

**COMPARISON OF HEMODYNAMIC PARAMETERS MEASURED BY
THORACIC ELECTRICAL BIOREACTANCE AND 3-D
TRANSESOPHAGEAL ECHOCARDIOGRAPHY IN ADULT CARDIAC
SURGERY PATIENTS.**

*Thesis submitted for the partial fulfillment for the requirement of the Degree of DM
(Cardiothoracic and Vascular Anaesthesia)*



BY

DR. NITHIYANANDHAN P

DM CARDIOTHORACIC AND VASCULAR ANAESTHESIA RESIDENT

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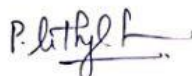
**DIVISION OF CARDIOTHORACIC AND VASCULAR
ANAESTHESIOLOGY, DEPARTMENT OF ANAESTHESIOLOGY,
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND
TECHNOLOGY, TRIVANDRUM, KERALA, INDIA – 695011**

DECLARATION

I hereby declare that this thesis entitled, “Comparison of hemodynamic parameters measured by thoracic electrical bioimpedance and 3-D transesophageal echocardiography in adult cardiac surgery patients” has been prepared by me under the capable supervision and guidance of **Dr. Prasanta Kumar Dash**, Professor, Department of Anaesthesiology, **Dr. Shrinivas Gadhinglajkar**, Professor, Department of Anaesthesiology, **Dr. Rupa Sreedhar**, Senior Professor, Department of Anaesthesiology, **Dr. Jayakumar K**, Senior Professor, Department of Cardiovascular and Thoracic Surgery, **Dr. Vivek Pillai**, Professor, Department of Cardiovascular and Thoracic Surgery, Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram, Kerala.

Date: 11/08/2020

Place: Thiruvananthapuram



Dr. Nithyanandhan P,

DM Cardiothoracic and Vascular
Anaesthesiology Resident, Division of
Cardiothoracic and Vascular Anaesthesiology
Department of Anaesthesiology, SCTIMST,
Thiruvananthapuram.

CERTIFICATE

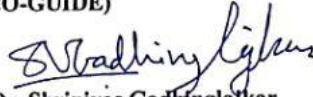
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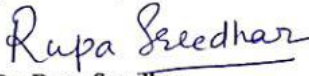
Dr. Prasanta Kumar Dash
Professor,
Division of Cardiothoracic and
Vascular Anaesthesiology,
SCTIMST, Thiruvananthapuram,
India.

(CO-GUIDE)



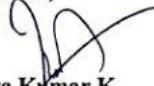
Dr. Shrinivas Gadhinjalakar
Professor,
Division of Cardiothoracic and
Vascular Anaesthesiology,
SCTIMST, Thiruvananthapuram,
India.

(CO-GUIDE)



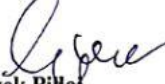
Dr. Rupa Sreedhar
Senior Professor,
Division of Cardiothoracic and
Vascular Anaesthesiology,
SCTIMST, Thiruvananthapuram,
India.

(CO-GUIDE)



Dr. Jaya Kumar K
Senior Professor,
Department of Cardiovascular and
Thoracic Surgery,
SCTIMST, Thiruvananthapuram,
India.

(CO-GUIDE)



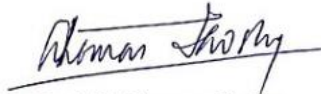
Dr. Vivek Pillai
Professor,
Department of Cardiovascular and
Thoracic Surgery,
SCTIMST, Thiruvananthapuram,
India.

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Date: 26/8/20

Place: Thiruvananthapuram



Prof. Dr. Thomas Koshy,

Senior Professor and Head,
Division of Cardiothoracic and
Vascular Anaesthesiology,
Department of Anaesthesiology,
SCTIMST, Thiruvananthapuram,
India.

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*Place: **Thiruvananthapuram.***

Dr. Nithyanandhan P

ABBREVIATIONS

CO – Cardiac Output.

TB – Thoracic Bioreactance.

TEE – Transesophageal Echocardiography.

VTI – Velocity Time Integral.

CSA – Cross Sectional Area.

LVOT – Left Ventricular Outflow Tract.

CABG - Coronary Artery Bypass Surgery.

HR – Heart Rate.

SV – Stroke Volume.

EF – Ejection Fraction.

SVV - Stroke Volume Variation.

CI – Cardiac Index.

VET – Ventricular Ejection Time.

SVR – Systemic Vascular Resistance.

PLR – Passive Leg Rise.

PAC – Pulmonary Artery Catheter.

OT – Operation Theatre.

BSA – Body Surface Area.

ICU – Intensive Care Unit.

PAC – Pulmonary Artery Catheter.

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INTRODUCTION

The hemodynamic monitoring of cardiac surgical patients remains one of the essential components of paramount importance in patient management. Among the various hemodynamic monitors available, Cardiac output(CO) monitor holds significant importance owing to its effectiveness in analysing the whole body perfusion, tissue oxygen delivery^[1] and alterations in blood pressure. CO is the amount of blood pumped by the left ventricle per minute. It can be calculated by estimating stroke volume(SV) which is the amount of blood ejected by the left ventricle per contraction and multiplying it with the heart rate(HR).

The ideal CO monitor should be readily available, easily interpretable, cost-effective, continuous, minimally or non- invasive and should have better reproducibility in different stressful physiological conditions. With the improvements in technology, various newer modalities of monitoring cardiac output have been discovered. Although CO monitoring using pulmonary artery catheterisation(PAC) with swan ganz catheter was considered as the gold standard in the earlier days, the unfavourable risk-benefit ratio of its invasiveness leads to the development of newer non -invasive and minimally invasive techniques^[2,3,4].

Among the newer techniques discovered in recent decades, transesophageal echocardiography(TEE) has gained popularity in the cardiac surgical operation theatres and peri-operative settings as it helps in visualisation of cardiac structures real-time and also estimates cardiac volumes and filling pressures apart from providing information about the contractility of the cardiac chambers^[5].

Because TEE is minimally invasive and requires knowledge to operate, the introduction of non- invasive thoracic bioreactance(TB) leads to an easy estimation of cardiac output^[6]. The added advantage of thoracic bioreactance is the ease in its estimation of

various other hemodynamic parameters like cardiac index(CI), stroke volume variation(SVV), ventricular ejection time(VET) and total peripheral resistance(TPR).

Cardiac output monitoring holds an imperative place in the goal-directed management of various conditions to improve patient outcomes. Since the cardiac output can be changed by various factors like volume status and cardiac contractility, the assessment of dynamic variants like SVV helps in knowing whether to intervene with volume or contractility.

Although studies have compared TEE with thermodilution PAC cardiac output monitoring with comparable results, no study till now have been done to compare real-time 3D TEE and thoracic bioreactance for assessing the cardiac output and hemodynamic parameters. The aim of the present study was to compare the hemodynamic parameters measured using bioreactance technology and TEE in adult cardiac surgery patients with TEE method as the reference method.

REVIEW OF LITERATURE

Cardiac output monitoring is a dynamic method of assessing hemodynamic parameters by which we can assume how well blood is supplied to the distal parts of the body with a normal cardiac output range between 4 - 8 litres/ minute, varying depending on the patient volume and positional status. There are various methods available globally to calculate cardiac output. They are,

Invasive-

Intermittent bolus pulmonary artery thermodilution,

Continuous pulmonary artery thermodilution;

Minimally invasive-

Lithium dilution CO (LiDCO),

Pulse contour analysis CO (PiCCO and FloTrac),

Oesophageal Doppler (ED),

Transesophageal echocardiography(TEE) and

Non-invasive-

Partial gas rebreathing,

Thoracic bioimpedance and bioreactance,

Endotracheal cardiac output monitor (ECOM),

Doppler method,

Cardiac magnetic resonance imaging and

Photoelectric plethysmography.

Among the methods mentioned here, pulmonary artery catheterisation and measurement of cardiac output were practised globally in initial days, but this being an

invasive one, various other techniques are developed to measure the cardiac output with comparable results.

Importance of cardiac output

The clinical significance of cardiac output is evident from the fact that the patient oxygen delivery depends on the cardiac output and arterial oxygen content. Any interruption or negative effect on either cardiac output or arterial oxygen content will affect the peripheral tissue oxygen delivery^[7,8].

$$\text{Oxygen delivery}(\text{DO}_2) = \text{Cardiac output} \times \text{Arterial oxygen content}(\text{CaO}_2).$$

$$\text{DO}_2 = \text{CO} \times \text{CaO}_2.$$

Or

$$\text{DO}_2 = \text{CO} \times \{(1.34 \times \text{Hb} \times \text{SaO}_2) + (\text{PaO}_2 \times 0.003)\}.$$

Oxygen consumption (VO_2) is the amount of oxygen consumed by the tissues per minute and can be calculated as follows

$$\text{VO}_2 = \text{CO} \times (\text{CaO}_2 - \text{CvO}_2).$$

$$\text{where } \text{CvO}_2 = (1.34 \times \text{Hb} \times \text{SvO}_2) + (\text{PvO}_2 \times 0.003)$$

The oxygen extraction ratio (ER) is the ratio between the actual oxygen delivered to the tissues against the oxygen that is utilised by the tissues^[9,10,11,12].

$$\text{ER} = \text{DO}_2 / \text{VO}_2.$$

The interrelationship between the body metabolism and oxygen consumption mechanism needs a better understanding of hemodynamic assessments in-particular the cardiac output. The critical care and perioperative settings are characterised by the release of various inflammatory mediators resulting in the alteration of the physiology and can be compensated by either increasing the oxygen extraction or cardiac output. The inability to match the increased demand of these clinical states leads to inadequate tissue oxygen extraction resulting in hypoxic injury to the tissues finally resulting in organ dysfunction.

Therefore to avoid these clinical scenarios, optimisation of the cardiac output and oxygen delivery should be our aim using various methods.

Importance in the perioperative setting

There is already enough evidence present to say that optimisation of the cardiac output in the perioperative period was associated with improved outcomes^[13,14,15]. Over the past few decades, the incidence of morbidities due to low cardiac output syndrome have come down with the help of advancement in the hemodynamic monitoring technologies and therapeutic interventions. The perioperative phase is characterised by the fluctuations in physiological states needing early diagnosing of the hemodynamic abnormalities and rapid intervention to minimise the adverse outcomes.

The perioperative outcome of the patient varies depending on the kind of surgery patient undergoes and some subset of surgical patients have higher than expected mortalities^[16]. The introduction of goal-directed therapy in cardiac surgical patients have lead to improved outcomes in high risk cardiac surgical patients although the reports of its utility in mild and moderate-risk patients are sparse^[17,18]. The goal-directed therapy includes the monitoring of static and dynamic hemodynamic parameters apart from the standard monitors used by the anesthesiologists like heart rate, blood pressure. The static monitors are stroke volume, cardiac output, mixed venous saturation and dynamic monitors are stroke volume variation and pulse pressure variation.

Smetkin et al did a study in 40 patients who had undergone off-pump coronary artery bypass surgery and had randomised them into a control group and a GDT group. The members in the control group were guided therapy by CVP (6-14 mmHg), MAP (60-100 mmHg), and HR (90/ minute), whereas in GDT group by MAP, HR, mixed venous saturation (MvO₂) (>60%), and intrathoracic blood volume index (850-1,000 mL/m²). The observations were made pre-, intra-, and 2, 4, and 6 hours postoperatively. ICU and hospital length of stay(

LOS) were decreased by 15% and 25%, respectively in the GDT group, although these differences were not statistically significant. There were no deaths in either group^[19].

Kapoor et al did a study in 27 patients with a euro score <3 who had undergone on-pump coronary artery bypass graft surgery. They randomly divided patients into control and GDT groups. Both groups were monitored and treated throughout the intraoperative period and up to 8 hours postoperatively. In the control group, management was guided by BP, HR, CVP, and UOP. In addition to these parameters, the GDT group was managed with pulse contour-based technology (FloTrac) and central venous oximetry to maintain the CI, SVI, systemic vascular resistance index (SVRI), oxygen delivery index (DO₂I), MvO₂ >70%, and SVV<10%. The patients in the GDT group had a shorter average duration of mechanical ventilation (13.8 h v 20.7h), fewer days of use of inotropic agents (1.6 vs. 3.8), shorter ICU LOS (2.6 d v 4.9 d), and shorter hospital LOS (5.6 d v 8.9 d)^[20].

A recent Cochrane systematic review including more than 5000 patients from 31 studies have indicated that the perioperative administration of fluids, with or without vasoactive drugs, targeted to increase global blood flow have shown reduced postoperative complications and hospital length of stay but did not alter the mortality^[21].

In a recent meta-analysis in cardiac surgical patients by Aya et al, they have found out that goal-directed hemodynamic therapy has shown improved patient outcome in terms of a reduction in postoperative complications and hospital length of stay^[22]. The utility of early goal-directed hemodynamic therapy to improve outcomes in non-cardiac surgery has been demonstrated in several randomised controlled trials^[23-33] whereas the benefits of GDT in cardiac surgery have not been investigated to the same extent.

Although this approach is still not widely practised in routine clinical care, there is considerable evidence to show that goal-directed hemodynamic strategies aiming at an optimization of cardiac output/cardiac index and DO₂ in selected high-risk surgical patients

like cardiac surgery can contribute to a reduction of postoperative morbidity and mortality. The initiation of GDT at any time irrespective of the clinical phase of the peri-operative period has shown benefit^[34].

Transesophageal echocardiography

Transesophageal echocardiography(TEE) is now a widely used monitor in the perioperative setting. It is an important tool for the assessment of cardiac structures, filling status and cardiac contractility^[35]. Doppler technique is used to measure CO by Simpson's method measuring SV multiplied by HR. Flow is measured by area under the Doppler velocity curve that gives velocity time integral(VTI) and cross-sectional area(CSA) is calculated by planimetry.

Measurement can be done at the level of pulmonary artery, mitral or aortic valve. TEE views used for measurement are the mid esophageal aortic long-axis view and deep transgastric long-axis view with pulsed wave Doppler. The ultrasound beam is parallel to the blood flow in transgastric view thus helping in estimating the actual blood flow across the left ventricular outflow tract(LVOT).

TEE has been validated with PAC with good limits of agreement^[36]. However, a skilled operator is required along with limited availability and cost factor being major limitations for its use. In the 2D method, the LVOT diameter was measured in the 2D ME-LAX view using the zoom function 1 centimetre from the insertion of the aortic leaflets in mid-systole. The machine software automatically derived the LVOT area(πr^2). However many studies have shown that LVOT is not circular and indeed, it's oval leading to better estimation of LVOT area with 3D method compared with 2D method.

