ROC curve was analyzed to identify the cut-off value of squeeze pressures before biofeedback for those with successful BFT, and found to be 60 mmHg, with a sensitivity of 85% and specificity of 55% (95% CI: 39.0-69.1) (Figure 1).

DISCUSSION

This study documented that BFT is beneficial in FI patients with high initial squeeze pressure on ARM, and in those with partial external sphincter failure. In addition, the results revealed that patients with spinal cord trauma history, concomitant internal and external sphincter failure on ARM, and anal sphincter tears (IAS+EAS) in EAUS were less responsive to BFT.

BFT is a non-invasive, non-drug and low-cost therapeutic approach for FI. There are reports with treatment success of 38-100% for FI patients.¹³⁻¹⁵ One study found that BFT was successful for 53% of patients,¹⁵ while another found full response in 41% of patients and partial response in 35% of patients.¹¹ In this study's patient group, the BFT response rate was higher (63.5%) than most of the

Table 2. Comparison of Anorectal Manometry Findings Between the Responders and Non-responders, and the Results Before and After Training

	Anal Squeeze Pressure (mmHg)			Anal Resting Pressure (mmHg)			Duration of Anal Canal Contraction (s)		
	Before Training	After Training	P	Before Training	After Training	P	Before Training	After Training	P
Responders	98.45 ± 39.62	132.3 ± 45.09	<.001	47.95 ± 19.06	52.32 ± 17.9	.031	1.56 ± 0.5	3.36 ± 0.78	<.001
Non-responders	68.8 ± 33.98	79.43 ± 38.23	<.001	41.08 ± 22.26	42.65 ± 23.32	.113	1.38 ± 0.5	1.92 ± 0.64	.008

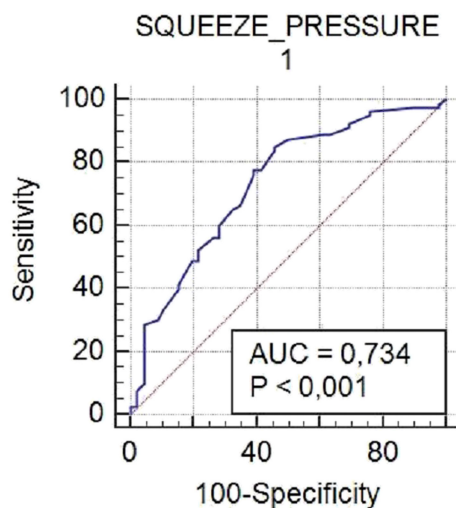
Table 3. Comparison of Median Anal Sphincter Pressure Changes According to Biofeedback Therapy Response

	Non-responders	Responders	P
Δ Resting Pressure mmHg, (median, min-max)	0.0 (-40 to 27)	0.0 (-40 to 70)	.634
Δ Squeeze Pressure, mmHg, (median, min-max)	5.5 (-55 to 70)	25 (-45 to 182)	<.001

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Table 4. Binary Logistic Regression Analysis to Predict the Independent Factors for BFT Response

	Beta	Standard Error	OR	P
Presence of previous spinal cord injury	2.579	1.166	13.179	.02
Defect both in the internal and external sphincter	1.548	1.147	4.701	.177
Resting pressure	0.025	0.026	1.025	.342
Squeezing pressure	1.118	0.546	3.059	.041
Duration of anal canal contractions	0.737	0.727	2.089	.311

**Figure 1.** Receiver-operating Characteristic (ROC) Curve Analysis to Show the Effectiveness of Squeeze Pressures Before Biofeedback Therapy on Treatment Success.

data reported in the current literature. This variability in treatment success may be due to differences in the BFT methods applied to patients, number of treatment sessions, and differences between the patient groups. For instance, only hospital-based BFT was applied, in combination with pelvic floor exercises and Kegel exercises performed at home. In the study of Heymen et al.,¹¹ the investigators applied both hospital and home-based BFT in patients with FI, while Sun et al.¹³ used only hospital-based BFT in patients who had FI after anorectal surgery. In several studies, the number of BFT sessions, and the mode of application of BFT therapy—as home-based or hospital-based, and alone or combined with pelvic floor muscle exercises, Kegel exercises, or sacral nerve stimulation—have been shown to be predictive factors for the treatment success in patients with FI.^{12,16} Norton et al.¹⁵ reported that BFT was not superior to conventional treatment for FI patients. In contrast, Heymen et al.¹¹ found that BFT was superior to conservative treatment and pelvic floor muscle exercises.

Previously, it has been suggested that BFT may provide improvements in resting anal sphincter tonus, the voluntary contraction of the anal sphincter and puborectalis muscle, abdominopelvic coordination during excretion, and rectal capacity functions in patients.^{1,3,9} A study by Sun et al.¹³ identified increases in resting and squeeze pressures of patients after BFT. This increase was shown to be higher in those who responded to BFT. At the same time, those with high anal squeeze pressure provided better response to BFT, and similarly, those without good sphincter functions provided less response.^{17,18} Similarly, this study documented that both anal resting and anal squeeze pressures increased in the BFT-positive-response group. The rate of response to BFT was significantly higher in patients with anal squeeze pressure above 60 mmHg. In contrast, the BFT response rate was significantly lower in patients with internal and external sphincter failure.

