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Title: Comparison of compliance rates and treatment efficiency in home-based with hospital-based pulmonary rehabilitation in COPD

Short title: Comparison of Home-based with Hospital-based Pulmonary Rehabilitation

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Abstract

Objective: We aimed to compare the home-based Pulmonary Rehabilitation (PR) with the hospital-based PR in terms of exercise compliance rates and efficiency of therapy in stable Chronic Obstructive Pulmonary Diseases (COPD).

Material and Methods: Stable severe and very severe COPD patients who were admitted consequently to our PR clinic were prospectively included in the study. The patients who completed the home-based PR for at least four days a week for two months as recommended were called Study Group. The patients who had completed the hospital-based PR in our clinic before this study were taken as a Control Group.

Results: Thirty five patients included in home-based PR but ten patients were incompatible with the exercise training and four patients were out of follow up. Twenty-one patients successfully completed home-based PR (Study Group) and compliance rate was 60%. Thirty seven patients who had previously underwent the hospital-based PR and 25 of them completed the exercise program (Control Group) thus their compliance rate was 67% . There was no difference between the two groups in terms of treatment compliance rates. The significant improvement in six-minutes walking distance, modified Medical Research Council dyspnoea and COPD assessment test scores were observed after PR in both groups and there was no difference in terms of the levels of improvement.

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**Conclusion**: This study showed that approximately two-thirds of COPD patients successfully completed home-based PR and also this program provided similar benefits in terms of quality of life and exercise capacity compared with hospital-based PR.

**Key Words**: pulmonary rehabilitation, dyspnoea, exercise capacity, walk test, COPD.

**INTRODUCTION**

Pulmonary Rehabilitation (PR) is defined as a comprehensive intervention based on a thorough patient assessment followed by patient-tailored therapies, and includes exercise training, education and behavior change, and it is designed to improve the physical and psychological condition of people with chronic respiratory disease and to promote the long-term adherence to health-enhancing behaviors\(^1\). It is integrated into lifelong care and management of chronic respiratory illness and requires active collaboration between the patient, their family and the PR team\(^2\). Due to the complex nature of respiratory diseases, many disciplines must be involved in co-treatment\(^3\).

Pulmonary rehabilitation is a useful treatment modality for almost all chronic respiratory patients, especially in Chronic Obstructive Pulmonary Diseases (COPD)\(^4\). Recent studies have shown that PR decreases the number of exacerbations and frequency of hospitalization in COPD patients\(^5-7\).

There are many PR organizational types, such as hospital-based\(^8\), telephone-mentoring with home-based\(^9\) or tele-monitorizational programs\(^10\). Hospital-based supervised programs are time-consuming and costly practices\(^11\). There are few studies comparing home-based PR and hospital-based PR\(^12-14\). Adherence to home care may vary according to societies and cultures. In our country, this study is the...
first study that compared hospital-based and home-based PR in COPD patients and examined the effect of pulmonary rehabilitation on the COPD Assessment Test (CAT) score which is an important assessment of disease outcomes. For this reason, there is a need for further studies on the effectiveness and benefits of unsupervised programs.

In this study, we compared home-based out-patient unsupervised PR and out-patient supervised hospital-based PR in terms of compliance and effectiveness.

Hypothesis of the study;

H1: Out-patient home-based PR is as effective as out-patient hospital based PR.

H2: Exercise compliance of home-based PR is as good as hospital-based PR.

MATERIAL AND METHODS

This study was combined prospective and retrospective cohort study. The Global Initiative for Chronic Obstructive Lung Disease (GOLD) stage 3-4 (forced expiratory volume in 1 second (FEV1) < 50%) stable COPD patients with shortness of breath and exercise intolerance applying to subsequently our PR policlinic were included in this study. Inclusion criteria were as follows: aged ≥40 years, at least one-year diagnosis of COPD according to the GOLD with post-bronchodilator FEV1 / Forced Vital Capacity (FVC) ratio of ≤0.7 and ≥10 pack-year smoking history. Exclusion criteria were as follows: having COPD exacerbation within the past six weeks prior to enrollment, respiratory disease other than COPD,
decompensated heart failure, uncontrolled hypertension (systolic blood pressure >200, diastolic blood pressure>110), comorbidities (orthopaedic or psychiatric) preventing exercise.

