

The Immediate, Intermediate, and Long-Term Effects of Osteopathic Manipulative Treatment on Pulmonary Function in Adults with Asthma

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CASE REPORT

Abstract

Context

Asthma is a common chronic obstructive lung disease with increasing prevalence and economic burden. The effect of osteopathic manipulative treatment (OMT) has been studied in patients with several lung diseases, including asthma; however, no clinical trials have studied effects beyond the immediate time period in adults with asthma using spirometry.

Objective

To examine the immediate, intermediate, and long-term effects of OMT on objective pulmonary function and subjective quality of life in asthmatic adults.

Methods

Twenty-five adults with asthma were recruited from the Des Moines University community. Standardized Asthma Quality of Life Questionnaire (AQLQ(S)) surveys and spirometry measures including forced expiratory volume in one second (FEV₁), forced vital capacity (FVC), the FEV₁/FVC ratio, and peak expiratory flow (PEF) were collected at baseline. Spirometry testing was performed immediately after and 3 days after each of 3 weekly standardized OMT sessions. Spirometry and AQLQ(S) surveys were collected again 4 weeks after the final OMT session. Spirometry results were analyzed using a repeated measure, linear mixed-effect model, and survey results were analyzed using paired t-tests.

Results

The study demonstrated statistically significant changes to the spirometry results, including the PEF and FEV₁/FVC ratio. The PEF measurements increased 3 days after the first treatment and remained elevated through the completion of the study. The FEV₁/FVC ratio decreased by 0.01 at 4 weeks post-OMT compared to baseline. There were no significant differences observed in the

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immediate, intermediate or long-term FEV₁ and FVC measurements post-OMT. However, there was a significant increase in the overall score and all 4 domains of the AQLQ(S), including Symptoms, Activity Limitations, Emotional Function, and Environmental Stimuli.

Conclusion

The results of this pilot study suggest that OMT may improve the quality of life in adults with asthma. Spirometry testing revealed a significant change in some measures of pulmonary function and participants reported an improvement in asthma-specific quality of life. The authors suggest that, in combination with preventive measures and pharmacologic therapy, OMT may offer additional benefit in the treatment of adults with asthma. The results also suggest a need for further study of the effects of OMT on respiratory function in asthmatic adults.

(continued on page 30)

Introduction

Asthma is a common chronic obstructive lung disease with an increasing prevalence and economic burden on society. In 2017, the prevalence of asthma in adults in the United States population was 8.3%, increased from 7.6% in 2015 and 7.4% in 2014.¹ Asthma is primarily a clinical diagnosis supported by spirometry results including forced expiratory volume in one second (FEV1), forced vital capacity (FVC), and the FEV1/FVC ratio.² Asthma is further defined by reversible bronchoconstriction, described as an increase in FEV1 of 200 mL and 12% or greater as compared to baseline after short-acting β_2 -agonist inhalation.^{3,4} Asthma is categorized based on patients' frequency and severity of symptoms.² Patients with intermittent and mild persistent asthma usually have normal spirometry results outside of an asthma exacerbation. Symptom triggers include environmental exposures, emotional extremes, respiratory infections, and exercise. Treatment aims to decrease the severity and frequency of symptoms. Standard treatment currently includes multiple classes of medications, the combination of which depends on the level of severity.² These pharmacologic approaches have proven to be effective at decreasing asthma symptoms by dilating patients' airways and decreasing pulmonary inflammation,² but they do not address the musculoskeletal aspect of respiration, a crucial component of respiratory function.⁵

Osteopathic manipulative treatment (OMT) is a cost-effective, noninvasive treatment utilized to remove allostatic load and reestablish a more natural homeostatic condition.⁶ OMT can be used to maximize the biomechanics of respiration by improving the compliance of the thoracic cage. The pathophysiology of asthma includes an autonomic nervous system (ANS) imbalance characterized by elevated parasympathetic cholinergic tone causing bronchoconstriction and airway hyperresponsiveness causing further reduction of airway caliber following stimuli. These features of asthma are partially addressed with pharmacologic management.³ OMT may further normalize the ANS's influence by targeting the vagus nerve and the first 6 thoracic spinal cord levels, which respectively contribute parasympathetic and sympathetic innervation to the lungs.⁷ Somatic dysfunctions at the occipitoatlantal (OA) joint are addressed to influence the vagus nerve, and the first 6 vertebrae of the thoracic spine with associated ribs are addressed to influence viscerosomatic facilitation.⁶ Inhibitory or stimulatory techniques such as rib raising can also be utilized to balance the ANS by affecting the sympathetic chain ganglia along the vertebral column.⁸ Doing so can help interrupt the cycle of viscerosomatic and somatovisceral reflexes that contribute to the development of somatic dysfunction and further augment symptoms of asthma.⁷ Finally, OMT may be useful in restoring optimal circulatory and lymphatic flow to and from the lungs by removing fascial

restrictions.⁷ By improving the biomechanical, autonomic, and circulatory mechanisms involved in the disease process, OMT can help maximize respiratory function and should therefore be considered as an additional treatment modality for patients with asthma.

