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Effects of Home-Based Pulmonary Rehabilitation with a Metronome-Guided Walking Pace in Chronic Obstructive Pulmonary Disease

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Despite documented efficacy and recommendations, pulmonary rehabilitation (PR) in chronic obstructive pulmonary disease (COPD) has been underutilized. Home-based PR was proposed as an alternative, but there were limited data. The adequate exercise intensity was also a crucial issue. The aim of this study was to investigate the effects of home-based PR with a metronome-guided walking pace on functional exercise capacity and health-related quality of life (HRQOL) in COPD. The subjects participated in a 12-week home-based PR program. Exercise intensity was initially determined by cardiopulmonary exercise test, and was readjusted (the interval of metronome beeps was reset) according to sub-maximal endurance test. Six-minute walk test, pulmonary function test, cardiopulmonary exercise test, and St. George's Respiratory Questionnaire (SGRQ) were done before and after the 12-week program, and at 6 months after completion of rehabilitation. Thirty-three patients participated in the program. Six-minute walking distance was significantly increased (48.8 m; $P = 0.017$) and the SGRQ score was also improved (-15; $P < 0.001$) over the six-month follow-up period after rehabilitation. There were no significant differences in pulmonary function and peak exercise parameters. We developed an effective home-based PR program with a metronome-guided walking pace for COPD patients. This rehabilitation program may improve functional exercise capacity and HRQOL.

Key Words: Pulmonary Disease, Chronic Obstructive; Rehabilitation; Exercise Test; Quality of Life

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is characterized by a pathological rate of decline in lung function with age, and, as a result, patients with COPD often complain of dyspnea and exercise intolerance (1). Exercise limitation, a very significant contributor to the poor quality of life of these patients, has been traditionally explained by the increased work of breathing and dynamic hyperinflation that results from the airflow limitation. However, several studies have clearly shown that skeletal muscle dysfunction is a very significant contributor to exercise limitation in these patients (2). Skeletal muscle dysfunction also contributes significantly to weight loss, a poor prognostic factor in patients with COPD (3). Thus, appropriate treatment of skeletal muscle dysfunction should be a priority in the clinical management of COPD, and currently, this is based mostly upon rehabilitation programs, nutritional support and, perhaps, oxygen therapy (4).

Pulmonary rehabilitation (PR) is multidisciplinary and comprehensive intervention for patients with chronic respiratory diseases who are symptomatic and often have decreased daily life activities. It is designed to reduce symptoms, optimize functional status, increase participation, and reduce health care costs through stabilizing or reversing systemic manifestations of the disease (5). Although pulmonary function did not change after PR, significant improvements in functional exercise capacity, dyspnea, and health-related quality of life (HRQOL) were consistently observed in various studies (6-11).

However, in spite of documented efficacy and strong recommendations, PR is largely underutilized because most programs

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have been carried out on an inpatient or outpatient basis (12). Inpatient programs are expensive, and in outpatient programs the subject must go to the hospital several days a week. Another problem is the long-term maintenance of benefits once the hospital-based PR program has been completed, since gains achieved diminish progressively if training is abandoned (13). For these reasons, home-based PR was proposed as an alternative to outpatient rehabilitation. However, there were limited data on the effectiveness of home-based PR (14-18). There was also a concern about determination and adjustment of the exercise intensity during conducting a home-based PR program (17, 19).

Thus, the aim of the present study was to investigate the effects of a 12-week home-based PR program with a metronome-guided walking pace on functional exercise capacity and HRQOL in patients with COPD of 3 university hospital-based centers.

MATERIALS AND METHODS

Study design and patient selection

This study was a multicenter, prospective, observational clinical trial. The subjects participated in a 12 weeks home-based PR program. The following evaluations were carried out at enrollment (initial visit), 12 weeks (immediately after the program), and 6 months after completion of rehabilitation: 1) pulmonary function tests; 2) cardiopulmonary exercise test; 3) six-minute walking test; 4) St. George's Respiratory Questionnaire (SGRQ) (Fig. 1).

