



Original Article

The effect of local heat therapy on fatigue among patients with chronic obstructive pulmonary disease: A randomized controlled clinical trial

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ABSTRACT

Background & Aim: Fatigue is one of the most prevalent symptoms among people with chronic obstructive pulmonary disease (COPD). Heat therapy is considered as one of the proposed methods to relieve the symptoms in these patients. Therefore, the aim of this study was to determine the effect of local heat therapy on fatigue among patients with COPD.**Methods & Materials:** This randomized controlled clinical trial study was conducted on 46 patients with chronic obstructive pulmonary disease referred to Allameh Bohlool Hospital in Gonabad, Iran in 2019. The participants were selected according to the inclusion criteria and were then randomly assigned to the two groups of intervention and placebo. Local packs were placed on the anterior of the chest twice a day for 23 minutes and for five days among the participants of both groups. The hot pack was 50°C for the patients in the intervention group, but it was equal to body temperature in the placebo group. The severity of fatigue was once measured before the intervention and then one day after the final intervention in both groups. The demographic information form and Krupp fatigue severity scale were used to collect the data. Descriptive statistics and chi-square, Mann-Whitney, and Wilcoxon tests were used to analyze the data. Besides, the level of significance was considered at least 0.05.**Results:** The results indicated that the two groups were homogenous in terms of demographic information and the type of disease ($P>0.05$). There was no statistically significant difference between the mean score of fatigue before the intervention in the experimental and placebo groups ($P=0.9$). However, the mean score of fatigue decreased significantly among the intervention group patients compared to those in the placebo group ($P<0.001$) after the intervention. There was also a significant difference between the two groups in the mean score of fatigue before and after the intervention ($P<0.01$).**Conclusion:** According to the results, topical heat therapy is effective in reducing fatigue among patients with COPD, but it is recommended to conduct further studies before the implementation of this approach.

Introduction

Chronic obstructive pulmonary disease (COPD) is a disease that prevents airflow into the lungs. Currently, 300 million people suffer from COPD in the world. According to the reports, the prevalence, morbidity, and mortality rates have increased in the last three decades, and there are between 100,000 and 150,000 deaths worldwide each year, according to the reports (1). The results of a survey conducted in Iran reported a 5.7% prevalence for COPD (2). The direct (the costs of medical care) or indirect (the costs

that are imposed on the family and the community as a result of absenteeism) costs of the disease cause a major socio-economic burden on various societies (1). Economic analysis shows that more than 70 percent of COPD patients' health care costs belong to emergency medical examinations and patient care in the hospital, which adds up to \$10 million per year (3). It is the third leading cause of death and the second leading cause of disability worldwide (4).

Fatigue, the mental feeling of fatigue or exhaustion, along with shortness of breath, are among the most common and distressing symptoms in patients with COPD (5). These symptoms prevent the individual's performance and social duties and roles and

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have many negative effects on the affected people's economic situation and quality of life (6). It is reported that tissue oxidation and decreased muscle strength, changes in muscle structure, sleep disorders, stress, and the side effects of the drugs can cause fatigue in patients with COPD; thus, the patients prefer physical inactivity so as to maintain their energy (2). Moreover, in case of respiratory problems and due to increased airway resistance, these patients need to use more energy on breathing, which, along with insufficient oxygen uptake, causes fatigue (7). The prevalence of mild to severe fatigue is estimated to be between 47% and 72% in patients with COPD (8). The results of Antoniu et al.'s research showed that patients with COPD experienced fatigue, even those with mild illness (9). The results of another study by Goertz et al. showed that severe fatigue is common in almost half of the patients with COPD. The most important result of that study is that severe fatigue was more common in patients with COPD than in those without COPD (10). Fatigue is associated with poor health conditions, increased disease burden, poor social participation, poor sleeping quality, and decreased physical activity (11). In patients with COPD, fatigue predicts mortality and leads to impaired quality of life and increased risk of hospitalization (2). However, despite its high prevalence and significant negative health consequences, fatigue often remains undiagnosed and, in turn, untreated (8). Patients with COPD have a reduced ability to cope with fatigue. However, health care providers easily ignore fatigue and the extent of fatigue in examining the clinical symptoms among these patients and pay little attention to this problem (12).

