

Effect of home-based pulmonary rehabilitation on health-related quality of life, lung function, exercise tolerance, and dyspnea in chronic obstructive pulmonary disorder patients in a tertiary care center in South India

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ABSTRACT

Context: Home-based pulmonary rehabilitation (PR) can increase compliance in chronic obstructive pulmonary disorder (COPD). There is paucity of data on this in India. **Aims:** To study the effectiveness of home-based PR on lung function, health-related quality of life, exercise tolerance and dyspnea among patients with COPD. **Setting:** The Department of Pulmonary Medicine, Christian Medical College, Vellore. **Subjects and Methods:** This was a quasi-experimental study which included COPD patients who found hospital-based PR impractical. Those willing for home-based PR constituted the intervention group and those unwilling, constituted the control group. Both groups received standard of care otherwise. At 6 weeks, forced expiratory volume in 1 sec (FEV1), St. George Respiratory Questionnaire (SGRQ), six-minute walk test distance (6MWD), COPD assessment test (CAT) score and modified Borg dyspnea scale were compared with their baseline values. **Statistical Analysis:** Student paired *t*-test. **Results:** A total of 42 patients completed the study, 21 in each arm. The baseline characteristics were comparable. The improvement in FEV1 was 90 ml in the intervention group and 4 ml in the control group ($P = 0.01$). There was no significant difference in 6MWD change. SGRQ score, Borg scale and CAT score improved significantly by 10.4, 2.4, and 3.4, respectively, in the intervention group when compared to the control group ($P = 0.01$). **Conclusions:** Home-based PR effectively provides tangible benefits in FEV1, QOL, exercise tolerance and dyspnea. It should be offered to those who are unable to avail institution-based PR, especially in this era of COVID pandemic.

KEY WORDS: Chronic obstructive pulmonary disorder, home-based pulmonary rehabilitation, quality of life

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INTRODUCTION

Globally, chronic obstructive pulmonary disorder (COPD) has emerged as a major cause of morbidity and mortality, expected to become the 3rd most leading cause of death and the 5th leading cause of loss of “Disability Adjusted Life

Years” (DALYs) as per the projection of the Global Burden of Disease Study. The region-wise projections for the

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developing countries including India were even worse.^[1] Of the total global DALYs due to chronic respiratory diseases in 2016, 32% occurred in India. In 2016, COPD and asthma were responsible for 75.6% and 20% of the chronic respiratory disease DALYs in India.^[2]

Considering the above data, the economic burden of COPD is enormous. The 2001 global Initiative for chronic obstructive lung diseases (GOLD) listed pulmonary rehabilitation (PR) as an established treatment for COPD. This was a huge step in the acceptance of PR as a standard treatment for the care of COPD patients. Since then and till now, the evidence and recommendation for rehabilitation have gained in leaps and bounds.^[3] PR is supported by compelling evidence that such programs deliver improvement in exercise capacity, reduction in breathlessness and improvement in health-related quality of life, irrespective of disease severity^[4] and also reduces the number of exacerbations and hospitalization.^[5]

Of the patients with COPD who are referred to PR, 8% to 50% never attend the same,^[6,7] while noncompletion rates range from 10% to 32%.^[8,9] This is due to either lack of access or patient-related factors. The practical reasons for this lack of access include shortage of programs, particularly in rural and regional centers, and an insufficient number of qualified health care professionals. Patient-related barriers to attendance have also been identified, with travel and transport to center-based programs being the most common obstacles to attendance in this disabled group.^[10,11]

Considering all the above drawbacks, alternative models were thought to overcome all these barriers and hence home based PR was proposed as a new model to enhance access and remove patient barriers, while containing the rising costs of healthcare associated with COPD.^[12-15] Direct comparison of home- and hospital-based PR has been made in a few studies.^[12-15] There are systematic reviews and meta-analysis available on the effect of PR in patients with COPD. Although there are few studies on PR for COPD in India, there is lack of data on the feasibility and effectiveness of such programs in the developing world. Hence, we decided to study the effectiveness of a home-based PR in COPD patients in a tertiary care hospital in South India, among the local urban population.

SUBJECTS AND METHODS

This is a quasi-experimental study carried out in the outpatient clinics of the Department of Pulmonary Medicine, Christian Medical College, Vellore, from 2018 to September 2019. Approval of the Institutional Review Board was obtained. The objectives of this study were to study the effect of home based PR in COPD. The outcomes of interest were; exercise tolerance, perceived dyspnea as assessed by Modified Borg dyspnea scale, St. George Respiratory Questionnaire (SGRQ), six-minute walk test distance (6MWD), Spirometry (forced expiratory volume in 1 s [FEV1]) and COPD assessment test (CAT) score.

