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Original Article

IMPROVING FUNCTIONAL CAPACITY AND QUALITY OF LIFE WITH COMPREHENSIVE PULMONARY REHABILITATION IN PATIENT WITH COPD

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ABSTRACT

Objective: To evaluate the effects of short – term comprehensive pulmonary rehabilitation program in improving Exercise Capacity & Quality of Life in patients with severe COPD.

To compare effectiveness of comprehensive pulmonary rehabilitation over education based program in patients with severe COPD.

Method: 14 Subjects in group A with mean age 60.64±3.23 received comprehensive pulmonary rehabilitation with education based program and 15Subjects in group B with mean age 60.64±3.09 received education program for 5days per week for 4weeks. The outcome was measured in terms of 6MWT and CRQ.

Result: Unpaired student t-test and paired t-test was used for statistical analysis. Statistically significant improvement in 6MWT and the quality of life measures found in group A than group B.

Conclusion: Short-term Comprehensive pulmonary rehabilitation program will be more effective than education based program in patients with severe COPD

KEY WORDS: 6MWT (six minute walk test), CRQ (chronic respiratory questionnaire), Borg Scale.

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INTRODUCTION

Chronic Obstructive Pulmonary Disease (COPD) is the major cause of chronic morbidity & mortality throughout the world [1,2]. Pathogenesis and clinical manifestation of COPD are restricted to pulmonary inflammation & structural remodeling. As in other inflammatory conditions, weight loss, peripheral muscle deconditioning & tissue depletion are commonly seen in COPD patients [3]. Peripheral muscle deconditioning causes the production of lactic acidosis at lower work rates & increases ventilatory requirements during exercise. This causes a mismatch between ventilatory capacity & ventilatory demand which leads to increased perception of dyspnea & exercise intolerance [4]. The sequel of exercise intolerance include impairment in exercise capacity, health related quality of life (HRQOL) & participation in daily activities. The characteristic symptoms of COPD are chronic and progressive dyspnea, cough and sputum production [5,6].

Pulmonary Rehabilitation is a restorative & Preventive process for patients with chronic respiratory disease &, to control symptoms, optimize functional capacity & reduce the economic and medical burden of patients with

disabling chronic disease [2,7,8]. In a systematic review of pulmonary rehabilitation for COPD published in Cochrane database 2006, author's concluded that rehabilitation relieves dyspnea and fatigue, improves emotional function and enhances patient's sense of control over their condition [9,10].

The exercise training over extremity improves aerobic capacity of skeletal muscles. This improvement in aerobic capacity increases the maximal oxygen uptake by skeletal muscles during exercise and decreases the production of lactic acidosis at lower work rates. There is a reduction in ventilatory demand during exercise, which reduces the perception of exercise related dyspnea and increases the mechanical efficiency of muscles in COPD patients [11].

However, beneficial effects of short term comprehensive rehabilitation have been poorly documented and also minimum duration of exercise training in pulmonary rehabilitation has not been extensively investigated [8]. So this study has been designed to investigate the beneficial effects of short term comprehensive pulmonary rehabilitation in improving exercise capacity & Quality of Life in patients with severe COPD.

Aim and Objective: To evaluate the effects of short – term comprehensive pulmonary rehabilitation program in improving Exercise Capacity & Quality of Life in patients with severe COPD and To compare effectiveness of comprehensive pulmonary rehabilitation over education based program in patients with severe COPD.

Purpose of the Study: To evaluate the effects of short term pulmonary rehabilitation in improving exercise capacity in terms of distance walked in 6 minutes & Quality of Life by using Chronic Respiratory Questionnaire (Self Administered Standardized Format).

Operational Definitions:

Cycle Ergo meter: It is used as a mode of exercise in cardiopulmonary exercise testing and rehabilitation of individuals with cardiopulmonary disorders.

Cardiopulmonary Exercise Testing (CPET): It provides a global assessment of the integrative exercise responses involving the pulmonary, cardiovascular, hematopoietic, neuropsychological and skeletal muscle systems, which are not adequately reflected through the measurement of the individual organ system. This relatively noninvasive, dynamic physiologic overview permits the evaluation of both sub maximal and peak exercise responses, thus providing the physician with relevant information in clinical decision making.

Quality of life: Health related quality of life (HRQOL) focuses on those areas of life that are affected by health status, and reflects the impact of respiratory disease (including co morbidities and treatment) on the ability to perform or enjoy activities of daily living. Research has consistently demonstrated that COPD impairs HRQOL. CRQ(chronic respiratory disease questionnaire) [5,6] is a reliable quality – of – life (QOL) instrument developed specifically for use with COPD patients.

