

Clinical Practice Guideline: **Spinal Manipulation for Treatment of Acute, Sub-Acute, and Chronic Low Back Pain**

Date of Implementation: **September 18, 2008**

Product: **Specialty**

POLICY

American Specialty Health – Specialty (ASH) clinical committees have determined that spinal manipulation for treatment of acute, sub-acute, and chronic low back pain is established as clinically effective, is professionally recognized, and has a favorable benefit:risk profile.

PROCESS AND DEFINITIONS

When developing, reviewing, and approving clinical policy, ASH peer-review committees consider whether the technique/procedure:

- Is established as clinically effective by:
 - Scientific information published in an acceptable peer-reviewed clinical science resource, and
 - The consensus opinion of the Evidence Evaluation Committee (EEC) when available;
- Is professionally recognized by:
 - Inclusion in the educational standards accepted by the majority of the professions' educational institutions,
 - Wide acceptance and use of the practice, and
 - Recommendations for use made by healthcare practitioners practicing in the relevant clinical area;
- Poses a health and safety risk; and
- Is plausible or implausible
 - A belief, theory, or mechanism of health and disease that can be explained within the existing framework of scientific methods, reasoning, and available knowledge is considered plausible.
 - A treatment intervention or diagnostic procedure that requires the existence of forces, mechanisms, or biological processes that are not known to exist within the current framework of scientific methods, reasoning, and available knowledge is considered implausible.

Substitution harm (indirect harm): Compromised clinical outcomes caused by:

- Utilizing a specific diagnostic or therapeutic procedure when the safety, clinical effectiveness, or diagnostic utility is either unknown or is known to be unsafe, ineffective, or of no diagnostic utility, *instead of* a diagnostic or therapeutic

- 1 procedure known to be safe, be clinically effective, or to have diagnostic utility;
 2 or
 3 • The utilization of a diagnostic or therapeutic procedure that is substantially less
 4 effective or safe than another procedure with established safety, and clinical
 5 effectiveness or utility.

6
 7 **Labeling effects (non-specific harm):** The harm that results from identifying in a
 8 patient a condition or a finding that is not clinically valid.
 9

10 **Safe:** The terms “safe” and “safety,” are used only with specific reference to the
 11 absence of direct harm. Direct harm would include any injury to a patient caused
 12 by the mechanical, thermal, biological, chemical, pharmacological, electrical,
 13 electromagnetic, or psycho-dynamic properties of a diagnostic or therapeutic
 14 procedure, and as such, the procedure would be considered unsafe.
 15

16 **Direct harm:** Any injury to a patient caused by the mechanical, thermal, biological,
 17 chemical, pharmacological, electrical, electromagnetic, or psycho-dynamic
 18 properties of a diagnostic or therapeutic procedure.
 19

20 **Benefit versus risk profile:** The relative effectiveness or utility of a therapeutic
 21 intervention or diagnostic procedure versus its potential for direct harm.

- 22 • Positive (benefits outweigh risks),
 23 • Negative (risks outweigh benefits), or
 24 • Equivocal (available information is inconclusive).
 25

26 **Description/Background**

27 Manual therapy is practiced by a variety of health care providers including, but not
 28 limited to: chiropractors, osteopaths, physical therapists, and naturopaths. Manual
 29 therapists differ with respect to the specific techniques they use, reflecting the diversities
 30 in their education, training, and philosophical foundations. Chiropractic spinal
 31 manipulation, for example, requires identification of spinal segmental joint dysfunction
 32 characterized by altered joint alignment, motion, or physiologic function in an intact
 33 spinal motion segment. The primary objectives of chiropractic spinal manipulation in the
 34 treatment of back pain are to alleviate musculoskeletal pain, muscle spasm, and
 35 functional impairment of the spine. This form of manipulation is a therapeutic procedure
 36 characterized by controlled force, leverage, direction, amplitude, and velocity
 37 (directional, high velocity, low amplitude thrust) (Peterson & Bergmann, 2002). This is
 38 distinguished from the use of the term spinal manipulation by other professions which
 39 may include a spectrum of manual therapies such as mobilization, soft tissue
 40 manipulation, and muscle-energy techniques.

