Patients with chronic obstructive pulmonary disease (COPD) can benefit from a comprehensive pulmonary rehabilitation program.\textsuperscript{1,2} Data suggests that dyspnea ratings, functional status, and health-related quality of life (HRQL) should be minimal measures included in any pulmonary rehabilitation intervention.\textsuperscript{3} Despite the widespread use of inspiratory muscle training (IMT) in pulmonary rehabilitation, controversy exists regarding the efficacy of the techniques used. Some investigators have found that non-linear resistive breathing devices do not provide reliable training loads.\textsuperscript{3,4} Some improvement in training load reliability can be achieved by controlling the rate of inspiratory flow with an incentive spirometer in combination with a resistive breathing device or by using a threshold load IMT device. Studies have also demonstrated that adequate training protocol ensures a training effect.\textsuperscript{5–7} Reported training intensity has ranged between 30% and 70% of maximal inspiratory pressure (MIP).\textsuperscript{1,6,8–10} Data comparing the effects of threshold and resistive training are lacking.

We hypothesized that targeted resistive IMT with a controlled training load has a similar efficacy to pressure threshold IMT. The purpose of this study was to compare the efficacy of IMT using a targeted

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**Comparison of Effectiveness of Pressure Threshold and Targeted Resistance Devices for Inspiratory Muscle Training in Patients with Chronic Obstructive Pulmonary Disease**

Shu-Fang Hsiao,\textsuperscript{1} Ying-Tai Wu,\textsuperscript{2} Huey-Dong Wu,\textsuperscript{3} and Tyng-Guey Wang\textsuperscript{1}

*Background and Purpose:* Previous studies have provided little information about the comparative efficacy of treatment with pressure threshold and targeted resistive inspiratory muscle training devices. This study compared the efficacy of these two types of inspiratory muscle training (IMT) devices on inspiratory muscle function, exercise capacity, and quality of life in patients with chronic obstructive pulmonary disease (COPD).

*Methods:* Forty-two patients with moderate to severe COPD were randomly assigned to either a control group, a group receiving pressure threshold inspiratory muscle training, or a group receiving targeted resistive inspiratory muscle training. The training intensity was 50% of patients’ maximal inspiratory pressure (MIP). Home-based training comprised two 15-minute sessions a day, 5 days a week for 8 weeks. Inspiratory muscle function measurement included MIP and inspiratory muscle endurance.

*Results:* Thirty patients completed the program, 10 from each group. Twelve patients were excluded because of changes in pharmacological regimen or admission to the hospital (n = 5), study withdrawal (n = 4), or poor compliance with the training program (n = 3). After training, a significant increase in endurance time was found for the threshold group and targeted resistive group (4.4 ± 3.2 min and 3.0 ± 2.9 min, respectively, both \( p < 0.05 \) vs control), with no significant difference between the 2 training groups. The 6-minute walking distance also increased significantly in both training groups (\( p < 0.05 \)).

*Conclusions:* Targeted resistive IMT with a controlled training load has a similar efficacy to the more popularly used pressure threshold IMT and can be incorporated in the treatment of COPD patients. The targeted resistance device offers a less expensive and easily used treatment choice.

*Key words:* Breathing exercises; Equipment design; Pulmonary disease, chronic obstructive; Respiratory function tests; Respiratory muscle training

resistive inspiratory muscle training device with IMT using a pressure threshold inspiratory muscle training device, in terms of the effects on inspiratory muscle strength, muscle endurance, exercise capacity, and HRQL.

**Methods**

**Study design**

Forty two subjects with moderate to severe COPD [forced expiratory volume in 1 second (FEV₁) < 2000mL, FEV₁/forced vital capacity (FVC) < 0.6] were recruited from the pulmonary clinic of one university hospital. None of the subjects were receiving oxygen therapy. Patients were excluded if they had evidence of restrictive lung disease or a history of cardiovascular disease or musculoskeletal conditions that could interfere with either the training or testing maneuvers. Patients were excluded from the final analysis if they had a change in pharmacological regimen, or if compliance with the training protocol was less than 80% (sessions completed/total possible sessions).

