Original Article

Pulmonary rehabilitation improves only some domains of health-related quality of life measured by the Short Form-36 questionnaire

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Submission: 18-02-2014
Accepted: 12-04-2014

Abstract:

BACKGROUND: Pulmonary rehabilitation (PR) has inconsistent effects on health-related quality of life (HRQL) in patients with chronic lung diseases. We evaluated the effect of PR on HRQL outcomes using the 36-item short form of the medical outcomes (SF-36).

METHODS: We retrospectively reviewed the files of all patients who completed PR in 2010, 2011, and first half of 2012. We collected information on demographics, symptoms, pulmonary function tests, 6-minute walk tests (6-MWT), and responses on the SF-36 survey, including the physical component score (PCS) and mental component score (MCS).

RESULTS: The study included 19 women and 22 men. The mean age was 69.8 ± 8.5 years. The diagnoses included chronic obstructive pulmonary disease (COPD; $n = 31$), asthma ($n = 3$), interstitial lung disease ($n = 5$), and obstructive sleep apnea (OSA; $n = 2$). The mean forced expiratory volume-one second (FEV1) was 1.16 ± 0.52 L (against 60.5 ± 15.9% of predicted value). There was a significant improvement in 6-MWT ($P < 0.0001$). The PCS improved post-PR from 33.8 to 34.5 ($P = 0.02$); the MCS did not change.

CONCLUSION: These patients had low SF-36 scores compared to the general population; changes in scores after PR were low. These patients may need frequent HRQL assessment during rehabilitation, and PR programs should consider program modification in patients with small changes in mental health.

Key words:

Health-related quality of life, pulmonary rehabilitation, Short Form-36, SF-36

Access this article online
Quick Response Code:
Website: www.thoracicmedicine.org
DOI: 10.4103/1817-1737.134068

Recent evidence-based guidelines recommend pulmonary rehabilitation (PR) for patients with chronic obstructive pulmonary disease (COPD) and other chronic lung diseases.[1,2] Health-related quality of life (HRQL) improves after PR in COPD patients in some but not all studies.[3] For example, Bailey and coworkers reported that PR increased six-minute walk distance (6-MWT) and scores on the short form-36 (SF-36) subscales but that there was no correlation between changes in the walk distance and scores on the subscales. In addition, the magnitude of changes in the 6-MWT was much greater than the changes on the scores on the SF-36 subscales.[4] The SF-36 is a self-administered questionnaire with 36 questions. It provides an 8-scale profile of functional health and well-being scores and a psychometrically based physical and mental health summary measures and is designed to assess quality of life in physical, mental, emotional, pain, and functional domains.[5,6] The constructs measured are not specific to any age, treatment, or disease group. This allows comparisons among diseases and treatments and allows individual patient assessment with comparisons to expected normal values and/or with comparison to baseline scores during longitudinal care and treatment.[7,8] We wanted to evaluate the effect of PR on HRQL using the SF-36 survey. In particular, we were interested in whether the composite scores improved and whether certain subscales of the SF-36 questionnaire improved.

Methods

Study design and study population

We retrospectively reviewed the rehabilitation files of 119 patients who completed pulmonary rehabilitation in 2010, 2011, and first half of 2012 at University Medical Center in Lubbock, TX. We enrolled patients who were older than 18 years old and who completed both an SF-36 survey and a 6-MWT before and after the completion of PR. We excluded patients who did not have both results or who stayed in PR fewer than eight weeks. We collected information on demographics, symptoms, and pulmonary function tests. The dyspnea index was taken from the "Guidelines for Pulmonary rehabilitation".[9] This index has 14 questions about dyspnea in routine situations ranging from "at rest" to "walking up a hill" with responses ranging from 1 (minimal) to 4 (unable to do). The 6-MWT and a SF-36 questionnaire were recorded before and after completion of the PR program. The SF-36 has eight subscales and two component scores (physical component score (PCS) and the mental component scores (MCS)). The SF-36 questionnaires were completed during the initial evaluation of patients before they started rehabilitation and during the last week of rehabilitation in a final assessment. The Institutional Review Board at Texas Tech University Health Sciences Center, Lubbock, TX, approved the study.

Pulmonary rehabilitation program

Each patient in PR participated in a customized comprehensive rehabilitation program. Patients attended two to three times per week, wherein each session lasted 30–60 minutes, and patients completed 36 sessions in total. Each patient received education about his/her disease and its management and exercise instruction. Patients participated in supervised exercise on treadmills, arm ergometers, recumbent stair steppers, and stationary bicycles during each session. Dyspnea, heart rate and O_2 saturation of the patients were monitored during each exercise session. Time and workload on each machine were increased as tolerated to a goal of 10 to 15 minutes on each exercise machine. Patients were emphasized on aerobic training. Patients also had lightweight training for the upper body during each session. Patients on chronic oxygen received supplemental oxygen during exercise. The medical director for the pulmonary rehabilitation program reviewed the progress of the patients every month. Patients were encouraged to participate in a low cost maintenance program after they completed their rehabilitation.

