

The use of spinal manipulative therapy for pediatric health conditions: a systematic review of the literature

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Introduction: *This study had two purposes. These were: (i) to conduct a search of the literature between 2007 and 2011 investigating the use of spinal manipulative therapy (SMT) for pediatric health conditions and (ii) to perform a systematic review of eligible retrieved clinical trials.*

Methods: *The Index of Chiropractic Literature and PubMed were electronically searched using appropriate search words and MeSH terms, respectively, as well as reference tracking of previous reviews. Studies that met the inclusion criteria were evaluated using an instrument that assessed their methodological quality.*

Results: *Sixteen clinical trials were found that met the inclusion criteria and were scored.*

Discussion: *Six clinical trials investigated the effectiveness of SMT on colic, two each on asthma and enuresis, and one each on hip extension, otitis media, suboptimal breastfeeding, autism, idiopathic scoliosis and jet lag. None investigated the effectiveness of SMT on spinal pain.*

Conclusion: *Studies that monitored both subjective and objective outcome measures of relevance to both patients and parents tended to report the most favorable response to SMT, especially among children with asthma. Many studies reviewed suffered from several methodological limitations. Further research is clearly required in this area of chiropractic health care,*

Introduction : *La présente étude avait deux objectifs : (i) effectuer un dépouillement d'ouvrages spécialisés rédigés entre 2007 et 2011 portant sur le recours à la manipulation rachidienne pour traiter des états pathologiques chez les enfants et (ii) effectuer un examen systématique des essais cliniques extraits qui ont été admissibles.*

Méthodes : *On a fait des recherches électroniques dans les bases de données de l'Index of Chiropractic Literature et PubMed à l'aide des critères de recherche appropriés et des termes du MeSH, respectivement, ainsi qu'un suivi des références des examens précédents. On a évalué les études répondant aux critères d'inclusion grâce à un instrument d'évaluation de leur qualité méthodologique.*

Résultats : *On a trouvé seize essais cliniques répondant aux critères d'inclusion et on les a notés.*

Discussion : *Six essais cliniques analysaient l'efficacité de la manipulation rachidienne sur les coliques, deux essais sur l'asthme et deux sur l'énurésie et les autres essais portaient respectivement sur l'extension de la hanche, l'otite moyenne, l'allaitement sous-optimal, l'autisme, la scoliose idiopathique et le décalage horaire. Aucun essai n'abordait l'efficacité de la manipulation rachidienne sur la douleur lombaire.*

Conclusion : *Les études qui ont surveillé à la fois les indicateurs de mesure de pertinence subjectifs et objectifs des patients et de leurs parents avaient tendance à ne rendre compte que de la plus favorable réponse à la manipulation rachidienne, notamment chez les enfants souffrant d'asthme. Dans de nombreuses études examinées, il manquait l'analyse de différentes autres méthodologies. De toute évidence, des recherches*

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especially with respect to the clinical effectiveness of SMT on pediatric back pain.
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KEY WORDS: pediatric, manipulation, spinal

Introduction

The use of complementary and alternative medicine (CAM) by pediatric patients is increasing,¹ with one study estimating the utilization rate of CAM by children to be 11.8%.² A Danish study reported that predictors of CAM use were concerns with the adverse effects of allopathic medications, limited clinical success of conventional treatment, increased school absenteeism and being under the age of 11 years, at least among a group of patients with gastrointestinal disorders.³ A Canadian cross-sectional descriptive study of patients visiting a pediatric outpatient clinic reported that factors influencing their use of CAM were “word of mouth,” physician referral, personal experience by the parents and no adequate resources offered by traditional medicine to manage many clinical conditions affecting children.⁴ Although most patients in that study were also under the care of a physician, almost one half of parents did not inform their medical provider they were seeking CAM care concurrently. Almost half of parents surveyed reported they did not believe CAM therapy conveyed any potential adverse effects and CAM users were less satisfied with primary care than were nonusers.⁴

The Centers for Disease Control and Prevention reported that manual therapy was the most commonly chosen type of CAM therapy for children, and the most common conditions presenting for care were of the musculoskeletal (MSK) system.⁵ Chiropractors were the most common CAM provider visited by children and adolescents,⁶ and the 2005 Job Analysis of the National Board of Chiropractic Examiners (NBCE) reported that patients aged 17 years and younger comprise 18.2% of a chiropractor’s practice.⁷ A 2009 Job Analysis published by Humphries⁸ reported that 91% of Swiss chiropractors treated children ages 6–17 years, and 78% of these chiropractors reported treating children younger than 5 years old.

Verhoef and Papadopoulos conducted a survey of Canadian chiropractors in 1999 that sought to determine how

plus approfondies s’imposent dans ce domaine des soins de santé chiropratiques, notamment par rapport à l’efficacité clinique de la manipulation rachidienne sur la douleur lombaire chez les enfants.
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MOTS CLÉS : enfants, manipulation, lombaire

frequently, and for what reasons, chiropractors treat patients under the age of 18 years.⁹ Based on the data extracted from 643 returned questionnaires and 525 diary cards, the researchers reported that the most common conditions treated were MSK complaints, followed by headache and muscular sprains/strains. Other conditions treated were asthma, articular joint conditions, otitis media, postural problems, enuresis, gastrointestinal, hyperactivity, colic, menstrual complaints and immune system problems (the order in which these conditions presented varied between the questionnaire and the diary cards).

