Original Article

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TANAFFOS

Role of Visual Biofeedback in COPD Patients on Structured Home-Based Pulmonary Rehabilitation Program: a Double-Blind, Parallel, Randomized Controlled Trial

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Background: Globally, COPD is the most common pulmonary disorder. Although Indoor Pulmonary rehabilitation (PR) programs increase exercise tolerance and improve quality of life in COPD, they also cause a significant escalation in the expenses of treatment. This study aimed to assess the effect of home-based PR programs in patients with mild to severely affected stable COPD, to determine the impact of visual biofeedback on pulmonary function and the quality of life of these patients.

Materials and Methods: This Double-blind, parallel, randomized controlled study was conducted at a tertiary care center from April 2023 to June 2024. The study enrolled 70 patients, who were randomized into group A (Incentive spirometry plus conventional pulmonary exercise) and group B (Conventional pulmonary exercises). Pulmonary indices, FEV1 (Forced Expiratory Volume in 1 sec), FVC (Forced Vital Capacity), FEV1/FVC (%), and Quality of life indices, St. George's Respiratory Questionnaire (symptoms score, activities score, impact score, and total score), were used as outcome measures. Data were recorded at baseline and after 4 weeks of a structured PR program and analyzed by SPSS version 24.0, and a p-value < 0.05 was chosen as the level of significance.

Results: There were 44 males and 26 females. Inter-group assessment after 4 weeks of PR program showed improvement in FEV1 (p-value: 0.043), FVC (p-value: 0.032), Symptom score (p-value: 0.038), Impact Score (p-value: 0.005), and Total score (p-value < 0.001).

Conclusion: Visual biofeedback can augment the PR program in stable COPD patients, and it can enhance the outcome even in a home-based rehabilitation program.

Keywords: COPD; Pulmonary rehabilitation programs; Quality of life; Visual biofeedback; Pulmonary indices

INTRODUCTION

Globally, chronic obstructive pulmonary disease (COPD) is the most common pulmonary disorder (1). In developing countries, wood combustion and cooking fires are common sources of air pollution, and they have long been linked with poverty and non-communicable pulmonary diseases (2,3). COPD typically occurs in people aged more than 45 years and primarily affects men. Tobacco smoking is the single most important factor involved in the genesis of COPD (4). Globally, the COPD prevalence rate is 11.4% among people aged more than 30 years, which is 10.6% in low- and middle-income countries (5). According to an Indian global burden of disease study, the prevalence of COPD increased from 3.3% in 1990 to 4.4% in 2016 (2,5). From 2007 to 2017, deaths and premature deaths due to COPD changed by 39% and 37%, respectively (6). From 1990 to 2016, in India, with a 36% mean percentage change, COPD was the second leading cause of disability-adjusted life years.

Pulmonary rehabilitation (PR) programs increase exercise tolerance and improve quality of life (7). Based on patient evaluation and treatment, a comprehensive, individualized PR intervention is planned, which includes education, exercise training, and behavior change. All aim to improve psychological and physical conditions, thus promoting long-term adherence to health-improving behaviors (8). According to Arkhipov et al., Indian COPD patients spend about 30% of their income on disease management (9). PR supports the recovery of hospitalized COPD patients by reducing symptoms, improving exercise tolerance, and improving quality of life; thus, it reduces the need for healthcare (8).

Most of the earlier studies used conventional indoor PR programs, causing a massive escalation of expenses in addition to the cost of treatment for COPD patients. This study addresses and provides insight into reducing expenses in the management of COPD patients by providing a home-based PR program augmented by a visual biofeedback device. This study hypothesized that biofeedback can augment and hasten the effects of conventional pulmonary exercise programs. This study aimed to assess the effect of a 4-week home-based biofeedback-augmented pulmonary exercise program on mild-to-severely affected stable COPD patients. The objective of this study was to determine the effect of visual biofeedback, incentive spirometer (IS), on pulmonary function and the quality of life of stable COPD patients.

