A pilot study on domiciliary pulmonary rehabilitation programme in the management of severe chronic obstructive pulmonary disease

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ABSTRACT

Introduction: Pulmonary rehabilitation is now an accepted modality of care in the management of chronic obstructive pulmonary disease (COPD) patients. However, in resource-limited settings, conventional pulmonary rehabilitation may not be feasible due to the high cost involved and the extensive infrastructure requirement. In view of these constraints, we designed a domiciliary pulmonary rehabilitation programme and evaluated its usefulness in the management of severe COPD.

Methods: A total of 20 patients suffering from severe COPD (ten patients each in the experimental and control groups) were enrolled in the study. The experimental group was subjected to domiciliary pulmonary rehabilitation along with medical management, while the control group underwent only conventional medical management. During the six-month study period, both groups were assessed for quality of life (clinical COPD questionnaire), exercise capacity (six-minute walk distance) and spirometry values (forced expiratory volume in one second and forced vital capacity).

Results: Statistically significant differences were observed in clinical COPD questionnaire scores in both groups from the fourth month (p-value is 0.002 and 0.001 at the end of four and six months, respectively). The results of the six-minute walk distance showed a similar trend (p-value is 0.009 and 0.001 at the end of four and six months, respectively). No significant difference was observed in either of the spirometry values.

Conclusion: The domiciliary pulmonary rehabilitation programme improves the quality of life and exercise endurance of patients with severe COPD, and thereby acts as a substitute for conventional pulmonary rehabilitation programmes in resource-limited situations.

Keywords: chronic obstructive pulmonary disease, domiciliary, pulmonary rehabilitation

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INTRODUCTION

Pulmonary rehabilitation (PR), which is recognised as an integral component of care provided to patients with moderate to severe chronic obstructive pulmonary disease (COPD), is an individually tailored, multidisciplinary programme aimed at reinstating patients to their highest possible functional capacity.[1] Support for such a programme has grown from the emerging concept that apart from being a disease of the lungs, COPD also has profound systemic effects. Studies have shown that besides pulmonary inflammation, the systemic inflammation occurring in this disease leads to the release of cytokines and oxygen radicals in the blood.[2] These inflammatory mediators, especially tumour necrosis factor (TNF-) alpha, are found to be related to the systemic effects of the disease, which comprise loss of fat-free mass, muscle wasting, weight loss and reduced exercise capacity.[2,3]

The traditional medical management of COPD is restricted to relieving bronchoconstriction and reducing local inflammation, while the systemic effects remain unattended. The conventional PR programme that is offered in an institutional setting has been proved to be effective in improving these systemic effects. However, it is difficult to deliver such programmes in resource-limited settings. The domiciliary pulmonary rehabilitation (DPR) programme has recently been conceptualised with the objective of reciprocating the systemic effects of conventional PR.[4,5] In the present study, we designed a DPR programme and analysed whether it induces any significant change in the quality of life and respiratory status of severe COPD patients.

METHODS

A total of 20 patients with severe COPD, who had stopped smoking at the time of enrolment, were recruited in the study from the outpatient department of Respiratory Medicine at the Himalayan Institute of Medical Sciences, a tertiary care hospital in the Himalayan region of India. The severity of disease was evaluated using the Global Initiative for COPD (GOLD) guidelines. The DPR protocol, which was duly approved by the institutional ethics committee, was explained to the patients, and those who were willing to participate in the programme were placed in Group I (experimental group; n = 10), while the remaining patients were placed in Group II (control group; n = 10).

This was a non-randomised unblinded study, as inclusion in the experimental group depended on informed consent provided by patients to participate in the DPR programme. Selection bias was elimimated by recruiting consenting and eligible patients in consecutive succession, and written informed consent was obtained from all participants. Recent ex-smokers, patients with acute exacerbations of COPD or other comorbid conditions and those who were not willing to participate in the study were excluded. No change was made to the medical treatment in patients of both groups after enrolment in the study.

Patients in Group I were first trained in the PR programme and then required to visit the hospital on a monthly basis for reinforcement training. The training schedule, which extended over a period of six hours, was divided into four sessions. In the first session, patients were educated regarding COPD using audiovisual aids. They also participated in group discussions and were encouraged to clarify their queries. In the second session, a trained dietician met the patients individually and offered dietary instructions, emphasising the need for a high-protein and low-carbohydrate diet. In the third session, a qualified respiratory physiotherapist conducted physical training to the participants using audiovisual aids. The training programme comprised diaphragmatic breathing (a breathing practice to enhance the use of the diaphragm while breathing), pursed lip breathing and chest expansion exercises.

