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The Comparison Between Blow Bottle Positive Expiratory Pressure (BBPEP) Device Versus Acapella on Oxygenation and Peak Expiratory Flow Rate (PEFR) Among Patients with Open Heart Surgery- A Comparative Study

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Dr. Abhaya Sanjay Mahadik

CONTENTS

ABBREVIATIONS

Sr. No.	Abbreviations	Full-Form
1	**2D Echo**	2-Dimensional Echocardiogram
2	**A.H.A.**	American Heart Association
3	**A.C.S.**	Acute Coronary Syndrome
4	**BBPEP Device**	Blow Bottle Positive Expiratory Pressure Device
5	**C.P.B.**	Cardiopulmonary Bypass
6	**C.P.T.**	Conventional Physiotherapy Treatment
7	**CVD**	Cardiovascular Diseases
8	**CAD**	Coronary Artery Disease
9	**CABG**	Coronary Artery Bypass Grafting
10	**COPD**	Chronic Obstructive Pulmonary Disease
11	**E.P.P.**	Equal Pressure Point
12	**EPAP**	Expiratory Positive Airway Pressure
13	**FiO2**	The Fraction of Inspired Oxygen
14	**F.V.C.**	Force Vital Capacity
15	**N.C.D.**	Noncommunicable Diseases
16	**NHLBIA**	National Heart, Lung and Blood Institute Association
17	**P.E.P.**	Positive Expiratory Pressure
18	**PEFR**	Peak Expiratory Flow Rate
19	**P.O.D.**	Postoperative Day
20	**PaCO2**	Partial Pressure of Carbon Dioxide
21	**PaO2**	Partial Pressure of Oxygen
22	**P.P.C.**	Postoperative Pulmonary Complications
23	**P.D.**	Postural Drainage
24	**PDPV**	Postural Drainage, Percussion and Vibration
25	**PSO2**	Skin Oxygen Partial Pressure
26	**SpO2**	Oxygen Saturation
27	**WHO**	World Health Organization

CHAPTER 1

INTRODUCTION

Worldwide people of all ages are affected by the Non-communicable Diseases (N.C.D.) and it is a leading cause of death globally. The cardiovascular disease, cancer, chronic respiratory diseases or diabetes are the main non-communicable diseases.[1] According to the World Health Organization (WHO), 41 million people die due to NCD which is equal to 71% of all death globally in which Cardiovascular Diseases (CVD) are the most common cause for death which account for 17.9 million deaths per year.[2] In India, the burden of non-communicable diseases is becoming a more serious situation. N.C.D. is mainly present at age 55 years or older in many developing countries while, in India onset is a decade earlier (>45years). In India, the Global Burden Diseases Collaborators found that CVD's are the largest burden of total mortality in India. The International Institute of Population Sciences stated that the total mortality of 2016 has a 28.1% contribution from CVD.[3] They also stated that from 1990 to 2016, the contribution rate of mortality of CVD's is increased by 34.3% in India. The more common leading cause of cardiovascular diseases is Coronary Artery Disease (CAD) and Stroke. WHO sated that in 2017, CAD is the leading cause of death and which account to 15.6%.[2,3,4] In recent days WHO published Progress Monitor 2020 of NCD. In which data included till 2019 and stated each country profile contents population, percentage and number of deaths due to NCD. According to this, India has 1,34,00,00 of total population in which 63% of deaths occurred due to NCD i.e. 5,995,000 in figure while 23% were premature NCD.[5] Relating to current COVID 19 pandemic NCD's are more responsible for morbidity and mortality of COVID 19. In which CVD's like hypertension and ischaemic heart diseases accounts more, 69.2% and 31.8% respectively.[6] Hence based on projection of WHO, if proper prevention strategies not prepared or applied till 2025 41 million people will die due to N.C.D. and in which more causative disease will be CVD with increased susceptibility for COVID 19.[1,6]

1.1: Coronary Artery Disease (CAD)

The main reason for CAD is Atherosclerosis of coronary arteries. CAD leads to an obstruction or reduction of blood flow to the heart. The plaques cause the obstruction in the artery and which leads to the narrowin g of the coronary artery. Depending on the degree of stenosis or narrowing, patients may experience angina, which may be symptomatic or remain asymptomatic until a plaque ruptures and thrombosis results in

Acute Coronary Syndrome (A.C.S.). Also, in later stage this ACS leads to "Myocardial Infraction" commonly term as "Heart Attack". In this, there is death of heart muscles which is supplied by concern blocked artery. [7]

There are many risk factors of CAD and they broadly divided into two types: modifiable and non-modifiable; [8]

1. Non-modifiable risk factors - Age, Gender, Ethnicity and Genetic disposition. [8]
2. Modifiable risk factors - Hyperlipidaemia, Hypertension, Diabetes, Smoking, Poor diet and Nutrition, Physical inactivity.[8]

1.1.1: Treatment for CAD

To treat these critical conditions of coronary artery disease patients should undergo cardiac surgery which is known as Coronary Artery Bypass Surgery (CABG), is a procedure to improve blood flow to heart. It is a type of Open-Heart Surgery. According to the National Heart, Lung and Blood Institute Association (NHLBI), open-heart surgery is a surgery in which anterior midline incision is taken to access the heart. It includes CABG, Valve Replacement Surgery and Surgery for Arterial Fibrillation. In the early 20th century, Alexis Carrel introduced CABG when he experimented first time on dogs where he performed carotid anastomosis with left coronary artery.[7,9,10] Every year, one million CABG are performed worldwide and according to the NHLBI, CABG is the most common type of open-heart surgery done on adults.[9] CABG is mainly done to improve blood supply to the heart in which a section of a blood vessel is grafted from the aorta to the coronary artery to bypass the blocked section of the coronary artery.[11] CABG is extremely effective in relieving symptoms of ischemic heart disease, improve left ventricular function and myocardial infraction since 1968.[12] As different literature has shown CABG is the most superior method of treatment for CAD mainly in high-risk patients and while comparing it with medical therapy, i.e. drugs like Beta-blockers, nitrates CABG has shown to increase survival in high-risk patients.[13] Yusuf et al. reported that patients who underwent CABG had significantly lower mortality than those who reported for medical treatment after five years.[14]

There are two types of approaches for the open-heart surgery either on-pump, also known as Cardio-Pulmonary Bypass (C.P.B.) or off-pump.[13] Literature reported that patients who undergo C.P.B. having more pulmonary complications than off-pump surgery. Studies also reported that C.P.B. approach patients have poor gas exchange and delays extubation according to arterial blood analysis criteria. In contrast, off-pump surgery patients show early extubation and more gas exchange after open-heart surgery.[15,16] Due to CPB there

is alteration inflammatory response because reduce perfusion and ventilation to lungs with major change in structure and function of respiratory function.[16]

1.2: Heart Valve Diseases

There are four valves in the human heart, which are Tricuspid, Pulmonary, Mitral and Aortic Valve. There is an occurrence of heart valve diseases when the valve is not functioning properly.[17] The main function of valves is to promote circulation through heart, pulmonary and systemic circulation. When there is any pathology in valve functioning, it leads to stenosis or regurgitation. When there is stenosis, it blocks the blood flow while regurgitation of valves allows blood to flow back across the closed valve into the previous chamber.[17]

1.2.1: Aortic Valve Disease & Medical Management

Aortic stenosis is mainly caused by calcification or degeneration of aortic valve which leads to narrowing of blood flow.[17] It mainly consists of uni-cuspid and bicuspid in which bicuspid is common while uni-cuspid shows symptoms in infancy.[17,18] According to the American Heart Association (A.H.A.), the aortic stenosis or the regurgitation needs aortic valve replacement or Transcatheter Aortic Valve Replacement (TAVR) and it is also a type of open-heart surgery.[19]

1.2.2: Mitral Valve Disease & Medical Management

Mitral regurgitation is the second most frequent indication for valve surgery.[17] Rheumatic heart disease is the most serious cause of rheumatic fever which leads to mitral valve regurgitation. There is papillary muscle rupture due to coronary artery disease in later stages of life, which causes the mitral regurgitation.[19] When disease progress, it shows symptoms. Dyspnoea is seen after pulmonary congestion and in later stage exercise intolerance and early fatigue leads to low cardiac output and cardiac arrhythmias.[17] A.H.A. suggests prosthetic valve replacement intervention for managing the primary and secondary mitral valve defect.[19]

1.2.3: Tricuspid Valve Disease & Medical Management

Tricuspid valve disease is most common among valvular diseases. It affects 65 to 80% of the population. The tricuspid valve defect some time gets missed because the symptoms which develop are not predictable. In the last stage of the disease, patients develop ventricular dysfunction.[20] The tricuspid stenosis also causes progressive degrees of right atrial hypertension. Right heart failure was seen in the advanced

tricuspid valve dysfunction and it shows hepatic enlargement, ascites, oedema, and low output syndrome. Tricuspid dysfunction should be treated by the Tricuspid Annuloplasty.[21]

1.3: Complications of Open-Heart Surgery

The postoperative phase of cardiac surgery is always associated with a high risk for pulmonary complications. Postoperative complications lead to several pulmonary abnormalities such as pneumonia, changes in chest radiograph, etc. There is an increase in the duration of hospital stay as postoperative pulmonary complications affect the recovery of patient condition.[22]

The initial postoperative phase after open-heart surgery is the most vulnerable period as there is a decrease in pulmonary function and which persists for several months after surgery hence patient needs close monitoring even if there are no symptoms.[23,24] The open-heart surgery is performed with either on-pump or off-pump. The patients who undergo open-heart surgery with C.P.B. has more risk of developing postoperative pulmonary complications.[15]

Faker Ali Ahmed, et al. found an increased incidence of pulmonary complications after open-heart surgery in early postoperative days and it was 15.08% with an overall mortality 18.5%. Patients who undergo CABG develop pulmonary complications (7.82%) while the valvular replacement is of 2.23% and 5.05% is of congenital heart diseases out of 18.5% of mortality rate.[25]

1.3.1: Effect of Anaesthesia

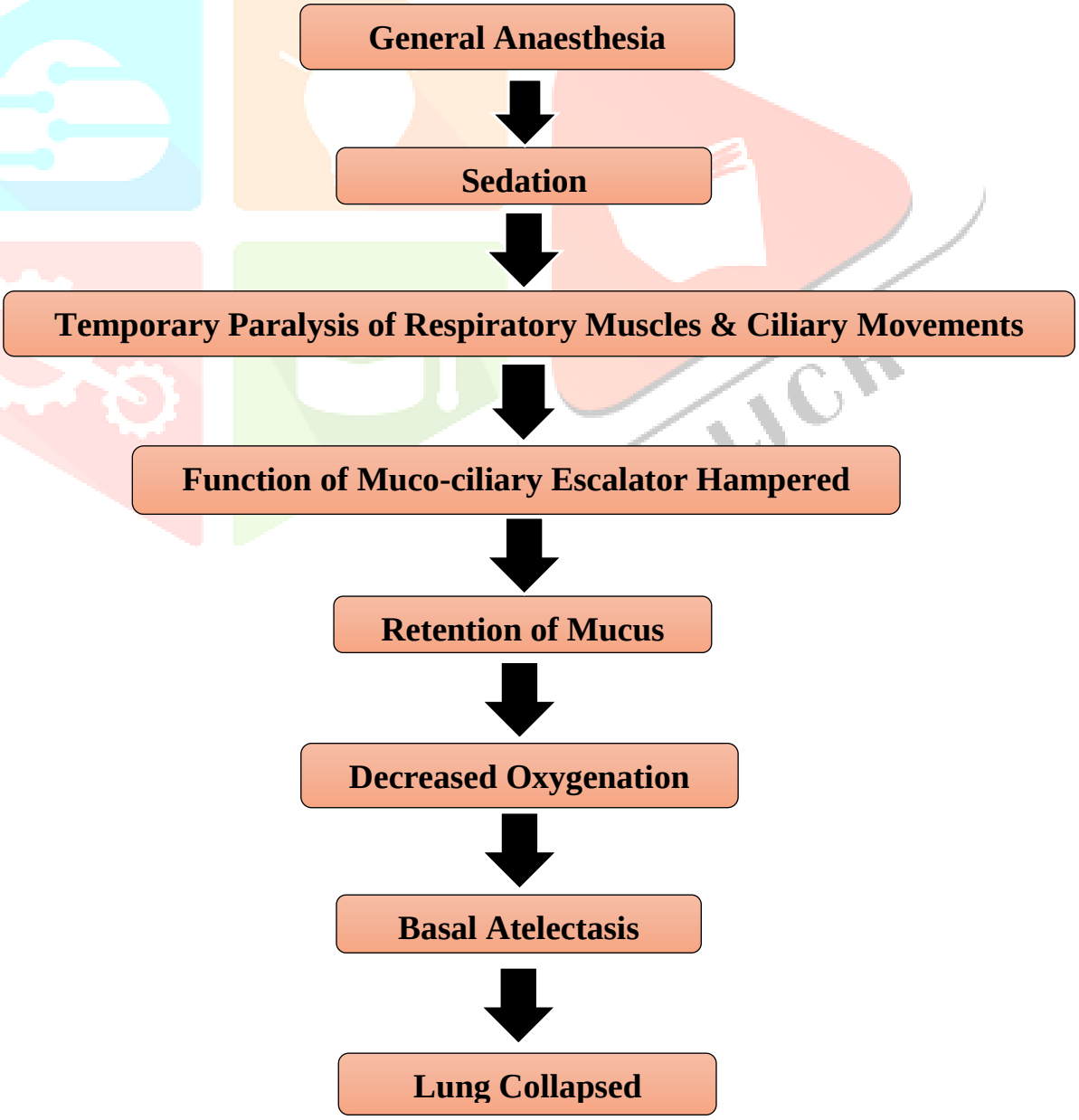
Ventilation and Gas exchange are the main functions of the Respiratory system. This function gets affected when patients undergo open heart or abdominal surgery due to effect of anesthesia and mainly they show pneumonia, atelectasis and impaired gas exchange[26,27] Respiratory system composes of airways, lungs, chest wall, intercostal muscles, diaphragm and neural pathways. As patients undergo invasive cardiac surgery, functions of all the components get altered and pulmonary complications are seen with changes chest radiograph.[28] Due to cardiopulmonary bypass and anaesthesia patients shows a reduction in oxygenation and lung volumes, which lead to **Atelectasis.**[15,16] Therefore, due to several factors the patient requires frequent attention.[29]

Patients who undergo open-heart surgery receive general anaesthesia, with or without the use of neuromuscular blocking agents. These anaesthetic agents cause loss of airway patency which results in loss of ability to manage secretions and loss of cough reflex[30] These patients also develop postoperative complications like pneumonia, acute respiratory distress syndrome (ARDS).[22] There is an obstruction to

oropharynx due to the **accumulation of mucus and saliva**.[30] Obstruction leads to the defect in oxygenation, which causes infection and also shows changes in the chest radiograph. Chest radiograph shows an increase in density, the elevation of the diaphragm, mediastinal displacement and compensatory over-inflation. All these findings are indicative of postoperative pulmonary complications leading to atelectasis.[22,28]

After the open-heart surgery, there is not only airway obstruction which causes defects in ventilation but also defects in gas exchange which causes an alteration in perfusion. The open-heart surgery patient receives general anaesthesia. The anaesthetic drug agents except ketamine and nitrous oxide cause a reduction in minute ventilation which depend upon the dose of a drug. There is a decrease in respiratory rate, tidal volume, or both this reduces in minute ventilation. So, there is a reduction in alveolar ventilation which increases PaCO2 leads to **ventilation/perfusion mismatch**.[27,30]

Flow Chart Explaining Effect of Anaesthesia on Pulmonary Function:[27,30]



1.4: Conventional Physiotherapy Treatment of Open-heart Surgery

In recent days, the cardiac rehabilitation program after open-heart surgery is an essential part of the recovery phase as patients develop postoperative pulmonary complications and these complications increase hospital stay and also increase the mortality and morbidity. These complications delay patient to return their work, especially for those with physically demanding jobs, and the financial consequences can be significant.[31,32]

Cardiac Rehabilitation is a comprehensive exercise, education and behavioural modification program design to improve the physical and emotional condition of patients with heart disease[33] and it is an integral part of modern cardiology treatment [34] or Coordinated, multifaceted interventions designed to optimize a cardiac patient's physical, psychological, and social functioning so that they may, by their own efforts, resume and maintain as normal a place as possible in the community.[35] Taylor RS et al. does an interventional review and they stated that exercise-based cardiac rehabilitation is effective in reducing cardiac deaths and also there is a significant improvement in the exercise tolerance which will help to improve quality of life after surgery and reduce primary complications.[36]

The main goal of cardiac rehabilitation is to improve the deteriorating effect of bed rest, drugs, anaesthesia after the open-heart surgery.[37] The cardiac rehabilitation includes four phases, i.e. inpatient phase (Phase 1), out-patient phase (phases 2, 3 and 4). Phase 1 cardiac rehabilitation should be started in-hospital stay immediately after surgery. The Phase 1 cardiac rehabilitation includes early mobilization, positioning, deep breathing exercises, active cycle of breathing technique, effective splinted coughing or huffing techniques, incentive spirometry to prevent and improve the postoperative pulmonary complications.[38,39] The main aim of early mobilization is to improve oxygenation. Early mobilization includes an active range of motion, thoracic mobility, bedside sitting, chair sitting, hall ambulation. With all these techniques, there are mechanical devices available to improve oxygenation they known as positive pressure devices such as Acapella, Flutter, Bubble-PEP, RC-Cornet. [40,41,42,43,44]

1.5: Positive-Expiratory-Pressure (P.E.P.) Therapy

Positive-expiratory-pressure (P.E.P.) therapy is a chest respiratory therapy that offers resistance to expiration and produces positive airway pressure.[45] P.E.P. Therapy was introduced in the 1970s in the United States. It used as an adjunct to conventional physiotherapy. It used to improve oxygenation, increase lung volume.[45] P.E.P. Therapy is mainly including breathing against an expiratory resistance and it suggested

in patients who undergo surgery or in pulmonary diseases.[45] When the patient exhales against expiratory resistance, it generates positive expiratory pressure and gives physiological benefit to the respiratory system by improving collateral ventilation.[45,46] Main physiological effects of PEP therapy are,

1. It improves collateral ventilation, [47,48,49]
2. Secretion clearance, [47,48,49,50,51]
3. Aerosol distribution [45,52,53] and
4. It improves functional residual capacity as these components affected in post-operative cardiac surgery condition. P.E.P. therapy is a non-invasive technique used in postoperative cardiac surgery to improve clinical outcomes. [45,50,54,55]

The physiological effects of P.E.P. therapy is based mainly on the equal-pressure-point theory. The equal-pressure point is where the intra-luminal and extra-luminal pressures equalize across the airway. Proximal to the equal-pressure point (i.e. toward the mouth), the external pressure around the airway is greater than the pressure within it, and the airway is compressed, which limits the flow.[56] P.E.P. prevents small airways from collapsing, promotes better or even gas distribution by opening the collapsed alveoli, and increases the expiratory time and volume. [44,57,58]

P.E.P. Therapy having three common indications which are

1) Increase lung volume,

2) Reduce hyperinflation and

3) Improve airway clearance. [46,47,58]

Hyperinflation is mainly due to the air-trapping initiated by airway obstruction. The airway obstruction may be due to muscle spasm, mucosal inflammation, hypersecretion, unstable airways, or reduced lung elastic recoil.[46] When this hyperinflation remains untreated, it leads to alteration in gas exchange, decreased ventilation and increased work of breathing.[45] When P.E.P. Therapy is administered in such patients, it increases expiratory time with a decrease in airway pressure and reduces airway collapse.[50,56,57,58] With PEP, E.P.P. shifts more centrally with stabilizing airways and decreases the risk of airway collapse.[45]

P.E.P. Therapy is administered by using devices which are known as P.E.P. devices. Several devices are used for P.E.P. Therapy. It includes Acapella, Flutter, TheraPEP, RC Cornet, etc. Acapella and Flutter are commonly used in clinical practice.[59]

1.6: Acapella-

DHD Healthcare, New York developed the Acapella.[60] It is an oscillatory P.E.P. device. Acapella has two physiological effects, 1. P.E.P. Effect and 2. Vibratory Effect. P.E.P. effect improves collateral ventilation by recruiting the alveoli while vibrating effect dislodges thick, sticky secretions from the airway walls. Hence, there is improvement in oxygenation and Pulmonary Function.[60,61,62] Airway oscillation may also decrease mucous viscoelasticity.[63]

Acapella is of two types, 1) "Acapella D.M." which is Blue in colour and 2) "Acapella D.H." which is Green in colour. Blue Acapella is used in patients who maintain expiratory flow above 15 L/min for less than 3 seconds while Green Acapella used in patients who maintain expiratory flow above or equal to 15 L/min for at least 3 seconds.[60,62,63] Acapella use for chest physiotherapy and it generates 10 to 20 cmH2O P.E.P. Acapella results in a significant increase in the mean values of sputum amount, a significant decrease in sputum viscosity, improved radiological signs of atelectasis, shorter duration of ventilator support, and fewer I.C.U. stay. Hence, acapella is a good representative to all conventional multimodality chest physiotherapy procedures with high success rate and can replace the exhausting, costly, and time-consuming conventional procedures in preventing pulmonary complications[64,65] and is a well-proven technique which is used to prevent pulmonary complications in postoperative open-heart surgery patient.

