

Infantile Colic Treated by Chiropractors: A Prospective Study of 316 Cases

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ABSTRACT

A prospective, uncontrolled study of 316 infants suffering from infantile colic and selected according to well-defined criteria shows a satisfactory result of spinal manipulative therapy in 94% of the cases. The median age of the infants was 5.7 wk at the beginning of the treatment. The results were evaluated by analysis of a diary continuously kept by the mother and an assess-

ment file comprised by interview. The study was carried out as a multicenter study lasting 3 months and involving 73 chiropractors in 50 clinics. The results occurred within 2 wk and after an average of three treatments. (J Manipulative Physiol Ther 1989; 12:281-288).

Key Indexing Terms: Infantile Colic, Manipulation, Chiropractic.

INTRODUCTION

Infantile colic is the term commonly used to describe persistent and most often violent crying for no apparent reason in otherwise healthy and thriving young infants. This crying is largely unaffected by the parents' efforts to comfort the infant (1-6). During the colic the infant appears to be distressed, and the infant's behavior is normally considered to be a reaction to pain (1, 2). The infant's inability to gain comfort from the measures employed by the parents distinguishes the crying of infantile colic from normal or physiological crying, which stops when the infant's physiological needs are met (2, 7).

The clinical picture of infantile colic is well described (1-3, 6, 8, 9), but sometimes other terms for the condition have been used, including paroxysmal fussing in infancy (6), evening colic (10), or three-month colic (1). The criteria used to define infantile colic must be well described because different sets of criteria have been used in earlier investigations (1, 5, 6, 11-13).

The debut of symptoms occurs in most cases at 1-4 wk of age, and most often the symptoms end spontaneously at 3-4 months of age (1, 2, 5, 14, 15). Infantile

colic is estimated to affect about 20% of all infants (1, 5, 6, 14, 15).

In spite of many hypotheses, the etiology of infantile colic still remains unknown (1, 2, 5, 6, 14, 16, 17). In the treatment of the condition, various drugs and dietary measures have been employed, but none have had great measures of success (2, 12, 16-20). In controlled clinical trials high placebo effects have been found (21-24). Modification of the parent-infant interaction has been suggested (25-27), and psychological support of the parents is recommended (6, 7, 18, 25).

Infantile colic is often considered a benign condition with a favorable prognosis within a short time limit (3), but the psychological consequences of the condition may possibly result in a disturbed mother-infant relationship (15, 27). There is evidence suggesting that uncontrollable crying is the precipitating factor in many cases of violence towards infants (2, 11, 27-31), and seen in this light it is justified to consider infantile colic a potentially hazardous condition.

Since the turn of the century, spinal manipulation has been used in the treatment of infantile colic (32). In Denmark, chiropractors have been treating infantile colic for years with anecdotal reports of success. In 1985 Nilsson (33), in a retrospective, uncontrolled questionnaire study, showed satisfactory results of chiropractic treatment in 90% of the infants. This study had been undertaken to further describe the possible effect of spinal manipulative therapy on the course of infantile colic in a well-defined group of patients seen in chiropractic practice.

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METHODS

The patients for this study were recruited from those patients who consulted one of the participating chiropractors for the treatment of infantile colic in the 3-month period from April to June 1985. Eligible infants were those whose parents, after thorough verbal and written information about the study, agreed to participate. In order to be included in this study the infants were required to fulfill all inclusion criteria (Table 1A). These strict criteria were chosen to ensure that the infants in this study did have infantile colic in its moderate or severe forms and were otherwise healthy.

Seventy-three chiropractors participated in this study, constituting a sample of 38% of the 191 active members of the Danish Chiropractic Association (1985). The basis for their participation was their positive response to an open invitation to participate in the study. No exclusion of interested volunteers was made, but they all had to attend meetings where thorough instruction of the study design and study procedures was given.

As seen in Figure 1, patient monitoring was carried out by a patient profile, a diary kept continuously by the mother, and three assessment forms.

During the first visit, a thoroughly structured interview consisting of 68 questions was conducted by the

TABLE 1.

