



The Effectiveness and Harms of Spinal Manipulative Therapy for the Treatment of Acute Neck and Lower Back Pain: A Systematic Review

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PREFACE

Quality Enhancement Research Initiative's (QUERI) Evidence-based Synthesis Program (ESP) was established to provide timely and accurate syntheses of targeted healthcare topics of particular importance to Veterans Affairs (VA) clinicians, managers and policymakers as they work to improve the health and healthcare of Veterans. The ESP disseminates these reports throughout the VA, and some evidence syntheses inform the clinical guidelines of large professional organizations.

QUERI provides funding for 4 ESP Centers and each Center has an active university affiliation. The ESP Centers generate evidence syntheses on important clinical practice topics, and these reports help:

- develop clinical policies informed by evidence;
- guide the implementation of effective services to improve patient outcomes and to support VA clinical practice guidelines and performance measures; and
- set the direction for future research to address gaps in clinical knowledge.

In 2009, the ESP Coordinating Center was created to expand the capacity of HSR&D Central Office and the 4 ESP sites by developing and maintaining program processes. In addition, the Center established a Steering Committee comprised of QUERI field-based investigators, VA Patient Care Services, Office of Quality and Performance, and Veterans Integrated Service Networks (VISN) Clinical Management Officers. The Steering Committee provides program oversight, guides strategic planning, coordinates dissemination activities, and develops collaborations with VA leadership to identify new ESP topics of importance to Veterans and the VA healthcare system.

Comments on this evidence report are welcome and can be sent to Nicole Floyd, ESP Coordinating Center Program Manager, at Nicole.Floyd@va.gov.

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EXECUTIVE SUMMARY

INTRODUCTION

Back pain and neck pain are among the most common symptoms prompting patients to seek care. Many treatments are used for back pain. Spinal manipulative therapy (SMT) is a treatment option available in VA. In order to better understand the potential role of SMT in treating acute back or neck pain, VA requested an up-to-date synthesis of the evidence.

The Key Questions are:

Key Question 1: What are the benefits and harms of spinal manipulation/chiropractic services for acute lower back pain (less than 6 weeks duration) compared to usual care or other forms of acute pain management?

Key Question 1A: What is the relationship between the use of spinal manipulation/chiropractic services for lower back pain and the use of opiate medication?

Key Question 2: What are the benefits and harms of spinal manipulation/chiropractic services for acute neck pain (less than 6 weeks duration) compared to usual care or other forms of acute pain management?

Key Question 2A: What is the relationship between the use of spinal manipulation/chiropractic services for acute neck pain and the use of opiate medication?

METHODS

Data Sources and Searches

Spinal manipulation is a topic that has been the subject of numerous prior systematic reviews, including 3 reviews by members of the ESP review team. Therefore, instead of searching for original evidence in databases such as PubMed, we instead began with reference mining existing systematic reviews, and then performing an update search to identify new studies published since the end date of the searches of the most recent reviews. Then we consulted our technical experts for any additional studies we might have overlooked.

Study Selection

Participants: Adults with acute (defined as 6 weeks or less) neck or lower back pain. Patients with sciatica were included. Studies of patients with chronic back pain were excluded, as were studies where we could not determine the duration of pain. If studies included patients with longer durations of pain, we included them if they presented stratified results or if the majority of patients had pain for less than 6 weeks duration. Studies of children were excluded.

Intervention: Spinal manipulation by any provider type. Studies where spinal manipulation was given alone or as part of a “package” of therapies were included. “Chiropractic care” was considered as including SMT for the great majority of patients.

Comparator (study design): Other forms of management for acute pain, such as analgesics, exercises, physical therapy, etcetera. Sham-controlled studies were included.

Outcome: Pain management, functional status, quality of life, opiate use, disability claims, return to work, health care utilization.

Timing: Studies had to report at least one outcome within 6 weeks to be eligible.

Setting: Ambulatory/outpatient settings. Studies in hospital settings were excluded.

