Comparative Study of Effect of Segmental Breathing Exercise and Deep Breathing Exercise in CABG Patients

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ABSTRACT

The study was experimental which was comparative in nature. The current study aims to evaluate the comparison of effect of segmental breathing exercise and deep breathing exercise in CABG patients. On the basis of inclusion and exclusion criteria 30 subjects were taken. Before initiating the study a

consent was taken from the patient which include the aim and objectives of the study. Subjects were divided into 2 groups. Each group contain 15 subjects. Subjects were divided randomly into each group. Pre-operative segmental breathing exercise were taught by therapist to group A along with conventional exercises and deep breathing exercise were taught by therapist to group B along with conventional exercises and then pre operative readings were taken. Conventional exercises include upper limb range of motion exercises, lower limb range of motion exercises and ambulation if necessary. Post operatively patients were asked to perform the exercises under observation by the therapist. Now, post operative readings for both the groups were taken 30 days of time period.

Data was meaningfully assorted through calculation of Mean and Standard Deviation. Thereafter Unpaired 't' test was applied for comparison of results of Incentive Spirometer and PEFR performed on group A and group B. The level of significance (P value) for Incentive Spirometer is 0.5434 and 0.6436. The level of significance (P value) for PEFR is 0.7187 and 0.7356. There was no significant difference in comparison of effect of segmental breathing exercise and deep breathing exercise in CABG patients.

The study concludes that there is no significant difference in Comparison of Effect of Segmental Breathing Exercise and Deep Breathing Exercise in CABG Patients.

Keywords: Segmental Breathing Exercise; Deep Breathing Exercise; Incentive Spirometer; PEFR; CABG.

INTRODUCTION

Harris, Croce and Tian¹ cited that the CABG procedure restores adequate blood flow to the heart by using an artery or vein from another part of the body to bypass the blocked vessels. In order to create a new passageway for oxygenated blood to reach the heart muscle, the artery or vein is connected around the obstruction. Patients with severe coronary heart disease (CHD), the main cause of death in Western nations, may benefit from coronary artery bypass grafting (CABG), a form of heart surgery. The condition is characterized by a slow accumulation of calcium and fatty deposits (plaque) in the arteries supplying the heart with blood. Chest pain results from a reduction in blood flow to the heart; a heart attack results from a full blockage of the arteries. The objectives of CABG surgery

are to enhance survival, decrease symptoms, and lower the risk of a heart attack.

According to Melly, Torregrossa, Lee, Jansens and Puskas² with yearly volumes of almost 200,000 individual cases in the US and an average incidence rate of 62 per 100,000 people in Western European nations, coronary artery bypass grafting (CABG) is still the most frequently done surgery technique worldwide. cardiac Numerous pioneers in cardiovascular surgery have embraced the CABG adventure, with both their achievements and mistakes. Conceptually. all of those contributions can be divided into three separate periods beginning at the turn of the 20th century. The experimental work that was done up until the early 1960s is the first, with reports of some setbacks but also some outstanding early clinical successes. Second, the development of evidence-based cardiac surgery was aided by testing a variety of grafts and making an effort to standardise them in modern coronary artery surgery. Third, minimally invasive surgery develops towards improved collaboration between traditional surgery and interventional medicine, much as other procedures in the 21st century.

Diodato and Chedrawy³ stated that the 1960s saw great advances in coronary artery The first successful surgery. human coronary artery bypass procedure was carried out in 1961 by Goetz et al.⁴. The first practical cardiac angiography that permitted visualization of the coronary arteries was invented in 1962 by Proudfit et al.⁵. In 1964, Kolesov completed the first successful internal mammary arterycoronary artery anastomosis⁶, and in 171 patients, Favoloro et al. reported that saphenous vein revascularization had restored coronary artery blood flow.⁷. In the 1970s, continued development of technique and conduits occurred. In 1973, Benetti, Subramian successfully Calafiore, and completed anastomosis on a beating heart⁸. The CABG procedure became more common and safer in the 1980s. By Duhaylongsod et al. in 1998, thoracoscopic harvesting of the left IMA was reported.⁹, and robotic and minimally invasive surgical techniques was also developed.^{10,11} Currently, the number of CABGs is decreasing, with an anticipated 300,000 cases in 2012, down from a peak of 519,000 operations in 2000.¹².

