JAOA ORIGINAL CONTRIBUTION

Incidence of Iatrogenesis Associated With Osteopathic Manipulative Treatment of Pediatric Patients

Natalie M. Hayes, DO
Todd A. Bezilla, DO

Context: Although studies have been published documenting the safety and efficacy of osteopathic manipulative treatment (OMT) in adults, no studies exist documenting the safety of OMT in pediatric patients.

Objective: To determine the incidence of iatrogenesis (ie, aggravations and complications) derived from OMT in the pediatric patient population.

Design: A retrospective review of medical records was conducted looking for documentation of aggravations or complications subsequent to OMT. Treatment-associated aggravations were defined as worsening of symptoms or complaints after treatment. Treatment complications were defined as cerebrovascular accidents, dislocation, fracture, pneumothorax, sprains and strains, or death as a treatment outcome. The authors documented all occurrences of treatment-associated aggravations or complications recorded at each office visit, as well as the timing of an aggravation between office visits.

Setting: Medical records of pediatric patients receiving OMT and being seen more than twice at osteopathic manipulative medicine offices in Pennsylvania and Virginia were reviewed.

Patients: Of 502 pediatric patients' medical records reviewed, 346 met the inclusion criteria of two or more office visits for which adequate follow-up data were available.

Results: No treatment-associated complications were documented. Thirty-one (9%) patients had documented treatment-associated aggravations. There was no significant difference between the proportion of male and female patients considered in the study, relative to a 50/50 distribution (females, 48%; males, 52%).

Conclusions: Osteopathic manipulative treatment appears to be a safe treatment modality in the pediatric population when administered by physicians with expertise in OMT. Future studies should be prospective and include larger numbers of patients to document the safety of OMT in this clinical application.

J Am Osteopath Assoc. 2006;106:605–608

Osteopathic manipulative treatment (OMT) is a treatment modality originating in osteopathic medicine. Osteopathic medicine has four major principles:

- The body is one dynamic unit of function, including the concept that mind-body-spirit are inseparable.
- The body is self-regulating and self-healing.
- Structure and function are interrelated.
- For each individual patient, a treatment regimen is designed based on the understanding and implementation of the first three principles.[1–4] Applying OMT to each patient is based on treating for a somatic dysfunction, defined as impaired or altered function of related components of the somatic (body framework) system: skeletal, arthrodial, and myofascial structures and related vascular, lymphatic, and neural elements.[5]

Different techniques are used in OMT; typically, the most used are high velocity/low amplitude (HVLA) thrust, muscle energy, counterstrain (CS), myofascial release (MFR), lymphatic pump, and cranial treatment (CR). The *Figure* provides a synopsis of these broad modalities[3,4,6–9]

Techniques are distinguished by their direction of application in relation to the restrictive barrier. In a direct technique, the physician moves the region of restriction through its range of motion toward or through a restrictive barrier (HVLA, muscle energy), whereas indirect techniques (CS) are directed away from or in the opposite direction of the restrictive barrier. The MFR and CR techniques are used with either direct or indirect intention or a combination of the two. Techniques are selected depending on the patient's presentation and level of cooperation. Indirect techniques are often preferred for acute painful problems, while some techniques such as muscle energy are dependent on the patient's voluntary movement following the osteopathic practitioner's specific instructions. Physician preference is another factor for technique selection and treatment approach.

From the Yale University School of Medicine (Hayes) in New Haven, Conn. Dr Bezilla is in private practice in Wilmington, Del. This study was conducted when both authors were at the Department of Osteopathic Manipulative Medicine, Philadelphia (Pa) College of Osteopathic Medicine.

Address correspondence to Natalie M. Hayes, DO, 66 Montoya Dr, Branford, CT 06405-2528.

E-mail: nhayesdo@aol.com

Submitted October 5, 2004; revision received March 21, 2005; accepted June 7, 2005.

