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EFFECTS OF STRUCTURED EXERCISE TRAINING IN CHRONIC OBSTRUCTIVE PULMONARY DISEASE: A RANDOMISED CONTROLLED TRIAL

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ABSTRACT **Background:** Chronic obstructive pulmonary disease is associated with a significant reduction in physical activity which contributes to patient's disability. Pulmonary rehabilitation including exercise training combined with disease specific education improves exercise capacity, symptoms and quality of life across all grades of COPD severity. This study was done to assess the effects of structured exercise training in COPD patients on number of exacerbations, quality of life, 6-minute walk test and level of biomarkers (plasma fibrinogen, CRP, albumin). **Materials and Methods:** This was a randomized control trial of one year duration. A total of 60 patients diagnosed with COPD (GOLD category C& D) were divided into intervention and control group by random allocation. Both groups were given pharmacological treatment and the intervention group was taught about structured exercises which include purse lip breathing, diaphragmatic breathing and lower limb exercises. All patients were followed up for one year. CAT score, dyspnea grading by mMRC scale and 6-minute walk test were assessed every 3 months. The level of plasma fibrinogen, CRP and albumin were measured every 3 months during this one year follow up period. **Results:** There was a significant reduction in number of exacerbations, number of hospital admissions and duration of hospitalization in intervention group. Also, significant improvement was observed in quality of life based on CAT score, BORG dyspnea scale, mMRC dyspnea scale and distance walked in 6MWT. A significant improvement in the level of biomarkers that include CRP, plasma fibrinogen and albumin were also noted. No difference was observed between the two group in terms of rate of decline in FEV1.**Conclusion:** There is improvement in rate of exacerbation, quality of life, dyspnea and the level of biomarkers following structured exercises.

KEYWORDS : Chronic obstructive pulmonary disease, Pulmonary rehabilitation, Exercise, Exacerbation, Biomarkers

INTRODUCTION

Chronic obstructive pulmonary disease is a heterogenous lung condition characterized by chronic respiratory symptoms (dyspnea, cough, sputum production and/or exacerbations) due to abnormalities of the airways (bronchitis, bronchiolitis) and/or alveoli (emphysema) that cause persistent, often progressive, airflow obstruction. COPD is now one of the top three causes of death worldwide and 90% of this death occurs in low and middle income countries[1]. Patients with advanced COPD may restrict their activities and may lead a sedentary lifestyle due to severe exercise limitation. This limitation causes social isolation, depression and skeletal muscle deconditioning which in turn restrict their activity and impair quality of life. Protein and calorie malnutrition occurs as the consequence of impaired nutritional intake caused by dyspnea. Malnutrition is augmented by increased metabolic demands caused by increased basal oxygen consumption, inefficient skeletal muscle oxygen utilization, and cachexia-producing cytokines such as tumor necrosis factor alpha. Pulmonary rehabilitation with its core components, including exercise training combined with disease specific education improves exercise capacity, symptoms and quality of life across all grades of COPD severity.

Research Objectives

This study was done to assess the effects of structured exercise training in COPD patients on number of exacerbations, quality of life, 6-minute walk test and level of biomarkers (plasma fibrinogen, C-Reactive Protein, albumin).

MATERIALS AND METHODS

This was a Randomized control trial conducted in the department of Respiratory medicine, MES medical college, a tertiary care center in North Kerala, from January 2018 to September 2019. All Patients with COPD (GOLD category C & D), with age more than 40 years and were willing to give consent were included in the study. People with serious other systemic diseases such as bronchiectasis, interstitial lung disease, coronary artery disease, structural heart disease, chronic kidney disease and chronic liver disease were excluded from the study. Patients who had undergone similar exercise training in the past were also excluded. The sample size was calculated as 60 based on previous study. Institutional ethical and scientific committee clearance was obtained and informed consent was secured from every participant involved in the study.

The selected patients were categorized into two groups, an intervention group and a control group, through random allocation using a computer system. Both groups were given standard pharmacological treatment and encouraged to ambulate. The intervention group were taught about structured exercises which includes purse lip breathing, diaphragmatic breathing and lower limb exercises to increase strength and stamina (leg pressing, leg swinging, ankle dorsi flexion, plantar flexion and hip flexion exercises). These exercises were performed 25 times a day in morning and evening at least 5 days a week. All 60 selected patients were followed up monthly for one year. The subjects included in the intervention group were reviewed monthly in the Pulmonary Rehabilitation Clinic to make sure they were following the structured exercises in the right manner and weekly telephonic communications was made to assure compliance. The number of exacerbations (hospitalization and OP visits) were assessed based on the GOLD definition of exacerbation (COPD exacerbation is defined as an event in the natural course of the disease characterized by a change in patients base line dyspnea, cough and/or sputum that is beyond normal day to day variations, is acute in onset and may warrant a change in regular medications). The quality of life was assessed by symptom score of CAT (COPD Assessment Test). Parameters like mMRC grading of dyspnea and 6-minute walk test were assessed every 3 months during the one year follow up. The level of biomarkers (serial change in biomarkers including plasma fibrinogen, CRP and albumin) were done during stable disease, not during exacerbation. The rate of decline in FEV1 was also documented during the study period.

