

Anal sphincter biofeedback and pelvic floor exercises for faecal incontinence in adults—a systematic review

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SUMMARY

Background: Faecal incontinence is a common health care problem. Biofeedback is extensively used in clinical practice to treat faecal incontinence.

Aim: To systematically review and evaluate the evidence from clinical studies on the effectiveness of biofeedback as a treatment for faecal incontinence in adults.

Methods: A systematic literature search was undertaken using electronic databases, with review of the retrieved references.

Results: The search identified 46 studies published in English using biofeedback to treat adults complaining of faecal incontinence. Those studies included a total

of 1364 patients. Of those studies with adequate data, 275 out of 566 patients (49%) were said to be cured of symptoms of faecal incontinence following biofeedback therapy and 617 out of 861 (72%) patients were reported to be cured or improved. Studies varied in the method of biofeedback used, criteria for success and the outcome measures used. Only eight of the 46 studies employed any form of control group.

Conclusions: The data suggest that biofeedback and exercises help a majority of patients with faecal incontinence. However, methodological variation, lack of controls and a lack of validated outcome measures are problems in evaluating these results.

BACKGROUND

Faecal incontinence is a common health care problem affecting over 1% of community-dwelling adults.¹ It has important personal and social ramifications for the individual.^{2, 3} Biofeedback has been extensively used in clinical practice to treat faecal incontinence and has been advocated to be 'the treatment of choice' for faecal incontinence.⁴ This paper aims to review the research evidence for the clinical use of biofeedback and pelvic floor exercises in adults with faecal incontinence.

METHODS

A search of the electronic databases Medline (from 1966 to May 2000) and Cinahl (1982 to February 2000) was made using the keywords 'faecal incontinence', 'exercise therapy' (Medline), 'muscle strengthening' (Cinahl) and/or 'biofeedback'. All references which appeared to be studies or reviews of biofeedback in adults were retrieved in hard copy and the reference list of each paper was searched for additional references, which in turn were obtained.

RESULTS

A total of 193 papers were identified by the initial electronic search. Of these, 51 were reviews of biofeedback or treatment of faecal incontinence with no clinical data, 43 were studies or reviews in children only, two were duplicate reports of the same study, two

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were descriptions of methods or equipment with no results, two were concerned with constipation and not incontinence, 26 were reviews in a foreign language and an additional seven appeared to be foreign studies. Eighteen papers were not about biofeedback, five did not have faecal incontinence as their focus and three included four or fewer patients. This left 34 studies for the current review. The additional search of reference lists from these publications found 12 further studies. Table 1 gives details of these 46 studies.⁵⁻⁵⁰

Included studies

A total of 1364 patients were reported. Where information about gender was given, in all but four studies the majority of patients were female (915 female vs. 288 male; 76% female). For 161 patients, their sex was not stated. The ages in the included studies ranged from 6 to 97 years (studies where the majority of participants were children were excluded). Mean or median ages varied from the 30 s in some studies to 70 s in others. Most were mixed or unstated aetiology groups, but a few studies related to specific patients groups (e.g. obstetric, or elderly) or to those with a common surgical history (e.g. sphincter repair, or anterior resection of the rectum).^{12, 17, 19, 41, 49} Two studies involved patients undergoing formation of an ileo-anal pouch and looked at the prophylactic rather than treatment effect of biofeedback; these patients initially had a covering stoma, so it was not known how many had the symptom of faecal incontinence.^{21, 35} One study followed a cohort of women who had a repaired third degree obstetric tear, treating symptomatic women more intensively than those without symptoms.⁴¹ The studies were from a range of countries; over half were from North America.

Methodological quality of studies

Only eight of the studies included any attempt at randomization, which is considered the best methodology for excluding bias in a treatment study.^{12, 21, 24, 30, 32, 35, 41, 49} Seven of these studies stated their methodology as randomized controlled trials, the eighth was a quasi-randomized study (with alternate patients allocated to treatment or control).⁴⁹ A few of the other studies quoted 'control data' from other patient populations, but this methodology cannot be considered as a controlled study of treatment effect. For

example, some case-time series reported a comparison of a patient series from a time when biofeedback was available with a series of results from when it was not.²⁶ Others compared patients who opted for, or were allocated to, biofeedback with those treated by conventional medical treatment;⁹ in these studies confounding variables other than treatment could have influenced the results.