COPD Management: Assessment and monitoring: Clinical Assessment: It is based on medical history and physical examination. 6MWT, CEPT, Reduction of risk factors, Disease Management: medications and Pulmonary rehabilitation.

According to ATS guidelines 2006, the essential components of pulmonary rehabilitation include: 1. Education, 2. Nutrition, 3. Psychosocial counseling and 4. Exercise training.

METERIALS AND METHODS

Design: The study was designed as an Experimental design consisted of two parallel Groups – Group A & Group B. Group A received comprehensive pulmonary rehabilitation program while Group B received Education based program.

Sample: Thirty subjects with stable severe COPD were recruited. After the approval from the physician and were included in the study after getting the informed consent . The diagnosis of COPD was made according to the Global Initiative for chronic obstructive lung disease (GOLD) diagnostic criteria [12].

Inclusion Criteria: Clinical diagnosis of severe COPD, (Gold staging criteria 4 – FEV_1 / FVC

< 70%, 30% ≤ FEV_1 < 50% predicted), Age group 55 – 65 years, An optimal bronchodilator therapy and clinically stable defined by no change in medication dosage or frequency of administration with no exacerbations or hospital admission in the preceding 4 weeks, No other significant disabling lung disease, serious heart problems or other medical condition that would interfere with the patient participation, Declared smoking cessation at least 6 months before enrolling and No participation in pulmonary rehabilitation program in the previous 6 months.

Exclusion criteria: Presence of any significant comorbid disease that might interfere with rehabilitation process and place the patient at undue risk for exercise training, Emphysema or large bullae seen on MRI / CT scan, Long term steroid therapy, Poor ability to comprehend and participate in the educational aspects of the program, Diagnosis of Diabetes or glucose intolerance and no oxygen desaturation to less than 85% during exercise testing on room air

Instrumentation: Equipment: electronically braked cycle ergo meter. (Cosmed bike – Ergo line), Pulse oxymeter, Free weights, Weighing machine, Stethoscope, Fixed height scale, Sphygmomanometer, Countdown timer and Space and facilities were Chest and heart hospital & Associates Gymnasium.

Procedure: Before participation, all subjects received verbal explanation of the purpose, risk, benefits and procedure of the study. Prior to initiation of the program, all patients had their condition evaluated. The initial evaluation included the following: A full history, Physical examination, Exercise capacity by 6 MWD and Quality of life by chronic respiratory disease questionnaire. Then they were randomly assigned to participate in either the Comprehensive pulmonary rehabilitation program (Group B).

Pulmonary rehabilitation program (Group A): After initial evaluation, a multidisciplinary team assessed each patient and an individual rehabilitation plan was formulated.

Protocol for Pulmonary Rehabilitation: Subjects participants in an outpatient pulmonary rehabilitation program 5 days per week for 4 weeks.

Comprehensive rehabilitation plan includes:

1. Education [13]: Subjects were encouraged to attend group classes which included discussion for the following topics: Understanding COPD, self management of COPD, respiratory medications, breathing techniques, coping with stress techniques, importance of regular exercise, when to call a doctor, controlled coughing techniques, how to prevent flare ups, energy conservation techniques and self care tips, oxygen therapy and sexuality. Classes and reading material were used to teach and enhance problem solving. Patients were provided ample opportunity to ask questions and raise concerns related to their lung disease and disability. Hand – outs covering all the topics were given to all subjects which provided valuable information regarding the topics taught.

2. Dietary Assessment and advice [14]: Subjects were assessed by senior dietician. Each subject's body mass index (BMI) and dietary history were assessed. They were encouraged to take small but frequent meals. Sufficient information was given regarding high calorie,protein and fiber rich food, tips to avoid getting short of breath while eating or right after meal, tips for improving appetite, meal , snack & dinning guidelines, alcohol guidelines and tips for gaining weight. Progress in any advised change in eating habits was assessed every week.

3. Psychological support: Patients met in weekly group sessions facilitated by a psychiatrist. Spouses or partners of patients were encouraged to attend. Sessions focused on difficulties commonly faced by patients such as depression, anxiety, fear and family or social problems. Relaxation techniques were introduced to help patients better cope up with the emotional stress of dyspnea.

