Effect of RC Cornet plus versus Aerobika on Pulmonary functions and sputum volume in bronchiectasis patients: Protocol of a Comparative study.

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Abstract

Background: Bronchiectasis is characterized by intractable dyspnea, decreased functional capacity, restricted airflow, acute exacerbation episodes, and irreversible blockage. A common symptom is a productive cough due to mucus hypersecretion. Clearing the lungs can prevent infections, enhance energy conservation, improve breathing, and lung function. Oscillating positive expiratory pressure (OPEP) devices, such as the RC Cornet Plus and Aerobika, are non-pharmacological interventions that facilitate sputum clearance by combining airway oscillations and positive pressure to keep airways open. These devices are safe compared to pharmacological therapies.

Objective: The Aerobika device has five resistance settings adjustable by the patient. Similarly, the RC Cornet Plus allows patients to determine optimal pressure and flow by turning the mouthpiece. Both are flow-dependent devices. However, the comparative effectiveness of these devices in bronchiectasis patient`s needs further exploration. To address this gap, comparative research is needed on Symptomatic and clinical outcomes.

Methods: A single-center, 18-month experimental comparative study with thirty participants will be selected based on inclusion and exclusion criteria, provided with study information, and asked for informed consent. They will be divided into two groups of 15 each: Group A (RC Cornet Plus with conventional chest physiotherapy) and Group B (Aerobika with conventional chest physiotherapy). Sputum volume and lung functions (FEV1, FVC, and FEV1/FVC) will be assessed on day 1 and reassessed on day 7 after a week of intervention with twice-daily physiotherapist visits.

Results: As of November 2023, we enrolled 30 participants, and the data collection process started from November 2023-November 2024. The expected results are that the significance of RC cornet will be more than that of the Aerobika device, and the expected results to be published in the end week of November 2024.

Conclusions: The study will conclude that is RC Cornet device is effective than Aerobika Device on pulmonary function and sputum volume. Clinical Trial: This study is registered under CTRI Number- CTRI/2024/07/071083, registered on 23/07/2024.

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Title

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Keywords: Bronchiectasis, Aerobika, RC Cornet Plus, Pulmonary function test, sputum volume, OPEP Device, Airway clearance devices.

INTRODUCTION

Bronchiectasis is a pulmonary condition in which the airways is not normal and is irreversibly damaged. According to the pathophysiology, abnormalities in the internal structure of the airways trigger the accumulation of mucus, persistent neutrophilic inflammation, and persistent airway infection, all of which worsen the already existing damage to the airways and complete a "vicious cycle"(1). Overabundance of mucus buildup in the lung airways linked to alterations in rheological characteristics, primarily an elevation in viscosity, resulting in mucociliary escalator dysfunction. These processes precede inflammation and infection, airway blockage, and parenchyma damage when combined with ineffective expectoration (2). Patients are more likely to develop opportunistic infections from inhaled pathogens as a result of neutrophil activity, which causes hypersecretion and the consequent buildup of extra mucus. A significant rise in mucus viscosity and/or mucus production rate (hypersecretion) is a consequence of several respiratory diseases. Pleuritic chest pain, haemoptysis, breathing difficulties, and fatigue are typical symptoms that accompany the traditional ones associated with a persistent cough, excessive sputum production, and recurrent respiratory infections. A pulmonary function test (PFT), sputum bacteriological culture, and a chest radiograph

are effective first investigations to perform on people who showed up with symptoms that are suggestive of bronchiectasis (3). Pulmonary function tests, or PFTs, seem to be confined to the follow-up of autoimmune individuals who have been diagnosed with definite lung involvement in clinical settings at present (4). It has long been considered that no number of pharmaceuticals could successfully manage individuals who have bronchiectasis, however, some aetiologies might react more favourably to a particular therapy (5). Optimization of airway mucus clearance by means of physiotherapy, either alone or in combination with adjuvant therapies; suppression, elimination, and prevention of airway bacterial colonization; decrease in airway inflammation, and promotion of physical performance and quality of life should be the primary goals of therapy (6). In order to efficiently handle bronchiectasis both over the long term as well as during an acute exacerbation, it is necessary to maintain adequate hydration and airway clearance, and the utilization of physiotherapy facilities needs to be emphasized to all patients (7).In clinical practice, a range of individual or combined therapies are applied based on different approaches to intervention. These include the use of positive expiratory pressure, vibration, airway oscillations, location, adjustments to pulmonary volume, and exhalation flow, and oscillations of the chest wall (8).

