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A preliminary assessment of the impact of cranial osteopathy for the relief of infantile colic

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Effectiveness

Summary In this open, controlled, prospective study, 28 infants with colic were randomized to either cranial osteopathic manipulation or no treatment; all were seen once weekly for 4 weeks. Treatment was according to individual findings, and administered by the same practitioner. Parents recorded time spent crying, sleeping and being held/rocked on a 24-hour diary. A progressive, highly significant reduction between weeks 1 and 4 in crying (hours/24 h) was detected ($P<0.001$) in treated infants; similarly, there was a significant improvement in time spent sleeping ($P<0.002$). By contrast, no significant differences were detected in these variables for the control group. Overall decline in crying was 63% and 23%, respectively, for treated and controls; improvement in sleeping was 11% and 2%. Treated infants also required less parental attention than the untreated group. In conclusion, this preliminary study suggests that cranial osteopathic treatment can benefit infants with colic; a larger, double-blind study is warranted.

Introduction

Infantile colic is a common cause of paroxysmal abdominal pains with resultant distress both to the child and parents alike; it usually commences between 2 and 3 weeks postnatally[1] and affects 8–40% of infants.[2,3] There are many possible aetiological factors, including incomplete lactose absorption[4,5] cow's milk intolerance,[5,6] familial and genetic factors[7,8] and dietary insults.[9] Undigested lactose may create an osmotic gradient that facilitates intraluminal retention of water, resulting in relative physiological dehydration of intestinal tissues, and may encourage bacterial growth producing gas with subsequent bloating, flatulence, borborygmi and cramp.[10,11] Stress factors in pregnancy, childbirth and inadequate postnatal care may also be important determinants in the development of infantile colic[1,12] although the exact role of adverse environmental circumstances before and during birth has yet to be determined.[13]

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The general lack of understanding and consensus on its development has led to a wide variety of treatment strategies for infantile colic, each with its own limitations and varying degrees of reliability.[2,14] As the repetitive, inconsolable bouts of colicky crying inevitably place a stress on family life, many parents turn to complementary therapies to help their child. Cranial osteopathy has gained a particular reputation in this regard even though evaluation by randomized controlled trials is lacking.[15]

Osteopathic treatment consists of the diagnosis of the musculo-skeletal strain patterns in the body, followed by techniques to release these strains. Specifically, the cranial osteopathic approach to infantile colic involves the application of gentle manual techniques to the head as well as any other areas of the infant body that demonstrate palpably increased ligamentous/muscular tone, or decreased/abnormal articular mobility. Very light tactile pressure is applied to the affected area until a palpable release of the relevant physical tensions and areas of dysfunction (including parts of the cranium) is achieved. Osteopathic treatment may alleviate the physical and biomechanical influences of childbirth. It is also feasible that by attempting to reduce the distortions and twists in the musculoskeletal framework, improving joint mobility, and reducing apparent muscular hypertonia in the infant, manipulation may reduce the somatic afferent load into the central nervous system.[16]

The objective of this preliminary study was to investigate the effect of cranial osteopathic manipulative treatment on the pattern of increased crying, irritability and disturbed sleep associated with infantile colic, as reported by the parents.

Methodology

Study design and participants

The study was a prospective, randomized, open, controlled trial comparing cranial osteopathic manipulation with no treatment for infants suffering from infantile colic. Infants and their parent(s) were seen weekly over a 4-week period (total of 5 visits). The study was pragmatic[17]; it was carried out at a single centre with all treatments given by the same osteopath (the principal author) following his usual clinical practice/management. Recruitment to the study was through health visitors (Gloucester and Cheltenham); by referral from local GP surgeries, osteopathic colleagues, the local National Childbirth Trust, and by self-referral. The study protocol conformed to the principles of the Declaration of Helsinki[18] and was approved by the West Gloucestershire Local Research Ethics Committee.

