

LONG-TERM EFFECTS OF A PULMONARY REHABILITATION PROGRAMME IN OUTPATIENTS WITH CHRONIC OBSTRUCTIVE PULMONARY DISEASE: A RANDOMIZED CONTROLLED STUDY

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ABSTRACT. Fifty patients with severe chronic obstructive pulmonary disease ($FEV_1 < 50\%$ pred.) were randomized to a rehabilitation group and a control group. The rehabilitation group took part in an individualized multidisciplinary, outpatient 12-month rehabilitation programme. Exercise training was intensive during the first 6 weeks and was then gradually replaced by an individual home-training programme and booster sessions. Controls received the usual outpatient care. Positive effects were found in terms of maximum symptom-limited exercise tolerance and walking distance (13.5 and 12.1% increase, respectively) in the rehabilitation group compared with the controls. Quality of life measurements showed minor beneficial effects on the Sickness Impact Profile, indicating a higher level of activity. No effect was seen on the St George's Respiratory Questionnaire or the Mood Adjective Check List. Patients expressed their enthusiasm for the rehabilitation programme in a study-specific questionnaire.

Key words: COPD; rehabilitation; exercise tolerance; quality of life; long-term effects.

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a debilitating condition presenting with a range of functional limitations in the patient's everyday life (9, 10). Pulmonary rehabilitation programmes are recommended in international guidelines (25) as they have been shown to have the potential to increase exercise capacity (8), and improve dyspnoea (8) and various aspects of quality of life (QOL) (18). However, these conclusions are based mainly on short-term studies.

Reports on the long-term effects of rehabilitation programmes on QOL have been inconclusive. In studies reporting beneficial long-term effects (7, 12, 14, 30, 31)

the same disease-specific measurement, the Chronic Respiratory Questionnaire (CRQ), has been used (13). Two further studies present an initial yet transient effect (6, 17), according to different measurements; the generic "Fragebogen zur Lebenszufriedenheit" and the disease-specific St George's Respiratory Questionnaire (16), respectively. Two follow-ups from one study (22, 29) found neither short-term nor long-term effects on the generic Quality of Well-Being scale, which is often used in health economy evaluations. Four studies (6, 17, 22, 31) followed the patients for at least 12 months but only two were controlled (22, 31).

Data on the long-term effects on exercise tolerance after rehabilitation programmes do not provide uniform answers either. One study (22) with a very long follow-up (72 months) demonstrated positive effects on maximum work-load and endurance compared with an educational control group for 18 but not 24 months after outpatient rehabilitation programmes. Another study (31) with an 18-month follow-up after home-based rehabilitation demonstrated no effect on walking distance compared with baseline, but a positive effect compared with that seen in a control group. Thus, there is a scarcity of long-term studies, of randomized controlled studies and studies including combinations of QOL measures, both disease-specific and generic.

The aim of the present study was to examine long-term effects of outpatient rehabilitation on exercise tolerance and various aspects of QOL, both disease-specific and generic, in a randomized controlled trial.

MATERIALS AND METHODS

Design

Patients with COPD were recruited consecutively and, when a sufficient number had been collected, randomized to produce a rehabilitation group and a control group of equal size. Physiological and QOL measurements were performed at

baseline and at follow-up 12 months later. The control group received the usual outpatient care. All the patients were given written information before consent. The design of the study was approved by the local ethics committee.

Patients

The patients were recruited from the outpatient Department of Pulmonary Medicine, Sahlgrenska University Hospital, Göteborg between April 1993 and March 1995. The criteria for the inclusion of patients were: a diagnosis of COPD, age 45–75 years, FEV₁ of < 50% pred. after bronchodilation and paO₂ of > 8 kPa and a stable clinical condition. COPD was diagnosed according to clinical criteria: chronic obstructive disease; developing after at least 10 pack years of smoking; debut of symptoms after 40 years of age; dyspnoea mainly elicited by exercise or infections; no history of clinically significant allergy. The exclusion criteria were disabling or severe diseases other than COPD or the co-existence of other causes of impaired pulmonary function. All the patients fulfilling these criteria were told about the rehabilitation programme and invited to participate. Of 58 patients invited to participate, 55 declared their interest in participating; one patient chose not to participate due to lack of time and two said they had no interest. Of 28 patients randomized to the rehabilitation group, two died during the intervention period (one of respiratory failure and one of a malignancy). Thus, 26 patients remained for evaluation in this group. Twenty-seven patients were randomized to the control group. One of them died of respiratory failure, one was excluded because of serious heart disease and one patient did not complete the follow-up examination, leaving 24 controls for comparative evaluation. If a patient suffered an acute exacerbation of his pulmonary disease at the time of assessment (baseline or follow-up), this was postponed for 3 weeks and then performed. Patients who developed a lasting deterioration in their COPD during the study period were not excluded.

