COMPARISON OF TRANSESOPHAGEAL ECHOCARDIOGRAPHY GUIDED MODIFIED 2-DIMENSIONAL AND M-MODE TRICUSPID ANNULAR PLANE SYSTOLIC EXCURSIONS WITH TRANSTHORACIC ECHOCARDIOGRAPHY GUIDED M-MODE TRICUSPID ANNULAR PLANE SYSTOLIC EXCURSION IN ADULT AND PAEDIATRIC CARDIAC SURGERIES FOR ASSESSMENT OF RIGHT VENTRICULAR FUNCTION

A DISSERTATION SUBMITTED TO

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY,

(An Institute of National Importance by an Act of Parliament, Ministry of Health and Family Welfare)

TRIVANDRUM, KERALA, INDIA – 695011

BY

Dr. MAMATHA MUNAF

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS FOR THE AWARD OF THE DEGREE OF

DM CARDIOTHORACIC AND VASCULAR ANESTHESIA

(DIVISION OF CARDIOTHORACIC AND VASCULAR ANAESTHESIOLOGY, DEPARTMENT OF ANAESTHESIOLOGY)

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SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY,

(An Institute of National Importance by an Act of Parliament, Ministry of Health and Family Welfare)

TRIVANDRUM, KERALA, INDIA – 695011

DECLARATION

This is to declare that the dissertation entitled **'Comparison of transesophageal echocardiography guided modified 2-dimensional and M-mode tricuspid annular plane systolic excursions with transthoracic echocardiography guided M-mode tricuspid annular plane systolic excursion in adult and paediatric cardiac surgeries for assessment of right ventricular function'** is a bonafide record of the work done by me, **Dr. MAMATHA MUNAF,** under the capable guidance and supervision of **Dr. THOMAS KOSHY**, Professor (Senior Grade) and Head, Division of Cardiothoracic and Vascular Anesthesiology and Department of Anesthesiology, **Dr. SUNEEL P. R** (Professor, Division of Cardiothoracic and Vascular Anesthesiology), **Dr. HARIKRISHNAN S** (Professor, Department of Cardiology) and **Dr. DEEPA S KUMAR** (Associate Professor, Department of Cardiology) in the Division of Cardiothoracic and Vascular Anesthesia, Department of Anesthesiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology.

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CERTIFICATE

This is to certify that this dissertation entitled '***Comparison of transesophageal echocardiography guided modified 2-Dimensional and M-mode Tricuspid Annular Plane Systolic Excursions with transthoracic echocardiography guided M-mode Tricuspid Annular Plane Systolic Excursion in adult and paediatric cardiac surgeries for assessment of right ventricular function***' is the bonafide record of the work done by **Dr. MAMATHA MUNAF** under our supervision and guidance in the Division of Cardiothoracic and Vascular Anaesthesiology, Department of Anaesthesiology, at Sree Chitra Tirunal Institute for Medical Sciences & Technology, Thiruvananthapuram, during the period of her study for the degree of DM, Cardiothoracic and Vascular Anesthesia between January 2018 to June 2021. She has shown keen interest in preparing this project.

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I am thankful to my colleagues in the Division of Cardiothoracic and Vascular Anesthesia who have been a constant source of support throughout my study. I express my gratitude to the technical assistants in the Department of Anesthesiology for their valuable assistance.

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Last but not the least, I thank lord almighty for giving me the power and opportunity to conduct and conclude this study.

Dr. MAMATHA MUNAF

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SYNOPSIS

OBJECTIVE: Moderate to severe dysfunction of right ventricle is associated with poor clinical outcome after cardiac surgery. TTE M Mode TAPSE is used preoperatively to assess RV function. We compared intraoperative TEE guided m-2D & M-Mode TAPSE measurements to preoperative TTE-guided M-mode TAPSE in terms of accuracy and inter-observer and intra-observer variability. In addition, intraoperative m-2D TAPSE and M-Mode TAPSE measurements were compared with RV FAC. The variations of m-2D TAPSE, M-Mode TAPSEs and RV FAC at different time points during surgery i.e., before CPB, after CPB and after sternal closure were also analysed.

STUDY DESIGN: A prospective, observational, non- randomised, non-blinded study.

STUDY SETTING: The study was done in adult and paediatric operating rooms in Sree Chitra Tirunal Institute, which is a tertiary referral centre for cardiac surgery.

PARTICIPANTS: Adult patients undergoing CABG and valvular surgeries and paediatric patients (both cyanotic heart diseases and acyanotic heart diseases) undergoing corrective surgeries were the participants

MEASUREMENTS: TTE guided M Mode TAPSE was measured in OPD as well as after anaesthesia induction. TEE guided m-2D TAPSE, Deep Trans-gastric M Mode TAPSE, Trans-gastric Right ventricular Inflow M Mode TAPSE and RV FAC were measured before pericardiotomy, after CPB and after sternal closure.

STATISTICAL ANALYSIS: To detect a minimum of 0.5 correlation between the parameters with 90% power and 5% alpha error with 10% drop-out rate because of technical reasons, the sample size was calculated as 42 per group.

RESULTS: m-2D TAPSE and deep Trans-gastric M Mode TAPSE before CPB correlated significantly with TTE M Mode TAPSE in both adult and paediatric groups. m-2D TAPSE had significant correlation with deep trans-gastric M Mode TAPSE and trans-gastric right ventricular inflow M Mode TAPSE at all time points and RV FAC measured before CPB in both the groups. TAPSE measured by all the three methods declined significantly during the surgery. RV FAC in children decreased after CPB and improved over pre- CPB values after sternal closure whereas it significantly improved over time in adults.

CONCLUSION: TEE guided m-2D TAPSE and Deep trans-gastric M Mode TAPSE are comparable to TTE guided M- Mode TAPSE in terms of accuracy and reproducibility. Trans-gastric right ventricular inflow M -Mode TAPSE is less accurate and shows poor reproducibility.

INTRODUCTION

Moderate to severe Right Ventricular (RV) dysfunction is related to poor post-operative clinical outcome.[1] Hence, it is important to reliably assess RV function during cardiac surgery. Preoperatively, Trans Thoracic Echocardiography (TTE) can be used to assess RV function by measuring Tricuspid Annular Plane Systolic Excursion (TAPSE) by M-Mode. It is reliable, validated and easily reproducible in adult patients. In contrast, intraoperative Transoesophageal Echocardiography (TEE) guided RV functional assessment is challenging due to the following concerns:

1. Unlike left ventricle (LV) which is easily approximated by geometric assumptions, RV has a complex structure. It is triangular in mid-esophageal 4 chamber view, crescent shaped in trans-gastric short axis view and has a wraparound appearance in Right Ventricular Inflow-outflow view. Hence it is difficult to define RV volume in a single view two dimensionally unless three dimensional volumetric models are used.[2]
2. The contraction of RV is peristaltic, unlike the piston-like movement of LV. In addition to longitudinal movement, inward movement of RV free wall and apex, the RV outflow tract (RVOT) contraction significantly affects RV output. Most of the 2D views fail to account for RVOT contribution.
3. Unlike in TTE, there is misalignment of ultrasound waves to the direction of motion of tricuspid valve in TEE which makes it more challenging to interpret TEE.
4. Pericardiotomy decreases RV longitudinal motion.[3] Hence any assessment based on the RV longitudinal motion is likely to be influenced by pericardiotomy.

Right Ventricular Fractional Area Change (RV FAC) is used intraoperatively to estimate global right ventricular function. It has good method agreement with Cardiac MRI and 3D volumetric estimation of right ventricular function. However, intraoperatively, tracing the endocardial border of right ventricle is time consuming and has poor interobserver variability. Poor echo window, foreshortened images and poor visibility of lateral wall in the presence of dilated heart chambers make RV FAC measurement challenging.

TEE guided Modified 2 D (m-2D) TAPSE, Deep Trans Gastric (DTG) M Mode TAPSE and Trans Gastric Right Ventricular Inflow (TG RVIF) M Mode TAPSE are other tools available for RV function assessment intraoperatively. Tissue Doppler Imaging (TDI) S´ velocity measurement necessitates excellent image acquisition. 3D volumetric estimation and 2D speckle tracking studies are time consuming, technology intensive and are not available in all echocardiography machines.

There is a need for a real time, easily reproducible and reliable method to asses right ventricular function which correlates well to M Mode TAPSE measured by TTE preoperatively and RV FAC measured intraoperatively. Hence, we undertook this study to validate the TEE guided M Mode TAPSEs and m-2D TAPSE and to evaluate their correlation to RV FAC during the course of surgery.

REVIEW OF LITERATURE

Left ventricle is a more predictable chamber. Being cylindrical in shape, geometric approximations are possible which ensures accurate estimation of volume and systolic function. Right ventricle, however, has a more complex anatomy, as explained by Dr. Timothy M Maus[1], MD in the editorial published in Journal of Cardiothoracic and Vascular Anaesthesia (JCVA). Right ventricle is triangular in Mid-Esophageal four Chamber (ME 4 Ch) view, crescent shaped in Trans gastric short axis view and gives an illusion of wrapping around aorta in the mid esophageal RV inflow-outflow view. Peristaltic movement of the right ventricle has contribution from longitudinal movement of its fibres, inward movement of the right ventricular free wall and apex and contraction of its outflow tract. Trans thoracic M Mode TAPSE is the corner stone of right ventricular function assessment preoperatively. It is easily available, reproducible and has excellent method agreement with cardiac MRI which is the gold standard for the same. However, cardiac surgeries are known to significantly affect the longitudinal motion of right ventricle.

Reduced long axis velocity of right ventricle during cardiac surgery could be due to cardiopulmonary bypass, cardioplegia, myocardial hypothermia or cardiac stunning[1]. Unsworth et al.[3] studied 110 patients who underwent surgery by midline sternotomy. The authors found that surgeries that preserved pericardial integrity like mediastinal mass excision, minimally invasive Aortic Valve Replacement (AVR) and robotically assisted minimally invasive CABG documented little or no decrease in the right ventricular tissue doppler velocities. However, procedures that required complete pericardial opening like Coronary Artery Bypass Graft (CABG) and AVR documented clear decrease in right ventricular long axis S´ velocity. Pericardium could be providing structural integrity to the longitudinal fibres to function adequately.

Donauer et al.[4] studied thirty patients who underwent CABG with cardioplegic cardiac arrest. They performed right ventricular 3-dimensional echocardiography and strain analysis. Significant reduction in peak longitudinal systolic strain (PLSS)of the right ventricular lateral wall, inferior wall, interventricular septum and outflow tract was documented. Circumferential contraction of the lateral wall increased by 4%

simultaneously. RV Ejection Fraction (EF) and RV FAC remained unchanged. This study demonstrated that reduction in longitudinal movement is compensated by an increase in radial motion of the RV free wall.

The reliability of TAPSE in the pre-pericardiotomy phase as a surrogate for right ventricular systolic function is evident. TTE guided M mode TAPSE cannot be used intraoperatively for open heart surgeries. Trans esophageal echocardiography (TEE) guided TAPSE measurements are readily available. Roberts et al.[5] studied 125 patients to estimate the concordance between TTE and TEE guided measurements of RV function. RV FAC, lateral S´ velocity, right sided index of myocardial performance (RIMP) and tricuspid valve annulus were measured by both methods. M Mode TAPSE measured by TTE was compared to transgastric (TG) M Mode TAPSE. The study showed underestimation of S´ and TG M Mode TAPSE. It was not adequately powered to demonstrate any difference in other measurements. Authors advised caution while using TTE validated parameters for TEE assessment of RV function.

Morita et al.[6] retrospectively analysed the medical records of 196 patients and compared intraoperative measurements of TEE guided modified TAPSE (m-TAPSE) to RV FAC. Modified TAPSE was measured as the difference between RV apex to lateral tricuspid annulus length in diastole and systole. In order to measure it precisely, a 4-chamber view of excellent sonographic quality was required. The investigators were required to exclude suboptimal images from data analysis for this reason. They found good correlation between the RV FAC and m-TAPSE. Due to the retrospective nature of the study, comparison of m-TAPSE to other measurements of RV function was not possible. Furthermore, we feel that it is not easy to fix the RV apex in different phases of cardiac cycle for accurate measurements. Another disadvantage of this technique is that the TAPSE measured is the distance between the lateral site of moving tricuspid annulus and the RV apex, which is moving as well during contraction, whereas the classic TAPSE measures only the actual movement of the lateral annulus of the tricuspid valve.

Korshin et al.[7] assessed the availability, inter-observer and intra-observer reliability and feasibility TAPSE measured by 5 different views and tricuspid annulus TDI. Method agreement of TEE TAPSE to TTE TAPSE was also studied. The study showed good agreement between TAPSE measured by TEE and TTE. Anatomical M Mode TAPSE (DTG and TG) had good correlation with TTE guided TAPSE and had low inter and intra observer variability. Tricuspid Annulus tissue doppler imaging (TDI) and Anatomical M mode TAPSE had higher reliability compared to 2D TAPSE. However, TDI is not commonly available, availability of the deep trans gastric and trans gastric Right Ventricular Inflow views are highly variable and anatomical M mode TAPSE is not available in all echo machines.

In Nottingham University Hospital, UK,[8] TTE M Mode TAPSE and TEE 2D TAPSE obtained under sedation were compared. Close correlation was found between TEE guided 2D TAPSE and TTE guided M Mode TAPSE. Images were found to be reliable and simple to obtain. In addition, RV Fractional Area Change (FAC) was found to have good correlation to TTE guided M- Mode TAPSE. Endocardial surface tracing to obtain RV FAC was challenging in this study. Furthermore, TEE was done under local anesthesia unlike intraoperative scenario where the patient would be under general anesthesia.

Sullivan et al.[9] studied patients who underwent pulmonary endarterectomy. Thermodilution cardiac index, RV FAC and Transgastric Right Ventricular Inflow M Mode TAPSE were measured before sternotomy, after pericardial incision and after sternal closure. On comparison of TAPSE and RV FAC to invasive thermodilution studies in pulmonary endarterectomy patients, TAPSE was found to decrease significantly following pericardiotomy, whereas RV FAC remained unaffected probably in view of increased radial contraction to compensate for decreased longitudinal motion.

Other complex measures[10] to assess right ventricular function are right ventricular global longitudinal strain or 3D speckle tracking echo strain which are not commonly available. In a study done in Ghent University Hospital, Belgium,[11] speckle tracking based strain and strain rate was not found to be promising.

Studies on right ventricular systolic function assessment by TAPSE in paediatric population is very limited. The study undertaken in university of Philadelphia[12] found significant correlation between TAPSE and exercise capacity in children with hypoplastic left heart syndrome. They recommended further studies and opined that TAPSE was reproducible. TAPSE was used as a tool to assess right ventricular systolic dysfunction in paediatric patients with dilated cardiomyopathy in Emory University School of Medicine, USA.[13] Moderate to severe right ventricular dysfunction in this group of patients was linked to worse clinical outcome including death, mechanical support or transplantation. Both these studies used TTE to assess TAPSE.

A recent study by Singh[14] et. al., published in May, 2020, attempted to asses longitudinal changes in right ventricular function (longitudinal and global) during cardiac surgery. They specifically evaluated the changes in a subset of patients who underwent redo surgeries as well. Images were acquired after anaesthesia induction, pericardiotomy, CPB and after sternal closure. Authors noticed acute decline in RV function during surgery, independent of pericardiotomy and CPB. The decline was present across different surgical approaches, different operative procedures and in primary as well as redo surgeries and persisted even after sternal closure. The authors could not explain the reason for this persistent decline. Further studies are indeed warranted to analyse the fresh data which are coming up which contradicts our current understanding.

Forner et. al.,[15] similarly conducted a study on 30 cardiac surgery patients. They measured the trans-thoracic M- Mode TAPSE after induction of anaesthesia and compared it to TAPSE measured by 6 different views using trans-esophageal echocardiography. Anatomical M-Mode measurement of TAPSE in mid esophageal 4 chamber view and Deep trans-gastric view showed good correlation to TTE guided TAPSE. Anatomical M Mode is not available in all echo machines.

AIMS AND OBJECTIVES

HYPOTHESIS

A novel simplified 'Modified 2D method of TAPSE (m-2D TAPSE)' measurement using regular mid-esophageal (ME) 4-Chamber view will show good agreement with TTE guided M Mode TAPSE in both adult and paediatric patients undergoing cardiac surgery.

Furthermore, between the two M-Mode trans gastric TEE measurements of TAPSE:

- Deep Trans gastric 4 chamber (M-Mode Deep Trans-gastric 4C-TEE-TAPSE) &
- Trans gastric Right Ventricular Inflow views (M-Mode RV IF-TEE-TAPSE) the former is more accurate.

We also propose that m-2D TAPSE is easier than all other methods of intraoperative RV function assessment namely M-Mode measurements of TAPSE and RV Fractional Area Change (FAC) in both adult and paediatric patients.

PRIMARY OBJECTIVE:

To compare intraoperative TEE guided m-2D & M-Mode TAPSE measurements to preoperative TTE-guided M-mode TAPSE in terms of accuracy and inter-observer and intra-observer variability.

SECONDARY OBJECTIVES:

1. To compare intraoperative m-2D TAPSE to M-Mode TAPSE measurements and RV FAC
2. To compare the variations of m-2D TAPSE, M-Mode TAPSEs and RV FAC at different time points during surgery: before CPB, after CPB and after sternal closure.

JUSTIFICATION FOR THE STUDY

1. Moderate to severe RV dysfunction has independent predictive value in postoperative outcome in cardiac surgery patients.
2. Gold standard of RV function assessment is cardiac MRI which cannot be used intraoperatively.
3. TTE- M Mode TAPSE is clinically validated against cardiac MRI but cannot be used intraoperatively.
4. There is a need for an easily obtainable commonly accessible TEE view to reliably assess RV function intraoperatively.
5. The most commonly accessed TEE view is mid-esophageal 4-Chamber view and M-Mode cannot be used in this view to assess TAPSE because of poor alignment of tricuspid annulus to the M-Mode axis in this view.
6. TEE guided M-Mode TAPSE is commonly measured with trans gastric RV inflow view and less with deep trans gastric 4 chamber view. Both these views are not easily obtainable unlike mid-esophageal 4 chamber view.
7. None of the studies had correlated all the accepted TEE guided intraoperative TAPSE measurements during different time points during surgery to RV FAC and to the validated preoperative TTE- TAPSE.
8. RV function assessment studies in paediatric population is sparse despite proven correlation of poor RV function to worse postoperative Outcome. TAPSE measurements in this population are studied only with TTE.
9. No studies are available from India comparing m-2D TEE TASPE to M Mode TEE/TTE TAPSE
10. No similar study has been done in SCTIMST in the past.
11. The primary aim of the study is thus to evaluate three different TEE TAPSE views at pre-specified time points during surgery, applying the modified 2D and all the described M-mode measurements to determine each approach’s feasibility (availability, accuracy and intra-/inter-observer reliability) and their agreement with RV FAC & preoperative TTE TAPSE in both adult and paediatric populations.

MATERIALS AND METHODS

STUDY DESIGN: A prospective, observational, non- randomised, non-blinded study.

STUDY SETTING: The study was done in adult and paediatric operating rooms in Sree Chitra Tirunal Institute, which is a tertiary referral centre for cardiac surgery.

PARTICIPANTS: Adult patients undergoing CABG and valvular surgeries and paediatric patients (both cyanotic heart diseases and acyanotic heart diseases) undergoing corrective surgeries were the participants.

INCLUSION CRITERIA:

- Patients posted electively for CABG, valvular or congenital heart surgery in SCTIMST
- Optimal images for TTE and TEE.

EXCLUSION CRITERIA:

- Contraindication to TEE probe placement like oesophageal strictures, oesophageal varices, oesophageal tumours, gastric ulcer, previous esophagectomy, esophageal diverticulum, tracheoesophageal fistula, previous bariatric surgery, hiatus hernia, large descending thoracic aortic aneurysm, unilateral vocal cord paralysis, esophageal varices, post‐radiation therapy.
- Emergency and re-do surgeries.

APPROVAL FROM TECHNICAL ADVISORY COMMITTEE (TAC)

Our study is approved by the technical advisory committee. TAC registration number is SCT-/S/2018/756

APPROVAL FROM INSTITUTIONAL ETHICS COMMITTEE(IEC)

Our study is approved by the Institute Ethics Committee of SCTIMST. IEC registration number is SCT/IEC/1235/AUGUST 2018.

DURATION OF THE STUDY:

12 Months -From June 2019 to May 2020

FUNDING:

No funding was required for the study

STUDY PROTOCOL

Preoperatively, M-Mode TAPSE was recorded by the cardiologists during the routine preoperative TTE examination. They also reported the RV function qualitatively as normal or dysfunctional (mild/moderate/severe) and hypertrophic or dilated based on visual assessment of apical 4 chamber view. After anesthesia induction, TTE guided M Mode TAPSE was repeated on table and documented. TEE probe was introduced and RV function assessment was done by measuring m-2D TAPSE and RV FAC (Image No. 1(A) and Image No. 1(B)) in the mid esophageal 4 chamber view. In case of difficulty in delineating the endocardial border while measuring RV FAC, agitated saline was used for better clarity. M Mode TAPSE was measured in both deep trans gastric 4-chamber view (Image No.2) and trans gastric RV inflow view (Image No. 3) using IE 33 echo machine (Philips Ultrasound, USA) in patients who satisfied the inclusion and exclusion criteria. Measurements were taken before pericardiotomy. Since RV function can be affected by the LV, ejection fraction of the left ventricle was also assessed using Simpson's disc method. The other factors which affect RV function such as its diastolic function, grade of tricuspid regurgitation, presence of pulmonary artery hypertension, use of inotropes was also be recorded for analysis.

The m-2D TAPSE was measured by annotating an 'arrow' at the lateral tricuspid valve annulus at end-diastole in a mid esophageal 4-chamber view (Image No. 4). Image was then scrolled to end-systole and the displacement was measured with the calliper (Image No. 5). Measurements were done at the end-expiratory period and average of two readings were recorded. Measurements by the principal and co-investigators were analysed for interpreting the accuracy and inter & intra-observer variability. These measurements were repeated after surgery in the post-CPB period and after sternal closure. Pre-CPB findings were compared to the trans-thoracic M Mode TAPSE (Image No. 6).