Infants were eligible for the study if they were between 1 and 12 weeks of age, had not been previously treated osteopathically, exhibited signs of infantile colic (see below) and there were no signs or symptoms indicative of other disease. Infantile colic was defined as at least 90 min of inconsolable crying per 24 h on 5 out of the previous 7 days (as reported by the parents prior to inclusion in the study), with normal behaviour outside of these periods.[19] Inconsolable crying during a colic attack was when the infants could not be comforted by being held, rocked or walked, or being soothed in any way. In addition, each infant was required to have displayed typical signs of colic: loud gurgling noises from the abdomen (borborygmi), knees drawn up to the chest, fists clenched and backward bending of the head or trunk.

Methods

All infants referred for the study were screened for possible inclusion; past medical history and general health were recorded and a routine osteopathic assessment (gross morphology, mobility, organ systems, mental and neurological status) was performed. In addition, muscular and ligamentous tone and restrictions in articulations were explored, as well as notable asymmetries of limb orientation and development, and distortions of the head, spine and body shape.

A written explanation of the objectives of the study was given to each parent plus a standardized information sheet and their written consent for the participation of their child in the study was obtained. They were made aware that they could withdraw their infant from the study at any time and also that, if randomized to the control group, their infant would not receive any osteopathic intervention for the duration of the study (4 weeks). However, osteopathic treatment could be made available, if required, at the end of that period.

Parents were then given a questionnaire about birth details, behaviour during a colic attack, sleeping and feeding patterns and past medical history; this provided confirmation of the eligibility of their infant for the study. Parents were also given a daily diary for use during the study; on this they recorded in every 24 h the amount of inconsolable crying, the total time spent sleeping, and the time the infant was being held or rocked (taken as an indication of low-level colic). Parents were asked to continue with bringing their infant to the clinic and

completing the diary card even if the symptoms of colic resolved during the 4-week period.

Treatment

Following screening, eligible infants were randomized (using a random number table) into a control and test group. All infants were brought to the osteopathic clinic once a week for 4 weeks. Equal time was spent with all participants/parents over the study period. The initial visit and interview was for an hour; infants in the control group were given a brief examination with minimal touch, whereas following their examination those in the treated group received cranial osteopathic manipulative therapy as required (week 0). Treatment was individualized, according to clinical findings, and involved standard cranial osteopathic techniques[20] until a palpable release of tensions and dysfunction was achieved. At the four subsequent half-hourly sessions (weeks 1–4), infants in the control group received no physical intervention; osteopathic manipulation in the treatment group was dependent on findings at each visit. All parents were able to ask questions, discuss their problems and receive counselling from the osteopath at each visit.

Statistical analysis

The two main endpoints in this study were the mean number of hours/24 h spent with colicky crying and the mean number of hours/24 h spent sleeping. For each infant, the difference in these parameters (daily average over the previous week) from weeks 1 to 4 was calculated and the mean change for each group separately was tested for significance using Student's *t*-test (paired). In addition, the difference between the means for the two groups was compared using a two-sample *t*-test. The percentage change in hours of crying (per 24 h) between week 1 and each subsequent visit was calculated and plotted graphically; a similar analysis was performed for the hours spent sleeping. Regression and correlation analyses were used to explore the relationship between crying time and sleeping time.

Results

Patient population

Forty-four infants were screened; of these, 28 (64%) fulfilled the inclusion criteria and were randomized to treatment or control (Fig. 1). The demographic characteristics of infants in the treated group were similar to those in the control group with respect to those factors considered likely to affect the severity or outcome of infant colic (Table 1). Males outnumbered females in a ratio of 3:1 overall, but with no significant difference between the control and test groups ($\chi^2 = 3.39, P > 0.05$).

Parents confirmed, at the initial visit, that the 'colic cry' differed from other crying and was accompanied by gurgling sounds with signs of abdominal discomfort and irritability, but none of the infants showed any signs of failure to thrive. At study commencement, the mean sleeping time of all infants was estimated at 11.9 h/24 h; parents frequently noted that sleep was often very restless.

