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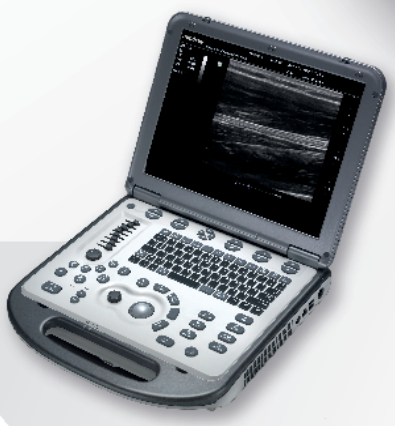

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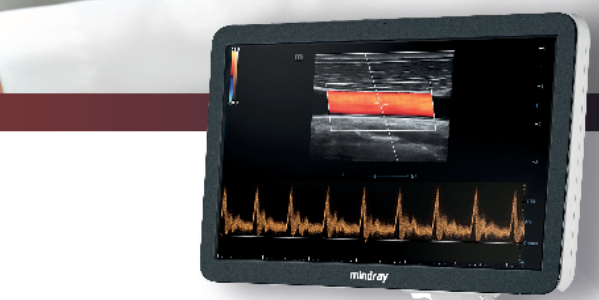

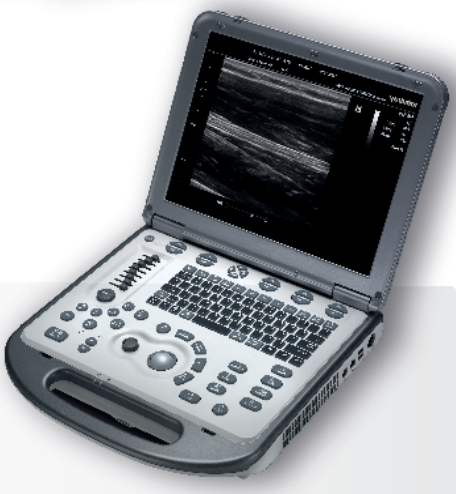

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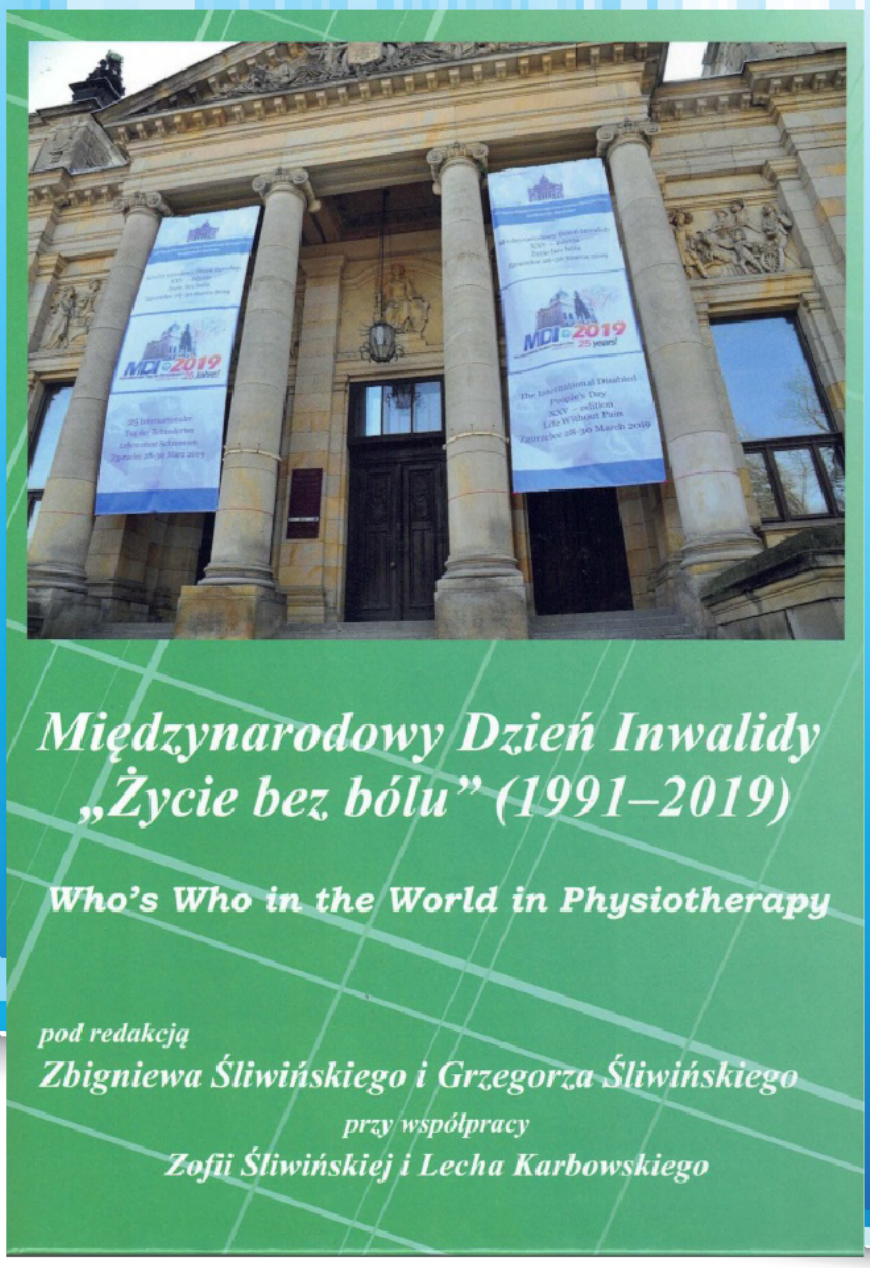

