### **Original Research Article**

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# Effect of home based pulmonary rehabilitation on health related quality of life in COPD patients

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#### ABSTRACT

**Background:** Pulmonary rehabilitation is a proven strategy in the management of COPD, it's a neglected area in our part of world and there are very few studies on home based pulmonary rehabilitation in COPD in our scenario and hence we evaluated the effectiveness of such a strategy. Aim of the research work was to study the effectiveness of home based pulmonary rehabilitation on health related quality of life, exercise tolerance, depression levels and perceived dyspnea as assessed by SGRQ (St. George Respiratory Questionnaire), 6MWTD (Six-Minute Walk Test distance), PHQ-9 (Patient Health Questionnaire-9), Modified Borg scale respectively.

**Methods:** Patients attending the Department of Pulmonary Medicine, Medical College Trivandrum, diagnosed as COPD based on GOLD guidelines who fulfil the inclusion and exclusion criteria were studied from January 2013 to June 2014. Patients were educated about the disease and need for rehabilitation, advised smoking cessation, nutritional modification. Breathing exercise, upper limb and lower limb exercises given for 6 weeks in a structured manner and followed up in every second week and analyzed using paired t- test. Pre and post rehabilitation assessment included the SGRQ, 6MWTD, PHQ-9, Modified Borg dyspnea scale was done.

**Results:** Around 40 patients had completed 6weeks of rehabilitation. There was a statistically and clinically significant improvement in quality of life, exercise tolerance, perceived dyspnoea was seen along with decrease in level of depression.

**Conclusions:** Home based pulmonary rehabilitation is a feasible alternative to institution based rehabilitation in the management of COPD and is associated with significant benefit.

Keywords: COPD, Home based, Pulmonary rehabilitation

#### **INTRODUCTION**

Globally, COPD has emerged as the major cause of morbidity and mortality, expected to become the 3<sup>rd</sup> most leading cause of death and the 5<sup>th</sup> leading cause of loss of Disability Adjusted Life Years' (DALY's) as per projection of the Global Burden of Disease Study (GBDS).The region-wise projections for the developing countries including India were even worse.<sup>1</sup> Although COPD has classically been considered to be an intra thoracic condition characterized by poorly reversible airway obstruction it has been now recognized as associated with systemic inflammation and extra pulmonary manifestations.<sup>2,3</sup> Systemic manifestations as result of the inflammatory mediators in the circulation are ischemic heart disease, heart failure, skeletal muscle wasting and cachexia, osteoporosis, normocytic anaemia, diabetes, metabolic syndrome, and depression, muscle wasting and weight loss are common manifestations of COPD.<sup>4</sup>

COPD is progressive disease with poor prognosis and has far reaching effect on quality of life of the patient. With disease advancement, co-morbidities and recurrent exacerbations a patient becomes disabled both physically and psychologically. Disability is a cause of further decreased activity, social isolation and depression which further disables him.<sup>5</sup> The aim of pulmonary rehabilitation is to break this vicious cycle and help the COPD patients to participate in daily activities. The principal goals of pulmonary rehabilitation are to reduce symptoms, improve quality of life, and increase physical and emotional participation in everyday activities.<sup>6,7</sup> The main components of pulmonary rehabilitation include exercise training, smoking cessation, nutrition counselling and education.

Based on the patients exercise tolerance, health status program should be tailored for each patient. Pulmonary rehabilitation covers a range of non-pulmonary problems that is not adequately addressed by medical therapy for COPD, including exercise de-conditioning, relative social isolation, altered mood states especially depression, muscle wasting, and weight loss. Pulmonary rehabilitation has been carefully evaluated in a large number of clinical trials and shown to increase peak workload, peak oxygen consumption, and endurance time, and a definite improvement in quality of life and depression.<sup>8</sup> Benefits have been reported from rehabilitation programs conducted in inpatient, outpatient, and home settings, irrespective of the setting all COPD patients should be advised pulmonary rehabilitation program tailored to their requirements.9 Although a promising option, pulmonary rehabilitation to be done in institutionalized structured manner, called for manpower and resources. There is evidence based recommendation that home-based rehabilitation is as equally effective as directly supervised rehabilitation training.<sup>10</sup> Still rehabilitation is not commonly practised in our part of world and in most of developing countries.<sup>11</sup>

So, a structured home based rehabilitation programme was designed by us tailored to the patient's available limited resources without any financial strain, and implemented it, so as to assess the effect of home based pulmonary rehabilitation on health related quality of life as well its effect on depression, perceived dyspnea and 6MWTD.