Response to treatment

All 26 infants who completed the study remained healthy throughout, with normal development. In the treatment group all 14 infants improved following cranial osteopathic manipulation; 4 (29%) required no further treatment after week 2 and a further 6 (43%) did not require any further treatment after week 3. All continued in the study. The remaining 4 (29%) infants in the treated group still showed mild levels of colic at the end of the study.

By comparison, only 2 (14%) infants in the control group showed a spontaneous improvement within the first 2 weeks of the study. The symptoms of colic worsened for two infants in the control group and each was admitted to hospital; one withdrew after 22 days in the study because of developing pneumonia, and the other after day 20 because of the deteriorating colic condition (there were no other study withdrawals). Of the remaining 10

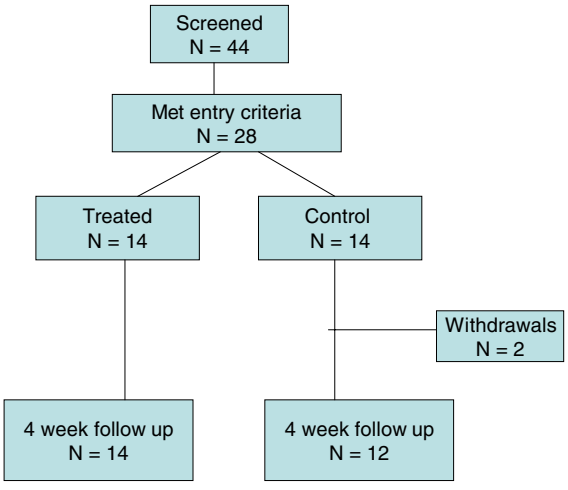

Figure 1 Patient recruitment.

Table 1 Characteristics of infants randomized into the study.

	Treated group ($n = 14$)	Control group ($n = 14$)
Males/females	13:1	9:5
Age at study entry (days): Mean ± SEM and (range)	46.4 ± 5.4 (12–83)	44.5 ± 5.0 (10–82)
Gestational age at delivery (days): mean ± SEM and (range)	277 ± 1.3 (266–280)	275 ± 3.4 (249–294) ($n = 13$)
Feeding		
Breast fed	10	7
Bottle fed	1	4
Mixed feeding	3	3
Delivery		
Normal vaginal delivery	11	13
Assisted delivery	2	4
Emergency Caesarean section	3	1
Elective Caesarean section	0	0
Presentation on delivery		
Occiput posterior	5	6
Occiput anterior	7	5
Breech	0	0
Not known	2	3
Nuchal cord	3	1
Foetal distress	7	6

Table 2 Mean (±SEM) hours spent crying (colicky cry) and sleeping per 24 h.

	Week 1	Week 2	Week 3	Week 4	Change week 1 to week 4
Crying					
Treated ($n = 14$)*	2.39 (±0.36)	1.89 (±0.35)	1.67 (±0.35)	0.89 (±0.28)	−1.5 (±0.32)**
Control ($n = 14$)†	2.06 (±0.24)	2.22 (±0.35)	1.87 (±0.31)	1.56 (±0.27)	−0.5 (±0.29)
Sleeping					
Treated ($n = 14$)	11.55 (±0.58)	12.51 (±0.55)	12.55 (±0.66)	12.90 (±0.58)	1.35 (±0.38)***
Control ($n = 14$)†	11.86 (±0.66)	11.79 (±0.64)	12.17 (±0.68)	12.04 (±0.79)	0.18 (±0.30)

**$P < 0.001$.
***$P < 0.002$.
*$n = 13$ from week 2 (incomplete diary entries).
†$n = 13$ at week 3, $n = 12$ at week 4 (withdrawals).

infants, 1 (10%) had improved by week 3, and a further 4 (40%) by week 4; however, a continuing pattern of colic behaviour was present in 5 (50%) at the end of the study.

