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Efficacy of Acapella on Spirometer Measures in Patients with Bronchiectasis

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ABSTRACT

Objectives: This research was carried out to find the efficacy of Acapella on spirometer measures in patients experiencing acute exacerbation of bronchiectasis. **Methods:** Thirty patients of both gender with acute exacerbation of bronchiectasis with age ranged from 40-55 years old contributed to this research, two groups of equal size were selected at random experimental groups (n= 15), group (A) as well as group (B), Group (A) were given Acapella, that conducted through a supervised session of three sets each one of 10 repetitions, two times daily for 14 days, in addition to routine physiotherapy program(breathing exercises, postural drainage, Percussion as well as vibration), while Group (B) were given only routine physical therapy program for 14 days. Spirometer measures forced vital capacity (FVC), forced expiratory volume in the first second (FEV1) as well as FEV1/FVC were assessed for all patients before the beginning and after the end of this study. **Results:** Non-significant differences ($p > 0.05$) were found among groups (A & B) on the pre-treatment mean values regarding FVC, FEV1 and FEV1 / FVC, whereas after treatment, there were statistically substantial variations in all evaluated variables, both within and between the two groups ($p < 0.05$). **Conclusion:** Acapella is an effective device for improving spirometer measures as well as pulmonary function in patients experiencing acute exacerbation of bronchiectasis

1. Introduction.

Bronchiectasis is a progressive in addition to persistent lung disease **[1].** This is in addition to the symptoms of a persistent cough, sputum expectoration, dyspnea and decreased exercise tolerance **[2].** The patients suffer from repeated lung infections that lead to bronchial inflammation as well as persistent dilation, decreased sputum clearance as well as bacterial colonization which can lead to further infection **[3].**

The advanced deterioration of pulmonary function due to recurrent aggravations is a major indication of morbidity as well as mortality in bronchiectasis **[4].**

In cases of severe bronchiectasis flare-up there are increased cough and sputum expectoration beside sputum viscosity change. It is important to remove secretions every day in patient with bronchiectasis, especially during acute exacerbation air way clearance is a must. Patient with mild exacerbation are treated at home with ten to fourteen days course of oral medications. Patients with moderate to severe exacerbation. During an exacerbation, hospitalized patients get IV antibiotics and participate in an intensive treatment programme that includes 1 to 2 daily supervised airway clearance techniques (ACTs) **[5].**

Different devices can be used in management of bronchiectasis (eg, Acapella, positive expiratory pressure (PEP), Flutter) were also implemented in the care of these individuals as well **[6].**

Twenty bronchiectasis patients showed similar improvement using the Acapella device compared to those using active cycle breathing techniques (ACBTs) **[7].**

The Acapella is a portable tool that provides both high-frequency oscillations with PEP. Acapella may compromise a good substitute to other ACTs as it requires less time from the therapist, Acapella used easily by patient, may be used during postural drainage (PD) different positions and used with patients suffering from different pulmonary diseases **[8].**

To clear chest secretions, Acapella chest rehabilitation device can be used. A continuous and oscillatory pressure levels areproduced, when patient expire through Acapella **[9].** Acapella involves an anti-weight cover in addition to a metal bar coupled with a handle as well as magnet **[10].** Acapella device can enhance the lung performance by improving secretions removal **[11].** Acapella can be done by the patient themselves, is effective regardless of the patient's PD position, and is safe for those with varying degrees of pulmonary function.

The most important measures of spirometer are the FVC, which is the maximal volume of air expired by maximum expiration after a maximal inspiration, expressed in liters at body temperature & pressure as well as saturated with water vapor and FEV1), which is the most amount of air that can be expired in the first sec. following a full inhale and subsequent forced holding of the breath, at core body temperature, expressed in litres and room pressure full of water vapor **[12].**

The purpose of this research was to determine whether or not Acapella improved spirometer readings in patients suffering from an acute exacerbation of bronchiectasis.

2. Materials and Methods

Study Design:

The current investigation has been planned for as a prospective randomized controlled trial. South Valley University's Department of Physical Therapy's Committee on the Ethics of Scientific Research provided the initial ethical approval (PT-IMG-02/2023-505) and clinical trials record number of NCT05838144.

Study participants and recruitment

Patients were split evenly between two groups using a computer algorithm written by a clinician who did not take part in the study. Patients' randomization codes remained unopened in sealed envelopes until after they had given their permission to participate in the research.

