CORRELATION BETWEEN INTRAOPERATIVE RENAL DOPPLER FLOW AND RENAL NEAR-INFRARED SPECTROSCOPY IN PREDICTING POSTOPERATIVE ACUTE KIDNEY INJURY IN PATIENTS UNDERGOING CORONARY ARTERY BYPASS GRAFTING SURGERY WITH CARDIOPULMONARY BYPASS

Dr . JAGADISH A

DM CARDIOTHORACIC AND VASCULAR
ANESTHESIOLOGY THESIS

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SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND

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A THESIS SUBMITTED BY

DR. JAGADISH A

TO

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

IN PARTIAL FULFILMENT OF THE REQUIREMENTS

FOR THE AWARD OF

DM CARDIOTHORACIC AND VASCULAR ANESTHESIOLOGY

YEAR 2020 TO 2023

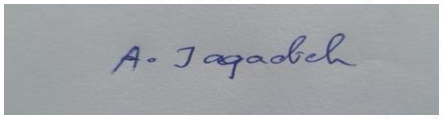
DECLARATION BY THE STUDENT

CERTIFICATE

I, Dr. Jagadish A hereby certify that I had personally carried out the workdepicted in the thesis titled, ***"correlation between intraoperative renal doppler flow and renal near-infrared spectroscopy in predicting postoperative acute kidney injury in patients undergoing coronary artery bypass grafting surgery with cardiopulmonary bypass"***

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

Signature



Dr. Jagadish A

Date – 06/08/2022

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

CERTIFICATE BY THE RESEARCH GUIDE

Name of the Guide: Dr. Prasanta Kumar Dash
Division/Department: Professor, Dept. of Anaesthesiology

This is to certify that Dr. Jagadish A, Department of Anaesthesiology of this institute has fulfilled the requirements prescribed for the Doctorate in Medicine (DM) degree in Cardiothoracic and Vascular Anaesthesiology of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

The thesis entitled, "***Correlation between intraoperative renal doppler flow and renal near-infrared spectroscopy in predicting postoperative acute kidney injury in patients undergoing coronary artery bypass grafting surgery with cardiopulmonary bypass***" was carried out under my direct supervision. No part of the thesis was submitted for the award of any degree or diploma prior to this date.

Clearance was obtained from the Institutional Ethics Committee for carrying out the study.

05/08/2022
Date:

Dr. Prasanta Kumar Dash

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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(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

CERTIFICATE BY THE RESEARCH GUIDE

Name of the Co-Guide: Dr. Saravana Babu

Division/Department: Associate Professor, Dept. of Anaesthesiology

This is to certify that Dr. Jagadish A, Department of Anaesthesiology of this institute has fulfilled the requirements prescribed for the Doctorate in Medicine (DM) degree in Cardiothoracic and Vascular Anaesthesiology of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

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Date: 05/08/2022

Dr. Saravana Babu

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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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

CERTIFICATE BY THE RESEARCH CO-GUIDE

Name of the Co-Guide: Dr. Vivek Pillai

Division/Department: Professor, Dept. of Cardiothoracic & Vascular Surgery.

This is to certify that Dr. Jagadish A, Department of Cardiothoracic & Vascular Surgery of this institute has fulfilled the requirements prescribed for the Doctorate in Medicine (DM) degree in Cardiothoracic and Vascular Anaesthesiology of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

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Dr. Vivek Pillai

Date: 05/08/2022

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

CERTIFICATE BY THE RESEARCH CO-GUIDE

Name of the Co-Guide: Dr. Varghese T Panicker.

Division/Department: Professor, Dept. of Cardiothoracic & Vascular Surgery.

This is to certify that Dr. Jagadish A, Department of Anaesthesiology of this institute has fulfilled the requirements prescribed for the Doctorate in Medicine (DM) degree in Cardiothoracic and Vascular Anaesthesiology of the Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum.

The thesis entitled, "***Correlation between intraoperative renal doppler flow and renal near-infrared spectroscopy in predicting postoperative acute kidney injury in patients undergoing coronary artery bypass grafting surgery with cardiopulmonary bypass***" was carried out under my direct supervision. No part of the thesis was submitted for the award of any degree or diploma prior to this date.

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Dr. Varghese T Panicker

Date: 05/08/2022

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Dr Jagadish

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LIST OF ABBREVIATIONS

SL NO	ABBREVIATION	FULL FORM
1.	CSA AKI	Cardiac surgery associated acute kidney injury
2.	AKI	Acute kidney injury
3.	RRI	Renal resistance index
4.	NIRS	Near infrared spectroscopy
5.	MRV	Mean renal velocity
6.	CPB	Cardio pulmonary bypass
7.	CABG	Coronary artery bypass grafting
8.	rSo-2	Regional oxygen saturation
9.	TEE	Transoesophageal echocardiography
10.	AKIN	Acute kidney injury network
11.	RIFLE	Risk, injury, Failure, Loss of kidney function, End stage kidney disease
12.	KDIGO	Kidney disease improving global outcomes
13.	BSA	Body surface area
14.	MAP	Mean arterial pressure
15.	NHYA	New York heart association
16.	AKI - CPB	Acute kidney injury associated with Cardio-pulmonary bypass

SYNOPSIS

CORRELATION BETWEEN INTRAOPERATIVE RENAL DOPPLER FLOW AND RENAL NEAR-INFRARED SPECTROSCOPY IN PREDICTING POSTOPERATIVE ACUTE KIDNEY INJURY IN PATIENTS UNDERGOING CORONARY ARTERY BYPASS GRAFTING SURGERY WITH CARDIOPULMONARY BYPASS

SYNOPSIS

BY

DR. JAGADISH A

DM CARDIOTHORACIC AND VASCULAR ANESTHESIOLOGY

of

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SYNOPSIS

BACKGROUND – Incidence of Acute Kidney injury in patients undergoing cardiac surgeries was 20 to 50%. Post-operative AKI can increase the risk of mortality up to 60%.Thus predicting the patient at risk of AKI is an important strategy for improving the care of such patients, during intra-operative and post -operative periods.

Renal near infrared spectroscopy (NIRS) is a promising tool to predict development of AKI after cardiac surgery .The ultrasound assessment of renal artery flow has been shown to be highly sensitive & specific in early detection of AKI after cardiac surgery. On the basis of doppler measurements of renal artery velocities, renal resistive index (RRI) is calculated.

We hypothesed that there will be a positive correlation between Renal Doppler parameters and Renal NIRS, thereby increasing the chance of predicting post-operative acute kidney injury in patients undergoing coronary artery bypass grafting.

METHODOLOGY – This study included 43 subjects undergoing elective coronary artery bypass grafting with CPB, Prospective observational study conducted in a Single centre tertiary care hospital. Patients with CKD, moderate/severe LV dysfunction, Diabetes mellitus (duration > 10 years),Hypertension (duration> 10 years) have been excluded from the study. Intraoperatively Renal resistance index/ Mean renal arterial pressure (during patient on cardio-pulmonary bypass), rSO-2 (both right and left renal) were collected. In post-operative period Blood urea, serum creatinine, eGFR were collected and AKI was assessed based on KIDGO criteria.

RESULTS – In analysis 43 percent of study participants who had developed AKI between days 1 to 3. Mean value of RRI among patients developed AKI was 0.7+/-0.09 with p value of 0.006. Mean value of rSo-2 in patients developed AKI was 74.62+/-2.57. Mean value of RRI among patients with no AKI was 0.6+/-.09.

CONCLUSION – Renal resistance index used in the intra-operative period was a reliable predictor of AKI in patients undergoing CABG with CPB.

INTRODUCTION

In the current era, patients undergoing coronary artery bypass grafting (CABG) have increased significantly. Acute kidney injury (AKI) is one of the major complication affecting the outcome of patients undergoing CABG with cardio-pulmonary bypass (CPB) **(1).**Incidence of cardiac surgery associated AKI is reported to be between 20 % and 50%(1). Hence identifying the risk of developing cardiac surgery associated AKI in the early perioperative period is important in predicting and preventing the severity of AKI. The mortality of patients with AKI requiring renal replacement therapy is around 40-70% (1).

The following table displays major risk factors of cardiac surgery associated acute kidney injury (CSA AKI). It can be broadly divided into three major factors as follows.

TABLE -1 RISK FACTORS FOR CARDIAC SURGERY ASSOCIATED – AKI (1)

Patient	Operative	Physiologic
Age Female gender Hypertension Chronic kidney disease Liver disease Diabetes mellitus Anaemia Smoking	Surgical complexity CPB duration Inability to separate from CPB Low hematocrit during CPB Prolonged Aortic cross clamp time	Hypotension Inotrope exposure Hypovolemia Venous congestion Blood transfusion Cardiogenic shock Diuretic usage

Diagnosing AKI in the early stages is of paramount importance because we can implement preventive strategies before the progression of the disease. The available pre-operative predictors of post-operative AKI after cardiac surgery are age, obesity, female gender, valve replacement surgeries, myocardial infarction, low cardiac output syndrome, blood transfusion, prolonged CPB time, high inotropic support and IABP support. The available renal biomarkers such as urinary IL-8, N-GAL, Blood urea nitrogen, serum creatinine, Cystatin and Netrin-1 can diagnose the AKI only after it has occurred [(2).]

Renal near infrared spectroscopy (NIRS) was reported to be a good predictor for diagnosing the onset of AKI after cardiac surgery in neonates[(3)]. It continuously measures the renal oxygen saturation (rSO_2) by near infrared spectroscopic technique. It utilizes the oxy-haemoglobin & deoxy-haemoglobin to provide an estimate of regional tissue oxygen saturation. Any reduction in NIRS values was associated with hypoperfusion and tissue ischemia. The $rSO_2 < 65\%$ or drop in 20% from the baseline value indicates tissue hypoxia[(4).]

The ultrasound assessment of renal artery flow has been shown to be highly sensitive & specific in the early detection of AKI after cardiac surgery[(5)]. Renal resistive index (RRI) as characterized by pulsed wave doppler ultrasonography, was a good predictor of AKI in the early stages. The value of RRI is mainly determined by the three parameters: 1. ratio of systolic to diastolic blood pressure, 2. intra-renal vascular compliance, 3. combination of venous pressure and interstitial pressure. Since the renal resistance index reflects decreased compliance and increased intra-capsular pressure, it offers a novel approach to the early diagnosis of AKI.

Transoesophageal echocardiography (TEE) is an important imaging modality in the intraoperative period for cardiac surgery[(6)]. TEE is useful in evaluation of native & prosthetic heart valves, in patients undergoing coronary artery bypass grafting surgeries, management of catheter-based intracardiac procedures such as atrial septal defect closure, transcatheter valve procedures. Apart from the regular usage of TEE for above mentioned procedures, the TEE

role now have been expanded in analysing renal doppler parameters. TEE technique to locate Renal and monitor perfusion was first published by Bandyopadhyay [5] . Till now studies conducted on monitoring renal perfusion & calculating RRI are done using transcutaneous ultrasound, which is not feasible to perform in cardiac surgery during the intraoperative period. Hence, using TEE as an alternative is need of an hour. Based upon renal doppler parameters (RRI) evaluated intra-operatively, the probability of predicting AKI becomes better.

There were no studies published up to date correlating renal NIRS and RRI in predicting AKI in patients undergoing CABG with CPB. Therefore, we conducted this study to evaluate the correlation between renal NIRS and RRI in predicting AKI in the peri-operative period in patients undergoing cardiac surgeries.

REVIEW OF LITERATURE

AKI was a major complication associated with cardiac surgery[1]. Cardiac surgery associated AKI was associated with higher risk of morbidity and mortality, prolonged length of hospital stay. Diagnosing cardiac surgery associated AKI is of vital importance. Three major criteria are available to diagnose AKI are as follows 1. Risk, injury, failure, Loss, end stage kidney disease (RIFLE) criteria 2. Acute kidney injury network (AKIN) criteria 3. Kidney disease : improving global outcomes (KDIGO) criteria.

TABLE -2

KDIGO criteria for the diagnosis of CSA-AKI[7]

Stage	**Serum creatinine**	**Urine output**
1	Increase in serum creatinine 1.5 – 1.9 fold from the baseline value	< 0.5 ml/kg/hour for 6-12 hours
2	Increase in serum creatinine 2.0-2.9 fold from the baseline value	< 0.5 ml/kg/hour for ≥ 12 hours
3	Increase in serum creatinine 3.0 fold from the baseline value	< 0.3 ml/kg/hour for ≥ 24 hours or anuria for ≥ 12 hours

Table - 3

Risk, injury, failure, Loss, end stage kidney disease (RIFLE) criteria[7]

Class	**Glomerular filtration rate (GFR)/ serum creatinine**	**Urine output**
Risk	Increase in serum creatinine 1.5 times from baseline or decrease in GFR >25%	< 0.5 ml /kg/ hour for 6 hours
Injury	Increase in serum creatinine 2 times from baseline or decrease in GFR >50%	< 0.5 ml /kg/hour for 12 hours
Failure	Increase in serum creatinine 3 times from baseline or decrease in GFR > 75%	< 0.3 ml/ kg/ hour for 24 hours or anuria for 12 hours.
Loss of kidney function	Complete loss of kidney function > 4 weeks	
End stage kidney disease	Complete loss of kidney function >3 months	

Table -4

Acute kidney injury network (AKIN) criteria [7]

Stage	Serum creatinine	Urine output
1	Increase in serum creatinine 1.5 times from baseline or ≥ 0.3 mg/dl increase from baseline	< 0.5 ml/kg/hour for > 6 hours
2	Increase in serum creatinine 2 times from baseline	< 0.5 ml/kg/hour for > 12 hours
3	Increase in serum creatinine 3 times from baseline or creatinine ≥ 4 mg/dl with acute increase of at least 0.5 mg/dl	< 0.3 ml/kg/hour for 24 hours or anuria for 12 hours

Intra-operative TEE and Renal resistance index

***Kajal et al*[8]** studied the intra-operative evaluation of renal resistance index with trans-oesophageal echocardiography for the assessment of acute renal injury in patients undergoing CABG. Study was conducted in patients with age of more than 18 years who underwent CABG. Total 115 patients was studied out of which 39 patients had RRI value greater than 0.7 remaining 76 patients had RRI value less than 0.7. They concluded the study with pre-operative RRI value of 0.68 has a sensitivity of 70% and specificity of 67% in predicting AKI

Cherry et al [9] studied the post-operative renal resistance index (RRI) using trans-esophageal echocardiography in the intra-operative period as early AKI bio-marker. It was a retrospective study. They have included 180 adult cardiac surgical patients. RRI was calculated during pre and post cardio-pulmonary bypass any values exceeding 0.74 are used to evaluate for an association with AKI, diagnosed using KDIGO criteria. Results are as follows in post cpb period 99 patients included 36 and 23 with values exceeding 0.74 and 0.79. Invariably all patients had acute kidney injury according to KDIGO, AKIN, RIFLE criteria. Authors concluded the study stating that Renal resistance index obtained intra-operatively in cardiac surgery patients was highly associated with AKI and its severity. Also correlating well with early detection of AKI.