Rehabilitation programme

The physiotherapy programme consisted of training sessions at the Department of Physiotherapy. These included bicycle training, arm training and training in breathing techniques. The sessions were scheduled: twice weekly for 6 weeks, once weekly for another 6 weeks, once every second week for 6 weeks and then once a month for the remaining period. Every session lasted 45 min, the first 15 min dedicated to breathing techniques in the initial phase and later to arm-training. However, breathing techniques were continuously reinforced later on. Breathing techniques taught were: pursed lips breathing and diaphragmatic breathing. A 30-min period was dedicated to bicycle training. The training programme was preceded by a symptom-limited incremental exercise test (W max). The levels initially tried during training sessions were 42 and 85% of W max at 2-min intervals after 5 minutes warming up at 50% of W max. These 2-min intervals at 42% and 85% were repeated for 25 min at most. The intensity of training was then gradually increased if possible. The physiotherapist used a Borg score (3) to help adjust to an appropriate level. A Borg score of 15 (hard) for "effort" was regarded as the upper level. Oxygen was given if the saturation levels fell below 90%. The patients also received instructions for daily walks and an individualized daily 30 min home-training programme. This included thorax and shoulder-girdle mobility training and muscle strength training. For upper extremity strength training, rubber bands were used

(Thera-Band Resistive Exerciser, The Hygienic Corporation, Akron, Ohio 44310, USA).

An occupational therapist gave the patients information about energy-saving techniques (two sessions). A dietitian informed them about nutrition in COPD and intervened in every case of weight loss, malnutrition or obesity. Two educational sessions with 8–10 patients in each were held on the following questions: what is COPD, what medication is used and what are its effects and does it help to quit smoking. The greater part of the information programme was individualized and included one visit every 3 months to a respiratory nurse and physician (COPD outpatient team). Topics included general information on the disease itself, how to manage medication, smoking and smoking cessation and self-care tips. The patient's partners were also invited to join the information programme.

Procedures

All the physiological and QOL assessments were blinded, except the walking test, which was performed by the nurse in the rehabilitation team. The subjects filled in the questionnaires after being instructed by a research nurse.

Physiological measurements

Routine spirometry was performed using a Sensormedics Spirometer 922, Yorba Linda, CA, USA, 15 min after the inhalation of 1 mg of terbutaline to reach optimal standardization. Carbon monoxide transfer factor (TLCO) was measured using the single-breath method. Values for prediction were those described by Berglund et al. (1) and Salorinne (23), respectively. Arterial blood gases (paO₂ and paCO₂) were measured in all patients. Exercise tolerance was assessed by (a) a 6-min walking distance test (6-mwd) with standardized instructions (5), (b) an incremental, symptom-limited cycle ergometer test (RE 820, Rodby Elektronik AB, Sweden). The 6-mwd was also performed every 3 months in the rehabilitation group. Nutritional status was assessed by: (a) body mass index (BMI), (b) % ideal body weight, and (c) fat-free body mass (24) using a body impedance analyser (BIA 101/s Akern-RJL Systems, Firenze, Italy).

QOL questionnaires

Disease-specific. We used a validated Swedish version (11) of the St George's Respiratory Questionnaire (16). It has 76 items divided into three sections: Symptoms (problems caused by specific respiratory symptoms), Activity (restriction of activity by dyspnoea) and Impacts (impact on everyday life caused by the disease). Every item has a predetermined weight quantifying the severity of problems or limitations. Component scores are calculated for each of the three sections and a total score including all items is derived. The scores range from 0 to 100% of possible distress. A low score thus indicates good health.