4. Supervised exercise training: Exercise plan was formulated on the basis of graded cardiopulmonary exercise testing.

Cardiopulmonary Exercise Testing [15]: An incremental symptom – limited exercise test was performed on an electronically braked cycle ergometer to determine the maximal work capacity of each patient. After a 2 min acclimatization period and two minute of pedaling

at 0 watt, the load was increased by 10 watts in every 30 seconds. Patients were instructed to maintain a speed of 60 rpm and to continue cycling until the subject could no longer continue. The last workload for which a subject was able to complete30 seconds of cycling was designated as the maximal work capacity (W_{max}). Modified Borg scale [16] was used to measure symptom of dyspnea and fatigue during the exercise test.

Endurance Training [17]: Before initiation of each training session, each patient was given 5 minutes of warm – up. On the cycle ergometer, patient exercised at 50% of the peak exercise capacity (W_{max}) achieved during the maximal incremental exercise test. Amount of work done in each session was kept constant until the patient could sustain it for 20 minutes. The exercise prescription was revised on a weekly basis and once the patient could exercise at the prescribed work level for 20 min., the work rate was increased by 10%. Patients exercised at a steady level for virtually the entire20 min and this was followed by a 5 minutes of cool – down period. During exercise, heart rate, Blood Pressure, SPO_2 and Borg scale for dyspnea and fatigue were monitored.

Strength Training [8]: The strength training program included following exercise which was performed by lifting weights using gymnastic apparatus:

a. Knee flexion involving predominantly Hamstrings Muscle.

b. Knee flexion involving predominantly Quadriceps muscle.

c. Chest press involving predominantly Pectoralis Major.

d. Combined movement of shoulder abduction and elbow flexion primarily involving Lattisimus Dorsi.

Patients started at 60% of the initial one repetition maximum (1 R.M. – The maximum load which can be moved only once over the full range of motion without compensatory movements) in the first week and performed 2 sets of 10 repetitions. This was gradually increased to 3 sets of 10 repetitions. This test was repeated each 2 weeks for new adjustments of the workload.

When the patients were able to perform three sets without undue difficulty, load was increased by 5% of the 1 R. M. Stretching of Hamstrings, Quadriceps, Shoulder and Neck was performed after the exercise session.

Criteria for Exercise Termination: Chest pain suggestive of ischemia, Fall in systolic pressure > 20mm Hg from the highest value during the test, Hypertension (> 250mm Hg systolic, >120mm Hg diastolic), Severe desaturation : $SpO_2 \leq 85\%$ when accompanied by symptoms & signs of hypoxemia, Sudden pallor, Loss of coordination, Mental confusion, Dizziness or faintness and Signs of respiratory failure.

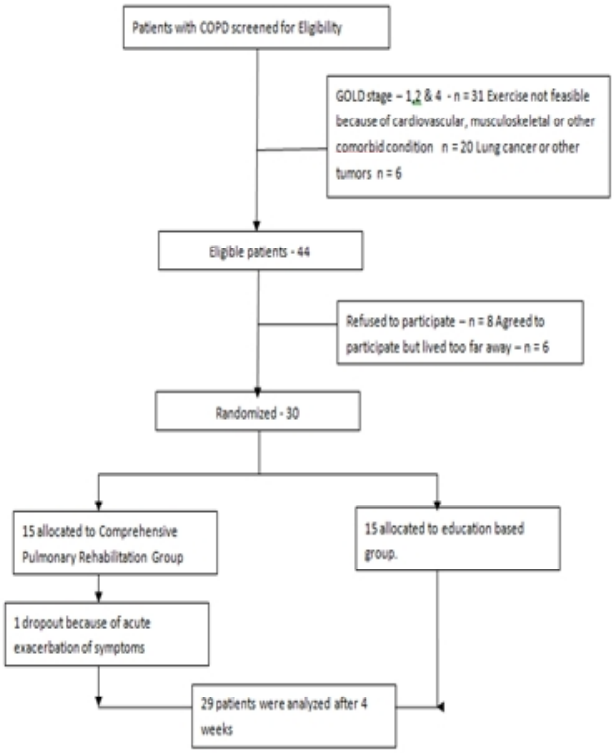
Education based Program (Group B): The goal of the education program was to conduct a series of health education classes that would provide the information and will include topics similar to that provided in the Group A, but in shorter and less intensive manner without the individualized instruction, and supervised exercise training. Patients in the education group attended 1 hour session scheduled weekly for 4 weeks. Hand – outs covering all the topics were given to all subjects that provides the valuable information regarding the topics taught. Nutritional and psychological intervention was same as given in group A.

