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Effectiveness of Vibrapep (OPEP) on Pulmonary Functions in Phase One of Cardiac Rehabilitation-A Randomized Controlled Trial

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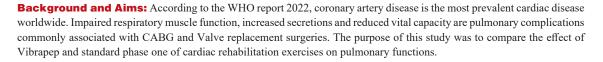
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Abstract



Methods: A Randomized Controlled Trial was conducted on 46 participants. Participants were randomly allocated into two groups, Vibrapep and phase one of cardiac exercises were given to Group A (n = 23), while Group B (n = 23) received only phase one cardiac rehabilitation exercises. The intervention was administered for twice a day for 5 days. Outcome measures such as Sputum volume, maximal inspiratory and expiratory pressure, thoracic expansion, SPO2 level, blood pressure and Peak expiratory flow rate were evaluated at baseline and on 5th day of the study.

Results: Wilcoxon test of within-group analysis revealed statistically significant improvements in all parameters for both the interventional and control groups ($p<0.05^*$), except in diastolic blood pressure, whereas, between group analysis done using Mann Whitney U test also showed statistical improvement in both groups on all parameters with ($p<0.05^*$).

Conclusion: Vibrapep exhibited to be an effective bronchial hygiene therapy in phase one of cardiac rehabilitation with respect to enhancing pulmonary functions such as sputum reduction, chest expansion, improved respiratory pressure's, Peak Expiratory Flow Rate along with Cardiac rehabilitation.

Keywords: Vibrapep, Cardiac rehabilitation, respiratory pressures, CABG, Pulmonary Functions.

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INTRODUCTION:

The age-standardized cardiovascular disease (CVD) death rate in India, according to the Global Burden of Disease study, is higher than the average for the world, which is 235 deaths per 100,000 people.¹ Hypertension (HTN), dyslipidemia, smoking, diabetes mellitus (DM), obesity, inactivity, and poor diet are risk factors for CVD that exhibit fluctuating patterns over time.²

Early postoperative days following open heart surgery had a higher prevalence of pulmonary problems (15.08%), with an 18.5% total mortality.³ Research indicates that patients undergoing median

sternotomy and valve replacement surgery undergo a change in their breathing pattern after the procedure, from primarily abdominal to thoracic breathing, which reduces their pulmonary functions. Following heart surgery, there is also a decrease in vital capacity, inspiratory capacity, FEV1, PEFR, and total lung capacity, which results in a restrictive pattern of pulmonary function.⁴ Both the postoperative decrease in respiratory function (PEFR), which restricts the capacity to cough, and sputum retention.⁴

Cardiopulmonary rehabilitation is a critical component of the preventive and recovery course that needs to begin as soon as

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feasible in order to minimize and prevent pulmonary complications.⁵ Physiotherapy plays a vital role in respiratory care following cardiac surgery which includes mobilization and chest physiotherapy, for the objective of collecting and clearing pulmonary secretions, the Vibrapep is a device that administers OPEP therapy. It helps with secretion clearance by providing PEP and oscillations in airflow to the lungs. Pressure and flow variations combine to produce vibrations in the thorax that generate the bronchial mucus to liquefy and loosen, which makes it easier to expulsion.⁶ Additionally, the Vibrapep aids in providing five different resistive positions in therapy to patient's needs with antigravity positions, which stabilizes and enlarges the airway and thereby exhibits improvement in pulmonary functions as compared to exercise alone.⁶ The goal of this research was to evaluate Vibrapep's effect on pulmonary functions during the phase one of cardiac rehabilitation.

METHOD:

The current study was conducted between July 2023 to May 2024 in the Intensive Thoracic Unit of a tertiary care hospital in Belagavi. The study was conducted out following institutional ethical committee approval. Clinical Trial Registry India (CTRI) number was obtained. According to ICMR all the Covid 19 precautions was taken. The subjects underwent screening for both inclusion and exclusion criteria. A total of 46 participants were enrolled in a randomized controlled trial with patients' undergoing CABG and Valve replacement surgeries. Before starting the intervention brief procedure about the intervention was given by the researcher. An informed consent was obtained from the subject. The participants were randomly allocated into group A (n=23) (interventional group) and group B(n=23) (control group) using envelope method. The study was a single blinded study. The statistical researcher for the study was blinded to both groups for the purpose to ensure accuracy in the data analysis. The subjects were oriented to the device being used in the study prior to the intervention. Baseline assessments for the SPO2 level, Blood pressure, peak expiratory flow rate, chest expansion, respiratory muscle strength, Sputum volume was conducted on day 2 of post operative day, prior to the treatment and post-intervention assessments was conducted on day 5 following the intervention. The intervention was given twice a day for 5 days from the 2nd Post operative day.7

Participants:

Inclusion criteria: Participants aged between 30 to 75 years of age of all gender. Participants having stable vitals following CABG. Participants of phase 1 cardiac rehabilitation. Participants who are willing to participate.

