Randomized Controlled Trial of Biofeedback, Sham Feedback, and Standard Therapy for Dyssynergic Defecation

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Background & Aims: **Constipation is a common disorder, and current treatments are generally unsatisfactory. Biofeedback might help patients with constipation and dyssynergic defecation, but its efficacy is unproven, and whether improvements are due to operant conditioning or personal attention is unknown.** ***Methods:*** **In a prospective randomized trial, we investigated the efficacy of biofeedback (manometric-assisted anal relaxation, muscle coordination, and simulated defecation training; biofeedback) with either sham feedback therapy (sham) or standard therapy (diet, exercise, laxatives; standard) in 77 subjects (69 women) with chronic constipation and dyssynergic defecation. At baseline and after treatment (3 months), physiologic changes were assessed by anorectal manometry, balloon expulsion, and colonic transit study and symptomatic changes and stool characteristics by visual analog scale and prospective stool diary. Primary outcome measures (intention-to-treat analysis) included presence of dyssynergia, balloon expulsion time, number of complete spontaneous bowel movements, and global bowel satisfaction.** ***Results:*** **Subjects in the biofeedback group were more likely to correct dyssynergia ($P < .0001$), improve defecation index ($P < .0001$), and decrease balloon expulsion time ($P = .02$) than other groups. Colonic transit improved after biofeedback or standard ($P = .01$) but not after sham. In the biofeedback group, the number of complete spontaneous bowel movements increased ($P < .02$) and was higher ($P < .05$) than in other groups, and use of digital maneuvers decreased ($P = .03$). Global bowel satisfaction was higher ($P = .04$) in the biofeedback than sham group.** ***Conclusions:*** **Biofeedback improves constipation and physiologic characteristics of bowel function in patients with dyssynergia. This effect is mediated by modifying physiologic behavior and colorectal function. Biofeedback is the preferred treatment for constipated patients with dyssynergia.**

Constipation is one of the most common digestive complaints and affects between 12%–19% of Americans.[1,2] Traditionally, constipation has been defined as less than 3 stools per week.[3] However, recent studies show that most constipated patients report and are often bothered by excessive straining, incomplete evacuation, or hard stools rather than infrequent stooling.[4–6]

Although there is some overlap, 3 subtypes of constipation have been described: dyssynergic defecation, slow transit constipation, and irritable bowel syndrome with constipation.[7–10] Dyssynergic defecation, also known as anismus[11] or pelvic floor dyssynergia,[9,12,13] is characterized by failure of the abdominal, rectal, pelvic floor, and anal sphincter muscles to coordinate and complete the act of defecation.[7,12–16] It is characterized by impaired propulsion of stool from the rectum, paradoxical anal contraction, or inadequate anal relaxation, or a combination of these mechanisms.[12,15] About one third of patients with chronic constipation seen in tertiary care centers have dyssynergia.[8,14,17,18]

The treatment of constipation remains unsatisfactory. Recent reviews have concluded that there is insufficient evidence to support the use of most traditional laxatives.[19,20] Schiller et al[21] found that only 53% of patients were satisfied with traditional medical therapies for constipation.

Biofeedback is an instrument-based behavioral learning program that incorporates the principles of "operant conditioning." Uncontrolled trials have reported that biofeedback might be useful to treat dyssynergia.[22–27] However, outcome variables were poorly defined, and objective parameters were rarely assessed.[9,26,27] A recent controlled study showed that biofeedback was superior to laxatives.[28] Some argue that biofeedback is not helpful in constipation,[29] and that the clinical improvement is due to the attention received rather than neuromuscular conditioning. Therefore, ideally biofeedback should be compared with sham feedback, and this has not been performed.

We hypothesized that patients with dyssynergic defecation receiving biofeedback would exhibit greater improvement in bowel symptoms and colonic and anorectal physiology than those receiving sham feedback or standard therapy. We performed a prospective randomized controlled trial to investigate the efficacy of biofeedback in dyssynergic patients by comparing the physiologic and symptomatic outcome of biofeedback therapy with standard therapy or sham feedback therapy.

Materials and Methods

Adult outpatients, 18–75 years old, who were referred to a tertiary care center with a complaint of constipation were invited to participate in the study. All subjects had failed routine management of constipation. Patients included fulfilled Rome II criteria for functional constipation,[30] exhibited a dyssynergic pattern of defecation during attempted defecation,[13] and had either prolonged difficulty with expelling a simulated stool (>1 minute) or prolonged delay (>20% marker retention)

Abbreviations used in this paper: CSBM, complete spontaneous bowel movement; ITT, intention to treat; s, seconds.

