DOI: 10.7860/JCDR/2023/58056.17769

Research Protocol

Physiotherapy Section

Effect of Aerobika Device versus Acapella Device on Sputum Volume and Lung Function in Chronic Obstructive Lung Disease Patients- A Research Protocol

VISHAKHA TAYADE[1], VISHNU VARDHAN[2]

ABSTRACT

Introduction: Chronic Obstructive Lung Disease (COPD) is an incurable, gradually worsening respiratory condition characterised by airflow limitation and blockage that cannot be completely reversed. Productive cough caused due to mucus hypersecretion is a common symptom of COPD. Clearing the lungs may aid in the conservation of energy and oxygen, as well as the prevention of lung infections. Therefore, Oscillating Positive Expiratory Pressure (OPEP) devices are designed to aid in sputum clearing in COPD patients. They are available in a variety of sizes and shapes and clear the airway with air pressure, oscillation, or high-frequency sound waves.

Need of the study: Chronic Obstructive Pulmonary Disease (COPD) makes it challenging for air to flow freely into and out of the lungs. Shortness of breath, cough, and mucus in the lungs are all possible symptoms. Clearing the lungs may aid in the conservation of energy and oxygen, as well as the prevention of lung infections. To help clear away excess sputum, numerous airway clearance devices can be used. They are available in a variety of sizes and shapes and clear the airway with air pressure, oscillation, or high-frequency sound waves.

Aim: To compare the effect of Aerobika vs. Acaplla device on sputum volume and lung function in COPD patients.

Materials and Methods: A comparative study will be performed in respiratory medicine OPD of Ravi Nair Physiotherapy College, Sawangi (Meghe), Wardha. Ethical approval was received from the Ethical Review Committee of Datta Meghe Institute of Medical Sciences, Deemed to be University. In this study 30 patients diagnosed with COPD will be categorised into two groups one group will receive aerobika device with conventional physiotherapy and another group will receive acapella device with conventional physiotherapy twice a day. Treatment will be given five days for one week. The assessment will be done on day one of the treatment and at the end of treatment which is first week. Sputum volume and lung function will be assessed by sputum collector and Pulmonary Function Test (PFT), respectively. The statistical analysis will be done using chi-square test. The parameters will be compared between both the groups for sputum volume and lung function over a period of one week. Data will be analysed in a statistical software SPSS 27.0.V.

Keywords: Acute exacerbation, COPD assessment test scale, Oscillating positive expiratory pressure device, Pulmonary function test

INTRODUCTION

Chronic obstructive pulmonary disease is a leading cause of morbidity and mortality, ranking sixth out of the top 30 causes of mortality in 2015 and projected to rise to third place (8.6%) in 2030, in accordance to the International Global Burden of Disease Study, In the next years, prevalence is expected to increase rather than a decline [1]. It is currently the world's fourth-biggest cause of death, after stroke, myocardial infarction disease, and acute respiratory infections. Three million persons with chronic obstructive pulmonary disease died in 2016 [2,3]. Uncontrollable dyspnoea, diminished functional capacity, periods of acute exacerbation, airway restriction, and blockage that cannot be entirely reversed are all symptoms of COPD [4,5]. COPD episodes are prevalent, resulting in a decline in health. Exacerbations are typically diagnosed when specific symptoms worsen or lung functions deteriorate [5,6].

Addressing concerns linked to minimising work of ventilation, enhancing clearing of the airways, enhancing mobility, and assisting with rehabilitation services are all part of physiotherapy's role in the management of COPD. Physiotherapy should be adapted to fulfill varied needs depending on if patients are in an acute exacerbation of COPD or a stable phase of the disease. The main objectives of pulmonary compete are to alleviate ailments, enhance the quality of life, and boost physical and emotional engagement in daily activities.

