

Biofeedback therapy for dyssynergic defecation

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Abstract

Dyssynergic defecation is one of the most common forms of functional constipation both in children and adults; it is defined by incomplete evacuation of fecal material from the rectum due to paradoxical contraction or failure to relax pelvic floor muscles when straining to defecate. This is believed to be a behavioral disorder because there are no associated morphological or neurological abnormalities, and consequently biofeedback training has been recommended for treatment. Biofeedback involves the use of pressure measurements or averaged electromyographic activity within the anal canal to teach patients how to relax pelvic floor muscles when straining to defecate. This is often combined with teaching the patient more appropriate techniques for straining (increasing intra-abdominal pressure) and having the patient practice defecating a water filled balloon. In adults, randomized controlled trials show that this form of biofeedback is more effective than laxatives, general muscle relaxation exercises (described as sham biofeedback), and drugs to relax skeletal muscles. Moreover, its effectiveness is specific to patients who have dyssynergic defecation and not slow transit constipation. However, in children, no clear superiority for biofeedback compared to laxatives has been demonstrated. Based on three randomized controlled studies in the last two years, biofeedback appears to be the preferred treatment for dyssynergic defecation in adults.

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INTRODUCTION

Chronic constipation is a common self-reported bowel symptom that affects 2%-30% of people in Western countries and has considerable impact on health expenses and quality of life^[1]. Most patients respond either to fiber-fluid supplementation or to judicious use of laxatives^[1]. Among the non-responders, outlet dysfunction type constipation seems particularly common; it affects up to 50% of referrals to a tertiary care center^[2].

Patients with outlet dysfunction can be divided into those with structural causes for obstructed defecation and patients with a functional defecation disorders^[3,4]. Possible structural causes for obstructed defecation include stricture, neoplasia, rectocele, enterocele, and Hirschsprung's disease. Functional defecation disorders include dyssynergic defecation (i.e., paradoxical contraction or failure to relax the pelvic floor and anal muscles during defecation) and inadequate defecatory propulsion (i.e., insufficient intra-rectal pressure due to inadequate contraction of abdominal wall muscles during defecation); both may lead to inadequate emptying of the rectum^[4]. It is unclear whether idiopathic megarectum is associated with dyssynergic defecation. Functional defecation disorders are believed to be more common than obstructed defecation and approximately as common as slow transit constipation; however, the true prevalence of these subtypes of constipation has not been documented. Functional defecation disorders may coexist with slowed transit through the colon. Dyssynergic defecation is commonly considered to be a form of maladaptive behavior because there is no discernable neurological or anatomical defect and because it can be eliminated by behavioral training^[4].

Diagnostic criteria for functional defecation disorders^[4] include those for functional constipation^[5], namely two or more of 6 symptoms present for the last 3 mo with an onset more than 6 mo in the past; the symptoms are straining, lumpy or hard stools, sensation of incomplete evacuation, sensation of anorectal obstruction/blockage, or manual maneuvers to facilitate defecation on more than 1/4 of bowel movements, or less than 3 bowel movements per week. To meet criteria for functional defecation disorders, the patient must also undergo

objective diagnostic testing and demonstrate at least two of three abnormalities: impaired evacuation of the rectum, inappropriate contraction or less than 20% relaxation of the pelvic floor muscles, and inadequate propulsive forces during defecation^[4].

An exhaustive explanation of the diagnostic work up of these patients is beyond the scope of this review. However, most normal subjects can easily evacuate a 50 mL water-filled balloon from the rectum. Additional anorectal testing includes anorectal manometry, anal electromyography (EMG) and evacuation proctography (defecography)^[4]. Anorectal manometry provides a comprehensive assessment of anal pressures, rectoanal reflexes, rectal pressures, sensation and compliance. Several types of recording devices are available, but perfused catheters and balloon probes are among the most commonly used. A paradoxical increment in anal pressure on straining efforts is a distinctive feature of dyssynergic defecation^[4]. An increment in muscle motor activity on straining may be demonstrated by means of EMG either by intra-anal electrodes or by electrodes taped to the peri-anal skin.