As shown in the flow chart in (Figure 1), 42 patients were eligible in this study and 12 patients dropped out due to their far residence. Block Stratified Randomization Software was used to randomly assign the remaining 30 patients (windows version 6.0 of randomization program (Rand.exe) to put the same number of samples in each of two groups when there are more than two stratified variables.

This study was done in cooperation with the South Valley University Faculty of Medicine's Chest Department. Each institution's ethics board gave its stamp of approval to the study's procedure; a documented statement of informed consent was signed by all of the patients.

The included patients on this research whose being suffered from bronchiectasis with acute exacerbation, their ages between 40 and 55 years, of both genders, with BMI from 25 to 34.9 kg/m^2. The patients with uncontrolled hypertension and diabetes, patients who have other health issues, such pulmonary embolisms or hemoptysis, that prevent them from performing airway clearance, and uncooperative patients were excluded.

Interventions

All the patients were examined medically for completion of medical history and clinical, laboratory and radiological assessment before treatment decision and regular evaluation.

Patients were randomly assigned to one of two treatment groups:

Group A: patients were given Acapella device (Smiths Medical ASD.Inc.6000Nathan Lane North Minneapolis, MN 55442 USA, 2020, CE approved)

Group B: patients were given only routine physiotherapy program.

Treatment administration

Group (A) : Fifteen patients were given Acapella device conducted through a supervised session of three sets each one of 10 repetitions, two times daily for ten days, in addition to routine physiotherapy program (breathing exercises, PD, Percussion as well as vibration).

Patient asked to sit in a relaxed comfortable position forward leaning while their elbows rested on a table to open the airway by slightly extending neck. Patient asked to take deep inspiration through the nose, hold breath for 3 seconds, then place Acapella mouthpiece in his/her mouth, tightly seal lips around the mouthpiece, then exhale as much as possible not forcefully through the mouthpiece, repeat this maneuver 9 more times, after the tenth time do 3 huffs, then a big cough to bring sputum out, take short break then repeat for two more sets for total 30 repetitions for every session.

Group (B): Fifteen patients were given only routine physiotherapy program (breathing exercises, PD, Percussion as well as vibration).

Patients performed regular thoracic expansion exercises at least one time every hour, with end-inspiratory hold for few seconds. The most preferable position of breathing exercises was the upright position (sitting, leaning forward or standing).

Inspiration was preferable to be done slowly and deeply, through the mouth or nose. A slow inspiration lead to distribution of air to depending lung regions The inspiration done actively and followed by a slight hold (2-5 seconds) to sustain a maximal inspiration before the expiration. A maximal inspiration with a breath hold led to decrease airway collapse and reverse atelectasis.

Expiration is normally a passive process through the process of quiet breathing, done by the way of the elasticity of the lung and chest wall.

Manual vibration and percussion were utilized in conjunction with PD to assist in secretion removal. Vibration was performed with the palmer side of the physiotherapist’s hands, and should be in full contact with the part of the chest wall of patient, or the two hands overlapped. Then, asked patient to take deep inspiration after the end of deep inspiration and throughout exhalation gently did an oscillating pressure on the chest wall till the end of the expiration.

Outcome measures

Spirometer measures: (CONTEC, SPIROMETER, SPM-A, CHINA, 2010) such as FVC, FEV1and FEV1/FVC.

Statistical Analysis

Due to a lack of relevant literature in addition to the difficulties involved in assessing the size of the effect, we conducted a pilot study with ten patients. The statistical software G*POWER estimated that each group would have 15 patients which is the minimum adequate sample size for the recent investigation (version 3.1.9.2; Franz Faul, Universitat Kiel, Germany). To compute the size of the effect, this program was implemented. In the computations, α= 0.05, ß= 0.19, effect size = 0.38, & allocation ratio N2/N1 = 1 were employed.

The chi-square test was used to figure out the distribution of the sexes. Means as well as standard deviations were used to display all of the data in the study. An unpaired t-test was performed to evaluate differences in subject characteristics between groups. In order to ensure that the data matched a normal distribution, the Shapiro-Wilk test was performed. Levene's testing for homogeneity of variances was performed to examine the homogeneity of the groups. Both a paired as well as unpaired t-test were used to analyze the variables before as well as after therapy in every group. In this study, statistical substantial was defined as a p-value of less than 0.05. The Windows version of the SPSS statistical software (version 23) was used for all statistical analysis (IBM SPSS, Chicago, IL, USA).

