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Comparative Study of Inspiratory Muscle Strength Training and Incentive Spirometer on Ventilatory Function in Postmenopausal Asthmatic Women

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ABSTRACT

Bronchial asthma is a significant medical issue all through the world which arrives at the epidemic proportions as its prevalence has increased over the last decades. Inspiratory muscle training (IMT) has been shown to improve inspiratory muscle function, lung volumes, work capacity**. Objective:** To compare the effectiveness of inspiratory muscle training (IMT) and incentive spirometer on ventilatory functions in post-menopausal asthmatic women. **Participants and methods:** A total of forty postmenopausal women suffering from asthma, their ages ranged from 50 to 60 years old, and their body mass index of the patient don't exceed 30kg/m^2. They were recruited from the outpatient chest clinic in Kasr El-Ainy Teaching Hospital, Cairo University, Egypt. They signed a consent form, confidentiality was assured. They assigned into two groups (A) who received inspiratory muscle training in the form of: Inspiratory threshold muscle training in addition to traditional chest physical therapy intervention (Deep breath, cough training) while patients in group (B): received traditional chest physical therapy intervention and incentive spirometer, three sessions per week for six weeks. Patients in both groups were assessed before treatment (pre-training) then after treatment (post-training) (after 6 weeks) to measure the lung functions using electronic spirometer. The training program was carried in the duration from June 2019 to December 2019. **Results:** The analysis of the results showed that pulmonary functions in postmenopausal women significantly improved using inspiratory muscle trainer than using incentive spirometer as it was indicated by improvements in FVC, FEV1, FEV1/FVC and MVV in the group (A) than in group (B). **Conclusion:** It could be concluded that inspiratory muscle training in patients with postmenopausal asthma improved ventilatory function by improving ventilatory muscle strength and endurance pattern and reduced symptoms in patients with asthma by increasing FVC and overall lung volume.

Introduction

Bronchial asthma is a complex syndrome that occurs in both adults and children. Its major characteristics include a variable degree of airflow obstruction, bronchial hyper responsiveness, and airway inflammation. The disease has its roots from infancy in most patients where genetic and environmental factors contribute to its inception and evolution [1]. Bronchial asthma is characterized as a complex respiratory illness portrayed via irritation and hyper responsiveness of bronchial smooth muscle that prompting reversible bronchospasm [2].

Bronchial asthma prompts debilitation of ventilatory capacity that outcomes in disintegration in useful limit and personal satisfaction and this disability is impacted by age, length and seriousness of the infection [3]. Bronchial asthma is caused by a combination of several factors as allergens (substances that commonly induce an allergic reaction), infections, dietary patterns, exercise, cigarette smoke, and stress especially in genetically predisposed people [3].

Menopause is related with diminished lung work and expanded respiratory side effects [4]. The estrogen hormone is a noteworthy factor in the rule of irritation in the airway, and sex contrasts in the asthma predominance [5]. Asthmatic patients suffer from the ill impacts of extended impediment in the airway similarly as air getting and lung hyperinflation which lead to changes in the thoraco-stomach mechanics and incapacity of inspiratory muscles disability. It was found that the training of inspiratory muscles (IMT) as a supplement to pharmacological treatment gave clinical advantages to asthmatic patients [6]. Inspiratory muscle training (IM training) is a technique that is designed to improve the performance of the respiratory muscles (RMs) that may be impaired in a variety of conditions [7].

Inspiratory muscle training (IMT) has been shown to improve inspiratory muscle function, lung volumes, work capacity, and power output in people who are healthy [8]. An incentive spirometer is a medical device that is commonly utilized following the medical procedure or with some lung conditions, for example, COPD or asthma. As it gauges how well lungs fill up with every breath. Incentive spirometer was created to animate the patient to perform deep breathing activities under supervision or autonomously. Additionally, to animate the patient visually to expand the total capacity of lung either by denoting the inspired volume in liters (or ml) or by transporting one or more balls on the inspired flow [9].