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nr 5/2021 (21)

Effects of the halotherapy versus Acapella device on the ventilatory functions in men patients with chronic obstructive pulmonary diseases: A randomized trial

Wpływ haloterapii i urządzenia Acapella na funkcje wentylacyjne u mężczyzn z przewlekłą obturacyjną chorobą płuc: badanie z randomizacją

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Abstract

Purpose. The aim of this study was to compare the effects of the halotherapy versus Acapella device as a method of airway clearance on the response of ventilatory functions in men patients with COPD. Materials and methods. Forty men patients participated in the study with moderate COPD on the basis of spirometric measures (Moderate 50% ≤ FEV1 < 80% of predicted). They were recruited from chest out-patient clinic of Police hospital. Their age ranged from 40 to 60 years and body mass index was 25–30 kg/m^2. They were randomly assigned into two groups. Group (A) received treatment by the green Acapella device associated with routine chest physiotherapy including (diaphragmatic breathing, pursed lip breathing and active cycle breathing) for 8 successive weeks, for 24 sessions, 3 times per week, 50 minutes for each session. With 2 sets per each session. Group (B) received halotherapy with natural salt associated with routine chest physiotherapy including (diaphragmatic breathing, pursed lip breathing and active cycle breathing) for 8 successive weeks, for 24 sessions, 3 times per week, 50 minutes for each session. With 2 sets per each session. Ventilatory parameters (FEV1, FVC and FEV1/FVC), six-minute walk distance (6MWD) and the status of the disease by COPD assessment test (CAT) were measured before and after 8 weeks of training. Results. Statistical analysis using the paired t-test between pre and post training showed that group (A) and (B) revealed significant increase in Ventilatory parameters (FEV1%, FVC% and FEV1/FVC%) for group A (7.06%, 1.51%, 5.78%) and for group B (6.7%, 1.95%, 4.96%) respectively, and distance of 6-min walk test with (16.89%) for group A and with (14.5%) for group B and significant decrease in the status of the disease by CAT post-treatment with (22.8%,) for group A and with (20.28%) for group B. Comparing the results among the two tested groups, There was no significant difference in the post-testing mean values of all measured variables between the two groups (A) and (B). Conclusions. Both halotherapy and Acapellla device are similarly effective in ventilatory parameters, distance of 6 min-walk test and COPD assessment test (CAT).