Stable COPD patients who were admitted to the PR clinic were prospectively recruited in the study between March and July 2017 and called study group. The multidisciplinary pulmonary rehabilitation program was designed as out-patient home-based PR. Each patients was evaluated by cardiologists and dieticians at the beginning of the program and necessary interventions were made. The patients and their families were taught in hospital once in detail the exercises they would do at home. Home program included breathing exercises, upper and lower extremity strengthening exercise with free weights and free walking for 5 days in a week for two months. Patients were asked to perform upper and lower extremity strengthening exercises with free weights, 3 times a week, 10 times repeated at home. In order for the exercises to be remembered by the patient, the exercise form was given to the patient. The patients were asked to walk daily in their own homes, taking the calculated distance based on the walking distance obtained from the six-minute walk test. It was taught how safe the heart rate, blood pressure and oxygen saturation intervals, and how they should behave when possible. They were told that they could get oxygen support and take a break if necessary. It was requested that the walking time be increased by 15 minutes, increasing by tolerance every 30 minutes. The method of calculating the number of free walking laps based on the six-minute walk test is given below;

\[
(\text{6 minutes walking distance} / 6) \times \text{Exercise time} = \text{Distance to walk}
\]

Distance to walk x% 80

If the distance to the corridor to be walked is known;
Distance to walk / Corridor length = Number of laps

An exercise follow-up form was given to the patients to record their daily exercises. A similar form filled by physiotherapist once a week during phone call. It was recorded whether the patient performed the exercises, and whether any problems existed. In this way, two schedules were evaluated together and the patients who were regularly performing all the exercises for 4 days a week were accepted as compatible with the rehabilitation program and these patients were taken Study Group.

Between October 2015 and March 2017, the patients with COPD who had previously completed outpatient hospital-based supervised PR for two days under supervision in our PR clinic and three days a week at home during two months and had inclusion criterias were taken as a Control Group and their data were analyzed retrospectively. The supervised exercise sessions had included breathing exercises, treadmill walking (15sc), cycle training (15sc), arm ergometer training (15sc), peripheral muscle training and stretching exercises with free weights. The aerobic exercise program was administered based on the heart rate determined according to the target heart rate (HR) method (HR target = rest HR + (% Aerobic intensity X HR reserve). Exercise intensity was 60% to 80% target HR. Oxygen saturation, HR, Borg fatigue, dyspnoea scores and distance covered were recorded during the exercises. The patient started strength training with 20% of the calculated one-repetition maximum (1-RM) weight and progressively increased to 40%. The dumbbells and lead weight bags were used in supervised exercise sessions. The study flow chart was given Figure 1.

Outcome measurements
Dyspnoea was assessed based on modified Medical Research Council’s (mMRC) dyspnea scale\textsuperscript{16} and the disease control status was measured by the COPD assesment test (CAT) for each patient\textsuperscript{17}. Exercise capacity was also assessed by Six Minute Walking Test (6MWT) based on the American Thoracic Society (ATS) standards\textsuperscript{18}. The six minute walk test is a sub-maximal exercise test used to assess aerobic capacity and endurance. Patients were asked to walk as far as possible in 6 minutes along a flat corridor. The distance in meters was recorded (6MWD). Standardised instructions and encouragement were commonly provided during the test. The 6MWT was performed twice for each patient. The all outcome measurements were applied before and after the PR.

