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A six week pulmonary rehabilitation programme in COPD patients in a resource limited setting.

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Abstract
Background.
Pulmonary rehabilitation (PR) is an evidence-based, multidisciplinary, and comprehensive intervention in patients with chronic obstructive pulmonary disease (COPD), which is recommended by all the available guidelines. Pulmonary rehabilitation improves the exercise capacity and quality of life (QoL) in COPD patients. We evaluated a six-week pulmonary rehabilitation program in a resource-limited setting.
Methods.
We studied the effect of pulmonary rehabilitation in patients with COPD. 115 patients were considered for the study. 100 patients fulfilled the criteria. They were randomised to receive standard treatment plus a 12-week pulmonary rehabilitation (PR) programme(n=50) or conventional treatment without pulmonary rehabilitation (Control group) (n=50). Assesment was carried out by using Spirometry, St.George's Respiratory Questionnaire (SGRQ), the 6-minutes walk test (6-MWT) initially and at the end of treatment period.
Results.
The baseline characteristics of both the groups were found to be similar. 45 patients (90%) from the active group (mean age, 59.17 ± 8.65 years; mean forced expiratory volume in one second (FEV1), 51.93 ± 14.09% of the predicted value); and 44 patients (88%) from the control group (mean age, 60.11± 9.56 years; mean FEV1 , 49.27 ± 13.34% of the predicted value) completed the study. There was no change in pulmonary function parameters in the active group and the control group. There was a statistically significant increase in the six-minute walk distance (6MWD) (increase by 66.38 meters, p< 0.001) and a significant decline in the total SGRQ score (by 13.71 units p< 0.001) in the Study group compared to Control group.
Conclusion: An outpatient-based 6-week rehabilitation program can be used in a resource-limited to improve the quality of life (measured by SGRQ), exercise tolerance(measured by 6MWT.
Keywords: *COPD, quality of life, pulmonary rehabilitation, 6-minute walking test, SGRQ.*

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Chronic Obstructive Pulmonary Disease (COPD) is a common, preventable and treatable disease that is characterized by persistent respiratory symptoms and airflow limitation that is due to airway and/or alveolar abnormalities usually caused by significant exposure to noxious particles or gases. The chronic airflow limitation that is characteristic of COPD is caused by a mixture of small airways disease (e.g., obstructive bronchiolitis) and parenchymal destruction (emphysema), the relative contributions of which vary from person to person(1)

Chronic Obstructive Pulmonary Disease (COPD) is a major cause of morbidity and mortality worldwide, it is a major public health problem. COPD stands fourth among the leading cause of death worldwide and is projected to become the 3 rd leading cause of death by 2020.(2). In 2012 , more than 3 million people died of COPD i.e. 6% of all deaths globally. The COPD burden is projected to increase in coming years because of continued exposure to COPD risk factors and changing demographics i.e. aging of the population(3).

Comprehensive management of patients with COPD includes pulmonary rehabilitation as one of the important components.ATS/ERS Standards for the Diagnosis and Management for Patients with COPD and the Global Initiative for Chronic Obstructive Lung Disease (GOLD) document has given pulmonary rehabilitation a huge importance. The evidence for improvement in exercise endurance, dyspnea, functional capacity, and quality of life is stronger for rehabilitation than for almost any other therapy in COPD, and documentation of its

favourable effect on health care utilization is increasing. Deterioration of respiratory physiology (declining FEV1) and progressive limitation of exercise capacity and physical activity levels are seen as COPD progresses. Exercise performance in COPD is limited because of dyspnea from ventilation limitation, gas exchange abnormalities and hyperinflation of lungs(4)(5), reduction in muscle mass of lower limbs(6). The patient gives up some strenuous physical activity and adopts a more sedentary lifestyle(7) because of dyspnea and fatigue. The activity limitation becomes detrimental to the patient, and is associated with high risk of mortality and hospital resources use(8). Pitta F et al(9)recently proved, by direct activity assessment that patients with COPD are quite sedentary. Decrease in both functional exercise capacity and physical activity appears to be related to increased healthcare use and mortality in COPD(10-14)

Definition of pulmonary rehabilitation by ATS/ERS(15)

"An evidence based, multidisciplinary and comprehensive intervention for patients with chronic respiratory diseases who are symptomatic and often have decreased daily life activities integrated into individual treatment of the patient, pulmonary rehabilitation is designed to reduce symptoms, optimize functional status, increase participation,reduce health care costs through stabilizing or reversing systemic manifestation of the disease"

ATS/ERS further describes the process of rehabilitation

"A pulmonary rehabilitation program involves patient assessment, exercise training, education, nutritional intervention and psychosocial support. When indicated nutritional and psychosocial intervention may be given, the above definition and description indicate pulmonary rehabilitation is delivered to patient based on individual needs".