Since fatigue is one of the most debilitating symptoms in people with COPD and interrupts their daily lives, it is necessary to pay attention to the evaluation and treatment of fatigue by health care providers as a professional intervention in these patients. Various drugs, including bronchodilators, corticosteroids, antibiotics, and mucoactive agents, have been used to treat chronic obstructive pulmonary disease

and reduce its symptoms (1). In addition to their beneficial effects, these drugs may have unwanted side effects as well. Besides, despite the high cost of treatment, it may not completely cure COPD patients (13). Accordingly, in addition to these drugs, non-pharmacological interventions are also used to relieve the symptoms. Training the patients and their families and providing special services for these patients such as breathing exercises, physical therapy, and occupational therapy to save energy during daily activities are among appropriate nursing interventions (6).

Heat therapy is one of the non-pharmacological methods proposed to alleviate the symptoms among COPD patients, which is expected to improve the symptoms through various mechanisms (14). Numerous changes occur when the body tissue temperature rises. One of these changes is the dilation of blood vessels. Increasing blood flow to the inflamed and damaged area removes toxic metabolites such as histamine and bradykinin and improves oxygen delivery (15). Another change caused by heat therapy is the activation of the parasympathetic system.

Following increased metabolism and increased blood circulation to tissues, excretion of wastes and harmful substances becomes easier and faster, and muscle function and efficiency increase. Heat therapy also facilitates the chemical interactions of body tissues by increasing body temperature to a certain extent (16). In general, the therapeutic effects of heat include pain relief, dilation of blood vessels, reduction of local swelling, wound healing, muscle relaxation and relief, improvement of tissue nutrition, and reduction of fatigue (15).

Different methods, such as local heat therapy, sauna, and spa bath, are used for heat therapy (17). The results of the related studies indicate that sauna therapy is associated with a reduced risk of acute and chronic respiratory disorders, improved airway obstruction, and improved quality of life in patients with COPD. In addition, no side effects have been observed regarding sauna therapy (18-19).

On the other hand, research results indicate the positive effect of systemic heat and a sauna's use for some chronic fatigue (20). As a result, it is expected to observe that local heat therapy can affect COPD patients' symptoms. Therefore, because of the benefits of heat therapy in previous studies and because it is difficult for everyone to access the sauna and hot water bath, local heat therapy is considered an easy, available, and affordable intervention and is more acceptable. In addition, due to some problems such as the increasing number of COPD patients referring to hospitals, the high cost of treatment, and the importance of proposing an effective and efficient intervention to alleviate the symptoms among these patients, this study aimed to determine the effect of local heat therapy on fatigue in patients with chronic obstructive pulmonary disease.

Methods

Study design

This study is a randomized controlled clinical trial that was conducted in Allameh Bohlool Gonabad Educational, Research and Medical Hospital (Iran) between December 2018 and March 2019.

Sample size

The sample size was calculated using G-Power software version 3 and the independent samples t-test. Given the reliability coefficient of 95%, the test power of 90%, and the effect size of 1.09, 23 participants were estimated for each group. Finally, considering a 5% drop rate probability, 24 individuals were selected for each group.