A. Inclusion criteria

1. The age of the infant should be between 2–52 wk.
2. Apart from the colic, the infant should have no symptoms suggestive of any other disease.
3. The infant should be reported to have at least one violent crying spell per day, lasting at least 1.5 hr, occurring at least 5 of the 7 preceding days. The infant should exhibit normal behavior outside the colicky periods.
4. The infant should have no other present or previous illness apart from the colic.
5. The infant should have a weight gain of at least 150 g/wk.
6. The infant should be reported to exhibit the following behavior during the colic: motoric unrest, frequent flexing of the knees towards the abdomen, and/or backward bending of the head and trunk.
7. During the colic the infant should not be able to be comforted effectively or lastingly by:
 - a. Being picked up, walked or cradled.
 - b. Change of the diaper.
 - c. Being offered food or comfort.

B. Criteria for exclusion

1. Failure to fulfill the inclusion criteria.
2. Fulfilling the inclusion criteria, but no spinal functional disturbance found at the examination.
3. Nonacceptance of participation by the parents.

C. The typical number of hours with colic per day ($n = 316$):

- Number of h with colic and (%) of n .
- 1.5–3 (24)
 - 4–5 (31)
 - 6–8 (32)
 - 9 or more (13)

chiropractor. This information was recorded in the patient profile and covered pregnancy, birth, feeding, thriving, the colic and its manifestations, previous treatment of the colic, previous illness and the treatment thereof. From the answers in the patient profile it could also be seen whether the infant fulfilled the inclusion criteria or not.

All of the mothers were given a diary to be kept continuously for 28 days. The diary contained a column for each day divided into three sections registering feeding, stools, colic periods, awake and sleep periods (Figure 2). Thorough verbal and written instructions were given for the recording procedure. The diary represents the mother's recording of symptoms, a method considered to be reliable (7, 34–36).

In order to monitor the changes in the symptoms, a structured assessment form was used by the chiropractor on the basis of interviews with the mother. These assessments were performed after 1 wk, after 2 wk and after 4 wk from the beginning of treatment. The information of the assessment form represents the mother's overall subjective evaluation of the infant's symptoms and changes thereof, and thus in contrast to the diary includes an element of the intensity of the colicky crying, comfortability of the infant, and, as in the diary, the length of the colic periods.

The chiropractic treatment was to consist of spinal manipulative therapy. During each consultation the

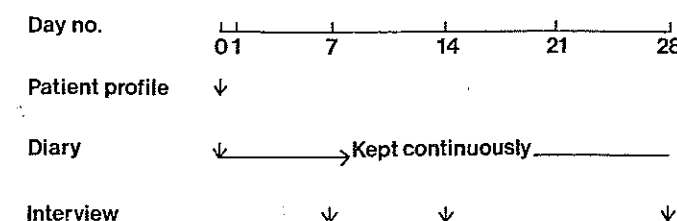


Figure 1. The study design.

Figure 2. The diary.

chiropractor was required to list his findings from the physical examination of the infant, particularly his findings from the movement palpation of the articulations of the vertebral column and pelvis. During each consultation the chiropractor also had to mark those articulations that were manipulated. The actual manipulative technique to be employed in each case was left to the discretion of the individual chiropractor.

During each consultation the chiropractor was required to mark both his findings from the examination of the infant and the articulations that had been manipulated. These above-mentioned recordings were kept in the examination form attached to the patient file.

In general, the chiropractic treatment of infants follows the same principles as for the treatment of adults, but with important practical modifications. The manipulative "crack" which accompanies the manipulation of adults is rarely, or never, released. The force applied during the manipulation is substantially decreased. The contact is usually exerted with one finger and the adjustive thrust is very modest, if performed at all. During the treatment the individual articular segments are moved through their normal range of movements, and restrictions of the normal mobility are overcome with great care. This is repeated at each consultation until free segmental mobility is achieved. Normally, the treatment itself does not trouble the infant to any major degree; the infant may whimper slightly during and shortly after the treatment, as also seen during the traditional physical examination of the infant.

RESULTS

Five hundred sixty-nine patients with colic symptoms consulted the 73 chiropractors during the 3-month study period, and of these, 316 infants fulfilled all the inclusion criteria. Of the 253 patients not included, 51 were excluded for lack of parents' consent to participate, or where no spinal functional disturbance was found on examination. The remaining 202 infants were excluded for not fulfilling the inclusion criteria, of which particularly past or present illness or insufficient weight gain were the main causes of exclusion.

