

## Acute Hemodynamic Response to Acapella in Phase 1 Cardiac Rehabilitation Following Coronary Artery Bypass Graft Surgery

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### Abstract

**Purpose:** The purpose of this study was to evaluate the acute hemodynamic response to Acapella in patients who underwent coronary artery bypass graft surgery (CABG). **Methods:** Fifteen (n=15, mean age: 57.6±9.8 years) post CABG patients were selected for this study from the cardiothoracic unit of Safdarjung Hospital, New Delhi. All patients used Acapella during their phase 1 cardiac rehabilitation program. They were asked to breathe from the diaphragm taking in a larger than normal breath, hold breath for 2 to 3 seconds and exhale actively but not forcefully, through the device, exhalation lasted approximately 3 to 4 times longer than inhalation. It was performed 10 to 20 PEP breaths. Patients were instructed to remove the mouthpiece and perform 2 to 3 'huffs' coughs to raise secretions as needed. These procedures had been repeated 3 to 4 times. Measurements of systolic blood pressure, diastolic blood pressure, heart rate, rate pressure product, arterial oxygen saturation and respiratory rate were taken before, during, immediately after and 30 minutes after using Acapella. Rate of perceived exertion and sputum amount were taken after using Acapella. Data were analysed by SPSS (20) by comparing the means of outcomes, using repeated measure ANOVA. **Results:** As a result of use of Acapella during cardiac rehabilitation, a significant improvement was observed in the sputum volume mean (7.7 ml), respiratory rate ( $p<0.001$ ) and  $\text{SpO}_2$  ( $p<0.001$ ). Acapella caused no significant hemodynamic response such as systolic blood pressure ( $p=0.239$ ), diastolic blood pressure ( $p=0.360$ ), heart rate ( $p=0.60$ ) and rate pressure product. **Conclusion:** Use of Acapella during phase 1 cardiac rehabilitation seems to be safe, without alteration on hemodynamic variables; in addition, it seems an effective adjunct for the removal of bronchial secretions in patients who underwent coronary artery bypass surgery.

**Keywords:** Acapella; hemodynamic; cardiac rehabilitation; Coronary artery bypass graft.

### Introduction

Cardiovascular disease has become the leading cause of morbidity and mortality in India during the last three decades. The genetic predisposition and acquisition of traditional risk factors at a rapid rate as a result of urbanization seems to be the major cause.

The facilities of modern diagnostic methods and new proven techniques to offer symptomatic relief and improve their prognosis are available.[1] Coronary artery bypass graft (CABG) surgery is the most frequently studied of all surgical procedures, probably in part due to its expense, the frequency with which it is performed, and the fact that it relates to coronary heart disease, the most common cause of death.[2]

Despite the success of these efforts, postoperative pulmonary complications (PPC) account for a substantial proportion of morbidity and mortality related to surgery and anaesthesia and lead to longer hospital stays. [3] Relating to cardiac surgery are the effects of anaesthesia, median sternotomy incision, topical cooling for myocardial protection, internal mammary artery dissection and use of cardiopulmonary bypass.[4]

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Cardiac rehabilitation programs are generally divided into three main phases inpatient, early outpatient, long term outpatient cardiac rehabilitation. Phase 1 delivers preventive and rehabilitation services to hospitalized patients and last for one to two weeks.[5] At this early phase, the focus of physiotherapy is prescription to avoid inactivity, and to maintain or improve pulmonary capacities and muscular strength.[6,7,8]

The effectiveness of standard chest physiotherapy (CPT) has been confirmed by many studies. Airway CPT is considered the base of physiotherapy and is characterized as “gold standard” of physiotherapy.[9] Chest physiotherapy is a routinely used therapy to prevent post operative pulmonary complications after cardiac surgery. The techniques used improve respiratory mechanics, pulmonary re-expansion and bronchial hygiene. Chest physiotherapy is given to maintain or improve alveolar ventilation. In cases where alveolar ventilation is reduced secondary to retained secretions, various techniques are available to the therapist to assist with secretion removal. These include gravity assisted drainage, positioning, percussion and vibrations, manual hyperinflation and airway suctioning.[10-12]

