Osteopathic Manipulative Treatment for Pediatric Conditions: A Systematic Review

abstract

BACKGROUND AND OBJECTIVES: Most osteopaths are trained in pediatric care, and osteopathic manipulative treatment (OMT) is available for many pediatric conditions. The objective of this systematic review was to critically evaluate the effectiveness of OMT as a treatment of pediatric conditions.

METHODS: Eleven databases were searched from their respective inceptions to November 2012. Only randomized clinical trials (RCTs) were included, if they tested OMT against any type of control in pediatric patients. Study quality was critically appraised by using the Cochrane criteria.

RESULTS: Seventeen trials met the inclusion criteria. Five RCTs were of high methodological quality. Of those, 1 favored OMT, whereas 4 revealed no effect compared with various control interventions. Replications by independent researchers were available for 2 conditions only, and both failed to confirm the findings of the previous studies. Seven RCTs suggested that OMT leads to a significantly greater reduction in the symptoms of asthma, congenital nasolacrimal duct obstruction (posttreatment), daily weight gain and length of hospital stay, dysfunctional voiding, infantile colic, otitis media, or postural asymmetry compared with various control interventions. Seven RCTs indicated that OMT had no effect on the symptoms of asthma, cerebral palsy, idiopathic scoliosis, obstructive apnea, otitis media, or temporomandibular disorders compared with various control interventions. Three RCTs did not perform between-group comparisons. The majority of the included RCTs did not report the incidence rates of adverse effects.

CONCLUSIONS: The evidence of the effectiveness of OMT for pediatric conditions remains unproven due to the paucity and low methodological quality of the primary studies. *Pediatrics* 2013;132:140–152

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KEY WORDS

pediatrics, complementary and alternative medicine, osteopathy, systematic review, effectiveness

ABBREVIATIONS

ADHD—attention-deficit/hyperactivity disorder
AE—adverse effect
CI—confidence interval
CNLDO—congenital nasolacrimal duct obstruction
CP—cerebral palsy
DV—dysfunctional voiding
DWG—daily weight gain
FDT—fluorescein disappearance test
GMFM—Gross Motor Function Measurement
IC—infantile colic
IS—idiopathic scoliosis
ITT—intention to treat
LOS—length of hospital stay
MD—mean difference
OM—otitis media
OMT—osteopathic manipulative treatment
PA—postural asymmetry
RCT—randomized clinical trial
ROB—risk of bias
SR—systematic review
TMD—temporomandibular disorder
UC—usual care

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Osteopathy is a branch of health care that was founded by A.T. Still during the 19th century in the United States.[1] Since then, osteopathy has evolved to encompass 2 distinct professions: nonphysician osteopaths and osteopathic physicians; the former are generally considered practitioners of alternative medicine, whereas the latter group that exists only in the United States has the same standing, training, and regulation as conventional physicians.[2]

Both nonphysician osteopaths and, to a lesser extent, osteopathic physicians use osteopathic manipulative treatment (OMT) to treat a wide variety of pediatric conditions.[3] OMT can be defined as "the therapeutic application of manually guided forces by an osteopathic physician to improve physiologic function and/or support homeostasis that has been altered by somatic dysfunction."[4] According to the Glossary of Osteopathic Terminology, OMT refers to a broad array of manipulative techniques ranging from articulatory to visceral manipulation and includes cranial osteopathy.[5] It seems relevant to clarify the difference between chiropractors and (nonphysician) osteopaths. The former "focuses on the relationship between the body's structure—mainly the spine—and its functioning."[6] Chiropractors primarily perform manipulations of the spine or the limbs with the goal of correcting subluxations,[7–9] whereas osteopaths employ mainly (but not exclusively) mobilizations of soft tissues such as fascia, ligaments, and muscles.[5] The similarities between the 2 professions are, however, undeniable.

The prevalence of OMT use in pediatric populations varies throughout the world. Data from the National Health Interview Survey 2007, Child Alternative Medicine survey as well as the Child Core Sample indicated that 2.3 million children (2.3%) in the United States had used OMT or chiropractic manipulation in 2007.[10]

Numerous clinical trials investigating the effects of OMT in pediatric patients have been conducted; however, no systematic reviews (SRs) evaluating the effectiveness of OMT in pediatrics have been published. The paucity of high quality research in OMT is a critical factor undermining the credibility of the osteopathic profession.[11]

The objective of this SR is to critically evaluate the effectiveness of OMT as a treatment option for pediatric conditions, by using data from randomized clinical trials (RCTs).

METHODS

The Preferred Reporting Items for Systematic Reviews and Meta-analyses guidelines were used to lend a reporting framework of this SR.

Eligibility Criteria

The present SR included all RCTs investigating the effect of OMT on pediatric conditions. Only children and adolescents ≤18 with a clinical condition were included. Any types of controls were considered admissible. Both published and unpublished RCTs were considered eligible. No gender, time, or language restrictions were imposed. Studies involving the use of OMT in conjunction with other treatments were included. Nonrandomized or uncontrolled trials were excluded. Studies of chiropractic manipulations were also excluded.

Data Source and Search Strategy

The first reviewer (Dr Posadzki) searched the following electronic databases (from their respective inceptions to November 2012): AMED (EBSCO), Cumulative Index to Nursing and Allied Health Literature (EBSCO), Embase (OVID), Medline (OVID), OSTMED.DR, PsycINFO, The Cochrane Library, ISI Web of Knowledge, Osteopathic Research Web, PEDro, and Rehabdata. Details of the Medline search strategy are available in the Appendix. Additionally, the reference lists of the located articles and key SRs of OMT were manually searched for further relevant literature. Hard copies of all retrieved articles were read in full.

