ROLE OF THE NEW P_aO_2/ (F_iO_2 X PEEP) [P/FP] RATIO AND STATIC LUNG COMPLIANCE IN FAST TRACKING CARDIAC SURGERY

Dr. HARI DEV J J

DM THESIS

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SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM

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A THESIS SUBMITTED BY

Dr. HARI DEV J J

TO

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM.

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE AWARD OF

Doctorate in Medicine in Cardio-Thoracic and Vascular Anaesthesiology

2021-2023

DECLARATION BY THE STUDENT

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I, Dr. Hari Dev J J, hereby certify that I had personally carried out the work depicted in the thesis titled, ***"ROLE OF THE NEW P_aO_2 / (F_i O_2 X PEEP) [P/FP] RATIO AND STATIC LUNG COMPLIANCE IN FAST TRACKING CARDIAC SURGERY."***

No part of this thesis has been submitted for the award of any other degree or diploma prior to this date.

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Date: 25th July 2023 **Dr. Hari Dev J J**

Place: Trivandrum Senior resident, SCTIMST

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SYNOPSIS

BY

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For DM Cardiothoracic and Vascular Anesthesia

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TRIVANDRUM

SYNOPSIS

Fast-tracking in cardiac surgery essentially deals with early weaning from mechanical ventilation and extubating the patient within 6-8 hours of surgery. In order to achieve fast-tracking, careful planning, patient selection, assessment and implementation of strategies that results in early awakening, de-intensification and transfer of the patient from ICU is necessary. This requires careful planning and assessment in the perioperative period so that the fast-track pathways does not compromise the patient safety in terms of morbidity and mortality.

In anesthesia and critical care, especially in the post cardiac -surgery milieu, there are no objective methods that can assess a patient's feasibility to be fast-tracked perioperatively. As the end point of fast-tracking essentially involves early weaning and tracheal extubation, this would essentially mean parameters that can predict weaning and extubation failures postoperatively. As cardiac surgery involves the use of cardiopulmonary bypass, known to cause systemic inflammatory response syndrome due to the extracorporeal circuit, pulmonary infiltrates and free radical injury initiates hypoxemia postoperatively and varying degrees of lung collapse, atelectasis and consolidation, pneumothorax and effusion (postoperative pulmonary complications) are extremely common can reduce static lung compliance postoperatively. Static lung compliance is the change in lung volume per unit change in pressure and its reduction can lead to delayed weaning from mechanical ventilation and hence prevent fast-tracking.

In the search for such objective parameters, P/F ratio which is commonly used in critical practices was considered. Due to the postoperative pulmonary complications – post cardiac surgery, it is a routine to apply positive end expiratory pressure (PEEP) during mechanical ventilation postoperatively to recruit the lungs and improve oxygenation.

The P/F ratio, especially in the setting of cardiac surgery, cannot adequately reflect the severity of disease.as it doesn't include PEEP. PaO2/ (FiO2 X PEEP) (P/FP Ratio) is a new formula which addresses this gap to appropriately calculate the severity of the disease by including PEEP in the formula. No research about application of this formula in the cardiac surgery setting is available and hence we decided to evaluate its usefulness along with Static lung compliance in predicting the patient's oxygenation status, need for respiratory support and pulmonary complications after cardiac surgery and hence help in decision makingin fast-tracking

A prospective observational study was carried out in the adult cardiac surgery ICU on 120 patients meeting the inclusion criteria. In the cardiac surgery intensive care unit (ICU), the P/FP ratios were calculated by incorporating PaO2 (from arterial blood gas analysis), FiO2 and the set PEEP from the ventilator, at the following time points: 1. immediately after ICU admission post-surgery, 2. after 1 hour and 3. 10 minutes before extubation. Static lung compliance was calculated from ventilator at 1 hour after receiving the patient in the ICU.

Patients were observed in the ICU for the following:1. any additional requirement of non-invasive ventilatory (NIV) support after extubation, 2. tracheal reintubations 3. any postoperative pulmonary complications documented radiologically. The P/FP ratio of $\leq$ 150 at 1-hour post-ICU admission was significantly associated with post-extubation NIV requirement ($p<0.001$) but not with the postoperative pulmonary complications (p value). The static lung compliance $\leq$ 24.6 ml/cm H0 at 1 hour post ICU admission was significantly associated with both post-extubation NIV requirement ($p<0.001$) and postoperative pulmonary complications ($p<0.001$).

To conclude the new P/FP ratio and static lung compliance can predict the requirement of non-invasive ventilatory support after extubation and development of postoperative pulmonary complications in patients undergoing cardiac surgery. These pulmonary parameters can be considered for inclusion in the existing fast-track protocols to predict fast-track failure in the cardiac surgery ICUs.

INTRODUCTION

INTRODUCTION

Containment of cost and expenditure with efficient resource utilisation have forced the pendulum back to the debate of early tracheal extubation in cardiac surgical patients and the evolution of fast-track anaesthesia care.[1] The pressure to reduce costs resulted from market forces and health care reforms with implementation of health insurance in the early 1990s which forced the clinicians to perform a greater number of cases with existing resources.[2] This gradually paved the way for fast-tracking in all fields of surgical specialities especially cardiac surgery without compromising outcomes in terms of mortality, morbidity and quality of life.[3,4]

Fast-tracking in cardiac surgery is a complex intervention involving several components of cardiac perioperative care, with the ultimate aim of early extubation after surgery, to reduce length of stay in the intensive care unit and in the hospital. Fast-track cardiac anaesthesia is defined as a perioperative anaesthetic approach that aims to facilitate tracheal extubation of patients within six hours after cardiac surgery. Most cardiac centres consider fast track extubation as tracheal extubation within 8 to 10 hours post- cardiac surgery.[5]

Fast- track cardiac surgery is a process of care, that involves a multidisciplinary approach aimed to improve the efficiency of care in cardiac surgical patients in which early extubation is a major key to the success.[4,5] The clinical approach for fast-tracking starts preoperatively which involves identification of the patients and their optimisation and continues in the intraoperative period and postoperatively.

Criteria for weaning the patient from mechanical ventilation and extubation are always individualised and depends on many factors especially the cardiorespiratory, neurological, metabolic and hemodynamic status.[6] As tracheal extubation after cardiac surgery usually happens in the post cardiac surgery ICU, there need to be certain parameters which would guide the clinician to early wean and extubate a post- cardiac surgery patient. One of such parameters is the P/F ($P_aO2/FiO2$) ratio, used commonly in anaesthesia and critical care practices. P/F ($P_aO2/FiO2$) ratio is the ratio of arterial oxygen partial pressure (P_aO2 in mmHg) to fractional inspired oxygen (FiO2 expressed as a fraction, not a percentage).[7]

One among the primary determinants of weaning from mechanical ventilation and tracheal extubation is the oxygenation status of the patient. Although a fair assessment of the oxygenation capacity of a patient can be deciphered by the P/F ratio, it can be influenced by the applied PEEP (Positive End Expiratory Pressure) on ventilator. As P/F ratio doesn't include PEEP, it misrepresents the severity of the disease.[8] Hence we intend to include PEEP in the existing P/F ratio to formulate the new P/FP ratio [P_aO2 x 5/FiO2 X PEEP] and evaluate its usefulness in assessing the oxygenation status of the patient effectively post-cardiac surgery.

Lung compliance is a mechanical property used to describe the elasticity of the lung parenchyma, chest wall, or respiratory system as a whole. It is defined as a change in volume (ΔV) per unit change in pressure (ΔP) and can be expressed mathematically as $\Delta V/\Delta P$.

Static compliance is defined as lung compliance without the presenceof gas flow. The difference between the plateau pressure (P_{plat}) during an inspiratory hold manoeuvre and the peak end-expiratory pressure (PEEP) can be used to calculate the static compliance (C_{stat}) as $V_T/(P_{plat} – PEEP)$. Cardiac surgery is associated with significant structural and functional changes in the respiratory system dueto the inflammatory process that is associated with the extracorporeal circuit, leading to reduced lung compliance.[9]

Postoperative pulmonary complications (PPC) as defined by occurrence of at least one among the following like atelectasis, lung collapse, respiratory failure, pneumothorax, pulmonary infections, though frequent, are under reported.[10] The occurrence of PPC is a major hindrance to fast-tracking as patients becomes more dependent on mechanical ventilation. Similarly noninvasive ventilation (NIV) requirement, which is reported to be high in cardiac surgery and tracheal reintubations prevents fast-tracking and results in prolonged ICU length of stay.[11] Use of objective pulmonary parameters that could predict such factors that prevent fast-tracking, in the immediate postoperative period can guide the clinician to take corrective measures in the fast-track pathway thereby reduing the ICU length of stay and overall morbidity. By this study we intended to assess the usefulness of P/FP ratio and static lung compliance as objective pulmonary parameters in predicting postoperative pulmonary complications , post extubation NIV requirement and tracheal reintubations that could aid in fast-tracking in cardiac surgery.

AIMS AND OBJECTIVES

Hypothesis

We hypothesized that the new P/FP ratio and static lung compliance can reliably predict post extubation - NIV requirement, tracheal reintubations after extubation and development of postoperative pulmonary complications after cardiac surgery and serves as useful objective pulmonary parameters that can guide the perioperative physician in fast-tracking the patient postoperatively in the ICU.

Objectives

Primary Objective

To evaluate the usefulness of the new P/FP ratio and static lung compliance as objective pulmonary parameters in predicting the surrogate markers of early weaning and extubation failure (fast-track failure) such as:

1. NIV (Non-Invasive Ventilation) requirements after extubation.
2. Tracheal reintubation.
3. Post operative pulmonary complications (PPC)

Secondary Objectives

1. To derive the optimal cut-off values of P/FP ratio and static lung compliance to predict fast-track failure.
2. To assess the effect of systolic and diastolic functions on P/FP ratio and static lung compliance.
3. To assess the effect of systolic and diastolic function on NIV requirement post-cardiac surgery.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Major surgeries including cardiac surgeries induces intense physiological responses like pain, altered gastrointestinal motility, changes in the hormonal and neurotransmitter levels, increased cardiac demand and impaired pulmonary function. These physiological stresses can result in delayed ambulation, prolonged ICU and hospital length of stay and significant postoperative complications. Blunting the physiological responses to surgery, pain and supporting the systems to maintain adequate perfusion and function becomes essentially the ultimate goal of anaesthesia practices. This by itself reduces the overall perioperative morbidity and promotes early recovery postoperatively.

In the early 1990s, Professor Henrik Kehlet, a gastrointestinal surgeon from Germany conceptualised a technique to promote early postoperative recovery called as "fast-tacking".[12,13] The term refers to a multimodal perioperative care regime that aims to decrease the postoperative organ dysfunction and complications to promote early postoperative recovery and reductions in the ICU and hospital length of stay and morbidity. The surgical centres worldwide started adopting and pioneering this approach and achieved impressive reductions in hospital stay and surgical morbidity. This indirectly reduced the health care costs on hospital stay during the time when there was sharp increase in surgical costs worldwide.

Changes in economy worldwide in the 1990s was the main driving force in the functioning of health care delivery systems. The constant pressure for cost reduction arouse from the market economy and health care reforms.[15]

Abatement of the federal health insurance - Medicare, with reconstitution of the joint federal and state health insurance programme - Medicaid with recession in the premium rates of health maintenance organisations resulted in reduced reimbursement of the healthcare expenses to the healthcare providers. “More procedures with less resources” was the main apothegm in the 1990s.[16]

This led to the emergence and rapid inception and formulation of various fast-track principles in all specialities of surgery particularly cardiac surgery.

FAST-TRACK SURGERY – PRINCIPLES AND PATHWAYS

Fast-track surgery is defined as an evidence based multidisciplinary approach in patient care that utilises combination of several patient centred, peri-operative interventions to facilitate early recovery after surgery. In fast-track surgery, patient care is individualised and protocolised. Each protocol in fast-tracking uses evidence garnered from extensive literature in perioperative medicine, and attempts to integrate these ideas into a safe programme of clinical pathways. For this to succeed, a multidisciplinary team should be involved fully in the fast-track programme and be informed and educated about their roles within the programme.[16,17] This also includes a well-structured and dynamic audit.

The primary objective of any fast-track programme is to achieve early ambulation, appropriate timely discharges from ICU and hospital and early return to functionality and productivity and hence the targeted interventions are applied in each phase of surgery – before, during and after.

Evidence suggests that each of these interventions has been shown to independently influence the outcome of patient undergoing surgery especially by reductions in morbidity.The synergistic effects of interventions at various phases of surgery promote early recovery postoperatively.[17,18] The successful functioning of the early and enhanced recovery pathway requires the involvement of anaesthesiologist right from the pre-anaesthetic assessment of the patient up to late into the post-surgical period.

The phases of fast-tracking involve: -

- Pre-operative phase: Patient education and optimisation for surgery.
- Operative phase: Surgical and anaesthetic techniques to reduce surgical stress response and pain including minimally access surgeries and administration of short acting anaesthetic drugs and regional blocks.
- Post-operative phase: Multimodal rehabilitative approach to achieve early tracheal extubation. Addressing pain and postoperative nausea and vomiting is an important goal during this period.

The multidisciplinary team involved in fast-tracking is responsible for evaluating and executing the best clinical practices based on evidence-based medicine which are flexible and individualised for each patient. The anaesthesiologists as perioperative physician has an important role in decision making and policy formulation. Figure 1 depicts the members involved in fast-track surgery team.

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Figure 1: Members of the inter-disciplinary fast-track surgery team.

Fast-tracking starts with preoperative evaluation and optimising organ function in patients with cardiac diseases, obstructive and restrictive lung diseases, diabetes mellitus, hypertension and other disorders, pharmacologically. Cessation of smoking needs special attention and pharmacological methods to enforce abstinence in alcoholics has resulted in reduced morbidity and enhanced recovery in such patients. Preoperative cessation of smoking for more than 6 months has shown to reduce postoperative pulmonary complications.[19]

Preoperative counselling of the patients regarding the procedure and plan of anaesthesia with emphasis on pain relief, reduces anxiety and improves postoperative outcome.[20,21] Causes of delayed recovery after surgery and the factors that needs to be addressed perioperatively are depicted in Figure 2:

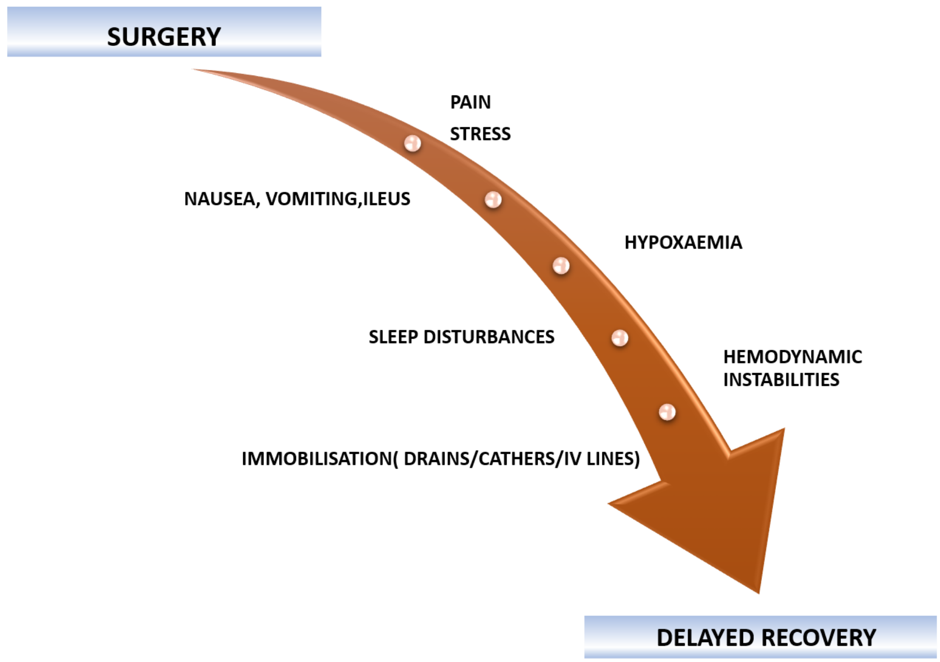


Figure 2: Factors contributing to postoperative morbidity.

Newer anesthetic techniques and short acting drugs have optimised conditions for surgeons to operate while allowing for early recovery of organ function postoperatively. Thus, the introduction of volatile anaesthetics such as desflurane and sevoflurane, short acting opioids like sufentanil and remifentanil, muscle relaxants like cistracurium and atracurium have facilitated early weaning and extubation after surgery.[22] Opioid free anesthesia by implementing multimodal analgesia with regional blocks whenever possible can significantly promote enhanced recovery after surgery and reduces incidence of postoperative nausea and vomiting. Surgical stress can lead to postoperative organ dysfunction and morbidity especially in major surgeries.

