TITLE: Chiropractic Interventions for Acute or Chronic Lower Back Pain in Adults: A Review of the Clinical and Cost-Effectiveness

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CONTEXT AND POLICY ISSUES:

Low back pain (LBP) is pain, discomfort, or tiredness in the region of the low back with or without radiating symptoms to the legs.\textsuperscript{1} Low back pain can be acute, subacute, or chronic.\textsuperscript{1} Often, low back pain cannot be traced back to a certain etiology.\textsuperscript{1} Thus, the etiology varies; for example, it can be related to infection, inflammation, arthritis, a fracture, or from more than one of these factors.\textsuperscript{1,2}

Low back pain is a common complaint in Canada, with a lifetime prevalence estimated at 84.0%.\textsuperscript{3} This is similar to other resource-rich countries, where it is approximated that 70.0% of people are affected by low back-pain.\textsuperscript{2}

Treatment for low back pain focuses on relieving pain and improving function; it does not aim to treat the underlying condition.\textsuperscript{1} One common way to treat low back pain is through chiropractic care;\textsuperscript{4} however, other conservative methods include standard medical care (i.e., medication), physical therapy, acupuncture, back school (a generic term that may include education, exercise, advice, and behavioural-cognitive approaches to protect the spine), and bed rest.\textsuperscript{1} The typical therapeutic option for chiropractic care is spinal manipulation\textsuperscript{1,5} but it may also include other treatments such as education/reassurance, soft-tissue therapy, therapeutic exercise prescription, electrotherapy, and ultrasound.\textsuperscript{3,6} Spinal manipulation is a manual therapy whereby the practitioner moves a joint beyond its usual end range of motion (but not beyond its anatomic range of motion), causing a popping or cracking sound.\textsuperscript{7} In Canada, spinal manipulation can be performed by chiropractors, physical therapists, and medical physicians.\textsuperscript{8}

In Canada, the medical expenditures for treating low back pain is estimated to be between six and twelve billions dollars per year.\textsuperscript{1} Public funding for chiropractic care varies across Canada.\textsuperscript{1}

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The question of clinical and cost-effectiveness of chiropractic care, especially compared to other treatments, often arises as low back pain is both costly (due to treatment costs, disability payments, work days lost, etc.) and highly prevalent in Canada. Several studies have been conducted with similar questions in mind. A health technology report entitled, “Costs and Outcomes of Chiropractic Treatment for Low Back Pain” was published by the Canadian Coordinating Office for Health Technology Assessment (CCOHTA) in 2005. In order to ensure the best, evidence-informed decisions are being made for patients with low back pain, an update to this CCOHTA Technology Report has been requested. The current HTIS report included both clinical and cost-effectiveness studies of chiropractic treatment for low back pain in adults that were published since the literature search timeframe of the CCOHTA technology report, February 2004.

RESEARCH QUESTIONS:

1. What is the clinical effectiveness and safety of chiropractic interventions for the management of acute or chronic lower back pain in adults?

2. What is the cost-effectiveness of chiropractic interventions for the management of acute or chronic lower back pain in adults?

METHODS:

A limited literature search was conducted on key health technology assessment resources, including PubMed, The Cochrane Library (Issue 4, 2008), University of York Centre for Reviews and Dissemination (CRD) databases, ECRI, EuroScan, international HTA agencies, and a focused Internet search. Results include articles published between 2004 and January 2009, and are limited to English language publications only. No filters were applied to limit the retrieval by study type.

HTIS reports are organized so that the higher quality evidence is presented first. Therefore, health technology assessment reports, systematic reviews, and meta-analyses are presented first. These are followed by randomized controlled trials (RCTs) and economic evaluations.

SUMMARY OF FINDINGS:

One health technology assessment, three systematic reviews, and one RCT were included. For an RCT to be included, it had to be published after the search dates of the included health technology assessment and systematic reviews. For economic evaluations, any relevant study type (except narrative reviews) was considered. If the relevant study was already mentioned in an HTA or systematic review, it was not included. No relevant literature was identified.