Statistical Population and Sampling

The research population contained all COPD patients admitted to the internal wards in the hospital. Inclusion criteria for the present study included the age of 40-70 years, stage 2-4 of the disease according to the global initiative for obstructive lung disease (GOLD) criterion, body mass index of 18.5-25, no history of mental and hyperthyroidism

based on the patient's self-report, consciousness, speaking and communication ability, stable physiological state to answer the questions, no structural disorder or known deformity and lesions (swelling, sores, scratches, and rash) in the chest area. The criteria were identified by the researcher based on interviews, physical examinations, and spirometry indicators. The patients who were reluctant to continue the study or those who lost consciousness during the intervention were excluded from the present study. In case of any clinical conditions where, according to the internist, it was not possible for the patient to continue topical heat therapy, the patient would be removed from the study. These criteria did not change until the end of the intervention.

The research units were selected based on availability according to the study's inclusion criteria and were then randomly assigned to the two groups using quadrupled blocks. In this method, the six possible conditions were listed, one number was assigned to each block, and a number was selected by a person other than the researcher by random. The main researcher registered patients and assigned them into intervention and control groups. In addition, blinding was not performed in this study.

Data collection

The data were collected using the patient's demographic profile and Krupp's fatigue severity scale (FSS). The demographic information form included age, gender, weight, height, level of education, marital status, hospitalization, and smoking history, which was completed before the intervention based on the patient's medical record or through interviewing the patient's self-report.

Fatigue was assessed using the special version of FSS for the Iranian. This scale includes 9 questions that are graded from zero (no fatigue) to 7 (severe fatigue) with a visual chart (2). The fatigue score is obtained based on the patient's responses to the questions on this scale. Any score of 36 and above (out of a maximum of 63) is indicative

of significant fatigue (7). FSS is a standard instrument with high internal consistency, high reliability, and validity for measuring fatigue severity. It has already been used in other studies in Iran, and the validity of its qualitative content has been confirmed (2, 7). The scale's reliability has also been determined in previous studies in Iran using the test-retest method, and it was reported between 0.78 and 0.95 (2).

After obtaining informed consent from the patients and assigning the groups, the necessary explanations about the study's objectives, stages, and duration were provided to the participants. The confidentiality of the information and the voluntary nature of the participants were observed in the study. Prior to the study, the severity of fatigue was measured and recorded in the two groups.

Intervention

The patients in both groups received routine COPD treatments. In the intervention group, hot packs were used for topical heat therapy, which was a special cotton bag with a standard size of 25×35 containing hydrophile silicate and was heated to 50°C by a hydrocollator. It was then placed in a special towel and used for 23 minutes on the chest's front in a semi-fowler position. The hot bag was used twice a day every 12 hours. The heat therapy continued for five days. In the placebo group, a similar hot pack was used at the same time yet with a temperature of 37°C (equal to body temperature) twice a day for five days. Krupp's fatigue severity scale was also measured and recorded 24 hours after the last intervention in both groups.

Ethical considerations

This research was conducted in 2018 after obtaining permission from the Higher Education Department in Gonabad University of Medical Sciences (no. A-10-1812-1), from the Regional Ethics Committee in Research in Gonabad University of Medical Sciences (no.IR.GMU.REC.1398.079), and

from the Registration Clinical trial (no. IRCT20161004030141N1).

The researcher first provided patients with a comprehensive explanation of the research and its objectives, and then a written informed consent form was completed by the volunteer patients. Other ethical considerations in this study included reassuring confidentiality of the information, allowing individuals to withdraw at any stage of the study, and disseminating the results of the study.

Data analysis

After collecting the data and entering them into SPSS software version 23, the normal distribution of the variables was examined by the Kolmogorov-Smirnov test. Some quantitative variables such as age, height, weight, BMI, the severity of fatigue before and after the intervention, and hospitalizations did not follow the normal distribution premises ($P < 0.05$).

Mann-Whitney test was used to test the homogeneity of the two groups in terms of quantitative variables of age, height, weight, BMI, and hospitalization times. In addition, the Chi-Square test was used to analyze the qualitative variables of sex, educational level, occupation, residence status, smoking history, income, respiratory problems, history, and COPD stage. The Wilcoxon rating test was used to compare fatigue severity before and after the intervention in each group. Moreover, the Mann-Whitney test was used to compare the severity of fatigue before and after the intervention between the groups and compare the mean severity of fatigue before and after the intervention in both groups. The level of significance of $P < 0.05$ was also considered for the present study.