Study Selection

All titles and abstracts identified in the electronic database search were screened for relevance. Articles appearing to meet the inclusion criteria were retrieved in full for further evaluation and validation according to predefined criteria. The data screening and selection process were carried out independently by 2 reviewers (Drs Posadzki and Lee). In case of disagreement, a third independent reviewer (Dr Ernst) was asked to decide.

Quality Assessment

The Cochrane tool was used to assess the risk of bias (ROB) of the RCTs.[12] This tool consists of 7 domains: adequate sequence generation, allocation concealment, patient blinding, assessor blinding, addressing of incomplete data, selective outcome reporting, and other sources of bias. Each domain can be scored as follows: H, high ROB; L, low ROB; and U, unclear ROB. Quality assessment process was conducted by 2 independent reviewers (Drs Posadzki and Lee) and subsequently validated by the third reviewer (Dr Ernst). Disagreements about whether a study was of low or high quality were settled through joint discussions.

Data Extraction

Data extraction was conducted by 2 reviewers (Drs Posadzki and Lee) by using a predefined form and subsequently validated by another reviewer (Dr Ernst). The following information was extracted from the included trials: first author and year of publication, characteristics of participants, experimental and control interventions, primary outcome measures, main results, author's conclusions, adverse effects (AEs), conflict of

interest, summary of quality score, and RCT's main limitations.

Data Synthesis

The posttreatment differences in any type of outcome measures between the intervention and control groups were assessed descriptively. The protocol stipulated that the data should be meta-analyzed if methodological, clinical, and statistical heterogeneity allowed.

Effect sizes were calculated for the effect of OMT on any type of outcome measures. Difference scores between experimental and control groups were calculated by using Cohen's d formulas.[13]

RESULTS

Our searches generated a total of 19 509 records, and 17 RCTs met our inclusion criteria (Fig 1). The key data from the included RCTs are presented in Table 1. Table 2 summarizes details of the OMT regimen. A total of 887 pediatric patients were included in the RCTs. The included trials originated from Belgium,[14] Germany,[15,16] Italy,[17,18] Spain,[19] Switzerland,[20] the United Kingdom,[21,22] and the United States.[23–30]

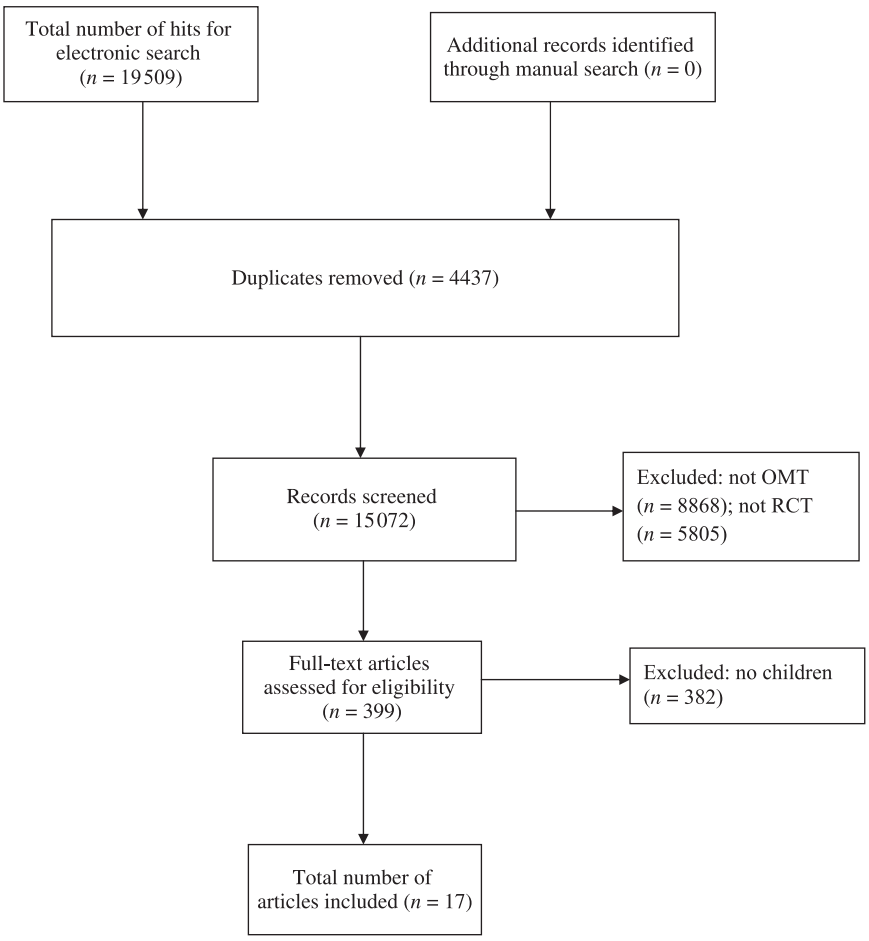

FIGURE 1
Preferred Reporting Items for Systematic Reviews and Meta-analyses diagram for included studies.

Cerebral Palsy

Duncan et al[25] aimed to assess the effectiveness of cranial osteopathy, myofascial release, or both versus acupuncture in 55 children with moderate to severe spastic cerebral palsy (CP). Fifteen children received 10 sessions of OMT, 18 had 30 sessions of acupuncture, and 22 were in the wait-list control arm. After a 24-week period, the authors reported no significant changes in Gross Motor Function Classification System (no *P* values, no confidence intervals [CIs]), Functional Independence Measure for Children/self care (no *P* values, no CIs), and Pediatric Evaluation of Disability Inventory/mobility (no *P* values, no CIs); and significant improvements in the total Gross Motor Function Measurement (GMFM) score ($P < .05$, no CIs) and in the mobility domain of the Functional Independence Measure for Children ($P < .05$, no CIs) in the OMT group compared with acupuncture or waiting list controls and concluded that OMT improved motor function in children with moderate to severe spastic CP.