In this study, Verhoef and Papadopoulos also reported that the frequency of presentation of various conditions was age-stratified.⁹ For patients under the age of 2 years old, the most common reason to seek out chiropractic care was for prevention (31.3%), colic (16.1%) and otitis media (16.1%). For patients aged between 2 and 4 years, reasons for seeking out care were prevention (42.1%), musculoskeletal problems (21%) and otitis media (7.1%); the order of presenting conditions was identical for patients aged 5 and 10 years. For patients older than 11 years the most common presenting complaint was MSK (52.5%), prevention (17.6%) and headaches (11.4%). Over 80% of chiropractors reported they provide either maintenance or supportive care for their pediatric patients. The most common treatment modality used by chiropractors was spinal manipulative therapy, followed by exercise, stretching, soft tissue therapy, ergonomic/postural advice and nutritional counseling. Lastly, it was reported that chiropractors who were themselves younger and presumably more likely to have received both formal and informal training specific to treating pediatric patients were more likely to treat patients under the age of 18 years.⁹

A decade later Miller *et al* conducted a survey that sought to describe the characteristics of pediatric patients presenting to a chiropractic teaching clinic between 2006 and 2010.¹⁰ Of all patients that presented to the clinic in

that time period, roughly 1 out of 5 were between the ages of two days and 15 years old. The most common presenting pediatric health condition was MSK (35%), followed by “excessive crying” (previously referred to as colic, at least according to Miller *et al*), which was the most common chief complaint (62.3%) among the largest cohort of pediatric patients seen at that clinic- patients under the age of 12 weeks. All children had previously presented for medical care and most of the infants (83%) under the age of 12 weeks had been referred to the chiropractor by their medical physician. In fact, Miller *et al* reported that the younger the child, the more likely the medical referral to a CAM.¹⁰ A contemporaneous survey by Hestbaek *et al* conducted in Denmark also reported that babies were the largest cohort of pediatric patients seen by chiropractors, most often for infantile colic, whereas older patients most commonly presented with MSK conditions, usually chronic in nature.¹¹

Gotlib and Rupert conducted two reviews of the literature, one published in 2005 and the other in 2007 that sought to determine the extent of evidence related to the use of manipulation for pediatric health conditions.^{12,13} Essentially the first study found a relative dearth of published clinical trials and these investigators judged the studies that did exist constituted a low level of scientific evidence.¹² Their second review was equally unsuccessful in terms of finding clinical trials that substantiate the claims of effectiveness made by many chiropractors in the field.¹³ This led the researchers to assert that there was no substantial shift in the body of knowledge during the intervening three and a half years between their two reviews.¹³ Since there were so few retrievable clinical trials from both literature reviews, the authors chose not to conduct a systematic review of each clinical trial retrieved at that time.

The purpose of this study was two-fold. First, we conducted a systematic review of the literature between 2007 and 2011, essentially advancing on the 2007 review by Gotlib and Rupert.¹³ Second, we performed a systematic review of all retrieved clinical trials that investigated the effects of spinal manipulative therapy on various clinical conditions affecting children.

Methods

The Index to Chiropractic Literature was searched using the subject keyword “manipulation,” which retrieved all

the ChiroSH (Chiropractic Subject Headings) containing the word “manipulation.” This was combined with the subject keywords “infant” or “child” or “adolescent.” Text words were also searched and included the following truncated words: “manipulat*” or “adjustment*” and “pediatric*” or “paediatric*” or “child*” or “adolescent*” or “infant*.” Some publication types were eliminated (letters, editorials, book reviews, meeting abstracts) and results were restricted to the years 2007–2011. PubMed was searched using the following MeSH terms: “Manipulation, Chiropractic” or “Manipulation, Spinal,” combined with the Mesh terms “Infant” or “Child” or “Adolescent.” In addition, the truncated text word “chiropract*” was searched, with appropriate age (birth to 18 years), language (English) and date (2007–2011) limiters. All results were examined and inclusion and exclusion criteria were applied. Reference tracking was performed of the citations in the previous reviews by Gotlib and Rupert^{12,13} as well as the UK Evidence Report by Bronfort *et al*¹⁴ completed in 2010 since that Report is widely accepted as one of the most comprehensive reviews of clinical studies investigating the effectiveness of manual therapies (including manipulation of the spine and peripheral joints) for all health conditions published to date.

Inclusion/exclusion criteria

Several inclusion/exclusion criteria were used to select studies eligible for this review. Inclusion criteria were as follows: subjects were age 18 or less; studies must involve more than two subject; treatments must have been administered by a chiropractor; treatment administered was manual, high-velocity low-amplitude (HVLA) thrusting spinal manipulations, most commonly associated with Diversified technique within the chiropractic profession; papers were written in English; were published between January 1980 and March 2011; prospective or retrospective studies including randomized controlled trials, controlled clinical/quasi-experimental trials, prospective cohort studies or retrospective case series; studies using some type of outcome measure for determining the effect of chiropractic care; published in peer-reviewed journal; and only studies involving human subjects.

