

ADVERSE EFFECTS OF SPINAL MANIPULATIVE THERAPY IN CHILDREN YOUNGER THAN 3 YEARS: A RETROSPECTIVE STUDY IN A CHIROPRACTIC TEACHING CLINIC

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ABSTRACT

Objective: The purpose of this study is to identify any adverse effects to chiropractic care occurring in the pediatric patient and to evaluate the risk of complications arising in the pediatric patient resulting from chiropractic care.

Methods: A 3-year retrospective study of pediatric case files from the Anglo-European College of Chiropractic (AECC) (Bournemouth, England) teaching clinic practice in Bournemouth, England. All files (n = 781) of pediatric patients younger than 3 years of age were selected manually in sequential order from current files stored in the AECC clinic presenting to the AECC clinic during a specific period. Most (73.5%) patients presenting were 12 weeks of age or younger (n = 574).

Results: Six hundred ninety-seven children received a total of 5242 chiropractic treatments, with 85% of parents reporting an improvement. Seven parents reported an adverse effect. There was a reaction rate of approximately 1 child in 100, or one reaction reported for every 749 treatments. There were no serious complications resulting from chiropractic treatment (reactions lasting >24 hours or severe enough to require hospital care).

Conclusion: This study shows that for the population studied, chiropractic manipulation produced very few adverse effects and was a safe form of therapy in the treatment of patients in this age group. (*J Manipulative Physiol Ther* 2008;31:419-423).

Key Indexing Terms: *Complications; Manipulation, Chiropractic Manipulation; Pediatrics; Child; Infant; Adverse Effects; Safety; Public Health*

Complementary and alternative care is increasingly used among the pediatric population and with this trend more children are receiving chiropractic treatment.¹⁻⁶ Studies have shown chiropractic care to be of benefit to the pediatric patient.⁷⁻⁹ Few serious incidents resulting from pediatric spinal manipulative therapy (PSMT) have been reported in the literature.¹⁰⁻¹³ Furthermore, there have been no studies of a large cohort of young children undergoing chiropractic spinal manipulation to assess any negative side effects.

A systematic review of all adverse events associated with spinal manipulation from all types of practitioners identified 13 directly associated events in the pediatric age group between the years of 1969 and 2001.¹² Nine of those cases were related to chiropractic manipulation. There has been one article that has provided an estimate of the risk of neurologic and/or vertebrobasilar (N/VB) accidents in the pediatric chiropractic patient.¹³ This article reviewed the literature concerning the occurrence of N/VB complications in patients receiving either specific chiropractic adjustments and/or nonspecific manipulations of the vertebral column. The article also investigated the number of pediatric (<18 years of age) visits to chiropractors in the same period, between 1977 and the first quarter of 1998. The risk of injury from SMT was calculated by computing both the number of adjustments that children received and the risks of N/VB injury. The result was an injury rate of 1 in 250 million.

Research is deficient in the subject of complications arising in the pediatric patient and the nature of side effects occurring in children as a result of chiropractic PSMT. The apparent trend of increasing numbers of children receiving chiropractic

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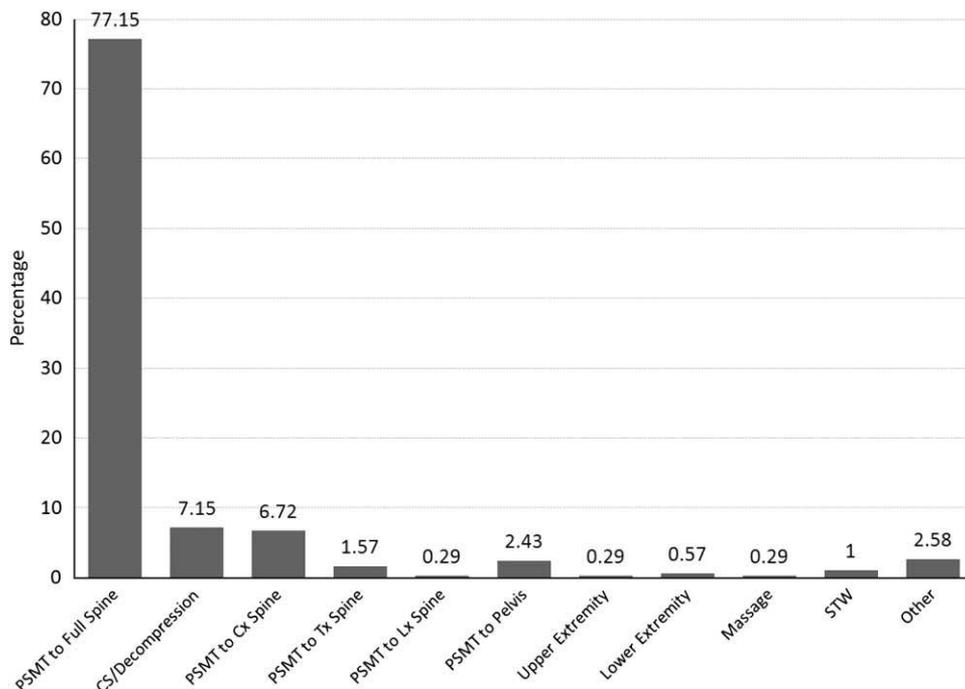