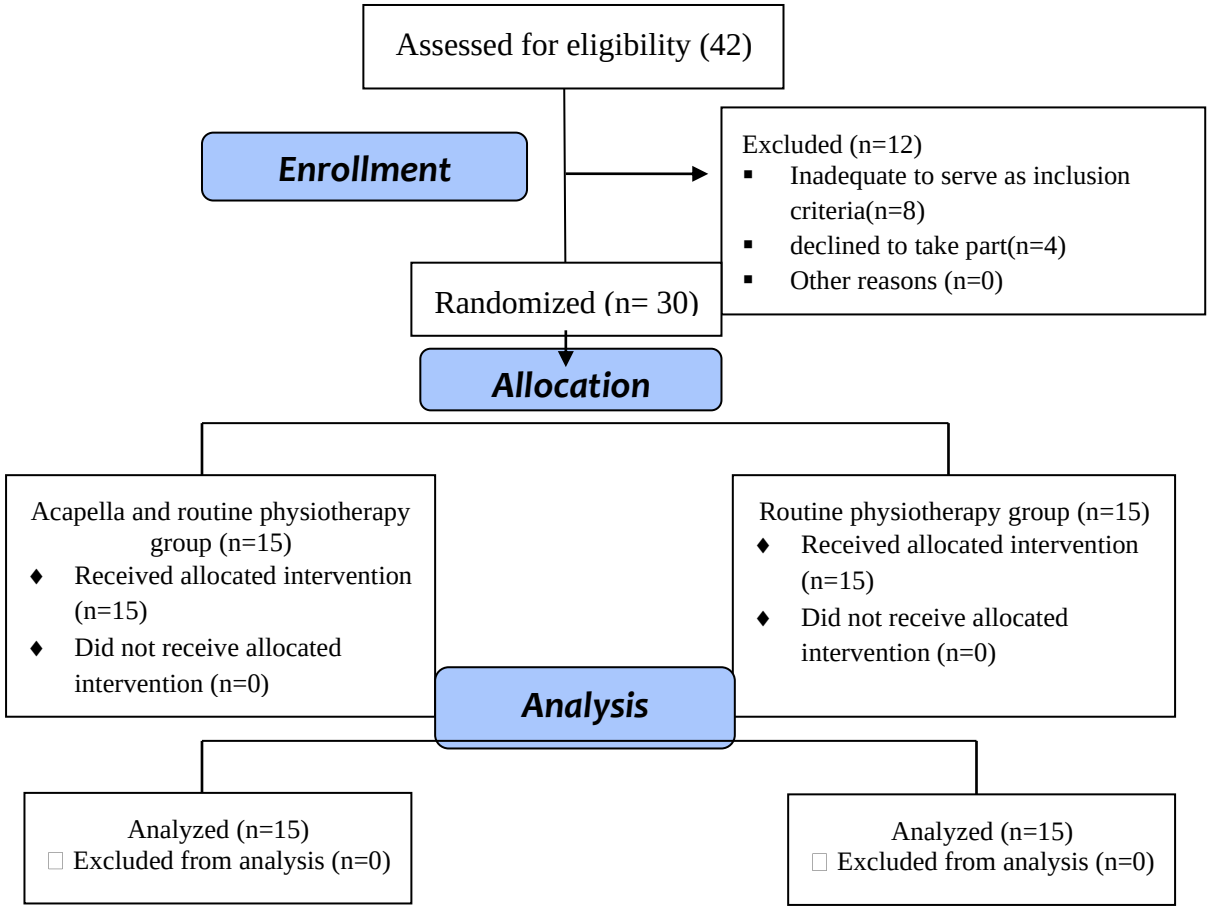

Figure (1): The flow chart of the study.

3. Results

A) Patients demographic data

There has been no significant difference in age, weight, height, or BMI among the two groups, which both contained 15 patients ($p > 0.05$) as in (Table 1).

Table (1): Comparison of age, weight, height as well as BMI between groups (A & B).

	Group (A) $\overline{X}$ ± SD	Group (B) $\overline{X}$ ± SD	t-value	p-value	Level of significant
Age (years)	50.8 ± 4.28	49.8 ± 3.32	0.71	0.481	N.S
Weight (kg)	81.7 ± 9.97	84.7 ± 14.7	0.66	0.519	N.S
Height (cm)	168.97 ± 7.94	164.7 ± 7.61	1.5	0.144	N.S
BMI (kg/m^2)	28.67 ± 4.04	31.25 ± 5.42	1.48	0.152	N.S

$\overline{X}$: Mean. SD: Standard Deviation. t-value: Unpaired test value. p-value: Probability value. NS: Non-Significant.

