The Use of Osteopathic Manipulation in a Clinic and Home Setting to Address Pulmonary Distress as Related to Asthma in Southwest Virginia

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ABSTRACT

Osteopathic Manipulative Therapy (OMT) is underutilized in addressing lung function and symptoms in asthma patients. The objective of this study was to determine if a single session of OMT can improve lung function and symptoms in patients suffering from asthma, and if patients can be taught a self-administered home OMT protocol to control their symptoms, in order to develop a protocol by which physicians can apply OMT to address lung disease in patients. This was a purposive randomized controlled quasi-experimental study which took place in family practice, pulmonology, and asthma specialist offices in southwest Virginia. The intervention was a ten-minute semi-individualized OMT protocol and a self-administered home OMT education session.

Variable baseline, within-subject study design was utilized, allowing each person to serve as his or her own control. Pre and posttest measurements included: participant spirometry FEV1, FVC, and PEF; thoracic excursion upper and lower rib cage motion; and a five-question rating scale to determine current asthma symptoms. A ten-minute OMT session included an individualized thoracic and rib screening and treatment, suboccipital release, diaphragm release, and thoracic pump. Comparison between pre- and post-OMT lung function and symptoms portrayed change. For the second part of the study, the participants were divided into two groups with group two receiving a ten-minute home OMT education session and a handout of the home

OMT techniques. All participants returned two weeks later for a follow up lung function assessment.

Statistically significant ($p<.05$) improvements after initial OMT were documented for 8 of 10 measurements. Only two spirometry values, FEV1 and PEF, did not significantly improve. The group who participated in the home OMT education session had statistically significant improvements in 3 of 10 measurements, including the upper and lower thoracic excursion measurements and the overall asthma symptoms rating.

With a simple, easy to repeat, 10 minute semi-individualized OMT session, researchers demonstrated improved lung function and symptoms in this group of participants in Southwest Virginia. The addition of a home OMT education session was demonstrated to be at least partially beneficial. Future studies should expand on this pilot study with the researchers recommending using a larger patient population including patients with lower pre-treatment spirometry values in order to accurately monitor potential for change.

Dedication

This thesis is dedicated to VCOM, which was gracious enough to give me the opportunity of a lifetime to explore international community medicine and allow me to expand my knowledge and perspectives as a physician. Also, I would like to thank my husband and family. Without their unwavering support and unending patience, I would not have accomplished all that I have.

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Chapter 1

Introduction

This first chapter will serve to introduce the problem which was chosen to be studied. The purpose, objectives, hypothesis, and limitations will be reviewed in order to introduce the research and create a better understanding for the reader.

Background of the problem

Lung disease is any disorder in which the lungs do not function properly. Lung disease has been classified into three main types: obstructive, restrictive, and defective in the transfer of oxygen from air to blood. Despite these classifications, most lung disease is actually a combination of the above. Some of the most common lung diseases include asthma, chronic bronchitis, chronic obstructive lung disease (COPD), emphysema and interstitial lung disease (Kaufman, 2006). In this project, I focused on the obstructive lung disease asthma. Obstructive disease is characterized by an increase in the resistance to airflow due to a partial or complete obstruction of the trachea, bronchi, or bronchioles. The individual disorders of emphysema, chronic bronchitis, asthma, and bronchiectasis have distinct clinical characteristics (Kumar, Abbas, & Fausto, 2005, p. 717).

Asthma is a chronic inflammatory disease which affects more than 20 million Americans (American Lung Association, 2005). This disease manifests as a reversible bronchospasm of smooth muscle which develops further into bronchial edema, viscous secretions, mucous plugging, and atelectasis (Camargo, 2006). About 4-5% of adults and 10% of children have been estimated to have symptoms of asthma (Kasper et al., 2005). These attacks, which are triggered by allergens, exercise, infections, weather changes, or other irritants, range from mild shortness of breath and coughing to wheezing, chest pain, and even hospitalization. This disease poses a significant burden on the United States. Asthma causes around 4000 deaths and costs the United States $6-$11 billion each year. Prescriptions drugs are the most significant medical expenditure, reaching a total of $5 billion a year (American Lung Association, 2005). In addition, asthmatic children miss 12.8 million days of school each year, while adults miss 24.5 million workdays (Scariati, Roberge, & Dye, 2006).

Asthma is characterized by narrowing of the bronchial airways and contraction of bronchial smooth muscle due to inflammation. In addition, there are antigen-antibody interactions that set off a metabolic cascade, which results in the formation of potent smooth muscle contractors such as leukotrienes. Bronchomotor tone is further controlled by an intricate balance between the adrenergic and cholinergic nervous systems with beta-receptor blockage in the lungs leading to bronchoconstriction (Camargo, 2006; Kasper et al., 2005; Kumar et al., 2005).

This obstructive lung disease is prevalent in southwest Virginia. In Virginia, one in sixteen children suffers from asthma and it is the leading cause of hospitalization. This disease affects low-income and minority patients the most, who are prevalent in southwest Virginia (CHIP of Virginia, 2002). The 2007 American Lung Association State of the Air Report shows that the particle pollution levels in the southwest counties in Virginia have increased over the years (American Lung Association, 2007). The CDC's Behavioral Risk Factor Surveillance System reported that, while the overall incidence of asthma in adults has dropped in the United States since 2004, the incidence in Virginia has actually risen ("Asthma,") as has the economic burden (Virginia Asthma

Coalition, 2004) (Figure 1). There were over 9,000 hospital discharges with a primary diagnosis of asthma in Virginia in 2004, with the total charges reaching $96 million (Virginia Asthma Coalition, 2004).

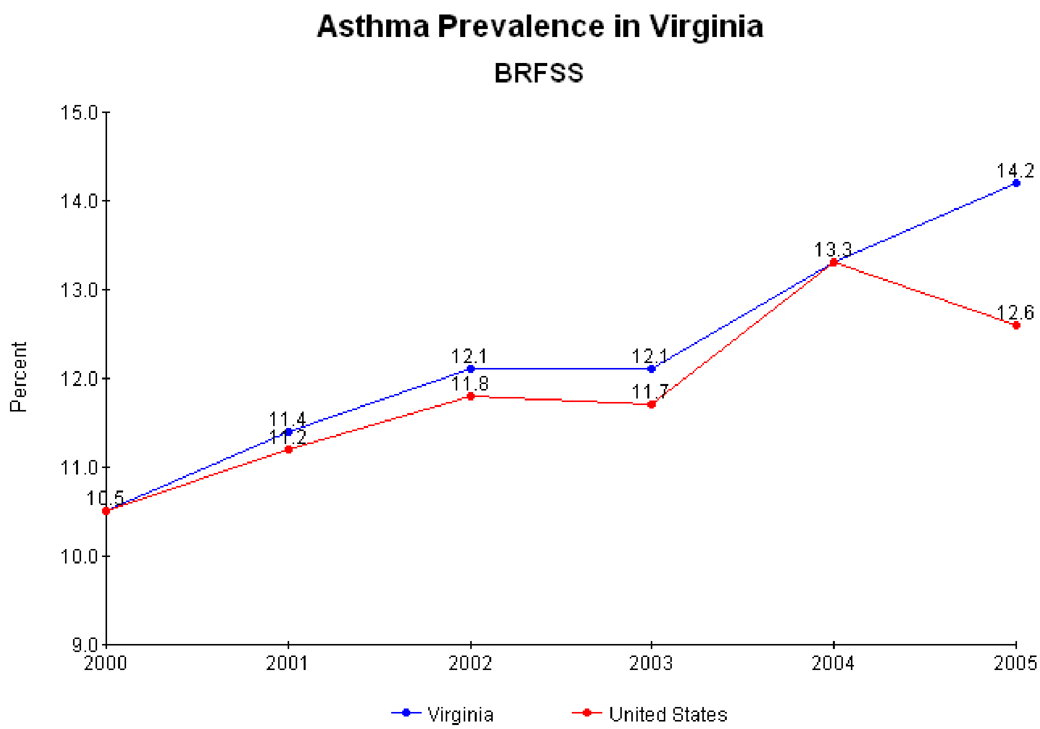


Figure 1. Prevalence of Asthma in the United States and Virginia

There are multiple pharmacologic medications designed to alleviate these lung diseases today. While these treatments have been effective in controlling asthma, there is another option for relieving patients with this condition. This option is osteopathic manipulative treatment (OMT). There is evidence in the literature, dating back from the beginning of osteopathy in 1874, that OMT has a role in controlling lung disease (Allen, 1971). The foundation of osteopathy is the intricate reciprocal relationship between the body’s structure and it’s function, along with the belief that the body contains within it an ability to heal itself (Ward, 2003). By applying this concept to patients with asthma, osteopathic physicians can address asthma in a unique way. In addition, there are no studies regarding home OMT treatment methods for patients with lung disease. These home treatments may be a way to address the issue of access to care in rural southwest Virginia and give patients another option for treating their lung condition.

Statement of the problem

There is a high prevalence of asthma in southwest Virginia and there are multiple osteopathic manipulative techniques (OMT) which are thought to improve lung function. However, the studies regarding the effectiveness of using osteopathic manipulative treatment (OMT) as an office treatment or a home treatment to address obstructive lung disease are inadequate.

Purpose of Study

The purpose of this study was to determine the viability of OMT treatment for asthma and the effectiveness of home OMT education, in order to implement a program to improve asthma control.

Research Objectives

1. Determine the relationship of OMT on lung function as demonstrated by basic spirometry, thoracic excursions, and subjective patient symptoms.

2. Compare lung function measures of asthma patients using self-administered home treatment as supplemental to doctor-administered OMT treatment with those of asthma patients who only receive doctor-administered OMT.

3. Determine the relationship among selected environmental factors such as job type, pets, and smoking habits with demographics characteristics of patients in this study.

4. Determine the relationship of age and gender on the use of OMT for asthma.

Research Hypotheses

1. A researcher-developed protocol of Osteopathic Manipulative Treatment, including screening and treatment of the thoracic and rib cage, diaphragm release, suboccipital release, and thoracic lymphatic pump, will significantly ($p<.05$) improve the spirometry values, thoracic excursion measurements, and symptoms in the selected group of participants suffering from asthma.
2. A researcher-developed educational session designed to teach asthma patients home OMT will significantly improve the spirometry, thoracic excursion measurements, and symptoms in those participants over a two-week time period, as compared to a group of asthma patients who do not do home OMT.
3. Differences in age and gender will be significantly related to response to OMT techniques for asthma.

4. There will be a significant relationship between environmental factors of job type, pets, and smoking habits and asthma symptoms in the chosen population.

Definition of Terms

For the purpose of my study, I have defined the following:

Asthma – A reversible obstructive lung disease characterized as a chronic inflammatory disorder of the airways that causes recurrent episodes of wheezing, breathlessness, chest tightness, and cough.

Environmental factors –Selected factors which may act as intervening variables and have an affect on the patient's asthma. The factors which will be studied in this project are work environment, home environment, smoking, exercise, and allergies.

Osteopathic manipulative therapy (OMT) – "The therapeutic application of manually guided forces by an osteopathic physician to improve physiologic function and/or support homeostasis that have been altered by somatic dysfunction." (Ward, 2003)

Spirometry – A test to measure how much air one can move in and out of their lungs and how quickly this can be done.

Thoracic Excursion – The difference between thoracic circumference at the end of forced inspiration and thoracic circumference at the end of forced expiration.

Limitations of Study

There are several limitations to this study. One of the most limiting factors is the number of subjects to which I had access. Due to time and financial constraints, I was only able to gather data from 32 subjects. Another limitation inherent in this study is reliance on patient compliance and effort. The results of the spirometry test are dependent upon the effort that the patient displays when doing the test. If the patient does not adequately try to perform the test as specified, then the results regarding lung function are inaccurate. Another part of the study which relies on the patient's compliance and effort is the request to perform home OMT maneuvers. In order to obtain correct results on the benefit of home OMT, the patient is required to actually perform the home OMT sessions as prescribed. Researchers did not make home visits to ensure that the patients were doing the techniques or that they were doing them correctly. Another limitation to this study is the two-week time period between clinic visits. During this time period, the researcher had no control over what the patient did and there are multiple variables which may have had an affect on patients' asthma and skewed the results of the study. These are all limitations over which the researcher had no control.

