4D QUANTIFICATION OF RIGHT VENTRICLE IN TOF POST ICR PATIENTS BY ECHOCARDIOGRAPHY AND ITS CORRELATION WITH CARDIAC MRI – A SINGLE CENTER OBSERVATIONAL STUDY

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A PROJECT REPORT SUBMITTED DURING THE COURSE OF POST DOCTORAL FELLOWSHIP IN PEDIATRIC CARDIOLOGY

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DECLARATION

I, Dr Ahmed Wayez, hereby declare that the project in this book titled "**4D QUANTIFICATION OF RIGHT VENTRICLE IN TOF POST ICR PATIENTS BY ECHOCARDIOGRAPHY AND ITS CORRELATION WITH CARDIAC MRI-A SINGLE CENTER OBSERVATION STUDY**" was undertaken by me under the supervision of the faculty, Department of Cardiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Thiruvananthapuram, Kerela.

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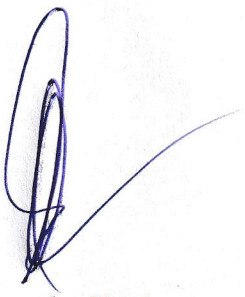
Date 31/12/2024

CERTIFICATE

I, hereby certify that the work in this project titled "**4D QUANTIFICATION OF RIGHT VENTRICLE IN TOF POST ICR PATIENTS BY ECHOCARDIOGRAPHY AND ITS CORRELATION WITH CARDIAC MRI-A SINGLE CENTER OBSERVATION STUDY**" is a certified record of original research work undertaken by Dr Ahmed Wayez done in the department of Cardiology, in partial fulfilment of the requirement for the purpose of award of post-doctoral fellowship degree.

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TITLE

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ABBREVIATIONS

CHD - congenital heart disease

CCHD - Cyanotic congenital heart disease

TOF - Tetralogy of Fallot

RVOTO - Right Ventricular outflow tract obstruction

PR - Pulmonary regurgitation

RBB - Right bundle branch

RBBB - Right bundle branch block

SCD - Sudden cardiac death

QRS d - QRS duration

RV - Right ventricle

RV EDV index - Right ventricular end-diastolic indexed volume

RV ESV index - Right ventricular end-systolic indexed volume

RV SV – Right ventricle stroke volume

RV SV index – Right ventricle stroke volume index

4D RVQ 4-dimension right ventricle quantification

CMRI - Cardiac Magnetic Resonance Imaging

NYHA - New York Heart Association

PVR - Pulmonary valve replacement

PPVR - Percutaneous pulmonary valve replacement

TAP – Transannular patch

MCR – Mono-cusp reconstruction

PA – Pulmonary atresia

SYNOPSIS

INTRODUCTION

Pulmonary regurgitation is a common sequel of TOF repair and is most severe in patients with a transannular patch (TAP). Regurgitation tends to increase with time and results in chronic volume overloading of the right ventricle, thus leading to right ventricle dysfunction and reduced exercise capacity. Therefore, TOF patients with pulmonary regurgitation need periodic follow up for clinical evaluation, regular imaging, and assessment for possible pulmonary valve replacement (PVR). Currently three sets of international guidelines provide recommendations for the indications and timing of PVR in repaired TOF. All the guidelines rely on the cardiac MRI assessment of RV quantification and functions. Since cardiac MRI scans are not widely available, poses difficulty in follow up of TOF repair patients. Now with the advent of new 4D echocardiography technologies it is possible for RV volume assessment and quantification, thus reducing cost and ease of follow up in these subsets of patients. We aimed to evaluate the feasibility, reproducibility, validation, and predictive model of 4D echocardiography (4D auto RVQ) for RV volume and function assessment, using cardiac MRI as gold standard.

METHODS

Forty patients (mean age, 22.27 $\pm$ 8.67 years), after TOF repair, referred for cardiac MRI, were included. Immediately after MRI, 4D echocardiography was performed using standard protocol. 4D echocardiography and MRI parameters analysed were right ventricle end-diastolic volume (RV EDV), right ventricle end-systolic volume (RV ESV), right ventricle

stroke volume (RV SV) and right ventricle ejection fraction (RV EF). The parameters were compared with those of CMR, the reference method.

RESULTS

4D auto RVQ data were successfully analysed in 81% of patients (40/49). 4D auto RVQ with cardiac MRI revealed significant correlations between RV EDV, ESV, and EF (148.10 ± 42.98 mL vs 195.98 ± 60.86 mL, r = 0.75); (79.33 ± 25.73 mL vs 100.86 ± 38.40 mL, r = 0.67); (46.49 ± 7.41% vs 48.86 ± 8.59%, r = 0.74, respectively). Compared with cardiac MRI, 4D auto RVQ underestimated RV end-diastolic volume (RV EDV), RV end-systolic volume (RV ESV), RV stroke volume (RV SV), and RV EF. Mean bias were -47.88 ml, -21.53 ml, -26.31 ml, -2.36% respectively. Good agreement for RV EDV, RV ESV and RV EF was found between 4D auto RVQ and cardiac MRI by Bland-Altman analyses. There was also good intra-observer correlation for RV volumes and EF on 4D echocardiography. Among the RV volumes RV EDV index on 4D echocardiography could best predict the cardiac MRI RV EDV index with sensitivity and specificity of 92 % and 78% respectively.

CONCLUSION

In patients after TOF repair, 4D echocardiography (4D auto RVQ) showed strong correlation, acceptable feasibility and reproducibility and good agreement with cardiac MRI in delineation of right ventricle dimension and right ventricle function in repair TOF patients. The present study has given us the evidence regarding potential use of 4D echocardiography in follow up of repair TOF patients that can be used in daily clinical practice. This in turn can

lead to reduction in the number of CMR patients usually undergo. Also, 4D echocardiography can be used in subsets of patients with contraindication to cardiac MRI.

Keywords: Tetralogy of Fallot, 4D auto right ventricle quantification, cardiac magnetic resonance, percutaneous pulmonary valve replacement.

INTRODUCTION

The management of Tetralogy of Fallot patients post intracardiac repair relies on the serial evaluation of the right ventricle (RV), for which cardiac magnetic resonance (CMR) is considered the gold standard. TOF patients post intracardiac repair are left with severe pulmonary regurgitation that ultimately leads to right ventricular dilatation. Hence require serial imaging to assess RV volumes and function. The accuracy of 2D echocardiography is lower compared to cardiac magnetic resonance imaging in assessing RV volumes and functions.[1]

Because of complex RV geometry, 2D echocardiography cannot capture both RV inflow and outflow within a single image acquisition. Hence for RV volumes and function assessment patients undergo serial cardiac magnetic resonance imaging which is considered gold standard. Since cardiac MRI is not readily available at every centre and is quite costly hence poses a significant challenge in follow up of patients.

A new semi-automated surface detection algorithm, 4D auto RVQ, for quantifying the right ventricle (RV) by echocardiography has recently been integrated into advanced echocardiography machine. The objective of our study is to see the correlation between 4D auto RVQ by echocardiography and its correlation with cardiac MRI. Our present study aims to find a correlation 4D echocardiography with cardiac MRI, that can be used for follow up and further management thus reducing the cost and referral for cardiac MRI.

AIMS & OBJECTIVES

PRIMARY OBJECTIVES

To study the correlation between 4D derived right ventricle volume (4D auto RVQ) in TOF-post ICR patients with cardiac MRI.

SECONDARY OBJECTIVES

To assess feasibility and reproducibility of 4D derived right ventricle volume (4D auto RVQ) in TOF-post ICR patients.

REVIEW OF LITERATURE

Tetralogy of Fallot (TOF) is the most common cyanotic congenital heart disease. It represents a spectrum of congenital heart defects (CHD) characterized by a consistent core morphology but a varied presentation and management. The specific anatomy of the right ventricular outflow tract (RVOT) and pulmonary arteries (PAs) plays a key role in determining the clinical presentation and treatment approach. The prevalence of TOF is approximately 0.5 per 1,000 live births, accounting for about 9% of all congenital heart diseases.[2] Some infants with TOF experience minimal impact from their cardiac condition and undergo uncomplicated elective repair within a few months of age. In contrast, others are critically ill during the newborn period, presenting a significant therapeutic challenge. The field of congenital cardiac surgery largely began with palliative procedures for TOF, and the advancements made in its surgical "corrections" were quickly applied to other congenital heart conditions. Surgery has significantly improved outcomes for patients with TOF, so that now, with access to surgical care, nearly all infants born with the condition survive. With the introduction of intracardiac repair, survival into adulthood has become common for patients with TOF, often accompanied by a favourable long-term prognosis..[3]

EVOLUTION OF SURGICAL TREATMENT

The initial surgical repair involves closing the ventricular septal defect and relieving the RVOT obstruction, which may include infundibulectomy with or without commissurotomy, transannular patch repair in cases of severe stenosis, or the placement of an RV-to-main pulmonary artery conduit if pulmonary atresia is present.[4,5] However, many patients develop significant pulmonary regurgitation, which can lead to right ventricular (RV) dilatation and dysfunction, right heart failure, arrhythmias, and an increased risk of sudden cardiac death.[6]

TECHNIQUE OF OPERATION IN PATIENT WITH TETRALOGY OF FALLOT

The outcome of TOF repair primarily depends on the relief of pulmonary stenosis, whether it is infundibular, valvar, pulmonary arterial, or a combination of these. After performing a median sternotomy, the external anatomy of the heart is examined, with special focus on the right ventricle (RV) and pulmonary artery anatomy, as well as the configuration of coronary arteries crossing the RV.

The primary goal of TOF repair is to eliminate intracardiac shunting, normalize right ventricular (RV) pressure and volume overload, and preserve normal myocardial function. This is achieved through complete closure of the ventricular septal defect (VSD) and, if present, an atrial septal defect, along with full relief of the RV outflow tract obstruction, while maintaining a competent pulmonary valve. However, this ideal outcome is typically reached only in a minority of patients, usually those with the most favourable RV outflow anatomy, including a normal or nearly normal pulmonary "anulus" and functioning pulmonary valve cusps. In most other cases, the repair will fall short of the ideal, requiring several important morphology-driven decisions during the procedure to best approach the desired outcome.

The decisions outlined here typically involve both technical and conceptual aspects:

- Choosing between transatrial or transventricular incisions for the repair.
- Deciding on the application and width of a transannular patch.
- Determining whether to preserve or sacrifice RCA branches.
- Managing the RV outflow tract in the presence of an anomalous LAD.
- Addressing abnormal pulmonary valve cusps and deciding whether to preserve or perform transannular patching.

- Handling atrial septal defects and PFOs.
- Managing the tricuspid valve when the septal leaflet function is impaired during VSD closure.
- Dividing or resecting obstructing septal and parietal muscle bands in the RV outflow tract.

TRANSANULAR PATCH

The decision to use a transannular patch is a common consideration, and it is now recognized as having significant long-term consequences. Recent studies continue to highlight the negative effects of large transannular incisions. A transannular patch inevitably leads to pulmonary regurgitation, and when this regurgitation is severe and prolonged, RV dysfunction will eventually develop. The degree of narrowing of the "anulus" can be measured quantitatively using a z-score (the number of standard deviations from normal). If the annulus z-score is -3 or lower, a transannular patch is likely necessary. After the patch is placed, patients typically experience free pulmonary regurgitation

PULMONARY REGURGITATION AND THE FATE OF RIGHT VENTRICLE

While several factors influence long-term outcomes after TOF repair, chronic pulmonary regurgitation (PR) is widely acknowledged as a major pathophysiological contributor.[7] Pulmonary regurgitation (PR) is a common complication following TOF repair, particularly severe in patients with a transannular patch (TAP). Unfortunately, PR tends to worsen over time, imposing a volume load on the right ventricle (RV), which is further aggravated by any distal pulmonary artery (PA) stenosis.[8,9] It is now understood that right ventricular (RV) remodeling in response to chronic volume overload, while initially compensatory, eventually becomes harmful. In the presence of chronic pulmonary regurgitation (PR), compensatory RV dilation and hypertrophy help maintain cardiac output and normal wall stress.

The link between pulmonary insufficiency and right ventricular (RV) end-diastolic volumes in patients with TOF was first recognized in the 1980s. This strong positive relationship has become more evident with the advent of cardiac magnetic resonance (CMR) imaging.[10,11]

Right ventricular (RV) dilation does not initially lead to a reduction in RV ejection fraction (EF), and stroke volume is maintained, allowing patients to experience a prolonged preclinical compensated phase during which symptoms are rarely reported. However, formal testing over these years often reveals reduced exercise capacity and neurohormonal activation, which correlates with increased RV volumes.[2,12,13] Eventually, these compensatory mechanisms become maladaptive, and patients with severe, prolonged pulmonary regurgitation (PR) begin to experience right ventricular (RV) contractile dysfunction.[14] The pathophysiologic progression can be worsened by coexisting abnormalities. For instance, tricuspid regurgitation, which occurs in about 30% of patients, creates a cycle of increasing RV dilation, which further exacerbates tricuspid regurgitation, perpetuating a vicious cycle.[15] For a time, right ventricular (RV) dysfunction can be reversible with intervention to eliminate pulmonary regurgitation (PR). However, as the damage progresses, permanent myocardial injury occurs. This results in the RV's inability to return to normal dimensions, even after pulmonary valve replacement (PVR), and eventually leads to further RV impairment. This increases the risk of ventricular arrhythmias, symptomatic heart failure, and sudden cardiac death.[16]

Most of these patients are either asymptomatic or experience mild to moderate limitations in exercise capacity, with considerable individual variation.[17] As a result, assessing RV function is crucial in managing these patients, as those with substantial dilation and symptoms may benefit from pulmonary valve replacement.[11]

Gatzoulis et el studied 793 patients from 6 center, they found that an moderate or severe PR was the main hemodynamic abnormality in patients with ventricular tachycardia and sudden death.[18] Khairy et al., in a multicenter study of 252 patients with repaired TOF, found that a history of syncope, moderate or severe pulmonary or tricuspid regurgitation, QRS duration $\geq$

180 milliseconds, cardiomegaly on chest x-ray (CT ratio $\geq$ 0.6) were associated with sudden death or clinical ventricular tachycardia.

Knauth et al., in a follow up study with cardiac MRI of post repair TOF patients found that severe RV dilation (end-diastolic volume Z-score $\geq$ 7 measures by CMR) and ventricular dysfunction (LV EF <55% or RV EF <45%) were independent predictors of adverse outcomes (death, sustained ventricular tachycardia, heart failure).[19]

ardiac MRI is the preferred method for longitudinal follow-up in patients with repaired TOF, as it is not limited by acoustic window, does not involve exposure to ionizing radiation, and is non-invasive. Given that cardiac MRI offers precise quantitative data on biventricular size and function, it is the preferred non-invasive imaging technique for these patients. At Boston Children's Hospital, postoperative TOF is the most common diagnosis among patients referred for CMR, representing 23% of cases.

In routine clinical practice, 2D echocardiography is the most used method for the non-invasive evaluation of cardiac function. However, due to the complex geometry of the heart, 2D echocardiography has significant limitations in assessing left ventricular function, particularly in evaluating RV volumes and ejection fraction (EF).

To address the issues of geometric assumptions and apical foreshortening, 4D echocardiographic imaging was developed. This technique enables the rapid acquisition of a pyramidal data set that captures the entire right ventricle.[20]

In one of the studies conducted at Netherlands by Van der Zwaan et al, comparing real time 3D echocardiography with cardiac MRI in patient with different congenital heart disease they found that real time 3D echocardiography imaging provides a fast and reproducible assessment of RV volumes and EF with fair to good accuracy compared with CMR reference data.[21]

RATIONALE AND JUSTIFICATION FOR THIS STUDY

The long-term sequelae in post-surgical TOF patients are progressive dilatation of right ventricle secondary to free pulmonary regurgitation caused by the transannular patch graft. The progressive dilatation is usually asymptomatic, hence follow up cardiac MRI is necessary to assess the right ventricle size and functions which is considered the gold standard for quantifying RV size and functions. The availability of cardiac MRI is limited to higher center and hence we need a tool to quantify RV size and function which can be comparable to cardiac MRI. Recently 4D echocardiography integrated into echo machine can be used to calculate RV size and functions which can be comparable to cardiac MRI, so wider population can undergo follow up imaging investigation without much difficulty.

4D Auto RVQ (Right Ventricle Quantification)

Quantifying the right ventricle has become increasingly important, particularly in patients with repair tetralogy of Fallot, where the functional and anatomical performance of this chamber plays a crucial role.

