Sustainability of bottle positive expiratory pressure (PEP) therapy in patients with Chronic Obstructive Pulmonary Disease (COPD) - A randomised controlled trail

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Abstract-

Background of the study:

Positive expiratory pressure treatment is applied to different pathological conditions also in combination with other physiotherapeutic techniques. The primary aim of present study is to investigate the effect of bottle pep therapy in patients with chronic obstructive pulmonary disease.(1) COPD is a preventable diseases characterized by an inflammatory respond due to various harmful particles and gases, particularly smoking .In recent years, the beneficial effects of pulmonary rehabilitation programs in addition to the current medical treatments in patients with chronic obstructive pulmonary disease have been emphasized .One of the main component of rehabilitation program in patients with copd is airway clearance techniques, which include conventional therapy, airway cleaning through breathing techniques, positive expiratory pressure (PEP) devices and high frequency chest wall oscillation (2).Currently, many commercial PEP devices are available which are expensive and not much used and prescribed because of the cost of those devices,. However, Bottle PEP can be used as an alternative to manufactures and marketed PEP devices since it can easily be made and it's also inexpensive and easy to administer.

Aim: To determine sustainability of Bottle Positive Expiratory Pressure (PEP) therapy in patients with chronic obstructive pulmonary diseases (COPD)

Objectives:

1) To examine the effect of Bottle PEP with chest PT on Dyspnea and peak expiratory flow rate (PEFR) in COPD patients

2) To examine the effect of chest PT alone on Dyspnea and peak expiratory flow rate (PEFR) in COPD patients 3) To compare effectiveness of BOTTLE PEP with Chest PT and Chest PT alone on Dyspnea and peak expiratory flow rate (PEFR) in COPD patients

Methodology:

•108 patients coming to pulmonology OPD were taken for the study. Patients having complaint of breathlessness cough and sputum production & diagnosed with chronic obstructive pulmonary disease patients were included in study.108 patients randomly divided into groups of 54 each, using a computer generated randomized table.

•Group A were given Bottle PEP therapy and chest physical therapy (Breathing exercise, thoracic mobility exercise, percussions, vibrations, huffing coughing Technique) every 6th hourly for one week interval.

•Group B were given only chest physical therapy (Breathing exercise, thoracic mobility exercise, percussions, vibrations, huffing coughing Technique) every 6th hourly for one week interval.

•The outcome measures, Peak expiratory flow rate and Dyspnea (MRC Grading) were assessed before and after the treatment.

•Statistical analysis was performed to note the difference at the end of the study.

Results:

Bottle PEP along with Chest PT has more beneficial effect in COPD patients as compared to Chest PT alone. The improvement in PEFR and Reduction of dyspnea was higher in group that received Bottle PEP and Chest PT as compared to the group that received Chest PT alone.

Conclusion:

The uses of Bottle PEP was more clearly understood during the study. As an addition, the effects of Bottle PEP and its uses to improve PEFR and reduce dyspnea in COPD was clearly depicted.

As per the study, analyzed data helps us to conclude that Bottle PEP along with Chest PT has more positive effects in increasing the PEFR and reducing the dyspnea in a COPD patient when being compared to the Chest PT alone.

Also Bottle PEP is an Inexpensive method as compared to using conventional PEP devices for patients with COPD.

Bottle PEP can be a highly sustainable treatment technique for patients for COPD.

INTRODUCTION

Chronic obstructive pulmonary disease is persistent narrowing (blocking, or obstruction) of the airways occurring with emphysema, chronic obstructive bronchitis, or both disorders. (1)

Emphysema is defined as widespread and irreversible destruction of the alveolar walls (the cells that support the air sacs, or alveoli, that make up the lungs) and enlargement of many of the alveoli. (1)

Chronic bronchitis is defined as cough that produces sputum for at least 3 months during two successive years. (2)

COPD is a preventable diseases characterized by an inflammatory respond due to various harmful particles and gases, particularly smoking. (2)

Chronic Obstructive Pulmonary Disease (COPD) is characterized by a variety of symptoms that can significantly impact patients' quality of life. Common symptoms of COPD include Persistent cough, sputum secretions that can be clear, white, yellow, or greenish, Dyspnoea and Wheezing ((2)).

