“EFFECT OF HAEMOGLOBIN LEVELS ON NEAR INFRARED SPECTROSCOPIC (NIRS) MONITORING IN CYANOTIC CONGENITAL HEART DISEASE PATIENTS” -A PROSPECTIVE OBSERVATIONAL STUDY

Dr. KARTHEEK HANUMANSETTY

DM CARDIOTHORACIC AND VASCULAR ANAESTHESIOLOGY THESIS

2020-2022

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM

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A THESIS SUBMITTED BY

Dr. KARTHEEK HANUMANSETTY

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 ANAESTHESIOLOGY

2020-2022

DECLARATION BY THE STUDENT

CERTIFICATE

I, Dr **Kartheek Hanumansetty** hereby certify that I had personally carried out the work depicted in the thesis titled, **"Effect of haemoglobin levels on near infrared spectroscopic (NIRS) monitoring in cyanotic congenital heart disease patients" - A prospective observational study.**

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Dr Kartheek Hanumansetty

Date: 14-08-2022

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The work under the thesis entitled, **"Effect of haemoglobin levels on near infrared spectroscopic (NIRS) monitoring in cyanotic congenital heart disease patients" - A prospective observational study,** 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.

Date 10-08-2022

Dr Suneel PR

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Date 11-01-2022

Dr Sabarinath Menon

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Last but not the least; I am deeply indebted to all my **patients**, who made this study possible. I thank almighty **God** for each day that He has been by my side.

\- ***Dr. Kartheek Hanumansetty***

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LIST OF ABBREVIATIONS

Abbreviation	Full Form
NIRS	Near infrared spectroscopy
$rScO_2$	Regional cerebral oxygenation
CPB	Cardiopulmonary bypass
CCHD	Cyanotic congenital heart disease
PaO_2	Partial pressure of oxygen in arterial blood
SaO_2	Arterial oxygen saturation
PvO_2	Partial pressure of oxygen in venous blood
SvO_2	Central venous oxygen saturation
FTOE	Fractional cerebral tissue oxygenation extraction
Pre-op	Pre-operative
Hb	Haemoglobin
Hct	Haematocrit
gms/dl	Grams/decilitre

SYNOPSIS

Introduction

Cerebral hypoxia is linked to neurologic injury and poor neurologic outcomes in paediatric cardiac surgery. Intraoperative, low cerebral saturations correlate with neurologic injury. Near infrared spectroscopy (NIRS) is one of the methods of non-invasive measurement of regional cerebral oxygenation($rScO_2$).

Aim of the study

To evaluate the effects of high haemoglobin and haemodilution effects of cardio pulmonary bypass on the $rScO_2$ monitoring intraoperatively, in children with cyanotic congenital heart disease patients (CCHD).

Review of literature

There is limited data on the accuracy of NIRS in patients with cyanotic congenital heart disease especially in extremes of cyanosis and polycythaemia. There is evidence to suggest that polycythaemia could interfere with NIRS monitoring. This is an area which needs systematic research.

Materials and methods

All patients with cyanotic congenital heart disease less than 18 years of age with haemoglobin >20 grams/dl were included in the study. All consecutive patients who satisfied the inclusion and exclusion criteria and were operated upon during the period between 1st of June 2020 to 15 of July 2022.

Conclusion

29 patients with haemoglobin >20 grams/dl were included in the study, of which 19 patients did not display NIRS values at baseline and the other 10 patients displayed NIRS values at baseline, indicating that haemoglobin was one of the many factors for lack of an NIRS value at baseline.

TABLE OF CONTENTS

1. INTRODUCTION

Cerebral hypoxia is linked to neurologic injury and poor neurologic outcomes in paediatric cardiac surgery. Intraoperative, low cerebral saturations correlate with neurologic injury(1). There is a need to monitor real time trends in cerebral oxygenation to facilitate timely diagnosis of cerebral hypoxia and to tailor interventions to treat cerebral hypoxia. Near infrared spectroscopy (NIRS) is one of the methods of non-invasive measurement of regional cerebral oxygenation($rScO_2$).

Children with cyanotic congenital heart diseases who receive delayed surgical correction experience chronic hypoxia and have elevated haemoglobin concentration as a compensatory mechanism that enables them to maintain near normal blood oxygen content (2). Children with univentricular physiology have polycythaemia as their treatment involves staged palliation which results in an admixture circulation and hypoxemia for the first several years of life. The children with chronic hypoxaemia are at risk of cerebral hypoxia during open and closed heart procedures and there is a need to monitor their real time cerebral oxygenation.

NIRS utilises two wavelengths of light to provide a ratio between oxyhaemoglobin and total haemoglobin. Factors affecting pigmentation that affects the reflection of light can potentially interfere with the readings of $rScO_2$. It is known that polycythaemia may prevent any recording of $rScO_2$ on NIRS in some patients with cyanotic congenital heart disease but this has not been systematically studied (3). Patients with similar haemoglobin concentrations may or may not show $rScO_2$ readings. We have noted that patients who did not show $rScO_2$ readings during induction of anaesthesia, start displaying $rScO_2$ values after initiation of cardiopulmonary bypass (CPB). This study aims to compare patients with polycythaemia who display $rScO_2$ values prior to cardiopulmonary bypass and those that do not.

2. AIMS & OBJECTIVES

The primary aim of this study was to evaluate the effects of high haemoglobin and haemodilution effects of cardio pulmonary bypass on the $rScO_2$ monitoring intraoperatively, in children with cyanotic congenital heart disease patients (CCHD).

Secondary aim is to evaluate the association between $rScO_2$ and partial pressure of oxygen in arterial blood (PaO_2), arterial oxygen saturation (SaO_2), partial pressure of oxygen in venous blood (PvO_2), central venous oxygen saturation (SvO_2) in these patients.

3. REVIEW OF LITERATURE

Introduction to NIRS:

Near infrared light (NIR) is a part of electromagnetic spectrum which extends from 700-1000 nm and is able to pass through biologic tissues with a change in intensity of its emergent light which can be measured. Light attenuation results from absorption by oxyhaemoglobin, deoxyhaemoglobin (oxygen dependant chromophores) and cytochrome c oxidase, myoglobin of variable concentrations, chromophores of fixed concentrations (melanin, water, collagen, lipids) and light scattering(3). Differential absorption spectra of the oxygen-dependent chromophores in the NIRS range permit spectroscopic separation and the measurement of tissue oxygenation and blood flow.

NIRS sensor is called an optode in which NIR rays travel in a curvilinear, or "banana-shaped," path in the region beneath the optode and this is referred to as reflectance spectroscopy (Main difference when compared to the everyday used pulse oximeter in which transmission spectroscopy is used i.e., light travels in a straight path – passes through structure of interest from one side and emerges from other side and the difference of intensity is measured). The penetration depth of the NIR is about half the distance between the light emitter and light detector(4).

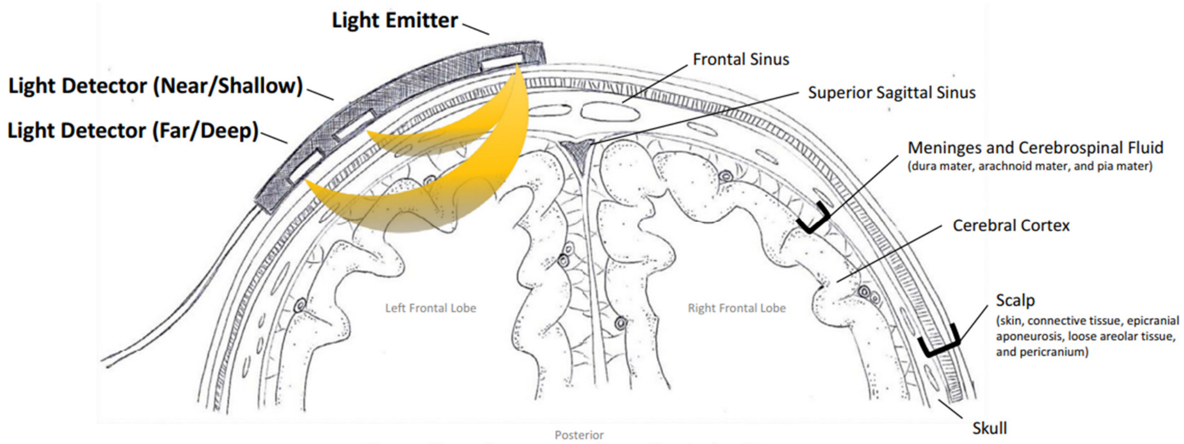

Fig.3.1.Cerebral tissue oximetry. Axial cross-section diagram of spatially-resolved reflectance mode spectroscopy (Source - K.L. Zaleski and B.D. Kussman / Journal of Cardiothoracic and Vascular Anesthesia 00 (2019) 1-12) (4).

NIRS measures smaller gas exchanging vessels with a diameter <100 micrometres such as arterioles, capillaries, and venules in the tissue beneath the sensor. 2 detectors – near and far, are used to differentiate from cerebral and extracerebral light absorption. The saturation $rScO_2$ displayed is an indicator of "Supply Vs Demand" – regional oxygen balance of brain tissue (Supply – Cerebral Oxygen delivery or DO2 & Demand - cerebral oxygen consumption or CMRO2)

NIRS uses different methodologies such as continuous wave, frequency domain, time domain and diffusion correlation spectroscopy(5). Continuous wave NIRS is commonly used in commercial NIRS systems as they are cost effective and portable. This technique emits light at a constant intensity and measures the emerging light intensity.

Main principle used in NIRS is "BEER LAMBERT" law – to measure light absorbance which is directly proportional to the distance travelled by the light in tissues. Along with this scattering of light also occurs and more amount of light gets absorbed when distance between the emitter and detector increases. Therefore a "Modified Beer Lambert" equation to reduce of scattering is being used Attenuation = $-\log I/I_o$ = ꞓcd (DPF) G where Io is the intensity of the incident light; I is the intensity of the emergent light; ɛ is the extinction coefficient of the absorbing compound (chromophore); c is the chromophore concentration; d is the light emitter-detector (inter-optode) distance; DPF is the differential path length factor; and G is an unknown value describing head shape, geometry of the optodes, and the scattering coefficient of the tissue(6).

In our current study 'INVOS 5100C oximeter' (Covidien, Mansfield, MA) system was used which provides non-invasive and continuous information of changes in regional oxygen saturation of blood. The measurement takes place in real time, providing an immediate indication of a change in the critical balance of regional oxygen delivery and oxygen consumption.

The INVOS adult regional saturation sensor, paediatric regional saturation sensor, and OxyAlert NIRS Sensor are disposable transducers capable of producing and detecting optical data from the patient, converting that data to electrical signals, and sending them to the INVOS system. They are applied to the forehead or somatic region via self-contained, medical-grade patient adhesive. Electrical signals from the detectors are sent through the shielded cable to the INVOS system for processing.

The INVOS system "reflects the colour of life." The harmless, near-infrared wavelengths generated by the system's light-emitting diodes (LEDs) easily pass-through scalp and bone tissue beneath the sensor. Once in vivo they are either absorbed or scattered back up to the sensor's shallow and deep detectors.

Red-coloured haemoglobin molecules within red blood cells have the highest light absorption of the wavelengths used. The exact shade of red of each haemoglobin molecule indicates the amount of oxygen it is carrying. The type and quantity of absorption data returned to the detectors reflects relative amounts of deoxyhaemoglobin and total haemoglobin, from which a regional oxygen saturation (rSO2) value unique to the specific area under the sensor is calculated. Values are measured continuously, with screen updates provided to clinicians every 5 seconds. Since brain cells and organ tissues die within minutes without proper oxygenation, measurement of this color provides potentially life-saving or life-changing information. When $rScO_2$ values show an oxygen deficit or change, the care team can intervene to potentially lessen or prevent adverse events.

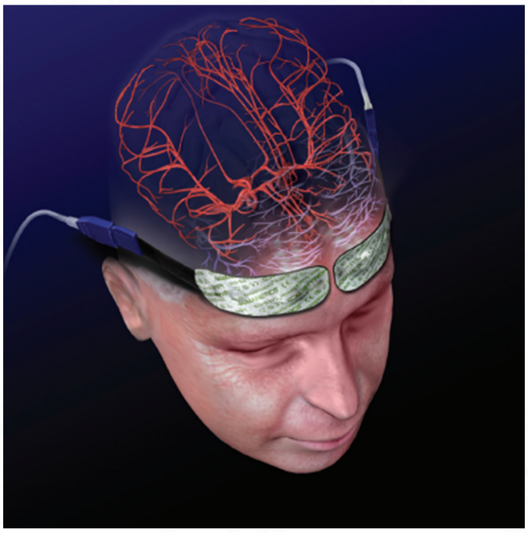

Fig.3.2. INVOS™ System (Model 5100C). (Source - Operator's Manual INVOS™ Regional Saturation Patient Monitoring System Model 5100C)

NIRS has several advantages over other neuromonitoring modalities (jugular bulb oximetry, transcranial Doppler sonography, electroencephalography) in that it is non-invasive, portable, provides continuous measurements, easy to use with respect to other commercial systems. NIRS is also being used for monitor oxygenation in somatic sites such as muscle, kidney, intestine, liver as a part of multisite approach(7).

Literature related to NIRS in paediatric cardiac surgical patients:

Kussman et al introduced the important concept that despite chronic hypoxemia in children with cyanotic congenital heart disease, compensatory increases in haemoglobin concentration and cerebral oxygen content serve to maintain normal cerebral oxygen extraction. They proposed that absolute NIRS values in chronic cyanotic children should fall in normal range as the measured difference between arterial and jugular bulb oxygen are similar as acyanotic children. In these chronic cyanotic patients, anaemia and or reduced cardiac output can cause neurological injury which can be detected by low $rScO_2$ values with NIRS monitoring(2).

Gottlieb et al in a case series, presented a group of patients in whom profound polycythaemia appeared to be a limitation to the measurement of cerebral oxygenation by NIRS (8). They hypothesised that, due to large amount of light being absorbed by the higher haemoglobin content in these polycythaemics, only small amount of light being reflected back to the photodetector, resulting in no numerical display. Also, Somanetics software also ensures that inaccurate values do not get displayed.

Liem et al studied effects of haemodilution on cerebral oxygenation with respect to changes in cerebral blood flow velocity. Partial plasma exchange transfusion was done in 10 neonates with a haematocrit > 65%. Changes in levels of different haemoglobins were continuously measured using NIRS and reported no difficulties in monitoring. They concluded that inspite of haemodilution in polycythaemia there was no improvement in cerebral oxygenation even with possible increase of cerebral perfusion(9).

Sunghee et al reported no effect of polycythaemia on $rScO_2$ monitoring but the mean baseline haematocrit chosen as cut off was low and the system used for NIRS monitoring system was not reported(10).

Erica D. Sood et al reported the importance of neurodevelopment evaluation using Bayley Scales of Infant and Toddler Development III at the age of 2 years for the children who have undergone cardiac surgery during infancy with intraoperative NIRS monitoring. They measured preoperative $rScO_2$ and the intraoperative lowest $rScO_2$ and percentage change from baseline rather than a single intraoperative value(11).

In surgical procedures conducted on cardiopulmonary (CPB), a critical period of reduction in $rScO_2$ include cannulation for CPB, low flow CPB, rewarming and separation from CPB. In a series of paediatric cardiac surgical patients with NIRS monitoring, NIRS provided alerted the clinician to risk of brain injury 58% of times (12).

There is limited data on the accuracy of NIRS in patients with cyanotic congenital heart disease especially in extremes of cyanosis and polycythaemia. There is evidence to suggest that polycythaemia could interfere with NIRS monitoring. This is an area which needs systematic research.

4. MATERIALS AND METHODS

Study Design

Prospective observational study

Study Setting

This study was conducted in the Department of Anaesthesiology, Cardiothoracic and Vascular Anaesthesia Division, *Sree Chitra Tirunal Institute for Medical Sciences and Technology*, Trivandrum, India – A tertiary referral centre, University level teaching hospital, operating about 600 paediatric open-heart surgeries per year.

Ethical Considerations

The study was started after obtaining clearance from the Institutional Ethics Committee, (IEC Regn. No. ECR/189/Inst/KL/2013/RR-16), Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, Kerala, India. (IEC certificate No. SCT/IEC/1612/DECEMBER-2020) (Annexure Page. 45). The background, purpose, procedures involved in the study, measures which were taken to ensure confidentiality of the study participants, the voluntary nature of the study and applicability of findings were explained. The study complied with the revised Helsinki Declaration (2013) and Good Clinical Practice Guidelines.

Informed and written consent (Consent form, Annexure, Page 53) was sought from the legal guardian/ parent of the participants of the study. They were informed of the purpose and importance of the study in English and Malayalam and their wards were enrolled in the study only if they consented.

Participant selection

Neonate, infants and children less than 18 years who are diagnosed with cyanotic CHD, either uncorrected or partially palliated patients who underwent palliative surgery or intracardiac repair.

Inclusion criteria:

All patients with cyanotic congenital heart disease less than 18 years of age with haemoglobin >20 grams/dl were included in the study

Exclusion criteria:

All patients with seizures, previous neurosurgeries, neurological deficits, non-consent for study participation were excluded from the study

Gender, class, caste, ethnicity, race has not been used as Inclusion and/or Exclusion criteria.

Recruitment: Every consecutive patient who fit into the inclusion criteria was recruited into the study. Recruitment was done by the principal investigator.

Sample size:

Patients with uncorrected cyanotic congenital heart disease and those with staged palliation represent form a limited segment of the population presenting for congenital heart surgery. We decided to recruit all consecutive patients who satisfied the inclusion and exclusion criteria and were operated upon during the period between 1st of June 2020 to 15 of July 2022.

Funding:

No extramural or intramural funding was required for the study.

Methodology:

Routine preanesthetic check was conducted on the day before surgery and the eligibility of the patient for the inclusion in the study was determined. Patients were advised to continue the prescribed preoperative drugs and premedicated depending on their age according to department protocol. Informed consent was obtained from the patients' parent/legal guardian.

On the day of surgery, after induction of general anaesthesia and elective endotracheal intubation, FiO2 was set to 0.5 and NIRS optodes were placed on the patient's right forehead and baseline $rScO_2$ was noted. After placement of invasive lines both arterial and venous blood gases were taken at the same time and analysed. For blood gas analysis, arterial blood sample was drawn from the arterial cannula inserted either in radial or femoral artery whereas venous blood was sampled from triple lumen inserted in right internal jugular vein in all patients except patients undergoing TCPC where blood samples were collected from the single lumen intravenous line in the internal jugular vein which was Bidirectional Glenn (BDG) line, inserted as a part of institutional protocol. Further blood gas analysis was done after initiation of CPB, just before termination of CPB and after protamine administration. Depending upon clinical needs further blood gas analysis was done. The following intraoperative blood gas parameters were collected - haemoglobin, haematocrit, PaO_2, SaO_2, PvO_2, SvO_2. $rScO_2$ values were continuously monitored and documented ever hour till the end of surgery.

In our institute, cardiopulmonary bypass was used with a flow rate of 2.0 to 2.4 l/m^2. Alpha-stat pH management was used. Cardiopulmonary bypass circuit was primed with Plasmalyte A, fresh frozen plasma administration as all these patients had higher haemoglobin / haematocrit. Priming additives used were albumin, bicarbonate and mannitol. Hypothermia was set between 28 to 32 degrees Celsius depending on the surgery.

The INVOS 5100C oximeter (Covidien, Mansfield, MA) was used for measurement of $rScO_2$. Three types of disposable sensors were used: (1) the neonatal sensor for patients with body weight ≤ 5 kg (OxyAlert NIRS-Cerebral neonatal regional oxygen saturation sensor; Covidien); and (2) the paediatric sensor for patients with body weight > 5 & < 40 kg (SomaSensor, Paediatric Cerebral/Somatic sensor; Covidien) (3) the adult sensor for > 40kg patient. The sensor was applied in the operating room and used to monitor the intra-operative $rScO_2$.

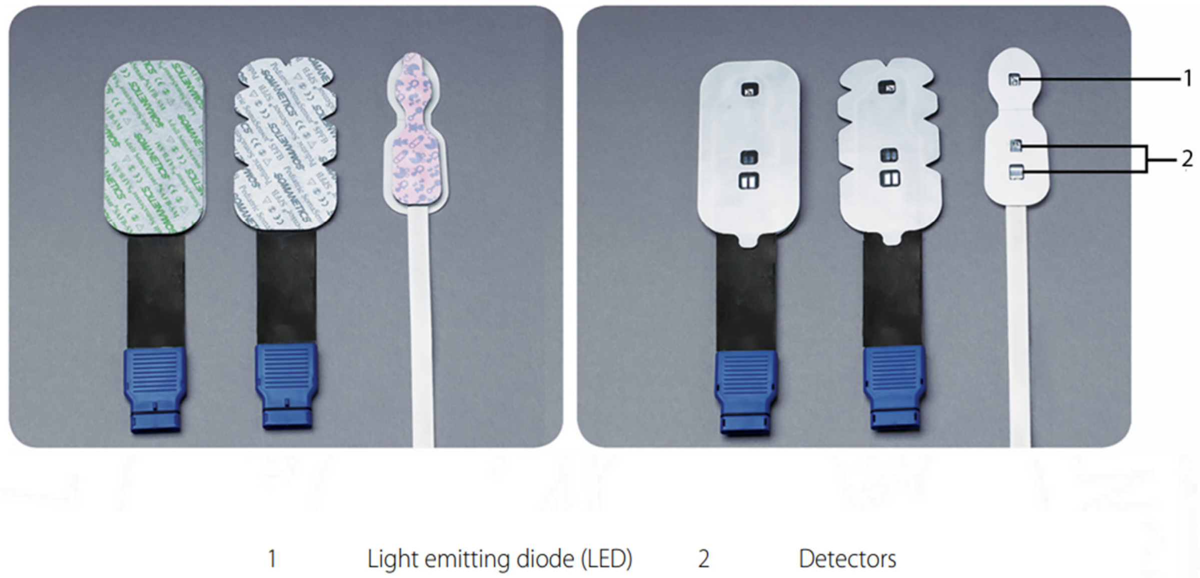

Fig.4.3. Disposable Sensors. (Source - Operator's Manual INVOS™ Regional Saturation Patient Monitoring System Model 5100C).

