Research Paper Review

Adding chiropractic manipulative therapy to standard medical care for patients with acute low back pain: the results of a pragmatic randomized comparative effectiveness study

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ABSTRACT

Study Design
Randomized controlled trial.

Objective
To assess changes in pain levels and physical functioning in response to standard medical care (SMC) versus SMC plus chiropractic manipulative therapy (CMT) for the treatment of low back pain (LBP) among 18 to 35-year-old active-duty military personnel.

Summary Of Background Data
LBP is common, costly, and a significant cause of long-term sick leave and work loss. Many different interventions are available, but there exists no consensus on the best approach. One intervention often used is manipulative therapy. Current evidence from randomized controlled trials demonstrates that manipulative therapy may be as effective as other conservative treatments of LBP, but its appropriate role in the healthcare delivery system has not been established.

Methods
Prospective, 2-arm randomized controlled trial pilot study comparing SMC plus CMT with only SMC. The primary outcome measures were changes in back-related pain on the numerical rating scale and physical functioning at 4 weeks on the Roland-Morris Disability Questionnaire and back pain functional scale (BPFS).

Results
Mean Roland-Morris Disability Questionnaire scores decreased in both groups during the course of the study, but adjusted mean scores were significantly better in the SMC plus CMT group than in the SMC group at both week 2 ($P < 0.001$) and week 4 ($P = 0.004$). Mean numerical rating scale pain scores were also significantly better in the group that received CMT. Adjusted mean back pain functional scale scores were significantly higher (improved) in the SMC plus CMT group than in the SMC group at both week 2 (P <

0.001) and week 4 (P = 0.004).

Conclusion

The results of this trial suggest that CMT in conjunction with SMC offers a significant advantage for decreasing pain and improving physical functioning when compared with only standard care, for men and women between 18 and 35 years of age with acute LBP.

ANALYSIS

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Background Information

Most systematic reviews on chiropractic manipulative therapy (CMT) have reported that it is effective in reducing low back pain (LBP) and its associated disability, at least moderately, for many patients. Nevertheless, the specific role of CMT in treating LBP within the healthcare delivery system has not yet been defined.

While literally hundreds of studies have investigated the effects of manipulative therapy for LBP, few of them have focused on manipulative therapy for acute LBP patients where the manipulation was delivered by doctors of chiropractic and where a standard medical care (SMC) intervention was included in both treatment groups. Hence, the primary objective of this study was to determine whether the addition of CMT to SMC reduces pain and increases physical functioning better than SMC alone for the treatment of acute LBP.

PERTINENT RESULTS

- A total of 213 potential participants were screened for inclusion in the study and 91 were enrolled. The target sample size was actually 100, but the researchers had to settle with only 91 participants because the grant period ended. Ultimately, 46 participants were randomized to the SMC group and 45 to the SMC plus CMT group.
- The mean age of participants was 26 years and 86% were male. Most participants (71%) had taken a medication for their back pain in the past week.
- Participants' expectation that they would be helped was higher among those in the SMC plus CMT group than those in the SMC alone group.
- Participants in the SMC group were seen by a medical provider from 0-8 times (mean of 1.4 visits), whereas those in the SMC plus CMT group had a mean of 1 SMC visit, plus a median of 7 visits for CMT (range 2-8).
- Adjusted mean Roland-Morris Disability Questionnaire (RMQ) scores were significantly better in the SMC plus CMT group than in the SMC group at both follow-ups (8.9 versus 12.9 at week 2 and 8.0 versus 12.0 at week 4). Nonetheless, mean RMQ scores were decreased in both

groups over the course of the study.

- Mean Numerical Rating Scale (NRS) pain scores were also significantly better in the group that received CMT than in the SMC group at both follow-ups (3.9 versus 6.1 at week 2 and 3.9 versus 5.2 at week 4).
- Global improvements indicating that pain was completely gone, much better, or moderately better were reported by 73% of participants in the SMC plus CMT group, but by only 17% in the SMC group.
- Mean satisfaction with care scores were also higher for the SMC plus CMT group (8.9 at both follow-ups) than for the SMC group (4.5 at week 2 and 5.4 at week 4).
- No serious adverse events (AEs) were reported, though 2 participants in the SMC plus CMT group reported mild transient AEs that resolved within 48 hours. One of the AEs was considered unrelated to trial interventions and the other one was considered possibly related.