In current clinical practice, manual measurements in Magnetic Resonance Imaging (MRI) are considered the gold standard for the quantitative assessment of RV volumes and ejection fraction. However, MRI may not always be accessible and is also time-consuming to perform.

Echocardiography-based 4D quantification tools for the right ventricle have been available for some time and are offered by several vendors. These tools provide more objective and accurate measurements compared to those obtained from 2D echocardiography, where accessing the desired views can be more challenging.

The 4D Right Ventricle Quantification tools are typically (semi-)automated, allowing for quick access to the measurements of interest.

HYPOTHESIS

In postoperative Tetralogy of Fallot patients, follow up of right ventricle assessment is done by cardiac MRI which is gold standard, a new semiautomated surface detection algorithm to quantify right ventricle volume (4D auto RVQ) can be correlated with cardiac MRI volumes.

RESEARCH QUESTION

Can 4D derived right ventricle volume by echocardiography in post operative Tetralogy of Fallot patients correlates with cardiac MRI derived right ventricle volumes?

MATERIALS AND METHODS

METHODOLOGY

Post TOF-ICR patients presenting to paediatric cardiology OPD, SCTIMST, Trivandrum for follow up and scheduled for cardiac MRI based upon the clinical features, ECG, chest Xray, echocardiographic parameters were included into the study. The 4D echocardiography for RV volumes were done once the patients cardiac MRI scan got over. We ensured minimum delay between two scans to avoid difference in loading conditions.

STUDY DESIGN

Single centre observational study done at GUCH OPD, Department of Cardiology, Sree Chitra Tirunal Institute of Medical Sciences and Technology (SCTIMST), Trivandrum.

STUDY PERIOD

January 2024 to August 2024

SAMPLE SIZE

The minimum sample size will be 40 patients

Assumptions

Alpha value 0.05

Power 0.90 (90%)

Required sample size as calculated by Sampsi command stata software is 40 patients.

INCLUSION CRITERIA

1. All adult patients post ICR for TOF
2. Children 12 to 18 years of age
3. Willing to give consent for study

EXCLUSION CRITERIA

1. Patients with contraindication for undergoing cardiac MRI (prior PPI, ICD).
2. Not in sinus rhythm
3. Poor echocardiographic window
4. Not willing to give consent.

STATISTICAL ANALYSIS

The normality of the data was evaluated using the Shapiro-Wilk test. Categorical variables are summarized as numbers and percentages. Continuous variables are presented as mean $\pm$ SD. Linear regression analysis with Pearson's correlation coefficient to evaluate the relation between 4D auto RVQ with cardiac MRI volumes. Intra-observer variability was determined using the Intraclass Correlation Coefficient. The agreement between 4D auto RVQ with cardiac MRI measurement using Bland-Altman analysis. P value of < 0.05 will be considered statistically significant.

ECHOCARDIOGRPAHY PROTOCOL

The patients lie in left lateral supine position, the ECG leads are attached and 4D echocardiography probe is selected from probe menu. An apical 4 chamber view is made such that right ventricle (RV) lateral wall, tricuspid valve (TV) and RV apex along with mitral valve (MV) comes into the echocardiographic frame as shown in Figure 1. A semi-automated segmentation algorithm is employed to measure the RV cavity volume throughout the cardiac cycle. This algorithm begins with user-defined landmarks that position and scale an initial 3D deformable model representing the RV endocardium, the tricuspid valve plane, and the RV outflow tract. The algorithm determines the deformation of the 3D model by solving a state estimation problem through an extended Kalman filter, which integrates RV geometry, a motion model, tissue tracking, and edge detection algorithms.

4D Auto RVQ workflow description

The fully integrated tool requires a 4D dataset of the right ventricle, captured using a TTE probe in a zoomed acquisition. This ensures the entire right ventricle and tricuspid valve are included, with a volume rate exceeding 12 volumes per second to enable accurate temporal assessment and calculation of volume and ejection fraction (EF), seen in Figure 2.

Before initiating 4D auto RV quantification, the first step involves adjusting the 2D gain and zoom settings as needed. During the **alignment stage**, the vertical axis should be positioned to pass through the center of the tricuspid valve (TV) and the RV apex. The lower horizontal plane should be aligned parallel to the tricuspid valve at its base, while the upper horizontal plane should align with the center of the RV, as shown in Figure 3. The alignment is done in 4 chamber and orthogonal 4 chamber views. Six **Landmark** points (see Figure 4) are then placed (two tricuspid annulus points and the RV apex point in the 4-chamber view, and the RV/LV anterior and posterior hinge points and the RV free wall point in the short axis mid

view. Placing of the landmarks is required to aid the previously described algorithm in generating the RV model displayed in the **Review** stage. The contours can be easily edited via the user interface, either at end-diastole or end-systole, using a 3x3 layout as shown in Figure 5. **Results** stage layouts provide the RV mathematic dynamic 3D model, referred to as a "**BEUTEL**" that represents changes in the RV cavity over the cardiac cycle. From this beutel, RV end-diastolic volume (EDV), end-systolic volume (ESV) and EF (defined as [EDV-ESV]/EDV x 100) are derived (see Figure 6,7 & 8). All measurements are transferred into the worksheet for reporting when selecting the **Approve and Exit** stage. At this point, the tool also stores the complete setup and the results together with the exact screen view.



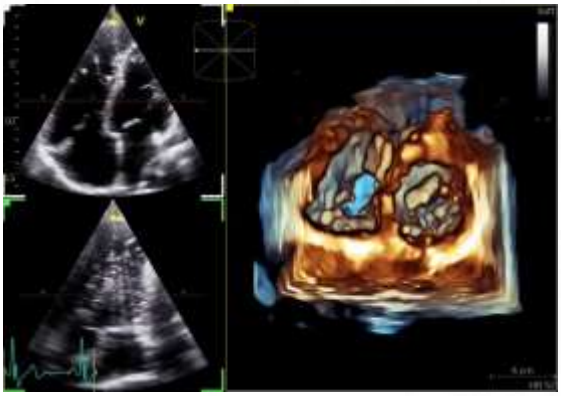
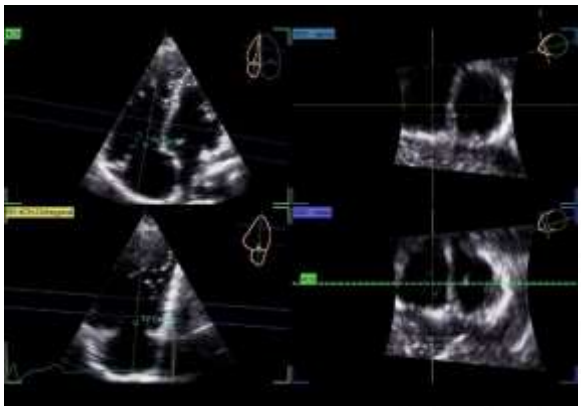


Figure 1 & 2: Fig 1; Apical 4C view with focussed right ventricle and in Fig 2; one-beat full-volume with a high frame rate a 3D volume data set was acquired and stored.



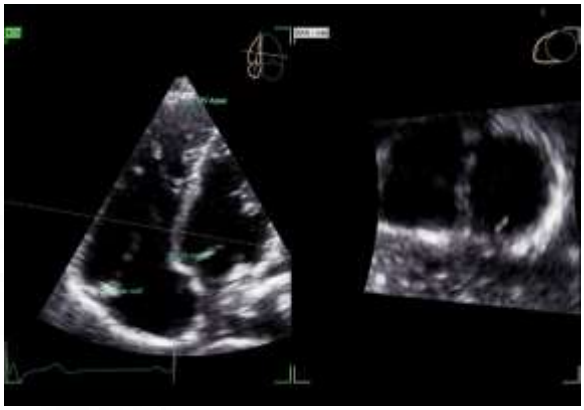
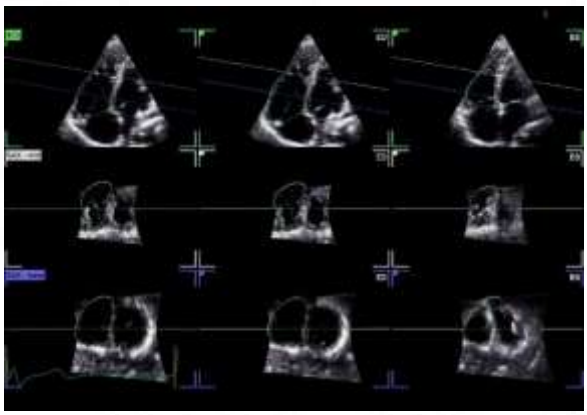


Figure 3 & 4: Fig 3; Alignment stage, here vertical axis was adjusted so that axis crosses TV centre point and RV apex, two horizontal planes with lower horizontal plane parallel to TV plane and upper at the centre of RV. Alignment was done in 4 chamber and orthogonal 4 chamber view. Fig 4; following alignment six landmark points was then placed two at tricuspid annulus points and one at apex. In short axis mid view RV/LV posterior and anterior points plus RV free wall points were placed.



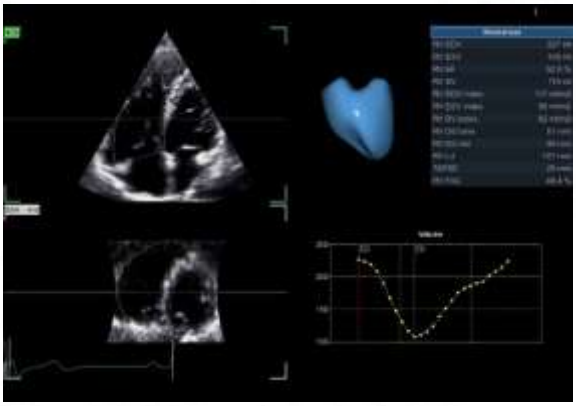
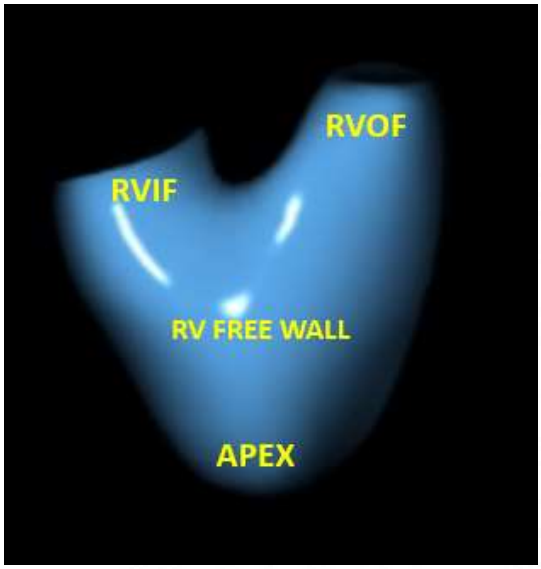


Figure 5 & 6: Fig 5; in review stage; 3 by 3 layout of ED/ES frames were provided and the software automatically delineates the RV endocardial border from the ED/ES phases, the options for manual editing of RV endocardial borders also available. In Fig 6; software by sequential analysis creates RV mathematic dynamic 3D model, referred to as a "**BEUTEL**" that represents changes in RV cavity over the cardiac cycle.



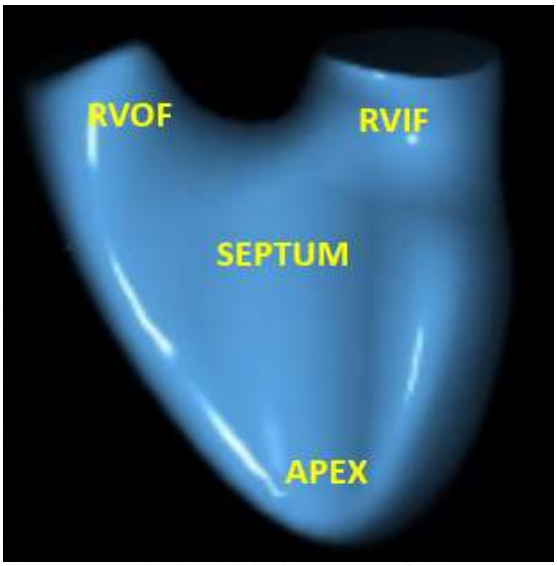


Figure:7 & 8 ; RV mathematic dynamic 3D model, referred to "**BEUTEL"**, that represents changes in the RV cavity over the cardiac cycle. Fig 7 showing the RV free wall along with inflow and outflow portions of RV. Fig 8 shows the septal portion of the RV; From this "**BEUTEL**" RV end diastolic volume (EDV), end-systolic volume (ESV) and EF are derived.

Table 1: Normal Values for Right Ventricle (RV) chamber size.[22]

PARAMETER	MEAN ± SD	NORMAL RANGE
RV EDV INDEX (ml/m2)		
Male	61 ± 13	35-87
Female	53 ± 10.5	32-74
RV ESV INDEX (ml/m2)		
Male	27 ± 8.5	10-44
Female	22 ± 7	8-36
RV 3D EF (%)	58 ± 6.5	<45

CMR PROTOCL in repaired tetralogy of Fallot patients.

All CMR examinations were conducted using a 1.5 Tesla scanner (Siemens) equipped with a 32-channel phased-array abdominal coil and ECG gating. The CMR protocol and imaging parameters are detailed below. No sedation was administered during the imaging process. Patients were trained in breath-holding techniques prior to the examination, with images acquired during one or two end-expiratory breath-holds lasting 8–12 seconds, depending on the heart rate. Patient weight and height were recorded before the procedure.

Cine steady-state free precession sequence images of the four-chamber and short-axis views were acquired, covering the entire ventricles. Phase-contrast imaging was performed perpendicular to the vascular structures, including the main pulmonary artery, branch pulmonary arteries, and ascending aorta. Late gadolinium enhancement sequences were obtained 10 minutes after contrast injection to assess myocardial contrast enhancement.

All images were analysed using commercially available software on a workstation. The endocardial layers of the ventricles were manually contoured on short-axis cine images, including the papillary muscles and trabeculations across all slices during end-diastolic and end-systolic phases. The workstation automatically calculated the end-diastolic volume index (EDVI), end-systolic volume index (ESVI), stroke volume index (SVI), and ejection fraction (EF). The presence of late gadolinium enhancement in both ventricles was also evaluated.

RESULTS

The purpose of this project was to study the correlation of right ventricle quantification by 4D echocardiography (4D auto RVQ) in TOF post ICR patients with cardiac MRI right ventricle volumes. We hypothesized that a new semiautomated 4D quantification of right ventricle by echocardiography can be correlated with cardiac MRI measurement of RV volumes which is considered a gold standard. 4D derived RV volumes (4D auto RVQ) has moderate to strong correlation with cardiac MRI volumes and can be used in day-to-day clinical practice in follow up for post TOF ICR patients.

Demographic Data

During the period of 8 months 49 TOF post ICR patients were included who underwent cardiac MRI and 4D echocardiography (4D auto RVQ). Adequate 4D auto RVQ data sets could be analysed in 40 of 49 patients (81%).

The patient baseline clinical and echocardiographic profiles shown in Table 2 and Figure 9.

The mean age of participants was 22.27 $\pm$ 8.67 years, with male and female population of 22 (55%) and 18 (45%) respectively as shown in figure.

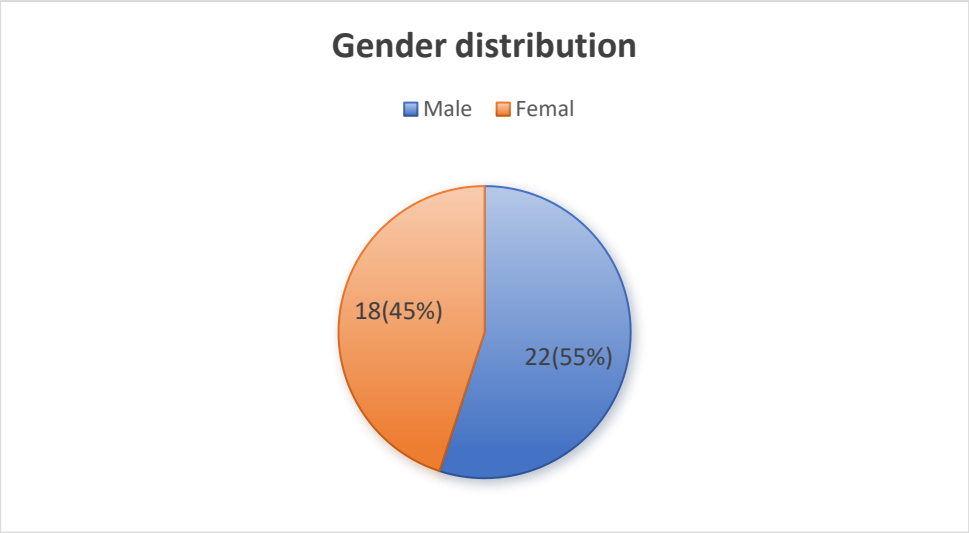


Figure 9: Gender distribution with slightly male preponderance of 55%

In our study population mean heart rate and body surface area (BSA) were 81.42 ± 11.75 beats/min and 1.48 ± 0.27 kg/m2 respectively.