1542-3565/07/$32.00
doi:10.1016/j.cgh.2006.12.023

in colonic transit.[7,9,12] They were required to have no evidence of structural or metabolic diseases that could cause constipation, as assessed by colonoscopy/barium enema and routine hematologic, biochemical, and thyroid function tests. Patients taking drugs known to be constipating, for example, opioids, were excluded, or they discontinued the drug 2 weeks before enrollment. Other exclusion criteria included severe cardiac or renal disease, previous gastrointestinal, spinal, or pelvic surgery except cholecystectomy, hysterectomy, or appendectomy, neurologic diseases such as multiple sclerosis, stroke, or spinal injury, impaired cognizance (Mini-Mental State score <15), legal blindness, pregnancy, rectal prolapse, anal fissure, and alternating constipation and diarrhea.

Randomization used the permuted blocks with 1:1:1 assignment into the 3 study groups (biofeedback, sham, and standard). Random numbers generated in advance were placed into sequentially numbered opaque envelopes, sealed, and used for subject assignment. Although the therapist and patient could not be blinded, the manometry reader was unaware of patient assignment or previous data. Standard protocols were used for each group to ensure that all patients received similar general guidelines for management of their constipation.

Outcome measures, assessed at baseline and after treatment, included anorectal manometry, balloon expulsion test,[7,31,32] and colonic transit study in which 3 different-shaped radiopaque markers (Sitzmark; Konsyl Pharmaceuticals, Fort Worth, TX) were administered on 3 consecutive days, and a plain abdomen x-ray was taken on day 6.[33] In a prospective stool diary starting 1 week before enrollment, subjects recorded the time, consistency (Bristol stool scale[34]: type 1, hard pellets and 7, watery stools), straining effort (1, normal; 2, moderately excessive; 3, severe) of each bowel movement, and feeling of incomplete evacuation (yes/no) and need for digital assistance (yes/no). Also, they rated the overall satisfaction with bowel function on a 100-mm visual analog scale. The study was approved by the Institutional Review Board, and all participants gave written informed consent.

Standard Treatment

A gastroenterologist, nurse therapist, and dietitian provided advice regarding bowel habits, exercise, laxatives, dietary fiber and fluid intake, and timed toilet training during an initial visit. This was reinforced by the nurse during 3 monthly follow up visits.

All patients were advised to attempt bowel movement for 5 minutes, twice a day, 30 minutes after eating, irrespective of their urge to defecate. The nurse therapist taught subjects how to improve their pushing effort by using postural and diaphragmatic breathing techniques[12,22] and instructed them to practice these maneuvers at home for 15 minutes 3 times a day. Magnesium hydroxide (Phillips Milk of Magnesia; Bayer, Tarrytown, NY) 1–2 tablespoons or magnesium gluconate (Magonate 500 mg; Fleming & Company, St Louis, MO) 2–4 tablets daily was recommended daily as the standard laxative, and subjects were instructed to titrate its use. All subjects were advised to refrain from using manual maneuvers, and if used, its use was recorded. Patients having no bowel movement for 48 hours were instructed to use 1 glycerin suppository, then after 72 hours a tap water enema, and after 96 hours 2 bisacodyl tablets orally (rescue laxatives). The dietitian advised subjects to consume a balanced, adequate calorie diet, increase fruit and vegetable intake to 5 servings per day, and consume 25 g of dietary fiber from natural food sources daily.

Biofeedback Treatment

In addition to receiving the instructions described under standard therapy, subjects had an initial training session by a nurse specialist followed by biweekly, 1-hour biofeedback sessions, up to a maximum of 6 therapy sessions during a period of 3 months. Biofeedback training was performed by placing a solid state manometry probe (Koningsberg Instruments, Pasadena, CA) and by using software (Amb B; Gaeltec Ltd, Dunvegan, Isle of Skye) for displaying the manometric data. Biofeedback treatment consisted of 3 components. The goal of rectoanal coordination was to increase the pushing effort as reflected by an increase in intra-abdominal/intrarectal pressures and synchronized relaxation reflected by a decrease in anal sphincter pressure. While sitting on a commode, subjects watched the manometric tracings on a computer monitor and received training with visual and verbal feedback techniques to correct dyssynergia.[12,22] The goal of simulated defecation[12,22] was to train subjects during a period of 3 trials to expel a silicone-filled artificial stool-FECOM.[35] Their posture and breathing techniques were continuously monitored, and appropriate advice and feedback were provided to improve defecatory effort. Patients with impaired rectal sensation received sensory conditioning by repeated inflations/deflations of a rectal balloon.[12,22]

Sham Feedback Treatment

In addition to receiving the basic instructions provided during initial and follow-up standard treatment, the sham group participated in up to 6 biweekly, 1-hour relaxation therapy sessions during a period of 3 months. At each session, the nurse therapist placed a manometry probe into the subject's rectum. Subsequently, they practiced progressive muscle relaxation under supervision by listening to an audiotape (The Relaxation Company, Rosalyn, NY) for 20 minutes. Intermittent balloon distentions were performed with the rectal probe to promote awareness for stooling and match the sensory conditioning provided under biofeedback. During each visit, 20 minutes was spent exploring the patient's symptoms and advising them about coping strategies.