Exercise capacity in COPD is limited in part by dyspnea resulting from static and dynamic hyperinflation(16).By breathing at increased lung volume ,the elastic work of breathing is increased and respiratory muscle are placed at a more of mechanical disadvantage(17);The contribution of increased dyspnea and prolonged expiratory time causes patient to breath in before the preceding breath is fully exhaled. This dynamic hyperinflation contributes to exertional dyspnea of COPD.

Exercise training indirectly reduces dynamic hyperinflation. After the beneficial training effects on the muscles of ambulation are achieved through exercise training, the respiratory rate is decreased(18).

The lower respiratory rate during exercise will allow more complete lung emptying with each breath thereby reducing dynamic hyperinflation.

I. Objectives :

The aims of the study were to evaluate the effects of an outpatient pulmonary rehabilitation program in a resource-limited setting. The study was designed to improve the exercise capacity, the quality of life in patients with COPD using 6MWT and SGRQ respectively, the study was also aimed at evaluating the effect on the mortality rate using BODE index.

II. Material And Methods.

This was a prospective randomised controlled study conducted for a period of two years. Consecutive patients who were diagnosed with COPD were examined at outpatient department, the patients have briefed about the study during the course of an evaluation. The patients were evaluated for their ability to participate in the rehabilitation program, with respect to the attending the program and the travel involved. All patients who were approached had their therapy optimised. patients who fulfilled the study criteria were included in the study. Severely ill patients who were unable to walk, or patients with unstable cardiovascular disease (unstable angina or recent acute myocardial infarction), had cognitive impairment, disabling arthritis, and severe neurological diseases were excluded from the study.

Study Design

The study participants were evaluated and randomised into two groups, optimal treatment pulmonary rehabilitation (study group) or optimal treatment without pulmonary rehabilitation (Control group) using a block randomisation technique. All patients were informed of the objectives and design of the study and an informed consent was obtained from each patient, which was approved by the institutional review board.

