

The Chiropractic Hospital-based Interventions Research Outcomes (CHIRO) Study: A randomized controlled trial on the effectiveness of clinical practice guidelines in the medical and chiropractic management of patients with acute mechanical low back pain

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FROM ABSTRACT

Evidence-based clinical practice guidelines for the management of patients with acute mechanical low back pain have been defined on an international scale.

Multicenter clinical trials have demonstrated that most mechanical low back pain patients do not receive evidence-based clinical practice guidelines treatments.

PURPOSE:

To determine if full evidence-based clinical practice guidelines-based study care [including chiropractic spinal adjusting] results in greater improvement in functional outcomes than family physician-directed usual care in the treatment of mechanical low back pain.

STUDY DESIGN/SETTING:

A two-arm, parallel design, prospective, randomized controlled clinical trial using blinded outcome assessment. Treatment was administered in a hospital-based spine program outpatient clinic.

PATIENT SAMPLE:

Inclusion criteria included patients aged 19 to 59 years with acute mechanical low back pain of 2 to 4 weeks' duration. Exclusion criteria included "red flag" conditions and comorbidities contraindicating chiropractic spinal manipulative therapy.

OUTCOME MEASURES:

Primary outcome: improvement from baseline in Roland-Morris Disability Questionnaire scores at 16 weeks.

Secondary outcomes: improvements in Roland-Morris Disability Questionnaire scores at 8 and 24 weeks; and in Short Form-36 (SF-36) bodily pain (BP) and physical functioning (PF) scale scores at 8, 16, and 24 weeks.

METHODS:

Patients were assessed by a spine physician, then randomized to study care (reassurance and avoidance of passive treatments, acetaminophen, 4 weeks of lumbar chiropractic spinal manipulative therapy, and return to work within 8 weeks), or family physician-directed usual care.

RESULTS:

36-study care (chiropractic manipulation) and 35 usual care patients completed all follow-up visits.

The primary outcome, the unadjusted mean improvement in Roland-Morris Disability Questionnaire scores, was significantly greater in the study care (chiropractic manipulation) group than in the usual care group.

Regarding unadjusted mean changes in secondary outcomes, improvements in Roland-Morris Disability Questionnaire scores were also greater in the study care (chiropractic manipulation) group at other time points, particularly at 24 weeks.

Similarly, improvements in SF-36 PF scores favored the study care (chiropractic manipulation) group at all time points.

CONCLUSIONS:

This is the first reported randomized controlled trial comparing full evidence-based clinical practice guidelines treatment, including spinal manipulative therapy administered by chiropractors, to family physician-directed study care (chiropractic manipulation) in the treatment of patients with mechanical low back pain.

Compared to family physician-directed study care (chiropractic manipulation), full evidence-based clinical practice guidelines treatment including chiropractic spinal manipulative therapy is associated with significantly greater improvement in condition-specific functioning.

KEY POINTS FROM AUTHORS:

- 1) "Current clinical practice guidelines for the treatment of acute low back pain have been derived from independent systematic reviews carried out on an international scale [and these guidelines include chiropractic spinal manipulation]."
- 2) Chiropractic assessment and/or spinal manipulative therapy was administered in a hospital-based spine program outpatient clinic to examine the effectiveness of current evidence-based clinical practice guidelines recommended treatments for patients with mechanical low back pain.
- 3) The specific objective of the present study was to compare the short-term outcome of treatment comprised exclusively of guideline-recommended therapies [including chiropractic adjusting] on the one hand, with family physician-directed "usual care" on the other hand, for patients with mechanical low back pain.

