REVIEW ARTICLE

Biofeedback therapy in fecal incontinence and constipation

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Abstract We examine the collected evidence for efficacy of biofeedback therapy (BFT) in incontinence and constipation by means of meta-analysis of randomized controlled trials. PubMed search was performed to identify treatment trials that match quality criteria (adequate control groups, randomization). They were entered into meta-analyses using fixed effect models and computing odds ratio (OR) and 95% confidence interval (CI) of treatment effects. For constipation, eight BFT trials were identified. In four trials, electromyographic (EMG) BFT was compared to non-BFT treatments (laxatives, placebo, sham training and botox injection), while in the remaining four studies EMG BFT was compared to other BFT (balloon pressure, verbal feedback) modes. Meta-analyses revealed superiority of BFT to non-BFT (OR: 3.657; 95% CI: 2.127–6.290, P < 0.001) but equal efficacy of EMG BFT to other BF applications (OR: 1.436; CI: 0.692–3.089; P = 0.319). For fecal incontinence, a total of 11 trials were identified, of which six compared BFT to other treatment options (sensory training, pelvic floor exercise and electrical stimulation) and five compared one BFT option to other modalities of BFT. BFT was equal effective than non-BFT therapy (OR: 1.189, CI: 0.689–2.051, P = 0.535). No difference was found when various modes BFT were compared (OR: 1.278, CI: 0.736–2.220, P = 0.384). Included trials showed a substantial lack of quality and harmonization, e.g. variable endpoints and missing psychological assessment across studies. BFT for pelvic floor dyssynergia shows substantial specific therapeutic effect while BFT for incontinence is still lacking evidence for efficacy. However, in both conditions the mode of BFT seems to play a minor role.

Keywords biofeedback therapy, constipation, incontinence.

A SHORT HISTORY OF BIOFEEDBACK APPLICATIONS IN MEDICINE

Biofeedback is a learning strategy originating from psychological learning theories, more specifically from ‘instrumental learning’ and ‘operant conditioning’ in the tradition of B. F. Skinner (1904–1990): If a behaviour, be it a complex human performance such as eating or a simple physiological task such as a muscle contraction, – is reinforced by intrinsic or extrinsic means, its likelihood to be repeated increases according to certain laws. Later, N. E. Miller [1909–2002] proposed that not only observable and verbal behaviour, but also the behaviour of autonomic functions may be ‘shaped’ in this way. Although this data could only be partially replicated in independent laboratories, it became evident that this technique carried the potential for a variety of applications in both psychology and medicine. Several published books, a few journals and hundreds of papers of – the late 1960s and early 1970s – expressed great enthusiasm about this possibility. A North Atlantic Treaty Organization conference in 1976,† which assembled more than seventy biofeedback researchers from around the
world, substantiated a broad range of applications for biofeedback technology in various areas of medicine. Among all areas of medicine, cardiovascular approaches received the most attention. Nevertheless, initial reports in journals such as Nature, The Lancet and the New England Journal of Medicine that supported the use of BFT as a way to control heart rate and blood pressure in patients diagnosed with cardiovascular diseases could not be substantiated later on. This is symptomatic of the belief in those days that behavioural medical approaches may eventually overcome the clinical limitations of conventional medicine in functional bodily disorders. Only very little of this belief can be found in today’s clinical medicine.

The comparably late start of the use of biofeedback applications in the field of gastroenterology was denoted in 1974 by the publication of a study that focused on biofeedback applications in patients with fecal incontinence and a review in the journal Gastroenterology. Interestingly, these applications were initially attributed to neuromuscular disorders and their treatment by biofeedback rather than to gastroenterology. The first published study by Schuster et al. marked the start of a series of studies, – both well and less well controlled, – in the treatment of fecal incontinence. The authors used a three-balloon system previously developed for anorectal manometry to provide visual feedback of recto-sphincteric reflex responses of both – internal anal sphincter relaxation and external anal sphincter contraction following rectal balloon distension – by means of observing a chart recorder. For many years, this has been the standard of biofeedback training in various laboratories. These initial studies included both adults and children, but later authors established a similar use of biofeedback therapy especially for incontinent children, and specifically for those with congenital disorders and encopresis.

