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Efficacy of inspiratory muscle training on inspiratory muscle strength, functional capacity, and quality of life in patients with interstitial lung disease. A single non-controlled clinical study

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Abstract

Introduction. The aim of this study was to investigate the effectiveness of low level laser therapy (extravascular laser blood irradiation) on glycaemic levels in type 2 diabetes mellitus patients The most disabling symptoms in interstitial lung disease (ILD) patients are exertional dyspnoea, functional limitations, and impaired quality of life (QoL), all related to inspiratory muscle dysfunction. Therefore, the purpose of this study was to investigate the impact of inspiratory muscle training by using a threshold device on inspiratory muscle strength, functional capacity, and QoL in patients with ILD.

Methods. A single non-controlled clinical study was conducted among 30 patients with different subtypes of ILD who received 30-minute threshold inspiratory muscle training 3 times per week for 12 weeks at 30% of the maximum inspiratory pressure (PI_{max}). PI_{max}, distance walked in a 2-minute walk test (2MWT), oxygen saturation (SO_2%), and QoL by the 36-item Short-Form Health Survey were measured before and after the intervention.

Results. A significant improvement was observed in all measured variables: PI_{max} ($p = 0.0001$), distance walked in 2MWT ($p = 0.003$), SO_2% ($p = 0.043$), and the QoL score ($p < 0.05$).

Conclusions. It was found that threshold inspiratory muscle training is recommended to be a part of the routine care for ILD patients to gain the benefits of improving the control of the symptoms.

Key words: interstitial lung disease, threshold inspiratory muscle training, maximum inspiratory pressure, 2-minute walk test, quality of life

Introduction

Interstitial lung disease (ILD) is a term describing a heterogeneous group of pulmonary disorders that share common physiological manifestations and clinical features [1]. It comprises more than 200 different lung conditions with varying degrees of inflammation and progressive interstitial fibrosis of the lung parenchyma resulting in progressive lung stiffness with consequent alteration in respiratory mechanics, impairment of gas exchange, and exertional dyspnoea [2, 3].

Dyspnoea on exertion is the key symptom in ILD patients, which progresses to the resting state with increasing disease severity. Gradual reductions in the total lung capacity and vital capacity, as well as degradation of diffusion capacity are the principal factors for the development of dyspnoea [4].

In patients with ILD, dyspnoea during activity is the most well-known and predominant exercise-limiting symptom. To avoid this symptom, the patients often limit the activity level, which exerts a deleterious effects on muscle function and results in skeletal muscle dysfunction and weakness, leading to a vicious cycle of deterioration of exercise capacity and aggravating symptoms [3].

It has been documented that reduced exercise capacity is associated with lower quality of life (QoL), which, in turn, is related to depression, fatigue, dyspnoea, social isolation, and poor survival. Patients with the worst exercise capacity reported the worst QoL [1, 3, 5].

Respiratory muscle dysfunction is profoundly associated with dyspnoea, limitation of exercise, and decreased health-related QoL [5, 6]. This association also applies to ILD patients, which was recently confirmed with ultrasound examination in individuals with fibrotic ILD who showed limited excursion of the diaphragm and lower diaphragmatic thickening during deep breathing [4, 7].

Several previous studies affirmed the advantageous impacts of inspiratory muscle training (IMT) on an assortment of outcomes in normal individuals [8, 9], as well as in patients with various disease conditions [10–12]. A program of threshold IMT in patients with sarcoidosis significantly improved exercise capacity, respiratory muscle pressures, dyspnoea perception, and lower limb fatigue [5]. Another recent study revealed that adding respiratory muscle training in the form of threshold IMT as a component of a pulmonary rehabilitation program in patients with ILD induced a significant improvement in exercise capacity, inspiratory muscle pressure, and dyspnoea perception [2]. Limited research has investigated the effects of IMT in ILD patients; however, a pilot study about the effects of threshold IMT in ILD patients showed

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considerable changes in inspiratory muscle function and proposed the modality as an effective training strategy to enhance inspiratory muscle function [13]. Therefore, the main objective of the present study was to investigate the impact of IMT by using a threshold device on the strength of inspiratory muscles, functional capacity, and QoL in patients with ILD.