Outcome Measures:

Functional Capacity: It was assessed using the 6 Minute Walk Test according to the ATS Gudelines [17]. Test was performed indoors, along a long, flat, straight enclosed corridor which was 30 m in length. Patients were instructed to walk as far as possible during the test and to give best effort. A therapist kept time and counted laps but did not walk along with patients. The test was carried out using the standardized conditions to ensure consistency in encouragement and subject motivation as after test. Two practice 6 min walk preceded a third walk to avoid any learning effect and the result of third walk was used for analysis, H. R., B. P., SPO_2 and Borg scale of dyspnea and Fatigue were recorded before the test, immediately after and 5 minutes after the completion of the test. 6 minute walk test was done at entry and after the completion of 4 weeks of program for both the groups.

Health related quality of life: This was assessed using the CRQ [17,18], a 20 item elf administered questionnaire that was designed for patients with COPD. Each question was rated by the patient using a 7 – point Likert scale, with lower scales indicating greater impairment in health status. The CRQ measures both physical and emotional function. Physical function was investigated by 5 items related to dyspnea and 4 items related to fatigue. Assessment of emotional function addressed both emotional state and self perception of mastery including question about frustration, depression, anxiety, panic and fear of dyspnea. The CRQ correlates with disease severity, and has been demonstrated to improve after pulmonary rehabilitation [8]. Questionnaires were administered at entry and after completion of 4 weeks of rehabilitation program for both the groups.

Fig. 1: Flow diagram of subject progress throughout the COPD study.



Data Collection: All the variables i.e. distance covered during six minute walk test and individual domains of Chronic Respiratory Disease Questionnaire were assessed at baseline and after 4 weeks of training program, for both the groups by the research student.

STATISTICAL ANALYSIS: A statistical software Package called SPSS10 was utilized for analysis of data. The values are reported as mean ± standard deviation. Unpaired student t – test was used to compare between group difference for all the dependant variables and paired t – test was used to analyze within group differences. Difference between the subject factor was grouped. (Group A – Comprehensive Pulmonary Rehabilitation program, Group B Education Based Program) and with a group subject factor was time. Readings were taken at two levels (Baseline and after 4 weeks) for all the dependant variables. Level of significance of $P < .05$ was set.

RESULTS AND TABLES

Table 1: Patient characteristics Demographic data:

Variables	Group A (n = 14)	Group B (n = 15)
	Mean ± Std. Deviation	Mean ± Std. Deviation
Age (Years)	60.64 ± 3.23	60.47 ± 3.09
BMI (Kg / cm^2)	20.15 ± 1.24	20.11 ± 1.09
Male : Female	12:02	12:03
FEV_1 (%age predicted)	38.96 ± 5.56	38.46 ± 3.52
FVC (%age predicted)	81.16 ± 6.26	80.76 ± 7.47
FEV_1 /FVC	48.34 ± 6.28	47.73 ± 3.87
6 MWD (m) (Baseline)	266.71 ± 18.88	264.47 ± 13.59
Total CRQ (Baseline)	9.50 ± .66	9.52 ± 1.01

Compliance during the program: Patients in both the group adhered to the training program. Compliance during the pulmonary rehabilitation program was excellent as patient in this group missed on an average only one of the 20 sessions. Any session missed were made up at the end of 4 week of program to ensure that all the subjects completed 20 sessions of training,

Changes in Six Minute Walk Test: At baseline, six minute walk distance was not significantly different between the groups. The baseline and post training values for both the groups are given in table 1.2. On within the group analysis, improvement in 6MWD was substantial for both the groups. Patient in the pulmonary rehabilitation group showed statistically significant improvement in 6 MWD with a mean improvement of 38.21 m. (t – value = 30.57, $p < 0.05$). However, subjects in the education based program also showed statistically significant

improvement with a mean improvement of 9.4m. (t – value = 13.30, p < 0.05).

Table 2: Comparison of mean values of 6 MWD at baseline and after training with in Group A (N = 14) and Group B (N = 15) – Paired t – test.

Groups	Baseline		After Training		t – value
	Mean	Standard Deviation	Mean	Standard Deviation	
A	266.71	18.88	304.93	23.26	30.57*
B	264.87	13.59	273.87	16.06	12.78*

NS – Not significant, * - Significant at the level of .05

On comparison between the groups (Table 3), there is a significant difference between Group A and Group B. Group A experienced clinically and statistically significant higher improvement in the six minute walk distance as compared to Group B (with p < 0.05).