Conference abstracts were excluded since, in general, the process for acceptance into a conference is less rigorous than the process of acceptance into a peer-reviewed journal. Similarly editorials, commentaries and expert

opinions were judged ineligible for inclusion in this study since these forms of evidence have been labelled as “Grey Literature” or “grey lit” in some circles¹⁵ and are considered of limited scientific value. We did find some studies that investigated the use of ‘osteopathic manipulation’ (OM) for some childhood illnesses, such as the study by Mills *et al.*¹⁶ However, OM often involves a manual therapy that often resembles segmental mobilization (low-velocity, low-amplitude oscillating motion): We therefore chose not to include studies using OM in our review. A study by Macias *et al* was excluded since it involved comparing the use of two non-manipulative manual procedures performed by medical doctors to reduce radial head subluxation.¹⁷

Using these criteria, 16 articles qualified for review.

Instrument Used to Review Eligible Articles

The articles selected for review were evaluated using an instrument developed by Sackett (see Table 1).¹⁸

Four authors (BG, JA, AM, EM) independently reviewed the studies meeting the inclusion criteria. Each author reviewed two articles, and the reviewer pairings were randomized for the 16 studies. The data from all included articles were recorded onto a data extraction sheet by the authors as part of the review. The authors checked and edited all entries for accuracy and consistency. Recorded data included study authors and quality score, details of the study design, sample, interventions, outcome measures, and main results/conclusions of the study. The four authors met on July 20th, 2011 to compare their graded scores. Any discrepancies of scores between the authors were settled via discussion until consensus was reached.

Results

The initial search strategy yielded 79 articles. Of these 79 articles, only 4 met our inclusion criteria.^{19–22} Although the study by Sandell *et al* included subjects age 17 to 20 years old, a decision was made to include it in this review.²⁰ The reviews by Gotlib and Rupert yielded 10 studies eligible for our review.^{23–32} Reference tracking yielded an addition two studies.^{32,33} After methodological quality assessment of each article using the grading instrument was conducted, papers were allocated scores out of a possible 50 points (Table 1). Articles are listed in descending order of their score using the Sackett criteria, along with a brief description of each study; in the event two or more

articles had the same score, they were arranged alphabetically (Table 2).

Overall, a total of 1980 children and adolescents were investigated in the 16 clinical trials that met our inclusion criteria. The largest number of paediatric patients investigated in any one study was 697,²¹ the fewest was six.²³ Six clinical trials investigated the effectiveness of SMT on colic, two on asthma, two on enuresis, and one each on hip extension, otitis media, difficulties with breast-feeding, autism, idiopathic scoliosis and jet lag. Although high velocity, low amplitude (HVLA) thrusts characterize SMT in general, since the patients in the clinical trials reviewed here were often infants, the intervention was often modified to use extremely low forces. Some authors characterize this form of SMT as pediatric-SMT (P-SMT) and we have adopted that convention where applicable. Studies in our review received scores between 48/50 and 18/50.

Discussion

Six studies investigated the use of SMT on children with colic.^{19,21,22,25,28,33} Five^{19,21,22,28,33} of the six studies reported that there was a reduction in the amount of “crying time” following the use of pediatric spinal manipulative therapy. Unfortunately four of these studies had limited or no follow up^{19,21,28,33} and three studies received the lowest scores using the Sackett scale. The study by Browning *et al* did report that both SMT and occipital-sacral decompression (OSD) resulted in decreased crying time (there was no control group).²² This study received a score of 41/50; however, since that study compared the use of one manual therapy (SMT) to another form of manual therapy (OSD) it is possible that the reduced rates of crying time could be attributed to the benefits of physical touch. The study by Olafsdottir *et al*, which was assigned a score of 37/50, reported no benefits in colic from P-SMT as compared to placebo.²³ Ferrance and Miller opined that there may be several reasons why clinical trials have not reported effectiveness of SMT for colic.³⁵ They posit there may be subgroup of colicky crying babies as yet unidentified, obfuscating the success of chiropractic interventions. They cite one study that reported improvement in outcome when crying infants were subdivided into “infant colic,” “irritable infant syndrome for musculoskeletal origin” and “ineffective feeding” groups. These authors do state that it is reasonable for parents to seek out chiropractic care for

Table 1 Scoring of methodological quality of each article using grading criteria developed by Sackett¹⁸

