Pediatric Osteopathic Manipulative Medicine: A Scoping Review

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abstract

CONTEXT: A common reproach precluding the use of osteopathic manipulative medicine (OMM) in pediatrics is a lack of evidence regarding its safety, feasibility, and effectiveness.

OBJECTIVE: We conducted a systematic, scoping review of pediatric osteopathic medicine to identify gaps in the literature and make recommendations for future research.

DATA SOURCES: We searched 10 databases using 6 key words and medical subject heading terms for any primary articles reporting OMM use in children published from database inception until initiation of the study.

STUDY SELECTION: Articles were selected if they reported primary data on OMM conducted in the United States on patient(s) 0 to 18 years old.

DATA EXTRACTION: Baseline study characteristics were collected from each article and the Grading of Recommendations, Assessment, Development, and Evaluations system was used to critically appraise each study.

RESULTS: Database search yielded 315 unique articles with 30 studies fulfilling inclusion and exclusion criteria. Of these, 13 reported the data required to demonstrate statistically significant results, and no significant adverse events were reported. The majority of studies were graded as providing weak clinical evidence because of significant methodologic flaws and biases.

LIMITATIONS: The review was limited to US-based studies and reports. Minimal discrepancies between reviewers were resolved via an objective third reviewer.

CONCLUSIONS: There is little strong, scientific, evidence-based literature demonstrating the therapeutic benefit of OMM for pediatric care. No strong clinical recommendations can be made, but it can be medically tolerated given its low risk profile. High-quality, scientifically rigorous OMM research is required to evaluate safety, feasibility, and efficacy in pediatrics.

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Drs DeMarsh, Belsky, and Huntzinger specifically conceived the presented study idea, created the database, and served as independent reviewers; Ms Gehred specifically assisted in the literature search and creation of the database; Mr Stanek conducted the statistical analysis of the work presented; Dr Kemper served as a guiding mentor for the project; and all authors contributed to the design and implementation of the research, analysis of the results and drafting and revising of the manuscript, approved the final manuscript as submitted, and agree to be accountable for all aspects of the work.

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Over the past few decades, the osteopathic medical profession has seen immense growth in the United States. Per the 2019 Osteopathic Medical Profession Report, ~7000 new osteopathic physicians graduated in 2019, bringing the total number of Doctors of Osteopathic Medicine (D.O.s) and osteopathic medical students in the United States to 151 373.[1] As of 2017, D.O.s composed ~8.5% of the physician workforce, but this number is expected to grow to >20% by 2030.[2] Among the 93 127 osteopathic physicians with a specialty reported, 6.9% specialized in pediatric medicine.[2]

The scope of practice of a board-certified D.O. in the United States includes the same privileges and responsibilities as medical doctors with additional training to perform osteopathic manipulative medicine (OMM). The American Academy of Osteopathy defines OMM as "the therapeutic application of manual techniques by an osteopathic physician to address the changes in body structure to improve physiologic function."[3] These manual interventions are often categorized as complementary or alternative medicine (CAM). The American Academy of Pediatrics recognizes the increasing interest of both patients and pediatricians to use CAM, as demonstrated with the creation of both a Section on Integrative Medicine[4] and a task force dedicated to CAM. This need for increased usage and awareness of supportive care options was most recently demonstrated in a cohort study conducted across the pediatric oncology field, in which researchers assessed current knowledge and perceptions of pediatric osteopathic medicine.[5] The desire to incorporate OMM as an adjunctive treatment modality was strongly expressed by pediatric oncology clinicians, patients, and caregivers.[5]

With an increasing number of D.O.s practicing in a progressively evidence-based culture, rigorous scientific evidence of sound methodologic quality is required to evaluate the use of CAM interventions. However, there is concern that many of the research studies conducted on OMM have lacked scientific rigor. The last pediatric osteopathic review by Posadzki et al[6] in 2013 revealed that of the 17 randomized controlled trials (RCTs) evaluated, "the evidence of the effectiveness of OMM for pediatric conditions remains unproven due to the paucity and low methodological quality of the primary studies."[6] With the significant growth in osteopathic pediatricians over the last decade, there is a need to update a review of the pediatric OMM literature.

OBJECTIVE

Given the concern for the amount and consistency of the available literature, a scoping review is needed to evaluate the current state of information in the field and create a baseline foundation of knowledge.[7,8] Although systematic reviews and meta-analyses remain the gold standard when formulating clinical guidelines for treatment of specific conditions based on evidence collected from RCTs, the aggregation of pediatric OMM research to date appeared insufficient for such analysis at this time.[7,8] Our aims for performing a scoping review were to (1) identify and analyze knowledge gaps in the pediatric osteopathic literature, (2) categorize types of research previously performed and assess their methodologic quality, and (3) assess whether there is a level of evidence necessary to make clinical recommendations.

DATA SOURCES

We followed the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) guidelines to conduct a literature search from each included database's inception to the date of study initiation (September 24, 2019).[9] In efforts to maintain a broad and comprehensive search, all studies published in peer-reviewed academic journals, regardless of study design, were eligible for inclusion in this review. A clinical librarian (A.G.) searched 8 medical literature databases, including Embase, Cumulative Index to Nursing and Allied Health Literature (CINAHL) Plus and Alt HealthWatch, Web of Science, Cochrane, OVID Medline, Clinicaltrials.gov, Osteomed.dr, and Proquest Dissertation. Additionally, the American Academy of Pediatrics' Section on Osteopathic Pediatricians research database, which serves as the reference database of citations of peer-reviewed pediatric osteopathic research, was reviewed.[10] Last, the cited references from any article ascertained were manually reviewed for any additional research that may have been missed in the online search. For instances in which >1 study used the same data set, only articles that presented novel findings were included, otherwise only the more comprehensive and recent study was chosen for analysis.

STUDY SELECTION

Search Terms

The entry terms used were "osteopathic manipulative treatment," "osteopathic manipulation," "orthopedic manipulation," and "osteopathy." The search was limited, when available, to only include the pediatric patient cohort (ages 0–18 years).[11]

Inclusion and Exclusion Criteria

All studies in which researchers investigated an aspect of pediatric OMM were assessed for inclusion. For purposes of this review, data from subjects who were >18 years old were excluded. Studies had to have

been conducted in the United States and written in English to be included. No articles were excluded on the basis of year performed, setting of the study (eg, rural versus urban, inpatient versus outpatient), or study design. The aim of this scoping review was to assess publications of primary data; therefore, any editorials, reviews, or published responses to previously conducted research were excluded.