**Statistical analysis**

Statistical analyses of the study were performed using Statistical Package for Social Sciences (SPSS) Version IBM Statistic 15.0 (SPSS Inc. Chicago, IL, USA). The normalizations of the test data were examined using the Shapiro Wilk test. Wilcoxon test was used for intra-group comparisons and Mann Whitney U test was used for intergroup changes in the data with no normal distribution. Variables were expressed as median, minimum and maximum, $p <0.05$ was considered statistically significant. The sample size estimation was performed in “G*Power”, a statistical software program to have 80% power with 5% type 1 error level to detect a minimum clinically significant differences of 54 meters\textsuperscript{19} of the 6-min walk test\textsuperscript{20} with the highest standard deviation of the study parameters.

**RESULTS**

Twenty-five patients prospectively included in home-based PR but 10 patients were incompatible with the exercise training and four patients were out of follow up. Twenty-one patients successfully completed home-based PR (Study Group). Thus compliance rate was calculated as 60% (21/35).
and sex matched 37 COPD patients were selected from out-patient hospital-based pulmonary rehabilitation retrospective cohort. Twelve of 37 patients failed to complete the hospital-based PR for various reasons (four patients due to comorbid problems, five patients transfer problems and three patients follow up problems). Thus 25 patients who had previously underwent the hospital-based PR completed the exercise program (Control Group) and their compliance rate was 67% (25/37). There was no difference in terms of compliance rate between two groups (p=0.504). When the initial values were compared, Study Group had higher age and higher CAT score than Control Group but did not reach statistical significance (p=0.05). The comparison of clinical and laboratory features of groups are given in Table 1.

Significant improvement in mMRC, CAT scores and 6MWD observed in both groups after PR (p <0.05) and there was no difference between the groups in terms of the level of improvement (p>0.05). These results are given in Table 2.

**DISCUSSION**

Pulmonary rehabilitation is a non-pharmacologic treatment that is effective on the clinical outcomes of COPD and also it is a very cost effective approach. But in our country although the prevalence of COPD is very high the number of PR centers is very limited. Thus, alternative PR program are needed for more patients to benefit. In this regard our study is important because it showed that home-based PR improved dyspnoea, exercise capacity and quality of life and also this improvement is similar to hospital-based PR.
Dyspnoea is the main symptom perceived by COPD patients and one of the most important goals of treatment is the reduction of dyspnoea. This study demonstrated that dyspnoea perception decreased with home-based rehabilitation and the level of improvement is similar to hospital-based PR. In a randomized controlled trial in which 58 COPD patients were included and the study group underwent home-based PR while the control group was given only standard medical treatment and the nursing counseling session. At the end of 12 weeks, it was determined a significant recovery with dyspnoea perception in the PR group. The another study compared home-based and central-based PR in term of treatment effectiveness. Dyspnoea perception was assessed by the Chronic Respiratory Questionnaire Self-Report scale different from our study. They observed that after PR, similar improvement of the dyspnoea score in both groups. We have not found any report that home or hospital-based PR is ineffective on dyspnoea perception in the literature.

Six minute walking test is widely used to evaluate the exercise capacities and therapeutic interventions effectiveness in COPD patients. This study showed that home-based PR improves 6MWD and also this improvement is similar to the hospital-based PR. In Designed as a daily life study, 6MWD was increased 65 meters at the end of the five weeks home-based PR similar to our study. In another study, COPD patients underwent home-based PR program which was composed of aerobic exercise (walking), limb muscle and respiratory muscle training during 12 weeks. They had gave each patient a metronome that beeped at preset intervals, individualized to patient’s target intensity to guarantee walking speed. Similar to our results, the patients’s exercise capacity was increased (6MWD=48m) and quality of life was improved end of the study.
The CAT is a practical alternative to longer-established health status questionnaires. This study demonstrates that there is a significant recovery in CAT score in severe and very severe COPD patients with home-based PR. We encountered only one study which had investigated the effect of home and hospital-based PR on CAT score in the literature. This study detected that, improvement in exercise capacity (6MWD) and CAT score in both groups similar to our results.