Data Analysis and Outcome Measures

Because constipation is a heterogeneous condition and no single parameter adequately defines constipation or represents an optimal way of assessing clinical outcome,[7,36] a range of subjective and physiologic measures of bowel function were used. Subjective primary outcome measures were the number of complete spontaneous bowel movements (CSBMs) per week and the scores on the global bowel satisfaction visual analog scale.

A spontaneous bowel movement was defined as a bowel movement that occurred naturally or without use of rescue laxatives, suppositories, or enemas within the previous 24 hours. A CSBM was defined as a bowel movement reported on a stool diary without a feeling of incomplete evacuation. The proportion of subjects who reported $\geq$20-mm positive change on visual analog scale was used as an index of global bowel satisfaction. Physiologic primary outcome measures were the presence of dyssynergic pattern during attempted defecation[7,12]

and the balloon expulsion time. Per-protocol and intention-to-treat (ITT) analyses were performed for all the primary outcome measures.

Secondary subjective outcome measures included stool frequency, stool consistency, straining effort, proportion of patients needing digital assistance for stooling, and a laxative consumption score per week (none, no laxatives; Type I, high-fiber diet ± bran and stool softeners; Type II, oral laxatives [magnesium oxide, 17 g polyethylene glycol (Miralax; Braintree Labs, Braintree MA); Type III, stimulants (bisacodyl); Type IV, enemas, suppositories, magnesium citrate, 236-g polyethylene glycol solutions [Golytely; Braintree Labs]). The secondary physiologic outcome measures included anal residual pressure, intrarectal pressure, and defecation index during attempted defecation, thresholds for first perception and urge to defecate, and the proportion of subjects with slow colonic transit time.[7,32,33] These secondary outcome measures were analyzed as ITT. The data analyst was unaware of the group randomization.

Statistical Analysis

The primary outcome measures for the 3 treatment groups were analyzed by using negative binomial regression analysis for CSBM, Fisher exact test for bowel satisfaction response rate and also for the proportion of subjects with dyssynergia, and mixed-model analysis of variance for balloon expulsion. The secondary outcome measure of number of stools per week was also analyzed by using negative binomial regression; the use of laxatives and digital assistance, and the proportion of subjects with slow transit (>20% marker retention) were analyzed by using exact probability from Fisher and McNemar tests. The stool consistency score, stool strain score, and the physiologic manometric data were analyzed by using mixed-model analyses of variance. The ITT and per-protocol analyses of the data after completion of treatment involved 2 questions; first, could the presence of treatment effects be established for each of the 3 treatment arms, and second, could the changes that occurred after treatment be differentiated among the treatment arms. Because the Bowel Satisfaction visual analog score was obtained after each visit, an ITT analysis was performed by carrying forward their last observation for the few subjects who had dropped out of the study; the baseline value was imputed forward to be their "post-treatment" value in 1 subject in the standard and sham groups and 3 subjects in the biofeedback group. Because of nonavailability of post-treatment stool diary data and post-treatment manometric and colonic transit data in some subjects who only attended the initiation visit, an ITT analysis was performed either by carrying forward their last observation or by imputing forward the mean baseline value for the number of CSBMs/week. We compared the data for pretreatment versus post-treatment for each intervention as well as the effects of biofeedback treatment across the groups. Baseline comparisons between treatment regimens were tested at the alpha level of $P = .05$, because "correction" for multiple comparisons would bias against any suggestion of pretreatment divergence despite the randomization. The preplanned comparisons between the biofeedback and sham feedback and between the biofeedback and standard treatment were also tested at the alpha level of $P = .05$. The data are expressed as mean ± standard error of the mean.

Results

Subject Demographics

Seventy-seven patients (69 women, 8 men; mean age, 43 years) with a mean duration of constipation for 17 years were recruited out of 377 subjects (Figure 1). Among these, 24 subjects (22 women) were randomized to receive standard therapy, 28 subjects (25 women) to biofeedback therapy, and 25 subjects (23 women) to sham feedback therapy. There were no differences in the demographic distribution among the 3 groups. Sixty-five subjects completed the study (23 in standard, 21 in biofeedback, and 21 in sham groups). Two (1 each in biofeedback and sham groups) developed comorbid illnesses and could not complete the study; 10 were noncompliant with the study protocol and were lost to follow up after the initiation visit, but all 12 subjects are included in the ITT analysis (Figure 1). The noncompliance rate did not differ among the groups ($P = .21$), but a type 2 error cannot be excluded. The mean (range) number of therapy sessions for both biofeedback and sham feedback groups was 5 (4–6).