| ARTICLE/CRITERIA | Bronfort JMPT 2001 | Balon NEJM 1998 | Rowe Chiro Osteo 2006 | Browning Clin Chiro 2008 | Olafsdottir Arch Dis 2001 | Wiberg Nordsreen JMPT 1999 | Sawyer JMPT 1999 | Sandell JCM 2007 |
|---|--------------------------|-----------------------|--------------------------------|--------------------------------|---------------------------------|-------------------------------------|------------------------|------------------------|
| ASSIGNMENT OF PATIENTS (/9) | 9 | 9 | 7 | 9 | 9 | 9 | 5 | 9 |
| BASELINE VALUES OF GROUPS (/8) | 8 | 8 | 4 | 8 | 4 | 8 | 8 | 8 |
| RELEVANCE OF OUTCOMES & CLINICAL SIGNIFICANCE (/7) | 7 | 7 | 7 | 3 | 7 | 3 | 7 | 5 |
| PROGNOSTIC STRATIFICATION (COMORBIDITY AND RISK FACTORS) (/6) | 6 | 6 | 6 | 6 | 6 | 6 | 6 | 3 |
| BLINDING STRATEGIES (/5) | 5 | 3 | 5 | 3 | 3 | 3 | 3 | 2 |
| CONTAMINATION/ CO-INTERVENTION (/4) | 4 | 3 | 4 | 4 | 0 | 2 | 0 | 0 |
| COMPLIANCE OF SUBJECTS TO STUDY PROCEDURES (/4) | 3 | 3 | 4 | 2 | 2 | 2 | 2 | 4 |
| DROP-OUT RATES OF SUBJECTS (/3) | 3 | 3 | 3 | 3 | 3 | 3 | 3 | 2 |
| FOLLOW-UP LEVELS (/2) | 2 | 2 | 1 | 2 | 2 | 1 | 2 | 0 |
| DATE OF PUBLICATION (/1) | 1 | 0 | 1 | 1 | 1 | 0 | 0 | 1 |
| TOTAL (/50) | 48 | 45 | 42 | 41 | 37 | 37 | 36 | 34 |

Table 1 (Concluded)

| ARTICLE/CRITERIA | Reed JMPT 1994 | Khorshid JSVR 2006 | Straub JMPT 2001 | Lebouef JMPT 1991 | Miller & Miller JMPT 2009 | Klougart JMPT 1989 | Wiberg JMPT 2010 | Miller JMPT 2008 |
|---|----------------------|--------------------------|------------------------|-------------------------|------------------------------------|--------------------------|------------------------|------------------------|
| ASSIGNMENT OF PATIENTS (/9) | 7 | 7 | 9 | 5 | 5 | 5 | 4 | 4 |
| BASELINE VALUES OF GROUPS (/8) | 8 | 4 | 0 | 8 | 0 | 4 | 4 | 0 |
| RELEVANCE OF OUTCOMES & CLINICAL SIGNIFICANCE (/7) | 7 | 7 | 7 | 5 | 7 | 3 | 3 | 3 |
| PROGNOSTIC STRATIFICATION (COMORBIDITY AND RISK FACTORS) (/6) | 6 | 3 | 0 | 6 | 6 | 6 | 6 | 6 |
| BLINDING STRATEGIES (/5) | 0 | 0 | 3 | 0 | 0 | 0 | 0 | 0 |
| CONTAMINATION/ CO-INTERVENTION (/4) | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| COMPLIANCE OF SUBJECTS TO STUDY PROCEDURES (/4) | 1 | 0 | 4 | 1 | 0 | 0 | 0 | 1 |
| DROP-OUT RATES OF SUBJECTS (/3) | 3 | 3 | 0 | 0 | 3 | 3 | 0 | 3 |
| FOLLOW-UP LEVELS (/2) | 1 | 2 | 2 | 0 | 0 | 0 | 1 | 0 |
| DATE OF PUBLICATION (/1) | 0 | 1 | 1 | 0 | 1 | 0 | 1 | 1 |
| TOTAL (/50) | 33 | 27 | 26 | 25 | 22 | 21 | 19 | 18 |

Table 2 Summary Chart of all 16 Clinical Trials Reviewed

| Reference | Objective | Trial Design | /50 | Patients/ Conditions | Interventions | Main Outcome Measures | Follow-Up Period | Main Results/ Conclusions |
|-------------------------------|--|---|-----|--|---|--|--|---|
| Bronfort, JMPT 2001 | To determine if SMT in addition to optimal medical management resulted in asthma-related outcomes in children. To assess the feasibility of conducting a full-scale, RCT in terms of recruitment, evaluation, treatment and ability to deliver sham SMT. | Prospective clinical case series with observer blinded, pilot randomized and 1 year follow-up | 48 | 36 patients 6–17 years old with mild to moderate asthma | 20 chiropractic treatments over the course of 3 months (active or sham SMT) | Pulmonary function test, parental diary, parental Q of L form, severity, am/pm peak expiration flow. | 12 months post-treatment follow up | After 3 months in combination with SMT and optimal medical management the children's Q of L increased significantly and were maintained at 1 year follow up. No change in lung function or hyper-responsiveness. Improvements unlikely to be from SMT alone. Further research is required as to which aspect of the encounter is responsible for improvement. |
| Balon, NEJM 1998 | To compare the effect of true SMT to sham SMT on asthmatic children. | RCT | 45 | 80 children aged 7–16 years with mild to moderate asthma | Treatment group received SMT and STT. Control group received STT and pressure to spine. No changes to pre-trial medication. | Change from baseline of peak expiratory outflow plus several other more qualitative outcomes. | Immediate (journals) and 2 and 4 months. | Small improvements in peak expiratory outflow as well as other indicators; no significant differences. |
| Rowe, Chiro Osteo 2006 | To conduct a pilot study and explore issues of safety, patient recruitment and compliance relevant to planning a RCT. | Pilot RCT | 42 | 6 subjects over 6 months with idiopathic scoliosis. | Standard medical care, standard medical care and chiropractic manipulation, standard care and sham manipulation. | Cobb angle and scoliosis QLI. | | There were not enough subjects to compare outcomes between treatment groups, however the study was successful in providing researchers with information needed to plan a full-scale study. |
| Browning, Clin Chiro 2008 | To compare 2 interventions for infantile colic (SMT and OSD). | Single-blinded, randomized comparison trial | 41 | 43 infants less than 8 weeks old who cried >3 hr/day 4 out of the previous 7 days. | SMT and OSD | Change in daily hours crying. | 4 weeks | Both SMT and OSD had significant benefits in reducing infant colic. Both groups cried less and slept more after 2 weeks of treatment. |
| Olafsdottir, Arch Dis 2001 | To investigate the efficacy of chiropractic SMT in the management of infantile colic. | Randomized, blinded, placebo controlled clinical trial | 37 | 86 infants | SMT and control | Parent diaries of hours crying. | 8 -14 days | Chiropractic SMT is no more effective than placebo in the treatment of colic. |
| Wiberg & Nordgreen, JMPT 1999 | To determine if there is a short-term effect of SMT in the management of infantile colic. | RCT | 37 | 41 infants aged 2–10 weeks | SMT and dimethicone | Parent diaries of hours crying. | Immediate or none | During days 4–7 crying decreased 1 hour in dimethicone group and 2.4 hours in SMT group. During days 8–11 crying decreased 1 hour in dimethicone group and 2.7 hours in SMT group. |