Exclusion Criteria: Participants who are uncooperative. Participants with hemodynamic instability. Subjects unable to understand or use the device appropriately. Participants having Active respiratory tract infection. Participants who are critically ill and with systemic illness.

Intervention:

All patients received conventional medical care following CABG and valve replacement surgery, comprising nebulization solutions (budecort, duolin, asthalin) and incentive spirometry (200-800 cc/ sec).

Group A received Vibrapep with conventional phase one of cardiac rehabilitation. Vibrapep (OPEP) intervention: Step:1 The patient was administered nebulization in propped up bed position, following which the Vibrapep (OPEP) device will be used to aid to clear the secretions. Step 2 The patient was instructed to be in relaxed long sitting position. Step:3 Starting at resting expiration the patient was instructed to take a deeper breath than normal. The patient was subsequently instructed to hold the device via the mouthpiece and take a short breath hold lasting about two seconds. Next, the patient was instructed to exhale. through the device for approximately for 4 seconds. The process was repeated for 10-20 breaths with huff coughing for 5-6 times, between sessions over a 15–20-minute treatment time, the intervention was given for 10x3 sets. Resistance was adjusted to help maintain a four second expiratory time.⁸

Group B received conventional rehabilitation exercises only as follows:

- Diaphragmatic breathing exercises. (5 repetitions x 3 sets)⁹: Procedure: Hands were put across the upper abdomen, just below the anterior coastline margin, in the semi-fowlers position of the patient. Following that, they were instructed to inhale deeply through their nose and gently exhale via their mouth. The directives were to lift the abdominal wall at inspiration and descend it upon expiration.
- Thoracic expansion exercise: The participants were seated. They were told to inhale deeply as they performed each of the exercises one at a time, hold the breath for three seconds, and then slowly exhale while returning to the starting position. This was done in flexion movement since post-CABG abduction of thoracic expansion is avoided. Three sets of seven to ten repetitions of the exercise were performed.
- Active range of motion exercises of upper limb⁹: hand pumps (10 x3 repetitions), shoulder rotations (10 x3 repetitions).
- Active range of motion exercises for lower limb Ankle toe movements: The patient was instructed to be in long sitting or edge of the bed, and instructed to take the foot towards the leg and away from the leg.
- Heel slides (10 x 3 repetitions) = patient was asked to flex and extend the bilateral limb one at a time. Bed side sitting= patient was instructed to perform dynamic quads with holds for 10 secs each. (10 x3 repetitions).
- Trunk Mobility Exercises (5 Repetitions x 3 Sets)
- Ambulation: Patient was ambulated after on POD 4 with assistance.
- Progression of ambulation was done with unsupported ward ambulation (2 rounds)
- Stair climbing and downstairs (10 reps x3 sets)9

OUTCOME MEASURES:

1. SPO2 Level: - was examined through pulse oximeter, the participant was instructed to be in comfortable semi fowlers position, with their arm supported at heart level, The pulse

oximeter clip was placed at index finger of the participants.

- 2. Blood pressure: was evaluated with patients in semi fowlers position, the cuff was applied 2.5 cm above the elbow crease (antecubital fossa), brachial artery pulse was palpated and stethoscope was positioned over it and acceptable readings were taken.
- 3. Thoracic expansion measurement: The participant was asked to be sitting in comfortable upright position, and was asked to breath in and the increase in the chest wall circumference was measured using a non-stretchable measuring tape at the axillary level, at the level of T4 and at xiphoid process. The participants were asked to rest both the hands-on hips, they were asked to inhale and exhale maximally and completely, three acceptable and reproducible readings at all the levels were taken.
- 4. Peak flow meter: -The patient was instructed to be in semi fowlers or sitting position and was advised to hold the device firmly with both hands with mouthpiece placed between the teeth, and close the lips tightly and was asked to inhale maximally and completely followed by forceful exhalation into device, three acceptable and reproducible readings were taken.
- 5. Maximal expiratory pressure- Measurement of maximum expiratory pressure (PEmax) gives a measure of expiratory muscle function and strength under static conditions. The participant was asked to sit upright and expire maximally through the mouthpiece of the pressure manometer. Three acceptable and reproducible readings were be taken.¹⁰
- 6. Maximal inspiratory pressure- was measured as an index for inspiratory muscle strength and the ability to reproduce it is significant of maximal inspiratory effort. The participant was asked to sit upright and inspire maximally through the mouthpiece pressure manometer to obtain the readings. Three acceptable and reproducible readings were be taken.¹¹
- Sputum volume: The process of sputum collection was done using a funnel container containing of markings, The patient was instructed to inhale the solution for ten to fifteen minutes, expectorate following the nebulization in pre and post intervention.

