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Biofeedback Treatment for Functional Anorectal Disorders: A Comprehensive Efficacy Review

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This review aimed to critically evaluate the literature on the efficacy of biofeedback for functional anorectal disorders, rate these biofeedback applications according to established guidelines, and make recommendations for this field based on the literature. The Medline and PsychInfo databases were searched to obtain all papers published from 1975 to 2003 that included the terms "biofeedback" and either "constipation," "pelvic floor dyssynergia," "fecal incontinence," or "anorectal pain." Adult and pediatric papers in any language were screened. Prospective studies with five or more participants and a description of the treatment protocol and outcome were selected for review. Seventy-four studies qualified for review: 33 trials on fecal incontinence (FI), 38 on pelvic floor dyssynergia (PFD) or functional constipation, and 3 on anorectal pain. Only 20% of studies were controlled outcome trials. Treatment protocols, etiological subgroups studied and outcome measures varied greatly. The overall average probability of successful treatment outcome for patients treated with biofeedback was 67.2% for functional FI and 62.4% for constipation. There were insufficient data to warrant such calculation for anorectal pain. According to standard efficacy rating criteria, biofeedback treatment is efficacious for functional constipation or PFD in children and probably efficacious in adults; probably efficacious for functional FI; and possibly efficacious for anorectal pain. Utilizing data from all applicable studies, we found that success rate per subject is significantly higher for biofeedback treatment than for standard medical care for PFD/functional constipation, and FI ($p < .001$ for both). Biofeedback treatment may therefore be viewed as a valuable adjunct to medical management of functional PFD/constipation and incontinence. A number of recommendations for future investigations are made based on the review.

KEY WORDS: biofeedback; fecal incontinence; constipation; anorectal pain; electromyography; manometry; pelvic floor; visceral sensation.

INTRODUCTION

The functional anorectal disorders are a subset of functional gastrointestinal disorders, and are characterized by symptoms thought to be indicative of dysfunction in anal and rectal

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physiological activity. In the current Rome II diagnostic criteria, three anorectal disorders are recognized: functional fecal incontinence (FI), functional anorectal pain, and pelvic floor dyssynergia (PFD; Whitehead et al., 2000). These disorders are diagnosed primarily based on the patients' report of symptoms and are of unknown etiology. By definition they are thought not to involve anatomical or biological pathology, and such competing causal explanations often need to be ruled out by means of tests before definite diagnosis can be made.

Biofeedback (BF) has been reported to be an effective treatment for fecal incontinence and PFD-type constipation in numerous published studies in the past 25 years. Past reviews of biofeedback for FI and constipation have generally not attempted to separate BF trials treating fecal incontinence and constipation of functional nature from those evaluating treatment of similar symptoms due to identified pathophysiology. Recent reviews have generally concluded that BF shows high degree of success for both fecal incontinence (Heymen et al., 2001; Hinninghofen & Enck, 2003; Norton & Kamm, 2001) and constipation (Heymen et al., 2003; Jorge, Habr-Gama, & Wexner, 2003; Rao, 2003, etc.), based mostly on the many uncontrolled studies in each area. They have, however, also noted a number of methodological limitations endemic in this body of literature, such as the varied criteria used to define successful outcome, the heterogeneity of participants, the varying and inconsistent follow-up assessments reported, and the relative dearth of controlled studies. The last point is underscored by the findings of a recent Cochrane review of BF and pelvic floor exercises for FI (Norton, Hosker, & Brazelli, 2003), which only evaluated evidence from randomized and quasi-randomized studies and concluded that there was insufficient evidence to judge whether BF is helpful for FI.

Biofeedback interventions have been far less studied for anorectal pain than the other functional anorectal disorders. In contrast with FI and constipation, each of which has been treated in more than 30 published BF trials, we only found three prospective studies in the literature on BF for anorectal pain, and none of these was a controlled trial.

Conservative medical management is effective in improving the symptoms of approximately half of patients with functional FI and constipation, but is ineffective in treating anorectal pain (Whitehead et al., 2000; Whitehead, Wald, & Norton, 2001). Because of the large bodies of published BF trials with positive outcomes for constipation and fecal incontinence, and because BF is a remarkably benign treatment that is relatively inexpensive compared to other medical interventions, BF is often applied in clinical settings to treat these disorders. However, limitations in the standards of evidence offered by the bulk of the research literature on BF treatment for these conditions have hampered insurance reimbursement.

Global efficacy ratings have not been applied in a systematic review of functional anorectal disorders to date.

Nature and Prevalence of the Functional Anorectal Disorders

Pelvic Floor Dyssynergia

This disorder, which has also been called anismus, outlet obstruction constipation or spastic pelvic floor syndrome, is a type of constipation characterized by a failure in chronically constipated patients to execute the relaxation of the puborectalis sling muscle and the external anal sphincter that is required for successful defecation. Instead, PFD patients paradoxically contract these muscles, effectively inhibiting defecation. This "dyssynergia"

of muscle activity is associated with symptoms of straining and incomplete or blocked evacuation. Diagnosis of PFD requires physiologic confirmation of the characteristic abnormal defecation dynamics through electromyographic (EMG), manometric (pressure) or radiologic testing, as well as exclusion of other causes for the constipation symptoms.

Because PFD requires clinical tests to confirm diagnosis, the population prevalence is not well known, but PFD is thought to account for 25–50% of chronic constipation cases (Lestar, Penninck, & Kerremans, 1989; Wald, Caruana, Freimanis, Bauman, & Hinds, 1990) and may be present in 50% of childhood constipation. This would indicate that PFD is very common, because constipation problems are prevalent in the general population. For example, Irvine, Ferrazzi, Pare, Thompson, & Ranu (2002) found in a random telephone survey of 1,149 individuals 18 years or older in Canada that 14.9% met Rome II criteria for functional constipation and twice as many, or 27.2%, had self-described constipation.

Constipation is often associated with psychological symptoms of anxiety and depression and significant impairment in quality of life (Burnett, Whitehead, & Drossman, 1998; Irvine et al., 2002). Constipation is more common in women than men across the life span, and the prevalence rises with age, especially after middle age.