The velocity-time integral (VTI) through the LVOT was obtained and traced using pulse-wave doppler in the deep transgastric window with optimal doppler alignment and the

sample volume located in a similar position to the one used for LVOT diameter measurement.

Stroke volume is calculated from the VTI of LVOT and CSA of LVOT. From the stroke volume, we can calculate the cardiac output.

$$SV = LVOT_{VTI} \times LVOT_{CSA}$$

$$CO = SV \times HR$$

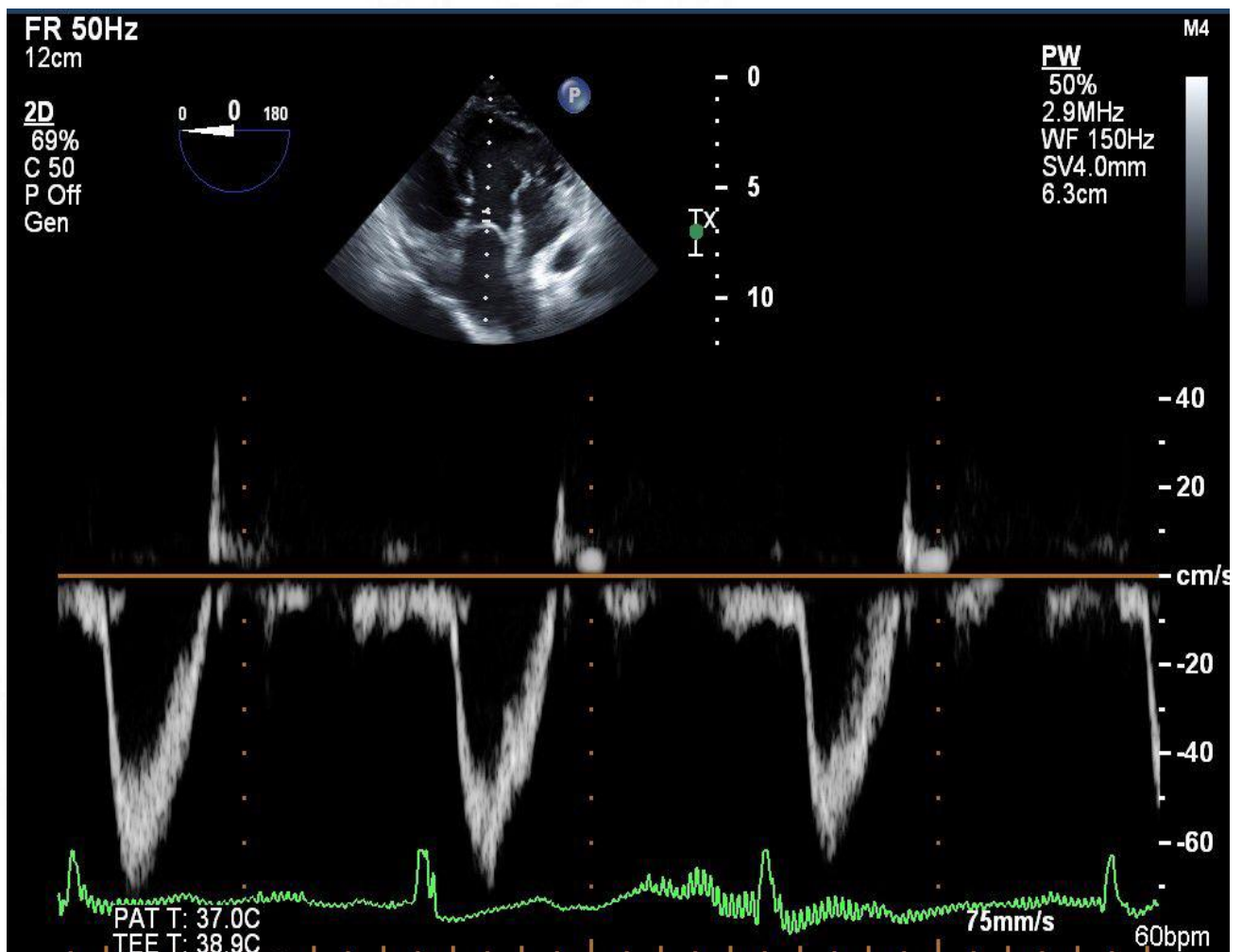


Figure 1: TEE Deep transgastric LVOT view with pulse-wave doppler measurement for calculating LVOT VTI.

The heart rate was noted to use the same value for the 3D method calculations. In the 3D method, imaging of the LVOT was obtained in the mid esophageal LVOT long-axis view using R-wave gated imaging over 2 to 4 heartbeats during a brief period of apnea and absence of electrical or motion interference to achieve the highest spatial and temporal resolution. The acquired 3D data later were accessed on 3D geometric quantification software (Q-Lab Version 8.1.2 Advanced Ultrasound Quantification Software, Philips Healthcare, Andover, MA) and analysed.

Briefly, the multi-planar reformatting planes were aligned to display the three geometrically orthogonal views (sagittal, coronal, and transverse) of the LVOT and the aortic valve in the mid-systolic position. The gain and brightness settings were adjusted to clearly delineate the edges of the LVOT, which was then planimetered in the en face view 1cm proximal to the insertion of the aortic valve leaflets. The cross-sectional area of LVOT thus obtained was used to calculate SV and CO by the continuity equation.

Advantages:

Among the various techniques available for the intraoperative hemodynamic assessment in cardiac surgeries, TEE emerged as the frontline monitoring modality in recent years. The unique ability of TEE in direct, real-time visualisation of cardiac structures provides an invaluable role in the intraoperative management of cardiac surgery.

The use of TEE in adult as well as in pediatric cardiac surgery has provided a large amount of new information not previously available, and an increasing number of complex procedures also in interventional cardiology is today simply not possible without TEE. The intraoperative monitoring of TEE in many cases have impacts on surgical decisions and post-operative medical management.

Bioreactance

Thoracic bioreactance (NICOM device, Cheetah medical, Portland, Oregon) is a modification of bioimpedance which reports the hemodynamic parameters by analysing the changes in the phase shift of electrical voltage signal applied across the thorax. Changes in electrical capacitive and inductive properties in the thorax occur secondary to change in intrathoracic volume^[37]. This method involves the placement of two dual electrodes on either side of the thorax. Sine-wave high frequency (75 kHz) current is transmitted into the body through one electrode and another electrode is used by the voltage input amplifier.

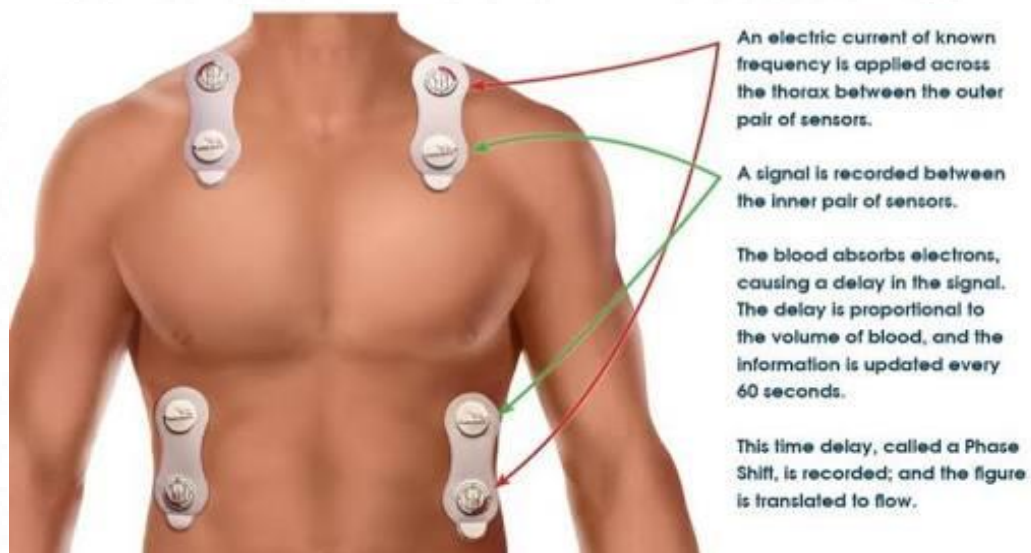


Figure 2: Picture showing correct placement of bioreactance cheetah electrodes (Reproduced from cheetah NICOM official website).

The system's signal processing unit detects the relative phase shift (dp/dt) of the input signal (picked up by the receiving electrodes) relative to the injected signal. As discussed above, the phase shift between the injected current and output signal received from the thorax is due to changes in pulsatile blood volume in the aorta.

$$SV = C \times VET \times dp/dt.$$

where

C - Constant of proportionality varies depending on demographics,

VET – Ventricular Ejection Time,

dp/dt – Relative phase shift.

CO is then calculated with the relation

$$CO = SV \times HR.$$

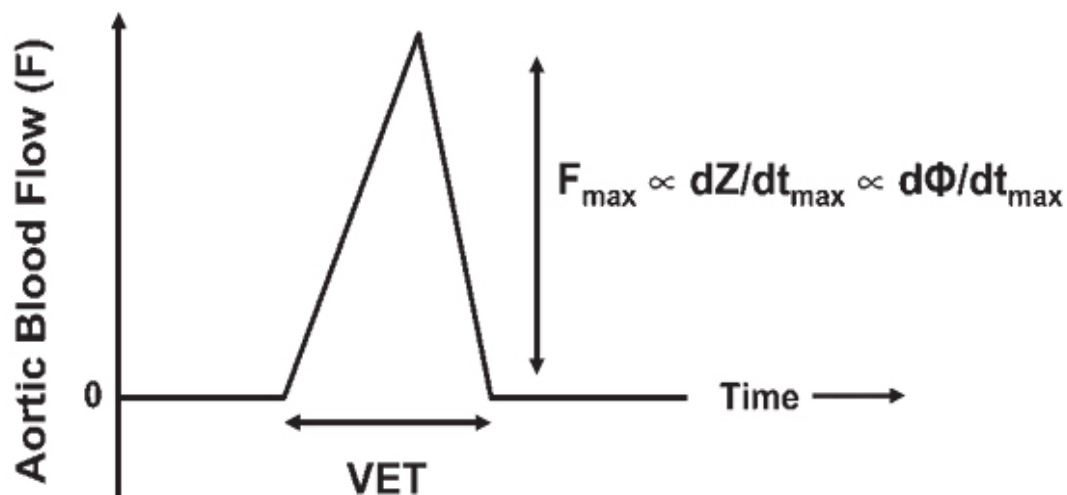


Figure 3: Schematic representation of cardiac output calculation by bioreactance method³⁷.

Electrocautery also affects its accuracy however if the device receives a signal for at least 20s over a minute, the CO value can be determined. Its ease of use in intubated patients, arrhythmias, emergency room (ER), ICU and operating room (OR) lead to the increased usage in recent times. Validating studies with PAC showed good correlation between the two methods with minimal bias. Berlin et al in a study compared the bioreactance cardiac output monitoring with the thermodilution method of monitoring and they concluded that over the wide range of cardiac output produced by hemorrhage and resuscitation in large pigs,

noninvasive cardiac output monitoring has an acceptable agreement with thermodilution cardiac output^[38].

Moreover, in comparison with pulse contour devices like PiCCO and esophageal doppler also showed comparable results^[39]. In a study done by Squara et al comparing the hemodynamic performance of bioimpedance with pulse contour analysis with thermodilution as the reference method, they have found out that both the methods of hemodynamic monitoring produced comparable results with the thermodilution method of cardiac output measurement during lung recruitment maneuver^[40].

The bioimpedance was initially utilised for assessing the fluid responsiveness by passive leg rise in intensive care unit and the studies have shown good correlation between predictability of NICOM, Cheetah monitor in diagnosing the fluid responsive patients^[41].

Advantages

The advantage of bioimpedance over bioimpedance technology was that bioimpedance does not depend on the static impedance which is influenced by the underlying level of thoracic fluid as phase shifts are produced by only the pulsatile aortic flow blood and it was also not affected by the distance of separation of placement of the electrodes, unlike bioimpedance.

The thoracic bioimpedance monitor also enables us in assessing other hemodynamic parameters like stroke volume variation, total peripheral resistance, ventricular ejection time and cardiac index. These measurements help in the management of patients in the perioperative period and to decide whether to resuscitate with volume or to start the inotropic drugs.

Hypothesis

In earlier studies, they have documented that TEE guided measurement of cardiac output correlated well with the cardiac output measured using cardiac magnetic resonance imaging technique(MRI)^[42].

Considering the intraoperative TEE as the reference method for the monitoring of hemodynamic parameters, we hypothesis that, Bioreactance method of hemodynamic parameters measurement correlates well with intraoperative 3D echocardiographic methods of hemodynamic parameter measurements.

Aims and objectives

Considering the intraoperative TEE as the reference method for the monitoring of hemodynamic parameters,

Our **primary objective** was to compare the non-invasive cardiac output and other hemodynamic parameters measured using bioreactance method with that of TEE method of cardiac output measurement.

Our **secondary objective** was to look for the sensitivity and reliability of bioreactance method for assessing volume responsiveness following passive leg raise.

Justification

Intraoperative TEE, although a useful tool for measurement of cardiac output, is not available in all operation theatres. Hence, there is a necessity for using a non-invasive cardiac output monitor which is easily available, reliable, and associated with no complications.

- Bioreactance method of cardiac output measurement is a non-invasive method and it is not associated with any known complications.

- It is a new technology which has been validated against gold standard thermodilution cardiac output measurement^[28].

- There are only very few studies available globally comparing the hemodynamic parameters measured by bioreactance with echocardiography and there are no studies available comparing the hemodynamic parameters between bioreactance and 3D TEE from our institute and from India.

Materials and methods

Study Design:

A Prospective, observational, non randomised and non blinded study.

Setting:

A tertiary referral centre, a university-level hospital, annually performing 1500 cardiac surgeries (SCTIMST).

Participants:

Adult patients coming for cardiac surgery.

Inclusion criteria:

- All Adult patients scheduled for elective cardiac surgery under CPB.
- Age group between 18 – 70 years.
- Normal sinus rhythm.
- Good and moderate LV function (EF > 30%)

Exclusion criteria:

- Patients in whom the pulsatility of the great vessels may not be reliably assessed such as, chest wall deformities, pleural effusion, pericardial effusion, open sternum, pulmonary edema.
- Contraindication to TEE probe placement.
- Patient refusing to participate in the study.
- Poor 3D-TEE image quality
- Emergency and Re-do surgeries.
- Patient with very severe LV dysfunction (LVEF < 30%) as the reliability is questionable.
- Patients with cardiac arrhythmias.
- Patients with aortic aneurysm.

