

The Short-term Effect of Spinal Manipulation in the Treatment of Infantile Colic: A Randomized Controlled Clinical Trial with a Blinded Observer

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# ABSTRACT

**Objective:** To determine whether there is a short-term effect of spinal manipulation in the treatment of infantile colic.

Design: A randomized controlled trial.

**Setting:** A private chiropractic practice and the National Health Service's health visitor nurses in the suburb Ballerup (Copenhagen, Denmark).

**Subjects:** Infants seen by the health visitor nurses, who fulfilled the diagnostic criteria for infantile colic.

**Intervention**: One group received spinal manipulation for 2 weeks, the other was treated with the drug dimethicone for 2 weeks.

# INTRODUCTION

Infantile colic was first described in 1894 as dyspepsia. Since then, different sets of diagnostic criteria have emerged, but there has never been complete agreement about any of these. However, the most accepted definition is: unexplainable and uncontrollable crying in babies from 0 to 3 months old, more than 3 hours a day, more than 3 days a week for 3 weeks or more, usually in the afternoon and evening hours.<sup>1-17</sup>

Several studies have described a difference in the quality of crying in infants with colic compared with normal infants. Infants with colic have more hours of crying per day and more periods of crying per day,<sup>1,10,18-20</sup> and the crying in infantile colic has a higher frequency/pitch.<sup>10</sup> Other studies describe motor unrest, typically with flexing of the knees against the abdomen, clenching of the fists, and extension or straightening of the trunk and extremities. Several studies conclude that infants with colic are perfectly normal but cry more than other infants.<sup>21-28</sup> All studies agree that apart from the increased crying, these infants are otherwise healthy, thriving, and have a normal weight gain.

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**Outcome Measure:** Changes in daily hours of crying as registered in a colic diary.

**Results:** By trial days 4 to 7, hours of crying were reduced by 1 hour in the dimethicone group compared with 2.4 hours in the manipulation group (P = .04). On days 8 through 11, crying was reduced by 1 hour for the dimethicone group, whereas crying in the manipulation group was reduced by 2.7 hours (P = .004). From trial day 5 onward the manipula-

tion group did significantly better that the dimethicone group.

**Conclusion:** Spinal manipulation is effective in relieving infantile colic. (J Manipulative Physiol Ther 1999;22:517-22)

Key Indexing Terms: Infantile Colic; Chiropractic Manipulation

The incidence of infantile colic among newborns is estimated to be between 8% and 49% in different studies.<sup>1-12,17,19,29-35</sup> An average of these estimates would put the incidence of infantile colic at 22.5%, and with a birth rate of 67,731 children in Denmark in 1992 this would mean that some 15,226 newborns would have infantile colic every year in a country with a population of 5 million (Statistisk månedsoversigt 1993:3:12).

Infantile colic is often described as a "benign self-limiting condition" that disappears spontaneously at 3 months of age. But a good observational study has shown that only 47% of infantile colic cases have disappeared at the age of 3 months, a further 41% disappeared before 6 months of age, and the remaining 12% of cases persevered until between the ages of 6 and 12 months.<sup>36</sup>

Although infantile colic may be regarded as a "benign self-limiting condition" that only results in a temporary delay in the development of child,<sup>33</sup> several studies suggest that the effects of infantile colic may be more severe than that. Some studies have concluded that infantile colic can lead to a negative mother-child relationship, which may persist for up to 3 years after the disappearance of symptoms.<sup>31,32,37-42</sup> Other studies conclude that these troublesome and screaming infants are in a high-risk group for ill treatment, for possible central nervous system damage, and even death from being shaken (shaken infant syndrome).<sup>10,21,43-50</sup>

The cause of infantile colic remains unknown. Many have pointed to increased air in the intestines as the cause.<sup>51-53</sup> But radiologic studies have shown that the amount of air in the intestines of infants with colic is the same as in normal infants.<sup>6,29,54</sup> Neither has it been possible to find constrictions in the intestines, and the gastrointestinal transit time in

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infants with colic is also normal. Others have investigated levels of intestinal hormones, fecal analysis, intestinal microflora, markers of intestinal damage, or occult blood in the stools and hydrogen-ion concentration in the breath, but none of these studies have convincingly identified abnormalities in infants with colic.<sup>12,34,52,55-59</sup>

Various modes of delivery (cesarean section, vaginal extraction, or vacuum extraction) have also been studied, but no differences could be identified in the incidence of colic in infants delivered by these three modes.<sup>60,61</sup> Neither does the use of pudendal block, epidural analgesia, general anesthesia, or intravenous oxytocin seem to increase the risk of infantile colic.<sup>62</sup>

Numerous treatments for infantile colic have been advocated, but most of these, such as music and different sound or vibrations (car-simulating devices), have been shown to be without any effect.<sup>3,18,63,64</sup> Treatment with sucrose seems to have a generalized analgesic effect in infants and may therefore also help in infantile colic.<sup>65</sup>