Table 3: Comparison of Mean Values of 6 MWD at baseline and after 4 weeks of training between Group A and Group B.

6 MWD	Group A (n = 14)	Group B (n = 15)	t - Value
	Mean ± Std. Dev.	Mean ± Std. Dev.	
Baseline	266.71 ± 18.88	264.47 ± 13.59	.37$^{N.S.}$
After 4 weeks	304.93 ± 23.26	273.87 ± 16.06	4.21*

NS – Not significant, * - Significant at the level of .05

Quality of Life Measures: The quality of life, Chronic Respiratory Questionnaire was used in which results are expressed as scores. With in Group A (Table 4), there is clinically as well as statistically significant improvement in total score as well as in individual domains (t = 24.56, p < 0.05), with all the domain exceeding the minimal clinically important difference of 0.5. However, within Group B (Table 5), there is statistically significant improvement in Dyspnea (t = 16.32, p < 0.05) and Fatigue domain (t = 11.90, p < 0.05) but an insignificant improvement in emotion (t = 9.89, p > 0.05) and mastery (t = 13.48, p > 0.05) domain of. Minimal clinical important threshold of 0.5 has not been reached in any of the domain within Group B. So, improvement in CRQ score within group B is statistically significant but, clinically insignificant.

On comparison between the groups (Table 1.6), there is statistically significant difference in all the domains of CRQ between Group A and Group B. Group A experienced significantly higher improvement in CRQ score as compared to Group B (t= 5.58, p < 0.05).

Table 4: Comparison of Mean values of CRQ at baseline and after training within Group A (N = 14) – Paired t – test.

Group A	Baseline	After Training	t - value
	Mean ± Std. Dev.	Mean ± Std. Dev.	
Dyspnea	2.12 ± .28	3.15 ± .31	16.32*
Fatigue	2.76 ± .39	3.74 ± .55	11.90*
Emotion	2.14 ± .32	2.8 ± .40	9.89*
Mastery	2.48 ± .49	3.43 ± .54	13.48*
Total	9.50 ± .66	13.12 ± .08	24.56*

NS – Not significant, * - Significant at the level of .05

Table 5: Comparison of Mean values of CRQ at baseline and after training within Group B (N = 15) – Paired t – test.

Group B	Baseline	After Training	t - value
	Mean ± Std. Dev.	Mean ± Std. Dev.	
Dyspnea	2.25 ± .47	2..52 ± .54	5.94*
Fatigue	2.57 ± .50	2.75 ± .65	2.32*
Emotion	2.18 ± .44	2.22 ± .47	1.59^{NS}
Mastery	2.53 ± .55	2.65 ± .70	1.70^{NS}
Total	9.52 ± .08	10.14 ± 1.70	3.31*

NS – Not significant, * - Significant at the level of .05

Table 6: Comparison of Mean values of CRQ at baseline and after 4 weeks of training between Group A and Group B.

CRQ	Group A (n = 14)	Group B (n = 15)	t - value
	Mean ± Std. Dev.	Mean ± Std. Dev.	
Dyspnea (After 4 weeks)	3.15 ± .31	2.52 ± .54	3.8*
Fatigue (After 4 weeks)	3.74 ± .55	2.75 ± .65	4.37*
Emotion (After 4 weeks)	2.80 ± .40	2.22 ± .47	3.55*
Mastery (After 4 weeks)	3.43 ± .54	2.65 ± .69	3.36*
Total (After 4 weeks)	13.12 ± 1.08	10.14 ± 1.70	5.58*

NS – Not significant, * - Significant at the level of .05

DISCUSSION

The duration of program in most of previous studies has been more than 6 weeks. Only a few studies have demonstrated the effects of a 3 – 4 week rehabilitation program, but the protocol of the exercise programs used have not been defined clearly in these studies. So, the present study was designed to examine the efficacy of a short term pulmonary rehabilitation lasting 4 weeks in terms of improving functional capacity

(as measured by 6 MWT) and QOL (as measured by CRQ).In the present study we compared the effectiveness of a comprehensive pulmonary rehabilitation program including formal exercise training sessions (Group A) with an Education based rehabilitation program (Group B).