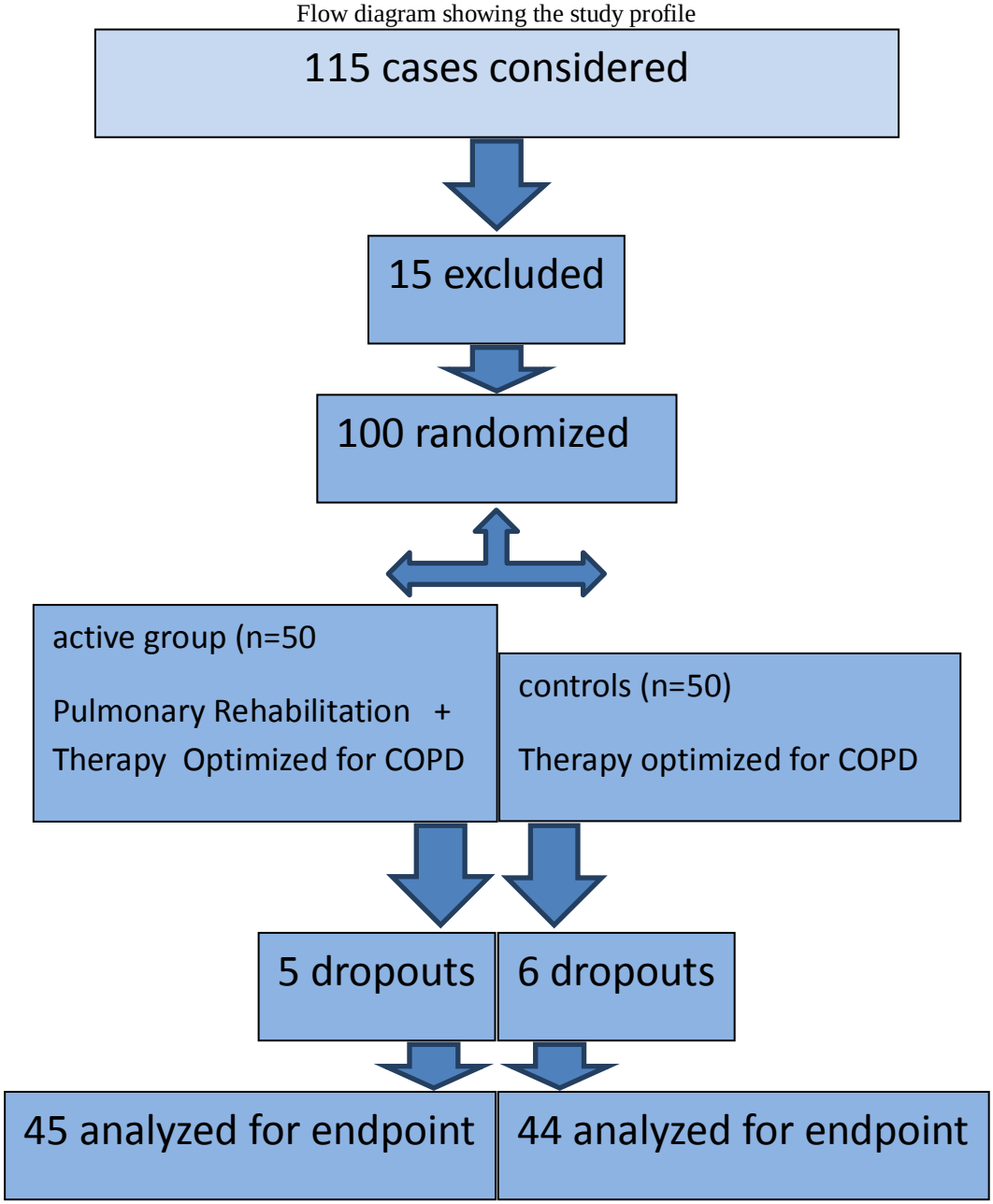
All had either given up smoking or were prepared to make an active effort to stop smoking during the proposed program, advice regarding smoking cessation was offered to all the patients. None of the study subjects had previously taken part in a supervised respiratory rehabilitation program.

We considered 115 patients for the study, 15 patients were excluded because they were not only suffering from COPD but also other cardiac and respiratory ailments.

The active group (n = 50) took part in a 6-week rehabilitation program in addition to standard COPD treatment. The control group (n = 50) received optimum treatment for COPD and were reviewed routinely as medical outpatients continuing optimum treatment for COPD.

Patients were assessed using a standard 6-min walk, spirometry, Borg dyspnoea scale and the SGRQ. Tests were done before the study, all tests were supervised by a blinded observer unaware of randomization who subsequently repeated these assessments within two weeks after completion of six weeks of a pulmonary rehabilitation program.

Flow diagram showing the study profile



Rehabilitation Program

Before the pulmonary rehabilitation, patients underwent an initial medical evaluation and involved advice regarding their diet and occupation. Simple exercises were taught to the patients without using any sophisticated types of equipment. The 6-week outpatient-based rehabilitation program involved two visits per week to the programme site and two unsupervised exercise schedule 2 days (once or twice daily) a week at home: each visit had 30 minutes of education and 60 min of exercises. There was a total of 24 sessions(12 outpatient visits and 12 home sessions).

The patients had twelve educational and exercise visits, their breathing problems and techniques were discussed during their visits in the educational session and were advised regarding the importance of home

exercise regimens. Exercises during their hospital visits involved 10 min warm-up period, 40 min of aerobic activity, strength training exercises and a 10-min cool-down period.