The patients who fulfilled the diagnostic criteria of COPD based on GOLD 2018 guidelines and categorized into Groups B, C, or D were recruited. All of them were on optimal COPD treatment as per their category. Based on a previous study done by Finnert *et al.*,^[16] the sample size was calculated to be 21 in each arm, which have provided 80% power and 5% error to determine the statistically significant difference in total SGRQ and each domain of SGRQ scores between the two groups. Accounting for drop outs, 25 patients were planned for recruitment to each arm.

All the subjects were instructed on the benefits of performing regular physical activity for the rest of their lives and its impact on their quality of life. All eligible patients were advised hospital-based PR. Those who found it inconvenient or impractical to come to the hospital were offered home-based PR and recruited in to the study. Those patients who were willing for home-based PR constituted the study group and those unwilling for home-based rehabilitation constituted the control group. Those in the study group underwent 30 min sessions of supervised PR which included breathing exercises, pursed lip and diaphragmatic exercises, upper and lower limb training, slow walking, with a session for 30 min. An additional session was scheduled as required. They were then advised to follow the same at home for 6 weeks. Telephonic calls were made every two weekly to ensure that they are continuing to perform the exercises at home and any clarifications sought were addressed. Both groups were assessed after 6 weeks. Pre- and post-rehabilitation assessment included symptom assessment, modified Borg's dyspnea scale, SGRQ, 6MWD, CAT score and FEV1. These were analyzed using Student paired *t*-test.

RESULTS

A total of 42 patients completed the study and were analyzed. Half of them (21) who were willing to undergo home-based PR constituted the study group. The other half (21) who did not undergo PR constituted the control group [Figure 1].

The baseline characteristics of clinical significance in both these groups have been tabulated below as the mean \pm (standard deviation) [Table 1]. The baseline characteristics of the two groups were similar. The mean age of the patients in the study group was 63.1 ± 8.01 years and that among the controls was 65 ± 10.7 years. The subjects were predominantly men and that could be largely explained by the fact that smokers are almost exclusively men in Southern India. Among the study group, 6 patients were in GOLD group B, 9 in group C and 6 in group D. Among the control group, 4 patients were in group B, 8 in group C and 9 group D. Hence, the distribution of the subjects among the different GOLD groups was similar. The mean baseline FEV1 was 150 ml more among those who underwent PR compared to those who did not, though the difference was not statistically significant.

The changes in dyspnea score, spirometry, six min walk test, and SGRQ are tabulated in Table 2. Compared to the baseline FEV1, there was a mean improvement of 90 ml in the FEV1 of those who underwent PR. This when compared to the drop in FEV1 of 4 ml among those who did not undergo PR was statistically significant ($P = 0.01$) [Table 2].

At baseline visit, the mean 6MWD for the intervention group was 386.25 ± 88.2 (95% Confidence interval [CI] 350–422) meters whereas the controls walked 376.4 ± 96.2 (95% CI-334–408) meters. The intervention group who underwent PR had a mean improvement of 20 meters after 6 weeks compared to the controls who had a mean increase of 7 meters. However, there was no statistically significant difference between the groups [Table 2].

At the baseline visit, the mean total SGRQ was slightly better in the intervention group compared to controls. However, the difference was not statistically significant ($P = 0.11$). At the follow-up visit after 6 weeks, the mean total SGRQ score in the intervention group improved from a baseline of 78.42 ± 14.5 to 68.16 ± 6.5 which was statistically significant ($P = 0.01$). However, in the control group, who did not undergo rehabilitation, there was worsening of the SGRQ score from 80 ± 5.0 to 82 ± 4.56 , which was also statistically significant ($P = 0.01$). The mean difference in the change in SGRQ scores between the intervention group and controls was also statistically significant ($P = 0.01$) as mentioned in Table 2.

Compared to the baseline mean Borg scale 3.64 ± 1.18 (95%

CI 3.32–3.97), there was statistically significant improvement by 2.5 points in the intervention group after 6 weeks. The mean difference between change in Borg’s score between the intervention group and the controls was also statistically significant ($P = 0.01$). At the end of the study after 6 weeks, the mean CAT score was reduced by 3.5, indicating improvement in the quality of life among the intervention group, whereas it slightly worsened in the control group. The mean CAT score improvement between both the groups was also statistically significant in cases ($P = 0.01$), at the end of the study as mentioned in Table 2.

