

**OUTCOMES OF MITRAL VALVE REPAIR IN
CHILDREN WITH CONGENITAL/ACQUIRED MITRAL
VALVE ANOMALY**



Dr. RAHUL SATHEESAN

MCH CARDIOTHORACIC AND VASCULAR SURGERY THESIS

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

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A THESIS SUBMITTED BY

Dr. RAHUL SATHEESAN

TO

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES
AND TECHNOLOGY, TRIVANDRUM

IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE
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श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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No part of the thesis has been submitted for the award/ any other degree or diploma to this date.

Date: 12/02/2023


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*Clearance was obtained from Institutional Ethics committee/ Institutional Animal Ethics/ Institutional Committee for stem cell research/ Other appropriate committees (if any , specify), for carrying out the study.

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Name of the Guide:
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
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Sometimes it is not easy to express in words especially when you have to say thanks to your parents for their constant undemanding love, dedication, sacrifice, Inspiring guidance, affectionate encouragement and never-ending enthusiasm, without which this study would not have seen the light of the day.

I would like to specially thank my wife Dr. Roshna and my parents for their constant support and care, encouragement and for being a pillar of strength throughout the duration of this study, without whom I would never been able to complete this endeavor.

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Dr. Rahul Satheesan

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SCTIMST

LIST OF ABBREVIATIONS

AR- Aortic Regurgitation

AVSD – AtrioVentricular Septal Defect.

BSA- Body surface area

CPB – Cardiopulmonary Bypass

ECHO- Echocardiography

IQR – Interquartile range

LV GLS- Left ventricular global longitudinal strain

LVEF – Left ventricular ejection fraction

LVIDD – Left ventricular internal diameter in diastole

LVIDS- Left ventricular internal diameter in systole

MR- Mitral regurgitation

MS- Mitral Stenosis

MV – Mitral valve

MVR – Mitral valve replacement

TEE – Trans Esophageal Echocardiography

TR – Tricuspid Regurgitation

TTE – TransThoracic Echocardiography

SYNOPSIS

INTRODUCTION

Mitral valve disease is a rare entity in the paediatric population and the incidence of congenital mitral valve disease being 0.5%(1). It is often found in association with ventricular septal defect 17%, and subaortic stenosis 12%(2,3). The disease of the mitral valve encountered in the paediatric population may vary from stenotic to regurgitant or a combined lesions. Mitral valve repair in paediatric population although showcase considerable results in the form of long term freedom from operation after mitral valve repair, some conditions may eventually end up in replacement. The reason for mitral valve repair durability in adults is due to the establishment of well developed classification of valvar pathology considering the morphological and etiological aspects of the valvar disease(4–6). According to recent evidences, mitral valve repair is definitely superior to replacement considering the many cons of replacement such as : 1. Patient prosthesis mismatch as the child grows, 2. Risks of anticoagulation , 3. The need for permanent pacemaker implantation owing to injury to the conduction system(7,8). Repair of complex congenital valve lesions all the more pose greater difficulty in front of the congenital heart surgeon as there are no described time tested techniques for the repair of these valves(4).

The spectrum of acquired mitral valve disease in children range from Rheumatic etiology to damaged valve from infective endocarditis sequeale. The majority were regurgitant lesions while stenotic lesions were of lower incidence. The mitral valve pathology presented alone or sometimes along with other valvular pathologies like tricuspid regurgitation and aortic regurgitation.

The different repair techniques adopted for the use of these acquired mitral valve diseases were extended commisurotomies, shortening of chordae, chordal reconstruction with PTFE, pericardial patching of leaflet tears, pericardial augmentation of posterior mitral leaflets, annuloplasty using prosthetic valve rings(9).

Operative technique

All 49 patients who underwent mitral valve repair were studied. Standard intra-operative monitoring strategies were utilized and a cardiopulmonary bypass (CPB)

circuit was used for all of the cases. After induction, in all the cases, TEE (Trans Esophageal Echocardiography) was used to assess the MV pathology in detail and the mechanism of MR. This would help the surgeon to plan a repair technique for the valve. All procedures were performed through a standard median sternotomy. Heparin was used to maintain an activated clotting time more than 200 seconds as a criteria for cannulation for CPB and 400 seconds as a criteria to go on CPB . Once gone on CPB, Antegrade cardioplegia was administered in all the cases. The technique of administration was decided by the grade of the AR. Those case with significant AR was administered ostial cardioplegia and those without AR was administered aortic root cardioplegia. Once the diastolic arrest of the heart was achieved, the MV was approached through the right atrium and trans septal approach. Other coexisting anomalies of the heart were also studied and their management plan was devised and executed simultaneously. The MV is assessed thoroughly by inspecting the valvar and the subvalvar apparatus using a nerve hook and the mechanism of MR was studied using the saline test. Then a repair plan was devised and the various repair techniques were performed based on the type of defect identified.

The various repair techniques that were used in the present study were 1.Valve annuloplasty 2. Commisuroplasty 3. Ring annuloplasty 4. Leaflet augmentation 5. Subvalvar repair 6. Alfieri stitch 7. Resection of supramitral membrane 8. Leaflet plication 9. PML advancement 11. Leaflet resection and their various permutations and combinations.

The Valve annuloplasty, commisuroplasty,leaflet augmentation techniques often used pericardial patch.

Every patient was monitored in intensive care unit (ICU) for close

observation and management. In early post-operative period,selected patients (those patients in which ring annuloplasty were done and pericardial patch were used)were treated with heparin bridging to warfarin from the first post-operative day to the next 3–6 months. Antiplatelet(s) (Aspirin/clopilet) were given orally prevent acute thrombosis from the rings or bovine pericardium used .

OBJECTIVES

Primary objective:

1 To Study Survival and outcomes for paediatric patients undergoing MV repair in this institute.

Secondary objective:

2. Secondary objective of our study is to determine any major adverse cardiac and cerebrovascular events in paediatric patients undergoing MV repair in this institute.

RESULTS:

Total 49 children were operated for MV repair. All operations were done as elective repair.

Out of the 49 children, 28 were male children and the rest were females.

Out of the 49 patients who were operated, 9 patients (18.4%) were had Rheumatic heart disease, whereas 40 patients (81.6%) didn't have Rheumatic heart disease.

It was found that majority of the patients (30.6%) were without any TR . 22.4% patients had grade 1,2,3 of Tricuspid Regurgitation respectively.

98% patients were without any PDA.

The associated cardiac anomalies in patients who underwent MV repair were

18 patients had ASD (36.7%), 11 patients with VSD(22.4%), 1 patient(2%) with Shone's complex, Pulmonary atresia with IVS and PDA respectively.

Of the patients who came for repair, 63.3% patients were with severe MR, 32.7% patients were with moderate MR, 2% had mild MR and no MR.

35 patients (71.4%) belonged to Type 2 defect of MV (Carpentier), 8 patients (16.3%) had type 1 defect, 5 patients (10.2%) had type 3 defect.

18.4% (9) patients required reoperation while of the total operated patients, 5 patients progressed to single ventricle pathway.

The incidence of infective endocarditis in the present study was found to be 2 (4.08%) patients out of the total 49 patients. But none of the patients had mortality due to infective endocarditis.

The mortality recorded in this study was 12.2% (6 patients) in this study.

MR measured at followup postoperatively showed 38.8% (19) patients with post op MR of 2+. Only 16.3%(8) patients had no MR on followup, while 12.2%(6) patients had MR1+. 14.3% (7)patients had 3+ MR and 6.1% (3) patients had severe MR on follow up.

In the above study, 77.6%(38) had improvement in the MR from the various repair techniques used.

On postop followup, 55.1%(27) patients had no aortic regurgitation, while only 24.5%(12) patients had grade 1 AR.

42.9% patients (21 patients) had undergone valve annuloplasty with an additional procedure. While pure valve annuloplasty was undergone by 22.4%(11). While ring annuloplasty was done by 18.4%(9) and only other procedures without valve annuloplasty was done by 16.3%(8) patients.

In the above study, 77.6%(38) had improvement in the MR from the various repair techniques used.

95.2% (20) patients had improvement with valve annuloplasty and additional procedure. While ring annuloplasty showed 77.8% (7) improvement post procedure. Valve annuloplasty alone contributed to 72.7% (8) patients having improvement and other procedures done alone showed 37.5%(3) patients having improvement, while 62.5%(5) had no improvement although the results were not significant.

The average age of the study population was 11.86 +/- 5.69, median age of 12 with an IQR of 7 -16.5 years. The average weight of the study population was 17.4 +/- 14.98 kg with median of 13 IQR of 6-25 years. The average post op icu stay was 4.59 +/- 3.27 days, with median of 4 days IQR of 3-5 days. Average days of mechanical ventilation was 1.55 days +/- 1.1 days with median of 1 IQR of 1-2. Average LVIDd was 43.12 +/- 8.28 mm with median of 42 mm IQR of 37 – 49. Average LVIDd (Z

score) was 0.73 +/- 1.8 median of 0.39 IQR -0.56 to 2.04mm. LVIDs average was 28.33 +/- 6.07mm with median of 28mm with IQR of 24 – 33 mm. Average LVIDs (Z score) was 1.54 +/- 2.69 median of 0.64 and IQR -0.01 to 2.51. LVEF average was 62.77 mm +/- 7.62 mm with median of 62 mm IQR of 58 – 69 mm. Average LVPWd was 6.6mm +/- 1.35 mm median of 7 mm IQR of 6-7mm. Average LVPWs was 9.42 +/- 1.87 mm median of 9 and IQR 8-11mm. LA average was 33.23 +/- 7.22mm with a median of 32mm and IQR of 29 – 38.5 mm. Average e wave was 1.46 mm +/- 0.52 mm median of 1.5 mm IQR of 1.15-1.85mm. Average a wave was 0.99 +/- 0.41 median of 0.8 IQR of 0.7 – 1.3. Average medial e' was 7.26 +/- 2.52 median of 7 and IQR of 5-9 while average medial a' was 5.59 +/- 1.68 median 6 and IQR of 4-7. Lateral e' was 9.38 +/- 3.33 median of 8 and IQR of 7-11. Average Lateral a' was 6.56 +/- 2.32 with a median of 6 and IQR of 5-8. Average Aortic velocity was 1.21 +/- 0.42 median of 1.2 IQR of 1-1.2. RV systolic pressure from TR jet was . Average IVC diameter was 14.61 +/- 4.09 mm with a median of 15 and IQR of 11 – 17.5mm. Average LV global longitudinal strain was 16.32% +/- 3.13 with a median of 16.25 IQR of 14.325 – 18.4. LV circumferential strain was 27.03 +/- 5.38 % with median 26.9 IQR 23.2-30%. Average LA Z score was 2.58 +/- 1.27 median of 2.54 IQR of 1.6 – 3.43.

85.7% female patients had improvement in the MR while 71.4% male patients only had improvement. This showed that females when treated had better results compares to male patients.