STATISTICAL ANALYSIS:

Following the compilation of study data in an Excel spreadsheet and tabulation in accordance with study protocol, the full statistical analysis is performed using SPSS software version 23. Normal distribution of the study was elicited using Kolmogorov Smirnov test, this method was used to confirm the accuracy of ongoing data. Analysis between both the study groups was done using independent T-test. Mann Whitney U test was used to compare between group analysis of group A and group B of SPO2, BP, Sputum volume, MEP, MIP, Thoracic expansion at axilla, T4 level, xiphoid process, PEFR. Whereas, Wilcoxon matched pair test was used to determine within group analysis in pre and post-test of both groups in SPO2, BP, Sputum volume, MEP, MIP, Thoracic expansion at axilla, T4 level, xiphoid process, PEFR. P less than 0.005 was considered statistically significant.

RESULTS:

The total number of participants were 46 who were being randomized equally into both groups. Both the study group received Conventional physiotherapy exercise as per the protocol which was given twice a day, along with Vibrapep in interventional group. Outcome Measures used in this study included measurement of blood pressure, Oxygen saturation level i.e. SPO2, amount of sputum produced, maximal pressure of inspiratory and expiratory strength, expansion level at xiphoid, T4 level and xiphoid process and Peak expiratory flow rates were determined before and after the study was conducted. On comparison of both groups, the mean age reported in Group A is 55.35 + 9.19, whereas in Group B it is 55.83+ 8.83. There was no statistical significance noted in both the groups in terms of age (p = 0.858) and BMI (p= 0.023). [Table 1]

In SPO2, compared to group B, group A's percent change was designated as 6.47 over 0.03 in group B, signifying slight increase of change. Given that group B had a larger effect size than group A, this justifies that group B showed better outcomes when compared within group. [Table 2,12]. With group A's effect size being 0.4490 and group B's being 0.71100, there was a statistically significant difference between each of the groups in the SBP component. In both groups, there was no statistically significant variance in diastolic blood pressure. [Table 3,4,12]

Maximal inspiratory pressure improved in both the group with effect size of group A showing increased value of effect size over group B, which signifies that group A showed better results as compared to group B. [Table 5,12] Maximal expiratory pressure showed improvement in interventional group and control group with effect size of Group A having higher Cohen's D value as per the standard parameter of reference with 0.6980 over 0.5120 in group B. [Table 6,12].Sputum volume markedly reduced in both the groups post intervention(p<0.005) [Table 7,12]

Thoracic expansion measurement improved in both the groups, at all levels in group A (P<0.05) while no statistical difference was seen in group B post intervention with minimal effect size difference. [Table 8,9,10,12] With an effective percentage change and effect size, peak expiratory flow rate improved in each group following the intervention. [Table 11,12]

TABLE 1: Comparison of Group A and Group B with mean age and

 BMI by independent t test

Variables	Group A		Gro	up B		р-	
	Mean	Std. Dev.	Mean	Std. Dev.	t-value	value	
Age in yrs	55.35	9.19	55.83	8.83	-0.1800	0.8580	
Weight in kgs	159.00	5.98	162.30	5.76	-1.9097	0.0627	
Height in cms	66.30	12.54	62.74	7.79	1.1584	0.2530	
BMI	26.20	4.31	23.78	2.37	2.3539	0.0231	

P<0.05* in BMI and Weight, Group A: Vibrapep with phase one cardiac rehabilitation: Group B: Phase one Cardiac Rehabilitation exercises

TABLE 2: Comparison of day 1 and day 5 time points with SPO2

 scores in Group A and Group B by Wilcoxon matched pairs test

Grou	ps	Changes from	Mean Diff.	SD Diff.	% of change	Z- value	P- value	Effect size
Grou A	ıp	Day 1 to Day 5	0.06	0.03	6.47	4.197 3	0.0001 *	0.739 0
Grou B	ıp	Day 1 to Day 5	0.06	0.03	5.95	4.166 8	0.0001 *	0.791 0

*p<0.05 Group A: Vibrapep with phase one cardiac rehabilitation: Group B: Phase one Cardiac Rehabilitation exercises

TABLE 3: Comparison of day 1 and day 5 time points with SBP scores in Group A and Group B by Wilcoxon matched pairs test

Groups	Changes from	Mean Diff.	SD Diff.	% of change	Z- value	P- value	Effect size
Group A	Day 1 to Day 5	7.70	8.72	5.97	3.7706	0.0002*	0.4490
Group B	Day 1 to Day 5	10.65	6.96	8.09	3.9199	0.0001*	0.7100

*p<0.05 Group A: Vibrapep with phase one cardiac rehabilitation: Group B: Phase one Cardiac Rehabilitation exercises

Table 4: Comparison of day 1 and day 5 time points with DBP

 scores in Group A and Group B by Wilcoxon matched pairs test

Groups	Changes from	Mean Diff.	SD Diff.	% of change	Z- value	P- value	Effect size
Group A	Day 1 to Day 5	-2.87	8.32	-3.72	1.372 8	0.169 8	0.111 0
Group B	Day 1 to Day 5	0.43	6.20	0.54	0.085 2	0.932 1	0.005 0