According to Shekar¹³ there are 2 alternative ways to perform CABG: the older method, known as on-pump CABG, and the more recent method, known as off-pump CABG. On whether approach is preferable, opinions are still divided. The majority of CABGs are carried out using the midline sternotomy method, which involves cutting through the breast bone in the middle.

An on-pump time-honored procedure that is performed while the heart is stopped. The blood supply must be provided to the rest of the body when the heart is stopped. As a surgeons employ result, the cardiopulmonary bypass machine, also referred to as the heart-lung machine or the pump, which is an artificial circulatory system that replaces the functions of the heart and lungs. The patient's unclean blood is transported through pipes (cannulas) to the pump, where it is cleaned before being pumped back into the body. Thus, the heart can be safely stopped with specialized medications that not only keep it stopped but also nourish it when it is still. After that, the bypass grafts are built. The heart is restarted at the conclusion of the treatment.

Off-pump CABG is regarded as the more recent technique for doing CABG. This method was created in response to the side effects of on-pump CABG, including stroke and a decline in higher mental function. Without using a heart-lung machine, this treatment is carried out while the patient's heart is still beating. When using this procedure, attaching grafts to the heart while it is pumping blood and moving constantly brings а new level of complication, comparable to threading a needle while a boat is rocking, while categorically avoiding the insertion of special pipes for the device, the use of artificial circulation, and severe aortic

manipulation. Special tools can mechanically stabilise the relevant heart region so that suturing can be done on a platform comparatively that is stationary.¹⁴ There have been worries that the continual mobility could lead to poor technique, which grafting could compromise the quality of these grafts. But the outcomes achieved by surgeons who have modified and refined this technique remain superb. ^{15,16} In a low-risk patient, the risk of death and/or complications following an off-pump CABG is likewise between 1% and 2%. Nevertheless, some skilled surgeons are currently doing this highly specialised treatment with good outcomes. Large clinical trials have not supported the claimed advantages of this technique, such as a decreased risk of stroke, neurocognitive dysfunction, organ dysfunction, and atrial fibrillation.¹⁷

Chauhan¹⁸ suggested that the Wright's Peak Flow (WPF) metre is a device that Hadron first used in 1942. It has been determined that this instrument is suitable and employed to assess PEFR for physiological studies. It is a reliable, sturdy, and lightweight instrument. The device is a lightweight plastic cylinder with dimensions of 15 x 5 cm and a weight of 72 g (without the mouthpiece). It comprises of a spring piston that freely moves on a rod inside the instrument's body. A sliding indication that moves independently is moved along a slot that is marked with a scale that ranges from 60 l/min to 800 l/min. A number of Mini peak flow metres, with typical ranges of 60-800 lpm for adults and 60-400 lpm for children, have been introduced more recently. When the operator resets the indicator to zero, the maximum movement of the piston is recorded by the indicator. The machine must be used with the air vents open and held horizontally. The individual was instructed to assume a comfortable, upright posture. After receiving the proper instructions, the participant was instructed to exhale as hard as they could into the peak flow metre while having their nose clipped, and to inspire as hard as they could. The readings were obtained while standing. PEFR was measured three times, with the greatest measurement of the three being taken in lit/min.

According to Dikshit¹⁹ healthy young Indian males and females possess average PEFRs of about 500 and 350 lpm, respectively. The PEFR peaks between the ages of 18 and 20 and remains at this level until around 30 years of age for men and 40 years of age for women before beginning to fall with advancing years.

According to Martin²⁰ Incentive Spirometers (IS) are disposable plastic devices that are recommended to lessen pulmonary problems following surgery by assisting in the production of sustained maximal inspiration.

Sharpless²¹ stated that inhalation therapy is used during post-operative surgery to keep the lungs functioning properly and to keep the lungs rid of fluid. The prior art offers incentive spirometers that motivate postoperative patients to breathe at a certain flow rate or until a desired volume has been breathed. These prior art incentive spirometers are often made so that the patient receives a visual reward when they inhale through a tube that is put in their The most popular design mouth. of incentive spirometers is a lightweight sphere suspended in a clear cylindrical column with a diameter just a little bit greater than the sphere's. The patient inhales air at a flow rate that causes the sphere to ascend in the cylindrical column. The column and sphere are placed in the inhalation flow path. Such incentive spirometers are made of plastic and are reasonably priced, making them acceptable for disposal after each patient uses them. The majority of patients can use and hold these gadgets with ease.