Significance of the Study

This project has the potential to significantly impact people in southwest Virginia living with an obstructive lung disease. If the primary researcher finds that

OMT improves lung function, as demonstrated by thoracic excursion, spirometry values, and a subjective improvement, then OMT may be a beneficial addition to the treatment regime of asthma patients. In addition, this project has the potential to financially impact the inhabitants of southwest Virginia living with an obstructive lung disease. The primary researcher will be teaching half of the subjects a home treatment regime which may enable them to control their symptoms without spending additional money on medications or physician visits. Another significant part of this project is the study of the longevity of OMT directed towards lung function. It will be useful to determine how long the treatments last, so that the treatment plans for these patients can be better validated. Lastly, this project has the potential to increase the use of OMT in southwest Virginia by increasing the awareness of its utility in asthma and encouraging physicians to utilize it.

A review of literature was utilized to determine previous work in the area, review methodological approaches and develop a strong conceptual grounding and theoretical base to guide the study and demonstrate its importance.

Chapter 2

Literature Review

In this chapter, the literature pertaining to asthma, asthma in Virginia, and the use of manipulation will all be explored. This will provide a background understanding for the reader and a foundation for the remaining chapters on the project itself.

Asthma

Asthma is a chronic inflammatory disease of the lungs (Goroll & Jr, 1995, p. 304; Kasper et al., 2005, p. 668; Kumar et al., 2005, p. 723). This inflammation increases the lung's responsiveness to stimuli, which results in episodic, reversible obstruction of the lower airways. The severity ranges from mild limitation of the patient's activity to severe and even life-threatening symptoms (Kasper et al., 2005, p. 668).

There is a complex pathophysiology associated with asthma which involves bronchial hyperresponsiveness, airway inflammation, and intermittent airway obstruction (Morris, 2007). Airway inflammation is the underlying disorder in asthma. There are several characteristics which lead to this inflammation, including mast cell degranulation, eosinophilic infiltration, recruitment and proliferation of T cells, and endothelial activation. Once this happens, the normal epithelial lining of the airways is denuded and goblet cells begin to proliferate. This edema causes sensitization of the bronchial walls and results in hyperresponsiveness to stimuli. This hyperresponsiveness results in airway obstruction (Goroll & Jr, 1995, p. 304).

The etiology of airway hyperresponsiveness is not clear; however, there are several triggers for airway reactivity, such as allergenic, pharmacologic, environmental, occupational, infectious, emotional, and exercise-related (Kasper et al., 2005, p. 668). Airway obstruction results from inflammation, acute bronchoconstriction, mucous plugging, airway edema, and remodeling. The early asthmatic response and bronchoconstriction results from an immunoglobulin E mediated cascade which follows an allergen exposure. The airway edema occurs anywhere from 6-24 hours after this allergen exposure. Mucous plugging is formed from exudates of serum proteins and cellular debris which can take weeks to resolve. Longstanding inflammation causes airway remodeling and structural changes, which may affect the reversibility of asthma (Morris, 2007).

In addition to these pathways of asthma, there is a neurogenic role as well. The bronchial smooth muscles have autonomic innervation which either directly or indirectly affects their function. Parasympathetics cause bronchial constriction while sympathetics cause bronchial relaxation. Both bronchial irritants and emotional stress appear to trigger vagal reflexes and stimulate bronchospasm (Goroll & Jr, 1995, p. 305).

Though the cause of asthma is unclear, there are several triggers which have been identified. There seems to be a genetic link in the sense that if someone in the family has asthma, it is likely that other family members will have it. Also, there are environmental triggers such as air pollution, smoke, and allergens. Some of the most common allergen triggers for asthma include animal dander, cockroaches, dust mites, mold, and pollen ("Lung Diseases: Asthma," 2006). The strongest allergens which lead to sensitization are dust mites and cockroach antigens which explains why there is a high prevalence of this disease in inner-city residents (Goroll & Jr, 1995, p. 305).

Other irritants which may act as triggers are cold air, strong odors, and scented products. There are other potential causes, including gastroesophageal reflux, infections, medicines such as aspirin and beta-blockers, and sulfites in foods (Lung Diseases: Asthma, 2006).

Asthma is prevalent in industrialized nations and affects an estimated 5-10% of the population. About 5 million of those affected are children younger than six years. There has been a recent rise in the prevalence and morbidity associated with asthma. Suspected causes for this increase are environmental allergens, increased air pollution, urbanization, and passive smoking. Asthma occurs in people of all races, but in the United States, there is a higher percentage of this disease in African Americans. In early childhood, the ratio of boys with asthma to girls is 2:1; however, after puberty the ratio is 1:1, and into adulthood it shifts to 1:2 (Morris, 2007). The gender differences have been studied and found to be similar in research studies (Berhane et al., 2000).

The clinical presentation of asthma includes wheezing, dyspnea, cough, and chest tightness. Although wheezing is the most common presentation, if the obstruction involves the smaller airways, then wheezing may not be present. The physical examination may vary from individual to individual. Between acute episodes, there may be no abnormal findings on exam. If the asthma is associated with allergies, there may be indication of this such as ocular shiners, a transverse crease on the nose, allergic rhinitis, and conjunctival inflammation. The anterior-posterior diameter of the chest may be increased due to hyperinflation of the lungs which may lead to abdominal breathing patterns. During an acute asthma attack, the physical exam will be different. The respiratory rate will likely be increased, there will likely be a wheeze or crackles heard on auscultation of the lungs, and the oxygen saturation will be decreased (Sharma, 2006).

Asthma is classified into four levels of severity: mild intermittent, mild persistent, moderate persistent, and severe persistent. Mild intermittent is characterized as having less than two episodes of asthma symptoms a week, normal peak expiratory flow (PEF) in between exacerbations, nighttime symptoms less than two times a month, and FEV1 over 80% predicted with a less than 20% variability in PEF. Mild persistent is characterized as having symptoms more than two times a week but less than one time a day, nighttime symptoms more than two times a month, FEV1 over 80% predicted, and 20-30% variability in PEF. Moderate persistent asthmatics have daily symptoms, daily use of a inhaled short-acting beta2-agonist, their activity is affected, nighttime symptoms happen more than once a week, FEV1 is between 60-80% of predicted and PEF variability is over 30%. Severe persistent asthmatics have continual symptoms, limited physical activity, frequent nighttime symptoms, FEV1 less than 60% predicted, and PEF variability over 30% ((NAEPP), 1997, p. 20). (Figure 2)

	Symptoms	Nighttime Symptoms	Lung Function
Mild Intermittent	• ≤ 2 times a week	≤ 2 times a month	• FEV1 ≥ 80% predicted

			• PEF variability < 20%
Mild Persistent	• 2 times a week but < 1 time a day • Activity may be affected	> 2 times a month	• FEV1 ≥ 80% predicted • PEF variability 20-30%
Moderate Persistent	• Daily symptoms • Daily use of inhaled short-acting beta2-agonist • Activity affected	> 1 time a week	• FEV1 60-80% predicted • PEF variability >30%
Severe Persistent	• Continual symptoms • Limited physical activity	Frequent	• FEV1 <60% predicted • PEF variability > 30%

Figure 2. Classification of asthma

Aside from clinical diagnoses, there are a few tests which can be performed to diagnose asthma. The National Asthma Education and Prevention Program recommends the use of spirometry to diagnose and follow asthma ((NAEPP), 1997). An obstructive disorder such as asthma presents with a normal forced vital capacity and a reduced FEV1. Also associated with asthma is a ≥ 12% or 200mL improvement in FEV1 after inhaling a short-acting bronchodilator (Sharma, 2006). Peak flow meters are another way of testing and monitoring asthma. Although it is a less reliable test, patients may use peak flow monitoring at home to assess their current asthma status (Morris, 2007). Laboratory tests are not indicated to diagnose asthma, but can be used to rule out other possible diagnoses.

Asthma carries a certain level of morbidity and mortality. The continuous inflammation may cause airway remodeling which results in further exacerbations of asthma. Overall, there is a 0.1% mortality each year from this disease. Despite advancements in therapy, the current mortality associated with asthma has risen over the last decades(American Lung Association, 2005). The morbidity associated with asthma is largely a diminished quality of life. Activity can be affected by the severity of asthma. It is estimated that about 100 million work and school days are lost each year because of this disease. In addition, more than 1.8 million emergency room visits are due to asthma (Morris, 2007). This places a large financial burden on everyone involved. The estimated direct medical cost to our nation, with prescription drugs accounting for the largest part, is around $11.5 billion, while the indirect costs, such as loss of productivity, add another $4.6 billion (American Lung Association, 2005).

The treatment of asthma may involve many avenues. The most successful treatment is the removal of irritating agents and triggers. The next line of treatment is one of two pharmacologic routes: inhibit smooth muscle contraction and reverse inflammation (Kasper et al., 2005, p. 669). Pharmacologic treatment varies depending on the severity of the disease, with each classification having different recommended treatments. To inhibit smooth muscle contraction, beta-adrenergic agonists, anticholinergics, and methylxanthines are used. To reverse or prevent inflammation, glucocorticoids, mast cell stabilizing agents, and leukotriene inhibitors are used. Treatment begins with a short-acting beta2 agonist, then a low-dose inhaled corticosteroid. The next step is to add a long-acting beta2 agonist and further medications to address the inflammation (Kasper et al., 2005, p. 669) .

Asthma in Southwest Virginia

Rural southwest Virginia is not immune to the perils of asthma. In fact, the prevalence for areas of southwest Virginia was higher than those for the United States in a study conducted in 2004. In Roanoke, the rate per 10,000 was 20.2 while the same rate in the United States was 17.0 (Virginia Asthma Coalition). Of the southwestern counties evaluated in a 2007 report from the American Lung Association, Wythe County had a 8.67% prevalence, Salem had a 8.65% prevalence, Roanoke County had a 8.62% prevalence, and Bristol had a 8.61% prevalence. Of those ranked, Salem, Roanoke, and Bristol all scored a C on the particle pollution scale (American Lung Association, 2007).

One toll of asthma is significant financial burden. In Virginia, there were 9,460 hospital visits, totaling $96 million, in 2004. This is a significant amount of money when considering the rural population. There are other risks besides financial when dealing with asthma. In Virginia, from 1999 to 2004, there were 680 asthma deaths (*Asthma in Virginia: A Comprehensive Data Report, 2006*). Death from asthma is rare and preventable, and this number demonstrates a lack of access to care or a problem in self-management of asthma which needs to be addressed.

A study conducted in 2001 analyzed the difference between urban and rural populations with asthma. It was found that in the rural areas, up to 95% of the study participants had primary care physicians taking care of their asthma treatment (Kuo & Craig, 2001). Therefore, it is important that these rural family practice physicians have methods to empower and treat their patients living with asthma.

Due to the increasing incidence and the economic burden of asthma, it is reasonable to begin to think about other options for asthma control. One other option for improving asthma control is to utilize osteopathic manipulation. The following literature review will serve to inform the reader as to why this treatment was chosen to further research.

Osteopathic Manipulation

Osteopathic manipulative treatment (OMT) is manual therapy delivered to alleviate somatic dysfunctions and improve physiologic function. The founder of osteopathy, Andrew Taylor Still, began teaching these methods in the first osteopathic school in 1892 and techniques have been expanded since then (Ward, 2003, p. 21). The principles and theory of OMT allow it to be utilized for a variety of conditions and disease states. There are several characteristics which make it a good choice for addressing various lung diseases, such as asthma. With the use of manipulative treatment, patients could have improved function of their lungs, enhanced healing of the airways, and improved quality of life with or without the concomitant use of standard pharmacologic treatment.

The autonomic nervous system plays a role in asthma through its innervations to the airways (Raji, 2005). The respiratory system receives innervation from a large pulmonary plexus which sits near the pulmonary artery. The lateral horn of thoracic spinal segments 2-7 send sympathetic neurons to this plexus. Most of these nerves target the glandular tissue which surrounds the bronchi as opposed to targeting the musculature like other nerves do. When stimulated, these beta-adrenergic receptors of the sympathetic nervous system cause bronchial dilation and viscous secretions. The parasympathetic innervations to the airways occur via the Vagus nerve. The pulmonary branches of this nerve terminate on bronchial smooth muscle, mucosal glands, and blood vessels. Parasympathetic stimulation causes bronchoconstriction, vasodilation, and hypersecretion of serous fluid (Blumenfeld, 2002, p. 230). By understanding the nervous system and the lungs, OMT techniques have been developed to address this area of concern. There are several techniques which are thought to balance the parasympathetics and sympathetics, thus improving the symptoms of asthma.

