

**SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL
SCIENCES AND TECHNOLOGY
THIRUVANANTHAPURAM**

DEPARTMENT OF CARDIOLOGY



Quantification of global longitudinal strain in patients with
systemic RV and its relation to exercise capacity

**A THESIS SUBMITTED FOR THE DEGREE OF PDF
PEDIATRIC CARDIOLOGY**

**Dr GOUSIA MUKHTAR
DECEMBER 2023**



DEPARTMENT OF CARDIOLOGY, SCTIMST, TRIVANDRUM CERTIFICATE

I hereby certify that the work in this dissertation titled “**Quantification of global longitudinal strain in patients with systemic RV and its relation to exercise capacity**” is a certified record of original research work undertaken by Dr. Gousia Mukhtar in the Department of Cardiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology in partial fulfillment of the requirement for the award of PDF Pediatric Cardiology degree.

Dr. Gousia Mukhtar

PDF, Pediatric Cardiology

Forwarded

The candidate, **Dr. Gousia Mukhtar**, has carried out the minimum required project

Dr Harikrishnan S

Professor and Head

Dept of Cardiology

Sree Chitra Tirunal Institute for Medical Science and Technology, Trivandrum-695011



DEPARTMENT OF CARDIOLOGY SCTIMST, TRIVANDRUM

DECLARATION BY CANDIDATE

I, Dr.Gousia Mukhtar, hereby declare that the project in this book, titled **“Quantification of global longitudinal strain in patients with systemic RV and its relation to exercise capacity”** was undertaken by me under the supervision of the faculty, Department of Cardiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology.

Thiruvananthapuram

Dr. Gousia Mukhtar

Date: 28/12/23

PDF, Pediatric Cardiology



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CERTIFICATE

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Guide:

Dr. KM Krishnamoorthy

Professor,

Dept of Cardiology

Sree Chitra Tirunal Institute for Medical Science and Technology,

Trivandrum-695011

TITLE

“Quantification of global longitudinal strain in patients with systemic RV and its relation to exercise capacity”

Primary Investigator

Dr.Gousia Mukhtar

Post doctoral Fellow, Division of Pediatric Cardiology

Department of Cardiology,

Sree Chitra Tirunal Institute for Medical Science and Technology, Trivandrum

Guide

Dr. KM Krishnamoorthy, MD, DM

Professor, Dept of Cardiology

Sree Chitra Tirunal Institute for Medical Science and Technology, Trivandrum

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ACKNOWLEDGEMENT

At the very outset, I am thankful to the Almighty Allah, my Lord, Cherisher and Sustainer.

At the completion of this academic venture, It gives me great pleasure to take this opportunity to thank all those who contributed to the completion of this study in many ways.

*I am greatly indebted to my guide, **Dr. K.M Krishnamoorthy**, for the continued support, guidance, and advice he has extended to me throughout my work towards this thesis.*

*My heartfelt and deepest thanks to Head of the department, **Dr.Harikrishnan. S** for his depth of knowledge and constant support throughout this study and through the whole journey.*

*I am highly grateful to **Dr. Arun Gopalakrishnan** for providing valuable suggestions and genuine advices that helped make the study better.*

*My deep thanks to **Dr Deepa. S. Kumar** and all the faculty members of department of cardiology for their expert and dedicated management of my patients.*

*I would like to thank **Dr. Sankara Sarma** for guidance in the statistical analysis and for constantly supporting me all the time in my work.*

I have no words to express my heartfelt gratitude and love to my family who provided the most precious support.

I would like to thank my colleagues for their valuable suggestions.

Finally, my sincere thanks to all the patients who were included in the study.

ABBREVIATIONS

RV	Right Ventricle
EF	Ejection Fraction
TGA-PS	Transposition of great arteries-post senning
ccTGA	Congenitally corrected Transposition of great arteries
AVVR	Atrioventricular valve regurgitation
CRT	cardiac resynchronization therapy
STE	Speckle Tracking echocardiography
GLS	Global Longitudinal Strain
AV block	Atrioventricular block
HF	Heart failure
6MWD	6 – minute walk distance
FAC	Fractional area change
LVEF	Left ventricle ejection fraction
ARNI	Angiotensin Receptor Neprilysin Inhibitor
ECG	Electrocardiography
RBBB	Right bundle branch block
LBBB	Left bundle branch block
NYHA	New York heart association

INTRODUCTION



Right ventricle systolic function is increasingly appreciated as a powerful determinant of patient outcome in a variety of conditions, including myocardial infarction, heart failure, valvular heart disease, pulmonary hypertension, and congenital heart disease. Perhaps no other situation highlights the importance of RV systolic function more evidently than systemic RV (SRV), where the morphologic RV must support the systemic circulation.¹ The most common clinical scenarios where a systemic right ventricle is encountered are complete transposition of the great arteries with previous atrial switch repair, congenitally corrected transposition of the great arteries, double inlet right ventricle mostly with previous Fontan palliation, and hypoplastic left heart syndrome palliated with the Norwood-Fontan protocol. Right ventricular geometry is not made to encounter this chronic pressure overload. Many factors explain the failure of right ventricle to sustain systemic circulation including its abnormal fibromuscular architecture, coronary artery supply mismatch, suboptimal pumping function of RV as it is supported by smaller papillary muscles as compared to mitral valve and infundibulum of right ventricle being a hypokinetic segment.² Therefore, the main concern regarding the long-term outcome of these patients is the function of the systemic RV. Although the RV can tolerate systemic pressures during childhood, after the third decade of life progressive deterioration of RV function is documented.³ Right ventricular dysfunction and failure are important determinants of adverse outcome, hence adequate monitoring and early detection of deterioration in RV function is crucial. Echocardiographic evaluation of the RV remains challenging because of its

complex geometry and irregular shape. Shortcomings of echocardiography can be overcome by magnetic resonance imaging, the best available technique in the assessment of the RV; however, its application is limited by higher costs, restricted availability, and contraindications common in a large proportion of s RV population (pacemaker implanted). With myocardial deformation assessed by speckle-tracking echocardiography (STE), regional myocardial function is quantified, and ventricular dysfunction may be detected earlier than with conventional echocardiography.⁴ This will have definite implications in the management of both TGA -Post senning and cc TGA patients as detection of any degree of ventricular systolic dysfunction at an early stage will help us to offer systemic (tricuspid) valve replacement at an appropriate time before significant ventricular dysfunction (EF < 40%) sets in.⁵ This should be especially true for TGA post senning patients in which systemic AVVR and ventricular dysfunction occurs more due to a failing systemic RV than in ccTGA in which it occurs due to an abnormal Ebsteinoid tricuspid valve.²



REVIEW OF LITERATURE

Eindhoven et al studied 42 patients (mean age 37 ± 7 years, 69% male) with a systemic RV [32 TGA-Mustard (34 ± 4 years after corrective surgery) and 10 ccTGA], and 32 healthy controls using QLAB STE package, in the iE33 ultrasound system (Philips Medical Systems)⁴ GLS of the systemic RV in patients was significantly lower than GLS of the systemic LV in healthy controls and average LS of the RV lateral wall was significantly reduced compared with average LS of the RV lateral wall and average LS of the LV lateral in healthy controls.

In the study by Kalogeropoulos et al¹⁶, 64 D-TGA patients post atrial switch with no baseline H/O heart failure or VT underwent RV GLS and other standard echocardiographic parameters were measured for association with and potential prediction of clinical events, defined as incident stage C heart failure or ventricular tachycardia. After a median of 2.4 years, 12 patients (19%) presented with clinical events (HF in 11 patients and VT in one patient), RV GS had the strongest association with clinical events ($P < 0.001$).