Wyatt et al[22] tested the effects of cranial osteopathy on general health and wellbeing, including physical function, in 142 children with CP. In this study, 71 patients received 6 sessions of cranial OMT, and 71 were on the waiting list. At 6-month follow-up, the authors reported no significant between-group differences in GMFM-66 (mean difference [MD] = 4.9 [95% CI: −4.4 to 14.1], no *P* values), Physical Summary Score (MD = 2.2 [95% CI: −3.5 to 8.0], no *P* values), and Psychological Summary Score (MD = 3.4 [95% CI: −0.8 to 7.7], no *P* values) of Child Health Questionnaire and concluded that there was no evidence that cranial osteopathy leads to sustained improvement in motor function, pain, or sleep in children aged 5 to 12 years with CP.

Respiratory Conditions

Belcastro et al[24] aimed to determine the effectiveness of OMT in 12 patients with bronchiolitis. Three subjects received 3 sessions of OMT, and 9 received postural drainage (no further details were provided). The authors reported no significant between-group differences in number of hospital days

TABLE 1 RCTs of OMT in Pediatrics

Reference	*n*/Characteristics of Participants/ Age or Age Range	Experimental Intervention	Control Intervention	Primary Outcome Measure	Main Result (Between Group Differences)	Effect Size (Cohen's d)	Authors' Conclusions	AEs	COI[a]	Quality Score[b]	Main Limitation(s)
Belcastro et al[24]	12/bronchiolitis/ ≥2 mo and ≤2 y	OMT; 3 times daily for 60–90 s	1. Postural drainage 2. Bronchodilators 3. Placebo bronchodilators	1.Respiratory rates 2. Number of hospital days	1. NR 2. NR	Insufficient data	"There were too few patients from which to draw any conclusions; however, a research protocol was established."	NM	NM	H,H,H,H,H,H,U	Lack of fully described randomization, blinding, ITT, follow-ups, small sample.
Bierent-Vass[15]	77/ADHD/≥6 y and ≤14 y	Visceral and cranial osteopathy; 4 sessions over 2 wk	No treatment	1.Conners Scale	1. NR	Insufficient data	"The osteopathic diagnosis and treatment can contribute a positive result in the treatment of children with ADD/ADHD."	NM	NM	U,H,H,H,H,H,U	Lack of blinding, control for placebo effects, clearly described randomization, allocation concealment, power calculations and statistical tests performed.
Brady[23]	Unknown number of pediatric patients with asthma/≥4 y and ≤17 y	OMT	NM	1. Forced expiratory volume in 1 second 2. Forced expiratory flow, midexpiratory phase	1. NS ($P = .982$ and $P = .081$) for TG and CG 2. NS ($P = .532$ and $P = .401$) for TG and CG	Insufficient data	"A specific OMT protocol did not significantly improve pulmonary function or subjective asthma symptoms, in pediatric patients with moderate persistent asthma"	NM	NM	U,U,H,H,H,H,U	Abstract only
Cerritelli et al[18]	101/premature infants/≥28 and ≤38 wk	OMT+UC	UC	1. LOS 2. DWG	1. Sig ($P = .03$) 2. Sig ($P = .03$)	Insufficient data	"(…) OMT plays an important role in the management of preterm infants hospitalization"	NM	NM	U,U,U,U,U,U,U	Abstract only

TABLE 1 Continued

Reference	*n*/Characteristics of Participants/ Age or Age Range	Experimental Intervention	Control Intervention	Primary Outcome Measure	Main Result (Between Group Differences)	Effect Size (Cohen's d)	Authors' Conclusions	AEs	COI[a]	Quality Score[b]	Main Limitation(s)
Duncan et al[25]	55/CP/≥20 mo and ≤12 y	OMT; 10 sessions of over a 24-wk, 20–60 min each	1. AT 2. WL	1. Gross Motor Function Classification System 2. GMFM 3. PEDI/m 4. PEDI/s/c 5. WeeFIM/m 6. WeeFIM/s/c	1. NS 2. Sig ($P < .05$) 3. NS 4. NS 5. Sig ($P < .05$) 6. NS	1. 0.11 2. 0.20 3. 0.04 4. 0.03 5. 0.12 6. 0.11	Osteopathy "(…) improved motor function in children with moderate to severe spastic CP."	NM	NM	L,L,H,L,L,L,U[c]	Lack of power and sample size calculations, small sample, no ITT or follow-up, implausible testing of effectiveness.
Guiney et al[26]	140/pediatric asthma/≥5 y and ≤17 y	OMT	Sham	1. PEF	1. Sig (no *P* values provided)	1. 0.42	"These results suggest that OMT has a therapeutic effect among this patient population."	NM	NM	U,H,H,H,H,H,U	Unequal distribution between the arms, lack of comparability between groups at baseline, sham procedure lacks credibility, lack of follow-up, poorly described end points and statistics; lack of *P* values.
Hasler et al[20]	20/postpubertal young girls with IS/$\bar{x}$ = 15.6	OMT; 3 sessions for 5 wk	Observation	1. Trunk morphology 2. Spine flexibility	1. NS 2. NS	1. 0.04 2. 0.49	"We found no evidence to support osteopathy in the treatment of mild adolescent idiopathic scoliosis."	None reported	None declared	L,L,H,L,L,L,U[c]	Small sample, no control for placebo effects.

