

# Dr. Chestnut's Research Review

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## *Latest Systematic Review of SMT: How to Critique the Critique*

Paige et al. (2017) Association of Spinal Manipulative Therapy with Clinical Benefit and Harm for Acute Low Back Pain. Systematic Review and Meta-analysis. JAMA;317(14):1451-1460

### QUOTE BOARD:

"Of 26 eligible RCTs [Randomized Controlled Trials] 15 RCTs (1711 patients) provided moderate quality evidence that SMT has a statistically significant association with improvements in pain."

"Twelve RCTs (1381 patients) produced moderate-quality evidence that SMT has a statistically significant association with improvements in function."

"No RCT reported any serious adverse event."

### Conclusion:

"Among patients with acute low back pain, spinal manipulative therapy was associated with modest improvements in pain and function at up to 6 weeks, with transient minor musculoskeletal harms."

## Dr. Chestnut's Scientific and Clinical Insights:

### Study Methodology/Description

This is a systematic review of the SELECTED literature with a meta-analysis of the data from the studies that met the inclusion criteria. The purpose of a systematic review is to look at the available research to ascertain the quality of valid evidence regarding specific effects or outcomes associated with a particular intervention.

Rather than looking at individual studies which can differ significantly in their conclusions, systematic reviews pool and analyze the data from a group of studies to get a better picture of the overall trend and quality of evidence. It is the equivalent of pooling all the data from all subjects in a study and looking at the overall trend of the effects of an intervention. Looking at any single subject in a study makes it easy to pick out the subject with the best or worst results to support a preconceived or biased conclusion. The same can be said about picking out chosen studies from the literature which support preconceived or biased conclusions.

Now, and this is VERY important, the same bias that can occur when choosing to look at any single subject from a study, or at any single study from a body of studies, can easily occur if one has bias in terms of which studies one includes in a systematic review. In other words, one can just as easily create a selection criteria for a group of studies that results in the inclusion and/or exclusion of studies that support a preconceived or biased conclusion.

***The validity of any systematic review rests entirely on the absence of bias with respect to inclusion criteria, data analysis, and quality rating. Thus the validity of any systematic review depends on the selection criteria regarding which studies are included and excluded, which outcomes are chosen to be studied, the statistical methods of analysis (meta-analysis) of the data, and the quality rating system for each study and the overall level of evidence.***

The accepted way to ensure the removal of bias from a systematic review is to clearly define the outcomes to be studied (in this case effectiveness and harms associated with SMT in acute low back pain), to clearly define the selection criteria for which studies on these outcomes will be included and excluded, and, to clearly define how the quality of each study and the overall evidence from the review will be rated. The accepted way to determine quality is based on the methodological validity of the study based on accepted rules of limiting bias and ensuring methodological validity such as: randomization; equality of subjects at baseline; blinding of patients, care providers, data collectors, and statisticians; inclusion of control or placebo groups; number of subjects; compliance; equality of care frequency and duration among groups; whether the study is prospective or retrospective etc.

If there is any bias the entire validity of the systematic review is destroyed. For this reason, the systematic review must clearly identify and define the body of literature searched (the data sources), the study inclusion/exclusion criteria, the statistical methods used for the meta-analysis of the data, the outcomes being measured, and, of course, the study and overall level of evidence rating systems.

Let's look at the methodology of this systematic review:

**Objective:** "To systematically review studies of the effectiveness and harms of SMT for acute ( $\leq 6$  weeks) low back pain."

**Data Sources:** "Search of MEDLINE, Cochrane Database of Systematic Reviews, EMBASE, and Current Nursing and Allied Health Literature from January 1, 2011, through February 6, 2017, as well as identified systematic reviews and RCTs, for RCTs of adults with low back pain treated in ambulatory settings with SMT compared with sham or alternative treatments, and that measured pain or function outcomes for up to 6 weeks. Observational studies were included to assess harms."