However, standard CPT is very labour-intensive and time-consuming both for hospitalized and non-hospitalized patients with impaired airway clearance. For this reason many patients refuse to do daily physiotherapy and interrupt it with all bad consequences. In recent years, devices of respiratory physiotherapy have emerged which offer alternatives to standard CPT which are less time-consuming and offer greater independence to the patient with lung disease. According to recent literature, devices of respiratory physiotherapy are introduced as alternative therapy methods[13-16] in order to facilitate and improve mobilization of mucus from airways, through which better lung ventilation and improved pulmonary function can be achieved. These devices are

safe and offer acceptable airway clearance to conventional CPT. Patients use devices of respiratory physiotherapy because of their benefits, such as the independent application and the reduced cost of therapy.[9]

One of the current devices of respiratory physiotherapy is positive expiratory pressure. [9] PEP device may give independence to patients as it can be carried out without an assistant and is easy and convenient in use.[17-19] Small clinical studies have reported improved tracheobronchial clearance and patient comfort with PEP devices compared to standard CPT.[20-21] Reduction in pulmonary infections/antibiotic courses and improved bronchodilation is also reported.[21-23] In addition, there has also been reported improvement in compliance and shorter hospital stays.[24] Other studies report PEP as an acceptable and effective treatment regimen to lung function.[16,25,26] There are different types of devices used to deliver PEP but one of the most commonly used is Acapella. The Acapella (Smiths Medical Inc, Carlsbad, California, USA) is a handheld airway clearance device that operates on the same principle as the Flutter, *i.e.* a valve interrupting expiratory flow generating oscillating PEP. Utilizing a counterweighted plug and magnet to achieve valve closure, the Acapella is not gravity dependent like the Flutter. The Acapella comes in three models, a low flow (<15 L/min), high flow (>15 L/min) and the Acapella Choice. The high and low flow models have a dial to set expiratory resistance while the Choice model has a numeric dial to adjust frequency. All models can be used with a mask or mouthpiece and can be used in line with a nebulizer. While these attributes may offer the Acapella some advantage over the Flutter A bench study of the performance characteristics of the two devices showed a slight advantage for the Acapella, with more stable wave form and a wider range of PEP at low air flow.[27]

The lack of evidence together with inconsistency responses of Acapella on hemodynamic were the requirements of this study. To our knowledge there is no research

describing the acute effect of Acapella on hemodynamic following coronary artery bypass surgery, the present study aimed to see the same. The present study therefore investigated the acute hemodynamic effect of Acapella in phase I cardiac rehabilitation following coronary artery bypass graft surgery.

### Material and Methods

The Study was conducted in a cardio thoracic and vascular surgery unit, Safdarjung hospital, New Delhi. Signed consent of patient prior to surgery was considered as willingness to participate in study. Inclusion criteria were elective CABG procedure, age of between 35 to 75 years, candidates for early extubation (6-8 hours after surgery), Temperature < 99°F. Exclusion criteria were, current smoking, Pulmonary embolism, Pneumothorax and hemothorax, Hemodynamic instability- Patients having mean arterial pressure less than 60 mm Hg and more than 100 mm Hg, cardiac arrhythmias, heart rate more than 160 beats per minute, Ventricular tachycardia ventricular fibrillation, Emergency surgery, Cerebral edema, Prolong ventilation > 24 hours, Left ventricular ejection fraction less than 35%, Intraoperative or postoperative CVA. Eligible patients were allocated to receive Acapella during their phase 1 cardiac rehabilitation.

The following pre-operative risk factors were assessed: patient age, sex, body mass index, history of smoking, lung function, and

functional capacity. Pre and post-operative characteristics including number of arteries that have been changed, amount of transfusion, total amount of drainage, duration of the drains, duration of intubation, perfusion, and aortic clamping were recorded. The Acute Physiology and Chronic Health Evaluation II (APACHE II) score was calculated in the first 24 hours of surgery (Table1).

