Midterm results of Mitral valve repair for Degenerative Mitral Valve Regurgitation: A retrospective study

THESIS PROJECT
BY

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2015-2017

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DECLARATION

I hereby declare that this thesis entitled "**Midterm results of Mitral valve repair for Degenerative Mitral Valve Regurgitation: A retrospective study**" has been prepared by me under the supervision and guidance of **DR. VIVEK. V. PILLAI**, Additional Professor and **PROFESSOR JAYAKUMAR K.** Senior Professor and Head of Department of Cardiovascular and Thoracic surgery, SCTIMST, Thiruvananthapuram.

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ACKNOWLEDGEMENT

I would like to express my gratitude to all those who have contributed towards the completion of this thesis.

First and foremost, I offer my sincere acknowledgement and heartfelt
gratitude for my Professor, *Dr. Jayakumar K.* (Professor and Head, Department of CVTS, Sree Chitra Tirunal Institute for medical Sciences and Technology), for his keen interest, constant inspiration and encouragement throughout the study. Mere words are insufficient to express my profound indebtedness and deep gratitude to my teacher and Guide *Dr. Vivek V. Pillai*, Additional Professor, Department of CVTS, Sree Chitra Tirunal Institute for medical Sciences and Technology. His depth of knowledge, readiness to help, understanding attitude, concern for excellence, limitless patience, invaluable guidance and able supervision has enabled me to undertake and complete the work on this project.

I am grateful to *Dr. Vargheese T. Panicker* and *Dr. Bineesh K. R***.**, for their constant help, support and encouragement throughout the duration of my course. I am also deeply indebted to my teacher *Dr. Baiju S. Dharan*, *Dr. Sabarinath Menon*, *Dr. Sudip Dutta Baruah and Dr. Sowmya Ramanan V.* who constantly supported and encouraged me.

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No words will be enough to acknowledge the great help provided by my senior *Dr. Simon Philipose* and my dear colleagues *Dr. Abid Iqbal V.T. Dr. Nikhil P.K., Dr.Mahendranath*

S.P. for their constant encouragement and support. I would like to thank my colleagues and friends *Dr. Renjith S, Dr. Paritosh Ballal, Dr. Kartik K and Dr. Sirish P.*for their support throughout my study.

And above all I am most thankful to my family who have guided me throughout my life to achieve my goals.

Date: **Dr. Debabrata Gohain**

CONTENTS

INTRODUCTION

Introduction

With the evolving techniques over the years, mitral valve (MV) repair has been progressively adopted for patients with degenerative mitral regurgitation and at present it is considered as the gold standard for surgical correction of mitral regurgitation (MR). Advantages of MVr compared to valve replacement include improved early and late outcome, better quality of life, better survival, better freedom from thromboembolism, and better preservation of left ventricular function. [1] [2] [3]

Mitral regurgitation was first corrected with a posteromedial annuloplasty by Merendino et al. [4] in 1959. In 1968, Carpentier [5] developed the concept of prosthetic ring annuloplasty and later on gave the 'French correction' technique for surgical correction of posterior leaflet prolapsed [6]. Further studies showed that repair of degenerative mitral valve regurgitation offers a reduced operative mortality and a better event-free survival when compared to mitral valve replacement .

Degenerative mitral valve disease is the most common cause of mitral regurgitation. [7] Mitral regurgitation is divided into either primary (a structural or degenerative abnormality of the mitral valve apparatus) or secondary mitral regurgitation (a disease of the left ventricle, which interferes with the function and integrity of the mitral valve apparatus). [8] [9] [10]

In primary mitral regurgitation there is myxomatous degeneration of the mitral valve leaflets and elongated and redundant chordal apparatus. Thickened redundant leaflets will prolapse back into the left atrium causing malcoaptation of leaflet edges

and subsequent regurgitation. Rupture of chordal structures is not uncommon in patients with mitral regurgitation which will then cause a further increase in the severity of mitral regurgitation because of unsupported segments of the mitral valve leaflets. Other causes of primary mitral regurgitation include rheumatic disease, with rare causes being drug-induced mitral valve disease, healed infective endocarditis, and mitral regurgitation associated with systemic disease.

Surgical intervention with repair or replacement is indicated in patients with severe mitral regurgitation and symptoms of left ventricular dysfunction (ejection fraction of <60% or end systolic diameter >40 mm) [(9)] Surgical repair is the preferred treatment for patients with primary mitral regurgitation and is associated with better outcomes than mitral replacement. [(11) (12)] Mitral regurgitation can usually be repaired by either resection of the flail and prolapsing leaflet segment or by reconstructive techniques using artificial polytetrafluoroethylene chords. Annular dilation occurs secondary to the mitral regurgitation caused by the leaflet pathology and is most commonly corrected with a complete or partial annuloplasty ring. [(13)]

This retrospective observational study is undertaken for patients undergoing mitral valve surgery following degenerative mitral valve regurgitation in SCTIMST from the year Jan 2010 to Dec 2015.

AIMS AND OBJECTIVES

Aims and Objectives

The study objective is to use the information for assessing:

1) Patient's survival

2) Freedom from re operation for MR

3) Anticoagulant related hemorrhage/thromboembolism

4) Incidence of endocarditis

5) Progression of MR

6) Durability of repair of AML, PML, AML + PML, Annuloplasty alone

7) Variability in functional status of the patient with time.

REVIEW OF LITERATURE

Review of Literature

Anatomy of Mitral Valve

1) *Mitral annulus*

The term annulus is used to described the junctional zone which separates the left atrium and left ventricle, this also gives attachment to the mitral valve. [14] It is not a rigid fibrous ring but pliable, changing shape during the cardiac cycle. It is a non-planar saddle shaped structure (Figure 1) [15], the commissural diameter being larger than the anteroposterior diameter (i.e. through A2 and P2). The highest point of the annulus is at the middle of anterior leaflet which is adjacent to the aortic valve. The aortic valve is in fibrous continuity with the aortic mitral leaflet (anterior) and the right and left fibrous trigones. (Figure 2) [16] This region of the annulus is thus fibrous and less prone to dilatation. Beyond this point, the remaining two-thirds of the annulus are mainly muscular allowing it to move freely with myocardial contraction and relaxation. In significant mitral regurgitation, this region is often seen to dilate, as well as being more prone to calcification.

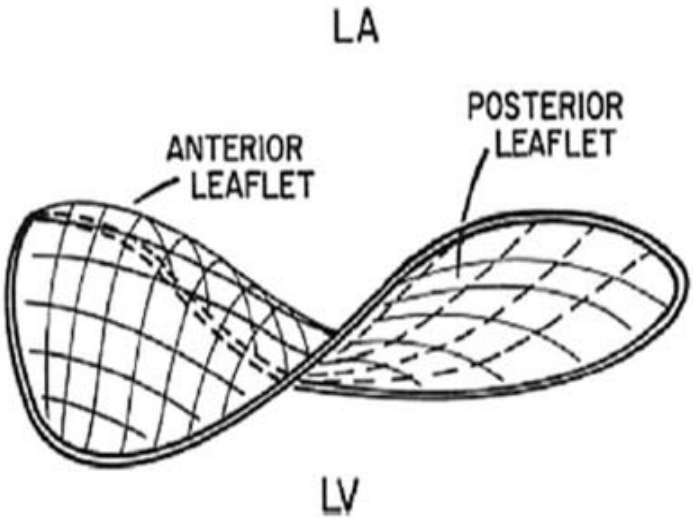

Fig 1: Mitral annulus

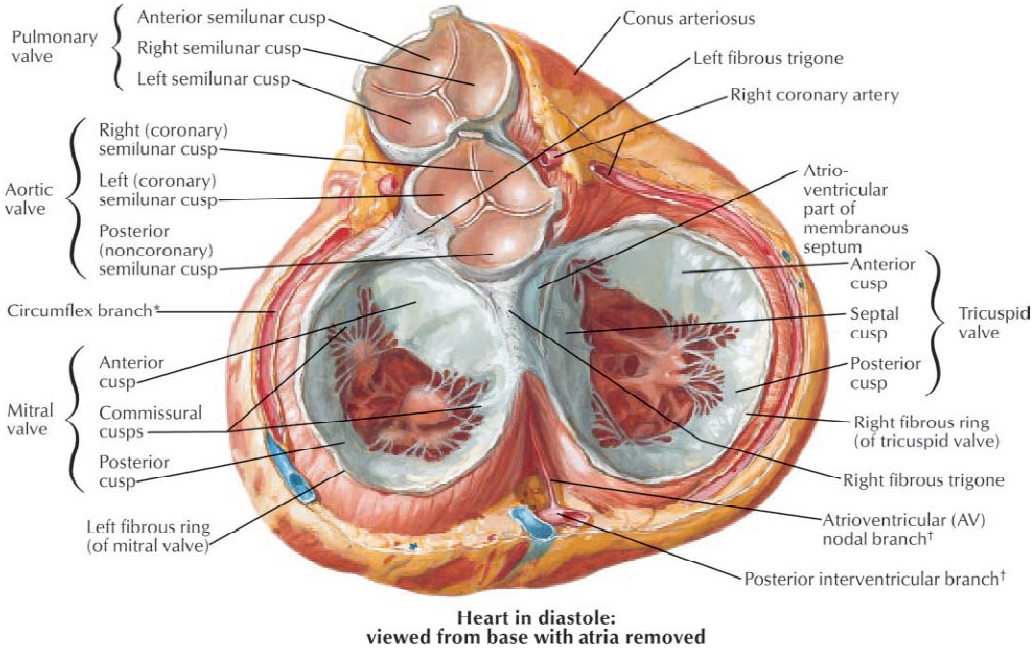

Fig 2: Relation of MV to Aortic valve and Fibrous trigone

2) Mitral valve leaflets

The MV comprises two leaflets, referred to as the anterior (aortic) and posterior (mural) leaflets [17]. The mural leaflet is narrow and extends two-thirds circumference of the mitral annulus. Its margin has two indentations which forms three scallops i.e. middle, posteromedial and anterolateral scallop. These indentations do not usually extend all the way through the leaflet to the annulus.

Carpentier's nomenclature [18] describes the most lateral segment as P1, P2 is central and most medial is P3 segment. There are two commissures, anterolateral commissure adjacent to P1 and posteromedial commissure next to P3 segment. The semicircular anterior leaflet of the MV comprises one third of the annular circumference, is broader than the posterior. It is in fibrous continuity with the left and non-coronary cusps of the aortic valve and with the interleaflet triangle between the aortic cusps that abuts onto the membranous septum [14] [19]. The anterior leaflet is also divided arbitrarily into three regions labeled A1, A2 and A3 corresponding to the adjacent regions of the posterior leaflet.