Study design: Only randomized controlled trials (RCTs) were eligible for assessing benefits. Both RCTs plus observational studies were used for assessing harms.

Data Abstraction and Quality Assessment

Data were extracted by 2 reviewers, and discrepancies were reconciled after discussion. Articles had data abstracted on the anatomical location of the pain, authors' description of the SMT provided, type of professional performing the treatment, co-interventions, whether that treatment was provided alone or as part of a package of other treatments, whether patients were selected as more likely to respond to SMT or unselected, data on any of the outcomes listed above (*eg*, pain, functional status, *etc*), as well as data needed to complete the Cochrane Back Group Risk of Bias assessment.

We assessed the quality of studies using the Cochrane Back Group Risk (CBG) of Bias Tool (ROB). This tool has 11 items in the following domains: randomization; concealment; baseline differences; blinding – patient; blinding – care provider; blinding – outcome; co-interventions; compliance; dropouts; timing; and intent to treat.

Data Synthesis and Analysis

We constructed evidence tables showing the study characteristics and results for all included studies. Random effects meta-analyses were conducted using the Hartung-Knapp Method.

RESULTS

Results of Literature Search

We identified 181 potentially relevant titles from our systematic review search and identified one additional title from the references of one of our included articles, for a total of 182 titles for screening. From the 49 systematic reviews we mined for references, we identified 136 potentially relevant titles. To this we added 15 titles recommended by experts and 1,639 titles identified in an update search for a total of 1,790 titles for screening.

After excluding 1,564 titles as clearly not relevant, we reviewed 226 abstracts. Of these, we excluded 28 abstracts and included 198 abstracts for full-text review. After full-text review, we excluded 150 articles: 77 articles rejected as studying patients with pain longer than 6 weeks or unspecified; 38 articles rejected for study design (*ie*, not a randomized controlled trial); 10 articles rejected as duplicate articles of already-screened articles; 9 articles rejected as providing relevant background information but not otherwise included; 7 articles rejected as not reporting

on SMT; 3 articles rejected for having no relevant outcome; 2 articles rejected for studying patients in hospital; 3 articles rejected for other reasons; and 1 article we were unable to retrieve.

Of the 48 included articles, we identified 40 articles relevant to effectiveness of SMT and 8 articles relevant to adverse events. Of the 40 effectiveness articles, 26 were included in the analyses. Of the 14 not included in the analyses, 3 publications were focused on the subpopulation of patients with sciatica, 2 publications were only relevant to clinical prediction discussions, 2 publications did not have the necessary outcome data, and one publication had a unique patient population judged by our TEP as clinically dissimilar to the other studies.

Quality Assessment

In the low back pain analysis, one study scored a high of 9 out of 11 possible points, 6 studies scored 7 points, 4 studies scored 6 points, 2 studies scored 4 points, 7 studies scored 3, and 6 studies scored 2 points (see Table 1).

Of the 26 studies, 25 studies met the timing criteria and 17 met the randomization criteria. None of the studies met the blinding of providers criteria, and only 4 met the criteria for blinding of patients. Using a threshold of 6, 12 studies were classified as high quality and 14 studies were classified as low quality.

Acute Low Back Pain without Sciatica

Twenty studies reported results that we could use for meta-analytic pooling.

Immediate-term Pain (less than 2 weeks)

There were 11 studies reporting immediate-term pain outcomes using a VAS or numeric rating scale, 2 comparing SMT to sham, and 9 comparing SMT to another therapy (Figure 3). The overall random effects pooled estimate was -8.49 mm (95% CI: -16.46, -0.52) favoring treatment with SMT. There was heterogeneity, with an $I^2 = 76.1\%$. There was no evidence of publication bias in the overall pooled result, with Begg's rank correlation = 0.15 and Egger's test p-value of 0.58. Two studies comparing SMT to sham reported non-statistically significant benefits.

