

## **A Low Cost Pulmonary Rehabilitation Programme for COPD Patients: Is it any Good?**

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### **Abstract**

**Chronic Obstructive Pulmonary Disease (COPD) is a major cause of chronic morbidity and mortality worldwide. Dyspnoea and exercise intolerance are the two most common symptoms of COPD patients, making Pulmonary Rehabilitation essential in COPD management.**

**Objectives: To study the effect of a low-cost outdoor and home based pulmonary rehabilitation program on Dyspnoea indices and Exercise tolerance in uncomplicated COPD patients.**

**Design: Prospective Comparative analysis**

**Methods and Outcome Measures: COPD patients were included in a six-month rehabilitation programme - 32 patients who completed the programme formed the study group while those who opted out (17 patients) formed the control group. The American Thoracic Society Dyspnoea Scale, VAS scale and the 6 minute walking distance (6-MWD) were analysed in both groups, who continued on a similar drug management.**

**Results: The Dyspnoea indices showed significant reduction of over 64 % in the study group. The mean 6-MWD showed an average increase of 78.41 metres in the study group, while the control group showed an average decrease of 8.5 metres after six months, also statistically significant.**

**Conclusion: Even a low-cost outpatient and home-based comprehensive rehabilitation program shows substantial objective benefits.**

**Keywords: Pulmonary rehabilitation, Out-patient, COPD, Dyspnoea, exercise tolerance.**

### **Introduction**

Chronic Obstructive Pulmonary Disease (COPD) is a major cause of chronic morbidity and mortality throughout the world. Many people suffer from this disease for years, dying prematurely from it or its complications. COPD is currently the fourth leading cause of death in USA<sup>1</sup>,

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Worldwide; COPD is the only leading cause of death that is increasing in prevalence. It is estimated that by the year 2020, COPD will be fifth amongst the conditions that will be the most burden to the society<sup>1</sup>. Every month, a new drug hits the market, with promises of 'relief' but falling short in really relieving the patient from the misery of the disease. It has been realized that drugs alone won't suffice if relief is desired. Over the past two decades there has been a gradual recognition of the benefits of pulmonary rehabilitation.

Numerous studies have confirmed the benefits of pulmonary rehabilitation at various levels<sup>2,3,4,5,6,7,8,20</sup>. Majority of the studies used elaborate rehabilitation programs most of which had an indoor rehabilitation component. This caused a massive escalation of expenses, which added to the cost of medication beyond the reach of the majority of COPD population in the developing countries.

Dyspnoea and fatigue after mild exertion (decreased exercise tolerance) are the two most common and palpable symptoms experienced by patients with COPD<sup>9,10</sup>.

Our present study tries addressing this problem. A home based trial on the outdoor patients was conducted to determine the impact of a low-cost pulmonary rehabilitation program in a group of COPD patients, compared with another group of COPD patients receiving only "routine" outpatient advice. Both groups continue receiving an optimal drug management.

## **Materials and Methods**

An attempt was made to find the difference in Dyspnoea indices and Exercise tolerance in patients completing the programme was compared with a control group, which received no rehabilitation.

**Centre:** This study was conducted at the Department of Physical Medicine & Rehabilitation and the Department of Respiratory Medicine at the Institute of Post Graduate Medical Education and Research, S.S.K.M. hospital, Kolkata. The Study was done over a Period of 30 Months from October 2002 to April 2005.

**Patient Selection:** During this period 112 patients with Chronic Obstructive Pulmonary Disease, diagnosed in accordance to the GOLD guidelines<sup>11</sup> were randomly selected and screened for the study; 69 patients met entry criteria. All the patients were given the option of being included in the study, they were explained and educated about the rehabilitation programme, the cost and commitment involved and the need to follow up on time. 44 patients enrolled for the programme while 25 refused citing various reasons.

Most important reason for refusal in 19 pts (76%) was distance from home & inability to make frequent and timely visits, the rest had no specific reason.

Among the 44 patients recruited in the program 32 patients came for the 6 month follow-up on time, thus completing the programme, leaving a dropout of 12 patients.

Reasons for dropping out included inconvenience to attend the regular follow-ups for such a long duration (4 patients), concurrent illness (3 patients), personal problems (1 patient), no specific reason (2 patients). Among other 34 left, 2 died during the tenure of the programme, one after

two weeks of starting the programme died from a severe exacerbation of COPD, the other died after six weeks following a road traffic accident. 32 patients went on to complete the programme, this comprised of 30 men and 2 women, with age groups ranging from 25 to 78 years. They formed the 'Rehab group'.