In particular, the growing use of oscillating positive expiratory pressure (OPEP) therapy via various devices is pointed out. Regarding the components that seem to work best at mobilizing mucus, recommendations are given. Exhaled breath from the patient activates the one-way valve and intermittently blocks the flow of air, resulting in oscillations and positive pressure (1). When a person actively exhales through the apparatus and inhales slight deeper-than-normal tidal volume, a series of oscillatory changes in the airway pressure take place. While the oscillations assist in thinning and loosening adherent mucus from the airway lumen, positive pressure works to stent the airways. The shear forces produced by these oscillations lessen the viscoelasticity of the bronchial fluids, promoting mucus mobilization. Using Aerobika, a portable mechanical Oscillatory Positive Expiratory Pressure (OPEP) device, individuals can exhale against a manually changeable resistance that can be varied. The RC Cornet Plus uses low-frequency acoustic wave technology to aid with secretion clearing. It consists of a mouthpiece, an angled tube, a valve hose, and a sound dampener. This results in oscillatory vibrations in the airways and a positive expiratory pressure. of exhaling via the tube, which increases the pressure inside the hose until it is enough to induce the hose end to open (9). The implementation of OPEP by physiotherapists enhances the results of physical therapy; thereby, the development of intelligent models of these devices provides improved functionality and deserves to be a component of therapeutic protocols (10).

Guidelines state that ACTs should be taught to people who have a chronic productive cough or have

difficulty expectorating sputum. ACTs are intended to facilitate the mucociliary clearance system of the body and facilitate the easier removal of sputum. Adjusting lung volumes, pressures, and flows, applying compressive or vibratory forces, and utilizing gravity are some of the mechanisms by which ACTs enhance sputum clearance. Sputum volume has been measured in airway clearance studies using a variety of techniques, including wet weight, dry weight, volume collected during and/or right after an intervention, and volume collected within 24 hours after the intervention. Measurements of sputum weight and volume appear to be straightforward or easy, but sputum collection and characterization are subject to well established regulations, such as the need for compliance when gathering sputum weight over predetermined time periods (11).

Lung function: Measures of lung function, in particular forced vital capacity (FVC) and forced expiratory volume in 1 second (FEV1), are commonly used as indicators of the effectiveness of pharmacotherapy treatments for COPD, CF, and bronchiectasis. As long as research adheres to guidelines, lung volume measurements could be deemed trustworthy enough to evaluate lung function both before and after ACT interventions The quality of data comparing methods of treatment toward developed the deficiency of adequately powered and randomized controlled trials lowers indicators of enhance lung functions, such as forced expiratory volume in 1 second (FEV1), forced lung capacity (FVC), and forced expiratory flow between 25% and 75% of FVC. (FEF25-75%) (13). Therefore, the purpose of this research is to compare the efffect of RC Cornet plus device versus the Aerobika device on sputum volume and lung functions in bronchiectasis patients.

Objectives

1. To evaluate the effect of RC Cornet Plus device on pulmonary functions and sputum volume in Bronchiectasis patients.
2. To evaluate the effect of Aerobika device on pulmonary functions and sputum volume in Bronchiectasis patients.
3. To evaluate and compare the effect of RC Cornet Plus device and Aerobika device on pulmonary functions and sputum volume in Bronchiectasis patients.

Hypothesis

Null Hypothesis (H0): There is no significant difference between the Effects of the RC Cornet Plus device and the Aerobika device on pulmonary functions and sputum volume in bronchiectasis patients.

Alternative hypothesis (H1): There is a significant difference between the Effects of the RC Cornet Plus device and the Aerobika device on pulmonary functions and sputum volume in bronchiectasis

patients.

MATERIALS AND METHODOLOGY

A Single Centre, open label, Experimental comparative study, will be conducted in the Outpatient Department and IPD of Ravi Nair Physiotherapy College and AVBRH Sawangi, Wardha, Maharashtra, India from November 2023- November 2024 on individuals with Bronchiectasis. The Ethical approval from the Institutional Ethical Committee of Datta Meghe Institute of Higher Education and Research had approved the study and the reference number is DMIHER(DU)/IEC/2023/1063. This study is registered under CTRI Number- CTRI/2024/07/071083, registered on 23/07/2024. All study-related facts, including an explanation of any adverse scenarios or discomforts, will be communicated with participants. The participants will also be made aware of their liberty to drop out from the research at any moment, for any reason, and a written consent form with informed consent will be acquired before the selection of participants.