Key words:

COPD, halotherapy, acapella device

Streszczenie

Cel. Celem pracy było porównanie wpływu haloterapii oraz urządzenia Acapella jako metody oczyszczania dróg oddechowych na odpowiedź funkcji wentylacyjnej u mężczyzn chorych na POChP. Materiały i metody. W badaniu wzięło udział czterdziestu mężczyzn z umiarkowaną POChP na podstawie pomiarów spirometrycznych (umiarkowane 50% ≤ FEV1 < 80% przewidywanej). Wybrano ich z poradni klatki piersiowej szpitala policyjnego. Ich wiek wahał się od 40 do 60 lat, a wskaźnik masy ciała wynosił 25–30 kg/m^2. Zostali oni losowo przydzieleni do dwóch grup. Grupa (A) była poddawana leczeniu urządzeniem Acapella połączonemu z rutynową fizjoterapią klatki piersiowej, w tym (oddychanie przeponowe, oddychanie z zaciśniętymi wargami i cykl aktywnego oddychania) przez 8 kolejnych tygodni, przez 24 sesje, 3 razy w tygodniu, po 50 minut na sesję 2 serie na sesję. Grupa (B) była poddawana haloterapii z naturalną solą oraz rutynowej fizjoterapii klatki piersiowej (w tym oddychanie przeponowe, oddychanie z zamkniętymi ustami i cykl aktywnego oddychania) przez 8 kolejnych tygodni, przez 24 sesje, 3 razy w tygodniu, 50 minut na każdą sesję, 2 serie na każdą sesję. Parametry wentylacyjne (FEV1, FVC i FEV1/FVC), dystans 6-minutowego marszu (6MWD) oraz stan zbadany za pomocą testu oceny POChP (CAT) mierzono przed i po 8 tygodniach treningu. Wyniki. Analiza statystyczna przy użyciu sparowanego testu t między wynikami przed i po treningu wykazała, że grupy (A) i (B) wykazały istotny wzrost parametrów wentylacji (FEV1%, FVC% i FEV1/FVC%) w grupie A (7,06%, 1,51% , 5,78%) i w grupie B (6,7%, 1,95%, 4,96%), oraz wzrost dystansu 6-minutowego marszu z (16,89%) dla grupy A i (14,5%) dla grupy B oraz znaczącą poprawę w zakresie stanu wg CAT po leczeniu: (22,8%) dla grupy A i (20,28%) dla grupy B. Porównując wyniki między dwiema badanymi grupami, nie stwierdzono istotnej różnicy w średnich wartościach po badaniu we wszystkich mierzonych zmiennych między dwiema grupami (A) i (B). Wnioski. Zarówno haloterapia, jak i urządzenie Acapella są podobnie skuteczne w zakresie parametrów wentylacji, teście dystansu 6-minutowego marszu i teście oceny POChP (CAT).