The exercise activity included
Upper limb exercise training: Patients were taught unsupported arm exercises by lifting free weights, diagonal arm raises, arm abduction into elevation and reverse, and arm abduction, forward flexion, and reverse.
Lower limb exercise training: patients were taught ground-based walking, During walking, they were instructed to use pursed lip breathing; climbing up and down stairs of 10 steps two to three times, and straight leg raises. They were asked to walk on level ground at a pace not resulting in marked dyspnoea for at least 15-20 minutes.
Breathing strategies
a). Pursed-lip breathing: Patients were advised to inspire through nose followed by expiration against partially closed lips, avoiding forceful exhalation. The patients were instructed to exhale twice as long as inhalation.
b).Diaphragmatic breathing: Patients consciously expanded the abdominal wall during inspiratory diaphragm descent and exhale slowly through pursed lips while drawing the abdomen inwards.
The program included endurance and strength training for the upper and lower limbs and education. The program was individually tailored and progressed. The aim of the program was to improve functional exercise capacity and quality of life. In addition, subjects were asked to perform unsupervised exercise schedule 2 days (once or twice daily) a week, patients were asked to perform these exercises at home and were advised to walk on level ground at a pace not resulting in marked dyspnoea for at least 20 minutes. The patients who missed 4 or more consecutive sessions were labelled as withdrawn/ failure to continue study and were considered as dropouts.

Educational component
Patients were educated in the following aspects- smoking cessation strategies, details on COPD symptoms, pathogenisis, medication use, benefits of exercise, nutritional advise, and avoiding environmental pollutants.
Dietary Assessment and Advice
Each patient had their body mass index (BMI) and dietary history assessed, and dietary advise were given to each one of them. Theywere assessedfor change in advised eating habits on weekly basis.
Occupational Therapy and Psychological Assessment
All patients and their family members were involved in an interactive session where a behavioural and psychosocial intervention were suggested. Relaxation technique was taught with special emphasis on Pranayama (breathing technique), advice was given on coping with low activity levels, and coping strategies for the loss of interest in leisure activities due to breathlessness.

Energy conservation and work simplification :
The patients were taught paced breathing, which is based on principles of reducing breath holding and timing the respiratory cycle with physical activities, optimizing body mechanics, advanced planning, prioritization of activities. The patients were taught to use purse lip breathing technique while performing activities.

Diagnosis of COPD
Spirometry was used for diagnosis and staging of COPD as per the Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines.An RMS Medspiror system was used, and all procedures were carried out according to ATS and ERS guidelines(19)
The parameters evaluated were: forced vital capacity (FVC), FEV1, the FEV1/FVC ratio. The tests were performed at the screening visit; at randomization; after pulmonary rehabilitation i.e. after 6 weeks. The presence of a post-bronchodilator FEV1/FVC < 0.70 confirms the presence of airflow limitation.The severity of airflow limitation was classified according to GOLD Guidelines into mild (FEV1 ≥ 80% predicted), moderate (50%≤ FEV1<80), severe (30%≤FEV1<50%) and very severe(<30%).

The Six Minute Walk Test
The six-minute walk test (6MWT) is a simple test used to measure the functional capacity of patients with respiratory disorders. The test measures the distance (6MWD; metres) that a patient can quickly walk on a flat hard surface in a period of six minutes. The 6MWT was performed indoor in our hospital, along a long, flat, straight, enclosed corridor with a hard surface 30 m in length(100-ft hallway), the length of the corridor being marked every 3 m. The beginning point and end of each 60-m lap was marked using a bright paint. Each test was given twice, with a 10– 15-minute interval between the two. The Spo2, pulse and BP were recorded before the 6MWT and procedure were explained to the patient. During the test, the patient was instructed to walk at his own pace as possible for six minutes and to decrease speed or interrupt the test if experiencing severe dyspnoea or any other limiting discomfort. The examiner gave patients verbal encouragement once per minute using

standard motivational phrases intended to ensure that patients walked at his own pace throughout the test.The post-walk Borg dyspnea and fatigue levels, SpO2 and pulse rate, the number of laps and the additional distance covered (the number of meters in the final partial lap) using the markers on the wall as distance guides, the total distance walked, rounding to the nearest meter was recorded. Walking test was performed as per ATS 2002 Guidelines.(20)

Significant change.
Minimal Important Difference (MID) has been described as 54 meters (Redelmeier 1997)(21)(22).

