



Research Paper

Assessment of Quality of life in Home versus Hospital Based Pulmonary Rehabilitation in COPD Patients: A Comparative Study

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Abstract

Background and Objectives: Chronic obstructive pulmonary disease (COPD) is characterized by limitation in airflow which is an incompletely reversible and is a 3rd leading cause of death worldwide 2020. Pulmonary rehabilitation has been shown to be effective therapeutic strategy to improve quality of life, Health status and exercise intolerance. Evidence indicates that benefits of home rehabilitation are on par with hospital based in western studies, with limited data on Indian population. Hence the current study has undertaken to correlate home PR with hospital PR under by using St. George Respiratory Questionnaire and BODE index

Materials and Methods: Prospective, randomized controlled study with 112 subjects were randomized to two groups to receive hospital or home pulmonary rehabilitation and were followed up for 3months (every week in hospital group and once in every 2weeks in home group). Anthropometric variables assessed by body-mass index, airflow limitation was assessed by spirometry, degree of dyspnea was assessed by Modified Medical Research Council (mMRC) scale and exercise tolerance was assessed by six-minute walk test (6MWT). Statistical analysis done by SPSS software IBMS version 22.

Results: 56 subjects were allocated in each group with mean age group 61.43 ± 7.26 and 64.04 ± 8.56 years in hospital and home group respectively and both study groups were matched in age, anthropometry, smoking status, and comorbidities. The mean baseline and post rehabilitation BODE index in Hospital group are 5.6 ± 2 and 4.5 ± 2 respectively with a mean difference of 1.5 ± 1.3 which is statistically significant. The mean baseline and post rehabilitation BODE index in home-based PR group are 4.6 ± 2 and 3.3 ± 2 respectively, with a mean difference of 1.3 ± 0.6 in home group which is statistically significant. The mean total score (SGRQ) at baseline was 45.87 ± 3.53 and 45.64 ± 2.97 in Hospital and Home group respectively. The mean total score at 12th week was 35.89 ± 6.4 and 38.58 ± 8.74 in Hospital and Home group respectively. The difference in scores of SGRQ at baseline and post rehabilitation between home and hospital groups was statistically not significant (P value >0.05), thus shows similar improvement in both study groups. However, attrition rate is more in Home-based group compared to Hospital-based group.

Conclusion: The outcomes of PR are between Home and Hospital Groups are comparable. The attrition rate is more in home-based PR group with lack of family support being important cause to poor adherence to PR. All COPD patients should be encouraged to utilize the healthcare facilities to undergo pulmonary Rehabilitation for improving their quality of life.

Introduction

Chronic obstructive pulmonary disease (COPD) is a major cause of chronic respiratory disorders with increased morbidity and mortality worldwide¹. COPD is the 4th leading cause of mortality and it is estimated to be the 3rd leading cause of death by 2020. India has a significant contribution to mortality from chronic obstructive pulmonary disease. The total DALYs contributing to Chronic respiratory disorders increased from 4.55(1990) to 6.4% (2016)². India contributed to the 32% of the total DALYs globally in 2016. During 2016, COPD accounts for the 75.6% of all chronic respiratory disease DALYs in India. The number of cases of COPD in increased from 28.1 million (1990) to 55.3 million (2016), with an increase in prevalence from 3.3% to 4.2%⁽²⁾. The prevalence of COPD in India is 5 percent and 2.7 percent in males and female's population respectively in 30 years age and above³.

COPD is a major health burden with increasing impact on cost of the health care worldwide⁵. COPD is characterized by limitation in the airflow which not completely reversible⁶. In most cases, the limitation of the airflow in COPD is progressive and shows an elevated inflammatory response of the airways to gases and harmful particles⁶. This gradual and continuous loss of lung function leads to emphysema due to the narrowing of small airways and destruction of lung parenchyma caused by chronic inflammation. Pulmonary rehabilitation is an important component of nonpharmacological therapy that has evolved as a standard adjunctive care for chronic obstructive pulmonary disease⁵. It is a comprehensive, multidisciplinary, patient-tailored intervention that includes patient assessment, exercise training, self-management education, and psychosocial support. Pulmonary rehabilitation has been clearly demonstrated to reduce dyspnea, increase exercise capacity, and improve quality of life in individuals with COPD

“*Pulmonary rehabilitation* is defined as a comprehensive intervention based on a thorough

patient assessment followed by patient tailored therapies that include, but are not limited to, exercise training, education, and behavior change, designed to improve the physical and psychological condition of people with chronic respiratory disease and to promote the long-term adherence to health-enhancing behaviors”⁷