Article Retrieval and Screening

The initial database search yielded 456 articles (CINAHL and Alt HealthWatch: 156, Cochrane: 15, Embase: 51, Journal of the American Osteopathic Association [JAOA]: 10, Medline: 168, Osteomed.dr: 12, ProQuest Dissertations: 12, Web of Science: 5). After computer-identified duplicate articles were removed, a total of 319 references were included (CINAHL and Alt HealthWatch: 74, Cochrane: 9, Embase: 26, JAOA: 3, Medline: 163, Osteomed.dr: 34, ProQuest Dissertations: 12, Web of Science: 0). With the addition of the American Academy of Pediatrics' Section on Osteopathic Pediatricians database (69 articles), a total of 388 articles were then manually assessed for duplication (73 articles), for a final total of 315 articles. Two blinded reviewers (S.D. and A.H.) independently screened titles and abstracts for fit, and an additional third reviewer (J.A.B.) assisted in the case of discrepancies. During the manual search of the bibliographies of the publications as described above, 3 additional articles absent from the original databases met inclusion criteria and were added. Once the preliminary screen was performed, duplicates and unqualified entries were removed on the basis of exclusion criteria, and complete texts were requested and were read in full for further evaluation and validation. The blinded two-reviewer system was again used for agreement for final

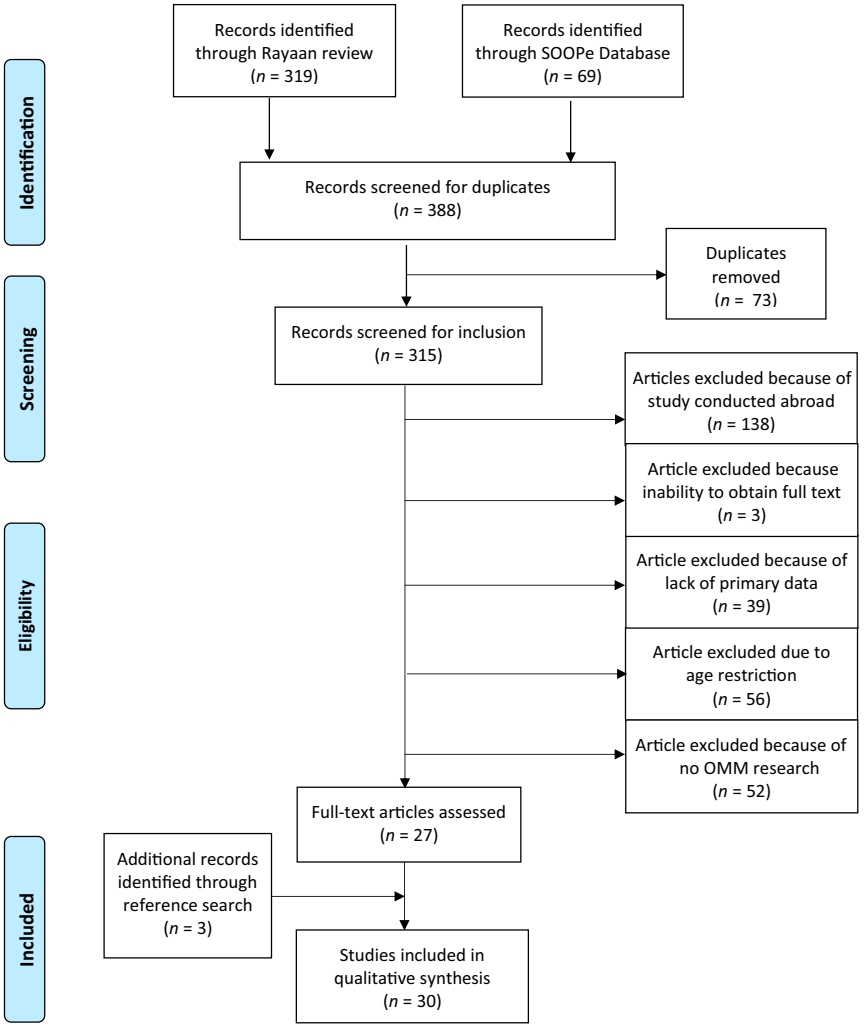

FIGURE 1

PRISMA flow diagram for assessment of studies to be included in scoping review. SOOPe, Section on Osteopathic Pediatricians; Adapted from Moher D, Liberati A, Tetzlaff J, Altman DG; The PRISMA Group. Preferred reporting items for systematic reviews and meta-analyses: the PRISMA statement. *PLoS Med.* 2009;6(7):e1000097.

inclusion of articles into scoping review. Five articles had discrepancies at this second level of evaluation and were resolved by the third reviewer. At final assessment, there were 30 primary articles that were fully analyzed (PRISMA Summary Flow Diagram,[12] Fig 1); citations for these articles are included in the reference list.[13–42]

DATA EXTRACTION

Once the final list of articles to be included was established, the predefined data elements were collected and stored in an Excel spreadsheet. Data elements extracted included article title, year published, journal, authors, location of study, study design, disease or condition focus, OMM technique(s) used, primary objective of study, inclusion and exclusion criteria, number of physicians providing OMM, protocolized versus nonprotocolized treatment use, statistical analysis reported, outcomes, and overall strengths, limitations, and potential biases. Protocolized treatment was defined as a systematic-based treatment approach using

a predefined prescriptive therapy regardless of the somatic dysfunction or physical findings of the individual subject being assessed. On the basis of the data above, primary outcome measures included (1) methodology of study design, (2) study conclusions, (3) study strengths, and (4) study limitations, including potential biases. Secondary outcomes included (1) conditions treated, (2) OMM techniques used, and (3) overall safety profile based on adverse events, when data were available.

The Grading of Recommendations, Assessment, Development, and Evaluations system was used to critically appraise the strength of evidence for the clinical utility of OMM in the pediatric population for specific conditions based on the original study data presented (Fig 2).[43,44] Through this system, the quality of evidence was assessed for each outcome, and a multistep grading process allowed complete analysis to conclude a strength of recommendation for each study.