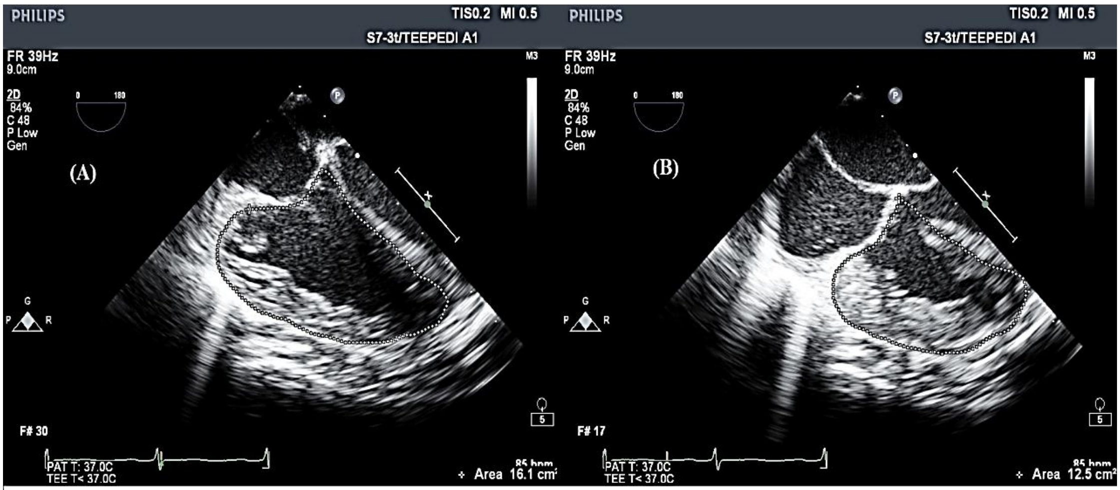


Image No. 1: (A): ***TEE ME 4 Chamber view showing endocardial border tracing for RV FAC meausrement at end diastole.***
Image No. 1: (B): ***TEE ME 4 Chamber view showing endocardial border tracing for RV FAC measurement at end systole.***

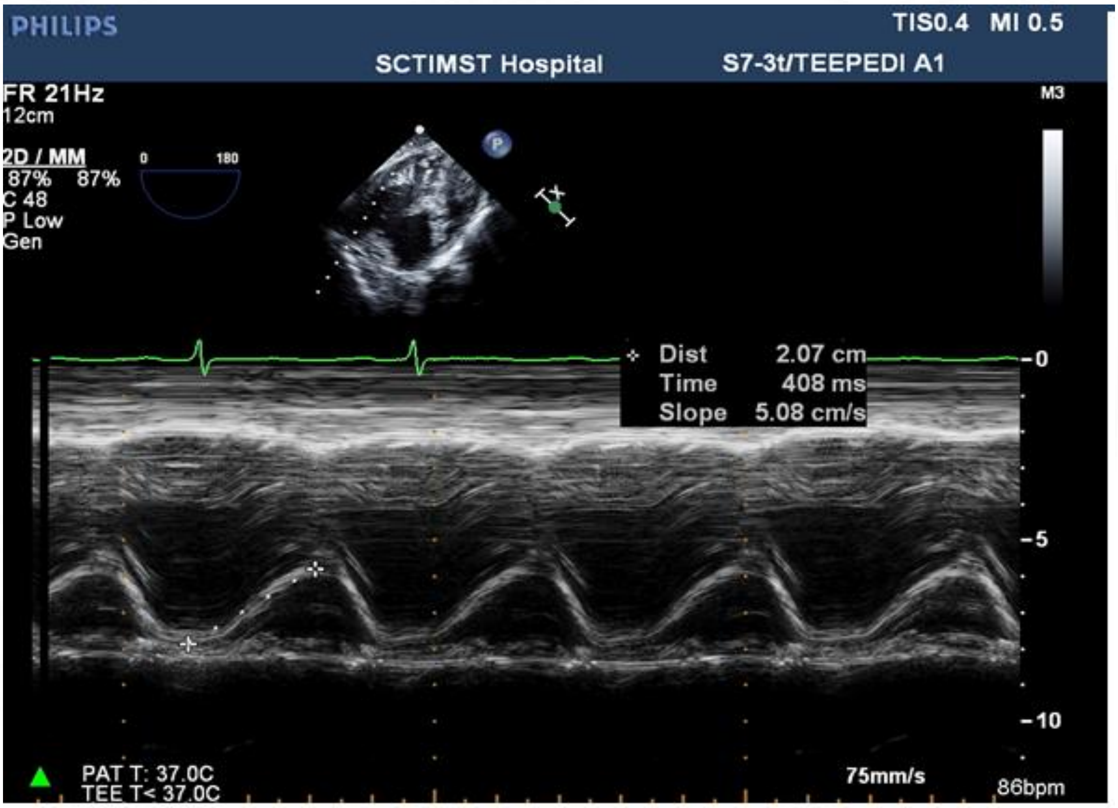


Image No. 2: ***Measurement of M-Mode TAPSE at Deep Transgastric 4 Chamber view.***

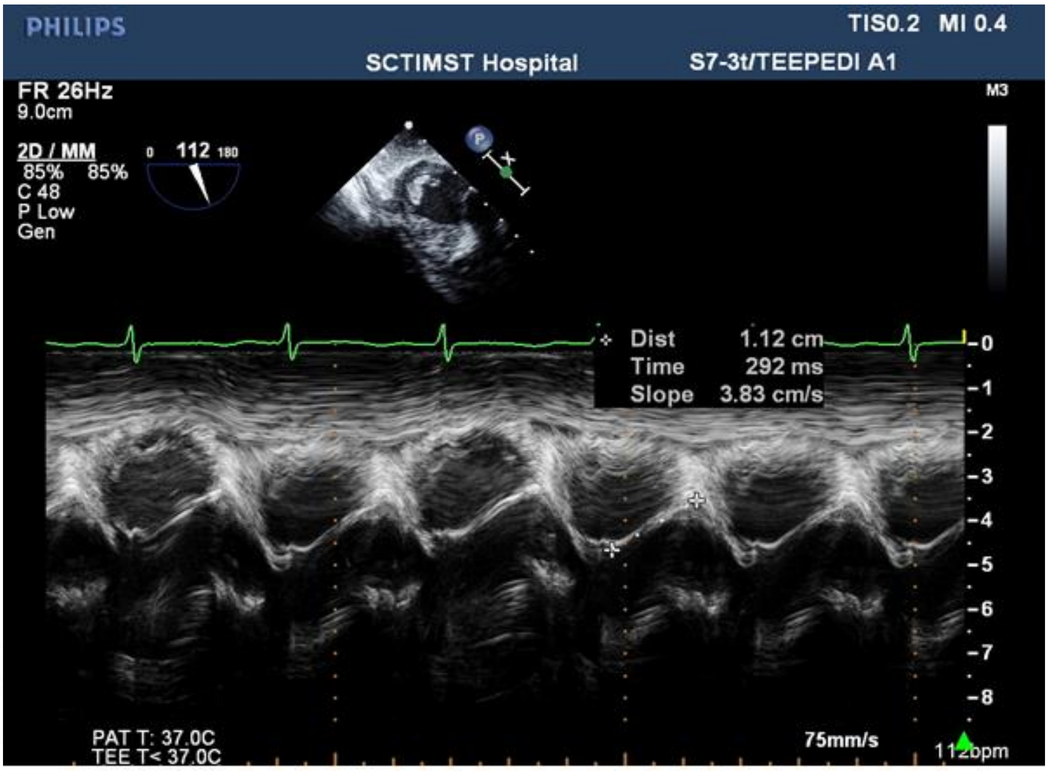


Image No. 3: ***TG RVIF view showing measurement of M Mode TAPSE***

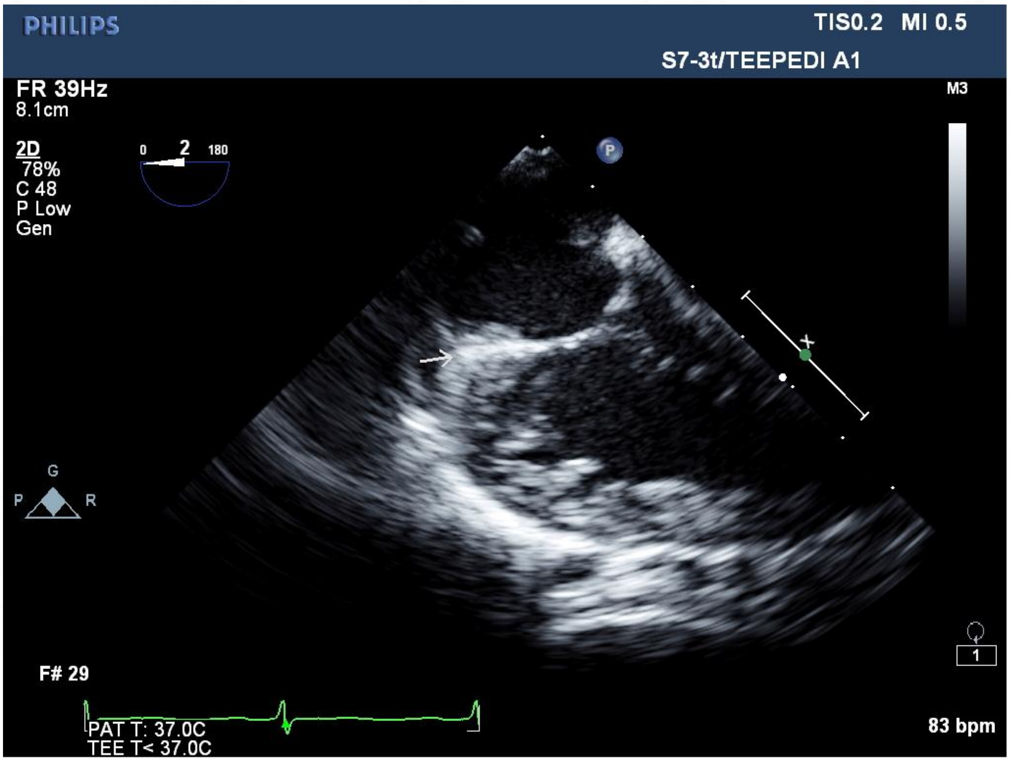


Image No. 4: ***Mid esophageal 4 Chamber view showing annotation arrow at the lateral end of tricuspid annulus at end diastole for the measurement of m-2 D TAPSE***

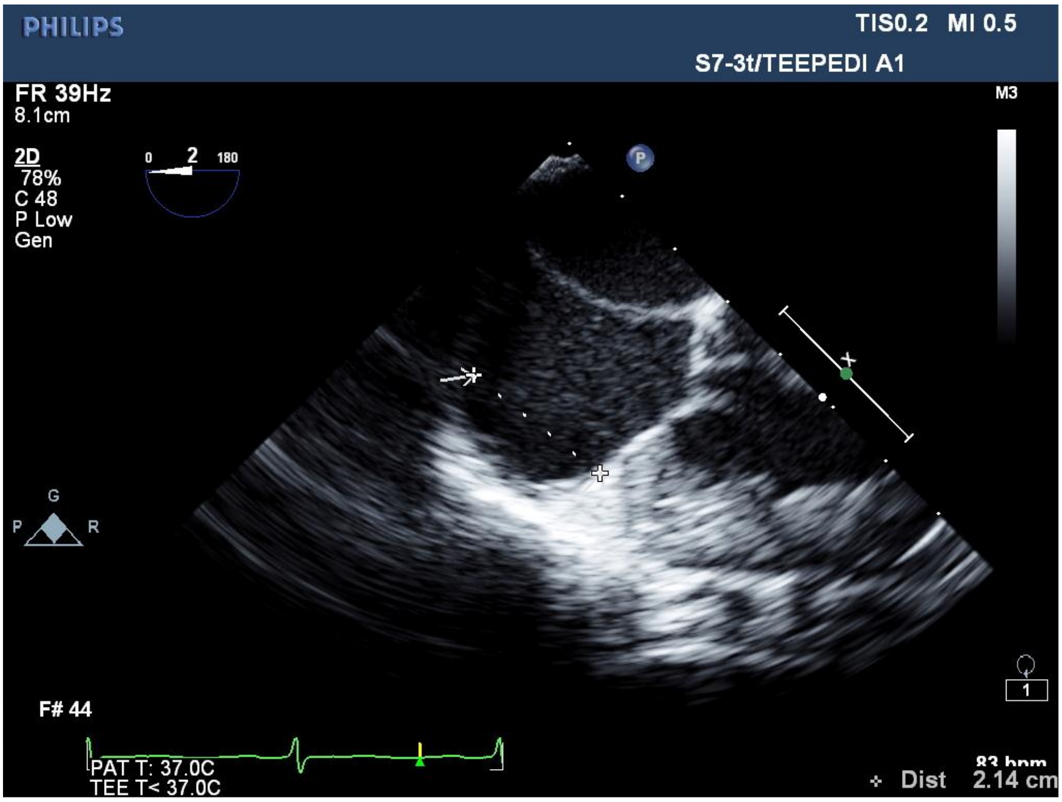


Image No. 5: ***ME 4 Chamber view showing the displacement of the lateral end of tricuspid annulus at end systole from the annotation arrow. Measurement of the diaplacement by calliper gives m-2D TAPSE.***

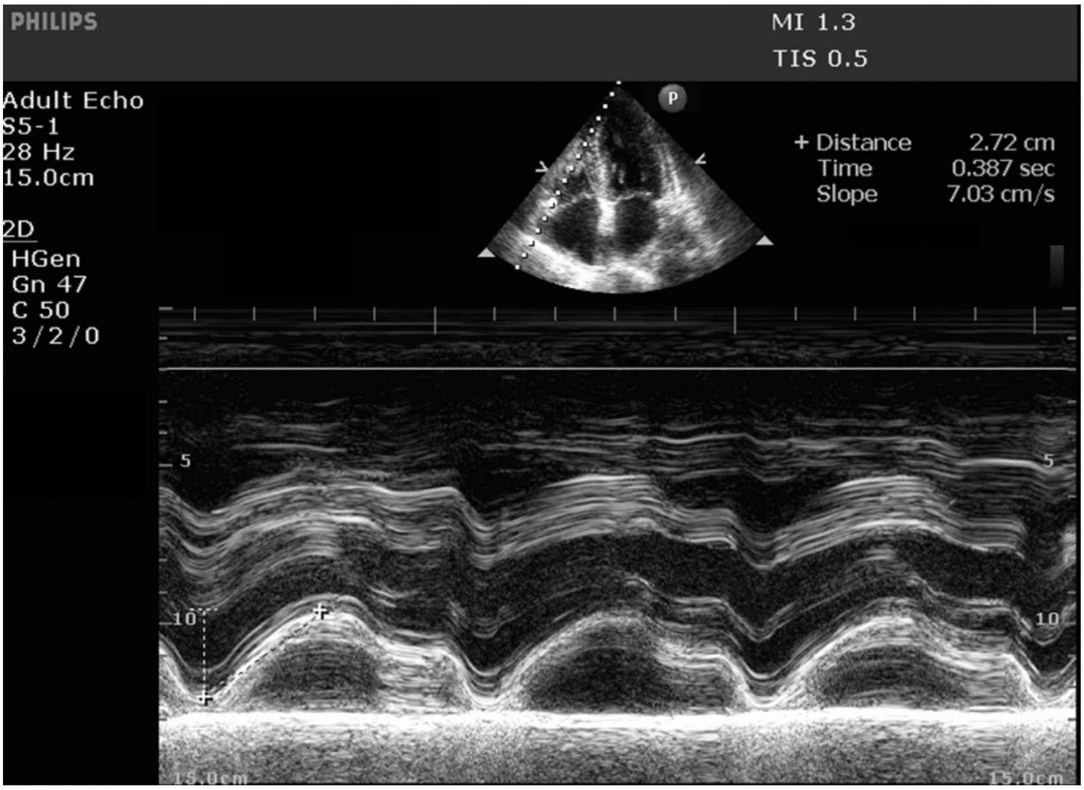


Image No.6: Apical 4 Chamber view in Trans-thoracic echocardiogram demonstrating the meausrement of M-Mode TAPSE.

INTERVENTIONS:

This study was a prospective observational study and no intervention was required.

OUTCOME PARAMETERS:

Evaluation of study objectives were the outcome parameters

STATISTICAL ANALYSIS

A sample size of 38 per group (Adult and Paediatric) was needed to detect a minimum of 0.5 correlation between the parameters with 90% power and 5% alpha error. Considering 10% drop-out rate because of technical reasons such as poor images or probe related issues, the sample size was calculated as 42 per group.

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

For normally distributed Quantitative parameters the mean values were compared between study groups using Independent sample t-test (2 groups). For normally distributed Quantitative parameters the mean values were compared between study groups using ANOVA (>2 groups).

For non-normally distributed Quantitative parameters, Medians and Interquartile range (IQR) were compared between study groups using Mann Whitney U test (2 groups).

The association between explanatory variables and categorical outcomes was assessed by cross tabulation and comparison of percentages. Odds ratio along with 95% CI is presented. Chi square test was used to test statistical significance

P value < 0.05 was considered statistically significant. IBM SPSS version 25 was used for statistical analysis.

RESULTS

Feasibility

A total of 84 patients satisfied all the inclusion criteria for the study. 42 patients were adults and 42 were in the paediatric age group. 32 patients in adult group and 20 patients in paediatric group could not be allotted to the study due to lack of echo images. Post sternal closure echocardiography could not be done in 10 adult patients and 13 paediatric patients due to the non- availability of TEE machine at that point of time. 17 adult patients and 4 paediatric patients had to be excluded due to poor TG RIGHT VENTRICULAR INFLOW M mode alignment to the tricuspid valve annulus. 5 adult patients and 3 paediatric patients had poor RV endocardial border demarcation and could not be included. Consort Diagram for adult and paediatric groups are represented by **Figure No. 1** and **Figure No. 2** respectively.

Figure No.1:

CONSORT DIAGRAM- ADULT GROUP

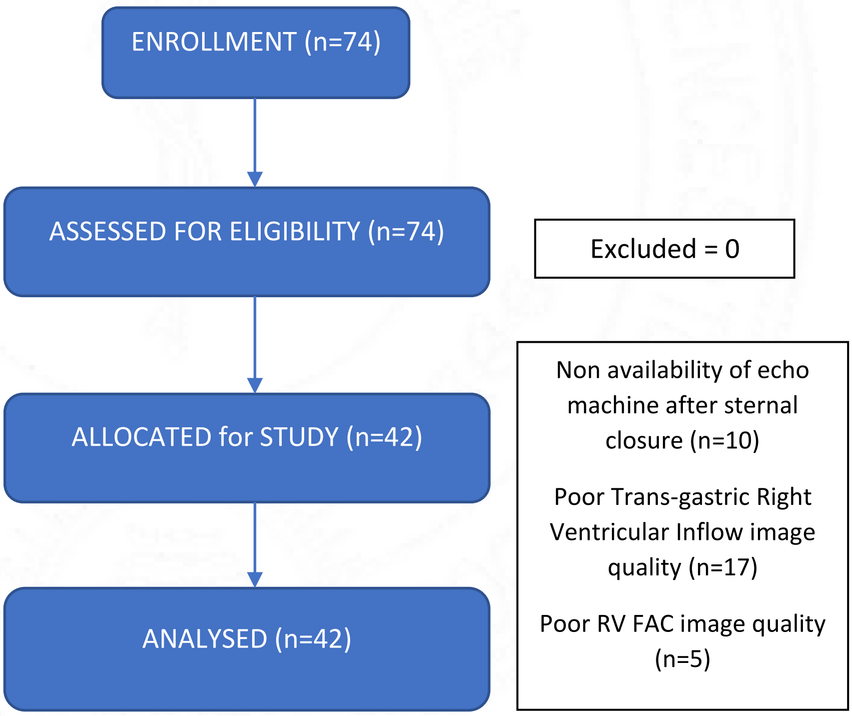
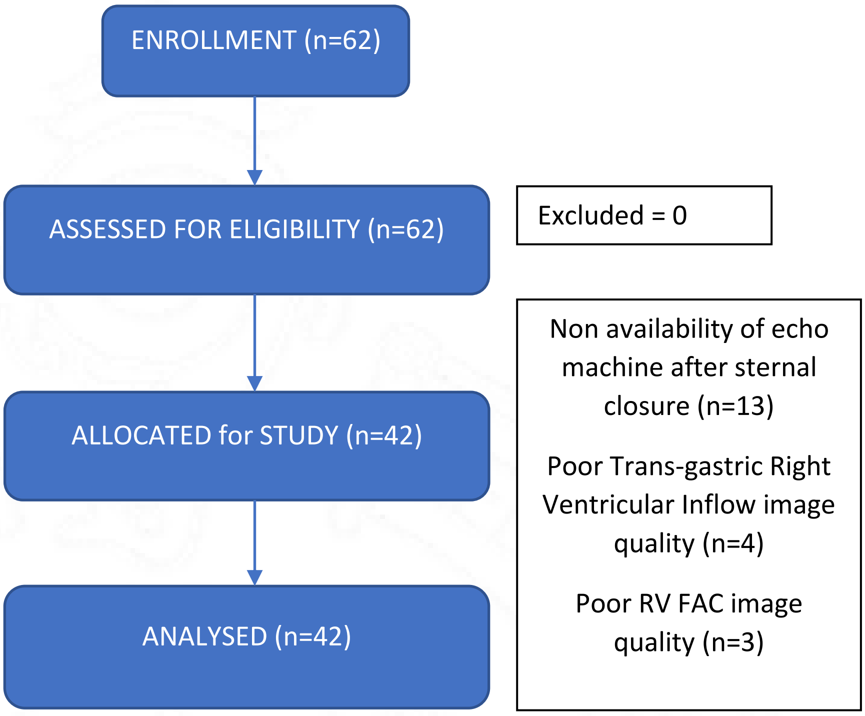


Figure No. 2:

CONSORT DIAGRAM- PAEDIATRIC GROUP



Population

Mean age of our adult study population was 59.2 ± 7.9 years and 33 of the 42 patients were males (78.57%). 42.8% of our adult group had LV systolic dysfunction (Ejection Fraction <55%) and all patients had good RV systolic function (TAPSE>16mm) in preoperative transthoracic echocardiographic evaluation. 26.2% patients had some degree of tricuspid regurgitation. However, only 2.76% documented presence of pulmonary artery hypertension.

Mean age of our paediatric study population was 2.65 ± 1.5 years and 29 of the 42 patients were males (69.05%). 47.62% of our paediatric group had LV systolic dysfunction (Ejection Fraction <55%) and 26.2% patients had decreased RV systolic function (TAPSE<16mm) in preoperative transthoracic echocardiographic evaluation. 19.05% patients had some degree of tricuspid regurgitation. However, only 11.9% documented presence of pulmonary artery hypertension.

More than half of the patients studied in the paediatric group were toddlers and nearly a quarter of them were children. 19% of the study population were infants. 90.5% of the adult patients underwent CABG. Among paediatric patients, Tetralogy of Fallot was the most common diagnosis (33%), followed by ASD with PAPVC (26.2%) and ASD (11.9%).

Demographic and echocardiographic parameters of all patients are summarised in **Table No. 1**. Age distribution of the patients in the paediatric group is represented in **Figure No. 3.** Description of the conditions for which adult and paediatric patients were operated on is shown in **Figure No. 4** and **Figure No. 5** respectively.

Table No. 1: Descriptive statistics of demographic and echocardiographic parameters in two groups of the study population (N=84).