Alper kararmaz et al [10] main aim of this study was to assess the relationship between trans-lumbar renal ultrasound derived RRI (RRI_{TLUSG}) and trans-esophageal ultrasonography derived renal resistance index (RRI_{TEE}). Study population were 60 patients undergoing cardiac surgery. Results are as follows there was a statistically significant correlation between the two RRI measurements. AUC of RRI_{TLUSG} and RRI_{TEE} was 0.85 and 0.82 respectively. So both parameters were comparable in detecting the post – operative acute kidney injury.

Hertzberg et al [11] conducted whether an raised renal resistance index (RRI) predicts AKI in patients undergoing cardiac surgery. It was a prospective cohort study. Studied involved ninety-six patients and RRI was measured the day before surgery. A cut off value of RRI – 0.7 is termed as elevated renal resistance index. In ninety-six patients 36% of patients developed AKI, had RRI value of > 0.7. authors concluded the study stating that elevated pre-operative RRI has increased risk of developing AKI.

Tugrul ormeci et al [12] studied correlation between cerebral renal near infrared spectroscopy and ipsilateral renal doppler ultrasonography parameters. Study was conducted in thirty-seven patients of age less than 3 months. Patients were divided into two groups based on the renal resistance index values. Group 1 patients had renal resistance index value greater than 0.8. Group 2 with patient's renal resistance index value less than 0.8. Post – operative outcome was compared between two groups. Group -1 had lower post-operative mean urine output, higher lactate values and hospital stay compared to group -2.

NIRS

Gist et al [4] studied role renal NIRS in predicting the AKI in pediatric population they found that reduction in renal nirs was not associated with AKI instead they observed that reduction in renal nirs was associated with a longer duration of mechanical ventilation, longer intensive care length of stay, longer hospital length of stay.

Flechet et al [13]studied NIRS based cerebral oximetry for prediction of severe acute kidney injury in critically ill children after cardiac surgery. It was a prospective observational study , Study population included critically ill children under 12 years, were monitored with cerebral NIRS, from PICU admission until they are successfully weaned from mechanical ventilation. Results as follows AUC of NIRS was around 0.68 and for clinical model which consists of baseline serum creatinine, blood pressure, heart rate frequency was 0.75. Authors concluded the study stating that combined clinical parameters with cerebral NIRS predicts the Acute kidney injury better than NIRS alone

Choi et al [14] evaluate the usefulness of renal regional oxygen saturation (rSo-2) in predicting the risk of acute kidney injury after cardiac surgery. It was a prospective observational study sample size involving hundred patients undergoing cardiac surgery. They defined the AKI using RIFLE criteria. Of total ninety-five patients studied thirty four of them developed AKI.

They found total period of low rSo-2 levels below the threshold values were significantly longer in patients with AKI. ROC curve demonstrated rSo-2 values less than 55% predicts Acute kidney injury better. They concluded the study stating intra-operative renal oxygen desaturation less than 55% predicts post-operative acute kidney injury better in patients undergoing adult cardiac surgery.

Matthew A Hazle et al [15] studied renal rSo-2 and biomarkers to predict ICU outcomes following cardiac surgery in infants under 6 months of age. They monitored the following biomarkers neutrophil gelatinase associated lipocalin (NGAL), interleukin – 18, kidney injury molecule -1, cystatin C. Renal rSo-2 was monitored twenty four hours post-surgery. Total forty nine patients were enrolled in the study. Authors diagnosed AKI using AKIN/KDIGO criteria. Forty two patients developed acute kidney injury by using AKIN/KDIGO criteria. Infants with AKI had prolonged periods of renal rSo-2 saturations less than 50%. They concluded the study stating patients with poor outcomes had prolonged periods of renal rSo-2 desaturation.

Colasacco colby et al [16] studied the role of renal rSo-2 in predicting AKI among infants after cardiac surgery. Authors monitored the renal rSo-2 continuously in intraoperative period, postoperative period day-1 and 2. They defined AKI as follows greater than forty percent increase in serum creatinine level or oliguria for greater than four hours. Renal rSo-2 on post operative day one has a strong correlation with increase in creatinine values. Renal rSo-2 values less than eighty percent predicts AKI with a specificity of seventy five percent and a sensitivity of hundred percent.

Gabe E Owens et al [17] studied the correlation between Renal rSo-2 with AKI in infants undergoing biventricular repair. It was a Prospective observational Study included forty patients with age less than twelve months. Renal rSO-2 data collected for forty eight hours

continuously in the postoperative period. Infants with low renal rSo-2 values had raise in serum creatinine levels and incidence of AKI was also higher. Infants with low renal rSo-2 also had more requirement of vasopressors and had increased lactate levels with prolonged duration of mechanical ventilation. Authors concluded the study stating that low renal rSo-2 values correlates with poor post operative outcomes with higher incidence of AKI.

Trans lumbar ultrasound guided Renal resistance index

***Bossard et a l*[2]** studied the early detection of AKI using doppler renal resistance index as surrogate marker in the post -operative period in patients undergoing elective cardiac surgery with cardiopulmonary bypass. Study included 65 subjects aged more than 60 years. All patients had either one of the risk factors for AKI. Doppler resistance index was measured in the immediate post -operative period. Eighteen subjects developed AKI with RRI value of 0.79 +/- 0.08. patient without AKI had RRI value of 0.68 +/- 0.06 with p value < 0.001. They concluded as RRI used in the immediate post-operative period after cardiac surgery with CPB enabled prediction of delayed AKI.

***Satyen et al*[18]** studied association between the Renal resistance index and its association with post-operative acute kidney injury. This study included 69 subjects out of which 14 developed AKI with post-operative index value of 0.732 with 95% confidence interval. Author concluded the study with renal resistance index of 0.77 has sensitivity and specificity of 57% and 85.5% respectively.

Ilaria et al [19]conducted an observational study relating Renal resistance index and acute kidney injury in aortic surgery. It is an prospective observational study. Study authors included 53 patients undergoing aortic surgery. Results are as follows twelve out of fifty-three patients

developed acute kidney injury. Authors found that percentage of RRI was helpful in identifying the AKI early with 90 percent specificity. Authors concluded the study results as such percentage of RRI was the useful predictor for detecting the AKI in the early stage and useful in early implementation of renal protective strategy.

Sebastien Ninet et al [20] studied renal resistive index for prediction of renal dysfunction reversibility. Main objective of this meta-analysis was to find out the diagnostic performance of renal resistance index. Total of nine studies have been included in the study. 273 patients have been included in the study Total of 176 patients have elevated Resistive index, 146 patients had persistent AKI. Raised renal resistive index or pulsatility index was associated with persistent acute kidney injury. Subsequently, the sensitivity and specificity were 0.83 and 0.84 respectively. So, elevated renal resistive was a good predictor of persistent Acute kidney injury in critically ill patients.

Descending thoracic aorta atheroma and AKI

Martina nowak-machen et al [21] studied the combined effects of descending thoracic aorta calcification and intra-aortic balloon pump counter pulsation in cardiac surgery patients, its effect on peri-operative acute kidney injury and in hospital mortality – a case control study. Total of four fifty-four patients were studied. Patients were divided into the following groups -IABP/-DTA atheroma, +IABP/-DTA atheroma, - IABP/+DTA atheroma, +IABP/+DTA atheroma. In patients with +IABP/+DTA atheroma, AKI incidence was 12.1% & in hospital mortality was 20.2%. Authors concluded the study stating that presence of IABP and DTA atheroma, increases the risk of AKI & in hospital mortality significantly comparing the patients without IABP and DTA atheroma.

Victor g et al [22] studied the influence of atherosclerosis of ascending aorta as a predictor of post operative AKI after cardiac surgery. Total 978 patients were included in the study, with mean age of fifty years. Using epiaortic scanning severity of atherosclerosis was graded as follows normal to mild, moderate, severe and subsequently patients were divided into three groups. Based upon the multivariate analysis results authors concluded that on postoperative day one, presence of atherosclerotic ascending aorta was a independent risk factor for post operative AKI.

Tomoko et al [23] role of aortic arch calcification as strong independent predictor of cardiovascular events in chronic haemodialysis patient. Aortic arch calcification was evaluated using chest x ray. Based upon the extended of calcification patients were graded into three subsets as grade 0, grade 1, grade 2. On analysis according to Kaplan – meier incidence of cardiovascular events were higher in grades two and three. Aortic arch calcification poses a significant risk of adverse cardio-vascular events especially in patients undergoing cardiac surgery.

Inotropic score and acute kidney injury

Kelong hou et al [24] evaluated the correlation between the vasoactive inotropic score with postoperative AKI in adult patients undergoing cardiovascular surgery. It was an retrospectively conducted study including 1935 adult patients. Vasoactive inotropic score was collected in the postoperative period in the first twenty four hours. Out of 1935 patients 291 patients developed postoperative AKI. Logistic regression analysis showed that vasoactive inotropic score was associated with AKI in the postoperative period. Authors concluded the study stating that vasoactive inotropic score was an independent predictor of AKI in patients

undergoing cardiac surgery and it also improves the prognostic accuracy of society of thoracic surgeons scoring system.

Michel G. Gaies et al [25] studied the role of vasoactive inotropic score in predicting the mortality and morbidity among infants after cardiopulmonary bypass. They had also studied the association between the vasoactive inotropic score and clinical outcome in infants. Study included total of 174 patients under six months of age. Out of which forty three percent were neonates. On analysis authors found high vasoactive inotropic score was associated with prolonged intensive care unit stay, prolonged duration of ventilation. Authors concluded the study stating that usefulness of vasoactive inotropic score has to be still further studied, proving its efficacy in this study.

Diuretic score and acute kidney injury

Balakrishnan m et al [26] studied the reno - protective effect of low dose frusemide infusion in high risk cardiac surgery patients. It was a prospective randomized double blinded placebo controlled study. Study was conducted among adult patients undergoing high risk elective cardiac surgical procedure. Patients were randomized to either receiving saline at two millilitre per kilogram or frusemide at four milligram per kilogram. In study results neither of the group was Reno protective. Frusemide group resulting in having higher urine output, higher postoperative fluid requirement. In frusemide group there was slight increase in peak serum creatinine (98 $\pm$ 33) level comparing placebo group (96 $\pm$ 33) . Both placebo and frusemide group had higher retinol binding protein/creatinine ratio. Authors concluded the study stating that frusemide infusion post-operatively had no reno protective effect.

AIMS & OBJECTIVE

Hypothesis

We hypothesize that,

By proving a positive correlation between renal Doppler parameters and renal NIRS, there will be an increased chance of early prediction of postoperative AKI in patients undergoing coronary artery bypass grafting.

Study aims &objectives:

Our Primary objectives were:

1. To evaluate the correlation between intraoperative renal Doppler parameters and intraoperative renal NIRS in predicting the post-operative AKI after cardiac surgery.

Our Secondary objective were:

1. Incidence of postoperative AKI in patients undergoing coronary bypass grafting surgery with cardio-pulmonary bypass
2. Correlation between renal rso-2 and delivery of oxygen (Do-2) during cardio-pulmonary bypass
3. Incidence of postoperative atrial fibrillation in patients developing AKI
4. The incidence of AKI in patients with DTA atheroma
5. Correlation between Diuretic score and AKI
6. Correlation between Inotropic score and AKI
7. Need for Dialysis, ICU stay, hospital stay and mortality

MATERIALS AND METHODS

MATERIALS AND METHODS –

After obtaining approval from Technical advisory committee **(SCT-/S/2020/1084)**, Institute ethics committee **(SCT/IEC/1609/DECEMBER-2020**), the study was registered under clinical trial registry **(CTRI/2021/08/035942**). This prospective observational study was conducted at Sree chitra tirunal institute for medical sciences and technology (SCTIMST), a single center tertiary care hospital performing around 1000 adult cardiac surgeries per year

Inclusion criteria:

a) Patients aged between 30 and 75 years, who underwent CABG using cardio-pulmonary bypass without repair or replacement of cardiac valves.

Exclusion criteria:

a) Patients with moderate / severe LV dysfunction
b) Diabetes mellitus (duration > 10 years)
c) Hypertension (duration> 10 years)
d) History of chronic kidney disease
e) AKI prior to surgery
f) Contraindications for TEE probe placement such as perforated viscus, esophageal stricture, esophageal tumor, esophageal perforation, esophageal diverticulum, active upper GI bleed.
g) Emergency surgery
h) Patient refusal
i) Redo surgeries

Study protocol:

A total of 48 patients fulfilling the inclusion criteria were included in the study. Patients were educated about the study in the presence of a witness. Written informed consent was taken from the patient or the relative of the patient as per institute protocol. During the process of obtaining consent, witnesses were allowed to counter-question the patient whether he/she understood the proposed study.

In the operation room, before induction of general anaesthesia, NIRS sensors were placed on the Morris parallelogram (surface marking for the placement of NIRS probe) of both right and left side (Figure 1).

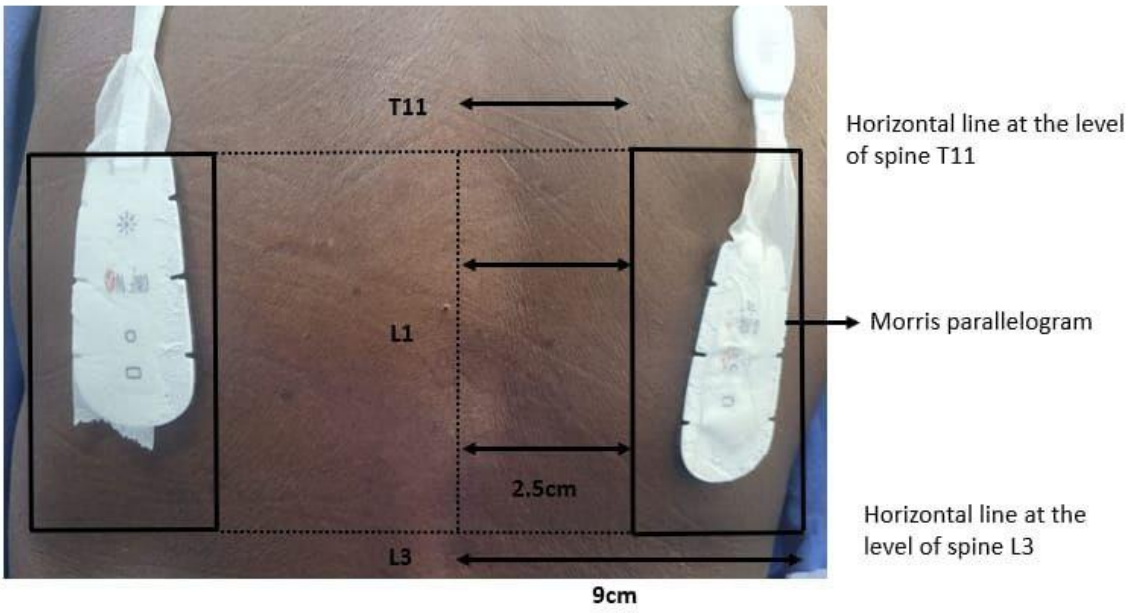


Figure 1 – Showing characteristic features of Morris parallelogram (surface marking for Right and Left Renal)

The baseline values of right and left renal rSO-2 were noted. After induction of general anaesthesia as per the institute protocol, an adult size real time three dimensional transoesophageal echocardiography (RT-3D TEE) probe was inserted and sequential

examination of the cardiac structures was performed using IE-33 ultrasound machine (Philips ultrasound, USA).