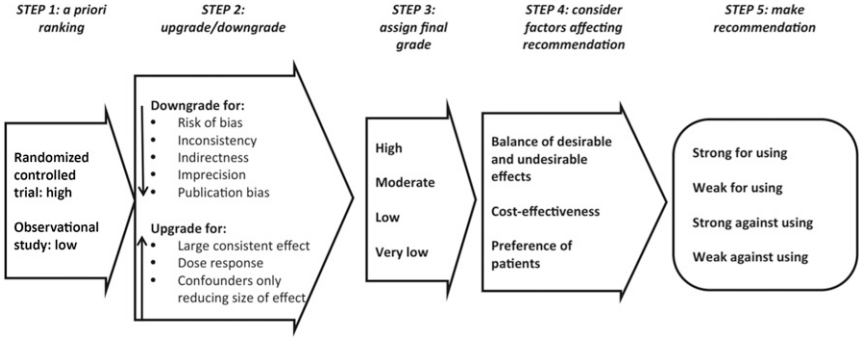

FIGURE 2
Criteria and process used to grade quality of evidence of studies included in review.

RESULTS

Study Characteristics

Thirty primary research articles were included in the final review. Most articles (23 of 30, 77%) were published in the JAOA, with representation from additional peer-reviewed journals in the field (Table 1). Most (26 of 30, 87%) were conducted in an outpatient setting and had both male and female representation in the study populations. There was a wide spectrum of study designs including 8 (27%) case reports, 7 (23%) cross-sectional surveys, 2 (7%) retrospective cohort studies, 4 (13%) prospective cohort studies, and 9 (30%) RCTs (Figs 3 and 4). Studies ranged in publication dates from 1960 to 2019, with the majority of studies (17 of 30, 57%) being published since 2000 (Fig 5).

Conditions Treated

A wide range of clinical conditions was investigated, most commonly musculoskeletal disorders (8 of 30, 27% of studies), neurologic syndromes (6 of 30, 20%), and otorhinolaryngologic diagnoses (5 of 30, 17%). Other conditions such as asthma, feeding difficulties, and dysfunctional urinary voiding were also assessed. The majority of articles were focused on OMM as a treatment modality (20 of 30, 66%) for different medical conditions, with the minority assessing its role in the prevention of illness (5 of 30, 17%). Researchers in the remaining articles analyzed baseline characteristics of OMM patients and incidences of somatic dysfunction (4 of 30, 13% of studies), with researchers in 1 study (1 of 30, 3% of studies) reporting safety and adverse outcome data.

Control and Comparison Groups in the RCTs

Nine of the studies were RCTs (Tables 2 and 3), 2 of which used a sham treatment group,[25,41] and the remaining 7 compared the addition of OMM to treatment as usual.[15,19,20,31–33,37] Wait-list controls were used in 2 of the studies[19,20] and OMM was compared with other complementary therapies in 3.[15,20,41] Additionally, researchers in 2 of these RCTs used a 4-pronged factorial design to compare multiple treatment groups.[15,41] In all but one of the studies, authors provided information to determine if intervention and control participants had similar baseline characteristics limiting residual confounding bias. In 7 (78%) of the RCTs, random allocation was adequately used. In 5 (56%) of the RCTs, the authors stated that the assessors were blinded to treatment allocation, and authors of 8 (89%) of the RCTs employed at least single blinding throughout the experimental comparison. Five (56%) of the RCTs were rated as providing strong clinical recommendations, with the other half rated as weak because of overall poor methodologic quality and small sample size (Table 3).

TABLE 1 Journals and Respective Number of Publications of Included Studies

Journal Title	No. Articles
Journal of the American Osteopathic Association	23
American Academy of Osteopathy Journal	2
Archives of Pediatrics and Adolescent Medicine	1
BMC Complementary and Alternative Medicine	1
Clinical Pediatrics	1
Journal of Bodywork and Movement Therapies	1
Journal of Pediatric Urology	1

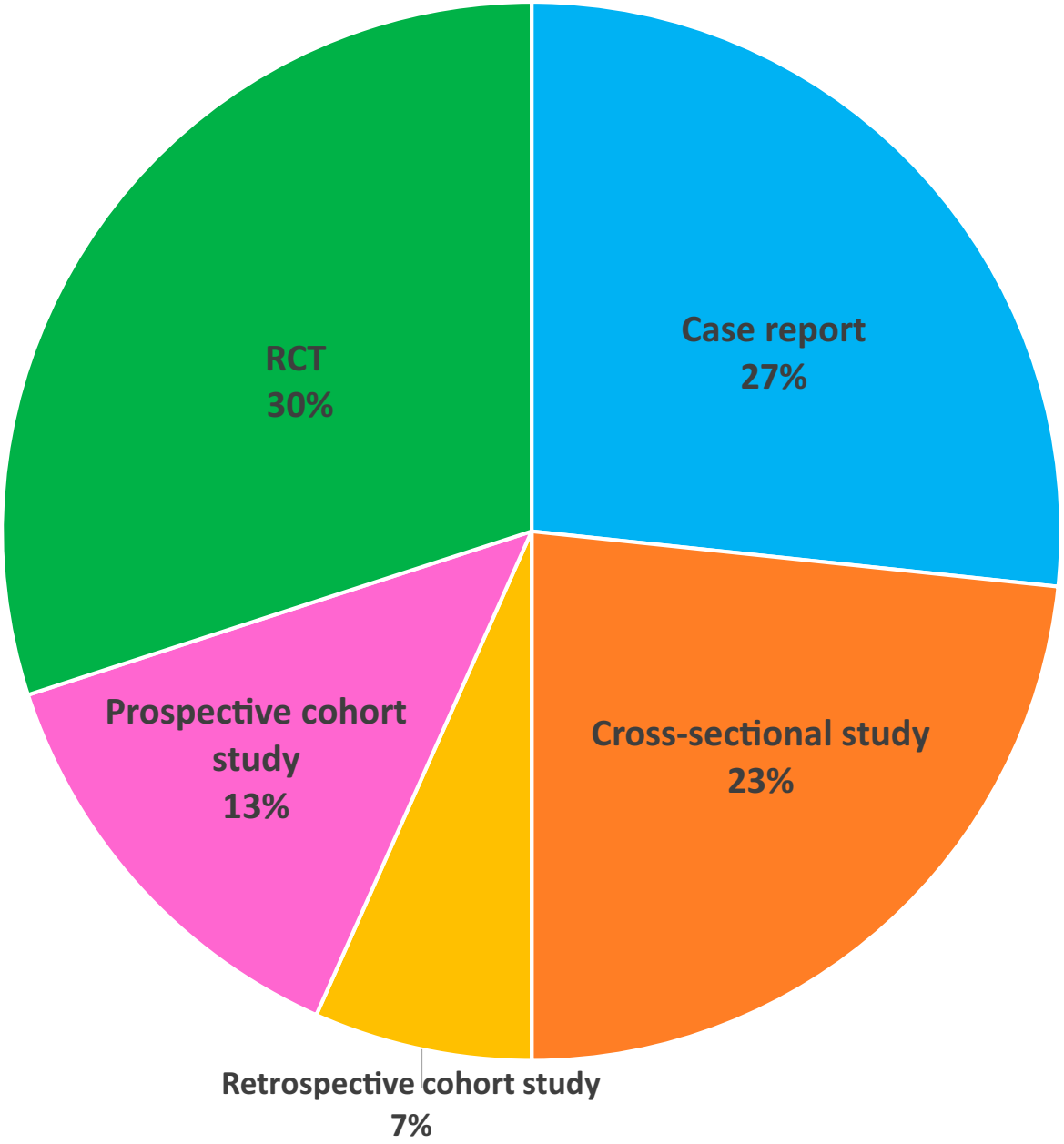

FIGURE 3
Relative abundance of type of study included in review.

