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## ORIGINAL CONTRIBUTION

# Effects of Osteopathic Manipulative Treatment on Pediatric Patients With Asthma: A Randomized Controlled Trial

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Asthma is a common chronic condition that has long plagued the pediatric patient population. Asthma in children can cause excessive school absenteeism, hospitalizations, and even death. Osteopathic manipulative treatment (OMT) is an underutilized noninvasive treatment method for patients with asthma. The use of OMT may help decrease mortality and morbidity rates among this patient group. The authors conducted a randomized controlled trial attempting to demonstrate the therapeutic relevance of OMT in the pediatric asthma population. With a confidence level of 95%, results for the OMT group showed a statistically significant improvement of 7 L per minute to 9 L per minute for peak expiratory flow rates. These results suggest that OMT has a therapeutic effect among this patient population. The authors suggest that more clinical trials are required to better demonstrate the effectiveness of OMT in patients with asthma.

Asthma is a common chronic condition and there is evidence that the prevalence level and mortality rate for childhood asthma has risen worldwide.<sup>1</sup> Several reasons have been offered in explanation of the rise in asthma rates among children, including underdiagnosis, underestimation of asthma severity in diagnosed patients, undertreatment, poor patient compliance with treatment regimens, and delayed care because patients' parents are often slow to sense a problem and bring children to physicians' offices for medical care.<sup>2</sup> Osteopathic manipulative treatment (OMT) is a noninvasive, cost-effective treatment for patients with asthma—a treatment that may help to decrease the morbidity and mortality often associated with asthma's presentation in the pediatric population.

## ▶ Asthma and the Osteopathic Approach

Osteopathic physicians are trained to evaluate all body systems in the diagnosis and treatment of their patients. Essential to this approach is the evaluation and

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treatment of the musculoskeletal system and a recognition of its role in patients' well-being.

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Indeed, the role of the musculoskeletal system in whole-patient healthcare has been the primary concern of osteopathic physicians for the past 100 years. Because the musculoskeletal system is an integral component of the respiratory mechanism, it follows that maximization of its efficiency allows for improved respiratory function.

Osteopathic manipulative (OM) techniques have been shown to increase vital capacity and rib cage mobility, improve diaphragmatic function, enhance the clearing of airway secretions, and possibly enhance autoimmune function.<sup>3</sup> In patients with asthma, OM techniques that focus on thoracic structure and function can be employed to maximize the effectiveness of the respiratory cycle.

A fully effective respiratory cycle can be achieved by increasing the mobility of the thoracic cage and the thoracic spine to allow for full excursion of the ventilatory mechanism. Although this component of respiration is only one of the many factors that affect the ability to breathe, failure to consider this mechanism during diagnosis and treatment creates a missed opportunity in asthma therapy.

Further, asthma itself produces a self-sustaining cycle of viscerosomatic and somatovisceral reflexes long recognized in the osteopathic medical literature.<sup>4</sup> Although pharmacologic agents have been proven effective in improving asthma symptoms—and also have demonstrated results for direct action on airways and pulmonary inflammation—the musculoskeletal component of respiration is clearly not addressed by pharmacologic therapy.

As a result of this conventional approach to treating asthma, breathing efficacy is not maximized and destructive somatovisceral pathways are allowed to continue their negative facilitative influence on the chronic cycle of recurrent asthma. Additionally, patients with chronic obstructive pulmonary disease exert considerable effort to overcome mechanical restrictions to respiration and any reduction in rigidity of the thoracic cage consequently reduces the work of respiration.<sup>5</sup> Allen and Kelso<sup>6</sup> indicate that OMT can directly affect mechanical restrictions and associated respiratory efforts in patients suffering from respiratory disease. More recently, Bockenbauer et al<sup>7</sup> found that thoracic cage excursion with forced respiration increased significantly after a single brief intervention using OM techniques.

By addressing these sometimes neglected components of asthma pathology, osteopathic physicians who use OMT when treating patients with asthma can help maximize thoracic respiratory motion, decrease the negative effect of somatovisceral reflexes, and contribute to the improvement of respiratory function.

Notable improvements (25% to 70%) in patients' peak expiratory flow rates (PEFs) have been reported following the use of OMT.<sup>8</sup> This positive effect has been attributed to several factors, including a decrease in patients' levels of anxiety, autonomic nervous system changes that relax the airways and smooth muscle tone, and, importantly, a mechanically improved chest wall motion.<sup>8</sup>

Peak expiratory flow rates have long been considered an objective measure of asthma severity and patient response to treatment.<sup>9</sup> Therefore, we sought to demonstrate that OMT can favorably affect respiratory function, as measured in PEFs, in pediatric patients with asthma.