Subjects and methods

Study design and patients

A single non-controlled clinical study was conducted among 30 ILD patients aged 45–55 years, recruited from the Chest Outpatient Clinic, Cairo University Hospitals, Al Kasr Elainy in Egypt. The sample size was determined in a pilot study to detect a 0.05% difference in primary variables (maximum inspiratory pressure [PI_{max}], distance walked in 2 minutes, QoL score). The calculation was based on a *t*-test (means: difference between 2 dependent means in matched pairs), type 1 error (alpha = 0.05), and type 2 error (beta = 95%). Considering a 15% drop-out rate, the appropriate minimum sample size for this study was 25 patients (25 patients in the group as a minimum). The G*Power software (version 3.1.9.2) was used for these calculations. The study was carried out between July 2019 and January 2020. Patients were included if they were clinically stable (no exacerbations over the previous 3 months), able to perform the exercise, and had no change in the medication treatment throughout the previous 3 months. Individuals with cardiovascular problems, cognitive disorders, acute infection, previously receiving pulmonary rehabilitation, or currently treated for cancer, orthopaedic, or neurological problems were excluded from the study. All participants were given a complete description of the study aims and procedures.

Assessment procedures

A data sheet was filled for each patient including personal data, duration of disease, and medications taken. Then, body weight and height were recorded. Body mass index was calculated by dividing weight in kilograms by squared height in meters. PI_{max}, functional exercise capacity, oxygen saturation (SO_2%), and QoL were evaluated for the allocated patients before and after the 12 weeks of the study period.

Inspiratory pressure

PI_{max} was measured by using a respiratory pressure meter (MicroRPM™), in accordance with the American Thoracic Society/European Respiratory Society guidelines. While the patient was in a sitting position and wearing a nasal clip, PI_{max} was assessed by means of forced inspiration starting from the residual volume. The best value obtained from at least 3 trials with 1-minute intervals was recorded, expressed in cm H_2O and taken as an index for inspiratory muscle strength [14].

Functional capacity

A 2-minute walk test (2MWT) was performed in accordance with the American Thoracic Society published guidelines, in a flat corridor. Each patient was instructed to cover as much ground as possible over 2 minutes. A pulse oximeter (OxyWatch™) was utilized for measuring heart rate and SO_2%, and blood pressure was assessed with a portable upper arm blood pressure monitor (Panasonic EW3109W). Two trials with a rest period of 30 minutes between them were conducted on the same day. The maximum distance covered in 2 minutes was measured in meters and taken as an index for functional capacity [15].

Quality of life

The 36-item Short-Form Health Survey (SF-36) is a simple tool for assessing QoL. It consists of 36 questions assessing 8 domains, namely physical function, role limitations owing to physical health, pain, social functioning, general health, role limitations owing to emotional problems, vitality, and mental health. The questionnaire was applied individually, with the patient rested and asked to answer all questions by circling the number that represented their opinion about their status. The participants were instructed that all questions should be filled. The general score was in the range of 0–100; increased score corresponded to a higher QoL [16].

Intervention

All the patients received a supervised program of IMT involving a threshold device (Respironics, NJ, USA, No. 8373-0730) 3 times per week for 12 weeks. The training intensity started with 30% of the initial PI_{max}. PI_{max} was adjusted and maintained at this percentage throughout the treatment (12 weeks) by measuring PI_{max} weekly and readjusting the intensity accordingly. The patient was asked to take deep inspiration through the system appropriate to overcome the adjusted training resistance in order to open the valve, then expire, and finally rest for 5–10 seconds, repeating this procedure for 30 minutes per session. All participants were instructed to maintain diaphragmatic breathing for the same duration of the session at home on days free of sessions.

Statistical analysis

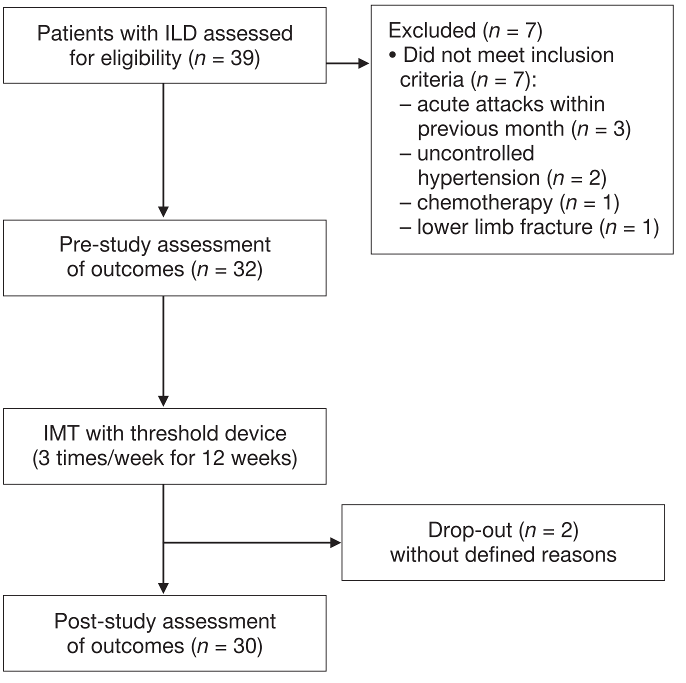
Analysis of data was performed by using the Statistical Package for the Social Sciences (SPSS) for Windows, version 16. Initially, data were examined for normality by the Shapiro-Wilk test; depending on the outcomes, data are expressed as mean and standard deviation for normally distributed data or as median and interquartile range for non-normally distributed data. Student's paired *t*-test was used for comparing the change between pre- and post-treatment values in normally distributed data (distance walked during 2MWT), while the Wilcoxon signed-rank test served to detect the change between pre- and post-treatment values in data showing inhomogeneous distribution (PI_{max}, SO_2%, and SF-36 survey results). For all tests, the results were considered significant if $p < 0.05$.