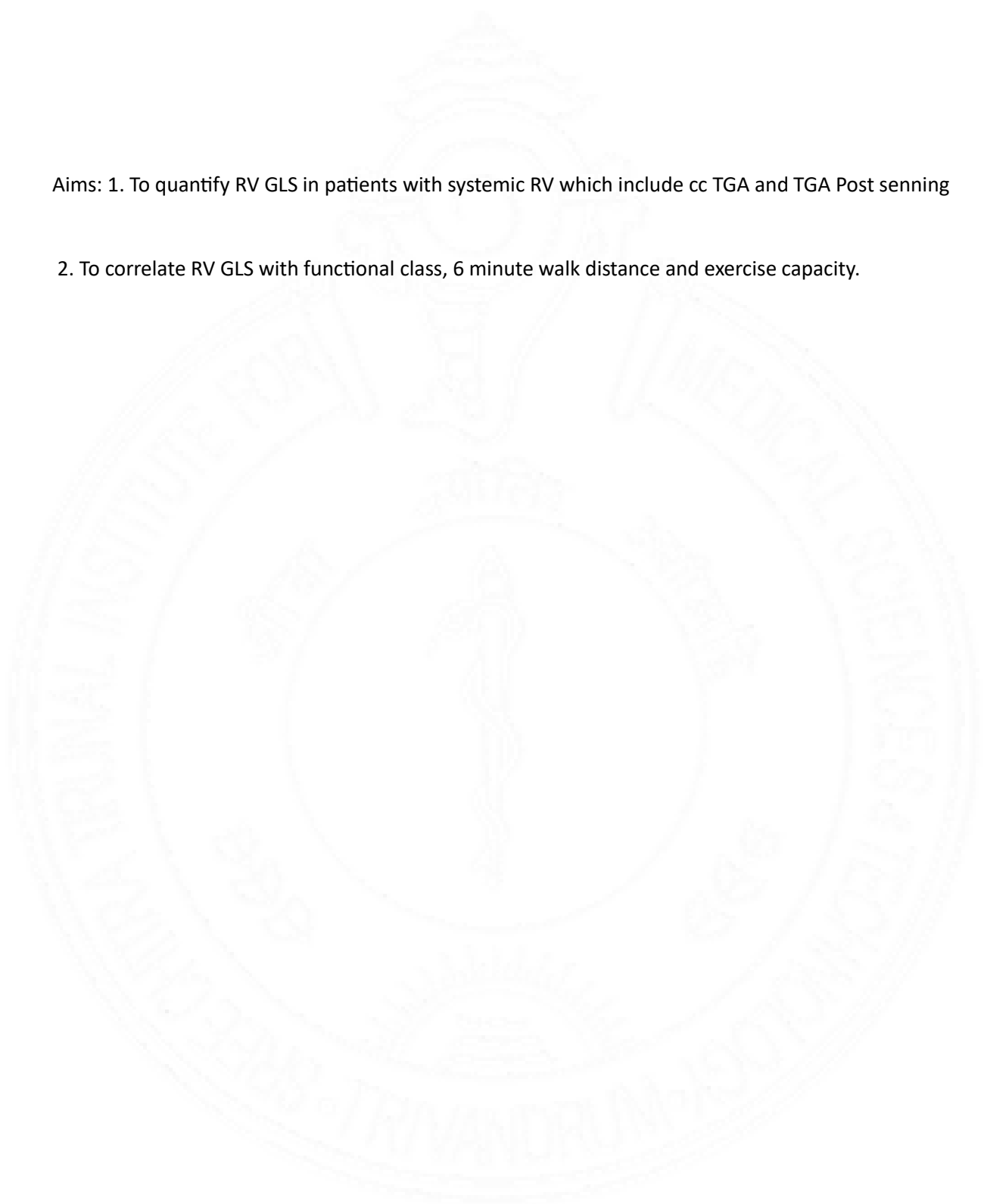
Ladouceur et al⁹ analysed the relation of echocardiographic parameters of sRV systolic function to objective measurements of exercise capacity. Only sRV GLS showed significant correlation with functional capacity as measured by peak oxygen uptake, VO_2 and it proved even more sensitive than CMR RVEF in predicting exercise performance.



AIMS AND OBJECTIVES

Aims: 1. To quantify RV GLS in patients with systemic RV which include cc TGA and TGA Post senning

2. To correlate RV GLS with functional class, 6 minute walk distance and exercise capacity.

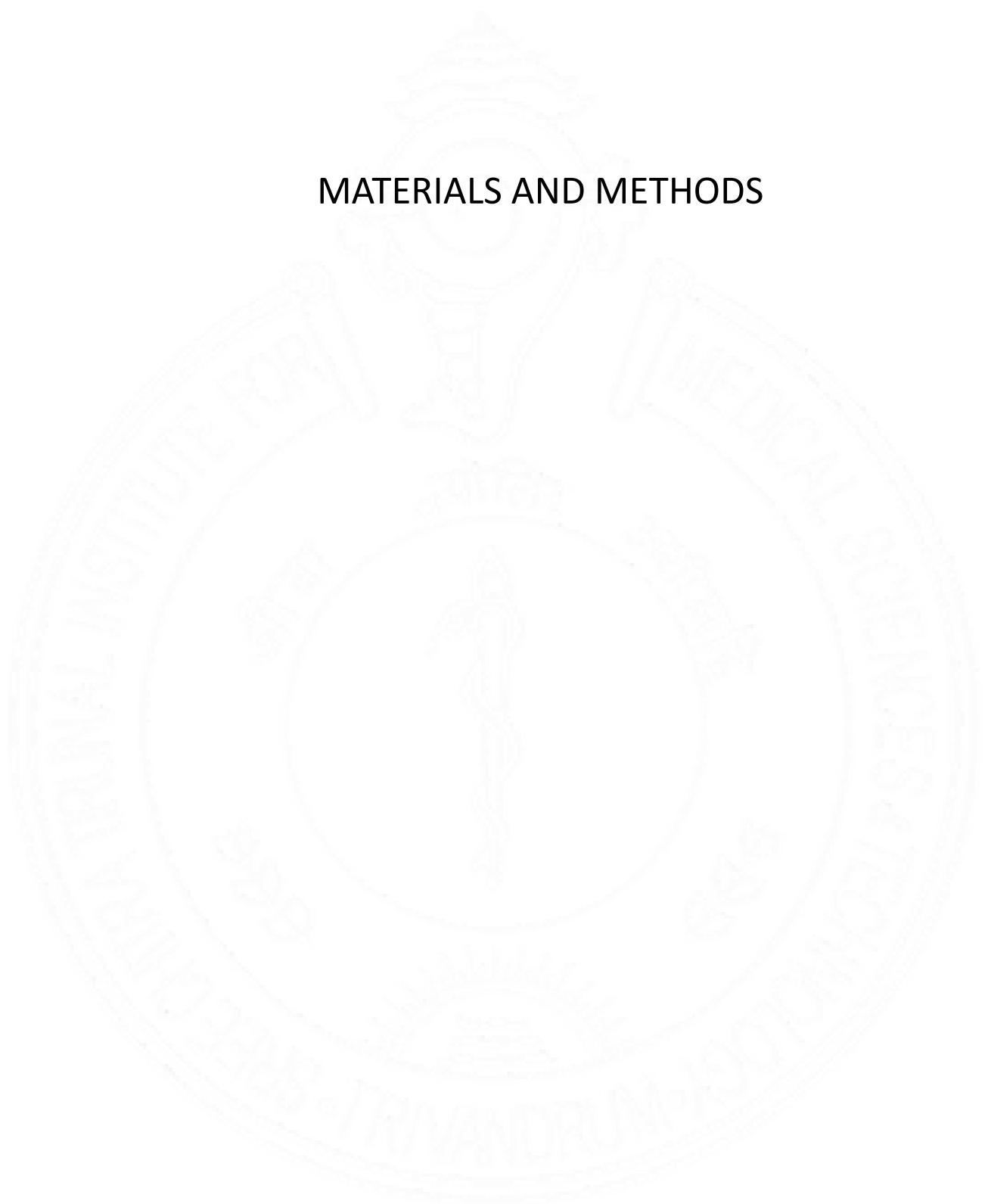


Hypothesis:

Myocardial deformation is reduced in adults with a systemic RV, and that it is related to clinical and echocardiographic parameters of cardiac function as well as to the exercise capacity



MATERIALS AND METHODS



- It is a cross-sectional study of adult patients with systemic RV who report to our Grown up Congenital Heart disease clinic or admitted in our department.
- All patients more than 16 yrs age with congenitally corrected transposition of great arteries and Transposition of great arteries post senning were included and Global longitudinal strain (GS) of the right ventricle and the right ventricle free wall strain calculated with RV Strain imaging from the apical RV focussed view.

Exclusion criteria

- Insufficient image quality for adequate speckle tracking,
- Irregular heart rhythm
- Univentricular patients.