We recruited patients from the pulmonary clinics of three university hospital-based centers. Patients were eligible for participation if they had stable COPD, that is, no change in medication and symptoms for 3 months before the study; were 40 yr or older; were current or former smokers of at least 10 pack-years; and had an FEV_1 less than 80% of the predicted value and FEV_1/FVC ratio less than 0.70. Those with cardiovascular instability, musculoskeletal or neurologic disorders that would inhibit exercise, or previous attendance at pulmonary rehabilitation were excluded.

Because all patients were diagnosed with COPD ranging from moderate to very severe according to the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines, they received optimal pharmacologic therapy including one or more long-acting inhaled bronchodilator in accordance with recommendations of the treatment guidelines.

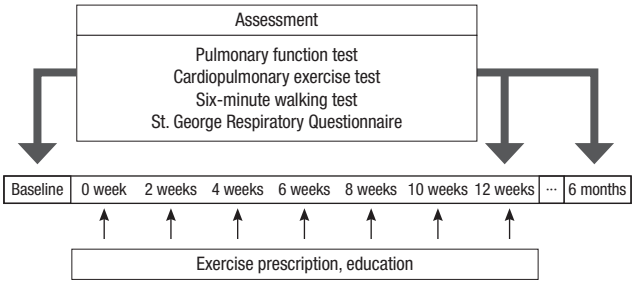

Fig. 1. Home-based pulmonary rehabilitation protocol.

Home-based exercise program

The home-based PR program was composed of aerobic exercise (walking), muscle strength training, education, respiratory muscle training, and stretching. Exercise intensity (walking speed) was determined by cardiopulmonary exercise test, and target intensity was 60% of the maximum work rate achieved during the test. To guarantee walking speed, we gave each patient a metronome that beeped at preset intervals, individualized to each patient's target intensity. Patient was instructed to walk with metronome in hands and synchronize steps with metronome beep.

Patients visited each clinic every 2 weeks for 12 weeks. At each visit, the exercise intensity was readjusted according to repeated sub-maximal endurance tests. Muscle strength training was done with elastic bands, and Threshold® (Respironics, Parsippany, NJ, USA) inspiratory muscle trainer was used for respiratory muscle training. Compliance was assessed by daily exercise diary.

Outcomes and measurements

One of our primary outcomes for effectiveness was the differences from baseline in HRQOL after 12-week home-based rehabilitation as measured by SGRQ. We used the Korean version of the questionnaire which was validated in a Korean research (20). The total score range from 0 to 100, with a lower score representing a better HRQOL. A change in score of 4 units is consistent with a clinically relevant change in the patient.

To examine changes of functional exercise capacity, the other primary outcome of our study, six-minute walking distance was measured twice at the beginning and once at the end of 12-week rehabilitation and 6 months according to established criteria (21). We used the better of the first two six-minute walking distances as the baseline value.

Patients also completed pulmonary function tests and cardiopulmonary exercise tests using the bicycle ergometer (SensorMedics Corp., Yorba Linda, CA, USA) at enrollment, 12 weeks, and 6 months.

Statistical analysis

All statistical analyses were performed using the statistical software package SPSS v12.0.1 (SPSS Inc., Chicago, IL, USA). Comparison of the outcomes of each assessment moment (at enrollment, 12 weeks, and 6 months) was performed with repeated measures analysis of variance (ANOVA). The last observation carried forward method was used for missing data. A value of $P \leq 0.05$ was considered statistically significant.

Ethics statement

The study was approved by the Kangdong Sacred Heart Hospital institutional review board (Approval No. 06-3) and institutional review boards of other 2 hospitals. All of the patients provided written informed consent.

