ABSTRACT

OBJECTIVE: The purpose of this study was to determine the efficacy of chiropractic manual therapy for infants with unexplained crying behavior and if there was any effect of parental reporting bias.

METHODS: Infants with unexplained persistent crying (infant colic) were recruited between October 2007 and November 2009 at a chiropractic teaching clinic in the United Kingdom. Infants younger than 8 weeks were randomized to 1 of 3 groups:

(i) infant treated, parent aware;
(ii) infant treated, parent unaware; and
(iii) infant not treated, parent unaware.

The primary outcome was a daily crying diary completed by parents over a period of 10 days. Treatments were pragmatic, individualized to examination findings, and consisted of chiropractic manual therapy of the spine. Analysis of covariance was used to investigate differences between groups.

RESULTS: One hundred four patients were randomized. In parents blinded to treatment allocation, using 2 or less hours of crying per day to determine a clinically significant improvement in crying time, the increased odds of improvement in treated infants compared with those not receiving treatment were statistically significant at day 8 (adjusted odds ratio [OR], 8.1; 95% confidence interval [CI], 1.4-45.0) and at day 10 (adjusted OR, 11.8; 95% CI, 2.1-68.3). The number needed to treat was 3. In contrast, the odds of improvement in treated infants were not significantly different in blinded compared with nonblinded parents (adjusted ORs, 0.7 [95% CI, 0.2-2.0] and 0.5 [95% CI, 0.1-1.6] at days 8 and 10, respectively).

CONCLUSIONS: In this study, chiropractic manual therapy improved crying behavior in infants with colic. The findings showed that knowledge of treatment by the parent did not appear to contribute to the observed treatment effects in this study. Thus, it is unlikely that observed treatment effect is due to bias on the part of the reporting parent.

Full text Article

Introduction

Excessive infant crying in otherwise healthy infants, traditionally called infant colic, continues to be an enigmatic condition with no known cause and no known cure. [1-3] Afflicting between 10% to 30% of all infants and consuming significant health care resources, [2] infant colic is a problem for parents and clinicians, both of whom try a wide range of therapies with often disappointing results.

Despite decades of research, a clear pathogenesis has not been elucidated. Notwithstanding, what is clear is that underlying disease is rare in the excessively crying baby [4] and that half of those affected recover by 6 months of age, [5] with a small proportion at risk of injury [6] or long-term developmental problems. [7-9] In an effort to help their child with what appears to be a painful condition, some parents choose complementary and alternative medicine (CAM), including chiropractic manual therapy. [9-12] To date, several randomized trials have been reported, [13-19] and although these trials demonstrate some reduction in crying, weaknesses in study methodologies have compromised their contribution to the evidence base. [20-23]

A Danish study in 1999 [13] showed manual therapy resulted in a significant reduction in crying in a 2-week trial when compared with simethicone (known to have no effect over placebo [3]) as a control. However, the parents were not blind to treatment allocation, which could have biased their reports of outcome. Similarly, a British study in 2006, comparing manual therapy with no treatment, showed significant declines in crying in the treatment group, but again, parents were not blind to the intervention received. [14] In contrast, a Norwegian study in 2002, which did blind the parents to treatment allocation, showed similar reductions in crying with manual therapy and with placebo. [15] However, the manual therapy in that trial was an intervention nonspecific to the patient. A British study in 2005 compared 2 manual therapies, and although participants in both treatment arms showed reductions in crying, there was no placebo group for comparison. [16] Finally, 3 South African studies showed that significant improvements in crying with manual therapy over detuned ultrasound [17] and medication [18, 19] can only be found in conference proceedings and therefore remain unpublished in the peer-reviewed literature. Based on these studies, there is some but not conclusive evidence to make a recommendation of manual therapy for the excessively crying baby. [22] For there to be a better understanding about the efficacy of chiropractic treatment for infants with colic, these methodological weaknesses should be addressed.

Therefore, the objectives of this study were to conduct a single-blind, randomized controlled trial comparing chiropractic manual therapy with no treatment and to determine whether parents' knowledge of treatment biases their report of change in infant crying. The questions posed were as follows:

(i) in colicky infants, is there a difference in crying time between infants who receive chiropractic manual therapy and those who do not, and

(ii) in colicky infants, is there a difference in infant crying time between parents blinded and parents not blinded to treatment?