1.7: Blow Bottle P.E.P. Device (BBPEP)-

Several types of P.E.P. devices are available. Many P.E.P. devices produce expiratory resistance bypassing the exhaled flow through a fixed orifice. The pressure generated increases with the expiratory flow. The devices like Acapella and Flutter also works on the same principle, but these commercial devices such as Acapella ($52) and Flutter ($69) are relatively more expensive.[66]

Zaman BA et al. proved that blow bottle P.E.P. device is more effective than Incentive Spirometer with EPAP in preventing postoperative complications following CABG surgery. Also said that deep breathing exercise with a P.E.P. device is more effective in improving SpO2 and PEFR in case of CABG patients.[40] Also**,** a study conducted by Annemarie L Lee documented the effects of P.E.P. therapy on COPD, cystic fibrosis and bronchiectasis. In these, P.E.P. therapy helps in facilitating the removal of secretions and thus improving ventilation.[67] Humaria et.al. used PEP Therapy in pleural disease patients and they found significant effect on respiratory parameters and intercostal drain. Hence Blow Bottle P.E.P. is a technique which is used to prevent pulmonary complications in postoperative open-heart surgery patient.[68]

CHAPTER 2

Need for the study

Acapella work on the mechanism of P.E.P. therapy which based on EPP. PEP is useful in improving pulmonary function and preventing pulmonary complications, but issue is Acapella cost around 3000 INR ($52). As per latest Ministry of Labour and Employment report average daily wage worker in rural area earns less than 500 INR ($6) per day.[69]

Hence Acapella is not affordable to all rural population. With this thought therapist redesign PEP device based on Blow Bottle PEP concept. This device is

1. Affordable to rural India,

2. It is user friendly,

3. Device is single user and easy to carry,

4. Easily discarded.

Therefore, my study was to find out the effect of BBPEP Device in compare to Acapella in the improvement of Oxygenation and PEFR values among patient with open-heart surgery.

CHAPTER 3

AIM & OBJECTIVES

3.1: Aim

To compare the effect of BBPEP Device and Acapella on Oxygenation and PEFR among patients with open-heart surgery.

3.2: Objectives

1. To compare the effect of BBPEP Device and Acapella on FiO2 and SpO2 among patients with open-heart surgery.
2. To compare the effect of BBPEP Device and Acapella on PEFR among patients with open-heart surgery.

CHAPTER 4

RESEARCH QUESTION

Is BBPEP is as effective as Acapella in improving oxygenation and values of PEFR among the patient with open heart surgery?

HYPOTHESIS

4.1: Null Hypothesis: The BBPEP Device will not show any improvement in Oxygenation and PEFR among patients with open-heart surgery patient.

4.2: Alternate Hypothesis: BBPEP Device will show similar or better changes in any improvement in Oxygenation and PEFR among patients with open-heart surgery patient.

CHAPTER 5

REVIEW OF LITERATURE

5.1: **Melkamu Kassa et. al. (2019)** published a chapter, "The Global Burden and Perspectives on Noncommunicable Diseases (NCDs) and the Prevention, Data Availability and Systems Approach of NCDs in Low-resource Countries". In this they gave information of increasing burden of NCD's on low resourced countries and high resourced countries. They included 84 studies from January 2011 to 2019 according to inclusion criteria which sourced from research engines like EBSCOhost, Science Citation Index, CINAHL database, PsycINFO, Cochrane Database of Systematic Reviews, published and unpublished abstracts and a hand search of reference lists and table of contents of relevant journals and books. They said that, there is 38 million deaths due to NCD's every year in which some are premature and preventable. With this growing according to WHO in 2025 NCD's will account 70% of deaths globally in which 85% in developing countries. In low resourced countries 70% of mortality is due to cardiovascular diseases i.e. coronary artery diseases while in high resourced countries it is 38%.[1]

5.2: Perianayagam Arokiasamy (2018) from the dept. Of Developmental Studies, International Institute for Population Sciences, Mumbai, India, published an article in 2018 on "India's escalating burden of noncommunicable diseases. He said that in mainly N.C.D.'s burden present in an individual with 55 years or older, but in India, the onset is a decade earlier, i.e. ≥45 years. This is becoming worse because of multiple chronic conditions which remain undiagnosed due to lack of awareness and insufficient health-care facilities. The India State-Level Disease Burden Initiative Collaborators produces an analysis of state variations in epidemiological transition levels from 1990-2016. They stated that between all N.C.D.'s cardiovascular diseases, i.e. ischemic heart disease and stroke has the largest burden of mortality in India in 2016, which is 28.1%. They also said that from 1990 to 2016, the mortality increased by 34.3% because of cardiovascular diseases. [3]

5.3: Faker Ali Ahmed Al-Qubati et. al. **(2013)** conducted study in the cardiac center, Thowra Hospital, Sana'a from Jan 2004 to Dec 2009 on "Incidence and outcome of pulmonary complications after open cardiac surgery". He did this study to find out rate of pulmonary complications after open-heart surgery and predisposing factors to these complications. 179 patients were included in the study and divided into following

3 groups, 1. Coronary artery grafting surgery - 88 patients included 72 males and 16 females. 2. Valve replacement surgery - 53 patients include 36 males and 17 females. 3. Congenital heart Disease - 38 patients include 22 males and 16 females. He found that 15.08% patients developed pulmonary complications in early post-operative period after open heart surgery with 18.5% of mortality rate. He also stated that 3.37% patients suffered from ARDS, 2.79% from Pneumonia, 1.11% from Atelectasis, 2.22% from Pleural Effusion and 0.55% from Pneumothorax.[25]

5.4: Humaria Ansari et al. (2017) studied on "Positive Expiratory Pressure (P.E.P.) Therapy in Patients with Diseases of the Pleura". They assess the effect of Positive Expiratory Pressure (P.E.P.) therapy in patients with an intercostal drainage tube. These patients grouped into two groups which were Intervention and Conventional Group. This study conducted on patients who had an intercostal drain and drain insertion being respiratory with pleural involvement. BBPEP intervention administered twice a day for five continuous days with C.P.T. for the Intervention group. The conventional group received C.P.T. which included diaphragmatic breathing, thoracic expansion exercises and pursed-lip breathing- 10 repetitions, three sets each day. The outcome measured was SpO2, Respiratory Rate, Chest Expansion and Dyspnoea which taken pre and post-treatment. Authors found that BBPEP therapy additional to the C.P.T. were more effective than only C.P.T. on respiratory parameters with intercostal drain.[68]

5.5: Zorana Mrsic et al. in 2017 published article on "Valvular Heart Disease" gives an outline of diagnosis and management of commonly occurring valvular heart diseases of four human heart valve. In this article key concepts included,

1. The valvular diseases are either congenital or acquired and is also present in either primary or secondary fashion,
2. The treatment program is mainly present on their appearance,
3. The valvular diseases present with pathological murmurs and which important for primary care,
4. To diagnose and to know the grading of severity of the valvular diseases the Echocardiogram (2D Echo) is an important test,
5. This 2D Echo is used by every cardiologist,
6. Chest imaging is also important and is mainly based on the severity of valvular dysfunction,

7. In the valvular diseases' surgery is indicated only when symptoms are seen or there are sever changes in left ventricular function,

8. The surgical procedure takes place only when cardiologist and cardiac surgeons agree.[17]

5.6: Nesma M. Allam et al. (2016) done study on "Effect of Combination of Acapella Device and Breathing Exercises on Treatment of Pulmonary Complications After Upper Abdominal Surgeries". This was done on 60 abdominal surgery patients. Patients divided randomly into two groups, Group A (Study Group) and Group B (Control Group). The study group received traditional physiotherapy treatment plus acapella, while the control group received traditional physiotherapy treatment. Both the group received treatment for three sessions in a week for four weeks and F.V.C. and FEV1 were taken pre and post every session. The author concluded that to treat postoperative pulmonary complications and removal of secretions combination of Acapella and Breathing Exercises were effective.[64]

5.7: Begum A et al. (2016) done study on "Comparative Study on The Immediate Effects of Deep Breathing Exercises with P.E.P. Device Versus Incentive Spirometry with EPAP On Preventing Pulmonary Complications Following CABG" who found the immediate effect of Deep Breathing Exercises with P.E.P. devices and Incentive Spirometry on preventing pulmonary complications following CABG. A study conducted on 30 subjects undergoing CABG who randomly divided into Group A & Group B; Group A received Deep Breathing with P.E.P. while Group B received Incentive Spirometer with EPAP. The author concluded that the P.E.P. device is more effective than Incentive Spirometer with EPAP in preventing postoperative complications after CABG.[40]

5.8: Dr Rachel Davison, Frca Dr Daniel Cottle, Frca North West (2010) did a study on "The effects of Anesthesia on respiratory function." In this, they said the multiple effects that general anaesthesia has on the respiratory system is essential if gas exchange and ventilation are to be maintained. The loss of a patent airway, hypoventilation and apnea cause hypercapnia, which has many undesirable effects. Anaesthetists must anticipate and prepare for these effects. A patent airway and ventilation must be maintained. Gas exchange is impaired by airway obstruction, V/Q mismatch, shunt and the reversal of HPV, any of which results in hypoxia. The anaesthetist must strive to maximize the F.R.C. and its oxygen content. Mechanical ventilation may be required, which can be improved with recruitment, PEEP and lung protective strategies. However, remember that mechanical ventilation can cause damage to the lung tissue. These problems extend into the

postoperative period. Patients must have adequate postoperative analgesia, and some may require supplemental oxygen.[27]

5.9: Regis Germerasca Mestriner et al. (2009) study done on "Optimum Design Parameters for a Therapist-Constructed Positive-Expiratory-Pressure Therapy Bottle Device" and found appropriate tubing Diameter and Length and Diameter of P.E.P. Bottle and their effect. The author did two experiments by using two bottle models which were composed of water partially filled, a compressed air source, a pneumotachometer and a manometer, tubing inner diameter range from 2-25mm and length 20-80cm long. In both experiments, the distal tip of the P.E.P. bottle tube was 10 cm below the surface of the water and 3 cm above the floor of the bottle. The author found the ≥ 8mm inner diameter did not increase the P.E.P. pressure above the 10 cm H2O water column pressure at any length or flow. The inner diameter of the tube must be ≥8 mm to achieve P.E.P. threshold-resistor.[66]

5.10: Hristara et al. in (2008) did review on "Current devices of respiratory physiotherapy" by to determine the effectiveness of those devices. Devices included were 1. High-Frequency Chest Wall Oscillation (HFCWO) device, 2. Oral High-Frequency Oscillation (OHFO) device, 3. Intrapulmonary Percussive Ventilation (IPV) device, 4. Incentive Spirometry (I.S.) device, 5. Flutter Device, 6. Acapella Device, 7. Cornet Device. According to research studies, P.E.P. devices designed to improve the patient's independence and compliance. These devices are effective in enhancing pulmonary function, lung oxygenation, clearing mucus from bronchi to prevent and decrease pulmonary complications. Also, these devices are easy to use and cost-effective.[59]

5.11: McCool FD, Rosen MJ. (2006) Studied on, "Non-pharmacologic airway clearance therapies: ACCP evidence-based clinical practice guidelines." In this, they found airway clearance may be impaired in disorders associated with abnormal cough mechanics, altered mucus rheology, altered mucociliary clearance, or structural airway defects. A variety of interventions are used to enhance airway clearance with the goal of improving lung mechanics and gas exchange and preventing atelectasis and infection. So formal systematic review of non-pharmacologic protrusive therapies was performed and constituted the basis for this section of the guideline. The MEDLINE database was searched for this review and consisted of studies published in the English language between 1960 and April 2004. The search terms used were "chest physiotherapy," "forced expiratory technique," "positive expiratory pressure," "high-frequency chest compression," "insufflation," and

"exsufflation." In general, studies of non-pharmacologic methods of improving cough clearance are limited by methodological constraints, and most were conducted only in patients with cystic fibrosis. Chest physiotherapy, including postural drainage, chest wall percussion and vibration, and a forced expiration technique (called huffing), increase airway clearance as assessed by sputum characteristics (i.e., volume, weight, and viscosity) and clearance of the radio aerosol from the lung, but the long-term efficacy of these techniques compared with unassisted cough alone is unknown. Other devices that allow patients to achieve the same benefits derived from chest physiotherapy without the assistance of a caregiver appear to be as effective as chest physiotherapy in increasing sputum production. And concluded that some non-pharmacologic therapies are effective in increasing sputum production, but their long-term efficacy in improving outcomes compared with unassisted cough alone is unknown.[47]

5.12: Darbee JC, Ohtake PJ, Grant BJ, Cerny FJ. (2005) Studied "Physiologic evidence for the efficacy of Positive Expiratory Pressure as an airway clearance technique in patients with cystic fibrosis." in this, individuals with cystic fibrosis (C.F.) have large amounts of infected mucus in their lungs, which causes irreversible lung tissue damage. Although patient-administered positive expiratory pressure (P.E.P.) breathing has been promoted as an effective therapeutic modality for removing mucus and improving ventilation distribution in these patients, the effects of P.E.P. on ventilation distribution and gas mixing have not been documented. Therefore, this preliminary investigation described responses in the distribution of ventilation and gas mixing to P.E.P. breathing for patients with moderate to severe C.F. lung disease. This study demonstrated the physiologic basis for the efficacy of P.E.P. therapy. The results confirm that low P.E.P. and high P.E.P. improve gas mixing in individuals with C.F., and these improvements were associated with increased lung function, sputum expectoration, and SpO2. The authors propose that improvements in gas mixing may lead to increases in oxygenation and thus functional exercise capacity.[50]

5.13: Pasquina P, Tramer MR Walder B. studied, (2003) "Prophylactic respiratory Physiotherapy after Cardiac Surgery: Systematic review" in this evidence is lacking as to whether prophylactic respiratory physiotherapy prevents pulmonary complications after cardiac surgery. Two published systematic reviews examined the relation between respiratory physiotherapy and outcome after different operations, but they obtained conflicting results. One found benefits from incentive spirometer and deep breathing exercises after upper abdominal surgery, but pooled data came from different endpoints such as atelectasis and pulmonary

infiltrates or consolidation. The other review found incentive spirometer to be of no benefit after cardiac and upper abdominal surgery.[39]

5.14: Fink JB. (2002) Studied on Positive Airway Pressure (P.A.P.) has been used since the 1930s to improve oxygenation, increase lung volumes and reduce venous return. More recently, P.A.P. has been identified as an effective method of splinting airway during expiration, improving collateral ventilation, increasing response to inhaled bronchodilators, and aiding secretion clearance in patients with cystic fibrosis and chronic bronchitis. A range of devices, administration techniques, and evidence supporting their clinical use is explored, suggesting that P.A.P. is equivalent to postural drainage in the clearance of secretions. P.A.P. produced by threshold and fixed orifice resistors generate different characteristic flow, and airway and esophageal pressure patterns that may contribute to different physiologic effects. They give future scope that the studies are required to better understand the effects of these differences.[44]

5.15: Monika Fagevik Olse´n (2014) conducted a review on "Physiological effects and clinical applications of Positive expiratory pressure therapy". This article describes clinical application and underlying physiology of PEP. This article described main physiological effects i.e. Increase lung volume, decrease hyperinflation, Improve airway clearance. It increases lung volume as patient exhale against expiratory resistance which augment inspiration and improve lung volume. Reduce in hyperinflation as there is increase expiratory time which results in more emptying of lung. PEP helps in airway clearance as it improves collateral ventilation which helps to mobilize the secretions.[45]

5.16: Tenling A, Hachenberg T, Tyden H, Wegenius G, Hedenstierna G (1998) conducted a study on "Atelectasis and gas exchange after cardiac surgery. They conducted a study on 18 patients who were undergone for mitral valve surgery. They conclude that large atelectasis at the dorsal part of the lungs was found in the first postoperative day of cardiac surgery.

5.17: Mohamed Y. Rady; Thomas Ryan; Norman J. Starr, (1997) conducted a study on "Early onset of acute pulmonary dysfunction after cardiovascular surgery: risk factors and clinical outcome." Total 1,461 patients were included in the study. In this study, they assessed patients for PaO2/FiO2 ratio and chest radiograph on the day of admission of cardiovascular I.C.U. Then they assessed postoperatively for renal, neurologic dysfunction nosocomial infections length of mechanical ventilation and hospitalization. They

concluded that the incidence of early postoperative pulmonary dysfunction is uncommon; however, once developed, it is associated with increased morbidity and mortality after cardiovascular surgery'. Advanced age, large body mass index, preoperative increased pulmonary arterial pressure, low stroke volume index, hypo-albuminuria, history of cerebral vascular disease, emergency surgery, and prolonged cardiopulmonary bypass time are risk factors for early onset of severe pulmonary dysfunction after surgery.

5.18: Vargas FS, Terra-Filho M conducted a study, (1997) "Pulmonary Function (P.F.) after coronary artery bypasses surgery in this, they said that after CABG adversely affects pulmonary function test. Purpose of the study was to assess the serial changes in the F.V.C. following CABG and identify factors that may influence these changes. They took 120 patients from postoperative day 1 to 10 in that 51 of received saphenous vein grafts (S.V.F.) and 69 received one internal mammary graft (I.M.G.), and they did PFT on POD1 and POD2 and compare values with preoperative values of F.V.C. And by that they concluded that there is marked decrease in F.V.C. F.V.C. immediately reduce after CABG and improves gradually. However, on the 10 P.O.D., the F.V.C. still remains more than 30% below preoperative values. These changes in F.V.C. not dependent on intra-operative variables. There is a slightly greater decrease in the F.V.C. after I.M.A. grafting than SVG. Therefore, there is only a slight tendency for patients undergoing I.M.A. grafting to have larger decreases in their pulmonary function.[24]

5.19: **Hardy KA. (1994),** A review of airway clearance: new techniques, indications, and recommendations in that, airway clearance techniques are indicated for specific diseases that have known clearance abnormalities. Murray and others have commented that such techniques are required only for patients with a daily sputum production of ≥ 30 mL. I have observed that patients with diseases known to cause clearance abnormalities can have sputum clearance with some techniques such as P.E.P., A.D., and A.C.B. when PDPV has not been effective. Therefore, it is reasonable to consider airway clearance techniques for any patient who has a disease known to alter mucus clearance-including cystic fibrosis, dyskinetic cilia syndromes, and bronchiectasis from any cause. Normalizing the vital capacity and functional residual capacity typically helps to improve the ability to cough and clear secretions. Assisted cough devices or maneuvers are described in other papers from this conference by Bach and Hill. Not all patients who have weak muscles require a nocturnal or continuous support and may benefit from P.E.P. mask treatments. Further studies are sorely needed.[58]

5.20: Lannefors L, Wollmer P. (1992) studied on "Mucus clearance with three chest physiotherapy regimes in cystic fibrosis: a comparison between postural drainage, P.E.P. and physical exercise." In this study effects of three different regimes of the chest physiotherapy was compared in this cross-over study. Mucus clearance was monitored in nine clinically stable cystic fibrosis (C.F.) patients. The patients performed: 1) postural drainage with thoracic expansion exercises + forced expiration technique (F.E.T.) in the left decubitus position; 2) positive expiratory pressure (P.E.P.)-mask breathing + F.E.T., and 3) physical exercise on a bicycle ergometer + F.E.T. All treatments had the same duration and F.E.T. was standardized. Mucus clearance was assessed using a technique based on the measurement of the elimination of inhaled radiolabeled particles. And concluded that, small differences in mucus clearance during chest physiotherapy with P.D., P.E.P. and Exercises, all combined with standardized F.E.T. Clearance during P.D. was greatest from the dependent lung, suggesting factors other than gravitational effects on mucus to be important.[48]

5.21: **Hengstum M, Festen J, Beurskens C, Hankel M, Beekman F, Corstens, (1991)** on theoretical grounds it is assumed that positive expiratory pressure mask physiotherapy (P.E.P.) as a means of promoting mucus clearance is especially effective in the more distal airways. In a randomized cross-over trial including a control measurement, the effect of P.E.P. and of the forced expiration technique combined with postural drainage (FET/PD) on regional lung clearance was evaluated in seven patients with chronic bronchitis and abundant sputum production (mean 32 g.day-1). P.E.P. consisted of positive expiratory pressure mask breathing interspersed with breathing exercises, forced expiration manoeuvres (huffing) and, if necessary, coughing. F.E.T. consisted of breathing exercises, huffing and also, if necessary, coughing. F.E.T. was combined with P.D. Following inhalation of a radio-aerosol regional lung clearance was estimated by means of gamma camera imaging. The results after P.E.P. appeared to be not significantly different from control. The mean clearance in all three lung zones (peripheral, intermediate and inner) was largest after FET/PD as compared with P.E.P. and control. Statistical significance (p less than 0.02) was reached only for clearance in the inner region. It is concluded that P.E.P. has no demonstrable effect on regional lung clearance in these patients.[46]

5.22: Falk M, Kelstrup M, Andersen JB, Kinoshita T, Falk P, Stovring S, Gothgen (1984) I they studied, "Acute effects of 4 different chest physical therapy regimens using a Randomized Cross-over Design in 14 patients with cystic fibrosis." And in this they give treatment in which A consisted of postural drainage,

percussion and vibration; treatment B of postural drainage and periodic application of a face mask with positive expiratory pressure (P.E.P.); treatment C of P.E.P. in the sitting position; treatment D of the forced expiration technique in the sitting position. In terms of sputum expectorated, treatments B and C were superior to treatment D and especially to treatment A (p less than 0.05). Skin oxygen tension, PSO2 was monitored continuously during and for 35 min after treatment. A substantial and prolonged decay in PSO2 was observed during treatment A, quite different from other patterns seen. During and even following treatment C, an increase in PSO2 was noted. P.E.P. was well accepted by the patients, who preferred treatment C, and we suggest it is incorporated in chest physical therapy regimens if the therapeutic objective is to increase expectoration.[43]

5.23: Braun SR, Birnbaum ML, Chopra PS., (1978) "Pre and postoperative pulmonary function abnormalities in coronary artery revascularization surgery." In this, they were conducted pulmonary function studies one to two days prior to two weeks after, and an average of 116 days after coronary artery revascularization surgery. In this study total, 19 patients were studied; the average age was 51 years. Pre-operation it was found that 11 of 19 patients had mild to moderate obstruction, 8 of 17 had diffusing capacity less than 80 percent of predicted, and 9 of 17 had mild hypoxemia. Many of these abnormalities seemed related to smoking. After surgery, significant reductions in volumes, diffusion and PaO2 were found at two weeks. Arterial oxygen tension (PaO2) had returned to preoperative levels. Correction of diffusion for volume showed there to be no change in any of the study periods suggesting chest wall alteration is a major component of the abnormality. So, they concluded two things 1) preoperative evaluation of the pulmonary status of patients scheduled for elective revascularization surgery is important. 2) The volume and diffusion abnormalities persist late into the postoperative period. The changes seem related primarily to the altered mechanics of the chest wall. Finally, since there is a gradual increase in the activities of the patent towards normal two weeks post-operation, there is an increase in the systemic oxygen demands. This may be a time when there is persistent hypoxemia.[23]

5.24: Abhaya Mahadik and et. al. (2020) conducted a study on "Immediate Effect of Blow Bottle Positive Expiratory Pressure (BBPEP) Device on Oxygen Saturation In Patients Who Underwent Open-Heart Surgery-A Randomized Pilot Study. This pilot was done on 20 patients who divided into experimental and control group. Control group received conventional physiotherapy treatment while experimental group received

conventional physiotherapy treatment with BBPEP device and oxygen saturation was noted after treatment in both groups. Author concluded that both the groups were showed significant improvement in oxygen saturation after treatment but experimental group showed more improvement in oxygen saturation compared to control group. Hence author concluded that BBPEP device is effective in improving oxygen saturation after open-heart surgery.[76]

CHAPTER 6

Material and Methodology

6.1: Study Design: A Comparative Study.

