A Structured Review of Outcome Measures Post Aerobic Training for Chronic Obstructive Pulmonary Disease (COPD) Patients

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Abstract

The purpose of this study was to evaluate the benefits of aerobic training program for patients with COPD in combination with pharmacological treatment through investigation of outcome measures for these patients. Thirty COPD patients with age >50 years old, participated in this study. They were clinically stable COPD, on optimized medical treatment all over the study, patients were randomly divided into two groups of 15 patients for each, study and control group. Patients of study group received hospital-based supervised aerobic training program in addition to medical treatment, while patients of control group received optimized medical treatment only. The exercise program was conducted three times/week for successive 6-8 weeks for the study group patients. Assessment included: Body mass index (BMI), pulmonary function test, modified medical research council (MMRC), six minute walk test (6-MWT), and BODE index were conducted at the starting and at the end of study. Comparing the baseline data with data after treatments, the results showed that: Within the control group, there was a statistically significant improvement in 6-m.w. distance with an increase of 15 meters with non statistically significant difference in Mean ±SD of BMI or spirometric parameters. While within the study group, there was a statistically significant improvement in 6- m w. Distance with an increase of 78 meters and also a significant increase difference in Mean ±SD of FVC% and FEV1/FVC as (85.87±17 vs 73.4±20% and 46.27±12.3 vs 49.2±12.7) with significant improvement in BODE score with greater number of patients who improved within the study group. The present study concluded that short term aerobic training program has the capacity to break the vicious circle of dyspnea, increasing inactivity and exercise intolerance and improve some components of bode index supporting the use of this multi dimensional index to evaluate the effect of training program for COPD patients.

Key Words: Outcome measures – Aerobic training – COPD patients.

Introduction

CHRONIC obstructive pulmonary disease (COPD) is a preventable and treatable disease state characterized by airflow limitation that is not fully reversible. The airflow limitation is usually progressive and is associated with an abnormal inflammatory response of the lungs to noxious particles of gases, primarily caused by cigarette smoking. Patients with COPD typically show a decrease in both FEV1 and FVC. The presence of airflow limitation is defined by a post-bronchodilator FEV1/FVC <0.70. Assessment of COPD severity is based on the patient’s level of symptoms, the severity of the spirometric abnormality, and the presence of complications such as respiratory failure, right heart failure, weight loss, and arterial hypoxemia [1].

Recent COPD guidelines such as GOLD (Global Initiative for Chronic Obstructive Pulmonary Disease), NICE (National Institute for Health and Clinical Excellence) and BTS (British Thoracic Society) underline the importance of pulmonary rehabilitation (PR) as a part of an integrative multidisciplinary approach regardless the stage of disease [2].

The American Thoracic Society and the European Respiratory Society have recently adopted the following definition of pulmonary rehabilitation: Pulmonary rehabilitation is an evidence-based multidisciplinary, and comprehensive intervention for patients with chronic respiratory diseases who are symptomatic and often have decreased daily life activities. Integrated into the individualized treatment of the patient, pulmonary rehabilitation is designed to reduce symptoms, optimize functional status, increase participation, and reduce health care costs through stabilizing or reversing systemic manifestations of the disease [3].

One of the important functions of pulmonary rehabilitation is to help selection of appropriate patients for surgery and to ensure that patients
make a truly informed choice about treatment options. Some patients may improve sufficiently after rehabilitation and choose to defer or delay the decision to pursue surgical options [4].

Pulmonary rehabilitation programs monitor outcomes partly as indicators of performance and to ensure quality, but also because many third-party payers now require such assessments to qualify for reimbursement [5,6].

Outcome measures usually include a functional assessment. Many programs use the 6-min walk test or the 10-m shuttle test. Both are widely applied tests of functional endurance that are of prognostic value. The shuttle walk test is an incremental test, but both it and the 6-min walk test are effort-dependent and subject to non respiratory limitations such as weakness, pain, or arthritis [6-8].

