Is Stimulating Acupoints on the Skin in Addition to Standard Medication More Effective for the Improvement Of Breathlessness in Ambulatory Patients With COPD Over the Age of 60 Than Standard Medication Alone?

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Is Stimulating Acupoints On The Skin In Addition To Standard Medication More Effective For The Improvement Of Breathlessness In Ambulatory Patients With COPD Over The Age Of 60 Than Standard Medication Alone?

Abigail D. Sbat, PA-S

A SELECTIVE EVIDENCE BASED MEDICINE REVIEW

In Partial Fulfillment of the Requirements For

The Degree of Master of Science

In

Health Sciences – Physician Assistant

Department of Physician Assistant Studies
Philadelphia College of Osteopathic Medicine
Philadelphia, Pennsylvania

June 18, 2015
OBJECTIVE: The objective of this selective EBM review is to determine whether or not stimulating acupoints on the skin in addition to standard medication is more effective for the improvement of breathlessness in ambulatory patients with COPD over the age of 60 than standard medication alone.

STUDY DESIGN: Review of three randomized controlled trials published in 2008, 2010, and 2012; selection was based on their relevance to the clinical question and if they contained patient oriented outcomes.

DATA SOURCES: Three peer-reviewed randomized controlled trials comparing the addition of acupuncture/Acu-Tens to standard treatment and standard treatment alone were found on PubMed.

OUTCOME(S) MEASURED: Each trial assessed the effect of skin stimulation by acupuncture and/or Acu-Tens on decreasing the amount of breathlessness that patients with COPD experience by obtaining lung function or utilizing a 6-minute walk test after the skin stimulation and evaluating the findings from a patient’s perspective via Visual Analogue Scale (VAS) or a 10-point Borg category ratio scale.

RESULTS: Two studies demonstrated a statistically significant improvement in breathlessness achieved with the addition of acupuncture/Acu-Tens to standard COPD therapy versus standard therapy alone. The third study failed to show improvement in breathlessness; it only demonstrated an improvement in walk distance.

CONCLUSIONS: Based on the three trials, the use of acupuncture/Acu-Tens is inconclusive when determining improved breathlessness in patients over the age of 60 with COPD.

KEY WORDS: acupuncture, COPD, pulmonary disease, breathlessness
INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is “a common preventable and treatable disease, characterized by persistent airflow limitation that is usually progressive and associated with and enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases”\(^1\). Shortness of breath is one of the most common symptoms in patients with this disease. Currently, COPD is the third leading cause of death in America\(^2\), and it affects 24 million Americans today\(^3\). The breathlessness that results from COPD can have a significant impact on patients in their everyday lives. Even simple tasks can become difficult to perform.

The cost to treat COPD is incredulous, with an estimated $37 billion spent annually on the care of patients in the United States\(^4\) alone. Reports have shown that there are 15 million office visits each year for patients with COPD\(^5\).

COPD is a well-studied disease and health care providers are aware of its cause; alveoli in the lungs are destroyed due to an immune or environmental insult, which hinders oxygen exchange, ultimately leading to airflow obstruction. Symptoms such as dyspnea, chronic cough, and chronic sputum production result. Tobacco use is the chief cause of the disease. However, patients exposed to second-hand smoke and fumes are also at risk. Alpha-1 antitrypsin deficiency is a hereditary risk factor.

Smoking cessation is the most important intervention for the improvement of COPD\(^1\). However, there are a variety of drug classes that are used to treat patients with COPD as well. Standard therapy consists of utilizing a drug class alone or in combination. Pharmacologic therapeutic options consist of bronchodilators, such as anti-cholinergics and beta\(_2\)-agonists, methylxanthines, inhaled corticosteroids, and phosphodiesterase-4 inhibitors. Non-therapeutic options include pulmonary rehabilitation, oxygen therapy, ventilatory support with non-invasive
ventilation, lung volume reduction surgery, bronchoscopic lung volume reductions, lung transplantation, and bullectomy. According to the Global Initiative for Chronic Obstructive Lung Disease, “The choice within each class depends on the availability and cost of medication and the patient’s response. Each treatment regimen needs to be patient-specific as the relationship between severity of symptoms, airflow limitation, and severity of exacerbations will differ between patients.”