Different medical treatments for infantile colic have also been used. Dicyclomine hydrochloride<sup>5,15,66</sup> was often used with some effect until the mid 1980s, when reports about serious side effects stopped this treatment.<sup>67-72</sup> Gripe-water, alcohol, atropine, skopyl, phenobarbital, meperidine, homatropine, and merbentyl have also been used with more or less convincing results.<sup>29,31,73-77</sup> Phenobarbital, homatropine, and alcohol have been studied in a double-blind design, which showed no effect compared with a placebo treatment,<sup>75</sup> and most other preparations have had serious side effects.<sup>78-82</sup>

One drug that is still used is dimethicone (Simethicone, Mylicon), and several good controlled studies have shown that this is no better than placebo treatment.<sup>3,67,72,83,84</sup>

Chiropractors and others have for many years manually treated infants with colic symptoms with apparently good results.<sup>4,7,30,60,61,85-90</sup> The background for this has been the purely clinical observation that functional disturbances of the vertebral column may cause symptoms similar to those of infantile colic, and several studies seem to support this clinical observation.<sup>7,30,61,86-92</sup>

In 1985 a retrospective study was undertaken in Denmark on the chiropractic treatment of infantile colic,<sup>89</sup> and this was followed in 1989 by a prospective multicenter study.<sup>7</sup> Both studies suggest that there seems to be a positive effect of spinal manipulation for infantile colic, but because none of these studies had a control group, it is impossible to assess whether the effect observed was significantly better than placebo.

This trial is a prospective, randomized controlled clinical trial with a blinded observer for the purpose of studying whether any effect exists beyond placebo from spinal manipulation in the treatment of infantile colic.

#### METHODS

Participants were recruited from April 1994 to July 1996 by health visitor nurses from the National Health Service in the suburb of Ballerup (Copenhagen, Denmark). The first 50 infants who fulfilled the inclusion criteria and whose parents consented were invited to take part in the study. The inclusion criteria were as follows.

- 1. The age of the infant was 2 to 10 weeks.
- 2. The infant did not show symptoms that could be a sign of any other disease than infantile colic.
- 3. The infant had 1 or more violent spells of crying per day. These spells must be at least 3 hours long per day and must have been present at least 5 of the 7 previous days. Apart from the attacks of infantile colic, the infant must show normal behavior.
- 4. The infant must not suffer from any known past or present disease.
- 5. The infant must have an average weight gain of at least 150 g/wk.
- 6. The infant had to show typical colic behavior during the spells of crying (ie, motor unrest; often flexing knees against the abdomen; or extending the trunk, neck, and extremities).
- 7. During attacks the infant cannot (or only temporarily) be comforted by (a) being picked up, walked, or cradled; (b) change of diaper; (c) being offered a dummy.

Fulfillment of the inclusion criteria was ensured by the health visitor nurse administering a structured diagnostic interview, after which the health visitor nurse gave the parents the verbal and written information, as approved by the regional ethics committee (permit number KA 93235g). Those who gave their written consent entered the study.

The structured diagnostic interview administered by the health visitor nurse was also an "infantile colic behavior profile" that measured the parents' subjective evaluation of the severity. In addition, parents of all participants were asked to complete an infantile colic diary for the duration of the trial. The diary registered the following for each 24 hours.

- 1. The infants periods of being awake, sleeping, and crying
- 2. Bowel movements
- 3. Feeding patterns

This diary has been validated in previous studies as a reliable, objective recording of the infant's behavior and symptoms, which is important because the parents could not be blinded.<sup>1,3,19,22,23,84,93-95</sup>

After completing the diary for a 1-week baseline observation period, the health visitor nurse randomly assigned the participants into 2 treatment groups by the blinded drawing of a ticket.

Both treatment groups received counseling and advice on breast-feeding technique, mother's diet, air swallowing, feeding by bottle, burp technique, observation of the infant's belly, stools and passing water, vomiting, eating and sleeping rhythm, and so forth as normally given to parents by the health visitor nurse.

In addition to the advice, 1 of the treatment groups was given dimethicone daily for 2 weeks as prescribed in the Danish PDR,<sup>96</sup> whereas the other treatment group was referred to a local chiropractor (J.M.M.W.) for spinal manipulation for a 2-week period. In practice, the 2-week treatment period varied in both groups between 12 and 15 days, thereby allowing for appointment scheduling problems around weekends and holidays.