**Data Extraction and Synthesis:** "Data extraction was done in duplicate. Study quality was assessed using the Cochrane Back and Neck (CBN) Risk of Bias tool. This tool has 11 items in the following domains: randomization, concealment, baseline differences, blinding (patient), blinding (care provider [care provider is a specific quality metric used by the CBN Risk of Bias tool]), blinding (outcome), co-interventions, compliance, dropouts, timing, and intention to treat. Prior research has shown the CBN Risk of Bias tool identifies studies at an increased risk of bias using a threshold of 5 or 6 as a summary score. The evidence was assessed using the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) criteria."

**Main Outcomes and Measures:** "Pain (measured by either the 100-mm visual analog scale, 11-point numeric rating scale, or other numeric pain scale), function (measured by the 24-point Roland Morris Disability Questionnaire or Oswestry Disability Index [range, 0-100]), or any harms measured within 6 weeks."

Well? What do you think? My guess is that you don't know what to think, you simply are in a position of having to trust that, since this is published in a respected peer-reviewed journal, and that the authors seem to be following the guidelines for systematic reviews, that this must be a valid review with valid, unbiased conclusions. In fact, you probably like the conclusions or findings since they appear to be in favor of chiropractic which makes it even more unlikely that you will do due diligence to ascertain whether or not the conclusions of this systematic review are valid.

Even if you were willing to do due diligence are you aware what doing due diligence would involve? Due diligence would involve that you critique the body of literature searched or the data sources, the study inclusion/exclusion criteria, the statistical methods used for the meta-analysis of the data, and, of course, whether or not the authors properly rated the level of evidence based on their analyses. My guess is your head is spinning. Don't feel bad, you are a clinician not a researcher, you are no different than the vast majority of chiropractors, medical doctors, dentists, veterinarians, or physiotherapists. Clinicians are not trained scientific researchers or experts in research methodology, they are trained in clinical implementation. They are trained to trust guidelines and recommendations and to blindly implement them - at the threat of facing professional sanctions if they do not!

How many clinicians do you think have the willingness, time, or ability to critique a study let alone a systematic review? My guess is far less than 1%. How many clinicians are going to get copies of every article that is included in this systematic review and take the time and/or have the ability to critique those studies for methodological validity and/or bias? How many clinicians are going to be familiar enough with the literature to immediately recognize which relevant studies, if any, have been excluded from this review? Again, my guess is far less than 1%. In fact, I would guess very few "researchers" will ever bother.

I'm sure you are getting the picture. This is why systematic reviews and the clinical guidelines that are based on them have so much power. First, most clinicians do not have the time or ability to read and critique the research. A systematic review is appealing because it claims to summarize all the research and even rate it for you in order to tell the clinician what the evidence says is or is not safe and effective. This is precisely why clinical guidelines are so often based on systematic reviews. Clinical education and practice are not based on the critique of research or the formulation of guidelines; clinical education and practice are based on learning, being convinced to have blind trust in, and the legal and professional enforced implementation of, clinical guidelines - which are based on systematic reviews. You can see the power and influence of systematic reviews!

What makes this particularly concerning and confusing is that systematic reviews of SMT have differed widely in their conclusions! To quote this paper, "As new trials continue to be published, and given these differences in conclusions among studies [systematic reviews], this review was conducted to provide updated estimates of the effectiveness and harms associated with spinal manipulation compared with other nonmanipulative therapies for adults with acute low back pain."

In other words what these authors are claiming to the world is that this systematic review solves the problems associated with previous reviews because it is providing an 'updated and all relevant study-included' estimate of the effectiveness and harms associated with SMT. A bold claim indeed but, one which if believed, would allow any clinician reading this review to feel confident that it contains the most up to date, most valid, and most trustworthy assessment of SMT.

Let's look at their overall recommendation based on their grading of the evidence:

"The quality of evidence was judged as moderate that treatment with SMT was associated with improved pain and function in patients with acute low back pain, **which was downgraded from high due to inconsistency of results**. The **quality of evidence was judged as high that SMT is commonly associated with transient minor musculoskeletal harms**, although they may be equally common following non-SMT manual therapy."

And their conclusions:

Among patients with acute low back pain, spinal manipulation therapy was associated with modest improvements in pain and function at up to 6 weeks, with transient minor musculoskeletal harms. **However, heterogeneity in study results was large.**

My guess is, now that you have seen, that based on their systematic review based on the most up-to-date available evidence, these authors downgraded the level of evidence for SMT from high to moderate, that you may have suddenly changed your first impression.