Results

In this study, the data from 46 patients with COPD were analyzed (Figure 1). Comparison of the two groups in terms of demographic information showed that the two groups were homogeneous in this respect (Table 1).

According to the Mann-Whitney test findings, there was no statistically significant

difference between the mean score of fatigue in the two groups before the intervention ($P = 0.9$). However, after the intervention, there was reported a statistically significant difference between the mean score of fatigue in the two groups ($P < 0.001$). The results of the Wilcoxon test showed that there was a statistically significant difference in the mean

score of fatigue in the intervention group ($P < 0.001$) before and after the intervention, but no significant statistical difference was observed in the control group ($P = 0.67$) (Table 2). The difference in the mean score of fatigue was also statistically significant in the two groups before and after the intervention ($P < 0.01$) (Table 3).

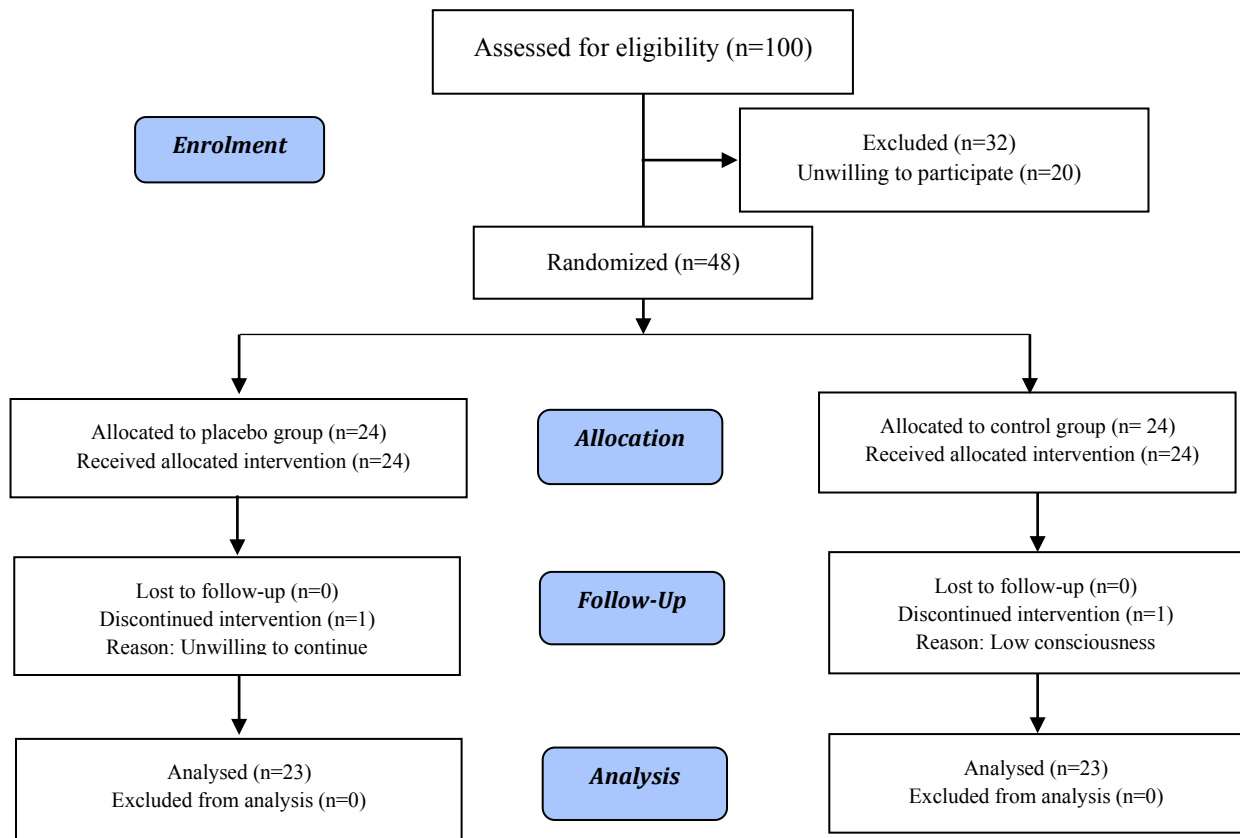


Figure 1. Consort flow diagram of the study

Table 1. Comparison of demographic information of the patients with COPD between the two groups

Variable	Intervention group (n=23)	Placebo group (n=23)	P-value
Average age *	63.69 (9.17)	63.30 (7.87)	0.72
Average weight *	55.39 (8.01)	57.10 (9.13)	0.55
Average height *	158.52 (7.21)	162.17 (9.20)	0.15
Average BMI *	21.99 (2.46)	21.67 (2.68)	0.53
Sex **			
N (%)	Male 10 (43.47)	14 (60.86)	0.23
	Female 13 (56.52)	9 (39.13)	
Stage of disease **			
N (%)	2 nd 9 (39.13)	4 (17.39)	0.22
	3 rd 9 (39.13)	14 (60.86)	
	4 th 5 (21.73)	5 (21.73)	
Smoking history **			
N (%)	Yes 5 (21.73)	5 (21.73)	1.0
	No 18 (78.26)	18 (78.26)	
Occupation **			
N (%)	Governmental /self-employed 5 (21.73)	8 (34.78)	0.42
	Household 12 (52.17)	9 (39.13)	
	Retired 6 (26.08)	6 (26.08)	
Income **			
N (%)	Insufficient 10 (43.47)	16 (69.5)	0.07
	Sufficient 13 (56.52)	7 (30.43)	
Place of residence **			