The first incentive spirometer was developed by Barlett in 1970s. At that point a wide range of kinds of incentive spirometers have been created. Generally, incentive spirometer is activated through an enlivened exertion, that is, breathing is pictured by an elevated plate and ball in a straightforward chamber during supported motivation on an aligned scale on the chamber. The elevated plate or ball on the spirometer shows either the enlivened volume (a volume situated motivation spirometer) or the produced stream (a flow oriented incentive spirometer). Incentive spirometer is utilized clinically as business as usual prophylactic and remedial routine in perioperative respiratory consideration. [10].

Ventilatory function tests help in the evaluation of the mechanical function of the lungs. It depends on sex, stature, weight and age. At the point when the patient plays out the test, real outcomes (observed) will be contrasted and the anticipated worth expected of an individual of sexual orientation, tallness and age to check whether he falls inside the "typical" go, or has a prohibitive or obstructive segment dependent on the consequences of the tests [11]. Clinical perceptions show that the menopause is for the most part connected with intensification of prior asthma. What's more, the menopause can likewise concur with the clinical start of asthma. A finding by implication bolstered by epidemiologic investigations which have recorded a top in the recurrence of asthma starting in ladies around the age of 50, the mean age of the beginning of the menopause. At the point when asthma starts at the menopause it is regularly portrayed by such highlights as nonattendance of a family ancestry of asthma, nonappearance of atopy, relationship with intermittent sinusitis and additionally urticaria/angioedema, high seriousness and need of fundamental steroids for control of manifestation [12].

Ladies were conceded for asthma at a rate of about 2.5:1 when contrasted and their age-equal men. Length of remain expanded relatively as the patient age expanded. Following 30 years old, the length of stay was somewhat more prominent for ladies than men. There is a higher frequency of asthma confirmations for grown-up ladies than grown-up men asthmatic patients, and ladies asthmatic patients experience longer medical clinic stays per affirmation also. These information show that grown-up ladies are all the more seriously influenced by asthma and raise the likelihood that hormonal or biochemical contrasts identified with sex may assume a job in the pathophysiology of asthma [13]. Asthma is considered as one of problems affecting medical, functional, social and psychological status of the patient associated with a lot of physiological changes in ventilatory function. So these patients are in a continuous need for medical care in order to face these changes [13]. Use of corticosteroids has several severe side-effects for example: hyperglycemia, insulin resistance, diabetes mellitus, osteoporosis, cataract, anxiety, depression, colitis, hypertension, amenorrhea and retinopathy [14]. So, the need for this study was developed to show improvement in pulmonary functions with safe physical therapy technique comparing the effect of each technique and who was better.

Materials and methods

Study Design

The study was designed as a randomized controlled trial. Ethical approval was obtained from the institutional review board of the Faculty of physical therapy, Cairo University before starting of the study and the clinical trial registration in Clinicaltrial.gov with an identifier number NCT04267666. The study was followed the Guidelines of Declaration of Helsinki on the conduct of human research.

Participants

Forty postmenopausal women suffering from asthma participated in this study. They were selected randomly from the outpatient chest clinic in Kasr El-Ainy Teaching Hospital, Cairo University, Egypt. They signed a consent form, confidentiality was assured. Their ages were ranged from 50 to 60 years, and their body mass index (BMI) don't exceed 30kg/m^2. All participants were asthmatic patient and clinically and medically stable cases. Exclusion criteria of the study were as follows: a participant who had chest infection, malignant diseases, Instability of patient's medical condition and Patients with chest trauma.

Participants were assigned randomly used sealed envelope into two groups (A&B) equally in number. Group (A): it consisted of twenty postmenopausal women suffering from asthma who received inspiratory muscle training (IMT) in the form of (Inspiratory threshold muscle training), In addition to chest physiotherapy in the form of (Deep breathing exercise- Cough training -Early ambulation). Group (B): it consisted of twenty postmenopausal women suffering from asthma who received incentive spirometer in addition to chest physiotherapy in the form of (Deep breathing exercise- Cough training -Early ambulation). Three sessions per week for six weeks.

Methods

Before the start of the first session, each postmenopausal woman was informed about the program of exercises, and informed consent form was signed from each woman before participation in the study. This study was carried in the duration from June 2019 to December 2019.

