ASSESSMENT OF COMMISSURAL MORPHOLOGY OF MITRAL VALVE WITH COMMISSURAL SCORE AND IT'S PREDICTION ON THE OUTCOME OF BALLOON MITRAL VALVOTOMY

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A PROJECT REPORT SUBMITTED DURING THE COURSE OF POST DOCTORAL FELLOWSHIP IN ADULT CARDIOLOGY AND INTERVENTIONS

DEPARTMENT OF CARDIOLOGY

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NOVEMBER 2024

DECLARATION BY THE STUDENT

CERTIFICATE

I, Dr. Karthikeyan T, hereby certify that I had personally carried out the work in the thesis titled, “Assessment of commissural morphology of mitral valve with commissural score and it’s prediction on the outcome of Balloon Mitral Valvotomy.”

Before this date, no part of this thesis has been submitted for the award of any other degree or diploma.

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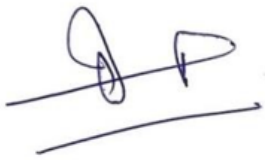


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I, hereby certify that the work in this project titled **" ASSESSMENT OF COMMISSURAL MORPHOLOGY OF MITRAL VALVE WITH COMMISSURAL SCORE AND IT'S PREDICTION ON THE OUTCOME OF BALLOON MITRAL VALVOTOMY "** is a certified record of original research work undertaken by Dr. Karthikeyan T. done in the department of Cardiology, in partial fulfilment of the requirement for award of post-doctoral fellowship degree under my supervision and care.



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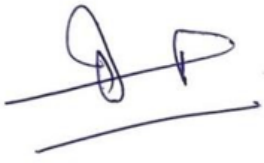
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"Alone we can do so little; together we can do so much"

-Hellen Keller

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ABBREVIATIONS

AF-Atrial fibrillation

AML-Anterior mitral leaflet

ARF-Acute Rheumatic Fever

BMI- Body Mass Index BSA- Body surface area

CAD- coronary artery disease

CMV- Closed mitral valvuloplasty

CO-Cardiac output

CI- Cardiac index

EF - Ejection fraction

Fr-French

GAS- Group A Streptococcus GLAS- Global Left atrial Strain LA- Left atrium

LAE-Left atrial enlargement

LAP- Left atrial pressure

LVEDP-Left ventricular end diastolic pressure

LVEF- Left ventricular ejection fraction

MAP-Mean arterial pressure

MPAP-Mean pulmonary artery pressure

MR- Mitral regurgitation

MS- Mitral stenosis

MV-Mitral valve

MVA- Mitral valve area

MVG-Mitral valve gradient

MVR-Mitral valve replacement

NYHA- New York Heart Association

PA-Pulmonary artery

PAH-Pulmonary artery hypertension

PASP-Pulmonary artery systolic pressure

PADP-Pulmonary artery diastolic pressure

PCWP-Pulmonary Capillary wedge pressure

PHT-Pressure half time

PVR- Pulmonary vascular resistance

RA-Right Atrium

RHD- Rheumatic heart disease

RVSP-Right ventricular systolic pressure

RVEDP- Right ventricular end diastolic pressure SD- Standard deviation

SR-Sinus rhythm

TEE- Transesophageal echocardiography

TMG- Transmitral gradient

VCAM-1- Vascular cell adhesion protein

SYNOPSIS

SYNOPSIS

Introduction:

Rheumatic heart disease (RHD) significantly contributes to cardiovascular disease and mortality in low- and middle-income countries, ranking as the sixth global and fifth Asian cause of disability-adjusted life years (DALYs). Among the cardiac valves affected by RHD, the mitral valve is most commonly involved, often with stenosis or regurgitation. Balloon Mitral Valvotomy (BMV), introduced by Kanji Inoue in 1984, revolutionized the treatment of severe mitral stenosis. BMV outcomes depend on valve morphology, traditionally assessed using the Wilkins score, which evaluates leaflet thickening, mobility, calcification, and sub-valvular thickening. However, the Wilkins score does not account for commissural morphology, an emerging predictor of BMV success. Commissural calcium presence is a critical determinant of outcomes, leading to the development of a commissural score by Sutaria et al. in 2006, which uses transesophageal echocardiography for commissural assessment. This study compares the effectiveness of the commissural score against the Wilkins score in predicting BMV outcomes.

Aims and objectives:

1. To investigate the role of commissural assessment in predicting the outcomes of BMV and identify the optimal method for assessing the commissures.
2. To compare the commissural score with Wilkins score in predicting outcomes of BMV.
3. To assess the role of commissural score in naïve and redo BMV cases.

Results:

52 Patients who were deemed eligible for the study after fulfilling inclusion and exclusion criteria were analysed. The mean age group is 42.92 ± 10.76 years and 75% were females. 40.38% were redo BMV cases. Most of the patients had fused non-calcific commissures (61.5% for medial commissure and 67.3% for lateral commissure) and

calcific commissures were present in 9.62% for medical commissure and 11.54% for lateral commissure. There is significant increase in mitral valve area (pre MVA – 0.97 +/-0.2 to post MVA 1.78 +/-0.34 cm2, p<0.001) and significant decrease in mean mitral valve gradient from 13.2+/-4.3mmHg to 5.8+/-5.8mmHg, p < 0.001. The majority, 25 out of 28 patients (89.29%) with a Wilkins Score ≤8, achieved a good outcome whereas only 17 out of 24 (70.83%) had good outcome if Wilkins score >8 though it is not statistically significant (p = 0.09). Similarly, patients with a commissural score > 2 demonstrated a higher percentage of good outcomes (84.85%) compared to those with a Commissural Score ≤2 but it is not statistically significant (p = 0.33). In our study it is found that those patients with higher Wilkins score had obtained minimal increase in mitral valve area (p = 0.03) and this more pronounced in redo BMV group (p = 0.02) than the naïve group. There is no significant difference in increase in mitral valve area in patients with commissural score </= 2 vs commissural scire >2. It is also observed in our study that among those patients with higher Wilkins scores (>8), those with commissural scores> 2 had a higher proportion of patients with good outcomes (77%) than those with commissural scores </= 2 (66%) though it is not statistically significant. There is a mild increase in the grade of MR post-procedure, though it is not statistically significant. There is a significant improvement in NYHA functional status post-procedure.

Conclusion:

Though the higher commissural score (>2) tends towards good outcomes in patients undergoing BMV, it doesn't precisely predict outcomes. Wilkins score is better in predicting the increase in mitral valve area than commissural score.

INTRODUCTION

INTRODUCTION

Rheumatic heart disease (RHD) contributes significantly to the burden of cardiovascular disease and mortality in low- and middle-income countries. Recent studies indicate that it ranks as the fifth leading cause of disability-adjusted life years (DALYs) in Asia and the sixth globally (1,2). Among the various cardiac valves affected by RHD, the mitral valve is most commonly involved, often presenting with stenosis and/or regurgitation (3).

Mitral stenosis (MS) was first described by Vieussens in 1705. Initially, surgical mitral commissurotomy and mitral valve replacement were the primary treatments for symptomatic patients. A major breakthrough occurred in 1984, when Japanese surgeon Kanji Inoue pioneered the technique of Balloon Mitral Valvotomy (BMV), revolutionising the approach to treating severe mitral stenosis (4). Since then, BMV has proven to be an effective option for many patients with suitable valve anatomy. However, the outcomes of BMV can vary depending on the specific characteristics of the valve (5).

The primary mechanism with which BMV helps in achieving adequate valve opening is commissural splitting. In selecting patients for BMV mitral valve morphology is assessed with two-dimensional transthoracic and transoesophageal echocardiography. Most of the interventionists across the world use Wilkin`s score for assessing BMV suitability. Wilkin score is a semi-quantitative score that uses leaflet thickening, mobility, calcification, and sub-valvar thickening as parameters and each is given grading from 0 or 1 to 4. The higher the score (Especially scores >8) more severe the disease and indicates a poor predictor of success (6). However, Wilkin's score doesn’t include commissural assessment in predicting the success of BMV. Most of the recent studies have shown the assessment of commissural morphology to be of value in predicting outcomes after BMV. The presence of commissural calcium is an independent predictor of outcome in BMV patients. Hence a new commissural score came up as proposed by Sutaira et al in 2006 (7) which uses a transoesophageal

echocardiography-based assessment of commissural morphology having scores from 0 to 4. The higher the score better the outcome of BMV. Further studies are required to assess the benefit of assessing only the commissures to predict BMV outcome. This study aims to assess the commissural score in comparison with Wilkins score in predicting the BMV outcome.