Functional fecal incontinence (FI) is defined by the Rome II criteria as recurrent uncontrolled passage of fecal material in an individual with a developmental age of at least 4 years, that is associated with fecal impaction, diarrhea, or nonstructural anal dysfunction (Whitehead et al., 2000). The etiology of functional FI is varied, and includes disturbance in intestinal motility (diarrhea or constipation), poor compliance or impaired sensation in the rectum, or weakened pelvic floor muscles. Muscle or nerve damage, for example due to disease processes or trauma such as obstetric injuries, as well as anatomical conditions like rectal prolapse, often causes or contributes to fecal incontinence, and these must be excluded as the primary symptom causes in order to diagnose functional FI. However, the fact that pathophysiology and physiological dysfunction may coexist as synergistic factors in FI complicates the diagnostic picture of many patients. Furthermore, functional fecal incontinence often coincides with PFD: Studies indicate that up to half of functional FI cases exhibit abnormal defecation dynamics. These patients have a mixed symptom presentation of chronic constipation punctuated by incontinence episodes due to fecal impaction.

Fecal incontinence is more common in women than men. This is partly due to the pelvic changes and trauma associated with childbirth, which increases the risk of FI 2.5 to 3 times regardless of delivery method (MacLennan, Taylor, Wilson, & Wilson, 2000). Secondly, FI is often causally related to irritable bowel syndrome and constipation, both of which affect women more frequently than men.

The prevalence of *functional* fecal incontinence, specifically, is not well known, as epidemiological studies have not distinguished between causes of FI. Prevalence estimates agree, however, that significant accidental passage of fecal matter for any reason occurs in about 1% of the general population: Nelson, Norton, Cautley, and Furner (1995) reported, based on a telephone sample of 2,570 households, that loss of solid stool was reported in 0.8% and liquid stool in 1.2% of individuals. A stratified nationwide postal survey of 5,430 U.S. adults performed by Drossman and colleagues (Drossman et al., 1993) found that 0.7% reported frequent incontinence of at least two teaspoons of fecal matter. Milder cases of fecal incontinence are far more common, however. In Drossman et al.'s sample (Drossman et al., 1993), 6.9% of adults reported frequent fecal staining of underwear.

The distribution of fecal incontinence is demographically uneven: It is more common in women than men, and is most prevalent at both ends of the age spectrum. The prevalence

of FI among seven-year-old children is 1.5% (Bellman, 1966; Schaefeer, 1979) and in such pediatric cases, FI is almost always related to fecal impaction (Lowery, Srour, Whitehead, & Schuster, 1985). FI prevalence rises to about 7% in adults over the age of 65 (Drossman et al., 1993; Kinnunen, 1991). It is a leading cause of institutionalization of elderly individuals. For that reason, and because dementia and immobility increase the risk of FI, the condition is much more prevalent in nursing homes, afflicting 45–47% of U.S. nursing home residents (Dey, 1997; Nelson, Furner, & Jesudason, 1998).

Because of the embarrassing and socially limiting nature of the symptoms, FI most likely has greater psychological and life impact than the other functional anorectal disorders. Several studies have demonstrated that FI has a broad and measurable adverse impact on patients' quality of life and is often associated with depression, social isolation, impairment of intimate relationships, and poor self-esteem (Burnett et al., 1998; Miner, 2004).

Functional Anorectal Pain

Two types of functional anorectal pain are recognized, which may overlap but have different presentation in regard to symptom duration, frequency, and intensity. Levator ani syndrome generally presents as a dull or indistinct feeling of pressure, ache or pain in the upper rectum. Rome II diagnostic criteria require this to have been experienced 12 weeks out of the last 12 months and for the duration of the episodes to be at least 20 min (Whitehead et al., 2000). It has been reported to affect 6.6% of the general population (Drossman et al., 1993), is more common in women than men and most commonly affects individuals between the ages of 30 and 60. Proctalgia fugax presents as sudden, severe anal or lower rectal pain that lasts from a few seconds to a few minutes. The pain is often intense enough to disrupt normal life activities (Thompson & Heaton, 1980) but rarely occurs more often than 5 times a year. Population prevalence estimates for proctalgia fugax vary from 8 to 14% (Drossman et al., 1993; Panitch & Schofferman, 1975) but because of the brief and infrequent nature of the episodes, few sufferers seek medical attention for the condition.

Aims

The aims of this review were: (1) to comprehensively examine the level of evidence for efficacy of biofeedback treatment of functional anorectal disorders in the published empirical world literature; (2) to rate treatment efficacy according to standard guidelines; and (3) to make recommendations based on the findings.

Review Methodology

The conditions of interests (COI) in this review were the three anorectal disorders described above. Medline and Psychinfo searches were used to identify all published empirical papers from 1975 through 2003 in all languages on adult and pediatric samples matching the search term "biofeedback" with the terms "pelvic floor dyssynergia," "constipation," "fecal incontinence," "anismus," or "anorectal pain." Papers were manually screened to select for review only prospective studies of biofeedback treatment that had at least five participants per group and provided a description of the treatment protocol and treatment outcomes. Studies where the anorectal conditions of all patients studied were recognized to

be secondary to physical trauma (such as obstetric injury) or structural pathology, postsurgical in nature or related to a major medical disorder (such as diabetes, multiple sclerosis, or spina bifida) were excluded, but studies on participant groups with anorectal problems of mixed etiology that were likely to include patients with the COIs were included for review. This inclusion of mixed etiology samples was deemed necessary as the majority of the studies found were on mixed groups and in many cases a definite etiological separation of functional anorectal conditions from other causal factors is difficult as the symptoms are often (especially in FI) multifactorial in nature. Because few studies on constipation BF separated outcomes for PFD and other constipation, we treated PFD and other functional (idiopathic) constipation as a single COI for the purposes of the review.

This search and screening methodology resulted in the identification of 33 studies of BF for fecal incontinence, 38 studies on constipation, and three studies on functional anorectal pain. The studies were categorized according to their design into randomized controlled trials, nonrandomized controlled trials, or uncontrolled trials. As this review focused on clinical efficacy, which requires comparison with other treatments, only studies that had one or more nonbiofeedback groups internal to the study design were classified as controlled outcome trials (thus, several studies that merely compared different variants of biofeedback were not regarded as controlled trials for the present purposes).

