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Effects of two types of equal-intensity inspiratory muscle training in stable patients with chronic obstructive pulmonary disease: A randomised controlled trial

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ABSTRACT

Purpose: We conducted a randomised controlled trial to assess the effects of daily breathing pattern changes to stable patients with COPD excluding the confounding factors of inspiratory muscle mobilization, by ensuring the load intensities of two inspiratory training devices were equal.
Patients and methods: Sixty patients with COPD were randomised to three groups: resistive-IMT group (T-IMT, 21 patients), threshold-IMT (R-IMT, 19 patients), and a control group (20 patients). Inspiratory load intensity for both methods was set at 60% of maximal inspiratory pressure (MIP), a measure of inspiratory muscle strength, which, along with health-related quality of life (HRQoL), degree of dyspnoea, and exercise capacity, were conducted before and after 8 weeks of daily IMT.
Results: At 8 weeks, there was no significantly difference of MIP between the R- and T-IMT groups ($P > 0.05$). Chronic Respiratory Disease Questionnaire and Transition Dyspnea Index scores improved significantly after each training program compared with controls ($P < 0.05$), and R-IMT was significant better ($P < 0.05$). R-IMT was better than T-IMT in performance of exercise ($P < 0.05$).
Conclusions: In summary, in clinically stable patients with COPD, 8 weeks of R-IMT was superior to 8 weeks of equal-intensity T-IMT in improving HRQoL, degree of dyspnoea, and exercise capacity.

1. Introduction

Chronic obstructive pulmonary disease (COPD) is defined as sustained expiratory flow-limited, small-airway disease and is a major cause of morbidity and mortality worldwide [1]. Dyspnoea, the major symptom leading to exercise limitation, derives partly from diaphragmatic dysfunction [2]. Diaphragm sarcopenia is well described as an vital extrapulmonary manifestation of COPD. It has been shown that declines in exercise capacity are correlated to diaphragmatic weakness [3] and ultimately affect quality of life [4]. Diaphragm sarcopenia also contributes to hypoxemia and hypercapnia in progressive stage [5].

Various pulmonary rehabilitation programs are standard care for stable patients with COPD to improve extrapulmonary disease manifestations [6]. Inspiratory muscle training (IMT), one type of pulmonary rehabilitation program, has diaphragmatic improvement as its goal. It is used frequently and has been extensively studied in recent years in stable patients with COPD [7].

Meta-analyses of randomised controlled trials (RCTs) in patients with COPD have demonstrated that IMT as a physical therapy increased inspiratory muscle strength and endurance, decreased dyspnoea, and improved exercise capacity and quality of life. They also showed that COPD patients with inspiratory muscle weakness, defined as Pi, max <60 cm H_2O were more likely to experience significant improvements in inspiratory muscle strength and

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functional exercise capacity when IMT was applied [7].

IMT is defined as persistent breathing training using an inspiratory training device according to official American Thoracic Society/European Respiratory Society statement [8]. Inspiratory muscle devices are classified into inspiratory resistive trainers (Fig. 1) and inspiratory threshold trainers (Fig. 2) on the basis of the principle of operation. Inspiratory muscle devices contain built-in spring-loaded valve, which provides a predetermined, continuous inspiratory load during the entire inspiratory phase. Inspiratory threshold trainers do not provide an equal inspiratory load to ensure the intensity of inspiratory training [9]. There are large differences in the operation principles between the two types of inspiratory muscle trainers. Inspiratory resistance generated by inspiratory resistive trainers depends on inspiratory flow rate, whereas threshold load is independent of inspiratory flow [7]. Load intensities can be adjusted in both devices.

However, the therapeutic effect of IMT remains undefined because of the lack of standardization of IMT devices and loads in previous studies. Various devices and loads create different training intensities and potentially cause various breathing pattern changes, which are the basis of the training effect. An optimised IMT program with proper devices and loads should be determined. In our previous respiratory mechanics study, we concluded that resistive-IMT evoke both diaphragmatic mobilization and breathing pattern (deep and slow respiration), whereas threshold-IMT group merely induce diaphragmatic mobilization [10]. There are few comparable RCTs comparing clinical therapeutic effects in COPD using IMT devices that differ in operation principle but that use equivalent loads, which to assess the effects of daily breathing pattern changes to stable patients with COPD, excluding the confounding factors of inspiratory muscle mobilization [7]. Therefore, we performed an adequately powered RCT on the effects of two IMT devices at equal load intensities in patients with COPD with inspiratory muscle weakness. We hypothesized that the resistive-IMT versus threshold-IMT in patients with COPD and inspiratory muscle weakness result in different therapeutic effect according to the changes of respiratory physiology during the two IMT practicing [10].

