

THE CHIROPRACTIC CARE OF INFANTS WITH COLIC: A SYSTEMATIC REVIEW OF THE LITERATURE

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Purpose: To perform a systematic review of the literature on the chiropractic care of patients with infantile colic.

Methods: The following databases were interrogated: MANTIS [1965-2010]; Pubmed [1966-2010]; Index to Chiropractic Literature [1984-2010]; EMBASE [1974-2010]; AMED [1967-2010]; CINAHL [1964-2010]; Alt-Health Watch [1965-2010], and PsychINFO [1965-2010]. Inclusion criteria were manuscripts addressing the chiropractic care of infantile colic published in the English language.

Results: Our systematic review of the literature revealed 26 articles meeting our inclusion criteria. These consisted of three clinical trials, two survey studies, six case reports, two case series,

four cohort studies, five commentaries, and four reviews of the literature. Our findings reveal that chiropractic care is a viable alternative to the care of infantile colic and congruent with evidence-based practice, particularly when one considers that medical care options are no better than placebo or have associated adverse events.

Conclusions: Chiropractic care is an alternative approach to the care of the child with colic. We encourage more research, both quantitative and qualitative, in this area of pediatric care.

Key words: chiropractic, infantile colic

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INTRODUCTION

A common definition of colic comes from Wessel and colleagues¹ "rule of 3": "crying during at least three hours per day on at least three days of at least three weeks . . ." There are other definitions of colic but common to all is excessive crying on the part of an infant that causes a great deal of distress, particularly for first-time parents. The occurrence of infantile colic in the population varies and ranges from 10% to 40% depending on the study methodology, the population, and the definition of infantile colic used.²⁻⁵ Excessive crying in infants is a serious problem and has negative consequences for both the parents and their child. Levitzky and Cooper⁶ found mothers experiencing both physical and psychological symptoms in response to their infant's colic. Thoughts and fantasies of aggression and even infanticide occurred at times during their infant's colic episodes. Abuse is a concern in these situations such as slapping, hitting, or shaking the baby.^{7,8} Not surprisingly, marital tension and social disruption within the family and poor sleeping habits and frequent temper tantrums on the part of the child were reported, even well past the course of the child's colic symptoms.^{9,10} Our review of the literature indicates that medical interventions are generally ineffective, and that the potential for

harm from pharmaceutical interventions motivates parents to seek alternative care approaches.^{11,12} Of the practitioner-based alternative therapies, chiropractic is the most popular for children.¹³ In the care of infants with colic, the chiropractor has a significant role to play with direct hands-on chiropractic care (i.e., chiropractic spinal manipulative therapy [SMT] and adjunctive therapies) as well as in the role of health educator and parent counselor. In the interest of and to inform evidence-based practice, we performed a systematic review of the literature on the chiropractic care of children with infantile colic.

METHODS

We performed a systematic review of the literature using the following databases: MANTIS [1965-2010], Pubmed [1966-2010], Index to Chiropractic Literature [1984-2010], EMBASE [1974-2010], AMED [1967-2010], CINAHL [1964-2010], Alt-Health Watch [1965-2010], and PsychINFO [1965-2010]. The authors independently reviewed the title and abstracts of all articles generated from the electronic database search, from the reference lists of relevant articles and other data sources subsequently retrieved. The full manuscript of reports relevant to the chiropractic care of children with colic were retrieved by applying the following eligibility criteria: (1) The manuscript was of a primary investigation/report (ie, case reports, case series, case control, randomized controlled trials (RCTs), and survey or surveillance studies) published in a peer-reviewed journal in the English language; (2) part or all of the study population involved patients 18 years or younger; and (3) the topic involved the chiropractic care of a patient with colic. Key words used were colic, infantile colic, cry baby, excessive crying, and related words as appropriate in the context of chiropractic care incorporating the Boolean operators (ie, AND, NOT, and OR). Additionally, chiropractic journals (ie, *Journal of Manipulative and*

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Physiological Therapeutics, Journal of the Canadian Chiropractic Association, Clinical Chiropractic, The Chiropractic Journal of Australia, and the *Journal of Clinical Chiropractic Pediatrics*) were hand searched for the last five years for possible relevant materials. The gray literature was also searched as well as the bibliography lists of all retrieved articles and relevant studies.