Słowa kluczowe

POChP, haloterapia, urządzenie Acapella

Introduction

Chronic obstructive pulmonary disease (COPD) is a heterogeneous chronic inflammatory disease, defined by persistent airflow limitation that is not fully reversible and is characterized by a mixture of small airways disease and parenchymal destruction. COPD is a significant healthcare burden and is the third most prominent cause of death worldwide [1]. Chronic obstructive pulmonary disease (COPD) is a condition characterized by chronic inflammation and extra-pulmonary changes that negatively affect physical function (e.g. lower levels of physical activity and reductions in muscle mass and strength) and quality of life [2]. Chronic obstructive pulmonary disease COPD is characterized by chronic inflammation found in the airways, lung parenchyma (respiratory bronchioles and alveoli) and pulmonary blood vessels. The pathogenesis of COPD is complex and involves many mechanisms. The defining features of COPD are not fully reversible airflow limitations during forced exhalation caused by loss of elastic recoil and airflow obstruction caused by mucus hypersecretion, mucosal edema, and bronchospasm. In COPD various disease processes occur such as airflow imitations, gas exchange abnormalities, air trapping, and mucus hypersecretion and in sever disease pulmonary hypertension and systemic features [3]. Spirometry is the most important test to diagnose COPD. Peak expiratory flow measurement may significantly underestimate the severity of the airflow limitation. Spirometry should measure the volume of air forcibly exhaled from the point of maximal inspiration (forced vital capacity, FVC) and the volume of air exhaled during the first second of this maneuver (FEV1) and the ratio of these two measurements (FEV1/FVC) should be calculated. A reduction in FEV1/FVC ratio is diagnostic of airway obstruction. An FEV1/FVC ratio of < 0.70 after bronchodilator is typically considered diagnostic of COPD [4]. The 6MWT is an inexpensive tool, is easily reproducible in outpatient settings, and yields sufficiently reliable results [5]. Halo therapy, inhalation of micronized salt in the controlled conditions of a halo chamber, has become increasingly popular in the general community worldwide. Although the claimed effects of halo therapy are plenty, i.e. bactericidal effect, improvement of immunity, improved rheological properties of secretion [6]. COPD Assessment Test (CAT) is a rigorously developed and validated eight-question, repaid assessment test of symptoms, well-being and activities of daily living. It is designed for regular, everyday use in primary care. Patients can complete the form at diagnosis and on each visit. CAT scores range from 0-40, being divided into four quartiles representing low, medium, high and very high impact on patient Symptoms and life quality [7].

Halotherapy has been shown to relieve symptoms in smokers and in patients with respiratory symptoms in general. It has been argued that halotherapy is beneficial in treatment of COPD patients [6]. Oscillating positive expiratory pressure (OPEP) devices alter expiratory airflow and can be either intrathoracic, as in the Flutter or Acapella, which are placed directly in the mouth to provide resistance during exhalation, or extra-thoracic, as in high frequency chest wall oscillation (HFCWO) devices, which are applied externally to the chest wall by an inflatable vest or cuirass [8]. The Acapella is another small hand-held device that combines the benefits of both PEP therapy and airway vibrations to mobilize pulmonary secretions [9].

The effectiveness of conventional physiotherapy interventions (CPT) in alleviating Chronic Obstructive Pulmonary Disease (COPD) symptoms has been proved, thus it helps reducing the long-term damage of the lung tissue, improving lung function and enhancing Health-Related Quality of Life (HRQoL). The efficacy of the Oscillatory Positive Expiratory Pressure (OPEP) devices have been proven experimentally. Such mechanical devices are proposed to be an alternative to CPT. Utilization of such devices could be a potential component of a treatment strategy to improve COPD symptom control and reduce risk of re-exacerbations and reduce the economic burden of treating COPD patients [10]. Halotherapy has been shown to produce well apparent anti-inflammatory, draining, mucolytic, immunomodulatory, and sanogenetic action. It is used as alternative method of treating respiratory diseases such as asthma, COPD and cystic fibrosis [11]. This study aimed to compare the effects of the Halotherapy and Acapella device as a method of airway clearance on the response of ventilatory functions in men patients with COPD. So this study was tried to conduct more easy physiotherapy intervention that may lead to improve the ventilatory functions in patients with COPD aiming to be more independent in the society and to lower the economic burden of its management.

Material and Methods

Design of the study

The study was designed as a prospective, randomized, double blind, pre- post-test trial.

Participants

A forty patients with COPD were recruited chest and out-patient clinic of Police hospital. They were referred from the Chest physician. They were enrolled and assessed for their eligibility to participate in this study. Their age ranged from 40 to 60years and their body mass index (BMI) was 25: 30 kg/m2. They were diagnosed of moderate COPD on the basis of spirometric measures i.e. Stage 2: Moderate (50% ≤ FEV1 < 80% of predicted) [12]. All the patients take their medical medication through the 8 weeks of the training. Subjects were excluded if they had History of surgery in thorax, COPD exacerbation, Irregular treatment, or Exacerbation in co-morbidities like chronic heart failure (CHF), chronic respiratory failure (CRF), etc. Written informed consent was obtained from each participant. This study was performed according to the Statement of the Declaration of Helsinki. This study was approved by the faculty of physical therapy Cairo university ethical committee number P.T.REC/012/002239.