Defecography is a radiographic test providing morphological and functional information on the anorectum. Several parameters may be assessed, such as pelvic floor descent, anorectal angle, rectocele, and rectal prolapse. Failure of the anorectal angle to become more oblique on straining provides indirect evidence of defective pelvic floor relaxation and impaired evacuation of contrast material is also suggestive of dyssynergia^[4]. There must be manometric, EMG, or radiologic evidence for inappropriate contraction or failure to relax the pelvic floor muscles on straining to diagnose dyssynergic defecation according to Rome III criteria^[4].

Evaluation of colon transit by means of radiopaque markers is not relevant to the diagnosis, but it may be performed to additionally test for slow transit constipation.

Patients with functional defecation disorders are often unresponsive to conservative medical management, and the surgical division of the pubo-rectalis muscle (which has been proposed for the treatment of dyssynergic defecation) has resulted in poor benefit and an unacceptable risk of anal incontinence^[1,6]. Treatment with botulinum toxin injection may provide temporary improvement, but it remains an investigational treatment. Therefore, behavioral treatment is a logical choice for these disabled patients^[4].

Biofeedback is a conditioning treatment where information about a physiologic process (contraction and relaxation of a muscle) is converted to a simple visual or auditory signal to enable the patient to learn to control the disordered function. Biofeedback is considered appropriate when specific pathophysiological mechanisms are known and the voluntary control of responses can be learned with the aid of systematic information about functions not usually monitored at a conscious level^[7]. As early as 1979, Thomas Almy and John Corson, in an enthusiastic editorial about the biofeedback treatment of fecal incontinence, pioneered the extension of behavior therapy to functional defecation disorders^[8]. However, the first paper dealing with the subject included only a small number of subjects and was not published until 1987 due to the preference for

conservative, drug-oriented therapy^[9].

BIOFEEDBACK TECHNIQUES FOR TREATING DYSSYNERGIC DEFECATION

Paradoxical increases in anal pressure and electromyographic (EMG) activity during straining is easily detected^[10,11]. Anal pressure may be measured by means of water-perfused catheters, solid state transducers or balloon catheters^[10]. No single technique seems superior to the others, and the choice relies on the researcher's training and experience.

Anal EMG may be recorded either by intra-anal probes or by peri-anal EMG electrodes stuck to the skin^[10,11]. The EMG activity used in biofeedback training is the averaged activity of large numbers of muscle cells rather than the activity of small groups of muscle cells innervated by a single axon. This averaged EMG activity is recorded with large electrodes on the skin or the mucosa of the anal canal rather than with needle electrodes. Averaged EMG recorded in this way is proportional to the strength of contraction of the underlying muscles.

Defective expulsion is commonly investigated by asking the patient to defecate a 50-mL water-filled rectal balloon; patients with functional defecation disorders usually fail this test^[11]. Some patients also have a higher threshold for perceiving the urge to defecate^[10], but the clinical significance of this sensory dysfunction is ill-defined, in contrast to the relevance of rectal sensory impairment in fecal incontinence^[12]. Ano-rectal imaging studies (defecography, ultrasonography, and pelvic floor MRI) may also help to characterize the physiological dysfunction responsible for outlet dysfunction, but they do not seem to influence treatment outcome^[4,13].

Biofeedback training protocols vary among different centers^[10,11]. In the next paragraph, a standard biofeedback protocol is described and differences in biofeedback procedures are outlined. A mainstay of behavior therapy is to first explain the anorectal dysfunction and discuss its relevance with the patient before approaching the treatment^[3,11]. Most protocols would then include training the patients on a more effective use of the abdominal muscles to improve pushing effort. Patients are next shown anal manometry or EMG recordings displaying their anal function and are taught through trial and error to relax the pelvic floor and anal muscles during straining^[10,13]. This objective is first pursued with the help of visual feedback on pelvic floor muscle contraction, accompanied by continuous encouragement from the therapist. When the patient has learned to relax the pelvic floor muscles during straining, the visual and auditory help are gradually withdrawn^[10,13]. Another retraining option is to simulate defecation by means of an air-filled balloon attached to a catheter, which is slowly withdrawn from the rectum while the patient concentrates on the evoked sensation and tries to facilitate its passage^[3,11]. In the next phase of training, the patient is taught to defecate the balloon by bearing down, without the assistance of the therapist. Some centers also add a balloon sensory retraining to lower the urge perception threshold^[14]. The number of

training sessions is not standardized, but 4 to 6 sessions are frequently provided. Individual training sessions last 30 to 60 min.