- RV myocardial deformation (longitudinal strain) was determined using the speckle tracking method by AutoStrain RV package in Epic (Philips Medical Systems).
- Good quality images were ensured by increasing the frame rate to at least 50 fps with breath held in expiration and more than 3 loops were archived. Both RV free wall strain and RV global longitudinal strain will be calculated using the RV focused Apical 4 chamber view.
- Average Longitudinal strain of the RV lateral wall in patients will be compared with average longitudinal strain of the subpulmonary right ventricle lateral wall.
- The global longitudinal RV strain is defined as the mean of the RV free wall and interventricular septum segment strains in the apical four-chamber view.⁶
- Longitudinal strain was defined as the maximal negative value of the strain curve during systole.

Other than RV strain, the following standard echocardiographic parameters were measured:

- (1) Chamber quantification measurements, including basal and mid RV diameters, end-diastolic and end-systolic RV area, and RV fractional area change
- (2) tricuspid annular plane systolic excursion (TAPSE)
- (3) s' , e' , and a' velocities at the tricuspid annulus using pulsed-wave tissue Doppler
- (4) Tissue Doppler myocardial performance index (MPI) of the right ventricle; and
- (5) LV ejection fraction.
- (6) RV dP / dT

According to the ASE guidelines 2015⁷, Global longitudinal RV free wall strain $> -20\%$ (i.e., < 20 in absolute value) is considered abnormal. The upper reference limit for the RV MPI is 0.55 using the tissue Doppler method. RV $S' < 10$ cm/s raises suspicion for abnormal RV function, particularly in younger adult patients.⁷ RV FAC $< 35\%$ indicates RV Systolic dysfunction

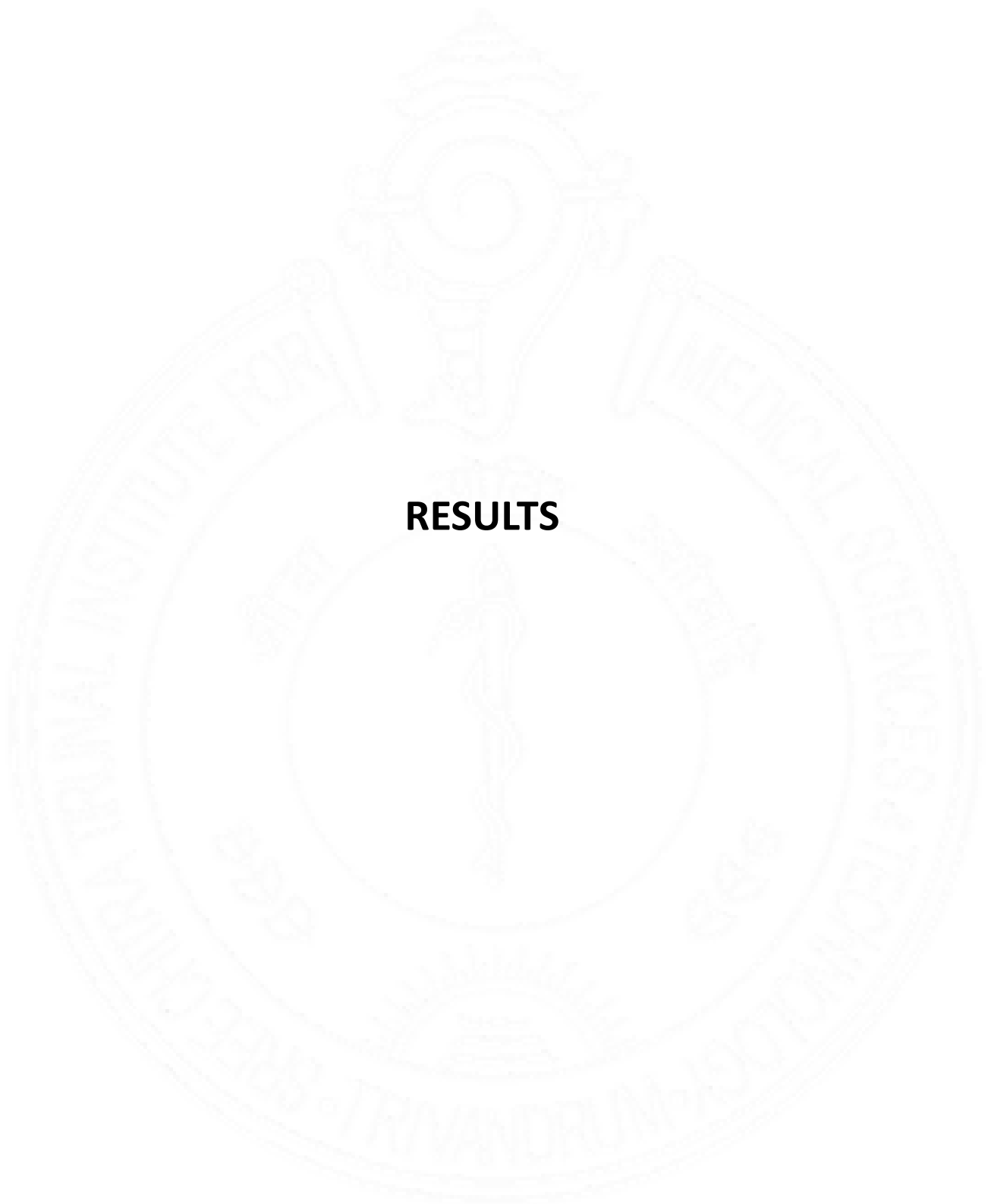
Other information collected was baseline clinical characteristics, NYHA Functional class, medications and ECG characteristics. The NT pro BNP was measured using adsorption assay.

The patients underwent 6 minute walk distance test as part of their evaluation of exercise capacity under supervision of the primary investigator. Exercise capacity is the maximum amount of physical exertion that a person can sustain. 6 minute walk distance is the only simple, practical yet objective way of assessing a patient's exercise capacity with almost no adverse effects as it allows the person to walk at their own pace⁸. Patients' baseline heart rate and blood pressure was noted prior to starting the test and if found to be elevated with respect to age, the test was not done. The patient's exercise capacity was correlated to the RV myocardial strain.

DATA ANALYSIS

The data analysis was performed using the SPSS Statistics software for Windows Version 21 by the principal investigator with the guidance of Prof Sankara Sarma, Department of Biostatistics, SCTIMST. Continuous variables were expressed as either mean standard deviation or median depending on the overall variable distribution. Descriptive summaries were presented as frequencies and percentages for categorical data. Continuous variables were compared using Student's t test or Mann-Whitney U test as appropriate. Group comparisons were made using χ^2 tests. Comparisons between three populations were assessed using analysis of variance (ANOVA). The data will be stored in the personal computer of the principal investigator for a period of three years, maintaining confidentiality.

RESULTS



- Sixty patients were eligible.
- Seven were excluded because of poor echo windows or univentricular physiology.
- Fifty three patients were studied. Out of which, 20 were ccTGA(37%) and 33 were post senning TGA patients(62%).
- None of our patients had undergone mustard procedure as an atrial redirection surgery. None of the ccTGA patients had undergone previous surgery.
- The demographic characters of the patients are given in Table 1.

Table 2 lists the arrhythmias seen in the cohort.

	All patients(n=53)	TGA-PS(n=33)	ccTGA(n=20)
Age, yrs	28.4 +/- 13.4	23.7 +/- 13.1	36 +/- 13.6
Time from repair,mean		21.8 +/- 6.2 yrs	-
Males,n(%)	32(60%)	21	11
Functional Class	FCI, (n=27)- 50.9% FC II (n=21)- 39.6% FC III (n=5)- 9.4%	20 FC I 9 FC II 4 FC III	7 FC I 12 FCII 1 FC III
Concomitant Cardiac lesions		TGA IVS =30 TGA VSD =3	IVS n=12 VSD PS n=8
Baffle stenosis or leakage		Two Baffle leak Five Baffle obstruction	-
Addtl Interventions		Pulmonary veinous baffle reconstruction(2), Baffle leak surgical closure(1), Device closure(1), TV repair (1) Awaiting TV repair(1)	TV Replacement(1) Awaiting TV replacement (2)
SBP,mean	116 +/- 17.4	118 +/- 17.1	121 +/- 17.9

DBP,mean	74.4 +/- 10.3	75	74
Heart rate,mean	78.7 +/- 13.8	72	80
Spo2		97(94-100)	ccTGA/VSD/PS = 87%(73%-98%) ccTGA/IVS=98%(96-100)
Pacemaker		1	5
Medications used	ACE-I = 15 ARNI= 22 Diuretics = 15 Aldactone=16 Beta blockers= 7 Warf=7 Dapa=13 Anti-arrythmics=6 Pul vasodilators= 3		

	Atrial arrhythmias	Conduction disturbance	PPI	CRT	EPS
TGA-PS	2 Aflutter, 2 AT, 1 Atrial Standstill with narrow QRS escape	2 Sinus Bradycardia 2 First degree AV Block	1	-	-
ccTGA	2 Afib, 1 AT, 2 Orthodromic AVRT	2 First degree AV Block, 1 Bifascicular block, 1 Intermittent 2:1 AV Block, 5 CHB	5 for CHB	1	2

Table2 lists the arrhythmias seen in the cohort.