Ethical approval

The research related to human use has complied with all the relevant national regulations and institutional policies, has followed the tenets of the Declaration of Helsinki, and has been approved by the Ethical Review Board of the Faculty of Physical Therapy, Cairo University (approval No: P.T.REC/012/002747).

Informed consent

Informed consent has been obtained from all individuals included in this study.



ILD – interstitial lung disease
IMT – inspiratory muscle training

Figure 1. Flow chart of the study

Table 2. Comparison between pre- and post-treatment measurements of the studied variables

Variable	Pre-treatment	Post-treatment	*p*
PI_{max} (cm H_2O)#	33.15 (30–33.72)	60 (52.47–67)	< 0.001**
2MWT (m)*	52.6 ± 8.11	84.2 ± 16.6	< 0.05**
SO_2%#	86 (86–87)	91 (89–92)	< 0.05**
QoL domains			
Physical function#	15 (10–21.25)	70 (65–80)	< 0.001**
Physical aspects#	25 (00–32.25)	75 (50–100)	< 0.001**
Emotional aspects#	33 (00–66.66)	100 (69.16–100)	< 0.001**
Vitality#	10 (10–12.5)	70 (57.5–80)	< 0.001**
Mental health#	20 (12–25)	80 (62–88)	< 0.001**
Social aspects#	25 (00–25)	75 (59.38–75)	< 0.05**
Pain#	22.5 (11.88–22.5)	72.5 (55–77.5)	< 0.05**
General health#	20 (10–31.25)	65 (53.75–70)	< 0.05**

PI_{max} – maximum inspiratory pressure, 2MWT – 2-minute walk test, SO_2% – percentage of arterial blood saturation with oxygen, QoL – quality of life

median (interquartile range), * mean ± standard deviation, ** significant values

Results

Figure 1 shows the flow chart of the current study. Out of the 39 patients with ILD who were assessed for eligibility, 7 did not meet the inclusion criteria; 32 patients were allocated to the study, 2 dropped out later without defined reasons. Therefore, 30 participants completed the study and their results were analysed after the intervention.

The data regarding baseline demographic and clinical characteristics of the study participants (age, gender, body mass index, time after the diagnosis, and the diagnosis) are presented in Table 1.

Comparing the pre- and post-treatment measurements of the studied variables revealed a statistically significant increase in PI_{max} ($p < 0.001$), the distance walked in 2 minutes ($p < 0.05$), and SO_2% ($p < 0.05$). Also, the SF-36 QoL survey scores demonstrated an improvement in all measured domains with $p < 0.05$ or $p < 0.001$, as shown in Table 2.

Table 1. Baseline demographic and clinical characteristics of the study group

Variable	Value
Age (years)#	46.5 (45–53.5)
Height (cm)*	154.37 ± 8.04
Weight (kg)*	76.23 ± 14.68
BMI (kg/m²)*	31.75 ± 6.48
Time after diagnosis (years)*	2.1 ± 0.7
Gender (*n*, %) (males/females)	8, 26.7% / 22, 73.3%
Diagnosis [*n* (%)]	
IPF	16 (53.3)
CTD-ILD	9 (30)
Sarcoidosis	3 (10)
NSIP	1 (3.3)
LIP	1 (3.3)

BMI – body mass index, IPF – idiopathic pulmonary fibrosis, CTD-ILD – connective tissue disease-associated interstitial lung disease, NSIP – nonspecific interstitial pneumonia, LIP – lymphocytic interstitial pneumonia
median (interquartile range), * mean ± standard deviation

Discussion

The current study was performed to evaluate the impact of IMT applied with a threshold device on inspiratory muscle strength, functional capacity, and QoL in patients with ILD. It was hypothesized that IMT would be an effective method for improving inspiratory muscle strength, functional capacity, and QoL.