According to a national health care usage survey, chronic low back pain was one of the most frequent reasons people sought alternative therapy (Eisenberg, et al., 1998). The main benefit derived from complementary and alternative medicine (CAM) therapy was symptom relief (Astin, 1998). Of the estimated 42% of the US population who utilized CAM therapies in 1997, almost one third sought chiropractic treatment (Coulter, et al., 2002). This reflects an increasing demand for CAM in general and an increasing belief that CAM therapy is more helpful than conventional medicine for treatment of back pain (Kessler, et al., 2001; Eisenberg, et al., 2001). In fact, up to 40% of patients with low back pain chose chiropractic care to address their health care needs (Waddell, 1996).

Evidence and Research

The effectiveness (including relative effectiveness) of spinal manipulation for low back pain has been assessed internationally in over 50 randomized controlled trials (RCT) and over 20 systematic reviews of these trials since 1974. These studies have evaluated different types of manual therapies by comparing them to reference or sham therapies. More than a third of the trials (18) evaluated manipulation performed by chiropractors. In the remaining trials, manipulation/mobilization was performed by doctors of osteopathy, physiotherapists, medical doctors, and manual therapists (Bronfort, et al., 2004). The studies were conducted on patients at varying stages within back pain episodes, (i.e., acute, sub acute and/or chronic). The reviews address nonspecific low back pain with the exception of two.

Eight systematic reviews of randomized trials published prior to 1997 evaluated the effectiveness of spinal manipulation for the treatment of acute and/or chronic low back pain (LBP) (Ottenbacher & Di Fabio, 1985; Anderson, et al., 1992; Di Fabio, 1992; Shekelle, et al., 1992; Koes, et al., 1996; Van Tulder, et al., 1997; Bronfort, 1999; Mior, 2001). Of the seven (7) reviews addressing acute LBP, six (6) favored manipulation (Ottenbacher & Di Fabio, 1985; Anderson, et al., 1992; Di Fabio, 1992; Shekelle, et al., 1992; Bronfort, 1999; Van Tulder, et al., 1997), while one found the evidence inconclusive for manipulation in general (Koes, et al., 1996) and chiropractic in particular (Assendelft, et al., 1996). The eighth review supported the effectiveness of manipulation, but did not distinguish acute and chronic LBP (Anderson, et al., 1992). Findings from the seven (7) reviews evaluating manipulation for the treatment of chronic LBP evolved over time. The earliest four (4) reviews found inconclusive evidence for effectiveness of manipulation (Ottenbacher & Di Fabio, 1985; Di Fabio, 1992; Shekelle, et al., 1992; Koes, et al., 1996). In contrast, the three (3) later reviews found moderate to strong evidence that manipulation was better than placebo, general medical practice, massage, bed rest, and analgesics (Van Tulder, 1997; Bronfort, 1999; Mior, 2001). None of the seven (7) reviews found evidence supporting ineffectiveness of manipulation or an advantage for standard medical care and other interventions.

Several systematic reviews were published between 2002 and 2008. Many of these reviews (Assendelft, et al., 2003; Assendelft, et al., 2004; Cherkin, et al., 2003; Chou & Huffman, 2007; Bronfort, et al., 2008) represent the investigators' specific attempts to address acknowledged biases and shortcomings of the older systematic reviews (e.g., Assendelft, et al., 1995). These systematic reviews include several recent high quality trials that compared chiropractic manipulation with reference treatments.