Some studies in the literature have examined the immediate effects of OMT on pulmonary function in patients with asthma, but to the authors' knowledge, there have been no studies on the intermediate and long-term effects using spirometry.^{5,9} In 2002, Bockenhauer et al⁹ aimed to quantify the immediate effects of a single OMT session on chronic asthma. The study found statistically significant improvements in thoracic wall motion measured by respiratory excursion and in subjectively reported ease of breathing and a non-statistically significant decrease in peak expiratory flow rate (PEF). More recently, Guiney et al⁵ performed a randomized controlled trial (RCT) utilizing OMT on pediatric patients with asthma. The OMT group showed a statistically significant improvement in PEF of 13 L/min when compared to a control group that received sham treatments. The authors of both studies suggested the use of spirometry in further investigations to determine the impact of OMT on pulmonary function.^{5,9}

Some studies have observed the effects of OMT on pulmonary function tests in patients with other lung diseases. Noll et al¹⁰ utilized spirometry on patients with chronic obstructive pulmonary disease (COPD) to quantify the immediate effects of OMT with a double-blind RCT utilizing 7 OMT techniques as compared to sham treatments. The OMT group showed a statistically significant decrease in the forced expiratory flow (FEF) in the 30 minutes immediately following treatment. Noll and colleagues suggested there may be other mechanisms affecting pulmonary function testing immediately after OMT.

Allen and Pence observed improvement of FVC after using a thoracic pump technique in hospitalized patients with various lower respiratory diseases, including asthma.¹¹ Swender et al¹² used spirometry in a single-blind RCT to evaluate pulmonary function in patients with cystic fibrosis following daily OMT versus sham treatments. They observed improvements in spirometry measures in both groups, with no statistical significance between the two.

Henderson et al⁸ demonstrated a decrease in salivary α -amylase, a biomarker for activation of the sympathetic nervous system (SNS), following a rib raising technique when compared to a sham treatment. However, they showed no statistically significant differences in cortisol level or salivary flow rate, the latter of which is used to measure parasympathetic activity. They concluded that SNS

(continued on page 31)

(continued from page 30)

activity may decrease immediately after five minutes of rib raising. Therefore, one potential explanation for the decreased FEF in COPD patients immediately after OMT in the study by Noll et al⁹ is decreased SNS activity, leading to uninhibited parasympathetic effects, including bronchoconstriction.³

Most recently, Lorenzo et al¹³ compared the effects of OMT to standard pulmonary rehabilitation (SPR) in a healthy population of medical students using spirometry and a survey to quantify objective and subjective change, respectively. They failed to demonstrate an objective change in FEV1, FVC, or the FEV1/FVC ratio with OMT as compared to SPR; however, they demonstrated a statistically significant subjective improvement in breathing ability in the OMT group.

The objective of the current study was to quantify the immediate, intermediate, and long-term effects of OMT on adult patients with a history of asthma. The quantitative effects that were measured include the FEV1, the FVC, the FEV1/FVC ratio, and the PEF. The long-term, subjective effects were measured via the Asthma Quality of Life Questionnaire with Standardised Activities (AQLQ(S)). It was hypothesized that OMT would improve pulmonary function, both objectively and subjectively. We predicted a significant increase in the mean FEV1/FVC ratio and PEF 3 days after each OMT session and a significant increase 4 weeks after the final OMT session, but no increase in the mean FEV1/FVC ratio or PEF immediately after OMT. The authors also predicted an increased overall mean AQLQ(S) score as well as an increased mean score within each domain, including Symptoms, Activity Limitations, Emotional Function, and Environmental Stimuli.

Methods

Design

This single arm clinical trial (registered at clinicaltrials.gov, identifier: NCT03864354) was approved by the Institutional Review Board at Des Moines University (DMU) in Des Moines, IA. Written informed consent was obtained from all participants.