Parameter	Adult (N=42)	Pediatric Population (N=42)
Age in years	59.19 ± 7.9	2.65 ± 1.5
Gender		
Male	33 (78.57%)	29 (69.05%)
Female	9 (21.43%)	13 (30.95%)
Baseline LV Ejection Fraction <55	18 (42.86%)	20 (47.62%)
Preop TAPSE <16mm	0 (0%)	11 (26.19%)
Presence of Pulmonary Hypertension	2 (4.76%)	5 (11.90%)
Presence of Tricuspid regurgitation	11 (26.19%)	8 (19.05%)

Figure No. 3: Bar diagram of distribution of age in the paediatric study population (N=42)

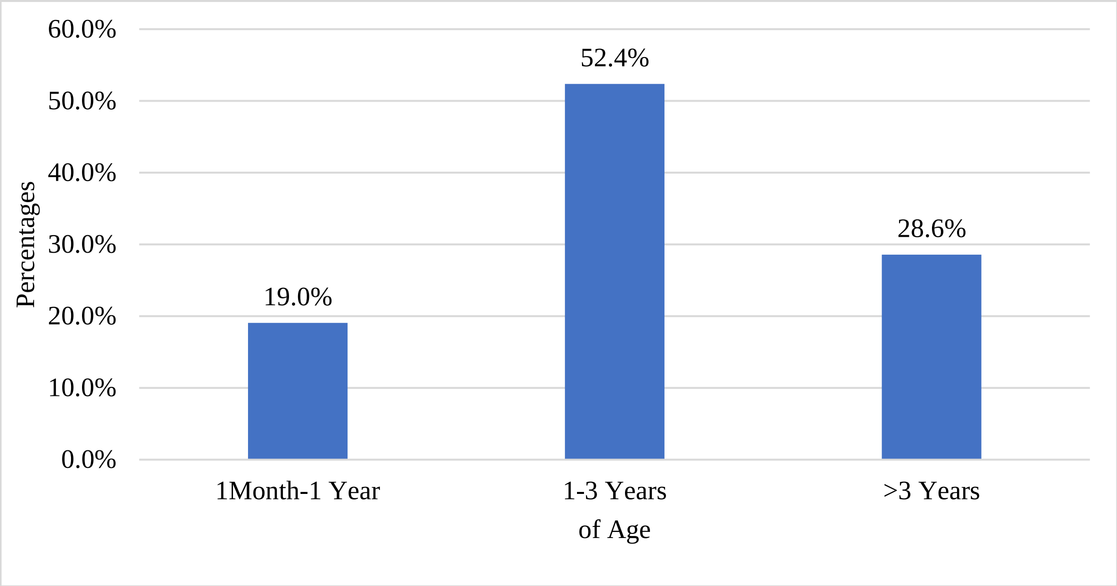
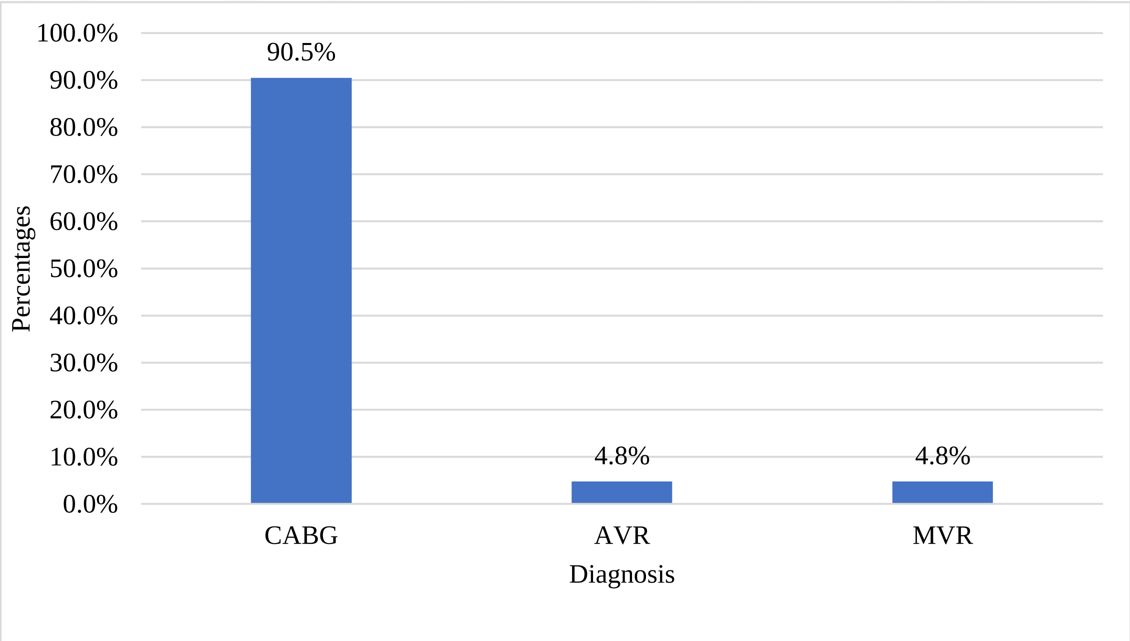
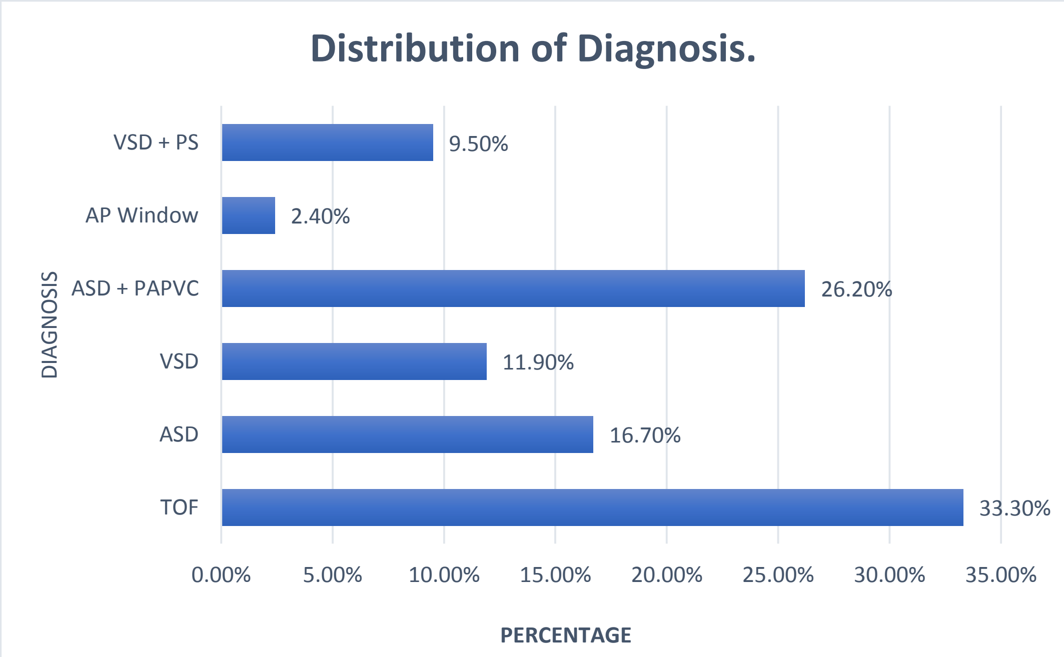


Figure 4: Bar diagram of distribution of diagnoses in adult study group (N=42).



Abbreviations: *CABG = Coronary Artery Bypass Graft, AVR = Aortic Valve Replacement, MVR = Mitral Valve Replacement.*

Figure 5: Bar diagram of distribution of diagnosis in paediatric study group (N=42)



Abbreviations: *TOF = Tetralogy of Fallot, ASD = Atrial Septal Defect. VSD = Ventricular Septal Defect, ASD PAPVC = ASD with Partial Anomalous Pulmonary Venous Connection, VSD PS = VSD with Pulmonary Stenosis, AP window = Aorto-pulmonary window.*

Right ventricular geometry, Tricuspid regurgitation and TTE M Mode TAPSE.

All the adult patients had a normal right ventricular geometry. However, only 16.7% of the paediatric group had a normal right ventricle. RV was dilated in 64.29% and hypertrophic in the remaining 19.05% of the paediatric group. Distribution of right ventricular geometry in each group is represented in **Table No. 2.**

Table No. 2: Comparison of Pre-operative right ventricular geometry between groups (N=84)

Pre-Op Right ventricular Geometry	Group	
	Adult Group (N=42)	Paediatric Group (N=42)
Dilated	0 (0%)	27 (64.29%)
Hypertrophic	0 (0%)	8 (19.05%)
Normal	42 (100%)	7 (16.67%)

All the patients had good right ventricular systolic function in the adult group (TAPSE>16mm). No association was found between the presence of tricuspid regurgitation and preoperative TAPSE in adults (p value = 0.908) as represented in **Table No. 3.**

However, paediatric patients showed significant association between the preoperative TAPSE and presence of tricuspid regurgitation (p value = 0.002) as represented in **Table No. 4.**

Table No. 3: Preoperative TTE- M Mode TAPSE and Preoperative TR Grade in adults (N=42)

Parameter	All patients	Mild TR	No TR	P value
TAPSE (mm)	20.9 ± 2.84	20.82 ± 2.96	20.94 ± 2.84	0.908

Table No. 4: Preoperative TTE- M Mode TAPSE and Preoperative TR Grade in Paediatric group (N=42)

Parameter	All patients	Mild TR	Severe TR	No TR	P value
TAPSE (mm)	17.64 ± 3.51	12.93 ± 0.05	15 ± 0	18.5 ± 3.32	0.002

Comparison of TTE M Mode TAPSE to TEE m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and Trans-gastric Right ventricular Inflow M Mode TAPSE measured before pericardiotomy.

TTE guided M mode TAPSE was compared to TEE guided m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and Trans-gastric Right Ventricular Inflow M Mode TAPSE. All the measurements were taken before pericardiotomy. Positive correlation (r>0) was found between the TTE guided M Mode TAPSE and all the three TEE guided measurements in the adult group, as shown in **Table No. 5**. However, the positive correlation was found to be significant only in the case of m-2D TAPSE (r = 0.379 and p value = 0.013).

Table No. 5: Correlation between Pre-operative TTE M Mode TAPSE and TEE m2-D TAPSE, TEE Deep Trans-gastric M Mode TAPSE and TEE Trans-gastric Right Ventricular Inflow M Mode TAPSE before CPB in adults (N= 42).

Parameter	Pearson Correlation (r)	P value
m-2D TAPSE	0.379	0.013
Deep Trans-gastric TAPSE	0.231	0.141
Trans-gastric Right Ventricular Inflow TAPSE	0.137	0.387

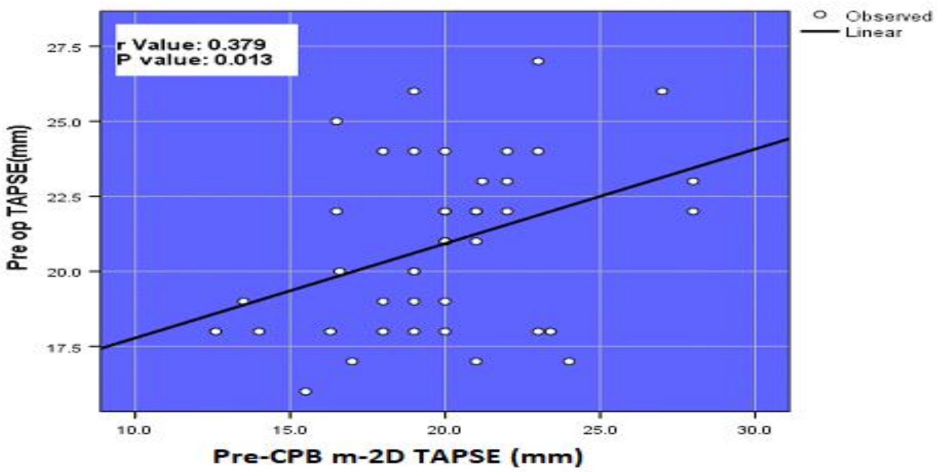
Similarly, in the paediatric group, all the three TEE guided measurements of RV systolic function, namely, m-2D TAPSE (r = 0.687), Deep Trans-gastric M Mode TAPSE (r = 0.315) and Trans-gastric Right Ventricular Inflow M Mode TAPSE (r = 0.660) showed positive correlation (r>0) with TTE guided M Mode TAPSE measured before pericardiotomy. Unlike in the adult group, all the positive correlations were statistically significant. **Table No. 6** demonstrates the same.

Table No. 6: Correlation between Pre-operative TTE M Mode TAPSE and TEE m2-D TAPSE, TEE Deep Trans-gastric M Mode TAPSE and TEE Trans-gastric Right Ventricular Inflow M Mode TAPSE before CPB in paediatric group (N= 42).

Parameter	Pearson Correlation (r)	P value
TEE m2-D TAPSE	0.687	<0.001
TEE Deep Trans-gastric M Mode TAPSE	0.315	0.042
TEE Trans-gastric Right Ventricular Inflow M Mode TAPSE	0.660	<0.001

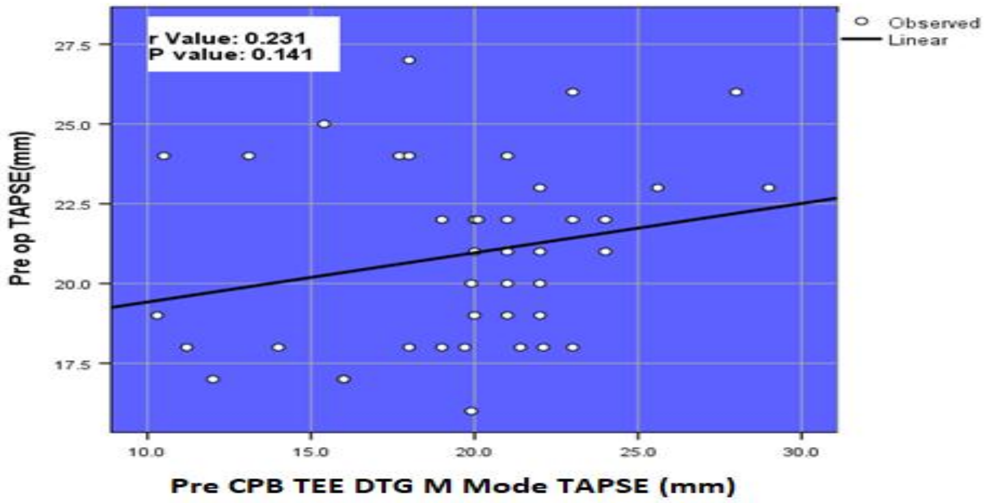
Figure No. 6, Figure No. 7 and **Figure No.8** represents correlation between the said parameters in scatter plot diagrams in adults. **Figure No. 9**, **Figure No. 10** and **Figure No. 11** shows the correlation between the TEE guided echocardiographic measurements and TTE guided M Mode TAPSE before pericardiotomy in the paediatric group.

Figure No.6: Scatter Plot of Pre-operative TTE M Mode TAPSE and TEE m2-D TAPSE in adults (N= 42)



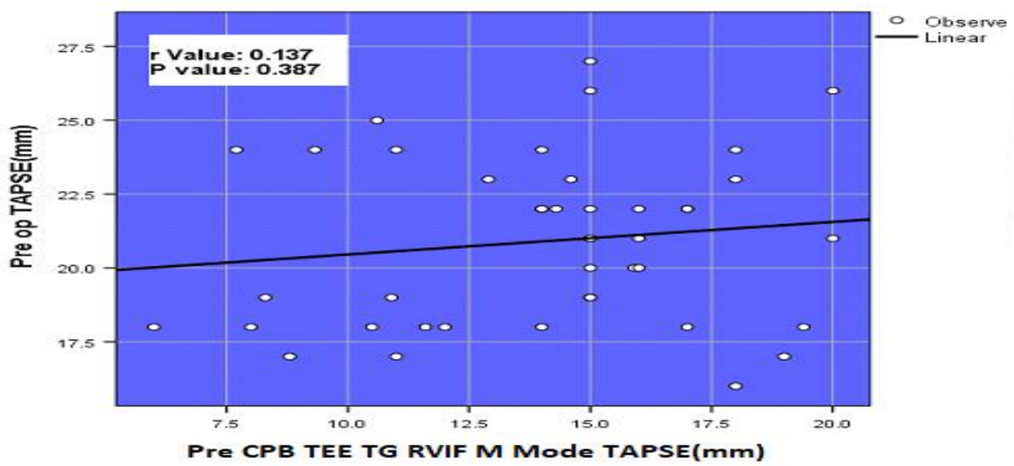
Individual scatter dots are centralized and individual values show lesser tendency to deviate from each other. It signifies good correlation (r = 0.379) between TTE guided M Mode TAPSE and m-2D TAPSE measured before pericardiotomy. The correlation is of statistical significance (p value = 0.013).

Figure 7: Scatter Plot of Pre-operative TTE M Mode TAPSE and TEE Deep Trans-gastric M Mode TAPSE before CPB in adults (N=42).



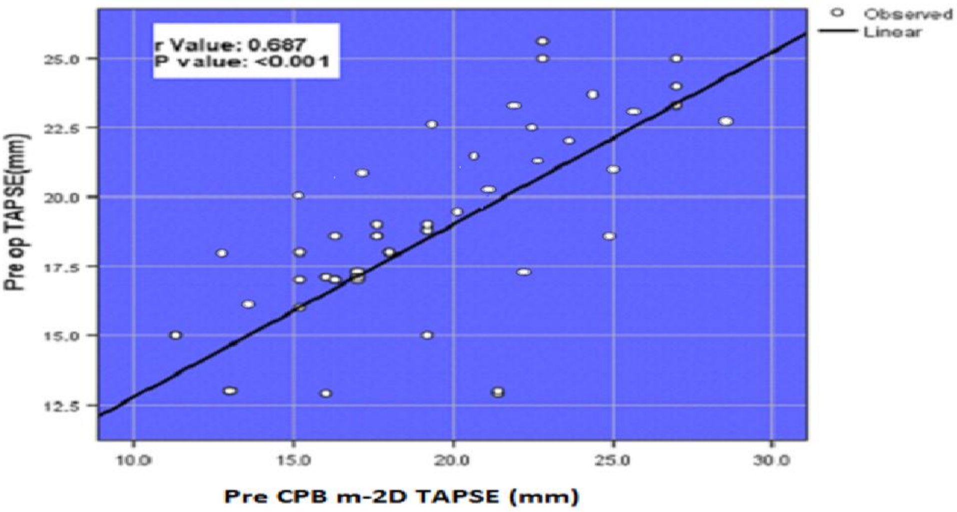
Individual scatter dots are less centralized and individual values show some tendency to deviate from each other. Positive r value (r = 0.231) signifies positive correlation between TTE guided M Mode TAPSE and Deep Trans-gastric M Mode TAPSE measured before pericardiotomy. The correlation is not of statistical significance (p=0.141).

Figure 8: Scatter Plot of Pre-operative TTE M Mode TAPSE and TEE Trans-gastric Right Ventricular Inflow M Mode TAPSE in adults



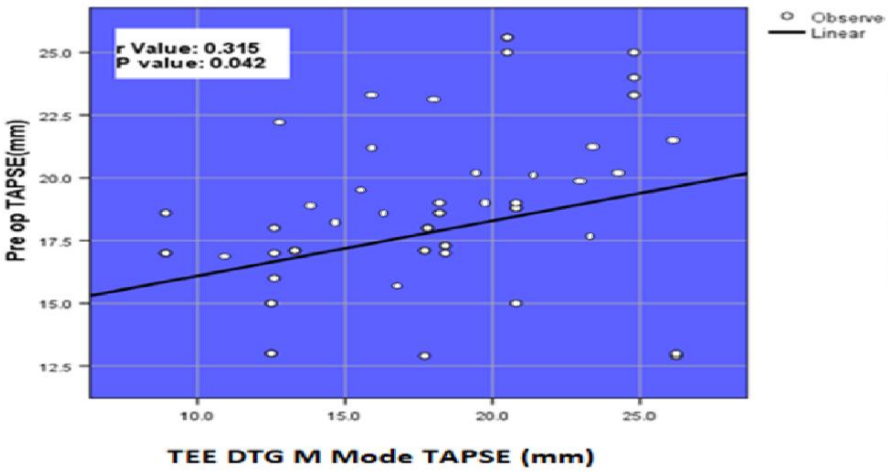
Individual scatter dots are poorly centralized and individual values show some tendency to deviate from each other. r value > 0 signifies positive correlation between TTE guided M Mode TAPSE and Trans-gastric Right Ventricular Inflow M Mode TAPSE measured before pericardiotomy. The correlation is not of statistical significance (p=0.387).

Figure 9: Scatter Plot of correlation between Pre-operative TTE M Mode TAPSE and TEE m2-D TAPSE before CPB in paediatric group (N= 42).



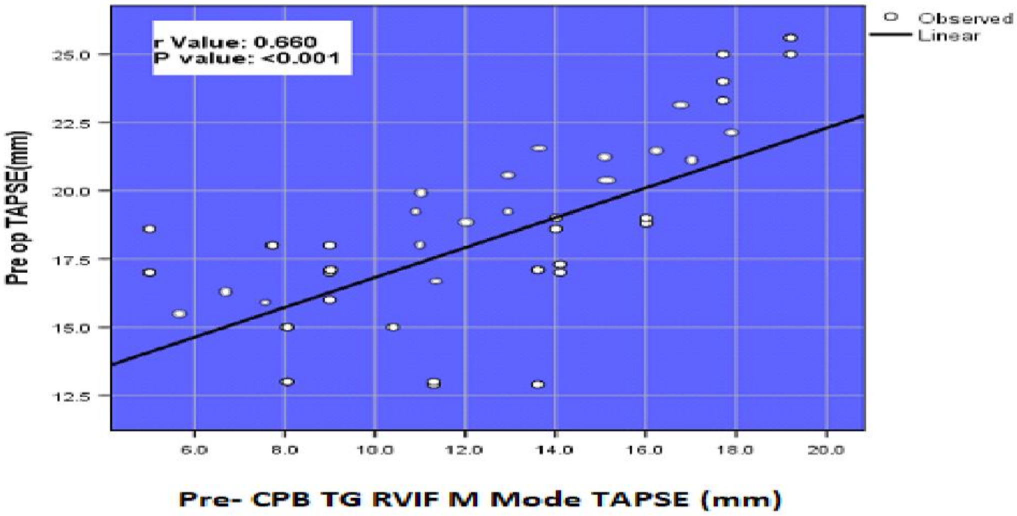
Individual scatter dots are centralized and individual values show lesser tendency to deviate from each other. It signifies good correlation (r=0.687) between TTE guided M Mode TAPSE and m-2D TAPSE measured before pericardiotomy. The correlation is of statistical significance (p<0.001).

Figure 10: Scatter plot of correlation between pre-operative TTE M Mode TAPSE and TEE Deep Trans-gastric M Mode TAPSE before CPB in paediatric group (N= 42).



Individual scatter dots are centralized and individual values show lesser tendency to deviate from each other. It signifies good correlation (r= 0.315) between TTE guided M Mode TAPSE and Deep Trans-gastric M Mode TAPSE measured before pericardiotomy. The correlation is of statistical significance (p value = 0.042).

Figure 11: Scatter Plot of correlation between Pre-operative TTE M Mode TAPSE and TEE Trans-gastric Right Ventricular Inflow TAPSE before CPB in paediatric group (N= 42).



Individual scatter dots are centralized and individual values show less tendency to deviate from each other. It signifies good correlation (r= 0.660) between TTE guided M Mode TAPSE and Trans-gastric Right Ventricular Inflow M Mode TAPSE measured before pericardiotomy. The correlation is of statistical significance (p value = <0.001).

Modified 2D TAPSE and RV FAC.

Correlation between TEE guided m-2D TAPSE and Right ventricular FAC in adult and paediatric group before CPB, after CPB and after sternal closure are depicted in **Table No. 7** and **Table No. 8** respectively.

RV FAC in adult population showed positive correlation (r=0.414) with m-2D TAPSE measured before pericardiotomy. The correlation was statistically significant (p value = 0.006). positive correlation between the two parameters continued after CPB and after sternal closure. However, they were no longer statistically significant.

Table No. 7: Correlation between Modified 2 D TAPSE and Right ventricular Fractional Area of Change in Adult group at different time periods (N= 42).

Right ventricular Fractional Area of Change	Pearson Correlation Coefficient (r)	P value
Pre CPB	0.414	0.006
Post CPB	0.075	0.635
Post sternal closure	0.246	0.116

Positive correlation (r>0) is demonstrable between RV FAC and m-2D TAPSE at all time points. Statistically significant correlation was present only before CPB.

Table No. 8: Correlation between Modified 2 D TAPSE and Right Ventricular Fractional Area of Change in Paediatric group at different time periods (N= 42)

Right ventricular Fractional Area of Change	Pearson Correlation (r)	P value
Pre CPB	0.572	<0.001
Post CPB	0.104	0.514
Post sternal closure	0.185	0.242

Positive correlation (r>0) is demonstrable between RV FAC and m-2D TAPSE at all time points. Statistically significant correlation was present only before CPB.

Comparison of Modified 2 D TAPSE with Deep Trans-gastric M Mode TAPSE and Trans-gastric Right ventricular Inflow M Mode TAPSE.

Correlation of Modified 2 D TAPSE with Deep Trans-gastric M Mode TAPSE and trans-gastric Right Ventricular Inflow M Mode TAPSE before CPB, after CPB and after sternal closure in adult and paediatric group is represented in **Table No. 9** and **Table No. 10** respectively.

Positive correlation was evident between modified 2 D TAPSE and Deep Trans-gastric M Mode TAPSE in the adult group before CPB, after CPB and after sternal closure. The correlation was statistically significant (p value 0.009 v <0.001 v <0.001). Similarly, m-2D TAPSE and Trans-gastric Right Ventricular Inflow M Mode TAPSE showed statistically significant positive correlation before CPB, after CPB and after sternal closure (p value <0.001 v <0.001 v<0.001).

Table No. 9: Correlation of Modified 2-Dimensional TAPSE with Deep Trans-gastric M Mode TAPSE and TG Right Ventricular Inflow M Mode TAPSE in Adults at different time periods (N= 42)

	Pre-CPB		Post-CPB		Post sternal closure	
	Pearson Correlation Coefficient	p value	Pearson Correlation Coefficient	p value	Pearson Correlation Coefficient	p value
Deep Trans-gastric M Mode TAPSE	0.396	0.009	0.675	<0.001	0.740	<0.001
Trans-gastric RV Inflow TAPSE	0.415	<0.001	0.655	<0.001	0.528	<0.001

Positive correlation was demonstrable between modified 2 D TAPSE and Deep Trans-gastric M Mode TAPSE in the paediatric group as well before CPB, after CPB and after sternal closure. The correlation was statistically significant (p value <0.001 v <0.001 v <0.001). Similarly, m- 2D TAPSE and Trans-gastric Right ventricular Inflow M Mode TAPSE showed statistically significant positive correlation at all the three time points studied (p value <0.001 v <0.001 v<0.001).

Table No. 10: Correlation of Modified 2-Dimensional TAPSE with Deep Trans-gastric M Mode TAPSE and Trans-gastric right ventricular Inflow M Mode TAPSE in paediatric group at different time periods (N= 42)

	Pre-CPB		**Post-CPB**		**Post sternal closure**	
	Pearson Correlation Coefficient	p value	Pearson Correlation Coefficient	p value	Pearson Correlation Coefficient	p value
Deep Trans-gastric M Mode TAPSE	0.786	<0.001	0.825	<0.001	0.919	<0.001
Trans-gastric Right Ventricular Inflow TAPSE	0.690	<0.001	0.641	<0.001	0.571	<0.001

Analysis of method agreement of TEE guided m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and TG Right Ventricular Inflow TAPSE to TTE guided M Mode TAPSE.

Comparison of different methods of measurement of RV function using TEE namely m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and TG Right Ventricular Inflow TAPSE to preoperative TTE guided M Mode TAPSE in adult and paediatric group is shown in **Table No.11** and **Table No. 12** respectively. Measurements taken before CPB are used for the analysis.

