BIOFEEDBACK INTERVENTIONS FOR GASTROINTESTINAL CONDITIONS: A SYSTEMATIC REVIEW

Ian D. Coulter, PhD, Joya T. Favreau, MD, Mary L. Hardy, MD, Sally C. Morton, PhD, Elizabeth A. Roth, MA, and Paul Shekelle, MD, PhD

Ian D. Coulter is a professor at the University of California Los Angeles School of Dentistry and one of the principal investigators on the Southern California Evidence-Based Practice Center project on complementary and alternative medicine (RAND Corp, Santa Monica, Calif). Joya T. Favreau is the coordinator of integrative medicine education at Cedars-Sinai Medical Center. Mary L. Hardy is the medical director of the Integrative Medicine Program at Cedars-Sinai Medical Center and a principal investigator on the Southern California Evidence-Based Practice Center project on complementary and alternative medicine. Sally C. Morton is the codirector of the Southern California Evidence-Based Practice Center and head of the RAND Statistics Group. Elizabeth A. Roth is a senior programmer and analyst for the Southern California Evidence-Based Practice Center. Paul Shekelle is a senior research associate for the Veterans Affairs Health Services Research and Development Services and the director of the Southern California Evidence-Based Practice Center.

Objective • *To review evidence for the efficacy of biofeedback in the treatment of gastrointestinal problems.*
Data Sources • *Studies were identified through a search of MEDLINE, HealthSTAR, EMBASE, Allied and Complementary Medicine, MANTIS, PsycINFO, Social Science Citation Index, Science Citation Index, and CINAHL.*
Study Selection • *Studies were selected if they used biofeedback as the intervention, addressed the treatment of a gastrointestinal condition, and included a control group.*
Data Extraction • *All titles (4397), articles, and/or abstracts (1362) were evaluated by 2 independent reviewers who extracted data on study design and quality, sample size, type of intervention, and outcomes.*
Data Synthesis • *We found 16 controlled trials of biofeedback for gastrointestinal problems. Ten studies had a comparison group that did not receive biofeedback (5 studies on constipation and/or encopresis, 3 on fecal incontinence, 1 on constipation, and 1 on abdominal pain). Of the 10 studies that had a "no biofeedback" control arm, 7 provided sufficient data to calculate an effect size. Of these 7 studies,*

2 favored biofeedback: 1 study revealed a reduction in fecal incontinence among adults, and the other study showed an improvement in constipation with fecal incontinence (encopresis) among children. The other 5 had nonsignificant results. Three studies had a "no biofeedback" comparison arm but insufficient data to calculate an effect size. One of these studies in adult fecal incontinence reported statistically significant improvement.
Conclusions • *The evidence is insufficient to support the efficacy of biofeedback for these gastrointestinal conditions. (Altern Ther Health Med. 2002;8(3):76-83)*

Gastrointestinal (GI) conditions pose a significant health problem and can be challenging to manage. Epidemiologic data reveal that 60 to 70 million people in the United States are currently affected by at least one of the variety of GI conditions[1]; 1.4 million people are disabled by these conditions. GI conditions cost the public $107 billion annually, including $87 billion spent on direct medical costs and $20 billion spent on indirect costs (eg, disability).[1,2] Four common GI conditions have proven difficult to treat with conventional therapy: irritable bowel syndrome (IBS), constipation in adults, fecal incontinence in adults, and constipation and encopresis in children. Biofeedback has been proposed as an alternative or adjunct to conventional therapy for these conditions.

Irritable bowel syndrome is a frequent clinical problem encountered by primary-care physicians as well as gastroenterologists. Epidemiologic studies show a high prevalence in the general population, with an estimated 14% to 24% of women and 5% to 19% of men having IBS.[3] This disorder accounts for 12% of visits to primary care providers and 28% of visits to gastroenterologists,[4] resulting in 2.4 to 3.5 million physician visits and 2.2 million medication prescriptions written annually in the United States.[5,6] In addition, IBS patients have an inferior quality of life and higher healthcare utilization than persons without the disorder.[7,8] Patients with IBS have greater disability, a 3-fold higher absenteeism from work, and 2-fold higher annual average healthcare costs than typical Americans.[9,10] A recent critical review of the pharmacologic treatment of IBS found most of the evidence for various treatments to be inconclusive.[11] With the recent withdrawal (due to a possible association with ischemic colitis) from

the market of alosetron (Lotronex), the first new drug for IBS in years, the need persists for a safe and effective treatment.

