Original Article

Outpatient Pulmonary Rehabilitation in Severe Chronic Obstructive Pulmonary Disease

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ABSTRACT

Objectives. An outpatient programme for rehabilitation of patients with severe ventilatory impairment due to chronic obstructive pulmonary disease (COPD) was conducted. Its main purpose was to assess the feasibility of the programme for COPD patients.

Methods. Initial assessment included a shuttle walking test, administration of the chronic respiratory disease questionnaire (CRDQ), assessment of the hospital anxiety and depression scale (HAD) and sickness impact profile (SIP). The patients were entered into a 6-week outpatient programme between January 2007 to July 2007 during which they attended twice weekly for a 2½ hour session. Assessment was repeated on completion of the study at three months and later at six months.

Results. The study included 44 (28 males) patients with COPD with a mean age 66 years. All patients had severe ventilatory impairment as defined by a forced expiratory volume in one second (FEV_1) of less than 40% of predicted. The shuttle walking distance improved significantly and was maintained at the improved level for six months. The improvement in all four dimensions of the CRDQ was statistically significant ($p<0.05$) and reached clinical significance for fatigue and for mastery. On entry, a notable level of depression was found in 32% of patients, and anxiety in 40 percent. There was a significant reduction in both of these that was maintained at six months ($p<0.05$). There was no improvement in the SIP at three months, but significant improvement was found at six months ($p<0.05$).

Conclusions. This study shows that a successful outpatient programme can be conducted in patients with severe ventilatory impairment, and that benefits in physical ability and in health-related quality of life (HRQOL) can be achieved. The improvements were maintained at six months. **[Indian J Chest Dis Allied Sci 2010;52:197-201]**

Key words: Chronic obstructive pulmonary disease, Pulmonary rehabilitation, Health-related quality of life

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is predicted to become the third most frequent cause of death in the world by the year 2020.[1] It is characterised by poorly reversible airflow limitation and dyspnoea.[2-4] As the disease progresses, some patients develop systemic manifestations, including exercise limitation,[4,5] peripheral muscle dysfunction,[5-7] pulmonary hypertension,[8] malnutrition[9,10] and recurrent exacerbations leading to hospitalisations.[11] Due to the lack of effect of most therapies on the decline of lung function,[2,3,12] COPD is perceived as being poorly responsive to treatment. However, several studies have identified the value of correcting gas exchange,[13,14] improving walk distance,[2,3,15-17] degree of functional breathlessness[18] and nutritional status.[19] Therefore, assessing and treating COPD solely on the basis of airflow limitation negates the importance of other treatable clinical manifestations of the disease.

Pulmonary rehabilitation (PR) is a therapy that without significantly improving lung function, impacts on some of the other consequences of the disease. The PR reduces healthcare resource utilisation,[20,21] improves health status,[22] decreases dyspnoea[18,23] and enhances exercise capacity.[24-27]

Rehabilitation programmes for patients suffering from COPD are now well established, particularly, in North America and in continental Europe; as these have been shown to improve patients' physical activity and HRQOL.[28-31] Published results have included patients with a wide variation in severity, the majority having disease of moderate severity.[32] The study concentrating exclusively upon patients with severe disease, an impatient study, lasting for weeks was found to be very expensive. In this study, we have designed a programme with elements of

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exercise, education and psycho-social support specifically for outpatients with severe disease using the entry criteria of FEV_1 less than 40% of predicted. The purpose of the study was to investigate the feasibility of an outpatient rehabilitation programme for such patients.

PATIENTS AND METHODS

Forty-four patients with severe COPD (FEV_1 less than 40% of predicted) were recruited from an outpatient chest clinic of the University College Hospital, Ibadan, Nigeria between January 2007 to July 2007. They were under regular surveillance and had either been referred for an opinion and assessment or had been identified following an emergency hospital admission. The patients were required to be in a stable state and on optimum drug therapy. No changes were made to their drug therapy during the period of study. Patients with other significant medical problems such as severe ischaemic heart disease or marked limb abnormality that would limit their exercise ability were excluded. Patients with 15% or more reversibility of their airflow obstruction were also excluded. Two patients, who were still smoking were not excluded. This study was approved by the Joint Ethical Committee of University College Hospital/University of Ibadan, Nigeria. All patients provided written informed consent to participate.

The baseline characteristics of the patients including measurements of ventilatory function together with bronchodilator response, a shuttle walking test[31] with two measurements being made at least 30 minutes apart, and assessment of oxygen saturation before and after the shuttle walk and of the degree of breathlessness on completion of the walk according to the Borg scale were recorded. A resting electrocardiogram was also recorded.

Standardised questionnaires were completed on the assessment day. These consisted of a condition specific measure, a psychological distress measure and a generic quality of life (QOL) measure. The chronic respiratory disease questionnaire (CRDQ) described by Guyatt *et al*[32] is a questionnaire administered by an interviewer examining four dimensions, each of which contains the following number of items: dyspnoea (5); fatigue (4); emotional function (7); and mastery (4). It includes questions about frustration, panic, fear of breathlessness, confidence and control of disease. An increase in score represents improvement, and a change of 0.5 per item within each dimension is associated with a minimally important change in health-related quality of life (HRQOL).[11] The questionnaire was administered by the chest physician. The hospital anxiety and depression scale (HAD)[33] and the sickness impact profile (SIP)[34] are both self-administered questionnaires. They are widely used in the assessment of functioning of people with illness or injury. The HAD is concerned with the level of symptoms of anxiety and depression. The SIP is a QOL measure comprising 12 sub-scale measures of different aspects of physical impairment, psychological and social functioning. From this profile an overall disability score is calculated.