The patients with LVGLS > -19.9% was 34 out of 42 patients (80.9%)

Reoperated cases having LV GLS >-19.9% was 6 patients out of 9(66.66%)

CONCLUSION

Mitral valve repair is a safe procedure in pediatric patients with good early and long term results. Even in pediatric patients Annuloplasty for incompetent mitral valve is essential to attain good long term competence. Ring annuloplasty if feasible should be considered. Left ventricle global longitudinal strain should be used for assessment of these patients as it helps in identifying covert heart failure and would guide in optimised heart failure management in pediatric patients.

TABLE OF CONTENTS

Sl. no	Contents	Page no
1.	Synopsis	Ix
2.	Introduction	1
3.	Objectives	2
4.	Review of literature	3
5.	Methodology	7
6.	Results	12
7.	Discussion	29
8.	Conclusion	32
9.	Limitations	33
10.	References	34
11.	Annexures	38

LIST OF TABLES

Table no.	Description	Page no
1.	The proportion of males to females for MV repair	12
2.	Proportion of Rheumatic to Non Rheumatic patients	13
3.	Prevalence of Tricuspid regurgitation	13
4.	Proportion of patients with PDA	14
5.	Proportion of other cardiac anomalies	15
6.	Prevalence of Grades of MR	15
7.	Prevalence of the MV lesions according to the Carpentier's Classification	16
8.	Number of patients requiring reoperations	17
9.	Number of patients progressing to Univentricular pathway	18
10.	Prevalence of Late mortality	19
11.	Prevalence of grades of MR on followup post MV repair	20
12.	Results of MR on followup	21
13.	Prevalence of Aortic regurgitation on followup	21
14.	Proportion of the different valve repair techniques used	23
15.	Results of various valve repair techniques	23
16.	Showing the Mean and Median of various parameters studied	24
17.	Genderwise outcomes of the mitral valve repair	25

LIST OF FIGURES

Figure no.	Description	Page no
1	The proportion of males to females for MV repair	12
2	Proportion of Rheumatic to Non Rheumatic patients	13
3	Prevalence of Tricuspid regurgitation	14
4	Proportion of patients with PDA	14
5	Proportion of other cardiac anomalies	15
6	Prevalence of Grades of MR	16
7	Prevalence of the MV lesions according to the Carpentier's Classification	17
8	Number of patients requiring reoperations	18
9	Number of patients progressing to Univentricular pathway	18
10	Incidence of Infective Endocarditis	19
11	Prevalence of Late mortality	20
12	Prevalence of grades of MR on followup post MV repair	21
13	Prevalence of Aortic regurgitation on followup	22
14	Proportion of the different valve repair techniques used	22
15	The prevalence of LV dysfunction	26
16	Classification based on Post operative LVIDD/LVIDS	27
17	Classification based on LV GLS	27
18	LV GLS in reoperated cases	28

INTRODUCTION

Mitral valve disease is a rare entity in the paediatric population and the incidence of congenital mitral valve disease being 0.5%(1). It is often found in association with ventricular septal defect 17% (25), and subaortic stenosis 12%(2,3). The diseases of the mitral valve encountered in the paediatric population may vary from stenotic to regurgitant or combined lesions(27). Mitral valve repair in paediatric population although showcase considerable results in the form of long term freedom from operation after mitral valve repair, some conditions may eventually end up in replacement. The reason for mitral valve repair durability in adults is due to the establishment of well developed classification of valvar pathology considering the morphological and etiological aspects of the valvar disease(4–6). According to recent evidences, mitral valve repair is definitely superior to replacement considering the many cons of replacement such as : 1. Patient prosthesis mismatch as the child grows, 2. Risks of anticoagulation , 3. The need for permanent pacemaker implantation owing to injury to the conduction system(7,8). Repair of complex congenital valve lesions all the more pose greater difficulty in front of the congenital heart surgeon as there are no described time tested techniques for the repair of these valves(4).

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REVIEW OF LITERATURE

In a study published by Cheul lee et al in 2010, they have found that MV repair as the primary option in children had durable results and acceptable reoperation rates (with majority of the patients undergone Re-repair successfully) and better survival rates. But the key factor on which the reoperation depended upon was the degree of residual mitral disease left after the primary repair procedure. In this study, the author had compared the results of MV repair in 139 children who underwent MV repair surgery between 1988 & 2007. They compared children with age ranging from 2 months to 17.6 years, out of which 14 patients were infants. MR was the predominant lesion (125 patients) and 71% of these patients had MR grade $\geq 3+$. 14 patients had MS with a median gradient of 9 mmhg. On followup, the author found that 29 patients required reoperations with 11 of them needing MV replacement. There were 3 late deaths. On followup, of the survivors, only 5 patients had MR grade 3+ and the degree of MS decreased significantly in 14 surviving patients who underwent Echo. Diseases of the mitral valve(10).

In a study by Prifti et al, for the assessment of early and midterm outcomes in cases of children undergoing MV repair with or without other congenital cardiac diseases, through multivariate analysis, they found that the variables for the poor outcomes in reoperations and midterm survival in cases undergoing MV repair were age < 1 year, Hammock mitral valve, Cardiothoracic ratio > 0.6 , and associated cardiac anomalies. The authors in this study analysed the results of 94 children between January 1990 and February 2001 who underwent MV repair for congenital diseases of the mitral valve. MS was present in 21 children and MR was seen in 73. They found that there was reasonable survival and reoperation free survival in these children with survival being 89.2% and reoperation free survival being 76.3% (3).

In a study published by Eva maria et al in 2016, they compared 20 infants and children with parachute and hammock mitral valves from January 1990 to June 2014 for the early and late results after surgery. Various repair techniques were employed in the management of these children with hammock valves having predominant MR and parachute valves having predominant MS. The surgical techniques employed included annuloplasty, commissurotomy, leaflet incision including papillary muscles.

The cumulative survival rate was found to be 43.7 +/- 1.6% , whereas the freedom from reoperation was found to be 53 +/- 1.8% in case of parachute valves, while that in hammock valve was 72.9 +/- 1.6% and 30 +/- 1.7% respectively. In this study also they found age(<1 year) to be an important risk factor for reoperation. They concluded that the reoperation risk was higher in the course of followup in cases of parachute and hammock mitral valves and that infants had a greater risk of reoperation and mortality(12).

In a study published by Takeshi et al on their 23 years of experience in the repair of mitral valves in infants and children with congenital mitral valve insufficiency due to carpentier type 3 mechanism(restricted leaflet motion), followup of the echocardiographic data of 23 subjects showed that the freedom from reoperation was 100 % at 30 days and upto 1 year, 97.9 % at 5, 10, 15 and 20 years. The survival rate was 100 % upto 5 years and 95.9% at 20 years. They concluded that these defects could be repaired with excellent long term outcomes using the various customised repair techniques for these valves(11).

In a study on long term outcomes of mitral valve insufficiency repair by the carpentier's technique applied on 145 paediatric subjects (from 1970 to 1995 by Chauvaud et al, they opined that the repair technique was a viable solution in children with stable long term outcomes and low mortality with low rates of reoperation. They also found that leaflet extension technique associated with prosthetic ring annuloplasty prevented reoperations in selected cases. Although in this study the study population was limited with exclusion of children with atrioventricular defect, atrioventricular discordance, straddling mitral valve, acquired diseases, Marfan syndrome, and degenerative disease (13).

In a study by Uva et al conducted in 20 infants between 1980 and 1993, comprising of congenital mitral incompetence abnormalities comprising of normal leaflet motion (3), leaflet prolapsed (2) and restricted leaflet motion (5), congenital mitral stenotic abnormalities including parachute valve (4), typical mitral valve (3), hammock valve(2), supramitral ring (1), they concluded that the mitral valve repair can be done in upto 70% of the cases, but the reoperation rates remained high. The reoperation rates were related to the increasing complexity of the mitral valve lesion, although the late results of the survivors were good (20).

In a study on 40 year experience in mitral valve replacement in children John W Brown et al, they found that MV replacement can be performed in the paediatric population with low initial mortality, although it has to be reserved for cases with medical and repair failure as they are associated with late complications such as thrombosis and other valve related complications. They also found increasing risk with usage of less than 23mm prosthetic valve size. Ross procedure is a durable option in children which also excludes the anticoagulation related risk factors. In this study from 1970 to 2010 they studied 97 patients who underwent MV replacement. The patients had etiologies ranging from congenital (67%), rheumatic (28%), endocarditis (5%). 5 children underwent Ross procedure (14).

In a study by Alfred E Wood et al on their 18 years of experience in the repair of the paediatric mitral valves, they studied 45 children with mitral valve anomalies. They compared the results in children in 2 groups, those children with isolated mitral valve anomalies and those with other complex intracardiac anomalies. They found that the incidence of early death was significantly higher in the second group of patients (26.6% vs 11.1%) . They reported a 74% to 85% survival and 66% to 85.7% freedom from reoperation after valve replacement(15).

In a study by Masuda et al, conducted in children aging from 1 month and 12 years of age with mitral regurgitation, they found that the repair with reconstruction of chordae tendinae had the best results (100%) as compared to the valve annuloplasty technique(92%). Reoperation rate was 4% , with 4 late deaths. 5 patients required valve replacement . They concluded that at 15 years the reoperation free rate and actuarial survival rate were 17 +/- 12% and 85 +/- 7 % respectively(16).

In a study by BahaaldinAlsoufi et al, conducted on 307 children between 1985 and 2004 found that the outcomes following mitral valve replacement children are dependent on patient's age, prosthesis size and other associated risk factors. Age less than 3 years, longer crossclamp times and higher prosthesis size/ BSA contributed to bad outcomes post mitral valve replacement. 20 years followup after the initial MV replacement surgery, only 33% of the subjects were alive, 51% had undergone reoperations, 17% deaths. The initial prosthesis used in the patients were 75% mechanical, 23% tissue and 2 % homograft (17).

In a study by Eldad et al, on the outcomes of mitral valve replacement in children, they found that the hospital mortality was significantly higher in younger children aged < 2 years(52%). They recorded 4 late deaths with the major postoperative events including thromboemboli, bleeding, endocarditis, cardiomyopathy, and orthotopic heart transplantation. The study subjects included 90 patients (37 males and 53 females). The patients considered in the study had etiologies including congenital, rheumatic, Atrioventricularseptal defect, myxomatous disease, endocarditis, Kawasaki's disease, Left atrial myxoma, idiopathic hypertrophic subaortic stenosis. The study also included 40% patients with previous mitral valve repair. They concluded that MVreplacement has a detrimental effect in failed AVSD cases and may be used as an option in other cases of failed MV repair (18).

