The Outcomes of Short Term Inspiratory Muscle Training (IMT) Combined with Chest Physiotherapy in Hospitalized COPD Patients

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Abstract
Objective: The objective of this study was to identify the outcomes of short term inspiratory muscle training (IMT) combined with chest physiotherapy (CP) on lung function, inspiratory muscle strength, exercise tolerance and quality of life of COPD patients. Materials and Methods: This randomized-controlled trial was conducted at the Terendak Armed Forces Hospital, Melaka. Eighteen hospitalized COPD patients (FEV1 50% to = 80% predicted) were randomized into intervention (IG) and control group (CG). The IG received IMT and CP treatments whilst the CG received only CP for a period of 4 weeks. Assessments of lung function (FEV1/FVC), inspiratory muscle strength (PImax), exercise tolerance (6MWT) and quality of life (SGRQ score) were taken at baseline and after 4 weeks. Results: Analysis showed IG group increased in FEV1/FVC by 19.4%, PImax by 54.7%, 6MWT by 33.2% and quality of life by 52.6% (All, p<0.05). The control group increased in FEV1/FVC by 8.7% (p>0.05), PImax by 15% (p<0.05), 6MWT by 18.9% (p<0.05) and quality of life by 15.6% (p<0.05). Conclusion: The present study has established that by combining inspiratory muscle training (IMT) and chest physiotherapy, provides superior effects on lung function, inspiratory muscle strength, exercise tolerance and quality of life among COPD patients.

Key Words: lung function; inspiratory muscle strength; exercise tolerance; quality of life.

Introduction
Chronic obstructive pulmonary disease (COPD) is a major cause of chronic morbidity, world's 4th leading cause of mortality that will further increase in its prevalence in the succeeding decades (The Global Initiative for Chronic Obstructive Lung Disease). The Regional Working Group for COPD reported that more than 6.3% population aged 30 and above suffered from COPD ranged between stage II and III, in the Asia-Pacific countries. In addition, more than 4.7% Malaysian population were diagnosed with COPD every year. Smoking was known as one of the main factors contributing to COPD besides lungs infections and environmental pollution.

COPD is a progressive and irreversible lung disease characterized by airflow limitation, which is worse on expiration and may lead to compression of small airways, resulting in air trapping in the lungs and subsequent hyperinflation. Prolonged inspiratory muscle dysfunction may further reduce inspiratory muscle strength and endurance that contribute to dyspnea, reduction in exercise tolerance and poor quality of life (QOL). Reduced lung ventilation or breathing capacity may act with coordination and interaction between neck, thorax, and abdominal muscles to alter the breathing pattern. Similarly factors, such as postural alteration, restrictive pulmonary disorder, inspiratory muscle weakness and improper activation of accessory muscles during breathing can further augment COPD symptoms.
Pulmonary rehabilitation program that consist of physical exercise, health education, and psychosocial approach is normally practiced in treating COPD patients by physiotherapists and other health care providers. Improved lung function, exercise tolerance and reduction of COPD symptoms were noted after pulmonary rehabilitation program. A systematic review has proposed that the use of IMT to be combined in the pulmonary rehabilitation in order to enhance lung function among patients with respiratory conditions. Maximal inspiratory pressure (PImax) is commonly used to measure functional strength of the inspiratory muscles. Hill et al stated that when stimulus or load is placed on the respiratory muscles, it augments inspiratory muscle strength, increases exercise capacity and decreases dyspnea. Effectiveness of the techniques are observed both in pressure threshold or targeted resistive devices of IMT and it was proven safe, feasible, and effective to be used as the training mode. In contrast, although previous systematic reviews show positive outcomes following IMT, but it is still inconclusive with regards to IMT guideline and protocol. Different methodological approach especially in modes, intensity, duration, treatment-base and inconsistent findings were noted from the previous studies. IMT efficacy is also influenced by the training intensity. A RCT study by Covey et al demonstrated significant changes by 17% ± 17 cm H2O (p <.05) from baseline in inspiratory muscle strength, respiratory endurance by 43% ±13 cm H2O (p < .05) and dyspnea score of CRQ by 23.7% ± 5.2 (p < .05). This study implemented 30 minutes of 30% to 60% PImax for 16 weeks. In another RCT, they used 60% to 80% PImax for 8 weeks and produced significant changes in the outcomes. Thus, there is a debate on the study methodological issues to which is the most effective guideline and protocol to be used in treating patients with respiratory conditions.