The literature shows the effects of home-based pulmonary rehabilitation is on par with Hospital based /community-based rehabilitation programmes. In view of the limited evidence in effectiveness of home-based PR in relation to Hospital based PR, especially in Indian ethnic population. Hence the present study is undertaken to compare the outcomes of home based and hospital based pulmonary rehabilitation among COPD patients

Materials and Methods

This study was a prospective, randomized control study conducted in the Department of Respiratory Medicine, Chettinad hospital and Research institute Tamilnadu, India. We included 112 stable COPD as our study sample size. In the study population COPD was diagnosed based on GOLD guidelines and subjects were categorized with disease severity based on spirometry. The study was conducted after obtaining approval from institutional Ethical Committee and after obtaining informed and written consent from the subjects.

Inclusion Criteria: All inpatient and outpatient subjects in the age group of 40-80 years including both genders. patients diagnosed with COPD as per the GOLD guidelines 2018 and patients who are willing to participate in Pulmonary rehabilitation program and willing to come for follow up

Exclusion Criteria: Subjects with acute exacerbation of COPD. Subjects with Severe orthopedic or neurological disorders limiting their mobility, Severe pulmonary arterial hypertension, Unstable angina or Recent MI, patients who are not willing for follow up during the course of program.

During first 2weeks of initiation of the program, all subjects were also given instructions on respiratory and physical exercises, which needs to be performed during outpatient/inpatient visits to the hospital. Subjects are divided randomly into two groups, i.e., hospital based and home-based pulmonary rehabilitation groups after obtaining informed consent. Baseline and follow up parameters as regards Quality of life (SGRQ), BODE index and spirometry were assessed for the both groups. PR was done under the supervision of the physician with trained respiratory therapists.

Home-based program subjects visited the hospital for follow up every 15days for 12 weeks. Subjects were advised to continue the PR at home for a minimum of 30minutes and at least thrice in a week.

Subjects in Hospital-based PR program were followed up every week for 12 weeks. Subjects were continued the PR in home every day for minimum of 30min for at least thrice in a week.

Subjects from both groups were followed up over mobile based communications once a week throughout the rehabilitation programme

Data Collection Tools

St. George Respiratory questionnaire

Health Related Quality of Life (HRQL) of participants was assessed by using St. George Respiratory Questionnaire (SGRQ). This questionnaire is a tool for evaluating the patient's perception of symptoms of their respiratory impairment. In our study Tamil, Telegu and English versions of SGRQ was used in our study. The SGRQ was designed to measure health related quality of life in patients with COPD

The questionnaire has been divided in to two parts.

Part I is designed to assess the Symptoms score, while part II is designed to evaluate the Activity and Impacts scores. Total score is also generated.

Part 1 was used to assess the participant's perception of symptoms over the duration of past

12 months. Part 2 of the questionnaire assess the patient's functional status of respiratory system. The Activity score measures the limitations in routine physical activities of the patients.

The Impacts score designed to measure the disturbances in psychological and sociological functions. It has been shown that Impact score relates not only to respiratory symptoms, but also correlates strongly with exercise tolerance as measured by 6minute walking test, degree of perception dyspnea as measured by modified Medical Council Research (mMRC) scale. Therefore, the Impacts score is the most essential component of the questionnaire that covers a wide range of disturbances experienced in their daily lives by respiratory patients.

This questionnaire has been interpreted by using excel based SGRQ calculator provided by University of London. It generates four scores i.e., Symptom score, Activity score, Impact Score ant Total score. The Total score denotes the impact of COPD patient on the overall status of health. It is expressed as a percentage. The increase I the total score implicates the worsening of HRQOL and overall health status. A total score 100 denotes lowest possible health status whereas a total score of 0 denotes highest possible health status. That is, as the SGRQ score increases, the HRQL of patient worsens.