Informed consent:

Informed written consent was obtained from the patient /relatives. Patient/ relatives were educated about the study protocol.

Approval from the institutional ethics committee:

Our study was approved by the Technical Advisory Committee (TAC) and the Institutional Ethics Committee (IEC) of SCTIMST. TAC registration number was SCT-/S/2018/846 & IEC registration number was SCT/IEC/1357/APRIL-2019.

Duration of study:

12 months.

Study protocol:

Patients were educated about the study in the presence of a witness one day prior to surgery during our pre-anaesthesia check-up. Following the pre-anaesthesia evaluation, all the patients were premedicated with Tab. Pantoprazole 40mg and Tab. Diazepam 5mg night before and on the day of surgery. In the operating room, after confirming the patient identity, the standard monitors (non-invasive blood pressure, pulse oximetry, and electrocardiogram) were attached. Baseline parameters (heart rate, systolic and diastolic blood pressure, SpO₂) were recorded. Apart from the above standard monitors, bioreactance cheetah electrodes were also placed on both the sides with one pair in the supraclavicular and another pair in the infraclavicular region. After placing the electrodes, the patient demographic details were entered in the cheetah for the further calculations of hemodynamic parameters.

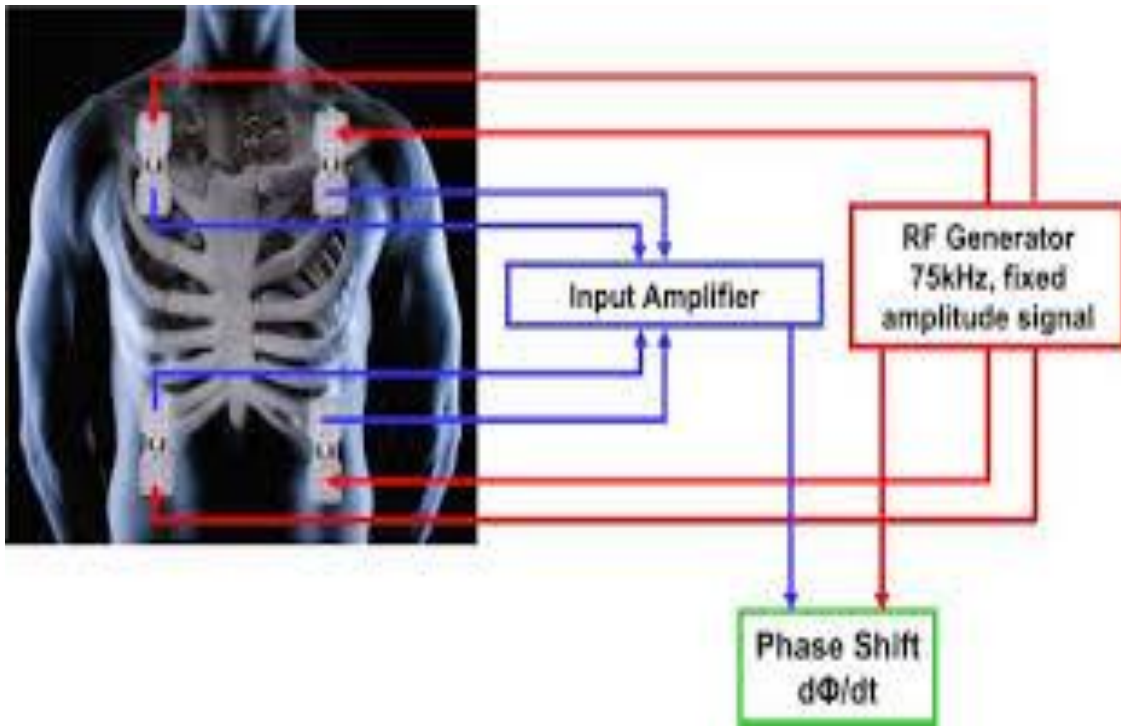


Figure 4: Picture showing frequency input and frequency sensing electrodes of bioreactance cheetah³⁷.

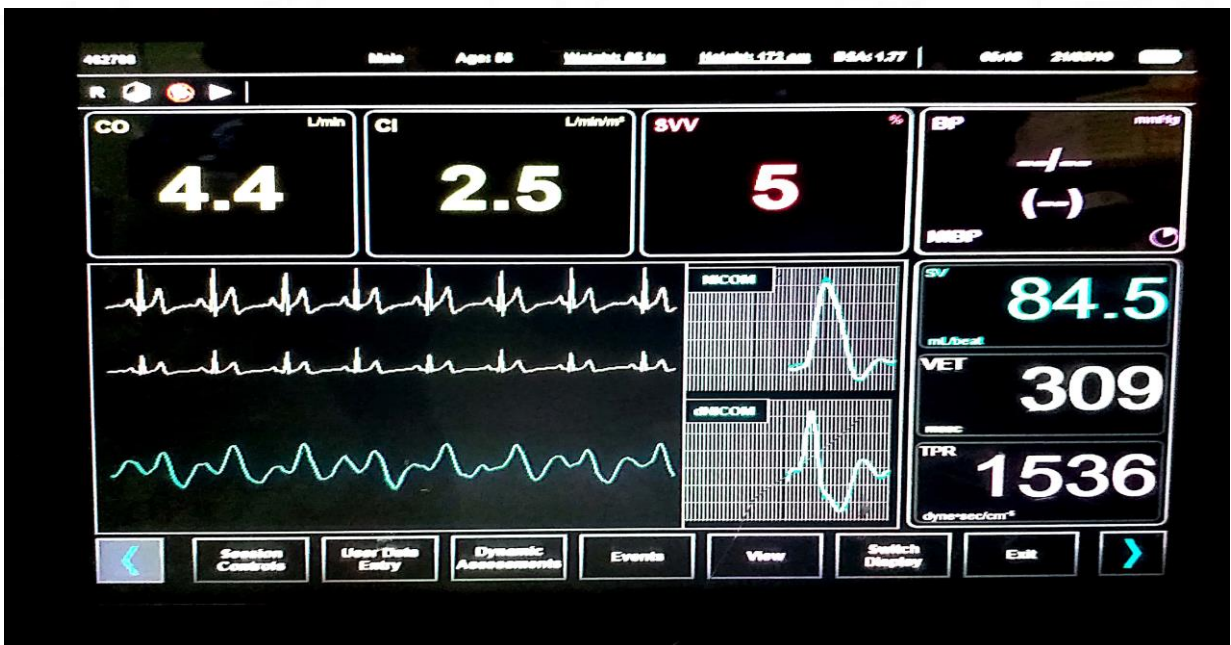


Figure 5: Display of the bioreactance cheetah monitor.

A 16G intravenous(IV) cannula and a 20G arterial catheter were secured after local anaesthesia infiltration as per our institute protocol. General anaesthesia was induced with midazolam, fentanyl, propofol and pancuronium followed by endotracheal intubation with appropriate sized cuffed endotracheal tube. The triple lumen central venous catheter(7.5 Fr) was placed in the right internal jugular vein(IJV) under ultrasound guidance. The femoral arterial line was inserted only in patients with left ventricular dysfunction and poor coronary targets. A temperature probe was kept in the nasopharynx. Anaesthesia was maintained with sevoflurane/ isoflurane, air-oxygen and fentanyl with intermittent boluses of muscle relaxants.

An adult-size TEE probe was inserted after induction of anesthesia and heart was inspected using IE 33 RT3D TEE ultrasound machine (Philips Ultrasound, USA). The study was performed in the 2D and 3D mode. After completion of TEE insertion, the patient was positioned for the surgery.



Figure 6: TEE probe used for performing hemodynamic calculations.

The baseline 3D values are calculated. In the 3D method, imaging of the LVOT was obtained from the mid-oesophageal LVOT long-axis view using R-wave gated imaging over 2 to 4 heartbeats during a brief period of apnea and absence of electrical or motion interference to achieve the highest spatial and temporal resolution. The acquired 3D data later were accessed

on 3D geometric quantification software (Q-Lab Version 8.1.2 Advanced Ultrasound Quantification Software, Philips Healthcare, Andover, MA) and analysed.

Briefly, the multi-planar reformatting planes were aligned to display the three geometrically orthogonal views (sagittal, coronal, and transverse) of the LVOT and the aortic valve in the mid-systolic position. The gain and brightness settings were adjusted to clearly delineate the edges of the LVOT, which was then planimetered in the en face view 1cm proximal to the insertion of the aortic valve leaflets. The cross-sectional area of LVOT thus obtained was used to calculate SV and CO by the continuity equation.

The velocity-time integral across the LVOT for calculation of the stroke volume was obtained from the deep trans-gastric view. From the velocity-time integral and cross-sectional area of the LVOT, stroke volume was calculated. Cardiac output was estimated from the stroke volume and heart rate.

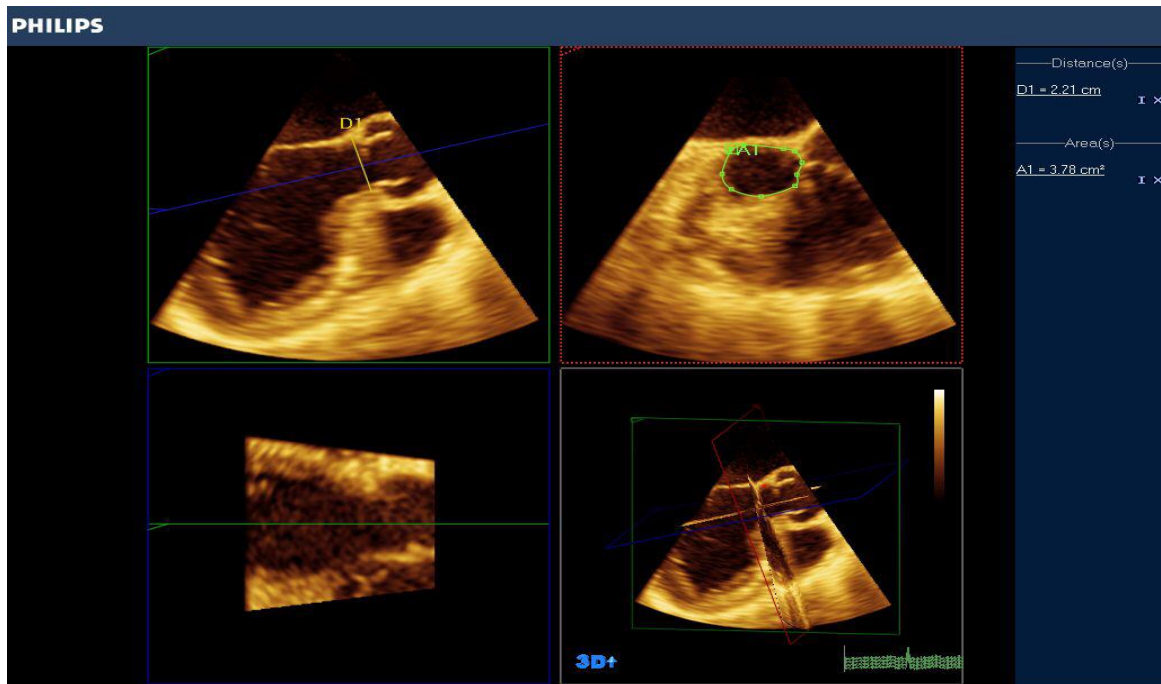


Figure 7: TEE measurement of LVOT area from 3D full volume Mid esophageal LVOT long axis view.

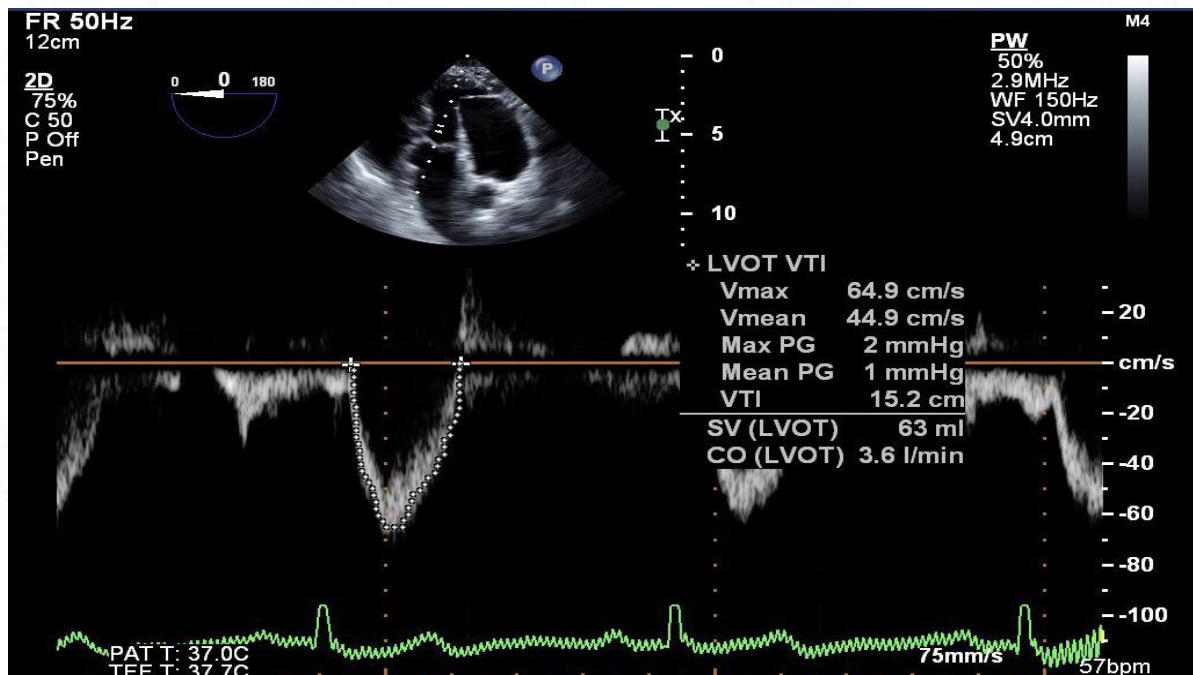


Figure 8: TEE measurement of cardiac output from the stroke volume measured through LVOT VTI and LVOT area.

Bioreactance monitor apart from providing information about the cardiac output, it also calculates various other hemodynamic parameters. The hemodynamic parameters obtained from bioreactance cheetah are

1. Cardiac output,
2. Cardiac index,
3. Ventricular ejection time,
4. Stroke volume,
5. Stroke volume index,
6. Stroke volume variation,
7. Thoracic fluid content,
8. Cardiac power index,
9. Total peripheral resistance,
10. Oxygen delivery index and
11. Chest wall impedance.