From the attachment point of each leaflet at the annulus to the free edge, the leaflet is described as having basal, clear and rough zones. The basal zone is described as the area where the leaflet connects to the atrioventricular junction. The thin central portion of the leaflet is the clear zone (Figure 3). The thick rough zone at the free edge of the leaflet is the main area of chordal attachment and the region of coaptation and apposition. [20]

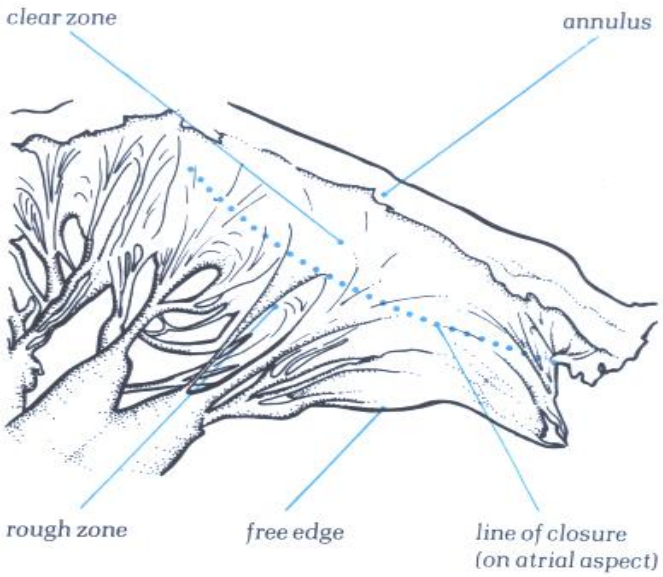

Fig 3: Mitral valve leaflet

3) Chordae tendinae

In the normal valve, the leaflets are attached to the papillary muscles via fan-shaped chords. There are three types of chordate tendinae depending on where they attach on the leaflet surface. (figure 4)

Primary chords attach to the free edge of the leaflets. Secondary chords attach to the ventricular surface of body of the leaflet, while tertiary chords attach directly to the ventricular wall and are found in the mural (posterior) leaflet only [(20).]

The posteromedial papillary muscle gives chords to the medial half of both leaflets (i.e. posteromedial commissure, P3, A3 and half of P2 and A2). Similarly, the

anterolateral papillary muscle chords attach to the lateral half of the MV leaflets (i.e. anterolateral commissure, A1,P1 and half of P2 and A2).

Among the secondary chords of the aortic (anterior) leaflet, there are two that are the largest and thickest which are termed strut cords, these arise from the tip of each papillary muscle and are thought to be the strongest. [14]

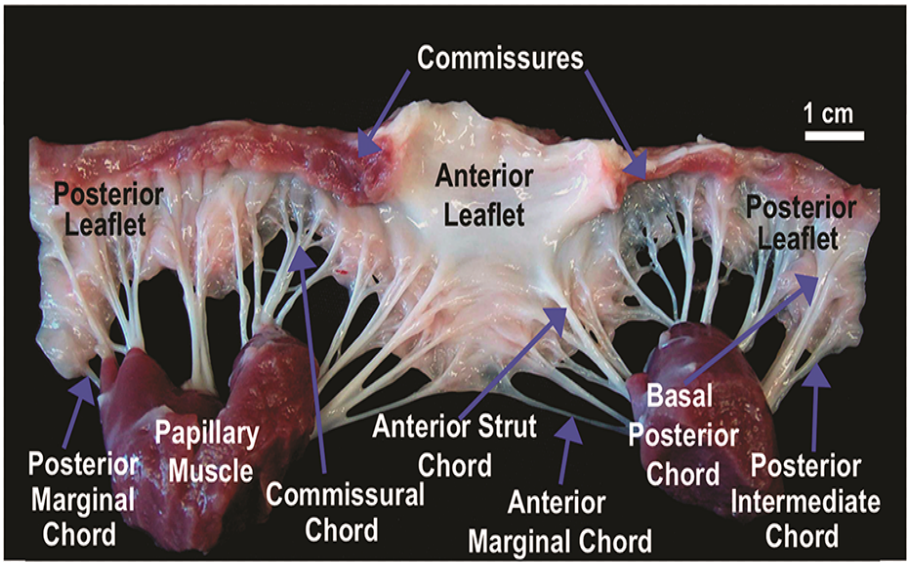

Fig 4: Chordae tendinae

4) Papillary muscles

There are two types of papillary muscle - anterolateral and posteromedial, which are positioned at mid to apical segments of the left ventricle. (Figure 5)

The anterolateral papillary muscle attach at the border of the anterolateral (lateral) and inferolateral (posterior) walls, and the posteromedial papillary muscle over the inferior wall of the left ventricle [21].

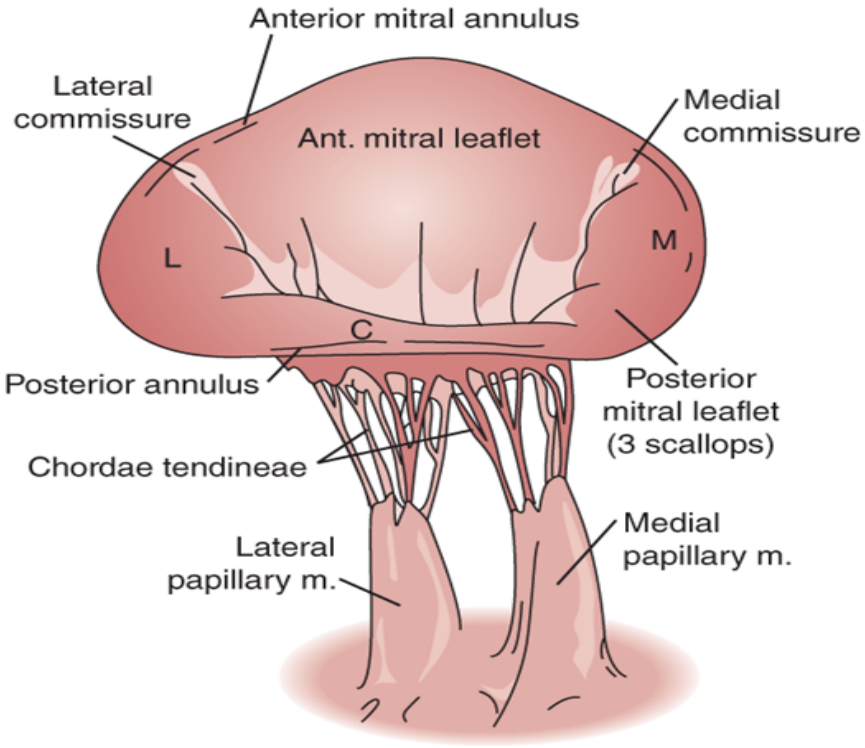

Fig 5: Papillary mucle

Classification of MR

A functional classification for the describing the underlying pathological changes that contributed to MR was developed by pioneering cardiac surgeon Alain Carpentier, MD, PhD.[17]

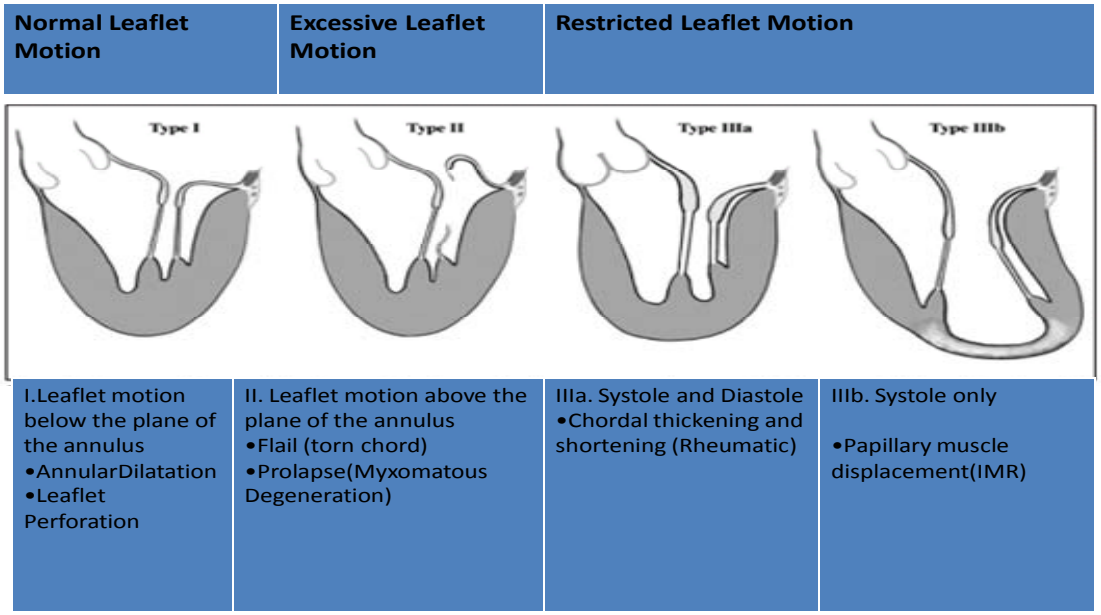

Fig 6: Types of MR: Carpentier Classification

As described in this classification (Figure 6), type I MR is characterized as normal leaflet motion but with annular dilatation or leaflet perforation;

type II lesions are related to leaflet prolapse and may be caused by myxomatous disease, such as chord rupture or elongation, or by papillary muscle rupture or elongation; and

type III lesions are caused by restricted leaflet motion.

- Type IIIA is typically caused by rheumatic valve disease with normal ventricular motion and subvalvular fibrosis and calcification;

- Type IIIB is typically caused by ischemic or idiopathic cardiomyopathy with impaired ventricular function and dilation but a “normal” morphology to the leaflets, chords, and papillary muscles, frequently with restriction at the P3 segment.

Degenerative Disease of the Mitral valve

Degenerative mitral valve disease is the most common cause of mitral regurgitation in Western countries. The main mechanism of mitral insufficiency is type II dysfunction (leaflet prolapse). [22] [23]

However, type I dysfunction with isolated annular dilatation has also been reported. Etiologies of degenerative mitral valve disease include fibroelastic deficiency, Barlow's disease, and Marfan's syndrome [24] [25]. In some cases the exact etiology remains undetermined.

