Efficacy of biofeedback for migraine: a meta-analysis

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CRD summary
The authors concluded that biofeedback was effective for the short- and long-term treatment of migraine. The authors' conclusions appear to be supported by the data presented, but the reliance upon before-and-after data may weaken the strength of these conclusions.

Authors' objectives
To evaluate the efficacy of biofeedback (BFB) for patients with migraine.

Searching
MEDLINE, PsycINFO, the Cochrane CENTRAL Register and PSYNDEX were searched from inception to June 2005; the search terms were reported. In addition, references lists in previous meta-analyses and primary studies were screened. Studies that were published in English or German were included.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs), uncontrolled and non-randomised studies were eligible for inclusion. Case studies and studies with fewer than 4 patients were excluded. Follow-up studies had to be of at least 6 months' duration. Most of the included studies were RCTs; other studies were pre-test post-test with and without control groups. In the follow-up studies, the duration of follow-up ranged from 6 to 60 months.

Specific interventions included in the review
Studies that evaluated individually-administered BFB, including BFB in combination with other behavioural therapies, were eligible for inclusion. Most of the included studies evaluated peripheral skin temperature feedback in combination with relaxation training, or electromyography feedback (EMG-FB), or blood-volume-pulse feedback or EMG-FB; other studies evaluated electroencephalography feedback, skin conductance feedback and forehead temperature feedback. The number of BFB sessions ranged from 3 to 24 (mean 11.0). Control interventions, where these existed, included waiting list, no treatment, placebo control, and alternative active treatments such as relaxation therapies and pharmacotherapies (propranolol and ergotamine).

Participants included in the review
Studies of adults with a diagnosis of migraine made according to a standard classification system, or studies that reported a description that included the characteristic features of migraine, were eligible for inclusion. Studies of patients diagnosed with migraine and tension type headache were included. In the included studies, where reported, the mean age of the patients was 37.1 years, 88.6% were female and the mean duration of migraine was 16.9 years.

Outcomes assessed in the review
Studies that assessed outcomes using standardised headache diaries, pain scales or other psychological questionnaires were eligible for inclusion. Studies that only reported physiological measures were excluded. The review assessed headache variables (including headache index, frequency, duration and migraine intensity), psychological variables (including self-efficacy, depression and anxiety) and medication index. Most of the included studies assessed multiple outcomes (median 3.5 per study, range: 1 to 10).

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
Two reviewers each coded data on study validity for 50% of the studies. Both raters coded a random sample of 20 studies and levels of agreement were assessed; inter-rater reliability ranged from 0.55 to 1.00 and any disagreements were resolved by discussion. The studies were assessed for 12 quality items relating to internal validity (study design, treatment allocation, drop-outs, type of outcome measure), external validity (timing of measurement, patient characteristics), construct validity (description of treatment, methods of diagnosis, changes in medication, blinding) and validity of statistical conclusion (sample size, statistical data).

Data extraction
Two reviewers each coded data for 50% of the studies. Both raters coded a random sample of 20 studies and levels of agreement were assessed; inter-rater reliability ranged from 0.55 to 1.00 and any disagreements were resolved by discussion.

For controlled studies, effect sizes were calculated as Hedge’s g (the difference between treatment and control group) and as pre-test post-test effect sizes. For studies without control groups and with active control groups, pre-test post-test effect sizes were calculated. The formulae used were reported. Where pre-post correlations were not reported, these were calculated from raw data (details were reported). Effect sizes were calculated for each outcome, each treatment group and each measurement point. For studies that did not report means and standard deviations, these were input based on available statistical data. For each study, the average effect sizes of all reported headache measures and all psychological measures were calculated with 95% confidence intervals (CIs). Variances of mean effect sizes were averaged after adjusting for covariance between individual effect sizes.

Methods of synthesis
How were the studies combined?
A pooled effect size (d) was calculated by averaging individual effect sizes weighted by the inverse of the variance. Pooled effect sizes with 95% CIs were calculated for headache relief from pre- to post-test. A fixed-effect model was used in the absence of significant statistical heterogeneity, while a random-effects model was used where heterogeneity was significant. Publication bias was assessed using a funnel plot. In addition, the number of unpublished studies showing zero effects that would be required to reduce the mean effect size to zero (i.e. the fail-safe N) was calculated.