In a study by J S Sachweh and colleagues on 32 children who underwent aortic and mitral valve replacements between 1981 and 2003, using St. Jude Medical Valves, they found that although the anticoagulation management post MVR had acceptable outcomes, the perioperative morbidity was significant in the case of MVR. When performing MVR, the surgeons often tend to oversize the valve in consideration of the growth potential, to avoid early intervention. The results were acceptable with acceptable postoperative mortality rates(2 late deaths in the study). The major cardiac complications that were encountered were complete heart block, ventricular fibrillation, myocardial infarction. Overall 10 year freedom from reoperation was 80.9% (19).

METHODS AND METHODOLOGY

STUDY TYPE- This is a Retrospective observational study.

STUDY POPULATION – All paediatric patients (0 to 18 years) who underwent MV repair at SCTIMST from 1st January 2011 to 31st December 2019 were considered in this study.

DATA COLLECTION PROCEDURE - All paediatric patients (0 to 18 years) who underwent MV repair at SCTIMST from 1st January 2011 to 31st December 2019 and who satisfied the inclusion and exclusion criteria were included in the study . Retrospective analysis was performed by principal investigator after going through medical records. All the patients underwent follow up after the procedure and routinely as per departmental protocol. Follow up involved Transthoracic ECHO. Patients who were lost to follow up were contacted through Telephonic interview. Patients were asked about symptoms in the follow up period. Data so collected from the medical records and telephonic interview was analyzed. Procedure DID NOT involve banking of biological samples, HIV testing, Genetic testing.

ELIGIBILITY CRITERIA

INCLUSION CRITERIA

All paediatric patients (0 to 18 years) who underwent MV repair at SCTIMST from 1st January 2011 to 31st December 2019 for mitral valve pathology (Both congenital and acquired).

EXCLUSION CRITERIA

1. Adult patients undergoing Mitral Valve Repair, Patients with ostium primum type of ASD, Cleft Mitral Leaflets.
2. Paediatric patient's bystanders who are unable to give informed consent, normal / healthy volunteer, relatives of student, staff of the institute.

Gender, class, caste, ethnicity, race will not be used as inclusion and/or exclusion criteria.

SAMPLE SIZE

49 paediatric patients who underwent MV repair in SCTIMST between 1st January 2011 till 31st December 2019 and who satisfied the inclusion and exclusion criteria were included in the study.

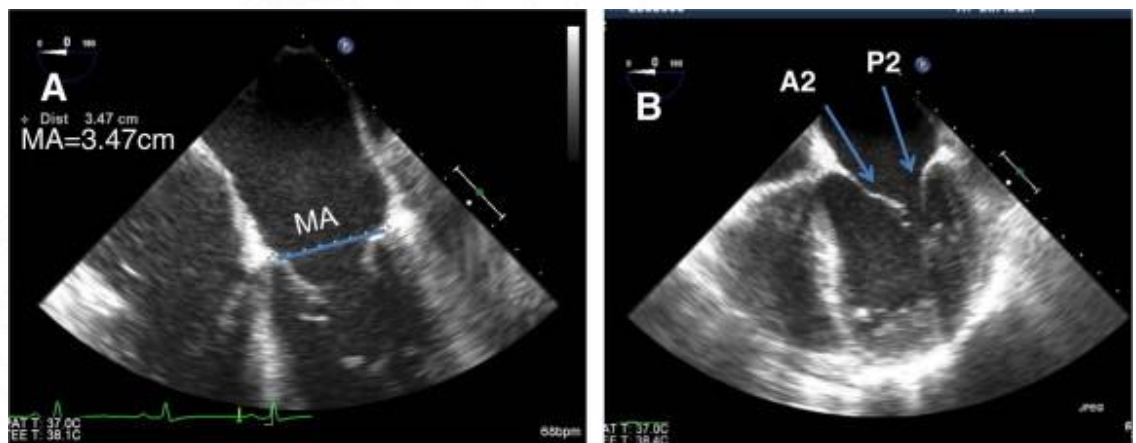
Operative techniques

All 49 patients who underwent mitral valve repair were studied. Standard intra-operative monitoring strategies were utilized and a cardiopulmonary bypass (CPB) circuit was used for all of the cases. After induction, in all the cases, TEE (Trans Esophageal Echocardiography) was used to assess the MV pathology in detail and the mechanism of MR. This would help the surgeon to plan a repair technique for the valve. All procedures were performed through a standard median sternotomy. Heparin was used to maintain an activated clotting time more than 200 seconds as a criteria for cannulation for CPB and 400 seconds as a criteria to go on CPB . Once gone on CPB, Antegrade cardioplegia was administered in all the cases. The technique of administration was decided by the grade of the AR. Those cases with significant AR was administered ostial cardioplegia and those without AR was administered aortic root cardioplegia. Once the diastolic arrest of the heart was achieved, the MV was approached through the right atrium and trans septal approach. Other coexisting anomalies of the heart were also studied and their management plan was devised and executed simultaneously. The MV is assessed thoroughly by inspecting the valvar and the subvalvar apparatus using a nerve hook and the mechanism of MR was studied using the saline test. Then a repair plan was devised and the various repair techniques were performed based on the type of defect identified.

The various repair techniques that were used in the present study were 1.Valve annuloplasty 2. Commisuroplasty 3. Ring annuloplasty 4. Leaflet augmentation 5. Subvalvar repair 6. Alfieri stitch 7. Resection of supramitral membrane 8. Leaflet plication 9. PML advancement 11. Leaflet resection and their various permutations and combinations.

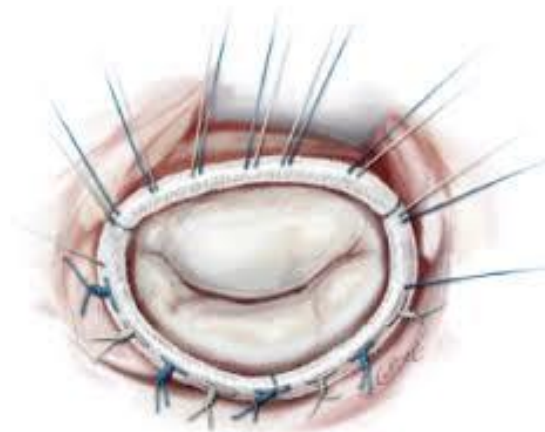
The Valve annuloplasty, commisuroplasty, leaflet augmentation techniques often used pericardial patch.

Every patient was monitored in the intensive care unit (ICU) for close observation and management. In early post-operative period, selected patients (those patients in which ring annuloplasty were done and pericardial patch were used were treated with heparin bridging to warfarin from the first post-operative day to the next 3–6 months. Antiplatelet(s) (Aspirin/clopilet) were given orally prevent acute thrombosis from the rings or bovine pericardium used .

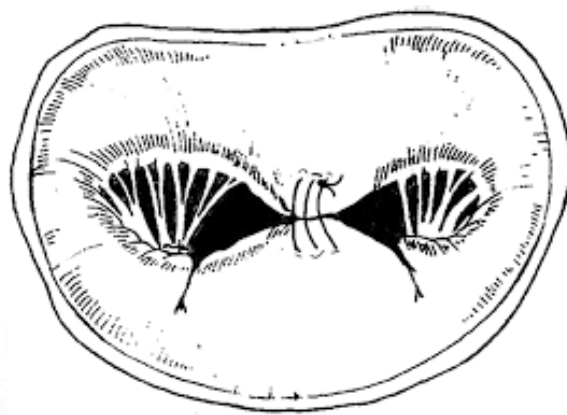


Mid esophageal view of the TEE done preoperatively in a patient with MR.

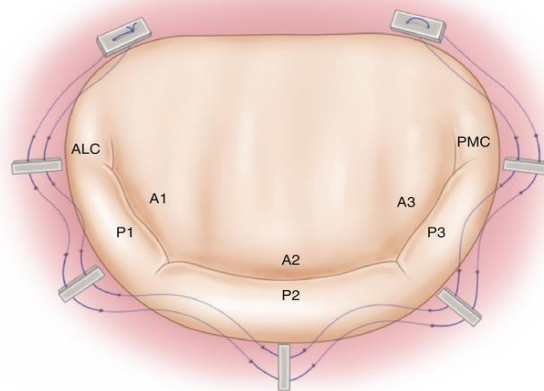
MA- Mitral annulus.



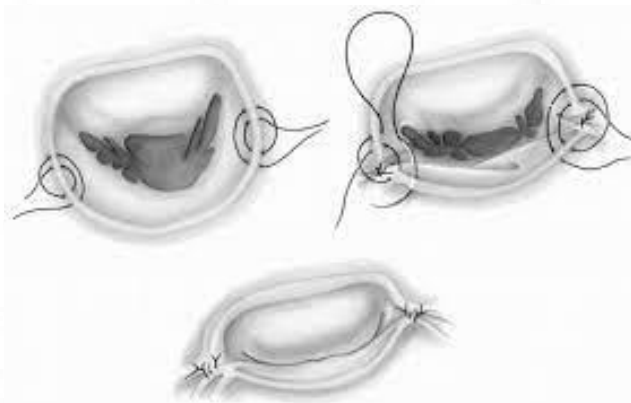
Ring Annuloplasty



Alfieri Stitch



Suture Annuloplasty of Mitral valve



Mitral valve commissuroplasty

STATISTICAL ANALYSIS

Quantitative Variables were expressed as mean , standard deviation. Qualitative variable were expressed as frequency and percentage. Association between categorical variables was analysed by chi-square test. A p- values <0.05 was considered as statistically significant. Data was entered in Microsoft excel and Data analysis was performed using SPSS ver24

RESULTS

Total 49 children were operated for MV repair . All operations were done as elective repair.

Out of the 49 children, 28 were male children and the rest were females.

SEX	Frequency	Percent
Male	28	57.1
Female	21	42.9
Total	49	100

Table 1 The proportion of males to females for MV repair

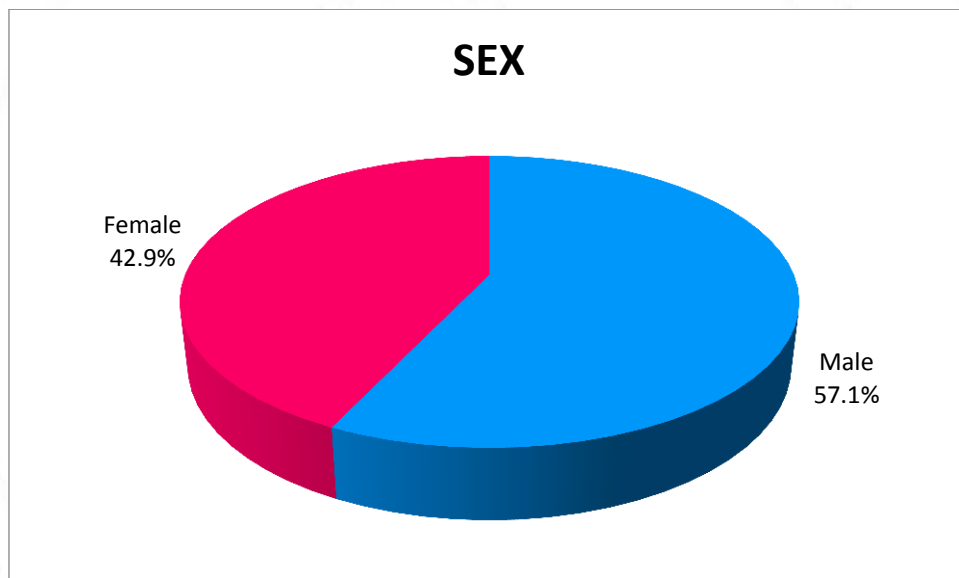


Figure 1 The proportion of males to females for MV repair

Out of the 49 patients who were operated, 9 patients (18.4%) had Rheumatic heart disease, whereas 40 patients (81.6%) didn't have Rheumatic heart disease.

