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Original Research Article

The Efficacy of Oscillating Positive Expiratory Pressure (OPEP) Therapy in Patients with Bronchiectasis - A Prospective Study

Chandrasekar S.[1], Mohamed Musthafa A.[2], Laila K.V.[3], Rajagopal T. P.[4]

[1]Senior Resident, Department of Pulmonary Medicine, Government Medical College, Kozhikode, Kerala.
[2]Associate Professor, Department of Pulmonary Medicine, Government Medical College, Kozhikode, Kerala.
[3]Associate Professor, Department of Pharmacology, Government Medical College, Kozhikode, Kerala.
[4]Professor, Department of Pulmonary Medicine, Government Medical College, Manjeri, Kerala.

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Corresponding author: Dr. Laila K.V.
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Abstract

Background: A characteristic feature in bronchiectasis is the impairment in clearance of secretions leading to frequent colonization and recurrent infection with various pathogenic organisms. This results in a vicious cycle of purulent secretions, bronchial damage, bronchial dilation, and further impairment. Chest physiotherapy (CPT) with postural drainage is the standard treatment for mobilization and removal of airway secretions. Airway clearance can be augmented by use of devices such as oscillating positive expiratory pressure (OPEP) devices which combines positive expiratory pressure therapy with high frequency oscillations within the airways.

Objectives: To study the efficacy of Oscillating Positive Expiratory Pressure (OPEP) Therapy compared with Conventional Chest Physiotherapy (CCPT) in patients with bronchiectasis in reducing exacerbations, improving lung functions, quality of daily life activity and healthy status.

Methods: A Prospective cohort clinical study conducted in patients with bronchiectasis in a tertiary care setting for a period between February 2018 and July 2019.A total of 130 patients were randomized into two groups to receive either Oscillating Positive Expiratory Pressure (OPEP) therapy using Acapella device or conventional **c**hest physiotherapy in addition to regular pharmacotherapy**.** All patients were reassessed every 2 months. FEV1 was measured at the beginning of study, 4th month and at the end. Comfort, well-being and adherence were assessed in the two study groups using a 5-point Likert scale at the end of the study. The Statistical software SPSS 22.0, and R environment ver.3.2.2 were used for the analysis of the data.

Results: The number of exacerbations was significantly less in OPEP group compared to CCPT group and the onset of exacerbations was later in the former group. Health related quality of life, comfort and wellbeing showed improvement in OPEP group.

Conclusion: The relatively lower exacerbation rates and their later onset, improvement in health-related quality of life, comfort and wellbeing in patients performing OPEP therapy compared with CCPT supports the use of OPEP therapy for airway clearance than other conventional airway clearance techniques in patients with Bronchiectasis.

Keywords: Bronchiectasis, Chest physiotherapy.

Introduction

Bronchiectasis is a condition where the bronchi are abnormally and permanently dilated and is characterized by destruction of epithelial, elastic and muscular elements of the bronchi. The clinical manifestations include chronic cough with plenty of mucopurulent expectoration [1] Bronchiectasis primarily affects the medium-sized bronchi, but it may extend to the distal bronchi and bronchioles [2]. One of the characteristic features is severe impairment in clearance of secretions leading to frequent colonization and recurrent infection with various pathogenic organisms. This results in purulent expectoration and a vicious cycle of bronchial damage, bronchial dilation, and impaired clearance of secretions sets in [3].

Chest physiotherapy (CPT) with postural drainage is the standard treatment for mobilization and removal of airway secretions. Airway clearance can be augmented by use of devices such as oscillating positive expiratory pressure (OPEP) devices which combines positive expiratory pressure therapy with high frequency oscillations within the airways [4]. This allows more air to enter peripheral airways via collateral channels, and also to go behind secretions, moving them towards larger airways from where they can easily be expelled [5]. Such devices include the Flutter valve and Acapella device both having similar pressure flow characteristics [6]. Acute exacerbations are a major cause of morbidity in bronchiectasis and the measures to reduce frequency of exacerbations play a major role in treatment [7] [8]. Even though several studies have compared the effects of oscillating PEP therapy with other airway clearance techniques there is considerable variability in study findings so that the overall effect of oscillating PEP therapy remains unclear [9-11].

Objectives

To study the efficacy of Oscillating Positive Expiratory Pressure (OPEP) Therapy compared with Conventional Chest Physiotherapy (CCPT) in patients with bronchiectasis in reducing exacerbations, improving lung functions, quality of daily life activity and healthy status.