Of the 25 patients who opted out of the programme, 17 patients were available for follow up at the end of six months; other 8 could not be contacted. This group of 17 subjects was taken as the default control group or the 'Non-rehab group'.

### **Inclusion criteria**

1. The diagnosis of patients suffering from mild to severe COPD was confirmed by history and physical examination, spirometry and chest x-rays in accordance to the GOLD guidelines. Patients with the diagnosis of chronic bronchitis and emphysema were accepted into the programme while patients with acute reversible airway diseases were excluded.
2. The patients were in a stable condition at the time of recruitment and were under the care of a primary care physician or a specialist receiving an acceptable medical regimen for their condition for over six months.
3. Expiratory airflow limitation was not reversible by bronchodilator inhalation (Reversibility was defined as an increase in FEV1 greater than 12% and/or 200 ml after inhalation of 200 µg of salbutamol).
4. Willingness to participate in all aspects of the study.

### **Exclusion criteria**

Presence of any other significant disabling lung disease, serious heart problems, neurological complications or other medical condition e.g. severe lumbar spondylosis or gross osteoarthritis of the knee that could interfere with the patients' compliance with the programme.

**Intervention:** All patients were titrated to an optimal drug management, mostly all patients receiving inhaled Ipratropium bromide (40µg puff) thrice daily with salbutamol inhalation (100µg puff) on an as needed basis.

Group I were the Rehab group, they were inducted into the programme. The whole programme was conducted on an outpatient basis training followed by home exercise programme.

It comprised of 4 major components:

1. Education
2. Exercise training
3. Psychosocial/behavioural intervention
4. Outcome assessment

**Education:** On the day of induction the patients were educated on pre decided topics about various aspects of the disease, its prognosis and its management. The patients were also briefed about the drugs they were prescribed, their utility and side effects, smoking cessation techniques and importance of having a good compliance. The patients were then explained about the components of the rehabilitation programme. The advice on nutrition and the required supplementation was given at this stage.

The patients were asked to return for 2 days for a supervised training for approximately 60-90 min/day. A senior physiotherapist aided with visuals of exercise manoeuvres gave the exercise training. All patients were given the same programme, with the intensity guided by the patient's Target Heart Rate (THR). The target heart rate was determined using the Karvonen's formula <sup>12</sup>

THR= heart rate before 6min walk + 50% -70 % x (heart rate after walk - heart rate before walk).

The patients were taught monitoring their own heart rate during the exercise training and were advised not to exert beyond the target heart rate or if they felt breathless.

**The exercise program** (Table I) comprised of three components:

- a) Postural relief techniques
- b) Chest specific manoeuvres
- c) General reconditioning exercises

**Exercise prescription**

- Frequency : 5 times per wk
- Intensity : 50%-80% of THR along with moderate perceived dyspnoea
- Timing : 30 min aerobics (walking and stair climbing exercise) 10-15 min strength training with home available weights up to 5 kgs (arm raises, supported bench presses, mini squats and incremental spirometry).

**TABLE I: The Pulmonary Rehabilitation Program**

1. Education	Disease Pathophysiology & prognosis, exercise conditioning, energy conservation, Nutrition & Smoking cessation advice and Importance of compliance to the programme etc. Supervised training for two days (1 hr sessions) to be followed at home. a) Postural relief techniques - 20° forward lean with support b) Chest specific maneuvers i. Controlled Breathing Techniques - Purse Lip & Diaphragmatic breathing (2-5 min BD) ii Postural drainage & huffing - 10-15min OD
2. Exercise Training	c) General reconditioning Exercises Arm raises -front, lateral, back with 1-5 kgs - (2 x10 reps) Supported pushups (2 x 10 reps) Slow stair climbing ex (2min) Mini Squats (2 X 10 reps) Brisk Walking (5 – 30 mins) Incentive spirometry at low intensity (2-5 mins)
3. Psychosocial / Behavioral Intervention	Advice and reinforcements to maintain a non-smoker status, screening for Depression etc.
4. Outcome Assessment	Dyspnoea Indices (ATS shortness of breath scale, perceived dyspnoea by VAS), Exercise tolerance by 6MWD.