The research objective was to study effect of home based pulmonary rehabilitation on health related quality of life as assessed by SGRQ in COPD patients and effect of home based pulmonary rehabilitation in COPD patients exercise tolerance, depression levels and on perceived dyspnea as assessed by 6MWTD, PHQ-9, Modified Borg dyspnea scale respectively.

#### METHODS

This was an interventional pre and post test design. This study was conducted at Department of Pulmonary Medicine, Govt. Medical College Trivandrum during time period of January 2013 to June 2014.

#### Study population

Patients attending Department of Pulmonary medicine, Medical College Trivandrum, those who were fulfilling the criteria for the diagnosis of COPD based on GOLD guidelines who satisfy the inclusion and exclusion criteria.

#### Sample size

Sample size was calculated as 35 including 10% dropout, based on the previous study published in chest journal.<sup>12</sup> For pre and post test method by applying the following formula

$$N = (Z_{1-\infty/2} + Z_{1-\beta})^2 / \delta + (Z_{1-\delta/2})^2 / 2,$$

Where, n= sample size,  $\delta$ =Standard difference calculated from above said study.

Replacing the values in above equation for  $\infty = 1\%$  (0.01), Power of study = 99%.

#### Inclusion criteria

All COPD patients attended the department of pulmonary medicine, who satisfy the following criteria were included:

- In Group B, C and D of combined COPD Assessment,
- On regular optimised treatment as per GOLD guidelines and as advised by the consultant,
- Motivated and willing to undergo pulmonary rehabilitation,
- Willing and consented to participate in the study.

#### Exclusion criteria

- Recent myocardial infarction, unstable angina,
- Severe pulmonary hypertension,
- Severe cognitive dysfunction or psychiatric illness,
- Inability to exercise due to severe lung or other disease (arthritis, stroke),
- Significant exercise-induced hypoxemia, not correctable with O<sub>2</sub> supplementation.

#### Materials and tools

Structured questionnaire, SGRQ, PHQ-9, BORG scale, weighing machine, measuring tape, pulse oxymeter,

empty 11 mineral water bottle to fill with sand to use as weight, cloth piece to make sand bag.

#### Procedure

Rehabilitation programme included detailed patient evaluation (questionnaire, physical examination, cardiology evaluation), patient education, pre rehabilitation assessment, exercise training (6weeks), follow up, post rehabilitation assessment. 15minutes health education was imparted to the patient regarding COPD- what patient must know, smoking cessation, COPD medications, breathing techniques, physical exercise, nutrition modification. Pre rehabilitation assessment was done-exercise capacity-6MWTD, quality of Life-SGRQ, percieved dyspnea-Modified Borg dyspnea scale, depression scale- PHQ-9.

#### Exercise training protocol

Exercise protocol adapted and modified from "Australian Lung Foundation protocol" for home based pulmonary rehabilitation" and keeping in line with the principles laid down in ATS guideline for rehabilitation. Total duration spanned 6weeks of training with 3 steps each of 2weeks.

#### Step 1

- Walking-6 min
- Breathing exercise

-Deep inspiration and expiration -10RM\*

-Purse lipped breathing-10RM

-Diaphragmatic breathing-10RM.

- \*RM-repetitive max-maximum number of repetition at a stretch without pause. A number of RM constitutes a set.
- Upper limb

-Wrist-flexion and extension, circumduction-10RM, -Elbow-flexion and extension-10RM,

-Shoulder-flexion and extension, adduction and abduction-10RM.

• Lower limb

-Ankle-flexion, extension, circumduction-10RM -Knee-flexion, extension-15RM

-Hip- flexion, extension-10RM

#### Step 2

- Walking-10 min
- Breathing exercise

-Deep inspiration and expiration -15RM -Purse lipped breathing-15RM -Diaphragmatic breathing-15RM.