Ferreira, et al. (2002) conducted a meta-analysis comparing spinal manipulation to NSAIDs. The pooled difference between therapies on a 100-point scale showed that manipulation reduced disability by 7 points and pain by 14 points. For chronic low back pain, the authors concluded no clinically important advantage of spinal manipulation over NSAIDs for disability and found the evidence for pain relief uncertain. For acute low back pain, manipulation was similar to medical care, exercise, and physiotherapy, but manipulation was also little better than placebo and no treatment (Ferreira, et al., 2003).

Pengel, et al. (2002) found the evidence inconclusive, but suggested that spinal manipulation might be useful for reducing transition from sub acute to chronic low back pain. The transition outcome is unique among systematic reviews of manipulation.

Assendelft, et al. (2003; 2004) reviewed trials published through 2000. They used a random-effects meta-regression to compare the effectiveness of spinal manipulative therapy with other therapies. These investigators concluded that spinal manipulation was more effective than sham treatments. It was neither superior nor inferior to physical therapy/exercise, general practice/analgesics or back school. In a companion review, Cherkin, et al. (2003) made a stronger conclusion that manipulation is as good as the comparison therapies, in addition to being superior to sham interventions.

Bronfort, et al. (2004) reviewed trials published through 2002. They conducted a best evidence synthesis (Slavin, 1995) which stressed fastidious criteria for formulating levels of evidence based on methodologic quality, quantity of trials, and statistical significance of findings. Statistical pooling of trial results was not conducted because of heterogeneity of patient population, interventions, outcomes, and follow-up time points. The authors did not feel they could pool any trial data because of methodological heterogeneity. Spinal manipulation had to demonstrate at least similarity of therapeutic effect to efficacious treatments or superiority to placebo/sham/ineffective interventions to be classified as an efficacious therapy. The investigators reported high quality evidence to support the effectiveness of manipulation for the relief of both acute and chronic back pain. The comparison interventions in the high quality trials included standard medical care, massage, bed rest, mobilization, physical therapy, soft tissue therapy, home exercise, McKenzie Therapy, an information booklet, and sham procedures. Evidence

from lower quality trials was generally consistent with the findings of the higher quality studies. The authors concluded that manipulation is a viable alternative for the treatment of LBP.

Woodhead and Clough (2005) determined that the evidence supported manipulation as a treatment for low back pain, particularly for chronic patients. Keller, et al. (2007) conducted a meta-analysis of randomized trials published through 2005. They computed a pooled effect size for manipulation for acute and for chronic low back pain. They found that manipulation had only a small to moderate effect size advantage over NSAIDs. This is not a negative finding in the light of the relative health risks of the two interventions.

Chou, et al. (2007) conducted a review of nonpharmacological treatments in developing a clinical practice guideline for the American Pain Society and the American College of Physicians. Randomized trials published by 2006 were included. The authors found evidence from systematic reviews and randomized trials supporting their recommendation of spinal manipulation for the treatment of acute and chronic low back pain.

Bronfort, et al. (2008) updated their best evidence synthesis for chronic low back pain (trials through 2007). The new trials were of moderate to high quality. The studies showed manipulation to be superior to medicine and acupuncture, and found that the addition of manipulation to medical care improved back function in the short and long term. Bronfort, et al. found that the updated review strengthened the evidence supporting the effectiveness of spinal manipulation. They concluded that the preponderance of the evidence for effectiveness and the low risk of serious adverse events support manipulation as a treatment option for chronic low back pain. Furthermore, manipulation is “at least as effective as other efficacious and commonly used interventions” (Bronfort, et al., 2008).

Licciardone, et al. (2005) studied osteopathic manipulative treatment; spinal manipulation is confounded with other therapies in this review. Hettinga, et al. (2008) concluded that a combination of manipulation and mobilization was efficacious but spinal manipulation alone was not. Most reviews identified effectiveness for manipulation alone; the difference in inference can be explained by atypical study selection and evidence synthesis methods. Ernst and Canter (2006) wrote what they called an unbiased systematic review of systematic reviews. This paper has been extensively criticized and discredited by authors with diverse backgrounds and expertise (Bronfort, et al., 2006).