The duration of anal canal contraction is one of the factors affecting incontinence. If individuals with sufficient external sphincter squeeze pressure do not have sufficient squeeze duration, it may cause anal incontinence.¹⁹ Marcello et al.²⁰ found that the mean squeeze duration was 3.2 seconds for anal continence. This present study found that there were significant increases in squeeze duration in BFT responders. It was also shown that incontinence continued in the majority of FI patients without improvement of squeeze durations. Another study similarly found a significant increase in squeeze durations after BFT, related with treatment response.¹³

The prevalence of FI usually increases with age, and it is also high in middle-aged women. In the present study, the mean age of participants was 54 years and nearly 70% were female.²¹⁻²⁵ However, the difference in distribution of age or gender in terms of treatment response to BFT was not identified. It is reported that the prevalence of FI increases due to trauma to the perineum through the vaginal tract (especially third- or fourth-degree vaginal

tears), which is one of the main causes of FI in women. However, while childbirth may cause FI without sphincter tears, every tear occurring during delivery does not cause FI.^{26,27} Of the participants in this study, 74 of 88 women (85%) had history of vaginal delivery. However, no significant difference between those with vaginal delivery and those without in terms of BFT treatment success was identified.

The degree of external sphincter tear affects the efficacy of BFT treatment. In particular, patients with third- or fourth-degree tears respond less favorably to BFT.²⁶⁻²⁹ Correspondingly, as the tear rate increased, less benefit from BFT was seen.

Sphincter dysfunction occurring after anorectal surgery disrupted rectal sensation and anal stenosis, and the disrupted sensorial and motor functions in the anal region may cause FI. The FI rates vary from 30% to 56% after anorectal surgery.³⁰ Of the patients in this study, 23 had a history of anorectal surgery. While 14 of these patients (60.8%) responded to BFT, 9 patients did not. However, the BFT response rates did not differ between the patients who had anorectal surgery and those who did not. The study by Sun et al.¹³ found 30 of 55 patients with anorectal surgery history responded to BFT. In another study, a clear improvement in the FI score was observed with BFT after anorectal surgery.⁹ However, in both studies, in contrast to this study, there was no comparison with a non-surgical group.

The American Neurogastroenterology and Motility Society and the European Society of Neurogastroenterology and Motility both recommend 6 BFT sessions of at least 1 hour per week for FI patients.¹⁰ BFT may require many sessions varying from a few weeks to months.^{31,32} The present study planned to include at least 7 sessions for those who did not see any benefit from BFT, with an average of 12 sessions for those who benefited. The sessions in this study lasted for 30 to 45 minutes, rather than 1 hour. However, it is believed that the face-to-face interviews at the hospital and the increased number of sessions motivated the increased positive responses in patients, affecting the treatment success rate.

The limitations of this study include the retrospective design of the study and the lack of homogeneity in the patient groups. Moreover, no information was obtained on whether patients also simultaneously experienced urinary incontinence, and the FI score and incontinence type

(urge or passive incontinence) were not identified either. A further limitation of this study is the lack of a control group. These limitations can be attributed to the retrospective nature of the study. However, we believe that conducting regular follow-up of the patients at the motility department, updating patient files regularly, and following the patients one-by-one during the BFT sessions, as well as the sufficient number of patients in the study, have addressed these deficiencies.

CONCLUSION

BFT is a non-invasive and inexpensive therapy. It has a high response rate and has no side effects. BFT is effective in the treatment of FI, especially in specific patient populations. BFT should be planned as a second-line treatment method in appropriate patients who do not respond to conservative treatments. In addition, BFT should not only be performed in tertiary treatment centers, but also in other centers, because it is an easy-to-apply treatment method.

Ethics Committee Approval: The study was approved by the Ethics Committee of Türkiye Yüksek İhtisas Training and Research Hospital.

Informed Consent: Written informed consent was obtained from the patients who participated in this study.

Peer review: Externally peer-reviewed.

Author Contributions: Concept – Ö.O., Y.O.; Design – Ö.O., Y.O.; Supervision – Y.O., Z.M.Y.; Resource – Ö.O., Y.O., Ö.A.; Materials – Ö.O., Y.O.; Data Collection and/or Processing – F.B., İ.T., D.A., V.G., M.Y.; Analysis and/or Interpretation – Ö.O., Y.O., Ö.A., Z.M.Y.; Literature Search – Ö.O., İ.T., F.B., M.Y.; Writing – Ö.O., İ.T., D.A.; Critical Reviews – Ö.O., Y.O., Z.M.Y.

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