Efficacy of spinal manipulation for chronic headache: a systematic review
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Authors' objectives
To determine the efficacy and effectiveness of spinal manipulation therapy (SMT) for chronic headache.

Searching
MEDLINE (from 1966 to 1998), EMBASE (from 1974 to 1998), CINAHL, CRAC, and MANTIS were searched. Citations were tracked and non-indexed chiropractic, osteopathic and manual medicine journals were handsearched. The reference lists from relevant papers were also examined. Studies in English, German, French, Dutch and any of the Scandinavian languages were eligible for inclusion. Abstracts from proceedings and unpublished studies were excluded.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) were eligible for inclusion if they had at least ten patients in the SMT arm.

Specific interventions included in the review
Comparisons of SMT with either placebo or other interventions were eligible. The included studies used SMT alone or in combination with massage, azapropazone or deep friction massage. SMT was performed by chiropractors, medical doctors, physical therapists or osteopaths. The number of sessions of SMT ranged from one to twelve (mean: 6) over one day to 8 weeks (mean: 4 weeks). Studies compared SMT with amitriptyline, deep friction, mobilisation, palpation and rest, cold packs, azapropazone and waiting-list.

Participants included in the review
Patients with chronic headaches were eligible for inclusion. In the review, chronic headache could include tension-type, cervicogenic and migraine headaches defined according to the International Headache Society criteria, but eligible participants were not restricted to these categories. The included studies were of patients with chronic migraine, chronic and episodic tension-type, chronic cervicogenic, cervicogenic-like, chronic muscle-tension, post-traumatic and neck pain-related headaches. The participants were aged from 15 to 70 years.

Outcomes assessed in the review
Studies that reported at least one outcome of relevance to the patients were eligible for inclusion. The primary outcomes in the review were patient-rated pain severity, frequency and duration. The included studies assessed outcomes from immediately post-treatment up to 12 weeks’ post-treatment. Side-effects were also assessed.

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
Validity was assessed and scored using the following criteria: inclusion and exclusion criteria explicitly defined; baseline comparability of the treatment groups; description of appropriate randomisation process; assessment using at least one main outcome measure that was valid and reliable; effective patient blinding; effective blinding of treatment providers; unbiased assessment of primary outcome; adequate post-intervention follow-up period (greater than 1 month for acute conditions and greater than 3 months for chronic); adequate description of interventions; differences in attrition bias between groups controlled for and explicitly described; SMT compared with existing efficacious therapy or commonly used treatment or, if compared with placebo, prior comparison with efficacious or commonly used therapies; clear definition of primary objective of study; use of appropriate statistical tests; adequate statistical power; the provision of confidence intervals or data to allow their calculation; drop-outs and missing data adequately described for each treatment group and accounted for in the analysis; intention-to-treat analysis used if appropriate; adjustment
for multiple statistical tests; and conclusions valid and related to primary outcome.

Studies scored one point for each criterion fully met and one half point for a criterion partially met. The maximum possible score was 100 points. In addition, study quality was assessed and scored using the 5-point Jadad scale that assesses randomisation, blinding and treatment of drop-outs. Two reviewers assessed and scored validity on the 100-point scale and reached consensus. Two reviewers assessed validity using the Jadad scale.

**Data extraction**

Two reviewers independently extracted the data. The tabulated information included the validity score, type of headache, type of intervention and control, the number of patients per treatment group and the results. For each study, the effect size differences and 95% confidence intervals were either calculated for SMT compared with control from the reported data, or estimated from reported values for statistical tests. Corrections were made to allow for effect size estimate bias arising from small sample sizes (fewer than 50 patients).

**Methods of synthesis**

How were the studies combined?

