Home vs Hospital-Based Pulmonary Rehabilitation for Patients With Chronic Obstructive Pulmonary Disease: A Spanish Multicenter Trial

María Rosa Güell, a Pilar de Lucas, b Juan Bautista Gáldiz, c Teodoro Montemayor, d José Miguel Rodríguez González-Moro, a Amaia Gorostiza, c Francisco Ortega, b José M. Bellón, a and Gordon Guyatt e

ORIGINAL ARTICLES

OBJECTIVE: To compare the effects of a simple home pulmonary rehabilitation program and an intensive hospital-based program in terms of the exercise tolerance and health-related quality of life (HRQOL) of patients with severe chronic obstructive pulmonary disease (COPD).

PATIENTS AND METHODS: Patients in this prospective, multicenter trial were randomized to 2 groups to receive hospital or home pulmonary rehabilitation. Patients in both groups attended 2 informative sessions about the disease and 4 physical therapy sessions. Patients in the hospital group then carried out a structured exercise program while home group patients performed low intensity exercises at home without supervision.

RESULTS: Twenty-eight patients were randomized to the hospital rehabilitation group and 23 to the home group. Both groups improved on the 6-minute walk test (mean difference, 8.7 m; \( P=.61 \)). HRQOL measured with the Chronic Respiratory Questionnaire also improved in both groups, but the change was greater on the domain of emotional function in the hospital rehabilitation group (mean difference between groups, 0.58 on a scale for which a value of 0.5 represents the smallest clinically relevant difference). The benefits were maintained in both groups 6 months after the programs ended.

CONCLUSIONS: This study demonstrates that the improvement in exercise tolerance achieved by COPD patients with an unsupervised home pulmonary rehabilitation program is similar to the gains of patients in an intensive hospital-based program. However, the hospital program afforded greater benefit on the HRQOL domain of emotional function.

Key words: COPD. Exercise tolerance. Health-related quality of life. Pulmonary rehabilitation, home care services. Pulmonary rehabilitation, hospital-based.

Comparación de un programa de rehabilitación domiciliario con uno hospitalario en pacientes con EPOC: estudio multicéntrico español

OBJETIVO: Estudiar el impacto de un programa simple de rehabilitación respiratoria domiciliario, comparado con uno intensivo hospitalario, sobre la capacidad de esfuerzo y la calidad de vida relacionada con la salud (CVRS) de los pacientes con enfermedad pulmonar obstructiva crónica.

PACIENTES Y MÉTODOS: Se ha realizado un estudio prospectivo y multicéntrico en el que se aleatorizó a pacientes con EPOC grave en 2 grupos: hospital (GH) o domicilio (GD). En ambos los pacientes recibieron 2 sesiones de educación y 4 de fisioterapia. Los del GH realizaron un programa estructurado de ejercicio en el hospital y los del GD, un programa de ejercicio de baja intensidad en el domicilio, sin supervisión.

RESULTADOS: Se aleatorizó a 28 pacientes en el GH y a 23 en el GD. Ambos grupos mostraron una mejoría similar en la prueba de la marcha de 6 min (diferencia media de 8.7 m; \( p = 0.61 \)). A pesar de que en ambos grupos mejoró la CVRS, medida con el Cuestionario de Enfermedad Respiratoria Crónica (CRQ), se objetivó un incremento mayor en el área de función emocional para el GH (diferencia media entre grupos: 0.58, en una escala donde un valor de 0.5 representa la diferencia mínima importante). Los beneficios del programa se mantuvieron en ambos grupos hasta 6 meses después de finalizarlo.

CONCLUSIONES: El estudio muestra que un programa domiciliario de rehabilitación respiratoria sin supervisión produce una mejoría similar en la capacidad de esfuerzo de los pacientes con EPOC que un programa intensivo hospitalario. Sin embargo, éste alcanza mayores beneficios en el área de la función emocional de la CVRS.

