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Effectiveness of Acapella along with institutional based chest physiotherapy techniques on pulmonary functions and airway clearance in post-operative CABG patients

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Background: Patients undergoing Coronary Artery Bypass Graft (CABG) surgery often develop pulmonary complications in the early post-operative period as result of decreased lung function and impaired cough. Conventional physiotherapy in early post-operative period aims at increasing lung volumes and airway clearance.
Objective: This study aimed to determine the effectiveness of the addition of Acapella to conventional chest physiotherapy in improving lung volumes and secretion clearance in early post-operative CABG patients.
Methods: Twenty patients of both genders (40–70 years) who had undergone CABG and were in Phase I of Cardiac Rehabilitation were involved in this pilot randomized control trial (9 control, 11 experimental). Post-surgery intervention commenced on post-operative day 2 (POD 2) and continued till POD 6. Patients in the control group were given conventional physiotherapy that included breathing exercises, incentive spirometry and manual techniques. Patient in the experimental group used an Acapella device along with the conventional intervention. Outcome measures considered were pulmonary function parameters (FVC, FEV1 & PEFR) and amount of sputum expectorated.
Results: A significant increase in lung volumes was observed in both the groups on POD 6 as compared to POD 2 (both < 0.01). However, the increase was significantly greater on POD 6 in experimental group than the control group [mean difference (95% CI) FVC: 0.44 L (0.24–0.63), FEV1: 0.43 L (0.19–0.66), PEFR: 0.86 L/s (0.57–1.14)]. The amount of sputum expectoration significantly greater in the experimental group as compared to the control group [2.71 mL (0.53–4.90)].

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Conclusion: The addition of Acapella enhanced the effect conventional physiotherapy in improving lung volumes and airway clearance in the early post-operative period for CABG patients.

Keywords: Acapella; CABG; chest physiotherapy.

Introduction

Patients undergoing cardiac surgeries are prone to distinct surgery related factors that influence the development of certain post-operative pulmonary complications (PPCs).[1] Studies reveal a post-operative change in breathing pattern from predominantly abdominal to thoracic breathing resulting in reduction of pulmonary functions in patients undergoing median sternotomy.[2,3] A decrease in VC, IC, FEV1, PEFR, TLC leading to a restrictive pattern of pulmonary function is also observed post cardiac surgery.[4–8] The causes cited for this decrease are multifactorial; sternotomy incision leading to decreased rib cage movement, respiratory depression due to anesthesia, diaphragm dysfunction leading to alterations in breathing patterns, presence of chest tubes, post-operative pain.[1–3,6,9–11] This significant impairment in pulmonary function is observed to persist up to almost one year post-operatively.[2,4–7,9] Additionally post-operative atelectasis is also observed in CABG patients,[7,12] which can further worsen the pulmonary function. A study done by Koyilil *et al.*[13] reported increased incidence of cough post-operatively following open-heart surgery. The severity of the cough correlated with the reduction in lung volume and was independent of the basic cardiac pathology and left ventricular function, cardiopulmonary bypass duration and smoking status. The researchers concluded that the primary cause of cough was the post-operative reduction in lung volume. While the post-operative decrease in PEFR reduces the ability to cough, the general anesthesia used during surgery causes impairment of mucociliary transport, both resulting in sputum retention.[6,14,15]

To summarize, the change in breathing pattern, reduction in lung volumes and sputum retention contribute to post-operative complications in CABG patients. A study done by Agostini *et al.* reported that patients with PPCs had a significantly higher hospital length of stay and higher frequency of ICU admissions and number of deaths.[16] This puts an additional burden on the patient and hospital.

In order to decrease the after-effects of decreased lung volumes and impaired secretion clearance post-operatively, physiotherapy interventions in the form of breathing exercises, incentive spirometry and physical maneuvers to recruit alveoli are often recommended.[17,18] Manual techniques, such as percussions and vibrations, are commonly used to aid removal of secretions.[19] However in the post-operative period, these techniques may not be well tolerated by all patients due to post-operative pain[20] and may be contraindicated in some patients due to inability to change body position. Some patients may not be able to self-apply these techniques without assistance and thus adherence and regular administration may depend on availability of therapist or caregiver. In addition, these techniques are also laborious and time consuming for the therapist.[20] Hence there is an increase in the use of assistive devices to aid removal of secretions. In the recent years, various devices have emerged that assist existing physiotherapy techniques in improving mobilization and removal of secretions.[21] These devices are safe, offer greater independence to patients and are less time-consuming for the therapist. Acapella is one such flow-operated Oscillatory Positive Expiratory Pressure (OPEP) device that consists of a counterweighted plug and metal strip that is attached to a magnet which oscillates when the patient exhales into the device resulting in airflow oscillations.[22] The resulting positive expiratory pressure (PEP) and oscillations assist mucus expectoration.[19,21]