The overall success rate of BF for each of the anorectal COI was calculated by averaging the success rates reported in all studies that provided that statistic after they had been weighted according to the number of participants in each study. It must be acknowledged that there was no common standard for defining treatment responder across studies, and most reports did not provide adequately detailed results to make it possible to apply any common standard in calculation. However, most of the studies reported the percentage of patients who were determined to have successful treatment outcome according to some standard, and these percentages were used regardless of the responder definition. Some studies reported multiple percentages based on different criteria for positive outcome, and in such cases, we selected a commonly used criterion, which was the percentage of patients with $\geq$75% improvement in symptoms. This was the middle of the range of criteria from 50 to 100% improvement used in the studies reviewed.

The overall success rate for standard medical care control groups was calculated in the same weighted way as described above, for PFD and FI trials (no such control group outcome was available for anorectal pain). The proportions of patients improving from BF and standard medical care, respectively, were statistically compared for each condition, using chi-square tests.

Finally, an overall efficacy rating for BF treatment of each of the three functional anorectal disorders was performed using published standard guidelines for evaluation of clinical efficacy of psychophysiological interventions (La Vaque et al., 2002).

Biofeedback Protocols Used for Anorectal Disorders

Biofeedback for PFD

Biofeedback interventions for PFD are directed at teaching patients to relax their pelvic floor muscles while simultaneously applying a downward intraabdominal pressure to generate propulsive force (Valsalva maneuver). This is done with the aid of visual or

auditory feedback to the patients providing information from either electromyography sensors (EMG) measuring electric activity in the external anal sphincter, an anal canal pressure sensor device, or both of these.

Biofeedback for Fecal Incontinence

The maintenance of continence depends on adequate rectal sensation to detect distention of the rectum, as well as on the capability to synchronously contract the external anal sphincter in response to the reflexive inhibition of the internal anal sphincter that occurs when the rectum fills (Whitehead, Engel, & Schuster, 1980). Biofeedback for fecal incontinence aims to enhance or restore these key functions. A variety of treatment protocols have been employed for this purpose, and these methods can be divided into three treatment approaches. The relative frequency of use of these approaches in published studies has been comprehensively reviewed recently by Heymen et al. (2001).

The most commonly reported training method is the use of variants of the *coordination* treatment protocol first developed at Johns Hopkins (Engel, Nikoomanesh, & Shuster, 1974). This involves training patients to coordinate or synchronize contractions of the pelvic floor muscles in response to intrarectal distention by simultaneously using pressure feedback from intrarectal balloon distension and pressure feedback from pelvic floor muscle contraction, and is performed with a balloon-tipped water-perfused catheter or a three-balloon probe.

Second in frequency of use is *strength training*, which aims to strengthen the external anal sphincter without employing rectal distension. Strength training is accomplished with the aid of either anal canal pressure feedback or intraanal or perianal electromyographic (EMG) feedback.

A third and far less often reported training approach involves systematically teaching patients to improve their ability to sense diminishing rectal distentions without training PFM contractions. This is done by using controlled amounts of intrarectal pressure applied via a computer-inflated balloon. Such sensory training is rarely done alone, but complements other BF training, and several studies have suggested that including it may enhance outcomes (Glia, Glyin, Golberg, & Lindberg, 1997; Latimer, Compbell, & Kasperski, 1984; Miner, Donnelly, & Read, 1990).

Biofeedback for Anorectal Pain

All three of the prospective studies of BF for anorectal pain used pressure feedback from the external anal sphincter.

Regardless of the specific biofeedback protocols used to treat anorectal disorders, the inclinic biofeedback training is almost invariable supplemented with other potentially therapeutic components. These often include advice, reassurance and patient education, prescribed pelvic floor home exercises, practice with balloon defecation, laxatives, enemas, fiber supplements, or the use of EMG biofeedback home trainer devices.

The number of BF sessions used in published studies to treat patients for functional anorectal disorders varies greatly, and ranges from 1–12 sessions. Many studies reported high success rates with as few as 3 or 4 sessions per patient.

Research on the Relative Effects of Different BF Protocols

Three studies have attempted to compare the relative benefits from coordination training, strength training, and sensory training for incontinence. Two of these (Latimer et al., 1984; Miner et al., 1990) used complex crossover designs that were inadequate for providing conclusions in regard to the relative effect of different treatment components (for example, did not control for order effects and were not adequately powered for multiple group comparisons). Heymen and colleagues (2000) randomized patients to four parallel groups, to compare EMG strength training alone, EMG training with a home trainer, and combined EMG and pressure feedback (coordination training) with or without a home trainer. They found no difference in outcome between the four groups, all of which improved significantly in incontinence after treatment.

Heymen et al. (2001) conducted a metaanalysis weighted by the number of participants, comparing FI treatment outcomes (measured in frequency of incontinence episodes) of 19 BF studies using *coordination* training versus 12 studies using strength training, and found no advantage for one treatment strategy over another. Within the subset of strength training studies, they also compared the six studies using EMG training to the six utilizing pressure feedback, and found EMG to produce significantly more favorable outcomes.

Three studies have compared EMG and pressure feedback training for PFD (Bleijenberg & Kuijpers, 1994; Glia et al., 1997; Wang, Luo, Qi, & Dong, 2003). Only Bleijenberg and Kuijpers (1994) found a difference in outcome, reporting EMG training to result in far higher success rate (73% vs. 22%) but their group sizes were quite small (11 and 9 participants, respectively). In contrast, a metaanalysis by Heymen et al. (2003) comparing outcomes in 13 studies using pressure feedback to those of 18 studies using EMG feedback found pressure feedback to be associated with significantly better outcomes on the average.

Review of BF Trials for PFD or Functional Constipation

A total of 38 studies on PFD or constipation without recognized organic causes met inclusion criteria for review (see Table I). Eight of these (23%) were controlled outcome studies. All except one of the controlled studies were studies on children.