Fourteen days after the beginning of treatment the results of the treatment were evaluated on the basis of the information gained from the diary and the assessment forms. A similar evaluation was carried out after 4 wk in order to estimate possible relapses.

The population is described according to age of debut of colic symptoms and age at which the chiropractic treatment was instituted. The median age at debut of colic was 2 wk. The median age at beginning of treatment was 5.7 wk. (Figure 3).

Figure 4 shows the periods where colic occurred for the whole population ($n = 316$).

Figure 5 is based on the 74% of the population where the colicky periods occurred so regularly that the typical hours for onset and stop of the symptoms could be given. For 85 of these infants more than one typical colicky period could be given. The percentage of infants with regular hours for the colicky periods and the diurnal distribution of these corresponds to the findings in other studied colic populations (1, 5, 6).

Two hundred seventy-six parents gave information about the typical number of colicky periods per day. An average number of colicky periods for this group is 2.5 colicky periods per day. For the whole population ($n = 316$) the average number of hours with colic per day was 5.5 (Table 1C).

Tables 2–4 show the results of the questions regarding the infants' behavior during the colic.

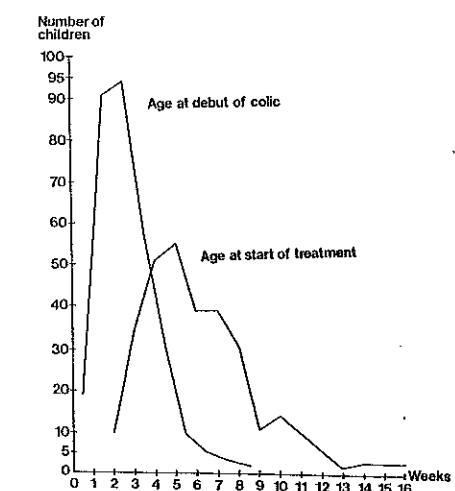


Figure 3. Distribution of the population with regard to age in weeks at onset of colic symptoms and age in weeks when chiropractic treatment was instituted.

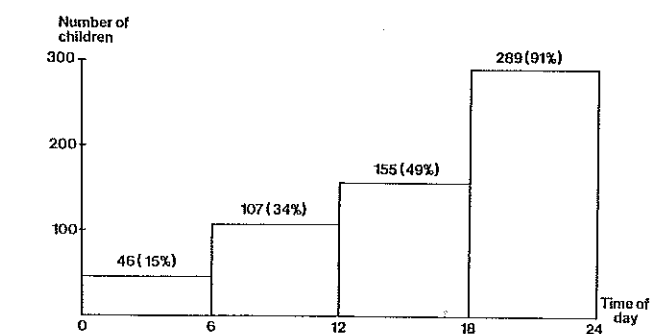


Figure 4. The occurrence of colic for the population ($n = 316$) with a division of the day into four 6-hr periods. More than one period could be marked.

Information about method of feeding was given for 94% of the group = 297 infants. Our figures are in Table 5 compared to a Danish investigation from 1976 carried out by Dehlholm et al. (37). Although one must allow for change in the feeding pattern since 1976 and the fact that our group has a median age of 5.7 wk compared to Dehlholm's population of 2-4 wk of age, the figures do not seem to indicate a dramatic difference in the feeding pattern between infants with infantile colic and the normal population (Table 5).

With respect to complications at birth and time of delivery, the figures for our group do not show any major differences compared to the 1983 figures for the country as a whole (38). Comparison between the two groups is shown in Table 6. Rubin and Pendergast concluded in their investigation that the method of delivery and labor problems did not seem to play any role in the subsequent development of colic (15).

Before consulting a chiropractor, 51% of the infants in our investigation had other forms of treatment for the colic. The methods and frequency of treatment are shown in Table 7. The high frequency of treatment is explained by the fact that all infants in the well-organized Danish health system have been seen by a health visitor 3-4 times before the age of 5 wk, and all infants are examined by the family physician at the age of 5 wk. Almost all deliveries are carried out in a hospital.

