Outpatient pulmonary rehabilitation in severe chronic obstructive pulmonary disease

ABSTRACT – *Background:* This is a study of an outpatient programme for rehabilitation of patients with severe ventilatory impairment due to chronic obstructive pulmonary disease (COPD). Its main purpose was to assess the feasibility of such a programme and so no control group was included.

Methods: The study included 44 patients (28 men) of mean age 66 years with COPD. They all had severe ventilatory impairment as defined by a forced expiratory volume in 1 second (FEV_1) less than 40% of predicted. Initial assessment included a shuttle walking test, the Chronic Respiratory Disease Questionnaire (CRDQ), the Hospital Anxiety and Depression scale (HAD) and the Sickness Impact Profile (SIP). The patients then entered a 6-week outpatient programme during which they attended twice weekly for a 2½ hour session. Assessment was repeated on completion of the study (the 3½ month assessment) and at 6 months.

Results: The shuttle walking distance improved significantly and was maintained at the improved level for 6 months. The improvement in all four dimensions of the CRDQ was statistically significant and reached clinical significance for fatigue and for mastery. On entry, a notable level of depression was found in 32% of patients, and of anxiety in 40%. There was significant reduction in both of these which was maintained at 6 months. There was no improvement in the SIP at 3 months, but significant improvement was found at 6 months.

Conclusions: This study shows that a successful outpatient programme can be conducted in patients with severe ventilatory impairment, and that apparent benefit in physical ability and in health-related quality of life can be achieved. The improvements were maintained at 6 months.

Rehabilitation programmes for patients suffering from chronic obstructive pulmonary disease (COPD) are now well established, particularly in North America and in continental Europe; they improve patients' physical activity and health-related quality of life[1–7]. A recent meta-analysis of 14 controlled trials of rehabilitation in COPD showed that there is improvement in dyspnoea and control over COPD. There was also improvement in exercise capacity, which was statistically significant, but its clinical importance was uncertain because the gain was little more than the minimum perceived by patients as important[8].

Published results have included patients with a wide variation in severity, the majority having disease of moderate severity. The only study concentrating exclusively upon patients with severe disease, an inpatient study, lasted 8 weeks and was therefore very expensive[5]. We have designed a programme with elements of exercise, education and psycho-social support specifically for outpatients with severe disease using the same entry criteria, ie $FEV_1 < 40\%$ of predicted. The purpose of the present study was to investigate the feasibility of an outpatient programme for such patients.

R J WHITE, MD, FRCP, *Respiratory Department*
S T RUDKIN, BSc, *Respiratory Department*
J ASHLEY, BSc, *Respiratory Department*
V A J STEVENS, Grad Dip Phys, *Physiotherapy Department*
S BURROWS, Grad Dip Phys, *Physiotherapy Department*
J C POUNSFORD, MD, FRCP, *Department of Care of the Elderly*
G CRATCHLEY, BSc, *Department of Clinical Psychology*
N R AMBLER, BSc, MSc, *Department of Clinical Psychology*
Frenchay Hospital, Bristol

Patients and methods

Forty-four patients with severe COPD (FEV_1 less than 40% of predicted) were recruited from an outpatient clinic. When asked if they wished to enter the rehabilitation programme, none declined the invitation. 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 were still smoking but they were not excluded. Five patients were receiving long-term oxygen therapy.

The baseline characteristics are shown in Table 1. They included: measurements of ventilatory function together with bronchodilator response; a shuttle walking test as described by Singh *et al*[9], 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. A resting electrocardiogram was recorded.

Standardised questionnaires were completed on the assessment day. They consisted of a condition specific measure, a psychological distress measure and a generic quality of life measure. The Chronic

Table 1. Mean baseline characteristics.

Age (years)	66 (SD 7.4)
Sex (M/F)	28/13
FEV1 (litres)	0.78 (SD 0.36)
FEV1 (% predicted)	25.7 (SD 10.3)
Shuttle distance (metres)	156.5 (SD 94)

SD=standard deviation.