Randomization

The randomization was done by tossing a coin. The patients had an equal chance of being allocated to either group. A blinded researcher saw the coin and allocated the patients according to their groups (figure 1).

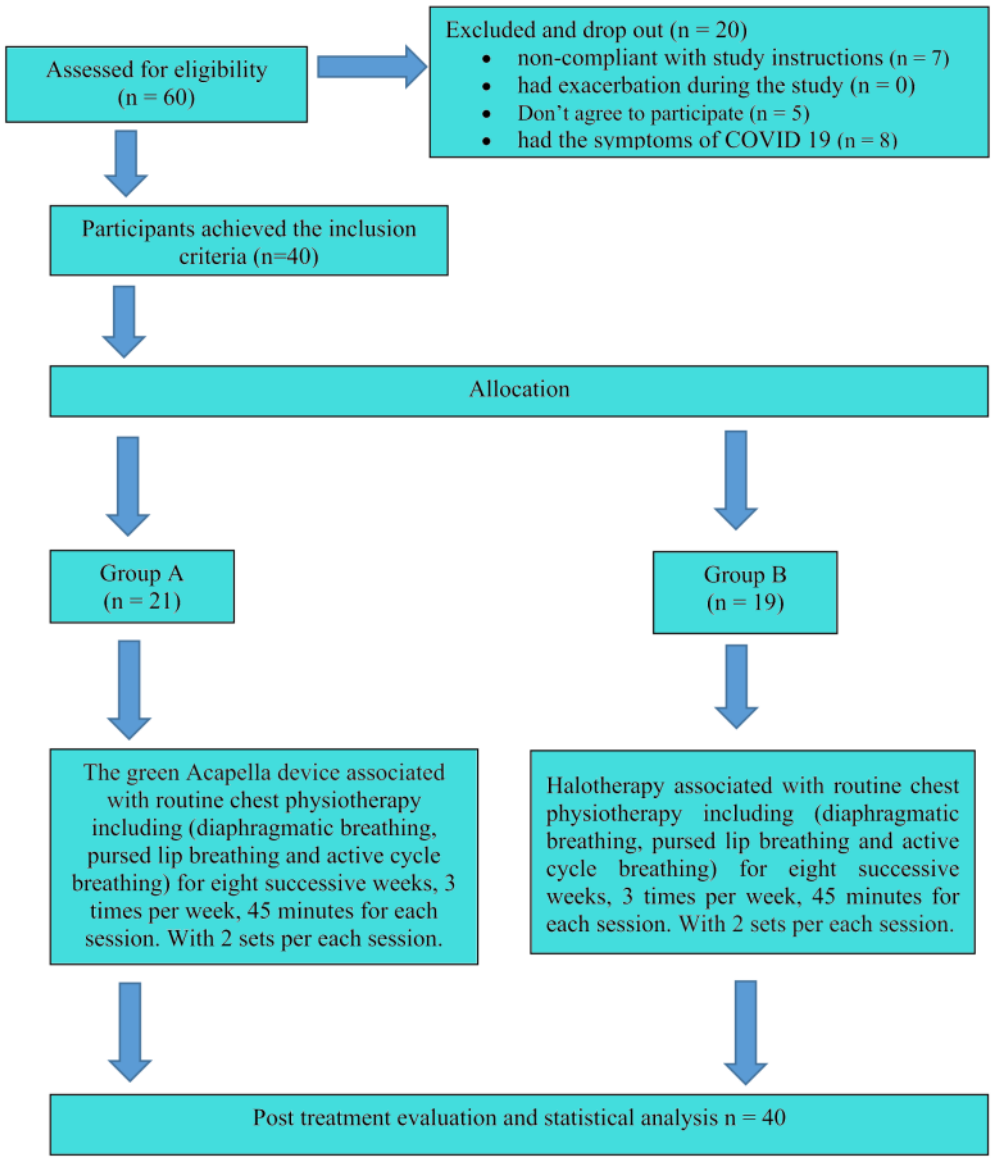

Figure 1. Flow chart of the study

Methods

Group (A) received treatment by the green Acapella device associated with routine chest physiotherapy including (diaphragmatic breathing, pursed lip breathing and active cycle breathing). Group (B) received Halo therapy with natural salt associated with routine chest physiotherapy including (diaphragmatic breathing, pursed lip breathing and active cycle breathing). Both groups received the treatment three sessions per week for 8 weeks.

The Acapella device for group A

The patients sat comfortably and upright while holding the mouthpiece tightly between the lips. The components of Acapella treatment was included breathing control (deep breathing), 10 breaths inhaled to three-quarter maximum breathing capacity, 2–3 sec breath hold, active exhalation to functional residual capacity through the acapella device and cough or forced expiration (huff) in a set cycle. The patients had to exhale gently for 3 to 4 sec through the device while it vibrated; the resistance in the current study was the lowest resistance setting in the first session. As the patient was improved, the resistance was adjusted upward by turning the dial clockwise. The patient did 10 breaths per cycle, 5 cycle per set with rest between cycles for 2 sets through 20 minutes per session [13].

The Halotherapy device for group B

The patient sat in quite comfortable room with suitable chair and plinth to do the breathing exercise during the halotherpy session. The session was done 3 time per week for 8 weeks at 10 Am. The session was about 45 minutes. Started with ¼ teaspoon of salt and increased the amount if needed, at the next refill. The microscopic salt particles came out of the device through the top white lid. The patients did the breathing exercises during the halotherapy session with 2 sets for each of breathing exercises [14].

The breathing exercise for both groups

Diaphragmatic breathing