The purpose, risk, and potential benefits of the study were explained to all subjects prior to obtaining their consent for participation. The study was approved by the Ethics Committee of National Taiwan University Hospital. All subjects attended a 30-minute educational session where pulmonary hygiene and breathing exercises were discussed. The subjects were then randomly assigned to a control group (no IMT), a group receiving pressure threshold IMT (threshold group), or a group receiving targeted resistive IMT (targeted resistive group) by a predetermined number sequence (systematic assignment).

**Measurements**

Measurements of pulmonary function, inspiratory muscle performance, exercise capacity, dyspnea, and HRQL were made at the commencement of the study and after 8 weeks for all subjects.

Pulmonary function tests were performed with a computerized spirometer (Chestgraph, HI-701, Chest M.I. Inc., Tokyo, Japan) using a standardized procedure. Predicted normal values were determined by the formulas of Yang developed in Taiwanese subjects.

MIP was defined as the maximal negative pressure that could be generated at the mouth from the residual volume and sustained for at least 1 second. An aneroid inspiratory force meter (Model 4103, Boehringer, Norristown, PA, USA) with a cylindrical mouthpiece was used for measurements. An 18-gauge needle was inserted in the proximal end of the mouthpiece. Patients performed 5 trials in the sitting position with 1 minute of rest between trials and the maximum value obtained from the 3 most similar efforts was used in the data analysis. The prediction equation developed by Enright et al was used to evaluate impairment.

The respiratory muscle endurance time (RMET) was defined as the maximal time that patients could breathe against 70% MIP using the pressure inspiratory muscle training device (Threshold®, No 730, Healthscans, NJ, USA). Patients had to generate a negative pressure during each inspiration and no load during expirations. Oxygen saturation (SpO₂) and heart rate (HR) were monitored with a pulse oximeter (3301 Hand-Held Pulse Oximeter, BCI, Inc., USA) during RMET.

Patients were familiarized with the RMET measurement by breathing for 5 minutes against a pressure threshold load equal to 30% of their MIP. Patients were then instructed to breathe against the test load (70% of their MIP) using a comfortable rate and depth of respiration until they were subjectively either too tired to continue or unable to get enough air. If 70% of the patient’s MIP exceeded the maximum pressure provided by the pressure inspiratory muscle training device (-41 cm H₂O), the pressure was set to -41 cm H₂O during RMET measurement.

Exercise capacity was measured with the 6-minute walking distance (6MWD) in accordance with the method described by Steele. Standard instructions were given prior to each test. Two walks were performed, including 1 practice walk. Distance, modified Borg scale, HR, respiratory rate (RR), and SpO₂ were recorded before and after the test.

The Taiwan version of the Medical Outcome Study 36-item Short-Form Health Survey questionnaires (SF-36) was used to assess HRQL. Scores were given on linear scales of 0 to 100, with 0 and 100 assigned to the lowest and highest possible scores, respectively.

**Inspiratory muscle training**

A home-based IMT protocol was used by subjects in the threshold group and the targeted resistive group. It comprised two 15-minute sessions a day, 5 days a week for 8 weeks, always with a nose clip on. Subjects were asked to keep a daily log to assure their compliance. The use of a daily log along with phone interviews have been shown to enhance training compliance. The training intensity for both training groups was set at 50% of the patient’s MIP. Patients were required to visit the laboratory every 2 weeks for rechecking of MIP and adjustment of the training load accordingly.

Subjects in the threshold group used the pressure threshold load inspiratory muscle training device (Threshold®, No 730, Healthscans, NJ, USA). The
pressure settings were adjustable in scales of 2 cm H2O (range, -7 cm H2O to -41 cm H2O) and the threshold pressure was independent of airflow rate or breathing rate. If 50% of the patient’s MIP was less than -41 cm H2O, the training load was set to -41 cm H2O.