Chronic obstructive pulmonary disease (COPD) is one of several chronic diseases that are becoming increasingly problematic worldwide. The reasons why chronic diseases are becoming so problematic are certainly associated with increasing prevalence in some cases, but this has not been well established for COPD. (3)

The impact of COPD on health systems could also be increasing due to a greater ability and capacity to manage the disease, the frequency of exacerbations, and enhanced survival of patients. Each of these considerations may be relevant in India where little is known regarding prevalence trends.

Management of COPD aims to alleviate symptoms, improve quality of life, and reduce exacerbations by **Enhancing Pulmonary Function, Management of Secretions**, **symptom management, and overall well-being in affected individuals.** Pulmonary rehabilitation, pharmacotherapy, and various respiratory therapies are integral components of COPD management strategies. Airway clearance techniques (ACTs), commonly performed by respiratory physiotherapists, are intended to aid secretion mobilization and expectoration and to mitigate complications associated with secretion retention (4). ACTs consist of a variety of approaches, such as forced exhalation, manual compression, and/or vibration of the thorax, deep breathing exercises, huffing, and high frequency chest wall oscillation (5). One such respiratory therapy gaining attention is the use of Positive Expiratory Pressure (PEP) devices

In recent years, the beneficial effects of pulmonary rehabilitation programs in addition to the current medical treatments in patients with chronic obstructive pulmonary disease have been emphasized. One of the main component of rehabilitation program in patients with copd is airway clearance techniques, which include conventional therapy, airway clearance through breathing techniques, positive expiratory pressure (PEP) devices and high frequency chest wall oscillation (1).

Breathing against an expiratory resistance, also known as positive expiratory pressure (PEP), is a therapeutic tool widely used either in intensive or non-intensive care settings. Expiration through a PEP resistance prevents airway closure and improves secretions clearance, functional residual capacity (FRC), and oxygenation. In the last decade, researches have proved that PEP therapy is effective for preventing respiratory complications after cardiac surgery also. (6) Recently, it has been found that PEP exercises using 5 cmH2O of resistance were effective at enhancing exercise-induced dyspnoea recovery in a population of patients with chronic obstructive pulmonary disease (COPD) (7).

Expiration through a PEP resistance prevents airway closure and improves secretions clearance, functional residual capacity (FRC), and oxygenation (7).

Currently, many commercial pep devices are available. Oscillatory positive expiratory pressure (PEP) with the Flutter device facilitates secretion removal. In the Flutter a steel ball vibrates inside a cone, causing air flow vibration. A new device, the Acapella, uses a counterweighted plug and magnet to create air flow oscillation (9) These devices are expensive and not much used and prescribed because of the cost of those devices, However, Bottle PEP can be used as

an alternative to manufactures and marketed PEP devices since it can easily be made and it's also inexpensive and easy to administer

The bottle-PEP is a device used in a plastic bottle, by filling with water to form pressure. Positive expiratory pressure treatment is applied to different pathological conditions also in combination with other physiotherapeutic techniques (8)

The present study focused on PEP treatment delivered using the PEP-bottle, which is a self-made respiratory device constituted by a water container and a piece of tubing: patients are asked to exhale through the tubing positioned inside the container. As the treatment is device dependent, characteristics of PEP-bottle must be defined because they are related to the delivered resistance. (11)

The effectiveness of PEP-bottle treatment has been established using a pressure of 10–20 cmH2O during expiration. To date, PEP-bottle exercise conforms to the most recent evidence, although lack of direction on its use has been reported in daily clinical practice on the other hand, thanks to the low cost and the ease of construction, PEP-bottle has been widely employed. Although PEP therapy is widely used in different settings, there is still lack of knowledge of its practice for patients with pulmonary diseases. (15)

AIMS & OBJECTIVES

Aim: To determine sustainability of Bottle Positive Expiratory Pressure (PEP) therapy in patients with chronic obstructive pulmonary diseases (COPD).

