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Perceived Improvements of Quality of Life (QoL) among Patients with Idiopathic Pulmonary Fibrosis (IPF) in Response to a 6-Week Rehabilitation Program

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Abstract

Idiopathic pulmonary fibrosis (IPF) is a chronic, life-limiting with an average life expectancy of 05 years following the onset of the disease, with no curative treatments. These patients need palliative care and rehabilitation is one of the methods that can be used to improve quality of life (QoL) among these patients. Yet the research conducted to assess benefits of pulmonary rehabilitation (PR) in terms of improving physical activity and QoL in IPF patients remains limited. Hence this study aims to evaluate the effect of a bespoke pulmonary rehabilitation programme, on the physical, physiological and psychological parameters and improvements of QoL among IPF patients. Eleven (11) subjects with IPF received 6 weeks of pulmonary rehabilitation. An interviewer administered quality of life questionnaire, six-minute walking test (6MWT), Incremental bicycle exercise tests were performed, and cardiac and respiratory parameters were assessed pre- and post-rehabilitation. The 6MWT was significantly increased following training (Pre 312.55 ± 89.99; Post, 380.73 ± 59.60). A significant improvement was observed in overall QoL (2.226 ± 0.026), dyspnoea (−0.455 ± 0.004) anxiety (−2.070 ± 0.038), depression (−2.217 ± 0.027) scores. No significant changes were found in the VO_2 max and other cardiopulmonary parameters, while non-significant improvement was seen in SpO_2 at peak exercise from 85.8 - 86.5. Bespoke pulmonary

rehabilitation program is beneficial in short term improvement of the functional exercise capacity, dyspnoea and QoL among IPF patients.

Keywords

IPF, 6MWT, Pulmonary Rehabilitation, QoL, Oxygen Uptake, VO_2

1. Introduction

Idiopathic Pulmonary Fibrosis (IPF) is a chronic, progressive, and life-threatening condition of unknown cause and the commonest of the Idiopathic Interstitial Pneumonia. In the UK, IPF has an annual incidence of approximately 4.6 per 10,000 and is increasing by 5% per annum [1].

The histological pattern of IPF is characterised by the deposition of excess collagen and other molecules of the extracellular matrix within the alveolar interstitium, together with a modest inflammatory cell infiltrate [2]. This pathological process results in a gradual loss of functioning alveolar units and a decline in pulmonary function. Consequently, people with IPF develop progressive breathlessness and eventually die from respiratory failure. Whilst new therapies which slow the decline in lung function have recently become available, there is still no cure for IPF which has a median survival of three years although the range is wide; some patients follow a slowly declining trajectory over many years whilst others may have a rapidly progressive course [3]. The majority of patients will therefore require supportive care at some point in the course of their disease and national guidelines recommend that oxygen therapy, pulmonary rehabilitation and palliative care should be offered when appropriate [4].

Pulmonary rehabilitation (PR) programmes are of proven value in the management of patients with Chronic Obstructive Pulmonary Disorder (COPD) in whom they improve exercise performance and quality of life (QoL) [5]. However, the benefit of such programmes in terms of improving exercise performance and QoL in people with IPF is less clear. Hence the aim of this study was to evaluate the effects of a PR programme by evaluating physical and physiological parameters and preserved QoL following rehabilitation. Specifically, we evaluated the six-minute walk test (6 MWT), Physiological parameters pertaining to Cardiovascular (heart rate, Blood pressure, Oxygen saturation) and the Respiratory systems (Maximum oxygen uptake, VO_2 and oxygen saturation) of the body.

1.1. Study Setting

The study assessed a bespoke pulmonary rehabilitation programme for people with IPF, in collaboration with clinical respiratory staff at Morriston Hospital, Swansea, UK. Patients undertaking PR were assessed before and after the completion of the programme, with quantification of cardiac and respiratory variables as markers of physiological function. Quality of life assessments was also

performed at the same time points via interviewer administered questionnaire. The following research questions will be addressed:

1.2. Amis and Objectives

1) Is bespoke pulmonary rehabilitation effective at improving physical function in people with IPF?

2) What is the effect of pulmonary rehabilitation on the 6 MWT.

3) How does pulmonary rehabilitation influence cardiac and respiratory physiology in people with IPF?

4) Does bespoke pulmonary rehabilitation result in improved quality of life in these patients?

2. Methods

2.1. Study Population

Ethical approval was taken from A-STEM research group, Faculty of Engineering, Swansea University (22.05.2016), followed by the approval of South West Wales Research Ethics Committee, UK (11.10.2016). The study was performed in accordance with the Declaration of Helsinki. Patients who were diagnosed with IPF who fulfilled the 2011 American Thoracic Society and European Respiratory Society guidelines for diagnosis [6], attending the respiratory clinic at Moriston Hospital were invited to participate in the study. A clinical assessment was performed on all potential participants, and their medical histories were reviewed.

