Spinal manipulation for low back pain: an updated systematic review of randomized clinical trials

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Authors' objectives
To assess the efficacy of spinal manipulation for patients with lower-back pain.

Searching
MEDLINE was searched from 1966 to June 1995 for English language publications using the following keywords: 'backache', 'musculoskeletal diseases', 'joint diseases', 'manipulation', 'osteopathy', 'chiropractic', 'evaluation studies', 'outcome and process assessment'. References given in relevant publications were further examined. Abstracts and unpublished studies were not selected.

Study selection
Study designs of evaluations included in the review
Randomised controlled trials (RCTs) where the treatment regime included manipulation or mobilisation of the spine (additional interventions were allowed) and the participants suffered from lower-back pain.

Specific interventions included in the review
Spinal manipulations studied included both high velocity thrust to a joint beyond its restricted range of movement and spinal mobilisations consisting of low velocity, passive movements within or at the limit of joint range. Manipulations were of the following types: osteopathic, chiropractic, rotational, Cyriax, Kaltenborn, Lewitt, Janda, Stoddard and Maitland. Comparison treatments included exercises and advice, spinal mobilisation, back school, analgesics, infrared heat, shortwave diathermy, ultrasound, non-steroidal anti-inflammatory drugs, massage, electrical stimulation and physiotherapy.

Participants included in the review
The participants were patients with both acute back pain, usually defined as having a duration of less than 6 weeks, and chronic lower-back pain, usually defined as having a duration beyond 6 weeks.

Outcomes assessed in the review
A study outcome was determined to be positive if the authors concluded that manipulation was more effective than the reference treatment. Outcomes assessed included pain intensity measured with a visual analogue scale, mean number of days until recovery, score on Oswestry Disability Scale, improvement in spinal flexion and straight leg raising, improvement in symptoms, and number of patients assessing treatment as effective.

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 authors performed the selection.

Assessment of study quality
The validity of the primary studies was assessed using the following criteria: homogeneity of study population, similarity of baseline characteristics, adequacy of randomisation, details of drop-outs according to treatment group, loss to follow-up, sample size, descriptions of interventions included, pragmatic study, cointerventions avoided, placebo-controlled, qualification of therapist, blinding of patients, relevant outcome measure, blinded outcome assessment, adequate follow-up period, intention to treat analysis, and frequencies of most important outcomes presented for each treatment group. All studies were scored on the stated criteria by two independent reviewers, and any disagreements were resolved by consensus or by a third reviewer.
Data extraction
The authors do not state how the data were extracted for the review, or how many of the authors performed the data extraction.

Methods of synthesis
How were the studies combined?
The studies were combined in a narrative review.

How were differences between studies investigated?
The studies were grouped according to the score obtained for the methodological quality of the study, and results reported for this grouping of studies.

Results of the review
Thirty-six RCTs were used to assess the efficacy of manipulation in lower-back pain.

Twelve RCTs (N=899) were used to assess the efficacy of manipulation versus other treatment modality in acute lower-back pain.

Eight RCTs (N=611 approximately, since the number of patients was not stated for one study) were used to assess the efficacy of manipulation versus other treatment modality in chronic back pain.

Twelve RCTs (N=2,240 approximately, since the number of patients was not stated for one study) were used to assess the efficacy of manipulation versus other treatment modality in acute, subacute and chronic lower-back pain.

Eleven RCTs (N=876 approximately, since the number of patients was not stated for 2 studies) were used to assess the efficacy of manipulation versus some kind of placebo in acute and chronic lower-back pain.

Only 5 studies had a methodological score of at least 50 points, out of a maximum of 100. Only 16 studies included an effect measure of at least 3 months. There appeared to be no clear relation between the methodological score and the overall outcome of the studies.

Acute lower-back pain: for manipulation versus other modalities, 5 studies reported positive effects of manipulation, 4 reported negative effects and 3 reported positive effects in a subgroup.

Chronic lower-back pain: for manipulation versus other modalities, 5 studies reported positive results, 2 reported negative results, and 1 reported no conclusion.

Subacute and chronic lower-back pain: for manipulation versus other modalities in mixed acute, subacute and chronic lower-back pain, 8 reported positive results, 1 reported positive results in a subgroup only, 2 reported negative results, and 1 reported no conclusion.

Manipulation versus some kind of placebo in mixed acute and chronic lower-back pain: 7 positive reports, 1 positive in a subgroup only, and 3 negative reports.

Authors' conclusions
The efficacy of spinal manipulation for patients with acute or chronic lower-back pain has not been demonstrated with sound randomised clinical trials. There are indications that manipulation might be effective in some subgroups of patients and further research is required on this topic. Future studies should be of sound methodological quality and should consider developing relevant prognostic indicators and a diagnostic classification system to help identify subgroups which could be studied.

CRD commentary
This review includes a rigorous scoring of primary studies on 17 stated methodological criteria and reports the most common methodological flaws found. These include lack of baseline comparison of treatment groups, inadequate description of randomisation method, incomplete details of drop-outs, small sample size, lack of blinding of patients, variable effect measures and inadequate analysis and presentation of data. The authors acknowledge that by limiting the literature search they may have omitted some relevant studies. No details are given of the methods used to select studies or to extract data from the included studies. A definition of low back pain which was used as an inclusion criteria for participants would have been helpful, and some indication of patient characteristics would have been useful in assessing generalisability of the results. It is stated that manipulation could be given separately or with other therapeutic modalities, but the reporting of results does not appear to take this into account. Positive and negative outcomes are reported without reference to the sample size of the studies. Despite the considerable heterogeneity among trials there is little exploration or discussion as to possible sources of this heterogeneity. Consideration of definition of inclusion criteria, characteristics of participants, duration of therapy, duration of follow-up, intention-to-treat analysis from raw data where possible, more rigorous evaluation of outcome measures used, weighted effects measures and accounting for specific aspects of quality assessment may have revealed possible sources of heterogeneity. The authors suggest there may be evidence that manipulation is more efficacious in certain subgroups of patients with acute or chronic low back pain. This albeit tentative suggestion does not appear to be supported by the evidence offered.

The authors have rigorously assessed the quality of the primary studies of spinal manipulation in patients with low back pain and found no conclusive evidence of efficacy of this therapy. The methodological flaws reported in the primary studies would appear to preclude any other conclusion.

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

Future research should include the development of a classification of lower-back pain and relevant outcome measures to be used in well-designed randomised trials of defined spinal manipulation.

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