Objectives:

1) To examine the effect of Bottle PEP with chest PT on Dyspnea and peak expiratory flow rate (PEFR) in COPD patients

2) To examine the effect of chest PT alone on Dyspnea and peak expiratory flow rate (PEFR) in COPD patients

3) To compare the effectiveness of BOTTLE PEP with Chest PT and Chest PT alone on Dyspnea and peak expiratory flow rate (PEFR) in COPD patients.

METHODOLOGY

Study design: Prospective study (Randomized Control Trial)

Study area: Narayana Hrudayalaya health city - Pulmonology OPD

Study Duration: 3 months

Study population: Subjects diagnosed with chronic obstructive pulmonary disease were selected according to the criteria of the study from the department of Pulmonology OPD.

Sampling: Simple random Sampling

Sample size (with justification): Total sample size = 108

Eligibility Criteria and Participants recruitment procedure

Inclusion criteria:

- COPD patients having COPD since the last 5years or less
- Patients above 18 years of age
- Patients complaining of breathlessness with activity

Exclusion criteria:

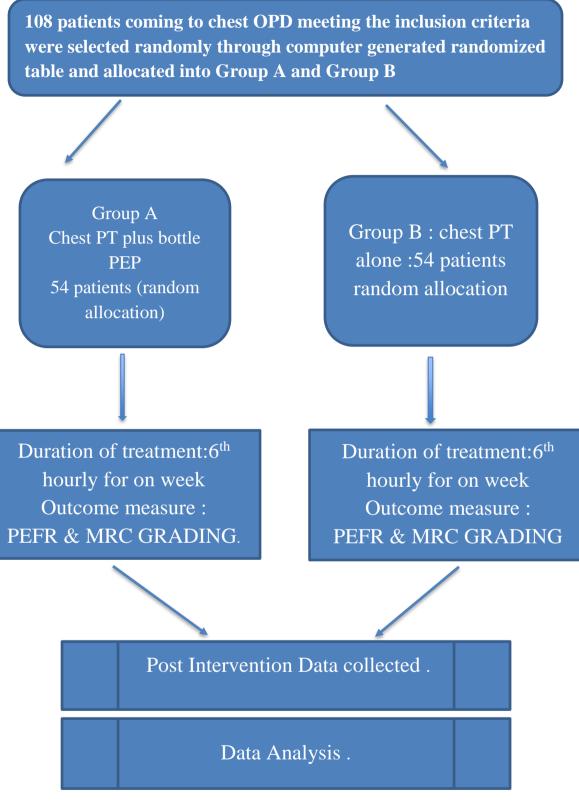
- Uncooperative patients
- Patients who have breathlessness at rest
- Patient having any cardiac, neuromuscular or restrictive disease pathology.

Group A will be given PEP therapy and chest physical therapy (Breathing exercise, thoracic mobility exercise, percussions, vibrations, huffing coughing Technique) every 6th Hourly for one week interval.

Group B will be given only chest physical therapy (Breathing exercise, thoracic mobility exercise, percussions, vibrations, huffing coughing Technique) every 6th hourly for one week interval.

The outcome measures of Peak expiratory flow rate and Dyspnea will be assessed before and after the treatment.

Outline:



TREATMENT PROTOCOL: <u>BOTTLE PEP TECHNIQUE</u>

Set up:

- Fill up the bottle with water to about a third to half way.
- Put the tubing in so it touches the bottom of the bottle.

Technique:

- 1. Take a deep breath in.
- 2. Blow out into the tubing for about 4 seconds. The water will bubble.
- 3. Blow as many breaths until you need a rest.

4. 'Huff' into the huff tube.