Inclusion criteria:

Patients who signed the written informed consent. Both male and female participants diagnosed with bronchiectasis, Age group 40 to 70 years, haemodynamically stable, conscious and oriented patients will be included in the study.

Exclusion criteria:

Uncooperative patients Participants with any other severe cardiorespiratory (such as MI, Unstable Angina, or arrhythmia) or neurological problem, the subjects having breathlessness of grade 4 and grade 5 on MMRC Scale, Patients with restrictive pulmonary distress. Rib fractures, Chest Trauma and Thoracic vertebral fracture. Acute thrombosis, Acute and present haemoptysis, Unhealed Surgery or injury to the mouth, face, skull, or oesophagus, Possible eardrum trauma, Lung barotrauma, Major cardiovascular deficit, enormous constraint of the respiratory pump Several, considerable nosebleeds Granuloma - development of the mucous membranes in central respiratory tract will be excluded from the study.

Sample size calculation:

The sample size was calculated using the Cochran formula.

15 patients will be recruited in Group A and 15 in Group B (n=30).

$$n = \frac{Z\alpha/2\ 2.P.(1-P)}{d2}$$

Where, Z α/2 is the significance level at 5% i.e., 95 %

Confidence interval = 1.96

P = Prevalence of Covid-19 = 9.88% = 0.0988

d = Margin of desired error = 4% = 0.04

N = 1.962 × 0.038 × (1-0.038) (0.04)2

= 28.65

=30

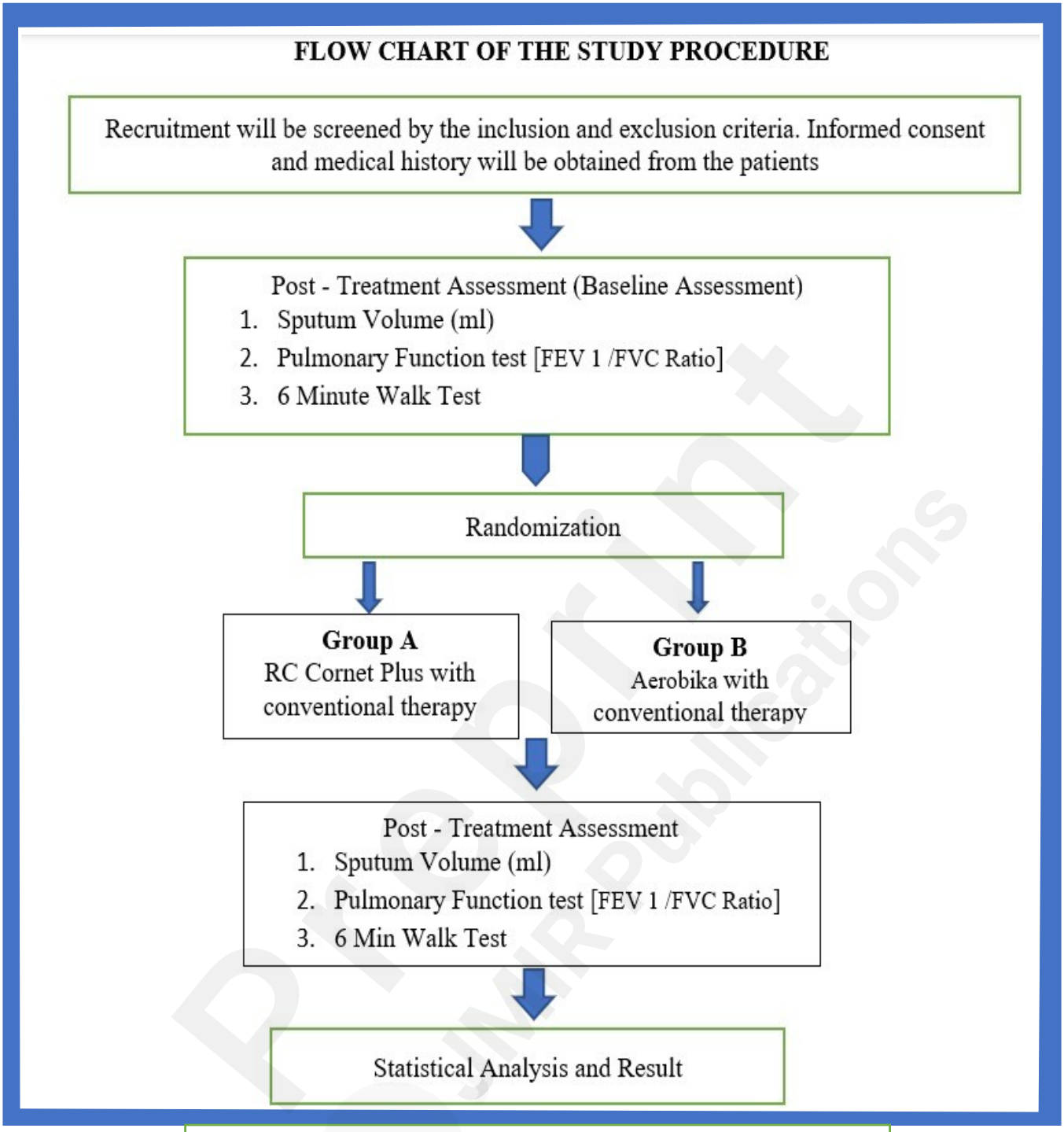
Ref Article: -Mikelson et al. (12)