Chronic obstructive pulmonary disease makes it challenging for air to flow freely into and out of the lungs [7-9]. Shortness of breath, cough, and mucus in the lungs are all possible symptoms. Clearing the lungs may aid in the conservation of energy and oxygen, as well as the prevention of lung infections. To help clear away excess sputum, numerous airway clearance devices can be used. They come in a variety of shapes and sizes (mouthpieces, masks, vests, etc.,) and clear the airway with air pressure, oscillation, or high-frequency sound waves [10,11]. The Aerobika device and Acapella device use airway oscillations to thin mucus to aid sputum clearance. They are less likely to have side effects than pharmaceutical treatments. These devices not only aid in the clearing of mucus in patients with stable COPD, but also enhance lung capacity, exercise ability, and standards of living [12-14].

The Aerobika device is a drug-free OPEP device that has been demonstrated to effectively evacuate sputum and open airways in COPD patients [12]. The Acapella is a small portable device that is used to clear the airway. It has both resistive and vibratory properties that aid in the loosening and clearing of secretions in the chest [15]. Acapella, according to the producers, may be a better option as it is self-executed and can be utilised in every postural drainage position, requires less therapist time, and is appropriate for patients with a variety of lung functions. The Acapella is a modern

gadget with an oscillating component that causes airway vibrations in addition to providing positive pressure. These vibrations may assist remove secretions from the airway walls in addition to the Positive Expiratory Pressure (PEP) mask. Mucous viscoelasticity can be reduced by airway oscillation. In this study, we will try to find out which is more beneficial for clearing secretions and improving lung function in COPD patients. The aim of the study is to compare the effect of Aerobika device and Acapella device between the age group of 40-70 years.

Research Hypothesis

Null hypothesis:

- There will be no significant difference between Aerobika and Acapella device on sputum volume and lung function in COPD patients.

Alternate hypothesis:

- There will be significant difference between Aerobika and Acapella device on sputum volume and lung function in COPD patients.