## ► **Methods**

This study was conducted over two years, from July 1997 to July 1999. Participants were selected from the pediatric asthma clinic of Peninsula Hospital Center in Far Rockaway, NY, and ranged in age from 5 years to 17 years. Participants were all established patients and were recorded in the clinic's asthma register.

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The diagnosis of asthma was based on guidelines from the National Institutes of Health–National Heart, Lung, and Blood Institute, patient response to therapy, and monitoring of PEFs.<sup>10</sup>

Exclusion criteria were as follows: (1) patients in acute distress, (2) patients who demonstrated a lack of cooperation with study protocols—or were otherwise unable to participate in measuring PEF, and (3) patients who were older than age 18 or younger than age 4. However, no potential subjects had to be excluded from the study for these or any other reasons. Also, all subjects were able to remain in the study through its conclusion.

Informed consent was obtained from study participants with their parents' knowledge and approval and treatment modalities were reviewed and accepted by the Peninsula Hospital Center Institutional Review Board.

Patients who entered this randomized controlled trial were subject to single-blind assignment within one of the two study groups. Treatment randomization was based on a 2:1 ratio because of the constraints associated with available resources.

A total of 140 pediatric cases were studied. Ninety cases were placed in the OMT group and 50 were assigned to the control group.

Patients' demographic characteristics are summarized in [Table-1](#).

**View this table: Table 1 Demographic Characteristics of Pediatric Patients with Asthma (N=140)**

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### **Peak Expiratory Flow Rates**

Peak expiratory flow measurements were recorded according to the guidelines of the 1989 Asthma Management Plan detailed by Woolcock et al<sup>11</sup> before and after osteopathic physicians delivered OMT. Three readings of PEFs were taken with patients seated and using a handheld peak-flow meter (Model No. 3103001, Mini Wright Peak Flow Meter Standard Adult, Cement Clarke, England). The best of these three PEF readings was recorded in standardized physician progress notes.

### **Study Groups**

A brief personal medical history and structural examination were obtained for all patients in both study groups. Somatic dysfunctions were identified in the rib and thoracic regions. Participants and their parents were not informed whether an osteopathic physician was performing OMT or if an allopathic physician was simulating OMT (sham procedure).

■ **Group 1: Osteopathic Manipulative Treatment (n=90)** — Osteopathic physicians performed OMT on pediatric patients using any of the following osteopathic manipulative (OM) techniques, as appropriate: rib raising, muscle energy for ribs, and myofascial release. These techniques are described in the benchmark osteopathic textbook *Foundations for Osteopathic Medicine*.<sup>12</sup> In physician progress notes, osteopathic physicians described the specific OM techniques they were going to use. They then performed OMT following standard protocols.

■ **Group 2: Sham Procedure (Control Group) (n=50)** — Because OMT was not performed by osteopathic physicians during patient encounters for patients in this group, an allopathic physician placed his hands on different regions of the body where OMT was performed for patients in the OMT group in an effort to control for a "therapeutic touch" variable.

### **Statistical Analysis**

Patients' PEF measurements were taken before and after OMT or the sham procedure. The differences in PEF measurements were then compared and analyzed in  $t$  tests using SYSTAT statistical software (Version 9.0 for Microsoft Windows, SPSS Science, Chicago, Ill). The degree of confidence was set at 95%.

## ► Results

As noted, there were 90 patients in the OMT group and 50 patients in the control group. All patients remained in the study through its completion. Differences were calculated between the pretreatment and posttreatment PEFs (ie, before and after OMT or sham procedure). Results are summarized in [Table 2](#). Differences were analyzed with  $t$  tests using SYSTAT statistical software, as noted. Confidence levels were set at 95%, and the predicted mean was set at zero.

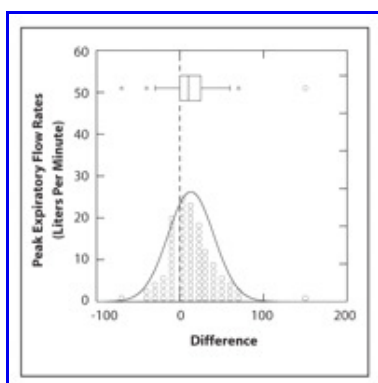
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**View this table:** [Table 2 Peak Expiratory Flow Rates for Pediatric Patients with Asthma Before and After Treatment Protocols \(Liters per Minute\)](#)

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Analysis of OMT group data with  $t$  tests suggested a 95% probability that PEFs improved between 7 L per minute and 19 L per minute; with a mean improvement of 13 L per minute ([Figure 1](#)). Statistical significance was set at 95% certainty. Peak expiratory flow rates in the OMT group show a statistically significant improvement of 7 L per minute to 9 L per minute. Greater variability between differences occurred in the control group, however. Yet analysis of the results for the control group showed a mean of zero in the pre- and posttreatment PEF peak-flow meter readings ([Figure 2](#)).