Gradually, the endurance was increased based on the patients' performance in subsequent visits, and the exercises were upgraded. The use of mechanical devices during training was avoided for easy reciprocation at home. Patients were advised to perform the exercises thrice a day at home before meals. They were also trained in energy conservation techniques in order to reduce effort of breathing during routine activities. In the concluding session, a professional psychologist assessed the patients' mental health and provided individualised counselling. Finally, the patients were given a self-explanatory feedback form to assess their compliance with the dietary instructions and physical exercises, which would be reviewed at subsequent visits.

Table I. Baseline demographic profile and outcome measures of recruited patients.

Parameter	Mean ± SD		p-value
	Group I (n = 10)	Group II (n = 10)	
Age (yrs)	60.5 ± 4.6	61.3 ± 5.9	0.529
Weight (kg)	51.9 ± 6.4	50.2 ± 3.7	0.853
Height (cm)	159.4 ± 5.2	158.9 ± 3.7	0.280
CCQ score	24.8 ± 1.8	24.7 ± 2.7	0.971
FEV_1 (% predicted)	43.6 ± 2.9	43.8 ± 3.0	0.912
FVC (% predicted)	67.7 ± 4.1	68.5 ± 4.9	0.971
6MWD (m)	233.8 ± 38.2	235 ± 29.0	0.971

SD: standard deviation; CCQ: clinical chronic obstructive pulmonary disease questionnaire; FEV_1: forced expiratory volume in one second; FVC: forced vital capacity; 6MWD: 6-minute walk distance

Patients in Group II underwent conventional medical management for COPD as per GOLD guidelines. The outcome measures of all patients were assessed on a monthly basis. Forced expiratory volume in one second (FEV_1) and forced vital capacity (FVC) were assessed using Morgan's spirometer (Spiro DS12 MDas 4.01, Morgan Medical Ltd, Rainham-Gillingham, Kent, UK). Exercise endurance was evaluated by the six-minute walk distance (6MWD) using standard guidelines.[6] Health-related quality of life and COPD control were estimated using a validated clinical COPD questionnaire (CCQ scoring).[7]

The CCQ scores, 6MWD results and the spirometry values between Groups I and II were compared using the Mann-Whitney U test, with the aid of the Statistical Package for the Social Sciences (SPSS) version 17.0 (SPSS Inc, Chicago, IL, US) for Windows. A p-value < 0.05 was considered to be statistically significant. The trend of changes in these study parameters in both groups was assessed by Wilcoxon signed rank test using SPSS 17.0 for Windows, and a p-value < 0.05 was considered to be statistically significant. The proportion of participants achieving the minimal clinically important difference (MCID) for CCQ score was compared between the two groups using the chi-square test.

RESULTS

A total of 20 male patients were enrolled in the study. They were offered the option of joining the DPR programme apart from their conventional medical management.

Table II. Outcome measures of Group I and II at 0, 2, 4 and 6 months.

Outcome measure	0 mth		2 mths		4 mths		6 mths	
	Value	p-value	Value	p-value	Value	p-value	Value	p-value
CCQ score								
Group I	24.8	0.971	22.4	0.247	14.9	0.002	13.9	< 0.0001
Group II	24.7		23.6		21.4		20.9	
6MWD (m)								
Group I	233.8	0.971	265.7	0.143	286.5	0.009	291.9	0.001
Group II	235.0		237.2		240.2		241.7	
FEV_1 (% predicted)								
Group I	43.6	0.912	43.8	0.971	3.9	0.853	44.2	0.684
Group II	43.8		43.6		43.5		43.8	
FVC (% predicted)								
Group I	67.7	0.971	68.7	0.796	68.9	0.631	68.6	0.912
Group II	68.5		68.8		68.8		68.9	

CCQ: clinical chronic obstructive pulmonary disease questionnaire; FEV_1: forced expiratory volume in one second; FVC: forced vital capacity: 6MWD: 6-minute walk distance

Ten patients consented to join the DPR programme and were named Group I (interventional group), while the remaining ten patients were treated as controls (Group II). Both groups were comparable with respect to their baseline parameters, including age, height, weight, 6MWD results, CCQ scores, FEV_1 (% predicted) and FVC (% predicted) values (Table I). Both groups were followed up for a period of six months, during which the patients were clinically assessed on a monthly basis. To reinforce the DPR programme, the interventional group underwent a six-hour training session in the PR clinic during each of their monthly visits. The outcome measures of the PR programme were analysed by recording the 6MWD results, CCQ scores, FEV_1% and FVC% values every two months in both the groups (Table II).

