

**Research Article**

**The effect of Acu-TENS on FEV<sub>1</sub>, six minute walk distance and dyspnoea in patients with chronic obstructive pulmonary disease: a randomised trial**

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**Abstract**

**Aim:** To see the effect of Acu-TENS on FEV<sub>1</sub>, six minute walk distance and dyspnoea in patients of COPD.

**Method:** Fifty five patients with a mean age of 68years suffering from chronic obstructive pulmonary disease with no previous exposure of TENS or acupuncture were selected. The experimental group received 45 minutes of Acu-TENS over acupoint bilaterally while the control group received placebo-TENS with identical electrode placement but no output despite a flashing light indicating stimulus delivery. Lung function was measured as FEV1 and FVC, six minute walk distance was measured using 6MWT, while dyspnoea was measured using a shortness of breath 100-mm visual analogue scale.

**Result:** After 45 minutes of Acu-TENS, the experimental group had increased FEV1 by 4.37% (95% CI 2.71 to 6.04) and FVC by only 0.65 % (95% CI -0.40 to 1.71). Six minute walk distance increased by 14.32 metres (95% CI 10.67 to 17.99) more in the experimental group. Dyspnoea decreased by 1.29 mm (95% CI-3.00 to 0.41) more than the control group.

**Conclusion:** Acu- TENS may be a useful non-invasive alternative in the management of dyspnoea in patients with chronic obstructive pulmonary disease. This study showed the effect of long-term Acu-TENS. A single session of Acu-TENS increases FEV1, 6MWT and reduces dyspnoea in patients with chronic obstructive pulmonary disease.

**Keywords:** Acupuncture points, TENS, Chronic obstructive pulmonary disease, Forced expiratory volume, Forced vital capacity, 6 Minute walk test, Dyspnoea

**1. Introduction**

Chronic obstructive pulmonary disease (COPD) is a chronic progressive condition characterised by airflow resistance which is not fully reversible lung function<sup>1</sup>. Dyspnoea, excessive sputum production, cough are the most common clinical features. It is estimated that three million people died due to COPD in 2005, it's going to be third leading cause of death world wide by 2030<sup>2</sup>. Half a million people die every year due to COPD in India, which is over 4 times the number of people who die due to COPD in USA and Europe<sup>3</sup> COPD can be managed by pharmacotherapy for relief of symptoms, rehabilitation programs and exercise to improve exercise tolerance<sup>4</sup>. Due to expensive medications and drug's adverse effects, alternative approaches for the management of patients with COPD needs to be explored.

Application of transcutaneous electrical nerve stimulation (TENS), a non invasive modality over specific acupoints (ACU-TENS) has been reported as an alternative mode of management for breathlessness in COPD patients<sup>5</sup>. A review of 16 randomised controlled trials, involving 2937 participants concluded that acupuncture is a safe and potentially effective intervention for patients with asthma and COPD<sup>6</sup>. Acu-Tens is believed to elicit similar responses to manual acupuncture in pain relief<sup>7,8,9</sup>. The effect of Acu-TENS on dyspnoea has been reported in some population<sup>5</sup>. Administration of Acu-TENS can be done by patient himself or the care givers. It may help to control dyspnoea and their by promote quality of life in patients with COPD, if proven to be effective.

Hence, the research question for this study of patients with COPD is – “what is the effect of Acu-TENS on lung functions, 6 Minute Walk distance (6MWD) and dyspnoea”.

## 2. Method

### 2.1 Design

A randomised, placebo controlled, pre-test and post test design was carried out.

### 2.2 Participants

Ambulatory subjects with a medical diagnosis of COPD were referred by medicine department of a municipal hospital.

#### Inclusion criteria

- Diagnosis of stage 1 or 2 COPD according to the GOLD classification<sup>10</sup>
- Willing to participate
- Ability to communicate and follow commands
- Independent in mobility

#### Exclusion criteria

- Co-existing IHD, DM or neurological deficit
- Subjects with cardiac pacemaker
- Sensory deficit
- Poor perception and/or cognitive function
- Episode of acute exacerbation of obstructive airway disease within one month prior to data collection
- Treated with bronchodilator within six hours prior to data collection
- Earlier exposure to TENS or acupuncture

### 2.3 Ethics

Study was approved by the AMC MET Ethics Committee of LG Hospital & AMC MET Medical College. Ahmedabad. Participants were fully informed of the study protocol and signed a consent form prior to participation.