B) Gender distribution

There has been no significant difference in the gender distribution of among the two groups ($p > 0.05$) as in (Table 2).

Table (2): Comparison of the frequency distribution and chi squared test for gender distribution between groups (A & B).

	Group (A)	Group (B)	X^2-value	p-value	Level of significant
Females	4 (26.67%)	2 (13.33%)	0.89	0.379	NS
Males	11 (73.33%)	13 (86.67%)			

$\overline{X}$: Mean. SD: Standard Deviation. X^2: Chi squared value. p-value: Probability value. NS: Non-Significant.

C) Measured variables

Non-significant differences ($p > 0.05$) were found among groups (A& B) on the pre-treatment mean values regarding FVC, FEV1 and FEV1 / FVC, where as following treatment there have been statistically significant differences in each group as well as between the 2 groups of all measured variables ($p < 0.05$) (Table 3).

Table (3): Comparison of FVC, FEV1 as well as FEV1 / FVC for the two groups (A & B).

		Group (A) $\overline{X}$ ± SD	Group (B) $\overline{X}$ ± SD	t-value	p-value
FVC	Pre- treatment	2.66 ± 0.44	2.81 ± 0.49	0.91	0.371^{NS}
	Post- treatment	3.31 ± 0.39	23.49 ± 2.68	2.44	0.022^{S}
	t-value	20.51	3.15	-	-
	p-value	0.0001^{S}	0.0001^{S}	-	-

FEV1	Pre- treatment	1.75 ± 0.35	1.98 ± 0.34	1.77	0.087^{NS}
	Post- treatment	2.65 ± 0.41	2.1 ± 0.32	4.1	0.0001^{S}
	t-value	13.04	5.19	-	-
	p-value	0.0001^{S}	0.0001^{S}	-	-
FEV1 / FVC	Pre- treatment	65.87 ± 7.76	70.48 ± 5.73	1.85	0.076^{NS}
	Post- treatment	79.97 ± 8.44	72.84 ± 6.18	2.64	0.014^{S}
	t-value	5.4	2.45	-	-
	p-value	0.0001^{S}	0.028^{S}	-	-

$\overline{X}$ **: Mean. SD: Standard Deviation. t-value: Paierd and Unpaired test value. p-value: Probability value. NS: Non- significant. S: Significant.**

4. Discussion

This research was carried out to investigate the impact of Acapella device on patients with acute exacerbation of bronchiectasis.

Thirty patients of both genders who suffered from bronchiectasis have taken part in the research. Each of the two groups consisted of 15 patients chosen at random. Group (A) were given Acapella device in addition to routine physical therapy program (breathing exercises, PD, Percussion as well as vibration), while group (B) were given only routine physical therapy program (breathing exercises, PD, Percussion and vibration).

The current study results showed anon- significant difference ($p > 0.05$) among groups (A&B) on the pre-treatment mean values regarding FVC, FEV1 and FEV1 / FVC, while after treatment all evaluated variables showed statistically significant differences between the two groups and within each group ($p < 0.05$).

The study of **Phillip et al., [13]** showed although there were no statistically substantial differences between individual ACTs, participants preferred oscillating PEP therapy more than other ACTs. This could be linked to increased mucus production. Further studies are needed to further examine the safety in addition efficacy of ACTs for both adults as well as children suffering from an acute aggravation of bronchiectasis, also these studies should include a greater number of participants as well as higher methodological quality**.**

Further studies stated that PEP therapy, oscillating PEP therapy, high frequency chest wall oscillation, PD as well as expiration with glottis open in lateral position (ETGOL) are safe as well as effective methods at increasing sputum production **[14, 15].**

These findings are in line with those of lee, **Williamson et al., [16]**, in which those who had a stable case of bronchiectasis found that oscillating PEP was more successful in enhancing sputum clearance than conventional PEP**.**

While the research of **Patterson et al., [8]** shows that the Acapella device could be a more acceptable and user-friendly airway clearing aid for people with bronchiectasis.

Acapella plus ACBTs were also found to be equally beneficial in a short-term clinical trial comparing the two treatments for patients having stable bronchiectasis **[7].**

Similar to our investigation, another research of serious aggravations managed with IV antibiotics found only minor, non- substantial increases in FEV1 **[17].**

Pulmonary function has always been the key outcome measure in all studies of airway clearance. Assuming that sputum retention causes a narrowing of the airways and subsequent airflow blockage **[8].** Despite the significance of pulmonary function measurements in airway clearance studies, **Van der Schans et al., [18]** hypothesizes that these measurements are insufficiently sensitive and specific to detect clinically relevant changes in sputum clearance.