However, the true beginning is illustrated by another case report by Kohlenberg in 1973. Kohlenberg treated a 13-year-old boy with fecal incontinence (encopresis and soiling) with a history of colorectal surgery (questionable) Hirschsprung’s Disease 2 years previously. At the time of the study the boy was supposed to undergo colectomy. It remains unclear from the publication whether the authors provided feedback from the anal sphincter (resting pressure) only, or from the external anal sphincter and rectum. Using a 3 cm balloon across the anal canal, the subject was taught to increase anal sphincter pressure. This resulted in a resting pressure increase of 35 mmHg at baseline to 50 mmHg posttreatment. Despite this increase, anal sphincter pressure remained too low to reliably maintain continence. Consequently, clinical improvement is poorly documented and reported.

When the first study that treated a series of patients with electromyographic (EMG) biofeedback was published in 1979, these historical roots of biofeedback training had already mostly been lost. Investigators using this technique often attributed it to physical therapy and rehabilitation. Consequently, BFT applications for the treatment of chronic constipation due to pelvic floor dyssynergia (anismus, spastic pelvic floor syndrome and puborectalis paradox), which started in 1987, but were renounced in 1980 were predominantly proposed and performed by paediatric and adult surgeons. In 1979, Schiller et al. successfully used a rectal infusion of saline as a training mode to improve sphincter functions in a patient with incontinence and chronic diarrhoea. This was a landmark study that supported the application of psychology-generated and theory-driven therapeutic strategies into clinical medical routine.

In summary, the approximate 30 years history of biofeedback training and the more than 20 years of its application in gastroenterology have resulted in two distinct and successful therapy modalities. These modalities have become the treatment of choice in clinical centres worldwide.

Randomized and controlled clinical trials for both incontinence and constipation will be meta-analysed to assess their overall efficacy in this review for the first time. Previous meta-analyses have only focussed on either incontinence or constipation.

METHODS

Two PubMed searches were conducted for publications of treatment trials between 1980 and 2008 using the following terms:

- Incontinence AND biofeedback; [fecal OR faecal] incontinence AND biofeedback; stool-incontinence AND biofeedback.
- Constipation AND biofeedback; anismus AND biofeedback; obstructive defecation AND biofeedback; dyschezia AND biofeedback; dyssynergia/dyssynergy AND biofeedback.

Reviews of the references found from the articles produced by the PUBMED search, including previous reviews and meta-analyses, were used to supplement data collection. Treatment trials with children were excluded (step 1), as were non-controlled and non-randomized trials (step 2). Only trials published in English language were selected.

All trials were independently assessed for eligibility by the authors (PE, IvdV). Data was then extracted from the selected publications. Any disagreement was resolved with a third independent reviewer (SK). Extracted data included the number of patients per treatment arm or who profited from therapy based on the primary outcome measure, or the average change of the primary outcome measure per treatment arm. Selected trials for each clinical condition (incontinence, constipation) were then subjected to different meta-analyses (Comprehensive Meta Analysis Version 2; Biostat, Englewood, New Jersey, USA) using fixed
effect models and computing odds ratios (OR) and 95% confidence intervals (CI). Significance levels were set at 0.05 for all tests.

**BIOFEEDBACK TREATMENT OF FECAL INCONTINENCE**

Reviews of BF applications in the treatment of fecal incontinence have been previously reported by us and others over the past 15 years, and it was always claimed that appropriately controlled clinical trials were missing. This has changed over the last decade, as a meta-analysis could show; therefore, this review focuses on randomized controlled trials only. Excluding treatment trials with children and uncontrolled, non-randomized trials, we identified 11 randomized and controlled trials that included various different control conditions (Fig. 1, Table 1).

**CONTROLLED TRIALS OF BF IN INCONTINENCE**

Among the 11 randomized and controlled trials, nine were included into the meta-analysis, while two were excluded: the study by Latimer et al. is a single case design with eight subjects that underwent different treatment modules in variable succession and therefore, no group comparison can be computed. The study by Davis et al. compares two strategies of surgery for anal sphincter repair, one with and one without biofeedback supplement and reports superiority of BF supplementation over surgery alone. However, the relative contribution of BF was not controlled for, e.g. by a pure education or pelvic floor exercise (PFE) group, and therefore cannot be estimated.