Vroomen, et al. (2000) noted some evidence for effectiveness for the treatment of sciatica. Bronfort, et al. (2004) was more cautious because of the lower quality of the two supporting trials; Lisi, et al. (2005) found definitive conclusions were premature. In

contrast, Luijsterburg, et al. (2007) found that spinal manipulation had no value for the care of radicular syndrome based on the same two trials. However, the treatment effect size data abstracted from the two randomized trials reviewed on the subject were dissimilar to the treatment effect data abstracted by Bronfort, et al. (2008).

Finally, a large practice-based, nonrandomized study comparing chiropractic and medical care supports the generalizability of RCT findings to general practice (Haas, et al., 2004; Haas, et al., 2005). This study found a clinically important advantage for chiropractic care (manipulation with adjunct soft tissue work and physical modalities) for chronic low back pain and a small advantage for the care of acute low back pain. The study suggested the greatest relative effectiveness for the subgroup of patients with pain radiating below the knee.

Safety

The potential risk of a major complication due to spinal manipulation is rare (Terrett & Kleynhans, 1992; Hurwitz, et al., 1996). The risk of cauda equina is estimated to be about 1 per 100 million for lumbar manipulations (Haldeman & Rubenstein, 1992). More common however is transient local muscle and/or joint soreness (Senstad, et al., 1997). This is in sharp contrast to the reported risks associated with medication in general where 220,000 deaths are reported each year or the significant risks associated with medications commonly used in the management of spinal pain. It has been reported that there may be as many as 10,000 to 20,000 fatalities (Lazarou, et al., 1998; Weingart, et al., 2000) as well as multiple organ systems adversely affected by the commonly used NSAIDs (Carson & Willett, 1993; Wolfe, et al., 1999). COX-2 inhibitors (Bombardier, et al., 2000) as well as the relatively benign analgesic acetaminophen (Whitcomb & Block, 1994) have also been associated with serious GI, cardiovascular and hepatic problems at rates that are orders of magnitude greater than complications due to spinal manipulation. A more detailed discussion including contraindications may be found in Bronfort, et al. (2008).

Two systematic reviews addressed safety of manipulation for lumbar disc herniations. Lisi, et al. (2005) found limited evidence of safety. Oliphant (2004) concluded, "The apparent safety of spinal manipulation, especially when compared with other "medically accepted" treatments for LDH [lumbar disc herniation], should stimulate its use in the conservative treatment plan of LDH."

Conclusions

A) There are over 50 trials on spinal manipulation summarized in over 20 systematic reviews.

- 1) Spinal manipulation is superior to placebo and no treatment for nonspecific low back pain.

- 2) Spinal manipulation is at least as good as other efficacious and commonly used therapies for nonspecific low back pain.
 - 3) There is preliminary evidence of effectiveness for the treatment of lumbar disc/sciatica from lower quality trials.
- B) Systematic reviews must be interpreted with caution because of lack of uniformity of review design and interpretation of evidence.
- 1) Findings depend on type of review performed, rules of evidence, threshold for important treatment effect, quality scoring system and interpretation, and the inclusion/exclusion of some studies.
 - 2) There is insufficient clinical homogeneity (treatment regimen, comparison group, outcomes, follow-up time points, and patients) to perform meaningful meta-analysis.
- C) Preventive and maintenance care with spinal manipulation have yet to be justified.
- D) Further dose-response studies are required to identify an optimal range of visits, number and type of adjunct therapies, and concentration of care including visit patterns.
- E) Well-defined subgroups of low back pain must be identified and studied.
- F) Severe adverse events are extremely rare. Most complications are mild and of short duration.
- G) Overall, the preponderance of evidence supports the use of spinal manipulation for the treatment of low back pain.
- 1) Spinal manipulation is recommended for acute and chronic low back pain.
 - 2) Spinal manipulation has both short-term and long-term benefit.

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