6.2: Study Setting: Cardiac Surgery Intensive Care Unit of Department of Cardiothoracic and Vascular Surgery in a Tertiary Care Teaching Hospital.

6.3: Study Population: Patients with open-heart surgery.

6.4: Clinical Trials Registry of India [CTRI] – This study is registered under CTRI .

6.5: Sample Size: 23 in each group and by adding a 10% attrition rate, the sample size in each group is 27.

α value: 0.95 β value: 0.8

6.6: Sampling Technique - Simple Random Sampling

6.7: Allocation Concealment - Postoperative open-heart surgery patients were allocated into Interventional and Control Group on the postoperative day 1, patient divided into groups by using seal envelope method

6.8: Study Duration: 1 year.

6.9: Outcomes:

I. The Fraction of Inspired Oxygen (FiO2),
II. Oxygen Saturation (SpO2),
III. Peak Expiratory Flow Rate (PEFR)

6.10: Method of selection of study subjects:

6.10.1: Inclusion Criteria

1. Age 20 yrs. and above.
2. Both male and female
3. Surgical approach with median sternotomy.
4. Patient with stable hemodynamics.
5. Uncomplicated surgery.

6. Participants were willing to participate.

6.10.2: Exclusion Criteria

1. Subject with pre diagnosed respiratory pathology.
2. Subject who has a history of smoking.
3. Subject already diagnosed with any neuromuscular disease which directly affects the lung functions.
4. Subject on drugs which will suppress or affect the outcome measures, e.g. bronchodilators.

6.11: Variables of study:

6.11.1 Dependent variables:

a. Fraction of Inspired Oxygen (FiO2),
b. Oxygen Saturation (SpO2),
c. Peak Expiratory Flow Rate (PEFR)

6.11.2 Independent variables:

a. Age
b. Gender

6.12: Operational definitions

Open Heart Surgery: Open heart surgery is any type of surgery where the chest is cut open and surgery is performed on the muscles, valve or arteries of the heart.

Postoperative Pulmonary Complications: A postoperative pulmonary complication encompasses almost any complication affecting the respiratory system after general anaesthesia and surgery.

Bubble Blow P.E.P.: Bubble Blow P.E.P. is a technique used to help adults or children who have a build-up of secretions in their lungs and struggle to clear them.

Acapella: The Acapella is a device that generating a positive pressure has an oscillatory component, causing airway vibrations. These vibrations help to dislodge thick, sticky secretions from the airway walls. Airway oscillation may also decrease mucous viscoelasticity**.**

Uncomplicated Surgery: Surgery performed with minimal variations of diagnostic and haemodynamic parameters from baseline or normal range.

CHAPTER 7

Research Methodology Specified and Explained for Data Collection

7.1 Peak Flow Meter:

Specification:

- **Model: Air zone personal peak flow meter**
- **A.T.S. Scale:** 60-800 L/min
- **Scale Increments:** 10LPM
- **Size:** 5-1/2”H X 1-3/4”W
- **Weight:** 42gm
- **It is marketed by**: Clement Clarke international.

Fig 1: Peak Flow Meter Device

Fig 2: Patient using Peak Flow Meter

7.2: Acapella:

Specification:

- **Model:** Acapella® DH
- **Expiratory Flow**: ≥15 L/min expiratory flow
- **PEP:** 10-20 cmH2O
- **Inspiratory: Expiratory Ratio:** 1:3 to 4
- **Size:** **Height**- 4cm; **Width**- 4cm; **Length**- 17cm; **Circumference**- 20cm

- **Weight:** 136gm
- **It is marketed by:** Smiths Medical Portex®

Fig 3: Acapella Device

Fig 4: Patient using Acapella

7.3: Oxygen Flow Meter with Humidifier:

Fig 5: Oxygen Flow Meter with Humidifier

7.4: Nose Clip:

Fig 6: Nose Clip

7.5: Blow Bottle:

Specification:

- **PEP:** 10-20 cmH2O
- **Inspiratory: Expiratory Ratio:** 1:3 to 4
- **Material Used:** Plastic Bottle with open top, Plastic Tube, Inch Tape**.**
- **PEP Bottle Specifications:**

I. Material- Hard Plastic

II. Dimensions- Weight- 40gm; Height- 25cm; Width- 10cm; Circumference- 20cm

III. Height of Water Column- 13cm

- **Tubing Specifications:**

I. Material- Rigid Tubing

II. Inner Diameter- ≥8mm

III. Length of Tubing- 30cm

IV. Depth in water column- 10cm; 3cm above from bottom of bottle surface.

Fig 7: BBPEP Device

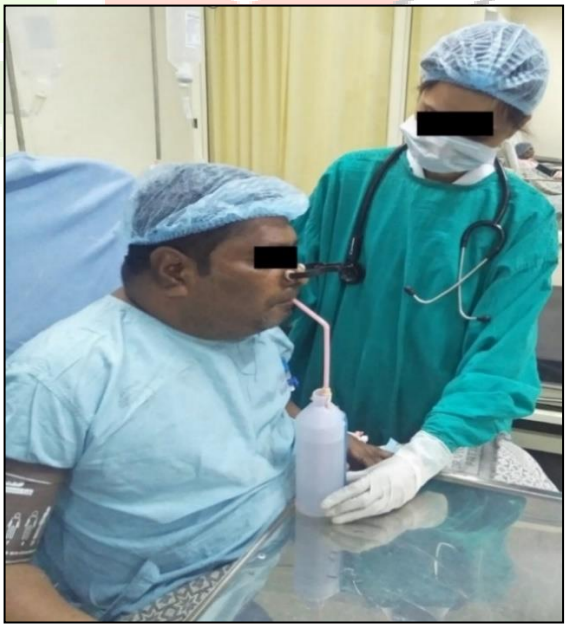


Fig 8: Patient using BBPEP

7.6: Procedure:

The study protocol was approved from the Institutional Ethical Committee. Sixty patients were screened for study protocol and 54 patients were selected according to inclusion and exclusion criteria. The study protocol was explained to patients and written consent was taken. Patients were divided into the Interventional Group (Group A) and Control Group (Group B) by using the seal-envelope method.

Patient assigns for study protocol from Post-operative Day (P.O.D.) 1 to P.O.D. 3 and received treatment twice a daily. For the ease of understanding and graphical representation, the six treatment sessions have been labelled as below given box.[70]

	10am	4pm
POD 1	1A	1B
POD 2	2A	2B
POD 3	3A	3B

Before the study was initiated, all the Baseline data such as vitals and values of FiO2, SpO2 and PEFR were noted. After that Interventional and Control Group were received treatment and again FiO2, SpO2 and PEFR values were noted. Outcome measures were noted before and after every session which was held on P.O.D. 1 to 3.

7.7: INTERVENTION:

Group A or Interventional Group- After an initial assessment, the Interventional Group received C.P.T. which as same as Control Group, it include Active Range of Motion Exercise for 10 repetitions, Deep Breathing Exercises: 3 sets of 10 breaths with 5-sec hold and 1 min of a rest period in between each set, Incentive Spirometer 10 breaths, **BBPEP:** 10 sets of 10 breaths with 5-sec hold and 1 min of a rest period in between each set followed by Huff for P.O.D. 1 to 3 and Bed ambulation on P.O.D. 3 only.

INTERVENTIONAL GROUP: -

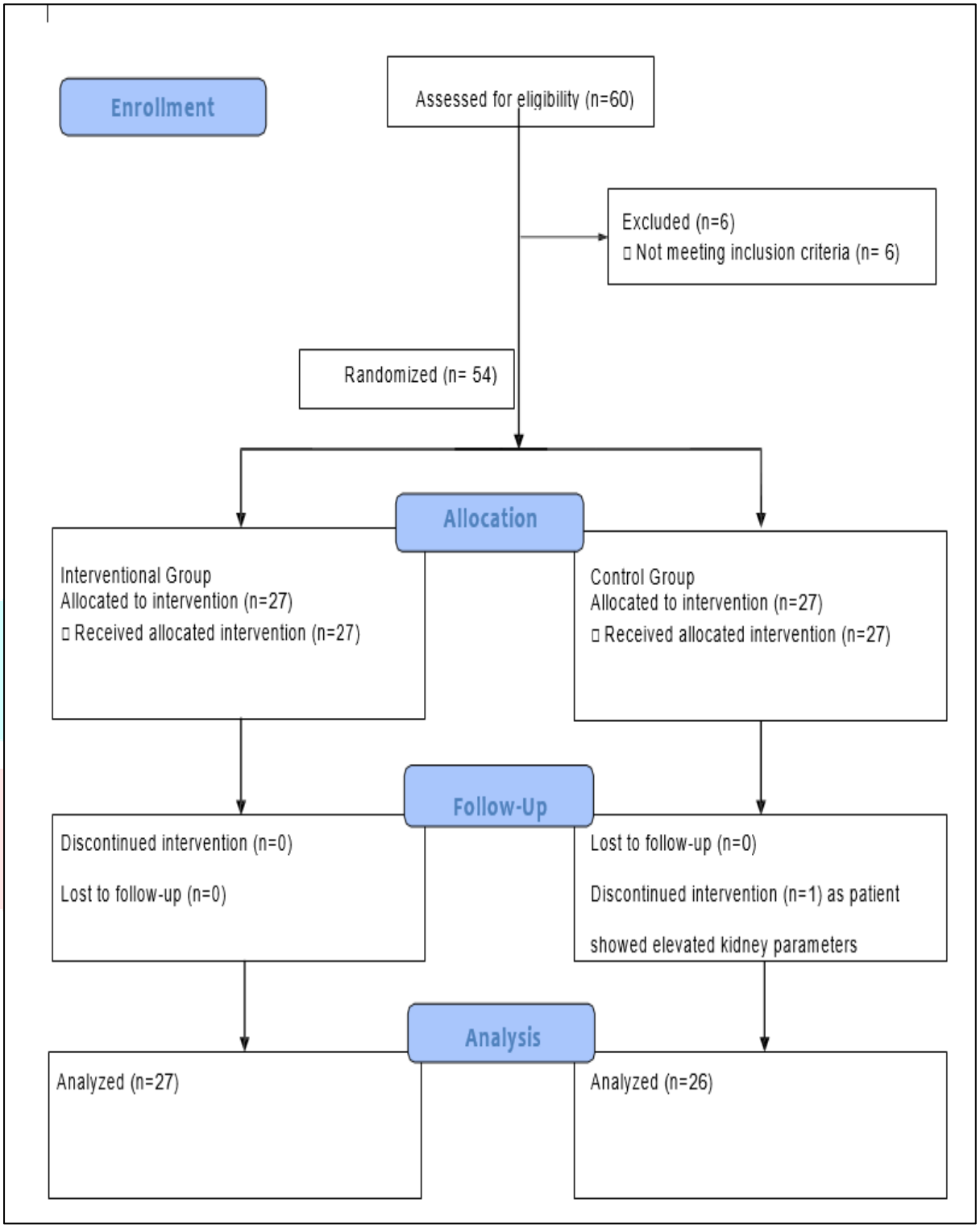
- The BBPEP intervention was carried out using a homemade BBPEP device. The device was made according to Re'gis Gemerasca Mestriner PT, Rafael Oliveira Fernandes PT et all in their article, i.e. optimum design parameters for a therapist-constructed positive-expiratory-pressure therapy bottle device which was published in respiratory care, April 2009.[66]
- P.E.P. bottle is made up of plastic container (height 25 cm, width 10 cm) with an open-top (so there will no pressure except atmospheric pressure against the air escaping from the tube) with an inner diameter of 8mm.
- The distal tip of the P.E.P. bottle tube is 10 cm below the surface of the water, i.e., a 10-cm water column and 3 cm above the bottom of the bottle and device is set up in front of the participant on a table.
- The lips are seal around the tubing and exhalation done with a little force for three seconds to create bubbles. 10 breaths were repeated, followed by two huffs.
- Total 10 sets of repetitions were given.

Group B or Control Group- After initial assessment patient received Conventional Physiotherapy Treatment (C.P.T.) which include Active Range of Motion Exercise for ten repetitions, Deep Breathing Exercises: 3 sets of 10 breaths with 5-sec hold and 1 min of a rest period in between each set, Incentive Spirometer 10 breaths, **Acapella** for P.O.D. 1 to 3 and Bed ambulation on P.O.D. 3 only.

CONTROL GROUP: -

- The first dial was set properly on the end of the Acapella® by rotating end toward the + (plus) to increase resistance or rotate the end toward – (minus) to decrease resistance.
- Then patient received sitting position with good posture to use the Acapella.
- The patient was instructed to take a fairly deep breath and hold it for about 3 seconds.
- Then the nose clip was attached and Acapella® mouthpiece was placed in a patient's mouth and instructed to seal the lips tightly around the mouthpiece.
- And exhale as much as possible (but not too forcefully) through the mouthpiece.
- This manoeuvre was repeated for 10 to 12 breaths. Coughing was resisted by the patient as much as possible.
- Followed by this manoeuvre patient instructed to huffs for 3 to 4 times.
- These steps were repeated for 15 minutes.

Study Flow Diagram based on CONSORT Guidelines



CHAPTER 8

Statistical Analysis

Data was analyzed by using SPSS software. For statistical level of significance, α is set as 0.05 at Confidence Interval 95%. Kolmogorov-Smirnov Test was used to check normal distribution of data. As data was not pass normality therefore non-parametric, Mann-Whitney-U-Test was used for statistical analysis.

CHAPTER 9

Result

The total calculated sample size was 54. They were divided into two groups; Interventional Group and Control group. Each group contained 27 subjects including 10% of attrition rate. Total 60 patients were screened in which according to the inclusion and exclusion criteria only 54 patients were selected. One patient was further excluded from the Control group during the study, as he developed complications. Finally, 53 patients (27 in Interventional Group and 26 in the Control Group) completed the study protocol and were included for data analysis. Fig.9 shows the patient distribution in the groups.

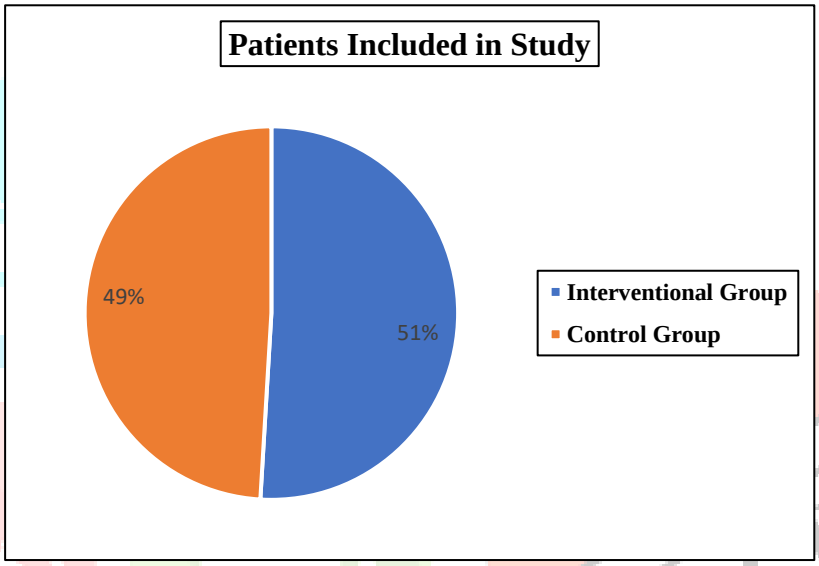


Fig.9: Patient Distribution in Groups

Table 1: Demographic and Baseline data with the Baseline Outcome Measures

Baseline Characteristics	Interventional Group	Control Group
Mean Age	56.25±11.76	59.59±14.05
Male/Female	13/14	18/9
Type of Surgery Open-Heart Surgery	CABG-17	CABG-22
	Valve Surgery- 7	Valve Surgery- 5
	CABG + Valve Surgery- 4	
Heart Rate	81.11±10.53	81.96±9.8
Respiratory Rate	19.81±4.15	19.18±4.22
Blood Pressure	Systolic- 115.37±11.41 Diastolic- 69.96±6.9	Systolic-115.37±11.41 Diastolic- 68.85±5.4
The Fraction of Inspired Oxygen (FiO2)	12.07 ± 1.2	12.03 ± 03
Oxygen Saturation (SpO2)	95.29 ± 0.6	95.03 ± 0.6
Peak Expiratory Flow Rate (PEFR)	116.16 ± 35.4	123.18 ± 43.0

Table 1 shows baseline characteristics. Baseline characteristics of both the group patients were equal.