TABLE 1 Continued

Reference	*n*/Characteristics of Participants/ Age or Age Range	Experimental Intervention	Control Intervention	Primary Outcome Measure	Main Result (Between Group Differences)	Effect Size (Cohen's d)	Authors' Conclusions	AEs	COI[a]	Quality Score[b]	Main Limitation(s)
Hayden and Mullinger[21]	28/infants with IC/≥1 wk and ≤12 wk	Cranial osteopathy; once weekly for 4 wk	No treatment	1. Mean number of hours spent crying 2. The mean number of hours spent sleeping	1. Sig ($P < .02$) 2. Sig ($P < .05$)	1. −0.34 2. 0.27	"(…) cranial osteopathic treatment can benefit infants with colic; a larger, double-blind study is warranted."	NM	NM	L,H,H,H,L,U,U	No clear exclusion criteria, short follow-up, lack of power and blinding.
Mills et al[27]	57/acute OM/≥20 mo and ≤12 y	OMT+UC; 9 sessions, 3 weekly, 3 biweekly, 3 monthly, 15–25 min	UC	1. Frequency of OM 2. Antibiotic use 3. Surgical interventions 4. Surgery-free months 5. Tympanograms 6. Audiometrics	1. Sig ($P = .04$) 2. NS ($P = .13$) 3. Sig ($P = .03$) 4. Sig ($P = .01$) 4. Sig ($P = .02$) 5. NS	1. −0.34 2. −0.29 3. 1.02 4. 0.46 5. 0.21	"The results of this study suggest a potential benefit of OMT as adjuvant therapy in children with recurrent acute OM; it may prevent or decrease surgical intervention or antibiotic overuse"	None reported	NM	L,L,H,H,L,U,U	Small sample, high drop-out rate, lack of placebo control arm and blinding.
Monaco et al[17]	28/TMD/$\bar{x}$ = 12	OMT	No treatment	Kinesiographics: 1. MO 2. MOV 3. MCV 4. OVA 5. CVA	1. NS 2. NS 3. NS 4. NS 5. NS	Insufficient data	"OMT can induce changes in the stomatognathic dynamics, offering a valid support in the clinical approach to TMD."	NM	NM	H,H,H,H,H,H,U	Small sample, no power calculations, lack of ITT, clear exclusion criteria, or control for placebo effects, fully unblinded, low internal validity, no follow-ups or drop-out rate.

TABLE 1 Continued

Reference	*n*/Characteristics of Participants/ Age or Age Range	Experimental Intervention	Control Intervention	Primary Outcome Measure	Main Result (Between Group Differences)	Effect Size (Cohen's d)	Authors' Conclusions	AEs	COI[a]	Quality Score[b]	Main Limitation(s)
Navarro et al[19]	30/CNLDO/ ≥2 wk and ≤9 mo	Cranial osteopathy; once only	Sham	1. FDT 2. Modified Jones test	1. Sig ($P < .05$) 2. Sig ($P < .05$) (both posttreatment)	Insufficient data	"Lacrimalis bone release produces lower FDT values and higher Jones values in the intervention group immediately after treatment. Therefore, we conclude that this technique is effective in the short term."	NM	None declared	H,H,U,H,H,H,U	Small sample, no power calculations.
Nemett et al[28]	21/DV/≥4 y and ≤11 y	OMT+UC; 4 sessions, 1 h each	UC	1. DV symptoms	1. Sig ($P = .008$)	Insufficient data	OMT "can improve short-term outcomes in children with DV, beyond improvements observed with standard treatments, and is well liked by children and parents."	NM	NM	H,H,H,H,L,U,U	Lack of blinding, control for placebo effects, randomization and allocation concealment poorly described, small sample, lack of power calculations.
Philippi et al[16]	32/infants with PA/≥6 wk and ≤12 wk	OMT; once a week for 45–60 min over 1 mo	Sham	1. Video-based measurements using 6-point scale	1. Sig ($P = .001$)	1.288	"Osteopathic treatment in the first months of life improves the degree of asymmetry in infants with postural asymmetry."	Aggravation of vegetative symptoms ($n = 4$) for osteopathy	NM	L,L,L,L,L,U,U[c]	Small sample, lack of objective and validated outcome measures and follow-up, wide CIs.
Steele et al[29]	26/young children with acute OM and its sequelae/ ≥6 mo and ≤24 mo	OMT+UC; 5 visits over 30 d	UC	1. Reflectometer 2. Tympanograms	1. NR 2. NR	Insufficient data	"The OMM protocol can be administered with no serious AEs"	None reported	None declared	L,H,H,L,L,U,U	Lack of power calculations, very small sample, implausible testing of effectiveness.

