Original Article

Home-based 'No Cost' Pulmonary Rehabilitation in Chronic Obstructive Pulmonary Disease

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Abstract

Background. There is a gap in the demand and supply for pulmonary rehabilitation (PR) in chronic obstructive pulmonary disease (COPD).

Methods. A randomised controlled trial that included 67 cases and 34 controls. The evaluable parameters were 6-minute walk test (6MWT), Borg scale, Airway questionnaire 20 (AQ20) and body-mass index, airflow obstruction, dyspnoea, and exercise capacity (BODE) index. These were evaluated at baseline and follow-up visits for three months. The home-based rehabilitation with unsupervised exercises, like walking, climbing stairs, getting up from squatting position, wall push up were advised for the case group in two sessions daily for 30 minutes each.

Results. Fifty-four cases and 31 controls could be analysed. The cases and controls were matching in age, sex and spirometry. The evaluable parameters were better in the controls at the baseline but these improved in the end for the cases. The 6MWT in cases improved significantly from 286.9±104.4 to 397.2±90.1 meters ($p<0.0001$). Whereas, in controls, 6MWT did not improve significantly, i.e. 342.8±75.8 meters at baseline and 352.4±71.0 meters at the end of the study ($p=0.1443$). Borg scale, AQ20 and BODE index in the cases also improved from 6.0375±1.517 to 3.648±1.184 ($p<0.0001$), from 14±2.984 to 8.462±3.155 ($p<0.001$) and from 5.815±2.075 to 4.204±1.709 ($p<0.0001$), respectively.

Conclusion. 'No cost' pulmonary rehabilitation, which can be delivered by even a primary care physician, is useful in patients with COPD. **[Indian J Chest Dis Allied Sci 2018;60:19-25]**

Key words: Pulmonary rehabilitation, No cost, Home based, COPD.

Introduction

Pulmonary rehabilitation (PR), an integral component of care for patients with moderate to severe chronic obstructive pulmonary disease (COPD), has limited prescription and implementation rate.[1,2] The burden of COPD has more than doubled from about 6.45 million in 1971 to about 14.84 million in 2011.[3] On the other hand, structured or non-structured rehabilitation services for COPD patients are not routinely available in developing countries.[4] India particularly has a severe shortage of infrastructure and human resources for health care. The workforce is concentrated in urban areas.[5] There are no big centers of excellence in India providing protocol-based rehabilitation services. Usually individual physicians of corporate hospitals in the urban centers advocate rehabilitation in un-structured informal manner.[6] Thus, the majority of the patients do not have an access to sophisticated rehabilitation in India. The present study was undertaken to evaluate if 'no cost', home-based pulmonary rehabilitation which can be done by a primary care physician at a primary care center is useful in COPD patients.

Material and Methods

A randomised controlled trial was done after the approval of the ethical committees of two tertiary care centers, one in Lucknow and another one in Delhi sequentially under the same principal investigator from January 2011 to March 2015. The patients were enrolled at the first centre and then due to the transfer of the principal investigator the study was continued at the first center by the co-investigators. The sample size was calculated by using the formula[7]:

$$N=2x\ [Z\alpha/2(\Psi+1)+Z\beta\sqrt{(\Psi+1)2-(\Psi-1)2\pi}]2/\ (\Psi-1)2\pi$$

where $\Psi = \rho01/\rho10$ and $\pi = \rho01+\rho10$

By this formula sample size was calculated to be 45 cases and 25 controls. However, the total number of patients was not limited to 70 as we were able to include more number of patients.

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After completing 61 patients at the first center the remaining 40 patients were included by the investigator at the second centre. An informed consent was obtained before enrollment from all the patients. Spirometry[8] and 6 minute walk test (6MWT)[9] were performed as per American Thoracic Society (ATS) guidelines. Patients satisfying inclusion criteria were enrolled in the study based on spirometry and 6MWT.

Inclusion criteria were: COPD patients in stage II, III and IV as per global initiative for lung disease (GOLD) guidelines[10] who were adequately treated for COPD for one month and had remained stable. Patients who could not follow-up after first visit; those in whom baseline hypoxia or drop in saturation to <90% on 6MWT; patients with any other uncontrolled systemic disease; patients requiring long-term oxygen therapy; patients with neuromuscular or orthopaedic conditions limiting exercise, pulmonary hypertension, were excluded. Those who could not follow-up were not included called up and reminded about follow-up visits. If they did not follow-up they were not included in the study. Patients with exacerbation were also withdrawn from the study.