According to Harmony²² exercises in segmented breathing can be described as conscious localised breathing directed to one section of the chest while the other segment is left relaxed. The use of segmental breathing exercises achieves a number of goals, including increased aeration and expansibility, which lowers the

risk of atelectasis, or stimulation of the cough reflex mechanism, which prevents an excessive buildup of secretions in the bronchial tree. Other goals include restoring normal motion to an area that has been operated on while concurrently reducing paradoxical breathing and preventing the patient from experiencing a panic attack by helping them feel more in control of their breathing.

According to Sarkar²³ the objectives of this exercise are to enhance ventilation, enhance the cough mechanism's efficacy, avoid pulmonary impairment, enhance respiratory muscle strength. endurance, and coordination, rectify inefficient or incorrect breathing patterns, and encourage relaxation. Exercises for segmental breathing can also be broken down into apical, lateral, and posterior segments.

to Rodrigues²⁴ segmental According breathing is the most effective therapy to promote thoracic mobility. These activities are meant to enhance the lung expansion of a certain segment. It helps to mobilise the thoracic cage, enhance gas exchange, develop strength. endurance. and effectiveness of the respiratory muscles, as well as increase and redistribute ventilation. Solomen and Aaron²⁵ that breathing exercises can be characterised as therapeutic interventions whose goal is the complete transformation of a particular breathing pattern. It aids by increasing lung volume, clearing secretions, improving gas exchange, controlling breathlessness, increasing exercise capacity, reducing blood pressure, and reducing obesity. In Deep Breathing, participants were instructed to take slow, deep breaths in through their noses before exhaling through their mouths. Air is warmed and made more humid when breathed by the nose, although airflow is twice as difficult. Muscle contraction strength and speed are slowly increased and decreased by inspiration. To maintain the patency of the tiny airway closure, exhalation is done through the mouth.

Russo, Santarelli, and Rourke²⁶ determined that breathing pattern, as defined by

respiratory rate, tidal volume, diaphragmatic activation, respiratory pauses, and passive versus active expiration, has a profound impact on not only respiration efficiency but also extends to cardiovascular function and autonomic function, where the effects are bidirectional.

Sewa²⁷ stated that one of the earliest and most often requested tests of pulmonary function is spirometry, which derives from the Latin spiro, which means "to breathe," and the Greek metron, which means "measure." It is a physiological test that gauges how quickly or slowly someone inhales or exhales air. It is a useful technique for assessing the respiratory system, serving as a complement to invasive testing, different lung imaging investigations, and patient history.

Westerdahl²⁸ concluded that following cardiac surgery, early postoperative chest physical therapy and deep breathing exercises can enhance recovery. Deep breathing exercises are used after surgery to correct any pulmonary abnormalities already present and to stop additional postoperative deterioration.

MATERIALS & METHODS

Study Design: Experimental studySamplingTechnique:Sampling will be used to collect sampleSource of Data:Subjects will be takenfrom the different cities of Punjab.

Eligibility

Inclusion Criteria

- Vitally stable patients.
- Age group of 40 80 years.

Exclusion Criteria

- Hemodynamically unstable patients.
- Patient after re-opening of sternum.
- Infected patients.
- Uncooperative patients.

Variables

Independent Variables

• Segmental breathing exercise.

• Deep breathing exercise.

- Dependent Variables
- CABG patients

PROCEDURE

On the basis of inclusion and exclusion criteria 30 subjects were taken from Dayanand Medical College and Hospital, Ludhiana. Before initiating the study a consent was taken from the patient or from their family member in order to keep their confidentiality. It includes the aim and objectives of the study. Subjects were divided into 2 groups with the help of convenient sampling. Each group contain 15 subjects. Subjects were divided randomly into each group. Pre-operative segmental breathing exercise were taught by therapist to group A along with conventional exercises which include upper limb range of motion exercises, lower limb range of motion exercises and deep breathing exercise were taught by therapist to group B along with conventional exercises which include upper limb range of motion exercise, lower limb range of motion exercises and then pre operative readings were taken with the help of incentive spirometer and PEFR. Patients who were advised for ambulation was also performed with the assistance of therapist. Post operatively patients were asked to perform the exercises that is group A is asked to perform segmental breathing exercise along with conventional exercises and group B is asked to perform deep breathing exercise along with conventional exercise under observation by the therapist. Now, post operative readings for both the groups were taken with the help of incentive spirometer and PEFR after30 days of time period. After that readings of pre and post operative incentive spirometer and PEFR of both the groups were compared.