The patients were categorized as follows for further analysis and comparative studies:

- *NIRS absent at baseline*
- *NIRS present at baseline*

All data was collected by the principal investigator and stored in data collection proforma.

Data analysis

Categorical and quantitative variables were expressed as frequency (percentage) and mean ± SD respectively.

Independent t test was used to compare quantitative parameters between categories.

Chi-square test was used to find association between categorical variables.

For all statistical interpretations, $p<0.05$ was considered the threshold for statistical significance. Statistical analyses were performed by using a statistical software package SPSS, version 20.0

5. RESULTS

In this prospective observational study, 29 consecutive patients posted for elective open-heart surgery for cyanotic congenital heart disease were recruited. All the patients were included in the study after satisfying all the inclusion criteria and divided into 2 groups – NIRS Absent At Baseline & NIRS Present At Baseline indicating the absence or presence of $rScO_2$ value respectively at the time of induction of anaesthesia

Demographics of the study population:

Our study population included patients up to 18 years of age. Youngest patient in the group was 1-year-old and the oldest was 17-year-old. Both the groups were comparable in terms of age, gender and weight.

Table 5.1. Comparison of age based on group

Age (Years)	NIRS ABSENT At Baseline		NIRS PRESENT At Baseline		t	P
	n	Percent	n	Percent		
<10	9	47.4	4	40	0.22	0.830
>10	10	52.6	6	60		
Mean ± SD	9.4 ± 5		9.8 ± 5.2			

Table 5.2. Comparison of gender based on group						
Gender	NIRS ABSENT At Baseline		NIRS PRESENT At Baseline		χ^2	p
	n	Percent	n	Percent		
Male	11	57.9	6	60	0.01	0.913
Female	8	42.1	4	40		

Table 5.3. Comparison of weight based on group					
Group	n	Mean (Kg)	SD	t	P
NIRS ABSENT At Baseline	19	26.4	14.6	0.32	0.749
NIRS PRESENT At Baseline	10	28.2	12.3		

Distribution of diagnosis and surgery done in the study population

Major subset of the cases were Double inlet left ventricle (DILV) – 9 cases, followed by Tetralogy of Fallot (TOF) – 7 cases. 3 cases each of Tricuspid Atresia, unbalanced Atrioventricular canal defect (AVCD) and pulmonary atresia (PA). Double outlet right ventricle (DORV) 2 cases, one case each of Critical pulmonary stenosis (Critical PS) and Transposition of great arteries (dTGA) with PS were included in the study.

Table 5.4. Distribution of diagnosis based on group				
Diagnosis	**NIRS ABSENT At Baseline**		**NIRS PRESENT At Baseline**	
	n	**Percent**	**n**	**Percent**
DILV	5	26.3	4	40
TOF	5	26.3	2	20
Tricuspid Atresia	2	10.5	1	10
Unbalanced AVCD	1	5.3	2	20
Pulmonary Atresia	3	15.8	0	0
Critical Pulmonary Stenosis	0	0	1	10
DORV	2	10.5	0	0
dTGA with PS	1	5.3	0	0

Abbreviations: DILV – Double Inlet Left Ventricle, TOF – Tetrology Of Fallot, AVCD – Atrio Ventricular Canal Defect, DORV – Double Outlet Right Ventricle, dTGA with PS – d Transposition of Great Arteries with Pulmonary Stenosis.

Out of 29 patients 18 patients had univentricular physiology, of which 13 patients underwent Ttotal Cavo-Pulmonary Circulation (TCPC), 4 patients underwent Bidirectional Glenn (BDG), one patient underwent Single stage Fontan.

Other 11 patients had a biventricular correctable physiology, underwent corrective intracardiac repair.

Table 5.5. Distribution of operation Proposed based on group				
Operation Proposed	**NIRS ABSENT At Baseline**		**NIRS PRESENT At Baseline**	
	n	**Percent**	**n**	**Percent**
TCPC	6	31.6	7	70
BDG	3	15.8	1	10
ICR	2	10.5	0	0
ICR + TAP	1	5.3	1	10
ICR + Conduit	2	10.5	0	0
ICR+MCR	1	5.3	0	0
ICR+RVOT Patch	0	0	1	10
ICR+TAP+MCR	2	10.5	0	0
Rerouting of LV to Aorta + Rastelli	1	5.3	0	0
Single Stage Fontan	1	5.3	0	0

Abbreviations: TCPC – Total Cavo Pulmonary Connection, BDG – Bi Directional Glenn, ICR – Intra Cardiac Repair, TAP – Trans Annular Patch, MCR – Mono Cusp Reconstruction, RVOT – Right ventricle outflow tract.

Comparison of Pre-operative Haemoglobin & Haematocrit:

All the patients included in the study had haemoglobin value greater than 20 gms/dl. Mean haemoglobin level in NIRS ABSENT At Baseline group is greater than NIRS PRESENT At Baseline group and is statistically significant.

All patients included in the study had haematocrit greater than 60%. Mean value in NIRS ABSENT At Baseline group is greater than NIRS PRESENT At Baseline group and is statistically just above the cut off level for statistical significance.

Table 5.6. Comparison of Pre-op Haemoglobin based on group

Group	n	Mean (gm/dl)	SD	t	p
NIRS ABSENT At Baseline	19	22.1	2.2	2.08	0.047
NIRS PRESENT At Baseline	10	20.6	0.4		

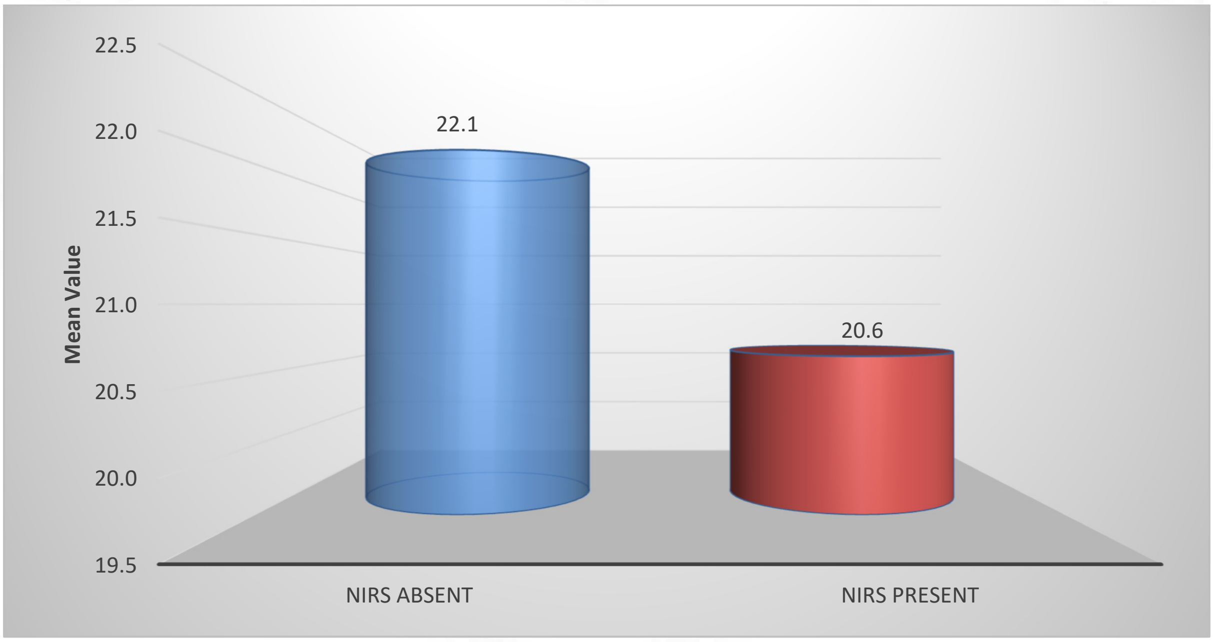

Fig.5.4. Bar diagram showing Comparison of Pre-op Haemoglobin based on group

Table 5.7. Comparison of Pre-op Haematocrit based on group					
Group	**n**	**Mean (%)**	**SD**	**t**	**p**
NIRS ABSENT At Baseline	19	67.1	5.6	1.98	0.058
NIRS PRESENT At Baseline	10	63.5	1.4		

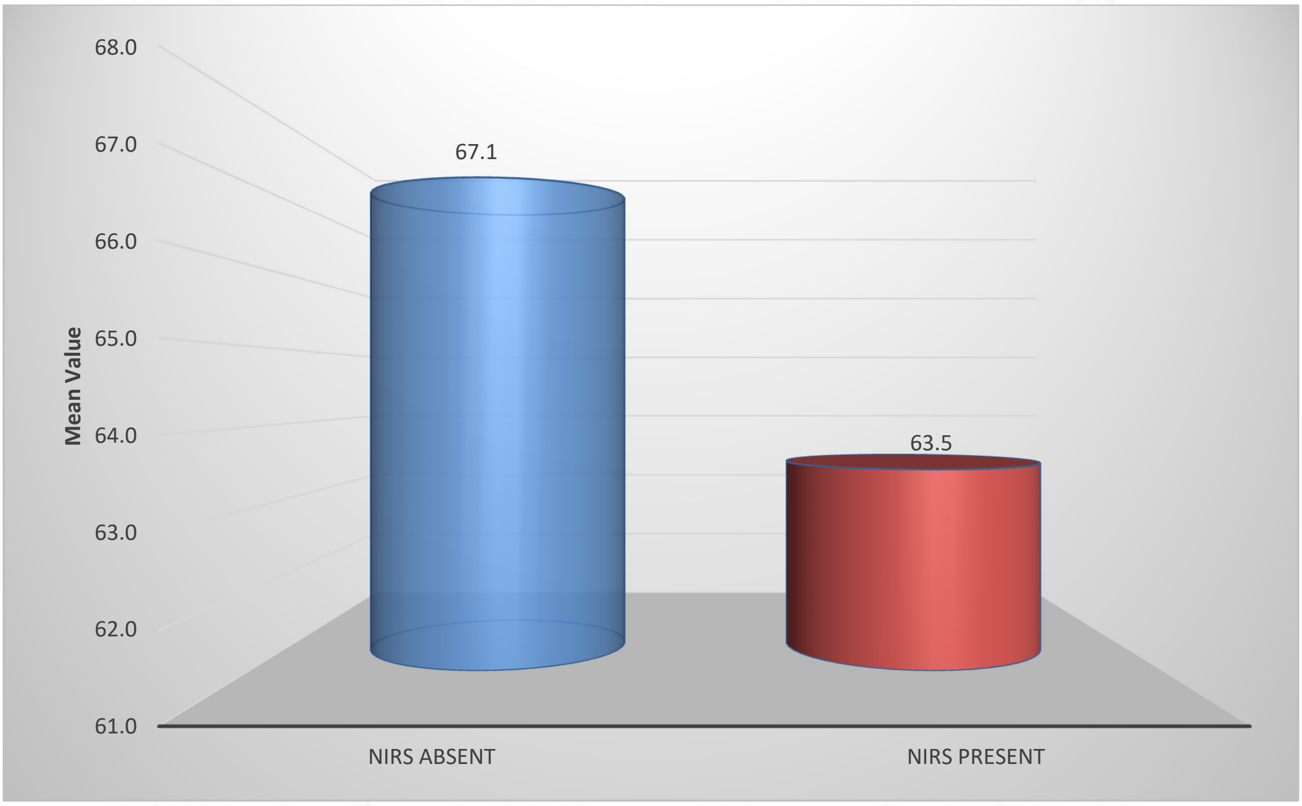

Fig.5.5. Bar diagram showing Comparison of Pre-op Haematocrit based on group

Comparison of Pre-operative SpO_2

All the patients included in the study were cyanotic congenital heart disease patients, hence all of them had low saturations. Mean in NIRS ABSENT At Baseline group is low when compared to NIRS PRESENT At Baseline group and is statistically significant.

Table 5.8. Comparison of Pre-op SpO_2 based on group					
Group	**n**	**Mean (%)**	**SD**	**t**	**p**
NIRS ABSENT At Baseline	19	75.8	4.5	3.3	0.003
NIRS PRESENT At Baseline	10	81.4	3.9		

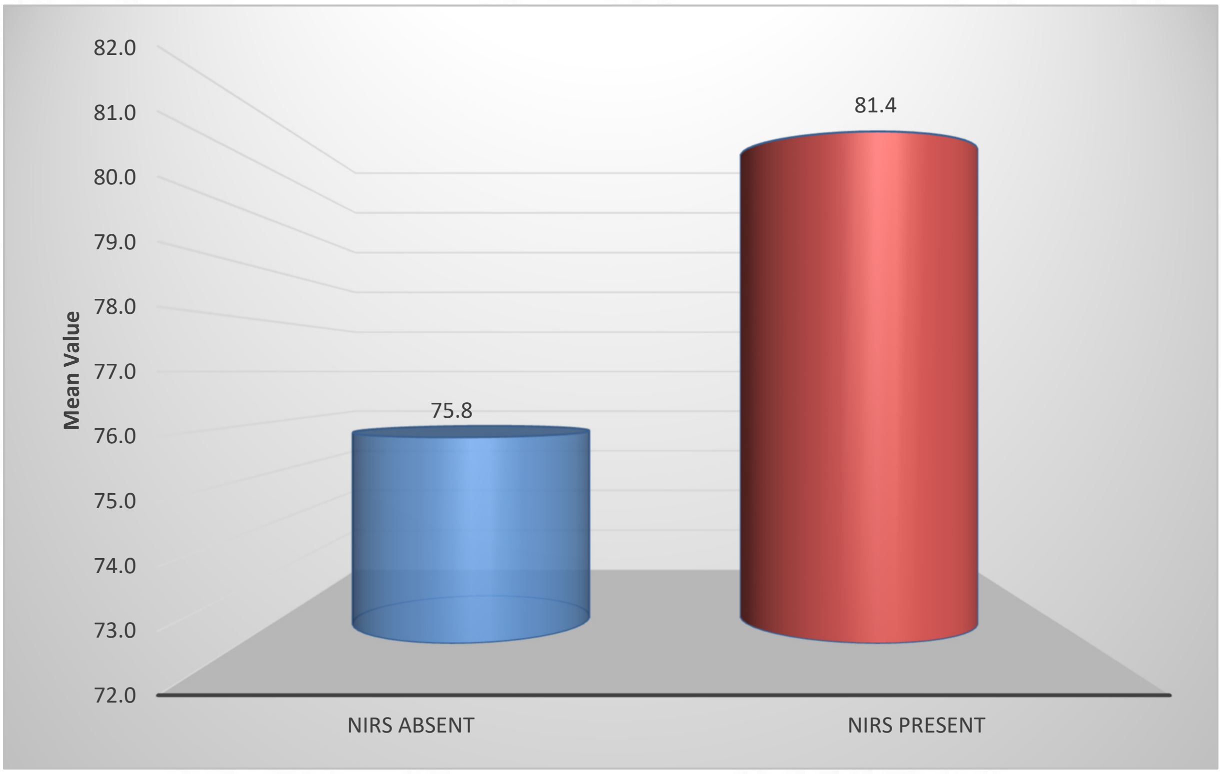

Fig.5.6. Bar diagram showing Comparison of Pre-op SpO_2 based on group

Comparison of CPB time

All the patients have undergone cardiac surgery after initiation on cardiopulmonary bypass (CPB). After the cardiac repair, in a stepwise manner the patient was weaned off CPB. Total time on CPB were comparable between both the groups.

Table 5.9. Comparison of CPB Time based on group					
Group	**n**	**Mean (mins)**	**SD**	**t**	**p**
NIRS ABSENT At Baseline	19	202.1	55.6	0.3	0.764
NIRS PRESENT At Baseline	10	209.0	62.8		

Comparison of different parameters after initiation of CPB

Comparison of intraoperative Haemoglobin at different time intervals:

Intraoperatively, after initiation of CPB, mean haemoglobin in NIRS ABSENT At Baseline (16±2) group was greater than mean of NIRS PRESENT At Baseline (13.6±0.7) group and statistically this was significant. Similarly, haemoglobin levels during bypass at different intervals were statistically significant between the groups. After bypass, haemoglobin levels between 2 groups were almost similar with no statistical significance.

Table 5.10. Comparison of haemoglobin at different interval of time based on group

Time interval	NIRS ABSENT At Baseline (n=19)		NIRS PRESENT At Baseline (n=10)		t	p
	Mean (gm/dl)	SD	Mean (gm/dl)	SD		
Baseline	22.3	2.2	20.7	0.4	2.33	0.028
Start of CPB	16.0	2.0	13.6	0.7	3.63	0.001
During CPB	15.4	1.7	12.9	1.4	2.8	0.015
Post CPB	16.0	1.6	14.9	1.9	1.58	0.127

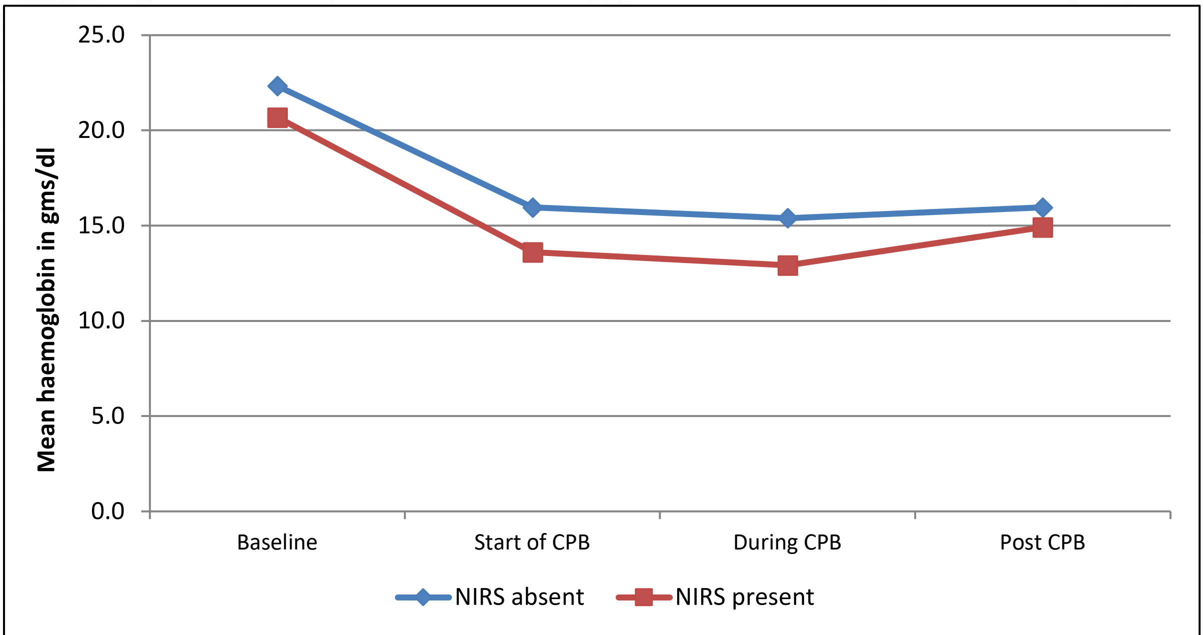

Fig.5.7. Graph showing comparison of mean haemoglobin at different interval of time based on group

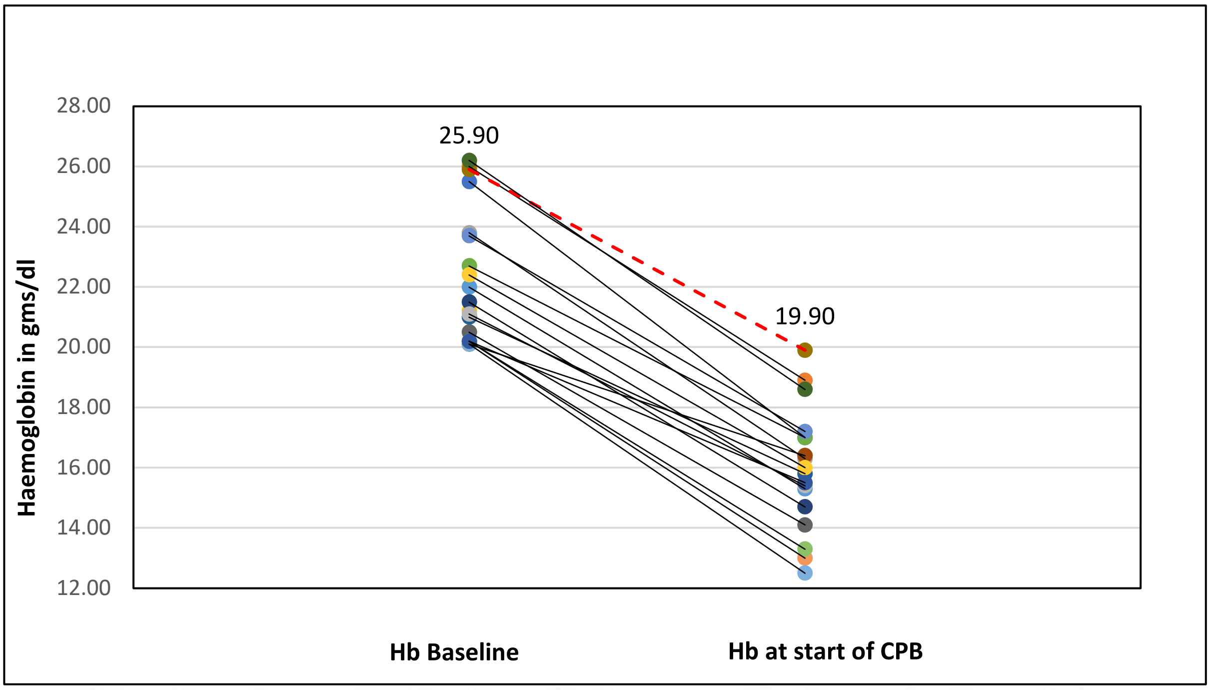

Fig.5.8. Graph showing comparison of haemoglobin at baseline & at the start of CPB in NIRS Absent at Baseline group

In the above graph, haemoglobin values at baseline and at the start of CPB of all the 19 patients in NIRS absent at baseline group were plotted and the line joining them shows the drop of haemoglobin just after initiation of CPB and the $rScO_2$ values were displayed. Out of 19 patients, 18 patients had an $rScO_2$ value after initiation of CP but 1 patient did not display NIRS value throughout the intraoperative period (marked with dotted line in the graph).