Some programs perform maximal cardiopulmonary exercise tests that test maximal capacity rather than endurance. These tests are usually combined with a dyspnea assessment as a rough gauge of effort, such as the Borg score or rating on a visual analog scale. Many programs also use dyspnea scales such as the Baseline and Transitional Dyspnea indices that assess dyspnea as related to function, effort, and task [9,6]. In addition, most programs use questionnaires to assess overall quality of life (or health status). The Short Form-36 is a commonly used proprietary instrument that tests overall health status. Disease-specific questionnaires such as the St. George's Respiratory Questionnaire (SGRQ) [6,10], or the Chronic Respiratory Disease Questionnaire (CRQ) are also commonly used [5,6].

A composite index has recently been described that combines body mass index (B), severity of airway obstruction (O), dyspnea index (D), and exercise capacity (E) (BODE index) and correlates with prognosis of patients with COPD [11,6].

The aim of this study was to evaluate the benefits of Outpatient Hospital-Based Exercise Program in addition to pharmacological treatment for patients with COPD using several validated methods to measure outcome as 6 MWT, MRC dyspnea score, BODE index and pulmonary function tests.

Patients and Methods

Thirty COPD patients presenting to Critical Care Department Kasr El-Aini Hospital during 2011-2012. All patients are ≥50 years of age; ≥10 pack-year history of cigarette smoking, they are clinically stable COPD (not suffering from a recent respiratory tract infection). The selected patients on Optimized medical therapy according to Global Initiative for Chronic Obstructive Lung Disease [12], and had not been engaged in any exercise-training program before participating in the study [13]. Patients with Other chronic diseases that may contribute to exercise limitation such as: Cardiac, renal, and liver diseases, metabolic, mental and neurological disorders were excluded from the study. Malignancies and those with Chronic hypoxemia at rest requiring continuous oxygen support (PaO₂<7.3kPa), those with Lack of motivation, Non-adherence were also excluded. Participants in the study were divided into two groups: Group I (Control group): 15 patients on medical treatment including short-acting bronchodilators, methyl-xanthines, sometimes inhaled short acting B2-agonist; inhaled glucocortico steroid combined with a short acting B2-agonist or inhaled short acting anticholinergic combined with short acting B2-agonist. Group II (Training group): 15 patients subjected to hospital based supervised aerobic training program in addition to medical treatment. All patients subjected to: Full history taking including medical and smoking history, clinical examination and Plain Chest X-ray (P-A view). Baseline & post study body mass index, Pulmonary function test: (Flow/volume loop ) using body plethysmography with highly transparent box; Sensor-medics V max series, 2130 Spirometer, V6200 Autobox, 6200DL, Six-Min Walk Test using Electrical treadmill (Schiller Quinton 4000) that has no inclination and BODE index were assessed.

Methods:

1- The body mass index (BMI), or Quetelet index: It is defined as the individual's body mass divided by the square of his height-with the value universally being given in units of kg/m² [14].

2- Pulmonary function test: (Flow/volume loop): Spirometry indices are reported comparing the individual’s value along with the predicted values [15]. The Forced vital capacity (FVC), the forced expiratory volume in the first second (FEV1), the ratio of FEV1 to FVC and the average of forced expiratory flow at 25-75% of forced vital capacity (FEF 25-75%) were measured. The presence of a post bronchodilator FEV1 <80% predicatd togeth- er with an FEV1/FVC <0.70 confirm the presence of airflow limitation that is not fully reversible [14]. Bronchodilator Reversibility Tests: Reversible airway obstruction characterized by increase in FEV1 that is both greater than 200ml (absolute change) and 12% (% change) above the pre-bronchodilator FEV1 is considered significant [1].
3- Modified medical research council: MMRC dyspnea questionnaire for assessing the severity of breathlessness [1].