Elements of biofeedback

Many different treatment modalities have been used in the name of 'biofeedback'. As described by the original authors, it was thought to be an operant conditioning therapy.¹⁰ The aim was for the patient to learn to enhance the presumed reflex contraction of the external anal sphincter in response to a reflex relaxation of the internal anal sphincter, induced by stimulating the recto-anal inhibitory reflex by distension of a rectal balloon.¹⁰ It has subsequently become evident that the external anal sphincter response is mostly a voluntary (if usually subconscious) response.⁵¹ Later authors have recognized this and have focused on training the patient to improve this voluntary response.

Three main modalities, with many variations and many adjunctive measures, have been described. Table 1 identifies the main modality used in each study, although there was a wide variety of methods used within each modality, and some studies gave very little detail on equipment or training programme used. No two studies have described exactly the same treatment as 'biofeedback'. Studies have used between one and 28 sessions over between 2 days and 1 year of therapy.

The first method is the use of an intra-anal electromyographic (EMG) sensor, anal manometric probe (measuring intra-anal pressure), or peri-anal surface electro-myographic electrodes to teach the patient how to exercise the anal sphincter, usually as a variation of pelvic floor muscle or 'Kegel' exercises, more commonly used for treatment of urinary incontinence.⁵² Some have used this simply to demonstrate correct isolation and use of an anal squeeze in response to rectal filling or an urge to defaecate. Others have devised a programme of home exercises and use the clinic biofeedback sessions to demonstrate correct technique and monitor progress in achievement. Early studies tended to focus on the peak muscle strength (squeeze increment), while later workers have suggested that it is the overall muscle

Table 1. Characteristics of included studies, outcome measures and results

Author (reference no.)	Year	Country	Patients (f/m)	Age in years (range)	Method of bio-feedback	Study entry conditions/patient group	% improved	No FI	Episodes↓ or good outcome	Method of evaluation→	RP	SP	Rectal sensory volume	F/U in months (mean)
Berti Riboli ⁵	1988	Italy	21 (15/6)	14–84	balloon	Daily FI: surgical/senile	86	16/21	18/21–90%↓		↑	↑	↓	
Buser ⁶	1986	USA	13 (7/6)	13–66	balloon	Delay in sensation	92	12/13			↑*	↑*	↓*	16–30
Cerulli ⁷	1976	USA	50 (36/14)	6–97	balloon	Consecutive, mixed	72	20/50	36/50–90%↓		↑*	↑*	↓*	4–108
Chiaroni ⁸	1993	Italy	14 (10/4)	24–75	balloon	Liquid stool FI	85	9/14	12/14–75%↓	D	↑*	↑*		3–21
Enck ⁹	1994	Germany	18 (14/4)	33–83	EMG	Mixed FI	71	4/18	6/7	Sq				60+
Engel ¹⁰	1974	USA	7 (5/2)	6–54	balloon	Mixed FI	84	38/49	41/49	Sc	↑*	↑*		
Fox ¹¹	1991	Canada	59 (?)	?	EMG	Not stated	79	22/39	31/39	Sq, Sc*				0
Fynes ^{12†}	1999	Ireland	40 (40/0)	18–48	Pressure	Consecutive obstetric injury	64	6/12	14/22–50%↓	D, Sq	→	→	↓*	21
Glia ¹³	1998	Sweden	26 (22/4)	32–82	balloon	Consecutive FI	83	6/12	10/12	Sc	↑*	↑*		30 (24–36)
Goldenberg ¹⁴	1980	USA	12 (6/6)	12–78	balloon	Surgical/medical	91	9/11	10/11	D, Sq, Sc*	↑*	↑*		18
Guillemot ¹⁵	1995	France	16 (13/3)	39–72	balloon	Patients chose BFB	77	10/13	90%↓	D	↑	↑		11
Hamalainen ¹⁶	1996	Finland	11 (9/2)	Mean 61.2	EMG	Rectal prolapse op	89	25/28	↓80%*	D, Sq, Sc*	↑	↑		
Ho ¹⁷	1996	Taiwan	13 (3/10)	Mean 62.1	balloon	Anterior resection	90	28/31	↓90%	Sc	↑	↑		
Hwang ^{18#}	1999	USA	16 (12/4)	33–84	EMG	J pouch/IRA	90	28/31	↓90%	Sq, Sc	↑	↑		
Jensen ¹⁹	1997	USA	28 (28/0)	23–57	EMG	Surgery for obstetric injury	90	28/31	↓90%	Sc	↑	↑		
Jensen ^{20#}	1991	USA	44 (43/1)	11–77	EMG	Mixed	73	4/15	11/15	Sq	↑	↑		1–23 (8)
Jorge ^{21†~}	1994	USA	26 (10/16)	17–69	None	Ileo-anal pouch with covering ileostomy	92	11/25	23/25*	D	→	→	↓	6
Keck ²²	1994	USA	15 (13/2)	29–65	balloon	Consecutive FI	100	7/8	8/8	D	↓	↓		
Ko ²³	1997	USA	25 (21/4)	31–82	EMG	Mixed	30	5/27	8/27	D	↑	↑		
Latimer ^{24†}	1984	Canada	8 (4/4)	8–72	balloon	Recruited	38	1/8	3/8	D, Sq	→	→		12
Lerol ²⁵	1999	France	27 (25/2)	29–74	balloon	Not stated	63	71/113	↓90%					5–60
Loening-Baucke ²⁶	1990	USA	8 (8/0)	35–78	balloon	Weekly FI	63	6/6			↑*	↑*		6
MacLeod ²⁷	1987	USA	113 (67/46)	25–88	EMG	Consecutive who failed exercises alone	63	15/24	↓50%	D	↑	↑	↓	8
Magrini ²⁸	1997	Italy	6 (5/1)	Mean 50	Pressure	Not stated	63	3/8	5/8	D	↑	↑		6–36
McHugh ^{1 29#}	1988	Canada	24 (19/5)	Mean 58	?	Consecutive FI	63	3/8	5/8					
McHugh ^{2 30†#}	1986	Canada	13 (10/3)	Mean 55.2	?	Failed fibre increase	63	3/8	5/8					
McIntosh ³¹	1993	USA	8 (8/0)	?	EMG	Treated for urinary incontinence, not responded to fibre/drugs	76	11/25	19/25	↓75%	D	→	↓	24
Mimer ^{32†}	1990	UK	25 (17/8)	17–76	balloon	Consecutive FI	81	43/100	67/100	Sc				12
Nicastro ³³	1997	Italy	116 (85/31)	11–86	EMG	Mixed FI	67	43/100	67/100					0
Norton ³⁴	1999	UK	100 (84/16)	14–82	Pressure	Mixed FI								