Studies regarding efficacy of Acapella as an aid to clear secretions has been evaluated in various pulmonary conditions,[23–25] however its scope to improve pulmonary function and cough mechanism in post cardiac surgery patients is insufficiently researched. This study hypothesized that the addition of Acapella to conventional Institutional Chest physiotherapy would aid in improving lung volumes and sputum expectoration compared to conventional Institutional Chest physiotherapy

alone in patients undergoing CABG surgery in the early post-operative period.

Methodology

This was a single-site randomized controlled feasibility pilot trial with assessor blinding and intention-to-treat analysis.

Approval to conduct this study was obtained from the Institutional Review Board, D. Y. Patil University, School of physiotherapy (DYPUSOP/019A/2018).

Participants

Patients of both genders in the age group of 40–70 years who had undergone CABG (through median sternotomy incision) and were currently hospitalized in the ICU of D.Y. Patil Hospital and Research Centre, Navi Mumbai, India and undergoing Phase 1 of cardiac rehabilitation were selected for this study. The number of patients selected in the study was based on the patient availability during the study period. Oral informed consent was taken from all the participating patients. Any patient with existing pulmonary disease or associated pulmonary complications, unstable cardiovascular status, infection, sepsis, uncontrolled diabetes, other metabolic problems and impaired cognition were excluded from the study. Additionally, patients who required long-term intubation post-operatively or reported too much pain (in spite of medications) were not included in the study. The patients were randomly allocated to either control or experimental groups using the lottery method – paper slips with numbers written and folded were handed to the participants. Patients who picked an odd number were allocated to the control group and an even number were allocated to the experimental group. After group allocation, the assessment and intervention procedures were explained to all participants.

Outcome measures

The primary outcome measures considered in the study were lung volumes measured using PFT (FVC, FEV1, PEFR) and the cumulative amount of sputum expectorated by Post-operative day 6 (POD 6).

The assessment began on POD 2 and was same for both the groups. Pain was assessed on the Numerical Rating Scale before intervention. The pulmonary function test (PFT) parameters were assessed pre- and post-intervention on POD 2 and post-intervention on POD 4 and POD 6. A handheld portable spirometer (EasyOne^{TM} Diagnostic Spirometer, ndd Medizintechnik AG, Switzerland) was used to measure PFT by the therapist. For this, patient was seated upright with back supported. The mouthpiece of spirometer was placed into patient's mouth and was asked to form a tight seal around it. Patient was then instructed to inspire at total lung volume and nose clip was applied. He/she then exhaled forcefully into the mouthpiece. Three attempts for FVC, FEV1 and PEFR were recorded and the highest value from

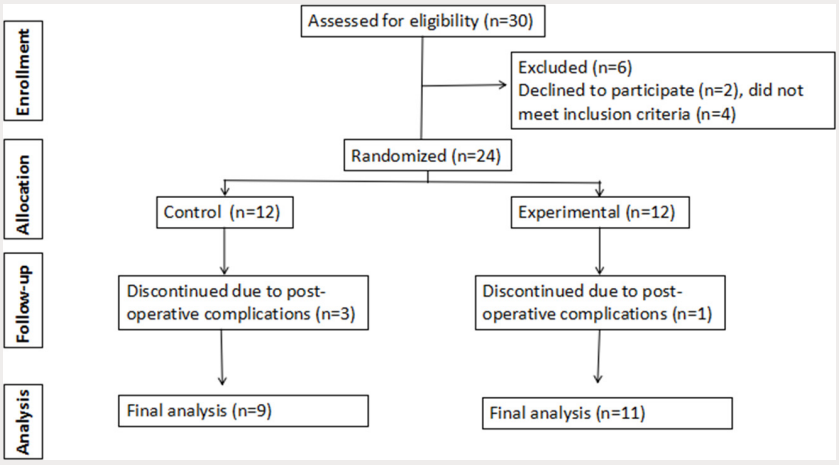

Fig. 1. Flowchart showing participation through the study.

the best attempt for each parameter was used in the data analysis.