Fibroelastic deficiency is most common in elderly patients with a relatively short history of mitral regurgitation. Valve analysis typically shows transparent leaflets with no excess tissue except in the prolapsing segment, and elongated, thin, frail, and often ruptured chordae. The annulus is often dilated and may be calcified. [24]

Barlow's disease appears early in life, and patients typically have a long history of a systolic murmur. The valve is billowing with typically thick leaflets and with marked excess tissue. The chordae are thickened and elongated, and may be ruptured. Papillary muscles are also occasionally elongated. The annulus is dilated and sometimes calcified. Histologically there is extensive myxoid degeneration with destruction of the normal three-layer leaflet tissue architecture. [24]

Marfan's syndrome with mitral regurgitation is characterized by excess leaflet tissue, which may be thickened (without myxoid degeneration), and a dilated annulus that is rarely calcified. [26]

Myxomatous Disease and Systolic Anterior Motion:

SAM can develop in patients with myxomatous MR when there is a reduction in the distance between the coaptation point and the septum. (Figure 7). This is typically caused by either a large posterior leaflet that pushes the coaptation point toward the septum or a very small annuloplasty ring with respect to the size of the elongated leaflets in patients with myxomatous disease. This may result in Left ventricular outflow tract obstruction, as well as residual MR [27].

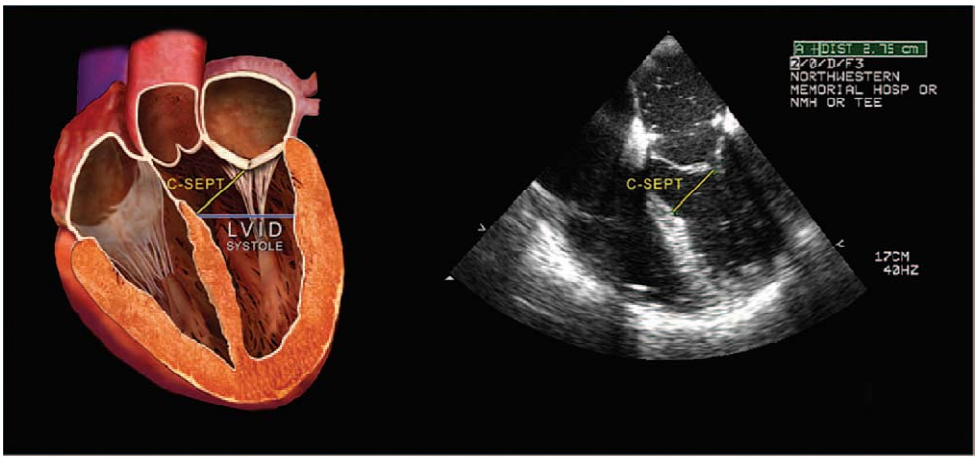

Fig: 7: Systolic anterior motion of Leaflet

C-SEPT: indicates distance from the coaptation point to the septum
LVID: left ventricular internal diameter.

SAM can be dealt by either complex leaflet reconstruction techniques such as sliding plasty or reduction of anterior leaflet height which are technically demanding, [28] or by use of large-diameter rings. [29] Certain rings e.g. Myxo ETlogix of Edwards Lifesciences are designed specifically for myxomatous disease to accommodate larger leaflets and move the coaptation point away from the septum. [30]

Surgical techniques:

The goals of valve repair (22) include preserving leaflet mobility, restoring a large surface of coaptation, and stabilizing the results with a remodeling annuloplasty

Valve Repair in Type I Dysfunction

Patients with type I dysfunction may have two different types of lesions. Annular dilatation is the most common lesion, which should be corrected with a complete rigid or semirigid remodeling annuloplasty. The second type of lesion is leaflet perforation, commonly seen in infective endocarditis and managed by patching.

Valve Repair in Type II Dysfunction

Posterior Leaflet Prolapse

Quadrangular resection with or without sliding plasty and Triangular resection –

Stay sutures are placed around the normal chordae to determine the prolapsed area. The prolapsed segment is then removed by performing a perpendicular incision to the free edge toward the annulus, thereby excising a quadrangular portion of the leaflet. Plication sutures are placed along the posterior annulus in the resected area. Finally, direct sutures of the leaflet remnants restore valve continuity. When the area of prolapsed is less extensive, the prolapsing area can be excised by triangular resection. Sliding plasty is done by partially detaching P_1 and P_3 from the annulus

(Figure 8). Multiple compression sutures are placed. P_1 and P_3 are translated medially to close the gap. Both segments are reapproximated to restore leaflet continuity, and a remodeling annuloplasty is performed. [31]

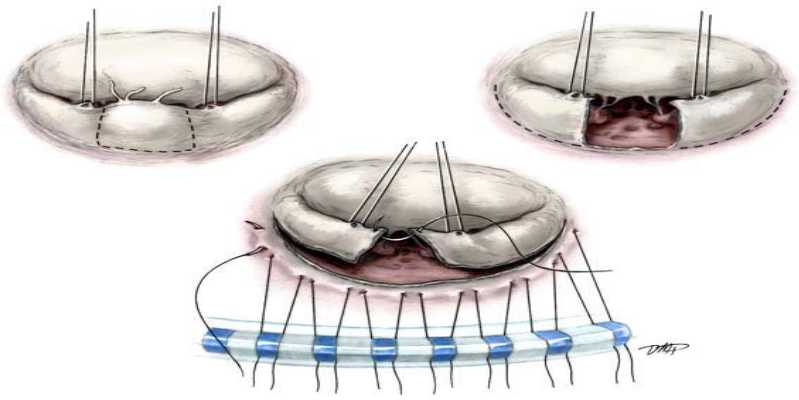

Fig 8: Quadrangular resection with sliding plasty

Anterior leaflet prolapse:

Triangular Resection –

Limited prolapse of the anterior leaflet with excess tissue can be treated by a small triangular resection of the prolapsed area, followed by direct closure with interrupted polypropylene sutures. [32] The triangular resection must not be extended to the body of the anterior leaflet as it reduces the coaptation area considerably and is incriminated as a risk factor for repair failure.

Chordal Transposition -

In the absence of normal secondary chordae, chordal transposition should be considered. If marginal chordae of the posterior segment opposite to the prolapsed area of the anterior leaflet are normal, they can be used for chordal transposition (Figure 9). This small segment is then detached and reattached to the free margin of the anterior leaflet at the site of prolapse. Interrupted sutures close the defect in the posterior leaflet. [33]

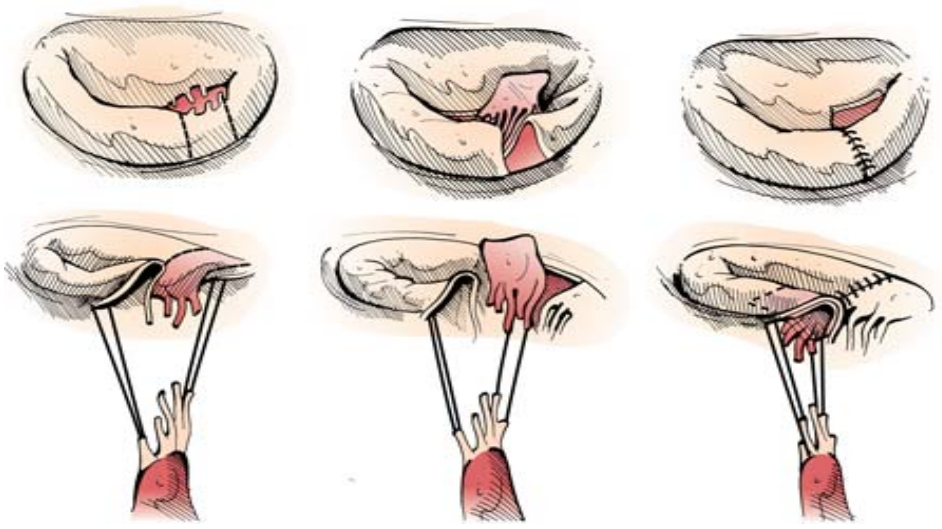

Fig 9: Chordal Transposition technique

Artificial Neochordae

This technique is particularly useful when the number of normal chordae is inadequate. The primary difficulty is determine the distance between the base of the papillary muscle and the free margin of the leaflet, in order to correct leaflet prolapse without causing leaflet restriction. According to the extent of leaflet prolapse, one or more 4–0 Gore-Tex sutures without pledgets are placed into the head of the papillary muscle. The Gore-Tex suture is now left aside while the leaflet reconstruction is performed. After ring annuloplasty, symmetrical leaflet apposition limits leaflet incompetence caused by the prolapsing anterior leaflet segment. Now both arms of the previously placed Gore-Tex suture are passed through the margin of the prolapsing leaflet segment (Figure 10). Optimal chordal height is achieved by intermittently testing valve competency with ventricular saline injections [33].

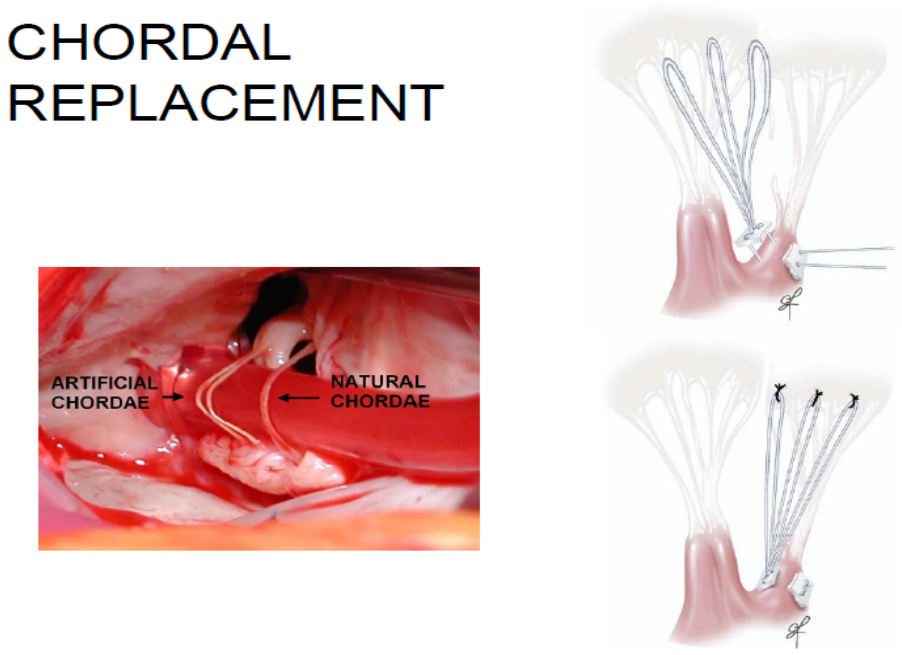

Fig 10: Neochordal reconstruction

Edge-to-Edge Approximation (Alfieri Repair)-

Alfieri's edge to edge technique effectively creates a double orifice mitral valve (Figure 11) and may be used to correct posterior, anterior or bileaflet prolapse. This technique involves suturing together anterior and posterior leaflets at a single point midway between the circumferences of the leaflets. [34]