	All patients	TGA-PS, n=33	ccTGA, n=20
NTpro BNP, pg/ml Median(Range), n=49	142(22-4940)	144(<70-3960) (n=30)	113(< 70-4940) (n=19)
6MWD(m),mean(Range), (n=46)	379 +/- 93 (258-644)	391 +/- 93 (258-644)	354 +/- 95 (258-516)
TMT, METS (n=36)	9-11 METS, n=26 5-8 METS, n= 9 < 5 METS, n= 1	9-11 METS, n=18 5-8 METS, n= 4 < 5 METS, n=1	9-11 METS, n=8 5-8 METS, n=5

Table 3 depicts biomarkers and exercise capacity evaluation of the patients.

Thirty six patients underwent a treadmill test, none of whom developed an arrhythmia during it. Nine patients had chronotropic incompetence , defined as inability to achieve 80% of the maximum predicted heart rate.

	All patients	TGA-PS(n=33)	ccTGA(n=20)
FPS, mean(Range)	55(50-83)		
RV FAC(%), mean	30.2 +/- 9.2	28 +/- 9.12	33.7 +/- 9
RV EF (Simpsons method),mean	41.2 +/- 10.19	39 +/- 10	44
Tricuspid Regurgitation			
Trivial to none	1	1	
Mild	29	18	11
Moderate	18	12	6
Severe	5	2	3
RV Diameter (Base)	34.4 +/- 7.4	35.7 +/- 7.3	32 +/- 7.3
RV Diameter (Mid)	41.2 +/- 7.6	40.4 +/- 7.6	42.4 +/- 7.6
TAPSE	13 +/- 2.3	12.4 +/- 2.38	13.9 +/- 2.4
RV dP / d T, median (n=36)	932 (404-1800)	932 (404-1515)	1010(551-1800)
Tricuspid S' Velocity, cm/sec (mean) (n=46)	8.33 +/- 2.1	8.15 +/- 2.3	8.6
RV Tei index(n=44)	0.64 +/- 0.16	0.66 +/- 0.16	0.60
LV EF(%)	63 +/- 9.02 (27-80)	61 +/- 8.5	65 +/- 9

Table 4 depicts the standard echocardiographic parameters of the cohort.

	All patients(n=53)	TGA-PS(n=33)	ccTGA (n=20)
RV 4CLS,mean	-16.79+/- 4.66	-15.23 +/- 4.4	-19.1 +/- 4.5
RV FWLS, mean	-20.01 +/- 7.1	-17.3 +/- 7.1	-24.34 +/- 7.34
Apex, mean	-18.5 +/- 7.51	-15.7 +/- 7.2	-23.43 +/- 7.68
Mid, mean	-20.24 +/- 5.0	-18.2 +/- 5.1	-23.86 +/- 5.05
Base, mean	-20.7 +/- 8.3	-19.6 +/- 8	-22.58 +/- 11.3

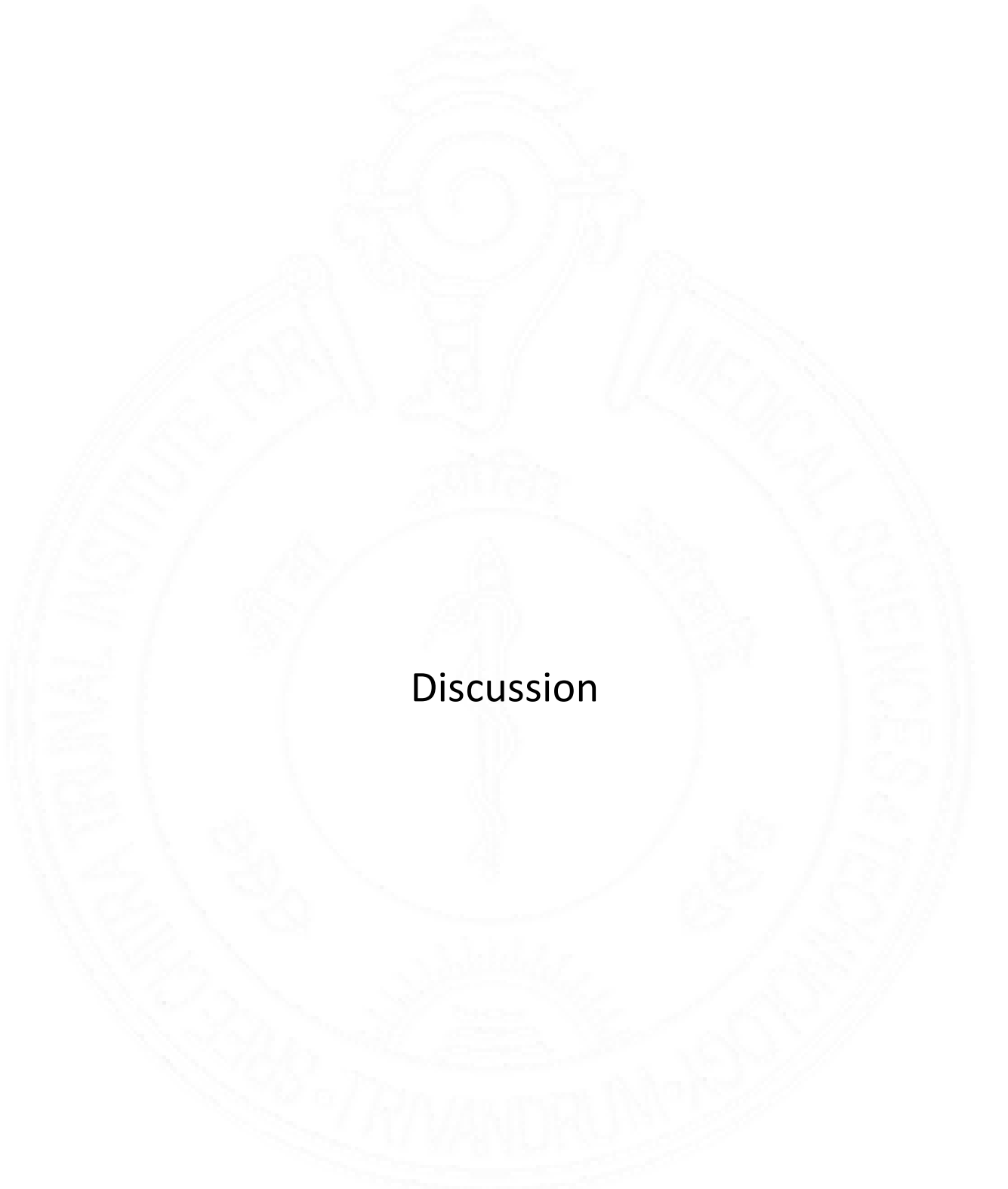
Table 5 depicts the strain parameters of the cohort.

	RV4CLS	RVFWLS
NT pro BNP		
P value	0.013	0.39
Pearson Correlation	0.355	0.12
6MWD		
P value	0.46	0.45
Pearson Correlation	-0.133	0.115
FAC		
P value	0.002	0.11
Pearson Correlation	-0.416	-0.22

Table 6 depicts the relation between NT pro BNP, 6MWD and FAC with Strain parameters by Pearson correlation test.

	RV 4CLS	RV FWLS
FC I	-17.2+/- 4.36	-19.2+/- 8.5
FC II	-17.3+/- 4.4	-21.1 +/- 5.4
FC III	-12.1 +/- 5.5	-15.9+/- 4.8
P-value	0.06	0.34

Table 7 shows the relation of functional Class with Strain parameters by ANOVA test, P-value shows a trend towards statistical significance.