Constipation in adults is the most common gastrointestinal (GI) complaint in the United States, affecting 4.4 million people at any given time. Most people treat themselves without seeking medical help, as is evident from the $725 million Americans spend on laxatives each year.[2] Despite self-medicating, constipation results in approximately 2 million annual doctor visits and 100000 annual hospitalizations.[1]

Fecal incontinence, defined as recurrent uncontrolled passage of fecal material, is a prevalent disorder that lacks adequate treatment. While the etiologies of this disorder vary, a large survey of US households indicated that 7% of the general population had fecal soiling, and almost 1% had gross fecal incontinence.[12,13] Fecal incontinence does not influence mortality, but several studies reporting lower quality of life measures on the Medical Outcomes Study Short-Form General Health Survey[14,15] indicate that the quality of life of these patients is greatly affected. Approximately $400 million is spent annually in the United States on appliances for fecal incontinence.[16]

Constipation with encopresis is common among children and has a prevalence of 1% to 2% in otherwise healthy school children.[17] Studies indicate that this condition accounts for 3% of visits to outpatient pediatric clinics[18] and 25% of visits to pediatric gastroenterology clinics.[19] Field surveys have shown that in western countries, up to 10% of children suffer from chronic constipation without encopresis.[20-22] Clinicians continue to struggle with these disorders because no adequate treatment is available.

A number of studies have hypothesized that the mind causes or contributes to GI disorders.[23-25] In the literature search described below, biofeedback was the most studied mind-body therapy for these GI conditions. Biofeedback is defined as a method that provides information to a patient about a targeted physiologic process that enables the individual to control that process through mental activity.[26,27] Medicare currently covers biofeedback for several conditions, including fecal and urinary incontinence. Precise estimates of the use of biofeedback are not available; however, a recent national survey found nearly 25% of all respondents had used biofeedback. Insurance coverage varied, but approximately 75% reported complete or partial insurance coverage.[28]

The purpose of this study is to synthesize the controlled trial evidence in the literature assessing the efficacy of biofeedback for GI conditions. The findings can be used to help healthcare providers care for patients with GI conditions and to identify future research needs.

MATERIALS AND METHODS
Literature Search

The following library databases were searched: MEDLINE, HealthSTAR, EMBASE, PsycINFO, Allied and Complementary Medicine, MANTIS, Psychological Abstracts, Social Science Citation Index, Science Citation Index, and CINAHL.

Our search included all studies focusing on mind-body therapies. We used the following Medical Subject Headings (MeSH) terms and the time interval 1974 to1999: mind/body metaphysics; mind body therapies; mind/body medicine; mind/body wellness; bodymind medicine; mind/body therapies; psychosomatics, psychosomatic, and psychosomatic medicine; wisdom of the body; self healing; placebo; healing force of nature; healing consciousness; biopsychosocial; psychoneuroimmunology; and wellness. We supplemented our database search by searching reference lists and conducting a survey of experts.

Two independent reviewers examined all titles, abstracts, and articles and resolved disagreements by consensus. The articles were not blinded or masked. Article review was intended to clearly delineate the mind-body modality used, the targeted body systems and conditions, the outcomes measured, and the type of study design used. All controlled trials were given a quality score based on the Jadad system,[29] which rates trials on a 0 to 5 scale, based on randomization, blinding, withdrawals, and dropouts.

As shown in Figure 1, we identified 4397 titles, from which 1362 articles were selected for further review, yielding 16 trials on biofeedback. Ten of the 16 had a "no biofeedback" comparison arm, and 7 of those 10 contained sufficient data to calculate an effect size. The other 6 studies did not have a "no biofeedback" comparison arm and compared different types of biofeedback or biofeedback-to-biofeedback plus additional therapies.

For the studies that compared biofeedback to a "no biofeedback" control group, we extracted the most clinically relevant outcome that could be converted into either a risk ratio (for dichotomous outcomes) or an effect size (for continuous outcomes). We excluded studies that did not have sufficient data to calculate either a risk ratio or an effect size with an associated confidence interval. Of the remaining 7 studies, 5 had clinically similar dichotomous outcomes. For each, we calculated a risk ratio and associated 95% confidence interval using the statistical package Stata (Stata Corporation, College Station, Tex). Since an event indicated a success in terms of each of these outcomes, a risk ratio greater than 1 indicates that the biofeedback treatment was successful compared to the control intervention. For the remaining studies, we calculated an effect size whose numerator was a "difference of differences," that is, the difference between the postintervention and preintervention means for the treatment group minus the same difference for the control group, and whose denominator was the pooled standard deviation. We used the unbiased effect-size estimate, assuming a correlation of 0 between the preintervention and postintervention measures, and calculated a 95% confidence interval using the formula given in Hedges and Olkin.[30] Since a higher value of each continuous measure indicates that the intervention is successful, a higher value of the effect size indicates that the biofeedback treatment was successful compared to the control intervention.