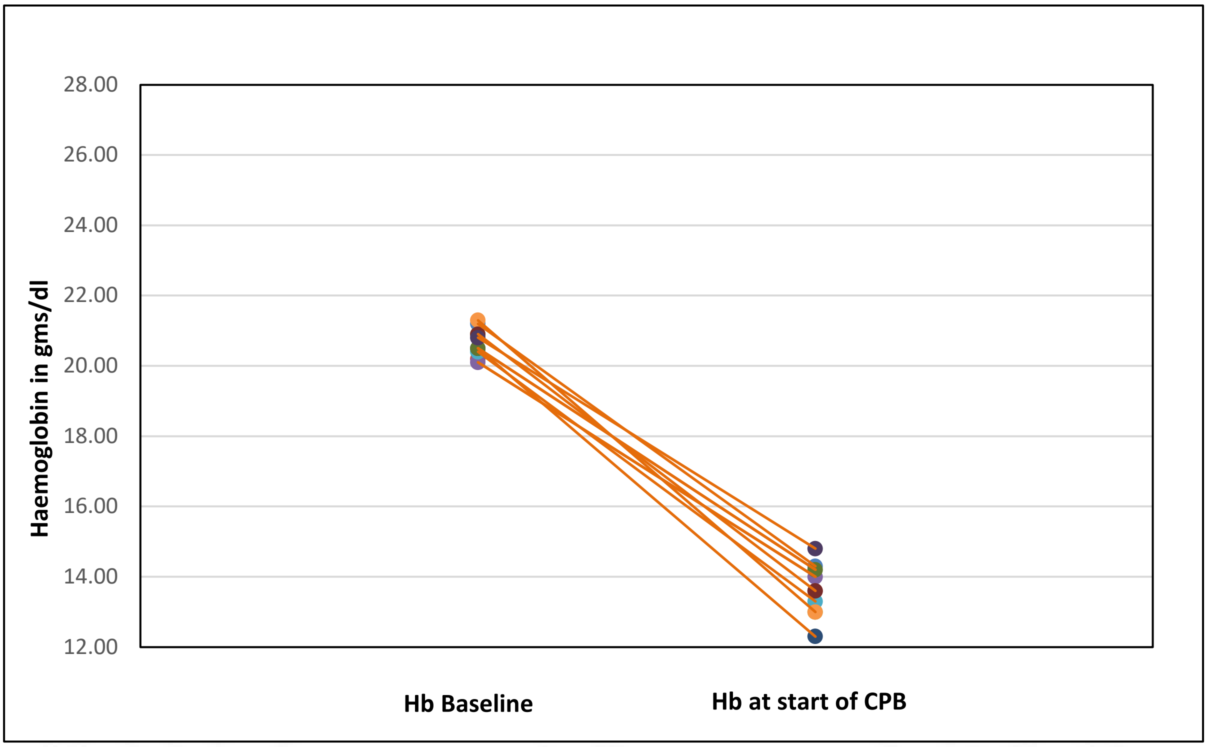

Fig.5.9. Graph showing comparison of haemoglobin baseline & at start of CPB in NIRS Present At Baseline group

In the above graph, haemoglobin values at baseline and at the start of CPB of 10 patients in the NIRS Present at baseline group were plotted.

In the above 2 graphs, haemoglobin baseline values and at start of CPB associated with NIRS absent group at Baseline were mostly higher than the in the NIRS present at Baseline group.

Comparison of intraoperative haematocrit at different time intervals:

Intraoperatively, after initiation of bypass mean haematocrit in NIRS ABSENT At Baseline group is greater than mean of NIRS PRESENT At Baseline group which was statistically significant. Haematocrit levels during bypass at different intervals were statistically significant between the groups. After bypass, haematocrit levels between 2 groups were similar and there was no statistical significance.

Table 5.11. Comparison of Haematocrit at different interval of time based on group

Time interval	NIRS ABSENT At Baseline (n=19)		NIRS PRESENT At Baseline (n=10)		t	p
	Mean (%)	SD	Mean (%)	SD		
Baseline	68.0	6.0	63.5	1.4	2.35	0.026
Start of CPB	48.9	5.7	42.0	2.5	3.64	0.001
During CPB	47.6	5.7	39.8	4.2	2.71	0.018
Post CPB	49.1	4.8	46.2	6.7	1.36	0.185

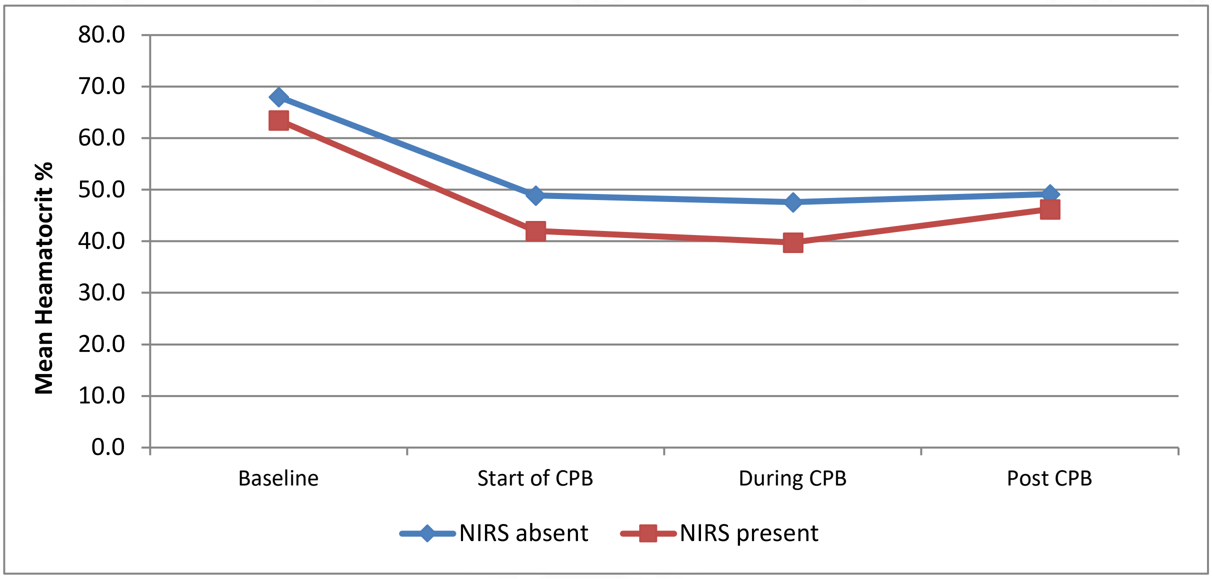

Fig.5.10. Graph showing comparison of Haematocrit at different intervals of time based on group

Comparison of intraoperative PaO_2 at different time intervals:

The baseline PaO_2 in the NIRS ABSENT At Baseline group were much less than NIRS PRESENT At Baseline group and were statistically very significant, whereas after initiation of bypass and even after post CPB means of the 2 groups were almost similar and there was no statistical difference between the groups.

Table 5.12. Comparison of PaO_2 at different interval of time based on group

Time interval	NIRS ABSENT At Baseline (n=19)		NIRS PRESENT At Baseline(n=10)		t	P
	Mean (mm Hg)	SD	Mean (mm Hg)	SD		
Baseline	48.2	3.5	60.3	2.7	9.6	p<0.01
Start of CPB	162.2	52.1	176.5	58.6	0.67	0.506
During CPB	170.6	58.6	174.3	60.4	0.12	0.909
Post CPB	95.4	58.4	110.1	41.2	0.71	0.486

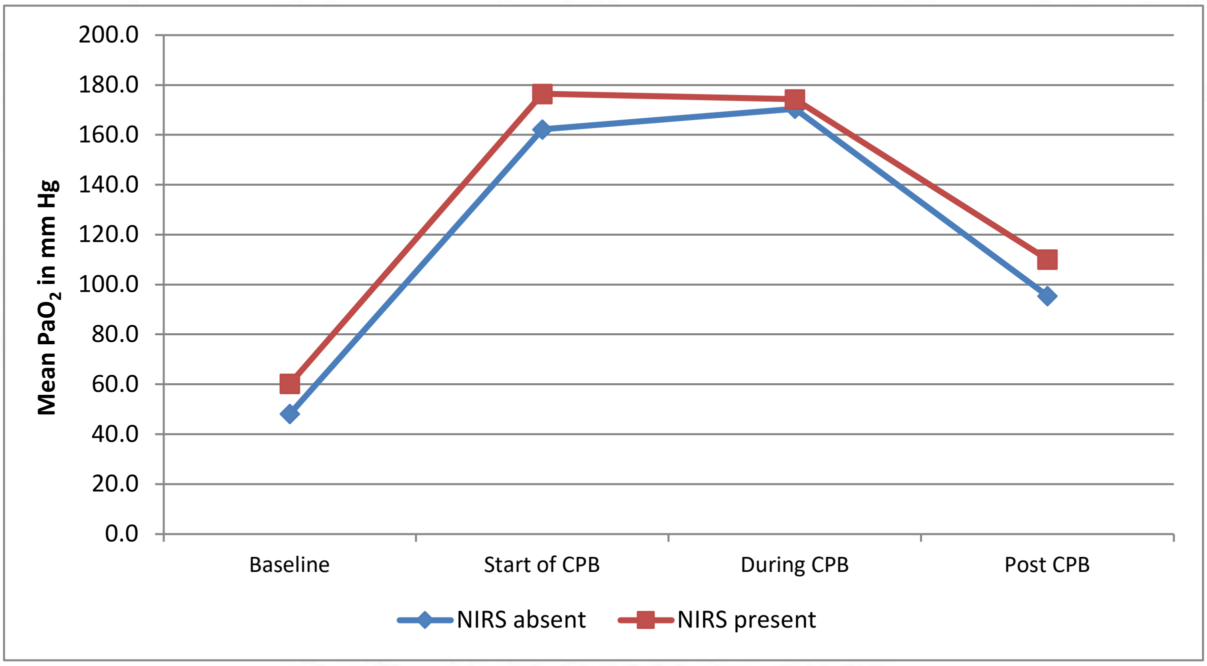

Fig.5.11. Graph showing comparison of PaO_2 at different interval of time based on group

Comparison of intraoperative SaO_2 at different time intervals:

Mean of Baseline SaO_2 in the NIRS ABSENT At Baseline group was lower than NIRS PRESENT At Baseline group and was statistically very significant. After initiation of CPB and after CPB the mean values in the both groups were almost similar and they were not statistically significant.

Table 5.13. Comparison of SaO_2 at different interval of time based on group

Time interval	NIRS ABSENT At Baseline(n=19)		NIRS PRESENT At Baseline(n=10)		t	p
	Mean (%)	SD	Mean (%)	SD		
Baseline	76.2	4.6	88.1	2.1	7.67	p<0.01
Start of CPB	98.5	1.6	98.7	0.9	0.44	0.663
During CPB	98.6	1.4	98.3	0.6	0.42	0.679
Post CPB	92.2	7.2	97.5	2.2	2.27*	0.32

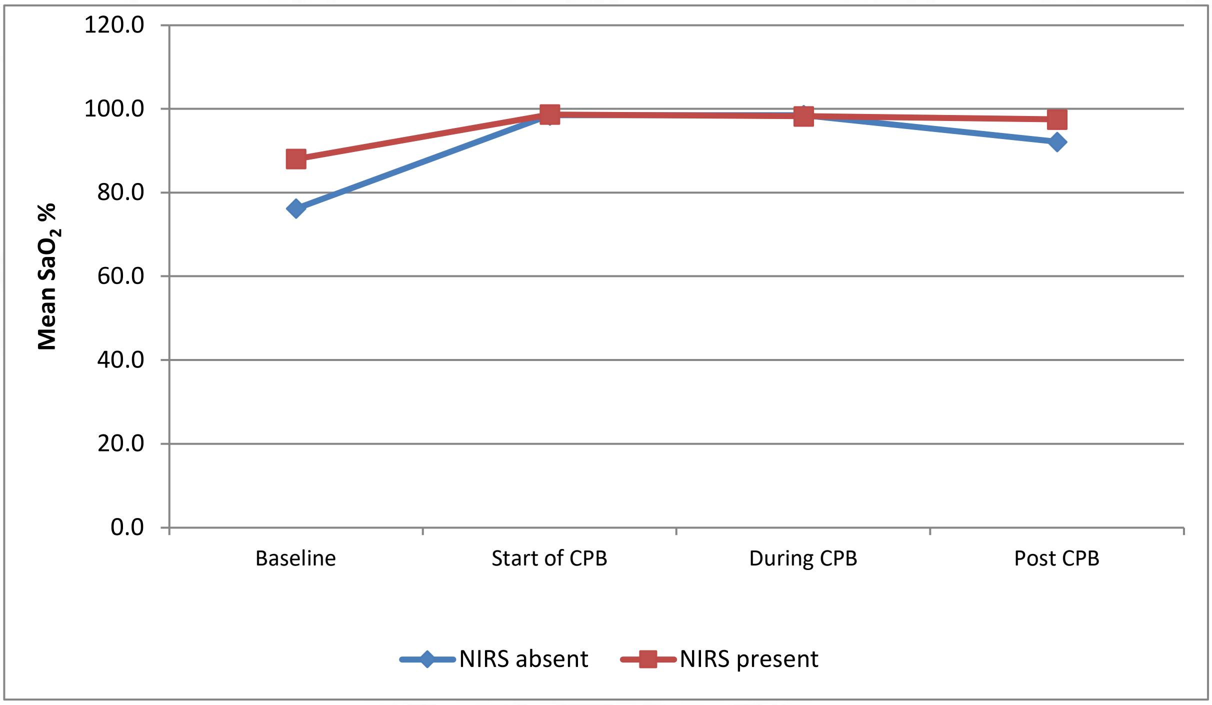

Fig.5.12. Graph showing comparison of SaO_2 at different interval of time based on group

Comparison of PvO_2 at different time intervals:

Means of baseline PvO_2 and at different time intervals during CPB were not statistically significant between the 2 groups.

Table 5.14. Comparison of PvO_2 at different interval of time based on group						
Time interval	NIRS ABSENT At Baseline (n=19)		NIRS PRESENT At Baseline (n=10)		t	p
	Mean (mm Hg)	SD	Mean (mm Hg)	SD		
Baseline	37.4	3.7	40.5	5.5	1.82	0.079
Start of CPB	54.6	10.4	53.9	11.7	0.17	0.865
During CPB	55.3	10.9	45.0	9.0	1.83	0.090
Post CPB	48.3	11.1	44.0	10.3	1	0.325

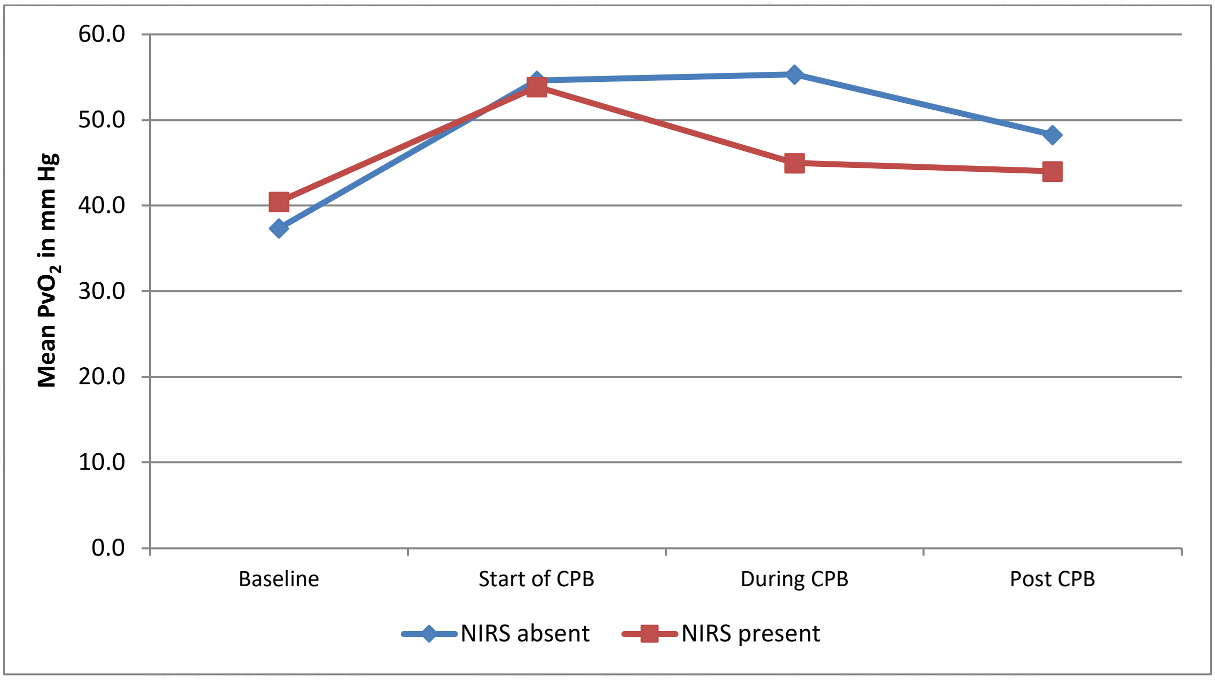

Fig.5.13. Graph showing comparison of PvO_2 at different interval of time based on group

Comparison of SvO_2 at different time intervals:

Means of baseline SvO_2 levels in the NIRS ABSENT At Baseline group were lower than NIRS PRESENT At Baseline group and were statistically significant. After initiation of bypass and the rest of the intraoperative values, there were no difference between the groups and not statistically significant.

Table 5.15. Comparison of SvO_2 at different interval of time based on group

Time interval	NIRS ABSENT At Baseline (n=19)		NIRS PRESENT At Baseline (n=10)		t	p
	Mean (%)	SD	Mean (%)	SD		
Baseline	58.6	6.8	66.0	8.6	2.53*	0.018
Start of CPB	81.6	8.7	83.3	7.8	0.51	0.611
During CPB	80.1	16.2	75.9	9.4	0.53	0.604
Post CPB	68.9	18.0	69.8	7.2	0.15	0.884

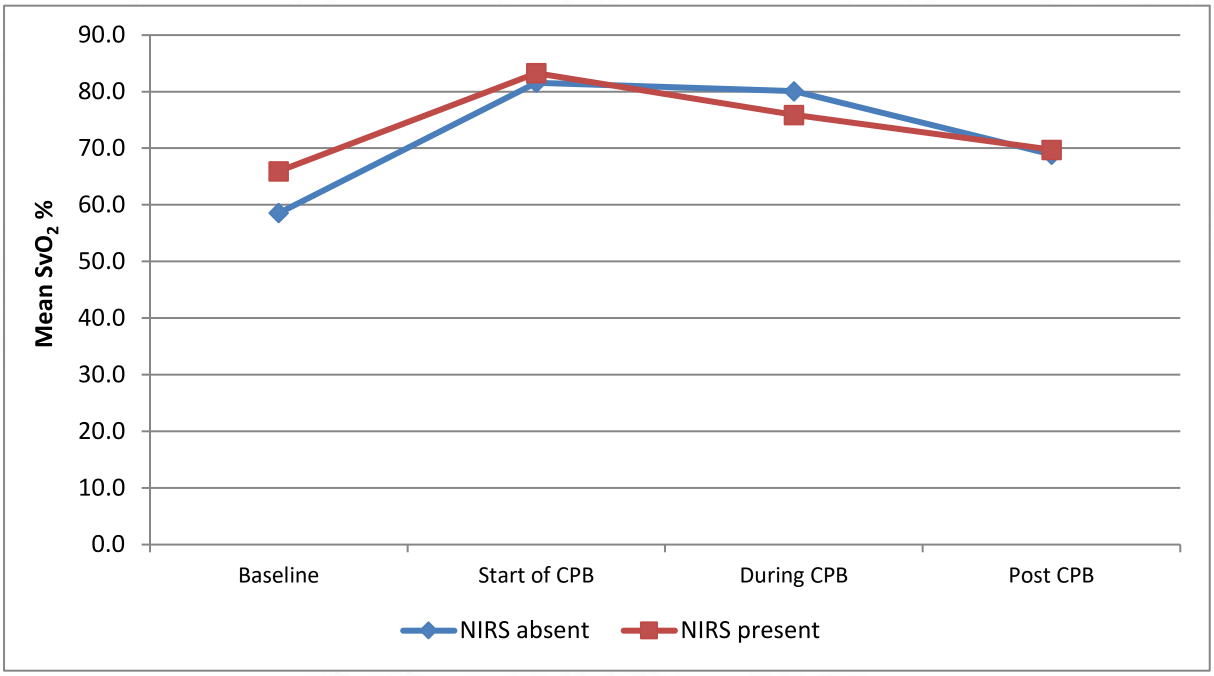

Fig.5.14. Graph showing Comparison of SvO_2 at different interval of time based on group

Comparison of $rScO_2$(NIRS) at different time intervals:

At Baseline 19 patients out of the 29 patients did not show any $rScO_2$ values – not recordable (NR), and for all these patients, except one, NIRS values appeared after the initiation of CPB.