BORG DYSPNEA SCALE
Borg dyspnea scale was used to grade dyspnea during the six-minute walk test, Significant change
The recommended minimally clinically important difference (MCID) is 1 unit for the BORG scale. We considered the same difference for significant change.(23)

Health-related Quality of life(HRQL)

HRQL was evaluated by a validated Hindi translation of the St. George's Respiratory Questionnaire (SGRQ) obtained from the St. George's, University of London , London SW17 0RE , UK, which is specifically designed for respiratory disease (Jones et al 1992). It is a self-administered questionnaire.The SGRQ is a 76-weighted-item self-administered questionnaire, in which results are expressed for symptoms, activity, impacts on daily life, and an integrated total score. 'SGRQ Calculator' was used to calculate the three SGRQ component scores and the Total score. The data entry was done according to the instructions given in the St George's respiratory questionnaire manual.

Analysis

The primary outcome measures were changes in the SGRQ total scores after 6 weeks. Secondary outcome measures were changes in walking distance at the same times and change in BORG index.

Values before the pulmonary rehabilitation program were compared with their respective values 6 weeks afterwards. All data are reported as means ± standard deviation (S.D.) and $p < 0.05$ was accepted as indicating a significant change. Statistical analysis was performed using an SPSS software. An unpaired t-test was done of the difference between the baseline measurement and the measurement at 6 weeks, and 95% confidence intervals (CIs) were constructed for the difference between the mean changes in each of the two groups. In addition, paired t-tests were performed within each group to assess whether changes from baseline had occurred.

Student's "t" test was applied to find out the significance of the difference in mean between two variables.

III. Results:

Forty-five patients in the active group completed the study, 3 patients did not turn up for initial evaluation, and 2 patients attended only two initial sessions. The reason for dropping out was non-medical (difficulty in commuting to the hospital)

Forty-four patients in the control group completed the study, 4 patients did not turn up for initial evaluation, and 1 patient was lost to follow up reason being non-medical (difficulty in commuting to the hospital), 1 patient had moved out to his sons place, working in another state and was not available for final evaluation

Dropouts were not considered for final analysis of the study.

More than 90 % of patients were smokers with a smoking history of 20-60 pack years emphasizing the fact that tobacco smoking is the most potent risk factor resulting in the development of COPD.

More than 90% of patients were suffering from moderate to severe COPD highlighting the fact that patients seek medical care late when they become breathless on exertion.

The mean FEV1 was 51.93%(±14.09)in the active group versus 49.27(±13.34) in the control group; the mean FVC was 83.71%(±15.30) in the active group versus 80.8%(±12.9) in the control group. There was no significant difference in sex distribution, age, or spirometry measures between the two groups. The groups were well matched for SGRQ scores and walking distances on study entry.

Quality of life measures

The SGRQ integrate total scores for the active group were 65.80(±6.47) at the study entry ($n = 45$). At 6 weeks, the mean SGRQ total score was 52.09(±6.74). This was significantly different from baseline ($p< 0.05$, paired t-test) with a mean reduction of total scores of 13.71.

The SGRQ integrated total scores for the control group were 66.67(±6.76) at study entry(N=44) and 65.35 (±6.66) at 6 weeks (end of the study). For the control group, there were no significant differences over the 6-week study period in scores for symptoms, impacts on daily life, activity, or integrated total scores.

The changes from baseline in SGRQ total score at 6 weeks were compared between the active and control groups: the mean difference was a reduction of 12.39 in favour of the active group ($p < 0.05$).

The analysis of the components of the total SGRQ, namely symptom score, activity score, and impact on daily living score revealed significant reductions in all three components in the active group ($p < 0.05$), and that the change in total scores could not be attributed principally to a change in any one component.

Six-minute walk distance

There was a mean increase of more than 54 m (a significant increase; Redelmeier et al 1997) i.e. a mean increase of 66.38 meters(CI 55.36 to 77.4) from baseline in the active group after 6 weeks of pulmonary rehabilitation. which was significantly greater than the mean change in the control group ($p < 0.05$)

It was observed that oxygen saturation at rest did not improve significantly from baseline with or without pulmonary rehabilitation. On the other hand, mMRC grade of dyspnea was significantly decreased after six weeks of pulmonary rehabilitation and showed no improvement after six weeks of standard COPD treatment. This was also observed in previous studies like Barakat et al.(24)Sanjay Shetty et al.(25)

Pulmonary function

There was no significant change in any of the parameters of the pulmonary function, neither within the active group nor within the control group.

