Is It Really Useful To Repeat Outpatient Pulmonary Rehabilitation Programs in Patients With Chronic Airway Obstruction?*
A 2-Year Controlled Study
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Study objectives: To answer the following questions: in patients with chronic airway obstruction (CAO), (1) can pulmonary rehabilitation lead to similar short-term gains at successive, yearly interventions, and (2) is there any real clinical or physiologic long-term benefit by yearly repetition of pulmonary rehabilitation programs (PRPs)?

Design: Randomized, controlled clinical study.

Setting: Pulmonary rehabilitation center.

Patients: Sixty-one CAO patients studied 1 year after completing an initial 8-week outpatient PRP (PRP1).

Intervention: Patients were randomly classified into two groups. A second PRP (PRP2) was completed by the first group (group 1) but not by the second group (group 2). One year later, a third PRP (PRP3) was performed by both groups.

Measurements: Lung function, cycloergometry, walking test, dyspnea, and health-related quality of life (HRQL) were assessed before and after PRP2, and before and after PRP3. The numbers of hospitalizations and exacerbations over the year were also recorded.

Results: Complete data sets were obtained from 36 patients (17 patients in group 1 and 19 patients in group 2). The two groups did not differ in any parameter either before PRP1, after PRP1, or at randomization. There was no significant change over time for airway obstruction in either group. After PRP2, exercise tolerance, dyspnea, and HRQL improved in group 1. Nevertheless, 1 year later, patients of group 1 did not differ from patients of group 2 in any outcome parameter, such that in comparison to before PRP1, only HRQL was still better in both groups 24 months after PRP1. Yearly hospitalizations and exacerbations per patient significantly decreased in both groups in the 2 years following PRP1, when compared to the 2 years prior. Nevertheless, at the 24-month follow-up visit, a further reduction in yearly exacerbations was observed only in group 1 but not in group 2 in comparison to what was observed at the 12-month follow-up visit. The PRP3 resulted in improvement in exercise tolerance in both groups.

Conclusion: In patients with CAO, an outpatient PRP can achieve benefits in HRQL and a decreased number of hospitalizations, which persist for a period of 2 years. Successive, yearly interventions lead to similar short-term gains but do not result in additive long-term physiologic benefits. Further reduction in yearly exacerbations seems to be the main benefit of an additional PRP.

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Key words: bronchial asthma; COPD; dyspnea; exercise tolerance; health-related quality of life

Abbreviations: BDI = baseline dyspnea index; CAO = chronic airway obstruction; HRQL = health-related quality of life; 6MWD = 6-min walking distance test; PRP = pulmonary rehabilitation program; PRP1 = initial 8-week PRP; PRP2 = second PRP; PRP3 = third PRP; SGRQ = St. George’s respiratory questionnaire; T0 = time prior to PRP1; T1 = time after PRP1; T2 = time prior to PRP2; T3 = time after PRP2; T4 = time prior to PRP3; T5 = time after PRP3; TDI = transitional dyspnea index

Rehabilitation for patients with chronic airway obstruction (CAO) is well established and widely accepted as a means of enhancing standard therapy in order to alleviate symptoms and optimize function independent of the stage of disease.1–4 Observational5 as well as randomized controlled studies6,7 have shown that intensive, multidisciplinary, outpatient pulmonary rehabilitation programs (PRPs) are an effective intervention in the short term and the long term, and decrease the use of health services. Nevertheless, PRPs are costly,3 and access to rehabilitation facilities is limited. As a result, a careful selection of patients for PRPs is required, and controversy exists regarding the most convenient schedule to
maintain the short-term benefit of a PRP.\textsuperscript{9,10} Among other issues, it is unclear whether a PRP repeated at a 1-year interval will result in effective maintenance or an improvement in a patient’s health status.

In a previous observational study,\textsuperscript{5} we observed that CAO patients who underwent an outpatient PRP still maintained an improved health-related quality of life (HRQL) 12 months postdischarge, despite a loss in the exercise tolerance improvement. Therefore, we designed a randomized controlled study for those patients completing that study\textsuperscript{5} to answer the following questions: (1) can pulmonary rehabilitation lead to similar short-term gains at successive, yearly interventions, and (2) is there any real clinical or physiologic long-term benefit by a yearly repetition of the PRP?

**Materials and Methods**

Patients gave their informed consent to participate in the study, which was approved by the Ethical Committee of Salvatore Mangieri Foundation, and was conducted according to the Declaration of Helsinki.