Major Categories of Osteopathic Manipulative Techniques

Counterstrain (CS)
Administered by applying a position of mild strain in the direction exactly opposite that of the strain reflex; involves a focal tender point and positioning the patient to maximal comfort to achieve the desired therapeutic response

Cranial Treatment (CR)
Typically a gentle approach to the head for evaluating structure and balancing membranous tensions

Myofascial Release/Soft Tissue Techniques (MFR)
Directed toward tissues other than skeletal or arthrodial elements; usually involves lateral stretching, linear stretching, deep pressure, traction and/or separation of muscle origin and insertion while monitoring tissue response and motion changes by palpation

Muscle Energy
Directed patient action from a precisely controlled position against a defined resistance by the physician

High Velocity/Low Amplitude (HVLA)
Mobilization with impulse treatment directed at improving joint motion

Lymphatic Pump
Directed at altering intrathoracic pressure to influence lymphatic movement

Figure. *Six major osteopathic manipulative techniques. (Adapted from the "Glossary of Osteopathic Terminology"[5] with permission from the Educational Council on Osteopathic Principles of the American Association of Colleges of Osteopathic Medicine.)*

In recent years, patients and physicians have been increasingly seeking treatment options other than pharmacologic agents[10,11] and surgical intervention,[12] with many institutions beginning to embrace alternative solutions for patient care. With this interest comes the need for research to determine the safety and efficacy of nonpharmacologic modes of therapy, including OMT.

Literature is available regarding the safety of manipulation in adults.[13–16] Published efficacy studies have involved OMT in both adult[17,18] and pediatric[19,20] populations. However, we were unable to find similar data pertaining to children. Therefore, the purpose of this study was to determine the incidence of treatment-associated aggravations or complications related to manipulation by reviewing medical records of pediatric patients receiving OMT.

Methods

The Philadelphia (Pa) College of Osteopathic Medicine's institutional review board approved this study. Medical records of 502 pediatric patients (aged ≤19 y) were reviewed from three osteopathic manipulative medicine offices in Pennsylvania and Virginia. These sites were chosen because they provided a spectrum of socioeconomic and geographic diversity. Patients represented insurance- and noninsurance-based care, as well as different geographic regions (small city, Lancaster, Pa; large city, Alexandria, Va; and metropolitan area, Philadelphia). Eleven licensed osteopathic physicians who had been in practice 1 to 32 years and had expertise in OMT administered the treatments.

Inclusion criteria included all pediatric patients with two or more office visits. Medical records of patients seen only once were excluded from this study. Data extracted from each record included the patient's sex, age at the first treatment, diagnoses, number of treatment sessions, techniques used, treatment-associated aggravations, and treatment-related complication.

Treatment-associated aggravations were defined as worsening of symptoms or complaints posttreatment. Treatment-associated complications were defined as cerebrovascular accidents, dislocation, fracture, pneumothorax, sprains and strains, or death as an outcome of treatment. Both treatment-related aggravations and complications were subjectively determined during the follow-up visit as reported by the patient or the patient's parent(s) and objectively through physical examination.

Independent of clinical site, and for each clinical parameter (diagnosis at initial visit; treatment-associated aggravation), lower and upper 95% binomial confidence limits were calculated. The binomial test was used to compare the proportions of patients against a 50/50 distribution. The time between treatment and onset of an aggravation, when there was one, was compared using a paired *t* test to the time between onset of aggravation and the next visit.

Results

Our retrospective review of the medical records of 502 patients revealed a total number of 3398 office visits. Patients received OMT at each office visit. Patients ranged in age from 1 day to 19 years (mean age, 7.27±5.68 y; median, 7 y); 166 (48%) were females, and 180 (52%), males. Confidence limits for the most common diagnoses at the first visit, excluding somatic dysfunction, are listed in *Table 1*. Somatic dysfunction was the most common diagnosis (n=1097). In order of frequency, the regions with somatic dysfunction were cranial (n=302), cervical (n=198), thoracic (n=174), sacral (n=118), lumbar (n=103), pelvic (n=94), lower extremity (n=76), costal (n=40), and upper extremity (n=6). Patients may have had more than one diagnosis at the initial visit.

Of the 502 patients, 156 were seen only once and thus excluded from analysis. Determining the incidence of com-

Table 1
Most Common Diagnoses at Initial Visit (N=502)*

Diagnosis†	%	95% Binomial Confidence Limits	
		Lower	Upper
Otitis media	10.56	8.01	13.58
Developmental delay	6.77	4.74	9.34
Well check	5.98	4.07	8.42
Plagiocephaly	5.58	3.74	7.96
Scoliosis	4.98	3.25	7.26
Asthma	4.78	3.09	7.03
ADHD	4.58	2.93	6.80
URTI	3.39	1.98	5.37
Migraine or cephalgia	2.99	1.68	4.88
Allergies or rhinitis	2.59	1.39	4.39
Closed head injury	2.59	1.39	4.39
Reflux	2.19	1.10	3.89

* Of 502 pediatric patients whose medical records were reviewed, 346 met the inclusion criteria of two or more office visits for which adequate follow-up data were available.
† Not included is somatic dysfunction, the most common diagnosis, and patients may have had more than one diagnosis at the initial visit.