Randomized Controlled Trials

In the only controlled study of adult PFD, Koutsomanis et al. (1995) compared a treatment protocol using perianal EMG biofeedback plus balloon defecation training versus balloon defecation alone in a randomized study of 60 adult constipation participants, most of whom had evidence of PFD. Patients with structural causes for their constipation were excluded. They found no difference in outcome between the groups. participants were treated in an average of three sessions with BF and two sessions for the balloon defecation practice.

Loening-Baucke (1990a) randomized 43 children age 5–16 who all had PFD defined by documented abnormal contraction of the external anal sphincter and pelvic floor during defecation attempts to receive either coordination-type biofeedback plus conventional medical care or only conventional care. All the children had fecal impaction and encopresis. The conventional care given to both groups included initial enema for disimpaction, daily laxatives, toileting schedule, and increased fiber in the diet.

Table I. Biofeedback Trials for Functional Constipation or PFD

Authors & year	# of patients (f/m)	Age range	Biofeedback method	Control treatment	Outcome comparison
A. Randomized controlled trials					
Koutsomanis Lennard-Jones, Roy, and Kamth (1995)	60 (53/7)	20–64	paEMG ($n = 30$)	Balloon defecation	69%/64% no difference
Loening-Baucke (1990a)	41 (10/31)	5–16	coord. ($n = 22$)	Medical management	55%/5% BF superior
Nolan, Catlo-Smith, Coffey, and Wells (1998)	29	4–14	coord. ($n = 14$)	Medical management	29%/40% no difference
Wald, Chandra, Gabel, and Chiponis (1987)	50 (40/10)	6–15	press. ($n = 24$)	Mineral oil ($n = 26$)	54%/54% no difference
van der Plas, Benninga, Redirop, et al. (1996)	192	5–16	coord. ($n = 98$)	Medical management	32%/33% no difference
Sunic-Omejc et al. (2002)	49 (22/27)	$M = 7.5$	coord. ($n = 25$)	Medical management	84%/62.5% BF superior
B. Nonrandomized controlled trials					
Cox et al. (1994)	26 (8/18)	4–16	paEMG ($n = 13$)	Medical management	88%/60% BF superior
Loening-Baucke (1995)	129	$M = 9$	coord. ($n = 61$)	Medical management	44%/62% no difference
C. Uncontrolled trials					
Beminga Buller, and Taminiau (1993)	29 (12/17)	5–16	paEMG	55	
Bleijenberg and Kuijpers (1987)	10	19–48	iaEMG	70	
Bleijenberg and Kuijpers (1994)	20 (15/5)	20–50	iaEMG/press.	73/22	
Dahl et al. (1991)	14 (10/4)	6–60	iaEMG	93	
Dailianas et al. (2000)	11		press.	64	
Emery et al. (1988)	65 (5/34)	5–77	paEMG	80	
Fleshman et al. (1992)	9 (8/1)	35–62	iaEMG	89	
Glia et al. (1997)	26 (23/3)	28–78	iaEMG, press., coord.	58	
Heymen et al. (1999)	36 (26/10)	18–82	iaEMG/press./coord.	not reported; significant improvement	
Ho, Tan and Goh (1996)	62 (38/24)	$M = 48$	press.	90	
Hibi, Iwai, Kimura, Sasaki, and Tsuda (2003)	10			60	
Karlbom, Hallden, Eig-Olofsson, Pahlman, and Graf (1997)	28 (23/5)	22–72	iaEMG	43	
Kawimbe, Papachrysostomou, Binnie, Clare, and Smith (1991)	15 (12/3)	22–76	iaEMG	not reported; significant improvement	
Keck et al. (1994)	12 (10/2)		press.	25	
Keren, Wagner, Heldenbert, and Golan (1988)	12	press.	100		
Ko et al. (1997)	17		iaEMG	76	
Koutsomanis, Lennard-Jones, and Kamm (1994)	20 (18/2)	adults	iaEMG	85	
Loening-Baucke (1991)	38 (10/28)	6–15	paEMG	37	
Lestar et al. (1991)	16 (10/6)	$M = 42.5$	press.	56	
McKee, Mcenvoe, Anderson, and Finlay (1999)	30 (30/0)	15–55	press.	32	
Papachrysostomou and Smith	122.		iaEMG	86	
Patankar et al. (1997)	116 (88/28)	33–85	iaEMG	84	
Rao, Enck, and Loening-Baucke (1997)	25.		coord., press., sens.	60	
Rhee et al. (1999)	45 (32/13)	21–72	iaEMG	69	
Rieger, Watlchow, Sarre, Saccone (1997b)	19 (18/1)	16–78	iaEMG	13	
Turnbull and Ritro (1992)	7.		press.	86	
Veyrac, Granel, Parelon, and Michel (1987)	12.		press.	83	
Wang et al. (2003)	50 (36/14)	16–71	coord., paEMG	62	
Weber, Ducrotte, Touchais, Roussigno and Denis (1987)	42		press.	65	
Wexner, Cheape, Jorge, Heymen and Jagelman (1992)	18		iaEMG	89	

Note. coord. = cordination biofeedback training; press. = Pressure biofeedback training; paEMG = perianal EMG biofeedback; iaEMG = Intraanal EMG biofeedback; MM = Medical management; PFE = Pelvic floor exercises; HT = Home trainer; M = mean.

One child dropped out of each group. The children who received BF showed higher rate of successful symptom resolution at seven months than controls (55% vs. 5% at 7 months and 50% vs. 16% at 12 month follow-up). The biofeedback group also exhibited a far higher rate of normalization of defecation dynamics (77% vs. 13%). This report is exemplary in many ways; It studied a well-defined PFD population in a successfully randomized (comparable groups) sample of adequate size with well-defined outcome criteria and a well-demarcated and uniform follow-up, and used a well-described biofeedback procedure.