An incentive spirometer (Respirex®2, DHD 22-1000, Diemolding Healthcare Division, Canastota, NY, USA) with an added resistance (DHD Inspiratory Muscle Training device, DHD 22-7500, Diemolding Healthcare Division, Canastota, NY, USA) was used for the targeted resistive group (Fig.). The patients were instructed to generate adequate inspiratory flow rates such that the ball in the incentive spirometer indicated a flow rate of 400 mL/sec. The training intensity, 50% of MIP, was adjusted by the attached leak disc and was measured by connecting an aneroid inspiratory force manometer.

### Results

Of the 42 patients enrolled, a total of 12 were excluded from the analysis for the following reasons: changes in pharmacological regimen or admission to hospital during the study period (n = 5), no interest in continued participation (n = 4), and poor compliance (n = 3). No differences of lung function and group assignment were found between these excluded patients and the final sample. No patients received oxygen therapy during the study period. The final sample consisted of 26 men and 4 women with moderate to severe COPD. The clinical characteristics and the results of pulmonary function tests are shown in Table 1. There were no significant differences in these variables among groups. As shown in Table 2, pulmonary medication was not changed during the study period. There were no significant differences in compliance with the training protocol between the threshold group and the targeted resistive group.

### Table 1. Clinical characteristics and pulmonary function data of the subjects.

<table>
<thead>
<tr>
<th></th>
<th>Control group (n = 10)</th>
<th>Threshold group (n = 10)</th>
<th>Targeted resistive group (n = 10)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Men:women</td>
<td>8:2</td>
<td>10:0</td>
<td>8:2</td>
</tr>
<tr>
<td>Age (years)</td>
<td>71.1 ± 3.9</td>
<td>68.2 ± 6.5</td>
<td>70.4 ± 5.3</td>
</tr>
<tr>
<td>Height (cm)</td>
<td>159.8 ± 9.9</td>
<td>165.4 ± 4.1</td>
<td>162.6 ± 6.2</td>
</tr>
<tr>
<td>Weight (kg)</td>
<td>59.6 ± 12.9</td>
<td>63.0 ± 7.2</td>
<td>57.0 ± 9.4</td>
</tr>
<tr>
<td>Resting HR (min⁻¹)</td>
<td>89.9 ± 14.0</td>
<td>88.4 ± 13.3</td>
<td>92.0 ± 10.3</td>
</tr>
<tr>
<td>Resting RR (min⁻¹)</td>
<td>21.2 ± 5.7</td>
<td>21.2 ± 5.7</td>
<td>20.1 ± 5.3</td>
</tr>
<tr>
<td>Resting SpO2 (%)</td>
<td>95.6 ± 1.8</td>
<td>95.2 ± 1.8</td>
<td>94.8 ± 2.1</td>
</tr>
<tr>
<td>FVC (L)</td>
<td>1.95 ± 0.47</td>
<td>2.27 ± 0.54</td>
<td>2.05 ± 0.32</td>
</tr>
<tr>
<td>FVC (% predicted)</td>
<td>75.2 ± 15.8</td>
<td>74.6 ± 15.5</td>
<td>74.6 ± 12.1</td>
</tr>
<tr>
<td>FEV₁ (L)</td>
<td>1.06 ± 0.23</td>
<td>1.21 ± 0.43</td>
<td>1.06 ± 0.22</td>
</tr>
<tr>
<td>FEV₁ (% predicted)</td>
<td>54.3 ± 12.1</td>
<td>50.2 ± 15.2</td>
<td>49.7 ± 11.4</td>
</tr>
<tr>
<td>FEV₁/FVC (%)</td>
<td>54.4 ± 7.5</td>
<td>52.8 ± 13.8</td>
<td>52.2 ± 11.0</td>
</tr>
</tbody>
</table>

HR = heart rate; RR = respiratory rate; SpO2 = pulse O2 saturation; FVC = forced vital capacity; FEV₁ = forced expiratory volume in 1 second.

