Acu-tens improves lung function in patients with chronic bronchial asthma: a randomized placebo-controlled trial

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Context
Bronchial asthma greatly affects patient's quality of life. Application of transcutaneous electrical nerve stimulation on acupuncture is a promising noninvasive modality that may assist in controlling dyspnoea and improving lung function in those patients.
Aims
This study investigated the effect of Acu-TENS on lung function [forced expiratory volume in 1 s (FEV1) and forced vital capacity (FVC)] and the modified medical research council dyspnoea scale.
Settings and design
This study was conducted as a double-blind randomized controlled trial among 40 male patients diagnosed with moderate chronic bronchial asthma selected from Elmenia University Hospitals.
Patients and methods
Their ages ranged from 35 to 45 years with a mean value of 41.45±2.74 years. They were assigned randomly to two equal groups: the experimental (Acu-TENS) group, which received 45 min of Acu-TENS on bilateral Dingchuan acupoints three sessions/week for 4 weeks, and the control (placebo-TENS) group, which received 45 min of placebo-TENS 3 sessions/week for 4 weeks. Lung function was measured as FEV1 and FVC using a portable spirometer. Dyspnoea was measured using the modified medical research council dyspnoea scale. Assessment was carried out before and after 1 month of treatment.
Results
The results revealed that after treatment there was a significant improvement in FEV1, which increased by 15.08%, and FVC, which increased by 13.18%, in favour of the Acu-TENS group when compared with the control group (P=0.037 and 0.016 for FEV1 and FVC, respectively). However, there was no significant difference in the modified medical research council dyspnoea scale between the Acu-TENS group and the placebo-TENS group after treatment (P=0.343).
Conclusion
It was concluded that Acu-TENS on bilateral Ding Chuan acupoints for 4 weeks is an effective approach for improving lung function (FEV1 and FVC).

Keywords:
acu-tens, bronchial asthma, dyspnoea, lung function

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Introduction

Bronchial asthma is a major health problem characterized by a chronic inflammatory disorder of the airways, in which many cells and cellular elements play a role. The global prevalence, morbidity, mortality and economic burden associated with asthma have increased since the 1970s, especially in children [1].

Asthma is currently one of the world's most common long-term noncommunicable disease, affecting about 300 million people worldwide and the number could increase further by another 100 million by year 2025 [2].

The chronicity of bronchial asthma and the fear of steroid therapy cause many patients to seek alternative methods of treatment such as physical therapy modalities, acupuncture and herbal medicine [3].

Acupuncture is one of the most popular complementary and alternative medical treatments and is classified according to stimulating materials or methods such as metal needle, laser stimulation, or herbal extracts (pharmacopuncture) [4].

Evidence suggests that acupuncture influences the immune system, as well as the nervous system [5,6].

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Eastern traditional medicine, including acupuncture and moxibustion, is once again being recognized in Japan and other Asian and Western countries where complementary and alternative medicine has so far been applied. In the West, acupuncture is considered to be an alternative medicine, as it may provide effective treatment for numerous conditions from drug addiction to chronic fatigue syndrome [7,8].

Traditionally, solid needles are inserted into points along meridians to restore the flow of energy. Needle acupuncture has possible risks such as infection, haemorrhage, needle fracture, fainting, excess sweating, convulsions, abortion, drowsiness, pneumothorax, cardiac tamponade, eye and orbit injury, abdominal organ injury, forgotten needles and allergic reaction to needles. However, modern acupuncture has involved other methods of stimulating points along meridians, including the use of electrical signals known as transcutaneous electrical nerve stimulation (TENS) or by applying pressure to the acupoint (acupressure) or using a low-intensity laser [9].

Application of TENS, a noninvasive modality, over responses to manual acupuncture in pain relief [10].

Thus, this study was conducted to investigate the effect of Acu-TENS applied on bilateral Ding Chuan acupoints to control dyspnoea and to improve lung functions in men with chronic moderate chronic bronchial asthma.

