

Observation of the curative effect of device-guided rehabilitation on respiratory function in stable patients with chronic obstructive pulmonary disease

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Abstract

Background: Chronic obstructive pulmonary disease (COPD) is a serious lung disease for individuals in middle age and especially in old people. The study was aimed to observe the curative effect of device-guided rehabilitation on respiratory functions in stable COPD patients.

Methods: Sixty-seven stable COPD patients were enrolled and assigned to the experiment group (n=36) and the control group (n=31). The conventional pulmonary rehabilitation treatments, including pursed lips breathing (PLB) and abdominal breathing training, were applied in the control group. Respiratory muscle training of the experiment group was performed using the respiratory endurance training device combined with traditional techniques. Both groups were assessed by 6-minute walk test (6MWT), COPD assessment test (CAT), body mass index, airflow obstruction, dyspnea, and exercise capacity (BODE) index. Besides, the pulmonary function (FVC%, FEV1%) were measured at 6 months before and after treatment.

Results: After treatment, the 6MWT, CAT, BODE index were significantly increased compared with pre-treatment in both groups ($P < .01$), but not FVC% and FEV1%. Compared with the control group, the combination therapy in the experiment group could significantly improve the 6MWT ($P = .0094$), CAT ($P = .0071$) and BODE index ($P = .0064$) as well as the changes of 6MWT ($P < .01$), CAT ($P < .01$), and BODE index ($P < .01$) before and after treatment.

Conclusions: The traditional respiratory training combined with device-guided pulmonary rehabilitation can improve the respiratory muscle function and athletic ability in stable COPD patients.

Abbreviations: 6MWT = 6-minute walk test, BODE = body mass index, airflow obstruction, dyspnea, and exercise capacity, CAT = COPD assessment test, COPD = chronic obstructive pulmonary disease, FEV1 = forced expiratory volume in the first second, FVC = forced vital capacity, PLB = pursed lips breathing.

Keywords: chronic obstructive pulmonary disease, isocapnic hyperpnea, pulmonary rehabilitation, respiratory endurance training device, respiratory function

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1. Introduction

Chronic obstructive pulmonary disease (COPD) is a common debilitating disease for individuals in middle age and especially in old people.^[1] It remains a major public health problem worldwide and causes significant morbidity and mortality, which may be the third most common cause of death in 2020.^[2] Acute exacerbations of COPD which has major impacts on the patient's health as a sustained worsening symptom have been the focus concerned by researchers.^[3] Management of COPD in stable phase to prevent exacerbations and improve lung and physical function has become increasingly concerned in recent years.^[4]

Pulmonary rehabilitation is an important component in the management of COPD, which can ameliorate the symptoms of COPD.^[5] Exercise is one of the most important components of any pulmonary rehabilitation program. Previous studies suggested that respiratory motor training could induce functional improvements in patients with stable chronic COPD.^[6–9] In addition, respiratory muscle endurance training increased breathing and cycling endurance in sedentary subjects.^[10] Currently, in China, pursed lips breathing, abdominal breathing, and inspiratory muscle training^[11] are widely used for patients with stable chronic COPD combined with general exercise training.^[12] However, dizziness and vertigo frequently occur during training, which are inaccurate and happen in the individualized breathing exercise methods as well. The SpiroTiger (Switzerland) is an individualized respiratory

endurance training device used to strengthen the respiratory muscles.^[13–15] Though exercise treatment has been shown to be diversely effective,^[16] there has been little report on the use of individualized respiratory muscles and endurance training equipment combined with conventional respiratory motor training for stable COPD patients.

In this study, the athletic ability, quality of life, and pulmonary function of COPD patients were assessed to determine whether conventional physical therapy exercise followed by individualized respiratory endurance training device could improve lung and physical functions of COPD patients.

