Research Paper Review

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A comparison of spinal manipulation methods and usual medical care for acute and sub-acute low back pain: a randomized clinical trial

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ABSTRACT

***Study design**: randomized controlled trial with follow-up to 6 months.*

***Objective**: this was a comparative effectiveness trial of manual-thrust manipulation (mtm) versus mechanical-assisted manipulation (mam); and manipulation versus usual medical care (umc).*

***Summary of background data:** low back pain (lbp) is one of the most common conditions seen in primary care and physical medicine practice. MTM is a common treatment for LBP. Claims that MAM is an effective alternative to MTM have yet to be substantiated. There is also question about the effectiveness of manipulation in acute and subacute LBP compared with UMC.*

***Methods**: a total of 107 adults with onset of lbp within the past 12 weeks were randomized to 1 of 3 treatment groups: mtm, mam, or umc. Outcome measures included the Oswestry LBP Disability Index (0-100 scale) and numeric pain rating (0-10 scale). Participants in the manipulation groups were treated twice weekly during 4 weeks; subjects in UMC were seen for 3 visits during this time. Outcome measures were captured at baseline, 4 weeks, 3 months, and 6 months.*

***Results**: linear regression showed a statistically significant advantage of mtm at 4 weeks compared with mam (disability = -8.1, p = 0.009; pain = -1.4, p = 0.002) and umc (disability = -6.5, p = 0.032; pain = -1.7, p < 0.001). Responder analysis, defined as 30% and 50% reductions in Oswestry LBP Disability Index scores revealed a significantly greater proportion of responders at 4 weeks in MTM (76%; 50%) compared with MAM (50%; 16%) and UMC (48%; 39%). Similar between-group results were found for pain: MTM (94%; 76%); MAM (69%; 47%); and UMC (56%; 41%). No statistically significant group differences were found between MAM and UMC, and for any comparison at 3 or 6 months.*

***Conclusion**: MTM provides greater short-term reductions in self-reported disability and pain scores compared with UMC or MAM.*

***Level Of Evidence**: 2.*

ANALYSIS

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Background Information
Spinal manipulative therapy (SMT) is used by various types of practitioners for the treatment of acute low-back pain (LBP). However, SMT was reported to be no more effective than inert interventions, sham SMT, or usual medical care in a recent Cochrane Review (1), and a recent meta-analysis reported that the effectiveness of SMT was equivocal (2).

Only studies involving manual-thrust manipulation (MTM) have been included in systematic reviews until now. The results of MTM studies, however, are not truly generalizable to mechanical-assisted manipulation (MAM). Even so, the use of MAM among chiropractic physicians is increasing; especially in America where it is the second most common type of manipulation.

The Activator MAM instrument was compared with MTM in 5 previous studies, but the results were equivocal, and no trial has compared Activator with usual medical care (UMC).

The purpose of the current study on the treatment of acute and subacute LBP was to compare:
- the effectiveness of MTM and MAM, and
- both types of manipulation with UMC.

PERTINENT RESULTS

- Out of 197 people who received a baseline examination, 112 were randomized, and 107 actually received treatment. Two out of the UMC group were later found to be ineligible and 3 of them never began treatment.
- The groups' baseline variables were considered to be equivalent. Mean participant disability was 39.9 and pain was 5.7, which were considered to be of moderate intensity.
- At 4 weeks, mean disability scores for the MTM group compared to the MAM group were significantly reduced, showing a -8.1 point ($p = 0.009$) further reduction in disability.
- MTM compared to UMC also showed a significant advantage for MTM, with a -6.5 ($p = 0.032$) further reduction in disability. On the other hand, disability in the MAM group compared to UMC showed a non-significant difference of only 1.5 points ($p = 0.609$).
- Pain scores at 4 weeks showed a significant advantage for MTM compared to MAM, with an adjusted mean difference between groups of -1.4 ($p = 0.002$). MTM also showed a further reduction of pain over UMC of -1.7 ($p < 0.001$), while the difference between MAM and UMC was not significant at -0.3 ($p = 0.480$).
- At least a 30% reduction in disability was attained by 75% of the MTM group as compared to about

50% of the MAM and UMC groups. At least a 50% reduction in disability was realized by 50% of the MTM group, whereas only 16% of the MAM and 39% of the UMC groups noticed that much reduction in disability.

- Greater than 30% reduction in pain was achieved by 94% of the MTM group as compared to 69% of the MAM and 56% of the UMC groups. Greater than 50% reduction in pain was achieved by 75% of the MTM group as compared to 47% of the MAM and 41% of the UMC groups.
- No adverse events were reported.

CLINICAL APPLICATION & CONCLUSIONS

MTM was shown to be superior to MAM and UMC in this study, yet the authors indicated that the magnitude of the treatment effect size and clinical significance were modest, but still relevant to patients with back pain.

Even though MTM performed better that MAM, patient preference should be considered in the management of patients with LBP and some of them may prefer a low-force type of manipulation like MAM. Nonetheless, based on the findings of this study, clinicians should consider using MTM when there are no treatment preferences or contraindications to high-velocity, manual manipulation.