BODE Index

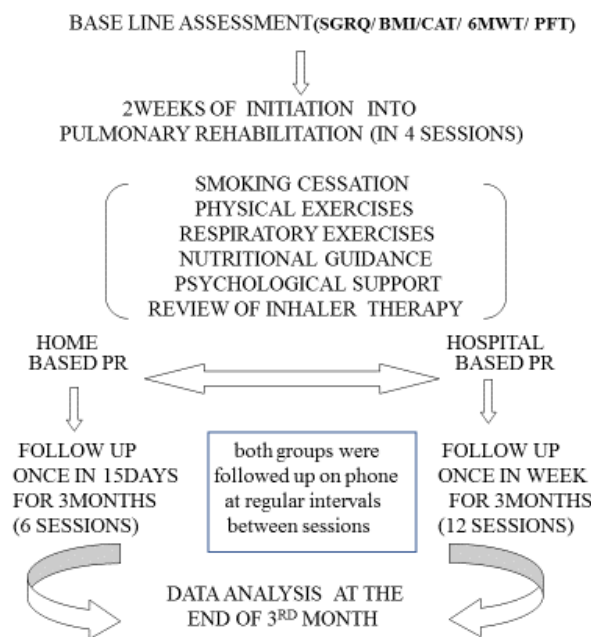
BODE Index is multidimensional grading system and has been used increasingly for the evaluation of outcome of treatment in COPD patients. It includes 4 components i.e., Anthropometric variables assessed by body-mass index, airflow limitation as assessed by spirometry, degree of dyspnea was assessed by Modified Medical Research Council (mMRC) scale and exercise tolerance was assessed by six-minute walk test(6MWT)

SCORING FOR THE COMPONENTS OF THE BODE INDEX:

Parameter	Points on BODE Index			
	0	1	2	3
Body mass index (kg/m ²)	> 21	≤ 21	-	-
FEV ₁ (% predicted)	≥ 65	50-64	36-49	≤ 35
6 minute walking distance (m)	≥ 350	250-349	150-249	≤ 149
MMRC dyspnea scale (score)	0-1	2	3	4

BODE groups are classified as: 1-2 points: BODE 0; 3-4 points: BODE 1; 4-6 points: BODE 2; 7-10 points: BODE 3.

Figure: Study Design



Statistical Analysis

Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. For Quantitative parameters the mean values were compared between study groups using Independent sample t-test (2 groups) / ANOVA (>2 groups). The change in the quantitative parameters, before and after the intervention was assessed by paired t-test (In case

of two time periods) or one-way repeated measures ANOVA (In case of comparison across more than 2 time periods). P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis.

Results

A total of 112 patients were enrolled in the study and categorized into two arms with 56 subjects in each group. Among hospital group 7 (12.5%) were

aged 40 to 50 years, 15 (26.79%) were aged 51 to 60 years, 27 (48.21%) were aged 61 to 70 years, 7 (12.5%) were aged >70 years. Among home group 3 (5.36%) were aged 40 to 50 years, 18 (32.14%) were aged 51 to 60 years, 23 (41.07%) were aged 61 to 70 years, 12 (21.43%) were aged >70 years. The difference in the proportion of age group between two groups was statistically not significant. (P value 0.320).

In this study there is a male preponderance with a 75.89% of male subjects in the total study population. Among hospital group 83.93% (47) were males, 16.07% (9) were females. In home group 67.86% (38) were males and 32.14% (18) were females.

Majority of the participants were underweighted in both Home and hospital groups. There are 39.83% (22) and 49.8% (29) subjects were underweight in hospital and homegroups respectively. 7.14% subjects with overweight in both groups. 5.35% & 1.7% were obese in hospital and home groups respectively.

Severity of the diseased assessed based on GOLD guidelines. Majority of the study population were having Moderate to severe COPD. Among study population 50.89% of subjects had Moderate disease, 37.51% had Severe disease and 11.60% had Very Severe disease.

Table 2: Comparison of mMRC at different follow up periods between Home and Hospital groups

Time periods	Group		Two-way repeated measures ANOVA	
	Hospital group	Home group	F value	P value
Baseline	2.77±0.42	2.56±0.50	17.308	<0.001
12 th week	1.19±0.39	1.44±0.50		

The above table shows comparison of mMRC from baseline to the end of 12th week between Home and Hospital based PR groups. In home group, mMRC at baseline was 2.56, while at the end of 12th week it was 1.44. In Hospital group, the baseline mMRC was 2.77 and at the end of

12th week it was 1.19. The mean difference between the study groups was statistically significant, thus mMRC shows better improvement in Hospital group in comparison to home-based group.

Table 3: Comparison for the 6MWT baseline and 12th week between the study groups

Time periods	Group		Two-way repeated measures ANOVA	
	Hospital	Home	F value	P value
Baseline	298.70±31.25	334.07±51.0	27.02	<0.001*
12 th week	411.44±30.7	384.30±27.34		

The mean 6MWT baseline in hospital group was 298.70±31.25, it was 334.07±51.0 in home group. The mean 6MWT 12th week follow up in hospital group was 411.44±30.7, it was 384.30±27.34 in

home group. The difference in 6MWT at different follow up periods between two groups was statistically significant.