The authors independently extracted data using a structured form. The key data extracted were: type of publication (ie, case report, RCTs, etc), subject characteristics (ie, age and gender), diagnosis, type of SMT/technique employed, as well as findings of interest (ie, outcome). Any discrepancies between reviewers with respect to the extracted data were discussed and resolved by referring to the original report. The information gathered forms the basis of our narrative review.

RESULTS

Our systematic review of the literature revealed 26 articles meeting our inclusion criteria. These consisted of three clinical trials,¹⁴⁻¹⁶ two survey studies,^{17,18} six case reports,¹⁹⁻²⁴ two case series,^{25,26} four cohort studies,²⁷⁻³⁰ five commentaries,³¹⁻³⁵ and four reviews of the literature.³⁶⁻³⁹

The clinical trials on infantile colic with chiropractic SMT involved the following. In a randomized clinical trial, Wiberg et al¹⁴ examined the response of subjects under chiropractic care (N = 25) versus those given dimethicone (N = 16), a commonly prescribed medication for colic. Based on parental daily diary for hours of crying, the subjects in the chiropractic group did significantly better. Olafsdottir et al¹⁵ examined subjects randomized to a chiropractic SMT group (N = 46) versus a no-treatment group (N = 40). The parents were blinded to the type of care their child received and in addition to a daily diary of hours of crying, they were asked to rate their child's response to care as "getting worse," "no improvement," "some improvement," "marked improvement," and "completely well." Essentially, the investigators found the subjects in both groups responded similarly leading Olafsdottir et al¹⁵ to conclude that, "Chiropractic SMT is no more effective than placebo in the treatment of infantile colic." Browning et al,¹⁶ in a randomized clinical trial, examined the response of subjects to chiropractic SMT (N = 22) versus occipitosacral decompression treatment (N = 21). The children were crying an average of more than three hours per day for at least four of the last seven days. By the end of the first week of the trial, the average number of hours of crying was reduced by an average of 2.1 hours/day in the SMT group and 2.0 hours/day in the occipitosacral decompression group. By the end of two weeks, the number of hours of sleep had increased in both groups: 1.7 hours/day in the SMT group and 1.0 hours/day in the occipitosacral decompression group. Four weeks after initiation of the study, 82% of the SMT group, and 67% of the occipitosacral decompression group had resolved colic.

One of the first to document in the peer-reviewed literature on the possible effectiveness of chiropractic care in infantile colic was Nilsson.¹⁷ In a retrospective uncontrolled questionnaire, Nilsson examined the presenting complaints, number of visits, change in patient symptoms, and number of days required to achieve positive changes in children presenting to multiple chiropractic practices (N = 10). Based on the response of 189 of 200

parents, the most popular presenting complaint was colic (N = 132). A majority of the parents indicated perceived effectiveness on the part of chiropractic with 70 of the 189 deemed "cured" while 48 improved and 12 were reported as "unchanged." No child was reported as "worse" with chiropractic care. Hestbaek et al,¹⁸ in a survey of chiropractic clinics in Denmark to characterize the care of patients 18 years or younger, found that babies 0 to 4 months of age were the most common pediatric patients and infantile colic was the most common presenting complaint.