Bias inherent in each method is given along with limits of agreement. Statistical analysis was done on the bias associated with each method to identify whether the bias was statistically significant when compared to preoperative TTE guided M Mode TAPSE, which was taken as the reference method. Bias associated with m-2D TAPSE (-0.97 in adults and 0.17 in paediatric group) and Deep Trans-gastric M Mode TAPSE (-1.29 in adults and -0.6 in paediatric group) were not statistically significant. However, Trans-gastric Right Ventricular Inflow M Mode

TAPSE was found to have high Bias (-0.68 in adult group and -6.14 in paediatric group) which was of statistical significance (<0.001 in both groups).

Table No. 11: Comparison of Preoperative TTE guided M Mode TAPSE to TEE guided Modified 2-Dimensional TAPSE, TEE Deep Trans-gastric M Mode TAPSE, TEE TG Right Ventricular Inflow TAPSE measured before CPB in adults (N=42),

Parameter	Bias (LOA)	r (Pearson correlation)	P value
m-2 D TAPSE	-0.9738 (-7.87 to 5.92)	0.379	0.080
Deep Trans-gastric M Mode	-1.2881 (-10.16 to 7.58)	0.231	0.072
TG Right Ventricular Inflow M Mode	-6.8376 (-15.08 to 1.41)	0.137	<0.001

Bias in each measurement when compared to TTE guided M mode TAPSE, along with limits of agreement is given. Higher the numerical value, higher the bias. Limits of agreement signify the numerical limits within which 95% of the observations fall. Statistical significance of the bias is represented in the last column. Significant bias was present in TG Right Ventricular Inflow M Mode TAPSE measurements.

Table No. 12: Comparison of Preoperative TTE guided M Mode TAPSE to TEE guided Modified 2-Dimensional TAPSE, TEE Deep Trans-gastric M Mode TAPSE, TEE Trans-gastric Right Ventricular Inflow TAPSE measured before CPB in paediatric group (N=42)

Parameter	Bias (LOA)	r (Pearson correlation)	P value
Modified 2-Dimenional TAPSE	0.1690 (-5.60 to 5.93)	0.687	0.712
Deep trans gastric 4 chamber	- 0.5952 (-10.69 to 9.50)	0.315	0.458
Trans gastric Right Ventricular Inflow	-6.1436 (-12.53 to 0.24)	0.660	<0.001

Bias in each measurement when compared to TTE guided M mode TAPSE, along with limits of agreement is given. Higher the numerical value, higher the bias. Limits of agreement signify the numerical limits within which 95% of the observations fall. Statistical significance of the bias is represented in the last column. Significant bias was present in Trans-gastric Right Ventricular Inflow TAPSE measurements.

Longitudinal changes in m-2D TAPSE, Deep Trans-gastric M Mode TAPSE, Trans-gastric Right Ventricular Inflow TAPSE and RV FAC before CPB, after CPB and after sternal closure.

Longitudinal changes in the measurements of RV function during the surgery, namely, m-2D TAPSE, Deep trans-gastric M Mode TAPSE, Trans-gastric Right Ventricular Inflow TAPSE M mode TAPSE and RV FAC in adult and paediatric group are shown in **Table No. 13** and **Table No. 14** respectively.

Measurements of longitudinal movement of the right ventricle documented a significant decline after CPB as well as after sternal closure in both adult and paediatric groups (p value<0.001). RV FAC, the global measurement of RV function, also showed significant changes after CPB as well as sternal closure.

While the TAPSE values declined, RV FAC in adults showed an increasing trend after the CPB as well as the sternal closure (46.35 ± 10.61 v 50.63 ± 13.02 v 52.63 ± 11.05). In the paediatric group, TAPSE values significantly declined, however, RVFAC decreased after the CPB and improved beyond the pre CPB values after the sternal closure (47.4 ± 11.04 v 43.36 ± 8.32 v 48.33 ± 12.95). the changes were statistically significant.

Table No. 13: Change of Modified 2 D TAPSE, Deep Trans-gastric M Mode TAPSE, Trans-gastric Right Ventricular Inflow TAPSE and RV FAC at different time points during cardiac surgery in adults (N=42)

Parameter	Time Periods (Mean± SD)			P value
	Pre CPB	Post CPB	Post sternal closure	
m-2D TAPSE	19.93 ± 3.42	17.04 ± 3.31	16.05 ± 2.59	<0.001
Deep Trans-gastric M Mode TAPSE	19.62 ± 4.24	15.78 ± 2.60	15.13 ± 3.22	<0.001
Trans-gastric Right Ventricular Inflow M Mode TAPSE	14.07 ± 3.52	11.95 ± 2.69	11.53 ± 2.27	0.001
RV FAC	46.35 ± 10.61	50.63 ± 13.02	52.63 ± 11.05	0.012

Table No. 14: Change of Modified 2 D TAPSE, Deep Trans-gastric M Mode TAPSE, TG Right Ventricular Inflow TAPSE and RV FAC at different time points during cardiac surgery in paediatric group (N=42)

Parameter	Time Periods (Mean± SD)			P value
	Pre CPB	Post CPB	Post sternal closure	
m-2D TAPSE	17.81 ± 3.87	10.63 ± 3.55	9.24 ± 4.47	<0.001
Deep Trans-gastric M Mode TAPSE	17.04 ± 5.03	10.82 ± 4.45	9.97 ± 4.54	<0.001
TG Right Ventricular Inflow M Mode TAPSE	11.49 ± 4.23	8.26 ± 3.33	7.74 ± 3.37	<0.001
RV FAC	47.44 ± 11.04	43.46 ± 8.32	48.33 ± 12.95	0.001

Measurement of Reliability.

Inter-observer and intra-observer variability in TEE guided m-2D TAPSE, Deep Trans-gastric M Mode TAPSE, Trans-gastric Right Ventricular Inflow M Mode TAPSE and TTE guided M Mode TAPSE in adult and paediatric group are shown in **Table No. 15** and **Table No. 16** respectively.

Preoperatively measured TTE guided M Mode TAPSE was used as the reference (7.83% interobserver variability v 9.47% intra-observer variability). In adult group, Deep Trans-gastric M mode TAPSE had the least percentage error (6.96% v 9.1%), even lesser than the reference. Modified 2-D TAPSE similarly had low bias and percentage error (10.56% v 13.10). Trans-gastric Right Ventricular Inflow M mode TAPSE had the highest variability among all the methods (53.45% v 30.48%).

Table 15: Measurement of reliability in adults (N=42)

Parameter	Mean (CI)	Range	r (Pearson correlation)	Bias (LOA)	Percentage error
Modified 2-D TAPSE					
Inter-observer	20.08 (19.07 – 21.07)	17.45 to 22.75	0.934	-0.04 (-1.10 to 1.02)	10.56
Intra-observer	20.86 (18.52 – 23.20)	17 to 28	0.978	-0.52 (-1.88 to 0.84)	13.10
Deep Trans-gastric M Mode TAPSE					
Inter-observer	20.68 (19.66 – 21.69)	18 to 22.50	0.970	-0.05 (-0.77 to 0.67)	6.96
Intra-observer	18.9 (14.98 – 22.82)	10.25 to 27.50	0.998	-0.56 (-1.42 to 0.30)	9.10
Trans-gastric Right ventricular Inflow M Mode TAPSE					
Inter-observer	14.78 (13.32 to 16.23)	12 to 18	0.668	-1.25 (-5.20 to 2.70)	53.45
Intra-observer	13.45 (10.12 – 16.77)	7.35 to 19	0.976	-1.29 (-3.34 to 0.76)	30.48
Preop TTE M Mode TAPSE					
Inter-observer	21.2 (19.87 – 22.53)	18 to 24	0.978	-0.20 (-1.03 to 0.63)	7.83
Intra-observer	21.75 (19.20 – 24.30)	16.50 to 27	0.990	-0.50 (-1.53 to 0.53)	9.47

Correlation coefficient signifies the correlation between repeated measurements of each parameter. Higher the numerical value, higher the correlation. Bias with limits of agreement provide a measurement of accuracy on repetition of the test. Higher bias indicates less accuracy on repetition. Higher percentage error conveys poor repeatability.

Preoperatively measured TTE guided M Mode TAPSE was used as the reference in paediatric group (9.27% interobserver variability v 10.19% intra-observer variability). m-2D TAPSE had the least percentage error (4.42% v 12.24%) in the paediatric group. Deep Trans-gastric M Mode TAPSE similarly had low interobserver variability (10.82%). Trans-gastric Right Ventricular Inflow TAPSE had the highest variability among all the methods (55.6% v 31.65%).

Table 16: Measurement of reliability in Paediatric group (N=42)

Parameter	Mean (CI)	Range	r (Pearson correlation)	Bias (LOA)	Percentage error
Modified 2-D TAPSE					
Inter-observer	17.65 (14.59 – 20.71)	11.15 to 26.75	0.999	-0.26 (-0.65 to 0.13)	4.42
Intra-observer	17.15 (13.96 to 20.33)	11.15 to 26.50	0.993	-0.69 (-1.74 to 0.36)	12.24
Deep Trans-gastric M Mode TAPSE					
Inter-observer	16.26 (12.97 – 19.54)	8.98 to 24.70	0.820	-0.17 (-1.05 to 0.71)	10.82
Intra-observer	16.57 (13.89 to 19.24)	12.30 to 23.40	0.987	-0.53 (-2.33 to 1.27)	21.73
Trans-gastric Right Ventricular Inflow M Mode TAPSE					
Inter-observer	10.45 (7.73 – 13.17)	4.51 to 15.85	0.939	-1.30 (-4.20 to 1.61)	55.60
Intra-observer	11.47 (8.68 to 14.27)	6.87 to 18.10	0.985	-1.15 (-2.96 to 0.67)	31.65
Preop TTE M Mode TAPSE					
Inter-observer	17.04 (14.76 – 19.31)	12.75 to 23.65	0.996	-0.13 (-0.92 to 0.66)	9.27
Intra-observer	17.86 (15.28 to 20.44)	12.80 to 25.05	0.994	-0.48 (-1.39 to 0.43)	10.19

DISCUSSION

Right ventricle is described as the red herring[1] in cardiac surgery due to the many fallacies associated with the measurement of its function. Global measurements require approximation of a geometrical shape which is impossible in the case of right ventricle due to its complex nature. Longitudinal movement provides an opportunity for measurement which echocardiographers world-wide have utilised over decades.

84 patients (42 adults and 42 children) were included in our study making it one of the very few studies that have attempted to assess RV function in the paediatric age group. Nearly 50% of our paediatric study population were toddlers, more than a quarter were children and the remaining were infants constituting a reasonable distribution of different age groups. Nearly 1/3rd of the paediatric study group suffered from cyanotic congenital heart disease, which is a good representation of the proportion of cyanotic and acyanotic cases dealt with in our institute.

We considered TTE guided TAPSE measurement as the reference standard for our study as it is universally considered to be accurate and reliable due to excellent alignment of the lateral tricuspid annulus with the M mode. TEE guided measurements namely m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and Trans-gastric right Ventricular Inflow M Mode TAPSE were specifically measured before pericardiotomy while documenting the pre-CPB values to exclude the influence of pericardiotomy on the longitudinal movement of the right ventricle.

m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and Trans-gastric Right Ventricular Inflow M Mode TAPSE had positive correlation ($r>0$) with TTE M Mode TAPSE in both adult and paediatric population. In the adult group, only m-2D TAPSE ($p=0.01$) had statistically significant correlation with the TTE guided M mode TAPSE. However, in paediatric study group, correlation shown by all the three methods were statistically significant (p values <0.001 v 0.042 v <0.001). Forner et. al.,[15] similarly demonstrated good agreement of 2D TAPSE and Deep Trans-gastric M Mode TAPSE with TTE guided M Mode TAPSE. Only adult patients were included in the study. No similar studies are available in the paediatric age group.

Our study demonstrated positive correlation between RV FAC and m-2D TAPSE before CPB, after CPB and after sternal closure in both paediatric (r= 0.572 v 0.104 v 0.185) and adult groups (r=0.414 v 0.075 v 0.246). This correlation was statistically significant only before CPB (p=0.006 in adult group vs p<0.001 in paediatric group). Morita et. al.,[6] showed similar correlation between m-2D TAPSE and RV FAC. The study concluded that m-2D TAPSE should be considered as an alternative to RV FAC as it was easily measurable. Skinner et. al.,[8] made similar observations and demonstrated a positive correlation (r=0.58) between RV FAC and m-2D TAPSE. They inferred that clarity of the lateral border of tricuspid annulus is better compared to the endocardial border delineation. Our study agrees with both these observations. Lack of significant correlation of m-2D TAPSE with RV FAC after pericardiotomy and sternal closure could be due to the reduction in RV longitudinal contraction after pericardiotomy[3] while the RV global function remained unchanged. Donauer et. al.,[4] demonstrated by strain analysis that while TAPSE decreased by 44% after sternal closure, RV global function measured by RV EF remained unchanged after pericardiotomy and sternal closure. Forner et. al.,[15] also documented good correlation of RV FAC and TEE guided TAPSE measurements.

m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and Trans-gastric Right ventricular Inflow M Mode TAPSE had statistically significant positive correlation before CPB, after CPB and after sternal closure in both adult (p = 0.009 v p< 0.001 v p<0.001) and paediatric groups (p<0.001 v p<0.001 v p<0.001). Very few studies have compared longitudinal changes and method agreement of different methods of TAPSE measurement by TEE during cardiac surgery and after sternal closure. Korshin et. al.,[7] documented good correlation between the different methods of TAPSE measurements after sternotomy, after pericardiotomy, after completion of CPB and after sternal closure. This is in agreement with our study.

On comparison of method agreement of different TEE guided measures to TTE guided M Mode TAPSE, it was found that m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and Trans-gastric Right ventricular Inflow M Mode TAPSE demonstrated positive correlation to preoperative TTE guided M Mode TAPSE. However, Trans-gastric Right ventricular Inflow M Mode TAPSE had significant (p<0.001) bias in both paediatric [-6.14(-12.5 to 0.24)]) and adult group [-6.83(-15 .08

to 1.41)], making it less accurate in assessing RV function. A study by Forner et. al.,[15] documented similarly high bias in the measurement of Trans-gastric Right ventricular Inflow M Mode TAPSE [Bias with LOA = -8.09(-9.75 to -6.43)]. While we found low bias [-1.22(-10.16 to 7.58)] in Deep Trans-gastric M mode TAPSE measurements, Forner et. al., documented higher bias [-5.73 (-7.14 to -4.33)].

m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and Trans-gastric Right ventricular Inflow M Mode TAPSE documented significant decline after CPB and sternal closure. Unsworth et. al.[3], documented similar decline in right ventricular long axis velocities after full opening of the pericardium in patients who underwent elective cardiac surgeries. This decrease in right ventricular long axis velocities persisted till the end of the surgery. They concluded that pericardial opening caused persistent and immediate fall in right ventricular long axis velocities. Our study is in agreement with the observations documented by Unsworth et. al., as we found that the decline in TAPSE persisted even after sternal closure.

RV FAC, however, showed significant increase ($p=0.012$) after CPB which was sustained even after sternal closure, in adults (46.35 ± 10.61 v 50.63 ± 13.02 v 52.63 ± 11.05). This could be secondary to the presence of adrenaline infusion (100%) after CPB in CABG patients, who constituted 90% of the patient population in adult study group. Inotropic effect of the adrenaline as well as recovery from myocardial stunning at the end of the surgery could be the reason why RV global functions showed sustained significant improvement ($p = 0.001$) even during sternal closure. In paediatric group, RV FAC declined after CPB and improved to values higher that pre CPB levels after sternal closure (47.44 ± 11.04 v 43.46 ± 8.32 v 48.33 ± 12.95). This change was also statistically significant. Post CPB decline could be due to the presence of myocardial stunning after CPB. Myocardial recovery by the end of the surgery along with the presence of milrinone (100% in patients with TOF) that reduced RV afterload could have led to improvement after sternal closure. This observation is contradictory to the findings of the study done by Singh et.al.[14], where they documented decreased FAC, TAPSE and RV strain after CPB and sternal closure in adult patients who underwent cardiac surgeries. The authors could not explain the reason for persisting global right ventricular dysfunction.

Measurement of reliability showed that Deep Trans-gastric M Mode TAPSE (inter observer variability v intra-observer variability 6.96% v 9.10%) had the least interobserver variability and intra-observer variability (measured as percentage error) in the adult group. It was lower than TTE guided M Mode TAPSE (7.83% v 9.47%), which was the reference. This was in concurrence with the study by Korshin et al.,[7] which documented similar interobserver variability of 8.5% and intra-observer variability of 9.2% for Deep Trans-gastric M Mode TAPSE. M- 2D TAPSE also documented values similar to TTE M Mode TAPSE (7.83% v 9.47%). However, Trans-gastric Right Ventricular Inflow M Mode TAPSE had unacceptably high inter and intra-observer variability (53.45% v 30.48%). This is in contrast to the strikingly low inter observer (12%) and intra-observer (11.2%) variability demonstrated by Korshin et al., in the measurement of the Trans-gastric right ventricular Inflow TAPSE. The study even recommended using Trans-gastric Right Ventricular Inflow M Mode TAPSE as it was readily available. Our study, however, found trans-gastric Right Ventricular Inflow M Mode TAPSE highly unreliable.

In the paediatric group, m-2D TAPSE had the least error (4.42% v 12.24%) during repetition. Trans-gastric Right Ventricular Inflow M Mode TAPSE (55.6% v 10.19%) documented poor repeatability in paediatric group as well. Obtaining a well aligned Trans-gastric Right ventricular Inflow TAPSE was not an easy task. Many cases could not be included in the study due to poor alignment of the M mode to the annulus in Trans-gastric Right Ventricular Inflow M Mode TAPSE.

All the patients were on inotropic supports after cardiopulmonary bypass. Noradrenaline and adrenaline infusions of appropriate concentrations were used in CABG and AVR patients, whereas MVR patients received dobutamine infusion and noradrenaline infusion as per institute protocol. Infusion of intravenous milrinone with intravenous noradrenaline were used in paediatric patients with doses being decided on a case to case basis. All the patients were transferred to cardiac surgery ICU uneventfully.

To summarise, with supportive evidence from available literature, we made the below mentioned interpretations.

1. Intraoperative TEE guided modified 2 D TAPSE and Deep Trans-gastric M Mode TAPSE are comparable to preoperative TTE guided M Mode TAPSE in terms of accuracy, inter-observer and intra-observer variability in adult and paediatric population.
2. Intraoperative TEE guided Trans-gastric Right ventricular Inflow M Mode TAPSE shows positive correlation but has less accuracy and high interobserver and intra-observer variability when compared to preoperative TTE guided M Mode TAPSE in both adult and paediatric population.
3. Intraoperative TEE guided modified 2 D TAPSE has significant correlation to RV FAC, Deep Trans-gastric M Mode TAPSE and Trans-gastric Right Ventricular Inflow M Mode TAPSE before pericardiotomy in both adult and paediatric population.
4. Intraoperative TEE guided modified 2 D TAPSE, Deep Trans-gastric M Mode TAPSE and Trans-gastric Right Ventricular Inflow M Mode TAPSE declined significantly after cardiopulmonary bypass and after sternal closure.
5. RV FAC significantly increased after CPB and after sternal closure in adults. In paediatric group, RV FAC declined after CPB and improved significantly after sternal closure to pre CPB levels.

LIMITATIONS OF THE STUDY

1. Anatomical M Mode was not available in our echocardiography machine. This made Trans-gastric Right Ventricular Inflow M Mode TAPSE measurement technically difficult.
2. Paediatric patients had a variety of diagnoses for which they were operated on. This led to lack of uniformity in our patient population. However, our patients do represent the common diseases for which paediatric cardiac surgery is being carried out in our institute.
3. Advanced measurements of RV function including 3D volumetric analysis and 2D strain analysis were not part of our study. They were excluded in the planning stage as we focussed on quickly attainable and universally available tools of measurement.

CONCLUSION

TEE guided modified 2 D TAPSE and Deep Trans-gastric M Mode TAPSE provide accurate and reproducible assessment of the right ventricular function intraoperatively before pericardiotomy comparable to TTE guided M Mode TAPSE in adult and paediatric patients undergoing cardiac surgery. We propose not to use Trans-gastric right ventricular inflow M mode TAPSE intraoperatively for assessment of the right ventricular function due to inaccuracy, high inter observer variability and high intra-observer variability of the method. Further studies over larger cohorts are recommended to support our interpretations.

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ABBREVIATIONS

1.	AP Window	-	Aorto-pulmonary Window
2.	ASD	-	Atrial Septal Defect
3.	AVR	-	Aortic Valve Replacement
4.	CABG	-	Coronary Artery Bypass Graft
5.	DTG	-	Deep Trans gastric
6.	FAC	-	Fractional Area Change
7.	M- Mode	-	Motion Mode
8.	MVR	-	Mitral Valve Replacement
9.	RVOT	-	Right Ventricular Outflow Tract
10.	TAPSE	-	Tricuspid Annular Plane Systolic Excursion
11.	TEE	-	Transesophageal Echocardiography
12.	TOF	-	Tetralogy of Fallot
13.	TG RV Inflow	-	Trans gastric Right Ventricular Inflow
14.	TTE	-	Transthoracic Echocardiography
15.	VSD	-	Ventricular Septal Defect

CONSENT FORM

I, ____, [**Participant's name/Age (in years)],** Son / daughter of ____________________________________

(Please tick boxes)

Declare that I have read the above information provide to me regarding the study:

TITLE: Comparison of Transesophageal Echocardiography guided Modified 2-Dimensional and M-Mode Tricuspid Annular Plane Systolic Excursion with Transthoracic Echocardiography guided M-Mode Tricuspid Annular Plane Systolic Excursion in adult and paediatric cardiac surgeries for assessment of Right Ventricular Function.

- And have clarified any doubts that I had. [ ]
- I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights [ ]
- I understand that the study staff and institutional ethics committee members will not need my permission to look at my health records even if I withdraw from the trial. I agree to this access [ ]
- I understand that my identity will not be revealed in any information released to third parties or published [ ]
- I voluntarily agree to take part in this study [ ]
- I received a copy of this signed consent form [ ]

Name:

Signature:

Date:

Name of witness:

Relation to participant:

(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 or 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.

___________________________________ ____________________

Dr. **Mamatha Munaf,**

Senior Resident, CTVA,

SCTIMST.

Study Independent contact person: Dr. Mala Ramanathan

IEC Member Secretary

Contact no: 0471-22524324

CHILD ASSENT FORM

Title of the study: Comparison of Trans-esophageal Echocardiography guided Modified 2-Dimensional and M-Mode Tricuspid Annular Plane Systolic Excursions with Transthoracic Echocardiography Guided M-Mode Tricuspid Annular Plane Systolic Excursion in adult and paediatric cardiac surgeries for assessment of Right Ventricular Function.

Principal Investigator: Dr. Mamatha Munaf, Senior Resident, Cardiac Anaesthesia

My name is Dr. Mamatha Munaf. I am trying to learn about the function of right side of the heart by different methods in children and adults undergoing heart surgeries.

If you agree, we will be assessing the function of the right side of your heart by a scan called echocardiography in the OPD as well as during surgery. It is done in OPD by using a probe on the chest wall, whereas during surgery, the probe is placed in to the food pipe. You will not feel any pain or discomfort during this process and both scans are routinely performed for all patients.

You may help us understand the advantage of one technique over the other if you agree to participate.

You should also know that if you decide to help us or if you decide to say "no," your choice will not affect your treatment in hospital.

Please talk this over with your parents before you decide if you want to be in my study or not.

I will also ask your parents to give their permission for you to be in this study, but even if your parents say "yes," you can still say "no" and decide not to be in the study.

If you don't want to be in my study, you don't have to be in it. Remember, being in the study is up to you and no one will be upset if you don't want to be in the study or if you decide to stop after we begin, that's okay, too.

You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you can call me or ask your parents to call me: 7094013291

Would you like to participate in this study?

YES/NO

____

(Signature of child with date)

Name of the Child: __________________________ Age of the Child: ____

Parent's/Guardian's name: ____________________

(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 or 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.

_________________________________ ___________________

Dr. **Mamatha Munaf,**

Senior Resident, CTVA,

SCTIMST.