BORG DYSPNEA

There was a significant decrease of 3.25 points (from 6.9 to 3.65) in the BORG Dyspnea Scale in the active group which received rehabilitation, whereas no change was seen in the control group.

IV. Discussion

The present study was conducted with an aim to know whether outpatient pulmonary rehabilitation program is effective in a resource-limited setting.

In this study we evaluated the effects of an outpatient pulmonary rehabilitation program in a resource-limited setting. The study was designed to improve the exercise capacity, the quality of life in patients with COPD using 6MWT and SGRQ respectively, the study was also aimed at evaluating the effect on the mortality rate using BODE index.

The duration of pulmonary rehabilitation is quite variable in different studies. Joint ACCP/AACVPR Evidence-Based Clinical Practice Guidelines states six to twelve weeks of pulmonary rehabilitation produces benefits in several outcomes suggesting that positive effect is apparent as early as six weeks after beginning of the program.

Spirometric values i.e FEV1 and FVC were also compared between the two study groups. Six weeks of pulmonary rehabilitation could not confer an advantage in terms of improvement in lung function characteristics. This observation is also supported by various other studies Nobuaki Miyahara et al.89, Barakat et al.(24) David Stav et al.(26), Andrew Reis et al.(27), Aman Pande et al.(28)Virendra Singh et al.(29)Sindhwani G et al.(30).

In the active group, at the end of six weeks, there was a significant improvement in the 6MWD and a significant reduction in SGRQ score as compared to the baseline values, also there was a significant improvement in BODE index.

It was observed that oxygen saturation at rest did not improve significantly from baseline with or without pulmonary rehabilitation. On the other hand mMRC grade of dyspnea was significantly decreased after six weeks of pulmonary rehabilitation and showed no improvement after six weeks of standard COPD treatment. This was also observed in previous studies like Barakat et al(24), Sanjay Shetty et al(25)Six Minute walk distance was measured at the beginning and at the of PR. The minimal clinically important change of 6MWD has been estimated to be 54 meters .In the present study, we found that the mean 6MWD in the patients who underwent PR at the end of six weeks increased by 66.38 meters(CI 55.36 to 77.4). This improvement is clinically and stastically significant. Patients in all stages of COPD had significant improvement in their 6MWD. Therefore this improvement was found to be independent of stage of COPD.No significant change improvement could be observed in 6MWT variables in patients of the control group. This improvement in 6MWD for the rehabilitation group agrees with several earlier studies Nobuoki Miyahara et al.(31)Finnerty et al.(32)Bendstrup et al.(33)Barakat et al.(24), Wijkstra P J et al.(34), Cambach W et al.(35), Bouveri et al.(36),David Verill et al.(37),Aman Pande et al.(28), Virendra Singh et al.(29), Sindhwani G et al.(30).

Our study results showed an increase of more than 54 meters on the 6MWD in 67% of the subjects who underwent PR programme. Study by BARAKATH found an increase of at least 54 meters in the 6MWD in 64% of the patients who underwent PR . The clinical relevance of the benefit of pulmonary rehabilitation is

illustrated by improved functional capacity as measured by six-minute walk test. The improvement in the 6MWD in the study group could be due to reconditioning and retraining of the respiratory and skeletal muscle groups. Recent studies have shown that training can raise the anaerobic threshold of the musculature in these patients.(38) It lowers their ventilatory requirement and blood lactate levels leading to better functional capacity.(39) However, aerobic physical conditioning does not modify lung function,(40)Thus, we presume that these mechanisms may hold true in this study.

Other variables of 6MWT like BORG dyspnea also improved significantly from baseline after 6 weeks of pulmonary rehabilitation Nobuaki Miyahara et al have also reported a significant improvement in their study.