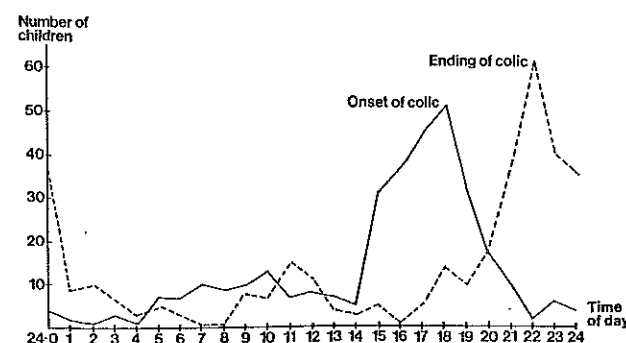


Figure 5. Time of onset and end of colic periods for those infants where the colic occurred with a regular diurnal pattern ($n = 233$).

TABLE 2. The infant's reaction during colic: motoric behavior

	Yes (%)	No (%)	n
Colic crying easily distinguishable from other crying?	91	9	312
Moves the arms vigorously, fists clenched?	94	6	311
Flexing of the knees towards the abdomen?	86	14	311
Bending stiffly backwards, legs extended?	76	24	309

TABLE 3. Gastrointestinal manifestations during colic

	Yes (%)	No (%)	n
Tense or distended abdomen?	57	43	303
Rumbling noises in the abdomen?	84	16	310
Does the child pass much air?	86	14	310
Does the child often pass stools?	35	65	306

TABLE 4. The infant's response to method of comfort (only temporary response)

	Yes (%)	No (%)	n
Comforted by a feed?	24	76	302
Comforted by a comforter?	8	92	307
Comfort by being picked up, being cradled?	31	69	300
Comforted by being carried prone?	45	55	302
Colic stopped by car ride?	67	33	264

TABLE 5. Comparison between present group ($n = 316$) and Dehlholm's investigation from 1979 regarding method of feeding ($n = 331$)

Method of feeding	Present group (%)	Dehlholm (%)
Breastfed entirely	67	57
Mixed breast and formula	15	23
Formula-fed entirely	18	20

TABLE 6. Comparison between present group and all births in Denmark in 1983 with regard to complications at birth and time of delivery

Type of complication	Present group (%)	Denmark 1983 (%)
Labor stimulation	17	17
Delivery by vacuum extractor	14	9
Caesarean section	10	12
Time of birth 40 wk \pm 2 wk	92	86

The changes in symptoms after spinal manipulative treatment, according to the assessment file, are given in Table 8. In 4% of the group no change in colic symptoms was recorded, and in 2% (6 patients) there was an increase in the colic symptoms. In the whole group no side effects of the treatment were reported. The number of missing observations due to absence of assessment file was 17. In the assessment file for week 1, 10 of these 17 had reported colic stopped or colic improved. The parents of the remaining seven infants were contacted, and it turned out that the reasons for the missing observations were cessation of colic (two

cases) and parental noncompliance (three cases), one data coding error, and one chiropractor noncompliance.

Two hundred fifty-six mothers had filled out the diary from day 1-14, and the registered number of colic hours per day is shown in Figure 6. It should be noted that the 5.2 hr with colic on day 0 are based on the retrospective information from the patient profile (average number of hours with colic for the last 2 days

TABLE 7. Other treatments prior to chiropractic treatment

Method of treatment	% of treated ($n = 157$)
Change of the diet	19
Dimethicon	78
Other medication	5
Other method of treatment (e.g., tea of camomile)	25

TABLE 8. Change in symptoms according to information gained from interview with the mother

Assessment	Colic stopped (%)	Colic improved (%)	No change (%)	Worse (%)	n
1 wk	35	56	8	1	307
2 wk	60	34	4	2	299
4 wk	85	12	2	1	262