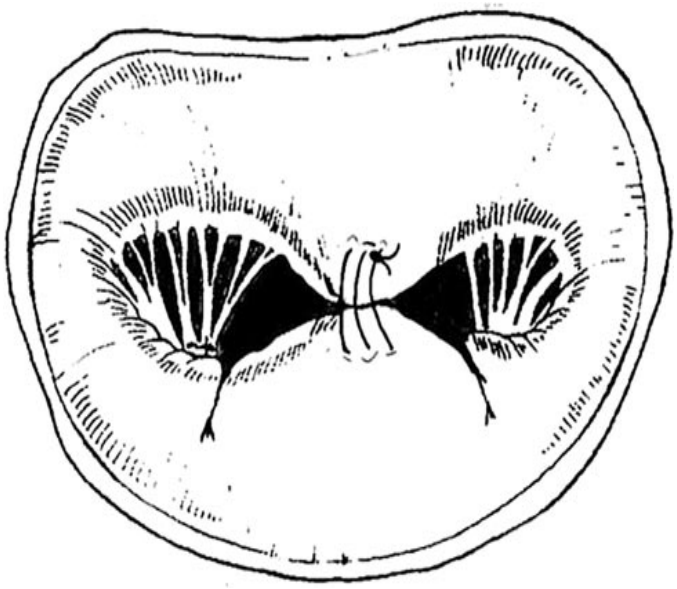

Fig 11: Alfieri Repair

Commissural Prolapse

Commissural prolapse is treated by resection of the prolapsed area and sliding plasty of the paracommissural area [33] (Figure 12).

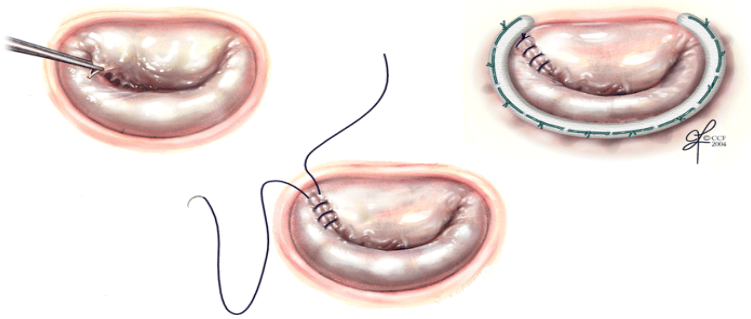

Fig 12: Commissuroplasty

Mitral Valve Repair in Type IIIA Dysfunction

In type IIIA dysfunction, correction of mitral regurgitation and adequate leaflet mobilization can be achieved by treating each type of lesion.

Leaflet restriction is often due to chordal thickening, retraction, and fusion. Resection of the secondary chordae can be done to increase leaflet mobility.

The fusion of marginal chordae is treated by chordal fenestration with removal of a triangular wedge of fibrous tissue.

Severe retraction of the posterior leaflet can be treated by detaching the posterior leaflet from the mitral annulus, and the secondary chordae are removed. Inserting a diamond-shaped segment of autologous glutaraldehyde-fixed pericardial patch between the posterior leaflet and the annulus restores posterior leaflet integrity. In the presence of commissural fusion, additional commissurotomy can be done.

Mitral Valve Repair in Type IIIB Dysfunction

Remodeling annuloplasty using an undersized ring is the technique of choice in type IIIB dysfunction [35]. (Figure 13)

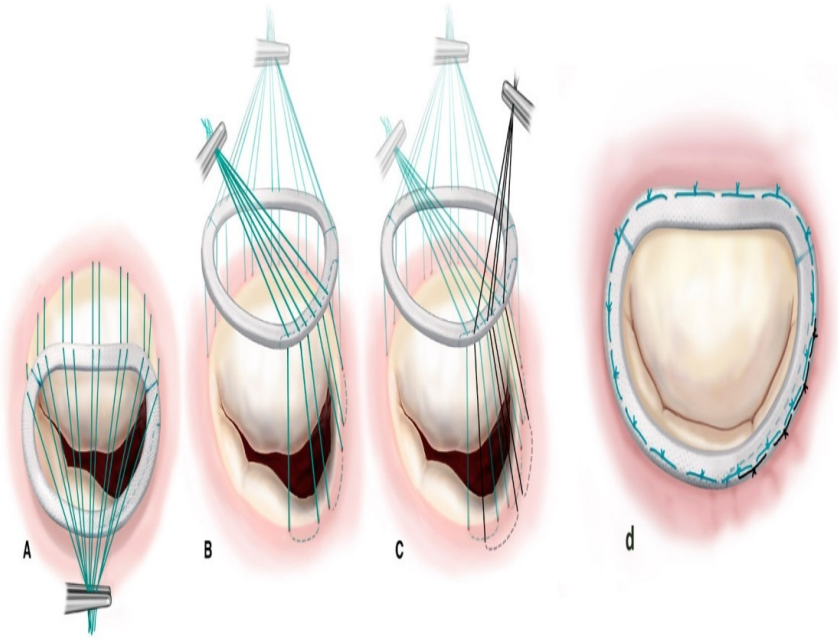

Fig 13: Remodeling annuloplasty

Annuloplasty rings

An ideal annuloplasty ring should be able to correct the abnormal dilatation of the posterior portion of the annulus, improve leaflet attachment, reinforce leaflet repairs and prevent further regurgitation,
while restoring the normal annular circumference and the dynamics of the annulus [36] (shape and size changes during the heart circle). (Figure 13)

Types of Annuloplasty rings:

- flexible,
- semi-rigid, or rigid,
- incomplete or complete,
- planar or saddle-shaped,
- adjustable and non-adustable.

Flexible bands are designed to maintain the three-dimensional contour of the native annulus and some of its natural dynamics.

The goal of *semi-rigid rings* is to maintain coaptation and valve integrity during systole, while allowing for good hemodynamics during diastole.

Rigid rings are designed to provide rigid support in large dilation.

Available Annuloplasty Rings

Edwards Lifesciences (Fig: 14)

- Carpentier-Edwards Classic Annuloplasty Ring
- Carpentier-Edwards Physio Annuloplasty Ring
- Carpentier-Edwards Physio II Annuloplasty Ring
- Carpentier-McCarthy-Adams IMR ETlogix Annuloplasty Ring
- GeoForm Ring
- Cosgrove-Edwards Annuloplasty System

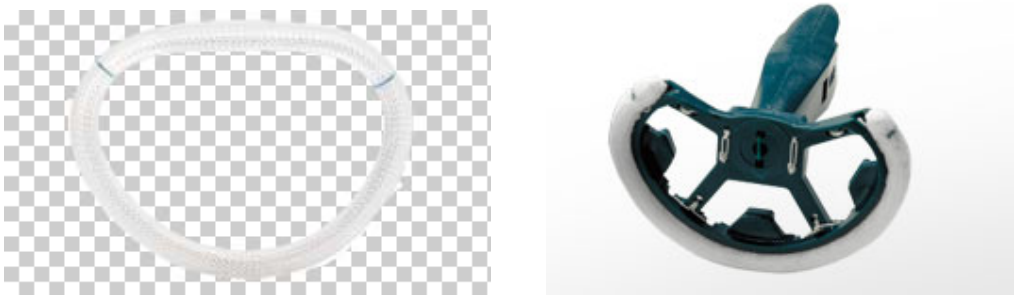

Fig: 14 Edwards Annuloplasty rings

St. Jude Medical (Fig: 15)

- St. Jude Medical Séguin Annuloplasty Ring
- St. Jude Medical Tailor Annuloplasty Ring
- St. Jude Medical Tailor Annuloplasty Band
- St. Jude Medical Rigid Saddle Ring

- St. Jude Medical Attune Annuloplasty Ring

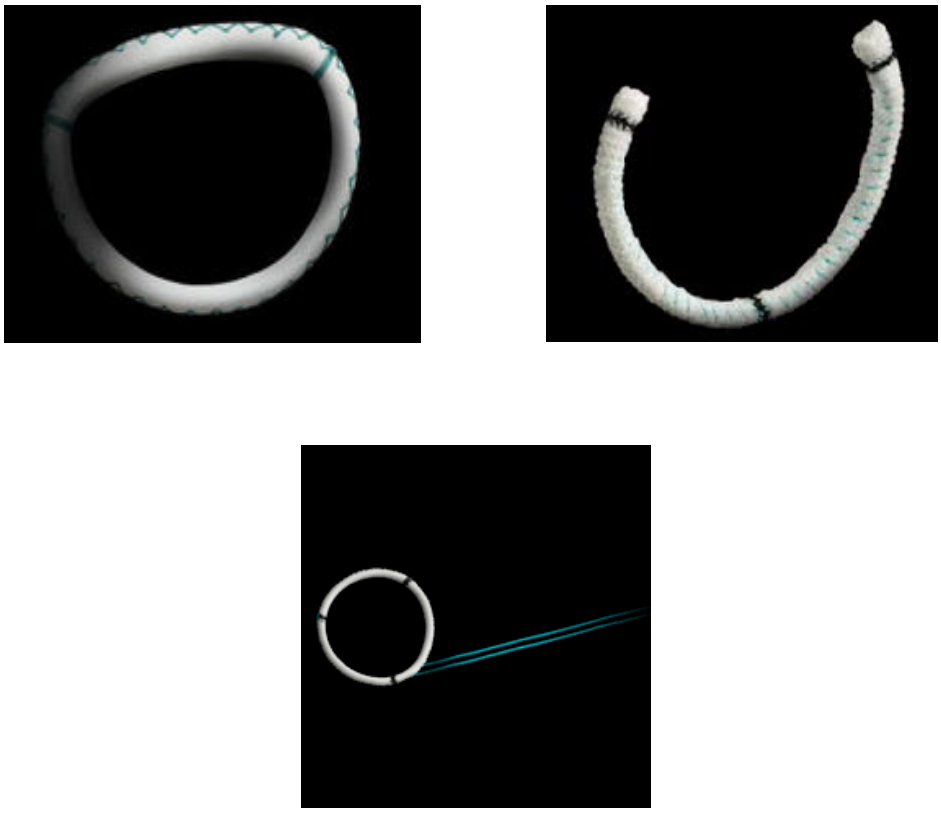

Fig: 15 St. Jude Medical Annuloplasty rings

Medtronic (Fig: 16)

- Profile 3D Ring
- CG Future Ring and Band System
- Duran AnCore Ring and Band System
- Simulus Adjustable Annuloplasty System
- Simulus Flexible Annuloplasty System
- Simulus Semi-Rigid Annuloplasty System

Fig: 16 Medtronic Annuloplasty rings

MATERIALS AND METHODS

Materials and Methods

Study group: Current study is a retrospective descriptive study. From Jan 2011 to Dec 2015, 167 patient with mitral regurgitation caused by degenerative disease underwent mitral valve repair at our centre. The patients were identified by initially going through SCTIMST information registry to isolate all patients having surgery for mitral regurgitation during this time frame. The patient's medical records were then reviewed in detail to select those having degenerative disease. The study group was further refined by selecting patients based on the inclusion and exclusion criteria's set for the study.