Normality Values:

Table 2 – Normality Test for All Parameters

	Kolmogorov-Smirnov[a]		
	Statistic	df	Sig.
Normality of FiO2			
FiO2 1A Pre	.355	52	.000
FiO2 1A Post	.442	52	.000
FiO2 1B Pre	.539	52	.000
FiO2 1B Post	.539	52	.000
FiO2 2A Pre	.539	52	.000
FiO2A Post	.490	52	.000
FiO2 2B Pre	.490	52	.000
FiO2 2B Post	.451	52	.000
FiO2 3A Pre	.451	52	.000
FiO2 3A Post	.427	52	.000
FiO2 3B Pre	.427	52	.000
FiO2 3B post	.304	52	.000
Normality of SpO2			
SpO2 1A Pre	.355	52	.000
SpO2 1A Post	.308	52	.000
SpO2 1B Pre	.337	52	.000
SpO2 1B Post	.321	52	.000
SpO2 2A Pre	.338	52	.000
SpO2 2A Post	.272	52	.000
SpO2 2B Pre	.234	52	.000
SpO2 2B Post	.225	52	.000
SpO2 3A Pre	.206	52	.000
SpO2 3A Post	.161	52	.002
SpO2 3B Pre	.143	52	.010
SpO2 3B post	.277	52	.000
Normality of PEFR			
PEFR 1A Pre	.264	52	.000
PEFR 1A Post	.255	52	.000
PEFR 1B Pre	.224	52	.000
PEFR 1B Post	.201	52	.000
PEFR 2A Pre	.210	52	.000
PEFR 2A Post	.315	52	.000
PEFR 2B Pre	.294	52	.000
PEFR 2B Post	.277	52	.000
PEFR 3A Pre	.265	52	.000
PEFR 3A Post	.292	52	.000
PEFR 3B Pre	.291	52	.000
PEFR 3B post	.313	52	.000

Normality was checked by using Kolmogorov-Smirnov Test. As the significance level was less than 0.05 the data was not normally distributed. Hence non-parametric test was used. (Table 2)

Session 1A FiO2

Ranks **Table 3: Pre & Post values of FiO2 for Session 1A**

	Group	N	Mean Value	Mean Rank	Sum of Ranks
FiO2 1A Pre	Interventional	27	12	27.20	734.50
	Control	26	12.03	26.79	696.50
	Total	53			
	Group	N		Mean Rank	Sum of Ranks
FiO2 1A Post	Interventional	27	10.55	30.19	815.00
	Control	26	9.84	30.69	616.00
	Total	53			

Test Statistics

Table 4: Test Statistic of FiO2 for Session 1A

	FiO2 1A Pre
Mann-Whitney U	345.500
Wilcoxon W	696.500
Z	-.111
Asymp. Sig. (2-tailed)	.912
	FiO2 1A Post
Mann-Whitney U	265.000
Wilcoxon W	616.000
Z	-2.342
Asymp. Sig. (2-tailed)	.019

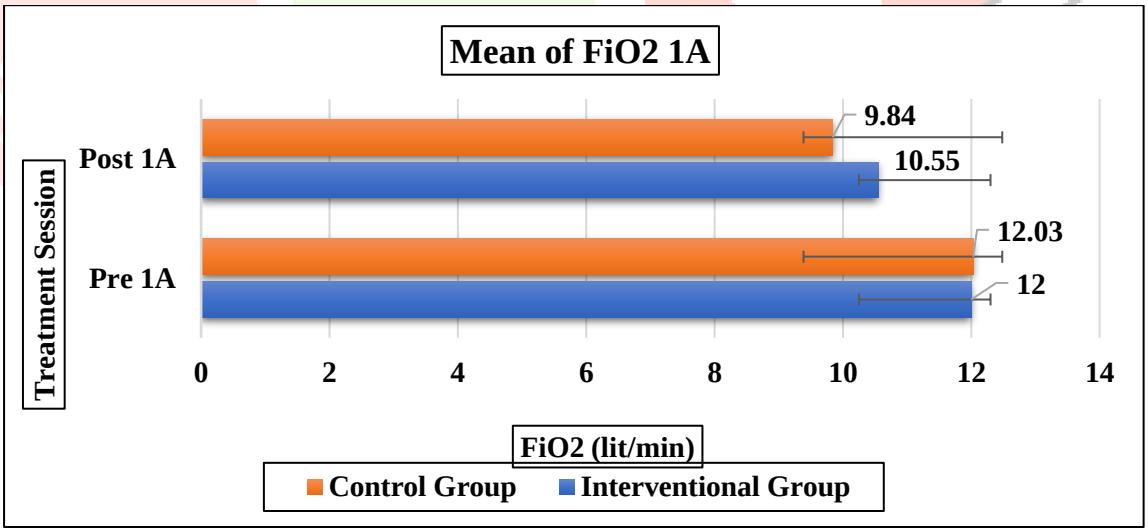


Fig.10: Graphical Representation of FiO2 values of Pre & Post Session 1A

Table 3 and 4 and Fig.10 shows a comparison of the mean distribution of pre and post FiO2 1A between Interventional and Control group. Interventional group has mean rank 27.20 on pre session and 30.19 on post session with mean value 12 and 10.55 respectively while Control group has 26.79 pre session and 30.69 on post session with mean value 12.03 and 9.84 respectively. The p-value for pre session is (0.001 < .912) and (0.001 < .019) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

Session 1B FiO2

Rank **Table 5: Pre & Post values of FiO2 for Session 1B**

	Group	N	Mean Value	Mean Rank	Sum of Ranks
FiO2 1B Pre	Interventional	27	9.9	27.52	743.00
	Control	26	9.84	26.46	688.00
	Total	53			
	Group	N		Mean Rank	Sum of Ranks
FiO2 1B Post	Interventional	27	7.92	27.52	743.00
	Control	26	7.84	26.46	688.00
	Total	53			

Test Statistics **Table 6: Test Statistic of FiO2 for Session 1B**

	FiO2 1B Pre
Mann-Whitney U	337.000
Wilcoxon W	688.000
Z	-.622
Asymp. Sig. (2-tailed)	.534
	FiO2 1B Post
Mann-Whitney U	337.000
Wilcoxon W	688.000
Z	-.622
Asymp. Sig. (2-tailed)	.534

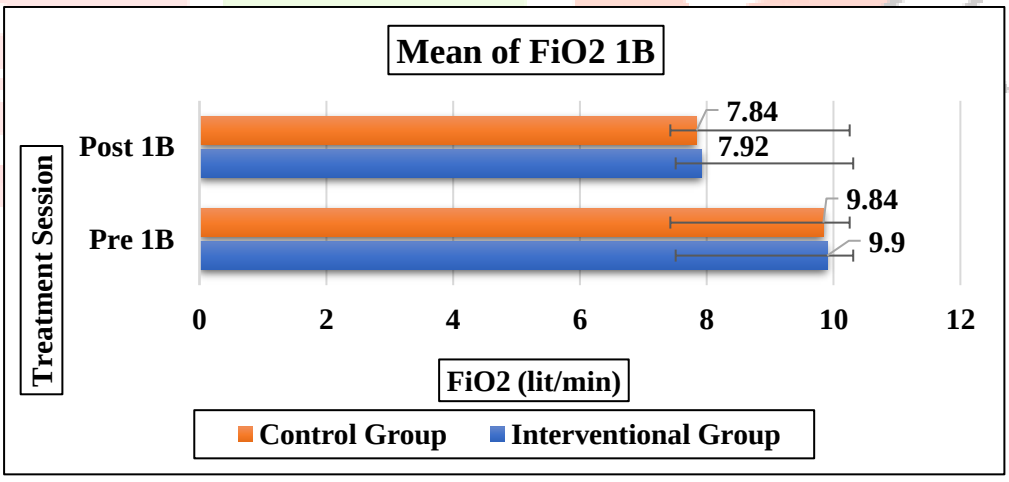


Fig.11: Graphical Representation of FiO2 values of Pre & Post Session 1B

Table 5 and 6 and Fig.11 shows a comparison of the mean distribution of pre and post FiO2 1B between Interventional and Control group. Interventional group has mean rank 27.52 on pre session and 27.52 on post session with mean value 9.9 and 7.92 respectively while Control group has 26.46 pre session and 26.46 on post session with mean value 9.84 and 7.84 respectively. The p-value for pre session is (0.001 < .534) and (0.001 < .534) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

Session 2A FiO2

Ranks **Table 7: Pre & Post values of FiO2 for Session 2A**

	Group	N	Mean Value	Mean Rank	Sum of Ranks
FiO2 2A Pre	Interventional	27	7.92	27.52	743.00
	Control	26	7.84	26.46	688.00
	Total	53			
	Group	N		Mean Rank	Sum of Ranks
FiO2A Post	Interventional	27	6.66	30.22	816.00
	Control	26	5.84	23.65	615.00
	Total	53			

Test Statistics **Table 8: Test Statistic of FiO2 for Session 2A**

	FiO2 2A Pre
Mann-Whitney U	337.000
Wilcoxon W	688.000
Z	-.622
Asymp. Sig. (2-tailed)	.534
	FiO2A Post
Mann-Whitney U	264.000
Wilcoxon W	615.000
Z	-2.632
Asymp. Sig. (2-tailed)	.008

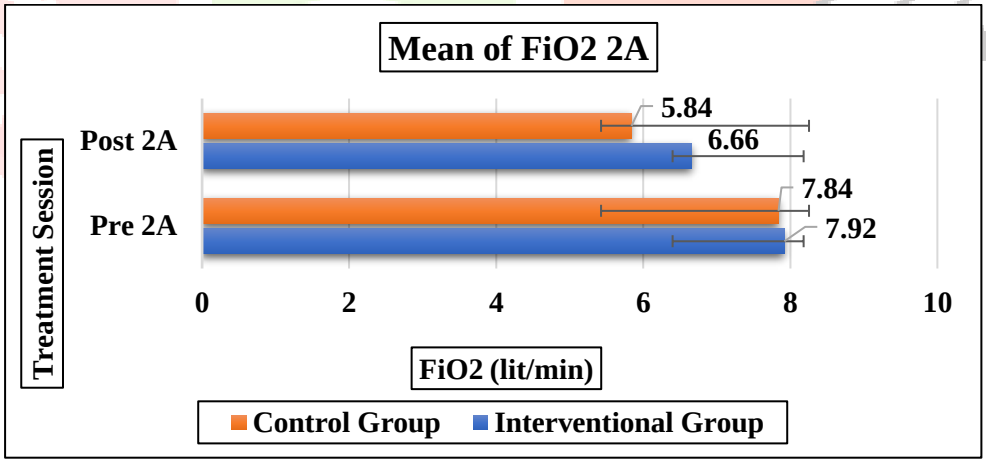


Fig.12: Graphical Representation of FiO2 values of Pre & Post Session 2A

Table 7 and 8 and Fig.12 shows a comparison of the mean distribution of pre and post FiO2 2A between Interventional and Control group. Interventional group has mean rank 27.52 on pre session and 30.22 on post session with mean value 7.92 and 6.66 respectively while Control group has 26.46 pre session and 23.65 on post session with mean value 7.84 and 5.84 respectively. The p-value for pre session (0.001 < .534) and (0.001 < .008) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

Session 2B FiO2

Ranks **Table 9: Pre & Post values of FiO2 for Session 2B**

	Group	N	Mean Value	Mean Rank	Sum of Ranks
FiO2 2B Pre	**Interventional**	27	6.66	30.22	816.00
	Control	26	5.84	23.65	615.00
	Total	53			
	Group	**N**		**Mean Rank**	**Sum of Ranks**
FiO2 2B Post	**Interventional**	27	4.88	29.93	808.00
	Control	26	4.07	23.96	623.00
	Total	53			

Test Statistics **Table 10: Test Statistic of FiO2 for Session 2B**

	FiO2 2B Pre
Mann-Whitney U	264.000
Wilcoxon W	615.000
Z	-2.632
Asymp. Sig. (2-tailed)	.008
	FiO2 2B Post
Mann-Whitney U	272.000
Wilcoxon W	623.000
Z	-2.062
Asymp. Sig. (2-tailed)	.039

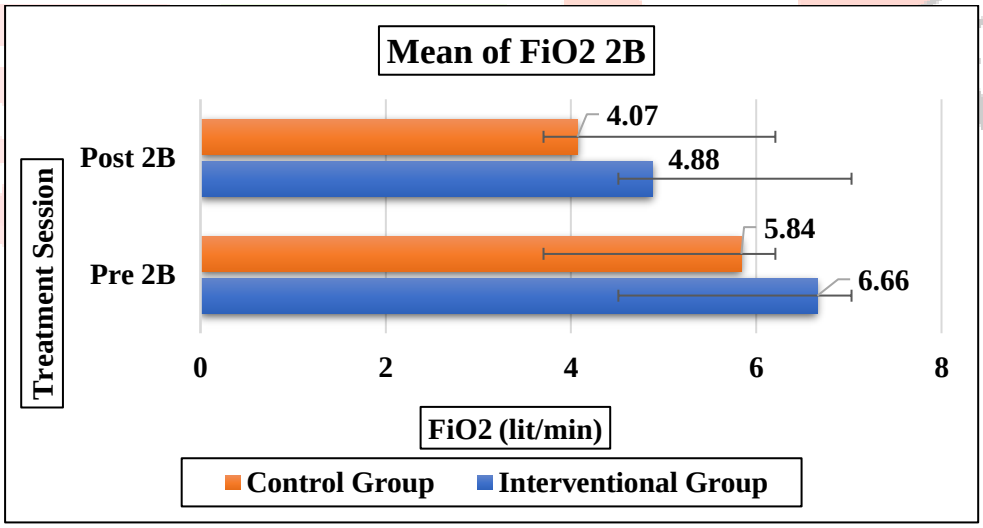


Fig.13: Graphical Representation of FiO2 values of Pre & Post Session 2B

Table 9 and 10 and Fig.13 shows a comparison of the mean distribution of pre and post FiO2 2B between Interventional and Control group. Interventional group has mean rank 30.22 on pre session and 29.93 on post session with mean value 6.66 and 4.88 respectively while Control group has 23.65 pre session and 23.96 on post session with mean value 5.84 and 4.07 respectively. The p-value for pre session is (0.001 < .008) for pre session and (0.001 < .039) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

Session 3A FiO2

Ranks **Table 11: Pre & Post values of FiO2 for Session 3A**

	Group	N	Mean Value	Mean Rank	Sum of Ranks
FiO2 3A Pre	Interventional	27	4.88	26.30	818.00
	Control	26	4	23.58	613.00
	Total	53			
	Group	N		Mean Rank	Sum of Ranks
FiO2 3A Post	Interventional	27	2.88	24.43	621.50
	Control	26	2.07	23.44	609.50
	Total	53			

Test Statistics **Table 12: Test Statistic of FiO2 for Session 3A**

	FiO2 3A Pre
Mann-Whitney U	262.000
Wilcoxon W	613.000
Z	-2.237
Asymp. Sig. (2-tailed)	.025
	FiO2 3A Post
Mann-Whitney U	258.500
Wilcoxon W	609.500
Z	-2.519
Asymp. Sig. (2-tailed)	.012

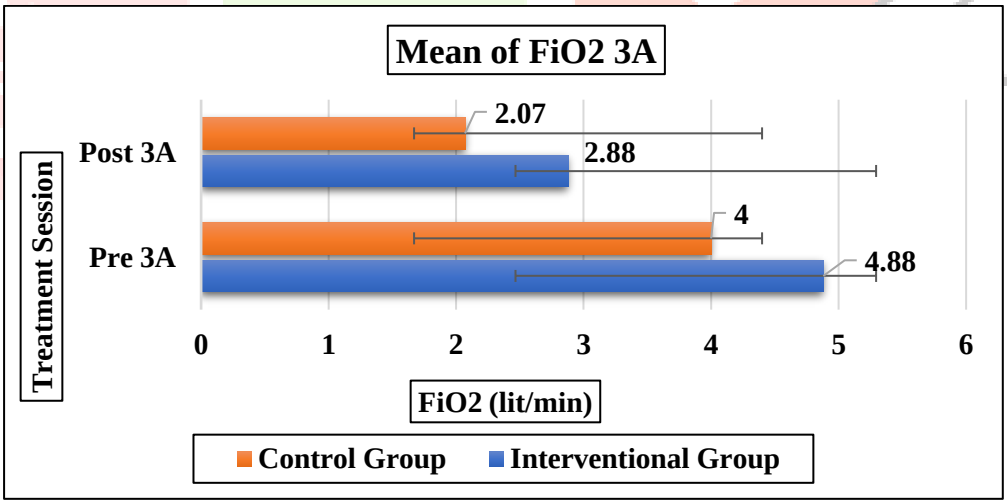


Fig.14: Graphical Representation of FiO2 values of Pre & Post Session 3A

Table 11 and 12 and Fig.14 shows a comparison of the mean distribution of pre and post FiO2 3A between Interventional and Control group. Interventional group has mean rank 26.30 on pre session and 24.43 on post session with mean value 4.88 and 2.88 respectively while Control group has 23.58 pre session and 23.44 on post session with mean value 4 and 2.07 respectively. The p-value for pre session is (0.001 < .025) for pre session and (0.001 < .012) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

Session 3B FiO2

Ranks **Table 13: Pre & Post values of FiO2 for Session 3B**

	Group	N	Mean Value	Mean Rank	Sum of Ranks
FiO2 3B Pre	Interventional	27	2.88	30.43	821.50
	Control	26	2.07	23.44	609.50
	Total	53			
	Group	N		Mean Rank	Sum of Ranks
FiO2 3B post	Interventional	27	1.07	29.69	801.50
	Control	26	0.5	24.21	629.50
	Total	53			

Test Statistics **Table 14: Test Statistic of FiO2 for Session 3B**

	FiO2 3B Pre
Mann-Whitney U	258.500
Wilcoxon W	609.500
Z	-2.519
Asymp. Sig. (2-tailed)	.012
	FiO2 3B post
Mann-Whitney U	278.500
Wilcoxon W	629.500
Z	-1.453
Asymp. Sig. (2-tailed)	.146

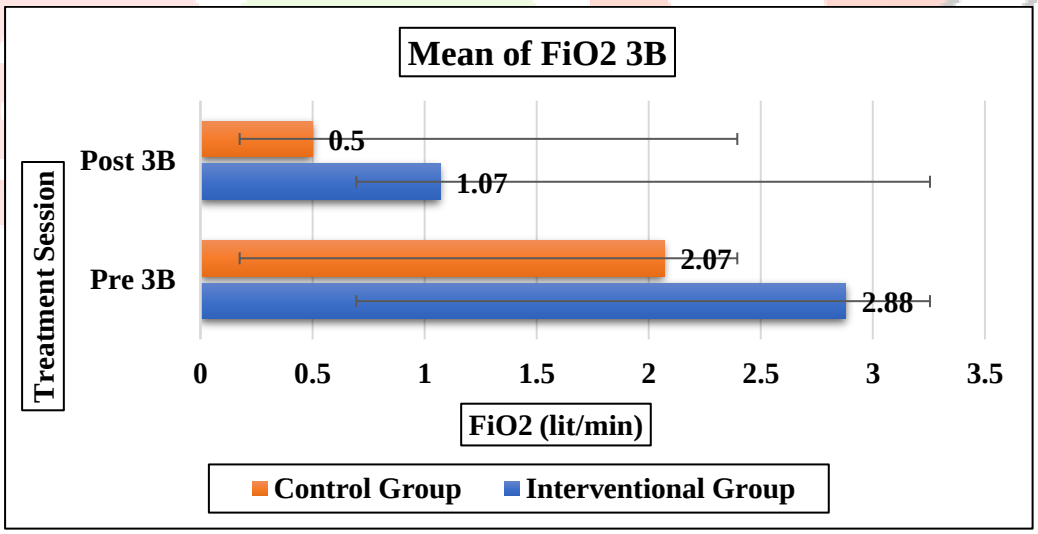


Fig.15: Graphical Representation of FiO2 values of Pre & Post Session 3B

Table 13 and 14 and Fig.15 shows a comparison of the mean distribution of pre and post FiO2 3B between Interventional and Control group. Interventional group has mean rank 30.43 on pre session and 29.69 on post session with mean value 2.88 and 1.07 respectively while Control group has 23.44 pre session and 24.21 on post session with mean value 2.07 and 0.5 respectively. The p-value for pre session is (0.001 < .012) and (0.001 < .146) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

Session 1A SpO2

Ranks **Table 15: Pre & Post values of SpO2 for Session 1A**

	Group	N	Mean Value	Mean Rank	Sum of Ranks
SpO2 1A Pre	Interventional	27	94	22.59	610.00
	Control	26	95	24.79	644.50
	Total	53			
	Group	N		Mean Rank	Sum of Ranks
SpO2 1A Post	Interventional	27	94	29.13	786.50
	Control	26	95	31.58	821.00
	Total	53			

Test Statistics **Table 16: Test Statistic of SpO2 for Session 1A**

	SpO2 1A Pre
Mann-Whitney U	293.500
Wilcoxon W	644.500
Z	-1.245
Asymp. Sig. (2-tailed)	.213
	SpO2 1A Post
Mann-Whitney U	232.000
Wilcoxon W	610.000
Z	-2.308
Asymp. Sig. (2-tailed)	.121

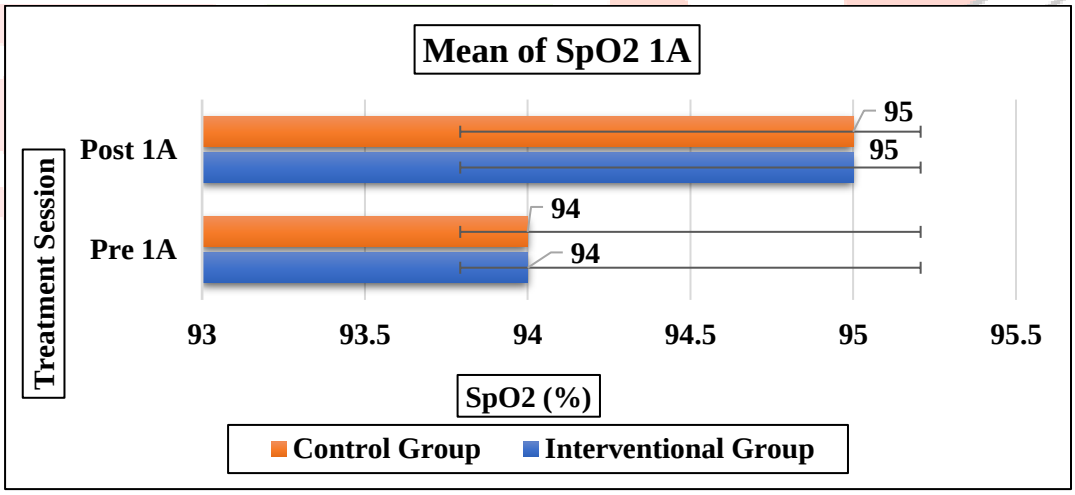


Fig.16: Graphical Representation of SpO2 values of Pre & Post Session 1A

Table 15 and 16 and Fig.16 shows a comparison of the mean distribution of pre and post SpO2 1A between Interventional and Control group. Interventional group has mean rank 22.59 on pre session and 29.13 on post session with mean value 94 and 95 respectively while Control group has 24.79 pre session and 31.58 on post session with mean value 94 and 95 respectively. The p-value for pre session is (0.001 < .213) and (0.001 < .121) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

Session 1B SpO2

Ranks **Table 17: Pre & Post values of SpO2 for Session 1B**

	Group	N	Mean Value	Mean Rank	Sum of Ranks
SpO2 1B Pre	Interventional	27	94.59	24.26	655.00
	Control	26	95.21	29.85	776.00
	Total	53			
	Group	N		Mean Rank	Sum of Ranks
SpO2 1B Post	Interventional	27	95.22	24.50	661.50
	Control	26	95.65	29.60	769.50
	Total	53			

Test Statistics **Table 18: Test Statistic of SpO2 for Session 1B**

	SpO2 1B Pre
Mann-Whitney U	277.000
Wilcoxon W	655.000
Z	-1.493
Asymp. Sig. (2-tailed)	.135
	SpO2 1B Post
Mann-Whitney U	283.500
Wilcoxon W	661.500
Z	-1.326
Asymp. Sig. (2-tailed)	.185

