The Impact of Exercise-Based Pulmonary Rehabilitation on Functional Capacity in Patients with Interstitial Lung Disease: A Randomized Controlled Trial

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Abstract

Objective: This randomized controlled trial aimed to evaluate the impact of exercise-based pulmonary rehabilitation on functional capacity in patients with interstitial lung disease (ILD).

Methods: A total of 100 patients with ILD were randomized into an intervention group (n=50) receiving a 12-week exercise-based pulmonary rehabilitation program or a control group (n=50) receiving usual care. Primary outcomes included the 6-minute walk test (6MWT) distance. Secondary outcomes included quality of life (SGRQ) and dyspnea severity (mMRC).

Results: The intervention group showed significant improvements in 6MWT distance $(370 \pm 55 \text{ meters vs.} 325 \pm 50 \text{ meters}, p < 0.01)$, SGRQ scores (48.2 $\pm 10.6 \text{ vs.} 58.0 \pm 13.0, p < 0.01)$, and mMRC dyspnea scores (1.7 $\pm 0.7 \text{ vs.} 2.6 \pm 1.0, p < 0.01$) compared to the control group. These improvements were sustained over 12 weeks.

Conclusion: Exercise-based pulmonary rehabilitation significantly enhances functional capacity, quality of life, and reduces dyspnea in patients with ILD. These findings support incorporating structured exercise programs into standard ILD management.

Keywords: Interstitial Lung Disease, Pulmonary Rehabilitation, Exercise Therapy, Functional Capacity, Quality of Life, Dyspnea, Randomized Controlled Trial

Introduction

Interstitial lung disease (ILD) is a group of disorders characterized by inflammation and scarring of the lung tissue, which can lead to progressive impairment in lung function and reduced quality of life. ILD encompasses various conditions, including idiopathic pulmonary fibrosis, nonspecific interstitial pneumonia, and others, each affecting the lungs' ability to oxygenate blood effectively (Antoniou et al., 2014). The disease is associated with significant morbidity and mortality, and current therapeutic options mainly focus on managing symptoms and slowing disease progression (Carlos et al., 2016).

Pulmonary rehabilitation has emerged as an effective non-pharmacological intervention for patients with chronic respiratory diseases, including chronic obstructive pulmonary disease (COPD) and asthma. It typically involves exercise training, education, and behavioral modification aimed at improving physical function and overall well-being (Basara et al., 2014). For patients with ILD, exercise-based pulmonary rehabilitation may offer substantial benefits by enhancing physical capacity and potentially improving respiratory symptoms and quality of life (Nishiyama et al., 2008).

Recent studies have demonstrated that exercise-based pulmonary rehabilitation can positively impact functional capacity and exercise tolerance in patients with chronic respiratory conditions. For example, a meta-analysis of pulmonary rehabilitation for COPD patients reported significant improvements in exercise

capacity, measured by the 6-minute walk test (6MWT), and quality of life. However, evidence supporting the effectiveness of similar interventions specifically for ILD patients remains limited (Ryerson et al., 2010).

A randomized controlled trial (RCT) is necessary to establish the efficacy of exercise-based pulmonary rehabilitation in this patient population. Such a study could provide robust data on the impact of this intervention on functional capacity and other relevant outcomes, thereby guiding clinical practice and potentially improving patient management strategies.

Literature Review

Interstitial Lung Disease and Functional Impairment: Interstitial lung disease (ILD) comprises a broad range of lung disorders characterized by diffuse inflammation and fibrosis of the interstitium, leading to progressive lung function decline (Antoniou et al., 2014). Patients with ILD often experience significant reductions in functional capacity, as measured by the 6-minute walk test (6MWT), a common assessment for exercise tolerance and functional status (Carlos et al., 2016). The progressive nature of ILD typically results in a deteriorating quality of life and increased disability, underscoring the need for effective management strategies (Pleasants and Tighe, 2019).

Pulmonary Rehabilitation in Respiratory Diseases: Pulmonary rehabilitation (PR) is a multidisciplinary intervention designed to improve the physical and psychological condition of individuals with chronic respiratory diseases. PR programs generally include exercise training, education, and psychosocial support, aiming to enhance exercise capacity, alleviate symptoms, and improve overall quality of life (Basara et al., 2014). The efficacy of PR has been well-documented in conditions such as chronic obstructive pulmonary disease (COPD) and asthma, with numerous studies highlighting significant improvements in functional capacity and quality of life measures (McCarthy et al., 2015).

Exercise-Based Pulmonary Rehabilitation and ILD: The application of exercise-based PR to ILD patients is an area of growing interest. Evidence suggests that exercise training can improve physical function and endurance in individuals with chronic respiratory conditions (Dowman et al., 2017). A study by Langer et al. (Nishiyama et al., 2008) found that a structured exercise program significantly improved 6MWT results in patients with idiopathic pulmonary fibrosis (IPF), a common form of ILD. Similarly, the research conducted by Spielmanns et al. (2016) reported positive effects of a pulmonary rehabilitation program on exercise capacity and dyspnea in patients with ILD.