**Patients**

Sixty-one consecutive patients with stable CAO (20 patients with COPD and 31 with chronic bronchial asthma) entered the study. One year before, they had undergone an initial 8-week PRP (PRP1) as a part of a study, the results of which have been published elsewhere\textsuperscript{5} (see also “Study Design”). Diagnosis of COPD was made according to the American Thoracic Society guidelines.\textsuperscript{11} COPD patients had history of smoking (> 20 pack-years), but all were ex-smokers. Asthma was characterized by dyspnea with wheezing, variable airflow limitation with reversible obstruction (range, 12 to 55%; mean ± SD, 28 ± 10%), and bronchial hyperresponsiveness\textsuperscript{12} in absence of smoking history. At the time they were recruited for this study, the patients were all in stable condition, as assessed by stability in blood gas values, and were free from exacerbations in the 4 weeks prior to their entry into the study. Patients with other organ failure or cancer, or who were unable to cooperate were excluded from the study. All asthmatic patients received inhaled steroids and bronchodilators, whereas all COPD patients received regular treatment with inhaled bronchodilators. No COPD patients received regular treatment with inhaled or oral steroids. Both COPD and asthmatic patients had received systemic steroids during the exacerbations of their diseases. No change in the routine therapy was made in the week preceding the inclusion into the study. During follow-up, patients were asked about changes in therapy. Care was taken so that the follow-up visits and assessments were made when patients were in a stable state and at least 2 weeks after exacerbations.

**PRP**

Our PRP was a day hospital-based, outpatient, multidisciplinary, 8-week PRP, which has been described elsewhere,\textsuperscript{9} and included the optimization of the pharmacologic treatment, three 3-h sessions per week for 8 to 10 weeks, with (1) supervised incremental exercise until achieving 30 min of continuous cycling at 50 to 70% of the maximal load achieved on an incremental cycleergometer exercise test carried out at hospital admission\textsuperscript{13}; (2) abdominal, upper-limb, and lower-limb muscle activities lifting progressively increasing light weights (300 to 500 g), shoulder, and full arm circling\textsuperscript{14}; (3) patient and family education; and (4) nutritional programs and psychosocial counseling, when appropriate. A multidisciplinary team consisting of chest physicians, nurses, physical therapists, a dietician, and a psychologist offered care. If desired, patients could rest in dedicated beds and have meals at the hospital facilities. After discharge from each PRP, the patients were encouraged to perform daily life activities, but no structured exercise programs were prescribed.

**Outcome Measurements**

Lung volumes and FVC were measured by means of a constant-volume body plethysmograph (Medical Graphics; St. Paul, MN). The predicted values according to Quanjer\textsuperscript{15} were used. Arterial blood gas levels were measured by means of an automated analyzer (model 840; Gilib Corning; Medfield MA) on samples from the radial artery while the patients were in the sitting position and breathing room air for at least 1 h. Maximal inspiratory pressure was measured at the level of functional residual capacity\textsuperscript{16} using a respiratory module system (Medical Graphics). The predicted values according to Bruschi et al\textsuperscript{17} were used.

Symptom-limited incremental exercise tests were performed on an electrically braked cycleergometer (Ergometri 800S; Sensormedics; Yorba Linda, CA) using the standard 1-min incremental cycle exercise protocol. Functional and metabolic data were determined at rest and during exercise by means of a computerized system (2900Z, Sensormedics). Mixed/expired gas data, breathing pattern, minute ventilation, oxygen uptake, carbon dioxide production, and respiratory exchange ratio were continuously monitored as average values of 20-s intervals. ECG activity was monitored continuously, and systemic arterial BP was registered every 3 min using a sphygmomanometer. After stabilization and a 2-min period of unloaded pedaling at 60 cycles per minute, the load was increased by 10 W each minute. The patients were strongly encouraged to cycle to the point of intolerable breathlessness, discomfort, or exhaustion, until the maximal heart rate was achieved or an abnormal ECG was noted (symptom-limited exercise test), or whenever the patient wanted to stop. At rest and at 10-W intervals, patients were asked their perceived breathlessness and leg fatigue by pointing to a number or phrase on a 10-point modified Borg scale\textsuperscript{18} set in large type on a sheet in front of them. Exercise capacity was evaluated also by means of the 6-min walking distance test (6MWTD).\textsuperscript{19} All measurements were performed and recorded under the supervision of a nurse not involved in the study.