### Table 2. Numbers of subjects taking pulmonary medications.

<table>
<thead>
<tr>
<th>Medication</th>
<th>Control group</th>
<th>Threshold group</th>
<th>Targeted resistive group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sympathomimetic agents</td>
<td>5</td>
<td>9</td>
<td>9</td>
</tr>
<tr>
<td>Anticholinergic bronchodilators</td>
<td>6</td>
<td>7</td>
<td>9</td>
</tr>
<tr>
<td>Methylxanthines</td>
<td>10</td>
<td>10</td>
<td>10</td>
</tr>
<tr>
<td>Steroids</td>
<td>3</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Antitussives</td>
<td>5</td>
<td>7</td>
<td>5</td>
</tr>
</tbody>
</table>
Inspiratory Muscle Training in COPD

Table 3. Data for inspiratory muscle strength, muscle endurance, and 6-minute walking distance before and after 8 weeks of inspiratory muscle training.

<table>
<thead>
<tr>
<th></th>
<th>Control group</th>
<th>Threshold group</th>
<th>Targeted resistive group</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Baseline Week 8</td>
<td>Baseline Week 8</td>
<td>Baseline Week 8</td>
</tr>
<tr>
<td>MIP (cm H2O)</td>
<td>58.2 ± 21.0</td>
<td>68.8 ± 17.4†</td>
<td>68.2 ± 14.1</td>
</tr>
<tr>
<td>Difference</td>
<td>10.6 ± 13.4</td>
<td>26.8 ± 19.4</td>
<td>56.6 ± 26.7</td>
</tr>
<tr>
<td>Percent change</td>
<td>25.7 ± 41.1</td>
<td>42.3 ± 33.3</td>
<td>53.9 ± 44.1</td>
</tr>
<tr>
<td>RMET (min)</td>
<td>3.3 ± 2.8</td>
<td>2.9 ± 3.0</td>
<td>3.4 ± 3.6</td>
</tr>
<tr>
<td>Difference</td>
<td>-0.4 ± 0.6</td>
<td>4.4 ± 3.2</td>
<td>3.0 ± 2.9†</td>
</tr>
<tr>
<td>Percent change</td>
<td>-18.8 ± 32.9</td>
<td>58.7 ± 328.1</td>
<td>220.1 ± 196.0*</td>
</tr>
<tr>
<td>6MWD (m)</td>
<td>408.6 ± 72.3</td>
<td>420.8 ± 66.3</td>
<td>449.5 ± 49.0†</td>
</tr>
<tr>
<td>Percent change</td>
<td>3.2 ± 7.1</td>
<td>6.5 ± 7.1</td>
<td>8.4 ± 5.5</td>
</tr>
</tbody>
</table>

* p < 0.05 among the 3 groups (Kruskal Wallis test).
† Significant difference between groups, p < 0.05 (Wilcoxon signed rank test).
MIP = maximal inspiratory pressure; RMET = respiratory muscle endurance time; 6MWD = 6-minute walking distance.

No significant differences in MIP, RMET, 6MWD, and dyspnea scores were found between the 3 groups at baseline. After 8 weeks, the RMET significantly increased in both the threshold group (by 4.4 ± 3.2 min) and targeted resistive group (by 3.0 ± 2.9 min) but not in the control group (Table 3). No significant differences in MIP were found among the 3 groups. At 8 weeks, the 6MWD increased significantly in the threshold group and targeted resistive group (by 32.3 ± 35.2 m and 40.6 ± 27.0 m, respectively), but not in the control group. There were no changes in exercise HR, RR, SpO2, the modified Borg scale result, and the SF-36 score after treatment in the 2 training groups.

Discussion

Both training methods were found to be effective, safe, and well tolerated in all patients. The results of this study confirm previous findings that inspiratory muscle training can significantly improve inspiratory muscle endurance in patients with COPD.3–7 No significant difference in efficacy was found between the 2 muscle training devices.