MATERIALS AND METHODS

This double-blind, parallel, randomized controlled study was conducted at a tertiary care center from June 2021 to December 2022. Sample size was calculated based on post-intervention variation in FEV1/FVC% in the IS treatment and control group using the formula,

Where σ_1 = 12.8, the SD of post intervention variation in FEV1/FVC% in IS treatment group,

σ_2 = 10.0, the SD of post-intervention variation in FEV1/FVC% in the control group (10).

d = min (σ_1, σ_2). The minimum mean difference was considered to be clinically significant.

Type I error a = 5% corresponding to a 95% confidence level.

Type II error β = 10% for detecting results with 90% power of the study. So, the required sample size was calculated to be 35 for each group.

The study has an allocation ratio of 1:1. Participants were enrolled after receiving ethical clearance from the institutional ethical committee based on the following criteria:

Inclusion criteria:

1. Aged 40 to 65 years, either sex.
2. Mild to severe stable COPD patients (GOLD Staging 1, 2, and 3).
3. Patients under the care of a pulmonologist receive treatment for at least 6 weeks.
4. The patients were willing to participate in the study.

Exclusion criteria:

1. Patient suffering from any other acute or chronic lung disease.
2. Patients with co-existing cardiac disease, bony spinal deformities, and suffering from any neuro-psychiatric illness.

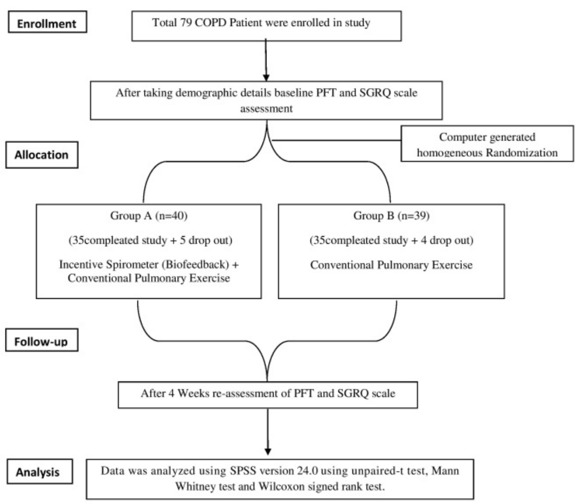
The study design flow chart is shown in Figure 1.

Informed verbal and written consent were obtained for each patient, and basic demographic details were collected. Participants were randomized into either group by the computer-generated homogeneous sampling method.

Group (A): Incentive spirometry plus conventional pulmonary exercise (IS+CPE)

Group (B): Conventional pulmonary exercise (CPE)

In this study, we used a tri-ball incentive spirometer (IS) (Standard Romson IS). It has three chambers (600, 900, and 1200 mL/s) with blue, yellow, and red color balls, respectively, in each chamber, and a mouthpiece. The balls are raised in each chamber upon the generation of adequate inspiratory flow rates by participants, which serve as visual biofeedback for the patient and encourage him/her to repeat the task (Figure 2).



Figures 1. Study design flow chart

Figure 2. Incentive Spirometer

Incentive spirometry exercise (only group A):

The patient was instructed to breathe out completely and close the mouthpiece of IS with lips tightly, then start breathing in slowly and deeply until the ball in the spirometer is lifted and remains suspended by the sustained flow. As the flow reaches > 300 ml/s, the ball in the first chamber starts floating; as the flow increases to 600 ml/s, the ball in the second chamber starts floating; and when the flow reaches > 900 ml/s, all three balls start floating (11). All the patients were instructed to perform the same task for 5–10 breaths per session and repeat it for at least 4 sessions daily for 4 weeks.

Conventional pulmonary exercises (for Groups A and B):

1. Education program: personal teaching and training supported by pamphlet (diagrammatic presentation of activities) distribution, e-learning video about pathophysiology and prognosis of disease, the role of reconditioning exercise, energy conservation, smoking cessation technique, and the importance of compliance with the program.
2. Postural relief techniques: 20° forward lean with support.
3. Chest-specific maneuvers and exercises; controlled breathing techniques; pursed lip and diaphragmatic breathing (2–5 min BD); and postural drainage and huffing (10–15 min OD).