Treatment Logistics, Efficacy and Safety

The techniques used to treat these dysfunctions and disorders included a wide variety of OMM treatment modalities (Table 2). Treatments were delivered in either a protocolized (14 of 30, 47% of studies) or nonprotocolized (16 of 30, 53%) manner by 1 (16 of 30, 53%) or multiple (14 of 30, 47%) osteopathic physicians (Table 2). Outcomes ranged from no effect to significant benefit of OMM on the basis of either qualitative or quantitative outcome measures (Table 3). Of the 30 studies analyzed, researchers in 13 reported the statistical analysis required to demonstrate statistically significant results. Previously validated and recognized scoring systems for collection of either quantitative or qualitative data were used in 30% (9 of 30) of the studies reviewed. In 1 study, researchers reported a participant with mild treatment-related aggravations that were self-resolved, requiring no interventions, and no additional treatment-related complications were reported.[26] No significant adverse events or deleterious effects associated with

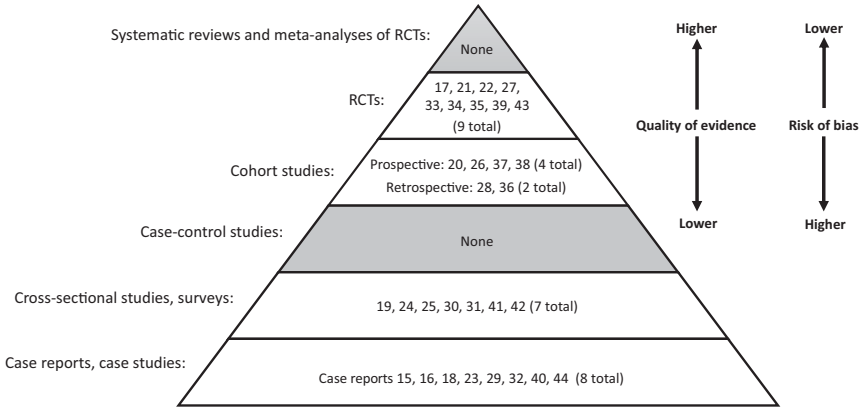

FIGURE 4
Hierarchy of data quality by type of study.

OMM were reported in any of the studies (Table 2), and many authors commented on the safety of OMM in their conclusions.

Strength of Evidence for Clinical Recommendations

We analyzed the methodologic quality of the research conducted and systematically graded the studies presented to assess the ability to make clinical recommendations based on those results. Twenty-one of the 30 studies reviewed received a final evaluation of weak evidence, with only 9 studies providing a strong level of evidence on which to make clinical recommendations. Among the RCTs, we identified 4 studies that were of high methodologic quality.[19,25,37,41] The strongest grades of research provided evidence of the benefit of OMM in regard to neurologic developmental disorders and otorhinolaryngologic disease prevention and treatment. Weak grades of research were prevalent for all other conditions included in this review. The majority of studies descriptively identify OMM as having a low risk to benefit ratio, but although none of the studies were specifically dedicated and powered to assess the safety of OMM.

DISCUSSION

Our aim with this systematic scoping review was to summarize and critically evaluate published osteopathic literature in the pediatric field to date. We conducted this review to (1) better understand the size and state of the most recent published literature on osteopathic practices in pediatrics, (2) assess the quality of RCTs to determine if adequate data has been collected, and (3) synthesize results to guide future research by identifying current literature gaps.

Thirty articles met our criteria and were included in the review. There was an upward trend in the number of articles published within the past 2 decades, with only 8 of the articles being published from 1960 to 2000 and the remaining 22 published between 2000 and September 2019. Although this may reflect the overall increasing number of journals and published medical literature, it may also reflect the growing number of practicing osteopaths. This may further corroborate the increasing demand for work to be done in the field, especially given the overall relatively small number of articles found to be reviewed in this article. Comprehensively, OMM for the treatment of musculoskeletal, neurologic, and otorhinolaryngologic disorders have been the most studied conditions in pediatrics to date.

Although the conducted research spanned all tiers of the hierarchical research pyramid, poor methodology of many of these studies and presence of potential biases significantly limited the quality of the evidence provided. As described in the 2006 study by Licciardione and Russo,[45] clinical outcomes can be heavily influenced by "the complex interaction of treatment credibility, subject expectations, and the influence of nonspecific treatment effects." This has inherently plagued osteopathic research because sham treatments have concern for a nonnegligible placebo effect with potential to artificially alter results.[45] A lack of both blinding and allocation concealment were noted in many

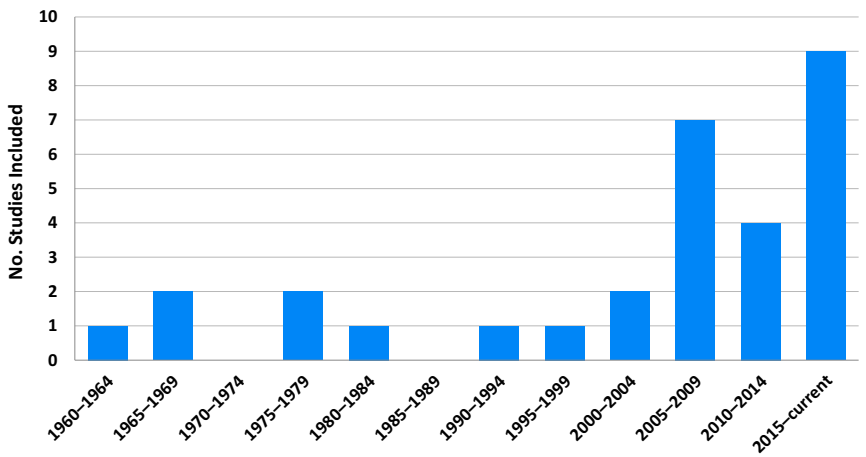

FIGURE 5
Studies included by year of publication.