2. Methods

2.1. Subjects

Total 80 patients with stable COPD received treatment at the Department of Respiratory Medicine, the Rehabilitation Medicine Center, and the Department of Geriatrics Jiaying Second Hospital during February 2013 to June 2015 were selected for eligibility test. Patients were divided into 2 groups by means of a random numbers table: the experimental group and the control group. Subsequently, total 13 patients (4 in the experiment group and 9 in the control group) who refuse to continue treatment, or could not continue treatment due to sudden changes in condition were removed. As a result total 67 stable COPD patients were enrolled and assigned to the experiment group ($n=36$; 16 female and 20 male; mean age = 63.82 ± 19.64 years) and the control group ($n=31$; 14 female and 17 male; mean age = 61.92 ± 17.92 years). The general information of patients including gender, age, comorbidity, course of the disease, and the disease stages between 2 groups was collected and compared. This study was approved by the Ethical Committee of Jiaying Second Hospital, and written informed consent was obtained from all participants. All patients were regularly treated in the Outpatient clinic at regular intervals within 6 months.

2.2. Inclusion and exclusion criteria

All subjects met the following inclusion criteria: conform to the criteria of stable COPD; patient's vital signs are stable; Mini-mental state examination (MMSE) score ≥ 27 who execute advance directives; actively cooperate with the treatment using a pulmonary function instrument after training; can tolerate daily treatment. While patients those: had severe COPD; with spinal cord injury; had long-term bed rest; had a recent myocardial infarction or angina; with Alzheimer disease or delirium; combined with cardiac, pulmonary, renal, hepatic diseases; had pleural diseases; with neck or chest deformities, were excluded.

2.3. Treatment

All patients received long-term oxygen therapy for 1 hour each day (set at 1~1.5L/min). The control group was treated with traditional techniques including PLB^[17] and abdominal breathing.^[18] The training period in each day (5 days in a week) was 30 minutes. Patients in the experimental group were treated with not only the traditional techniques, but also the respiratory endurance training device (SpiroTiger, Switzerland). SpiroTiger was the first portable device for respiratory muscle therapy in the world, which was designed by scientists from Switzerland. It can train the respiratory muscles selectively through mandatory inhalation and expiration, which is helpful to those with limited



Figure 1. The use of the respiratory endurance training device.

respiratory volume such as COPD or pulmonary cystic fibrosis to improve the respiratory function (Fig. 1).^[13–15] In the light of official instructions for parameter setting, the breathing bag capacity of the device was calculated based on the formula as follows: male, breathing bag capacity = $0.0576 \times H$ (height, cm) $- 0.026 \times A$ (age) $- 4.34/2$; female, breathing bag capacity = $0.0434 \times H - 0.026 \times A - 2.89/2$. The breathing bag volume is approximately 50% of vital capacity. At the first week of training, the breathing frequency was set at about 10 and 14 breaths/min and slowly increased to about 20 breaths/min at the end of the second week. Then it was maintained to the end of the training. Minute Ventilation = Tidal volume (mL) \times Respiratory rate (n). The training intensity was adjusted when necessary on the basis of the patients' feedback. Higher training intensity was considered only when the patients do not feel tired with the current intensity before next training. Patients were trained for 30 minutes a day, 5 times per week. In addition, according to the condition and characteristics of patients, the following drugs: inhaled β_2 -agonist, inhaled corticosteroid, anticholinergic, xanthine, antibiotics, and systemic corticosteroid were chosen and used during the course of treatment.

Training in 2 groups should be suspended in case of acute respiratory infection, acute exacerbations of COPD, or other diseases emerged, unless diseases were assessed and proved not to impact further training. The heart rate of patients in 2 groups was calculated based on the formula: Target heart rate = $(170 - \text{age}) - (180 - \text{age})$ bpm.

2.4. Assessment methods

The athletic ability and pulmonary function of patients were determined and assessed 6 months before and after treatment. Athletic ability was evaluated by 6-minute walk test (6MWT),^[19] quality of life assessed by COPD assessment test (CAT),^[20] while pulmonary rehabilitation was scored by body mass index, airflow obstruction, dyspnea, and exercise capacity (BODE) index.^[21] Pulmonary function measurements, including forced vital capacity (FVC), forced expiratory volume in the first second (FEV1), the percentage of predicted FVC (FVC%), the percentage of predicted FEV1 (FEV1%) were performed using the Quark PFT 3 (Cosmed, Rome, Italy).