The daily diary was completed without difficulty by most parents. The one exception was a mother with an infant in the treated group who, from week 2, recorded only her infant's sleeping and awake time.

Crying patterns

The mean hours of colic crying per 24 h of the babies who underwent osteopathic treatment showed a progressive reduction at weeks 2, 3 and 4 (Table 2) reaching a significant reduction from week 1 of 1.5 h (±0.32 SEM) by week 4 ($P < 0.001$). In the control group there was an increase at week 2 in hours spent crying, followed by a slight decline to week 4; the difference of 0.5 h from weeks 1 to 4 was not significant ($P > 0.07$). The difference between the two groups in the mean reduction in crying time of 1.0 (95% confidence interval: 0.14, 2.19) hours/24 h was found to be statistically significant ($P < 0.02$) in favour of the treated group.

The overall reduction in crying per 24 h from weeks 1 to 4 was 63% for the treatment group and 23% for the control group (Fig. 2).

Sleeping patterns

There was a progressive improvement in the amount of restful sleep gained over the 4-week period for babies who underwent cranial osteopathic treatment; only a minimal improvement was observed in the control group (Table 2). The mean increase of 1.35 ± 0.38 h in the hours/24 h spent sleeping between week 1 and 4 was highly significant for the treated group ($P < 0.002$). By comparison the control group showed a mean difference of only 0.18 ± 0.30 h which was not significant ($P > 0.3$). The difference between the treated and control groups of 1.17 (95% confidence interval: 0.29, 2.27) hours/24 h in the mean increase in sleeping time was significant ($P < 0.05$). The overall improvement in sleeping time by week 4 was 11% for infants in the treated group and less than 2% in the control group (Fig. 3).

Further statistical analysis for the crying time and sleeping time per 24 h for both groups over the 4-week period revealed that in the osteopathically treated group these parameters showed a reciprocal correlation ($r = -0.432; P < 0.001$ highly significant). No correlation between sleeping and crying over the period of study was detected for the control group ($r = -0.220, P > 0.125$) (Fig. 4).

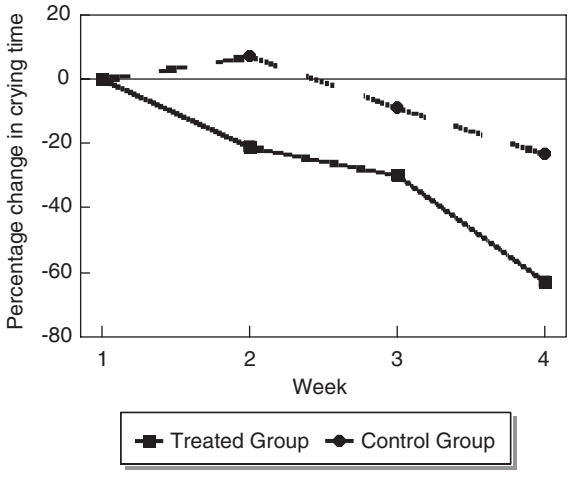

Figure 2 Mean percentage change in hours/24 h spent crying for treated and control groups.

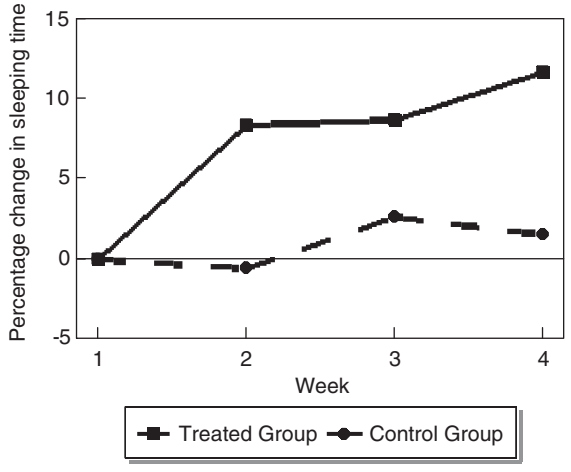

Figure 3 Mean percentage change in hours/24 h spent sleeping for treated and control groups.