Central neuraxial blockade and regional nerve , attenuate the surgical stress response, thereby reducing postoperative organ dysfunction and morbidity allowing enhanced recovery.[23] Improved respiratory function and pain relief, reduced cardiovascular demands and postoperative ileus, are advantages of regional anesthetic techniques in fast-tracking.[23] A recent meta-analysis of regional anaesthetic studies by *Rodgers et al* showed a 30% reduction in morbidity compared with general anaesthesia techniques.[24]

The use of minimally invasive surgical techniques has been associated with a reduction in inflammatory responses associated with surgery.[25] Postoperative pulmonary function seems to be improved and incidence of postoperative ileus is reduced with minimal invasive approaches.[25,26] Intraoperative hypothermia results in increased chances of bleeding due to coagulopathy, reduced metabolism and excretion of anesthetic drugs and poor wound healing. A fall of core temperature of 2-4°C usually happens after 2 hours of surgery in operating rooms and during rewarming there is release of catecholamines that exacerbates the stress response of surgery.[27] A large meta-analysis of 26 randomised trials concluded that routine use of nasogastric tube may be detrimental by increasing the incidence of pneumonia and delaying early enteral feeding. Early ambulation should be encouraged with adequate analgesia, to prevent venous stasis in lower limbs and development of deep vein thrombosis as well loss of muscle mass. Early enteral feeding is promoted and initiated six hours after surgery, even after colonic surgeries with bowel anastomosis.[28] Principles for optimising management postoperative pain have been developed, providing adequate analgesia which allows early ambulation and physiotherapy.

Postoperative pain management in fast-track surgery involves education of staff and patients, establishment of an acute pain services, and the use of multimodal analgesic techniques. Postoperative ileus, caused by a combination of inhibitory neural sympathetic visceral reflexes and intestinal inflammatory mediators, may be decreased by epidural analgesia with decreased use of opioids, promoting minimally invasive surgery, and medications such as droperidol, phenothiazines and antihistaminics.[28] These perioperative interventions are the building blocks of fast-track anesthesia and surgery that promote early and enhanced recovery after surgery. (Figure 3)

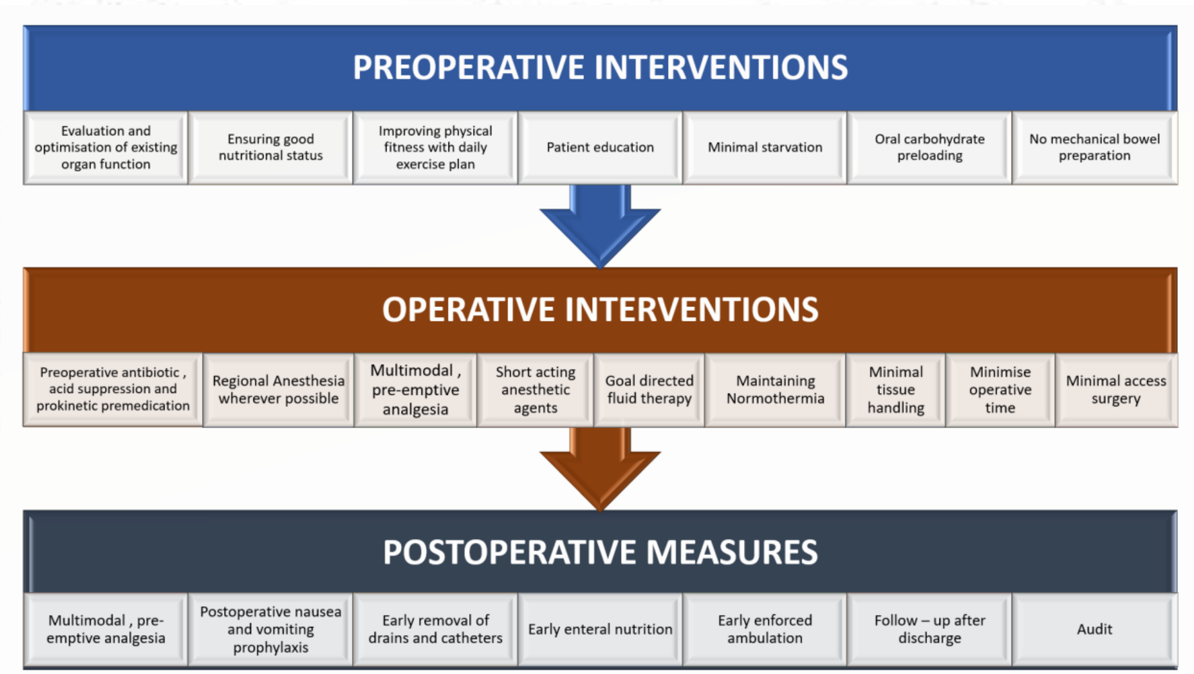


Figure 3: Components of fast-track surgery

ENHANCED RECOVERY AFTER SURGERY (ERAS)

Fast- track surgery pathways has evolved over years into the formulation of enhanced recovery after surgery protocols (ERAS) which is defined as evidence-based protocols that optimise perioperative care to minimise surgical stress response and pain, reduce morbidity, decrease hospital length of stay, and hasten recovery.[29] ERAS is synonymous with fast-tracking which accumulates evidence-based protocols in individual domains and creates specific fast-track pathways for various surgical principles (Figure 4). Currently the guidelines are published by the ERAS® Society and in some cases also as a joint effort with other medical societies such as The European Society for Clinical Nutrition and Metabolism (ESPEN) and the International Association for Surgical Metabolism and Nutrition (IASMEN), part of the International Surgical Society (ISS).

Figure 4: Elements of ERAS

FAST-TRACK CARDIAC CARE

Fast tracking in cardiac surgery was introduced as an approach by which patients could be extubated early and transferred out of the intensive care unit on the day of surgery in an attempt to reduce ICU and potentially hospital length of stay, which would reduce resource utilization and improve overall health care efficiency. The risk-adjusted outcomes seen in 30-day composite causatum of interest supports the fact that fast tracking is indeed safe and does not adversely impact patient safety in cardiac surgery.[30]

Cheng et al [1] proposed two pathways for fast-track cardiac recovery which would reduce the ICU length of stay. (Figure 4) The first model called as the parallel model, incorporates a cardiac recovery area (CRA) that is separate and distinct from the main ICU allowing cardiac patients to get shifted directly out of the cardiac recovery unit bypassing ICU entirely.

The second model or the integrated model, maintains patients in the same area but the care they received is tailored appropriate to their level of illness, with the potential of increasing the nurse patient ratio, if in need, as this is a strong determinant of cost and frequently a limitation on resource use. The final pathway is to bypass ICU completely- the ultrafast track approach.

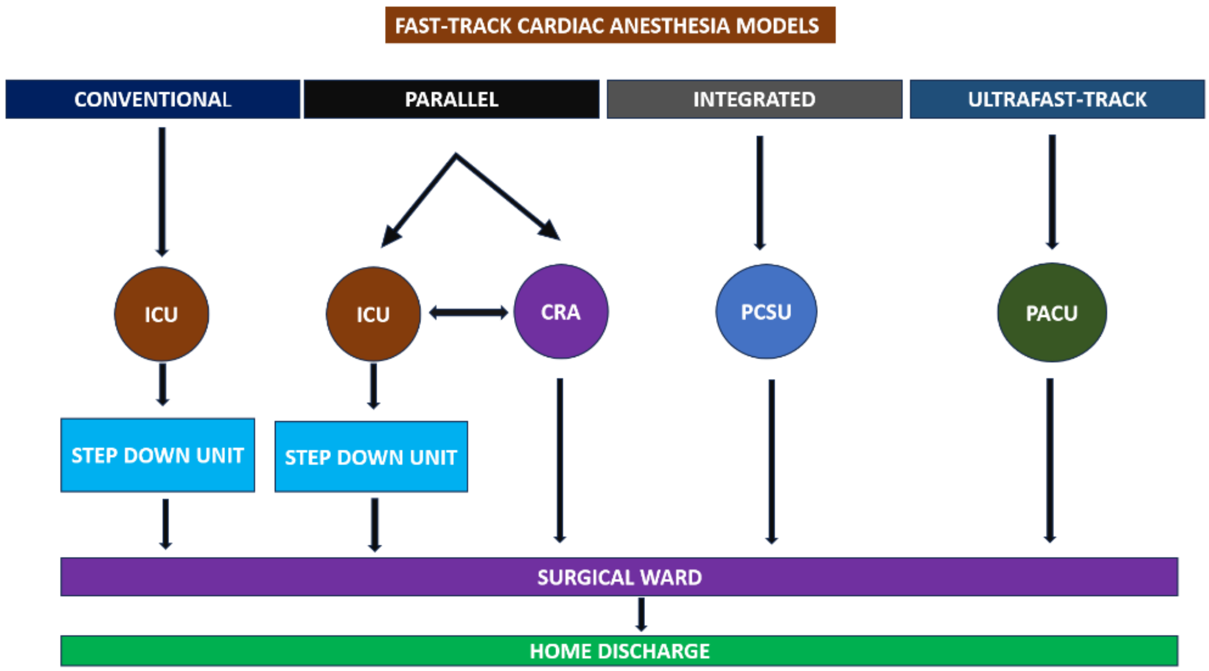


Figure 5: Fast-track cardiac care models

Fast-track cardiac anaesthesia is a perioperative anaesthetic management strategy that targets early tracheal extubation of patients within 1 - 6 hours post-cardiac surgery. Most centres worldwide consider fast-track extubation up to 8 - 10 hours post-surgery. Fast track cardiac surgery or pathways is a multidisciplinary approach aimed to enhance perioperative care in cardiac surgical patients in which early extubation is the key goal.

The outcome in terms of perioperative mortality and morbidity is dependent on patients preoperative health status and postoperative complications.[31]

Becker et al. inferred that the postsurgical acute physiology score (APS) was the most compelling predictor of mortality. They concluded that the postoperative APS emulated the overall influence of surgical skill, anaesthetic technique, quality of post-surgical care, and the presurgical health status of the patient.[32] In an analysis of 885 consecutive coronary artery bypass graft (CABG) patients who had undergone fast track cardiac anaesthetic management, 75% of patients were weaned and extubated within ten hours after surgery.

Age, intraoperative use inotropes calculated as inotropic score, intra-aortic balloon pump (IABP), and postoperative atrial fibrillation were found to be associated with failed weaning from mechanical ventilation and unable to meet extubation criteria. Hence other than age, major predictors of early tracheal extubation are the intra and postoperative factors rather than the preoperative factors which play only a minor role in fast-tracking. Furthermore, intraoperative and postoperative complications were shown to be major predictors of increased ICU length of stay.[33] In risk models, preoperative use of IABP and age were associated in terms of multivariable analysis with time to weaning from mechanical ventilation and extubation. While in a risk process model, intraoperative events also significantly contributed to determining the time to extubation.

ICU length of stay is a commonly used as a yardstick for indirect measurement of the health care cost. However, reduced ICU length of stay does not necessarily imply decreased health care expenditure but also depends on proportionally decreased variable cost settings.

The economic consequences of post-CABG complications are more expensive than an uncomplicated recovery. Patients extubated early in the postoperative period recover to baseline performance in the mini-mental state examination 24 hours faster than the conventional prolonged mechanical ventilation group[3,33]. This enhanced recovery of mental state allows for earlier mobilisation by early removal of intercostal drains , early enteral nutrition resulting in reduced ICU and hospital length of stay.

There was a direct correlation of prolonged ventilatory requirement with increasing dosage of narcotics used. This study by *London et al* inferred that the intraoperative clinical events compared to preoperative risk factors, are more important factors in determining the timing of weaning from mechanical ventilation and tracheal extubation. This study emphasises that any patient can be fit for fats-tracking in cardiac care, while the major determinants of prolonged ICU stay being the intra and postoperative course. [34] In their study, there is a nadir in the time of extubation happening between 10 and 12 hours after surgery. Also, the relation between time to extubation and ICU length of stay is not consistent as discharge from the ICU usually occurs at particular times of the day that depends on nurse shift changes.[34] In a study by *Butterworth et al* which included 1,094 patients who underwent CABG at forty centres , the authors concluded that there was no statistically significant difference between vecuronium and pancuronium in duration of mechanical ventilation and interestingly the use of short-acting opioid or neuromuscular blocking agents had no association with ICU length of stay after extubation.[35]

ENHANCED RECOVERY AFTER CARDIAC SURGERY -ERACS

Enhanced recovery after cardiac surgery (ERACS) is a multidisciplinary, multimodal approach that aims to achieve enhanced cardiac perioperative care. ERACS invloves multiple and concise evidence-based pathways that has proven to enhance patient recovery by reducing the postoperative mechanical ventilatory time, postoperative complications, intensive care unit (ICU) in-hospital length of stay (LOS).[36] Early tracheal extubation, defined as within 6 hours after cardiac surgery, is the cornerstone of the ERACS concept. Early weaning from mechanical ventilation and extubation is considered safe even in high risk patients.[37] ERAS Cardiac Society (ERACS) released its first expert review consensus guidelines for patients undergoing cardiac surgery in 2019.The class 1 recommendations under ERACS protocol is summarised in Table 1. Ultra fast-track anaesthesia is defined as tracheal extubation of a patient within 1 hour after cardiac surgery.[36,37]

COR	LOE	RECOMMENDATIONS
I	A	Tranexamic acid or epsilon aminocaproic acid is recommended during on-pump cardiac surgical procedures.
I	B-R	Perioperative glycemic control is recommended.
I	B-R	A care bundle of evidenced based best practices is recommended to reduce surgical site infections.
I	B-R	Goal directed fluid therapy is recommended to reduce postoperative complications.
I	B-NR	A multimodal, opioid-sparing, pain management plan is recommended postoperatively.
I	B-NR	Persistent hypothermia after CPB should be avoided in the early postoperative period
I	B-NR	Maintenance of chest tube patency is recommended to prevent retained blood.
I	B-NR	Postoperative systematic delirium screening is recommended at least once per nursing shift.
I	C-LD	Smoking and hazardous alcohol consumption should be stopped 4 weeks before elective surgery.

Table 1: ERACS recommendations. COR – Class of recommendations, Class I – strong LOE-Level of evidence, B-R: Randomised, NR- Non Randomised, LD -Limited Data

FAST-TRACK FAILURE

A proportion of patients though adequately optimised and managed perioperatively under fast-track management strategies fails to complete the fast-track pathway and requires prolonged mechanical ventilation and additional ICU resources. This is termed as fast-track failure. To be of concern, fast-track failure has been shown to be associated with increased morbidity and mortality. Hence the concept of fast-tracking needs to be applied to a carefully selected patient group and monitoring the clinical course in each step of the pathways becomes absolutely necessary in early identification of fast-track failure.[38] Therefore, for an appropriate patient selection, recognition of risk factors predicting fast-track failure needs to be established. In several studies, fast-track failure was associated with factors such as age, female sex, unstable angina, preoperative use of diuretics, preoperative institution of intra-aortic balloon pump, re- explorations due to bleeding, high inotrope score and atrial fibrillation.[38,39]

In a study conducted by *Hendrikx et al*, with a sample size of 1097 patients who were fast-tracked in post anesthesia care unit (PACU), multivariate and univariate logistic regression analysis showed that the incidence of fast-tracking failure was 6.3%. The fast-track failures were associated with significant increases in the incidence of pericardial effusion leading to tamponade or excessive bleeding requiring re-explorations, new-onset atrial arrhythmias, ventilator associated pneumonia (VAP), postoperative delirium, and sepsis. Likewise, the ICU and hospital length of stay, and up to 5-year mortality, were significantly higher in the fast-track failure group.

The European System for Cardiac Operative Risk Evaluation II (EuroScore II) and blood products transfusion was identified as independent risk factors for fast-track failure, with only limited statistical strength as it remains unclear as whether increased blood transfusion was itself a surrogate marker for underlying confounders, such as difficult surgical milieau or other comorbidities.[40] *Branca et al* described nine risk factors of fast -track failure: advanced age, female sex, unstable hemodynamics, renal failure, recent MI (myocardial infarction), stroke , valve surgeries, emergency surgery, and redo-surgeries. In other studies, the causes of failed early extubation derived were heterogenous. The main determinants in these studies were reduced sensorium, hypoxemia, hemodynamic instability and excessive bleeding, while the risk factors for failed early extubation appear to be similar in younger and older age groups from a study conducted by *Kogan et al.* As elderly patients are screened and optimised stringently preoperatively, the similarity in risk factors between elder and younger population can be justified.[39,40,41]

From the literature review it becomes imperative that there are no specific objective parameters that can predict fast-track failure perioperatively, hence this study aims to introduce objective parameters that can predict fast-track failure. One among the primary reasons that leads to increased ICU and hospital length of stay thereby preventing fast tracking is the development of postoperative pulmonary complications (PPC) after cardiac surgery. PPC alone has been associated with increased health care cost in cardiac surgery.[42]

During cardiopulmonary bypass, blood flow is solely provided to the bronchial vasculature, placing the lungs in a relative ischemic zone. Reperfusion of the pulmonary vasculature occurs after in pulmonary arterial flow is established. This leads to ischemia–reperfusion injury with a state of systemic inflammatory response characterized by increased microvascular permeability, increased pulmonary vascular resistance and pulmonary edema with defective gas exchange. These physiological changes leads to the development of postoperative pulmonary complications after cardiac surgery.[43]

The VENICE international cohort study, an international multicentre prospective trial on 707 patients concluded that the occurrence of PPC was significantly associated with a ICU and hospital LOS preventing fast-tracking.[44] PPC was defined as the occurrence of at least one among the following pulmonary complications like atelectasis, pleural effusion, pulmonary oedema, pneumonia, pneumothorax or aspiration pneumonia. Hence predicting the occurrence of postoperative pulmonary complication can be a surrogate marker for predicting fast-track failure after cardiac surgery.