The renal artery was visualized using TEE probe by the following technique described by Bandyopadhyay [5]

TEE imaging of renal artery

Using multiplane TEE probe in vascular pre-set

STEP - 1 - Mid-oesophageal four chamber view.

FIGURE – 2 - showing mid oesophageal four chamber view

STEP - 2 - Trans-gastric short axis Mid papillary view.

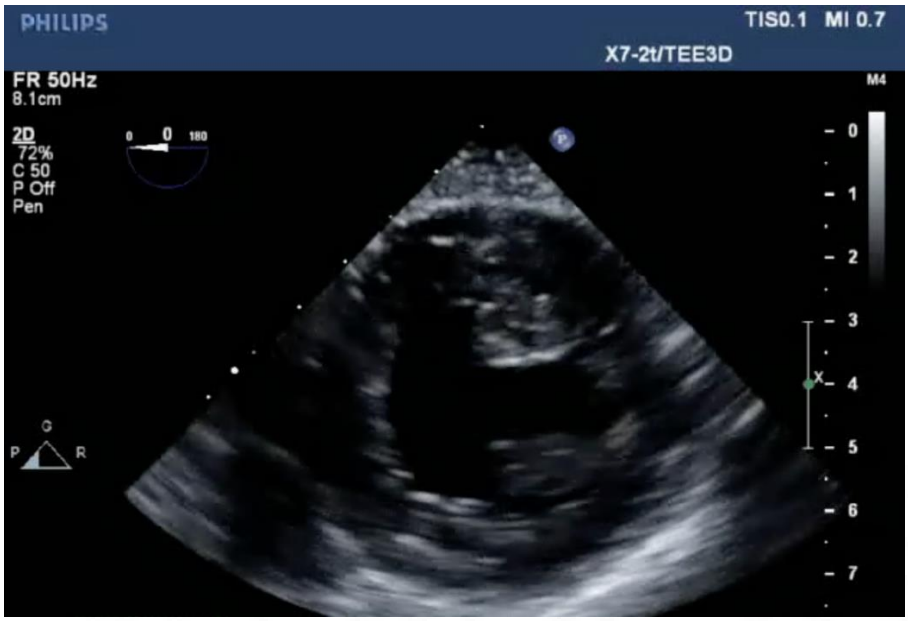


FIGURE -3 - showing Trans gastric midpapillary short axis view

STEP - 3 – Then Probe was turned towards the left up to 90 – 270 degree until short axis view of descending aorta was imaged.

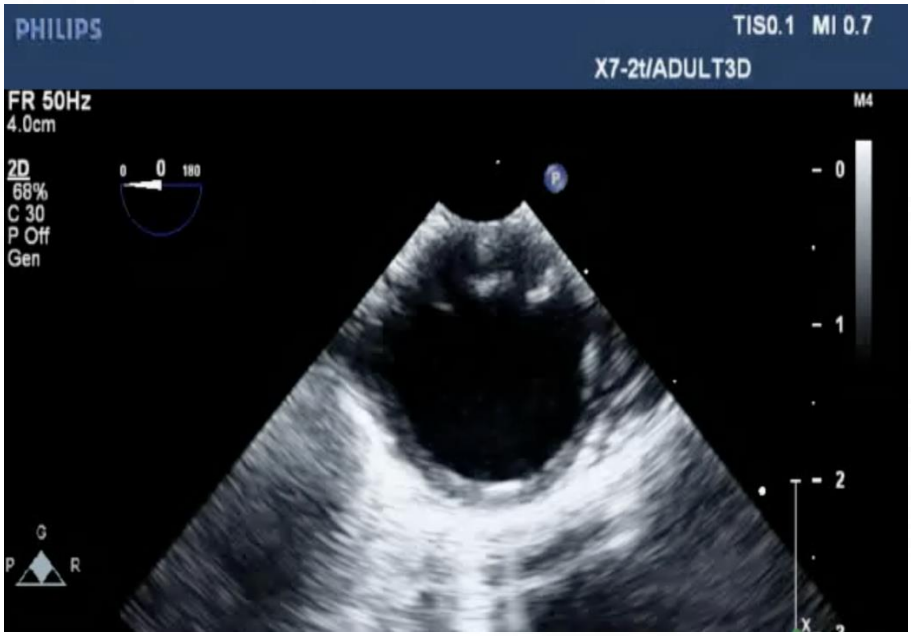


FIGURE – 4 – showing descending thoracic aorta short axis view

STEP - 4 – Then probe was advanced 4-6 cm following the aorta & origin of the left renal artery and left kidney was visualized by using colour flow doppler

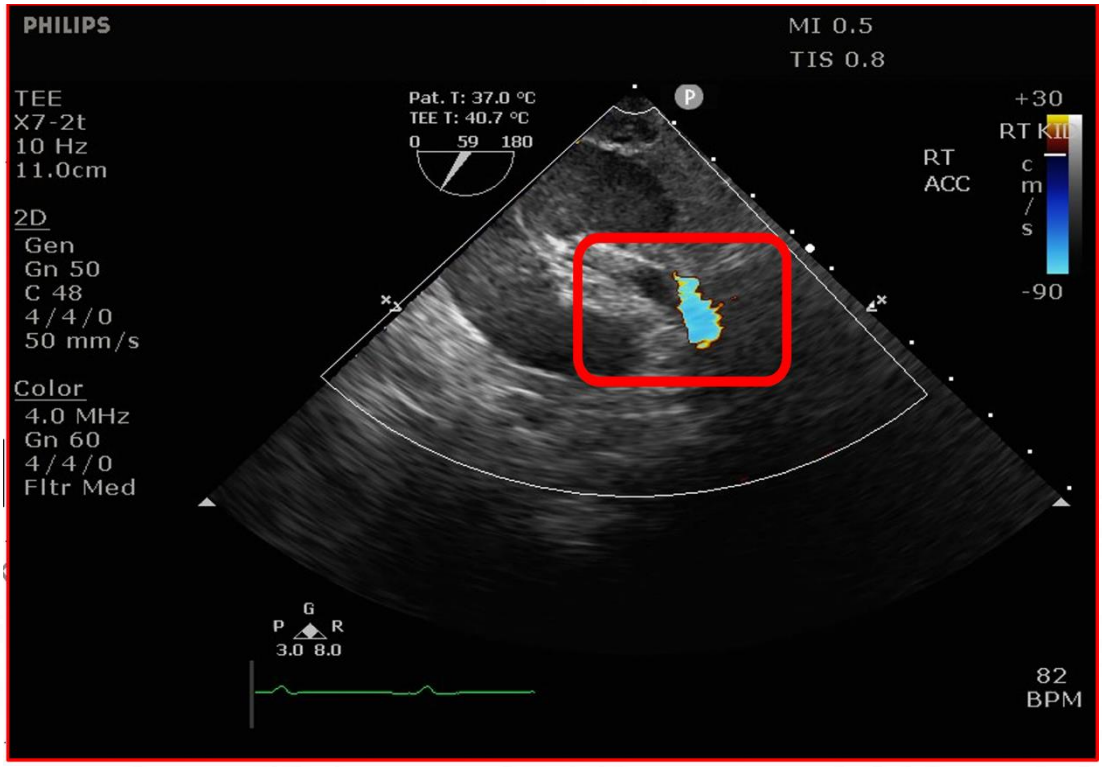


FIGURE – 5 – showing renal with renal artery using colour flow doppler

STEP- 5 – Probe was turned 90- 270 degree towards right from the trans – gastric short axis mid papillary view, then right kidney with right renal was visualized.

The characteristic bilateral renal artery flow velocity patterns are recorded by applying pulsed wave doppler. Renal artery spectral doppler waveform has a systolic and diastolic peak indicating the respective peak velocities.

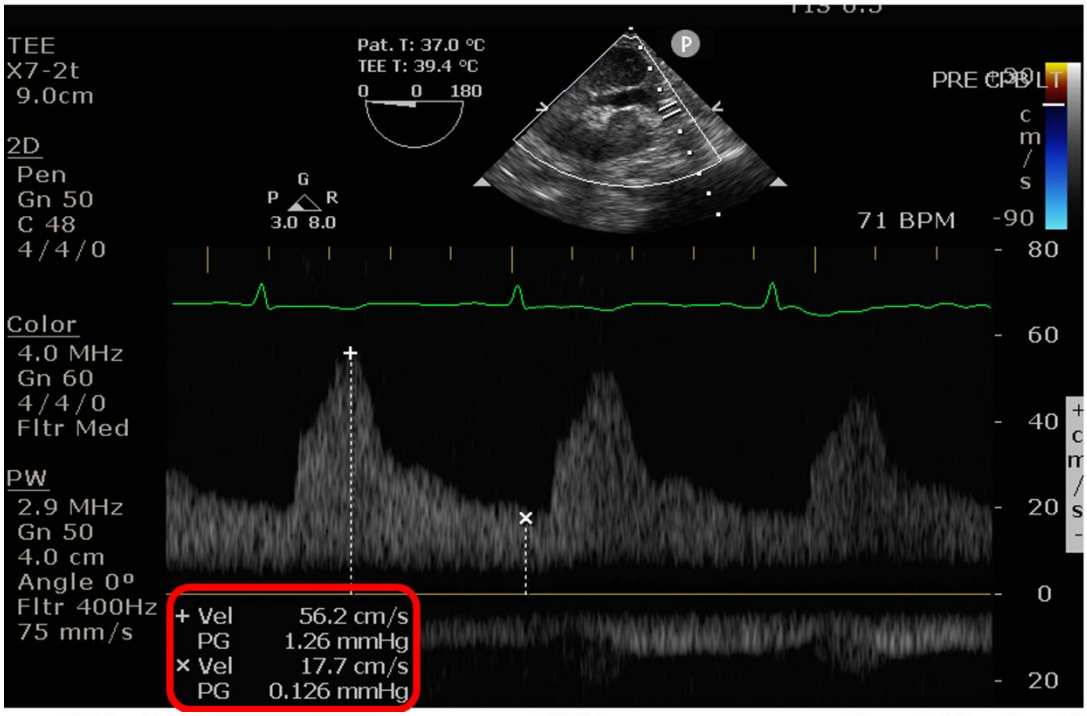


FIGURE – 6 – showing pulse wave doppler of renal artery demonstrating peak systolic velocity (+) and minimum diastolic velocity (x)

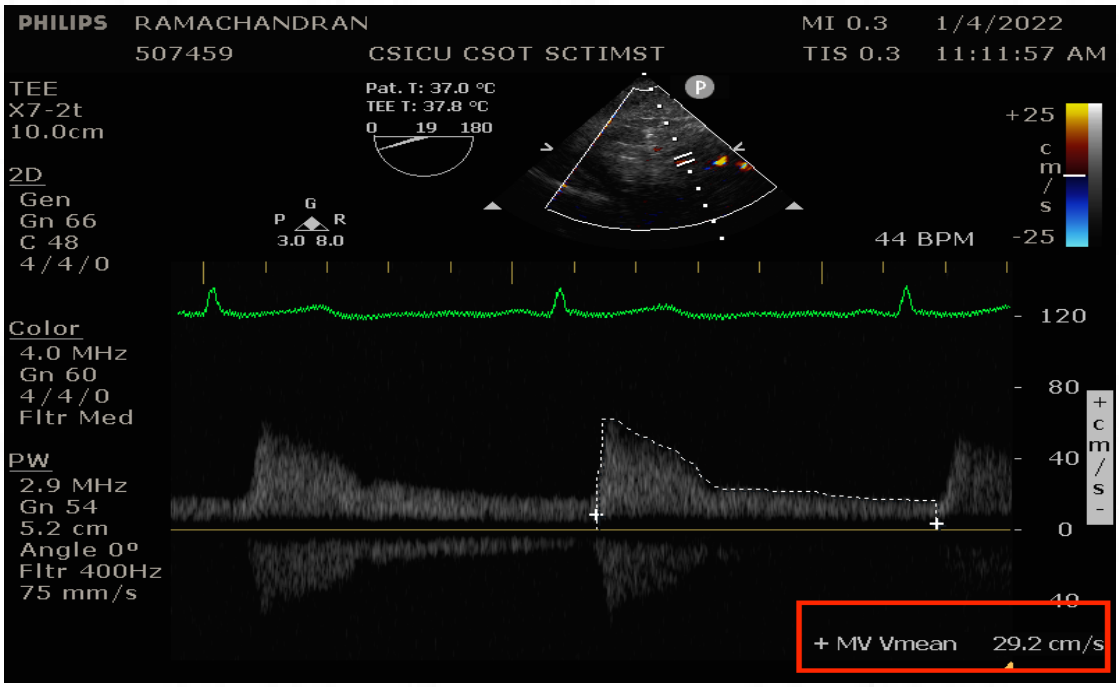


FIGURE - 7 – showing mean renal velocity (+) measured during pre CPB and post CPB periods

On the basis of doppler measurements of renal artery velocities, resistive index was calculated using the following formula –

RI = (peak systolic velocity – minimum diastolic velocity) / peak systolic velocity.

When the patient was on cardio-pulmonary bypass, the renal mean velocity was measured from the continuous flow spectral waveform by the pulse wave doppler to the renal arteries.