4- Treadmill six-minute walk test: Use of a treadmill to determine the 6MWD allow constant monitoring during the exercise. Standardized instructions and encouragement similar to those for the corridor walk were given, according to ATS guidelines [16]. Patients were instructed to walk “as far as possible” during the time that is, as fast as possible. They were told that they could slow down or even stop if necessary. There was no warming up before test. The initial treadmill speed was zero, and the test began when treadmill activated and the patient started walking. The patient controlled the treadmill speed during the test and could stop to rest at any time, as in the hallway test. Before, during, or after treadmill walk test, the walk testing was discontinued if the patient had thoracic pain, intolerable dyspnea, cramps, dizziness, staggering, diaphoresis, pallor, or an SpO2 <90% [16].

5- BODE index: Variables and point values used in the BODE index [11]. Table (1).

<table>
<thead>
<tr>
<th>Variable</th>
<th>BODE score</th>
</tr>
</thead>
<tbody>
<tr>
<td>≥350</td>
<td>0</td>
</tr>
<tr>
<td>250-349</td>
<td>1</td>
</tr>
<tr>
<td>150-249</td>
<td>2</td>
</tr>
<tr>
<td>≤149</td>
<td>3</td>
</tr>
</tbody>
</table>

(N.B): All the previous measurements were done for all patients before and at the end of the study.

6- Exercise Prescription: An Outpatient Hospital-Based Exercise Program for a period of 8 weeks of aerobic training as graduated treadmill exercises was initiated upon the results of the exercise testing, so the exercise prescription was individually designed. Frequency of sessions: 3 times per week that are equally spaced throughout the week. Regular supervision of exercise sessions: Aiming to achieve optimal physiologic benefits. Duration of each session: 20-30 minutes. Intensity of exercise: An adequate training intensity for endurance conditioning usually targeted 70%-85% of the individually determined maximal heart rate [17]. The maximal heart rate can be estimated from the formula (220 minus age) [18]. The exercise session was subdivided into: Warm up phase: 5-10min of both light muscular stretching & inspiratory muscle training to avoid muscle strains and injuries. Exercise phase: 9-13min. Of treadmill exercise using Electrical treadmill (Schiller Quinton 4000) with different speeds & inclination grades. Cool down phase: This relaxation period after the exercise session ensures that body not experience any muscular problems. It includes 5-7min. Of continued exercise with a speed 1km/h with inclination grade 0.0%.

Progression of exercise includes:

• First week of training should be at 60-70% of the individually determined maximum heart rate to allow for the development of motor skills and musculoskeletal conditioning.

• As patient’s tolerance for exercise improved, the duration of walking increase gradually and the target is increased by 5-10% of the maximum heart rate.

• After 4 weeks of training, exercise intensity achieves a level of 80% of maximum heart rate, as it was increased gradually every 2 weeks.

Statistical analysis:

Data were statistically described in terms of Mean±Standard deviation (±SD), median and range. Comparison between the both groups was done using Student t-test for independent samples. Within group comparison was done using paired t-test. p-values less than 0.05 was considered statistically significant. All statistical calculations were done using computer program SPSS (Statistical Package for the Social Science; SPSS Inc., Chicago, IL, USA) version 15 for Microsoft Windows.

Results

When compare baseline data with data after 8 weeks within each group it showed that: Within control group, there was a statistically significant improvement in 6MWD with an increase of 15 meters while no statistically significant difference in the Mean±SD of BMI and spirometric data as shown in Table (2). While training group: There was a statistically significant improvement in 6MWD with an increase of 78 meters and also a significant increase in the Mean±SD of FVC% and FEV1/FVC with no statistically significant in the Mean±SD of BMI and other spirometric data as shown in Table (3). As regards BODE index: Within both control and study group there was a statistically significant improvement in BODE score as shown in Tables (4,6), with greater number of
patients improved within study group as shown in Tables (5,7).

When compare characteristics between control and study groups after training program: There was a statistically significant improvement in the Mean±SD of FEV1& FVC% and 6MWD of study group higher than control group after training program as shown in Table (8). As regards BODE index, there was a statistically significant improvement in Mean±SD of BODE index of study group more than control group after training program as shown in Table (9).

Table (2): BMI, Functional characteristics in control group baseline and after 6-8 weeks of medical treatment.