The current treatment offered to patients with COPD targets anatomic and physiologic abnormalities that are reversed with medications or invasive surgical procedures. If health care providers further study the mechanisms associated with COPD, they can begin to acknowledge that the peripheral nervous system, specifically the autonomic nervous system, has not been explored to great lengths. This nervous system plays a role in the symptomatic response of patients with COPD, such as dyspnea and cough. No direct treatment options available are being studied to address this physiologic mechanism. In the second edition of Harrison’s Pulmonary and Critical Care Medicine, “A discrepancy or mismatch between the feed-forward message to the ventilatory muscles and the feedback from receptors that monitor the response of the ventilatory pump increases the intensity of dyspnea.” Also, for patients experiencing anxiety pertaining to the hyperventilation that can occur from COPD, breathlessness can worsen because “in patients with expiratory flow limitation, the increased respiratory rate that accompanies acute anxiety leads to hyperinflation, increased work and effort of breathing, and a sense of an unsatisfying breath.” For this reason, acupuncture can be a therapeutic option stimulating the nervous system in such a way that relieves the breathlessness stemming from COPD. With acupuncture, acupuncture points are identified and designated as areas of electrical sensitivity. Inserting needles at these locations stimulates numerous sensory receptors which ultimately
activate the nerves that transmit impulses to the hypothalamic-pituitary system at the base of the brain. This area of the brain is responsible for the release of endorphins, which decrease the stress response. Acupuncture also “acts by blocking the action of the parasympathetic nervous system, and to enhance the action of the sympathetic nervous system. These two systems are responsible for constricting and relaxing bronchial smooth muscle.” This is similar to the mechanism of β₂-adrenergic receptor agonists, or bronchodilators. Transcutaneous electrical nerve stimulation or “TENS is a method of electrical stimulation which primarily aims to provide a degree of symptomatic pain relief by exciting sensory nerves and thereby stimulating either the pain gate mechanism and/or the opioid system.” When a patient is experiencing breathlessness, this puts stress on the body. Consequently, acupoint stimulation decreases that stress response providing relaxation and decreasing the effort it takes to breathe. Furthermore, acupuncture and TENS are other modalities that are not only cost-effective, but can also be applied before resorting to invasive procedures when COPD becomes uncontrolled or unresponsive to pharmacologic treatment.

**OBJECTIVE**

The objective of this selective EBM review is to determine whether or not stimulating acupoints on the skin in addition to standard medication is more effective for the improvement of breathlessness in ambulatory patients with COPD over the age of 60 than standard medication alone.

**METHODS**

Three peer-reviewed randomized controlled trials were used for this review. Each study’s population was comprised of ambulatory patients with COPD who are 60 years of age or older and are currently on standard medical regimens for their condition. The Inclusion Criteria used
for the selection of studies chosen to answer the EBM question included patients who had not tried acupuncture treatments before, were currently compliant with a standard treatment regimen, were able to walk unassisted, and patients who were outpatients. For this review, a comparison was made between patients with COPD on a standard treatment regimen and who were receiving acupuncture and patients with COPD who were solely on a standard treatment regimen.

Acupuncture was the intervention used. The specific form of acupuncture varied amongst the studies, but the same method of stimulating precise acupoints via external stimuli to activate the areas controlling respiration was administered. After the acupoints were stimulated, each trial monitored its patients with either the Visual Analogue Scale or the 10-point Borg Category Ratio Scale as a way to assess how the patients felt before and after the event. Along with this subjective way of measuring the effectiveness of acupuncture, two of the studies carried out 6-minute walk tests to objectively measure how patients’ walk distance improved after the treatment.