Patients and methods

Study design

This study is a randomized, placebo-controlled, single-blinded, pretest and post-test design study.

Patients

Forty male patients diagnosed by a physician with moderate chronic bronchial asthma (according to Asthma Management Handbook [11]) were selected to participate in this study from chest patients who attended Elmenia University Hospital. Their ages ranged from 35 to 45 years with a mean value of 41.45±2.74 years. Primary medical examination was carried out by a physician for every patient to obtain a complete medical picture of the health status of patients. The study excluded patients with renal failure, myocardial infractions, cardiovascular problems or neurological disorders, as well as patients with unstable medical condition, lung cancer or other respiratory-related disorders that may affect the results, such as emphysema. All patients did not take medications for bronchial asthma. All patients were given a full explanation of the treatment protocol and a written informed consent form for participation and publication of results was signed by all patients.

Intervention

Patients who met the selection criteria were divided randomly into two equal groups, the experimental (Acu-TENS) group and the control (placebo-TENS) group. Patients were randomly allocated to either group (Acu-TENS or placebo-TENS) by a blinded and independent research assistant by opening sealed envelopes that contained a computer-generated randomization card. The patients were blinded as to on which group they were allocated. Randomization and blinding were used to prevent bias.

Preparatory procedures

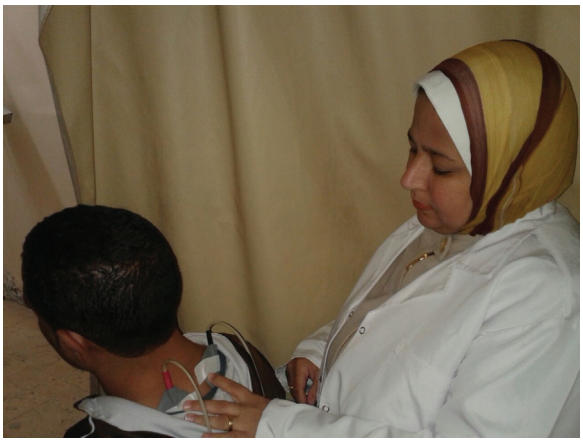
Each patient was informed about the experimental process and the significance of study and provided consent. Patient's skin was cleansed with alcohol to remove skin debris and reduce skin resistance; all equipments were checked up, calibrated and prepared before application.

Acu-TENS procedures

The experimental group received 45 min of Acu-TENS at bilateral acupoints Ex-B1 (known as Ding Chuan in Traditional Chinese Medicine) three times/week for 4 weeks.

Each acupoint (Ex-B1) was determined. Ex-B1 is located at 0.5 cun lateral to the spinous process of the seventh cervical vertebra by an expertise in physical therapy (Fig. 1), where 1 cun is the distance between the medial creases of the interphalangeal joints of an individual's middle finger. Once determined, each

Figure 1



Location of acupoint Ex-B1 and attachment of 5×5 cm^2 adhesive electrodes to it.

acupoint was cleaned with an alcohol swab and then 5×5 cm^2 adhesive electrodes were attached. Both electrodes were attached to a TENS machine (Myo 200 electrotherapy device; GymnaUniphy, Bilzen, Belgium) (Fig. 2). Parameters of stimulation were as follows: 4 Hz frequency and 200 μs pulse width; intensity was set at the highest intensity tolerable by the patient without sensation of discomfort [12].

The control group received 45 min of placebo-TENS. Participants could see the output light flashing but no current was transmitted to the acupoint throughout the 45 min.

Assessment

The demographic and clinical data were collected and included age, weight, height, lung function and the modified medical research council dyspnoea scale. The primary outcomes measured were forced vital capacity (FVC) and forced expiratory volume in 1 s (FEV1) using a portable spirometer (MicroLab ML3500; Micro Medical Ltd, Chatham, UK). All measurements were performed in the sitting position and the best of three trials was recorded. The secondary outcome measured was dyspnoea using the modified medical research council dyspnoea scale (Table 1) [13]. Assessment was carried out before start and after one month of treatment.

