Executive Summary

Evidence Report:

Behavioral and Physical Treatments for Tension-type and Cervicogenic Headache

---

Prepared for

Foundation for Chiropractic Education and Research
P.O. Box 4689
Des Moines, IA 50306-4689

by

Duke University Evidence-based Practice Center
Center for Clinical Health Policy Research
2200 W. Main Street, Suite 230
Durham, NC 27705

EXECUTIVE SUMMARY

Top

Background

Tension-type headache and cervicogenic headache are two of the most common non-migraine headaches. Population-based studies suggest that a large proportion of adults experience mild and infrequent (once per month or less) tension-type headaches, and that the one-year prevalence of more frequent headaches (more than once per month) is 20%-30%; a smaller percentage of the population (roughly 3%) has been estimated to have chronic tension-type headache (≥ 180 days per year). Estimates of the prevalence of cervicogenic headache have varied considerably, due in large part to disagreements about the precise definition of the condition. A recent population-based study, which used the diagnostic criteria of the International Headache Society (IHS), found that 17.8% of subjects with frequent headache (≥ 5 days per month) fulfilled the criteria for cervicogenic headache; this was equivalent to a prevalence of 2.5% in the larger population. This agrees with an earlier clinic-based study which found that 14% of headache patients treated had cervicogenic headache.

The impact of tension-type headache on individuals and society appears to be significant. According to one population-based study, regular activities were limited during 38% of tension-type headache attacks, and 4% of respondents indicated that their headaches affected their attendance at work. Eighty-nine percent of tension-type headache sufferers reported that their headaches had negatively affected their relationships with friends, colleagues, and family. Little is known about the personal and societal impact of cervicogenic headache.

Nearly all patients with tension-type headache have used medications at one time or another to treat their headaches. But pharmacological treatments are not suitable for all patients, nor are they universally effective. Drug treatments may also produce undesired side effects. Partly for these reasons, significant interest has developed among both patients and health care providers in alternative treatments for tension-type headache, including behavioral and physical interventions. Cervicogenic headache, when diagnosed as such, is commonly treated with non-pharmacological interventions, especially physical treatments.

The behavioral interventions most frequently studied for the treatment of headache may be classified into three broad categories: relaxation training, biofeedback training (often administered in conjunction with relaxation training), and cognitive-behavioral (or stress-management) therapy. The physical treatments most frequently studied are acupuncture, cervical spinal manipulation, and physiotherapy. Though there are exceptions, these behavioral and physical interventions are primarily aimed at the prevention of headache episodes rather than the alleviation of symptoms once an attack has begun.

If effective and available, these non-pharmacological treatments may be the first choice for most patients and may also be well suited for the significant minority of patients who: (a) have poor tolerance of pharmacological treatments; (b) have medical contraindications for pharmacological treatments; (c) experience insufficient relief from, or are unresponsive to, pharmacological treatment; (d) wish to become pregnant (or are nursing); (e) have a history of long-term, frequent, or excessive use of analgesic or abortive medications that can aggravate headache problems; or (f) simply prefer to avoid medication use.

Top

Objectives

The objective of this report is to describe and assess the evidence from randomized controlled trials (RCTs) and other prospective, comparative clinical trials (CCTs) for the efficacy and safety of behavioral and physical treatments for tension-type and cervicogenic headache. The report is limited to therapies that have been studied specifically among populations of patients with tension-type or cervicogenic headache. As a result, some treatments routinely used by health care providers to treat these types of headache may not be represented.

Top

Methodology

The literature review addressed the questions:

> (1) What are the effects on headache frequency and/or headache intensity when behavioral treatments are compared to no intervention (wait-list control), "placebo" or sham interventions, alternative behavioral or physical treatments, and drug therapies among patients with tension-type or cervicogenic headache?
>
> (2) What are the effects on headache frequency and/or headache intensity when physical treatments are compared to no intervention (wait-list control), "placebo" or sham interventions, alternative physical or behavioral treatments, and drug therapies among patients with tension-type or cervicogenic headache?

To be considered for the review, studies were required to be prospective, controlled trials of behavioral or physical treatments aimed at the prevention of attacks of tension-type or cervicogenic headache or the relief of symptoms of individual episodes of headache in patients with tension-type or cervicogenic headache. The behavioral interventions considered included the broad categories of relaxation, biofeedback, cognitive-behavioral (or stress-management) therapy, and hypnosis. Physical interventions considered for this report included acupuncture; cervical spinal manipulation; low-force techniques, such as cranial sacral therapy; massage (including trigger point release); mobilization; stretching; heat therapy; ultrasound; transcutaneous electrical nerve stimulation (TENS); surgery; and exercise (including postural exercises). Acceptable control treatments included wait-list/no intervention, sham interventions (placebo), other behavioral or physical treatments, and preventive or acute drug therapies.

Although the use of a specific set of diagnostic criteria (e.g., those developed by the Ad Hoc Committee on the Classification of Headache or the Headache Classification Committee of the IHS) was not required, diagnoses had to be based on at least some of

the distinctive features of tension-type headache or cervicogenic headache and had to exclude features characteristic of migraine. Both episodic and chronic tension-type headache were included. Trials involving patients with "mixed" migraine and tension-type headache, chronic daily headache, and post-traumatic headache were considered on a case-by-case basis and were included only if they met reasonable criteria for tension-type or cervicogenic headache.