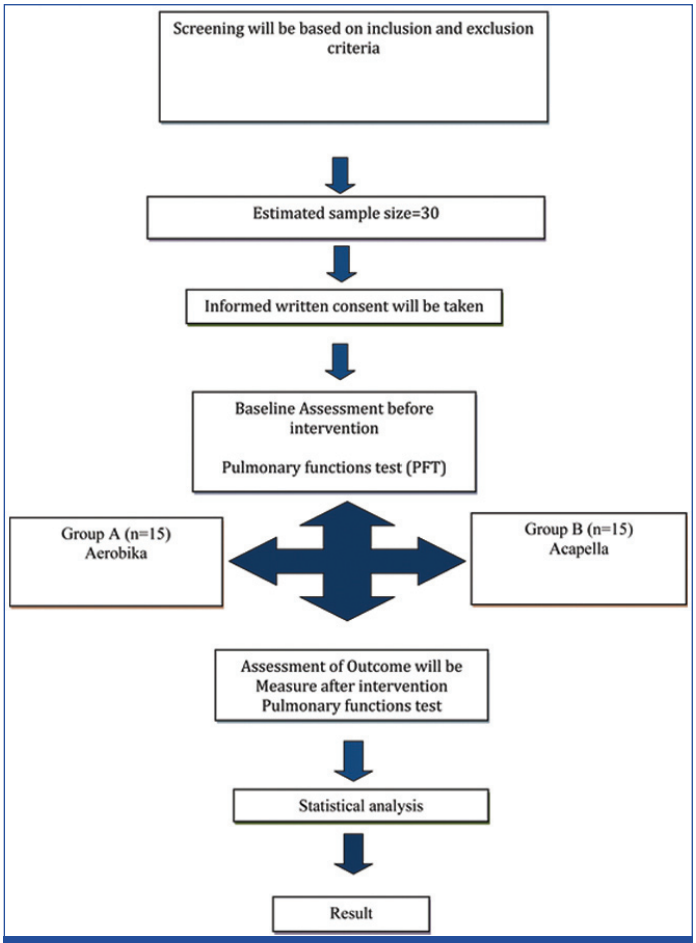
REVIEW OF LITERATURE

The study will be conducted to see the effect of aerobika device versus acapella device on sputum volume and lung functions in COPD patients. The Aerobika device can help to open the blocked or collapsed airways, as well as loosen mucus so it can flow to the larger airways of the lungs and be coughed out. The Acapella device clears mucus from the airways by using vibrations and positive pressure or resistance. When the patient will breathe out, it vibrates to remove mucus from the airway walls, allowing the airways to stay open for longer. This makes it possible for mucus to migrate up the airways. As the airways open, vibrations help thin and eliminate mucus, allowing it to be expelled. A study done by Burudpakdee C et al., the Aerobika device was shown to decrease the frequency of exacerbations in COPD patients in documented real-world evidence research [16]. The proposed device was linked to reduce in the severity of exacerbations, as well as a decrease in the rates of rehospitalisation and Emergency Room (ER) visits [16]. A study done by Khourdigian-Sinani S et al., on the Aerobika OPEP device's cost-effectiveness for the treatment of COPD exacerbations and concluded that the Aerobika OPEP device should be considered as a potential aspect of a therapy plan for COPD patients in order to enhance symptom control and minimise their incidence of exacerbations [17]. A decrease in hospitalisation and re-hospitalisation episodes could have a considerable influence on COPD's huge financial burden [17,18]. In a study done by Leemans G et al., on approaching the effect of an OPEP device in chronic obstructive pulmonary disease using functional respiratory imaging and concluded that utilising an Aerobika device improves airflow, which improves Internal Airflow Distribution (IAD) and affects the deposition of concomitant medications in the body in COPD patients [19]. Another study done by Shamakh M et al., on comparison of the effects of acapella versus hand-held PEP on pulmonary functioning in the management of chronic obstructive pulmonary disorders concluded that PEP and Acapella improved respiratory functioning in mild COPD. Compared to Acapella and PEP, benefits from ACBT alone were less significant [20].

MATERIALS AND METHODS

Material Required

1. Aerobika device
2. Acapella device
3. Sputum collector
4. Mask



[Table/Fig-1]: Flow chart represents the procedure and selection criteria of the study.

Methodology

Ethical approval

This comparative study will be conducted in Wardha's Acharya Vinoba Bhave Rural Hospital's Department of Respiratory Medicine from January 2023 to June 2023. After receiving ethical approval from the Datta Meghe Institute of Medical Research's Institutional Ethical Committee, the proposal for this comparative study was ethically approved by Departmental Research Committee, Ravi Nair Physiotherapy College on 11th May, 2022 with reference number DMIMS(DU)/IEC/2022/900. It was registered in the Clinical Trial Registry-India (CTRI) with the registration number CTRI/2022/06/043311. An informed consent will be filled by participants. The participants will be assigned and allocated in two experimental groups, Group A receiving a 1-week programme with Aerobika device and Group B receiving a 1-week programme with Acapella device.

Study design and sample size: Before inclusion, all the participants will be informed regarding the aim and procedure of research. Those participants who will meet the inclusion criteria will be give the written informed consent. In comparative study, those participants diagnosed with COPD will be enrolled for one week protocol.

The sample size was calculated by the biostatistician of the institute using Cochran formula [21].

$$n=\frac{Z\alpha/2^2.P.(1-P)}{d^2}$$

Where, $Z\alpha/2^2$ is the level of significance at 5% i.e., 95%

Confidence interval=1.96

P=Overall rate of COPD=3.8%=0.038 [21]

d=Desired error of margin=4%=0.04

$$N=\frac{N=1.962\times0.038\times(1-0.038)}{(0.04)^2}$$

$$=28.65$$

$$=30$$

Participants

Inclusion criteria: Haemodynamically stable, conscious and oriented both male and female participants of age group between 40 to 70 years diagnosed with COPD and who will sign the written informed consent will be included in the study.

Exclusion criteria: The participants with breathlessness with grade 4 and grade 5. Participants with other cardiorespiratory, neurological, infective pulmonary conditions, rib fractures, chest trauma and thoracic vertebral fracture will be excluded from the study.