Health technology assessments

In 2008, ECRI published an evidence report on spinal manipulation for low back pain. Four research questions were posed in the ECRI HTA: How did spinal manipulation technique compare to other non-invasive treatments like massage, exercise, ultrasounds, and physical therapy in terms of: 1) pain relief, 2) quality of life, and 3) likelihood of returning to work?; and, 4) What are the associated adverse events with spinal manipulation therapy? The evidence base included for the first three questions was restricted to RCTs. There were no limits regarding study design for the fourth question.
To be included, the study had to focus on patients with nonspecific low-back pain; thus, the patients did not have pain attributable to a definite disease or disorder such as cancer. The specific spinal manipulation technique assessed was rapid long-lever or short-lever, high-thrust spinal adjustments. Spinal manipulation was defined as a passive dynamic thrust that causes an audible release in attempt to increase the joint’s range of motion. Follow up times that were less than or equal to one month were considered short term, longer than one month but less than six months were considered intermediate term, and six months or longer were considered long term. This report did not specify that a chiropractor was the health care practitioner performing the spinal manipulation; however, it was mentioned that the majority of practitioners performing spinal manipulation in the U.S. are chiropractors. The literature search ended April, 2008.

While the authors stated the databases searched and study inclusion criteria, they did not state how many reviewers’ included/excluded studies and how disagreements were resolved. The included studies were assessed for quality of evidence (by an internally developed ECRI instrument; maximum score 10 indicates highest quality and 5.0 or lower indicates an unacceptable level of quality), but it is unclear how many reviewers assessed quality and how disagreements were resolved. Eighteen RCTs were included that addressed the research question related to pain relief, four RCTs were related to quality of life, and two RCTs were related to the likelihood of returning to work. One systematic review, two case series, and two case reports were included that addressed adverse events (no RCTs reporting adverse events were identified).

Regarding the research question related to pain relief in the short-term follow up (5 studies), it was found that patients who received spinal manipulation were more likely to experience statistically significant less pain than patients receiving other treatment (p=0.02). The study quality of included RCTs was labeled as moderate (median score 8.0, range 6.5 to 9.1). Patients also experienced statistically significant less pain (p=0.012) in the intermediate follow up (3 studies). However, the authors stated that the differences were not clinically significant. Two scales to assess pain referenced in the main report are: the 100 mm Visual Analog Scale and the Numeric Rating Scale. For clinically significant findings, the minimum pain relief difference should be 20 points for the 100 Visual Analog Scale and 2 points for the Numeric Rating Scale. However, no test scores were reported. Also, it was not stated which studies used which measure. The results on pain relief were not broken into acute and chronic pain.

The authors also studied the effect of spinal manipulation on disability as part of the first research question related to pain relief. The authors analyzed seven studies on disability at the short-term follow up and found that patients who received spinal manipulation reported improved disability; this difference was statistically significant (p=0.0005). However the authors stated this difference was not clinically significant. For intermediate follow up (three studies), no statistically, or clinically, significant differences were found (p=0.07). The study quality of the included RCTs was labeled as moderate (median score 7.95, range 6.5 to 9.1) for the RCTs on disability. The clinical measures for disability were measured either by the Roland Morris Disability Questionnaire (which requires at least a 3 point difference to be considered clinically significant) and the Oswestry Disability Index (which requires at least a 10 point difference to be considered clinically significant). Again, it was not stated which studies used which measure.

The moderate scoring of study quality for both pain and disability were mainly due to a lack of blinding of outcome assessors and subjective nature of evaluating pain and disability as well as high drop out rates (>15.0%). The level of heterogeneity, as measured by \( I^2 \), was approximately 60.0% for pain and disability in the short-term follow up and approximately 80.0% for pain and
disability studies in the intermediate-term follow up. The only robust statistically significant finding was the disability outcome at short-term follow up.

No conclusions regarding quality of life could be formulated regarding spinal manipulation compared to other noninvasive treatments. The quality-assessment score for the included RCTs was moderate (median score 7.6, range 7.3 to 8.3) mainly due to lack of blinding of outcome assessors, subjective nature of evaluating QOL, and high drop-out rates (>15.0%).

