Biofeedback Benefits Only Patients With Outlet Dysfunction, Not Patients With Isolated Slow Transit Constipation

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Background & Aims: **Biofeedback is reported to be as effective for slow transit constipation as for pelvic floor dyssynergia and no more effective than education. We aimed to test the hypothesis that biofeedback benefits only patients with pelvic floor dyssynergia, describe the physiologic mechanism of treatment, and identify predictors of success.** ***Methods:*** **Fifty-two patients (49 women; average age, 35 years), all with delayed whole gut transit, included 34 with pelvic floor dyssynergia, 12 with slow transit only, and 6 who met only 1 of 2 criteria for pelvic floor dyssynergia. All received 5 weekly biofeedback sessions directed at increasing rectal pressure and relaxing pelvic floor muscles during straining plus practice defecating a balloon. Patients were retested by questionnaire; symptom diary; balloon defecation; transit study at 1, 6, 12, and 24 months; and anorectal manometry at 1 and 6 months.** ***Results:*** **At 6 months, greater improvements were seen in pelvic floor dyssynergia compared with slow transit only; 71% versus 8% reported satisfaction ($P = .001$), and 76% versus 8% reported ≥3 bowel movements per week ($P < .001$). Improvements were maintained at 24 months of follow-up. Biofeedback eliminated dyssynergia in 91% and enabled 85% to defecate the balloon. Satisfaction was correlated with improved ability to defecate the balloon ($\rho = .73$; $P < .001$), reductions in dyssynergia ($\rho = .69$; $P < .001$), and increased rectal pressure during straining ($\rho = .36$; $P < .01$). Success was predicted by pelvic floor dyssynergia, milder constipation, and less frequent abdominal pain at baseline.** ***Conclusions:*** **Biofeedback is an effective treatment for pelvic floor dyssynergia but not slow transit constipation.**

Constipation is a symptom that affects 12%–19% of adults in the United States.[1] Several pathophysiologic mechanisms are recognized that may cause constipation, including megacolon or megarectum (dilated, atonic bowel) and drug side effects. However, the most commonly recognized types of constipation are slow transit constipation and outlet dysfunction.[2]

Slow transit constipation is defined as delayed transit throughout the colon and is believed to result from reduced numbers of high-amplitude propagating contractions[3,4] associated with decreased numbers of interstitial cells of Cajal.[5,6] Diagnosis is based on transit studies showing abnormally prolonged transit of radiopaque markers or radioisotopes through the colon.[7,8]

Outlet dysfunction–type constipation refers to difficulty evacuating the rectum. Preston and Lennard-Jones[9] were the first to describe this type of constipation; they showed that a subgroup of patients with constipation failed to relax the pelvic floor muscles during defecation and instead paradoxically contracted these muscles. Subsequent investigators supported their observation,[10] and biofeedback techniques were developed to teach patients to evacuate the rectum by relaxing the pelvic floor muscles.[11,12] However, Duthie and Bartolo[13] found that up to 80% of constipated patients who exhibit paradoxical contraction of the pelvic floor muscles in the gastroenterology clinic may show normal pelvic floor relaxation during defecation at home, and others have noted that a significant proportion of asymptomatic people show paradoxical contraction of the pelvic floor when tested in the clinic. Rao et al[14] showed that inadequate intrarectal pressure during attempts at defecation may also explain failure to evacuate the rectum. These observations have led to controversy over whether pelvic floor dyssynergia is a distinct mechanism for constipation.

Biofeedback training to teach relaxation of the pelvic floor was reported to be effective in a number of trials,[12,15,16] with the median response rate approximately 67%.[12] However, there have been no randomized controlled trials to confirm efficacy in adults. The St Mark's group[17–19] reported that biofeedback was equally effective in patients with slow transit constipation and those with outlet dysfunction characterized by paradoxical con-

Abbreviations used in this paper: ANCOVA, analysis of covariance; MIX, mixed; PFD, pelvic floor dyssynergia with slow transit; STO, slow transit only.

0016-5085/05/$30.00
doi:10.1053/j.gastro.2005.05.015

traction of the pelvic floor and that biofeedback training resulted in acceleration of whole gut transit time in patients with slow transit constipation. This claim of equal efficacy in slow transit constipation and outlet dysfunction constipation was supported by an independent research group.[20] The St Mark's group also reported that biofeedback was no more effective than education and training performed with verbal feedback but without instruments to assist patients in learning to relax the pelvic floor.[17] These 2 observations, that biofeedback to teach relaxation of the pelvic floor is as effective in patients who do not demonstrate pelvic floor dysfunction as a cause of their constipation as it is in patients with pelvic floor dyssynergia and that visual feedback is no more effective than education, challenge claims that biofeedback training makes a specific contribution to the treatment of constipation that is distinct from education or psychotherapy.