Palabras clave: EPOC. Capacidad de esfuerzo. Calidad de vida relacionada con la salud. Programa domiciliario de rehabilitación respiratoria. Programa hospitalario de rehabilitación respiratoria.
Introduction

Systematic reviews of a large number of randomized controlled trials have shown that pulmonary rehabilitation leads to slight or moderate improvements in the health-related quality of life (HRQOL) of patients with chronic obstructive pulmonary disease (COPD).1,3 Rehabilitation also has a positive impact on lowering health care costs, mainly by reducing the number of exacerbations and hospital admissions.4-8 Such programs in hospital settings are costly, however, even in an outpatient setting.1,3,6,9 In addition, capacity is limited and programs may be unable to accommodate all who might benefit from them.

Home-based pulmonary rehabilitation programs have been introduced in recent years, and evidence suggests that they may afford similar benefits to those of hospital-based rehabilitation.10,11 However, most home programs tested in trials have used resource- and exercise-intensive methods that might not be applicable in some settings.

The aim of this study was to test the hypothesis that a simple unsupervised home-based pulmonary rehabilitation program might achieve the same results as a more intensive, structured hospital-based one. A randomized trial was designed to compare the benefits of 2 such programs in terms of exercise tolerance and HRQOL in patients with COPD.

Patients and Methods

Patients

Patients diagnosed with severe or very severe COPD12 were enrolled consecutively as they were referred to 4 Spanish hospitals for pulmonary rehabilitation in Barcelona, Bilbao, Madrid, and Seville. The inclusion criteria were age between 50 and 75 years, classification as an ex-smoker or smoker intending to quit, forced expiratory volume in 1 second (FEV1) between 30% and 50% of reference, and stable condition free of exacerbations in the last 4 weeks. Patients were excluded if they had a significant response to bronchodilators (increase in FEV1 of >15% from baseline after inhalation of 200 µg of salbutamol), severe hypoxemia (PaO2 <60 mm Hg), a diagnosis of asthma, severe coronary artery disease, or orthopedic disease limiting mobility. All patients gave their written informed consent to participation. The ethics committee of each hospital approved the study protocol.

Study Design

The patients were randomized to receive hospital- or home-based pulmonary rehabilitation on the basis of assignments received in sealed envelopes.

All patients were prescribed standard medical treatment (inhaled salmeterol, ipratropium bromide, and budesonide) to take throughout the study period. During exacerbations antibiotics were added if a respiratory infection was thought to be the cause, and/or an oral steroid (prednisone) was prescribed to treat dyspnea.

Tests for inclusion were performed by all patients. Tests for study evaluations were subsequently carried out at 3 times: at baseline in stable situation before rehabilitation, after 9 weeks of pulmonary rehabilitation, and again 6 months after the end of the program. The personnel who carried out the tests were blinded as to group assignment.

Pulmonary Rehabilitation Program

Structured program. Patients in both groups attended 2 informative sessions about the disease. In these sessions a video with basic information about COPD and instructions for managing medications was played in all 4 hospitals. Discussion was encouraged. During the first week, all patients were also given instructions on respiratory physical therapy exercises, which were performed during outpatient visits to the hospital. This therapy was supervised by a respiratory physical therapist in 4 sessions. Breathing retraining was included and patients were shown how to drain secretions when necessary. Techniques for training respiratory muscles using a threshold device (Threshold IMT-Respirronics, Cedar Grove, New Jersey, USA) were taught. Arm exercises, to perform with weights, were also included in the program. The physical therapist also taught the home-program patients the walking pace needed to train leg muscles.

From week 2 until week 9, a muscle training program was implemented; hospital-group patients attended 3 times per week for this program. Respiratory muscle training consisted of 2 sessions of 15 minutes each with the threshold device. The inspiratory pressure load was set at 40% of the maximum inspiratory pressure (Plm max). Arm training consisted of 30 minutes of lifting weights; the patient began with weights of 0.5 kg on each arm and the weight was gradually raised by 1 kg each week up to tolerance. Leg training consisted of 30 minutes on a cycle ergometer. To determine the degree of effort that would be appropriate for training, the patients took a symptom-limited exercise stress test according to the protocol of Jones.16 Training began with a load that was 60% of the maximum reached on the progressive stress test. The load was gradually raised by increments of 10 W up to tolerance, which was assessed by heart rate stability, oxygen saturation, and blood pressure, in addition to the patient’s subjective feeling of tolerance.