TABLE 2 Description of Techniques Used, Treatment Parameters, and Adverse Effects Reported by Study

Reference	Type of Study	OMM Technique(s) Used as Experimental Intervention	No. Providers/ Protocolized Treatment	Adverse Events
Alexander[13]	CR	OCM, BLT, MFR, ME, MI	1/No	None reported
Apoznanski et al[14]	CR	OCM, BLT, MFR	1/No	None reported
Castillo et al[16]	CR	OCM, ME, AT, MFR	1/No	None reported
Feely and Kapraun[21]	CR	BLT, BMT, MFR, AT	1/No	None reported
Heineman[27]	CR	OMM techniques not specified	1/No	None reported
Lund et al[30]	CR	OMM techniques not specified	Multiple/no	None reported
Summers et al[38]	CR	OMM techniques not specified	1/No	None reported
Weatherly[42]	CR	MFR, AT, BLT, Inhibition, HVLA	1/No	None reported
Davis et al[17]	CSS	Confirmatory factor analysis	1/Yes	None reported
Frymann[22]	CSS	OMM techniques not specified	1/No	None reported
Frymann[23]	CSS	Structural examination, no treatment	Multiple/yes	None reported
Kaiser et al[28]	CSS	Structural examination, no treatment	Multiple/no	None reported
Lund and Carreiro[29]	CSS	Characteristics for disease classification, no treatment	Multiple/no	None reported
Upledger[39]	CSS	Examined with CST motion testing, no treatment techniques	1/Yes	None reported
Waddington et al[40]	CSS	Osteopathic screening for asymmetry and motion restriction, no treatment techniques	3/Yes	None reported
Hayes and Bezilla[26]	RCS	No limitation of techniques used	Multiple/no	Iatrogenesis from OMM relatively low, no treatment-related complications, treatment-associated aggravations self-resolved, did not need follow-up
Przekop et al[34]	RCS	MFR, HLVA, ME	Multiple/yes	None reported
Degenhard and Kuchera[18]	PCS	OCM, MFR	1/No	None reported
Frymann et al[24]	PCS	OMM techniques not specified	1/No	None reported
Purse[35]	PCS	Inhibition, lymphatic pump	1/Yes	15% had complications related to disease or anesthesia, none were OMM-related
Purse[36]	PCS	Inhibition, lymphatic pump	1/Yes	17% (reported as 5%) had complications related to disease, none were OMM-related
Belcastro et al[15]	RCT	Rib-raising, MFR	1/Yes	None reported
Duncan et al[19]	RCT	CST, MFR	3/Yes	None reported
Duncan et al[20]	RCT	CST, MFR	3/Yes	None reported
Guiney et al[25]	RCT	Rib raising, ME, MFR	Multiple/yes	None reported
Mills et al[31]	RCT	AT, MFR, BMT	4/Yes	None reported
Nemett et al[32]	RCT	MPT-OA, BLT, BMT	Multiple/no	None reported
Noto-Bell et al[33]	RCT	ME	1/Yes	None reported
Steele et al[37]	RCT	BLT, MFR, OCM	7/Yes	None reported
Wahl et al[41]	RCT	OCM, BMT, BLT, MFR	Multiple/no	None reported

AT, articulatory technique; BLT, balanced ligamentous tension; BMT, balanced membranous tension; CCS, case-control study; CR, case report; CS, cohort study; CSA, cross-sectional analysis; CSS, Concussion Symptom Score; CST, craniosacral technique; HVLA, high velocity low amplitude; MFR, myofascial release; ME, muscle energy; MI, muscle inhibition; MPT-OA, manual physical therapy based on osteopathic approach; OCM, osteopathic cranial manipulation; RR, retrospective review.

studies, which lends to a high potential for expectation and retrospective biases.[45] Furthermore, a protocolized treatment approach was used in less than half of the studies, which contributed to the rating of low research quality given low likelihood of reproducibility. This highlights a continued paucity of high-quality scientific research available for clinicians to make evidence-based clinical recommendations when treating children. In addition, it perpetuates the lack of support for OMM use in the pediatric clinical setting.

Overall, the majority of studies included in this review provided weak evidence to support the use of OMM. Only one-third of the studies were RCTs, and furthermore, only half of these provided data of high enough caliber to make isolated recommendations based on clinical evidence. As concluded by Podazski et al,[6] there is not currently an indication for which the effectiveness of OMM has been shown consistently enough to make strong clinical recommendations for any particular condition. Given this, OMM has not been studied well enough to be

TABLE 3 Demographics, Measures, Outcomes, Strengths, Limitations, and Overall Grade of Evidence by Study Included