Discussion

This study investigated the effect of chiropractic manual therapy in infants with infantile colic and the effect that blinding has on the report of crying time by the parent. In previous studies, [**13, 14, 16-19**] any apparent effect that an intervention had on crying time in colicky infants has been challenged for lack of blinding of the parents and the consequential potential for reporting bias. In studies of interventions for excessive crying in infants, there is no alternative to the outcome being based on the parent's self-report of crying behavior, and although crying diaries in themselves have been shown to be valid measures, [**27, 28**] the influence of the parent knowing whether or not his/her child was treated raises suspicions, rightly or wrongly, about any observed treatment effect. We attempted to overcome this impediment by purposively designing the trial to observe what, if any, effect the parent knowing about their child's treatment had on the report of crying time. The treatment was based on evidence that showed that such therapy has been implicated in reduced crying, and previous authors have hypothesized that colic is a musculoskeletal disorder. [**13, 29, 30**] Moderate finger pressure on irritable muscles has shown a relaxation response in adults, which included decreased heart rate and increased alpha and beta brainwave activity, which hallmark a relaxation response. [**30**] A reduction in heart rate secondary to a therapeutic manual impulse at the suboccipital region has been similarly demonstrated in infants. [**31**] Other research corroborates the safety of the treatment found in this trial. [**32**]

In answer to our first question, the results of our study showed statistically significant differences in the change in crying time between infants receiving treatment and no treatment in parents blinded to treatment allocation and a greater odds of improvement in the treated group toward the end of the 10-day trial period. Although the results were not always statistically significant, the trend was for the treated infants to show a greater reduction in crying than those in the nontreated group within 2 to 3 days. This suggests that any beneficial effect of treatment is apparent early on, thus quickly reassuring anxious and distressed parents. The question on group allocation posed at the end of the study suggests that the procedures taken to blind parents were reasonably successful,

and the degree of blinding was not dissimilar between the treated and nontreated groups. When comparing the effects of parents blinded and not blinded to treatment, there were no significant differences in the reduction in crying, indicating that blinding the parent had no biasing effect on the report of infant crying behavior. Other studies [**13, 14, 16-19**] where the lack of parental blinding has been cited as a possible explanation for an observed treatment effect might therefore be reconsidered in the light of this finding. The only other study [**15**] in which parents were blinded reported no differences in effect between groups. Possible explanations for differences in the findings from this study and the one reported here include differences in treatment and control groups (their participants underwent motion palpation and holding/soothing, whereas our control group did not receive any clinical handling) and in the primary outcome measure. Moreover, it is likely that the study of Olafsdottir et al [**15**] included more infants at the severe end of the crying spectrum (as all had been previously treated unsuccessfully in the health care system), and the analysis did not account for the large dropout in the control group, which may have included the highest criers, as other studies show. [**13, 33**]

All dropouts in this study occurred in the no-treatment group, which has also been shown to be the case in other studies. [**13, 33**] Although the parents of these infants were apparently "blind" to the treatment group, we can speculate that any lack of improvement deterred parents from returning to the clinic. Alternatively, these parents may have correctly guessed that their child was not being treated and left the trial to be treated elsewhere. This is supported by our findings of no difference between the treatment groups in which parents were blinded and not blinded to treatment. We found a clinically significant effect of chiropractic manual therapy in this patient group but, importantly, that this is evident despite whether or not parents know their child was treated. We can conclude that any reporting bias by the parent was not responsible for the observed effect of treatment in this study.

A relatively low number of parents (n = 5 [15%]) reported that their child was not treated in the NTB group. It is also true that this was greater in the TB group, where 17 (49%) of the parents considered that either their child was not treated or they did not know. One reason for this is that we are, of course, not comparing like with like because the second is a composite figure. In addition, the 9 who dropped out in the NTB group might be assumed to have done so because their babies were not being treated. If this assumption were true, this would raise the number of patients who were not being treated to 14 (41%). When combined with the number of parents who did not know (20; 59%), this would bring the total to 100% compared with the 48% in the TB group, in line with what might be expected.

Limitations

This randomized trial did have limitations that caution interpretation of the findings, not least conducting a trial in a routine practice setting and the consequential problems of loss to follow-up. This was compounded by the fact that we decided, for ethical

reasons, to discharge patients who were recovered early on in the trial. [34] Together with small sample sizes from the outset and variability within our data sets, this meant that estimates of effects in the target population were imprecise, thus compromising, at least in part, their clinical use.

Although we paid particular attention to blinding the parents, it was not possible to exclude the parent from the treatment room altogether because of regulations governing chiropractic treatment for minors in the United Kingdom. Moreover, we only checked parents for blinding at the end of the study. By asking parents to state whether or not they thought their child was being treated, it was inevitable that any change in their child's condition by the end of the treatment period would have influenced their decision. Thus, we did not know the parents' “beliefs” day by day throughout the study period at times when they were completing the crying diary. Furthermore, as a single-blind trial, we only attempted to blind the parents. It was obviously not possible to blind those administering the treatment, and thus, the findings of this study may be subject to practitioner bias. The practitioners in this trial had no part in reporting outcomes from care.