The patients were randomised with centrally administered, computer generated, randomisation scheme. They were divided in 2:1 case: control ratio; 67 patients were taken into case group and 34 patients were taken into control group. The demographic data of both the groups was collected in a structured proforma. The patients were enquired about Airways Questionnaire 20 (AQ20)[11] and Borg scale.[12] The AQ20 has 20 items with yes/no responses and it takes 2 minutes to complete. The AQ20 has discriminative properties and responsiveness that are similar to more complex questionnaires such as the St. George's Respiratory Questionnaire (SGRQ) and Chronic Respiratory Disease Questionnaire (CRDQ). Body composition was evaluated with body mass index (BMI). The outcome of 6MWT i.e., distance walked and saturation before and after the test were recorded. BODE index[13] was calculated on the basis of BMI, airflow obstruction, dyspnoea, and exercise capacity index.

Pulmonary Rehabilitation

The pulmonary rehabilitation programme consisted of upper and lower extremity exercise to be performed at home without any supervision (Table 1). The exercises were designed in consultation with physiotherapist of the institute. The investigator and/or co-investigators advised the patients to perform simple exercises like walking, climbing stairs, straight leg raising, getting up from squatting position and wall push up. They were instructed to walk at 90% of speed of 6MWT in two sessions daily for 30 minutes each. They were told to walk in an incremental manner; rest if they felt breathless and continue walking after breathlessness subsided. The straight leg raising, getting up from squatting position and wall push up were advised twice per day 10 times during each session. They were advised to keep the legs raised and stay in squatted position for 30-45 seconds. Since the aim of the rehabilitation was that the treating physician should be able to give the advise on exercises in a short period of time, the investigators and co-investigators themselves advised the patients about the exercises. In addition, they were given dietary guidance of high protein diet, small frequent meals (5-6 meals per day) and intake of processed food whenever possible (Table 1). It was ensured that exercise plan met all components of pulmonary rehabilitation as per the definition.[14] Controls who were doing any form of exercise were excluded from the study. They were advised to continue the same routine they had prior to inclusion in the trial. However, they were given dietary advice and on the completion of the trial, the controls too were enrolled for the exercise programme.

Table 1. Rehabilitation programme for cases

Exercise
Isotonic exercises (endurance training): walking with or without climbing stairs
Two sessions daily for 30 minutes each
To walk at 90% of speed of 6MWT
To walk in incremental manner; rest if breathless and continue walking after breathlessness subside
Isometric exercises (strength training): straight leg raising, getting up from squatting position and maintain the legs raised and squatted position for 30-45 seconds
Upper limb exercise (isometric exercises): wall push up
Isometric exercises about 10 times during each session
Diet
High protein diet
Frequent meals (5-6 meals per day)
Intake of processed food whenever possible

The schedule of follow-up visits is given in table 2. The subjects were asked to come to the hospital for follow-up and reinforced about their exercise programme on each follow-up visit. The last visit was at longer interval to find out if they were able to do the rehabilitation despite longer gap of counselling. Patients in both the groups were given a diary to collect information on medical events, to ensure the medicine intake and regularity in rehabilitation. The diary of case group had schedule design which the patient have to fill after each exercise session daily at home, which was checked on follow up to ensure the compliance.

Table 2. Follow-up visit schedule

	15 days	15 days	15 days	15 days	30 days
Visit 0	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5

The outcome was measured at the follow-up visits scheduled at the study center at the time of enrollment. The assessment of Borg scale and 6MWT was performed during all the visits. AQ20, BODE index and spirometry were measured in the beginning and at the end of study. All the details of follow-up were recorded in the proforma. Compliance of 80% was taken for the outcome measurement.

Pre-specified primary outcome was taken as change in 6MWT between the first and the last visit. The change in the dyspnoea domain by AQ20, Borg scale and BODE index at completion of the study were taken as secondary outcome variables.

The intervention dropout rate and intervention completion rate were calculated depending on the number of participants who dropped out *versus* those who completed the study in comparison with those who were assigned the pulmonary rehabilitation.[13]

A "serious adverse event" was defined as death, hospitalisation (initial or prolonged), disability or permanent damage, other important medical events, elicited from participant, care providers or patient records.