Generic. Functional status was measured using a validated Swedish version (27, 28) of the Sickness Impact Profile (2). This is a well-known, generic health status questionnaire constructed to facilitate comparisons between different health conditions over a range of important functional aspects. It consists of 136 weighted items grouped into 12 categories: ambulation, body care and movement, mobility, emotional behaviour, social interaction, alertness behaviour, communication, work, sleep and rest, eating, home management and

Table I. Baseline characteristics by groups

Variable	Rehabilitation group	Control group
Patients, n	26	24
Men/women, n/n	14/12	12/12
Age, years	66.0 (5.4)	66.8 (5.4)
Current smokers, n	6	4
Pack years	35.8 (11.9)	40.1 (21.1)
FEV ₁ % pred.	30.7 (11.4)	34.1 (10.2)
VC % pred.	60.0 (15.4)	66.0 (16.)
TLCO % pred.	45.5 (14.3)	43.5 (17.2)
paO ₂ kPa	10.0 (1.2)	9.4 (0.9)
paCO ₂ kPa	5.4 (0.5)	5.4 (0.7)
BMI	22.8 (3.8)	23.1 (4.3)
%IBW	90.4 (15.0)	92.8 (17.4)
FFM kg	48.1 (7.7)	50.4 (10.4)

BMI = Body Mass Index; % IBW = % of ideal Body Weight; FFM = Fat-free Body Mass. Values are either numbers (*n*) or means and standard deviations. All comparisons between groups were non-significant except for pO₂ ($p < 0.05$).

recreation and pastimes. Patients simply check all the items that apply to them today in relation to their health. A predetermined weighting system reflects the severity of dysfunction. The scale scores are expressed as a percentage of maximum dysfunction to form a 0–100 scale. A score of 0 indicates no dysfunction, a score of $> 0 \leq 10$ indicates slight to moderate dysfunction and a score of > 10 indicates marked dysfunction. The scores in the categories ambulation, body care and movement, and mobility form a physical dimension and the categories emotional behaviour, social interaction, alertness behaviour and communication form a psychosocial dimension, while all 12 categories are included in an overall Sickness Impact Profile score.

Well being. The Mood Adjective Check List measures var-

ious aspects of emotional well being (26). We used a shortened 38-item version covering three basic dimensions of mood: pleasantness/unpleasantness, activation/deactivation and calmness/tension. The scores from all the items form an overall Mood Adjective Check List score, range 1–4. On this scale, higher scores indicate a more positive emotional state.

Study-specific questionnaire

Patients in the treatment group answered specific questions about changes in the severity of their dyspnoea and their views on the structure of the rehabilitation programme and its usefulness.

Statistical analysis

Descriptive statistics were calculated for baseline data in the two groups. Differences within the groups were tested by Fisher's non-parametric permutation test for paired observations (4). Comparisons between the groups used Fisher's non-parametric permutation test (4). Post-hoc item analysis of the Sickness Impact Profile categories that differed between groups was performed using Fisher's exact test. A p -value of < 0.05 was regarded as significant.

RESULTS

Baseline characteristics. Baseline characteristics for the treatment and control groups are given in Table I. The subjects were heavy smokers or former smokers and had severe airways obstruction but no respiratory insufficiency. Maximal exercise capacity (Table II) was reduced to 51% predicted (20) in the rehabilitation and 53% in the control group. There were no significant differences between the groups except in terms of paO₂.

Table II. Outcome measures in the rehabilitation and control groups. Mean values (SE) at baseline and at 12 months follow-up are given and differences within groups outlined

