neurogastroenterology & motility

Neurogastroenterol Motil (2009) **21,** 1133–1141 doi: 10.1111/j.1365-2982.2009.01345.x

REVIEW ARTICLE

Biofeedback therapy in fecal incontinence and constipation

P. ENCK,* I. R. VAN DER VOORT† & S. KLOSTERHALFEN*,‡

*University Hospital, Department of Psychosomatic Medicine and Psychotherapy, Tübingen, Germany
†University Hospital Charité, Department of Gastroenterology, Berlin, Germany
‡Institute of Clinical Neurobiology and Medical Psychology, University of Düsseldorf, Düsseldorf, Germany

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.*

Address for correspondence
Professor Dr Paul Enck, Tübingen University Hospital, Department of Psychosomatic Medicine and Psychotherapy, Research Laboratories, Frondsbergstr 23, 72076 Tübingen, Germany.
Tel: +49 7071 29 89118; fax: +49 7071 29 4382;
e-mail: paul.enck@uni-tuebingen.de
Received: 7 January 2009
Accepted for publication: 21 April 2009

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,[1] which assembled more than seventy biofeedback researchers from around the

© 2009 Blackwell Publishing Ltd

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*,[2] *The Lancet*[3] and the *New England Journal of Medicine*[4] 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[5] and a review in the journal *Gastroenterology*.[6] Interestingly, these applications were initially attributed to neuromuscular disorders and their treatment by biofeedback rather than to gastroenterology.[1]

The first published study by Schuster *et al.*[5] 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[7] 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[8] 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[9] in 1973. Kohlenberg treated a 13-year-old boy with fecal incontinence (encopresis and soiling) with a history of colorectal surgery for (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) BFT was published in 1979,[10] 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,[11] but were renounced in 1980[12] were predominantly proposed and performed by paediatric and adult surgeons. In 1979, Schiller *et al.*[13] 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 (see below) 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

© 2009 Blackwell Publishing Ltd

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[14–17] and others[18–20] 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;[21] 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.*[22] 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.*[23] compares two strategies of surgery for anal sphincter repair, one with and one without biofeedback supplement and reports superiority of BFT supplementation over surgery alone. However, the relative contribution of BFT 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 BFT, e.g. sensory training alone, BFT augmented by electrical stimulation, or BF provided by ultrasound, to 'pure' EMG BFT (see Table 1).

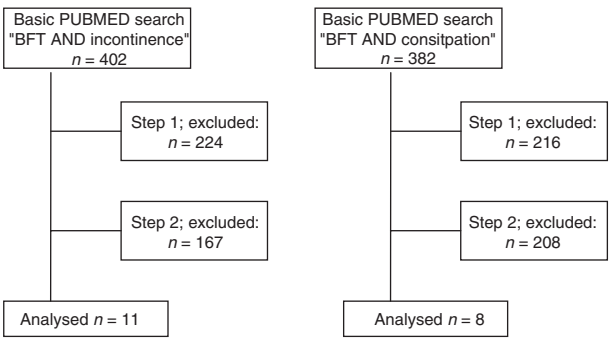

Figure 1 Selection and screening process of PubMed literature for BFT studies in fecal incontinence (left) and constipation (right) (see text for details of the search terms).

For the study by Norton *et al.*,[24] group 3 (BFT alone) was compared to group 5 (BFT plus additional home training), for the study by Solomon *et al.*,[25] we included group 2 (BFT by manometry) and group 1 (BFT by ultrasound).

The other group compared EMG BFT to other forms of therapy, mostly PFEs. Six studies were included that compared BFT to PFE,[22,25,26] to sensory training,[27] to treatment as usual (TAU, group 1 in the study by Norton *et al.*),[24] or to electrical stimulation.[28]

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 BFT.