Apart from the surgical causes and cardiovascular hemodynamic instability, failed weaning from mechanical ventilation and tracheal reintubations following extubation usually is the result of development of PPC. Those patients who develop pulmonary complications postoperatively usually requires positive pressure ventilation either invasive or non-invasive to prevent hypoxemia and hypoventilation. Studies have reported that the use of non-invasive ventilation (NIV) in patients with acute respiratory failure may decrease the need for re-intubation after cardiac surgery.

A meta-analysis comparing patients administered non-invasive ventilation and conventional management after cardiac surgery showed that the use of NIV improved the oxygenation and decreased the need for tracheal re-intubation. There are no studies in cardiac surgery assessing the risk factors for post extubation NIV requirement and tracheal reintubations post extubation. The present aims at assessing the usefulness of objective pulmonary parameters that can predict postoperative pulmonary complications (PPC), post extubation NIV requirement and tracheal reintubations demanding dependence on positive pressure ventilation that can be a surrogate marker for fast-track failure.

P/FP RATIO AND STATIC LUNG COMPLIANCE

PaO2/FiO2 ratio (P/F ratio) is the ratio of arterial oxygen partial pressure (PaO2 in mmHg) to fractional inspired concentration of oxygen (FiO2). It is a simple and rough tool to evaluate the oxygenation status of a patient which is easily reproducible at bedside. The primary use of P/F ratio in critical care is to classify acute respiratory distress syndrome (ARDS) based on the oxygenation of patients in the Berlin definition of ARDS as 300 to 200 as Mild ARDS, 200 to 100 as Moderate ARDS and less than 100 as Severe ARDS with PEEP > 5 CM H20.[46]

The PaO2/FiO2 ratio does not accurately reflect the severity of lung disease and may vary even in non-pulmonary pathology (e.g., a change in cardiac output or mixed venous oxygen saturation). It also wrongly projects the oxygenation status without the knowledge of the positive end expiratory pressure (PEEP) applied in ventilator.

Changes in the PEEP values without altering the FiO_2 gives a different PaO_2 altogether and the ratio fluctuates considerably even when altering only the PEEP. Though the P/F ratio appears to be direct reflection of oxygenation at bedside, it represents an intricate and dynamic cardio-pulmonary interaction. Many studies have proven the correlation of rise in PaO_2, concentration of hemoglobin saturated with oxygen and P/F ratio with the addition of PEEP suggesting alveolar recruitment. These results are consistent with studies in critical care medicine in patients with acute respiratory distress syndrome.

The only study in critical care setting with the use of a new P/F ratio with inclusion of PEEP is by Palanidurai et al, in which the author used the formula PaO_2 X 10 / (FiO_2 X PEEP) in ARDS patients46. The newly formulated P/FP ratio had a constant 10 which was incorporated as more than 50% of patients enrolled in ARDS network trials had a baseline PEEP more than 10. They concluded that the P/FP ratio has a greater predictive ability for predicting mortality in ARDS for patients with a PEEP more than 5cmH_2O in mechanical ventilation than the conventional P/F ratio and its prognostic ability progressively increases with increasing levels of PEEP. Lung compliance is defined as the change in lung volume per unit change in the transpulmonary pressure while Static compliance is defined as the lung compliance without the presence of gas flow. The difference between the plateau pressure (Pplat) derived from the ventilator after applying an inspiratory hold maneuver and the peak end-expiratory pressure (PEEP) can be used to calculate the static compliance (CSTAT). It is calculated as CSTAT = VT / (Pplat – PEEP). Normal value being 70-100 ml/cm H_2O. There is a sharp increase in the work of breathing when CSTAT is less than 25 ml/cmH_2O.

According to Badenes et al, mechanical ventilation after cardiac surgery is associated with significant structural and functional changes in the respiratory system due to the systemic inflammatory response due to the extracorporeal circuit, leading to reduced lung compliance. In a similar study static lung compliance was shown to be reduced post-cardiac surgery but this parameter was not sensitive enough to identify the prognosis of the patients with regards to weaning from mechanical ventilation and tracheal extubation.[9,]

Lung compliance and oxygenation indices may help in early detection and prevention of post cardiac surgery pulmonary complications that necessitates alveolar recruitment maneuvers which decreases the intrapulmonary shunt due to atelectasis, deciding ventilatory strategies and administering immediate therapeutic measures such as intercostal drainage for pneumothorax, pleural effusion etc. The new P/FP ratio that includes PEEP, which is a major determinant of oxygenation, which can reliably reflect the actual oxygenation status, and static lung compliance were selected as the potential objective pulmonary parameters in the present study that could predict fast-track failure in terms of occurrence of PPC, requirement of NIV-post extubation and reintubations after tracheal extubation.

MATERIALS AND METHODS

MATERIALS AND METHODS

Study design

A prospective observational study.

Study setting

Adult cardiac surgery intensive care unit (ICU) of Sree Chitra Tirunal Institute for Medical Sciences and Technology which is a tertiary referral center performing 800-1000 adult cardiac surgeries annually.

Participants

120 adult patients undergoing coronary artery bypass grafting (CABG), aortic and mitral valve surgeries.

Inclusion criteria

1. Elective CABG, aortic and mitral valve surgeries with median sternotomy and two-lung ventilation.
2. Adult patients (age 18 years or older)
3. Ability to provide informed consent

Exclusion criteria

a. Non-elective cardiac surgery
b. Patient’s refusal
c. Pregnancy
d. Thoracotomy approach with one-lung ventilation
e. Previous pulmonary resection

f. Patients with acute kidney injury requiring dialysis

g. Patients with chronic kidney insufficiency (stage III or greater)

h. Patients already intubated before arrival in operating theatre.

i. Pneumonia in the previous 30days

j. Post COVID patients with baseline hypoxemia/active COVID patients

Study protocol

In the operating room, standard ASA monitors were attached. An arterial room air blood sample was collected during arterial line insertion for blood gas analysis. Baseline P/F ratio (FiO_2-21%) was calculated. After induction of general anesthesia, all patients underwent cardiac surgery via median sternotomy.

Intraoperative ventilation strategies were based on patient's respiratory status. Volume-controlled ventilation with a tidal volume of 6-8 mL/kg and a minimum PEEP of 5cmH2O was used to provide adequate ventilation and oxygenation. No patients were ventilated during the conduct of cardiopulmonary bypass (CPB). The aortic cross clamp time, and CPB time were noted. After the completion of surgery, all patients were shifted to cardiac surgery ICU and electively ventilated till the tracheal extubation criteria is met.

Postoperative observations

All patients were mechanically ventilated in the ICU with tidal volumes of 6-8ml/kg and PEEP adjusted according to patient's pulmonary status. The new P/FP ratio was calculated from the PaO_2, FiO_2 and PEEP using the formula: [PaO_2 X 5] / [FiO_2 X PEEP]. The arbitrary number 5 is taken as the conversion factor as majority of the cardiac centres worldwide administer a PEEP of 5 cmH2O in adult post cardiac surgical patients[10]. Anyhow the minimum value of PEEP to be kept was considered as 1 cm H2O for the study protocol. The P/FP ratios were calculated at three time points: 1. immediately after receiving the patient in ICU (PFP-ICU), 2. 1 hour after receiving the patient in ICU (PFP-1 HOUR) and 3. 10 minutes before extubation (PFP-PRE EXT).

The static lung compliance (C_{STAT}) was calculated at 1 hour after receiving the patient in the ICU. It was calculated with the parameters derived from ventilator applying inspiratory pause using the formula $C_{STAT} = V_T / (P_{PLAT} – PEEP)$, where V_T is the tidal volume, P_{PLAT} is the plateau pressure and PEEP is the applied positive end expiratory pressure.

In Hamilton Medicals Ventilator, the displayed C_{STAT} values were directly taken without inspiratory pause as the ventilator calculates it by by the least square fit method. Duration of mechanical ventilation, occurrence of postoperative pulmonary complications (PPC) [atelectasis, pleural effusion, pneumothorax and pulmonary edema] before extubation, post-extubation requirement of NIV and tracheal reintubation were noted. The PPCs were defined based on European joint taskforce published guidelines for perioperative clinical outcome definitions.[59] PPCS were identified with the help of chest x-rays and lung ultrasound Decision regarding requirement of ventilatory support in the form of NIV after extubation, was based on the institutional protocol with patient documenting PaO2 </=65 mmHg with FiO2 more than 80%, PaCO2>60 mmHg or inadequate respiratory effort at any point after extubation. The time taken for the NIV requirement after extubation and the duration of the NIV support were also noted.

Preoperative Details

Diabetes (Yes/No)	
Hypertension (Yes/No)	
Smoking	
Reactive Airway Disease	
Ejection Fraction (TTE)	
Diastolic Function (TTE/TEE)	

TTE – Transthoracic Echocardiography TEE- Trans Esophageal Echocardiography

Intraoperative Details

CABG (OPCAB/ON Pump)	
Valvular surgery (Aortic/Mitral)	
CPB time	
Aortic Cross clamp time	
Preoperative PO2/FiO2 ratio in room air	
P/FP ratio after protamine reversal	

OPCAB – Off Pump CABG
CPB – Cardio Pulmonary Bypass, P/FP ratio – PO2/(FI02×PEEP)

Postoperative details

P/FP ratio on admission to ICU	
P/FP ratio at 1hr post ICU admission	
Static Lung Compliance assessed at 1hr post ICUadmission	
Alveolar Recruitment Maneuver performed?	
P/FP ratio pre extubation (10 mts before)	

Postoperative Pulmonary Complications

Pneumonia (Consolidation /infiltrates in CXR/LUS)	
Pneumothorax (Assessed with CXR /LUS)	
Pleural effusion (CXR/LUS)	
Acute pulmonary edema (Clinical signs, CXR/LUS)	
Tracheal reintubation	

CXR – Chest Xray
LUS – Lung Ultrasound

Postoperative Non pulmonary complications.

Postoperative ventricular dysfunction	
Pericardial effusion	
Increased bleeding (drain output)	

Ventilatory Requirements

Duration of Invasive Mechanical Ventilation (hours)	
Time until tracheal extubation (hours)	
Tracheal reintubation	
Post extubation NIV requirement	
Non-Invasive mechanical ventilation (hours)	

NIV – Non-Invasive Ventilation

Statistical Analysis

Sample size for the study was calculated based on a previous study by *Esteve J et al*[7] with a prevalence of 0.81 for high survival based on P/F ratio. The sample size needed for the study was 102 to obtain a power of 90% and an alpha error of 5%. All statistical analysis were performed using the SPSS version 25 statistical software (IBM SPSS, Inc). The continuous variables with normal distribution were expressed as mean ± SD or median interquartile range (IQR). The quantitative variables were compared using t-test, and categorical variables were compared using Chi square test or Fisher's exact test. The cut off values for P/FP ratios and Static lung compliance was derived with the help of area under ROC and Youden's J statistic. p value < 0.05 was considered statistically significant.

OBSERVATIONS & RESULTS

OBSERVATIONS AND RESULTS

Demographic Profile

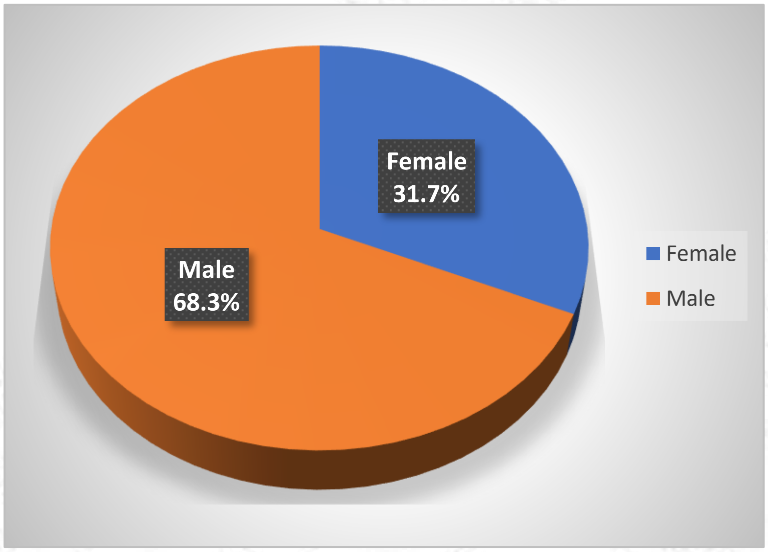
Table 2: Gender distribution of patient population

SEX	Frequency (n)	Percentage (%)
Female	38	31.7
Male	82	68.3
Total	120	100

Table 3: Demographic profile of patient population

Age (yrs)	56.7 ± 11.5
BMI (kg/m^2)	23.6 ± 3.16
BSA (m^2)	1.67 ± 0.2

Figure 6: **Gender distribution of patient population**

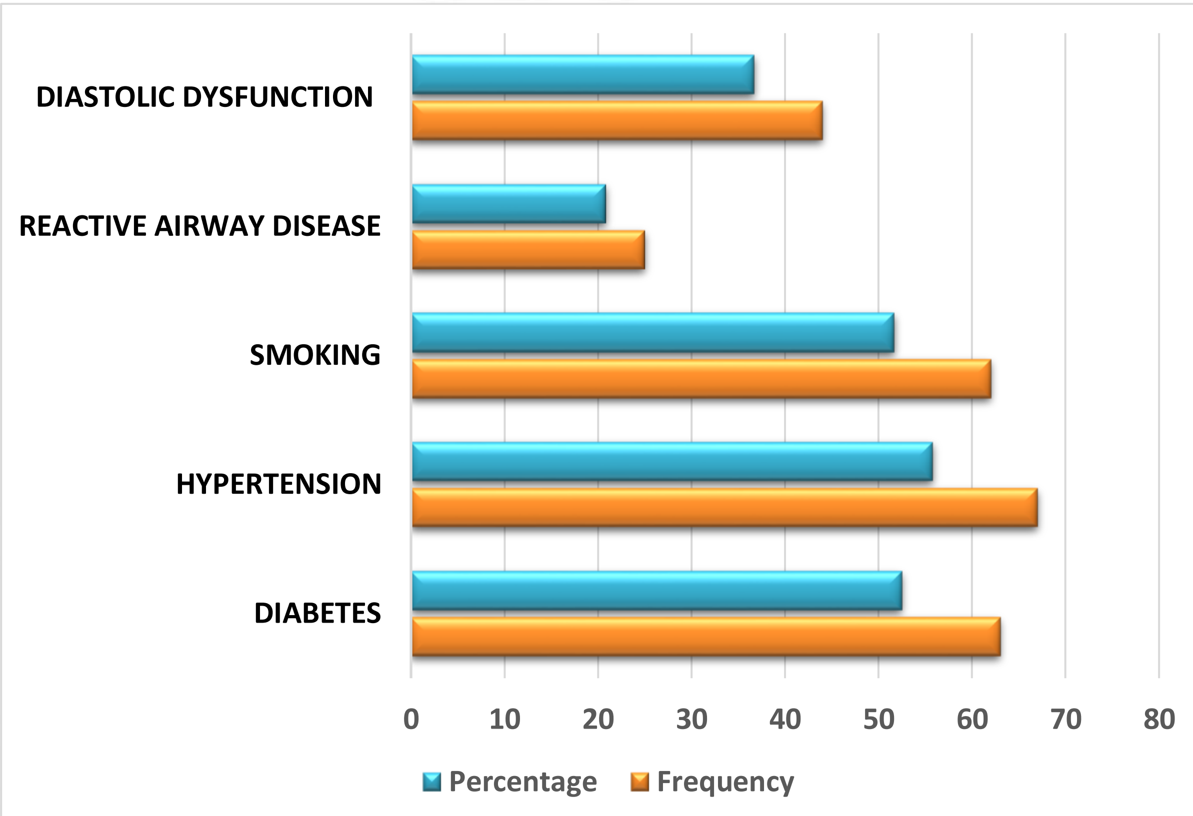


Among 120 patients included in the study, 68.3% were males (n = 82) and the rest 31.7% were females (n=38). (Table 2, Figure 5)

