

Biofeedback Is Superior to Laxatives for Normal Transit Constipation Due to Pelvic Floor Dyssynergia

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See CME Quiz on page 930.

Background & Aims: Uncontrolled trials suggest biofeedback is an effective treatment for pelvic floor dyssynergia (PFD), a type of constipation defined by paradoxical contraction, or inability to relax, pelvic floor muscles during defecation. The aim was to compare biofeedback to laxatives plus education. **Methods:** Patients with chronic, severe PFD were first treated with 20 g/day fiber plus enemas or suppositories up to twice weekly. Nonresponders were randomized to either 5 weekly biofeedback sessions (n = 54) or polyethylene glycol 14.6–29.2 g/day plus 5 weekly counseling sessions in preventing constipation (n = 55). Satisfaction with treatment, symptoms of constipation, and pelvic floor physiology were assessed 6 and 12 months later. The biofeedback group was also assessed at 24 months. Laxative-treated patients were instructed to increase the dose of polyethylene glycol from 14.6 to 29.2 g/day after 6 months. **Results:** At 6 months, major improvement was reported by 43 of 54 (80%) biofeedback patients vs 12 of 55 (22%) laxative-treated patients ($P < .001$). Biofeedback's benefits were sustained at 12 and 24 months. Biofeedback also produced greater reductions in straining, sensations of incomplete evacuation and anorectal blockage, use of enemas and suppositories, and abdominal pain (all $P < .01$). Stool frequency increased in both groups. All biofeedback-treated patients reporting major improvement were able to relax the pelvic floor and defecate a 50-mL balloon at 6 and 12 months. **Conclusions:** Five biofeedback sessions are more effective than continuous polyethylene glycol for treating PFD, and benefits last at least 2 years. Biofeedback should become the treatment of choice for this common and easily diagnosed type of constipation.

Chronic constipation affects 2%–30% of people in Western countries.¹ One of the most frequent subtypes of constipation is dyssynergic defecation, which is

referred to in this manuscript as pelvic floor dyssynergia (PFD) because this is the term recommended by the Rome II working team; it is defined by inappropriate (paradoxical) contraction or failure to relax the pelvic floor muscles during attempts to defecate.²

Uncontrolled studies suggest that approximately 70% of patients with PFD benefit from biofeedback in which electronically augmented information on muscle tension or anal canal pressure is used to teach patients how to more effectively relax the pelvic floor during defecation.³ However, there are no controlled trials in adults comparing biofeedback with laxatives, although laxatives are cheaper and more readily available.

The aims of this parallel group, randomized controlled trial were (1) to compare biofeedback with laxative treatment of PFD (polyethylene glycol [PEG] 14.6 g/day) with respect to satisfaction with treatment (the primary outcome variable), stool frequency, laxative use (other than PEG), straining frequency, sense of incomplete evacuation, and feeling of blocked defecation; (2) to identify physiologic mechanisms for biofeedback training effects; and (3) to identify clinical and physiologic characteristics of patients that predict response to treatment.

Patients and Methods

Patients

Inclusion criteria.

1. Severe constipation present for more than 12 months and unresponsive to standard medical treatment.
2. Fulfills Rome II⁴ criteria for chronic constipation, ie, 2 or more of 6 symptoms present for at least 12 weeks of the

Abbreviations used in this paper: EMG, electromyogram; PEG, polyethylene glycol; PFD, pelvic floor dyssynergia.

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0016-5085/06/\$32.00

doi:10.1053/j.gastro.2005.11.014

preceding 12 months: straining, lumpy or hard stools, sensation of incomplete evacuation, sensation of anorectal obstruction/blockage, or manual maneuvers to facilitate defecation on more than one fourth of bowel movements, or less than 3 bowel movements per week.

3. Paradoxical contraction or failure to relax pelvic floor muscles during attempts to defecate as shown by both anal canal pressures and a surface electromyogram (EMG) recorded from the anal canal.
4. Inability to defecate a 50-mL, water-filled balloon within 5 minutes.
5. Failure to respond to a 30-day trial of dietary fiber (20 g/day) plus laxatives, enemas, or suppositories up to twice a week.

Exclusion criteria.