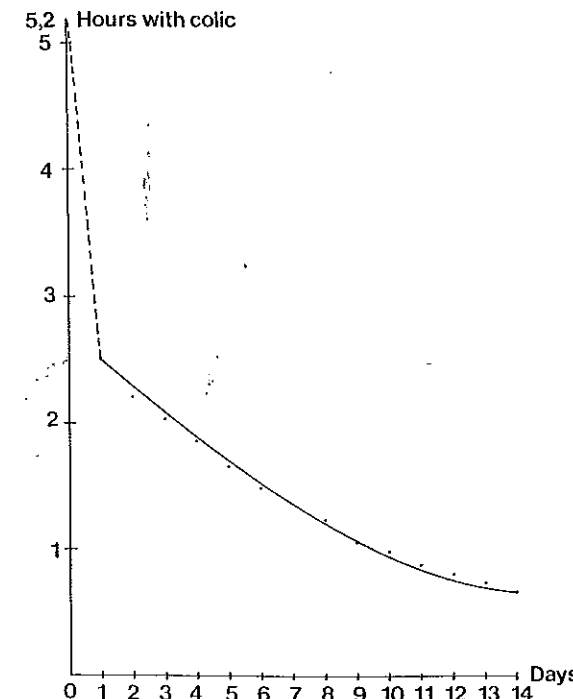


Figure 6. Average daily length of colic from days 1-14 based on 256 complete diary recordings for the period. Day 1 = 2.5 hr, day 14 = 0.65 hr. The average time with colic on day 14 represents a 75% reduction in colic crying time compared to day 1.

before treatment). The rest of the data has been taken from the more objective and prospective diary.

Figure 6 shows a reduction of the daily recorded length of colic from 2.5 hr on day 1 to 0.65 hr on day 14. According to the patient profile, the average number of colic periods per day was 2.5, i.e., before the treatment was initiated. For week 1 the average number of colic periods was 1.3, and for week 2 it was 0.9.

Twenty-three percent of the mothers gave information to the assessment file that the change of symptoms occurred on the first day of treatment. For the two weeks the average number of spinal manipulative treatments was three (1-5).

Information about the treatment that each infant received during each consultation was gained from the examination form. Ninety-four percent of the infants were manipulated in the upper cervical articulations (the atlanto-occipital articulations, the atlantoaxial articulations). Only 6% of the infants had received manipulations in areas of the spine that did not include the upper cervical articulations. Fifty-three percent of the infants were manipulated in the upper cervical articulations only, while 41% of the infants, in addition to the upper cervical manipulation, were manipulated in the thoracic articulations as well (in most cases in the mid-thoracic articulations T4/5-T8/9). The 6% that were not manipulated in the upper cervical region were treated with manipulation in other parts of the spine (lower cervical, midthoracic, thoracolumbar, lumbosacral, and sacroiliac articulations or combinations involving two or more of the above-mentioned areas).

DISCUSSION

This study has been carried out as a multicenter study in private chiropractic practices. The sampling frame of the study is all the infants whose parents during the 3-month study period consulted one of the participating chiropractors for the treatment of infantile colic. Our study population was selected according to our inclusion and exclusion criteria (Table 1A-B). This sampling method reduced the number of infants from 518 to 316. This reduction resulted from our wish to ensure a group of infants as well-defined and homogeneous as possible, and also to ensure that the infants did suffer from infantile colic and no other disease. Several studies of infantile colic have been criticized for not having precisely defined infantile colic or for not having adequately described their sampling methods (1, 2, 5, 6).

Although selected, our population may well be representative of infantile colic in its moderate and more

severe forms, because chiropractic treatment of infantile colic is a commonly used choice of therapy in Denmark and because our population resembles other described groups with infantile colic.

The number of chiropractors and patients in this study indicates how widely this method of treatment is used in Denmark. In 1985 the number of births in Denmark was about 50,000. Infantile colic is estimated to affect about 20% of these infants. From the number of infants seen by the participating 38% of all the Danish chiropractors during the 3 months study period, we can assume that 20–40% of all infants in Denmark suffering from infantile colic are being treated by chiropractors.

Compared to randomized, controlled trials, clinical series without control groups are relatively simple and quick to perform. To maintain the multicenter design of the study we did not consider it possible to carry out this study in a randomized, controlled design. One of the advantages of our study design was that it allowed the chiropractors to work under study conditions that did not differ much from the normal clinical practices with this patient group. In our opinion, this was reflected in the relatively large number of chiropractors who volunteered to participate in the study.