Parental involvement

Parents of the treated infants recorded holding and rocking their infants for a significantly less time per 24 h than those with infants in the control group. The mean difference between week 1 and 4 for the treated group was 1.3 h ($P < 0.015$) and 2.0 h for the control group ($P > 0.05$).

Discussion

This study provides evidence to suggest a beneficial effect of cranial osteopathic manipulation for infants suffering from infantile colic. A highly significant reduction in colicky crying and a similarly significant increase in the sleeping period were observed in those infants who received active treatment. By comparison, there were no

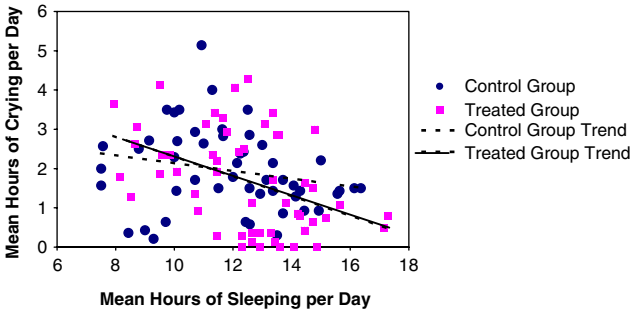

Figure 4 Relationships between mean weekly hours spent crying and sleeping/24 h over the 4-week study period; scatter plot (and trend lines) for individual infants in the treated and control groups.

significant changes in daily crying or sleeping patterns over the 4-week study for infants in the control group. These differences in the main study variables were further reinforced by measurement of the time spent being rocked or held; those who were treated osteopathically again showed a significant improvement compared with infants who remained untreated.

This is the first account, to our knowledge, of a randomized trial to investigate treatment effects following cranial osteopathic manipulation for infantile colic. There is limited information in the literature on chiropractic spinal manipulation of colicky infants; two randomized controlled trials reported positive results[21,22] whereas a third concluded that chiropractic offers no greater efficacy than placebo.[23] A strong placebo effect (following parental counselling) or the number of treatments given have been postulated to explain these differences.[24,25]

The unsettled behaviour observed in this cohort of infants may have been associated with trauma experienced during a difficult delivery; foetal distress was noted in 50% of the treated group, and 39% of the control group, whilst 21% and 7% of each group, respectively, had been delivered by emergency Caesarean section. It has been suggested[1,12] that the factors associated with a significantly increased occurrence of infantile colic were a 'psychological' complication of pregnancy, a bad experience of pregnancy or labour, and a sibling with a history of infantile colic. However, no significant association with true obstetric complications was found in these studies, although an increased risk of colic was observed following both forceps deliveries and epidural anaesthesia.

It may be argued that any delivery requiring surgical or assisted intervention is stressful for the infant—a 'psychological' complication of a physically demanding process—''in which strong pressures are exerted onto the foetal head and body''.[26]

The association of colic with physically and psychologically traumatic deliveries may well cause lingering stress effects in the infant; the effects of stress on increasing gut motility and therefore decreasing the time taken for lactose to be digested in the stomach are widely acknowledged. It also remains a possibility that the physical tension palpable in affected infants may be secondary to the pain and discomfort associated with the colic condition itself.