*p <0.05 Group A: Vibrapep with phase one cardiac rehabilitation: Group B: Phase one Cardiac Rehabilitation exercises

Table 5: Comparison of day 1 and day 5 time points with Maximal inspiratory pressure scores in Group A and Group B by Wilcoxon matched pairs test

Groups	Changes from	Mean Diff.	SD Diff.	% of change	Z- value	P- value	Effect size
Group A	Day 1 to Day 5	2.02	1.71	-101.75	3.666 9	0.0002 *	0.593 0
Group B	Day 1 to Day 5	1.39	0.99	-88.89	3.723 6	0.0002 *	0.575 0

*p <0.05 Group A: Vibrapep with phase one cardiac rehabilitation: Group B: Phase one Cardiac Rehabilitation exercises **Table 6:** Comparison of day 1 and day 5 time points with Maximal expiratory pressure scores in Group A and Group B by Wilcoxon matched pairs test

Groups	Changes from	Mean Diff.	SD Diff.	% of change	Z- value	P- value	Effect size
Group A	Day 1 to Day 5	2.96	1.99	73.91	3.8230	0.0001 *	0.698 0
Group B	Day 1 to Day 5	1.74	1.74	44.44	3.2958	0.0010 *	0.512 0

*p <0.05 Group A: Vibrapep with phase one cardiac rehabilitation: Group B: Phase one Cardiac Rehabilitation exercises

Table 7: Comparison of day 1 and day 5 time points with Sputum volume scores in Group A and Group B by Wilcoxon matched pairs test

Groups	Changes from	Mean Diff.	SD Diff.	% of change	Z- value	P- value	Effect size
Group A	Day 1 to Day 5	3.57	1.03	76.28	4.197 5	0.0001 *	0.927 0
Group B	Day 1 to Day 5	2.22	0.67	56.67	4.197	0.0001 *	0.919 0

*p <0.05 Group A: Vibrapep with phase one cardiac rehabilitation: Group B: Phase one Cardiac Rehabilitation exercises

Table 8: Comparison of day 1 and day 5 time points with Thoracic expansion at axilla scores in Group A and Group B by Wilcoxon matched pairs test

Groups	Changes from	Mean Diff.	SD Diff.	% of change	Z- value	P- value	Effect size
Group A	Day 1 to Day 5	0.42	0.38	36.23	3.4078	0.0007*	0.5520
Group B	Day 1 to Day 5	0.20	0.33	15.79	2.3664	0.0180*	0.2710

*p <0.05 Group A: Vibrapep with phase one cardiac rehabilitation: Group B: Phase one Cardiac Rehabilitation exercises

Table 9: Comparison of day 1 and day 5 time points with Thoracic expansion at T4 level scores in Group A and Group B by Wilcoxon matched pairs test

Groups	Changes from	Mean Diff.	SD Diff.	% of change	Z- value	P- value	Effect size
Group A	Day 1 to Day 5	0.15	0.22	15.00	2.803	0.0007*	0.339 0
Group B	Day 1 to Day 5	0.02	0.10	1.45	0.000	1.0000	0.043 0

*p <0.05 Group A: Vibrapep with phase one cardiac rehabilitation: Group B: Phase one Cardiac Rehabilitation exercises **Table 10:** Comparison of day 1 and day 5 time points with Thoracic expansion at Xiphoid process scores in Group A and Group B by Wilcoxon matched pairs test

Groups	Changes from	Mean Diff.	SD Diff.	% of change	Z- value	P- value	Effect size
Group A	Day 1 to Day 5	0.22	0.24	17.08	3.1798	0.0015*	0.4650
Group B	Day 1 to Day 5	0.04	0.14	2.87	0.0000	1.0000	0.0870

*p <0.05 Group A: Vibrapep with phase one cardiac rehabilitation: Group B: Phase one Cardiac Rehabilitation exercises **Table 11:** Comparison of day 1 and day 5 time points with Peak flow meter scores in Group A and Group B by Wilcoxon matched pairs test

Groups	Changes from	Mean Diff.	SD Diff.	% of change	Z- value	P- value	Effect size
Group A	Day 1 to Day 5	65.76	20.42	95.10	4.1973	0.0001*	0.9160
Group B	Day 1 to Day 5	45.57	34.82	58.14	3.5585	0.0004*	0.6420

*p <0.05 Group A: Vibrapep with phase one cardiac rehabilitation: Group B: Phase one Cardiac Rehabilitation exercises