1. Slow transit constipation defined by evacuation of less than 80% of radio opaque markers 5 days after ingestion.
2. Barium enema consistent with abnormally dilated rectum or colon.
3. Abnormal biochemistry or thyroid function tests.
4. Taking anticholinergic or other constipating medications.
5. Prior treatment with PEG.
6. Previous abdominal surgery except appendectomy or cholecystectomy.

Sample size. In a prior study from our group,⁵ 71% of patients with PFD reported “fair” or “major” improvement in response to biofeedback, closely matching the average response rate of 70% in published uncontrolled studies.³ The smallest deviation from this response rate between biofeedback-treated and laxative-treated groups that would be clinically meaningful is 25%. Fifty-three patients per group would be required to detect a difference of this magnitude with 90% power at α of 0.01 (2-sided).

Recruitment and screening. All patients referred to a tertiary gastroenterology clinic for diagnosis and management of chronic constipation between January 2001 and March 2003 were screened, and those who met the first 2 inclusion criteria were invited to participate: 238 agreed (Figure 1).

Trial of standard medical care. During a 30-day, run-in period, all patients were prescribed 20 g/day of fiber plus laxatives, enemas, or suppositories (patient’s preference) up to twice a week. Patients also kept a daily log in which they recorded bowel movements and the presence (or absence) of straining; sensation of incomplete evacuation; hard or pellety stools; sensation of anorectal blockage; use of laxatives, enemas, or suppositories; and abdominal pain or bloating severe enough to interfere with daily activities.

At the end of this 1-month trial of standard medical care, 11 patients were excluded for noncompliance (not keeping the diary or almost daily use of laxatives), and the remaining 227 patients, who remained constipated, progressed to the whole gut transit study by the Hinton technique.⁶ Sixty-one patients

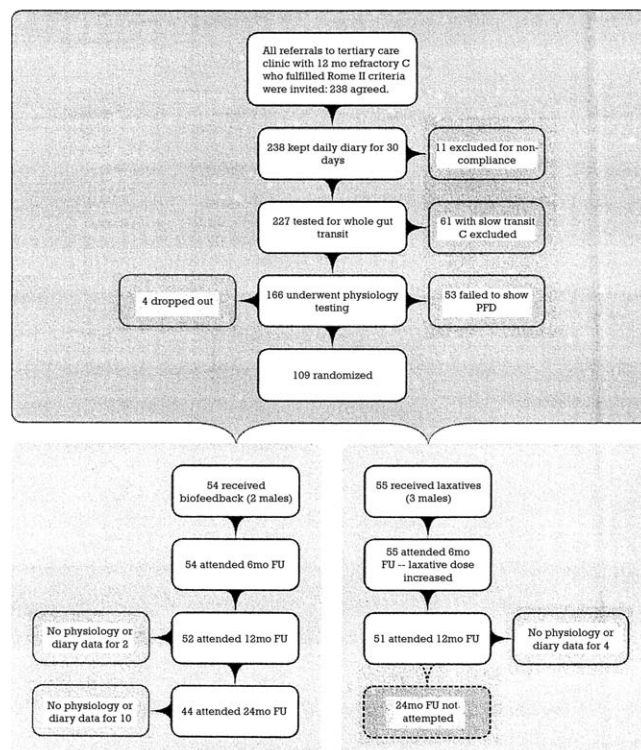


Figure 1. CONSORT table showing the disposition of all patients.

had abnormally delayed transit (slow transit constipation, defined as the retention of 20% or more of the radio opaque markers 5 days after ingestion), and they were excluded. The remaining 166 patients progressed to evaluation of pelvic floor physiology by anorectal manometry and balloon defecation testing, which identified 113 as having PFD. Four patients declined further participation, leaving 109 to be randomized.

This study was conducted in accordance with the recommendations of the Declaration of Helsinki (Edinburgh revision, 2000). Patients provided written informed consent after a detailed explanation of the aims, procedures, and risks associated with participation. All patients were informed that 2 alternative treatments were being compared: biofeedback to teach pelvic floor relaxation vs a new laxative preparation to soften stools and make them easier to pass. Patients assigned to the biofeedback group received a more detailed oral explanation of the rationale for biofeedback training, and patients assigned to the laxative group received more detailed information about the potential benefits of the PEG laxative.