### 2.4 Procedure

Demographic data such age, gender, BMI, smoking history and medications were recorded. Subject randomisation was done. Eligible participant were randomly assigned to either experimental (Acu-TENS) or control (placebo TENS) group.

Lung functions, 6MWD and dyspnoea were measured after the participant rested for 30 minutes. All participants then received 45 min of either Acu-TENS or placebo TENS. Participants were blind to group allocation. Participants in control group were explained that the stimulation frequency was not perceivable by humans. One investigator was responsible for the application of both interventions. Then lung functions, 6MWD and dyspnoea were measured again.

**Table 1 Participants Classification According To Baseline Characteristics In Both Groups**

VARIABLE	EXPERIMENTAL	CONTROL
AGE		
<50 years	05	05
50-60 years	11	12
>60 years	12	10
GENDER		
MALE	20	21
FEMALE	8	06
SMOKING		
EX-SMOKER	10	10
SMOKER	13	10
NON-SMOKER	05	07
BMI		
UNDER-WT	08	09
NORMAL	11	08
OVER-WT	09	10

**Table 2 Baseline Outcome Measures - mean (SD) of both groups**

OUTCOME MEASURE	EXPERIMENTAL	CONTROL
FEV1 % PRED	72.79 (8.02)	73.26 (8.11)
FVC % PRED	70.46 (5.31)	70.15 (4.47)
6MWD (mt)	324.10 (36.11)	323.30 (37.49)
DYSPNOEA (mm)	56.54 (7.96)	56.966.73)

## 2.5 Intervention

A written informed consent was obtained from all the participants who fulfilled the inclusion criteria. The experimental group receive 45 min of Acu-TENS at bilateral acupoints Ex-B1<sup>11</sup>. These points are known as Ding Chuan in Traditional Chinese Medicine. They are located at 0.5 ‘cun’ lateral to the spinous process of C<sub>7</sub> vertebra, were 1 ‘cun’ is the distance between the medial creases of the interphalangeal joints on an individual’s middle finger<sup>5</sup>. Each acupoint was cleaned with an alcohol swab to reduce the resistance for passage of current. A non conductive 5x5 cm<sup>2</sup> plastic film was punctured in the middle creating a pore of diameter.08 cm. This film was placed over the participant’s skin, with the pore directly over the marked acupoint. A 5x5 cm<sup>2</sup> electrode was then placed over each plastic film. This configuration restricts electrical stimulation to the acupoint only.

**Stimulation<sup>5</sup>:** Frequency – 4 Hz; Pulse Width – 200 micro seconds; Intensity – highest tolerable by the participant.

The control group received 45 min of placebo TENS. A non conductive plastic film with no central pore was placed on the skin over each acupoints. Participants could see the flashing light but no current was transmitted to the acupoints.

Confirmation of absence of electrical stimulation employed by this method was obtained by five participants prior to data collection.

## 2.6 Outcome measures

Lung function was measured according to American thoracic society guidelines<sup>12</sup> using a Helios RMS spirometer. Forced expiratory volume in one second (FEV1) and forced vital capacity (FVC) where used to measure lung functions. All tests were done in sitting position and the best of 3 was recorded.

Dyspnea was tested using a visual analogue scale<sup>13</sup> which was having 0 to 100 mm scale where zero meant “No breathlessness at all” and 100 meant the worst sensation experience.

Six minute walk distance was measured with the help of six minutes walk test (6MWT), performed according to ATS guidelines<sup>14</sup>. The 6MWT is a practical simple test that requires a 100-ft hallway but no exercise equipment or advanced training for technicians. Walking is an activity performed daily by all but the most severely impaired patients. This test measures the distance that a patient can quickly walk on a flat, hard surface in a period of 6 minutes (the 6MWD). It evaluates the global and integrated responses of all the systems involved during exercise, including the pulmonary and cardiovascular systems, systemic circulation, peripheral circulation, blood, neuromuscular units, and muscle metabolism. Most activities of daily living are performed at submaximal levels of exertion; the 6MWD may better reflect the functional exercise level for daily physical activities.

## 2.7 Data analysis

Analysis was done by intention to treat. Statistical significance was reported as p value from independent t-tests. A statistical significance level was set at  $p < 0.05$ .