RESULTS

General characteristics

Thirty-three patients were enrolled from the participating centers and began the home-based PR program. However, six patients dropped out during rehabilitation due to a lack of motivation (n = 3), or COPD exacerbation (n = 3). Twenty-seven patients finally completed the home-based PR program and measurements at 12 weeks.

The general characteristics and overall measurements of twenty-seven participants are summarized in Table 1. The mean age was 66 yr, and there was only one woman included. The mean body mass index (BMI) was 21.6 ± 3.3 kg/m^2. In the baseline spirometry, mean FEV_1 was 1.27 ± 0.51 L/min (48.7% of predicted) and mean FVC was 2.96 ± 0.82 L/min (77.9% of predicted). The patients had moderate to very severe COPD according to the GOLD guidelines. Of these, 48.1% were classified as GOLD II (moderate COPD), 37.0% as GOLD III (severe COPD), and 14.8% as GOLD IV (very severe COPD). The mean pre-rehabilitation six-minute walking distance was 512.1 ± 197.1 meters. Initial maximal workload (Wmax) and peak oxygen uptake (VO_2 max) were measured as low as 80.8 ± 28.9 W and 17.3 ± 5.4 mL/kg/min, respectively.

Table 1. General characteristics and baseline measurements of study patients

Parameters	Measured values
Age (yr)	66.2 ± 7.8
Men : Women (No.)	26 : 1
BMI (kg/m^2)	21.6 ± 3.3
Pulmonary function	
FEV_1 (L/min)	1.27 ± 0.51
FEV_1 (% predicted)	48.7 ± 16.5
FVC (L/min)	2.96 ± 0.82
FVC (% predicted)	77.9 ± 17.2
DL_{CO} (% predicted)	74.4 ± 22.5
SGRQ score	
Total	44.9 ± 15.9
Symptoms	42.4 ± 16.8
Activities	69.3 ± 23.9
Impacts	31.8 ± 16.0
6MWD (m)	512.1 ± 197.1
Peak exercise parameters	
VO_2 max (mL/kg/min)	17.3 ± 5.4
Wmax (W)	80.8 ± 28.9

Values are given as the mean ± SD. BMI, body mass index; FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; DL_{CO}, Diffusion lung capacity for carbon monoxide; 6MWD, six-minute walking distance; SGRQ, St. George Respiratory Questionnaire; VO_2 max, maximal oxygen uptake; Wmax, maximal workload.

Primary outcomes

The comparisons of measurements at enrollment, 12 weeks, and 6 months after completion of rehabilitation showed that our home-based PR strategy was associated with statistically and clinically significant improvements in six-minute walking distance ($P = 0.017$) and total SGRQ score ($P < 0.001$). We also observed significant differences for symptoms ($P = 0.026$), activities ($P < 0.001$), and impacts domain of SGRQ ($P < 0.001$). The improvement of SGRQ scores greatly exceeded minimum clinically important difference (less than -4.0). These effects of rehabilitation on functional exercise capacity and HRQOL lasted over 6 months (Fig. 2).

Secondary outcomes

Pulmonary functions estimated by forced expiratory volume in 1 second and forced vital capacity were slightly increased in number after home-based pulmonary rehabilitation. Statistically, however, there were no significant differences in pulmonary functions over the six-month follow-up period (Table 2).