Reference	*n*/Characteristics of Participants/Age or Age Range/Sex	Control Intervention	Primary Outcome Measures	Main Outcomes and Author's Conclusions	Overall Strengths of Study	Overall Limitations of Study	Final Grade	Recommendation Level
Alexander[13]	1/NPDH/15 y/female	N/A	Report of pain on Likert scale	Promising approach in using manual treatments for managing NDPH, given improved pain and ROM	Discusses specific somatic dysfunctions addressed and treatment targets	Subjective bias, no blinding, cannot rule out spontaneous resolution of treatment or imply causality	Low	Weak
Apoznanski et al[14]	1/Dacryostenosis/9 mo/male	N/A	Reported symptoms per mother, need for other interventions	OMM has the potential to be conservative first-line treatment given resolution of symptoms, may decrease the need for antibiotics and invasive procedures, additional research needed	Hypothesis and treatment choice rooted in detailed underlying pathophysiology and anatomy, thorough physical examination, workup, and trial of SOC before treatment	Subjective bias, no blinding, cannot rule out spontaneous resolution of treatment or imply causality, significant burden of treatment duration required	Low	Weak
Belcastro et al[15]	12/bronchiolitis/ 2–11 mo/male, female	Postural drainage, Bronkosol, or normal saline	Mean hospital stay, signs of respiratory distress	Too few patients to draw conclusions, but established a research protocol	Sound study methodology, randomized trial, blinded when possible	Small study population, not entirely blinded	Moderate	Weak
Castillo et al[16]	1/concussion/1 5 y/ female	N/A	CSS assessment, BESS to determine the degree of vestibular dysfunction, ability to perform ADLs	OMM as part of a multidisciplinary approach to concussion can help quicken recovery and improve quality of life, further research needed	Validated objective measuring tools to assess objective and subjective clinical data, robust description of SD and techniques, wide variety of OMM techniques used	Small population, nonblinded, cannot rule out spontaneous resolution, CSS after treatment remained in clinically significantly altered range	Low	Weak
Davis et al[17]	57/severe spastic CP/0–12 y/male, female	NA	Relationships between fascial and spinal motion restrictions, spasticity	Fascial and spinal motion restrictions may be correlated with VAS rating of child's muscle spasticity	Robust statistical analysis, sound methodology, empirical data showing factorial validity of several osteopathic concepts and the relationships between them	Small population, missing data imputed with multiple regression, data potentially not able to be extrapolated to other populations	High	Strong
Degenhard and Kuchera[18]	8/recurrent AOM/ 7–35 mo/male, female	None	Assessment of recurrence of AOM 1 y after OMM	OMM may change the progression of recurrent AOM, overall should decrease the number of episodes, more research needed	Thorough case descriptions, long-term follow-up after treatment with no LTF subjects, comprehensive subjective and objective data included	Small population, poorly defined diagnostic criteria, limited documentation, bias of sample base, anecdotal data subject to recall bias, nonblinded	Low	Weak
Duncan et al[19]	55/moderate-severe spastic CP/20 mo to 12 y/male, female	Nontherapeutic play time (to control for effect of attention) in addition to SOC	GMFCS, GMFM total percentage, PEDI mobility, PEDI self-care, WeeFIM mobility,	Improved motor function in children with moderate-severe spastic CP with OMM versus acupuncture	Tri-armed, single-blind, randomized wait-list control, pediatric neurologist confirmed	Small population, imputation used for missing data, suboptimal compliance in control group, high drop-	High	Strong

TABLE 3 Continued

Reference	*n*/Characteristics of Participants/Age or Age Range/Sex	Control Intervention	Primary Outcome Measures	Main Outcomes and Author's Conclusions	Overall Strengths of Study	Overall Limitations of Study	Final Grade	Recommendation Level
			WeeFIM self-care scores		diagnosis, solid randomization, SOC maintained throughout with no adjuvant therapies, single-blind, good interobserver reliability, no statistically significant differences for baseline group characteristics	out rate (especially in most severe patients), few patients in the age range with reported largest treatment effect, potential for biased sample population		
Duncan et al[20]	69 subjects/ moderate-severe spastic CP/11 mo to 12 y/ male, female	Nontherapeutic play time (to control for effect of attention) in addition to SOC	Qualitative data collection via open ended question and VAS to assess symptoms	OMM or acupuncture, either individually or in combination, in addition to SOC, will decrease the degree of muscle tone and/ or improve function and QoL in children with spastic CP	SOC maintained throughout, head to head qualitative and quantitative analysis of complementary interventions	Very small population, subjective bias of parental responses, poor study design or ability to crossover between treatment arms, unknown if results are statistically significant, unclear randomization technique	Moderate	Weak
Feely and Kapraun[21]	1/infantile scoliosis/ 14 mo/female	NA	Radiologic measurement of the rib vertebral angle difference	OMM can dramatically improve infantile idiopathic scoliosis and prevent its progression	Theory of treatment approach supported by anatomic pathophysiology of condition, significant long-term follow-up	Very small population, cannot rule out spontaneous resolution, many confounding variables, cannot imply causation, nonblinded	Very Low	Weak
Frymann[22]	209/routine outpatient pediatric patients/18 mo to 12 y/male, female	NA	Differences in birth and early development in kids with and without learning difficulties, traumatic patterns in craniosacral mechanism in kids w/ learning disabilities	No specific trauma patterns correlated to learning disabilities, critical period of susceptibility <2 y, OMM more effective in younger patients	Moderate population size, comprehensive baseline data on cranial strain patterns and newborn data, standardized assessment of patients	No blinding, treatment modalities are not described	Moderate	Weak
Frymann[23]	1250/newborns/0–5 d/male, female	NA	Prevalence of strain patterns in infants	Certain nonphysiologic strain patterns in the developmental portions of the occiput may be implicated in the production of nervous altered nervous and respiratory and circulatory symptoms	Large population, comprehensive labor history obtained, robust vol of data obtained	Inconclusive clinical and long-term significance of findings, unclear interphysician reliability	Low	Weak
Frymann et al[24]	186/general outpatient	Watchful observation	Houle's Profile of Development for	Support for OMM to help improve sensorimotor	Sound quantitative descriptive data,	Only partially blinded, inappropriate	Moderate	Strong

TABLE 3 Continued

Reference	*n*/Characteristics of Participants/Age or Age Range/Sex	Control Intervention	Primary Outcome Measures	Main Outcomes and Author's Conclusions	Overall Strengths of Study	Overall Limitations of Study	Final Grade	Recommendation Level
	pediatrics, with and without neurologic deficits/18 mo to 12 y/male, female		neurologic assessment	performance in children with neurologic deficits	repeated measures design, blinding to coinvestigators, well-matched group baseline characteristics	randomization technique, large treatment group drop-out rate		
Guiney et al[25]	140/asthma/5–17 y/male, female	Sham treatment	Peak expiratory flow	OMM has a therapeutic effect on respiratory status in pediatric asthma patient, more clinical trials are required	Highest level of evidence (RCT), no subjects had LTF	OMM experience varied among practitioners, small population size, randomization was based on a 2:1 ratio, single blind only, did not assess full pulmonary function testing, single treatment without LTF	High	Strong
Hayes and Bezilla[26]	346/gen peds/0–18 y/male, female	No control	Treatment-associated complications, aggravations	OMM appears to be a safe treatment modality in the pediatric population when administered by physicians with OMM expertise	Large number of patient encounters, diverse patient population, varied levels of physician experience	Subjective and recall bias, many patients excluded from analysis because of LTF, difficult to assess causation, nonblinded, spectrum of length of practice	Moderate	Weak
Heineman[27]	1/headache/10 y/female	NA	Resolution of symptoms	Consider OMM as a safe and cost-effective option for conservative management of secondary pediatric headache	Detailed SD findings with anatomic correlates are described	Cannot rule out spontaneous resolution, vague, unreproducible methodology, no LTF	Low	Weak
Kaiser et al[28]	537/gen peds/0–21 y/male, female	NA	Patient population demographics and diagnostic characteristics	Descriptive data of population and diagnoses to provide understanding of potential role of OMM as an adjunctive medical therapy	Large sample, descriptive data collected, multilevel provider data, longer duration, robust statistical analysis	Single-site specialty clinic; low number young patients, disproportionate age distribution, sampling bias (insured)	Moderate	Strong
Lund and Carreiro[29]	407/gen peds/0–18 y/male, female	NA	Patient population demographics and diagnostic characteristics	Descriptive data on provided on common indications for OMM in the pediatric population to be used for clinical acumen, research agenda, and curriculum development	Dual clinic sites, large number of clinic visits	Retrospective bias, unclear diagnostic criteria, minimal patient demographic data obtained	Moderate	Strong
Lund et al[30]	2/premature infants/25 wk gestational age/female, female	N/A	Feeding tolerance, wt gain, avoidance of surgical intervention	OMM may improve nipple feeding, more research required	OMM physicians separate from medical decision-makers	Small sample (2), twins, vague or unreproducible methodology, no significant LTF, limited focus of results	Very Low	Weak
Mills et al[31]		SOC					Moderate	Weak