Abbreviations: ADHD, attention deficit hyperactivity disorder; URTI, upper respiratory tract infection.

plications or aggravations after OMT was therefore based on the remaining 346 patients (mean age, 7.37±5.51 y; median, 7 y; 3242 total visits). Only patients with a follow-up visit had documented treatment-related complications or aggravations from a previous visit. The average number of visits per patient was greater than nine, with a median of six.

No OMT-related complications were documented; 31 (9%) of 346 patients (mean age, 8.43±4.67 y; median, 8 y; 409 office visits) reported an OMT-associated aggravation. The average number of visits per patient in this subgroup was greater than 13, with a median of 8. Patients whose medical records were reviewed received CR, MFR, or both. Muscle energy and HVLA techniques were also incorporated into the treatment regimen for some adolescents.

The most common OMT-associated aggravations are shown in *Table 2*. Six patients had complete resolution of the treatment-associated aggravation within 24 hours, one after 48 hours, and nine other patients were at baseline or had improved symptoms before the next office visit. Four patients had improved symptoms after the next OMT visit, while the medical records of 11 did not have documented comments regarding the treatment-associated aggravation in subsequent visits. The total incidence of patients with an OMT-related aggravation was 9%. No significant difference was found between the three study sites for patients with an OMT-associated aggravation (P=.339).

There was no significant difference between the proportion of male and female patients considered in the study, relative to a 50/50 distribution (females, 48%; males, 52%). Only 7 (2%) of the patients were seen for well-child visits.

The duration of time a patient was seen by a physician after having an OMT-associated aggravation was greater than the time interval from the initial office visit to the onset of an OMT-associated aggravation. Although not significant at the α=.05 level, the probability value was highly suggestive of a difference (P=.067). On average, patients were seen 357 days over and above the duration of time preceding the onset of a treatment-associated aggravation.

Comment

The findings of our study suggest that the incidence of documented iatrogenesis from OMT is relatively low and OMT appears to be safe in the pediatric population when used by physicians with expertise in OMT. Patients whose medical records were included in this study had no documented treatment-related complications. Although such complications are not common in childhood, they were selected because they are adverse events that may prevent the use of—or referral for—OMT. Some treatment-associated aggravations involved soreness or an increase in symptoms for a few days after treatment, which could be a normal response as tissues adapt to changes introduced as the result of OMT.[9] Treatment-associated aggravations resolved over time. Patients with an OMT-associated aggra-

Table 2
Incidence of Posttreatment Aggravations in Pediatric Patients (n=346)

OMT-Associated Aggravation	No. of Patients	Incidence, % (95% CI)
Worsening symptoms	7	2.0 (0.8–4.1)
Behavior problems	5	1.4 (0.5–3.3)
Irritability	5	1.4 (0.5–3.3)
Pain	4	1.2 (0.3–2.9)
Soreness	4	1.2 (0.3–2.9)
Headache	2	0.6 (0.1–2.1)
Dizziness	1	0.3 (0.0–1.6)
Flu-like symptoms	1	0.3 (0.0–1.6)
Treatment reaction	1	0.3 (0.0–1.6)
Tiredness	1	0.3 (0.0–1.6)
Total	**31**	**9.0 (6.2–12.5)**

Abbreviations: CI, confidence interval; OMT, osteopathic manipulative treatment.

vation did not require an additional visit for the aggravation; their next visit was a regularly scheduled appointment. The timing of the documented aggravation and its relation to the previous and follow-up appointments might indicate that the aggravation was related temporally to the OMT yet was not significant enough to require immediate follow-up. This possibility also suggests that an OMT-associated aggravation did not deter patients from continuing to receive OMT.

One limitation to our study involved the number of patients who were seen only once. However, many one-time visits were well-child visits. Most likely, if a child had ill effects from OMT treatment, the parent would have notified the physician; however, this likelihood cannot always be assumed. In contrast, 98% of patients included in the study were not being seen for wellness checks, indicating that parents were seeking treatment for children's medical conditions. Because patients may have somatic dysfunction in several regions depending on their presentation, it is not surprising that somatic dysfunction was the most common diagnosis.

A second limitation, given the retrospective nature of this study, was discriminating a true OMT-associated aggravation from a secondary event that was due to daily activities. One patient who was teething had increased screaming and crying the night of treatment, while another had neck pain after OMT and participation in extracurricular activities (ie, twirling and dancing). Thus, some aggravations may be a result of normal childhood events rather than being related to a given treatment.