Table 5.16. Comparison of $rScO_2$(NIRS) at different interval of time based on group

Time interval	NIRS ABSENT At Baseline (n=19)		NIRS PRESENT At Baseline (n=10)		t	p
	Mean	SD	Mean	SD		
Baseline	NR	NR	63.1	7.1	-	-
Start of CPB	67.1	7.0	64.4	6.7	1	0.327
During CPB	66.2	7.9	68.9	7.2	0.88	0.390
Post CPB	65.5	7.0	65.9	6.6	0.16	0.877

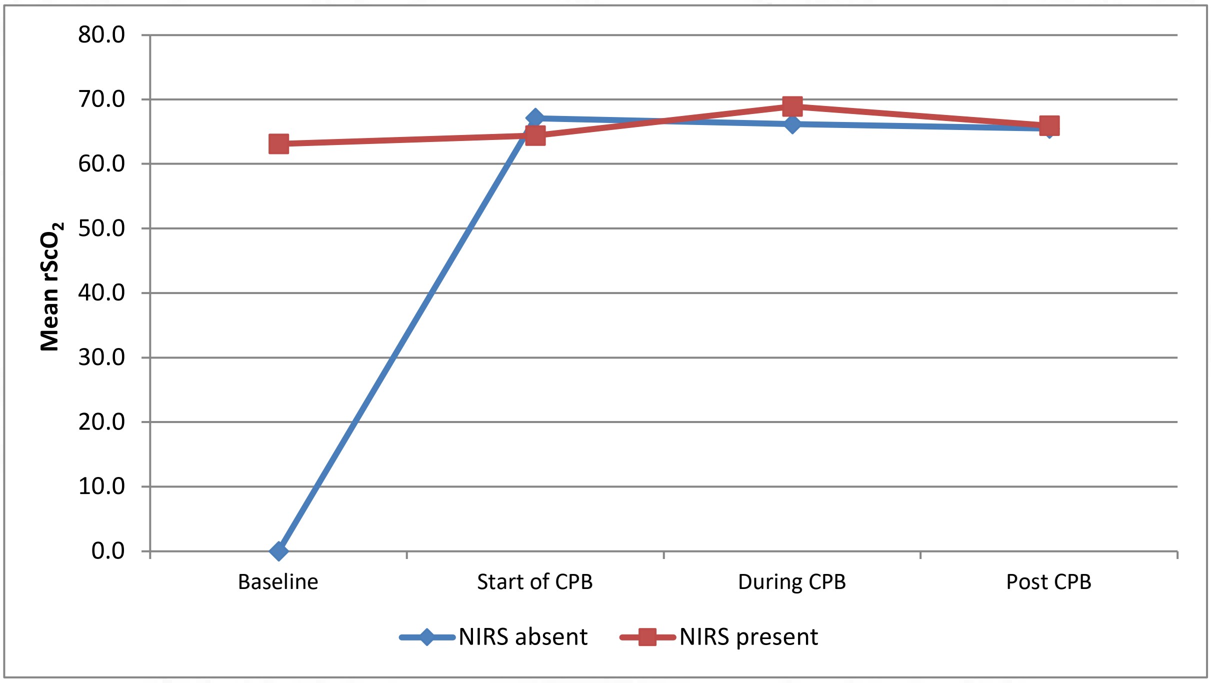

Fig.5.15. Graph showing comparison of $rScO_2$(NIRS) at different interval of time based on group

Comparison of Fractional Cerebral Tissue Oxygen Extraction (FTOE) at different time intervals:

FTOE was calculated using $(SaO_2-rScO_2)/SaO_2$ at four different time intervals. As there were no baseline values displayed in NIRS Absent At Baseline group, no comparison was made at baseline. The rest of the values showed no significant statistical difference between the 2 groups, indicating that FTOE was similar among the groups.

Table 5.17. Comparison of *Fractional Cerebral Tissue Oxygen Extraction*						
Time interval	**NIRS ABSENT At Baseline (n=19)**		**NIRS PRESENT At Baseline (n=10)**		**t**	**p**
	Mean	**SD**	**Mean**	**SD**		
Baseline	NR	NR	28.2	8.3	-	-
Start of CPB	31.9	7.0	34.7	6.5	1.02	0.316
During CPB	29.7	7.6	32.9	5.7	0.96	0.353
Post CPB	29.7	8.1	32.3	7.3	0.81	0.425

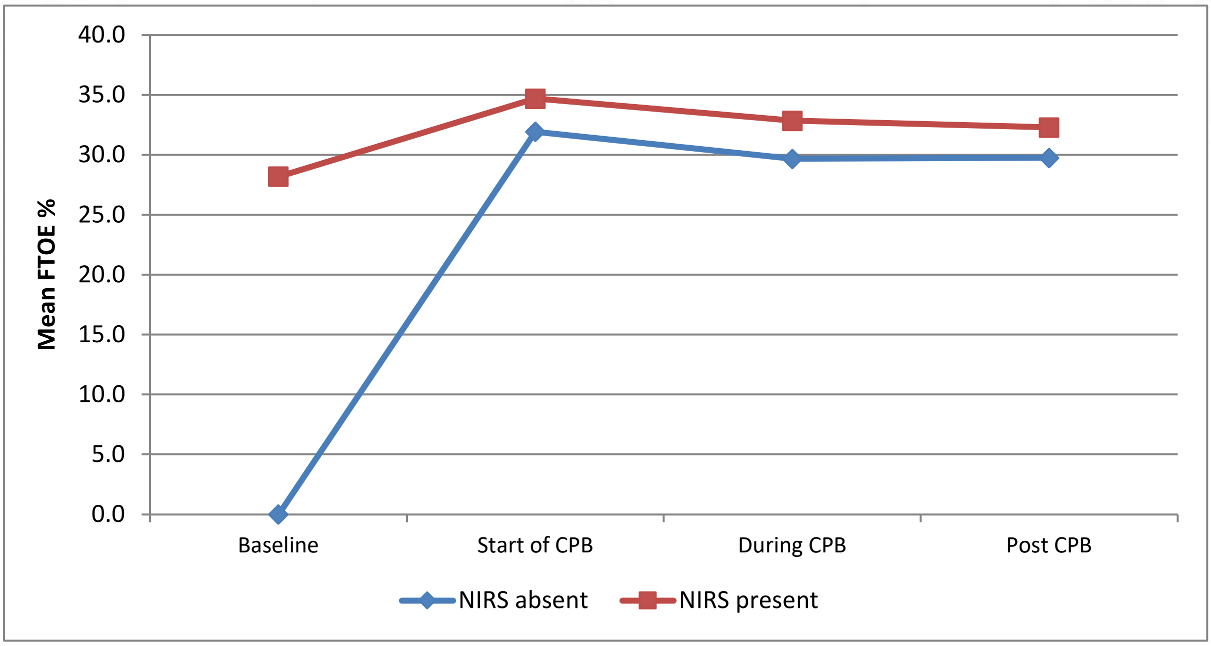

Fig.5.16. Graph showing comparison of Fractional Cerebral Tissue Oxygen Extraction

15-year-old diagnosed with DILV, during BDG surgery had baseline haemoglobin of 25.9 gms/dl, haematocrit of 75.9%, PaO_2 of 40.1 mm Hg was in the NIRS ABSENT At Baseline group. After initiation of CPB, haemoglobin decreased to 19.9 gms/dl and haematocrit of 60.7 %, and PaO_2 157 mm Hg but $rScO_2$ values did not appear. Post operatively, haematocrit and PaO_2 were 53% and 50.5 mm Hg respectively and the $rScO_2$ values still absent. This was the only case whose NIRS $rScO_2$ values were absent whole throughout the surgery.

10-year-old patient who was diagnosed with pulmonary atresia presenting for cavo-pulmonary shunt surgery was in the NIRS ABSENT group At Baseline (haemoglobin and PaO_2 of 20.1 gms/dl, and 41.2 mm Hg respectively) and at start of CPB her NIRS readings appeared with a haemoglobin of 16.4gms/dl and PaO_2 of 200 mm Hg. However, after weaning of CPB and later in the postoperative period, NIRS was unable to record any values. Her haemoglobin and PaO_2 at this time were 18.1gm/dl and PaO_2 of 53.2 mm Hg

6. DISCUSSION

NIRS is based on different absorption spectrum of infrared light by oxy and deoxyhaemoglobin to estimate regional cerebral oxygenation ($rScO_2$). When compared to other neuro-monitors, NIRS provides absolute values, allows continuous measurement (when compared to transcranial Doppler) for prolonged periods perioperatively with no movement artifacts (when compared to EEG), non-invasive (when compared to jugular venous oxygen saturation)(13).

In this prospective observational study, we aimed to analyse the functioning of Near-Infrared Spectroscopy in patients presenting for surgery with cyanotic congenital heart disease and polycythaemia. The study owes its origin to the observation that the NIRS values are undetectable in some cyanotic congenital heart disease patients-which elicits the clinician response of changing and reapplying the probes and/or giving up on monitoring cerebral oxygenation. The fortuitous observation that the NIRS starts working on initiation on cardiopulmonary bypass inspired us to study this phenomenon in detail.

Our study population was patients less than 18 years of age with a haematocrit of 20 gms/dl or greater as we reasoned that this is the target group which is likely to influence the NIRS function that we wanted to study. Haemoglobin of greater than 20gm/dl is a unique subset of patients within cyanotic congenital heart disease among patients presenting for correction of congenital heart diseases-therefore, our study population was limited by the availability of patients, which compelled us to recruit consecutive patients who were eligible according to the criteria set for haemoglobin level.

Of the 29 patients recruited into the study, 19 patients had $rScO_2$ values absent at baseline, either at or immediately after induction of anaesthesia, while other 10 patients had $rScO_2$ values from induction. 18 patients of the NIRS Absent At Baseline group started to display $rScO_2$ values from initiation of CPB, while 1 patient never displayed $rScO_2$ values throughout the intraoperative period. Baseline haemoglobin, haematocrit were higher and PaO_2, SaO_2, SvO_2 were lower in NIRS absent at baseline group and were statistically significant when compared to NIRS present at baseline group. Similarly at the start of CPB and during CPB also haemoglobin and haematocrit in NIRS absent group were significantly higher and statistically significant. PaO_2, SaO_2, PvO_2, SvO_2 values at the start of CPB and during CPB were not different between the groups.

Kussman et al studied the effects of chronic hypoxia and cerebral oxygen saturation in paediatric congenital heart disease patients posted for cardiac catheterisation laboratory(2). Their study included both cyanotic and acyanotic congenital heart disease. The observation reported in our study, absent NIRS value at induction of anaesthesia, was not observed in their study. The highest haemoglobin level in their study group was 17.5 gm/dl compared to our inclusion criteria of haemoglobin levels of 20 gms/dl or greater. Their study being conducted in the cardiac catheterisation laboratory, enabled these researchers to reliably obtain jugular venous blood for analysis, a facility that we lacked. Jugular oxygen saturation enabled these researchers to obtain cerebral oxygen extraction, measured as difference between the $rScO_2$ and jugular bulb saturation. They found that initial $rScO_2$ and cerebral oxygen extraction in cyanotic children is comparable to acyanotic children at baseline. They caution that an abnormally low $rScO_2$ in cyanotic congenital heart disease should not be assumed to be "normal" for that child and a cause for low $rScO_2$ should be sought. Similar to the study by Kussman, the baseline $rScO_2$ in the group NIRS PRESENT was within the normal range (63.1±7.1). In the NIRS ABSENT group the $rScO_2$ values after the initiation of cardiopulmonary bypass and thereafter, the $rScO_2$ values were in the normal range (67.1±7) The FTOE, which is a measure of balance between oxygen delivery and extraction remained identical in both of our study groups.

Fractional Cerebral Tissue Oxygen Extraction (FTOE) is measured as $(SaO_2-rScO_2)/SaO_2$, which indicates balance between oxygen delivery and consumption by brain tissue. An increase in FTOE indicates increased oxygen consumption by brain tissue, whereas a decrease suggests less utilisation of oxygen by brain tissue such as secondary to neuronal cell death)(13). In normal healthy children $rScO_2$ was 68%±10% and FTOE was 30% ±11% (14). In our study we observed that the FTOE is similar in both the groups after the initiation of cardiopulmonary bypass indicating that cerebral oxygen consumption is comparable in both the groups. The absence of NIRS at baseline, therefore, has no bearing on cerebral oxygen consumption. In our study, the observation that the NIRS value in both groups are similar during CPB is in agreement with the findings of Kussman et al. (2) The brain of cyanotic children have $rScO_2$ values that are comparable to non-cyanotic children.

Gottlieb et al did a retrospective study of 10 patients (0.55%) chosen from 1820 patients either intraoperatively or in cardiac catheterisation laboratory who did not show any $rScO_2$ values initially and analysed their data(8). All 10 patients were found to be cyanotic and severely polycythaemic with a mean haematocrit of 63.9% ± 4% and baseline peripheral oxygen saturation was 73% ± 6% at room air. Our study differs from that of Gottlieb et al in that we systematically studied polycythaemic patients. Our patients fall into one of two categories, NIRS PRESENT At Baseline or NIRS ABSENT At Baseline and in the latter group the NIRS values appeared only after the initiation of cardiopulmonary bypass. In one patient in the NIRS ABSENT group, no NIRS values appeared during the entire period of surgery.

In the study by Gottlieb et al 9 out of 10 patients were of single ventricle physiology, underwent a palliative or corrective or cardiac catheterisation procedure whereas in our study, 18 patients underwent palliative surgery and other 11 patients underwent reparative surgery. Out of the 10 patients in the study by Gottlieb et al, 5 showed $rScO_2$ values during gradual haemodilution just before initiation of CPB at a mean haematocrit of 61.8% ± 4.2%, another 4 patients showed $rScO_2$ values after initiation of CPB with a mean haematocrit of 35.5% ± 2.9%. In our study we found that the rScO2 values appeared at mean haematocrit of 48.9±5.7%. Other differences between our study and that of Gottlieb et al, was that we studied our patients prospectively and hence we could define our study population and collect data not mentioned in the latter study.

Skin pigmentation and ambient light are said to be other factors that may lead to an unrecordable NIRS value. In our patients, who were of uniform ethnicity and similar skin pigmentation, the NIRS values which were absent at baseline became accessible, with the same optode, after the haemodilution of cardiopulmonary bypass. It is impossible to identify the exact haematocrit at which NIRS values start to appear as patients undergo a predetermined haemodilution during the cardiopulmonary bypass. We propose that skin pigmentation plays only a limited role in whether or not NIRS values are available prior to haemodilution. The children are well shielded from ambient light when surgical drapes are applied and has little chance of interfering with the NIRS readings.

Two mechanisms may explain why NIRS values are absent at baseline in polycthaemia. One, the higher haemoglobin concentration may absorb much of the emitted light from the emitting optode and thereby not leaving enough light to be detected by the receiving optode. Second, the machine algorithm which is designed to fail reporting during instances where incorrect readings are likely as with hyperpigmentation, high ambient light, hyperbilirubinemia and extreme viscosity or polycythaemia(8). We found statistically significant differences between haemoglobin levels of those with NIRS Absent at Baseline and with NIRS Present at baseline, the mean haemoglobin levels being 22.3 and 20.7 respectively. The ability of the NIRS monitor to display value in polycythaemic patients is determined by absolute haemoglobin levels and small increments in haemoglobin levels can mean the difference between present or absent NIRS values. Besides, low PaO_2 and SaO_2 are also a determinant of the ability of the NIRS monitor to display a value but such low values of PaO_2 leads to polycythaemia.

Liem et al studied NIRS and internal carotid artery velocity in 10 neonates with a haematocrit > 65% who underwent therapeutic haemodilution. Partial plasma exchange transfusion was done in. Even though haematocrit was at a higher level they did not report any difficulties in monitoring of NIRS values. They concluded that in spite of haemodilution in polycythaemia there was no improvement in cerebral oxygenation even with possible increase of cerebral perfusion and attributed that increased cerebral blood flow was due to decreased arterial oxygen content but not as a result of decreased viscosity. The study population being neonates having a higher percentage of foetal haemoglobin, findings of Liem et al may not be comparable to our study(9).

Wong et al did a prospective observational study on 21 cyanotic congenital heart disease patients below 18 years of age posted for cardiac surgery with the objective to demonstrate an increase in $rScO_2$ after surgery similar to improvement of arterial blood gas saturation and pulse oximetry SpO_2 values. 15 patients underwent corrective surgery and other 6 palliative surgery. Data were collected at 6 different time intervals – Pre CPB, during CPB, Post CPB, Day 1 & 2 in PICU, at discharge. They concluded that post CPB $rScO_2$ did not change from pre CPB values and even decreased at hospital discharge. The baseline of these patients was comparatively high when compared to other studies and they attributed this to intubation and ventilation done minutes prior to taking pre CPB values as these were small children and uncooperative for induction(15).

7. LIMITATIONS OF THE STUDY

1) Post induction placement of optodes with FiO_2 of 0.5 (uncooperative children).
2) Gradual haemodilution could not be performed (not practiced in our institute) and specific levels of haemoglobin and PaO_2 levels at which NIRS values were appearing in NIRS absent group could not be established.
3) It was an observational study, hence only trends of $rScO_2$ values were studied without any interventions.

8. CONCLUSION

29 patients with haemoglobin >20 gms/dl were included in the study, of which 19 patients did not display NIRS values at baseline and the other 10 patients displayed NIRS values at baseline, indicating that haemoglobin was one of the many factors for lack of an NIRS value at baseline. Further comparison among intraoperative blood gas analysis at various specific time intervals revealed, PaO_2, SaO_2, SvO_2 in the NIRS Absent at Baseline group were significantly lower when compared to NIRS Present at baseline group. The ability of the NIRS monitor to display a value at baseline in polycythaemic patients is a function of the absolute haemoglobin level and PaO_2 and is not a function of cerebral oxygen extraction.

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ANNEXURES

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

TAC Registration No: SCT-/S/2020/1119 **Date: 27.07.2020**

Project title: EFFECT OF HAEMOGLOBIN LEVELS ON NEAR INFRARED SPECTROSCOPIC (NIRS) MONITORING IN CYANOTIC CONGENITAL HEART DISEASE PATIENTS

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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).

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Appendix-1

First comments

Number Sample size of thirty reasoning is not appropriate. The study can be a pilot study due to limitations expressed by the PI. International studies are availablė regarding the same subject. (Wong JJ, Chen CK, Moorakonda RB, et al. Changes in Near-Infrared Spectroscopy After Congenital Cyanotic Heart Surgery. Front Pediatr. 2018;6:97. Published 2018 Apr 13. doi:10.3389/fped.2018.00097 Details about NIRs monitoring must be mentioned.

Answer: We accept the review that the description of the study be changed to a pilot study. The study quoted by the TAC (Wong JJ, Chen CK, Moorakonda RB, et al. Changes in NearInfrared Spectroscopy After Congenital Cyanotic Heart Surgery. Front Pediatr. 2018;6:97. Published 2018 Apr 13. doi:10.3389/fped.2018.00097) is an observational study done in 25 patients. However, this study was not designed to detect the abnormalities in NIRS that we aim to study. Further, despite the constraints mentioned in the collecting the requisite sample size due to the rare nature of the disease being studied, we are hopeful of enrolling more patients than in the aforementioned study

The monitoring algorithm is different for different companies.
Answer: The details of the NIRS algorithm have now been incorporated.

In consent process column, instead of patients, you can mention as parents. Consent form also must be modified accordingly.
Answer: Consent form has been modified to incorporate consent of the parents.

Patient information sheet must explain what is NIRS?
Answer: Patient information sheet explains NIRS.

In Proforma patient details must be removed
Patient details removed from the proforma.

Second comment

Hospital number is mentioned in pro forma and must be removed.
Answer: Hospital no. removed from the proforma.

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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 नं./Telephone No.: 0471-2443152 फैक्स/Fax: 0471-2446433, 2550728
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DST@ 1971-2021 DEPARTMENT OF SCIENCE & TECHNOLOGY

Institutional Ethics Committee

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

SCT/IEC/1612/DECEMBER-2020 21.12.2020

Dr Kartheek Hanumansetty
Senior Resident, Cardiac Anaesthesia
Department of Anaesthesiology, SCTIMST

Dear Dr Kartheek Hanumansetty,

Thank you for submitting documents related to your proposal titled "**EFFECT OF HAEMOGLOBIN LEVELS ON NEAR INFRARED SPECTROSCOPIC (NIRS) MONITORING IN CYANOTIC CONGENITAL HEART DISEASE PATIENTS** (IEC/1612)" to the IEC for review.

The following documents were reviewed:

1. Checklist
2. Full proposal
3. IEC Application Form
4. Covering letter addressed to the Chairman, IEC, SCTIMST dated 15.11.2020 forwarded by HOD
5. Proforma
6. TAC Approval Letter
7. Patient Information Sheet in English
8. Patient Information Sheet in Malayalam I
9. Consent Form in English
10. Consent Form in Malayalam
11. CV of Dr Kartheek Hanumansetty with KMC registration number
12. CV of Dr. Suneel P R with TCMC registration number
13. CV of Dr Sabarinath Menon with TCMC registration number
14. Covering letter addressed to the Chairman, IEC, SCTIMST dated 15.11.2020
15. Proof of document for TCMC registration
16. MCI registration certificate of PI

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The following members of the Students Sub-Committee of the Institutional Ethics Committee participated in the discussions held 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

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PATIENT INFROMATION SHEET

TITLE: EFFECT OF HAEMOGLOBIN LEVELS ON NEAR INFRARED SPECTROSCOPIC (NIRS) MONITORING IN CYANOTIC CONGENITAL HEART DISEASE PATIENTS

AIM OF THE STUDY (why are we doing this study?)

Cerebral hypoxia is linked to neurologic injury and worsened neurologic outcomes in pediatric cardiac surgery. Lower intraoperative cerebral saturations are correlated with worse neurodevelopmental outcomes. Therefore real-time trends of cerebral oxygenation provide insight and are possibly a marker of oxygenation changes occurring throughout the brain. Hence there is a need to study the effects of polycythemia on NIRS monitoring for cerebral oxygenation as it has several advantages over other neuromonitoring modalities.

What is the duration of the study?