Thoracic structure also plays a role in lung function and asthma. The thoracic cage must be able to move unimpeded in order to maintain sufficient arterial supply, venous and lymphatic drainage, and response to the neural regulatory system. The ribs, surrounding musculature, and diaphragm all influence the physiology of the lungs (Ward, 2003, p. 506). Many OMT techniques address structure as it relates to function. In treating asthma, there are many structures which can be manipulated to improve their function. OMT can be directed towards the rib cage, the musculature, and the diaphragm to improve their mobility and thus improve the symptoms of asthma.

In addition to neural and structural influences, there are lymphatic influences on respiration. Osteopathic physicians have long been interested in the role of lymphatics in maintaining health. Proper lymphatic drainage encourages proper tissue activity and metabolism and aids in immunologic function. Effective lymphatic drainage of the lungs is normally achieved by contraction of the diaphragm and thoracic cage movement during respiration. However, in patients with asthma, both of these mechanisms may be compromised, leading to impaired lymphatic drainage. This impairment results in reduced healing time, a diminished ability to fight infection, and decreased ability for medications to reach their target tissues. There are several OMT techniques which address the problem of lymphatics: rib raising, diaphragm release, and lymphatic pumps (Sevarese et al, 2003, p. 125).

An article written by two osteopathic physicians describes the benefit that OMT can have on treating respiratory problems. After a 69-year-old man was admitted to the hospital with respiratory failure, the physicians prescribed treatment which combined OMT with standard patient care to apply the many benefits of OMT to address this problem. In the end, the authors describe respiration as “a dynamic orchestration involving coordinated reflex neural activity; abdominal, diaphragmatic, and other muscular contractions; motions of fascial planes; and the movement of more than 146 joints" (Stretanski & Kaiser, 2001, p. 448). These physicians had found that the altered structure of this patient's thoracic cage resulted in inefficient function of his respiratory system. With appropriate osteopathic correction, this man's respiration improved dramatically.

Previous Research on the Use of Various Types of Manipulation for Asthma

While osteopathic manipulation is frequently used to address asthma in practice, there are limited studies which prove its effectiveness. In fact, there are very few research papers which evaluate any use of OMT which makes its use for asthma both difficult and important to study. Some researchers have studied the use of manipulation with asthma, chronic obstructive pulmonary disease, and other respiratory problems such as pneumonia and post-surgery lung function. The chiropractic community has put together several studies regarding the use of their manipulation on asthmatics, which is similar to osteopathic manipulation on some levels. For those reasons, the chiropractic literature will be used here to provide some background and review for this study which uses osteopathic manipulation.

The literature in the chiropractic research is inconsistent. Some studies reveal that chiropractic manipulation benefits patients with asthma, and some studies demonstrate that there is no benefit. This may be due to the variability across techniques, patients, and chiropractors. One of the largest studies in the chiropractic literature was conducted with 420 participants in Australia. This study was designed to explore what effects chiropractic manipulation had on symptoms, depression and anxiety, and level of immunity in asthma patients. Dr.Hayek found that the group undergoing the manipulation had a significant improvement in asthma symptoms, depression, and anxiety. In addition, it was found that the treatment group had increases in IgA and a decrease in cortisol, which suggests increased immunological capacities caused by manipulation. This would benefit the patient by warding off asthma attacks and reducing the incidence of airway infections (Ali et al., 2002).

Another chiropractic study of children with asthma demonstrated varying results. This study demonstrated that objective measurements of lung function did not change with the administration of chiropractic manipulation. However, there was a 20% reduction in bronchodilator use, 10-28% improvement in quality of life scores, and a 39% reduction of the asthma severity ratings. Overall, there was a 50-75% improvement rating (Bronfort, Evans, Kubic, & Filkin, 2001). This study demonstrates a subjective, but not an objective improvement.

There were two large chiropractic studies conducted which both demonstrated no statistically significant benefit associated with manipulating patients with asthma (Balon et al., 1998; Nielsen, Bronfort, Bendix, Madsen, & Weeke, 1995). However, both trials demonstrated an improvement in patient-perceived asthma symptoms, with Nielsen's study showing a patient-rated asthma severity decreasing by 34% (Nielsen et al., 1995). A retrospective literature review study found that, overall, the chiropractic literature involving the use of manipulation for asthma patients demonstrated an increase in subjective measures, but not objective measures (Balon & Mior, 2004).

Within the osteopathic literature, there are similar displays of variation, but the results tend to be more favorable for the benefits of OMT. Just as the chiropractic community studied manipulating children with asthma, so did the osteopathic profession. In one study, conducted by Guiney, Chou, Vianna, & Lovenheim (2005), OMT was shown to have a beneficial effect on pediatric asthma patients. It was found that, after OMT treatment, there was a statistically significant improvement in peak expiratory flow rates (Guiney et al., 2005).

Another well-known osteopathic study was conducted to quantify the effects of OMT on patients with chronic asthma. In this study, ten subjects were used in a pretest-posttest crossover design. Respiratory excursion, peak expiratory flow rates, and subjective measures of asthma symptoms were monitored. The results demonstrated that respiratory excursion significantly increased after the administration of OMT, while peak expiratory flow rates and subjective asthma symptoms did not improve (Bockenhauer, Julliard, Lo, Huang, & Sheth, 2002). These results are encouraging, because previous research and educational literature demonstrates the importance of thoracic cage movement to facilitate breathing; however, the peak expiratory flow and symptoms data is disappointing. There are, however, several critiques to this particular study. First of all, all subjects were treated for the same dysfunction, whether or not they had that dysfunction, which is not how OMT is practiced in the clinical setting. Also, there was a very low power in this study, which only had ten participants. Another critique focused on the choice of objective measures. While peak flow meters are a useful monitoring device, it has been shown that spirometry is a more credible means of measuring pulmonary function (Cali, 2002).

Problems in the Literature

As is evident from the above studies, there is a gap in the literature pertaining to the use of osteopathic manipulation to treat asthma. There are only a handful of studies conducted on this topic and the results are inconsistent. Most of the studies seem to agree that there is a patient-perceived improvement regardless of objective measures of improvement. I hope to add to these studies with my own research on the use of OMT to treat asthma. Using some of the techniques and methods from the above research, I attempted to solidify and answer the question of its benefit in this population. In addition, I sought to answer a question which had not been asked in past research: Can patients be taught home OMT techniques which benefit their symptoms? Many osteopathic physicians teach their patients things they can do at home to help (Paulus, 2005), but there is no research to further explore this practice. If it proves beneficial, this research may provide a viable solution to the problem of access to care, financial resources, and empowerment of asthmatic patients in rural southwest Virginia.

Chapter 3

Methodology

This chapter will be used to explain the methodology used in this research project. The population, sample, study design, instrumentation, and data analysis will be explained.

Population

The population was asthma patients in treatment in clinics in Giles, Blacksburg, and Christiansburg during the time period of October to November 2007. Purposive sampling was used to select from the population of people age 6-56 at the three clinics.

Sample

From the population of asthma patients, as previously defined, a sample of 32 participants was enrolled in the study using a well defined process approved by IRB. Physician clinics in Giles, Blacksburg, and Christiansburg were surveyed for their prevalence of patients with asthma. The physicians were asked to hand out information sheets to any patient that met the criteria set and invite them to participate in the study. The participants were given an outline of the dates and asked to come to the clinic at those times. At that time, the informed consents were signed and the participants were randomly assigned to either the group receiving only

OMT in the office (group 1) or the group who will be trained in home manipulation (group 2). Thus, the criteria for the purposive sample selection were: attendance at the clinic during the time period, access to information and invitation to participate in the study.

Procedure

Design

This is a quasi-experimental research study to determine relationships between OMT and lung function. The independent variables were the OMT delivered to the subject and research-selected environmental factors based on the related literature, while the dependent variable is lung function as measured by spirometry, thoracic excursion, and subjective assessment. A variable baseline, within-subject study design was utilized. With this design, patient baseline symptoms and lung function were assessed at a point in time. Then, a treatment was introduced and the measurements continued. This allowed for the measured variables to be compared before and after the treatment, in order to determine if the treatment had an effect. The baseline measurement occurred at different times for each subject,to control for the effect of time on treatment. This particular design has been used by many osteopathic researchers in the past and has been shown to be a valid means of designing a study (Ward, 2003, p. 1180). The steps of the project can be visualized in Figure 3.

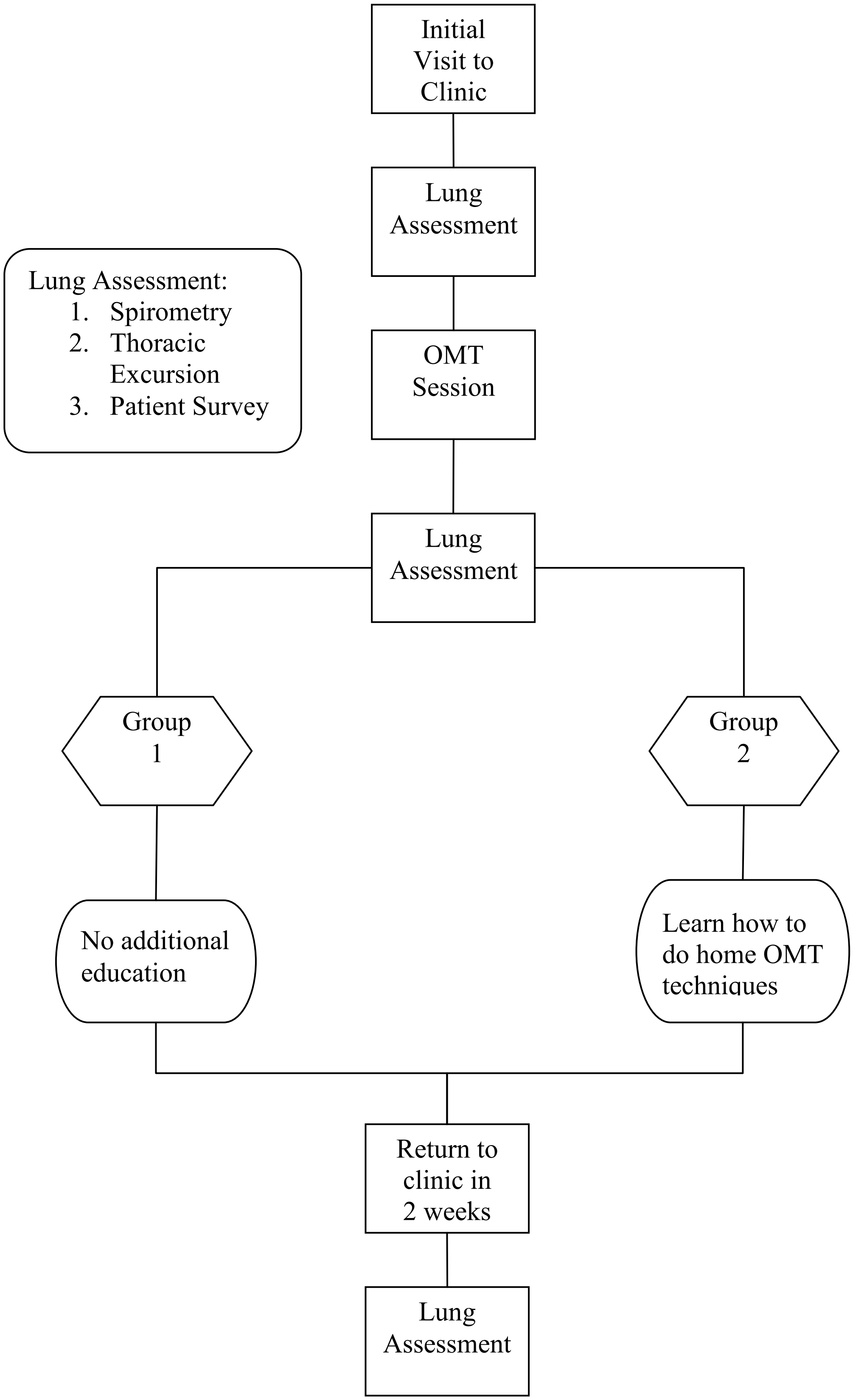

Initial Visit to Clinic
Lung Assessment
Lung Assessment:
1. Spirometry
2. Thoracic Excursion
3. Patient Survey
OMT Session
Lung Assessment
Group 1
Group 2
No additional education
Learn how to do home OMT techniques
Return to clinic in 2 weeks
Lung Assessment

Figure 3. Study Design

For part of the study, each participant served as his or her own control. This was due to the uniqueness and individuality of the disease process. Each person's lung function is unique and should not be compared to others. However, the changes in lung function can be compared. A second phase of the study compared the two groups; one received home treatment and one did not.