There are several different instruments for measuring Health-related quality of life in patients of COPD, of which the CRQ and the SGRQ have been demonstrated to be reproducible, valid and responsive. The SGRQ has the advantage of being standardized and validated questionnaire (the Hindi language is also validated- Ashutosh N Aggarwal et al.(41)allowing comparison between studies and different interventions, hence it was chosen in our study. We have observed that the mean improvement in SGRQ integrated total score was 13.71(CI 10.9 to 16.47) in patients receiving 6 weeks of the pulmonary rehabilitation programme. A sub-analysis of the components of the total SGRQ namely symptom score, activity score and impact on daily living score also revealed a significant reduction in patients receiving pulmonary rehabilitation suggesting that the change in the total SGRQ score could not be attributed to any single component. However, the changes in the total SGRQ score and its components were not statistically significant from baseline in the control group. A similar observation has also been reported by Finnerty et al.(32), Barakat et al.(24), Griffiths et al.(42)

There was a statistically significant improvement in exercise capacity, quality of living and also BODE index which suggests us that pulmonary rehabilitation should be offered outright at the diagnosis of COPD and the same effect can be obtained in resource limited settings utilizing the simple exercises and techniques instead of costly equipments.

V. Conclusion

Even though there have been significant advances in the understanding of the management of COPD, it is now widely conceptualized that COPD is a disease with significant systemic consequences, should be managed more comprehensively. In this regard, pulmonary rehabilitation is an effective option for the treatment of COPD. Yet there are obstacles in the implementation of the pulmonary rehabilitation program in resource-poor settings apart from illiteracy, ignorance, dependency on drug treatment and smoking being taken as social custom.

In the present study, we designed a simple pulmonary rehabilitation program with minimal resources not requiring sophisticated equipment and incorporating simple exercise technique.

In conclusion, the present study demonstrated that a 6-week program of outpatient based pulmonary rehabilitation even done with limited resource without sophisticated equipment can achieve a clinically significant improvement in patients quality of life and functional capacity in patients with COPD.

TABLE
BASELINE CHARACTERISTICS FOR ACTIVE AND CONTROL GROUPS AFTER EXCLUDING THE DROPOUTS

	ACTIVE(n=45)	CONTROL(n=44)	P value
AGE(Years)	59.17(±8.65)	60.11(±9.56)	>0.6
SMOKING pack years	40.49(±13.98)	43.35(±14.42)	>0.3
mMRC	2.42(±0.49)	2.52(±0.54)	>0.3
BMI (Kg/m^2)	19.93(±1.85)	20.09(±1.87)	>0.6
SPO2 REST(%)	97.8(±1.25)	97.7(±1.08)	>0.6
FEV1			
Liters	1.19(±0.37)	1.12(±0.40)	>0.3
% PRED	51.93(±14.09)	49.27(±13.34)	>0.3
FVC			
Liters	2.53(±0.51)	2.41(±0.51)	>0.2
% PRED	83.71(±15.30)	80.8(±12.9)	>0.3

TABLE
BASELINE 6MWT AND SGRQ VARIABLES FOR ACTIVE AND CONTROL GROUPS

	PARAMETERS	ACTIVE(n=45)	CONTROL(n=44)	P value
1.	**6 MWT**			
	6MWD(meters)	300.7(±24.89)	292.1(±24.5)	>0.1
	BORG	6.90(±1.21)	6.5(±1.30)	>0.1
	SPO2 %	92.06(±2.09)	92.77(±2.16)	>0.1

2.	**SGRQ SCORE**			
	SYMPTOMSCORE	67.9(±7.4)	69.31(±8.85)	>0.4
	ACTIVITYSCORE	59(±8.16)	60.23(±8.17)	>0.4
	IMPACTON DAILY LIVING SCORE	69.02(±6.86)	69.53(±6.44)	>0.7
	TOTAL INTEGRATEDSCORE	65.80(±6.47)	66.67(±6.76)	>0.5

TABLE
SGRQ SCORES FOR THE CONTROL GROUP (N=44)

PARAMETERS	INITIAL	FINAL (>6 WEEKS)	DIFFERENCE OF MEAN	P VALUE
SYMPTOM SCORE	69.31(±8.85)	65.46(±10.99)	-3.85	>0.07
ACTIVITY SCORE	60.23(±8.17)	59.42(±8.43)	-0.81	>0.6
IMPACT ON DAILY LIVING SCORE	69.53(±6.44)	68.71(±6.04)	-0.82	>0.5
TOTAL INTEGRATED SCORE	66.67(±6.76)	65.35(±6.66)	-1.32	>0.3

all values are mean(±SD)

TABLE
SGRQ SCORES FOR THE ACTIVE GROUP (N=45)