Your child/your ward will be followed up for study purpose from the time of general anaesthesia in the operating room till the end of surgery.

Description of the procedure

As per routine institution protocol, all standard monitoring will be done. Along with that we will be monitoring your child/your ward cerebral oxygenation using NIRS. NIRS monitoring is routine during congenital heart surgery and helps in assessing the degree of the oxygenation of the brain. NIRS monitoring involves application of electrodes (similar to electrocardiogram electrodes applied on the chest) to the forehead. The electrodes transmits light which is reflected back to the electrodes by the blood in the brain-enabling us to study the degree of cerebral oxygenation. NIRS has been routinely used during adult and paediatric cardiac surgery for more than two decades. The study involves observing NIRS values in your child during surgery

There will be no foreseeable risks and discomforts involved in this study.

What are the benefits from this study and whether you will be benefitted from this study?

The study is beneficial in monitoring perioperative cerebral oxygenation and in predicting the risk of neurological insult in patients undergoing cardiac repair for cyanotic congenital heart diseases. If cerebral hypoxia is detected then appropriate measures can be initiated to treat and subsequently prevent cerebral hypoxia as much as possible.

Can you withdraw from this study after it starts?

Your consent for participation of your ward/child in this study is entirely voluntary and you/your child/your ward will be free to decide to withdraw from this study, if you feel so. If you do so, this will not affect your usual treatment in 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 but if your child/your ward develops any side effects or problems due to the study, these will be treated at no extra cost to you. We are unable to provide any monetary compensation, however.

Will you have to pay for the study?

This study does not require you to pay any additional charges over and above what you will have to bear for the routine expenditure for the operation.

Will your personal details be kept confidential?

Your child/your ward personal details will be kept confidential. The result of this study will be sent for publication in a medical journal upon its completion, but you will not be identified by name or any other form of identification in such a publication or any presentation anywhere.

Number of subjects

Total of thirty patients will be included in the study.

If you have any further questions, please ask any of the study investigators listed below:

i) **Dr. H Kartheek, DM Senior resident, (Cardiothoracic & Vascular Anesthesia), Division of Cardiac Anesthesia (Ph: 9885743657; email: kartheek45@gmail.com)**

ii) **Dr. Suneel P R, Professor, Division of cardiac Anesthesia (Ph : 9847280218 ; email: suneelpr@gmail.com)**

iii) **Dr. Sabarinath Menon, Additional Professor, Cardiovascular and Thoracic surgery department (Ph: 9995284442; email: sabarinathmenon@sctimst.ac.in)**

iv) ***Dr.Mala Ramanathan, Member Secretary, IEC & Additional Professor(study independent contact person, tel:04712524-234)***

രോഗിക്കുള്ള കാര്യവിവരണപത്രം

പഠന ശീർഷകം: ജന്മനാ സൈനോട്ടിക് ഹൃദ്രോഗമുള്ള രോഗികളിൽ നിയർ ഇൻഫ്രാറെഡ് സ്പെക്ട്രോസ്കോപ്പി നിരീക്ഷണത്തിലെ (എൻഐആർഎസ്) ഹീമോഗ്ലോബുലിൻ നിലവാരത്തിന്റെ പ്രഭാവം

പഠന ലക്ഷ്യം (ഞങ്ങൾ എന്തിന് ഈ പഠനം നടത്തുന്നു)

തലച്ചോറിലെ കലകളിലെ പ്രാണവായുവിന്റെ ദൗർലഭ്യം (ഹൈപ്പോക്സിയ) ന്യൂറോളജിക്കലായ ക്ഷതവുമായി ബന്ധപ്പെട്ടിരിക്കുകയും കുട്ടികളുടെ ഹൃദ്രോഗ ശസ്ത്രക്രിയയിൽ മോശമാകുന്ന ന്യൂറോളജിക്കലായ പരിണിത ഫലങ്ങളുണ്ടാക്കുകയും ചെയ്യും. ശസ്ത്രക്രിയയ്ക്കിടയിലെ തലച്ചോറിന്റെ കുറഞ്ഞ പൂരിതാവസ്ഥകൾ മോശമായ ന്യൂറോ വികാസഫലങ്ങളുമായി പാരസ്പര്യമുള്ളതാണ്. ആകയാൽ തലച്ചോറിലെ യഥാസമയത്തുള്ള പ്രണവായു സമ്പുഷ്ടതയുടെ പ്രവണതകൾ ഇൻസൈറ്റ് നൽകുന്നതും തലച്ചോറിലാകെ സംഭവിക്കുന്ന പ്രണവായു സമ്പുഷ്ടതയുടെ വ്യതിയാനങ്ങളുടെ സൂചകമാകാൻ സാദ്ധ്യതയുള്ളതുമാണ്. ആകയാൽ തലച്ചോറിലെ പ്രണവായു സമ്പുഷ്ടതയിലെ എൻഐആർഎസ് നിരീക്ഷണത്തിന്റെ രീതികൾക്ക് മറ്റ് ന്യൂറോ നിരീക്ഷണ രീതികളെക്കാൾ (മോഡാലിറ്റി) അനേകം നേട്ടങ്ങളുണ്ട്.

പഠനത്തിന്റെ കാലയളവ് എത്രയാണ്?

ശസ്ത്രക്രിയാ മുറിയിൽ താങ്കളുടെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളിന് പൊതുവായ മയക്കൽ നൽകുന്നതു മുതൽ ശസ്ത്രക്രിയ പൂർത്തിയാകുന്നതു വരെ പഠനത്തിനായി താങ്കളുടെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളെ പിന്തുടരും.

നടപടിയുടെ വിവരണം

സ്ഥാപനത്തിലെ പതിവ് നടപടിക്രമപ്രകാരം എല്ലാ അംഗീകൃത നിരീക്ഷണവും നടത്തും. അതിനൊപ്പം ഞങ്ങൾ താങ്കളുടെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളുടെ തലച്ചോറിലെ പ്രാണവായു സമ്പുഷ്ടത എൻഐആർഎസ് ഉപയോഗിച്ച് നിരീക്ഷിക്കും. ജന്മനായുള്ള ഹൃദ്രോഗ ശസ്ത്രക്രിയയിൽ എൻഐആർഎസ് നിരീക്ഷണം പതിവും തലച്ചോറിലെ പ്രാണവായുവിന്റെ നില മനസ്സിലാക്കുന്നതിന് സഹായവുമാണ്. എൻഐആർഎസ് ൽ ഇലക്ട്രോഡുകൾ (നെഞ്ചിൽ വയ്ക്കുന്ന ഇസിജി ഇലക്ട്രോഡുകളോട് സമാനമായ) നെറ്റിയിൽ വയ്ക്കുന്നു. ഇലക്ട്രോഡുകൾ പ്രകാശം പ്രസരിപ്പിക്കുകയും അവ തലച്ചോറിലെ രക്തം തിരിച്ച് ഇലക്ട്രോഡുകളിലേക്ക്

തിരിച്ചയയ്ക്കുകയും പ്രാണവായുവിന്റെ നില പഠിക്കാൻ ഞങ്ങളെ പ്രാപ്തരാക്കുകയും ചെയ്യുന്നു. രണ്ടിലേറെ ദശാബ്ദമായി പതിവായി എൻഐആർഎസ് മുതിർന്നവരിലും കുട്ടികളിലുമുളള ഹൃദയ ശസ്ത്രക്രിയയിൽ ഉപയോഗിക്കുന്നു. പഠനത്തിൽ താങ്കളുടെ കുട്ടിയുടെ എൻഐആർഎസ് മൂല്യങ്ങൾ നിരീക്ഷിക്കുന്നതുൾപ്പെടുന്നു.

മുൻകൂട്ടി കാണാവുന്ന അപായങ്ങളോ അസ്വസ്ഥതകളോ ഈ പഠനത്തിൽ ഇല്ല.

ഈ പഠനത്തിൽ നിന്നുള്ള നേട്ടങ്ങളെന്തെല്ലാം ഈ പഠനത്തിൽ നിന്നും താങ്കളുടെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളിന് നേട്ടമുണ്ടാക്കുമോ?

ശസ്ത്രക്രിയാസമയത്തെ തലച്ചോറിലെ പ്രണവായു സമ്പുഷ്ടത നിരീക്ഷിക്കുന്നത് ജന്മനായുള്ള സൈനോട്ടിക് ഹൃദ്രോഗങ്ങളുടെ ഹൃദയരോഗങ്ങളുടെ ഹൃദയതകരാർ പരിഹരിക്കുന്നതിന് ശസ്ത്രക്രിയയ്ക്ക് വിധേയരാകുന്ന രോഗികളിൽ ന്യൂറോളജിക്കലായ അവമതിയുടെ അപായ സാദ്ധ്യത പ്രവചിക്കുന്നതിനും പ്രയോജനപ്രദമാണ്. തലച്ചോറിലെ പ്രാണവായുവിന്റെ ദൗർലഭ്യം കണ്ടെത്തിയാൽ ചികിത്സിക്കാനുള്ള ഉചിതമായ നടപടികൾക്ക് തുടക്കമിടാനും അതിനൊപ്പം സാദ്ധ്യമാകുന്നിടത്തോളം തലച്ചോറിലെ പ്രണവായുവിന്റെ ദൗർലഭ്യം തടയാനും കഴിയും.

പഠനമാരംഭിച്ച ശേഷം താങ്കളുടെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളിന് **പിൻമാറാനാകുമോ?**

താങ്കളുടെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളിന്റെ പഠനത്തിലെ പങ്കാളിത്തം തികച്ചും സ്വമേധയായുള്ളതും സമ്മതം പിൻവലിക്കാൻ ഏതു സമയത്തും താങ്കളുടെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളനി് സ്വാതന്ത്ര്യമുള്ളതുമാണ്. താങ്കളങ്ങനെ ചെയ്താലും ഈ ആശുപത്രിയിലെ താങ്കളുടെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളിന്റെ പതിവ് ചികിത്സയെ ഒരുതരത്തിലും ബാധിക്കില്ല.

പഠന സംബന്ധിയായി എന്തെങ്കിലും പരിക്ക് താങ്കളുടെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളി**നുണ്ടായാലെന്ത് സംഭവിക്കും?**

ഈ പഠനത്തിന്റെ ഭാഗമായി താങ്കളുടെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളിന് പരിക്കൊന്നും ഞങ്ങൾ പ്രതീക്ഷിക്കുന്നില്ല, പക്ഷേ എന്തെങ്കിലും പാർശ്വഫലങ്ങളോ പ്രശ്നങ്ങളോ ഉണ്ടായാൽ ഈ ആശുപത്രിയിൽ താങ്കൾക്കധിക ചിലവില്ലാതെ ചികിത്സിക്കും. എന്നിരുന്നാലും നഷ്ടപരിഹാരം നൽകാൻ ഞങ്ങൾക്കാവില്ല.

പഠനത്തിനായി താങ്കളുടെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാൾ **പണംമുടക്കണോ?**

ശസ്ത്രക്രിയയ്ക്കായുള്ളപതിവ് ചിലവിലധികം താങ്കൾ ഈ പഠനത്തിനായി നൽകേണ്ടതില്ല.

താങ്കളുടെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളിന്റെ വ്യക്തിപരമായ വിവരങ്ങൾ രഹസ്യമായിരിക്കുമോ?

താങ്കളുടെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളിന്റെ വ്യക്തിപരമായ വിവരങ്ങൾ രഹസ്യമായിരിക്കും. ഈ പഠനം പൂർത്തിയാകുമ്പോൾ ഫലങ്ങൾ ഒരുവൈദ്യശാസ്ത്ര ജേർണലിൽ പ്രസിദ്ധീകരിച്ചേക്കാം പക്ഷേ താങ്കളുടെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളിനെ പേരുകൊണ്ട് പ്രസിദ്ധീകരണത്തിലോ പ്രദർശനത്തിലോ ഒരിടത്തും തിരിച്ചറിയാനാകില്ല.

പങ്കെടുക്കുന്നവരുടെ എണ്ണം

ആകെ 30 രോഗികളെ ഈ പഠനത്തിലുൾപ്പെടുത്തും.

താങ്കൾക്ക് കൂടുതൽ ചോദ്യങ്ങളുണ്ടെങ്കിൽ താഴെ നൽകിയിരിക്കുന്ന ഗവേഷകരോട് ചോദിക്കുക

i) ഡോ. കാർത്തീക്, ഡിഎം സീനിയർ റെസിഡന്റ്, കാർഡിയേ ാ തൊറാസിക് ആന്റ് വാസ്ക്കുലാർ അനസ്തീഷ്യ, ഡിവിഷൻ ഓഫ് കാർഡിയാക് അനസ്തീഷ്യ (ഫോൺ 9885743657) kartheek45@gmail.com

ii) ഡോ. സുനീൽ പി ആർ, ഡിവിഷൻ ഓഫ് കാർഡിയാക് അനസ്തീഷ്യ (ഫോൺ 9847280218) ഇമെയിൽ suneelpr@gmail.com

iii) ഡോ ശബരീനാഥ് മേനോൻ, അഡീഷണൽ പ്രൊഫസർ, കാർഡിയോ വാസ്ക്കുലാർ ആന്റ് തൊറാസിക് അനസ്തീഷ്യ (ഫോൺ 9995284442) ഇമെയിൽ sabarinathmenon@sctimst.ac.in

iv) ഡോ മാല രാമനാഥൻ, മെമ്പർ സെക്രട്ടറി, & പ്രൊഫസർ (പഠനത്തിൽ നിന്നും സ്വതന്ത്രമായി ബന്ധപ്പെടാവുന്ന വ്യക്തി ഫോൺ. 04712524-234

CONSENT FORM

I ___________________________ (parent/guardian) give consent on behalf of my child/my ward, named ___________________________Date of Birth / Age ___________ (in days/months/years), to participate in this study titled:

"EFFECT OF HAEMOGLOBIN LEVELS ON NEAR INFRARED SPECTROSCOPIC (NIRS) MONITORING IN CYANOTIC CONGENITAL HEART DISEASE PATIENTS"

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 child/my ward participation in the study is voluntary and that my child/ward is 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/my child/my ward permission to look at my child/my ward health records both in respect of the current study and any further research that may be conducted in relation to it, even if my child/my ward 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 of my child/my ward that arise from this study provided such a use is only for scientific purpose(s). [ ]

(v) I agree on behalf of my child/my ward to take part in the above study. [ ]

(vi) I voluntarily agree on behalf of my child/my ward to take part in this study [ ]

(vii) I have received a copy of this signed consent form [ ]

Name of the parent/guardian:
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- 9885743657

Dr H Kartheek

(Principal investigator).

സമ്മതപത്രം

ഞാൻ (അച്ഛൻ/അമ്മ/രക്ഷകർത്താവ്) .... എന്റെകുട്ടി/രക്ഷാകർതൃത്വത്തിലുള്ള (പേര്) .... ജനനതീയതി/വയസ്സ് . ... മാസങ്ങളിൽ/വർഷത്തിൽ) ....

ജന്മനാ സൈനോട്ടിക് ഹൃദ്രോഗമുള്ള രോഗികളിൽ നിയർ ഇൻഫ്രാറെഡ് സ്പെക്ട്രോസ്കോപ്പി നിരീക്ഷണത്തിലെ (എൻഐആർഎസ്) ഹീമോഗ്ലോബുലിൻ നിലവാരത്തിന്റെ പ്രഭാവം എന്ന പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതം നൽകുന്നു

(പ്രസക്തമായ കോളങ്ങളിൽ ശരിയടയാളമിടുക)

1. എനിക്കു തന്ന കാര്യവിവരണപത്രം വായിക്കുകയും മനസ്സിലാക്കുകയും ചോദ്യങ്ങൾ ചോദിക്കാൻ എനിക്ക് അവസരം ലഭിക്കുകയും ചെയ്തു. [ ]
2. എന്റെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളിന്റെ പങ്കാളിത്തം സ്വമേധയായാണെന്നും, എന്റെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളിന്റെ പതിവ് ചികിത്സയെയോ നിയമപരമായ അവകാശങ്ങളോയോ ബാധിക്കാതെ ഏതു സമയത്തും പങ്കെടുക്കുനനതിനുള്ള എന്റെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളിന്റെ അനുവാദം പിൻവലിക്കാമെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. [ ]
3. ഈ പഠനത്തിന്റെയും ഇതുമായി ബന്ധപ്പെട്ട ഭാവിയിലെ പഠനങ്ങളുടെയും ക്ലിനിക്കൽ പരിശോധനയുടെ സ്പോൺസർ, സ്പോൺസറിനുവേണ്ടി പ്രവർത്തിക്കുന്നവർ, എത്തിക്സ് കമ്മിറ്റിയും നിയന്ത്രണാധികാരികളും എന്നിവർക്ക് പഠനത്തിൽനിന്നും കുട്ടി/ രക്ഷാകതൃത്വത്തിലുള്ളയാൾപിൻമാറിയാലും ഈ പഠനവുമായി ബന്ധപ്പെട്ട ആരോഗ്യരേഖകൾ എന്റെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളിന്റെ അനുവാദം കൂടാതെ പരിശോധിക്കാമെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. അതിന് ഞാൻ സമ്മതിക്കുന്നു.
   എന്നിരുന്നാലും എന്റെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാളിന്റെ വ്യക്തിപരമായവിവരങ്ങൾ മൂന്നാം കക്ഷികൾക്കോ പ്രസിദ്ധികരണത്തിനോ നൽകില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. [ ]
4. ശാസ്ത്രീയ ഉദ്ദേശത്തോടെയുള്ള ഉപയോഗത്തിന് ഈ പഠനത്തിൽനിന്നുള്ള വിവരങ്ങൾ ഉപയോഗിക്കുന്നതിന് തടസ്സമാവില്ലെന്ന് ഞാൻ സമ്മതിക്കുന്നു.
5. എന്റെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാൾക്കുവേണ്ടി ഈ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു. [ ]
6. ഞാൻ എന്റെ കുട്ടി/രക്ഷാകതൃത്വത്തിലുള്ളയാൾക്കുവേണ്ടി സ്വമേധയാ ഈ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു. [ ]
7. സമ്മതപത്രത്തിന്റെ ഒപ്പിട്ട ഒരു പ്രതി എനിക്ക് ലഭിച്ചു. [ ]

അച്ഛൻ/അമ്മ/രക്ഷകർത്താവിന്റെ 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- 9885743657

ഡോ. എച്ച് കാർത്തീക്. ജഗദീഷ്

പ്രധാന ഗവേഷകൻ

PROFORMA

EFFECT OF HAEMOGLOBIN LEVELS ON NEAR INFRARED SPECTROSCOPIC(NIRS)MONITORING 0N CYANOTIC CONGENITAL HEART DISEASE PATIENTS

Age/sex Weight:

Diagnosis:

Operation proposed: Pre op

HB/hematocrit:

SpO2:

Echo findings:

I/O echo:

Significant I/O changes:

CPB time:

Aortic Cross clamp time:

Surgical proceduredone:

Time to awakening:

Time to extubation:

Neurological status postop:

Other information:

	Baseline	**5'**	**10'**	**15'**	**30'**	**60'**	**2h**	**3h**	**4h**	**5h**	**6h**	**7h**	**8h**	**9h**	**10h**
Heart rate															
rhythm															
SpO2															
S/D/MAP															
Temp(NP)															
rScO2(NIR S)															
Hb/Hct															
PaO2/Sao 2															
PvO2/Svo2															
CPB															

