

Spinal manipulative therapy – no better, no worse than other treatments for low-back pain...

Where do we go from here?

Transferring Research into Practice

The purpose of *Linkages* is to critically review the best available evidence in the literature regarding soft-tissue injury and to disseminate these reviews to clinical decision-makers in health-care delivery, workplace, policy and compensation settings. For these reviews, we draw on topical, English-language articles about the diagnosis, treatment and prevention of soft-tissue injury.

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IT'S ESTIMATED THAT BETWEEN 70 AND 85 PER CENT of the population experiences low-back pain at some time in their lives.¹ For some people, this is a benign, transient, self-limiting condition. Yet for others, it develops into a disabling disorder that impedes most activities of daily living for extended periods of time.

The emotional, physical and financial costs associated with low-back pain are high. This explains why such an enormous effort is being made to find more effective treatments. Many studies have attempted to substantiate treatments ranging from acupuncture to analgesics.

Spinal manipulative therapy (SMT) features prominently in many current guidelines for the management of both acute and chronic low-back pain.² However, the recommendations contained in these guidelines vary widely and it's safe to say consensus is lacking.

In this edition of *Linkages*, we take a closer look at the role of SMT versus other common available treatments for both acute and chronic low-back pain. These include: care by a general practitioner, the use of analgesic medication, physical therapy and/or exercise, and attending back school. We also compare SMT to a variety of other back pain therapies that have been judged ineffective according to scientific evidence but which are in use nevertheless.

In their Cochrane Review, Assendelft et al. attempted to update, improve, and resolve inconsistencies in previous systematic reviews by incorporating data from recent, high-quality randomized controlled trials on the use of SMT for low-back pain. Their goal was to provide evidence-based support for individual and collective treatment decisions.

The value of systematic reviews

Every year, six million new articles reporting results of biomedical research are published. The sheer volume of new publications makes it nearly impossible for health professionals, consumers and policy-makers to keep up with the literature and make timely, evidence-based decisions on patient care, treatment choice and health policy.

Traditionally, research results have been summarized in non-systematic narrative reviews. However, these are open to bias because the author's subjective opinion about the quality of articles may influence the narrative review. Systematic reviews offer a better alternative. They apply scientific strategies in ways that limit bias to the assembly, critical appraisal, and synthesis of all relevant studies that address a specific clinical question.

Although systematic reviews are supposed to use methods that minimize bias and error, they are not immune from flaws in methodology which can compromise the validity of results. This is why it so important to "review the reviews."

In this edition of *Linkages*, we report on a recently published Cochrane systematic review of spinal manipulative therapy for low-back pain. One internal and two external clinical experts provided commentaries on the relevance and applicability of the results. We thank all those who contributed to this issue of *Linkages*.

Questions about *Linkages*?

You will find this issue of *Linkages* (and an archive of previous issues) on the Institute's web site (www.iwh.on.ca). They can be downloaded at no charge in PDF format. For more information about *Linkages*, please contact Mana Rezai at the Institute for Work & Health, by phone at (416) 927-2027 ext 2182, by fax at (416) 927-4167, or by e-mail at mrezai@iwh.on.ca.



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ARTICLE REVIEWED

Assendelft WJJ, Morton SC, Yu Emily I, Suttorp MJ, Shekelle PG.

Spinal manipulative therapy for low-back pain (Cochrane Review).

Cochrane Library, 2004: Issue 1. Ann Intern Med. 2003 Jun 3; 138 (11): 871-81.

OBJECTIVES

The objectives of this Cochrane Review were:

- to assess whether spinal manipulation is more likely to produce rapid recovery from low-back pain than other treatments (measured as percentage of patients recovered, self-reported levels of pain and functional capacity)
- to assess whether spinal manipulation is better than other treatments in establishing long-term effects (measured as percentage of patients recovered, pain and functional status)

TYPES OF STUDIES INCLUDED

- Truly randomized studies
- Studies that measured at least one clinically relevant outcome (pain, global improvement, back pain-specific functional status, or generic functional status)
- Studies with a follow-up measurement of at least one day (24 hours)
- Studies published as a full report before January 2001

TYPES OF PARTICIPANTS

- **Setting** The studies involved patients in primary, secondary or tertiary care settings.
- **Duration of complaints** All patients with back pain were included, regardless of duration. For subgroup analysis, patients were categorized as *acute* (duration of pain less than three weeks), *sub-acute* (duration of pain three to 13 weeks) or *chronic* (pain lasting longer than 13 weeks).
- **Radiation pattern** All patients with back pain were included, regardless of radiation pattern. For subgroup analysis, patients were categorized as having pain that either did or did not radiate below the knee.