How were differences between studies investigated?
Statistical heterogeneity was assessed using the Q statistic. The influence on the results of the following factors was examined in subgroup analyses: type of control condition (waiting list, placebo control, relaxation and pharmacotherapy); formulae used to calculate effect size; study design (effect sizes using data from RCTs versus pre-test post-test); type of headache variable; type of psychological variable; method used to measure headache variables (structured diary or other); and BFB modality. Weighted regression was used to examine the effects of five predictors: treatment setting, years with migraine, gender, age and validity score. These predictors were then used to explain the variance in follow-up effect sizes. The analysis was repeated after classifying drop-outs as nonresponders.

Results of the review
Fifty-five studies (n=2,229) were included: 38 RCTs (n=1,640) and 17 pre-test post-test studies (n=589). These studies provided data on 84 active BFB treatments and 33 control treatments.

The overall completion rate was 86.2%; for follow-up studies the completion rate was 95%. None of the studies reported intention-to-treat analysis. The overall study quality scores ranged from 3 to 11 (mean 7.3).

BFB was associated with a medium statistically significant effect size on headache compared with baseline (d=0.58, 95% CI: 0.52, 0.64; based on 84 effect sizes). The studies were statistically homogeneous (Q=78.94).

BFB was associated with a small to medium statistically significant effect size on headache compared with waiting-list control (d=0.45, 95% CI: 0.26, 0.63; based on 14 effect sizes, n=574), but there was no significant difference in effect size between BFB and placebo control, relaxation and ergotamine. The largest pre-test post-test effect sizes were found for the effects of BFB on headache frequency (d=0.70, 95% CI: 0.60, 0.80; based on 33 effect sizes, n=623) and self-efficacy (d=0.89, 95% CI: 0.58, 1.19; based on 7 effect sizes, n=68).
Significant medium-to-large effects were seen for all BFB modalities, but there were no significant differences between modalities.

Follow-up studies (15 studies).

BFB was associated with a medium-to-large statistically significant effect size on headache (d=0.69, 95% CI: 0.51, 0.88; based on 26 effect sizes). Significant heterogeneity was found (Q=20.09).

The weighted regression analysis showed a significant negative association between the effect size in follow-up studies and validity score and number of headache years, and a significant positive association between effect size and treatment setting.

The symmetrical funnel plot suggested the absence of publication bias. It was estimated that 4,776 unpublished studies showing zero effects would be required to reduce the mean effect size to zero.

Authors' conclusions
BFB was associated with a short- and long-term medium effect size in patients with migraine, significantly reducing pain and psychological symptoms.

CRD commentary
The review addressed a clear question that was defined in terms of the participants, intervention, outcomes and study design. Several relevant sources were searched. The authors made only limited attempts to reduce language bias and made no attempt to minimise publication bias, although the potential for publication bias was assessed and no evidence of it was found. Study validity was assessed using specified criteria but only the overall composite score was presented; this makes it difficult to comment independently on the quality of the included studies. Some attempts were made to reduce reviewer error and bias in the extraction of data and assessment of validity of some studies, but reviewer errors and bias might have been a limitation.

The studies were pooled using meta-analysis and multiple outcome measures within individual studies were taken into account. Statistical heterogeneity was assessed and potential sources of heterogeneity (including study quality) were extensively investigated. The meta-analyses were largely based on pre-test post-test effect size data and there were only limited comparisons with alternative treatments. The authors' conclusions appear to be supported by the data presented, but the reliance upon before-and-after data might weaken the strength of these conclusions.

Implications of the review for practice and research
Practice: The authors stated that BFB can be recommended as an alternative effective nonmedical treatment for patients with chronic migraine and is suitable for the long-term prevention of migraine attacks. Research: The authors stated the need for further studies to evaluate the effects of behavioural treatments for headaches on a wide range of outcomes, including aspects of pain, quality of life, coping strategies, use of health services, and work and occupational outcomes. There is also a need to confirm the superiority of BVP-FB and to examine the relationship between changes in self-efficacy and perceptions of illness and the treatment effects of BFB.

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