Studies without a comparable control group are sensitive to bias, and the placebo effect of the treatment modality cannot be accurately assessed.

The chiropractors in this study were all volunteers and therefore likely to be convinced of the efficacy of their treatment. Consequently, they may tend to judge the outcome of the treatment as positive. This potential source of bias may be reflected in the answers of the assessment files. We do not think, however, that bias has played a major role here. In their overall evaluations of the changes in the infants' colic symptoms 94% of the mothers state "no colic" or "colic improved," according to the answers in the assessment files. When this information is compared to the recordings of the diaries, a reduction in the registered daily length of colic crying time from 2.5 hr on day 1 to 0.65 hours on day 14 was found. So the mothers' overall evaluation of the changes in the infants' colic symptoms (the assessment form) is matched by a substantial, recorded reduction of colic crying time.

As will be seen in Figure 6, there is a dramatic reduction in hours with colic occurring on the first day of treatment. This raises a problem because, prior to the treatment, the mothers state an average of about 5.2 hr with colic per day, whereas the diary registers only 2.5 hr for the first day. The number of actual

hours of colic per day, prior to consulting the chiropractor, is probably smaller than the stated average of 5.2 hr, but, on the other hand, since the parents reported some effect immediately after the first treatment, i.e., before the diary was commenced, it must be greater than the recorded 2.5 hr for the first day. If we had realized how quickly the effect would occur we could have instituted a baseline registration two days before the first treatment was given, and this uncertainty could thus have been eliminated.

Our results show that 14 days will suffice to register a change. This is important because by choosing a longer span of time one approaches the theoretical time of natural cessation of colic symptoms. As the average age after 2 wk of assessment in this study was 7.7 wk we feel that, on the whole, we can disregard the influence from spontaneous cessation of colic symptoms (5, 6, 14–16).

A common problem in prospective studies is that not all of the patients can be followed for the entire study period, as some of them are always likely to drop out. The number of drop-outs in this study is so small and so well described that we do not consider it a problem.

The treatment modality in this study was manipulation given according to the findings from the physical examination, notably the movement palpation examination. It is therefore interesting to note the high degree of agreement as to which articulations were to be manipulated. In 94% of the cases the upper cervical articulations were manipulated, either solely or in combination with manipulation of articulations in the mid-thoracic spine. In their study of 683 new-born infants, Buchmann and Bülow (39) found 34% of the infants to exhibit functional disturbance of the articulations of the upper cervical spine. However, they did not relate these findings to later developments of infantile colic.

In controlled double blind clinical trials placebo effects of 25%–70% have been noted (11, 21–23). Our study design does not provide us with the means to estimate the placebo effect of manipulation. This can be done using a design where the group to receive manipulation is randomly allocated to either normal manipulation or placebo (sham) manipulation.

Does chiropractic treatment influence the course of infantile colic? Yes, probably. This study shows that 94% of the mothers state "no colic" or "colic improved," a satisfactory result from a clinical point of view. The results suggest that manipulation constitutes an effective treatment of the condition. But the results must not be overinterpreted because of the above-discussed possible influence from factors other than the

manipulation. The promising results of chiropractic treatment for this troublesome condition should be investigated further.

CONCLUSION

The results of this study suggest that spinal manipulation of the vertebral column in infants with infantile colic constitutes an effective treatment of the condition. The results show a satisfactory effect of the treatment in 94% of the cases within 14 days from the start of treatment. The results occur shortly after the treatment has been initiated and show both a reduction of the daily length of the colic periods and a reduction of the number of colic periods per day. In this study, an average of three treatments was found to be required to obtain a satisfactory result. No side effects were reported.

The promising results of this study invite further investigations. Because of the study design of this study a number of questions have not been sufficiently answered. Further studies must be designed in such a way that the number of sources of noise (bias) affecting the interpretation of the results is reduced so that the placebo effect can be more accurately estimated. At present, a study design involving two clinics, recruitment of the patients by the health visitors, random allocation of the infants to either an untreated control group or to two groups to receive chiropractic treatment (one to receive manipulation according to palpatory findings and one to receive sham manipulation), blinded assessment for all three groups, the use of a diary for the registration of symptoms, and baseline diary registration is in preparation.

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