AIMS AND OBJECTIVES

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1. To investigate the role of commissural assessment in predicting the outcomes of BMV and identify the optimal method for assessing the commissures.
2. To compare the commissural score with Wilkins score in predicting outcomes of BMV.
3. To assess the role of commissural score in redo BMV cases.

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Epidemiology-

The incidence of acute rheumatic fever (ARF) varies significantly and is influenced by socioeconomic conditions and advancements in the timely treatment of group A streptococcal (GAS) infections. While the incidence has declined in high-income countries, occasional outbreaks and a resurgence of the disease have still been observed in some regions. Globally, it is estimated that approximately 470,000 cases of ARF occur annually, with around 60% progressing to rheumatic heart disease (RHD). Most prospective studies report an annual incidence of ARF ranging between 8 and 51 cases per 100,000 children and adolescents (8).

In India, the prevalence of ARF and RHD varies considerably, ranging from very low to extremely high levels. Much of the available data is derived from school-based surveys, hospital admission records, and national registries. However, recent research from two endemic areas indicates that the annual incidence is less than 20 cases per 100,000 people.

ARF predominantly affects children of school-going age. While RHD does not exhibit a gender preference, it is more commonly observed in females. This difference is attributed to variations in autoimmune responses, which result in differing levels of valvular damage and disease severity (9,10).

Pathogenesis-

The exact mechanisms underlying the development of acute rheumatic fever (ARF) remain incompletely understood. However, substantial evidence suggests that molecular mimicry plays a central role, involving an exaggerated autoimmune response triggered by Group A Streptococcal (GAS) pharyngitis. This initial infection activates a cascade of immune responses, including the proliferation of T and B lymphocytes stimulated by Streptococcal antigens and superantigens. These immune cells produce antibodies and cytokines that target Streptococcal carbohydrates and myosin. The severity and clinical presentation of this

autoimmune reaction vary between individuals, influenced by factors such as genetic predisposition, the virulence of the infecting strain, and environmental conditions. It is estimated that 0.3–3% of patients with GAS pharyngitis progress to develop ARF, depending on these factors (11).

An alternative hypothesis involves the upregulation of vascular cell adhesion molecule-1 (VCAM-1) and other adhesion molecules. Damage to the valvular endothelium caused by anti-carbohydrate antibodies results in the overexpression of VCAM-1. This molecule interacts with very late antigen (VLA) expressed on activated T and B lymphocytes, facilitating their migration into the valvular tissue. VCAM-1 expression is considered a key marker of inflammation, signaling the infiltration of immune cells. Endothelial disruption caused by anti-Streptococcal antibodies exposes subendothelial structures, initiating a cascade of valvular damage. As the leaflets become inflamed and damaged, revascularization occurs, enabling lymphocytes to infiltrate the valve tissue from both external and internal sources. This cycle of injury and immune activation leads to progressive valvular destruction, scarring, and chronic lesions over time (12).

In the acute phase, rheumatic valvulitis primarily manifests as valvular regurgitation. Chronic inflammation, however, results in valve stenosis and/or persistent regurgitation. In advanced stages of rheumatic heart disease (RHD), mitral stenosis (MS) develops due to commissural fusion, which affects various components of the mitral valve apparatus. In regions where RHD is endemic, the disease often follows a severe, aggressive course, with recurrent episodes of ARF contributing to its progression (13).

Pathologic Evolution of Mitral Stenosis-

In acute rheumatic fever with active carditis, small translucent nodules often form along the closure line of the mitral valve and, less commonly, on the subvalvular chordae. Microscopic examination of these nodules reveals the proliferation of fibroblasts and

macrophages. Over time, these nodular vegetations transition from translucent to opaque and grey, eventually leading to thickening of the valve leaflets. Structural changes in the valve involve the loss of normal morphology due to fibrin deposition, hyalinization, and eventual endothelial covering of the leaflets. These processes culminate in the fusion of the valve commissures.

A study by Brock et al.(14) highlighted that the initial point of leaflet fusion occurs at the "critical area of tendon insertion," which refers to the site where the shortest and most direct chordae attach to the cusps. Fusion at these critical points immobilizes adjacent portions of the cusps, further promoting commissural fusion. Once mitral stenosis is fully established, three distinct forms are identified:

1. **Commissural**: Characterized by fusion of the commissures with minimal involvement of the cusps or chordae.
2. **Cuspal**: The leaflets become stiff, rigid, and leathery, often progressing to calcification.
3. **Chordal**: In this type, the chordae are fused, shortened, and thickened, limiting leaflet mobility.

Mixed forms, combining features of these types, are also observed. Despite the anatomical variations in mitral stenosis, the impact on atrioventricular filling is often similar across different forms (15).

Pathophysiology of Mitral Stenosis-

Under normal conditions, the mitral valve orifice measures between 4 and 6 square centimeters, facilitating a shared chamber-like connection between the left atrium and left ventricle during diastole. Early in diastole, a slight pressure gradient exists between the left atrium and left ventricle, which quickly equalizes, allowing efficient blood flow during most

of the filling phase.

In mitral stenosis, the narrowing of the mitral valve orifice impedes the free flow of blood from the left atrium to the left ventricle, resulting in a sustained pressure gradient between the two chambers. This gradient increases left atrial pressure, which in turn leads to left atrial enlargement and pulmonary congestion. The restricted flow also limits left ventricular diastolic filling, reducing cardiac output as the severity of the stenosis progresses.

Because the left atrium must generate sufficient force to propel blood across the stenotic valve, mitral stenosis causes significant structural and functional changes in the atrium. These changes, including left atrial enlargement, can predispose individuals to complications such as atrial fibrillation and an increased risk of thrombus formation within the left atrium.

Understanding the role of left atrial function in mitral stenosis is crucial, as well as identifying methods to accurately assess these changes and their impact on disease progression and management.

Table 1: Classification of Mitral Stenosis Severity

Severity	Mitral Valve Area (cm^2)	Mean Pressure Gradient (mm Hg)	Pulmonary Artery Systolic Pressure (mm Hg)
Mild	**Greater than 1.5**	**Less than 5**	**Less than 30**
Moderate	**Between 1.0 and 1.5**	**5 to 10**	**30 to 50**
Severe	**Less than 1.0**	**Greater than 10**	**Greater than 50**

According to the 2020 ACC/AHA Guidelines for the Management of Valvular Heart Disease, the stages of mitral stenosis (MS) are categorized based on a combination of factors,

including the patient's symptoms, the structural characteristics of the valve, hemodynamic parameters, and the impact of valve obstruction on the left atrium (LA) and pulmonary circulation (16).

Table: Stages of Mitral Stenosis (MS) Based on 2020 ACC/AHA Guidelines

Stage	Definition	Valve Anatomy	Valve Hemodynamic	Hemodynamic Consequences	Symptoms
A: At Risk	Risk of developing MS	Mild doming of the valve during diastole	Normal trans mitral flow velocity	No left atrial (LA) or pulmonary abnormalities	None
B: Progressive	Progressive MS	Rheumatic changes with commissural fusion and diastolic doming of leaflets	Mitral valve area >1.5 cm^2; increased trans mitral flow velocities	Mild to moderate LA enlargement; normal pulmonary pressures at rest	None
C: Asymptomatic Severe	Severe MS without symptoms	Rheumatic changes with commissural fusion and diastolic doming of	Mitral valve area ≤1.5 cm^2; diastolic pressure half-time ≥150 ms	Severe LA enlargement; pulmonary artery systolic pressure (PASP) >50	None

Stage	Definition	Valve Anatomy	Valve Hemodynamic	Hemodynamic Consequences	Symptoms
		leaflets		mm Hg	
D: Symptomatic Severe	Severe MS with symptoms	Rheumatic changes with commissural fusion and diastolic doming of leaflets	Mitral valve area ≤1.5 cm²; diastolic pressure half-time ≥150 ms	Severe LA enlargement; PASP >50 mm Hg	Reduced exercise tolerance; exertional dyspnea

Abbreviations: MS: Mitral stenosis, mm Hg: Millimeters of mercury, MVA: Mitral valve area, PHT: Pressure half-time, PASP: Pulmonary artery systolic pressure, LA: Left atrium

The guidelines recommend intervention for mitral stenosis under the following conditions:

- For symptomatic patients (NYHA class II, III, or IV) with severe rheumatic MS (MVA ≤1.5 cm², Stage D) and valve morphology suitable for intervention.
- For asymptomatic patients with severe rheumatic MS (MVA ≤1.5 cm², Stage C) and favorable valve morphology.

