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TANAFFOS

Efficacy of Halotherapy for Improvement of Pulmonary function Tests and Quality of Life of Non-Cystic Fibrosis Bronchiectatic Patients

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Background: Halotherapy is a treatment modality suggested for patients with chronic pulmonary diseases. In this technique, inhalation of crystal salt stones extracted from mines improves patients' pulmonary function tests and symptoms by facilitating the secretion or expulsion of phlegm and mucus and reducing the risk of bacterial infections. Bronchiectasis is chronic disease of the airways characterized by irreversible dilation of airways. It has a progressive course and despite the available treatments, many of these patients eventually enter the advanced phase of disease. The aim of this study was to evaluate the effect of halotherapy on pulmonary function tests and quality of life of non-CF bronchiectatic patients.

Materials and Methods: This clinical trial evaluated the results of spirometry and 6-minute walk test as well as the quality of life (according to SF-36 questionnaire) of stable non-CF bronchiectatic patients presenting to the pulmonary clinic before and after the use of salt spray for 2 months.

Results: Of 40 study patients, 20 were excluded due to various reasons and 20 were evaluated. The mean age of patients was 35±11 years and the underlying cause of disease was chronic pulmonary infection in 65% of cases. Comparison of the results of pulmonary function tests and 6-minute walk test and quality of life indices in SF-36 questionnaire before and after the intervention showed no significant difference (P>0.05). However, 65% of patients were satisfied with halotherapy and requested to receive the medication again.

Conclusion: Our study results indicated that 2-month halotherapy with Salitair inhaler containing salt crystals extracted from the Klodawa mine in Poland could not improve the pulmonary function tests or quality of life of non-CF bronchiectatic patients. No significant side effects were noted in understudy patients. Future studies with larger sample size and longer duration of treatment are recommended to better determine the efficacy of this treatment modality.

Key words: Non-CF bronchiectasis, Inhalation therapy, Halotherapy, Hypertonic saline

INTRODUCTION

Bronchiectasis is a chronic airway disease characterized by abnormal and irreversible dilation and destruction of bronchial walls and "Mucociliary Clearance System". As the result, the patient experiences recurrent coughs associate with thick and sometimes bloody sputum, dyspnea, rhinosinusitis and chronic respiratory infections (1-4). Chronic nature of these symptoms directly affects and reduces the quality of life of patients (5). The prevalence of this condition has reported to be 52/100,000

in the United States and 37/100,000 in Finland (6, 7). This disease is idiopathic in 50 to 80% of cases. Other suggested etiologies include viral, bacterial and fungal infections, chronic obstructive pulmonary disease, airway obstruction due to various causes, inhalation of burning substances, foreign body aspiration, allergic bronchopulmonary aspergillosis, amyloidosis, Celiac disease, immunologic disorders, and congenital disorders (8-10). Respiratory physiotherapy, inhaled mucolytic drugs, bronchodilators and antibiotics are the treatment options available for this condition to control infection and facilitate the secretion or expulsion of phlegm and mucus (11-15). However, the disease usually has a progressive course and despite the above-mentioned treatments many patients eventually enter the advanced phase of pulmonary disease and may require invasive treatments such as surgery or even lung transplantation (16). On the other hand, increased serious side effects of medications and related allergic reactions have encouraged physicians to use drug-free treatment methods. Halotherapy is among these treatment modalities and is a type of speleotherapy. In 1840 Dr. Felix Bochkowsky noticed that crystal salt miners had a better health status than other miners. Their respiratory symptoms had been alleviated as well. The first halotherapy clinic was established around Krakow in Poland by MstislavPoljakowski, one of the Bochkawsky's assistants. In this treatment method, crystal salt stones extracted from the mines are inhaled by patients. Efficacy of this method in CF patients has been evaluated in several studies and in spite of reducing the number of exacerbation attacks, increased FEV1 as well (17, 18). However, the bronchial environment and concentration of electrolytes in CF is much different than in bronchiectasis due to other causes. Furthermore, in the majority of previous studies liquid forms of hypertonic saline compounds were used. Therefore, in the present study we used a drug product with the brand name "Salitair" made in England containing 220 g of crystal salt stones extracted from the mines of Klodawa in Poland and packed in a glass bottle along with a simple inhalation device (with two filters, salt crystals are placed in between them). It mixes the inhaled air with tiny particles of crystal salts. This form of drug intake is easy and may have higher acceptance by the patients. To the best of our knowledge, no study has evaluated the efficacy of halotherapy in treatment and resolution of symptoms of non-CF bronchiectatic patients. The present study evaluated the efficacy of halotherapy for improving the lung function tests and quality of life of non-CF stable bronchiectatic patients presenting to the Pulmonary Clinic of Masih Daneshvari Hospital.