Most of the patients with diagnosis of tetralogy of Fallot (TOF) were operated at our Institute comprising 92.50% with only 3 patients out of 40 (7.50%) were operated elsewhere as shown in Table 2.

The most common surgery performed was intracardiac repair with transannular patch in 27 (67.50%) patients and next common surgery was intracardiac repair with transannular patch and mono-cusp reconstruction (MCR) in 9 (22.50%) patients. Only few of the study population underwent intracardiac repair with infundibular resection comprising 7.5% of the study population. Intracardiac repair with right ventricle to pulmonary artery conduit (RV-PA conduit) was performed in only one patient as shown in Table 2.

In the present study the median age at operation for the study population was 3 (1.95, 6.12) years and in terms of gender, the median age at operation for male and female were 3 (2,6) and 2.8 (1.8,6) years respectively.

Most of the patients coming for follow up in paediatric outpatient department (OPD) at our institute were asymptomatic (90%). 4 patients comprising 10% of the study population reported to have dyspnoea on exertion NYHA functional class II. None of the follow up cases post TOF ICR reported to have symptoms of angina on exertion, palpitation, giddiness, presyncope and syncope as shown in Table 2.

As a part of routine investigation in follow up patient of TOF post ICR, mean cardiac thoracic ratio (CT ratio) found to be 0.55± 0.05 and mean QRS duration on ECG found to be 141.78 ± 23.06 milliseconds.

Following cardiac MRI in 40 patients in our study population, 12 (30%) patients met the criterial for eligibility of pulmonary valve replacement (PVR) and hence been referred for

further workup of either percutaneous or surgical pulmonary valve replacement as shown in Table 2.

In our study population adequate 4D echocardiography (4D auto RVQ) data sets could be analysed in 40 of 49 patients (81%). In 9 of our follow up patients echocardiographic window of right ventricle was very poor hence excluded from analysis.

Table 2: Patient characteristics (n = 40)

Clinical data	
Age (y)	22.27 ± 8.67
Male (y)	21.61 ± 9.36
Female (y)	22.81 ± 8.25
Sex distribution %	
Male	22 (55.00%)
Female	18 (45.00%)
Heart rate (beats/min)	81.42 ± 11.75
Body surface area (kg/m2)	1.48 ± 0.27
TOF subtypes	
1. TOF with severe pulmonary stenosis	35 (87.50%)
2. TOF with pulmonary atresia	2 (5.00%)
3. TOF with absent pulmonary valve	3 (7.50%)
Mean age at operation	3 (1.95, 6.12)
Male	3 (2,6)
Female	2.8 (1.8,6)
Operation performed	
1. ICR with TAP	27 (67.50%)
2. ICR with TAP and mono-cusps reconstruction	9 (22.50%)
3. ICR with infundibular resection	3 (7.50%)
4. ICR with RV to PA conduit	1 (2.50%)
Clinical	
1. Symptoms (%)	4 (10%)
2. Cardiac Thoracic Ratio on chest Xray (mean)	0.55 ± 0.05
3. QRS duration on ECG (mean)	141.78 ± 23.06
Outcomes after MRI scan (%)	
1. Medical follow up	28 (70.00%)
2. Eligible for pulmonary valve replacement (PVR)	12 (30.00%)

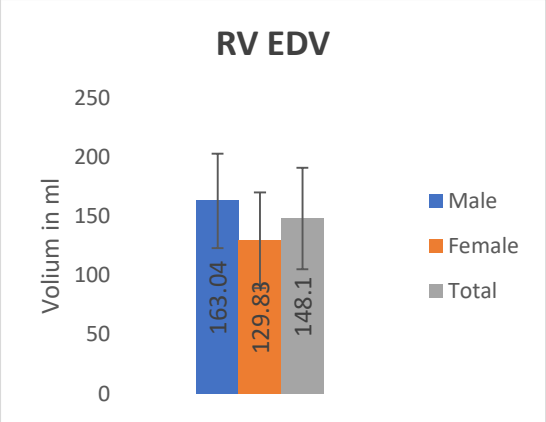


Figure 9

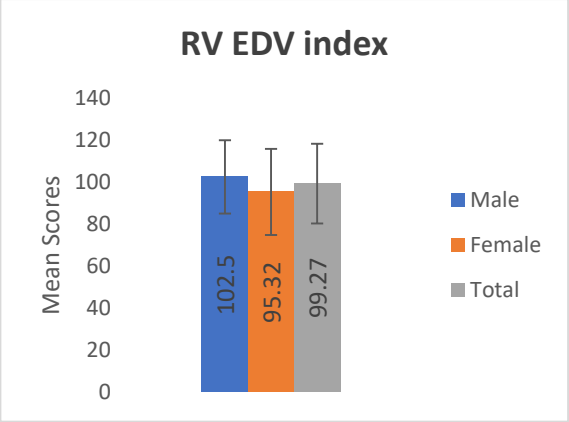
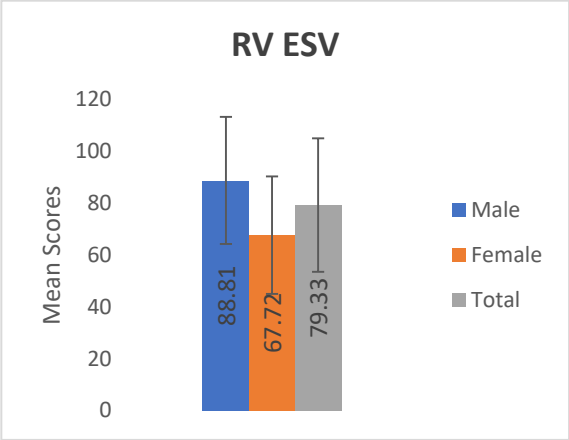


Figure 10

Figure 9 & 10: The mean Right ventricle End diastolic volume (RVEDV) and Right ventricle end diastolic volume index (RVEDVi) by 4D echocardiography (4D auto RVQ) was 148.10 ml and 99.27 ml/m2 respectively.

As shown in Figure 9 and 10 in our study populations the mean Right ventricle End diastolic volume (RVEDV) and Right ventricle end diastolic volume index (RVEDVi) by 4D echocardiography (4D auto RVQ) was 148.10 ml and 99.27 ml/m2. In terms of gender distribution, the RVEDV and RVEDVi of male was 163.04 ml and 102.50 ml/m2 respectively and for the females the RVEDV and RVEDVi was 129.83 ml and 95.32 ml/m2 respectively as measured by 4D echocardiography (4D auto RVQ).



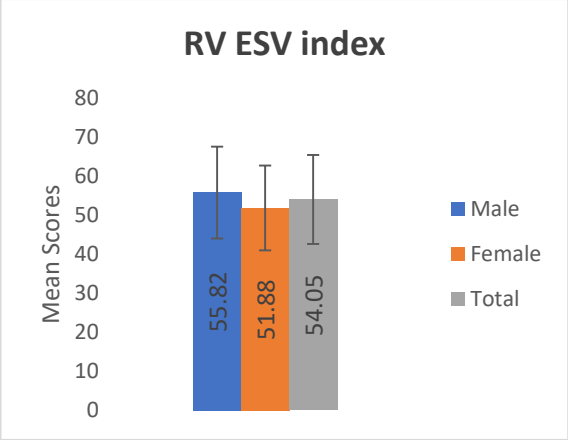


Figure 11 Figure 12

Figure 11 & 12: The mean Right ventricle End systolic volume (RVESV) and right ventricle end systolic volume index (RVESV index) by 4D echocardiography (4D auto RVQ) was 79.33 ml and 54.05 ml/m2 respectively.

As shown in Figure 11 & 12 in our study populations the mean Right ventricle End systolic volume (RVESV) and Right ventricle end systolic volume index (RVESV index) by 4D echocardiography (4D auto RVQ) was 79.33 ml and 54.05 ml/m2. In terms of gender distribution, the RVESV and RVESV index of male was 88.81 ml and 55.82 ml/m2 respectively and for the females the RVESV and RVESV index was 67.72 ml and 51.88 ml/m2 respectively as measured by 4D echocardiography (4D auto RVQ).

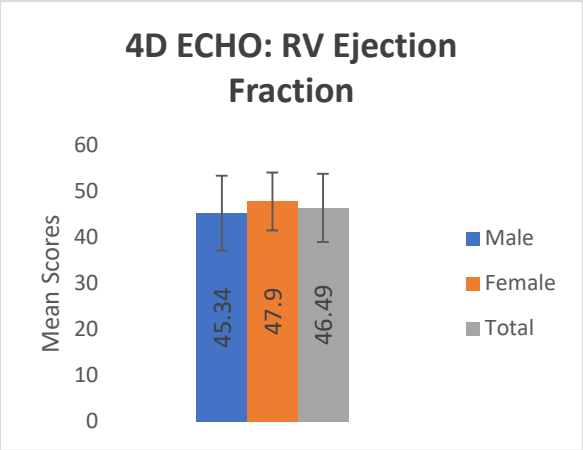


Figure 13

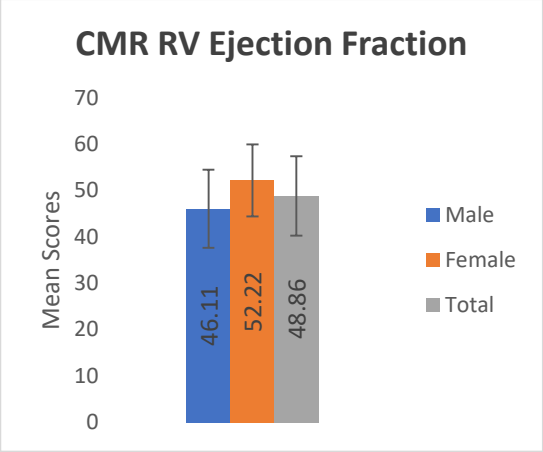
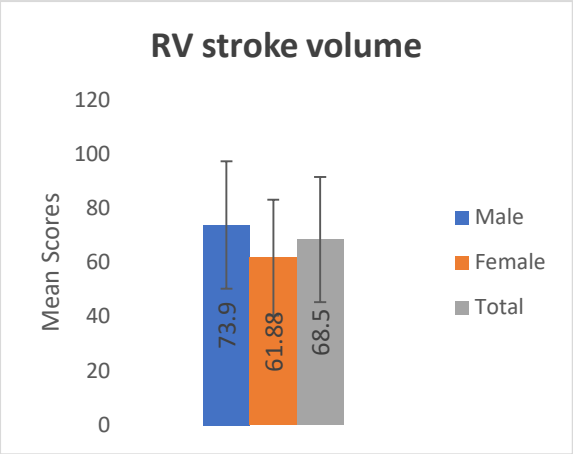


Figure 14

Figure 13 & 14: The mean Right ventricle Ejection Fraction (RVEF) by 4D echocardiography (4D auto RVQ) was 46.49%. The mean Right ventricle Ejection Fraction measured by cardiac MRI was 48.46% in the study population.

As shown in Figure 13 & 14 in our study populations the mean Right ventricle Ejection Fraction (RVEF) by 4D echocardiography (4D auto RVQ) was 46.49%. The mean Right ventricle Ejection Fraction measured by cardiac MRI was 48.46%. In terms of gender distribution, RV EF of male population was 45.34% and female population RVEF was 47.90% by 4D echocardiography (4D auto RVQ). The RV EF measured by cardiac MRI shows that male has RV EF of 46.11% and female has RV EF of 52.22%.



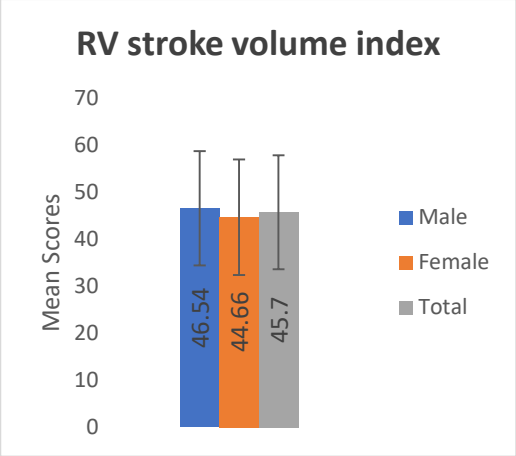


Figure 15 Figure 16

Figure 15 & 16: The mean Right ventricle stroke volume (RV SV) and Right ventricle stroke volume index (RV SV index) by 4D echocardiography (4D auto RVQ) was 68.50 ml and 45.70 ml/m2 respectively.

As shown in Figure 15 & 16 in our study populations the mean Right ventricle stroke volume (RV SV) and Right ventricle stroke volume index (RV SV index) by 4D echocardiography (4D auto RVQ) was 68.50 ml and 45.70 ml/m2 respectively. In terms of gender distribution, the RV ESV and RV ESV index of male was 79.33 ml and 46.54 ml/m2 respectively and for the females the RVESV and RVESV index was 61.88 ml and 44.66 ml/m2 respectively as measured by 4D echocardiography (4D auto RVQ).

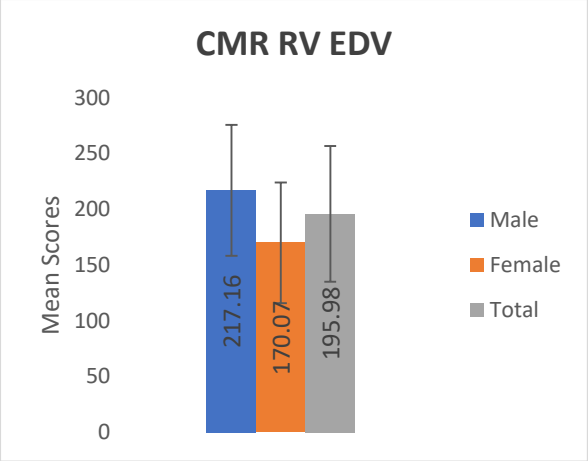


Figure 17

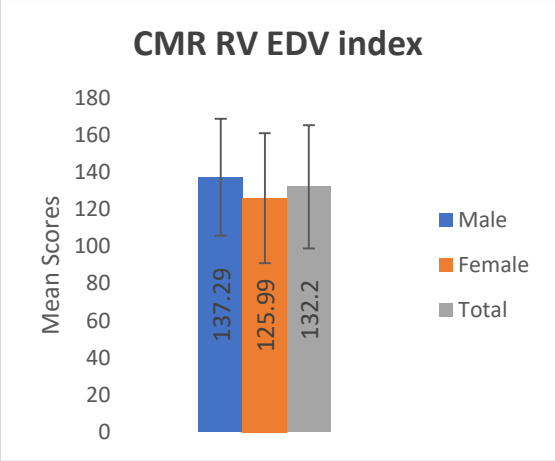


Figure 18

Figure 17 & 18: The mean Right ventricle End diastolic volume (RV EDV) and Right ventricle end diastolic volume index (RV EDV index) by cardiac MRI measured as 195.98 ml and 132.20 ml/m2 respectively.

As shown in Figure 17 & 18 in our study populations the mean Right ventricle End diastolic volume (RVEDV) and Right ventricle end diastolic volume index (RV EDV index) by cardiac MRI measured as 195.98 ml and 132.20 ml/m2. In terms of gender distribution, the RVEDV and RV EDV index of male was 217.16 ml and 137.29 ml/m2 respectively and for the females the RVEDV and RV EDV index was 170.07 ml and 125.99 ml/m2 respectively as measured by cardiac MRI.