Amount of sputum expectorated during every intervention (for each session/day) was recorded by collecting it in a sputum container with markings on it. The total amount of sputum expectorated (in mL) from POD 2 to POD 6 was noted on POD 6.

Interventions

Similar post-operative medical care in terms of ventilation and pain medications and standard institutional cardiac rehabilitation protocol (e.g., bedside mobilizations and ambulation) was followed for all the patients as per the hospital policy. Chest physiotherapy intervention with respect to the study, started on POD 2 for both groups. The same therapist (principal investigator of this study) administered the interventions in both groups for all sessions. The average time for treatment ranged between 20 min and 40 min. The interventions were given with the patients lying with back supported and the head end angled at 45°.[26]

For the control group, the treatment included diaphragmatic breathing exercises[19] (10 repetitions, 2 sets, twice a day) and segmental breathing exercises (10 repetitions, 3 sets, twice a day) along with percussions and vibrations. Incentive spirometry[19] was given as 10 repetitions of 3 sets, twice a day. Patient was encouraged to cough out and expectorate secretions, if any, in a measured cup.

In the experimental group, similar intervention as above was followed, except instead of percussion and vibration, Acapella green[27,28] (Smiths Medical ASD, Inc., USA) was prescribed twice a day with at least 4 hourly gaps between two sessions. For Acapella, the patients were asked to hold the device with a tight seal at the mouth, take a breath larger than normal tidal volume and hold for 2–3 s before exhaling into the device.[19] This exhalation into Acapella was repeated 8–10 times after which the patients were instructed to perform 2–3 huffs and expectorate in the measuring cup. This cycle of 8–10 breaths in Acapella followed by 2–3 huffs was repeated 4–6 times. This set was performed twice a day.[29]

The study ceased on POD 6 as the average stay of post CABG patients in our ICU ranged between 6 and 8 days.

Statistical analysis

The data was analyzed using SPSS software (version 18). For any within-group comparison of outcomes, one-way ANOVA was used with Bonferroni as the post-hoc test. For any between-group comparisons of outcomes (i.e., between control and experimental groups), an unpaired '*t*' test was performed. The level of significance was set at < 0.005.

Results

A total of 30 subjects were considered for inclusion in the study, of which 6 had to be excluded. The remaining 24 subjects were randomly allocated to control and experimental group. None of the included subjects had any major co-existing co-morbidity except diabetes. Four patients (3 from control and 1 from experimental group) dropped out due to post-operative complications (infection at the scar site and arrhythmia), while 20 patients completed the study procedures. The general demographics of the subjects included in the study are represented in Table 1. The mean age and BMI of the four subjects who dropped out was 51.25 ± 5.737 and 26.36 ± 4.478.

All the patients had undergone CABG on pump. Of the 20 subjects, 10 patients had only saphenous vein graft, 4 had only internal mammary artery graft and 6 had arterial and venous grafts.

The pulmonary volumes (FVC, FEV1 and PEFR) and the total amount of sputum production in both groups showed a statistical improvement post intervention on all the days. However, it was observed that the improvement was more on POD6 in both the groups (Table 2). Table 3 compares the mean differences in the lung volumes between POD

Table 1. Descriptive demographics.

Variables	Control ($n = 12$)	Experimental ($n = 12$)	p value
Males/Females	8/4	11/1	
Age (in years)	57.75 ± 4.95	54.5 ± 5.23	0.193
BMI	24.64 ± 2.66	23.77 ± 1.66	0.295
Smokers	2	3	
Controlled diabetics	2	3	

Note: Data presented is as mean ± SD BMI: Body Mass Index.

Table 2. Comparison of lung volumes and amount of sputum expectorated within and between control and experimental groups.