TABLE 3 Continued

Reference	*n*/Characteristics of Participants/Age or Age Range/Sex	Control Intervention	Primary Outcome Measures	Main Outcomes and Author's Conclusions	Overall Strengths of Study	Overall Limitations of Study	Final Grade	Recommendation Level
	57/AOM/6 mo to 6 y/male, female		Frequency of AOM episodes, antibiotic use, surgical interventions, behaviors, audiometric performance	OMM has potential benefit as adjuvant therapy in recurrent AOM; may prevent or decrease surgical intervention or antibiotic overuse	Multisite, randomized and controlled adequately, both objective and subjective data obtained, powered appropriately, robust statistics	Single blind only, subjective bias, lack of allocation concealment		
Nemett et al[32]	32/refractory dysfunctional voiding patients/4–11 y/male, female	SOC	Vesicoureteral reflux and postvoid urine residuals	Improvement or resolution of dysfunctional voiding symptoms more prominent in the treatment group	Multisite, prospective, randomized, controlled study with sound methodology, diagnostic reliability, reproducible logistics	Small population, lack of LTF, high attrition rate (but similar between groups), difference in assessment between control and intervention group disproportionate sample of disease severity	Moderate	Weak
Noto-Bell et al[33]	55/swimmers/8–17 y/male, female	Control and sham	ROM, flutter kick speed	Single application of ME by using postisometric relaxation increased ROM but did not immediately improve their swimming performance	Objective data measurements, randomized with comparison with both sham and no intervention	Sampling bias error, no provider blinding, small population, no LTF, significant performance variability as potential confounder, single treatment	Moderate	Weak
Przekop et al[34]	83/adolescent headache/13–18 y/male, female	SOC of pharmacologic treatment	Headache frequency, pain intensity, general health, health interference, tender points	Multimodal treatment group had better improvement in headache frequency, general health, and number of tender points	All diagnoses made by subspecialist using standardized criteria, extremely similar between-group characteristics, few missing data	OMM was not evaluated separately, retrospective bias, insurance limited treatments, small population, nonblinded, selection bias, detection bias, prone to confirmation bias	Moderate	Weak
Purse[35]	204/patients with measles/1–12 y/male, female	No control group	Bacterial complication rates after measles infection	Claims OMM to be considered of distinct value in the prevention of bacterial complications of measles	Significant long-term follow-up, low drop-out rate, large population	Nonblinded, nonrandomized, low patient diversity, minimal statistical analysis	Low	Weak
Purse[36]	100/children with URI/1–18 y/male, female	No intervention	Rate of complications with URI	Restricted upper cervical motion correlated with AOM; restricted thoracic motion correlated with acute bronchitis or acute bronchial pneumonia; ability to relieve restriction correlated with no or fewer complications, allergies not	Techniques are described systematically and would be reproducible, systematic methodology, standardized treatment protocols, significant LTF	Retrospective, nonblinded, nonrandomized, noncontrolled, limited demographic data, minimal statistical analysis	Low	Weak

TABLE 3 Continued

Reference	*n*/Characteristics of Participants/Age or Age Range/Sex	Control Intervention	Primary Outcome Measures	Main Outcomes and Author's Conclusions	Overall Strengths of Study	Overall Limitations of Study	Final Grade	Recommendation Level
				correlated with number of URI or complications				
Steele et al[37]	52/AOM/6 mo to 2 y/male, female	SOC	Tympanometric and acoustic reflectometer data, duration of middle ear effusion	Standardized OMM protocol administered adjunctively with SOC may result in faster resolution of middle ear effusion after AOM than SOC alone	Dual-site, prospective, sound randomization strategy, partial blinding, SOC control group; diverse patient population, objective instrument data, replicable protocol, no significant intergroup differences	Partial blinding, small population, no standardized scale for subjective data, potentially biased sample population, not insignificant drop-out rate	Moderate	Strong
Summers et al[38]	1/Pierre-Robin Sequence/15 d/male	NA	Subjective improvement in feedings, wt gain	OMM can be used in multidisciplinary approach to help alleviate difficulties with breathing, latch, and suckling	Novel description, used proven physiologic principles to support treatment	No objective measures besides wt gain, potentially a tincture of time, small population	Very Low	Weak
Upledger[39]	203/grade schoolchildren/male, female	NA	CST motion restriction, learning difficulties, behavior problems, coordination deficits	Positive relationship between CST motion restriction and behavioral problems and/or learning disabilities, and motion coordination problems; additional association between CST restriction and complicated delivery	Standardized examination with verified interexaminer agreement and objective third party assistance, specific sequence and objective measure of motion variables	Only partial blinding, potentially biased sample population, unreliable or potentially confounding medical history, no α levels given	Moderate	Weak
Waddington et al[40]	100/newborns/6–72 h/male, female	NA	SDSS	Cranial, cervical, lumbar, and sacral region SD common in healthy newborns; total SDSS related to the length of labor	All assessing physicians shared a very similar palpatory assessment style, great baseline data never before assessed, very thorough and standardized examination	Some significantly differing assessments between examiners, inherent subjectivity of physical examination, potential for significant changes >6hrs after delivery, potentially excluded most severe SD from analysis	Moderate	Strong
Wahl et al[41]	90/recurrent AOM/12–60 mo/male, female	4 protocol groups: double placebo, echinacea plus sham OMM, true OMM plus placebo echinacea, true echinacea plus OMM	Episodes of AOM	A regimen of up to 5 OMM treatments does not significantly decrease the risk of AOM	Strong randomization technique, 4 protocolized groups, 2-by-2 factorial analysis, significant treatment duration and LTF, significant patient diversity, small drop-out rate; strong blinding techniques	Unclear diagnostic criteria, small population, did not reach statistical power, poor compliance with OMM treatment and LTF, significant differences between study group demographics	High	Strong
Weatherly[42]		NA					Low	Weak