CLINICAL APPLICATION & CONCLUSIONS

Acute LBP patients who received CMT in addition to standard medical care noticed statistically and clinically significant improvements in pain levels and LB function scores over the SMC only group at both weeks 2 and 4.

The authors pointed out another study by Juni et al. (1) that used similar methods, including the use of the same primary outcome measures. Interestingly, Juni et al. reported no differences between SMC alone and SMC plus CMT groups at 2 weeks. The authors of the current study suggested several differences between the studies that may have explained the contradictory findings, as follows: the sample in the current study was younger, more ethnically diverse, and included fewer women; also, Juni et al. had substantially fewer losses to follow-up.

Because of the disparate findings of these 2 studies, firm conclusions about whether SMC plus CMT is superior to SMC alone are not possible and further research will be required to clarify the issue.

STUDY METHODS

This was a randomized controlled trial pilot study that compared CMT plus standard medical care with SMC alone in active duty military personnel.

The inclusion criteria were:

- male and female US active duty military personnel,
- 18 and 35 years of age, and
- acute low back pain that was defined as less than 4 weeks duration.

The exclusion criteria were:

- subjects planning to leave the post within 6 weeks from the date of screening,
- LBP for more than 4 weeks duration,
- pregnancy, and
- conditions in which CMT was contraindicated.

Interventions

- *Standard Medical Care (SMC)*: patients received the standard medical care delivery protocol for low back pain that was utilized at the study's medical facility. Medical care varied somewhat, but could include education about self-management, analgesics and anti-inflammatory agents, physical therapy and modalities such as heat/ice, and referral to a pain clinic.
- *Chiropractic Manipulative Therapy (CMT)*: that was provided in addition to SMC. A doctor of chiropractic provided the patients with up to 2 visits weekly for a period of 4 weeks. All patients received high-velocity low-amplitude (HVLA) manipulation as the primary mode of treatment, with ancillary treatments at the doctor's discretion.

Outcome Measures

The primary outcomes used in this study included:

- Back-related pain using the Numeric Rating Scale (NRS)
- Physical functioning as per the Roland-Morris Questionnaire (RMQ) and the Back Pain Functional Scale (BPFS)

Secondary outcomes included:

- Patient satisfaction that was measured using an 11-point numerical rating scale which asked 'How satisfied are you with the overall results of your care?'
- Global improvement on a 7-point Likert scale where subjects were asked 'Compared to your first visit, your back pain is:'. Responses ranged from 1 equal to "Completely gone" to 7 equal to "Much worse."

Outcomes were measured at baseline, 2 weeks and 4 weeks.

The principal investigator and data analysts were blinded as to treatment allocation; however, blinding of the participants and treating clinician was not possible.

STUDY STRENGTHS / WEAKNESSES

This was a well-planned and well-executed study, but there were several limitations:

- Firstly, the follow-up rates were disproportionate between the groups, with an 85% follow-up at both endpoints for the SMC plus CMT group, but only 61% and 63% for the SMC group at weeks 2 and 4, respectively. It is worrisome when participants fail to follow through in a study because there may be an underlying reason that systematically affects the study's results (2). Was the treatment painful? Were the participants not improving and therefore prone to quit treatment? Were the patients "cured" quickly and did not feel it was necessary to return for further treatment? Accordingly, the results may have been different if follow-up had been more robust. On the other hand, even though the possibility of attrition bias cannot be ruled out in this study, the analyses of the imputed data did not differ from the analyses that included only the observed data.

- The second limitation is that the prescription of medications was tracked at the beginning of care, but detailed data regarding actual medication use during the trial was not gathered. Thus, any differences in medication use during the trial may have influenced the study's results.
- Lastly, both the participants and the treating clinician were not blinded to treatment group assignment, though both the principal investigator and analyst were blinded.

Additional References

1. Juni P, Battaglia M, Nuesch E, et al. A randomised controlled trial of spinal manipulative therapy in acute low back pain. Ann Rheum Dis 2009; 68: 1420-1427.
2. Schulz KF, Grimes DA. Sample size slippages in randomised trials: exclusions and the lost and wayward. Lancet 2002; 359(9308): 781-5.