Given the heterogeneity of the studies selected, these individual study statistics are not pooled together into an overall risk ratio or effect size.

RESULTS
Quality of the Evidence

Complementary and alternative therapies, including
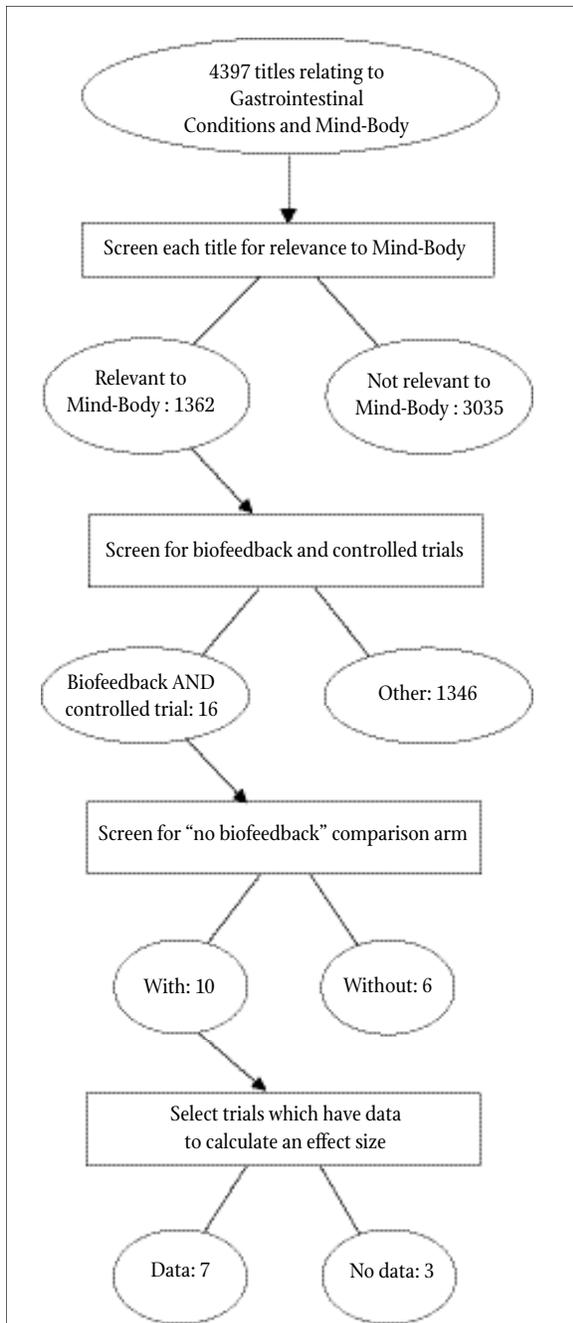
FIGURE 1. Selection and screening process for studies of biofeedback interventions in gastrointestinal conditions.

biofeedback, pose particular methodological challenges. With biofeedback, it is not feasible to do a double-blind study, and none of the studies were thus described. Conceptually, therefore, the maximum possible Jadad score for biofeedback studies is 3. Thirteen of the studies were described as randomized, but only 6

reported appropriate randomization. The remaining studies did not report on their method of randomization. Of the 16 studies, 5 had a Jadad score of 3, 5 had a score of 2, and 6 had a score of 1 or 0. Empiric evidence in other fields has shown that studies scoring 2 or lower report exaggerated results compared with studies scoring 3 or higher.[31] A further methodological problem common to most studies was lack of statistical power. A "small" effect size (the absolute value of difference in the treatment and control group means divided by the standard deviation) is commonly defined as .2, a "medium" effect size as .5, and a "large" effect size as .8.[32] Of the 16 biofeedback studies identified, 2 (12%) had sufficient power to detect a medium-sized effect, 3 studies (19%) were powered sufficiently to detect a large effect, and 11 studies (69%) had less than 25 patients in each comparison group, meaning they were not powered to detect even large effects.