2.2. Inclusion and Exclusion Criteria

Patients attending the Interstitial Lung Disease Clinic at Moriston Hospital, Swansea, who had been diagnosed with IPF by a Multi-Disciplinary Team, according to the American Thoracic Society (ATS) and European Respiratory Society (ERS) guidelines were eligible to participate. Patients were not eligible to participate if: they had experienced a respiratory infection within the previous two months; had known coronary or valvular heart disease; had any other serious co-morbid condition (e.g. emphysema, uncontrolled diabetes, renal disease); had significant hypoxia (oxygen saturation below 85%) when breathing air and undergoing conventional screening for a pulmonary rehabilitation programme; had musculoskeletal problems that would make it impossible to exercise; were current smokers.

2.3. Experiment Protocol

The Participants were given information about the particulars of the study and the written consent was obtained after answering any question they had on the study. This was followed by registration of the patients for the PR programme. Once the registration was completed, they completed interviewer administered QoL questionnaire immediately before and immediately after the completion of

the rehabilitation programme. The questionnaire consisted of two parts: the European Quality of Life—5 Dimensions (EQ5D) questionnaires developed by the EuroQol Group [7] and the Hospital Anxiety and Depression Score (HADS) [8].

This was followed by a baseline physiological assessment. The participants were asked not to consuming alcohol and caffeine 24 hours and 6 hours respectively before the test. To maintain consistency all tests were conducted on the same time of the day ± 1 hour.

On day one, the participants undertook a 6 MWT to determine their functional (walking) capacity), in line with the ATS guidelines [9]. On the second day, they were asked to complete an incremental bicycle exercise test on a stationary bicycle (ergometer) (VIAsprint™ 150P Ergometer, Vyaire Medical, IL, USA) in accordance with methods described by McNarry *et al*. [10], Arena *et al*. [11] and Senanayake *et al*. [12]. Participants first completed three minutes of warmup, followed by an increased rate of resistance at a rate of 10 - 15 $W \cdot min^{-1}$, depending on the individual's age-predicted maximum workload. They were asked to always maintain a cadence of 55 - 60 rpm and to continue cycling until they reached their limit of exercise tolerance. Throughout the test, patients were asked to breathe through a facemask which continuously sampled the inspired and expired air using a tube flow sensor (MCD Medgraphics Ultima CardiO2; MGC Diagnostics, MN, USA). Breath-by-breath data were analysed using the Breeze software package (Version 6.4.1, Medical Graphics, MN, USA). Aerobic threshold (AT) was identified by using methods used by Castro *et al*. and Senanayake *et al*. [13] [14]. Blood oxygen saturation was continuously monitored (Nonin Model 7500, Plymouth, MN, USA).

2.4. Data Analysis

The One-Sample Kolomogorov-Smirnov Test was used to test the null hypothesis with the assumption that data obeyed a Normal distribution. If this assumption was violated, then the influence of the rehabilitation intervention on each variable was assessed using Wilcoxon Signed Rank tests. One-sample Kolmogorov-Smirnov tests showed that none of the quantified variables were Normally distributed. Statistical significance was assumed at the $p < 0.05$ level.

3. Discussion

This research aimed to determine if bespoke pulmonary rehabilitation programme had any impact on the cardiopulmonary response and its effects on exercise and functional capacity of IPF patients using the 6 MWT as a benchmark. This test evaluates the integrated response of all the systems involved during exercise, especially the pulmonary and the cardiovascular system [9]. The results of our study showed that the level of dyspnoea was reduced while exercise capacity and the QoL of the patients significantly improved after the completion of the rehabilitation programme.

Dyspnoea is identified as a major symptom of IPF which results in difficulties

in conducting the daily physical activity, contributes to exercise intolerance, panic attacks and an overall reduction in QoL [15] Prevention of dyspnoea is considered a key goal in the management of IPF [15]. A similar study conducted by Nishiyama *et al*. and Ozalevli *et al*. [16] [17] demonstrated the possibility of increasing exercise capacity, by lowering dyspnoea perception without changing lung function, leading to an improvement in QoL. This comes in par with the findings of our study which indicated a significant improvement in dyspnoea perception and exercise capacity following the PR programme, where the group average 6 MWT distance improved from 312 meters (pre rehabilitation) to 380 meters (post rehabilitation), while increasing the average group laps from 30 (pre) to 37 (post) laps (**Table 1**). Du Bios *et al*. established a minimal clinical important difference (MCID) for 6 MWD as 24 - 45 m among patients with IPF [18]. The significant improvement found in our study goes above this MCID threshold indicating the clinically meaningful effect of our PR programme (**Figure 1**). These findings are in accord with the studies done by Vainshelboim *et al*. [19], Holland *et al*. [20] and Nishiyama *et al*. [21], where there was an improvement on exercise capacity and a reduction in dyspnoea leading to improved perceived QoL.