Recruitment procedure: Patients who came to the respiratory medicine OPD at the Acharya Vinoba Bhave Rural Hospital in Sawangi, Wardha. Diagnosed with COPD with the age group of 40-70 years. The patients suffering from restrictive lung disease, rib fractures, chest trauma and thoracic vertebral fracture will be excluded.

Procedure

Participant timeline: The conventional physiotherapy will comprise of pursed-lip breathing, diaphragmatic breathing, thoracic expansion, active limb mobility exercises, early ambulation and improved functional capacity. Along with conventional physiotherapy, acapella and aerobika devices will be given five days for one week twice a day to Group A and Group B, respectively. Each patient will be required to complete one week of rehabilitation after enrolment in the study. The screening will be done at baseline on the first day and then at the end of first week.

Implementation

The outcome of the study result can be implemented in clinical practice for the given condition as an evidence-based practice.

Dependent variable: sputum volume and PFT

Independent variable:

- **Acapella:** Materials and Methods 22 Specifications-PORTEX Acapella DH Vibratory PEP Therapy System with Mouth Piece Green Product Dimensions: 18 cm×7 cm×7 cm
- **Aerobika:** Lupin Aerobika OPEP Device (1 pcs)

  Dimensions: 15 (cm)×5 (cm)×20 (cm)

Study Procedure

Assessment of the patient will be started after approval from the concerned authority individuals are first screened as per the inclusion and exclusion criteria, and the individuals fulfilling the criteria will then explain the purpose of the study.

Group A: Aerobika Device

- The patient will be taken in the high sitting positions. Patients will be taught how to put the mouthpiece and seal their lips around it during the initial training session.
- The patient will take a deep breath and hold it for 2 to 3 seconds before actively but gently expelling through the device. Exhalation should last three to four times as long as inhalation. Cheeks should be firm and flat.
- Continue to inhale deeply and long exhalation for 10 to 20 breaths followed by 2 to 3 huffs- cough for clearing the airways.
- Along with the above-mentioned treatment, conventional physiotherapy will also be given five days for one week twice a day for 15 to 20 minutes which will comprise of pursed-lip breathing, diaphragmatic breathing, thoracic expansion, active limb mobility exercises, focused treatment on early ambulation and improved functional capacity.

Group B: Acapella Device

- The patient will be in high-seated; Patients will be instructed to exhale via the device with the resistance dial set to the lowest level for 3 to 4 seconds during the initial training session.
- Patients will be advised to exhale more or less strongly if their exhalation will either slow or just too fast
- If a patient's expiration is too sluggish or excessively quick, they will be told to exhale more or less forcefully. Breathing control, 10 breaths using the Acapella device inhaling to three-quarter maximum breathing capacity, 2-3 seconds breath-hold, active exhalation to functional residual capacity, cough or forced expiration (huff) in a predefined cycle are all part of the Acapella treatment.
- Conventional physiotherapy, which will include pursed-lip breathing, diaphragmatic breathing, thoracic expansion, active limb mobility exercises, focused treatment on early ambulation, and enhanced functional ability, will be given five days for 15 to 20 minutes for one week twice a day, in addition to the above-mentioned treatment.

Outcome Measures

Primary outcomes measures:

1. Sputum volume (mL): It has been evaluated in airway clearance techniques using alternative means such as sputum wet weight, dry weight, and volume collected at baseline on the first day and then at the end of 1st week.
2. Pulmonary Functions Test (PFT): The test assesses lung volume, capacity, rates of flow, and gas exchange.
   - Forced Vital Capacity (FVC)
   - Forced Expiratory Volume in one second (FEV1)
   - FEV1/FVC

Secondary Outcomes Measures

COPD assessment test (CAT) scale: The CAT was developed in order to have a short and easy tool which could be administered in the clinical setting [22]. It is a validated tool measuring and quantifying the impact or burden of COPD on the individual [23]. The scoring of CAT is from 0 to 40. Higher scores denote a more severe impact of COPD on a patient's life.