1- Inspiratory muscle training (IMT) for all participants in group A:

The threshold trainer is a little plastic handheld device provided by respironics. It incorporates a mouthpiece and an adjusted spring loaded valve. The valve controls a consistent inspiratory pressure training load and the patient must generate the inspiratory pressure together for the inspiratory valve to be opened and permit inward breath of air. The measure of resistance can be balanced by changing the pressure of the spring-loaded valve. Modification from 7cm H_2O to 41cm H_2O is possible [15].

Inspiratory muscle trainer device (IMT):

Threshold inspiratory muscle training devices impose a threshold or critical opening pressure that must be defeated before of the inspiratory flow. During that task, inspiratory muscles at first do an isometric contraction until opening of the threshold valve to permit inspiratory flow after which the contraction gets isotonic in nature.

Preparatory phase:

A-**Preparation of device:**

- The therapeutic tool was continuously sterilized with alcohol every session.
- The control knob on the top of the inspiratory muscle training device was turned to align the red edge of the pressure indicator to the setting prescribed.
- The mouthpiece was attached to the device [16].

B-Preparation of patient:

The patient was in the comfortable sitting position and then put the nose clip on the patient's nose with the goal that the entirety of the breathing is done through the mouth and ensuring that the lips are fixed around the mouthpiece and the tongue not block it.

Application phase:

1.After setting the maximum training; the user recognized the load at which they could effectively execute ten breaths at greatest resistance relying upon the patient's pace of apparent effort.

2.Training was begun with a load at low intensity 20-30% of the patient maximum 10 repetition method using IMT device.

3.Training was begun with a load at low intensity 20-30% of the patient maximum 10 repetition method using IMT device.

4.Progress slowly and monitor carefully.

5.As the inspiratory muscle became stronger the inspiratory load was progressed to 50% of maximum effort over 3 weeks as tolerated.

6.Patient took full breath in (maximal and deep inspiration) then longer and slow expiration. Continue this breathing pattern for 10-20 breath.

7.Repeated step (5), 4-6 times or about 10-15minutes with rest in between 30 seconds.

8.They were received the traditional physical therapy program which include deep breathing, cough and early ambulation.

9.The session was repeated three times per week for 6 weeks [17].

2- Incentive spirometer (IS) for all participants in group B:

Therapeutic modality which relies on patient voluntary effort to perform a hyperinflation maneuver and provides visual biofeedback. It includes a mouthpiece connected to three chambers containing three floating balls creating a sub-ambient pressure. The visual input of balls rising in chambers, colored lights reflect the degree of inspiratory effort [10].

Incentive spirometer:

Patient needed to create a high inspiratory pressure. The ball provides a visible feedback input of the inspiratory flow and shows the gained flow on a well calibrated scale on the spirometer transparent cylinder. If the patient flows greater than 300 milliliters per second, the float ball in first chamber will rise. As patient flow increases to 600 milliliters per second the second ball float will rise. If the patient flow exceeds 900 milliliters per second all three will be suspended. Patient should encourage holding the balls up for a few seconds [10].

Preparatory phase:

A-Preparation of device:

- ❖ The therapeutic tool was continuously sterilized with alcohol every session.
- ❖ Check the mouthpiece attached to the device.

B-Preparation of patient:

The patient set in comfortable position and be sure that all of the breathing was performed throughout the mouth and ensuring that the lips are fixed around the mouthpiece and the tongue not impede it.

Application phase:

- ❖ Instruct the patient to exhale, letting all the breath out.
- ❖ Instruct the patient to inhale slowly, breathing in until unable to do so any more (slow breathing prevents or minimizes pain from sudden pressure changes in the chest).
- ❖ Patients were asked to get as many balls as possible to reach the top of each of the three columns.
- ❖ Ask the patient to hold the breath for 2-3 seconds then exhale slowly.
- ❖ This process was repeated 10 times or about 10-15minutes with rest in between 30 seconds.
- ❖ They were received the traditional physical therapy program which include deep breathing, cough and early ambulation.
- ❖ The session was repeated three times per week for 6 weeks [18].