TYPES OF INTERVENTIONS

In this review, *spinal manipulative therapy (SMT)*—referred to either as *manipulation* or *mobilization*—was compared with another treatment or sham manipulation delivered to a control group to relieve low-back pain.

TYPES OF CONTROL GROUPS

The authors used available research evidence and “the collective clinical judgment of similar effectiveness of the Editorial Board of the Cochrane Back Review Group to group the therapies into clusters of presumed effectiveness” as follows:

- ***Sham manipulation*** (No definition was provided by the researchers.)
- ***Conventional general practitioner care and analgesics*** Although general practitioners may suggest other therapy for back pain in addition to prescribing medication, empirical evidence shows that 80 per cent of initial visits to primary care providers for back pain result in a prescription for analgesics. Therefore the authors considered these two categories were sufficiently similar to pool them.
- ***Physical therapy and exercise*** Both are considered to be active therapies; empirical evidence shows that exercises are often a key component of physical therapy, making up 30 per cent, 33 per cent, and 100 per cent of the treatment delivered in three studies of “physical therapy” for patients with low-back pain. Therefore Assendelft et al. considered these interventions to be homogeneous enough to pool.
- ***Traction, use of corsets, bed rest, home care, topical gel, no treatment, diathermy, and minimal massage*** Empirical evidence shows these treatments lack evidence of benefit or have evidence of harm.
- ***Back school*** The researchers defined this category as “treatments that did not conceptually fit with any other group,” adding that “co-interventions were allowed.”



OUTCOME MEASURES

Pain (measured on a 100-mm visual analogue scale [VAS]) and functional status (as measured by, for example, the 24-point Roland Morris Disability Questionnaire [RMDQ]) were the primary outcomes used in this review.

The timing of follow-up measurement was divided into: *short-term* (the outcome measurement closest to three weeks was chosen) or *long-term* (the outcome measurement closest to six months was chosen).

SEARCH STRATEGY FOR IDENTIFICATION OF STUDIES

The following databases were searched:

- the Cochrane Central Register of Controlled Trials 2000, Issue 1
- MEDLINE from January 1966 to January 2000
- EMBASE from January 1988 to January 2000
- CINAHL from January 1982 to January 2000

One reviewer ran the search developed by the Cochrane Back Group, using free text words and MeSH headings, without language restrictions. In addition, references from retrieved articles were screened.

METHODS

Two reviewers independently screened titles, abstracts and full-text articles to determine the final selection of the trials to be included in the review. The methodological quality was assessed by the same two reviewers using the 10-item internal validity Cochrane Back Group, the five-item original Jadad and five-item modified Jadad scales. Because true double-blinding cannot be achieved in studies of SMT, the authors gave one point if the control patients were treated with a sham and another point if a post-treatment assessment showed that patients could not determine whether they received “real” or “sham” SMT. At all stages disagreements were resolved by consensus.

The following separate, stratified analyses were conducted:

- control groups with various clusters as defined in “Types of interventions”
- short-term and long-term follow-up
- low-quality trials versus high-quality trials (multiple criteria and scales were used in the absence of a consensus on a “gold standard” for quality, especially for interventions such as SMT, for which true double-blinding is not feasible)
- acute, sub-acute and chronic patients
- manipulation versus mobilization

Adverse effects were assessed. (The incidence of severe side-effects such as vertebrobasilar accidents and cauda equina syndrome is low.)

RESULTS

The search strategy identified 1153 titles and abstracts which were then screened for potential inclusion. After reviewing the full text of 72 articles, 53 articles (representing 39 studies) met the inclusion criteria. The studies included a total of 5486 patients; study sample sizes ranged from 19 to 666 (median, 92). Quality varied but tended to be higher in the more recent studies.