Materials and Methods

A Prospective cohort clinical study conducted in patients diagnosed with bronchiectasis in a tertiary care setting for a period between February 2018 and July 2019. The study was approved by the Institutional ethical committee. All adult patients diagnosed as having moderate to severe bronchiectasis based on Bronchiectasis severity Index [12] were included in the study after obtaining informed consent. Those with frank hemoptysis, hemodynamic instability, recent pneumothorax or myocardial infarction were excluded. Sample size was calculated based on the formula $n=(z\text{-alpha} + z\text{-beta})^2 \times S.D^2 \times 2 / d^2$. (z-alpha =1.96, z-beta=0.84, SD=1, mean(d)=0.5). According to this formula minimum number of 63 in each group was required.

After detailed history and clinical examination, baseline assessment was made. Grade of dyspnea according to modified MMRC scale, sputum quantity, smoking status, prior hospitalizations, antibiotic usage, available sputum culture reports were noted. Chest radiograph and

HRCT Thorax findings were recorded to assess radiological extent.

Patients who met inclusion criteria were randomly assigned into two groups. In addition to routine pharmacotherapy in all patients, those in Group 1 were instructed for regular home based Oscillating Positive Expiratory Pressure (OPEP) therapy using Acapella device and those in Group 2 were instructed for home based conventional chest physiotherapy (CCPT).

Patients in both groups were reassessed every 2 months to verify whether they follow the techniques as instructed. Patients were asked to maintain a diary to note down the number of times they performed the respective techniques each day and they were advised to report if there were any worsening of symptoms. Spirometry was done to measure FEV1 at the beginning of study, 4th month and at the end of 1 year. A monthly telephone call to all patients to encourage for good adherence was made. All patients were followed up for 1 year. Comfort, well-being and adherence were assessed in the two study groups using a 5-point Likert scale at the end of the study.

Statistical analysis

The Statistical software namely SPSS 22.0, and R environment ver.3.2.2 were used for the analysis of the data. Student t test (two tailed, independent) have been used to find the significance of study parameters on continuous scale between two groups (Inter group analysis) on metric parameters. Leven`s test for homogeneity of variance have been performed to assess the homogeneity of variance. Chi-square/ Fisher Exact test have been used to find the significance of study parameters on categorical scale between two or more groups. Fisher exact test used when cell samples are very small.

Results

Total 133 patients who met the inclusion criteria were randomized into two groups, of which 65 were in the OPEP group and 68 in the CCPT group. One patient each from both groups lost follow up and another one in CCPT was excluded due to acute myocardial infarction during the study period. A total of 64 patients in OPEP group and 66 patients in CCPT group completed the study.

Table`1: Age, gender, dyspnea grade, sputum quantity distribution

variables	OPEP group (n=64)	CCPT group (n=66)	Total (n=130)	P value
Age in years				
• <20	0(0%)	1(1.5%)	1(0.8%)	0.416
• 20-30	7(10.9%)	5(7.6%)	12(9.2%)	
• 31-40	4(6.3%)	7(10.6%)	11(8.5%)	
• 41-50	21(32.8%)	24(36.4%)	45(34.6%)	
• 51-60	16(25%)	17(25.8%)	33(25.4%)	
• 61-70	12(18.8%)	12(18.2%)	24(18.5%)	
• >70	4(6.3%)	0(0%)	4(3.1%)	
Gender				
• Female	37(57.8%)	38(57.6%)	75(57.7%)	0.978
• Male	27(42.2%)	28(42.4%)	55(42.3%)	
Dyspnea grade				
• 1	0(0%)	0(0%)	0(0%)	0.813
• 2	42(65.6%)	42(63.6%)	84(64.6%)	
• 3	22(34.4%)	24(36.4%)	46(35.4%)	
Sputum				

• Moderate	45(70.3%)	43(65.2%)	88(67.7%)	0.529
• Severe	19(29.7%)	23(34.8%)	42(32.3%)	

Table 2 Comparison of Clinical variables

Variables	OPEP group (n=64)	CCPTgroup (n=66)	Total (n=130)	P value
Cough	64(100%)	66(100%)	130(100%)	1.000
Hemoptysis	0(0%)	0(0%)	0(0%)	1.000
Chest pain	0(0%)	0(0%)	0(0%)	1.000
Fever	0(0%)	0(0%)	0(0%)	1.000
Diabetes	35(54.7%)	20(30.3%)	55(42.3%)	0.005**
Hypertension	21(32.8%)	22(33.3%)	43(33.1%)	0.950
TB	29(45.3%)	25(37.9%)	54(41.5%)	0.390
CAD	9(14.1%)	8(12.1%)	17(13.1%)	0.743

Bronchiectasis Severity Index (BSI) was used to assess severity of bronchiectasis. BSI scoring includes HRCT Score, FEV1, and Medical Research Council Dyspnoea grade, Bacterial Colonisation (pseudomonas aeruginosa or other pathogenic bacteria), prior hospital admission and Exacerbations. Score below 4 was considered as mild, 5 to 8 as moderate and 9 or more score considered as severe bronchiectasis.