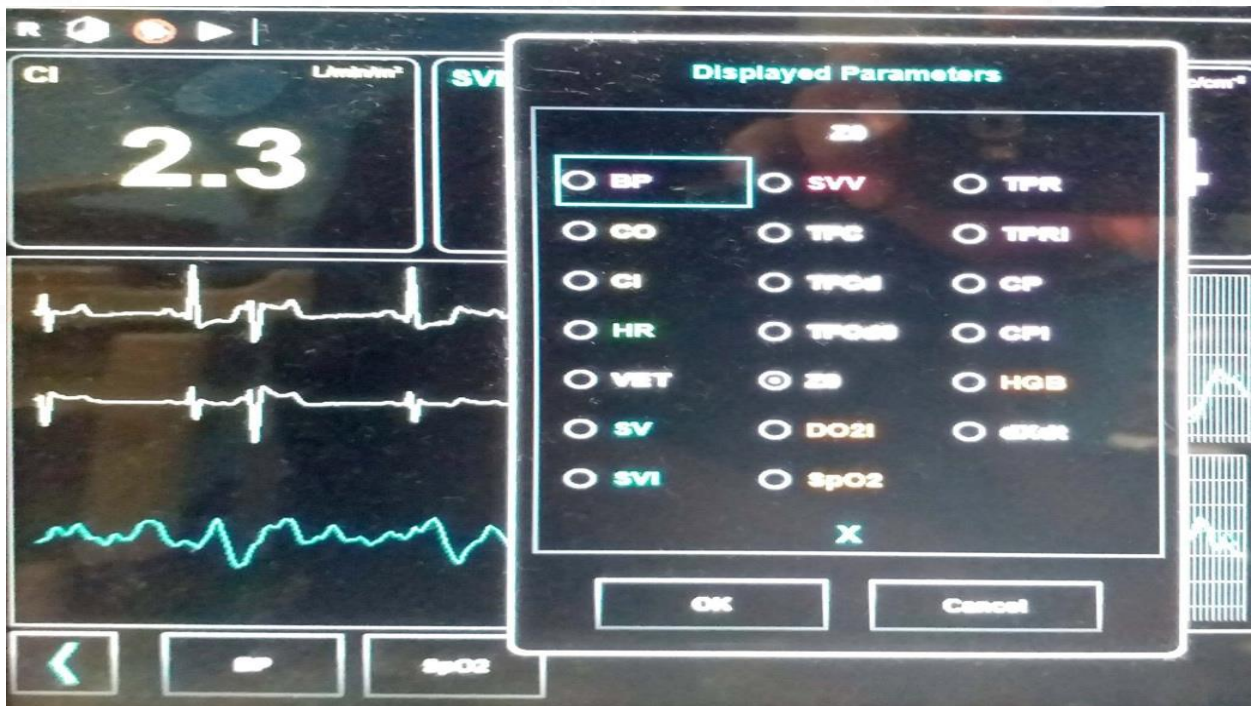


Figure 9: Hemodynamic parameters that can be measured in cheetah monitor.

Echocardiographic and bioreactance (using cheetah) measurements were performed at the baseline, before sternotomy, before and after passive leg raise and after the sternum is closed at stable hemodynamic parameters. The hemodynamic parameters measured were

1. Stroke volume,
2. Cardiac output,
3. Stroke volume variation,
4. Cardiac index,
5. Ventricular ejection time and
6. Total peripheral resistance.



Figure 10: Pictorial representation of passive leg raise maneuver (Reproduced from cheetah NICOM official website).

During the dynamic assessment of hemodynamic parameters like stroke volume variation to diagnose fluid responsiveness, the operation theatre assistant was asked to lift the leg of the patient to 30-45 degree for a period of 30 seconds, hemodynamic calculations in

the echocardiography were done from the variation in the stroke volume across the respiratory cycle with the pulse wave Doppler VTI of the LVOT in the deep trans-gastric view. The ventilator settings during the dynamic assessment were tidal volume 8-10 ml/kg, respiratory frequency 12/minute with positive end-expiratory pressure of 5cm H₂O. For bioreactance, the stroke volume variation was calculated by the software and finally, those results were compared with the stroke volume variation calculated from the transesophageal echocardiography.

$$\text{Stroke volume variation (\%)} = \frac{SV_{\text{MAX}} - SV_{\text{MIN}}}{SV_{\text{MEAN}}}$$

SV_{MAX} – Maximum stroke volume.

SV_{MIN} – Minimum stroke volume.

SV_{MEAN}– Mean stroke volume.

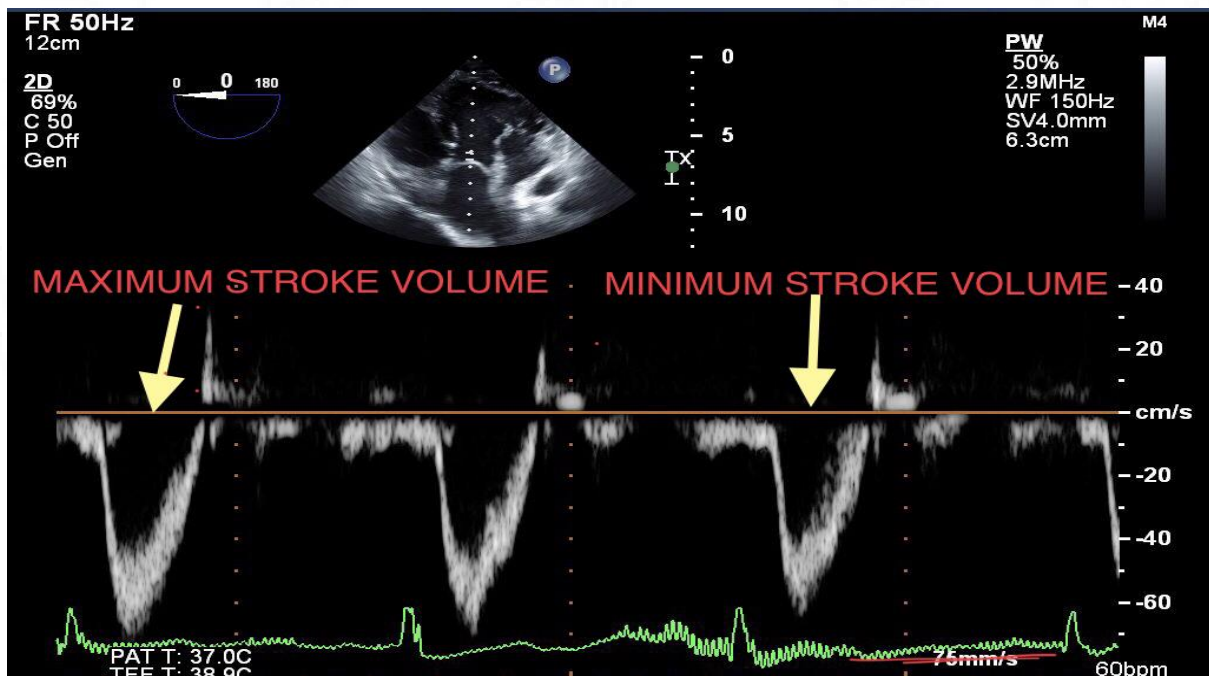


Figure 11: TEE Deep transgastric LVOT view showing variation in stroke volume.

The ventricular ejection time in the echocardiography was calculated from the pulse wave doppler VTI across the LVOT in the deep trans-gastric view and the duration was measured from the onset to termination of transaortic flow velocity. The results were compared with the bioreactance cheetah values.

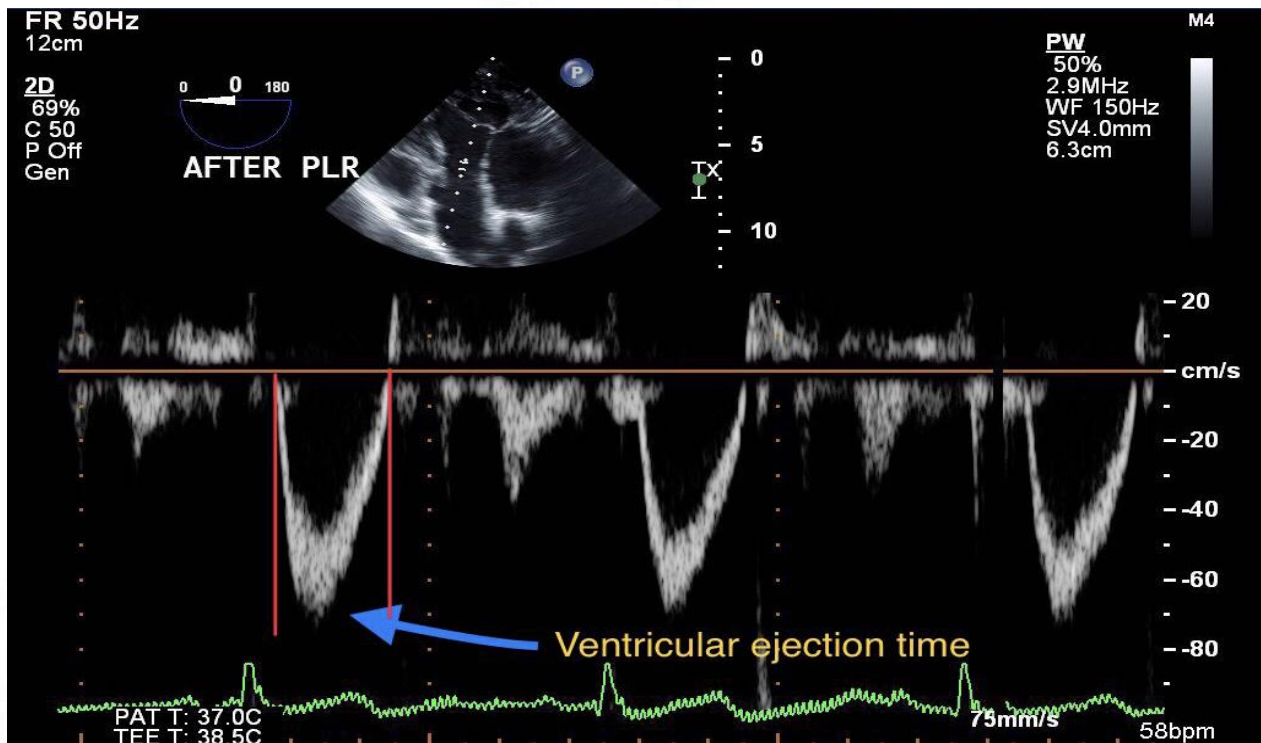


Figure 12: TEE method of measurement of VET from the LVOT VTI.

The systemic vascular resistance(SVR) was calculated from the mean arterial pressure(MAP), central venous pressure(CVP) and cardiac output measured from the 3D TEE.

After the calculation of SVR, it was compared with the total peripheral resistance given by the bioreactance cheetah.

$$SVR = \frac{MAP - CVP}{CO} \times 80$$

Patients with inadequate 2D and 3D imaging quality were excluded from the study at this stage.

Patients with significant electrical interference in the measurement of bioactance hemodynamic parameters were also excluded from the study.

The acquired images were retrieved using CDs and kept with the principal investigators for three years.

After completion of the surgical procedure, the patient was shifted to the postoperative surgical intensive care unit for further management.

Statistical Analysis

Expecting correlation coefficient of 0.6 to achieve 90% power with alpha error of 5%, 30 patients was recruited as the study sample. Descriptive analysis was carried out by mean and standard deviation for quantitative variables, frequency and proportion for categorical variables. Non normally distributed quantitative variables were summarized by median and interquartile range (IQR). Data was also represented using appropriate diagrams like bar diagram, pie diagram and box plots.

The reliability between the two methods was evaluated by calculating the intra class correlation coefficient(ICC). The method chosen for ICC assessment was two-way mixed effects method, with single rater measurement and we looked at absolute agreement. ICC values less than 0.5 were indicative of poor reliability, values between 0.5 and 0.7 indicated moderate reliability, values between 0.7 and 0.9 indicated good reliability and values greater than 0.90 indicated excellent reliability.

P value < 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis^[43].

Observation

A total of 30 adult cardiac surgery patients who had undergone coronary artery bypass grafting had been studied. The data was collected, tabulated, analyzed and the following observations were made.

Table 1: Descriptive analysis of age in study population (N=30)

Parameter	Mean \pm SD	Minimum	Maximum
Age	57.7 \pm 9.49	36.00	74.00

Table 2: Descriptive analysis of gender in the study population (N=30)

Gender	Frequency	Percentages
Male	26	86.67%
Female	4	13.33%

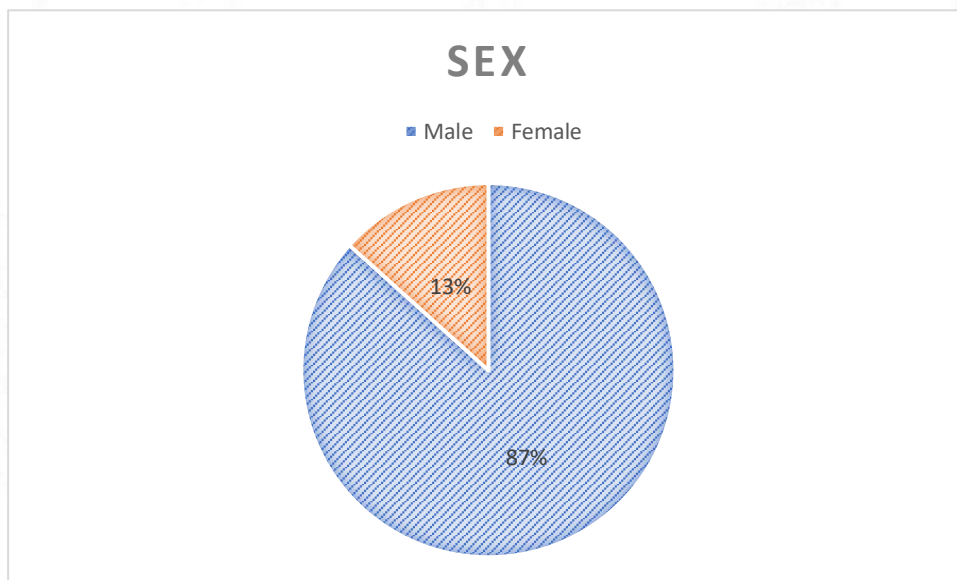


Figure 13: Graphical representation of gender statistics.

Table 3: Parameters measured with mean and standard deviation values.