Table 2 (Continued)

| Reference | Objective | Trial Design | /50 | Patients/ Conditions | Interventions | Main Outcome Measures | Follow-Up Period | Main Results/ Conclusions |
|---------------------|--|---|-----|--|--|--|---|---|
| Sawyer, JMPT 1999 | A pilot study assessing the feasibility of conducting a full scale RCT investigating the efficacy of SMT for children with chronic otitis media with effusion. | Prospective, parallel-group, observer-blinded, randomized feasibility study | 36 | 22 patients age 6 months to 6 years. | SMT or sham SMT | Parent diaries, presence or absence of effusion. | 4 weeks | Recruitment is feasible. Parents are compliant with daily diaries and willing to participate in active and sham SMT. Objective outcomes involving tympanometry and otoscopy are extremely challenging and should be performed by validated examiners in future studies. |
| Sandell, JCM 2007 | To investigate the effect of chiropractic treatment on hip joint extension ability and running velocity. | Prospective, randomized, controlled experimental pilot study | 34 | 17 male middle distance runners age 17–20. | SMT and control | Hip extension and running velocity | Immediate or none | Treatment group showed significantly greater hip extension ability after chiropractic treatment than controls. Treatment group did not show a significant decrease in time for running 30 m after treatment. |
| Reed, JMPT 1994 | To evaluate chiropractic management of primary nocturnal enuresis in children. | Controlled clinical trial for 10 weeks plus 2 weeks post of non-treatment | 33 | 46 children (31 in treatment group and 15 in control group). | High velocity short lever SMT or sham SMT | Frequency of “wet” nights | 2 weeks | Baseline treatment group had 9.1 nights/2 weeks wet. Post treatment group had 7.6 nights/2 weeks wet. Baseline control had 11.1 nights/2 weeks wet. Post treatment group had no change. |
| Straub, JMPT 2001 | To determine the effect of chiropractic care on jet lag in athletes travelling from Finland to the USA and returning to Finland. | Randomized (blinded in the sham and active groups) in 3 groups | 26 | 15 Finnish junior elite athletes, ranged 6–21 years (mean age 18.3 years). | Sham SMT, active SMT, control group (toggle/re-coil procedure) | Psychological assessment POMS, heart rate, sleep disturbances, jet lag evaluation. | 5 day follow up after returning to Finland. | Chiropractic care does not reduce the effects of jet lag. |
| Lebouef, JMPT 1991 | To observe the effect of SMT on nocturnal enuresis. | Prospective study | 25 | 171 children aged 4–15 years (mean age 8.3). | SMT; 94% received upper cervical | Parental diaries, clinician assessment (hours crying, intensity, feeding, stools). | None but checked in at 1, 2 and 4 weeks. | 85% better or stopped at 1 week. 95% better or stopped at 2 weeks. 97% better or stopped at 4 weeks. |
| Khorshid, JVSR 2006 | To identify the difference in efficacy between upper cervical and full spine adjustment in autistic children. | Randomized clinical trial | 23 | 14 autistic children | Atlas Orthogonal upper cervical adjustment or full spine adjustment. | Autism Treatment Evaluation Checklist (ATEC), leg length analysis & x-rays. | Immediate or non | Improvement of ATEC scores was seen in 6/7 children under upper cervical adjustment and in 5/7 children under full spine adjustment. |