Long-term studies indicate that approximately 70% to 80% of patients who achieve a successful initial outcome following percutaneous balloon mitral valvuloplasty (PBMV) remain symptom-free after 10 years. Additionally, 30% to 40% maintain freedom from recurrent symptoms after 20 years (17,18).

Rheumatic mitral valve (MV) pathology manifests in four distinct forms: commissural involvement (30%), cuspal changes (15%), chordal alterations (10%), and combined pathology (45%) (19). The mechanisms by which balloon mitral valvuloplasty (BMV) increases the mitral

valve area (MVA) include:

1. Commissural splitting (primary mechanism),
2. Annular stretching, and
3. Fracture of nodular calcium within the leaflet tissue.

Al Zaibag et al. demonstrated that the principal mechanism for valve dilation during single-balloon BMV is splitting one or both commissures. This phenomenon was also observed with the double-balloon technique (20). Reid et al. proposed that annular stretching contributes to the increase in MVA. Two-dimensional echocardiography revealed a slight reduction in MVA within 24 hours post-percutaneous mitral valvuloplasty (PMV), with no significant change after a month, indicating that annular stretching may play a role in valve dilation (21). Additionally, balloon dilation can cause the fracture of nodular calcium within the leaflet tissue (22).

Waller et al. examined mitral valves from surgical and necropsy specimens. They found that single-balloon dilation caused superficial cracking, double-balloon dilation resulted in deeper splitting of fused commissures, and oversized balloons led to annular and left atrial wall injury. Valves previously subjected to commissurotomy exhibited splitting near healed cracks (19). Ribeiro et al. observed that commissural splitting occurred more frequently in calcified commissures (81%) than in noncalcified ones (65%). This finding underscores that commissural splitting is the primary mechanism for MVA enlargement after successful BMV using either single or double balloons (23).

A successful BMV procedure is defined by:

1. A ≥50% increase in MVA from baseline,
2. A final MVA >1.5 cm^2, and
3. The absence of mitral regurgitation exceeding Sellers grade 2.

Various echocardiographic scoring systems have been devised to evaluate BMV outcomes.

Wilkins Scoring System

Developed in 1988 by Wilkins and colleagues at Massachusetts General Hospital, this system predicts PMV outcomes using four parameters: MV calcification, leaflet thickening, leaflet mobility, and subvalvular fibrosis (6).

Grade	Leaflet Mobility	Valvar Thickening	Subvalvular Thickening	Valvular Calcification
1	Highly mobile, restricted only at tips	Near normal (4–5 mm)	Minimal thickening just below valve	Single area of increased echo brightness
2	Reduced mobility at leaflet base and mid	Mild thickening, marked at margins	Thickening extending to one-third of chordal length	Scattered brightness at leaflet margin
3	Movement mainly at leaflet base	Thickening through entire leaflets (5–8 mm)	Thickening to distal third of chordae	Brightness extending to leaflet midportion
4	Minimal/no forward leaflet movement	Marked thickening (>8–10 mm)	Extensive thickening and shortening to papillary muscles	Extensive brightness across leaflet tissue

Patients with a score <9 generally achieve optimal outcomes, while scores >11 are associated with suboptimal results (6).

Reid Scoring System

In 1989, Reid and colleagues introduced another scoring method based on leaflet motion, thickness, subvalvular disease, and commissural calcium. Each feature was scored as 0 (mild),

1 (moderate), or 2 (severe). Commissural calcium was graded as 0, 1, or 2 depending on the number of calcified commissures (24).

Morphological feature	**Definition**	**Grade**	**Score**
Leaflet motion	H/L ratio:		
	• <0.25	Mild	0
	• 0.26–0.44	Moderate	1
	• ≥0.45	Severe	2
Leaflet thickness	MV/PWAo ratio:		
	• 1.5–2	Mild	0
	• 2.1–4.9	Moderate	1
	• ≥5.0	Severe	2
Subvalvular disease	• Thin faintly visible chordae tendineae	Absent-mild	0
	• Areas of increased density equal to the endocardium	Moderate	1
	• Areas denser than the endocardium with thickened chordae tendineae	Severe	2
Commissural calcium	• Homogenous density of mitral valve orifice	Absent	0
	• Increased density of anterior/posterior	One commissure	1
	• Increased density of both commissures	Two commissures	2

Other scoring systems include the Lung and Cormier system, developed by French

interventionists. This system considers chordal length and valve calcification to assess BMV suitability (25).

The **3D Echocardiography (Anwar) score** evaluates the mitral valve (MV) leaflets and subvalvular apparatus using real-time three-dimensional echocardiography (RT3DE).

RT3DE Parameters

Valvular Apparatus

The anterior and posterior mitral valve leaflets are assessed in segments: A1, A2, A3 (anterior) and P1, P2, P3 (posterior).

RT3DE						
	Valvar apparatus					
	Anterior leaflet			Posterior leaflet		
	A1	A2	A3	P1	P2	P3
Thickness (0–6) (0 = normal, 1 = thickened)	0–1	0–1	0–1	0–1	0–1	0–1
Mobility (0–6) (0 = normal, 1 = limited)*	0–1	0–1	0–1	0–1	0–1	0–1
Calcification (0–10) (0 = no, 1–2 = calcified)†	0–2	0–1	0–2	0–2	0–1	0–2
	Subvalvular apparatus†					
	Proximal third		Middle third	Distal third		
Thickness (0–3) (0 = normal, 1 = thickened)	0–1		0–1	0–1		
Separation (0–6) (0 = normal, 1 = partial, 2 = no)	0,1,2		0,1,2	0,1,2		

* Normal = 0, mild = 1 to 2, moderate = 3 to 4, severe $ 5.

† Normal = 0, mild = 1 to 2, moderate = 3 to 5, severe $ 6.

The total RT3DE score, calculated by summing the scores of leaflets and subvalvular apparatus, ranges from 0 to 31 points. MV involvement is classified as follows:

- **Mild**: <8 points,
- **Moderate**: 8–13 points,
- **Severe**: ≥14 points (26).

Commissural Assessment and Scoring

Commissural splitting is the primary mechanism for increasing MVA during balloon mitral valvuloplasty (BMV), making commissural evaluation critical. While 3D echocardiography provides detailed visualisation, 2D echocardiography remains less widely adopted for commissural assessment.

In 2005, **Sutaria et al** (7)**.** proposed a scoring system based on transoesophageal echocardiography (TEE) to predict BMV outcomes. This system evaluates commissural fusion and calcification:

Commissure Score	**Morphology**
0	No fusion of either commissure, calcification of both commissures, or one commissure fused and the other calcified.
1	Partial fusion of one commissure, with the other unfused or calcified.
2	Extensive fusion of one commissure, with the other unfused or calcified, or partial fusion of both commissures.
3	Extensive fusion of one commissure, partial fusion of the other, with no

Commissure Score	Morphology
	calcification.
4	Extensive fusion of both commissures without calcification.

Predictive Value of Commissural Scores

The study by Sutaria et al. found that higher commissural scores were associated with better BMV outcomes. Among patients with a commissural score of 4, 76% had favorable results, compared to only 19% for a score of 1. A commissural score ≥2 was predictive of good outcomes, with a positive predictive accuracy of 67% and a negative predictive accuracy of 82% ($P < 0.001$) (7).

In another study by Sarath Babu et al., it was found that Patients with higher commissural scores (3–4) demonstrated significantly better outcomes after BMV, with 94% achieving favourable results, compared to only 20% of those with scores of 0–2 ($p < 0.001$). A higher commissural score correlated with more significant post-BMV increases in the mitral valve area (2D MVA).While a Wilkins score <8 typically predicts a good outcome, patients with a Wilkins score >8 but a commissural score >2 still had a 50% chance of a favourable result (27).

Current Debates and Limitations

There is ongoing debate regarding the utility of 2D echocardiographic parameters in predicting BMV outcomes for patients with rheumatic mitral stenosis. This is especially relevant for assessing outcomes in repeat BMV cases, where the predictive value of echocardiographic scoring systems remains uncertain. This study aims to address these gaps and improve the understanding of echocardiographic predictors for successful outcomes**.**

MATERIALS AND METHODS

Methodology

Study Design: Observational study

Study setting: Department of Cardiology, Sree Chitra Tirunal Institute of Medical Sciences and Technology (SCTIMST), Trivandrum

Study period: 6 Months

Inclusion Criteria:

1. Rheumatic severe mitral stenosis with MVA < 1.5 cm2 and favourable valve morphology.
2. Age > 18 years

Exclusion Criteria:

1. Moderate or severe MR or other valve lesions requiring surgical correction
2. Presence of left atrial (LA) and/or LA appendage thrombus
3. History of recent thromboembolic events within the last month
4. Associated significant coronary artery disease requiring surgical revascularization
5. Acute rheumatic activity and/or infective endocarditis
6. Bi commissural calcium

The principal investigator recruited the patients in consultation with the co-investigators. Once they fulfilled the inclusion and exclusion criteria, both naïve and redo BMV patients were recruited.