**TABLE II: American Thoracic Society (ATS) shortness of breath scale. <sup>13</sup>**

<b>0</b>	<b>None</b>	Not troubled by Shortness of Breath (SOB) when hurrying on the level ground or walking up a slight hill.
<b>1</b>	<b>Mild Moderate</b>	Troubled by SOB when doing so. Walks up more slowly than people of same age on level ground because of breathlessness or has to stop for breath when walking at own pace at level ground.
<b>3</b>	<b>Severe</b>	Walks up more slowly than people of some age on the level because of breathlessness or has to stop for breath when walking at own pace at level round.
<b>4</b>	<b>Very Severe</b>	Too breathless to leave house, breathlessness on dressing / undressing.

The patients were also given an illustrated handout of the exercise program. The patients were asked to start the exercises with minimum repetitions gradually increasing it to the recommended level according to their tolerance.

**Psychosocial/behavioural intervention**

At each follow-up, the patient and their family members were addressed and encouraged to speak about the difficulties they faced in coping up with their day-to-day life. Efforts were made to determine if the patient was at any point showing any features of depression, anxiety, fear, or was having any family or social problems. The primary behavioural intervention that was done was to help the patient to quit smoking completely.

**Outcome assessment**

All the patients were asked to follow-up after 3 months and finally after 6 months. Measures of outcome were grouped into two categories:

1. Dyspnoea indices (on American Thoracic Society scale for shortness of breath and Visual Analogue Scale) were assessed.
2. Exercise tolerance by the 6 Minute Walking Distance

**Dyspnoea Indices** - The shortness of breath is a scale issued by the American Thoracic Society (ATS) <sup>13</sup> is shown in Table II. The grading is made considering patient’s condition in the last 24 hours. This grading is a modification of the Medical Research Council (MRC) dyspnoea scale. The ATS dyspnoea measured was developed for epidemiological studies and has similar indications to the MRC.

The second dyspnoea index was the perceived dyspnoea index measured using a Visual Analogue Scale (VAS). This was administered to the patients after the 6 min Walking Distance (6MWD). The VAS <sup>14</sup> is usually a 100 mm line anchored at either end with descriptors, such as “none” to “very severe.” When used to measure dyspnoea, these anchors are qualified to read “no shortness of breath” to “maximum shortness of breath”. The patient was asked to mark his perceptible dyspnoea level on the line; this value was measured and noted. The validity and the reliability of this test is firmly established <sup>15,16</sup>.

**Exercise tolerance** - this was determined by the 6MWD<sup>17</sup>. To measure the 6 MWD, the patient was asked to walk; covering as much distance as possible during six minutes, along a calibrated 20m long path, walking to and fro, and the total distance covered at the end of 6 minutes was recorded. During the duration of the walk, the patient was allowed to stop for a breather if he or she felt it necessary. On the first day, a practice walk was

scheduled, while the testing was done the next day.

The Non- Rehab group – received no rehabilitation intervention, they continued with their optimal drug regimen. Along with that they were also given the ‘routine’ OPD advice regarding the importance of quitting smoking and other precautions and instructions (except exercises and walking) that are given in the out patient setup. This group of patient was called back (by phone or by post) at the end of three months and finally after six months to assess the Dyspnoea indices and administer the 6MWD test. These patients were instructed about the procedure before taking the test.

The outcome assessment was carried out by a physician who was not involved in the management of the patients, and he was not informed about which Group the patient belonged to. This was done to eliminate any sort of assessment bias.

**Statistical evaluation:** the mean values of the Dyspnoea indices (ATS and VAS) and the mean change in the 6MWD after six months were used as a primary outcome measures for this trial. The calculations were done separately for the rehab and the non-rehab group. Descriptive statistics were carried out for both the groups to check how well both the group’s matched.

The Age and sex distribution, socio-economic group and education levels were compared using relevant statistical tests. Both groups were found to be well matched.

The base line and end study parameters were compared using the appropriate nonparametric tests.

Mann-Whitney U test was used to compare between the Rehab and Non-Rehab groups as non parametric values were being compared, while Wilcoxon’s matched pairs of Signed Rank test was used to compare the values within the Group. The statistical evaluation was done using STATISTICA (version 6) statistical software.

**Results**

A total of 49 subjects were involved in the study with 32 patients forming the Rehab group (study group) while 17 patients were included in the Non-rehab group (control group).