A key characteristic of IPF is the impairment of lung tissue due to fibrosis leading to a gradual loss of oxygen uptake leading to a reduction in O_2 saturation (SpO_2). This occurs mainly due to the alveolar ventilation-perfusion mismatching (VA/Q), oxygen diffusion limitations and low mixed venous oxygen content [20]. However, our results showed an increase in SpO_2 at peak exercise from 85.8 - 86.5 (**Table 2**). Although statistically not significant this is an indication of improvement in oxygen uptake and delivery and we predict this will become statistically significant with an increase in the study population. Studies conducted by both Nishiyama *et al*. [21] and Ozalevli *et al*. [17] revealed that PR has no effect on respiratory functions and the gas exchange in IPF. Hence this increase

Table 1. Values for six-minute walk distance (6 MWD) and maximum/minimum ranges for Oxygen saturation (SpO_2), Heart rate and blood pressure before pulmonary rehabilitation (PR) and after PR.

Variable	N	Pre	Post
Weight (kg)	11	88.08 ± 16.41	86.64 ± 15.59
BMI (kg/m^2)	11	30.63 ± 5.11	30.18 ± 4.82
6 Min Walk Test (m)	11	312.55 ± 89.99	380.73 ± 59.60
No. of Laps	11	30.91 ± 8.83	37.91 ± 5.99
SpO_2 (%) Min	11	85.82 ± 5.71	86.55 ± 5.24
Max	11	92.55 ± 3.96	92.10 ± 2.74
Heart Rate (BPM) Min	11	81.55 ± 13.66	88.45 ± 16.92
Max	11	105.18 ± 22.91	118.45 ± 26.18

Values are presented as means ± SD *p < 0.05, **p < 0.01.

Table 2. Cardiopulmonary indices were calculated pre- and post-intervention. Ve; Minute ventilation measured in breaths per minute, VO_2 Max; Maximum volume of uptake of oxygen measured (averaging the highest VO_2 values obtained in the last 10 seconds before the limit of exercise was reached), VO_2/HR; the ratio of volume of oxygen uptake against the heart rate, Ve/VCO_2 Ventilatory equivalent for carbon dioxide and Ve/VO_2; Ventilatory equivalent for oxygen.

Variable	N	Pre	Post
V_E (BPM)	11	63.13 ± 18.69	59.67 ± 18.51
VO_2 Max (ml/kg/min)	11	15.99 ± 4.79	14.80 ± 4.88
VO_2/HR	11	11.45 ± 2.07	10.55 ± 1.57
V_E/VO_2	11	46.00 ± 5.87	47.18 ± 6.77
V_E/VCO_2	11	44.00 ± 4.80	45.27 ± 7.56

Values are presented as means ± SD *p < 0.05, **p < 0.01.

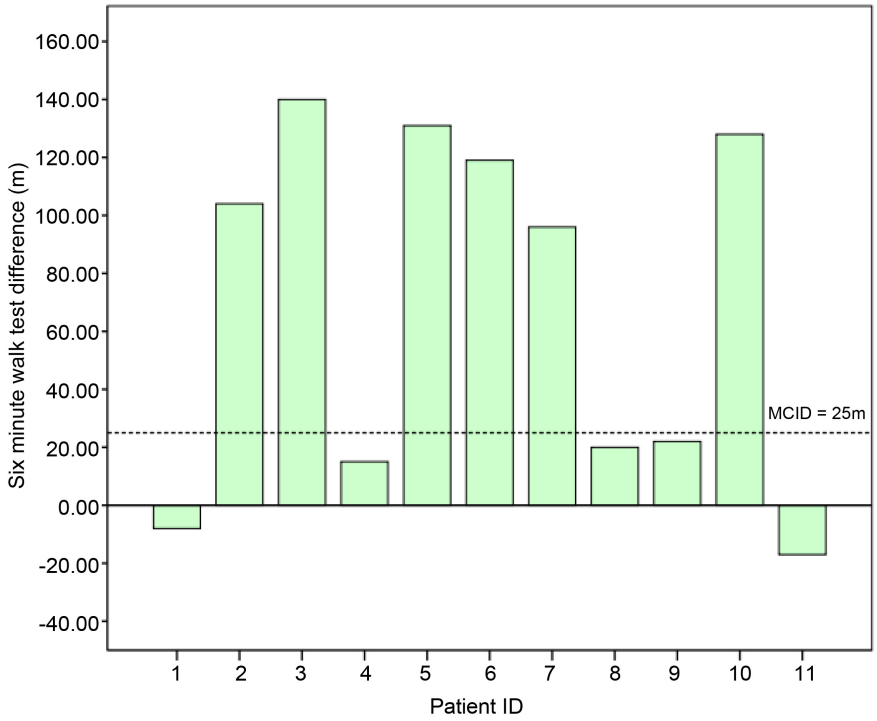

Figure 1. Individual changes 6 MWT after the 6-week pulmonary rehabilitation programme.

seen in our study could be due to improvements in the cardiopulmonary response of these individuals. This is backed by the observations we made in the HR of these individuals following PR, where maximum HR was relatively unchanged (slightly lower in some individual cases) post rehabilitation indicating an improvement in the cardiac function of these patients (**Table 1**). Ozalevli *et al.* [17] suggest that the improvements in the oxygen saturation might be an important functional parameter contributing to the increase in 6 MWT.