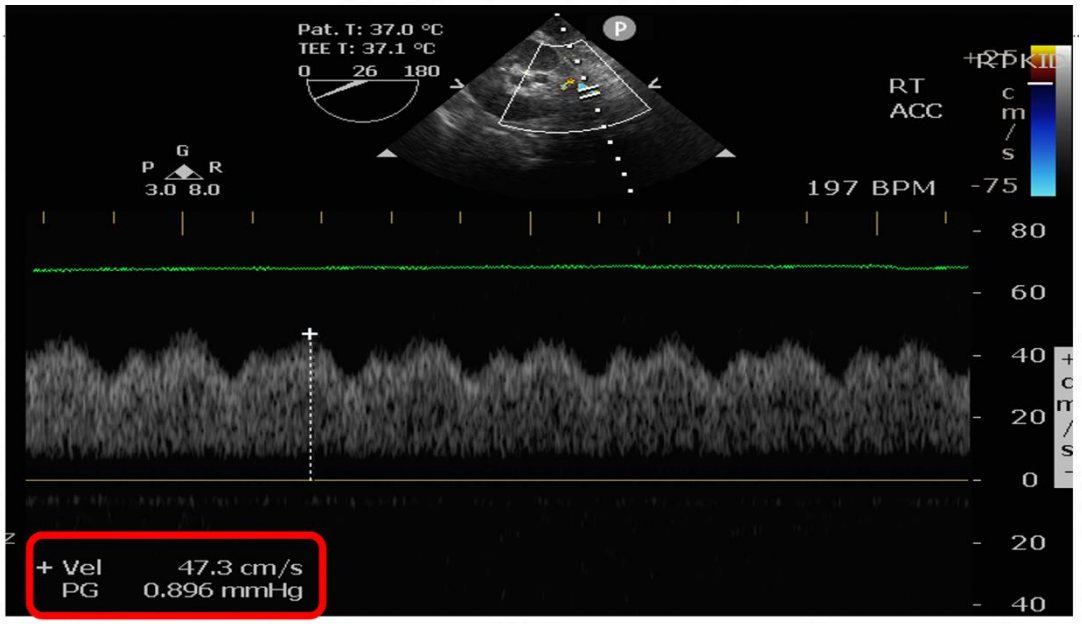


FIGURE – 8 showing mean renal velocity measured on CPB

The following observations were made intra-operatively during the following time periods: 1. *Pre CPB periods , 2. On CPB after aortic cross clamping, Half -an-hour after aortic cross clamping, 3. Post CPB (after protamine).*

A. PRE CPB PERIOD -

1. Mean arterial pressure, Cardiac output,

2. Renal resistance index (both right and left renal),

3. Mean renal arterial velocity,

3. rSO-2 (both right and left renal),

4. Haemoglobin,

5. Left ventricle ejection fraction,

6. Grade of descending thoracic aorta atheroma.

B. ON CPB –

Zero minutes (after aortic cross clamping) and thirty minutes after CPB

1. Mean arterial pressure, Cardiac output, Delivery of oxygen (do-2)

2. Mean renal arterial velocity

3. rSO-2 (both right and left renal),

4. Haemoglobin.

C. POST CPB PERIOD –

1. Mean arterial pressure, Cardiac output,

2. Renal resistance index (both right and left renal),

3. Mean renal arterial velocity,

3. rSO-2 (both right and left renal),

4. Haemoglobin,

5. Left ventricle ejection fraction.

<u>In post-operative period following data were collected</u>

1. Urine output, Blood urea, serum creatinine, eGFR daily for three consecutive post-operative days.
2. Inotrope score **{**calculated using following formula Dopamine dose (mcg/kg/min) + Dobutamine dose (mcg/kg/min) + 100 x epinephrine dose (mcg/kg/min)**}**
3. Diuretic score
4. Left ventricular ejection fraction, Cardiac output, Hemoglobin
5. Acute kidney injury and its stage (KIDGO criteria)
6. Incidence of atrial fibrillation,
7. Duration of ICU stay, need of dialysis, duration of hospital stays, in-hospital mortality.

STATSTICAL METHODS

STATISTICAL METHODS:

AKI was considered as primary outcome variable. RRI and renal NIRS were considered as primary explanatory variable.

Descriptive analysis were done by using mean and standard deviation for quantitative variables, frequency, and proportion for categorical variables. Median and interquartile range (IQR) were used for non-normally distributed quantitative variables. Data was represented with appropriate bar diagram, pie diagram, box plots were ever necessary.

Quantitative variables were checked for normal distribution within each category of explanatory variable by visual inspection of histograms and normality Q-Q plots. Shapiro-wilk test was conducted to assess normal distribution. Shapiro wilk test p value of >0.05 was considered as normal distribution.

Chi square test /Fisher's Exact test were used for comparison of categorical variables. For normally distributed Quantitative parameters the mean values were compared between study groups using independent sample t-test (2 groups).

Univariate Binary logistic regression analysis was performed to test the association between the explanatory variables and study group. Odds ratio was unadjusted presented with 95% confidence interval.

p value < 0.05 was considered statistically significant. Software used for statistical analysis was IBM SPSS version 22.

Sample size :

Based up on the previous study a sample size of 40 was required to detect a correlation of 0.43 between renal NIRS and renal Doppler parameters in predicting the post-operative AKI with an alpha error of 0.05 and power of 80%[12].

RESULTS

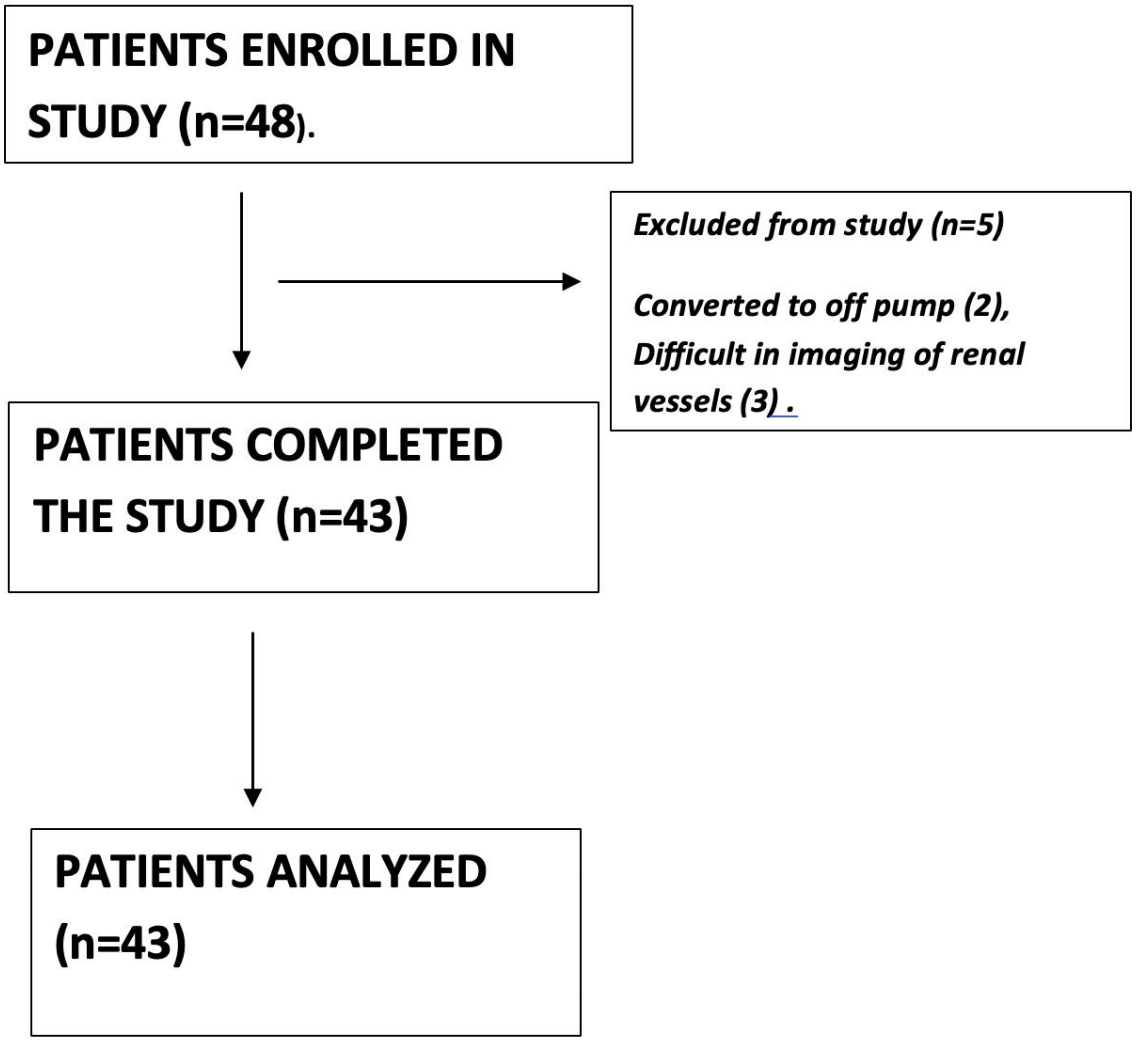

PATIENTS ENROLLED IN STUDY (n=48).
Excluded from study (n=5)
Converted to off pump (2), Difficult in imaging of renal vessels (3) .
PATIENTS COMPLETED THE STUDY (n=43)
PATIENTS ANALYZED (n=43)

Table 5:

Demographic profile and preoperative clinical features of patients

Total number of patients		**n = 43**
Age (years)		59.23 ± 1.33
sex	Male Female	36 (83.72%) 7 (16.28%)
Height (cm)		167.67 ± 8.93
Weight (cm)		65.50 ± 9.78
BSA (m^2)		1.71 ± 0.19
Diagnosis	Double vessel disease Triple vessel disease	11(25.5%) 32 (74.5%)
NHYA class	Class - II Class - III	26 (60.46%) 17 (39.53%)
Rhythm	Sinus	43

Abbreviations : BSA – Body surface area; NYHA – New York heart association.

Table 1 shows that the average age of the study subjects involved in the study was 59.23 ± 1.33 years. Males were in a larger proportion (83.72%) compared to females (16.28%). Majority of the patients presented with NYHA class – II symptoms (60.46%), whereas 39.53% patients presented with NYHA class – III symptoms. All the 43 study subjects were in normal sinus rhythm.

Intraoperative details -

Table 6:

Descriptive analysis of Mean arterial pressure (MAP), Haemoglobin, Ejection fraction, Cardiac output, Delivery of oxygen in the study population (N=43)

	PRE CPB	CPB		POST CPB
		0 - minutes	30 - minutes	
Haemoglobin	13.54 ± 1.64	8.44 ± 1.21	9.01 ± 1.11	12.64 ± 1.54
EF	60.54 ±4.83	-	-	61.54 ±5.93
MAP	80.74 ± 9.73	60.74 ± 6.51	62.23 ± 4.44	81.44 ± 3.62
Cardiac output	4.47 ± 0.86	4.67 ± 0.95	4.77 ± 0.86	5.27 ± 1.77
Delivery of oxygen (Do-2)	-	650.54 ± 90.08	610 ± 92.67	-

(Abbreviations - MAP – Mean arterial pressure, EF – ejection fraction)

Table – 6 showing mean arterial pressure was maintained within normal limits in Pre CPB, CPB, Post CPB periods. Mean Ejection fraction value was 60 percent. None of the patient had low cardiac output. Hemoglobin was maintained as per 2019 EACTA guidelines [27] in all time periods .

Table -7 :

Descriptive analysis of RRI, MRV, rSo-2 values

	PRE CPB	CPB		POST CPB
		0 - minutes	30 - minutes	
RRI	0.61 ± 0.04	-	-	0.77 ± 0.02
MRV	22.51 ± 7.56	29.98 ± 7.35	34.61 ± 6.45	32.25 ± 5.59
rSo-2	71.50 ± 3.20	73.54 ± 4.40	74.50 ± 5.34	73.50 ± 2.14

(Abbreviations – RRI – Renal resistance index, MRV – Mean renal velocity, CPB – cardiopulmonary bypass)

Table – 7 shows there was significant increase in RRI, MRV values comparing Pre CPB, Post CPB periods. There was no fall in rSO-2 values in any of the time periods.

Post operative details –

Table – 8 –

Descriptive analysis of Blood urea, serum creatinine, eGFR, urine output.

	Day -1	Day-2	Day-3
Blood urea	12.62 ± 2.46	13.41 ± 3.56	11.31 ± 4.74
Serum creatinine	0.81 ± 0.43	0.71 ± 0.20	0.72 ± 0.36
eGFR	95.51 ± 10.56	100.41 ± 7.68	98.41 ± 8.76
Urine output	2234.41 ± 250.74	2333.51 ± 150.78	2114.78 ± 157.66

(Abbreviations – eGFR – glomerular filtration rate)

Table – 8 shows slight raise in creatinine levels in postoperative day -1, remaining all other values of blood urea, eGFR , urine output are within normal limits.

Table -9

Descriptive analysis of Inotropic score, Diuretic score, Cardiac output, Ejection fraction, Haemoglobin.

	Day -1	Day-2	Day-3
Inotropic score	10.60 ± 2.65	7.62 ± 2.46	4.62 ± 2.46
Diuretic score	54.62 ± 9.76	42.46 ± 8.78	29.83 ± 7.58
Cardiac output	4.62 ± 1.10	3.99 ± 1.76	4.00 ± 1.46
Ejection fraction	60.64 ± 3.78	62.12 ± 5.37	59.94 ± 4.87
Haemoglobin	13.62 ± 1.87	11.62 ± 2.57	12.73 ± 2.46

Table – 9 shows fall in hemoglobin on day two, three post operative days due to increased drain output, there was progressive decrease in inotropic score, diuretic score due to a decrease in usage of inotropes and diuretics in post operative day two and three.

Table 10 –

Analysis of RRI values in AKI and NON - AKI groups during Pre CPB and Post CPB time periods

RRI	*AKI*		
	Yes	*No*	*p – value*
Pre CPB	0.61 ± 0.04	0.63 ± 0.03	0.2171
Post CPB	0.77 ± 0.05	0.69 ± 0.03	0.0018

(Abbreviations – CPB – cardiopulmonary bypass, RRI – renal resistance index)

Table – 10 – RRI shows significant difference in post CPB time period with p – value less than 0.05. In pre CPB time period there was no significant difference.

Table 11 –

Analysis of rSo-2 values in AKI and NON - AKI groups during Pre CPB and Post CPB time periods

rSO-2	*AKI*		
	Yes	*No*	*p - value*
Pre CPB	72.50 ± 2.20	72.43 ± 3.47	0.0812
Post CPB	73.67 ± 2.47	74.50 ± 4.67	0.0934

(Abbreviations – CPB – cardiopulmonary bypass)

Table – 11 – There was no significant change in rSo-2 values in pre CPB and post CPB time periods.