#### Study design

The study was single group pre and post test experimental design. Independent variables were Acapella and Phase 1 cardiac rehabilitation. The dependent variables were heart rate (HR), systolic blood pressure (SBP), diastolic blood pressure (DBP), oxygen saturation (SpO<sub>2</sub>), respiratory rate (RR), Rate pressure product (RPP), Sputum amount (ml), Rate of perceived exertion (RPE) and Hospital stay.

#### Protocol

To study the acute hemodynamic effect of Acapella in phase 1 cardiac rehabilitation following coronary artery bypass surgery, 15 patients are randomly selected after detailed cardiovascular and respiratory assessment; suitable patients were included after inclusion and exclusion criteria. Reading of heart rate, arterial oxygen saturation, systolic blood pressure, diastolic blood pressure, respiratory rate, rate pressure product, rate of perceived exertion and sputum amount were taken

**Table 1. Demographic and operative variables of the patients**

| Subject Characteristics   | (n=15)      |
|---|-------------|
| Age (years)   | 57.6 (9.8)  |
| Height (cm)   | 158.6 (7.9) |
| Weight (kg)   | 65.4(9.9)   |
| BMI (kg/m <sup>2</sup> )  | 26.1(4.7)   |
| Number of graft used (n)  | 3.07(0.4)   |
| Duration of intubation (hours)  | 7.6(2.9)    |
| Hospital stay(days)   | 16.2(9.3)   |
| APACHE II   | 7.6(2.5)    |
| APACHE II= Acute Physiology and Chronic Health Evaluation II, data presented as mean and Standard deviation |             |

before using Acapella, during the time of using Acapella, immediately after using Acapella and 30 minutes after Acapella.

Subjects were evaluated before the surgery by the investigator, who explained the physiotherapeutic protocols and interventions to be followed after the surgery. Routine physiotherapy treatment according to hospital protocol was given. Subjects were encouraged to clarify any questions regarding the study.

*Procedure*

Acapella device was selected depending upon the patient’s ability to maintain an expiratory flow of 15 liter per minute (LPM) or greater for three seconds. All patients enrolled for the study (n=15) were able to maintain expiratory flow  $\geq$ 15 LPM therefore, green Acapella were used for all of them. At initial setting of the device frequency adjustment dial was turned counter-clockwise to the lowest frequency-resistance setting, then frequency/ resistance increase clockwise. Proper resistance range was selected to produce the desired I: E ratio of 1:3 to 1:4.[11]

Patients were explained with complete procedure prior to examination. Patients were asked to sit comfortably and place mouthpiece in mouth and maintain a tight seal on

mouthpiece during exhalation. Patients were asked to breath from diaphragm taking in a larger than normal breath. Hold breath for 2 to 3 seconds. Patients were instructed to exhale actively but not forcefully, through the device, exhalation should last approximately 3 to 4 times longer than inhalation. They were asked to Perform 10 to 20 PEP breaths and then asked to remove the mouthpiece and perform 2 to 3 ‘huffs’ coughs to raise secretions as needed. This procedure had been repeated 3 to 4 times. All the dependent variables were taken pre-test before using Acapella, during test at the time using Acapella, post-test immediately after using Acapella and 30 minutes after using acapella.[29]