The home group was told to follow the same respiratory muscle and arm muscle training exercises. Their leg training consisted of unsupervised street walking daily at a pace of 4 km/h marked by a podometer according to the following protocol: 15 minutes daily in the first week, 30 minutes the second to the fourth weeks, and 45 minutes from the fifth through the ninth weeks. The home patients also went up and down stairs for 5 minutes before and after each walk.

Follow-up period after the program. At the end of the ninth week, the patients in both groups were instructed to continue the same training routine independently, without supervision. Hospital group patients were given weights at this time. (Home group patients had received weights at the beginning of the program.) This period lasted 6 months.

Outcome Measures

All tests were performed by all patients 1 week before the pulmonary rehabilitation program began, at the end of the 9-week structured program, and again 6 months later (at the end of the follow-up period).

Respiratory muscle function. Plm max and the maximal expiratory pressure (PEmax) were measured using the method of Black and Hyatt17; reference values for a Mediterranean population18 were used. Respiratory muscle endurance was assessed using the method of Dekhuijzen et al.19 In that method the time patients are able to maintain an inspiratory pressure of 70% of Plm max (TPlm max70) is recorded.

Arm muscle exercise tests. Patients began the test by lifting 2.5-kg weights with each arm as many times as possible. They

GÜELL MR ET AL. HOME VS HOSPITAL-BASED PULMONARY REHABILITATION FOR PATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE: A SPANISH MULTICENTER TRIAL

Arch Bronconeumol. 2008;44(10):512-8 513
TABLE 1
Baseline Characteristics of Patients in the Hospital and Home Pulmonary Rehabilitation Groups

<table>
<thead>
<tr>
<th>Variables</th>
<th>Hospital Group (n = 28)</th>
<th>Home Group (n = 23)</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age, y</td>
<td>63.2 (6.6)</td>
<td>66 (5.8)</td>
<td>.17</td>
</tr>
<tr>
<td>FEV1, L</td>
<td>1.1 (0.25)</td>
<td>1.15 (0.29)</td>
<td>.50</td>
</tr>
<tr>
<td>FEV1, % predicted</td>
<td>37.5 (7.1)</td>
<td>39 (7.6)</td>
<td>.48</td>
</tr>
<tr>
<td>FVC, L</td>
<td>2.87 (0.67)</td>
<td>2.75 (0.60)</td>
<td>.52</td>
</tr>
<tr>
<td>FVC, % predicted</td>
<td>72.5 (17.9)</td>
<td>70.5 (12.1)</td>
<td>.66</td>
</tr>
<tr>
<td>FEV1/FVC, %</td>
<td>39.1 (8.3)</td>
<td>42.4 (8.1)</td>
<td>.16</td>
</tr>
<tr>
<td>RV, %</td>
<td>176 (38)</td>
<td>173 (49)</td>
<td>.83</td>
</tr>
<tr>
<td>predicted TLC, %</td>
<td>113 (18)</td>
<td>109 (20)</td>
<td>.56</td>
</tr>
<tr>
<td>PaO2, mm Hg</td>
<td>67.3 (8.5)</td>
<td>68.5 (10.5)</td>
<td>.64</td>
</tr>
<tr>
<td>PaCO2, mm Hg</td>
<td>44 (10.8)</td>
<td>42.5 (5.4)</td>
<td>.53</td>
</tr>
<tr>
<td>PElast, cm H2O</td>
<td>73 (29.4)</td>
<td>70.7 (23.7)</td>
<td>.77</td>
</tr>
<tr>
<td>TPlast, min</td>
<td>64.5 (5.93)</td>
<td>64.6 (4.63)</td>
<td>.99</td>
</tr>
<tr>
<td>Arm lifts, n</td>
<td>19.1 (12.1)</td>
<td>19.3 (12.4)</td>
<td>.96</td>
</tr>
<tr>
<td>Weight-holding time, min</td>
<td>2.04 (1.67)</td>
<td>1.88 (1.99)</td>
<td>.79</td>
</tr>
<tr>
<td>6MWT, m</td>
<td>448 (80)</td>
<td>467 (47)</td>
<td>.33</td>
</tr>
<tr>
<td>Dyspnea</td>
<td>3.86 (1.09)</td>
<td>3.79 (1.11)</td>
<td>.84</td>
</tr>
<tr>
<td>Fatigue</td>
<td>4.95 (1.19)</td>
<td>4.88 (0.98)</td>
<td>.82</td>
</tr>
<tr>
<td>Emotional function</td>
<td>4.94 (1.14)</td>
<td>5.39 (1.02)</td>
<td>.15</td>
</tr>
<tr>
<td>Mastery of disease</td>
<td>5.07 (1.37)</td>
<td>5.25 (1.47)</td>
<td>.6</td>
</tr>
</tbody>
</table>