Once the patients were recruited, baseline clinical parameters were documented in the data collection sheet. The clinical parameters include

Sex	Prior heart failure admissions
Age	NYHA functional class
History of Cerebrovascular accident (CVA) –	History of rheumatic fever

Including Transient ischemic attacks and stroke	
Naïve / Redo BMV	Patient height
Sinus rhythm / Atrial fibrillation	Duration of symptoms

7.

8. Various Echocardiographic parameters also will be recorded.

Left atrial size
Left ventricular function by ejection fraction
Wilkins score
Commissural score
Mitral valve area (2 dimensional planimetry)
Mitral valve gradient
Right ventricular systolic pressure

2D transthoracic and transoesophageal echocardiography (TEE) assessments were done in all the patients` pre-procedure, and transthoracic echo is done 24–48 hours post-procedure and after 1 month. The MV area was evaluated using planimetry, trans-mitral gradient, commissural splitting, and peak systolic pulmonary artery pressure (PSPAP) through tricuspid regurgitation peak velocity. MV Wilkins score were estimated, depending on the assessment of four parameters (MV leaflets' mobility, thickness and calcification, and subvalvular involvement), and each parameter was given a score of 0–4. By calculating the sum of those scores, a total score of 0–16/16 (Normal MV = 0/16, mild MV involvement = 1–4/16, moderate MV involvement = 5–8/16, and severe MV involvement > 8/16) will be obtained. TEE assessment includes the assessment of the mitral valve in mid oesophageal view and its commissures. The anterolateral commissure was visualized in the transverse plane by

advancing and retracting the probe, thereby scanning the commissure length from the leaflet tip to the annulus. The posteromedial commissure was scanned in the longitudinal plane by rotating the probe clockwise and anti-clockwise. Commissural calcification were identified by high intensity echoes casting an acoustic shadow. Each commissure was assigned a score to reflect the likelihood of splitting using a commissural score. Anterolateral and posteromedial commissures were scored individually according to whether non-calcified fusion was absent (0), partial (1), or extensive (2). Calcified commissures usually resist splitting and scored 0. Scores for each commissure were combined, giving an overall commissure score for each valve of 0 to 4, with higher scores reflecting an increased likelihood of commissural splitting. A high score indicated extensively fused, non-calcified commissures that were, therefore, more likely to split. A low score indicated either minimal fusion or the presence of resistant commissural calcification.

The hemodynamic data is also recorded by cardiac catheterization prior and after BMV.

Left atrial pressure
Left ventricular end diastolic pressure
LA – LV gradient
Pulmonary artery pressure
Mitral valve area

The following definitions were used to assess the outcomes:

I. The optimal result is defined as a split of one or more mitral valve commissures with:
    a. An increase in mitral valve area of at least 50% from the basal
    b. A final valve area of >1.5 cm2
    c. Absence of sellers' grade of >2 MR.

II. "Suboptimal" outcome

   a. A final valve area < 1.0 cm2

   b. Post dilation mean LA pressure >10 mmHg

   c. Change in area 1.0 cm2 before the procedure

   d. Presence of more than moderate MR.

III. Poor outcome

   a. Need for MVR due to severe MR

Mortality

Procedure-related deaths within one month of the procedure.

Outcomes:

Primary Outcome:

1. To compare the outcome of BMV between the Wilkins and commissural scores done preoperatively.

Secondary outcomes:

1. To assess the clinical profile of patients undergoing BMV in our institute.
2. To assess the difference in outcome between naïve and redo BMV patients based on the preoperative assessment by both Wilkins and commissural score.

Statistical analysis:

- All the data collected were entered into excel sheet
- All computation and statistical analysis were done using Stata version 16.0 (StataCorp, College Station, TX, USA).
- Mean and standard deviation were calculated for continuous variables, and Percentages were used for describing the categorical variables.

- An unpaired students ‘t’ test was used to assess the significance of the difference between the means of two independent groups (A).
- Pearson correlation co-efficient (r) was calculated to study the relationship between two continuous variables, the significance of which was tested with a ‘t’ test.
- If the data is non-parametric, spearman correlation is used.
- p value < 0.05 was considered as statistically significant.

ETHICAL JUSTIFICATION

Several studies have investigated the role of commissural assessment in predicting the outcomes of BMV. Despite the growing body of research on BMV and commissural assessment, there is still a lack of clarity on the best approach for assessing the commissures and predicting the procedure's outcomes. This study aims to investigate the role of commissural assessment in predicting the outcomes of BMV and identify the optimal method for assessing the outcomes of BMV.

RESULTS

RESULTS

During 1 year period 52 patients were enrolled for the study. The baseline demographic profile of the patient population is given in the Table (1).

The Mean age group of the study population is 45.92 years ± 10.76 years. 39 (75%) of the study population are females.

Almost 45% of the study population had baseline NYHA FC II and III whereas only 3.85% had FC IV. Only 2 patients have a history of rheumatic fever in the past. More than 2/3rd (40.38%) of the patients were undergoing a redo BMV procedure. Among 21 patients who were redo cases, 19 had undergone BMV in the past, and 2 underwent CMV in the past. 17 patients among 21 (80.9%) who are undergoing redo procedure underwent BMV in the past and the rest (19.1%) underwent CMV in the past. 14 patients had either current Atrial fibrillation or paroxysmal Atrial fibrillations. Among them 10 patients had Atrial fibrillation during the procedure and 4 patients has past history of atrial fibrillation which was reverted and was in sinus rhythm during the procedure.

The loop diuretics and beta-blockers are the most commonly prescribed medications. A high percentage of patients with severe mitral stenosis are being treated with beta-blockers (90.38%) and loop diuretics (94.23%). Only 30.77% of patients are prescribed digoxin, which may indicate that digoxin is being used selectively, likely in patients who have atrial fibrillation or significant heart failure symptoms that require rate control or enhanced myocardial contractility.

	Mean ± SD	Range
Age (Years)	45.92 ± 10.76	23 - 70

Patient height (Cms)	158.1 ± 7.8	140 – 185
	Number (n)	**Percent**
Sex **Male**	13	25%
Female	39	75%
NYHA - Baseline		
II	25	48%
III	25	48%
IV	2	3.85%
H/O Rheumatic fever	2	3.85%
Redo Cases	21	40.38%
Redo BMV/CMV		
BMV	19	36.54%
CMV	2	3.85%
Number of redo procedures		
1	17	32.69%
2	4	7.69%
H/O of AF		
Current AF	10	19.23%
Paroxysmal AF	4	7.69%
Number of dilatations given.		
1	19	36.54
2	20	38.46

3	11	21.15
4	2	3.85
Medications:		
Betablocker	47	90.38
Loop Diuretics	49	94.23
Potassium sparring diuretics	40	76.92
Digoxin	16	30.77

Table 1: Baseline characteristics table

The mean value for the MORRIS index in the study population is 0.08 sec, with a standard deviation (SD) of 0.04. This indicates that the values are generally clustered around the mean, with a low degree of variability (since the SD is relatively small). The mean value of Macruz index is 1.9, with an SD of 0.72. The range of values for MACRUZ is from 0.50 to 3.0. The higher mean indicates that most of the patients had significant LA enlargement according to the ECG criteria. The QRS axis values range from -30 to +120 with the mean QRS axis of +71.34, with a SD of 27.42.

	Mean ± SD	**Range**
MORRIS (sec)	0.08 ± 0.04	0.04 – 0.20
MACRUZ	1.9 ± 0.72	0.50 – 3.0
QRS Axis	+71.34 ± 27.42	-30 to +120

Table 2: ECG Characteristics of study population

ECHO Parameters:

In our study, the mean LA diameter is 45.75 mm, with a standard deviation (SD) of 6.1 mm, ranging from 34 mm to 69 mm, indicating a dilated left atrium.

	Mean	SD	Range
LA SIZE (mm)	45.75	6.1	34 – 69
LVEF (%)	60.05	10.06	34 - 76

Table 3: ECHO Parameters

Commissural Characteristics:

In our sample, both the **Medical** and **Lateral Commissures** show a predominance of **fused** cases. About 10% of both commissures have fused and calcific cases, indicative of more advanced pathology and poor outcomes.

