

Rubinstein SM, van Middelkoop M, Assendelft WJJ, et al. Spinal Manipulative Therapy for Chronic Low-Back Pain. Spine 2011;36(13):E825-E846.

Design: Meta-analysis of randomized clinical trials

PICOS:

- **Patients:** adults with radiating or non-radiating low back pain lasting on average more than 12 weeks, exclusive of postoperative patients and those with specific pathologies (including sciatica with radiculopathy)
- **Interventions:** a variety of spinal manipulative therapy (SMT) techniques
- **Comparisons:** four main clusters of comparison were used
 - o SMT vs. inert interventions
 - o SMT vs. sham SMT
 - o SMT vs. all other interventions
 - o SMT in addition to any intervention vs. that intervention alone
- **Outcomes:** only patient-reported outcomes (pain, function, overall response to treatment, quality of life, return to work) were included; physiological measures (range of motion, straight leg raise test) were not included
- **Study types:** only randomized trials were included, published subsequent to the previous Cochrane review in 2000

Search strategy and selection:

- Databases from 2000 to 2009 included MEDLINE, Cochrane Library, EMBASE, CINAHL, PEDro, and the Index to Chiropractic Literature
- Other searches included the reference list of all included studies and electronic registries of ongoing trials; however, proceedings of meetings and other unpublished “grey literature” were not included
- Risk of bias (RoB) was evaluated using the Cochrane Back Review Group criteria, which has 12 items (randomization, allocation concealment, blinding, attrition, co-interventions, baseline similarity)
 - o Because all outcomes were patient-reported, the patients were the assessors of outcome, and no study met the blinding criteria
 - o Low RoB was credited if 6 of the 12 criteria were met and there was no fatal flaw
 - o “Fatal flaws” were considered to be either 50% attrition at the time of outcome measurement or baseline imbalance sufficient to suggest that randomization had failed
- Two authors read all articles, and disagreements about inclusion were resolved through discussion with a third author

Results:

- Quality of evidence was evaluated using five principal domains
 - o Limitations in design (downgraded when more than 25% of patients were from studies with a high RoB)

- Inconsistency of results (downgraded in the presence of significant statistical heterogeneity and widely differing estimates of treatment effect)
- Indirectness (downgraded when more than 50% of patients were outside the target group, such as studies that only enrolled older patients or used inexperienced practitioners)
- Imprecision (downgraded when there were less than 400 patients for continuous outcomes or 300 patients for dichotomous outcomes)
- Other (e.g., publication bias)
- Five levels of evidence were described
 - High quality: further research is unlikely to change confidence in the estimate of effect; there are sufficient data with narrow confidence intervals and no known reporting biases
 - Moderate quality: further research is likely to have an important impact on confidence in the estimate of the treatment effect and may change the estimate; one of the above domains is not met
 - Low quality: further research is very likely to have an important impact on the estimate of effect and is likely to change the estimate; two domains are not met
 - Very low quality: great uncertainty about the estimate; three domains are not met
 - No evidence from RCTs
- 26 trials were included in the review; only 9 met the criteria for a low RoB
- A total of 29 outcome comparisons were made between SMT and other interventions, and most evidence was graded as low or very low
- For comparison of SMT with inert interventions and with sham SMT, all of the evidence was graded very low for all pain, function, and recovery outcomes
- For comparison of SMT with all other therapies (which included back school, physiotherapy, exercise, standard medical care, and physical modalities), there was high quality evidence that SMT provided better pain relief at 1 and 6 months
 - The magnitude of these effects was small; SMT was more effective (on a pain scale from 0-100) by only 2.76 points at 1 month and 4.55 points at 3 months
 - There was also high quality evidence that SMT did not provide statistically more effective pain relief at 12 months
 - There was high quality evidence that SMT provided better functional improvement at 1 month than other interventions, moderate quality evidence of no SMT effect at 3 months, and high quality evidence of no SMT effect at 6 and 12 months
 - There was low quality evidence that SMT had no significant effect on return to work at any short or long term interval compared to other interventions
- For comparison of SMT plus any intervention to the intervention alone, there was low quality evidence that the addition of SMT to another intervention

provided more pain relief at 1 month, high quality evidence at 3 months, low evidence of equivalent pain relief at 6 months, and high quality evidence of better pain relief at 12 months

- There was not sufficient data to permit separate analysis of patients with and without radiating pain, since most studies did not present separate data

Authors' conclusions:

- Although SMT was statistically superior to other interventions in pain relief in the short term, these differences were small and clinically unimportant
- There is controversy in interpreting comparisons of continuous outcomes in pain literature, since the mean difference between groups may not represent the difference in treatment effectiveness
- Neither the technique (high-velocity low-amplitude thrust) nor the type of practitioner was shown to have an effect on the pooled estimate of treatment effect
- The meta-analysis suffered from the small number of studies with low risk of bias; this is a common difficulty in systematic reviews
- A surprising number of current studies still do not register their protocols in any trial registry; this is a generally accepted international procedure
- The decision to refer for SMT or for other interventions should not be based on an expectation of clinically important relative benefit of SMT, but on other considerations, such as cost, patient preference, and relative safety

Comments:

- The review is an update of a Cochrane Review done in 2000 of SMT for low back pain, in which the third author was the first author (Assendelft et al 2000)
- The current review includes very few of the studies which were included in 2000, and the forest plots have no studies which were used in the 2000 review
 - o Many of the exclusions appear to have been of studies of pain which did not clearly exceed 12 weeks in duration; the 2000 review was for both acute and chronic back pain
- The same authors wrote a Cochrane Review of the same subject dated 2011; the full-length Cochrane Review has a few more studies, but the summaries and conclusions are essentially the same
- Although numerous diverse interventions (including bone-setting and naprapathy, which is not practiced in Colorado) are pooled in Figures 3 and 4, the statistical heterogeneity is not especially great for most analyses
- Because 3 of the 12 items in the risk of bias scale deal with blinding, the impracticality of blinding in SMT means that a low risk of bias will be difficult to achieve, even if the studies are otherwise generally adequate
- Levels of evidence are reported in a manner difficult to interpret in some cases
 - o Functional status at 1, 3, 6, and 12 months is reported in both Table 3 and Figure 4

- Table 3 reports levels of evidence for the Roland-Morris scale with levels of evidence at 1, 3, 6 and 12 months of low, high, low, and high respectively
- Figure 4 (and the text which describes it) pool all functional scales (R-M plus Oswestry) and report high, moderate, high, and high levels of evidence respectively
- Levels of evidence similarly are not plausibly related to levels of effectiveness
 - There is no biologically plausible mechanism whereby the added pain-relieving effectiveness of SMT is low at 1 month, high at 3 months, equivalent at 6 months, and high again at 12 months
 - The levels of evidence are directly related to the quality and availability of the data and indirectly to the effectiveness of SMT
- Table 4 shows that there was “high quality” evidence that SMT plus any intervention was more effective than that intervention alone at 12 months; the mean pain for SMT was 3.31 lower (95% CI, 6.6 to 0.02)
 - The effect size is quite small, but the numbers (n=1000) are large
 - It would seem that further research could change the estimate of effect, given the proximity of the lower end of the confidence interval to zero
- In spite of all limitations, the meta-analysis does combine data from some large and recent studies of SMT in a useable fashion

Assessment: Adequate to support evidence statements:

- Good evidence that SMT is comparable to exercise, standard medical care, and physiotherapy in reducing chronic low back pain, and good evidence that that SMT does not provide a clinically important superior pain relief over these interventions