

Original Article

## Efficacy of Biofeedback Therapy in Clinical Practice for the Management of Chronic Constipation and Fecal Incontinence

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### Abstract

**Background:** Chronic constipation (CC) and fecal incontinence (FI) are often secondary to pelvic floor neuromuscular sensory or motor dysfunction. Biofeedback therapy (BFT) uses visual and verbal feedback to improve anorectal coordination, strength and sensation. In clinical trials, BFT demonstrated response rates between 70% and 80%. The purpose of this study is to determine the effectiveness of BFT in clinical practice.

**Methods:** In this retrospective observational cohort study, the charts of all patients who completed BFT at our centre were reviewed. A positive response to BFT was defined as improvement in ARM profile from baseline or subjective symptom improvement or both. Descriptive statistics were used to analyze the data.

**Results:** One hundred thirty patients with an average age of  $57.5 \pm 16.4$  years and 79.2% female were included. Of all patients, 43.1% were referred for CC, 37.7% for FI, 16.9% for alternating CC and FI, and 2.3% for rectal pain. The overall response rate to BFT was 76.2% (n=99). Of those that responded, 64.6% (n=64) demonstrated both ARM and symptom improvement, 27.3% (n=27) had ARM improvement but no symptom improvement, and 8.1% (n=8) had symptom improvement but no ARM improvement. In patients with FI, the overall response rate was 79.6% (n=39) with symptom improvement in 67.3% (n=33). In those with CC with dyssynergic defecation (n=53), the overall response rate was 69.8% (n=37); however, only 45.3% (n=24) had symptomatic improvement.

**Conclusion:** In our clinical practice, although overall response rates to BFT are similar to published reports, patients with CC with dyssynergic defecation are less likely to have symptomatic response compared with those with FI.

**Keywords:** *biofeedback therapy (BFT); chronic constipation (CC); fecal incontinence (FI)*

Chronic constipation (CC) and fecal incontinence (FI) are common disorders that are seen by both primary care and subspecialty physicians. The prevalence of CC and FI has been reported to be as high as 14% (1, 2) for both disorders. Multiple studies have demonstrated that these conditions can significantly decrease a patient's quality of life and social functioning. Those with CC have been shown to have lower overall (3) and disease-related quality of life (4). In a study of patients with CC in the United States, those with associated abdominal

symptoms had disrupted productivity 3.2 days per month and those without abdominal symptoms had disrupted productivity 1.2 days per month (5). Fecal incontinence is associated with decreased health-related quality of life, increased symptom interference with daily activities and increased psychological distress (6).

Both conditions can be related to anorectal neuromuscular sensory or motor dysfunction. Dyssynergic defecation (DD) is a subtype of CC that occurs in at least one-third of patients with

CC (7). This occurs when there is an inadequate increase in intrarectal pressure or when there is paradoxical contraction or impaired relaxation of the anal sphincter and pelvic floor muscles during attempted defecation, leading to a functional outlet obstruction (8). A diagnosis is made using the Rome IV criteria, which requires both subjective symptoms and objective testing. This criteria is satisfied in those with either CC or irritable bowel syndrome with constipation and impaired evacuation as seen with two of the following three tests: balloon expulsion test (BET), anorectal manometry (ARM) or by imaging (8). The Rome IV criteria gives a diagnosis of fecal incontinence to those who have uncontrolled passage of fecal material occurring after the age of 4 (8). The causes of FI are numerous, with anal sphincter weakness being the most common. This can occur secondary to trauma, degeneration, connective tissue disease and neuropathy, among others (8). Conventional therapies for both these disorders include dietary changes (i.e., adjusting fibre intake), behavioural therapy and a variety of pharmacological therapies (7, 9, 10). However, these therapies are often insufficient to achieve satisfactory outcomes in a number of patients because they do not target the underlying functional mechanism of disease.