5. Cough and spit if needed.

6. Repeat again.

7. Do for minutes

8. Carry out this treatment 2 times a day.

9. After using the equipment it should be washed and left to dry in a clean place until it is next used.

10. It is recommended that the bottle and tubing should be changed once a week to reduce the risk of infection.

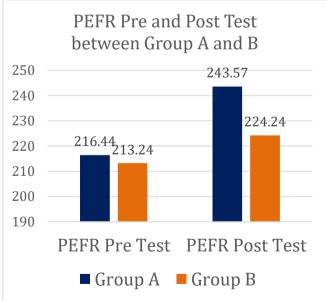
Data analysis:

The pre-test and post-test values were analyzed and the data was managed by word 2011 and analyzed by SPSS 27.For within the group, paired T-test was used and between the groups independent sample test was used **Paired T test:Within Group Comparison between Group A and Group B**

Table-1 S. No Parameter Mean Standard Mean **P-Value** ± **Deviation** difference A **GROUP** A PEFR 1 **Pre-Test** 216.44 ± 40.162 < 0.001* Post- Test 243.57 ± 41.602 27.13 2 MRC Pre-Test 2.80 ± 0.655 Post-Test 1.30 ± 0.500 1.50 < 0.001* **GROUP B** В PEFR 1 Pre-Test 213.24 ± 31.500 Post-Test 224.24 ± 31.628 11 < 0.001* 2 MRC Pre-Test 2.70 ± 0.571 Post-Test 1.83 ± 0.575 0.87 < 0.001*

Statistical Software: SPSS Version 27; Statistical Test: Paired T-Test; P-Value <0.05-Significant*

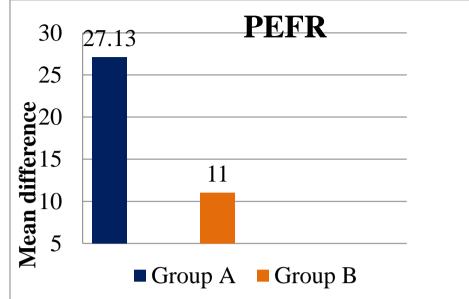
COMPARISON OF PRE TEST AND POST TEST MEAN VALUES OF PEAK EXPIRATORY FLOW RATE (PEFR) FOR GROUP A AND GROUP B



Graph 1: Comparison of Pre- test and Post- test PEFR of Group A & Group B

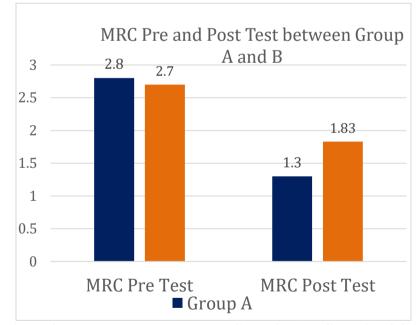
The PEFR had a minimal change from pre- test value of 213.24 to post- test value of 224.24 with a mean difference of 11 in Group B. However in Group A the change was higher from a Pre- test value of 216.44 to a post-test value of 243.53 with a mean difference of 27.13.

MEAN DIFFERENCE OF PRE TEST AND POST TEST VALUES OF PEAK EXPIRATORY FLOW RATE (FVC) FOR GROUP A & GROUP B



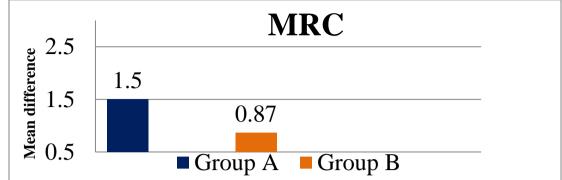
Graph 2: Mean difference between Pre-test and post-test values of PEFR in GROUP A & GROUP B The Mean difference between Pre-test and post-test values of PEFR in GROUP A is 27.13, whereas in GROUP B the value is 11.