The patients entered the programme within two weeks of assessment. This was a six weeks course during which groups of 8-12 patients attended twice weekly for a 2½ hour session. Where there were difficulties with transport, it was provided. The programme schedule comprised three main elements: an exercise programme, individual goal setting and education. Each session began with a series of exercises which included specific arm, leg and walking steps, sit to stand walking and wall press-up. The exercises were supervised by a physiotherapist and the nurse educator and suitable exercises were prescribed according to the patient's abilities. Patients were asked to repeat each exercise for a maximum of four minutes. They were given advice on how to pace themselves and on stopping to relieve breathlessness. The nurse educator and the respiratory physician examined each patient during the session to review their circumstances and to set individual goals. The patients were asked to identify activities lost to them with the worsening of the COPD symptoms but where there was some scope for resumption, throughly planned and paced in stages. These included tasks such as cooking a meal, looking after grandchildren, increasing walking distance with a regular trip (say to the nearby bus stop).

After an interval for rest, the patients had an education session and discussion covering a variety of topics relating to the lung condition and its management. These talks were given by the nurse educator, physiotherapist respiratory physician and the psychiatrist. The educational topics covered the following aspects: how our lung work, breathing and breath control, chronic bronchitis and emphysema, use of steroid, living with breathlessness, diet and the lungs, using inhalers and nebulisers, and further advice. Assessment was repeated within two weeks of completion of the programme (approximately three months from first assessment) and again three months later (the six months assessment).

Statistical Analysis

The questionnaires used are standard measures, the psychometric properties of which have been used in previous studies.[32-34] Statistical analysis was carried out using Statistical Package for Social Science (SPSS) software version 13. Baseline characteristics and

exercise data are presented as mean ± SD (standard deviation). Mean and ranges were identified for quality of life scores. The differences were compared using repeat measures analysis of variance and where analysis of variance identified a significant difference, post hoc tests were computed. Mean difference and 95% confidence interval (CI) are presented where necessary. Analysis was performed at baseline, three months and six months. A p value of <0.05 was considered statistically significant.

RESULTS

The data of patients completing 10 or more of the 12 sessions were analysed. Two patients were dropped from the study, one because of an exacerbation of the lung condition and the other because of the possible development of tuberculosis. Six patients were lost to discontinue treatment between three and six months.

There were 28 males and 14 females with a mean age of 66 (ISD 7.4) years. There was no significant change in forced expiratory volume in one second (FEV_1), vital capacity, peak expiratory flow rate or baseline oxygen saturation. Following the repeat shuttle walk there was no change in the oxygen saturation or in the degree of breathlessness as measured on the Borg scale.

There was a statistically significant improvement of 25 metres (95% CI: 11, 39) in the mean shuttle distance, which was maintained at six months, the mean improvement over baseline being 33 metres (95% CI: 15, 50) (Table 1). Data on patient-reported outcomes is shown in table 2.

Table 1. Objective outcome parameters during the study

Parameters	Baseline (n=42)	3 Months (n=42)	6 Months (n=36)
FEV_1 (L)	0.77±0.36	0.74±0.34	0.70±0.26
VC (L)	1.97±0.74	1.99±0.66	1.92±0.64
PEFR (L/min)	148.3±61.5	142.6±51.4	137.9±40.2
Shuttle distance (metres)	156.5±94	182.6±104†	193.9±103
Borg scale*	3.56±0.8	3.66±0.8	3.71±0.9
Oxygen saturation* (%)	91.05±4.0	90.46±5.4	90.29±5.4

Data is shown as mean±SD; *Measured on completion of shuttle test. †p<0.001; FEV_1=Forced expiratory volume in the one second; VC=Vital capacity; PEFR=Peak expiratory flow rate

All four dimensions of the CRDQ improved significantly and, apart from breathlessness, the improvements were maintained at the six months review. Although six subjects dropped out at six months, there was still a significant decline in the mean fatigue score from 2.7 at three months to 1.6 at six months (p<0.05). In addition, at six months a significant improvement compared to baseline was maintained (14.8 to 16.4) (Table 2). Therefore, the mean difference in fatigue met the estimated minimum change for clinical significance at both three and six months, while the change in mastery was clinically significant at six months.