Statistical analysis

Descriptive statistics were used to describe the study population with means, standard deviations, and inter-quartile ranges. The primary analysis considered the effect of rehabilitation on the 6-MWT and on the PCS and MCS. The secondary analysis considered the effect of rehabilitation on the SF-36 subscales. We used the paired-sample *t*-tests to determine which factors significantly improved the patient after complete PR. Pearson's correlation was used to determine the correlation of SF-36 pre- and post-rehabilitation. The cohort was stratified by gender, age, dyspnea score, forced expiratory volume-one second (FEV1), walk distance, and change in walk distance to compare pre- and post-PR changes in SF-36 subscales, PCS, and MCS. Effect size was calculated by dividing the difference in pre-PR and post-PR values on subscales, PCS and MCS by the standard deviation of the pre-PR value or by a standard deviation calculated from a pooled variance from the pre-and post-PR values. Statistical analysis was performed using Statistical Package for the Social Sciences software (SPSS version 16.0). *P*-values <0.05 were consider statistically significant. A Bonferroni correction was used when there were multiple comparisons in the subscale analysis.

Results

We reviewed pulmonary rehabilitation files of 119 patients who completed a PR program from 1st January 2010 to 30th June 2012. After reviewing the chart, 78 patients were excluded from the study due to incomplete SF-36 data, and 41 patients were included in the study. The excluded patients did not differ from the included patients in age, percent with COPD, mean FEV_1, or mean 6-MWT ($P > 0.05$ for all comparisons). The characteristics of the 41 patients who completed rehabilitation and had two SF-36 results are reported in Table 1. The mean age of study patients was 69.8 ± 8.5 years. The patients had 1.05 ± 1.0 comorbidities (range 0-4) other than chronic lung disease. The baseline body mass index (BMI) was 28.1 ± 9.6 kg/m^2. The average FEV1 was 1.16 ± 0.52 L (against 42.4 ± 19.4% of predicted value). Most patients (85.4%) were on chronic oxygen therapy. Most of the patients had COPD (31of 41 cases); other patient had interstitial lung disease with restrictive ventilatory defects (*n*-5), asthma (*n*-3), and obstructive sleep apnea (*n*-2).

Our patients participated in the PR program for 21.8 ± 8.3 weeks; this time included the absences for acute illness and other unavoidable personal responsibilities. The 6-MWT increased after PR (728.1 ± 283.8 feet pre-PR *vs*. 925.6 ± 341.5 feet post-PR, $P < 0.001$ by paired *t*-tests). The gait speed increased from 138.8 ± 55.6 feet/minute pre-PR to 160.7 ± 76.8 post-PR ($P < 0.001$ by paired *t*-tests). The correlation between the initial and final SF-36 was 0.97 ($P < 0.001$). There was a significant correlation between the baseline dyspnea index and SF-36 summary scores before and after rehabilitation (r = −0.51 for the baseline SF-36, $P < 0.001$; r = −0.49 for post-rehabilitation SF-36, $P < 0.001$). SF-36 composite and subscale scores are reported in Table 2. The effect sizes ranged from 0.06 (no effect) to 0.53 (moderate effect) using a pooled variance to calculate the standard deviation and from 0.1 (no effect) to 1.16 (large) using the baseline standard deviation for the calculation.

There were statistically significant improvements in PCS score (33.8 ± 0.6 pre-PR *vs*. 34.5 ± 0.5 post-PR, $P = 0.02$) and in role-physical score (30.0 ± 1.4 pre-PR *vs*. 31.5 ± 1.4 post-PR, $P = 0.005$). The mean change in PCS was 0.63 ± 1.70 with a median of 0.60 and an inter-quartile range of −3.50 to 7.00. The mean change in MCS was −0.26 ± 1.94 with a median of −0.50 and an interquartile range of −4.4 to 4.5. Patients with

Table 1: Baseline and demographic data of study population

Variable	Result
Age (years)	69.8±8.5
Sex	
Male	22
Female	19
BMI (kg/m^2)	28.1±9.6
FEV1	1.16±0.52 L (42.4±19.4%)
6-minute walk test (feet)	
Pre-PR	728.1±283.8
Gait speed (feet/minute)	138.8±35.8
Dyspnea index	24±1.6
Diagnosis	
COPD	31
Restrictive lung disease	5
Asthma	3
OSA	2
Duration of PR (weeks)	21.8±8.3

n = 41, Summary variables are presented as mean ± SD for quantitative variables and as counts (%) for discrete variables, PR-pulmonary rehabilitation an FEV1 > 58% of predicted (median value), a dyspnea score greater than 22 (median value), a walk distance <800 feet (median value), and an increase in walk distance of 150 feet (median value, an approximation of the minimal clinically important difference) had a significant increase in PCS [Table 3]. Walk distance and gait speed increased in all subgroups, except in patients with higher dyspnea scores (≥22).