External validity is often problematic in randomized trials, and this study is no exception. Infants were treated in an outpatient teaching clinic by different final-year student interns accompanied by experienced clinicians. This does not reflect treatment that is received in established chiropractic practices. Similarly, most parents were referred by general practitioners, midwives, and health visitors in the area, and in many cases, parents expected to pay for treatment. Whether our sample represents the population of parents of infants with excessive crying symptoms is therefore questionable. Moreover, the inclusion criterion that allowed for the mother's diagnosis of excessive crying is a subjective one, although paradoxically, this may increase the generalizability of the findings and all infants did fit the routine definition of colic for amount of crying previously shown in the research. [1-3, 25-29] Also, diary information and parental reporting of accurate time crying may be subject to recording error or bias.

Finally, we used 2 cutoffs in the change in crying time with which to categorize improvement in our participants. The more conservative of these was 2 or less hours per day of crying, which has been reported in the literature as a “normal” level of crying. [24, 35] The other cutoff of more than 30% reduction in crying was entirely arbitrary on our part and is open to challenge. However, we felt it necessary to define these end points to report the findings in clinically significant terms rather than as group mean statistically significant decreases in crying time that are more difficult to interpret from a clinical perspective. Both cutoff points were chosen for the practical reason to increase the robustness of the clinical results because cutoff points can be considered arbitrary. We did not mix the cutoff points but purposely kept them separate, to address any criticism concerning an idiosyncratic cutoff point.

Conclusion

In conclusion, the findings of this study demonstrate a greater decline in crying behavior in colicky infants treated with chiropractic manual therapy compared with infants who were not treated. The findings also showed that knowledge of treatment by the parent did not appear to contribute to the observed treatment effects in this study. Thus, it is unlikely that observed treatment effect is due to bias on the part of the reporting parent.

J Manipulative Physiol Ther. 2012 (Oct); 35 (8): 600–607

Joyce E. Miller, BS, DC, DABCO, David Newell, PhD, Jennifer E. Bolton, PhD

Associate Professor, Anglo-European College of Chiropractic, Bournemouth, UK. Electronic address: jmiller@aecc.ac.uk.

References:

1. Douglas P, Hill P.
Managing infants who cry excessively in the first few months of life.
BMJ. 2011;343:d7772

2. Morris S, St James-Roberts I, Sleep J, Gillham P.
Economic evaluation of strategies for managing crying and sleeping problems.
Arch Dis Child. 2001;84:15–19

3. Lucassen P.
Colic in infants.
Clin Evid. 2010;02:309

4. Freedman SB, Al-Harthy N, Thull-Freedman J.
The crying infant: diagnostic testing and frequency of serious underlying disease.
Pediatrics. 2009;123:841–848

5. Crotteau CA, Wight ST, Eglash A.
Clinical inquiries. What is the best treatment for infant colic?.
J Fam Pract. 2006;55:634–636

6. Reijneveld SA, van der Wal MF, Brugman E, Hira Sing RA, Verloove-Vanhorick SP.
Infant crying and abuse.
Lancet. 2004;364:1340–1342

7. Savino F, Castagno E, Bretto R, Brondello C, Palumeri E, Oggero R.
A prospective 10-year study of children who had severe infantile colic.
Acta Paeditry Suppl. 2005;94:129–132

8. Wolke D, Rizzo P, Woods S.
Persistent infant crying and hyperactivity problems in middle childhood.
Pediatrics. 2002;109:1054–1060

9. Miller JE, Phillips HL.
Long-Term Effects of Infant Colic: A Survey Comparison of Chiropractic Treatment and Nontreatment Groups
J Manipulative Physiol Ther 2009 (Oct); 32 (8): 635–638

10. Hestbaek L, Jørgensen A, Hartvigsen J.
A Description of Children and Adolescents in Danish Chiropractic Practice: Results from a Nationwide Survey
J Manipulative Physiol Ther. 2009 (Oct); 32 (8): 607–615

11. Kemper KJ, Vohra S, Walls R.
The Use of Complementary and Alternative Medicine in Pediatrics
Pediatrics. 2008 (Dec); 122 (6): 1374-86 ~ **FULL TEXT**

12. Barnes PM, Bloom B, Nahin R.
In: Complementary and alternative medicine use among adults and children:
United States, 2007. CDC Natl Health Stats Report No. 23. 2008;p. 1–23

13. Wiberg JMM, Nordsteen J, Nilsson N.
The Short-term Effect of Spinal Manipulation in the Treatment of Infantile Colic: A Randomized Controlled Clinical Trial with a Blinded Observer
J Manipulative Physiol Ther 1999 (Oct); 22 (8): 517–522

14. Hayden C, Mullinger B.
A preliminary assessment of the impact of cranial osteopathy for the relief of infant colic.
Complement Ther Clin Pract. 2006;12:83–90