The patient practiced these exercises initially in the semi fowler's position. The therapist placed one hand flat below the breast bone and the other hand flat on the abdomen. Then asked the patient to inhale slowly through the nose, the abdomen push out against the therapist ´s hand and moving the lower hand outward. When the patient exhaled, the abdomen went in (the diaphragm ascended and pushed on lungs to help expel trapped air).the exercise was done with 5 repetitions for each set / 4 sets. The exercise was repeated (with rest as needed) until satisfactory movement was achieved [15]

Pursed lip breathing

The patient practiced these exercises in the sitting position. The patient was taught to breathe in slowly through the nose to prevent air gulping. The patient held the breath for a count of three, pursed the lips as if whistling, then exhaled for six slow counts. The recommended counting rhythm was changed to one that was more comfortable to the patients according to each patient. The exercise was done with 5 repetitions /4 sets [16]

Active cycle of breathing

The patient was put in a relaxed, sitting, or reclined position. he did several minutes of relaxed diaphragmatic breathing (breathing control). Patient was instructed to take three to four active deep inspirations with passive relaxed exhalations (thoracic expansion), then did relaxed diaphragmatic breathing (breathing control) again, then toke 2 to 3 huffs (forced expiratory technique) started at low volume, followed by 2 to 3 huffs at higher volume, followed by relaxed breathing control, the cycle was repeated 2 to 4 times as tolerated [17].

Outcomes measurements

Measurement of ventilatory functions

For each patient before and after the study, spirometry device model (Vitalograph 6000, Irland) was used to measure FVC, FEV1 and FEV1/FVC. The height and weight were measured before the measurements of ventilatory functions. Then the patients sat comfortably and upright while putting the nose clip and relax. Then the patient was asked to inhale as deeply as possible while holding the mouthpiece. Then the patient exhaled for as long as possible for at least 6 seconds The patient repeated the blow three times or more to obtain good test quality [18].

COPD Assessment Test (CAT) chart

COPD Assessment Test (CAT) chart was used to measure the status of the disease by. All the Patients completed the Arabic version of the form of the CAT chart before and after 8 weeks of training and the therapist calculated the total score for each patient [7].

