



Speleotherapy as an Effective Treatment of Chronic Obstructive Pulmonary Disease

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Abstract

Objectives: Chronic obstructive pulmonary disease (COPD) as a liberal illness requires constant anti-inflammatory therapy. As praise of conventional treatments, patients often turn to alternate therapy. Current study aimed to evaluate the first study in Iran emphasizing on halotherapy influence on improving lung function testing results and relieving symptoms of Chronic Obstructive Pulmonary Disease patients, presented at respiratory referral hospital, Tehran in 2016.

Materials and Methods: In this double-blind clinical study, 84 components suffering from COPD detached to two experimental and control groups. Following two months treatment with salitair or placebo, one month clearance phase was carried. Eventually, groups were treated with salitair and placebo for next two months. Influence was determined assessed 6-minute walk distant, arterial oxygen saturation drop of six minutes walking, CAT enquiry and spirometry FEV1, FVC and FEV1/FVC parameters.

Results: Current study revealed that halotherapy might exert a positive effect on 6-minute walk distant and arterial oxygen saturation drop of six minutes walking parameters, since has no effect on CAT enquiry and FEV1, FVC and FEV1/FVC parameters.

Conclusions: Advice for containing halotherapy as a healing treatment for COPD is doubtful. More studies are recommended to be done, including a larger study group to supply the best evidence.

Keywords: Chronic obstructive pulmonary disease (C08.381.495.389); Spirometry (E01.370.386.700.750); Vaporizers (E07.605); Halotherapy; Spleotherapy; Salitair

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Introduction

Chronic obstructive pulmonary disease (COPD) is a chronic worldwide disease [1-4]. COPD was supposed as the tenth most wide-spread temperate agent to un compromising restriction [5]. It was generally the fourth superior cause of mortality [6]. About 210 million people are supposed to suffer from COPD, worldwide [7]. Chronic airflow restriction, often belonging to panting and reduced walking distance distinguish COPD [5,6]. Chronic character of symptoms directly influences patient's quality of life [5,8]. Respiratory physiotherapy, bronchodilators, smoking cessation [9], rehabilitation [10], inhaled drug treatments [11] and antibiotics are available therapy [8]. Sever medication's side-effects and allergic responses, made physicians prefer to use natural salt to cure COPD [12]. Halotherapy known as speleotherapy is a compartment, applying normal salt in a reserved atmosphere as a therapy for disease treatment [13,14]. In Europe, natural salt chambers are used to relieve respiratory diseases [15-17]. Some researches have been conducted on the effect of inhaled salt particles in COPD patients, instead of salt caves around the world [12]. Iran lacks any study; about efficacy of halotherapy treatment on COPD patients. We hypothesized halotherapy may relieve symptoms in COPD patients for the first time in Iran. Hence the particular aims of current pilot study were investigating the result of halotherapy on improving lung function testing results and relieving symptoms in COPD patients referring to respiratory referral hospital in 2016.

Materials and Methods

Two hundred patients with symptoms such as dyspnea, chronic cough, or sputum production for months or years and acute exacerbation were investigated by spirometry testing and recognized as COPD by expert physician. Primary included population of this double-blind clinical trial, was

84 untreated COPD components, as 31 components lack regular drug use, 15 components due to irregular referral, two individuals due to passing away and six components due to the need for long-term use of corticosteroid were excluded. Finally, 30 components were analyzed. The current study was registered in Iranian Registry of Clinical Trials (IRCT) as; IRCT2016080927995N2.

Inclusion and exclusion criteria

Inclusion criteria: COPD components on GOLD criteria [9,11], stable components older than 18 years.

Exclusion criteria: History of surgery in thorax, COPD exacerbation, unbearable complications of COPD, huge changes in treatment regimen, missing patients throughout the study, irregular treatment, smoking, exacerbation in comorbidities like CHF, CRF, etc.

Initiate and demographic data

After explaining side-effects such as dry mouth and throat, itching and skin irritation and rarely bronchospasm to the patient, consents to participate in the trial was signed by components. Demographic data such as age, sex, occupation, smoking history, lung disease information, history of corticosteroid, and consumed medications were recorded. Inventory of disease form as CAT (COPD Assessment Test) [9,11] including dominant clinical signs of disease, such as cough and phlegm, feeling heavy chest, reduced energy level and physical health, such as restricted muscle activity was also completed. Components underwent pulmonary function tests such as spirometry and 9-minute walk test. The results also were recorded.