 Table 1. Pretreatment characteristics of the 2 treatment groups

 from the infantile colic profile (P value given for the significance
 of any differences is based on unpaired t tests, unless otherwise

 noted)
 Description
 Description

Variable	Dimethicone group mean $(\pm SE) (n = 20)$	Manipulation group mean $(\pm SE) (n = 25)$	Significance of difference
Mothers' age (yr)	27.9 (± 4.3)	29.0 (± 3.9)	<i>P</i> = .35
Infants' age on entry into trial (wk)	5.9 (± .7)	4.9 (± .5)	<i>P</i> = .26
Age at colic debut (wk)	2.2 (± .3)	1.2 (± .3)	<i>P</i> = .02
No. weeks with the disorder on entry into trial	3.7 (± .8)	3.7 (± .5)	<i>P</i> = .98
Hours of colic/day	5.2 (±.7)	$4.3(\pm .3)$	P = .18
Days without colic the last week	.35 (± .17)	.52 (± .17)	<i>P</i> = .49
Birth weight (g)	3462 (± 129)	3545 (±11)	P = .63
Weight gain/week (g)	235 (± 11)	199 (± 16)	P = .08
Birth (gestation week)	39.6 (± .5)	40.0 (± .3)	P = .50
Duration of birth (h)	7.8 (± 1.2)	11.1 (± 2.2)	<i>P</i> = .23
Boy/girl ratio	9/11	16/9	$P = .20 (\chi^2)$
No. older siblings	.70 (± .20)	.92 (± .17)	P = .41

At the end of the first treatment week and again at the end of the second treatment week the health visitor nurse administered the infantile colic behavior profile, registering the parents' subjective evaluation of change. Throughout the 2 treatment weeks the parents continued to fill in the diaries of infantile colic behavior. At the end of the 2-week treatment period all diaries and colic behavior profiles were interpreted by a blinded observer, who was unaware of the treatment administered to that infant.

For those infants who were randomly assigned to spinal manipulation, a routine case history was taken and physical examination performed, including motion palpation of the articulations of vertebral column and pelvis. Those articulations found to be restricted in movement were manipulated/mobilized with specific light pressure with the fingertips for a period of up to 2 weeks (3 to 5 treatment sessions) until normal mobility was found in the involved segments.<sup>7,30,61,85,86,88,89,92</sup>

The main outcome measure was the percent change within each child of the mean hours of infantile colic behavior per day as registered in the diaries.

# RESULTS

Fifty-seven parents of infants were interviewed for the study; 50 were recruited for the trial, 25 were randomly assigned to the dimethicone treatment and 25 to the spinal manipulation group. All 25 in the manipulation group completed 13 days of treatment compared with only 16 in the dimethicone group. Of the 9 dropouts in the dimethicone group, 5 dropped out before the first week's diary was handed in, and therefore we have no objective registration of hours of crying for those 5 subjects. However, for 4 of the 5 we have the mothers subjective evaluation in the infantile colic behavior profile from the end of week 1. In this, 2 described the condition as "worsened" and 2 as "much worsened." All data from those 5 have been omitted from the

 Table 2. On the basis of information from the diaries, the mean
 daily hours of infantile colic in the pretreatment baseline observation period and changes in daily hours of infantile colic after the

 start of treatment (statistical significance of differences between
 the 2 treatment groups is given as P values from unpaired t tests)

Variable	Dimethicone group mean (± SE)	Manipulation group mean (± SE)	Significance of difference
Pretreatment colic $(h/day) (n = 45)$	3.4 (± .4)	3.9 (± .4)	<i>P</i> = .28
Change in colic (h/day) from pretreatment to days $0-3$ ( $n = 43$ )	-1.0 (± .5)	-1.6 (± .4)	<i>P</i> = .37
Change in colic (h/day) from pretreatment to days 4-7 ( $n = 42$ )	-1.0 (± .6)	-2.4 (± .4)	<i>P</i> = .04
Change in colic (h/day) from pretreatment to days $8-11$ ( $n = 40$ )	-1.0 (± .4)	-2.7 (± .3)	<i>P</i> = .004

analysis, leaving 20 in the dimethicone group. Of these, a further 3 dropped out on day 7 because of worsening. One had other treatment at the same time as dimethicone and was excluded from the trial.

The pretreatment characteristics of the 2 treatment groups, as stated in the infantile colic profile representing the mothers subjective perception, are given in Table 1. It is noted that before the start of treatment the 2 groups only differed significantly with respect to the age when infantile colic began, specifically 1.2 weeks of age for the manipulation group versus 2.2 weeks for the dimethicone group.

Table 2 lists the mean number of hours with colic per day before treatment and the change in mean daily hours of colic after the start of treatment in the 2 treatment groups on the basis of information from the infantile colic diaries representing an objective registration. Results have been averaged into blocks of 4 days to minimize the effect of random day-to-day variation. The reduction in daily hours of infantile colic is significantly greater in the spinal manipulation group from days 4 to 7 onward.