Inclusion criteria:

1. All patients undergoing MV Repair for degenerative mitral valve regurgitation in our institute between January 2010 to December 2015.

2. Age group 21 – 70 years.

Exclusion criteria:

1. Previous mitral surgery
2. Ischemic MR
3. Mitral valve stenosis
4. Any procedure other than mitral valve procedure

5. Patient who presented in cardiogenic shock (acute leaflet rupture)

6. Age group <20 years and >71 years

OBSERVATIONS AND RESULTS

Observation and Results

Patient's characteristics

A total of 167 patients had undergone mitral valve repair during the study period. From the 167 patients, 33 patients had rheumatic heart disease, 29 patients had associated coronary artery disease, 8 patients had undergone MV repair due to congenital heart disease, 16 patients had either associated severe AS/AR and 3 patients suffered from infective endocarditis. 81 patients fulfilled our criteria and were taken up for the study (figure 17).

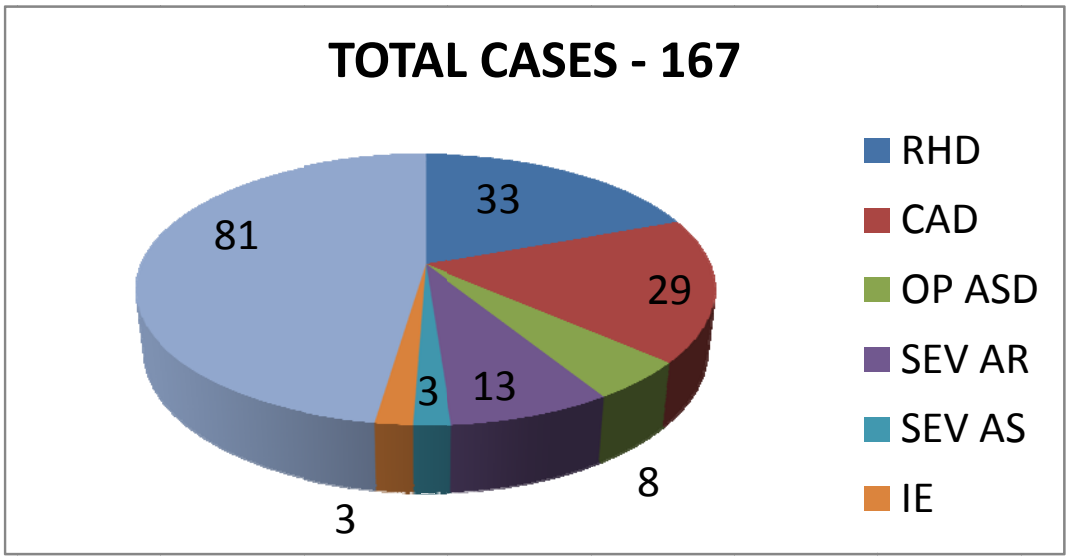

Fig 17: Case distribution

Table 1 : Preoperative patient data

Gendre	Male	60
	Female	21
NYHA Class	I	0
	II	5
	III	72
	IV	4
MR Grading	II	1
	III	8
	IV	72
Cardiac Rhythm		
	Sinus	71
	AF	10
Valve Affected		
	Isolated PML prolapse	57
	Isolated AML prolapse	15
	Bileaflet prolapse	9

Surgical Procedures:

Operations were performed through median sternotomy. Follwing aorto-bicaval cannulation patients were taken into cardiopulmonary bypass with moderate hypothermia (30-32*C). Myocardial protection obtained by cold antegrade root cardioplegia combined with topical cooling.

Mitral valve was exposed by standard left atriotomy. Valve analysis showed that 57 (70.3%) of the patients in the study group had posterior leaflet prolapse with rupture of one or more chordae and was the prevalent mechanism of MR. AML prolapse was noted in 15 (18.5%) patients while in 9 (11.1%) patients bileaflets were affected. Repair techniques that were undertaken were Quadrangular resection with or without sliding plasty, triangular resection, neochordal reconstruction, chordal transfer and Alfieri repair. Isolated PML repair was done for 53 (65.4%) patients, AML repair was done in 11 (13.6/%) patients and 4 (4.9%) patients underwent bileaflet repair. While commissuroplasty was done for 4 (4.9%) patients and annuloplasty alone in 9 (11.1%) patients (Fig 18**)**.

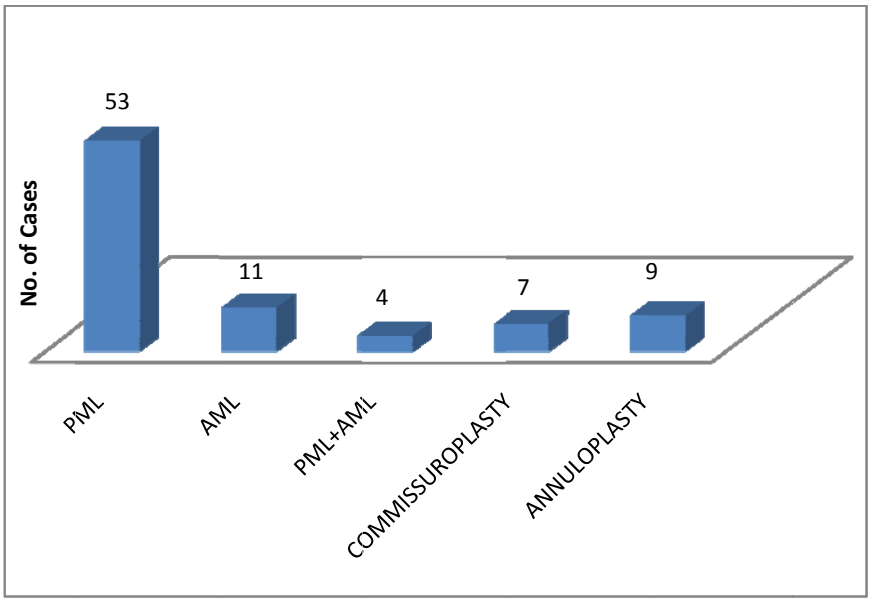

Fig 18: Types of repair

PML repair: The most common technique used was triangular resection (n=33), followed by quadrangular resection without sliding plasty (n=19) and with sliding plasty (n=1), neochordal reconstruction (n=3) (Fig 19).

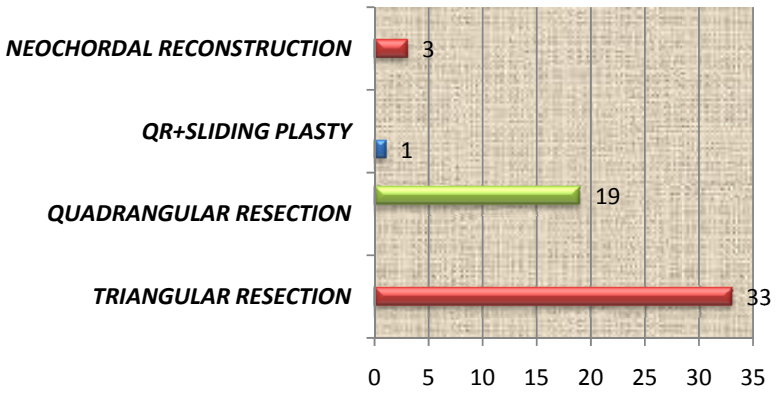

Fig: 19 Types of PML repair

AML repair: Neochordal reconstruction was done for 6 patients, 4 patients underwent chordal transfer technique while Alfieri repair was undertaken for 1 patient (Fig 20**).**

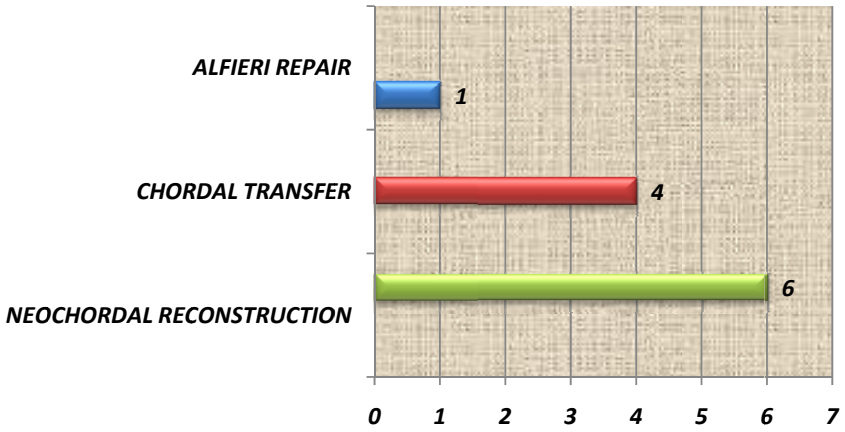

Fig 20: Types of AML repair

Prosthetic rings: Most commonly applied prosthetic ring was SJ Tailor complete flexible rings (n=43) followed by SJ Tailor incomplete flexible rings (n=3), SJ Tailor rigid ring (n=2), Duran Ancore ring (n=12), CE classic ring (n=9) and Saddle ring (n=8) (Fig 21).

