The Effectiveness of Outpatient Pulmonary Rehabilitation in Chronic Lung Disease*

A Randomized Controlled Trial

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Background: Patients with chronic pulmonary disease have been shown to benefit from pulmonary rehabilitation programs. Published work has often been from specialized teaching centers and has involved inpatient stay. We assessed an entirely outpatient-based program of pulmonary rehabilitation in patients with chronic lung disease, using the St. George’s Respiratory Questionnaire (SGRQ) (which measures health-related quality of life) as the primary outcome measure.

Methods: We undertook a randomized, prospective, parallel-group controlled study of an outpatient rehabilitation program in 65 patients with COPD (44 men and 21 women; mean age, 69.5 years [SD, 9.2 years]; FEV1, 41% predicted [SD, 18.5%]). The active group (n = 36) took part in a 6-week program of education (2 h weekly) and exercise (1 h weekly). The control group (n = 29) were reviewed routinely as medical outpatients. The SGRQ was administered under supervision by a blinded observer at study entry, 12 weeks, and 24 weeks.

Results: The SGRQ in the active group was 59.9 (SE, 2.0) at study entry (n = 36), 47.4 (SE, 2.3) at 12 weeks (n = 32), and 50.6 (SE, 2.5) at 24 weeks (n = 24). The SGRQ in the control group was 59.3 (SE, 2.5) at study entry and did not change significantly over 24 weeks. There was a difference of 10.4 points (confidence interval [CI], 3.6 to 17.3) between the two groups at 12 weeks (p < 0.001) and of 8.1 points (CI, 1.4 to 14.9) at 24 weeks (p = 0.02) in favor of the active group.

Conclusions: A 6-week outpatient-based program significantly improved quality of life in patients with moderate-to-severe COPD. Benefit was still evident after 24 weeks.

Key words: lung diseases; pulmonary rehabilitation; quality of life

Abbreviations: BMI = body mass index; CI = confidence interval; SGRQ = St. George’s Respiratory Questionnaire

The role of rehabilitation in the management of patients disabled by chronic lung disease (principally COPD) has been the subject of much interest. Much initial work1 was based on inpatient-based treatment, where the expense precludes widespread application, but several recent trials2,3 have looked at the efficacy of outpatient-based treatment.

We wished to assess the effectiveness of a less intensive, exclusively outpatient-based 6-week program of rehabilitation in patients with COPD, to see if the same benefits in quality of life and exercise capacity could be obtained at less cost and time to both medical team and patients. We therefore undertook a randomized controlled trial of a 6-week program of pulmonary rehabilitation vs usual outpatient review at three monthly intervals. The program incorporated among other features both an educational and a physiotherapy-based exercise component, since both are believed to be important in achieving benefit in COPD.4 The principal outcome measure was change in quality of life as measured by the St. George’s Respiratory Questionnaire (SGRQ), assessed at 3 months and 6 months.

Materials and Methods

Patients

Patients accepted into the study were known to the respiratory team at the hospital as having long-standing airways disease, classified as COPD, and were approached during attendance at
an outpatient clinic by a respiratory nurse specialist (I.B.), who discussed the study in the course of assessing their condition and progress. All had had their therapy optimized, the role of oral or inhaled steroids and nebulized bronchodilator therapy having been assessed in all patients. Patients were assessed as to their ability to comply with the requirements of the program, specifically the time and travel commitments involved. All had either given up smoking or were prepared to make an active effort to stop smoking during the proposed program.

Contraindications to entry into the study were dementia or marked agitation or depression evident to the investigators, and unstable medical conditions, such as congestive cardiac failure, cor pulmonale, malignancy, or cerebrovascular accident. None had previously taken part in a supervised respiratory rehabilitation program.

Patients were assessed using a standard 6-min walk, and completed the SGRQ; both tests were supervised by a blinded observer who subsequently repeated these assessments at 12 weeks and 24 weeks. Patients were then randomized to either the rehabilitation program or to routine outpatient attendance at 3-month intervals. Randomization was in blocks of 10, using random numbers.