The CCQ score, which reflects the health-related quality of life, demonstrated a significant improvement in Group I from the fourth month of initiation of the programme (Fig. 1). The MCID for the CCQ score was 4.1.[8] 20% of the patients from Group II and 100% of patients from Group I achieved this target at the end of the study period (p = 0.0002). Similarly, the 6MWD score, which is a measure of the exercise capacity of the patient, also showed significant improvements in Group I from the fourth month of the study (Fig. 2). However, no difference was observed between the two groups in their spirometry parameters (FEV_1% and FVC%).

Intra-group comparison of CCQ scores and 6MWD values revealed that both these parameters showed persistent improvement with time in the experimental group. The p-values for change in CCQ scores between baseline and two months, between two and four months and between four and six months were 0.017, 0.005 and 0.041, respectively, while the corresponding values for 6MWD were 0.005, 0.005 and 0.028, respectively. In the control group, the CCQ score showed some improvement between baseline and two months (p = 0.009) and between two and four months (p = 0.009). However, the trend in improvement was not continued beyond four months, since no significant improvement was observed in the CCQ score between four and six months (p = 0.51). The 6MWD values were non-significant at all the time points in the control group (p = 0.176 between baseline and two months; p = 0.079 between two and four months and p = 0.6 between four and six months). During the course of the study, two patients from the control group and one from the interventional group had to be hospitalised due to an exacerbation of COPD.

DISCUSSION

In this study, we have shown that the DPR programme, when administered with conventional medical treatment, has a positive impact in improving the quality of life and exercise tolerance of severe COPD patients. This effect was demonstrable from the fourth month of the programme and was not accompanied by concomitant improvement in spirometry parameters like FEV_1 or FVC.

PR programmes significantly improve the health status of COPD patients and have already been incorporated into the GOLD guidelines for management of moderate to severe COPD.[9-12] However, their administration either requires frequent attendance to PR clinics or hospitalisation for a few days. Thus, the feasibility of such a programme in resource-limited settings is questionable owing to infrastructural inadequacy. DPR programmes were conceptualised to bridge this gap, and few studies have shown the positive

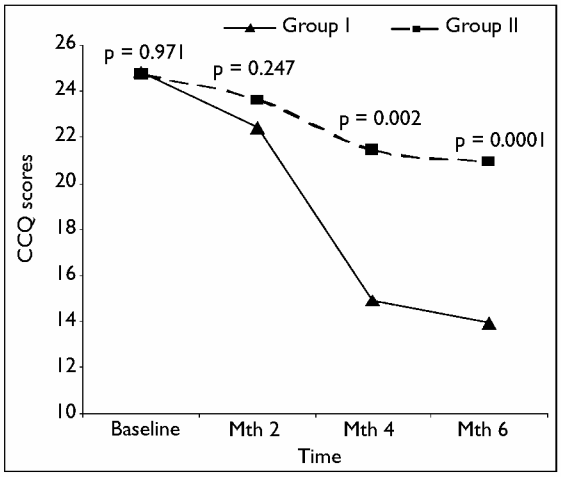

Fig. 1 Graph shows the comparison of clinical COPD questionnaire scores in the two groups of patients.

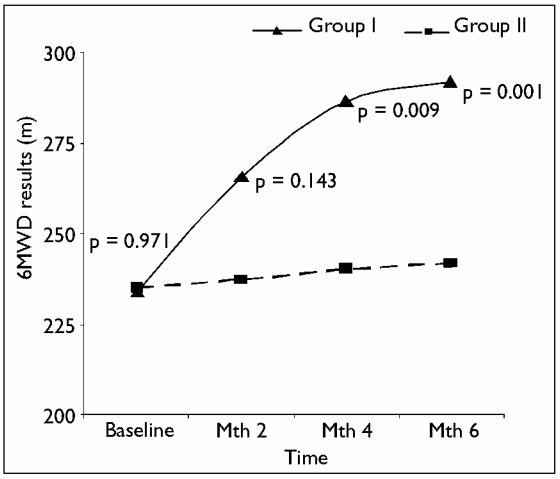

Fig. 2 Graph shows the comparison of six-minute walk distance (6MWD) in the two groups of patients.

impact of such programmes on the quality of life of COPD patients.[4,5,13,14] The present study objectively reinforces these positive findings and records the beneficial effects of the DPR programme on exercise capacity and quality of life in severe COPD patients. This study is the first of its kind from India, which has one of the highest disease burdens of COPD in the world and is in need of effective DPR programmes so as to improve the overall management of these patients.[15] The PR programme included in this study did not require any sophisticated instrument and is thus easily adaptable in resource-limited settings.