N (%)	Urban 11 (47.82)	6 (26.08)	
	Rural 12 (52.17)	17 (73.91)	

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History of respiratory disease ** N (%)	Fewer than 1 year	1 (4.34)	6 (26.08)	0.12
	1 – 5 years	14 (60.86)	11 (47.82)	
	More than 5 years	8 (34.78)	6 (26.08)	
Hospitalization * N (%)		6.34 (3.6)	4.21 (2.1)	0.06

* Mann-Whitney ** Chi-square

Table 2. The comparison of the mean score of severity of fatigue before and the intervention between the two groups

Group	Before the intervention	After the intervention	P-value
	Mean (SD)	Mean (SD)	
Intervention	56 (5.39)	42.73 (4.98)	< 0.001 *
Placebo	56.21 (4.60)	55.34 (7.92)	0.676
P-value	0.90	<0.001 **	

Table 3. The comparison of the changes in the mean score of severity of fatigue before and the intervention between the two groups

Group	Mean deviation (SD)
Intervention	-13.26 (5.89)
Placebo	-0.86 (7.82)
P value	<0.001 *

* Mann-Whitney

Discussion

The study results showed that local heat therapy of the chest affects fatigue among patients with COPD. The results of Kim et al.'s study showed that eight weeks of local heat therapy improves muscle strength and increases skeletal muscle capillaries in muscle fibers. This study showed that inactive heat could be used to treat conditions associated with capillary and muscle weaknesses (21). Since decreased muscle strength and changes in muscle structure cause fatigue among patients with COPD, the results of this study confirmed the positive effect of heat therapy on improving muscle function and improving related fatigue.

Sleeping disorders are among the most common causes of fatigue among patients with COPD. 23% of COPD patients complain about sleeping disorders, and poor sleeping quality is the third most common symptom resulting from shortness of breath and fatigue (22). Sawatari et al. reported that topical heat therapy affects sleeping quality (23). Therefore, the results of this study also confirmed the improvement of fatigue following heat therapy.