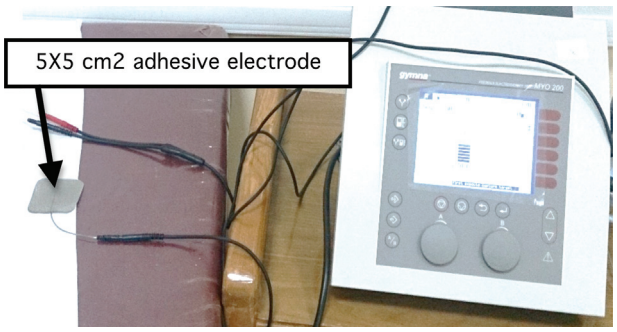
Sample size and statistical analysis

Statistical analysis was performed using SPSS for windows, version 18 (SPSS Inc., Chicago, Illinois, USA). To avoid a type II error, a preliminary power analysis [power (1–α-error P)=0.95, α=0.05, effect size=1.2] determined a sample size of 20 for each group in this study. This effect size was calculated according to data obtained from Maa *et al.* [14] considering FVC as a primary outcome. As shown in Fig. 3, all selected patients were divided into two equal groups, the experimental (Acu-TENS) group and the control (placebo-TENS) group and completed the procedures of the study. The current test involved two independent variables. The first one was the tested group, between-patient factor, which had two levels (the study group and the control group). The second one was the (training periods) within-patient factor, which had two levels (pre and post). In addition, this test involved three tested dependent variables (FVC and FEV1). Accordingly, the 'paired t-test' was used to compare between 'pre' and 'post' t-tests for all dependent variables for each group. The 'unpaired t-test' was conducted to compare oxygen saturation, FVC and FEV1 between the two groups before and after tests. In addition, nonparametric tests 'Wilcoxon signed-rank tests' were used to compare pretest and post-test values for dyspnoea scale for each group and the 'Mann–Whitney test' was conducted to compare the dyspnoea scale between the two groups in the pretest and post-test values with the α level 0.05 [15].

Table 1 The modified medical research council dyspnoea scale

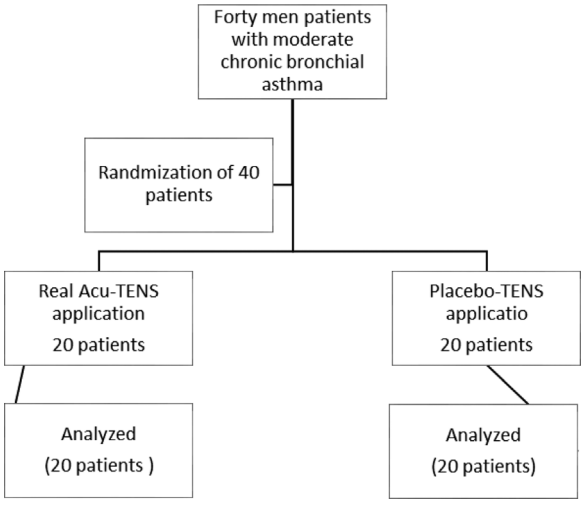
Grades of dyspnoea	Descriptions
0	Not troubled by breathlessness except on strenuous exercise
1	Shortness of breath when hurrying on the level or walking up a slight hill
2	Walks slower compared with people of the same age on the level because of breathlessness, or has to stop for breath when walking at own pace on the level
3	Stops for breath after walking about 100 m or after a few minutes on the level
4	Too breathless to leave the house or breathless when dressing or undressing

Figure 2



TENS machine (Myo 200 electrotherapy device) and the 5×5 cm^2 adhesive electrodes.

Figure 3



Data analysis flow chart.

Results

Baseline and demographic data

There were no statistically significant differences (*P*? 0.05) between patients in both groups concerning age, weight, height and BMI (Table 2). There were also no statistically significant differences between groups for any outcome variables at baseline (preintervention).