Parameter	Mean \pm SD	Minimum	Maximum
Bioreactance method			
LVEF (%)	55.8 \pm 13.61	32.00	64.00
LVOT DIA(mm)	20.16 \pm 1.74	16.30	23.00
LVOT Area (cm ²)	4.01 \pm 0.77	2.62	5.66
Baseline_ HR(/mt)	72.33 \pm 15.74	52.00	107.00
Baseline_ BSA (m ²)	1.68 \pm 0.12	1.41	1.96
Before Passive Leg Rise_ HR (/mt)	67.3 \pm 13.96	42.00	100.00
After Passive Leg Rise_ HR (/mt)	66.77 \pm 14.31	42.00	100.00
Before Sternotomy_ HR (/mt)	71.47 \pm 16.97	50.00	128.00
After Sternotomy_ HR (/mt)	86.37 \pm 11.12	60.00	120.00
TEE Method			
Baseline_ Max LVOT VTI	14.44 \pm 3.18	7.12	18.40
Baseline_ Min LVOT VTI	12.34 \pm 3.1	5.12	17.20

Table 4: Intra class correlation coefficient (measure of reliability) in SV assessment by bio reactance method and TEE method.

SV	Intra class Correlation (ICC)	95% CI		P Value
		Lower bound	Upper bound	
LVOT SV	0.732	0.510	0.863	<0.001
Before Sternotomy_ SV	0.784	0.595	0.891	<0.001
After Sternotomy_ SV	0.575	0.277	0.773	<0.001
Before Passive LEG rise_ SV	0.642	0.378	0.814	<0.001
After Passive LEG rise_ SV	0.751	0.540	0.873	<0.001

The LVOT stroke volume showed good reliability between the two methods with ICC of 0.732 at baseline, 0.784 before sternotomy and 0.751 after passive leg rise whereas the reliability was moderate after sternotomy (0.575) and before passive leg rise(0.642). The statistically significant P value < 0.05 at all the times of measurement had clearly showed that there was a good correlation between the two methods of hemodynamic monitoring.

Figure 14: Intra class correlation coefficient (measure of reliability) in SV assessment by bio reactance method and TEE method

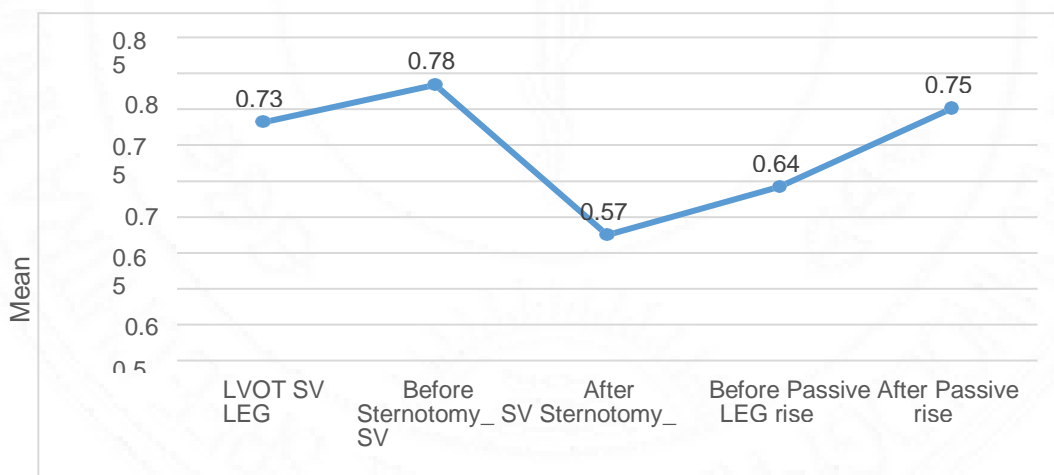


Table 5: Intra class correlation coefficient (measure of reliability) in SVV assessment by bio reactance method and TEE method

SVV	Intra class Correlation (ICC)	95% CI		P Value
		Lower bound	Upper bound	
SVV	0.694	0.450	0.842	<0.001
Before Sternotomy_ SVV	0.569	0.269	0.769	<0.001
After Sternotomy_ SVV	0.392	0.043	0.656	0.015
Before Passive LEG rise_ SVV	0.607	0.321	0.792	<0.001
After Passive LEG rise_ SVV	0.371	0.019	0.642	0.020

The LVOT stroke volume variation showed moderate reliability between the two methods of hemodynamic monitoring with ICC of 0.694 at baseline, 0.569 before sternotomy and 0.607 before passive leg rise whereas the reliability was poor after sternotomy (0.392) and after passive leg rise(0.371).

Figure 15: Intra class correlation coefficient (measure of reliability) in SVV assessment by bio reactance method and TEE method

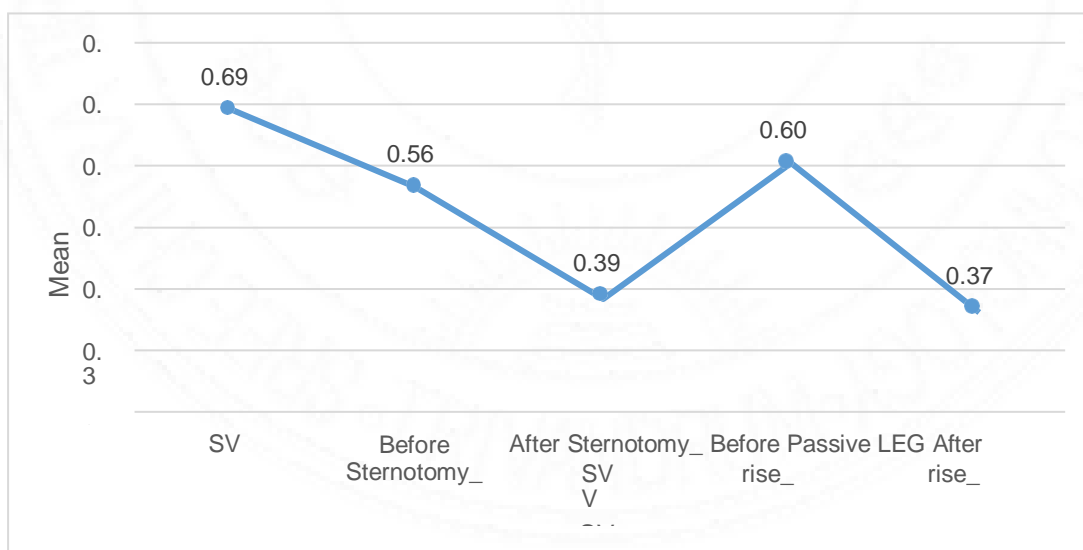


Table 6: Intra class correlation coefficient (measure of reliability) in CO assessment by bioreactance method and TEE method.

CO	Intra class Correlation (ICC)	95% CI		P Value
		Lower bound	Upper bound	
LVOT CO	0.763	0.560	0.880	<0.001
Before Sternotomy_ CO	0.732	0.510	0.863	<0.001
After Sternotomy_ CO	0.657	0.393	0.820	<0.001
Before Passive LEG rise CO	0.650	0.383	0.817	<0.001
After Passive LEG rise_ CO	0.780	0.587	0.889	<0.001

The cardiac output showed good correlation between the two methods with ICC of 0.763 at baseline, 0.732 before sternotomy and 0.780 after passive leg rise whereas the reliability was moderate after sternotomy (0.657) and before passive leg rise(0.65). The statistically significant P value < 0.05 at all the times of measurement had clearly showed that there was a good reliability between the two methods of hemodynamic monitoring.

Figure 16: Intra class correlation coefficient (measure of reliability) in CO assessment by bio reactance method and TEE method

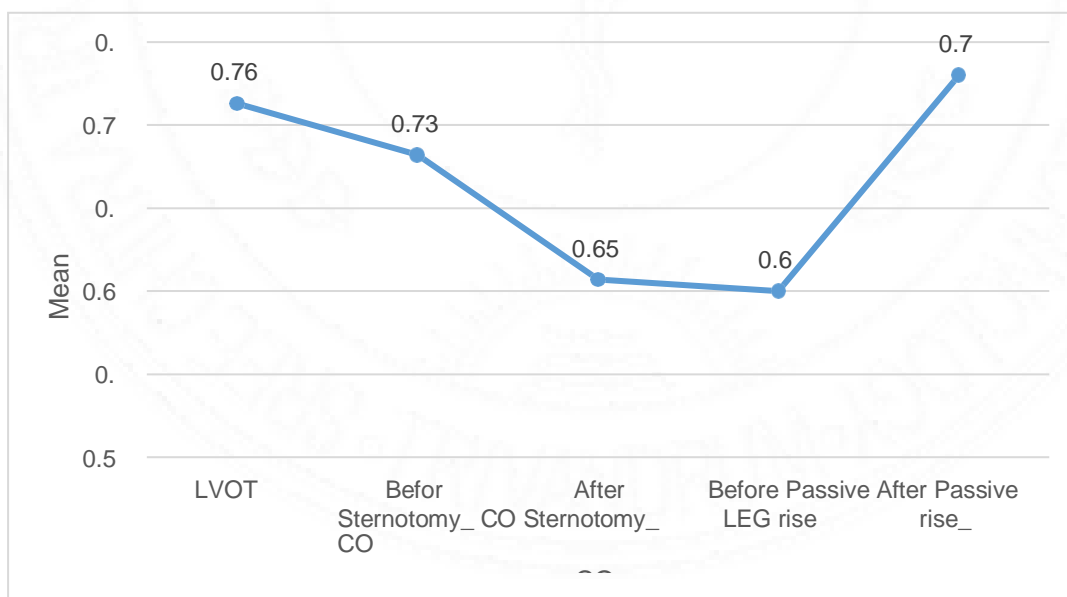


Table 7: Intra class correlation coefficient (measure of reliability) in CI assessment by bio reactance method and TEE method.

CI	Intra class Correlation (ICC)	95% CI		P Value
		Lower bound	Upper bound	
Base line CI	0.798	0.619	0.899	<0.001
Before Sternotomy_ CI	0.685	0.436	0.837	<0.001
After Sternotomy_ CI	0.603	0.316	0.789	<0.001
Before Passive LEG rise CI	0.554	0.247	0.760	0.001
After Passive LEG rise_ CI	0.732	0.509	0.863	<0.001

The cardiac index showed good correlation between the two methods with ICC of 0.798 at baseline and 0.732 after passive leg rise whereas the reliability was moderate before and after sternotomy with ICC of 0.685 and 0.603 respectively and before passive leg rise(0.554). The statistically significant P value < 0.05 at all the times of measurement had clearly showed that there was a good reliability between the two methods of hemodynamic monitoring.

Figure 17: Intra class correlation coefficient (measure of reliability) in CI assessment by bio reactance method and TEE method

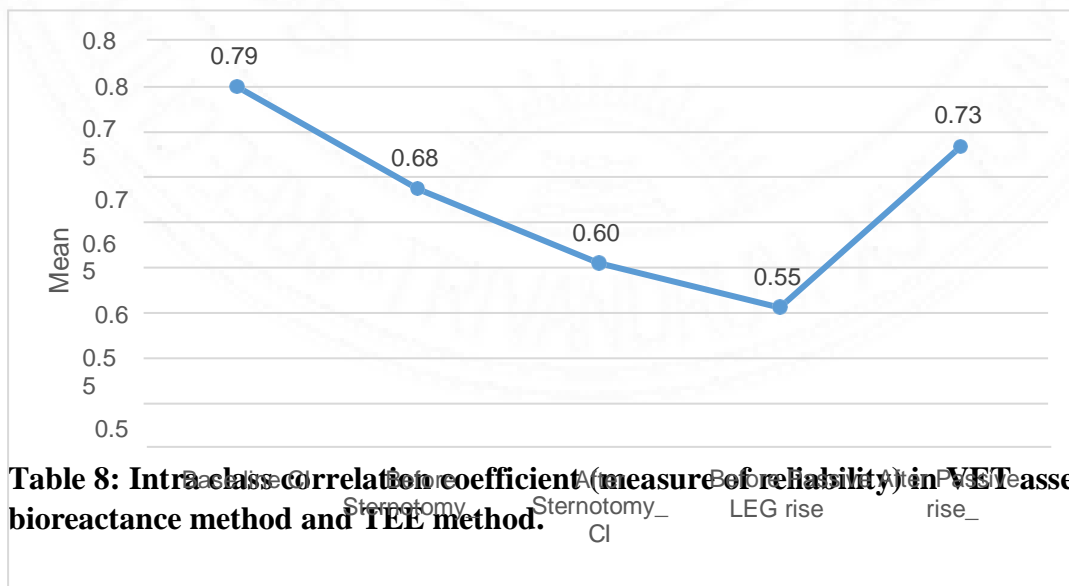


Table 8: Intra class correlation coefficient (measure of reliability) in VET assessment by bio reactance method and TEE method.

VET	Intra class Correlation (ICC)	95% CI		P Value
		Lower bound	Upper bound	
Base line VET	0.279	-0.084	0.577	0.064
Before Sternotomy_ VET	0.508	0.187	0.731	0.002
After Sternotomy_ VET	0.303	-0.058	0.598	0.049
Before Passive LEG rise VET	0.359	0.004	0.633	0.024
After Passive LEG rise_ VET	0.371	0.019	0.642	0.020

The ventricular ejection time showed poor reliability during all the phases of hemodynamic measurement with ICC of 0.279 at baseline, 0.303 after sternotomy, 0.359 before passive leg rise and 0.371 after passive leg rise while the reliability was moderate only during before sternotomy with ICC of 0.508.