The Subjective Pulmonary Function Test (PFT) was performed at baseline and in the 4th week of follow-up with the Geratherm Spirostick, which uses the Blue Cherry software platform and runs on a Windows 10 system. During the test, a disposable Spiroflow flow sensor and nose clips were used. During testing, patients were asked to breathe in as deeply as possible and breathe out completely through the spirometer. They repeated the whole process at least three times, and the highest reading was selected (12).

Outcome Measures

1. Pulmonary indices: FEV1 (forced expiratory volume in 1 sec), FVC (forced vital capacity), and FEV1/FVC (%) are specific for the diagnosis and prognosis of COPD (13).
2. Quality of Life: George's Respiratory Questionnaire (SGRQ) (By Hindi translated version).

In chronic lung disease, quality of life is measured by SGRQ. It is a disease-specific instrument having 4 domains: symptoms score, activity score, impact score, and total score, with Cronbach's alpha statistics (> 0.9 in the overall questionnaire and > 0.7 in the subdomains). SGRQ has high internal consistency. Its core ranges from 0 (no impairment) to 100 (maximum impairment) for each domain, and the total questionnaire and change of 4 units are considered clinically relevant (14). Follow-up of participants was done by teleconsultation twice a week in the first week, then weekly once for three weeks, and a physical follow-up after 4 weeks.

Statistical Analysis

The collected data were summarized as mean ± SD (median) and percentage, depending on the nature of the variable. Data analysis was done using SPSS version 24.0, and a p-value < 0.05 was chosen as the level of significance. The intragroup comparison of PFT between the baseline and the 4-week follow-up was done by a paired t-test, while the intragroup comparison of the SGRQ questionnaire was done by a Wilcoxon signed rank test. The intergroup comparison of PFT at baseline and 4 weeks of follow-up was done by an unpaired t-test, while the intergroup comparison of the SGRQ questionnaire at baseline and 4 weeks of follow-up was done by a Mann-Whitney test.

Ethical Consideration:

Ethical Clarence, Ref no: 107th ECM II B- Thesis/P2

RCT registration Number: REF/2021/07/045578; CTRI/2023/03/051095

RESULTS

A total of 70 enrolled patients completed this study (35 in each group). There were 44 males and 26 females, with a male: female ratio of 1.7:1. The mean age of the enrolled patients was 55.70 ± 7.3 in group A and 52.79 ± 7.3 in group B. There were 80% educated patients and 20% uneducated patients. Baseline demographic characteristics of both groups indicate homogeneous demographic distribution (Table 1). On objective baseline pulmonary function assessment by unpaired t-test, there was no significant difference in FEV1 (p value -0.563), FVC (p value -0.744), or FEV1/FVC% (p value -0.604) between group A (IS + CPE) and group B (CPE) (Table 2). On subjective baseline quality of life (SGRQ questionnaire) assessment by Mann-Whitney test, there was no significant difference in symptom score (p-value - 0.676), activity score (p-value - 0.206), impact score (p-value - 0.11) and total score (p-value - 0.137) between both group A (IS + CPE) and group B (CPE) (Table 3). This indicates the homogeneous clinical distribution of the sample.

Table 1. Baseline characteristics of the participants

Characteristics	Result (n=70)	Group A	Group B
Age (mean ± SD) years	54.25±7.3	55.70±7.30	52.79±7.30
Male	44 (63.6%)	20 (57.6%)	24 (69.7%)
Female	26 (36.4%)	15 (42.4%)	11 (30.3%)
Male: Female	1.7:1	1.4:1	1.12:1
Educated: Uneducated	4:1	3.6:1	4:4:1
Duration of illness (Mean ± SD) (years)	3.37±2.42	3.17±1.9	3.57±2.94

Table 2. Inter-group pulmonary function test assessment by unpaired t-test (*:significant)

Pulmonary Indices	Time of Assessment	Group A (n=35) Mean±SD	Group B (n=35) Mean±SD	p-value
FEV1	Baseline	1.3±0.49	1.23±0.44	0.563
	At 4th week	1.6±0.52	1.35±0.46	0.043*
FVC	Baseline	2.17±0.53	2.12±0.64	0.744
	At 4th week	2.46±0.48	2.16±0.64	0.032*
FEV1/ FVC	Baseline	60.7±20.6	58.61±10.9	0.608
	At 4th week	65.47±20.8	63.2±11.3	0.584