MASTER CHART

Name	Age	Gender	Weight(kg)	Hospital no.	Diagnosis	Operation Proposed	CPB Time(mins)	Pre-op Hb	Pre-op Hematocrit	Pre-op SpO2	Parameters	Baseline	1	2	3	4	5	6	7	8	9	10	
Althaf	10Y	M	25	466471	Tricuspid Atresia	TCPC	210	21	62.5	74	HR	54	58	57	52	55	61	65	68	62	59	64	
Althaf	10Y	M	25	466471	Tricuspid Atresia	TCPC	210	21	62.5	74	Rythm	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	
Althaf	10Y	M	25	466471	Tricuspid Atresia	TCPC	210	21	62.5	74	SpO2	73	80	82	79	83	100	100	100	91	89	91	
Althaf	10Y	M	25	466471	Tricuspid Atresia	TCPC	210	21	62.5	74	S/D/MAP	116/65/79	108/61/77	101/57/72	93/49/64	99/49/61	-/-/58	-/-/61	-/-/64	100/48/63	99/50/65	95/50/62	
Althaf	10Y	M	25	466471	Tricuspid Atresia	TCPC	210	21	62.5	74	Temperature	36	36	35.8	35.5	35.4	32	32	32	36	36	36	
Althaf	10Y	M	25	466471	Tricuspid Atresia	TCPC	210	21	62.5	74	rScO2(NIRS)	-	-	-	-	-	68	70	72	67	69	66	
Althaf	10Y	M	25	466471	Tricuspid Atresia	TCPC	210	21	62.5	74	HB	25.5	-	-	-	-	17	-	15	15.8			
Althaf	10Y	M	25	466471	Tricuspid Atresia	TCPC	210	21	62.5	74	Hct	77.2	-	-	-	-	53	-	46.2	47.5			
Althaf	10Y	M	25	466471	Tricuspid Atresia	TCPC	210	21	62.5	74	PaO2	51	-	-	-	-	130		170	65			
Althaf	10Y	M	25	466471	Tricuspid Atresia	TCPC	210	21	62.5	74	SaO2	77	-	-	-	-	99.5		99.2	93			
Althaf	10Y	M	25	466471	Tricuspid Atresia	TCPC	210	21	62.5	74	PvO2	39	-	-	-	-	58.3		56	55			
Althaf	10Y	M	25	466471	Tricuspid Atresia	TCPC	210	21	62.5	74	SvO2	52	-	-	-	-	79.8		81	79			
Althaf	10Y	M	25	466471	Tricuspid Atresia	TCPC	210	21	62.5	74	CPB	-	-	-	-	-	Yes	Yes	Yes	-	-	-	
Thanha	15Y	F	36	471342	DORV + VSD + Severe PS	ICR (Rastelli + PA Plasty)	190	26.8	75	78	HR	72	68	70	74	66	-	64	69	75	69		
Thanha	15Y	F	36	471342	DORV + VSD + Severe PS	ICR (Rastelli + PA Plasty)	190	26.8	75	78	Rythm	NSR	NSR	NSR	NSR	NSR	ACC	NSR	NSR	NSR	NSR		
Thanha	15Y	F	36	471342	DORV + VSD + Severe PS	ICR (Rastelli + PA Plasty)	190	26.8	75	78	SpO2	73	78	81	79	100	100	100	94	92	89		
Thanha	15Y	F	36	471342	DORV + VSD + Severe PS	ICR (Rastelli + PA Plasty)	190	26.8	75	78	S/D/MAP	72/58/65	96/73/81	91/60/68	88/55/66	82/54/67	-/-/58	-/-/55	98/60/72	100/62/74	96/56/70		
Thanha	15Y	F	36	471342	DORV + VSD + Severe PS	ICR (Rastelli + PA Plasty)	190	26.8	75	78	Temperature	36	36	36	35.2	32	32	32	36	36	36		
Thanha	15Y	F	36	471342	DORV + VSD + Severe PS	ICR (Rastelli + PA Plasty)	190	26.8	75	78	rScO2(NIRS)	-	-	-	-	74	69	73	72	66	68		
Thanha	15Y	F	36	471342	DORV + VSD + Severe PS	ICR (Rastelli + PA Plasty)	190	26.8	75	78	HB	26	-	-	-	18.9		16.9	14.9				
Thanha	15Y	F	36	471342	DORV + VSD + Severe PS	ICR (Rastelli + PA Plasty)	190	26.8	75	78	Hct	76	-	-	-	55		51.7	48				
Thanha	15Y	F	36	471342	DORV + VSD + Severe PS	ICR (Rastelli + PA Plasty)	190	26.8	75	78	PaO2	51	-	-	-	137		183	62.5				
Thanha	15Y	F	36	471342	DORV + VSD + Severe PS	ICR (Rastelli + PA Plasty)	190	26.8	75	78	SaO2	74	-	-	-	99.1		99.5	93				
Thanha	15Y	F	36	471342	DORV + VSD + Severe PS	ICR (Rastelli + PA Plasty)	190	26.8	75	78	PvO2	37	-	-	-	56.4		57.5	51.8				
Thanha	15Y	F	36	471342	DORV + VSD + Severe PS	ICR (Rastelli + PA Plasty)	190	26.8	75	78	SvO2	53	-	-	-	83.7		87.9	69				
Thanha	15Y	F	36	471342	DORV + VSD + Severe PS	ICR (Rastelli + PA Plasty)	190	26.8	75	78	CPB	-	-	-	-	Yes	Yes	Yes	-	-	-		
Anandu	15Y	M	42	249853	DILV	TCPC	240	20.7	64	81	HR	85	78	76	73	61	-	66	74	85	90	88	
Anandu	15Y	M	42	249853	DILV	TCPC	240	20.7	64	81	Rythm	NSR	NSR	NSR	NSR	NSR	ACC	NSR	NSR	NSR	NSR	NSR	
Anandu	15Y	M	42	249853	DILV	TCPC	240	20.7	64	81	SpO2	85	88	89	90	100	100	100	100	100	100	100	
Anandu	15Y	M	42	249853	DILV	TCPC	240	20.7	64	81	S/D/MAP	92/56/65	84/64/73	76/59/66	79/54/64	-/-/58	-/-/55	-/-/60	-/-/57	99/54/68	94/51/65	98/50/62	
Anandu	15Y	M	42	249853	DILV	TCPC	240	20.7	64	81	Temperature	36	35.1	34.2	34	32	32	32	34	36	36	36	
Anandu	15Y	M	42	249853	DILV	TCPC	240	20.7	64	81	rScO2(NIRS)	60	58	55	57	76	82	79	84	75	73	71	
Anandu	15Y	M	42	249853	DILV	TCPC	240	20.7	64	81	HB	21.2				14.3				16.4			
Anandu	15Y	M	42	249853	DILV	TCPC	240	20.7	64	81	Hct	64				46				50.1			
Anandu	15Y	M	42	249853	DILV	TCPC	240	20.7	64	81	PaO2	62.4				201				73.8			
Anandu	15Y	M	42	249853	DILV	TCPC	240	20.7	64	81	SaO2	90.1				100				99.5			
Anandu	15Y	M	42	249853	DILV	TCPC	240	20.7	64	81	PvO2	36.4				58.4				54.5			
Anandu	15Y	M	42	249853	DILV	TCPC	240	20.7	64	81	SvO2	62.8				84.6				78.5			
Anandu	15Y	M	42	249853	DILV	TCPC	240	20.7	64	81	CPB	-	-	-	-	Yes	Yes	Yes	Yes	-	-	-	
Devananda	7Y	M	19	364393	DILV	Single Stage Fontan	260	23.8	72.4	74	HR	100	104	96	92	100	-	-	85	90	95	99	101
Devananda	7Y	M	19	364393	DILV	Single Stage Fontan	260	23.8	72.4	74	Rythm	NSR	NSR	NSR	NSR	NSR	ACC	ACC	NSR	NSR	NSR	NSR	NSR
Devananda	7Y	M	19	364393	DILV	Single Stage Fontan	260	23.8	72.4	74	SpO2	74	85	87	88	100	100	100	100	100	100	100	100
Devananda	7Y	M	19	364393	DILV	Single Stage Fontan	260	23.8	72.4	74	S/D/MAP	84/58/69	90/51/66	87/54/65	92/55/69	-/-/50	-/-/54	-/-/51	-/-/52	-/-/55	94/56/65	89/51/64	92/54/66
Devananda	7Y	M	19	364393	DILV	Single Stage Fontan	260	23.8	72.4	74	Temperature	36	35	34.9	34.8	32	30	30	32	34	36	36	36
Devananda	7Y	M	19	364393	DILV	Single Stage Fontan	260	23.8	72.4	74	rScO2(NIRS)	-	-	-	-	66	68	65	69	66	72	74	71
Devananda	7Y	M	19	364393	DILV	Single Stage Fontan	260	23.8	72.4	74	HB	23.8				16.3		12.6		12.4	16.2		
Devananda	7Y	M	19	364393	DILV	Single Stage Fontan	260	23.8	72.4	74	Hct	72.3				49.9		38.8		38.4	49.5		
Devananda	7Y	M	19	364393	DILV	Single Stage Fontan	260	23.8	72.4	74	PaO2	49.8				182		224		209	250		
Devananda	7Y	M	19	364393	DILV	Single Stage Fontan	260	23.8	72.4	74	SaO2	77				99.5		99.6		99.5	99.6		
Devananda	7Y	M	19	364393	DILV	Single Stage Fontan	260	23.8	72.4	74	PvO2	39.2				56		58.6		56.7	51.7		

Devananda	7Y	M	19	364393	DILV	Single Stage Fontan	260	23.8	72.4	74	SvO2	56.6				85		91.3		85.9	79.8		
Devananda	7Y	M	19	364393	DILV	Single Stage Fontan	260	23.8	72.4	74	CPB	-	-	-	-	Yes	Yes	Yes	Yes	Yes	-	-	-
Abhishek	13Y	M	67	266206	Pulmonary Atresia	ICR+Conduit	200	20.5	63	81	HR	80	71	80	79	72	75	68	81	84	90		
Abhishek	13Y	M	67	266206	Pulmonary Atresia	ICR+Conduit	200	20.5	63	81	Rythm	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR		
Abhishek	13Y	M	67	266206	Pulmonary Atresia	ICR+Conduit	200	20.5	63	81	SpO2	84	95	100	100	100	100	100	100	100	100		
Abhishek	13Y	M	67	266206	Pulmonary Atresia	ICR+Conduit	200	20.5	63	81	S/D/MAP	86/50/62	94/56/66	90/54/63	97/56/66	-/-/61	-/-/64	-/-/59	-/-/57	91/54/65	98/58/69		
Abhishek	13Y	M	67	266206	Pulmonary Atresia	ICR+Conduit	200	20.5	63	81	Temperature	36	36	35	34	32	32	32	32	36	36		
Abhishek	13Y	M	67	266206	Pulmonary Atresia	ICR+Conduit	200	20.5	63	81	rScO2(NIRS)	-	-	-	-	66	63	61	62	66	64		
Abhishek	13Y	M	67	266206	Pulmonary Atresia	ICR+Conduit	200	20.5	63	81	HB	21.2				16.4				15.5			
Abhishek	13Y	M	67	266206	Pulmonary Atresia	ICR+Conduit	200	20.5	63	81	Hct	65				50.2				50			
Abhishek	13Y	M	67	266206	Pulmonary Atresia	ICR+Conduit	200	20.5	63	81	PaO2	51				171				105			
Abhishek	13Y	M	67	266206	Pulmonary Atresia	ICR+Conduit	200	20.5	63	81	SaO2	82.6				99.5				99			
Abhishek	13Y	M	67	266206	Pulmonary Atresia	ICR+Conduit	200	20.5	63	81	PvO2	42				74				68			
Abhishek	13Y	M	67	266206	Pulmonary Atresia	ICR+Conduit	200	20.5	63	81	SvO2	69.5				85				84			
Abhishek	13Y	M	67	266206	Pulmonary Atresia	ICR+Conduit	200	20.5	63	81	CPB	-	-	-	-	Yes	Yes	Yes	Yes	-	-		
Aleena	8Y	F	29	350477	TOF	ICR + TAP	220	20.2	61	80	HR	80	102	98	-	-	-	-	111	118			
Aleena	8Y	F	29	350477	TOF	ICR + TAP	220	20.2	61	80	Rythm	NSR	NSR	NSR	-	-	-	-	NSR	NSR			
Aleena	8Y	F	29	350477	TOF	ICR + TAP	220	20.2	61	80	SpO2	80	92	94	100	100	100	100	100	100			
Aleena	8Y	F	29	350477	TOF	ICR + TAP	220	20.2	61	80	S/D/MAP	90/50/66	82/48/62	88/51/65	-/-/63	-/-/51	-/-/52	-/-/54	77/59/68	84/61/69			
Aleena	8Y	F	29	350477	TOF	ICR + TAP	220	20.2	61	80	Temperature	36	30	35	34.5	32	32	32	36	36			
Aleena	8Y	F	29	350477	TOF	ICR + TAP	220	20.2	61	80	rScO2(NIRS)	68	70	65	68	70	71	74	67	65			
Aleena	8Y	F	29	350477	TOF	ICR + TAP	220	20.2	61	80	HB	20.2			13.6		12.9		13.6				
Aleena	8Y	F	29	350477	TOF	ICR + TAP	220	20.2	61	80	Hct	61			41.5		40		41				
Aleena	8Y	F	29	350477	TOF	ICR + TAP	220	20.2	61	80	PaO2	62.7			195		239		81.1				
Aleena	8Y	F	29	350477	TOF	ICR + TAP	220	20.2	61	80	SaO2	92			97.8		97.9		97				
Aleena	8Y	F	29	350477	TOF	ICR + TAP	220	20.2	61	80	PvO2	37.7			44.7		36.3		34.2				
Aleena	8Y	F	29	350477	TOF	ICR + TAP	220	20.2	61	80	SvO2	75.5			83		68.7		64.2				
Aleena	8Y	F	29	350477	TOF	ICR + TAP	220	20.2	61	80	CPB				Yes	Yes	Yes	Yes	-				
Manju	15Y	F	32	491725	Tricuspid Atresia	TCPC	160	22	70	75	HR	100	88	90	94	84	80	-	90	92			
Manju	15Y	F	32	491725	Tricuspid Atresia	TCPC	160	22	70	75	Rythm	NSR	NSR	NSR	NSR	NSR	NSR	-	NSR	NSR			
Manju	15Y	F	32	491725	Tricuspid Atresia	TCPC	160	22	70	75	SpO2	75	81	80	81	81	78	100	100	100			
Manju	15Y	F	32	491725	Tricuspid Atresia	TCPC	160	22	70	75	S/D/MAP	125/88/95	104/71/85	104/64/84	107/70/85	94/59/73	81/52/64	-/-/54	-/-/58	78/48/59			
Manju	15Y	F	32	491725	Tricuspid Atresia	TCPC	160	22	70	75	Temperature	36	35	35	34.2	33.2	33	32	32	36			
Manju	15Y	F	32	491725	Tricuspid Atresia	TCPC	160	22	70	75	rScO2(NIRS)	-	-	-	-	-	68	72	74	66			
Manju	15Y	F	32	491725	Tricuspid Atresia	TCPC	160	22	70	75	HB	22	-	-	-	-	15.3	-	12.8	12.6			
Manju	15Y	F	32	491725	Tricuspid Atresia	TCPC	160	22	70	75	Hct	70	-	-	-	-	48	-	39	38.5			
Manju	15Y	F	32	491725	Tricuspid Atresia	TCPC	160	22	70	75	PaO2	51.3	-	-	-	-	199	-	138	93.5			
Manju	15Y	F	32	491725	Tricuspid Atresia	TCPC	160	22	70	75	SaO2	77.6	-	-	-	-	99.5	-	99.3	97.8			
Manju	15Y	F	32	491725	Tricuspid Atresia	TCPC	160	22	70	75	PvO2	37.7	-	-	-	-	53.9	-	65.1	46.5			
Manju	15Y	F	32	491725	Tricuspid Atresia	TCPC	160	22	70	75	SvO2	62.4	-	-	-	-	83.9	-	92.8	76.8			
Manju	15Y	F	32	491725	Tricuspid Atresia	TCPC	160	22	70	75	CPB	-	-	-	-	-	Yes	Yes	-	-			
Abhinav	12Y	M	30	292555	Unbalanced AVCD	TCPC	300	20.9	65	82	HR	100	98	98	96	104	108	104	105	-	-	114	
Abhinav	12Y	M	30	292555	Unbalanced AVCD	TCPC	300	20.9	65	82	Rythm	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	-	-	NSR	
Abhinav	12Y	M	30	292555	Unbalanced AVCD	TCPC	300	20.9	65	82	SpO2	82	84	9	93	95	100	100	100	100	100	100	
Abhinav	12Y	M	30	292555	Unbalanced AVCD	TCPC	300	20.9	65	82	S/D/MAP	90/60/72	101/59/89	100/71/81	115/77/87	106/69/89	-/-/65	-/-/68	-/-/67	-/-/69	-/-/65	98/52/68	
Abhinav	12Y	M	30	292555	Unbalanced AVCD	TCPC	300	20.9	65	82	Temperature	36	35.5	35	34.8	34.5	32	32	32	32	32	36	
Abhinav	12Y	M	30	292555	Unbalanced AVCD	TCPC	300	20.9	65	82	rScO2(NIRS)	56	58	54	59	56	62	64	65	64	65	59	
Abhinav	12Y	M	30	292555	Unbalanced AVCD	TCPC	300	20.9	65	82	HB	20.9	-	-	-	-	13	12	-	-	-	12.2	
Abhinav	12Y	M	30	292555	Unbalanced AVCD	TCPC	300	20.9	65	82	Hct	65	-	-	-	-	40.5	37.2	-	-	-	37	
Abhinav	12Y	M	30	292555	Unbalanced AVCD	TCPC	300	20.9	65	82	PaO2	62.7	-	-	-	-	235	153	-	-	-	91.8	
Abhinav	12Y	M	30	292555	Unbalanced AVCD	TCPC	300	20.9	65	82	SaO2	89.4	-	-	-	-	99.5	99.1	-	-	-	97.5	
Abhinav	12Y	M	30	292555	Unbalanced AVCD	TCPC	300	20.9	65	82	PvO2	44.3	-	-	-	-	70.6	61	-	-	-	42	
Abhinav	12Y	M	30	292555	Unbalanced AVCD	TCPC	300	20.9	65	82	SvO2	73.3	-	-	-	-	93	88.7	-	-	-	69.7	
Abhinav	12Y	M	30	292555	Unbalanced AVCD	TCPC	300	20.9	65	82	CPB	-	-	-	-	-	Yes	Yes	Yes	Yes	Yes	-	
Jabeena	13Y	F	32	422711	TOF	ICR+MCR	280	22.7	67.6	75	HR	80	75	85	88	-	-	-	-	-	103	110	
Jabeena	13Y	F	32	422711	TOF	ICR+MCR	280	22.7	67.6	75	Rythm	NSR	NSR	NSR	NSR	-	-	-	-	-	NSR	NSR	
Jabeena	13Y	F	32	422711	TOF	ICR+MCR	280	22.7	67.6	75	SpO2	75	82	81	79	100	100	100	100	100	100	100	
Jabeena	13Y	F	32	422711	TOF	ICR+MCR	280	22.7	67.6	75	S/D/MAP	91/61/74	83/64/72	77/59/67	100/64/77	-/-/55	-/-/52	-/-/54	-/-/59	-/-/51	88/48/60	92/50/62	
Jabeena	13Y	F	32	422711	TOF	ICR+MCR	280	22.7	67.6	75	Temperature	36	35	34.8	34.7	32	32	32	32	32	36	36	