On the other hand, early pulmonary rehabilitation programs which include aerobic and strength training, early ambulation, and with or without IMT has been shown to demonstrate positive outcomes in COPD patients. Clinii et al found that early pulmonary rehabilitation just after, or even during an acute episode in the hospital is feasible and effective. In addition, many out-patient and home-based IMT programs were reported in the previous studies compared to hospitalized IMT program. Thus, it is essential to identify the IMT outcomes as early as during patients' hospital admission to determine the needs for including the exercise training into the pulmonary rehabilitation protocol.

Besides early program, duration of IMT may also influence the outcomes. Most of the previous studies were between 6 weeks to 12 months duration of program. Effects of early program on hospitalized patients using IMT between 4 weeks to 3 months were not clearly defined in the previous studies. The previous study reported research duration ranging from 6 to 24 months. However, none of the studies were short term and less than 6 weeks duration.

Materials and Methods

Study design

A prospective, single-blind randomized control trial (RCT) was carried out at Terendak Armed Forces Hospital, Melaka Malaysia. Subjects were among the hospitalized COPD patients who were diagnosed with mild to moderate COPD and referred by a respiratory physician for study enrolment. Lung function with FEV1 between 50% to =80% predicted and FEV1/FVC < 0.70 without significant co morbidity were used as the study inclusion criteria. Eighteen COPD patients were enrolled as the subjects based on sample size calculation suggested by Snedecor and Cochran. The subjects were blinded and randomly assigned into intervention (IG) and control (CG) groups via systematic randomization. Nine subjects were allocated to each group. The study was ethically approved by the hospital authority and medical research committee of Malaysia National University. Subjects were given the consent form to complete prior to the study.

Intervention

The intervention group (IG) received chest physiotherapy, which consisted of active cycle breathing
technique (ACBT) and postural drainage (PD) for 15 minutes, once a day, 5 days a week for 4 weeks prior to the IMT. Then, they received inspiratory muscle training (IMT) for 15 minutes, once a day, 5 days a week for 4 weeks. IMT protocol was performed using a "patient module of pressure threshold Respifit-S unit" for 30 repetitions in 15 minutes with intensity of 30% of baseline maximum inspiratory pressure (PImax). IMT was progressed until 60% of subjects PImax with 10% resistance increment weekly. One day training was given to therapists and patients prior to the study. The control group (CG) received chest physiotherapy treatment only.

Measures
The study was done for 4 weeks, in which screening, pre and post test data were collected from both groups. Lungs function parameter such as FEV1, FEV1/FVC was measured using spirometry analyser Spirolab II; Medical International Research (MIR); Roma, Italy and Inspiratory muscle strength (PImax) was determined using Respifit-S model: E. Biegler Medizinelektronik, Mauerbach Austria. The distance achieved in 6 minute walking test (6MWT) was used to determine the exercise tolerance level as suggested by McGavin et al.22 Quality of life (QOL) was measured using the St. George's Respiratory Questionnaire (SGRQ) which consisted of 3 domains and 1 total Score with score 0 represents the maximum quality of life (QOL) achieved and score 100 means worst QOL as proposed by Jones et al.23

Data Analysis
Percentage of changes and mean (±SD) of FEV1/FVC, PImax, 6MWT distance achieved and SGRQ total score from baseline to 4 weeks of treatment were the outcomes of the study. Paired sample t tests were used to determine significant differences in the measured variables between baseline and posttest values. An alpha level of less than .05 was used for all statistical tests.

Results
All subjects completed the study without any dropouts reported. Demographic and health characteristics of the subjects are presented in Table 1. There were no significant differences found between the groups at baseline in relation to age, body weight, body mass index and physical activity level. There was no statistically significant differences between the 2 groups at baseline with FEV1/FVC ranged from 0.20 to 0.44, 20.0 cmH2O to 50.0 cmH2O for PImax, 150 meter to 290 meter for 6MWT, and 41.68 % to 75.89 % for SGRQ. Paired sample t test was conducted to evaluate the significant changes of the 4-weeks study on FEV1/FVC, PImax, 6MWT and SGRQ.