The authors stated that no conclusions regarding the likelihood of returning to work could be made from the RCTs retrieved. The quality-assessment score was moderate (median score 7.7, no range given).

The fourth question looked at the adverse events associated with spinal manipulation therapy. The authors concluded that mild adverse events such as headache and tiredness occurred frequently after treatments; however, serious adverse events were very rare.

The authors of the ECRI report also evaluated cost of chiropractic treatment for low back pain and retrieved two RCTs and one comparative, nonrandomized study. According to one RCT evaluated, chiropractic care was more costly [total outpatient costs based on 681 Health Maintenance Organization (HMO) patients] than medical care alone. But, chiropractic care with physical modalities was less costly than medical care with physical modalities.

The second RCT summarized was the United Kingdom back pain exercise and manipulation (UK BEAM) trial. The authors reported that the UK BEAM trial authors concluded that, in a primary care setting, it is cost-effective to add spinal manipulation therapy (with or followed by exercise) to best care. No definition of best care was stated, nor were any numbers or statistics provided.

A comparative, nonrandomized study, based on 2,780 patients, found that the overall costs of chiropractic care were 22.0% higher for acute low back pain patients and 16.0% lower for chronic low back pain patients when compared to medical care. However, costs for office visits among patients with acute low back pain were 78.0% to 82.0% higher for chiropractic patients than for medical care patients. Among chronic low back pain patients, costs were 52.0% to 60.0% higher. It is unclear how many of the 2,780 patients suffered with acute low back pain and how many suffered from chronic low back pain. No further information was stated regarding the costing information (e.g., dollars, the geographical location of the patients).

The ECRI authors concluded that, compared to noninvasive treatment options, spinal manipulation therapy provided greater pain relief as measured by pain intensity and disability in the short-term follow-up period and pain intensity in the intermediate follow-up period. These differences were not found to be clinically significant, however. No overall conclusions were made regarding the included economic evaluations.

**Systematic reviews and meta-analyses**

McIntosh and Hall published “Low back pain (acute)” in 2007. One of the main objectives was to determine the effects of non-drug treatments for nonspecific acute low back pain. One such treatment was spinal manipulation. Acute low back pain was defined as pain lasting <12 weeks. The quality of the evidence included was evaluated using Grading of Recommendations Assessment, Development and Evaluation (GRADE). The authors stated which databases were searched, that the search timeframe ended May 2007, and that more than one person selected
the papers; however, it was unclear how disagreements were resolved. The authors did not state whether chiropractors were the practitioners performing the spinal manipulation.

For pain relief, one systematic review and one RCT were included. Based on the systematic review, the authors concluded that, in the short term, spinal manipulation was more effective than placebo or sham treatment in reducing pain (100 mm Visual Analogue Scale: 10 mm, 95% CI 2 mm to 17 mm). The RCT findings were that chiropractic adjustment significantly reduced pain at two weeks (p=0.03) and at four weeks (p=0.03) compared to placebo. Both conclusions were judged to be based on low-quality evidence.

For disability, one systematic review and one RCT were included that compared spinal manipulation to placebo or sham. One additional RCT was included that compared spinal manipulation to the specific back treatment called the McKenzie back treatment. Based upon the systematic review and RCT that used placebo or sham as a comparator, the authors stated that spinal manipulation and chiropractic adjustment did not have a significant effect on disability in either short- or long-term follow up (the systematic review used the Roland Disability Questionnaire, the RCT did not state its evaluative tool for disability). This conclusion was based on low-quality evidence. The RCT that used the McKenzie back treatment as a comparator found that patients who had the McKenzie back treatment had an increase in disability at five days and at four weeks compared to patients receiving spinal manipulation. The authors stated that no statistical analyses were performed. This conclusion is based on low-quality evidence.