The compliance rates for PR programs are vary from 10% to 50%. Holland et al clarified that compliance rates of home-based and centre-based PR are 70% and 49% respectively. Similarly, Morgan et al reported a general compliance rate of 70% but compliance rate is higher in home-based PR than central-based PR. In our study, the compliance rates of home-based and hospital based PR were 60% and 67% respectively. The reason for dropping out the home program were mainly follow-up problems, while the reasons for discontinuing the hospital-based PR were transfer problems and comorbidities in our study. On the light of the results of this study, we think that patients who can continue their exercises together with their relatives at home, have more transfer problems and who do not want to wait in waiting list of direct supervised program can be taken to home-based programs. Recently some methods have been developed to increase the compliance of exercise program such as web-based exercise, activity monitors, tele coach applications, videos and phone mentoring. Future studies are needed in this regard.

It is investigated in which patients the PR is more successful. In a study examining the baseline demographic and clinical characteristics of the PR, it was demonstrated that the outcomes were independent of age, sex and chronic hypoxemic respiratory failure, and patients with better respiratory function and lower BODE scores (body mass index, airflow obstruction, dyspnea, and

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exercise capacity index) gave more successful results. In another study, researchers found that pulmonary rehabilitation results in significant improvement in quality of life, dyspnea, and functional capacity independent of baseline disease burden. There are also some studies suggesting that depressive mood is effective on PR success. The baseline characters of the groups were similar in our study. Anyway the purpose of our study was not to answer to the question of which patient might have more PR gain. Our study shows that home-based and hospital-based PR programs have similar gains and are caused by factors other than baseline characteristics.

As a conclusion this study showed that patients who underwent home-based PR had achieved similar benefits to hospital-based PR in terms of exercise capacity, dyspnoea perception and quality of life. The similarities obtained from both programs can be attributed to the fact that the patients in the hospital-based program may not have regular home exercise programs. On the other hand, the patients were given home-based PR had regular exercise for at least four days. At the same time, we think that once a week phone calls can be increased home patients’ motivation. We believe that future studies on home-based PR involving more patients and more comprehensive evaluation may alter daily practice.

The important limitation of this study is the small number of patients are included especially female gender. An another limitation is the data of hospital-based group were obtained from retrospective cohort.
Ethics Committee Approval: Ethics committee approval was received for this study from the Haseki Ethics Committee (Protocol Number: 517). The study was conducted in accordance with the Helsinki Declaration. A written informed consent was obtained from each patient.

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Conflict of Interest: No conflict of interest was declared by the authors.

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Table 1: Comparison of baseline demographic and clinical features changes between two groups before pulmonary rehabilitation

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<table>
<thead>
<tr>
<th>Variables</th>
<th>Study Group</th>
<th>Control Group</th>
<th>z</th>
<th>p*</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>n=21</td>
<td>n=25</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Male/female (n,%)</td>
<td>20/1(95.2 / 4.8)</td>
<td>22/3(88/12)</td>
<td>-0.858</td>
<td>0.39</td>
</tr>
<tr>
<td>Age (year)</td>
<td>65.14(50-80)</td>
<td>61.24(53-75)</td>
<td>-1.954</td>
<td>0.05</td>
</tr>
<tr>
<td>BMI (kg/m²)</td>
<td>25.09(18.29-35.99)</td>
<td>25.73(17.04-32.77)</td>
<td>-0.761</td>
<td>0.44</td>
</tr>
<tr>
<td>Smoking (pack/year)</td>
<td>64.52(13-160)</td>
<td>47.6(0-200)</td>
<td>-1.429</td>
<td>0.15</td>
</tr>
<tr>
<td>6MWD (m)</td>
<td>337(133-464)</td>
<td>388(228-489)</td>
<td>-1.832</td>
<td>0.06</td>
</tr>
<tr>
<td>mMRC/0-4</td>
<td>2.71(1-4)</td>
<td>2.48(1-4)</td>
<td>-0.731</td>
<td>0.46</td>
</tr>
<tr>
<td>CAT</td>
<td>21.52(4-36)</td>
<td>17(2-30)</td>
<td>-1.934</td>
<td>0.05</td>
</tr>
<tr>
<td>FVC (L)</td>
<td>1.87(0.94-3.08)</td>
<td>2.09(1.04-3.80)</td>
<td>-1.125</td>
<td>0.26</td>
</tr>
<tr>
<td>FVC, %</td>
<td>49.92 (22-92)</td>
<td>57.75(5-126)</td>
<td>-1.467</td>
<td>0.14</td>
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<tr>
<td>FEV₁(L)</td>
<td>1.02(0.56-1.98)</td>
<td>1.08(0.50-2.50)</td>
<td>-0.762</td>
<td>0.44</td>
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<tr>
<td>FEV₁, %</td>
<td>34.90(19-77)</td>
<td>39.75(20-89)</td>
<td>-0.871</td>
<td>0.38</td>
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<tr>
<td>FEV₁/FVC</td>
<td>53.94(32.24-70)</td>
<td>51.12(32.47-69.60)</td>
<td>-1.269</td>
<td>0.20</td>
</tr>
</tbody>
</table>