Meta-analysis revealed similar efficacy of basic BFT protocol over other BF modes in terms of efficacy (Fig. 2A) (OR = 1.278, 95% CI: 0.736–2.20, $P = 0.384$). When BFT was compared to other treatment options, similar efficacy of these therapies to BFT was noted (OR = 1.189, CI: 0.689–2.051; $P = 0.535$) (Fig. 2B).

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[29,30] 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.[31] It is also evident from the studies reported here that BFT is lacking a true medical control treatment, as the PFE regimens that were adopted to match BFT 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.*[24] 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[32] 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[33] will have to prove or disprove this.

© 2009 Blackwell Publishing Ltd

Table 1 Randomized controlled trials of BFT in fecal incontinence

References	*n*	Age (years)	Age range (years)	Sex (F : M)
Latimer *et al.* (22)	8	30.1	8–72	4 : 4
Whitehead *et al.* (27)	18	72.7	65–92	15 : 3
Miner *et al.* (52)	25	54.6	17–76	17 : 8
Fynes *et al.* (53)	40	32	18–48	40 : 0
Heymen *et al.* (54)	34	74	36–88	29 : 11
Norton *et al.* (24)	171	56	26–85	159 : 12
Solomon *et al.* (25)	120	62	n.r.	107 : 13
Davis *et al.* (23)	38	60	26–78	38 : 0
Mahony *et al.* (55)	60	30.5	22–42	60 : 0
Ilnyckyi *et al.* (26)	23	59	26–75	23 : 0
Naimy *et al.* (28)	49	36	22–44	49 : 0

References	Initial diagnostic evaluation	Evaluation at the end of study	Sessions	Home training
Latimer *et al.* (22)	Yes	Yes	8 (2/week)	Yes
Whitehead *et al.* (27)	Yes	Yes	8 (2/week)	Yes
Miner *et al.* (52)	Yes	Yes	3	No
Fynes *et al.* (53)	Yes	Yes	12	Yes
Heymen *et al.* (54)	Yes	No	>1/week	In 2 of 4 groups
Norton *et al.* (24)	Yes	Yes	Maximum 6	In 1 of 4 groups
Solomon *et al.* (25)	Yes	Yes	5	Yes
Davis *et al.* (23)	Yes	Yes	6	Yes
Mahony *et al.* (55)	Yes	Yes	12	Yes
Ilnyckyi *et al.* (26)	Yes	Yes	4	No
Naimy *et al.* (28)	Yes	Yes	2	Yes

References	Evaluation	Follow-up	Design	Control
Latimer *et al.* (22)	Diary	6 months	Single case cross-over	Variable components
Whitehead *et al.* (27)	Diary	6 months	Waiting list cross-over	PFE
Miner *et al.* (52)	Diary	<2 years	3 Arm cross-over	Sensory training
Fynes *et al.* (53)	SGA	Not done	2 Parallel groups	Sensory training
Heymen *et al.* (54)	SGA	Not done	3 Parallel groups	+Balloon, +HT, +sensory training
Norton *et al.* (24)	SGA	1 year	4 Parallel groups	TAU, PFE, BFT + HT
Solomon *et al.* (25)	SGA	Not done	3 Parallel groups	3 Modes of BFT
Davis *et al.* (23)	SGA	9 months	2 Parallel groups	Surgery only
Mahony *et al.* (55)	SGA	Not done	2 Parallel groups	Electrical stimulation
Ilnyckyi *et al.* (26)	SGA	Not done	2 Parallel groups	PFE
Naimy *et al.* (28)	SGA	Not done	2 Parallel groups	Electrical stimulation

SGA, subjective global assessment; TAU, treatment as usual; HT, home training; PFE, pelvic floor exercises; n.r., not reported.