Figure 18: Intra class correlation coefficient (measure of reliability) in VET assessment by bio reactance method and TEE method

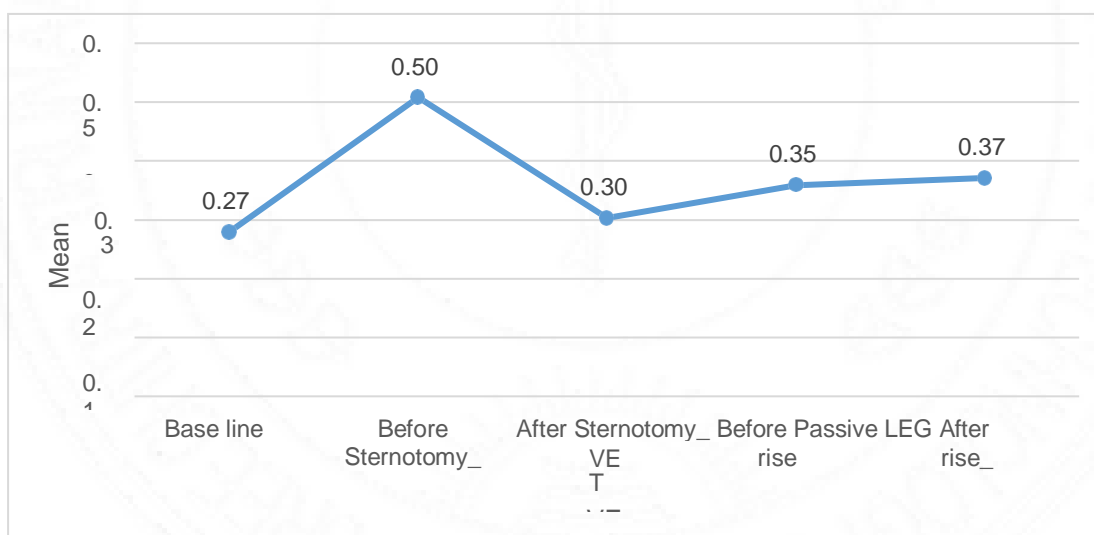
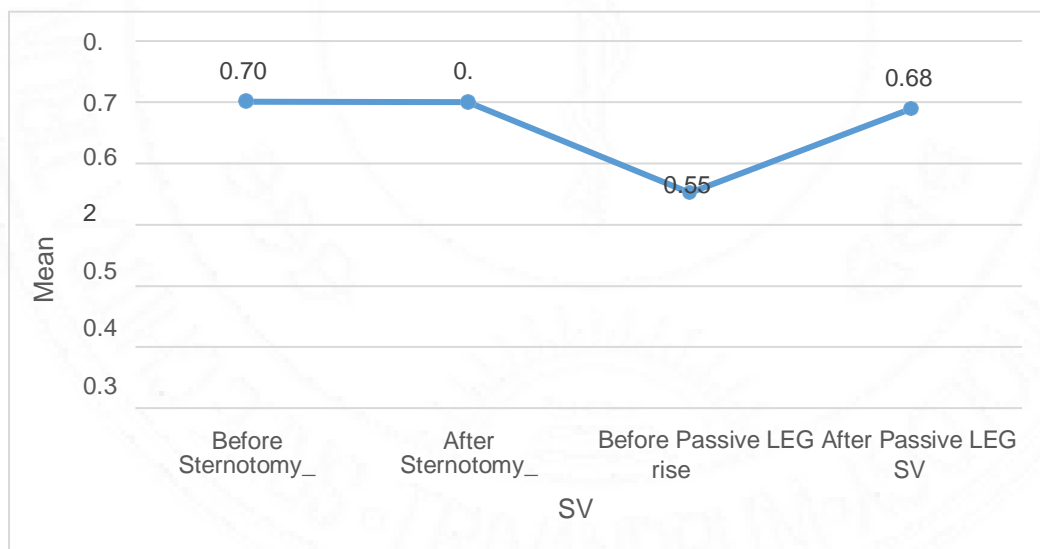


Table 9: Intra class correlation coefficient (measure of reliability) in SVR assessment by bioreactance method and TEE method.

SVR	Intra class Correlation (ICC)	95% CI		P Value
		Lower bound	Upper bound	
Before Sternotomy_ SVR	0.701	0.460	0.845	<0.001
After Sternotomy_ SVR	0.700	0.460	0.845	<0.001
Before Passive LEG rise SVR	0.552	0.245	0.758	0.001
After Passive LEG rise_ SVR	0.689	0.441	0.839	<0.001

The systemic vascular resistance showed good correlation between the two methods before and after sternotomy with ICC of 0.701 and 0.700 respectively whereas correlation between the two methods showed moderate reliability before and after passive leg rise with ICC of 0.552 and 0.689 respectively.

Figure 19: Intra class correlation coefficient (measure of reliability) in SVR assessment by bio reactance method and TEE method



Discussion

The outstanding importance of the cardiac output measurement was evidenced by the previous studies that it has a direct role in predicting the perioperative outcomes^[44]. Although the clinical utilisation of TEE in the intra-operative period has increased over the years with the advancement of 3D technology, dynamic assessment of fluid responsiveness like stroke volume variation are still not being studied extensively. In our study, we have compared the semi-invasive method of cardiac output and hemodynamic parameters measurement via transesophageal echocardiography with the non-invasive bioactance(cheetah) method of monitoring in 30 adult patients posted for the CABG surgery.

For estimating the stroke volume in our study, we have used 3D TEE method of calculating the left ventricular outflow tract area instead of 2D TEE method of calculation due to the fact that the LVOT cross-sectional area was not circular and it was elliptical leading to underestimation of the LVOT area by the 2D TEE method as highlighted in the study by Saitoh et al resulting in a false estimation of stroke volume and cardiac output^[45].

The LVOT stroke volume measured by the two methods showed good reliability with ICC of 0.732 at baseline, 0.784 before sternotomy and 0.751 after passive leg raise whereas the reliability was moderate after sternotomy (0.575) and before passive leg raise(0.642). The statistically significant P value < 0.05 at all the times of measurement had clearly shown that there was a good correlation between the two methods of hemodynamic monitoring.

The correlation of cardiac output between the two methods was good with ICC of 0.763 at baseline, 0.732 before sternotomy and 0.780 after passive leg raise whereas the reliability was moderate after sternotomy (0.657) and before passive leg raise(0.65). The

reason for the difference in the reliability after the sternotomy may be due to alteration in the heart-lung mechanics and also due to the presence of sternal wires which has the tendency to affect the phase shift of the cheetah measurement^[6].

Cheung H et al did a study in which they had compared the non-invasive bioreactance method of cardiac output measurement with the pulmonary artery catheter thermodilution method of measurement in 50 American Society of Anesthesiologists physical status I-III patients, posted for adult off-pump CABG surgery and they have found a good correlation between the two methods of hemodynamic monitoring with the conclusion saying that NICOM device was a safe, convenient, and reliable device for measuring continuous non-invasive cardiac output and cardiac index, and the trends of change in CO during the surgery were similar between NICOM and PAC^[46].

Rich D et al in a study performed in pulmonary hypertensive(PH) patients posted for cardiac catheterisation comparing cardiac output measurement before and after vasodilator challenge voiced that CO measured via NICOM bioreactance method was precise and correctly estimated CO at rest and during the variations in CO with vasodilator challenge in patients with PH^[47].

The results reported from the above studies corresponded well with the results of our study though they have compared bioreactance with the thermodilution method of cardiac output measurement in a different subgroup of patients. There was no literature available at present globally to demonstrate the reliability of hemodynamic measurement between the two methods(Bioreactance vs TEE) of monitoring although enough evidence was there to show a good comparison of the individual methods of cardiac output monitoring with the gold standard thermodilution and cardiac magnetic resonance imaging.

In one study done by Doherty et al in primigravida, they have compared the cardiac output estimation by the non-invasive bioreactance NICOM monitor with trans-thoracic echocardiography and they have found out that stroke volume and CO measurements obtained using NICOM were comparable to those obtained with echocardiography, with acceptable limits of agreement^[48].

The dynamic assessment of fluid responsiveness like stroke volume variation and pulse pressure variation helps in predicting the fluid responders more accurately compared with the static parameters like central venous pressure, pulmonary capillary wedge pressure in the mechanically ventilated patients^[49-52]. However, the dynamic parameters may be negatively influenced by the drugs used for general anesthesia as it produces vasodilation and other vasodilators used in the perioperative period as evidenced by the earlier study^[53].

In our study, stroke volume variation measured between the bioreactance and transesophageal echocardiography showed moderate reliability between the two methods of hemodynamic monitoring with ICC of 0.694 at baseline, 0.569 before sternotomy and 0.607 before passive leg rise whereas the reliability was poor after sternotomy (0.392) and after passive leg raise(0.371). The poor reliability of the stroke volume variation between the two methods can be attributed to the effect of general anesthesia, perioperative usage of the vasoactive agents and temperature differences in the intraoperative period affecting the peripheral vasculature.

The conflicting results of good reliability between left ventricular end-diastolic volume variation(LVEDVV) measured from TEE with the stroke volume variation estimated from the Flo-Trac/vigileo were demonstrated by the Haidan et al in 26 patients, who had undergone elective craniotomy for brain tumour resection or intracranial aneurysm, for predicting the volume responsiveness^[54].

The left ventricular systolic performance estimation using echocardiography holds a significant place during the intraoperative TEE examination^[55,56]. However some systolic parameters of echocardiographic evaluation like ejection fraction and other volume-based indices were affected by the loading conditions. To overcome this, many load-independent parameters like myocardial performance index, rate-corrected mean velocity of fibre shortening were identified for demonstrating the left ventricular systolic performance.

The myocardial performance index requires the estimation of the left ventricular ejection time. The left ventricular ejection time can be calculated using M-mode of aortic valve opening or doppler estimation of onset and termination of trans aortic blood flow velocity. The gold standard method till now was not yet described but the good correlation between the above two methods was shown in the study by Swanithan et al^[57]. In our study, we used the doppler method of calculating the left ventricular ejection time and compared with the VET measured by the bioactance cheetah monitor.

The ventricular ejection time measured between the two methods showed poor reliability during all the phases of hemodynamic measurement with ICC of 0.279 at baseline, 0.303 after sternotomy, 0.359 before passive leg raise and 0.371 after passive leg raise while the reliability was moderate only during before sternotomy with ICC of 0.508. The conflicting results between the two methods could be explained by the fact that bioactance method of measurement was affected by the volume of electrically participating tissues lying between the two current sensing electrodes which can be increased or decreased based on the patient body mass index and changes in the peripheral vascular resistance^[58].

The systemic vascular resistance(SVR) depends on the various neurohumoral factors and sometimes it was affected by the local metabolites^[59,60]. The clinical implications are owing to its alterations in the cardiac output produced by the changes in

the systemic vascular resistance. It also determines the blood flow to the peripheral tissues. The estimation of SVR aids in therapeutic management during the perioperative period^[61].

The systemic vascular resistance showed good correlation between the two methods before and after sternotomy with ICC of 0.701 and 0.700 respectively whereas the correlation between the two methods showed moderate reliability before and after passive leg raise with ICC of 0.552 and 0.689 respectively.

In summary, hemodynamic parameters like cardiac output, cardiac index, stroke volume, systemic vascular resistance measured by the two methods correlated fairly well whereas dynamic indices like stroke volume variation and left ventricular systolic determinant like ventricular ejection time was not correspondingly reproduced. Despite these differences, in times of emergency bioreactance monitor can be used effectively to monitor the hemodynamic parameters as it is a non-invasive technique and does not need the expertise to monitor.

Limitations

The following are the limitations of our study,

- 1) We have included only patients with ejection fraction more than 30% so the reliability of bioreactance in hemodynamic monitoring in patients with severe left ventricular dysfunction was still unanswered.
- 2) The need of technical expertise for performing the 3D TEE examination and it cannot be done without any experience.
- 3) The dynamic indices of fluid responsiveness like stroke volume variation following passive leg rise can be better studied in the absence of anaesthesia as it has the tendency to affect the reliability.
- 4) We didn't have a cut off for height of the patients as height determines the distance of separation of the electrodes. Taller the patient, farther the electrodes and results may not correlate.

Conclusion

- 1) The results of the study clearly showed that bioreactance cheetah method of monitoring correlated well with transesophageal echocardiography for measuring cardiac output, stroke volume, cardiac index and systemic vascular resistance.
- 2) The added advantage of the bioreactance cheetah monitoring was its better safety profile owing to its non-invasiveness.
- 3) Dynamic parameter assessment like stroke volume variation using bioreactance still need to be examined further to credit its reliability especially when the patient was under anaesthesia.
- 4) There was a poor correlation between the two methods while comparing the ventricular ejection time leading to the conclusion that there is a difference in the doppler technology compared with the cheetah software.

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INFORMED CONSENT FORM

TITLE: Comparison of haemodynamic parameters measured by thoracic electrical bioreactance and 3-D transesophageal echocardiography in adult cardiac surgery patients.

(Please tick boxes)

I, _____, (Participant's name)

Declare that I have read the above information provided to me regarding the study, and have clarified any doubts that I had. []

- I also understand that my 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 []
- I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access []
- I understand that my identity will not be revealed in any information released to third parties or published []
- I voluntarily agree to take part in this study []
- I received a copy of this signed consent form []

Name:

Name of witness:

Signature:

Relation to participant:

Date:

(Person Obtaining Consent)

I attest that the requirements of informed consent for the medical research project described in this form have been satisfied. I have discussed the research project with the participant and explained to him or her in non-technical terms all of the information contained in this informed consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

Dr. Nithyanandhan P ,
Senior Resident, CVTA,
SCTIMST.
(7397625589)

STUDY INDEPENDENT CONTACT PERSON

Dr. MALA RAMANATHAN,
MEMBER SECRETARY,
INSTITUTIONAL ETHICAL COMMITTEE,
0471- 2524234.

കാര്യബോധത്തോടെയുള്ള സമ്മതപത്രം

പഠനത്തിന്റെ പേര്

ഹൃദയശസ്ത്രക്രിയയ്ക്ക് വിധേയരാകുന്ന മുതിർന്ന രോഗികളിൽ രക്തചംക്രമണ സൂചകങ്ങൾ അളക്കുന്നതിന് തൊറാസിക ഇലക്ട്രിക്കൽ ബയോറിയാക്ടൻസും 3ഡി ട്രാൻസ് ഈസോഫേജിയൽ എക്കോ കാർഡിയോഗ്രാഫിയുമുപയോഗിക്കുന്നതിന്റെ താരതമ്യം.

ഞാൻ.....(പങ്കെടുക്കുന്നയാളുടെ പേര്)

ജനനതീയതി/വയസ്സ് (വർഷത്തിൽ).....