With respect to case reports, Pluhar and Schobert¹⁹ described the care of a 3-month-old female suffering from colic in addition to sleep interruption and poor appetite. The patient was medically diagnosed and prescribed Levsin and Semithicone, which provided only temporary effectiveness. Following a trial of full-spine chiropractic adjustments, the patient's symptoms improved based on direct observation and parental reports. Cuhell²⁰ described the care of a 12-day-old male with colic and excessive intestinal gas. An initial trial of chiropractic care resulted in limited success. The addition of nutritional supplementation and continued chiropractic care resulted in resolution of the child's symptoms. Van Loon²¹ presented the care of a three-month-old male with medically diagnosed colic. Medical care consisted of change in his infant formula to a soy-based formula followed by a change to evaporated milk with water and finally to corn syrup and boiled water with no improvement. The patient's crying became so severe that his mother presented him to an emergency facility on two consecutive days. Blood work and chest X-ray examination were unremarkable and a prescription of Pedialyte was not helpful. The patient received chiropractic adjustments along with craniosacral therapy with positive outcomes. Killinger and Azad²² presented the care of an 11-month-old male with severe, complicated, late onset infantile colic. At 5½ months of age, lancing was performed to facilitate dentition. Following surgery, the patient began to develop severe digestive problems, severe constipation, developmental delays, and restless sleep. Upper cervical specific chiropractic adjustments directed at the atlas resulted in positive outcomes. Sheader²³ described the care of an infant with symptoms of colic and breastfeeding difficulties. The patient presented with a rash, excessive crying, shaking, screaming, and vomiting during and after feeding. Commercial baby formulas were tried but were unsuccessful and resulted in constipation. The formula Nutramigen was prescribed resulting only in a mild rash, but the crying, shaking, and screaming continued. The patient responded positively to chiropractic adjustments focused to the upper cervical spine. Hewitt²⁴ described the care of an eight-week-old female described by her mother as a "fussy, high maintenance" baby. The child suffered from increased gas, difficulty falling asleep, and a strong preference for nursing on the right breast. Chiropractic examination revealed cervical spine and cranial dysfunctions. Care provided utilized Diversified Technique and cranial therapy. Following five visits over a three-week period, the infant no longer was irritable, went to sleep easily, was able to turn her head more fully to the right, and nursed well on both breasts. Long-term follow-up six months later revealed the child with continued good health.

Leach²⁵ described in a case series presentation the care of two infants with pediatrician-diagnosed infantile colic. The interven-

tion was the PulStar Function Recording and Analysis System device (PulStar FRAS, Sense Technology, Inc, Pittsburgh, PA) that administered low force impulses (ie, approximately 3-4 lbs. of force) at each segmental level of spinal dysfunction. Crying was reduced by 50% after a single session of instrumental adjusting in a six-week-old girl and after four sessions in a nine-week-old boy, based on colic diaries maintained by their mothers. The average number of hours of uninterrupted daily sleep increased from 3.5 hours to 6.5 hours after a single session. Within 10 days of care, the symptoms of colic resolved and average total daily sleep improved to 14.5 hours. At 30-day follow-up, the results were maintained. Hipperson²⁶ described the care of a seven-week-old and 10-week-old males medically diagnosed with colic. Upper cervical, mid-thoracic, sacroiliac, and cranial dysfunctions were present in both patients. Each infant received Diversified Technique SMT along with cranial therapy to areas of spinal and cranial dysfunctions. Treatment specific to each child was provided over a three-week period with complete resolution of all presenting symptoms.

With respect to cohort studies, Klougart et al²⁷ examined 316 infants (average age = 3.6 weeks) with colic cared for by 73 chiropractors located in 53 clinics. A total of three visits were attended over a two-week period. The infants' parents were asked to maintain daily diaries noting the number of hours of crying as well as estimates of symptom improvement. The average number of daily hours of crying over two days before treatment (retrospective estimate) was 5.2 hours. At day 1, the average number of hours of daily crying was 2.5 hours. By day 14, the average hours of daily crying was 0.65 hours, a 74% reduction in daily hours of crying from baseline. Six percent of the patients reported no change or worse, whereas 34% improved and 60% reported resolution of colic symptoms. Wiberg et al²⁸ presented data correlating colic with a faster and therefore possibly a more forceful delivery in infants with colic. From 40 of 45 mothers of infants with colic, the mean duration of birth was estimated at 9.7 hours. In a group of 22 mothers of infants without any colic symptoms, the mean duration of birth was estimated at 14.3 hours. A two-tailed unpaired Student *t*-test comparison indicated a faster birth process in the colic group, with a statistical significance at $P < .05$. Vestager et al²⁹ published similar findings from hospital data. Infants diagnosed with colic had a statistically significant shorter second phase of birth compared to infants in a control group. Miller and Phillips,³⁰ performed a retrospective file review of colicky children receiving care at a chiropractic clinic ($N = 117$) and those not receiving chiropractic care ($N = 111$) from a child care center in similar region of England. The investigators found that children in the chiropractic group were twice as likely to not experience long-term sequelae of infant colic, such as temper tantrums, and frequent nocturnal waking, when compared to the control group.