The wide variation in the reported frequency for colicky crying (8–40%) underlines the difficulty in defining the nature and severity of colic.[3,14,19,27–29] Uncontrollable colic crying with concurrent abdominal discomfort has been shown to differ from normal crying[9,29] and appears to be the most common variable measured.[30–32] This study adopted the definition of colic proposed by Klougart et al.[19]; by also recording other outcome variables (sleep, and time spent comforting the infant) we gained a wider picture of the colicky infant. It is possible that the uncomfortable, writhing infant who does not sleep well and needs constant parental attention is experiencing a mild level of colic. A small proportion (about one-third) of infants in the treated group, although markedly improved at week 4, fell into this category. These infants may have benefited from a longer period of treatment, and future studies might consider this possibility. Alternatively, together with some of the infants in the control group with continuing colic at the end of the study (5, plus one withdrawal due to colic: 43%) they may represent a sub-group of infants with lactose intolerance. This is in line with the reported background level of lactose intolerance in the community; Webster[33] noted that 1 in 4 (24%) of a population of 137 children whose ages ranged from 6 to 18 years were found to be lactose intolerant.

The duration and severity of the colic are related to the age of onset, that is, the earlier the symptoms start the more severe and long lasting they are likely to be.[8] In our study some infants were included from 10-days old, whilst others were nearer 12 weeks of age. As the peak incidence of colic appears to be 6–8 weeks, and the condition shows a natural history of improvement over time, a degree of variability in response to the treatment might be expected. However, the study design did not allow for establishing the normal pattern of colic for each infant prior to randomization. Use of a daily diary for assessment of the infant over 3 or more days before inclusion in the study is recommended.

The positive trends observed in our preliminary study warrant further investigation utilizing a double-blind technique. Our study was not double blind because the medical advice offered when it was being designed opposed any 'sham' treatment for a control group and advised that the infants should not be removed from their parents. The placebo effects of simply handling the infants, therefore, could not be addressed by the chosen study design. The unblinded study may have generated additional stress in parents of infants in the control group, resulting in negative effects on the infant; this could possibly explain the apparent skewing of the data at week 2 for the crying and sleeping variables (Figs. 2 and 3) in this group. By contrast, awareness of the treatment group may

have positively influenced parental recording of colicky symptoms for infants in the treated group. However, it is interesting that the improvement noted by parents of treated infants was also detected osteopathically: no further manipulation was found to be necessary after week 3 for 72% of this group. Also, the relationship between maternal stress and colic remains a matter for debate.[14] Future study designs will require further consideration of both the placebo and blinding issues.

One reason for conducting this preliminary investigation was to explore the feasibility of obtaining parental consent and commitment for a study involving an untreated control group. Even though some parents expressed disappointment at their infant's allocation, none withdrew from the study because of this. This finding may relate to a desire to alleviate the stress on family life associated with infantile colic and the current lack of other satisfactory treatment modalities. Based on personal experience and conversations with health visitors, it seems that infants referred to osteopaths are generally those showing moderate-to-severe symptoms unresponsive to orthodox medical management.

The fact that only one practitioner delivered all treatments is both a strength and a weakness of this study. The advantage of consistency in osteopathic diagnosis, manipulative therapy and assessment of treatment outcome must be weighed against the uncertainty of wider applicability. A larger multi-centred study is currently being considered—and is both feasible and desirable.

The results obtained in our study lend support to the thesis that cranial osteopathy can help alleviate the abnormal behavioural symptoms associated with infantile colic. The progressive and sustained improvement in crying patterns observed in the treated group may have resulted from a normalization in musculo-skeletal tone, which was possibly achieved by osteopathic manipulation. Also, the treatment strategy may have resulted in a reduction of the somato-visceral neurological load. The small reduction in crying time observed for infants in the control group may have been associated with the normal growth and development of the infant and the natural progressive history of this condition of improvement over time.

In conclusion, our preliminary study suggests that the net result of cranial osteopathic treatment is a more relaxed infant who cries significantly less, sleeps significantly longer and more restfully, and needs less comforting and placating. This at least is the parents' perception. The psycho-social consequences are implicit, with the parents benefiting from the improved state of the child and the quality of the parenting thus being enhanced.

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