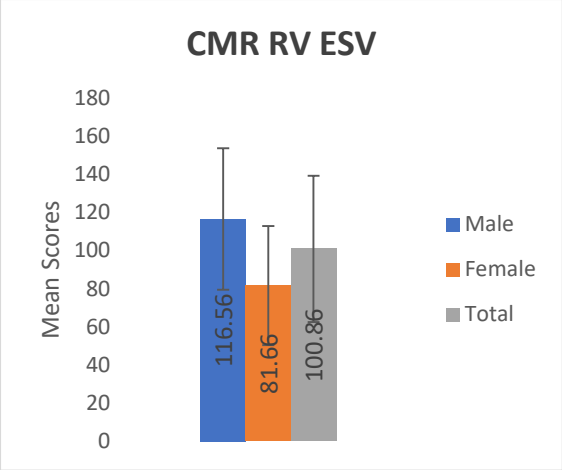


Figure 19

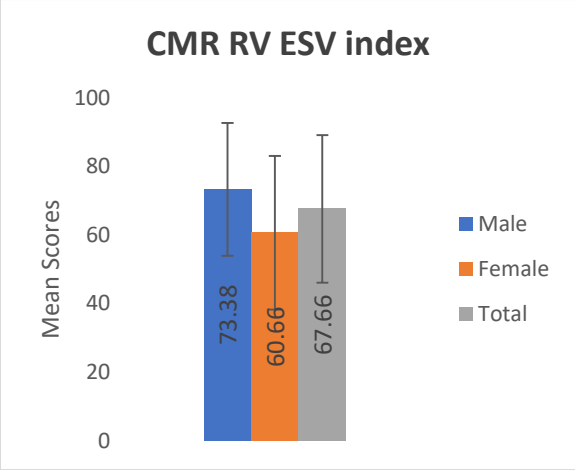


Figure 20

Figure 19 & 20: The mean Right ventricle End systolic volume (RV ESV) and right ventricle end systolic volume index (RV ESV index) by cardiac MRI measured as 100.86 ml and 67.66 ml/m2 respectively.

As shown in Figure 19 & 20, in our study populations the mean Right ventricle End systolic volume (RVESV) and Right ventricle end systolic volume index (RV ESV index) by cardiac MRI measured as 100.86 ml and 67.66 ml/m2. In terms of gender distribution, the RVESV and RV ESV index of male was 116.56 ml and 73.38 ml/m2 respectively and for the females the RVESV and RV ESV index was 81.66 ml and 60.66 ml/m2 respectively as measured by cardiac MRI.

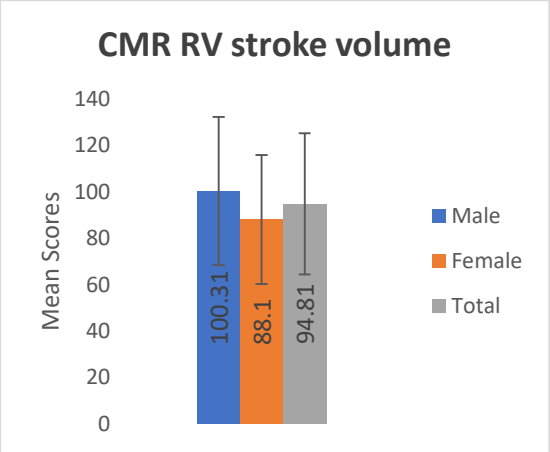


Figure 21

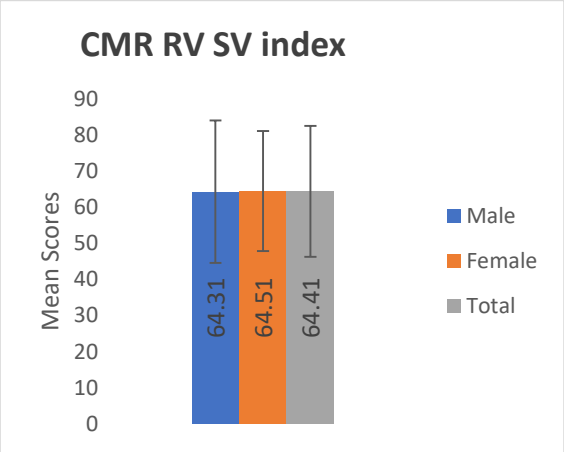


Figure 22

Figure 21 & 22: The mean Right ventricle stroke volume (RV SV) and Right ventricle stroke volume index (RV SV index) by cardiac MRI measured as 94.81 ml and 64.41 ml/m2 respectively.

As shown in Figure 21 & 22, in our study populations the mean Right ventricle stroke volume (RV SV) and Right ventricle stroke volume index (RV SV index) by cardiac MRI measured as 94.81 ml and 64.41 ml/m2 respectively. In terms of gender distribution, the RV ESV and RV ESV index of male was 100.31 ml and 64.31 ml/m2 respectively and for the females the RVESV and RV ESV index was 88.10 ml and 64.51 ml/m2 respectively as measured by cardiac MRI.

Table 3: Correlation of RV volumes by 4D echocardiography (4D auto RVQ) with cardiac MRI volumes in TOF post ICR patients

Parameters	4D auto RVQ Mean (SD) ml	CMR in ml	Correlation co-efficient	P-value
RV EDV	148.10 ± 42.98	195.98 ± 60.86	0.75	< 0.001
RV ESV	79.33 ± 25.73	100.86 ± 38.40	0.67	< 0.001
RV EF	46.49 ± 7.41	48.86 ± 8.59	0.74	<0.001
RV SV	68.50 ± 23.14	94.81 ± 30.40	0.56	<0.001
RV EDVI	99.27 ± 19.00	132.20 ± 33.18	0.54	<0.001
RV ESV I	54.05 ± 11.40	67.66 ± 21.51	0.47	0.002

In the present study we found that mean right ventricle end diastolic volume (RV EDV) measured by 4D echocardiography (4D auto RVQ) was 148.10 ± 42.98 ml and CMR derived right ventricle end diastolic volume (RV EDV) was 195.98 ± 60.86 ml. The correlation co-efficient between 4D auto RVQ and cardiac MRI derived right ventricle end diastolic volume was found to be 0.75, suggesting strong correlation between the measurements of 4D auto RVQ and cardiac MRI as shown in Table 3

In the present study we found that mean right ventricle end systolic volume (RV ESV) measured by 4D echocardiography (4D auto RVQ) was 79.33 ± 25.73 ml and CMR derived right ventricle end systolic volume (RV ESV) was 100.86 ± 38.40 ml. The correlation co-efficient between 4D auto RVQ and cardiac MRI derived right ventricle end systolic volume was found to be 0.67, suggesting strong correlation between the measurements of 4D auto RVQ and cardiac MRI as shown in Table 3

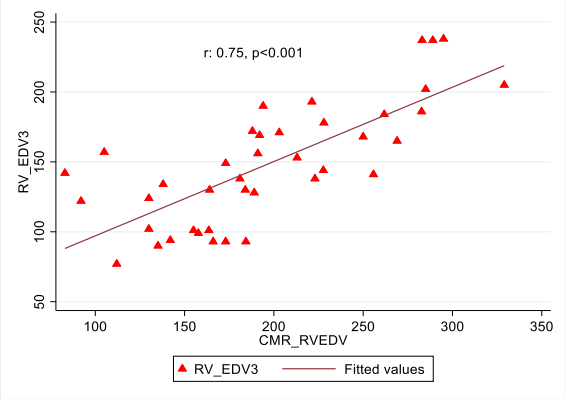
In the present study we found that mean right ventricle ejection fraction (RV EF) measured by 4D echocardiography (4D auto RVQ) was 46.49 ± 7.41 % and CMR derived right ventricle ejection fraction (RV EF) was 48.86 ± 8.59 %. The correlation co-efficient between

4D auto RVQ and cardiac MRI derived right ventricle ejection fraction was found to be 0.74, suggesting strong correlation between the measurements of 4D auto RVQ and cardiac MRI as shown in Table 3

In the present study we found that mean right ventricle stroke volume (RV SV) measured by 4D echocardiography (4D auto RVQ) was 68.50 $\pm$ 23.14 ml and CMR derived right ventricle stroke volume (RV SV) was 94.81 $\pm$ 30.40 ml. The correlation co-efficient between 4D auto RVQ and cardiac MRI derived right ventricle stroke volume was found to be 0.56, suggesting moderate correlation between the measurements of right ventricle stroke volume by 4D auto RVQ and cardiac MRI as shown in Table 3.

In the present study we found that mean right ventricle end diastolic volume index (RV EDV index) measured by 4D echocardiography (4D auto RVQ) was 99.27 $\pm$ 19.00 ml and CMR derived right ventricle end diastolic volume index (RV EDV index) was 132.20 $\pm$ 33.18 ml. The correlation co-efficient between 4D auto RVQ and cardiac MRI derived right ventricle end diastolic volume index was found to be 0.54, suggesting moderate correlation between the measurements of 4D auto RVQ and cardiac MRI as shown in Table 3.

In the present study we found that mean right ventricle end systolic volume index (RV ESV index) measured by 4D echocardiography (4D auto RVQ) was 54.05 $\pm$ 11.40 ml and CMR derived right ventricle end systolic volume (RV EDV index) was 67.66 $\pm$ 21.51 ml. The correlation co-efficient between 4D auto RVQ and cardiac MRI derived right ventricle end systolic volume index was found to be 0.47, suggesting moderate between the measurements of 4D auto RVQ and cardiac MRI as shown in Table 3.



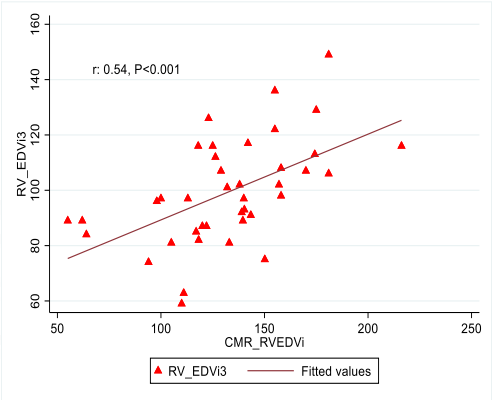
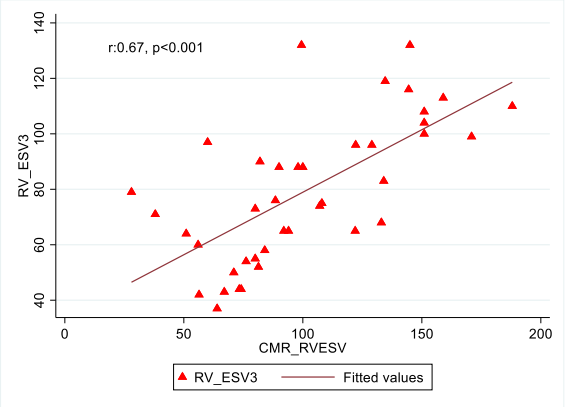


Figure 23

Figure 24

Figure 23 & 24; The graph shows the strong correlation between 4D echocardiography (4D auto RVQ) derived right ventricle end diastolic volume (RV EDV) with cardiac MRI and moderate correlation of end diastolic volume index (RV EDV index) with cardiac MRI.



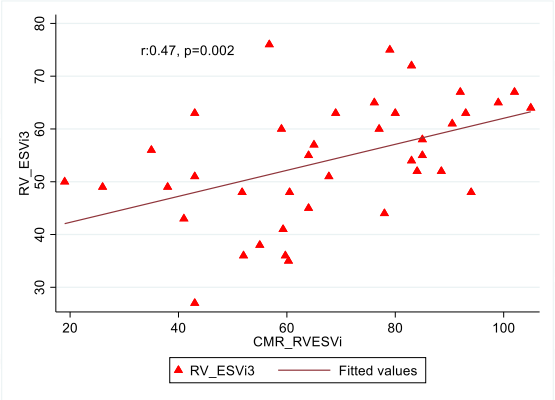


Figure 25

Figure 26

Figure 25 & 26: The graph shows strong correlation between 4D echocardiography (4D auto RVQ) derived right ventricle end systolic volume (RV ESV) with cardiac MRI and moderate correlation between end systolic volume index (RV ESV index) with cardiac MRI.

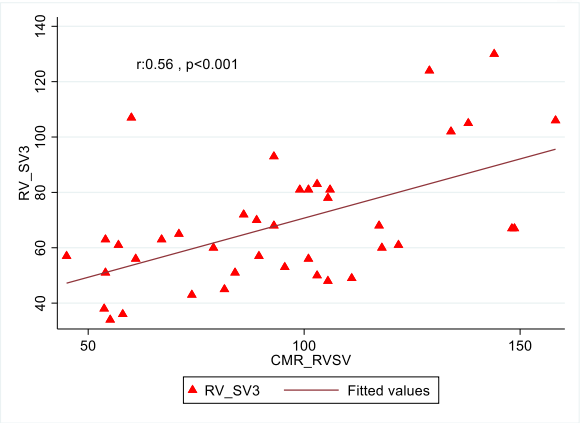


Figure 27

Figure 27: The graph shows strong correlation between 4D echocardiography (4D auto RVQ) derived right ventricle stroke volume (RV SV) with cardiac MRI.

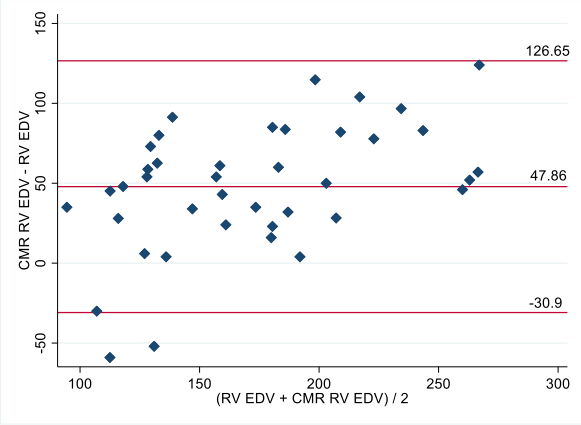


Figure 28

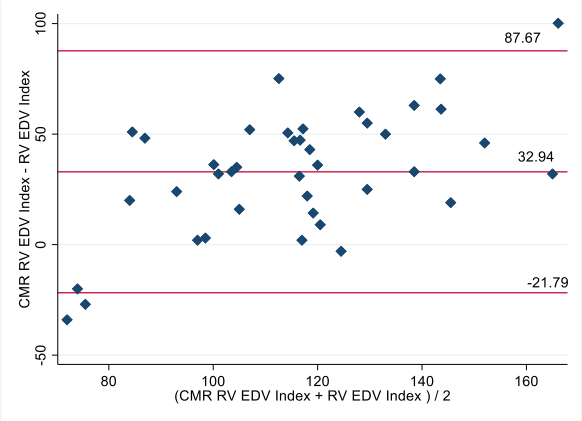


Figure 29

Figure 28 & 29; the Bland-Altman analysis between 4D echocardiography derived RV end diastolic volume and end diastolic volume index with cardiac, the plot shows good agreement between RV end diastolic volume with cardiac MRI.

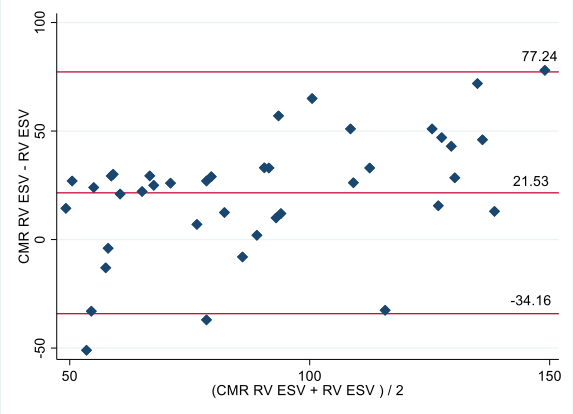


Figure 30

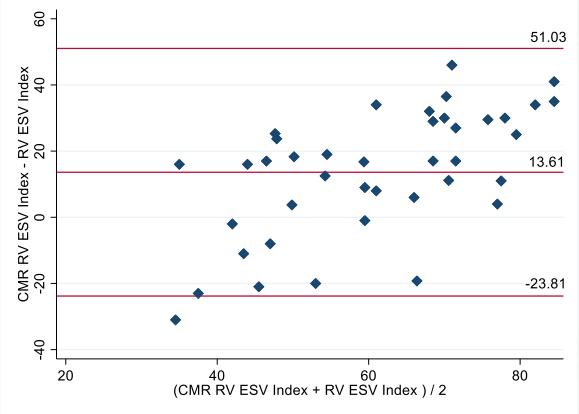


Figure 31

Figure 30 & 31; the Bland-Altman analysis between 4D echocardiography derived RV end systolic volume and end systolic volume index with cardiac, the plot shows good agreement between RV end systolic volume with cardiac MRI.

