# Pulmonary rehabilitation in outpatients with asthma or chronic obstructive lung disease

# A pilot study of a "modular" rehabilitation programme

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# Summary

*Study/Principles:* Pulmonary rehabilitation programmes are often costly and dependent on the infrastructure of specialised centres. We developed a modular, outpatient-based rehabilitation programme, which is inexpensive and can be implemented in a variety of settings. The aim of this study was to determine the effects and feasibility of this programme.

*Methods:* Thirteen patients with COPD and 7 patients with asthma were enrolled by their primary care physician because of dyspnoea. Initial assessment included cardiopulmonary exercise testing, six-minute walking distance, lung function testing and multiple questionnaires addressing dyspnoea, depression and quality of life issues. The training consisted of 36 sessions of high intensity training of 2 hours duration to improve exercise tolerance, including 30 minutes of stationary cycling at the anaerobic threshold. Another complete

assessment was done on completion of the study at 3 months.

*Results:* The six-minute walking distance improved significantly from 401 to 551 m (p <0.0001). The maximal exercise capacity increased significantly from 85 W to 99 W (p <0.001). The anaerobic threshold remained unchanged despite the high intensity training. There was a reduction of dyspnoea and an improvement of quality of life.

*Conclusion:* This study shows that our outpatient rehabilitation programme leads to a benefit in exercise tolerance and health related quality of life comparable to other programmes published in the literature. The rehabilitation programme was very well accepted among patients, primary care physicians and health insurers.

Key words: pulmonary rehabilitation; exercise tolerance; lung diseases; obstructive/physiopathology; quality of life

# Introduction

Exercise intolerance is the most disabling, distressing consequence of chronic obstructive lung diseases. Cardiopulmonary rehabilitation programmes aim at improving dyspnoea, exercise tolerance and overall quality of life. Several studies have shown benefits of rehabilitation in patients with chronic obstructive pulmonary disease (COPD) and asthma [1–4]. However, no consensus exists as to the best methods of exercise training [5], and mechanisms contributing to improved exercise capacity still need to be elucidated.

We developed an inexpensive, outpatient based rehabilitation programme in the Kantonsspital St. Gallen in collaboration with the Lung Association of St. Gallen. The purpose of the present study was to investigate the feasibility and efficacy of an outpatient rehabilitation programme in patients with COPD and asthma.

# Patients and methods

#### Patients

Twenty patients  $(13 \ \circ, 7 \ \circ)$  were assigned to the study by their primary care physicians. COPD was diagnosed in 13 patients according to ATS criteria [6] 7 were asthmatics. The patients were required to be in a clinically stable condition (no exacerbations within the last 8 weeks)

and on optimum drug management for initial evaluation. No changes were made to their drug therapy during the study period. Patients with severe heart disease, musculoskeletal disorders, peripheral vascular disease or other disabling diseases were excluded from the study.

#### Study design

An initial assessment was performed in all patients. It included lung function testing with bronchodilator response, a six minute walking test and a cardiopulmonary exercise testing. Standardised questionnaires were completed on the assessment day. They consisted of a condition specific measure, a psychological distress measure and a generic quality of life measure.

Within 2 weeks, the patients entered the rehabilitation programme. After completion of the programme, another full assessment was performed.

#### Outcome measures

#### Lung function testing

TLC, residual volume (RV), FVC, FEV<sub>1</sub> and diffusion capacity were measured at the initial evaluation. Static lung volumes were determined in a whole body plethysmograph (Jaeger, Würzburg, Germany). FEV<sub>1</sub> and FVC were measured by a pneumotachograph (Jaeger, Würzburg, Germany). Diffusion capacity was determined by the single-breath method. At completion of the rehabilitation programme all lung function tests were repeated.

#### Cardiopulmonary exercise testing

The cardiopulmonary exercise testing was performed on a cycle ergometer (Jaeger, Würzburg, Germany). The patients breathed through a mouthpiece and wore a nose clip during the test. Minute ventilation, oxygen uptake and carbon dioxide output were measured breath-by-breath and averaged over 30 s periods. Heart rate and arterial oxygen saturation were monitored simultaneously. After 2 min of unloaded pedalling, the workload increased continuously (ramp protocol). Patients were instructed to stop when they could not continue because of dyspnoea or general fatigue.

The anaerobic threshold was determined by the V-slope method [7].

#### Six minute walking distance

After two training sessions to become familiar with the test, patients were instructed to walk as far as possible for a period of 6 min without encouragement [8].

#### Questionnaires

The MOS 36-item short-form health survey (SF-36) [9] is a widely used instrument to evaluate the health status of a population. It includes questions about physical role and health, pain, general health, vitality, social inte-

# Results

Twenty patients were included in the study. Eighteen patients completed the initial and final cardiopulmonary exercise testing, 10 of these also completed the required six-minute walking tests. Six of the 13 COPD patients were smokers, 4 of them quit smoking during the study period. The rehabilitation programme was well tolerated and accepted among patients; there were no adverse events. Patients' baseline characteristics are shown in Table 1.