*Statistical analysis*

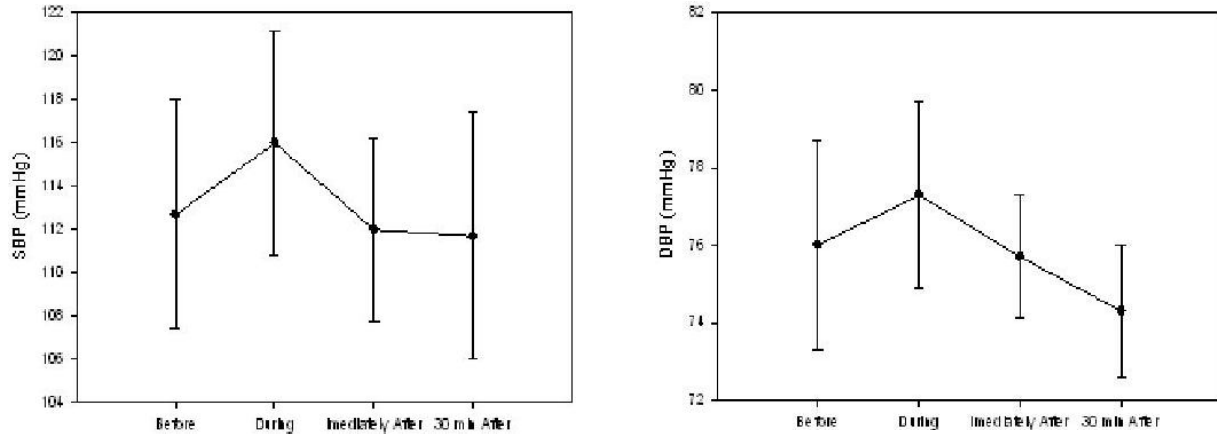
Statistical analysis was obtained by using SPSS version 20. Demographic data of the patients including age, height, weight, BMI, number of grafts used are summarized in table1. A repeated measure analysis of variance (ANOVA) was used to determine the effect of Acapella. A multiple test readings were taken, a post hoc analysis was performed using a Bonferroni test, to compare the difference between each reading. An alpha value of 0.05 was set to significant difference.

**Table 2. Effect of Acapella on hemodynamic variables**

| Variables                | SBP                          | DBP      | HR       | RPP          | RR       | SPO <sub>2</sub> |         |
|--------------------------|------------------------------|----------|----------|--------------|----------|------------------|---------|
|                          | Mean+SE                      | Mean+SE  | Mean+SE  | Mean+SE      | Mean+SE  | Mean+SE          |         |
| <b>Before</b>            | 112.7±5.3                    | 76.0±2.7 | 85.4±3.1 | 9585.3±534.5 | 19.1±0.5 | 95.4±0.5         |         |
| <b>During</b>            | 116.0±5.2                    | 77.3±2.6 | 84.6±3.4 | 9793.3±575.8 | 19.3±0.5 | 96.1±0.4         |         |
| <b>Immediately after</b> | 112.0±4.5                    | 75.7±1.6 | 84.8±3.1 | 9434.3±421.9 | 17.7±0.5 | 97.4±0.3         |         |
| <b>30 minutes after</b>  | 111.7±5.7                    | 74.3±1.7 | 84.0±3.3 | 9340.0±552.2 | 17.8±0.5 | 97.7±0.2         |         |
| A Z                      | F                            | 1.46     | 1.10     | 0.62         | 2.13     | 17.36            | 18.05   |
|                          | P                            | 0.239    | 0.360    | 0.608        | 0.11     | <0.001           | <0.001  |
| Post Hoc analysis        | before vs. during            | 1        | 1        | 1            | 1        | 1                | 0.5     |
|                          | before vs. immediately after | 1        | 1        | 1            | 1.0      | 0.0001*          | 0.0010* |
|                          | before vs. 30 minutes after  | 1        | 1        | 0.4          | 0.4      | 0.0013*          | 0.0007* |

\* Significant difference; SBP : Systolic Blood Pressure; DBP: Diastolic Blood Pressure; HR : Heart Rate, RPP: Rate Pressure Product, RR : Respiratory Rate, SPO<sub>2</sub>: Arterial Oxygen Saturation, Before : Reading before using Acapella, During: Reading during using Acapella, after doing two sets of PEP breathing, Immediately after: Reading immediately after using Acapella, 30 minutes after: Reading 30 minutes after using Acapella, SE : Standard Error,