Table 2 (Concluded)

| Reference | Objective | Trial Design | /50 | Patients/ Conditions | Interventions | Main Outcome Measures | Follow-Up Period | Main Results/ Conclusions |
|------------------------------|--|--------------------------------|-----|---|---|---|--|---|
| Miller & Miller JMPT 2009 | To describe the circumstances, clinical features, role, and results of chiropractic management of infants who were referred to a chiropractic clinic for failure to adequately feel at the breast. | Clinical case series | 22 | 114 infants (12 weeks or younger) cases of hospital-diagnosed or lactation consultant diagnosed feeding problems that were treated with chiropractic therapy in addition to routine care and followed to short-term result. | Treatment aimed at releasing the area of tension, imbalance or pain producing tissue through routine low force chiropractic manual therapy. | Outcome after treatment was based on mother's rating of improvement in their infant's symptoms. This was a form of a 10-point numerical rating scale as well as discussion with the parents | Short term | Treatment was chiropractic therapy in addition to any support given elsewhere. All children showed some improvement with 78% being able to exclusively breastfeed after 2 to 5 treatments within a 2-week time period. Cooperative multidisciplinary care to support breastfeeding was demonstrated in this population. Chiropractic treatment may be a useful adjunct to routine care given by other professionals in cases of diagnosed breastfeeding problems with a biomechanical component. |
| Klougart, JMPT 1989 | To observe the effect of regular PSMT on colicky infants. | Prospective uncontrolled study | 21 | 316 infants age 2–52 weeks. | SMT at the discretion of the 73 Chiropractors involved | Parental diaries and clinician assessments performed after 1, 2 and 4 weeks post treatment. | A similar evaluation performed at the 14-day mark was performed at 4 weeks to estimate relapses. | SMT of the vertebral column in infants with colic constitutes effective treatment. Results show a satisfactory effect of the treatment in 94% of cases within 14 days from the start of treatment. Further studies must be designed in such a way that the number of sources of bias affecting the interpretation of results is reduced. This will more closely estimate a placebo effect. |
| Wiberg, JMPT 2010 | To investigate if the outcomes of excessively crying infants treated with chiropractic care was associated with age and/or can be partially explained by age. | Retrospective evaluation | 19 | 276 infants who fit the inclusion criteria. | Chiropractic manipulation as decided by the treating Chiropractor. | Parental reports were noted as improved uncertain, or non-recovered. | None or immediate follow up | Data matched the clinical experience of good treatment effect independent of the infant's age. Slightly older age and longer duration of treatment were found to explain covariables linked to crying infant's improvement. |
| Miller, JMPT 2008 | To identify adverse effects of PSMT on children under the age of three years to evaluate risk of complications. | 3 year retrospective study | 18 | 697 children under the age of three years with colic and/or irritability due to biomechanical disorders likely resulting from birth trauma. | 77% received full spine PSMT; others received cervical spine decompression, segmental SMT etc. | Parental perception of improvement, no change or worsening of symptoms. | Immediate or none | 85% improved. 15% showed no change. ~1% had an adverse reaction (n = 7) and 3 of 7 were perceived to be regular side effects of PSMT. |

a colicky infant for a therapeutic trial of 4–6 treatments, given its favorable risk/benefit ratio, providing other serious diagnostic possibilities have been ruled out.³⁵

Ernst conducted a systematic review of RCTs investigating the effectiveness of SMT on infantile colic [Au-

thors' note: it is highly unusual for only one author to conduct a systematic review due to the inescapable risk of investigator bias].³⁶ His review only found three^{22,25,28} of the six studies we reviewed here; nevertheless, Ernst concluded that the current evidence from RCTs does not

show that SMT is an effective treatment for infant colic.³⁶ A more recent systematic review of the literature by Perry, Hunt and Ernst³⁷ assessing the use of nutritional supplementation and other types of CAM therapy for infant colic discussed four RCTs involving the use of SMT; two of the studies were the ones previously reviewed by Ernst³⁶ [inexplicably, Perry, Hunt and Ernst³⁷ chose not to review the study by Browning²² in their review, although it was included in Ernst's³⁶ earlier review] and the other two studies were ones we did not select for our review since they did not meet our inclusion criteria. The study by Mercer and Nook we excluded from our review since it was not published in a peer-reviewed journal but rather was presented at a chiropractic conference.³⁸ We excluded the study by Hayden and Mullinger since the authors compared the use of cranial osteopathy to a no-treatment group.³⁹ This was incorrectly classified as a 'manipulation' study by Perry *et al*³⁷ since cranial osteopathy does not use the HVLA thrust that characterizes manipulation; rather, cranial osteopathy is an extremely low-force technique that uses approximately 5 g of pressure, an amount equal to the weight of a nickel placed on a person's eyelid⁴⁰. In any event, Perry *et al*³⁷ discussed the low methodological quality of these studies, with the exception of the study by Olafsdottir *et al*,²⁵ and concluded that there is no evidence of a clinical effect on colic using SMT, although they did conclude that there were some encouraging results from studies investigating the use of fennel, extract, mixed herbal tea, and sugar solutions.

The two studies that received the highest scores using the Sackett instrument both investigated the use of SMT on children with asthma.^{27,30} Bronfort *et al* conducted a practice-based clinical trial that monitored the effects of adding SMT to the optimum medical management 36 children with asthma were receiving.²⁷ Unlike the study by Balon *et al*³⁰ described below, Bronfort *et al*²⁷ considered both subjective and objective outcome measures as equally relevant. After three months of care, children receiving both SMT and optimal medical management reported increased improvements in their quality of life, even at one year follow up. No change in lung function was reported. This study was scored the highest in our review, scoring 48/50.