Study Independent contact person: Dr. Mala Ramanathan

IEC Member Secretary

Contact no: 0471-22524324

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സമ്മതപത്രം

പഠന ശീർഷകം:

മുതിർന്നവരിലും കുട്ടികളിലും ചെയ്യുന്ന ശസ്ത്രക്രിയയിൽ വലത് വെൻട്രിക്കിളിന്റെ പ്രവർത്തനം വിലയിരുത്താൻ, ട്രാൻസ്സ് ഈസോഫജിയൽ എക്കോകാഡിയോഗ്രഫിയുടെ മാർഗ്ഗനിർദ്ദേശാനുസരണം ചെയ്യുന്ന പരിഷ്ക്കരിച്ച ദ്വിതല എം മോഡ് ട്രൈകസ്പിഡ് ആനുലാർ പ്ലെയിൻ സിസ്റ്റോളിക് എക്സക്കർഷനും ട്രാൻസ്സ് തൊറാസിക് എക്കോകാഡിയോഗ്രഫിയുടെ മാർഗ്ഗനിർദ്ദേശാനുസരണം ചെയ്യുന്ന എം മോഡ് ട്രൈകസ്പിഡ് ആനുലാർ പ്ലെയിൻ സിസ്റ്റോളിക് എക്സക്കർഷനും തമ്മിലുള്ള താരതമ്യം

ഞാൻ (പങ്കെടുക്കുന്നയാളുടെ പേര് .... ജനനതീയതി/വയസ്സ് (വർഷത്തിൽ) .... പുത്രൻ/പുത്രി.............. ....(അച്ഛൻ/ അമ്മയുടെ പേര്)...

മുകളിൽപറഞ്ഞ പഠനസംബന്ധമായി എനിക്ക് നൽകിയ വിവരങ്ങൾ വായിച്ചതായി ഞാൻ പ്രസ്താവിക്കുന്നു.

ദയവായി പ്രസക്തമായ കോളങ്ങൾ അടയാളപ്പെടുത്തുക.

- എനിക്കുണ്ടായ സംശയങ്ങൾ പരിഹരിച്ചു [ ]
- എന്റെ ഈ പഠനത്തിലുള്ള പങ്കാളിത്തം സ്വമേധയായുള്ളതാണെന്നും, എനിക്ക് ഒരു കാരണവും കൂടാതെ ഏതുസമയത്തും, എനിക്കുള്ള വൈദ്യശുശ്രൂഷയെയോ നിയമപരമായ അവകാശങ്ങളെയോ ബാധിക്കാതെ പിൻവാങ്ങാമെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. [ ]
- ഈ പഠനത്തിന്റെ ഗവേഷകർ, നൈതീക കമ്മിറ്റി, നിയന്ത്രണാധികാരികൾ എന്നിവർക്ക് എന്റെ ആരോഗ്യവിവരങ്ങൾ ഞാൻ പഠനത്തിൽനിന്നും പിൻവാങ്ങിയാലും പരിശോധിക്കാൻ എന്റെ സമ്മതം അവശ്യമില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. ഇതിനു ഞാൻ സമ്മതിക്കുന്നു, [ ]
- ഭാവിയിൽ മൂന്നാം കക്ഷികൾക്കോ പ്രസിദ്ധീകരണത്തിനോ നൽകുമ്പോൾ എന്റെ വ്യക്തിവിവരങ്ങൾ വെളിപ്പെടുത്തുകയില്ലെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. [ ]

- സ്വമേധയാ പഠനത്തിൽ പങ്കെടുക്കാൻ ഞാൻ സമ്മതിക്കുന്നു. [ ]
- സമ്മതപത്രത്തിന്റെ ഒപ്പിട്ട ഒരു പ്രതി എനിക്ക് കിട്ടി. [ ]

പേര്	സാക്ഷിയുടെ പേര്
ഒപ്പ്	ഒപ്പ്
തീയതി	തീയതി

(സമ്മതം വാങ്ങുന്നയാൾ)

മെഡിക്കൽ റിസർച്ച് പ്രോജക്ടിനാവശ്യമായ സമ്മതപത്രത്തിനു വേണ്ടുന്ന എല്ലാ ഘടകങ്ങളും തൃപ്തികരമായി നിർവഹിച്ചിരിക്കുന്നുവെന്ന് ഞാൻ ബോധ്യപ്പെടുത്തുന്നു. പഠനപങ്കാളിയുമായി

ഗവേഷണപദ്ധതിയെപ്പറ്റി സാങ്കേതികേതര പദങ്ങളുപയോഗിച്ച് എല്ലാ വിവരങ്ങളെപ്പറ്റിയും ചർച്ച നടത്തുകയും പ്രതീക്ഷിക്കാവുന്ന അപകടസാധ്യതകളും പാർശ്വഫലങ്ങളും വിശദീകരിക്കുകയും ചെയ്തു. പങ്കാളിയെ ചോദ്യങ്ങൾ ചോദിക്കാൻ പ്രേരിപ്പിക്കുകയും എല്ലാ ചോദ്യങ്ങൾക്കും ഉത്തരം നൽകുകയും ചെയ്തു എന്നും ഞാൻ സാക്ഷ്യപ്പെടുത്തുന്നു.

സമ്മതപത്രം വാങ്ങുന്ന ആളുടെ പേരും ഒപ്പും
ഡോ മമത മുനാഫ് (ഫോൺ. 7094013291)
സീനിയർ റസിഡന്റ് **CVTA, SCTIMST.**

പഠനവുമായി ബന്ധമില്ലാത്ത വ്യക്തിയെ ബന്ധപ്പെടുന്നതിന് ദയവായി സ്ഥാപനത്തിലെ നൈതീക കമ്മിറ്റി മെംബർ സെക്രട്ടറി ഡോ. മാല രാമനാഥനെ ബന്ധപ്പെടാം. ഫോൺ 04712524234, email: iec.mem.sec@sctimst.ac.in

PATIENT INFORMATION SHEET

Title of the study:

Comparison of Transesophageal Echocardiography guided Modified 2-Dimensional and M-Mode Tricuspid Annular Plane Systolic Excursion to Transthoracic Echocardiography guided M-Mode Tricuspid Annular Plane Systolic Excursion in adult and paediatric cardiac surgeries for assessment of Right Ventricular Function.

Study numbers: we expect to involve 42 adult and 50 paediatric patients in the study.

What is Trans-thoracic echocardiography (TTE) and Trans-esophageal echocardiography (TEE)?

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

What is Tricuspid Annular Plane Systolic Excursion (TAPSE)?

Blood from the body is received by the right atrium from where it flows to the right ventricle which eventually pumps the blood to lungs for oxygenation. The right atrium and ventricle are separated by a valve called tricuspid valve. The movement of the lateral part of the valve to the tip of the heart can be measured during each pumping action of the heart. This is called TAPSE. If it is less than 16 mm in adults, it shows that the right ventricle is not able to pump blood well into lungs. This will help to predict about the chance of patient continuing to have problems even after surgery. Depending from the image from which this measurement is taken, there are different ways of measuring of TAPSE like M Mode TAPSE and modified 2D TAPSE.

How is TEE performed?

This will be done when you are under anesthesia and will not cause any discomfort to you. Your Anaesthesiologist will insert the lubricated probe into your mouth. He or she will then gently guide it down your throat into your oesophagus. Your oesophagus lies directly behind your heart. During this process, Anaesthesiologist will take care to protect your teeth and mouth from injury.

What are the risks and side-effects?

We do not expect that our study will cause any injury to you because our study protocol is a part of routine intra-operative TEE examination. You will be under the effect of anesthesia while the test is being performed, thus you are unlikely to experience any discomfort.

Why are we doing this study?

The purpose of this study is to compare whether intraoperative TEE measurement called TAPSE, as explained, is as good as the TAPSE measured by TTE before surgery. It will help in determining the most accurate and reliable method.

Can you withdraw from this study after it starts?

Your participation in this study is entirely voluntary and you are also free to decide to withdraw permission to participate in this study. If you do so, this will not affect your usual treatment at this hospital in any way.

What will happen if you develop any study related injury?

We do not expect any injury to happen to you because of our study as it is a part of routine examination during the surgery.

Will you have to pay for the study? No.

Will your personal details be kept confidential?

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

If you have any further questions, please ask:

Dr. Mamatha Munaf, Senior Resident, Division of Cardiac Anaesthesiology. (Ph No: 7094013291)

Dr. Thomas Koshy, Professor, Division of Cardiac Anaesthesiology

Dr. Suneel PR, Professor, Division of Cardiac Anaesthesiology

Dr. Harikrishnan S, Professor, Cardiology

Dr. Deepa S Kumar, Assistant Professor, Cardiology

Study Independent contact person: Dr. Mala Ramanathan, IEC Member Secretary

Contact no: 0471-22524324

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കാര്യവിവരണ പത്രം

പഠന ശീർഷകം:

മുതിർന്നവരിലും കുട്ടികളിലും ചെയ്യുന്ന ശസ്ത്രക്രിയയിൽ വലത് വെൻട്രിക്കിളിന്റെ പ്രവർത്തനം വിലയിരുത്താൻ, ട്രാൻസ് ഈസോഫേജിയൽ എക്കോകാഡിയോഗ്രഫിയുടെ മാർഗ്ഗനിർദ്ദേശാനുസരണം ചെയ്യുന്ന പരിഷ്ക്കരിച്ച ദ്വിതല എം മോഡ് ട്രൈകസ്പിഡ് ആനുലാർ പ്ലെയിൻ സിസ്റ്റോളിക് എക്സ്ക്കേർഷനും ട്രാൻസ്സ് തൊറാസിക് എക്കോകാഡിയോഗ്രഫിയുടെ മാർഗ്ഗനിർദ്ദേശാനുസരണം ചെയ്യുന്ന എം മോഡ് ട്രൈകസ്പിഡ് ആനുലാർ പ്ലെയിൻ സിസ്റ്റോളിക് എക്സ്ക്കേർഷനും തമ്മിലുള്ള താരതമ്യം

പഠന നമ്പർ: ഈ പഠനത്തിൽ 42 മുതിർന്ന രോഗികളെയും 42 കുട്ടികളായ രോഗികളെയും പങ്കെടുപ്പിക്കാമെന്ന് ഞങ്ങൾ പ്രതീക്ഷിക്കുന്നു.

ട്രാൻസ് തൊറാസിക് എക്കോ കാർഡിയോഗ്രഫി (റ്റിറ്റിഇ), ട്രാൻസ്സ് ഈസോഫേജിയൽ എക്കോകാഡിയോഗ്രഫി(റ്റിഇഇ) എന്നിവ എന്താണ്?

ഹൃദയത്തിന്റെയും അതിന്റെ രക്തക്കുഴലുകളുടെയും, ചലിക്കുന്നതും ഉയർന്ന ഗുണനിലവാരമുള്ളതുമായ ചിത്രങ്ങൾ സൃഷ്ടിക്കുന്നതിന് ശബ്ദതരംഗങ്ങളുപയോഗിക്കുന്ന ഒരു പരിശോധനയാണ് എക്കോ കാർഡിയോഗ്രഫി. ഹൃദയത്തിലെ പ്രശ്നമുള്ള മേഖലകൾ ഇതിന് ചൂണ്ടിക്കാണിക്കുവാനാകും, ആയത് വാൽവ് മാറ്റശസ്ത്രക്രിയക്കുമുൻപും ശേഷവുമുള്ള ഹൃദയവാൽവിന്റെ പ്രവർത്തനം വിലയിരുത്താൻ സഹായകമാണ്. സാധാരണ എക്കോകാഡിയോഗ്രഫിചെയ്യുന്നത് നെഞ്ചുവഴിയാണ്. എന്നിരുന്നാലും മയക്കലിന് വിധേയമായിരിക്കുമ്പോൾ കാർഡിയാക് സർജൻ ശസ്ത്രക്രിയനടത്തുന്നത് അതേ മേഖലയിലായതിനാൽ റ്റിറ്റിഇ ചെയ്യാനാകില്ല. അതിനാൽ എക്കോ കാർഡിയോഗ്രഫിയുടെ നിരീക്ഷണ ഉപകരണം ഈസോഫാഗസിലൂടെ (അന്നനാളം) കടത്തുന്നു. റ്റിഇഇയിൽ അറ്റത്ത് ട്രാൻസ്ഡ്യൂസർഘടിപ്പിച്ച വഴക്കമുള്ള ഒരു കുഴലുണ്ട് (പ്രോബ്). അനസ്തീഷ്യോളജിസ്റ്റ് താങ്കളുടെ തൊണ്ടയിലൂടെ ഈസോഫാഗസിൽ പ്രോബ് എത്തിക്കുന്നു(താങ്കളുടെ വായിൽനിന്നും ആമാശയത്തിലേക്കുള്ള വഴി). ഇത് ചെയ്യുന്നത് താങ്കൾ മയക്കലിന് വിധേയമായി ബോധരഹിതമായിരിക്കുമ്പോഴാണെന്നതിനാൽ താങ്കൾക്ക് അസ്വസ്ഥതയുണ്ടാക്കില്ല. ഈസോഫാഗസ് ഹൃദയത്തിന്റെ നേരെ പുറകിലാണെന്നതിനാൽ താങ്കളുടെ ഡോക്ടർക്ക് താങ്കളുടെ ഹൃദയത്തിന്റെ കൂടുതൽ വിശദമായ ചിത്രങ്ങൾ ലഭിക്കാൻ ഈ സമീപനം സഹായിക്കും.

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ട്രൈകസ്പിഡ് ആനുലാർ പ്ലെയിൻ സിസ്റ്റോളിക് എക്സ്ക്കേർഷൻ (റ്റാപ്സി)

ശരീരത്തിൽനിന്നുള്ള രക്തം വലത് എട്രിയം സ്വീകരിച്ച് അവിടെനിന്ന് വലത് വെൻട്രിക്കിളിലേക്ക് പ്രവഹിപ്പിക്കുകയും അവിടെനിന്ന് പ്രണവായുകലർത്താൻ രക്തം ശ്വാസകോശത്തിലേക്ക് പമ്പ് ചെയ്യുകയും ചെയ്യുന്നു. വലത് എട്രിയവും വെൻട്രിക്കിളും തമ്മിൽ ട്രൈകസ്പിഡ് എന്നറിയപ്പെടുന്ന വാൽവുകൊണ്ട് വേർതിരിക്കപ്പെട്ടിരിക്കുന്നു. വാൽവിന്റെ വശത്തുനിന്ന് ഹൃദയത്തിന്റെ അറ്റത്തേക്കുള്ള ചലനം ഹൃദയത്തിന്റെ ഓരോ പമ്പിങ്ങ് പ്രവർത്തനത്തിലും അളക്കാനാകും. ഇതിനെയാണ് റ്റാപ്സി എന്ന് വിളിക്കുന്നത്. അത് മുതിർന്നവരിൽ 16 മില്ലീമീറ്ററിൽ കുറവാണെങ്കിൽ അതുകാണിക്കുന്നത് ശ്വാസകോശത്തിലേക്ക് രക്തം നന്നായി പമ്പ് ചെയ്യാൻ വലത് വെൻട്രിക്കിനിന് കഴിയുന്നില്ല എന്നാണ്. ശസ്ത്രക്രിയ കഴിഞ്ഞാലും രോഗിക്ക് പ്രശ്നങ്ങൾ തുടരാൻ സാദ്ധ്യതയുണ്ടോയെന്ന് പ്രവചിക്കാൻ ഇത് സഹായിക്കും. അളവെടുത്ത ഈ ചിത്രത്തെ അവലംബിച്ചുകൊണ്ട് എം മോഡ് റ്റാപ്സി, പരിഷ്ക്കരിച്ച 2ഡി റ്റാപ്സി എന്നീ വ്യത്യസ്ഥമായ മാർഗ്ഗങ്ങളിലുടെ റ്റാപ്സി അളക്കാനാകും.

റ്റിഇഇ എങ്ങിനെയാണ് ചെയ്യുന്നത്?

ഇത് ചെയ്യുന്നത് താങ്കൾ മയക്കലിന് വിധേയമായിരിക്കുമ്പോഴാണെന്നതിനാൽ താങ്കൾക്ക് ഒരു അസ്വസ്ഥതയുമുണ്ടാക്കില്ല. താങ്കളുടെ അനസ്തീഷ്യോളജിസ്റ്റ്, മയപ്പെടുത്തിയ പ്രോബ് താങ്കളുടെ വായിൽ കടത്തും. എന്നിട്ട് സാവകാശം തൊണ്ടയിലൂടെ അത് താങ്കളുടെ ഈസോഫാഗസിലേക്ക് നയിക്കും. ഹൃദയത്തിന് നേരേ പുറകിലാണ് താങ്കളുടെ ഈസോഫാഗസ് സ്ഥിതിചെയ്യുന്നത്. ഈ പ്രക്രിയക്കിടയിൽ താങ്കളുടെ പല്ലുകൾക്കും വായ്ക്കും പരുക്കുണ്ടാകാതെ സംരക്ഷിക്കാൻ അനസ്തീഷ്യോളജിസ്റ്റ് ശ്രദ്ധിക്കും.

അപായങ്ങളും പാർശ്വഫലങ്ങളും എന്തെല്ലാം ?

ശസ്ത്രിക്രിയക്കിടയിലുള്ള പതിവ് റ്റിഇഇ പരിശോധനയുടെ ഭാഗമാണ് ഞങ്ങളുടെ പഠന പദ്ധതി എന്നതിനാൽ ഞങ്ങളുടെ പഠനംകൊണ്ട് താങ്കൾക്ക് പരുക്കുണ്ടാകുമെന്ന് ഞങ്ങൾ പ്രതീക്ഷിക്കുന്നില്ല. ഇത് ചെയ്യുന്നത് താങ്കൾ മയക്കലിന് വിധേയമായിരിക്കുമ്പോഴാണെന്നതിനാൽ താങ്കൾക്ക് ഒരു അസ്വസ്ഥതയും അനുഭവപ്പെടാൻ സാദ്ധ്യതയില്ല.

ഞങ്ങൾ എന്തിന് ഈ പഠനം നടത്തുന്നു?

വിശദീകരിച്ചപോലെ റ്റാപ്സി എന്ന് വിളിക്കുന്ന റ്റിഇഇ അളവെടുപ്പ് ശസ്ത്രക്രിയക്കിടയിൽ നടത്തുന്നത് ശസ്ത്രക്രിയക്കുമുൻപുനടത്തുന്ന റ്റാപ്സി റ്റിഇഇ അളവെടുപ്പുപോലെ ഫലപ്രദമാണോഎന്ന് താരതമ്യംചെയ്യുക എന്നതാണ് ഈ പഠനത്തിന്റെ ഉദ്ദേശം. വളരെകൃത്യവും വിശ്വസനീയവുമായ രീതി തീരുമാനിക്കാൻ അത് സഹായിക്കും.

3

പഠനമാരംഭിച്ചശേഷം താങ്കൾക്ക് പിൻമാറാമോ?

താങ്കളുടെ പഠനത്തിലുള്ള പങ്കാളിത്തം തികച്ചും സ്വമേധയായാണ്, പഠനത്തിലെ പങ്കാളിത്തത്തിൽ നിന്നും പിൻമാറാൻ തീരുമാനമെടുക്കാൻ താങ്കൾക്ക് സ്വാതന്ത്ര്യമുണ്ട്. താങ്കളങ്ങിനെ ചെയ്താലും താങ്കളുടെ ഈ ആശുപത്രിയിലെ പതിവ് ചികിത്സയെ ഒരുവിധത്തിലും ബാധിക്കില്ല.

പഠനവുമായി ബന്ധപ്പെട്ട് താങ്കൾക്ക് എന്തെങ്കിലും പരുക്കുണ്ടായാലെന്ത് സംഭവിക്കും ?

ശസ്ത്രിക്രിയക്കിടയിലുള്ള പതിവ് റ്റിഇഇ പരിശോധനയുടെ ഭാഗമാണ് ഞങ്ങളുടെ പഠന പദ്ധതി എന്നതിനാൽ ഞങ്ങളുടെ പഠനംകൊണ്ട് താങ്കൾക്ക് പരുക്കുണ്ടാകുമെന്ന് ഞങ്ങൾ പ്രതീക്ഷിക്കുന്നില്ല.

പഠനത്തിനായി താങ്കൾ പണം ചിലവാക്കണോ?

വേണ്ട

താങ്കളുടെ വ്യക്തിവിവരങ്ങൾ രഹസ്യമായിരിക്കുമോ?

പഠനഫലങ്ങൾ ഒരു വൈദ്യശാസ്ത്ര ജേർണലിൽ പ്രസിദ്ധീകരിക്കമെങ്കിലും താങ്കളെ വ്യക്തിപരമായി തിരിച്ചറിയാനിടയാക്കുന്നതൊന്നും പ്രസിദ്ധീകരണത്തിലോ, പഠനഫലങ്ങളുടെ പ്രദർശനത്തിലോ ഉണ്ടാവില്ല.

താങ്കൾക്ക് കൂടുതൽ എന്തെങ്കിലും ചോദ്യങ്ങൾ ഉണ്ടെങ്കിൽ ദയവായി ഡോ. മമതാ മനാഫ്, കാർഡിയാക് അനസ്തീഷ്യോളജി സീനിയർ റസിഡന്റിനോട് ചോദിക്കുക (ഫോൺ: 7094013291). ഇമെയിൽ. mamathamunaf@gmail.com

പ്രധാന ഗവേഷകന്റെ പേര്. ഡോ. മമത മുനാഫ്

ഡോ തോമസ് കോശി, പ്രൊഫസർ കാർഡിയാക് അനസ്തീഷ്യോളജി

ഡോ. സുനീൽ പിആർ, പ്രൊഫസർ കാർഡിയാക് അനസ്തീഷ്യോളജി

ഡോ ഹരികൃഷ്ണൻ എസ്, പ്രൊഫസർ കാർഡിയോളജി

ഡോ ദീപ എസ് കുമാർ, അസിസ്റ്റന്റ് പ്രൊഫസർ കാർഡിയോളജി

പഠനവുമായി ബന്ധമില്ലാത്ത വ്യക്തിയെ ബന്ധപ്പെടുന്നതിന് ദയവായി സ്ഥാപനത്തിലെ നൈതീക കമ്മിറ്റി മെംബർ സെക്രട്ടറി ഡോ. മാല രാമനാഥനെ ബന്ധപ്പെടാം. ഫോൺ 04712524234, email: iec.mem.sec@sctimst.ac.in

OBSERVATION CHART

Comparison of Transesophageal Echocardiography guided Modified 2-Dimensional and M-Mode Tricuspid Annular Plane Systolic Excursion with Transthoracic Echocardiography (TTE) guided M-Mode Tricuspid Annular Plane Systolic Excursion in adult and paediatric cardiac surgeries for assessment of Right Ventricular Function.

Hospital number of the patient:

Age: Weight:

Gender: Height:

BSA (kg/cm^2):

Diagnosis: Surgery:

Date of Surgery:

Preoperative features:

NYHA: Pulmonary Hypertension:

Heart rate and rhythm: Blood Pressure:

Preoperative Transthoracic Echocardiographic measurements

TAPSE from Apical 4 chamber view (mm)		Z-score:
Right Ventricular (RV) Function (FAC)	Normal (≥32%)/ Dysfunction: mild (25-31) / mod (18-24%) / severe (<18%)	
RV Geometry Normal (VSD, CABG, Valvular Heart Diseases)/ Volume overload (ASD) / Pressure overload (TOF)	Normal/Volume overload/Pressure overload	
Degree of TR (if any)	Mild/Moderate/ Severe	
Pulmonary arterial pressure	Normal / ……………. mm Hg	
LV Ejection Fraction	Normal / Dysfunction: mild / mod / severe	

Intraoperative Transesophageal measurements (End-Expiratory- two readings)

	Pre CPB	**Post CPB**	**After Sternal closure**
m2D TAPSE (ME 4C view) (mm)	/	/	/
M-Mode TAPSE (DEEP TRANSGASTRIC 4C) (mm)	/	/	/
M-Mode TAPSE (TG RV inflow) (mm)	/	/	/
RV FAC (actual value. use agitated saline if required)	/ /	/ /	/ /
LV EF (actual value)			
Degree of TR if any Mild/Moderate/ Severe			
Inotropes (if any) ……………………………(dose)			
Pulmonary arterial pressure (mm Hg)			
RV diastolic function E/A			

Technical Advisory Committee (Clinical Studies)

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

TAC Registration No: SCT-/S/2018/756 **Date: 21.06.2018**

Project title: COMPARISON OF TRANSESOPHAGEAL ECHOCARDIOGRAPHY GUIDED MODIFIED 2-DIMENSIONAL AND M-MODE TRICUSPID ANNULAR PLANE SYSTOLIC EXCURSION WITH TRANSTHORACIC ECHOCARDIOGRAPHY GUIDED M-MODE TRICUSPID ANNULAR PLANE SYSTOLIC EXCURSION IN ADULT AND PEDIATRIC CARDIAC SURGERIES FOR ASSESSMENT OF RIGHT VENTRICULAR FUNCTION

Principal Investigator:
Dr. Mamatha Munaf, Senior Resident, Department of (Division of Cardiac) Anesthesiology, SCTIMST Degree: M.D. (Anesthesiology), DNB(Anesthesiology), M.B.B.S.
Co-Principal Investigator(s)
Dr. Thomas Koshy, Professor, Department of Cardiac Anesthesiology, SCTIMST Degree: PDCC (Cardiac & Neuro Anesthesia), M.D. (Anesthesiology), D.A. (Anesthesiology) M.B.B.S.
Dr. Suneel PR, Professor, Department of Cardiac Anesthesiology, SCTIMST Degree: PDCC (Cardiac Anesthesia), M.D. (Anesthesiology), M.B.B.S.
Dr. Deepa S Kumar, Assistant professor, Department of Cardiology, SCTIMST Degree: M.B.B.S, DCH, DNB (paediatrics), DM(cardiology), PDCC (paediatric cardiology)
Dr Harikrishnan S, Professor, Department of Cardiology, SCTIMST Degree: MBBS, MD(General Medicine), DM(Cardiology), DNB(Cardiology), FRCP, FACC

Members who participated in the TAC meeting on 16/06/2018

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

Dr. Varghese T Panicker, Dr. Rupa Sreedhar, Dr. Jayadevan ER, Dr. Syam K, Dr. Krishna Kumar K, and Dr. Bijulal S stayed away from the proceedings when the projects in which they are involved as investigator were discussed (#762, 768, 769, 772, 775, 776, 778, 782, 784, 785).