Fig 1. Percentage of children receiving specific types of chiropractic manipulation ($n = 699$).

treatment requires that the profession accurately assess the risk of possible complications to the pediatric patient. Once the number of complications or adverse events and the number of treatments are known within a given period, the risk of potential adverse events can be put into context. The youngest and most vulnerable population, those younger than 3 years of age, were chosen as the subjects for study.

METHODS

The study was a retrospective review of 781 cases of pediatric patients presenting to the Anglo-European College of Chiropractic (AECC) teaching clinic located in Bournemouth, United Kingdom, during the period from January 2002 to December 2004. All cases were selected manually and in alphabetical order from the files stored in the AECC clinic. The inclusion criteria for selecting files were all cases of pediatric patients younger than 3 years of age who had presented to the AECC clinic within the designated period. There were no exclusion criteria.

Information from each file was extracted and recorded in a data sheet including information on how many treatments were received, the type of treatment, the outcome of the treatment, and whether any negative side effects were reported. This was determined by reading notes for each treatment session for all pediatric patients who received treatment. For data that could not be stored numerically, a coding system was used to identify the variables under each heading.

The study was approved by the AECC Research Ethics subcommittee (United Kingdom).

Type of Treatment

Information on the type of treatment that the patients received was collected and grouped under the following categories: PSMT to more than one spinal region or pelvis; PSMT to the cervical, thoracic, or lumbar spine, respectively; PSMT to the pelvis; occipital sacral decompression technique; upper extremity treatment; lower extremity treatment; massage; and soft tissue work. If any treatment implemented did not fit within one of the categories, it was grouped under “other.” The most common treatment type under “other” was instrument-treatment.

Outcome of Treatment

The outcome of the treatment was identified by parental comments on improvement, no change, or worsening of their child’s symptoms. The information about each treatment was reported in the following visit to the clinic or by telephone consultation with the parent. The outcome was recorded in the data sheet as improved, no change, or worse.

Negative Side Effects

Negative side effects were detected by interpreting parental comments in the follow-up to the previous treatment

Table 1. Descriptions of reactions from PSMT reported by parents

Number	Sex	Age at time of reaction (wk)	Description of reaction
1	Male	8	After the first treatment of cervical spine SMT for the treatment of infant colic, the parents telephoned to say the infant was not feeding well and was mildly distressed. The tutor told the parents to monitor the infant closely and to take him to the general practitioner for examination if he did not begin to feed normally within a few hours. The next day the parents called to say that the infant was fine and they resumed care at the clinic for their child.
2	Female	8	After the fourth treatment of cervical and thoracic SMT for the treatment of infant colic, the mother called the clinic to say the baby had been crying since the treatment. The intern spoke to the mother and stated that it as unlikely that the treatment had caused any harm, but if she was concerned, she should seek the advice of her general practitioner. The mother was satisfied with this and said that the crying was probably because of constipation. That evening, the baby slept better than usual, and the mother returned and completed the course of care for her child.
3	Female	6	The parent's returned to the clinic a few hours after the first treatment with cervical spine SMT (in treatment of infant colic) stating that they thought that the baby had a "head tilt" since the adjustment. The tutor examined the child and found full cervical range of motion with no antalgic posture. The parents were satisfied with this, did not feel there was any reaction from treatment, and continued care.
4	Female	7	The mother reported that the baby cried a lot after the first visit for cervical spinal SMT for the condition of infant colic, went to sleep for 2 hours, and awoke and continued to cry. She attended the clinic for 3 more visits and then self-discharged. When telephoned, she said the baby was "doing fine" and did not require more care.
5	Male	5	The parents told the intern that they would not attend the next (7th) visit because after the 6th visit of SMT for the condition of infant colic, the baby was restless and crying for almost 8 hours. They stated they did not wish to continue with treatment.
6	Male	17	On the 25th visit of a child who had been closely monitored since birth trauma, the intern adjusted the pelvis and the baby began to cry instantly. The mother felt that this was a cry of pain. The intern brought a tutor in to examine the infant. The tutor performed a corrective adjustment to the ileum and the baby stopped crying. The mother telephoned later that day to say that the child was fine. The mother continued to bring her child for monitoring and care when required for the next several months.
7	Female	12	At the 11th visit consisting of cervical spine manipulation for the condition of kinematic imbalance due to suboccipital strain (KISS), the baby cried during the treatment and continued to cry upon returning home. The intern telephoned the mother the following day. She said that the baby was better, but she wished to stop treatment.