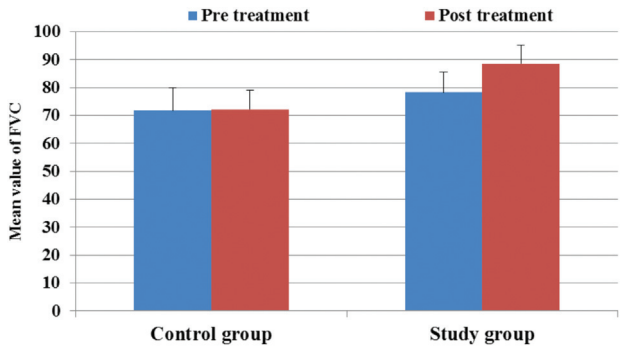
Forced vital capacity

As presented in Table 3 and illustrated in Fig. 4, the 'paired *t*-test' revealed that there was a significant increase in FVC in the study group with a percentage of improvement of 13.18%. However, the 'paired *t*-test' revealed that there was no significant difference in FVC in the control group with a percentage of improvement (0.69%). Considering the effect of the tested group (first independent variable) on FVC, the 'unpaired *t*-test' revealed that the mean pretreatment values between the two groups showed that there were no significant differences. However, the mean post-treatment values between the two groups showed that there was a significant increase in FVC (mean difference=16.41) in favour of the study group.

Forced expiratory volume in 1 s

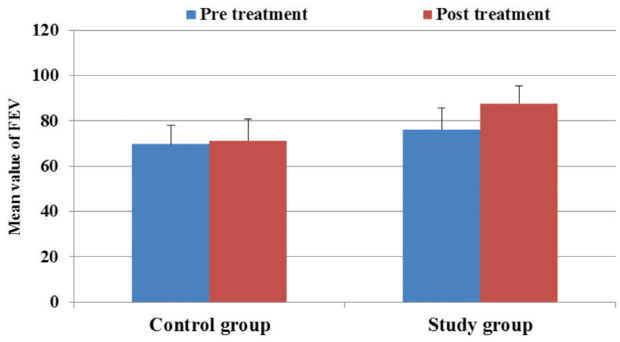
As presented in Table 4 and illustrated in Fig. 5, the 'paired *t*-test' revealed that there was a significant increase in FEV1 in the study group with a percentage of improvement of 15.08%. However, the 'paired *t*-test' revealed that there was no significant difference in FEV1 in the control group with a percentage of improvement of 2.15%. Considering the effect of the tested group (first independent variable) on FEV1, the 'unpaired *t*-test' revealed that the mean pretreatment

Figure 4



Mean±SD values of forced vital capacity (FVC) before test and after test in both groups.

Figure 5



Mean±SD values of forced expiratory volume (FEV) before test and after test in both groups.

Table 3 Mean±SD, *t*-value and *P*-value of the forced vital capacity before and after test in both groups

FVC	Means±SD		*t*-value	*P*-value
	Pretest	Post-test		
Study group	78.33±8.02	88.66±6.8	−8.598	0.013*
Control group	71.75±7.36	72.25±6.55	−0.48	0.664
t-value	1.129	3.316		
P-value	0.31	0.016*		

FVC, forced vital capacity. *Significant level is set at α level <0.05.

Table 4 Mean±SD, *t*-value and *P*-value of the forced expiratory volume in 1 s before and after test in both groups

FEV1	Means±SD		*t*-value	*P*-value
	Pretest	Post-test		
Study group	76.25±8.18	87.75±9.74	−4.223	0.024*
Control group	69.75±9.32	71.25±7.63	−1.192	0.319
t-value	1.048	2.666		
P-value	0.335	0.037*		

FEV1, forced expiratory volume in 1 s. *Significant level is set at α level<0.05.