COMPARISON OF PRE TEST AND POST TEST MEAN VALUES OF MRC GRADING (DYSPNEA) FOR GROUP A AND GROUP B



Graph 3: Comparison of Pre and post treatment MRC grading (DYSPNEA) of Group A & Group B The MRC grading for dyspnea had apparently shown a minimal reduction in grade from 2.7 to 1.83 with a mean difference of 0.87 in Group B. However in Group A the change in reduction of MRC grade was higher from a pre-test value of 2.8 to post –test value of 1.3 with a mean difference of 1.5.

MEAN DIFFERENCE OF PRE TEST AND POST TEST VALUES OF MRC GRADING (DYSPNEA) FOR GROUP A & GROUP B



Graph 4: Mean difference between Pre-test and post-test values of PEFR in GROUP A & GROUP B

The Mean difference between Pre-test and post-test values of MRC GRADING in GROUP A is 1.50, whereas in GROUP B the value is 0.87

PEFR:

In Table 1 and Graph 1 pre-test and post-test mean values of PEFR for Group A and Group B mentioned.

In table 1 and Graph 2 mean difference values of PEFR is mentioned.

The mean Pre-test and post-test mean difference values of PEFR in GROUP A is 27.13, whereas in GROUP B the value is 11.

The corresponding 'P' value for the Group A and Group B is the same i.e., less than 0.001.

Therefore based on the pre- test and post- test mean difference of PEFR, the result shows there is a significant difference between Group A and Group B and it also indicates the pre- test-post-test mean difference of PEFR for Group A is statistically significant than Group B.

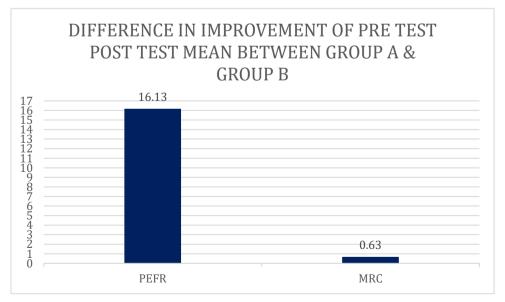
MRC:

In Table 1 and Graph 3 pre-test and post-test mean values of MRC for Group A and Group B mentioned

In table 1 and Graph 4 mean difference values of MRC is mentioned.

The mean Pre-test and post-test mean difference values of MRC in GROUP A is 1.50, whereas in GROUP B the value is 0.87.

The corresponding 'P' value for the Group A and Group B is the same i.e., less than 0.001. The mean difference of improvement from Pre- test PEFR to post Test PEFR between Group A and Group B is 16.13 and for MRC grading it is 0.63



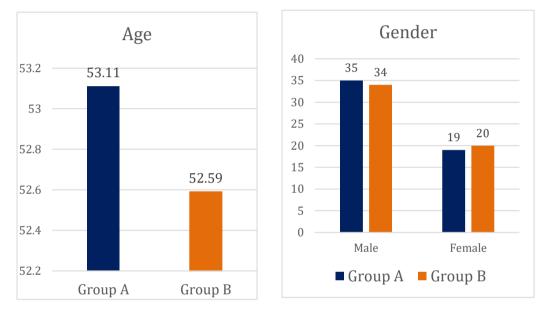
Graph 5: Mean Difference in improvement of pre- test and post- test PEFR and MRC between GROUP A and GROUP B

Therefore based on the pre- test and post- test mean difference of MRC, the result shows there is a significant difference between Group A and Group B and it also indicates the pre- test-post-test mean difference of MRC for Group A is significant than Group B

Demographic Characteristics:

Table-2					
S. No	Parameter	Group A	Group B		
		Mean ± Standard Deviation			
1	Age	53.11± 8.50	52.59 ± 6.80		
		Frequency (%)			
2	Gender				
	Female	19 (35.2%)	20 (37%)		
	Male	35 (64.8%)	34 (63%)		