As shown in **Table 2**, there were no significant changes in the VO_2 max and other cardiopulmonary parameters post rehabilitation indicating they had no

effect on the improvements in dyspnoea and 6 MWT. Nishiyama *et al*. [22] and Spirit *et al*. [23] also stated that peripheral muscle weakness is a predictive factor in exercise intolerance. Peripheral muscle adaptations due to a reduction in weight and BMI following rehabilitation could be another factor contributing to the improvements in the 6 MWT and increased perceived QoL of these patients.

IPF causes a significant psychological impact on diseased individuals. This ranges from depression, anxiety, Trauma and stigma [24]. Studies conducted by Senanayake *et al*. and Akhtar *et al*. [25] reported that most of the IPF patients exhibit depression and anxiety. Following rehabilitation both the overall HAD depression score and HAD anxiety scores improved greatly (**Table 3**). The same trend is seen in sleep and relaxation scores, contributing to the improved preserved QoL.

Jastrzebski *et al*. [26], Ong *et al*. [27] says, improving the QoL of IPF patients is considered as one of the major goals in IPF management. Significant improvements in Total QoL following rehabilitation were found in our study supporting the evidence of the effectiveness of our programme. Improvements were observed in all the categories of the QoL questioners. Furthermore, non-significant improvements of sleep and relaxation scores were observed in patients individually suggesting that the PR programme has some positive effect on better sleep leading to a better QoL (**Table 4**).

4. Limitations

When considering the results reported here we must be mindful of potential confounders relating to both the IPF patient population and also our study design. Whilst we consider our sample of 15 patients to be representative of people with IPF, one limitation of this study is the relatively small number of participants which reduced the statistical power of our analyses. We excluded patients who had co-morbid conditions that might influence respiratory and cardiac functions. However, we were also mindful of the potential influence of too strict

Table 3. Key results extracted from QoL questioners "EQ5D and HADS" pre- and post-PR, where MRC dyspnoea scale refers to breathlessness.

Variable	N	Pre	Post
MRC dyspnoea scale (0-4)	11	2.91 ± 0.94**	2.45 ± 0.69**
HAD Depression	11	4.09 ± 3.15	3.27 ± 3.10**
HAD Anxiety	11	6.09 ± 3.81	4.45 ± 3.33
QoL Total	8	400.0 ± 103.12	445.0 ± 72.16**
Social activity score	8	80.63 ± 21.78*	89.38 ± 19.72**
Leisure Activity score	8	77.5 ± 22.99	90.0 ± 28.28**
Personal Care	8	85.0 ± 18.32*	90.0 ± 15.12**
Sleep and Relaxation	8	73.75 ± 27.22	85.63 ± 16.35*
Roles and Routine	8	83.13 ± 27.38*	90.0 ± 21.38**

Values are presented as means ± SD *$p < 0.05$, **$p < 0.01$.

Table 4. Differences between the selected parameters before and after six weeks of the PR programme.

	Difference (95% CI)	Statistical Significance
6 Min Walk Test	68.182	0.004
MRC (1-4)	−0.455	0.016
HAD Depression (0-21)	−2.070	0.038
HAD Anxiety (0-21)	−2.217	0.027
QoL Total	2.226	0.026
Social activity score	8.75	0.262
Leisure Activity score	12.50	0.147
Personal Care	5.00	0.155
Sleep and Relaxation	11.88	0.074
Roles and Routine	6.87	0.102
Weight (kg)	−1.400	0.161
BMI kg/m^2	−1.122	0.262
VO_2 Max	−1.735	0.083

a set of exclusion criteria on both recruitment and the applicability of our results to the wider IPF population.

5. Conclusions and Recommendations

The results of our study indicate the bespoke PR program is of benefit in short term improvement of the functional exercise capacity, dyspnoea and QoL among IPF patients. We believe with the increase in the number of participants will result in statistically significant results in other categories of the QoL questioners. Hence, we recommend using this study as a pilot study for a larger study in the future and to measure the sustainability of these improvements with a follow-up.

Conflicts of Interest

The authors declare no conflicts of interest regarding the publication of this paper.

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