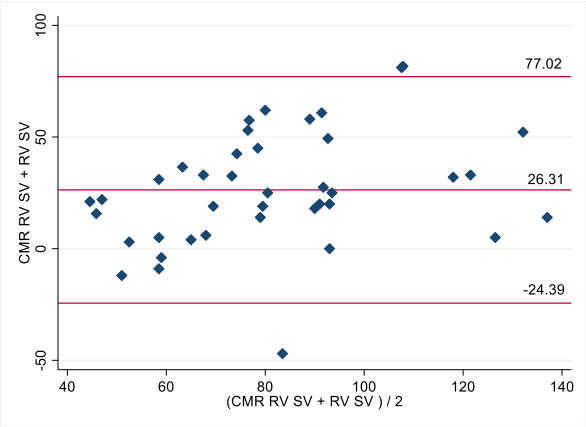


Figure 32

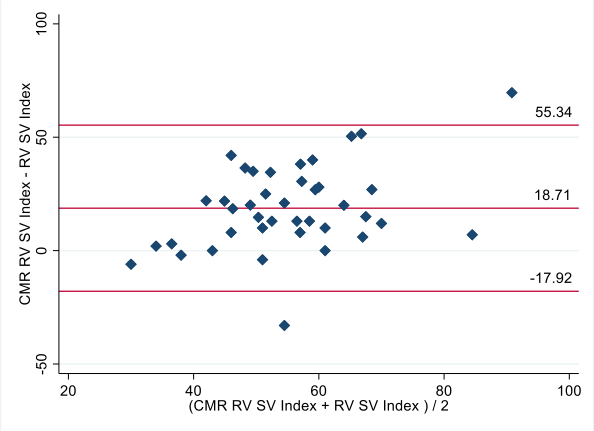


Figure 33

Figure 32 & 33; the Bland-Altman analysis between 4D echocardiography derived RV stroke volume and stroke volume index with cardiac, the plot shows good agreement between stroke volume with cardiac MRI.

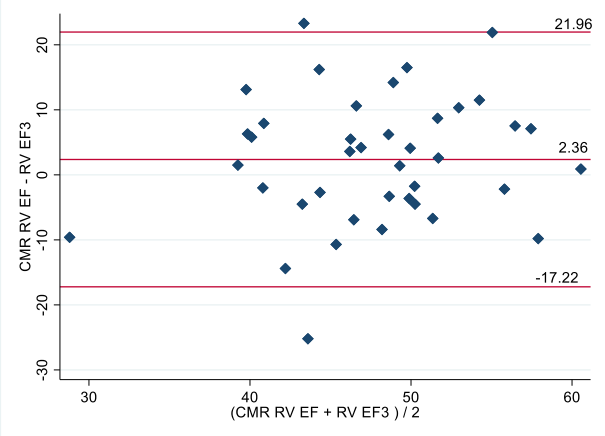


Figure 34

Figure 34; the Bland-Altman analysis between 4D echocardiography derived RV ejection fraction with cardiac, the plot shows good agreement between ejection fraction with cardiac MRI.

Table 4: Bland Altman comparison

Variable	4D auto RVQ	CMR	Mean differnece	95% limits of agreement
RV EDV (ml)	148.10 ± 42.98	195.98 ± 60.86	-47.88	-30.90 to 126.65
RV EDVI (ml/m2)	99.27 ± 19.00	132.20 ± 33.18	-32.93	-21.79 to 87.67
RV ESV (ml)	79.33 ± 25.73	100.86 ± 38.40	-21.53	-34.16 to 77.24
RV ESVI (ml/m2)	54.05 ± 11.40	67.66 ± 21.51	-13.06	-23.81 to 51.03
RV SV (ml)	68.50 ± 23.14	94.81 ± 30.40	-26.31	-24.39 to 77.02
RV EF (%)	46.49 ± 7.41	48.86 ± 8.59	-2.36	-17.22 to 21.96

Table 4; the Bland-Altman comparison between 4D echocardiography with cardiac MRI, the results shows that RV volumes were underestimated on 4D echocardiography with mean difference in RV end diastolic volume and indexed volume of -47.88 ml and -32.93 ml/m2. The mean difference in RV end systolic volume and indexed volume between 4D echocardiography and cardiac MRI was -21.53 ml and -13.06 ml/m2 respectively. The mean difference in RV stroke volume was -21.31 and mean difference between RV EF on 4D echocardiography compared to cardiac MRI was -2.36%.

Table 5: Intra observer variability

Parameters	Average ICC values (95%CI)	P value
RV EDV	0.96 (0.94 - 0.98)	<0.001
RV ESV	0.94 (0.91 - 0.97)	<0.001
RV EF	0.84 (0.73 - 0.91)	<0.001
RV SV	0.95 (0.92 - 0.97)	<0.001
RV EDV index	0.91 (0.86 - 0.95)	<0.001
RV ESV index	0.84 (0.73 - 0.91)	<0.001

The intra observer variability as shown in Table 5 was assessed by acquiring three different full-volume images of right ventricle at different interval. The different full images thus acquired used to derive RV volumes by 4D auto RVQ. As shown in Table 5 the average

reliability for all variables is > 0.8 shows good reliability by their intraclass correlation coefficient (ICC) values.

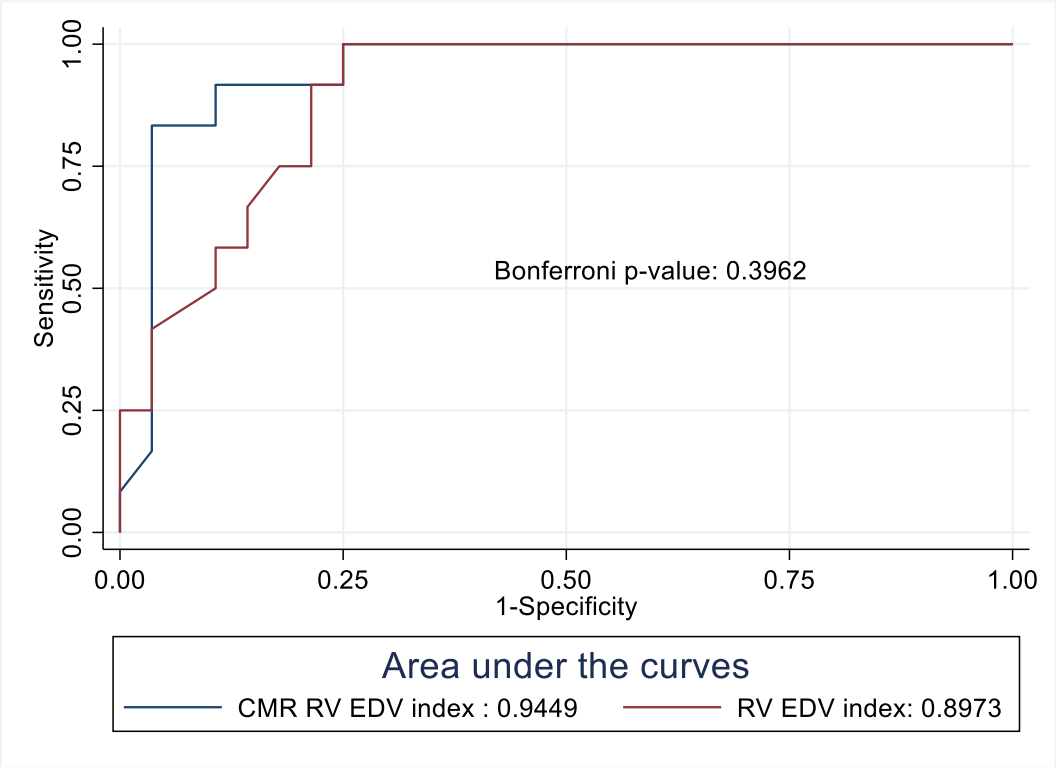


Figure 35: ROC curve, the cut off for RV EDV index is 100 ml/m2, with sensitivity and specificity of 92 % and 78% respectively.

Table 6:

Parameters	AUC	Cut-off (ml/m2)	Sensitivity	Specificity
RV EDVI (CMR)	0.94	150	84	94
RV EDVI (4DE)	0.89	100	92	78

As shown in ROC table 6, the area under the curve (AUC) for CMR RV EDV index and 4D RV EDV index are 0.94 and 0.89 respectively. The sensitivity for CMR and 4D echocardiography for RV EDV index are 84% and 92% respectively, specificity are 94% and 78% respectively.

DISCUSSION

Our study recruited 40 patients who were on follow up post intracardiac repair (ICR) for tetralogy of Fallot. All patients underwent cardiac MRI scan based on the findings of severe pulmonary regurgitation (PR) and dilated right ventricle (RV) on echocardiography, broad QRS on ECG and increased CT ratio on chest X-ray.

Demographic characteristics of the post operative intracardiac repair TOF patients

The demographic characteristics (Table 2) among the 40 TOF post ICR patients showed that mean age of the study population was 22.27 $\pm$ 8.67 years and mean age of male population was 21.61 $\pm$ 9.36 years compared to female whose mean age in our study found to be 22.81 $\pm$ 8.25 years. The study has 55 % of male and 45 % of female participants. The epidemiological data also suggest that TOF has a nearly equal sex distribution with perhaps a slight predominance in males, this is in accordance to our study that has slight male preponderance. The mean heart rate of the study population 81.42 $\pm$ 11.75 beats/min and mean body surface area (kg/m2) was 1.48 $\pm$ 0.27. In a study conducted by van der Zwaan et al correlating RV volumes by 3D real time echocardiography with cardiac MRI volumes, the mean age in their study population was also 26.30 $\pm$ 10.50 years which is similar to our study population.[21] 55% (22) of the study population are male which is similar to the study by van der Zwaan el el, that had male population of 68%. The mean heart rate and body surface area were also similar to the previous studies comparing real time 3D echocardiography derived right ventricle volume with cardiac MRI.[23]

In the present study 35 patients (87.50%) had a diagnosis of TOF with severe pulmonary stenosis and 2 patients (5.00%) of patients has a diagnosis of TOF with pulmonary atresia, similarly few patients comprising only 7.50% of the study population had a diagnosis of TOF with absent pulmonary valve. TOF with pulmonary atresia and TOF with absent pulmonary valve are severe and rare form of tetralogy of Fallot respectively.[24,25]

In our study the median age for intracardiac repair for the tetralogy of Fallot patients was 3 (1.95, 6.12) years, for males the median age at operation was 3 (2,6)years and for females median age at operation was 2.8 (1.8, 6) years. In an early surgical outcome study by Majani et al for Tetralogy of Fallot patients in an African setting, their study also shown that mean age of operation was 3 years in resource limited settings.[26] This is in accordance to our data which also shows that the mean age for operation in our study population was 4.48 years and there was no difference in mean age of operation in males and females.

In our study of follow up post intracardiac repair TOF patients, majority of the patients were asymptomatic and only 4 patients out of 40 had symptoms of dyspnoea on exertion, NYHA functional class II. None of the study participants had symptoms of angina on exertion, palpitation, giddiness, presyncope and syncope. In one of the long-term outcome studies following intracardiac repair in tetralogy of Fallot patients by Lee et al found that vast majority of follow up patients had excellent functional status on follow up (NYHA class I in 94% of patients and NYHA class II in 6% of the patients.[27] In our present study all the patients had excellent NYHA functional class, 90% of the patients were in NYHA class I and 10% of the patients were in NYHA functional class II.

In the present study the mean cardiac thoracic ratio (CT ratio) on chest X ray PA view was 0.55 ± 0.05 and on electrocardiography (ECG) all the follow patients were in sinus rhythm with right bundle branch block in lead V1 and the mean QRS duration on ECG was 141.78 ± 23.06 milliseconds. In a study of long term follow up post intracardiac repair of tetralogy of Fallot patients Lee et al found that mean QRS duration was 147 ± 24 milliseconds,[27] our study also showed similar elevation of the QRS duration following complete intracardiac repair of tetralogy of Fallot.

All follow up patients in our study population had electrocardiographic pattern of right bundle branch block (RBBB). The previous studies had observed that right bundle branch block is routinely observed after trans-atrial repair, proposed mechanism of right bundle branch block after trans-atrial is usually produced by infundibular resection and is associated with delayed activation of the pulmonary outflow tract and base of the right ventricle which results from damage to portions of the right ventricular conduction system.[28]

In our present study among the 40 patients who underwent cardiac MRI scan for assessment of right ventricle volume and function and regurgitant fraction, 12 patients that constituted 30% of the study population, were eligible for pulmonary valve replacement post results of cardiac MRI scan. 28 participants (70%) were advised for medical follow up post MRI scan. The indications for pulmonary valve replacement (PVR) in patients with severe pulmonary regurgitation (PR) when CMR values of RV EDV index > 150 ml/m2 and/or RV ESV index > 80 ml/m2 and or at least moderate tricuspid regurgitation (TR), or at least moderate RVOT obstruction, or RV ejection fraction of <47%, LV ejection fraction of < 55%, large RVOT aneurysm, QRS duration of > 160 milliseconds or ventricular tachyarrhythmia.[29]

4D echocardiography quantification (4D auto RVQ) of Right ventricle functions

The important finding of our study is that in consecutive patients post intracardiac repair for tetralogy of Fallot, 4D auto RVQ imaging was feasible in 40 out of 49 patients (>81%). In the study by van der Zwaan et al they also found that real time 3D quantification in postoperative congenital heart disease patients is feasible in >80% of the patients,[21] this is in accordance to our present study. Feasibility of 3D echocardiography has been reported to vary between 50% and 80% of all patients after TOF repair.[30,31]

In the present study with 40 patients following up in OPD post intracardiac repair for tetralogy of Fallot, we found that mean right ventricle end diastolic volume (RV EDV) and mean right ventricle end diastolic volume index as measured by 4D echocardiography were 148.10 ± 42.98 ml and 99.27 ± 19.00 ml/m2 respectively. In terms of gender distribution, male RV EDV and RV EDV index were measured by 4D echocardiography were 163.04 ± 39.80 ml and 102.50 ± 17.44 ml/m2. In female patients the RV EDV and RV EDV index measured by 4D echocardiography were 129.83 ± 40.49 ml and 51.88 ± 10.87 ml/m2 respectively. In a study by van der Zwaan et al in post operative patients for various congenital heart disease comparing 3D real time echocardiography (3D RTE) volumes of right ventricle with cardiac MRI volumes they found RV EDV volume was 185 ± 71 ml, which was higher compare to our study, the probable reason for higher right ventricle end diastolic volume RV EDV is that the study mentioned constituted mixed population of post operative congenital heart disease where as our study population constituted only patients of tetralogy of Fallot post intracardiac repair.

In the present study in 40 patients post TOF repair the right ventricle end systolic volume and right ventricle end systolic volume indexed to body surface area found to be 79.33 ± 25.73 ml and 54.05 ± 11.40 ml/m2 respectively. Gender wise male RV end systolic volume and indexed volume was 88.81 ± 24.54 ml and 51.88 ± 10.87 ml/m2 respectively. In female population RV ESV and indexed volume were 67.72 ± 22.66 ml and 51.88 ± 10.87 ml/m2 respectively.

The right ventricle stroke volume (RV SV) and RV SV indexed to body surface area in the present study measured by 4D echocardiography was 68.50 ± 23.14 ml and 45.70 ± 12.09 ml/m2 respectively. The cardiac MRI stoke volume and indexed volume of the population was 94.81 ± 30.40 ml and 64.41 ± 18.17 ml/m2 respectively. Male population right ventricle stroke volume and indexed to body surface area measured by 4D echocardiography was

73.90 ± 23.56 ml and 46.54 ± 12.15 ml/m2 respectively. Similarly female population RV stroke volume and indexed volume measured by 4D echocardiography was 47.90 ± 6.29 ml and 44.66 ± 12.30 ml/m2.

The right ventricle ejection fraction in the study population measured by 4D echocardiography was 46.49 ± 7.41%, RV EF measured by cardiac MRI was 48.86 ± 8.59%. The RV EF for male population 45.34 ± 8.17% and female population 47.90 ± 6.29% measured by 4D echocardiography method, the cardiac MRI RV EF for male and female population measured as 46.11 ± 8.41% and 52.22 ± 7.75% respectively.

