

Clinical Practice Guideline: **Spinal Manipulative Therapy for Treatment of Children with Non-Musculoskeletal and Related Disorders**

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POLICY

American Specialty Health – Specialty (ASH) clinical committees have determined that the use of spinal manipulative therapy (SMT) for non-musculoskeletal and related disorders (i.e., asthma, infantile colic, nocturnal enuresis, or otitis media) in children is professionally recognized; however, the literature is insufficient to conclude that it is either clinically effective or ineffective and the benefit:risk profile is unknown. ASH clinical committees have determined that SMT for non- musculoskeletal and related disorders in children poses a health and safety risk through substitution harm.

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

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

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

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

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

- Positive (benefits outweigh risks),
- Negative (risks outweigh benefits), or
- Equivocal (available information is inconclusive).

Description/Background

Manual therapy is practiced by a variety of health care practitioners including, but not limited to: chiropractors, osteopaths, physical therapists, and naturopaths. Manual therapists differ with respect to the specific techniques they use, reflecting the diversities in their education, training, and philosophical foundations.

Chiropractors commonly use spinal manipulation (or spinal manipulative therapy (SMT)) on their pediatric patients (Lee et al., 2000). The use of complementary and alternative medicine, including chiropractic, in children and adolescents appears to be increasing over the last several years (Cohen and Kemper, 2005).

This policy focuses primarily on the benefits and risks associated with the provision of high-velocity, low-amplitude (HVLA) manipulation in children with non-musculoskeletal and related disorders.

Evidence and Research

The literature on spinal manipulation for the treatment of musculoskeletal and related disorders in children shows potential beneficial effects in a few conditions, though the evidence is generally very limited and of low quality. The evidence base for the provision of SMT in children is largest in the treatment of asthma, infantile colic, nocturnal enuresis, and otitis media. However, for each of these conditions there is insufficient evidence to support the use of SMT. The scientifically acceptable published evidence base for the provision of SMT in children for the prevention or treatment of other musculoskeletal and related disorders is non-existent or non-informative.

Two systematic reviews of chiropractic manipulation for pediatric health conditions were identified (Gotlib and Rupert, 2005; 2008). The 2008 review was simply an update of the 2005 paper. They identified through June 2007 two systematic reviews, 10 randomized clinical trials (RCTs), three observational studies, and 177 descriptive (e.g., case series, case reports) studies. Both the 2005 and 2008 reviews showed low levels of support for manipulation in pediatric health conditions (e.g., infantile colic, asthma, enuresis, Kinetic Imbalance due to Suboccipital Strain Syndrome [KISS]), with a preponderance of case studies or small case series and very few experimental and observational studies. The authors concluded: “The health interests of pediatric patients would be advanced if more rigorous scientific inquiry was undertaken to examine the value of manipulative therapy in the treatment of pediatric conditions.”

Hawk et al. (2007) completed a comprehensive systematic review of chiropractic care (including SMT) for musculoskeletal and related disorders in both adults and children. They identified 47 studies through April 2005 applicable to children: asthma (14 total; three [3] RCTs, one [1] systematic review, five observational studies, one case series, and four case reports); infantile colic (eight total; two RCTs, one systematic review, one observational study, and four case reports); otitis media (eight total; one RCT, one observational study; three case series, and three case reports); nocturnal enuresis (five total; one RCT, one systematic review, one observational study, and two case reports); constipation (five case reports); and jet lag (one RCT). The authors drew the following conclusions about the evidence from the pediatric literature:

1. *The adverse effects reported for SMT for all age groups and conditions were rare and when they did occur, were transient and not severe.*
2. *Evidence from both controlled studies and usual practice is adequate to support the “total package” of chiropractic care, including SMT, other procedures, and unmeasured qualities such as belief and attention, as providing benefit to patients with asthma and infantile colic.*

3. *Evidence was promising for the potential benefit of manual procedures for children with otitis media.*
4. *There is insufficient evidence to make conclusions about chiropractic care for patients with other conditions.*

Asthma

Hondras et al. conducted two Cochrane reviews of manual therapy for asthma, one in 2002 and an update in 2005. In the first review, which included two RCTs of chiropractic high-velocity low amplitude (HVLA) SMT, the authors found insufficient evidence to make any firm conclusions about SMT in the treatment of asthma. The second review, which included an additional RCT comparing massage therapy with a relaxation control, found significant differences in lung function; however, the trial was small and poorly reported. The authors' conclusions:

There is insufficient evidence to support the use of manual therapies for patients with asthma. There is a need to conduct adequately-sized RCTs that examine the effects of manual therapies on clinically relevant outcomes. Future trials should maintain observer blinding for outcome assessments, and report on the costs of care and adverse events. Currently, there is insufficient evidence to support or refute the use of manual therapy for patients with asthma.

Similar conclusions were stated in the review by Gleberzon et al. (2012) and Clar et al. (2014).

Infantile colic

Hughes and Bolton (2002) conducted a systematic review that included two RCTs and a clinical cohort of babies with infantile colic. Although no appreciable differences were detected between active and sham arms in the RCTs, the authors concluded that provision of chiropractic care may result in reduction of parent-reported symptoms (e.g., hours of crying).