Respiratory Disease Questionnaire (CRDQ) described by Guyatt *et al*[10] 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[11]. The questionnaire was administered by the respiratory nurse. The Hospital Anxiety and Depression scale (HAD)[12] and the Sickness Impact Profile (SIP)[13] 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 quality-of-life measure comprising 12 subscale measures of different aspects of physical impairment, psychological and social functioning. From this profile an overall disability score is calculated.

Within 2 weeks of assessment the patients entered the programme. This was a 6-week course during which groups of 8–12 patients attended twice weekly for a 2½ hour session. Where there were difficulties with transport, a minibus owned by a local community welfare organisation was used. This was hired twice a week and was driven by two volunteer drivers, both of whom had COPD and had completed the programme.

The programme timetable comprised three main elements: an exercise programme; individual goal setting; and education. Each session began with a series of exercises which included specific arm and leg exercises, trampoline, steps, wall press-ups, sit to stand and walking. The exercises were supervised by a physiotherapist and respiratory nurse and suitable exercises were prescribed according to the patients' abilities. Patients were asked to repeat each exercise for a maximum of 4 minutes. They were given advice on how to pace themselves and on stopping to relieve breathlessness.

The respiratory nurse and a clinical psychologist saw 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, through planned and paced stages. These included tasks such as cooking a meal, looking after grandchildren, increasing walking distance with a regular trip, say, to the post office, and specific light gardening tasks.

After an interval for rest the patients had an education session and discussion covering a variety of topics relating to lung conditions and their management. These talks were given by nurses, physiotherapists, physicians, respiratory technician and the clinical psychologist (Table 2).

Assessment was repeated within 2 weeks of completion of the programme (approximately 3 months from first assessment) and again 3 months later (the 6-month assessment).

Statistical methods

The questionnaires used are standard measures, the psychometric properties of which have been detailed elsewhere[10–13]. Comparisons were made at each point of the patients' assessments using Student's *t* test.

Results

Forty-four patients were recruited for the study. The measurements from patients completing ten or more of the twelve sessions were analysed. Two patients dropped out from the study, one because of an exacerbation of the lung condition and one because of the possible development of tuberculosis. Six patients were lost to analysis between 3 and 6 months.

Outcome measures (Table 3 and 4)

There was no significant change in FEV_1, vital capacity, peak 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.

Table 2. Education topics.

- How our lungs work
- Stress, breathlessness and relaxation
- Breathing and breathing control
- Chronic bronchitis and emphysema
- Chest infections
- Steroids
- Living with breathlessness
- Diet and the lungs
- When to call your general practitioner
- Lung function tests
- Using inhalers and nebulisers
- Quiz and further advice

There was a significant improvement of 25 metres (95% CI 11, 39) in the mean shuttle distance, which was maintained at 6 months, the mean improvement over baseline being 33 metres (95% CI 15, 50).

All four dimensions of the Chronic Respiratory Disease Questionnaire improved significantly and, apart from breathlessness, the improvements were maintained at the 6-month review. The mean difference in fatigue met the estimated minimum for clinical significance at both 3 and 6 months, and the difference in mastery was clinically significant at 6 months.

In the 35 patients completing the SIP, there was no statistically significant improvement in the first 3 months but this reached significance during the second 3 months (n=29).

The HAD scale showed a statistically significant reduction in both the anxiety and depression subscale scores. Before the course, 17 patients (40%) had a significant level of anxiety, according to the recommended cut-off score of equal to or greater than 8. 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 8 was noted in 13 patients (32%) before the course. On completion of the programme this had fallen to 11 (27%). The reduction in the degree of depression remained significant at 6 months.

The cost of the programme has been calculated in relation to staffing, and was estimated to be about £400 per patient; attending the programme only, without the detailed assessments, would have reduced the costs by approximately a third. No account has been taken of non-staff running costs and the capital and depreciation costs of equipment.