	Frequency	Percent
RHEUMATIC	9	18.4
Non RHEUMATIC	40	81.6
Total	49	100

Table 2 Proportion of Rheumatic to Non Rheumatic patients

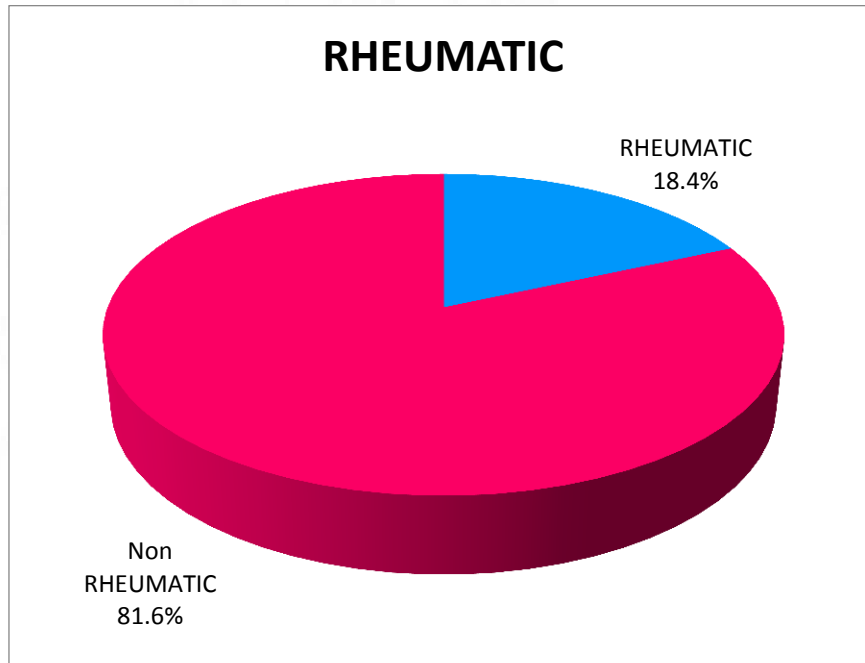


Figure 2 Proportion of Rheumatic to Non Rheumatic patients

The associated anomalies in patients for MV repair were:

Tricuspid Regurgitation

TR	Frequency	Percent
0	15	30.6
1	11	22.4
2	11	22.4
3	11	22.4
Total	48	98

Table 3 Prevalence of Tricuspid regurgitation

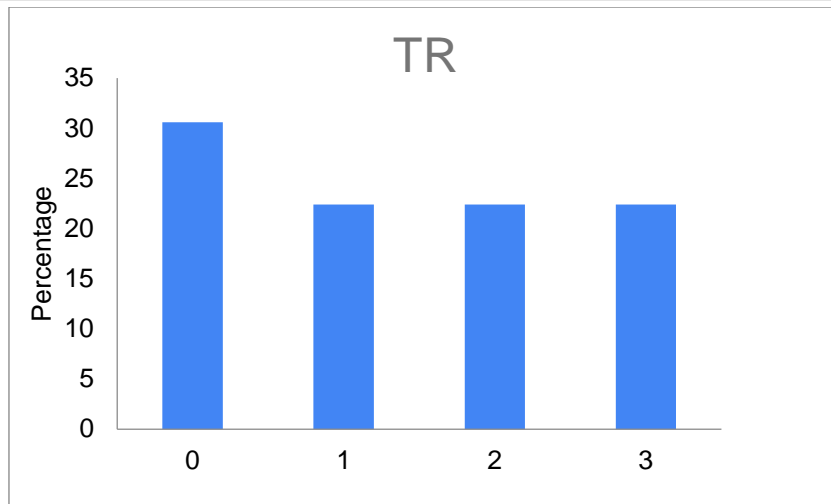


Figure 3 Prevalence of Tricuspid regurgitation

It was found that majority of the patients (30.6%) were without any TR . 22.4% patients had grade 1,2,3 of Tricuspid Regurgitation respectively.

PDA	Frequency	Percent
Yes	1	2
No	48	98
Total	49	100

Table 4 Proportion of patients with PDA

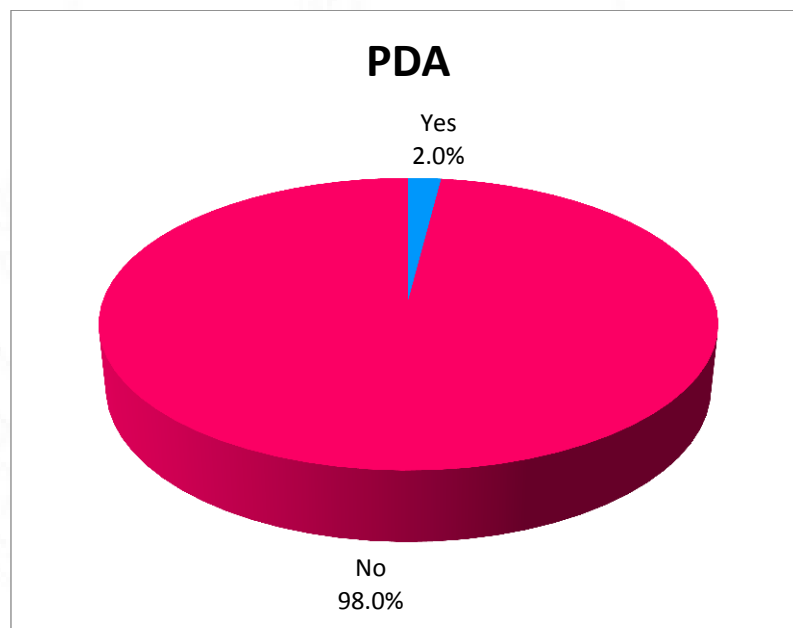


Figure 4 Proportion of patients with PDA

98% patients were without any PDA.

ASSOCIATED CARDIAC ANOMALIES	Frequency	Percent
VSD	11	22.4
ASD	18	36.7
SHONE'S COMPLEX	1	2
PULMONARY ATRESIA, IVS	1	2
PDA	1	2

Table 5 Proportion of other cardiac anomalies

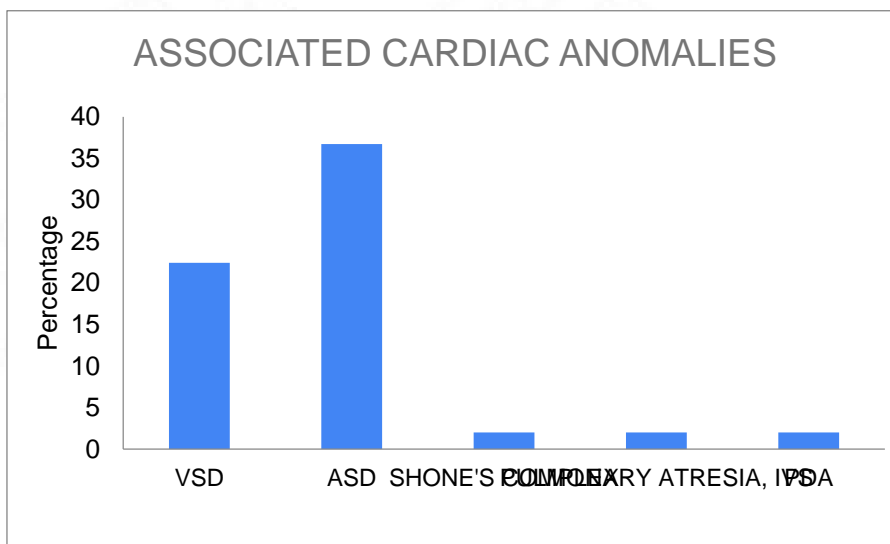


Figure 5 Proportion of other cardiac anomalies

The associated cardiac anomalies in patients who underwent MV repair were 18 patients had ASD (36.7%), 11 patients with VSD(22.4%), 1 patient(2%) with Shone’s complex, Pulmonary atresia with IVS and PDA respectively.

MR	Frequency	Percent
No MR	1	2
Mild	1	2
Moderate	16	32.7
Severe	31	63.3
Total	49	100

Table 6 Prevalence of Grades of MR

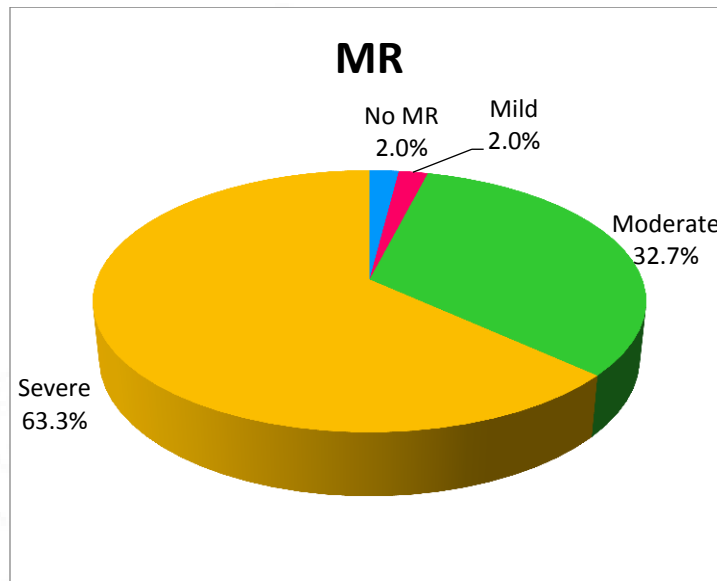


Figure 6 Prevalence of Grades of MR

Of the patients who came for repair, 63.3% patients were with severe MR, 32.7% patients were with moderate MR, 2% had mild MR and no MR.