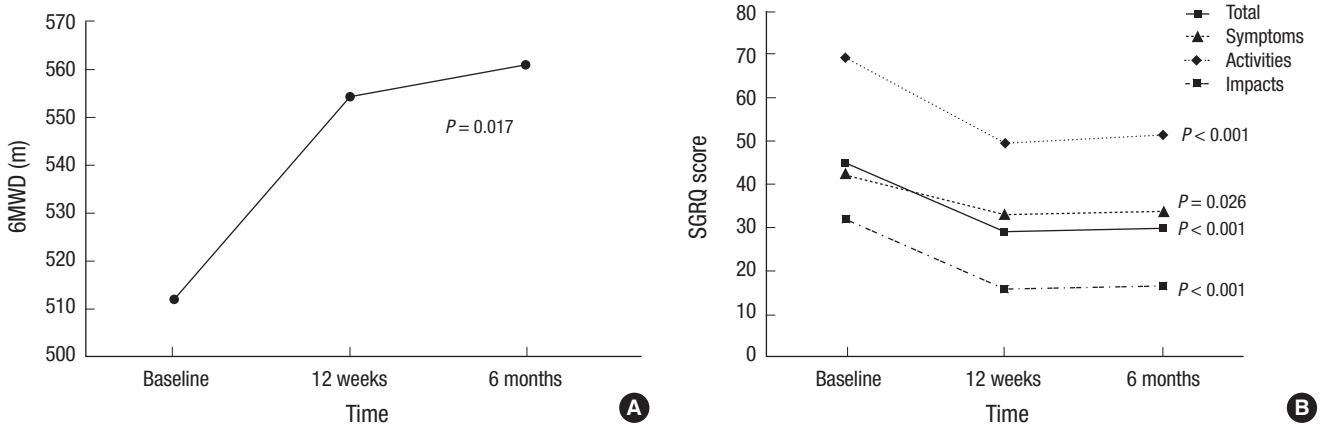

Fig. 2. Improved pulmonary and physical functions by exercise. (**A**) Six-minute walking distance (6MWD) and (**B**) St. George's Respiratory Questionnaire (SGRQ) score differences from baseline to 6 months after completion of rehabilitation.

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Table 2. Changes in pulmonary function and peak exercise parameters according to the study interventions from baseline to 6 months after completion of rehabilitation

Outcomes	Baseline	12 weeks	6 months	*P* value
Pulmonary function				
FEV_1 (L/min)	1.27 ± 0.51	1.30 ± 0.52	1.32 ± 0.53	0.239
FEV_1 (% predicted)	48.7 ± 16.5	48.8 ± 17.9	49.2 ± 18.7	0.671
FVC (L/min)	2.96 ± 0.82	3.09 ± 0.74	3.10 ± 0.85	0.155
FVC (% predicted)	77.9 ± 17.2	79.0 ± 20.1	80.2 ± 19.4	0.407
Peak exercise parameters				
VO_2 max (mL/kg/min)	17.3 ± 5.4	16.3 ± 5.1	17.0 ± 5.6	0.540
Wmax (W)	80.8 ± 28.9	81.0 ± 32.1	79.8 ± 31.3	0.637

Values are given as the mean ± SD. FEV_1, forced expiratory volume in 1 second; FVC, forced vital capacity; VO_2 max, maximal oxygen uptake; Wmax, maximal workload.

Meanwhile, one of twenty-seven participants did not want to do the cardiopulmonary exercise test again, so twenty-six patients finally completed the exercise test after rehabilitation. However, changes in peak exercise parameters assessed by maximal oxygen uptake and maximal workload also did not reveal any clinical significance (Table 2).

DISCUSSION

PR is an increasingly popular and effective option for patients with moderate to very severe COPD. Rehabilitation aims to prevent deconditioning and allow the patient to cope with their disease, and is individually tailored and designed to optimize each patient's physical and social performance and autonomy (22, 23).

PR leads to statistically significant and clinically meaningful improvements in HRQOL and functional exercise capacity, and reduces dyspnea (6-11). However, a report suggested that a rehabilitation program consisting of exercise and education twice a week for 8 weeks had no effect on functional exercise capacity and well being in patients with moderate COPD (24). Another studies showed a deterioration in functional exercise capacity and HRQOL over 12 months after completion of PR (13), and the improvements achieved through a hospital-based training could be maintained when supported by home-based or regional healthcare-based training programs (25, 26).