The baseline dyspnea index (BDI) and the transitional dyspnea index (TDI)\textsuperscript{20} were used to assess chronic exertion dyspnea prior to each PRP and before/after PRP changes in dyspnea, respectively. BDI is a multidimensional instrument based on three components that evoke dyspnea: magnitude of task, magnitude of effort, and functional impairment.\textsuperscript{20} Each component scores from 0 (severe impairment) to 4 (not impaired). A baseline focal score is obtained as the sum of the three components ranged from 0 to 12, the lower the rating the worse the dyspnea. The TDI provides specific criteria for each of the three components to measure change from the baseline state. Change in each component scores from −3 (major deterioration) to +3 (major improvement); a TDI focal score is obtained by adding scores for each of the three components (range, −9 to +9). Italian translations of the BDI and the TDI were administered.\textsuperscript{20}

The HRQL was evaluated by means of the St. George’s respiratory questionnaire (SGRQ).\textsuperscript{21} The SGRQ consists of 76 items and measures three components. The first section, "sym-
The SGRQ, "symptom," contains items concerned with the level of symptomatology; the second section, "activity," is concerned with physical activities that either cause or are limited by breathlessness; the final section is "impact," which covers such factors as employment, being in control of health, panic, stigmatization, need for medication, expectations for health, and disturbances of daily life. The three components of the SGRQ are scored separately in the range from 0 to 100%, with a score of 0 indicating no impairment, and a total score is computed. The SGRQ scores are calculated using weights attached to each item in the questionnaire. Italian translations of the SGRQ were administered.22

For the purpose of this study, we defined exacerbations as episodes not requiring hospitalization but requiring a change of usual medication and prescription of systemic steroids and/or antibiotics by the general practitioner or the respiratory physician. Hospital admission was decided by the patients’ general practitioners, who were aware of but did not participate in the study. The number of hospitalizations and exacerbations not requiring hospitalization in the last 2 years (follow back) prior to PRP-1 were recorded. These data were obtained asking the patients at follow-up visits, from the hospital registers, and interviewing relatives or the general practitioner. After discharge from the PRP1, patients were asked to keep a record of hospital admissions and exacerbations for the following 2 years. Furthermore, data were collected from hospital registers, interviewing relatives, or the general practitioner. Finally, mortality rate was recorded at the follow-up visit in both groups.

**Study Design**

Sixty-one CAO patients were evaluated 1 year after completing PRP1, the results of which have been published elsewhere.5 They were randomly included into two groups: group 1 (30 patients) underwent another second PRP (PRP2) and related post-PRP evaluations 1-year after PRP-1; group 2 (31 patients, control) did not undergo PRP2. At the end of the second year, patients of both groups underwent clinical and physiologic evaluations and underwent the third PRP (PRP3). Patients of both groups underwent follow-up visits at the outpatient clinic at baseline, 6 months, 12 months, 18 months, and 24 months. The same physicians (K.F. and L.B.) saw the patients at each follow-up visit and encouraged the patients to contact her/him at any time if a medical problem arose. Outcome measures were assessed prior to PRP1 (T0), after PRP1 (T1), prior to PRP2 (T2), after PRP2 (T3), prior to PRP3 (T4), and after PRP3 (T5). The technicians who collected data were blinded to a patient’s allocation to PRP2 or the control group. Figure 1 shows the trial profile.

**Statistical Analysis**

Results are expressed as mean ± 1 SD when specified. All analyses were performed using statistical software (BMDP PC 90, Los Angeles, CA). Differences between groups and within group (time course) were evaluated by multivariate or univariate analysis of variance for repeated-measure options. Differences between paired or unpaired groups of data were evaluated by t test with Bonferroni adjustment and were applied as requested by analysis of variance interaction. χ² analysis was performed for evaluation of differences between groups in hospitalizations and exacerbations at 1 year and 2 years. A p value < 0.05 was considered significant.

**RESULTS**

Figure 1 shows the profile of number of patients at each phase of the study. The short-term and 12-
month results of PRP1 in 61 patients have been reported previously.\(^5\) No patient died during the study. All 30 patients of group 1 completed PRP2.

**Dropouts**

Eleven patients in group 1 and 10 patients in group 2 did not perform evaluations at T4 due to personal, transport, or familial problems. Four more patients (two patients in each group) were excluded from the study due to intervening pathologic conditions (one bladder cancer, two limb traumas, one sudden onset of ischemic heart disease). Therefore, complete data sets were obtained from 17 patients in group 1 and 19 patients in group 2. Dropouts did not differ from patients evaluated in any anthropometric, clinical, or functional characteristics recorded at T0, T2 (Table 1), or, in the case of group 1, at T3. Neither hospitalizations nor exacerbations in the 2 years preceding PRP1 were different between the two groups. The dropouts from the two groups were generally similar (Table 1).