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.

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

Signature of the Member Secretary, TAC (Clinical Studies)

Copy to IEC

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)
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Institutional Ethics Committee
(IEC Regn No. ECR/189/Inst/KL/2013/RR-16)

SCT/IEC/1235/AUGUST-2018

07.09.2018

Dr. Mamatha Munaf
Senior Resident
Department of Anaesthesiology
SCTIMST, Thiruvananthapuram

Dear Dr Mamatha Munaf,

The Institutional Ethics Committee reviewed and discussed your application to conduct the study entitled "COMPARISON OF TRANSESOPHAGEAL ECHOCARDIOGRAPHY GUIDED MODIFIED 2-DIMENSIONAL AND M-MODE TRICUSPID ANNULAR PLANE SYSTOLIC EXCURSION WITH TRANSTHORACIC ECHOCARDIOGRAPHY GUIDED M-MODE TRICUSPID ANNULAR PLANE SYSTOLIC EXCURSION IN ADULT AND PEDIATRIC CARDIAC SURGERIES FOR ASSESSMENT OF RIGHT VENTRICULAR FUNCTION (IEC/1235)" on 17th August, 2018.

The following documents were reviewed:
Original submission

1. Covering letter addressed to the Chairman, IEC, SCTIMST dated 21.07.2018 with check list
2. TAC Approval Letter
3. IEC Application Form
4. Project Proposal
5. Forwarding Letter from the HOD
6. Proforma
7. CV of Principal Investigator and Co- Principal Investigators
8. Patient Information Sheet and Consent Form in English and Malayalam

Revised submission

1. *Covering letter addressed to the Chairman, IEC, SCTIMST dated 31.08.2018 with checklist*
2. *TAC Approval Letter*
3. *IEC Application Form*
4. *Project Proposal*
5. *Forwarding Letter from the HOD*
6. *Proforma*
7. *Patient Information Sheet and Consent Form in English and Malayalam*
8. *Child Assent Form in English and Malayalam*
9. *Declaration Form*
10. *CV of Principal Investigator and Co- Principal Investigators*

Page 1 of 2

The following members of the Ethics Committee were present at the meeting held on 17th August, 2018 at G. Parthasarathi Board Room, AMCHSS, SCTIMST

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. R V G Menon	M Tech, PhD	Male	Lay Person (Chairman)	No
2.	Dr. V. Raman Kutty	M D, M Phil, M P H	Male	Health Sciences Expert/Clinician	Yes
3.	Dr. K R S Krishnan	M.E., Ph.D.	Male	Medical Technology	Yes
4.	Dr. Rema M. N	MD	Female	Basic Medical Scientist	No
5.	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,

MRamanathan

Mala Ramanathan
Member Secretary, IEC

Page 2 of 2

MASTER CHART- ADULT

Sl.No	Age	Sex	Diagnosis	Pre op TAPSE(mm)	Pre op RV Func	Pre op RV GEO	Degree OF TR	PAP Pre op	LVEF preop	m2D1	DTG4C1	TG RV IF1	m2D2	DTG4C2	TG RV IF2	m2D3	DTG4C3	TG RV IF3	RV FAC 1	RV FAC2	RV FAC3	LV EF1	LV EF2	LV EF3	TR1	TR2	TR3	INOTROPE1	INOTROPE2	INOTROPE3	PAP1	PAP2	PAP3	E/A1	E/A2	E/A3
1	69	M	CABG	17	Normal	N	MILD	Normal	60	24	16	19	15	11	12	14	9	11	44	38	40	63	57	55	NIL	Nil	Nil	NA 0.025	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1	0.9	0.9
2	64	M	CABG	27	Normal	N	MILD	Normal	52	23	18	15	13	13.1	10.8	13	10	11	40	36	42	50	50	60	NIL	Nil	Nil	NA 0.025	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1	0.9	0.8
3	51	F	CABG	17	Normal	N	NIL	Normal	60	17	12	11	12	13	9	12	12	10	38	34	40	59	62	64	Nil	Nil	Nil	Noradrenaline 0.05	Noradrenaline 0.05	Noradrenaline 0.05	N	N	N	1	1.1	0.9
4	64	M	CABG	21	Normal	N	NIL	Normal	55	20	24	20	15	15	10	15	10	12	39	34	34	55	48	50	NIL	Nil	Nil	Nil	Adrenaline 0.025, Noradrenaline 0.05	Noradr 0.05	N	N	N	1	0.9	1
5	46	M	CABG	22	Normal	N	NIL	Normal	60	28	20	16	18	14	10	18	11	10	42	30	40	70	57	58	Nil	Nil	Nil	Nil	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1.1	1	1.2
6	63	M	CABG	23	Normal	N	NIL	Normal	74	21.2	25.6	14.6	23.5	22.5	14.5	24	23	16	54.5	58.9	60	60	67	70	Nil	Nil	Nil	Nil	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1.2	1.2	1
7	74	M	CABG	26	Normal	N	NIL	Normal	46	19	28	20	26.4	18.7	20	14	11.1	9.52	39.4	56	58	35	44	50	NIL	Nil	Nil	NIL	Adrenaline 0.15, noradrenaline 0.1	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1.3	1.4	1.1
8	54	M	CABG	24	Normal	N	Nil	Normal	67	18	17.7	9.32	15.9	14.6	8.8	16	13	10	50	64	70	36	55	59	Nil	Nil	Nil	Nil	Adrenaline 0.1, noradrenaline 0.1	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1.1	1	0.9
9	61	M	CABG	24	Normal	N	Nil	Normal	45	22	10.5	7.7	16	14	14	16	14	14	43	38	44	44	50	55	Nil	Nil	Nil	Nil	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1.1	1	0.9
10	52	M	CABG	19	Normal	N	Mild	Normal	43	19	20	8.3	18	11	9	16	12	10	65	34	36	41	52	55	Nil	Nil	Nil	Nil	Adrenaline 0.05, noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	0.83	0.67	0.8
11	55	M	CABG	17	Normal	N	Nil	Normal	55	21	16	8.8	18	15	14	19	15	14	71	48	48	68	65	62	Nil	Nil	Nil	Nil	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1.5	1.1	1.1
12	64	M	CABG	25	Normal	N	Nil	Normal	68	16.5	15.4	10.6	20	16	16.5	17	15	15	41	63.9	65	70	65	67	Nil	Nil	Nil	Nil	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1.3	1.1	1.1
13	56	M	CABG	16	Normal	N	Nil	Normal	50	15.5	19.9	18	23	18	14	14	13.3	9	36.24	51.4	62	43	64.5	66	Nil	Nil	Nil	Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	Adr 0.025, NA0.05	N	N	N	2	1.8	1.9
14	58	F	CABG	18	Normal	N	Nil	Normal	61	16.3	19.7	11.6	23	17	9	19	17	7.4	42	70	75	57	67	70	Nil	Nil	Nil	Nil	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1.1	1.5	1.7
15	63	M	CABG	18	Normal	N	MILD	Normal	58	20	18	14	20	18	14	17	16	9	45	70	65	60	55	70	Nil	Nil	Nil	Nil	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1	0.9	1.1
16	59	M	AVR	18	Normal	N	NIL	Normal	58	23	21.4	10.5	20	12.6	12.7	15	15	11.9	38.6	66	59.7	44	73	75	Nil	Nil	Nil	Nil	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1.2	0.9	1.1
17	53	M	CABG	18	Normal	N	Nil	Normal	79	12.6	11.2	8	14	14	8	13.3	13.9	12.9	45	38.9	44.7	60	65	60	Nil	Nil	Nil	Nil	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	0.8	0.6	0.8
18	72	M	CABG	23	Normal	N	Mild	Normal	56	28	22	18	20	18	16	21.4	19.4	13.1	62.7	58	57	70	66	64	Mild	Mild	Mild	Nil	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	0.9	1	1.1
19	55	F	CABG	26	Normal	N	Nil	Normal	70	27	23	15	17	17	10	18	19	11	42.8	50	45	60	62	68	Nil	Nil	Nil	Nil	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1	0.9	1
20	67	F	CABG	23	Normal	Normal	Nil	Normal	64	22	29	12.9	18	17	14	18	16	15	48	45	47	81	75	72	Mild	Nil	Nil	Nil	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	0.6	0.8	0.9
21	71	M	CABG	18	Normal	Normal	Nil	Normal	61	23.4	22.1	19.4	14	13.1	8	14	13	9	21	43	44	47	56	59	Nil	Nil	Nil	Nil	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1.1	1	1
22	58	M	CABG	18	Normal	Normal	Nil	Normal	36	14	14	6	10	9	7	14	13	9	46	40	50	46	58	59	Nil	Mild	Nil	Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1.1	0.9	1
23	65	M	CABG	24	Normal	Normal	NIL	Normal	38	20	13.1	11	16	17	11	16	16	11	48.72	45	50	25	40	45	Nil	Nil	Nil	Noradrenaline 0.05	Adrenaline 0.1, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1.1	0.9	1.2
24	57	M	CABG	19	Normal	Normal	Trivial	Normal	58	13.5	10.3	10.9	14.6	15.9	12.9	10.5	11.8	9.38	32.7	55.6	47.9	59	61	60	Nil	Nil	Nil	Nil	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	0.8	0.7	0.9
25	39	M	CABG	22	Normal	Normal	NIL	Normal	71	16.5	20.1	14.3	20.5	18.5	13.6	13	10	7	67	82	61	62	83	82	NIL	Nil	Nil	NIL	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1.2	0.8	1.4
26	56	M	CABG	20	Normal	Normal	NIL	Normal	68	16.6	19.9	15.9	15	14	11	15	13	12	41	45	50	50	55	55	MILD	Nil	Nil	NIL	Adrenaline 0.025, Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.05	N	N	N	1.1	0.9	1
27	55	M	MVR	22	Normal	Normal	Mild	Mild PAH	55	22	24	14	18	18	11	18	19	12	42.6	30	40	70	57	58	Nil	Nil	Nil	NIL	Adrenaline 0.025, Noradrenaline 0.06	Adrenaline 0.025, Noradrenaline 0.06	N	N	N	1.2	1.2	1
28	49	F	CABG	21	Normal	Normal	Mild	Normal	49	20	21	15	16	16	10	16	15	10	55	56	60	60	67	70	Nil	Nil	Nil	NIL	Adrenaline 0.025, Noradrenaline 0.07	Adrenaline 0.025, Noradrenaline 0.07	N	N	N	1.3	1.4	1.1

29	59	F	CABG	20	Normal	Normal	NIL	Normal	53	19	22	16	17	17	13	17	18	13	40	56	58	50	66	65	Nil	Nil	Nil	NIL	Adrenaline 0.025, Noradrenaline 0.08	Adrenaline 0.025, Noradrenaline 0.08	N	N	N	1.1	1	0.9
30	66	M	CABG	18	Normal	Normal	NIL	Normal	39	19	23	17	18	19	14	18	19	15	49.5	64	70	54	55	59	Nil	Nil	Nil	Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.09	Adrenaline 0.025, Noradrenaline 0.09	N	N	N	1.1	1	0.9
31	72	M	CABG	19	Normal	Normal	mild	Normal	55	18	21	15	16	17	15	16	18	15	42	38	44	48	50	55	Nil	Nil	Nil	NIL	Adrenaline 0.025, Noradrenaline 0.10	Adrenaline 0.025, Noradrenaline 0.10	N	N	N	1	0.7	0.8
32	54	M	AVR	22	Normal	Normal	NIL	Normal	49	21	19	14	18	19	12	16	18	11	66	34	36	41	52	55	Nil	Nil	Nil	NIL	Adrenaline 0.025, Noradrenaline 0.11	Adrenaline 0.025, Noradrenaline 0.11	N	N	N	1.6	1.1	1.1
33	75	M	CABG	21	Normal	Normal	NIL	Normal	50	20	22	16	17	18	11	17	16	11	68	48	48	68	65	62	Nil	Nil	Nil	NIL	Adrenaline 0.025, Noradrenaline 0.12	Adrenaline 0.025, Noradrenaline 0.12	N	N	N	1.3	1.1	1.1
34	58	M	MVR	20	Normal	Normal	mild	Mild PAH	48	19	21	15	16	16	13	17	16	13	40	63	65	70	65	67	Nil	Nil	Nil	NIL	Adrenaline 0.025, Noradrenaline 0.13	Adrenaline 0.025, Noradrenaline 0.13	N	N	N	2	1.8	1.9
35	59	M	CABG	22	Normal	Normal	NIL	Normal	45	21	20	17	15	16	14	16	19	15	35	51	62	43	64	66	Nil	Nil	Nil	NIL	Adrenaline 0.025, Noradrenaline 0.14	Adrenaline 0.025, Noradrenaline 0.14	N	N	N	1.1	1.5	1.7
36	61	F	CABG	22	Normal	Normal	NIL	Normal	54	20	23	17	15	15	11	15	15	11	42	68	75	57	67	70	Nil	Nil	Nil	NIL	Adrenaline 0.025, Noradrenaline 0.15	Adrenaline 0.025, Noradrenaline 0.15	N	N	N	1	0.9	1.1
37	49	F	CABG	24	Normal	Normal	NIL	Normal	60	23	21	18	18	17	12	19	20	12	45	66	65	60	55	70	Nil	Nil	Nil	NIL	Adrenaline 0.025, Noradrenaline 0.16	Adrenaline 0.025, Noradrenaline 0.16	N	N	N	1.2	0.9	1.1
38	66	M	CABG	18	Normal	Normal	NIL	Normal	66	18	19	12	15	16	13	15	16	13	39	66	58	44	65	64	Nil	Nil	Nil	NIL	Adrenaline 0.025, Noradrenaline 0.17	Adrenaline 0.025, Noradrenaline 0.17	N	N	N	0.8	0.6	0.8
39	53	M	CABG	19	Normal	Normal	NIL	Normal	56	20	22	15	12	13	8	12	13	8	45	39	45	60	65	60	Nil	Nil	Nil	NIL	Adrenaline 0.025, Noradrenaline 0.18	Adrenaline 0.025, Noradrenaline 0.18	N	N	N	0.9	1	1.1
40	50	M	CABG	24	Normal	Normal	mild	Normal	54	19	18	14	14	14	9	15	17	10	63	58	57	70	63	64	Nil	Nil	Nil	NIL	Adrenaline 0.025, Noradrenaline 0.19	Adrenaline 0.025, Noradrenaline 0.19	N	N	N	1	0.9	1
41	54	F	CABG	22	Normal	Normal	NIL	Normal	49	20	21	15	15	16	12	15	16	12	43	50	45	60	61	65	Nil	Nil	Nil	NIL	Adrenaline 0.025, Noradrenaline 0.20	Adrenaline 0.025, Noradrenaline 0.20	N	N	N	0.6	0.8	0.9
42	60	M	CABG	21	Normal	Normal	NIL	Normal	44	21	20	15	20	19	14	20	19	14	48	45	47	54	60	61	Nil	Nil	Nil	Noradrenaline 0.05	Adrenaline 0.025, Noradrenaline 0.21	Adrenaline 0.025, Noradrenaline 0.21	N	N	N	1.1	1	1

MASTER CHART- PEDIATRIC

Paeds	Age	Sex	Diagnosis	Pre op TAPSE(mm)	Pre op RV Func	Pre op RV GEO	Degree OF TR	PAP Pre op	LVEF preop	m2D1	DTG4C1	TG RV IF1	m2D2	DTG4C2	TG RV IF2	m2D3	DTG4C3	TG RV IF3	RV FAC 1	RV FAC2	RV FAC3	LV EF1	LV EF2	LV EF3	TR1	TR2	TR3	INOTROPE1	INOTROPE2	INOTROPE3	PAP1	PAP2	PAP3	E/A1	E/A2	E/A3
1	5	F	SV ASD, PAPVC	18.8	Normal	DILATED	NIL	Normal	56	19.2	20.8	16	19	20	15	18	19	15	54	53	60	46	58	59	Nil	Nil	Nil	Nil	Noradr 0.05	Noradr 0.025	Normal	Normal	Normal	0.9	1	1
2	3/12	M	AP window SV ASD PAPVC	17	Normal	DILATED	NIL	Normal	66	16.3	8.95	5.01	7.5	5.44	3.63	4.7	6.09	3.4	51	46	69	25	40	45	mild	mild	nil	nil	Milrinone 0.5, Noradr 0.05	Milrinone 0.5, Noradr 0.05	Mild	Normal	Normal	1.1	0.8	0.9
3	1yr 3Mo	M	TOF	12.9	Normal	Hypertrophied	Trivial	PS 69	65	21.4	26.2	11.3	10.1	16.9	8.72	3.62	8.35	3.5	61.9	33.4	29.5	59	61	60	Nil	Nil	Nil	Nil	Mil 0.5, noradr 0.05	Mil 0.5, noradr 0.05	Normal	Normal	Normal	1	1	0.8
4	1YR 10Mo	F	VSD PS	15	Normal	Dilated	Severe	Reactive. 40	70	11.3	12.5	8.06	9.15	8.6	6.05	5.11	4.03	5.85	28	29.7	51.9	62	83	82	Severe	Mild	Mild	Nil	Mil0.5, noradr 0.05	Mil 0.5, noradr 0.05	severe	Mild	Mild	0.7	0.8	0.8
5	4YR 1 MO	M	ASD PAPVC	18.6	Normal	Dilated	Nil	Nil	69	17.6	18.2	14	16	17	10	16	15	10	54	32	40	50	55	55	Nil	nil	nil	nil	noradr 0.05	Noradr 0.025	Nil	Nil	Nil	2	1.3	1.2
6	1Yr 1 Mo	M	TOF VALV PS	17.1	Normal	hypertrophied	Nil	Normal	70	17	13.3	9.02	7.93	8	7.31	9	12	8	63.6	52	55	54	56	53	nil	nil	nil	nil	Milrinone 0.5, Noradr 0.05	Milrinone 0.5, Noradr 0.05	nil	Nil	Nil	0.6	1.1	1
7	3	M	ASD	17.3	Normal	Dilated	Nil	Normal	65	17	18.4	14.1	12	11	6	13	12	7	45	44	48	55	53	55	Nil	Nil	NIl	Nil	noradr 0.05	noradr 0.05	Nil	Nil	Nil	1	0.6	1.1
8	3	F	VSD	23.3	Normal	Normal	Nil	Normal	50	27	24.8	17.7	15	13.7	11.7	14	15.6	11.7	50.8	54	64	54	60	61	Nil	Nil	Nil	Nil	Mil 0.5, noradr 0.05	Mil 0.5, noradr 0.05	Nil	Nil	Nil	1	0.7	1.2
9	2	F	TOF	13	Fair	Hypertrophic	NIL	Normal	50	13	12.5	8.06	9.15	8.6	6.05	5.11	4.03	5.85	29	32	30	54	50	47	Moderate	Moderate	moderate	MIL 0.5	MIL 0.5,	MIL 0.5, adr 0.05	Nil	Nil	Nil	0.6	0.6	0.7
10	5	M	ASD	18	Normal	Dilated	Nil	Mild PAH	68	18	17.8	7.73	8.1	8.4	11.3	9.72	11.9	10.8	37.6	44.1	36.7	66	50	56	Nil	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	1.1	1	1
11	7Mo	M	TOF	16	Good	Hypertrophic	Nil	Infundibular PS 56	70	15.2	12.6	9	7	6.27	4.64	4.74	4.43	4.1	45	49	49	56	54	53	nil	nil	nil	nil	Mil 0.5, noradr 0.05	Mil 0.5, noradr 0.05	Normal	Normal	Normal	0.8	1	1.1
12	5	M	Warden	25.6	Good	Dilated	Nil	Normal	70	22.8	20.5	19.2	8.37	12.7	12.7	9.51	11.5	10.4	52.07	42.9	30.2	66	55	59	Nil	Nil	Nil	Nil	Dobut 2.5	Dobut 0.1	Normal	Normal	Normal	1	1	1.1
13	5Mo	M	VSD	17.1	Good	Normal	Nil	Normal	70	16	17.7	13.6	11	8	7	9	8	7	36	45	54	60	55	54	nil	nil	nil	nil	Noradr 0.05	Noradr 0.05	Normal	Normal	Normal	1	1	0.9
14	3	F	SV ASD, PAPVC	18.8	Normal	DILATED	NIL	Normal	56	19.2	20.8	16	19	20	15	18	19	15	54	53	60	46	58	59	Nil	Nil	Nil	Nil	Noradr 0.05	Noradr 0.025	Normal	Normal	Normal	0.9	1	1
15	4	M	SV ASD PAPVC	17	Normal	DILATED	NIL	Normal	66	16.3	8.95	5.01	7.5	5.44	3.63	4.7	6.09	3.4	51	46	69	25	40	45	mild	mild	nil	nil	Milrinone 0.5, Noradr 0.05	Milrinone 0.5, Noradr 0.05	Mild	Normal	Normal	1.1	0.8	0.9
16	3	M	TOF	12.9	Normal	Enlarged	Trivial	Normal	65	21.4	26.2	11.3	10.1	16.9	8.72	3.62	8.35	3.5	61.9	33.4	29.5	59	61	60	Nil	Nil	Nil	Nil	Mil 0.5, noradr 0.05	Mil 0.5, noradr 0.05	Normal	Normal	Normal	1	1	0.8
17	2	F	VSD PS	15	Normal	Dilated	Severe	Reactive. 40	70	11.3	12.5	8.06	9.15	8.6	6.05	5.11	4.03	5.85	28	29.7	51.9	62	83	82	Severe	Mild	Mild	Nil	Mil0.5, noradr 0.05	Mil 0.5, noradr 0.05	severe	Mild	Mild	0.7	0.8	0.8
18	3	M	ASD PAPVC	18.6	Normal	Dilated	Nil	Nil	69	17.6	18.2	14	16	17	10	16	15	10	54	32	40	50	55	55	Nil	nil	nil	nil	noradr 0.05	Noradr 0.025	Nil	Nil	Nil	2	1.3	1.2
19	2	M	TOF VALV PS	17.1	Normal	Dilated	Nil	Normal	70	17	13.3	9.02	7.93	8	7.31	9	12	8	63.6	52	55	54	56	53	nil	nil	nil	nil	Milrinone 0.5, Noradr 0.05	Milrinone 0.5, Noradr 0.05	nil	Nil	Nil	0.6	1.1	1
20	4	M	ASD	17.3	Normal	Dilated	Nil	Normal	65	17	18.4	14.1	12	11	6	13	12	7	45	44	48	55	53	55	Nil	Nil	NIl	Nil	noradr 0.05	noradr 0.05	Nil	Nil	Nil	1	0.6	1.1
21	2	F	VSD	25	Normal	Normal	Nil	Normal	55	27	24.8	17.7	15	13.7	11.7	14	15.6	11.7	50.8	54	64	54	60	61	Nil	Nil	Nil	Nil	Mil 0.5, noradr 0.05	Mil 0.5, noradr 0.05	Nil	Nil	Nil	1	0.7	1.2
22	3	F	TOF	13	Fair	Hypertrophic	NIL	PS 56	50	13	12.5	8.06	9.15	8.6	6.05	5.11	4.03	5.85	29	32	30	54	50	47	Moderate	Moderate	moderate	MIL 0.5	MIL 0.5,	MIL 0.5, adr 0.05	Nil	Nil	Nil	0.6	0.6	0.7
23	2	M	ASD	18	good	Normal	Nil	Normal	68	18	17.8	7.73	8.1	8.4	11.3	9.72	11.9	10.8	37.6	44.1	36.7	66	50	56	Nil	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	1.1	1	1
24	10months	M	TOF	17	Good	Hypertrophic	Nil	Infundibular PS 56	70	15.2	12.6	9	7	6.27	4.64	4.74	4.43	4.1	45	49	49	56	54	53	nil	nil	nil	nil	Mil 0.5, noradr 0.05	Mil 0.5, noradr 0.05	Normal	Normal	Normal	0.8	1	1.1
25	2	M	SV ASD PAPVC	25	Good	Dilated	Nil	Normal	70	22.8	20.5	19.2	8.37	12.7	12.7	9.51	11.5	10.4	52.07	42.9	30.2	66	55	59	Nil	Nil	Nil	Nil	Dobut 2.5	Dobut 0.1	Normal	Normal	Normal	1	1	1.1
26	6	M	VSD	17.1	Good	Normal	Nil	Normal	70	16	17.7	13.6	11	8	7	9	8	7	36	45	54	60	55	54	nil	nil	nil	nil	Noradr 0.05	Noradr 0.05	Normal	Normal	Normal	1	1	0.9
27	5	F	SV ASD, PAPVC	19	Normal	DILATED	NIL	Normal	56	19.2	20.8	16	19	20	15	18	19	15	54	53	60	46	58	59	Nil	Nil	Nil	Nil	Noradr 0.05	Noradr 0.025	Normal	Normal	Normal	0.9	1	1
28	3	M	OS ASD	17	Normal	DILATED	NIL	Normal	66	16.3	8.95	5.01	7.5	5.44	3.63	4.7	6.09	3.4	51	46	69	25	40	45	nil	Nil	Nil	Nil	noradr 0.05	Noradr 0.05	Normal	Normal	Normal	1	0.8	1