Therapeutic sessions are professionally demanding and a highly trained and motivated therapist is essential. No study has addressed the necessary training required for an individual to administer biofeedback therapy. Particularly, it is unclear whether the adequate provider should be either physician, psychologist, or nurse. Experience varies among centers, but the low cost reimbursement provided for behavior therapy is likely to influence future choices.

Controlled studies systematically comparing different biofeedback protocols to each other are lacking. However, a recent meta-analysis showed that in open label studies, the mean success rate with pressure biofeedback was slightly greater than with EMG biofeedback (78% *vs* 70%)^[15]. No differences were found between anal *vs* perianal EMG recording. In addition, adding balloon feedback did not seem to influence the therapeutic outcome^[13]. However, the majority of studies in the last ten years have utilized EMG biofeedback rather than pressure feedback even in the absence of scientific evidence^[13]. There are no standardized protocols, and centers use different combinations of laboratory EMG training, home EMG training, and balloon feedback, depending on the researcher's experience.

EFFICACY OF BIOFEEDBACK TREATMENT FOR DYSSYNERGIC DEFECATION

Uncontrolled studies

In 1987 Bleijenberg and Kuijpers^[9] were the first to report the efficacy of EMG biofeedback treatment combined with oatmeal porridge defecation in 10 patients affected by spastic pelvic floor syndrome, later redefined as functional defecation disorder^[4]. Treatment was a complete success in 7 patients and a partial success in two others. This open label trial stimulated a number of uncontrolled studies to investigate the efficacy of behavior therapy in functional defecation disorder^[7]. Therapeutic outcome varied greatly among centers with success rates ranging from 18% to 100% of patients studied^[15,16].

A major drawback to assessing this literature was the huge variance in inclusion criteria, outcome criteria, follow-up intervals, and therapeutic protocols^[13,17]. Additional limitations were small sample size (often no more than 30 subjects studied) and lack of any control group^[17]. However, the majority of uncontrolled studies in adults reported a favorable outcome in about two thirds of patients, without side effects^[7,11,13,17]. Coexisting morphological abnormalities of the pelvic floor, namely rectocele, intussusception and abnormal perineal descent, seemed not to influence behavior treatment outcomes^[18]. Researchers were unable to identify any functional variable that could predict treatment outcome, but anxious patients appear to be less likely to succeed^[13,17].

Although the majority of published uncontrolled studies reported beneficial effects of treatment, a series of studies from the St. Mark's group cast doubts on whether biofeedback training has specific value in the treatment

of functional defecation disorder: these investigators reported similar benefits of biofeedback therapy in patients, irrespective of whether they had slow whole gut transit or functional defecation disorder^[19,20] (See below for contrasting views). They also suggested that the autonomic innervation of the colon may influence the outcome of biofeedback treatment^[21].

Controlled studies

Randomized, controlled trials were first performed in the pediatric population. In 1987 Wald *et al*^[22] compared pressure biofeedback therapy with mineral oil in a group of 55 encopretic children; 16 of whom showed evidence of functional defecation disorder. Although a trend toward greater improvement in the biofeedback group was evident, the difference in success rate did not reach significance. In another controlled study^[23], a well-defined pediatric population of 43 children with functional defecation disorder was randomized to receive either biofeedback therapy plus conventional care (laxatives) or conventional treatment only. All children had fecal impaction and encopresis. The biofeedback group did significantly better than the conventional one, with about half of patients showing successful symptoms resolution at one year follow-up compared to 16% in the conventional-care-only group. The clinical benefit was correlated with normalization of defecation dynamics. Similar benefits were reported in another controlled study^[24] in the pediatric population, but the follow-up was too short (3 mo) to draw firm conclusions.