Variable	Time	Group	Mean	SD	Z-VALUE	P-VALUE
1. SPO2 LEVEL	Pre	Group-A	0.96	0.03	-0.6810	0.4958
		Group-B	0.97	0.02		
	Post	Group-A	0.90	0.02	-2.2958	0.0217*
		Group-B	0.91	0.03		
	Difference	Group-A	0.06	0.03	0.7030	0.4820
		Group-B	0.06	0.03		
2. SYSTOLIC BLOOD PRESSURE	Pre	Group-A	129.00	10.47	-1.8454	0.0650
		Group-B	131.74	5.56		
	Post	Group-A	121.30	5.48	0.0659	0.9475
		Group-B	121.09	5.21		
	Difference	Group-A	7.70	8.72	-1.9882	0.0468*
		Group-B	10.65	6.96		
3. DIASTOLIC BLOOD PRESSURE	Pre	Group-A	77.13	8.95	-1.4170	0.1565
		Group-B	80.65	4.60		
	Post	Group-A	80.00	3.02	-0.6591	0.5098
		Group-B	80.22	4.60		
	Difference	Group-A	-2.87	8.32	-0.7579	0.4485
		Group-B	0.43	6.20		

Effectiveness of Vibrapep (OPEP) on Pulmonary functions in phase one of cardiac rehabilitation-A Randomized controlled trial