In a seminal study, Sadeghian et al. showed that topical heat therapy affects the gastrointestinal function of patients who are

fed through the nasal-gastric catheter (24). Nutritional problems are also common among COPD patients who are associated with fatigue. These patients will have nutritional feeding due to shortness of breath, a feeling of heaviness, and difficulty in breathing after eating meals, which eventually leads to weight loss, fatigue, weakness, and intolerance toward activities (25). On the other hand, the results of studies have shown that nutritional conditions are related to spirometry parameters (26). Fatigue is also directly related to changes in spirometry parameters (12). Therefore, this study also supports the results of the present study.

Basic needs and fatigue are associate with psychological complications in patients (27). Mohammadian et al. stated that topical heat therapy with hot packs reduces anxiety among patients with acute coronary syndrome. They also concluded that respiration and oxygen delivery are improved following topical heat therapy with hot packs (17). Mohammadpour et al. also concluded that topical heat therapy on the chest improves respiration and the percentage of oxygen saturation in the blood (28). Although the research population differs in these studies, the results showed a positive effect of heat therapy on vital organs and its efficacy even in acute and

emergency situations. On the other hand, because the functions of the heart and lungs are interdependent, these studies also support the results of the present study.

The results of a seminal study by Kikuchi et al. indicated that systemic heat therapy at 60°C affects the spirometry parameters, exercise endurance, and pulmonary functions among patients with COPD and can improve airway obstruction (19). Although fatigue among COPD patients was not directly examined in this study due to the direct relationship between fatigue and spirometry parameters (12). Because insufficient oxygen uptake causes fatigue in patients with respiratory problems, the improvement of airway obstruction and oxygen delivery from heat therapy has a positive effect on fatigue and, consequently, confirms the present study results. Soejima et al. also showed that the fatigue among patients with chronic fatigue syndrome (CFS) was significantly improved following systemic heat therapy (20). In this study, the effect of heat on chronic fatigue has been studied, and COPD patients are among those who experience chronic fatigue. The results of this study also indicated the effectiveness of heat therapy on fatigue, which is consistent with the results of the present study.

Beaver claimed that systemic heat therapy affects the quality of life among patients with type 2 diabetes. The results of this study showed that heat therapy helped improve fatigue, significantly. He also asserted that stress, physical health, general health, and social performance improved following repeated heat therapy (29). Although heat therapy was not investigated in COPD patients in this study, fatigue mechanism is similar in chronic diseases such as diabetes and COPD (30), which in turn confirms the positive effect of heat on fatigue in the present study.

Accordingly, to justify the improvement of fatigue following local heat therapy in the present study, it is recommended to take into account the positive effects of heat therapy, including relaxation, increased blood circulation to tissues and improvement of

nutrition, acceleration of the excretion of harmful wastes, facilitated chemical interactions, muscle relaxation and increased performance and efficiency of muscles (16). On the other hand, reducing the pulmonary arteries' resistance and their dilation following topical heat therapy causes better oxygen exchange among the alveoli at the lungs and blood. Therefore, improvement of fatigue can be an indicator of the fact that motor coordination, oxygen supply, and strength of the intercostal muscles increase as a result of local heat therapy (7).

In this study, because of respecting patients' comfort and convenience in the semi-fowler position and their acceptance of this condition, local thermotherapy was only performed in the front of the chest. It is suggested that topical heat therapy should be performed on the back or the sides of the chest in future studies.

Limitations of the study

One of the limitations of this study was the difficulty to access the research community of a large number of patients with COPD and the small sample size. Moreover, it was not possible to apply blinding methods on patients because they could easily detect heat.

Conclusion

In case the results of the present study on the effect of topical heat therapy on reducing fatigue among patients with COPD are confirmed, it can be used as a safe, non-invasive, and cost-effective intervention in more extensive studies.

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Conflict of Interest

There is no conflict of interest.

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