Are you wondering upon which scientific grounds these authors downgraded the level of evidence for SMT from high to moderate? One might think from reading their comment that there was some new evidence that got included in this review that caused the downgrading of the level of evidence for SMT. That's actually not what they are saying. In fact, there was not a single study included that was newer than 2013. In fact, only one was from 2013, one from 2012, one from 2007, and the rest from prior to 2004, many from the 1990's and 1980's and one from 1977.

What they are saying is that their own meta-analysis of the data resulted in a rating of the level of evidence for SMT as high but they subsequently downgraded this based on the fact that there was a high level of heterogeneity of results. Based on the studies these authors chose to include, there was, amongst these studies, a high level of heterogeneity of results or a high inconsistency of results, and based on this fact, according to the GRADE system of grading recommendations, the authors could justify downgrading the level of evidence from high to moderate. A high level of heterogeneity? Every single study included in this review was in favor of SMT! So, there was no heterogeneity with respect to whether or not the results showed a positive effect of SMT on pain and function (which is why their own meta-analysis rated the level of evidence as high), there was just heterogeneity with respect to the amount of benefit of SMT.

I hope you are wondering why there would be such a high level of heterogeneity of results between studies. Are you aware that, these authors, and virtually all other authors of systematic reviews of SMT, do not differentiate between a study that includes 2 manipulations from one that includes a proper course of care? Did you also know that these authors did not even consider number of SMT sessions with respect to the ability to explain the heterogeneity of results?

Did you know that they also did not provide any analysis regarding study quality as an explanation for the heterogeneity even though they admit that many of the studies they chose to include were low quality and, most importantly, that the high quality studies tended to report larger benefits for SMT? To quote the authors, "This study has limitations. First there were limitations in the quality and quantity of original research [that met their specific inclusion criteria]. More studies were classified as low quality than high quality. Nevertheless, high quality studies tended to report larger benefits." The question being begged is, why not exclude the low quality studies and properly determine if this is a possible explanation for heterogeneity rather than simply use heterogeneity to downgrade the level of evidence for SMT from strong to moderate and then claim that study quality could not explain this without any data to back up this statement?

Did you know that these authors also defined SMT as EITHER thrust manipulation or mobilization? That's right, they arbitrarily defined mobilization as SMT for this study. On what basis did they do this? None were provided. Would analyzing results based on whether or not SMT vs mobilizations was provided, combined with a minimum number of treatment sessions, have provided an explanation for heterogeneity? We will never know but, if we look at studies with proper frequency and duration of chiropractic SMT care which show significant improvements compared to other treatments we can make educated guesses. I refer you to my review of the Bishop study from my March 2017 Research Review.

Over the next months I will be critiquing the studies included in, and excluded from, this and other systematic reviews. I am confident you will become both enlightened and shocked. My guess is you may also become disillusioned and cynical, and perhaps a bit angry; I certainly became all three.

### **Clinical Importance/Main Clinical Gem**

The clinical importance of this systematic review is that, with great cultural authority, the level of evidence for SMT is rated as below that of NSAIDs and no better than many other non-pharmacological alternatives. This conclusion is based on the inclusion of many studies that involved a few mobilizations from physical therapists or medical doctors which were defined as valid SMT care. It is also, as you will see, based on the exclusion of studies that involved proper courses of thrust SMT.

I believe the opioid crisis and the forced admission that drugs, surgery, and usual physiotherapy interventions have been ineffective for decades has created a sense of panic amongst those ethically or emotionally unable or unwilling to recognize the strong evidence regarding the effectiveness of chiropractic SMT.

The only reason the opioid crisis was able to grow is because there was fertile soil created by the fact that medical doctors were acutely aware of the ineffectiveness of drugs, surgery, and physiotherapy and far too many were unwilling to even consider referral for chiropractic SMT. Now that there has been a forced admission of the ineffectiveness of usual medical care and physiotherapy (the very justification for why they were willing to prescribe opioids) and a forced demand for non-pharmacological intervention alternatives, chiropractic has been put in a position to be recognized as the most evidence-based, safest, and most cost-effective choice for patients with low back pain. This is clearly an unacceptable premise to many.