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[14–17,20,34] before randomization of different control conditions became standard. Similar to a recent meta-analysis,[35] 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[11,36–38] different modes of BF training were compared, and patients were randomized to receive one of the treatments options. In contrast, the most recent studies[29,30,39,40] 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

© 2009 Blackwell Publishing Ltd

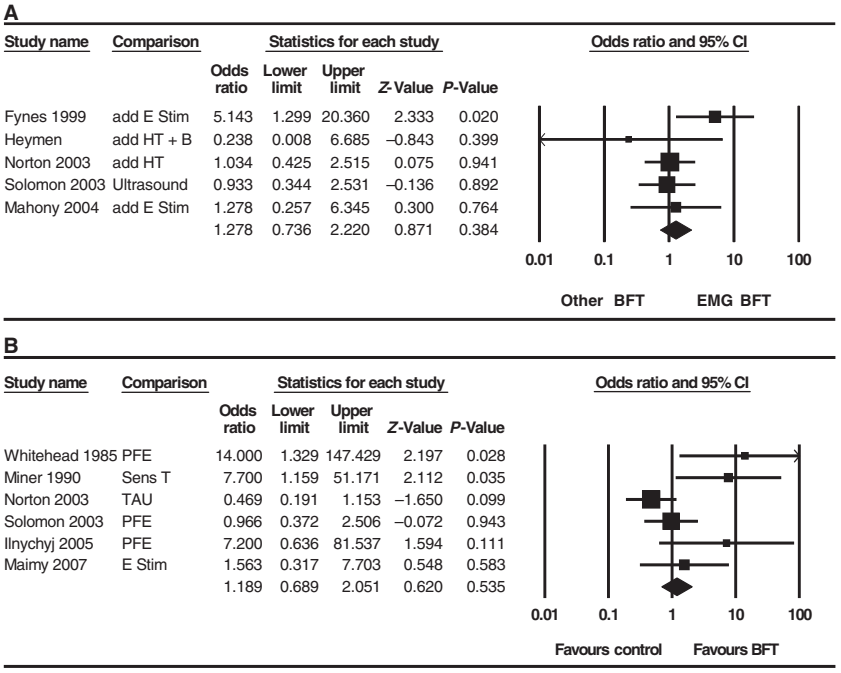

Figure 2 (A) Forest plot of five incontinence treatment studies comparing BFT studies (EMG or pressure BF) to other BFT modalities. Other BF modes included additional electrical stimulation (add E Stim), additional home training (add HT) and balloon pressure (P); see text for details. The odds ratio (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.

(CI: 2.127–6.290, $P < 0.001$) (Fig. 3B) in favour of BF. It should be noted, however, that when BFT was compared to the 'best' control strategy in two of the four studies (TAU in the study by Rao *et al.*;[29] diazepam in the study by Heymen *et al.*[38]), the OR dropped to 3.234 (CI: 1.875–5.578, $P < 0.001$). The long-term effects in the study by Farid *et al.*[30] were equal between botolinum toxin treatment and BFT and resulted in an improved OR of 4201 (CI: 2.4239–7.267, $P < 0.001$) in favour of BFT.

As is evident from Table 2, some features of BF in constipation therapy still need harmonization. While most studies implement at least one screening strategy to verify the diagnosis of pelvic floor dyssynergia and to evaluation therapy success, mostly anorectal manometry, other screening strategies are less common or further screening is less common are less common. However, psychological assessment has been know to be of importance for BFT patient exclusion as early as 1979[10] and as a predictor of therapy success in some studies.[11] Psychological assessment was used in two of the eight trials and home training was included in 3/8 trials, but its modalities and compliance have not been reported. The number of training sessions varies substantially, as does the duration of therapy and the follow-up period to control for success maintenance. While earlier studies used symptom diaries for the monitoring of therapy progress, recent studies have adopted the use of the subjective global assessment scale from treatment trials of functional bowel disorders, such as in irritable bowel syndrome.[41]

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

© 2009 Blackwell Publishing Ltd

Table 2 Randomized controlled trials of BFT in constipation

References	*n*	Age (years)	Range (years)	Sex (F : M)	Duration
Bleijenberg and Kuipers (11)	20	37	20–50	15 : 5	7 (2–15)
Koutsomanis *et al.* (36)	60	40.5	20–64	53 : 7	13
Glia *et al.* (37)	20	55.0	28–78	23 : 3	11
Heymen *et al.* (38)	36	61	18–82	26 : 10	n.r.
Chiarioni *et al.* (39)	109	34.1	n.r.	104 : 5	n.r.
Heymen *et al.* (40)	84	50	n.r.	n.r.	15.6
Rao *et al.* (42)	77	43	18–75	69 : 8	17
Farid *et al.* (30)	48	39.6	20–69	33 : 15	n.r.