Table 4: Comorbidities of patients

Comorbidities	Count	Percentage
Diabetes	63	52.5%
Hypertension	67	55.8%
Smoking	62	51.7%
Reactive airway disease	25	20.83%
Diastolic dysfunction	44	36.7%

Figure 7: Comorbidities of patients

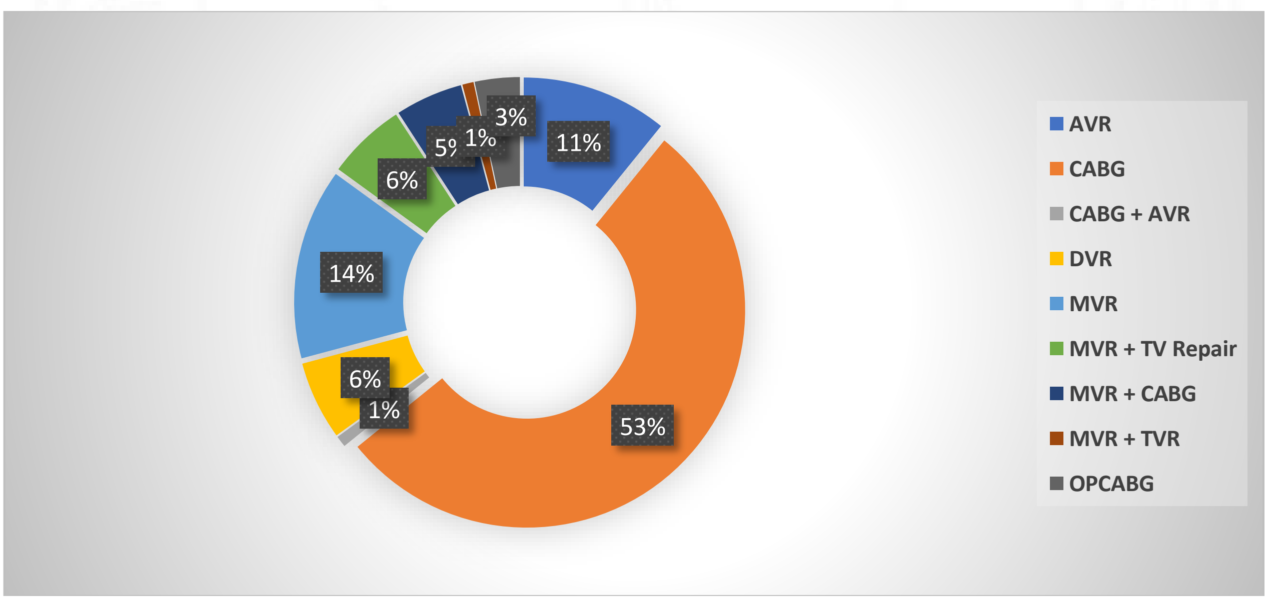


The incidence of diagnosed type – 2 diabetes mellitus (including patient on insulin and oral hypoglycemic agents was 52.5% (n = 63), hypertension -55.8% (n=67) and smoking 51.7% (n= 62), where all smokers belonged to male gender. Reactive airway disease as defined by bronchial asthma or chronic obstructive pulmonary disease was seen in 21% of patients (n=25) (Table 4, Figure 6).

Table 5: Surgical procedures done in the patient population

SURGERY	Frequency(n)	Percentage (%)
AVR	13	10.8
CABG	64	53.3
CABG + AVR	1	0.8
DVR	7	5.8
MVR	17	14.2
MVR + TV Repair	7	5.9
MVR+ CABG	6	5.0
MVR+TVR	1	0.8
OPCABG	4	3.3
Total	120	100

Figure 8: Surgical procedures done in the patient population

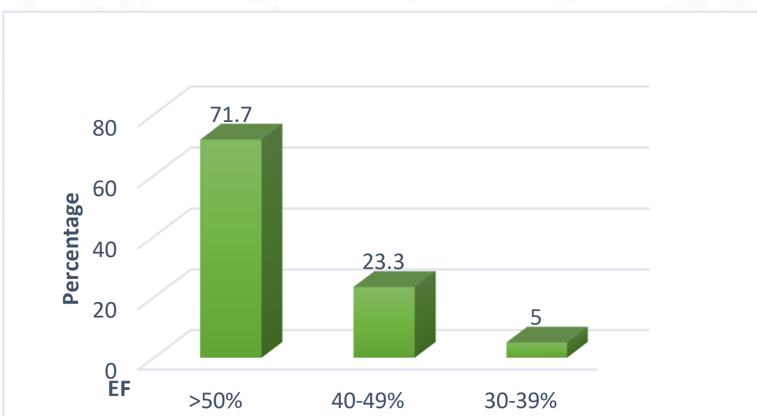


CABG- coronary artery bypass grafting contributed to the most performed surgery (53%, n= 64) followed by mitral valve replacement (MVR) [14%, n = 17]. Four CABGs were performed off -pump (OPCABG) [3.3%, n = 4] [Table 5, Figure 7]. AVR – aortic valve replacement, DVR- double valve replacement, TV repair – tricuspid valve repair, TVR- tricuspid valve replacement.

Table 6: Left ventricular systolic function- classification of patient population based on ejection fraction.

Systolic function (Ejection Fraction)	Frequency (n) (percentage)
>50%	86 (71.7%)
40-49%	28 (23.3%)
30-39%	6 (5%)

Figure 9: Left ventricular systolic function- classification of patient population based on ejection fraction.

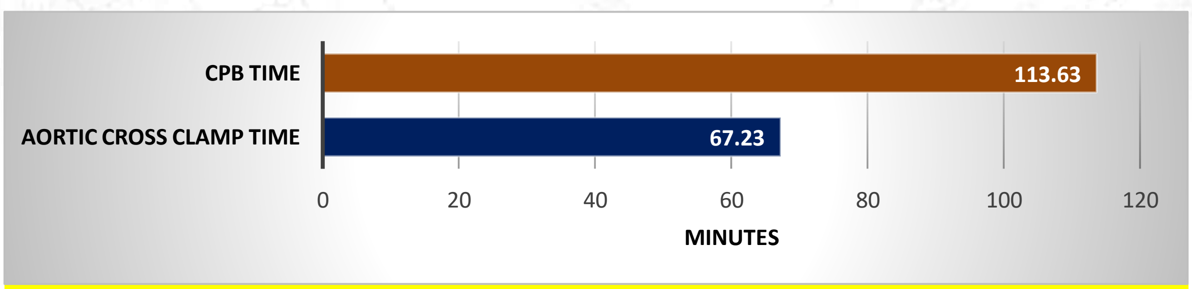


34 patients out of 120, (28.3%) had reduced left ventricular systolic function characterised by ejection fraction <50 %. (Table, Figure 8) While diastolic dysfunction was seen in 36.7% of patients (n= 44) [Table 4, Figure 6]

Table 7: Aortic cross clamp time and cardiopulmonary bypass (CPB) time

Time	Mean ± SD
Aortic Cross clamp time (mts)	67.23 ± 21.6
CPB time (mts)	113.63 ± 31.83

Figure 10: The mean aortic cross clamp time and cardiopulmonary bypass (CPB) time



The mean aortic cross clamp time was 67.23± 21.6 (SD) in minutes and the mean cardiopulmonary bypass time was 113.63 ± 31.83(SD) in minutes. SD – standard deviation.

Table 8: Trend of the potential objective pulmonary parameters (P/FP ratio, Static lung compliance)

	Mean ± SD	**Range**
P/FP - ICU	269.2 ± 106.9	85 - 568.75
P/FP - 1 HOUR	257.8 ± 124.6	78.5 - 682
P/FP - PRE - EXT	272.6 ± 86.8	110 - 493
P_{PLAT} – 1 HOUR (cm H20)	15.3 ± 4	8 - 24
C_{STAT} – 1 HOUR (ml/cmH20)	31.6 ± 7.9	19.09 - 56.2

Data shown as mean ± (SD) or n in percentages (%) and range. P/FP- PaO2/(FiO2XPEEP), PRE-EXT -pre-extubation, P/FP -ICU – at intensive care unit admission, P_{PLAT} – Plateau Pressure, C_{STAT} – static lung compliance

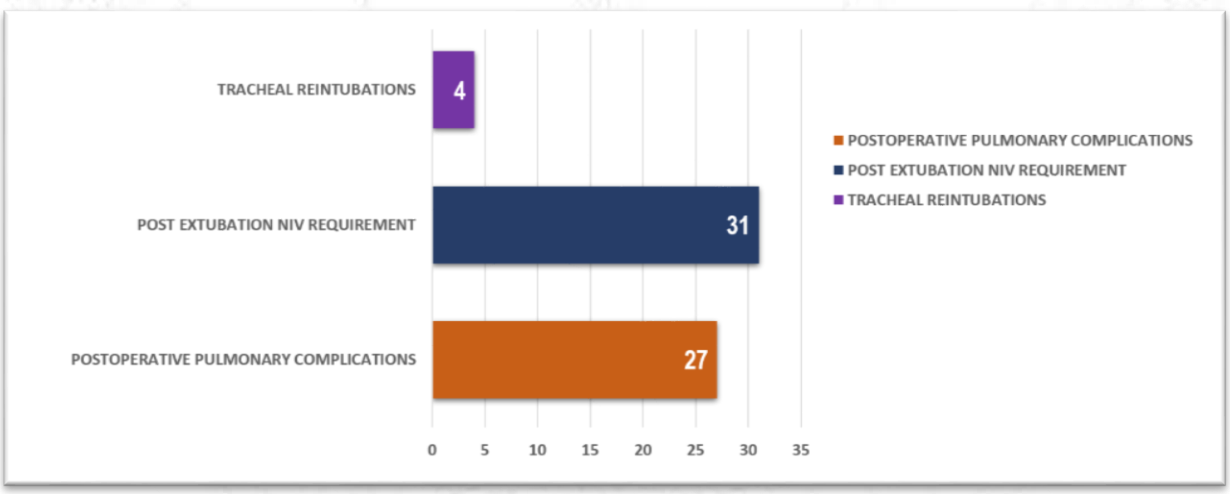
While, P/FP ratio measured on patient receival to ICU after surgery showed values around 269.2± 106.9, P/FP ratio at 1 hour after ICU admission showed men value around 257.8. P/FP ratio prior to extubation ranged from 110-493 with mean value of 272.6. The plateau pressure obtained by inspiratory hold in ventilator ranged from value as low as 8 to 24 cm H20. The static lung compliance measured at 1 hour after ICU admission showed mean value of 31.6 ml/cm H20.

Table 9 – Parameters denoting Fast-track weaning and extubation failures- Incidence

Parameters	Frequency	Percentage
PPC	27	22.5%
Tracheal Reintubations	4	3.3%
Post extubation NIV requirement	31	25.8%
	Mean ± SD	
Duration of NIV (hours)	24.1 ± 5.2	

Data are shown as Frequency(n) & in percentages (%), mean ± SD
NIV- Non Invasive Ventilation, PPC-Postoperative pulmonary complications, SD – Standard Deviation

Figure 11: Parameters denoting fast-track weaning and extubation failures- Incidence



The incidence of postoperative pulmonary complications (PPC) was 22.5% (n= 27). 31 patients needed support of non-invasive ventilation (NIV) after tracheal extubation which contributed to 25.8%. Reintubations after tracheal extubation was needed in 4 patients (3.3%). (Table 9, Figure 10) These were considered as the surrogate markers for fast-track failure in the study.

Table 10 - Multivariate associations between the objective pulmonary parameters and the primary outcome

	Post extubation NIV requirement				t value	p value	PPC				t value	p value	Tracheal Reintubations				t value	p value
	No (n=89)		Yes (n=31)				No (n=93)		Yes (n=27)				No(n=116)		Yes(n=4)			
	Mean	SD	Mean	SD			Mean	SD	Mean	SD			Mean	SD	Mean	SD		
P/FP - ICU	288.54	103.11	213.58	98.97	4.342	0.001*	272.46	105.61	257.87	112.33	0.623	0.534	268.47	107.79	289.75	83.39	-0.39	0.697
P/FP – 1 HOUR	284.98	116.82	179.73	114.47	3.516	<0.001*	265.99	116.26	229.53	149.05	1.343	0.182	257.66	125.34	261.56	118.41	-0.061	0.951
P/FP - PRE EXT	288.33	80.60	227.54	89.29	-7.693	0.001*	277.08	83.10	257.26	98.52	1.045	0.298	271.54	87.07	304.13	81.57	-0.737	0.463
Pplat	13.94	3.34	19.26	3.23	7.467	<0.001*	14.66	3.74	17.59	4.29	-3.475	0.001*	15.28	4.06	16.25	4.03	-0.468	0.641
Cstat	34.24	7.13	24.06	4.32	7.467	<0.001*	32.97	7.54	26.90	7.39	3.7	<0.001*	31.81	7.88	25.67	6.46	1.538	0.127

There was statistically significant difference in P/FP -ICU values between patients requiring NIV post-extubation and not (mean 213.58 vs 288.54 respectively, p value -0.001) and PFP – 1 HOUR (mean 179.73 vs 284.98 respectively, p value <0.001) and P/FP -PRE-EXT values (mean 227.54 vs 288.33 respectively, p value 0.001).

Similarly, there was statistically significant difference in C_{STAT} values between patients requiring NIV post-extubation and not (mean 24.06 vs 34.24 respectively, p value <0.001). The C_{STAT} values in patients developing postoperative pulmonary complications (PPC) was less 26.9 compared to 32.97 in patients without PPC and was statistically significant (p value < 0.001).

The P/FP ratios at various time points were neither statistically different in groups requiring and not requiring NIV- post extubation, nor in patients with and without PPC.

Neither P/FP ratio and C_{STAT} values could predict tracheal reintubations as these values were statistically insignificant. (p value > 0.1).

Table 11: **Predictive ability of the parameters (P/FP & C_{stat}) for post extubation NIV requirement**

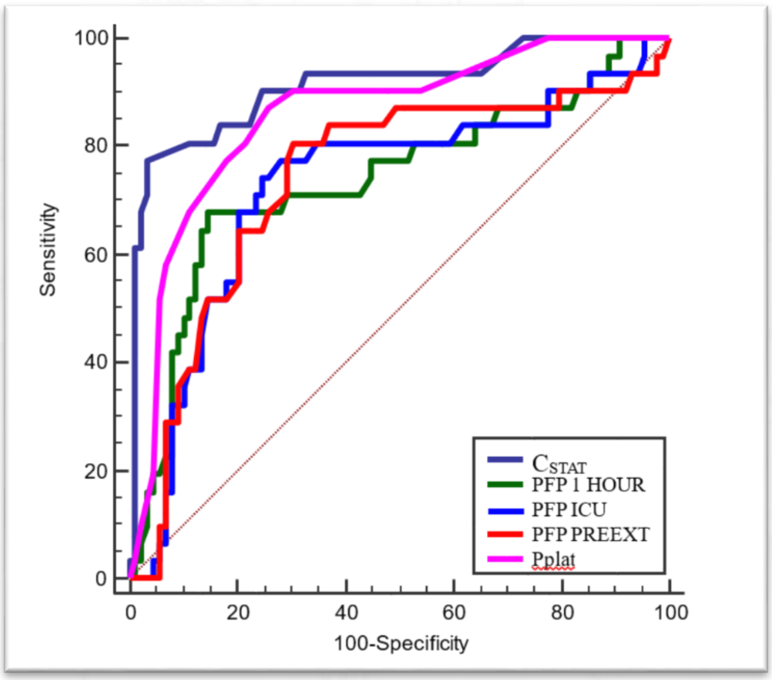
Variable	Cstat	PFP 1 HOUR	PFP ICU	PFP PREEXT	Pplat
Requiring NIV (n=31, 25.8%)					
Not requiring NIV(n=89,74.2%)					
AUROC	0.911	0.736	0.727	0.738	0.858
Standard Error	0.0347	0.0583	0.0579	0.057	0.0396
95% Confidence interval	0.845 -0.955	0.648 -0.813	0.639 -0.805	0.649 -0.814	0.783 -0.915
Z statistic	11.851	4.057	3.928	4.165	9.032
Youden index J	0.7405	0.5314	0.4947	0.5031	0.6125
Optimal cut off	≤24.6	≤150	≤223.3	≤252.5	>15
Sensitivity	77.42	67.74	74.19	80.65	87.1
Specificity	96.63	85.39	75.28	69.66	74.16
Positive Likelihood Ratio	22.97	4.64	3	2.66	3.37
Negative Likelihood Ratio	0.23	0.38	0.34	0.28	0.17
Positive Predictive Value	88.9	61.8	51.1	48.1	54
Negative Predictive Value	92.5	88.4	89.3	91.2	94.3
p Value	<0.001*	<0.001*	<0.001*	<0.001*	<0.001*

Youden index J – a single statistic that indicates the performance of a dichotomous test.

Z statistic - a numerical measurement that describes a value's relationship to the mean of a group of values.