• Upper limb

-Wrist-flexion and extension, circumduction-15RM -Elbow-flexion and extension-15RM -Shoulder-flexion and extension, adduction and abduction-15RM.

Lower limb

-Ankle- flexion, extension, circumduction-15RM -Knee- flexion, extension-25RM -Hip-flexion, extension-15RM.

#### STEP 3

- Walking-10min
- Breathing exercise

-Deep inspiration and expiration -15RM -Purse lipped breathing-15RM -Diaphragmatic breathing-15RM.

• Upper limb

-Wrist-flexion, extension, circumduction-15RM -Elbow-flexion, extension-10RM with weight -Shoulder-flexion, extension, adduction, abduction-10RM with weight.

• Lower limb

-Ankle- flexion, extension, circumduction-15RM -Knee-flexion, extension-15RM with weight -Hip-flexion, extension-15RM -Stair climbing -5min.

Patient were trained and initiated into step 1 and started off with one set each of all exercises and gradually increased to 3 sets each. At the end of one week a telephonic follow up done, on completion of two weeks subjects were followed up in OPD and assessed regarding the ease at which they were doing the exercise and answered their queries. If patient can do exercise without interruption they were stepped up to step 2, else they continued in step 1 subjects continued the exercise at home, a telephonic follow up was done at the end of week3.

On completion of week4, subjects were again followed up in person and assess the ease at which they are doing the exercise, if at ease stepped up, else continued at same step.

Again telephonic follow up done at the end of 5<sup>th</sup> week. Subjects on completion of week 6 returned back for reassessment. Weight needed for weight training was calculated for each weight training exercise as the load with which the patient can do 10 repetitive max, which was gradually increased as and when patients were comfortable.

Reassessment was done with the following parameters: exercise capacity-6MWTD, quality of life-SGRQ, perceived dyspnea-Modified Borg scale, depression scale-PHQ-9. All the subjects were encouraged and advised to continue the rehabilitation program. Pre and post-test were done by neutral person to avoid bias.

#### RESULTS

Study comprised of 40 subjects with 33 (83%) males and 7 (17%) females. Mean age was 58.5 +/-6.97 with mean BMI of 20.88+/-1.98; mean smoking index is 549.88+/-317.98. Mean duration of illness was 6.55 years+/-2.81 with mean exacerbation rate of 1.88+/-0.91 in the previous one year (Table 1).

#### Table 1: General demographic characteristics.

	Ν	Minimum	Maximum	Mean	Std. Deviation
Age	40	48	80	58.68	6.97
BMI	40	17.50	24.50	20.88	1.98
Duration of Illness	40	3	15	6.55	2.81
Exacabration in last one year	40	1	4	1.88	0.91

#### Table 2: Mean of pre and post intervension.

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	Mean	N	Std. deviation	Std. error mean
SGRQ(pre)	54.11	40	3.93	0.62
SGRQ(post)	45.77	40	4.94	0.78
6MWT(pre)	175.18	40	79.40	12.55
6MWT(post)	239.05	40	97.22	15.37
BORG(pre)	6.08	40	1.42	0.23
BORG(post)	4.13	40	0.97	0.15
PHQ-9(pre)	10.55	40	1.74	0.26
PHQ-9(post)	5.45	40	2.21	0.35
FVC(l/min)-pre	1.94	40	0.49	0.08
FVC(l/min)-post	1.98	40	0.50	0.08
%predicted fvc-pre	63.99	40	10.68	1.69
%pred.post	64.96	40	10.19	1.61
FEVI(L/min)-pre	1.21	40	0.35	0.06
FEV1-post	1.24	40	0.35	0.05
FEV1%predicted	50.78	40	11.64	1.84
%fev1 post	51.13	40	8.43	1.33
FEV1/FVC(POST BD-pre)	61.91	40	3.83	0.61
FEV!/FVC post BD-post	61.80	40	4.79	0.76
Symptom(pre)	64.83	40	5.99	0.95
Symptom(post)	49.14	40	6.50	1.03
Activity(pre)	73.95	40	4.49	0.71
Activity9Post)	64.61	40	4.17	0.66
Impact(Pre)	43.19	40	3.44	0.54
Impact(post)	35.58	40	3.08	0.49