A 2006 report by Ernst and Canter entitled, “A systematic review of systematic reviews of spinal manipulation” concluded that spinal manipulation is not an effective intervention for back pain. After searching systematic reviews between 2000 and May 2005, 16 systematic reviews on spinal manipulation were retrieved. Three systematic reviews focused on low back pain and a fourth systematic review evaluated both low back and neck pain. The initial selection of articles was conducted by one author and two authors had to agree to include a study. It is unclear how disagreements about inclusion were resolved. The authors stated the searched databases. Quality of the included systematic reviews was not stated. This article did not focus on chiropractor-administered spinal manipulation.

One systematic review focused on chronic low back pain whereas the other two did not specify the type of low back pain evaluated. All three stated that the clinical effectiveness of spinal manipulation was not supported. The fourth systematic review that evaluated spinal manipulation in both low back pain and neck pain concluded that there was some confidence regarding the effectiveness of using spinal manipulation for treating low back pain and neck pain. No statistical analyses or descriptive statistics were stated, nor was chronic defined.

Ernst and Canter stated that spinal manipulation was associated with frequent, mild adverse effects and with rare but potentially serious complications. No statistics were reported.

Van Tulder, Koes, and Malmivaara conducted a systematic review published in 2006. The authors’ goal was to assess RCTs that evaluated non-invasive treatments for nonspecific low back pain. One of the treatments was spinal manipulation; however, it was not specified whether a chiropractor performed the spinal manipulation. Two reviewers selected the studies for inclusion. Search dates were not stated and included studies were not evaluated for quality.

The authors retrieved two RCTs that compared spinal manipulation versus sham for acute low back pain (pain lasting less than six weeks). The improvement in function was not statistically

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significant although the authors reported that it was clinically relevant (2.8 mm difference on Roland Morris scale; 95% CI -0.1 to 5.6). The Roland Morris Questionnaire indicates disability on a scale of 0 to 24 with 24 being the most severe. Of note, the ECRI report\textsuperscript{9} indicated that a 3 point difference on the Roland Morris scale is required to be considered clinically significant. The authors evaluated twelve RCTs that compared spinal manipulation to other conventionally accepted therapies and they reported no statistically significant improvements.

The authors evaluated three RCTs for spinal manipulation versus sham treatment for chronic low back pain (pain lasting ≥12 weeks). Spinal manipulation was found to be statistically more effective than sham for pain relief in the short term (10 mm; 95% CI 3 to 7 mm) as well as pain relief in the long term (19 mm; 95% CI 3 to 35 mm). In addition, spinal manipulation was found to be statistically more effective on patient function in the short term (3.3 points on the Roland and Morris Disability Questionnaire; 95% CI 0.6 to 6.0). When compared to other conventionally accepted therapies, spinal manipulation did not have any statistically significant differences in pain relief or function. Short term and long term were not defined.

The risk of serious complications from spinal manipulation was stated to be low for patients with acute or chronic low back pain.

**Randomized controlled trials**

In 2008, Juni \textit{et al.} published, “A randomized controlled trial of spinal manipulative therapy in acute low back pain.”\textsuperscript{12} The patients were adults (20 to 55 years) who presented at an emergency department with low back pain lasting less than four weeks. Random allocation and allocation concealment were both adequate. In addition, the authors employed an intention-to-treat analysis.

Patients were randomly allocated to standard care alone (n=52) or standard care with spinal manipulation therapy (n=52). Care was provided by a specialist, not necessarily a chiropractic specialist. Standard care included prescribing analgesics (i.e., paracetamol, diclofenac, dihydrocodeine) as well as general advice on returning to normal activities and avoiding bed rest. Pain intensity, as measured by the 11 point box scale (BS-11) and analgesic use were the outcomes measured. The BS-11 is a patient administered rating scale ranging between 0 and 10, with a score of 10 being indicative of the most severe pain. Secondary outcomes included disability at day 14 as measured by the Roland Morris Questionnaire. The outcomes were recorded daily by the patients from day one to 14. There were no statistical differences between the two groups for pain, analgesic use, or disability. In a 6 month follow up (n=50 for spinal manipulative therapy and n=51 in control group), no differences existed. The authors concluded that there was no evidence that spinal manipulative therapy provided a clinical benefit when added to standard care.