Discussion

Forty-one patients completed PR and had a valid SF-36 survey results pre and post-PR. These patients had a mean age of 69.8 years, a mean FEV1 of 1.16 L (42% of predicted value), a mean 6-MWT of 728 feet, and at least one comorbidity. They had a significant increase in walk distance after PR. Their baseline scores on the SF-36 subscales were all low compared with the expected population-based values. The PCS improved post-PR; the MCS did not improve. Thus, PR has more effect on aerobic fitness, involved in walking and physical symptoms than on mental/emotional symptoms.

The absolute changes in the PCS and other subscale scores were small (<5) and possibly do not represent clinically important differences. However, the effect size for the PCS, MCS, and the SF-36 subscales ranged from none till large. This makes the interpretation of changes in the SF-36 results difficult. The use and interpretation of this generic HRQL survey could be based on patient assessment, expert opinion, distributional calculations, and/or clinical anchors to determine important changes with an intervention.[10,11] The best approach might involve clinical anchors (for example, a decreased number of COPD flares) with an expectation that the change exceeds the normal variability in the test. That information is not available for pulmonary disease patients and rehabilitation; and consequently, we need longitudinal studies that correlate SF-36 changes with important clinical events. In addition, there was a poor correlation between changes in the 6-MWT and the HRQL, and this increases the complexity of analysis of outcomes with PR and other interventions.

The SF-36 is a generic HRQL questionnaire that has been studied in the patients of COPD and other chronic health conditions.[12] We used this tool in our study because it is self-administered and has good performance characteristics.[13] Benzo reported that PR in COPD patients improved all subscales except role-physical and body pain domains.[14] The changes in PCS and MCS were

Table 2: SF-36 data pre- and post-pulmonary rehabilitation

Factors	Pre-rehabilitation	Post-rehabilitation	*P* - value*	Effect size I	Effect size II
Physical-function	27.1±1.2	28.1±1.0	0.09**	0.41	0.83
Role-physical	30.0±1.4	31.5±1.4	0.005	0.47	1.07
Body pain	44.6±1.9	44.8±1.6	0.78	0.06	0.11
General health	35.6±1.5	37.1±1.3	0.06	0.47	0.93
Vitality	39.3±1.7	40.3±1.5	0.05**	0.29	0.58
Social-functioning	38.9±1.9	39.1±1.7	0.77	0.06	0.1
Role-emotional	39.9±2.1	38.7±1.8	0.13	0.29	0.63
Mental health	46.5±1.9	46.7±1.5	0.86	0.06	0.11
PCS+	33.8±0.6	34.5±0.5	0.02**	0.53	1.16
MCS++	37.7±0.9	37.4±0.7	0.39	0.18	0.33
6-MWT-gait speed (feet/minute)	138.8±55.6	160.7±76.8	<0.001	0.16	0.39
6-MWT-distance (feet)	728.1±283.8	925.6±341.5	<0.001	0.3	0.7

Summary variables are presented as mean ± SD, *paired t-test, **not significant after the Bonferroni correction, Effect size I- calculated with a pooled variance to determine the SD, Effect size II- calculated with the pre-PR baseline SD + PCS = Physical component score, ++MCS = Mental component score

Table 3: Patient characteristics and changes in PCS after PR

Factor	Pre-PR		Post-PR		*P*-Value*	Effect size**
Gender	Male	Female	Male	Female	M=0.12	M=0.75
	33.8±0.8	33.9±0.8	34.4±0.6	34.5±0.7	F=0.09	F=0.75
Age (years)	≤70	>70	≤70	>70	≤70=0.09	≤70=1.10
	33.7±0.7	33.9±0.9	34.5±0.6	34.4±0.7	>70=0.11	>70=0.55
Dyspnea score	<22	≥22	<22	≥22	<22=0.33	<22=0.38
	34.6±0.8	33.1±0.7	34.9±0.7	34.0±0.6	≥22=0.03	≥22=1.29
FEV1, % predicted	≤58	>58	≤58	>58	≤58=0.21	≤58=0.5
	34.1±0.8	33.4±0.8	34.5±0.8	34.3±0.6	>58=0.05	>58=1.13
6-MWT	≤800	>800	≤800	>800	≤800=0.02	≤800=1.0
(feet)	33.2±0.7	34.9±1	33.9±0.6	35.5±0.8	>800=0.3	>800=0.6
Δ 6-MWT	<150	≥150	<150	≥150	<150=0.57	<150=0.25
(feet)	33.9±0.8	33.8±0.8	34.1±0.6	34.9±0.7	≥150=0.02	≥150=1.38