Jabeena	13Y	F	32	422711	TOF	ICR+MCR	280	22.7	67.6	75	rScO2(NIRS)	-	-	-	-	72	74	68	70	74	68	66	
Jabeena	13Y	F	32	422711	TOF	ICR+MCR	280	22.7	67.6	75	HB	22.7	-	-	-	17	-	-	13.9	-	14.7	-	
Jabeena	13Y	F	32	422711	TOF	ICR+MCR	280	22.7	67.6	75	Hct	67.6	-	-	-	51.9	-	-	41	-	45.5	-	
Jabeena	13Y	F	32	422711	TOF	ICR+MCR	280	22.7	67.6	75	PaO2	47.1	-	-	-	80.6	-	-	197	-	89.1	-	
Jabeena	13Y	F	32	422711	TOF	ICR+MCR	280	22.7	67.6	75	SaO2	76.3	-	-	-	94.3	-	-	99	-	95.5	-	
Jabeena	13Y	F	32	422711	TOF	ICR+MCR	280	22.7	67.6	75	PvO2	39	-	-	-	51.5	-	-	52.2	-	49.3	-	
Jabeena	13Y	F	32	422711	TOF	ICR+MCR	280	22.7	67.6	75	SvO2	65.2	-	-	-	77	-	-	81.1	-	73.7	-	
Jabeena	13Y	F	32	422711	TOF	ICR+MCR	280	22.7	67.6	75	CPB	-	-	-	-	Yes	Yes	Yes	Yes	Yes	-	-	
B/o Athira	1Y	M	9	484595	Pulmonary Atreisa	ICR + Conduit	180	21.5	65	78	HR	130	108	105	-	-	-	111					
B/o Athira	1Y	M	9	484595	Pulmonary Atreisa	ICR + Conduit	180	21.5	65	78	Rythm	NSR	NSR	NSR	-	-	-	NSR					
B/o Athira	1Y	M	9	484595	Pulmonary Atreisa	ICR + Conduit	180	21.5	65	78	SpO2	75	78	78	100	100	100	83					
B/o Athira	1Y	M	9	484595	Pulmonary Atreisa	ICR + Conduit	180	21.5	65	78	S/D/MAP	78/54/62	72/48/59	69/45/57	-/-/45	-/-/48	-/-/43	83/55/65					
B/o Athira	1Y	M	9	484595	Pulmonary Atreisa	ICR + Conduit	180	21.5	65	78	Temperature	36	35.5	35	32	32	32	36					
B/o Athira	1Y	M	9	484595	Pulmonary Atreisa	ICR + Conduit	180	21.5	65	78	rScO2(NIRS)	-	-	-	55	53	54	51					
B/o Athira	1Y	M	9	484595	Pulmonary Atreisa	ICR + Conduit	180	21.5	65	78	HB	21.5	-	-	14.7	-	-	16.2					
B/o Athira	1Y	M	9	484595	Pulmonary Atreisa	ICR + Conduit	180	21.5	65	78	Hct	65	-	-	45.6	-	-	49.5					
B/o Athira	1Y	M	9	484595	Pulmonary Atreisa	ICR + Conduit	180	21.5	65	78	PaO2	50	-	-	78	-	-	45.3					
B/o Athira	1Y	M	9	484595	Pulmonary Atreisa	ICR + Conduit	180	21.5	65	78	SaO2	80	-	-	95.8	-	-	83.9					
B/o Athira	1Y	M	9	484595	Pulmonary Atreisa	ICR + Conduit	180	21.5	65	78	PvO2	36.1	-	-	45	-	-	35					
B/o Athira	1Y	M	9	484595	Pulmonary Atreisa	ICR + Conduit	180	21.5	65	78	SvO2	60.6	-	-	77.8	-	-	65.4					
B/o Athira	1Y	M	9	484595	Pulmonary Atreisa	ICR + Conduit	180	21.5	65	78	CPB	-	-	-	Yes	Yes	Yes	-					
Mary Medona	10Y	F	28	322546	Pulmonary Atreisa	TCPC	160	20.1	62	65	HR	85	76	71	74	72	70	68	74	75			
Mary Medona	10Y	F	28	322546	Pulmonary Atreisa	TCPC	160	20.1	62	65	Rythm	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR			
Mary Medona	10Y	F	28	322546	Pulmonary Atreisa	TCPC	160	20.1	62	65	SpO2	65	73	72	70	72	70	75	85	84			
Mary Medona	10Y	F	28	322546	Pulmonary Atreisa	TCPC	160	20.1	62	65	S/D/MAP	88/52/64	101/59/71	86/53/63	89/56/64	87/54/63	-/-/55	-/-/52	-/-/51	79/45/56			
Mary Medona	10Y	F	28	322546	Pulmonary Atreisa	TCPC	160	20.1	62	65	Temperature	36	35	34.5	34.4	34.4	32	32	32	36			
Mary Medona	10Y	F	28	322546	Pulmonary Atreisa	TCPC	160	20.1	62	65	rScO2(NIRS)	-	-	-	-	-	84	86	85	-			
Mary Medona	10Y	F	28	322546	Pulmonary Atreisa	TCPC	160	20.1	62	65	HB	20.1	-	-	-	-	16.4	-	16.6	18.1			
Mary Medona	10Y	F	28	322546	Pulmonary Atreisa	TCPC	160	20.1	62	65	Hct	62	-	-	-	-	50.3	-	50.9	56			
Mary Medona	10Y	F	28	322546	Pulmonary Atreisa	TCPC	160	20.1	62	65	PaO2	41.2	-	-	-	-	200	-	137	53.2			
Mary Medona	10Y	F	28	322546	Pulmonary Atreisa	TCPC	160	20.1	62	65	SaO2	62.4	-	-	-	-	99.7	-	99.4	77.8			
Mary Medona	10Y	F	28	322546	Pulmonary Atreisa	TCPC	160	20.1	62	65	PvO2	35.3	-	-	-	-	59.2	-	63.3	46.8			
Mary Medona	10Y	F	28	322546	Pulmonary Atreisa	TCPC	160	20.1	62	65	SvO2	48.9	-	-	-	-	89	-	90.3	70.1			
Mary Medona	10Y	F	28	322546	Pulmonary Atreisa	TCPC	160	20.1	62	65	CPB	-	-	-	-	-	Yes	Yes	Yes	-			
Amal	1Y	M	5.5	494526	TOF	ICR+TAP	300	20.5	65	78	HR	140	120	115	-	-	-	-	-	140	135		
Amal	1Y	M	5.5	494526	TOF	ICR+TAP	300	20.5	65	78	Rythm	NSR	NSR	NSR	-	-	-	-	-	NSR	NSR		
Amal	1Y	M	5.5	494526	TOF	ICR+TAP	300	20.5	65	78	SpO2	76	79	75	100	100	100	100	100	89	91		
Amal	1Y	M	5.5	494526	TOF	ICR+TAP	300	20.5	65	78	S/D/MAP	66/39/46	71/37/48	74/40/50	-/-/38	-/-/41	-/-/43	-/-/39	-/-/44	68/31/44	70/36/45		
Amal	1Y	M	5.5	494526	TOF	ICR+TAP	300	20.5	65	78	Temperature	36	35	34	28	28	28	28	28	36	36		
Amal	1Y	M	5.5	494526	TOF	ICR+TAP	300	20.5	65	78	rScO2(NIRS)	-	-	-	65	58	62	66	61	58	61		
Amal	1Y	M	5.5	494526	TOF	ICR+TAP	300	20.5	65	78	HB	20.5	-	-	14.1	-	-	10.9	-	14.5	-		
Amal	1Y	M	5.5	494526	TOF	ICR+TAP	300	20.5	65	78	Hct	65	-	-	43.8	-	-	33.6	-	43.9	-		
Amal	1Y	M	5.5	494526	TOF	ICR+TAP	300	20.5	65	78	PaO2	51.2	-	-	225	-	-	126	-	84.3	-		
Amal	1Y	M	5.5	494526	TOF	ICR+TAP	300	20.5	65	78	SaO2	82.3	-	-	99.8	-	-	99.2	-	97.6	-		
Amal	1Y	M	5.5	494526	TOF	ICR+TAP	300	20.5	65	78	PvO2	41.2	-	-	37.3	-	-	37.9	-	36.4	-		
Amal	1Y	M	5.5	494526	TOF	ICR+TAP	300	20.5	65	78	SvO2	69.2	-	-	77.1	-	-	76.2	-	75.9	-		
Amal	1Y	M	5.5	494526	TOF	ICR+TAP	300	20.5	65	78	CPB	-	-	-	Yes	Yes	Yes	Yes	Yes	-	-		
M Nasim	2Y	F	9	496753	TOF	ICR+RVOT Patch	130	20.1	61.9	86	HR	140	136	134	125	-	-	137					
M Nasim	2Y	F	9	496753	TOF	ICR+RVOT Patch	130	20.1	61.9	86	Rythm	NSR	NSR	NSR	NSR	-	-	NSR					
M Nasim	2Y	F	9	496753	TOF	ICR+RVOT Patch	130	20.1	61.9	86	SpO2	86	85	88	81	100	100	100					
M Nasim	2Y	F	9	496753	TOF	ICR+RVOT Patch	130	20.1	61.9	86	S/D/MAP	96/53/64	88/54/67	90/64/73	-/-/48	-/-/52	-/-/55	96/62/71					
M Nasim	2Y	F	9	496753	TOF	ICR+RVOT Patch	130	20.1	61.9	86	Temperature	36	35.6	35	32	32	32	36					
M Nasim	2Y	F	9	496753	TOF	ICR+RVOT Patch	130	20.1	61.9	86	rScO2(NIRS)	64	61	64	70	71	68	65					
M Nasim	2Y	F	9	496753	TOF	ICR+RVOT Patch	130	20.1	61.9	86	HB	20.1	-	-	14	-	-	18.3					
M Nasim	2Y	F	9	496753	TOF	ICR+RVOT Patch	130	20.1	61.9	86	Hct	61.9	-	-	43.5	-	-	55.9					
M Nasim	2Y	F	9	496753	TOF	ICR+RVOT Patch	130	20.1	61.9	86	PaO2	58.6	-	-	197	-	-	105					
M Nasim	2Y	F	9	496753	TOF	ICR+RVOT Patch	130	20.1	61.9	86	SaO2	85.9	-	-	99.7	-	-	99.5					
M Nasim	2Y	F	9	496753	TOF	ICR+RVOT Patch	130	20.1	61.9	86	PvO2	44.9	-	-	38.1	-	-	39.2					
M Nasim	2Y	F	9	496753	TOF	ICR+RVOT Patch	130	20.1	61.9	86	SvO2	71.6	-	-	73.3	-	-	78.2					
M Nasim	2Y	F	9	496753	TOF	ICR+RVOT Patch	130	20.1	61.9	86	CPB	-	-	-	Yes	Yes	Yes	-					

Rajesh	15Y	M	48	484035	DILV	BDG	120	25.9	75.9	75	HR	80	76	88	84	80	85					
Rajesh	15Y	M	48	484035	DILV	BDG	120	25.9	75.9	75	Rythm	NSR	NSR	NSR	NSR	NSR	NSR					
Rajesh	15Y	M	48	484035	DILV	BDG	120	25.9	75.9	75	SpO2	82	78	74	78	80	76					
Rajesh	15Y	M	48	484035	DILV	BDG	120	25.9	75.9	75	S/D/MAP	95/71/80	91/64/75	-/-/65	-/-/62	-/-/60	98/65/75					
Rajesh	15Y	M	48	484035	DILV	BDG	120	25.9	75.9	75	Temperature	36	35	34	32	32	36					
Rajesh	15Y	M	48	484035	DILV	BDG	120	25.9	75.9	75	rScO2(NIRS)	-	-	-	-	-	-					
Rajesh	15Y	M	48	484035	DILV	BDG	120	25.9	75.9	75	HB	25.9	-	19.9	-	17.6	17.3					
Rajesh	15Y	M	48	484035	DILV	BDG	120	25.9	75.9	75	Hct	75.9	-	60.7	-	56.9	53					
Rajesh	15Y	M	48	484035	DILV	BDG	120	25.9	75.9	75	PaO2	40.1	-	157	-	132	50.5					
Rajesh	15Y	M	48	484035	DILV	BDG	120	25.9	75.9	75	SaO2	70.5	-	99	-	98.9	86.3					
Rajesh	15Y	M	48	484035	DILV	BDG	120	25.9	75.9	75	PvO2	32.5	-	37.5	-	38.1	33.1					
Rajesh	15Y	M	48	484035	DILV	BDG	120	25.9	75.9	75	SvO2	59	-	54.4	-	72.4	62.3					
Rajesh	15Y	M	48	484035	DILV	BDG	120	25.9	75.9	75	CPB	-	-	Yes	Yes	Yes	-					
Rathi Selvi	17Y	F	35	265929	Tricuspid Atresia	TCPC	150	20.4	63	72	HR	74	67	70	69	77	74	71	93			
Rathi Selvi	17Y	F	35	265929	Tricuspid Atresia	TCPC	150	20.4	63	72	Rythm	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR			
Rathi Selvi	17Y	F	35	265929	Tricuspid Atresia	TCPC	150	20.4	63	72	SpO2	82	80	83	79	100	100	100	100			
Rathi Selvi	17Y	F	35	265929	Tricuspid Atresia	TCPC	150	20.4	63	72	S/D/MAP	96/58/71	93/55/68	89/56/69	99/61/74	-/-/62	-/-/59	-/-/63	103/69/81			
Rathi Selvi	17Y	F	35	265929	Tricuspid Atresia	TCPC	150	20.4	63	72	Temperature	36	35.5	34	33.8	32	32	32	36			
Rathi Selvi	17Y	F	35	265929	Tricuspid Atresia	TCPC	150	20.4	63	72	rScO2(NIRS)	52	55	54	54	58	61	61	54			
Rathi Selvi	17Y	F	35	265929	Tricuspid Atresia	TCPC	150	20.4	63	72	HB	20.4	-	-	-	13.3	11.6	-	14.1			
Rathi Selvi	17Y	F	35	265929	Tricuspid Atresia	TCPC	150	20.4	63	72	Hct	63	-	-	-	40.8	33.5	-	43.2			
Rathi Selvi	17Y	F	35	265929	Tricuspid Atresia	TCPC	150	20.4	63	72	PaO2	58.5	-	-	-	273	267	-	174			
Rathi Selvi	17Y	F	35	265929	Tricuspid Atresia	TCPC	150	20.4	63	72	SaO2	87.4	-	-	-	99	97.8	-	98.7			
Rathi Selvi	17Y	F	35	265929	Tricuspid Atresia	TCPC	150	20.4	63	72	PvO2	32.8	-	-	-	56.8	49	-	68.1			
Rathi Selvi	17Y	F	35	265929	Tricuspid Atresia	TCPC	150	20.4	63	72	SvO2	54.1	-	-	-	89.9	88.5	-	75.4			
Rathi Selvi	17Y	F	35	265929	Tricuspid Atresia	TCPC	150	20.4	63	72	CPB	-	-	-	-	Yes	Yes	Yes	-			
Adhil Krishna	8Y	M	27	357839	Unbalanced AVCD	TCPC	250	21	64	75	HR	84	95	80	103	-	-	-	120			
Adhil Krishna	8Y	M	27	357839	Unbalanced AVCD	TCPC	250	21	64	75	Rythm	NSR	NSR	NSR	NSR	-	-	-	NSR			
Adhil Krishna	8Y	M	27	357839	Unbalanced AVCD	TCPC	250	21	64	75	SpO2	72	92	93	99	100	100	100	88			
Adhil Krishna	8Y	M	27	357839	Unbalanced AVCD	TCPC	250	21	64	75	S/D/MAP	87/52/63	79/54/68	80/60/69	-/-/52	-/-/58	-/-/54	-/-/49	85/50/61			
Adhil Krishna	8Y	M	27	357839	Unbalanced AVCD	TCPC	250	21	64	75	Temperature	36	34.5	34	32	32	32	32	36			
Adhil Krishna	8Y	M	27	357839	Unbalanced AVCD	TCPC	250	21	64	75	rScO2(NIRS)	-	-	-	72	69	74	70	73			
Adhil Krishna	8Y	M	27	357839	Unbalanced AVCD	TCPC	250	21	64	75	HB	21			15.8	-	14.5	14.4	18.8			
Adhil Krishna	8Y	M	27	357839	Unbalanced AVCD	TCPC	250	21	64	75	Hct	64			48	-	46	45.5	57			
Adhil Krishna	8Y	M	27	357839	Unbalanced AVCD	TCPC	250	21	64	75	PaO2	47			183	-	287	166	58.6			
Adhil Krishna	8Y	M	27	357839	Unbalanced AVCD	TCPC	250	21	64	75	SaO2	74			98.7	-	99.1	98.8	82.2			
Adhil Krishna	8Y	M	27	357839	Unbalanced AVCD	TCPC	250	21	64	75	PvO2	34			71.8	-	67.7	52.1	38.9			
Adhil Krishna	8Y	M	27	357839	Unbalanced AVCD	TCPC	250	21	64	75	SvO2	56			93.6	-	91.8	83.9	59			
Adhil Krishna	8Y	M	27	357839	Unbalanced AVCD	TCPC	250	21	64	75	CPB	-	-	-	Yes	Yes	Yes	Yes	-			
Johan Joshy	2Y	M	10	474410	Critical Pulmonary Stenosis	BDG	120	21.3	64.5	80	HR	136	121	126	128	132	131	124				
Johan Joshy	2Y	M	10	474410	Critical Pulmonary Stenosis	BDG	120	21.3	64.5	80	Rythm	NSR	NSR	NSR	NSR	NSR	NSR	NSR				
Johan Joshy	2Y	M	10	474410	Critical Pulmonary Stenosis	BDG	120	21.3	64.5	80	SpO2	80	83	84	100	100	100	92				
Johan Joshy	2Y	M	10	474410	Critical Pulmonary Stenosis	BDG	120	21.3	64.5	80	S/D/MAP	85/59/70	87/62/68	84/59/65	-/-/51	-/-/54	-/-/55	97/50/67				
Johan Joshy	2Y	M	10	474410	Critical Pulmonary Stenosis	BDG	120	21.3	64.5	80	Temperature	36	35.5	35	32	32	32	36				
Johan Joshy	2Y	M	10	474410	Critical Pulmonary Stenosis	BDG	120	21.3	64.5	80	rScO2(NIRS)	76	78	74	72	78	80	72				
Johan Joshy	2Y	M	10	474410	Critical Pulmonary Stenosis	BDG	120	21.3	64.5	80	HB	21.3	-	-	13	-	-	16.1				
Johan Joshy	2Y	M	10	474410	Critical Pulmonary Stenosis	BDG	120	21.3	64.5	80	Hct	64.5	-	-	39.9	-	-	49.4				
Johan Joshy	2Y	M	10	474410	Critical Pulmonary Stenosis	BDG	120	21.3	64.5	80	PaO2	61.1	-	-	107.9	-	-	62.9				
Johan Joshy	2Y	M	10	474410	Critical Pulmonary Stenosis	BDG	120	21.3	64.5	80	SaO2	86.2	-	-	98.3	-	-	91.7				
Johan Joshy	2Y	M	10	474410	Critical Pulmonary Stenosis	BDG	120	21.3	64.5	80	PvO2	42.6	-	-	42.6	-	-	46.1				
Johan Joshy	2Y	M	10	474410	Critical Pulmonary Stenosis	BDG	120	21.3	64.5	80	SvO2	69.6	-	-	77	-	-	77.1				
Johan Joshy	2Y	M	10	474410	Critical Pulmonary Stenosis	BDG	120	21.3	64.5	80	CPB	-	-	-	Yes	Yes	Yes	-				
Rifana	6Y	F	16	404057	DORV	BDG	200	26.2	79.8	75	HR	85	88	83	81	100	102	98	95	105		
Rifana	6Y	F	16	404057	DORV	BDG	200	26.2	79.8	75	Rythm	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR		
Rifana	6Y	F	16	404057	DORV	BDG	200	26.2	79.8	75	SpO2	76	75	78	81	100	100	100	100	85		
Rifana	6Y	F	16	404057	DORV	BDG	200	26.2	79.8	75	S/D/MAP	78/58/64	81/60/69	89/61/69	85/59/68	-/-/48	-/-/52	-/-/48	-/-/54	81/52/63		
Rifana	6Y	F	16	404057	DORV	BDG	200	26.2	79.8	75	Temperature	36	35	34.5	34	32	32	32	32	36		
Rifana	6Y	F	16	404057	DORV	BDG	200	26.2	79.8	75	rScO2(NIRS)	-	-	-	-	75	78	72	71	68		
Rifana	6Y	F	16	404057	DORV	BDG	200	26.2	79.8	75	HB	26.2	-	-	-	18.6	-	17.5	-	17.7		
Rifana	6Y	F	16	404057	DORV	BDG	200	26.2	79.8	75	Hct	79.8	-	-	-	56.8	-	53.5	-	54.8		

Rifana	6Y	F	16	404057	DORV	BDG	200	26.2	79.8	75	PaO2	49.4	-	-	-	263	-	73.6	-	50.9			
Rifana	6Y	F	16	404057	DORV	BDG	200	26.2	79.8	75	SaO2	80.8	-	-	-	99.1	-	94.9	-	84.8			
Rifana	6Y	F	16	404057	DORV	BDG	200	26.2	79.8	75	PvO2	39.7	-	-	-	55.6	-	46.3	-	34.4			
Rifana	6Y	F	16	404057	DORV	BDG	200	26.2	79.8	75	SvO2	61.7	-	-	-	83.5	-	78.2	-	60.4			
Rifana	6Y	F	16	404057	DORV	BDG	200	26.2	79.8	75	CPB	-	-	-	-	Yes	Yes	Yes	Yes	-			
Anurudh	11Y	M	24	448643	TOF	ICR+TAP+MCR	240	23.7	72	78	HR	101	91	-	-	-	-	-	93	99			
Anurudh	11Y	M	24	448643	TOF	ICR+TAP+MCR	240	23.7	72	78	Rythm	NSR	NSR	-	-	-	-	-	NSR	NSR			
Anurudh	11Y	M	24	448643	TOF	ICR+TAP+MCR	240	23.7	72	78	SpO2	78	75	100	100	100	100	100	99	96			
Anurudh	11Y	M	24	448643	TOF	ICR+TAP+MCR	240	23.7	72	78	S/D/MAP	98/59/68	73/55/65	-/-/50	-/-/50	-/-/48	-/-/52	-/-/54	70/44/53	87/53/66			
Anurudh	11Y	M	24	448643	TOF	ICR+TAP+MCR	240	23.7	72	78	Temperature	36	35	32	28	28	28	28	36	36			
Anurudh	11Y	M	24	448643	TOF	ICR+TAP+MCR	240	23.7	72	78	rScO2(NIRS)	-	-	66	69	62	65	66	63	64			
Anurudh	11Y	M	24	448643	TOF	ICR+TAP+MCR	240	23.7	72	78	HB	23.7	-	17.2	-	-	16.4	-	17.1	-			
Anurudh	11Y	M	24	448643	TOF	ICR+TAP+MCR	240	23.7	72	78	Hct	72	-	52.6	-	-	50.3	-	52.3	-			
Anurudh	11Y	M	24	448643	TOF	ICR+TAP+MCR	240	23.7	72	78	PaO2	47.4	-	224	-	-	122	-	227	-			
Anurudh	11Y	M	24	448643	TOF	ICR+TAP+MCR	240	23.7	72	78	SaO2	76.5	-	99	-	-	98.2	-	99.3	-			
Anurudh	11Y	M	24	448643	TOF	ICR+TAP+MCR	240	23.7	72	78	PvO2	39.7	-	61.1	-	-	43.5	-	48.7	-			
Anurudh	11Y	M	24	448643	TOF	ICR+TAP+MCR	240	23.7	72	78	SvO2	61	-	89.5	-	-	77	-	77.8	-			
Anurudh	11Y	M	24	448643	TOF	ICR+TAP+MCR	240	23.7	72	78	CPB	-	-	Yes	Yes	Yes	Yes	Yes	-	-			
Haadiya Nowrin	1Y	F	8	488551	TOF	ICR	130	20.2	61.1	77	HR	110	102	-	-	116							
Haadiya Nowrin	1Y	F	8	488551	TOF	ICR	130	20.2	61.1	77	Rythm	NSR	NSR	-	-	NSR							
Haadiya Nowrin	1Y	F	8	488551	TOF	ICR	130	20.2	61.1	77	SpO2	80	82	100	100	88							
Haadiya Nowrin	1Y	F	8	488551	TOF	ICR	130	20.2	61.1	77	S/D/MAP	101/68/76	89/54/67	-/-/51	-/-/48	97/44/69							
Haadiya Nowrin	1Y	F	8	488551	TOF	ICR	130	20.2	61.1	77	Temperature	36	35	32	32	36							
Haadiya Nowrin	1Y	F	8	488551	TOF	ICR	130	20.2	61.1	77	rScO2(NIRS)	-	-	61	57	55							
Haadiya Nowrin	1Y	F	8	488551	TOF	ICR	130	20.2	61.1	77	HB	20.2	-	13	-	14.6							
Haadiya Nowrin	1Y	F	8	488551	TOF	ICR	130	20.2	61.1	77	Hct	61.1	-	39.9	-	44.9							
Haadiya Nowrin	1Y	F	8	488551	TOF	ICR	130	20.2	61.1	77	PaO2	43	-	104	-	44.4							
Haadiya Nowrin	1Y	F	8	488551	TOF	ICR	130	20.2	61.1	77	SaO2	75.6	-	97.7	-	81.3							
Haadiya Nowrin	1Y	F	8	488551	TOF	ICR	130	20.2	61.1	77	PvO2	29	-	47.4	-	30							
Haadiya Nowrin	1Y	F	8	488551	TOF	ICR	130	20.2	61.1	77	SvO2	43.1	-	77.2	-	49.7							
Haadiya Nowrin	1Y	F	8	488551	TOF	ICR	130	20.2	61.1	77	CPB	-	-	Yes	Yes	-							
Md Navaf	12Y	M	31	363512	Unbalanced AVCD	TCPC	200	20.5	62.4	83	HR	90	94	90	-	-	-	90	88				
Md Navaf	12Y	M	31	363512	Unbalanced AVCD	TCPC	200	20.5	62.4	83	Rythm	NSR	NSR	NSR	-	-	-	NSR	NSR				
Md Navaf	12Y	M	31	363512	Unbalanced AVCD	TCPC	200	20.5	62.4	83	SpO2	82	86	84	100	100	100	100	100				
Md Navaf	12Y	M	31	363512	Unbalanced AVCD	TCPC	200	20.5	62.4	83	S/D/MAP	79/54/62	88/58/66	88/59/67	-/-/45	-/-/48	-/-/53	90/58/71	80/51/62				
Md Navaf	12Y	M	31	363512	Unbalanced AVCD	TCPC	200	20.5	62.4	83	Temperature	36	35	34	32	28	28	28	36				
Md Navaf	12Y	M	31	363512	Unbalanced AVCD	TCPC	200	20.5	62.4	83	rScO2(NIRS)	57	55	52	60	64	59	64	67				
Md Navaf	12Y	M	31	363512	Unbalanced AVCD	TCPC	200	20.5	62.4	83	HB	20.5	-	-	12.3	-	13	13.8	-				
Md Navaf	12Y	M	31	363512	Unbalanced AVCD	TCPC	200	20.5	62.4	83	Hct	62.4	-	-	37.9	-	40	42.4	-				
Md Navaf	12Y	M	31	363512	Unbalanced AVCD	TCPC	200	20.5	62.4	83	PaO2	56.5	-	-	123	-	176	80.8	-				
Md Navaf	12Y	M	31	363512	Unbalanced AVCD	TCPC	200	20.5	62.4	83	SaO2	85	-	-	98.2	-	98.5	96.8	-				
Md Navaf	12Y	M	31	363512	Unbalanced AVCD	TCPC	200	20.5	62.4	83	PvO2	37.8	-	-	51.2	-	54.5	35	-				
Md Navaf	12Y	M	31	363512	Unbalanced AVCD	TCPC	200	20.5	62.4	83	SvO2	57.4	-	-	78.5	-	84.3	63.7	-				
Md Navaf	12Y	M	31	363512	Unbalanced AVCD	TCPC	200	20.5	62.4	83	CPB	-	-	-	Yes	Yes	Yes	-	-				
Angelina Mariya	6Y	F	18	401091	DILV	TCPC	220	20.9	64	86	HR	105	102	98	94	-	-	88	94	108			
Angelina Mariya	6Y	F	18	401091	DILV	TCPC	220	20.9	64	86	Rythm	NSR	NSR	NSR	NSR	-	-	NSR	NSR	NSR			
Angelina Mariya	6Y	F	18	401091	DILV	TCPC	220	20.9	64	86	SpO2	86	84	85	84	85	90	100	100	100			
Angelina Mariya	6Y	F	18	401091	DILV	TCPC	220	20.9	64	86	S/D/MAP	104/49/62	99/47/60	104/48/64	-/-/59	-/-/56	-/-/52	-/-/54	96/52/65	99/51/67			
Angelina Mariya	6Y	F	18	401091	DILV	TCPC	220	20.9	64	86	Temperature	36	35	34	33.9	28	28	28	36	36			
Angelina Mariya	6Y	F	18	401091	DILV	TCPC	220	20.9	64	86	rScO2(NIRS)	63	59	63	56	59	64	72	74	71			
Angelina Mariya	6Y	F	18	401091	DILV	TCPC	220	20.9	64	86	HB	20.9	-	-	13.6	-	10.7	-	16.7	-			
Angelina Mariya	6Y	F	18	401091	DILV	TCPC	220	20.9	64	86	Hct	64	-	-	41.8	-	32.9	-	57.1	-			
Angelina Mariya	6Y	F	18	401091	DILV	TCPC	220	20.9	64	86	PaO2	56.7	-	-	123	-	93.6	-	178	-			
Angelina Mariya	6Y	F	18	401091	DILV	TCPC	220	20.9	64	86	SaO2	87.9	-	-	98.5	-	97.4	-	98.3	-			
Angelina Mariya	6Y	F	18	401091	DILV	TCPC	220	20.9	64	86	PvO2	47.7	-	-	42.6	-	36.6	-	38.8	-			
Angelina Mariya	6Y	F	18	401091	DILV	TCPC	220	20.9	64	86	SvO2	69.7	-	-	71.9	-	65.3	-	59.4	-			
Angelina Mariya	6Y	F	18	401091	DILV	TCPC	220	20.9	64	86	CPB	-	-	-	-	Yes	Yes	Yes	-	-			
Radhika Mol	17Y	F	35	507450	TOF	ICR+TAP+MCR	180	21.1	64.2	72	HR	80	74	72	-	-	-	-	85				
Radhika Mol	17Y	F	35	507450	TOF	ICR+TAP+MCR	180	21.1	64.2	72	Rythm	NSR	NSR	NSR	-	-	-	-	NSR				
Radhika Mol	17Y	F	35	507450	TOF	ICR+TAP+MCR	180	21.1	64.2	72	SpO2	78	82	75	100	100	100	100	94				