Findings for FEV1/FVC showed a significant increase for IG from baseline (M = 0.67, SD = 0.03) to post-test (M = 0.80, SD = 0.03, t8 = 3.93, P = 0.04). The control group showed no significant difference from baseline (M =0.69, SD = 0.04) to post-test (M =0.75, SD = 0.03, t8 = -1.94, P = 0.08). On an average, percentage of changes from baseline to post-test for the IMTG was 19.4%, whereas only 8.7% noted in the CG.

Inspiratory muscle strength (PImax) of IG showed a significant increase between baseline (M = 26.2, SD
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The CG also showed significant improvement from baseline (M = 21.3, SD = 1.80) to post-test (M = 24.5, SD = 2.50, t8 = -4.72, P = 0.02). Percentage of changes from baseline to post-test for the IG was 46.6%, whereas only 15.0% in the CG. Exercise tolerance (6MWT) of IG showed a significant increase between baseline (M = 225.56, SD = 56.37) and post-test (M = 300.56, SD = 61.56, t8 = -8.58, P = 0.001), similarly for the CG from baseline (M = 185.56, SD = 40.65) to post-test (M = 220.56, SD = 40.41, t8 = -5.42, P = 0.01). Percentage of changes from baseline to post-test for the IMTG was 33.3%, whereas only 18.9% in the CPG.

As for the quality of life (SGRQ), the IG showed a significant increase between baseline (M = 60.34, SD = 10.64) and post-test (M = 51.18, SD = 8.14, t8 = -6.33, P = 0.01). The CG also showed significant improvement from baseline (M = 60.67, SD = 8.47) to post-test (M = 51.18, SD = 8.14, t8 = -6.33, P = 0.01). Percentage of changes from baseline to post-test for the CPG was 15.6%, whereas only 15.0% in the CPG. Table 2 presents the outcomes of the intervention after 4 weeks.

Table 2. Study outcomes for the intervention group (IG) and control group.

<table>
<thead>
<tr>
<th>Variable</th>
<th>IG (n = 9)</th>
<th></th>
<th>% Changes</th>
<th>CG (n = 9)</th>
<th></th>
<th>% Changes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lung Function (FEV1/FVC)</td>
<td>0.67 (0.03)</td>
<td>0.80 (0.03)</td>
<td>19.4</td>
<td>0.69 (0.04)</td>
<td>0.75 (0.03)</td>
<td>8.7</td>
</tr>
<tr>
<td>Inspiratory Muscle Strength (Plmax)</td>
<td>26.2 (9.2)</td>
<td>38.4 (20.5)</td>
<td>46.6</td>
<td>21.3 (1.8)</td>
<td>24.5 (2.5)</td>
<td>15.0</td>
</tr>
<tr>
<td>Exercise tolerance (6MWT distance achieved)</td>
<td>225.6 (56.4)</td>
<td>300.6 (61.6)</td>
<td>33.2</td>
<td>185.6 (40.7)</td>
<td>220.6 (40.4)</td>
<td>18.6</td>
</tr>
<tr>
<td>Quality of life (SGRQ total score)</td>
<td>60.34 (10.64)</td>
<td>28.61 (5.16)</td>
<td>52.6</td>
<td>60.67 (8.47)</td>
<td>51.18 (8.14)</td>
<td>15.6</td>
</tr>
</tbody>
</table>

Discussion
This study evaluated the effect of combination of short term IMT with chest physiotherapy treatments reviews that reported combined IMT with either one of these interventions. The intervention utilized includes upper and lower extremity aerobic exercise, strength training, pulmonary rehabilitation program, education; breathing techniques in which subjects had significant improvement in lung function, dyspnea, inspiratory muscle strength, exercise tolerance and quality of life.19

Besides issue on treatment combination, significant changes in this study outcome also could be attributed by the IMT training prescription. The systemic review by O’Brien et al3 found only 1 out of 5 RCT was conducted for the 4-week duration, whereas, another 4 RCT conducted between 8 to 16-weeks duration which showed significant changes on the study outcomes. However, they employed different type and intensity of IMT using either pressure threshold or targeted resistive IMT with intensity of
30% to 70% of PImax. Furthermore, Geddes et al.\textsuperscript{25} also in supportive of this finding, in which 16 studies depicted significant improvement following either IMT with targeted resistive or pressure threshold in their systemic reviews. This shows that IMT does give significant changes in study outcomes whether given for short or long term duration with intensity ranging from 30% - 70% of PImax.