Discussion

Like in other studies^{4,9}, this study has shown that right ventricular global longitudinal strain is reduced in patients with systemic RV and it correlates with functional class of the patient and biochemical markers like NT – pro BNP. Post Senning TGA patients have reduced strain than ccTGA patients. Reduced RV FAC correlated with reduced RV GLS as well. Though patients with 6-minute walk distance of < 400 m had lower RV GLS, the P- value was not significant. This may be explained by the fact that patients who walked more than 400 m also had reduced RVGLS which may indicate that RV GLS falls even before the patients exercise capacity has fallen and that RV GLS may detect subclinical deterioration. Also, there may be many other factors which affect 6 minute walk distance in these patients, like baffle pathology or pulmonary hypertension. We have excluded patients who underwent or were candidates for single ventricle palliation as both ventricles face the systemic circulation in such cases.

After a mean period of 21.8 +/- 6.2 yrs after repair, 71% had RV FAC of less than 35% and 78% had RV GLS of less than -20% which is similar to that found in other studies³ and could also mean that RV GLS was more sensitive in diagnosing RV dysfunction.

Eindhoven et al studied 42 patients (mean age 37+7 years, 69% male) with a systemic RV [32 TGA-Mustard (34+4 years after corrective surgery) and 10 ccTGA], and 32 healthy controls using QLAB STE package, in the iE33 ultrasound system (Philips Medical Systems)⁴ GLS of the systemic RV in patients was significantly lower than GLS of the systemic LV in healthy controls and average LS of the RV lateral wall was significantly reduced compared with average LS of the RV lateral wall and average LS of the LV lateral in healthy controls.

RV GLS in our study cohort was higher than RV GLS in their cohort (-16.79% vs -14.2%) and the RV FWLS was -20.01 +/- 7.1(vs -16.1 +/- 3.6% in their cohort). This may be due to the dedicated software package i.e.. RV auto STRAIN used to calculate the RV strain in our study (vs QLAB STE package). AutoSTRAIN is the first TOMTEC application to be integrated on the Philips EPIQ CVx ultrasound system. AutoSTRAIN measures longitudinal strain along the endocardium. As GLS is highest in the endocardium and lowest in the epicardium, we should expect Auto STRAIN to give higher values.¹⁰

As in other studies¹¹, the RV GLS as well as the RVFWLS in TGA post senning patients was less than that in ccTGA. In the study by Eindhoven et al⁴, only the average LS of the RV lateral wall was significantly decreased in patients with TGA-Mustard compared with ccTGA but the GLS did not significantly differ. Various reasons have been put forward to explain this including absence of atrial function, a post-operative state in TGA-post senning patients and that RV has to face systemic pressures right from the birth in cc TGA patients.⁴

In the overall cohort and in TGA -post senning patients, RV FWLS was minimum at the apex as compared to base and mid levels, as reported by other studies as well^{4,8} while as in ccTGA , no significant difference was found(Table 5). In a metanalysis studying normal values of RV GLS in children, there was a significant base to apex gradient with apex having lower segmental strain than base (P-value < 0.05).^{10,12} The segmentation of RV into apex, mid and base is in relation to septum but anatomically RV is composed of inlet, trabeculated apical myocardium and the infundibulum and

it would have been better that strain could be measured separately in these regions but presently we do not have software for the same.

Similar to the findings in the study by Eindhoven et al, our study also found a significant relationship of lower RV GLS with higher NT – pro BNP (P-value= 0.013, $r = 0.355$) and lower RV fractional area change (P-value = 0.002, $r = -0.416$), while as worsening FC also showed a trend towards lower RV GLS(P-value 0.06), though it did not reach statistical significance. NT- pro BNP is proven to be a marker for risk stratification in adults with systemic RV^{13,14,15}. Only fifteen patients (28%), were on no medications at all.

In the study by Kalogeropoulos et al¹⁶, 64 D-TGA patients post atrial switch with no baseline H/O heart failure or VT underwent RV GLS and other standard echocardiographic parameters were measured for association with and potential prediction of clinical events, defined as incident stage C heart failure or ventricular tachycardia. After a median of 2.4 years, 12 patients (19%) presented with clinical events (HF in 11 patients and VT in one patient), RV GS had the strongest association with clinical events(P< 0.001). Though our study did not evaluate relationship with clinical events, it showed a significant relationship of NT pro BNP with GLS and NT pro BNP is a known marker of risk stratification in systemic RV.

Ladouceur et al⁹ analysed the relation of echocardiographic parameters of sRV systolic function to objective measurements of exercise capacity. Only sRV GLS showed significant correlation with

functional capacity as measured by peak oxygen uptake, VO₂ and it proved even more sensitive than CMR RVEF in predicting exercise performance. Though we have not measured VO₂, 6MWD and treadmill test may be simple and easily available measure of exercise capacity. As treadmill test is available in a limited number of patients, we have not correlated it with strain parameters.

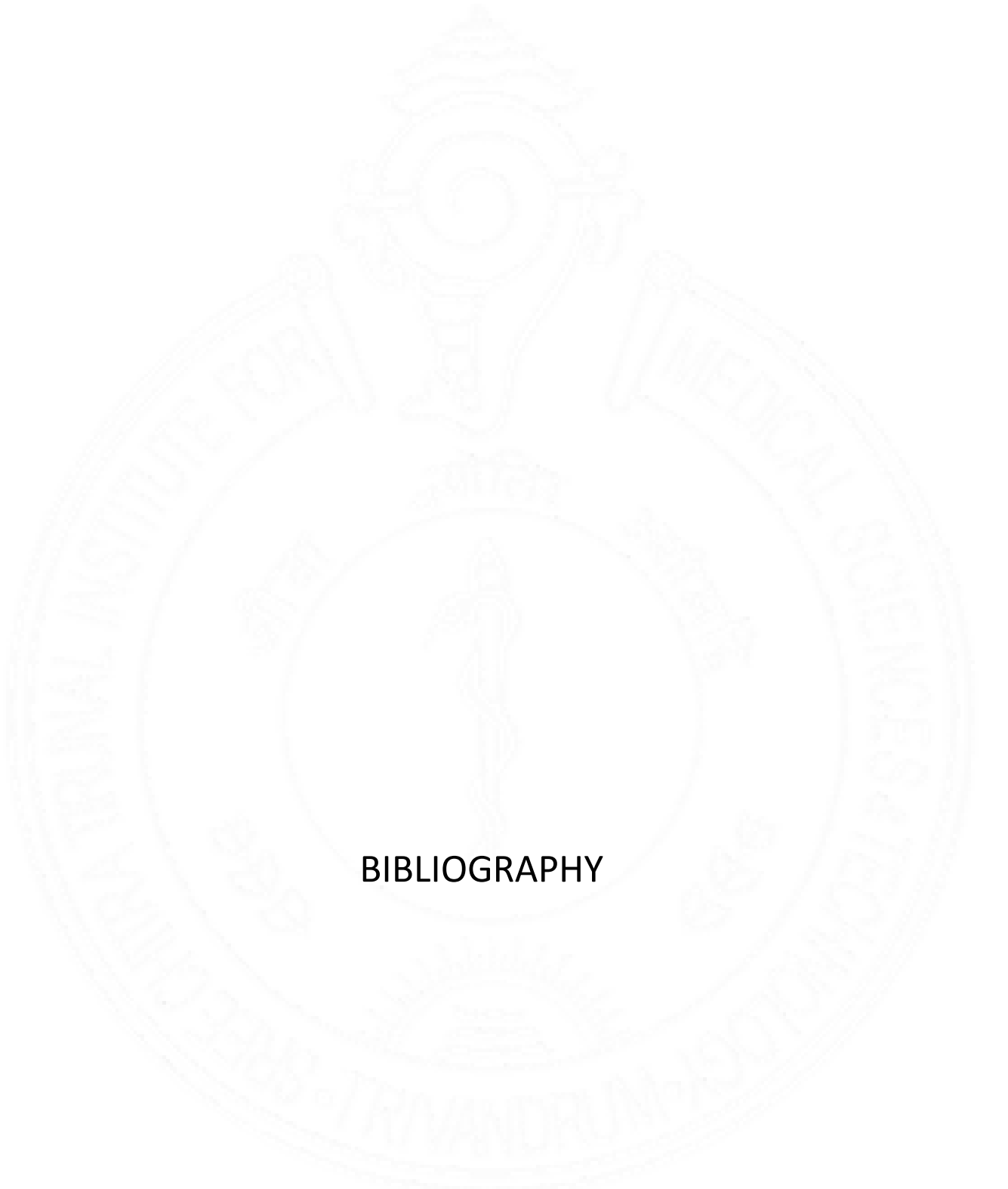
Iriat et al in their study showed that conventional echocardiographic variables including RVEF by Simpsons, RVFAC, RV dP/ dT , TAPSE and even RV Longitudinal strain did not correlate well with RVEF calculated by MRI, which is considered the gold standard except for lateral tricuspid valve annulus, s' which showed a weak correlation.¹⁷

The limitations of the study is that we have not measured VO₂ which may be a better measure of exercise capacity than 6 minute walk distance which is affected by many confounders. We do not have follow up data of the cohort since it was a cross sectional study. The strength is that it is the first study to measure RV strain in systemic RV by autoSTRAIN RV which is a more dedicated software.