DISCUSSION

At the end of our home-based PR program, the subjects in the study group had a mean increase in the FEV1 by 90 ml ($P < 0.01$). In a prospective study, comparing a group of 190 COPD patients undergoing PR with 67 patients receiving standard pharmacotherapy, a mean improvement of FEV1 from 1240 mL to 1252.4 mL was found in the former, while the values changed from 1367 mL to 1150 mL in the latter ($P < 0.001$).^[17] These observations suggest that the improvement of lung function in COPD patients undergoing PR should be also included among the expected outcomes and routinely assessed as an index of clinical success during the treatment. A minimal clinically important difference (MCID) provides a guide as to whether intervention offers a minimum level of perceived benefit and moves beyond the concept of statistical differences. Studies have shown that in COPD, MCID of 100 ml for trough FEV1 has been proposed based on clinical anchoring to endpoints.^[18] The improvement in the intervention group of our study just falls short of this.

Interestingly, other studies^[19] did not show significant

Table 1: Baseline characteristics of cases and controls expressed as mean±standard deviation

Parameters	Intervention group (n=21)	Control group (n=21)
Age	65 (10.7)	63.1 (8.0)
Sex (male: female)	19:2	18:3
BMI	21.4 (3)	23.1 (2.7)
Duration of COPD in years	5 (2.6)	6.5 (1.9)
FEV1	1.23 (0.4)	1.08 (0.4)
FEV1%	50.11 (15.4)	47.57 (20.4)
6MWD	386.2 (88.2)	376.4 (96.2)
Borg scale	6.03 (1.15)	6.12 (1.14)
CAT score	29.90 (3.91)	29.45 (6.3)
SGRQ total	78.42 (14.5)	80 (2.6)

BMI: Body mass index, COPD: Chronic obstructive pulmonary disorder, FEV: Forced expiratory volume 1 s, CAT: COPD assessment test, SGRQ: St. George respiratory questionnaire, 6MWD: 6 min walk distance

Table 2: Change in variables from baseline to 6 weeks

Study variables	Intervention group			Control group			Difference between both groups (P)
	Baseline	6 weeks	Difference with P	Baseline	6 weeks	Difference with P	
Mean FEV1	1.23±0.4	1.32±0.6	+90 ml (0.5)	1.08±0.5	1.04±0.4	+4 ml (0.4)	0.01
Mean 6MWD (m)	386.2±88.2	406±84.5	20 (0.5)	376.4±96.2	343±90.5	7 (0.5)	0.34
Mean SGRQ score	78.42±14.5	68.16±6.5	-10.4 (0.01)	80±2.6	82±4.56	+2 (0.01)	0.01
Mean Borg score	6.03±1.15	3.64±1.18	-2.4 (0.03)	6.12±1.14	5.19±1.01	-1 (0.4)	0.01
Mean CAT score	29.90±3.91	26.4±8.5	-3.4 (0.01)	29.45±6.3	30.3±5.1	0.8 (0.01)	0.01

FEV1: Forced expiratory volume 1 s, 6MWD: 6 min walk distance, SGRQ: St. George respiratory questionnaire, CAT: Chronic obstructive pulmonary disorder assessment test

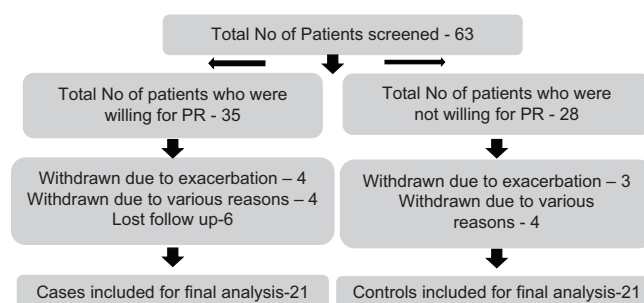


Figure 1: Consort diagram

modification of pulmonary function after a home-based training program. PR causes a change in peripheral myopathy but not ventilatory limitation. The airflow limitation in most cases is both progressive and associated with an abnormal inflammatory response of the lungs to noxious particles or gases.^[20]

Postrehabilitation, in our study, the patients walked farther than the controls (20 m vs. 7 m). Previous studies have concluded that 25 m to 30 m are the minimum clinically important difference in 6 MWD.^[18] This is also comparable with other studies. In a well-designed study, Maltais *et al.*^[21] demonstrated that a home-based PR program is as effective as conventional PR in patients with moderate-to-severe COPD. After 6 weeks of training, subjects achieved better performance with their 6MWD increased by an average of 42.8 m after rehabilitation and also had reduction in shortness of breath. The simple, low-cost, and easy-to-execute protocol described in this study seems to be adequate for the majority of patients with COPD. An attempt was made to encourage adherence through weekly telephone contact to encourage the subjects to perform the rehabilitation exercises. The MCID found for severe COPD patients was 26 m.^[19] Our sample size was perhaps inadequate to show a significant difference in the walk distance.