Correlation of 4D echocardiography (4D auto RVQ) of right ventricle with Cardiac MRI

As shown in Table 3 there is strong correlation between right ventricle end diastolic volume (RV EDV) derived by 4D echocardiography (4D auto RVQ) with cardiac MRI ($r = 0.75$, $P < 0.001$). Dragulescu et al study on corelation with real time 3D echocardiography and cardiac MRI found very strong correlation of real time 3D echocardiography with cardiac MRI, our present study has also strong correlation of RV EDV on 4D echocardiography with cardiac MRI ($r=0.99$, $P<0.001$).[32] van der Zwaan et al study on corelation with real time 3D echocardiography and cardiac MRI found very strong correlation of real time 3D echocardiography with cardiac MRI, our present study has also strong correlation of RV EDV on 4D echocardiography with cardiac MRI ($r=0.93$, $P<0.001$).[23] The reason for difference as compared to our study in terms of correlation is that our study populations has significant RV dilatation which has resulted in significant underestimation of RV volumes and hence the correlation between 4D echo volumes and CMR volumes not as strong compared to the above mentioned study.

As shown in Table 3 right ventricle end systolic volume (RV ESV) on 4D echocardiography has strong correlation with cardiac MRI derived right ventricle end systolic volume, with correlation co-efficient (r=0.67, P<0.001). Dragulescu et al study on corelation with real time 3D echocardiography and cardiac MRI found very strong correlation (r=0.99, P<0.001) of real time 3D echocardiography with cardiac MRI, our present study has strong correlation of RV EDV on 4D echocardiography with cardiac MRI. van der Zwaan et al study on corelation with real time 3D echocardiography and cardiac MRI found very strong correlation ((r=0.91, P<0.001) of real time 3D echocardiography with cardiac MRI, our present study has strong correlation of RV EDV on 4D echocardiography with cardiac MRI. The difference in correlation in our study compared to the above-mentioned study is due to significant underestimation of right ventricle end systolic volume by 4D echocardiography compared to cardiac MRI.

As shown in Table 3, there is strong correlation between right ventricle end diastolic volume (RV EF) derived by 4D echocardiography (4D auto RVQ) with cardiac MRI (r = 0.74, P <0.001). Dragulescu et al study on corelation with real time 3D echocardiography and cardiac MRI found very strong correlation (r=0.87, P<0.03) of real time 3D echocardiography with cardiac MRI, our present study has strong correlation RV EF on 4D echocardiography with cardiac MRI. van der Zwaan et al study on corelation with real time 3D echocardiography and cardiac MRI found strong correlation (r=0.74, P<0.05) of real time 3D echocardiography with cardiac MRI, our present study has strong correlation of RV EDV on 4D echocardiography with cardiac MRI. The above-mentioned study by Dragulescu et al and van der Zwaan et al is in accordance to our study.

As shown in Table 3, there is a moderate correlation between 4D echocardiography derived right ventricle end diastolic volume index (RV EDVI) with cardiac MRI, correlation coefficient (r=0.54, P < 0.001). Also, moderate correlation between 4D echocardiography

derived RV ESV index with cardiac MRI (r=0.47, P = 0.002). In the study conducted by Grewal et al they found the moderate correlation between RV EDV index on RT3D echocardiography with cardiac MRI because of underestimation of the right ventricle end diastolic volume index (RV EDVI) by 3D RT echocardiography.[31]

As shown in table there is a moderate positive correlation between right ventricle stoke volume (RV SV) derived by 4D echocardiography compared to cardiac MRI with correlation coefficient (r=0.56, P<0.001). In correlation study by Greiner et al they found the similar moderate correlation between 4D echocardiography RV stroke volume (RV SV) with cardiac MRI (r=0.43, p<0.01).[33]

Reproducibility of 4D echocardiography (4D auto RVQ) in the measurements of right ventricle (RV) volumes and ejection fraction (EF).

The results of the intra-observer variability analysis of 4D echocardiography (4D auto RVQ) as shown in table are low for calculating right ventricle volumes and ejection fraction, with excellent correlation coefficients. Several studies by Van der Zwaan et, Grewal et al and Hadeed et al in their studies found that the ICCs for intra-observer variability for right ventricle (RV) quantification analysis were acceptable for all the right ventricle (RV) variables as shown in Table 5.

Validation of 4D echocardiography derived RV volumes and EF with cardiac MRI volumes.

As shown in Table 4, in Bland-Altman comparison we found significant difference between measurements of 4D auto RVQ and CMR RV volumes, mean differences in RV EDV and RV EDVI was -47.88 ml and -32.93 ml respectively, the differences in present study are due to significant underestimation of right ventricle volumes by 4D echocardiography. The underestimation of RV EDV and RV EDVI by 4D echocardiography in comparison to CMR

is mainly due to a lower spatial resolution leading to less defined endocardial borders. In echocardiography, a similar difference in tracing of one millimetre resulted in a volume difference of 11%. Similar difference we noted in mean RV ESV and RV ESVI between two techniques, -21.53 and -13.06 respectively. The minimum mean difference between the two imaging techniques was between RV EF with mean difference of only -2.26% with 95% limits of agreement of -17.22 to 21.96. In the present study we found wide level of agreement between 4D echocardiography end diastolic (RV EDV) and end systolic volume (RV ESV) and CMR volumes. In our study there is a high level of agreement for RV EF on 4D echocardiography with CMR. The discrepancy between 3DE and MRI increases in severely dilated right ventricles, especially due to challenges in acquiring a single volume encompassing the entire right ventricle, including the outflow tract and also the agreement with CMR worsens in adults with cardiac dysfunction as shown in previous studies, Jenkins et al and Grapsa et el.[34,35]

Predictive model of 4D echocardiography derived RV volumes with the cardiac MRI volumes.

As shown in Table 6 and Figure 35, the RV EDV index on 4D echocardiography could best predict the cut off for cardiac MRI volumes for the pulmonary valve replacement with sensitivity and specificity of 92% and 78% respectively. Hence the RV EDV index on 4D echocardiography could screen the patients for cardiac MRI as only those patients with RV EDV index of more than 100 ml/m2 should be sent for MRI scan as these patients will have high likelihood of meeting the cut off required for pulmonary valve replacement. Hence reducing the burden of cardiac MRI for the patients. In a study by Pezza et al RV EDV index is the echocardiographic measure that best correlates to CMR in detecting RV dilatation (AUC 1, CI 95%:1.00;1.00) which is in agreement to our present study.[36]

LIMITATIONS

1. This was a single centre study with a limited number of patients.
2. The patients underwent cardiac MRI scan that were clinically indicated; hence this would have likely introduced bias towards higher ventricular volumes.
3. In our study population, significant number of patients had hypertrophied and dilated right ventricle this would have resulted in underestimation of right ventricle volume on 4D echocardiography (4D auto RVQ) due to misinterpretation of RV endocardial borders.
4. Limits of agreement on Bland-Altman analysis were relatively wide; this may be explained by underestimation of right ventricle volume on 4D echocardiography (4D auto RVQ)
5. In the present study, we have included patients based upon their good apical window assessed on standard 2D echocardiography, so the actual success rate thus obtained does not reflect the actual success rate of 4D echocardiography (4D auto RVQ) in our study population.

CONCLUSION

4D echocardiography (4D auto RVQ) showed strong correlation, acceptable feasibility and reproducibility and good agreement with cardiac MRI in delineation of right ventricle dimension and right ventricle function in repair TOF patients.

The present study has given us the evidence regarding potential use of 4D echocardiography in follow up of repair TOF patients that can be used in daily clinical practice. This in turn can lead to reduction in the number of CMR patients usually undergo.

Also, 4D echocardiography can be used in subsets of patients with contraindication to cardiac MRI.

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ANNEXURES

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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Institutional Ethics Committee

COSCO Registration No: ECR/1859/Inst/KL/2013/RR-24
OHR Registration No:ECINEWINST/2022/2775

SCT/IEC/2284/NOVEMBER-2024 30.11.2024

Dr. Ahmed Wayez
Post Doctoral Fellow
Department of Cardiology
SCTIMST, Thiruvananthapuram

Dear Dr. Ahmed Wayez,

The Institutional Ethics Committee held on 2nd November, 2024, reviewed and discussed your application to conduct the study titled "**4D QUANTIFICATION OF RIGHT VENTRICLE IN TOF POST-ICR PATIENTS BY ECHOCARDIOGRAPHY AND ITS CORRELATION WITH CARDIAC MRI: A SINGLE-CENTER OBSERVATIONAL STUDY (IEC /2284)** ".

Principal Investigator	Dr. Ahmed Wayez , PDF – Paediatric Cardiology, Department of Cardiology, SCTIMST
Co-Principal Investigator(s)	Dr. Krishnamoorthy KM, Professor, Senior Grade, Department of Cardiology, SCTIMST Dr. Deepa S Kumar, Additional Professor, Department of Cardiology, SCTIMST Dr. Arun Gopalakrishnan, Additional Professor, Department of Cardiology, SCTIMST
Duration of the study	January 204 to August 2024

The following members of the Ethics Committee were present at the meeting held on 2nd November, 2024

Sl. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. Annapurna V	MD	Female	Basic Medical Scientist	No
2.	Dr. Manoj Murhekar	MD (Preventive & Social Medicine)	Male	Social Scientist	No
3.	Dr. Indu PV	MBBS, DPM, MPhil, PhD	Female	Clinician	No
4.	Adv. N Anand	BAL, LLB	Male	Legal Expert	No
5.	Smt. Rekha Radhakrishnan	M.A (Eng.), B.Ed	Female	Lay person	No
6.	Dr. Manikandan.S	MBBS,MD,PDCC	Male	Clinician	Yes
7.	Dr. Syam K	MBBS, MD, DM	Male	Clinician	Yes
8.	Dr. Biju Soman	MBBS,MD, DPH, MSc, DLSHTM	Male	Basic Medical Scientist	Yes
9.	Dr. Srinivas G	PhD	Male	Basic Medical Scientist (Member Secretary)	Yes

The following documents were reviewed:

Original submission

1. Covering letter addressed to the Chairman, IEC, SCTIMST
2. IEC Application Form
3. Assent Form in English and Malayalam
4. Study Consent Form in English and Malayalam
5. Patient Information Sheet in English and Malayalam
6. Declaration form
7. CV of PI and Co-PIs
8. Study Proposal

Revised submission

1. Covering letter addressed to the Chairperson, IEC, SCTIMST
2. Responses to IEC comments
3. Checklist Form
4. IEC Application Form
5. Study Proposal
6. Data Collection Proforma
7. Patient Information Sheet in English and Malayalam
8. Assent Form in English and Malayalam
9. Study Consent Form in English and Malayalam
10. CV of PI and Co-PIs
11. Declaration form

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

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

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

Sincerely,

Dr. G. Srinivas
Member Secretary, IEC

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE (IEC)
SCTIMST, THIRUVANANTHAPURAM

4D QUANTIFICATION OF RIGHT VENTRICLE IN TOF POST ICR PATIENTS BY ECHOCARDIOGRAPHY AND ITS CORRELATION WITH CARDIAC MRI A S

by AHMED WAYEZ

General metrics

34,318	5,397	205	21 min 35 sec	41 min 30 sec
characters	words	sentences	reading time	speaking time

Score

77

This text scores better than 77% of all texts checked by Grammarly

Writing Issues

278	145	133
Issues left	Critical	Advanced

Plagiarism

3 %

13 sources

3% of your text matches 13 sources on the web or in archives of academic publications

Data Collection Proforma

Study ID	
Age	
Gender	
Diagnosis	
Date of TOF surgery	
Time since TOF Surgery	
Date of cardiac MRI	
Date of echocardiography	
Heart Rate (per min)	
Weight (Kgs)	
Height (cm)	
Body Mass index (Kg/m2)	
Symptoms	
Angina	
Dyspnoea	
Palpitation	
Syncope	
Chest Xray	
ECG	
ECHO (4D auto RVQ)	
RV EDV	
RV EDV index	
RVESV	
RV ESV index	
RV SV	
RV SV index	
RV EF %	
TAPSE	
RVFAC %	
Cardiac MRI	
RV EDV	
RV EDV index	
RV ESV	
RV ESV index	
RV SV	
RV SV index	
RV EF %	

CONSENT FORM

STUDY TITLE

4D quantification of right ventricle in TOF post ICR patients by echocardiography and its correlation with cardiac MRI – A single center observational study

Participant's name : Date of Birth / Age (in years)

I_____ (patient name)

Please tick boxes

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

[ ] I also understand that my participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights.

[ ] I understand that the study staff and institutional ethics committee members may 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 may 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:
Date:

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 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.

_____ _____

Name and Signature of Person Obtaining Consent

Dr. Ahmed Wayez

PDF Pediatric Cardiology

Dept. of Cardiology SCTIMST

For any technical clarifications, please contact Dr. Srinivas G, Member Secretary, IEC, SCTIMST (Email: **iec.mem.sec@sctimst.ac.in**, Phone no. 0471-2524689)

ASSENT FORM

FOR PARTICIPANTS AGED 12-18 YEAR

STUDY TITLE

4D quantification of right ventricle in TOF post ICR patients by echocardiography and its correlation with cardiac MRI – A single centre observational study

Participant's name: Date of Birth / Age (in years):

I _____ _____,
son/ daughter of _____ (Please tick boxes).

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

[ ] I also understand that the participation of my child 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 may not need my permission to look at my child's health records even if I withdraw consent from the study. I agree to this access.

[ ] I understand that my child's identity may not be revealed in any information released to third parties or published.

[ ] I voluntarily agree for my child to take part in this study.

[ ] I received a copy of this signed consent form.

Name:

Signature:
Date:

Name of witness:
Relation to participant:
Date:

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 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.

_____ _____

Name and Signature of Person Obtaining Consent

Dr. Ahmed Wayez

PDF Pediatric cardiology

Dept. of Cardiology SCTIMST

For any technical clarifications, please contact Dr Srinivas G, Member Secretary, IEC, SCTIMST (Email: **iec.mem.sec@sctimst.ac.in**, Phone no. 0471-2524689)

CONSENT FORM

FOR PARENTS OF PARTICIPANT 12-18 YEARS

STUDY TITLE:

4D quantification of right ventricle in TOF post ICR patients by echocardiography and its correlation with cardiac MRI – A single centre observational study

Participant's name : Date of Birth / Age (in years):

I_____,
parent/guardian of _____ (Please tick boxes).

[ ] Declare that I have read the above information provided to me regarding the study: 4D quantification of right ventricle in TOF post ICR patients by echocardiography and its correlation with cardiac MRI – A single center observational study

[ ] I also understand that my child's participation in this study is entirely voluntary and that I am free to withdraw permission to continue to participate at any time without affecting my usual treatment or my legal rights.

[ ] I understand that the study staff and institutional ethics committee members may not need my permission to look at my child's health records even if I withdraw from the trial. I agree to this access.

[ ] I understand that my child's identity will not be revealed in any information released to third parties or published.

[ ] I voluntarily agree for my child to take part in this study.

[ ] I received a copy of this signed consent form.

Name:	Name of witness:
Signature:	Relation to participant:
Date:	Date:

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 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.