Abbreviations: CRQ, Chronic Respiratory Questionnaire; FEV1, forced expiratory volume in 1 second; FVC, forced vital capacity; PElast, maximal expiratory pressure; TPlast, maximal inspiratory pressure; RV, residual volume; TLC, total lung capacity; TPlast, time the patient was able to maintain inspiratory pressure at 70% of the TPlast; 6MWT, 6-minute walk test.

*Data are expressed as means (SD).

Results for numerical values were expressed as means (SD). Results for categorical data were expressed as absolute frequencies and percentages. The numerical variables were compared between groups at baseline using the t test; successive measures were compared with baseline measures using the t test for repeated measures. Analysis of covariance was also used to compare results for the 2 groups at 9 weeks, just after the end of structured pulmonary rehabilitation, and again 6 months later. This type of analysis allows between-group differences to be studied while taking into consideration the respective baseline values.

Categorical variables were compared using the Pearson χ² test or the Fisher exact test.

Statistical significance was set at P ≤ 0.05. Patients for whom all data were available were entered into the analysis for the group to which they were assigned. SPSS version 14 (SPSS Inc, Chicago, Illinois, USA) was used for all analyses.

Results

Fifty-seven patients with severe stage-III COPD according to the classification of the Global Initiative for Chronic Obstructive Lung Disease were enrolled. All were men. The mean (SD) FEV1 was 38.5% (6.9%) of reference. Twenty-nine were randomized to the hospital training group and 28 to the home group. Six of the 57 patients withdrew from the study during the 9-week structured program. One in the hospital group and 4 in the home group left for lack of motivation and 1 in the home group withdrew because of chest pain. Eight patients were withdrawn during the 6-month follow-up period, 5 from the hospital group (3 for lack of cooperation and 2 for exacerbation) and 3 from the home group (for lack of cooperation). Thus, 51 patients (28 in the hospital group and 23 in the home group) completed the structured program and 43 (23 in the hospital group and 20 in the home group) completed all 6 months of follow-up. Table 1 shows that the baseline characteristics of patients in both groups were similar, with no significant between-group differences.

Table 2 shows changes in all variables in the entire population after the 9-week period of structured pulmonary rehabilitation and again after 6 months. Tables 3 and 4 compare changes in the 2 groups for all variables in the study, also at both moments of evaluation after training. The data are shown as group means and differences between them after adjustment for baseline values, with 95% confidence intervals.

Respiratory Muscle Function

After 9 weeks of structured pulmonary rehabilitation, patients in both the hospital and home groups had statistically significant improvements in PElast and TPImax and the gains were maintained throughout the 6-month period of follow-up (Table 2). After adjustment for baseline values, there were no significant between-group differences at either of the 2 moments of analysis (Table 3).