Patient groups were split at the median value for age, dyspnea, FEV1, 6-MWT, and change in 6-MWT, The PCS values for each subgroup were compared before and after PR, Median values: Age = 70 years, dyspnea score = 22, FEV1 (% predicted) = 58 %, 6-MWT = 800 feet, Change in 6-MWT post rehab = 150 feet, Abbreviations: 6-MWT = 6-minute walk test, PCS = Physical component score **Effect size calculated with the baseline standard deviation (see methods), **P*-values significant at the conventional level (≤ 0.05) in this table are not significant after correction for multiple comparisons small in this study. Boueri reported significant improvement in physical function, vitality, emotional role, mental health, and health change following PR in COPD patients.[7] Bailey reported that 6-MWT and most subscales on the SF-36 improved post-PR but there was no correlation between the change in the 6-MWT and the change in SF-36 scales.[4] Leupoldt reported that improvement in PCS and MCS correlated best with reductions in dyspnea.[15] These studies demonstrate that SF-36 scores are consistently low in COPD patients and do not demonstrate a consistent change in subscales following rehabilitation. This could reflect differences in study populations and/or rehabilitation programs. In addition, the SF-36 is a generic HRQL instrument that may not be as useful in COPD patients as other survey instruments might be.

Our patients did not have any change on their MCS scores. The lack of a more robust effect of PR on the mental health domains in this particular HRQL survey could be attributed to the following considerations. First, the simplest explanation might involve the possibility that PR largely improves physical fitness and has less effect on mental health. Then our expectation of SF-36 to improve significantly is misplaced. Second, the SF-36 may not be the best instrument for evaluating COPD patients. Buss and Silva have concluded that a disease-specific instrument St. George's respiratory questionnaire (SGRQ) has better discriminative properties than the SF-36.[16] Wilke noted that the SGRQ correlated with the SF-36 PCS at particular time points during a longitudinal study but that the changes overtime correlated poorly.[17] Third, COPD is a chronic disease with both respiratory and systemic effects complicated by acute exacerbations. It is possible that these patients slowly adjust to poor health and that their perception of their overall health changes very slowly following any intervention. Finally, patient responses during longitudinal studies may change because of changes in priorities and changes in their understanding of their medical problems during interventions. In addition, recollection of responses on the initial survey could influence the responses on follow-up surveys. Future studies on PR should use serial HRQL surveys to determine the time course for changes in these parameters. It is possible that patients will improve with exercise tolerance, but no change in HRQL need a change in their rehabilitation program. For example, these patients may need a more directed assessment of comorbidity, medication use, and psychiatric disorders.

The limitations in our study include the retrospective collection of information and the relatively small study population. We included all patients who met the inclusion criteria and did not restrict the study population to COPD patients. We did not use a disease -pecific questionnaire, such as the SGRO, but did use a comprehensive symptom scale for dyspnea and found a good correlation between dyspnea and SF-36 summary scores. The PR program used in this center may differ from other programs, and its results might differ from other programs.

Conclusion

In summary, this study demonstrates that patients with chronic lung disease have low scores on the SF-36 composite scales. The PR increases the 6-MWT and the SF-36 PCS. These results suggest that PR need to add more components to address mental health and outcome studies that need to address differences among patients with improvement in mental health and no improvement in mental health. However, limitations in time and personnel resources make this difficult. Some patients might benefit from a self-directed mental health projects using workbooks. Physicians should remember that changes in complex chronic diseases following any intervention are not necessarily uniform and generic health indices may identify problems not detected by disease-specific questionnaires.

Acknowledgments

We thank Lori Stroud, who supervises the pulmonary rehabilitation program at University medical Center, for her assistance with this project.

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How to cite this article: Limsuwat C, McClellan R, Amiri HM, Nugent K. Pulmonary rehabilitation improves only some domains of health-related quality of life measured by the Short Form-36 questionnaire. Ann Thorac Med 2014;9:144-8.

Source of Support: Nil, **Conflict of Interest:** None declared.