Statistical Analysis

Primary and secondary outcome measures of two groups were compared at baseline and all the subsequent follow up intervals. Comparison of categorical data was done using Chi-square test and quantitative variables were compared using Student 't'-test. Analysis of variance (ANOVA) paired analysis was performed to assess the 6MWT during follow-up visits. The post-hoc analysis (Turky's comparison test) comparing each visit with each other was also performed. Intention to treat analysis was performed. However, we excluded those who did not comply or failed to follow up after first visit to avoid compliance bias.

The confidence level of the study was kept at 95%, hence a 'p' value less than 0.05 indicated a statistically significant inter group difference. A significant difference between two groups was considered to be the impact of rehabilitation.

Results

Out of a total of 101 patients enrolled in the study, 67 patients underwent pulmonary rehabilitation and comprised of case group. Thirty-four patients who did not undergo pulmonary rehabilitation constituted the control group. Sixteen patients were excluded from the analysis, of which 13 belonged to case group and three in the control group. Amongst 13 dropouts from the cases, nine patients did not do the exercise as advised, three did not follow-up and one patient had an exacerbation before the second visit. Amongst three dropouts of control group, two patients did not follow-up and one patient had an exacerbation before the second visit. Therefore, 54 from the case group and 31 from the control group were analysed.

The mean age of the patients in control group was 65.1±7.3 years and that in case group was 59.2±8.8 years. There was no statistically significant age difference between the two groups (p=0.054). The mean BMI of patients in control group and case group was 19.1±2.7 kg/m^2 and 18.4±3 kg/m^2, respectively. Although the mean BMI of patients in the case group was lower as compared to the control group, yet the difference was not significant statistically (p=0.308). One patient in control group and two patients among case group were women. Statistically, there was no significant difference in gender-wise proportion between the two groups (p=0.61). Forced expiratory volume in first second (FEV_1) (% predicted) in control group was 43.6±14.0% and that in case group was 37.3±13.1%. The difference was not significant statistically (p=0.191). Thus, the two groups were matched for age, BMI, gender and FEV_1 % predicted.

Baseline (visit 0) 6MWT of case group was 286.9±104.4 (95% confidence interval [CI] 258.4 to 315.4) meters whereas, that of control group was 344.4±75.2 (95% CI-315 to 370) meters. The control group had significantly better 6MWT (p=0.0058) compared to cases at the baseline visit. The case at visit 0 were more symptomatic with AQ20 [14±2.9 (95% CI 13.2 to 14.8)] compared to controls [AQ20 of 11.9±2.6 (95% CI 11.0 to 12.9)]. Thus, AQ20 was also significantly better (p=0.0015) in control group compared to cases. The Borg scale was almost similar in both the groups at visit 0 (6.037±1.157 *versus* 6.129±1.147), (p=0.770). The BODE index in case group at the baseline visit was 5.815±2.075 (95% CI 5.249 to 6.381) and that in control group was 4.419±1.785 (95% CI -3.765 to 5.074). The difference was statistically significant (p=0.0017). Thus, overall the control group had better evaluation parameters than the case group at the baseline visit.

The follow-up of the primary efficacy end-point variable, i.e., 6MWT for both the groups is given in table 3. The 6MWT in case group improved from a baseline of 286.9±104.4 meters to 333.5±94.4, 358.2±97.1, 373.0±94.1, 386.7±91.3, 397.2± 90.1 meters for visit 1, visit 2, visit 3, visit 4 and visit 5, respectively. One-way analysis of variance (ANOVA) paired analysis showed that the improvement was very significant (p<0.0001) in successive visits. The post-hoc analysis (Turkey's multiple comparison test) comparing each visit with each other was found to be significant. On the contrary, the 6MWT in control group had neither improved nor deteriorated significantly (Table 3).