Wiberg³¹ provided a commentary on the effectiveness of chiropractic care based on the clinical trials by Wiberg et al¹⁴ and Olafsdottir et al¹⁵ along with a clinical trial by Mercer and Nook⁴⁰ published in abstract form in a conference proceeding. According to Wiberg,³¹ with respect to the subjects' age, all the trials accounted for the natural history in that half of the subjects ceased to cry after three months. The participants ranged in age from 0 to 10 months. With respect to the diagnosis of colic,

Mercer and Nook⁴⁰ allowed a pediatrician to make the diagnosis. The Wiberg and Olafsdottir trials^{14,15} had similar inclusion criteria with respect to hours of crying, etc. With respect to blinding, the parents in the Olafsdottir study¹⁵ were ideally blinded with the parents not knowing what type of care their child received. Given that dimethicone has been shown to be no better than placebo,^{9,41,42} Wiberg et al¹⁴ considered the subjects in the dimethicone group as receiving placebo. In the Olafsdottir study,¹⁵ the control group was "no care." The treatments rendered in the three trials may explain the differences in the results obtained. Although the Olafsdottir study¹⁵ had ideal blinding to eliminate bias on the part of the parents, Wiberg et al¹⁴ argued that a dose-response may be the explanatory variable in that the Olafsdottir study¹⁵ utilized a suboptimal treatment protocol with no proven therapeutic effect. We concur with this statement in that no study or case report beyond the Olafsdottir clinical trial (ie, of pre-experimental or quasi-experimental design) has ever been published by Olafsdottir to demonstrate their treatment protocol has some semblance of effectiveness. Olafsdottir et al¹⁵ described the treatment rendered in the active SMT group as "The treatment was given three times, at intervals of two to five days, for a period of eight days." Wiberg et al¹⁴ utilized a treatment protocol described as, "For a period of up to 2 weeks (3 to 5 treatment sessions) until normal mobility was found in the involved segments." We find the protocol by Wiberg et al¹⁴ to be more congruent with chiropractic practice in that SMT was performed on dysfunctional articulations dependent on the presence (or absence) of articular fixations, vertebral malpositions, etc. It would seem that Olafsdottir et al¹⁵ utilized a predetermined time line to provide care, regardless of the presence or absence for indicators of chiropractic SMT. Furthermore, it may be argued that the Wiberg study¹⁴ was more pragmatic and real life and may differentiate an effectiveness trial from an efficacy trial (ie, under laboratory conditions).³¹

Hughes and Bolton³² offered their opinion on the topic and commented that "the evidence suggests that chiropractic has no benefit over placebo in the treatment of infantile colic" despite their assertion that there is good evidence that taking a colicky infant to a chiropractor will result in fewer reported hours of crying by the parents. Miller³³ and Miller et al³⁴ addressed the topic of cry-babies by providing a framework for care based on what is taught at the Anglo-European College of Chiropractic with suggestions to "widen our view" on the childhood disorder. The authors admonish that chiropractors should perform a thorough clinical workup to determine if the excessive crying on the part of the infant is due to colic or another cause (ie, gastroesophageal reflux or cows milk protein intolerance). From a chiropractic perspective, the authors described an association between musculoskeletal imbalance and irritable behavior and proposed a causal relationship between the two. They refer to this as Irritable Infant Syndrome of Musculoskeletal Origin (IISMO). Kingston³⁵ commented that studies suggest that chiropractic treatment can have a positive effect on the symptoms of colic. However, according to the author, this may be due to the fact that parents are made to feel more able to cope with their child's condition rather than the true effectiveness of chiropractic SMT in decreasing the symptoms of colic.

With respect to systematic reviews, Talmage and Resnick³⁶ reviewed the literature using the Medline and MANTIS databases with key words “infantile colic,” “crying,” “infant,” “manipulation,” and “abdominal cramps.” The authors addressed the definition, etiology, prevalence, and management strategies utilized by medical doctors and chiropractors. According to Talmage and Resnick,³⁶ management should focus on making the appropriate diagnosis, reassuring the parents, and instituting a pharmacologic treatment and/or a conservative manual treatment of chiropractic SMT. As part of their review of the literature on the chiropractic care of patients with nonmusculoskeletal conditions, Hawk et al.³⁷ concluded that there is insufficient evidence to make conclusions regarding the evidence on the chiropractic care of infants with colic. Ernst³⁸ reviewed the randomized clinical trials on colic¹⁴⁻¹⁶ and concluded that the evidence for chiropractic SMT for colic is not based on rigorous clinical trials and therefore fails to demonstrate effectiveness. Recently, as part of their systematic review of the evidence of manual therapy for both musculoskeletal and nonmusculoskeletal conditions, Bronfort et al.³⁹ erroneously concluded that chiropractic SMT for colic “is not effective when compared to sham SMT” since no clinical trial on colic has ever involved sham SMT.