Randomization. We prepared 60 sealed envelopes containing assignment to the biofeedback group and 60 identical envelopes containing assignment to the laxative group. These envelopes were shuffled to produce a random sequence and were dispensed to patients in sequence as they qualified for the study. The investigators were not able to anticipate the next assignment.

Anorectal manometry. Standard⁷ procedures were used to determine whether anal canal resting pressures decreased normally when the patient strained to defecate vs

paradoxically increasing because of an inappropriate contraction of pelvic floor muscles. Patients were asked to strain as if they were defecating for 10 seconds on 3 trials separated by 30-second rest intervals and were considered to have PFD if there was an increment in anal pressure of at least 10 mm Hg over resting pressure that lasted for at least 10 seconds on all 3 trials. Additional physiologic parameters were measured as previously described⁵ that might predict which patients are most likely to respond to biofeedback training: resting pressure in the anal canal, maximum anal canal pressure when the patient squeezed to prevent defecation, minimum volume of rectal distention required to elicit reflex relaxation of the anal canal during defecation, maximum volume of rectal distention that the patient was able (willing) to tolerate, and compliance of the rectum to distention (measured as the pressure in the distending balloon when 100 mL air was inflated). Manometric tracings were scored manually by 1 investigator, who was blind to the patient's treatment group.

Anal electromyography. A surface intraanal EMG probe connected to a portable instrument (Myotron-120; Enting Instruments & Systems, Dorst, The Netherlands) was used to measure pelvic floor EMG responses to attempted defecation. A sustained increase in averaged EMG activity during straining trials that was greater than 50% above resting EMG levels (ie, a paradoxical contraction) was indicative of PFD.

Balloon defecation test. A lubricated Foley catheter was inserted in the rectum and filled with 50 mL water. The patient was asked to expel this balloon within 5 minutes while sitting on a toilet in a private bathroom. The results of the diagnostic tests were communicated to the patients in both groups.

Treatment Protocol

Biofeedback training. One of the authors (G.C.) provided 5 weekly 30-minute training sessions identical to those previously reported.⁵ Patients were first taught to strain more effectively and to coordinate expulsion efforts with their breathing. Next, they were taught to relax pelvic floor muscles during straining using the EMG instrument described above. The averaged EMG signal was displayed in microvolts, and patients watched the display while contracting and relaxing. In the final phase of training, patients practiced defecating a 50-mL, air-filled balloon while the trainer gently pulled on the catheter connected to the balloon. At the conclusion of biofeedback training, all patients were told that their pushing efforts had improved; this was done to ensure that patients entering the follow-up phase of the study had a positive expectation and would be motivated to return for follow-up assessments.

Laxative and bowel retraining protocol. For the first 6 months, patients consumed 14.6 g (1 packet) daily of PEG 4000 (SELG 250; Promefarm, Milano, Italy) dissolved in 250 mL water. After 6 months, they were advised to increase the PEG dosage to 14.6 g twice a day. These patients attended five 30-minute counseling sessions, equivalent to the contact time for biofeedback patients, which were provided by a

physician. The counseling sessions focused on bowel retraining, with particular emphasis on avoiding unnecessary straining, correct defecating posture, and attempting defecation at a routine time each day. The physiology of constipation was discussed, and the relevance of different mechanisms for constipation was explained. Patients were told that defecation is a complex process, which is influenced by fecal consistency and stool transit to the rectum. Adverse effects of PEG were also discussed.

Follow-up. All patients were evaluated 6 and 12 months after the start of treatment. At these visits, patients rated their satisfaction with treatment and underwent anorectal manometry, anal EMG, and balloon defecation tests. Biofeedback patients (but not laxative-treated patients) were also asked to return 24 months after initiation of treatment to repeat these tests. Patients were reminded by telephone to keep symptom diaries for 30 days prior to the 6-month and 12-month follow-up visits. Laxative-treated patients were telephoned monthly to inquire about adverse effects and adherence to taking the prescribed dose of PEG.

Outcome variables. The primary outcome variable was the patient's response to the question, "How would you grade your symptom improvement: worse (scored 0), no improvement (1), mild (2), fair (3), or major improvement (4)." Secondary outcome variables were the symptoms reported in the patient's diary.