**Randomization**

As shown also in Table 1, the characteristics at T0 and T2 of patients who completed the study were not different between groups. Hospitalizations and exacerbations in the 2 years preceding PRP1 were the same. No change in medical therapy or cases of lack of compliance to medical therapy were observed in either group during the follow-up compared to the period before inclusion in the study.

**Lung and Respiratory Muscle Function**

As shown in Figure 2, there was no significant change over time either in lung function or in inspiratory muscle function in either group.

**Exercise Tolerance**

As shown in Figure 3 and described in the previous study,\(^5\) at T1, patients of both groups showed an increase in exercise tolerance as assessed by peak work rate and 6MWD, which was lost at T2. At T3, exercise tolerance increased again in group 1. Nevertheless, at T4, this benefit was lost again, such that exercise tolerance in patients of group 1 was not significantly different from control subjects who did not attend any other PRP but PRP1. PRP3 resulted in a new improvement in exercise tolerance for both groups (Fig 3).

**Subjective Sensations**

Table 2 shows the time course of dyspnea as assessed by the BDI and the TDI. Each PRP was followed by an improvement in the TDI, but no difference was observed between the two groups at any time in either index. As shown also in Figure 3, each PRP was followed by a significant short-term improvement in dyspnea at isoworkload, as assessed

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**Table 1—Anthropometric, Demographic, and Functional Data of All Randomized Patients Before PRP1 (T0) and at Randomization (T2)**

<table>
<thead>
<tr>
<th>Variables</th>
<th>Group 1</th>
<th>Group 2</th>
</tr>
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<tbody>
<tr>
<td></td>
<td>Completed</td>
<td>Withdrawn</td>
</tr>
<tr>
<td>Patients, No.</td>
<td>T0</td>
<td>T2</td>
</tr>
<tr>
<td>Asthma/COPD diagnosis, No.</td>
<td>8/9</td>
<td>8/9</td>
</tr>
<tr>
<td>Male/female gender, No.</td>
<td>12/5</td>
<td>12/5</td>
</tr>
<tr>
<td>Age, yr</td>
<td>60 ± 7</td>
<td>61 ± 8</td>
</tr>
<tr>
<td>Height, cm</td>
<td>166 ± 7</td>
<td>—</td>
</tr>
<tr>
<td>Weight, kg</td>
<td>76 ± 11</td>
<td>77 ± 14</td>
</tr>
<tr>
<td>FEV(_1), % predicted(\dagger)</td>
<td>64 ± 26</td>
<td>64 ± 19</td>
</tr>
<tr>
<td>FVC, % predicted(\dagger)</td>
<td>79 ± 19</td>
<td>78 ± 14</td>
</tr>
<tr>
<td>FRC, % predicted</td>
<td>121 ± 28</td>
<td>121 ± 31</td>
</tr>
<tr>
<td>Peak workload, W</td>
<td>75 ± 16</td>
<td>82 ± 19</td>
</tr>
<tr>
<td>(\text{V}O_2) peak, mL/kg/min</td>
<td>16.5 ± 3.5</td>
<td>16.1 ± 3</td>
</tr>
<tr>
<td>6MWD, m</td>
<td>458 ± 65</td>
<td>439 ± 114</td>
</tr>
<tr>
<td>MIP, % predicted</td>
<td>63 ± 18</td>
<td>66 ± 26</td>
</tr>
<tr>
<td>Pa(_{\text{O}_2}), mm Hg</td>
<td>79 ± 9</td>
<td>78 ± 13</td>
</tr>
<tr>
<td>Pa(_{\text{CO}_2}), mm Hg</td>
<td>39 ± 4</td>
<td>42 ± 14</td>
</tr>
<tr>
<td>BDI</td>
<td>7.0 ± 1.2</td>
<td>7.5 ± 1.3</td>
</tr>
<tr>
<td>SGRQ, %</td>
<td>44 ± 16</td>
<td>38 ± 16</td>
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</table>

*Data are presented as mean ± SD unless otherwise indicated. MIP = maximal inspiratory pressure; FRC = functional residual capacity.
\(\dagger\)After bronchodilator.
by the Borg scale; but at T4, no difference was observed between the two groups and with T0. The sensation of leg fatigue paralleled dyspnea.