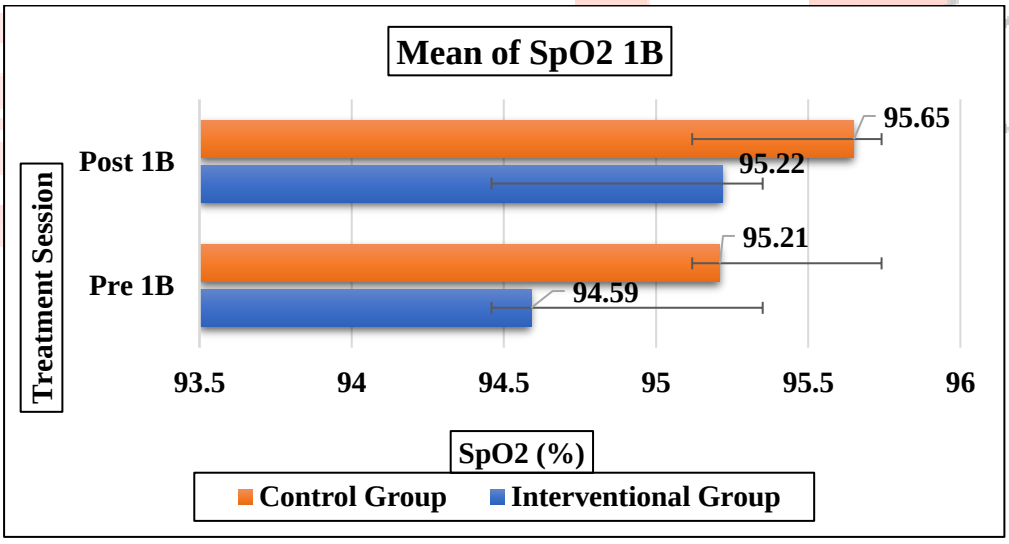


Fig.17: Graphical Representation of SpO2 values of Pre & Post Session 1B

Table 17 and 18 and Fig.17 shows a comparison of the mean distribution of pre and post SpO2 1B between Interventional and Control group. Interventional group has mean rank 24.26 on pre session and 24.50 on post session with mean value 94.59 and 95.22 respectively while Control group has 29.85 pre session and 29.60 on post session with mean value 95.21 and 95.65 respectively. The p-value for pre session is (0.001 < .135) and (0.001 < .185) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

Session 2A SpO2

Ranks **Table 19: Pre & Post values of SpO2 for Session 2A**

	Group	N	Mean Value	Mean Rank	Sum of Ranks
SpO2 2A Pre	Interventional	27	94.92	22.17	809.00
	Control	26	94.65	23.92	622.00
	Total	53			
	Group	N		Mean Rank	Sum of Ranks
SpO2 2A Post	Interventional	27	95.92	29.96	598.50
	Control	26	97.11	32.02	832.50
	Total	53			

Test Statistics **Table 20: Test Statistic of SpO2 for Session 2A**

	SpO2 2A Pre
Mann-Whitney U	271.000
Wilcoxon W	622.000
Z	-1.583
Asymp. Sig. (2-tailed)	.113
	SpO2 2A Post
Mann-Whitney U	220.500
Wilcoxon W	598.500
Z	-2.425
Asymp. Sig. (2-tailed)	.015

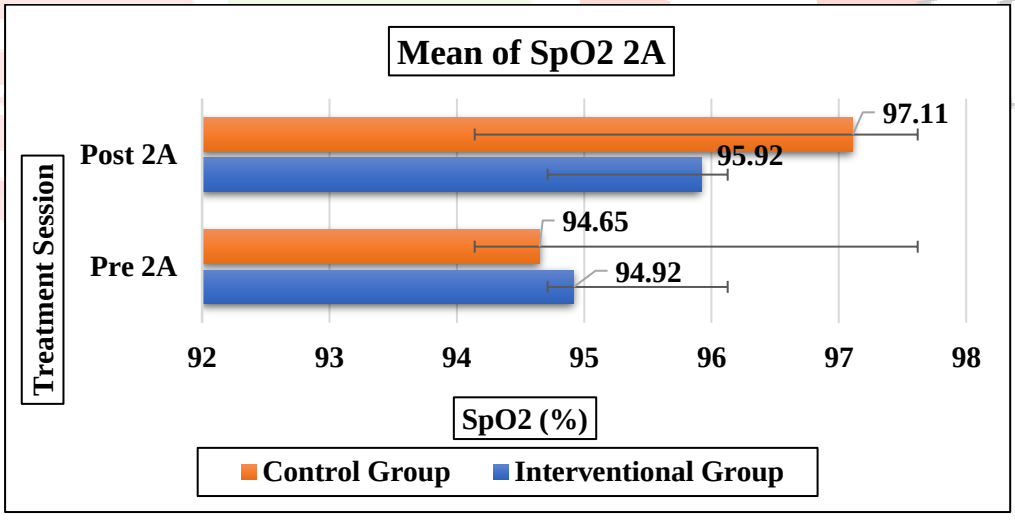


Fig.18: Graphical Representation of SpO2 values of Pre & Post Session 2A

Table 19 and 20 and Fig.18 shows a comparison of the mean distribution of pre and post SpO2 2A between Interventional and Control group. Interventional group has mean rank 22.17 on pre session and 29.96 on post session with mean value 94.92 and 95.92 while Control group has 23.92 pre session and 32.02 on post session with mean value 94.65 and 97.11 respectively. The p-value for pre session is (0.001 < .113) and (0.001 < .015) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

Session 2B SpO2

Rank **Table 21: Pre & Post values of SpO2 for Session 2B**

	Group	N	Mean Value	Mean Rank	Sum of Ranks
SpO2 2B Pre	**Interventional**	27	94.74	20.94	812.50
	Control	26	94.26	23.79	618.50
	Total	53			
	Group	N		Mean Rank	Sum of Rank
SpO2 2B Post	**Interventional**	27	95.96	30.09	565.50
	Control	26	97.24	33.29	865.50
	Total	53			

Test Statistics **Table 22: Test Statistic of SpO2 for Session 2B**

	SpO2 2B Pre
Mann-Whitney U	267.500
Wilcoxon W	618.500
Z	-1.581
Asymp. Sig. (2-tailed)	.114
	SpO2 2B Post
Mann-Whitney U	187.500
Wilcoxon W	565.500
Z	-3.014
Asymp. Sig. (2-tailed)	.003

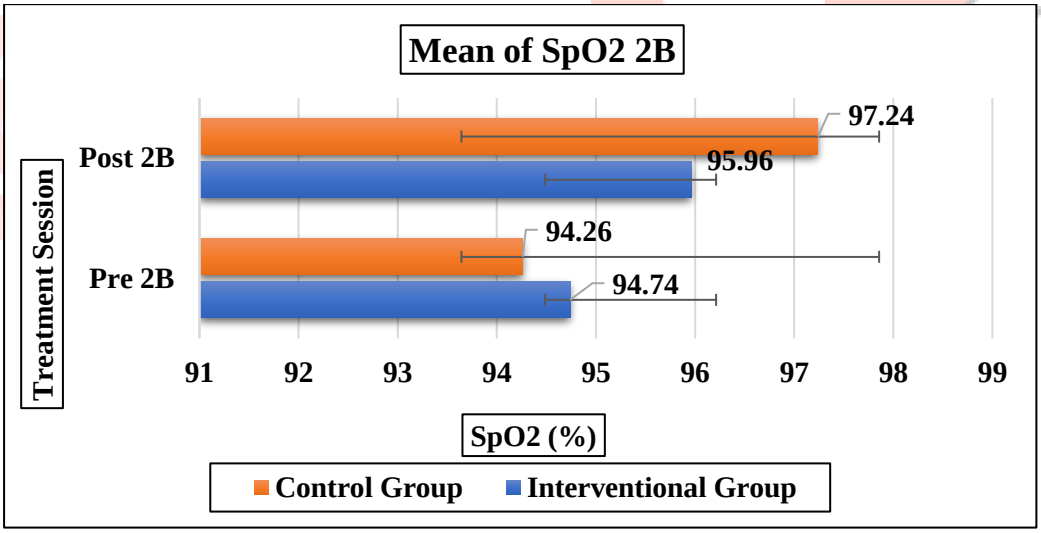


Fig.19: Graphical Representation of SpO2 values of Pre & Post Session 2B

Table 21 and 22 and Fig.19 shows a comparison of the mean distribution of pre and post SpO2 2B between Interventional and Control group. Interventional group has mean rank 20.94 on pre session and 30.09 on post session with mean value 94.74 and 95.96 respectively while Control group has 23.79 pre session and 33.29 on post session with mean value 94.26 and 97.24 respectively. The p-value for pre session is (0.001 < .114) and (0.001 < .003) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

Session 3A SpO2

Ranks **Table 23: Pre & Post values of SpO2 for Session 3A**

	Group	N	Mean Value	Mean Rank	Sum of Ranks
SpO2 3A Pre	Interventional	27	95	23.67	696.50
	Control	26	95.38	28.25	734.50
	Total	53			
	Group	N		Mean Rank	Sum of Ranks
SpO2 3A Post	Interventional	27	97.29	25.80	639.00
	Control	26	98	30.46	792.00
	Total	53			

Test Statistics **Table 24: Test Statistic of SpO2 for Session 3A**

	SpO2 3A Pre
Mann-Whitney U	318.500
Wilcoxon W	696.500
Z	-.600
Asymp. Sig. (2-tailed)	.549
	SpO2 3A Post
Mann-Whitney U	261.000
Wilcoxon W	639.000
Z	-1.635
Asymp. Sig. (2-tailed)	.102

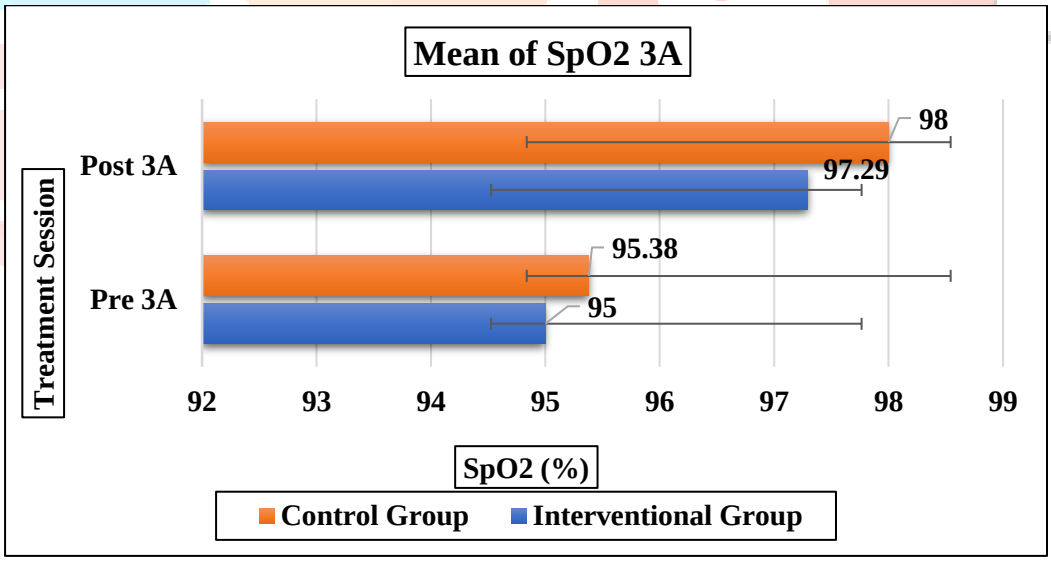


Fig.20: Graphical Representation of SpO2 values of Pre & Post Session 3A

Table 23 and 24 and Fig.20 shows a comparison of the mean distribution of pre and post SpO2 3A between Interventional and Control group. Interventional group has mean rank 23.67 on pre session and 25.80 on post session with mean value 95 and 97.29 respectively while Control group has 28.25 pre session and 30.46 on post session with mean value 95.38 and 98 respectively. The p-value for pre session is (0.001 < .549) and (0.001 < .102) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

Session 3B SpO2

Ranks **Table 25: Pre & Post values of SpO2 for Session 3B**

	Group	N	Mean Value	Mean Rank	Sum of Ranks
SpO2 3B Pre	Interventional	27	96.96	23.43	632.50
	Control	26	97.65	28.19	798.50
	Total	53			
	Group	N		Mean Rank	Sum of Ranks
SpO2 3B post	Interventional	27	98.81	25.85	698.00
	Control	26	99.07	30.71	733.00
	Total	53			

Test Statistics **Table 26: Test Statistic of SpO2 for Session 3B**

	SpO2 3B Pre
Mann-Whitney U	254.500
Wilcoxon W	632.500
Z	-1.741
Asymp. Sig. (2-tailed)	.082
	SpO2 3B post
Mann-Whitney U	320.000
Wilcoxon W	698.000
Z	-.596
Asymp. Sig. (2-tailed)	.551

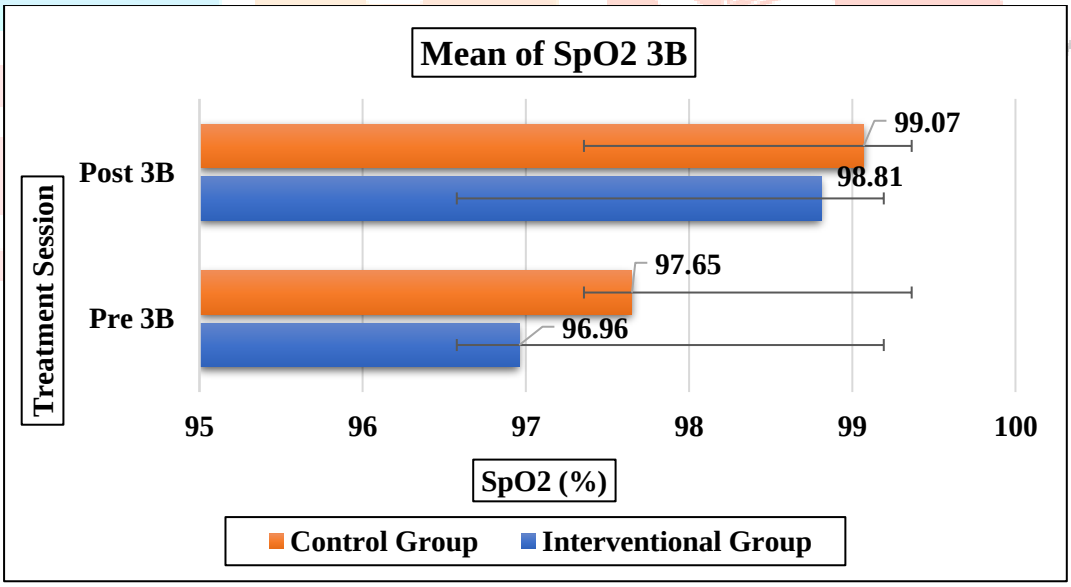


Fig.21: Graphical Representation of SpO2 values of Pre & Post Session 3B

Table 25 and 26 and Fig.21 shows a comparison of the mean distribution of pre and post SpO2 3B between Interventional and Control group. Interventional group has mean rank 23.43 on pre session and 25.85 on post session with mean value 96.96 and 98.81 respectively while Control group has 28.19 pre session and 30.71 on post session with mean value 97.65 and 98.81 respectively. The p-value for pre session is (0.001 < .082) and (0.001 < .551) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

Session 1A PEFR

Ranks **Table 27: Pre & Post values of PEFR for Session 1A**

	Group	N	Mean Value	Mean Rank	Sum of Ranks
PEFR 1A Pre	Interventional	27	146.15	24.69	691.00
	Control	26	137.03	28.46	740.00
	Total	53			
	Group	N		Mean Rank	Sum of Ranks
PEFR 1A Post	Interventional	27	151.92	25.59	666.50
	Control	26	137.03	29.40	764.50
	Total	53			

Test Statistics **Table 28: Test Statistic of PEFR for Session 1A**

	PEFR 1A Pre
Mann-Whitney U	313.000
Wilcoxon W	691.000
Z	-.723
Asymp. Sig. (2-tailed)	.470
	PEFR 1A Post
Mann-Whitney U	288.500
Wilcoxon W	666.500
Z	-1.183
Asymp. Sig. (2-tailed)	.237

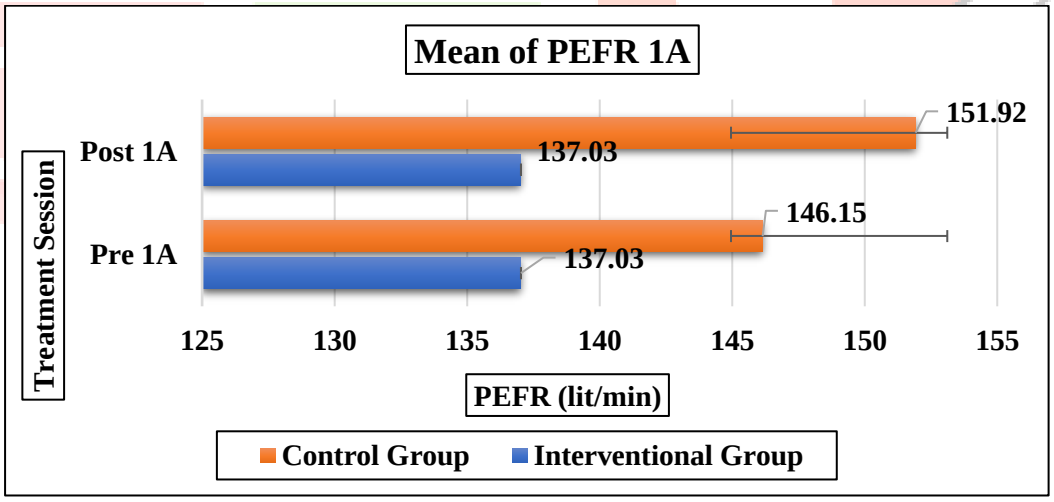


Fig.22: Graphical Representation of PEFR values of Pre & Post Session 1A

Table 27 and 28 and Fig.22 shows a comparison of the mean distribution of pre and post PEFR 1A between Interventional and Control group. Interventional group has mean rank 24.69 on pre session and 25.59 on post session with mean value 137.03 and 137.03 respectively while Control group has 28.46 pre session and 29.40 on post session with mean value 146.15 and 151.92 respectively. The p-value for pre session is (0.001 < .470) and (0.001 < .237) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

Session 1B PEFR

Ranks **Table 29: Pre & Post values of PEFR for Session 1B**

	Group	N	Mean Value	Mean Rank	Sum of Ranks
PEFR 1B Pre	Interventional	27	144.44	21.61	610.50
	Control	26	175	31.56	820.50
	Total	53			
	Group	N		Mean Rank	Sum of Ranks
PEFR 1B Post	Interventional	27	138.88	22.65	584.50
	Control	26	176	32.56	846.50
	Total	53			

Test Statistics **Table 30: Test Statistic of PEFR for Session 1B**

	PEFR 1B Pre
Mann-Whitney U	232.500
Wilcoxon W	610.500
Z	-2.212
Asymp. Sig. (2-tailed)	.027
	PEFR 1B Post
Mann-Whitney U	206.500
Wilcoxon W	584.500
Z	-2.682
Asymp. Sig. (2-tailed)	.007

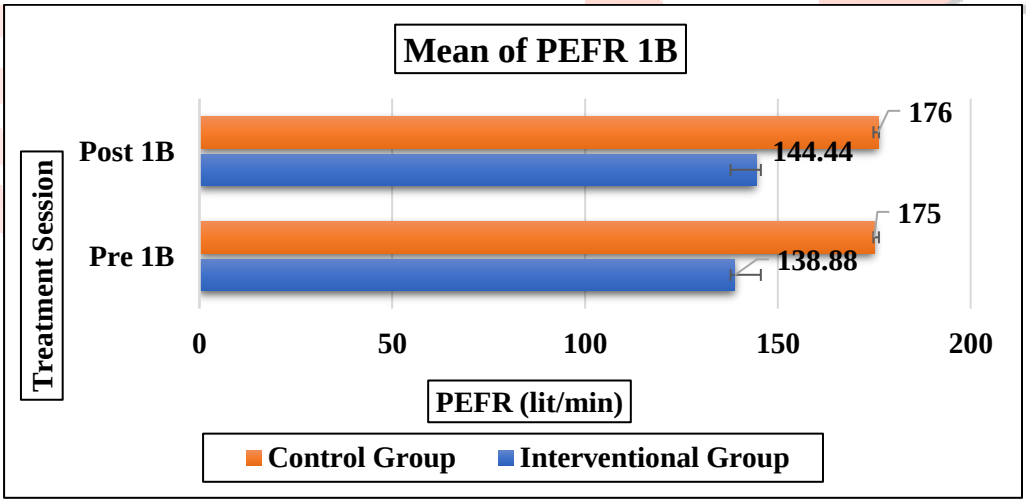


Fig.23: Graphical Representation of PEFR values of Pre & Post Session 1B

Table 29 and 30 and Fig.23 shows a comparison of the mean distribution of pre and post PEFR 1B between Interventional and Control group. Interventional group has mean rank 21.61 on pre session and 22.65 on post session with mean value 138.88 and 144.44 respectively while Control group has 31.56 pre session and 32.56 on post session with mean value 175 and 176 respectively. The p-value for pre session is (0.001 < .027) and (0.001 < .007) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

Session 2A PEFR

Ranks **Table 31: Pre & Post values of PEFR for Session 2A**

	Group	N	Mean Value	Mean Rank	Sum of Ranks
PEFR 2A Pre	Interventional	27	172.22	22.37	604.00
	Control	26	176.92	28.04	729.00
	Total	53			
	Group	N		Mean Rank	Sum of Ranks
PEFR 2A Post	Interventional	27	194.44	26.00	702.00
	Control	26	221.15	31.81	827.00
	Total	53			