Description of Measurement Tools

Incentive Spirometer: According to Restrepo⁵³ utilising a device that emits feedback when the patient inhales at a predefined flow or volume and maintains the inflation for at least five seconds, incentive spirometry-also known as sustained maximal inspiration-is carried out. The patient is asked to hold the spirometer

upright, breathe normally, and then firmly wrap their lips over the mouthpiece. The following phase is a slow inhalation to raise the ball (flow-oriented) or the piston/plate (volume-oriented) in the chamber to the predetermined objective. The mouthpiece is withdrawn after inhaling fully, followed by a breath hold and regular exhale. The proper use of incentive spirometry by the patient and encouragement of adherence to therapy may be facilitated by training parents, guardians, and other health carers in the technique.

Eltorai⁵⁴ stated that incentive spirometers can either be volume- or flow-oriented. The chamber of a flow-oriented IS device has three connected columns, and inside are floats made of lightweight plastic. The patient inhales through a flexible tube that is attached to the chamber in an effort to lift the floating objects by inspiratory flow produced by negative intrathoracic pressure. A flexible tube with a mouthpiece is attached to a chamber with volume measurements presented in volume-oriented IS equipment. A piston in the chamber rises to the greatest amount of air displaced when the patient inhales.



Peak Expiratory Flow Rate: According to Reshmarani⁵⁵ the most popular lung function test is the peak expiratory flow rate (PEFR), which is simple, dependable, and reproducible. Hardon first stated that PEFR

can be used as a technique to assess lung function, namely ventilation, 1942.



Dhillon and Jain^{56,57} stated that the maximum flow rate at which air is compelled from the lungs, measured in L/min, is known as the PEFR. PEFR is regarded as acceptable and valid for determining airway blockage and the strength of the respiratory muscles. Height, age, sex, and body surface area are a few examples of variables that can change its

value. For males, the typical range is 450–550 L/min, and for females, 320–470 L/min.

Statistical Analysis

Two groups were taken with 15 subjects in each group. Group A received segmental breathing exercises whereas Group B received deep breathing exercises. With the help of an Incentive Spirometer and Peak Expiratory Flow Rate readings were measured. Both pre-operative and postoperative readings were taken from both devices.

The paired t-test and unpaired t-test were used to calculate the preoperative and postoperative values

RESULT

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Group	Group A	Group B
Male (%)	66.7	73.3
Female (%)	33.3	26.7
Male(f)	10	11
Female(f)	5	4





Table No: 2 Comparison of Age Between Groups A and B

Unpaired T Test	Comparison		
	Age		
	Group A	Group B	
Mean	58.53	57.13	
S.D.	7.230	9.486	
Number	15	15	
Mean Difference	1.40		
Unpaired T Test	0.455		
P value	0.6529		
Table Value at 0.05	2.05		
Result	Not-Significa	nt	

Table 2 denoted the comparison of age between groups A and B. The Mean + SD value of group A is 58.53+7.230 and the Mean + SD value of group B is 57.13+9.486. The P value is 0.6529, which is statistically not significant.



Figure No: 2 Diagram Showing Comparison of Age Between the Groups

Table No: 3 Comparison of Pre and Post Operative Incentive Spirometer Reading Within Group A

Paired T Test	Group A		
	Incentive spirometer reading (cc)		
Table No 3	Pre Operative	Post Operative	
Mean	1220.00	900.00	
S.D.	534.456	367.423	
Number	15	15	
Mean Difference	320.00		
Paired T Test	3.506		
P value	0.0035		
Table Value at 0.05	2.15		
Result	Significant		

Table 3 denoted the comparison of pre and post operative incentive spirometer reading among group A. The Mean + SD value of pre operative incentive spirometer reading of group A is 1220.00 + 534.456 and the Mean + SD value of post operative incentive spirometer reading of group A is 900.00 + 367.423. The P value is 0.0035, which is statistically significant

Figure No: 3 Diagram Showing Comparison of Pre and Post Operative Incentive Spirometer Reading Within Group A.