I believe there is now a concerted effort to downgrade the rating of evidence for chiropractic. They have no justification to upgrade the level of evidence for safety, effectiveness, or cost-effectiveness for usual medical care, surgery, or physiotherapy so they know that their only option to deny the clinical superiority of chiropractic is to try to downgrade chiropractic to make it appear that it is no better than other alternatives. They are, by the way, also redefining physiotherapy as SMT and mobilizations as SMT in the literature. This systematic review and the recent review of nonpharmacological therapies for low back pain published in the *Annals of Internal Medicine* as the basis for the ACP guidelines are perfect examples of this (Chou et al (2017) Nonpharmacological therapies for low back pain: A systematic review for an American College of Physicians Clinical Practice Guideline 166:493-505).

Over the next year I will be exposing this for you and arming you with the evidence you need to defend, promote, and practice chiropractic SMT or adjustment with evidence-based certainty, pride, and dignity. My goal is not to pretend chiropractic is perfect or that chiropractic SMT works every time for every patient. My goal is to expose the fact that, when a fair, unbiased interpretation of the literature is used, which compares results from studies with a minimum frequency and duration of chiropractic SMT to other alternatives, that chiropractic SMT is the most effective, most cost-effective, and a very safe intervention choice that should be recognized as the preferred first option (excluding those with fracture or instability from trauma, tumor, or infection).

### Dr. Chestnut's Commentary

I will end by pointing out a few of the most glaring biases of this systematic review. I will specifically critique the studies included in this review over the following months, for now I just want to point out a glaring bias with their selection criteria that you probably missed and to remind you of the biases regarding ignoring the frequency of care and defining mobilization as SMT.

This is how they describe their selection criteria. "Search of MEDLINE, Cochrane Database of Systematic Reviews, EMBASE, and Current Nursing and Allied Health Literature from January 1, 2011, through February 6, 2017, as well as identified systematic reviews and RCTs, for RCTs of adults with low back pain **treated in ambulatory settings** with SMT compared with sham or alternative treatments..."

On what methodological validity basis did they choose to exclude studies which involved patients being treated in non-ambulatory or hospital settings? NONE!! There is no quality rating scale on earth that would include this as a valid inclusion or exclusion criteria. Whether or not a subject received care in a hospital or not has NOTHING to do with the validity of the study!

I bet this slipped by you. It seems so innocent and unimportant - until you realize that some of the most powerful evidence for chiropractic comes from studies where care was performed in a hospital setting. The Meade study out of the United Kingdom and the Bishop study out of British Columbia, Canada are two of the most powerful studies showing the greater effectiveness of chiropractic compared to usual medical/physiotherapy care. Both of these studies were excluded based on this seemingly innocuous but highly biased selection criteria. Another very important RCT which showed that chiropractic was superior to both placebo and the drug diclofenac (NSAID Voltaren) was the 2013 study by Von Heymann et al. published in Spine. This study was conducted in ambulatory settings but was still, for no explicable reason that I can find, excluded from this systematic review with respect to pain and function (inexplicably it was included for harms). I wonder what the addition of these three studies would have done to the level of evidence for SMT and to the level of homogeneity of evidence for SMT?!

On what basis is it valid to ignore frequency and duration of care or to not include a minimum frequency of SMT as a selection criteria? Could these authors scientifically justify the premise that number of manipulations is irrelevant and has no ability to effect results? Could these authors justify the premise that there is no difference between 1-2 treatments sessions of SMT over a period of 6 weeks versus a greater number of treatment sessions? Of course not. On what basis could they defend defining SMT as being synonymous with mobilization? None, and none was provided.

Consider this foreshadowing for what is coming in future research reviews where I identify and critique the studies included in this systematic review.

Talk to you next month.

Remember, evidence-based clinical excellence elicits the best possible patient outcomes which produces extraordinary ethical practice success.

You don't need to exaggerate, you just need to be aware of the evidence for chiropractic and practice and communicate based upon this evidence.

I hope to see you in Detroit Feb 17 and 18 for my Evidence-Based Clinical Protocols Seminar. For more info and to register go to [www.thewellnesspractice.com](http://www.thewellnesspractice.com).