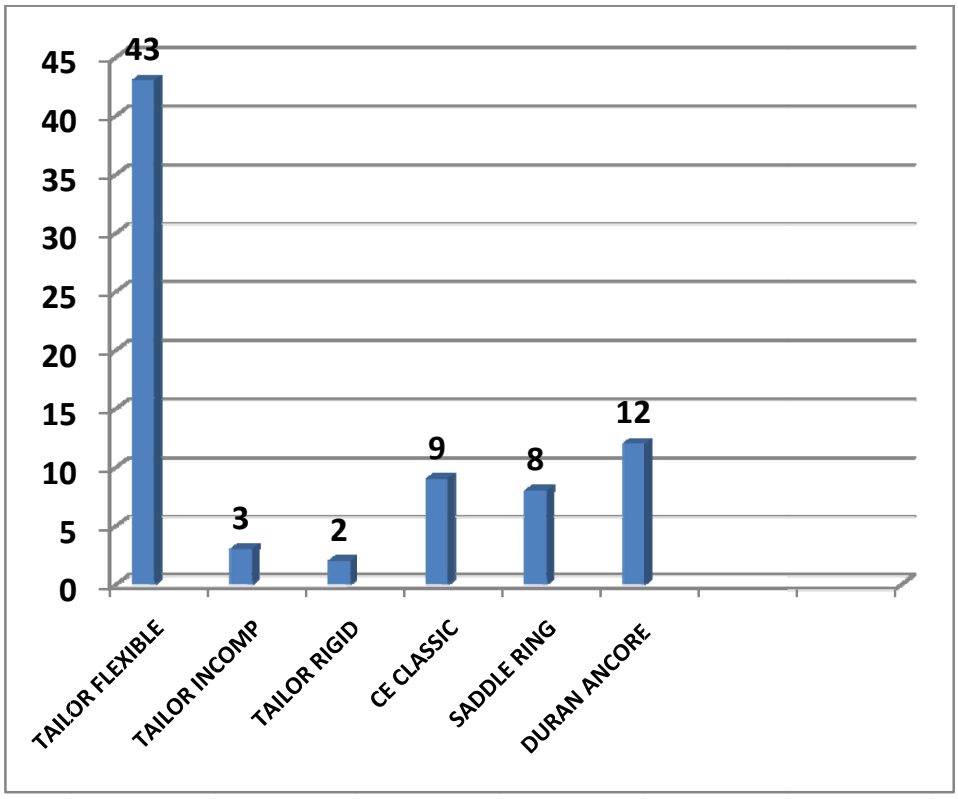

Fig 21: Types of Annuloplasty ring applied

Statistical Analysis:

Different patient variables have been analyzed from preoperative factors to post operative outcome. Statistical analysis was performed using dedicated software (SPSS® version 22.0). Continuous variables were presented as mean values ± standard deviation. Actuarial survival and freedom from reoperation were calculated by the Kaplan Meier method.

Results:

Progression of MR:

Post OP TEE findings showed that 15 patients had no MR following the procedure. Trivial MR (1+) was seen in 43 cases while 23 patients had mild MR (1-2+). Patients were followed up on yearly basis. At the end of five years it was noted that majority of the cases (n=40) had only trivial MR (1+), 17 patients had no MR, 16 patients had mild MR (1-2+) and only 8 patients had progression to moderate MR (3+). (Figure: 22)

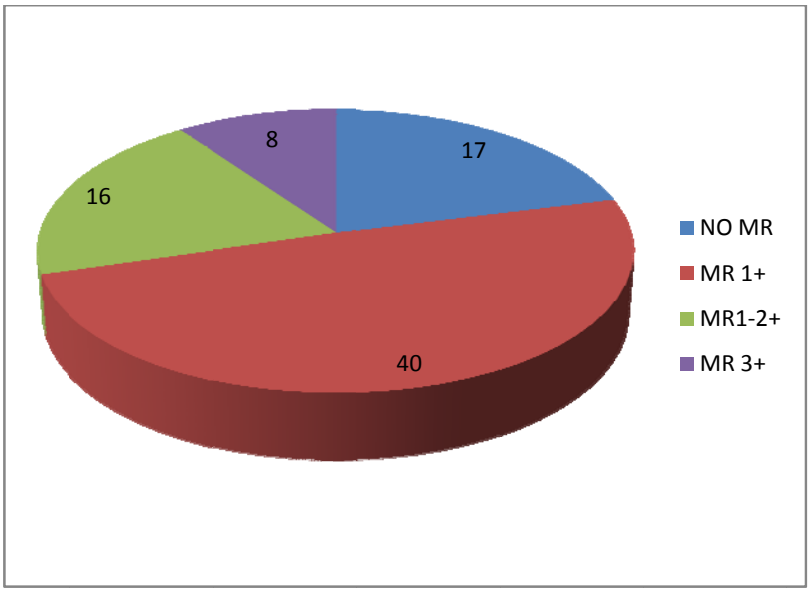

Fig 22: Progression of MR:

Progression of MR associated with Type of procedure:

In the present study it was noted that of 11 patients who underwent isolated Anterior mitral leaflet prolapse, 3 patients had progression to moderate MR (27.2%). For isolated Posterior mitral leaflet prolapse, out of 53 patients, 3 patient progressed to moderate MR (5.6%). In Bileaflet repair group 1 patient out of 4 had moderate MR (25%), while following Annuloplasty alone progression to moderate MR was seen in 1 patient out of 9 (11.11%). (Figure 23)

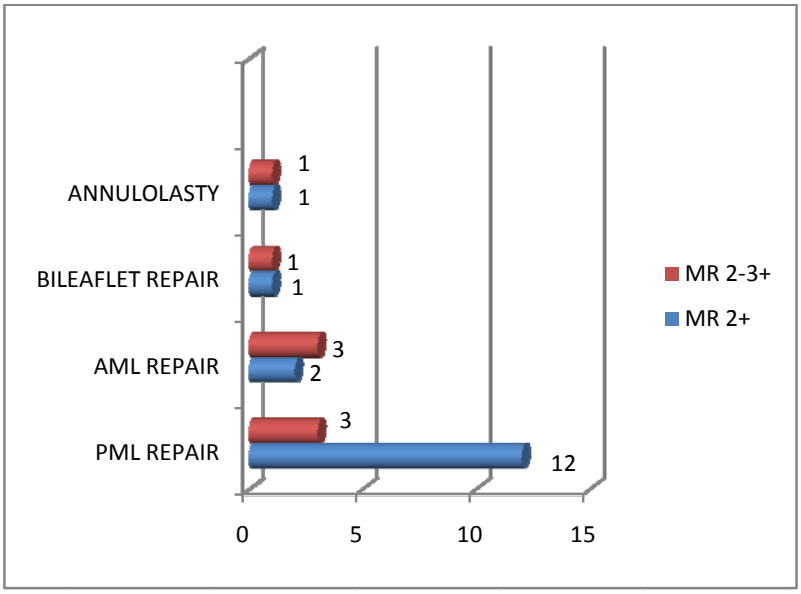

Fig: 23 Progression of MR associated with type of Procedure

Variability of Functional status of the patient with time:

Following MV repair, there was significant improvement in NYHA functional class from FC III – IV preoperatively to FC I – II in the post operative period. 78 patients (96.3%) remained in Functional class I – II in the post operative follow up

period, while worsening of symptoms with progression to Functional class III – IV was noted for 3 patients of whom one presented with severe MR and underwent redo surgery with MV replacement. One patient developed atrial fibrillation leading to palpitation and dyspnoea on exertion, while the third patient suffered from thromboembolism requiring emergency thromboembolectomy. (Fig: 24)

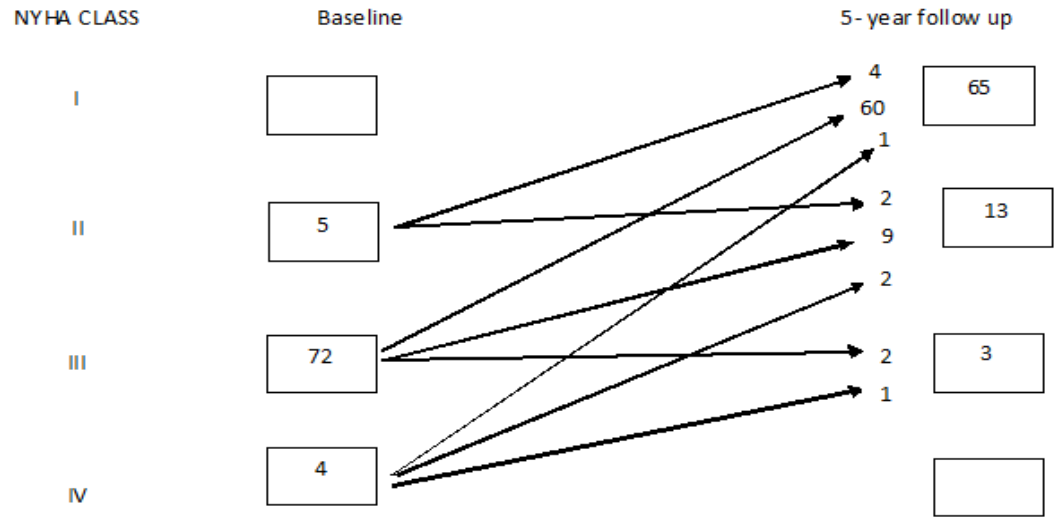

Fig: 24 Variability of Functional status

Cardiac Rhythm

Majority of the patient in the study were in Sinus rhythm prior to surgery (n=71) and also during the post op follow up period. They received Warfarin/Acitrom for a period of 3 months and then the medication was discontinued. One patient developed AF in the 5th postoperative month who was DC verted and rhythm was

reverted back to sinus. The remainining study population with AF (n = 10) were kept on Warfarin/Acitrom medication.

Incidence of Morbidity and Mortality:

There was no death noted in the study population during the follow up period.

One patient suffered from thromboembolism of Right iliac artery due to deranged INR, who was on Acitrom medication due to AF. The patient underwent Right transfemoral thromboembolecomy.

Incidence of CVA was noted for one case and was kept on medical management.

Incidence of Rehospitalisation:

During the follow up period, 4 patients were readmitted for the following indications (Figure 25).

1. One patient underwent redo surgery. He had initially undergone MV repair (chordal transfer + #27 tailor ring annuloplasty) for A2 and A3 prolapse following chordal rupture. Patient presented with worsening of symptoms (FC III) within six months. TTE showed P2 and P3 prolapse and slight buckling of annuloplasty ring end. Patient was taken up for MV replacement.

2. CVA occurred in one case. He was admitted in the neurology department and kept on medical management.

3. One patient was admitted due to thromboembolism of Right iliac artery and underwent Right transfemoral thromboembolecomy.
4. One patient who was in sinus rhythm preoperatively developed AF in the 5th post operative month. Patient was admitted due to increasing palpitation and DC verted following which he remained in sinus rhythm.