Recruitment: According to the sample size the participants will be divided into Group A (RC Cornet Plus device with conventional Physiotherapy) and Group B (Aerobika device® with conventional physiotherapy). The primary researcher physiotherapist will carry out allocation of the patients. Both groups will be having n=15 patients each.

Allocation: Allocation will be overseen by the principal investigator and research coordinator. In order to be recruited in both groups, participants will need to manually choose their group allocation from an envelope that has been sealed.

Implementation: After dividing the patients into two groups, the sputum volume(ml), 6-minute walk test (vitals, distance, RPE, rests, etc.) and pulmonary functions (FVC, FEV1, FEV 1 /FVC Ratio) will be assessed as a baseline outcome measure. A planned regimen will be performed in both groups for a week. The physiotherapist will visit the patients twice a day, and after 1-week, the sputum volume, 6 min. walk test and Pulmonary functions (FVC, FEV1, FEV 1 /FVC Ratio) will be reassessed as a post-intervention outcome measure.

According to SPIRIT guidelines, the study protocol has been reported in [Table/Fig-1].



[Table/Fig-1]: CONSORT flow diagram (SPIRIT guidelines) for Research Protocol.

Interventions

Group A: - RC Cornet Plus device with Conventional Physiotherapy

The Cornet is made up of a flexible latex-free hose enclosed in a semi-circular tube. Patients were asked to inhale deeply through their noses and exhale through the RC Cornet while firmly holding

their lips to the mouthpiece while sitting or partially lying down. The patient will experience a low-pitched, rough sound and vibration in their chest. This was replicated with 10 repetitions spread over 6 sets of 10 minutes, interspersed with moments of relaxation. The patient then proceeded to cough and huff. The RC-Cornet's mouthpiece was turned to increase the vibration and PEP in the airway. When exhaling, oscillations in airflow and pressure are also produced (13).

Group B: - Aerobika device® with Conventional Physiotherapy

The Canadian company Trudell Medical International produces the drug-free, mechanical Aerobika, a hand-held device with five resistance-setting options. Occasionally, while exhalation, a 1-way valve in the device apparatus unfastens and shuts, causing oscillations in the airways and resistance to termination airflow. We'll be using the Aerobika device while erect. During the first training session, patients will learn the method of positioning the mouthpiece and sealing their lips around it. Instruct the patient to inhale deeply, hold it for two to three seconds, and then gently and actively exhale through the device. The active exhalation should come after 3-4 times the length of the inhalation. Cheek's ought to be firm and flat. To clear the airways, keep inhaling deeply and exhaling slowly for 10 to 20 breaths. Then, cough or huff for two to three times. In addition to the aforementioned intervention, standard physical therapy will be administered. This will include active limb mobility exercises, diaphragmatic breathing, pursed-lip breathing, thoracic expansion, and early ambulation-focused treatment (14).

Conventional Physiotherapy Program for both the Groups:

Along with study intervention with devices, Both Groups received conventional physiotherapy twice daily for 15 to 20 minutes for a week, which included exercises to improve functional capacity and early ambulation as well as pursed-lip breathing, diaphragmatic breathing and thoracic expansion, Active Cycle of Breathing Technique, Effective huffing and coughing Techniques.

Outcome Measures:

Primary Outcome Measures:

1. **Pulmonary function test**

   These particular measures will be computed by the equipment called Spirometry (RMS HELIOS401) (15).

   Parameter includes:

   Forced Vital Capacity (FVC) - The Maximum Volume of Air that a Patient Can Exhale as Rapidly and Forcefully as Possible After Maximum Inspiration is Known as Forced Vital Capacity (FVC), (FVC maneuver). Normal values: The vital capacity (VC) and the forced vital capacity (FVC) should be within 200 ml.