There were 29 comparisons of SMT with other treatments in patients with acute or sub-acute pain; 29 comparisons of SMT in patients with sub-acute or chronic pain; and 14 comparisons of SMT in patients with mixed or uncertain durations of pain. Most studies excluded patients with sciatica, although 12 comparisons were restricted only to patients with sciatica. (The results of these trials were not reported by Assendelft et al.)

ACUTE LOW-BACK PAIN

Compared with those receiving sham therapy, patients receiving treatment that included SMT had clinically important short-term improvements in pain and function. However, the improvement in function did not reach statistical significance.

When SMT was compared with the group of therapies judged to be ineffective or possibly even harmful, the patients who received SMT reported a statistically significant short-term improvement in pain. However, the clinical significance of this finding is questionable (4-mm difference in pain, measured on a 100-mm scale). Improvement in short-term function for patients receiving treatment with SMT compared with the ineffective therapies was clinically significant, but did not reach statistical significance (2.1 point difference on the RMDQ [95% CI, -0.2 to 4.4]). The differences between patients treated with SMT and those treated with any of the conventionally advocated therapies were not statistically or clinically important.

CHRONIC LOW-BACK PAIN

Results in patients with chronic low-back pain were similar to results in those with acute low-back pain. According to Assendelft et al.: “The only findings of statistical or clinical significance were the comparisons of SMT with either a sham manipulation (improvement in short-term pain, 10-mm [95% CI, 3 to 17-mm], improvement in long-term pain, 19-mm [95% CI, 3 to 35-mm],

improvement in short-term function, 3.3 points on the RMDQ [95% CI, 0.6 to 6.0]), or the group of therapies judged to be ineffective or perhaps harmful (improvement in short-term pain, 4-mm [95% CI, 0 to 8] improvement in short-term function, 2.6 points on the RMDQ [95% CI, 0.5 to 4.8]).”

OTHER CLINICAL VARIABLES AND SENSITIVITY ANALYSES

The authors assessed the effect of pain radiating down the leg as a characteristic that could affect the overall conclusions of this review but found it made little difference. Data were insufficient to allow assessment of the effect of SMT as a treat-

ment for patients with clearly defined sciatica. A sensitivity analysis involving 25 studies that used manipulation (not including mobilization) alone or predominantly—instead of combining manipulation with other therapies—produced essentially the same results as the primary analysis. In addition, the results did not differ when only those studies that scored three or more on the Jadad scale (which has previously been shown to be a threshold associated with bias) or only those studies that scored three or more on the modified Jadad scale were analyzed. The authors also found no significant difference in effectiveness depending on the profession of the manipulator.

CONCLUSIONS

The effectiveness of SMT has been the subject of persistent debate. The authors of this review found no evidence that SMT was either superior or inferior to other advocated therapies, including analgesics, exercise, physical therapy and attendance at back schools. Based on their results, they concluded that SMT is one of several options which are only modestly effective for patients with low-back pain. Truly effective therapy for these patients remains elusive. Faced with this information, consideration of all factors relevant to patient care is warranted before rendering a clinical decision. These factors include, but are not limited to, treatment side-effects, costs, patients’ and physicians’ views and preferences, and the feasibility of the interventions.³



What does this mean?

Each patient is an individual with unique needs. When choosing a treatment for low-back pain, either acute or chronic, clinicians should consider the risks and costs for each option and apply one or a combination of potential remedies with the knowledge that no one treatment has proven superior to the rest.

All the research on low-back pain to date has failed to produce a single, strong remedy for this common ailment. Perhaps the time has come to shift the focus of researchers, health care providers and policy-makers to methods of prevention, attacking this problem from the opposite end of the disease paradigm.

COMMENTS

Clinicians look to systematic reviews and clinical practice guidelines to assist them in making the most appropriate decisions in caring for their patients.

Unfortunately, for the clinician wondering whether a patient with low-back pain (LBP) would benefit from spinal manipulation, reviewing the many systematic reviews and over a dozen international practice guidelines will provide no clear answer. Although the majority of the systematic reviews and clinical practice guidelines favour the use of spinal manipulation for LBP, there is a lack of consistent evidence with regards to which patient population would benefit most from this treatment.