One of the most significant outcomes of airway clearing is an increase in sputum clearance, however, sputum expectoration is still a patient's personal experience **[18].** According to previous, Acapella has been shown to reduce the amount of sputum expectorated daily from the first day to the fourteenth, where the percentage drop-off from baseline is greatest on the last day of antibiotic treatment. The every daymucus quantity expectorated by regular ACTs changed all through the antibiotic duration, with the average percentage change from base being nearly zero on the last day of antibiotics. Patients whose treatment included the Acapella demonstrated higher mucus clearance **[8].**

Patterson, et al., [8] demonstrated that various patients favored to utilize devices that are easy to use to help clear the airways as well as subsequent evaluation. It was hypothesized that using the Acapella would make it easier to maintain regular airway clearing. The Acapella has the potential to be a more convenient option for frequent airway clearance.

Park et al., [19] concurred with the current study's findings, which showed that Acapella's chest wall vibration as well as oscillation increased oxygenation in addition FEV1 in lobectomy patients compared to conventional physiotherapy**.**

Another trial found that Acapella was as effective as standard airway clearance for treating acute bronchial aggrevations in the home care setting **[20].** Also, **Figueiredo et al., [21]** discovered that high-frequency oscillation, in conjunction with PEP, improves sputum expectoration in bronchiectasis as well as mechanically ventilated patients**.**

Sputum production was higher with the Acapella than with the conventional method of airway clearance (90 % ACBT, 10% PEP), however the difference was not statistically significant after just one treatment session **[8].** When contrasted to standard ACTs (ACBTs 90%, PEP 10%) either PD with cough as well as breathing, sputum production was higher when the oscillating PEP (Acapella device either Flutter device) was used. However, this difference did not show a significant **[8, 22]**

In addition, sputum clearance is better after using the Acapella than after using the threshold inspiratory muscle trainer. Along with that cause, the Acapella was patients' first choice **[23].**

In addition to previous, Acapella can prevent alveolar collapse but also increasing lung volume. It also aids in secretion mobilization and expectoration, preventing the buildup of secretions that can lead to infection. Strengthening the muscles required for breathing can also help avoid muscle atrophy. In addition, it facilitates the discharge of pulmonary secretion and leads to an increase in lung volume.The acapella device forces additional air into the peripheral airways via collateral pathways, where it pushes back secretions as well as directs them to the larger airways where they're beingdischarged with minimal resistance and without collapsing the alveoli **[24].**

In another study, Participants' pulmonary function tests improved, although not statistically significantly (FEV1, FVC, maximal mid-expiratory flow (MMEF), vital capacity (VC), peak expiratory flow (PEF)) before as well as after an ACTs, when tests were done at the outset of an exacerbation and again after therapy, hospital discharge, or after antibiotics were stopped. However, none of the research looked into whether or not one particular method of airway clearing was superior to another in terms of improving pulmonary function. Only single study investigated that a slight substantial modification in pulmonary function tests after 14 days **[25].**

In contrast to our study **Mamalyga et al., [26]** found that the Acapella restores only volumetric parameters. Patients should be instructed to keep using the Acapella device for vibration treatment even after they are released from care. Using an acapella simply raises trans-pulmonary pressure, and as a result, alveoli collapse during inspiration due to the negative pressure. Because of this, it is not as effective as other breathing devices**.**

Our current study showed that the Acapella is an effective device for improving spirometer measures as well as pulmonary function among patients suffering from acute aggravations of bronchiectasis.

Conclusion

Acapella is an effective tool for improving spirometer measures in addition pulmonary function in patients experiencing acute exacerbation of bronchiectasis and it can be added as physical therapy program. Acapella has been shown to be more successful in enhancing pulmonary functions in patients with bronchiectasis.

Strength

The current study's use of an objective, valid, and trustworthy measurement tool could be seen as a point of strength in our attempt to determine the combined effect of Acapella on spirometer measures in patients experiencing acute exacerbation of bronchiectasis which previously did not report.

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Data Availability

Datasets used and/or created during this investigation can be obtained from the relevant author with a reasonable request.

Disclosure statement

No author has a vested interest in the results of this study or has benefited monetarily in any way.

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