Changes in Functional Capacity: The minimum clinically important difference for 6 MWT has been estimated to be 30m [19]. Our training program led to substantial improvement in walking distance by 38.2m in favor of the patients receiving the comprehensive pulmonary rehabilitation program (Group A). So the comprehensive pulmonary rehabilitation group exceeded the minimal clinically important threshold. The result of the study is in accordance with the findings of Juan Pablo de Torres et al who demonstrated that in their study that the patients receiving 6 – 8 weeks of rehabilitation experienced a mean improvement of 65m [20]. The comparatively small improvement in our study can be due to the small duration of the training period used.

Improvement in 6 MWD in Group B patients is only 9m which is statistically relevant but clinically not relevant. Reason for the lack of improvement of 6 MWD in patients receiving an education based program (Group B) could be that the exercise program carried out at home is not significant to produce an improvement in physical performance.

Comprehensive pulmonary rehabilitation group showed significantly higher improvement in 6MWD as compared to education – based group. This improvement can be mainly attributed to the various physiological changes associated with the moderate exercise training as has also been shown by many studies [21]. So, this improvement in 6 MWD in comprehensive pulmonary rehabilitation group can be explained by the decreased ventilatory requirement for exercise after a rigorous training. The main explanation for reduced ventilation is reduced metabolic loading rather than increased V_T, reduced physiological dead space, and enhanced CO_2 elimination as has been previously postulated [21], also it could be due to decreased exercise induced oxidative stress after sub maximal exercise as has been studies concluded by Evi M Mercken et al (2005) and they demonstrated that this decrease was accompanied by a significantly improved exercise capacity in patients with COPD after rehabilitation [11].

Desensitization of dyspnea can also be considered as one of the reasons that lead to an improved exercise capacity in patients who received exercise training. Desensitization of dyspnea can be ascribed to an improvement in respiratory muscle function or to a reduction in respiratory muscle load [10].

Psychological factors may also contribute to the improvement in 6 MWT because improvement in motivation can be translated to improved functional capacity. But this factor can be easily eliminated as the other group (Education based group), whose anthropometrics and disease severity did not differ significantly from those in the comprehensive pulmonary rehabilitation group, was also included in the study. Moreover the training program was also identical in both the groups in all respects except that the rigorous cycle exercise training program was not preset in the education based group. The effects observed in this education based group are not significant which suggest that the significant improvement in functional exercise capacity observed in comprehensive pulmonary rehabilitation group could be more because of the physiological changes associated with exercise training and not altogether because of motivational effects.

Changes in Health Related Quality of Life (HRQOL): For HRQOL, self administered CRQ version [6] has been used which has an established threshold of 0.5. In Group A patients, improvements in CRQ scales for each of the four domains were manifested which was statistically as well as clinically significant as the mean values for each domain exceeded the minimal clinically important difference of 0.5. But in Group B, although the total score of CRQ as well as the individual domain of dyspnea and emotion showed statistically significant improvement but this improvement was not clinically significant.

Significant improvement in quality of life score in group A can be more because of physiological

benefits of the inclusion of an intensive supervised exercise program rather than psychological effects. Whereas the small improvement that occurred in Group B could be the effect of factors other than physiological benefits, such as behavioral modification and self efficacy of symptom management. It has been proposed that high levels of self – efficacy of symptom management, higher level of positive social support and lower levels of negative interaction is associated with low levels of depression, anxiety and a less impaired quality of life in COPD patients [9]. Several home care programs have been published [10]. These have generally yielded no evidence of physiological improvement in exercise tolerance (e.g. improved VO_2 max) through some improvement in more effort dependant measures (e.g. 6 MWD) is sometimes seen [10]. Patients in the present study experienced improvement in functional outcomes even after having severe impairment in lung function. This is in consensus with the results of previous studies [21]. Study done by Richard Cassaburi has also shown that even patients with severe lung function can have improved condition following pulmonary rehabilitation [21]. In summary, the result of our study lead us to reject the null hypothesis and thus imply that even a short term (4 week) pulmonary rehabilitation can have significant improvements in functional capacity and quality of life.

Limitation of the Study: Sample size was small, There was no control over the rest period which was given to few patients in the initial sessions for not being able to complete the full 20 minutes cycle ergo meter training in one go and though all the patients in education based group were given common advice, there was no control over the amount of physical activity they were engaged in.

CONCLUSION

In conclusion, this study demonstrated that in patients with severe COPD, 4 week Pulmonary Rehabilitation program achieved a clinically significant improvement in patient's functional capacity and quality of life. Moreover, this improvement was significant higher than the patients receiving only education based program. These findings suggest that even if the program duration doesn't exceed one month, it can still benefit the patients with COPD.

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Conflicts of interest: None

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