In contrast to the successful studies described above, the largest randomized, controlled study in pediatric constipation (192 children), which compared laxatives plus EMG biofeedback therapy to laxatives alone, failed to show any benefit from biofeedback^[25]. A criticism of this study was that not all the subjects had functional defecation disorder. However, a similar failure to show superior efficacy with biofeedback was reported in a controlled study considering a smaller sample of children with both functional defecation disorder and encopresis^[26]. In both studies, improved defecation dynamics were reported in biofeedback-treated patients, but this did not translate into greater symptom improvement.

In the adult population, four controlled studies were published prior to 2005. Two of these studies compared different biofeedback techniques to each other^[27,28] and two studies compared EMG biofeedback to simulated defecation^[19,29].

Heymen *et al*^[27] compared intra-anal EMG biofeedback to (1) a combination of EMG and intra-rectal balloon distension training, (2) EMG and home trainers, and (3) a combination of all three techniques. All groups showed significant improvement from pretreatment, but no significant differences were found among treatment strategies. Glia *et al*^[28] found peri-anal EMG biofeedback to be superior to pressure biofeedback combined with balloon defecation training. However, neither Glia *et al* nor Heymen *et al* had sufficient sample size to provide a meaningful analysis.

Bleijenberg *et al*^[29] found an intra-anal EMG biofeedback to be superior to balloon defecation training (90% *vs*

60% improved). Although the sample size was too small to draw reliable conclusions, subjects who failed balloon defecation training were then given biofeedback training, yielding an 80% success rate.

The St. Marks group^[19] studied a series of 60 adults with functional constipation unresponsive to conservative management and randomized them either to EMG and rectal balloon biofeedback or to abdomino-pelvic muscular coordination training and balloon feedback. After only two unsatisfactory sessions, patients who were judged unable to respond, were switched to the alternative treatment. At the end of treatment, approximately 50% of patients in both groups rated their symptoms as significantly improved. The outcome did not correlate with colon transit time, the presence of functional defecation disorder, or other functional and clinical variables. In addition, the St. Marks group recently reported biofeedback to be no more effective than bowel training and education for fecal incontinence in a large, controlled, randomized study^[30]. These results challenge both the effectiveness of behavior therapy and the claim that retraining makes a specific contribution to the treatment of constipation other than education and/or psychotherapy.

To determine whether biofeedback is equally effective in slow transit constipation and dyssynergic defecation and also whether the benefits are due to education alone, we conducted an open study on 52 patients with slow transit constipation (objectively documented) who were unresponsive to conservative measurements^[3]. Thirty-two of them showed evidence of dyssynergic defecation, 6 formed a mixed group who satisfied some but all criteria for dyssynergic defecation, and 12 had slow transit only. All patients received 5 weekly sessions of a biofeedback protocol, including improved use of the abdominal muscles to strain, anal EMG and balloon biofeedback to teach relaxation of the pelvic floor on straining, and simulated defecation.

Functional ano-rectal and clinical parameters were evaluated both before and after behavior therapy. After six months, 71% of patients with functional defecation disorder and slow transit reported satisfaction with treatment *versus* 8% in the slow transit only group. The results were well maintained at follow-up 2 years later^[3]. Patients' satisfaction was correlated with improved rectal emptying as demonstrated by successful balloon expulsion and reductions in dyssynergia at manometry. A significant increase in rectal pressure on straining was also evident. Interestingly, biofeedback training resulted in a significant decrement in the threshold volume of balloon distention required to produce a sensation of urge to defecate, although no specific sensory retraining had been provided. Treatment success was predicted by pelvic floor dyssynergia, milder constipation, and less frequent abdominal pain at baseline.

This study allowed us to conclude that biofeedback therapy is specifically indicated for dyssynergic defecation and that retraining works through teaching patients to relax the pelvic floor and anal muscles during straining. Since biofeedback therapy is time-consuming, dedicated trained personnel are not easily found, and

drug treatments (laxatives, muscle relaxants) are cheaper and more easily available, we were in strong need of a randomized, controlled study to prove that biofeedback is more effective than laxatives or placebo. This need was reinforced by the recent statement of the American College of Gastroenterology's Chronic Constipation Task Force that osmotic laxatives, namely polyethylene glycol and lactulose, are effective in improving stool frequency and consistency in all patients with chronic constipation^[31].