CLASSIFICATION OF CONGENITAL MV LESIONS	Frequency	Percent
TYPE 1 NORMAL LEAFLET MOTION ANNULAR DILATATION	8	16.3
LEAFLET DEFECT	4	8.2
TYPE 2 LEAFLET PROLAPSED - ELONGATED CHORDATE	35	71.4
TYPE 3 RESTRICTED LEAFLET MOTION - SHORT CHORDATE	5	10.2

Table 7 Prevalence of the MV lesions according to the Carpentier's Classification

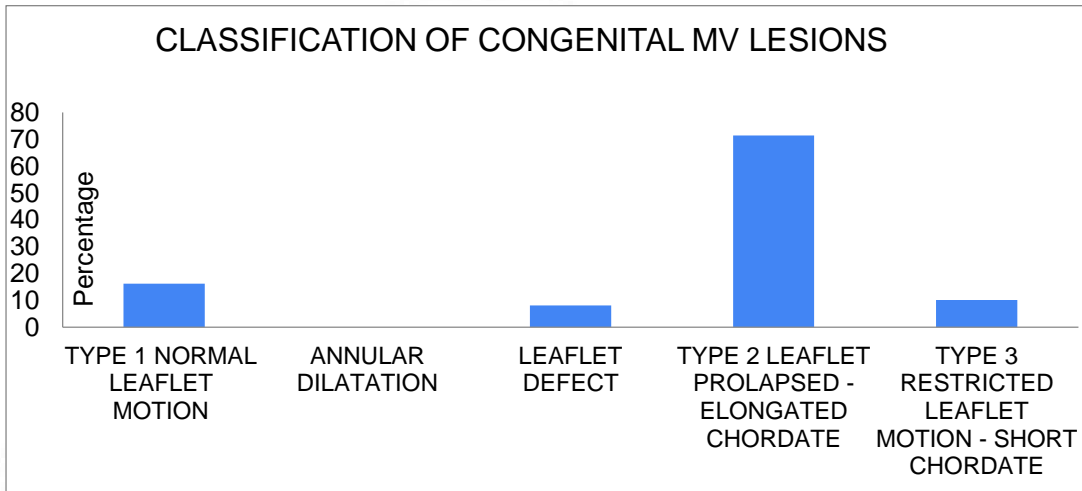


Figure 7 Prevalence of the MV lesions according to the Carpentier’s Classification

35 patients (71.4%) belonged to Type 2 defect of MV (Carpentier), 8 patients (16.3%) had type 1 defect, 5 patients (10.2%) had type 3 defect.

NUMBER OF PATIENTS REQUIRING REOPERATIONS	Frequency	Percent
Yes	9	18.4
No	40	81.6
Total	49	100

Table 8 Number of patients requiring reoperations

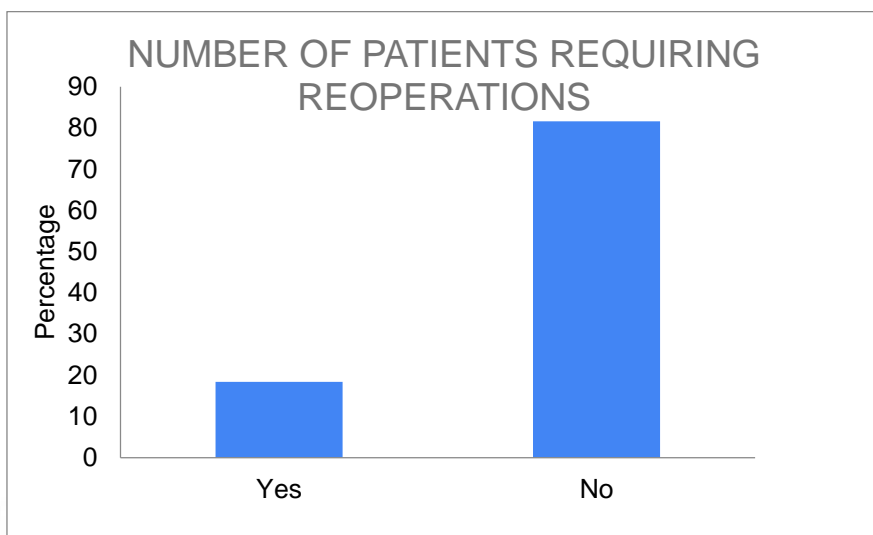


Figure 8 Number of patients requiring reoperations

NUMBER OF PATIENTS PROGRESSING TO UNIVENTRICULAR PATHWAY	Frequency	Percent
Yes	5	10.2
No	44	89.8
Total	49	100

Table 9 Number of patients progressing to Univentricular pathway

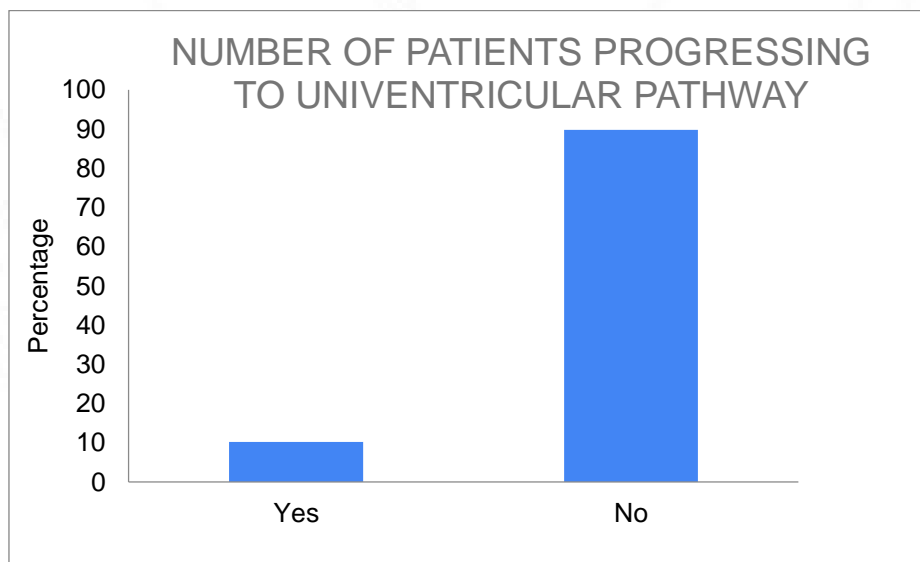


Figure 9 Number of patients progressing to Univentricular pathway

18.4% (9) patients required reoperation while of the total operated patients, 5 patients progressed to single ventricle pathway.

The incidence of infective endocarditis in the present study was found to be 2 (4.08%) patients out of the total 49 patients. But none of the patients had mortality due to infective endocarditis.

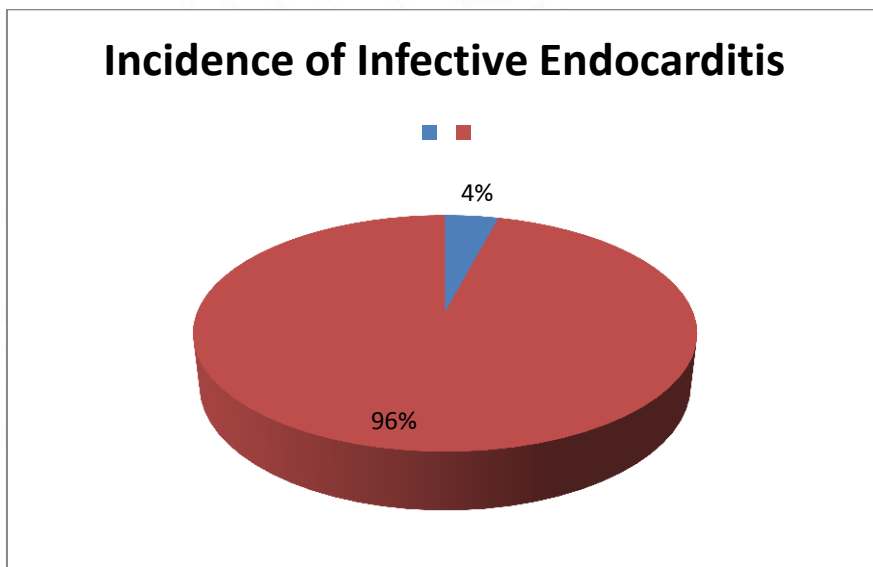


Figure 10 Incidence of Infective Endocarditis

LATE MORTALITY	Frequency	Percent
Yes	6	12.2
No	43	87.8
Total	49	100.0

Table 10 Prevalence of Late mortality

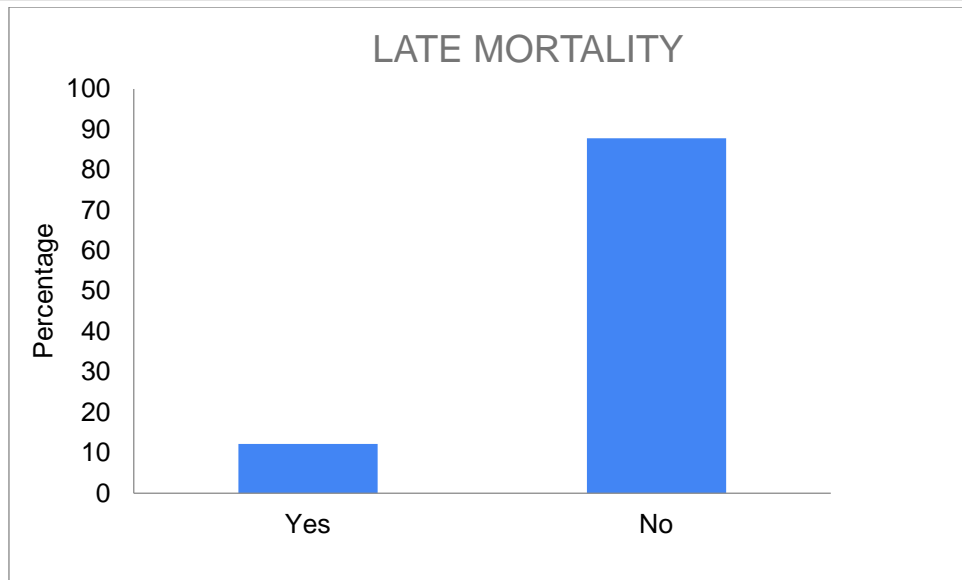


Figure 11 Prevalence of Late mortality

The late mortality recorded in this study was 12.2% (6 patients) in this study.