Table 12 –

Analysis of MRV values in AKI and NON - AKI groups during CPB (0-MIN and 30-MIN after aortic cross clamping)

MRV	*AKI*		
	Yes	*No*	*p - value*
CPB (0 – MIN)	29.98 ± 6.47	29.25 ± 4.88	0.4373
CPB (30 – MIN)	34.61 ± 6.45	29.65 ± 6.55	0.016

(Abbreviations – MRV – Mean renal velocity, CPB – cardiopulmonary bypass, MIN - minutes)

Table – 12 – MRV shows significant difference in 30 – minutes after aortic cross clamping on CPB with p – value less than 0.05. In zero minutes after aortic cross clamping on CPB there was no significant difference.

Table 13 –

Analysis of rSo-2 values in AKI and NON - AKI groups during CPB (0-MIN and 30-MIN after aortic cross clamping)

rSo-2	*AKI*		*p – value*
	Yes	*No*	
CPB (0 – MIN)	71.50 ± 4.47	70.40 ± 5.48	0.091
CPB (30 – MIN)	70.49 ± 5.59	71.49 ± 6.77	0.174

Table – 13 – There was no significant change in rSo-2 values between zero minutes and thirty minutes after aortic cross clamping on CPB.

(Abbreviations – CPB – cardiopulmonary bypass, rSo-2 – regional oxygen saturation, MIN - minutes)

Table- 14:

Logistic regression analysis of Renal resistance index (RRI) and rSO-2 influencing Acute kidney injury in study population (N=43).

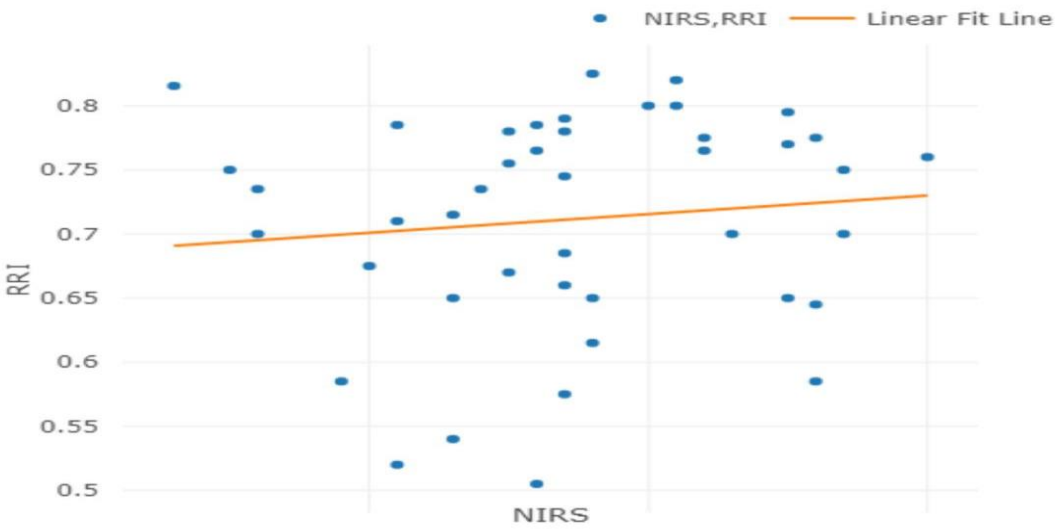
This table shows odds ratio of renal resistance index was 0.000002 indicating 'protective factor' or useful in predicting acute kidney injury. For rSo-2 , odds ratio is around 0.874 indicating no association with acute kidney injury, in the intra-operative period.

Parameters	AKI		Odds ratio (95% CI)	P-value
	Yes (N=22)	No (N=21)		
RRI	0.75 ± 0.06	0.67 ± 0.09	0.000002 (0.000-0.034)	0.780
rSo-2	74.27 ± 2.73	72.9 ± 3.71	0.874 (0.719-1.062)	0.175

(Abbreviations – RRI – renal resistance index)

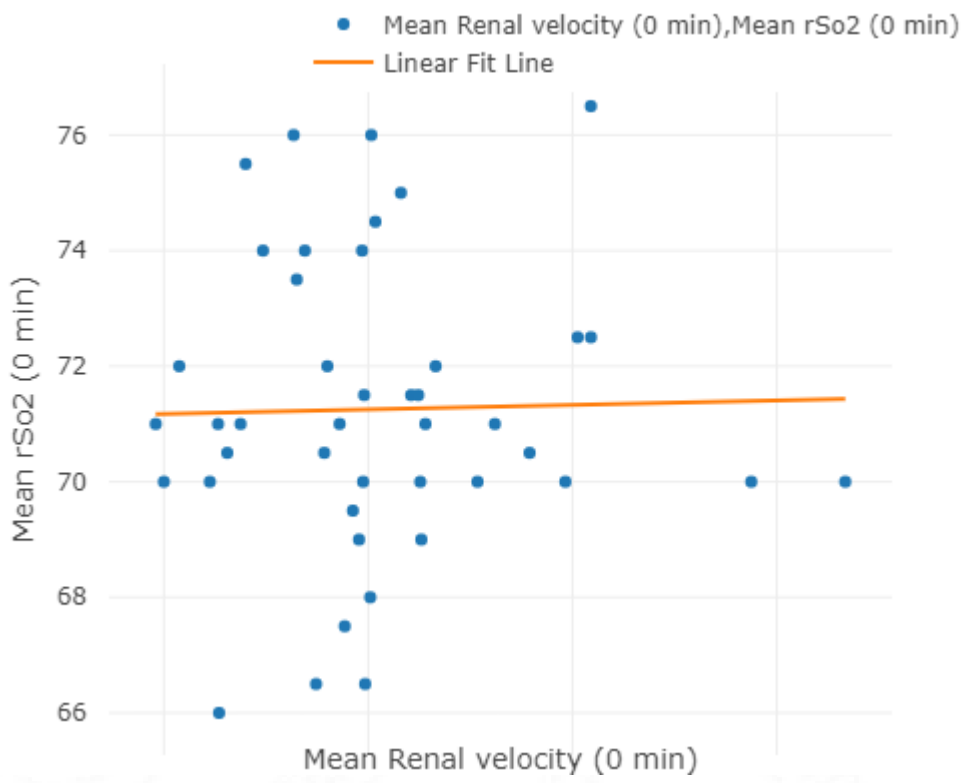
CORREALTION BETWEEN rSO-2 & RRI

Scatter plot for correlation between RRI and NIRS in the study population (N= 43)



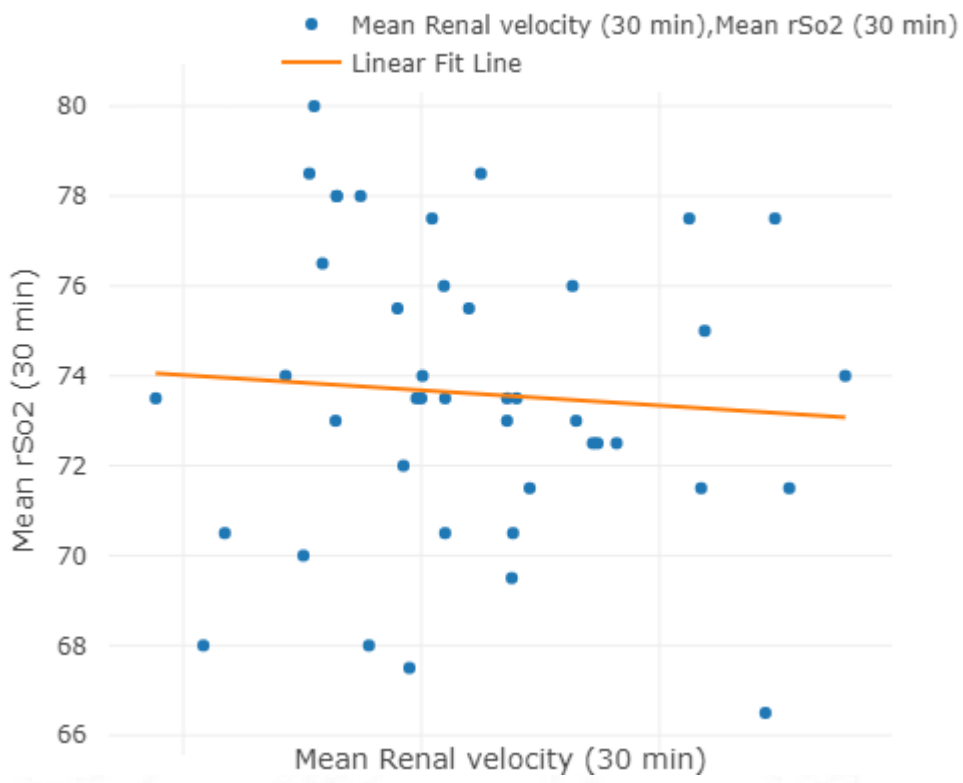
Pearson correlation co-efficient showing R – VALUE of 0.11 showing ***weak correlation.***

CORRELATION BETWEEN rSO-2 & mean renal velocity during CPB (0-min)



Pearson correlation co-efficient showing R – VALUE of 0.02 showing ***no or negligible relationship.***

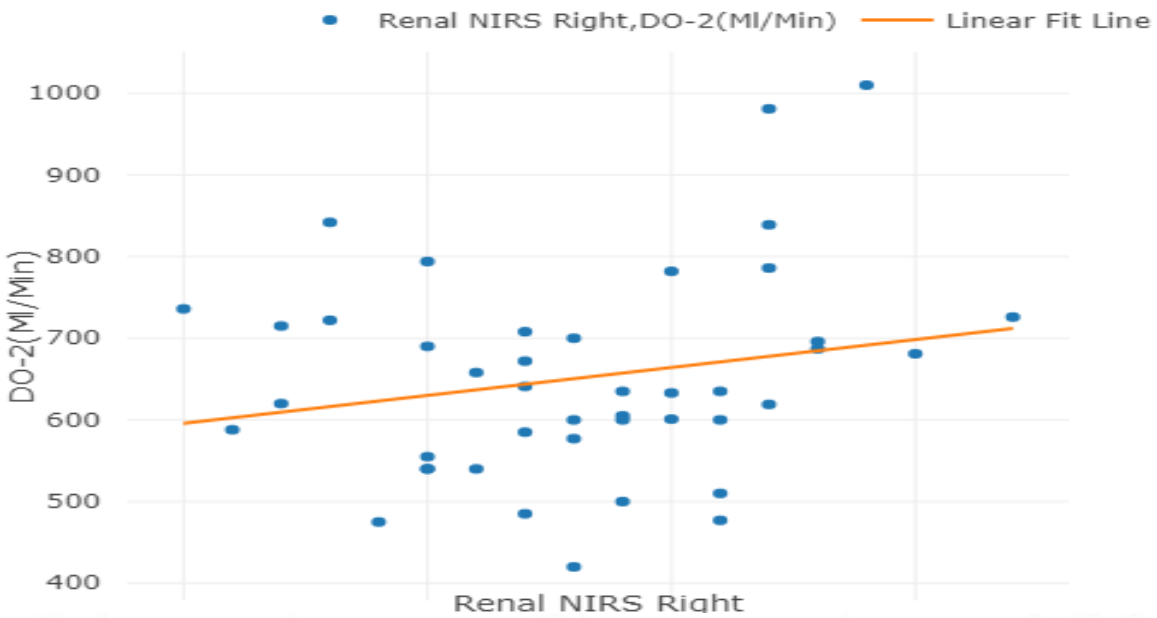
CORRELATION BETWEEN rSO-2 & mean renal velocity during CPB (30-min)



Pearson correlation co-efficient showing R – VALUE of - 0.07 showing ***no or negligible relationship.***

CORRELATION BETWEEN rSO-2 & DO-2

Scatter plot for correlation between DO-2 (Ml/Min) and Renal NIRS in the study population (N= 43)



R- value – 0.15 Showing ***positive correlation*** between rso-2 and do-2.

Table-15:

Descriptive analysis of atrial fibrillation in the study population (N=43).

Among 43 study subjects only two of our subjects had atrial fibrillation. Incidence of atrial fibrillation in our study was 4.65%.

Atrial fibrillation	Frequency	Percentage
Yes	2	4.65%
No	41	95.35%

INCIDENCE OF ACUTE KIDNEY INJURY –

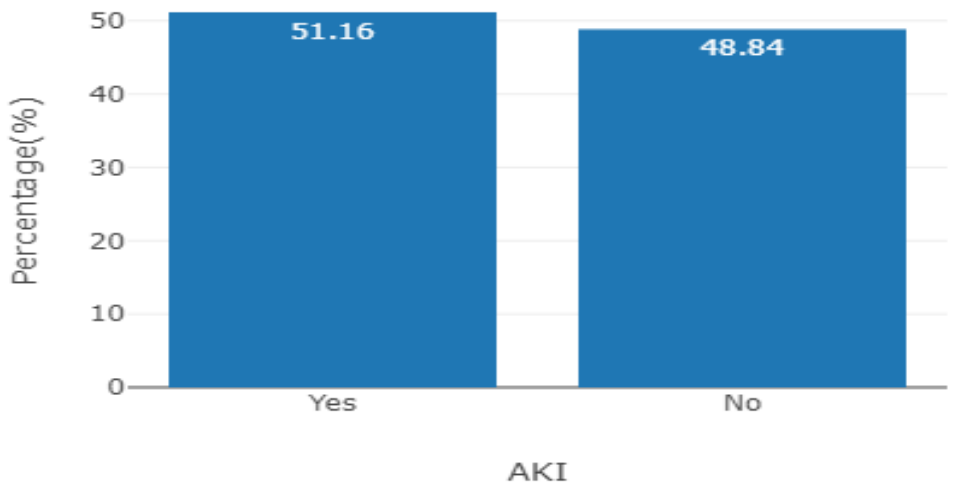
Table-16:

Descriptive analysis of Acute kidney injury in the study population (N=43).

In our study incidence of acute kidney injury was 51.16 percentage.

AKI	Frequency	Percentage
Yes	22	51.16%
No	21	48.84%

(Abbreviations – AKI – Acute kidney injury)



DESCENDING THORACIC AORTA ARTHEROMA & ACUTE KIDNEY INJURY

Table-17:

Descriptive analysis of Descending thoracic aorta Atheroma in the study population (N=43).

Among forty three study subjects nineteen patients had descending thoracic aorta atheroma contributing around 44.19 percentage.

DTA Atheroma	Frequency	Percentage
Yes	19	44.19%
No	24	55.81%

(Abbreviations – DTA – descending thoracic aorta)

Table-18:

Comparison of Descending thoracic aorta atheroma and Acute kidney injury (N=43)

The frequency of acute kidney injury among patients with descending thoracic atheroma was 57.89 percentage.