Table 3. Inter-group comparison of St. George's Respiratory Questionnaire (SGRQ) assessment by Mann-Whitney test (*: significant)

SGRQ Indices	Time of Assessment	Group A (n=35) Mean±SD	Group B (n=35) Mean±SD	p-value
Symptom score	Baseline	75.58±7.62	76.37±8.41	0.676
	At 4th week	68.82±5.36	71.35±4.5	0.038*
Activity score	Baseline	80.89±9.58	77.79±9.39	0.206
	At 4th week	54.64±6.92	57.83±5.49	0.264
Impact score	Baseline	47.06±16.5	41.37±13.9	0.11
	At 4th week	18.22±9.5	26.97±13.1	0.005*
Total score	Baseline	62.49±10.8	58.74±8.79	0.137
	At 4th week	38.28±5.57	44.29±6.84	<0.001*

At the 4th week of follow-up, intra-group assessment of pulmonary indices by paired t-test shows significant (p-value: < 0.001) improvement in FEV1 and FVC in group A (IS + CPE) and FEV, FVC, and FEV1/FVC % in group B (CPE) (Table 4), and intra-group assessment of Quality of Life (SGRQ questionnaire) indices by Wilcoxon signed rank test shows significant (p-value: < 0.001) improvement in symptom score, activity score, impact score, and total score in both the groups (Table 5).

Table 4. Intra-group pulmonary function test assessment by paired t-test (*:significant)

	Pulmonary Indices	Baseline	4th week follow-up	p-value
Group A (n=35) Mean±SD	FEV1	1.3±0.49	1.6±0.52	< 0.001*
	FVC	2.17±0.53	2.46±0.48	< 0.001*
	FEV1/ FVC (%)	60.7±20.6	65.47±20.8	0.237
Group B (n=35) Mean±SD	FEV1	1.23±0.44	1.35±0.46	< 0.001*
	FVC	2.12±0.64	2.16±0.64	< 0.001*
	FEV1/ FVC (%)	58.61±10.9	63.2±11.3	< 0.001*

Table 5. Intra-group St. George's Respiratory Questionnaire (SGRQ) assessment by Wilcoxon signed rank test (* significant)

	SGRQ Indices	Baseline	4th week follow-up	p-value
Group A (n=35) Mean±SD	Symptom score	75.58±7.62	68.82±5.36	< 0.001*
	Activity score	80.89±9.58	54.64±6.92	< 0.001*
	Impact score	47.06±16.5	18.22±9.5	< 0.001*
	Total score	62.49±10.8	38.28±5.57	< 0.001*
Group B (n=35) Mean±SD	Symptom score	76.37±8.41	71.35±4.5	< 0.001*
	Activity score	77.79±9.39	57.83±5.49	< 0.001*
	Impact score	41.37±13.9	26.97±13.1	< 0.002*
	Total score	58.74±8.79	44.29±6.84	< 0.001*

The intergroup assessment at the 4th week of follow-up of objective pulmonary function assessment by unpaired t-test shows a significant difference in FEV1 (p-value: 0.043) and FVC (p-value: 0.032) between both group A (IS + CPE) and group B (CPE) (Table 2). and intergroup assessment of Subjective Quality of Life (SGRQ questionnaire) indices by Mann-Whitney test shows a significant difference in symptom score (p-value 0.038), impact score (p-value 0.005), and total score (p-value < 0.001) between both group A (IS + CPE) and group B (CPE) (Table 3).

DISCUSSION

The objective of this study was to determine the effect of visual biofeedback, incentive spirometer (IS), on pulmonary function and quality of life in mild to severe stable COPD patients (GOLD Staging 1, 2, and 3). Pulmonary indices used to assess pulmonary function were FEV1, FVC, and FEV1/FVC (%), and quality of life was assessed using the SGRQ questionnaire, which has quality indices such as symptom score, activity score, impact score, and total score indices. All these were assessed at baseline and after 4 weeks of a home-based conventional pulmonary exercise program with and without visual biofeedback augmentation.