Measurement of the distance of 6 min-walk test

A 30 meter straight course was marked tape or cones. The patient was instructed to walk" Laps" at a comfortable pace (one lap is 60 meters). The timer is started upon the therapist´s "go" the patient walked laps for 6 minutes and was then instructed to stop (used of the patient´s typical assistive device and or orthosis was permitted).The number of laps was recorded, including any distance at the end that did not constitute an entire lap. The number of rest breaks the patient´s required, as well as the number of episodes of loss of balance were recorded. Total distance was calculated and compared to published norms. The normal value on the basis of studies is considered distance > 600 for men. [19].

Statistical analysis

The statistical analysis was conducted by using statistical SPSS program version 22 for descriptive statistics including the mean and standard deviation for age, weight, height, BMI. Also this study conducted to analysis changes in CAT, 6 MWT and expiration (FVC, FEV1 and FVC/FEV1), a paired t-test was conducted. Independent t-test was used to compare between the results of groups. The statistical significance level was set at $\alpha = 0.05$.

The statistical analysis was conducted by using statistical SPSS Package program version 22 for Windows (SPSS, Inc., Chicago, IL). Descriptive statistics including the mean and standard deviation or standard error for age, weight, height, BMI, CAT, 6 MWT and expiration (FVC, FEV1 and FVC/FEV1,) variables.

Results

Statistical tests revealed no violations of the assumptions of normality and homogeneity of variance for any of the dependent variables. Results revealed non-significant differences ($P > 0.05$) between the two groups regarding to demographic characteristics as shown in Table 1.

Table 1. Demographic and clinical characteristics of participants in all groups

	Group A (n = 21) Mean ± SD	Group B (n = 19) Mean ± SD	Comparison		Significance
			t-value	P-value	
Age [years]	49.80 ± 5.85	50.10 ± 5.68	0.17	0.87	NS
Weight [kg]	84.50 ± 6.59	84.25 ± 5.85	0.13	0.9	NS
Height [cm]	170 ± 6.97	170.85 ± 5.67	0.42	0.67	NS
BMI [kg/m^2]	29.17 ± 2.22	28.79 ± 2.26	0.53	0.6	NS

Data are represented as (Mean ± SD); BMI = Body Mass Index; Level of significance at (0.05)

Data were statistically described in terms of mean ± standard deviation (± SD). Paired (t) test was be used to compare the results pre and after training within the group. Unpaired (t) test was be used to compare the results between groups; level of significance was measured at P value ≤ 0, 05. (1) Pulmonary function tests: FEV1 improved in both groups with percentage of increase in group; A: 7.06% and, B: 6.7%. There was no significant difference between both group (P = 0.071), FVC improved in both groups with percentage of increase in group; A: 1.51% and, B: 1.95%. There was no significant difference between both group (P = 0.081) and FEV1/FVC improved in both groups with percentage of increase in group; A: 5.78% and, B: 4.96%There was no significant difference between both group (P = 0.585), (2) six-minute walk test distance (6MWD) improved in both groups with percentage of increase in group; A: 16.89% and, B: 14.5%. There was no significant difference between both group (P = 0.242). (3) COPD assessment test CAT improved in both groups with percentage of decrease in group; A: 22.8% and, B: 20.28%. There was no significant difference between both group (P = 0.104). The results of both groups as shown in Table 2.