Immediate-term Function (less than 2 weeks)

There were 10 studies reporting immediate-term function measured with the RMDQ or ODI, 3 comparing SMT to sham, and 7 comparing SMT to another therapy (Figure 4). The overall random effects pooled estimate was an effect size of -0.24 (95% CI: -0.55, 0.08) favoring treatment with SMT. There was heterogeneity, with an $I^2 = 52.1\%$. There was no evidence of publication bias in the overall pooled result, with Begg's rank correlation = 0.17 and Egger's test p-value of 0.14. Three studies compared SMT to sham and the overall random effects pooled estimate was an effect size of -0.14 (95% CI: -0.26, -0.11).

Short-term Pain (3-6 weeks)

There were 12 studies reporting short-term pain using VAS or numeric rating scale, 2 comparing SMT to sham, and 10 comparing SMT to another therapy (Figure 4). The overall random effects pooled estimate across all studies was an effect size of -9.95 mm (95% CI: -15.6, -4.3) favoring treatments with SMT. There was heterogeneity, with an $I^2 = 67.2\%$. There was no evidence of

publication bias in the overall pooled result, with Begg's rank correlation of 0.92 and Egger's test p-value of 0.58.

Short-term Function (3-6 weeks)

There were 8 studies reporting short-term function outcomes measured with the RMDQ or ODI, 2 comparing SMT to sham and, 6 comparing SMT to another therapy (Figure 5). The overall random effects pooled estimate was an effect size of -0.39 (95% CI: -0.71, -0.07). There was heterogeneity, with an $I^2 = 72.1\%$. There was no evidence of publication bias, with Begg's rank correlation = 0.85 and Egger's test p-value = 0.10. Two studies comparing SMT to sham reported non-statistically significant benefits.

Exploring Sources of Heterogeneity

There was significant heterogeneity in almost all the pooled analyses of SMT, suggesting that there are other factors influencing the outcome. In addition to the comparison group, we investigated 5 possible sources of heterogeneity: outcome, timing of the outcome, intervention, patients, and study quality.

There were no statistically significant differences in the effect of SMT based on any of these variables, although there was a suggestion that SMT's benefit was greater for thrust (as compared to non-thrust) SMT, and in studies of better methodological quality. The 3 studies that reported the largest beneficial effects for SMT all selected patients based on specific criteria.

Other Outcomes

Too few studies included outcomes other than pain and function to allow us to draw conclusions. Four studies reported return-to-work or duration of sick leave (2 of which reported no differences between groups and one each reported shorter and longer sick leave for the SMT group), one study reported no differences in SF-12 outcomes, and 2 studies reported utilization data.

Acute Low Back Pain with Sciatica

We found 3 randomized controlled clinical trials using SMT in patients with back pain and sciatica. This was too few to draw conclusions.

Adverse Events

In the 26 RCTs of SMT for acute low back pain included in our pooled analyses, 18 publications made no mention of any assessment of adverse events, 3 publications made general comments about adverse events ("no adverse effects were documented..."), and 5 publications reported on specific adverse events, none of which were judged to be related to the treatment except for "the treatment hurts" being statistically more common in the group of patients receiving SMT (as part of a package of therapies) compared to those receiving conventional medical care.

SMT in General

We identified 8 studies that prospectively assessed adverse events in patients receiving SMT, generally by asking consecutive patients receiving SMT from a sample of manual therapy clinicians to complete a survey. The results of these studies, which ranged from 68 patients to

1,058 patients, are broadly consistent. Mild, transient adverse events are reported by 50%-60% of patients, with the most common reported events being local discomfort or an increase in pain.

Serious Adverse Events

There have been numerous case reports, collections of case reports, and systematic and non-systematic reviews of serious adverse events of SMT, of SMT for low back pain, and of SMT for neck pain. The limitations of not being able to assess causality and not being able to calculate frequency have not been overcome.