Mitral regurgitation (follow up)	Frequency	Percent
0	8	16.3
1	6	12.2
2	19	38.8
3	7	14.3
4	3	6.1
Death	6	12.2
Total	49	100

Table 11 Prevalence of grades of MR on followup post MV repair

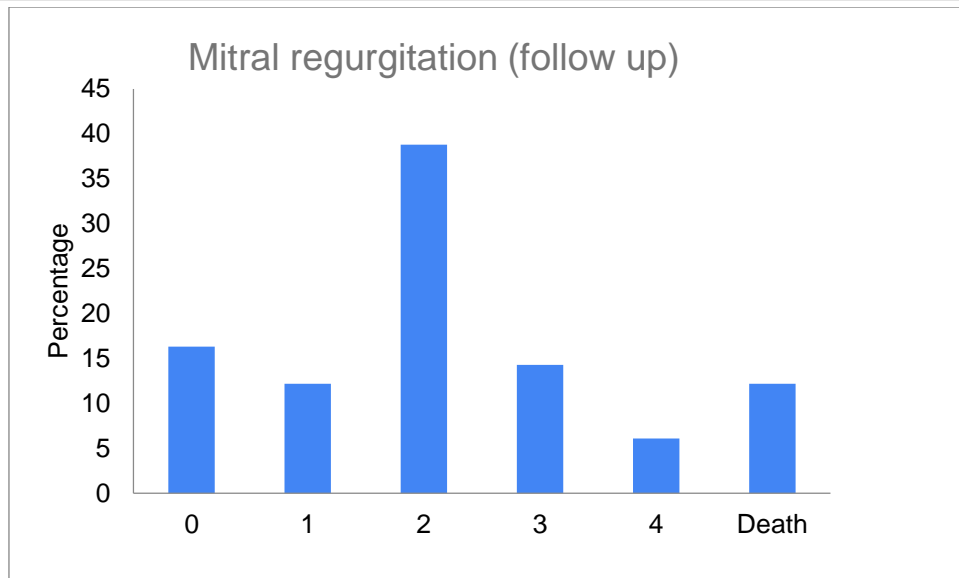


Figure 12 Prevalence of grades of MR on followup post MV repair

MR measured at followup postoperatively showed 38.8% (19) patients with post op MR of 2+. Only 16.3%(8) patients had no MR on followup, while 12.2%(6) patients had MR1+. 14.3% (7)patients had 3+ MR and 6.1% (3) patients had severe MR on follow up.

Results of MR on followup

Outcome	Frequency	Percent
Improvement	38	77.6
No improvement	11	22.4
Total	49	100

Table 12 Results of MR on followup

In the above study, 77.6%(38) had improvement in the MR from the various repair techniques used.

Aortic regurgitation	Frequency	Percent
0	27	55.1
1	12	24.5
2	4	8.2
Death	6	12.2
Total	49	100

Table 13 Prevalence of Aortic regurgitation on followup

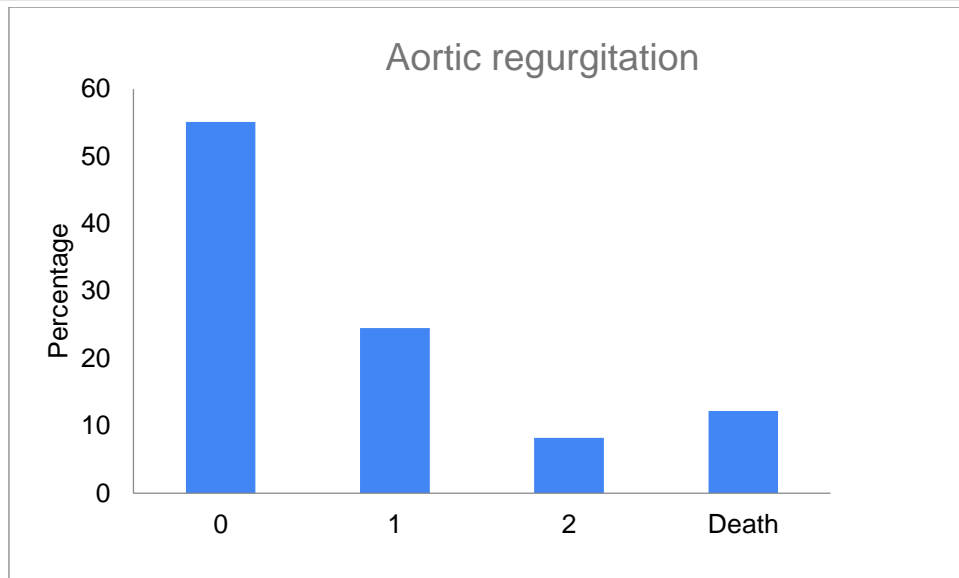


Figure 13 Prevalence of Aortic regurgitation on followup

On postop followup, 55.1%(27) patients had no aortic regurgitation, while only 24.5%(12) patients had grade 1 AR.

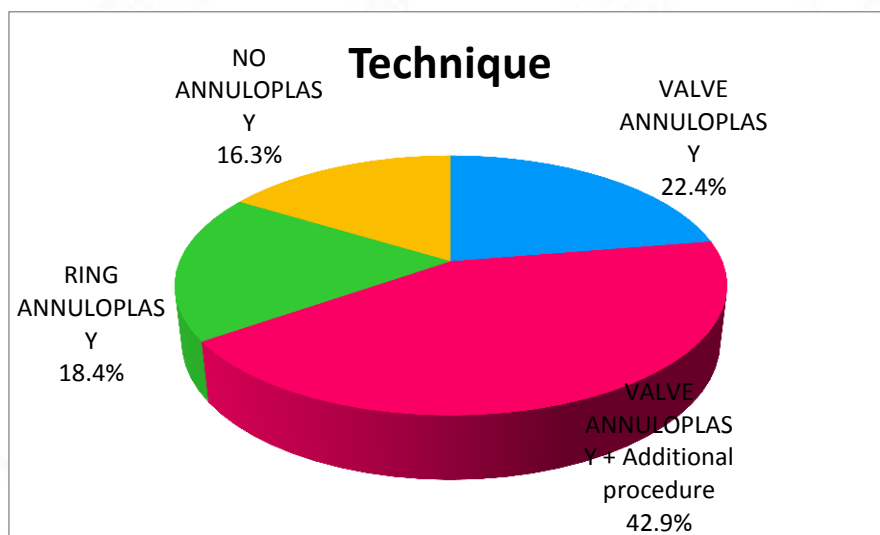


Figure 14 Proportion of the different valve repair techniques used.

42.9% patients (21 patients) had undergone valve annuloplasty with an additional procedure. While pure valve annuloplasty was undergone by 22.4%(11). While ring annuloplasty was done by 18.4%(9) and only other procedures without valve annuloplasty was done by 16.3%(8) patients.

Technique	Frequency	Percent
VALVE ANNULOPLASY	11	22.4
VALVE ANNULOPLASY + Additional procedure	21	42.9
RING ANNULOPLASY	9	18.4
NO ANNULOPLASY	8	16.3
Total	49	100

Table 14 Proportion of the different valve repair techniques used.

Technique	Outcome				Total		χ^2	df	p
	Improvement		No improvement		N	%			
	N	%	N	%					
VALVE ANNULOPLASY	8	72.7	3	27.3	11	100.0	1.407	1	0.236
VALVE ANNULOPLASY + Additional procedure	20	95.2	1	4.8	21	100.0			
RING ANNULOPLASY	7	77.8	2	22.2	9	100.0			
NO ANNULOPLASY	3	37.5	5	62.5	8	100.0			
Total	38	77.6	11	22.4	49	100.0			

Table 15 Results of various valve repair techniques

The above table shows that 95.2% (20) patients had improvement with valve annuloplasty and additional procedure. While ring annuloplasty showed 77.8% (7) improvement post procedure. Valve annuloplasty alone contributed to 72.7% (8) patients having improvement and other procedures done alone showed 37.5% (3) patients having improvement, while 62.5% (5) had no improvement although the results were not significant.

Results

	N	mean \pm sd	Range	Median	IQR
AGE	49	11.86 \pm 5.69	3 - 22	12	7 - 16.5
WEIGHT	49	17.4 \pm 14.98	3.2 - 68	13	6 - 25
AVERAGE DAYS OF POSTOP ICU STAY	49	4.59 \pm 3.27	2 - 21	4	3 - 5
AVERAGE DAYS OF MECHANICAL VENTILATION	49	1.55 \pm 1.1	1 - 7	1	1 - 2
LVIDd	43	43.12 \pm 8.28	25 - 61	42	37 - 49
LVIDs	43	28.33 \pm 6.07	17 - 42	28	24 - 33
LVEF (Simpson's method)	43	62.77 \pm 7.62	36 - 77	62	58 - 69
LVPWd	43	6.6 \pm 1.35	4 - 9	7	6 - 7
LVPWs	43	9.42 \pm 1.87	6 - 14	9	8 - 11
LA	43	33.23 \pm 7.22	19 - 52	32	29 - 38.5
E wave	41	1.46 \pm 0.52	0.5 - 2.7	1.5	1.15 - 1.85
A wave	41	0.99 \pm 0.41	0.4 - 2.1	0.8	0.7 - 1.3
Medial e'	43	7.26 \pm 2.52	3 - 15	7	5 - 9
Medial a'	43	5.59 \pm 1.68	3 - 9	6	4 - 7
Lateral e'	43	9.38 \pm 3.33	5 - 19	8	7 - 11
Lateral a'	43	6.86 \pm 2.32	4 - 11	6	5 - 8
Aortic velocity	42	1.21 \pm 0.42	0.8 - 2.9	1.2	1 - 1.2
RV systolic pressure from TR jet	39	186.56 \pm 155.06	15 - 782	202	27 - 252
IVC diameter	33	14.61 \pm 4.09	8 - 25	15	11 - 17.5
LV global longitudinal strain	42	16.32 \pm 3.13	10.8 - 23.5	16.25	14.325 - 18.4
LV circumferential strain	39	27.03 \pm 5.38	12 - 41.6	26.9	23.2 - 30
LVIDd(Z)	43	0.73 \pm 1.8	-2 - 4.98	0.39	-0.56 - 2.04
LVIDs(Z)	43	1.54 \pm 2.69	-2.09 - 8.87	0.64	-0.01 - 2.51
LA(Z)	43	2.58 \pm 1.27	-0.06 - 5.75	2.54	1.6 - 3.43

Table 16 Showing the Mean and Median of various parameters studied.