<table>
<thead>
<tr>
<th>Characteristics within control group (n=15)</th>
<th>Baseline data</th>
<th>After 6-8 weeks of medical treatment</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m²) Mean±SD</td>
<td>25.75±5.09</td>
<td>25.72±5.11</td>
<td>0.317</td>
</tr>
<tr>
<td>FVC% Mean±SD</td>
<td>62.27±9.86</td>
<td>60.87±20.31</td>
<td>0.581</td>
</tr>
<tr>
<td>FEV1 Mean±SD</td>
<td>34.80±14.05</td>
<td>34.67±13.70</td>
<td>0.788</td>
</tr>
<tr>
<td>FEV1/FVC% Mean±SD</td>
<td>47.66±8.30</td>
<td>47.77±11.18</td>
<td>0.125</td>
</tr>
<tr>
<td>FEF25-75% Mean±SD</td>
<td>11.87±6.73</td>
<td>12.20±6.95</td>
<td>0.875</td>
</tr>
<tr>
<td>6min walk Distance (in meters) Mean±SD</td>
<td>36.07±7.88</td>
<td>51.40±19.98</td>
<td>0.002*</td>
</tr>
</tbody>
</table>

*p-value<0.05 statistically significant

BODE: The body-mass index (B), degree of airflow obstruction (O), functional dyspnea (D) and exercise capacity (E).

Table (3): BMI, Functional characteristics in study group baseline and after 6-8 weeks of aerobic training program.

<table>
<thead>
<tr>
<th>Characteristics within aerobic group (n=15)</th>
<th>Baseline data</th>
<th>After 6-8 weeks of training program</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m²) Mean±SD</td>
<td>25.54±3.93</td>
<td>25.54±3.93</td>
<td>1.00</td>
</tr>
<tr>
<td>FVC% Mean±SD</td>
<td>73.40±20.70</td>
<td>85.87±17.01</td>
<td>0.001*</td>
</tr>
<tr>
<td>FEV1% Mean±SD</td>
<td>48.40±20.95</td>
<td>51.00±18.97</td>
<td>0.127</td>
</tr>
<tr>
<td>FEV1/FVC% Mean±SD</td>
<td>49.20±12.69</td>
<td>46.27±12.29</td>
<td>0.033*</td>
</tr>
<tr>
<td>FEF25-75% Mean±SD</td>
<td>24.40±19.62</td>
<td>24.33±19.56</td>
<td>0.972</td>
</tr>
<tr>
<td>6min walk Distance (in meters) Mean±SD</td>
<td>41.53±9.55</td>
<td>119.53±27.39</td>
<td>0.001*</td>
</tr>
</tbody>
</table>

*p-value<0.05 statistically significant.

Table (4): BODE index in control group baseline and after 6-8 weeks of medical treatment.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Baseline</th>
<th>After 6-8 weeks of medical treatment</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BODE index Mean±SD</td>
<td>7.07±1.33</td>
<td>6.47±1.41</td>
<td>0.000*</td>
</tr>
</tbody>
</table>

*p-value<0.05 statistically significant.

BODE: The body-mass index (B), degree of airflow obstruction (O), functional dyspnea (D) and exercise capacity (E).

Table (5): Change in BODE index after 6-8 weeks of medical treatment.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Change in BODE index</th>
<th>Improved*</th>
<th>Not improved</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (% within the group)</td>
<td>9 (60%)</td>
<td>6 (40%)</td>
<td></td>
</tr>
</tbody>
</table>

*p-value<0.05 statistically significant.

BODE: The body-mass index (B), degree of airflow obstruction (O), functional dyspnea (D) and exercise capacity (E).

Table (6): BODE index in study group baseline and after 6-8 weeks of training program.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>BODE index Mean±SD</th>
<th>Baseline</th>
<th>After 6-8 weeks of training program</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BODE index (n=15)</td>
<td>6.80±1.32</td>
<td>5.00±1.73</td>
<td>0.001*</td>
<td></td>
</tr>
</tbody>
</table>

*p-value<0.05 statistically significant.

BODE: The body-mass index (B), degree of airflow obstruction (O), functional dyspnea (D) and exercise capacity (E).