Table 1. (cont.)

Author (reference no.)	Year	Country	Patients (f/m)	Age, years (range)	Method of bio-feedback	Study entry conditions/patient group	% improved	No FI	Episodes↓ or good outcome	Method of evaluation→	RP	SP	Rectal sensory volume	F/U in months (mean)
Oresland ^{35†} ~	1988	Sweden	38 (20/18)	18–58	balloon	Ileo-anal pouch with covering ileostomy				D, Sc	→	→	↑cap	12+
Patanekar ¹ ³⁶	1997	USA	72 (43/29)	34–87	EMG	Multicentre	85		53/59 ↓75%*	D				
Patanekar ² ³⁷	1997	USA	25 (13/12)	34–85	EMG	Mixed FI	83		↓75%*	D	↑*			
Rao ³⁸	1996	USA	22 (20/2)	15–78	balloon	Failed conservative	53	10/19	10/19 ↓50%*	D, Sq, Sc*	→	↑*	↓*	12
Rieger ³⁹	1997	Australia	30 (28/2)	29–85	EMG	Mixed	67	6/30		Sc*				12
Ryn ⁴⁰	2000	Sweden	37 (36/1)	22–82	EMG	Mixed	60% SR		22/37 SR	Sq, Sc*				37–54 (44)
Sander ⁴¹ †	1999	Denmark	48 (48/0)	22–36	None	Consecutive 3rd degree obstetric tear	70%	2/2	7/10		↑*	↑*		12
Sangwan ⁴²	1995	USA	28 (22/6)	30–74	Pressure	Not stated	75				→	→		4–47 (21)
Schmidbauer ⁴³	1992	Germany	19 (?)	?	EMG	Not stated	79	10/19	15/19		→	↑*	→	
Solomon ⁴⁴	2000	Australia	44 (?)		Ultra-sound	Not stated				Sc*				
Sousa ⁴⁵ #	1994	Brazil	28 (?)	?	balloon	Not stated					→	↑*	↓*	
Van Tets ⁴⁶	1996	Netherlands	12 (12/0)	29–64	EMG	Pudendal neuropathy	0	0/12	0/12		↑	↑		2–38 (15)
Wald1 ⁴⁷	1981	USA	17 (11/6)	10–79	balloon	Mixed FI, rectal sensation < 30 mLs	71	10/17	12/17 ↓75%					(20)
Wald2 ⁴⁸	1984	USA	11 (?)	?	balloon	Diabetics sensation < 70 mLs	73	6/11	8/11 ↓75%				↓	1
Whitehead ⁴⁹ †	1985	USA	18 (15/3)	65–92	balloon	Elderly	67		12/18 ↓75%	D		↑		
Wiesel ⁵⁰	2000	UK	13 (8/5)	26–56	Pressure	Multiple sclerosis (only 9 FI, others constipated)	78		7/9					