Recruitment and Criteria

The first step was to recruit participants. This was accomplished through five rural clinics in southwest Virginia whose locations included: Christiansburg, Giles, and Blacksburg. Two months before the study began, these clinics were given fliers advertising the study, to place in their waiting rooms. In addition, the physicians were given the inclusion and exclusion criteria and were asked to introduce the study to any of their patients who matched the criteria. All interested patients either left contact information with the clinics for the primary researcher to contact them, or they were given contact information and asked to contact the primary researcher for further information. Based on this initial contact with the primary researcher, the patient was officially enrolled in the study. The sample size was not adequate at this stage. To supplement the initial sample, the primary researcher used the physicians and their records to select patients who met the criteria and they were contacted and asked to participate. The combined strategy of self-selection and active solicitation provided a cross section of the patients across the geographical clinic service area.

The inclusion criteria included participants aged 6 to 56 years, diagnosed with mild intermittent, mild persistent, moderate persistent, or severe persistent asthma and participants who had the diagnosis for more than three months. My exclusion criteria included patients with congestive heart failure, pneumonia in the past three months, an active infection, an oral steroid burst in the last three months, hospitalization in the last three months, and OMT treatment in the last three months. These criteria were selected based on previous research (Bockenhauer et al., 2002; Guiney et al., 2005).

First Visit

After the patients had been recruited, they came to the specified clinic on a specified start date. Each participant was coded and recorded in the code book to ensure confidentiality throughout the study. The participants were given the informed consent and allowed a chance to ask questions about the study. Afterwards, the participants were randomly assigned to either group 1 or 2 on an alternating basis. If a participant expressed that they did not have anyone who was able to administer the home OMT treatment, then they were automatically placed in the no-home-treatment group (group 1). Each participant was also given a questionnaire regarding their demographics, disease state, medications, medical history, and environmental exposure (Appendix B). The patients were given an asthma quality of life questionnaire (AQLQ) to determine their current quality of life as related to asthma. This questionnaire was developed in the UK and has been utilized in several studies concerning asthma. A shortened version called the Mini-AQLQ was used for this study (Appendix A). This tool was developed to shorten the amount of time a patient has to spend filling out a survey and has been found to be a good measurement of asthma quality of life (Juniper, Guyatt, Cox, Ferrie, & King, 1999).

Once the above coding and administration of the questionnaire was finished, the study began with a pre-manipulation lung function assessment. This included a pre-OMT survey regarding the participants' current perception of their lungs and lung function (Appendix C). Also, thoracic excursion was measured. The last pre-OMT assessment was a pulmonary function measurement using a portable spirometer.

Patient Survey

The pre-OMT survey consisted of questions designed to identify the patient's perceived current lung function. There were questions asking the participant to rate their lung function, score how well they can breathe, and describe their symptoms. More specific information on the questionnaire is included in the instrumentation section of this Thesis.

Thoracic Excursion

The thoracic excursion was measured using the cloth tape technique discussed by Bockenhauer, Chen, Julliard & Weedon (2007). At peak inhalation, the participant was asked to hold his/her breath while the researcher used a cloth tape to measure the circumference of the upper and lower chest wall. The upper thoracic excursion measurement was taken at the level of the fifth thoracic spinous process and the third intercostals space at the mid-clavicular line. The lower thoracic excursion measurement was taken at the level of the tenth thoracic spinous process and the xiphoid process (Bockenhauer et al.,2007). The patient was asked to hold his/her breath at peak exhalation for these measurements to be repeated. The upper and lower thoraric measurements in inhalation and exhalation were repeated and averaged. Then, the total thoracic excursion was calculated by taking the difference in the inhalation and exhalation measurements.

Spirometry

The spirometry test for pulmonary function was taken using a Brentwood portable spirometer. Each patient was entered into the program database on a laptop before beginning. The patient was given verbal directions on how to perform the test. The participant was given a nose clip and a mouthpiece. The patient's number was recorded on the mouthpiece and they used the same one throughout the duration of the study. With the nose clip in place, the participant stood up straight and took a deep breath in. Then, they placed the mouthpiece in their mouth being sure to create a tight seal around it before blowing out as hard as they could and as long as they could. As they performed the test, participants received instructions based on a study conducted in 1985. Researchers studied the influence of various instructions given during spirometry. They examined the instructions to blow hard, blow fast, and blow long. It was found that by instructing the patient to blow harder, the most stable pattern of results was obtained (Harm, Marion, Creer, & Kotses, 1985). At the end of exhalation, they removed the mouthpiece and breathed normally. The participant was asked to repeat this test for a total of three trials. The researcher examined the results to ensure that all values were similar, and then the best of the three was recorded in the diagnostics program on the laptop. The values examined were forced vital capacity (FVC), forced expiratory volume in 1 second (FEV1), and peak expiratory flow (PEF).

Spirometry is an easy, noninvasive test which can be easily performed in a primary care office setting. There are no adverse side effects documented from the use of spirometry aside from minor discomfort (Ferguson, Enright, Buist, & Higgins, 2000, p. 1151). Office spirometry is recommended for patients with respiratory symptoms such as dyspnea, wheezing, and chronic cough, to detect airway obstruction due to asthma or COPD (Ferguson et al., 2000, p. 1146). It is also recommended to help diagnose and track the progression of asthma (NAEPP 1997, p. 17) Spirometry was chosen over the use of peak flow meters for several reasons. First of all, peak expiratory flow alone is insensitive to obstruction of the smaller airways. Also, results from a peak flow meter are highly dependent on the patient's effort, which can be better monitored using spirometry. (Ferguson et al., 2000, p. 1153). Another disadvantage of using peak flow meters is their inter- and intra - subject variability (Gardner, Crapo, Jackson, & Jensen, 1992). For all of these reasons, spirometry was chosen as the form of measuring lung function in this study.

OMT Session

After the pre-OMT measurements were taken, a five- to ten-minute OMT session was performed. This time frame was chosen to accurately reflect the typical clinical situation in a busy rural family practice clinic in southwest Virginia. The OMT techniques were chosen for their effectiveness in addressing pulmonary dysfunction, their ease of delivery, and their comfort to the patient. The techniques chosen were: an individualized thoracic/rib treatment with muscle energy or facilitated positional release, a diaphragm release, a myofascial technique for the occipito-atlantal joint, and a thoracic lymphatic pump.

Individualized Thorax and Rib Treatment

In order to effectively treat a patient with OMT, it is important to locate a dysfunction and treat it. It would not be in accordance with the osteopathic philosophy for this study to pick out specific treatments to perform on every participant. Instead, the participant must be screened to discern his or her specific needs. As stated by Bockenhauer, “a protocol that permits individualization of therapy to address each subject’s particular somatic dysfunctions would be more appropriate” (Bockenhauer et al., 2002, p. 374). Therefore, in this study, the participants were screened using the Stiles technique for upper thoracic (T1-6) and rib lesions. These areas were chosen because the sympathetic innervations to the lungs is derived from spinal nerves coming from T1-6 and because of the mechanical restriction that rib dysfunctions can create on breathing.

The Stiles screening technique allows the physician to determine the area of greatest restriction in the patient. By identifying and treating this key lesion, the patient gets the greatest benefit. While doing the screen, the physician is palpating for end-feel. A dysfunction is found when a hard end-feel is palpated. The area of greatest restriction (AGR) is the area that has the hardest end-feel (Grentz, Yonts, Stiles, Broadwater, & Jones, 2004, p. 15). To screen, the physician places their left hand on the patient’s left shoulder while the patient is seated on a manipulation table. The physician’s right thumb and thenar eminence is placed over the left articular column. Through the left hand, the physician introduces slight flexion or extension, sidebending and left rotation while translating anterior/medial with the right thenar eminence and thumb. This springing motion is repeated as the physician moves his or her hand down the thoracic spine. These steps are then repeated on the right side of the patient (Grentz et al., 2004, p. 16). The physician notes the AGR in the thoracic region and then determines if this indicates a thoracic vertebra or rib dysfunction. If it is a thoracic vertebra, then the restriction will be localized to one to two segments and the hardness of the end-feel will decrease as the physician palpates laterally. If it is a rib lesion, the hard end-feel will worsen as the physician palpates laterally (Grentz et al., 2004, p. 17).

Once the AGR is found in the thoracic region, the dysfunction can be appropriately corrected with muscle energy or facilitated positional release. Muscle energy is a direct technique in which the physician localizes the muscles surrounding the involved joint and then positions the joint into its area of restriction. The patient is then instructed to move that portion of their body away from the restriction for 3 to 5 seconds while the physician resists using isometric counterforce. The patient then relaxes, allowing the involved muscle to relax. The physician then moves the joint further into the restricted barrier and the process is repeated. After 3-4 rounds, the treatment is complete (Dowling, 1997, p. 86). Facilitated positional release (FPR) is an indirect myofascial release which normalizes hypertonic muscle tissue. In this technique, the physician will place the appropriate region of dysfunction into a position of ease and shorten the muscles involved. A facilitating force such as compression, torsion, or a combination of these is applied. The physician holds the patient in this position for 3-4 seconds and then releases (Shiowitz, 1997, p. 91).

If AGR is found in the ribs, patients are screened to find the key rib lesion. To do this, the patient will be supine on the treatment table. The physician places their monitoring fingers over two to three ribs and monitors movement while the patient takes deep breaths. When a rib or group of ribs does not move properly during inspiration or expiration, then there is dysfunction. Once the dysfunctional rib or ribs are found, the physician will treat the key rib with muscle energy or facilitated positional release. For a group of inspired ribs, the key rib is the bottom rib; for a group of expired ribs, the key rib is the top one (Grentz et al., 2004, p. 177).

Diaphragm Release

A direct soft tissue technique is used to address the diaphragm. The diaphragm has several attachments in the thorax. An area that has been noted to cause problems with respiration is the arcuate ligaments. The ligaments are thickenings of the thoracolumbar fascia and thus connect the thoracic region and the lumbar region – a prime area for dysfunction. This ligament passes over the psoas major muscle and arches from the crus of the diaphragm to the transverse process of the first lumbar vertebrae. In addition, part of this ligament passes over the quadratus lumborum muscle and attaches to the 12th rib. In order to address this area, the patient lies supine on the treatment table while the physician stands on the right side of the patient, facing the head of the table. The physician places his/her right hand underneath the patient's left lower ribs and his/her left hand underneath the patient's right lower ribs. The physician's middle three fingers contacted the space lateral to the vertebral column in between the 11th and 12th ribs. The physician then exerts a gentle superior, lateral, and caudal force. This position is held for several seconds until the physician palpates a release and relaxation of the structures underneath the finger pads. The physician then repositions, takes up more slack in the tissues, and holds this position until release is palpated again (Harden, 2007).

Occipito-Atlantal Joint

The next region which needs to be addressed is the occipito-atlantal (OA) joint. This region is closely linked with the Vagus nerve, which controls the parasympathetic responses of respiration. This area is treated with a passive myofascial technique. The patient lies supine on the treatment table with the physician standing at the head of the table. The physician cups his/her palms underneath the patient's head and places the fingers in the occipital sulcus bilaterally. Traction is slowly applied and maintained for a few seconds before being slowly released. This is repeated several times to ensure a proper linear stretch and release of hypertonic muscles in this region (Spinaris & DiGiovanna, 1997, p. 111).