Table 2. Patient-reported outcome parameters during the study

Parameters	Baseline (n=42)	Mean Difference (95%CI) from Baseline	
		3 Months (n=42)	6 Months (n=36)
CRDQ			
Dyspnoea	14.3 (5.1)	1.9 (0.5, 3.5)*	1.7(-0.2, 3.5)*
Fatigue	14.8 (4.9)	2.7 (1.5, 4.1)*	1.6(0.03, 3.2)
Emotion	33.8 (97.2)	3.2 (1.8, 4.6)*	2.5 (0.2, 4.8)*
Mastery	18.5 (4.7)	2.0 (0.7, 3.3)*	2.8 (1.3, 4.2)*
HAD			
Anxiety	6.7 (3.9)	-0.7 (-0.04, -1.4)*	-0.8(-0.2, 1.8)*
Depression	6.1 (2.9) (n=35)	-0.5 (-0.2, 1.2)* (n=35)	-0.69-0.1, 1.4)* (n=29)
SIP (total)	11.9 (8.3)	+0.5 (-1.9, 2.8)	-1.5(-3.3, 0.3)*

*=p<0.05; Data at three and six months compared to baseline; CI=Confidence interval; CRDQ=Chronic respiratory disease questionnaire; HAD=Hospital anxiety and depression scale; SIP=Sickness impact profile

In 35 patients completing the SIP, there was no statistically significant improvement in the first three months but this reached significance during the next three months (n=29). The HAD scale showed a statistically significant reduction in both the anxiety and depression sub-scale scores. Before the course, 17 patients (40%) had a significant level of anxiety, according to the recommended cut-off score equal to or greater than eight. On completion of the programme the number above the cut-off level had fallen to 11 (27%). Clinically significant depression as defined by the cut-off score of eight was noted in 13 (32%) patients before the programme. However, on completion of the programme, this had decreased to 11 (27%). The reduction in the degree of depression remained significant at six months.

DISCUSSION

This study has shown that a successful outpatient based rehabilitation programme is feasible and possible in patients with very severe COPD. Significant improvements can be achieved in shuttle walking distance, quality of life and psychological measurements, and the improvement is maintained for at least three more months without further intervention. As this was an open study we are unable to identify the relative importance of the various elements of the programme, and in the absence of a control group we cannot be sure that some of the improvements would not have occurred spontaneously. However, this is unlikely as the patients were in a stable state when they entered into the programme.

In common with other studies, there was no improvement in ventilatory function. Therefore, improvements in the shuttle distance and QOL scores were independent of changes in ventilatory function. The mean improvements in fatigue at three and six months and in mastery at six months were clinically significant. The SIP did not change at the first assessment but did improve at six months. The reason for this delayed effect is not clear. These results are in agreement with those from previous studies,[35-37] where the clinical relevant degree of change in the CRDQ have been assessed.

Few studies have addressed the effects of rehabilitation programmes on anxiety and depression. We found significant levels of both traits in our patients and have shown sustained improvements in both.

All our patients had very severe COPD with a mean FEV_1 of 0.7 litre at baseline. Previous rehabilitation programmes have included patients with a wide range of severity, and in general, these have been patients with a mean FEV_1 of more than one litre. The only comparable study of COPD patients is that of Goldstein *et al*[30] where the inclusion criterion was the same, *i.e* FEV_1 less than 40% of predicted. They found an improvement in walking distance and small improvements in CRDQ. However, the intervention was an inpatient programme lasting eight weeks and was followed by outpatient supervision for 16 weeks. In the inpatient study by Moser *et al*[38] of 42 patients, the mean FEV_1 was 0.9 litre. They found that functional improvement tended to occur in those with the best lung function, and one of their conclusions was that the most severely impaired patients may not be good candidates for a rehabilitation programme.

Other programmes have included patients with very variable severity of impaired lung function and have been conducted both in the home and as outpatients. Wijkstra *et al*[39] described a supervised home programme and found improvements in exercise tolerance and in QOL as measured by the CRDQ. The improvement in CRDQ was 14 points. The greater improvement in this study may be accounted for by a different patient population; their patients had an FEV_1 less than 60% of predicted, giving a mean FEV_1 of 1.3 litres, indicating a less severe disease. The outpatient study by Ries *et al*[26] compared a comprehensive outpatient programme with another one involving only education; and found improvement in exercise tolerance and in symptoms, but no improvement in depression. Although there were some severely ill patients, they also included those with mild disease, and the mean FEV_1 was 1.2 litres. Strijbos *et al*[40] compared a hospital-based programme with a home-based programme, each of which lasted 12 weeks, together with a control group. They found beneficial effects in exercise capacity in each of the active arms of the study. No measurements for QOL were made. Again, these were patients with impaired lung function of variable severity, with an FEV_1 of less than 65% of predicted as the entry criterion. It should also be noted that there was an average bronchodilator response of 20% suggesting that the patients were not comparable with ours in severity or in reversibility, since we had specifically excluded patients with 15% or greater reversibility with bronchodilator.

In the present study, losing six subjects to follow-up did not change the result of the analysis for any outcome measure. This was similar to the findings of Lacesse *et al*[23] in the Cochrane review of pulmonary rehabilitation for COPD.

CONCLUSIONS

The present study has shown that even with severe disease it is feasible to conduct outpatient programme that is not too expensive and appears to show benefits. It remains to be shown that patients with severe disease could achieve the same benefits in other settings, such as a home-based programme. Randomised trials are needed to answer these questions and to assess the effect of various programmes on the utilisation of healthcare resources.

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