Future studies should be prospective and include larger numbers of patients to determine more accurately the incidence of iatrogenesis and the covariates that might be related to its frequency. Such studies will help to determine the safety of OMT in the pediatric population.

Acknowledgments

The authors thank Bruce Stouch, PhD, for statistical contributions and Russell Gene Clayton, DO, for reviewing the manuscript.

References

1. Seffinger MA. Osteopathic philosophy. In: Ward RC, ed. *Foundations for Osteopathic Medicine*. Baltimore, Md: Williams & Wilkins; 1997:3–12.

2. Martinke DJ, Dowling DJ. The philosophy of osteopathic medicine. In: DiGiovanna EL, Schiowitz S, eds. *An Osteopathic Approach to Diagnosis and Treatment*. 2nd ed. Philadelphia, Pa: Lippincott-Raven; 1997:4–7.

3. Bezilla TA. Pediatric osteopathic manipulation: expanding diagnostic and treatment options. *Altern Complement Ther*. 2000;6:283–290.

4. Lesho EP. An overview of osteopathic medicine. *Arch Fam Med*. 1999;8: 477–484.

5. Glossary Review Committee, for the Educational Council on Osteopathic Principles and the American Association of Colleges of Osteopathic Medicine. *Glossary of Osteopathic Terminology*. July 2006. Available at: http://www.do-online.osteotech.org/pdf/sir_collegegloss.pdf . Accessed October 25, 2006.

6. Ward RC, ed. *Foundations for Osteopathic Medicine*. Baltimore, Md: Williams & Wilkins; 1997:667–696,781–794,809–818,901–913,941–967.

7. DiGiovanna EL, Schiowitz S, eds. *An Osteopathic Approach to Diagnosis and Treatment*. 2nd ed. Philadelphia, Pa: Lippincott-Raven; 1997.

8. Greenman PE. *Principles of Manual Medicine*. 2nd ed. Philadelphia, Pa: Williams & Wilkins; 1996.

9. DiGiovanna EL, Kuchera ML, Greenman PE. Efficacy and complications. In: Ward RC, ed. *Foundations for Osteopathic Medicine*. Baltimore, Md: Williams & Wilkins; 1997:1015–1023.

10. Kemper KJ, Wornham WL. Consultations for holistic pediatric services for inpatients and outpatient oncology patients at a children's hospital. *Arch Pediatr Adolesc Med*. 2001;155:449–454.

11. Scharff L, Kemper KJ. For chronic pain, complementary and alternative medical approaches. *Contemp Pediatr*. 2003;20:117–141.

12. Mills MV, Henley CE, Barnes LLB, Carreiro JE, Degenhardt BF. The use of osteopathic manipulative treatment as adjuvant therapy in children with recurrent acute otitis media. *Arch Pediatr Adolesc Med*. 2003;157:861–866.

13. Stevinson C, Ernst E. Risks associated with spinal manipulation. *Am J Med*. 2002;112:566–571.

14. Gross AR, Aker PD, Quartly C. Manual therapy in the treatment of neck pain. *Rheum Dis Clin North Am*. 1996;22:579–598.

15. Fiechtner JJ, Brodeur RR. Manual and manipulation techniques for rheumatic disease. *Med Clin North Am*. 2002;86:91–103.

16. Vick DA, McKay C, Zengerle CR. The safety of manipulative treatment: review of the literature from 1925 to 1993. *J Am Osteopath Assoc*. 1996;96:113–115.

17. Noll DR, Shores JH, Gamber RG, Herron KM, Swift J Jr. Benefits of osteopathic manipulative treatment for hospitalized elderly patients with pneumonia. *J Am Osteopath Assoc*. 2000;100:776–782. Available at: http://www.jaoa.org/cgi/reprint/100/12/776, Accessed October 27, 2006.

18. Wells MR, Giantinoto S, D'Agate D, Areman RD, Fazzini EA, Dowling D, et al. Standard osteopathic manipulative treatment acutely improves gait performance in patients with Parkinson's disease. *J Am Osteopath Assoc*. 1999;99:92–98. Available at: http://www.jaoa.org/cgi/reprint/99/2/92. Accessed October 27, 2006.

19. Frymann VM, Carney RE, Springall P. Effect of osteopathic medical management on neurologic development in children. *J Am Osteopath Assoc*. 1992;92:729–744.

20. Purse FM. Manipulative therapy of upper respiratory infections in children. *J Am Osteopath Assoc*. 1966;65:964–972.