Thoracic Lymphatic Pump

The last OMT technique which is used is the lymphatic pump. This technique is performed after the somatic dysfunctions found in the OA region, thoracic vertebra, rib cage, and diaphragm are addressed. This technique allows free movement of lymphatic fluid which is important in asthma patients. The patient is asked to lie supine on the treatment table with the physician at the head of the table. The physician places his/her thenar eminences on the patients chest just below the clavicles, with the fingers spreading out over the rib cage. The patient is asked to take a deep breath and exhale fully. During exhalation, the physician increases the pressure on the rib cage, exaggerating the motion. As the patient inhales, the physician releases the pressure, and then reapplies it when the patient exhales. This cycle is repeated for 5-10 respirations (Kimberly, 2000, p. 429).

After the OMT, the thoracic excursion and spirometry measurements were repeated. The patient was also asked to fill out a survey regarding their estimation of lung function immediately after the OMT session (Appendix D). These results were compared to the pre-OMT results.

Division into Groups

The patients were randomly assigned to one of two groups on an alternating basis. Both groups underwent the procedure described above. However, group 2 received additional training in home OMT maneuvers which were to be administered by a spouse, family member, or friend.

Home OMT education session

The group receiving home OMT instructions were given an instruction sheet (Appendix F) describing the techniques and the application of them. The instruction sheet was written and tested on non-participants who were not familiar with OMT to ensure that the participants in the study would be able to understand the instructions. Each participant also received personal demonstration by the primary researcher to ensure that they understood the procedures. This group was then asked to perform the techniques at home three to four times a week and keep track of their progress. The techniques taught were three simple, low risk, soft tissue techniques; suboccipital release, pectoral traction, and rib raising.

Suboccipital Release

The suboccipital release is a soft tissue technique performed on the suboccipital muscles. Here, the patient is supine on a treatment table or floor with the operator sitting at the head of the table. The operator places his or her finger pads palm up beneath the patient's suboccipital muscles. The operator then slowly and gently applies force towards the ceiling and towards themselves to stretch the muscles. This position is held until the underlying muscles begin to relax. This action may be repeated until maximal response is obtained (Kimberly, 2000, p. 37; Nicholas & Nicholas, 2007, p. 86).

Rib Raising

This technique is performed with the patient lying supine on a treatment table or floor. The operator is seated on either side of the patient. The operator's hands are placed palm up underneath the patient's back. The pads of the fingers should be on the paravertebral musculature. The operator then exerts a gentle lateral and upward force to engage the soft tissue. This stretch is held for several seconds and then released. The operator then moves down the spine and repeats this maneuver. Once the operator has done this along the rib cage of the patient, he or she switches sides and repeats the technique (Nicholas & Nicholas, 2007, p. 104).

Pectoral Traction

This technique is again performed with patient lying supine on the treatment table or floor. The operator is at the head of the patient. The operator places his/her hand over the pectoralis muscle and grasps the inferior margins called the anterior axillary fold between his/her fingers and palms. Next, the operator leans backwards and pulls the pectoralis muscle medially and superiorly. The patient is then told to take in a deep breath and let it all out while the operator continues to hold this traction. The patient completes two to three respiratory cycles before the operator gently releases his/her hold (Kimberly, 2000, p. 62).

Two Week Follow-Up

Both groups of participants were then asked to return to the clinic two weeks after their initial visit. The patients were asked to fill out the Mini-AQLQ again to assess their asthma quality of life. Also, the patients were given a follow-up questionnaire to ask about their participation in the study and their views on its effectiveness (Appendix E). Then, thoracic excursion and spirometry was performed to determine their pulmonary function after two weeks. At follow up, 30 out of the 32 participants returned.

Instrumentation

In order to implement this study, several instruments were used. There was a questionnaire, pre and post-OMT survey, thoracic excursion measurement, spirometer, and a 2 week follow up survey. The appropriate reliability and validity of these instruments will be further discussed here.

The thoracic excursion method created by Bockenhauer (2007) has been assessed for reliability. It was found to be a reliable and useful instrument in the clinical setting for evaluating thoracic excursion. This method was shown to be most reliable when used to measure changes which are expected to be greater than 0.6

cm. Also, his study showed that better reliability is met if measurements are repeated and averaged, which was done in this protocol (Bockenhauer et al., 2007, p. 195). An additional aspect which improved the reliability and validity of this instrument was that there was only one person taking the measurements. Therefore, inter-rater reliability is not a concern (McKenzie, Neiger, & Smeltzer, 2005, p. 103).

There have been many studies to validate the use of spirometry to evaluate lung function. However, many of these studies have determined the accuracy and precision of hospital-based instruments which are operated by trained technicians. Based on review by experts in this field, it was determined that this type of spirometry is acceptable for the purpose of detecting airway obstruction.

Additional strategies were employed to assure valid results based on studies that showed certain procedures, if not addressed, could limit validity. (Studies conducted on spirometry results obtained from outpatient clinicsyielded poor results.) In one study, less than one third of the sessions obtained two acceptable measurements, and most of the measurements lasted less than the required six seconds (Eaton et al., 1999, p. 421). This same study demonstrated that a two-hour spirometry training workshop resulted in the nurses obtaining better test sessions (Eaton et al., 1999, p. 422). With this knowledge, and in order to obtain valid spirometry values, the researcher studied the technique of administering the test, worked with a pulmonologist to ensure correct technique, and practiced several times before beginning the study.

The pre and post OMT surveys, as well as the follow up survey, were examined for reliability. Internal consistency is the method used to ensure that these instruments were reliable. This was established with a Crombach alpha coefficient of .834.

The validity of these instruments was ensured with content validity testing. With this method, a panel of experts reviewed each survey to ensure that each question was appropriate (McKenzie et al., 2005, p. 104) and addressed all the research objectives which the instrument was intended to measure.

The asthma quality of life questionnaire (AQLQ) has been validated by many previous studies and has been found to be a valid instrument for assessing asthma symptoms (Juniper et al., 1999; Juniper et al., 1992; Juniper, Guyatt, Ferrie, & Griffith, 1993). The panel of experts for this study also concluded that the AQLQ was valid.

Data Analysis

In order to analyze the data, both SPSS (SPSS Graduate Pack 14.0 for Windows) and SAS systems were used. The pre- and post-OMT spirometry values, two thoracic excursion values, and the five patient symptom questionnaire answers were compared and analyzed. Each set of values was tested for normality using a Q-Q plot before further statistical tests were run. If the data was normal, then a paired-sample t-test was conducted to evaluate the impact of OMT on the participants' lung function and symptom scores on each of the instruments. An Eta-Squared test was then performed on all significant findings to determine the magnitude of the effect of OMT on scores.

If the data were skewed, a Wilcoxon 1-sample test or signed rank test was performed to test the significance of the median.

To analyze the results of the AQLQ, the two surveys were scored separately. To score the survey, all 15 of the responses were added and then that number was divided by 15. This gave a score between 1 and 7. A score of 7 means the patient has no impairments due to their asthma and a score of 1 means there is significant impairment. After the degree of impairment was determined for each participant at the beginning and at the end of the study, the results were compared. The designers of the AQLQ found the minimal important difference (MID), meaning "the smallest difference in score which patients perceive as beneficial and would mandate, in the absence of troublesome side effects and excessive cost, a change in the patient's management" (Juniper, 1991, p. 28). The MID for the AQLQ is close to 0.5 on the 7 point scale. This means that a change of 0.5 or more reflects a significant change (Juniper, Guyatt, Willan, & Griffith, 1994).

In order to analyze the level of improvement of asthma that home OMT treatments had for the participants, a bivariate data analysis called the t-test was utilized (McKenzie et al., 2005, p. 333). If the data was found to be normal, then a paired-sample t-test was conducted on the initial and follow-up values to determine if there was a difference between group 1 and group 2. An Eta squared test was performed on all significant ($p<.05$) values to determine the magnitude of effect that the intervention had on the scores. If the data was skewed, then a Wilcoxon 1-sample test or signed rank test was performed to test the significance of the median values.

Chapter Four

Results

In this chapter, the final results of the study will be displayed. They will be organized into the four specific objectives.

The purpose of this study was to determine the viability of OMT treatment with asthma and the effectiveness of home OMT education, in order to implement a program to improve asthma control. The principle investigator studied the use of OMT on 32 asthma patients in Blacksburg, Christiansburg, and Giles by designing and implementing a protocol involving delivering OMT to all participants and testing pre- and post-OMT lung function. Lung function was measured by spirometry, thoracic excursion, and a five question patient symptom rating scale.

In addition to determining the immediate effect of OMT on asthma symptoms, the investigator placed the participants into two groups -- one who received education on home OMT techniques, and one who did not -- in order to determine the effectiveness of including a home OMT education session in basic patient treatment. All but two participants then returned for a two week follow up lung assessment. The investigator analyzed the data using both SPSS and SAS systems. After each set of values was tested for normality, a paired sample t-test was conducted to evaluate the impact of OMT on the participants' lung function and symptom scores on each of the instruments. An Eta squared test was also performed on all significant findings to determine the magnitude of the effect that OMT had on scores. If the data were skewed, a t-test could not be used, so a Wilcoxon 1-sample test or signed rank test was performed to test the significance of the median value.

The demographics of the sample are important in interpreting the overall results of the data analysis. The principle investigator was able to recruit a total of 32 participants for this study, of which 30 returned for follow up. There were 10 male and 22 female participants (see Figure 4). Of these participants, the ethnicity was primarily Caucasian with one Hispanic participant and two who classified themselves as others (see Figure 5). The age of the participants varied from age 6 to 56 with a mean age of 30 (see Figure 6). The participants had a wide range of classification of asthma. There were 11 patients with mild intermittent, eight with mild persistent, nine with moderate persistent, and three with severe persistent asthma (see Figure 7). Ten of the participants had been hospitalized for asthma-related complications in the past. Also of interest is that five of the participants had tried either chiropractic or osteopathic manipulation for relief of their asthma symptoms.