TABLE 1 Continued

Reference	*n*/Characteristics of Participants/ Age or Age Range	Experimental Intervention	Control Intervention	Primary Outcome Measure	Main Result (Between Group Differences)	Effect Size (Cohen's d)	Authors' Conclusions	AEs	COI[a]	Quality Score[b]	Main Limitation(s)
Vandenplas et al[14]	34/infants with obstructive apnea/≥1.5 mo and ≤4.0 mo	OMT; 2 treatments over 2 wk; 30 min each	Mobilization	1. Polysomnographic recordings	1. NS ($P = .43$)	−0.15	"Osteopathy may have a positive influence on the incidence of obstructive apneas during sleep in infants (…)"	NM	NM	H,H,L,L, L,U,U	No follow-up, small sample, lack of power calculations, implausible testing of effectiveness, unequal distribution between the arms.
Wahl et al[30]	84 young children with OM/ ≥12 mo and ≤60 mo	OMT (5 visits over 3 mo) + Echinacea (10 d)	1. Sham OMT + placebo 2. OMT + placebo 3. OMT + Echinacea	1. The occurrence of a first episode of acute OM	1. NS ($P > .05$)	Insufficient data	"A regimen of up to five OMTs does not significantly decrease the risk of acute OM."	$N = 2$ (both not OMT related)	None declared	L,L,L,L,L,L,U[c]	Lack of full compliance with OMT, not powered enough.
Wyatt et al[22]	142 children with CP/ ≥5 y and ≤12 y	Cranial osteopathy; 6 sessions, over 7 mo	WL	1. GMFM-66 2. CHQ	1. NS 2. NS	1. 0.20 2. 0.24	" (…) no statistically significant evidence that cranial osteopathy leads to sustained improvement in motor function, pain, sleep or quality of life in children aged 5–12 years with CP nor in QOL of their carers."	None reported	None declared	L,U,H,L,L,L,U[c]	Low internal validity.

CG, control group; CHQ, Child Health Questionnaire; CVA, closing velocity average; m, mobility; MCV, maximal closing velocity; MO, maximal mouth opening; MOV, maximal opening velocity; NM, not mentioned; NR, not reported; NS, not significant; OMM, osteopathic manipulative medicine; OVA, opening velocity average; PEDI, Pediatric Evaluation of Disability Inventory; PEF, peak expiratory flow; QOL, quality of life; s/c, self-care; Sig, significant; TG, treatment group; WeeFIM, Functional Independence Measure for Children; WL, wait list.

[a] Authors' conflict of interest.

[b] Refers to 7 domains of quality assessment based on the Cochrane tool for assessing ROB. The following domains are scored: adequate sequence generation, allocation concealment, patient blinding, assessor blinding, incomplete data addressed, selective outcome reporting, and other sources of bias. Each domain is scored as H-high ROB, L-low ROB, or U-unclear ROB.

[c] High quality.

or respiratory rates (no statistical tests were reported) and concluded that the study included too few patients to draw any conclusions.

Brady[23] aimed to determine whether OMT had an effect on an unknown number of children with moderately severe asthma. The allocation between the arms was not presented. The author reported insignificant changes between the groups in forced expiratory volume in 1 second ($P = .982$ and $P = .081$, no CIs) and forced expiratory flow, midexpiratory phase ($P = .532$ and $P = .401$, no CIs) and concluded that OMT did not improve pulmonary function or subjective asthma symptoms in pediatric patients.

Guiney et al[26] tested OMT in 140 pediatric asthmatic patients. In this study, 90 patients received OMT (details were not provided), and 50 underwent a sham procedure (light touch only). The authors reported significant improvements in peak expiratory flow in the OMT group (no *P* values [95% CI: 7.3 to 18.7]) compared with controls (no *P* values [95% CI: −9.8 to 10.4]) and concluded that OMT has a therapeutic effect in this patient population.

Vandenplas et al[14] aimed to test whether OMT could reduce the incidence of obstructive sleep apnea. Of the 34 infants in this study, 15 received 2 sessions of OMT, and 13 received 2 sessions of gentle mobilizations over a period of 2 weeks. These authors reported no significant intergroup difference in the decline in the number of obstructive apneas ($P = .43$, no CIs); and significant (within group) decrease in the number of apneas in the OMT group ($P = .01$, no CIs) and concluded that OMT may have a positive influence on the incidence of apneas during sleep in infants with a previous history of obstructive apnea, as measured by polysomnography.

Otitis Media

Mills et al[27] aimed to study effects of OMT as an adjuvant to usual care (UC) in 57 children with recurrent acute otitis media (OM). Of 57 subjects, 25 received 9 sessions of OMT plus UC, and 32 received equal amount of UC only. At 6-month follow-up, the authors reported no significant changes in antibiotics use ($P = .13$ [95% CI: −0.38 to 0.05]) and audiometrics (no *P* values [95% CI: −6.10 to 4.16 for final speech awareness threshold]); and significant improvements in the number of episodes of acute OM (MD = −0.14 [95% CI: −0.27 to 0.00], $P = .04$), mean surgery-free months ($P = .01$ [95% CI: 0.16 to 1.34]) and normalized tympanograms (MD = 0.55 [95% CI: 0.08 to 1.02], $P = .02$) in the OMT group compared with controls and concluded that OMT might be beneficial as an adjuvant therapy in children with recurrent acute OM.

Steele et al[29] aimed to describe a research protocol for studying the efficacy of OMT on middle ear effusion after an episode of acute OM in 56 young children. Seven subjects received 5 sessions of OMT plus UC over 30 days, and 27 received UC (antibiotics and surgery). The authors did not report any between-group comparisons and concluded that the OMT protocol can be administered with no serious AEs.

Wahl et al[30] aimed to assess the efficacy of *Echinacea purpurea* and/or OMT for the prevention of acute OM in otitis-prone children. Of the 90 children in the study, 46 received 5 sessions of OMT plus either real or placebo *Echinacea*, and 44 received sham OMT (palpation of the cranial bones and muscles and other structures) plus either real or placebo *Echinacea* over 3 months. The authors reported no significant between-group differences in risk of having at least 1 episode of acute OM (relative risk = 0.72 [95% CI: 0.48 to 1.10], $P > .05$) and concluded that a regimen of up to 5 OMTs does not significantly decrease the risk of acute OM.