Key words used in the search for this topic included acupuncture, COPD, pulmonary disease, and breathlessness. Each article was written in English and published between 2008 and 2012. The chosen articles were found through the PubMed database by the author, and selected based on their relevance to the clinical question and if they contained patient-oriented outcomes. Summary of statistics were reported by using p-values and confidence intervals.
<table>
<thead>
<tr>
<th>Study</th>
<th>Type</th>
<th>#Pts</th>
<th>Age (yrs)</th>
<th>Inclusion Criteria</th>
<th>Exclusion Criteria</th>
<th>W/D</th>
<th>Interventions</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lau, 2008 (1)</td>
<td>RCT</td>
<td>46</td>
<td>Mean age of 75 y/o</td>
<td>Pts with stage I or II COPD according to GOLD classification, able to communicate, independent in mobility, and with no previous experience with Acu-Tens/acupuncture</td>
<td>Pts with co-existing ischemic heart disease, cardiac pacemaker, diabetes mellitus, neurological deficit, or poor cognitive function, previously received Acu-Tens, and had acute exacerbations within 1 month of study</td>
<td>0</td>
<td>Experimental group received 45 minutes of Acu-TENS over acupoints, while control group received placebo-TENS with identical electrode placement but no electrical output</td>
</tr>
<tr>
<td>Ngai, 2010 (2)</td>
<td>RCT</td>
<td>28</td>
<td>&gt; 67 y/o</td>
<td>Patients with diagnosis of COPD based on the GOLD guideline and attending regular follow-up at the respiratory clinic</td>
<td>Pts unable to perform spirometry testing, confused/incommunicable, allergic to aqueous gel, or suffering from URI or COPD exacerbation in the past 6 weeks and/or having musculoskeletal disorders</td>
<td>0</td>
<td>4-weeks of 45-min, 5-days/week, of Acu-TENS vs placebo-TENS vs Sham-Tens</td>
</tr>
<tr>
<td>Suzuki, 2012 (3)</td>
<td>RCT</td>
<td>68</td>
<td>&lt;75 to &gt; or = to 75 y/o</td>
<td>Pts with stage II-IV COPD, clinically stable, no changes in medication within past 3 months, and no signs of edema; stage II or higher dyspnea, able to walk unassisted, no pulmonary rehabilitation in the previous 6 mo., outpatients only.</td>
<td>Pts presenting with evidence of CV or collagen disease, renal failure, thyroid dysfunction, hepatic function disorder, cancer, and mental disorders</td>
<td>6</td>
<td>Traditional acupuncture needling vs. placebo needling 1 time per week for 12 weeks.</td>
</tr>
</tbody>
</table>
OUTCOMES MEASURED

The outcome measured was a decrease in COPD-associated breathlessness using the Visual Analogue Scale (VAS) and the 10-point Borg Category Ratio Scale. Patients rated their breathlessness on one of these scales before and after acupuncture was performed. The VAS measured patients’ dyspnea in a range of 0-mm to 100-mm where 0-mm signified “no shortness of breath” and 100-mm signified “shortness of breath as bad as can be.” The 10-point Borg Category Ratio Scale measured how patients felt with 0 signifying “breathing very well, barely breathless” and 10 signifying “severely breathless.” Furthermore, two of the studies utilized a 6-minute walk test (6MWT) in conjunction with the scales. Effectiveness of acupuncture was analyzed in one of the studies by measuring the distance a patient could walk for 6 minutes before and after the treatment.

In the randomized, placebo-controlled, pre-test and post-test study by Lau et al., dyspnea was measured using the VAS before and after a patient’s Acu-TENS treatment, and “all measurements were performed in the sitting position and the best of 3 trials was recorded." Improvement in symptoms was based on a decrease in the pre-test/post-test VAS score and a mean change from baseline as compared to the control group.

In the randomized controlled trial by Ngai et al., dyspnea was measured on the VAS before and after a patient’s Acu-TENS treatment. This study also measured the outcomes by performing a 6MWT, which had patients walk down a 100-foot hallway for 6 minutes and their distance walked was assessed before and after they received an Acu-TENS treatment. Improvement in breathlessness was measured based on a decrease in the pre-test/post-test VAS score and how much further a patient could walk after Acu-TENS.
In the randomized, placebo-controlled, single blind study by Suzuki et al., dyspnea was measured by having patients rate how they felt before and after an acupuncture treatment on the 10-point Borg Category Ratio Scale. A 6MWT was also performed before and after an acupuncture treatment. Distance was not measured for the 6MWT, but the 10-point Borg Category Ratio Scale was used to assess the patient-oriented outcome after the walk.