In these aspects, home-based PR was examined for the effectiveness in several studies (14-18). In 1996, Wijkstra et al. first reported the effects of home rehabilitation in several patients with COPD. The rehabilitation group did not show any improvement in exercise tolerance and cardiocirculatory parameters, but a small improvement in exertional dyspnea comparing with no rehabilitation group (14). However, another small controlled trial of home-based rehabilitation group versus standard medical treatment group revealed significant improvement of exercise tolerance, dyspnea, and HRQOL in the home rehabilitation group (16). Direct comparisons of the effects of the hospital-based outpatient rehabilitation and home-based rehabilitation also showed that home-based programs were not inferior to hospital-based program to improve dyspnea and health status (15, 18). Although limited data, home-based program was not inferior to center-based program, and appeared to be superior in terms of the adherence to exercise.

This study was meaningful that we confirmed the effectiveness of home-based PR in improving functional exercise capacity and quality of life with our own rehabilitation program. Exercise intensity was determined individually using the result of cardiopulmonary exercise test, and was readjusted according to sub-maximal endurance tests at each visit. Especially, we used metronome to guarantee this exercise intensity in the actual exercise. To date, only one recent research used a metronome to maintain the prescribed walking speed during home-based PR, and better improvement of exercise capacity was shown in the group walking paced by a metronome rather than the group walking a prescribed distance in a given period of time (19). Furthermore, our rehabilitation program consisted of not only aerobic exercise (walking), but also muscle strength training, education, respiratory muscle training, and stretching. We think that we developed an effective and convenient home-based PR program for COPD patients.

Meanwhile, 18% of participants dropped out of our study. The reasons for dropping out were lack of motivation and COPD exacerbation. The rate of COPD exacerbation (9.1%) was less than or similar to that of other studies concerning home-base PR (16, 17). Three patients complained of being exhausted after cardiopulmonary exercise test and decided not to continue. These patients declined to take part in the present study because of the inappropriate perception of the necessity for exercise test and the benefits of rehabilitation program, not because of their medical conditions. Thus, although comparison cannot be made with a control group, these dropouts probably did not induce the attrition bias. Measurement of maximal oxygen uptake in COPD patients has been traditionally used to determine the exercise intensity in the pulmonary rehabilitation. Therefore, to provide home-based pulmonary rehabilitation program more easily, the development of other method that can replace the cardiopulmonary exercise test is needed. More detailed information for motivation of the patients will also be helpful to reduce the dropout rate during rehabilitation program.

The present study had several limitations. First, the number of patients was relatively small. Second, only one female patient was included. Therefore, the results cannot be generalized to female COPD patients, since a previous study suggests that gender might influence COPD manifestations (27). Third, this study was an uncontrolled, observational study. A further study in a larger patient sample with a control group is warranted to clarify the results of the present study.

In summary, our home-based PR program could improve functional exercise capacity and HRQOL, and these effects lasted over 6 months after completion of rehabilitation. The use of

a metronome for home-based rehabilitation may be an effective and convenient method to maintain the exercise intensity.

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C. Kim, Y. B. Park, Y-S Jin, Y. J. Yang, and S-S Lee have no conflicts of interest to disclose. Y-M. Oh has been an investigator in industry-sponsored studies (MSD Korea, AstraZeneca Korea, Boehringer Ingelheim Korea, Handok and GlaxoSmithKline) and in university-sponsored studies (Asan Institute for Life Science, University of Ulsan College of Medicine). YMO has participated as a speaker at scientific meetings organized and financed by pharmaceutical companies (Handok, Pfizer Korea, GlaxoSmithKline, AstraZeneca Korea, MSD Korea, and Boehringer Ingelheim Korea) and a magazine company (Korea Doctors' Weekly). YMO developed an educational presentation for a pharmaceutical company (Diachi Sankyo Korea). S-D. Lee serves as a consultant to GlaxoSmithKline and Nycomed, and has participated as a speaker at scientific meetings organized and financed by various pharmaceutical companies (GlaxoSmithKline, AstraZeneca Korea, Nycomed and Boehringer Ingelheim).

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