Table 4: Comparison of symptom score (SGRQ) between Home and Hospital groups

Symptoms score	Group		P value
	Hospital (Mean± SD)	Home (Mean± SD)	
Baseline	53.01 ± 4.2	52.2 ± 3.89	0.294
12 th week	45.93 ± 4.68	42.7 ± 4.33	0.097

The mean symptoms score baseline in hospital group was 53.01 ± 4.2, it was 52.2 ± 3.89 in home group. The mean symptoms score post op in hospital group was 45.93 ± 4.68, it was 42.7 ±

4.33 in home group. The difference in symptoms score baseline between two groups was statistically not significant.

Figure 2: Comparison of mean of symptoms score between the study groups

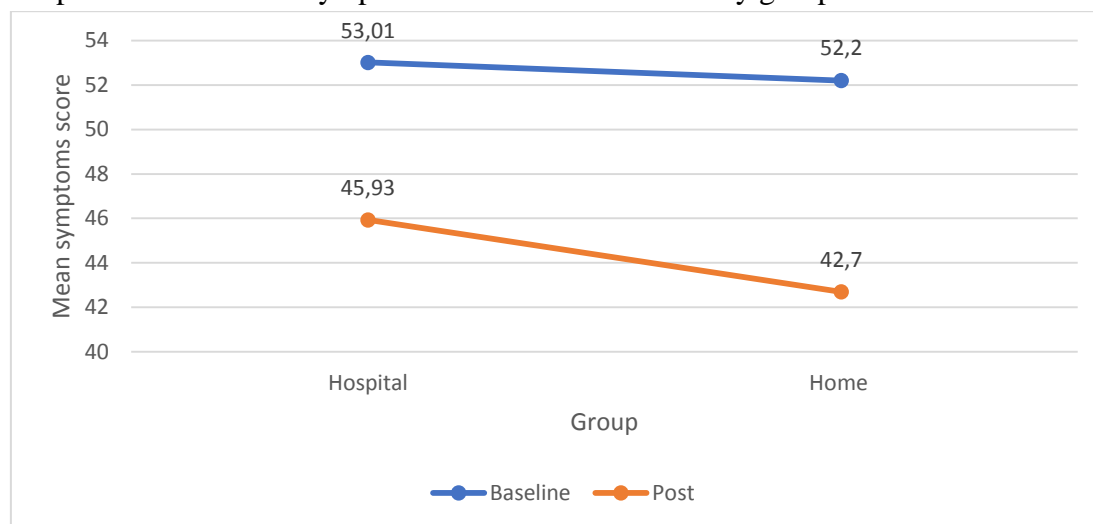


Table 5: Comparison of Activity score (SGRQ) between Home and Hospital groups

Activity score	Group		P value
	Hospital (Mean± SD)	Home (Mean± SD)	
Baseline	50.5 ± 6.04	50.18 ± 5.5	0.770
12 th week	41.05 ± 6.94	41.5 ± 9.1	0.790

The mean activity score baseline in hospital group was 50.5 ± 6.04, it was 50.18 ± 5.5 in home group. The mean activity score post op in hospital group was 41.05 ± 6.94, it was 41.5 ± 9.1 in home

group. The difference in activity score baseline and post activity score between two groups was statistically not significant (P value >0.05).

Table 6: Comparison of Impact score (SGRQ) between Home and Hospital groups

Parameter	Group		P value
	Hospital (Mean± SD)	Home (Mean± SD)	
Baseline	41.3 ± 6.16	42.68 ± 6.27	0.244
12 th week	30.21 ± 9.56	32.42 ± 8.41	0.241

The mean impact score baseline in hospital group was 41.3 ± 6.16, it was 42.68 ± 6.27 in home group. The mean impact score post op in hospital group was 30.21 ± 9.56, it was 32.42 ± 8.41 in

home group. The difference in impact score baseline and post impact score between two groups was statistically not significant. (P value >0.05).

Table 7: Comparison of mean of total score (SGRQ) between Home and Hospital groups

Parameter	Group		P value
	Hospital (Mean± SD)	Home (Mean± SD)	
Baseline	45.87 ± 3.53	45.64 ± 2.97	0.704
12 th week	35.89 ± 6.4	38.58 ± 8.74	0.088

The mean total score baseline in hospital group was 45.87 ± 3.53, it was 45.64 ± 2.97 in home group. The mean total score post op in hospital group was 35.89 ± 6.4, it was 38.58 ± 8.74 in

home group. The difference in total score baseline and post total score between two groups was statistically not significant. (P value >0.05).