So how does this influence the clinician's decision regarding the patient with LBP? The clinician who does not practice spinal manipulation may find that there is too much uncertainty in the evidence and this may negatively impact the decision to refer for spinal manipulation. However, for the clinician who practices manipulation, the large variation in the evidence may in fact provide support to utilize manipulation for just about any patient population presenting with LBP.

Will the new findings of the recent systematic review by Assendelft et al. change clinical decision-making? Not likely. Although the review appeared to “dethrone” the superiority of spinal manipulation, no other treatment was found to be better. A clinician who is thinking about referring a patient for spinal manipulation may decide that usual GP care, physical therapy, exercise and back school are just as effective as manipulation and therefore not make the referral. On the other hand, the clinician who practices manipulation may find comfort in knowing that this review failed to find any treatment more effective than spinal manipulation for LBP. Therefore this clinician will likely continue to promote its use.

Although the review by Assendelft et al. attempted to be comprehensive in its scope, there are a number of deficiencies that may limit its usefulness in the decision-making process for clinicians. Here are some examples:

- This review fails to address the immediate effects of spinal manipulation. Patients presenting with LBP often seek immediate relief.



- Patients often present with sciatica. Unfortunately the data in this review was insufficient to assess the effectiveness of spinal manipulation for this patient population which could not be evaluated.
- The review did not address the comparative effectiveness of manipulation when combined with exercise and/or education or the effectiveness of varied combinations of manipulative techniques on different LBP syndromes.
- Questions about the safety of manipulation for LBP when compared to other treatments such as anti-inflammatory medication remain unanswered.
- Although there are multiple and complex factors influencing clinical decision-making, clinician preferences and consistency of the evidence are important factors that cannot be overlooked. In the case of spinal manipulation and LBP, the current evidence suggests that “if you have a hammer in your hand everything looks like a nail.”

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COMMENTS

Commendably, *Linkages* aspires to “...critically review the best available evidence *in the literature...*” (emphasis added). In the past two decades, systematic reviews and meta-analyses of randomized controlled trials (RCTs) have been widely considered the best available evidence (not just in the literature). If this is so, prudent clinicians would expend their limited time allocation for keeping abreast of the burgeoning biomedical literature most efficiently by critically appraising relevant systematic reviews/meta-analyses rather than original articles.

Unfortunately, from the perspective of the reviews’ targeted consumers (patients, clinicians and policy-makers, according to Assendelft et al.), the ever-evolving statistical manipulations are difficult to comprehend and critically appraise; ironically, they have to be accepted on blind faith much more so than the original trials whose bias the reviews are intended to protect us from.

Even the RCTs don’t fulfill their potential to inform clinical practice (at least regarding manual therapy). The subjects and their presentations are more homogeneous in the RCT setting than in practice. Averaging response data makes it difficult to identify subgroups which responded very well or very poorly. When it comes to dosage and intensity of intervention, these are usually arbitrary and standardized in the research setting.

I have found reports of cases and case series to be more relevant to clinical practice than RCTs, systematic reviews and various analyses of chiropractic/spinal manipulative therapy (SMT)—despite their supposed advantage of producing non-biased, quantifiable results. Not only have I been unable to identify my patients and practice in these research studies, but I find their results to be inconclusive.

Enter this unblinded review by Assendelft et al., aiming to update estimates of the “effectiveness” of SMT and to resolve discrepancies among previous systematic reviews/meta-analyses (including Assendelft’s) by including

more, recent “high quality” studies. However, of the 11 newer studies incorporated, only one was ranked “good” by the authors on all three rating scales (Jadad, modified Jadad, Cochrane Back Review Group); another ranked “good” only on the latter scale; the rest were ranked poorly.