References	Manometry	Defecography	EMG	Colon transit	Balloon expulsion test	Psychological tests	Follow up
Bleijenberg and Kuipers (11)	Yes	No	No	Yes	Yes	Yes	Not done
Koutsomanis *et al.* (36)	No	No	No	Yes	Yes	No	2–3 months
Glia *et al.* (37)	Yes	Yes	Yes	Yes	Yes	No	6 months
Heymen *et al.* (38)	Yes	Yes	Yes	Yes	No	No	Not done
Chiarioni *et al.* (39)	Yes	No	Yes	No	Yes	No	6–12 months
Heymen *et al.* (40)	Yes	No	No	Yes	No	Yes	3 months
Rao *et al.* (42)	Yes	No	No	Yes	Yes	No	Not done
Farid *et al.* (30)	Yes	Yes	Yes	No	Yes	No	1 year

References	session	HT	Evaluation	Design	Control
Bleijenberg and Kuipers (11)	8	yes	diary	parallel group	Balloon BFT
Koutsomanis *et al.* (36)	1–7	no	diary, SGA	parallel group	visual FB only
Glia *et al.* (37)	1–2/week	yes	diary	parallel group	Pressure-BFT
Heymen *et al.* (38)	n.r.	yes	diary	parallel group	BFT + balloon T
Chiarioni *et al.* (39)	5	no	SGA	parallel group	laxatives
Heymen *et al.* (40)	12	no	SGA	parallel group	Diazepam; placebo
Rao *et al.* (42)	6/3 months	no	SGA	parallel group	sham BFT; TAU
Farid *et al.* (30)	8	no	questionnaire	parallel group	BOTOX injection

SGA, subjective global assessment; TAU, treatment as usual, HT, home training; FB, Feedback; n.r., not reported.

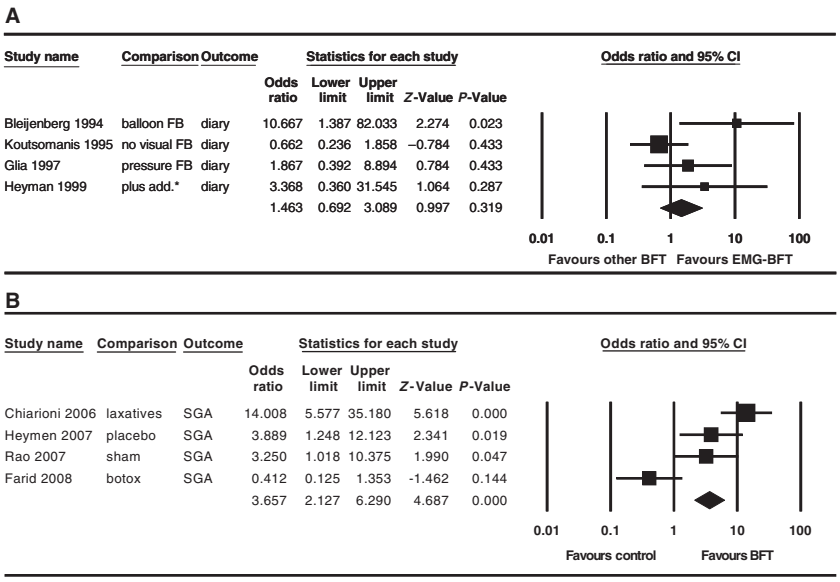

Figure 3 (A) Forest plot of four constipation treatment studies included comparing BFT studies (EMG BF) to other BFT modalities. Other BF modes included pressure and balloon FB, verbal feedback only, and additional modes (plus add) such as additional home training; see text for details. The odds ratio (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.