Participants were recruited by email, class announcements, and word of mouth targeting DMU students and faculty. Inclusion criteria for participation in the study included age over 18 years and a diagnosis of asthma, regardless of whether spirometry was used in the diagnosis. Subjects were excluded if they were a current smoker, diagnosed with any other respiratory disease apart from asthma, or had received manual treatment 30 days prior to or during the study

including OMT from a licensed physician, chiropractic treatment, or massage therapy.

The study was conducted over a period of 8 weeks. At week 0, participants completed the initial AQLQ(S) and performed baseline spirometry testing. During weeks 1, 2, and 3 of the study, a standard OMT protocol was performed followed by spirometry testing. Spirometry was performed again 3 days after each session to measure the intermediate effect of OMT. At week 7, participants completed the post-OMT spirometry testing and AQLQ(S) to measure the objective and subjective long-term effects.

Pulmonary Function Measurements

Pulmonary function testing was performed using a portable spirometer (McKesson LUMEON, Andover, MA, USA). Testing was conducted by one member of the research team (K.K.) throughout the entire study, after training with a licensed pulmonologist. Subjects were required to perform spirometry until three trials deemed acceptable by the spirometry software (Easy on-PC), based upon guidelines from the American Thoracic Society, were obtained.¹⁴ The trial with the best overall effort was used for analysis. The spirometry measures used to assess participants' pulmonary function included FEV1, FVC, the FEV1/FVC ratio, and PEF.

Asthma Quality of Life Questionnaire

Participants completed an Asthma Quality of Life Questionnaire with Standardised Activities (AQLQ(S)) to subjectively measure asthma severity. The AQLQ(S) is a 32-item survey which asks participants to recall their experiences during the previous 2 weeks as related to 4 domains: Symptoms, Activity Limitations, Emotional Function, and Environmental Stimuli. Each item is rated on a 7-point Likert scale, with 1 being severely impaired and 7 being not impaired at all. The survey was completed in week 0 to establish a subjective baseline value of asthma severity as perceived by the participant and again in week 7 to compare their perceived asthma severity after receiving OMT.

OMT Protocol

An OMT protocol was derived from a survey of the DMU Osteopathic Manipulative Medicine (OMM) Department faculty as well as current and past DMU Predoctoral OMM Fellows. The survey assessed the approach each participant would use when treating an asthmatic patient with OMT. Based on the survey results, the authors developed the standardized OMT protocol used during each of the three OMT sessions. These sessions lasted 21.3 ± 3.6 minutes. The protocol included the following techniques, performed in the order represented here: supine occipitoatlantal (OA)

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joint balanced ligamentous tension (BLT), supine cervical spine Still technique, supine thoracic inlet myofascial release (MFR), stimulatory supine rib raising soft tissue, supine rib BLT, supine abdominal diaphragm MFR, seated thoracic spine Still technique, and seated posterior rib Still technique.

After the OMM Fellows (A.J., S.T., E.K., A.B.) completed the treatment protocol, participants were screened for somatic dysfunction resolution by a board-certified neuromusculoskeletal medicine/osteopathic manipulative medicine (NMM/OMM) physician (K.H. or J.P.). If inadequate resolution at a specific body region was found, that region was retreated using the same technique included in the protocol. The retreatment lasted 6.3 minutes on average and was performed by the same OMM Fellow. The protocol's final step involved one minute of stimulatory tapotement, or rhythmic tapping of the tissues, applied to the paraspinal region at the levels of the first 6 thoracic vertebrae. This was included to target the lung viscerosomatic reflex area and potentially temper parasympathetic cholinergic tone to decrease bronchoconstriction.

Data Analysis

Changes in FEV1, FVC, the FEV1/FVC ratio, and PEF were determined by calculating the mean for all participants at each time point. The immediate effect of OMT was determined by comparing the measurements taken immediately after each treatment to baseline. The intermediate effect was determined by comparing the measurements 3 days after treatment to baseline. The long-term effect was determined by comparing the measurements 4 weeks after the final OMT session to baseline. Each comparison was analyzed using a linear mixed-effect model of repeated measure on random subjects. The Westfall method was used to adjust p-values. Changes in participants' survey results were determined by calculating the mean for the overall scores and for each of the 4 domains, then comparing the post-OMT values to the pre-OMT values. These values were analyzed using paired t-tests.

Statistical analysis was performed using IBM SPSS® Software and the statistical platform R by Chunfa Jie, PhD of the Des Moines University Research Department.