Musculoskeletal Function

Hasler et al[20] tested the effect of OMT on trunk morphology and spine flexibility in 20 adolescents with idiopathic scoliosis (IS); 10 received 3 sessions of OMT over 5 weeks, and 10 had no intervention. The authors reported no significant between-group differences in trunk morphology ($P = .44$, no CIs) and spinal flexibility ($P = .43$, no CIs) and concluded that there was no evidence to support OMT as an effective treatment of mild adolescent IS.

Monaco et al[17] aimed to evaluate the effects of OMT on mandibular kinematics in 28 children with temporomandibular disorders (TMDs). In this study, 14 subjects received OMT (no details provided), and 14 had no intervention. The authors reported no significant changes in maximal closing velocity (no *P* values, no CIs), opening velocity average (no *P* values, no CIs), closing velocity average (no *P* values, no CIs), and maximal mouth opening ($P < .07$, no CIs); and significant (intragroup) improvements in maximal mouth opening velocity ($P < .03$, no CIs) in the OMT group and concluded that OMT can induce changes in stomatognathic dynamics, supporting this clinical approach to TMD.

Philippi et al[16] aimed to assess the therapeutic efficacy of OMT in 32 infants with postural asymmetry (PA), 16 of whom received 4 sessions of OMT over 1 month and 16 of whom had sham therapy (light touch only). The authors reported significant reductions in PA in the OMT group compared with the sham group ($P = .001$ [95% CI: 2.0 to 7.3]) and concluded that OMT in the first months after birth reduces the degree of asymmetry in infants with PA.

Other Conditions

Bierent-Vass[15] tested the hypothesis that OMT is effective for attention-deficit/hyperactivity disorder (ADHD). Of the 77 children included in the study,

50 received 4 sessions of OMT over 2 weeks, and 27 had no such treatment. This author reported <50% of improvement in symptoms, as measured by the Conners Scale, in the OMT group (no statistical tests were reported) and concluded that OMT can have a positive effect on the treatment of children with ADHD.

Cerritelli et al[18] tested the effects of OMT on the length of hospital stay (LOS) and daily weight gain (DWG) in 101 premature infants. In this study, 47 infants received OMT + UC (no details provided), and 54 received UC only. The authors reported significant improvements in LOS ($P = .03$, no CIs) and DWG ($P = .03$, no CIs) in the OMT group compared with controls and concluded that OMT plays an important role in the management of hospitalized preterm infants.

Hayden and Mullinger[21] aimed to investigate the effect of cranial OMT on the pattern of increased crying, irritability, and disturbed sleep associated with infantile colic (IC). Of the 28 infants in this study, 14 received 4 sessions of cranial OMT over 4 weeks, and 14 received no treatment. These authors reported significant improvements in crying (MD = 1.0 [95% CI: 0.14 to 2.19], $P < .02$) and time spent sleeping (MD = 1.17 [95% CI: 0.29 to 2.27], $P < .05$) in the treatment group and concluded that cranial OMT can benefit infants with colic.

Navarro et al[19] aimed to evaluate the efficacy of cranial osteopathy in 30 children with congenital nasolacrimal duct obstruction (CNLDO); 15 infants received 1 session of cranial osteopathy, and 15 received 1 sham treatment (light touch only). The authors reported significant posttreatment improvements ($P < .05$, no CIs) and no between groups differences at 14 weeks follow-up ($P > .05$, no CIs) in the fluorescein disappearance test (FDT) and the modified Jones test in the OMT group compared with controls and concluded that cranial OMT is an effective short-term therapy for CNLDO.

Nemett et al[28] aimed to determine whether OMT plus UC improves dysfunctional voiding (DV) more effectively than UC alone. Of the 21 children studied, 10 received 4 sessions of OMT, and 11 received UC, which included medications, establishment of timed voiding and evacuation schedules, dietary modifications, behavior modification, pelvic floor muscle retraining, biofeedback training, and treatment of constipation. At 3-month follow-up, the authors reported significant improvement in DV symptoms in the OMT group compared with controls ($P = .008$, no CIs) and concluded that OMT can improve short-term outcomes in children with DV.

Effect Size of OMT Interventions

In 9 of the 17 RCTs, statistics needed for effect size calculations were not reported. Effect sizes (Cohen's d) in the remaining trials ranged from 0.03 (small) to 1.288 (large); $\bar{x} = 0.20$ (small) (Table 1).

ROB

Five of the RCTs included here had a high ROB with regard to adequate sequence generation. Nine trials had a high ROB with regard to allocation concealment. Twelve RCTs had high ROB with regard to patient blinding. Nine RCTs had high ROB with regard to assessor blinding. Six RCTs had a high ROB with regard to addressing of incomplete data and selective outcome reporting. All 17 RCTs had an uncertain ROB from other sources. Thus, the overall quality of the RCTs was poor, and no RCT was free of major methodological limitations. Also, 4 RCTs failed to provide any details about the OMT, making them impossible to be replicated.[15,17,18,23]

Safety of OMT

Eleven RCTs did not report the incidence rates of AEs.[14,15,17–19,21,23–26,28] Four RCTs mentioned that no AEs had occurred.[20,22,27,29] Philippi et al[16] reported that 4 patients had had aggravation of vegetative symptoms after OMT. Two AEs reported in the study by Wahl et al[30] were related to *Echinacea* and placebo and not to OMT.

DISCUSSION

The aim of this article was to summarize and critically evaluate the evidence for or against the effectiveness of OMT in pediatric conditions. Seventeen trials were found; 7 of them favored OMT, whereas the remaining 7 revealed no effect, and 3 did not report between-group comparisons. In general, small and biased RCTs favored OMT, whereas the largest and most methodologically sound studies failed to reveal effectiveness. The evidence from RCTs of OMT for treating pediatric conditions is thus limited, weak, and contradictory. Independent replications were available for 2 conditions only: OM and CP; and in both cases the results were contradictory.[22,30] Independent replications could not be found for any other conditions. Thus there is no indication for which the effectiveness of OMT has been shown by more than 1 RCT.