Table 2 General characteristics of all patients

Groups	Age (years)		Height (cm)		Weight (kg)		BMI	
	Group A	Group B	Group A	Group B	Group A	Group B	Group A	Group B
Mean	39.98	39.19	169.50	166.10	72.65	71.45	25.15	25.89
SD	2.656	2.721	9.77	9.19	11.22	11.13	2.00	3.44
Minimum	36	35	152.00	149.00	52.00	58.00	21.64	20.80
Maximum	45	44	184.00	182.00	96.00	91.00	30.10	34.25
t-value	0.801		1.13		0.34		−0.84	
P-value	0.430		0.264		0.736		0.408	
Level of significance	NS		NS		NS		NS	

values between two groups showed that there were no significant differences. However, the mean post-treatment values between the two groups showed that there was a significant increase in FEV1 (mean difference=16.5) in favour of the study group.

Dyspnoea scale

As presented in Table 5 and illustrated in Fig. 6, within-group comparison of the median scores of dyspnoea before and after tests were 2.5 and 2, respectively, in the study group. 'Statistical analysis using the nonparametric Wilcoxon signed-rank tests' revealed that there was no significant difference in the dyspnoea scale before treatment in the study group. Meanwhile, the median score of the dyspnoea scale before and after tests were 2.5 and 2.5, respectively, in the control group. Statistical analysis using the nonparametric 'Wilcoxon signed-rank tests' revealed that there was no significant difference in the dyspnoea scale after treatment in the control group. Considering the effect of the tested group (first independent variable) on the dyspnoea scale, the 'Mann–Whitney tests' revealed that the median pretreatment and post-treatment scores between the two groups revealed that there was no significant difference between the two groups.

Discussion

This study investigated the effect of Acu-TENS on lung function (FEV and FVC) and the modified medical research council dyspnoea scale. The results of current study revealed that there was a significant improvement in FEV in 1 s and forced vital capacity in favour of the Acu-TENS group. However, there was no significant difference in the modified medical research council dyspnoea scale between the Acu-TENS and the placebo-TENS group.

The result of the current study is supported by that of Liu *et al.* [16], who examined the effect of Acu-TENS on patients with stable chronic obstructive pulmonary disease (COPD) and concluded that Acu-TENS over acupoints of bilateral EX-B1 (Dingchuan), BL-13 (Feishu), BL-23 (Shenshu) and ST-36 (Zusanli) improved FEV1(1)% predicted and reduced Dyspnoea Visual Analogue Scale and COPD assessment test scores in patients with stable COPD.

Table 5 Median score, *U*, *Z* and *P* values of the modified medical research council dyspnoea scale before and after tests in both groups

Dyspnoea scale	Median scores		*Z*-value	*P*-value
	Pre	Post		
Study group	2.5	2	−1.414	0.157
Control group	2.5	2.5	0.000	1.00
U-value	8	4		
Z-value	0.000	−1.528		
P-value	1.000	0.343		

*Significant level is set at α level<0.05.

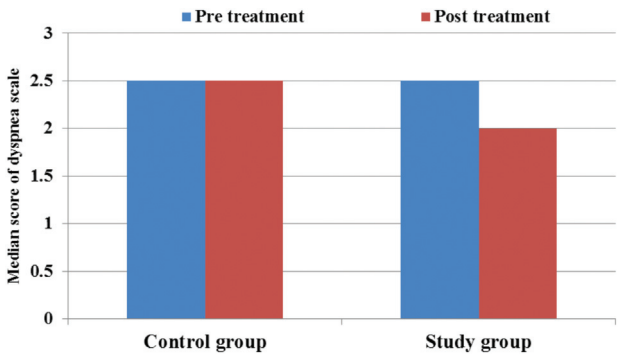
The results of this study are in agreement those by Ngai *et al.* [17], who investigated the effect of Acu-TENS over acupuncture points Lieque and Dingchuan for 45 min before a symptom-limited treadmill exercise test in patients with asthma, after exercise. The results showed that Acu-TENS therapy significantly reduced the decline of FEV1 following exercise training in patients with asthma.

Moreover, the results of this study are in agreement with those of Ngai *et al.* [18], who examined the effect of 4 weeks of 45-min, 5 days/week, of either Acu-TENS (over Dingchuan) on physical and psychosocial function in COPD patients and reported that 4 weeks of Acu-TENS improved the functional capacity of patients with COPD, which may be due to bronchodilation induced by elevation of β-endorphin.