Two serious adverse events occurred in each group. None of which appeared to be related to the group assignment.

**Economic evaluations**

No economic evaluations about chiropractic interventions for low back pain were identified.

**Limitations**

One major limitation to the health technology assessment and systematic reviews found on chiropractic interventions was that they focused on spinal manipulation therapy rather than
chiropractic care as a whole. Moreover, much of the literature did not specify whether the practitioner administering the spinal manipulation therapy was a chiropractor. Practitioners in the studies could have been, for example, chiropractors, osteopaths, or physical therapists.

Another critical limitation to this research is that much of the evidence in this field is of moderate to low quality. Evidence that is not of high quality may be vulnerable to a variety of biases which can affect the outcome of a study. Canter and Ernst published a systematic review in 2005 that examined reviews of spinal manipulation for back pain and identified sources of bias. The authors included and assessed the quality of 29 reviews by answering five questions regarding methodology (e.g., Was there an explicitly and repeatable method for searching the scientific literature?). The authors stated that the six high quality reviews (scoring five out of five) were more likely to have negative conclusions of effectiveness and the sixteen reviews that scored zero points on methodological quality were more likely to have positive conclusions of effectiveness. That is, there is an inverse relationship between quality and conclusions of effectiveness (-0.558 Spearman 2 tailed p<0.01 n=29). When analyzed by authorship, it was concluded that reviews whose authors included a Doctor of Chiropractic or Doctor of Osteopathy were more likely to have scored low on the methodological quality rating (-0.449 Spearman 2 tailed p<0.05 n=29).

Lastly, the only economic information found was in the ECRI report. No additional economic evaluations, Canadian or otherwise, were retrieved.

CONCLUSIONS AND IMPLICATIONS FOR DECISION OR POLICY MAKING:

The purpose of this HTIS report was to update the 2005 CCOHTA technology report, “Costs and Outcomes of Chiropractic Treatment for Low Back Pain”¹. The CCOHTA technology report concluded:

Chiropractic care for LBP is similar in effectiveness to that of standard medical care and physical therapy. The evidence from other countries is inconclusive about the costs for chiropractic treatment of LBP, relative to physical therapy or medical care. A well-designed Canadian study that compares the cost-effectiveness of LBP care provided by chiropractors, physical therapists and primary care physicians, would be of benefit.¹

The updated literature search in this HTIS report resulted in inconsistent findings with regard to whether spinal manipulation therapy was helpful for acute and chronic pain in the short term and long term. The results were also inconsistent for whether spinal manipulation improved disability/function in the short term or long term. Some of the research was of lower quality evidence. None of the evidence suggested that spinal manipulation therapy could improve quality of life or increase likelihood of returning to work. Again, quality of evidence was low. Evidence on adverse events was minimal, but the literature consistently reported that patients commonly experienced mild adverse events, and rarely experienced serious adverse events. Given the low level of evidence and contradictory or lack of effect on health outcomes, it is difficult to make any positive statements regarding the clinical effectiveness of spinal manipulation.

ECRI reported minimally on costing information from two American articles. Both studies stated that chiropractic care alone was more expensive than medical care alone, when assessing outpatient costs or office costs. However, when combined with other treatments, one paper reported chiropractic care was less expensive, and the second study stated that costs were lower only for patients with chronic low back pain. One cost-effectiveness analysis was included.
in the ECRI report\(^9\) whereby it was concluded that spinal manipulation therapy is cost-effective when provided with or following exercise and added to best care. The information presented in all three studies, however, was too general to allow for any strong conclusions. No relevant Canadian economic evaluations, either full or partial, were retrieved (in this or the CCOHTA \(^1\) technology report). No conclusions for the cost-effectiveness of spinal manipulation therapy in a Canadian setting can be made.

Despite years of published evidence on spinal manipulation and chiropractic care, it is difficult to draw any conclusions regarding the clinical and cost-effectiveness of chiropractic care or spinal manipulation therapy performed by a chiropractor.

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