15. Olafsdottir E, Forshei S, Fluge G, Markestad T.
Randomised Controlled Trial of Infantile Colic Treated With Chiropractic Spinal Manipulation
Arch Dis Child. 2001 (Feb); 84 (2): 138–141

16. Browning M, Miller J.
Comparison of the Short-term Effects of Chiropractic Spinal Manipulation and Occipito-sacral Decompression in the Treatment of Infant Colic: A Single-blinded, Randomised, Comparison Trial
Clinical Chiropractic 2008 (Sep); 11 (3): 122–129

17. Koonin SD, Karpelowsky AS, Yelverton CJ, Rubens BN.
A comparative study to determine the efficacy of chiropractic spinal manipulative therapy and allopathic medication in the treatment of infantile colic [abstract].
In: World Federation of Chiropractic 7th Biennial Congress. Orlando, FL: World Federation of Chiropractic; 2002;p. 18

18. Mercer C, Nook BC.
The efficacy of chiropractic spinal adjustments as a treatment protocol in the management of infantile colic.
In: Haldeman S, Murphy B editor. 5th Biennial Congress of the World Federation of Chiropractic. Auckland:
World Federation of Chiropractic; 1999;p. 170–171

19. Karpelowsky AS.
The efficacy of chiropractic spinal manipulative therapy in the treatment of infantile colic.
MSc Dissertation. Health Sciences, Technikon Witwatersrand. Johannesburg, 2004.

20. Ernst E.
Chiropractic spinal manipulation for infant colic: a systematic review of randomised trials.
Int J Clin Pract. 2009;63:1351–1353

21. Bronfort G, Haas M, Evans R, Leiniger B, Triano J.
Effectiveness of Manual Therapies: The UK Evidence Report
Chiropr Osteopath. 2010 (Feb 25); 18: 3

22. Hussereau D, Clifford T, Aker P, Leduc D, Mensinkai S.
Spinal manipulation for infantile colic.
Ottawa: Canadian Coordinating Office for Health Technology Assessment. 2003. Technology report No 42.

23. Volkening DA.
The short-term effect of spinal manipulation in the treatment of infantile colic: a randomized controlled clinical trial with

a blinded observer.
J Manipulative Physiol Ther. 2000;23:365

24. Canivet C, Hagander B, Jakobsson I, Lanke J.
Infantile colic-less common than previously estimated?.
Acta Paediatr. 1996;85:454–458

25. Pauli-Pott U, Becker K, Mertesacker T, Beckmann D.
Infants with “colic”—mothers' perspectives on the crying problem.
J Psychosom Res. 2000;48:125–132

26. Barr RG, Rotman A, Yaremko J, Leduc D, Francoeur TE.
The crying of infants with colic: a controlled empirical description.
Pediatrics. 1992;90:14–21

27. St. James-Roberts I, Hurry H, Bowyer J.
Objective confirmation of crying durations in infants referred for excessive crying.
Arch Dis Child. 1993;68:82–84

28. Barr RG, Kramer MS, Boisjoly C, McVey-White L, Pless IB.
Parental diary of infant cry and fuss behaviour.
Arch Dis Child. 1988;63:380–387

29. Wiberg KR, Wiberg JM.
A Retrospective Study of Chiropractic Treatment of 276 Danish Infants With Infantile Colic
J Manipulative Physiol Ther. 2010 (Sep); 33 (7): 536–541

30. Diego MA, Field T, Sanders C, Hernandez-Reif M.
Massage therapy of moderate and light pressure and vibrator effects on EEG and heart rate.
Int J Neurosci. 2004;114:31–45

31. Koch LE, Koch H, Graumann-Brunt S, Stolle D, Ramirez J-M, Saternus K-S.
Heart rate changes in response to mild mechanical irritation of the high cervical spinal cord in infants.
Forensic Sci Int. 2002;128:168–176

32. Miller JE, Benfield K.
Adverse effects of spinal manipulative therapy in children younger than 3 years: a retrospective study in a chiropractic teaching clinic.
J Manipulative Physiol Ther. 2008;31:419–423

33. McRury JM, Zolotor AJ.
A randomized controlled trial of a behavioural intervention to reduce crying among infants.
J Am Board Fam Med. 2010;23:315–322

34. Hawk C, Schneider M, Ferrance RJ, Hewitt E, Van Loon M, Tanis L.
Best practices recommendations for chiropractic care for infants, children, and adolescents: results of a consensus process.
J Manipulative Physiol Ther. 2009;32:639–647

35. Clifford TJ, Campbell K, Speechley KN, Gorodzinsky F.
Sequelae of infant colic: evidence of transient infant distress and absence of lasting effects on maternal mental health.
Arch Pediatr Adolesc Med. 2002;156:1183–1188