In our study, the effect of PR was well seen in the patient's quality of life, the effort tolerance and the perceived dyspnea as assessed by improvement in the respiratory questionnaire, CAT and Borg scale. Dyspnea is a significant limiting factor for exertion in patients with COPD. Thus, it is to be expected that any intervention that helps to diminish dyspnea should be associated with improved functional capacity and quality of life in patients with COPD. In our study, only the subjects in the home-based rehabilitation group exhibited improvement in the symptom, activity, impact domains of the SGRQ, which is related to dyspnea. As shortness of breath limits physical activities, the clinically significant reduction in the activity domain score may also be considered as an indirect measure of improvement in dyspnea. Despite using different protocols, other studies on home-based rehabilitation have also demonstrated that dyspnea may be reduced in patients with COPD.^[17] Different factors might have influenced improvements in quality of life. The subjects additionally benefited from supervision on their technique of use of inhaled medication, which may also have contributed to improved respiratory function and a possible reduction in pulmonary hyperinflation, resulting in improved physical capacity.^[17] Thus, the improvement in the quality of life likely occurred from a combination of these factors, rather than merely the training itself.

In a randomized controlled trial of a home-based 12-week training program involving 58 severe or very severe COPD patients, a significant improvement in quality of life, dyspnea and exercise tolerance ($P < 0.008$),^[21] but

not with pulmonary function could be demonstrated. In another nonrandomized observational study of 102 COPD patients, who followed a 7-week program of PR, the authors concluded that patients with worse disease status (combination of lower FEV₁, more hyperinflation, lower exercise capacity, and worse quadriceps force) improved most in endurance exercise capacity.^[22]

We also, found statistically significant improvement of the quality of life as assessed by the SGRQ. Studies have shown that in COPD, the minimal clinically significant difference seen in SGRQ scoring is a reduction by at least 4 points. Our study has shown both clinically and statistically significant improvement in SGRQ scores post rehabilitation by a score of 10 points, which implies high clinical significance.^[23]

The CAT is a simple to use patient-completed quality of life instrument that contains eight questions covering the impact of symptoms in COPD. It is not known how the CAT score performs in the context of clinical PR programs or what the minimum clinically significant difference is.^[24] CAT score is simple to implement as an outcome measure. In our study also, CAT score showed significant improvement by a reduction in score by 3 points among cases. In studies in COPD, the minimally clinical difference in Borg's scale is an improvement by 1 point. In our study, there is an improvement in Borg's scale by 3 points post rehabilitation which is both clinically and statistically significant.

In this era of COVID-19 pandemic, where there is hesitancy and hindrance to provide face-to-face institutional PR, home-based PR would be a better and safer alternative for COPD patients. Supervised tele-PR is now gaining popularity, as it has been found to be comparable to institutional rehabilitation.^[25]

This study has a few limitations. First, there was no long-term follow-up of the subjects in the home-based rehabilitation group, and we do not know how much these subjects adhered to the exercises on their own. The nonrandomized nature of the study was also a significant factor. The factors such as socio-economic status, educational status were not matched here as those factors also may influence their nature of learning and the performance of PR. The sample size was calculated based on the domains in the SGRQ. Hence, the sample size may not have been adequate for the other parameters such as FEV₁ and 6MWD.

CONCLUSIONS

From our study we conclude that a low-cost, home-based PR program is effective intervention in COPD with improvement in lung functions (improvement in FEV₁), improvement in the quality of life as measured by an increase in SGRQ, Borg, and CAT score. The study also supports the hypothesis that home-based PR can

enhance the physical capacity of patients with COPD and improvement of the quality of life. Whether in a resource limited setting, home-based PR program can replace the hospital-based PR program, requires further randomized trials. In this era of COVID-19 pandemic, home-based PR could indeed be a better option for COPD patients.

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Conflicts of interest

There are no conflicts of interest.

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