**Figure 1: Shows changes in hemodynamic variables 1A: Systolic blood pressure, 1B: Diastolic blood pressure at before, during, immediately after and 30 minutes after using Acapella in patients following CABG surgery**



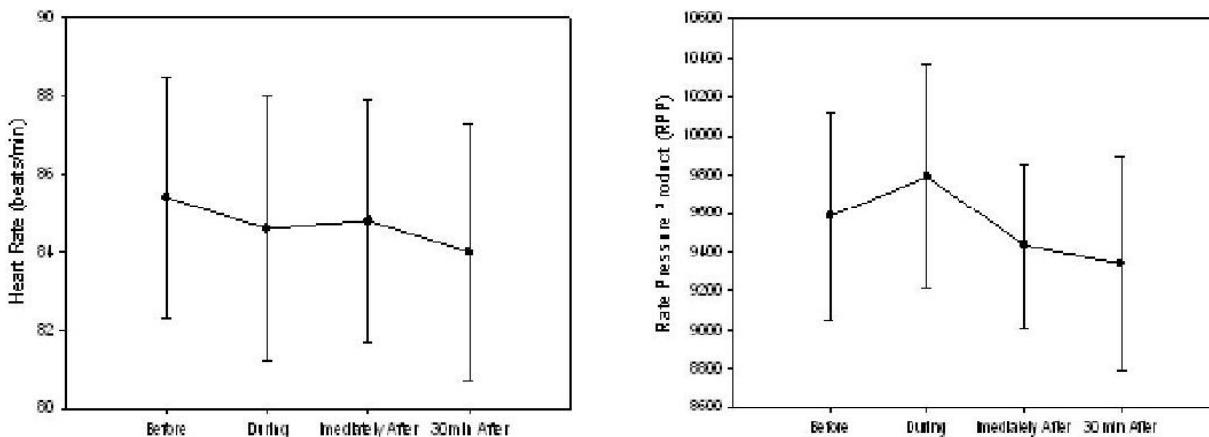
**Results**

Fifteen patients (n=15), two female and thirteen male who had undergone off-pump coronary artery bypass surgery, were finally enrolled in the study. The demographic and operative characteristics of the patients shown in table 1. A one-way repeated measures ANOVA was conducted to compare the hemodynamic effect of Acapella on systolic blood pressure, diastolic blood pressure, heart rate, rate pressure product, respiratory rate and SpO<sub>2</sub> in post CABG patient during phase 1 cardiac rehabilitation at before, during, immediately after and 30 minutes after using Acapella.

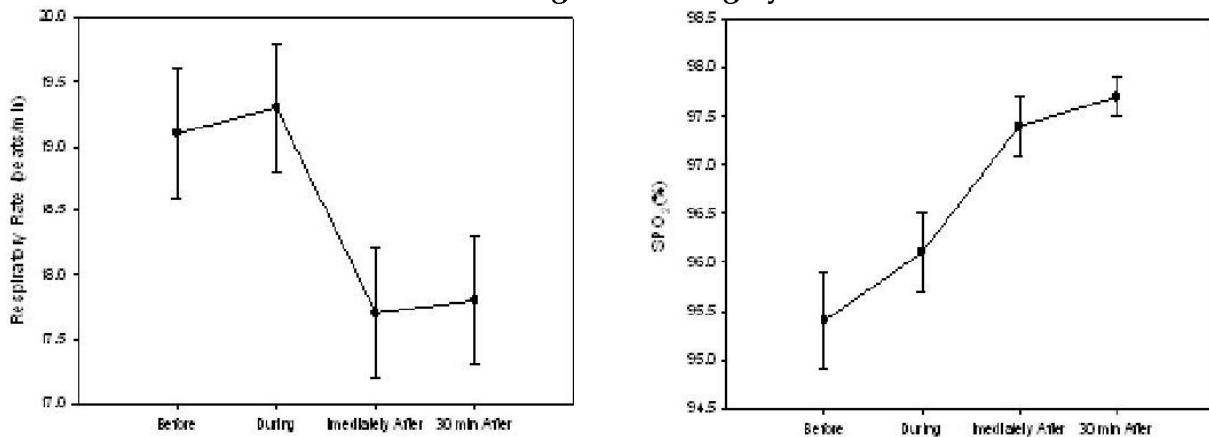
Repeated measure ANOVA could not find any difference between the readings of systolic blood pressure ( $F=1.46, p=0.239$ ), diastolic blood pressure ( $F=1.10, p=0.360$ ), heart rate ( $F=0.62, p=0.608$ ) and rate pressure product ( $F=2.13, p=0.110$ ) in response to Acapella. However, there were significant improvement in respiratory rate which was  $19.1 \pm 0.5$  before using Acapella and  $17.8 \pm 0.5$  after using Acapella ( $F=17.36, p<0.001$ ), and SpO<sub>2</sub> ( $F=18.5, p<0.001$ ). (Table 2) (fig 1,2,3)