Results

The study enrolled 25 participants, none of whom were lost to follow up. The characteristics of the study subjects are presented in *Table 1*. The mean age of participants was 25.6 ± 2.85 with a range from 22 to 33 years. Participants were primarily female (68% female, 32% male) and Caucasian (88% Caucasian, 8% Asian, 4% Hispanic). Medications

were actively used by 64% of patients in the study and 36% either did not take their prescribed medications or had no prescription.

PEF measurements increased significantly from 7.43 L/sec at baseline to 7.87 L/sec three days after the first OMT treatment and remained elevated through the completion of the study (*Table 2, Figure 1D*). A general decrease was observed in the FEV1 as compared to baseline (*Table 2, Figure 1A*), but without statistical significance. Results for the FVC measurements as compared to baseline show slight variation above and below baseline, but no statistically significant differences (*Table 2, Figure 1B*). Apart from the increased FEV1/FVC ratio immediately following the second OMT session, the FEV1/FVC ratio decreased marginally for each time point, but the only statistically significant change was a decrease in the mean final, long-term measurement from 0.81 at baseline to 0.80 in week 7 ($p < 0.05$) (*Table 2, Figure 1C*). Spirometry results are summarized in *Table 2* and were analyzed utilizing a repeated-measure ANOVA with confidence levels set at 95%.

Differences between pre- and post-OMT AQLQ(S) results were analyzed for the overall scores and for each of the quality of life

Table 1. Participant Characteristics, N=25^a

Characteristic	Value
Sex	
Female	17 (68)
Male	8 (32)
Age, mean (SD), y	25.6 (2.86)
Race	
Caucasian	22 (88)
Asian	2 (8)
Hispanic	1 (4)
Tobacco Use	0 (0)
Medication Use	
Yes	16 (64)
No	9 (36)

^a Data are given as No. (%) unless otherwise indicated.

Table 2. Effect of OMT on Objective Pulmonary Function: Spirometry Results Over Time

	Mean Measurements (SD)			
	FEV1, L	FVC, L	FEV1/FVC	PEF, L/sec
Week 0: Baseline	3.60 (0.65)	4.45 (0.86)	0.81 (0.08)	7.43 (1.54)
Week 1				
Immediate	3.55 (0.56)	4.43 (0.87)	0.81 (0.08)	7.33 (1.69)
Three days post-OMT	3.58 (0.55)	4.46 (0.85)	0.81 (0.08)	7.87 (1.55)*
Week 2				
Immediate	3.56 (0.58)	4.42 (0.90)	0.82 (0.08)	7.76 (1.61)*
Three days post-OMT	3.55 (0.64)	4.47 (0.96)	0.80 (0.08)	7.78 (1.50)*
Week 3				
Immediate	3.53 (0.54)	4.41 (0.82)	0.81 (0.08)	7.84 (1.46)*
Three days post-OMT	3.55 (0.59)	4.44 (0.89)	0.81 (0.09)	7.70 (1.46)*
Week 7: Long Term	3.57 (0.63)	4.49 (0.93)	0.80 (0.08)*	7.78 (1.46)*

*P < 0.05

Abbreviations: OMT, Osteopathic Manipulative Treatment; FEV1, Forced Expiratory Volume in One Second; FVC, Forced Vital Capacity; PEF, Peak Expiratory Flow