2.5. Statistical analysis

All data analysis was performed using SPSS17.0 software (SPSS Inc, Chicago, IL). The Kolmogorov–Smirnov test showed that all quantitative data which expressed as (x s) were normally distributed. Differences between groups and among groups were examined with the paired-samples t test and the independent samples t test, respectively, while the categorical data were analyzed by chi-square (X^2) test. A $P < .05$ indicated that the difference was statistically significant. In addition, scale scores among groups and the changes in values in each group before and after treatment were determined by Mann–Whitney U test.

3. Results

3.1. Demographic characteristics

Baseline characteristics of patients in the experimental and control groups were presented in Table 1. There were no significant difference in gender ($P = .9531$) and age ($P = .4791$) in the 2 groups. In addition, other baseline characteristics of patients including the course of the disease, PaCO₂, PaO₂, comorbidity, and the disease stages in 2 groups were also similar.

3.2. Athletic ability and pulmonary function

The 6MWT, CAT score, and BODE index had no differences in the 2 groups before treatment. Six months after treatment, all the values were much better than that before treatment in both the experiment group and the control group (Table 2). Additionally, the 6MWT value of the experiment group was much higher (434.92 ± 101.58) than that of the control group (376.06 ± 89.57 , $P = .0094$). However, the CAT score was lower in the experiment group than that in the control group (11.22 ± 6.60 vs 14.90 ± 4.41 , $P = .0071$). Similarly, the BODE index were 3.58 ± 1.36 and 4.38 ± 1.23 in the experiment and control groups, respectively, with a significant difference ($P = .0064$).

After pulmonary function test, although trends toward improvement were seen after treatment, the FVC% and

Table 1
Baseline characteristics of patients in the experimental and control groups.

	Experiment (n=36)	Control (n=31)	P value
Gender (male/female)	20/16	17/14	.9531
Age (y, $x \pm s$)	63.82 \pm 19.64	63.82 \pm 19.64	.4791
Course of disease (y, $x \pm s$)	19.02 \pm 12.75	17.52 \pm 11.60	.8202
PaCO ₂	44 \pm 7	44 \pm 6	.6219
PaO ₂	63 \pm 12	62 \pm 15	.5273
Disease stage			
Stage I	2	2	.8773
Stage II	7	9	.3587
Stage III	13	10	.7405
Stage IV	14	10	.5725
Comorbidity			
Osteoporosis/osteopenia	18	16	.8952
Hypertension	15	15	.5812
Ischemic heart disease	3	4	.6026
Diabetes	5	3	.5961
Previous stroke	5	2	.3210
Arrhythmia	3	4	.5420
Chronic renal failure	2	2	.8773
Congestive heart failure	1	1	.9144

Table 2
The 6 MWT, CAT score, and BODE index in 2 groups.

	Group	Before	After	P1
6MWT (m)	Experiment (n=36)	380.75 \pm 107.68	434.92 \pm 101.58	<.0001
	Control (n=31)	335.77 \pm 92.40	376.06 \pm 89.57	<.0001
	P2	0.0735	0.0094	
CAT score	Experiment (n=36)	20.89 \pm 8.32	11.22 \pm 6.60	<.0001
	Control (n=31)	20.58 \pm 7.10	14.90 \pm 4.41	<.0001
	P2	0.8721	0.0071	
BODE index score	Experiment (n=36)	4.94 \pm 1.53	3.58 \pm 1.36	<.0001
	Control (n=31)	4.94 \pm 1.21	4.38 \pm 1.23	<.01
	P2	0.7881	0.0064	

P1, comparison between before and after treatment in the same group; P2, comparison between experiment and control group at the same time point. Data were presented as mean \pm standard deviations.

6MWT=6-min walk test, BODE=body mass index, airflow obstruction, dyspnea, and exercise capacity index, CAT=COPD assessment test.