Moreover, Ngai *et al.* [19] examined the effect of TENS on EX-B1 (Dingchuan) for 45 min. The results showed that the application of 45 min of Acu-TENS appeared to alleviate symptoms in a patient with acute exacerbation of COPD. The role of adjunctive Acu-TENS therapy during acute exacerbation warrants further investigation.

Moreover, the results of the current study are in accordance with those of Lau and Jones [20], who investigated the immediate effect of a single 45-min session of transcutaneous electrical nerve stimulation over acupoints (Acu-TENS) on lung function and dyspnoea in patients with chronic obstructive pulmonary disease. Lau and Jones [20] reported that

Figure 6



Median score of the dyspnoea scale before test and after test in both groups.

45 min of Acu-TENS significantly increased FEV1 more than that in the control group and significantly decreased shortness of breath compared with the control group. However, effect of long-term Acu-TENS warrants further investigation.

According to traditional Chinese medicine (TCM), acupuncture is a suitable treatment for bronchial asthma. The effectiveness of acupuncture treatment for asthma can be attributed to the following mechanisms.

Acupuncture results in immediate bronchodilating response in asthma patients as acupuncture has a short-term effect on bronchial asthma. Moreover, acupuncture caused a short-term reduction in airway resistance [21].

Stimulating nerves located in muscles and other tissues leads to the release of endorphins and other neurohumoral factors and changes the processing of pain in the brain and spinal cord and causes bronchodilation [22].

Asthma is associated with changes in the levels of inflammatory mediators such as tumour necrosis factor and interleukin-8 that have been associated with airflow limitation [18]. Acupuncture significantly decreased serum levels of antigen-specific IgE and total IgE and so the production of the Th2-specific cytokines IL-4 and IL-13 in the anti-CD3 mAb-activated splenocytes was significantly suppressed, which may help in asthma treatment [23].

The results of the current study showed that acupuncture treatment for asthma is effective, which is in accordance with the following authors.

Joos *et al.* [24] investigated the effects of acupuncture treatment according to the principles of TCM compared with those of acupuncture treatment using points not specific for asthma. Several peripheral blood parameters (eosinophils, lymphocyte subpopulations, cytokines and in-vitro lymphocyte proliferation) and patients' general well-being were determined before and after acupuncture treatment. The authors concluded that patients with asthma benefitted from acupuncture treatment given in addition to conventional therapy. Furthermore, acupuncture performed in accordance with the principles of TCM showed significant immunomodulating effects.

Mohamed and Shaban [25] investigated the effect of irradiation with laser for acupuncture points as an adjunctive or alternative treatment for chronic respiratory diseases. They concluded that there was a significant improvement in FEV1 and 6 min walk distance after 10 days of laser when compared with the medical treatment group only.

Chu *et al.* [21] studied the efficacy of acupuncture in asthma patients. Dyspnea, wheezing and pulmonary function test were measured before and after acupuncture. Among the three patients with asthma who included in the study, needle stimulation on selected acupoints, without the use of any short-acting bronchodilator, cause immediate improvement of FEV1 with improvement in clinical symptoms; this is in accordance with the results of the current study.

Stockert *et al.* [26] investigated whether treatment with laser acupuncture and probiotics according to TCM portends a clinical benefit to standard medical treatment performed according to paediatric guidelines in asthmatic school-aged children. Peak flow variability and FEV1 were measured and the quality of life was assessed with a standardized questionnaire. The results showed that laser acupuncture and probiotics have a beneficial clinical effect on bronchial hyperactivity in school age children with intermittent or mild persistent asthma and might be helpful in the prevention of acute respiratory exacerbations.