Variable	Rehabilitation group (n = 26) (Intention to treatment)		Control group (n = 24)	
	Baseline	12 months	Baseline	12 months
6-mwd, m	312 (14.6)	350 (17.7)**	308 (15.4)	306 (20.8) ns
W max, W	60.6 (5.1)	70.0 (5.0)**	62.4 (3.9)	63.2 (4.9) ns
FFM kg	48.1 (1.5)	48.5 (1.6) ns	50.4 (2.12)	50.2 (2.0) ns
Days in hospital†	2.3 (0.9)	7.2 (2.9)*	2.0 (0.9)	3.6 (1.7) ns
SGRQ total score	48.6 (2.6)	48.9 (3.4) ns	45.3 (3.0)	45.8 (3.3) ns
SGRQ symptoms score	60.3 (4.7)	52.8 (4.6) ns	47.7 (3.6)	43.6 (4.7) ns
SGRQ activity score	64.3 (3.0)	65.0 (3.5) ns	64.7 (3.7)	64.3 (2.9) ns
SGRQ impacts score	35.4 (3.2)	38.0 (3.8) ns	33.1 (3.4)	35.6 (4.1) ns
SIP total score	9.05 (1.1)	8.98 (1.1) ns	7.78 (1.4)	8.88 (1.4) ns
SIP physical score	6.09 (0.7)	6.37 (1.0) ns	6.04 (1.0)	7.17 (1.4) ns
SIP psychosocial score	5.94 (1.5)	5.74 (1.2) ns	4.02 (1.3)	4.43 (1.2) ns
MACL total score	3.01 (0.12)	3.04 (0.12) ns	3.08 (0.11)	3.11 (0.11) ns

* $p < 0.05$; ** $p < 0.01$ (Fisher's permutation test); ns = non-significant; 6-mwd = 6 min walking distance; Wmax = maximum symptoms-limited incremental exercise test; FFM = Fat-free Body Mass; † Days in hospital during the past 12 months; SGRQ = St George's Respiratory Questionnaire; SIP = Sickness Impact Profile; MACL = Mood Adjective Check List.

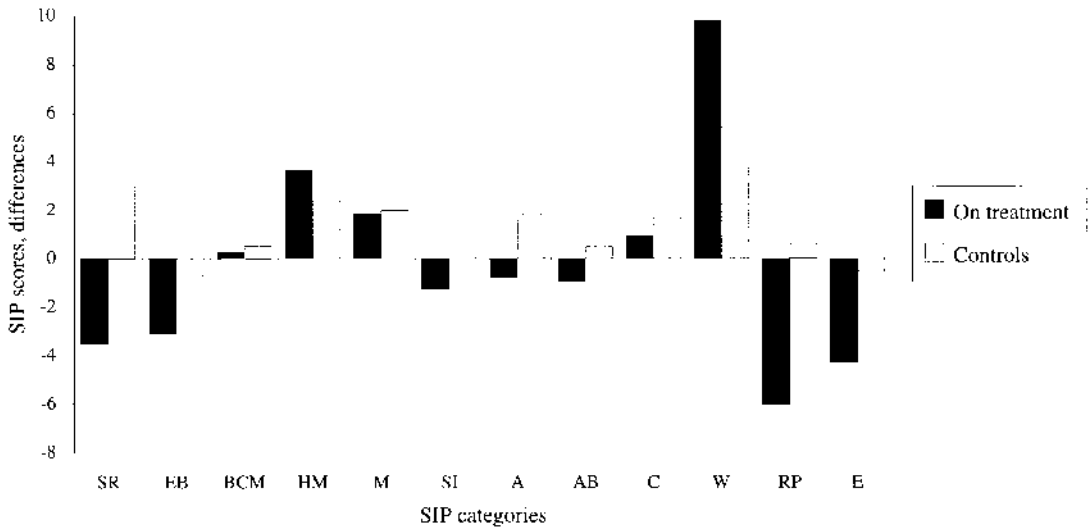


Fig. 1. Mean changes in Sickness Impact Profile (SIP) scores, 0–1 months: on treatment group compared with controls. Data are shown for the categories: sleep/rest, emotional behaviour, body care/movement, home management, mobility, social interaction, alertness behaviour, communication, work, recreation/pastimes and eating. Lower scores indicate better health status.

Adherence to the rehabilitation programme. All 26 patients completed the educational programme. Twenty patients were regarded as compliers, as they completed the essential parts of the exercise training programme (range 17–36 visits); six patients were non-compliers (2–9 visits), two due to lack of motivation and four to a deterioration in their COPD. Three of these patients also presented with other health problems (heart disease, dysphagia, osteoporosis and chronic urinary tract infection).