The percentile change in daily hours of infantile colic is graphically illustrated for each of the 2 treatment groups as mean percent change for each child (Fig 1). The error bars  $\pm 1$  SE drawn in that graph show that the 2 groups differ significantly from treatment day 5 onward in that the reduction in hours with infantile colic is significantly greater in the manipulation group at a .05 significance level.

After trial day 12 (13 days after the start of treatment on day 0), the number of missing records became too large to allow any statistical analysis. Apart from the 9 dropouts already mentioned, this was caused by practical scheduling problems, as described earlier.

As part of the examination, the entire spine was motion palpated and this could be regarded as equivalent to mobilization. The restrictions of motion that were treated were primarily in the upper and midthoracic area, but in addition some lower thoracic and lumbar motion segments were treated. The mean number of treatment sessions was 3.8.

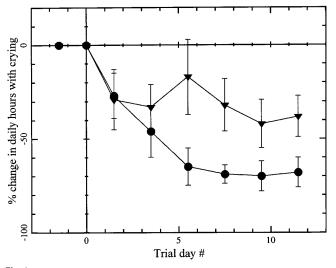


Fig 1. Graph showing the percentile reduction in daily hours with infantile colic before and after the start of treatment on day 0. Circles represent the manipulation group, triangles the dimethicone group. The error bars (1 SE) show that from day 5 onward the two groups differ significantly.

## DISCUSSION

When we compare our results with those of the only other prospective trial on spinal manipulation in the treatment of infantile colic,<sup>7</sup> we see that the results are virtually identical for our manipulation group. In the previous trial, mean daily hours with colic were reduced by 66% on day 12 of the trial, and in our trial we saw a reduction of 67% on day 12 in the manipulation group, whereas our dimethicone group only had a reduction in daily hours with colic of 38% by day 12. These similarities strengthen the conclusion that a positive effect of spinal manipulation exists in the treatment of infantile colic. These strong similarities perhaps also suggest that we may be dealing with an underlying anatomic/physiologic disease mechanism rather than a psychosocial one, but that remains to be clarified.

Initially we planned to have a baseline observation period of 7 days, but soon after the start of the project we had to revise this to 4 days because the families demand for fast action was too strong. If we had upheld the 7-day baseline observation period, it would have been difficult to recruit a sufficient number of participants because parents would have sought help elsewhere. The problem is understandable in retrospect because families of infants with colic are under a tremendous psychologic strain, as anyone with infantile colic experience will appreciate. We do not think that reducing the length of the baseline observation period has any effect on the validity of the results because this was the same for both treatment groups.

We would also have liked a longer follow-up period, but once again families with small infants are busy families (colic or not). It was our impression, that it would not have been possible to keep those participants who still had colic in the trial much longer, whereas those who were helped by the treatment would want to get on with normalizing their family lives. The result of a longer follow-up period would thus have been an unacceptably high number of dropouts. Furthermore, in the previous trial on spinal manipulation in the treatment of infantile colic, they had a follow-up at 4 weeks but found that the reduction in crying was clearly within the first 14 days, and no significant change occurred in the last 2 weeks of follow-up.<sup>7</sup>

The pretrial characteristics of the 2 treatment groups show only 1 significant difference. The age of the infant when colic started was 2.2 weeks in the dimethicone group compared with 1.2 week in the manipulation group (P = .02), and this could potentially be a problem. If infantile colic tends to disappear spontaneously after a given number of weeks, the difference could have meant that infants in the manipulation group might be more likely to experience spontaneous alleviation of symptoms than those in the dimethicone group, and this could be the reason for the observed effect. But because the age of the infant on entry into the trial also has the same 1-week difference in age and because both groups on entry had infantile colic for 3.7 weeks, this could not have been the reason for the observed difference.

If, on the other hand, infantile colic tends to stop spontaneously at a given age, then the 1-week age difference would instead have favored a higher rate of spontaneous disappearance in the dimethicone group, and this was not evident. So even if the difference in age on debut of symptoms was statistically significant, it did not affect the validity of our results.

There were 9 dropouts in the dimethicone group and none in the manipulation group. This could be interpreted as a sign of parents' bias against dimethicone, but inspection of the data in the last infantile colic profile completed before dropout show clearly that for all where information is available, the dropout was due to a genuine worsening of symptoms and not parents' bias. By excluding data from the dropouts, we are excluding more severe cases from the dimethicone group, and this has the effect of making that group appear better that it actually was. Thus we are introducing a serious bias against showing an effect of spinal manipulation, and despite this the manipulation group did significantly better.

Spinal manipulation is normally used in the treatment of musculoskeletal disorders, and the results of this trial leave open 2 possible interpretations. Either spinal manipulation is effective in the treatment of the visceral disorder infantile colic or infantile colic is, in fact, a musculoskeletal disorder, and not, as normally assumed, visceral. This study does not address this issue.

# CONCLUSION

Spinal manipulation has a positive short-term effect on infantile colic.

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