Comparison of BODE index with severity of COPD

Table 8: Comparison of BODE index in relation to the severity of COPD in Hospital group

S.NO	GOLD STAGE	Mean BODE at Baseline	Mean BODE at 12thweek	P value
1	Moderate obstruction	2.5	1.12	<0.001*
2	Severe obstruction	6.83	5.66	
3	Very Severe obstruction	8.5	8.5	

In Hospital based group the Mean Pre & Post BODE are 5.6 ± 2 and 4.5 ± 2 respectively. As the severity of the disease increases the scores

increase. The mean difference in Post BODE Index was 1.5 ± 1.3 with statistical significance (P Value < 0.001)

Table 9: comparison of BODE index in relation to the severity of COPD in Home group

GOLD STAGE	Mean BODE at baseline	Mean BODE at 12thweek	P value
Moderate	2.54	1.18	<0.001*
Severe	7.16	5.5	
Very Severe	8.5	8.5	

Pre & Post mean of BODE in home group are 4.6 ± 2 and 3.3 ± 2 . The difference in the mean of Post BODE Index was 1.3 ± 0.6 with statistical significance

The BODE index has decreased in both groups in post rehabilitation in moderate to severe COPD

Among study population 16.7% of them dropped out of program during follow up. In this study more dropout rate observed in Home based group (12.06%) compared to Hospital group (4.63%). In our study nearly 72.3% of the dropouts were attributed their reason to lost to follow up as lack of family support. 55.6% pointed out financial instability. Physical inability was a factor in 44.5% of participants. 22.3% of them had occupation related issues as their reason for poor adherence to rehabilitation program.

Discussion

Chronic obstructive pulmonary disease is the 2nd leading cause of morbidity and mortality in India. Pulmonary rehabilitation is a comprehensive and multidisciplinary program designed for the patients with chronic respiratory diseases with a patient tailored approach and to optimize physical and psychosocial condition and improve quality of life. In our country the sources of pulmonary rehabilitation program are underutilized and are

limited to tertiary care centers. The current study was undertaken to focus on efficacy and outcomes of home-based pulmonary rehabilitation in relation to hospital-based PR program.

A total of 112 subjects were included in the study and were randomized to receive hospital and home-based rehabilitation. Among study population, patients were matched according to age, sex, BMI, anthropometric parameters, smoking status and co-morbidities. Majority of the participants are over 60 years with male preponderance in both the groups. According to Jenkins¹², there are barriers between the evaluation of risk for COPD among men and women, in terms of diagnosis, prognosis, and management of the disease. Even though most of the women population are nonsmokers, they are often exposed to Biomass fuel and other indoor and outdoor environment pollutants¹³. Exposure to biomass fuels is probably the leading cause of COPD in younger women^{13,14}.

Most of the subjects were underweight in this study. 50% of them were underweight in Home group and 39.83% are underweight in hospital-based group with and 5.35% & 1.7% are obese in hospital and home groups respectively.

Severity of COPD measured based on GOLD guidelines. In the overall study population, 40% of

them had severe COPD, 11.6% had very severe COPD and 54.12% participants had moderate COPD. Majority of subjects in the study population were having moderate and severe COPD

Exercise tolerance was assessed by the distance walked by subjects in six minutes duration. The outcomes of 6MWT at different follow up periods between study groups within group was statistically significant with better improvement in hospital group (P value <0.001). Post pulmonary rehabilitation there is a statistically and clinically significant improvement in exercise tolerance as measured by the distance walked in six minutes in both study groups. Post rehabilitation Mean 6MWD increased despite severity of COPD. In an outpatient-based PR study conducted by *Shahin Barakat et al*⁽¹⁷⁾ showed remarkable improvement in a mean 6MWD of more than 54 min the study group after 14 weeks of PR course, which was statistically significantly greater than the mean change in the control group. In another hospital-based study done by Renata Cláudia Zanchet et al¹⁸, in South America, there was significant improvement in the 6MWT (pre-PR = 513 ± 99 m and post PR = 570 ± 104 m) post rehabilitation. In a home-based PR study conducted *Shaik et al*⁽²⁰⁾ in Coastal Andhra showed significant improvement in the 6MWT between pre and post rehabilitation following an eight-week PR program. Virendra singh et al⁽¹⁹⁾ conducted rehabilitation program in north India showed a statistically significant improvement in 6MWT following a 4weeks of pulmonary rehabilitation. In the study held by Oliveira et al,⁽⁴⁶⁾ found that the difference in the distance walked in meters as measured by 6MWT following PR program was statistically significant in both the outpatient and home-based groups. in an Egyptian study conducted by Elkhateeb et al,⁽²¹⁾ demonstrated a statistically significant improvement in BODE score (including distance walked in meters in 6 minutes) following an eight weeks pulmonary rehabilitation program. In a study done by Cote et al,⁽²³⁾ in North America, showed that post

rehabilitation improves 6MWT and was associated with significant outcomes.