**Quality of Life**

Figure 3 shows also the time course of the HRQL. In the previous study, it was reported that the total SGRQ score improved after PRP1; unlike exercise tolerance and dyspnea, the benefits of which were lost at T2, it had not worsened in comparison to T1.5 Total SGRQ did not significantly change at T4 in either group independent of the participation in PRP2. As a result, in both groups, the HRQL was still better at T4 than at T0.

**Figure 2.** Time course of airway obstruction (left panel) and inspiratory muscle strength (right panel) in patients of group 1 (filled circles) and group 2 (open squares) who completed the study. Lines and marks represent mean values for each group and time. Vertical bars represent SD. There was no significant difference between or within groups. MIP (%pred) = maximal inspiratory pressure percent predicted.

**Figure 3.** Evolution of exercise tolerance as assessed by 6MWD (upper-left panel) and cycloergometry peak workload (upper-right panel), dyspnea as assessed by Borg scale at isoload (lower-left panel), and HRQL (by SGRQ) (lower-right panel) in patients of group 1 (filled circles) and group 2 (open squares) who completed the study. Lines and marks represent mean values for each group and time. Vertical bars represent SD * = p < 0.05 after vs before each PRP. § = p < 0.05 vs T0. SGRQTot(%) = total SGRQ percentage.
Hospitalizations and Exacerbations

Figure 4 shows the frequency distribution of hospitalizations. In the second-year follow-up, the substantial lack of hospitalizations observed in the first year following PRP1 was maintained in both groups, independent of the participation to PRP2. The frequency distribution of exacerbations is shown in Figure 5. In the year following PRP2, 8 of 17 patients of group 1 but 0 of 19 control patients suffered from no exacerbation. X² analysis showed that the difference was significant. This means also a significant further reduction in exacerbations observed in group 1 but not in group 2 in comparison to the first year after PRP1.

DISCUSSION

This study shows that successive, yearly interventions of pulmonary rehabilitation lead to similar short-term gains but do not result in additive long-term benefits in dyspnea, exercise tolerance, or HRQL. Nevertheless, additional PRP is associated with reduction in exacerbations not requiring hospitalizations.

Our study is consistent with previous reports confirming that an outpatient (day hospital-based) PRP for CAO patients, including lower-limb and upper-limb exercise training and education, can achieve benefits in HRQL and hospitalizations that persist for a period of 2 years. Our study also contributes original additional information, in that it clearly establishes that pulmonary rehabilitation leads to similar short-term gains at successive, yearly interventions also in exercise tolerance and dyspnea. Furthermore, to our knowledge it is the first study to add the notion that an additional PRP at a yearly interval does not result in additive long-term benefits in exercise tolerance and HRQL, other than those induced by an initial PRP. Although the significantly

<table>
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<tr>
<th></th>
<th>T0</th>
<th>T1</th>
<th>T2</th>
<th>T3</th>
<th>T4</th>
<th>T5</th>
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<tbody>
<tr>
<td>G1</td>
<td>7.0 ± 1.2</td>
<td>6.9 ± 1.5</td>
<td>6.9 ± 1.2</td>
<td>7.4 ± 1.8</td>
<td>—</td>
<td>6.9 ± 1.2</td>
</tr>
<tr>
<td>G2</td>
<td>6.4 ± 2.5</td>
<td>5.3 ± 2.2</td>
<td>5.2 ± 1.7</td>
<td>—</td>
<td>4.3 ± 2.7</td>
<td>5.8 ± 1.7</td>
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</table>

*Data are presented as mean ± SD. G1 = group 1; G2 = group 2.
†Before/after PRP changes.
lower number of exacerbations observed only in group 1 in the second year may be attractive, the results of our study cast doubts on the real need of successive yearly PRP. Indeed, we wonder whether the transient benefits in exercise tolerance and dyspnea observed after each successive yearly intervention (Fig 3) and the further reduction in exacerbations but not in hospitalizations (Fig 4, 5) make worthwhile to use (at least in a range of 2 years) health resources for “old” patients having already undergone one PRP, rather than for “new” patients still naive to the intervention.