	Frequency
Medical commissure	
Fused	32 cases (61.54%)
Partly fused	8 cases (15.38%)
Not fused	7 cases (13.46%)
Fused and calcific	5 cases (9.62%)
Lateral Commissure	
Fused	35 cases (67.31%)
Partly fused	8 cases (15.38%)
Not fused	3 cases (5.77%)
Fused and calcific	6 cases (11.54%)

Table 4: Commissural characteristics

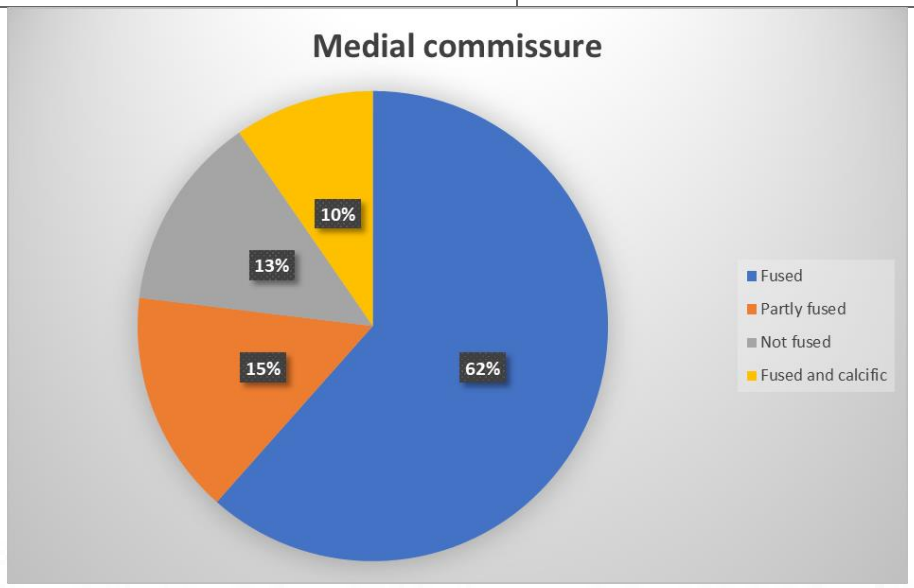


Figure 1: Baseline medial commissure characteristics

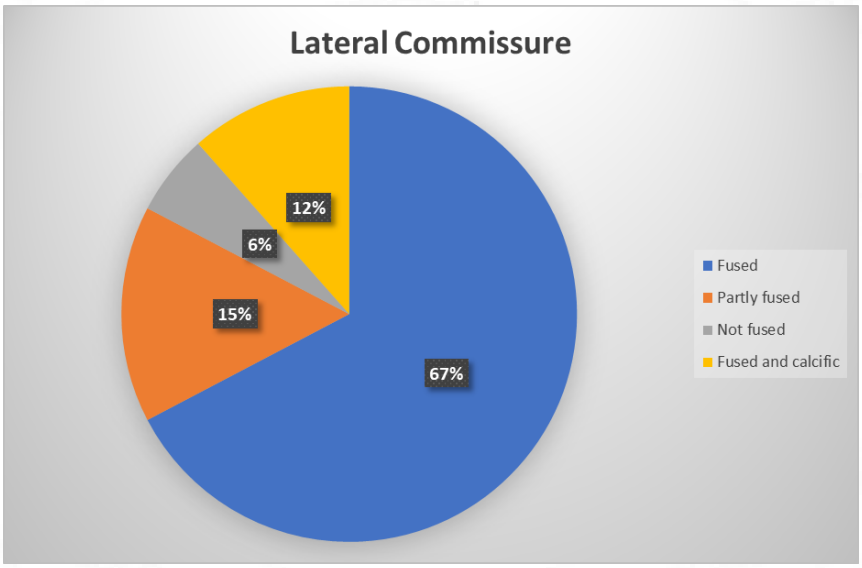


Figure 2: Baseline lateral commissure characteristics

The **Wilkins score** is often used to predict the likelihood of successful mitral valve interventions such as balloon mitral valvotomy or surgical repair. A higher Wilkins score (usually above 8) is associated with poorer outcomes from such interventions, as more severe leaflet calcification and reduced mobility hinder procedural success. The mean Wilkins score of 8.5 indicates that most of the patients had unfavourable valves.

The **commissural score** typically evaluates the extent of commissural fusion in mitral

valve stenosis, an important factor influencing valve function and the potential for successful intervention. The mean score is 2.9, with a standard deviation of 1.15.

	Mean	SD	Range
Wilkins score	8.5	1.95	5 - 12
Commissural score	2.9	1.15	1 - 4

Table 5: Mean Wilkins scora and commissural score

- **Low Commissural Fusion (Scores 0-1)**:
    - **Commissural Score 0** (No fusion) was found in **2 patients (3.8%)**, and **Commissural Score 1** (Minimal fusion) was observed in **4 patients (7.7%)**. Together, these represent **11.5%** of the population. These findings indicate that a minority of patients have unfavourable valve anatomy regarding poorly fused / calcific valve.
- **Moderate Commissural Fusion (Score 2)**:
    - **Commissural Score 2** (Moderate fusion) was seen in **13 patients (25%)**, representing a quarter of the population. This group likely has moderate involvement of the commissures, which may still allow for some interventional benefit.
- **Severe Commissural Fusion (Scores 3-4)**:
    - The majority of patients have more severe commissural fusion, with **Commissural Score 3** found in **12 patients (23.1%)** and **Commissural Score 4** (Complete fusion) in **21 patients (40.4%)**. Together, these groups represent **63.5%** of the cohort, indicating that most patients in this sample have significant

mitral valve commissural involvement, likely better valve for percutaneous intervention.

COMMISSURAL SCORE	Number (n)
0	2 cases (**3.8%**)
1	4 cases (**7.7%**)
2	13 cases (**25.0%**)
3	12 cases (**23.1%**)
4	21 cases (**40.4%**)

Table 6: Commissural score

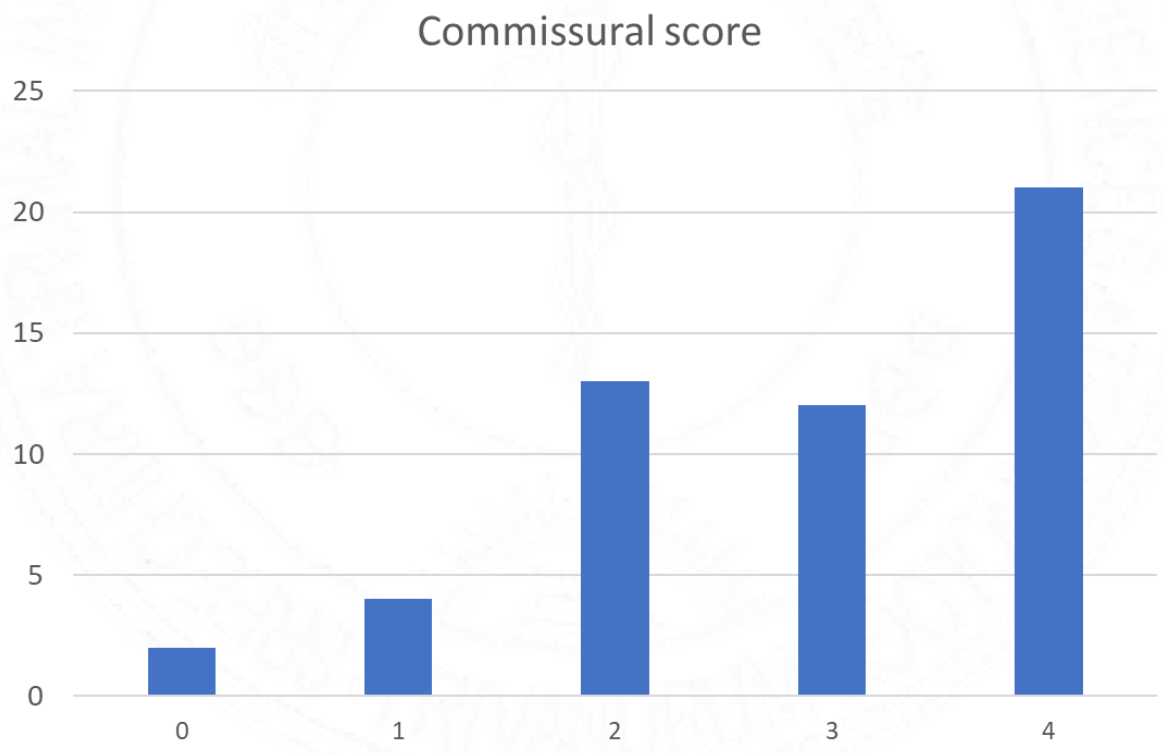


Figure 3: Commissural score

Valve Morphology:

- **Leaflet Mobility**: Most (59.62%) of patients have moderate restriction in leaflet mobility (Score 2), but a substantial proportion (32.69%) have **severe impairment** (Score 3), with some cases showing **complete immobility** (Score 4).
- **Valve Thickness**: Most patients exhibit **moderate valve thickening** (Score 2), but a notable percentage (25%) show **severe thickening** (Score 4)
- **Sub valvular Thickening**: There is **moderate to severe thickening** of the sub valvular apparatus in **96.15%** of patients (Scores 2 and 3), indicating that sub valvular pathology is a significant contributor to mitral stenosis in this cohort.
- **Valvular Calcification**: Interestingly, most patients (36.54%) show **no calcification** (Score 0), suggesting that calcification is not a predominant feature of the disease in this sample. However, **moderate calcification** is still present in about half of the cohort.