DTA Atheroma	AKI	
	Yes	**No**
Yes (N = 19)	11 (57.89%)	8 (42.11%)
No (N = 24)	11 (45.83%)	13 (54.17%)

(Abbreviations – DTA – descending thoracic aorta, AKI – acute kidney injury)

Bar Diagram showing incidence of AKI in patients having Descending thoracic aorta atheroma is higher comparing to patients who do not have atheroma

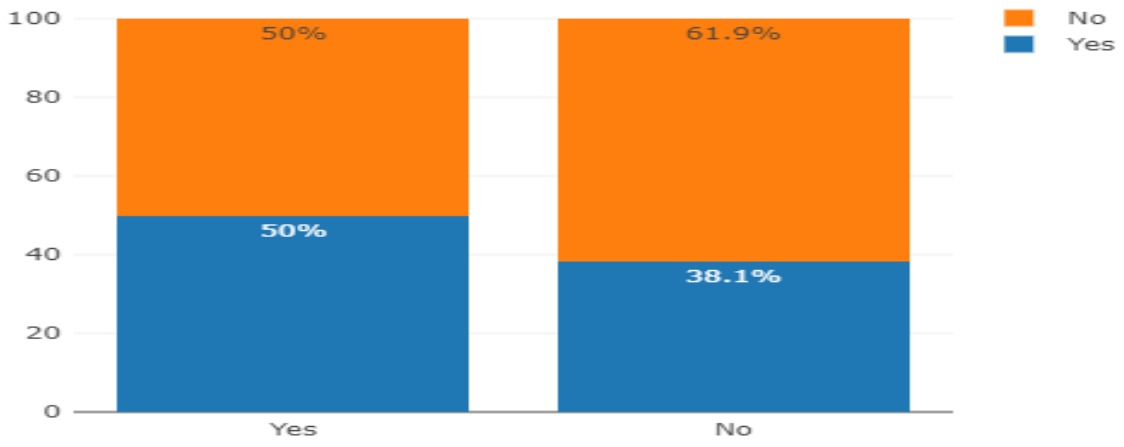


Table -19

Frequency of AKI in different groups according to katz grading

Table – 19 - showing incidence of AKI was high among patients with intimal thickening (katz grade -2) proving the role of arterial stiffness in AKI. Katz grade 3 and 4 had less incidence of AKI comparing to katz grade -2.

KATZ grading	AKI
1	Nil
2	5 (22.73%)
3	4 (18.18%)
4	2 (9.09%)
5	Nil

(Abbreviations – Acute kidney Injury)

Table – 20 Analysis of Inotropic and diuretic score in patients with AKI and NON – AKI group.

Parameters	AKI		p-value
	Yes	No	
Inotropic score	11.14 ± 1.75	7.20 ± 3.18	0.0062
Diuretic score	41.22 ± 12.84	55.12 ± 11.34	0.0190

Table – 20 showing patients with higher inotropic score and lower diuretic score has increased risk of AKI with p- value < 0.05.

Table –21

Descriptive analysis of Hospital stay, ICU stay, need for dialysis in the study population (N=43).

	AKI	
	yes	*no*
Hospital stay	6.00 ± 1.00	4.00 ± 1.00
ICU stay	3.00 ± 1.00	2.00 ± 0.00
Need for dialysis	0	0

(Abbreviations – ICU – Intensive care unit)

Table – 20 – showing there was no significant difference in two groups in terms of hospital stay, ICU stay. None of our patients required dialysis.

DISCUSSION

DISCUSSION –

Cardiac surgery -AKI

Incidence of AKI was high in cardiac surgery comparing other surgeries. There are many reasons for high incidence such as patient underlying co-morbidities, intraoperative and perioperative care. The prevalence of AKI was especially higher in older age groups who require more complex surgeries. These established risk factors in addition to longer operations, procedures performed on cardiopulmonary bypass with aortic cross-clamping, supportive measures such as inotropes, fluid and blood administration, vasopressors and mechanical circulatory support all these factors combined increases the risk of AKI in patients undergoing cardiac surgery, especially with cardiopulmonary bypass [(1).]

AKI – CPB

Features of AKI associated with CPB are multifactorial. Four major factors playing an important role in the pathogenesis of AKI-CPB are as follows 1. Reduced renal perfusion pressures 2. Activation of proinflammatory mediators 3. Direct nephrotoxicity 4. Generation of micro emboli [(28)]. Tumor necrosis factor, interleukin – 6, interleukin – 8 are key proinflammatory mediators studied in the AKI related to CPB. In a study published by okusa et al [(29)] shows that instituting CPB itself decreases renal perfusion pressure by 30%. Micro emboli generated during CPB can directly damage renal capillaries resulting in AKI. Studies conducted on off-pump coronary artery bypass grafting show decreased incidence of AKI compared on pump coronary artery surgeries, again highlighting the contribution of CPB in AKI [(28)] .

Risk factors for developing AKI-CPB [30][31]

Patient factors	Surgical factors
Age	Hemodilution
Female gender	Intraaortic balloon pump use
Preoperative renal insufficiency	Valve surgery and combined valve – CABG procedures
EF < 40%	CPB duration
Emergency surgery	
Diabetes mellitus	

Intraoperative RRI and NIRS

The incidence of CSA-AKI was reported to be 25 – 50% [1]. It is important to develop newer diagnostic modalities for predicting patients with AKI. The renal resistance index was a valuable tool in assessing renal perfusion [19]. Bossard et al [2] demonstrated the utility of RRI in predicting the AKI. Another modality helpful in predicting AKI was Renal NIRS. Various studies done on intraoperative NIRS monitoring have shown its value in predicting postoperative AKI, especially among neonates and infants. Studies in adult cardiac surgical patients were sparse. Based on these aspects the present study was conducted to evaluate the correlation between intraoperative RRI and renal NIRS in predicting postoperative AKI in patients undergoing coronary artery bypass grafting with CPB.

In our study, the incidence of AKI was around 51.16 %. Previous studies conducted in cardiac surgery-associated AKI have shown the same results as seen in our study [1]. The reason for this finding can be attributed to various risk factors associated with the patients in our study. Risk factors are as follows 1. The mean age group in our study was 59.23 ± 1.33, 2. The frequency of DTA atheroma was 44.19%, 3. On CPB with aortic cross clamping, 4. Diabetes mellitus, 5. Hypertension. Above mentioned risk factors were seen in our study subjects contributing to an increased incidence of AKI in our study.

RRI and AKI

In our study, we included 43 patients out of which 22 patients developed AKI. The mean RRI value of patients who developed AKI was 0.75 ± 0.06 and in non-AKI group RRI value was 0.67 ± 0.09. Previous studies done on RRI by satyen et al[18] have shown cutoff value for RRI was 0.71 with sensitivity & specificity of 70% & 80% respectively. Kajal et al[8] studied the role of pre-operative RRI, a value of 0.68 has good predictability of AKI in patients undergoing cardiac surgery. A study conducted by Bossard et al[2] showed that RRI predicts AKI with 85% sensitivity and 94% specificity. In contrast, Renal rso-2 is less sensitive 50% and highly specific 93%[14]. In our study patients with AKI in post cardio-pulmonary bypass period has an RRI value of 0.75, correlating well with all previously conducted studies in patients undergoing cardiac surgery.

Mean renal velocity during CPB and AKI

A study conducted by Da zhu et al [32] shows a normal value of mean renal velocity in pediatric patients was 30 centimeter per second. In our study, we measured mean renal velocity on CPB in two time periods (immediately after aortic cross-clamping, 30 minutes after cross-clamping).

Thirty minutes after cross-clamping our mean renal velocity among patients having AKI was 34.61 ± 6.45, patients who did not had AKI mean renal velocity was 29.65 ± 6.55. The difference in values between two groups was statistically significant. Showing the importance of measuring mean renal velocity in an intraoperative period in predicting AKI.

NIRS and AKI

There was no significant difference in the renal NIRS values between the AKI and non-AKI groups. In the study conducted by Flechet M et al[33] postoperative renal rSo-2 values showed decreasing trend and subsequently, patients developed AKI. Choi et al[14] described the cut-off value of the rSo-2 level as 55%, below 55% there was an increased risk of developing acute kidney injury. In our study, we did not notice any such fall in rSo-2 values in patients who developed AKI. Facts that may be attributed to the same value of rSo-2 are as follows –

1. All the studies done in renal NIRS predicting AKI were predominately studied in the pediatric age group with less muscle mass, whereas in adults thickness of muscle mass may impair depth of penetration of infrared waves leading to variation in projected value.

2. rSo-2 values were monitored only in the specific time period continuous trend of values was not recorded.

3. Increase in a fraction of oxygen on cardiopulmonary bypass.

4. In post cardiopulmonary bypass period increased cardiac index due to inotropes.

Renal doppler parameters and renal NIRS

There were no studies published in the literature showing the correlation between RRI and renal NIRS in patients undergoing cardiac surgery. We find no correlation between RRI and renal NIRS intraoperatively (R-value – 0.11). Patients with AKI had higher RRI values in

contrast there was no fall in NIRS (rSo-2 values). On performing regression analysis for RRI and rSo-2 values in association with AKI, results show renal NIRS was not a good intraoperative modality to predict AKI. As rSo-2 values only reflect the oxygenation of the renal neglecting the other factors that leads to AKI such as systemic inflammatory response syndrome (SIRS), nephrotoxic drugs and increased renal vascular resistance. Logistic regression analysis shows RRI as a reliable intraoperative predictor of AKI comparing NIRS.

Correlation between mean renal velocity and NIRS immediately after aortic cross clamping shows positive correlation but after 30 minutes of aortic cross clamping period, correlation becomes slightly negative. The main factor contributing to this finding was an increase in mean renal velocity after a while on CPB. Causes for the increase in mean renal velocity are an increase in interstitial edema, CPB altering the vasomotor tone of renal arteries, microemboli generation on CPB [(28)]. This finding also proves that prolonging CPB time also increases the risk of AKI in the post-operative period.

At the same time, it also provides insight into acute kidney injury was multifactorial as it includes inotropes, leading to increased renal vascular resistance resulting in flow limitation resulting in AKI and an increase in interstitial edema also can add insult to the renal resulting in acute kidney injury. Other extra-renal factors such as cardiac index altering renal blood flow, SIRS (systemic inflammatory response syndrome) and usage of nephrotoxic drugs all contribute to renal injury.

DTA ATHEROMA AND AKI

Patients with DTA atheroma in our study have high incidence of AKI, comparing patients with no atheroma. A study conducted by Nowak-Machen M et al [21] showed that descending thoracic atheroma has increased the risk of stroke, multiorgan failure and death. Another study conducted by Greenwood et al [34] shows an increase in arterial stiffness results in barotrauma to glomeruli resulting in decreased eGFR**.** Another important factor was atheroembolism to renal arteries as consequence leading to inflammatory reaction and endothelial overgrowth in 7 to 10 days[22]. Our study results also showed an increased incidence of AKI in patients having katz grade – two (intimal thickening) proving the role of arterial stiffness in the pathophysiology of patients having AKI.

Renal rSO2 and Delivery of oxygen (do-2) during CPB

Renal rSo-2 & do-2 show positive correlation in our study. A study conducted by Yumiko et al [35] shows a positive correlation between rSO-2 and do-2. It was obvious as an increase in fio-2 increases do-2 and in turn rso-2 values.

Atrial Fibrillation and AKI

UpToDate literature shows Incidence of Atrial fibrillation in CABG was 5 – 40% [36] and the incidence of atrial fibrillation in AKI was 16 %[37]. In our study incidence of atrial fibrillation was four percent, the incidence of atrial fibrillation among patients with AKI was nine percent. Incidence of Atrial fibrillation was very less since the study was conducted in patients with good left & right ventricular function. Patients with chronic kidney disease, autonomic neuropathy and chronic hypertension were excluded from the study. Most of the patients were on perioperative beta blockers eliminating the risk of atrial fibrillation in the postoperative period[38].

Inotropic score and AKI

In study conducted by kelong hou etal [24] shows that higher the vasoactive inotropic score greater the risk of AKI. Patients receiving more inotropes suggest hemodynamic instability that exists in the patient. The presence of hemodynamic instability invariably results in post operative AKI as proven in previous studies [39]. Our study results were also proving the higher the inotropic score greater the risk of postoperative AKI.

Diuretic score and AKI

Patients requiring a higher dose of a diuretic have an increased risk of developing postoperative renal dysfunction [40]. Increased usage of diuretics results in activation of renin-angiotensin activating system as a consequence peripheral vascular resistance will increase resulting in impairment of renal perfusion [41]. In a study conducted by Lombardi et al [42] shows an increase in usage of loop diuretics increases the risk of postoperative renal dysfunction. Our study results show patients with AKI has lower diuretic score (due to higher usage of diuretic) and patients without AKI has higher lower diuretic. Our Study results suggest lower the diuretic score greater the risk of AKI.

There was no statistical difference in the duration of hospital stay between patients having AKI and patients not having AKI. Hospital stay was not prolonged in any of the patients. The duration of ICU stay was prolonged in two patients who had atrial fibrillation. Regarding the severity of AKI maximum number of patients with AKI had only stage -1 AKI according to KDIGO criteria. All patients had recovered from AKI with none of the patients requiring dialysis. We had no in-hospital mortality in our study population.

The novelty of the study lies in the correlation between rSO-2 values and Renal resistance index (RRI) in predicting AKI in cardiac surgery, to date no such studies have been published. The single examiner performed all Renal resistance index calculations; hence the bias of inter-observer variability has been eliminated.

LIMITATIONS

We Acknowledge that there are certain limitations to our study. Study subjects from single center probably a multi-center study involving more study participants would have given a more conclusive result. We did not continue the measurement of RRI and NIRS values in the postoperative period. And postoperative follow up period was limited for three days only. Long term outcomes such as recurrent AKI episodes, progression to chronic kidney disease, adverse cardiovascular events were not studied. The imaging of renal vessels by TEE is not described in any guidelines. So the imaging of renal vessels needs expertise and it cannot be performed by a novice echocardiographer. Renal NIRS measurements were monitored at certain time points and they were not monitored continuously throughout the intraoperative period. Since all the renal doppler measurements has been performed by an experienced echocardiographer, inter and intra observer variability was not performed.

CONCLUSION

CONCLUSION –

1. In our study the Incidence of AKI associated with cardiac surgery was 49.5% which complies with the results of the multicentric studies published in the literature.

2. Although intraoperative renal resistive index and mean renal velocities predicted the occurrence of post operative AKI after cardiac surgery, renal NIRS did not predicted the occurrence of postoperative AKI. Also, there was no correlation between the Renal doppler and renal NIRS values during CPB period and post CPB period.

3. The incidence of AKI among patients having DTA Atheroma was 59 percent indicating that DTA atheroma is one of the risk factors for the occurrence of AKI in patients undergoing cardiac surgery with CPB.