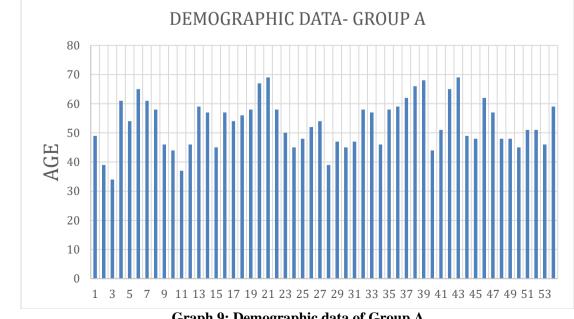
The Mean Age of population for Group A is 53.11 ± 8.50 and for Group B is 52.59 ± 6.80 . Group A had 35.2% Females and 64.8% Males. Whereas Group B had 37% females and 63% Males



Graph 6: Mean value of age in Group A and Group B

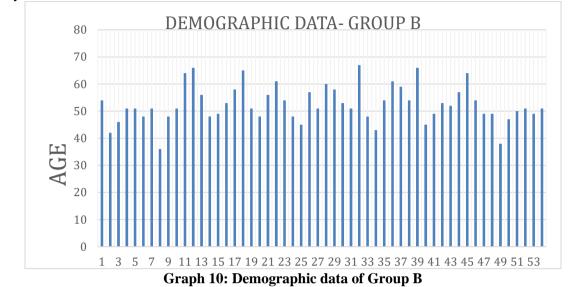
Graph 7: Gender Population of total Males and Females included in the study for Group A and B

Description of Demographic Data:



Graph 9: Demographic data of Group A

Majority of them, a total of 13 subjects (24 %) had age of 46-50 years, 13 subjects (24%) had age 56-60 years, 7 subjects (12.9%) had age of 51-55 years, 6 subjects (11.1%) had 41-45 years, 6 subjects (11.1%) had age of 61-65 years, 5 subjects (9.25%) had age of 66 -70 years, 3 subjects (5.5%) had a ge group of 35-40 years and 1 subject (1.18%) had a ge of 34 years.



Majority of them, a total of 18 subjects (33.33 %) had age of 51-55 years, 14 subjects (25.9%) had age 46-50 years, 8 subjects (14.8%) had age of 51-55 years, 5 subjects (9.25%) had age of 61 -65 years, 4 subjects (7.4%) had age of 41 - 45 years, 3 subjects (5.5%) had a ge group of 66-70 years and 2 subjects (3.7%) had age of 36-40 years. Between Group Comparison of Group A and Group B (Independent T test)

Table-3					
S. No	Parameter	t- value	P-Value		
А	PEFR				
1	Pre-Test	0.461	0.646		
2	Post-Test	2.719	0.008*		
В	MRC				
1	Pre-Test	0.783	0.435		
2	Post-Test	-5.180	<0.001*		

Statistical Test: Independent T-Test; P-Value <0.05-Significant*

In Table 3 the obtained t value is mentioned.

The obtained Independent't' value for PEFR is 2.719 and for MRC grading it is -5.180.

The corresponding 'p' value for PEFR between both groups is the less than 0.05.

The corresponding 'p' value for MRC between both groups is the less than 0.01.

Therefore, the result shows there is a statistical significance difference in PEFR and MRC Grading between two groups **Results:**

This interventional study was conducted to analyze the sustainability of BOTTEL PEP in patients with COPD and to compare the effect of BOTTLE PEP with Chest PT and Chest PT alone in patients with COPD.

A total of 108 Patients were taken in the study. They were selected by Simple random sampling method and assigned into two groups. Group A (BOTTLE PEP with Chest PT) consisted of 54 patients and Group B (Chest PT alone) consisted of 54 patients.

PEFR

• The mean value of pre intervention in Group A, who received BOTTLE PEP along with Chest PT, is 216.44, whereas post intervention value increased to 243.57.

The paired't' value (p<0.001).

• The mean value of pre intervention in Group B, who received Chest PT 213.24, whereas post intervention value increased to 224.24.

The P value is less than 0.001 (p<0.001).

MRC:

The mean value of pre intervention MRC in Group A, who received BOTTLE PEP along with Chest PT, is 2.8, whereas post intervention value decreased to 1.5. The P value is less than 0.001 (p<0.001).