The primary aim of this study was to determine whether biofeedback to teach relaxation of the pelvic floor muscles benefits only patients with outlet dysfunction–type constipation versus whether, as claimed by the St Mark's group, it improves constipation equally well in patients with slow transit constipation who do not have outlet dysfunction. Secondary aims were to determine whether physiologic parameters identify the mechanism of biofeedback training effects (ie, whether clinical benefits of biofeedback are related to changes in pelvic floor physiology or are nonspecific) and to determine whether physiologic parameters or clinical symptoms recorded at baseline identify the patients who are most likely to respond to biofeedback training.

Materials and Methods

Patients

Seventy-five consecutive patients referred to the gastroenterology clinic of the Division of Gastrointestinal Rehabilitation of the University of Verona at Valeggio s/M Hospital, Azienda Ospedaliera di Verona, for refractory, long-standing (at least 12 months) constipation between June 1997 and January 2001 were screened for the study. All patients were evaluated by history, complete medical examination, biochemical studies to exclude secondary causes of constipation such as hypothyroidism and drug side effects, and a barium enema study to identify those with megacolon or megarectum. All patients were then enrolled into a 1-month run-in phase to confirm that they met inclusion criteria (see following text). The study was conducted in compliance with the Declaration of Helsinki.

Run-in Period

For 30 days, all patients were treated with conservative medical management consisting of 30 g/day of fiber supplementation. They were allowed to take laxatives or enemas during this run-in period. All patients were asked to keep a symptom diary in which they recorded (1) laxative and/or enema use, (2) number of bowel movements, (3) straining at stool, (4) experience of severe pain, and (5) experience of severe bloating. Pain and bloating were defined as severe if they were intense enough to interfere with usual daily activities. At the end of the 1-month run-in period, patients' diaries were reviewed. Five patients were excluded (2 for not keeping the diary and 3 for almost-daily consumption of laxatives). The remaining 70 patients underwent a Sitzmark test[21] of whole gut transit while abstaining from laxatives and enemas (see following text).

Inclusion/Exclusion Criteria

To be included, patients had to (1) report <3 bowel movements per week by history, (2) fail a test of a high-fiber diet (at least 30 g/day for 30 days during the run-in period), and (3) have an abnormally delayed whole gut transit study defined as ≥ 5 of 20 Sitzmarks remaining in the colon 5 days after ingestion. Patients were enrolled regardless of whether they reported anorectal symptoms suggestive of outlet dysfunction. Patients were excluded if they had (1) previous abdominal surgery except for appendectomy; (2) megacolon, megarectum, or hypothyroidism; or (3) resolution of symptoms on conservative medical management (fiber supplementation).

Fifty-two patients who satisfied inclusion and exclusion criteria were invited to participate in a behavioral therapy trial, and all agreed and signed an informed consent statement. These 52 patients with slow transit constipation included 49 women and 3 men with an average age of 34.9 ± 10.2 years (mean $\pm$ SD; range, 23–63 years).

Study Design

Figure 1 shows the study design. Patients who satisfied inclusion/exclusion criteria at the end of the run-in phase were evaluated by anorectal manometry and balloon defecation tests and were classified as either slow transit only (STO), pelvic floor dyssynergia with slow transit (PFD), or mixed (MIX). The STO group included patients who retained ≥ 5 Sitzmarks 5 days after ingesting 20 of them and who satisfied neither of the 2 criteria for PFD. The PFD group included patients with slow transit constipation (≥ 5 of 20 Sitzmarks remaining 5 days after ingestion) who met both of 2 criteria: paradoxical contraction or failure to relax the pelvic floor muscles during attempts to defecate and inability to evacuate a 50-mL water-filled balloon within 5 minutes. The MIX group included patients with slow transit constipation who satisfied one but not both of the criteria for PFD. All patients (regardless of diagnostic group assignment) received 5 sessions of biofeedback training to teach relaxation of the pelvic floor during defecation and were then followed up by repeat manometry, balloon defecation, Sitzmark study of transit, 1-month symptom diary, and ratings of satisfaction with treatment outcome at clinic visits 1 month and again 6 months after the conclu-