RESULTS

In the Lau et al. study, 46 patients were chosen based on being diagnosed with Stage I or II COPD, ability to communicate, independence in mobility, and without previous experience with Acu-TENS\textsuperscript{10}. “Eligible participants were then randomly assigned to either the experimental (Acu-TENS) or control (placebo-TENS) group\textsuperscript{10}.” Each group went through 45 minutes of acupuncture, with the control group receiving a placebo version of the technique. In the experimental group, the Acu-TENS electrodes were placed on the EX-B1 acupoint bilaterally, “lateral to the spinous process of the 7\textsuperscript{th} cervical vertebra\textsuperscript{10}.” All patients were asked to fill out the VAS before and after the treatment. The pre-test to post-test score using the VAS was 81-mm to 67-mm respectively, signifying a large effect on decreasing breathlessness. Also, the change in mean from baseline was a 13% decrease in the breathlessness score. The experimental group’s “shortness of breath had decreased by 11-mm on the VAS (95% CI -14 to -8) more than the control group.\textsuperscript{10}.”

<table>
<thead>
<tr>
<th>Pre-test Score: Placebo-TENS</th>
<th>Post-test Score: Placebo-TENS</th>
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<tbody>
<tr>
<td>77-mm</td>
<td>74-mm</td>
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<table>
<thead>
<tr>
<th>Pre-test Score: Acu-TENS</th>
<th>Post-test Score: Acu-TENS</th>
</tr>
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<tbody>
<tr>
<td>81-mm</td>
<td>67-mm</td>
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</table>

In the Ngai et al. study, 28 patients were chosen who had a diagnosis of COPD, and were attending regular follow-up at the respiratory clinic\textsuperscript{11}. The patients were randomly placed in an
experimental Acu-TENS group and a controlled Placebo-TENS group. The treatment was administered 5 days a week for 4 weeks. As in the Lau et al. study, the EX-B1 acupoint was stimulated. For the results of the 6MWT seen in Table 3, the Acu-TENS group had a significant increase in patient walk distance (p = 0.045) when compared to the Placebo-TENS group. Dyspnea was measured on the VAS with a pre-treatment score of 18.0-mm and a post-treatment score of 18.0-mm.

Table 3: 6MWT Pre-test and Post-test Distances in Ngai Study

<table>
<thead>
<tr>
<th>Pre-Test Distance: Placebo-TENS</th>
<th>Post-test Distance: Placebo-TENS</th>
</tr>
</thead>
<tbody>
<tr>
<td>325.7 meters</td>
<td>333.8 meters</td>
</tr>
<tr>
<td>Pre-Test Distance: Acu-TENS</td>
<td>Post-test Distance: Acu-TENS</td>
</tr>
<tr>
<td>305.8 meters</td>
<td>329.5 meters</td>
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</tbody>
</table>

Table 4: VAS Scores Before and After Treatment in Ngai Study

<table>
<thead>
<tr>
<th>Pre-test Score: Placebo-TENS</th>
<th>Post-Test Score: Placebo-TENS</th>
</tr>
</thead>
<tbody>
<tr>
<td>24.5-mm</td>
<td>24.5-mm</td>
</tr>
<tr>
<td>Post-test Score: Acu-TENS</td>
<td>Post-test Score: Acu-TENS</td>
</tr>
<tr>
<td>18.0-mm</td>
<td>18.0-mm</td>
</tr>
</tbody>
</table>