The baseline bowel symptom profiles including stool frequency, stool consistency, straining effort, and laxative use were comparable and similar between the 3 groups, including the percentage of subjects needing digital assistance to defecate (Table 1). With regards to manometric features, there were no differences between subjects who were randomized to sham feedback or standard therapy. However, the biofeedback group exhibited a significantly higher baseline mean resting sphincter pressure ($P = .02$) and mean anal residual pressure ($P = .0067$) and higher threshold for first perception ($P = .01$) when compared with the standard group (Table 1). Also, the baseline defecation index was significantly lower when compared with standard group ($P = .03$) and the sham feedback group ($P = .0069$). These data suggest that patients who were randomized to receive biofeedback had relatively greater pelvic floor dysfunction.

Outcome Measures

Subjective parameters. *Primary outcome measures.* An ITT analysis showed that patients who received biofeedback exhibited a significant increase in the numbers of CSBMs per week when compared with the baseline period ($P < .02$), as well as the sham ($P < .05$) and the standard groups ($P = .006$) (Figure 2*A*). There was no significant change in CSBMs in the standard or sham groups, when compared with the baseline period. A per-protocol analysis also showed similar increase in the numbers of CSBMs in patients who received biofeedback when compared with the baseline period (2.5 ± 0.3 vs 5.1 ± 0.2, $P = .018$), sham group ($P = .02$), and standard group ($P = .001$) but not in patients who received sham (1.7 ± 0.2 vs 2.6 ± 0.2, $P = .12$) or standard therapy (1.4 ± 0.5 vs 1.6 ± 0.3, $P = .7$).

An ITT analysis showed a significant percentage ($P < .0001$) of subjects who reported improved global bowel satisfaction when compared with baseline, with all 3 treatments (Figure 2*B*). Subjects who received biofeedback (%) also reported greater improvement in bowel satisfaction when compared with those who received sham feedback ($P = .04$) but not standard therapy. A per-protocol analysis also showed a significant change in the global bowel satisfaction from baseline in all 3 groups ($P < .001$). However, patients who received biofeedback exhibited a greater improvement than those who received sham feedback

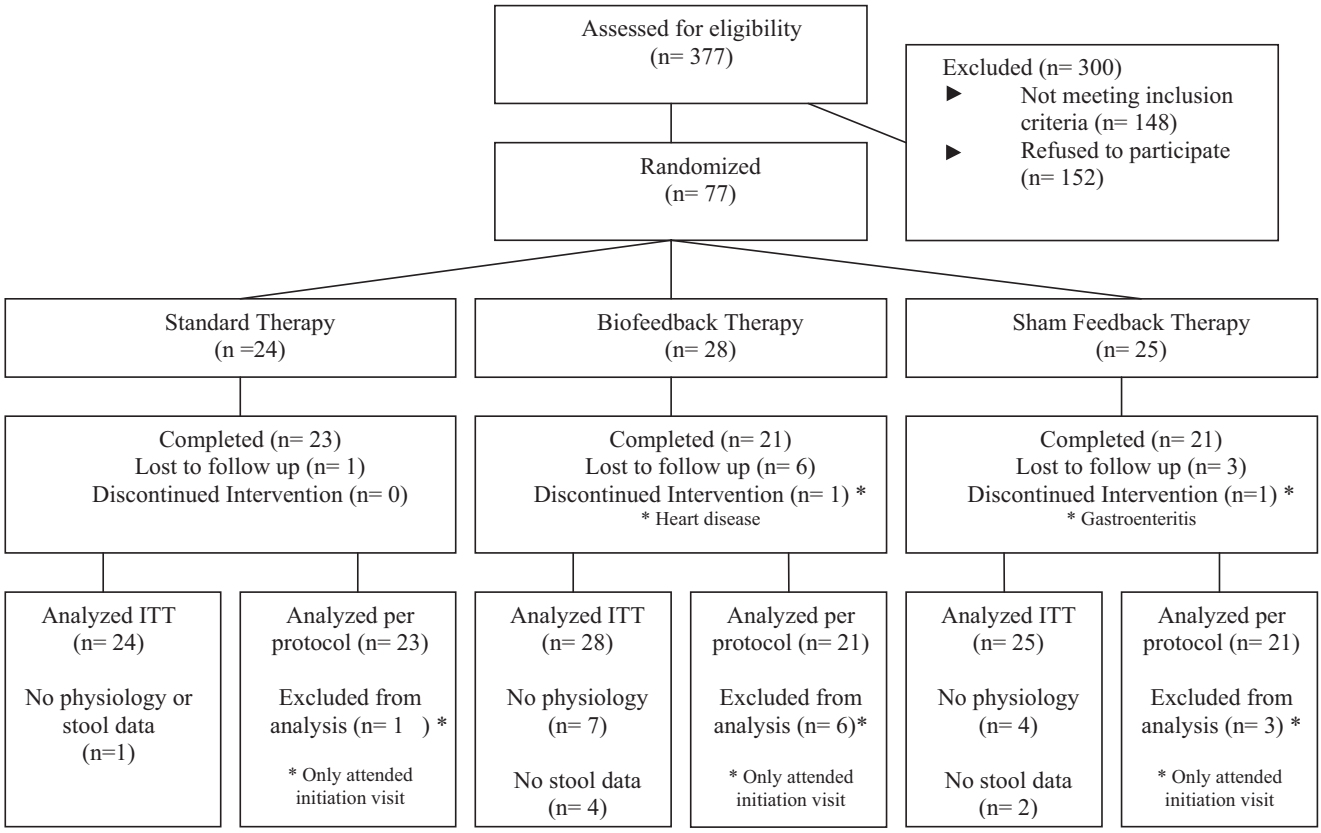

Figure 1. Table showing the recruitment, randomization, analysis and follow up of Participants.