Table 2. Paired (t) test for all dependent variables of both groups

	Group A			Group B		
	Pre	Post	P-value	Pre	Post	P-value
FEV1 [%]	61.67 ± 1.99	66.03 ± 1.71	< 0.01	62.89 ± 3.15	67.11 ± 1.97	< 0.01
FVC [%]	91.99 ± 3.79	93.39 ± 3.37	< 0.01	93.4 ± 3.55	95.22 ± 3.05	0.002
FEV1/FVC [%]	67.06 ± 2.27	70.92 ± 2.1	< 0.01	67.27 ± 2.01	70.61 ± 1.42	< 0.01
6MWD [m]	299.25 ± 7.986	349.8 ± 11.024	< 0.01	301.2 ± 7.55	344.9 ± 14.78	< 0.01
CAT	21.04 ± 1.27	16.2 ± 1.26	< 0.01	21.15 ± 1.17	16.86 ± 1.24	< 0.01

*Data are expressed in means ± SD, FEV1/FVC: Forced expiratory volume in the first second/forced vital capacity, 6MWD: Six-minute walk distance, CAT: COPD assessment test, *significant: p ≤0.05.*

Discussion

This study aimed to was to compare the effects of the Halotherapy and Acapella device as a method of airway clearance on the response of ventilatory functions in men patients with COPD. Statistical analysis revealed significant increase in the ventilatory functions and distance of six-minute walk test 6MWD and significant decrease in COPD assessment test CAT post-treatment at both groups. Comparing the results between both treated groups, it was revealed that there was a significant improvement ($p < 0.05$) in the post-treating mean values of FEV1, FVC, FEV1/FVC, 6MWD distance and CAT in both group. There was no significant difference in the post-treating mean values of all measured variables between the two experimental groups (A) and (B) ($p > 0.05$). The results of the current study Halotherapy device versus Acapella device had valuable significant effect on ventilatory function in COPD patients but with no significance difference between their effects.

For the acapella´s group the results of the current study come in agreement with Shamakh et al [20] who applied their study on 60 patients with moderate COPD Stage II, age range of 40-65, were randomly classified into three equal groups. The study found that Training with the Acapella device increased FEV1 (%) with 10.49%, FEV1/FVC (%) with 8.52%. and Walking distance in the six-minute walk test with 20.09%, also the Quality of life using COPD assessment test scores (CAT) revealed improvements as the test scores decreased by 22.99%.

The result of this study coincided with results achieved by Jayson and Vaishnavi [21] who reported that the acapella device showed improvements in the COPD symptoms which assessed by the Fev1% value, this is evident from the mean value of Pre- test (55.70) and Post-test (63.90). Acapella group showed a significant difference with ($P \leq 0.001$).

The result of the current study was consistent with Sethi et al., [22] who compared separate studies on obstructive pulmonary disease patients using Acapella device or lung flute device, there were small improvements in the pulmonary functions (FEV1% predicted, FVC% predicted and FEV1/FVC) in both groups (Acapella device or lung flute device).

According to the results of the Halotherapy group, this result of current study comes in agreement with the study done by Weinreich et al [23] who reported that the halotherapy group showed improvement in walking distance 75 meters of the 6MWT ($p > 0.05$), and FEV1% (2%), ($p > 0.05$) during the treatment period.

The current work reflected that halotherapy device improves 6-minute walk distant, this result is in agreement with Eslaminejad et al [24] who demonstrated study revealed that halotherapy might exert a positive effect on 6-minute walk distant with significant increase after treatment, in experimental group ($P = 0.02$).

The findings of this study is consistent with the findings of Kendrová et al [25] who documented that despite improvements in spirometry in the FEV1 and FEV1 /FVC, the rese-

archers did not record a statistically significant difference in spirometry ($p > 0.05$) after spa treatment together with speleotherapy and the improvement in FEV1 parameter at the end of treatment was by 4.07% and FEV1 /FVC was by 4.26%

From the findings of this study we recommended to use a method to measure the mucociliary clearance also to increase the sample size and the duration of the interventions to be long enough to determine if other parameters such as arterial blood gases were impacted with the Halotherapy or the Acapella. Also, there is a need of further studies to compare the effect of Halotherapy and the Acapella device on other respiratory diseases.

Conclusion

It was therefore concluded that Halotherapy device and Acapella device had valuable significant effect on ventilatory function in COPD patients and also on the symptoms of the disease. Furthermore, there was no significant difference between the effects of both them. Therefore, physiotherapists can conveniently use either of them in the management of COPD.

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