Data collected were tabulated using MS Excel and analyzed using SPSS statistical software version 16. Categorical variables were represented using frequency and percentage. Comparison of various parameters between groups and within group over time were done using t Test and chi-squared test.

RESULTS

A total of 60 patients were enrolled in the study. They were categorized into an intervention group and control group each consisting of 30 individuals. Only male patients were willing to participate in the study. The mean age of intervention group was 68.3 ± 6.7 and that of control group was 65.4 ±8.4. No significant difference was seen with respect to age between the groups (t=1.48, p=0.145). There was no significant difference between the occupation status of the intervention and control group. With respect to the socio-economic status according to the BG Prasad socioeconomic classification, both groups were comparable (chi=6.38, p=0.173).

There was no significant difference between the number of exacerbations (t=2.35, p=0.022), number of admissions (t=.42, p=0.679) and duration of admission in days (t=0.79, p=0.434) between the study (intervention) and control group in the previous year (table 1).

Table 1: COPD Exacerbations in the Previous Year.

	Intervention			Control			t	p
	Mean	SD	N	Mean	SD	N		
No of exacerbation	4.5	1.0	30	3.9	1.0	30	2.35	0.022
No of admission	2.1	1.0	30	2.0	0.8	30	0.42	0.679
Duration of admission	11.1	6.2	30	10.0	4.5	30	0.79	0.434

Following the intervention a significant difference was noted between the study (intervention) and control group with respect to number of exacerbations (t=2.93, p=0.005), number of admissions (t=6.41, p=<0.000) and duration of admission in days (t=6.19, p=<0.000) during the study period (table 2).

Table 2: COPD Exacerbations During Study Period.

	Intervention			Control			t	p
	Mean	SD	N	Mean	SD	N		
No of exacerbation	3.0	1.1	30	3.9	1.4	30	2.93	0.005
No of admission	0.9	0.7	30	2.1	0.8	30	6.41	0.000
Duration of admission	3.9	3.4	30	10.5	4.8	30	6.19	0.000

There was no significant difference between the intervention and control group in CAT score at baseline. Improvement in CAT score was noted in intervention group from third months onwards (figure 1A). Similarly, no significant difference in mMRC scale dyspnea grading between the two groups at baseline and improvement was noted in intervention group at the end of study (figure 1 B). During 6-minute walk test, no significant difference in BORG scale and distance walked at baseline between the two groups. Improvement in each parameter was noted in intervention group from 6months onwards (figure 1 C&D). During spirometry assessment both groups exhibited a similar rate of decline in FEV1 (figure 1 E).

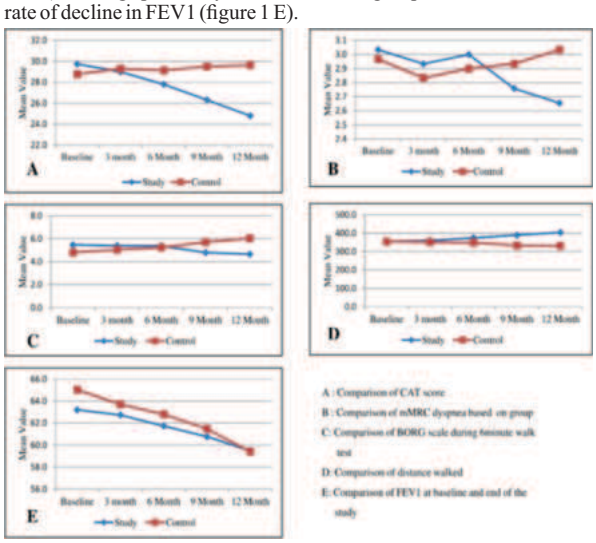

Figure 1: Comparison of Different Parameters Across the Study Period

During evaluation of biomarkers, C-reactive protein values between intervention and control group at baseline had no significant difference, improvement was noted in the intervention group denoted by the negative difference in the mean values (table3). Similarly, fibrinogen levels improved in intervention group and a significant change can be noted from 12 month onwards (table 3). There was no significant difference in albumin level between the two groups at baseline. With regards to improvement in albumin values as shown in table 3, a significant change can be noted at 12th month in intervention group.