Mehl-Madrona *et al.* [27] tested the effect of acupuncture and craniosacral therapy as complementary therapies on pulmonary function and quality of life for people suffering from asthma. Pretreatment and post-treatment assessment of pulmonary function, asthma quality of life, depression and anxiety was carried out. Medication use was also assessed. The study concluded that acupuncture and/or craniosacral therapy are potentially useful adjuncts to the conventional care of adults with asthma, but the combination of the two does not provide additional benefit over each therapy alone.

Nagy [28] compared the effectiveness of 6 weeks' laser acupuncture and inspiratory muscle trainer on COPD patients' immunity. CD4, CD8 and CD4/CD8 ratio were screened at the beginning and immediately after 6 weeks. The results revealed that laser acupuncture and inspiratory muscle trainer were effective in improving COPD patients' immunity (CD4, CD8 and CD4/CD8 ratio), with better results obtained in the laser acupuncture group.

Maa *et al.* [14] studied the effect of acupuncture or acupressure. It was incorporated into the standard care on adult patients with chronic obstructive pulmonary disease. Six-minute walking, the Dyspnoea Visual

Analogue Scale, the modified Borg scale, St George's Respiratory Questionnaire and the Bronchitis Emphysema Symptom Checklist were used at the beginning and end of the 8 weeks of treatment. Patients with clinically stable, chronic obstructive asthma experienced clinically significant improvements in the quality of life when their standard care was supplemented with acupuncture or acupressure.

Habashy [29] compared the effect of low-level laser therapy on ventilatory functions in asthmatic children with diaphragmatic breathing exercises. The spirometric parameters of FVC, FEV1 and FEV1/FVC% were measured before and after treatment that was conducted for three months. It was concluded that there was a statistically significantly higher improvement in all measured parameters of ventilatory functions (FVC, FEV1 and FEV1/FVC) in study groups (A and B) compared with the control group (group C), and that low-level laser therapy was significantly superior to diaphragmatic breathing exercises in improving pulmonary functions of children with stable asthma.

Christensen *et al.* [30] investigated the effect of acupuncture on seventeen patients with stable bronchial asthma. They were randomly assigned to receive either correct acupuncture or placebo acupuncture. The effect of therapy on pulmonary function was assessed daily by the patients at home. Morning and evening peak expiratory flow rate, number of puffs of β2-agonist aerosol needed and subjective symptoms of asthma were recorded in a diary. The correctly treated group improved significantly throughout the study. Moreover, compared with the placebo group, a significant improvement was found in all assessed parameters 2 weeks after beginning therapy.

The result of this study is contradictory to the findings of Tandon and Soh [31], who compared real and placebo acupuncture on bronchial reactivity to histamine on 16 patients with moderately severe asthma. The authors concluded that a single treatment with acupuncture is unlikely to provide improvement in the management of acute bronchial asthma.

The findings of this study are contradictory to the study by Gruber *et al.* [32], who investigated the possible protective effect of a single laser acupuncture treatment on cold dry air hyperventilation-induced bronchoconstriction in 44 children and adolescents with exercise-induced asthma. The results revealed that there were no significant differences in the mean maximum cold dry air challenge between real acupuncture and placebo acupuncture that induced reduction in forced expiratory volume in 1 s. The authors concluded that single laser acupuncture treatment offers no protection against exercise-induced bronchoconstriction in paediatric and adolescent patients.

Limitations of the study

This study was limited by the following factors: physical and psychological condition of the patient during the period of treatment, possible human error in the application of measurement or therapeutic procedures, cooperation of the patient, patient lifestyle and practicing exercises and variability between patients and their reaction effects on the rate of recovery.

Further, studies are recommended to study the effect of Acu-TENS on the quality of life in chronic bronchial asthma patients. Further studies are needed to differentiate between the effect of Acu-TENS and other physical therapy interventions in the treatment of bronchial asthma patients. More extensive studies should be conducted to ensure the efficacy of Acu-TENS meter in different ages and sexes.

Conclusion

The results of current study showed that Acu-TENS is an effective approach in improving lung function (FEV and FVC) in men with chronic moderate chronic bronchial asthma.

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Nil.

Conflicts of interest

There are no conflicts of interest.

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