AUROC–Area Under Receiver Operating Characteristics Curve

Figure 12. Multiple receiver operating characteristics curve comparing predictive ability of parameters for post extubation NIV requirement



The ability of P/FP ratios and C_{STAT} to accurately predict post – extubation NIV requirement was analysed with multiple ROC curves comparing AUROC (Area Under Receiver Operating Characteristics Curve) of PFP – 1 hour, PFP-ICU, PFP-PRE EXT and $C_{STAT.}$ Youden index J was used to derive the optimal cut-off of each parameter with maximum sensitivity and specificity.

C_{STAT} showed the maximum AUROC (0.911) (Figure 11) with optimal cut off being ≤24.6 at which it could predict post extubation NIV requirement with 97 % specificity and 78 % sensitivity ($p < 0.001$).

P/FP -1 HOUR values ≤150 were predictive of post extubation NIV requirement with a specificity of 85.4 % AUROC (0.736) (p value < 0.001). PFP ICU and PRE -EXT with optimal cut off of ≤223.3 and ≤252.5 respectively had a sensitivity of 67.8% and 74.2 % respectively with AUROC of 0.727 and 0.738 respectively (p value < 0.01) (Table 11, Figure 11).

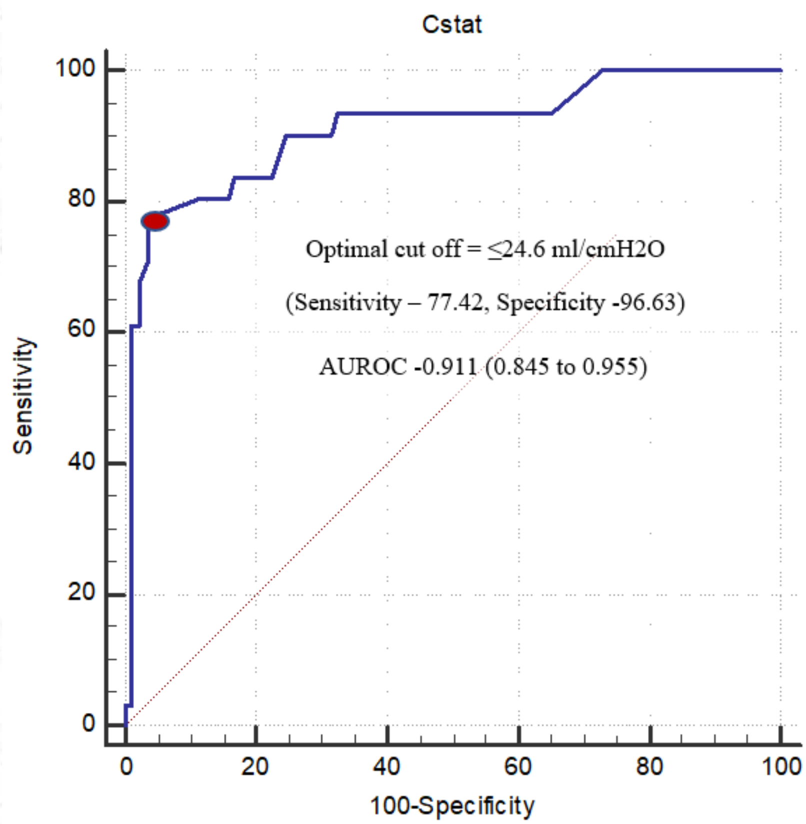


Figure 13(a). ROC of C_{STAT} with optimal cut-off to predict post extubation NIV requirement

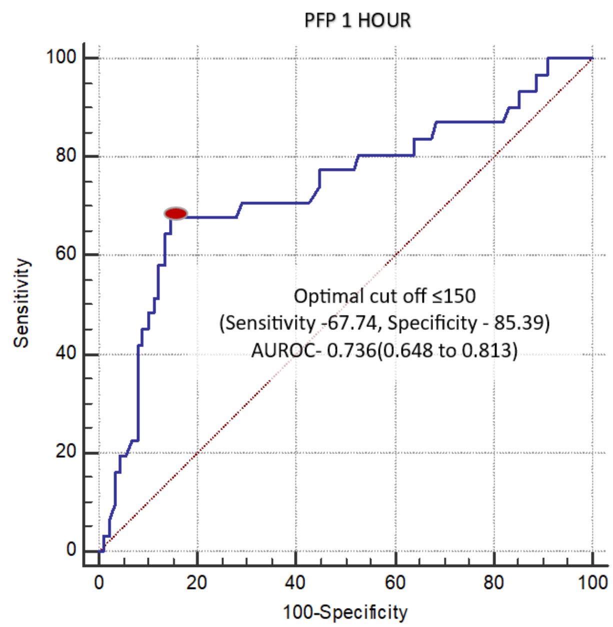


Figure 13(b). ROC of PFP 1 HOUR with optimal cut -off to predict post extubation NIV requirement.

Table 12: Predictive ability of the parameters for postoperative pulmonary complications

Variable	Cstat	PFP 1 HOUR	PFP ICU	PFP PRE-EXT	Pplat
PPC present (n = 27, 22.5%)					
PPC absent (n = 93, 77.5%)					
AUROC	0.748	0.585	0.552	0.589	0.686
Standard Error	0.062	0.0739	0.0691	0.0669	0.064
95% Confidence interval	0.660 - 0.823	0.492 - 0.674	0.458 - 0.642	0.495 - 0.678	0.595 - 0.768
z statistic	3.996	1.15	0.746	1.324	2.91
Youden index J	0.4743	0.3357	0.2605	0.2139	0.3823
Optimal cut-off	≤24.6	≤136.6	≤196	≤202	>17
Sensitivity	59.26	51.85	51.85	40.74	62.96
Specificity	88.17	81.72	74.19	80.65	75.27
Positive Likelihood Ratio	5.01	2.84	2.01	2.1	2.55
Negative Likelihood Ratio	0.46	0.59	0.65	0.73	0.49
Positive Predictive Value	59.3	45.2	36.8	37.9	42.5
Negative Predictive Value	88.2	85.4	84.1	82.4	87.5
p value	<0.001*	0.25	0.4554	0.1855	0.0036

PFP-ICU- P/FP ratio calculated on patient arrival to ICU, PFP- 1 hour – P/FP ratio calculated at 1 hour after receiving the patient to ICU, PFP – PRE EXT – P/FP ratio calculated just before extubation, *- p < 0.05

Figure 14. Receiver operating characteristics curve showing predictive ability of C_{STAT} for Postoperative pulmonary complications.

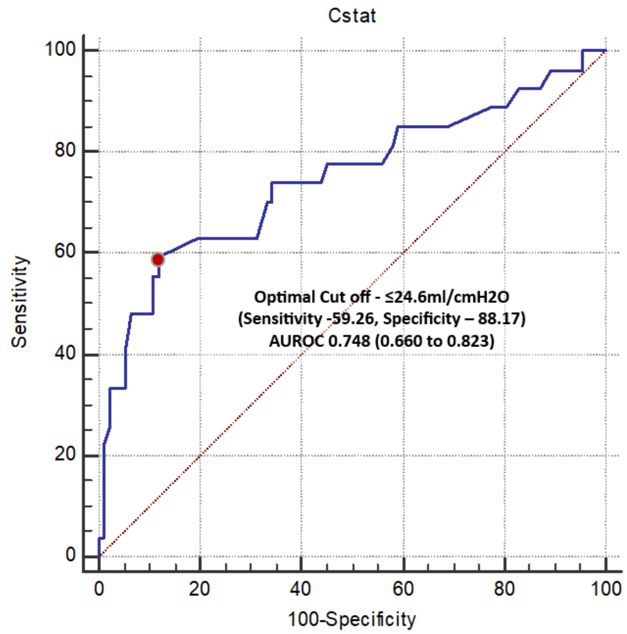
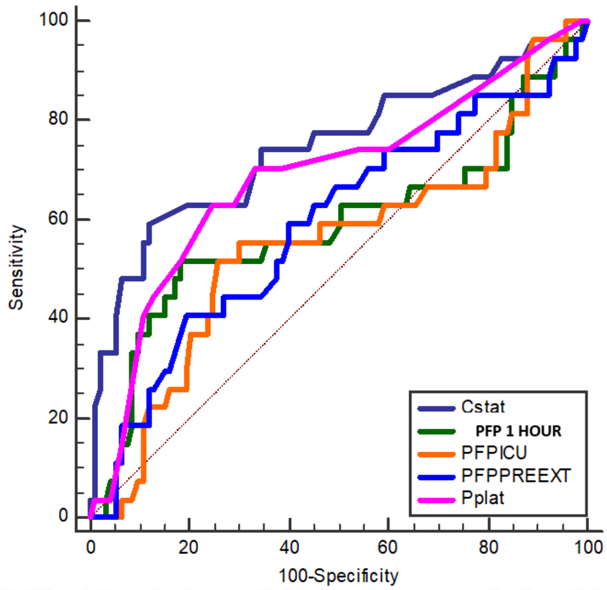


Figure 15. Multiple Receiver operating characteristics curve comparing predictive ability of parameters for postoperative pulmonary complications (PPC)



Maximum AUROC

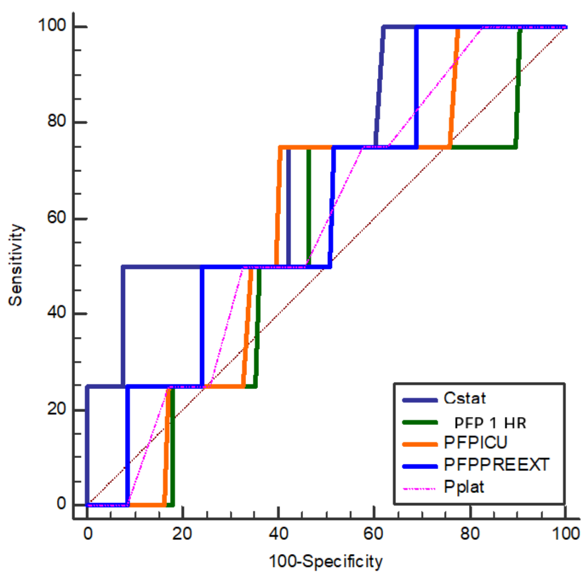
C_{STAT} **(0.748)**
(0.660 to 0.823)

The ability of C_{STAT} to predict the development of postoperative pulmonary complications (PPC) is validated by a higher AUROC (0.748) with a specificity of 88% with an optimal cut off of ≤24.6, p value <0.001. None of the values of P/FP ratios measured at different time points were significantly associated with postoperative operative pulmonary complications statistically. (Table 12, Figure 13,14)

Table 13: Predictive ability of the parameters for Tracheal Reintubation

Variable	Cstat	PFP -1 HOUR	PFP ICU	PFP PRE EXT	Pplat
Reintubation- Yes (n=4, 3.3%)					
Reintubations – No (n=116, 96.7%)					
AUROC	0.722	0.524	0.582	0.617	0.583
Standard Error	0.146	0.156	0.131	0.138	0.134
95% Confidence interval	0.633 - 0.800	0.431 - 0.616	0.488 - 0.671	0.524 - 0.705	0.489 - 0.672
z statistic	1.518	0.152	0.627	0.848	0.618
Youden index J	0.4224	0.2845	0.3448	0.3103	0.1724
Optimal cut off	≤21.77	>275	>282.5	>260	>14
Sensitivity	50	75	75	75	50
Specificity	92.24	53.45	59.48	48.28	54.31
Positive Likelihood Ratio	6.44	1.61	1.85	1.45	1.09
Negative Likelihood Ratio	0.54	0.47	0.42	0.52	0.92
Positive predictive value	18.2	5.3	6	4.8	3.6
Negative predictive value	98.2	98.4	98.6	98.2	96.9
p value	0.129	0.8794	0.5305	0.3963	0.5368

Figure 16: Multiple Receiver operating characteristics curve comparing predictive ability of parameters for tracheal reintubations



No parameters showed statistical significance

Low PFP ratios or C_{STAT} were not significantly associated with tracheal reintubations statistically (p value >0.1) with low AUROCs.(Table 13, Figure 15)

Table 14: Risk factors for post extubation NIV requirement.

Parameters	Patient group with post extubation- NIV requirement	χ^2	p value
Diastolic Dysfunction	n= 23, 74.2%	25.347	<0.001
Smoking	n= 22, 71%	6.235	<0.013
EF<45%	n=8, 25.8%	5.63	<0.018
PPC	n=19, 61.3%	36.07	<0.001

Values are expressed as percentage incidence. χ^2-Chi square test was used to examine the influence of categorical variables on test statistic. EF- Ejection Fraction, PPC- Postoperative pulmonary complications, NIV- Non -invasive Ventilation.

Moderate left ventricular systolic dysfunction with ejection fraction < 45 % ($\chi2$ - 5.63), development of PPCs ($\chi2$ - 36.07), diastolic dysfunction ($\chi2$ - 25.35) and h/o smoking ($\chi2$ - 6.25) were associated with post-extubation NIV requirement p value < 0.01.

Table 15: Influence of systolic and diastolic dysfunction on PFP-1hour and static lung compliance

	PFP-1 HOUR (<150)	χ^2	p value	Cstat <24.6	χ^2	p value	PPC	χ^2	p value
EF<45%	n=8, 24.2%	4.69	0.03	n=7, 26.9%	5.31	0.021	n=5, 18.5%	0.81	0.368
Diastolic Dysfunction	n=18, 54.5%	6.27	0.012	n=19, 73.1%	18.95	0.001	n=17, 63%	10.37	0.001

Values are expressed as percentage incidence. χ^2-Chi square test used to examine the influence of categorical variables on test statistic.

Patients with low ejection fraction < 45% (moderate left ventricular systolic dysfunction) and diastolic dysfunction had low P/FP -1 HOUR (< 150) ($p < 0.05$) and C_{STAT} < 24.6 ml/cm H20 ($p < 0.05$), while diastolic dysfunction had correlation with development of PPCs. (χ^2 - 10.37) (p value -0.001) (Table 15)

Table 16– Correlation of CPB time and aortic cross clamp time with variables

Correlation of CPB time with variables	Pearson Correlation r	p value
PFP - 1 HOUR	-0.002	0.982
PFP - PRE EXT	0.027	0.771
PFP - ICU	-0.149	0.105
Cstat	-0.028	0.76
Correlation of Cross clamp time with variables		
PFP - 1 HOUR	0.026	0.781
PFP - PRE EXT	0.011	0.906
PFP - ICU	-0.142	0.124
Cstat	-0.03	0.746

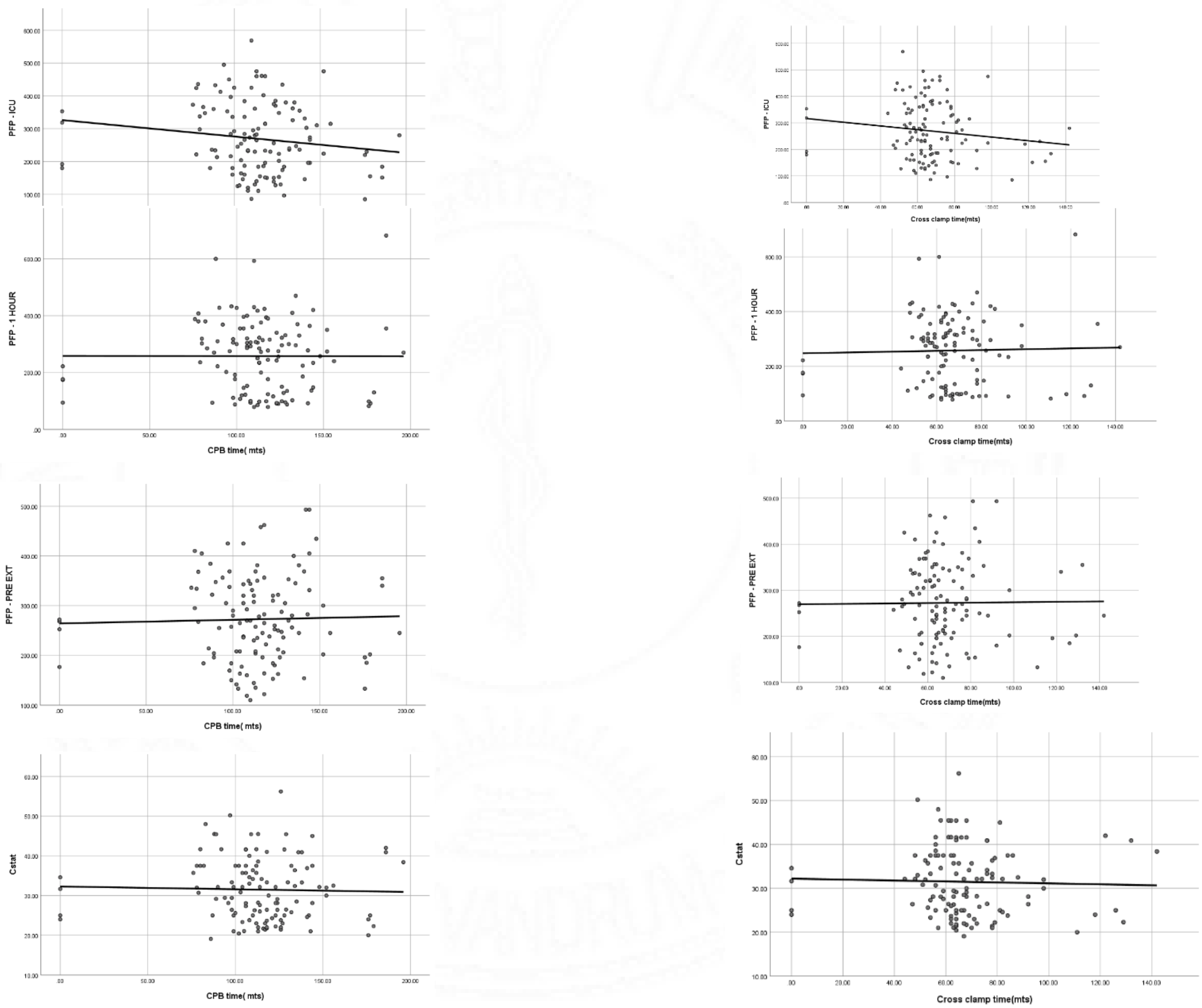
Pearson r – Pearsons's product moment correlation coefficient, measure of linear correlation between two sets of data.