CONCLUSION

- Global Longitudinal Strain of patients with systemic RV is reduced.
- TGA –PS patients have lower RV GLS than ccTGA
- Low RV GLS is significantly related to worsening functional Class and higher NT pro BNP.
- Though patients with reduced 6MWD had lower strain, the difference was not significant



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श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम

तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM

Thiruvananthapuram - 695 011, Kerala, India

(An Institute of National Importance under Govt. of India)

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

Institutional Ethics Committee

(IEC Regn No. ECR/189/Inst/KL/2013/RR-21)

SCT/IEC/2101/AUGUST/2023

30.10.2023

Dr. Gousia Mukhtar

Post Doctoral Fellow

Department of Cardiology

SCTIMST, Thiruvananthapuram

Dear Dr. Gousia Mukhtar,

The Institutional Ethics Committee held on 24th August, 2023, reviewed and discussed your application to conduct the study titled "QUANTIFICATION OF GLOBAL LONGITUDINAL STRAIN IN PATIENTS WITH SYSTEMIC RV AND ITS RELATION TO EXERCISE CAPACITY- A SPECKLE TRACKING ECHOCARDIOGRAPHIC STUDY" (IEC/2101).

Principal Investigator	Dr. Gousia Mukhtar, Post-doctoral fellow, Department of Cardiology, SCTIMST
Co-Principal Investigator(s)	Dr. KM Krishnamoorthy, Professor, Department of Cardiology, SCTIMST Dr. Arun Gopalakrishnan, Additional Professor, Department of Cardiology, SCTIMST Dr. Deepa S Kumar, Additional Professor, Department of Cardiology, SCTIMST
Duration of the study	5 months

The following members of the Ethics Committee were present at the meeting held on 24th August, 2023

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. Kala Kesavan P	MBBS,MD	Female	Basic Medical Scientist	No
2.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
3.	Adv. Priya Kaimal	LLM, MBL	Female	Legal Expert	No
4.	Dr. P. Manickam	BSMS, MSc (Epid)., PhD	Male	Health Science Expert/ Social Scientist	No
5.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
6.	Dr. Manikandan.S	MBBS,MD,PDCC	Male	Clinician	Yes
7.	Dr. Syam K	MBBS, MD, DM	Male	Clinician	Yes
8.	Dr. Srinivas G	PhD	Male	Basic Medical Scientist (Member Secretary)	Yes

The following documents were reviewed:

Original submission

1. Covering letter addressed to the Member Secretary, IEC, SCTIMST dated 08.06.2023
2. Declaration form
3. Checklist Form
4. IEC Application Form
5. Project Proposal
6. Consent Form and Information Sheet
7. CV of PI and Co-PIs
8. TCMC Registration Acknowledgement form
9. Proforma
10. Responses/Amendments made based on the Reviewer's comments
11. Consent Form and Information Sheet in Malayalam
12. SRC Recommendation Letter

Revised submission

1. Covering letter addressed to the Member Secretary, IEC, SCTIMST dated 14.10.2023
2. Declaration form
3. Checklist Form
4. IEC Application Form
5. Project Proposal
6. Consent Form and Participant Information sheet for cases in English and Malayalam
7. CV of PI and Co-PIs
8. Proforma
10. Responses/Amendments made based on the Reviewer's comments
11. TCMC Registration Certificate
12. Consent Form and Participant Information sheet for controls in English and Malayalam

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



Proforma

1. Age
2. Gender
3. Congenitally corrected transposition of great arteries or Post Senning Transposition of great arteries
4. Type of atrial switch
5. Any additional surgery
6. Baffle pathology
7. QRS duration
8. QTc interval
9. Drugs on
10. Arrhythmias
11. Associated lesions
12. N- Terminal pro- Brain Natriuretic peptide, if done
13. 6 minute walk distance
14. Treadmill test if done
15. Right ventricle End diastolic area, Right ventricle End systolic area, Fractional Area Change
16. Right ventricle Diameter at base
17. Tricuspid regurgitation Severity
18. Mitral regurgitation Severity
19. Trans annular plane systolic excursion
20. e'
21. a'
22. s'
23. Myocardial performance Index of Right ventricle
24. Isovolumic relaxation time
25. Isovolumic contraction time
26. Left ventricle ejection fraction
27. Isovolumic myocardial acceleration
28. Right ventricle dp/dt
29. Right ventricle Global longitudinal strain
30. Right ventricle Free wall longitudinal strain

Consent form :

TITLE OF THE STUDY : Quantification of global longitudinal strain in patients with systemic RV and its relation to exercise capacity- A speckle tracking echocardiographic study.

STUDY NUMBER :

PARTICIPANT S NAME , DATE OF BIRTH /AGE IN YEARS

I -----Son /Daughter of -----

Declare that I have read the above information provided to me regarding the study :
'Quantification of global longitudinal strain in patients with systemic RV and its relation to exercise capacity- A speckle tracking echocardiographic study' and I have clarified any doubts that I had .

- I also understand that my participation in the study is entirely voluntary and that I am free to withdraw to continue to participate any time without affecting my usual treatment or my legal rights.
- I also understand that study investigators will be using some of the data like history and other clinical details, Investigation parameters like ECG, Echocardiographic study, Radiological imaging (Cardiac MRI) parameters for the study if already done in the hospital during the study.
- I also understand that I will have to undergo echocardiography as part of my routine follow up investigations and speckle tracking echocardiography which is an entirely non invasive test will be done in the same sitting.
- I also understand that no additional cost will be incurred / no additional drugs would be used and there is no additional risks to me while being part of the study.
- I understand that the study staff and Institutional Ethics committee members will not need my permission to look at my health records even if I withdraw from the study. I agree to this access.
- I understand that my identity will not be revealed in any information released to third parties or published.
- I voluntarily agree to take part in this study
- I received a copy of this consent form

Name

Signature

Date

Name of witness

Principal investigator :

Dr Gousia Mukhtar

Ph no. 9419330457

Dr. Srinivas G, Member Secretary, I E C, SCTIMST, & Scientist - G, Department of Biochemistry, SCTIMST, (email iec.mem.sec@sctimst.ac.in).

DATE

(Person obtaining consent)

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

-----NAME AND SIGNATURE OF PERSON OBTAINING
CONSENT

സമ്മതപത്രം

പഠനശീർഷകം: സിസ്റ്റമിക് ആർവി ഉള്ള രോഗികളിലെ ഗ്ലോബൽ ലോഞ്ചിട്രൂഡിനൽ സമ്മർദ്ദവും വ്യയാമ ശേഷിയുമായുള്ള ബന്ധത്തിന്റെ അളവെടുപ്പ്- ഒരു സ്പെക്കിൾ ട്രാക്കിംഗ് എക്കോകാർഡിയോഗ്രാഫി പഠനം.