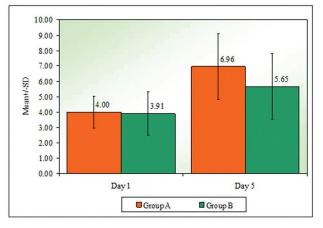
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DifferenceGroup-B1.741.742.03210.0421* A_{ACP} Group-A4.671.00 A_{ACP} A_{ACP} A_{ACP} A_{ACP} A_{ACP} Group-B3.910.752.38370.0171* A_{ACP} Group-A1.110.45 A_{ACP} A_{ACP} A_{POSt} Group-B1.100.45 A_{ACP} A_{ACP} $A_{DDIfference}$ Group-B2.220.674.0204 A_{ACP} $A_{DDIfference}$ Group-B1.240.37 A_{ACP} A_{ACP} A_{POSt} Group-B1.240.37 A_{ACP} A_{ACP} A_{POSt} Group-B1.240.37 A_{ACP} A_{ACP} A_{POSt} Group-B1.430.46 A_{ACP} A_{ACP} A_{POSt} Group-B1.430.46 A_{ACP} A_{ACP} A_{POSt} Group-B1.430.46 A_{ACP} A_{ACP} A_{POSt} Group-B1.0116.96 A_{ACP} A_{ACP} A_{POSt} Group-A1.0116.96 A_{ACP} A_{ACP} A_{POSt} Group-A1.160.22 A_{ACP} A_{ACP} A_{POSt} Group-A1.520.63 A_{ACP} A_{ACP} A_{POSt} Group-A1.160.22 A_{ACP} A_{ACP} A_{POSt} Group-A1.160.22 A_{ACP} A_{ACP} A_{POSt} Group-A1.160.23 A_{ACP} A_{ACP			Group-B	5.65	2.14		
Image: Constraint of the section of the sec			Group-A	2.96	1.99		
PreGroup-B3.910.752.38370.0171*6. SPUTUM VOLUMEPostGroup-A1.110.45		Difference	Group-B	1.74	1.74	2.0321	0.0421*
6. SPUTUM VOLUME Image: Constraint of the sector of the sect		Dro	Group-A	4.67	1.00	2.3837	0.0171*
6. SPUTUM VOLUME Post Group-B 1.70 0.70 -2.8780 0.0040* $Difference$ Group-A 3.57 1.03 A_{0204} A_{0001}^* $Difference$ Group-B 2.22 0.67 A_{0204} A_{0001}^* Pre Group-A 1.15 0.32 A_{0001}^* A_{0001}^* Pre Group-B 1.15 0.32 A_{0001}^* A_{0001}^* Pre Group-B 1.24 0.37 A_{0001}^* A_{0001}^* Pre Group-B 1.43 0.46 A_{0001}^* A_{0001}^* $Difference$ Group-B 1.43 0.46 A_{0001}^* A_{0001}^* Pre Group-B 1.43 0.46 A_{0001}^* A_{0001}^* $Difference$ Group-B 0.20 0.33 A_{0001}^* A_{0001}^* Pre Group-A 1.01 16.96 A_{0001}^* A_{0001}^* A_{0001}^* Pre Group-B 1.50 0.62 -3.2954 0.010* A_{0019}^* A_{0019}^* <t< td=""><td></td><td>Pre</td><td>Group-B</td><td>3.91</td><td>0.75</td></t<>		Pre	Group-B	3.91	0.75		
$ \frac{1}{10000000000000000000000000000000000$	6 SPUTUM VOLUME	Post	Group-A	1.11	0.45	-2.8780	0.0040*
$\frac{\text{Difference}}{\text{Group-B}} & 2.22 & 0.67 & 4.0204 & 0.0001^{*} \\ \hline \text{Group-B} & 1.15 & 0.32 & \\ -0.5492 & 0.5828 & \\ -0.549 & 0.5828 & \\ -0.549 & 0.5828 & \\ -0.549 & 0.5828 & \\ -0.549 & 0.5828 & \\ -0.549 & 0.5828 & \\ -0.549 & 0.5828 & \\ -0.549 & 0.5828 & \\ -0.549 & 0.5828 & \\ -0.549 & 0.548 & \\ -0.549 & 0.548 & \\ -0.549 & 0.548 & \\ -0.549 & 0.548 & \\ -0.549 & 0.548 & \\ -0.549 & 0.010^{+} & \\ -0.5$	0. SI OTOMI VOLOMIL		Group-B	1.70	0.70		
$\frac{1}{10000000000000000000000000000000000$		Difference	Group-A	3.57	1.03	4.0204	0.0001*
$ \frac{Pre}{F} + P$			Group-B	2.22	0.67		
$ \frac{1}{10000000000000000000000000000000000$		Pre	Group-A	1.15	0.32	-0.5492	0.5828
$\frac{1}{10000000000000000000000000000000000$			Group-B	1.24	0.37		
$\frac{1.2522}{1.2522} = 0.2105$ $\frac{1.2522}{0.2105} = 0.2105$ $\frac{1.2522}{0.0104} = 0.2105$ $\frac{1.2522}{0.0044^{*}} = 0.2105$ $\frac{1.252}{0.0044^{*}} = 0.2105$ $\frac{1.252}{0.0044^{*}} = 0.2105$ $\frac{1.252}{0.0044^{*}} = 0.2105$ $\frac{1.252}{0.0044^{*}} = 0.2105$ $\frac{1.252}{0.0010^{*}} = 0.2105$		Post	Group-A	1.57	0.43		
$\frac{\text{Difference}}{\text{Group-B}} = 0.20 = 0.33 = 2.0102 = 0.044^{*}$ $\frac{\text{Group-A}}{\text{Group-A}} = 1.01 = 16.96 = -3.2954 = 0.0010^{*}$ $\frac{\text{Group-B}}{\text{Group-B}} = 1.50 = 0.62 = -3.2954 = 0.0010^{*}$ $\frac{\text{Group-A}}{\text{Group-A}} = 1.16 = 0.22 = -3.287 = 0.0199^{*}$ $\frac{\text{Group-B}}{\text{Group-B}} = 1.52 = 0.63 = -2.3287 = 0.0199^{*}$			Group-B	1.43	0.46	1.2522	0.2105
Group-B 0.20 0.33 2.0102 0.0444* here Group-A 1.01 16.96 -3.2954 0.0010* SION LEVEL AT T4 Post Group-A 1.16 0.22 -3.2954 0.0010* Borner-B Joine-A 1.16 0.22 -3.2954 0.0010* Borner-B Group-B 1.16 0.22 -2.3287 0.0199* Difference Group-A 0.15 0.22 2.2189 0.0265*		Difference	Group-A	0.42	0.38	2.0102	0.0444*
Pre Group-B 1.50 0.62 -3.2954 0.0010* 8. THORACIC EXPAN- SION LEVEL AT T4 LEVEL Post Group-A 1.16 0.22			Group-B	0.20	0.33		
S. THORACIC EXPAN- SION LEVEL AT T4 LEVEL Post Group-B 1.50 0.62 -5.2954 0.0010* B. THORACIC EXPAN- SION LEVEL AT T4 LEVEL Post Group-A 1.16 0.22 -2.3287 0.0199* Difference Group-A 0.15 0.22 -2.3189 0.0265*	SION LEVEL AT T4	Pre	Group-A	1.01	16.96	-3.2954	0.0010*
SION LEVEL AT T4 Post Group-B 1.52 0.63 -2.3287 0.0199* Difference Group-A 0.15 0.22 2.2189 0.0265*			Group-B	1.50	0.62		
Group-B 1.52 0.63 -2.3287 0.0199* LEVEL Group-A 0.15 0.22 Difference 2.2189 0.0265*		Post	-	1.16	0.22	-2.3287	0.0199*
Difference 2.2189 0.0265*			Group-B	1.52	0.63		
Group-B 0.22 0.10		Difference	Group-A	0.15	0.22	2.2189	0.0265*
			Group-B	0.22	0.10		

Effectiveness of Vibrapep (OPEP) on Pulmonary functions in phase one of cardiac rehabilitation-A Randomized controlled trial

9.THORACIC EX- PANSION LEVEL AT XIPHOID LEVEL	Pre	Group-A	1.30	0.36		
		Group-B	1.52	0.41	-19662	0.0493*
	Post	Group-A	1.52	0.40	-0.3186*	0.7501
		Group-B	1.56	0.40		
	Difference	Group-A	0.22	0.24	2.6802	0.0074*
		Group-B	0.04	0.14		
10.PEAK FLOW METER	Pre	Group-A	69.15	14.52	-18454	0.0650
		Group-B	78.39	26.87		
	Post	Group-A	134.91	18.89	2.2958	0.0217*
		Group-B	123.97	20.21		
	Difference	Group-A	65.76	20.42	2.5704	0.0102*
		Group-B	45.57	34.82		