There are various ways of evaluating inspiratory muscle endurance. Clanton et al suggested that continuous breathing against 65% of MIP for more than 10 minutes indicates normal respiratory muscle endurance.19 The method used in this study is similar to that suggested by Clanton, and was shown to be safe, clinically useful, and requiring no sophisticated equipment, while it appeared to be sensitive to changes. Only 2 of the 30 subjects could endure 10 minutes of testing at baseline whereas 5 subjects in each training group were able to endure 10 minutes after 8 weeks of training. Our results showed that RMET increased to 587.5% and 220.1% of baseline values in the threshold group and targeted resistive group, respectively (both p < 0.05 vs control). Such improvements are of significance clinically and comparable to those of other studies.3–7,9,10,16,20–22 The threshold group appeared to have the greater percent improvement compared with the targeted resistive group, a finding that may be related to the relatively lower performance of the former at baseline. However, greater familiarity of subjects in this group with the testing device after 8 weeks is a possible contributing factor to this difference.

Previous researchers have reported that inspiratory muscle endurance relates to muscle performance.14 Clanton and Diaz noted that endurance time probably reflected a combination of the endurance and force production characteristics of the muscle being studied.14 In the present study, a positive correlation was found between changes in MIP and RMET (r = 0.410, p < 0.05). Improvements in muscle endurance appeared to be accompanied by improvements in muscle strength.

Interestingly, no significant differences in MIP were found in the 2 treatment groups compared to the control group. Previous studies have shown significant improvement of MIP, that ranged between 5.8% and 53.9%,3–7,10,16,20–22 Only mild impairment in MIP (72.7 to 78.1% predicted at baseline) in our subjects might be one of the reasons for the lack of significant changes in MIP. The use of a training protocol that did not emphasize strength training might have been another factor contributing to the results. The improvement in MIP was 42.3% in the threshold group, and 53.9% in the targeted resistive group. The extent of the increase in MIP from baseline in the control group (25.7%) suggests that the initial MIP measurement may have been underestimated. Additional practice sessions for subjects and the use of a larger sample might be needed to reduce such effects. In addition, the use of a sham training group rather than a control group may be more appropriate.

The 6-minute walk test has been widely used to assess general exercise ability. In this study,
both training groups showed significant increases in the distance walked compared with the control group. This finding is consistent with some previous reports. However, the small percentage improvements of distance — 8.4% for the targeted resistive group and 6.5% for the threshold group — may not be clinically relevant. Our study also found that changes in MIP were positively correlated with the 6MWD ($r = 0.395, p < 0.05$); however, there was insufficient evidence to conclude that improvements in respiratory muscle strength accounted for the improvement in 6MWD. Subjects reported similar mild to moderate breathlessness with no changes in the modified Borg scale after training. This finding also suggests that many COPD patients may themselves limit their speed to avoid dyspnea. Further study is needed to explore the relationship between exercise ability and self-reported dyspnea scores.

In this study, HRQL was measured with the Taiwan version of the SF-36. Dekhuijzen et al. found that psychological parameters changed after IMT. Even though many subjects in our study reported that they felt better after IMT training, the SF-36 scores did not improve significantly. It is possible that the SF-36 is not sensitive enough to detect the changes resulting from IMT in this study. Some investigators have suggested that disease-related quality of life questionnaires, such as the St. George’s Respiratory Questionnaire, may be more sensitive measures for COPD patients who have difficulties with activities of daily living.

From the patients’ viewpoint, the devices had different advantages and disadvantages. IMT with a targeted resistive inspiratory muscle training device can provide positive feedback for patients and improve their motivation, and is considerably less expensive than a manometer. But it was difficult to determine whether the subjects were exercising at target intensity with this device. The use of a threshold load IMT device ensures consistency of training intensity. However, some of the subjects in this study reported that it was difficult to keep the pressure threshold device dry and clean in the highly humid climate of Taiwan. We also found some difficulties in providing exact resistance as indicated with the commercially available pressure threshold device when the threshold pressure was low, i.e. less negative than -9 cm H$_2$O.

In summary, inspiratory muscle training significantly improved inspiratory muscle endurance and 6MWD in COPD patients compared with controls. The targeted-resistance device is as effective as the pressure threshold device, and can be recommended to patients in Taiwan based on some advantages reported in this study.

### References