In the Suzuki et al. study, 68 patients were chosen according to having the diagnosis of stage II-IV COPD, no changes in medication within the past 3 months, no signs of edema, the ability to walk unassisted, an outpatient status, and no pulmonary rehabilitation in the previous 6 months. Acupuncture treatment with stimulation of acupoints close to the respiratory accessory muscles was given 1 time per week for 12 weeks to the real acupuncture group (RAG). The placebo acupuncture group (PAG) received placebo needling at the same acupoints for the same amount of time as the RAG. On the 10-point Borg Category Ratio Scale, patients were asked to document their breathlessness before treatment as a baseline, and then after the 12 weeks were over. “The difference between baseline and final volumes was compared using analysis of covariance with baseline values and age as covariates and treatment group as the factor of interest.” After the 12-week treatment period, the Borg scale score for the RAG decreased from
5.5 to 1.9. No improvement was seen in the Borg scale score for the PAG (4.2 to 4.6). The difference in the scores between the RAG and the PAG “was statistically significant...; mean difference by analysis of covariance, -3.58; (95% CI, -4.27 to -2.90)\textsuperscript{12}.”

<table>
<thead>
<tr>
<th>Table 5: 10-Point Borg Category Ratio Scale Scores</th>
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<tbody>
<tr>
<td><strong>Borg Scale Score</strong></td>
</tr>
<tr>
<td><strong>PAG</strong></td>
</tr>
<tr>
<td><strong>RAG</strong></td>
</tr>
</tbody>
</table>

**DISCUSSION**

The benefit of acupuncture therapy on decreasing breathlessness in patients with COPD is a subject matter that is not fully understood. The findings in this review provide evidence that acupuncture does have a slight positive impact on breathlessness when the correct acupoints are stimulated. However, this impact is not effective enough to rid these patients of breathlessness to a point of total relief.

Lau et al. and Suzuki et al. both proved that the effect of acupuncture on breathlessness was statistically significant. This can be seen in the patient reports found in the pre-test and post-test VAS and 10-point Borg Category Ratio Scale in concordance with a 6MWT from each study respectively. In contrast, Ngai et al. did not demonstrate any improvement in breathlessness; the study only revealed an increase in walk distance.

There were, however, limitations to the randomized controlled trials examined in this review. In all three studies, the sample sizes, which were mentioned earlier in this review under the RESULTS section, were not large enough to truly see the effects of acupuncture on a vast group of people. In the Ngai et al. and Suzuki et al. studies, no follow-up was conducted, which did not enable the long-term effects of the acupuncture to be observed. In Suzuki et al., the acupuncture therapists were not blinded. In the Lau et al. study, patients did not have their
bronchodilators with them during the trial, so normal resting levels of breathlessness may be altered. Also, the study was done in one, single session.

Even though acupuncture is a form of Chinese traditional medicine, it is more widely used in the United States today for many conditions including, but not limited to migraines, chronic pain, osteoarthritis, addiction, insomnia, constipation, and so on. Acupuncture therapy is a safe and cost-effective choice of treatment and “the FDA approved acupuncture needles for use by licensed practitioners in 1996.” Because of its rise in popularity, acupuncture is more readily available for patients who are willing to utilize it as adjunctive therapy to their current treatment regimen.

CONCLUSION

In conclusion, the evidence obtained was inconclusive and conflicting to support the subject matter of acupuncture being utilized to decrease breathlessness in ambulatory patients with COPD who are 60 years of age and older. Two studies, Lau et al. and Suzuki et al. proved the effectiveness of acupuncture pre- and post-therapy. However, Ngai et al. was inconsistent and did not show any significant improvement in regards to breathlessness. All of the studies demonstrated affirmative results in specific areas, but these results were not significant for the topic of interest and were, therefore, inconclusive.

Because the evidence gathered for this review is inconclusive, more research is needed to verify whether or not acupuncture is truly beneficial and should be included in the treatment of patients with COPD. Acquiring larger sample sizes all with patients in the same stage of COPD, extending the time-frame of each study to at least 6 months, planning for a longer follow-up protocol, stimulating the same acupoints in all trials, and every study performed should evaluate patients consistently with Visual Analogue Scale, a 6MWT, and full pulmonary function tests to
see the true effects of acupuncture overtime are all essential to improving the outcomes of this non-pharmaceutical treatment in patients with COPD.
References