The remaining nine studies can be subdivided into two groups: one group with five studies that compared different modalities of BF, e.g. sensory training alone, BF augmented by electrical stimulation, or BF by ultrasound, to ‘pure’ EMG BF (see Table 1).

For the study by Norton et al., group 3 (BF alone) was compared to group 5 (BF plus additional home training), for the study by Solomon et al., we included group 2 (BF by manometry) and group 1 (BF by ultrasound).

The other group compared EMG BF to other forms of therapy, mostly PFEs. Six studies were included that compared BF to PFEs to sensory training, to treatment as usual (TAU, group 1 in the study by Norton et al.), or to electrical stimulation.

This grouping and sequence of presentations partially reflects the historical course of published studies, rather than a logical course. Initially, the different biofeedback modes were tested against each other, as there was no ‘TAU’, and a ‘no treatment control’ seemed unethical given the psychological burden of the patients. The other options of management appeared after the initial success of BF.

Meta-analysis revealed similar efficacy of basic BF protocol over other BF modes in terms of efficacy of treatment compared to true sham stimulation, a similar efficacy of these therapies to BF was noted.

When BF was compared to other treatment options, similar efficacy of these therapies to BF was noted.

Given the small number of studies that were included into the meta-analyses, this result in not surprising. As is evident from the forest plot in Fig. 2(B), the two largest studies are responsible for the overall negative result, while the three small scale studies reported positive results. It should be noted, however, that similar to small scale drug studies, the risk of placebo responses is substantially higher with small sample sizes. It is also evident from the studies reported here that BF is lacking a true medical control treatment, as the PFE regimens that were adopted to match BF vary substantially in the number of sessions, the duration of treatment and the amount of supplementation, e.g. by home training.

So far, the most well controlled study by Norton et al. points into another direction. As it seems from their four-arm study, patients benefit an average of 70% irrespective of the individual treatment they received, and with or without BF. This leaves the question open as to whether this reflects a placebo response only, or whether specific and unspecific effects are mixed. In a recent study evaluating electrical stimulation therapy compared to true sham stimulation, a similar result was found. Patients in both groups improved significantly in symptoms, but not in physiological measures of anorectal function; thus, supporting the notion that predominantly unspecific (placebo) effects may be responsible for treatment effects. Future studies will have to prove or disprove this.
BIOFEEDBACK TREATMENT OF CHRONIC CONSTIPATION

Similar to the treatment of fecal incontinence, a large number of uncontrolled or poorly controlled trials of BFT in pelvic floor dyssynergia were published before randomization of different control conditions became standard. Similar to a recent meta-analysis, we identified eight randomized controlled trials of BF therapy in constipation [Fig. 1, above].

CONTROLLED TRIALS OF BF IN CONSTIPATION

The eight randomized controlled treatment trials reflect two distinct treatment modalities. In four (earlier) studies different modes of BF training were compared, and patients were randomized to receive one of the treatments options. In contrast, the most recent studies compared BF training to conventional non-BF treatment, including laxatives, diazepam, botox injection and TAU (Table 2).

Separate meta-analyses both treatment groups reveal overall equal efficacy of EMG BF treatment compared to other modes of BF (Fig. 3A), but moderate superiority of BFT over different conventional treatments for constipation of pelvic floor dyssynergia type (Fig. 3B). As can be seen, the meta-analysis does not favour EMG BFT alone over other BF treatment modalities (pressure BF, visual feedback only) (OR = 1.436; CI: 0.692–3.089; P = 0.319, ns).

When EMG BFT was compared to non-BF therapies, three of the four studies reported superiority of BFT while one did not; this yields an overall OR of 3.657
Figure 2  [A] Forest plot of five incontinence treatment studies comparing BFT studies [EMG or pressure BF] to other BFT modalities. Other BF modes included additional electrical stimulation [add EMG or pressure BF], additional home training [add HT], and balloon pressure [P]; see text for details. The odds ratio [OR] [1.278] and the 95% confidence interval [CI: 0.736–2.220] indicate non-significant differences [P = 0.384] and similar efficacy. [B] Forest plot of six incontinence treatment studies comparing BFT studies [EMG or pressure BF] to other treatment modalities. Other treatments pelvic floor exercises [PFE], sensory training [Sens T], treatment as usual [TAU], and electrical stimulation [E Stim]; see text for details. The OR [1.189] and the 95% CI [0.689–2.051] indicate non-significant differences [P = 0.535] and similar efficacy.