DISCUSSION

Despite the popularity of the Wessel definition for colic, other definitions for colic exist. Others have defined colic as crying for several hours per day,⁴³ crying for more than two hours per day,⁴⁴ and overall duration of more than three hours per day.⁴⁵ Where crying time was not used in the definition, infantile colic was defined as unexplained crying.⁴⁶ Given the number of definitions characterizing colic in the scientific literature, it is not surprising that colic is a poorly defined clinical entity, and consequently, its causative factors are even less well understood. Theories on the pathophysiology of colic are divided into two groups: gastrointestinal factors (ie, hypersensitivity to certain foods, alteration in gut microflora, excessive gas, intestinal hypermotility, hormonal alterations, etc) and nongastrointestinal factors (ie, variant of normal crying, consequence or reflection of atypical parenting, reflections of problems in parent-infant interaction, maternal smoking, etc).⁴⁷⁻⁴⁹ Adding to this complexity are a number of pediatric conditions that may present with symptoms of excessive crying such as neurological abnormalities, ocular foreign bodies or abrasions, infections such as otitis media, acid reflux, constipation, rashes, urinary tract infections, occult fracture, etc.⁵⁰ A unifying theory of colic pathogenesis therefore does not exist, and given the heterogeneity of the disorder, not one treatment approach is superior over all others, and a number of care approaches exist (orthodox and alternative) with some measure of effectiveness. The diagnostic confounder may explain, in part, the mixed results obtained with chiropractic SMT.

Evidence-Based Chiropractic Practice

Since first coined by Guyatt and colleagues,⁵⁰ the term “evidence-based medicine” (EBM) has dominated healthcare policy and the individual approach to patient care, whether in allo-

pathic or CAM therapies. The term was used to “deemphasizes intuition, unsystematic clinical experience, and pathophysiologic rationale as sufficient grounds for clinical decision making and stresses the examination of evidence from clinical research.” Evidence-based practice (EBP)—the delivery of care following the principles of EBM—has been defined as the conscientious, explicit, and judicious integration of a clinician’s individual clinical expertise with the best available external evidence from systematic research and the more thoughtful identification and compassionate use of individual patients’ predicaments, rights, and preferences in making clinical decisions about their care.⁵¹ Based on our systematic review of the literature, we found that certain aspects of the published literature are inconsistent with both our clinical experience (as well as those of other chiropractors) and the wishes of parents in choosing chiropractic care for their colicky infant. In particular, the systematic reviews by Ernst³⁸ and Bronfort et al.³⁹ provide sweeping conclusions that do not support chiropractic care for infantile colic. In many cases we do not find these conclusions justified. Ernst, for example, criticizes the Wiberg study¹⁴ due to lack of blinding of the parents/evaluators, issues with recruitment, and lack of control for placebo effects. These criticisms are valid insofar as the study design. However, the purpose of the Wiberg study was to compare chiropractic SMT versus an established medical treatment for infantile colic—dimethicone. What the investigators found was the superiority of chiropractic care in its totality—specific and nonspecific effects—over an established medical treatment. On the issue of lack of blinding, we concur that this may bias the parents/evaluators. *Ceteris paribus* (“all things being equal”), one would have to accept that this bias would be distributed in both sets of parents/evaluators, including those parents whose children received medical care. Ernst chose to place bias only on the part of the parents of children receiving chiropractic SMT. Ernst contends that there may be a degree of disappointment on the part of the parents of children in the medication group (knowing their child did not receive chiropractic SMT) and impact their subjective evaluation so that their expectations on the effectiveness of medical care are much less compared to the greater expectations of effectiveness on the part of the chiropractic parents. Such assumptions by Ernst are unfounded. Ernst criticized the study by Browning et al.,¹⁶ a comparison trial of two manual techniques: chiropractic SMT and occipitosacral decompression. Due to limitations in research design (ie, lack of a control group), the study was prone to bias due to placebo effects, natural history, and regression to the mean. However, from a clinical perspective, the study demonstrates that both treatment approaches are viable options of care. Ernst embraced the findings of the Olafsdottir study¹⁵ due to its large sample size and its attempt to control for placebo effects. Olafsdottir et al.¹⁵ found the subjects in both groups (chiropractic SMT vs. no treatment) responded similarly and therefore concluded that chiropractic SMT is no more effective than placebo. The treatment rendered in the active group was described as “Dysfunctional articulations were manipulated and mobilized using light finger-tip pressure.” Notwithstanding our criticisms of the poor characterization of the description of care applied in all the clinical trials on colic, we have doubts about the appropriateness of the chiropractic SMT and treatment protocol rendered in the