Summary of Results for Key Questions and Strength of Evidence

Key Question 1: What are the benefits and harms of spinal manipulation/chiropractic services for acute lower back pain (less than 6 weeks duration) compared to usual care or other forms of acute pain management?

Twenty-six studies of SMT treatments for acute low back pain found overall statistically significant evidence of a clinical benefit that was, on average, modest. However, there was substantial heterogeneity in results, with some studies reporting much larger effects and some studies reporting no effect at all. We explored 6 potential sources of heterogeneity, and although type of manipulation, patient selection, and study quality may explain some of the heterogeneity, most of the differences in outcome between studies remain unexplained.

We judged the quality of evidence as moderate that treatment with SMT improved the outcomes of pain and function in patients with acute low back pain, due to heterogeneity of results.

We judged the quality of evidence as high that transient minor musculoskeletal adverse events are common following SMT, although they may be equally common following non-SMT manual therapy.

We judged the quality of evidence as insufficient regarding SMT and outcomes for patients with low back pain and sciatica.

Key Question 1A: What is the relationship between the use of spinal manipulation/chiropractic services for lower back pain and the use of opiate medication?

Among the 26 studies included in our pooled analysis only one specifically reported on the use of opiate medications.

With only a single study reporting this outcome and that one not reporting the actual use by treatment group, we classified the quality of evidence as insufficient for this outcome.

A number of studies have reported on the association of chiropractic care and opioid use using claims data. While these studies have reported lower use of opioids in patients also or first receiving chiropractic care because of their observational design the studies are not able to control for selection bias and therefore were not considered as evidence for this report.

Key Question 2: What are the benefits and harms of spinal manipulation/chiropractic services for acute neck pain (less than 6 weeks duration) compared to usual care or other forms of acute pain management?

Only 5 studies were identified of SMT compared to a non-SMT treatment group for patients with acute neck pain. Although each study reported favorable results on at least one outcome, in total only 198 patients have been studied in total.

We rated the evidence as low that SMT improves outcomes in patients with acute neck pain due to study quality concerns and imprecision of results (too few studies).

Key Question 2A: What is the relationship between the use of spinal manipulation/chiropractic services for acute neck pain and the use of opiate medication?

None of the included studies reported on the use of analgesic medications or opiate medication as an outcome.

DISCUSSION

Limitations

In general, we did not find evidence of publication bias, although no evidence of bias is not the same as evidence of no publication bias.

Study Quality

Study quality was highly variable and in our pooled analysis is split about equally between studies considered “high” and studies considered “low” quality. Our analysis found no evidence to support a hypothesis that our results are due to low-quality studies with inflated effect sizes.

Heterogeneity

Heterogeneity in the results is the primary limitation of this analysis. The statistical evidence of heterogeneity was significant and visual inspection of the forest plots illustrated this: some studies of SMT found positive results, while others, for the same outcome, found essentially no benefit ($ES = 0$, $ES = 0.06$, *etc*). Our investigation of multiple potential sources of heterogeneity yielded no results that were statistically significant, although visually there were suggestions that the type of SMT may be important. Nevertheless, the majority of heterogeneity remains unexplained and the large degree of heterogeneity may limit the enthusiasm of some clinicians and policymakers for advocating more widespread use of SMT.

Applicability of Findings to the VA Population

We identified no studies specific to VA population. Nevertheless, acute back pain in primary care is probably quite similar within VA to outside VA, and these results have to be considered at least moderately applicable to VA populations.

Research Gaps/Future Research

There continues to be a great deal of unexplained heterogeneity in results of SMT for acute low back pain, so a research gap is better understanding what contributes to patient selection and intervention to improve the consistency of the result. This could include an attempt at replication of the clinical prediction rule RCT or new RCTs with more detailed data collection on the patient clinical characteristics and details of the SMT intervention. For neck pain, there are simply too few studies to draw firm conclusions. Additional RCTs are warranted. Attention should be paid to collecting clinical variables and details of the intervention to use in the exploration of possible heterogeneity of treatment effects.