## 3. Results

### 3.1 Participant Flow

A total of 55 participants (41Male and 14Female) met the inclusion criteria. The mean age was 66.5 years in experimental group and 69.5 in control group.

Mean BMI was 22.3 kg/m<sup>2</sup> in experimental group and 22.5 kg/m<sup>2</sup>. Mean % predicted FEV1 in experimental group was 72.79% (SD 8.02) and in control group it was 73.26% (SD 8.11) and mean % predicted FVC in experimental and control group was 70.46% (SD 5.31) and 70.15(SD 4.47) respectively. 10 participants (37.04%) were ex-smokers (i.e., they had stopped smoking for more than 12 months), 13participants (46.43%) were current smokers and 05participants (17.86%) were non-smokers in experimental group. 10 participants (35.71%) were ex-smokers (i.e., they had stopped smoking for more than 12 months), 10 participants (37.04%) were current smokers and 07participants (25.92%) were non-smokers in control group.

Both groups were similar in terms of gender, age, BMI, 6MWD, Dyspnoea and % Predicted FEV1 and FVC and also medications. Medications prescribed were- theophylline, salbutamol, ipratropium bromide or salbutamol with ipratropium as required.

### 3.2 Effect of intervention

All participants completed the trial without any adverse effects.

Increase in FEV1 by 4.37% predicted (95% CI 2.71 to 6.04,  $p < 0.05$ )

FVC also increased by 0.65% predicted (95% CI -0.40 to 1.71,  $p < 0.05$ )

Six minute walk distance had increased by 14.32 metres (95% CI 10.67 to 17.99,  $p < 0.05$ ) and

Decrease in Dyspnoea scale by 1.29 mm (95% CI-3.00 to 0.41,  $p < 0.05$ ) was seen in the experimental group than control group

Effects of intervention in group data as well as within and between group data are presented in the table 3

**Table 3. Lung function, 6MWD and dyspnoea of experimental group and control group with mean (SD) of each group, within groups and between groups – mean  $\pm$  SD & C.I.**

Outcome	Groups				Difference within groups		Difference between groups
	Pre		Post		Post minus pre		Post minus pre Exp minus Con
	Exp	Con	Exp	Con	Exp	Con	
<b>Lung function</b>							
FEV 1 (% Pred)	72.79 (8.02)	73.26 (8.11)	78.64 (5.97)	75.11 (6.27)	5.85 (2.90)	1.48 (3.25)	4.37 $\pm$ 0.83 2.70 to 6.04
FVC (% Pred)	70.46 5.31	70.15 4.47	73.82 4.65	72.85 3.83	3.35 2.42	2.7 1.29	0.65 $\pm$ 0.53 -0.40 to 1.71
6MWD (mt)	324.1 36.11	523.3 37.49	340.2 35.18	325.1 34.15	16.07 6.57	1.741 6.93	14.32 $\pm$ 1.82 -0.40 to 1.71
Dyspnoea SOB VAS (0-100mm)	56.5 7.96	56.96 6.73	52.5 5.68	54.22 4.43	-4.03 3.07	-2.74 3.2	-1.29 $\pm$ 0.85 -3.00 to 0.41

## 4. Discussion

The effect of single session of bilateral application of TENS for 45 minutes in patients with COPD showed increase in FEV<sub>1</sub>, 6MWD and decrease in dyspnoea. This has been reported in earlier studies<sup>15,16,17,5</sup>.

Dyspnoea which is the commonest symptom in COPD is associated with increased bronchial and systemic inflammation<sup>18,19,20</sup>. Airflow limitation has been associated with changes in levels of inflammatory mediators such as tumor necrosis factor and interleukin-8<sup>21</sup>. Maier et al<sup>22</sup> showed that inflammation increases cytokine levels which are transmitted to Hypothalamus via sensory pathways. Tracey<sup>23</sup> found that a suppressive effect on the release of cytokines was caused by the release of Acetylcholine. Cytokine synthesis is suppressed by release of glucocorticoids via negative feedback. Thus, dyspnoea is reduced by suppression of inflammatory mediators either via afferent or efferent vagus nerve stimulation. Whether decrease in dyspnoea is due to hypothalamic activity associated with endorphin release was inconclusive in a study by Ken SL and Alice YM Jones<sup>5</sup>.