Figure 4. Gender classification of participants

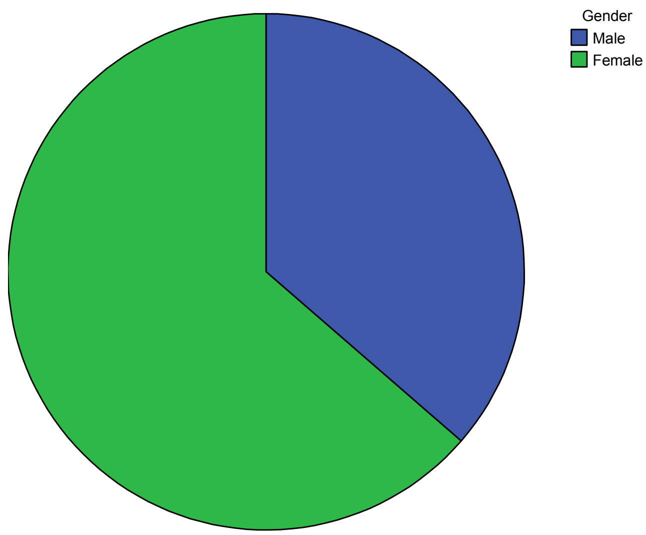


Figure 5. Ethnicity classification of participants

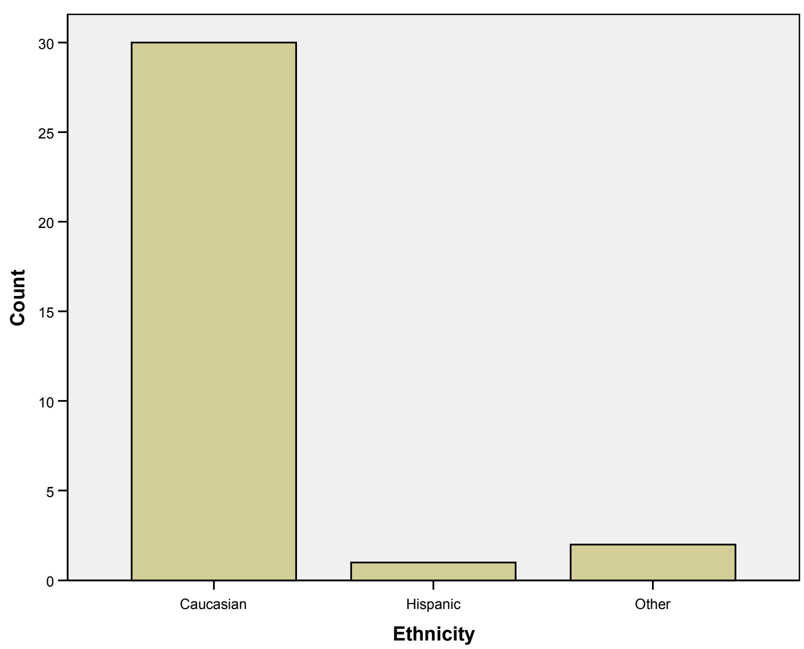


Figure 6. Histogram of age of participants

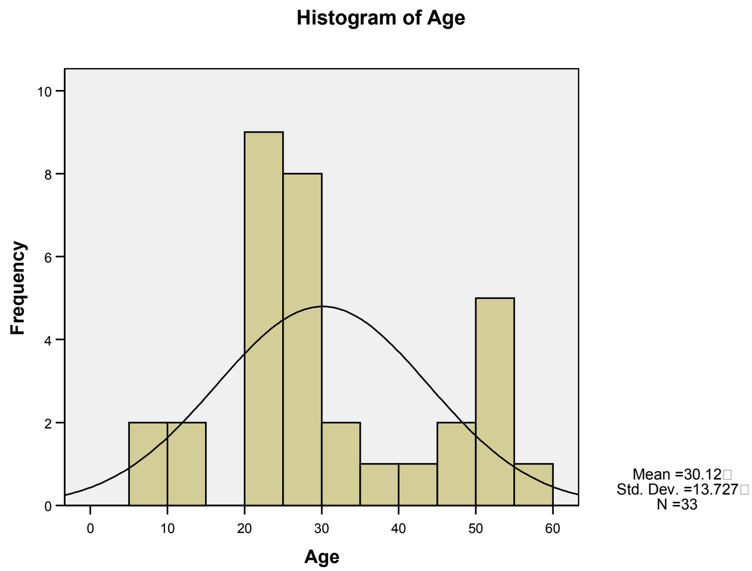
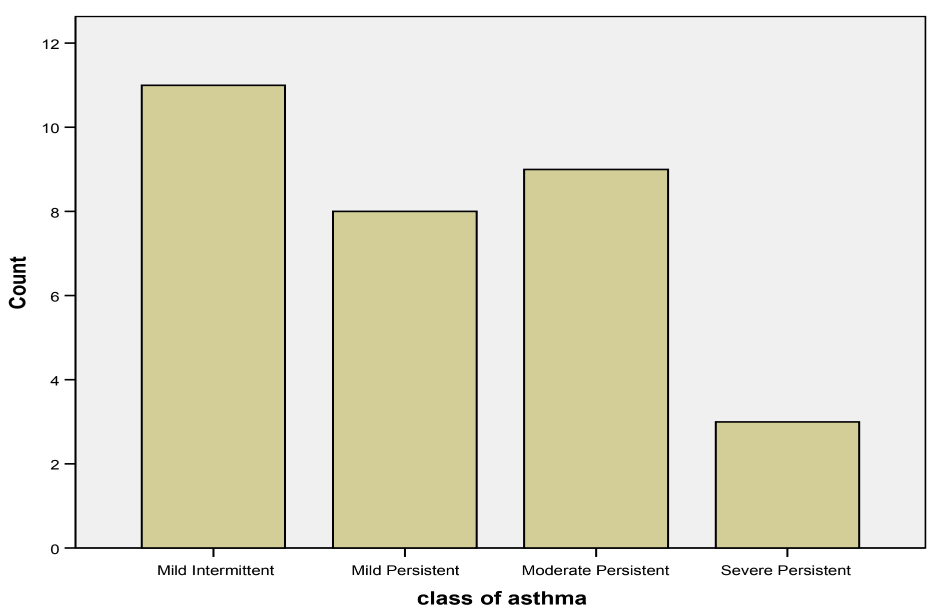


Figure 7. Classification of asthma participants



The results of the data analysis provided findings for each of the research objectives as shown below.

Objective 1. Determine the relationship of OMT on lung function as demonstrated by basic spirometry, thoracic excursions, and subjective patient symptoms.

The relationship of OMT on lung function for each of the instruments was assessed separately for each of the 32 participants.

Spirometry

Analysis of the spirometry data (FEV1, FVC, and PEF) demonstrates normality. The paired-sample t-test showed a significant ($p<.05$) increase between the pre and post-OMT FVC values, but the change in FEV1 or PEF values were not significant. Results are displayed in Table 1. Although all 32 participants carried a diagnosis of asthma and suffered symptoms, only 1 had a FVC value of less than 84%, 5 had an FEV1 value of less than 80%, and 5 had a PEF of less than 80% before OMT, which was the result of physician care over a period of time before this research began. Therefore, there was limited potential for improvement in the spirometry values. Participants who had lower starting spirometry values showed the largest improvement ranging from a 15% to a 34% improvement after the OMT session.

Table 1. Pre and Post-OMT Spirometry Value Statistics

	Mean	Standard Deviation	T(31)	P (Eta Square)
Pre FVC Post FVC	98.32 101.29	13.32 12.57	2.49	.019 (.167)
Pre FEV1	93.78	15.64	.289	.774

Post FEV1	94.22	14.57		
Pre PEF Post PEF	92.33 91.23	20.18 18.39	.629	.534

N=32, p<.05

Thoracic Excursion

Analysis of the upper and lower rib cage excursion demonstrates normality. The paired-sample t-test for the upper ribs shows a statistically significant increase (p<.05) in upper rib thoracic excursion from pre-OMT (M=.89, SD=.55) to post-OMT (M=1.22, SD=.61, t(31)=5.51, p=<.0001) with an eta squared statistic of .49. The analysis demonstrated an equally statistically significant increase (p<.05) in thoracic excursion of the lower ribs from pre-OMT (M=1.18, SD=.75) to post-OMT (M=1.77, SD=.89, t(31)=11.04, p=<.0001) with an eta squared statistic of .79. Results are displayed in Table 2.

Table 2. Pre and Post-OMT Thoracic Excursion Measurements

	Mean	Standard Deviation	T(31)	P	Eta squared
Pre Upper Ribs Post Upper Ribs	.89 1.22	.55 .66	5.511	<.0001	.49
Post Upper Ribs Post Lower Ribs	1.18 1.78	.74 .89	11.04	<.0001	.99

N=32, p<.05

Patient Symptoms

Analysis of the five patient symptom questions demonstrated skewness, therefore a Wilcoxon 1-sample test was performed. The analysis of all five of the questions: current shortness of breath, chest tightness, wheezing, ability to take a deep breath, and overall asthma symptoms from pre to post-OMT showed statistically significant ($p<.05$) improvement in the medians as seen in Table 3.

Table 3. Pre and Post-OMT Asthma Symptoms

Symptom (scale of 1 to 10)	Pre OMT Median (St Dev)	Post OMT Median (St Dev)	Difference in Median	P using Wilcoxon 1 sample test
Shortness of Breath	9.0 (2.21)	10.0 (1.49)	1.0	.0012
Chest Tightness	8.0 (1.91)	9.0 (1.60)	1.0	<.0001
Wheezing	10.0 (2.18)	10.0 (1.06)	0.0 (difference in mean 0.758)	.0239
Ability to Take a Deep Breath	8.0 (1.67)	9.0 (1.22)	1.0	<.0001
Overall Asthma Symptoms	8.0 (2.04)	9.0 (1.17)	1.0	<.0001

N=32, $p<.05$

Objective 2. Compare lung function measures of asthma patients using self-administered home treatment as supplemental to doctor administered OMT treatment with asthma patients who only receive doctor administered OMT.

Participants were divided into two groups; 16 were in the control with no home OMT, and 14 were in the home OMT education group. The difference in lung function measures were again analyzed separately for each of the instruments used. In addition, scores from the Mini AQLQ were analyzed and compared for each group to determine if adding home OMT improved the participants' quality of life as related to asthma.

Spirometry

Analysis of the three spirometry values, FEV1, FVC, and PEF, demonstrated normality. The paired sample t-test did not show significant improvement from baseline to follow up for any of the three values. Results are displayed in Table 4.

Table 4. Paired sample t-test results for spirometry at baseline and follow up

	Mean	Standard Deviation	T(29)	P
Baseline FVC Follow Up FVC	98.32 99.92	13.32 14.06	0.965	.3433
Baseline FEV1 Follow Up FEV1	93.78 94.66	15.64 14.71	.578	.5681
Baseline PEF Follow Up PEF	92.33 92.2	20.18 17.87	.458	.6512

N=30, p<.05

Thoracic Excursion

The values obtained for upper and lower thoracic excursion were found to be normal. The paired sample t-test for the upper ribs shows a statistically significant (p<.05) improvement in the upper rib thoracic excursion from the initial visit (M=.89, SD=.55) to the follow up visit (M=1.05, SD=.53, t(29)=2.51, p=.0177) with an Eta squared statistic of .18. (See Table 5).

To further explore this improvement, an ANOVA test was used to find the least squares means value when factoring in the difference in the two groups (home OMT and control) and the genders of the participants. The Type III Test of Fixed Effects demonstrated an interaction between gender and the two groups. Therefore, to determine the interaction between home OMT and gender, the data were evaluated using the slice option of the Glimmix procedure to get a difference in the least squares means. Both genders had statistically significant improvements ($p<.05$) in the upper rib thoracic excursion value from the initial visit to the follow up visit (Gender 1 p=<.0001, Gender 2 p=.0238) as displayed in table 6. The group that underwent the home OMT protocol had a statistically significant change from baseline (p=.0008) as compared to the group that did not do home OMT (p=.8474). (See table 7).

The paired sample t-test for the lower ribs shows a statistically significant ($p<.05$) improvement in lower rib thoracic excursion from the initial visit (M=1.18, SD=.75) to the follow up visit (M=1.38, SD=.78, t(29)=3.63, p=.0011) with an Eta squared statistic of .31. See table 5. In order to further delineate this improvement, an ANOVA test was used to get a least squares means value and test the effect of self-administered home OMT and gender on the change in lower rib thoracic excursion from initial to follow up visit. The group who participated in the home OMT protocol had statistically significant ($p<.05$) improvement in lower rib thoracic excursion as compared to the group who did not do home OMT (p=.0045). There was no significant difference between males and females (p=.1383).

Table 5. Paired sample t-test results for upper and lower rib thoracic excursion measurements

	Mean	Standard Deviation	T(29)	P	Eta squared
Baseline Upper Ribs FU Upper Ribs	.89 1.05	.55 .53	2.51	.0177	.18
Baseline Lower Ribs FU Lower Ribs	1.18 1.38	.75 .78	3.63	.0011	.31

N=30, p<.05

Table 6. Upper ribs comparison of the interaction between gender and home OMT sliced by gender

	Control	Home OMT	Difference in Means	P
Male	-0.04167	0.9167	-.9583	<.0001
Female	-0.01500	0.2636	-.2786	.0238

N=30, p<.05

Table 7. Upper ribs comparison of the interaction between gender and home OMT sliced by home OMT

	Male Mean	Female Mean	Difference in Means	p
Control	-0.04167	-0.01500	-0.02667	0.8474
Home OMT	0.9167	0.2636	0.6530	0.0008

N=30, p<.05

Patient Symptoms

Analysis of the data obtained from the ranking scale demonstrated skewness. Therefore, the data were analyzed using a Wilcoxin 1-sample test which demonstrated no statistically significant ($p<.05$) improvements in the median values for the rating of shortness of breath, chest tightness, wheezing, or ability to take a deep breath from baseline to follow up. There was a significant improvement in the rating of overall asthma symptoms from baseline (M=8, SD=2.04) to follow up (M=9.0, SD=1.47, p=.0386). (See Table 8).

Table 8. Wilcoxin 2 sided test for the rating scale.