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

© 2009 Blackwell Publishing Ltd

'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,[43] and other placebo treatment options raise ethical concerns[44] when patients are expecting clinical help for a socially devastating medical condition.

As the study by Koutsomanis *et al.*,[36] 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' (ibd, p. 99). Other studies have found similar results with constipation treatment,[24,25] and a recent non-controlled study[45] 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.[46] 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,[47,48] 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 GASTOENTEROLOGY?

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[49] and Welgan[50] 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 electrogastrography 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 (H_2 blockers, protone 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

© 2009 Blackwell Publishing Ltd

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

This work was supported by the Else Kröner Fresenius Stiftung, Bad Homburg, Germany.

REFERENCES

1 Beatty J, Legewie H, eds. *Biofeedback and Behavior*. New York: Plenum Press, 1977.
2 Brener J, Kleinman RA. Learned control of decrease in systolic blood pressure. *Nature* 1970; **226**: 1063–4.
3 Pickering T, Gorham G. Learned heart-rate control by a patient with a ventricular parasystolic rhythm. *Lancet* 1975; **305**: 252–3.
4 Stone RA, DeLeo J. Psychotherapeutic control of hypertension. *New Engl J Med* 1976; **294**: 80–4.
5 Engel BT, Nikoomanesh P, Schuster MM. Operant conditioning of rectosphincteric responses in the treatment of fecal incontinence. *New Engl J Med* 1974; **290**: 646–9.
6 Hubel KA. Voluntary control of gastrointestinal functions: operant conditioning and biofeedback. *Gastroenterology* 1974; **66**: 1085–8.
7 Engel BT. The treatment of fecal incontinence by operant conditioning. *Automedicus* 1978; **2**: 101–8.
8 Olness K, McParland FA, Piper J. Biofeedback: a new modality in the management of children with fecal soiling. *J Pediatr* 1980; **86**: 505–9.
9 Kohlenberg RJ. Operant conditioning of human anal sphincter pressure. *J Appl Behav Anal* 1973; **6**: 201–8.
10 MacLeod JH. Biofeedback in the management of partial anal incontinence: a preliminary report. *Dis Colon Rectum* 1979; **22**: 169–71.
11 Bleijenberg G, Kuipers JHC. Treatment of spastic pelvic floor syndrome with biofeedback. *Dis Colon Rectum* 1987; **30**: 108–11.
12 Denis P, Crayon G, Galmiche JP. Biofeedback: the light at the end of the tunnel? Maybe for constipation. *Gastroenterology* 1980; **80**: 23–4.
13 Schiller LR, Santa Ana C, Davis GR, Fordtran JS. Fecal incontinence in chronic diarrhea. Report of a case with improvement after training with rectally infused saline. *Gastroenterology* 1979; **77**: 751–3.
14 Enck P. Biofeedback training in disordered defecation: a critical review. *Dig Dis Sci* 1993; **38**: 1953–60.
15 Schäfer R, Enck P. Biofeedback applications in gastroenterology. *Eur J Gastroenterol Hepatol* 1996; **8**: 534–9.