Rehabilitation Program

The 6-week outpatient-based rehabilitation program involved two visits per week: a 2-h education visit and a 1-h exercise visit. Participants were also invited to attend the local "Breathe Easy" club, which convenes monthly, and subsequent "drop-in" exercise sessions at 8 weeks, 9 weeks, and 10 weeks. Those who provided primary care were also invited to the education visits, and all patients were given an information pack that included a tailored schedule and action plan. During the course of the program, patients underwent an initial medical assessment and then received input from a team comprised of a physiotherapist, an occupational therapist, a respiratory specialist nurse, and a dietician.

Physiotherapy

The physiotherapist discussed breathing problems and techniques at each of the six educational visits, and emphasized home exercise regimes. At the exercise visits, there was a 10-min warm-up period, 25 min of aerobic activity, and a 10-min cool-down period. The aerobic activity included diagonal arm raises, arm abduction into elevation and reverse, and arm abduction, forward flexion, and reverse; treadmill or static bicycle exercise; step-ups with three step heights; and straight leg raises. In addition, subjects were asked to exercise once or twice daily a minimum of five times a week, using a walking program with nine levels, the maximum level being 10 min of rest and then 10 min of walking.

Dietary Assessment and Advice

Each patient’s body mass index (BMI) and dietary history were assessed, and progress in any advised change in eating habits was assessed each week.

Occupational Therapy Assessment

The occupational therapist interviewed each patient during week 1 and week 2, making referrals to social services and other agencies as appropriate. During week 3 and week 4, the occupational therapist gave advice on coping with low activity levels, and discussed coping strategies for the loss of interest in leisure activities due to breathlessness.

Psychological Input

A liaison nurse counselor discussed anxiety and relation techniques in week 2, sleep problems in week 5, and led an open discussion on relaxation techniques in week 6.

Analysis

The primary outcome measures were changes in the SGRQ total scores after 12 weeks and 24 weeks. Secondary outcome measures were changes in walking distance at the same times. An unpaired t test was done of the difference between the baseline measurement and the measurement made at 12 weeks or 24 weeks, and 95% confidence intervals (CIs) were constructed for the difference between the mean changes in each of the two groups. In addition, paired t tests were performed within each group to assess within group whether change from baseline had occurred.

Results

One hundred eight patients who were believed to fulfill the criteria of the study were approached, and they agreed to provisional assessment and detailed discussion of the requirements of the study. Of these, 100 patients were randomized for study. Fifty patients were randomized to the active group; of these, 10 patients did not attend their first study review, leaving 40 patients starting the study. Fifty patients were randomized to the control group; of these, 17 patients did not attend their first study review, leaving 33 patients starting the study. Four patients in each group were excluded from analysis as their diagnosis on review was not COPD (lung fibrosis [n = 5], bronchiectasis [n = 3]), leaving 65 patients with COPD recruited to the study (Fig 1). The mean FEV₁ was 0.99 L (SD, 0.36 L) in the active group, and 1.06 L (SD, 0.50 L) in the control group; the mean FVC was 1.85 L (SD, 0.65 L) in the active group and 1.85 L (0.67 L) in the control group. There was no significant difference in sex distribution, age, smoking history, or spirometry between the two groups (Table 1).

Quality-of-Life Measures

The SGRQ is a 76-weighted-item questionnaire, in which results are expressed as scores for symptoms, activity, impacts on daily life, and an integrated total score. The groups were well matched for SGRQ scores and walking distances on study entry (Table 2).

The SGRQ integrated total scores for the control group were 59.3 (SE, 2.5) at study entry (n = 29), 58.5 (SE, 3.7) at 12 weeks (n = 23), and 57.1 (SE, 3.0) at 24 weeks (n = 25). For the control group, there were no significant differences over the 6-month study period in scores for symptoms, impacts on daily life, impacts, or integrated total scores (Table 3).
The SGRQ integrated total scores for the active group were 59.9 (SE, 2.0) at study entry (n = 36), which closely matched the scores in the control group. At 12 weeks, the mean SGRQ total score was 47.4 (SE, 2.3; n = 32; Table 3). This was significantly different from baseline (p < 0.001, paired t test), with a mean reduction in total score of 11.6 (CI, 6.8 to 16.3). The changes from baseline in SGRQ total score at 12 weeks were compared between the active and control groups: the mean difference was a reduction of 10.4 (CI, 3.6 to 17.3) in favor of the active group (p < 0.01). At 24 weeks, the mean SGRQ total score in the active group was 50.6 (SE, 2.5). This was significantly different from baseline (p < 0.001, paired t test), with a mean reduction in total score of 9.7 (CI, 4.6 to 14.7). Changes from baseline in SGRQ total score at 24 weeks were compared between the two groups: the mean difference was a reduction of 8.1 (CI, 1.4 to 14.9) in favor of the active group (p < 0.02).