Table 1. Effects of Treatment on Secondary Outcome Measures Including Stool Patterns, Laxative Use, Need for Digital Assistance With Stooling, and Manometric Pressure Profiles (Mean ± Standard Error of the Mean or Percentage)

	Biofeedback		Sham feedback		Standard	
	Baseline	After	Baseline	After	Baseline	After
Subjective parameters						
No. of stools/wk	6.1 ± 0.1	7.1 ± 0.1[a]	6.2 ± 0.2	5.4 ± 0.1	5 ± 0.1	4.7 ± 0.1
Stool consistency (1–7)	3.5 ± 0.2	3.9 ± 0.2	3.5 ± 0.2	3.4 ± 0.2	3.4 ± 0.2	3.5 ± 0.2
Stool strain score (1–3)	1.99 ± 0.1	1.85 ± 0.1	2.0 ± 0.1	1.8 ± 0.1	1.9 ± 0.1	1.9 ± 0.1
Laxative consumption (%)						
Types I–II	70%	85%	64%	76%	67%	75%
Types III–IV	30%	11%	32%	16%	33%	21%
Digital assistance (%)	36%	14%[b,c]	32%	32%	33%	24%
Physiologic parameters						
Anal resting pressure	67 ± 3[d]	60 ± 4	60 ± 5	54 ± 4	56 ± 4	55 ± 4
Anal residual pressure (*mm Hg*)	81 ± 6[d]	39 ± 5[e]	67 ± 6	68 ± 6	60 ± 5	61 ± 5
Intrarectal pressure (*mm Hg*)	32 ± 5	49 ± 4[e]	39 ± 4	38 ± 4	34 ± 4	34 ± 3
Defecation index	0.4 ± 0.1[d]	1.7 ± 0.2[e]	0.7 ± 0.1	0.7 ± 0.2	0.6 ± 0.1	0.6 ± 0.1
First sensation threshold (*mL*)	43 ± 9[a]	29 ± 7[b]	39 ± 8	33 ± 11	27 ± 9	20 ± 2
Urge to defecate threshold (*mL*)	185 ± 17	171 ± 15	200 ± 15	191 ± 13	186 ± 14	184 ± 22

[a]$P = .019$, biofeedback vs standard for number of stools.
[b]$P = .03$ vs baseline.
[c]$P = .02$ vs sham feedback.
[d]$P < .002$ vs sham and standard.
[e]$P < .003$ vs baseline, sham, and standard.