By way of comparison, three patients in the control group developed unstable COPD with frequent hospitalizations. One patient developed Parkinson's disease. One patient among the compliers in the rehabilitation group developed chronic respiratory insufficiency with long-term oxygen treatment, but no one among the controls.

Changes in physiological and QOL data. Table II presents data for baseline and follow-up for the rehabilitation group (intention to treat) and controls. Walking distance and maximum exercise tolerance increased significantly in the rehabilitation group (12.1 and 13.5%, respectively) but not in the control group. The 6-min walking distance increased continuously even after the initial intensive training period (data not shown). No increase in fat-free body mass was noted. No significant changes were seen for QOL data in either group. Table III compares the changes in the

treatment group (both intention to treat and on treatment) with the changes among the controls. Changes in the treatment group differed significantly from those in the control group in terms of exercise tolerance but not for fat-free body mass or QOL data. However, when it comes to the Sickness Impact Profile, there is a tendency for patients to deteriorate in the control group after 12 months but to stay the same in the treatment group (Fig. 1). This difference between groups did not reach significance for any of the Sickness Impact Profile factors. A post hoc analysis of differences in the Sickness Impact Profile categories on item level revealed less dysfunction in the rehabilitation group on two items: "I lie down more often during the day in order to rest" (factor SR) and "I am not doing any of my usual physical recreation or activities" (factor RP), $p < 0.05$.

Smoking status. There were six smokers in the rehabilitation group and four among the controls. Two patients in the rehabilitation group and two in the control group stopped smoking.

Days in hospital. Days in hospital increased in the rehabilitation group ($p < 0.05$) but also in the control group (ns). However, when the changes within both groups were compared they were not significantly different (Table III). The data on hospitalization were skewed. One patient accounted for 50% of the increase in the treatment group.

Table III. Comparison of changes between the treatment group and controls. Mean differences (SE), baseline - 1-12 month follow-up

	Rehabilitation group (intention to treat)	Rehabilitation group (on treatment)	Control group
Variable	(n = 26)	(n = 20)	(n = 24)
$\Delta 6$ -mwd, metres	38.0 (10.1)*	45.5 (11.3)*	-2.2 (11.5)
ΔW max, Watts	8.2 (2.5)* ¹	11.3 (2.1)**	-0.7 (2.3) ²
Δ FFM kg	0.4 (0.4) ns	0.4 (0.4) ns	-0.2 (0.6)
Δ Days in hospital	4.9 (2.7)*	0.5 (0.8) ns	1.6 (1.7)
Δ SGRQ total score	0.3 (2.2) ns	-0.2 (1.9) ns	2.1 (2.9)
Δ SIP total score	-0.07 (1.0) ns	-0.02 (1.2) ns	1.1 (1.1)
Δ MACL total score	0.03(0.1) ns	0.1 (0.1) ns	0.0 (0.1)

For explanations see Table I. ns = non-significant. * $p < 0.05$; ** $p < 0.01$ (Fisher's permutation test); ¹ n = 25 (one follow-up test missing due to cardiac arrhythmia).

² n = 21 (one follow-up test missing due to cardiac arrhythmia, also two control patients refused to perform test no. 2).

Study-specific questionnaire: (rehabilitation group only). The form was completed by 21 patients. Eleven reported a reduction in dyspnoea. Of 10 patients reporting no improvement in dyspnoea, 5 belonged to the subgroup of non-compliers. The last question on this form "Do you have other comments on the rehabilitation programme?" gave 1-4 descriptive answers from 18 patients. The most common replies related to better emotional well being, a positive feeling that someone cares about me, a feeling of greater security and positive experience from learning respiratory techniques. Other comments were: more knowledge and easier to cope with the disease. One patient considered the programme helpful, but heavy and laborious at the same time.

DISCUSSION

Most studies on the effect of rehabilitation programmes in patients with COPD have focused on whether or not improvements in physical performance can be achieved and thus present data before and immediately after a period of intensive physical training. Whether the effects of these training sessions on exercise tolerance or comprehensive QOL measures can be sustained for longer periods and whether practical models for continuous training can be developed has not been studied to the same degree. Only two controlled studies have focused on some of these issues. Ries et al. (22) using a scheme with monthly reinforcement after an 8-week outpatient rehabilitation programme demonstrated improvements in exercise tolerance but not QOL using the Quality of Well-Being scale. Wijkstra et al. (31)

developed a scheme with intensive home training following a 3-month outpatient rehabilitation programme. They showed better performance after rehabilitation compared with controls, but not versus baseline. The present study supports the hypothesis that lasting effects on exercise tolerance can be achieved after 12 months with an initial intensive period of outpatient training followed by reinforcement sessions and an individual home training plan. The level of increase in exercise tolerance was comparable to that reported in short-term studies (8).