Arm Strength

After 9 weeks of structured training, patients in both groups had improved arm muscle strength and endurance (number of lifts, P < 0.05; time holding the lifted weight, P = 0.03). The improvement was maintained until the end of the follow-up period (Table 2). No significant between-group differences were detected at either of the 2 evaluation times (Table 3).
The distance walked in 6 minutes increased significantly in both groups, both at the end of the 9-week structured period and after the 6-month follow-up period (Table 2). No significant between-group differences at either of the 2 moments of analysis were detected after adjustment for baseline values (Table 3). The mean increases exceeded the threshold of clinical significance in the hospital group (66.6 m) and approached that threshold in the home group (52.2 m).

**Leg Strength**

**HRQOL**

Scores on all CRQ domains improved in the hospital group after both the structured training period and the follow-up period of 6 months. Patients in the home-training group had improved scores only for dyspnea at both evaluation times (Table 2). All HRQOL scores were higher in the hospital group than in the home group, but the differences were significant only in the domain of emotional function (Table 4). The mean increase on all 4 CRQ domains exceeded the threshold of clinical significance after structured
rehabilitation at the 9-week assessment and after the follow-up period. The increases were as follows for each moment of evaluation, respectively: dyspnea, 0.87 and 0.66; fatigue, 0.56 and 0.57; emotional function, 0.76 and 0.75; mastery of disease, 0.6 and 0.6. In the home training group, the mean increase was clinically significant only for dyspnea (0.56 and 0.55, respectively).

Discussion

This study demonstrates the usefulness of pulmonary rehabilitation in patients with COPD. Similar improvements in both exercise tolerance and symptoms (dyspnea) were achieved with both the home and hospital programs. However, greater improvement in HRQOL, particularly in the area of emotional function, was observed when training took place at the hospital.

Although the value of specific muscle training is currently being debated, the findings of 2 meta-analyses and more recent randomized controlled trials indicate that when an adequate mouth pressure is assured, it is possible to improve the strength and endurance of respiratory muscles. We found that both groups improved respiratory muscle function significantly in measures of both strength (PImax) and endurance (TP1max/70), consistent with the previously mentioned findings. Previous authors have also shown that such training can improve HRQOL and exercise tolerance, although general training must be included in the regimen, making it difficult to assign these effects exclusively to respiratory muscle training. Recently, the ATS recommended jointly with the European Respiratory Society that respiratory muscle training should be included in pulmonary rehabilitation programs when there is an indication that those muscles are weak. Our patients’ training was structured and sufficient mouth pressure was assured. Specific exercises were set within the context of a general exercise program for arms and legs. Our findings with regard to HRQOL and exercise tolerance are consistent with reports in the literature, although it is generally accepted that the benefits cannot be attributed specifically to the training of inspiratory muscles in particular but rather to the program as a whole.

Few studies have analyzed the benefits of arm exercises, even though such training has important metabolic and ventilatory repercussions. After arm muscle training, our patients had significantly greater strength and endurance, consistent with previous findings.

Patients in both our training groups also experienced statistically significant improvement in exercise tolerance, likewise consistent with the literature. The improvement in the 6-minute walk test distance reached the threshold over which there is a perceived difference in walking tolerance. Earlier studies have analyzed the effect of training leg muscles at home, but they have generally applied high intensity programs under close supervision. Only Puente Maestu et al tested a training program based on walking. They compared a physiotherapist-supervised hospital-based training program with a walking program for which patients used a pedometer, finding that both groups gained exercise tolerance but that the improvement was greater for the supervised patients.

Randomized controlled trials of home-based programs have documented significant improvements in HRQOL in COPD patients. Strijbos and coworkers found that exercise tolerance, dyspnea, and the feeling of well-being improved for patients in both a hospital-based pulmonary rehabilitation program and a home-based one. In our trial, dyspnea and walk-test distance improved in the home group, indicating that the patients were following the training program properly. We might speculate that the lack of improvement in other HRQOL dimensions in the unsupervised home group is the result of insufficient psychological and emotional support from the pulmonary rehabilitation staff, as this was an aspect of care that was received by the hospital-training group. The method used for training in our study was different from programs used by other researchers. Wijkstra et al prescribed home-based programs that were much more

| Abbreviations: CI, confidence interval; CRQ, Chronic Respiratory Questionnaire. | Data are shown as means (SD). Means were adjusted for baseline values by analysis of covariance. |