The overall quality of life was assessed using the SF-36 score, consisting of 8 items. Seven of these showed improvement compared to baseline (p < 0.05, fig. 1). Basal dyspnoea, measured as Mahler's index, improved significantly (p < 0.01). gration and mental role and health. These 8 items can be summarized in a Physical Component Summary Scale (PCS) and a Mental Component Summary Scale (MCS).

The Hospital Anxiety and Depression scale (HAD) [10] is a self-administered questionnaire concerned with the level of symptoms of anxiety and depression. It consists of 14 items which produce separate scores for anxiety and depression.

Basal dyspnoea was rated according to Mahler's dyspnoea index [11]. The scores depend on ratings for three different categories: functional impairment; magnitude of task, and magnitude of effort. At the baseline state, dyspnoea was rated in five grades from 0 (severe) to 4 (unimpaired) for each category. At completion of the study, changes in dyspnoea were rated by seven grades, ranging from -3 (major deterioration), to +3 (major improvement).

#### Rehabilitation programme

The rehabilitation programme consisted of 36 sessions (3 times weekly during 12 weeks) and included warm-up gymnastics, high intensity upper and lower extremity training and cycling on a home trainer at the anaerobic threshold for 30 min. The level of the anaerobic threshold was assessed at the cardiopulmonary exercise test at the beginning of the study and was kept constant throughout the 36 sessions. At the end of each session, relaxation exercises were performed. The complete session lasted 2 hours. The patients were supervised by a physiotherapist in groups of 5.

Every second week the patients attended an education session covering a variety of topics relating to lung conditions and their management. The education session included training of inhalation techniques, counselling for smoking cessation and information about the disease, nutrition and alternative treatment options such as surgery.

#### Statistical analysis

The analysis of quality-of-life questionnaires was performed as described elsewhere in more detail [9, 10]. Comparisons of patients' parameters was done using Wilcoxon's signed-rank test. Primary outcome variables were overall quality of life and maximum exercise capacity; secondary outcome variables included walking distance, oxygen uptake, anaerobic threshold and mental health issues including depression, anxiety and sense of coherence. The significance level was set at 0.05. Numbers are given as means ± standard error of the mean (SEM).

Anxiety and depression scores, assessed by HAD, were not significantly changed by the rehabilitation programme (HAD scores 7.0  $\pm$  0.9 vs. 6.66  $\pm$  0.91 and 5.6  $\pm$  0.86 vs. 5.5  $\pm$  1.4, respectively).

The maximum exercise capacity increased significantly from 85 to 99 W (p <0.001), and the sixminute walking distance improved from 401 to 551 m (p <0.01) (fig. 2). The maximum oxygen uptake increased accordingly (1.38 ± 0.3 l/min vs. 1.52 ± 0.4 l/min, p <0.05). As expected, there was no significant change in lung function (FEV<sub>1</sub>: 1.961±0.8 [mean ± SEM] vs. 1.91±0.8, p = 0.68) after the rehabilitation programme. Unexpectedly, the anaerobic threshold remained unchanged despite the

#### Quality of Life (SF-36) Figure 1 Scores of the 8 SF-36 Physical Health categories. Seven of 8 items improved after the rehabilita-Physical tion programme Mental Health Role (p < 0.05). Representation of the diagram according to Steiner 100 et al. [15]. Pain Mental Role 0 General Health Social Integration Vitality Before Rehabilitation — After Rehabilitation

#### Table 1

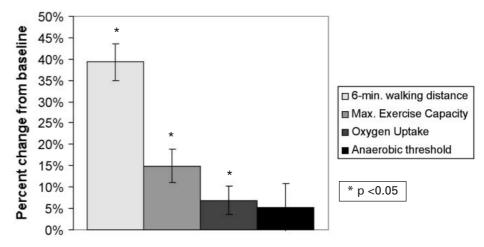
Baseline characteristics of patients at study entry. Values are given as mean (range).

	COPD (n = 13)	Asthma (n = 7)
Age (years)	62 (49–78)	58 (32-82)
Sex (♂/♀)	5/8	2/5
FEV <sub>1</sub> (litres)	1.6 (0.9–3.0)	2.7 (1.8-3.5)
FEV <sub>1</sub> (% predicted)	56 (44–108)	100 (86–127)
6 min walking distance (meters)	390 (305–425)	427 (310–550)
Max. exercise capacity (Watt)	78 (47–112)	102 (41–129)

#### Figure 2

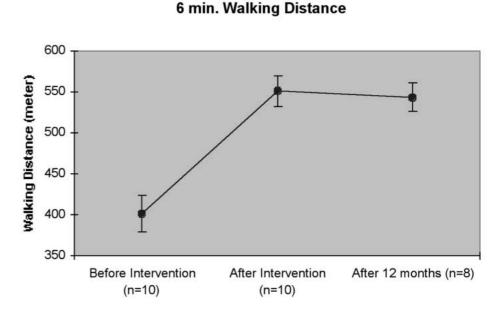
Percent improvement in cardiopulmonary exercise testing parameters. Values are mean % change  $\pm$  SEM. Six minute walking distance (n = 10), maximum oxygen uptake (n = 20) and exercise tolerance (n = 20) improved significantly (p <0.01, p <0.05 and p <0.001, respectively), whereas the anaerobic threshold remained unchanged (p>0.80).