Physiologic variables used to investigate the mechanism of biofeedback treatment were changes in anal canal pressure and pelvic floor EMG when straining to defecate and ability to defecate a 50-mL, water-filled balloon within 5 minutes. Additional physiologic variables were evaluated as possible predictors of response to treatment (see above).

Data Analysis

The primary analysis of treatment efficacy was a Mann-Whitney *U* test comparing the biofeedback group to the laxative-treated group at 6-month follow-up and (separately) at 12-month follow-up. Satisfaction ratings were available for all 109 patients randomized to treatment, although, at 12 months, these ratings were obtained by telephone in 2 biofeedback patients and 4 laxative-treated patients. The secondary outcome variables were analyzed by general linear models analysis of variance for repeated measures comparing the 2 treatment groups at pretreatment, 6 months, and 12 months. At 12 months, missing data for 2 biofeedback subjects and 4 laxative subjects were replaced by the last observations for that patient carried forward. Thus, both the primary and secondary efficacy analyses were by intent to treat. The α level for these analyses was $P < .01$.

To test the mechanism for treatment effects, χ^2 tests compared the biofeedback with the laxative-treated group at 6 months with respect to decreases in anal canal pressure and pelvic floor EMG during straining to defecate and ability to defecate the balloon. Secondary analyses of mechanism compared all patients who reported a major improvement in

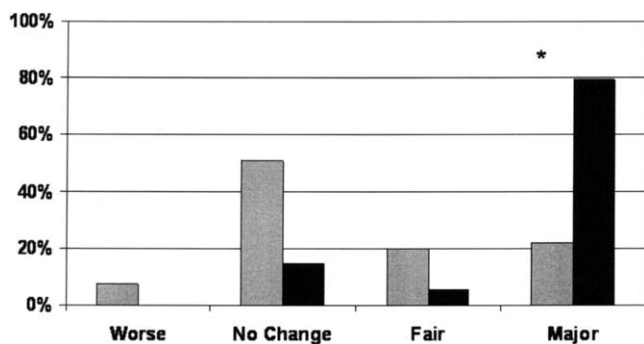


Figure 2. Proportion of laxative-treated patients (shaded bars) and biofeedback-treated patients (solid bars) reporting different treatment outcomes at 6 months. *Differences between groups were significant at $P < .001$.

constipation to all patients who reported less favorable results. Alpha was $P < .01$ for these analyses.

Logistic regression was used to identify variables that predict which patients might benefit from biofeedback training. A more liberal α of $P < .05$ was used for identification of predictor variables.

Results

Comparability of Treatment Groups

The biofeedback and laxative-treated groups were similar in age (33.3 ± 1.5 vs 35.1 ± 1.4 years, respectively; mean \pm standard error) and sex (3 males vs 2 males). All patients were of Italian descent.

Adherence

All patients completed 5 sessions of biofeedback training or medication counseling as prescribed. All laxative-treated patients reported during monthly telephone calls that they took at least 90% of the prescribed dose during the first 6 months, and all reported taking the prescribed 2 packets of PEG for months 7–9; however, two thirds subsequently reduced their intake back to 1

packet daily for the remainder of the 12-month trial because of adverse effects (4 patients) or intolerance for the taste of PEG.

Efficacy of Biofeedback

At both 6 months and 12 months, 43 of 54 (79.6%) of biofeedback-treated patients reported “major” satisfaction compared with 12 of 55 (21.8%) laxative-treated patients ($\chi^2 = 36.43$, $P < .001$). When the biofeedback group was reassessed at 24 months follow-up, 44 of 54 (81.5%) reported major satisfaction. Figure 2 provides greater detail by showing the distribution of satisfaction ratings made by patients in each treatment group at 6 months ($Z = 5.83$, $P < .001$). Over half (58.2%) of laxative-treated patients rated their outcomes as “no change” or “worse” compared with 14.8% of biofeedback-treated patients. A similar distribution of individual ratings was seen at 12 months when 50.6% of laxative-treated patients rated their outcomes as “no change” or “worse” compared with 14.8% of biofeedback-treated patients ($Z = 5.74$, $P < .001$).