- 4) "Patients were excluded if they had signs of a spinal "red flag" condition (eg, cauda equina syndrome, fracture, malignancy, systemic signs of infection, and active inflammatory process), any spinal nerve root irritation or deficit, or were pregnant. Patients were also excluded if they had persisting pain in any other areas of their spine (eg, chronic neck pain), had previous spinal surgery, or were involved in a third-party insurance claim (workers compensation or other personal injury insurer)."
- 5) The chiropractic was limited to a maximum 4 weeks of lumbar spinal manipulative therapy using conventional side-posture, high-velocity, low-amplitude techniques. Spinal manipulative therapy was specifically limited to the lumbar spine (ie, no treatment was directed to the cervical or thoracic regions) and was administered by a registered chiropractor.
- 6) Chiropractic treatment was conducted in the outpatient clinic "at a frequency of two to three times per week, for a maximum period of 8 weeks at the discretion of the attending chiropractor."
- 7) "Chiropractic spinal manipulative therapy was administered only to the lumbosacral spine region, again at a frequency of two to three times a week for a maximum of 4 weeks. No patients in the study care group received neck manipulation or any form of chiropractic treatment other than conventional side-posture, high-velocity, low-amplitude, lumbar spinal manipulations."
- 8) Family physicians providing usual care were not offered specific treatment recommendations but were simply advised to treat at their own discretion.
- 9) "There were no instances of patients reporting adverse effects or requesting that their chiropractic treatment be discontinued."
- 10) Patients randomized to the usual care group received treatment from a variety of professionals including family physicians, massage therapists, kinesiologists, and/or physiotherapists.
- 11) At the primary follow-up point of 16 weeks, 78% of patients in the usual care group were still taking narcotic analgesic medications on either a daily or as needed basis.
- 12) "Condition-specific improvement at 16 weeks clearly favored the study care group, with mean Roland-Morris Disability Questionnaire improvement scores of 2.7 in the study care (chiropractic manipulation) group compared with only 0.1 in the usual care group."
- 13) Improvements in Roland-Morris Disability Questionnaire scores also favored the study care (chiropractic manipulation) group at 8 and 24 weeks.

14) Study care (chiropractic manipulation) treatment was associated with a trend toward greater overall mean improvement in SF-36 scores.

15) This is the first randomized controlled clinical trial assessing the efficacy of full, multimodal, evidence-based clinical practice guidelines therapy for patients with acute mechanical low back pain.

16) Studies show that "treatments commonly recommended by primary care physicians are often highly guideline discordant, and that primary care physicians are highly resistant to changing their patterns of practice for managing patients with acute mechanical low back pain."

17) "The results of this study demonstrated that in equivalent groups of patients with acute mechanical low back pain of less than 4 weeks' duration, carefully controlled and comprehensive evidence-based clinical practice guidelines care [specifically chiropractic spinal adjusting] was associated with greater improvement in terms of condition-specific functioning (Roland-Morris Disability Questionnaire scores) at 16 weeks after treatment initiation."

18) The importance of improving patient outcomes with acute back pain "is important because the development of chronic and often refractory low back pain is commonly preceded by a poor outcome from the management of the patient's acute mechanical low back pain."

19) 78% of patients in the usual care group and 0% of patients in the study care (chiropractic manipulation) group were also taking narcotic analgesic medications after 16 weeks of management.

20) These authors suggest that an explanation for their results being at odds from other studies is because those other studies did not use chiropractors for the manipulation, but rather use others (osteopaths, orthopedic surgeons, family physicians, kinesiologists, naturopaths, and physiotherapists). These authors suggest that these other health care professionals that may perform spinal manipulation may have lower levels of training and clinical acumen.

COMMENTS FROM DAN MURPHY

The most important aspects of this study are:

1) Evidence-based clinical practice guidelines for the treatment of acute low back pain have been derived from independent systematic reviews carried out on an international scale and include only the very best evidence; and this evidence and these guidelines include chiropractic spinal manipulation.

- 2) Based upon the evidence-based clinical guidelines for acute mechanical low back pain, these authors evaluated the effectiveness of traditional chiropractic spinal adjusting, up to 12 patient visits in a month. The results for those who were randomized to receive the evidence-based treatment, including chiropractic spinal adjusting, were significantly superior to those who received a variety of "usual" treatment approaches that did not include chiropractic spinal adjusting.
- 3) No patients who received the evidence-based treatment, including chiropractic spinal adjusting, were taking narcotic drugs at the 16-week follow-up assessment, while 78% of those who received "usual" treatment were taking narcotic drugs.
- 4) There were no adverse reactions to the chiropractic spinal adjusting.