*Study Group: Home-based Pulmonary Rehabilitation group. Control Group: Hospital-based Pulmonary Rehabilitation group. BMI: Body Mass Index, 6MWD: 6 Minute Walking Distance, mMRC: modified Medical Research Council dyspnoea score, CAT: COPD Assessment test, FVC: Forced Vital Capacity, FEV₁: Forced Expiration Volume in one second. *Man Whitney U test. p<0.05. Data are expressed as median (min-max) or %.
Table 2: Comparison of PR efficacy in terms of exercise capacity, dyspnoea and disease control level between two groups

| Variables | Study Group | | | | Control Group | | | | | | Difference analysis between groups | | |
|-----------|-------------|--------|---------|--------|-------------|--------|---------|--------|---------|-----------------|--------|---------|
|           | n=21        | Before PR | After PR | z     | p*      | Before PR | After PR | z     | p*      | ∆Grup1          | ∆Grup2 | z        | p**   |
| 6MWD(m)   | 337(133-464)| 382(171-589) | -       | 2.364 | 0.01   | 388(228-489) | 455(268-550) | -     | 4.130 | p<0.0001 | 44.19(-87-138) | 66.56(-28-192) | -       | 0.717 | 0.47  |
| mMRC(0-4) | 2.71(1-4)   | 1.95(0-4)   | -       | 2.344 | 0.01   | 2.48(1-4)   | 1.48(0-4)   | -     | 3.898 | p<0.0001 | 0.76(-2-3)     | 1.48(0-4)    | -       | 1.053 | 0.29  |
| CAT       | 21.52(4-36) | 14.85(3-27) | -       | 3.475 | 0.001  | 17(2-30)    | 11.52(1-27) | -     | 4.240 | p<0.0001 | 6.66(-4-23)    | 5.48(-1-14)  | -       | 0.299 | 0.76  |

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Study Group: Home-based Pulmonary Rehabilitation group. Control Group: Hospital-based Pulmonary Rehabilitation group. PR: Pulmonary Rehabilitation, 6MWD: 6 Minute Walking Distance, mMRC: modified Medical Research Council dyspnoea score, CAT: COPD Assesment test. *Wilcoxon rank test,**Man Whitney U test. p<0.05. Data are expressed as median (min-max). Results are shown as change between postpulmonary rehabilitation and baseline levels.

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Stage 3-4 COPD Patients (n=72)

- Study Group (Homebased PR)
  - Prospective cohort (n=35)
    - Excluded (n=14)
      - Discontinued intervention (n=10)
      - Lost to follow-up (n=4)
    - Analysed (n=21)

- Control Group (Hospital-based PR)
  - Retrospective cohort (n=37)
    - Excluded (n=12)
      - Comorbidities (n=4)
      - Transfer problems (n=5)
      - Compliance problems (n=3)
    - Analysed (n=25)

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