A recent meta-analysis\(^{35}\) that included seven of the eight trials discussed here noted a substantial lack of quality of trials: the authors noted unclear randomization and concealment, missing sample size calculation, missing or incomplete blinding, and a high loss to follow up. Most surprising is the fact that none of the trials used quality-of-life criteria as primary or secondary endpoints, despite the widely acknowledged fact that chronic constipation affects daily quality-of-life substantially.\(^{42}\) Only three of the eight studies\(^{11,29,30}\) refer to this fact in the introduction and/or discussion and only two\(^{29,30}\) assess the psychological features of constipated patients prior and/or posttherapy.

**DISCUSSION**

Thirty years of biofeedback application and more than 20 years of its application in gastroenterology, have resulted in two distinct and successful therapy modalities which have become the treatment of choice in clinical centres worldwide. As was noted early in the history of BFT,\(^1\) randomized controlled trials will become important to separate specific treatment effects from unspecific placebo effects, which are due to the enormous amount of attention and time BFT provides to patients. As our two meta-analyses seem to indicate, BFT is still lacking sufficient evidence for efficacy in fecal incontinence. This is probably due to a lack of alternative and conventional medical treatment options against which it can be compared, while in constipation caused by pelvic floor dyssynergia, the
overall success seems warranted. This is a surprising finding, given the fact that the use of BFT in incontinence has an almost 20 years longer history than the use of BFT in chronic constipation, and has generated a larger body of clinical evidence, although lower in degree, i.e. with less randomized controlled trials. This is probably due to the more homogenous patient population of "pelvic floor dyssynergia" compared to

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### Table 2 Randomized controlled trials of BFT in constipation

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### Figure 3

(A) Forest plot of four constipation treatment studies included comparing BFT studies (EMG BF) to other BFT modalities. Other BF modes included pressure and balloon FB, verbal feedback only, and additional modes (plus add) such as additional home training; see text for details. The odds ratio (OR) (1.436) and the 95% confidence interval (CI: 0.692–3.089) indicate non-significant differences (P = 0.319) and similar efficacy.

(B) Forest plot of four constipation treatment studies included comparing BFT studies to non-BFT modalities. Non-BFT included laxatives, placebo, sham feedback, and botox injection; see text for details. The OR (3.657) and the 95% CI (2.127–6.290) indicate significant superiority of BFT over other therapies (P < 0.001). SGA, subjective global assessment of therapy efficacy.
‘fecal incontinence’. In both cases, however, patient selection, screening, therapy modalities, and evaluation of therapeutic success are far from being standardized, and may substantially affect the currently reported success rates.

With both indications, incontinence and constipation, we noted a subdivision of the few randomized studies: one that tested BFT against other modifications of BFT, and one that tested BFT against various other treatment options available. Both strategies reflect a methodological problem that occurs with many treatments in a routine medical setting, in contrast to an experimental psychology setting. True sham biofeedback means ‘false feedback’ and is not easy to implement and difficult to blind, and other placebo treatment options raise ethical concerns when patients are expecting clinical help for a socially devastating medical condition.

As the study by Koutsomanis et al., it has been questioned whether instrumental feedback is really necessary to achieve treatment success. In this study, the investigators compared a group which received verbal feedback by an instructor to a group receiving feedback by visual display of pelvic floor EMG during straining. It was shown that the response rate was similar in both groups and resulted in improvement of approximately 50%. The authors conclude that ‘training in abdominal muscle contraction with pelvic floor relaxation is equally effective with or without a measuring device’, but admit that constant encouragement and praise by an instructor is necessary, as is a ‘good rapport between patient and instructor’ (ibid, p. 99). Other studies have found similar results with constipation treatment and a recent non-controlled study found a telephone assessment was equally effective as a face-to-face evaluation in patients with incontinence.