• The mean value of pre intervention MRC in Group B, who received Chest PT is 2.7, whereas post intervention value decreased to 1.83. The P value is less than 0.001(p<0.001).

The improvement of PEFR in Group A (27.13) is higher than Group B (11)

The reduction of Dyspnea (MRC) in Group A (1.50) is higher than Group B (0.87).

The mean difference of PEFR and MRC between Group A and Group B is 16.13 and 0.63 respectively and their corresponding independent't' value is 2.179 (p<0.05) and - 5.180 (<0.01) respectively.

From the above data it is clearly understood that a combination of BOTTLE PEP along with Chest PT is much more efficient than Chest PT alone to improve the PEFR and reduce the Dyspnea in patients with COPD.

Thus, these data points out the relevant role of BOTTLE PEP, not only in improving PEFR and reducing Dyspnea but it is also an effective, inexpensive and easy to use alternative means to conventional expensive PEP devices, that can be used routinely in patients with COPD.

Discussion:

This current study shows a significant improvement in peak expiratory flow rate and reduction of Dyspnea. Only a few studies exist in the literature comparing the effect of bottle PEP and using bottle PEP as an alternative to other PEP devices in patients of COPD.

A study conducted by Samaradnyi Hichkad, B. R. Ganesh.² found the Effect of Blow Bottle Device and Flutter on Functional Capacity, Dyspnea, Fatigue, and Peak Expiratory Flow Rate in Mild to Moderate COPD Patients. Their results were similar to results of our study but they compared Bottle PEP with flutter device. Also they used few more outcome measures.

A study was conducted Zhaoning Xu, Zhuo Han & Dedong Ma.¹ to find out the efficacy and safety of long-term use of a positive expiratory pressure device in chronic obstructive pulmonary disease patients. They concluded that regular daily use of PEP device is safe and may improve exercise capacity in subjects with COPD or pre-COPD. PEP device could be used as an add-on to pulmonary rehabilitation programs due to its efficacy, safety, and low cost.

A study was conducted by Benedetta Liverani et,al⁸ to investigate the effects of PEP-bottle therapy in patients with pulmonary diseases and, secondarily, to provide a physiological analysis of its use. They concluded that PEP-bottle therapy has been proved to improve lung volume, to reduce hyperinflation, and to remove secretions and the cost of a PEP-bottle device is significantly lower if compared with other commercially available devices having the same therapeutic purposes.

In Conclusion there is a significant differences in improvement of PEFR and Dyspnea when BOTTLE PEP is given up as a treatment technique with Chest PT as compared to giving Chest PT alone". BOTTLE PEP can be a useful technique, which can be used along with Chest PT for patients with COPD patients.

BOTTLE PEP as a homemade device, is as an inexpensive and easy to use alternative to the conventional PEP devices for patients with COPD.

"The BOTTLE PEP can be a sustainable treatment technique in COPD"

Limitations and recommendations:

This study was conducted for a shorter period of time, in upcoming studies time period can be increased. More parameters can be used as outcome measures.

Conclusion:

The study concludes that BOTTLE PEP can be a useful technique, which can be used along with Chest PT for patients with COPD patients.

"There is a significant differences in improvement of PEFR and Dyspnea when BOTTLE PEP is given up as a treatment technique with Chest PT as compared to giving Chest PT alone".

BOTTLE PEP as a homemade device, is as an inexpensive and easy to use alternative to the conventional PEP devices for patients with COPD.

"The BOTTLE PEP can be a sustainable treatment technique in COPD".

CONFLICTS OF INTEREST

The authors do not have any conflict of interest to declare.

ETHICAL APPROVAL

The study was approved by the research committee and a formal permission was obtained from concerned authorities

of the hospital and associated departments. No ethical issues arouse during the study. STATEMENT OF INFORMED CONSENT

Informed consent was obtained during the study. The subjects were informed that the confidentiality of the data was maintained. The subjects were informed that their participation was on voluntary basis and can withdraw from the study at any time.

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