F/m: female/male; FI: faecal incontinence; †study with treatment controls; # abstract only; ~ patients not treated for faecal incontinence (prevention study); → method of evaluation; D: diary; Sq: symptom questionnaire; Sc: score; RP: resting pressure; SP: squeeze pressure; volumes: rectal distension volume at first sensation; SR: Short-term results; LR: long-term results; FU: follow up period; *quoted as statistically significant difference from pre-treatment value; cap: capacity.

capacity (strength and endurance of the squeeze) that is important.^{8, 27, 37}

The second modality is the use of a three-balloon system to 'train' the patient to correctly identify the stimulus of rectal distension and to respond without delay by immediate and forceful external anal sphincter contraction to counteract reflex inhibition of the internal anal sphincter. Some have felt that sensory delay is an important factor in faecal incontinence and that abolishing any delay in response to the sensation of distension is the crucial element in successful therapy.^{6, 32}

The third method is the use of a rectal balloon to 'retrain' the sensory threshold, usually with the aim of enabling the patient to discriminate (and thus respond to) smaller rectal volumes. However, tolerance of larger volumes by the use of progressive distension and urge resistance is also reported.^{34, 35}

One study has used anal ultrasound to show patients contraction of the anal sphincter on a screen.⁴⁴ Two studies have attempted to evaluate the different components of biofeedback in randomized controlled trials.^{24, 32} Unfortunately, both had very complex designs which makes analysis of the different components impossible from the data presented, except that improving (lowering) the threshold for sensing rectal distension did seem to be beneficial in reducing symptoms.³²

Two studies used exercises alone, without any mention of biofeedback equipment.^{21, 41} Adjunctive therapies have included the use of electrical stimulation.^{12, 41} The second of these abandoned the stimulation due to anal pain. Others mention the use of medication (bulking agents or anti-diarrhoeals) and dietary modification. The majority of studies mention that patients were instructed to practice at home, but few specified in detail what instructions were given to the patients. Some instructed patients to squeeze whenever rectal distension was felt; others gave a structured exercise programme. Those studies that specified a home exercise programme asked patients to aim for squeezes of between 10 and 40 s duration, with 10–60 squeezes per day.

OUTCOME (Table 1)

A wide variety of outcome measures was employed in the studies reviewed, and some did not state their method for gathering data. Most took reduction of episodes of faecal incontinence as their primary end-point, although few explicitly stated that diaries or questionnaires were used to gather this information. Criteria for success varied

from 90% to 50% reduction in episodes of incontinence.^{5, 7, 29} Success rates ranged from 0% to 100%.^{28, 46} Thirty-four studies quoted an overall response rate (usually combined cure and improvement). Of these, only three had a response rate under 50%; 13 had a response rate of 50–75%; and 19 studies had a response rate of 75% or greater (six over 90%).