Table 3. Comparison of 6MWT on follow-up of cases *versus* controls

Visit	Cases	Controls	p-value
Visit-0	286.9±104.4	342.8±75.9	0.0058
Visit-1	333.5±94.4	344.3±75.2	0.5651
Visit-2	358.2±97.1	338.9±84.6	0.3419
Visit-3	373.0±94.1	348.0±72.5	0.1750
Visit-4	386.7±91.3	349.3±70.7	0.0371
Visit-5	397.2±90.1	352.4±70.1	0.013
p-value	<0.0001	0.1443	

Definition of abbreviation: 6MWT=6 minute walk test

The ANOVA paired analysis showed that the difference in 6MWT was insignificant (p=0.1443) and findings were not significant even on post-hoc analysis in the follow-up visits in the control group. The baseline and the last visit 6MWT in case group was 286.9±104.4 and 397.2±90.1 (95% CI 372.3 to 422) meters, respectively and that of control group was 342.8±75.9 and 352.4±71.1 (95% CI 326 to 378.4) meters, respectively. Thus, the improvement in the case group was such that the 6MWT, which was significantly worse in the beginning of the study compared to the control group, was significantly better (p=0.013) at the end of the study.

The comparison of Borg scale between the cases and the control group is given in table 4. The Borg scale at visit 0 in case group was 6.037±1.517 and that in the control group was 6.129±1.147 (p=0.770). At the end of the study it improved to 3.648±1.184 (95% CI 3.325 to 3.971) in the cases and 5.194±1.014 (95% CI 4.882 to 5.565) in the control group. Though, the Borg scale improved in both the groups, it was significantly better in case group than the control group (p=0.0001) at the end of the study.

Table 4. Comparison of Borg scale on follow-up of cases *versus* controls

Visit	Cases	Controls	p-value
Visit-0	6.037±1.517	6.129±1.147	0.770
Visit-1	5.519±1.514	6.129±1.147	0.039
Visit-2	4.889±1.423	5.839±1.068	0.0008
Visit-3	4.481±1.397	5.581±1.025	0.0001
Visit-4	4.037±1.258	5.290±1.039	0.0001
Visit-5	3.648±1.184	5.194±1.014	0.0001
p-value	<0.0001	<0.001	

The comparison between case and control group in AQ20, which was also a secondary efficacy variable is given in table 5. The baseline AQ20 in the case group and the control group was 14.0±2.984 and 11.94±2.632, respectively. The case group had significantly worse (p=0.0015) quality of life in terms of symptoms compared to controls at the beginning of the study. At the end of the study it reversed and the symptoms were significantly worse (p=0.00040, CI -1.095 to 3.656) in the control group compared to cases. The AQ20 in case group improved significantly to 8.462±3.155 (95% CI 7.602 to 9.324, p<0.001), whereas there was no improvement in the controls at the end of study (10.84±2.660) (95% CI 9.863 to 11.81, p=0.107).

Table 5. Comparison of AQ20 and BODE index of cases *versus* controls

Variable	Cases	Controls	p-value
AQ20			
Visit-0	14.0±2.984	11.94±2.632	0.0015
Visit-5	8.462±3.155	10.84±2.660	0.00040
p-value	<0.001	0.107	
BODE index			
Visit-0	5.815±2.075	4.419±1.785	0.0017
Visit-5	4.204±1.709	3.903±1.660	0.429
p-value	<0.0001	<0.243	

Definition of abbreviations: AQ20=Airway questionnaire 20; BODE=Body-mass index, airflow obstruction, dyspnoea and exercise

The BODE index comparison at the beginning and end of the study between the case group and control group is given in table 5. The BODE index in case and control groups was 5.815±2.075 and 4.419±1.785, respectively. The BODE index improved significantly to 4.204±1.709 (95% CI 3.737 to 4.670, p<0.0001) in case group and remained almost the same i.e. 3.903±1.660 (95% CI 3.294 to 5.074) in the control group (p<0.243). It was significantly worse in cases compared to controls at visit 0 (p=0.0017). At the end of the study, the significant difference in BODE index had become insignificant (p=0.429, CI 1.056 to 0.4550).

The intervention dropout rate was 19.4%, intervention completion rate was 80.6%, study completion rate was 84.2% and study drop out rate was 15.8%. No serious adverse events were recorded. Those who were lost to follow-up were contacted telephonically to confirm the absence of any serious adverse events.