Biofeedback therapy (BFT) involves the use of visual and verbal feedback to improve anorectal sensory function, pelvic floor strength and pelvic muscle coordination. It has been shown to be an effective therapy for both CC with DD and FI. In CC with DD, the goal of treatment is to improve coordination of the anorectum and pelvic floor muscles to lead to a more effective defecation pattern. Studies have demonstrated that BFT is more effective than sham treatment (11), polyethylene glycol laxatives (12), dietary modification (11) and diazepam (13) in the treatment of CC with DD. In these studies, the participant response rate of BFT in this patient group was as high as an 80%. The goal of BFT in FI is to improve squeeze pressure of the anal sphincter, to improve anorectal coordination during the squeeze maneuver and to enhance the sensation of the presence of stool in the rectum. Studies have demonstrated that BFT is superior to patient education (14) and pelvic floor exercises alone (15). Efficacy of BFT in these studies has been shown to be as high as 70%. In the trials of BFT for both CC with DD and FI, the outcome measures used to determine efficacy have been variable. Typically, symptom improvement is the primary outcome in these studies, with improvement in ARM profile being a secondary outcome. It is important to note that these efficacy rates are in the setting of controlled trials where training is intensive. Participants often participate in multiple sessions over a short period of time. However, access to BFT remains limited in many areas. In a recent survey (16) of Canadian gastroenterologists, only 41.7% indicated having access to BFT. Given that this is a limited resource, it is unclear how BFT in the management of CC with DD and FI performs in the 'real world'. Many centres offer patients only three sessions of BFT compared

with the four to six sessions—at least—recommended by the American Neurogastroenterology and Motility Society and European Society of Neurogastroenterology and Motility (17). Furthermore, these sessions are often spread out and may be shorter in duration to maximize the number of patients that can access this effective but limited therapy. The aim of our study was to determine the effectiveness of BFT in the management of CC and FI in clinical practice in a Canadian tertiary care centre.

## METHODS

### Patient Population

This study was approved by the research ethics board at the University Health Network in Toronto, Ontario. In this retrospective, observational cohort study, the charts of all patients who underwent BFT at our centre between January 1, 2008, and August 15, 2016, were reviewed. All patients who underwent baseline and post-BFT ARM, reported pre-BFT and post-BFT symptoms, and completed a course of BFT were included in the analysis. Patient age, sex, indication for BFT and number of completed sessions were collected.

### Anorectal Manometry and Balloon Expulsion Testing

All included patients underwent ARM and BET before referral for BFT and during the final BFT session. Anorectal manometry (Sierra Scientific Instrument, ManoScan 360, Model A100) and BET were performed according to a departmental standard protocol as has previously been published (18). To determine the residual anal sphincter pressures, the percent anal sphincter relaxation, the intrarectal pressures and the recto-anal pressure gradient during attempted defecation, the average of three bear down attempts was used. Maximal squeeze pressures were determined as an average of two squeeze maneuvers. All patients underwent BET where they attempted to expel a nonlatex balloon inserted into the rectum and then filled with 50 mL of water. The time taken to expel the balloon was recorded. The Manoview AR™ software V2.0 (Given Imaging) was used to collect and analyze the data. In those with FI, note was made of the presence of a weak anal sphincter and of inadequate anal sphincter squeeze pressures. Dyssynergic defecation was defined by presence of paradoxical anal sphincter contraction or inadequate increase in intrarectal pressure during straining, as well as a prolonged BET greater than one minute.

### Biofeedback Therapy

BFT was delivered by a trained nurse as per our department standard protocol using the same ARM catheter and software as is used to perform the ARM. Patients who participate in BFT were scheduled for three sessions. The first session serves as mainly a teaching session where counselling of patients on appropriate fibre intake and exercise occurs. During the

subsequent training sessions, the ARM software is used to display the manometric pressure profile to patients and provide visual feedback when the pelvic floor exercises were taught. In those with FI, the focus of therapy is to strengthen the anal sphincter pressure profile and improve rectal sensation as indicated. In those with CC with DD, the focus of training is to improve defecation technique, coordination of abdominal wall contraction and relaxation of the pelvic floor muscles. A balloon (similar to the one used in BET) was provided to the patient so that they can practice the balloon expulsion exercise at home in between training sessions.

### Response to Therapy

Response to BFT was defined as either objective improvement in the ARM profile at the last session compared with baseline as documented in the final BFT session or subjective symptom improvement reported by the patient—or both. A positive ARM response in those with FI was defined as an increase in resting or maximum squeeze anal sphincter pressures of at least 5% above baseline. In those with CC with DD, a positive ARM response was noted if there was resolution of the dyssynergic manometric pressure profile with attempted defecation and the BET was less than one minute. On chart review, a positive symptom response was noted if the patient described improvement in bowel symptoms (e.g., decrease in FI episodes, improvement in CC symptoms).

### Statistical Analysis

The retrospective data was analyzed using descriptive statistics. Mean age and standard deviation using a 95% confidence interval was calculated. Mean number of BFT sessions was calculated. Sex and indication for BFT are expressed as the percentage of included patients. Response rate to BFT was calculated using the number of positive responses over the number of participants who underwent BFT for a particular indication.