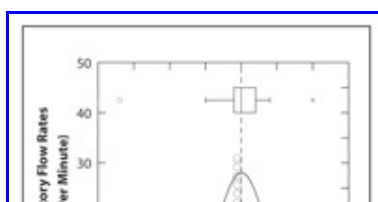


**Figure 1.** Difference for Group 1, osteopathic manipulative treatment (OMT) group (n=90), as demonstrated in a  $t$  test. This graph shows a 95% probability that OMT will increase peak expiratory flow rates between 7 L per minute and 19 L per minute. Data includes the difference of peak-flow meter readings before and after OMT and a mean of no difference. The calculated mean of the OMT group was 13.0 with a standard deviation of 27.4  $t$  and a confidence level of 4.5.

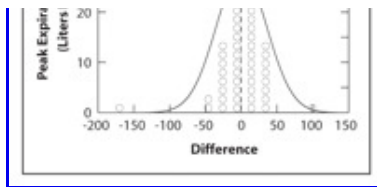
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**Figure 2.** Difference for Group 2, control group (n=50) who received a sham procedure, as demonstrated in a  $t$  test. This graph shows a 95% probability that an allopathic physician placing his or her hands on a patient without providing osteopathic manipulative treatment will change the patient's peak expiratory flow rates between -10 L per minute and 10 L per minute. Data included the difference of peak expiratory flow rates before and after a sham procedure and a mean of no difference. The calculated



mean of the control group was 0.3 with a standard deviation of 35.5 t and a confidence level of 0.06.

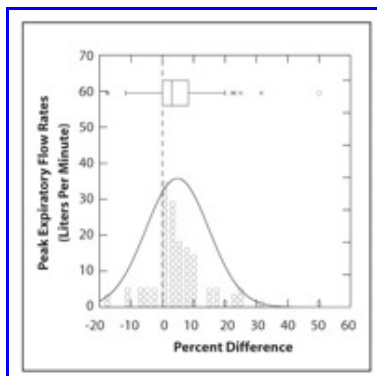
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We calculated percent differences by dividing the calculated difference of pre- and posttreatment PEF peak-flow meter readings, further dividing this quantity by the pretreatment peak-flow meter readings, and then multiplying the total by 100. Percent difference data was analyzed in a similar way, as described elsewhere, using *t* test analysis.

Percent difference data when analyzed by *t* tests showed a mean increase of 4.8% in PEFs for patients in the OMT group ([Figure 3](#)) versus a mean increase of 1.4% in PEFs for patients in the control group ([Figure 4](#)).

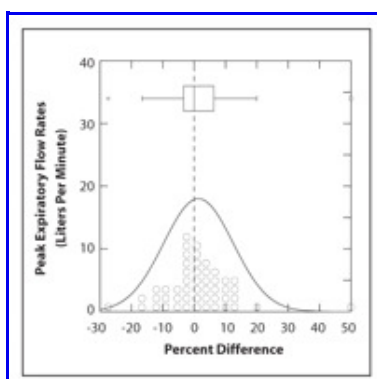


**Figure 3.** Percent difference for Group 1, osteopathic manipulative treatment (OMT) group ( $n=90$ ), as demonstrated in a *t* test. This graph shows a 95% probability that OMT will increase peak expiratory flow rates between 2.7% to 6.9%. Data includes the difference of peak-flow meter readings before and after OMT and a mean of no percentage difference. The calculated mean of the OMT group was 4.8% with a standard deviation of 10.0 t and a confidence level of 4.6.

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**Figure 4.** Percent difference for Group 2, control group ( $n=50$ ) who received a sham procedure, as demonstrated in a *t* test. This graph shows a 95% probability that an allopathic physician placing his or her hands on a patient without providing osteopathic manipulative treatment will change the patient's peak expiratory flow rates before and after a sham procedure and a mean of no percentage difference. The calculated mean of the control group was 1.4% with a standard deviation of 11.1 t and a confidence level of 0.9.