_____

Name and Signature of Person Obtaining Consent
Dr. Ahmed Wayez
PDF Pediatric cardiology
Dept. of Cardiology SCTIMST

ശ്രീ ചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആന്റ് ടെക്നോളജി,
തിരുവനന്തപുരം
രോഗികൾക്കുള്ള കാര്യവിവരണ പത്രം

പഠനശീർഷകം: എക്കോ കാർഡിയോഗ്രഫി വഴി ടെട്രോളജി ഓഫ് ഫാലോയുടെ ഐസിആറിന് (തീവ്രമായ ഹൃദയ പുനരധിവാസം) ശേഷം വലത് വെൻട്രിക്കിളിന്റെ ശേഷി 4ഡി യിലൂടെ വിലയിരുത്തലും കാർഡിയാക് എംആർഐയുമായുള്ള അതിന്റെ പാരസ്പര്യവും - ഒരു ഏക കേന്ദ്ര നിരീക്ഷണ പഠനം

ഗവേഷകരുടെ പേര്

ഡോ. അഹമ്മദ് വയേസ്, ഡോ. കോ. എം. കൃഷ്ണമൂർത്തി, ഡോ. ദീപ എസ് കുമാർ, ഡോ. അരുൺ ഗോപാലകൃഷ്ണൻ

പ്രിയ പങ്കാളി/പങ്കെടുക്കുന്നയാളുടെ രക്ഷകർത്താവ്,

എക്കോ കാർഡിയോഗ്രഫി വഴി ടെട്രോളജി ഓഫ് ഫാലോയുടെ ഐസിആറിന് (തീവ്രമായ ഹൃദയ പുനരധിവാസം) ശേഷം വലത് വെൻട്രിക്കിളിന്റെ ശേഷി 4ഡി യിലൂടെ വിലയിരുത്തലും കാർഡിയാക് എംആർഐയുമായുള്ള അതിന്റെ പാരസ്പര്യവും - ഒരു ഏക കേന്ദ്ര നിരീക്ഷണ പഠനത്തിൽ പങ്കെടുക്കുന്നതിന് ഞങ്ങൾ താങ്കളെ സ്വാഗതം ചെയ്യുകയും നന്ദി പ്രകാശിപ്പിക്കുകയും ചെയ്യുന്നു. സാദ്ധ്യമാകുന്നിടത്തോളം പരമാവധിരോഗികളെ പഠനത്തിലുൾപ്പെടുത്താമെന്ന് ഞങ്ങൾ പ്രതീക്ഷിക്കുന്നു. പഠനത്തിൽ താങ്കൾ പങ്കെടുക്കുന്നതിന് മുമ്പ് എന്തുകൊണ്ട് ഈ ഗവേഷണം നടത്തുന്നു എന്ന് അറിയേണ്ടത് പ്രധാനമാണ്. ഈ പത്രിക പ്രസക്തമായ എല്ലാ വിവരങ്ങളും താങ്കൾക്ക് നൽകും. പഠനത്തിന്റെ സ്വഭാവം, ഉദ്ദേശം, നേട്ടങ്ങൾ, അപായങ്ങൾ, ്സ്വസ്ഥതകൾ, മുൻകരുതലുകൾ എങ്ങനെയാണ് ഈ പദ്ധതി നടപ്പാക്കുന്നത് എന്നിവ ഇത് നൽകും. ഇത് ശ്രദ്ധാപൂർവ്വം വായിക്കുകയും മനസ്സിലാക്കുകയും ചെയ്യേണ്ടത് പ്രധാനമാണ്. ഈ പത്രികയിൽ ശാസ്ത്രപദങ്ങളുണ്ടായേക്കാം ആകയാൽ താങ്കൾക്ക് ഏന്തെങ്കിലും സംശയമോ അല്ലെങ്കിൽ കൂടുതൽ വിവരങ്ങളാവശ്യമോ എങ്കിൽ പഠനസംഘാംഗങ്ങളോടോ താഴെനൽകിയിരിക്കുന്ന ബന്ധപ്പെടാനുള്ള വ്യക്തിയോടോ സമ്മതപത്രം ഒപ്പിടുന്നതിന് മുമ്പോ ശേഷം പഠനകാലത്ത് എപ്പോഴുമോ ചോദിക്കൻ താങ്കൾക്ക് സ്വാതന്ത്ര്യമുണ്ട്.

ഇപ്പോഴത്തെ പഠനത്തിൽ അടങ്ങിയിരിക്കുന്നതെന്തെല്ലാം?

താങ്കളുടെ ഹൃദയത്തിന്റെ വലത്തെ അറ കൂടുതൽ അതിന്റെ വലുപ്പം കണക്കാക്കാൻ മെച്ചപ്പെടുത്തിയ എക്കോകാർഡിയോഗ്രഫി സങ്കേതം ഉപയോഗിക്കുന്നു. താങ്കൾ ശ്രീചിത്രയിലെ ഒപിഡിയിൽ ആനുകാലികമായി തുടർ ചികിത്സയ്ക്ക് വരികയും എക്കോകാർഡിയോഗ്രഫിക്ക് വിധേയമാകുകയും ചെയ്യുന്നതിനാൽ ഇതിന് കുറച്ചുകൂടെ സമയം സ്കാനിന് എടുത്താൽമതിയാകും. രക്തനാളങ്ങളുടെ ഒരു കുത്തിവയ്പ്പും ആവശ്യമില്ല. നിശ്ചയിക്കപ്പെട്ട കാർഡിയാക് എംആർഐ സ്കാൻ കഴിയുമ്പോൾ എക്കോകാർഡിയോഗ്രഫി സ്കാൻ നടത്തും. മറ്റ് പരിശോധനകൾ (നെഞ്ചിന്റെ എക്സ്റേ, ഇലക്ട്രോകാർഡിയോഗ്രഫി) എന്നീ താങ്കളുടെ പതിവ് തുടർ പരിശോധനകളും നടത്തും. ഗണനപത്രം താങ്കൾക്ക് നൽകുകയും താങ്കൾ സമ്മതിക്കുന്നു എന്നും നടപടികളെപ്പറ്റി മനസ്സിലാക്കി എന്നും ഉറപ്പിക്കാൻ സമ്മതപത്രത്തിൽ ഒപ്പു വയ്ക്കാൻ ഡോക്ടർ താങ്കളോട് ആവശ്യപ്പെടും.

ഇതിന് എത്ര സമയമെടുക്കും

ആശുപത്രി സന്ദർശനം പതിവ് ചികിത്സയ്ക്കായാണ്, നടത്തുന്ന പരിശോധനകൾപതിവ് തുടർചികിത്സയുടെ ഭാഗമാണ്. ആധുനീകരമായ എക്കോകാർഡിയോഗ്രഫി വിശദമായുള്ളതും ഏകദേശം 10 മിനിട്ട് അധികമെടുക്കുന്നതുമാണ്. താങ്കളുടെ /താങ്കളുടെ കുട്ടിയുടെ അവലോകനവും പരിശോധനയും പതിവുപോലെ താമസംവിനാ നടക്കും.

പങ്കെടുക്കുന്നയാളുടെ ഉത്തരവാദിത്തങ്ങൾ എന്തെല്ലാം?

താങ്കളുടെ പങ്കെടുക്കാനുള്ള താങ്കളുടെ കുട്ടിയെ പങ്കെടുപ്പിക്കാനുള്ള തീരുമാനം സ്വമേധയായും താങ്കളുടെ തീരുമാനത്തിന് വിധേയവുമാണ്. ഏത് സമയത്തും എന്ത് കാരണത്താലും മുൻകൂർ അറിയിപ്പില്ലാതെ താങ്കൾക്ക് പങ്കെടുക്കണ്ട എന്ന് തീരുമാനിക്കാം.

പങ്കെടുക്കുന്നവർക്ക് പ്രതീക്ഷിക്കുന്ന അപായങ്ങളെന്തെല്ലാം?

പഠനത്തിൽ മെച്ചപ്പെടുത്തിയ എക്കോകാർഡിയോഗ്രഫിയും കാർഡിയാക് എംആർഐയുമാണ് അടങ്ങിയിരിക്കുന്നത്. ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നയാൾക്ക് പങ്കാളിത്തം കൊണ്ട് അധികമായി അപായമൊന്നും ഉണ്ടാകില്ല.

പങ്കെടുക്കുന്നവർക്ക് ഗുണവിഷണംകൊണ്ട് എന്ത് നേട്ടമാണ് പ്രതീക്ഷിക്കുന്നത്?

ഈ പഠനത്തിൽ ഹൃദയത്തിന്റെ വലത് അറ കാണാനും വലുപ്പം കണക്കാക്കാനുമായി മെച്ചപ്പെടുത്തിയ എക്കോകാർഡിയോഗ്രഫി സങ്കേതം ഉപയോഗിക്കുന്നതാണ് അടങ്ങിയിരിക്കുന്നത്. താങ്കളുടെ കാലാകാലങ്ങളിൽ വലത് അറയുടെ വലുപ്പം വിലയിരുത്തുന്നത് തുടർ ചികിത്സയ്ക്ക് ആവശ്യമാണ്. ഇപ്പോൾ കാർഡിയാക് എംആർഐ അതിന്റെ വലുപ്പം വിലയിരുത്താൻ ഉപയോഗിക്കുന്നു എക്കോകാർഡിയോഗ്രഫി അതിന് അനുയോജ്യമല്ല. കാർഡിയാക് എംആർഐ നീണ്ടകാലം താമസമുള്ളതും സമയ എളുപ്പം ലഭിക്കുന്നതുമല്ല. ഈ പുതിയ മെച്ചപ്പെടുത്തിയ എക്കോകാർഡിയോഗ്രഫിയിലൂടെ വലത് ഹൃദയ അറയുടെ വലുപ്പവും പ്രവർത്തനവും കണ്ടുകാക്കാൻ സാധ്യമാകും, അങ്ങനെ തുടർചികിത്സയ്ക്ക് വലത് അറയുടെ വിലയിരുത്തൽ എളുപ്പത്തിൽ നടത്താനാകും.

ഈ പരിശോധനയിൽ പങ്കെടുക്കുന്നവർക്ക് പ്രതിഫലം നൽകുമോ?
ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നതിന് പ്രതിഫലം നൽകില്ല.

എന്റെ ഈപഠനത്തിലെ പങ്കാളിത്തം രഹസ്യമായി സൂക്ഷിക്കുമോ?
താങ്കളുടെ എല്ലാ പഠനരേഖകളും രഹസ്യമായിരിക്കും. ഒരു പ്രസിദ്ധീകരണത്തിലും പദ്ധതിയുടെ വെളിപ്പെടുത്തലിലും താങ്കളുടെ വ്യക്തി വിവരങ്ങളുണ്ടാകില്ല. പഠന രേഖകൾ വിശകലനത്തിനും തുടർ ചികിത്സയ്ക്കുമായി അനന്തമായി സൂക്ഷിക്കും.

പഠനകാലത്ത് എനിക്ക് പഠനത്തിൽ നിന്നും പിൻമാറാമോ?
താങ്കൾക്ക് കഴിയും. താങ്കളുടെ തീരുമാനം പതിവ് വൈദ്യപരിചരണത്തെ ബാധിക്കില്ല.
പുതിയ കണ്ടെത്തലുകൾ/വിവരങ്ങൾ ഏതെങ്കിലുമുണ്ടായാൽ എന്നെ അറിയിക്കുമോ?
അറിയിക്കും.

പഠനസംബന്ധമായ പരുക്കുണ്ടായാലെന്ത് സംഭവിക്കും?
പഠനസംബന്ധമായ പരുക്ക് വളരെ കുറവാണ്. അത്തരം സംഭവങ്ങളിൽ രോഗിയെ നടപടിക്രമപ്രകാരം കൈകാര്യം ചെയ്യും.

താങ്കൾക്ക് കൂടുതൽ ചോദ്യങ്ങളുണ്ടെങ്കിൽ ദയവായി ചോദിക്കുക. ഡോ അഹമ്മദ് വയാസ് (പ്രധാന ഗവേഷകൻ), സീനിയർ റെസിഡന്റ്, കാർഡിയോളജി വിഭാഗം (ഇമെയിൽ ahmedwayez11@gmail.com, ഫോൺ 9557265409)
സാങ്കേതിക വിശദീകരണങ്ങൾക്ക് ദയവായി ബന്ധപ്പെടുക ഡോ. ശ്രീനിവാസ് ടി, മെമ്പർ സെക്രട്ടറി, ഇമെയിൽ iec.mem.sec@sctimst.ac.in, ഫോൺ 0471-2524689.

പഠന സമ്മതപത്രം

പഠനശീർഷകം: എക്കോ കാർഡിയോഗ്രഫി വഴി ടെട്രോളജി ഓഫ് ഫാലോയുടെ ഐസിആറിന് (തീവ്രമായ ഹൃദയ പുനരധിവാസം) ശേഷം വലത് വെൻട്രിക്കിളിന്റെ ശേഷി 4ഡി യിലൂടെ വിലയിരുത്തലും കാർഡിയാക് എംആർഐയുമായുള്ള അതിന്റെ പാരസ്പര്യവും - ഒരു ഏക കേന്ദ്ര നിരീക്ഷണ പഠനം

പങ്കെടുക്കുന്നയാളുടെ പേര് ജനനതീയതി/വയസ്സ് (വർഷത്തിൽ)

ഞാൻ _____.

മാതാപിതാക്കൾ/രക്ഷിതാവ് _____
(ദയവായി തെരഞ്ഞെടുത്തുക)

എക്കോ കാർഡിയോഗ്രഫി വഴി ടെട്രോളജി ഓഫ് ഫാലോയുടെ ഐസിആറിന് (തീവ്രമായ ഹൃദയ പുനരധിവാസം) ശേഷം വലത് വെൻട്രിക്കിളിന്റെ ശേഷി 4ഡി യിലൂടെ വിലയിരുത്തലും കാർഡിയാക് എംആർഐയുമായുള്ള അതിന്റെ പാരസ്പര്യവും - ഒരു ഏക കേന്ദ്ര നിരീക്ഷണ പഠനം സംബന്ധിച്ച് എനിക്ക് മുകളിൽ നൽകിയിട്ടുള്ള വിവരങ്ങൾ ഞാൻ വായിച്ചു.

എനിക്കുണ്ടായ സംശയങ്ങൾ പരിഹരിച്ചു. [ ]

എന്റെ ഈ പഠനത്തിലുള്ള പങ്കാളിത്തം സ്വയമേവയാണെന്നും, പതിവ് ചികിത്സയെയോ നിയമപരമായ അവകാശങ്ങളെയോ ബാധിക്കാതെ എനിക്ക് ഏതുസമയത്തും പിൻമാറാൻ സ്വാതന്ത്ര്യമുണ്ടെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. [ ]

ഞാൻ പിൻമാറിയാലും പഠന സംഘത്തിനും, ഇൻസ്റ്റിറ്റ്യൂഷണൽ എത്തിക്സ് കമ്മിറ്റി അംഗങ്ങൾക്കും എന്റെ ആരോഗ്യരേഖകൾ പരിശോധിക്കാൻ എന്റെ സമ്മതം ആവശ്യമില്ലെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. അതിനു ഞാൻ സമ്മതിക്കുന്നു. [ ]

മൂന്നാം കക്ഷികൾക്ക് നൽകുമ്പോഴോ പ്രസിദ്ധീകരിക്കുമ്പോഴോ എന്റെ വ്യക്തിവിവരങ്ങൾ നൽകില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. [ ]

ഞാൻ സ്വയമേവ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു. [ ]

ഈ പത്രികയുടെ ഒപ്പിട്ട ഒരു പ്രതി എനിക്ക് ലഭിച്ചു. [ ]

പേര്
ഒപ്പ്
തീയതി

സാക്ഷിയുടെ പേര്
പങ്കെടുക്കുന്നയാളുമായുള്ള ബന്ധം
തീയതി

സമ്മതപത്രം വാങ്ങുന്നയാൾ

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

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സമ്മതപത്രം ശേഖരിക്കുന്ന
ഗവേഷകന്റെ പേര്

ഡോ അഹമ്മദ് വയാസ്,

സീനിയർ റെസിഡന്റ്, കാർഡിയോളജി വിഭാഗം

കാർഡിയോളജി വിഭാഗം ഒപ്പ് തീയതി

സാങ്കേതിക വിശദീകരണങ്ങൾക്ക് ദയവായി ബന്ധപ്പെടുക ഡോ. ശ്രീനിവാസ് കെ, മെമ്പർ സെക്രട്ടറി, ഇമെയിൽ iec.mem.sec@sctimst.ac.in, ഫോൺ 0471-2524689.