LEAFLET MOBILITY (WILKINS)	N	Percent
1	1	1.92
2	31	59.62
3	17	32.69
4	3	5.77
VALVE THICKNESS (WILKINS)		
1	5	9.62
2	24	46.15
3	10	19.23
4	13	25
SUBVALVULAR THICKENING (WILKINS)		

1	2	3.85
2	27	51.92
3	23	44.23
VALVULAR CALCIFICATION (WILKINS)		
0	19	36.54
1	15	28.85
2	14	26.92
3	4	7.69

Table 7 : Components of Wilkins score

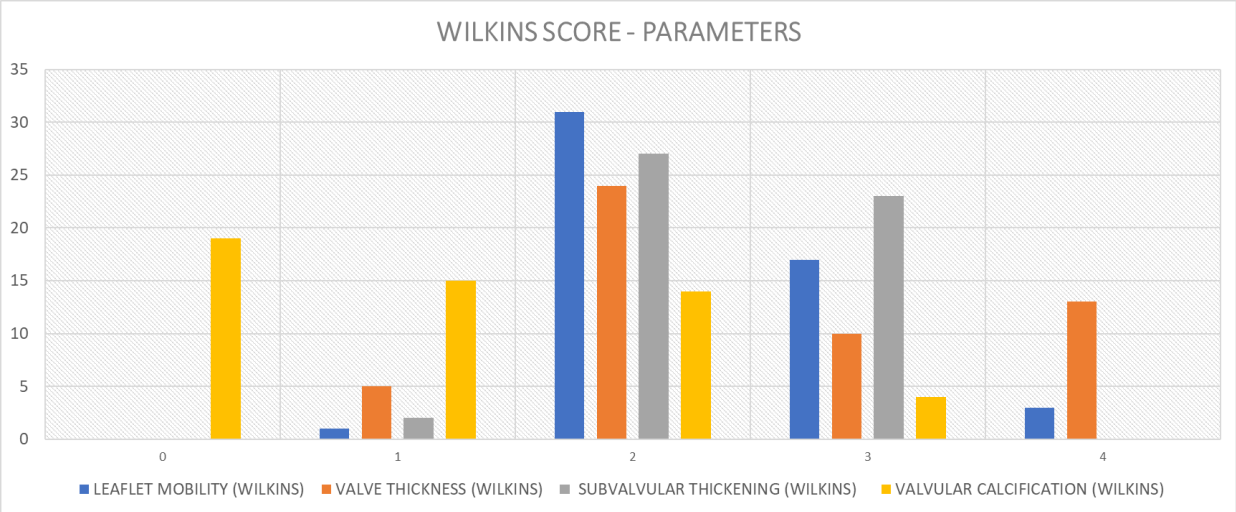


Figure 4: Wilkins score - parameters

The pre-procedure mitral valve area (MVA) indicates that, on average, the mitral valve area is 0.97 cm². There is moderate variability (SD of 0.20), with values ranging from 0.527 cm² (indicating more severe mitral stenosis) to 1.39 cm². After the procedure, the mitral valve area increases significantly to a mean of 1.78 cm², reflecting an improvement in valve opening. The range shows improvement from a minimum of 1.04 cm² to a maximum of 2.78 cm², indicating successful intervention with a substantial increase in valve area. The increase in

mitral valve area averages 1.12 cm^2, which is a substantial improvement post-procedure. The variation (SD of 0.75) indicates that while the majority of patients experienced significant improvement, the degree of increase may vary. The P value of < 0.001 indicates that the change observed after the procedure is statistically significant.

The mean pre-procedure mitral valve gradient is 13.2 mmHg, indicating severe stenosis. The range from 6 mmHg to 29 mmHg reflects significant variability, with some patients experiencing more severe obstruction than others. After the procedure, the mean mitral valve gradient improves significantly to 5.8 mmHg, suggesting a successful reduction in the pressure gradient across the mitral valve and it is statistically significant (P<0.001). The range from 2 mmHg to 13 mmHg reflects a successful outcome for most, though the gradient may still be elevated in some cases.

Before the procedure, the mean degree of mitral regurgitation (MR) is 1.63. The range from 0 to 3 suggests that patients exhibit varying degrees of MR, with some showing no regurgitation and others experiencing moderate regurgitation. After the procedure, the mean MR increases to 2.31, suggesting a worsening of regurgitation, potentially due to changes in valve dynamics after intervention. The range from 0 to 4 indicates variability, with some patients showing improvement or no change, while others experience worsening of regurgitation. While the procedure improved mitral valve area and gradient, it appears that mitral regurgitation slightly worsened after the procedure, with an increase in the average MR score from 1.63 to 2.31. However, this increase in MR does not overshadow the benefits of the procedure, particularly when it comes to reducing symptoms related to mitral stenosis. Among those patients who developed MR 7 patients (13.46%) developed commissural MR**.**

	Mean	**SD**	**Range**	**P value**
Mitral valve area (2D) – Pre (cm2)	0.97	0.2	0.527 – 1.39	

Mitral valve area (2D) – Post (cm2)	1.78	0.34	1.04 – 2.78	< .001
Increase in MVA (cm2)	1.12	0.75		
Mean MV gradient (Pre) (mmHg)	13.2	4.3	6 – 29	
Mean MV gradient (Post) (mmHg)	5.8	2.96	2 - 13	< .001
MR pre procedure	1.63	0.74	0 – 3	
MR Post procedure	2.31	0.92	0 - 4	< .001

Table 8: Results of outcome

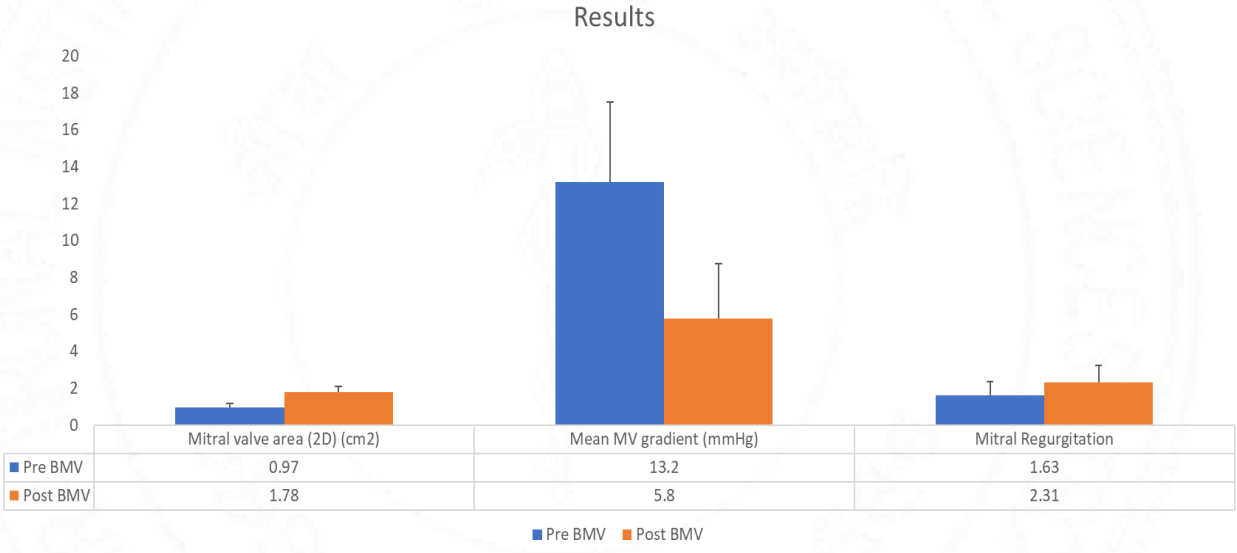


Figure 5: Comparison of individual parameters of outcome

The mean pulmonary artery pressure (PA pressure) before the procedure is elevated (33.78 mmHg). After the BMV procedure, the mean PA pressure decreased to 30.13 mmHg. This reduction is significant and reflects an improvement in pulmonary hemodynamic due to the increase in mitral valve area and reduced obstruction. Although PA pressure remains elevated compared to normal values, this decrease suggests some relief in pulmonary

congestion.