Prior to treatment, there were no differences between the groups on any of the clinical symptoms reported on the patients’ diaries (Table 1 and Figures 3 and 4). However, at 6 and 12 months, biofeedback patients reported significantly less straining (Figure 3) and fewer incomplete bowel movements (Figure 4) compared with laxative-treated patients. Table 1 shows that the biofeedback-treated patients also had significantly greater reductions in laxative use, blocked bowel movements, and abdominal pain compared with laxative-treated patients. Conversely, laxative-treated patient reported significantly less hard stools than biofeedback-treated patients at 12 months. Stool frequency improved to approximately the same extent in both groups.

Table 1. Constipation Symptoms Reported in Diary

	Weekly frequency (mean \pm SE)					
	Pretreatment		6-Month follow-up		12-Month follow-up	
	Biofeedback	Laxative	Biofeedback	Laxative	Biofeedback	Laxative
BMs	3.91 (.38)	3.98 (.32)	5.87 (.29) ^a	4.91 (.34) ^a	5.18 (.37) ^a	6.00 (.30) ^a
Laxative doses	1.72 (.10)	1.54 (.11)	0.59 (.13) ^{a,b}	1.24 (.16)	0.48 (.13) ^{a,b}	1.20 (.16) ^a
Blocked BMs	2.96 (.30)	2.71 (.29)	1.02 (.29) ^{a,b}	2.55 (.36)	0.94 (.28) ^{a,b}	2.58 (.36)
Digital evacuations	1.11 (.29)	1.33 (.34)	0.70 (.22)	1.53 (.40)	0.69 (.22)	1.55 (.40)
Abdominal pain	1.06 (.14)	1.13 (.14)	0.37 (.09) ^{a,b}	1.00 (.16)	0.38 (.09) ^{a,b}	0.96 (.17)
Hard or lumpy BM	1.15 (.13)	1.33 (.15)	0.76 (.09) ^a	0.45 (.11) ^a	0.72 (.09) ^{a,b}	0.31 (.09) ^a

BM, bowel movement.

^a $P < .01$ within group change from pretreatment.

^b $P < .01$ between groups (biofeedback vs laxative groups).

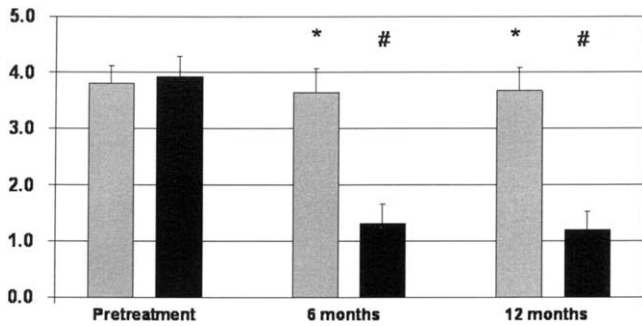


Figure 3. Average number of bowel movements per week accompanied by straining in laxative-treated patients (shaded bars) and biofeedback-treated patients (solid bars). *T* bars show standard errors. *Indicates significant difference ($P < .01$) between groups at 6 months or 12 months; #indicates a significant ($P < .01$) change from pretreatment within the biofeedback group.

Physiologic Mechanism for Biofeedback Effects

The proportion of biofeedback-treated patients exhibiting paradoxical increases in pelvic floor EMG during defecation decreased from 100% before treatment to 16.7% at 6 months and remained at this level even at 24-month follow-up (Figure 5). By contrast, 96.4% of laxative-treated patients continued to show paradoxical increases in pelvic floor EMG at 6 and 12 months. The proportion of patients who failed to decrease anal canal pressures during defecation showed an identical pattern (Table 2). The proportion of biofeedback subjects who were unable to evacuate a 50-mL, water-filled balloon decreased from 100% to 18.5% at 6 months, remained at this level at 12 months, and decreased further to 16.7% at 24 months. By contrast, 96.4% of laxative-treated patients were still unable to evacuate the balloon at 6 and 12 months.