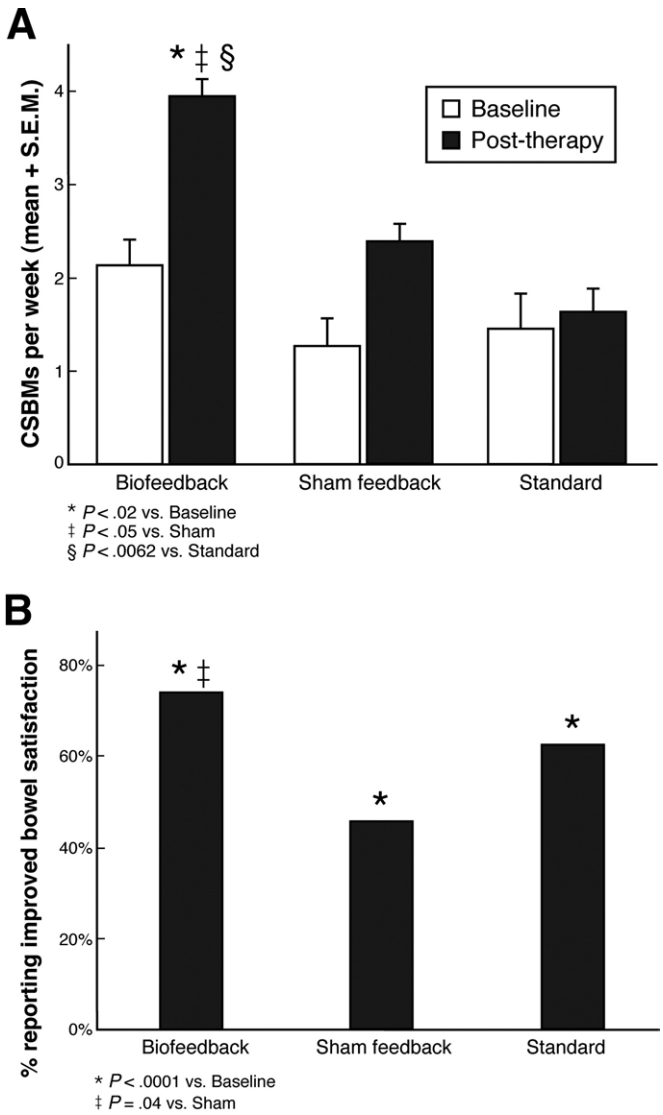

Figure 2. Results for subjective outcome measures. (*A*) Number of CSBMs/wk in each of the 3 treatment groups before and after treatment. (*B*) Percentage of subjects who reported improved global bowel satisfaction and a visual analog scale with each treatment.

(86% vs 48%, $P = .018$), but not when compared with those who received standard therapy.

Secondary outcome measures. After treatment, the mean stool frequency per week increased significantly in the biofeedback group when compared with standard group ($P = .01$) but not sham group (Table 1). There was a nonsignificant trend toward softer stools and lesser degree of straining in patients who received biofeedback but not in the other groups (Table 1). The laxative consumption score did not change in any of the groups, although there was a nonsignificant trend toward lesser use of stimulants, enemas, and suppositories (Table 1). A need for digital assistance with stooling lessened significantly ($P = .03$) in the biofeedback group but not in the other 2 groups (Table 1). Also, the need for digital assistance decreased significantly in the biofeedback group when compared with the sham group ($P = .02$).

Physiologic parameters. *Primary outcome measures.* An ITT analysis showed that the dyssynergia pattern was corrected in 79% receiving biofeedback, 4% receiving sham, and 8.3% with standard treatment. Biofeedback was superior to baseline, sham, and standard treatments ($P < .0001$). There was no difference in the sham or standard treatment groups when compared with baseline (Figure 3*A*). A per-protocol analysis showed that the dyssynergia pattern was corrected in 81% of patients receiving biofeedback but only in 2% of patients receiving sham feedback or standard therapy. Biofeedback was superior to baseline, sham, and standard therapy ($P < .0001$).

An ITT analysis showed that the balloon expulsion time decreased significantly in subjects who received biofeedback when compared with their baseline ($P < .0001$) but not in the sham ($P = .15$) or standard ($P = .08$) treatment groups. Also, biofeedback was superior to sham ($P = .003$) or standard ($P = .03$) treatment (Figure 3*B*). A per-protocol analysis showed that the balloon expulsion time decreased in subjects who received biofeedback, when compared with baseline (137s ± 27s vs 26s ± 8s, $P = .001$) and when compared with sham feedback ($P = .04$). There was no change in the sham group (119s ± 25s vs 109s ± 30s) and in the standard group (142s ± 27s vs 78s ± 23s).

Secondary outcome measures. ITT analysis indicated that the anal residual pressure decreased ($P < .0001$), the intrarectal pressure increased ($P < 001$), and defecation index increased significantly ($P < .0001$) in the biofeedback group when compared with baseline, but they were unchanged in other groups (Table 1). Furthermore, the anal residual pressure, intrarectal pressure, and the defecation index improved significantly in the biofeedback group ($P < .001$), when compared with those who received either standard therapy or sham feedback. In the biofeedback group, the threshold for first sensory perception ($P = .001$) but not an urge to defecate decreased significantly when compared with baseline. There was no difference in sensory thresholds among the 3 groups.

At baseline, on average between 68%–80% of subjects with dyssynergia had slow colonic transit time (Figure 3*C*). After treatment, when compared with their baseline, the proportion of subjects with slow colonic transit decreased significantly with biofeedback ($P = .0018$) and standard treatments ($P = .01$) but not with sham feedback ($P = .07$).

Discussion

In this prospective, randomized controlled trial, biofeedback therapy significantly improved bowel function in subjects with chronic constipation and dyssynergic defecation. Subjects who received biofeedback had a greater number of CSBMs and greater satisfaction with bowel function and were more likely to discontinue the use of digital maneuvers than subjects receiving standard treatment or sham feedback treatment.

Symptomatic improvement with biofeedback was also matched by improvement in physiologic characteristics of colorectal function. During attempted defecation, the dyssynergic pattern was corrected in 79% of patients who received biofeedback but was unchanged with the other 2 therapies. Other manometric indices of rectoanal coordination during defecation such as the defecation index and rectal sensory perception also improved significantly only in the biofeedback group, as did the time taken to expel an artificial stool. Furthermore, in subjects who were randomized to biofeedback therapy, some of the baseline parameters such as resting sphincter pressure, anal