പഠനമ്പർ:

പങ്കെടുക്കുന്നയാളുടെ പേര്:.....ജനനതീയതി/വയസ്സ് (വർഷത്തിൽ)

ഞാൻ.....മകൻ/മകൾ

- സിസ്റ്റമിക് ആർവി ഉള്ള രോഗികളിലെ ഗ്ലോബൽ ലോഞ്ചിട്രൂഡിനൽ സമ്മർദ്ദവും വ്യയാമ ശേഷിയുമായുള്ള ബന്ധത്തിന്റെ അളവെടുപ്പ്- ഒരു സ്പെക്കിൾ ട്രാക്കിംഗ് എക്കോകാർഡിയോഗ്രാഫി പഠനം.എന്ന മുകളിൽപ്പറഞ്ഞ പഠനസംബന്ധമായ കാര്യവിവരണപത്രം വായിച്ചു മനസ്സിലാക്കിയതായും എനിക്കുണ്ടായ സംശയങ്ങൾ സംബന്ധിച്ച സംശയങ്ങൾ പരിഹരിച്ചതായും ഞാൻ പ്രഖ്യാപിക്കുന്നു. []
- എന്റെ പങ്കാളിത്തം സ്വമേധയായും, ഏതു സമയത്തും കാരണം കാണിക്കാതെ, എന്റെ വൈദ്യപരിചരണത്തെയോ നിയമപരമായ അവകാശങ്ങളെയോ ബാധിക്കാതെ പിൻമാറാമെന്നും ഞാൻ മനസ്സിലാക്കുന്നു []
- രോഗചരിത്രവും ക്ലിനിക്കൽ വിശദാംശങ്ങളും ഇസിജി, എക്കോകാർഡിയോഗ്രാഫി പരിശോധന, റേഡിയോളജിക്കൽ ഇമേജിംഗ് (കാർഡിയാക് എംആർഐ) മുതലായ ആശുപത്രിയിൽ നടത്തിയ പരിശോധനകളുടെയും വിവരങ്ങൾ പഠനത്തിനായി ശേഖരിക്കുമെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. []
- എന്റെ പതിവ് തുടർ ചികിത്സയുടെ ഭാഗമായി എക്കോകാർഡിയോഗ്രാഫിക് വിധേയമാകേണ്ടിവരുമെന്നും പൂർണ്ണമായും ശരീരത്തിൽ പ്രവേശിക്കാതെയുള്ള സെപ്റ്റൽ ട്രാക്കിംഗ് എക്കോകാർഡിയോഗ്രാഫിയും ഒരേസമയം ചെയ്യുമെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. []
- പഠനത്തിന്റെ ഭാഗമായി അധികച്ചിലവ്, അധികമായ മരുന്നുകൾ, അപായം എന്നിവയുണ്ടാകില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. []
- ഞാൻ പഠനത്തിൽ നിന്നും പിൻമാറിയാലും, പദ്ധതിയിൽ പ്രവർത്തിക്കുന്ന മറ്റുള്ളവർ, നൈതീകകമ്മിറ്റി അംഗങ്ങൾ, നിയന്ത്രണാധികാരികൾ എന്നിവർക്ക് എന്റെ ആരോഗ്യരേഖകൾ ഇപ്പോഴത്തെ പഠനവുമായോ ഭാവിയിലുണ്ടാകുന്ന ഇതുമായി ബന്ധപ്പെട്ടെടുക്കേണ്ടവർക്കുവേണ്ടിയോ പരിശോധിക്കാൻ എന്റെ അനുവാദം ആവശ്യമില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. അതിന് ഞാൻ സമ്മതിക്കുന്നു. []
- പ്രസിദ്ധീകരിക്കുമ്പോഴോ മൂന്നാംകക്ഷികൾക്ക് നൽകുമ്പോഴോ എന്റെ വ്യക്തിവിവരങ്ങൾ നൽകില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. []
- ശാസ്ത്രീയ ഉദ്ദേശത്തോടെയെങ്കിൽ പഠനത്തിലുണ്ടാകുന്ന വിവരങ്ങളോ ഫലങ്ങളോ ഉപയോഗിക്കുന്നത് പരിമിതപ്പെടുത്താതിരിക്കാൻ ഞാൻ സമ്മതിക്കുന്നു []
- ഈ സമ്മതപത്രത്തിന്റെ ഒപ്പിട്ട ഒരു പ്രതി എനിക്ക് ലഭിച്ചു. []

- ഞാൻ സ്വമേധയാ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതിക്കുന്നു. []

പങ്കെടുക്കുന്നയാളുടെ/നിയമപരമായി അംഗീകരിക്കാവുന്ന പ്രതിനിധിയുടെ ഒപ്പ് (തള്ളവിരലടയാളം)
തീയതി

പേര്

ഒപ്പ്

സാക്ഷിയുടെ പേര്

പങ്കെടുക്കുന്നയാളുമായുള്ള ബന്ധം

ഗവേഷകയുടെ ഒപ്പ്

തീയതി

പഠനഗവേഷകയുടെ പേര്

ഫോൺ നമ്പർ **9419330457**

ഡോ. ശ്രീനിവാസ് ജി, സയന്റിസ്റ്റ് -ജി, ബയോകെമിസ്ട്രി വിഭാഗം, **SCTIMST**, മെമ്പർ സെക്രട്ടറി,
ഇൻസ്റ്റിറ്റ്യൂഷണൽ എത്തിക്സ് കമ്മിറ്റി **SCTIMST**, ഇമെയിൽ iec.mem.sec@sctimst.ac.in

സമ്മതപത്രം വാങ്ങുന്നയാൾ

മെഡിക്കൽ റിസർച്ച് പ്രോജക്ടിനാവശ്യമായ സമ്മതപത്രത്തിനു വേണ്ടുന്ന എല്ലാ

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

സമ്മതപത്രം വാങ്ങുന്ന ആളുടെ പേര്

ഒപ്പ്

INFORMATION SHEET

TITLE OF THE STUDY : Quantification of global longitudinal strain in patients with systemic RV and its relation to exercise capacity- A speckle tracking echocardiographic study

STUDY NUMBER :

PARTICIPANT S NAME , DATE OF BIRTH /AGE IN YEARS

.....

What is meant by systemic right ventricle?

Heart has four chambers. The two upper one are the atria and the lower one are the ventricles. The right ventricle normally pumps into the low pressure pulmonary circulation from where the blood flows to the lungs for oxygenation. And the left ventricle pumps blood to the high pressure systemic circulation which supplies blood to the body. You are aware that you have a congenital heart disease that was present since birth. In the congenital heart disease that u have, the right ventricle has to face the systemic circulation as a result of which, it has the tendency to fail early.

What is global longitudinal strain ?

You are aware that as part of our normal institute protocol and scientific reason, u are required to undergo echocardiography test from time to time when u come to Out patient department. During the same echocardiography test, we also do the global longitudinal strain of your right ventricle which is actually defined as the percentage change in its dimension as compared to its original dimension. It is believed that this strain test is more accurate in diagnosing systemic RV failure as compared to the 2d Echocardiography which we normally do.

Does it involve any interventional procedure

It does not any interventional procedure. Echocardiography is a non invasive test. Only the investigations which you would already undergo in the process of evaluation of the disease would be utilized for the study.

If you take part what will you have to do ?

For this study , we ll be using some of the data like history and other clinical details , investigations that are already done for management of the disease and do the strain study in

addition to normal echocardiography. No additional cost will be incurred and no additional drugs will be given.

Can u withdraw from this study after it starts ?

Your participation is entirely voluntary and you are free to withdraw permission to participate from the study. If you do so , it will not affect your usual treatment at this hospital.

Wether there is any risk related to this study?

There is no individual risk to the patient himself. Rather , there is a potential benefit as we may be able to recognize RV failure at the earliest.

Will your personal details be kept confidential ?

The results of this study will be published in a medical journal but you will not be identified by name in any publication or presentation of results. However , your medical notes may be reviewed by people associated with the study, without your additional permission should you decide to participate in the study.

If at any time you experience any problems or you have any further questions ,

Please ask Dr Gousia Mukhtar (Principal investigator) , gousiamukhtar@gmail.com

Ph no. 9419330457

Dr. Srinivas G, Member Secretary, I E C, SCTIMST, & Scientist - G, Department of Biochemistry, SCTIMST, (email - iec.mem.sec@sctimst.ac.in).

കാര്യവിവരണപത്രം

പഠനശീർഷകം: സിസ്റ്റമിക് ആർവി ഉള്ള രോഗികളിലെ ഗ്ലോബൽ ലോഞ്ചിസ്റ്റുഡിനൽ സമ്മർദ്ദവും വ്യയാമ ശേഷിയുമായുള്ള ബന്ധത്തിന്റെ അളവെടുപ്പ്- ഒരു സ്പെക്കിൾ ട്രാക്കിംഗ് എക്കോകാർഡിയോഗ്രാഫി പഠനം.