Radhika Mol	17Y	F	35	507450	TOF	ICR+TAP+MCR	180	21.1	64.2	72	S/D/MAP	108/64/74	98/59/72	91/55/68	-/-/59	-/-/62	-/-/64	-/-/61	106/61/75				
Radhika Mol	17Y	F	35	507450	TOF	ICR+TAP+MCR	180	21.1	64.2	72	Temperature	36	35	34	28	28	28	28	36				
Radhika Mol	17Y	F	35	507450	TOF	ICR+TAP+MCR	180	21.1	64.2	72	rScO2(NIRS)	-	-	-	55	51	54	50	57				
Radhika Mol	17Y	F	35	507450	TOF	ICR+TAP+MCR	180	21.1	64.2	72	HB	21.1	-	-	15.4		14.6		16.1				
Radhika Mol	17Y	F	35	507450	TOF	ICR+TAP+MCR	180	21.1	64.2	72	Hct	64.2	-	-	47		44.8		49.4				
Radhika Mol	17Y	F	35	507450	TOF	ICR+TAP+MCR	180	21.1	64.2	72	PaO2	46.5	-	-	171		194		124				
Radhika Mol	17Y	F	35	507450	TOF	ICR+TAP+MCR	180	21.1	64.2	72	SaO2	71.7	-	-	98.8		99.1		99.2				
Radhika Mol	17Y	F	35	507450	TOF	ICR+TAP+MCR	180	21.1	64.2	72	PvO2	37.1	-	-	53.1		41		59.6				
Radhika Mol	17Y	F	35	507450	TOF	ICR+TAP+MCR	180	21.1	64.2	72	SvO2	55.1	-	-	85.1		37.9		87.1				
Radhika Mol	17Y	F	35	507450	TOF	ICR+TAP+MCR	180	21.1	64.2	72	CPB	-	-	-	Yes	Yes	Yes	Yes	-				
Giribalan	8Y	M	20	489393	DILV	TCPC	170	22.4	68.4	70	HR	90	85	92	94	101	96	92	104	100			
Giribalan	8Y	M	20	489393	DILV	TCPC	170	22.4	68.4	70	Rythm	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR			
Giribalan	8Y	M	20	489393	DILV	TCPC	170	22.4	68.4	70	SpO2	72	75	78	76	100	100	100	95	93			
Giribalan	8Y	M	20	489393	DILV	TCPC	170	22.4	68.4	70	S/D/MAP	96/62/74	90/52/70	88/50/69	92/58/70	-/-/50	-/-/54	-/-/51	91/58/67	96/60/70			
Giribalan	8Y	M	20	489393	DILV	TCPC	170	22.4	68.4	70	Temperature	36	35	34	33.9	32	32	32	36	36			
Giribalan	8Y	M	20	489393	DILV	TCPC	170	22.4	68.4	70	rScO2(NIRS)	-	-	-	-	62	66	61	59	64			
Giribalan	8Y	M	20	489393	DILV	TCPC	170	22.4	68.4	70	HB	22.4	-	-	-	16	-	-	16.3	-			
Giribalan	8Y	M	20	489393	DILV	TCPC	170	22.4	68.4	70	Hct	68.4	-	-	-	48.9	-	-	49.9	-			
Giribalan	8Y	M	20	489393	DILV	TCPC	170	22.4	68.4	70	PaO2	51.9	-	-	-	212	-	-	66.7	-			
Giribalan	8Y	M	20	489393	DILV	TCPC	170	22.4	68.4	70	SaO2	76.8	-	-	-	99.2	-	-	93	-			
Giribalan	8Y	M	20	489393	DILV	TCPC	170	22.4	68.4	70	PvO2	44.4	-	-	-	61.2	-	-	53.7	-			
Giribalan	8Y	M	20	489393	DILV	TCPC	170	22.4	68.4	70	SvO2	67.7	-	-	-	92.1	-	-	86.2	-			
Giribalan	8Y	M	20	489393	DILV	TCPC	170	22.4	68.4	70	CPB	-	-	-	-	Yes	Yes	Yes	-	-			
Md Shayan	8Y	M	25	383968	DILV	TCPC	180	20.1	61	84	HR	77	80	76	79	71	-	75					
Md Shayan	8Y	M	25	383968	DILV	TCPC	180	20.1	61	84	Rythm	NSR	NSR	NSR	NSR	-	NSR	NSR					
Md Shayan	8Y	M	25	383968	DILV	TCPC	180	20.1	61	84	SpO2	75	78	76	100	100	100	95					
Md Shayan	8Y	M	25	383968	DILV	TCPC	180	20.1	61	84	S/D/MAP	97/54/65	81/49/59	83/51/61	-/-/48	-/-/47	-/-/51	89/53/65					
Md Shayan	8Y	M	25	383968	DILV	TCPC	180	20.1	61	84	Temperature	36	35	33.9	32	28	32	36					
Md Shayan	8Y	M	25	383968	DILV	TCPC	180	20.1	61	84	rScO2(NIRS)	-	-	-	63	68	62	70					
Md Shayan	8Y	M	25	383968	DILV	TCPC	180	20.1	61	84	HB	20.1	-	-	12.5	-	-	18.1					
Md Shayan	8Y	M	25	383968	DILV	TCPC	180	20.1	61	84	Hct	61	-	-	38.8	-	-	55.2					
Md Shayan	8Y	M	25	383968	DILV	TCPC	180	20.1	61	84	PaO2	47.4	-	-	103	-	-	129					
Md Shayan	8Y	M	25	383968	DILV	TCPC	180	20.1	61	84	SaO2	77	-	-	98.3	-	-	97.6					
Md Shayan	8Y	M	25	383968	DILV	TCPC	180	20.1	61	84	PvO2	33	-	-	42.2	-	-	53					
Md Shayan	8Y	M	25	383968	DILV	TCPC	180	20.1	61	84	SvO2	56.4	-	-	72.9	-	-	78					
Md Shayan	8Y	M	25	383968	DILV	TCPC	180	20.1	61	84	CPB	-	-	-	Yes	Yes	Yes	-					
Md Arshad	10Y	M	33	356761	DILV	TCPC	210	20.5	64	83	HR	98	87	85	96	101	88	79	95	91			
Md Arshad	10Y	M	33	356761	DILV	TCPC	210	20.5	64	83	Rythm	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR	NSR			
Md Arshad	10Y	M	33	356761	DILV	TCPC	210	20.5	64	83	SpO2	83	85	81	100	100	100	100	100	100			
Md Arshad	10Y	M	33	356761	DILV	TCPC	210	20.5	64	83	S/D/MAP	98/56/66	89/52/64	85/54/61	-/-/49	-/-/53	-/-/54	-/-/51	101/59/69	94/53/64			
Md Arshad	10Y	M	33	356761	DILV	TCPC	210	20.5	64	83	Temperature	36	35	34.5	32	32	32	32	36	36			
Md Arshad	10Y	M	33	356761	DILV	TCPC	210	20.5	64	83	rScO2(NIRS)	66	69	62	59	64	67	70	62	59			
Md Arshad	10Y	M	33	356761	DILV	TCPC	210	20.5	64	83	HB	20.5	-	-	14.2		13.6		13.5	-			
Md Arshad	10Y	M	33	356761	DILV	TCPC	210	20.5	64	83	Hct	64	-	-	42.4		41.7		41.4	-			
Md Arshad	10Y	M	33	356761	DILV	TCPC	210	20.5	64	83	PaO2	63.9	-	-	103		225		141	-			
Md Arshad	10Y	M	33	356761	DILV	TCPC	210	20.5	64	83	SaO2	87.9	-	-	97.3		99		98.5	-			
Md Arshad	10Y	M	33	356761	DILV	TCPC	210	20.5	64	83	PvO2	33.5	-	-	66.9		43.3		44.1	-			
Md Arshad	10Y	M	33	356761	DILV	TCPC	210	20.5	64	83	SvO2	52.3	-	-	89.6		74.3		69.5	-			
Md Arshad	10Y	M	33	356761	DILV	TCPC	210	20.5	64	83	CPB	-	-	-	Yes	Yes	Yes	Yes	-	-			
Sreedharan	14Y	M	45	273235	DILV	TCPC	300	20.8	65	81	HR	93	89	90	86	-	65	88	98				
Sreedharan	14Y	M	45	273235	DILV	TCPC	300	20.8	65	81	Rythm	NSR	NSR	NSR	NSR	-	NSR	NSR	NSR				
Sreedharan	14Y	M	45	273235	DILV	TCPC	300	20.8	65	81	SpO2	86	84	100	100	100	100	100	100				
Sreedharan	14Y	M	45	273235	DILV	TCPC	300	20.8	65	81	S/D/MAP	98/56/70	91/54/64	-/-/55	-/-/51	-/-/56	-/-/52	-/-/59	98/52/65				
Sreedharan	14Y	M	45	273235	DILV	TCPC	300	20.8	65	81	Temperature	36	34.5	32	32	28	32	32	36				
Sreedharan	14Y	M	45	273235	DILV	TCPC	300	20.8	65	81	rScO2(NIRS)	69	66	63	72	75	71	70	67				
Sreedharan	14Y	M	45	273235	DILV	TCPC	300	20.8	65	81	HB	20.8	-	14.8		14.4		13.4	14.5				
Sreedharan	14Y	M	45	273235	DILV	TCPC	300	20.8	65	81	Hct	65	-	45.5		44.3		41.1	44.5				
Sreedharan	14Y	M	45	273235	DILV	TCPC	300	20.8	65	81	PaO2	59.6	-	207		138		168	113				
Sreedharan	14Y	M	45	273235	DILV	TCPC	300	20.8	65	81	SaO2	89	-	98.9		98.5		98.8	97.7				
Sreedharan	14Y	M	45	273235	DILV	TCPC	300	20.8	65	81	PvO2	47	-	66.8		54.1		53.9	38.2				

Sreedharan	14Y	M	45	273235	DILV	TCPC	300	20.8	65	81	SvO2	73.5	-	92.2		86.8		86.5	61.9				
Sreedharan	14Y	M	45	273235	DILV	TCPC	300	20.8	65	81	CPB	-	-	Yes	Yes	Yes	Yes	Yes	-				
Mariyam	5Y	F	14	430703	DILV	BDG	130	20.2	61.5	84	HR	81	65	70	80	83	90						
Mariyam	5Y	F	14	430703	DILV	BDG	130	20.2	61.5	84	Rythm	NSR	NSR	NSR	NSR	NSR	NSR						
Mariyam	5Y	F	14	430703	DILV	BDG	130	20.2	61.5	84	SpO2	86	84	100	100	100	88						
Mariyam	5Y	F	14	430703	DILV	BDG	130	20.2	61.5	84	S/D/MAP	98/55/67	95/52/65	-/-/55	-/-/51	-/-/58	101/53/66						
Mariyam	5Y	F	14	430703	DILV	BDG	130	20.2	61.5	84	Temperature	36	35	32	32	32	36						
Mariyam	5Y	F	14	430703	DILV	BDG	130	20.2	61.5	84	rScO2(NIRS)	-	-	68	71	65	69						
Mariyam	5Y	F	14	430703	DILV	BDG	130	20.2	61.5	84	HB	20.2	-	13.3	-	15.3	14.4						
Mariyam	5Y	F	14	430703	DILV	BDG	130	20.2	61.5	84	Hct	61.5	-	40.9	-	46.8	44.1						
Mariyam	5Y	F	14	430703	DILV	BDG	130	20.2	61.5	84	PaO2	50	-	116	-	129	63.5						
Mariyam	5Y	F	14	430703	DILV	BDG	130	20.2	61.5	84	SaO2	76.8	-	95.5	-	97.3	91.5						
Mariyam	5Y	F	14	430703	DILV	BDG	130	20.2	61.5	84	PvO2	38.5	-	47	-	53.7	46.9						
Mariyam	5Y	F	14	430703	DILV	BDG	130	20.2	61.5	84	SvO2	59.5	-	77.5	-	80.3	19.2						
Mariyam	5Y	F	14	430703	DILV	BDG	130	20.2	61.5	84	CPB	-	-	Yes	Yes	Yes	-						
Ajmal	14Y	M	32	291450	dTGA with PS	Rerouting of LV to Aorta + Rastelli	300	20.2	64	72	HR	70	72	68	64	-	-	-	60	78			
Ajmal	14Y	M	32	291450	dTGA with PS	Rerouting of LV to Aorta + Rastelli	300	20.2	64	72	Rythm	NSR	NSR	NSR	NSR	-	-	-	-	NSR			
Ajmal	14Y	M	32	291450	dTGA with PS	Rerouting of LV to Aorta + Rastelli	300	20.2	64	72	SpO2	75	74	76	100	100	100	100	100	100			
Ajmal	14Y	M	32	291450	dTGA with PS	Rerouting of LV to Aorta + Rastelli	300	20.2	64	72	S/D/MAP	105/54/65	98/51/65	102/56/68	-.-/56	-/-/59	-/-/52	-/-/57	-/-/61	114/61/71			
Ajmal	14Y	M	32	291450	dTGA with PS	Rerouting of LV to Aorta + Rastelli	300	20.2	64	72	Temperature	36	35.5	35	32	28	28	28	28	36			
Ajmal	14Y	M	32	291450	dTGA with PS	Rerouting of LV to Aorta + Rastelli	300	20.2	64	72	rScO2(NIRS)	-	-	-	68	62	69	74	65	71			
Ajmal	14Y	M	32	291450	dTGA with PS	Rerouting of LV to Aorta + Rastelli	300	20.2	64	72	HB	20.2	-	-	15.5		13.4		12.1	14.2			
Ajmal	14Y	M	32	291450	dTGA with PS	Rerouting of LV to Aorta + Rastelli	300	20.2	64	72	Hct	64	-	-	47		40.5		37.2	44			
Ajmal	14Y	M	32	291450	dTGA with PS	Rerouting of LV to Aorta + Rastelli	300	20.2	64	72	PaO2	49.4	-	-	146		176		129	106			
Ajmal	14Y	M	32	291450	dTGA with PS	Rerouting of LV to Aorta + Rastelli	300	20.2	64	72	SaO2	79.4	-	-	99.2		98.5		97.9	97.5			
Ajmal	14Y	M	32	291450	dTGA with PS	Rerouting of LV to Aorta + Rastelli	300	20.2	64	72	PvO2	35.5	-	-	68.9		71.1		66.7	59.8			
Ajmal	14Y	M	32	291450	dTGA with PS	Rerouting of LV to Aorta + Rastelli	300	20.2	64	72	SvO2	56.5	-	-	86.5		89.9		87.1	39.4			
Ajmal	14Y	M	32	291450	dTGA with PS	Rerouting of LV to Aorta + Rastelli	300	20.2	64	72	CPB	-	-	-	Yes	Yes	Yes	Yes	Yes	-			

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INTRODUCTION
Cerebral hypoxia is linked to neurologic injury and poor neurologic outcomes in paediatric cardiac surgery. Intraoperative, low cerebral saturations correlate with neurologic injury (1). There is a need to monitor real time trends in cerebral oxygenation to facilitate timely diagnosis of cerebral hypoxia and to tailor interventions to treat cerebral hypoxia. Near infrared spectroscopy (NIRS) is one of the methods of non-invasive measurement of regional cerebral oxygenation(rScO2).

Children with cyanotic congenital heart diseases who receive delayed surgical correction experience chronic hypoxia and have elevated haemoglobin concentration as a compensatory mechanism that enables them to maintain near normal blood oxygen content (2). Children with univentricular physiology have polycythaemia as their treatment involves staged palliation which results in an admixture circulation and hypoxemia for the first several years of life. The children with chronic hypoxaemia are at risk of cerebral hypoxia during open and closed heart procedures and there is a need to monitor their real time cerebral oxygenation.

NIRS utilises two wavelengths of light to provide a ratio between oxyhaemoglobin and total haemoglobin. Factors affecting pigmentation that affects the reflection of light can potentially interfere with the readings of rScO2. It is known that polycythaemia may prevent any recording of rScO2 on NIRS in some patients with cyanotic congenital heart disease but this has not been systematically studied (3). Patients with similar haemoglobin concentrations may or may not show rScO2 readings. We have noted that patients who did not show rScO2 readings during induction of anaesthesia, start displaying rScO2 values after initiation of cardiopulmonary bypass (CPB). This study aims to compare patients with polycythaemia who display rScO2 values prior to cardiopulmonary bypass and those that do not.

AIMS & OBJECTIVES The primary aim of this study was to evaluate the effects of high haemoglobin and haemodilution effects of cardio pulmonary bypass on the rScO2 monitoring intraoperatively, in children with cyanotic congenital heart disease patients (CCHD).

Secondary aim is to evaluate the association between rScO2 and partial pressure of arterial oxygenation (PaO2), arterial oxygen saturation (SaO2), partial venous oxygen saturation (PvO2), central venous oxygen saturation (SvO2) in these patients.

REVIEW OF LITERATURE Introduction to NIRS: Near infrared light (NIR) is a part of electromagnetic spectrum which extends from 700-1000 nm and is able to pass through biologic tissues with a change in intensity of its emergent light which can be measured. Light attenuation results from absorption by oxyhaemoglobin, deoxyhaemoglobin (oxygen dependant chromophores) and cytochrome c oxidase, myoglobin of variable concentrations, chromophores of fixed concentrations (melanin, water, collagen, lipids) and light scattering (3). Differential absorption spectra of the oxygen-dependent chromophores in the NIRS range permit spectroscopic separation and the measurement of tissue oxygenation and blood flow.