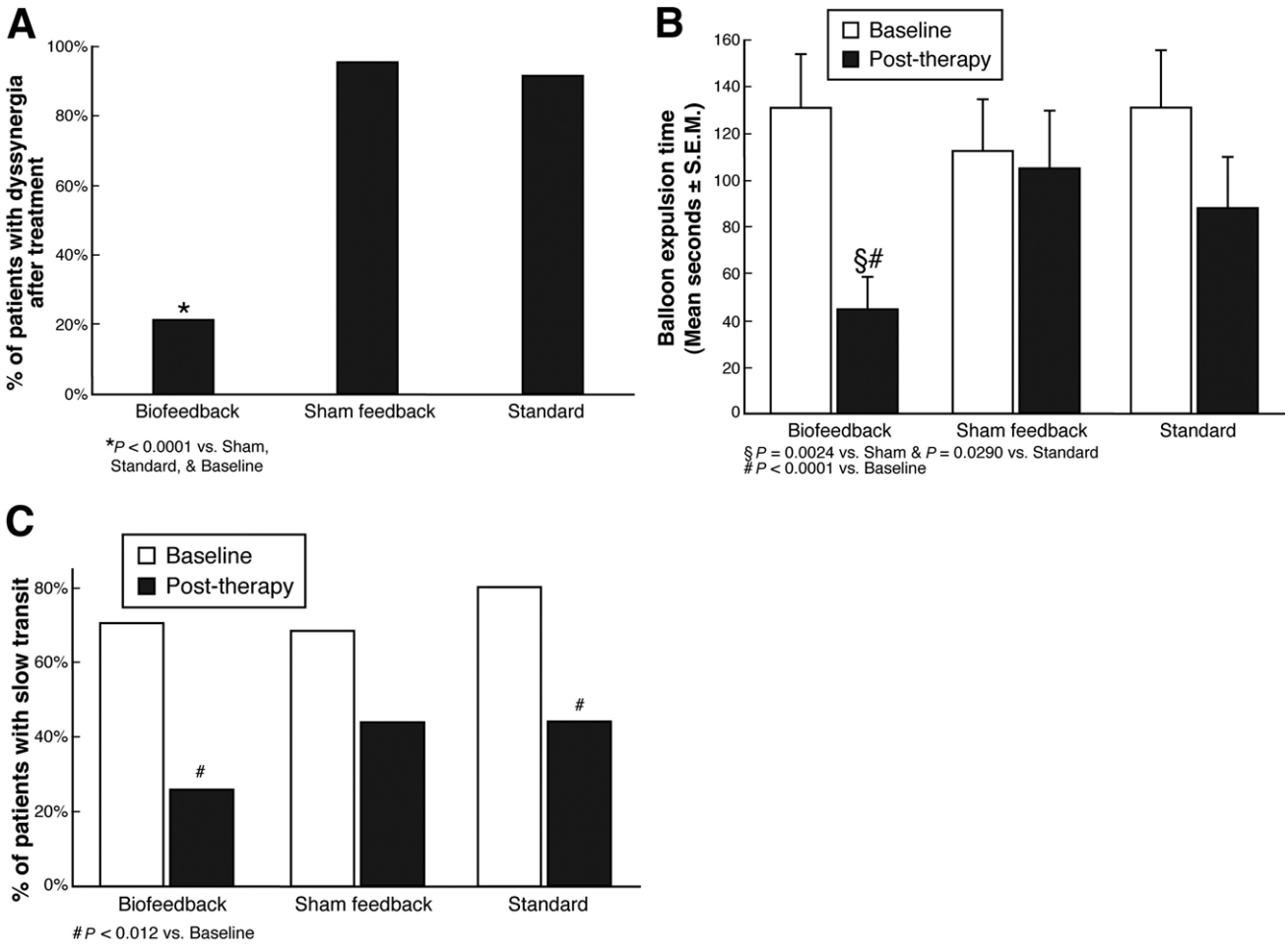

Figure 3. Results for the physiologic outcome measures. (*A*) Proportion of patients who exhibited a dyssynergic pattern on anorectal manometry after each treatment. (*B*) Effect of each treatment on the balloon expulsion time. (*C*) Percentage of subjects with slow transit in the colon before and after each treatment.

residual pressure, and first sensory perception were higher and defecation index was lower, suggesting a relatively greater pelvic floor dysfunction. After biofeedback, there was a significant improvement in these parameters when compared with the other treatments, suggesting a greater therapeutic benefit.

Our findings emphasize the importance and relevance of performing neuromuscular conditioning to correct dyssynergia and improve bowel function. The clinical improvement seen in our subjects was achieved by modifying the underlying physiologic behavior, because patients who received sham feedback also received a similar degree of attention and advice from the same therapist regarding coping strategies but failed to exhibit an improvement in the range of primary and secondary outcome measures. Thus, biofeedback therapy appears to be effective in improving both subjective and physiologic characteristics of bowel function in patients with dyssynergic defecation.