However, the evidence base for exercise-based PR specifically for ILD remains less robust compared to other respiratory conditions. A systematic review by Ferreira et al. (2009) highlighted that while preliminary studies are promising, there is a need for larger, well-designed randomized controlled trials (RCTs) to validate these findings and establish standardized PR protocols for ILD patients.

Gaps and Future Directions: Despite the promising results from smaller studies, several gaps remain in the current understanding of exercise-based PR for ILD. Most existing studies have small sample sizes and varying methodologies, which limits the generalizability of the results (Holland et al., 2013). Additionally, the optimal exercise regimen, including intensity, duration, and type of exercises, remains unclear (Garvey et al., 2016). Future research should focus on conducting large-scale RCTs to address these gaps, evaluate the long-term effects of exercise-based PR, and identify the most effective components of rehabilitation programs for ILD patients.

Methodology

Study Design: This study was a randomized controlled trial (RCT) designed to evaluate the impact of exercise-based pulmonary rehabilitation on functional capacity in patients with interstitial lung disease (ILD). The trial was conducted at a tertiary hospital and adhered to the CONSORT guidelines for reporting RCTs.

Participants

- **Inclusion Criteria:** Patients aged 40-80 years diagnosed with ILD based on clinical, radiographic, and histopathological criteria. Participants needed to have a 6-minute walk test (6MWT) distance of less than 400 meters and stable disease for at least 6 months prior to enrollment.
- **Exclusion Criteria:** Patients with other significant chronic illnesses, recent exacerbations, or contraindications to exercise were excluded.

A total of 100 patients were recruited and randomly assigned to either the intervention group (n=50) or the control group (n=50) using a computer-generated randomization list.

Intervention

Exercise-Based Pulmonary Rehabilitation Program: The intervention group participated in a structured pulmonary rehabilitation program for 12 weeks. The program included:

- Aerobic Training: Supervised sessions of moderate-intensity walking or cycling for 30 minutes, three times a week.
- **Strength Training:** Resistance exercises targeting major muscle groups, performed twice a week.
- **Education:** Weekly educational sessions focusing on disease management, breathing techniques, and lifestyle modifications.

Sessions were conducted by certified pulmonary rehabilitation specialists and included pre- and post-exercise assessments.

Control Group: Participants in the control group received usual care, which included standard medical management and recommendations for physical activity. They were not provided with structured exercise or educational sessions during the study period.

Outcome Measures

Primary Outcome: Functional capacity was assessed using the 6-minute walk test (6MWT) at baseline, 6 weeks, and 12 weeks. The 6MWT measures the distance walked in six minutes and is a reliable indicator of exercise capacity and overall functional status.

Secondary Outcomes:

- **Quality of Life:** Evaluated using the St. George's Respiratory Questionnaire (SGRQ) to assess respiratory symptoms and quality of life.
- **Dyspnea Severity:** Measured using the Modified Medical Research Council (mMRC) dyspnea scale.
- **Exercise Tolerance:** Assessed by the Incremental Shuttle Walk Test (ISWT) at baseline and at the end of the intervention.

Data Collection

Data were collected at baseline, 6 weeks, and 12 weeks. Assessments were conducted by trained research personnel blinded to group allocation. All participants completed a comprehensive questionnaire on demographics, disease history, and medication use at the start of the study.

Statistical Analysis

Data were analyzed using Statistical Package for the Social Sciences (SPSS) version. Descriptive statistics were used to summarize participant characteristics. Between-group differences in the 6MWT and secondary outcomes were analyzed using independent t-tests for continuous variables and chi-square tests for categorical variables. Changes within groups over time were evaluated using paired t-tests. A p-value of <0.05 was considered statistically significant.

Ethical Considerations

The study was approved by the ethics committee. Informed consent was obtained from all participants prior to enrollment.

Findings

Participant Characteristics: A total of 100 patients with interstitial lung disease (ILD) were randomized into the intervention (n=50) and control groups (n=50). Table 1 summarizes the baseline characteristics of the participants in both groups.

Table 1: Baseline Characteristics of Participants					
Characteristic	Intervention Group	Control Group (n=50)	p-value		
	(n=50)				
Age (years)	62.4 ±8.1	61.9 ±7.9	0.74		
Gender	30/20	28/22	0.68		
(Male/Female)					
Duration of ILD	5.2 ±3.4	4.9 ±3.2	0.62		
(years)					
Baseline 6MWT	320 ±45	315 ±47	0.65		
Distance (meters					
Baseline SGRQ Score	58.3 ±12.4	59.1 ±13.1	0.73		
Baseline mMRC	2.3 ±0.9	2.5 ±1.0	0.46		
Dyspnea Score					
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Table 1: Baseline Characteristics of Participants

Primary Outcome: 6-Minute Walk Test (6MWT): Table 2 presents the changes in 6MWT distance from baseline to 12 weeks for both groups.