16 Rao S, Enck P, Loening-Baucke V. Biofeedback therapy for defecation disorders. *Dig Dis* 1997; **15** (Suppl.): 78–92.
17 Musial F, Enck P. Biofeedback in pelvic floor disorders. In: Pemberton J, Swash M, Henry MM, eds. *The Pelvic Floor*. London: W.B.Saunders, 2002: 393–404.
18 Heymen S, Jones KR, Ringel Y, Scarlett Y, Whitehead WE. Biofeedback treatment of fecal incontinence – a critical review. *Dis Colon Rectum* 2001; **44**: 728–36.
19 Norton C, Kamm MA. Anal sphincter biofeedback and pelvic floor execises for faecal incontinence in adults – a systematic review. *Aliment Pharmacol Ther* 2001; **15**: 1147–54.
20 Palsson OS, Heymen S, Whitehead WE. Biofeedback treatment for functional anorectal disorders: a comprehensive efficacy review. *Appl Psychophysiol Biofeedback* 2004; **29**: 153–74.
21 Norton C, Cody JD, Hosker G. Biofeedback and/or sphincter exercises for the treatment of faecal incontinence in adults. *Cochrane Database Syst Rev* 2006: CD002111.
22 Latimer PR, Campbell D, Kasperski J. A components analysis of biofeedback in the treatment of fecal incontinence. *Biofeedback Self Regul* 1984; **9**: 311–24.
23 Davis KJ, Kumar D, Poloniecki J. Adjuvant biofeedback following anal sphincter repair: a randomized study. *Aliment Pharmacol Ther* 2004; **20**: 539–49.
24 Norton C, Chelvanayagam S, Wilson-Barnett J, Redfern S, Kamm MA. Randomized controlled trial of biofeedback for fecal incontinence. *Gastroenterology* 2003; **125**: 1320–9.
25 Solomon MJ, Pager CK, Rex J, Roberts R, Manning J. Randomized, controlled trial of biofeedback with anal manometry, transanal ultrasound, or pelvic floor retraining with digital guidance alone in the treatment of mild to moderate fecal incontinence. *Dis Colon Rectum* 2003; **46**: 703–10.
26 Ilnyckyj A, Fachnie E, Tougas G. A randomized-controlled trial comparing an educational intervention alone vs. education and biofeedback in the management of faecal incontinence in women. *Neurogastroenterol Motil* 2005; **17**: 58–63.
27 Whitehead WE, Burgio KL, Engel BT. Biofeedback treatment of fecal incontinence in geriatric patients. *J Am Geriatr Soc* 1985; **33**: 320–4.
28 Naimy N, Lindam AT, Bakka A *et al.* Biofeedback vs. electrostimulation in the treatment of postdelivery anal incontinence: a randomized, clinical trial. *Dis Colon Rectum* 2007; **50**: 2040–6.
29 Rao SS, Seaton K, Miller M *et al.* Randomized controlled trial of biofeedback, sham feedback, and standard therapy for dyssynergic defecation. *Clin Gastroenterol Hepatol* 2007; **5**: 331–8.
30 Farid M, El Monem HA, Omar W *et al.* Comparative study between biofeedback retraining and botulinum neurotoxin in the treatment of anismus patients. *Int J Colorectal Dis* 2009; **24**: 115–20.
31 Enck P, Klosterhalfen S. The placebo response in functional bowel disorders: perspectives and putative mechanisms. *Neurogastroenterology* 2005; **17**: 325–31.
32 Norton C, Gibbs A, Kamm MA. Randomized, controlled trial of anal electrical stimulation for fecal incontinence. *Dis Colon Rectum* 2006; **49**: 190–6.