FEV₁% of patients in both the experiment group and the control group, the difference was not significant compared with that before treatment, nor that between the 2 groups (Table 3). As shown in Table 4, the change of 6MWT before and after treatment in the experiment group (57.75 ± 8.12) was much more significant than that of the control group (35.67 ± 5.96 , $P < .01$). In addition, similar observation regarding the change of CAT was found in the experiment group (9.88 ± 0.97) compared with control subjects (5.67 ± 0.76 , $P < .01$). Furthermore, the change of BODE value also existed a significant difference ($P < .01$) between the experiment group (1.36 ± 0.23) and control group (0.54 ± 0.07 , $P < .01$). However, the changes of FVC% and FEV₁% were not significant.

4. Discussion

COPD causes shortness of breath, chronic cough, and wheezing and is a common inflammatory lung disease in people over the age of 40.^[22] Effective treatment for stable COPD is particularly urgent to improve the quality of life and reduce medical

Table 3
The FVC%, FEV₁%, and RMS values of patients in 2 groups.

	Group	Before	After	P1
FVC% (%)	Experiment (n=36)	63.94 \pm 17.43	65.50 \pm 17.51	.0607
	Control (n=31)	61.85 \pm 20.68	63.54 \pm 21.89	.0822
	P2	0.6563	0.9186	
FEV ₁ % (%)	Experiment (n=36)	50.03 \pm 12.83	51.74 \pm 13.23	.0787
	Control (n=31)	50.57 \pm 14.85	51.38 \pm 16.14	.3538
	P2	0.8722	0.4888	

P1, comparison between before and after treatment in the same group; P2, comparison between experiment and control group at the same time point. Data were presented as mean \pm standard deviations.

FVC% = the percentage of predicted forced vital capacity, FEV₁% = the percentage of predicted forced expiratory volume in the first second, RMS = root-mean-square.

Table 4
Training-related changes in the 2 groups.

	Experiment group	Control group	P value
n	36	31	
Δ 6MWT	57.75 ± 8.12	35.67 ± 5.96	<.01
Δ CAT	9.88 ± 0.97	5.67 ± 0.76	<.01
Δ BODE	1.36 ± 0.23	0.54 ± 0.07	<.01
Δ FVC%	1.69 ± 0.20	1.64 ± 0.18	>.05
Δ FEV1%	1.51 ± 0.11	1.55 ± 0.15	>.05

Δ 6MWT = changes of 6MWT from before to after training, Δ CAT = changes of Δ CAT from before to after Training, Δ BODE = changes of Δ BODE from before to after training, Δ FVC% = changes of Δ FVC% from before to after training, Δ FEV1% = changes of Δ FEV1% from before to after training.

expenditure. In this study, the curative effect of respiratory endurance training was compared with the traditional techniques for breathing training. The results showed that athletic ability, life quality, and the pulmonary function of the experiment group were improved compared to the controls. Baseline characteristics of patients in the experimental and control groups such as gender, age, course of disease, and disease stage were comparable in the experimental and control groups in the study.

The traditional techniques are effective in the management of patients with stable COPD [23,24] to some extent. The similar results were obtained in our study. The 6MWT was improved from (335.77 ± 92.40)m to (376.06 ± 89.57)m, BODE index score was improved from (4.94 ± 1.21) to (4.38 ± 1.23) and the CAT score was improved from (20.58 ± 7.10) to (14.90 ± 4.41) in the control group. The exercise performance was improved a lot after being treated with PLB and abdominal breathing exercise. However, the traditional techniques have some disadvantages, such the lack of visual feedback and control of exercise intensity, and the high risk of excessive ventilation. Previous studies suggested that device-guided rehabilitation for paced slow breathing would improve clinically relevant parameters on exercise capacity, pulmonary function in patients with chronic heart failure.[25] The use of special equipment in the pulmonary rehabilitation of patients with stable COPD is better availability.[26] Wei et al[27] indicated that encourage type lung volume apparatus could improve respiratory volume and blood oxygen saturation, and decrease respiratory insufficiency, and increase training compliance of COPD patients. The breathing exercise using an individualized respiratory device for COPD patients in our study revealed that athletic ability, respiratory muscle strength, life quality, especially the BODE index which were used to assess the COPD severity synthetically were improved in the experiment group compared to the control group treated with traditional breathing training. The valve control mechanism of respiratory endurance training device would collect the air that patients breathe before it enters lungs. It is beneficial to mix the exhaled air with the fresh air to control the concentrations of carbon dioxide during each inhalation. This will protect patients from hyperventilation to prevent dizziness, nausea, and headache in the long breathing process.[28] In addition, the visualized biological feedback system of the respiratory endurance training device draws patients' attention to training. All participants in this study were well tolerated of over-breathing training by SpiroTiger and no treatment was suspended because of the intensity of the training. From the results, patients also increased their exercise performance as a result of training by respiratory endurance training device. Their 6MWT was increased from (380.75 ± 107.68)m to (434.92 ± 101.58)m, BODE index score was improved from (4.94 ± 1.53) to (3.58 ± 1.36) and the CAT