Symptom	Baseline Median (St Dev)	Follow Up Median (St Dev)	Difference in Median	P using Wilcoxin 2-sided test
Shortness of Breath	9.0 (2.21)	9.0 (1.80)	0	.487
Chest Tightness	8.0 (1.91)	9.0 (2.04)	1.0	.735
Wheezing	10.0 (2.18)	10.0 (1.52)	0	.848
Ability to take a deep breath	8.0 (1.67)	10.0 (1.51)	2	.3485
Overall Asthma Symptoms	8.0 (2.04)	9.0 (1.47)	1	.0386

N=30, p<.05

Mini Asthma Quality of Life Questionnaire (MAQLQ)

This questionnaire was answered by all participants at the initial visit and again at the follow up visit. It was scored according to the protocol designed by the researchers who invented the questionnaire which was described in Chapter three of this Thesis.

The scores for the MAQLQ obtained are broken up into different categories. There is an overall score and separate scores for environmental, emotion, activity, and symptoms of asthma. Each category is scored on a scale of one to seven. The best score is a 7, which means that the patient has no impairments in quality of life due to his or her asthma, and the lowest score is a 1, which means that his or her quality of life is severely impaired by asthma. Each patient was scored in each of the categories and given an overall score for the initial visit and the follow up visit. Next, the Minimal Important Difference (MID) was obtained for each participant. The MID is defined as "the smallest difference in score which patients perceive as beneficial and would mandate, in the absence of troublesome side effects and excessive costs, a change in the patient's management" (Juniper et al., 1994). For this questionnaire, the MID has been found to be 0.5. Therefore, if the difference in the environmental score in patient 1 went from a 4 initially to a 4.5 at follow up, then whatever intervention was added to this patient's asthma management during those 2 weeks would be considered beneficial enough to keep it as a permanent asthma management technique for that patient.

After scoring all participant responses and determining the MID, a Chi-Squared analysis was run. The number of patients who had a significant change in their scores was compared between the control and home OMT group and were separated using a Fisher's exact test. Then, each score was tested in a model using logistical regression to determine the relationship and effect home OMT had on the scores. None of the categories on the MAQLQ significantly changed due to the addition of home OMT to regular asthma treatment.

Table 9. Chi-Squared test to determine affect of Home OMT on MID scores from the MAQLQ

Category	Group	MID <0.5 (not significant)	MID > 0.5 (significant)	Chi square value
Overall	Control	5/16	11/16	0.8731

	Home OMT	4/14	10/14	
Symptoms	Control Home OMT	7/16 4/14	9/16 10/14	0.3055
Activity	Control Home OMT	10/16 8/14	6/16 6/14	0.8232
Emotional	Control Home OMT	6/16 3/14	10/16 11/14	0.2272
Environmental	Control Home OMT	8/16 7/14	8/16 7/14	1.0

N=30, p<.05

Home OMT group follow up questionnaire

Those in the home OMT group answered questions regarding the usefulness and perceived benefit of the home treatments. When asked how many times a week they performed the home OMT, two participants answered *1 time a week*, six participants answered *2-3 times a week*, and seven answered that they did the home OMT *more than 2-3 times a week*. When asked how easy it was to do the home OMT techniques on a scale from zero to ten with zero being not very and ten being very, one participant rated a *7,* three rated an *8*, two rated a *9*, and nine rated a *10*. When asked what effect the participants thought the home OMT had on their asthma symptoms, two answered *a lot of improvement*, ten answered *some improvement*, one answered *not very much improvement*, and two answered *no change*. (See Figure 8).

Figure 8. Home-OMT Follow Up Indicators

Question Asked	Answers	Frequency
Frequency of OMT use	Zero times	0
	1 time a week	2
	2-3 times a week	5
	More than 2-3 times a week	7
Ease of home OMT (0 – not easy, 10 – very easy)	0	0
	1	0
	2	0
	3	0
	4	0
	5	0
	6	0
	7	1
	8	2
	9	2
	10	9
Perceived effect	A lot of improvement	2
	Some improvement	9
	Not very much improvement	1
	No change	2
	Symptoms worsened	0

N=14

Objective 3. Determine the relationship among selected environmental factors with demographics of patients in this study.

In order to explore this objective, each participant filled out an initial questionnaire which asked about environmental factors, living conditions, and other participant characteristics (See Appendix B)

Overall, there were 20 students, three teachers, two customer service workers, one hair stylist, one cleaner, one homemaker, one office manager, one machinist, one banker, and one horse handler. There were no current smokers enrolled in the study, so the impact of smoking on asthma symptoms could not be explored. Only four of the participants said they had no allergies. Otherwise, 25 had allergies to dust, 26 to pollen, 21 to cats, 17 to dogs, 18 to trees, 13 to flowers, eight to mold, one to feathers, one to hay, and one to cockroaches. Fourteen of the participants did not own a pet. Eleven had cats, 11 had dogs, two had horses, one had a sheep, three had cows, two had birds, and three had fish. Thirty of the participants are receiving active treatment from their physician for asthma while two were not. The majority of people saw either allergists (11) or family practice (10) physicians for their asthma, while nine saw a pulmonologist, and one saw an internist. As for medication use, all but two participants use an albuterol inhaler regularly. Fourteen use an inhaled steroid, thirteen use a leukotriene inhibitor (Singulair), six use a home nebulizer, and five use various other allergy medications. Overall, the participants had been diagnosed with asthma anywhere from .5 to 30 years prior to enrolling in the study.

Ten had been hospitalized before for asthma or related complications. Five participants answered that they had had either osteopathic or chiropractic manipulation for their asthma in the past. In total, 21 of the participants exercise at least three to four times a week (see Figure 11).

Figure 9. Patient Questionnaire Responses

Question	Response	Answer
Occupation	Student	20
	Teacher	3
	Customer Service	2
	Hair Stylist	1
	Cleaner	1
	Homemaker	1
	Office Manager	1
	Machinist	1
	Banking	1
	Horse Handler	1
Smoke	Yes	0
	No	32
Allergies to:	Dust	25
	Pollen	26
	Cats	21
	Dogs	17

	Trees	18
	Flowers	13
	None	4
	Other	Mole (8), Feather (1), Hay (1), cockroaches (1)
Pets in or around house:	Cats	11
	Dogs	11
	Horses	2
	Sheep	1
	Cows	3
	Chickens	0
	Birds	2
	None	14
	Other	Fish (3), Hamster (1)
Duration of Asthma diagnosis	0-5 yrs	6
	6-10 yrs	6
	11-15 yrs	5
	16-20 yrs	4
	21-25 yrs	5
	26-30 yrs	4
	> 30 yrs	2
Treated for Asthma	Yes	30
	No	2

Type of Physician Treating	Family Practice Pulmonologist Allergist Internist Other	10 9 11 2 0
Type of Medications Used	Albuterol Inhaler Home nebulizer Inhaled Steroid Oral Steroid Leukotriene Inhibitor Allergy medication	30 6 14 0 13 5
Ever been Hospitalized?	Yes No	10 22
Had OMT or chiropractic manipulation for asthma?	Yes No	5 27
Regular Exercise	Yes No	21 11

N = 32

Objective 4. Determine the relationship of age and gender on the use of OMT for asthma.

Due to the uneven distribution of ages and limited number of participants, the data gathered was not sufficient to draw conclusions about the relationship of age on the use of OMT for asthma.

However, the researchers did use the data to begin exploring the relationship of gender on the use of OMT for asthma. There were no differences found in spirometry results, lower rib thoracic excursion, or MAQLQ based on gender. As discussed in the findings from Objective 2, there are indications that gender had an effect on the upper rib thoracic excursion data. Overall, more in depth analysis and a larger population is needed to draw further conclusions.

Chapter Five

Summary, Conclusions, and Recommendations

This final chapter serves to discuss the summary of the results, the conclusions which can be drawn from this study, and recommendations both for future practice as well as future studies.

Summary

The purpose of this study was to determine the viability of OMT treatment for asthma and the effectiveness of home OMT education in order to implement a program to improve asthma control. The following objectives were addressed:

1. Determine the relationship of OMT on lung function as demonstrated by basic spirometry, thoracic excursions, and subjective patient symptoms.
2. Compare lung function measures of asthma patients using self-administered home treatment as supplemental to doctor administered OMT treatment with asthma patients who only receive doctor administered OMT.
3. Determine the relationship among selected environmental factors with demographics of patients in this study.
4. Determine the relationship of age and gender on the use of OMT for asthma.

Chapter Four demonstrated the results of each of these objectives while Chapter Five builds on the findings to develop conclusions on the viability of OMT treatment on asthma symptoms, as well as the effectiveness home OMT education in improving asthma control.

Conclusions

Initial pre and post OMT lung assessment

Statistically significant ($p<.05$) improvements were documented for 8 out of 10 measurements, which included upper and lower rib thoracic excursion, patient ratings of ability to take a deep breath, shortness of breath, wheezing, tightness in the chest, and overall asthma symptoms, and spirometric FVC value. To strengthen the significance, further statistics in the form of the Eta-Squared analysis demonstrated that OMT had a large effect on the changes. Statistical significance was not determined for 2 of the 10 tests, including spirometric FEV1 and PEF values. One potential explanation for the spirometry data being not significant is that the patient population which was recruited was already receiving quality care and their asthma symptoms were already well controlled in regards to pulmonary function, as was demonstrated by the data in chapter four regarding the participant spirometry values.

The fact that the patient subjective symptoms improved after OMT, but the objective spirometric values did not improve is an interesting finding. There are several possible explanations for this. Perhaps the patients felt better because their musculoskeletal restrictions were alleviated, giving improvement in the thoracic excursion measurements, but the physiology and functioning of the lungs themselves were not affected which is why the spirometry values did not change. Another explanation is that the subjects enjoyed the hands-on approach and it is a placebo effect, meaning the patients feel better but there is no justifiable physiologic reason behind it.

Use of Home OMT

The use of home OMT demonstrated statistically significant ($p<.05$) improvements at the two week follow up in three of the ten measurements including upper and lower thoracic excursion and the overall asthma symptom rating. The majority of the participants found the home OMT sessions to be easy to perform and beneficial. There were no significant ($p<.05$) improvements from baseline in seven out of ten measurements including the three spirometry values, FEV1, PEF, and FVC, and the patient symptoms of ability to take a deep breath, chest tightness, wheezing, shortness of breath.

Environmental impact

The majority of the participants were students. None of the asthmatics in this study were smokers. The majority of the participants had allergies, most commonly to cats, dogs, trees, dust, and pollen. Half of the participants had pets in or around the house with the majority owning cats and dogs. All but two of the participants were actively being treated by a physician for their asthma. The majority of the participants relied on an allergist or a family practitioner for the treatment of their asthma symptoms. The majority of the participants exercise regularly. Only five of the participants had ever had osteopathic or chiropractic manipulation to try to alleviate asthma symptoms.

Effect of age and gender

The data was not sufficient to draw conclusions regarding the impact that age or gender may have on the benefit of OMT for asthma symptoms.

Hypothesis test:

1. A researcher developed protocol of Osteopathic Manipulative Treatment, including screening and treatment of the thoracic and rib cage, diaphragm release, suboccipital release, and thoracic lymphatic pump will significantly ($p<.05$) improve the spirometry values, thoracic excursion measurements, and symptoms in the selected group of participants suffering from asthma.

This hypothesis is accepted at the .05 level.

2. A researcher-developed educational session designed to teach asthma patients home OMT will significantly improve the spirometry, thoracic excursion measurements, and symptoms in those participants over a two week time period as compared to a group of asthma patients who do not do home OMT.

This hypothesis failed to be accepted due to the equivocal findings. There is sufficient evidence to demonstrate that teaching asthma home OMT techniques to alleviate asthma symptoms is beneficial; however, another investigation is needed to further explore this.

3. There will be a significant relationship between environmental factors and asthma symptoms in the chosen population.

This hypothesis failed to be accepted due to a lack of adequate information to draw a conclusion. Further investigation is needed.

4. Differences in age and gender will be significantly related to response to OMT techniques for asthma.

This hypothesis failed to be accepted due to the limitations previously discussed. Further investigation is needed to delineate this relationship.

Recommendations for Future Research

Based on the findings and conclusions, recommendations were made for future research and related areas of study:

1) In future studies, the limited time series of two weeks could be expanded to a longer time series design, first to validate the two week results from this study, and second, to document change at subsequent two week intervals depending on time constraints and resources.