Olafsdottir study¹⁵ despite claims of consensus from 14 chiropractors. We are not aware, based on our review of the literature, that such a technique has been scrutinized for some measure of effectiveness in a lower level research design or case report. As Wiberg³¹ commented, despite adequate blinding, the Olafsdottir study¹⁵ did not truly reflect “real-life” chiropractic care of infants with colic. Additionally, the primary outcome measure (ie, symptom scoring) was “filled in” by the principal investigator rather than by the evaluating parents and open to questionable objectivity. Given the array of SMT techniques practiced by chiropractors, Ernst’s sweeping statement that spinal manipulation is not effective based on one RCT is counter to the scientific method.

Bronfort et al³⁹ concluded that there is no evidence that “manual therapy is more effective than sham therapy for the treatment of colic.” This is a somewhat misleading statement. In fact, to date, there are actually *no* clinical trials comparing chiropractic SMT to sham therapy with respect to infantile colic. A sham therapy is an inactive treatment or procedure that is intended to mimic as closely as possible the “active” therapy while at all times remaining safe.⁵² The Olafsdottir study¹⁵ compared chiropractic SMT versus no treatment. The Wiberg study¹⁴ and Browning study¹⁶ examined chiropractic SMT versus dimethicone and occipitosacral decompression, respectively. Based on our systematic review of the literature, the conclusion of the Bronfort review on colic are unjustified and places into question the veracity of their work.

Regarding safety of spinal manipulation, Ernst³⁸ described it as not risk-free. We concur with this statement insofar as that no clinical intervention (ie, orthodox or alternative) is without risk. However, what we know about chiropractic SMT and children is that essentially it is safe. Ernst referenced the study by Miller and Benfield⁵³ that advised to expect an adverse event of 1 in 100 children under chiropractic care. However the study by Miller and Benfield⁵³ classified an adverse event based on parental reports of excessive crying following chiropractic SMT. Ernst’s lack of critical appraisal failed to consider that in five of the seven infants reported with an adverse event, infantile colic was the presenting complaint for chiropractic care and thus a confounder. Furthermore, data from the study were from a chiropractic college teaching clinic. To what extent the findings translate to real-world experience have to be considered. Arguably, the prevalence of adverse events may be much less than “1 in 100.” The most comprehensive systematic review of the literature on adverse events associated with pediatric SMT by Vohra et al⁵⁴ found only 10 of 14 cases of direct adverse events attributable to pediatric chiropractic SMT spanning 100 years of the chiropractic care of children. A further examination of the cases involving chiropractic (ie, 10 of 14 cases) revealed patients with preexisting conditions and/or injuries from trauma that places into question the fault on the part of chiropractic.⁵⁵ In a chiropractic practice-based research network, Alcantara et al⁵⁶ examined the safety and effectiveness of pediatric chiropractic and found, based on the chiropractor responders, three adverse events per 5,438 office visits from the treatment of 577 children. The parent responders indicated two adverse events from 1,735 office visits involving the care of 239 children. Both sets of responders indicated a high rate of improvement with respect to

the children’s presenting complaints, in addition to salutary effects unrelated to the children’s initial clinical presentations.