Table 2. Changes in ONTW T Distance					
Time Point	Intervention Group	Control Group (n=50)	p-value		
	(n=50)				
Baseline (meters)	320 ±45	315 ±47	-		
6 Weeks (meters)	350 ±50	320 ±48	< 0.01		
12 Weeks (meters)	370 ±55	325 ±50	< 0.01		

Table 2: Changes in 6MWT Distance

The intervention group showed significant improvements in 6MWT distance at both 6 and 12 weeks compared to the control group (p < 0.01).

Secondary Outcomes

Quality of Life (SGRQ Score): Table 3 shows the changes in quality of life scores as measured by the St. George's Respiratory Questionnaire (SGRQ).

Table 3: Changes in SGRQ Score					
Time Point	Intervention Grou	p Control Group (n=50)	p-value		
	(n=50)				
Baseline	58.3 ±12.4	59.1 ±13.1	-		
6 Weeks	52.7 ±11.2	57.8 ±12.4	0.03		
12 Weeks	48.2 ±10.6	58.0 ±13.0	<0.01		

Table 3: Changes in SGRQ Score

Significant improvements in SGRQ scores were observed in the intervention group, indicating better quality of life compared to the control group at 6 and 12 weeks (p < 0.05).

Dyspnea Severity (mMRC Score): Table 4 presents the changes in dyspnea severity as measured by the Modified Medical Research Council (mMRC) dyspnea scale.

Table 4. Changes in invike Dyspilea Score				
Time Point	Intervention Group	Control Group (n=50)	p-value	
	(n=50)			
Baseline	2.3 ±0.9	2.5 ±1.0	-	
6 Weeks	1.9 ±0.8	2.4 ±0.9	0.02	
12 Weeks	1.7 ±0.7	2.6 ±1.0	< 0.01	

Table 4: Changes in mMRC Dyspnea Score

The intervention group experienced a greater reduction in dyspnea severity compared to the control group, with significant differences at both 6 and 12 weeks (p < 0.05).

Discussion

Main Findings: This randomized controlled trial investigated the impact of exercise-based pulmonary rehabilitation on functional capacity in patients with interstitial lung disease (ILD). Our findings indicate that the structured exercise program significantly improved key outcomes, including the 6-minute walk test (6MWT) distance, quality of life as measured by the St. George's Respiratory Questionnaire (SGRQ), and dyspnea severity assessed by the Modified Medical Research Council (mMRC) dyspnea scale. Patients in the intervention group demonstrated notable improvements in 6MWT distance, with an increase of 50 meters by 12 weeks, compared to only 10 meters in the control group. This enhancement in exercise capacity underscores the effectiveness of the exercise-based program in improving functional status and endurance in ILD patients. Additionally, the significant reduction in SGRQ scores and mMRC dyspnea scores among the intervention group reflects an improved quality of life and reduced breathlessness, aligning with findings from previous studies on pulmonary rehabilitation in chronic respiratory diseases (Gloeckl et al., 2018; McCarthy et al., 2015).

Comparison with Existing Literature: Our results are consistent with previous research highlighting the benefits of pulmonary rehabilitation in respiratory conditions. For instance, a study by Dowman et al. (2017) demonstrated that exercise training improved exercise capacity and quality of life in patients with idiopathic pulmonary fibrosis (IPF), a common form of ILD. Similarly, the review by Spielmanns et al. (2016) reported that pulmonary rehabilitation could positively impact functional outcomes and dyspnea in patients with various forms of ILD. However, our study adds to this body of knowledge by providing robust evidence from a well-designed RCT and including a larger sample size, thus enhancing the generalizability of the findings. Despite the promising results, it is important to note that the magnitude of improvement in functional capacity and quality of life in ILD patients may vary depending on individual characteristics and disease severity. The current study's sample predominantly included patients with moderate ILD, which may limit the applicability of the findings to those with more advanced disease or other types of ILD.

Implications for Clinical Practice: The positive outcomes observed in this study support the integration of exercise-based pulmonary rehabilitation into the management plan for ILD patients. The improvements in exercise capacity, quality of life, and dyspnea suggest that such programs can be a valuable adjunct to conventional treatments, offering a non-pharmacological approach to enhance patient well-being and functionality. Clinicians should consider recommending structured exercise programs as part of a comprehensive treatment strategy for ILD patients, especially those who are stable enough to participate.

Limitations and Future Research

While the study provides valuable insights, there are several limitations to consider. The study was conducted at a single institution, which may affect the generalizability of the results. Additionally, the adherence to the exercise program varied among participants, which could influence the outcomes. Future research should focus on multicenter trials to confirm these findings and explore the optimal components of pulmonary rehabilitation programs for ILD. Investigating the long-term effects of exercise-based rehabilitation and its impact on disease progression and survival would also be beneficial.

Conclusion

In conclusion, exercise-based pulmonary rehabilitation is an effective intervention for improving functional capacity and quality of life in patients with ILD. Our study provides strong evidence supporting the implementation of structured exercise programs in the management of ILD, highlighting their potential to enhance patient outcomes and overall well-being.

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