## RESULTS

One hundred sixty-eight patients participated in our BFT program during the study period. Thirty-eight patients who did not have documentation of symptom response (i.e., did not return the symptom diary, did not return for follow-up assessment, or had no documentation of symptom response) were excluded. A total of 130 patients (female, 79.2%; average age,  $57.5 \pm 16.4$  years) who completed BFT with complete records were included in the analysis. All patients completed either two or three sessions, with an average of 2.9 BFT sessions completed. The indications for BFT are demonstrated in [Table 1](#). Of all patients, 40.8% ( $n=53$ ) underwent BFT for CC with DD. Meanwhile, 37.7% ( $n=49$ ) underwent BFT for FI. In the charts of 16.9% ( $n=22$ ) of patients, alternating CC and FI was indicated as the reason for undergoing BFT. Rectal pain was the

**Table 1.** Indication for BFT ( $n=130$ )

Indication	% patients (n)
CC with DD	40.8% (53)
CC without DD	2.3% (3)
FI	37.7% (49)
Alternating FI/CC	16.9% (22)
Rectal pain	2.3% (3)

indication for BFT in 2.3% ( $n=3$ ) of patients. Three patients (2.3%) had CC without DD. The baseline ARM data for each group is summarized in [Table 2](#).

The overall response rate to BFT (defined as improvement in ARM profile, symptoms or both) for all indications was 76.2% ( $n=99$ ). Of those that responded, 64.6% ( $n=64$ ) demonstrated both ARM and symptom improvement, 27.3% ( $n=27$ ) had ARM improvement but no improvement in their presenting symptom, and 8.1% ( $n=8$ ) had subjective symptom improvement but no improvement as compared with their baseline ARM profile. Among the BFT responders, 72.7% ( $n=72$ ) had symptom improvement (with or without change in baseline ARM profile).

[Table 3](#) demonstrates response rates to BFT by both indication and type of response (either improvement in ARM profile from baseline at the last BFT session, symptom improvement or improvement in both). In those with CC with DD, the overall response rate was 69.8% ( $n=37$ ), however only 45.3% ( $n=24$ ) had a symptomatic improvement. In patients with FI, the overall response rate was 79.6% ( $n=39$ ), with 67.3% ( $n=33$ ) indicating an improvement in their symptoms. In this group, 37 (75.5%) subjects had an improvement in ARM profile. Thirty-six of these subjects had a documented final maximum squeeze pressure, with a median improvement in maximum squeeze pressure of 30.5 mmHg above baseline (range: 7.8–91.1) and median percentage improvement of 53.7% above baseline (range: 5.8% to 368.4%). In those with alternating FI and CC symptoms, the overall response rate was 86.4% ( $n=19$ ), with 68.2% ( $n=15$ ) reporting symptom improvement.

## DISCUSSION

In this cohort, the overall response rate to BFT for any indication was 76.2%, which is similar to published response rates for BFT in patients with FI and CC with DD ([17](#)). Biofeedback therapy clinical trials typically use symptomatic improvement as a primary endpoint. When symptomatic improvement was examined in our study, response rates to BFT in those with FI and alternating FI/CC symptoms were similar to published reports. However, the effectiveness of BFT to improve symptoms in the CC with DD patient subgroup was 45.3%, which is lower as compared with previously published results that demonstrated a symptomatic improvement with BFT of 70% to

**Table 2.** Baseline ARM measurements by indication

Indication	Average mean anal sphincter resting pressure (mmHg±SD)	Average mean residual anal sphincter pressure with simulated defecation (mmHg±SD)	Average maximum anal sphincter pressure with squeeze (mmHg±SD)	Average balloon expulsion time (seconds±SD)
CC with DD (n=53)	72.9 ± 27.0	78.3 ± 33.3	169.7 ± 78.8	271 ± 66.8
FI (n=49)	52.0 ± 71.0	46.3 ± 23.6	99.6 ± 71.0	93.6 ± 124.5
Alternating FI/CC (n=22)	52.0 ± 22.96	58.2 ± 27.5	113.1 ± 44.3	208.6 ± 112.8