Studies were included only if allocation to treatment groups was randomized or quasi-randomized (based on some nonrandom process unrelated to the treatment selection or expected response). Concurrent cohort comparisons and other non-experimental designs were excluded.

Relevant controlled trials were identified by searching MEDLINE (January 1966 through September 1999) using the MeSH term "headache" (exploded) and a published strategy for identifying randomized controlled trials. Additional search strategies included computerized bibliographical searching of the PsycINFO, MANTIS, and CINAHL databases and the Cochrane Controlled Trials Register; hand-searching of the Chiropractic Research Archives/Abstracts Collection (CRAC) (conducted by members of a research team headed by Drs. Gert Bronfort and Niels Nilsson); hand-searching of the non-MEDLINE-indexed journal, *Headache Quarterly: Current Treatment and Research;* searching the references of relevant review articles, meta-analyses, and included trials; and consulting with experts in the field of headache.

Studies identified by the literature search were screened for further review based on criteria focusing on patient population, intervention, study design, and type of outcome data reported.

Included studies were evaluated for methodological quality with respect to three domains: randomization, blinding, and description of dropouts. In addition, the behavioral and physical interventions tested were assessed for clinical appropriateness by experienced clinicians using a scale previously developed for trials of physical treatments for headache.

Information on patients, methods, interventions, outcomes, and complications/adverse effects were abstracted from the original reports directly into specially designed, computerized tables similar in format to the final evidence tables envisaged for the report. We collected trial data on symptomatic outcomes related to head pain and did not consider physiological or other measures not directly relevant to the patients' symptomatic experience.

We preferred that outcome data be based on daily recording of headache symptoms by patients, rather than on global or retrospective assessments performed by patients or investigators. Outcomes were recorded for all time points reported for which the dropout rate was ≤ 20%.

For preventive trials, we recorded results for headache frequency, headache index, headache duration, and headache intensity. In the relatively few cases in which a

behavioral or physical intervention was aimed at the relief of symptoms of an individual attack of headache, we recorded results for headache relief and headache intensity.

For dichotomous outcomes (e.g., success/failure), we required that the threshold for distinguishing between success and failure be clinically significant; for example, we interpreted a 50% or more decrease in headache frequency as meeting this criterion. Dichotomous outcomes meeting our definition of a clinically significant threshold were reported as proportions (or response rates for each treatment) which may be directly compared (difference in proportions). We also used these proportions to calculate odds ratios and numbers-needed-to-treat.

When outcome data were reported on an ordinal scale, we selected a threshold based on the definition of clinically significant improvement described immediately above and converted these data into dichotomous form. If categorical data could not be split into dichotomous outcomes meeting the a priori definition, they were not included in the analysis.

When outcomes were reported on a continuous scale (e.g., mean headache index or mean headache frequency) and variance estimates were also available, we re-scaled and standardized the continuous outcome data for each treatment condition in each study using a published method. In the case of the behavioral trials, we then used the resulting standardized outcome measures to calculate summary effect sizes for each type of treatment, using a multi-variable, random-effects model, controlling for study. For the purposes of this meta-analysis, the behavioral interventions were grouped into categories based in part on statistical considerations and in part on clinical considerations.

Because some of the behavioral trials that reported continuous data did not permit effect size calculation, the sample of studies included in the meta-analysis may be subject to bias. To investigate this potential bias, we calculated another measure of effectiveness, the percentage of improvement (in headache index or frequency) from pre- to post-treatment. Because large differences between the percentage improvement scores from studies *included in the meta-analysis* and those from studies *excluded from the meta-analysis* would suggest bias, we compared the mean percentage improvement scores (weighted for sample size) of the two groups.

We also used the standardized outcome measures described above to calculate individual effect sizes for pair-wise comparisons of active behavioral treatments with control treatments for every trial with a control arm, and to calculate effect sizes for all pair-wise comparisons in those few trials of physical treatments for which effect sizes could be calculated.

Top

Summary of Findings

Behavioral Treatments

Thirty-five trials of behavioral treatments were included in the report; 23 of these reported continuous outcome and variance data and were included in a meta-analysis. The principal findings of the analysis were:

- Behavioral treatments for tension-type headache have a consistent body of research indicating efficacy. The effect size data suggest that each of the interventions examined (relaxation training, cognitive-behavioral therapy with or without relaxation training, EMG biofeedback combined with relaxation training, and EMG biofeedback alone) is effective for reducing tension-type headache symptoms when compared to wait-list control.

- The collection of trials and the results of the meta-analysis provide little guidance for choosing among the treatments considered. The summary effect size estimates for the various categories of behavioral therapy are statistically indistinguishable.

- Clinically, behavioral treatments are often used in combination. Five of the trials we reviewed were designed to test the incremental benefit of adding EMG biofeedback to relaxation training, and seven trials allowed estimating the incremental benefit of adding cognitive-behavioral therapy to relaxation training. Finally, three trials examined the effect of adding relaxation to EMG biofeedback. None of these studies found a statistically significant incremental benefit to the added component; however, all the studies were too small to detect small, but potentially clinically significant differences.