MATERIALS AND METHODS

This clinical trial was conducted on 40 clinically stable, non-CF bronchiectatic patients (according to the clinical definition and HRCT findings of this disease) presenting to pulmonary clinic of Masih Daneshvari Hospital in 2011. The inclusion criteria were having stable, non-CF bronchiectasis (no need for hospitalization in the past month, not requiring systemic glucocorticoid and no systemic antibiotic intake in the past month). The exclusion criteria were hospitalization due to the exacerbation of underlying respiratory disease during the conduction of study, development of respiratory infections during the study, development of intolerable side effects, major change in patients' drug regimen during the intervention period, not showing up for pulmonary function tests, 6-minute walk test or filling out the quality of life questionnaire (Table 1).

After selection of patients, they were thoroughly informed about the method of conduction of the study and drug side effects (xerostomia, dryness of mucosa, and rarely bronchospasm) and written informed consent was obtained from them. Using a checklist, patients' demographic characteristics (age, sex, marital status, and

level of education), food or drug allergy, cigarette smoking and information about the disease (duration of disease, possible cause of bronchiectasis, history of antibiotic therapy in the past month due to the exacerbation of symptoms) were recorded. Also, SF-36 quality of life questionnaire was filled out for patients.

Patients were then referred for spirometry and 6-minute walk test and the results were recorded. Salitair inhalers filled with 70 g crystal salt were delivered to patients and the correct method of using the drug (inhalation through the inhaler for 25 minutes per day for 2 months) was thoroughly explained and instructed to patients. Patients were requested to come back two months later to repeat the spirometry and 6-minute walk test and fill out the SF-36 quality of life questionnaire. In order to monitor the correct use of drug and know the possible side effects, patients were followed up weekly by phone. In case of development of drug side effects (rarely bronchospasm) or exacerbation of the previous disease symptoms, type of complication was recorded and the necessary therapeutic measures were carried out. We tried our best not to change patients' drug regimen during their treatment course. In case of any change in patients' drug regimen or their hospitalization, the patient would be excluded from the study. SF-36 quality of life questionnaire contains 36 questions and evaluates the quality of life of patients with different diseases. This questionnaire has been translated to Farsi and its validity and reliability have been confirmed (19). The questionnaire evaluates 8 scales along with two more that summarize the above mentioned scales and include general index of physical health (including physical functioning, role limitations due to physical problems, bodily pain and general health perceptions) and general mental and emotional health index (including social functioning, general mental health, vitality, role limitations due to emotional problems and mental and emotional health). Each scale is scored from 0 to 100 and a higher score indicates higher quality in that scale.

RESULTS

Of 40 understudy patients, 20 were excluded from the study (9 subjects due to not correctly using the drug in the mentioned time period, one subject due to respiratory infections, 2 due to hospitalization during the study period for reasons other than drug consumption, one due to drug side effect of severe xerostomia and 7 because of not showing up after the completion of treatment course for retesting). A total of 20 subjects were statistically analyzed out of which 10 were males and 10 were females. The mean (±SD) age of patients was 35 ± 11 years (range 20-53 years) and 12 patients were married. In terms of level of education, 2 were illiterate, 9 were below high school diploma, 5 had high school diploma and 4 had educational level higher than high school diploma. Five patients had drug allergy and 3 mentioned food allergy. Four patients were ex-smokers. None of the patients were current smokers. The underlying cause of disease was chronic pulmonary infection in 13 patients (65%), other causes in 3 (15%) and unknown in 4 (20%) patients. The mean duration of disease was 23±12 years (range 5-47 years). No statistically significant difference was detected in spirometric results before and after the intervention ($P>0.05$)(Table 2). No statistically significant difference was found in the results of 6-minute walk test before and after the intervention ($P>0.05$)(Table 2). The understudy treatment method caused no change in any of the SF-36 quality of life questionnaire scales of patients ($P>0.05$)(Table 3). Also, no important side effects such as bronchospasm requiring discontinuation of treatment were observed during the study. Only one patient had to discontinue the drug because of severe xerostomia. Xerostomia occurred in 5 other patients as well but was alleviated or completely resolved by taking some measures and a few recommendations given to patients and thus, the need for discontinuation of drug was obviated. In general, 13 patients (65%) were satisfied with halotherapy and asked for re-administration of drug, 2 (10%) believed that it is ineffective and 5 (25%) were not satisfied with it.

Table 1. The inclusion and exclusion criteria of patients.

