Biofeedback treatment for functional anorectal disorders: a comprehensive efficacy review

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CRD summary
This review aimed to critically evaluate the literature on the efficacy of biofeedback for functional anorectal disorders. The authors concluded that biofeedback is significantly more successful for the treatment of functional constipation and functional faecal incontinence than standard medical care. Data from individual studies were inappropriately pooled. Consequently, the findings of the review cannot be considered reliable.

Authors' objectives
To critically evaluate the literature on the efficacy of biofeedback (BF) for functional anorectal disorders; to rate these BF applications according to established guidelines; and to make recommendations for this field based on the literature.

Searching
MEDLINE and PsycINFO were searched from 1975 to 2003 for relevant publications in any language; the search terms were reported.

Study selection
Study designs of evaluations included in the review
Prospective studies with at least 5 participants per group were eligible for inclusion. Randomised controlled trials (RCTs), non-randomised controlled studies and uncontrolled studies were selected for the review.

Specific interventions included in the review
Studies evaluating a clearly described BF treatment were eligible for inclusion. The specific interventions evaluated were coordination BF training, pressure BF training, perianal electromyographic (EMG) BF and intra-anal EMG BF, alone or in combination. Where relevant, the control groups were usually managed medically.

Participants included in the review
Studies including adult or paediatric patients with either pelvic floor dyssynergia (PFD), functional faecal incontinence (FI) or functional anorectal pain were eligible for inclusion. Studies where anorectal disorders were secondary to physical trauma, structural pathology or a major medical disorder were excluded. Studies of mixed etiology were eligible where a definitive etiology was difficult to establish. Where reported, the patients were aged from 4 to 97 years.

Outcomes assessed in the review
The authors accepted any clearly described outcome measure. The primary outcome of interest was overall success rate for BF, the definition of which varied between studies.

How were decisions on the relevance of primary studies made?
The authors did not state how the papers were selected for the review, or how many reviewers performed the selection.

Assessment of study quality
The authors did not state that they assessed validity.

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

Data on basic study characteristics, including success rate as defined in each individual study, were extracted. The
percentage number of treatment responders was extracted regardless of the response criteria used within the individual studies. Where studies presented multiple percentages based on different criteria, the percentage of participants with at least 75% improvement was used.

**Methods of synthesis**

How were the studies combined?
The overall success rate of BF for each condition of interest was calculated by averaging the success rates reported in all studies, where reported, weighted according to the number of participants in each study. The overall success rates for standard medical care control groups were calculated in the same way for PFD and FI trials (no such control group outcome was available for anorectal pain). For each condition, the proportions of patients improving from BF and standard medical care were compared using chi-squared tests. In addition, an overall efficacy rating for BF treatment of each of the three functional anorectal disorders was performed using published standard guidelines for the evaluation of clinical efficacy of psychophysiological interventions (see Other Publications of Related Interest).

How were differences between studies investigated?
Heterogeneity was not formally assessed, although some characteristics of the included studies were presented and/or discussed in the review article.

**Results of the review**

A total of 74 studies (n=2,797) were included. Thirty-eight (n=1,526) were in PFD or constipation, 33 (n=1,205) were in FI and 3 (n=66) were in functional anorectal pain.

The overall success rate for 1,107 patients treated for PFD or functional constipation with BF was significantly higher than for the 233 patients who received standard medical care (62.4% versus 45.0%, p<0.001).

The overall success rate for the 1,170 patients treated for FI with BF was significantly higher than for the 87 patients who received standard medical care (67.2% versus 35.9%, p<0.001).

According to standard efficacy rating criteria, BF treatment was rated as efficacious for functional constipation or PFD in children and probably efficacious in adults; probably efficacious for functional FI; and possibly efficacious for anorectal pain.

**Authors' conclusions**

BF provides a significantly higher probability of successful outcome in the treatment of functional constipation and functional faecal incontinence than standard medical care; the margin of advantage may be substantial.

**CRD commentary**

This review question was broadly defined, primarily in terms of the interventions and participants of interest. The search for relevant studies covered two electronic databases and was not limited by language. Though study validity was not formally assessed, some relevant aspects of methodological quality were discussed in the results of the review. However, the authors did not state whether they took an steps to minimise error or bias in the selection of, or extraction of data from, relevant primary studies. In addition, the statistical methods used to assess the efficacy of BF relative to standard medical care (whereby within-study comparisons were ignored and overall success rates for each group were separately calculated before being compared) were inappropriate. Consequently, the findings of the review cannot be considered reliable.

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

Practice: The authors recommended that BF be offered routinely to patients to augment standard medical care, especially since it is a safe and relatively inexpensive intervention that is well accepted by patients.
Research: The authors stated the need for well-designed, randomised controlled outcome trials to conclusively establish efficacy, as well as large studies powered to analyse patient characteristics as predictors of outcome.

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**Other publications of related interest**

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