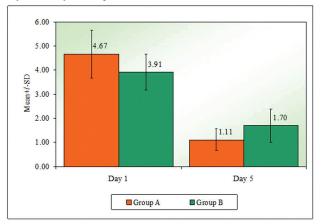
*p <0.05 Group A: Vibrapep with phase one cardiac rehabilitation: Group B: Phase one Cardiac Rehabilitation exercise

Comparison of Group A and Group B with Maximal expiratory pressure scores at day 1 and day 5 time points.



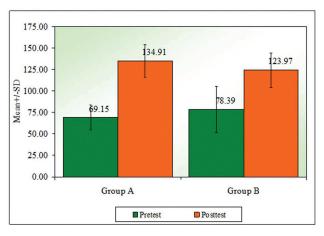
Group A-Vibrapep intervention Group B- Cardiac Rehabilitation

Comparison of Group A and Group B with Sputum volume scores at day 1 and day 5 time points



Group A-Vibrapep intervention Group B- Cardiac Rehabilitation

Comparison of day 1 and day 5 time points with Peak flow meter scores in Group A and Group B



Group A-Vibrapep intervention Group B- Cardiac Rehabilitation

DISCUSSION:

The current study intended to evaluate and compare the effect of Vibrapep in combination with conventional physiotherapy exercises on pulmonary function parameters namely sputum clearance, thoracic expansion level, maximal inspiratory and expiratory pressure, peak expiratory flow rate, blood pressure and oxygen level saturation in phase one of cardiac rehabilitation.

Numerous studies indicate a higher prevalence of CABG in men compared to women, i.e. the majority of CABG patients were men with 87.5%,¹² In our present study, the percentage of male were 60.87% while female participants accounted for about 39.13 %. This could be due to higher prevalence of risk factors associated such as diabetes mellitus, hypertension, and smoking in men as compared to women.¹³

Participants in Group A and Group B of our study had average ages of 55.35 + 9.19 and 55.83 + 8.83, respectively. Additionally, research suggests that similar results with patients who underwent CABG in India had a mean age of 57 ± 9.6 years, which is comparable to the results of our current study.¹⁴ The average age of the participants is accordingly represented in our current study in a comparable method.

The average BMI of the Group A was 26.20 + 4.31 kg/m2 and Group B was 23.78+2.37 Kg/m2, which indicates that participants enrolled in the study exhibited body mass index ranging from normal to overweight category according to the WHO guidelines. As per literature, obesity or overweight doesn't affect early or late risk mortality in CABG patients.^{15,16} Patients who undergo coronary artery bypass grafting are more susceptible to complications related to pulmonary function.

In current study sputum volume exhibited significant reduction in both the groups, when compared between and within analysis, as the probable mechanism of Vibrapep aided in airway clearance device that functions on two principles: Asynchronous Dynamic Oscillations facilitate mucus shearing from the bronchial walls, which provided continuous PEP above baseline with applied pressure and flow change, and Higher Level of PEP, which regulated and enlarged the airway to promote collateral ventilation⁶, thereby aided in reducing secretions post treatment. In accordance to this study, it has been demonstrated that oscillating devices, like Acapella, reduce mucus's viscoelastic characteristics, which facilitates airway mobilization done in comparison of acapella versus ACBT technique with valve replacement surgeries.¹⁷ The working mechanism behind this is after the glottis opens, there is a build-up of high intrapulmonary pressures that cause supramaximal, turbulent expiratory flows.¹⁸

Following cardiac surgery, patients' capacity to inhale and exhale on their own and the strength of the respiratory muscles are both impaired. In the present study the participants maximal inspiratory pressure remained at -1cm H2O to -2cm H2O till POD 3, it showed slight increment on day five, Maximal inspiratory pressure has demonstrated significant improvement in both groups, as the Vibrapep constitutes of 0 to 4 pressure settings on the Vibrapep, which offers a steady rise in pressure followed by an abrupt drop in pressure caused by the quick commencement of high velocity airflow⁶, it might be because the inspiratory muscles are exposed to a load of resistance. (3 and 4) daily for twice a day for 5 days, it is repeatedly executed ten times while coughing and huffing; as a result, the muscle's capacity to produce tension and lengthen their sarcomeres will increase.¹⁹