A secondary analysis of the components of the total SGRQ score, namely symptom score, activity score, and impact on daily living score, revealed significant reductions in all three components in the
active group (for each, \( p < 0.01 \)), so that the change in total scores could not be attributed principally to a change in any one component.

**Walking Distance**

The mean distances walked over 6 min, supervised by a physiotherapist blinded to the subjects’ randomization, are summarized in Table 4. The active group had a shorter 6-min mean distance at study entry, although it did not differ significantly from that of the control group. There was a mean increase of 51 m (CI, 20 to 81 m) in the active group after 12 weeks, which was significantly greater than the mean change in the control group (\( p < 0.02 \)). There was a mean increase of 53 m in the active group compared with baseline at 24 weeks, but this did not reach statistical significance either within the active group or in comparison with the control group.

**Dropouts**

In the active group, 10 patients dropped out after randomization and before the first study visit; 4 patients failed to attend the second visit, and a further 8 patients failed to attend for the third visit. In the control group, 17 patients dropped out completely after randomization, 6 patients were unable to attend the second visit (3 of whom did attend the third visit), and 1 patient failed to attend the third visit only (due to intercurrent illness). Where a reason could be elicited, the inconvenience of hospital attendance was cited.

**Discussion**

The current study has shown the sensitivity of the SGRQ in detecting improvements in quality of life in patients with COPD. There are several different instruments for measuring health-related quality of life in patients with COPD, of which the chronic respiratory disease questionnaire, the SGRQ, and the baseline dyspnea index have been demonstrated to be reproducible, valid, and responsive.\(^5\) The most comprehensive disease-specific instrument, the chronic respiratory disease questionnaire,\(^6\) deals with perceptions of dyspnea, fatigue, patients’ sense of control over their disease, and emotional dysfunction. It depends in part on each patient identifying areas of life disturbed by disease, so that the result is individualized, and is difficult to compare between different studies. The SGRQ has the advantage of being a standardized questionnaire, allowing comparison between studies and different interventions, and hence was chosen for this study. It has been shown to follow other indexes of disease activity in patients with both asthma and COPD.\(^7\) The SGRQ routinely takes about 10 min to administer, which in our study was not simply self-administered, but was supervised by an observer blinded to the patients’ randomization. Each component of the questionnaire gives a weighted score between 0 and 100, including the total, with normal values in healthy individuals of < 7 for each component. A change of 4 points in the total score has been shown to represent the minimally clinically significant change.\(^8,9\) Thus our results, with reduction in total scores (within the active group) of 11.6 at 3 months and 9.7 at 6 months, clearly represent clinically significant benefits from the treatment program. These results are superior to those established using the same instrument of quality of life to assess the efficacy of inhaled salmeterol in COPD, where a reduction in total score within group of 6.8 was found with a dosage of 50 \( \mu g \) bid.\(^10\) They are comparable to the changes observed by Griffiths et al.\(^2\) That group studied the effect of outpatient rehabilitation in patients with COPD, and observed a mean improvement in total SGRQ score of 9.4 points at 6 weeks, which remained significant at 4.8 points after 1 year.

The nature of the pulmonary rehabilitation that should be offered is not clear from the literature. Our study did not attempt to unravel this, merely attempting to incorporate those areas where there was some evidence for efficacy. For example, there is

<table>
<thead>
<tr>
<th>Parameter</th>
<th>Active Group</th>
<th>Control Group</th>
</tr>
</thead>
<tbody>
<tr>
<td>Total integrated score</td>
<td>59.9 (2.0)</td>
<td>59.3 (2.5)</td>
</tr>
<tr>
<td>Walking distance, m</td>
<td>245 (18)</td>
<td>273 (19)</td>
</tr>
</tbody>
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*Data are presented as mean (SE).
evidence to indicate that not only is a low BMI associated with increased mortality in COPD, but that treating this successfully leads to an improvement in survival.\textsuperscript{11} In the present study, dietary goals were set at an initial interview; of 5 underweight participants, all achieved some weight gain, while of 11 overweight participants, 6 achieved some weight loss.