- The question of combining drug and behavioral therapy has been examined in a single study which suggested that amitriptyline with cognitive-behavioral therapy and relaxation training leads to better headache outcomes than the behavioral component alone. Longer-term 6-month results no longer showed significant differences, perhaps because the behavioral therapy resulted in slower onset of improvement.

- A large number of studies could not be included in the meta-analysis because they did not report variance data to allow calculation of effect size scores, even though they met all other inclusion criteria. Comparison of percentage improvement scores from trials included in, and excluded from, the meta-analysis did not substantially change our interpretation of the analysis.

Physical Treatments

Seventeen controlled trials of physical treatments were reviewed. The main findings were as follows:

- Four trials of acupuncture compared to sham acupuncture suggest a modest improvement in headache outcomes; however, statistically significant findings reported in a small pilot study are probably spurious because of an inappropriate statistical analysis. Another trial was so poorly reported that it was impossible to evaluate it. Acupuncture was less effective than physiotherapy in one study, but this study had a high dropout rate in the acupuncture arm, which may have biased the estimates of effect.

- Cervical spinal manipulation was associated with improvement in headache outcomes in two trials involving patients with neck pain and/or neck dysfunction and headache. Manipulation appeared to result in immediate improvement in headache severity when used to treat episodes of cervicogenic headache when compared with an attention-placebo control. Furthermore, when compared to soft-tissue therapies (massage), a course of manipulation treatments resulted in sustained improvement in headache frequency and severity. However, among patients without a neck pain/dysfunction component to their headache syndrome – that is, patients with episodic or chronic tension-type headache – the effectiveness of cervical spinal manipulation was less clear. No placebo or no-treatment control studies of manipulation have been performed in these populations. In one trial conducted among patients with episodic tension-type headache, manipulation conferred no extra benefit when added to a soft-tissue therapy (deep friction

massage). In another trial conducted among patients with tension-type headache, amitriptyline was significantly better than manipulation at reducing headache severity during the 6-week treatment period; there was no significant difference between the two treatments for headache frequency during the same period. Interpretation of these results is difficult because all patients received the same relatively low dose of amitriptyline (30 mg). Despite the uniform and relatively low dose of amitriptyline, however, adverse effects were much more common with amitriptyline (82% of patients) than with manipulation (4%). During the 4-week period after both treatments ceased, patients who had received manipulation were significantly better than those who had taken amitriptyline for both headache frequency and severity. Although amitriptyline is usually continued for longer than 6 weeks, the return to near-baseline values for headache outcomes in this group contrasts with a sustained reduction in headache frequency and severity in those who had received manipulation.

- Very limited conclusions may be reached about the efficacy of physiotherapy on the basis of the trials reviewed in this report. One study found that deep friction massage was significantly less effective than cervical spinal manipulation at reducing headache severity and frequency in patients with cervicogenic headache. Another trial – this one conducted among patients with tension-type headache – found that physiotherapy (massage, cryotherapy, TENS, passive stretching, relaxation, and headache education) was significantly more effective than acupuncture at reducing headache severity, but this trial had a high dropout rate in the acupuncture arm, which may have biased the results. A single trial conducted among patients with post-traumatic headache found that physiotherapy (mobilization) was significantly better than cold-pack therapy at reducing headache index; however, results from this trial were difficult to interpret due to several methodological and design flaws.

- Of two studies of cranial electrical stimulation (CES) for tension-type headache, one suggested that the technique is effective, and the other did not.

- A single small trial comparing aerobic exercise with a behavioral intervention among patients with tension-type headache was inconclusive.

- A single study of therapeutic touch suggested an effect on headache severity; however, since the only comparator treatment was sham therapeutic touch, it is possible that the observed effect may be due to nonverbal cues delivered to the subjects by the non-blinded therapist, with patients in the genuine therapeutic touch group responding with a greater expectancy or placebo response.

Top

Future Research Needs

The trials reviewed in this report suggest that several behavioral and physical treatments are effective in treating tension-type and/or cervicogenic headache. However, further research is needed on many topics. The methodological shortcomings of many of the currently available studies limit certainty about the effectiveness of these treatments. These shortcomings include the relative lack of no-treatment controls, lack of credible blinding (in those cases in which blinding was possible), short duration of follow-up, and small numbers of patients.

Behavioral and physical treatments have typically been studied in populations that may be favorably disposed to these forms of therapy. At least in some instances, patient expectations have been assessed and found not to bias results; overall, however, the generalizability of findings from studies conducted in such populations to the wider medical clinical setting has been inadequately demonstrated.

There is a need for further trials that directly compare behavioral and physical interventions with established pharmacological therapies. Also needed are studies examining the integration of behavioral and physical treatments into clinical care in primary or specialized treatment settings. Effective implementation of behavioral and physical interventions may also require information regarding the costs and cost-effectiveness of behavioral and physical interventions (as compared to established pharmacological therapies), including long-term studies of these issues.