Biofeedback treatment of fecal incontinence: a critical review
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Authors’ objectives
To critically evaluate the literature on the efficacy of biofeedback treatment for faecal incontinence (FI), to compare different types of biofeedback, and to identify those patient characteristics which predict a successful outcome.

Searching
MEDLINE was searched for articles published between 1970 and 1999 that included the terms ‘biofeedback’ and ‘faecal incontinence’. Studies of children and adults reported in any language were screened. In addition, the citations in the identified articles were examined.

Study selection
Study designs of evaluations included in the review
Prospective studies with at least five patients were included.

Specific interventions included in the review
A variety of biofeedback treatment protocols were used. Eighteen studies used a treatment protocol first developed at Johns Hopkins University (see Other Publications of Related Interest), which involves coordinating pelvic floor muscle (PFM) contractions in response to intrarectal distention (coordination). The second protocol involved training patients to improve sensation to diminishing rectal distentions without training PFM contractions (sensory). Four studies used sensory training in sequence with, or in combination with other treatment strategies. The third treatment protocol employed strategies to strengthen the PFM without including rectal distention (strength); this was used in thirteen studies.

The different treatment strategies used different instrumentation. Sensory training of the rectum utilised an intrarectal pressure, balloon feedback device. Strength training biofeedback used either the anal canal pressure or the intra-anal electromyographic feedback of PFM. Finally, coordination biofeedback training utilised pressure feedback of intrarectal balloon distention and PFM contractions in a simultaneous feedback protocol. This was generally performed using a balloon-tipped water perfused catheter or a Schuster-type three-balloon probe.

Participants included in the review
Children and adults with FI. Very little information on the participants in the studies was reported in the review. Nine studies (one of which included two investigations) were of paediatric patients.

Outcomes assessed in the review
The treatment outcome was defined as the percentage of patients with a reduction in incontinent episodes. However, a variety of outcome measures have been used. Most studies reported the percentage of patients that improved without stating to what degree they improved. Other studies report the outcome based on how many patients improved by a predetermined value; this ranged from complete continence to a 75 or 90% reduction in FI. In two studies, the outcome was reported as a percentage reduction in FI for the whole group.

Most studies determined the outcome by subjective reports in a diary format. Several authors have proposed incontinence severity scores, which record the frequency, consistency and/or the amount of soiling. Unfortunately, most of these scoring systems merge incontinence severity with pad usage or other treatment and quality of life measures, making it difficult to compare the outcomes.

How were decisions on the relevance of primary studies made?
The authors do not state how the papers were selected for the review, or how many of the reviewers performed the selection.
Assessment of study quality
The authors do not state that they assessed validity.

Data extraction
The authors do not state how the data were extracted for the review, or how many of the reviewers performed the data extraction.

The data extracted included the sample size, study design, treatment type, number of sessions, outcome and measure.

Methods of synthesis
How were the studies combined?
A meta-analysis, weighted by the number of participants, was conducted. This compared the treatment outcome (defined by the percentage of participants with a reduction in incontinent episodes) of studies using coordination training with those using strength training. Since there were no studies using only sensory feedback, it was not included in the meta-analysis.

How were differences between studies investigated?
The authors do not describe any formal statistical tests for heterogeneity, nor do they discuss the sources of heterogeneity between the studies.

Results of the review
Thirty-five articles were reviewed. Four studies used a parallel treatment design, of which only 2 randomised the patients to the treatment groups. The other 31 studies investigated biofeedback treatment in uncontrolled experimental designs comparing pre- and post-treatment symptom frequency or severity in a variety of ways. The meta-analysis included 31 investigations with a total of 694 participants.

The meta-analysis failed to show any advantage for one treatment strategy over another (chi-squared(1) = 0.432, N=694, P=0.511).

Nineteen studies used coordination training with a mean success rate of 67% (228 of the 339 participants improved).

Twelve studies used pelvic floor strength training with a mean success rate of 70% (247 of the 355 participants improved). Six of the strength training studies used electromyographic biofeedback with a mean success rate of 74% (146 of the 197 participants improved), and six used pressure feedback of the anal canal with a mean success rate of 64% (101 of the 158 participants improved); this demonstrated a significant difference in treatment outcome in favour of electromyographic feedback over pressure strength training (chi-squared(1) = 4.299, N=355, P=0.038).

Authors' conclusions
The majority of the studies reported positive results when using biofeedback to treat FI, but quality research was lacking. It was recommended that future research use improved experimental designs, include long-term follow-up data, and employ sample sizes that enable meaningful analyses.

CRD commentary
The authors stated their review question and the inclusion criteria clearly. The literature search was clearly described, but was restricted to one database (MEDLINE) with very limited search terms. In addition, the authors did not report any attempts to identify unpublished or grey literature. This narrow search strategy might have missed relevant studies, thus allowing the introduction of selection bias. Publication bias was not assessed.

The authors did not report any details relating to how the studies were selected and the data extracted, such as how many of the reviewers were involved, whether the studies were examined independently, whether the reviewers were
blinded to the source, and how disagreements were resolved.

Details of the studies were tabulated and supplemented with a narrative discussion of controlled and quasi-controlled studies. Unfortunately, this data lacked detail regarding the participants’ characteristics, the interventions, settings, outcome measures and side-effects.

The validity of the individual studies was not assessed, although the studies were weighted for the meta-analysis by the number of participants.

Heterogeneity between the studies was not statistically evaluated.

The authors’ conclusion, that most studies reported positive results using biofeedback to treat FI but that quality research was lacking, is supported. However, this conclusion should be interpreted with caution given that the restricted search strategy may have missed other relevant studies, and study quality and heterogeneity were not assessed. Further details of the primary studies would also have been useful when interpreting the data.

**Implications of the review for practice and research**

Practice: The authors did not state any implications for practice.

Research: The authors state that well-controlled studies that demonstrate the efficacy of biofeedback, compared with medical management and no treatment, are needed for patients with FI. They recommend that patients with pelvic floor weakness and/or poor rectal sensation should be examined in prospective, randomised, parallel designed studies that compare sensory, strength and coordination biofeedback strategies. The authors give recommendations for how this research should be carried out.

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This is a critical abstract of a systematic review that meets the criteria for inclusion on DARE. Each critical abstract contains a brief summary of the review methods, results and conclusions followed by a detailed critical assessment on the reliability of the review and the conclusions drawn.