**Table 3.** Response rate by indication for BFT and by response type

Indication	Response type	Response rate (%)
All indications (n=130)	ARM and symptom	64/130 (49.2%)
	ARM alone	27/130 (20.7%)
	Symptoms alone	8/130 (6.2%)
	ARM and/or symptom	99/130 (76.2%)
	Symptoms with or without ARM response	72/130 (55.4%)
	No response	31/130 (23.8%)
CC with DD (n=53)	ARM and symptom	21/53 (39.6%)
	ARM alone	13/53 (24.5%)
	Symptoms alone	3/53 (5.7%)
	ARM and/or symptom	37/53 (69.8%)
	Symptoms with or without ARM response	24/53 (45.3%)
	No response	16/53 (30.2%)
CC without DD (n=3)	ARM and symptom	0/3 (0%)
	ARM alone	2/3 (66.7%)
	Symptoms alone	0/3 (0%)
	ARM and/or symptom	2/3 (66.7%)
	Symptoms with or without ARM response	0/3 (0%)
	No response	1/3 (33.3%)
FI (n=49)	ARM and symptom	31/49 (63.3%)
	ARM alone	6/49 (12.2%)
	Symptoms alone	2/49 (4.1%)
	ARM and/or symptom	39/49 (79.6%)
	Symptoms with or without ARM response	33/49 (67.3%)
	No response	10/49 (20.4%)
Alternating FI/CC (n=22)	ARM and symptom	12/22 (54.5%)
	ARM alone	4/22 (18.2%)
	Symptoms alone	3/22 (13.6%)
	ARM and/or symptom	19/22 (86.4%)
	Symptoms with or without ARM response	15/22 (68.2%)
	No response	3/22 (13.6%)
Rectal pain (n=3)	ARM and symptom	0/3 (0%)
	ARM alone	2/3 (66.7%)
	Symptoms alone	0/3 (0%)
	ARM and/or symptom	2/3 (66.7%)
	Symptoms with or without ARM response	0/3 (0%)
	No response	1/3 (33.3%)



81% in this patient population (17). One potential explanation for this observation is that in our practice, three BFT sessions were performed compared with the up to six sessions that were used in previous studies (17). Hence, the current recommendations of BFT for the treatment of DD suggests four to six sessions (17). However, in our experience, three sessions of BFT is commonly employed outside of the clinical trial setting. Our study suggests that three sessions of BFT may be sufficient to teach and reinforce the anal sphincter strengthening exercises that are used in the treatment of FI but may not be adequate for giving instruction on appropriate coordination of the pelvic floor muscles during defecation that is required for correction of DD. It is also conceivable that the techniques taught during BFT for FI are more easily practiced at home compared with those for DD. The exercises for the latter can be more challenging to practice without the visual feedback and coaching of the therapist that occur during the BFT sessions. The visual feedback used in BFT is important for developing understanding of the muscle movements and coordination required to correct DD. In those with FI, the coordination required to improve anal sphincter tone is often easily understood in the absence of visual feedback. Finally, BFT may not be the only therapy required to improve constipation symptoms in those with DD. Chronic constipation can be multifactorial in nature. While correcting pelvic floor dyssynergy is an essential first step, many of these patients will require additional therapy to improve bowel movement frequency and form (10). Given the nature of this study and the practice setting, information regarding additional therapy for CC was not collected and likely remained unchanged during the BFT sessions. Thus, it is possible that a proportion of patients with CC needed optimization of their bowel regimen to fully benefit from BFT. Whereas in FI, the primary problem is often weakness of the anal sphincter rather than a problem with stool form, and improvement in anal sphincter muscle strength may be enough to produce symptomatic improvement.

In this study, symptom response was determined by documentation of a patient's subjective self-report of improvement. This is not as robust as using a validated symptom questionnaire like those typically used in clinical trials. Use of validated questionnaires allows for documentation of smaller changes in symptoms and helps eliminate some of the subjective nature of symptom reporting. This possibility may, in part, contribute to why the symptom response rate in our cohort was lower than that in published reports. In addition, the role of adjuvant therapy in patient symptom improvement was not documented. This may affect the reported response rate either positively or negatively because the effect of additional medications or therapies cannot be adequately controlled for. Finally, the efficacy of BFT for management of rectal pain and CC without DD cannot

be adequately assessed given the small number of patients in this cohort who were treated for these indications.

Despite the limitations, this study offers an insight on the use of BFT in clinical practice outside of the strict protocols of clinical trials. While BFT for the treatment of FI maintains efficacy, improvements can be made to optimize the management of CC with DD using BFT. Our study illustrates that three sessions of BFT is not sufficient to manage DD, following the recommendation in consensus guidelines on biofeedback therapy of using four to six sessions (17). Given the lack of availability of BFT in our resource-limited hospital setting, it would be important to explore the efficacy of other therapies, such as pelvic floor physiotherapy, as potential alternatives for the management of both FI and CC with DD.

