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Research Paper Review

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Efficacy of Chiropractic Manual Therapy on Infant Colic: A Pragmatic Single-Blind, Randomized Controlled Trial

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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.

ANALYSIS

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Background Information

Infantile colic, or excessive crying, affects between 10% and 30% of young children and can consume a great deal of resources in health care (not to mention being a huge source of stress for parents and babies!). To date, no clear cause of infant colic has been identified, although it has become clear from previous research that it is rare to find an underlying disease. Roughly 50% of infants affected recover in 6 months (a long 6 months for those involved!) – this condition is self-limiting, but within a widely variable timeframe. Although there is some evidence to support the use of manual therapy for the treatment of infant colic, as a whole it is not yet conclusive. This literature has been reviewed in two prior systematic reviews (1, 2). Reported issues with previous studies include:

- Lack of blinding
- Possible bias toward treatment, due to parents being aware of the treatment their child was receiving
- Using parent reported improvements as the main outcome measure

This study attempted to improve on these shortcomings and remove these potential sources of bias.

PERTINENT RESULTS

- 104 infants were included in the study – 33 in the non-blinded treatment group, 35 in the blinded treatment group, and 34 in the blinded, non-treatment group.
- No significant differences were seen in the demographics among the three groups.
- Twelve patients dropped out before the end of the study.
- *Overall, greater differences in crying time were found in infants receiving chiropractic treatment, regardless of whether the parents were blinded or not. The greatest reduction in crying was reported within 2-3 days of beginning treatment, suggesting that the benefits of treatment are likely to be apparent early on (which helps to reassure parents).*
- The efforts to blind parents appeared to be successful with parents showing very low ability to correctly identify which treatment group their infant belonged to.

- As well, there were no significant differences seen in the decrease in crying time between the blinded and non-blinded treatment groups.
- *Importantly, no adverse effects of treatment were reported*, while one parent in the non-treatment group reported increased crying.

CLINICAL APPLICATION & CONCLUSIONS

This study supports the use of chiropractic manual therapy in infants presenting with colic. Importantly, the study also suggests that the effectiveness of chiropractic manual therapy cannot be attributed to parent bias – this is certainly an improvement on existing studies! This study should lead practitioners to reconsider the existing research supporting the use of chiropractic manual therapy for colic, which has been criticized for the lack of parental blinding. Another interesting observation was that improvement from this treatment would likely become apparent early on – demonstrating that a short course of therapy is certainly a reasonable option for this condition.

STUDY METHODS

Infants were included in the study based on the mother's diagnosis of colic combined with a baseline crying diary of 3 or more days. Further inclusion criteria were: infant age less than 8 weeks, infants born at a gestational age of 37 weeks or later, a birth weight greater than or equal to 2500 grams, and no other existing conditions or illnesses. Eligible infants were enlisted from the chiropractic teaching clinic at the Anglo-European College of Chiropractic.

The infants were randomized into 3 groups:

1. A group where the infant was treated and the parent was not blinded to the treatment (T[NB]);
2. a group where the infant was treated and the parent was blinded to the treatment (T[B]); and
3. a group where the infant was not treated and the parent was blinded to the treatment (NT[B]).

Treatments were performed by a final year chiropractic intern and supervised by an experienced clinician. All treatments were individualized, based on patient examination, and included chiropractic manual therapy in the form of tactile pressure of approximately 2N applied to spinal joints and paraspinal muscles without rotation. The treatment period lasted up to 10 days with patients released from care before the end of the 10 days if parents reported complete resolution of their symptoms. The number of treatments given was based on the individual examination findings and results of treatments for each infant – a pragmatic approach to treatment. Parents in the non-blinded treatment group were able to observe the treatment being given while parents in the blinded treatment group placed their infant on the treatment table and then sat behind a screen so they were unable to observe whether their infant was treated or not.

Patients in the non-treatment group were also placed by their parents on the treatment table and the parents then sat behind the screen as well. In both blinded groups, the practitioner followed a set verbal script to make sure parents were unable to determine which group their infant was in. The script consisted of four sentences. "We will begin treatment now; it will be just one more minute; that is the end of treatment; we will stop now."

Parents completed a questionnaire on infant demographics at baseline and then completed a 24-hour crying diary throughout the length of the study. The primary outcome measure used was crying time, as extracted from the crying diary. Secondary outcome measures included a global improvement scale completed at discharge, rating the parents' impression of change in their infant, parent reports of any adverse effects seen during the course of treatment, and a test of blinding. This involved asking parents from the blinded groups to guess whether their infant had received treatment or not.

STUDY STRENGTHS / WEAKNESSES

Strengths

- The authors addressed the possible issue of bias due to parent reported outcomes by creating blinded and non-blinded treatment groups.
- A fairly large sample size was utilized making the results more statistically significant.
- As it was not possible to blind the practitioners, the possibility of practitioner bias remains. However, by giving the practitioners no part in reporting outcomes in this study, this potential bias was avoided (for the most part).

Weaknesses

- Using the Anglo-European College of Chiropractic as a centre to recruit study subjects may bias participants in all groups toward manual therapy, since they voluntarily seek care at that facility.
- Treatments were performed by final-year students (with an experienced clinician in attendance) – this may make the treatment experience less reflective of what a more experienced chiropractor could achieve. Having said that, this sort of treatment is relatively simple to administer, so it is within reason that an intern could apply it with a high degree of efficacy.
- Because parents reported crying times, we have to be aware of the possibility of recording error.

Additional References

1. Hawk C et al. Chiropractic care for nonmusculoskeletal conditions: A systematic review with implications for whole systems research. J Comp Alt Med 2007; 13(5): 491-512.
2. Gleberzon B, Arts J, Mei A & McManus EL. The use of spinal manipulative therapy for pediatric health conditions: A systematic review of the literature. J Can Chiro Assoc 2012; 56(2): 128-41.