The study scoring second highest in terms of methodological design in this review was by Balon *et al*, which compared SMT versus sham SMT among 80 children

diagnosed with asthma.³⁰ Using peak expiratory flow as measured by spirometry as a primary outcome measure, the researchers reported there was no significant difference between the two groups. This study was scored 45/50. Ferrance and Miller have suggested that SMT may convey benefits to the thoracic spine biomechanics of children with asthma.³⁵ Even though there is no evidence that SMT improves lung function itself, Ferrance and Miller noted that the studies by Bronfort *et al*²⁷ and Balon³⁰ reported other important clinical outcomes include improvements in patients' quality of life as well as other subjective symptoms. It is noteworthy that in a systematic review of the literature pertaining to the use of chiropractic care for asthma, Kaminskyj *et al* concluded that SMT should be used as an adjunct to, rather than a replacement of, traditional medical management.⁴¹

Two clinical trials investigated the use of SMT for enuresis.^{26,31} One study involved the use of SMT targeted to the upper cervical spine²⁶ and the other study compared SMT to a sham treatment (activator set to "zero").³¹ Although both clinical trials reported children experienced improvement in terms of fewer "wet nights," both studies suffered from several methodological flaws (no description of blinding strategy or safeguards against contamination or co-interventions) and were scored 25/50 and 33/50 respectively.

In general, the clinical trials involving children or adolescents with jet lag²⁴ or otitis media²⁶ did not report any clinically meaningful improvements following SMT. However, another study investigating the effects of hip manipulation compared to a control group of adolescents age 17–20 years old did report favorable results attributable to SMT.²⁰ Compared to a control group, the adolescents who received SMT were found to have statistically significant improvements in hip extension immediately after the intervention; however, this group of subjects failed to demonstrate improvements in running time 30 minutes post-intervention. This study involved very few subjects (n = 17), no significant follow-up period, provided no information with respect to contamination or co-intervention and provided minimal information on blinding strategies.

A feasibility pilot study involving the use of spinal manipulation for six patients with adolescent idiopathic scoliosis was conducted by Rowe *et al*.²³ The outcome measures of this randomized, controlled clinical trial in-

cluded x-ray line marking (calculating the Cobb angle, the gold standard used to measure the magnitude of spinal curvature) as well as quality of life survey instruments. The researchers reported that a larger RCT was viable since chiropractors and orthopedic surgeons were easily recruited and worked cooperatively, and patient compliance and recruitment was good. SMT was safely used, with only two transient, self-limiting adverse reactions reported.²³

Khorshid *et al* conducted a very small randomized clinical trial comparing full spine HVLA-SMT to Upper Cervical adjustments (manipulation) among 14 children with autism.³³ The researchers reported both forms of manual therapy resulted in improvements in 6 of 7 children in the upper cervical care (UCC) group and 5 of 7 children in the SMT group as measured by the Autism Treatment Evaluation Checklist.³³ However, it was reported that the children in the UCC group had higher average improvements in their ATEC score, with one child in the UCC group reportedly no longer meeting the criteria to be considered autistic. Similar to the Browning *et al*²² study, it is unknown whether the positive benefits reported are due to differences between the interventions themselves or if they are attributable to the benefits of physical contact between the practitioner and the patient.

The effect of SMT among 114 infants identified as demonstrating 'suboptimal breastfeeding' was investigated in a prospective case series.³³ Based on the mothers' subjective reports of improvement in the ability to exclusively breastfeed (i.e. the infant did not require bottle feeding supplementation), as well as monitoring the infant's weight, Miller *et al*³³ reported 89 infants (78%) responded favorably to SMT.

Among adults,^{12,42-44} even among older adults,^{45,46} the body of knowledge investigating the clinical effectiveness of chiropractic care in general, and SMT in particular, for spinal pain has experienced exponential growth over the past decade. This notable accrual of peer-reviewed literature is observable not only in terms of the sheer numbers of studies being published but, upon further review, also in terms of improvements in their methodological designs. However, the same cannot be said for children and adolescents. The most startling finding from our review was that there was not a single clinical trial investigating the effectiveness of SMT for children or adolescents with back pain. This is especially puzzling since MSK

conditions were the most common presenting chief complaint to chiropractors for pediatric patients other than infants. This is disturbing since the occurrence of back pain in the pediatric population has been calculated to be roughly 20%, with the prevalence increasing with age and a prevalence higher among girls than boys.⁴⁷ That said, most cases of pediatric back pain are often non-specific and self-limiting and rarely require hospitalization, although many children with spinal pain report that it often interferes with their activities of daily living.⁴⁷

One reason for this paucity of literature may be that this group of patients is typically excluded by design from well-designed double-blinded controlled clinical trials. Other reasons may be difficulties in obtaining ethical review approval, limited funding opportunities for chiropractors and perhaps a relatively small number of researchers available to undertake rigorous clinical trials. However, since third party payors, governing bodies and other stakeholders are all encouraging healthcare providers to rely on researched evidence to guide their clinical decisions whenever possible, rather than only on their own clinical experiences (see commentaries),⁴⁸ this knowledge gap leaves the field practitioner in the unenviable position of finding him or herself unable to comply with the one of the fundamental tenets of evidence-based medicine.