Ernst³⁸ also raised the issue of cost. We found an online advertisement for Dentinox Infant Colic (product containing semithicone) at a cost of £2.59 to £2.79.⁵⁷ These prices are considerably much less than the £100 to £300 estimated by Ernst for chiropractic visits. However, if one examines this in the context of the available medical treatment options for infantile colic, we believe that parents should not be dissuaded from chiropractic care, and that comparing the cost of chiropractic to the cost of a treatment found to be ineffective is not helpful to the analysis. Semithicone is a surfactant that reduces the surface tension of bubbles in the gastrointestinal tract to facilitate passage of gas. Two clinical trials comparing semithicone to placebo demonstrated no benefit. The one trial demonstrating benefit for semithicone was of such poor quality (ie, poorly defined inclusion/exclusion criteria) that its findings are questionable.^{9,58}

Other pharmaceutical interventions for colic may have other associated problems. Anticholinergic drugs relax the smooth muscles of the gut to prevent spasms. Despite findings of benefit with this approach for infantile colic, adverse events are reported such as drowsiness, diarrhea and constipation, apnea, seizures, and coma.⁵⁸ Methyloscopolamine is a muscle relaxant to treat gastric or intestinal hypersensitivity or secretions. This intervention has been found to make colic worse and may be unsafe.⁵⁸ Hardoin et al¹⁰ described eight infants with apnea and cyanosis after receiving colic medication.

Given the relative safety of pediatric SMT, we believe that chiropractic offers a safe and effective alternative treatment approach for the child with infantile colic. In addition, care approaches beyond chiropractic SMT are available through chiropractic care. Reassurance of the parents, infant massage, homeopathic and naturopathic remedies, dietary changes and use of infant formulas, sucrose, gripe water, reduction of sensory stimulation, or referral to an acupuncturist or a homeopath or naturopath are all viable care approaches and have been recommended as such.^{59,60}

Our systematic review of the literature revealed some of the challenges and limitations in research design of clinical trials involving chiropractic SMT. These include the use of an appropriate treatment and sham or placebo protocol, the challenge of blinding, and medical care as a confounder.⁶¹⁻⁶³ In addition to the clinical trials examined, the uncontrolled studies from case reports, case series, and cohort studies add further to the evidence (ie, as part to the evidence hierarchy of EBM) not considered by previous reviews.^{38,39} First and foremost, uncontrolled studies demonstrate the chiropractic clinical expertise and confirm the needs and wants of parents for their colicky child. Second, these lower level design studies inform the design and implementation of randomized clinical trials. Consider that the Olafsdottir study¹⁵ utilized a treatment protocol of questionable integrity and unproven effectiveness and yet is touted as the best clinical trial from which to judge the effectiveness of chiropractic.

From a clinical and research perspective, our findings support the growing criticisms of CAM practitioners and researchers about the limitation of the RCTs in capturing the full nature of

chiropractic care. First, care rendered by chiropractors goes beyond SMT and utilizes other care approaches as previously described. The totality of chiropractic care is therefore complex and provides a research challenge. Second, to date, no study has characterized an appropriate sham therapy from which to compare active SMT care for infantile colic. Third, the array of chiropractic SMT techniques utilized by chiropractors leads to great practice variability in addition to nonstandardized and individualized treatments according to the needs of each patient. Fourth, the science, art, and philosophy of chiropractic care address nonspecific, multifactorial conditions of patients with complex, chronic conditions. The theoretical framework of chiropractic is founded on the detection and removal of the spinal subluxation⁶⁴ rather than the treatment of specific symptoms. Fifth, recruitment and randomization can be problematic because of the patient's beliefs, practices, and preferences. Finally, RCTs minimize or exclude the impact of the doctor-patient relationship (ie, the nonspecific effects) on the outcomes, whereas in chiropractic (as with other CAM therapies), the nonspecific therapeutic effects of the clinical encounter are embraced and considered an important aspect of care. There is a growing movement toward whole systems research as a useful approach to determining effectiveness of care in CAM research.⁶⁵ We support these efforts given our findings from this systematic review.

CONCLUSION

Despite the infancy of pediatric chiropractic research and counter to previous reviews of the literature on the subject, our findings support chiropractic as an alternative approach to infantile colic. In the context of safety and effectiveness of chiropractic SMT for infantile colic, a trial of chiropractic care is warranted and congruent with the needs and wants of parents for their colicky infant and in keeping with biomedical ethics. We encourage further research in this field.

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