(or on the same day as the treatment). A negative side effect was defined by any adverse reaction reported by the parent. Negative side effects were recorded as none reported or reported. When an adverse reaction was reported by the parents, a description of the reaction was detailed. These reactions were graded as mild (transient and lasting <24 hours), moderate (requiring medical [general practitioner] treatment), and severe (requiring hospital treatment).

Data Analysis

The data were analyzed using descriptive statistics. The number of patients in each category was ascertained and the percentage calculated. The estimation of the risk of a pediatric patient experiencing an adverse reaction was calculated by dividing the number of patients who were reported to have had an adverse reaction (n = 7) by the total number of pediatric patients who had been treated and had a reported outcome to care (n = 697). The risk of pediatric adverse reactions occurring per treatment session was also estimated. The collective number of treatments was calculated from the number of visits (n = 5242). The number of patients in the study who reported an adverse reaction was

then divided into the total number of treatment sessions to determine the rate of reactions in this study population.

RESULTS

Of the 781 pediatric patients who presented for examination, 462 (59.15%) were male and 319 (40.85%) were female. Most (73.5%) patients were 12 weeks or younger of age (n = 574). The most common age group was between 5 and 8 weeks of age. Most infants presented for the treatment of colic or irritability because of biomechanical disorder, often attributed to birth trauma. Six hundred ninety-nine (89.5%) received treatment, and 82 (10.5%) were dismissed to seek help elsewhere. Five hundred thirty-one (77.11%) received PSMT to the full spine, 50 (7.15%) occipital-sacral decompression, 47 (6.72%) PSMT to the cervical spine only, 11 (1.57%) PSMT to the thoracic spine only, 2 (0.29%) PSMT to the lumbar spine only, and 17 (2.43%) to the pelvis only. Two (0.29%) received upper extremity treatment and 4 (0.57%) lower extremity treatment. Nine (1.29%) received massage and soft tissue work, and 18 (2.58%) received another form of treatment. Figure 1 shows the treatment types.

Of the 699 patients who received treatment, 697 (99.71%) reported an outcome to the care ($n = 5242$ treatments) they received. Two (.0003%) were lost to follow-up. Most parents, 594 (85.22%), reported an improvement in their child's presenting symptoms. One hundred three (14.78%) parents reported that there was no change in their child's symptoms. No parents reported worsening of symptoms. However, of the 697 patients whose parents reported outcomes to care, there were 7 cases in which the parents reported an adverse reaction to treatment. This equates to approximately 1% of patients experiencing a negative side effect. All of these adverse reactions to care were mild in nature, that is, they were transient in nature and required no medical care. All adverse reactions are described in [Table 1](#). There were no serious complications resulting from chiropractic treatment (reactions lasting >24 hours or severe enough to require hospital care).

The descriptions of the reported adverse reactions were examined for classifying into the categories of mild, moderate, or severe. In one, the parents decided that a perceived reaction was not a problem after all and was normal for the child. Another case of increased irritability may have been because of the child having constipation and was not actually a reaction to care. Third, a possible new "head tilt" was determined to be a normal posture resulting from full range of motion. As described, 3 of the 7 reported negative side effects were not actually adverse reactions to care and could be regarded as "perceived" side effects to treatment. If these 3 perceived reactions are removed from the data, the reaction rate is calculated at 1 reaction per 1310 treatments (5242 treatments divided by 4 reactions). To conclude, there were 7 reported reactions to treatment; 4 of these were classified as actual negative reactions to care.