The average age of the study population was 11.86 +/- 5.69, median age of 12 with an IQR of 7 -16.5 years. The average weight of the study population was 17.4 +/- 14.98

kg with median of 13 IQR of 6-25 years. The average post op icu stay was 4.59 +/- 3.27 days, with median of 4 days IQR of 3-5 days. Average days of mechanical ventilation was 1.55 days +/- 1.1 days with median of 1 IQR of 1-2. Average LVIDd was 43.12 +/- 8.28 mm with median of 42 mm IQR of 37 – 49. Average LVIDd (Z score) was 0.73 +/- 1.8 median of 0.39 IQR -0.56 to 2.04mm. LVIDs average was 28.33 +/- 6.07mm with median of 28mm with IQR of 24 – 33 mm. Average LVIDs (Z score) was 1.54 +/- 2.69 median of 0.64 and IQR -0.01 to 2.51. LVEF average was 62.77 mm +/- 7.62 mm with median of 62 mm IQR of 58 – 69 mm. Average LVPWd was 6.6mm +/- 1.35 mm median of 7 mm IQR of 6-7mm. Average LVPWd was 9.42 +/- 1.87 mm median of 9 and IQR 8-11mm. LA average was 33.23 +/- 7.22mm with a median of 32mm and IQR of 29 – 38.5 mm. Average e wave was 1.46 mm +/- 0.52 mm median of 1.5 mm IQR of 1.15-1.85mm. Average a wave was 0.99 +/- 0.41 median of 0.8 IQR of 0.7 – 1.3. Average medial e’ was 7.26 +/- 2.52 median of 7 and IQR of 5-9 while average medial a’ was 5.59 +/- 1.68 median 6 and IQR of 4-7. Lateral e’ was 9.38 +/- 3.33 median of 8 and IQR of 7-11. Average Lateral a’ was 6.56 +/- 2.32 with a median of 6 and IQR of 5-8. Average Aortic velocity was 1.21 +/- 0.42 median of 1.2 IQR of 1-1.2. RV systolic pressure from TR jet was . Average IVC diameter was 14.61 +/- 4.09 mm with a median of 15 and IQR of 11 – 17.5mm. Average LV global longitudinal strain was 16.32% +/- 3.13 with a median of 16.25 IQR of 14.325 – 18.4. LV circumferential strain was 27.03 +/- 5.38 % with median 26.9 IQR 23.2-30%. Average LA Z score was 2.58 +/- 1.27 median of 2.54 IQR of 1.6 – 3.43.

Gender	Outcome				Total		χ^2	df	p
	Improvement		No improvement		N	%			
	N	%	N	%					
Male	20	71.4	8	28.6	28	100	1.407	1	0.236
Female	18	85.7	3	14.3	21	100			
Total	38	77.6	11	22.4	49	100			

Table 17 Genderwise outcomes of the mitral valve repair

The above results show that 85.7% female patients had improvement in the MR while 71.4% male patients only had improvement. This showed that females when treated had better results compares to male patients.

Classification based on Post operative LVEF

The prevalence of LV dysfunction by measurement of LVEF was 2.3%.

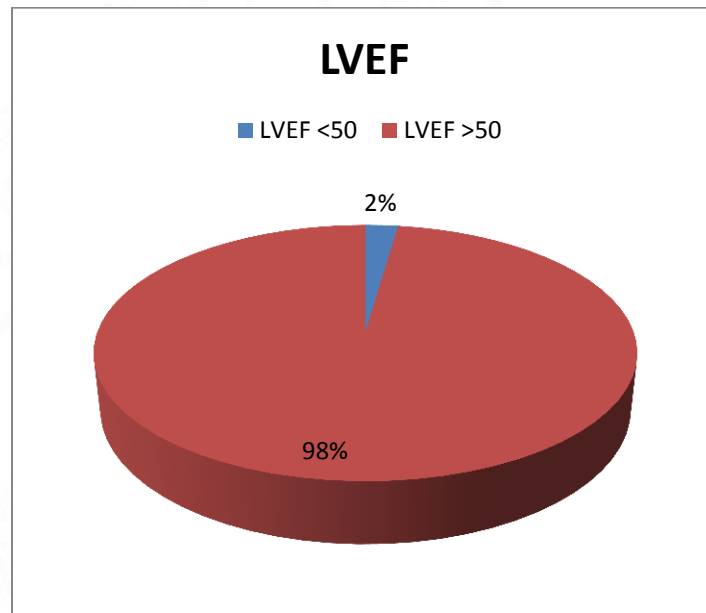


Figure 15 The prevalence of LV dysfunction

Classification based on Post operative LVIDD/LVIDS

The patients with LVIDD > 56mm was 3 out of 43 patients(6.9%).

The patients with LVIDS >40mm was 1 out of 43 patients (2.3%)

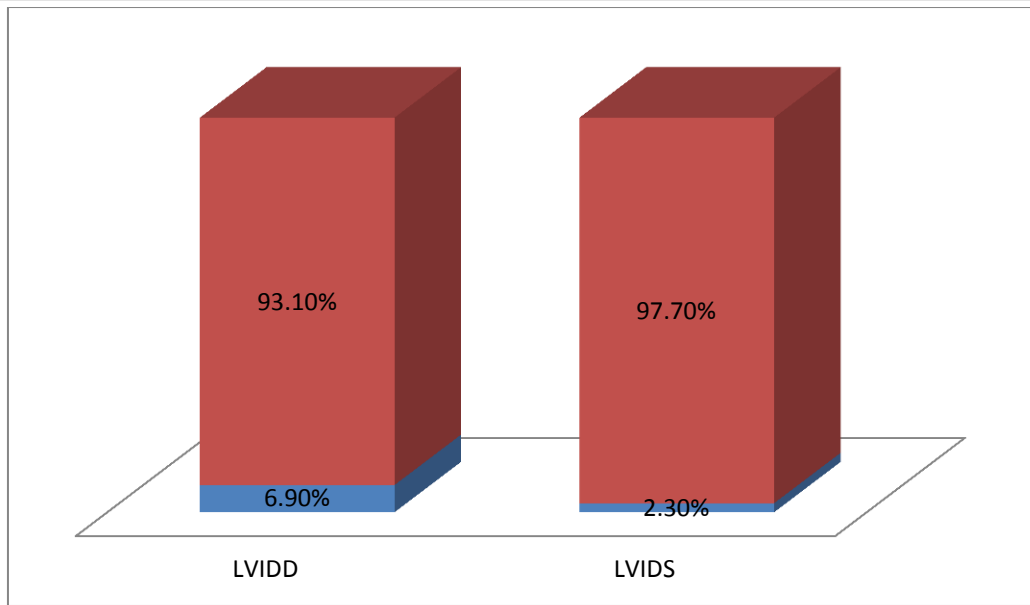


Figure 16 Classification based on Post operative LVIDD/LVIDS

Classification based on LV GLS

The patients with LVGLS > -19.9% was 34 out of 42 patients (80.9%)

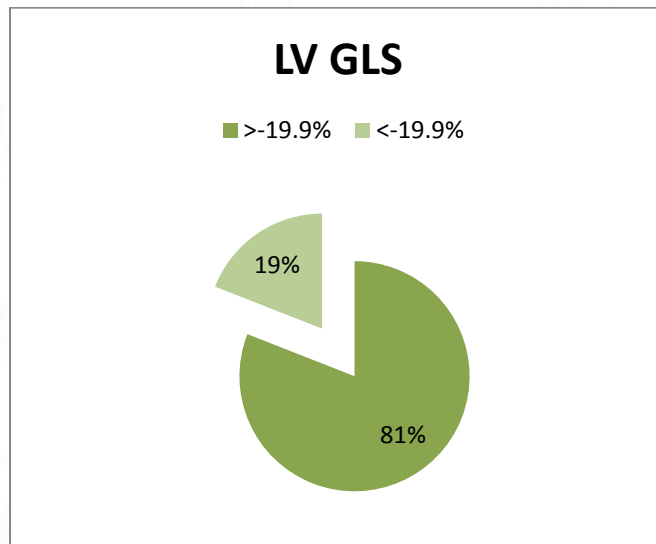


Figure 17 Classification based on LV GLS

Reoperated cases having LV GLS >-19.9% was 6 patients out of 9(66.66%)

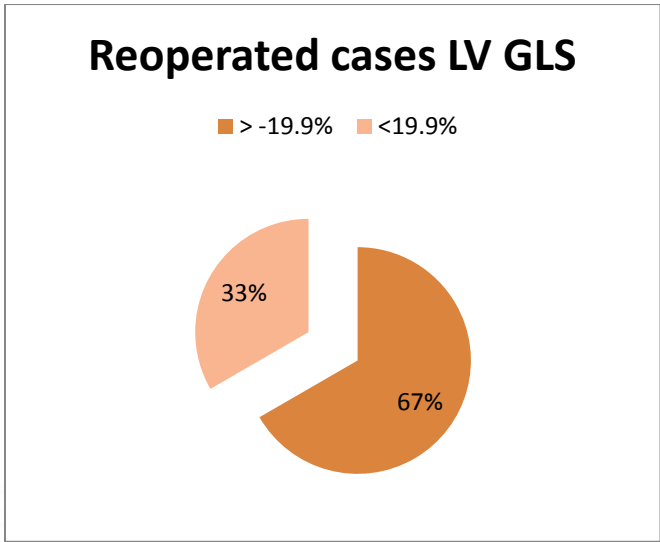


Figure 18 LV GLS in reoperated cases

DISCUSSION

Mitral valve disease is a rare entity in the paediatric population and the incidence of congenital mitral valve disease being 0.5%(1). As the subvalvar apparatus are underdeveloped and easily damaged, the repair of the mitral valve in paediatric population itself poses a great challenge according to a study by Eva maria et al (12). There are a lot of techniques of mitral valve repairs documented in the present available literatures but there is no consensus on the best or optimal type of repair needed for the each condition of the mitral valve in the paediatric population , partly due to the complexity of the valve and partly due to the associated complex congenital cardiac condition that accompanies it(22). According to a study by Roland et al, mitral valve reconstruction techniques using various permutations and combinations according to the disease provide optimal results with good long term survival and decreased reoperations at follow-up (23).

In a study by Talwar et al on mitral valve repair in children with Rheumatic heart disease, the late mortality post operatively was found to be 2.6% (24) whereas in another study their overall late deaths at 15 years were reported to be 3% (10). In our study , we observed that we had 12.2% late deaths without any (26) early in-hospital mortality.

The associated cardiac anomalies in patients who underwent MV repair were 18 patients with ASD (36.7%), 11 patients with VSD (22.4%), 1 patient (2%) with Shone's complex, Pulmonary atresia with IVS and PDA respectively whereas 63% patients were without any associated cardiac anomalies. Whereas review of a study done by Kazu minami et al showed that 41% of the study subjects were without any associated cardiac anomalies and the maximum associated cardiac anomaly was VSD in contrast to ASD in our study (26).

In our study, 63.3% patients had severe MR with the most common mechanism of MR being Type 2 mechanism (Carpentier classification) of leaflet prolapsed. Incidence of Coexisting MS in the study was found to be 0.04 % (2 patients) with incidence of parachute mitral valve also 0.04% (2 patients). Whereas review in

literatures showed incidence of severe MR > 60% with maximum MR belonging to the type 1 and type 2 mechanisms in children > 2 years of age(23).

The grade of MR came down significantly at followup with observed maximum recurrence of MR on followup being 38.8% Grade 2 MR, with 6.1% patients having recurrence of grade 4 MR with 77.6% patients having improvement in MR grades with surgical intervention. The number of patients requiring reoperation was 9 (18.4%) which is comparable to the current literature that showed reoperation rates varying from 15- 20% (15).

42.9% patients in our study underwent valve annuloplasty with additional procedure followed by 22.4% having undergone valve annuloplasty alone while only 16.3% patients underwent other procedures without annuloplasty. Our results showed that adding valve annuloplasty played a key role (72.7%) in the improvement of the mitral regurgitation grades. The addition of a ring to the annuloplasty repair improved the results to 77.8%. Although many literature projected good outcomes with valve annuloplasty (28), adding a ring annuloplasty, the idea incurred from adult correction was overlooked by many authors(15).