Mean amount of sputum collected after using Acapella is 11.4 ml. Mean of rated perceived exertion after using Acapella is 2.8 and the mode of hospital stay of fifteen patients were 16 days.

**Figure 2: Shows changes in hemodynamic variables 2A: Heart rate, 2B: Rate pressure product at before, during, immediately after and 30 minutes after using Acapella in patients following CABG surgery**



**Figure 3: Shows changes in hemodynamic variables 3A:respiratory rate, 3B:SPO<sub>2</sub> at before, during, immediately after and 30 minutes after using Acapella in patients following CABG surgery**



The result suggests that Acapella really does not have any abnormal hemodynamic effect in post CABG patients. Specifically, our results suggest that Acapella can safely be used in post CABG patients without any abnormal hemodynamic changes. Additionally, there were a substantial improvement in oxygenation, respiratory rate and expectorated sputum volume (11.4 ml) this further suggest that Acapella is effective in removing bronchial secretion and improving oxygenation in post CABG patients.

## Discussion

The effect of Acapella on hemodynamic performance was evaluated in a group of patients who underwent coronary artery bypass graft surgery (CABG). The result shows that in coronary artery bypass grafts patients there were minimal changes in systolic blood pressure, diastolic blood pressure, heart rate, rate pressure product during treatment, immediately after treatment and 30 minutes after treatment. However, there were statistically significant improvement in respiratory rate and SPO<sub>2</sub> following immediately after using Acapella and 30 minutes after using Acapella.

This study considered a clinically significant change one that was greater than 10 percent. When examining the systolic blood pressure,

diastolic blood pressure, heart rate, rate pressure product was no significant ( $p > 0.05$ ). This can possibly be explained that Acapella could not demonstrate any change in these hemodynamic variables. Rate pressure product (RPP) is the best non-invasive index which results from multiplying systolic blood pressure by heart rate, has been recognized as a relevant parameter in evaluating ventricular function. It has been speculated that high values at peak exertion thus reflecting cardiac work are more likely related to good ventricular function and no ischemia.[19-21] Low rate pressure product value before using Acapella denotes normal myocardial oxygen consumption. As the values of rate pressure product during, immediately after and 30 minutes after using Acapella provide no significant changes in values denotes that the use of Acapella do not increase myocardial oxygen demand.

As per our knowledge there is no study available to date to demonstrate the hemodynamic changes specifically in coronary artery bypass surgery patients. Most of the studies done on the patients with pulmonary diseases; however the results of these studies are in accordance of present study. The present study demonstrated an improvement in SPO<sub>2</sub> and respiratory rate ( $p < 0.05$ ) after using Acapella. This result is in accordance with the studies of Darbee *et al* in 2005[30] in which the research evaluated the