2) While this pilot study had enough participants to draw statistically significant conclusions, for future studies or replications of this study, this investigator recommends a larger participant size which will allow for a more widely distributed age range, ethnicity, and asthma classification for further investigation into variability of response to OMT for asthma symptoms.

3) Although the education session for the home OMT group in this study was sufficient enough to teach participants the skills necessary, making and distributing video or DVD instructions to this group would allow the researcher to strengthen the education session and further ensure proper technique at home.

4) In future research, adding exclusion criteria in the protocol which would require researchers to recruit a sample with lower baseline spirometry lung function values would allow for a clearer investigation of the effects of OMT on these values.

5) The home OMT education session could be strengthened by lengthening the time that participants practice home OMT techniques with the instructor and having weekly follow ups to ensure correct techniques are being used.

6) This pilot study attempted to recruit participants from rural areas and teach them how to do OMT techniques at home to alleviate asthma symptoms; however, future research may extend further into rural communities to evaluate the effectiveness of this education session in more rural and possibly less educated areas.

7) This pilot study explored a possible OMT session which could be utilized in a regular office visit to further aid in alleviating asthma symptoms; however, future studies could progress and add to this an actual physician visit to determine the overall ease of incorporation and perceived benefit from both the physician and the patient.

Recommendations for Practice

Due to the overall positive findings regarding the use of OMT for asthma symptoms, it is recommended that these treatments be regarded as viable options for asthma patients. The protocol was a simple, semi-individualized way to address asthma symptoms and create an immediate improvement in lung function.

Throughout the study, although the participants were not asked to comment, the principle investigator received many comments about OMT. Many times, immediately following the sessions, the participants would get up off of the OMT table and exclaim how good they felt and how amazed they were at their ability to breathe deeply. These were unsolicited comments which go to support the use of these treatments for asthma patients.

Regardless of what the numbers of the measurements say, if the patient feels that his or her lung function has increased and that asthma symptoms are improved, then that is enough to show physicians that this is a successful way to treat their patients. I strongly recommend that any physician who is treating asthma study and learn the techniques used in this study and incorporate them into regular treatment protocol for asthmatics.

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Appendix A

MINI ASTHMA QUALITY OF LIFE QUESTIONNAIRE PATIENT ID ____________________

SELF-ADMINISTERED DATE ____________________

Please complete **all** questions by circling the number that best describes how you have been during the **last 2 weeks as a result of your asthma.**

IN GENERAL, HOW MUCH OF THE TIME **DURING THE LAST 2 WEEKS** DID YOU:

		All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	Hardly Any of the Time	None of the Time
1.	Feel SHORT OF BREATH as a result of your asthma?	1	2	3	4	5	6	7
2.	Feel bothered by or have to avoid DUST in the environment?	1	2	3	4	5	6	7
3.	Feel FRUSTRATED as a result of your asthma?	1	2	3	4	5	6	7
4.	Feel bothered by COUGHING?	1	2	3	4	5	6	7
5.	Feel AFRAID OF NOT HAVING YOUR ASTHMA MEDICATION AVAILABLE?	1	2	3	4	5	6	7
6.	Experience a feeling of CHEST TIGHTNESS or CHEST HEAVINESS?	1	2	3	4	5	6	7
7.	Feel bothered by or have to avoid CIGARETTE SMOKE in the environment?	1	2	3	4	5	6	7
8.	Have DIFFICULTY GETTING A GOOD NIGHT'S SLEEP as a result of your asthma?	1	2	3	4	5	6	7
9.	Feel CONCERNED ABOUT HAVING ASTHMA?	1	2	3	4	5	6	7
10.	Experience a WHEEZE in your chest?	1	2	3	4	5	6	7

MINI ASTHMA QUALITY OF LIFE QUESTIONNAIRE PATIENT ID ____________________

SELF-ADMINISTERED DATE ____________________

IN GENERAL, HOW MUCH OF THE TIME **DURING THE LAST 2 WEEKS** DID YOU:

	All of the Time	Most of the Time	A Good Bit of the Time	Some of the Time	A Little of the Time	Hardly Any of the Time	None of the Time
11. Feel bothered by or have to avoid going outside because of WEATHER OR AIR POLLUTION?	1	2	3	4	5	6	7

HOW **LIMITED** HAVE YOU BEEN **DURING THE LAST 2 WEEKS** DOING THESE ACTIVITIES **AS A RESULT OF YOUR ASTHMA**?

	Totally Limited	Extremely Limited	Very Limited	Moderate Limitation	Some Limitation	A Little Limitation	Not Limited
12. STRENUOUS ACTIVITIES (such as hurrying, exercising, running up stairs, sports)	1	2	3	4	5	6	7
13. MODERATE ACTIVITIES (such as walking, housework, gardening, shopping, climbing stairs)	1	2	3	4	5	6	7
14. SOCIAL ACTIVITIES (such as talking, playing with pets/children, visiting friends/relatives)	1	2	3	4	5	6	7
15. WORK-RELATED ACTIVITIES* (tasks you have to do at work)	1	2	3	4	5	6	7

*If you are not employed or self-employed, these should be tasks you have to do most days.

DOMAIN CODE:

Symptoms: 1, 4, 6, 8, 10
Activity Limitation: 12, 13, 14, 15
Emotional Function: 3, 5, 9
Environmental Stimuli: 2, 7, 11

Appendix B

Patient Questionnaire

Demographics

Gender: ____ Male ____ Female

Age ____

Ethnicity: ___ Caucasian ___ African American ___ Hispanic ___ Asian ___ Other

Town of Residence: ________________________

Town of this Clinic: ________________________

Environmental

Occupation: ______________________________ Years in Current Occupation: ____

Do you smoke? If no, skip next two questions.

a. Yes
b. No

How long have you been a smoker? ___________

How many packs a day do you smoke? ____________

Do you have allergies to any of the following? (check all that apply)

a. Dust
b. Pollen
c. Cats

d. Dogs
e. Trees
f. Flowers
g. Other ________________________
h. None

What types of pets are in or around the house?

a. Cats
b. Dogs
c. Horses
d. Sheep
e. Cows
f. Chickens
g. Birds
h. Other ___________
i. None

Medical

How long have you been diagnosed with asthma? _________

How often do you experience symptoms of asthma?

a. less than 2 times a week
b. 2 times a week
c. More than 2 times a week
d. Daily
e. Continual

How often do you have nighttime symptoms of asthma?

a. less than 2 times a month
b. more than 2 times a month

c. more than 1 time a week
d. frequently

Do you receive treatment from a physician for your asthma?

a. Yes
b. No

What type of physician do you see for your asthma?

a. Family Practice
b. Pulmonologist
c. Allergist
d. Internist
e. Other

What types of medications do you use for your asthma?

a. Albuterol inhaler
b. Home nebulizer
c. Inhaled steroid
d. Oral steroid
e. Singulair
f. Other ____

Have you ever been hospitalized for asthma? If so, how long ago?

a. Yes ______________________
b. No

Have you ever had osteopathic manipulative treatment (OMT) for your asthma?

a. Yes
b. No

Do you exercise regularly (3-4 times a week)?

a. Yes
b. No

Appendix C

Patient ID: ________________

Pre-OMT Patient Survey

1. Right now, how would you rate your ability to take a deep breath?
   (not able) 1 2 3 4 5 6 7 8 9 10 (easily)

2. Right now, how would you rate your shortness of breath?
   (short of breath) 1 2 3 4 5 6 7 8 9 10 (not short of breath)

3. Right now, how would you rate your chest tightness?
   (very tight) 1 2 3 4 5 6 7 8 9 10 (not tight)

4. Right now, can you feel yourself wheezing?
   (Lots of wheezing) 1 2 3 4 5 6 7 8 9 10 (no wheezing)

5. Right now, how would you rate your overall asthma symptoms?
   (Very poor) 1 2 3 4 5 6 7 8 9 10 (Very good)

Appendix D

Patient ID: ________________

Post-OMT Patient Survey

1. Right now, how would you rate your ability to take a deep breath?
   (not able) 1 2 3 4 5 6 7 8 9 10 (easily)

2. Right now, how would you rate your shortness of breath?
   (short of breath) 1 2 3 4 5 6 7 8 9 10 (not short of breath)

3. Right now, how would you rate your chest tightness?
   (very tight) 1 2 3 4 5 6 7 8 9 10 (not tight)

4. Right now, can you feel yourself wheezing?
   (Lots of wheezing) 1 2 3 4 5 6 7 8 9 10 (no wheezing)

5. Right now, how would you rate your overall asthma symptoms?
   (Very poor) 1 2 3 4 5 6 7 8 9 10 (Very good)

Appendix E

Participant ID:

<u>Follow-up Survey</u>

1. Right now, how would you rate your ability to take a deep breath?
   (not able) 1 2 3 4 5 6 7 8 9 10 (easily)

2. Right now, how would you rate your shortness of breath?
   (short of breath) 1 2 3 4 5 6 7 8 9 10 (not short of breath)

3. Right now, how would you rate your chest tightness?
   (very tight) 1 2 3 4 5 6 7 8 9 10 (not tight)

4. Right now, can you feel yourself wheezing?
   (Lots of wheezing) 1 2 3 4 5 6 7 8 9 10 (no wheezing)

5. Right now, how would you rate your overall asthma symptoms?
   (Very poor) 1 2 3 4 5 6 7 8 9 10 (Very good)

6. Do you feel like the OMT done 2 weeks ago was beneficial for your asthma?
   a. Yes
   b. Undecided
   c. No

7. If OMT was available to you, would you use it to help control your asthma?
   a. Yes
   b. Undecided
   c. No

8. Over the last 2 weeks, did the amount of medication you use for your asthma change?
   a. Yes (explain) ___________________________
   b. No

The below questions are for those who participated in the home OMT group.

1. Did you perform the home OMT sessions? How often?
   a. No
   b. 1 time a week
   c. 2-3 times a week
   d. more than 2-3 times a week

2. How do-able were the home OMT techniques?
   a. Extremely do-able

b. Moderately do-able
c. Somewhat do-able
d. Not very do-able

3. What effect did the home OMT sessions have on your asthma symptoms?
   a. A lot of improvement
   b. Some improvement
   c. Not very much improvement
   d. No change
   e. Symptoms worsened

Appendix F

Patient Home OMT Protocol

You have been selected to participate in the home OMT education group for this study. This part of the study is designed to determine the benefit of adding home OMT treatments to address asthma symptoms. You will need to have a family member or friend administer these treatments. The treatments are designed to be easily administered with no risk to the participant. The total OMT session should take five to ten minutes to perform. These sessions can be done daily for the next two weeks if desired, but no less than four times a week.

Three techniques will be demonstrated and taught to you today. Pictures and instructions are provided as well so that you can make sure you are administering the techniques properly over the course of the next two weeks.

If you have questions about these techniques or need to discuss them further in the next two weeks, you may contact me (Macy Latter) at 540 921-7583.

1. **Suboccipital Release**
   1. The participant should lie on the floor face up.
   2. The operator sits at the head of the patient.
   3. The operator places his/her finger pads palm up underneath the patient's head where the muscles of the neck meet the bone of the skull.
   4. The operator slowly and gently applies pressure upward and backwards through their finger pads into the tissues.
   5. Hold this position as the tissues begin to relax around your fingers.
   6. This may take 30 seconds to 2 minutes

2. **Rib Raising**
   1. The participant should lie on the floor face up.
   2. The operator sits on either side of the participant.
   3. The operator places his/her hands palms up underneath the participant's upper body with the pads of the fingers beside the spine on the musculature closest to the operator.
   4. The operator then exerts a gently force upward and towards themselves pulling the soft tissue and muscles towards the operator.
   5. This stretch is held for several seconds before being released.
   6. The operator then slides their hands further down the upper body and repeats steps 4 and 5.
   7. After treating the upper half of the back, the operator switches sides and repeats the technique.

3. **Pectoral Traction**
   1. The participant should lie on the floor face up.
   2. The operator sits at the head of the participant.

3. The operator places his/her hands over the muscle which runs just over the armpit grabbing the edge of this muscle gently between the fingers and palms.
4. The operator then leans backwards and pulls this muscle backwards towards themselves and centrally towards the participant's head.
5. The participant is then asked to take several deep breaths while the operator holds this position.
6. After several cycles of breathing in and out in this position, the operator gently releases the muscle.