Two recent randomized controlled studies6,7 in COPD patients have shown long-term results of a PRP similar to ours. Griffiths et al6 in a study vs standard medical management, evaluated the effect of an outpatient PRP on use of health care and patients’ well being over 1 year. Compared with the control group, the rehabilitation group showed greater improvements in walking ability, and in general and disease-specific health status. Similar to our study, the number of patients admitted to hospital was not different, but the rehabilitation group underwent more primary-care consultations.6 In a study vs standard care, Guell et al7 examined the short-term and long-term effects of an outpatient PRP. These authors found significant differences between groups, in 6MWD and in day-to-day dyspnea, fatigue, and emotional function measured by the chronic respiratory questionnaire. The improvements were evident at the third month and continued with somewhat diminished magnitude in the second year of follow-up. In agreement with our study, those authors7 found that the PRP group experienced a significant reduction in exacerbations but not in hospitalizations. Our protocol was more “intensive” and shorter (2 months) than in that study,7 in which patients were somehow treated up to 12 months.

There are relative few data on the strategies to maintain short-term benefits of an initial PRP. In a randomized study of additional 12-week supervised training, Swerts et al9 concluded that a PRP should be continued to stabilize the effect of an initial 8-week PRP. More recently, in a nonrandomized study, Grosbois et al10 found long-term benefits induced by exercise maintenance (either at home or structured and supervised) compared with no intervention. Our study differs from those studies,9,10 in that it was a multidisciplinary intervention that was offered at a yearly interval rather than continuing immediately after the PRP. Our day hospital-based PRP included exercise training, education, and psychosocial support. It has been demonstrated that in COPD patients, respiratory rehabilitation is likely to improve exercise capacity and HRQL if it includes exercise training. The relative contribution of education and psychological support needs to be clearly established.23,24

Figure 5. Frequency distribution of exacerbations during 1-year before and the 2 years following PRP1 in 17 patients of group 1 (upper panels) and 19 patients of group 2 (lower panels) who completed the study.
lead to long-term improvement in HRQL of COPD patients. In agreement with Reardon et al., our study showed that sustained improvement in HRQL is unrelated to exercise tolerance. This result probably reflects the comprehensive nature of the PRP and the fact that HRQL depends on more than just exercise ability.

Given the lack of changes in medical therapy during the follow-up period, the short-term and long-term lack of changes in lung function after the PRP is not surprising and is consistent with previous reports (Fig 2). The findings of our study are in line with the observation that impairment of lung function weakly predicts dyspnea and exercise tolerance in COPD. The lack of changes in maximal inspiratory pressure (Fig 2) is not surprising, as our PRP did not include any specific respiratory muscle training.

Our study showed that in both groups, hospitalizations were significantly reduced in the 24 months after discharge, in comparison to prior to PRP1 (Fig 4). A role of the 6-month interval visits on the hospitalizations cannot be excluded. Indeed, reductions in hospitalizations were observed in both groups, and both groups underwent the visits. Rather interestingly, the only difference between the two groups was in the second-year exacerbations (Fig 5). It seems that an additional yearly PRP may be useful in further reducing the number of exacerbations not requiring hospitalization. Which component of the program most influenced this result is not clear. Most of the COPD patients in both groups had quit smoking during the 2 years before PRP1, and this may have influenced the exacerbations in the following years. The educational program performed may have resulted in a better self-management of disease. Although we can only speculate on the causes of decrease in hospitalizations and in exacerbations, a direct effect of exercise conditioning cannot be ruled out. Indeed, it has been demonstrated that in COPD patients, the utilization of health-care services is related to ventilatory and peripheral muscle force, and that ability to perform the activity of daily life is associated with a better survival after an exacerbation. Although it has been shown that hospitalizations and exacerbations are important determinants of health status in COPD patients, whether or not the maintenance of good HRQL observed in patients of our study is related to reduced hospitalizations and exacerbations is still speculative.

**Limitation of the Study**

Our study is limited by the small sample size. No patients of group 1 withdrew from PRP2; nevertheless, at T4, only 36 patients of the groups combined were available for evaluation. Apart from withdrawals due to intervening pathologic conditions, the proportion of patients who withdrew from the study is rather high but it was similar in the two groups, and dropouts were not different from patients completing the study. It is noteworthy that in the study by Guell et al., 21% of patients withdrew from the study.

In conclusion, with the limitation of the small sample size, we have shown that in patients with CAO, an outpatient PRP can achieve benefits in HRQL and hospitalizations that persist for a period of 2 years. Successive, yearly interventions lead to similar short-term gains but do not result in additive long-term physiologic benefits. Maintenance of reduction in yearly exacerbations seems to be the main benefit of an additional PRP. Whether or not these limited benefits make it worthwhile to perform yearly repetitions of the PRP in a generalized way must be carefully evaluated on the basis of cost/benefit ratio considerations. Whether or not these results apply to longer follow-up or to other respiratory abnormalities remains also to be evaluated.

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