physiological responses to two airways clearance intervention high frequency chest wall oscillation and low positive expiratory pressure breathing in subjects who have moderate to severe cystic fibrosis demonstrated improvement in ventilation distribution, gas mixing and increase in SPO<sub>2</sub> during positive expiratory pressure breathing. Study done by Padkao *et al* in 2010[31] demonstrated that the conical PEP device decreases lung hyperinflation, is safe to use and trends to increase the duration of exercise in chronic obstructive pulmonary disease patients compared to normal breathing. This study is in accordance with the studies of Thompson *et al* in 2002[32] who concluded that the daily use of flutter device is effective as active cycle of breathing in patients with non cystic fibrosis bronchiectasis and has high level of patients acceptability. This study is in accordance done by MAH Abu-Rayan *et al* in 2009[33] demonstrated that Acapella is the good representative of all conventional multimodality chest physiotherapy procedures resulted in significant improvement in oxygenation. Another study of Van der Scahns *et al* 1993[34] is in accordance with study concluding that in healthy subjects positive expiratory pressure increases tidal volume by the activity of both inspiratory and expiratory muscles, while functional residual capacity remains unchanged.

Use of cardiopulmonary bypass in on-pump CABG shows significant effect on cardiovascular system, due to inflammatory responses, manipulation of heart, freezing. One common problem after CPB is arrhythmia which further causes hypotension, tachycardia, heart failure and stroke. As this study is done on off-pump coronary artery bypass surgery patients hemodynamic consequences occurring in surgery due to displacement of heart is marked decreased in cardiac output (cardiac index <2 litre min<sup>-1</sup>m<sup>-2</sup>) leading to reduced mixed venous saturation, often <70%. The present study demonstrate no significant changes on hemodynamic parameters like heart rate, systolic blood pressure, diastolic blood pressure, rate pressure product, this study is in accordance

with MAH Abu-Rayan *et al* in 2009[33] also found that there were significantly lesser hemodynamic effect regarding heart rate and mean arterial pressure.

Our study result demonstrate that the mean sputum volume of patients expectorated after using Acapella were 7.7 ml. The study of Naraparaju *et al* in 2010[35] is in accordance with concluded that there is increased sputum clearance following the use of Acapella when compared to the threshold inspiratory muscle trainer in bronchiectasis patients. Another study done by MAH Abu-Rayan *et al* 2009[33] found that there were significant increase in mean values of sputum amount in comparison with multimodality chest physiotherapy. In contrast, van der Scahns *et al* in 1993[34] in a study were not in accordance with present study, who demonstrated that changes in lung volume in relation with positive expiratory pressure breathing did not lead to improvement of mucus clearance in cystic fibrosis patients.

The result of this study would yield future insight into the use of Acapella as a therapeutic intervention in phase 1 cardiac rehabilitation in patient following coronary artery bypass surgery. These effects become relevant to physiotherapist when determining the relative cardiovascular risk to pulmonary benefits of Acapella in respiratory patients who have undergone coronary artery bypass surgery. Such an understanding is crucial to minimize its adverse effect when prescribing Acapella to remove secretions of patient in phase 1 cardiac rehabilitation, who have undergone Coronary artery bypass surgery.

There were several limitations encountered during the study. The first was minimal amount of information on Acapella device itself. We could find no studies that directly establish the safety efficacy of Acapella in cardiac surgery patients. In addition due to lack of time and resources we were limited in number of patients that could participate in the study.

The study sample was too small to make determinations about the relative hemodynamic safety of the device

additionally; we could not collect waveform on Acapella device that shows the device is vibratory.

This study suggests the need for additional studies to be performed on large scale to proof the safety and efficacy of Acapella to mobilize secretions in persons with coronary artery bypass surgery.

## Conclusion

The overall results of the study lead us to the conclusion that the uses of Acapella during phase 1 cardiac rehabilitation seems to be safe, without alteration on hemodynamic variables, in addition, it seems an effective adjunct for the removal of bronchial secretions in patients undergone coronary artery bypass surgery. It can be concluded that Acapella may be considered safe and effective in coronary artery bypass graft patients during phase 1 cardiac rehabilitation.

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## Conflict of interest

The authors have no conflict of interest to declare.

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