score was improved from (20.89 ± 8.32) to (11.22 ± 6.60). These changes were significantly larger than that of the control group. The more increased parameters than 20 m distance in 6-MWT, 4 in CAT, and 0.8 in BODE were big enough to prove that SpiroTiger might have better advantages than the traditional breathing training method in improving the exercise capacity of patients. Scherer et al conducted a respiratory muscle training with a new portable device on patients with COPD and ventilatory limitation. They found after respiratory muscle training with a new portable device, the respiratory muscle endurance measured through sustained ventilation was large (258%) and respiratory muscle endurance measured through incremental inspiratory threshold loading, maximal expiratory pressure, 6-min walking distance, O₂peak and the SF-12 physical component score were all improved a lot compared with those in control group. Although treadmill endurance was considerably increased in respiratory muscle training (RMT) group than that of the control, changes in dyspnea, maximal inspiratory pressure, treadmill endurance and the SF-12 mental component score did not differ significantly between the 2 groups.[15] One reason may be that the individual improvements varied widely. Koppers et al randomized 36 patients with COPD to RMT by paced tube breathing or sham training (control). Both groups trained twice daily for 15 minutes, 7 days per week, for 5 weeks and patients receiving RMT showed great improvements in endurance exercise capacity (constant-load exercise on cycle ergometry, 18 min vs 28 min, *P* < .001), perception of dyspnea (Borg score, 8.4 vs 5.4, *P* < .001), and respiratory muscle endurance capacity (sustainable inspiratory pressure, 25 cm H₂O vs 31 cm H₂O, *P* = .005).[29] Bernardi et al reported a comparable result. After normocapnic hyperpnea (NH) in COPD, maximal inspiratory pressure significantly increased (81.5 ± 31.6 vs 91.8 ± 30.6 cmH₂O, *P* < .01), exercise endurance time (+150 s, *P* = .04), 6-MWT (+30 m, *P* < .05) all increased. As expected, NH improves inspiratory muscle performance, exercise capacity.[30] However, it is still controversial whether the addition of RMT to a pulmonary rehabilitation program is worthwhile, and which patients in particular will benefit from it.

Abdominal muscle is critical during expiration, such as in forced expiration and coughing. The FVC% and the FEV₁% in 2 groups were improved compared with that before treatment, but no significant difference was found in 2 groups after treatment. It suggests that neither of the traditional methods of breathing training nor the equipment can make a significant improvement on the lung function of patients. Scherer et al reported the FEV1%, PEF%, and FVC% had no significant changes compared with the control. This might be because that respiratory muscle training helps slow down or stop the disease progression, but cannot reverse the lung lesions that have occurred.

There were some limitations in our study. First, due to the lack of measurement information for sternocleidomastoid and pectoralis major muscles, and the median frequency in the time-frequency domain, there was no comprehensive evaluation of muscle strength and endurance with integrated electromyography. Second, the respiratory rate and dynamic training pattern should be selected carefully and further studies are needed. Third, the sample size of this study was small, and the results of this study should be further confirmed by more prospective studies with larger sample size. Even so, these results were also of clinical significance for the therapy of COPD.

In conclusion, the respiratory rehabilitation using respiratory endurance training device could ease breathing difficulties, and

improve health-related quality of life of stable COPD patients. The device-guided rehabilitation would play important auxiliary effect during drug therapy for COPD.

Author contributions

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