Sunic-Omejc et al. (2002) randomized 49 children under the age of 5 with well-defined chronic constipation without organic pathology to 12-week treatment regimens consisting of standard medical management either with or without BF. Abnormal defecation dynamics were found in 56% of BF participants and 58% of controls at baseline. Standard management included oral laxatives, disimpaction, high-fiber diet, and toilet scheduling. The biofeedback group received coordination feedback training in the clinic and practiced Kegel exercises at home. participants in the two groups were comparable in clinical and demographic characteristics. At the end of 12 weeks, significantly more children in the BF group (84% vs. 62.5%) had successful treatment outcome according to well-defined bowel symptom criteria. Clinical improvement was correlated with normalization of manometry findings and defecation dynamics. The absence of a medium-term or long-term follow-up was the main shortcoming in this otherwise well-conducted study. The young age of the participants in the study is noteworthy, as clinicians sometimes consider age 5 to be the lowest age suited for BF training of this kind.

van der Plas, Benninga, Redekop, et al. (1996a) randomly divided children aged 5–16 years who had been diagnosed with pediatric constipation into a group that received standard medical care plus five biofeedback sessions using anal canal pressure and EMG feedback (98 patients), and a group that only received standard medical care (94 patients). About 60% of the study sample had abnormal defecation dynamics on manometric testing (PFD) prior to treatment. Treatment involved the same number of clinic visits for both groups and both received the same standard care, including laxatives, dietary advice, toilet training, and the keeping of a bowel habit diary. After treatment, 32% of the BF group and 33% of the standard care group had successful symptom resolution, defined as defecation at least 3 week, soiling and/or encopresis less than twice a month, and no laxative use. Both groups also had equivalent outcomes at 6, 12 and 18-month follow-ups, although the success rate was higher at these points, or about 50% for both groups. In contrast with the equal clinical outcome between the groups, the group that received biofeedback-augmented treatment had a significantly greater rate of normalization of defecation dynamics after treatment (a change from 38% to 86% of participants) compared to the standard care group (41 to 52%). This normalization of physiological activity, however, was unrelated to clinical outcome.

Nolan et al. (1998) compared standard medical care alone or with the addition of 3–4 session coordination biofeedback in 29 children with PFD between the ages of 4 and 14. There were no significant differences in outcomes between the two groups; 4 out of 14 BF children and 6 out of 15 controls improved. However, like van der Plas, Benninga, Redekop, et al. (1996) above, these investigators found that the biofeedback training group showed greater normalization of paradoxical defecation activity, even though this did not translate into greater symptom improvement.

Wald et al. (1987) randomized a mixed group of 50 children to either pressure biofeedback or mineral oil treatment. All but three participants had fecal impaction or stool retention,

and 16 had manometric evidence of PFD. The two groups were comparable on all clinical and demographic characteristics. The investigators found no difference in outcome after treatment or at follow-up, but there was a nonsignificant trend for the PFD children to do better with biofeedback and those with normal defecation physiology to respond better to mineral oil.

Nonrandomized Controlled Trials

Cox et al. (1994) compared 13 children receiving 1–6 sessions of perianal biofeedback and standard medical care to 13 age- and gender matched controls receiving only standard medical care. All the children had PFD and ranged in age from 4 to 16 years. Unlike in most studies, the BF group was weaned off the standard care during the BF intervention. The children received 1–6 biofeedback training sessions with perianal EMG, and conducted parent-supervised sphincter exercises at home. The biofeedback group was significantly more improved at 16-month follow-up in regard to constipation and encopresis and rated lower on laxative use and pain during defecation.

Loening-Baucke (1995) compared long-term treatment outcomes for PFD children treated with an intensive standard medical management program alone to 63 children who also received 1–6 biofeedback sessions to train normalization of defecation dynamics. At 3–5 year follow-up, 62% of conventionally treated children and 50% of those who had succeeded in biofeedback (the difference was not significant between those two groups) were improved. A significantly lower proportion (23%) of children who had failed biofeedback training improved. Twenty-one of the children in the BF group had been randomized to that treatment as a part of the author's previous trial. The remaining 42 BF recipients (2/3 of the BF group) were only provided with BF after 6 months of standard medical management efforts had failed to produce results. The author concluded that biofeedback does not enhance long-term symptom outcomes in PFD, but this conclusion is hardly justified, due to the flawed comparison: Applying BF to a subset of children who have been unresponsive to intensive multimodal treatment effort for 6 months is hardly a fair test of the value of this treatment modality as an adjunct to standard medical management.

Uncontrolled Trials

Twenty-nine uncontrolled studies on functional constipation were found in the literature. These are summarized in Table I (C). Seventeen of these were on BF for adult participants, five were on children, and eight included both adults and child participants. Reported success rates varied greatly, ranging from 13 to 100%, but most of the uncontrolled studies reported 50% or better success rate. Two studies (see Table I (C)) did not report success rates or present data to calculate these, but both reported significant improvement from BF treatment.

Review of BF Trials for Fecal Incontinence

A total of 34 studies met inclusion criteria for review (see Table II). Five of these (15%) were controlled outcome studies.