Discussion

The new millennium has seen refinements of our understanding of rehabilitative exercise training.[16] We designed simple exercises based on the available recommendations and proven that even simple exercises are valuable in the management of patients with COPD.[2,17] These consisted of endurance training of the lower limb with walking,[12,18] climbing stairs,[19,20] strength training of lower limb with straight leg raising/squats[21] and upper limb strength training with wall push ups.[22] It has been shown that when facilities to determine the target speed is not available,

walking at greater than 90% of speed of 6MWT can achieve the desired target intensity.[18,23] Thus, these patients were advised to walk at 90% of speed of 6MWT. Slow incremental exercises guided by their ability to tolerate the exercise with the periods of rest if desired are useful.[16] Hence, they were advised to increase the distance walked and were asked to take rest for a while if tiredness/inability to walk prevailed. Since the total effective training time should ideally be 20-60 minutes and our patients were unsupervised, we advised the patients to do these exercises twice in a day for 30 minutes each.[4,12] Strength training exercises advised 10 times during each session was also based on recommendations.[12,17] The exercises performed 3-5 times a week have shown benefit, hence compliance of 80% was considered acceptable.

Previous studies[24-34] have now shown that home-based pulmonary rehabilitation is as good. Most of the studies on home-based pulmonary rehabilitation[24-32] including the studies performed by Dias[33] *et al* and Pradella[34] *et al* have utilised health care providers and/or sophisticated equipment at hospital/home. But in countries with the paucity of infrastructure and man-power, like ours, it may not be feasible to provide target speed or supervision or treadmill at home to all the patients. We did not use any such manpower or equipment. Thus, *to the best of our knowledge*, no study has previously done a "no cost" unsupervised pulmonary rehabilitation which can be easily explained by the physician to the patient and followed at home. It requires five minutes of explanation by the physician without the use of any equipment.

The utilisation of rehabilitation is poor even in developed countries. In countries, like Canada and United Kingdom the reported access to pulmonary rehabilitation is less than 2%.[35,36] No formal study on pulmonary rehabilitation access to COPD patients from India is available. But it is likely that only a fraction of patients receive rehabilitation. If primary physicians treating COPD patients, use our exercise programme, the gap in the management of rehabilitation can be bridged.

A comprehensive evaluation included 6MWT for the physical performance, Borg dyspnoea scoring for the physical status, AQ20 for respiratory health related quality-of-life, and BODE index for the physical and functional status. We observed that, the case group which begun with a mean disadvantage of about 60 meters in 6MWT distance at the beginning of the study, developed an advantage of about 45 meters over the control group at the end of the study. Overall improvement in 6MWT distance in the case group was very significant (mean 111 meters, $p<0.0001$) and that in controls was insignificant (mean 10 meters, $p=0.1443$). The improvement was similar to other pulmonary rehabilitation studies.[26] Apart from absolute increase in 6MWT distance at the end of the study, it also showed consistent gradual improvement in the case group over three months period showing that skeletal muscle strength and endurance gradually.[16] It needs to be emphasised that minimum clinically important improvement in 6MWT has been estimated to be 54 meters; our patients had double the desired significant improvement in 6MWT distance.[37]

Borg scale, the 10-point category ratio scale was 6 and 6.1 in the case and the control group, respectively which improved to 3.6 in the case group and to 5.1 in the control group. Borg scale is a subjective scale. It correlates poorly with objective outcomes like lung function and exercise capacity; hence it was taken as secondary efficacy variable.[40] Similarly, AQ20 and BODE which were taken as secondary efficacy variables had also improved significantly in the case group ($p<0.001$). The AQ20 requires less time and comparative studies have shown a good correlation of AQ20 with other traditional questionnaire.[11,17] BODE index captures the beneficial effects induced by pulmonary rehabilitation. Also, the post-rehabilitation response in BODE may play a role in their long-term survival.[38]

The intervention completion rate was 80.6% and the intervention dropout rate was 19.4%, which is similar to the other rehabilitation studies.[42] Only nine out of 67 cases enrolled in the rehabilitation group were unable to do the exercises at home. Another finding of the study was that none of the patients had any major adverse events during the study. Home rehabilitation programmes have been reported to be safe.[40]

Conclusions

A pulmonary rehabilitation, which involves unsupervised and undetermined exercise advised by the treating physicians can be useful with acceptable dropout rate without any adverse event. We went ahead with a model based on 'no cost' rehabilitation and tried to find out if it is any good. Initial counseling followed by reinforcement in subsequent visits about simple exercise is adequate to improve the quality-of-life of patients with COPD, if facilities for proper rehabilitation are not available. It is not only better accepted and more suitable but is also more feasible for the lifelong maintenance of rehabilitation.

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