Outcome measures:

The assessment of the participants in the two groups (A and B) was done before treatment (pre-training) then after treatment (post-training) (after 6 weeks) to measure lung functions using electronic spirometer.

Electronic Spirometer: It was used for ventilatory functions measurement Ventilatory which included:

● **FVC** (Forced vital capacity).
● **FEV1** (Forced expiratory volume).
● **FEV1/FVC**.
● **MVV** (Maximum voluntary ventilation).

FVC (Forced vital capacity): is one of the most helpful tests to evaluate the general capacity to move air all through the lungs (ventilation). This is the most extreme measure of air that can be strongly and quickly breathed out after a full breath (maximal motivation) [19].

FEV1 (Forced expiratory volume): is the volume of air persuasively breathed out in one second during the FVC test [20].

MVV (Maximum voluntary ventilation): is the maximum air, which can be lapsed in a moment by most deepest and quickest breathing [21].

❖ **Ventilatory Function Test:**
❖ - It was performed before the start and after the finish of treatment period (after 6 weeks).
❖ -The patient was told to assume the erect standing position conveying the breathing cylinder that was associated with the spirometry and in its opposite end expendable mouthpiece to forestall disease was embedded.
❖ - Her age, weight and stature were embedded into the screen of the mechanical assembly.
❖ - Then she was instructed to perform the test while wearing nasal clip.

❖ **Procedures to measure FVC:**
❖ 1- The patient was asked to place mouthpiece in her mouth and close her lips firmly around it.
❖ 2- Inhale slowly and fully and fill her lungs completely.
❖ 3- Blow out as hard and fast as much as she can.
❖ 4- These procedures were repeated 3-5 times with rest in between and the maximum value was recorded for assessment.
❖ 5- During the FVC test FEV1, FEV1/FVC, and MVV were recorded.

● **Statistical analysis**

Results were expressed as mean ± standard deviation (SD). Paired t test was used to compare between the "pre" and "post" tests for both groups regarding forced vital capacity (FVC), forced expiratory volume in one second (FEV1), FEV1/FVC, and (Maximum voluntary ventilation) MVV, the unpaired t test was used to compare between both groups after treatment. There was significant difference with p values of $< (0.05)$.

Results

Comparing the general characteristics of the subjects of both groups revealed that there was no significance difference between both groups in the mean age, and BMI ($p > 0.05$) (Table 1).

Table 1: *General characteristics of the two studied groups (A&B).*

	Group B	**Group B**	**MD**	**t-value**	**p-value**	**Sig**
	Mean ± SD	**Mean ± SD**				
Age (years)	54.66 ± 3.03	55.13 ± 3.28	0.47	0.4	0.68	**NS**
Weight (kg)	81 ± 8.13	78.8 ± 6.76	-2.2	-0.8	0.42	**NS**
Height (cm)	170.06 ± 5.75	169.26 ± 5.98	-0.8	-0.37	0.71	**NS**
BMI (kg/m²)	27.93 ± 1.69	27.45 ± 1.12	- 0.48	-0.91	0.36	**NS**

SD: Standard Deviation, MD: Mean difference, t value: Unpaired t value, p-value= Probability value, NS= Non-significant.

Within and between group comparison

There was a significant increase in the FVC, FEV1, FVC/FEV1 and MVV after treatment compared with that before treatment within both studied groups ($p < 0.05$). There was no significant difference between groups (A) and (B) in all parameters before treatment ($p > 0.05$). A significant increase was found in FVC, FEV1, FVC/FEV1 and MVV of group (A) after treatment compared with that of group (B) ($p < 0.05$) (table 2).