Rehabilitation programmes for COPD can be organized in different ways. Inpatient rehabilitation is convenient for the patients but costly. Home-based rehabilitation requires the care-givers to spend a great deal of time travelling. The outpatient model used in this study appears to be more economical. However, it requires the patients to come to the rehabilitation clinic regularly and so its use is limited to urban areas within a short distance. Our data show that most patients (95%) with severe COPD without respiratory insufficiency take an interest in a rehabilitation programme of this kind and that the majority (77%), when offered it, are able to comply.

However, in contrast to some other long-term studies (7, 12, 14, 31), no significant overall effect on QOL (St George's Respiratory Questionnaire, Sickness Impact Profile and Mood Adjective Check List) was seen. The reason for this is not clear. One possible explanation is the varying psychometric properties of the measurements used in different studies. Even reliable and valid instruments differ in terms of both what and how they measure QOL; e.g. concepts covered, scoring systems

and responsiveness. The absence of changes after rehabilitation seen in generic measurements like the Quality of Well-Being or Sickness Impact Profile probably reflects a limited responsiveness in these comprehensive forms (19, 22). The studies that demonstrate long-term effects on QOL (7, 12, 14, 31) have all used the Chronic Respiratory Questionnaire (CRQ) (13). The CRQ is disease-specific, its dyspnoea section is patient-specific and two of its other three sections cover emotional reactions to COPD as well as coping aspects. In fact, there are some parallels between items in the CRQ and the free comments made by the patients in our study-specific questionnaire. In contrast to the St George's Respiratory Questionnaire and the Sickness Impact Profile, which focus primarily on physical function, there is no strong correlation between improvements in CRQ scores and exercise tolerance (21). Other authors using the St George's Respiratory Questionnaire (17) and other measurements (6, 22) have also found no significant change in QOL after long-term follow-up. The St George's Respiratory Questionnaire has been shown to be responsive (15) in many respects. These facts suggest that the conflicting data on QOL after rehabilitation for the study-specific questionnaires depend at least in part on the different domains covered by the CRQ compared with the St George's Respiratory Questionnaire; i.e. they do not focus on the same aspects of disease-specific QOL. However, a tendency to arrested deterioration was seen in the Sickness Impact Profile and item analyses indicate a higher level of activity after rehabilitation.

Pulmonary rehabilitation is now under debate. In the authors' opinion there are several arguments in favour of pulmonary rehabilitation in COPD: the severity of the disease, the low availability of more effective treatments, such as lung transplantation and emphysema surgery, the positive effects on exercise tolerance and dyspnoea, the patients' compliance and appreciation, and the positive effects seen on QOL as defined by the CRQ. One remaining issue, however, is to show the significance of these effects also using other QOL measures.

In conclusion, our data show that lasting effects on physical fitness can be achieved with an outpatient rehabilitation programme. QOL has not been shown to improve as a result of rehabilitation, but our data point to a possible arrest in deterioration when compared with the controls. Patients expressed their gratitude and enthusiasm for the therapeutic approach.

ACKNOWLEDGEMENTS

This study was supported by grants from the King Oscar II Jubilee Foundation, the Swedish Union of patients with heart and lung diseases and the Medical Faculty, University of Göteborg. We gratefully acknowledge the assistance of Mrs Eva Fröström, our respiratory nurse, Mrs Lillemor Kinnäs, our physiotherapist, Mrs Ann Mari Grönberg, our dietician, Mrs Ann Wingårdh, our occupational therapist and Mrs Ann-Marie Hilmersson, clinical research nurse, for her assistance with the QOL forms, and Nils-Gunnar Pehrsson, for assistance with the statistical analyses.

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Accepted February 16 1999

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