	Control	Experimental	*P* value (between experimental and control)	Mean differences (95% CI) (between experimental and control)
FVC (in L)				
Pre intervention POD 2	0.26 ± 0.06	0.39 ± 0.13	**0.020**	**0.12 (0.02–0.22)**
Post intervention POD 2	0.32 ± 0.05	0.55 ± 0.31	**0.043**	**0.23 (0.007–0.46)**
Post intervention POD4	0.44 ± 0.10	1.08 ± 1.25	**0.014**	**0.64 (0.24–1.52)**
Post intervention POD 6	0.54 ± 0.12	1.11 ± 0.40	< **0.001**	**0.56 (0.27–0.86)**
P value (from Pre intervention POD 2 to POD 6)	< **0.001**	**0.001**		
FEV1 (in L)				
Pre intervention POD 2	0.25 ± 0.06	0.42 ± 0.23	**0.057**	**0.16 (0.005–0.34)**
Post intervention POD 2	0.30 ± 0.04	0.51 ± 0.20	**0.009**	**0.20 (0.05–0.35)**
Post intervention POD4	0.4033 ± 0.10	0.72 ± 0.27	**0.004**	**0.32 (0.11–0.53)**
Post intervention POD 6	0.51 ± 0.10	1.11 ± 0.48	**0.002**	**0.60 (0.25–0.94)**
P value (from Pre intervention POD 2 to POD 6)	< **0.001**	< **0.001**		
PEFR (in L/s)				
Pre intervention POD 2	0.57 ± 0.12	0.79 ± 0.36	**0.112**	**0.21 (−0.05 to 0.48)**
Post intervention POD 2	0.63 ± 0.13	1.04 ± 0.37	**0.006**	**0.41 (0.13–0.68)**
Post intervention POD4	0.87 ± 0.39	1.47 ± 0.47	**0.007**	**0.60 (0.19–1.02)**
Post intervention POD 6	0.94 ± 0.17	2.02 ± 0.49	< **0.001**	**1.07 (0.71–1.44)**
P value (from Pre intervention POD 2 to POD 6)	**0.006**	< **0.001**		
Total Sputum production on POD 6 (in mL)	7.55 ± 1.01	10.27 ± 2.96	**0.018**	**2.71 (0.53–4.90)**

Notes: Data presented as mean ± SD (95% CI). POD – post-operative day, FVC – Forced Vital Capacity, FEV1 – Forced Expiratory Volume in first second, PEFR – Peak Expiratory Flow Rate, POD – Post-operative day, CI – confidence interval.

6 and pre intervention POD 2 values for both the groups. A 107% and 104% increase, respectively, in FVC and FEV1 from POD 2 pre-intervention to POD 6 was observed in the control group while the experimental group showed an increase by 184% and 164%, respectively, for the same parameters. PEFR increased by 64% from POD 2 pre-intervention to POD 6 in the control group, while a 155% increase was observed in the experimental group. The results indicate that the experimental group showed a significantly greater improvement in lung volumes on POD 6 as compared to the control group. The sputum production was also significantly more in the experimental group.

Discussion

The results of this study indicate that inclusion of Acapella along with other conventional physiotherapy techniques increased the lung volumes and airway clearance as compared to conventional physiotherapy techniques alone in post-operative CABG patients.

Table 3. Comparison of the mean differences in lung volumes between POD 6 and POD 2 Pre-intervention between the experimental and control group.

	Control	Experimental	*P* value (between mean differences of POD 6 and Pre intervention POD 2 between experimental and and control)	Mean differences (95% CI) (POD 6 and Pre intervention POD 2 between experimental and control)
FVC (in L)	0.28 ± 0.09	0.72 ± 0.26	**0.0002**	**0.44**
[Mean differences between POD 6 and Pre intervention POD 2 (95% CI)]	(0.18–0.37)	(0.45–0.98)		**(0.24–0.63)**
FEV1 (in L)	0.26 ± 0.08	0.69 ± 0.33	**0.0013**	**0.43**
[Mean differences between POD 6 and Pre intervention POD 2 (95% CI)]	(0.17–0.34)	(0.35–1.02)		**(0.19–0.66)**
PEFR (in L/s)	0.37 ± 0.14	1.23 ± 0.38	**< 0.001**	**0.86**
[Mean differences between POD 6 and Pre intervention POD 2 (95% CI)]	(0.22–0.51)	(0.84–1.16)		**(0.57–1.14)**

Notes: Data presented as mean ± SD (95% CI). POD – post-operative day, FVC – Forced Vital Capacity, FEV1 – Forced Expiratory Volume in first second, PEFR – Peak Expiratory Flow Rate, POD – Post-operative day, CI – confidence interval.

