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

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

Searching
MEDLINE was searched from 1966 to May 2000 using the search terms 'exercise therapy' and/or 'biofeedback'. CINAHL was searched from 1982 to May 2000 using the search terms 'muscle stimulation' and/or 'biofeedback'. All reports which appeared to be of studies or reviews of biofeedback were retrieved. The reference lists of all retrieved papers were examined for additional studies.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs), non-randomised controlled trials and case series were included.

Specific interventions included in the review
Electromyographic-based interventions, a three-balloon system, a one-balloon system, and ultrasound-based interventions.

Participants included in the review
The participants included were adults with faecal incontinence. Seventy-six per cent of the patients were female and 24% were male. The patients were aged from 6 to 97 years, with the median and mean ages between the trials ranging from the 30's to the 70's.

Outcomes assessed in the review
A wide variety of outcome measures were employed, of which the most common was the number of episodes of faecal incontinence. The criteria used for a successful outcome varied between the studies, ranging from a 50 to 90% reduction in the number of episodes. The majority of the primary studies lacked information on how the patients recorded data on the number of incontinent episodes per day.

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 report the method used to assess validity, or how the validity assessment was performed. A sparse overview of the methodological quality of the studies was given.

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.

Data were extracted on the following topics; the study authors; the year of publication; the country in which the study was conducted; the number of patients enrolled and the gender ratio of the patients; the method of biofeedback; the study entry point; the study population; the percentage of patients who improved; the number of patients who did not have faecal incontinence at the end of the study; the number of patients who had reduced episodes or other good
outcomes; the method of evaluating the outcomes; the resting pressure; the squeeze pressure; and the mean follow-up in months.

**Methods of synthesis**

How were the studies combined?
A narrative synthesis was undertaken.

No attempt was made to assess publication bias.

How were differences between studies investigated?
The authors do not report a formal investigation of the differences between the studies. However, an overview of the methodological variation between the studies was given.

**Results of the review**

Forty-six studies involving 1,364 patients were included. There were 7 RCTs (n=198), one non-randomised controlled study (n=18), and 38 studies (n=1,197) of a non-comparative design. Of the 7 RCTs, 5 included only female patients. The RCTs involved 149 (75.3%) female patients and 49 (24.7%) male patients.

Thirty-four studies recorded an overall response rate; this usually consisted of a combination of those whose symptoms of faecal incontinence were cured and those whose symptoms were improved. However, details were reported for 35 studies: the success rates were below 50% in 3 studies, between 50 and 75% in 13 studies, between 75 and 90% in a further 13 studies, and greater than 90% in 6 studies. It was not possible to ascertain from where these data had been taken; thus, it was not possible to discern whether any method of biofeedback demonstrated a pattern of greater or less effectiveness over the other methods.

A total of 26 studies reported on the proportion of patients who were cured of faecal incontinence: 49% (275 of the 566 patients) did not report incontinence at the end of the study or follow-up period. The data tabulated did not show a correlation between the type of biofeedback intervention and the rate of successful therapy. Seventy-two per cent (617 of the 861 patients) were designated as responders, but the definition of ‘response’ varied markedly between the studies.

Three studies compared patients who did not have symptoms of faecal incontinence. Two studies consisted of patients undergoing closure of an ileostomy, while the third addressed women who had suffered a third-degree peri-natal tear; one of the studies investigating ileostomy closure investigated balloon biofeedback while the other 2 studies investigated exercise only. None of the 3 studies found a significant benefit for treated patients over the control group.

**Authors' conclusions**
The data suggested that biofeedback and exercise help a majority of patients with faecal incontinence.

**CRD commentary**
The research question specified the participants and interventions of interest, but did not specify a priori the outcomes of interest or the comparisons required for the treatments.

The search strategy was appropriate but was limited to MEDLINE and CINAHL, both of which have a bias against studies from continental Europe. In addition, non-English studies were excluded. These factors may have introduced a significant risk of bias. However, there appears to have been no attempt to ascertain whether any bias, such as publication bias, was present.

The report would have been improved by including a detailed account of how the studies were assessed for inclusion and how the data were abstracted. The report would have benefited from additional detail on the validity of the studies and the process by which validity was assessed.

The data presented were appropriate, but there were some inconsistencies and ambiguities between the commentary in
the text and the data tabulated.

The conclusions drawn appear appropriate, and the authors were correct to cite the methodological flaws in the evidence base as a concern.

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

Practice: The authors state that biofeedback may be considered as a first-line therapy for faecal incontinence, given the lack of side-effects of the therapy, the comparatively small risk that the therapy could exacerbate symptoms, and the adverse effect profile of surgery.

Research: The authors state that research with appropriate methodologies, including appropriate controls and the use of validated outcome measures, is required in this area.

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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.