The studies were grouped by type of headache and described. The studies were then combined by evaluating the level of evidence for the efficacy of some interventions, taking account of the type of comparison intervention (established efficacious treatment, commonly used therapy or placebo), quality scores, the number of RCTs and the statistical significance of the results. The evidence was classified as strong, moderate, limited or inconclusive. Strong evidence was defined as at least two RCTs scoring 50 points or more on quality criteria with statistically-significant results. Moderate evidence was defined as one RCT scoring 50 points or more on quality criteria with statistically-significant results. Limited evidence was defined as at least one RCT scoring 21 to 49 points or at least two RCTs scoring 20 points with statistically-significant results, or at least two RCTs scoring 20 points or less on quality criteria with no statistically-significant results. Inconclusive evidence was defined as conditions for limited evidence not met or conflicting evidence from eligible RCTs.

Treatment efficacy was assessed as follows according to the type of comparison intervention: evidence of efficacy was indicated when SMT had a similar effect to an established efficacious treatment, or was better than placebo or a commonly used therapy; evidence of inefficacy was indicated when SMT was inferior to an established efficacious treatment, placebo or a commonly used therapy, or had an effect similar to placebo. Superiority or inferiority was indicated when the effect size equalled plus or minus 0.5.

How were differences between studies investigated?

Sensitivity analyses were performed by using different cut-off points for the quality score to reclassify the level of evidence, and also by using different effect size cut-off points to classify efficacy.

**Results of the review**

Nine RCTs (683 patients) were included.

Most of the included RCTs had substantial methodological flaws. The quality scores ranged from 21 to 87 out of 100 points.

There were 2 RCTs of SMT versus amitriptyline: one involved 218 patients with chronic migraine and the other involved 150 patients with chronic and episodic tension-type headaches. The quality scores were 87 and 75, respectively. There was moderate evidence that, in the short term, SMT is similar to amitriptyline for the prevention of chronic tension-type headaches and migraine.

There was one RCT (75 patients) of SMT plus massage versus massage for episodic tension-type headaches. The quality score was 56 points. SMT added to massage did not improve episodic tension-type headaches.

There was one RCT (53 patients) of SMT versus massage for cervicogenic headache. The quality score was 67 points. There was moderate evidence that SMT is better than massage for cervicogenic headache.
The sensitivity analysis showed that the conclusions remained the same when different criteria were used to classify the level of evidence and to assess efficacy.

In 2 RCTs of SMT versus amitriptyline, adverse effects were reported by more than 50% of the patients on amitriptyline (drowsiness, dry mouth, weight gain) compared with 5% of those on SMT (most commonly muscle soreness and neck stiffness). None of the included studies reported serious side-effects, such as vertebrobasilar accidents, with SMT.

**Authors' conclusions**
SMT may be better than massage for cervicogenic headache and may be of similar benefit to prescription drugs for tension-type headaches and migraine. The authors caution that the evidence is based on a small number of studies and that further research is required.

**CRD commentary**
The review question was clear in terms of the study design and intervention. Participants with chronic headache were eligible, but the criteria for this group were broadly defined. The inclusion criteria were not defined in terms of outcomes, but the preferred primary outcomes for use the review were stated. Several relevant databases were searched and papers in several languages were eligible. However, the search terms were not stated and the methods used to select the studies were not described. Unpublished studies were excluded and this, as the authors correctly stated, raises the possibility of publication bias. Two reviewers assessed study quality and extracted data, which reduces the potential for bias and error. Validity was assessed using defined criteria, some relevant information on the included studies was tabulated, and the characteristics of the individual studies were adequately summarised.

The studies were appropriately combined by considering the level of evidence for specified interventions, and a sensitivity analysis was used to explore the influence of the cut-off point on the results. However, the level of evidence was not discussed in relation to the specific studies on which the classifications were based, and the conclusions were based predominantly on one study per intervention. Hence, as the authors stated, it is not possible to comment on whether the results from the review can be applied to all participants in all settings by all practitioners. The authors were correct to advise caution when interpreting the conclusions of this review.

**Implications of the review for practice and research**
Practice: The authors did not state any implications for practice.

Research: The authors state that further studies are required to assess the cost-effectiveness of SMT and to evaluate long-term outcomes. They also state that future studies should be rigorously designed, executed and analysed, and should have follow-up periods of sufficient length.

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