.....പുത്രൻ/ പുത്രി

(ദയവായി കളങ്ങളിൽ അടയാളപ്പെടുത്തുക)

- മുകളിൽ നൽകിയ പഠനത്തിന്റെ വിവരങ്ങൾ വായിച്ചു മനസ്സിലാക്കിയതായും എനിക്കുണ്ടായ സംശയങ്ങൾ പരിഹരിച്ചതായും ഞാൻ പ്രസ്താവിക്കുന്നു []
- എന്റെ ഈ പഠനത്തിലുള്ള പങ്കാളിത്തം പൂർണ്ണമായും സ്വമേധയായാണെന്നും അനുവാദം എനിക്ക് ഏതുസമയത്തും എന്റെ ചികിത്സയെയും നിയമപരമായ അവകാശങ്ങളെയും ബാധിക്കാതെ പിൻവലിക്കാൻ അവകാശമുണ്ടെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. []
- ഞാൻ ഈ പഠനത്തിൽ നിന്നും പിൻമാറിയാലും പഠനം നടത്തുന്നവർക്കും സ്ഥാപനത്തിലെ നൈതിക കമ്മിറ്റി അംഗങ്ങൾക്കും എന്റെ ആരോഗ്യരേഖകൾ പരിശോധിക്കുന്നതിന് എന്റെ അനുവാദം ആവശ്യമില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. അതിനോട് ഞാൻ യോജിക്കുന്നു.[]
- എന്നെ തിരിച്ചറിയാനുതകുന്ന വിവരങ്ങൾ ഒന്നും ഭാവിയിൽ മറ്റുള്ളവർക്കു നൽകുകയോ പ്രസിദ്ധീകരിക്കുകയോ ചെയ്തില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. []
- ഞാൻ സ്വമേധയാ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു []
- സമ്മതപത്രത്തിന്റെ ഒപ്പിട്ട ഒരു കോപ്പി എനിക്കു കിട്ടി []

പങ്കെടുക്കുന്നയാളുടെ ഒപ്പ് തീയതി.....

പഠന ഗവേഷകന്റെ ഒപ്പ്.....തീയതി.....

സാക്ഷിയുടെ ഒപ്പ്.....തീയതി.....

സാക്ഷിയുടെ പേര്

രോഗിയുമായുള്ള ബന്ധം.....

പഠന ഗവേഷകന്റെ പേര്

(സമ്മതം വാങ്ങുന്നയാൾ)

മെഡിക്കൽ റിസർച്ച് പ്രോജക്ടിനാവശ്യമായ സമ്മതപത്രത്തിനു വേണ്ടുന്ന എല്ലാ ഘടകങ്ങളും തൃപ്തികരമായി നിർവഹിച്ചിരിക്കുന്നുവെന്ന് ഞാൻ ബോധ്യപ്പെടുത്തുന്നു. പഠനപങ്കാളിയുമായി ഗവേഷണപദ്ധതിയെപ്പറ്റി സാങ്കേതികേതര പദങ്ങളുപയോഗിച്ച് എല്ലാ വിവരങ്ങളെപ്പറ്റിയും ചർച്ച നടത്തുകയും പ്രതീക്ഷിക്കാവുന്ന അപകടസാധ്യതകളും പാർശ്വഫലങ്ങളും വിശദീകരിക്കുകയും ചെയ്തു. പങ്കാളിയെ ചോദ്യങ്ങൾ ചോദിക്കാൻ പ്രേരിപ്പിക്കുകയും എല്ലാ ചോദ്യങ്ങൾക്കും ഉത്തരം നൽകുകയും ചെയ്തു എന്നും ഞാൻ സാക്ഷ്യപ്പെടുത്തുന്നു.

സമ്മതപത്രം വാങ്ങുന്ന ആളുടെ പേര്.....
ഒപ്പ്.....

ഡോ. നിത്യാനന്ദൻ പി, സീനിയർ റെസിഡന്റ്,
അനസ്തീഷ്യ ഡിപ്പാർട്ട്മെന്റ് (ഫോൺ 7397625589)

ഡോ. മാലാ രാമനാഥൻ
മെമ്പർ സെക്രട്ടറി
ഇൻസ്റ്റിറ്റ്യൂഷണൽ എത്തിക്സ് കമ്മിറ്റി
ഫോൺ 0471- 2556226

PATIENT INFORMATION SHEET

Title of the study: Comparison of haemodynamic parameters measured by thoracic electrical bioimpedance and 3-D transesophageal echocardiography in adult cardiac surgery patients.

Study numbers: We request you to participate in the study wherein we are planning to compare the hemodynamic parameters measured by thoracic electrical bioimpedance and transesophageal echocardiography in adult cardiac surgery patients. We hope to include 30 people from this hospital in this study.

What is cardiac output?

Heart works as a pump in the body to pump out blood effectively to the various organs of the body. Cardiac output is the blood pumped by the heart every minute.

What are the methods available to measure cardiac method?

There are various methods available to calculate the cardiac output which varies from totally invasive technique to non invasive technique. In our study we are comparing the cardiac output measured by minimally invasive trans esophageal echocardiography and non invasive bioimpedance method.

What is thoracic electrical bioimpedance ?

Thoracic electrical bioimpedance is one of the non invasive methods for measuring the cardiac output. This method involves placement of two dual electrodes on either side of the thorax. Sine-wave high frequency (75 kHz) stimulus is transmitted into the body through one electrode and other electrode is used by the voltage input amplifier. It analyses changes in the phase of amplified voltage signal to the stimulus applied across the thorax and gives the cardiac output value measured over 60s.

.What is Trans-esophageal echocardiography?

Trans-esophageal echocardiography or TEE is a test that uses sound waves to create high-quality moving pictures of the heart and its blood vessels. This can pin point the problematic areas of the heart and helpful in assessing the function of heart. Usually echocardiography is performed via chest (transthoracic echocardiography). However, under anesthesia, transthoracic echocardiography cannot be performed during cardiac surgery as the surgeon will be operating in that area. Hence echocardiography probe is inserted via esophagus (food pipe) in every patient undergoing open heart surgery. TEE involves a flexible tube (probe) with a transducer at its tip. The Anesthesiologist will guide the probe down your throat and into your esophagus (the passage leading from your mouth to your stomach). This will be done when you will be unconscious under anesthesia and it will not cause any discomfort to you. This approach allows your doctor to get more detailed pictures of your heart because the esophagus is directly behind the heart.

What is 3D Trans-esophageal echocardiography?

3dimensional echocardiography helps us to visualize the heart structure in a 3 dimensional format and make accurate functional assessments.

What are the risks and side-effects?

We do not expect that our study will cause any injury. You will be under the effect of anesthesia while the test is being performed, thus you will not experience any discomfort.

Why are we doing this study?

The purpose of this study is to compare the hemodynamic parameters measured by non invasive thoracic electrical bioimpedance and minimally invasive trans esophageal echocardiography in adult cardiac surgery patients.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also 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 because our 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 will be published in a 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. Nithiyanandhan P, Senior Resident, Department of Anaesthesia.(Phone No: 7397625589)

Dr.Prasanta kumar dash, Professor, Department of Anaesthesia.(Phone No: 9349336584)

STUDY INDEPENDENT CONTACT PERSON

Dr. MALA RAMANATHAN,

MEMBER SECRETARY,

INSTITUTIONAL ETHICAL COMMITTEE,

0471- 2524234.

രോഗികൾക്കുള്ള കാര്യവിവരണപത്രം

പഠനത്തിന്റെ പേര്

ഹൃദയശസ്ത്രക്രിയയ്ക്ക് വിധേയരാകുന്ന മുതിർന്ന രോഗികളിൽ രക്തചംക്രമണ സൂചകങ്ങൾ അളക്കുന്നതിന് തൊറാസിക ഇലക്ട്രിക്കൽ ബയോറിയാക്ടൻസും 3ഡി ട്രാൻസ് ഈസോഫേജിയൽ എക്കോ കാർഡിയോഗ്രാഫിയുമുപയോഗിക്കുന്നതിന്റെ താരതമ്യം.

പഠന നമ്പർ

ഹൃദയശസ്ത്രക്രിയയ്ക്ക് വിധേയരാകുന്ന മുതിർന്ന രോഗികളിൽ രക്തചംക്രമണ സൂചകങ്ങൾ അളക്കുന്നതിന് തൊറാസിക ഇലക്ട്രിക്കൽ ബയോറിയാക്ടൻസും 3ഡി ട്രാൻസ്സോഫേജിയൽ എക്കോ കാർഡിയോഗ്രാഫിയുമുപയോഗിക്കുന്നതിന്റെ താരതമ്യം നടത്താൻ ഞങ്ങളുദ്ദേശിക്കുന്ന പഠനത്തിൽ പങ്കെടുക്കാനാ താങ്കളോടഭ്യർത്ഥിക്കുന്നു. ഈ ആശുപത്രിയിർന്നിന്നും 30 പേരെ ഈ പഠനത്തിൽ ഉൾപ്പെടുത്താമെന്ന് ഞങ്ങൾ പ്രതീക്ഷിക്കുന്നു.

ഹൃദയത്തിന്റെ ശേഷി എന്നാലെന്ത്?

ശരീരത്തിന്റെ വിവിധ അവയവങ്ങളിലേക്ക് രക്തം വേണ്ടും വിധം ഒഴുക്കുവാൻ ഹൃദയം ഒരു പമ്പ് പോലെ പ്രവർത്തിക്കുന്നു. ഓരോ മിനിറ്റിലും ഹൃദയം പമ്പ് ചെയ്യുന്ന രക്തത്തിന്റെ അളവാണ് ഹൃദയത്തിന്റെ ശേഷി.

ഹൃദയത്തിന്റെ ശേഷി അളക്കാൻ ലഭ്യമായ രീതികളെന്തെല്ലാം?

ഹൃദയത്തിന്റെ ശേഷി അളക്കാൻ, ശരീരത്തിൽ കടന്നും കടക്കാതെയുമായി വിവിധ രീതികൾ ലഭ്യമാണ്. ഞങ്ങളുടെ പഠനത്തിൽ ഹൃദയശേഷി അളക്കാനായി കുറഞ്ഞ അളവിൽ ശരീരത്തിൽ കടക്കുന്ന ട്രാൻസ് ഈസോഫേജിയൽ എക്കോ കാർഡിയോഗ്രാഫിയും ശരീരത്തിൽ കടക്കാതെയുള്ള ബയോറിയാക്ടൻസ് രീതിയും തമ്മിലുള്ള താരതമ്യം നടത്തുന്നു.

തൊറാസിക ഇലക്ട്രിക്കൽ ബയോറിയാക്ടൻസ് എന്താണ്?

ഹൃദയത്തിന്റെ ശേഷി അളക്കുന്നതുമുള്ള ശരീരത്തിൽ കടക്കാതെയുള്ള രീതികളിലൊന്നാണ് തൊറാസിക ഇലക്ട്രിക്കൽ ബയോറിയാക്ടൻസ്. നെഞ്ചിന്റെ രണ്ടുവശത്തുമായി രണ്ട് ഡ്യൂവൽ ഇലക്ട്രോഡുകൾ ഘടിപ്പിക്കും. ഉയർന്ന ആവൃത്തിയിലുള്ള (70kHz) സൈൻ തരംഗങ്ങൾ ഒരു ഇലക്ട്രോഡിലൂടെ കടത്തിവിടുകയും രണ്ടാമത്തെ ഇലക്ട്രോഡ് വോൾട്ടേജ് ഇൻപുട്ട് ആംപ്ലിഫയറുമായി ഘടിപ്പിക്കുകയും ചെയ്യും. അത് ആംപ്ലിഫൈ ചെയ്ത വോൾട്ടേജ് സിഗ്നലുകളും നെഞ്ചിനുകുറുകെ നൽകിയ പ്രേരകവുമായി വിശകലനം ചെയ്യുകയും ഹൃദയത്തിന്റെ ശേഷിയുടെ മൂല്യം നൽകുകയും ചെയ്യും.

ട്രാൻസ് ഈസോഫേജിയൽ എക്കോ കാർഡിയോഗ്രാഫി എന്നാലെന്ത്?

ഹൃദയത്തിന്റെയും അതിന്റെ രക്തക്കുഴലുകളുടെയും ഉയർന്ന ഗുണനിലവാരമുള്ള ചിത്രങ്ങൾ ലഭിക്കാൻ ശബ്ദതരംഗങ്ങളുപയോഗിച്ച് നടത്തുന്ന പരിശോധനയാണ് ട്രാൻസ് ഈസോഫേജിയൽ എക്കോ കാർഡിയോഗ്രാഫി. ഹൃദയത്തിന്റെ പ്രശ്നബാധിതമായ മേഖലകൾ കാണിക്കാനും ഹൃദയത്തിന്റെ പ്രവർത്തനം വിലയിരുത്താനും ഇത് സഹായിക്കും. സാധാരണ എക്കോകാർഡിയോഗ്രാഫി ചെയ്യുന്നത് നെഞ്ചുവഴിയാണ്. എന്നിരുന്നാലും, മയക്കലിനു വിധേയമായി ഹൃദയശസ്ത്രക്രിയനടത്തുന്ന ഹൃദയ ശസ്ത്രക്രിയാവിദഗ്ദ്ധൻ ആ മേഖലയിലാണ് ശസ്ത്രക്രിയനടത്തുന്നത്. എന്നതിനാൽ ഹൃദയം തുറന്നുള്ള ശസ്ത്രക്രിയയിൽ, എല്ലാരോഗികളിലും എക്കോകാർഡിയോഗ്രാഫി പ്രോബ്, ഈസോഫാഗസ് (അന്നനാളം) വഴി കടത്തുന്നു. റ്റിഇഇയിൽ ഒരു ട്രാൻസ്ഡ്യൂസർ അറ്റത്ത് ഘടിപ്പിച്ച് വഴക്കമുള്ള ഒരു കുഴലുണ്ട് (പ്രോബ്). മയക്കുന്ന ഡോക്ടർ താങ്കളുടെ തൊണ്ടയിലൂടെ പ്രോബ് ഈസോഫാഗസിലേക്ക് (താങ്കളുടെ വായിൽനിന്നും വയറ്റിലേക്കുള്ള വഴി) കടത്തും. ഇത് ചെയ്യുമ്പോൾ താങ്കൾ മയക്കത്തിന് വിധേയമായിരിക്കയാൽ അസ്വസ്ഥതകളൊന്നുമുണ്ടാവില്ല. ഈസോഫാഗസ് ഹൃദയത്തന്

തൊട്ടുതാഴെയാകയാൽ ഈ സമീപനം ഡോക്ടർക്ക് താങ്കളുടെ ഹൃദയത്തിന്റെ കൂടുതൽ വ്യക്തമായ ചിത്രങ്ങൾ കിട്ടാൻ സഹായിക്കും.

എന്താണ് 3ഡി ടാൻസ് ഈസോഫേജിയൽ എക്കോ കാർഡിയോഗ്രാഫി?

ഹൃദയത്തിന്റെ പ്രവർത്തനം കൂടുതൽ കൃത്യമായി വിലയിരുത്താൻ 3 വശങ്ങളും ഉൾക്കൊള്ളുന്ന 3വശങ്ങളുള്ള എക്കോകാർഡിയോഗ്രാഫി സഹായിക്കും.

അപായങ്ങളും പാർശ്വഫലങ്ങളുമെന്തെല്ലാം?