Gotlib and Rupert (2008) reported on the systematic review by Husereau et al. (2003), which included four RCTs of spinal manipulation performed by chiropractors, concluding:

There is no convincing evidence that spinal manipulation alone can affect the duration of infantile colic symptoms.

Dobson et al. (2012) identified six studies representing a total of 325 infants. Of the six included studies, five were suggestive of a beneficial effect and one found no evidence that manipulative therapies had any beneficial effect on the natural course of infantile colic. Five studies measured daily hours of crying allowing these studies to be combined. This analysis suggested that manipulative therapies had a significant effect on infant colic - reducing average crying time by one hour and 12 minutes per day (mean difference (MD) -1.20; 95% confidence interval (CI) -1.89 to -0.51). However, when combining only those

studies with a low risk of performance bias (parental 'blinding'), the improvement in daily crying hours was not statistically significant (MD -0.57; 95% CI -2.24 to 1.09). Analysis of data from three studies that measured 'full recovery' from colic as reported by parents found that manipulative therapies did not result in significantly higher proportions of parents reporting recovery (OR 11.12; 95% CI 0.46 to 267.52). The quality of the studies was variable. One of the studies recorded adverse events and none were encountered. The studies included in this meta-analysis were generally small and methodologically prone to bias, which makes it impossible to arrive at a definitive conclusion about the effectiveness of manipulative therapies for infantile colic. Further research is required where those assessing the treatment outcomes do not know whether or not the infant has received a manipulative therapy. There are inadequate data to reach any definitive conclusions about the safety of these interventions.

Nocturnal enuresis

Gleberzon et al. (2012) identified two clinical trials on the effects of SMT on alleviating nocturnal enuresis. SMT had better results than sham adjustment; however, the studies were small and not of high quality. Although both clinical trials reported children experienced improvement in terms of fewer "wet nights," both studies suffered from several methodological flaws. The authors concluded there is insufficient evidence to support the use of chiropractic in the treatment of nocturnal enuresis, but further research is warranted. Clar et al. (2014) also stated that the evidence was inconclusive for SMT and dysfunctional voiding. High quality RCTs with careful monitoring of benefits, harms, and costs are suggested.

Otitis media

One RCT of 57 children (Mills et al., 2003) and a feasibility study of 22 (Sawyer et al., 1999) addressed SMT for children with otitis media. Recurrences, episodes, and symptoms decreased in the SMT groups in the RCT. The osteopathic manipulation/mobilization group had fewer surgeries than the control (usual medical care) group in the RCT. Data on adverse events was included in only the RCT and feasibility study. No harms were reported in the RCT; two transient events (muscle soreness and irritability) were reported in Sawyer et al. (1999). In general, the clinical trials involving children with otitis media did not report any clinically meaningful improvements following SMT (Gleberzon et al., 2012; Clar et al., 2014). Pohlman and Holton-Brown (2012) determined there was limited quality evidence for the use of SMT for children with otitis media and no evidence to support or refute using SMT for otitis media. No serious adverse events were noted in any included studies. Authors stated it is possible that some children may benefit from SMT or SMT combined with other therapies. More rigorous studies are needed to provide evidence and a clearer picture for both practitioner and patients.

1 **Safety**

2 The potential risk of a major complication due to spinal manipulation is rare (Hurwitz, et
3 al., 1996; Todd et al., 2014). These rare, serious adverse events attributed to SMT in
4 children included quadriplegia and death. Evidence of complications associated with SMT
5 in children comes primarily from case reports and case series. While serious adverse events
6 may be associated with pediatric spinal manipulation; neither causation nor incidence rates
7 can be inferred from observational data (Vohra et al., 2007). No serious complications from
8 SMT have been reported from any of the published RCTs or observational studies
9 involving SMT in children. Several minor transient adverse reactions have been reported.
10 Based on a review of the literature, both the possible harms and possible benefits of SMT
11 in children appear to be minimal. These results were described by Todd et al. (2014) and
12 Clar et al. (2014) in a later reviews of the literature on adverse events.

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14 Clinicians need to provide pediatric patients and their parents or guardians with
15 information regarding the benefits, harms and alternatives relevant to making an informed
16 treatment decision.

17 **Conclusions**

- 18 1. SMT of non-musculoskeletal conditions in children is professionally recognized.
19 Among the available research on children, there is insufficient evidence to support
20 the use of SMT for asthma, infantile colic, nocturnal enuresis, or otitis media. ASH
21 is unaware of any randomized or non-randomized comparison studies to support
22 the use of SMT for children in the treatment of other conditions.
- 23 2. The literature precludes reliable estimates of the risks of minor or major harms
24 associated with spinal manipulation for children; however, rare serious adverse
25 events (i.e., resulting in permanent disability and death) associated with cervical
26 spine manipulation (not performed by a chiropractor) in children have been
27 reported. Therefore, additional caution should be used when utilizing SMT with
28 infants and children.
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