Table (7): Change in BODE index after 6-8 weeks of study training program.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Change in BODE index</th>
<th>Improved*</th>
<th>Not improved</th>
</tr>
</thead>
<tbody>
<tr>
<td>n (% within the group)</td>
<td>13 (86.6%)</td>
<td>2 (13.33%)</td>
<td></td>
</tr>
</tbody>
</table>

*p-value<0.05 statistically significant.

BODE: The body-mass index (B), degree of airflow obstruction (O), functional dyspnea (D) and exercise capacity (E).

Table (8): Comparison of BMI, functional characteristics between control and study Group after 6-8 weeks of training program.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>Control group (n=15)</th>
<th>Aerobic group (n=15)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BMI (kg/m²) Mean±SD</td>
<td>25.72±5.11</td>
<td>25.54±3.93</td>
<td>0.66</td>
</tr>
<tr>
<td>FVC% Mean±SD</td>
<td>60.87±20.31</td>
<td>85.87±17.01</td>
<td>0.002*</td>
</tr>
<tr>
<td>FEV1% Mean±SD</td>
<td>34.67±13.70</td>
<td>51.00±18.97</td>
<td>0.006*</td>
</tr>
<tr>
<td>FEF25-75% Mean±SD</td>
<td>12.20±6.95</td>
<td>24.33±19.56</td>
<td>0.065</td>
</tr>
<tr>
<td>6min walk Distance (in meters) Mean±SD</td>
<td>51.40±19.98</td>
<td>119.53±27.39</td>
<td>0.000*</td>
</tr>
</tbody>
</table>

*p-value<0.05 statistically significant.

BODE: The body-mass index (B), degree of airflow obstruction (O), functional dyspnea (D) and exercise capacity (E).

Table (9): Comparison of BODE index between control and study group after 6-8 weeks of training program.

<table>
<thead>
<tr>
<th>Characteristic</th>
<th>BODE index Mean±SD</th>
<th>Control group (n=15)</th>
<th>Aerobic group (n=15)</th>
<th>p value</th>
</tr>
</thead>
<tbody>
<tr>
<td>BODE index after 6-8 weeks of training program</td>
<td>6.47±1.41</td>
<td>5.00±1.73</td>
<td>0.017*</td>
<td></td>
</tr>
</tbody>
</table>

*p-value<0.05 statistically significant.

BODE: The body-mass index (B), degree of airflow obstruction (O), functional dyspnea (D) and exercise capacity (E).
Control group Aerobic group

Discussion

The quality of life for a person suffering from COPD diminishes as the disease progresses. American Lung Association (ALA) survey revealed that half of all COPD patients (51%) say their condition limits their ability to work. It also limits them in normal physical exertion (70%), household chores (56%), social activities (53%), sleeping (50%), and family activities (46%). According to an ALA survey, at least half of COPD patients are expected to benefit from rehabilitation [19].

This study was designed to evaluate benefits of Outpatient Hospital-Based Exercise Program for people with COPD, as a non-pharmacological treatment method, using several validated instruments to measure outcomes after Pulmonary rehabilitation as, 6 MWT, MRC dyspnea score, BODE index and pulmonary function tests. While previous studies had established the efficacy of pulmonary rehabilitation for COPD: A randomized controlled trial by Griffiths et al., [20] showed that, an outpatient pulmonary rehabilitation program was cost-effective and was likely to result in financial benefit to the health service. Kozora et al., [21], found reductions in patients with COPD with anxiety and depression after pulmonary rehabilitation compared with matched control subjects.

To clarify the effect of aerobic training, the present study conducted a training program of 6-8 weeks. Most previous studies were fully consistent with this. Green et al., [22] who compared 4 weeks with 7 weeks of rehabilitation and concluded that 4 weeks of rehabilitation was less effective. While Sneed & Paul et al., [23] found that longer rehabilitation programs (6 months or longer) yield significantly greater effects, concluded that although measurable physiological changes may occur within weeks, behavioral changes may require longer time periods.