Table II. Biofeedback Trials for Functional Fecal Incontinence

Authors & year	# of patients (f/m)	Age range	Biofeedback method	Control treatment	Outcome comparison
A. Randomized controlled trials					
Norton et al. (2003)	171 (159/12)	26–85	sens., coord., press. ($n = 49$)	MM/MM+PFE/MM+ PFE+BF/MM+PFE+BF+HT	BF:53%, MM 54% no group differences
van der Plas, Benninga, Buller, et al. (1996)	71	5–16	perianal EMG ($n = 38$)	MM/MM+BF	39%/19%, no group difference
Miner et al. (1990b)	25 (17/8)	17–76	sens. press./coord. ($n = 12$)	Ballon inflation w/o feedback	Only BF group improved; 76% (44%)
B. Nonrandomized controlled trials					
Loening-Baucke (1990b)	17	35–78	coord.	MM	50%/56% no group differences
Guilllemot et al. (1995)	24 (19/5)	39–78	press.	MM	56%*/0%* BF superior short-term
				% improved (% symptom-free)	
C. Uncontrolled trials					
Arhan et al. (1994)	47	5–18	coord.	69	
Buser and Miner (1986)	13 (7/6)	13–66	coord.	92 (92)	
Cerulli, Nikoomanesh, and Schuster (1979)	50 (36/14)	6–97	coord.	72 (40)	
Chiariaoni, Seattolini, Bonafante, and Vantini (1993)	14 (10/4)	24–75	coord.	86 (64)	
Enck, Daublin, Lubke, and Strohmeyer (1994)	18 (14/4)	33–83	coord.	(22)	
Engel et al. (1974)	7 (5/2)	6–54	coord.	(71) 57	
Faure, Ferriere, Maurauge, and Rolland (1995)	26		coord.	62	
Fox et al. (1991)	59		EMG	84 (78)	
Glia et al. (1998)	22 (22/4)	32–82	coord.	64	
Heymen et al. (2000)	34 (23/11)	36–88	EMG., press, coord.	not reported, no significant improvement	
Keck et al. (1994)	15 (13/2)	29–65	press.	73 (27)	
Ko et al. (1997)	25 (21/4)	31–82	EMG	92 (44)	
Latimer et al. (1984)	8 (4/4)	8–72	Press/Sens/Coord.	100(88)	
MacLeod (1987)	113 (67/46)	25–88	EMG	63	
McLeod (1983)	50 (26/24)	$M = 55$	EMG	72	
Magrini, Pallotta, Koch, and Capurso (1997)	6 (5/1)	$M = 50$	press.	100(100)	
Martinez-Puente, Pascual-Montero, and Garcia-Olmo (2003)	53 (42/11)	26–83	sens., press., coord.	66	
Nicastro et al. (1997)	116 (85/31)	11–86	EMG	81	
Norton, Chelvanayagama, Wilson-Barmett, Redfern, and Kamm (2003)	100 (84/16)	14–82	press.	67 (43)	
Olness, Mcferland, and Piper (1980)	50	4–15	coord.	60	
Patankar et al. (1997a)	72 (43/29)	34–87	EMG	85	
Rao, Welcher, and Pelsang (1996)	19	15–78	press/sens/coord.	53 (53)	
Rieger et al. (1997a)	30 (28/2)	29–85	EMG	67 (20)	
Ryn et al. (2000)	37 (36/1)	22–82	EMG	60	
Sangwan et al. (1995)	28 (22/6)	30–74	press.	75	
Wald (1981)	17 (11/6)	10–79	coord.	71 (59)	
Whitehead, Burgio, and Engel (1985)	18 (15/3)	65–92	coord.	67	

Note. coord. = cordination biofeedback training; press. = Pressure biofeedback training; paEMG = perianal EMG biofeedback; iaEMG = Intraanal EMG biofeedback; MM = Medical management; PFE = Pelvic floor exercises; HT = Home trainer; M = mean.

Randomized Controlled Trials

Norton et al. (2003) randomly assigned 171 well-characterized adult FI patients to four groups: (1) a standard care group; (2) standard care plus instruction in anal sphincter exercises taught verbally and via digital examination; (3) standard care, anal sphincter exercises plus computer-assisted BF involving coordination techniques with visual feedback of sphincter contractions; or (4) same as group 3 plus daily use of an EMG home trainer device. Outcome measures were wide-ranging, and included symptom diary, quality of life and psychological questionnaires, continence score, patient's self-assessment of symptom improvement, and repeated anal manometry testing. Nineteen percent of participants dropped out before completing the study. About half of participants in all groups who completed the study improved after treatment, with no significant group differences on any outcome measures after treatment nor at 1-year follow-up: 53% of patients improved from standard care alone compared to 54% in the biofeedback group (group 3). Improvement was seen across a wide range of bowel symptom, psychological and physiological outcome measures, and most treatment responders still showed improvement at 1-year follow-up. Interestingly, anal canal pressures improved across all groups, including the standard care group.

This trial appears to have been methodologically sound in most regards, including group sizes, outcome measures, effective randomization to treatments, and characterization of participants. It is the largest trial comparing BF to other treatments to date. However, the report lacked detail in regard to the biofeedback protocol used, and the number of biofeedback sessions completed by the BF group participants was not provided.

van der Plas, Benninga, Buller, et al. (1996) allocated 71 children who had well-characterized childhood FI without constipation to standard care and laxatives or standard care, laxatives, and biofeedback. The biofeedback group showed a nonsignificant trend toward more clinical improvement (39% vs. 19%, $p = .07$) after treatment. At 12 and 18 months approximately half of the children in both groups showed successful symptom resolution. This study was generally adequate in design and methods, although a larger sample might have revealed a significant short-term outcome advantage for biofeedback.

Miner and colleagues (1990) randomized 25 adults to either three-session sensory biofeedback training or the same amount of balloon inflations in the bowel without feedback or instruction. This was followed by a complicated crossover design where patients in both initial groups received other biofeedback components. However, the first part of the study constituted a controlled comparison of active sensory feedback versus no feedback, and the investigators found that only the active biofeedback group significantly reduced the frequency of fecal incontinence episodes from pre- to posttreatment evaluation. However, because of the small sample in this underpowered trial, the group comparison was not significant.

Nonrandomized Controlled Trials

Guillemot et al. (1995) treated 16 patients with constipation of varied etiology with biofeedback and compared them to eight patients who were treated with medications. All patients were adults. participants were allowed to select which treatment they received. Significant improvements relative to baseline was found in the biofeedback group only at

6-month follow-up, but the improvement was no longer significant at the last follow-up at 24–36 months. The authors did not report a statistical group comparison of outcome. They did not report success rate either. However, as they presented individual summary scores for fecal incontinence for all participants, we were able to calculate a 56% 6-month success rate for biofeedback, using ≥75% reduction in incontinence summary score as a criterion, versus 0% success for the control group.

Loening-Baucke (1990b) compared nine incontinent adult patients treated with standard medical management to eight patients who received pressure BF in addition to standard care, and found no advantage in the addition of biofeedback (50% success rate for BF versus 56% for conventional therapy at 3 months, and 38% versus 55% at 1-year follow-up).

Uncontrolled Trials

Twenty-seven uncontrolled studies on fecal incontinence were found in the literature. These are summarized in Table II (C). Fifteen of these were on BF for adult participants, three were on children, and eight included both adults and children. One paper (Glia et al., 1998) did not report success rate, but stated that there was no significant success after BF treatment. All the remaining studies except one (Enck et al., 1994) reported success rates above 50% for BF.