All 43 biofeedback patients who reported major improvement at 6 months demonstrated decreases in anal canal pressure and pelvic floor EMG when straining,

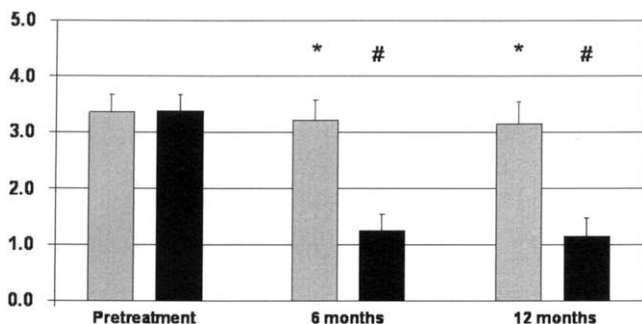


Figure 4. Average number of incomplete bowel movements per week in laxative-treated patients (shaded bars) and biofeedback-treated patients (solid bars). *T* bars show standard errors. *Indicates significant difference ($P < .01$) between groups at 6 months or 12 months; #indicates a significant ($P < .01$) change from pretreatment within the biofeedback group.

whereas only 2 of 11 (18.2%) patients reporting fair or no improvement showed relaxation of the pelvic floor. Among laxative-treated patients, only 2 of 12 who reported major improvement (16.7%) and none of those who did not report major improvement showed relaxation of the pelvic floor at 6 months.

The threshold volume of rectal distention required to elicit an urge to defecate was lower at 6 months and 12 months in biofeedback-treated vs laxative-treated patients. No other physiologic measure in this study (except anal pressure change and pelvic floor EMG during straining to defecate and ability to defecate a 50-mL, water-filled balloon, which were reported above) showed a differential response to these treatments.

Predictors of Response to Biofeedback

T tests on all clinical and physiologic variables listed in Tables 1 and 2 identified 4 variables that were associated with the success of biofeedback training at $P < .05$ or better: sensation of incomplete evacuation ($t = 2.37, P = .021$), straining with bowel movements ($t = 2.42, P = .019$), and sensation of blocked evacuation ($t = 2.11, P = .040$) predicted a better response to biofeedback, whereas digital facilitation of defecation predicted a poorer response to such training ($t = -4.13, P < .001$). When these 4 variables were entered into a logistic regression analysis, the only significant independent predictor of major improvement at 6 months was digital facilitation of defecation ($\beta = -.624, \text{Wald} = 6.143, P = .013$). Patients using digital facilitation were less likely to benefit from biofeedback training. Nagelkerke's R^2 showed that 32.6% of the variance in treatment outcome was explained.

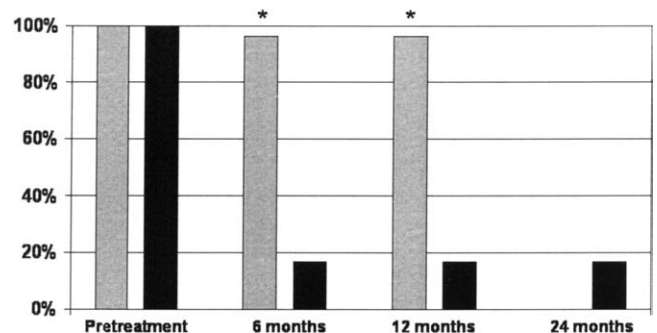


Figure 5. Proportion of laxative-treated (shaded bars) and biofeedback-treated (solid bars) patients who exhibited paradoxical increases in pelvic floor EMG when straining to defecate at each time point. *Groups were significantly different ($P < .001$) at 6 and 12 months.