The average age of the patient groups were-

Rehab Group = 50.13 ± 3.86 years

Non-rehab Group = 49.12± 6.77 years

The mean base line values were thus-

	Rehab Gp	Non-rehab Gp	p value
ATS (SOB) grading	2.28	2.24	0.793
VAS -perceived dyspnoea	45.3mm	46.8mm	0.614
6MWD-	330.72m	321.53m	0.689

The baseline parameters between the two groups were

compared using the Mann-Whitney U test. There was no significant difference found between the values of the two groups.

The mean End Study values were -

	Group I	Group II	p value
ATS (SOB) grading	0.72	1.88	<.0001
VAS -perceived dyspnoea	16mm	46.2mm	<.0001
6MWD-	409.13m	313.0m	<.0001

The end study parameters showed a significant difference between the Rehab and Non-Rehab groups when compared using the Mann-Whitney U test. Comparing the baseline and the end study values within the group showed decrease in dyspnoea indices in both the groups. In the rehab group (Group I) the ATS grade was reduced by 1.56 (68.42% reduction), which was statistically significant, while the same in the non-rehab group was 0.36 (16.07% reduction), which was not significant (Fig I). The perceived dyspnoea index measured by VAS showed a significant 29.3 mm (64.68%) reduction in the rehab group while the reduction was 0.6 mm (1.28%) in the non-rehab group (Fig II), which was not found to be significant. The change in the 6 minute walking distance (6MWD) was most significant (Fig III). In the rehab groups there was a mean increase of 78.41 m (23.71%) among the subjects. This difference was highly significant statistically. While in the non-rehab group the mean 6 MWD showed a decrease by 8.53m (2.65%) at the end of six months (Table III).

## Discussion

In patients with COPD, dyspnoea and a reduced capacity for work are two of the most disabling symptoms experienced<sup>9,10</sup>. Findings in this study indicate definite benefits of an outdoor and home-based comprehensive pulmonary rehabilitation program in patients with COPD as compared with patients who received only ‘routine’

outpatient advice.

We found that the patients in the Rehab group showed significant improvements in dyspnoea indices. At the end of the study these patients felt less ‘breathless’ and were able to tolerate higher levels of exertion. The improvements noted in the dyspnoea levels and exercise tolerance concurred with most previous findings.

Goldstein<sup>3</sup> showed significant benefits in dyspnoea levels of 45 patients who participated in an 8-week inpatient pulmonary rehabilitation program followed by 16 weeks of supervised outpatient care.

Reardon<sup>5</sup> in a controlled study of an outpatient pulmonary rehabilitation program showed a 2.3 unit increase in the Transitional Dyspnoea Index (TDI), indicating significantly reduced dyspnoea levels, along with reduction of exertional dyspnoea measured by VAS.

In one of the largest studies on pulmonary rehabilitation Ries<sup>2</sup> concluded that patient’s receiving comprehensive pulmonary rehabilitation showed significantly improved exercise endurance and reported less dyspnoea and greater comfort when walking as compared to patients who received education alone.

Exercise tolerance was measured using the 6-minute walking distance (6MWD). In our study we noted an increase of 78.41m (23.71%) in the 6MWD after six months. Redelmeir<sup>17</sup> suggested that the minimal clinically meaningful increase in the 6MWD is about 54 m. We anticipated some improvements in the 6MWD as the patients were on an exercise regimen targeted to counter the deconditioning effects of COPD. It is also worth noting that the non-rehab group actually showed a decrease of 8.53 m at the end of the six-month study. The value, though non-significant, is suggestive of a reduction in exercise tolerance

Our findings correlated with most trials of pulmonary

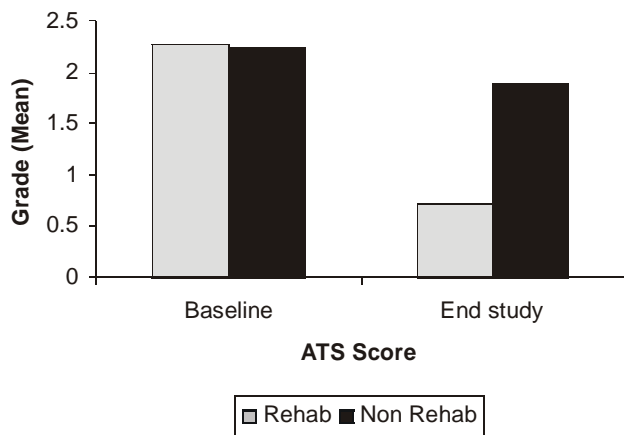
**TABLE III: Comparison between various parameters of the two groups**