Acapella is shown to be effective in aiding sputum clearance in variety of conditions.[25,30] Studies in mechanically ventilated ARDS patients showed that Acapella aided in optimally clearing the secretions from the airways.[23,31] Studies in bronchiectasis patients also demonstrated an increase in sputum volume production following use of Acapella.[24,32]

Acapella combines the resistive effect of PEP with high-frequency oscillations in the airways during exhalation to facilitate secretion clearance.[27,33–35] PEP allows back pressure to be generated that opens and splints the peripheral airways. This encourages collateral ventilation and airflow to move behind the secretions.[23,34–37] The pressure gradient across the secretions forces it to move more centrally and thus help in secretion clearance.[36,37] In addition, the oscillations produce vibrations within the airway wall that further help to displace secretions into the airway lumen.[33–35] Some studies indicate that the oscillations generated by the OPEP devices can cause break down of the mucus macro-molecules bonds reducing the viscoelasticity (thickness) of the secretions and thus further enhance their transport through the airways.[38,39]

Another study that assessed the pressure characteristics of Acapella under laboratory conditions, suggested that the oscillation frequency range produced by Acapella (8.5–21 Hz)[33,40] coincides with that of ciliary beating frequency (12–15 Hz) in tracheobrochial tree[41,42] and respiratory system resonance frequency[33] and this also facilitates the secretion movement.[43] Comparative studies between Acapella and other PEP devices (Flutter, Shakers) reveal that though these devices have similar operating performances and produce similar pressure waveforms, Acapella produces higher frequency of oscillation than those of other PEP devices at low-pressure levels.[27,44]

In this study, we too observed an increase in sputum production in the experimental group using Acapella as compared to the control group, probably through the mechanisms explained earlier. This was also accompanied with an increase in lung volumes, though earlier studies show mixed results. Use of Acapella did not change lung function following lung resection surgery[20] or bronchiectasis,[24] however a significant improvement in lung volumes was observed in patients who had undergone upper abdominal surgeries,[45] video-assisted thoracic surgery[46] and CABG.[47] The change in lung volumes observed in this study could be a cumulative effect of breathing exercises[19,30] and better airway clearance due to Acapella.

Moreover, patients reported to be comfortable with the use of Acapella as compared to incentive spirometry[20,32] or manual techniques like percussion and vibration which probably was because Acapella did not irritate or stimulate the chest wall or wound directly but internally transmitted the vibration to the secretions in the airways.[20] As

Acapella is not gravity-dependent, it is easier to use in patients with low expiratory flow rates and in whom change of positions is difficult.[27,44]

The other advantages of Acapella lie in the fact that it is available in different models that allow selection of device based on the patient's expiratory flow capacity. Furthermore, Acapella can be used along with nebulizer[21] whenever the need be. All the above-mentioned advantages of Acapella may have helped the patients in improving their lung volumes and aided in easier clearance of secretions in subjects in this study.

This study has some limitations. The sample size in the study was small as it was confined by the number of patients available at the time of study. To establish the clinical relevance of the percent changes observed in the lung volumes between pre and post intervention, future studies with larger sample sizes is recommended. The pre-operative spirometry values were also not available, hence the immediate post-operative change in lung volumes could not be assessed. In addition, the study was restricted to POD6 for reasons mentioned earlier. Future studies for longer periods of time to assess the long term effects are suggested for generalizing the usability of Acapella in patients undergoing CABG.

Conclusion

This pilot RCT suggests that the effect of conventional physiotherapy techniques in improving lung volumes and secretions clearance is enhanced with the use of Acapella in the post-operative period in CABG patients. However, further studies with larger sample size and patients with co-existing pulmonary conditions are recommended to establish the effectiveness of Acapella in post-cardiac surgery patients. Studies of longer duration can be conducted to assess the long-term effect of Acapella in post-operative cardiac patients.

Conflict of Interest

The authors declare that there is no conflict of interest.

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Not applicable.

Author's Contributions

The study was conceptualized and designed by BJ and AT. BJ did the data collection and drafted the initial paper. AT critically reviewed the paper for intellectual content and subsequently revised the paper. Both the authors approved the final version of the paper.

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