# Journal Review II

*By Ron Feise, DC*

## Spinal Manipulation and Mobilization as First-Line Choice

**Vernon H, Humphreys K, Hagino C. Chronic mechanical neck pain in adults treated by manual therapy: a systematic review of change scores in randomized clinical trials. *J Manipulative Physiol Ther* 2007;30:215-27.**

**Synopsis.** This was a systematic review of randomized clinical trials in patients with chronic neck pain. This review excluded studies that examined patients with whiplash, headache, or arm pain. The researchers performed a comprehensive literature search in MEDLINE, CINAHL, AMED, MANTIS, Index to Chiropractic Literature, Alt HealthWatch, the Cochrane Database of Systematic Reviews, the Cochrane Controlled Trials Registry, and several EBSCO Information Services databases of clinical trials of chronic neck pain treated with manual therapies up to December 2005. Selections from the initial search were made by 2 investigators. Selected studies were scored using the Cochrane Collaboration Back Review Group for Spinal Disorders list. Two assessors scored studies separately, and disagreements were resolved by consensus. A cutoff score of 60% was used for selecting trials for analysis.

**Mean effect size for manipulation.***

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|---|---|
| *6 weeks* | 1.63 |
| *12 weeks* | 1.56 |
| *52 to 104 weeks* | 1.22 |

There were no serious adverse events reported in the manipulation studies. Mobilization studies demonstrated a similar positive benefit, but massage studies did not.

**Research Quality.** Overall, this was a high-quality systematic review.

*Quality Details.* This study used the following: 1) appropriate design; 2) a clearly focused question; 3) clearly stated and appropriate inclusion and exclusion criteria; 4) a clearly described, thorough search of the literature; 5) multiple independent reviewers selecting and appraising the studies; 6) a thorough assessment of the studies; 7) a description of the data extraction process; and 8) a conclusion that flowed logically from the evidence.

**Conclusion.** There is evidence that patients with chronic neck pain show clinically important short- and long-term improvements from a course of spinal manipulation or mobilization. The current evidence does not support a similar level of benefit from massage.

**Comment.** *Spinal manipulation and mobilization should be considered a first-line choice for patients with chronic neck pain. Previous research has suggested rare serious adverse events in this population, and overall, these methods are safer than medications, even non-prescription, or surgery.*[1-4]

*"Effect size" is a statistic used to document treatment effect (benefit/no benefit). Following is a benchmark for effect size: .2 means there is a small treatment effect; .5 means there is a medium treatment effect; and > .8 means there is a large treatment effect.[5]

## Spinal Surgery Fails to Demonstrate Benefit

**Peul WC, van Houwelingen HC, van den Hout WB, Brand R, Eekhof JA, Tans JT, Thomeer RT, Koes BW; Leiden-The Hague Spine Intervention Prognostic Study Group. Surgery vs. prolonged conservative treatment for sciatica. *N Engl J Med* 2007;356:2245-56.**

**Synopsis.** This was a randomized clinical trial that examined the benefit of surgery in patients with 6 to 12 weeks of severe sciatica. Two hundred eighty-three patients were randomly assigned to conservative treatment or surgery. Conservative treatment consisted of pain medications and being invited to visit a Web site. Crossover was 39% from the control group to the surgery group, and 11% of the surgical group did not receive the assigned surgery.

There was no overall difference in disability scores during the first year. There was a small benefit for relief of leg pain in the surgery group during the first few weeks, but that evaporated. In both groups, the probability of perceived recovery after 1 year of follow-up was 95%. Complications in the surgical group occurred in 4.4% of all surgical pa-

tients: 5 patients required repeat surgery, 2 had dural tears, and 1 had a wound hematoma.

**Research Quality.** *Overall, this was a poor-quality clinical trial.*

*Quality Details.* This study used the following: 1) appropriate design; 2) clearly stated inclusion and exclusion criteria; 3) concealed randomization assignment; 4) treatment methods described; 5) valid, reliable, and relevant primary outcome measure; 6) suitable measurement period; and 7) acceptable sample size. This study failed with the following: 1) blinding; 2) crossover; and 3) appropriate control intervention.

**Conclusion.** The authors failed to acknowledge that because of poor design/ implementation, the data provide little value.

***Comment.*** *Lumbar-spine disorders rank fifth among disease categories in the cost of hospital care, so this procedure is of economic importance to the medical system.[6] The following issues negate the positive view advocated by this research group:*

1) The researchers failed to use blinding. Blinding helps prevent measurement bias and protects the randomization sequence after allocation.[7] Open studies are more likely to favor experimental interventions over the controls.[8] Studies that are not double-blinded can exaggerate effect estimates by 17%.[7] For decades, hundreds of thousands of patients have received surgical arthroscopic treatment for osteoarthritis of the knee. But until recently, no research team had explored whether arthroscopic treatment provided benefit beyond the placebo effect. Moseley randomized patients to a placebo arthroscopy group (a surgical incision followed by closure), an arthroscopic lavage group (a surgical incision followed by a fluid rinse and closure), or a standard arthroscopic debridement group.[9,10] The patients and the physicians performing the postoperative assessment remained blinded as to treatment. The outcomes after arthroscopic lavage or arthroscopic debridement were no better than those after a placebo procedure. And the placebo patients thought that their procedure was worthwhile and would recommend it to family and friends. Spine surgeons have yet to demonstrate that their treatment is better than placebo.

2) The large crossover rate in this study negated the benefits of randomization, and we have no data demonstrating that patient characteristics did not contribute to systematic bias and distorted findings.

3) The patients in this study suffered severe pain for 6 to 12 weeks prior to assignment and were most likely on pain medication before the study. So those assigned to conservative care got more of the same therapy that had already failed. Moreover, 70% of all patients in this study preferred a surgical approach rather than the pain medication alternative offered to the conservative control group. Although a majority of the control patients improved (because of the natural history), the nocebo (negative placebo) effect of the control intervention cannot be ruled out, nor can an exaggerated surgical effect.

It is unfortunate that this study failed to design its study protocols in a rigorous fashion. This paper does, however, serve as a reminder that high-quality medical journals (in this case, *N Engl J Med*) are not effective screening tools for valid and reliable research conclusions. Readers must beware and always perform a critical appraisal of the study methods and data before accepting a conclusion. This study fails to offer guidance to the patient or practitioner. It does, however, provide guidance to other research teams needing to avoid methodological shortfalls.

Although some patients, such as those with bowel/bladder dysfunction and/or progressive motor deficit, have definite indications for surgery, most patients do not. Clinicians should consider both the benefits and risks of specific treatments. Surgery carries a burden of more frequent and serious adverse events than spinal manipulation without evidence of superior benefits. Moreover, a recent high-quality randomized clinical trial designed and conducted by a medical research team demonstrated clear benefit for spinal manipulation over placebo without any adverse events.[11]

**Warning.** Practitioners should not automatically use information from research studies to make decisions about patient care because health care literature suffers from inconsistent quality and frequently distorts research findings. Before relying on the findings of a research study, a practitioner should perform a critical appraisal to determine whether the conclusion is supported by the study's data. Moreover, the results of a study can only provide the likelihood of effects. Even conclusions from multiple studies do

not give a definitive answer. Rather, they indicate *the direction of the evidence.* ■

*These reviews are excerpts from* Direction of the Evidence*, published by the Institute of Evidence-Based Chiropractic, whose aim is the integration of science into chiropractic practice in order to improve patient outcomes. Dr. Feise can be reached at rjf@chiroevidence.com.*

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