Of those studies that gave data on patients who were free of the symptom of faecal incontinence, 275 out of 566 patients (49%) were said to have no incontinence at the end of the study or follow-up period. Criteria for 'responders' varied greatly, but overall, 617 out of 861 patients were reported as responders (72%). Many did not specify a follow-up period. Some studies had no follow-up and reported results at the end of the treatment period only.^{12, 34} Of those studies that had longer follow-up, most included a wide variation within a mean. Only four studies reported results at two or more years for all patients.^{9, 15, 32, 40} One study reported immediate results and then further results at 3 years follow-up, with success deteriorating from 22 to 15 out of 37 patients over time.⁴⁰

Three studies included patients who were not necessarily symptomatic prior to inclusion. Two looked at patients undergoing an ileo-anal pouch procedure and randomized patients to exercises or biofeedback.^{21, 35} Although there was some short-term benefit in recovery of bowel function after ileostomy closure, neither study found any sustained benefit, with controls having equally good function at 1 year after closure. A study of women who had sustained a third degree obstetric tear found that 21% were symptomatic (mostly flatus incontinence) at 3 months after delivery. Symptomatic women had intensive physiotherapy, the others were instructed to exercise. Two of the initially symptomatic women still had flatus incontinence at 1 year and one previously asymptomatic woman had developed flatus incontinence. None had faecal incontinence, which compares favourably to published rates of symptoms after third degree tears.⁴¹

Few studies used any tests of statistical significance and some that quoted significance figures did not specify what statistical tests were used.

Predictors of outcome

From these studies, there are few clear indicators of which patients are likely to benefit from biofeedback, and some of the evidence is contradictory. Few studies

had the benefit of anal ultrasound to define sphincter structural defects. Two studies did not find that success correlated with defects, while another obtained better results if the anal sphincters were structurally intact.^{25, 34, 39} Pudendal nerve damage was the common factor in the only study to find no benefit at all from biofeedback, but others have found that success is independent of pudendal nerve function.^{25, 46} Although patients with pudendal neuropathy failed to increase their anal squeeze pressure, this did not preclude symptomatic improvement.²⁵ Pre-treatment manometry does not seem to predict success or failure, but sensitivity to balloon distension with air may be important; some authors conclude that those with an initially insensitive rectum are less likely to respond, whilst others find that decreasing sensory threshold is the single most important element of biofeedback.^{7, 23, 32, 39, 47} Many studies have shown improvement in both resting and squeeze anal pressures, but improvement did not necessarily correlate with symptomatic relief. For example, one study found that pressures increased in both successes and failures;⁵ another found that even those who failed to improve their pressures could improve their symptoms.²⁵ Two studies concluded that duration rather than strength of squeeze was the important element.^{8, 37}

DISCUSSION AND CONCLUSIONS

A recent Cochrane review of controlled studies of biofeedback and exercises for faecal incontinence concluded that 'there is not enough evidence from trials to judge whether these treatments are helpful, nor which aspects of the treatment are the most helpful and which patients are the most likely to be helped'.⁵³ The data from the studies in the current review suggest that biofeedback and exercises do seem to have an effect in clinical practice and a role in the treatment of patients with faecal incontinence, with only one treatment study reporting no benefit at all and the majority improving at least 50% of patients at least to some degree. However, methodological problems, lack of controls and lack of validated outcome measures are problems in evaluating these results.

Additionally, it cannot be claimed that 'biofeedback' is the effective element in what is inevitably a complex package of care, including: assessment and the opportunity to discuss these taboo symptoms; time and attention with an enthusiastic therapist; patient

information and teaching; and often supplementary advice on diet, medication and lifestyle. It is not known whether these elements, exercises alone, or the biofeedback itself, are the determining factor in symptom improvement. Well-designed controlled trials are needed to clarify these issues.

The variation in home exercise regimes mirrors the findings in urinary incontinence, but possibly with less variation, although many papers did not specify their instructions or even whether patients were told to practice at home.⁵⁴ There is a lack of expert consensus on the most effective exercise regime and insufficient data to make recommendations, as no study has compared different exercise programmes.⁵⁵

No study has reported adverse events from biofeedback and it seems unlikely that the treatment itself could cause worsening of symptoms. Given this, and the potential for adverse events from surgery, biofeedback may be considered as a first-line option in therapy for many patients with faecal incontinence which has not responded to simple dietary advice or medication.⁵⁶ Surgery should be reserved for those with major structural abnormalities of the anal sphincter, severe symptoms and those who fail to respond to biofeedback. Although some results from the studies reviewed here are equivocal, the majority report at least some positive benefit. Faecal incontinence has a major negative impact on quality of life for those affected and there is a need to develop and rigorously evaluate a range of treatment options for these patients.^{2, 3}

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