© 2009 Blackwell Publishing Ltd

33 Bols EM, Berghmans BC, Hendriks EJ *et al.* A randomized physiotherapy trial in patients with fecal incontinence: design of the PhysioFIT-study. *BMC Public Health* 2007; **7**: 355.
34 Heymen S, Jones KR, Scarlett Y, Whitehead WE. Biofeedback treatment of constipation: a critical review. *Dis Colon Rectum* 2003; **46**: 1208–17.
35 Koh CE, Young CJ, Young JM, Solomon MJ. Systematic review of randomized controlled trials of the effectiveness of biofeedback for pelvic floor dysfunction. *Br J Surg* 2008; **95**: 1079–87.
36 Koutsomanis D, Lennard-Jones JE, Roy AJ, Kamm MA. Controlled randomised trial of visual biofeedback versus muscle training without a visual display for intractable constipation. *Gut* 1995; **37**: 95–9.
37 Glia A, Gylin M, Gullberg K, Lindberg G. Biofeedback retraining in patients with functional constipation and paradoxical puborectais contraction. *Dis Colon Rectum* 1997; **40**: 889–95.
38 Heymen S, Wexner SD, Vickers D, Nogueras JJ, Weiss EG, Pikarsky AJ. Prospective, randomized trial comparing four biofeedback techniques for patients with constipation. *Dis Colon Rectum* 1999; **42**: 1388–93.
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 alternative treatments for patients with pelvic floor dyssynergia-type constipation. *Dis Colon Rectum* 2007; **50**: 428–41.
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.
42 Rao SS, Seaton K, Miller MJ *et al.* Psychological profiles and quality of life differ between patients with dyssynergia and those with slow transit constipation. *J Psychosom Res* 2007; **63**: 441–9.
43 Burnette MM, Adams HE. Detection of noncontingent feedback in EMG biofeedback. *Biofeedback Self Regul* 1987; **12**: 281–93.
44 La Vaque TJ, Rossiter T. The ethical use of placebo controls in clinical research: the Declaration of Helsinki. *Appl Psychophysiol Biofeedback* 2001; **26**: 23–37.
45 Byrne CM, Solomon MJ, Rex J, Young JM, Heggie D, Merlino C. Telephone vs. face-to-face biofeedback for fecal incontinence: comparison of two techniques in 239 patients. *Dis Colon Rectum* 2005; **48**: 2281–8.
46 Anonymous. Anismus and biofeedback. *Lancet* 1992; **339**: 217–8.
47 Jarrett ME, Emmanuel AV, Vaizey CJ, Kamm MA. Behavioural therapy (biofeedback) for solitary rectal ulcer syndrome improves symptoms and mucosal blood flow. *Gut* 2004; **53**: 368–70.
48 Rao SS, Ozturk R, De Ocampo S, Stessman M. Pathophysiology and role of biofeedback therapy in solitary rectal ulcer syndrome. *Am J Gastroenterol* 2006; **101**: 613–8.
49 Moore JG, Schenkenberg T. Psychic control of gastric acid response to anticipated feeding and biofeedback training in a man. *Gastroenterology* 1974; **66**: 954–9.
50 Welgan P. Learned control of gastric acid secretion in ulcer patients. *Psychosom Med* 1974; **36**: 411–9.
51 Herman PM, Craig BM, Caspi O. Is complementary and alternative medicine (CAM) cost-effective? A systematic review. *BMC Complement Altern Med* 2005; **5**: 11.
52 Miner PB, Donnelly TC, Read NW. Investigation of mode of action of biofeedback in treatment of fecal incontinence. *Dig Dis Sci* 1990; **35**: 1291–8.
53 Fynes MM, Marshall K, Cassidy M *et al.* A prospective, randomized study comparing the effect of augmented biofeedback with sensory biofeedback alone on fecal incontinence after obstetric trauma. *Dis Colon Rectum* 1999; **42**: 753–8.
54 Heymen S, Pikarsky AJ, Weiss EG, Vickers D, Nogueras JJ, Wexner SD. A prospective randomized trial comparing four biofeedback techniques for patients with faecal incontinence. *Colorectal Disease* 2000; **2**: 88–92.
55 Mahony RT, Malone PA, Nalty J, Behan M, O'connell PR, O'herlihy C. Randomized clinical trial of intra-anal electromyographic biofeedback physiotherapy with intra-anal electromyographic biofeedback augmented with electrical stimulation of the anal sphincter in the early treatment of postpartum fecal incontinence. *Am J Obstet Gynecol* 2004; **19**: 885–90.

© 2009 Blackwell Publishing Ltd

Copyright of Neurogastroenterology & Motility is the property of Blackwell Publishing Limited and its content may not be copied or emailed to multiple sites or posted to a listserv without the copyright holder's express written permission. However, users may print, download, or email articles for individual use.