ഞങ്ങളുടെ പഠനം പര്യടനങ്ങളുണ്ടാകുമെന്ന് വിചാരിക്കുന്നില്ല. ഈ പരിശോധന നടക്കുമ്പോൾ താങ്കൾ മയക്കത്തിന് വിധേയമായിരിക്കുമ്പോഴാകയാൽ താങ്കൾക്ക് അസ്വസ്ഥതകളുമുണ്ടാവില്ല.

ഞങ്ങളെതിന് ഈ പഠനം നടത്തുന്നു?

ഹൃദയശസ്ത്രക്രിയയ്ക്ക് വിധേയരാകുന്ന മുതിർന്ന രോഗികളിൽ രക്തചംക്രമണ സൂചകങ്ങൾ അളക്കുന്നതിന് ശരീരത്തിൽ കടക്കാതെയുള്ള തൊറാസിക് ഇലക്ട്രിക്കൽ ബയോറിയാക്ടൻസും പരിമിതമായി മാത്രം ശരീരത്തിൽ കടന്നുള്ള ട്രാൻസ് ഈസോഫേജിയൽ എക്കോ കാർഡിയോഗ്രാഫിയുമുപയോഗിക്കുന്നതും താരതമ്യം ചെയ്യുക എന്നതാണ് ഈ പഠനത്തിന്റെ ഉദ്ദേശം.

പഠനമാരംഭിച്ചശേഷം താങ്കൾക്ക് പഠനത്തിൽനിന്നും പിൻമാറാമോ?

ഈ പഠനത്തിലെ താങ്കളുടെ പങ്കാളിത്തം സ്വയമേവയുള്ളതും പങ്കെടുക്കുന്നതിനുള്ള അനുവാദം സ്വതന്ത്രമായി പിൻവലിക്കാവുന്നതുമാണ്. അങ്ങിനെയൊന്നും ചെയ്യുന്നതുകൊണ്ട് ആശുപത്രിയിലെ താങ്കളുടെ സാധാരണ ചികിത്സയെ ഒരു വിധത്തിലും ബാധിക്കില്ല.

പഠനവുമായി ബന്ധപ്പെട്ട് പര്യടനങ്ങളായാലേന്ത് സംഭവിക്കും?

ഞങ്ങളുടെ പഠനം കൊണ്ട് താങ്കൾക്ക് പരിക്കുണ്ടാകുമെന്ന്ഞങ്ങൾ പ്രതീക്ഷിക്കുന്നില്ല.

പഠനത്തിനായി താങ്കൾ പണം ചിലവഴിക്കണോ?

വേണ്ട.

താങ്കളുടെ വ്യക്തി വിവരങ്ങൾ രഹസ്യമായി സൂക്ഷിക്കുമോ?

താങ്കളുടെ വ്യക്തിവിവരങ്ങൾ രഹസ്യമായി സൂക്ഷിക്കും. പഠനഫലങ്ങൾ വൈദ്യശാസ്ത്ര ജേർണലിൽ പ്രസിദ്ധീകരിക്കുമെങ്കിലും താങ്കളെ പേരുകൊണ്ട് തിരിച്ചറിയാനിടയാക്കുന്നതൊന്നും പ്രസിദ്ധീകരണത്തിലോ പ്രദർശനങ്ങളിലോ ഉണ്ടാകില്ല.

താങ്കൾക്ക് കൂടുതൽ ചോദ്യങ്ങളുണ്ടെങ്കിൽ ദയവായി ചോദിക്കുക

ഡോ. നിത്യാനന്ദൻ പി, സീനിയർ റെസിഡന്റ്, അനസ്തീഷ്യ ഡിപ്പാർട്ട്മെന്റ് (ഫോൺ 7397625589)

ഡോ. പ്രശാന്തകുമാർ ഡാഷ്, പ്രൊഫസർ, അനസ്തീഷ്യ ഡിപ്പാർട്ട്മെന്റ് (ഫോൺ 9349336584)

പഠനത്തിൽ നിന്നും സ്വതന്ത്രമായ ബന്ധപ്പെടാനുള്ള വ്യക്തി

ഡോ. മാലാ രാമനാഥൻ

മെമ്പർ സെക്രട്ടറി

ഇൻസ്റ്റിറ്റ്യൂഷണൽ എത്തിക്സ് കമ്മിറ്റി

OBSERVATION CHART

Study title: Comparison of haemodynamic parameters measured by thoracic electrical bioreactance and 3-D transesophageal echocardiography in adult cardiac surgery patients.

Preoperative information:

Name: Age: Weight:

Gender: Hospital number: BSA:

Date of surgery:

Diagnosis & Surgery:

Preoperative medical history:

Hypertension:

Preoperative Echocardiography:

LVEF:

3D TEE measurements baseline:

PARAMETER	3D TEE measurement	Doppler
LVOT DIAMETER (mm)		
LVOT AREA (cm ²)		
HR (beats/ mt)		
Maximum LVOTVTI (cm)		

Minimum LVOTVTI (cm)		
SVV by Doppler (%)		
LVOT SV (LVOT -CSA * Maximum LVOT VTI)		
LVOT CO (lit/min)		
BSA (m ²)		
CI (lit/min/m ²)		
VENTRICULAR EJECTION TIME (ms)		

Hemodynamic parameters before passive leg rising test :

PARAMETERS	BIOREACTANCE	TEE
HR		
SV		
SVV		
CO		
CI		
VET		
SVR		

Hemodynamic parameters following passive leg rise:

PARAMETERS	BIOREACTANCE	TEE
HR		
SV		
SVV		
CO		
CI		
VET		
SVR		

Hemodynamic parameters before sternotomy:

PARAMETERS	BIOREACTANCE	TEE
HR		
SV		
SVV		
CO		
CI		
VET		
SVR		

Hemodynamic parameters after sternum closure:

PARAMETERS	BIOREACTANCE	TEE
HR		
SV		
SVV		
CO		
CI		
VET		
SVR		

HR- HEART RATE

SV- STROKE VOLUME

SVV- STROKE VOLUME VARIATION

CO- CARDIAC OUTPUT

CI- CARDIAC INDEX

VET- VENTRICULAR EJECTION TIME

SVR- SYSTEMIC VASCULAR RESISTANCE.



Technical Advisory Committee (Clinical Studies)
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
THIRUVANANTHAPURAM – 695011, INDIA

TAC Registration No: SCT-/S/2018/846

Date:23.11.2018

Project title: COMPARISON OF HAEMODYNAMIC PARAMETERS MEASURED BY THORACIC ELECTRICAL BIOREACTANCE AND 3D TRANSESOPHAGEAL ECHOCARDIOGRAPHY IN ADULT CARDIAC SURGERY PATIENTS.

Principal Investigator: Dr. Nithyanandhan Palanisamy, Senior Resident, Department of Cardiac Anaesthesiology, SCTIMST Degree: M.D. (Anaesthesiology), M.B.B.S.
Co-Principal Investigator(s) Prof. Prasanta Kumar Dash, Professor, Department of Cardiac Anaesthesiology SCTIMST Degree: M.B.B.S., M.D., PDCC
Prof. Shrinivas Gadhinglajkar, Professor, Department of Cardiac Anaesthesiology, SCTIMST Degree: M.B.B.S., M.D., PDCC
Prof. Rupa Sreedhar, Professor, Department of Cardiac Anaesthesiology SCTIMST Degree: M.B.B.S., D.A., M.D., PDCC
Prof. Jayakumar, Professor, Department of Cardiovascular & Thoracic Surgery, SCTIMST Degree: M.B.B.S., M.S., M.ch.
Prof. Vivek Pillai, Additional Professor, Department of Cardiovascular & Thoracic Surgery, SCTIMST Degree: M.B.B.S., M.S., M.ch.

Members who participated in the TAC meeting on 03/11/2018

Dr. Rupa Sreedhar (Chairperson)
Dr. Prasantakumar Dash
Dr. Krishna Kumar K
Dr. Sankara Sarma P
Dr. Ashalatha. R
Dr. Bijulal S
Dr. Jayadevan ER
Dr. Syam K
Dr. Sanjay G
Dr. Varghese T. Panicker
Dr. K. Shivakumar (Member Secretary)

Dr. Syam K, Dr. Prasantakumar Dash, Dr. Rupa Sreedhar, Dr. Varghese T. Panicker, Dr. Krishna Kumar K and Dr. Sanjay G stayed away from the proceedings when the projects in which they are involved as investigator were discussed (# 844,845,846,849,852,856,857).

Risk Classification of the project (Minimum/ Moderate/ High): Minimum

Requirement of DSMB: No

Recommended members of DSMB: Not applicable

Recommendations of TAC:

Recommended for consideration of IEC in the light of the responses received from the investigator

The PI may note that there can be no additions / alterations in the documents approved by TAC when they are submitted to the IEC.

Signature of the Member Secretary, TAC (Clinical Studies)

Note for IEC

Copy of the investigator's responses to questions/suggestions from TAC is attached (Appendix-1).



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)

Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

Institutional Ethics Committee
(IEC Regn No. ECR/189/Inst/KL/2013/RR-16)

SCT/IEC/1357/APRIL-2019

29.04.2019

Dr. Nithyanandhan Palanisamy
Senior Resident
Department of Anaesthesiology
SCTIMST, Thiruvananthapuram

Dear Dr. Nithyanandhan Palanisamy,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "COMPARISON OF HAEMODYNAMIC PARAMETERS MEASURED BY THORACIC ELECTRICAL BIOREACTANCE AND 3D TRANSESOPHAGEAL ECHOCARDIOGRAPHY IN ADULT CARDIAC SURGERY PATIENTS (IEC/1357)" on 12th April, 2019.

The following documents were reviewed:

Original submission

1. Covering letter addressed to the Chairman, IEC, SCTIMST with check list
2. Forwarding letter from the HOD
3. TAC Approval Letter
4. IEC Application Form
5. Project Proposal
6. Observation Chart
7. Patient Information Sheet and Informed Consent Form in English and Malayalam
8. CV of Principal Investigator and Co-Principal Investigators

Revised submission

1. Covering letter addressed to the Chairman, IEC, SCTIMST dated 24.04.2019 with check list
2. TAC Approval Letter
3. IEC Application Form
4. Project Proposal
5. Observation Chart
6. Patient Information Sheet and Informed Consent Form in English and Malayalam
7. CV of Principal Investigator and Co-Principal Investigators

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The following members of the Ethics Committee were present at the meeting held on 12th April, 2019 at G. Parthasarathi Board Room, AMCHSS, SCTIMST

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. R V G Menon	M Tech, PhD	Male	Lay Person (Chairman)	No
2.	Dr. Rema M. N	MD	Female	Basic Medical Scientist	No
3.	Dr. Kala Kesavan. P	MBBS, MD	Female	Basic Medical Scientist	No
4.	Dr. K R S Krishnan	M.E., Ph.D.	Male	Medical Technology	Yes
5.	Dr. Hari Krishna Varma PR	Ph.D(Materials Science)	Male	Medical Technology	Yes
6.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
7.	Dr. S S Giri Sankar	LL.M. Ph.D.	Male	Legal Expert	No
8.	Dr. Aneesh V Pillai	BA. LLB (Hons.), LL.M, Ph. D, SET (Law)	Male	Legal Expert	No
9.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
10.	Dr. Hari Krishnan S	MD, DM (Cardiology) DNB (Cardiology)	Male	Clinician	Yes
11.	Dr. Anand Kumar A	MD, DM	Male	Clinician	No
12.	Dr. Mala Ramanathan	PhD	Female	Social Scientist (Member Secretary)	Yes

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,














Mala Ramanathan
Member Secretary, IEC

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Sources included in the report

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Synopsis

The hemodynamic monitoring of cardiac surgery patients remains one of the essential component of paramount importance in patient management. Among the various hemodynamic monitors available, cardiac output(CO) monitoring holds significant importance owing to its effectiveness in analysing the whole body perfusion, tissue oxygen delivery^[1] and alterations in blood pressure. CO is the amount of blood pumped by the left ventricle per minute. There are various methods available for calculating cardiac output, pulmonary artery catheter due to its invasiveness, although considered as gold standard, has lost its ground. The newer techniques like thoracic electrical bioactance and transesophageal echocardiography has gained significance due to its less invasiveness. The aim of the present study was to compare the hemodynamic parameters measured using bioactance technology and TEE in adult cardiac surgery patients with TEE method as the reference method.

Materials and methods

This prospective, observational, non randomised and non blinded study was performed in the Sree chitra tirunal institute for medical sciences and technology, after getting approval from the institutional ethical committee (SCT/IEC/1357/APRIL-2019). Thirty adult patients who were posted for coronary artery bypass graft were included in the study after getting the written informed consent. In the operation theatre in addition to the standard ASA monitors, electrical bioactance cheetah electrodes were also placed before induction. An adult-size TEE probe was inserted after induction of anesthesia and heart was inspected using IE 33 RT3D TEE ultrasound machine (Philips Ultrasound, USA). The study was performed in the 2D and 3D mode. Echocardiographic and bioactance (using cheetah) measurements were performed before sternotomy, before and after passive leg rise and after the sternum is closed at stable haemodynamic

parameters. Patients with inadequate 2D and 3D imaging quality and significant electrical interference in measurement of bioimpedance hemodynamic parameters were excluded from the study.

Results

The LVOT stroke volume, cardiac output and systemic vascular resistance showed good reliability between the two methods with ICC of above 0.7 at baseline, before sternotomy and after passive leg rise whereas the reliability was moderate after sternotomy 0.5 and before passive leg rise 0.6. The statistically significant P value < 0.05 at all the times of measurement had clearly showed that there was a good correlation between the two methods of hemodynamic monitoring. The LVOT stroke volume variation showed moderate reliability between the two methods of hemodynamic monitoring with ICC of 0.694 at baseline, 0.569 before sternotomy and 0.607 before passive leg rise whereas the reliability was poor after sternotomy (0.392) and after passive leg rise(0.371). The ventricular ejection time showed poor reliability during all the phases of hemodynamic measurement with ICC of 0.279 at baseline, 0.303 after sternotomy, 0.359 before passive leg rise and 0.371 after passive leg rise while the reliability was moderate only during before sternotomy with ICC of 0.508.

Conclusion

In summary, hemodynamic parameters like cardiac output, cardiac index, stroke volume, systemic vascular resistance measured by the two methods correlated fairly well whereas dynamic indices like stroke volume variation and left ventricular systolic determinant like ventricular ejection time was not correspondingly reproduced. Despite these differences, in times of emergency bioimpedance monitor can be used effectively to monitor the hemodynamic parameters as it is a non-invasive technique and does not need the expertise to monitor.