DISCUSSION

The design of the study does not provide information on the effectiveness of pediatric chiropractic treatment but only documents the type of treatment given, parent perception of improvement in the child's condition, and reaction to treatment.

Although no parents reported a worsening of their child's presenting symptoms, 7 parents expressed that they believed their child had an adverse effect to the treatment they received for their child.

Six of these reported reactions involved increased crying after the treatment. Because it is known that adults may have mild reactions to SMT with increased soreness,¹⁴ it is entirely plausible that infants (even with PSMT forces reduced relative to the patient's size and weight) may experience soreness that may increase irritability. It is difficult to compare these adverse reaction risk assessments with already published work in the literature as there have been no similar studies. The single systematic review¹² shows a very low risk of severe reactions to chiropractic PSMT (9 cases in a 30-year

period). Our study showed no severe reactions and only 4 actual mild reactions.

It is also difficult to precisely compare these pediatric adverse effect rates to those of adults, as the negative side effects experienced by adults are different. The adverse reactions reported in the present study consisted of increased crying time and restlessness in 6 of 7 complaints. In adults, the range of mild side effects is reported to include local discomfort, headache, tiredness, and radiating discomfort.¹⁴ The similarities are that the discomfort occurs the same day or one day after treatment and lasts a short period—less than 2 days in adults and less than 24 hours in infants. In children, there was no loss in activity of daily living as they could continue with normal mobility including sucking and eating. In adults, 11% of those with an adverse effect experienced loss in activity of daily living.¹⁴

Although this study has strengths, such as the large number of patients, there are also many weaknesses. For example, 2 patients were lost to follow-up. There was no long-term follow-up on 3 of the patients who had a mild reaction to treatment. It is also noted that many parents may not report reactions either because they may not recognize it as such, or they may be satisfied with the care and choose not to report after treatment. In effect, parental report has limitations. Furthermore, the records may not be totally reliable, and all reactions may not be reported. Because of these weaknesses, it is likely that there is underreporting of reactions to care in this population.

Furthermore, this is a difficult age group on which to collect accurate data. Data were collected only on the youngest of pediatric patients who cannot describe a negative effect for themselves. This is a difficult group to study, but essential, because they are generally left out of such studies merely because of inability to report. It is important this population affords the same respect as other patients who are old enough to complain. Parents are astute readers of infant's body language and its meaning, and their opinion must be accepted in such a study.

If the results of this study can be extrapolated to the wider infant and toddler population that presents to chiropractors, a parental report of an adverse reaction is likely to occur at the rate of approximately 1 for every 100 children presented to a chiropractic office for treatment. The actual rate of adverse reactions is expected to be about 1 case in approximately 1300 chiropractic treatments.

Application to Practice

Our findings suggest that when parents present their child for chiropractic care, the doctor of chiropractic must ensure that the parents understand that increased crying time after treatment may be a temporary reaction to care and can be expected to subside in less than 24 hours. This can be seen as a normal (but rare) reaction to treatment. This practice of informing the parent of a potential reaction has been

instituted at the teaching clinic. Providers are also educated to be proactive and request information about any possible reaction to the last treatment in the routine history-taking in each visit. Furthermore, the Chiropractic Reporting and Learning System¹⁵ developed as a part of clinical risk management to report all patient safety incidents has been expanded to include parent's reports of side effects to treatment. This has been instituted to prospectively collect all parental reports of negative reactions to pediatric treatment. This will result in a more accurate accounting of adverse reactions to treatment in our clinic.

CONCLUSION

More research is required into the issue of adverse effects occurring in all age groups of children who are treated by chiropractors. Adverse effects are best collected prospectively. Prospective investigations into the frequency and types of negative side effects are essential to document safety of chiropractic treatment for this age group and to gain knowledge of the types of reactions young children experience. This will allow chiropractors to inform parents of what is a normal reaction to chiropractic treatment and to detect any risks of our treatment in pediatric care. This study provides evidence that chiropractic treatment is a safe form of therapy for children younger than the age of 3 and documents that there were no serious complications resulting from chiropractic manipulation in this group of children of this age range.

Practical Applications

- Safety of chiropractic treatment for infants and children is under appropriate scrutiny.
- Based on this analysis of 697 pediatric patients undergoing 5242 treatments, chiropractic manipulation resulted in very few adverse effects and is safe for young children and infants.

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