**Lung Function**
In the lung functions summary, the finding in this study shows positive changes. The significant changes 19.4% from baseline after 4-week intervention was also reported by Barakat et al.\textsuperscript{26} and Cortopassi et al.\textsuperscript{27} with changes of 16.2% and 2.6%, respectively in FEV1/FVC. The changes in the current study most likely can be due to the absence of co-morbidity among the subjects also may be influenced by the medical treatments.

**Inspiratory muscle strength**
As for the inspiratory muscle strength, current finding shows significant improvements 4 weeks after IMT. The recorded inspiratory muscle strength was lower than the previous study which was between 26.2 cmH2O and 38.4 cmH2O (+12.2 cmH2O; 46.6% changes). However, greater changes in percentage from baseline was noted compared to 86 cmH2O to 104.25 cmH2O (+18.25 cmH2O; 21% changes), 64.7 cmH2O to 75.5 cmH2O (p=0.001) (+10.8 cmH2O; 16.6% changes), respectively in the previous study.\textsuperscript{18,27} The significant changes in IG could be influenced by highly motivated subjects, normal body mass index and previous history of physical activity level.\textsuperscript{28}

**Exercise tolerance**
In exercise tolerance summary, this study shows significant improvement in 6MWT distance achieved from 225.6 (±56.4m) to 300.6 (±61.6m) with increase 75 m from baseline distance achieved (33.2% changes). The percentage changes from baseline were higher than 313 (± 72 m) to 392 (± 82 m) with +56 m (21.8% changes); and 256 (± 41 m) to 312 (± 54 m) with +79 m (25.2% changes), respectively, in the previous studies.\textsuperscript{16,29} Although the six minute walking distance in healthy adults has been reported to range from 400 m to 700 m, but an improvement of 54 m has been shown to be clinically important difference.\textsuperscript{30} This supports the current findings that an increment of 75 m following IMT was noted although the distance achieved was less than 400 m.

**Quality of life**
There was a significant improvement in the total score of Saint George's Respiratory Questionnaire (SGRQ) that was used as a tool to measure the quality of life (QOL) with reduction from 60 (± 10.6) to 28 (± 5.6) (p = 0.001), and 52.6% changes from baseline. Previous studies also found significant improvement with 18.1 (± 5.1) to 22.4 (± 5.2), (p < .05), 78.7 to 86.6 (p = 0.001), respectively, although they used Chronic Respiratory Disease Questionnaire (CRQ) as a tool to measure QOL.\textsuperscript{11,27} Whereas studies by Garcia et al.\textsuperscript{31} and Fernández et al.\textsuperscript{29} that have used SGRQ also reported significant improvement with reduction of total score from 58 (±2.2) to 50 (±2.1) (p < 0.05); and 55.3 (± 15.0) to 40.5 (± 13.8) (p = .001), respectively. In QOL summary, the current and previous study shows significant improvement on QOL although most of the previous study used different study methodology.

**Conclusions and Limitations**
This study suggests that combination of IMT with chest physiotherapy treatments for at least 4-week duration can produce benefits for lung function, inspiratory muscle strength, exercise tolerance and quality of life among hospitalized mild to moderate COPD patient. Therefore, the study also would like to recommend either pressure threshold or targeted resistive IMT mode to be used as a part of physiotherapy treatments for treating patients with respiratory conditions especially for COPD.

A few limitations of the study were noted. The study was conducted in the military environment in which the study subjects were among the military and ex-military personnel who has mean age younger than actual non-military COPD patients, history of good physical activity level and body mass index less than 30. The result may be argued if it is to be generalized outside from the military environment. In addition, medications that prescribed by the physician during hospitalization period could also be the confounding factor in the outcomes. Future study may be conducted to compare IMT intervention alone in order to reveal its benefits thus establish the IMT protocol.

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