Data Collection and Management

Data of the study will be stored in a safe, secured storeroom with limited access for later review by a biostatistician, a researcher in charge.

STATISTICAL ANALYSIS

Data will be analysed in a statistical software SPSS 27.0.V. The statistical analysis will be done using Chi-square test. The parameters will be compared between both the groups for sputum volume and lung function over a period of one week. A p-value of <0.05 was considered to be significant.

Ethical Approval and Dissemination

The patients who participate in the study and the DMIMSU, which will finance it, will be able to access the study's findings. Data will be stored in the DMIMSU storage device after the study is completed and the results are published.

Patient Consent

Principal Investigators will get the participant's written informed consent on a printed form (in their native language) with signatures and provide verification of confidentiality.

Confidentiality

The patients will be informed about the study protocol, and the primary investigator will collect subjective data. The confidentiality declaration, as well as the signatures of the principal investigator, the patient, and a witness, will be included on the consent form. If the patient's consent is required to share some information for the study, he/she will be given total assurance of his privacy.

Funding

Any public or commercial organisations will not provide direct financing for this project.

REFERENCES

[1] Murray CJ, Lopez AD. Mortality by cause for eight regions of the world: Global burden of disease study. The Lancet. 1997;349:1269-76.
[2] Boutou AK. Physical inactivity and sedentarism among COPD patients: What about dynamic hyperinflation? COPD J Chronic Obstr Pulm Dis. 2019;16:108-08.
[3] Tashkin DP. Heroin smoking and COPD. Chest. 2019;155:247-48.
[4] Gómez FP, Rodriguez-Roisin R. Global Initiative for Chronic Obstructive Lung Disease (GOLD) guidelines for chronic obstructive pulmonary disease: Curr Opin Pulm Med. 2002;8:81-86.
[5] Miravitlles M. Effect of exacerbations on quality of life in patients with chronic obstructive pulmonary disease: A 2 year follow up study. Thorax. 2004;59:387-95. 10.1136/thx.2003.008730.
[6] Anthonisen NR. Antibiotic therapy in exacerbations of chronic obstructive pulmonary disease. Ann Intern Med. 1987;106:196.
[7] Omachi TA, Blanc PD, Claman DM, Chen H, Yelin EH, Julian L, et al. Disturbed sleep among COPD patients is longitudinally associated with mortality and adverse COPD outcomes. Sleep Med. 2012;13:476-83.
[8] Zwerink M, Brusse-Keizer M, van der Valk PD, Zielhuis GA, Monninkhof EM, van der Palen J, et al. Self management for patients with chronic obstructive pulmonary disease. Cochrane Database Syst Rev. 2014;2014(3):CD002990.
[9] Hopkinson NS, Dayer MJ, Moxham J, Polkey MI. Abdominal muscle fatigue following exercise in chronic obstructive pulmonary disease. Respir Res. 2010;11:15.
[10] Hopkinson NS, Sharshar T, Ross ET, Nickol AH, Dayer MJ, Porcher R, et al. Corticospinal control of respiratory muscles in chronic obstructive pulmonary disease. Respir Physiol Neurobiol. 2004;141:01-12.
[11] van der Schans CP, Postma DS, Koëter GH, Rubin BK. Physiotherapy and bronchial mucus transport. Eur Respir J. 1999;13:1477-86.
[12] Svenningsen S, Paulin GA, Sheikh K, Guo F, Hasany A, Kirby M, et al. Oscillatory positive expiratory pressure in chronic obstructive pulmonary disease. COPD J Chronic Obstr Pulm Dis. 2016;13:66-74.
[13] Bourbeau J, McIvor RA, Devlin HM, Kaplan A. Oscillating positive expiratory pressure (OPEP) device therapy in Canadian respiratory disease management: Review, care gaps and suggestion for use. Can J Respir Crit Care Sleep Med. 2019;3:233-40.
[14] Wolkove N, Kamel H, Rotaple M, Baltzan MA. Use of a mucus clearance device enhances the bronchodilator response in patients with stable COPD. Chest. 2002;121:702-07.
[15] Volsko TA, DiFiore J, Chatburn RL. Performance comparison of two oscillating positive expiratory pressure devices: Acapella versus Flutter. Respir Care. 2003;48:124-30.
[16] Burudpakdee C, Seetasith A, Dunne P, Kauffman G, Carlin B, Coppolo D, et al. A real-world study of 30-day exacerbation outcomes in Chronic Obstructive Pulmonary Disease (COPD) patients managed with aerobika OPEP. Pulm Ther. 2017;3:163-71.
[17] Khoudigian-Sinani S, Kowal S, Suggett JA, Coppolo DP. Cost-effectiveness of the Aerobika* oscillating positive expiratory pressure device in the management of COPD exacerbations. Int J Chron Obstruct Pulmon Dis. 2017;12:3065-73.
[18] Wedzicha JA Ers Co-Chair, Miravitlles M, Hurst JR, Calverley PM, Albert RK, Anzueto A, et al. Management of COPD exacerbations: A European Respiratory Society/American Thoracic Society guideline. Eur Respir J. 2017;49(3):1600791.
[19] Leemans G, Belmans D, Van Holsbeke C, Kushnarev V, Sugget J, Ides K, et al. A functional respiratory imaging approach to the effect of an oscillating positive expiratory pressure device in chronic obstructive pulmonary disease. Int J Chron Obstruct Pulmon Dis. 2020;15:1261-68.
[20] Shamakh M, Badr N, El-Batanouny M, Shendy M. Acapella versus hand-held positive expiratory pressure on pulmonary functions in management of chronic obstructive pulmonary diseases. J Adv Pharm Educ Res. 2020;10:27-34.
[21] Regional COPD Working Group: COPD prevalence in 12 Asia-Pacific countries and regions: Projections based on the COPD prevalence estimation model. Respirology. 2003;8:192-98.
[22] Putcha N, Puhan MA, Drummond MB, Han MK, Regan EA, Hanania NA, et al. A simplified score to quantify comorbidity in COPD. PLoS ONE. 2014;9(12):e114438.
[23] Jones PW, Brusselle G, Dal Negro RW, Ferrer M, Kardos P, Levy ML, et al. Properties of the COPD assessment test in a cross-sectional European study. Eur Respir J. 2011;38:29-35.