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The primary outcome of this randomized controlled trial was to show that OMT can significantly improve PEFs in pediatric patients with asthma. Using *t* test analysis of the mean change in PEFs, we were able to demonstrate that the

use of OM techniques can significantly improve pulmonary function in pediatric patients with asthma.

A summary of our results is provided in [Table 3](#).

**View this table:** [Table 3 Peak Expiratory Flow Rates for Pediatric Patients with Asthma Summary of t Test Analysis \(Liters Per Minute\)](#)

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## ► Comment

Osteopathic principles and practice emphasize the importance of the musculoskeletal system as a major component in patient well-being. With OMT, physicians are able to affect the motion of this system, maximizing it and, as a result, improving overall function.

The respiratory system's high level of dependence on the musculoskeletal system is demonstrated most dramatically in the paralytic state induced by many poisons that halt respiration by completely disabling the musculoskeletal system. Suffocation follows even though the lungs themselves are completely healthy.

Similarly, when a person has broken ribs, respiratory function is compromised to an extent that correlates directly with the number of ribs broken. Although one broken rib is an inconvenience, several adjacent fractures in the ribs can be life threatening. It follows that if the muscles and bones of the thorax are working optimally, they can serve the complex process of respiration most efficiently. If these structures are inhibited, respiration suffers.

The therapeutic goal of OMT is maximization of physiologic motion of the musculoskeletal system. Just as an athlete stretches and exercises prior to competition in an effort to "loosen up" and achieve "peak" performance, so too the musculoskeletal system works most efficiently when barriers to motion are removed. Given the interdependent relationship that exists between the respiratory system and the musculoskeletal system, it seems that—by increasing physiologic motion of thoracic structures—OMT is a helpful addition to the list of treatment modalities available to clinicians treating patients with respiratory conditions, including asthma.

This study demonstrates that OMT may significantly improve pulmonary function for pediatric patients with asthma. The design of a randomized controlled trial increases the validity of the study significantly. The mean increase of PEFs for children with asthma who were in the OMT group for this study was 13 L per minute; patients in the control group showed no improvement at all. We therefore propose the use of OMT in treating pediatric patients with asthma as it is a safe, noninvasive, cost effective means of enhancing treatment for patients with this disease.

Although we are encouraged by the results of our study, we also recognize its limitations, one of which is the fact that several different osteopathic physicians performed OMT for patients in the OMT group. Because OMT skills and the OM techniques used may vary tremendously among individual practitioners, another variable may have been introduced inadvertently. To correct for this variable, future studies might instead make use of one osteopathic physician.

Additionally, although group assignment was masked (ie, single blind), physician assessment was not. The physicians who were responsible for measuring and recording patient PEFs were not blinded as to the study group to which patients were assigned (ie, OMT or sham procedure). Thus, physicians might have unconsciously affected patient

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PEFs with subtle acts of encouragement or discouragement. The use of blinded physicians (or a blinded respiratory technician) in measuring and documenting PEFs may correct for this confounding variable.

Finally, although PEFs have been used to estimate pulmonary function in patients with asthma, full pulmonary function spirometry would provide researchers with a better indication of the exact physiological aspect of pulmonary function that has been altered by OMT.

## ► Conclusion

To our knowledge, this is the first randomized controlled trial of OMT and pediatric asthma. To determine fully the efficacy of OMT in pediatric asthma, however, a trial with a larger sample size that allows for long-term follow up, full measures of pulmonary function, and consistent application of OMT in experimental groups is needed. It can be said that the various techniques available for osteopathic manipulation may make patients "feel better," but they have not been proven to be of significant specific benefit for patients with asthma.<sup>13</sup>

In a previous study,<sup>14</sup> chiropractors delivered multiple chiropractic treatments to children with asthma and measured their response to treatment. However, that study failed to show a statistically significant rise in PEFs.<sup>14</sup> Our current study, however, demonstrates a statistically significant improvement of pulmonary function in pediatric patients, as measured in PEFs, after OMT. We strongly encourage further investigation where resources permit.

Certainly, the demonstration of a solid relationship between osteopathic principles and practice and a positive therapeutic effect in this large and increasing patient population could have far-reaching implications for the promotion and integration of OMT by osteopathic physicians.

## ► Acknowledgment

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From the Department of Family Practice at Peninsula Hospital Center in Far Rockaway, NY. Currently, Dr Vienna is in private practice in Massachusetts. Dr Lovenheim, who was a student at the time of the study, is currently a resident in pediatrics at Maimonides Medical Center in Brooklyn, NY.

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