Review of BF Trials for Anorectal Pain

Randomized Controlled Trials

Three clinical trials of BF for functional anorectal pain were found in the literature (see Table III), none of which were randomized.

Nonrandomized Controlled Clinical Trials

Only one study was found in the literature that examined biofeedback treatment in any kind of controlled fashion. In that study, Ger and colleagues (2002) provided three different treatments to adults who had anorectal pain without organic pathology and had failed conservative medical management; biofeedback (14 patients) electrogalvanic stimulation (29 patients), and steroid caudal block (11 patients). At follow-up 2–36 months after treatment completion, 43% of BF patients versus 38% of those who had electrogalvanic stimulation and 18% of patients who had steroid block treatment reported successful pain relief. These results were not statistically different between groups. Apart from the lack of randomization into groups and the broad variability in follow-up time points across participants, the conclusions that may be made from this study are very limited due to the confound that many participants received more than one of the test treatments, in varying order.

Uncontrolled Trials

A couple of uncontrolled studies have offered a suggestion that BF may be successfully used to treat anorectal pain. Grimaud and colleagues (1991) treated 12 patients with

Table III. Biofeedback Trials for Functional Anorectal Pain

Authors & year	# of patients (f/m)	Age range	Biofeedback method	% improved	
Uncontrolled trials (no controlled outcome trials were found in the literature)					
Grimaud, Bouvier, Naudy, Guien, and Salducci (1991)	12 (8/4)	24–66	press.	100	
Heah, Ho, Tan, and Leong (1997)	16 (7/9)	39–66	press.	% not reported, significant improvement	
Nonrandomized controlled trials					Outcome comparison: Comments
Ger et al. (1993)	38 (17/21)	$M = 71$	press.	Electrogalvanic stimulation, steroid caudal block	No group difference; 43% improved after BF

Note. coord. = cordination biofeedback training; press. = Pressure biofeedback training; paEMG = perianal EMG biofeedback; iaEMG = Intraanal EMG biofeedback; MM = Medical management; PFE = Pelvic floor exercises; HT = Home trainer; M = mean.

functional anorectal pain with pressure biofeedback to enhance control of the external anal sphincter, and reported that all patients improved, with a mean of eight sessions needed to achieve benefit. The improvement was maintained in 11 of the 12 patients beyond a 16-month follow-up.

Heah et al. (1997) treated 16 patients with balloon pressure biofeedback. The patients were significantly lower on pain scores as a group after treatment. Success rate was not stated in this report. However, it was noted that all but two out of the 16 patients discontinued use of analgesics after treatment.

Assessment of the Quality of the Literature

A critical examination of the reviewed studies highlighted five major shortcomings shared by the majority of the published studies on BF treatment of functional anorectal disorders to date.

1. *The great majority of studies did not use non-BF control groups*. Of all the identified studies meeting selection criteria, 80% had no non-BF control group. Uncontrolled outcome studies, no matter how numerous, offer little help in establishing the efficacy of a treatment because they do not allow the necessary direct assessment of the relative impact of the treatment tested on the problem compared to other types of intervention. Additionally, uncontrolled trials are highly vulnerable to bias that may inflate success rates, such as self-selection of the most highly motivated or most qualified patients into the experimental treatment. Uncontrolled studies adding BF to standard medical management are especially problematic in studies of disorders like PFD and functional FI where, as mentioned above, a substantial proportion of patients are known to respond well to conventional medical management (which may involve such things as practical symptom management advice, diet changes, habit training, and laxatives). In the absence of direct comparison with patients receiving standard care only, treatment response must be very high to offer any assurance that it is in excess of what might be expected from standard care. Only a minority of the uncontrolled studies in the literature provided BF to patients who had failed to benefit standard medical care, which seems more reasonable in studies without control groups (making patients their own controls) to be able to attribute the observed treatment response to the BF intervention.
2. *Sample sizes were often too small for full utility of the results*. Studies employing controlled comparisons or crossover designs sometimes clearly lacked power to reach the conclusions that they aimed for. Uncontrolled studies were often too small to allow analysis of factors that might predict outcome, such as demographic variables or manometric findings.
3. *Outcome measures and treatment responder definitions varied greatly*. The most common report of clinical outcome was the proportion of patients who were "improved" after treatment or at follow-up by some specified or nonspecified standard. The lack of uniformity in what is deemed clinical improvement in this body of research makes comparison of outcomes across studies very difficult.
4. *Enrollment criteria varied greatly across studies and were often overly inclusive*. In many of the studies reviewed, participants with functional anorectal disorders

were mixed with similar symptoms due to other conditions (for example, symptoms attributable to bowel surgery or obstetrical sphincter tear). Likewise, patients with slow-transit constipation were sometimes grouped together with PFD-type constipation patients in constipation BF trials, even when the biofeedback treatment tested aimed at normalizing defecation dynamics (which was only relevant to the PFD patients). Another source of heterogeneity was the extreme age range of participants. Several studies treated individuals from elementary school age children to people beyond retirement age together as a single study group.

5. *Follow-up assessments were highly variable and missing in several studies*. In some studies, only medium-term or long-term follow-up but no immediate posttreatment changes were reported. Sometimes the range of the follow-up period was so variable across individuals within a study as to render it largely meaningless.

Relative Success Rates of BF and Standard Medical Care

Several of the studies on both FI and functional constipation used standard medical care as a control group in controlled evaluation of biofeedback. This enabled us to calculate and statistically compare the relative success rate of BF versus standard medical care for these two conditions, using all applicable studies for each quantification. The overall success rates for 1,107 patients treated for functional constipation with biofeedback was significantly higher ($\chi^2 = 24.04$; $p < .001$) at 62.4%, compared with 45.0% success rate for the 233 patients who received standard medical care. Similarly, the overall success rate of 67.2% for the 1,170 patients treated for functional fecal incontinence with biofeedback was significantly higher ($\chi^2 = 35.42$; $p < .001$) compared with 35.9% success rate for the 87 patients who received standard medical care.