Inclusion criteria	Exclusion criteria	
Bronchiectasis due to causes other than CF (based on the clinical and radiographic findings)	Hospitalization due to the exacerbation of underlying respiratory disease during the study	2 subjects
No hospitalization during the past month	Respiratory infection during the study	1 subject
No administration of glucocorticoids in the past month	Major change in drug regimen of patients during the study	
Not receiving new systemic antibiotics in the past month	Development of intolerable side effects	1 subject
	Not showing up for spirometry, 6-minute walk test or filling out the SF-36 questionnaire	7 subjects
	Not correctly or regularly using the drug during the study period	9 subjects
		A total of 20 subjects

Table 2. Comparison of spirometry and 6-minute walk test results before and after the intervention (mean ±SD).

Test	Variables	Before the intervention	After the intervention	P value
Spirometry	FEV_1 (%)	43±21	44±20	0.806
	FVC (%)	48±19	49±21	0.553
	FEV_1/FVC (%)	82±18	84±13	0.692
	FEF_{25-75}	30±26	30±26	0.940
Walk-test	BORG dyspnea scale before the test	0.6±1	0.8±1.4	0.779
	Walked distance (meter)	415±82	432±84	0.119
	Oxygen saturation rate (%) before the test	90±3	90±4	0.787
	Oxygen saturation rate (%) after the test	84±7	82±11	0.579
	BORG dyspnea scale after the test	2.4±1.8	2.9±1.5	0.394
	Requiring oxygen (frequency, percentage)	6(30%)	4(20%)	0.688

* Paired t-test

Table 3. Comparison of the results of SF-36 quality of life questionnaire before and after the intervention (mean and SD).

General scale	Variable	Before the intervention	After the intervention	P value
Physical health	Physical functioning	53±23	57±21	0.772
	Role limitations due to physical problems	52±22	61±21	0.098
	Bodily pain	61±18	62±27	0.957
	General health	52±12	53±16	0.742
	Summary of physical health	51±16	55±17	0.562
Mental and emotional health	Social functioning	61±23	67±26	0.288
	Emotional functioning	60±17	67±20	0.084
	Vitality	52±13	51±14	0.489
	Mental health	41±19	47±19	0.056
	Summary of mental and emotional health	51±13	55±15	0.229

* Paired t-test

DISCUSSION

The present study was a clinical trial to assess the efficacy of halotherapy (using Salitair) for improving the quality of life and pulmonary function tests of non-CF bronchiectatic patients. Of a total of 40 patients that entered the study and received the medication, 20 were excluded from the study. Evaluation of the 20 remaining cases revealed that in contrast to our hypothesis,

halotherapy had no significant effect on the results of spirometry, 6-minute walk test or quality of life of patients. In our knowledge, to date, no randomized or controlled clinical trial has evaluated the effect of halotherapy on non-CF bronchiectatic patients. However, the efficacy of this method for CF patients has been investigated in a few studies and it has been revealed that this treatment modality can reduce the number of exacerbation attacks and increase FEV1 (17). In some studies, bronchiectatic patients have been evaluated as well. One study assessed the efficacy of halotherapy (10-20 inhalations during an hour period once a day) in 124 patients suffering from various respiratory diseases (including 6 bronchiectatic patients) versus 15 control subjects receiving placebo. Results showed an improvement in clinical symptoms of the majority of patients (18). The positive effect of this treatment modality has been confirmed for other respiratory diseases such as asthma, chronic obstructive pulmonary disease and acute and chronic bronchitis as well (20-26). Various mechanisms have been suggested for the observed therapeutic effects; among which, we may name the followings: improved mucociliary clearance, control and elimination of bacterial infections, control of inflammatory reactions, stimulation of the immune system, and regulating the activity of metabolic mediators (regulating and adjusting the secretion of serotonin and reducing the lipid peroxidation and the antioxidant system imbalance)(27). The best effect was observed by using dry sodium chloride with 1-16 mg/m^2 concentration and 2-5 µm particles. Other factors i.e. the adequate temperature-humidity regime and the hypobacterial and allergen-free air environment saturated with aeroions can affect their efficacy in treatment of diseases (18). In a study in Russia in 2003 on COPD patients, inhalation of crystal salt for 60 minutes per day for 10-25 days and repeating this treatment once or twice a year improved the expulsion of respiratory secretions and reduced clinical symptoms in 78% of patients. Also, no side effects were observed in patients even in the elderly subjects (25). Despite the suggested molecular mechanisms and the results of clinical studies, our study failed to show an improvement in the results of pulmonary function tests, 6-minute walk test or quality of life of patients. Small sample size and short-duration of the intervention may be responsible in this respect. However, no important side effects were observed either and 65% of patients were satisfied with halotherapy. Thus, future studies with a larger sample size and longer duration are required to illuminate the efficacy of this treatment modality.

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