This SR reveals serious methodological limitations in almost all of the RCTs. For instance, only 3 (17%) RCTs had reasonably large sample sizes.[18,22,26] Three trials employed patient blinding,[14,16,30] and 7 (41%) used blinded assessors.[14,16,20,22,25,29,30] Only 4 (23%) RCTs controlled for placebo effects by employing sham procedures,[16,19,26,30] and the sham procedure was not credible in 2 of those trials.[16,19] Of the 2 RCTs that employed credible sham-interventions, 1 was positive[26] and 1 was negative.[30] Other sources of bias pertained to the lack of power and sample size calculations,[14,15,17,19,24,25,28–30] objective outcome measures,[16] equal distribution between study arms,[26] or patient compliance with OMT.[30] Only 1 (5.8%) RCT

TABLE 2 Details of OMT Regimen

Reference	Details of Treatment (Quote Where Appropriate)
Belcastro et al[24]	OMT was administered in the following sequence and manner: scapular release, rib-raising, intercostal fascial release, anterior and posterior diaphragm release, cervical fascial release. The sequence was performed by 1 physician.
Bierent-Vass[15]	NM
Brady[23]	NM
Cerritelli et al[18]	NM
Duncan et al[25]	"The treating osteopathic physician, based on his or her structural findings, treated the child in whichever sequence he or she deemed appropriate for that visit. Osteopathic manipulative treatment was limited to the use of direct or indirect techniques of osteopathy in the cranial field, myofascial release, or both."
Guiney et al[26]	"Osteopathic physicians performed OMT on pediatric patients using any of the following osteopathic manipulative (OM) techniques, as appropriate: rib raising, muscle energy for ribs, and MFR. […] They then performed OMT following standard protocols."
Hasler et al[20]	"Parietal interventions act directly on the locomotor system (muscles, joints, ligaments, tendons) and, thereby, influence the function of the inner organs, whereas, vice versa, visceral osteopathic treatment works on the inner organs, which, by their connective tissues, interact with the locomotor system."
Hayden and Mullinger[21]	"Treatment was individualized, according to clinical findings, and involved standard cranial osteopathic techniques until a palpable release of tensions and dysfunction was achieved."
Mills et al[27]	"Treatments were gentle techniques on areas of restriction consisting of articulation, MFR, balanced membranous tension, BLT, facilitated positional release, and/or counterstrain treatments."
Monaco et al[17]	NM
Navarro et al[19]	The therapist stands beside the patient. The cranial hand stabilizes the child's forehead. The caudal hand grasps the lacrimal bone and holds it using thumb and forefinger. The therapist then mobilizes the lacrimal bone laterally from left to right, right to left, top to bottom and from back and forth to get more elasticity of bone fibers. [First author's own translation.]
Nemett et al[28]	" (…) gentle mobilization of body tissues to relieve movement restrictions, and thereby achieve balanced alignment and mobility and postural symmetry, with particular attention to the thoracolumbar spine, thoracic and pelvic diaphragms, pelvis, pelvic organs, and lower extremities."
Philippi et al[16]	"At each visit the osteopathic technique, and the area it was applied to, was adapted depending on the diagnostic palpation of the osteopath who assessed and treated position, tissue quality, mobility, and relation to the environment of the skull, sacrum, iliac and coccygeal bones, thorax, sternum, diaphragm, and abdomen."
Steele et al[29]	1. Treatment of the sacroiliac joints bilaterally using BLT + thoracolumbar junction and diaphragm using MFR + the rib cage using MFR OR 2. Treatment of the rib cage using BLT + cervicothoracic area using MFR + cervical area using BLT + craniocervical junction using suboccipital inhibition + venous sinus drainage technique + occipital decompression technique + sphenobasilar symphysis decompression technique
Vandenplas et al[14]	" (…)the infants in the osteopathic treatment group were mainly treated with functional techniques for the specific dysfunctions found at that visit. In this group a "black box" design was chosen to meet the individuality of the child and the treatment principles of osteopathy."
Wahl et al[30]	"Treatment modalities were limited to cranial osteopathy, balanced membranous/ligamentous tension, and/or MFR (applied directly or indirectly). These treatments consist of gentle manipulations of the cranium, pelvis, diaphragm, and other structures. No high velocity or thrusting maneuvers were performed."
Wyatt et al[22]	"Each child was assigned an osteopath who planned the course of therapy based on their assessment of the child's individual needs"

BLT, balanced ligamentous tension; MFR, myofascial release technique.

used intention to treat (ITT) analyses.[16] There were no follow-ups in the majority of the trials.[14,16,17,20,21,23–26,28,29] One trial that favored OMT failed to report *P* values,[26] making its conclusions questionable. Two RCTs were available as abstracts only.[18,23] Five RCTs (29.4%) were of high methodological quality.[16,20,22,25,30] Of those, 1 favored OMT, whereas 4 revealed no effects. Of those high quality trials that arrived at negative conclusions, 3 were executed by investigators not affiliated with osteopathic institutions. Similarly, 4 trials were done by nonosteopaths as lead authors, and all of them were negative.[20,22,23,30]

