Rubinstein SM, Terwee CB, et al. Spinal manipulative therapy for acute low-back pain (Review). Cochrane Database of Systematic Reviews 2012, Issue 9, Art No. CD008880.pub2.

Design: Meta-analysis of randomized clinical trials

PICOS:

- **P**atient population: Adult participants with a mean duration of low back pain (LBP) of 6 weeks or less; patients with postpartum pain, postoperative pain, or "failed back syndrome" were excluded
    - **I**nterventions: Both spinal manipulation and spinal mobilization were studied, and both were designated by the acronym SMT
        - Mobilization was low-grade velocity, small or large amplitude passive movement techniques within the patient's joint range of motion
        - Manipulation was high velocity, low amplitude impulse on a synovial joint near the end of the patient's range of motion, generally producing an audible crack from cavitation of the joint
    - **C**omparison intervention: Study inclusion demanded that the unique contribution of SMT to the outcome be identifiable, excluding studies with multi-modal treatment in which SMT was one of the modalities; main clusters were:
        - SMT vs. inert interventions
        - SMT vs. sham SMT
        - SMT vs. all other therapies
        - SMT as an adjunct to other interventions
        - One form of SMT vs. another form of SMT (e.g., supine vs. side-lying SMT)
    - **O**utcomes: Only patient-reported outcomes were included; physiologic measures such as degrees of straight leg raising were not evaluated
        - Pain on a visual analog or numerical rating scale
        - Back-specific function (Oswestry, Roland-Morris)
        - Global recovery judged as the number of patients recovered or nearly recovered
        - Return to work and/or SF-36 as secondary measures
    - **S**tudy types: Randomized trials with more than one day of follow-up; exclusion of nonrandom assignment (alternate allocation, day of birth)

Study selection and evaluation:

- Databases included the Cochrane Central Register, MEDLINE, EMBASE, CINAHL, PEDro, Index to Chiropractic Literature through March 2011
- Reference lists of included studies were also screened, as were registered trials from the US Clinical Trials registry and the WHO registry
- Risk of bias was assessed using the Cochrane Risk of Bias considerations (dealing with appropriate randomization, allocation concealment, follow-up, etc.); since all outcomes were patient-reported, blinding of the outcome

assessor was not distinguished from blinding of the patient, which in nearly all studies was not practical

- Clinical relevance was measured by the pooled effect size of the pain and function scales
    - Small; mean group difference <10% of the outcome scale
    - Medium: mean group difference 10-20% of the scale
    - Large: mean group difference >20% of the scale
- Overall quality was assessed by the risk of bias, by the degree of precision (wide or narrow confidence intervals in the treatment effect), consistency between studies, and directness (study population closely resembles the patient population likely to be seen in clinical practice)
    - High quality: Further research is unlikely to change the level of evidence; low bias with sufficient precision
    - Moderate quality: Further research likely to change confidence in the size of the treatment effect and may change the estimate of the effect
    - Low quality: Further research is very likely to have an important impact on the confidence in the treatment effect and is likely to change it
    - Very low quality: great uncertainty about the treatment effect
    - No evidence: no information from RCTs

Results:

- 20 trials were identified (2674 patients) which fulfilled inclusion criteria, 16 of which were included in quantitative meta-analysis
    - 7 studies compared SMT to inert interventions (booklet, detuned ultrasound or diathermy, bed rest, short-wave diathermy)
    - 1 study compared SMT to sham SMT
    - 8 studies compared SMT to other interventions (exercise, PT, standard medical care, back school)
    - 4 studies compared SMT as an adjunct to other treatment (standard medical care, PT, exercise)
    - 3 studies compared different forms of SMT
- Most studies were conducted in primary care; two were in an occupational setting
- Most treatments were done by physical therapists (9 studies) or chiropractors (5 studies); other trials studied treatment by osteopathic doctors or combinations of providers
- Most studies were considered to have a high risk of bias; one third had a low risk of bias, representing 34% of all patients
- For the comparison of SMT versus inert interventions, pain and function were studied
    - For pain, there was low quality evidence that SMT was not significantly different from inert interventions at one week follow-up, and low quality evidence that SMT was significantly better than inert treatment at one and three month follow-up