Practitioner preference may also be a consideration when choosing a manipulative technique; for instance, when clinician limitations preclude the administration of MTM due to factors such as practitioner-patient size differences or the practitioner being physically impaired.

It has previously been suggested that MTM and MAM are therapeutically equivalent; however, this study is at odds with that notion.

It is interesting to note that no adverse events were reported in this study; especially considering that adverse event rates have exceeded 50% of patients in some studies (3, 4). Even so, the occurrences of serious adverse events following lumbar spinal manipulation are thought to be extremely rare (5). (WRITER'S NOTE: *a conversation with one of the current study's co-investigators revealed that adverse events were only reported if they met the threshold that was required by the Institutional Review Board; they did not report minor nuisances. Also, participants were not specifically asked to complete adverse event-related questionnaires*.)

STUDY METHODS

This was a prospective, randomized clinical trial that evaluated the comparative effectiveness of MTM, MAM, and UMC for treatment of acute and subacute LBP.

Group allocation was concealed until the time of randomization; however, neither participants nor treating clinicians were blinded as to treatment assignment. The principal investigator was blinded and did not interact with the participants. The collection of data and primary data analysis were conducted by a research coordinator and a biostatistician who were not blinded to group allocation.

Inclusion criteria – participants were required to:

- have a new episode of LBP within the previous 3 months,

- be at least 18 years of age,
- speak and understand English,
- have self-reported pain of at least 3 (0-10 scale),
- have self-reported disability of at least 20 (0-100 scale),
- agree to be randomized,
- be present for 2 office visits per week over 4 weeks, and
- cooperate with follow-up data collection.

Exclusion criteria included the following:

- chronic LBP (> 3 months duration);
- prior chiropractic, medical, or physical therapy treatment for the current episode of LBP;
- radicular signs/symptoms including leg pain below the knee, numbness or weakness of the lower leg, or positive nerve root tension/neurological signs;
- contraindications to spinal manipulation (ex. history of metastatic cancer, severe osteoporosis, fracture or instability, prolonged anticoagulant or oral steroid use); and
- current use of prescription pain medications.

Participants were allowed to take over-the-counter medications for their LBP during the study.

Interventions

- *Manual Thrust Manipulation (MTM)*: A single licensed chiropractor applied the MTM, which involved high-velocity low-amplitude thrust manipulation with the participant in a side posture position. The spinal levels where manipulation was applied were determined via static and motion palpation.
- *Mechanical Assisted Manipulation (MAM*): A single certified Activator Methods chiropractor applied MAM to participants in the prone position using the Activator IV Instrument. The spinal levels where manipulation was applied were determined using palpation and the Activator method of leg length analysis.
- *Usual Medical Care (UMC)*: A single medical physician who was board certified in physical medicine and rehabilitation provided UMC. UMC participants were prescribed over-the-counter analgesic and NSAID medications and were told that most new episodes of back pain are typically self-limiting. They were also given advice to stay physically active and avoid prolonged bed-rest.

Participants in the chiropractic treatment groups were seen twice per week for 4 weeks, whereas UMC patients were seen a total of 3 times (initial and then at 2 and 4 weeks). The chiropractors applied manipulation in the thoracic, lumbar, and sacroiliac joints as they deemed necessary. However, no manipulation of other spinal or peripheral joints was permitted. All participants were given a copy of an educational booklet that gave information about proper posture and movements during activities of daily living.

Outcomes were assessed at baseline, 4 weeks, 3 months, and 6 months. The Oswestry LBP Disability Index of self-reported disability was the primary outcome measure. The secondary outcome was a self-reported pain-intensity scale that was the average of three different 0 to 10 numeric pain rating scales: 1) current pain, 2) worst pain in the past 24 hours, and 3) average pain over the past week.

The primary comparison of groups in the statistical analysis was MTM to MAM. Secondary comparisons were MTM to UMC and MAM to UMC. In addition, participants were considered to be

"responders" if they achieved at least 30% or 50% decreases in an outcome.

STUDY STRENGTHS / WEAKNESSES

This was a well-planned and well-executed study that closely followed the CONSORT guidelines for reporting randomized trials. However, it only involved a single-center and the sample size was modest (i.e. just big enough to attain 80% power). In addition, there was no placebo comparison group, so it cannot be said that MAM and UMC are not effective, only that MTM is more effective. Furthermore, there was no natural-history (non-treatment) control group, so it is not possible to determine what part of the healing response was due to natural history, direct treatment effect, or non-specific factors. As mentioned above, it was also not possible to blind participants and providers as to treatment group.

Only 3 clinicians participated in this study, one for each type of treatment. It is therefore possible that some of the treatment response was the result of participant-provider interaction, rather than the direct effect of the treatment.

Lastly, some of the differences observed between the manipulation groups and the UMC group may have been related to the discrepancy in the number of visits participants received (8 for manipulation and only 3 for UMC). The authors justified their chosen methodology as being similar to the "real world" setting where chiropractors typically see patients about 8 times and medical providers see theirs about 2 times.

Additional References

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