Treatment

In order to perform double-blind clinical study, 50% of capsules were pharmaceutical discharged and filled with pieces of plastic as placebo. Salitair capsules were marked as 2 and 5. Salitair and placebo were randomized delivered to components for phase 1. After instructing the correct usage of inhaler, components were asked to recruit hospital after two months. After two months using drugs, spirometry and six minutes walking tests were obtained and components went through one month clearance phase. Components treated with placebo received phase two placebo treatments. Afterward salitair was delivered to components crossed-over; as no. 5 treated components received no. 2 and no. 2 treated components received no. 5 for the phase 2. After two months using drugs, third spirometry and six minutes walking tests were obtained and final consisted components were 30.

Spirometry

Forced vital capacity (FVC), forced expiratory volume in the 1st second (FEV1) and the FEV1/FVC were assessed using spirometer (Spiro lab II, Italy).

Six minute walk test (6MWT)

The 6MWT was carried out using a motorized treadmill (COSMED, Italy). The distance that a patient can quickly walk on a flat, hard surface in a period of six minutes was measured.

Statistical analysis

Data were analyzed using statistical software SPSS16. Qualitative variables were explained as frequency and relative frequency (percent) and quantitative variables were explained as range, mean and standard deviation. To evaluate effect of halotherapy on status of the disease, spirometry results and 9-minute walk test, were analyzed

using paired t-test. P value <0.05 was considered significant.

Results

Thirty components included 15 experimental components receiving placebo in phase 1 and 2, and 15 case components receiving Solitaire 2, 5 in phase 1 and 2.

Demographics analysis

Thirty individuals were 28 men and two women. The experimental group included 15 male and the experimental group included 13 male and two female. The average age of the two groups showed no significant difference (58.33 ± 15.94 vs. 61.20 ± 10.85 ; $P < 0.05$). Smoking unit analysis based on pack/year revealed that the average pack/year of two groups showed no significant difference (48.90 ± 53.37 vs. 61.28 ± 37.58 ; $P < 0.05$). Also, no valuable side-effects such as bronchospasm and requirement of discontinuing treatment were observed during the study.

Disease status measures

Eight scales of CAT enquiry [17], each pointed 0-5 revealed that average CAT point of the case group showed significant symptoms reduction after treatment against before the study (16 ± 7.75 vs. 12.93 ± 7.26 ; $P < 0.001$). Average CAT point of the experimental group showed no significant symptoms reduction after treatment against before the study (14.36 ± 6.25 vs. 13.53 ± 6.33 ; $P < 0.001$). To compare symptoms reduction, repeated Measure test was used. In accordance with $F = 0.8$, P value = 0.77; graph 1 noticed no significant variation between symptoms decreasing after treatment against before the treatment in two groups.

Pulmonary Tests

FEV1 represented no significant difference after treatment, in experimental group ($P = 0.71$). FEV1 showed no significant difference in control group after treatment ($P = 0.88$). Total corresponding of FEV1 in two groups, using paired t-test, represented no significant association after treatment ($F = 0.00$; P value = 1.00).

FVC represented no significant difference after treatment, in experimental group ($P = 0.61$). FVC showed no significant difference after treatment, in control group ($P = 0.98$). Total corresponding of FVC in two groups, using paired t-test, showed no significant association after treatment ($F = 0.07$, P value = 0.79). FEV1/FVC showed no significant difference after treatment, in experimental group ($P = 0.83$). Comparison of FEV1/FVC after treatment, in control group represented no significant difference ($P = 0.98$). Total corresponding of FEV1/FVC in two groups, using paired t-test, showed significant association after treatment ($F = 0.07$, P value = 0.78). Six minutes walking distance represented significant increase after treatment, in experimental group ($P = 0.02$). Comparison of six minutes walking distance after treatment, in control group revealed no significant difference ($P = 0.23$). Total corresponding of six minutes walking distance in two groups, using paired t-test, showed no significant differences after treatment ($F = 0.07$, P value = 0.79). Arterial oxygen saturation drop of six minutes walking showed significant increase after treatment, in experimental group ($P = 0.01$). Comparison of arterial oxygen saturation drop of six minutes walking after treatment, in control group represented no significant difference ($P = 0.07$). Total corresponding of arterial oxygen saturation drop of six minutes walking in two groups, using paired t-test, showed no significant differences after treatment ($F = 0.16$, P value = 0.68).