Although an improvement in the 6MWD test by DPR has also been demonstrated by authors like Maltais et al[5] and Lomundal and Steinbekk,[14] certain studies have failed to document any significant improvement in the exercise capacity of patients. Lum et al conducted a self-management PR programme and did not find a significant change in the 6MWD results after 12 weeks of follow-up.[4] This does not concur with our findings, as we observed an improvement after four months of intervention. Moreover, the patients recruited in the former study were older (mean age was 80 years), on medical management (based on St George's respiratory questionnaire [SGRQ] scores) and in a relatively more stable condition compared to our subjects. Similarly, the failure to document significant improvement in the 6MWD test by Monninkhof et al[16] could be explained by the inclusion of subjects with relatively better SGRQ scores and respiratory statuses in their study (mean FEV_1 = 56.1% predicted vs. 43.8% in our study). The training sessions in the present study were also more intense and frequent, which could have accounted for improved patient motivation and compliance. Spirometry values (FEV_1 and FVC) did not show any significant change during the study period in both groups. This finding is similar to that of several studies, including those with DPR or conventional PR.[4,13]

There were a few limitations in our study, including a small sample size, inclusion of only male patients and obvious selection bias due to the study being non-randomised and unblinded. However, the result of this pilot study would provide a foundation for an adequately powered randomised controlled trial in the future. In addition, it would be important to have a longer follow-up period in order to examine if the beneficial effects observed with the DPR programme would persist.

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REFERENCES

1. Lacasse Y, Wong E, Guyatt GH, et al. Meta-analysis of respiratory rehabilitation in chronic obstructive pulmonary disease. Lancet 1996; 348:1115-9.
2. Wouters EF. Chronic obstructive pulmonary disease. 5: systemic effects of COPD. Thorax 2002; 57:1067-70.
3. Wouters EF, Creutzberg EC, Schols AM. Systemic effects in COPD. Chest 2002; 121(5 Suppl):127S-30S.
4. Lum CM, Woo J, Yeung F, Hui DSC, Hui E. Semi-supervised, domiciliary pulmonary rehabilitation prgramme: a controlled clinical trial. Hong Kong Med J 2007; 13(Suppl 5):S42-5.
5. Maltais F, Bourbeau J, Shapiro S, et al. Effects of home-based pulmonary rehabilitation in patients with chronic obstructive pulmonary disease: a randomized trial. Ann Intern Med 2008; 149:869-78.
6. ATS Committee on Proficiency Standards for Clinical Pulmonary Function Laboratories. ATS Statement: guidelines for the six-minute walk test. Am J Respir Crit Care Med 2002; 166:111-7.
7. van der Molen T, Willemse BW, Schokker S, et al. Development, validity and responsiveness of the Clinical COPD Questionnaire. Health Qual Life Outcomes 2003; 1:13.
8. Kocks JW, Tuinenga MG, Uil SM, et al. Health status measurement in COPD: the minimal clinically important

difference of the clinical COPD questionnaire. Respir Res 2006; 7:62.
9. Bernard S, Whittom F, Leblanc P, et al. Aerobic and strength training in patients with chronic obstructive pulmonary disease. Am J Respir Crit Care Med 1999; 159:896-901.
10. Berry MJ, Rejeski WJ, Adair NE, Zaccaro D. Exercise rehabilitation and chronic obstructive pulmonary disease stage. Am J Respir Crit Care Med 1999; 160:1248-53.
11. Lacasse Y, Goldstein R, Lasserson TJ, Martin S. Pulmonary rehabilitation for chronic obstructive pulmonary disease. Cochrane Database Syst Rev 2006, 4:CD003793.
12. Fromer L, Cooper CB. A review of the GOLD guidelines for the diagnosis and treatment of patients with COPD. Int J Clin Pract 2008; 62:1219-36.
13. Singh V, Khandelwal DC, Khandelwal R, Abusaria S. Pulmonary rehabilitation in patients with chronic obstructive pulmonary disease. Indian J Chest Dis Allied Sci 2003; 45:13-7.
14. Lomundal BK, Steinsbekk AA. Observational studies of a one year self-management program and a two year pulmonary rehabilitation program in patients with COPD. Int J Chron Obstruct Pulmon Dis 2007; 2:617-24.
15. Country profiles of Environmental Burden of Disease. Available at: www.who.int/quantifying_ehimpacts/national/countryprofile/india.pdf. Accessed July 19, 2011.
16. Monninkhof E, van der Valk P, van der Palen J, van Herwaarden C, Zielhuis G. Effects of a comprehensive self-management programme in patients with chronic obstructive pulmonary disease. Eur Respir J 2003; 22:815-20.