Out of 130 patients 72 (55.4%) were categorized into moderate and 58(44.6%) were categorized into severe bronchiectasis. There was no significant difference in distribution of moderate and severe bronchiectasis in both groups (p=0.610). Hence both groups were comparable(Table 3).

Table 3: Patients distribution based on Bronchiectasis severity index

BSI	OPEP group (n=64)	CCPT (n=66)	Total (n=130)	P value
• Moderate	34(53.1%)	38(57.6%)	72(55.4%)	0.610
• Severe	30(46.9%)	28(42.4%)	58(44.6%)	

Table 4: Number of exacerbations per patient requiring antibiotics

Number of exacerbations per patient requiring antibiotics (mean)	OPEP group (n=64)	CCPTgroup (n=66)
During study	3.02	3.124
End of study	1.77	2.23

Number of exacerbations per patient requiring oral or iv antibiotics in OPEP group before and after study was 3.02 and 1.77 respectively. Number of exacerbations per patient requiring oral or iv antibiotics in CCPT group before and after study were 3.124 and 2.23 respectively. OPEP group have less exacerbation (1.77) than CCPT group (2.23) [Table 4]

Kaplan Meier function analysis was used to analyze time for 1st pulmonary exacerbation during study. Time for 1st pulmonary exacerbation in OPEP group was 212 days compared with 191 days in CCPT group. Significant log rank test done p=0.078. There was significant difference between OPEP and CCPT group. [Table 5, Figure 1]

Table 5: Time of onset of first exacerbation

Variables	Mean onset of first exacerbation(days))			
	Estimate	SE	Lower CI	Upper CI
OPEP group (n=64)	212.164	5.840	200.719	223.610
CCPT group (n=66)	191.390	8.043	175.626	207.154
OVERALL	204.787	4.907	195.169	214.404

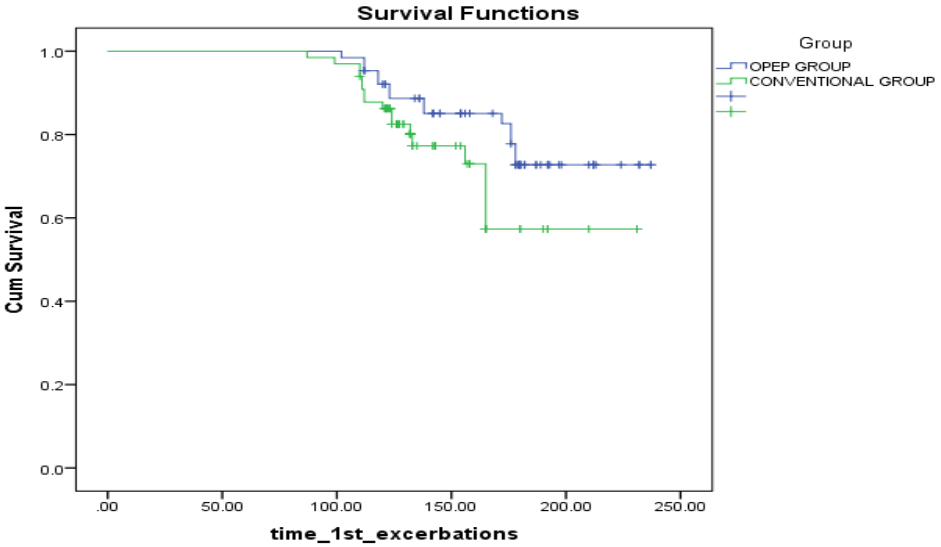

Figure1. Kaplan meier plot -onset of 1st exacerbation

There was no significant difference in lung function changes in both groups. P value of FEV1 at 1, 4 and at end of study were 0.732, 0.995 and 0.957 respectively. [Figure 2,Table 6]

Table 6: Comparison of FEV1 in two groups

variables	OPEP group	Conventional group	Total	P value
FEV1 1st Month	61.89±7.93	61.39±8.54	61.64±8.22	0.732
FEV1 4th month	60.69±8.01	60.70±8.68	60.69±8.32	0.995
FEV1 at end of study	61.61±8.23	61.53±8.57	61.57±8.37	0.957