From a psychological standpoint it is not surprising to learn that verbal instruction and reinforcement can be as effective a feedback mode as a visual or auditory mediated technical feedback display. It may only be surprising for physicians not used to sitting with their patients for much longer that a few minutes. The more important question, generated by these papers is whether constant verbal instruction is the more practical (and affordable) way of BFT than the use of simple designed measurement devices (and not a physiological laboratory) which may be taken home with the patient. This would allow more training, privacy, and lower total costs in comparison to other modalities previously used. As can be seen in Tables 1 and 2, the modalities of home training have not yet been thoroughly explored.

More recent papers demonstrated biofeedback treatment to be effective in patients with chronic anal pain and solitary rectal ulcer syndrome but all these studies are still uncontrolled and it remains to be shown whether these conditions offer further applications of BFT for pelvic floor disorders.

**IS THERE A FUTURE FOR BFT IN GASTROENTEROLOGY?**

As stated above, the few applications of BF technique in gastroenterology, besides the use of BFT for the treatment of incontinence and constipation, have not gained clinical importance due to a lack of independent replication and randomized controls. However, this can be partially attributed to technological problems, such as the inaccurate measurement of biological events in the gastrointestinal tract or their inappropriate and non-contingent feedback to the patient. As an example, the early studies on BF application to control gastric acid secretion in peptic ulcer disease by Moore and Schenkenberg and Welgan used rather unreliable gastric juice aspiration techniques to measure acid output, their feedback technique was either visual or auditory, respectively, but presented at intervals not allowing fast contingent feedback. However, with the frequent availability of portable pH-monitoring systems which allow contingent and continuous feedback of acidity, it should be feasible to test a BF application, e.g. to control for lower oesophageal sphincter competence in preventing gastro-oesophageal reflux disease. Similarly, monitoring of [radiolabelled] gastric emptying, bile reflux, small bowel motility and/or electro-gastrography should be possible with currently available recording technology.

Integrated psycho-somatic or bio-behavioural approaches in the treatment of gastrointestinal diseases have attracted attention in the past mainly when conventional medical treatment, e.g. pharmaceutical or surgical strategies have failed. The history of peptic ulcer disease is a well-established example, shifting back and forth from psychosomatic medicine to gastroenterology for the last 50 years whenever new technologies were born (e.g. selective vagotomy, gastroscopy), new drugs were developed (H2 blockers, protease pump inhibitors), and insights were gained (e.g. on the role of helicobacter pylori infection). Maybe, such a dualistic way of thinking, a disease being either somatic or psychosomatic, will fade in the future. It is evident from the examples of fecal incontinence and chronic constipation, that behavioural medical techniques, such as biofeedback, are not thought of as alternative medical treatments, but as a
valuable routine management possibility at low costs and with little or no side-effects.51

At least for constipation due to pelvic floor dyssynergia (anismus, spastic pelvic floor syndrome) the collected evidence underlines superiority of BFT over other management options and makes BFT the treatment of choice for this condition. In contrast, BFT for fecal incontinence is not different in efficacy from other treatment modalities.

A more homogenous disease mechanism in case of ‘pelvic floor dyssynergia’ as compared to ‘fecal incontinence’ may account for this difference in BFT efficacy.

ACKNOWLEDGMENT

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39 Chiarioni G, Whitehead WE, Pezza V, Morelli A, Bassotti G. Biofeedback is superior to laxatives for normal transit constipation due to pelvic floor dyssynergia. *Gastroenterology* 2006; **130**: 657–64.

40 Heymen S, Scarlett Y, Jones K, Ringel Y, Drossman D, Whitehead WE. Randomized, controlled trial shows biofeedback to be superior to alternate native treatments for patients with pelvic floor dyssynergia-type constipation. *Dis Colon Rectum* 2007; **50**: 426–41.

41 Whitehead WE, Palsson OS, Levy RL et al. Reports of ‘satisfactory relief’ by IBS patients receiving usual medical care are confounded by baseline symptom severity and do not accurately reflect symptom improvement. *Am J Gastroenterol* 2006; **101**: 1057–106.