| Health-Related Quality of Life After the 9-Week Period of Structured Pulmonary Rehabilitation and 6 Months Later* |
|---|---|---|---|---|---|---|
| No. | Values | No. | Values | Difference | 95% CI | P |
| CRQ Dyspnea | 27 | 4.65 (0.15) | 23 | 4.43 (0.16) | 0.21 | -0.22 to 0.65 | .33 |
| CRQ Fatigue | 27 | 5.44 (0.14) | 23 | 5.25 (0.16) | 0.19 | -0.24 to 0.62 | .37 |
| CRQ Emotional function | 27 | 5.82 (1.53) | 23 | 5.24 (1.67) | 0.58 | 0.12-1.03 | .01 |
| CRQ Mastery of disease | 27 | 5.75 (0.17) | 23 | 5.33 (0.19) | 0.42 | -0.09 to 0.93 | .11 |
| Follow-up evaluation after 6 months | CRQ Dyspnea | 23 | 4.51 (0.18) | 17 | 4.38 (0.21) | 0.13 | -0.44 to 0.70 | .65 |
| CRQ Fatigue | 23 | 5.48 (0.18) | 17 | 5.17 (0.21) | 0.32 | -0.24 to 0.87 | .26 |
| CRQ Emotional function | 23 | 5.89 (0.17) | 17 | 5.16 (0.19) | 0.73 | 0.21-1.25 | .01 |
| CRQ Mastery of disease | 23 | 5.84 (0.17) | 17 | 5.34 (0.19) | 0.50 | -0.02 to 1.02 | .06 |
intensive than our home program. They provided supervision by a physical therapist or a physician who had contact with each patient at least once a week. Other simpler home programs, such as those applied by Hernández et al.,14 Puente-Maestu et al.,31 and Boxal et al.,32 who also observed HRQOL improvements, likewise provided greater emotional support for patients than our program did. In all those studies, the patient was visited at home or went to the hospital at least once a week. The program of Hernández et al.14 was also simple but more structured than ours. Patients in their study visited the hospital every 2 weeks to record changes in exercise accomplished, in terms of intensity or time tolerated. Wedzicha et al.,31 however, did not find that HRQOL improved in COPD patients who followed a home-based pulmonary rehabilitation program, even though the patients were supervised by a physical therapist. Those authors attribute the lack of benefit to the short duration of the program, the severity of disease, and the low intensity of exercise.

Finally, we would like to point out that benefits were retained in both groups, as shown by the results 6 months after the end of the structured period. Few studies have investigated the maintenance of pulmonary rehabilitation benefits over the long term, whether hospital-based or home-based exercise regimens were tested. Studies that have done so, however, have reported that benefits lasted no longer than 1 or 2 years.33,34

A limitation of our study is the small patient size, which could have meant that the study would lack statistical power. However, this limitation did not prevent us from finding statistically significant differences in both groups. We therefore believe the validity of our results has not been undermined. Another limitation is the high percentage of patients who abandoned training, 10.5% quitting during the first 9 weeks of structured pulmonary rehabilitation and an additional 25% in the 6-month follow-up period. Those rates are similar to the ones reported for other studies.10,13,14 It is noteworthy that more patients withdrew from the home program than from the hospital-based one. The high number of withdrawals from the home group seems predictable and might be attributable, in our opinion, to the lack of specialist supervision and psychological and emotional support, which encourage greater adherence to therapy.

In conclusion, the benefits of either a hospital-based or simple unsupervised home-based pulmonary rehabilitation program are similar in terms of improved exercise tolerance. However, greater HRQOL improvement comes from a hospital-based training program, above all in the domain of emotional function. Although this study was carried out in a small number of patients, the results indicate that home-based pulmonary rehabilitation can provide an alternative to traditional programs, allowing rehabilitation to be prescribed for larger numbers of patients.

Acknowledgments

The authors thank Coloma Sotomayor, Mercè Sangenís, Fátima Morante, and Araceli González for their care and dedication to the patients in this study.

REFERENCES