Recently, three randomized, controlled studies coming from different centers have provided satisfactory answers to this question. The first of them^[32] compared 5 weekly sessions of biofeedback to a commonly prescribed osmotic laxative (polyethylene glycol [PEG] in incremental dosage (14.6-29.2 g/d) given in combination with 5 weekly counseling sessions. Patients with normal transit constipation secondary to dyssynergic defecation were randomized either to the biofeedback (54 patients) or to the laxative group (55 patients). Follow-up assessment extended up to 12 mo in the laxative group and to 24 mo in the biofeedback group. Satisfaction with treatment, symptoms of constipation, and pelvic floor physiology were assessed at pretreatment, every six months in the first year, and at 24 mo. At six months, major clinical improvement was reported by 80% of patients in the behavior group *versus* only 20% in the PEG group. Biofeedback benefits were well sustained for the whole two-year follow-up interval. Clinical benefits correlated well with objective evidence of a reduction or elimination of paradoxical contractions of the pelvic floor during straining. The only clinical variable that correlated with treatment outcome was digital facilitation of defecation, which predicted failure; anorectal physiology could not predict outcome. Interestingly, laxatives consumption other than PEG was significantly decreased in the biofeedback group compared to the PEG group at 6-12 mo follow-up, while bowel frequency was significantly increased in both group compared to baseline.

Rao *et al*^[33] conducted a randomized trial comparing biofeedback to sham feedback (relaxation therapy) and to standard medical care (diet, exercise, and laxatives). A significantly greater proportion of subjects receiving biofeedback (88%) reported more than a 20% improvement in global satisfaction and stool frequency on a visual analog scale compared to subjects receiving sham biofeedback (48%), but not when compared to standard care (70%). The authors also reported a significant improvement in favor of the biofeedback group to normalize the dyssynergic pattern and improve on a defecation index, with trends in favor of biofeedback subjects reducing balloon expulsion time and decreasing colonic marker retention compared to alternative treatment groups.

In a third randomized controlled trial, Heymen *et al*^[34] randomly assigned 84 constipated subjects with dyssynergic defecation to receive either biofeedback ($n = 30$), diazepam ($n = 30$), or placebo ($n = 24$). An important feature of this study was that all subjects were trained to do pelvic floor muscle exercises to correct pelvic floor dyssynergia during 6 biweekly 1-h sessions, but only the

biofeedback patients received EMG feedback. All other patients received pills (muscle relaxant or placebo) 1-2 h before attempting defecation. Biofeedback was superior to diazepam by intention-to-treat analysis (70% *vs* 23% reported adequate relief of constipation), and also superior to placebo (38% successful). In addition, biofeedback patients had significantly more unassisted BMs compared to placebo, with a trend favoring biofeedback over diazepam. Biofeedback patients also reduced pelvic floor EMG during straining significantly more than diazepam patients.

Limitations of biofeedback training

The negative outcomes reported in controlled studies have been in the pediatric population. These poorer outcomes may be due to the inclusion of children whose constipation was not due to functional defecation disorder, since it is known that patients with other etiologies for their constipation respond poorly to biofeedback. In addition, biofeedback training requires complex cognitive processing and sustained attention that may be beyond the abilities of younger children. Finally, the quality of the therapist-patient relationship and the skills and experience of the therapist seem to influence the success of behavior therapy, and there is currently a shortage of trained personnel to provide this form of treatment.

In conclusion, a series of controlled studies have now shown that functional defecation disorder, one of the most frequent and disabling subtypes of adult constipation, can be treated effectively with biofeedback training. This form of treatment is more effective than laxatives, and it has no known adverse effects. Although this training is relatively expensive to provide, it produces improvements that are sustained for up to two years. For these reasons, we may conclude that biofeedback training is the treatment of choice for functional defecation disorder.

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