The homogeneity of the randomization in the study was indicated by no significant difference in baseline demographic and clinical (Pulmonary indices & SGRQ indices) characteristics between the two groups, i.e., Group A (IS + CPE) and Group B (CPE).

Pulmonary indices

This study indicates FEV1, FVC, and FEV1/FFVC (%) improved after 4 weeks of the home base PR program in both groups, i.e., Group A (IS + CPE) and Group B (CPE) from baseline; however, on inter-group comparison, visual biofeedback with conventional pulmonary exercise group (IS+CPE) showed significant improvement over conventional pulmonary exercise group (CPE) in FEV1 and FVC parameters but no significant improvement in FEV1/FFVC (%). This is akin to a study by El-Koa et al. (15) that found a statistically significant increase in FEV1/FVC in the incentive spirometry (IS) group after 2 months of IS training but no difference in FVC. They concluded that incentive spirometry improves ABG, some parameters in pulmonary functions, and diaphragmatic functions in COPD patients, but the participants enrolled in this study were unstable COPD patients. Negi et al. (16) concluded, "In COPD patients with mild to severe dyspnea, ventilatory muscle strength improves with both Resistive Inspiratory Devices and IS." Heydari et al. (17) concluded that "it is a good complementary tool for bedside PR in COPD patients." In both studies by Negi et al. and Heydari et al. (16,17), they did not use pulmonary indices (FEV1, FVC, and FEV1/FVC (%) as an assessment tool. In contrast, Agostini et al. (18) concluded that "incentive spirometry did not augment recovery of lung function in COPD patients." This study was conducted on patients following thoracotomy and lung resection.

St. George's Respiratory Questionnaire (SGRQ) indices

Jácome and Marques suggested that "a change of 4 units in the SGRQ score is considered clinically relevant." (14). In this study, there was an observable change in the SGRQ indices of both groups, i.e., Group A (IS + CPE) and Group B (CPE). On inter-group comparison, there was a significant difference in symptom score, impact score, and total score, except for activity score. This is akin to Jácome and Marques (14), who found "PR significantly improved symptom score, activity score, and SGRQ total score, although on lung function and emotional state it had no significant effect." The small sample size and only mild COPD patient enrollment may be the reason for this.

Pulmonary rehabilitation (PR)

According to Giggins et al., "Biofeedback is the technique of providing unknown biological information to patients in real time; these additional details are beyond the naturally available information to patients." (19). In this study, we used an IS, which is an economical, user-friendly, and visual biofeedback device that keeps users engaged and motivated during practice. McCarthy et al. (7), Gallagher and Christine (20) state, "In COPD patients, the addition of PR to the plan of care can reduce dyspnea, thus improving quality of life and exercise capacity, leading to cost-effective, accessible, quality care, and optimal outcomes."

This study indicates PR plays a vital role in recovery, prevention of future attacks, and complications of COPD. When any routine rehabilitation program gets supplemented by biofeedback, it enhances and augments the outcome of the program. Incentive spirometry in the rehabilitation of COPD patients offers the opportunity to improve the accuracy of the task, increase patient confidence, boost their engagement in their rehabilitation, and reduce the need for healthcare professionals to monitor the implementation of rehabilitation programs.

Limitations of the study

While enrolling the patients' effects, extrinsic factors like drugs were not considered in this study. The study lacks long-term follow-up. As a telephonic follow-up was done for all the participants, reliance on the patient's information was more prevalent in this study, which itself can confound the data.

CONCLUSION

Visual biofeedback can enhance and augment the PR program for COPD patients. Incentive Spirometry is an economical, user-friendly, and cost-effective visual feedback device that can be used independently and freely. This maximizes COPD patients' motivation to participate in the PR program. To overcome the limitations of the study, it requires a long-term, inpatient study with a large sample size to reduce bias and confounding factors. Adding visual feedback can enhance the outcome, even in a home-based rehabilitation program.

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