Format for CV of the Investigators

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Last Name-	First Name	Middle Name
Date of Birth (dd/mm/yy)- 12/02/1989		Sex- Male
Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordinator) Principal Investigator		
Professional Mailing Address (Include Institution name)		Study Site Address (Include Institution name)
Senior Resident, Department of Cardiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum		Senior Resident, Department of Cardiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum
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Academic Qualifications (Most recent qualification first)

Degree/Certificate	Year	Institution, Country
DM Cardiology	2023	Jawaharlal Institute of Postgraduate medical education and research, Puducherry, India
MD General Medicine	2019	Aligarh Muslim University, Aligarh India
MBBS	2015	Aligarh Muslim University, Aligarh India

Details of professional registration: (Travancore Cochin Medical Council, including Registration Number and Year of Registration) 97860/19-03-2024

Current and previous positions (most recent position first)

Month and Year	Title	Institution/Company, Country
01/01/2024 - current	Senior Resident (PDF Paediatric Cardiology)	SCTIMST, Trivandrum, India

01/01/2021 – 31/12/2023	Senior Resident (DM Cardiology)	Jawaharlal Institute of Postgraduate medical education and research, Puducherry, India
17/05/2016-08/10/2019	Junior Resident (MD General Medicine)	Aligarh Muslim University, India

Summary of relevant research experience:

1) Upadhya P, Garg S, A J, Ponraj ND, **Wayez A**. An unexpected and unusual cause of pulmonary hypertension in a patient with hypersensitivity pneumonitis: partial anomalous pulmonary venous connection causing pulmonary artery hypertension. *Monaldi Arch Chest Dis*. 2023;10.4081/monaldi.2023.2497
2) **Wayez A**, Zafar L, Aijaz M, Afroz N. Study of platelet indices in dengue fever with thrombocytopenia and correlation of immature platelet fraction (IPF) with platelet recovery. Archives of Haematology Case Reports and Reviews. 2020; 5. 001-005. 10.17352/ahcrr.000021
3) Left and right ventricular dysfunction, cardiac biomarkers and cardiovascular outcomes of patients undergoing renal transplant- Prospective cohort study. Dissertation April 2021- August 2023. Guide- Dr. Santhosh Satheesh

Signature: Ahmad Wayez	Date: 26/06/2024 Place: Thiruvananthapuram

MASTERS CHART

Serial_NO	name	Hosp_id	age	sex	Diagnosis
1	JEFFREY_JOSEPH_K_J	493038	21	M	TOF_SEV_PS
2	FATHIMA_HISANA	312130	13	F	TOF_ABSENT_PV
3	PRATHEEKSHA_P	380941	14	F	TOF_SEV_PS
4	SANDHYA_S	8800916	40	F	TOF_SEV_PS
5	BHUVANESWARI_G	195550	39	F	TOF_SEV_PS
6	DHANESH_V_S	191676	24	M	TOF_SEV_PS
7	ASHIK_M_S	293554	17	M	TOF_SEV_PS
8	SNEHA_SAJEEV	300979	15	F	TOF_SEV_PS
9	SHAFEEQ_T	236793	21	M	TOF_SEV_PS
10	PRIYA_K	9303360	33	F	TOF_SEV_PS
11	NANDANA_M	9903249	26	F	TOF_SEV_PS
12	ASHISH_V_G	216297	21	M	TOF_SEV_PS
13	SUMAYYA_N_R	223666	20	F	TOF_SEV_PS
14	MUKESH_C	9605049	35	M	TOF_SEV_PS
15	SHABNA_R_I	9906996	26	F	TOF_SEV_PS
16	JOJITH_J	351449	13	M	TOF_SEV_PS
17	MUHAMMED_ADNAN_K	342027	12	M	TOF_SEV_PS
18	SREERAJ_R	9302987	32	M	TOF_PA
19	MUHAMMED_S	226964	21	M	TOF_SEV_PS
20	RAJENDRAN_K	8907419	42	M	TOF_SEV_PS
21	SREEBALA_K_C	383011	12	F	TOF_SEV_PS
22	ANN_MARIYA_NOBLE	410752	13	F	TOF_ABSENT_PV
23	SANKARI_SARUMATHI_J	214099	28	F	TOF_ABSENT_PV
24	DEVANANDA_B	265986	27	F	TOF_SEV_PS
25	GEETHU_KRISHNA_U	328481	27	F	TOF_SEV_PS
26	VIGNESH_R_NAIR	383885	13	F	TOF_PA
27	MUHAMMED_SINAN_K	290514	16	F	TOF_SEV_PS
28	ANUJITH_ELHANAN	321470	13	M	TOF_SEV_PS
29	ABDUL_RAHMAN_BASHEER_K_T	503462	23	M	TOF_SEV_PS
30	JOEL_JOSEPH	352820	12	M	TOF_SEV_PS
31	ANFAL_T	297759	17	M	TOF_SEV_PS
32	NATCHIAPPAN_N	229876	23	M	TOF_SEV_PS
33	GEOS_JOHNY	9501112	30	M	TOF_SEV_PS
34	SATHEESH_KUMAR	16895	37	M	TOF_SEV_PS
35	ARUN_B	341669	27	M	TOF_SEV_PS
36	ARYANANDHA_D	383637	14	F	TOF_SEV_PS
37	HALEEMA_H	379969	13	F	TOF_SEV_PS
38	VIVEK_T	209306	24	M	TOF_SEV_PS
39	MUHAMMED_HANIFA	218931	21	M	TOF_SEV_PS
40	SUDAR_ARUN	284438	16	M	TOF_SEV_PS

place_of_operation	age_at_operation_YEARS	Operation
0	1	ICR_TAP
1	2	ICR_TAP
1	1.5	ICR_TAP
0	11	ICR_TAP
1	17	ICR_TAP
1	2	ICR_TAP
1	6	ICR_TAP_MCR
1	2	ICR_TAP
1	3	ICR_TAP
1	10	ICR_TAP
1	3	ICR_TAP
1	3	ICR_TAP
1	1.5	ICR_TAP
1	12.5	ICR_TAP
1	2.5	ICR_TAP
1	1.6	ICR_TAP_MCR
1	2.5	ICR_TAP
1	0.08	ICR_TAP
1	1.9	ICR_TAP
1	12	ICR_TAP
1	2.7	ICR_TAP_MCR
1	1.2	ICR_TAP_MCR
1	8	ICR_TAP
1	1.8	ICR_TAP
1	5	ICR_TAP_MCR
1	4.6	ICR_PA_CONDUIT
1	1.75	ICR_MCR
1	4.66	ICR_TAP_MCR
0	1	ICR_TAP
1	2.5	ICR_TAP_MCR
1	3	ICR_INFUNDIBULAR RESECTION
1	4.9	ICR_TAP
1	9.5	ICR_TAP
1	11	ICR_TAP
1	15.75	ICR_TAP_MCR
1	6.25	ICR_INFUNDIBULAR RESECTION
1	2.9	ICR_INFUNDIBULAR RESECTION
1	2.25	ICR_TAP
1	3	ICR_TAP
1	3.5	ICR_TAP

heart rate1	heart rate2	heart rate3	height	weight	bsa	angina	DOE
77	79	84	172	69	1.81	0	0
85	88	92	155	50	1.47	0	0
94	88	98	132	20	0.88	0	0
78	76	64	161	61	1.64	0	1_FC_II
74	78	80	149	55	1.48	0	0
58	54	60	181	74	1.94	0	0
52	56	58	170	47	1.53	0	0
71	76	69	156	49	1.46	0	0
75	78	70	171	62	1.73	0	0
110	109	115	165	54	1.59	0	0
78	80	68	155	33	1.23	0	1_FC_II
68	70	68	172	62	1.73	0	0
68	72	70	171	50	1.58	0	0
88	87	88	162	75	1.8	0	0
75	78	76	161	67	1.71	0	0
68	70	68	150	60	1.55	0	0
96	98	100	153	56	1.52	0	0
74	76	78	162	42	1.41	0	0
92	96	98	162	53	1.55	0	0
88	81	79	170	52	1.59	0	0
71	77	70	136	26	1.01	0	0
94	96	90	138	31	1.1	0	0
83	84	88	157	60	1.6	0	0
79	80	84	158	75	1.77	0	0
82	88	84	145	42	1.3	0	0
91	94	97	128	25	0.92	0	0
80	84	82	168	43	1.46	0	0
90	90	92	137	13	1.15	0	0
94	96	98	166	53	1.58	0	0
94	90	92	135	26	1.01	0	0
70	72	74	179	74	1.92	0	1_FC_II
98	96	100	146	35	1.21	0	0
77	79	78	161	50	1.51	0	0
82	84	80	169	62	1.71	0	1_FC_II
78	80	86	154	44	1.38	0	0
100	102	100	153	35	1.25	0	0
85	86	88	131	31	1.06	0	0
80	82	86	165	60	1.75	0	0
88	86	88	178	70	1.87	0	0
72	74	76	165	55	1.6	0	0

Palpitations	syncope	MEDICATIONS	CT_RATIO	QRSd	RBBB	MFU_PVR	RV_EDV1	RV_EDV2
0	0	0	0.44	160	1	MFU	130	157
0	0	0	0.49	150	1	MFU	129	140
0	0	0	0.6	150	1	MFU	73	81
0	0	0	0.63	126	1	PVR	154	177
0	0	0	0.6	110	1	MFU	89	76
0	0	0	0.55	160	1	PVR	210	227
0	0	0	0.59	110	1	MFU	132	172
0	0	0	0.54	150	1	MFU	111	119
0	0	0	0.48	160	1	MFU	143	132
0	0	0	0.58	150	1	MFU	119	141
0	0	0	0.52	150	1	MFU	100	96
0	0	0	0.55	145	1	MFU	178	187
0	0	0	0.57	140	1	MFU	134	132
0	0	0	0.64	180	1	PVR	183	178
0	0	0	0.5	150	1	MFU	194	147
0	0	0	0.57	140	1	MFU	135	138
0	0	0	0.58	170	1	PVR	239	180
0	0	0	0.65	174	1	PVR	151	162
0	0	0	0.52	160	1	MFU	157	199
0	0	0	0.54	96	1	MFU	99	116
0	0	0	0.58	138	1	PVR	108	98
0	0	0	0.54	100	1	MFU	93	94
0	0	0	0.6	110	1	PVR	237	270
0	0	0	0.5	160	1	MFU	186	181
0	0	0	0.54	110	1	MFU	132	141
0	0	0	0.58	151	1	PVR	108	96
0	0	0	0.54	131	1	MFU	143	163
0	0	0	0.56	148	1	MFU	133	115
0	0	0	0.49	130	1	MFU	137	138
0	0	0	0.63	156	1	MFU	94	80
0	0	0	0.49	120	1	PVR	227	221
0	0	0	0.62	170	1	PVR	133	119
0	0	0	0.55	127	1	MFU	172	205
0	0	0	0.59	198	1	MFU	167	197
0	0	0	0.52	102	1	MFU	80	129
0	0	0	0.5	147	1	MFU	97	99
0	0	0	0.55	127	1	MFU	71	82
0	0	0	0.56	133	1	PVR	231	214
0	0	0	0.5	147	1	PVR	196	189
0	0	0	0.54	135	1	MFU	193	176

RV_EDV3	RV_ESV1	RV_ESV2	RV_ESV3	RV_EF1	RV_EF2	RV_EF3	RV_SV1	RV_SV2
153	69	75	75	47.2	52.6	51.1	61	83
128	66	70	65	48.9	50.1	49.4	63	70
77	30	40	42	58.3	50.9	44.8	42	41
186	92	115	119	39.8	34.8	36.2	61	61
93	36	30	37	59.9	61.1	60.1	53	47
237	101	108	113	52.1	52.5	52.4	109	119
149	59	92	55	55	46.1	62.8	72	79
122	58	66	71	47.5	44.8	41.5	53	53
157	91	88	97	36.3	33.3	37.2	52	44
142	67	76	79	43.6	54.9	44.1	52	65
93	52	47	44	47.8	50.5	52.7	48	48
193	110	118	132	38.6	36.7	31.7	69	68
130	81	75	76	39.6	43.3	41.3	53	57
184	120	128	116	34.4	27.7	36.9	63	49
138	113	65	65	41.8	56.1	52.5	81	82
156	83	78	88	38	43.8	43.5	51	61
178	136	98	96	43.2	45.6	45.7	103	82
138	74	99	68	51	39	50.7	77	63
165	85	123	104	45.7	38.3	36.7	72	76
93	41	53	43	58.9	54.4	53.9	58	63
130	60	55	65	44.5	44	49.9	48	43
101	51	50	50	45.5	47	50.4	42	44
238	115	122	108	51.5	54.7	54.7	122	147
172	109	108	90	41.2	40	47.3	76	72
124	67	70	64	49.4	49.9	48.5	65	70
94	65	55	58	40	42.9	38.5	43	41
169	93	99	88	34.7	39	47.9	49	63
134	76	63	73	42.9	45.3	45.5	57	52
144	72	69	96	47.6	50.4	33.2	65	70
90	55	47	52	41.9	41.3	41.8	39	33
205	126	114	99	44.7	48.5	51.7	102	107
141	84	64	74	36.6	46.1	47.8	49	55
190	80	90	83	53.8	56.1	56.2	93	115
168	105	125	110	37.5	36.8	33.6	63	73
102	44	69	60	45.1	46.6	41.8	36	60
101	31	54	44	67.9	45.7	56.9	66	45
99	40	43	54	43.5	47.8	45.5	31	39
237	134	133	132	42.2	38	44.4	98	81
202	98	98	100	49.9	48.1	50.3	98	91
171	109	93	88	43.6	47.1	48.6	84	83

RV_SV3	RV_EDVi1	RV_EDVi2	RV_EDVi3	RV_ESVi1	RV_ESVi2	RV_ESVi3	RV_SVi1	RV_SVi2
78	72	87	85	38	41	41	34	46
63	88	95	87	45	48	44	43	48
34	82	92	87	34	45	48	48	47
67	94	108	113	56	70	72	37	37
56	60	51	62.83	24	20	63	36	31
124	108	117	122	52	56	58	56	62
93	86	112	97	39	60	36	47	52
51	76	82	84	40	45	49	36	37
57	83	76	89	53	51	56	30	25
63	75	89	89	42	48	50	33	41
49	81	78	75	42	38	36	39	39
61	103	108	112	63	68	76	40	40
53	85	83	82	51	47	48	34	36
68	102	99	102	67	71	65	35	27
72	113	86	81	66	38	38	47	48
68	87	89	101	54	50	57	33	39
81	158	119	117	90	64	63	68	54
70	107	115	98	53	70	48	55	45
60	101	128	106	55	79	67	46	49
50	62	73	59	26	33	27	37	40
65	106	97	129	59	54	65	47	43
51	84	85	92	46	45	45	38	40
130	148	169	149	72	76	67	76	92
81	105	102	97	62	61	51	43	41
60	101	108	96	51	54	49	50	54
36	118	104	102	70	60	63	47	45
81	98	111	116	64	68	60	34	43
61	115	100	116	66	55	63	49	45
48	87	88	91	45	43	60	41	44
38	93	80	89	54	47	52	39	33
106	118	115	107	65	59	52	53	56
67	110	98	116	70	53	61	40	45
107	114	136	126	53	60	55	61	76
56	98	115	97	61	73	64	37	42
43	58	93	74	32	50	43	26	43
57	78	80	81	25	43	35	53	36
45	67	77	93	38	40	51	29	37
105	132	122	136	76	76	75	56	46
102	105	101	108	52	52	54	52	49
83	121	110	107	68	58	55	53	52

RV_SVi3	CMR_RVEDV	CMR_RVEDVi	CMR_RVESV	CMR_RVESVi	CMR_RVSV	CMR_RVSVi	
43	213	117	108	59.3	105.5	57.7	
43	189	122	122	78	67	43	CMR_RVEF
39	112	120	56.4	60.5	55.1	59.1	49.35
41	282.7	174.3	134.6	83	148.1	92.56	35
25	166	111	64	43	101	67	49
64	289	155	159	85	129	70	52.4
61	173	113	80	52	93	61	61
35	92	64	38	26	54	38	44
33	105	62	60	35	45	27	53
39	83	55	28	19	54	37	58
40	184.32	150.15	73.31	59.72	111.01	90.43	43
35	221.28	126.3	99.44	56.76	121.84	69.54	66
34	183.99	118.21	88.48	51.74	95.51	55.86	60.23
38	261.82	137.99	144.47	76.14	117.35	76.14	55
42	181	105	94	55	86	50	51.91
44	191	132	98	65	93	65	44.82
53	228	142	129	80	99	61	48
50	223	158	133	94	89	63	49
39	269	181	151	102	118	79	43
32	173	110	67	43	103	67	40
64	164	175	92	99	71	76	43
46	155	139	71	64	84	74	61
81	295	181	151	92	144	88	43
46	188	100	82	43	106	56	53
46	130	98	51	38	79	59	48
39	142	157	84	93	58	64	56
56	192	125	90	59	101	66	60
53	138	118	80	69	57	49	40
30	227.7	143.4	122.2	77.02	105.5	66.45	52
37	135.14	139.57	81.36	84.03	53.7	55.5	41
55	329	170	170.9	88.5	158.21	81.93	46.32
56	255.77	216.17	107.09	90.51	148.69	125.66	39.8
71	194	123	134	85	60	38	48.07
33	250	140	188	105	61	35	58.13
31	130	94	56	41	74	53	31
46	163.6	133	74.1	60.3	89.53	72.86	24
42	157.72	140.29	76.16	67.75	81.55	72.54	56
60	283	155	145	79	138	75	54.71
54	285	158	151	83	134	74	51.71
52	203	129	100	64	103	65	48
							47
							50