29	8 Mo	M	TOF	13	Normal	Enlarged	Trivial	Normal	65	21.4	26.2	11.3	10.1	16.9	8.72	3.62	8.35	3.5	61.9	33.4	29.5	59	61	60	Nil	Nil	Nil	Nil	Mil 0.5, noradr 0.05	Mil 0.5, noradr 0.05	Normal	Normal	Normal	1	1	0.9
30	6 Mo	F	VSD PS	15	Normal	Dilated	Severe	Reactive. 40	70	11.3	12.5	8.06	9.15	8.6	6.05	5.11	4.03	5.85	28	29.7	51.9	62	83	82	Severe	moderate	moderate	Nil	Mil0.5, noradr 0.05	Mil 0.5, noradr 0.05	Seve	severe	severe	0.7	0.6	0.7
31	2	M	ASD PAPVC	19	Normal	Dilated	Nil	Nil	69	17.6	18.2	14	16	17	10	16	15	10	54	32	40	50	55	55	Nil	nil	nil	nil	noradr 0.05	Noradr 0.025	Nil	Nil	Nil	2	1.3	1.2
32	3	M	TOF VALV PS	17.1	Normal	Dilated	Nil	Normal	70	17	13.3	9.02	7.93	8	7.31	9	12	8	63.6	52	55	54	56	53	nil	nil	nil	nil	Milrinone 0.5, Noradr 0.05	Milrinone 0.5, Noradr 0.05	nil	Nil	Nil	0.6	1.1	1
33	4	M	ASD	17	Normal	Dilated	Nil	Normal	65	17	18.4	14.1	12	11	6	13	12	7	45	44	48	55	53	55	Nil	Nil	NIl	Nil	noradr 0.05	noradr 0.05	Nil	Nil	Nil	1	0.6	1.1
34	1	F	VSD	24	Normal	Normal	Nil	Normal	40	27	24.8	17.7	15	13.7	11.7	14	15.6	11.7	50.8	54	64	54	60	61	Nil	Nil	Nil	Nil	Mil 0.5, noradr 0.05	Mil 0.5, noradr 0.05	Nil	Nil	Nil	1	0.7	1.2
35	4	F	TOF	13	Fair	Hypertrophic	NIL	PS 56	50	13	12.5	8.06	9.15	8.6	6.05	5.11	4.03	5.85	29	32	30	54	50	47	Moderate	Moderate	moderate	MIL 0.5	MIL 0.5,	MIL 0.5, adr 0.05	Nil	Nil	Nil	0.6	0.6	0.7
36	3	M	ASD	18	good	Normal	Nil	Normal	68	18	17.8	7.73	8.1	8.4	11.3	9.72	11.9	10.8	37.6	44.1	36.7	66	50	56	Nil	Nil	Nil	Nil	Nil	Nil	Normal	Normal	Normal	1.1	1	1
37	3	M	TOF	18	Good	Hypertrophic	Nil	Infundibular PS 56	70	15.2	12.6	9	7	6.27	4.64	4.74	4.43	4.1	45	49	49	56	54	53	nil	nil	nil	nil	Mil 0.5, noradr 0.05	Mil 0.5, noradr 0.05	Normal	Normal	Normal	0.8	1	1.1
38	4	M	SV ASD	25.6	Good	Dilated	Nil	Normal	70	22.8	20.5	19.2	8.37	12.7	12.7	9.51	11.5	10.4	52.07	42.9	30.2	66	55	59	Nil	Nil	Nil	Nil	Dobut 2.5	Dobut 0.1	Normal	Normal	Normal	1	1	1.1
39	4	M	TOF	12.9	Normal	Enlarged	Trivial	Normal	70	16	17.7	13.6	11	8	7	9	8	7	36	45	54	60	55	54	nil	nil	nil	nil	Noradr 0.05	Noradr 0.05	Normal	Normal	Normal	1	1	0.9
40	6 Mo	F	VSD PS	15	Normal	Dilated	Severe	Reactive. 40	56	19.2	20.8	10.4	10	9	8	9	8	6	54	53	53	46	58	59	Nil	nild	mild	Nil	Mil 0.5, noradr 0.05	Mil 0.5, noradr 0.05	Normal	Mild	Mild	1	0.8	1
41	3	M	ASD PAPVC	18.6	Normal	Dilated	Nil	Nil	66	16.3	8.95	5.01	7.5	5.44	3.63	4.7	6.09	3.4	51	46	69	25	40	45	Nil	Nil	Nil	Nil	Noradr 0.05	Noradr 0.05	Normal	Normal	Normal	1	1	0.9
42	2	M	TOF VALV PS	17.1	Normal	Dilated	Nil	Normal	70	17	13.3	9.02	7.93	6	5	10	9	8	63.6	55	56	65	54	56	Nil	Nil	Nil	Nil	Mil 0.5, noradr 0.05	Mil 0.5, noradr 0.05	Normal	Normal	Normal	0.9	1	0.8

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COMPARISON OF TRANSESOPHAGEAL ECHOCARDIOGRAPHY GUIDED MODIFIED 2-DIMENSIONAL AND M-MODE TRICUSPID ANNULAR PLANE SYSTOLIC EXCURSIONS WITH TRANSTHORACIC ECHOCARDIOGRAPHY GUIDED M-MODE TRICUSPID ANNULAR PLANE SYSTOLIC EXCURSION IN ADULT AND PAEDIATRIC CARDIAC SURGERIES FOR ASSESSMENT OF RIGHT VENTRICULAR FUNCTION

A DISSERTATION SUBMITTED TO

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, (An Institute of National Importance by an Act of Parliament, Ministry of Health and Family Welfare) TRIVANDRUM, KERALA, INDIA – 695011 BY Dr. MAMATHA MUNAF IN PARTIAL FULFILLMENT OF THE REQUIREMENTS

FOR THE AWARD OF THE DEGREE OF

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DM CARDIOTHORACIC AND VASCULAR ANESTHESIA
(DIVISION OF CARDIOTHORACIC AND VASCULAR ANAESTHESIOLOGY, DEPARTMENT OF ANAESTHESIOLOGY)

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SYNOPSIS

OBJECTIVE: Moderate to severe dysfunction of right ventricle is associated with poor clinical outcome after cardiac surgery. TTE M Mode TAPSE is used preoperatively to assess RV function. We compared intraoperative TEE guided m-2D & M-Mode TAPSE measurements to preoperative TTE-guided M-mode TAPSE in terms of accuracy and inter-observer and intra-observer variability. In addition, intraoperative m-2D TAPSE and M-Mode TAPSE measurements were compared with RV FAC. The variations of m-2D TAPSE, M-Mode TAPSEs and RV FAC at different time points during surgery i.e., before CPB, after CPB and after sternal closure were also analysed.

STUDY DESIGN: A prospective, observational, non- randomised, non-blinded study.

STUDY SETTING: The study was done in adult and paediatric operating rooms in Sree Chitra Tirunal Institute, which is a tertiary referral centre for cardiac surgery.

PARTICIPANTS: Adult patients undergoing CABG and valvular surgeries and paediatric patients (both cyanotic heart diseases and acyanotic heart diseases) undergoing corrective surgeries were the participants

MEASUREMENTS: TTE guided M Mode TAPSE was measured in OPD as well as after anaesthesia induction. TEE guided m-2D TAPSE, Deep Trans-gastric M Mode TAPSE, Trans-gastric Right ventricular Inflow M Mode TAPSE and RV FAC were measured before pericardiotomy, after CPB and after sternal closure.

STATISTICAL ANALYSIS: To detect a minimum of 0.5 correlation between the parameters with 90% power and 5% alpha error with 10% drop-out rate because of technical reasons, the sample size was calculated as 42 per group. RESULTS: m-2D TAPSE and deep Trans-gastric M Mode TAPSE before CPB correlated significantly with TTE M Mode TAPSE in both adult and paediatric groups. m-2D TAPSE had significant correlation with deep trans-gastric M Mode TAPSE and trans-gastric right ventricular inflow M Mode TAPSE at all time points and RV FAC measured before CPB in both the groups. TAPSE measured by all the three methods declined significantly during the surgery. RV FAC in children decreased after CPB and improved over pre- CPB values after sternal closure whereas it significantly improved over time in adults. CONCLUSION: TEE guided m-2D TAPSE and Deep trans-gastric M Mode TAPSE are comparable to TTE guided M- Mode TAPSE in terms of accuracy and reproducibility. Trans-gastric right ventricular inflow M -Mode TAPSE is less accurate and shows poor reproducibility. INTRODUCTION

Moderate to severe Right Ventricular (RV) dysfunction is related to poor post-operative clinical outcome.1 Hence, it is important to reliably assess RV function during cardiac surgery. Preoperatively, Trans Thoracic Echocardiography (TTE) can be used to assess RV function by measuring Tricuspid Annular Plane Systolic Excursion (TAPSE) by M-Mode. It is reliable, validated and easily reproducible in adult patients. In contrast, intraoperative Transoesophageal Echocardiography

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(TEE) guided RV functional assessment is challenging due to the following concerns: 1. Unlike left ventricle (LV) which is easily approximated by geometric assumptions, RV has a complex structure. It is triangular in mid-esophageal 4 chamber view, crescent shaped in trans-gastric short axis view and has a wraparound appearance in Right Ventricular Inflow-outflow view. Hence it is difficult to define RV volume in a single view two dimensionally unless three dimensional volumetric models are used.2 2. The contraction of RV is peristaltic, unlike the piston-like movement of LV. In addition to longitudinal movement, inward movement of RV free wall and apex, the RV outflow tract (RVOT) contraction significantly affects RV output. Most of the 2D views fail to account for RVOT contribution.

3. Unlike in TTE, there is misalignment of ultrasound waves to the direction of motion of tricuspid valve in TEE which makes it more challenging to interpret TEE.

4. Pericardiotomy decreases RV longitudinal motion.3 Hence any assessment based on the RV longitudinal motion is likely to be influenced by pericardiotomy.

Right Ventricular Fractional Area Change (RV FAC) is used intraoperatively to estimate global right ventricular function. It has good method agreement with Cardiac MRI and 3D volumetric estimation of right ventricular function. However, intraoperatively, tracing the endocardial border of right ventricle is time consuming and has poor interobserver variability. Poor echo window, foreshortened images and poor visibility of lateral wall in the presence of dilated heart chambers make RV FAC measurement challenging. TEE guided Modified 2 D (m-2D) TAPSE, Deep Trans Gastric (DEEP TRANSGASTRIC) M Mode TAPSE and Trans Gastric Right Ventricular Inflow (TGRIGHT VENTRICULAR INFLOW) M Mode TAPSE are other tools available for RV function assessment intraoperatively. Tissue Doppler Imaging (TDI) S´ velocity measurement necessitates excellent image acquisition. 3D volumetric estimation and 2D speckle tracking studies are time consuming, technology intensive and are not available in all echocardiography machines. There is a need for a real time, easily reproducible and reliable method to asses right ventricular function which correlates well to M Mode TAPSE measured by TTE preoperatively and RV FAC measured intraoperatively. Hence, we undertook this study to validate the TEE guided M Mode TAPSEs and m-2D TAPSE and to evaluate their correlation to RV FAC during the course of surgery.
REVIEW OF LITERATURE

Left ventricle is a more predictable chamber. Being cylindrical in shape, geometric approximations are possible which ensures accurate estimation of volume and systolic function. Right ventricle, however, has a more complex anatomy, as explained by Dr. Timothy M Maus1, MD in the editorial published in Journal of Cardiothoracic and Vascular Anaesthesia (JCVA). Right ventricle is triangular in Mid-Esophageal four Chamber (ME 4 Ch) view, crescent shaped in Trans gastric short axis view and gives an illusion of wrapping around aorta in the mid esophageal RV inflow-outflow view. Peristaltic movement of the right ventricle has contribution from longitudinal movement of its fibres, inward movement of the right ventricular free wall and apex and contraction of its outflow tract. Trans thoracic M Mode TAPSE is the corner stone of right ventricular function assessment preoperatively. It is easily available, reproducible and has excellent method agreement with cardiac MRI which is the gold standard for the same. However, cardiac surgeries are known to significantly affect the longitudinal motion of right ventricle. Reduced long axis velocity of right ventricle during cardiac surgery could be due to cardiopulmonary bypass, cardioplegia, myocardial hypothermia or cardiac stunning1. Unsworth et al.3 studied 110 patients who underwent surgery by midline sternotomy. The authors found that surgeries that preserved pericardial integrity like mediastinal mass excision, minimally invasive Aortic Valve Replacement (AVR) and robotically assisted minimally invasive CABG documented little or no decrease in the right ventricular tissue doppler velocities. However, procedures that required complete pericardial opening like Coronary Artery Bypass Graft (CABG) and AVR documented clear decrease in right ventricular long axis S´ velocity. Pericardium could be providing structural integrity to the longitudinal fibres to function adequately. Donauer et al.4 studied thirty patients who underwent CABG with cardioplegic cardiac arrest. They performed right ventricular 3-dimensional echocardiography and strain analysis. Significant reduction in peak longitudinal systolic strain (PLSS)of the right ventricular lateral wall, inferior wall, interventricular septum and outflow tract was documented. Circumferential contraction of the lateral wall increased by 4% simultaneously. RV Ejection Fraction (EF) and RV FAC remained unchanged. This study demonstrated that reduction in longitudinal movement is compensated by an increase in radial motion of the RV free wall. The reliability of TAPSE in the pre-pericardiotomy phase as a surrogate for right ventricular systolic function is evident. TTE guided M mode TAPSE cannot be used intraoperatively for open heart surgeries. Trans esophageal echocardiography (TEE) guided TAPSE measurements are readily available. Roberts et al.5 studied 125 patients to estimate the concordance between TTE and TEE guided measurements of RV function. RV FAC, lateral S´ velocity, right sided index of myocardial performance (RIMP) and tricuspid valve annulus were measured by both methods. M Mode TAPSE measured by TTE was compared to trans gastric (TG) M Mode TAPSE. The study showed underestimation of S´ and TG M Mode TAPSE. It was not adequately powered to demonstrate any difference in other measurements. Authors advised caution while using TTE validated

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parameters for TEE assessment of RV function. Morita et al.6 retrospectively analysed the medical records of 196 patients and compared intraoperative measurements of TEE guided modified TAPSE (m-TAPSE) to RV FAC. Modified TAPSE was measured as the difference between RV apex to lateral tricuspid annulus length in diastole and systole. In order to measure it precisely, a 4-chamber view of excellent sonographic quality was required. The investigators were required to exclude suboptimal images from data analysis for this reason. They found good correlation between the RV FAC and m-TAPSE. Due to the retrospective nature of the study, comparison of m-TAPSE to other measurements of RV function was not possible Furthermore, we feel that the it is not easy to fix the RV apex in different phases of cardiac cycle for accurate measurements. Another disadvantage of this technique is that the TAPSE measured is

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the distance between the lateral site of moving tricuspid annulus and

the RV apex, which is moving as well

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during contraction, whereas the classic TAPSE measures only the actual movement of the lateral annulus of the tricuspid

valve. Korshin et al.7 assessed the availability, inter-observer and intra-observer reliability and feasibility TAPSE measured by 5 different views and tricuspid annulus TDI. Method agreement of TEE TAPSE to TTE TAPSE was also studied. The study showed good agreement between TAPSE measured by TEE and TTE. Anatomical M Mode TAPSE (DEEP TRANSGASTRIC and TG) had good correlation with TTE guided TAPSE and had low inter and intra observer variability. Tricuspid Annulus tissue doppler imaging (TDI) and Anatomical M mode TAPSE had higher reliability compared to 2D TAPSE. However, TDI is not commonly available, availability of the deep trans gastric and trans gastric RIGHT VENTRICULAR INFLOW views are highly variable and anatomical M mode TAPSE is not available in all echo machines. In Nottingham University Hospital, UK,8 TTE M Mode TAPSE and TEE 2D TAPSE obtained under sedation were compared. Close correlation was found between TEE guided 2D TAPSE and TTE guided M Mode TAPSE. Images were found to be reliable and simple to obtain. In addition, RV Fractional Area Change (FAC) was found to have good correlation to TTE guided M- Mode TAPSE. Endocardial surface tracing to obtain RV FAC was challenging in this study. Furthermore, TEE was done under local anesthesia unlike intraoperative scenario where the patient would be under general anesthesia. Sullivan et al.9 studied patients who underwent pulmonary endarterectomy. Thermodilution cardiac index, RV FAC and TG RIGHT VENTRICULAR INFLOW M Mode TAPSE were measured before sternotomy, after pericardial incision and after sternal closure. On comparison of TAPSE and RV FAC to invasive thermodilution studies in pulmonary endarterectomy patients, TAPSE was found to decrease significantly following pericardiotomy, whereas RV FAC remained unaffected probably in view of increased radial contraction to compensate for decreased longitudinal motion. Other complex measures10 to assess right ventricular function are right ventricular global longitudinal strain or 3D speckle tracking echo strain which are not commonly available. In a study done in Ghent University Hospital, Belgium,11 speckle tracking based strain and strain rate was not found to be promising. Studies on right ventricular systolic function assessment by TAPSE in paediatric population is very limited. The study undertaken in university of Philadelphia12 found significant correlation between TAPSE and exercise capacity in children with hypoplastic left heart syndrome. They recommended further studies and opined that TAPSE was reproducible. TAPSE was used as a tool to assess right ventricular systolic dysfunction in paediatric patients with dilated cardiomyopathy in Emory University School of Medicine, USA.13 Moderate to severe right ventricular dysfunction in this group of patients was linked to worse clinical outcome including death, mechanical support or transplantation. Both these studies used TTE to assess TAPSE. A recent study by Singh14 et. al., published in May, 2020, attempted to asses longitudinal changes in right ventricular function (longitudinal and global) during cardiac surgery. They specifically evaluated the changes in a subset of patients who underwent redo surgeries as well. Images were acquired after anaesthesia induction, pericardiotomy, CPB and after sternal closure. Authors noticed acute decline in RV function during surgery, independent of pericardiotomy and CPB. The decline was present across different surgical approaches, different operative procedures and in primary as well as redo surgeries and persisted even after sternal closure. The authors could not explain the reason for this persistent decline. Further studies are indeed warranted to analyse the fresh data which are coming up which contradicts our current understanding. Forner et. al.,15 similarly conducted a study on 30 cardiac surgery patients. They measured the trans-thoracic M- Mode TAPSE after induction of anaesthesia and compared it to TAPSE measured by 6 different views using trans-esophageal echocardiography. Anatomical M-Mode measurement of TAPSE in mid esophageal 4 chamber view and Deep trans-gastric view showed good correlation to TTE guided TAPSE. Anatomical M Mode is not available in all echo machines. AIMS AND OBJECTIVES

HYPOTHESIS

A novel simplified 'Modified 2D method of TAPSE (m-2D TAPSE)' measurement using regular mid-esophageal (ME) 4-Chamber view will show good agreement with TTE guided M Mode TAPSE in both adult and paediatric patients undergoing cardiac surgery. Furthermore, between the two M-Mode trans gastric TEE measurements of TAPSE: • Deep Trans gastric 4 chamber (M-Mode Deep Trans-gastric 4C-TEE-TAPSE) & • Trans gastric Right Ventricular Inflow views (M-Mode RV IF-TEE-TAPSE)

the former is more accurate.

We also propose that m-2D TAPSE is easier than all other methods of intraoperative RV function assessment namely M-Mode measurements of TAPSE and RV Fractional Area Change (FAC) in both adult and paediatric patients.

PRIMARY OBJECTIVE:

To compare intraoperative TEE guided m-2D & M-Mode TAPSE measurements to preoperative TTE-guided M-mode TAPSE in terms of accuracy and inter-observer and intra-observer variability.

SECONDARY OBJECTIVES:

1. To compare intraoperative m-2D TAPSE to M-Mode TAPSE measurements and RV FAC

2. To compare the variations of m-2D TAPSE, M-Mode TAPSEs and RV FAC at different time points during surgery: before CPB, after CPB and after sternal closure.

JUSTIFICATION FOR THE STUDY

1. Moderate to severe RV dysfunction has independent predictive value in postoperative outcome in cardiac surgery patients. 2. Gold standard of RV function assessment is cardiac MRI which cannot be used intraoperatively.

3. TTE- M Mode TAPSE is clinically validated against cardiac MRI but cannot be used intraoperatively.

4. There is a need for an easily obtainable commonly accessible TEE view to reliably assess RV function intraoperatively.

5. The most commonly accessed TEE view is mid-esophageal 4-Chamber view and M-Mode cannot be used in this view to assess TAPSE because of poor alignment of tricuspid annulus to the M-Mode axis in this view.

6. TEE guided M-Mode TAPSE is commonly measured with trans gastric RV inflow view and less with deep trans gastric 4 chamber view. Both these views are not easily obtainable unlike mid-esophageal 4 chamber view.

7. None of the studies had correlated all the accepted TEE guided intraoperative TAPSE measurements during different time points during surgery to RV FAC and to the validated preoperative TTE- TAPSE.

8. RV function assessment studies in paediatric population is sparse despite proven correlation of poor RV function to worse postoperative Outcome. TAPSE measurements in this population are studied only with TTE.

9. No studies are available from India comparing m-2D TEE TASPE to M Mode TEE/TTE TAPSE

10. No similar study has been done in SCTIMST in the past.

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The primary aim of the study is thus to evaluate three different TEE TAPSE views at pre-specified time points during surgery, applying the

modified 2D and all the described M-mode measurements

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to determine each approach's feasibility (availability, accuracy and intra-/inter-observer reliability) and their agreement with

RV FAC & preoperative TTE TAPSE in both adult and paediatric populations.

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MATERIALS AND METHODS

STUDY DESIGN: A prospective, observational, non- randomised, non-blinded study.

STUDY SETTING: The study was done in adult and paediatric operating rooms in Sree Chitra Tirunal Institute, which is a tertiary referral centre for cardiac surgery.

PARTICIPANTS: Adult patients undergoing CABG and valvular surgeries and paediatric patients (both cyanotic heart diseases and acyanotic heart diseases) undergoing corrective surgeries were the participants. INCLUSION CRITERIA:

• Patients posted electively for CABG, valvular or congenital heart surgery in SCTIMST • Optimal images for TTE and TEE.

EXCLUSION CRITERIA:

• Contraindication to TEE probe placement like oesophageal strictures, oesophageal varices, oesophageal tumours, gastric ulcer, previous esophagectomy, esophageal diverticulum, tracheoesophageal fistula, previous bariatric surgery, hiatus hernia, large descending thoracic aortic aneurysm, unilateral vocal cord paralysis, esophageal varices, post-radiation therapy.

• Emergency and re-do surgeries.