പഠനനമ്പർ:

പങ്കെടുക്കുന്നയാളുടെ പേര്, ജനനതീയതി/വയസ്സ് (വർഷത്തിൽ)

സിസ്റ്റമിക് ഇടത് വെൻട്രിക്കിൾ എന്നാലെന്ത്?

ഹൃദയത്തിന് നാല് അറകളുണ്ട്. മുകളിലുള്ള രണ്ടറകൾ അട്രിയയും താഴെയുള്ളവ വെൻട്രിക്കിളുകളും. വലത് വെൻട്രിക്കിൽ സാധാരണയായി കുറഞ്ഞ മർദ്ദമുള്ള പൾസമറി രക്തചംക്രമണത്തിലേയ്ക്ക് രക്തം പമ്പുചെയ്യുകയും അവിടെനിന്നും രക്തം പ്രാണവായുപുരിതമാകാൻ ശ്വാസകോശത്തിലേയ്ക്ക് പ്രവഹിക്കുകയും ചെയ്യും. ഇടതു വെൻട്രിക്കിൾ ഉയർന്നമർദ്ദമുള്ള സിസ്റ്റമിക് രക്തചംക്രമണത്തിലേക്ക് രക്തം പമ്പുചെയ്യുകയും അവടെനിന്ന് ശരീരത്തിന് രക്തം നൽകുകയും ചെയ്യുന്നു. താങ്കൾക്ക് ജനിച്ചപ്പോൾ മുതൽ ജന്മനായുള്ള ഹൃദ്രോഗമുണ്ടെന്ന് അറിയാമല്ലോ. താങ്കൾക്കുള്ള ജന്മനായുള്ള ഹൃദ്രോഗത്തിൽ വലത് വെൻട്രിക്കിൾ വ്യവസ്ഥാപരമായ രക്തചംക്രമണം നേരിടേണ്ടിവരുന്നതിനാൽ അതിന് നേരത്തെതന്നെ പരാജയപ്പെടാനുള്ള പ്രവണതയുണ്ട്.

എന്താണ് ഗ്ലോബൽ ലോഞ്ചിസ്റ്റുഡിനൽ സമ്മർദ്ദം?

താങ്കൾ ഔട്ട്പെഷ്യന്റ് വിഭാഗത്തിൽവരുമ്പോൾ സാധാരണയായുള്ള ഇൻസ്പിററ്റുട്ട് നടപടിക്രമങ്ങളുടെയും ശാസ്ത്രീയമായകാരണങ്ങളുടെയും ഭാഗമായി കാലാകാലങ്ങളിൽ എക്കോകാർഡിയോഗ്രാഫി പരിശോധനയ്ക്ക് വിധേയരാകേണ്ടതുണ്ടെന്ന് താങ്കൾക്കറിയാമല്ലോ. ആ എക്കോകാർഡിയോഗ്രാഫി പരിശോധനയ്ക്കിടെ താങ്കളുടെ വലത് വെൻട്രിക്കിളിന്റെ ഗ്ലോബൽ ലോഞ്ചിസ്റ്റുഡിനൽ സമ്മർദ്ദവും ഞങ്ങൾ പരിശോധിക്കുന്നു. ഇത് യഥാർത്ഥ അളവുമായി താരതമ്യപ്പെടുത്തുമ്പോൾ അതിന്റെ അളവിലെ മാറ്റം ശതമാനമായി നിർവ്വചിക്കുന്നു. സിസ്റ്റമിക് ആർവിയിലെ പരാജയം നിർണ്ണയിക്കുന്നതിൽ, നമ്മൾ സാധാരണയായി ചെയ്യുന്ന 2ഡി എക്കോകാർഡിയോഗ്രാഫിയെക്കാൾ ഈ സമ്മർദ്ദ പരിശോധന കൂടുതൽ കൃത്യമാണെന്ന് വിശ്വസിക്കപ്പെടുന്നു.

ഇതിലെന്തെങ്കിലും ഇടപെടൽ നടപടികളുണ്ടോ?

ഇതിൽ ഇടപെടൽ നടപടികളൊന്നുമില്ല. എക്കോകാർഡിയോഗ്രാഫി പരിശോധന ശരീരത്തിൽ പ്രവേശിക്കാതെയുള്ളതാണ്. രോഗത്തിന്റെ വിലയിരുത്തലിന് താങ്കൾ വിധേയമായ പ്രക്രിയയിൽ നടത്തിയ പരിശോധനകൾമാത്രമേ പഠനത്തിനായി ഉപയോഗിക്കുകയുള്ളൂ.

താങ്കൾ പങ്കെടുക്കുന്നു എങ്കിൽ എന്ത് ചെയ്യണം?

ഈ പഠനത്തിനായി ഞങ്ങൾ താങ്കളുടെ രോഗചരിത്രവും ക്ലിനിക്കൽ വിശദാംശങ്ങളും പോലുള്ള ചില വിവരങ്ങൾ ഉപയോഗിക്കും. രോഗം കൈകാര്യം ചെയ്യുന്നതിനായി ഇതിനകം നടത്തിയ പരിശോധനകളും സാധാരണ എക്കോകാർഡിയോഗ്രാഫിക്യൂറമേ സമ്മർദ്ദപഠനവും നടത്തും. അധികച്ചിലവുണ്ടാകില്ല. അധികമായി മരുന്നുകളും നൽകില്ല.

പഠനമാരംഭിച്ചശേഷം താങ്കൾക്ക് പിൻമാറാനാകുമോ?

താങ്കളുടെ പങ്കാളിത്തം പൂർണ്ണമായും സ്വയമേവയാണ്. താങ്കൾക്ക് എതുസമയവും പഠനത്തിൽനിന്നും പിൻമാറാൻ സ്വാതന്ത്ര്യമുണ്ട്. താങ്കളങ്ങനെ ചെയ്താലും ഈ ആശുപത്രിയിലെ പതിവ് ചികിത്സയെ ഒരുവിധത്തിലും ബാധിക്കില്ല.

ഈ പഠനവുമായി ബന്ധപ്പെട്ട് എന്തെങ്കിലും അപായമുണ്ടോ?

രോഗിക്ക് വ്യക്തിപരമായി ഒരപായവുമില്ല. തന്നെയുമല്ല, ഞങ്ങൾ ഒരു പക്ഷേ ആർവി പരാജയം നേരത്തെ കണ്ടെത്തിയേക്കാമെന്ന നേട്ടവുമുണ്ട്.

താങ്കളുടെ വ്യക്തിവിവരങ്ങൾ രഹസ്യമായിരിക്കുമോ?

പഠനഫലങ്ങൾ ഒരു വൈദ്യശാസ്ത്ര ജേർണലിൽ പ്രസിദ്ധീകരിക്കാൻ നൽകും., പക്ഷേ, പ്രസിദ്ധീകരണത്തിലോ ഫലങ്ങൾ പ്രദർശിപ്പിക്കുന്നതിലോ താങ്കളെ പേരുകൊണ്ട് തിരിച്ചറിയാനാകില്ല. എന്നിരുന്നാലും, താങ്കൾ പഠനത്തിൽ പങ്കെടുക്കുകയാണെങ്കിൽ, താങ്കളുടെ ചികിത്സാരേഖകൾ പഠനവുമായി ബന്ധപ്പെട്ടയാളുകൾ, താങ്കളുടെ വീണ്ടുമുള്ള അനുവാദമില്ലാതെ, അവലോകനം ചെയ്തേക്കാം

താങ്കൾക്ക് എന്തെങ്കിലും പ്രശ്നങ്ങളോ കൂടുതൽ ചോദ്യങ്ങളോ ഉണ്ടെങ്കിൽ ദയവായി ചോദിക്കുക, ഡോ. ഗൗസിയ മുക്താർ (പ്രധാന ഗവേഷക) മൊബൈൽ നമ്പർ 9419330457, ഇമെയിൽ gousiamukhtar@gmail.com

ഡോ. ശ്രീനിവാസ് ജി, സയന്റിസ്റ്റ് -ജി, ബയോകെമിസ്ട്രി വിഭാഗം, SCTIMST, മെമ്പർ സെക്രട്ടറി, ഇൻസ്റ്റിറ്റ്യൂഷണൽ എത്തിക്സ് കമ്മിറ്റി SCTIMST, ഇമെയിൽ iec.mem.sec@sctimst.ac.in