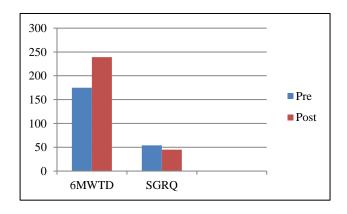
Majority i.e. 57.5% were manual labours who either limited their work or quit due to disease per say rest 20% did office job, 15% field staff and 15% housewife. 20 (50%) were current smokers in our study 13 (32.5%) were ex-smokers and 7 (17.5%) had firewood smoke exposure. Of the 20 subjects who were current smokers 17 were willing to quit and were not smoking for entire duration of program. 57.5% of our subjects had grade 2 mMRC dyspnea, were as 32.5% belonged to grade 3 and only 10% to grade 1. On GOLD combined COPD assessment 20 (50%) were in group D, 16 (40%) in group B and 4 (10%) group C. Most of our subjects, 85% were fully compliant to inhaler and medical treatment and rest 15% were partially compliant. Mean of paired samples are summed up in Table 2. Paired mean difference of pre and post for SGRQ (8.34+/-0.51, CI:7.32-9.35; P<0.001,

symptom (15.68+/-0.89 CI:13.8-17.49 P<0.001, activity (9.3+/-0.6, 8.11-10.57), impact (7.61+/-0.45 6.68-8.53, P<0.001). For 6MWT (63.86+/-5.04; CI 74.07-53.68, p<0.001) for BORG dyspnea scale (1.95+/-0.13; CI1.68-2.22; p<0.001), and PHQ-9 (5.10+/-0.29; CI 5.51-5.68;

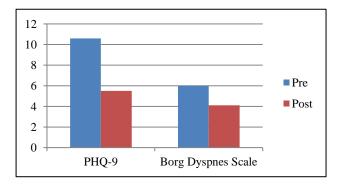
p<0.001 were statistically significant. But on analysis of lung functions, both FEV1 1nd FVC, paired mean differences of FVC (0.03+/-0.02, CI-0.07-0.22; p=0.2), FEV 1 (0.03+/-0.02; Ci 0.06-0.10, p=0.1) were not statistically significant (Table 3).

	Paired Differences						
	Mean SD		Std. error	95% Confidence interval of the difference		t	Sig. (2- tailed)
			mean	Lower	Upper		
SGRQ (pre)-SGRQ (post)	8.34	3.19	0.50	7.32	9.36	16.55	0.000
6MWT-6MWT (post)	-63.86	31.88	5.04	-74.07	-53.68	-12.67	0.000
BORG (pre)-BORG (post)	1.95	0.84	0.13	1.68	2.22	14.58	0.000
PHQ-9(Pre)-PHQ-9 (post)	5.10	1.82	0.29	4.52	5.68	17.69	0.000
FVC(l/min)-pre - FVC(l/min)-post	-0.029	0.14	0.02	-0.08	0.02	-1.29	0.203
%predicted fvc-pre - %pred.post	-0.96	5.18	0.82	-2.62	0.68	-1.18	0.245
FEVI(L/min)-pre - FEV1-post	-0.03	0.11	0.02	-0.06	0.01	-1.67	0.104
FEV1%predicted - %fev1 post	-0.35	6.88	1.09	-2.56	1.85	-0.32	0.748
FEV1/FVC (post BD-pre) - FEV!/FVC post BD-post	0.11	3.83	0.61	-1.11	1.34	0.18	0.855
Symptom (pre)-Symptom (post)	15.68	5.65	0.89	13.87	17.49	17.54	0.000
Activity (pre)-Activity (Post)	9.35	3.84	0.61	8.12	10.58	15.39	0.000
Impact (Pre)-Impact(post)	7.61	2.88	0.45	6.68	8.53	16.69	0.000

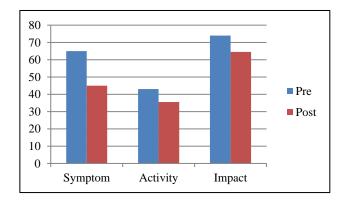




## Figure 1: Pre and post changes in SGRQ and 6MWTD.







## Figure 3: Changes in domains of SGRQ, symptoms, activity and impact.

In this study, the results showed a statistically improvement in SERG, 6MWT (Figure 1), PHQ, BORG dyspnea scale (Figure 2) and the domains of SGRQ, symptoms, activity and impact (Figure 3).