Traditional Chinese medicine presumes that dyspnoea is due to deficiency of flow of 'Qi' (energy). Acupuncture technique may restore the 'Qi' balance and thereby reduce dyspnoea<sup>24,5</sup>. Tan and Horn<sup>25</sup> did not get a satisfactory explanation of 'Qi' flow and balance in accordance to western medicine. While Takeshige et al<sup>26</sup> speculated that acupuncture points stimulation can modify respiration by influencing the respiratory centres in medulla. Jobst et al<sup>27</sup> and Lau & Jones<sup>5</sup> have hypothesised that acupuncture stimulates hypothalamus which releases endogenous opiates, thereby reducing dyspnoea. Therefore opiates are prescribed to suppress respiration which modulates the sensation of breathlessness<sup>28</sup>.

### 4.1 Effect of Acu-TENS on lung function

Various criteria for evaluation of short term response to a bronchodilator are found in different studies like  $\geq 15\%$  improvement over pre-bronchodilator FEV<sub>1</sub><sup>29</sup>,  $\geq 12\%$  improvement plus an absolute volume increase of  $\geq 200$  ml<sup>30</sup> and an absolute improvement over pre-bronchodilator FEV<sub>1</sub> of  $\geq 10\%$  predicted value<sup>31</sup>

An increase in FEV<sub>1</sub> by 4.37 % more after Acu-TENS than placebo TENS was found in this study. This improvement did not reach these standards. There is no direct action of Acu-TENS on airways but the effect may be through central processing of neural signals.

This study showed that Acu-TENS improved FEV<sub>1</sub> by nearly 5 % more than placebo TENS. However this improvement did not reach the GOLD standard set for "bronchodilator evaluation". Moreover a reduction in dyspnoea score by 1.29 mm more than placebo TENS is also significant.

FVC was improved in Acu-TENS over Placebo TENS by only 0.65 %. This was statistically insignificant. A clinically significant change in FVC was not expected with one session of Acu-TENS.

Short-term reproducibility of the 6MWD is excellent with a good quality-assurance program, with patients tested by the same technician, and after one or two practice tests<sup>32</sup>. ATS guidelines recommend that change in 6MWD can be expressed as an absolute value. ATS guidelines also state that statistically significant mean increase in 6MWD in a group of study participants is often much less than a clinically significant increase in an individual patient. In one study of 112 patients (half of them women) with stable, severe COPD, the smallest difference in 6MWD that was associated with a noticeable clinical difference in the patients' perception of exercise performance was a mean of 54 m (95% confidence interval, 37–71 m)<sup>33</sup>.

While in this study absolute increase of 14.32 metres was found in 6MWT in Acu-TENS group as compared to placebo TENS group.

## 5. Limitations

- The severity of COPD of the participants was mild to moderate. It should be noted that the effect of Acu-TENS on patients may be more significant and dramatic if patients had high level of dyspnoea.
- Effect of only single session of Acu-TENS in COPD patients was focused in this study.
- Participant's dyspnoea may not have returned to normal resting levels as most participants travelled to the centre by public transport and had to walk some distance to reach the centre, despite 30 minutes of rest before the lung function

measurement.

- The effect of Acu-TENS or placebo TENS over acupuncture points was compared in this study rather than its application over non-acupuncture points. So, it was inconclusive that whether the positive effect of Acu-TENS was Acu-point specific or due to the general effect of TENS.
- Quality of life was not measured, although lung function is related to dyspnoea and it does determine a person's quality of life.

## 6. Conclusions

This study concluded that compared to placebo TENS, bilateral application of Acu-TENS at acupuncture points EX-B1 for 45 minutes in ambulatory patients with COPD lead to an improvement in dyspnoea, 6MWD and lung functions.

TENS is a non-invasive user friendly, low cost electrotherapy modality.

Application of TENS may help dyspnoea management in patients with COPD and thereby improve quality of life. The beneficial effect of Acu-TENS in this study suggests that Acu-TENS may be a useful alternative approach for the management of patients with COPD.

## 7. Future Recommendations

- The comparative effect of high TENS and low TENS on COPD patients can be studied.
- The effect of Acu-TENS on non acupoints in COPD also can be studied.
- The comparative effects of Acu-TENS and medications on dyspnoea can be studied
- Long term effect of TENS on frequency and severity of COPD
- Quality of life improvement can be one of the parameter to study the effect of TENS in COPD patients

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