Evidence Synthesis

A summary of the evidence from the 10 studies with a "no biofeedback" group is presented in the Table. Of the 10 studies with a "no biofeedback" comparison arm, 7 had sufficient data to calculate an effect size, shown in Figure 2, which displays 2 side-by-side plots in which the studies are ordered vertically by population (adults and children), by condition (fecal incontinence and constipation) for the adults, then by comparison group, and then by sample size. The risk ratios are plotted on the log odds scale. Of these 7 studies, 2 favored biofeedback. One study reported a reduction in fecal incontinence among adults, and the other study reported an improvement in constipation with encopresis among children.

The study favoring biofeedback to reduce fecal incontinence among adults was performed by Miner, Donnelly, and Read.[33] They randomized 25 subjects (68% women, aged 30 to 76 years) to biofeedback or a control group. During three 20-minute sessions, these subjects were taught how to recognize when a rectal balloon was inflated with small volumes of air and to reduce or eliminate their sensory delay. The control group was taught the same procedure, but they received no instruction on how to improve their performance. The authors reported that biofeedback significantly reduced the fecal incontinence episodes per week, but the control intervention did not (Figure 2). The functional improvement was sustained more than 2 years in those patients available for follow-up (73%). The Jadad score for this study is 2 for randomization and description of withdrawals and dropouts.

Biofeedback used by children (aged 5 to 16 years, N = 66) who had constipation with encopresis was evaluated by van der Plas et al in comparison to usual and customary care.[34] These researchers reported that at 6 months, children receiving biofeedback training showed higher success rates than the control group. Successful treatment was defined as less than 2 episodes of fecal incontinence, regular bowel movements, and no laxatives. The Jadad score for this study is 3 for appropriate randomization and a description of withdrawals and dropouts.

Of the remaining 5 studies, none had statistically significant results favoring biofeedback (Figure 2). Four studies that

Evidence table of studies, by population and condition

Study, year	Condition	Comparison group	Number of subjects	Design	Mean age or range (y)	% women	Follow-up	Outcome	Jadad score
Miner et al, 1990[34]	Fecal incontinence (adults)	Rectal balloon, without directions on improvement	25	RCT	30-76	68	> 6 mo	Fecal incontinence	2
Guillemot et al, 1995[36]	Fecal incontinence (adults)	Usual and customary care	24	CCT	Not reported	56	6 mo	Fecal incontinence	1
McHugh et al, 1986[37]	Fecal incontinence (adults)	Dietary fiber	15	RCT	55	67	> 6 mo	Fecal incontinence	2
Koutsomanis et al, 1995[38]	Constipation (adults)	Rectal balloon, without directions on improvement	51	RCT	20-63	88	> 6 mo	Stool frequency	3
van der Plas et al, 1996[39]	Encopresis* (children)	Usual and customary care	187	RCT	9	44	> 6 mo	Stool frequency and fecal incontinence	2
Loening-Bauck et al, 1995[40]	Encopresis (children)	Usual and customary care	129	RCT	10	24	4.1 y	Stool frequency and fecal incontinence	3
van der Plas et al, 1996[35]	Encopresis (children)	Usual and customary care	66	RCT	5-16	33	> 6 mo	Stool frequency, fecal incontinence, use of laxatives	3
Wald et al, 1987[41]	Encopresis (children)	Usual and customary care	45	RCT	6-15	20	12 mo	Stool frequency and fecal incontinence	2
Nolan et al, 1998[42]	Encopresis (children)	Usual and customary care	29	RCT	4-14	7	6 mo	Stool frequency	2
Benninga et al, 1996[43]	Recurrent abdominal pain (children)	Usual and customary care	29	RCT	9	55	< 6 mo	Abdominal pain	1

CCT indicates controlled clinical trial; RCT, randomized controlled trial.

* Fecal incontinence with constipation.