Table 2: *dependent variables for both groups*

		Group (A) (n = 20)	**Group (B) (n = 20)**	**P value***
FVC (L)	Pre-treatment	2.33 ± 0.31	2.3 ± 0.32	0.8 NS
	Post-treatment	2.6 ± 0.3	2.35 ± 0.32	0.04S
	P value**	0.001 S	0.001S	
FEV1 (L)	Pre-treatment	1.36 ± 0.15	1.43 ±0.3	0.47 NS
	Post-treatment	1.76 ± 0.14	1.46 ± 0.28	0.001 S
	P value**	0.0001 S	0.002S	
FVC/FEV1 (%)	Pre-treatment	60.91 ± 6.81	61.75 ±7.63	0.61 NS
	Post-treatment	68.19 ± 5.33	62.7 ± 7.51	0.02 S
	P value**	0.0001 S	0.02S	

MVV (L/min)	Pre-treatment	55.44 ± 6.17	57.01 ± 11.98	0.65 NS
	Post-treatment	70.48 ± 5.74	58.01 ± 11.53	0.001 S
	P value**	0.0001 S	0.001S	

* Inter-group comparison; ** intra-group comparison of the results pre- and post-treatment.
NS P > 0.05 = non-significant, S P < 0.05 = significant, P = Probability.
FVC (Forced vital capacity).
FEV1 (Forced expiratory volume).
MVV (Maximum voluntary ventilation).

Discussion

Statistical analysis revealed a significant increase in FVC (post training) in group A (IMT group) more than group B (IS group) and a significant increase in FEV1 (post training) in group A (IMT group) more than group B (IS group) and a significant increase in FVC/FEV1 (post training) in group A (IMT group) more than group B (IS group) and a significant increase in MVV (post training) in group A (IMT group) more than group B (IS group) respectively. The analysis of the results of the current study showed that pulmonary functions in postmenopausal women significantly improved using inspiratory muscle trainer than using incentive spirometer as it was indicated by improvements in FVC, FEV1, FEV1/FVC and MVV in the group (A) than in group (B).

Severe bronchial asthma is progressively prevalent in ladies. Asthma in ladies is related with wealth mortality danger and ladies with asthma were found to visit the crisis branch of asthma more regularly than men. Coming about hospitalization rates for asthma reflected the differentiation in its inescapability and earnestness as observed among individuals [22].

Asthma that starts around the onset of menopause is as often as possible portrayed by stamped clinical seriousness and poor reaction to treatment. The airway irritation present in ladies with menopausal asthma is inadequately receptive to corticosteroids treatment and inclined to visit extreme intensifications. Aviation route aggravation ought to be checked in ladies with menopausal asthma [23]. Postmenopausal hormone treatment expands subsequence danger of asthma. Then again, contemplates have shown that hormone replacement treatment (HRT) is related with better lung work [24].

Non menstruating women for the last 6 months had significantly lower FEV1 values, lower forced vital capacity values, and more respiratory problems than those menstruating regularly. The menopausal progress infers a progression of hormonal and metabolic alterations. As ovarian capacity diminishes and fertility disappears, flowing estrogen levels are first expanded and afterward decline. There is a move in estrogen creation from the ovaries to extra gonadal destinations. With menopause, ladies likewise become more insulin safe, trailed by expanded hazard for cardiovascular infections. Moreover, with the presence of climacteric manifestations, exogenous hormones are broadly utilized; these hormones interface with a changing prior hormonal and metabolic status [13].

Inspiratory muscle training (IMT) considered as one of the essential components of respiratory rehabilitation program. The rationale behind IMT is that enhancing respiratory muscle function which can possibly diminish the seriousness of breathlessness and enhances the tolerance of patients to exercise [25]. Incentive spirometry (IS) is proposed on the hypothetical basis of urging the patients to inhale to the total lung capacity, to support that expansion and by opening collapsed alveoli to prevent occurrence of atelectasis; postoperative hypoxemia may be reduced with this technique. It is characterized by active It is described by dynamic recruitment of the diaphragm and other inspiratory muscles. Likewise, it announced better end of pulmonary discharges and diminished danger of chest contamination [26].

Incentive spirometry training of the respiratory muscle improves the surfactant production which prompts lessening surface strain, expanding lung consistence, diminishing crafted by breathing and opening collapsed alveoli to forestall atelectasis [27]. Regarding pulmonary diseases patients, a few examinations have demonstrated that training of inspiratory muscle improved the strength and endurance of the inspiratory muscle. Furthermore, it might forestall or postpone the beginning of ventilatory muscle weakness and disappointment, and has been appeared to diminish dyspnea after some time [19].