The present study implemented moderate to high intensity training program that targeted 80-85% of the individually determined maximal heart rate in-order to maximize the training effects. Initially the intensity should be at 60-70% for the first 3-4 sessions. As patient’s tolerance for exercise improved, the duration of walking increase gradually and the target is increased by 5-10% of the maximum heart rate. After 4 weeks of training, exercise intensity achieve a level of 80% of maximum heart rate. Similarly Gimenez et al., [24] confirmed that high training intensity is required to elicit physiologic training effects. While pervious studies were not fully consistent with this, Clark and colleagues [25] examined the efficacy of low-intensity isotonic exercises of the upper and lower extremities performed at home in a group of 40 patients with COPD. They demonstrated a dramatic improvement in treadmill walking time and suggested that their program would be applicable in patients with COPD with a wide range of functional defects.

The present study demonstrated that short term aerobic training program (6-8 weeks) didn’t show a statistically significant improvement in BMI due to while Stav and co-workers [26], found that prolonged pulmonary rehabilitation program (three years) may improve BMI. Measurement of BMI may not accurately reflect changes in body composition in these patients and that measurement of FFM (fat free mass) may be required to estimate body cell mass [27].

The present study showed that, there was a statistically significant improvement of both FEV 1 & FVC physiological parameters of study group
when compared with control group. Gohar [28], was fully consistent with this, he found that there was a significant improvement of both FVC and FEV 1 parameters in COPD patients undergo lower limb exercise for 6 weeks. While Stav and co-workers [26], demonstrated that outpatient prolonged pulmonary rehabilitation program (three years) didn’t improved FEV1, but has an important beneficial impact on the rate of FEV 1 decline. In addition, it increased endurance time and work. As the result PR should be considered as a disease modifier [29].

The present study showed that 6MWD increased by 78 meters after 6-8 weeks of aerobic training program. This improvement was statistically significant. Redelmeir et al., [30] suggested that the minimal clinically meaningful increase in the 6MWD is about 54 meters. While De-Torres et al., [31] demonstrated that the mean improvement in 6MWD was 65m after 6-8 weeks of PR. Other study noted an increase of 78.41m in 6MWD after six months of outpatient and home-based program [32].

The present study used BODE index to evaluate the effect of aerobic training. It demonstrated that 13 patients or 86.6% showed a statistically significant improvement in BODE score after 6-8 weeks of training program in contrast, control group showed 9 patients or 60% improvement after 6-8 weeks of optimal medical treatment. This finding supports the use of this multi-dimensional index to evaluate the effects of pulmonary rehabilitation, as has been in study done by Cote & Celli [33].

Although PR has minimal effect on lung function, it improves dyspnoea [34], exercise capacity, and healthcare resource utilization [35]. Two of these outcomes, dyspnoea and exercise capacity, are components of the BODE index. As such, the BODE index could be used to evaluate the effect of PR. For this Cote & Celli [33]. Defined one unit change in BODE as being clinically significant, because it implies a change in any of its component of a magnitude large enough to influence clinical outcomes. Indeed, one unit change in the Modified Medical Research Council scale predicts mortality [36]. Likewise, one unit change in the 6MWD in the BODE score far exceeds the 50m considered to be clinically significant changes for this test [30]. Similarly, one unit change in the FEV1 component of the BODE index reflects the thresholds that have been accepted by the ATS/European Respiratory Society and Global Initiative for Chronic Obstructive Lung Disease (GOLD) as the basis for the physiological staging of COPD [37,38].

In conclusion the present study found that short-term aerobic training program has the capacity to: Break out the vicious circle of dyspnea, increasing inactivity and exercise intolerance—the hallmark features of COPD patients and improve some components of BODE index supporting the use of this multi-dimensional index to evaluate the effects of pulmonary rehabilitation. This findings suggested that even if the program duration does not exceed 8 weeks, it can still benefit patients with COPD. Further studies are needed to compare the responsiveness of used outcome measures after pulmonary rehabilitation, detect the best practical tools to evaluate the responsiveness to PR, and to detect the best predictor of survival following pulmonary rehabilitation.

References