Paired T Test	Group B		
	Incentive spirometer reading (cc)		
Table No 4	Pre Operative	Post Operative	
Mean	1100.00	840.00	
S.D.	533.854	334.451	
Number	15	15	
Mean Difference	260.00		
Paired T Test	3.926		
P value	0.0015		
Table Value at 0.05	2.15		
Result	Significant		

Table No: 4 Comparison of Pre and Post Operative Incentive Spirometer Reading Within Group B

Table 4 denoted the comparison of pre and post operative incentive spirometer reading among group B. The Mean + SD value of pre operative incentive spirometer reading of group B is 1100.00 + 533.854 and the Mean + SD value of post operative incentive spirometer reading of group B is 840.00 + 334.451. The P value is 0.0015 which is statistically significant.

Figure No: 4 Diagram Showing Comparison of Pre and Post Operative Incentive Spirometer Reading Within Group B.



Table No: 5 Comparison of Pre and Post Operative Peak Expiratory Flow Rate Reading Within Group A

Parred T Test	Group A		
	PEFR (PEFR L/min EU scale)		
Table No 5	Pre Operative Post Operative		
Mean	507.80	498.40	
S.D.	86.210	86.296	
Number	15	15	
Mean Difference	9.40		
Paired T Test	14.723		
P value	0.0000		
Table Value at 0.05	2.15		
Result	Significant		

Table 5 denoted the comparison of pre and post operative peak expiratory flow rate reading among group A. The Mean + SD value of pre operative peak expiratory flow rate of group A is 507.80 + 86.210 and the Mean + SD value of post operative peak expiratory flow rate of group A is 498.40 + 86.296. The P value is 0.0000 which is statistically significant.



Figure No: 5 Diagram Showing Comparison of Pre and Post Operative Peak Expiratory Flow Rate Reading Within Group A

Table No: 6 Comparison of Pre and Post Operative Peak Expiratory Flow Rate Reading Within Group B.

Paired T Test	Group B		
	PEFR (PEFR L/min EU scale)		
Table No B	Pre Operative	Post Operative	
Mean	519.67	509.67	
S.D.	92.348	94.433	
Number	15	15	
Mean Difference	10.00		
Paired T Test	10.351		
P value	0.0000		
Table Value at 0.05	2.15		
Result	Significant		

Table 6 denoted the comparison of pre and post operative peak expiratory flow rate reading among group B. The Mean + SD value of pre operative peak expiratory flow rate of group B is 519.67 + 92.348 and the Mean + SD value of post operative peak expiratory flow rate of group B is 509.67 + 94.433. The P value is 0.0000 which is statistically significant.

Figure No: 6 Diagram Showing Comparison of Pre and Post Operative Peak Expiratory Flow Rate Reading Within Group B.



Unpaired T Test	Comparison				
	Incentive spirom	Incentive spirometer reading (cc)			
	Pre Operative	Pre Operative			
	Group A	Group B	Group A	Group B	
Mean	1220.00	1100.00	900.00	840.00	
S.D.	534.456	533.854	367.423	334.451	
Number	15	15	15	15	
Mean Difference	120.00		60.00		
Unpaired T Test	0.615		0.468		
P value	0.5434		0.6436		
Table Value at 0.05	2.05		2.05		
Result	Not-Significant		Not-Significant		

Table No: 7 Comparison of Pre and Post Operative Incentive Spirometer Reading Between the Groups A and B.

Table 7 denoted the comparison of pre and post operative incentive spirometer reading between groups A and B. The Mean + SD value of pre operative incentive spirometer reading of group A and B is 1220.00 + 534.456 and 1100.00 + 533.854 and the Mean + SD value of post operative incentive spirometer reading of group A and B is 900.00 + 367.423 and 840.00 + 334.451. The P value of pre operative reading for both the groups A and B is 0.5434 and P value of post operative reading for both the groups A and B is 0.6436 which is statistically not significant.