    - For function, there was moderate quality evidence that SMT was not significantly different from inert interventions at one week follow-up, and low quality evidence that SMT was not significantly better at one and three months
    - For global recovery, there were non-significant but conflicting results, with one study showing benefit with SMT and the other showing benefit from inert treatment
    - For return to work, no results were available
- For SMT versus sham SMT, there was very low quality evidence that SMT was not significantly different from sham SMT for pain and for functional status; no results were available for return to work
- For SMT versus all other interventions, pain, function, return to work, and global recovery were studied
    - Most of the included studies were rated as having a high risk of bias; only one had a low risk and six had high risk of bias
    - Nevertheless, the studies did not report that SMT was superior to comparison interventions for pain, function, RTW, and recovery
    - The evidence of a lack of difference between SMT and other interventions was low quality due to the high risk of bias
    - Most of the comparison interventions consisted of physical therapy, massage, back school, McKenzie exercise, and other specific exercise
- For SMT as an adjunct to other interventions (usual care, advice, exercise), there was one study with low risk of bias and 2 studies with high risk of bias; data were available for pain, function, recovery, and RTW
    - For pain, there was low quality evidence that SMT was not superior to the control intervention at one week, one month, or three months
    - For function, there was low quality that SMT added to usual care was superior at one week follow-up, but not at one month or three months
    - For recovery, there were conflicting results which were non-significant
    - For RTW, there was very low quality evidence that SMT had no significant effect
- For one SMT technique versus another form of SMT, the authors did not attempt to pool the data, but estimated that side-lying and supine thrust SMT was better than non-thrust SMT for pain, function, and recovery

Authors' conclusions:

- In the absence of high quality information from low-bias RCTs, no strong conclusions or recommendations can be made for the use of SMT for acute LBP
- Because acute LBP has a favorable natural history, demonstrating a clinically relevant effect is difficult
- Baseline pain scores were at moderate or low levels in most studies; therefore, floor effects, in which there is too little room for improvement, may have occurred
- Most current studies of SMT are for subacute and chronic LBP; therefore, the effect of SMT on acute LBP is not likely to be resolved soon

- Most of the studies had a high risk of bias, and many presented data in a way not conducive to meta-analysis; therefore, pooled estimates may have been compromised
- Studies at high risk of bias are generally known to yield larger treatment effects than better quality studies; it is not known how this may have influenced the overall results
- The nonspecific low back pain concept includes a heterogeneous group of patients; efforts are being made to improve the classification of pain through more precise definitions of LPB and more complete descriptions of SMT

Comments:

- The authors note that some common threats to the validity of meta-analyses and systematic reviews, namely poor control of bias in RCTs and publication bias in which studies appear in journals, would generally be expected to yield a higher, not a lower estimate of the effect of SMT for LBP
- In at least one study (Skargren 1997), the description of SMT is manipulation, and the description of the control intervention includes providing a large number of patients (36%) with mobilization, which is included in the general definition of SMT; this is not likely to affect the overall conclusions of the meta-analysis, but does illustrate the often vague nature of the comparisons made in published studies
- Similarly, short-wave diathermy is included in the designation of "inert interventions" for that group of comparisons, but SW diathermy was also included in the group of comparisons between SMT and active treatments
- Despite the difficulties with the comparisons, most of the biases would tend to inflate a treatment effect of SMT, making it unlikely that a clinically meaningful effect of SMT compared to other interventions for acute LBP was missed

Assessment: High quality meta-analysis which supports a statement that there is good evidence that SMT does not have a clinically greater therapeutic effect for acute nonspecific LBP (6 weeks duration or less) than other interventions such as physical therapy