Discussion

This double-blind controlled study evaluated the effect of halotherapy on COPD determined by FVC, FEV1, FEV1/FVC, CAT enquiry and six minutes walking distance during the five months extent of the study. Iran lacks any study; responsible for efficacy of halotherapy treatment on COPD patients. This fact led us conducting current study. We chose spirometry, which is a sensitive test used in clinical diagnosis of COPD. The employment was not seasonally dependent and was conducted over a whole year. There was statistically significant improvement in recorded CAT parameters of symptoms reduction levels in experimental and control groups, after treatment ($P=0.01$, $P=0.041$). Our speculation on CAT parameters revealed halotherapy has no impact on COPD clinical status. Whereas, in a well-constructed retrospective case-control study showed, halotherapy has influence on COPD clinical status [18]. There were significant distinctness at clinical status between treatment and control groups in one of the previous studies [18] and the treatment group appeared to have statistically significant improvement in CAT parameters of symptoms reduction. Therefore, our study lacks the clinical significance and it is questionable. As opposed to CAT, there was no statistically significant improvement recorded in all spirometry parameters in experimental group; following treatment. This is incompatible with one earlier study showing improvement of all spirometry parameters after the treatment with salt aerosols versus placebo [19]. It may be because of using salt room chambers which differs from speleotherapy in most of halotherapy studies. No statistically significant difference in FEV1 parameter was recorded in experimental and control groups; following treatment ($P=0.7$, $P=0.88$). The results imply that halotherapy has no impact on FEV1 parameter of COPD. This is incompatible with Horvath's study; which patients in the case group had a significantly lower FEV1 than the control group [20]. This is also incompatible with one previous study showing overall 14% improvement of the FEV1 and significant improvement in patient's condition [19]. In an earlier study, patients in case group had a statistically significantly improved FEV1% with 3% (0.07 liters). There was a statistically insignificant increase in FEV1% of 2% in another study (0.04 liters) [21]. Otherwise, FEV1 results of our study is equivalent to some previous studies detecting no statistically significant difference in spirometric testing results before and after the intervention ($P>0.05$) [22,23]. There was no statistically significant difference in FVC parameter recorded in experimental and control groups; following treatment ($P=0.61$, $P=0.98$). This is adverse to a former study which revealed overall improvement of FVC by 4%, demonstrating significant improvement in patient's condition [19]. There was no statistically significant difference recorded in FEV1/FVC parameter in experimental and control groups; following treatment ($P=0.83$, $P=0.98$). Total comparison of FEV1/FVC, also recorded no significant difference in two groups ($P=0.78$). This is in agreement with previous studies ($p<0.05$) [22]. The results indicate that halotherapy has no impact on FVC and FEV1/FVC parameters of COPD. There was statistically significant improvement in recorded 6-minute walk distant parameter in experimental, after treatment ($P=0.02$), while in control group there was no significant improvement ($P=0.23$). Our theory on 6-minute walk distant parameter revealed halotherapy has significant impact on COPD clinical status. Our findings are similar to a previous study reporting patients in case group had a statistically significantly improved six minutes walking test with 90 meters ($p<0.01$) [24] and improvement with 75 meters ($p<0.01$) [21]. Another study, established no significant differences

in the case of 6-minute walk test due to the treatment ($P>0.05$) [22]. There was statistically significant improvement in recorded arterial oxygen saturation drop of six minutes walking parameter in experimental, after treatment ($P=0.01$), while in control group showed no significant improvement ($P=0.07$). Our speculation on arterial oxygen saturation drop of six minutes walking parameter revealed halotherapy has significant impact on COPD clinical status.

Conclusion

Our study strength is its sketch. Totally, there were several limitations to our study which was restricted by the availability of COPD components in following up. In conclusion, current study displayed that halotherapy might exert a positive effect on six minute walk distant and arterial oxygen saturation drop of 6 minutes walking parameters, whereas has no influence on CAT and spirometry FEV1, FVC and FEV1/FVC parameters. Hence, at this point, recommendations for inclusion of halotherapy as a therapy for COPD, is questionable. Future studies are needed, including a larger sample size to provide the best available evidence and randomized controlled trials need to be considered.

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