CPB – Cardio Pulmonary Bypass, PFP-PaO2/(FiO2 X PEEP) ratio, PRE EXT-Pre Extubation, Cstat- Static Lung Compliance. ICU- Intensive Care Unit

There were no correlation between CPB time and aortic cross clamp time with P/FP ratios and static lung compliance (C_{STAT}).(p value > 0.05) (Table 16, Figure 16)

Figure 17: Correlation between cardiopulmonary bypass time and Aortic cross clamp time with P/FP ratios and static lung compliance (C_{STAT})

***CPB* time** | **Aortic Cross clamp time**



DISCUSSION

DISCUSSION

The common pulmonary parameters which are clinically correlated for tracheal extubation are PaO2, PaO2/FiO2 (P/F) ratio and PaCO2 with adjusted ventilator settings. These parameters independently depend on the inspired concentration of oxygen (FiO2) and the presence of shunts and hence are not reliable indices of oxygenation status of a patient. To the best of our knowledge, there were no studies published in the literature where the P/FP ratio and static lung compliance were assessed to predict the requirement of NIV, occurrence of PPC tracheal reintubations after extubation which can be surrogate markers for fast-track failure.

The results from our study demonstrated that the P/FP ratio and static lung compliance can serve as reliable objective pulmonary parameters to predict the post extubation NIV requirement and PPC which may delay early weaning and fast-tracking in cardiac surgical patients. The essential concept of fast-tracking in cardiac surgery involves early weaning and extubation of patients within six to eight hours after cardiac surgery and transfer of the patient to the step down ICU on the same day of surgery , that aims to decrease resource utilization and improve overall cost reduction.[49]

Fast-track failure has been demonstrated to be associated with increased morbidity and mortality[50]. To prevent fast-track failures in cardiac surgery, the need exists for attaining well-defined respiratory parameters as one of the goal in aiming optimal results[51].

Therefore, in the present study we evaluated the role of P/FP ratio and Cstat to predict the post extubation NIV requirement, PPC and tracheal reintubations which could be included as objective pulmonary parameters in existing fast-track protocols. In our study, we aimed to introduce a pulmonary parameter with cut off values (P/FP 1 HOUR ≤150 and Cstat ≤ 24.6ml/cmH2O) to identify the high-risk patients who may require post extubation NIV and develop PPC. This will help in decision making regarding weaning and extubation strategies in postoperative cardiac surgical patients.

In a study in acute respiratory distress syndrome (ARDS) patients, PEEP was incorporated in the P/F ratio to study the effect of the PEEP on P/F ratio47. Their analysis found that the addition of PEEP into the P/F ratio increases its ability to predict in-hospital mortality in ARDS patients. Also, it helped to identify the presence and aids grading in severity of ARDS. In our study, we studied the role of P/FP ratio to assess the oxygenation status in post cardiac surgical patients. We found that although the P/FP ratios at different time points predicted the requirement of NIV, the optimal cut off value of PFP-1 HOUR (≤150) was more specific in predicting the need of NIV post extubation (specificity -85.39, positive predictive value – 61.8). The PFP -1 HOUR can guide the intensivist in making appropriate decision on early extubation during fast-tracking after cardiac surgery.

The C_{STAT} is defined as change in lung volume per unit change in pressure when there is absence of gas flow. It was calculated from the ventilator derived parameters like tidal volume, plateau pressure and PEEP [C_{STAT} = tidal volume/ (plateau pressure -PEEP)].52

The C_{STAT} may be decreased in air trapping, pulmonary edema, atelectasis, consolidation, pneumonia, pneumothorax, hemothorax, pleural effusion, pneumomediastinum and abdominal distention52,53. The systemic inflammatory response syndrome caused by the extracorporeal circuit can induce infiltrates in the pulmonary parenchyma and vasculature which can lead to reduction in lung compliance.53 Although, studies had shown that CSTAT was reduced in patients after cardiac surgery, but it was not sensitive and accurate enough to help in assessing the prognosis of the patients with regard to weaning from mechanical ventilation and tracheal extubation. Monitoring CSTAT may help to identify the pulmonary complications early and hence can aid in implementing preventive and treatment strategies like alveolar recruitment maneuvers for collapse-atelectasis and intercostal drainage tube placement for pneumothorax or pleural effusion.[54]

In our study , C_{STAT} of patients at 1 hour of ICU admission ranged from 19.09 to 56.2 ml/cmH2O with a mean value of 31.6 ± 7.9.The optimal cut-off of C_{STAT} value .(≤24.6 ml/cmH2O) was strongly associated with post extubation NIV requirement (Sensitivity-77.4, Specificity-96.63 and positive likelihood ratio of 22.97) was and PPC (sensitivity of 59.26, specificity of 88.17 and positive likelihood ratio of 5.01). Studies have shown that the incidence of PPC was very high after cardiac surgery.[44,54] Therefore it is extremely important to predict the development of PPC early in the postoperative period. We recommend the Cstat value >24.6 ml/cmH2O at 1 hour of ICU admission as a reliable pulmonary parameter to safely execute weaning and tracheal extubation during fast-tracking.

There is a significant reduction in the left ventriculr stroke work during positive pressure ventilation as it helps in decreasing the left ventricular transmural pressure gradient in systole. It also helps in reducing the extravascular lung water.[55] Hence those patients with systolic and diastolic dysfunction can become NIV dependant post extubation that becomes evident from our study. This implies that the weaning and tracheal extubation may not be easy in patients with systolic or diastolic dysfunction. It needs a strategic approach with reliable pulmonary parameters to guide weaning from mechanical ventilatory support.

In our study we found that patients with systolic and diastolic dysfunction had low P/FP ratio (≤150 p and Cstat (≤24.6ml/cmH2O) at 1 hour of ICU admission. So, we recommend that all patients with systolic and diastolic dysfunction should undergo a delayed tracheal extubation and also the NIV support should be commenced electively soon after tracheal extubation. Studies have shown that increase in CPB time does not affect Po_2 , in our study too, there wasn't any correlation.[56] In our study , the requirement of NIV support after tracheal extubation was 25.8% and the incidence of PPC was 22.5%. The ideal ventilatory modes and parameters which needs to be set during the conduct of CPB still remains to be defined and validated.

Low tidal volume ventilation with high PEEP and alveolar recruitment manoeuvres shall be considered in an open-lung ventilatory strategy on CPB to reduce the PPC.[57] Preoperative intensive physiotherapy to strengthen respiratory muscles were shown to be beneficial and could decrease the incidence of PPCs in patients who underwent CABG surgery[58].

Prophylactic use of continuous positive airway pressure also has shown to decrease PPCs by preventing atelectasis formation[58]. The scope of this study was with limited focus and serves to attract future prospective randomised studies on fast tracking after cardiac surgery.

CONCLUSION AND LIMITATIONS

CONCLUSION

- Clinical manifestation of fast-tracking failure are evident by delayed extubation beyond 6 hours, with delayed mobilisation to step down ICU / PACU (Post Anaesthesia Care Unit) and transfer to normal ward beyond 36 hours. This statistically correlated in terms of post extubation NIV requirement and development of postoperative pulmonary complications.

- Combined P/FP ratio ≤ 150 and Static lung Compliance ≤ 24.6 ml/cmH20 at 1 hour after receiving the patient in ICU after surgery, strongly predicts post extubation NIV requirement.

- While, static lung compliance ≤ 24.6 ml/cmH20 at 1 hour can independently predict the development of PPC, which leads to fast-track failure.

- Static lung compliance and the new P/FP ratio can alley the clinical doubts regarding early weaning and extubation and predict fast-track failure within 1hr. These parameters can be a good predictor and has a potential to be well considered for inclusion in the existing fast-track protocols in cardiac surgery.

- Systolic (EF<45%) and Diastolic-dysfunction, smoking, postoperative pulmonary complications had an independent statistically significant association with post extubation NIV requirements, while diastolic-dysfunction had a strong association with only postoperative pulmonary complications.

LIMITATIONS

- We acknowledge that there were certain limitations in our study. First, this is a prospective observational study with limited sample size.
- Second, all patients in our study followed the institutional protocol for tracheal extubation. So, the observations of our study cannot be directly implemented in patients planned for fast-tracking after cardiac surgery.
- Third, the present study was conducted in a heterogenous cardiac surgical population which included CABG, valve surgeries and combination of both. This could have independently influenced the heart lung interactions and respiratory physiology, thereby affecting the absolute values of P/FP ratios and static lung compliance.
- Fourth, we did not analyse the requirement of NIV support and occurrence of PPC in patients with LV systolic and diastolic dysfunction.
- Finally, the institutional protocols vary regarding NIV administration or re-tracheal intubations which could influence the outcome of the present study in different ICU settings. Future multicentric studies with large sample size and randomization is needed to validate the results of our study and to add strength to the literature.

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ANNEXURES

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)
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Institutional Ethics Committee
(IEC Regn No. ECR/189/Inst/KL/2013/RR-21)

SCT/IEC/1874/MAY/2022 21.10.2022

Dr. Hari Dev JJ
Senior Resident
Department of Anaesthesiology
SCTIMST, Thiruvananthapuram

Dear Dr. Hari Dev,

The Institutional Ethics Committee held on 13th May, 2022, reviewed and discussed your application to conduct the study titled "**ROLE OF THE NEW PAO2/(FIO2 X PEEP) [P/FP] RATIO AND STATIC LUNG COMPLIANCE IN FAST TRACKING CARDIAC SURGERY**" (IEC/1874).

The following members of the Ethics Sub-committee were present at the meeting held on 13th May, 2022.

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. Pradeep S	MBBS, MD	Male	Basic Medical Scientist	No
2.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
3.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
4.	Dr. P. Manickam	BSMS, MSc (Epid).,PhD	Male	Health Science Expert/ Social Scientist	No
5.	Adv. Priya Kaimal	LLM, MBL	Female	Legal Expert	No
6.	Dr. Manikandan.S	MBBS,MD,PDCC	Male	Clinician	Yes
7.	Dr. Srinivas G	PhD	Male	Basic Medical Scientist (Member Secretary)	Yes

The following documents were reviewed:

Original submission

1. Checklist Form
2. Abbreviations
3. Covering letter addressed to the Chairman, IEC, SCTIMST dated 02.09.2021
4. IEC Application Form
5. Declaration form
6. Forwarding letter
7. Research Proposal
8. Proforma
9. Patient Information Sheet in English and Malayalam
10. Informed Consent Form in English and Malayalam
11. CV of PI and Co-PIs
12. SRC Recommendation letter

Revised submission

1. Covering letter addressed to the Member Secretary, IEC, SCTIMST dated 15.10.2022
2. Checklist Form
3. Abbreviations
4. Covering letter addressed to the Chairman, IEC, SCTIMST dated 02.09.2021
5. IEC Application Form
6. Declaration form
7. Forwarding letter
8. Research Proposal
9. Proforma
10. Patient Information Sheet in English and Malayalam
11. Informed Consent Form in English and Malayalam
12. CV of PI and Co-PIs

IEC Decision

The IEC approved the conduct of the study in the present form.

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,

Dr. G. Srinivas
Member Secretary, IEC

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE (IEC)
SCTIMST, THIRUVANANTHAPURAM

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
INSTITUTIONAL ETHICS COMMITTEE (IEC)
SCTIMST
THIRUVANANTHAPURAM

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PATIENT INFORMATION SHEET

Title of study:

ROLE OF THE NEW PaO2/(FiO2 X PEEP) [P/FP] RATIO AND STATIC LUNG COMPLIANCEIN FAST TRACKING CARDIAC SURGERY

What is P/FP ratio and Static lung Compliance?

P/FP ratio is an index of oxygenation of arterial blood in your body. It helps in managing ventilationstrategy in ICU and identifying complications.
Static lung compliance is the measure of expandability of lung for a particular change in pressurewhen there is no flow of air in and out of lungs.

How can these be calculated?

P/FP ratio can be calculated from the arterial blood gas analysis which we routinely perform in ourICU. This doesn't require an additional prick since we will be routinely placing a cannula in radial/femoral artery under anesthesia for all cases, from which blood can be aspirated.

Static lung compliance is a value that is obtained from the ventilator when it is connected to you formechanical ventilation.

What are the risks and side-effects?

There are no risks or side effects associated as this an observational study without intervention.

Why are we doing this study?

Majority of the cardiac surgeries involves cardiopulmonary bypass which maintains the oxygenation and perfusion during the surgery. Due to this reason, as well due to the effect of residual anesthesia , you will be mechanically ventilated until you are fully awake , hemodynamically stable and maintaining good oxygenation. After all surgeries, prolonged mechanical ventilation can deteriorate your health , so weaning early from ventilator is extremely important . P/FP ratio and static lung compliance may help in deciding ventilation strategies postoperatively as well may help to predict early pulmonary complications.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you will be free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.
What will happen if you develop any study related injury?
We do not expect any injury to happen to you as this is an observational study

Will you have to pay for the study?
No.

Will your personal details be kept confidential?

Your personal details will be kept confidential. The result of this study maybe be published ina medical journal but you will not be identified by name in any publication or presentation of results.

If you have any further questions, please ask:

Dr. Subin Sukesan, Additional Professor, Division of Cardiac Anesthesia, Department of Anesthesia (Tel:8289983726)

Name of the PI**: Dr. Hari Dev J J**, Senior Resident, Division of Cardiac Anesthesia, Department of Anesthesia (Tel:9074555232 or email id: jjharidev@gmail.com)

Signature of the PI:

For any clarifications regarding the study's ethics clearance, you may contact:-

Dr. Shrinivas G,
Member Secretary of SCTIMST- IEC,Phone number:0471-2524689,
Email id : iec.mem.sec@sctimst.ac.in

INFORMED CONSENT

I,________________________________S/o, D/o, H/o, w/o, F/o, M/o or G/o ________________ ______(Name of the patient) aged_______(in years), declare that I have read the above informationprovided to me regarding the study **"Role of the new PaO2/ (FiO2 X PEEP) [P/FP] ratio and Static lung compliance in fast tracking Cardiac surgery"**

Please tick the relevant boxes

- I confirm that I have read and understood the information sheet dated… for the above study and have the opportunity to ask questions []
- I also understand that my ward's participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights []
- Iunderstandthattheinvestigatorsandinstitutionalethicscommitteememberswillnotneedm y permission to look at the health records even if I withdraw my ward from the trial. I agree tothis access []
- I understand that my ward's identity will not be revealed in any information released to thirdparties or published []
- I voluntarily agree to allow my ward to take part in this study []
- I received a copy of this signed consent form []

Name:

Signature :

Date:

Name of witness:

Relation to participant:

Date:

Signature:

(PERSON OBTAINING CONSENT)

I attest that the requirements for informed consent for the medical research project described in thisform have been satisfied. I have discussed here search project with the parents/guardian/participant and explained to him or her in nontechnical terms all of the information contained in this informed consentform, including any risks and adverse reactions that may reasonably be expected to occur. I furthercertify that I encouraged the participant to ask questions and that all questions asked were answered.

____

Name and Signature of Person Obtaining Consent (For Principal Investigator)

Contact No: 9074555232

Dr. Hari Dev J.J (Principal Investigator)

<u>രോഗിക്കുള്ള കാര്യവിവരണപത്രം</u>

ശീർഷകം

"ഹൃദയശസ്ത്രക്രിയ്ക്കുശേഷം ആരോഗ്യം വീണ്ടെടുക്കുന്നത് ത്വരിതപ്പെടുത്തുന്നതിന്റെ അളവ്കോലായി പി/എഫ്.പി റേഷിയോയും ശ്വാസകോശത്തിന്റെ സ്റ്റാറ്റിക് കോംപ്ലിയൻസും വഹിക്കുന്ന പങ്കിനെ അടിസ്ഥാനമാക്കിയുള്ള പഠനം."