TABLE 3 Continued

Reference	*n*/Characteristics of Participants/Age or Age Range/Sex	Control Intervention	Primary Outcome Measures	Main Outcomes and Author's Conclusions	Overall Strengths of Study	Overall Limitations of Study	Final Grade	Recommendation Level
	1/scoliosis/10 y/female		Improvement in flexibility, Cobb angle measurement	Inconclusive; OMM may be of utility as adjuvant therapy to decrease or prevent progression of curvature of scoliosis, more research needed	Theory of treatment approach supported by anatomic pathophysiology of condition	Small population, subjective bias, unable to assess correlation and causation and anecdotal and subjective evidence, confirmation bias, lack of blind, verification bias		

ADL, activities of daily living; AOM, otitis media; AT, articulatory techniques; BESS, Balanced Error Scoring System; BLT, balanced ligamentous tension; BMT, balanced membranous tension; CP, cerebral palsy; CSS, Concussion Symptom Score; CST, craniosacral technique; gen peds, general pediatrics; GMFCS, Gross Motor Function Classification System; GMFM, Gross Motor Function Measure; HVLA, high velocity low amplitude; LTF, long-term follow-up; ME, muscle energy; MFR, myofascial release; MI, muscle inhibition; MPT-OA, manual physical therapy based on osteopathic approach; N/A, not applicable; NDPH, new daily persistent headache; OCM, osteopathic cranial manipulation; PEDI, Pediatric Evaluation of Disability Inventory; QoL, quality of life; ROM, range of motion; SD, somatic dysfunction; SDSS, somatic dysfunction severity score; SOC, standard of care; WeeFIM, Functional Independence Measure for Children; URI, upper respiratory infection; VAS, visual analog scale.

actively recommended, but it appears to be generally safe, with no adverse events reported in any of the included studies. By using a similar format as proposed by Klein et al, currently, OMM can be medically tolerated (Table 4), but dedicated, large population, multi-institutional RCTs will be required to investigate the safety, efficacy, and feasibility of OMM as a recommended adjunctive treatment modality.[46] Once the safety of OMM practices is established for certain conditions and in specific populations, the efficacy can be further evaluated, and the feasibility of incorporating treatment into practice can be established.

It is our hope that this scoping review provides a framework for future research studies in the osteopathic pediatric literature, to optimally provide the best care for children. Given the identified issues, we suggest the following 3 recommendations for future investigation regarding pediatric osteopathic research in the United States:

- An increase in the volume of research conducted in the field to support evidence-based practice. In the Sicily statement by Dawes et al,[47] "Evidence-based practice requires that decisions about health care are based on the best available, current, valid and relevant evidence. These decisions should be made by those receiving care, informed by the tacit and explicit knowledge of those providing care, within the context of available resources." By assessing the studies conducted to date, a minimal number of strong recommendations are able to be made, but solid baseline knowledge can be gleaned and a framework for conducting future research studies can be recommended.

TABLE 4 Clinical Decision-Making Giving Information Available Regarding Safety Versus Efficacy for Use of Novel Treatment Modalities

		Effective	
		Yes	No or unknown
Safe	Yes	Recommend	Tolerate
	No	Monitor	Avoid

- Future RCTs conducted must be of strongly graded methodologic quality with adherence to the Consolidated Standards of Reporting Trials statement.[48] Effective, high-quality research must be ascertained to propel the field of osteopathic medicine forward in an increasingly evidence-based world. The standardized process in which research is conducted needs to be upheld without denigrating the pillars of osteopathic practice. To remedy this, we suggest that osteopathic studies be conducted similar to procedural and surgical trials to conduct mixed methodology, prospective, controlled, sufficiently powered studies. Researchers of these studies should first assess feasibility and safety of OMM within a certain patient population. These data could then be used to assess efficacy and then subsequently compare with an active control in a large-scale study to assess benefit.
- Researchers examining OMM must increase their use of evidence-based treatments as comparison or control groups in their research. These research efforts should focus on pediatric osteopathic practices most often delivered, yet understudied, such as treatments of musculoskeletal disorders, common pediatric otorhinolaryngologic diseases, and the use of osteopathic cranial manipulation. Longitudinal, multimodal studies of factorial design proving the benefit of the addition of OMM into the current standard of treatment will be necessary to garner widespread acceptance for integration.

LIMITATIONS

This scoping review has several limitations that should be considered when interpreting these results. First, although our search was extensive, we cannot be certain that all pediatric osteopathic literature was identified. However, to address this, we searched 10 comprehensive databases with guidance from librarian experts. Second, we were only able to include articles in the English language because of limited resources for translational purposes. Given the difference in practice rights between US-trained osteopathic physicians who are trained medical doctors with additional training in musculoskeletal medicine versus European osteopaths who are solely trained in musculoskeletal medicine, we purposefully narrowed our data set to include only US-based studies. By doing so, the scope of practice and the medical training of the treating physicians were presumed to be standardized and allowed the data presented to be extrapolated to the patient population for which we intend to make clinical recommendations. Although minimal inconsistencies in grading the level of evidence of these studies were encountered, attempts were made to negate discrepancies by using 2 independent, blinded reviewers and an additional reviewer to clarify any incongruities.

CONCLUSIONS

Although we identified an increasing number of published pediatric osteopathic research studies, there continues to be a paucity of high-quality, methodologically sound literature supporting OMM effectiveness in this population. Based on this, strong clinical recommendations cannot be made at this time, but OMM can be medically tolerated given its low risk profile. More robust, scientifically rigorous studies must be conducted to guide evidence-based recommendations regarding osteopathic medicine and its use as an adjunctive therapy. Osteopathic physicians should focus future research on RCTs for common pediatric conditions to begin investigating efficacy and move the pediatric osteopathic research field forward.

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ABBREVIATIONS

CAM: complementary or alternative medicine
CINAHL: Cumulative Index to Nursing and Allied Health Literature
D.O.: Doctor of Osteopathic Medicine
JAOA: Journal of the American Osteopathic Association
OMM: osteopathic manipulative medicine
PRISMA: Preferred Reporting Items for Systematic Reviews and Meta-Analyses
RCT: randomized controlled trial

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