Efficacy Ratings of BF for Functional Anorectal Disorders

According to the AAPB/SNR efficacy rating guidelines (La Vaque et al., 2002), a treatment for a particular condition of interest can only be rated as "efficacious," which is Level 4 in the hierarchical rating system for evidence for treatment efficacy, when the following six criteria are met (paraphrased here from the published guidelines);

a. The experimental treatment has been found in randomized studies to be statistically significantly superior or equal to a control group (no treatment, alternative treatment, or placebo group);
b. The studies have been conducted on well-defined participants with a specific problem;
c. The studies used valid and clearly specified outcome measures related to the problem;
d. The data are appropriately analyzed;
e. Diagnostic and treatment procedures are clearly defined in a manner that makes replication by others possible; and
f. The superiority of equivalence of the investigational treatment has been shown in at least two independent research settings.

We concluded that the studies of Loening-Baucke (1990a) and Sunic-Omejc et al. (2002), described above, together satisfy all the above criteria a–f, and therefore rated the BF treatment of functional constipation "Level 4—efficacious" according to the standard guidelines, at least when applied to treat children. There have been no controlled comparisons of BF versus standard medical care for PFD in adults. In light of the many uncontrolled studies with high success rates in adult samples, however, we assigned BF for adult PFD or functional constipation the efficacy rating of "Level 3—probably efficacious." This rating requires, according to the AAPB/SNR guidelines, "Multiple observational studies, clinical studies, waitlist-controlled studies and within subject and intrasubject replication studies that demonstrate efficacy" (La Vaque et al., 2002).

In the case of functional fecal incontinence, only two randomized controlled studies have been published that satisfy many of the methodological criteria to determine the efficacy of treatment. One of these found BF to produce better outcomes than medical management (van der Plas, Benninga, Buller, et al., 1996) but success rates for both groups were very low. The other study (Norton et al., 2003) found no advantage to BF compared to standard care. These equivocal results are at odds with the high success rates for BF seen almost universally in this body of empirical work, and which we found to be significantly above what is reported for standard management in the same literature. We therefore concluded that BF for functional fecal incontinence met the criteria for "Level 3—probably efficacious" according to the criteria cited above.

Biofeedback treatment for anorectal pain has been poorly investigated to date. We assigned this application of BF the rating of "Level 2—possibly efficacious," which requires "at least one study of sufficient statistical power with well-defined outcome measures, but lacking randomized assignment to a control condition internal to the study" (La Vaque et al, 2002). We felt that this criterion was met mostly due to the study of Grimaud and colleagues (1991).

Recommendations for Future Research Work

Our systematic review of the current state of the empirical literature identified several shortcomings and unmet knowledge needs in this research domain that should be addressed by future work. On the basis of these observations, we make the following eight recommendations for consideration in planning of future research in this area:

1. *Use of control groups and randomization into groups*. Conducting additional sizable and well-designed studies that conclusively determine and quantify the value of BF as an adjunct treatment in the management of functional anorectal disorders should be the top priority in this research domain, especially for PFD in adults and functional FI. The minimally adequate comparison group is a group receiving standard medical care of good quality. However, random assignment to either BF or a placebo group receiving a face-valid alternate treatment that does not involve the therapeutic mechanisms of BF, is a recommended standard for future studies (Whitehead, 2004).
2. *Homogeneity and clear characterization of participants enrolled in studies*. Participants should be similar in regard to etiology and severity of symptoms. If more than one etiologic or severity group is included, the studies must have adequate sample sizes to accommodate comparison of outcomes for these subgroups.

3. *Adoption of standard outcome measures and ways to define treatment responders*. An unambiguous criterion of quantifiable symptom status of the target symptoms, as experienced by the patients, should be the primary criterion for success (Whitehead et al., 1999), and it is highly desirable for the same primary outcome measures to be used across all studies of BF for the same condition.
4. *Clear description and standardization of treatment protocols*. Generalizability of the findings of BF studies is dependent on clinicians being able to utilize the same clinical method. In the majority of studies to date, the treatment is not sufficiently described to allow replication with reasonable expectation of similar outcome. This must be improved in future work.
5. *Greater attention to statistical power and sample sizes*. To be of value to the field, studies must be conducted with adequate power to enable conclusions about the hypotheses they test.
6. *Ensuring adequate amount of training sessions for all patients in the BF arm*. In many studies, some of the participants received as little as one BF training session. Consistent treatment protocols with a fixed minimum amount of sessions that allow for repeated practice even after the basic skills are mastered may enhance outcomes. The importance of such standard is underlined by the recent findings of Gilliland et al. (1997) in their large case series of 194 BF-treated constipation patients. They found that those of their patients who received four or less BF sessions were less than half as likely to improve clinically as the ones who received five or more sessions.
7. *Use of long-term follow-up outcome assessments at fixed intervals*. For comparability across studies, fixed intervals (without excess variability) are desirable. We recommend at least 6-month and 12-month follow-ups as a desirable standard for all studies for both BF and control groups, and if possible, also additional follow-up points at 18 and 24 months.
8. *Research on participant characteristics that modulate probability of success*. Many participant variables that may affect the probability of good treatment outcome have not been examined due to the limited size and poor methodologies of most studies. For example, it is presently not known whether psychological factors such as depression or anxiety affect probability of success. Increased understanding of which patients are likely to benefit, or how to prepare patients in such a way that they respond better to biofeedback, may further enhance the success of this treatment.

Conclusions

1. Our review and analysis of the literature indicates that BF provides a significantly higher probability of successful outcome in treatment of functional constipation and functional fecal incontinence than standard medical care, and that the margin of advantage may be substantial. We therefore recommend that BF be offered routinely to patients to augment standard medical care, especially because it is a safe and relatively inexpensive intervention that is well accepted by patients.
2. The empirical evidence is not sufficiently clear to provide an indication of which protocols are most likely to produce treatment success, and all of the commonly applied methods appear to have yielded good outcomes in multiple studies.

3. Continued research work is called for by the present state of the empirical literature in this domain, and these should primarily be well-designed randomized controlled outcome trials to conclusively establish efficacy, as well as large studies powered to analyze patient characteristics as predictors of outcome.

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