Test Statistics **Table 32: Test Statistic of PEFR for Session 2A**

	PEFR 2A Pre
Mann-Whitney U	324.000
Wilcoxon W	702.000
Z	-.505
Asymp. Sig. (2-tailed)	.613
	PEFR 2A Post
Mann-Whitney U	226.000
Wilcoxon W	604.000
Z	-2.452
Asymp. Sig. (2-tailed)	.014

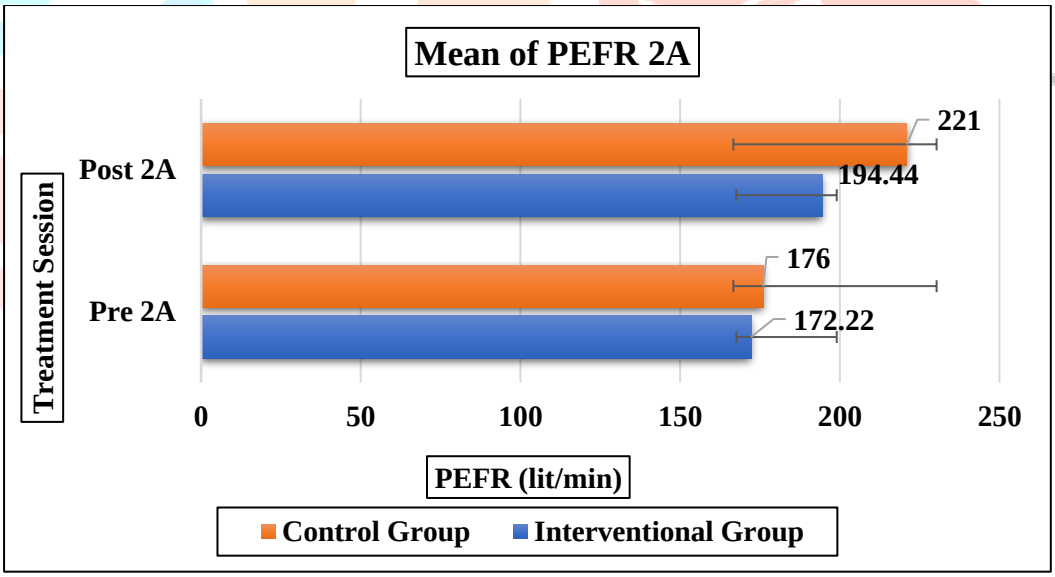


Fig.24: Graphical Representation of PEFR values of Pre & Post Session 2A

Table 31 and 32 and Fig.24 shows a comparison of the mean distribution of pre and post PEFR 2A between Interventional and Control group. Interventional group has mean rank 22.37 on pre session and 26.00 on post session with mean value 172.22 and 194.44 respectively while Control group has 28.04 pre session and 31.81 on post session with mean value 176 and 221 respectively. The p-value for pre session is (0.001 < .613) and (0.001 < .014) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

Session 2B PEFR

Ranks

Table 33: Pre & Post values of PEFR for Session 2B

	Group	N	Mean Value	Mean Rank	Sum of Ranks
PEFR 2B Pre	Interventional	27	193.14	23.11	624.00
	Control	26	212.96	31.04	807.00
	Total	53			
	Group	N		Mean Rank	Sum of Ranks
PEFR 2B Post	Interventional	27	221.15	23.11	624.00
	Control	26	234	31.04	807.00
	Total	53			

Test Statistics

Table 34: Test Statistic of PEFR for Session 2B

	PEFR 2B Pre
Mann-Whitney U	246.000
Wilcoxon W	624.000
Z	-2.027
Asymp. Sig. (2-tailed)	.043
	PEFR 2B Post
Mann-Whitney U	246.000
Wilcoxon W	624.000
Z	-2.036
Asymp. Sig. (2-tailed)	.042

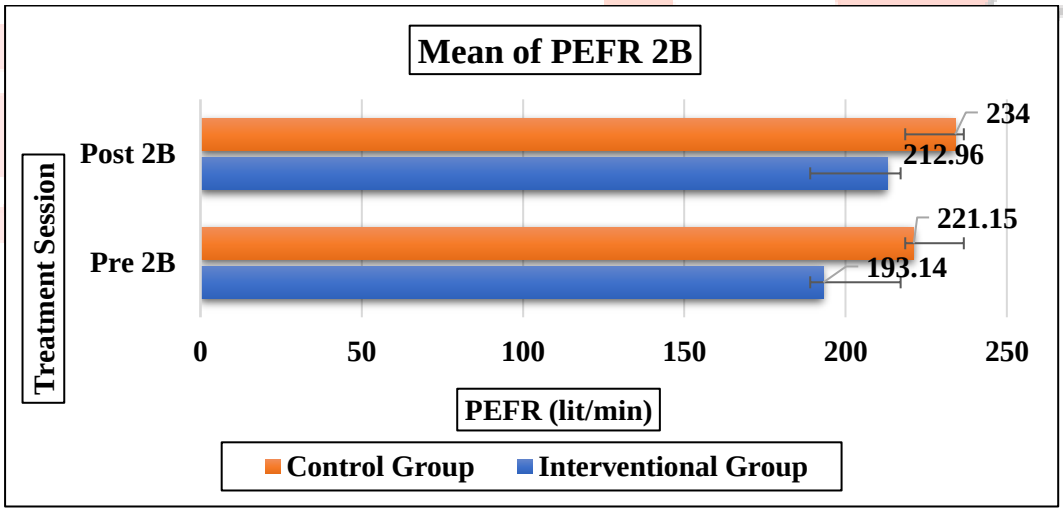


Fig.25: Graphical Representation of PEFR values of Pre & Post Session 2B

Table 33 and 34 and Fig.25 shows a comparison of the mean distribution of pre and post PEFR 2B between Interventional and Control group. Interventional group has mean rank 23.11 on pre session and 23.11 on post session with mean value 193.14 and 212.96 respectively while Control group has 31.04 pre session and 31.04 on post session with mean value 221.15 and 234 respectively. The p-value for pre session is (0.001 < .043) and (0.001 < .042) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

Session 3A PEFR

Ranks **Table 35: Pre & Post values of PEFR for Session 3A**

	Group	N	Mean Value	Mean Rank	Sum of Ranks
PEFR 3A Pre	Interventional	27	214.89	21.00	567.00
	Control	26	234	30.62	796.00
	Total	53			
	Group	N		Mean Rank	Sum of Ranks
PEFR 3A Post	Interventional	27	300	23.52	635.00
	Control	26	336	33.23	864.00
	Total	53			

Test Statistics **Table 36: Test Statistic of PEFR for Session 3A**

	PEFR 3A Pre
Mann-Whitney U	257.000
Wilcoxon W	635.000
Z	-1.816
Asymp. Sig. (2-tailed)	.069
	PEFR 3A Post
Mann-Whitney U	189.000
Wilcoxon W	567.000
Z	-3.121
Asymp. Sig. (2-tailed)	.002

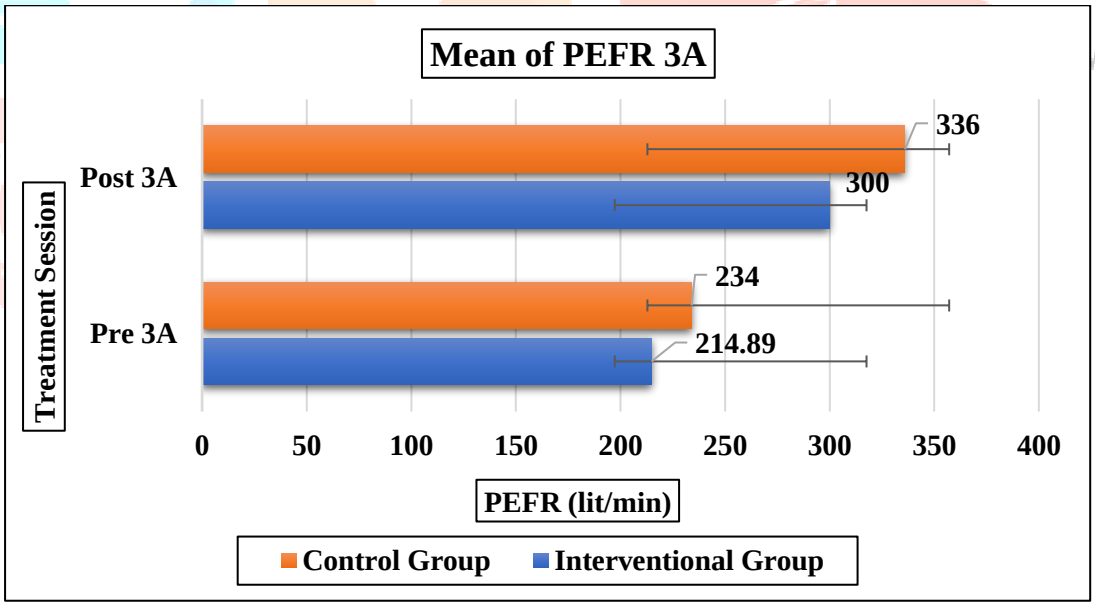


Fig.26: Graphical Representation of PEFR values of Pre & Post Session 3A

Table 35 and 36 and Fig.26 shows a comparison of the mean distribution of pre and post PEFR 3A between Interventional and Control group. Interventional group has mean rank 21.00 on pre session and 23.52 on post session with mean value 214.89 and 300 respectively while Control group has 30.63 pre session and 33.23 on post session with mean value 234 and 336 respectively. The p-value for pre session is (0.001 < .069) and (0.001 < .002) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

Session 3B PEFR

Ranks **Table 37: Pre & Post values of PEFR for Session 3B**

	Group	N	Mean Value	Mean Rank	Sum of Ranks
PEFR 3B Pre	Interventional	27	261	22.93	619.00
	Control	26	280.76	30.23	805.00
	Total	53			
	Group	N		Mean Rank	Sum of Ranks
PEFR 3B post	Interventional	27	316.66	23.19	626.00
	Control	26	336.53	31.96	812.00
	Total	53			

Test Statistics **Table 38: Test Statistic of PEFR for Session 3B**

	PEFR 3B Pre
Mann-Whitney U	241.000
Wilcoxon W	619.000
Z	-2.151
Asymp. Sig. (2-tailed)	.031
	PEFR 3B post
Mann-Whitney U	248.000
Wilcoxon W	626.000
Z	-2.020
Asymp. Sig. (2-tailed)	.043

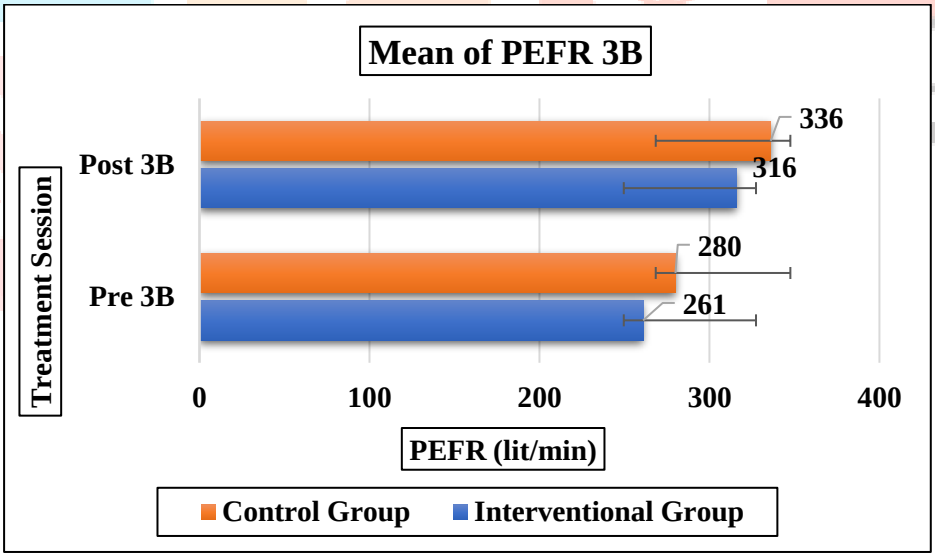


Fig.27: Graphical Representation of PEFR values of Pre & Post Session 3B

Table 37 and 38 and Fig.27 shows a comparison of the mean distribution of pre and post PEFR 3B between Interventional and Control group. Interventional group has mean rank 22.93 on pre session and 23.19 on post session with mean value 261 and 316 respectively while Control group has 30.23 pre session and 31.96 on post session with mean value 280 and 336 respectively. The p-value for pre session (0.001 < .031) and (0.001<.043) for post session, which shows no statistically significant difference. This indicate both Interventional and Control group showed equal effect after receiving treatment.

CHAPTER 10

DISCUSSION

Non-communicable Diseases are leading cause of death worldwide and is reason for 41 million deaths globally. CVD's are main leading cause among all NCD's. According to WHO, India has 1,34,00,00 of total population in which 63% of deaths occurred due to NCD i.e. 59,95,000 in figure till 2018.[5] Every year 1 million patients undergo cardiac surgery as it is a treatment for choice CVD's.[71] Following cardiac surgery most of the patients develop pulmonary complications which lead to increase in hospital stay and additional cost with increase morbidity.[13] Studies report that following CABG, 7.82% of patients develop pulmonary complications while 2.23%% after valvular surgery which leads to increase in hospital stay and increases morbidity rate.[25,72,73,74,75] To prevent post-operative pulmonary complications CPT is given in early post-operative phase. Now a day PEP therapy is used as an adjunct to CPT, as it shows additional effect's, such as improvement in collateral ventilation,[47,48,49] enhances the clearance of secretion,[47,48,49,50,51] amplify aerosol distribution[45,52,53] and optimise functional residual capacity which is affected in post-operative cardiac surgery condition.[45,50,54,55] Several PEP devices are available but they are expensive compare to BBPEP device which is cost-effective and easily available. As PEP therapy is a non-invasive technique used in postoperative cardiac surgery to improve clinical outcomes. In our study we compared the effect of BBPEP and Acapella in patients with open-heart surgery on Oxygenation and Peak Flow Rate.

Before conducting main study, a pilot study was conducted on "Immediate effect of Therapist made BBPEP on oxygenation in patients who undergo open-heart surgery". Study was conducted on 20 open-heart surgery patients, in which intervention group received BBPEP on POD 1 and showed statistically immediate improvement in oxygen saturation.[76] This therapist made BBPEP device is easily accessible and cost-effective. The present study also showed that BBPEP is equally effective in improving oxygen saturation among post-operative open-heart surgery when compared with Acapella.

As per our knowledge, the present study should be the first study conducted on rural population in India to see the effect of BBPEP in comparison with Acapella on Oxygenation and PEFR among the patients with open-heart surgery. FiO2, SpO2 and PEFR were taken as an outcome measure. Pre-treatment the Baseline parameters of both group of patients were equal. (Table 1) At POD 1 pre-treatment, both groups

required equal amount of FiO2 (Table 4 & Fig.10) to maintain SpO2 above 90% (Table 16 & Fig.16), while post-treatment from POD 1 to POD 3 requirement of FiO2 (Table 14 & Fig.15) significantly reduced to maintain SpO2 above 90% (Table 26 & Fig.21) in both the groups. And we found that the BBPEP shows equally effective as Acapella.

SpO2 showed significant improvement from POD 1 to 3 at low amount of FiO2 in both groups. We also found that their significant equal improvement in both the group from POD 1 to 3 in PEFR values. There was a reduction in requirement of FiO2 with significant improvement in SpO2 and PEFR in both groups due to addition of PEP Therapy.

When patient expires against the resistance of a water column, it creates PEP in tubing which transferred into the airways in patients' lungs. This PEP keeps the alveoli patent or recruit the collapsed alveoli as per EPP, EPP shifts more distally which stabilize and support the alveoli. Hence, there is decrease in the airway resistance and improvement in the lung compliance, which increases Functional Capacity and Tidal Volume (TV).[42,76,77,78] As there is decrease in the airway resistance which lead to improvement in SpO2 and PEFR.

When patient perform BBPEP, in which patient has to exhale against resistance of water column due to that there is increase in expiratory phase time with increase in expiratory flow but constant PEP or not increases PEP in hazards manner as we used tubing which has ≥8mm of inner diameter. It leads to dilate the alveoli and more air goes behind the mucus through collateral channels which dislodges the mucus towards centre. Hence there is improvement in collateral ventilation which facilitate airway clearance and prevent alveolar collapse. It ultimately results in improvement in SpO2 and PEFR.[42,56,76]

When there is exhalation against resistance of water column, it initially increases the expiratory time. Further once EPP shifts more distally there is increase in expiratory volume as there is reopening of collapsed alveoli. By using BBPEP though it increases PEP but it not reach the hazardous level as it absorbed by the lung parenchyma when it exceeds more[66] than 10 to 20 cm of H2O according to the American Association for Respiratory Care.[79] This PEP pressure is reduced in post-operative period due to anaesthesia, analgesia, etc. Hence, patient need additional ventilatory support to survive. This required pressure can be generated by using therapist made or home-made BBPEP device.[66] In present study, the experimental group

used Therapist made BBPEP which generate essential amount of PEP which further improves pulmonary function and showed decline in demand of FiO2 with improvement in SpO2 and PEFR.

In an RCT conducted by Begum Zaman, et al. on 30 CABG patients in Northeast (NE) state of India compared the effect of Deep Breathing Exercises with PEP Device (Group A) with Incentive Spirometry with EPAP (Group B) for prevention of postoperative pulmonary complications and found significant improvement in Group A when compared to Group B in SpO2 and PEFR from POD 0 to 3. It was concluded that Deep Breathing Exercises with PEP Device are more effective in improving SpO2 and PEFR than EPAP and Incentive Spirometry in postoperative CABG patients.[40] Our present study also showed that BBPEP group also has significant improvement in SpO2 and PEFR in postoperative patients.

Similarly, an RCT was conducted in conducted in Swedish population by Charlotte Urell et al., at Uppsala University, Sweden on cardiac surgery patients in which higher rate of deep breathing with PEP device were given to improve PaO2 and SpO2 in early postoperative days. It was found that there is significant improvement in PaO2 and SpO2 in patients who had performed higher rate of deep breathing with PEP device. She further states that, the initial POD 1 and 2 are the critical phase to prevent or to minimize the postoperative pulmonary complications after cardiac surgery. The author suggests that, by using PEP device there is recruitment of alveoli and augmentation of lung tissue due to increase in lung volume. Hence author concluded that, PEP device can be use in alteration to other non-invasive ventilation techniques or devices after cardiac surgery to prevent or to reduce postoperative pulmonary complications.[41] The existing study was conducted in rural population of India in which, we found that by using therapist made or homemade, cost-effective BBPEP device in early post-operative phase of cardiac surgery to improve oxygenation showed significant improvement in SpO2 due to recruitment of alveoli.

In another Swedish study conducted by Westerdahi et. al., compare the effect of three different breathing technique on cardiac surgery patients in early post-operative phase for prevention of pulmonary complications. They concluded that by using Blow Bottle there was significant improvement in parameters of pulmonary function compared with only breathing exercise group. Hence author recommended Blow Bottle after surgery to prevent pulmonary complications and also said that, this technique is cost-effective, easy to use.[80] In rural India there is negligible evidence available regarding the use of BBPEP, present study was conducted in which, we found BBPEP is not only effective in preventing pulmonary complication after open-

heart but also equally effective like Acapella to prevent pulmonary complications and improve pulmonary function in early post-operative open-heart surgery.

CHAPTER 11

CONCLUSION

This whole study showed that post-operative open-heart surgery patients, oxygen saturation improved gradually with less oxygen supply and lung function also improved by using BBPEP as well Acapella. Both devices are statistically equally effective.

BBPEP device is 70 times cheaper than Acapella and can be made with minimal resources which are easily available. Hence BBPEP Device is as effective as Acapella.

CHAPTER 12

CLINICAL IMPLICATION

BBPEP device and Acapella is equally effective in improving and preventing the pulmonary complications after open-heart surgery. As BBPEP is cost-effective. It cost only 20 cent which is less than 70 times compare to cost of Acapella. BBPEP also made from easily available material and cost-effective material so it is implicable in rural set-up to improve and to prevent pulmonary complications after surgery.

Now a days, COVID 19 disease is affecting or spreading all over world. Mainly COVID 19 affecting pulmonary function and also having high risk infection spread from one person to another person. In this COVID 19 pandemic we can use this BBPEP device to improve and to prevent pulmonary complications. We chose this BBPEP device because, it is a single user device, cost less than a dollar compares to other PEP devices and also easy to sterilize. So, it can be given in the COVID 19 patients to improve and to prevent pulmonary complications. Hence, this BBPEP Device is a device of choice in this era. To supporting this Maharashtra OTPT Council, give guidelines for "Chest Management of COVID 19 in Indian Setup" they also recommend BBPEP in COVID 19 patients to improve and to prevent pulmonary complications.

CHAPTER 13

FUTURE SCOPE

1. BBPEP can be used with a greater number of samples in different conditions. We can also compare with other PEP equipment to know and to compare its effectiveness.
2. With all this documentation we will patent this BBPEP device and available for all the population.