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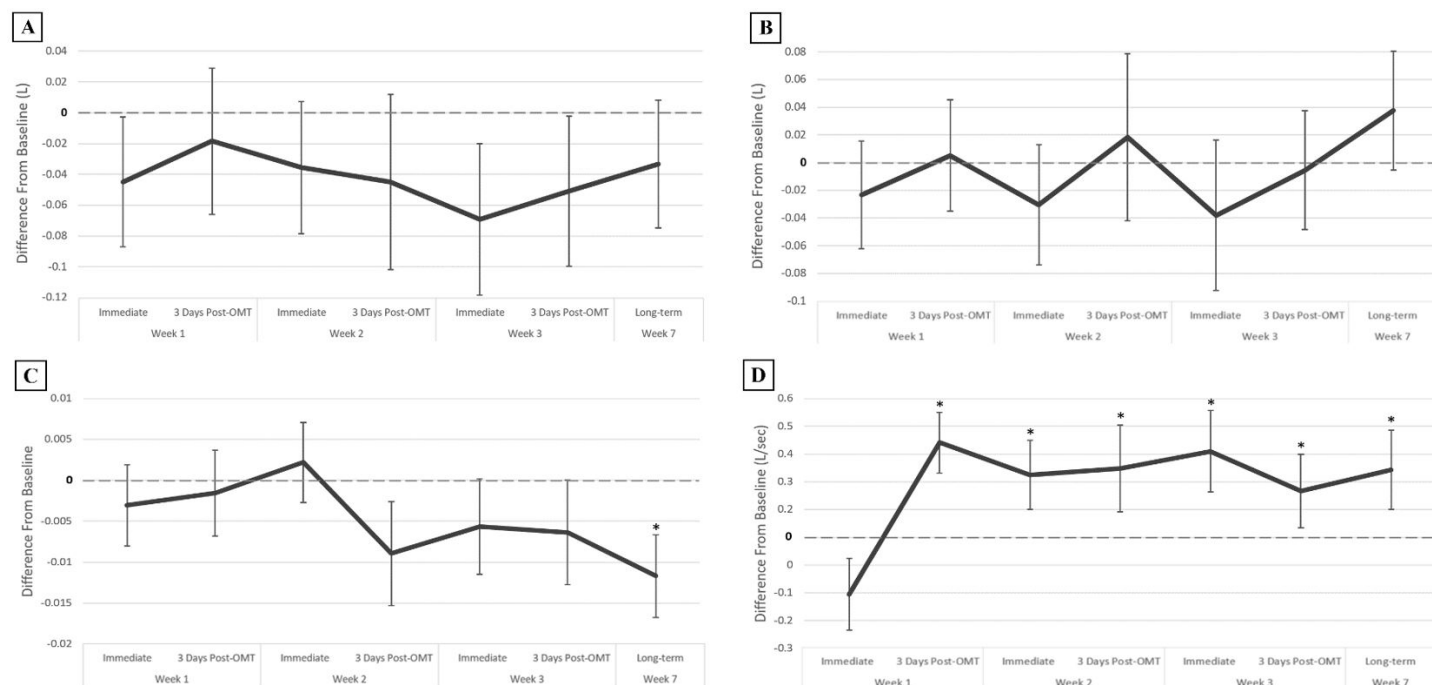


Figure 1. Change in objective pulmonary function results over time, compared to baseline. Spirometry results include (A) forced expiratory volume in one second (FEV1), (B) forced vital capacity (FVC), (C) FEV1/FVC ratio, and (D) peak expiratory flow (PEF). * $P < 0.05$.

domains. Analysis, summarized in *Table 3* and *Figure 2*, showed a statistically significant increase from the baseline results.

Table 3. Effect of OMT on Subjective Pulmonary Function: AQLQ(S) Results Pre- and Post-OMT Sorted by Average Score and Domain

	Mean Scores (SD)		
	Pre-OMT	Post-OMT	p-value
Average	6.02 (0.66)	6.45 (0.46)	0.0000629*
Symptoms	5.82 (0.74)	6.38 (0.44)	0.0000122*
Activity Limitation	6.33 (0.52)	6.57 (0.47)	0.00353*
Emotional Function	5.86 (0.93)	6.38 (0.69)	0.00117*
Environmental Stimuli	5.95 (0.93)	6.38 (0.55)	0.0169*

* $P < 0.05$

Abbreviations: OMT, Osteopathic Manipulative Treatment; AQLQ(S), Asthma Quality of Life Questionnaire with Standardized Activities

Discussion

The results of this study demonstrated statistically significant changes in both objective and subjective measurements of pulmonary function in adults with asthma after receiving OMT. Spirometry measurements of FEV1, FVC, and the FEV1/FVC ratio were used to quantify airway obstruction as a result of bronchoconstriction. The OMT protocol was designed in part to influence sympathetic and parasympathetic tone as it pertains to bronchoconstriction in asthma. The FVC increased, whereas the

FEV1 decreased from baseline, resulting in the overall decrease in the FEV1/FVC ratio. Although this decrease from 0.81 to 0.80 was statistically significant, it is not clinically significant.² Therefore, it is proposed that the current study's treatment protocol had minimal effects on the bronchoconstriction component of asthma.