### Rehab Group

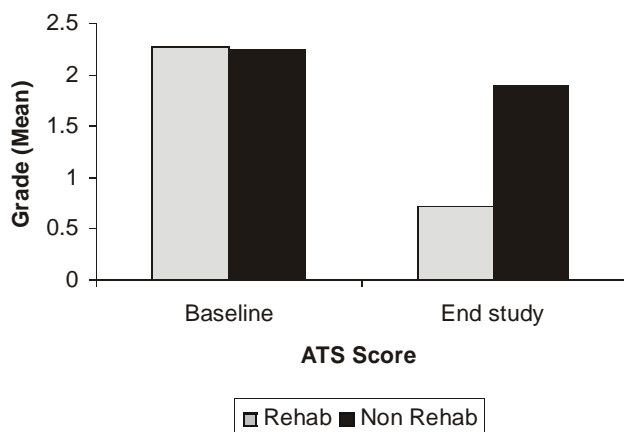
	Baseline	End study	Diff	% age	p-value
<b>ATS gr</b>	2.28	0.72	-1.56	68.42	<0.001
<b>VAS</b>	45.3 mm	16 mm	-29.3 mm	64.68	<0.001
<b>6MWD</b>	330.72m	409.13m	78.41m	23.71	<0.001

### Non-Rehab Group

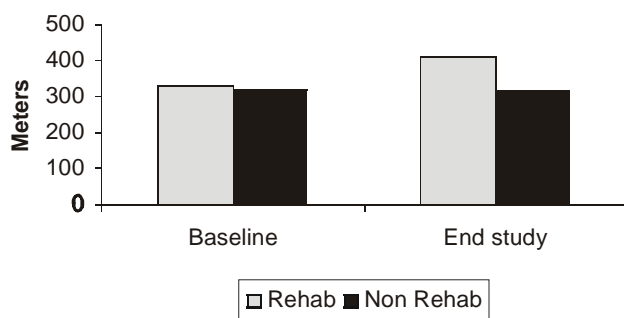
	Baseline	End study	Diff	% age	p-value
<b>ATS gr</b>	2.24	1.88	-0.36	16.07	0.156
<b>VAS</b>	46.8 mm	46.2 mm	-0.6	1.28	0.568
<b>6MWD</b>	321.53m	313.0m	-8.53m	2.65	0.453



**Fig- 1.** Comparison of Dyspnoea index using ATS shortness of breath scale between the Rehab and Non Rehab Group at Baseline and after 6 months.



**Fig- 2.** Comparison of perceived dyspnoea using VAS scale between the Rehab and Non Rehab Group at Baseline and after 6 months.



**Fig- 3.** Comparison of exercise tolerance using 6 MWD between the Rehab and Non Rehab Group at Baseline and after 6 months.

rehabilitation as shown by a meta-analysis done by Casaburi<sup>18</sup> who reviewed 36 uncontrolled studies that evaluated the effect of exercise training on exercise performance in over 900 patients with COPD. It was noted that training improved exercise tolerance in all these patients. This finding is supported by numerous controlled and uncontrolled trials showing the rehabilitation program with lower extremity exercise is better than other forms

of therapy, such as optimisation of medication, education, breathing retraining, and group therapy<sup>2,3,4,5</sup>. These results of short-term rehabilitation parallel other studies. In severe chronic obstructive pulmonary disease, the 6-min walk distance predicts mortality better than other traditional markers of disease severity. Its measurement is useful in the comprehensive evaluation of patients with severe disease<sup>19</sup>. Bendstrup<sup>20</sup> in a controlled 12-wk study of outpatient pulmonary rehabilitation, the 6-min walk distance increased by 80 m at 6 wk (halfway in the program), 113 m at the end of the program, and 96 m 12 wk after the program ended. These changes were all significantly greater than those of the control group.

In essence, our findings concurred with most of the international findings, showing improvements of dyspnoea levels and exercise tolerance with pulmonary rehabilitation. But the most striking thing was that the rehabilitation programme used was a compact, outpatient and home-based program using less time in the hospital, minimal resources but producing significant benefits comparable to similar studies. These findings support the prescription of similar rehabilitation program to all patients with COPD.

## Conclusion

Even a low-cost outpatient and home-based comprehensive rehabilitation program showed substantial benefit in objective measures of dyspnoea and exercise tolerance. It should be considered as a mandatory component of COPD management and future research should be targeted on the effects of more streamlined low-cost programme, on various parameters and concerns of patients with COPD.

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