CHAPTER 15

ABSTRACT

Background: Worldwide people of all ages are affected by the Noncommunicable Diseases (N.C.D.) and it is a leading cause of death globally. According to the World Health Organization (WHO), 41 million people die due to noncommunicable diseases which is equal to 71% of all death globally in which cardiovascular diseases are the most common cause for death. The International Institute of Population Sciences stated that from 1990 to 2016, the contribution rate of mortality of cardiovascular diseases is increased by 34.3% in India. The more common leading cause of cardiovascular diseases are Coronary Artery Disease (CAD) and Stroke, also WHO says in 2017, CAD is the leading cause of death and which is 15.6%. To treat these critical conditions of coronary artery disease patients should undergo cardiac surgery which is known as Coronary Artery Bypass Grafting Surgery (CABG). According to the A.H.A., Cardiac Rehabilitation is a comprehensive exercise, education and behavioural modification program design to improve the physical and emotional condition of patients with heart disease. Early mobilization includes an active range of motion, thoracic mobility, bedside sitting, chair sitting, hall ambulation (chair sitting). With all these techniques, there are mechanical devices available to improve oxygenation they known as positive pressure devices such as Acapella, Flutter, Bubble-PEP, RC-Cornet. Bubble P.E.P. also used to prevent pulmonary complications in postoperative open-heart surgery patient. On the other hand, the therapist-made bubble-PEP device which is made from inexpensive and easily accessible materials consisting of a container (e.g. bottle) and tubing. Therefore, the bubble P.E.P. is relatively cheaper and readily accessible.

Aim: To compare the effect of BBPEP Device and Acapella on Oxygenation and PEFR among patients with open-heart surgery.

Objectives:

1. To compare the effect of BBPEP Device and Acapella on FiO2 and SpO2 among patients with open-heart surgery.
2. To compare the effect of BBPEP Device and Acapella on PEFR among patients with open-heart surgery.

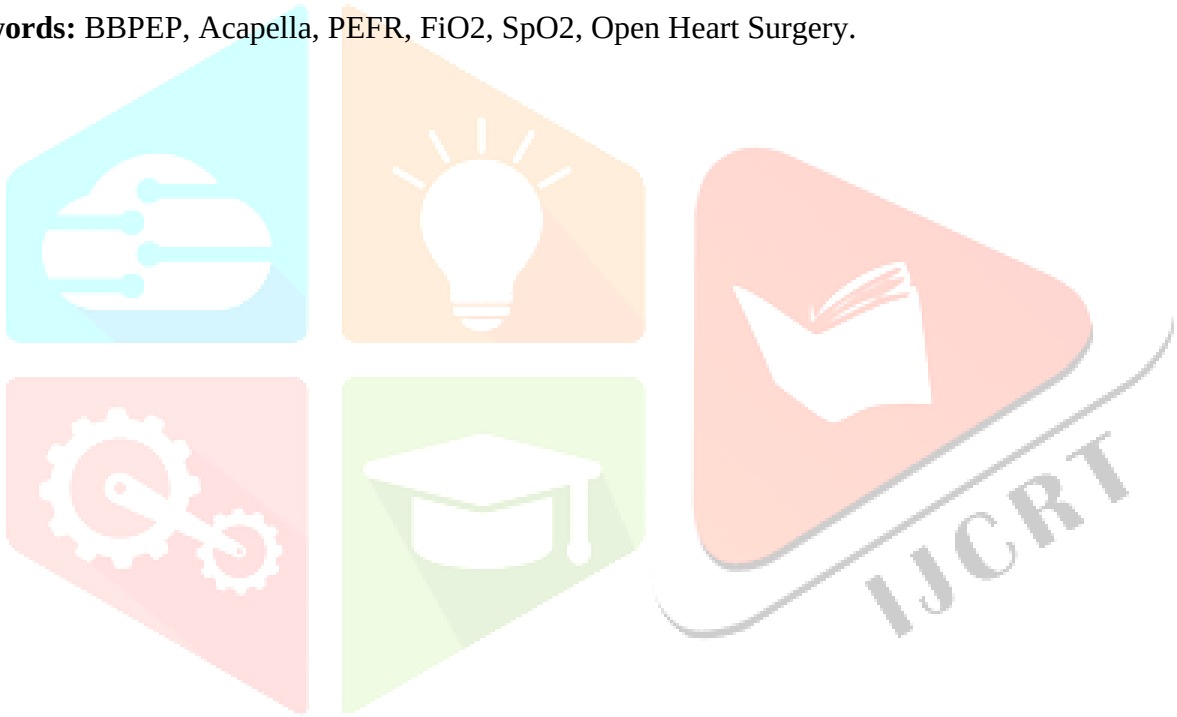
Methodology: The study done on 54 samples. Samples were randomly divided into two groups, i.e. BBPEP and Acapella group. Both the group received intervention from P.O.D. 1 to 3 twice a day. FiO2, SpO2 and PEFR were taken pre- and post-treatment in every session. Data were collected and analysis was done.

Statistical analysis: normality was checked by using Kolomogrov-Smirnov Test. Data did not pass the normality test, so a non-parametric test was used for data analysis.

Result: There was no significant difference between both groups.

Conclusion: The BBPEP and Acapella is equally effective in improving oxygenation and PEFR in the patient who undergo open-heart surgery.

Keywords: BBPEP, Acapella, PEFR, FiO2, SpO2, Open Heart Surgery.



CHAPTER 16

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CHAPTER 17

ANNEXURES

1. **Information to Participants**
2. **Consent letter in English Language**
3. **Consent letter in the Marathi Language**
4. **Screening form**
5. **Proforma**
6. **Master-Chart**
7. **CTRI**
8. **Publication**
9. **Copyright**
10. **Plagiarism**

ANNEXURE I

INFORMATION TO PARTICIPANTS

I. Investigator:

II. Project Title:

The comparison between Blow Bottle Positive Expiratory Pressure (BBPEP) device versus Acapella on Oxygenation and Peak Expiratory Flow Rate (PEFR) among patients with open heart surgery- A Randomized Control Trial.

III. Introduction:

You are invited to take part in a research study. It is important that you read this description to understand your role in it.

Please give your consent to participate in this clinical study only if you have completely understood the nature & course of this study & if you are aware of your rights as a participant.

IV. What is the purpose of this study?

The present difficulty you are facing due to your knee pain hampers your day to day activities.

Thus, in this study measure will be taken so that the pain will decrease and the main thing is that your function would also improve by performing the neuromuscular training in combination with the lateral or neutral insole. Hence, the purpose of this study is to compare the effectiveness of lateral wedge insole v/s neutral insole in combination with neuromuscular training on pain and function in patients with medial compartment osteoarthritis of the knee.

V. The Study Design:

The participant in the study will be divided randomly by a chit method into two groups and will be given treatment. The duration of the study is three days and participants included will be assessed pre and post in every treatment session.

VI. Study Procedures:

If you agree to participate in the study, all assessments will be done & if you fulfil inclusion criteria, you will be among the **54** participants, who will be given treatment in accordance to the group they have been allotted.

VII. Statistical Analysis:

After the collection of data, it will be checked for normality, and if it passes normality values, then accordingly, statistical analysis will be done.

VIII. Possible Risks to you:

No risks are involved in the study, as the treatment is non-invasive.

IX. Possible benefits to you:

By participating in this study, you may find improvement in your breathing by indirect removal of your mucus secretions. However, there is no guarantee that being in this study will definitely improve the above-mentioned symptoms.

X. Compensation:

Participation in this study will cost you nothing. No compensation will be provided for your participation.

XI. Possible benefits to other people:

The results of the research may provide benefits to the society in terms of advancement of physiotherapy knowledge and/or therapeutic benefit to prospective patients.

XII. The alternatives you have:

If you do not wish to participate in the study, you have an option of receiving the standard treatment for your condition.

XIII. Cost to the participant:

You will not be charged for the treatment in this given in this study.

XIV. Who is paying for this research?

No funding. The institution will provide the required infrastructure and other facilities required for the study.

XV. What should you do in case of injury or medical problem during this research study?

Your safety is the prime concern. There would possibly be no injury during the study. If it does, you will be provided medical care at this institute for any physical injury or illness that may occur, as a result of your participation in this study. This medical care will be at no cost to you.

XVI. Can you decide to stop participating in the study once you start?

The participation in this research is purely voluntary & you have the right to withdraw from this study any time during the course of the study without giving any reasons. However, it is advisable to talk to the research

team prior to stopping the treatment. You may be advised about how best to stop the treatment safely. Though advisable that you give the investigators the reason for withdrawing, it is not mandatory.

XXI. Contact for further information:

Thank you for taking the time to read the information about this study. Before signing this document, you may ask questions about anything that you do not understand. The study staff will answer their questions before, during & after the study.

If you have questions about the study or how it is being run, or a possible research related illness or injury, you can contact: _____ Department of Physiotherapy during office hours.

If you have questions about your rights as a research participant or complaints regarding the research study, you should call Ethical Chairman who is a Member Secretary of Committee for Academic Research Ethics during working hours.

I have read (or someone has read to me) the information provided above. I have been given an opportunity to ask questions and all of my questions have been answered to my satisfaction. I have been given a copy of this form, as well as a copy of the Subject's Bill of Rights.

BY SIGNING THIS FORM, I WILLINGLY AGREE TO PARTICIPATE IN THE RESEARCH IT DESCRIBES.

Name of Subject:

Name of Legal Representative (if applicable):

Signature of Subject or Legal Representative:

Date and Place:

ANNEXURE II

CONSENT FORM

TITLE: - "The comparison between Blow Bottle Positive Expiratory Pressure (BBPEP) device versus Acapella on Oxygenation and Peak Expiratory Flow Rate (PEFR) among patients with open heart surgery- A Randomized Control Trial."

PARTICIPANTS: - I confirm that _____ (Investigator) has explained me the purpose of the research, then procedure and possible risk and benefits that I may experience. I have read and understood this consent to participate as a subject in this research project.

Name: -

Date: -

Signature: -

INVESTIGATOR: I have explained to _____ the purpose of the research, the procedure required and the possible risk and benefits to the best of my ability. I have made every effort to make participant understand and clear all questions put forward.

Date: -

Name: -

Signature: -

ANNEXURE III

संमतीपत्र

संशोधनाचे शीर्षक: "The comparison between Blow Bottle Positive Expiratory Pressure (BBPEP) device versus Acapella on Oxygenation and Peak Expiratory Flow Rate (PEFR) among patients with open heart surgery- A Randomized Control Trial."

संशोधक: "The comparison between Blow Bottle Positive Expiratory Pressure (BBPEP) device versus Acapella on Oxygenation and Peak Expiratory Flow Rate (PEFR) among patients with open heart surgery- A Randomized Control Trial." या संशोधना विषयी सांगितले असून या , शिर्षका खालील सर्व फायदे आणि तोटे मला समजले आहेत आणि मला येणाऱ्या कुठल्याही अडचणीबाबत कुणी ही जबाबदार राहणार नाही . मी या संशोदन कार्यातसहभागी होण्यास संमती दते आहे .

सहभागी व्यक्तीचे नाव :

सहभागी व्यक्तीचे स्वाराक्षरी :

मी गृहीत धरते कि ,ज्या व्यक्ति चे हे पत्र सही केलेलेआहे , ते या संशोधना बाबत सगळे समजुन सहभागी झाले आहेत .

संशोधकाचे सही : **तारिक :**

ANNEXURE IV

SCREENING FORM

1. **Patient's Name:**
2. **Patient's Code:**
3. **Age/Gender:**
4. **I.P.D. Number:**
5. **Diagnosis:**
6. **Date:**
7. **Vitals:**
    - Heart Rate(bpm)-
    - Respiratory rate (cpm)-
    - Blood Pressure (mmHg)-
    - SpO_2(%)-
    - FiO_2(%)-
8. **Inclusion Criteria:**
    - Postoperative individuals age 20 yrs. and above.
    - Surgical approach with median sternotomy.
    - Patient with stable vitals.
    - Uncomplicated or Uneventful surgery.
    - Participants willing to participate.
9. **Exclusion Criteria:**
    - Subject with diagnosed respiratory pathology.
    - Subject who was ex-smoker or are smokers.
    - Subject already diagnosed with any neuromuscular disease which directly affects the lung functions.
10. **Withdrawal Criteria:**
    - The patient who become vitally unstable after surgery.
    - Patient who will not willing to continue treatment.

Subject Signature **Investigator Signature**

Guide Signature

ANNEXURE V

PERFORMA

Name:

Patient's Code:

Assigned Group:

Age/Gender:

Address:

I.P.D. Number:

Diagnosis:

Vitals:

	DAY 1		DAY 2		DAY 3	
	1A	1B	2A	2B	3A	3B
Heart Rate(bpm)						
Pre-Treatment						
Post Treatment						
Respiratory rate (cpm)						
Pre-Treatment						
Post Treatment						
Normal Blood Pressure(mmHg)						
Pre-Treatment						
Post Treatment						
SpO_2 (%)						
Pre-Treatment						
Post Treatment						
FiO_2						
Pre-Treatment						
Post Treatment						
PEFR						
Pre-Treatment						
Post Treatment						

Subject Signature **Investigator Signature**

Guide Signature

ANNEXURE VI

MASTER CHART

BBPEP						Baseline Characteristics			
Sr. No.	Assigned Gr.	Pt Code	Age	Gender	Diagnosis	HR	RR	SPO2	NBP
						bpm	cpm	%	mmHg
1	BBPEP Gr.	1	62	F	CABG	75	20	95	104/70
2	BBPEP Gr.	3	55	M	CABG	95	26	96	110/60
3	BBPEP Gr.	5	70	F	CABG	96	19	95	89/60
4	BBPEP Gr.	7	60	F	CABG	70	21	95	121/60
5	BBPEP Gr.	9	52	F	CABG	71	16	94	130/65
6	BBPEP Gr.	11	59	F	VSD Closure	97	17	95	112/67
7	BBPEP Gr.	13	41	M	AVR	96	19	95	100/70
8	BBPEP Gr.	15	40	F	MVR	65	21	96	140/70
9	BBPEP Gr.	17	65	M	CABG	90	15	95	109/80
10	BBPEP Gr.	19	65	M	CABG	70	19	95	110/60
11	BBPEP Gr.	21	55	F	CABG + MVR	70	15	95	121/60
12	BBPEP Gr.	23	60	F	CABG	90	19	95	127/80
13	BBPEP Gr.	25	65	F	CABG	77	21	96	105/70
14	BBPEP Gr.	27	72	M	CABG	75	25	97	125/81
15	BBPEP Gr.	29	49	M	CABG	70	21	95	115/70
16	BBPEP Gr.	31	69	M	CABG	90	20	95	112/66
17	BBPEP Gr.	33	45	M	MVR	85	16	95	124/76
18	BBPEP Gr.	35	52	M	CABG	80	18	96	120/75
19	BBPEP Gr.	37	55	M	CABG	77	26	95	110/68
20	BBPEP Gr.	39	70	F	CABG + MVR	97	21	96	109/75
21	BBPEP Gr.	41	27	F	MVR	75	22	95	120/79
22	BBPEP Gr.	43	55	F	MVR	66	17	95	131/75
23	BBPEP Gr.	45	61	M	CABG + MVR	71	14	95	129/70
24	BBPEP Gr.	47	29	F	MVR	90	15	96	101/70
25	BBPEP Gr.	49	66	F	CABG	80	27	96	116/73
26	BBPEP Gr.	51	65	M	CABG	82	30	95	121/60
27	BBPEP Gr.	53	55	M	CABG	90	15	95	104/79

POD 1 (Morning)						POD 1 (Afternoon)					
1A Pre			1A Post			1B Pre			1B Post		
FiO2	SPO2	PEFR	FiO2	SPO2	PEFR	FiO2	SPO2	PEFR	FiO2	SPO2	PEFR
12	95	200	10	95	100	10	95	100	8	96	100
12	96	100	10	96	200	10	96	200	8	97	250
13	95	100	13	94	100	10	94	150	8	95	100
13	95	100	13	95	100	10	95	150	8	95	100
12	94	100	12	94	100	10	94	150	8	96	100
10	95	150	10	95	100	10	95	150	8	96	100
12	95	100	10	95	150	10	95	150	8	95	150
10	96	150	10	93	100	10	93	100	8	94	100
13	95	200	10	95	150	10	95	150	8	95	150
13	95	150	13	94	200	10	94	200	8	95	200
10	95	100	10	95	150	10	95	150	8	95	150
13	95	100	13	95	100	10	95	100	8	96	100
13	96	200	13	94	100	10	94	100	8	95	100
10	97	150	10	94	200	10	94	200	8	95	200
13	95	150	10	95	150	10	95	150	8	95	150
13	95	150	10	93	150	10	93	150	8	95	150
13	95	200	13	95	150	10	95	150	8	95	150
13	96	150	13	96	200	10	96	200	8	96	200
13	95	100	13	95	150	10	95	150	8	96	150
10	96	100	10	94	100	10	94	100	8	95	100
10	95	100	10	95	100	10	95	100	8	95	100
10	91-95	150	8	94	100	8	94	100	6	95	100
13	95	100	10	94	150	10	94	150	8	95	150
13	96	100	10	95	100	10	95	100	8	95	100
13	96	100	10	93	100	10	95	100	8	94	100
13	95	200	10	94	200	10	94	200	8	95	200
13	95	200	10	95	200	10	95	200	8	95	200

POD 2 (Morning)						POD 2 (Afternoon)					
2A Pre			2A Post			2B Pre			2B Post		
FiO2	SPO2	PEFR	FiO2	SPO2	PEFR	FiO2	SPO2	PEFR	FiO2	SPO2	PEFR
8	96	200	6	95	150	6	95	150	4	96	150
8	96	300	6	97	300	6	95	300	4	98	350
8	95	200	10	96	200	10	95	250	8	95	250
8	95	150	6	96	150	6	94	150	4	96	200
8	96	200	6	97	200	6	96	200	4	98	200
8	95	200	6	96	200	6	95	200	4	96	200
8	95	150	10	96	150	10	93	150	8	94	150
8	95	150	6	95	150	6	95	150	4	95	150
8	95	200	6	96	200	6	95	200	4	96	200
8	94	200	10	95	200	10	94	200	8	95	250
8	95	150	6	96	150	6	94	150	4	96	200
8	95	150	8	96	150	8	95	150	6	96	150
8	94	150	6	95	150	6	94	150	4	95	150
8	95	200	6	95	200	6	94	200	4	94	200
8	95	200	6	96	200	6	93	200	4	96	200
8	94	150	6	96	150	6	95	150	4	96	200
8	94	150	6	96	150	6	94	150	4	95	150
8	95	200	6	96	200	6	95	200	8	95	250
8	95	150	10	96	150	10	96	150	8	97	150
8	94	150	6	97	150	6	96	150	6	96	150
8	95	100	6	96	100	6	94	100	4	95	100
6	94	150	6	95	150	6	94	150	4	96	150
8	95	150	6	96	150	6	95	150	4	96	200
8	95	100	6	96	100	6	96	100	4	97	150
8	95	100	6	97	100	6	95	100	4	98	100
8	94	250	6	96	250	6	96	250	4	96	250
8	95	200	6	96	200	6	95	250	4	98	250

POD 3 (Morning)						POD 3 (Afternoon)					
3A Pre			3A Post			3B Pre			3B Post		
FiO2	SPO2	PEFR	FiO2	SPO2	PEFR	FiO2	SPO2	PEFR	FiO2	SPO2	PEFR
4	95	200	2	95	300	2	97	300	2	96	300
4	96	350	2	98	350	2	98	350	0	100	400
8	95	250	6	97	300	6	96	300	2	100	350
4	98	200	2	100	250	2	99	250	4	100	300
4	98	200	2	98	200	2	98	250	0	100	300
4	95	200	2	96	250	2	96	250	0	99	300
8	95	200	6	96	250	6	96	250	2	98	300
4	95	150	2	99	200	2	100	200	1	100	250
4	96	250	2	98	250	2	99	250	0	95	300
8	94	250	6	95	250	6	95	250	4	97	250
4	96	200	2	98	250	2	98	250	0	100	250
6	94	150	4	96	150	4	95	150	1	100	200
4	93	150	2	97	200	2	96	200	2	99	250
4	95	250	2	97	300	2	96	300	0	100	400
4	96	200	2	97	250	2	97	250	2	99	300
4	94	200	2	98	200	2	96	200	0	100	300
4	95	150	4	98	200	4	95	200	2	97	250
8	91	250	6	95	250	6	94	250	4	96	250
8	94	150	4	96	200	4	95	200	1	100	300
6	95	150	4	97	200	4	96	200	2	98	250
4	94	100	2	95	250	2	95	250	0	100	350
4	95	150	2	98	200	2	96	200	0	98	250
4	94	200	2	95	200	2	95	200	0	99	250
4	95	150	2	100	200	2	97	200	0	99	300
4	96	100	2	98	200	2	98	200	0	100	250
4	95	250	2	98	250	2	97	250	0	98	300
4	96	250	2	98	250	2	98	250	0	100	350