4. we found a positive correlation between renal rso-2 and do-2 (delivery of oxygen) during the cardio-pulmonary bypass period. It gave a conclusion that renal rso-2 value depends on the changes in the do-2 during the cardiopulmonary bypass time.

5. In our study, the incidence of Atrial fibrillation in patients with AKI was 9%. The lower rate of atrial fibrillation occurrence in patients with AKI may be attributed to the less severe grade of AKI (stage -one) in all the patients.

6. Higher inotropic score greater the risk of post operative AKI.

7. Lower diuretic score suggests higher the risk of post operative AKI.

Several studies needed in the perspective of therapeutic intervention such as maintaining higher renal perfusion pressures, higher hemoglobin targets, usage of selective renal vasodilators in patients with higher intra-operative RRI values.

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DATA COLLECTION PROFORMA

PROFORMA

Name of the patient:

Age: Sex: M/F Date of surgery:

Weight (kg): Height (cm): Body surface area (m2): BMI (kg/m2):

Hospital number:

Diagnosis:

Proposed surgery:

Preoperative features:

Presenting complaints: NYHA class: Heart rate and rhythm:

Co-morbidities: Co-morbidities Duration:

Pre-op medications:

Haemoglobin:

Pre-op Renal parameters

Blood urea: Serum Creatinine: eGFR:

Pre-op Transthoracic 2DE echo report

LVEF (%): LVIDD (mm): LVIDS (mm):

MR Grade: AR Grade: TR/PR Grade:

Pre-op ABG: PaO2: PCO2: SaO2/SPO2:

Na+ - K+ - HCO_3^- -

	Blood pressure	Mean Arterial Pressure	Cardiac output	RRI/MnRAP		Renal NIRS		Hb (mg/dl)	LVEF	DO-2
				Right	Left	Right	Left			
Before sternotomy (Baseline)										
On CPB After ACC									-	
30 minutes after ACC									-	
Post CPB (after protamine)										

INTRA-OPERATIVE DATA

DTA/Aortic Arch atheroma – yes/no Katz Grade:

Inotropes/vasopressors while coming off CPB:

POST – OPERATIVE DATA

	Blood urea (mg/dl)	S. creatinine	e-GFR	Urine output (ml)	Inotrope score	LVEF	CO	Diuretic score	Hb (g/dl)	SaO2 /SpO2
DAY 1										
DAY 2										
DAY 3										

Serum Electrolytes: (Na^+/K^+ /HCO_3^-)

Day 1: / / Day 2: / / Day 3: / /

Acute kidney Injury (KIDGO criteria): yes/ no AKI stage:

Duration of ICU stay:

Need of Dialysis: Yes/No

Tracheostomy: Yes/No

Atrial fibrillation:

Duration of Hospital Stay:

In-hospital Mortality:

Technical Advisory Committee (*Clinical Studies*)

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
THIRUVANANTHAPURAM – 695011, INDIA

TAC Registration No: SCT-/S/2020/1084 **Date: 15.07.2020**

Project title: CORRELATION BETWEEN INTRAOPERATIVE RENAL DOPPLER FLOW AND RENAL NEAR-INFRARED SPECTROSCOPY IN PREDICTING POSTOPERATIVE ACUTE KIDNEY INJURY IN PATIENTS UNDERGOING CORONARY ARTERY BYPASS GRAFTING SURGERY WITH CARDIOPULMONARY BYPASS

Principal Investigator:
Dr. Jagadish A, Senior Resident, Department of Anaesthesiology SCTIMST Degree: MBBS, MD
Co-Principal Investigator(s):
Dr. Prasanta Kumar Dash, Professor, Department of Anesthesiology, SCTIMST Degree: MBBS, DA, MD, PDCC
Dr. Saravana Babu, Assistant Professor, Department of Anesthesiology, SCTIMST Degree: MBBS, MD, DM, FTEE
Co- Investigator(s):
Dr. Vivek V Pillai, Professor, Department of cardiovascular and thoracic surgery, SCTIMST Degree: MBBS, MS, Mch, AATS Graham EHM valve fellow
Dr. Varghese T Panicker, Additional professor, Department of cardiovascular and thoracic surgery, SCTIMST Degree: MBBS, MS, Mch

Members who participated in the TAC meeting on 20/06/2020

Dr Harikrishnan S (Chairman)
Dr Manikandan S
Dr Narayanan Namboodiri
Dr Jayadevan E R
Dr Sylaja P N
Dr Ramshekhar N Menon
Dr Unnikrishnan K P
Dr Syam K
Dr Sanjay G
Dr Deepti A N
Dr Sabarinath Menon
Dr Jayanand Sudhir B
Dr Srinivas G (Member Secretary)

Dr Sabarinath Menon, Dr Ramshekhar N Menon, Dr Sylaja P N, Dr Deepti A N, Dr Manikandan S, Dr Narayanan Namboodiri, Dr Srinivas G, Dr Sanjay G, Dr Harikrishnan S, Dr Unnikrishnan K P, Dr Syam K and Dr Jayadevan E R stayed away from the proceedings when the projects in which they are involved as investigator were discussed (#1072,1087, 1089, 1092, 1093, 1095, 1096, 1097, 1098, 1099, 1100, 1101, 1103, 1107, 1108, 1111, 1113, 1114, 1116, 1118, 1119, 1120, 1121, 1122, 1123, 1127, 1129, 1130)

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.

Dr Srinivas G
MEMBER SECRETARY
TAC (Clinical Studies)
SCTIMST

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, त्रिवेंद्रम - 695 011, केरल, भारत
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY
TRIVANDRUM - 695 011, KERALA, INDIA
(एक राष्ट्रीय महत्व का संस्थान, विज्ञान एवं प्रौद्योगिकी विभाग, भारत सरकार)
(An Institution of National Importance, Department of Science and Technology, Government of India)
टेलीफॉन न./Telephone No.: 0471-2443152 फैक्स/Fax: 0471-2446433, 2550728
ई-मेल/E-mail: sct@sctimst.ac.in वेबसाइट/Website: www.sctimst.ac.in

Institutional Ethics Committee

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

SCT/IEC/1609/DECEMBER-2020 21.12.2020

Dr. Jagadish A
Senior Resident
Department of Anaesthesiology SCTIMST

Dear Dr. Jagadish,

Thank you for submitting documents related to your proposal titled "**CORRELATION BETWEEN INTRAOPERATIVE RENAL DOPPLER FLOW AND RENAL NEAR-INFRARED SPECTROSCOPY IN PREDICTING POSTOPERATIVE ACUTE KIDNEY INJURY IN PATIENTS UNDERGOING CORONARY ARTERY BYPASS GRAFTING SURGERY WITH CARDIOPULMONARY BYPASS** (IEC/1609)" to the IEC for review.

The following documents were reviewed:

1.Checklist
2. Covering letter addressed to the Chairperson, IEC, SCTIMST dated 18.11.2020 forwarded by HOD
3. Covering letter addressed to the Chairperson, IEC, SCTIMST dated 18.11.2020
4. IEC Application Form
5. Full proposal
6. TAC Approval Letter
7. Patient Information Sheet in English
8. Consent Form in English
9. Patient Information Sheet in Malayalam
10. Consent Form in Malayalam
11. CV of Dr. Jagadish A ,with TNMC registration number
12. CV of Dr. Prasanta Kumar Dash, with TCMC registration number
13. CV of Dr. Saravana Babu with TNMC registration number
14. CV of Dr. Vivek V Pillai, without registration number
15. CV of Dr. Varghese T Panicker with TCMC registration number

The following members of the Students Sub-Committee of the Institutional Ethics Committee participated in the discussions held on Dec 9 2020 at the offices and residences of the members

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. Harikrishnan S	MD, DM (Cardiology) DNB (Cardiology)	Male	Clinician	Yes
3.	Dr. Kala Kesavan. P	MBBS, MD	Female	Basic Medical Scientist	No
4.	Dr. Rema M. N	MD	Female	Basic Medical Scientist	No
5.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
6.	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

Ouriginal
by Turnitin

Document Information

Analyzed document	Jagadeesh Thesis.docx (D142876473)
Submitted	2022-08-13 09:01:00
Submitted by	Dr P K Dash
Submitter email	dash@sctimst.ac.in
Similarity	3%
Analysis address	sadh.sctims@analysis.urkund.com

MASTER CHART

pre cpb				RRI		RENAL NIRS
	blood pressu	MAP	CARDIAC OU	RIGHT	LEFT	RIGHT
1	120/80	75	3.7	0.6	0.61	79
2	110/90	95	4	0.5	0.56	75
3	110/78	90	3	0.59	0.6	64
4	130/70	90	3.6	0.7	0.65	72
5	110/70	75	2.9	0.68	0.71	72
6	110/70	70	2.8	0.64	0.68	70
7	120/75	90	4.2	0.62	0.64	69
8	110/70	70	3.8	0.65	0.66	69
9	110/70	72	2.2	0.67	0.61	72
10	130/90	97	3.5	0.59	0.62	76
11	120/80	85	3.5	0.63	0.6	74
12	140/90	75	3.5	0.58	0.6	73
13	136/90	81	2.9	0.54	0.58	75
14	140/66	88	4	0.63	0.64	68
15	110/70	80	2.4	0.61	0.59	74
16	100/70	72	4	0.57	0.58	75
17	120/80	85	4.1	0.62	0.62	70
18	110/70	78	3.5	0.58	0.62	71
19	150/90	86	4.1	0.64	0.72	73
20	160/90	90	3.6	0.7	0.65	75
21	130/90	70	3.7	0.68	0.71	68
22	140/80	78	4.1	0.64	0.68	75
23	150/90	86	3.9	0.62	0.64	68
24	130/90	88	4	0.65	0.66	70
25	120/80	76	4.2	0.67	0.61	67
26	130/90	86	3.5	0.59	0.62	69
27	120/80	76	4	0.63	0.6	72
28	120/90	78		0.58	0.6	70
29	130/90	86	2.9	0.54	0.58	68
30	120/80	78	3.1	0.63	0.64	70
31	126/86	80	3.5	0.61	0.59	69
32	136/78	78	3	0.57	0.58	72
33	132/78	90	2.9	0.62	0.62	70
34	128/74	72	4	0.58	0.62	68
35	132/70	78	3.6	0.64	0.72	72
36	128/74	80	4.1	0.58	0.62	75
37	132/76	78	3.6	0.62	0.59	68
38	142/80	92	3.2	0.61	0.72	70
39	132/88	76	2.8	0.58	0.62	72
40	140/78	90	3.2	0.64	0.58	68
41	124/72	72	3	0.62	0.63	68
42	132/80	80	2.8	0.7	0.68	72
43	112/76	70	3.1	0.72	0.7	68

post cpb				RRI		RENAL NIRS
	blood pressu	MAP	CARDIAC OU	RIGHT	LEFT	RIGHT
1	130/70	100	3.5	0.72	0.75	76
2	130/80	94	5	0.41	0.6	73
3	110/70	75	4.5	0.67	0.68	70
4	110/70	75	4.5	0.7	0.7	78
5	123/65	82	6	0.7	0.72	68
6	130/90	95	3.2	0.7	0.64	76
7	136/90	109	4.2	0.5	0.67	71
8	110/70	74	5	0.8	0.78	72
9	120/80	75	3.9	0.73	0.76	75
10	130/90	95	2.7	0.6	0.57	76
11	110/80	75	6.2	0.75	0.8	77
12	130/60	84	3.5	0.7	0.62	71
13	150/60	83	4.2	0.75	0.78	72
14	130/90	80	4.4	0.57	0.58	73
15	110/70	75	4.6	0.79	0.8	76
16	120/80	70	5.1	0.74	0.8	77
17	130/70	89	3.7	0.72	0.71	70
18	132/70	89	3.7	0.58	0.5	70
19	130/90	80	3.9	0.82	0.83	74
20	140/90	80	4.4	0.8	0.77	72
21	110/70	85	3.4	0.6	0.44	69
22	130/70	75	4.5	0.8	0.8	74
23	120/80	78	6.8	0.7	0.6	79
24	120/60	76	5	0.73	0.77	67
25	110/70	75	5.2	0.7	0.7	68
26	130/70	80	4.2	0.76	0.8	72
27	128/72	80	4	0.73	0.8	70
28	105/55	72	4	0.82	0.82	74
29	110/70	72	4.2	0.56	0.67	74
30	110/70	70	5.2	0.74	0.77	67
31	113/60	75	5.8	0.78	0.82	75
32	120/80	81	4.8	0.79	0.73	82
33	102/60	70	3.75	0.68	0.69	72
34	130/70	85	5.6	0.75	0.8	77
35	150/90	110	3	0.67	0.63	73
36	120/80	79	5.2	0.77	0.8	70
37	130/70	85	4	0.6	0.7	75
38-screensho	120/80	80	4.5	0.62	0.67	80
SUSEELA-39	110/70	73	5	0.68	0.72	77
sainudeen40	117/65	72	4	0.79	0.77	73
subash 41	120/80	75	4	0.74	0.73	66

marthand42	120/80	75	5	0.811	0.82	65
43	100/60	70	4.82	0.76	0.74	78

					right	
LEFT	HB	LVEF		TEMP	SYSTOLIC	DIASTOLIC
68	10.5	70			77	25
73	10.1	66			55	28
70	11.1	55			65.4	29
79	11.7	60			78.4	22.8
73	10.2	67			80	30
69	11.5	50			51.3	16.9
68	11.4	55			46.3	21.5
75	10.3	68			120	23.7
72	11.2	57			90	24.2
80	12	58			61	24
75	11.5	51			74	18.2
76	11.1	54			45.8	14.9
80	10	75			95.4	22.9
74	9.6	67			49.2	21
79	9.8	60			90.4	18.3
78	11.2	62			55.5	14.4
73	10.5	61		34.8	56.9	23
73	10.5	61			56.4	23
74	9.2	55			131	23.4
74	11.1	55			142	26.8
72	10	70			52.5	19.9
76	9.7	60			89.2	16.6
76	10.8	62			54.7	16.5
68	8.9	60			78.2	20.7
68	10.1	55			90	25
75	11.1	67			48.3	11.3
76	10	65			90	24
77	11	57			87.7	15.7
74	11	60			50	22
78	10	56			66.4	17.2
76	9.8	68.3			113	24
78	11	68			88.7	23
75	9.4	70			73.8	23.3
79	10.9	68			121	29.6
70	10.1	60			110	35.8
71	11.1	60			154	34.2
73	11.5	65			44.2	17.3
76	11	60			50.2	18.6
76	9	65			93.8	29.4
72	10.5	57			115	24
70	10.7	57			67.3	17

68	10.7	65			72	13.6
79	10.5	68			164	34.5

CONSENT FORMS

രോഗിക്കുള്ള കാര്യവിവരണ പത്രം

ശീർഷകം: കാർഡിയോ പൾമനറി ബൈപാസസോടെ, കൊറോണറി ആർട്ടറി ബൈപാസ് ഗ്രാഫ്റ്റ് ശസ്ത്രക്രിയയ്ക്ക് വിധേയമാകുന്ന രോഗികൾക്ക് ശസ്ത്രക്രിയാനന്തരം സംഭവിക്കുന്ന വൃക്കയുടെ ഗുരുതരമായ പരുക്ക് പ്രവചിക്കുന്നതിൽ ശസ്ത്രക്രിയാസമയത്തെ വൃക്കയുടെ ഡോപ്ളർ പ്രവാഹവും വൃക്കയുടെ ഇൻഫ്രാറെഡ് സ്പെക്ട്രോസ്കോപ്പിയുമായുള്ള പാരസ്പര്യം.