Table 2. Physiology Data

	Pretreatment		6-Month follow-up		12-Month follow-up		24 Months
	Biofeedback	Laxative	Biofeedback	Laxative	Biofeedback	Laxative	Biofeedback
Anal pressure increase: n (%)	54/54 (100)	55/55 (100)	9/54 (16.7) ^{a,b}	53/55 (96.4)	9/54 (16.7) ^{a,b}	53/55 (96.4)	9/54 (16.7) ^b
EMG increase: n (%)	54/54 (100)	55/55 (100)	9/54 (16.7) ^{a,b}	53/55 (96.4)	9/54 (16.7) ^{a,b}	53/55 (96.4)	9/54 (16.7) ^b
Unable to evacuate balloon: n (%)	54/54 (100)	55/55 (100)	10/54 (18.5) ^{a,b}	53/55 (96.4)	9/54 (16.7) ^{a,b}	53/55 (96.4)	10/54 (18.5) ^b
Anal resting pressure: mm Hg, mean (SE)	62.11 (1.73)	60.67 (1.77)	61.83 (1.73)	59.93 (1.68)	62.54 (1.73)	60.13 (1.66)	62.20 (1.60)
Anal squeeze pressure: mm Hg, mean (SE)	148.81 (3.50)	139.78 (4.43)	149.56 (3.48) ^b	142.71 (3.77)	149.56 (3.48) ^b	142.71 (3.77) ^b	149.28 (3.48) ^b
RAIR threshold: mL, mean (SE)	16.67 (.88)	14.73 (.89)	15.19 (.83) ^b	14.55 (.81)	15.19 (.83) ^b	14.73 (.89)	15.19 (.98)
Urge threshold: mL, mean (SE)	81.48 (5.17)	68.18 (3.97)	54.63 (1.99) ^{a,b}	68.18 (3.75)	54.63 (1.99) ^{a,b}	67.27 (3.72)	52.78 (1.57) ^b
Maximum tolerable volume: mL, mean (SE)	252.78 (9.66)	242.73 (8.74)	222.22 (6.29) ^b	240.00 (8.35)	223.15 (6.83) ^b	246.36 (8.69)	215.74 (5.42) ^b
Compliance: mm Hg, mean (SE)	13.72 (.46)	14.07 (.52)	14.11 (.45) ^b	13.91 (.53)	14.17 (.44) ^b	13.84 (.51)	13.94 (.45)

^a*P* < .01 between groups (biofeedback vs laxative groups).

^b*P* < .01 within group change from pretreatment.

Discussion

Efficacy Evaluation

This large randomized controlled study showed that biofeedback for pelvic floor relaxation during defecation is more effective than laxatives for the treatment of PFD-type constipation. The differences in outcome were robust (4-fold difference in the proportion reporting major improvement; see Figure 2), and improvements were sustained for 2 years without additional training.

Patients' ratings of improvement were supported by changes in specific symptoms of constipation reported in diaries: as compared with laxative-treated patients, biofeedback-treated patients showed greater reductions in straining, sensation of incomplete evacuation, sensation of blocked defecation, abdominal pain, and laxative use (ie, patients treated with daily PEG used more laxatives in addition to PEG than were used by biofeedback-treated patients).

We have previously shown⁵ that biofeedback reduces the symptoms of constipation in patients with PFD but does not benefit patients with slow transit constipation. This type of biofeedback works only in patients with PFD as a cause of constipation, and it works by enabling these patients to learn to relax the pelvic floor during attempted defecation. The unique contribution of the current large randomized controlled trial is to show that biofeedback is more effective than laxatives, which are cheaper and more readily available than biofeedback.

The only randomized controlled trials published previously that compared biofeedback with laxatives were

limited to children, and all of them failed to show a significant advantage for biofeedback.^{8–11} However, 3 of these trials included children who did not have PFD but had other causes for constipation, and the third study lacked statistical power.¹¹ In contrast to these negative studies in children, uncontrolled studies in adults³ suggest that biofeedback is effective in over 70% of patients—a rate similar to what was found in this study. Biofeedback may be more effective in adults than it is in children because it requires complex cognitive processing and sustained attention beyond the abilities of many children.

Preliminary reports of 2 other randomized controlled trials of biofeedback therapy in adults with PFD were presented at Digestive Disease Week in May 2005. In 1 of these studies, Heymen et al¹² showed that a similar form of biofeedback was more effective than either of 2 control treatments: 5 mg diazepam (which is a skeletal muscle relaxer) or a placebo pill. Response rates (defined by a report of "adequate relief" 3 months after the end of training) were 71% for biofeedback, 20% for diazepam, and 33% for placebo tablets. The second study was reported by Rao et al,¹³ who compared biofeedback with sham biofeedback (relaxation therapy) and with standard medical treatment with diet, exercise, and laxatives. At the end of training, the response rate (defined as greater than 20% improvement in a visual analog scale rating of global satisfaction and stool frequency) was significantly greater in the biofeedback group (88%) compared with the relaxation training group (48%) but not compared

with the standard therapy group (70%). These 2 studies support the conclusions of the current study, but neither provided long-term follow-up data to show that improvements were sustained.