This randomised controlled study evaluated and compared the therapeutic effects of 8 weeks of training using two types of IMT (inspiratory threshold load devices and inspiratory resistive devices) in clinically stable COPD patients with inspiratory muscle weakness. Training load intensities of the two devices were adjusted in the same level using mouth pressure-detecting method. Primary outcome was inspiratory muscle function. Secondary outcomes were degree of dyspnoea, pulmonary function, health-related QoL (HRQoL), and exercise capacity.

2. Methods

2.1. Study design

This study was a prospective, randomised clinical, controlled trial that was performed on stable COPD patients who were referred to the Guangzhou Institute of Respiratory Disease in 2016. Our study has been reviewed and appears on the ClinicalTrials.gov site (Identifier: NCT03101774; Clinical trial date of registration: March 29, 2017), and all experimental protocols were approved by the Ethics Committee of First Affiliated Hospital of Guangzhou Medical university (April 25, 2016; Reference: 2016–11). Written informed consent was obtained from the patients prior to study participation. All methods of the experimental protocol were carried out in accordance with the medical law and regulations of our country. To ensure the rights of all participants were protected, the researchers strictly adhered to the Declaration of Helsinki and the ethical principles in designing and conducting clinical research.

2.2. Patients

All patients with spirometry-proven COPD were screened for inclusion. Inclusion criteria included: (1) Moderate, severe and very severe COPD (postbronchodilator FEV_1/FVC <70% and FEV_1 <50% of predicted (GOLD B, C and D, respectively); (2) Inspiratory muscle weakness (maximal inspiratory pressure <60 cm H_2O) [7]; (3) bronchial dilation test (BDT) negative; and (4) no history of pulmonary rehabilitation. Exclusion criteria were (1) Time from most recent exacerbation larger than 2 month, (2) with no medication changes in 1 month prior to enrolment. (3) Obesity (BMI>30 m^2/kg). (4) Severe orthopaedic problems having a major impact on daily activities; (5) previous inclusion in a rehabilitation programme (<1 year); (6) concomitant heart failure and pulmonary vascular diseases; (7) diagnosed psychiatric or cognitive disorder;

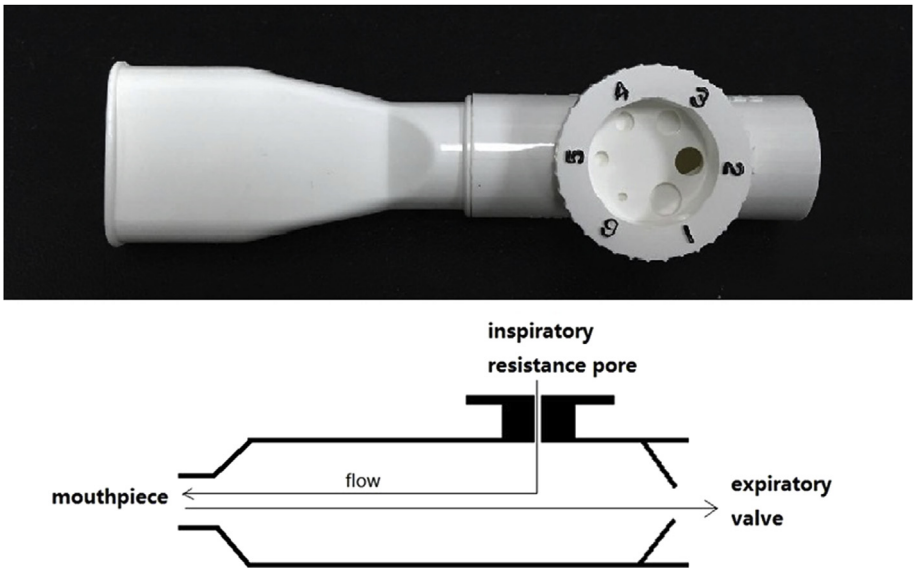

Fig. 1. Respiratory resistance device (PFLEX, Respironics Inc,USA).