## CONCLUSION

In our clinical practice, the overall manometric and symptomatic response rates to BFT are similar to published reports. Patients presenting with CC with DD had a lower symptom response rate compared with those with FI when BFT was limited to three sessions. Given that resources to provide BFT are limited, further studies are needed to determine the components of BFT that are most predictive for symptom response. This will guide optimization of BFT protocols in clinical practice and help optimize the collaboration with other therapists (such as pelvic floor physiotherapists) to provide effective BFT to our patients.

## Authors' Contributions

CP designed the study, collected data, analyzed data, interpreted data and drafted the manuscript. LL designed the study, interpreted data, and critically revised the manuscript. SH provided BFT and critically revised the manuscript.

## References

1. Soares NC, Ford AC. Prevalence of, and risk factors for, chronic idiopathic constipation in the community: Systematic review and meta-analysis. *Am J Gastroenterol* 2011;106(9):1582–91.
2. Menees SB, Almario CV, Spiegel BMR, et al. Prevalence of and factors associated with fecal incontinence—results from a population-based survey. *Gastroenterology* 2018;154(6):1672–81.
3. Belsey J, Greenfield S, Candy D, et al. Systematic review: Impact of constipation on quality of life in adults and children. *Aliment Pharmacol Ther* 2010;31(9):938–49.
4. Marquis P, De La Loge C, Dubois D, et al. Development and validation of the patient assessment of constipation quality of life questionnaire. *Scand J Gastroenterol* 2005;40(5):540–51.
5. Heidelbaugh JJ, Stelwagon M, Miller SA, et al. The spectrum of constipation-predominant irritable bowel syndrome and

- chronic idiopathic constipation: US survey assessing symptoms, care seeking, and disease burden. *Am J Gastroenterol* 2015;110(4):580–7.
6. Crowell MD, Schettler VA, Lacy BE, et al. Impact of anal incontinence on psychosocial function and health-related quality of life. *Dig Dis Sci* 2007;52(7):1627–31.
  7. Rao SS, Patcharatrakul T. Diagnosis and treatment of dyssynergic defecation. *J Neurogastroenterol Motil*. 2016;22(3):423–35.
  8. Rao SS, Bharucha AE, Chiarioni G, et al. Functional anorectal disorders. *Gastroenterology* 2016;150(6):1430–42.
  9. Paquette IM, Varma MG, Kaiser AM, et al. The American Society of Colon and Rectal Surgeons' clinical practice guideline for the treatment of fecal incontinence. *Dis Colon Rectum* 2015;58(7):623–36.
  10. Camilleri M, Ford AC, Mawe GM, et al. Chronic constipation. *Nat Rev Dis Primers* 2017;3:17095.
  11. Rao SS, Seaton K, Miller M, et al. Randomized controlled trial of biofeedback, sham feedback, and standard therapy for dyssynergic defecation. *Clin Gastroenterol Hepatol*. 2007;5(3):331–8.
  12. Chiarioni G, Whitehead WE, Pezza V, et al. Biofeedback is superior to laxatives for normal transit constipation due to pelvic floor dyssynergia. *Gastroenterology* 2006;130(3):657–64.
  13. Heymen S, Scarlett Y, Jones K, et al. Randomized, controlled trial shows biofeedback to be superior to alternative treatments for patients with pelvic floor dyssynergia-type constipation. *Dis Colon Rectum* 2007;50(4):428–41.
  14. Ilnyckyj A, Fachnie E, Tougas G. A randomized-controlled trial comparing an educational intervention alone vs education and biofeedback in the management of faecal incontinence in women. *Neurogastroenterol Motil* 2005;17(1):58–63.
  15. Heymen S, Scarlett Y, Jones K, et al. Randomized controlled trial shows biofeedback to be superior to pelvic floor exercises for fecal incontinence. *Dis Colon Rectum* 2009;52(10):1730–7.
  16. Parker CH, Tomlinson GA, Correia AJ, et al. Predictability of functional defecation disorder in patients with chronic constipation using a standardized constipation symptom questionnaire. *Gastroenterology* 2014;146(5):S717.
  17. Rao SS, Benninga MA, Bharucha AE, et al. ANMS-ESNM position paper and consensus guidelines on biofeedback therapy for anorectal disorders. *Neurogastroenterol Motil* 2015;27(5):594–609.
  18. Parker CH, Tomlinson G, Correia A, Liu LWC. The use of standardized questions in identifying patients with dyssynergic defecation. *JCAG* 2018. doi:10.1093/jcag/gwy010.