പഠനത്തിന്റെ ഉദ്ദേശം (ഞങ്ങൾ എന്തിന് ഈ പഠനം നടത്തുന്നു.)

ഭൂരിഭാഗം ഹൃദയ ശസ്ത്രക്രിയകകളും കാർഡിയോ പൾമോണറി ബൈപാസിന്റെ സഹായത്തോടെയാണ് നടത്തുന്നത്. ഓപ്പറേഷൻ ചെയ്യുമ്പോൾ അവയവങ്ങളിലേയ്ക്കുള്ള രക്തയോട്ടവും നിയന്ത്രിക്കുന്നത് ഈ ഉപകരണമാണ്. ശസ്ത്രിക്രിയാനന്തരം രോഗിയെ സാധാരണയായി വെന്റിലേറ്ററിലാണ് പരിപാലിക്കുന്നത്. പൊതുവായുള്ള ആരോഗ്യവും, ബി.പി., ഹൃദയതാളം, ഇവയെല്ലാം കൃത്യമായി സാധാരണനിലയിൽ ആയാൽ മാത്രമേ രോഗിയെ വെന്റിലേറ്ററിൽ നിന്നും മാറ്റുകയുള്ളൂ. എന്നാൽ വെന്റിലേറ്ററിൽ അധികനാൾ ഘടിപ്പിക്കുന്നത് ശ്വാസകോശത്തിൽ ഉണ്ടാക്കുന്ന മാറ്റങ്ങൾക്ക് കാരണമായേക്കാമെന്ന് പഠനങ്ങൾ സൂചിപ്പിക്കുന്നു. അതിനാൽ വെന്റിലേറ്ററിൽ നിന്നും രോഗിയെ ക്രമാനുഗതമായി വിച്ഛേദിക്കുന്നത് അത്യന്താപേക്ഷിതമാകുന്നു. രക്തധമനിയിൽ നിന്നും എടുക്കുന്ന ശുദ്ധരക്തത്തിൽ ഓക്സിജന്റെ അളവ് നിരീക്ഷിക്കുന്ന പി/എഫ്.പി.റേഷ്യയോ വെന്റിലേറ്റർ ചികിത്സയെ സഹായിക്കുമെന്ന് വിശ്വാസിക്കുന്നു. ശ്വാസകോശത്തിന്റെ വികസനം സൂചിപ്പിക്കുന്ന സ്റ്റാറ്റിക് കോംപ്ലിയൻസും അതുവഴി ശരീരത്തിലെ ഓക്സിജന്റെ അളവ് നിരീക്ഷിക്കുന്നതിലൂടെ രോഗിയുടെ വെന്റിലേറ്റർ സമയം കുറക്കാൻ സഹായകരം ആകുമെന്ന് കരുതുന്നു.

പഠനത്തിന്റെ കാലദൈർഘ്യം എത്ര?

താങ്കളെ ആശുപത്രിയിൽ നിന്നും വിടുതൽ ചെയ്യുന്നതുവരെ നിരീക്ഷിക്കും. നടപടിയുടെ വിശദീകരണം സ്ഥാപനത്തന്റെ പതിവ് നടപടിക്രമ പ്രകാരം എല്ലാ അംഗീകൃത നിരീക്ഷണങ്ങളും നടത്തും. താങ്കളുടെ ശരീരത്തിലെ ശുദ്ധരക്തത്തിൽ നിന്നും ഓക്സിജന്റെ അളവ് നിർണ്ണയിക്കുകയും, വെന്റിലേറ്ററിന്റെ സഹായത്തോടെ ശ്വാസകോശത്തിന്റെ വികസനക്ഷമത നിരീക്ഷിക്കുകയും ചെയ്യും. ഈ പഠനത്തിൽ പ്രതീക്ഷിക്കാവുന്ന അസ്വസ്ഥതകളെ അപകട സാധ്യതകളോ ഒന്നും ഉണ്ടാകുകയില്ല.

ഈ പഠനത്തിന്റെ നേട്ടങ്ങൾ എന്തെല്ലാം? താങ്കൾക്ക് ഈ പഠനത്തിൽ നിന്നും നേട്ടം ഉണ്ടാകുമോ?

ഹൃദയശസ്ത്രിക്രിയാനന്തരം രോഗിയുടെ വെന്റിലേറ്റർ സമയം ചുരുക്കാൻ ഉതകുന്നതാകും ഈ പഠനം എന്ന് കരുതുന്നു. വെന്റിലേറ്ററിൽ നിന്ന് മാറ്റുന്ന രോഗിക്ക് നോൺ ഇൻവേസീവ് വെന്റിലേഷൻ ആവശ്യമായി വരുമോ എന്ന് മുൻകൂറായി തീരുമാനം എടുക്കാനും ഈ പഠനം സഹായകരം ആകുമെന്ന് വിശ്വസിക്കുന്നു

പഠനം ആരംഭിച്ച ശേഷം താങ്കൾക്ക് പിന്മാറാൻ ആകുമോ?

താങ്കളുടെ പഠനത്തിലെ പങ്കാളിത്തം തികച്ചും സ്വമേധയായുള്ളതും സമ്മതം പിൻവലിക്കാൻ ഏതുസമയത്തും താങ്കൾക്ക് സ്വാതന്ത്ര്യമുള്ളതുമാണ്. താങ്കളങ്ങനെ ചെയ്താലും ഈ ആശുപത്രിയിലെ താങ്ങളുടെ പതിവ് ചികിത്സയെ ഒരു തരത്തിലും ബാധിക്കില്ല.

പഠന സംബന്ധമായി എന്തെങ്കിലും പരിക്ക് താങ്കൾക്ക് ഉണ്ടായാൽ താങ്കൾ എന്ത് സംഭവിക്കും?

ഈ പഠനത്തിൽ താങ്കളുടെ പരിശോധനകളുടെയും ചികിത്സയുടെയും വിവരങ്ങൾ വിശകലനം ചെയ്യുക മാത്രമേ ചെയ്യുന്നുള്ളൂ. എന്നതിനാൽ താങ്കൾക്ക് പരിക്കൊന്നും ഞങ്ങൾ പ്രതീക്ഷിക്കുന്നില്ല. പക്ഷേ താങ്കൾക്കെന്തെങ്കിലും പാർശ്വഫലങ്ങളോ പ്രശ്നങ്ങളോ ഉണ്ടായാൽ ഈ ആശുപത്രിയിൽ താങ്കൾക്കധികം ചെലവില്ലാതെ ചികിത്സിക്കും. എന്നാലും സാമ്പത്തികമായ നഷ്ടപരിഹാരം നല്കാനാകില്ല.

പഠനത്തിനായി താങ്കൾ പണം മുടക്കണോ?

പതിവ് ചിലവിലധികമായി താങ്കൾ പണം മുടക്കേണ്ടതില്ല.

താങ്കളുടെ വ്യക്തിപരമായ വിവരങ്ങൾ രഹസ്യമായിരിക്കുമോ?

താങ്കളുടെ വ്യക്തിപരമായ വിവരങ്ങൾ രഹസ്യമായിരിക്കും. ഈ പഠനം പൂർത്തിയാകുമ്പോൾ ഫലങ്ങൾ ഒരു വൈദ്യശാസ്ത്ര ജേർണലിൽ പ്രസിദ്ധീകരിച്ചേക്കാം. പക്ഷേ താങ്കളെ പേരുകൊണ്ട് പ്രസിദ്ധീകരണത്തിലോ പ്രദശനത്തിലൊ ഒരിടത്തും തിരിച്ചറിയാനാകില്ല.

പഠന പങ്കാളികളുടെ എണ്ണം?

ഈ പഠനത്തിൽ ആകെ 120 രോഗികളെ ഉൾപ്പെടുത്തും.

താങ്കൾക്ക് കൂടുതൽ ചോദ്യങ്ങൾ ഉണ്ടെങ്കിൽ താഴെ നല്കിയിരിക്കുന്ന ഗവേഷകരോട് ചോദിക്കുക.

1. **ഡോ. ഹരി ദേവ് ജെ.ജെ.**
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   ഡിവിഷൻ ഓഫ് കാർഡിയോവാസ്കുലാർ& തൊറാസിക് സർജറി,
   ശ്രീ ചിത്തിര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഓഫ് മെഡിക്കൽ സയൻസ് & ടെക്നോളജി
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4. **ഡോ ശ്രീനിവാസ്. ജി**
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   ഇൻസ്റ്റിറ്റ്യൂഷണൽ എത്തിക്സ് കമ്മിറ്റി
   ശ്രീ ചിത്തിരാ തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഓഫ് മെഡിക്കൽ സയൻസ് & ടെക്നോളജി
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<u>സമ്മതപത്രം</u>

" ഹൃദയ ശസ്ത്രക്രിയക്ക് ശേഷം ആരോഗ്യം വീണ്ടെടുക്കുന്നത് ത്വരിതപ്പെടുത്തുന്നതിന്റെ അളവുകോലായി പി/എഫ്.പി റെഷിയോയും ശ്വാസകോശത്തിന്റെ സ്റ്റാറ്റിക് കോംപ്ലിയൻസും വഹിക്കുന്ന പങ്ക് " എന്ന പഠനത്തിൽ പങ്കെടുക്കാൻ ഞാൻ (പങ്കെടുക്കുന്നയാളുടെ പേര്)..
.... സമ്മതം നൽകുന്നു.
ജനനതീയതി/വയസ്.. മാസങ്ങളിൽ /വർഷത്തിൽ)
.... (അച്ഛൻ /അമ്മയുടെ പേര്)

<u>((പ്രസക്തമായ കോളങ്ങളിൽ ശരിയടയാളമിടുക)</u>

1. **"ഹൃദയ ശസ്ത്രക്രിയക്ക് ശേഷം ആരോഗ്യം വീണ്ടെടുക്കുന്നത് ത്വരിതപ്പെടുത്തുന്നതിന്റെ അളവുകോലായി പി/എഫ്.പി റെഷിയോയും ശ്വാസകോശത്തിന്റെ സ്റ്റാറ്റിക് കോംപ്ലിയൻസും വഹിക്കുന്ന പങ്ക് "** എന്ന പഠന സംബന്ധമായി ....തീയതിയിൽ എനിക്കു തന്ന കാര്യ വിവരണ പത്രം വായിക്കുകയും മനസ്സിലാക്കുകയും ചോദ്യങ്ങൾ ചോദിക്കാൻ എനിക്ക് അവസരം ലഭിക്കുകയും ചെയ്തു. [ ]

2. എന്റെ പങ്കാളിത്തം സ്വമേധയായാലാണെന്നും, എന്റെ പതിവ് ചികിത്സയെയോ നിയമപരമായ അവകാശങ്ങളെയോ ബാധിക്കാതെ ഏതു സമയത്തും പങ്കെടുക്കുന്നതിനുള്ള എന്റെ അനുവാദം പിൻവലിക്കാമെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. [ ]

3. ഈ പഠനത്തിന്റെയും ഇതുമായി ബന്ധപ്പെട്ട ഭാവിയിലെ പഠനങ്ങളുടെയും ക്ലിനിക്കൽ പരിശോധനയുടെ സ്പോൺസർ, സ്പോൺസറിനു വേണ്ടി പ്രവർത്തിക്കുന്നവർ, എത്തിക്സ് കമ്മിറ്റിയും നിയന്ത്രണാധികാരികളും എന്നിവർക്ക് പഠനത്തിൽനിന്നും ഞാൻ പിൻമാറിയാലും ഈ പഠനവുമായി ബന്ധപ്പെട്ട ആരോഗ്യരേഖകൾ എന്റെ അനുവാദം കൂടാതെ പരിശോധിക്കാമെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു, അതിന് ഞാൻ സമ്മതിക്കുന്നു. എന്നിരുന്നാലും എന്റെ വ്യക്തിപരമായ വിവരങ്ങൾ മൂന്നാം കക്ഷികൾക്കോ പ്രസിദ്ധീകരണങ്ങൾക്ക് നൽകുകയോ ഇല്ലെന്നു മനസ്സിലാക്കുന്നു . [ ]

4. ശാസ്ത്രീയ ഉദ്ദേശത്തോടെയുള്ള ഉപയോഗത്തിന് ഈ പഠനത്തിൽനിന്നുള്ള വിവരങ്ങൾ ഉപയോഗിക്കുന്നതിന് തടസ്സമാവില്ലെന്ന് ഞാൻ സമ്മതിക്കുന്നു.[ ]

5. ഞാൻ ഈ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു. [ ]

6. ഞാൻ സ്വമേധയാ ഈ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു. [ ]

7. സമ്മത പത്രത്തിന്റെ ഒപ്പിട്ട ഒരു പ്രതി എനിക്ക് ലഭിച്ചു. [ ]

പേര്

ഒപ്പ്

തീയതി

സാക്ഷിയുടെ പേര്

രോഗിയുമായുള്ള ബന്ധം

ഒപ്പ്

<u>സമ്മതപത്രം വാങ്ങുന്ന ആൾ</u>

മെഡിക്കൽ റിസേർച്ച് പ്രോജക്റ്റിനാവശ്യമായ സമ്മതപത്രത്തിനു വേണ്ടുന്ന എല്ലാ ഘടകങ്ങളും തൃപ്തികരമായി നിർവഹിച്ചിരിക്കുന്നുവെന്ന് ഞാൻ ബോധ്യപ്പെടുത്തുന്നു. പഠനപങ്കാളിയുമായി ഗവേഷണ പദ്ധതിയെപ്പറ്റി സാങ്കേതികേതര പദങ്ങളുപയോഗിച്ചു എല്ലാ വിവരങ്ങളെ പറ്റിയും ചർച്ച നടത്തുകയും പ്രതീക്ഷിക്കാവുന്ന അപകട സാധ്യതകളും ,പാർശ്വഫലങ്ങളും വിശദീകരിക്കുകയും ചെയ്തു. പങ്കാളിയെ ചോദ്യങ്ങൾ ചോദിക്കാൻ പ്രേരിപ്പിക്കുകയും എല്ലാ ചോദ്യങ്ങൾക്കും ഉത്തരം നൽകുകയും ചെയ്തു എന്നും ഞാൻ സാക്ഷ്യപ്പെടുത്തുന്നു.