Keene, [28] expressed that the Inspiratory Muscle Training provided a type of muscle exercise that built the inspiratory muscles for obstructive lung disease (asthma) patients. The resistance training helped the patients to improve muscle function which prompted decline their degrees of dyspnea and an effective method to improve their personal satisfaction. The study came in concur with study by Scherer et al. [29] who examined the impacts of hyperpnea training, we randomized thirty COPD patients and ventilatory impediment to training of the respiratory muscle (RMT; n = 15) with another portable device or to an incentive spirometer breathing exercises (controls; n = 15). The two groups prepared twice day by day for 15 min for 5 days for consistently for 8 weeks. They reasoned that locally situated respiratory muscle aerobic exercise with the new device utilized right now practical and has helpful impacts in subjects with COPD and ventilatory limitation.

This came in agree with study by Basso-Vanelli al. [30] they examined the impacts of inspiratory muscle training and breathing exercises in adapted to furthermore, without weakness of respiratory muscle in 25 subjects completed the study: 13 in the inspiratory muscle training group, and 12 in the breathing exercises group. Subjects were evaluated through measurements of the respiratory muscle strength and endurance, thoracoabdominal excursion measurements, and the 6-min walk test, before and after training by spirometry, they presumed that both interventions increased capacity of exercise and reduction of dyspnea during the physical exertion. However, training of the inspiratory muscle was more effective in increasing both strength and endurance of the inspiratory muscle, which achieve a lessened sensation of dyspnea. Likewise, subjects with weakness of the respiratory muscle that performed training of the inspiratory muscle had gains higher in both strength and endurance of the inspiratory muscle however not of dyspnea and submaximal exercise capacity.

Likewise, the study came in concur with study by Beaumont et al. [31] who considered the impacts of Inspiratory Muscle Training in COPD Patients: A Systematic Review and Meta-Analysis. They reasoned that inspiratory muscle training (IMT) utilizing threshold devices improves the inspiratory muscle strength, exercise capacity and quality of life, diminishes dyspnea. Also, the study came in agree with study by Mahishale et al. [32] who studied the effect of training of the inspiratory muscle, utilizing deep breathing exercises and incentive spirometer on lung function on sixty postpartum ladies with caesarean section. Thirty in the control group they performed diaphragmatic breathing exercises. Thirty in the experimental group performed diaphragmatic breathing exercises in addition to training of the inspiratory muscle using the incentive spirometer. Outcome measures were FEV1 values and incentive spirometer reading and abdominal strength were taken before and after the treatment program. They reported that before and after treatment inter group comparison of FEV1 and incentive spirometer reading indicated a statistically significant improvement in the experimental group when contrasted to the control group with $p<0.05$. However, no significant difference was found in the strength of abdominal muscle in both of the groups. The investigation reasons that utilizing incentive spirometer training of the inspiratory muscle alongside with the diaphragmatic breathing improves lung functions in the immediate postpartum ladies with caesarean section, which can help in early come back to their functional activities.

In contradiction Lisboa [33] found non-significant improvement in these measurements after training by IMT for five weeks but he observed an increase in the tidal volume and the inspiratory time reduction. In other studies, Troosters et al. [34] and Cilione et al. [35], the improvement in the inspiratory muscle strength, following the basic training, was statistically significant but not exceeded the clinically important difference for improvement.

Also, Murray and Mahler, [36] was concluded that inspiratory muscle training (IMT) increased the strength or endurance of the respiratory muscles, diminished dyspnea severity and improved the ability of individuals to perform different daily activities. Inspiratory muscle training improved strength, endurance of the inspiratory muscle, functional exercise capacity, and dyspnea reduction at rest and during exercise. So it was strongly proposed that training of the inspiratory muscle is a very fundamental addition to the pulmonary rehabilitation programs [28].

Conclusion

it could be concluded that inspiratory muscle training in patients with postmenopausal asthma improved ventilatory function by improving ventilatory muscle strength and endurance pattern and reduced symptoms in patients with asthma by increasing FVC and overall lung volume. This caused direct decrease in airway resistance.

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Conflicts of interest

There are no conflicts of interest.

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