Mechanism Analysis

Biofeedback had the intended effect of teaching patients how to relax their pelvic floor muscles during defecation. Following biofeedback training, 83% demonstrated relaxation of the pelvic floor by decreasing anal canal pressures, by decreasing pelvic floor EMG, and by evacuating the balloon when straining to defecate. All biofeedback-treated patients reporting major improvement demonstrated relaxation of the pelvic floor by all 3 measures.

Patient Characteristics That Identify Responders to Biofeedback

Four clinical symptoms that were present before treatment—digital facilitation of defecation, sensation of incomplete evacuation, sensation of blocked evacuation, and frequency of straining—were significantly associated with successful biofeedback training. However, these symptoms were correlated; the only symptom that made an independent contribution to outcome was digital facilitation of defecation, which predicted failure. No physiologic measures identified which patients with PFD were likely to respond to biofeedback.

In a previous study,⁵ clinical symptoms that predicted successful biofeedback training included milder constipation (ie, more frequent bowel movement and less frequent use of laxatives) and less frequent abdominal pain prior to treatment; digital facilitation was not a significant predictor. Differences between studies in the predictors of successful biofeedback training are likely due to different patient populations; the previous study included patients with slow transit constipation, whereas patients with delayed whole gut transit were excluded from the current study. The utility of these variables for identifying candidates for biofeedback treatment requires confirmation.

Study Limitations

This study was not masked: the patients were aware of the 2 alternative treatments under investigation. However, biofeedback and PEG treatments were equally novel to all patients. The physician who provided biofeedback training and counseling sessions and who evaluated the symptom outcomes was also unmasked; however, the physician who scored the manometric tracings was unaware of the patient's treatment assignment. It is unlikely that patient ex-

pectation or investigator bias accounted for the differences in treatment response because (1) the primary outcome—greater satisfaction with treatment results in the biofeedback-treated patients—was supported by diary measures of decreased laxative use, straining, sensation of incomplete evacuation, blocked defecation, and abdominal pain, as well as by physiologic evidence that biofeedback patients learned to relax the pelvic floor and to defecate a water-filled balloon that simulated defecation of stool.

The dose of PEG used in this study could have been too low. However, this seems unlikely because Chaussade and Minic¹⁴ found a daily dose of 10 g PEG 4000 to be as effective as 20 g for improving stool frequency and less likely to produce watery stools, and Corazziari et al¹⁵ found that 14.6 g daily was better tolerated than 29.2 g. We used 14.6 g/day for the first 6 months and 29.2 g daily for months 7–12. Moreover, our PEG-treated patients showed significant increases in stool frequency comparable with the biofeedback-treated group (Table 1), and, at 12 months, they showed greater reductions in the frequency of hard or lumpy stools than the biofeedback-treated patients.

Another possible limitation of this study is that we restricted enrollment to patients with normal whole gut transit times. Many patients with PFD also have delayed whole gut transit times, and it is possible that the differences in treatment effectiveness between biofeedback and laxatives would have been smaller in such patients because they might have shown a better response to laxatives. Although we do not know whether laxatives would be more effective in such patients, we have shown in a previous study⁵ that biofeedback is highly effective in patients who have PFD associated with abnormally slow transit times. We showed that the benefits of biofeedback were limited to patients who learned to relax pelvic floor muscles during straining and that biofeedback led to significant reductions in the use of laxatives. We also showed that 65% of patients with PFD plus slow transit normalized their whole gut transit time following biofeedback, suggesting that the delays in transit were an artifact of outlet obstruction in many patients with pelvic floor dyssynergia.

The effectiveness of biofeedback training for PFD depends in part on the skills of the biofeedback therapist and the particular techniques used to carry out the training. All patients were treated by 1 physician who is highly experienced in biofeedback training. It is unknown whether similarly good outcomes will be obtained in other research or clinical settings.

Implications for Clinical Practice

These data show a clear superiority for biofeedback relative to daily doses of PEG for the treatment of this common and easily diagnosed subtype of constipation. Five 30-minute training sessions led to a major improvement for 80% of patients, and these improvements were maintained for at least 2 years. By contrast, laxative treatment with PEG was relatively ineffective, was poorly tolerated when the dose was increased, and required continuous treatment. Based on these findings, biofeedback training should be the first-choice treatment for patients with this form of constipation.

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Received August 30, 2005. Accepted November 9, 2005.

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Supported by grants R01 DK57048 and R24 DK67674.