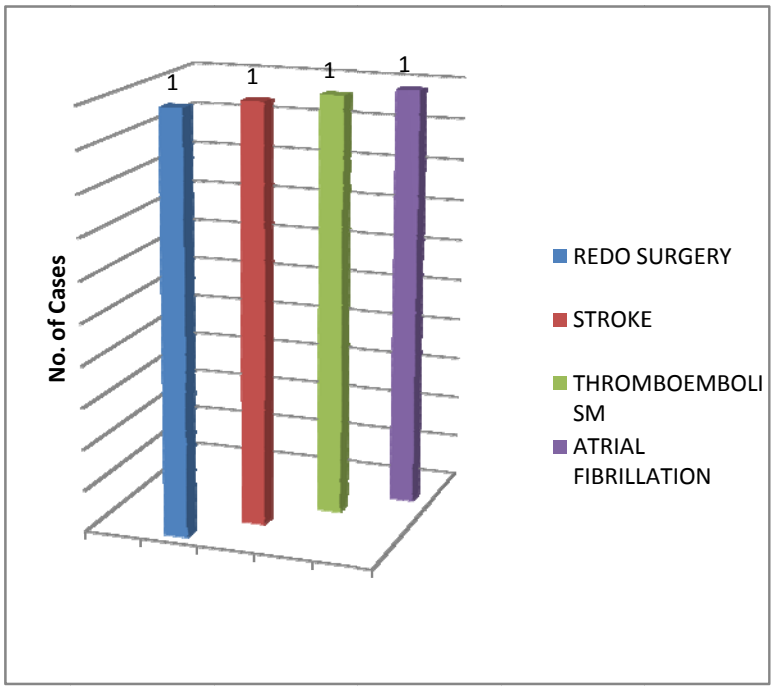

Fig: 25 Incidence of Rehospitalisation

DISCUSSION

Discussion:

Freedom from Progression of MR:

In the present study we found that majority of the patients during the five year follow up had trivial MR (1+), 17 patients had no MR, 16 patients had mild MR (1-2+) and only 8 patients had progression to moderate MR (3+). Our freedom from progression to severe MR was 90%. Nardi et al. [37] showed that in their series of 10 year follow up freedom from progression to severe MR was 85%, while a study by Gaur et al. [38] reported it to be 98.5%.

11 patients who underwent isolated Anterior mitral leaflet prolapse, 3 patients had progression to moderate MR (27.2%). For isolated Posterior mitral leaflet prolapse, out of 53 patients, 3 patient progressed to moderate MR (5.6%). In Bileaflet repair group 1 patient out of 4 had moderate MR (25%), while following Annuloplasty alone progression to moderate MR was seen in 1 patient out of 9 (11.11%). Thus according to our study, the freedom from recurrent moderate to severe MR was 72.8% with AL prolapse, 94.4% after PL prolapse, and 75% following bileaflet repair. Similar results were found in study done by David TE et al. [39] where freedom from severe recurrent MR at 12 years was 86% for patients with AL prolapse, 92% for patients with PL prolapse, and 86% for patients with BL prolapse. A study by De Bonis et al [40] found freedom from recurrent severe MR at 97.8 % for patients with AL prolapse and 100% for patients with PL prolapse at 15 years follow up.

Freedom from Reoperation:

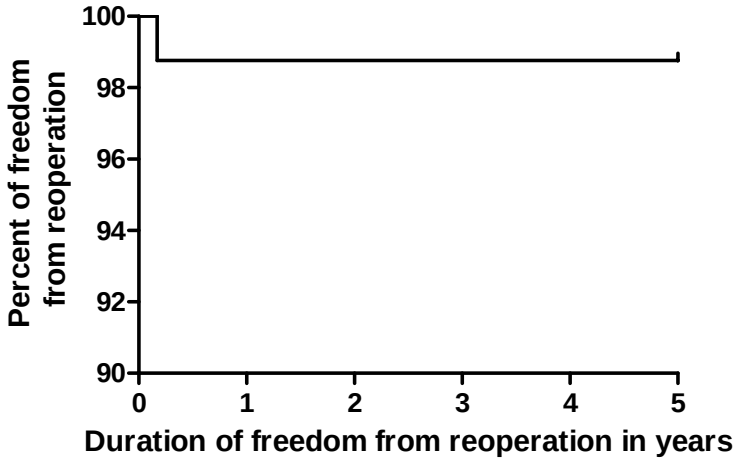

Fig: 26 Freedom from Reoperation:

Our study showed a freedom from reoperation of 98.7% (Mean duration of freedom from reoperation= 4.94±0.06 years) with only one patient undergoing redo surgery within the 5 year study period (Fig. 26). Similar results were also reflected in other study groups like Nardi et al. [37] (95%), Gaur et al. [38] (96%). A systematic review of 'Longterm outcomes of Mitral Valve Repair Versus Replacement for Degenerative Disease done by McNeely et al. [41] showed that results of freedom from reoperation following MV repair were comparable to the present study with findings of Mohty et al., Zhou et al. and Gillinov et al. being 93%, 97.6% and 94 % respectively.

Freedom from Thromboembolic events:

Two patients of our study group suffered from thromboembolic episodes during the five year study period. One patient suffered from Right iliac artery thromboembolism requiring emergency transfemoral thromboembolectomy and the other patient had an episode of CVA requiring medical management. The Freedom from Thromboembolic events was 97.53% in the present study (Mean duration of freedom from thromboembolic event = 4.94±0.07 years). A study by Seeburger J et al. [42] showed Freedom from Thromboembolism of 97.6% during a 5 year study following MV repair. Similar findings were seen in the study conducted by Nardi et al. [37] (98%) and of Gaur et al. [38] (97.7%) . (Fig. 27)

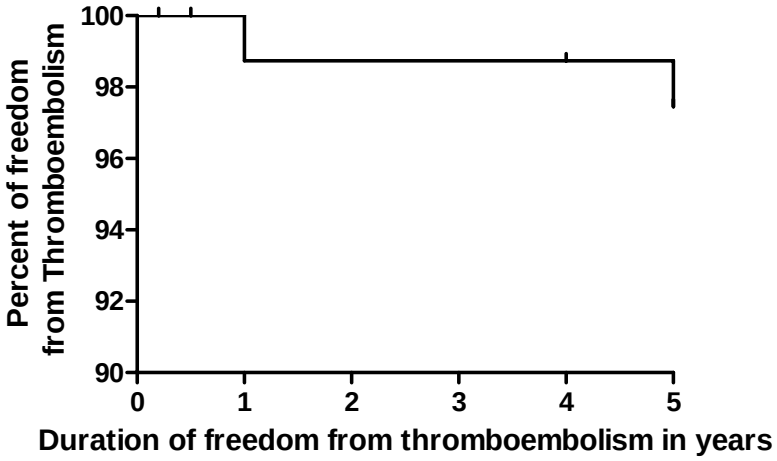

Fig: 27 Freedom from Thromboembolism

Freedom from Infective Endocarditis:

None of the patient in our study group suffered from infective endocarditis during the follow up period. Similar result had been noted in a study conducted by David TE et al. [39] who found freedom from infective endocarditis to be 99% in his study group.

Survivability :

There has been no mortality recorded in the present study. The overall survival rate following MV repair as documented in various other studies are similar to our study. In the 12 year study by Gillinov et al. [43] survivability was 95%. In the study by Gaur et al. [38] was 96.4%, confirming that post operative survival is satisfactory after MV repair.

The current study is a single centre experience regarding surgical repair of mitral valve. Our centre is apex centre for cardiac disease with skills and excellence gained over 40 yrs. The outcome analysis shows excellent and promising results and our results substantiates the results over worldwide.

Our study indicates that progression to moderate MR was more following AML repair in comparison to PML repair. We also found that freedom from re operation was less after AML repair. But due to small sample of study, these findings cannot be statistically proved.

We found that there was significant improvement in NYHA functional class from FC III – IV preoperatively to FC I – II in the post operative period in 96.3% of the study population. Also there was less incidence of morbidity e.g. stroke or other major thromboembolic events. There were no incidence of Infective endocarditis or death noted in this study.

Limitations of the study

This study was mainly retrospective invoving only one centre. The patient volume was low because of which the strength of the statistical analysis is low.

CONCLUSION

Conclusion

With the constant evolution of better techniques of repair for mitral valve, it has become a low risk and durable surgical procedure. Due to its low incidence of post operative morbidity and mortality, MV repair can be considered as the first line of surgical intervention in patients with degenerative mitral valve diseases.

REFERENCES

REFERENCES

1. Paolo Nardi, Antonio Pellegrino, Antonio Scafuri, et al: Survival and durability of mitral valve repair surgery for degenerative mitral valve disease. J Card Surg 2011;26:360-366

2. Grigioni F, Tribouilloy C, Avierinos JF, et al: Outcomes in mitral regurgitation due to flail leaflets a multicenter European study. J Am Coll Cardiol Imaging 2008;1:133-141.

3. Zhou YX, Leobon B, Berthoumieu P, et al: Long-term outcomes following repair or replacement in degenerative mitral valve disease. Thorac Cardiovasc Surg 2010;58:415-421.

4. Merendino K, Thomas G, Jesseph J. The open correction of rheumatic mitral regurgitation and/or stenosis with special reference to regurgitation treated by posteromedial annuloplasty utilizing a pump-oxygenator. Ann Surg 1959;150:5—22.

5. Carpentier A. A new technique of reconstructive mitral valvuloplasty. Presse Med 1969; 77:251—3.

6. Carpentier A, Relland J, Deloche A, et al. Conservative management of the prolapsed mitral valve. Ann Thorac Surg 1978;26:294-302.

7. A. Marc Gillinov, Delos M. Cosgrove, Eugene H. Blackstone, et al. Durability of mitral valve repair for degenerative disease. J Thorac Cardiovasc Surg 1998;116:734-43.

8. Rick A Nishimura, Alec Vahanian, Mackram F Eleid, et al: Mitral valve disease—current management and future challenges. The Lancet, Volume 387, Issue 10025, 26 March–1 April 2016, Pages 1324-1334.

9. Vahanian A, Alfi eri O, Andreotti F, et al, and the Joint Task Force on the Management of Valvular Heart Disease of the European Society of Cardiology, European Association for Cardio-Thoracic Surgery. Guidelines on the management of valvular heart disease (version 2012). Eur Heart J 2012; 33: 2451–96.

10. Nishimura RA, Otto CM, Bonow RO, et al. 2014 AHA/ACC guideline for the management of patients with valvular heart disease: a report of the American College of Cardiology/American Heart Association Task Force on practice guidelines. Circulation 2014; 129: e521–643.

11. Jokinen JJ, Hippelainen MJ, Pitkanen OA, Hartikainen JE. Mitral valve replacement versus repair: propensity-adjusted survival and quality-of-life analysis. Ann Thorac Surg 2007; 84: 451–58.