This contradiction is especially problematic since the provision of chiropractic care for children is not without controversy, as witnessed by the 2002 Position Statement of the Canadian Paediatric Society (CPS).⁴⁹ The CPS provided a historical review of chiropractic, a discussion of chiropractic philosophies (principally relying on a study by Biggs *et al*)⁵⁰ and provided utilization rates of chiropractic services by children. The CPS also provided the issues surrounding the varying attitudes towards vaccinations within the chiropractic community. One of the areas of controversy discussed by the CPS was the advice given by some chiropractors to parents that the birthing process is itself a traumatic event requiring chiropractic treatment to realign an infant's spine and that, without this spinal realignment, many childhood illnesses may result. Lastly, the CPS noted that many chiropractors claim to treat a wide variety of non-NMS conditions for children in the absence of supportive clinical evidence, ranging from colic to asthma to otitis media.⁴⁹

No adverse effects were reported in any of the clinical trials reviewed. This echoes the recent conclusion reached

by Humphreys,⁵¹ which itself was an update of his early work.⁵² Humphreys reported that there are no reports of serious or catastrophic adverse effects in any clinical trials or systematic reviews found using pediatric manual therapy (pediatric MT), although he does note that there is insufficient research evidence in this field of study. Therefore, he contends, no accurate estimation of the rate of adverse effects of pediatric MT can be made.⁵¹

Limitations

There were several limitations in this review. It is possible that the inclusion criteria were too restrictive and that we erred when not including clinical trials investigating the use of osteopathic manipulation on conditions affecting children and adolescents. It is possible our search strategy failed to capture relevant articles suitable for this review, especially articles published in languages other than English.

More importantly, we may have mis-scored components of the clinical trials we reviewed. At times we were unable to identify the manner in which randomization was done, or how blinding of either subjects or treating practitioners was performed. In such instances, we tended to err on the side of caution and assign the lowest grade option available to us on the Sackett scale. Elsewhere, some studies were very vague with respect to how subject compliance to study protocols was monitored, and many studies failed to indicate how they ensured there was no contamination or co-interventions. For example, a number of studies stated patients were instructed to continue with their prescribed medications, but there was no indication whether or not parents were instructed not to change household routines (i.e. changes with sleeping routine for colicky infants) or not to introduce other forms of therapy (i.e. massage, use of heat) during the duration of the clinical trial.

Whether or not “crying time” should be scored as an “objective” or “subjective” outcome measure spawned considerable debate among the authors of this review. On the one hand, the amount of time an infant cries can be timed and documented; on the other hand, as intimated by Ferrance and Miller,³⁵ each bout of infant crying may be due to different causes, making the decision to ascribe each episode of crying to “colic” more subjective in nature. At the end of the day, we chose to consistently designate “crying time” as a subjective outcome measure.

Conclusion

We conducted a systematic review of 16 clinical trials investigating the use of SMT for pediatric health conditions. None of the 16 studies investigated the effectiveness of SMT for spinal pain among children or adolescents. Studies that monitored both subjective and objective outcome measures of relevance to both patients and parents tended to report the most favorable response to SMT, especially among children with asthma. Five of the six studies investigating the effectiveness of SMT for infantile colic reported favorable results, notwithstanding their methodological deficiencies and small sample size. Going forward, if shown to be a valid theory, studies investigating the effect of SMT on colic ought to better differentiate between subgroups of crying infants, monitor the effect of SMT on larger groups of infants and generally use more robust study methodologies, especially in terms of blinding allocation and avoiding co-interventions and contaminations of other external factors.

With respect to clinical trials investigating the use of SMT for children with asthma, future studies should focus more on daily activity outcome measures (reduction in use of medication), physical outcome measures (breathing ability) and subjective measures (ease of breathing, patient satisfaction) and less on physiological responses (lung function as measured by spirometry).

The findings from our review are comparable, although not identical, to the conclusions provided in the UK Evidence Report authored by Bronfort et al, who stated: “*In children, the evidence is inconclusive regarding the effectiveness for otitis media and enuresis, and is not effective for infantile colic and asthma when compared to sham manipulation.*”^{12p3}

We can do no better than to parrot the conclusions reached by two very different groups of authors separated by a 10 year gap. The first group of authors, the Canadian Paediatric Society, stated in 2001: “*Chiropractic treatment for children and adolescents is not uncommon. Open and honest discussions with families using or planning to use chiropractic for their children will, hopefully, bring about a rationale use of this treatment in selected musculoskeletal conditions for which there is proof of efficacy, and enable parents to make informed choices about this form of therapy...[I]deally, collaborative evidence-based research into chiropractic care for diverse paediatric con-*

ditions should define those patients best suited for chiropractic therapy.”^{49p88}

The other group of authors, Ferrance and Miller, reached a similar conclusion in 2010: “*The efficacy of chiropractic care in the treatment for non-musculoskeletal disorders has yet to be definitely proven or disproven, with the burden of proof still resting upon the chiropractic profession.*”^{35p1} We hope that another decade will not pass before the chiropractic research community finally meets the challenges identified by these authors and fills in the glaring evidentiary gap of the use of SMT for pediatric health conditions of all kinds, especially spinal pain.

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