Systematic review of randomized controlled trials of the effectiveness of biofeedback for pelvic floor dysfunction

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CRD summary
The authors concluded that meta-analysis of available evidence suggested that biofeedback was the best option for pelvic floor dysfunction, but that high-quality evidence was lacking and good quality research is needed. In view of differences between the small number of identified trials and discrepancies in analysis, the review findings should be interpreted with caution.

Authors' objectives
To evaluate the effectiveness of biofeedback in adults with pelvic floor dysfunction.

Searching
CINAHL, EMBASE, MEDLINE, PsycINFO, EBM review, and the Cochrane Central Registry of Controlled Trials were searched. Search dates ranged from 1950 to April 2007. Search terms were reported. No language restrictions were applied. Reference lists of retrieved articles (including previous reviews) were also screened.

Study selection
Randomised controlled trials (RCTs) that evaluated biofeedback in adults with pelvic floor dysfunction were eligible for inclusion. The review defined biofeedback as an intervention that included visual, auditory or verbal feedback using an instrument.

The primary review outcome was symptomatic improvement in defaecation (however defined). Secondary outcomes were quality of life and levels of depression or anxiety (however defined).

The included trials differed in inclusion criteria, exclusion criteria and treatment protocols. A minority of trials defined pelvic floor dysfunction using the Rome Foundation criteria. Trials compared biofeedback with non-biofeedback treatments (laxatives, conservative management, sham feedback, and diazepam or diazepam placebo) and with other types of biofeedback. Most trials evaluated electromyography biofeedback, but different methods were used (intra-anal acrylic plugs, adhesive electromyography pads, and manometry). Other types of biofeedback evaluated included balloon, manometry and electromyography home trainer used either singly or combined with each other or with electromyography. The number of biofeedback sessions ranged from one to 10. Most included patients were female; their mean age ranged from 34 to 61 years (where reported).

One reviewer screened titles and abstracts. Two reviewers then independently selected studies from identified reports. Disagreements were resolved with a third reviewer.

Assessment of study quality
Two reviewers independently assessed validity using the following criteria: randomisation method, allocation concealment, blinding, and losses to follow-up. Disagreements were resolved with a third reviewer.

Data extraction
For each trial, two reviewers independently extracted the proportion of patients with symptomatic improvement in defaecation. Disagreements were resolved with a third reviewer. Authors were contacted if required.

Methods of synthesis
Where possible, pooled odds ratios (OR) and 95% confidence intervals (CI) were calculated using a random-effects model. Otherwise trials were discussed in a narrative synthesis. Biofeedback was compared with any other treatment and with other types of biofeedback.
Results of the review

Seven RCTs were included (n=413 patients; range 21 to 109). Trial quality was poor. Three trials had a drop-out rate of more than 15%. Three trials reported appropriate randomisation. Two trials reported allocation concealment. Three trials reported sample size calculation. None of the trials used adequate blinding. Duration of follow-up ranged from three to 12 months.

Biofeedback versus non-biofeedback (three RCTs): Biofeedback was associated with a statistically significant symptomatic improvement for pelvic floor dysfunction compared with non-biofeedback treatments (OR 5.861, 95% CI 2.175 to 15.794).

Comparing different biofeedback methods: In the text, the authors stated that electromyography biofeedback was associated with a statistically significant improvement compared with non-electromyography biofeedback (OR 6.738, 95% CI 2.914 to 15.580) and provided reference to four trials. These four trials were not the same as the four trials shown in the associated forest plot. In addition, one of the referenced trials compared electromyography treatment with electromyography plus interventions that included electromyography biofeedback, so would not be eligible for a comparison of electromyography versus non-electromyography biofeedback.

One trial reported that biofeedback significantly improved depression and inadequacy scores measured using Symptom Checklist 90.

One trial reported no significant difference between biofeedback and non-biofeedback in quality of life.

Authors’ conclusions

High-quality evidence was lacking, even though biofeedback is the recommended treatment for pelvic floor dysfunction. Meta-analysis of the available evidence suggested that biofeedback was the best option, but further good quality research is required.

CRD commentary

The review question was clearly stated and inclusion criteria were appropriately defined. Several relevant sources were searched. No language restrictions were applied. No specific attempts to minimise publication bias were reported. Methods were used to minimise reviewer errors and bias in the extraction of data and assessment of validity, but the initial stage of study selection was performed by one reviewer, introducing the potential for error and bias.

Study quality was assessed and results were clearly reported, but quality was generally poor. In the discussion section, the authors suggested interpreting results with caution due to the clinical and methodological heterogeneity among the small number of identified trials. In addition to this, there were discrepancies (noted in the results section above) that cast doubt on the reliability of the analysis comparing different types of biofeedback. In view of differences between the small number of identified trials and discrepancies in analysis, review findings should be interpreted with caution.

Implications of the review for practice and research

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

Research: The authors stated that well-designed studies are required to evaluate the effectiveness of biofeedback for adults with pelvic floor dysfunction. Future studies should compare different types of biofeedback, use adequate randomisation methods, blind the outcome assessor, and evaluate standardised outcomes, including measures of quality of life and psychopathology.

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