Discussion

This study has shown that a successful outpatient based rehabilitation programme is possible in patients

Table 3. Mean physical measures (and standard deviation).

	Baseline $n = 42$	3 months $n = 42$	6 months $n = 36$
FEV_1 (litres)	0.77 (0.36)	0.74 (0.34)	0.70 (0.26)
VC (litres)	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)

*Measured on completion of shuttle test. †$p < 0.001$.

Table 4. Quality of life data.

		Mean difference (95% CI) from baseline	
	Baseline (SD) $n = 42$	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 (7.2)	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)	–0.5 (–0.2, 1.2)*	–0.6 (–0.1, 1.4)*
	$n = 35$	$n = 35$	$n = 29$
SIP (total)	11.9 (8.3)	+0.5 (–1.9, 2.8)	–1.5 (–3.3, 0.3)‡

* $p < 0.05$

† There was a significant decline in the fatigue score ($p < 0.05$). However, at 6 months there was still a significant improvement from baseline.

‡ There was no significant difference between baseline and 3 months, but there was a significant difference between baseline and 6 months ($p < 0.05$). A reduction in score represents improvement.

with very severe COPD. Significant improvements can be achieved in shuttle walking distance and quality of life and psychological measurements, and the majority of these improvements persist for at least 3 more months without further intervention. Since 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, we think this is unlikely since the patients were in a stable state when entered into the programme and even those who were recruited following hospital admission were not started until they were stable.

In common with other studies, there was no improvement in ventilatory function. Had any improvement been seen the greater shuttle distance and the improved quality-of-life scores could have been attributable to such a change.

The clinically relevant degrees of change in the CRDQ have been assessed[11]. The mean improvements in fatigue at 3 and 6 months and in mastery at 6 months were clinically significant. The Sickness Impact Profile (SIP) did not change at the first assessment but did improve at 6 months. The reason for this delayed effect is at present unexplained.

Few studies have addressed the effects of rehabilitation programmes on anxiety and depression. We found significant levels of both in this group of patients and have shown sustained improvement in depression and short-term improvement in anxiety.

All our patients had very severe COPD with a mean FEV_1 of 0.78 litre. Previous rehabilitation programmes have included patients with a wide degree of severity and in general these have been patients with a mean FEV_1 of more than 1 litre. The only comparable study of COPD patients is that of Goldstein *et al*[5]. Their inclusion criterion was the same, ie FEV_1 less than 40% of predicted. They found an improvement in walking distance and small improvements in CRDQ. However, theirs was an inpatient programme lasting 8 weeks and was followed by outpatient supervision for 16 weeks. It was expensive, costing approximately 12,000 Canadian dollars per patient.

In the study by Moser *et al*[14] of 42 patients, the mean FEV_1 was 0.91 litre but this also was an inpatient programme. 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 were not good candidates for a rehabilitation programme.

Other programmes have included patients with very variable severity of impaired lung function and have taken place both in the home and as outpatients. Wijkstra *et al*[3] described a supervised home programme and found improvements in exercise tolerance and in quality of life as measured by the CRDQ. The improvement in CRDQ was 14 points. This greater improvement 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 group.

The outpatient study by Ries *et al*[6] compared a comprehensive outpatient programme with one involving education only; they 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*[7] 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 quality-of-life measurements were made. Again, these were patients with impaired lung function of variable severity, with an FEV_1 less than 65% of predicted as an 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 more reversibility with bronchodilator.

Our study has shown that even with severe disease it is practicable to conduct an outpatient programme which is not too expensive and appears to show benefit. It remains to be shown whether patients with severe disease could achieve the same benefits by other means, for example, from 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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Address for correspondence: Dr R J White, Consultant Physician, Respiratory Department, Frenchay Hospital, Frenchay Park Road, Bristol BS16 1LE.