Adults	Time at follow-up, Outcome	Sample Size	Comparison Group	Risk Ratio	Effect Size
Fecal Incontinence					
Miner, 1990[34]	1 month, decrease in incontinent episodes per week	n=25	vs sham biofeeedback		
Constipation					
Koustsomanis, 1995[38]	FU not reported, bowel frequency increased	n=51	vs muscle training		
Children					
Constipation with Fecal Incontinence (Encopresis)					
van der Plas, 1996[39]	6 months, success	n=187	vs conventional		
Loening-Baucke, 1995[40]	4.1 years, stools per week	n=129	vs conventional		
van der Plas, 1996[35]	6 months, success	n=66	vs conventional		
Nolan, 1987[42]	6 month, remission	n=29	vs conventional		
Wald, 1998[41]	6 month, remisssion or markedly improved	n=45	vs mineral oil		

Risk Ratio scale: 0.1 1 2 7   Favors Treatment

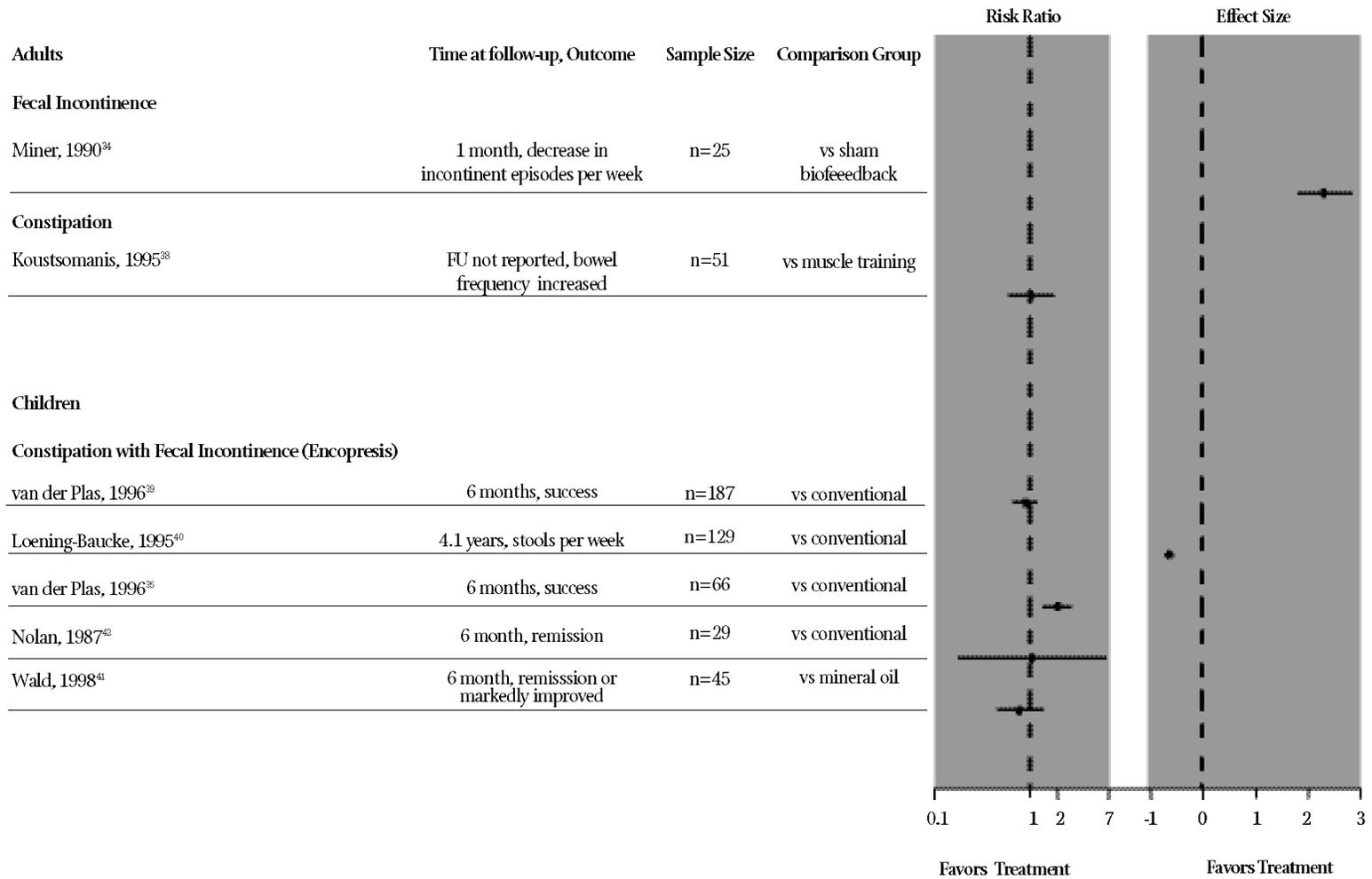Effect Size scale: -1 0 1 2 3   Favors Treatment

FIGURE 2 Effect size/risk ratio on 7 studies with sufficient data and a "no biofeedback" control arm

compared biofeedback to usual and customary care in children with constipation and encopresis ranged in size from 29 to 59 subjects.[35-38] Outcomes, including fecal incontinence episodes and frequency of bowel movements, were measured from 3 to 18 months; 1 study had a 4-year follow-up. None of the 4 studies reported a statically significant effect favoring biofeedback. One study[39] evaluated adults with constipation (N = 51) and showed no improvements in frequency of bowel movements.