The findings of the present study showed that 12 weeks of IMT using a threshold device induced significant effects on PI_{max}, the distance walked in 2 minutes during 2MWT, and the scores of the 8 domains in the SF-36 QoL questionnaire among patients with ILD. The gains were independent of gender or the underlying diagnosis.

PI_{max} is a non-invasive indicator of the strength of inspiratory muscles, specifically the diaphragm, and can be used to examine patients with inspiratory muscle weakness [17].

The current study demonstrated improvements in inspiratory muscle strength, functional capacity, and QoL in ILD patients. Also, we observed that post-intervention PI_{max} was higher than its value before the study, which was attributed to a change in diaphragmatic strength as a result of the training method used. Threshold IMT is characterized by a one-way valve mechanism in which the patient should create adequate pressure to overcome the spring-loaded valve in order to allow airflow to commence; this is achieved by an initial isometric contraction of the diaphragm to generate the threshold pressure required to open the valve, followed by an isotonic contraction. Recently, the threshold type of IMT has been shown to have the greatest activation effect on the diaphragm among respiratory muscle training modes [9, 18]. Increasing the diaphragm strength and thus its pressure-generating potential could be caused by adaptive structural changes in the form of an increase in type I fibre proportion and by the type 2 hypertrophy induced by the training method used [19].

As dysfunction of the inspiratory muscles along with the rapid shallow pattern of breathing are important causes of dyspnoea and exercise limitation in ILD patients [4], in addition to the close correlation between PI_{max} and exertional dyspnoea [17], the positive change induced in inspiratory muscle strength as an effect of IMT, manifested by higher PI_{max} at the end of the study, is functionally reflected as increasing SO_2% and the distance walked in 2MWT as a measure of functional capacity.

In patients with chronic lung diseases, functional exercise capacity is commonly evaluated with field exercise tests based on walking [15]. In the current study, the utilization of the 6-minute walk test was intended to assess the functional capacity, but the patients were unable to finish one test trial owing to dyspnoea; thus, 2MWT was applied as a functional exercise capacity assessment tool, which was better endured by the patients.

The validity of 2MWT as a tool to assess functional exercise capacity was reported in patients before and after cardiac surgery, patients with muscular inflammatory diseases [15], and patients with multiple sclerosis [20].

The SF-36 QoL questionnaire was used in this study as it has been accounted for as an appropriate instrument for evaluating QoL in idiopathic pneumonic fibrosis as a subtype of ILD [21].

Another important outcome of the current study is the significant increase in the scores of all SF-36 domains at the end of the study. This could have resulted from the improved diaphragm muscle strength that led to increased functional exercise performance and hence improved the patients' ability to perform their activities of daily living, which was reflected as higher QoL.

The results of the current study support the hypothesis reported in literature about a strong association between the degree of physical effort during daily living activities and respiratory muscles strength [22]. Consequently, improving respiratory muscle strength can result in increased exercise capacity [10].

Previous research is available concerning positive effects of threshold IMT on improving PI_{max} in different conditions, as in athletes practising different types of sports, with greater effects when compared with other IMT modes [23], or among the elderly [9]. In chronic obstructive pulmonary disease, threshold IMT significantly improved PI_{max}, functional exercise capacity, as well as dyspnoea and QoL [24]. Threshold IMT is a suggested therapeutic intervention in cases of respiratory muscle weakness in patients with bronchiectasis as it induced a significant increase in diaphragmatic strength [25].

The findings of this research coincide with a recent analysis in the field of idiopathic pulmonary fibrosis, which indicates an increase in dyspnoea control, exercise performance, and QoL as an effect of IMT [26].

Limitations

This study has some limitations, such as the absence of a control group, gender disparity, disease complexity under the umbrella of ILDs with potentially specific clinical presentations, and lack of long-term follow-up of the patients to check the sustainability of the improvements.

Conclusions

A 12-week IMT with a threshold device is an effective method to improve inspiratory muscle strength, functional exercise capacity, and QoL in ILD patients. On the basis of the obtained outcomes, threshold IMT should be included in physical therapy programs for ILD patients.

Disclosure statement

No author has any financial interest or received any financial benefit from this research.

Conflict of interest

The authors state no conflict of interest.

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