Acapella						Baseline Characteristics			
Sr. No.	Assigned Gr.	Pt Code	Age	Gender	Diagnosis	HR	RR	SPO2	NBP
						bpm	cpm	%	mmHg
1	Acapella Gr.	2	65	F	CABG	76	21	94-95	101/64
2	Acapella Gr.	4	65	F	ASD Closure	74	30	96	129/70
3	Acapella Gr.	6	65	M	CABG	92	20	94	116/73
4	Acapella Gr.	8	75	M	CABG	85	16	95	112/64
5	Acapella Gr.	10	37	M	CABG	63	30	94	150/60
6	Acapella Gr.	12	65	M	CABG	90	21	94	104/64
7	Acapella Gr.	14	67	M	CABG	90	20	91-90	131/75
8	Acapella Gr.	16	58	M	CABG	86	23	95	116/69
9	Acapella Gr.	18	65	M	CABG	82	14	93	105/71
10	Acapella Gr.	20	75	M	CABG	80	19	93	112/68
11	Acapella Gr.	22	75	M	CABG	100	19	94	101/69
12	Acapella Gr.	24	36	M	DVR	76	21	95	120/75
13	Acapella Gr.	26	73	F	CABG	82	20	94	102/67
14	Acapella Gr.	28	35	F	ASD	86	20	94	126/70
15	Acapella Gr.	30	54	M	CABG	93	15	95	116/70
16	Acapella Gr.	32	65	M	CABG	72	12	95	112/79
17	Acapella Gr.	34	75	F	CABG	94	20	93	103/65
18	Acapella Gr.	36	50	M	CABG	90	16	91	120/79
19	Acapella Gr.	38	45	M	MVR	84	13	95	104/62
20	Acapella Gr.	40	40	M	CABG	92	22	95	104/64
21	Acapella Gr.	42	64	F	CABG	79	20	95	100/79
22	Acapella Gr.	44	56	M	CABG	72	20	95	120/67
23	Acapella Gr.	46	74	M	CABG	80	16	95	110/60
24	Acapella Gr.	48	30	M	CABG	92	15	94	121/64
25	Acapella Gr.	50	60	F	MVR	60	19	95	102/70
26	Acapella Gr.	52	65	F	CABG	71	16	94	116/73
27	Acapella Gr.	54	75	F	CABG	72	20	95	100/68

POD 1 (Morning)						POD 1 (Afternoon)					
1A Pre			1A Post			1B Pre			1B Post		
FiO2	SPO2	PEFR	FiO2	SPO2	PEFR	FiO2	SPO2	PEFR	FiO2	SPO2	PEFR
12	95	100	10	95	100	10	95	150	8	95	200
12	96	100	10	97	100	10	96	150	8	94	150
13	95	100	10	95	200	10	95	250	8	97	250
13	95	150	10	95	150	10	95	200	8	95	200
12	96	200	10	95	200	10	95	250	8	95	250
10	95	100	10	95	100	10	95	200	8	97	200
12	95	150	10	95-94	150	10	100	150	8	99	150
10	95	150	8	97	150	8	97	150	6	97	150
13	95	150	8	94	150	8	95	200	6	96	200
13	96	200	10	96	200	10	95	200	8	96	200
10	94	200	10	99	200	10	95	250	8	95	250
13	95	150	10	95	150	10	95	150	8	96	150
13	96	100	10	95	100	10	94	100	8	95	100
10	94	100	10	96	100	10	95	100	8	95	100
13	95	200	10	95	200	10	94-93	200	8	95	200
Excluded						Excluded					
13	93	150	10	96	150	10	95	150	8	95	150
13	95	150	10	94	150	10	94-93	150	8	94	150
13	95	200	10	95	200	10	95-94	250	8	96	250
13	95	150	10	95	150	10	95	150	8	95	150
10	95	100	10	96	100	10	95	100	8	95	100
10	95	200	10	95	200	10	94	200	8	94	200
10	95	150	10	95	200	10	95	200	8	95	200
13	95	250	10	95	250	10	95	250	8	96	250
13	96	100	10	95	100	10	94	100	8	96	100
13	95	100	10	97	100	10	95	100	8	96	100
13	95	100	10	95	100	10	95	200	8	98	200

POD 2 (Morning)						POD 2 (Afternoon)					
2A Pre			2A Post			2B Pre			2B Post		
FiO2	SPO2	PEFR	FiO2	SPO2	PEFR	FiO2	SPO2	PEFR	FiO2	SPO2	PEFR
8	95	200	6	98	250	6	94	250	4	98	250
8	94	150	6	98	200	6	94	200	4	97	200
8	93	250	6	97	300	6	92	300	4	96	300
8	95	200	6	98	250	6	95	250	6	98	250
8	93	250	6	95	300	6	95	300	4	96	300
8	94	200	6	95	200	6	91	200	4	94	200
8	100	150	6	94	200	6	95	200	4	94	200
6	98	150	4	100	200	4	98	200	2	100	200
6	94	200	4	99	250	4	94	250	4	100	250
8	95	200	6	96	200	6	94	200	4	96	200
8	95	250	6	98	250	6	94	250	4	98	250
8	95	150	6	96	200	6	94	200	4	98	200
8	94	100	6	97	150	6	95	150	4	99	200
8	95	100	6	97	150	6	96	150	4	98	200
8	91	200	6	94	250	6	91	250	4	95	250
Excluded						Excluded					
8	94	150	6	96	200	6	94	200	4	98	250
8	94	150	6	97	200	6	95	200	4	96	200
8	94	250	6	95	250	6	94	250	4	97	250
8	94	150	6	96	200	6	95	200	4	98	250
8	95	100	6	100	200	6	94	200	6	96	200
8	95	200	6	98	200	6	94	200	4	98	250
8	95	200	6	100	250	6	95	250	4	96	250
8	95	250	6	96	300	6	95	300	4	99	300
8	94	100	6	100	200	6	94	200	4	98	200
8	95	100	6	95	150	6	94	150	4	96-100	200
8	95	200	6	100	250	6	95	250	4	98	300

POD 3 (Morning)						POD 3 (Afternoon)					
3A Pre			3A Post			3B Pre			3B Post		
FiO2	SPO2	PEFR	FiO2	SPO2	PEFR	FiO2	SPO2	PEFR	FiO2	SPO2	PEFR
4	95	250	2	95	300	2	97	300	0	98	350
4	98	200	2	98	250	2	99	250	0	100	300
4	95	300	2	95	300	2	96	300	1	99	350
6	95	250	4	96	300	4	99	300	1	99	350
4	98	300	2	99	300	2	99	300	0	100	350
4	96	200	2	96	250	2	97	250	0	95	300
4	94	200	2	95	200	2	91	200	0	96	300
2	100	200	2	99	250	2	100	250	0	98	300
2	98	250	2	100	300	2	98	300	0	100	300
4	94	200	2	95	250	2	100	250	0	98	300
4	96	250	2	98	300	2	98	300	0	98	350
4	95	200	2	99	300	2	99	300	0	100	350
4	95	200	2	100	300	2	100	300	0	100	400
4	95	200	2	100	250	2	99	250	1	99	300
4	91	250	2	95	300	2	97	300	1	98	350
Excluded						Excluded					
4	94	250	2	98	300	2	96	300	1	100	400
4	94	200	2	96	300	2	96	300	0	99	300
4	95	250	2	98	300	2	95	300	2	100	350
4	96	250	2	100	350	2	99	350	0	99	400
6	94	200	2	100	300	2	96	300	2	100	300
4	96	250	2	100	300	2	96	300	2	100	300
4	94	250	2	100	300	2	95	300	2	100	350
4	95	300	2	100	300	2	99	300	0	100	300
4	97	200	2	100	300	2	100	300	0	100	350
4	94	200	2	100	250	2	98	250	0	100	300
4	96	300	2	100	300	2	100	300	0	100	400

ANNEXURE VII

CLINICAL TRIALS REGISTRY - INDIA

CLINICAL TRIALS REGISTRY - INDIA
ICMR - National Institute of Medical Statistics

PDF of Trial
CTRI Website URL - http://ctri.nic.in

Clinical Trial Details (PDF Generation Date :- Sun, 19 Jul 2020 07:56:52 GMT)

CTRI Number	CTRI/2019/07/020462 [Registered on: 31/07/2019] - **Trial Registered Prospectively**
Last Modified On	19/07/2020
Post Graduate Thesis	Yes
Type of Trial	Interventional
Type of Study	Physiotherapy (Not Including YOGA)
Study Design	Other
Public Title of Study	comparison of blow bottle pep and acapella on oxygen extent and measuring value of how fast a person can exhale in open heart surgery patient.
Scientific Title of Study	The comparison between Blow Bottle Positive Expiratory Pressure (BBPEP) device versus Acapella on Oxygenation and Peak Expiratory Flow Rate (PEFR) among patients with open heart surgery- A Comparative Study.

Secondary IDs if Any

Secondary ID	Identifier
NIL	NIL

Details of Principal Investigator or overall Trial Coordinator (multi-center study)

Details of Principal Investigator	
Name	Abhaya Sanjay Mahadik
Designation	MPT Student
Affiliation	DVVPFs COPT, Ahmednagar.
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Details Contact Person (Scientific Query)

Details Contact Person (Scientific Query)	
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Details Contact Person (Public Query)	
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page 1 / 4

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Source of Monetary or Material Support

Source of Monetary or Material Support
> none

Primary Sponsor

Primary Sponsor Details	
Name	Dr Vithalrao Vikhe Patil Foundations College of Physiotherapy
Address	r. Vitthalarao Vikhe Patil Foundations College Of Physiotherapy, Department Of Cardiovascular and Respiratory Sciences, Opp. to Govt. Milk Dairy, Vilad Ghat, Ahmednagar.
Type of Sponsor	Private medical college

Details of Secondary Sponsor

Name	Address
NIL	NIL

Countries of Recruitment

List of Countries
India

Sites of Study

Name of Principal Investigator	Name of Site	Site Address	Phone/Fax/Email
Abhaya Sanjay Mahadik	DVVPFS Memorial Hospital.	Cardiac Surgery Unit, Opp. to Govt. Milk Dairy, Vilad Ghat, Ahmednagar, 414111. Ahmadnagar MAHARASHTRA	9022393871 mahadikabhaya19@gmail.com

Details of Ethics Committee

Name of Committee	Approval Status	Date of Approval	Is Independent Ethics Committee?
Institutional Ethical Commite	Approved	29/01/2019	Yes

Regulatory Clearance Status from DCGI

Status	Date
Not Applicable	No Date Specified

Health Condition / Problems Studied

Health Type	Condition
Patients	Pulmonary collapse

Intervention / Comparator Agent

Type	Name	Details
Intervention	structured physiotherapy protocol	Group B or BBPEP Group- Patient with open heart surgery will be receiving conventional physiotherapy treatment after open heart surgery will be Active Range of Motion, Deep Breathing Exercise, Incentive Spirometer, Splinted Coughing and Ambulation along with BBPEP.• Total 10 sets of repetitions.

Comparator Agent	structured physiotherapy protocol	Acapella group- Patient receiving conventional physiotherapy treatment after open heart surgery will be Active Range of Motion, Deep Breathing Exercise, Incentive Spirometer, Splinted Coughing and Ambulation along with Acapella, for 15 mins.

Inclusion Criteria

Inclusion Criteria	
Age From	20.00 Year(s)
Age To	90.00 Year(s)
Gender	Both
Details	1 Post-operative individuals age 20 yrs. and above. 2 Surgical approach with median sternotomy. 3 Patient with stable vitals. 4 Uncomplicated or Uneventful surgery. 5 Participants willing to participate.

Exclusion Criteria

Exclusion Criteria	
Details	• Subject with diagnosed respiratory pathology. • Subject who were ex-smoker or are smokers. • Subject already diagnosed with any neuromuscular disease which directly affects the lung functions.

Method of Generating Random Sequence	Coin toss, Lottery, toss of dice, shuffling cards etc
Method of Concealment	
Blinding/Masking	Not Applicable

Primary Outcome

Outcome	Timepoints
1 Fraction of Inspired Oxygen (FiO2) 2 Oxygen Saturation(SpO2) 3 Peak Expiratory Flow Rate	outcomes will be taken pre treatment and 20 mins after treatment.

Secondary Outcome

Outcome	Timepoints
nil	nil

Target Sample Size	**Total Sample Size=**57 **Sample Size from India=**57 **Final Enrollment numbers achieved (Total)=**54 **Final Enrollment numbers achieved (India)=**54
Phase of Trial	N/A
Date of First Enrollment (India)	20/08/2019
Date of First Enrollment (Global)	No Date Specified
Estimated Duration of Trial	**Years=**1 **Months=**6 **Days=**0
Recruitment Status of Trial (Global)	Not Applicable
Recruitment Status of Trial (India)	Completed
Publication Details	Pilot study published on 28th Feb. 2020 in "International Journal of Current Research." Study Title:

	Immediate effect of Blow Bottle Positive Expiratory Pressure Device (BBPEP) on oxygen saturation in patients who underwent open heart surgery- A Randomised Pilot Study.
Brief Summary	To find out the effect of BBPEP technique in compare to Acapella in improvement of oxygenation and PEFR values among patient with open heart surgery. Study protocol was approved from the Institutional Ethical Committee. 60 patients were screened for study protocol and 54 patients selected according to inclusion and exclusion criteria. The study protocol was explained to patients and written consent was taken. Patients were divided into BBPEP and Acapella Group by using chit method. Patient assigns for study protocol from Post-operative Day (POD) 1 to POD 3 and received treatment twice a daily. Then the SpO_2, PEFR, FiO2 and the vitals of the patient will be taken and intervention will be given. Before treatment demographic data and vitals and values of FiO2, SpO2 and PEFR were noted. After that BBPEP and Acapella both groups received treatment and again FiO2, SpO2 and PEFR values were noted. Group A or Acapella group- After initial assessment patient received Conventional Physiotherapy Treatment (CPT) which include Active Range of Motion Exercise for 10 repetitions, Deep Breathing Exercises: 3 sets of 10 breaths with 5 sec hold and 1 min of rest period in between each set, Incentive Spirometer 10 breaths, Acapella and Bed ambulation on POD 3. Group B or BBPEP group- After an initial assessment, the BBPEP group received CPT which include Active Range of Motion Exercise for 10 repetitions, Deep Breathing Exercises: 3 sets of 10 breaths with 5-sec hold and 1 min of a rest period in between each set, Incentive Spirometer 10 breaths, BBPEP: 10 sets of 10 breaths with 5-sec hold and 1 min of a rest period in between each set followed by Huff and Bed ambulation on POD 3. Total calculated sample size was 54. It divided into two groups BBPEP and Acapella group. Each group contained 27 samples with 10% of attrition rate. Total 60 patients were screened in which according to the inclusion and exclusion criteria 54 samples were selected. 1 patient was excluded from the acapella group during study as he developed complications. Total 53 patients (27 in BBPEP group and 26 in Acapella group) received the intervention and were included for data analysis. This study showed that BBPEP is equally effective compare to Acapella on Oxyegenation and Peak Expiratory Flow Rate in patient who undergo open-heart surgery. BBPEP device is easily available and cost-effective device. In rural population it is eaisly available and everyone can used it.

ANNEXURE VIII

PUBLICATION

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INTERNATIONAL JOURNAL OF CURRENT RESEARCH

International Journal of Current Research
Vol. 12, Issue, 02, pp.10112-10115, February, 2020

DOI: https://doi.org/10.24941/ijcr.37982.02.2020

RESEARCH ARTICLE

IMMEDIATE EFFECT OF BLOW BOTTLE POSITIVE EXPIRATORY PRESSURE (BBPEP) DEVICE ON OXYGEN SATURATION IN PATIENTS WHO UNDERWENT OPEN HEART SURGERY- A RANDOMIZED PILOT STUDY

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Key Words:
BBPEP,
Open Heart Surgery,
Oxygen Saturation.

ABSTRACT

Background: Open heart surgery patients usually develop pulmonary complications such as atelectasis, pneumoniain early postoperative period. Literature reported that to prevent or reduce these complications we can use Positive Expiratory Pressure (PEP) therapy techniques with Conventional Physiotherapy Treatment (CPT). **Methods:** The study design was Randomized Pilot Study. 20 patients included (n=20), 10 patients in each group, Control and Interventional group. Control Group received CPT while Interventional Group received CPT with Blow Bottle PEP (BBPEP) on Post-operative Day (POD) 1 and 2, twice a day and oxygen saturation noted pre and post treatment. Unpaired-t test was used. **Result:** The therapist made cost-effective and easily BBPEP therapy showed a short-term improvement in oxygen saturation with significant p-value 0.03. **Conclusion:** BBPEP device is effective in improving oxygenation in early POD i.e. on 1st and 2nd after open-heart surgery.

Citation: ***Abhaya S. Mahadik, Arijit Kumar Das, Abhijit D. Diwate.*** **2020.** "Immediate effect of blow bottle positive expiratory pressure (bbpep) device on oxygen saturation in patients who underwent open heart surgery- a randomized pilot study", *International Journal of Current Research*, 12, (02), 10112-10115.

ANNEXURE IX

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Government of India

सत्यमेव जयते

Extracts from the Register of Copyrights

Dated : 24/03/2021

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2.	Name, address and nationality of the applicant	:	ABHAYA MAHADIK , A/P SAINAGAR RAHURI FACTORY-413706 INDIAN DR. ABHIJIT D. DIWATE , DR. VITHALRAO VIKHE PATIL FOUNDATION'S COLLEGE OF PHYSIOTHERAPY, VADGAON GUPTA, MIDC, AHMEDNAGAR.-414111 INDIAN DR. ARIJIT K. DAS , DR. VITHALRAO VIKHE PATIL FOUNDATION'S COLLEGE OF PHYSIOTHERAPY, VADGAON GUPTA, MIDC, AHMEDNAGAR.-414111 INDIAN
3.	Nature of the applicant's interest in the copyright of the work	:	AUTHOR
4.	Class and description of the work	:	LITERARY/ DRAMATIC WORK
5.	Title of the work	:	BLOW BOTTLE POSITIVE END EXPIRATORY PRESSURE DEVICE (BBPEP)
6.	Language of the work	:	ENGLISH
7.	Name, address and nationality of the author and if the author is deceased, date of his decease	:	ABHAYA MAHADIK , A/P SAINAGAR RAHURI FACTORY-413706 INDIAN DR. ABHIJIT D. DIWATE , DR. VITHALRAO VIKHE PATIL FOUNDATION'S COLLEGE OF PHYSIOTHERAPY, VADGAON GUPTA, MIDC, AHMEDNAGAR.-414111 INDIAN DR. ARIJIT K. DAS , DR. VITHALRAO VIKHE PATIL FOUNDATION'S COLLEGE OF PHYSIOTHERAPY, VADGAON GUPTA, MIDC, AHMEDNAGAR.-414111 INDIAN
8.	Whether the work is published or unpublished	:	PUBLISHED
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DEPUTY REGISTRAR OF COPYRIGHTS

Therapist made Blow Bottle Positive Expiratory Pressure (BBPEP) Device

Therapist made Blow Bottle Positive End Expiratory Pressure (BBPEP) device work on same mechanism of other commercial PEP devices and also used to prevent pulmonary complications. Commercial devices are expensive but this BBPEP made from inexpensive and easily accessible materials consisting of a container (e.g. bottle) and tubing. Since the bubble PEP is relatively cheaper and readily accessible. So, the people who unable to take the commercial devices they can easily use this BBPEP device. This BBPEP device help adults or children who have a build-up of secretions in their lungs and struggle to clear them.

The Therapist made Blow Bottle Positive End Expiratory Pressure device made up of plastic container (height 25 cm, width 10 cm) with an open top (so there will no pressure except atmospheric pressure against the air escaping from the tube) with an inner diameter of 8mm.

BBPEP Device

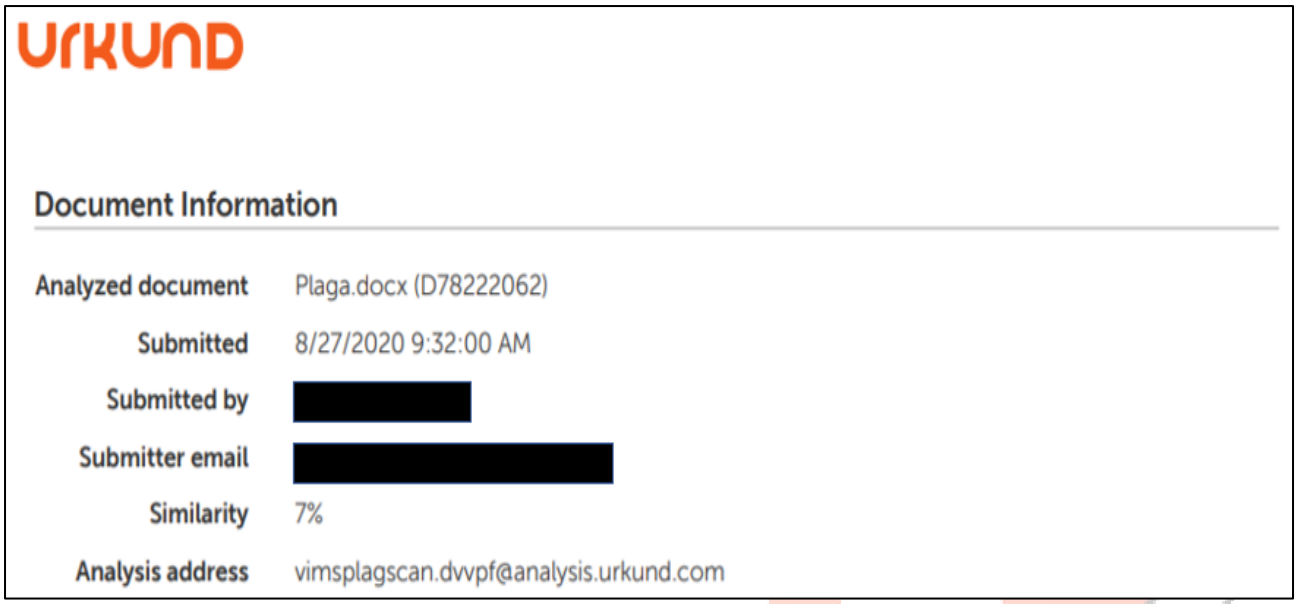
Patient Using BBPEP

Authors:

Abhaya Mahadik
Abhijit D. Diwate
Arijit K Das

ANNEXURE X

PLAGARISM



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