Health related quality of life is measured by using St. George Respiratory Questionnaire which includes four components i.e. symptom score, activity score, impact score and total score. The mean total score baseline in hospital group was 45.87, it was 45.64 in home group. The mean total score post Rehabilitation in hospital group was 35.89, it was 38.58 in home group. The difference in total score and activity score and impact scores and symptom scores at baseline and post rehabilitation between two groups was statistically not significant. The difference in the activity and total scores, impact score and activity scores in individual groups from baseline to post rehabilitation was statistically significant (P <0.05). Post pulmonary rehabilitation there is a statistically and clinically significant improvement in the health-related quality of life measured in terms of SGRQ Scores in outpatient and home based rehabilitation group. SGRQ scores improved despite COPD severity, however moderate and severe had better results when compared to very severe group. The study results correlated with analysis of *Shahin Barakat et al*,⁽¹⁷⁾ shown in his hospital based pulmonary rehabilitation study that there was a significant difference from baseline SGRQ Scores with a mean improvement in total scores to 12.8. following a 14 weeks of rehabilitation program. *Zanchet et al*¹⁸ conducted a center-based rehabilitation for comparison of pre and post pulmonary rehabilitation showed statistically significant improvement in total scores of SGRQ with baseline and post rehabilitation SGRQ scores of 46 ± 15% and 38 ± 15% following a six-week pulmonary rehabilitation programme.

Survival and mortality of COPD is predicted by BODE index. The higher the BODE, the more risk of mortality due to COPD and related cause. Mean Pre & Post BODE in Hospital and Homegroups showed significant reduction in the BODE index following rehabilitation which is statistically significant. *Shahin Barakat et al*¹⁷, found a

significant reduction in the score of BODE index following rehabilitation. Oliveira et al²⁵, in his outpatient-based study, showed that there was a significant reduction BODE index in the outpatient and at-home groups at the end of the 12-week period. *Elkhateeb et al*²¹, in outpatient-based PR course demonstrated a significant improvement in BODE score (P-value 0.001) following an 8weeks rehabilitation program. *Cote et al*²³, in his center based pulmonary rehabilitation study showed that post rehabilitation improves BODE and shows better results following rehabilitation

This study showed 16.7% of attrition rate among total study population. Out of which 4.63% lost to follow up in Hospital rehabilitation group and 12.06 % of them lost to follow up in Homebased rehabilitation group. The most common cause to poor adherence attributed to low socioeconomic status (42.74%) and lack of family support (31.96%). The other causes include physical instability (19.23%) and occupation related issues (6.03%). The subjects who lost to follow up has been contacted over phone at regular intervals and were continued PR in later follow ups, but they were excluded from study as per exclusion criteria. Fisher MJ et al conducted hospital-based rehabilitation study in which 23% of participants had not completed the PR course, of which nearly half of them were lost to follow up due to medical reasons such as Hospitalizations and exacerbations). Lost to follow up by study population cannot be predicted based on initial sociodemographic, psychological or clinical variables¹⁵.

Limitations of study

A limitation of our study is the small patient size is one the limitations of our study, but we believe that validity of our statistical results has not been undermined. Another significant limitation is the high percentage (16.7%) of patients were lost to follow up during program, specially more attrition rate observed in Home based PR group (12.06%).More number of withdrawals from the

home-based PR group attributes to lack of family support, physical instability and low socioeconomic status as the reasons for their poor adherence to rehabilitation program. The validity and reliability of the information regarding the optimal frequency and method of performance of the pulmonary rehabilitation techniques performed by patient at home is uncertain.

Conclusion

This study demonstrated that both home based and hospital based pulmonary rehabilitation can improve quality of life. But there is comparatively a more attrition rate in Home based group. Hence necessary steps should be taken to prevent dropouts, including Health education, family counselling and community-based support. All COPD patients should be encouraged to utilize the nearest available healthcare facilities to undergo pulmonary Rehabilitation for improving their quality of life.

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