Forced Expiratory Volume in One Second (FEV1)- It is a measure of the volume that expires in first second of an FVC manoeuvre.

Normal values: Forced expiratory volume in persons with normal pulmonary functions is: FEV 1 = 75%-85% of total vital capacity.

FEV 1 /FVC Ratio- It will be obtained by dividing predicted FEV1 by predicted FVC.

Peak expiratory flow rate (PEFR)-PEFR is the maximum flow attained during an FVC manoeuvre. Expressed in litre/ second

Normal range for adults- 100-850 L/min.

2. **Sputum volume (mL):**

Alternative measures, like sputum wet mass, dry mass, and the quantity collected at baseline preintervention on the first day and then postintervention at the end of the first week, have been used to evaluate it in the clearance of airway techniques (16).

Secondary outcome measures: -

1. **Six Minute Walk Test:**

The 6MWT will be performed according to ATS guidelines (17).

STATISTICAL ANALYSIS

The mean and standard deviation (SD) of the outcome variable values will be checked for normal distribution, and the findings will be measured and statistically analyzed. Median statistics will be used to identify skewed distributions and interquartile ranges (IQR). For descriptive statistics, binary and categorical variable frequencies and percentages will be added up. The following explanation will assist with the examination of the inferential statistics.

Primary outcome

Inferential statistics will be utilised to compare the mean change in the variable (Sputum Volume, PFT, Six-minute walk test) at baseline and after 5 days for the two groups. Then, a separate t-test will be used. The responses from the respondents will be evaluated with respect to the primary variable's fluctuation between the baseline and the time period monitored throughout. For research participants, random effects will be generalized, and fixed effects will be investigated by determining treatment group and number of visits. A 95% confidence interval (CI) will be used to assess the impact size over the mean difference on the key variable from the baseline to the last visit.

Primary end point (description)

Either a parametric test or a non-parametric test will be used to assess statistical significance for the difference in effect sizes between the groups at the 5% significance level. A t-test (Unpaired) will be used to determine whether the difference in mean values between two groups is statistically significant if the values show a normally distributed distribution. If the data are not normally distributed, they can be transformed using mathematical methods to become normally distributed. Suppose the data for all key variables continue to show signs of non-normal distribution. In that case, additional non-parametric tests (Wilcoxon test, Mann-Whitney U, and Chi-square test) will be used.

DISCUSSION

The purpose of the particular study will be to find out how RC Cornet plus and Aerobika affects pulmonary functions and sputum volume in bronchiectasis patients. Clinicians find it challenging to select the optimal therapy for each patient based on their symptoms and general health because of the growing number of OPEP devices available, each with distinct features and scant information on the device's overall performance. The numerous variations in pathology related to different conditions for which this treatment has been used. Small sample size and short duration studies that have made it demanding to obtain strong indication in terms of mechanism and consequent enhancement of lung function, have further impeded the development of OPEP as a recognized ACT. The current overview also highlights the mounting evidence that OPEP therapy improves mucus secretion mobilization in the range of conditions for which these devices have been utilized. This is important because a common reason for these patients to end up in the hospital is a pathogen infection that is made worse because of secretion retention in the lung airways. Moreover, Bourbeau and colleagues have noted that the variety of OPEP devices in circulation run distinct operating systems. generate distinct pressure pulse waveforms, and have different cleaning and usability characteristics; as a result, these devices might not be interchangeable and might not provide patients with the same benefits. It is imperative that healthcare providers who recommend these devices root their choices on advertised clinical evidence of their effectiveness. Additionally, subject recruitment and proper commands and instructions on optimal use of the device—including how to perform potent huff coughs—are essential to maximizing the therapeutic effect (2).

This article sheds light on how OPEP-based therapies may eventually fall more broadly under the category of ACTs that physicians can use to treat pulmonary airway diseases involving the production of chronic mucus secretions. It does this by highlighting significant improvements in device attributes and performance as well as significant clinical evaluations. The three most often utilized markers of clinical outcome are pulse oximetry, sputum volume, and lung function. The most often reported outcome measures by patients include cough-related quality of life, health, and dyspnea. To increase the likelihood of proving to be significantly beneficial and to guide the individualized prescription of ACTs for bronchiectasis, guidelines for standardizing and implementing the most important clinical and patient-reported outcome measures in long-term studies are desperately needed (18).

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