Three studies had a "no biofeedback" comparison arm but did not have sufficient data to calculate an effect size. One of these studies reported a significant effect for biofeedback.

Guillemot et al[40] examined results from a controlled clinical trial of biofeedback to treat fecal incontinence in 24 adult men and women over 6 months. The authors reported that the fecal incontinence score was significantly lower at 6 months for the biofeedback group (n = 16) than for the control group (n = 8) that received usual and customary care. However, the improvement deteriorated over time (30 months); no biofeedback was given after 6 months. The Jadad score for this study is 1 for withdrawals and dropouts.

McHugh et al[41] reported on a randomized study of fecal incontinence in 18 subjects (67% women, mean age 55 years) that compared a dietary fiber intervention to a standardized biofeedback protocol and to a voluntary sphincter exercise. This study used a crossover design. Outcomes measured included fecal incontinence, fecal staining, and number of bowel movements. There was no significant difference in treatment results between the biofeedback and the voluntary sphincter exercise. The Jadad score for this study is 2 for randomization and description of withdrawals and dropouts.

In a third study in children (55% girls, median age 9 years, n = 29), Benninga et al[42] found that children with recurrent abdominal pain benefited equally from biofeedback and usual and customary care and from usual and customary care alone. The Jadad score for this study is 1 for randomization.

Lastly, 6 studies used some form of biofeedback in all study arms. Because none of these studies had a "no-biofeedback" arm, they could not establish the efficacy of biofeedback itself, only the comparative efficacy of various types of biofeedback.[43-48]

In summary, our literature search identified 10 studies (5 on constipation with encopresis, 3 on fecal incontinence, 1 on constipation, and 1 on abdominal pain in children) that provided information on the efficacy of biofeedback.

COMMENT

Our literature search did not find convincing evidence supporting the efficacy of biofeedback for these GI disorders. In 5 controlled trials of biofeedback in children that provided sufficient data to calculate an effect size, all but 1 study failed to demonstrate statistically significant benefits. Furthermore, there is no evidence to suggest that these negative results were due to insufficient statistical power because in 3 studies the point estimate of effect actually favored the comparison group. Only 1 study provided appropriate data to calculate an effect size in adults, and it supported the use of biofeedback for fecal incontinence. One study of biofeedback in adults had a quality score characterized as "good," and this study did not report any benefits of biofeedback. We also found 3 studies of lesser quality, 1 reporting no benefit and 2 reporting some benefit of biofeedback. These diverse results will need to be clarified by additional research.

Despite reports (as anecdotes or case series) of effective treatment for fecal incontinence with biofeedback, we identified only 3 studies that appropriately address efficacy. Two of the 3 studies reported benefits from biofeedback for adults with fecal incontinence; however, both had a quality score of "poor." Additionally, specific causes of fecal incontinence were rarely identified. Perhaps biofeedback is

beneficial for certain subgroups of patients. Future research needs to focus on randomized controlled trials that compare biofeedback to medical management, with a subgroup analysis based on the etiology of the disease.

Several factors prevent any stronger conclusions being drawn from the data. Because of the heterogeneity of the studies, insufficient data on means and variance measures, we could not perform a meta-analysis. Instead, we have attempted in our discussion of the results to consider each study individually and together with other studies of the same condition. Secondly, the identified studies had many methods problems, including insufficient statistical power and design flaws. However, as previously noted, there is no evidence to suggest that studying more subjects would have resulted in more favorable results, and research in other fields shows that studies with better design and execution usually report smaller rather than larger effects of an intervention. Therefore, it is unlikely that insufficient statistical power or design flaws alone are responsible for the negative results to date.

Biofeedback may be efficacious for other medical conditions, but, based on the studies we examined, there is no strong evidence supporting biofeedback as a useful treatment for the GI diseases on which we focused. Future studies need to be randomized controlled trials of well-defined populations with adequate sample size to allow for meaningful statistical analysis and appropriate length of follow-up. Until such studies are reported, the use of biofeedback for these GI conditions is based more on faith than evidence.

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