12. Moss RR, Humphries KH, Gao M, et al. Outcome of mitral valve repair or replacement: a comparison by propensity score analysis. Circulation 2003; 108 (suppl 1): II90–97.

13. Seeburger J, Falk V, Borger MA, et al. Chordae replacement versus resection for repair of isolated posterior mitral leaflet prolapse: a egalite. Ann Thorac Surg 2009; 87: 1715–20

14. Karen P. McCarthy. Anatomy of the mitral valve: understanding the mitral valve complex in mitral regurgitationEuropean Journal of Echocardiography (2010) 11, i3–i9

15. Jacob P. Dal-Bianco, MD. Anatomy of the Mitral Valve Apparatus – Role of 2D and 3D Echocardiography. Cardiol Clin. 2013 May; 31(2)

16. Ormiston JA, Shah PM, Tei C, Wong M. Size and motion of the mitral valve annulus in man. I. A two-dimensional echocardiographic method and findings in normal subjects. Circulation 1981;64:113–120.

17. Angelini A, Ho SY, Thiene G, Anderson RH. Anatomy of the mitral valve. In: Boudoulas H, Wooley CF, eds. Mitral Valve: Floppy Mitral Valve, Mitral Valve Prolapse, Mitral Valve Regurgitation. 2nd ed. NY: Futura Publishing Company; 2000. p5–29.

18. Carpentier AF, Lessana A, Relland JY, Belli E, Mihaileanu S, Berrebi AJ, Palsky E, Loulmet DF. The 'physio-ring': an advanced concept in mitral valve annuloplasty. Ann Thorac Surg 1995;60:1177–85; discussion 1185–6.

19. Silver MD, Gotlieb AI, Schoen FJ. Cardiovascular pathology. In: Silver MM, Silver MD, eds. Examination of the Heart and of Cardiovascular Specimens in Surgical Pathology. 3rd ed. Churchill Livingstone Publishers; New York, Edinburgh; 2001.

20. Lam JHC, Ranganathan N, Wigle ED, Silver MD. Morphology of the human mitral valve: chordae tendineae: a new classification. Circulation 1970;41:449–58.

21. Rusted IE, Scheifley CH, Edwards JE. Studies of the mitral valve. I. Anatomic features of the normal mitral valve and associated structures. Circ 1952;6:825–31.

22. Carpentier A. Cardiac valve surgery: the “French correction.” *J Thorac Cardiovasc Surg*. 1983;86:323–337.

23. Cohn LH, Couper GS, Aranki SF, et al: The long-term results of mitral valve reconstruction for the “floppy” valve. *J Card Surg* 1994; 9(suppl 2):278-281.

24. Carpentier A, Chauvad S, Fabiani JN, et al: Reconstructive surgery of mitral valve incompetence: Ten-year appraisal. *J Thorac Cardiovasc Surg* 1980; 79(3):338-348.

25. Carpentier AF, Pellerin M, Fuzellier JF, et al: Extensive calcification of the mitral valve anulus: Pathology and surgical management. J Thorac Cardiovasc Surg 1996; 729–730, 111(4):718-729.

26. Fuzellier JF, Chauvaud SM, Fornes P, et al: Surgical management of mitral regurgitation associated with Marfan’s syndrome. *Ann Thorac Surg* 1998; 66(1):68-72.

27. Fedak et al. Evolving Concepts and Technologies in Mitral Valve Repair. Circulation.; 117:963-974.

28. Quigley RL. Prevention of systolic anterior motion after repair of the severely myxomatous mitral valve with an anterior leaflet valvuloplasty. Ann Thorac Surg.; –182, 80:179

29. Adams DH, Anyanwu AC, Rahmanian PB, Abascal V, Salzberg SP, Filsoufi F. Large annuloplasty rings facilitate mitral valve repair in Barlow's disease. Ann Thorac Surg. 2006; –2100., 82:2096

30. McCarthy PM, McGee EC, Rigolin VH, Zhao Q, Huskin AL, Subacius H, Underwood S, Kane BJ, Mikati I, Bonow RO. Initial clinical experience with Myxo-ETlogix mitral valve repair ring. J Thorac Cardiovasc Surg.

31. Lawrence H. Cohn. Mitral Valve Repair. Operative techniques in Thoracic and cardiovascular surgery, Vol 3, No 2, 1998: pp 109 - 125

32. Grossi A, LaPietra A, Galloway AC, et al: History of mitral valve anterior leaflet repair with triangular resection. *Ann Thorac Surg* 2001; 72(5):1794-1795.

33. Duran CM et al. Surgical techniques for the repair of anterior mitral leaflet prolapse. J Card Surg. 1999 Nov-Dec;14(6):471-81

34. Alfieri O, Maisano F, De Bonis M, Stefano PL, Torracca L, Oppizzi M, La Canna G. The double-orifice technique in mitral valve repair: a simple solution for complex problems. *J Thorac Cardiovasc Surg*.2001;122:674–681.

35. MA Acker et al.: Mitral-Valve Repair versus Replacement for Severe Ischemic Mitral Regurgitation. N Engl J Med 2014; 370:23-32

36. Apostolos D. Bisbos et al. Mitral Valve Regurgitation: Surgical Treatment. Hellenic J Cardiol 44: 418-426, 2003

37. Nardi et al. Survival and Durability of Mitral Valve Repair Surgery for Degenerative Mitral Valve Disease. J Thorac Cardiovasc Surg,2011;26:360-366

38. Gaur et al. Mitral valve repair versus replacement in the elderly: Short-term and long-term outcomes. J Thorac Cardiovasc Surg, 2014 ;148:1400-6
39. David TE. A comparison of outcomes of mitral valve repair for degenerative disease with posterior, anterior, and bileaflet prolapsed. J Thorac Cardiovasc Surg, 2005, vol. 130 (pg. 1242 – 1249).
40. De Bonis M. Similar long-term results of mitral valve repair for anterior compared with posterior leaflet prolaps, J Thorac Cardiovasc Surg, 2006, vol. 131 (pg. 364 – 370).
41. McNeely et al. Longterm outcomes of Mitral Valve Repair Versus Replacement for Degenerative Disease. Curr Cardiol Rev. 2015 May; 11(2): 157–162.
42. Seeburger J et al. Minimal invasive mitral valve repair for mitral regurgitation: results of 1339 consecutive patients.Eur J Cardiothorac Surg. 2008 Oct;34(4):760-5
43. Gillinov et al. Durability of mitral valve repair for degenerative disease. J Thorac Cardiovasc Surg 1998;116:734-43

PROFORMA

Midterm results of MV Repair for Non rheumatic degenerative Mitral valve regurgitation

Sl No.

Diagnosis:

Procedure:

Type of Annuloplasty ring:

Date of Surgery:

Number of Reoperations:

Date of Follow up:

Clinical Examination Findings:	(Yes)	(No)
Dyspnea on Exertion -		
Angina -		
Fatiguability -		
Functional class (I-IV) -		
Heart Rhythm (SR/AF) -		

Use of Anticoagulants(Yes/No) -

Total number of hospitalization for deranged INR-

Any incidence of	(Yes)	(No)
Stroke -		
TIA -		
Hematuria -		

Hematoma -

Pre Op ECHO findings:

Post Op ECHO findings:

MR Grade -

Ejection fraction-

Incidence of Infective Endocarditis (Yes/No):

Technical Advisory Committee (Clinical Studies)

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

TAC Registration No: SCT-/S/2016/480 **Date: 17.05.2016**

Project title: Midterm results of Mitral valve repair for Degenerative Mitral Valve Regurgitation: A retrospective study.

Principal Investigator:
Name: Dr. Debabrata Gchain, Senior Resident, Department of CVTS, SCTIMST Degree: M.S. (General surgery), M.B.B.S.
Co-Principal Investigator(s)
(1) Name: Dr. Vivek V. Pillai, Associate Professor, Department of CVTS, SCTIMST Degree: M.Ch CVTS , M.S. (General surgery), M.B.B.S.
(2) Name: Dr. Jayakumar K, Head and Senior Professor, Department of Cardiovascular and Thoracic surgery, SCTIMST Degree: M.Ch. (Cardiothoracic surgery), M.S. (General Surgery), M.B.B.S.

Members who participated in the TAC meeting on 07/05/2016
Dr. Rupa Sreedhar (Chairperson)
Dr. Prasantakumar Dash
Dr. Mathew Abraham
Dr. Sankara Sarma P.
Dr. Ashalatha R
Dr. Krishna Kumar K
Dr. Syam. K
Dr. Bijulal S
Dr. Jayadevan E.R.
Dr. K. Shivakumar (Member Secretary)

Dr. Krishnakumar, Dr.Mathew Abraham, Dr. Syam, and Dr Jayadevan stayed away from the proceedings when the projects in which they are involved (# 468, 475, 476, 481, 485, 471, 477, 490,478, 479, 489,) as investigators were discussed.

Risk Classification of the project (Minimum/ Moderate/ High): Minimum
Requirement of DSMB: No
Recommended members of DSMB: Not applicable

Recommendations of TAC:
Recommended for consideration of IEC in the light of the responses received from the investigator

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

Signature of the Member Secretary, TAC (Clinical Studies)

Note for IEC
Copy of the investigator's responses to questions/suggestions from TAC is attached (Appendix-**1**).

25

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
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Institutional Ethics Committee
(IEC Regn No. ECR/189/Inst/KL/2013)

SCT/IEC/931 /JUNE -2016 09.06.2016

Dr. Debabrata Gohain
Senior Resident
Department of CVTS
SCTIMST, Thiruvananthapuram

Dear Dr. Debabrata Gohain,

Thank you for submitting documents related to your proposal titled "MIDTERM RESULTS OF MITRAL VALVE REPAIR FOR DEGENERATIVE MITRAL VALVE REGURGITATION: A RETROSPECTIVE STUDY"(IEC/931) to the IEC for review.

List of Documents

1. Covering letter addressed to the Chairperson, IEC, SCTIMST, with check list dated 17.05.2016
2. TAC Approval Letter
3. IEC Application Form
4. Project Proposal
5. Protocol
6. Declaration Form
7. CV of Principal Investigator and Co- Investigators

IEC Recommendations

1. The abbreviations used in the title should be expanded.
2. A list of all abbreviations used and their expanded names should be appended.

One set of all the documents including those revised may be submitted. The covering letter should indicate the revisions made.

Sincerely,

Mala Ramanathan
Member Secretary, IEC

ABBREVIATIONS

1. MV - Mitral Valve
2. MVr - Mitral Valve Repair
3. MR - Mitral Regurgitation
4. AML - Anterior Mitral Leaflet
5. PML - Posterior Mitral Leaflet