Table 3: Comparison of Level of Biomarkers Across the Study Period

Change in CRP	Intervention			Control			t	p
	Mean	SD	N	Mean	SD	N		
Baseline to 3 months	0.0	0.5	30	0.1	0.4	30	0.82	0.414
Baseline to 6 months	-0.2	0.8	30	0.0	0.8	30	1.3	0.197
Baseline to 9 months	-0.2	0.9	29	0.1	0.7	30	1.56	0.124
Baseline to 12 months	-0.6	0.7	29	0.1	0.7	30	3.72	0.000
Change in Fibrinogen	Intervention			Control			t	p
	Mean	SD	N	Mean	SD	N		
Baseline to 3 months	2.0	9.8	30	1.2	7.0	30	0.38	0.705
Baseline to 6 months	2.8	12.5	30	3.5	9.9	30	0.23	0.820
Baseline to 9 months	-3.6	16.9	29	3.8	12.0	30	1.93	0.058
Baseline to 12 months	-7.2	16.5	29	3.6	16.8	30	2.49	0.016
Change in Albumin	Intervention			Control			t	p
	Mean	SD	N	Mean	SD	N		
Baseline to 3 months	0.06	0.21	30	0.04	0.18	30	0.4	0.687
Baseline to 6 Months	0.02	0.51	30	0.03	0.21	30	0.1	0.921
Baseline to 9 months	0.09	0.36	29	0.00	0.20	30	1.23	0.224
Baseline to 12 months	0.19	0.34	29	-0.01	0.22	30	2.73	0.009

DISCUSSION

Chronic obstructive pulmonary disease is associated with a significant reduction in physical activity and poor health-related quality of life. Pharmacological treatment has limited role in improving exercise capacity of these patients. Dyspnea is one of the most frequently reported symptoms which significantly reduce exercise capacity. Earlier the management of COPD has focused mainly on pharmacological treatment of the airway obstruction. However, over the last two decades, there is growing evidence of systemic manifestations in COPD patients and their negative effects, which led to the development and use of non-pharmacological management, such as pulmonary rehabilitation[2]. Exercise training is the core of lung function rehabilitation which improve patient's exercise endurance, alleviate dyspnea, improve ventilation burden and facilitate the rehabilitation of whole body. Pulmonary rehabilitation and pharmacological therapy should be used together for better management of chronic obstructive pulmonary disease[3].

The study showed a significant reduction in number of exacerbations and number of hospital admissions after initiating structured exercises. Similarly, the study by Foglio R et al also showed a reduction in number of exacerbations and number of hospital admissions following pulmonary rehabilitation.[2] There was a significant decrease in number of days of hospital admission which is similar to a study by Wright RW et al, demonstrated a reduction in number of days of hospital admission following pulmonary rehabilitation[3].

In the present study, a significant improvement in CAT score is seen following exercises. A study by Fang Xi et al also showed a significant improvement in CAT score [4]. There was a significant improvement in the mMRC dyspnea score following pulmonary rehabilitation. In a study by Paz-Díaz et al there is a significant improvement in mMRC dyspnea scale.[5]

The study showed an improvement in CRP values following structured exercises. A study by Ipek Candemir et al showed a decrease in CRP values but decrease in values was not statistically significant[6]. After structured exercises for one year, there was a significant reduction in fibrinogen values. Similarly in a study by Maria Tereza Aguiar Pessoa Morano et al there is a significant reduction in the fibrinogen values following pulmonary rehabilitation[7].

There was an improvement in albumin level too in the intervention group. In a study by Ugur Gonlugur et al Serum albumin level decreased with declining in pulmonary function[8]. Another study by Maria Tereza Aguiar Pessoa Morano et al showed no significant change in albumin values following pulmonary rehabilitation[7].

There is a significant improvement in BORG dyspnea scale and distance walked in 6MWT. Similarly, study by Fang Xi et al showed a significant improvement in distance walked in 6MWT[4]. A study by Nield et al showed training with purse lip breathing causes improvement in BROG dyspnea scale[9].

The rate of decline in FEV1 is similar in intervention and control group. No difference was observed between the two group in terms of change in FEV1 during the study period. This observation was in accordance with the study by Lan CC which showed no significant change in the FEV1 decline rate[10].

CONCLUSION

The study concludes that there is improvement in symptoms and in the level of biomarkers following structured exercises training in COPD patients. There is a significant decrease in number of exacerbations,

number of hospital admissions and duration of hospital admissions. The study showed an improvement in quality of life, dyspnea grading, 6-minute walk test and the level of biomarkers. There is no significant change in rate of decline in FEV1 following structured exercises training in COPD patients.

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