In terms of the clinical conditions treated, the populations of individuals were heterogeneous across the included RCTs and included children with ADHD,[15] asthma,[23,26] bronchiolitis,[24] CP,[22,25] CNLDO,[19] DV,[28] IC,[21] IS,[20] obstructive apnea,[14] OM,[27,29,30] PA,[16] and TMD.[17] The control interventions were also heterogeneous, including the use of acupuncture,[25] bronchodilators,[24] mobilization,[14] postural drainage,[24] sham therapy,[16,19,26,30] UC alone,[18,27–29] or no intervention.[15,17,20,21] The primary outcome measures were also heterogeneous. The OMTs themselves varied from cranial osteopathy[15,19,21,22,25,30] to a combination of wide variety of OMT techniques such as articulation, balanced ligamentous/membranous tension, counterstrain, facilitated positional release, muscle energy, myofascial release, or rib-raising (Table 2). The frequency of OMT sessions varied across RCTs, from a single intervention[19] to ten 20- to 60-minute sessions over 24 weeks[25] (Table 1). Therefore, due to the clinical and methodological heterogeneity of the data, a meta-analysis would not have been reasonable.

Hayes and Bezilla[3] found no OMT-associated complications and concluded that "OMT appears to be a safe treatment modality in the pediatric population". However, these conclusions

are based on a sample that is too small to allow generalizability. It is also possible that OMT-related complications are underreported. Eleven (64%) of the included RCTs failed to report the incidence rates of AEs. This may amount to a serious breach of publication ethics. Authors and journal editors might consider making sure that the situation improves in the future.

In general, reporting of trial methodology and results was often inadequate. To make progress in this area, future studies of OMT should follow the accepted standards of trial design and reporting (eg, CONSORT guidelines).[31] Such studies should also have sufficiently large sample sizes based on power calculations, use blinding, follow-ups, ITT data analysis, validated and objective outcome measures, and control for nonspecific effects.

Our review has several limitations that should be considered when interpreting its results. Firstly, even though our searches were extensive, we cannot be entirely certain that all relevant RCTs were located. Secondly, due to the methodological, statistical, and clinical heterogeneity of the included studies, statistical pooling was deemed impractical. Thirdly, publication bias could have prevented negative studies from being published. Fourthly, few RCTs were located for each specific pediatric condition; thus, our conclusions cannot be as confident as we would have liked them to be.

CONCLUSIONS

The effectiveness of OMT for pediatric conditions remains unproven. The low methodological quality and paucity of the primary studies is remarkable. More robust RCTs are needed to clarify the many open questions regarding the effectiveness of OMT. Until such data are available, OMT cannot be regarded as an effective therapy for pediatric conditions, and osteopaths should not claim otherwise.

APPENDIX: DETAILED SEARCH STRATEGY FOR MEDLINE

CONCEPT 1

Osteopath$.ti,ab OR Osteopath$ adj3 manipulat$ OR Osteoapth$ adj3 therap$ OR Osteoapth$ adj3 treatment OR Osteoapth$ adj3 medic$ OR Osteoapth$ ADJ3 (viscera$ OR cranial OR craniosacral OR nervous OR neural OR musculoskelet$ OR nonmusculoskeletal OR non-musculoskelet$).ti,ab OR (manual adj2 therap$).ti,ab OR manual adj2 medic$.ti,ab OR Spencer Technique$.ti,ab OR Jones Technique$.ti,ab OR Strain-Counter Strain.ti,ab OR Positional Release Technique$.ti,ab OR Viscera$ Manipulation$.ti,ab OR Cranial Osteopath$.ti,ab OR Cranio-Sacral Technique $.ti,ab OR Myofascial release.ti,ab OR Soft tissue release.ti,ab OR Muscle energy technique$.ti,ab OR (hand$ adj therap$).ti,ab OR (bone$ adj setter$).ti,ab OR (bodywork adj3 therap$).ti,ab OR (mobili?ation$ adj3 spin$).ti,ab OR (spin $ adj3 adjustment$).ti,ab OR (spin$ adj4 manipulat$).ti,ab OR High velocity thrust$.ti,ab OR Low amplitude thrust$.ti,ab OR HVLA.ti,ab OR Manipulat$ therap $.ti,ab OR Manipulat$ joint$.ti,ab OR Subluxation$.ti,ab OR exp osteopathic medicine/ OR exp manipulation, spinal/ OR exp musculoskeletal manipulations/ OR exp manipulation osteopathic/ OR exp alternative medicine/ OR exp Complementary Therapies/ OR manipulation, osteopathic.sh OR osteopathic medicine.sh OR OMT.tw OR osteopath$.tw

CONCEPT 2

(randomized controlled trial).pt. OR (clin$ adj5 trial$).ti,ab. OR ((singl$ or doubl$ or tripl$ or trebl$) adj5 (blind$ or mask$ or sham)).ti,ab OR random$.ti,ab OR control$.ti,ab. OR prospectiv$.ti,ab. OR exp clinical trial/ OR follow-up studies/or prospective studies/ OR double-blind method/or random allocation/or single-blind method/ OR exp Research Design/

CONCEPT 3

exp Infant/ OR (infant$ or infancy or newborn$ or baby$ or babies or neonat$ or preterm$ or prematur$).tw. OR exp Child/ OR (child$ or schoolchild$ or school age$ or preschool$ or kid or kids or toddler$).tw. OR Adolescent/ OR (adoles$ or teen$ or boy$ or girl$).tw. OR Minors/ OR Puberty/ OR (minor$ or pubert$ or pubescen$).tw. OR exp Pediatrics/ OR (pediatric$ or paediatric$).tw. OR exp Schools/ OR (nursery school$ or kindergar$ or primary school$ or secondary school$ or elementary school$ or high school$ or highschool$).tw.

1 AND 2 AND 3

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