പഠനത്തിന്റെ ഉദ്ദേശം (ഞങ്ങളെന്തിന് ഈ പഠനം നടത്തുന്നു)

വൃക്കയ്ക്ക് പരുക്കുണ്ടാകാൻ വർദ്ധമാനമായ സാദ്ധ്യതയുള്ള പ്രായമേറിയ രോഗികളിലാണ് പലപ്പോഴും കൊറോണറി ആർട്ടറി ബൈപാസ് ഗ്രാഫ്റ്റ് ശസ്ത്രക്രിയ (CABG) നടത്തുന്നത്. ഹൃദയശസ്ത്രക്രിയയ്ക്ക് വിധേയരാകുന്ന രോഗികളിലെ വളരെ പ്രധാനപ്പെട്ട സങ്കീർണ്ണതയാണിത്. രോഗിക്ക് വൃക്കയുടെ ഗുരുതരമായ പരുക്ക് ഉണ്ടാവാനുള്ള സാദ്ധ്യത പ്രവചിക്കുകഎന്നത് ഇത്തരം രോഗികളുടെ പരിപരണം മെച്ചപ്പെടുത്തുന്നതിന് പ്രധാനമായ തന്ത്രമാണ് ഞങ്ങൾ റീനൽ നിയർ ഇൻഫ്രാറെഡ് സ്പെക്ട്രോസ്കോപ്പിയും ട്രാൻസിസോഫേജിയൽ എക്കോകാർഡിയോഗ്രഫിയും ഉപയോഗിച്ചണ് താങ്കളുടെ വൃക്ക ഞങ്ങൾ നിരീക്ഷിക്കുന്നത്. ശസ്ത്രക്രിയാനന്തരം വൃക്കയ്ക്ക് പരുക്കുണ്ടാകാനുള്ള സാദ്ധ്യത അത്തരം രോഗികളെ കണ്ടെത്താൻ ഇവ സഹായകമാണ്. ഭാവിയിൽ ഹൃദയശസ്ത്രക്രിയയ്ക്ക് വിധേയരാകാൻപോകുന്ന രോഗികളിൽ പതിവ് ക്ലിനിക്കൽ പരിപരങ്ങളിൽ ഈ ഉപകരണങ്ങളും ഉപയോഗിക്കാവുന്നതാണ്.

പഠനത്തിന്റെ കാലദൈർഘ്യം എത്ര?

താങ്കളെ ആശുപത്രിയിൽനിന്നും വിടുതൽ ചെയ്യുന്നതുവരെ നിരീക്ഷിക്കും.

നടപടിയുടെ വിശദീകരണം

സ്ഥാപനത്തിന്റെ പതിവ് നടപടിക്രമപ്രകാരം എല്ലാ അംഗീകൃത നിരീക്ഷണങ്ങളും നടത്തും. അതിനോടൊപ്പം താങ്കളുടെ വൃക്കയിലെ പുരിതാവസ്ഥയും വൃക്കയിലെ സമ്മർദ്ദവും ട്രാൻസിസോഫേജിയൽ എക്കോകാർഡിയോഗ്രഫിയുപയോഗിച്ച് രേഖപ്പെടുത്തും. ഈ പഠനത്തിൽ പ്രതീക്ഷിക്കാവുന്ന അപായ സാദ്ധ്യതയോ അസ്വസ്ഥതകളോ ഒന്നും ഉണ്ടാവില്ല.

ഈ പഠനത്തിന്റെ നേട്ടങ്ങളെന്തെല്ലാം, താങ്കൾക്ക് ഈ പഠനത്തിൽ നിന്നും നേട്ടമുണ്ടാകുമോ?

ഹൃദയശസ്ത്രക്രിയയ്ക്ക വിധേയരാകുന്ന രോഗികളിൽ വൃക്കയ്ക്ക് പരിക്കുണ്ടാകാനുള്ള അപായസാദ്ധ്യത പ്രവചിക്കുന്നതിൽ നേട്ടമുണ്ടാകും. വൃക്കയുടെ പരുക്ക് പ്രവചിക്കുന്നതായി തെളിയിക്കപ്പെട്ടിട്ടുള്ളതിനാൽ ഈ ഉപകരണം താങ്കൾക്കും നേട്ടമുണ്ടാക്കും. ആകയാൽ വൃക്കയുടെ പരിക്ക് പരമാവധി സാദ്ധ്യമാകുന്നിടത്തോളം കുറയ്ക്കാൻ അനുയോജ്യമായ നടപടികൾക്ക് ചെയ്യാനാകും.

പഠനമാരംഭിച്ചശേഷം താങ്കൾക്ക് പിൻമാറാനാകുമോ?

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

പഠനസംബന്ധിയായി എന്തെങ്കിലും പരിക്ക് താങ്കൾക്കുണ്ടായാലെന്ത് സംഭവിക്കും?

ഈ പഠനത്തിൽ താങ്കളുടെ പരിശോധനകളുടെയും ചികിത്സയുടെയും വിവരങ്ങൾ വിശകലനം ചെയ്യുക മാത്രമേ ചെയ്യുന്നു എന്നതിനാൽ താങ്കൾക്ക് പരിക്കൊന്നും ഞങ്ങൾ പ്രതീക്ഷിക്കുന്നില്ല. പക്ഷേ താങ്കളെക്കൊന്തെങ്കിലും പാർശ്വഫലങ്ങളോ പ്രശ്നങ്ങളോ ഉണ്ടായാൽ ഈ ആശുപത്രിയിൽ താങ്കൾക്കധികചിലവില്ലാതെ ചികിത്സിക്കും. എന്നാലും സാമ്പത്തികമായ നഷ്ടപരിഹാരം നൽകാനാവില്ല.

പഠനത്തിനായി താങ്കൾ പണം മുടക്കണോ?

ശസ്ത്രക്രിയയ്ക്കായുള്ള 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 പ്രദർശനത്തിലോ ഒരിടത്തും തിരിച്ചറിയാനാകില്ല.

പഠന പങ്കാളികളുടെ എണ്ണം

ഈ പഠനത്തിൽ ആകെ 40 രോഗികളെ ഉൾപ്പെടുത്തും.

താങ്കൾക്ക് കൂടുതൽ ചോദ്യങ്ങളുണ്ടെങ്കിൽ താഴെ നൽകിയിരിക്കുന്ന ഗവേഷകരോട് ചോദിക്കുക

1. ഡോ. എ ജഗദീഷ്, ഡിഎം സീനിയർ റെസിഡന്റ് (കാർഡിയോ തൊറാസിക് ആന്റ് വാസ്കുലാർ അനസ്തീഷ്യ), ഡിവിഷൻ ഓഫ് കാർഡിയാക് അനസ്തീഷ്യ, ഫോൺ,: 9445920019 ഇമെയിൽ jaga2992@gmail.com
2. ഡോ പ്രസന്നകുമാർ ഡാഷ്, പ്രൊഫസർ, ഡിവിഷൻ ഓഫ് കാർഡിയാക് അനസ്തീഷ്യ, ഫോൺ,: 9349336584 ഇമെയിൽ dash@sctimst.ac.in
3. ഡോ. ശരവണ ബാബു, അസിസ്റ്റന്റ് പ്രൊഫസർ, ഡിവിഷൻ ഓഫ് കാർഡിയാക് അനസ്തീഷ്യ, ഫോൺ 9446304043, ഇമെയിൽ sarv4u@sctimst.ac.in
4. ഡോ. വിവേക് വി പിള്ള, പ്രൊഫസർ , ഡിവിഷൻ ഓഫ് കാർഡിയോവാസ്കുലാർ ആന്റ് തൊറാസിക് സർജറി, ഫോൺ944623867, ഇമെയിൽ vvp@sctimst.ac.in

സമ്മതപത്രം

കാർഡിയോ പൾമനറി ബൈപാസസോടെ, കൊറോണറി ആർട്ടറി ബൈപാസ് ഗ്രാഫ്റ്റ് ശസ്ത്രക്രിയയ്ക്ക് വിധേയമാകുന്ന രോഗികൾക്ക് ശസ്ത്രക്രിയാനന്തരം സംഭവിക്കുന്ന വൃക്കയുടെ ഗുരുതരമായ പരുക്ക് പ്രവചിക്കുന്നതിൽ ശസ്ത്രക്രിയാസമയത്തെ വൃക്കയുടെ ഡോപ്ളർ പ്രവാഹവും വൃക്കയുടെ ഇൻഫ്രാറെഡ് സ്പെക്ട്രോസ്കോപ്പിയുമായുള്ള പാരസ്പര്യം. എന്ന പഠനത്തിൽ പങ്കെടുക്കാൻ ഞാൻ (പങ്കെടുക്കുന്നയാളുടെ പേര്) .... സമ്മതം നൽകുന്നു

ജനനതീയതി/വയസ്സ് ... . മാസങ്ങളിൽ/വർഷത്തിൽ)

..... (അച്ഛൻ/അമ്മയുടെ പേര്)

(പ്രസക്തമായ കോളങ്ങളിൽ ശരിയടയാളമിടുക)

1. കാർഡിയോ പൾമനറി ബൈപാസസോടെ, കൊറോണറി ആർട്ടറി ബൈപാസ് ഗ്രാഫ്റ്റ് ശസ്ത്രക്രിയയ്ക്ക് വിധേയമാകുന്ന രോഗികൾക്ക് ശസ്ത്രക്രിയാനന്തരം സംഭവിക്കുന്ന വൃക്കയുടെ ഗുരുതരമായ പരുക്ക് പ്രവചിക്കുന്നതിൽ ശസ്ത്രക്രിയാസമയത്തെ വൃക്കയുടെ ഡോപ്ളർ പ്രവാഹവും വൃക്കയുടെ ഇൻഫ്രാറെഡ് സ്പെക്ട്രോസ്കോപ്പിയുമായുള്ള പാരസ്പര്യം. എന്ന പഠനസംബന്ധമായി .... തീയതിയിൽ എനിക്കു തന്ന കാര്യവിവരണപത്രം വായിക്കുകയും മനസ്സിലാക്കുകയും ചോദ്യങ്ങൾ ചോദിക്കാൻ എനിക്ക് അവസരം ലഭിക്കുകയും ചെയ്തു. [ ]
2. എന്റെ പങ്കാളിത്തം സ്വമേധയായാണെന്നും, എന്റെ പതിവ് ചികിത്സയെയോ നിയമപരമായ അവകാശങ്ങളെയോ ബാധിക്കാതെ ഏതു സമയത്തും പങ്കെടുക്കുന്നതിനുള്ള എന്റെ അനുവാദം പിൻവലിക്കാമെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. [ ]
3. ഈ പഠനത്തിന്റെയും ഇതുമായി ബന്ധപ്പെട്ട ഭാവിയിലെ പഠനങ്ങളുടെയും ക്ലിനിക്കൽ പരിശോധനയുടെ സ്പോൺസർ, സ്പോൺസറിനുവേണ്ടി പ്രവർത്തിക്കുന്നവർ, എത്തിക്സ് കമ്മിറ്റിയും നിയന്ത്രണാധികാരികളും എന്നിവർക്ക് പഠനത്തിൽനിന്നും ഞാൻ പിൻമാറിയാലും ഈ പഠനവുമായി ബന്ധപ്പെട്ട ആരോഗ്യരേഖകൾ എന്റെ അനുവാദം കൂടാതെ പരിശോധിക്കാമെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. അതിന് ഞാൻ സമ്മതിക്കുന്നു. എന്നിരുന്നാലും എന്റെ വ്യക്തിപരമായവിവരങ്ങൾ മൂന്നാം കക്ഷികൾക്കോ പ്രസിദ്ധീകരണത്തിനോ നൽകില്ലെന്ന് ഞാൻ 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. സമ്മതപത്രത്തിന്റെ ഒപ്പിട്ട ഒരു പ്രതി എനിക്ക് ലഭിച്ചു. [ ]

പേര്

ഒപ്പ്

തീയതി

സാക്ഷിയുടെ പേര്

രോഗിയുമായുള്ള ബന്ധം

ഒപ്പ്

സമ്മതപത്രം വാങ്ങുന്ന ആൾ

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

സമ്മതപത്രംവാങ്ങുന്ന ആളുടെ പേര്

ഒപ്പ് തീയതി

ബന്ധപ്പെടാനുള്ള നമ്പർ- 9445920019

എ. ജഗദീഷ്

പ്രധാന ഗവേഷകൻ

CONSENT FORM

I give consent _____ (Participant's name)

_____Date of Birth / Age _____(in months/years),

_____ (Father/Mother's name) to participate in this study titled:
"Correlation between intraoperative renal doppler flow and renal near-infrared spectroscopy in predicting postoperative acute kidney injury in patients undergoing coronary artery bypass grafting surgery with cardiopulmonary bypass"

Please tick the relevant boxes

(i) I confirm that I have read and understood the information sheet dated_____ for the above study and have had the opportunity to ask questions. []
(ii) I understand that my participation in the study is voluntary and that I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected. [ ]
(iii) I understand that the Sponsor of the clinical trial, others working on the Sponsor's behalf, the Ethics Committee and the regulatory authorities will not need my permission to look at my health records both in respect of the current study and any further research that may be conducted in relation to it, even if I withdraw from the trial. I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published. [ ]
(iv) I agree not to restrict the use of any data or results that arise from this study provided such a use is only for scientific purpose(s) [ ]
(v) I agree to take part in the above study. [ ]
(vi) I voluntarily agree to take part in this study [ ]
(vii) I have received a copy of this signed consent form [ ]

Name:
Signature:
Date:

Name of witness:
Relation to participant:
Date:

(Person Obtaining Consent)
I attest that the requirements for 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/her in nontechnical 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 by me.

Name and Signature of Person Obtaining Consent:

Contact number- 9445920019

A. Jagadish

(Principal investigator).