In our study maximal expiratory pressure also showed a significant improvement in both the groups while the interventional group showed 73.91% of change over 44.44% in group B post intervention with (p<0.05%), as Vibrapep is an oscillatory positive expiratory pressure device, which works on the two primary physiological benefits: (1) PEP, which maintains airway flexibility and inhibits collapse during expiration, and (2) oscillations in airflow, which promoted mucociliary clearance.²⁰ Importantly literature suggests that an OPEP device should provide optimal expiratory pressure of 10cm H2O, the VibraPEP exhibits around 8-16cm H2O, which might have exhibited better expiratory flow pressure in the current study.²¹ Determination of the maximum expiratory pressure PEmax gives quantitative data regarding the function of the expiratory muscles under static conditions.¹⁰

Peak expiratory flow rate in the current study revealed statistical significance (p<0.05), with group A exhibiting 95.10% of improvement while group B showed 58.14% of improvement post evaluation, the reason behind this would be, because lung capacity and expiratory flow rate are directly correlated, coughing will be less effective in the postoperative phase when lung volumes are reduced.¹ Vibrapep might have helped in enhancing Peak expiratory flow rate by increasing and promoting intrapulmonary pressures, resulting in an increase in functional residual capacity. Peak Expiratory flow rate increasing ung volume.¹

The research suggests that for mucus to travel proximally, it requires to be a minimum 10% difference in the peak inspiratory and expiratory flow rates. In order to overcome the associated shear force to effectively move the mucus, the peak expiratory flow rate is required to be greater than 30 to 60 L/min.¹⁸ In current study increase in PEFR was noted more than 60 L/min, The mechanism worked behind this is by the intraluminal pressure and the pressure from the static elastic recoil will both be reduced since the forced exhale is initiated at a smaller lung capacity, and the ensuing equal pressure point will be more peripheral.¹⁸ This justifies the result obtained from the current study with interventional group being more effective than conventional group alone.

Thoracic expansion levels at axilla, xiphoid and T4 level demonstrated statistical and clinical significance at (p<0.05), in both the groups, while the interventional group out passed the control group at all three levels, as the collateral ventilatory system may have been activated by the thoracic expansion exercise, aiding the passage of air distal to mucus plugs in the peripheral airway.²² This could be elucidated by a decrease in rib cage muscular tension and an improvement in mechanical properties induced on by rib cage movement.²⁰ As a result of the lungs expanding due to negative pleural pressure, inspiration widens the airways, temporarily reducing airflow resistance and facilitating the passage of air beyond mucus.¹⁸ And also, additionally, there is an 8.5cm H2O transmural pressure gradient produced during an average expiration (Levitzky 1991), and during exercise or forced expirations, this gradient can exceed 20cm H2O in the proximal airways leading to better expansion,¹⁸ so this mechanism coincides with our current study. As in CABG patients undergo median sternotomy incision patients develop pain and dramatically reduction in movement of inhalation and exhalation is observed especially in phase one of cardiac rehabilitation, thoracic cage movements are restricted due to pain at baseline, post physical therapy thoracic expansion exercises in flexion demonstrated increased thoracic expansion level at all three levels.

In current study, SPO2 level showed better health outcomes in both the groups, few literatures suggests that post intervention there is increase in oxygen saturation level, slight increased effect of change was seen in group B as compared to group A, Imran M et al, reported this could be due to patients in group A had sedative effects of medications on the respiratory status of the patients, individually.²³ A systematic review conducted by Jingjun Li also reported a significant difference in SPO2 post cardiac rehabilitation exercises.²⁴

There are very few evidences on how OPEP devices effects on blood pressure component, according to the results exhibited in the present study, significant difference was seen in Systolic blood pressure in both the groups, which is supported by a study conducted by Yosef Leven brown et al on effect of PEP devices on cardiac output and oxygen delivery, which concluded that when PEP or OPEP is used there is reduced pressure differences between systemic pressure and right atrial pressure resulting from an increase in alveolar pressure that is transmitted throughout the thorax,²⁵ whereas, no significant difference was seen in diastolic blood pressure in both the groups, since there was no clinical significance exhibited by OPEP on DBP, this is supported by a study done by Suchai Surapichpong et al on efficacy of the Oscillatory positive pressure breathing circuit on airway clearance concluded that no difference was seen in diastolic blood pressure with very slight difference seen in SBP.²⁶

The limitation of the study included long term effect or follow up was not done, so the carry over effect of vibrapep therapy is not known. The study was administered for a small population (n=46), the study exhibited a gender bias as it predominantly included male patients. To address this issue, further research should be conducted with an equivalent representation of both genders, to generalize the potential differences seen in the results, few dropouts were being detected during intervention due to unstable vitals. A multi-centre trial allocating a large sample size can be used in future studies. Studies comprising of 7 days or more intervention should be administrated with chest x-ray, ABG analysis, six-minute walk test outcomes for further research.

No other studies have been carried out as per knowledge in determining Vibrapep with conventional cardiac rehabilitation exercises, Nevertheless, our current study has indicated effect of Vibrapep in phase one of cardiac rehabilitation, in improving pulmonary functions, while additional study is required to validate the results in many aspects.

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Conflict of Interest: There is no conflict of interest

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