Exercise and training are regarded as important components of rehabilitation programs, although the duration, intensity, and nature of the exercise required for sustained benefit are unclear,\textsuperscript{12} and there are few controlled trials assessing this. One controlled trial showed that outpatient-based rehabilitation including education and exercise training > 3 months gave improvements in exercise tolerance sustained for 6 months.\textsuperscript{13} An uncontrolled study demonstrated that 5 h/wk of exercise training and educational input over 6 weeks was associated with a significant improvement in shuttle walking distance, which was maintained for 6 months.\textsuperscript{14} Another uncontrolled study of 44 patients with COPD showed a significant improvement in dyspnea with an outpatient program of as little as 1.5 h/wk of supervised education, breathing training, and exercises, although as expected there was no evidence of a physiologic training response.\textsuperscript{15} Thus, our program which included 1 h of supervised exercise per week plus a program for home exercise might reasonably have been expected to be sufficient to improve dyspnea, although clearly it is not established whether this is the optimal regimen.

Guidelines\textsuperscript{16,17} on pulmonary rehabilitation have reviewed the strength of the evidence for current practices. One analysis gave the strength of evidence for improvement in quality of life with rehabilitation as grade B, and outlined three randomized controlled trials addressing this topic; of these, only one trial used a control group with no rehabilitation or educational input and was also outpatient-based rehabilitation.\textsuperscript{18} The American Thoracic Society review\textsuperscript{17} did not identify any further studies of the type described in the current article, namely exclusively outpatient-based rehabilitation with a control group not receiving anything other than standard medical care. Our literature search reveals two articles\textsuperscript{2,3} that are of this type. The regimen described by Griffiths et al\textsuperscript{2} was very similar to our own, involving a 6-week outpatient-based program, and showed improvements in quality of life that were maintained for a year. This study comes from a center of excellence in research in pulmonary rehabilitation, and it cannot be assumed that similar results can be obtained in nonteaching hospitals. Engstrom et al\textsuperscript{3} also used an initial 6-week rehabilitation program, but they described a gradual transition from this to a home-based program and also incorporated booster sessions. It is of interest that in their study, no significant effect was seen on the scores achieved with the SGRQ, although minor improvements in exercise tolerance were observed.

In conclusion, this study demonstrated in a controlled study that a 6-week program of outpatient-based pulmonary rehabilitation of 3 h/wk achieved a clinically significant increase in patients’ quality of life that was maintained for at least 6 months. There was also an increase in exercise tolerance maintained for at least 3 months. This was achieved in a nonteaching hospital environment, suggesting that the results of previous studies can be extrapolated beyond centers dedicated to these regimens.

Table 4—Six-Minute Walking Distances for Control and Active Groups*

<table>
<thead>
<tr>
<th>Groups</th>
<th>Study Entry</th>
<th>3 mo</th>
<th>6 mo</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control</td>
<td>273 (19)</td>
<td>266 (22)</td>
<td>281 (21)</td>
</tr>
<tr>
<td>Sample size</td>
<td>28</td>
<td>23</td>
<td>23</td>
</tr>
<tr>
<td>Active</td>
<td>245 (18)</td>
<td>304 (19)\textsuperscript{†}</td>
<td>320 (28)</td>
</tr>
<tr>
<td>Sample size</td>
<td>36</td>
<td>32</td>
<td>22</td>
</tr>
</tbody>
</table>

*Data are presented as mean (SE) or No. \(p < 0.02\).
REFERENCES
4 Clark CJ. Setting up a pulmonary rehabilitation programme. Thorax 1994; 49:270–278
10 Jones PW, Bosh TK. Quality of life changes in COPD patients treated with salmeterol. Am J Respir Crit Care Med 1997; 155:1283–1289