PARAMETERS	INITIAL	FINAL (6WEEKS)	DIFFERENCE OF MEAN	P VALUE
SYMPTOM SCORE	67.9 (±7.4)	53.07 (±11.94)	-14.83	<0.001
ACTIVITY SCORE	59.00 (±8.16)	44.71 (±7.61)	-14.29	<0.001
IMPACT ON DAILY LIVING SCORE	69.02 (±6.86)	56.00 (±6.52)	-13.02	<0.001
TOTAL INTEGRATED SCORE	65.80 (±6.47)	52.09 (±6.74)	-13.71	<0.001

all values are mean(±SD)

TABLE
6 MINUTE WALK TEST VALUES FOR THE CONTROL GROUP (N=44)

Parameter	Study entry	Final(>6 weeks)	Difference between mean	P value
6MWD (meters)	292.10(±24.5)	299(±24.7)	6.9	>0.2
SpO2 (%)	92.77(±2.16)	92.93(±2.16)	0.16	>0.7
BORG DYSPNEA SCALE	6.5(±1.30)	6.5(±1.30)	0	1

TABLE
6 MINUTE WALK TEST VALUES FOR THE ACTIVE GROUP (N=45)

Parameter	Study entry	Final(>6 weeks)	Difference between mean	P value
6MWD (meters)	300.7(±24.89)	367.08(±27.64)	+66.38	<0.001
SpO2 (%)	92.06(±2.09)	93.77(±1.78)	+1.71	<0.001
BORG DYSPNEA SCALE	6.90 (±1.21)	3.65(±1.11)	-3.25	<0.001

all values are mean(±SD)

TABLE
Spirometry values for the control group (n=44)

Parameters		Initial	Final (6 weeks)	Difference between mean	P value
FEV_1	**Liters**	1.12 (±0.40)	1.15 (±0.39)	0.03	>0.7
	% predicted	49.27 (±13.34)	50.50 (± 13.1)	1.23	>0.7
FVC	**Liters**	2.41 (±0.51)	2.46 (±0.5)	0.05	>0.6

	% predicted	80.8 (±12.9)	83.18 (±12.61)	2.38	>0.4

all values are mean(±SD)

TABLE
Spirometry values for the active group (n=45)

Parameters		**Study entry**	**Final(6 weeks)**	**Difference between mean**	**P value**
FEV_1	**Liters**	1.19 (±0.37)	1.24 (±0.38)	+0.05	>0.5
	% predicted	51.93 (±14.09)	53.7 (±14.3)	+1.77	>0.5
FVC	**Liters**	2.53 (±0.51)	2.62 (±0.48)	+0.09	>0.4
	% predicted	83.71 (±15.30)	86.68 (±14.98)	+2.9	>0.3

all values are mean(±SD)

TABLE
COMPARISON OF CHANGE IN PARAMETERS FROM BASELINE BETWEEN ACTIVE GROUP(N=45) AND CONTROL GROUP(N=44)

		Change from baseline		**difference of mean**	**p value**
Parameter		**active group**	**control group**		
mMRC dyspnea scale		0.47(±0.50)	0.00(±0.00)	0.47	<0.0001
FEV_1	**Liters**	0.05 (±0.07)	0.03 (±0.05)	0.02	>0.1
	% predicted	1.77 (±3.15)	1.23 (±2.7)	0.54	>0.3
FVC	**Liters**	0.09 (±0.13)	0.05 (±0.05)	0.04	>0.05
	% predicted	2.9 (±5.44)	2.38 (±3.30)	0.52	>0.05
6 MWT					
6mwd (meters)		66.38(±9.05)	6.9(±4.60)	59.481	<0.001
Borg scale of dyspnea		3.25(±1.01)	0.00(±0.00)	3.25	<0.0001
Oxygen Saturation %		1.71(±1.04)	0.16(±0.48)	1.55	<0.001
SGRQ SCORES					
Symptom score		14.83(±8.60)	03.85(±4.75)	10.98	<0.001
Activity score		14.29(±4.74)	0.81(±3.012)	13.48	<0.001
impact on daily living score		13.02(±3.74)	0.82(±1.55)	12.20	<0.001
Total integrated score		13.71(±2.54)	1.32(±1.44)	12.39	<0.001

all values are mean(±SD)

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