The global bowel satisfaction was greater for biofeedback and when compared with sham feedback, although subjects in the other 2 groups improved to a lesser degree over baseline. This observation suggests that carefully monitored therapy with coping strategies might improve satisfaction with bowel symptoms in some patients, at least temporarily, but might not produce real and effective change in bowel function. This finding underscores the need for performing objective assessments of bowel function; reliance on global satisfaction with bowel function as a sole measure of improvement might be inadequate and could be influenced by other factors such as desire to please the investigators.[37] Finally, these observations emphasize the need for randomized controlled trails including sham therapy in patients with functional gastrointestinal disorders in whom there is high likelihood of placebo effect.[37,38]

The aforementioned findings are in agreement with and confirm those recently described by Chiarioni et al,[28] but there are significant methodologic differences that merit discussion. Our study included a sham biofeedback arm along with standard therapy and laxatives. We believe that a well-designed sham therapy is essential for an optimal comparative assessment of a behavioral therapy, because it provides the attention, the coping skills, and other support that these patients desperately seek. This is particularly important because patients with dyssynergia have significant psychological dysfunction and impaired quality of life.[39] Furthermore, in our study, the biofeedback therapy was administered by a nurse who also administered the sham therapy and laxative therapy, under supervision of a physician, whereas in their study, biofeedback was administered by a knowledgeable and skilled neurogastroenterologist,

and the laxative therapy was administered by another physician, raising concerns for equitable management. Also, unlike our study, they excluded patients with coexisting slow transit constipation that accounts for at least two thirds of patients with dyssynergia,[12,17,40] a finding further reaffirmed in this study. We observed a significant improvement in the colonic transit time in subjects who received biofeedback and standard therapy but not in subjects who received sham feedback. Thus, biofeedback therapy improves colonic function and reverses the slow transit. This finding further attests that the slowing of colonic transit is secondary to the dyssynergia. Patients in their study were also younger (mean age, 33 years) when compared with our group (mean age, 43 years). Finally, we used a range of subjective and objective outcome measures including CSBMs per week, which is regarded as a better index of assessing bowel movements than stool frequency alone.[41] Although we accept the limitation that ours was a short term assessment (3 months) and the study by Chiarioni et al assessed improvement at 6 months and 1 year, there are concerns with their long-term study; all patients who received 5 sessions of biofeedback were told, irrespective of their outcome, that they had improved. This approach potentially introduces a subjective bias by falsely elevating expectations regarding perceived therapeutic benefit for a behavioral therapy, especially when told by a physician who is also providing care for the patient. In spite of these differences, both studies found that biofeedback therapy was superior to standard therapy including laxatives.

The limitations of our study include small sample size resulting from high screen failure rate and unwillingness among some potential subjects to participate, referral bias to a tertiary care center, comorbid illnesses, strict entry criteria, and the subject's desire to receive only biofeedback. The screen failure and dropout rate is similar to that reported in a previous study of biofeedback for incontinence.[42] Furthermore, biofeedback is labor intensive (250 therapy sessions in this trial) and requires motivation and multiple hospital visits (many subjects lived at least 2 hours away); these factors contributed to the variation in noncompliance. Also, our results might not be applicable to all patients in the community setting. However, most experts agree that the diagnosis of dyssynergia requires physiologic assessment that is generally available only in referral centers.[7,12,18,25,32]

One approach has been to perform biofeedback for all patients with symptoms of difficult defecation.[43] Although pragmatic, many patients with normal colonic and anorectal function and those with slow transit constipation might not benefit with biofeedback.[25] Thus, such an approach might not be cost-effective.

In one other randomized study without controls, subjects who received electromyogram-based biofeedback improved to a similar extent (about 40%) as those who received muscle coordination training, although use of digital maneuvers was unaffected.[24] In our study, similar to Chiarioni et al,[28] we combined these techniques and found greater improvement. This suggests that a multi-component biofeedback program designed to correct the underlying pathophysiology is likely to be more effective than single component training.

Because dyssynergic defecation is associated with chronic constipation, it is important to know whether biofeedback is effective in the long-term. Uncontrolled studies have reported improvement in 50%–71% of subjects undergoing biofeedback,[25,43,44] but a recent controlled trial showed improvement with biofeedback at 1 year when compared with laxatives.[28] Thus, it seems likely that the benefit is sustained. In our study, the laxative consumption score did not change in any of the groups, suggesting that behavioral therapy might not change life-long habits, at least in the short-term, although Chiarioni et al[28] observed decreased use of laxatives in the biofeedback group compared with laxative group. Also, whether some patients require periodic reinforcement with biofeedback to maintain their benefits is unknown.[22,43]

In conclusion, on the basis of our results, biofeedback therapy is the preferred treatment for patients with chronic constipation and dyssynergic defecation and especially for those who have failed standard therapy.

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Supported by NIH grant RO1 DK 57100-05 and grant RR00059 from the General Clinical Research Centers program, National Center for Research Resources.

The authors sincerely acknowledge the expert technical and nursing assistance of Mrs Mary Stessman, RN, and the superb secretarial support of Mrs Heidi Vekemans.