സമ്മതപത്രം വാങ്ങുന്ന ആളുടെ പേര്

ഒപ്പ്

തീയതി

ബന്ധപ്പെടാനുള്ള നമ്പർ - 9074555232

ഹരി ദേവ് ജെ.ജെ
(പ്രധാന ഗവേഷകൻ)

MASTER CHART

Sl.no	SEX	AGE	SURGERY	PFP - IC	PFP - 1 HOUR	PFP - PRE EXT	PaO2 -Pre NIV	FiO2-Pre NIV	duration of mechanical ventilation(	P/F ratio pre NIV	Timing of NIV postextubation	Pplat	Cstat	NIV	Duration of NIV(HRS	REINTUBATI	POPC	Alveolar recruitment manouvre	Diabetes	Hypertension	POPC	Ejection Fracti	Reactive airway disease	Diastolic dysfunction	CPB time(mts)	Cross clamp time(mts)
1	1	68	CABG	160	177	150			16			18	25	0		0	0	0	1	1	0	68	0	1	39	56
2	1	72	CABG	284	320	425			14.5			12	41.6	0		0	0	0	1	1	0	58	0	1	106	64
3	1	64	CABG	140	97.6	135	112	0.4	15	280	0	21	21	1	28	0	1	0	1	1	1	42	1	1	113	70
4	1	32	AVR	300	376	350			8.5			14	32.14	0		0	0	0	0	0	0	66	0	0	114	74
5	0	35	MVR	373	388	336			9			14	35.71	0		0	0	0	0	0	0	54	0	0	76	53
6	0	41	MVR	366	380	405	84	0.44	11	193		12	37.5	1	26	0	1	0	0	0	1	51	0	0	82	63
7	0	56	CABG	362	470	256			17			11	36.36	0		0	0	0	0	0	0	65	0	0	134	78
8	1	53	MVR+CABG	151	682	340			20			10	42	0		0	0	0	0	0	0	58	0	0	186	122
9	1	72	CABG	273	360	350			17			11	45.45	0		0	0	0	1	0	0	56	1	1	109	62
10	1	56	AVR	187	400	343			9			14	35.7	0		0	0	0	0	0	0	48	0	0	106	70
11	0	59	DVR	127.7	89.79	180	76	0.44	14	172.72		17	26.4	1	32	0	0	1	1	0	0	64	0	0	124	92
12	0	44	MVR+TVRepair	280	417.5	320			9			12	41.66	0		0	0	0	0	0	0	65	0	0	112	61
13	1	49	CABG	461	424	458	74	0.44	18	168.2	1	18	21.7	1	30	0	1	0	1	0	1	46	1	1	116	68
14	1	64	CABG	302.7	364	493			16.5			18	25	0		0	0	0	1	1	0	52	0	1	142	81
15	0	58	MVR+CABG	85	82.14	133			22			20	20	0		0	0	1	1	0	0	54	0	1	176	111
16	1	42	MVR	180	93.75	214	71.5	0.44	8	162.5		21	19.09	1	24	1	1	1	1	0	1	56	1	0	86	67
17	1	40	MVR+TVRepair	233	123.6	122			8.5			19	23.68	0		0	0	1	1	0	0	64	0	0	118	62
18	1	46	DVR	196	234	493	84	0.44	20	191		16	28.12	1	22	0	1	0	0	0	1	62	0	1	144	92
19	0	48	DVR	224	274	300			18			15	30	0		0	0	0	0	0	0	48	0	0	152	98
20	0	36	MVR+TVRepair	150	316	222	89	0.36	7	247.2		15	30	1	16	0	0	0	0	0	0	68	1	1	119	68
21	1	63	CABG	86	78.5	110			20			18	25	0		0	0	1	1	1	0	56	0	0	110	67
22	1	54	CABG	153	150	162.5	96	0.4	18	240	0	21	21.42	1	30	0	0	0	1	1	0	38	0	1	126	78
23	1	71	CABG	273.3	420	405			16.5			12	37.5	0		0	0	0	1	1	0	46	1	1	144	84
24	1	72	CABG	247	330	345			17.5			11	40.9	0		0	1	0	1	1	1	57	0	1	136	76
25	1	69	CABG	125	107.14	141.6	93	0.4	16	232.5	0	22	20.45	1	23	0	1	1	1	1	1	45	1	1	102	64
26	1	60	MVR	221.6	408	410			21			12	37.5	0		0	0	0	0	0	0	64	0	0	78	54
27	1	53	MVR	213.3	428	347.5			18.5			14	32.14	0		0	0	0	0	1	0	62	0	0	90	67
28	0	77	CABG	150	91.07	152.7	82	0.44	19	205		18	22.22	1	22	0	1	0	1	1	1	46	0	0	123	79
29	0	78	CABG	146	122	177.1	78.4	0.4	19.5	196	0	19	21.05	1	18	0	1	1	1	1	1	42	1	1	105	63
30	0	56	CABG	236	224	381.2			17			11	40.9	0		0	0	0	0	1	0	68	0	1	138	76
31	0	48	MVR	436	236	334			8.5			13	30.7	0		0	0	0	0	0	0	64	0	0	79	56
32	1	45	CABG	96.42	87.5	236			12			17	26.47	0		0	0	1	0	0	0	69	0	0	129	76
33	1	63	CABG	402	394	245	87.5	0.36	15	243.1	1	21	21.42	1	28	0	1	0	0	1	1	56	0	1	117	64
34	1	72	CABG	120	93.75	118.7			12.5			13	34.61	0		0	0	0	1	1	0	44	1	1	108	58
35	1	70	CABG	204	396	265			14			14	32.14	0		0	0	0	0	1	0	47	0	1	104	48
36	0	48	DVR	236	410	353	89	0.36	16	247.2		12	37.5	1	24	0	0	0	1	0	0	57	0	1	132	86
37	1	61	CABG	155	314	278			17			12	34.16	0		0	0	0	1	0	0	53	1	1	115	69
38	0	37	MVR	360	600	322			10			11	45.49	0		0	1	0	0	0	1	63	0	0	88	61
39	1	62	OPCABG	180	174	268			9.5			12	31.66	0		0	0	0	1	1	0	38	0	0	0	0
40	1	52	CABG	425	427.5	280			12			12	37.5	0		0	0	0	1	1	0	47	0	0	100	48
41	1	48	CABG	568.8	593	343.75			17			11	36.36	0		0	0	0	0	0	0	71	0	0	110	52
42	0	56	AVR	425	430	270			18			12	34.16	0		0	1	0	0	0	1	58	0	0	110	76
43	0	69	CABG+AVR	280	270	245			24			13	38.4	0		0	0	0	1	1	0	57	0	0	196	142
44	0	33	MVR+TVRepair	460	390	356.25			8.5			10	41	0		0	0	0	0	0	0	36	0	0	118	64
45	1	70	CABG	164	146	163.3	78	0.36	18	216.7	1	23	23.33	1	32	0	0	0	1	1	0	64	1	1	104	54
46	0	70	CABG	380	300	305			18.5			15	33.33	0		0	0	0	1	1	0	58	1	1	130	76
47	1	54	CABG	370	275	252.5	87.5	0.44	22	198.9		16	28.12	1	26	0	1	0	0	1	1	48	1	1	124	68
48	1	56	CABG	127	120	133			18			19	30.83	0		0	0	1	0	0	0	62	0	0	103	51
49	1	62	CABG	353	275	305			16.5			16	28.12	0		0	0	0	1	0	0	64	0	0	96	55
50	1	69	CABG	146	91.8	154	95.6	0.4	14.5	239	0	21	24.6	1	18	0	1	1	1	1	1	40	1	1	141	82
51	1	42	MVR	337.5	319	368			8.5			12	41.66	0		0	0	0	0	0	0	51	0	0	80	56
52	1	45	AVR	475	234	257.5			10			17	28.2	0		0	0	0	1	0	0	63	0	0	113	72
53	1	64	AVR	111.1	100	160	83	0.44	9	188.63		24	23.8	1	23	0	0	1	1	0	0	57	0	1	108	69
54	1	51	CABG	315	277.5	265	72	0.36	10.5	200		18	21.77	1	17	1	1	1	1	1	1	46	0	1	118	64
55	1	53	CABG	130	85.4	144.4	84	0.44	11	190.1		22	23	1	24	0	1	0	1	0	1	46	1	1	112	62
56	0	68	MVR+CABG	230	91.6	185			17			21	25	0		0	0	1	1	1	0	64	0	1	177	126
57	1	56	AVR	375	340	320			8			14	32.14	0		0	0	0	0	1	0	42	0	0	123	72
58	1	68	CABG	336	292	238			14			15	27.33	0		0	0	0	1	1	0	58	0	1	106	54
59	0	41	MVR	432.5	310	204.16			8.5			12	29.16	0		0	0	0	0	0	0	66	0	0	89	64
60	0	48	MVR	412.5	368.7	255			9			12	41.66	0		0	1	0	0	0	1	63	0	0	92	62
61	1	39	MVR+TVRepair	196	78.57	163.8	81.7	0.44	12	185.7		19	22	1	30	0	0	1	0	0	0	68	0	0	118	62
62	1	42	CABG	361.1	305	230			16			14	35.71	0		0	0	0	0	0	0	66	0	0	112	63

59	0	41	MVR	432.5	310	204.16			8.5			12	29.16	0		0	0	0	0	0	0	66	0	0	89	64
60	0	48	MVR	412.5	368.7	255			9			12	41.66	0		0	1	0	0	0	1	63	0	0	92	62
61	1	39	MVR+TVRepair	196	78.57	163.8	81.7	0.44	12	185.7		19	22	1	30	0	0	1	0	0	0	68	0	0	118	62
62	1	42	CABG	361.1	305	230			16			14	35.71	0		0	0	0	0	0	0	66	0	0	112	63
63	1	59	CABG	216	111	169.4			14.5			23	26.4	0		0	0	1	1	1	0	54	0	0	98	47
64	1	54	CABG	292.5	300	290			13			16	25.6	0		0	0	0	1	1	0	59	0	0	100	53
65	0	32	MVR	298	302.5	267.5			16			12	37.5	0		0	0	0	0	0	0	53	0	0	80	56
66	1	62	MVR+CABG	155	130	202	77.5	0.44	22	176.13		21	22.3	1	32	0	1	0	0	1	1	62	0	1	179	129
67	0	61	CABG	450	433	425			12			10	50.2	0		0	0	0	1	1	0	52	0	0	97	49
68	1	60	CABG	315	245	282.5			15			15	33.33	0		0	0	0	1	1	0	61	0	0	118	64
69	1	72	CABG	230	116	238	82	0.36	14.5	227.7		20	24.3	1	14	0	0	1	0	1	0	54	0	1	121	64
70	1	68	CABG	434.3	331.2	287.5			21			12	41.6	0		0	0	0	1	1	0	57	0	1	128	66
71	1	64	CABG	265	235	204			20			14	38.57	0		0	0	0	1	1	0	48	1	0	113	56
72	1	73	CABG	202	98.79	212	86	0.4	18.5	215	0	21	22	1	26	0	0	0	1	1	0	41	1	1	126	67
73	1	46	MVR	234	222	196			9			11	45.45	0		0	0	0	0	0	0	63	1	0	89	64
74	0	69	CABG	240	102.3	270			11			19	25.8	0		0	0	1	1	1	0	46	0	0	132	73
75	1	44	MVR	424	380	295			8.5			10	32	0		0	1	0	0	0	1	52	0	0	78	52
76	1	53	DVR	475	350	202			20			11	32	0		0	0	0	0	0	0	47	0	0	152	98
77	1	71	CABG	184	135	206			21			22	45.45	0		0	0	1	1	1	0	56	0	0	129	68
78	1	52	AVR	460	322.5	208	76	0.36	8.5	211		12	22	1	17	0	0	0	1	0	0	53	0	1	113	72
79	0	51	AVR	384	286	236			9.5			13	41.6	0		0	0	0	0	0	0	61	0	0	106	68
80	1	68	CABG	326	296	280			11.5			14	32.4	0		0	0	0	0	1	0	43	0	0	134	78
81	1	54	CABG	284	305	337.5			12			12	33.33	0		1	1	0	0	1	1	58	0	0	98	54
82	1	38	MVR	236	270	384.3			9.5			18	25	0		0	0	0	0	0	0	67	0	0	87	60
83	1	69	AVR	180	87.5	184	78	0.36	9.5	216.6		19	21	1	27	0	1	1	0	1	1	46	0	0	99	57
84	1	52	CABG	266	147.5	331.2			16.5			10	45	0		0	0	0	1	1	0	59	0	0	144	81
85	0	48	CABG	315	240	245			18			12	32.5	0		0	0	0	0	1	0	67	0	0	156	88
86	0	64	CABG	385	256	260			17.5			12	29.1	0		0	0	0	1	1	0	53	0	0	124	68
87	1	68	CABG	151.4	176.6	462			21			14	26.42	0		0	0	0	1	1	0	54	0	0	118	61
88	1	48	MVR+CABG	220	98.2	196	83.2	0.44	19.5	189.1		21	24	1	33	0	1	1	1	0	1	48	0	1	176	118
89	1	63	CABG	353.1	176.5	272			10			13	34.6	0		0	0	0	0	0	0	34	0	0	0	0
90	1	67	CABG	160	153.1	305			11.5			16	28.1	0		0	0	0	1	1	0	57	0	0	106	58
91	1	48	AVR	396.9	317.5	368.75			9.5			17	29.4	0		0	0	0	0	0	0	61	0	0	98	59
92	0	44	MVR	495	202	356.25			10			11	29.43	0		0	0	0	0	0	0	64	0	0	94	63
93	1	68	CABG	174	95.23	247.2	113	0.4	16	282.5	0	22	25	1	26	0	1	1	1	1	1	42	0	1	128	64
94	1	59	CABG	230	250	307.5			17			12	37.5	0		0	0	0	0	1	0	63	0	0	112	62
95	0	53	CABG	232	306.25	270			14.5			12	33	0		0	0	0	0	1	0	67	0	0	108	49
96	0	58	CABG	336	192	257.5			17.5			14	32.14	0		0	0	0	0	1	0	58	0	0	99	44
97	0	47	MVR+TVR	186	98.8	196	78.5	0.44	21	178.4		21	23	1	20	0	1	1	1	0	1	57	0	0	117	71
98	1	57	CABG	318.8	222	252.5			10.5			14	25	0		0	0	0	0	1	0	41	0	1	0	0
99	1	56	DVR	223.3	296	250	73.6	0.44	22	167.3		21	23.8	1	18	0	0	1	0	1	0	40	0	0	126	84
100	1	51	AVR	266	304	320			11			12	37.5	0		0	0	0	0	1	0	62	0	0	106	59
101	0	68	AVR	295	307.5	331.25			8.5			19	26.3	0		0	0	0	1	0	0	59	0	1	111	63
102	1	62	CABG	234	292.5	292.5			14.5			10	40	0		0	0	0	1	1	0	66	0	0	108	56
103	0	51	MVR+TVRepair	254.2	355	208			10			14	35.7	0		0	0	0	1	1	0	68	0	0	104	65
104	1	74	CABG	184	200	235			12			18	26	0		0	0	0	1	1	0	53	1	0	114	62
105	1	78	CABG	138.3	92.8	184			14			22	25	0		0	0	1	1	1	0	57	1	0	123	66
106	1	61	CABG	196	136.6	282.5	81.2	0.44	16.5	184.54		20	21	1	23	0	1	0	1	1	1	46	0	1	143	78
107	1	63	DVR	310.4	257.5	434.4			20			14	32.14	0		0	0	0	1	0	0	55	0	1	148	82
108	1	72	CABG	256.2	242.5	310			18			16	28.12	0		0	0	0	1	1	0	63	1	1	123	63
109	0	39	MVR+TVRepair	282.5	285	368.75			10.5			11	45.5	0		0	0	0	0	0	0	64	0	0	113	58
110	1	68	CABG	110.4	272.5	381.25			12			18	27.6	0		0	0	0	1	1	0	48	0	0	114	59
111	1	74	CABG	130	128.3	196	94.2	0.4	12.5	235.5	0	23	23	1	26	0	0	0	1	1	0	38	1	1	127	64
112	1	32	AVR	245	355	208			10			12	37.5	0		0	0	0	0	0	0	70	1	0	102	57
113	0	62	CABG	380	370	400			12.5			14	28.5	0		1	1	0	0	1	1	62	0	1	135	67
114	1	60	CABG	331.2	278	368.75			13			13	36.9	0		0	0	0	0	1	0	64	1	0	141	79
115	1	54	CABG	355	186	245			16			12	33.3	0		0	0	0	1	1	0	52	1	0	138	78
116	1	53	CABG	348	322.5	321.8			16.5			8	56.2	0		0	0	0	1	1	0	58	0	0	126	65
117	1	62	CABG	192	94.04	176.6			17			24	24	0		0	1	1	0	1	1	30	0	1	0	0
118	0	47	MVR	347.5	285	184			14.5			10	48	0		0	0	0	0	0	0	63	0	0	83	57
119	0	61	MVR+CABG	184	355	355			22			11	40.9	0		0	0	0	1	1	0	61	0	0	186	132
120	0	41	MVR	248	275	282.5			10.5			11	45.4	0		0	0	0	0	0	0	66	0	0	90	61

PROFORMA

Demographic Details

Study ID Number:
Age:
Sex:
Height:
Weight:
BMI:
BSA:

Preoperative Details

Diabetes (Yes/No)	
Hypertension (Yes/No)	
Smoking	
Reactive Airway Disease	
Ejection Fraction (TTE)	
Diastolic Function (TTE/TEE)	
TAPSE	
Preoperative Hemoglobin	
Serum Creatinine	

TTE – Transthoracic
Echocardiography TEE-
Trans Esophageal
Echocardiography
TAPSE – Tricuspid Annular Systolic Plane Excursion

Intraoperative Details

CABG (OPCAB/ON Pump)	
Valvular surgery (Aortic/Mitral)	
CPB time	
Aortic Cross clamp time	
Preoperative PO2/FiO2 ratio in room air	
P/FP ratio after protamine reversal	

OPCAB – Off Pump CABG

Postoperative Details

P/FP ratio on admission to ICU	
P/FP ratio at 1hr post ICU admission	
Static Lung Compliance assessed at 1hr post ICUadmission	
Alveolar Recruitment Manoeuvre performed?	
P/FP ratio pre extubation (10 minues before extubation) (If no fast tracking, after 6 hrs)	

Postoperative Pulmonary Complications

Pneumonia (Consolidation /infiltrates in CXR/LUS)	
Pneumothorax (Assessed with CXR /LUS)	
Pleural effusion (CXR/LUS)	
Acute pulmonary edema (Clinical signs, CXR/LUS)	
Tracheal reintubation	

CXR – Chest Xray
LUS – Lung Ultrasound

Postoperative Non pulmonary complications.

Postoperative ventricular dysfunction	
Pericardial effusion	
Increased bleeding	

Ventilatory Requirements

Number of days of ICU stay	
Invasive Mechanical Ventilation (hours)	
Hours until tracheal extubation	
Tracheal reintubation	
Post extubation NIV requirement	
Non Invasive mechanical ventilation (hours)	

NIV – Non Invasive Ventilation

95

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