PARTICULARS OF CONTRIBUTORS:
1. Resident, Department of Cardio-Respiratory Physiotherapy, Ravi Nair Physiotherapy College, Datta Meghe Institute of Medical Sciences, Wardha, Maharashtra, India.
2. Professor and Head, Department of Cardio-Respiratory Physiotherapy, Ravi Nair Physiotherapy College, Datta Meghe Institute of Medical Sciences, Wardha, Maharashtra, India.

NAME, ADDRESS, E-MAIL ID OF THE CORRESPONDING AUTHOR:
Dr. Vishnu Vardhan,
Professor and Head, Department of Cardio-Respiratory Physiotherapy, Ravi Nair Physiotherapy College, Datta Meghe Institute of Medical Sciences,
Wardha-442107, Maharashtra, India.
E-mail: vishnudiwakarpt@gmail.com

PLAGIARISM CHECKING METHODS: [Jain H et al.]
- Plagiarism X-checker: Jun 20, 2022
- Manual Googling: Oct 08, 2022
- iThenticate Software: Nov 22, 2022 (16%)

ETYMOLOGY: Author Origin

AUTHOR DECLARATION:
- Financial or Other Competing Interests: None
- Was Ethics Committee Approval obtained for this study? Yes
- Was informed consent obtained from the subjects involved in the study? Yes
- For any images presented appropriate consent has been obtained from the subjects. Yes

Date of Submission: **May 27, 2022**
Date of Peer Review: **Aug 27, 2022**
Date of Acceptance: **Nov 26, 2022**
Date of Publishing: **May 01, 2023**