#### DISCUSSION

According to a Cochrane review on pulmonary rehabilitation which reviewed 31 RCT's since 2001 and included in-patient, out-patient or home-based rehabilitation program of at least four weeks duration that included exercise therapy with or without any form of education and or psychological support delivered to patients with exercise limitation attributable to COPD, statistically significant improvements were found for all the four important domains of QoL (dyspnea, fatigue, emotions and patient's control over disease). The effect was larger than the minimal clinically important difference (MCID).<sup>13</sup> Statistically significant improvement noted in total score as well as two of the three domains with exception of that of the symptom.

For SGRQ scores the MCID is assessed as follows: 4 unit change- slightly efficacious, 8 unit change- moderately efficacious, 12 unit change- very efficacious treatments.

In this study, the mean total SGRQ change was 9.24, suggesting a moderate efficacious effect. Where as in individual domains, mean changes were for symptom was 15.68, activity 9.34 and impact on life 7.61 suggesting a very efficacious, moderately efficacious, slightly efficacious effect respectively. Except for the mean change observed in the symptom domain all the results were in consistent with the Cochrane review. Changes in symptom may be attributed to the meticulous selection of patients before enrolling as in this study we have included only really motivated yet symptomatic patients. Regarding 6MWTD the MCID is a matter of debate. Redelmeier D et al, came out with data to support an improvement of 54m to be a clinically important difference in chronic lung disease.<sup>14</sup> ATS 2002 came out with the cut off of 54m as MCID, but went on to further clarify that at least 70m difference is needed to say with 95% confidence that a change has occurred. Wise RA et al. estimated MCID for the 6MWT to be 54-80 meters using both distributional and discriminative methods.<sup>15</sup> But in 2008, Puhan MA et al, put forward much lower MCID that is 35m for COPD patients.<sup>16</sup> But in this study change in 6MWTD is 63.87 (95%, 53.68-74.07 and P<0.001), statistically significant improvement noticed with more or less clinically significant change.

PHQ-9 score obtained in our study was 5.10 (95%, CI 4.52-5.68) which is above the MCID of 5 but as the lower limit of confidence interval is below 5, clinical importance could not be established in spite of statistical co-relation (P<0.001) and the results are consistent with that of the available literature.<sup>17</sup>

Regarding Modified Borgs dyspnea scale the recommended MCID is 1-unit. It is graded as a powerful effect intervention when there is a change of 2 units and moderate when change is 1 unit.<sup>18</sup> Mean change in Borg obtained in our study was 1.95 (95%, CI 1.68-2.22), suggesting a strong statistical and moderate clinical significance. This is again in line with the available literature.

The beneficial effects of pulmonary rehabilitation were established without a demonstrable effect on lung function measurements, such as forced expiratory volume in one second ( $FEV_1$ ). Possible explanation being the fact that pulmonary rehabilitation identifies and treats the systemic effects of COPD and its common co-

morbidities. In this study, no significant change could not be identified in FVC and FEV1. But contrary to the famous belief there are sporadic evidence pouring in recently stating that PR has ability to substantially stop the FEV1 decline when added to drug treatment. As most of these studies are observational cohort study, finding warrants confirmation by further research.

#### CONCLUSION

Home based rehabilitation showed a significant increase in quality of life, exercise tolerance and a significant reduction in depression and perceived dyspnea. Results are in agreement with the Cochrane review on pulmonary rehabilitation except for that of 6MWTD and the symptom domain of the SGRQ. Home based pulmonary rehabilitation is a feasible alternative to institution based rehabilitation in the management of COPD and is associated with significant benefits.

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