APPROVAL FROM TECHNICAL ADVISORY COMMITTEE (TAC)

Our study is approved by the technical advisory committee. TAC registration number is SCT-/S/2018/756 APPROVAL FROM INSTITUTIONAL ETHICS COMMITTEE(IEC)

Our study is approved by the Institute Ethics Committee of SCTIMST. IEC registration number is SCT/IEC/1235/AUGUST 2018. DURATION OF THE STUDY: 12 Months -From June 2019 to May 2020 FUNDING: No funding was required for the study STUDY PROTOCOL Preoperatively, M-Mode TAPSE was recorded by the cardiologists during the routine preoperative TTE examination. They also reported the RV function qualitatively as normal or dysfunctional (mild/moderate/severe) and hypertrophic or dilated based on visual assessment of apical 4 chamber view. After anesthesia induction, TTE guided M Mode TAPSE was repeated on table and documented. TEE probe was introduced and RV function assessment was done by measuring m-2D TAPSE and RV FAC (Image No. 1(A) and Image No. 1(B)) in the mid esophageal 4 chamber view. In case of difficulty in delineating the endocardial border while measuring RV FAC, agitated saline was used for better clarity. M Mode TAPSE was measured in both deep trans gastric 4-chamber view (Image No.2) and trans gastric RV inflow view (Image No. 3) using IE 33 echo machine (Philips Ultrasound, USA) in patients who satisfied the inclusion and exclusion criteria. Measurements were taken before pericardiotomy. Since RV function can be affected by the LV, ejection fraction of the left ventricle was also assessed using Simpson's disc method. The other factors which affect RV function such as its diastolic function, grade of tricuspid regurgitation, presence of pulmonary artery hypertension, use of inotropes was also be recorded for analysis.

The m-2D TAPSE was measured by annotating an 'arrow' at the lateral tricuspid valve annulus at end-diastole in a mid esophageal 4-chamber view (Image No. 4). Image was then scrolled to end-systole and the displacement was measured with the calliper (Image No. 5). Measurements were done at the end-expiratory period and average of two readings were recorded. Measurements by the principal and co-investigators were analysed for interpreting the accuracy and inter & intra-observer variability. These measurements were repeated after surgery in the post-CPB period and after sternal closure. Pre-CPB findings were compared to the trans-thoracic M Mode TAPSE (Image No. 6). INTERVENTIONS:

This study was a prospective observational study and no intervention was required. OUTCOME PARAMETERS:

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Evaluation of study objectives were the outcome parameters

STATISTICAL ANALYSIS

A sample size of 38 per group (Adult and Paediatric) was needed to detect a minimum of 0.5 correlation between the parameters with 90% power and 5% alpha error. Considering 10% drop-out rate because of technical reasons such as poor images or probe related issues, the sample size was calculated as 42 per group. All Quantitative variables were checked for normal distribution within each category of explanatory variable by using visual inspection of histograms and normality Q-Q plots. Shapiro- Wilk test was also conducted to assess normal distribution. Shapiro-Wilk test p value of <0.05 was considered as normal distribution. For normally distributed Quantitative parameters the mean values were compared between study groups using Independent sample t-test (2 groups). For normally distributed Quantitative parameters the mean values were compared between study groups using ANOVA (<2 groups). For non-normally distributed Quantitative parameters, Medians and Interquartile range (IQR) were compared between study groups using Mann Whitney U test (2 groups). The association between explanatory variables and categorical outcomes was assessed by cross tabulation and comparison of percentages. Odds ratio along with 95% CI is presented. Chi square test was used to test statistical significance

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P value > 0.05 was considered statistically significant. IBM SPSS version 25 was used for statistical analysis.

RESULTS

Feasibility
A total of 84

patients satisfied all the inclusion criteria for the study. 42 patients were adults and 42 were in the paediatric age group. 32 patients in adult group and 20 patients in paediatric group could not be allotted to the study due to lack of echo images. Post sternal closure echocardiography could not be done in 10 adult patients and 13 paediatric patients due to the non-availability of TEE machine at that point of time. 17 adult patients and 4 paediatric patients had to be excluded due to poor TG RIGHT VENTRICULAR INFLOW M mode alignment to the tricuspid valve annulus. 5 adult patients and 3 paediatric patients had poor RV endocardial border demarcation and could not be included. Consort Diagram for adult and paediatric groups are represented by Figure No. 1 and Figure No. 2 respectively. Population Mean age of our adult study population was 59.2 ± 7.9 years and 33 of the 42 patients were males (78.57%). 42.8% of our adult group had LV systolic dysfunction (Ejection Fraction >55%) and all patients had good RV systolic function (TAPSE<16mm) in preoperative transthoracic echocardiographic evaluation. 26.2% patients had some degree of tricuspid regurgitation. However, only 2.76% documented presence of pulmonary artery hypertension.

Mean age of our paediatric study population was 2.65 ± 1.5 years and 29 of the 42 patients were males (69.05%). 47.62% of our paediatric group had LV systolic dysfunction (Ejection Fraction >55%) and 26.2% patients had decreased RV systolic function (TAPSE>16mm) in preoperative transthoracic echocardiographic evaluation. 19.05% patients had some degree of tricuspid regurgitation. However, only 11.9% documented presence of pulmonary artery hypertension. More than half of the patients studied in the paediatric group were toddlers and nearly a quarter of them were children. 19% of the study population were infants. 90.5% of the adult patients underwent CABG. Among paediatric patients, Tetralogy of Fallot was the most common diagnosis (33%), followed by ASD with PAPVC (26.2%) and ASD (11.9%).

Demographic and echocardiographic parameters of all patients are summarised in Table No. 1. Age distribution of the patients in the paediatric group is represented in Figure No. 3. Description of the conditions for which adult and paediatric patients were operated on is shown in Figure No. 4 and Figure No. 5 respectively.

Right ventricular geometry, Tricuspid regurgitation and TTE M Mode TAPSE. All the adult patients had a normal right ventricular geometry. However, only 16.7% of the paediatric group had a normal right ventricle. RV was dilated in 64.29% and hypertrophic in the remaining 19.05% of the paediatric group. Distribution of right ventricular geometry in each group is represented in Table No. 2. All the patients had good right ventricular systolic function in the adult group (TAPSE<16mm). No association was found between the presence of tricuspid regurgitation and preoperative TAPSE in adults (p value = 0.908) as represented in Table No. 3. However, paediatric patients showed significant association between the preoperative TAPSE and presence of tricuspid regurgitation (p value = 0.002) as represented in Table No. 4.

Comparison of TTE M Mode TAPSE to TEE m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and Trans-gastric Right ventricular Inflow M Mode TAPSE measured before pericardiotomy.

TTE guided M mode TAPSE was compared to TEE guided m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and Trans-gastric Right Ventricular Inflow M Mode TAPSE. All the measurements were taken before pericardiotomy. Positive correlation (r<0) was found between the TTE guided M Mode TAPSE and all the three TEE guided measurements in the adult group, as shown in Table No. 5. However, the positive correlation was found to be significant only in the case of m-2D TAPSE (r = 0.379 and p value = 0.013).

Similarly, in the paediatric group, all the three TEE guided measurements of RV systolic function, namely, m-2D TAPSE (r = 0.687), Deep Trans-gastric M Mode TAPSE (r = 0.315) and Trans-gastric Right Ventricular Inflow M Mode TAPSE (r = 0.660) showed positive correlation (r<0) with TTE guided M Mode TAPSE measured before pericardiotomy. Unlike in the adult group, all the positive correlations were statistically significant. Table No. 6 demonstrates the same.

Figure No. 6, Figure No. 7 and Figure No.8 represents correlation between the said parameters in scatter plot diagrams in adults. Figure No. 9, Figure No. 10 and Figure No. 11 shows the correlation between the TEE guided echocardiographic measurements and TTE guided M Mode TAPSE before pericardiotomy in the paediatric group.

Modified 2D TAPSE and RV FAC.

Correlation between TEE guided m-2D TAPSE and Right ventricular FAC in adult and paediatric group before CPB, after CPB and after sternal closure are depicted in Table No. 7 and Table No. 8 respectively.

RV FAC in adult population showed positive correlation (r=0.414) with m-2D TAPSE measured before pericardiotomy. The correlation was statistically significant (p value = 0.006). positive correlation between the two parameters continued after CPB and after sternal closure. However, they were no longer statistically significant.

Comparison of Modified 2 D TAPSE with Deep Trans-gastric M Mode TAPSE and Trans-gastric Right ventricular Inflow M Mode TAPSE.

Correlation of Modified 2 D TAPSE with Deep Trans-gastric M Mode TAPSE and trans-gastric Right Ventricular Inflow M Mode TAPSE before CPB, after CPB and after sternal closure in adult and paediatric group is represented in Table No. 9 and Table No. 10 respectively.

Positive correlation was evident between modified 2 D TAPSE and Deep Trans-gastric M Mode TAPSE in the adult group before CPB, after CPB and after sternal closure. The correlation was statistically significant (p value 0.009 v >0.001 v >0.001). Similarly, m-2D TAPSE and Trans-gastric Right Ventricular Inflow M Mode TAPSE showed statistically significant positive correlation before CPB, after CPB and after sternal closure (p value >0.001 v >0.001 v>0.001).

Positive correlation was demonstrable between modified 2 D TAPSE and Deep Trans-gastric M Mode TAPSE in the paediatric group as well before CPB, after CPB and after sternal closure. The correlation was statistically significant (p value >0.001 v >0.001 v >0.001). Similarly, m- 2D TAPSE and Trans-gastric Right ventricular Inflow M Mode TAPSE showed statistically significant positive correlation at all the three time points studied (p value >0.001 v >0.001 v>0.001).

Analysis of method agreement of TEE guided m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and TG Right Ventricular Inflow TAPSE to TTE guided M Mode TAPSE. Comparison of different methods of measurement of RV function using TEE namely m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and TG Right Ventricular Inflow TAPSE to preoperative TTE guided M Mode TAPSE in adult and paediatric group is shown in Table No.11 and Table No. 12 respectively. Measurements taken before CPB are used for the analysis.

Bias inherent in each method is given along with limits of agreement. Statistical analysis was done on the bias associated with each method to identify whether the bias was statistically significant when compared to preoperative TTE guided M Mode TAPSE, which was taken as the reference method. Bias associated with m-2D TAPSE (-0.97 in adults and 0.17 in paediatric group) and Deep Trans-gastric M Mode TAPSE (-1.29 in adults and -0.6 in paediatric group) were not statistically significant. However, Trans-gastric Right Ventricular Inflow M Mode TAPSE was found to have high Bias (-0.68 in adult group and -6.14 in paediatric group) which was of statistical significance (>0.001 in both groups).

Longitudinal changes in m-2D TAPSE, Deep Trans-gastric M Mode TAPSE, Trans-gastric Right Ventricular Inflow TAPSE and RV FAC before CPB, after CPB and after sternal closure.

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Longitudinal changes in the measurements of RV function during the surgery, namely, m-2D TAPSE, Deep trans-gastric M Mode TAPSE, Trans-gastric Right Ventricular Inflow TAPSE M mode TAPSE and RV FAC in adult and paediatric group are shown in Table No. 13 and Table No. 14 respectively. Measurements of longitudinal movement of the right ventricle documented a significant decline after CPB as well as after sternal closure in both adult and paediatric groups (p value>0.001). RV FAC, the global measurement of RV function, also showed significant changes after CPB as well as sternal closure. While the TAPSE values declined, RV FAC in adults showed an increasing trend after the CPB as well as the sternal closure (46.35 $\pm$ 10.61 v 50.63 $\pm$ 13.02 v 52.63 $\pm$ 11.05). In the paediatric group, TAPSE values significantly declined, however, RVFAC decreased after the CPB and improved beyond the pre CPB values after the sternal closure (47.4 $\pm$ 11.04 v 43.36 $\pm$ 8.32 v 48.33 $\pm$ 12.95). the changes were statistically significant.

Measurement of Reliability. Inter-observer and intra-observer variability in TEE guided m-2D TAPSE, Deep Trans-gastric M Mode TAPSE, Trans-gastric Right Ventricular Inflow M Mode TAPSE and TTE guided M Mode TAPSE in adult and paediatric group are shown in Table No. 15 and Table No. 16 respectively. Preoperatively measured TTE guided M Mode TAPSE was used as the reference (7.83% interobserver variability v 9.47% intra-observer variability). In adult group, Deep Trans-gastric M mode TAPSE had the least percentage error (6.96% v 9.1%), even lesser than the reference. Modified 2-D TAPSE similarly had low bias and percentage error (10.56% v 13.10). Trans-gastric Right Ventricular Inflow M mode TAPSE had the highest variability among all the methods (53.45% v 30.48%).

Preoperatively measured TTE guided M Mode TAPSE was used as the reference in paediatric group (9.27% interobserver variability v 10.19% intra-observer variability). m-2D TAPSE had the least percentage error (4.42% v 12.24%) in the paediatric group. Deep Trans-gastric M Mode TAPSE similarly had low interobserver variability (10.82%). Trans-gastric Right Ventricular Inflow TAPSE had the highest variability among all the methods (55.6% v 31.65%). DISCUSSION

Right ventricle is described as the red herring1 in cardiac surgery due to the many fallacies associated with the measurement of its function. Global measurements require approximation of a geometrical shape which is impossible in the case of right ventricle due to its complex nature. Longitudinal movement provides an opportunity for measurement which echocardiographers world-wide have utilised over decades.

84 patients (42 adults and 42 children) were included in our study making it one of the very few studies that have attempted to assess RV function in the paediatric age group. Nearly 50% of our paediatric study population were toddlers, more than a quarter were children and the remaining were infants constituting a reasonable distribution of different age groups. Nearly 1/3rd of the paediatric study group suffered from cyanotic congenital heart disease, which is a good representation of the proportion of cyanotic and acyanotic cases dealt with in our institute.

We considered TTE guided TAPSE measurement as the reference standard for our study as it is universally considered to be accurate and reliable due to excellent alignment of the lateral tricuspid annulus with the M mode. TEE guided measurements namely m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and Trans-gastric right Ventricular Inflow M Mode TAPSE were specifically measured before pericardiotomy while documenting the pre-CPB values to exclude the influence of pericardiotomy on the longitudinal movement of the right ventricle.

m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and Trans-gastric Right Ventricular Inflow M Mode TAPSE had positive correlation (r<0) with TTE M Mode TAPSE in both adult and paediatric population. In the adult group, only m-2D TAPSE (p=0.01) had statistically significant correlation with the TTE guided M mode TAPSE. However, in paediatric study group, correlation shown by all the three methods were statistically significant (p values >0.001 v 0.042 v >0.001). Forner et. al.,15 similarly demonstrated good agreement of 2D TAPSE and Deep Trans-gastric M Mode TAPSE with TTE guided M Mode TAPSE. Only adult patients were included in the study. No similar studies are available in the paediatric age group.

Our study demonstrated positive correlation between RV FAC and m-2D TAPSE before CPB, after CPB and after sternal closure in both paediatric (r= 0.572 v 0.104 v 0.185) and adult groups (r=0.414 v 0.075 v 0.246). This correlation was statistically significant only before CPB (p=0.006 in adult group vs p>0.001 in paediatric group). Morita et. al.,6 showed similar correlation between m-2D TAPSE and RV FAC. The study concluded that m-2D TAPSE should be considered as an alternative to RV FAC as it was easily measurable. Skinner et. al.,8 made similar observations and demonstrated a positive correlation (r=0.58) between RV FAC and m-2D TAPSE. They inferred that clarity of the lateral border of tricuspid annulus is better compared to the endocardial border delineation. Our study agrees with both these observations. Lack of significant correlation of m-2D TAPSE with RV FAC after pericardiotomy and sternal closure could be due to the reduction in RV longitudinal contraction after pericardiotomy3 while the RV global function remained unchanged. Donauer et. al.,4 demonstrated by strain analysis that while TAPSE decreased by 44% after sternal closure, RV global function measured by

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RV EF remained unchanged after pericardiotomy and sternal closure. Forner et. al.,15 also documented good correlation of RV FAC and TEE guided TAPSE measurements.

m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and Trans-gastric Right ventricular Inflow M Mode TAPSE had statistically significant positive correlation before CPB, after CPB and after sternal closure in both adult (p = 0.009 v p> 0.001 v p>0.001) and paediatric groups (p>0.001 v p>0.001 v p>0.001). Very few studies have compared longitudinal changes and method agreement of different methods of TAPSE measurement by TEE during cardiac surgery and after sternal closure. Korshin et. al.,7 documented good correlation between the different methods of TAPSE measurements after sternotomy, after pericardiotomy, after completion of CPB and after sternal closure. This is in agreement with our study.

On comparison of method agreement of different TEE guided measures to TTE guided M Mode TAPSE, it was found that m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and Trans-gastric Right ventricular Inflow M Mode TAPSE demonstrated positive correlation to preoperative TTE guided M Mode TAPSE. However, Trans-gastric Right ventricular Inflow M Mode TAPSE had significant (p>0.001) bias in both paediatric [-6.14(-12.5 to 0.24)]) and adult group [-6.83(-15 .08 to 1.41)], making it less accurate in assessing RV function. A study by Forner et. al.,15 documented similarly high bias in the measurement of Trans-gastric Right ventricular Inflow M Mode TAPSE [Bias with LOA = -8.09(-9.75 to -6.43)]. While we found low bias [-1.22(-10.16 to 7.58)] in Deep Trans-gastric M mode TAPSE measurements, Forner et. al., documented higher bias [-5.73 (-7.14 to -4.33)].

m-2D TAPSE, Deep Trans-gastric M Mode TAPSE and Trans-gastric Right ventricular Inflow M Mode TAPSE documented significant decline after CPB and sternal closure. Unsworth et. al.3, documented similar decline in right ventricular long axis velocities after full opening of the pericardium in patients who underwent elective cardiac surgeries. This decrease in right ventricular long axis velocities persisted till the end of the surgery. They concluded that pericardial opening caused persistent and immediate fall in right ventricular long axis velocities. Our study is in agreement with the observations documented by Unsworth et. al., as we found that the decline in TAPSE persisted even after sternal closure.

RV FAC, however, showed significant increase (p=0.012) after CPB which was sustained even after sternal closure, in adults (46.35 $\pm$ 10.61 v 50.63 $\pm$ 13.02 v 52.63 $\pm$ 11.05). This could be secondary to the presence of adrenaline infusion (100%) after CPB in CABG patients, who constituted 90% of the patient population in adult study group. Inotropic effect of the adrenaline as well as recovery from myocardial stunning at the end of the surgery could be the reason why RV global functions showed sustained significant improvement (p =0.001) even during sternal closure. In paediatric group, RV FAC declined after CPB and improved to values higher that pre CPB levels after sternal closure (47.44 $\pm$ 11.04 v 43.46 $\pm$ 8.32 v 48.33 $\pm$ 12.95). This change was also statistically significant. Post CPB decline could be due to the presence of myocardial stunning after CPB. Myocardial recovery by the end of the surgery along with the presence of milrinone (100% in patients with TOF) that reduced RV afterload could have led to improvement after sternal closure. This observation is contradictory to the findings of the study done by Singh et.al.14, where they documented decreased FAC, TAPSE and RV strain after CPB and sternal closure in adult patients who underwent cardiac surgeries. The authors could not explain the reason for persisting global right ventricular dysfunction.

Measurement of reliability showed that Deep Trans-gastric M Mode TAPSE (inter observer variability v intra-observer variability 6.96% v 9.10%) had the least interobserver variability and intra-observer variability (measured as percentage error) in the adult group. It was lower than TTE guided M Mode TAPSE (7.83% v 9.47%), which was the reference. This was in concurrence with the study by Korshin et al.,7 which documented similar interobserver variability of 8.5% and intra-observer variability of 9.2% for Deep Trans-gastric M Mode TAPSE. M- 2D TAPSE also documented values similar to TTE M Mode TAPSE (7.83% v 9.47%). However, Trans-gastric Right Ventricular Inflow M Mode TAPSE had unacceptably high inter and intra-observer variability (53.45% v 30.48%). This is in contrast to the strikingly low inter observer (12%) and intra-observer (11.2%) variability demonstrated by Korshin et al., in the measurement of the Trans-gastric right ventricular Inflow TAPSE. The study even recommended using Trans-gastric Right Ventricular Inflow M Mode TAPSE as it was readily available. Our study, however, found trans-gastric Right Ventricular Inflow M Mode TAPSE highly unreliable.

In the paediatric group, m-2D TAPSE had the least error (4.42% v 12.24%) during repetition. Trans-gastric Right Ventricular Inflow M Mode TAPSE (55.6% v 10.19%) documented poor repeatability in paediatric group as well. Obtaining a well aligned Trans-gastric Right ventricular Inflow TAPSE was not an easy task. Many cases could not be included in the study due to poor alignment of the M mode to the annulus in Trans-gastric Right Ventricular Inflow M Mode TAPSE.

All the patients were on inotropic supports after cardiopulmonary bypass. Noradrenaline and adrenaline infusions of appropriate concentrations were used in CABG and AVR patients, whereas MVR patients received dobutamine infusion and noradrenaline infusion as per institute protocol. Infusion of intravenous milrinone with intravenous noradrenaline

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were used in paediatric patients with doses being decided on a case to case basis. All the patients were transferred to cardiac surgery ICU uneventfully.

LIMITATIONS OF THE STUDY

1. Anatomical M Mode was not available in our echocardiography machine. This made Trans-gastric Right Ventricular Inflow M Mode TAPSE measurement technically difficult. 2. Paediatric patients had a variety of diagnoses for which they were operated on. This led to lack of uniformity in our patient population. However, our patients do represent the common diseases for which paediatric cardiac surgery is being carried out in our institute.

3. Advanced measurements of RV function including 3D volumetric analysis and 2D strain analysis were not part of our study. They were excluded in the planning stage as we focussed on quickly attainable and universally available tools of measurement.

CONCLUSIONS

1. Intraoperative TEE guided modified 2 D TAPSE and Deep Trans-gastric M Mode TAPSE are comparable to preoperative TTE guided M Mode TAPSE in terms of accuracy, inter-observer and intra-observer variability in adult and paediatric population.

2. Intraoperative TEE guided Trans-gastric Right ventricular Inflow M Mode TAPSE shows positive correlation but has less accuracy and high interobserver and intra-observer variability when compared to preoperative TTE guided M Mode TAPSE in both adult and paediatric population.

3. Intraoperative TEE guided modified 2 D TAPSE has significant correlation to RV FAC, Deep Trans-gastric M Mode TAPSE and Trans-gastric Right Ventricular Inflow M Mode TAPSE before pericardiotomy in both adult and paediatric population.

4. Intraoperative TEE guided modified 2 D TAPSE, Deep Trans-gastric M Mode TAPSE and Trans-gastric Right Ventricular Inflow M Mode TAPSE declined significantly after cardiopulmonary bypass and after sternal closure.

5. RV FAC significantly increased after CPB and after sternal closure in adults. In paediatric group, RV FAC declined after CPB and improved significantly after sternal closure to pre CPB levels.

Hence, we conclude that TEE guided modified 2 D TAPSE and Deep Trans-gastric M Mode TAPSE can be used intraoperatively before pericardiotomy for accurate assessment of right ventricular function comparable to TTE guided M Mode TAPSE in adult and paediatric patients undergoing cardiac surgery. We also propose not to use Trans-gastric right ventricular inflow M mode TAPSE intraoperatively for assessment of right ventricular function due to inaccuracy and high inter observer variability and intra-observer variability of the method.

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3/7	SUBMITTED TEXT	19 WORDS	75% MATCHING TEXT	19 WORDS
	during contraction, whereas the classic TAPSE measures only the actual movement of the lateral annulus of the tricuspid		during contraction, whereas the traditional TAPSE measures only the actual motion of the lateral site of the tricuspid	

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	The primary aim of the study is thus to evaluate three different TEE TAPSE views at pre-specified time points during surgery, applying the		The primary aim of the study was thus to evaluate five different TEE TAPSE views at pre-specified time points during surgery, applying the	

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to determine each approach's feasibility (availability, accuracy and intra-/inter-observer reliability) and their agreement with	to determine each individual approach's feasibility (availability a nd intra-/inter-observer reliability) and their agreement with
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MATERIALS AND METHODS STUDY DESIGN: A prospective, observational, non-randomised, non-blinded study.	Materials and methods Study Design: A Prospective, observational, non randomised and non blinded study.
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P value > 0.05 was considered statistically significant. IBM SPSS version 25 was used for statistical analysis. RESULTS Feasibility A total of 84	P value > 0.05 was considered statistically significant. IBM SPSS version 22 was used for statistical analysis[43]. Observat ion A total of 30
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