#### Percent change in cardiopulmonary exercise parameters



#### Figure 3

Walking distance at study entry (n = 10), at completion of the rehabilitation programme (n = 10) and after 12 months (n = 8). Two patients were lost to follow-up due to death (n = 1) and serious illness (n = 1).



high intensity training at the anaerobic threshold (1.07  $\pm$  0.4 vs. 1.07  $\pm$  0.3, p = 0.80). However, the pulse rate at the anaerobic threshold decreased significantly (124  $\pm$  3 vs 118  $\pm$  2, p = 0.0019). The improvement in walking distance remained significant at 12 months follow-up (fig. 3).

COPD and asthma patients were analysed as one group. When analysis was done for each group separately, the improvement in walking distance and exercise capacity remained significant.

## Discussion

Numerous studies have been performed on the effect of rehabilitation on exercise performance and quality of life in COPD [4]. This study demonstrated a significant and clinically relevant increase of the walking distance, the maximum exercise capacity and the maximum oxygen uptake, comparable to the effects described by lung reduction surgery in patients suffering from emphysema [12]. Furthermore, dyspnoea and overall quality of life were significantly improved after the rehabilitation programme. These effects, though being primary endpoints of this pilot study, were not the only aims of our study group. The lack of data on the feasibility of modular outpatient rehabilitation programmes in Switzerland was our second important challenge.

The first unique feature of this programme is its "modularity" – it can be performed in a similar fashion anywhere if the following four "modules" are available:

- 1. A pulmonologist examining the patients entering the programme.
- 2. A physiotherapist with rehabilitation skills and enthusiasm teaching a group of five patients.
- 3. A fitness centre containing several ergometers and MTT training facilities.
- 4. The local branch of the league for lung health (Swiss Lung Association) offering to organize educational programmes.

The geographic density of the availability of all four services is high enough in Switzerland to start a sufficient number of programmes to serve more than 90% of all patients with chronic obstructive lung disease. On top of the well-accepted benefit for the patient's physical health and quality of life, these programmes are less expensive as compared to the conventional hospital-based rehabilitation programmes. The patients are expected to show similar improvements of their physical health and overall quality of life as in this pilot study: A known effect, though not demonstrated in this study, is the reduction of exacerbations and hospitalisations in patients after successful rehabilitation. At an estimated cost of 2150 € per patient, it can be extrapolated that only three to five days in hospital per year could offset the costs of this sort of programme.

The second unique feature of this study is the repeated measurement of the ventilatory anaerobic threshold. Its level is of special interest in patients with ventilatory limitation. It determines the work that can be performed without excessive lactate production. The accumulation of lactate as the major acidic moiety produced by muscle cells leads to a fall in pH, and this, in turn, induces a steep increase in ventilation with consecutive dyspnoea. An increase of the anaerobic threshold could therefore lead to an improvement of dyspnoea and physical health in these patients. The determination of the ventilatory anaerobic threshold is of course controversial in patients with COPD, due to the fact that these patients often do not reach the anaerobic threshold because of early ventilatory limitation. However, we were able to determine the anaerobic threshold with computer-assistance in 18 of the 20 patients. This clearly shows that it is a useful tool in the assessment of patients with mild to moderate ventilatory limitation. In spite of the high intensity training, we could not demonstrate a significant increase of the anaerobic threshold. Possible explanations include a lack of power due to small sample size, the heterogeneity of the patients in the sample, and the lack of adjustment of the training intensity during rehabilitation. However, the significant fall in the pulse rate at the anaerobic threshold indicates a better tolerance of a similar workload after rehabilitation.

Therefore, more studies are needed to investigate different modes of training with the aim of improving the anaerobic threshold including the adjustment of training intensity. Obviously, the finding of a clear advantage of high intensity training over low intensity training [13] is dependent on the outcome measure. Improving maximal workload and maximal oxygen consumption may be less important than improving aerobic capacity.

This study was planned as a pilot study to examine the feasibility and acceptance of this novel kind of "modular" rehabilitation programme. Therefore, we did not include an untreated control group. This may limit the validity of this study. However, a spontaneous increase in exercise tolerance and walking distance is not to be expected, as previous studies have shown a high reproducibility of cardiopulmonary exercise performance in trained and untrained individuals [14]. Additionally, the lack of improvement of lung function suggests that the increase in exercise tolerance is not directly related to a fluctuation in disease severity, i.e. improvement after an exacerbation.

In summary, our study demonstrated that this outpatient-based rehabilitation programme is effective and well accepted among patients, primary care physicians and health insurers. The relatively simple design of the programme makes it feasible independently of expensive equipment. This type of programme is unique and novel, as it can be based on practising physicians and physiotherapists, as well as the widely available fitness centres. Cardiopulmonary exercise testing is mandatory to evaluate the anaerobic threshold in order to set the optimal training intensity. More studies are needed to determine the optimal frequency and intensity of the training, as the improvement of the anaerobic threshold could become an additional measure of successful rehabilitation.

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