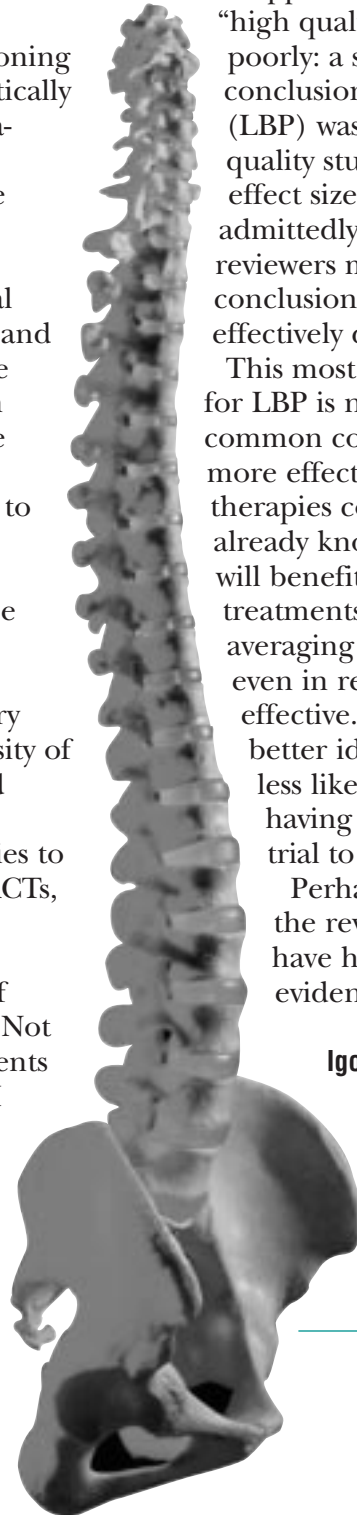
It apparently makes no difference that these “high quality” articles were mostly rated poorly: a subanalysis found that the authors’ conclusion about SMT for low-back pain (LBP) was unaffected, whether or not low quality studies were incorporated into the effect size calculations. If applying the admittedly subjective rating systems used by reviewers makes no difference in the conclusion, how valid is the process? How effectively does it exclude potential bias?

This most recent review concludes that SMT for LBP is no more effective than other common conservative treatments and only more effective than sham treatment and therapies considered to be ineffective. I already know that different patients with LBP will benefit more from one of the common treatments than another. This is what the averaging of results reflects consistently, even in reviews finding SMT to be more effective. What I need to know is how to better identify in advance those who are less likely to benefit from SMT without having to put them through a therapeutic trial to find out.

Perhaps the time has come to review the reviews in terms of the ranking they have held in the hierarchy of clinical evidence.

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COMMENTS

This review of *Spinal Manipulative Therapy for Low-back Pain* is important and relevant for the general practitioner, for physicians at the back clinics and for patients with low-back pain.

The review included randomized studies involving patients with low-back pain, regardless of radiation (defined as pain below the knee). The back pain was categorized as acute (less than three weeks duration), sub-acute (three to 13 weeks) and chronic pain (longer than 13 weeks).

Seventy to 85 per cent of the population will experience low-back pain at some time in their lives. Although low-back pain is seen as a benign and self-limiting condition by the physician, the patient feels it is a painful and disabling experience and demands treatment.

There are lots of treatment options available, and spinal manipulation is one of them. From my experience as a physician at a back clinic, some patients feel spinal manipulation is a quick and effective way to get rid of their back pain within three to five treatments, while others feel they need to be manipulated regularly to keep the back pain away. Still, others report no effect at all.

Most patients referred to my back clinic have undergone manipulation, along with other treatments, and have experienced little or no positive effects. My personal experience is that spinal manipulation is most effective in patients with localized back problems of fairly short duration.

The conclusion of this review is that spinal manipulation has no statistically or clinically significant advantage over general practitioner's care, analgesics, physical therapy, exercises or back school, for either acute or chronic conditions.

The question is: how does a general practitioner or physician at a back clinic interpret a review and make use of it in the clinical setting?

An important part of treatment for non-specific low-back pain is to inform patients about the condition, to explain the prognosis and to advise them about how to behave while they are in pain (i.e. to avoid bed rest). It is also vital to reassure them that daily activity is not harmful. However, before recommending a treatment, the physician must consider several factors (i.e. the effectiveness, the costs, the patient's expectations, opinion and experience).

In the case of relapse, the goal of any clinician should be to educate his or her patients with regards to managing their back pain. At this stage, it is essential that the clinician consider whether the recommended treatment is active or passive.

Based on these considerations, I believe this review is very important. Since spinal manipulative therapy is no better or worse than other treatments for low-back pain, it can be an option for managing this condition. However, the physician should emphasize the importance of avoiding long-lasting treatments that produce little or no positive effect.

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