Recently the concept of the global longitudinal strain has come up as a reliable independent predictor of post operative LV dysfunction. Many literatures highlight the usefulness of this tool as a reliable indicator for predicting of LV dysfunction(when LV GLS was > -19.9%) and preventing the sequel of recurrent heart failure admissions and poor quality of life of the patient post surgery(28,29,30) .From our current study we observed that out of the total patients for whom the variable was measured,80.9% (34 out of 42 patients) had GLS > -19.9%. While from the other echocardiographic parameters measured, only one patient(2.3%) had LVEF < 50%, 3 patients with LVIDD > 56 mm (6.9%) and 1 patient with LVIDS > 40mm (2.3%).

When the LV GLS values for reoperated patients were calculated, it was found that 6 patients out of the total 9 patients reoperated amounting to 66.66% had LV GLS > -19.9%. This signifies that reoperation might not always be a worsening factor of the LV function.

So from the above observation , we get an idea as to the number of patients with impending LV dysfunction whom we may recruit for management of heart failure and prevent recurrent hospitalizations thereby increasing the number of their quality life years.

Finally, we observed no incidence of any cerebrovascular events in any of the study patients which is better than the current worldwide results which project the event rates up to 1.6% post MV repair(30).

CONCLUSION

Mitral valve repair is a safe procedure in pediatric patients with good early and long term results. Even in pediatric patients Annuloplasty for incompetent mitral valve is essential to attain good long term competence. Ring annuloplasty if feasible should be considered. Left ventricle global longitudinal strain should be used for assessment of these patients as it helps in identifying covert heart failure and would guide in optimised heart failure management in pediatric patients.

LIMITATIONS

As the study is retrospective, lapses in data recoding can produce error in the results.

Sample size was limited due to patients lost to follow up.

Ostium Primum Atrial Septal Defect and Cleft Mitral Leaflet were excluded from the study, thus limiting the sample size.

Also, Echocardiography parameters may not be accurate in some cases due to lack of cooperation.

All post op echo parameters could not be measured in all patients because of patient factors.

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ANNEXURES

Congenital Mitral Stenosis in children

Identified parameters for the study

1. Mean age , weight
2. sex
3. Males to females ratio
4. Mitral regurgitation
5. Mitral stenosis
6. Rheumatic/Non Rheumatic
7. Associated cardiac anomalies
 - a. VSD
 - b. AS (Valvar/Subvalvar)
 - c. ASD
 - d. Shone's complex
 - e. Pulmonary Atresia, IVS
 - f. TR
 - g. TGA
 - h. PFO
 - i. PDA
8. Classification of Congenital MV lesions
 - a. Type 1 normal Leaflet motion
 - i. Annular dilatation
 - ii. Cleft leaflet
 - iii. Leaflet defect
 - b. Type 2 leaflet prolapsed
 - i. Elongated chordate
 - c. Type 3 restricted leaflet motion

- i. Short chordate
- ii. Fused commissures
- iii. Others
- d. Mitral valve stenosis
 - i. Type a (normal papillary muscles)
 - 1. supraaavalvar ring
 - 2. Papillary muscle commissural fusion
 - ii. Type b (abnormal papillary muscle)
 - 1. Parachute valve
- 9. Surgical techniques of congenital mitral valve repair
 - a. Supraaavalvar repair
 - i. Resection of a supraaavalvar membrane
 - b. Valve repair
 - i. Rigid, annuloplasty
 - ii. Semirigid, complete ring
 - iii. Semirigid, partial ring
 - c. Leaflet procedure
 - i. Leaflet/cleft suture
 - ii. Triangular leaflet resection
 - iii. Leaflet augmentation
 - d. Alfieri stitch
 - e. Commissurotomy
 - f. Subaavalvar repair
 - i. Chordal replacement
 - ii. Papillary muscle splitting
- 10. Average days of post op icu stay
- 11. Average days of mechanical ventilation
- 12. Incidence of endocarditis
- 13. Echo parameters
 - a. Mv orifice area and mean resting end diastolic gradient

- i. 4-6 cm²
- ii. Mild 2-4cm² (< 5 mmhg)
- iii. Moderate 1-2 cm² (5-10mmhg)
- iv. Severe < 1cm² (> 10mmhg)
- b. Regurgitant fraction
 - i. Mild <20%
 - ii. Moderate 20-40%
 - iii. Moderate 40-60%
 - iv. Severe >60%

14. Cardiac cath
 - a. Pulmonary arterial pressures
15. Number of patients requiring reoperations
16. Number of patients progressing to univentricular pathway
17. Mortality
 - a. Early
 - b. Late

Follow up echo parameters:

LVIDd

LVIDs

LVEF (Simpson's method)

LVPWd

LVPWs

LA

LV inflow doppler:

- E wave
- A wave
- Edt

Tissue doppler:

- Medial e'
- Medial a'
- Lateral e'
- Lateral a'

Mitral regurgitation: (Yes/No)

- Grade (1/2/3/4)

Aortic velocity

Aortic regurgitation: (Yes/No)

- Grade (1/2/3/4)

RV systolic pressure from TR jet

IVC diameter, and respiratory variation

LV global longitudinal strain

LV circumferential strain

Document Information

Analyzed document	Dr Rahul Thesis.pdf (D158578069)
Submitted	2/14/2023 5:39:00 AM
Submitted by	Dr P K Dash
Submitter email	dash@sctimst.ac.in
Similarity	4%
Analysis address	sadh.sctims@analysis.urkund.com

Sources included in the report

W	URL: http://www.sctimst.ac.in/ Fetched: 2/14/2023 5:40:00 AM	2
SA	Sree Chitra Tirunal Institute, Thiruvananthapuram / Sai Suraj Thesis edit.pdf Document Sai Suraj Thesis edit.pdf (D78220926) Submitted by: vtp@sctimst.ac.in Receiver: vtp.sctims@analysis.urkund.com	6
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i OUTCOMES OF MITRAL VALVE REPAIR IN CHILDREN WITH CONGENITAL/ACQUIRED MITRAL VALVE ANOMALY Dr. RAHUL SATHEESAN MCH CARDIOTHORACIC AND VASCULAR SURGERY THESIS YEAR: 2020-2023

100% **MATCHING BLOCK 1/9** **W**

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM An Institution of National Importance

established by an Act of the Indian Parliament (ActNo.52 of 1980) Dept. of Science and Technology, Govt. of India
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ii OUTCOMES OF MITRAL VALVE REPAIR IN CHILDREN WITH CONGENITAL/ACQUIRED MITRAL VALVE ANOMALY A THESIS SUBMITTED BY Dr. RAHUL SATHEESAN TO

100% **MATCHING BLOCK 2/9** **W**

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM

IN PARTIAL FULFILMENT OF THE REQUIREMENTS FOR THE AWARD OF MCH CARDIOTHORACIC AND VASCULAR SURGERY YEAR: 2020 – 2023

iii



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
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Institutional Ethics Committee

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

SCT/IEC/1973/NOVEMBER/ 2022

23.12.2022

Dr. Rahul Satheesan
Senior Resident
Department of CVTS
SCTIMST, Thiruvananthapuram

Dear Dr. Rahul Satheesan,

The Institutional Ethics Committee held on 19th November, 2022, reviewed and discussed your application to conduct the study titled "OUTCOMES OF MITRAL VALVE REPAIR AND REPLACEMENT IN CHILDREN WITH CONGENITAL / ACQUIRED MITRAL VALVE ANOMALY " (IEC/1973).

The following members of the Ethics Committee were present at the meeting held on 19th November, 2022

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Prof. C.C. Kartha	MBBS,MD	Male	Basic Medical Scientist (Chairman)	No
2.	Dr. Kala Kesavan P	MBBS,MD	Female	Basic Medical Scientist	No
3.	Smt. Sathi Nair	MA (English Literature)	Female	Lay Person	No
4.	Dr. Pradeep S	MBBS, MD	Male	Basic Medical Scientist	No
5.	Dr. Rejnish Kumar	MBBS,MD ,DNB	Male	Clinician	No
6.	Dr. Christina George	MD Psychiatry	Female	Clinician	No
7.	Dr. P. Manickam	BSMS, MSc (Epid),PhD	Male	Health Science Expert/ Social Scientist	No
8.	Adv. N Anand	BAL, L.LB	Male	Legal Expert	No
9.	Dr. Manikandan.S	MBBS,MD,PDCC	Male	Clinician	Yes
10.	Dr. Narayanan Namboodiri. K K	MBBS,MD,DM	Male	Clinician	Yes
11.	Dr. Biju Soman	MBBS,MD, DPH, MSc, DLSHTM	Male	Basic Medical Scientist	Yes
12.	Dr. Srinivas G	PhD	Male	Basic Medical Scientist (Member Secretary)	Yes

SCT/IEC/1973/NOVEMBER-2022

The following documents were reviewed:

Original submission

1. Checklist Form
2. Covering letter addressed to the Chairman, IEC, SCTIMST dated 16.09.2022
3. TAC Application Form
4. IEC Application Form
5. Declaration Form
6. Project Proposal
7. Proforma
8. Patient Information Sheet and Consent Form in English and Malayalam
9. Telephone Recruitment Script in English and Malayalam
10. Assent Form
11. CV of PI and Co-PIs
12. SRC Recommendation Letter

Revised submission

1. Checklist Form
2. Covering letter addressed to the Chairman, IEC, SCTIMST dated 18.12.2022
3. TAC Application Form
4. IEC Application Form
5. Declaration Form
6. Project Proposal
7. Participant Information Proforma
8. Participant Information Sheet and Consent Form in English and Malayalam
9. Telephone Recruitment Script in English and Malayalam
10. Assent Form
11. CV of PI and Co-PIs

IEC Decision

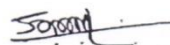
The IEC approved the conduct of the study in the present form.

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



								4+		NIL	NIL	NIL		56	2.12	38	2.38	61	9	12	51	5.03	1.3	0.8		5	3	8	10	
								3+		NIL	NIL	NIL		38	-0.51	26	0.38	61	5	7	30	2.27	1.2	0.8		10	4	18	7	
								3+		NIL	YES	NIL		38	-1.09	22	-1.42	73	4	10	34	2.73	0.8	0.8		4	5	6	6	
								3+		NIL	NIL	NIL		35	-0.47	24	0.44	61	6	9	24	1.2	1.6	0.5		8	4	6	4	



3+	1	0	34+RA	10*3	-12.10%	23.80%			
2+	1.2	0	30+RA	9*2	-16.00%	28.80%			
2+	0.9	1+	78+RA	14*5	-10.80%				
0	1.2	1+	21+RA	13*3	-18.70%	29.80%			