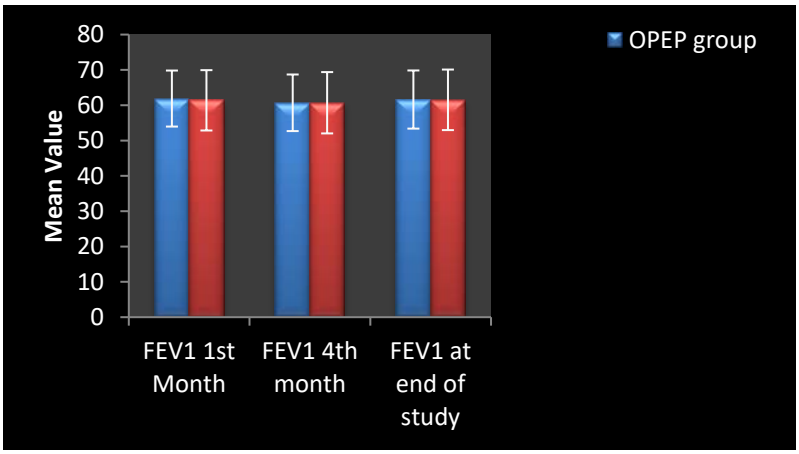

Figure 2: Comparison of FEV1 in two groups

Distribution of SGRQ scores (0-100) in both groups were studied (Table 7).

Table 7: Distribution of SGRQ score in two groups

	OPEP group (n=64)	CCPT group (n=66)	Total (n=130)
SGRQ AT BASELINE (0-100)			
• <70	25(39.1%)	19(28.8%)	44(33.8%)
• 70-80	28(43.8%)	40(60.6%)	68(52.3%)
• >80	11(17.2%)	7(10.6%)	18(13.8%)
SGRQ AT THE END (0-100)			
• <50	40(62.5%)	16(24.2%)	56(43.1%)
• 50-70	23(35.9%)	47(71.2%)	70(53.8%)
• >70	1(1.6%)	3(4.5%)	4(3.1%)

Table 8: Comparison of mean SGRQ

	OPEP group	CCPT group	Total	P value
SGRQ at baseline	72.20±8.99	73.38±7.73	72.80±8.37	0.425
SGRQ at the end	47.39±9.85	56.55±9.42	52.04±10.64	<0.001**

Mean SGRQ values at baseline and at the end of study in OPEP group was 72.20±8.99 and 47.39±9.85 respectively. Similarly Mean SGRQ values before and after study in CCPT group was 73.38±7.73 and 56.55±9.42. Mean SGRQ values in both groups were improved which was more OPEP group than CCPT group and was statistically significant ($p<0.001$). [Table 8, Figure 3]. Comfort, wellbeing and adherence in both groups were studied at end of the study with likert scale (0-4). The score was higher in OPEP group than CCPT group ($p<0.001$).

Discussion

Bronchiectasis is characterized by inflammation and infection causing damage that potentiates impaired mucociliary clearance. Treatment is focused on breaking the vicious cycle of mucus stasis, infection, inflammation, and airway destruction.[13] Airway clearance techniques help in reducing further airway damage by decreasing bacterial colonization and thereby reducing the number of exacerbations and hospitalizations [14]. These are non-pharmacological methods to improve symptoms and Quality of Life by reducing the frequency of exacerbations [15].

This prospective clinical study compared the efficacy of Oscillating Positive Expiratory Pressure (OPEP) Therapy compared with Conventional chest physiotherapy (CCPT) in patients with Bronchiectasis. Among a total number of 130 patients, 65 were randomized to OPEP group and 68 to CCPT group. The baseline characteristics at the beginning of study were comparable between each group.

The total number of exacerbations per patient requiring antibiotics in CCPT group before and after study were 3.124 and 2.23 respectively and that in OPEP were 3.02 and 1.77 respectively. There was significant difference between OPEP and CCPT group in the time of onset of first exacerbation during the study which was 212 days in OPEP group compared with 191 days in CCPT group. Health related quality of life was assessed using SGRQ which showed improvement in OPEP group. Similar results were found in a study conducted by Murray et al [16]. Comfort, wellbeing and adherence both groups were studied with likert type scale (0-4) at the end and found higher in OPEP group.

Conclusion

The relatively lower exacerbation rates and their later onset, improvement in health-related quality of life, comfort and wellbeing in patients performing OPEP therapy compared with CCPT supports the use of OPEP therapy for airway clearance

than other conventional airway clearance techniques in patients with Bronchiectasis.

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