The increase in PEF in all but the immediate measurement in week 1 suggests a positive intermediate and long-term effect. While the PEF is indicative of an effect on bronchoconstriction, this value is also dependent on participant respiratory effort. The OMT protocol used in this study specifically addressed somatic dysfunctions that impact the work of breathing. The statistically significant increase in the PEF may therefore be directly related to removing

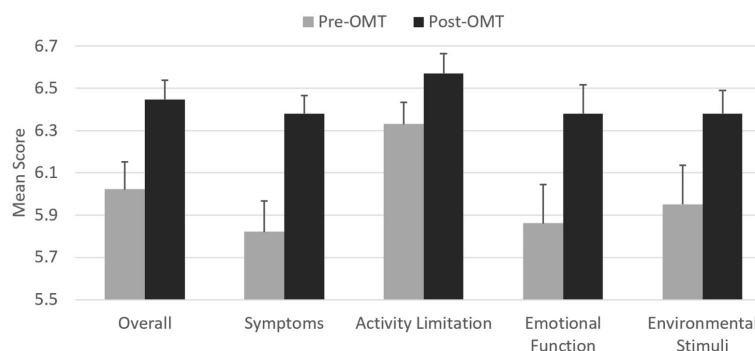


Figure 2. Pre- and Post-OMT Asthma Quality Life Questionnaire with Standardized Activities (AQLQ(S)) results.

(continued on page 34)

restrictions in the musculoskeletal system with OMT, allowing participants to exhale with greater force. These results expand upon previous research that demonstrated a statistically significant increase in PEF immediately after OMT in pediatric asthmatics.⁵

The use of spirometry is a strength of the current study, as prior studies used peak flow meters to measure the effects of OMT in asthmatics.^{5,9} The study design included a total of 8 spirometry measurements. However, since all spirometry results were compared to baseline, the only true representation of the immediate effect of OMT was the measurement immediately after the first OMT session. Considering the increase in PEF results, the second and third treatments may have served to maintain the changes observed as a result of the first treatment. To evaluate the true immediate effect of multiple OMT treatments, future studies might consider spirometry testing before and after each treatment, as was done by Lorenzo et al,¹³ to establish a baseline for each treatment.

There were several external factors not controlled for in this study that could have influenced data results. Due to the timing of the study, participants were often exposed to cold temperatures just before receiving OMT and some presented with symptoms of upper respiratory infections, both of which are known to exacerbate asthma symptoms.¹⁵ In addition, although participants were prohibited from receiving OMT from a licensed physician during the study, many of the subjects were osteopathic medical students who practice OMT skills regularly. The authors attempted to control for this by performing the study when the curricula covered body regions other than those included in the study's protocol. Participants were not instructed to limit activities that would potentially exacerbate their asthma symptoms and medication use was not monitored.

Implications of the objective findings of the current study require further research. While some of the objective data suggest that pulmonary function in asthmatics did improve with OMT as indicated by the increase in PEF, there was either no statistical difference or a significant decrease in FEV, FEV1, and the FEV1/FVC ratio. Therefore, future studies with a control group and larger sample size are needed to better define the relationship between OMT and pulmonary function. In addition, a sham treatment group could be used to rule out the placebo effect. Other limitations include not stratifying asthma severity and not randomizing treatment providers.

Diagnosis, severity level, and medical management of asthma are largely determined clinically by the patient's level of impairment from and frequency of symptoms.² The quality of life domains

assessed by the AQLQ(S) used in this study therefore bear important weight clinically, as they have the potential to alter medical management, patients' ability to function in their desired lifestyle, and overall patient satisfaction. Patients' attitudes about their treatment have also been shown to positively influence compliance.¹⁶ The current study found an improvement in participants' subjective quality of life after OMT, suggesting potential clinical significance of using OMT as an adjunct to treatment for asthmatic patients.

Conclusion

The goal of OMT is to address the body's structure to maximize function and treat medical diagnoses. In the present study, OMT was used to remove restrictions in the respiratory system, maximize efficiency, and decrease the work of breathing in asthmatic adults. This study demonstrated statistically significant changes to the spirometry results including the PEF and FEV1/FVC ratio. The PEF measurements increased 3 days after the first treatment and remained elevated through the completion of the study, suggesting positive intermediate and long-term effects of OMT on pulmonary function. Participants' pulmonary function as measured subjectively by the AQLQ(S) also demonstrated a statistically significant increase. Improvement in a patient's perception about their condition could lead to improved adherence to therapy and better long-term outcomes. In addition to the current treatment regimen for asthma, including preventive measures and pharmacologic therapy, this study suggests that integrating OMT into the treatment of adult asthmatics may effectively improve patients' objective and subjective respiratory function by optimizing the body's structure and function. Future studies using control groups, larger sample sizes, and fewer confounding factors are needed to further identify the effects of OMT on pulmonary function of adult asthmatics.

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