Figure No: 7 Diagram Showing Comparison of Pre and Post Operative Incentive Spirometer Reading Between the Groups A and B



Table No: 8 Comparison of Pre and Post Operative Peak Expiratory Flow Rate Reading Between the Groups A and B

Unpaired T Test	Comparison			
-	PEFR (PEFR L/min EU scale)			
	Pre Operative	Pre Operative		
	Group A	Group B	Group A	Group B
Mean	507.80	519.67	498.40	509.67
S.D.	86.210	92.348	86.296	94.433
Number	15	15	15	15
Mean Difference	-11.87		-11.27	
Unpaired T Test	0.364		0.341	
P value	0.7187		0.7356	
Table Value at 0.05	2.05		2.05	
Result	Not-Significant		Not-Significant	

Table 8 denoted the comparison of pre and post operative peak expiratory flow rate reading between groups A and B. The Mean + SD value of pre operative peak expiratory flow rate reading of group A and B is 507.80 + 86.210 and 519.67 + 92.348 and the Mean + SD value of post operative incentive spirometer reading of group A and

B is 498.40 + 86.296 and 509.67 + 94.433. The P value of pre operative reading for both the groups A and B is 0.7187 and P value of post operative reading for both the groups A and B is 0.7356 which is statistically not significant.

Figure No: 8 Diagram Showing Comparison of Pre and Post Operative Peak Expiratory Flow Rate Reading Between the Groups A and B



DISCUSSION

In the present study, we examined the comparison of effect of segmental breathing exercise and deep breathing exercise in CABG patient. From the results, we found that there is no significant difference in the effect of both exercises in CABG patients. Two groups were taken with 15 subjects in each group. Group A received segmental breathing exercise whereas group В received deep breathing exercise. With the help of Incentive Spirometer and Peak Expiratory Flow Rate readings were measured. Both pre operative and post operative readings were taken from both the devices.

The unpaired 't' test value for pre operative incentive spirometer readings of both the groups is 0.615 and for post operative incentive spirometer readings of both the groups is 0.468.

The unpaired 't' test value for pre operative PEFR of both the groups is 0.364 and for post operative PEFR of both the groups is 0.341.

In this present study there is no significant difference in both the techniques that is segmental breathing exercise and deep breathing exercise after CABG. This could be possible because of the biofeedback patient receives while performing incentive spirometer and PEFR. Apart from this we can also say that patient performing the techniques repetitively can also enhance their performance leading to better results.

Renault et al.⁴⁰ revealed the maximal respiratory pressure, spirometric variables, and oxygen saturation of patients who underwent post-CABG deep breathing exercises and incentive spirometry were not significantly different.

Jenkins et al.³⁵ stated that when incentive spirometer, deep breathing exercise, and control group (which only did early mobilisation, coughing/huffing) were examined, there was no difference between the groups in recovery of pulmonary function or incidence of pulmonary complication.

Urell et al.³⁸ recommended a higher rate of deep breathing exercises in phase 1 following cardiac surgery since it was shown that 30 deep breaths during the first postoperative days had a better effect than performing 10 deep breaths hourly. Additionally, they noted that because patients remain immobile during the first and second postoperative days, breathing exercises may be more crucial for recovery

from anaesthesia and surgery than they are later on.

Seved et al.⁴⁵ indicated that patients who receive scheduled breathing exercises following coronary artery bypass surgery have higher oxygenation. These treatments include deep breathing exercises, incentive spirometry, and directed cough manoeuvres. Light et al.⁵² indicated that pleural effusions can develop after CABG surgery due to the involvement of two variables in its pathophysiology. First, a bloody pleural effusion can result from trauma during surgery that causes blood to enter the pleural space. Second, a pleural effusion may develop as a result of immunologic disturbances brought on by the procedure. Additionally, they reported that 10% of patients who undergo CABG surgery will also experience pleural effusions that take up more than 25% of the hemithorax. The majority of effusions resulting from CABG surgery are left-sided or, in cases when they are bilateral, are greater on the left side.

Gunjal et al.⁵⁰ highlighted that in cases of pleural effusion, segmental breathing exercises are thought to have a greater impact on chest expansion and pulmonary function than deep breathing exercises. observed that participants who Thev engaged in deep breathing exercises saw improvements in lung expansion at the middle lower and lobes. whereas participants engaged in segmental breathing saw superior improvements across the board.

CONCLUSION

According to the study's findings, there is no discernible difference between the effects of deep breathing exercises and segmental breathing exercises on CABG patients.

Limitations

- 1. Sample size was small.
- 2. Randomisation was not done.
- 3. Limited outcome measures.

Declaration by Authors Ethical Approval: Approved

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