The mean left atrial (LA) pressure before BMV is elevated (23.48 mmHg), consistent with the obstruction in the mitral valve. After BMV, the mean LA pressure decreased to 16.53 mmHg, significantly reducing the pressure load on the left atrium. This reduction in LA pressure is a positive outcome, suggesting that the procedure has relieved some of the obstruction and improved the flow from the left atrium to the left ventricle. It also likely contributes to symptom relief (Reduced pulmonary congestion).

The mean left ventricular (LV) end-diastolic pressure before the procedure is 10.52 mmHg. The mean LV end-diastolic pressure post-BMV increased slightly to 11 mmHg, which is not a significant change compared to pre-procedure values (**P value**: 0.257).

	Mean	**SD**	**Range**	**P value**
Pre-Mean PA Pressure	33.78	15.12	17 - 82	
Post-Mean PA pressure	30.13	13.92	12 – 74	<0.001
Pre-LA mean pressure	23.48	7.86	7 – 44	
Post LA mean pressure	16.53	5.92	4 – 34	<0.001
Pre-LV end-diastolic pressure	10.52	3.65	4 – 20	

Post LV end-diastolic pressure	11	3.99	4 - 21	0.257

Table 9: Hemodynamic parameters pre and post-procedure

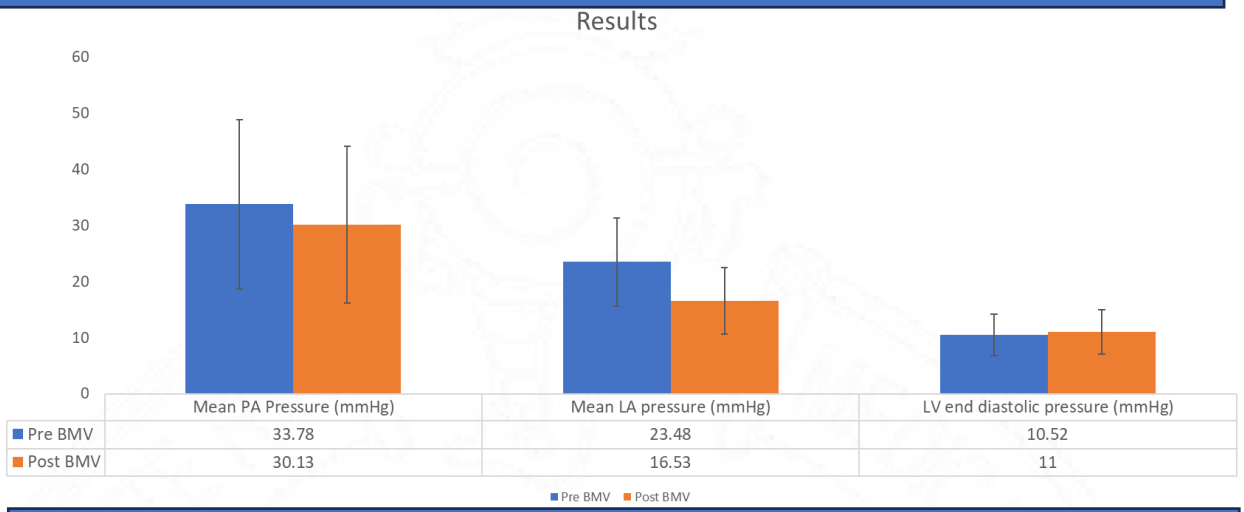


Figure 6: Hemodynamic parameters pre and post-procedure

Post BMV Medial Commissure status:

Most patients (73.08%) had a complete splitting of the medial commissure. This is typically considered a successful outcome, as splitting the commissure helps to relieve the obstruction in the mitral valve and increases the effective orifice area. This is an essential aspect of improving blood flow across the valve in mitral stenosis.

A smaller proportion of patients (17.31%) had a partial splitting of the medial commissure. While this may indicate some improvement, it suggests that the full release of the stenotic valve did not occur in these patients. This might result in less-than-optimal improvement in valve opening.

In a few patients (7.69%), the medial commissure did not split. This could indicate that the stenotic valve was more rigid/calcific that did not open up during procedure.

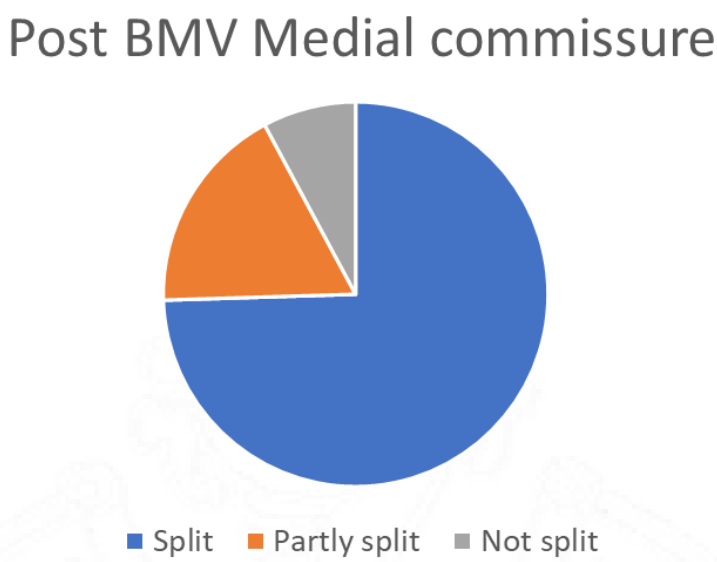


Figure 7: Post BMV Medial commissure status

Post BMV Lateral Commissure status:

A high percentage (80.77%) of patients experienced complete splitting of the lateral commissure, indicating a successful outcome for most patients.

A smaller portion (15.38%) had partial splitting of the lateral commissure, suggesting that in these patients, the commissure was partially opened but not fully. This partial split can still improve symptoms, but the full benefit might not have been achieved.

A very small number of patients (1.92%) had no splitting at the lateral commissure, indicating that this was a rare outcome. This could suggest a more rigid or calcified mitral valve, making it more resistant to balloon dilation.

To summarise, for both the medial and lateral commissures, the majority of patients experienced complete splitting, which is a positive outcome in BMV. In a minority of cases, there was only partial splitting or no splitting, particularly in the medial commissure.

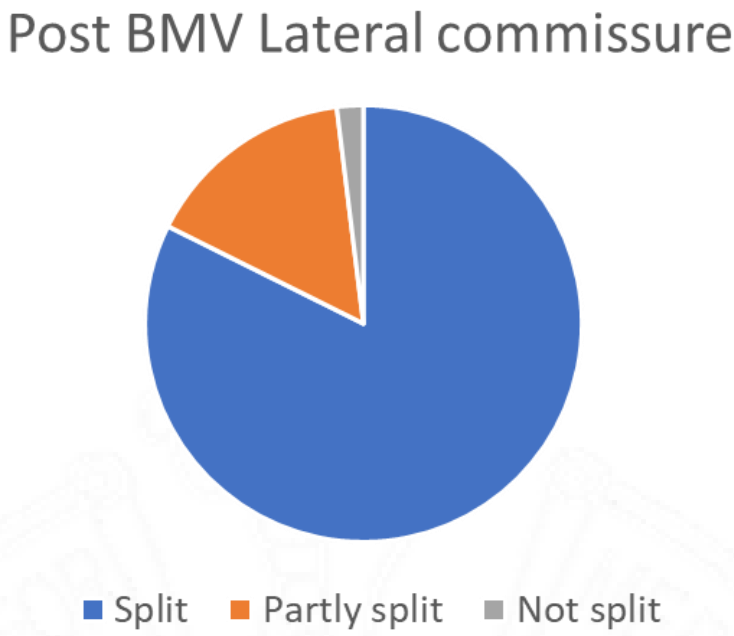


Figure 8: Post BMV Lateral commissure status

	N	Percentage
Post BMV Medial commissure		
Split	38	73.08
Partly split	9	17.31
Not split	4	7.69
Post BMV Lateral commissure		
Split	42	80.77
Partly split	8	15.38
Not split	1	1.92

Table 10: Outcomes of commissures post BMV

OVERALL OUTCOMES:

SCORES	N	Percent	Overall outcome			Increase in MV area (Mean ±SD) Cm2
			Good outcome	Suboptimal outcome	Poor outcome	
Wilkins Score <= 8	28	53.85 %	25	2	1	1.24 ± 0.84
Wilkins Score > 8	24	46.15 %	17	4	3	0.87 ± 0.58
Commissural score <= 2	19	36.54 %	14	3	2	1.1 ± 0.82
Commissural score > 2	33	63.46 %	28	3	2	1.06 ± 0.72

Table 11: Comparison of Wilkins and commissural score with overall outcome and increase in MV area

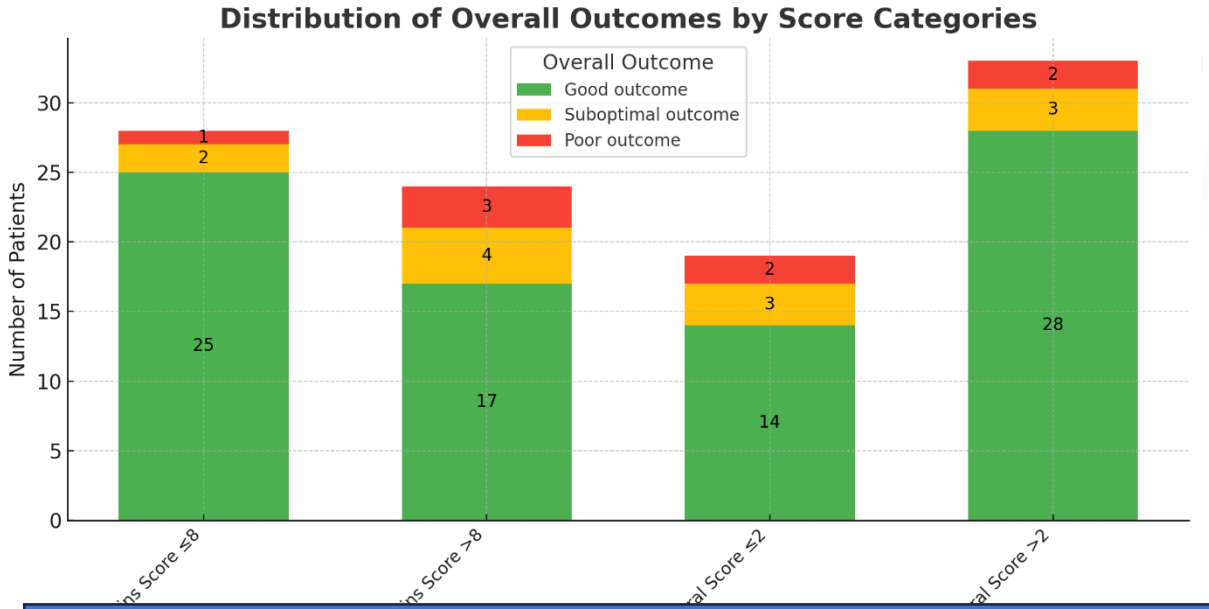


Figure 9: Distribution of Overall Outcomes by Wilkins and commissural score

1	Correlation with Wilkins score vs Outcomes	
		Overall outcome
	Wilkins score	0.2359

	p-value	0.0923
2	Correlation with Commissural Score vs Outcomes	
	Commissural Score	-0.1357
	P-value	0.3376
	Correlation with Wilkins score vs Mitral valve area	
3		Increase in MV area.
	Wilkins score	-0.2199
	P-value	0.1728
	Correlation with Commissural score vs Mitral valve area	
Total		Increase in MV area
	Commissural score	0.1215
	P-value	0.4551

Table 12: Correlation with Wilkins score vs Outcomes

Analysis of Wilkins score with outcomes and increase in mitral valve area:

The majority, 25 out of 28 patients (89.29%) with a Wilkins Score ≤8 (Which is considered a favourable valve for BMV), achieved a good outcome, reflecting a favourable prognosis with a substantial increase in MV area 1.24 ± 0.84 cm^2.

However, patients with a Wilkins Score >8 had a lower percentage of good outcomes i.e., 17 out of 24 (70.83%) compared to those with a score ≤8. Additionally, their increase in MV area was less significant (0.87 ± 0.58 cm^2).

Analysis of commissural score with outcomes and increase in mitral valve area:

Similarly, patients with a commissural score > 2 (Which is considered a favourable valve for BMV) demonstrated a higher percentage of good outcomes (84.85%) compared to those with a Commissural Score ≤2, with a comparable increase in MV area (1.06 ± 0.72 cm^2).

However, patients with a Commissural Score ≤2 demonstrated only 73.68% of a good outcome with a near similar increase in the MV area.

To conclude,

- Patients with Wilkins Score ≤8 and Commissural Score >2 achieved the best outcomes with a higher percentage of good outcomes and significant increases in MV area.

- Wilkins Score >8 is associated with a higher likelihood of suboptimal and poor outcomes and a smaller increase in MV area, suggesting less favourable procedural success.

As the data is non parametric and doesn't follow normal distribution spearman correlation is used to assesses the correlation between.

The positive correlation coefficient ($\rho = 0.2359$) suggests a weak positive relationship between the Wilkins score and overall outcome, meaning higher Wilkins scores might be associated with suboptimal or poor outcomes. However, the p-value (0.0923) is greater than the conventional threshold of 0.05, indicating that this correlation is not statistically significant. Hence, the relationship could be due to chance.

Similarly, the negative correlation coefficient ($\rho = -0.1357$) suggests a weak negative relationship between the Commissural Score and overall outcome, implying that higher Commissural Scores might be associated with good outcomes. However, the p-value (0.3376) is significantly higher than 0.05, indicating that this correlation is not statistically significant.

The negative correlation coefficient ($\rho = -0.2199$) suggests a weak negative relationship between Wilkins score and the increase in Mitral Valve (MV) area. This indicates that patients with higher Wilkins scores tend to have a smaller increase in MV area post-procedure. However, the p-value (0.1728) is also greater than 0.05, meaning this relationship is not statistically significant.

A correlation coefficient of 0.1215 indicates a very weak positive correlation. Higher Commissural scores are slightly associated with a greater increase in MV area, though this association is not statistically significant.

To conclude,

- Higher Wilkins scores might be weakly associated with suboptimal / poor outcomes but with a smaller increase in MV area.

- Higher Commissural Scores might be weakly associated with good outcomes and with a greater increase in MV area.

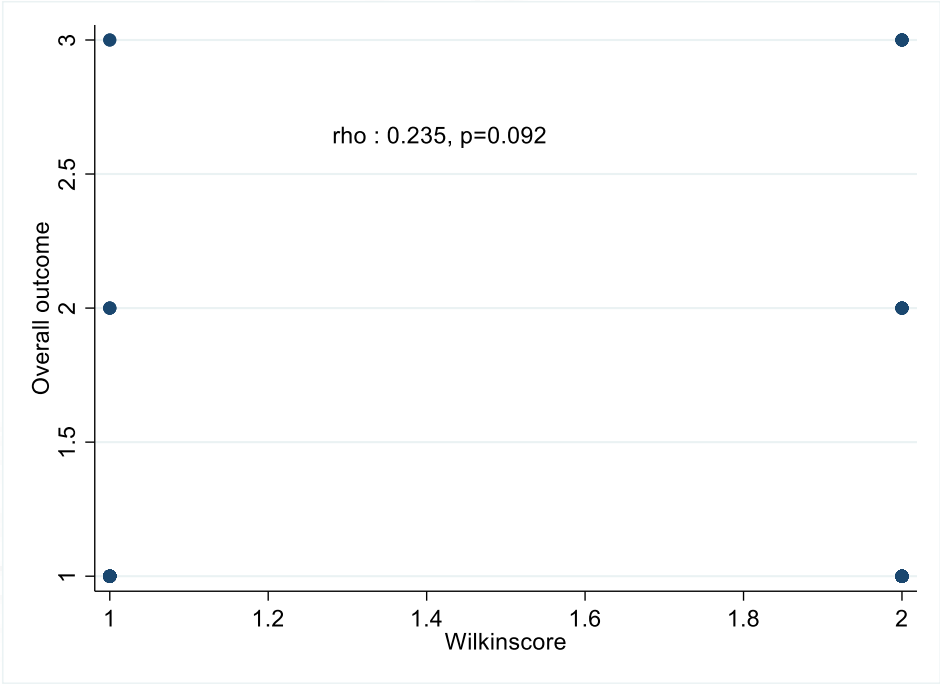


Figure 10: Spearman correlation between Wilkins score (≤8/>8) and overall outcome

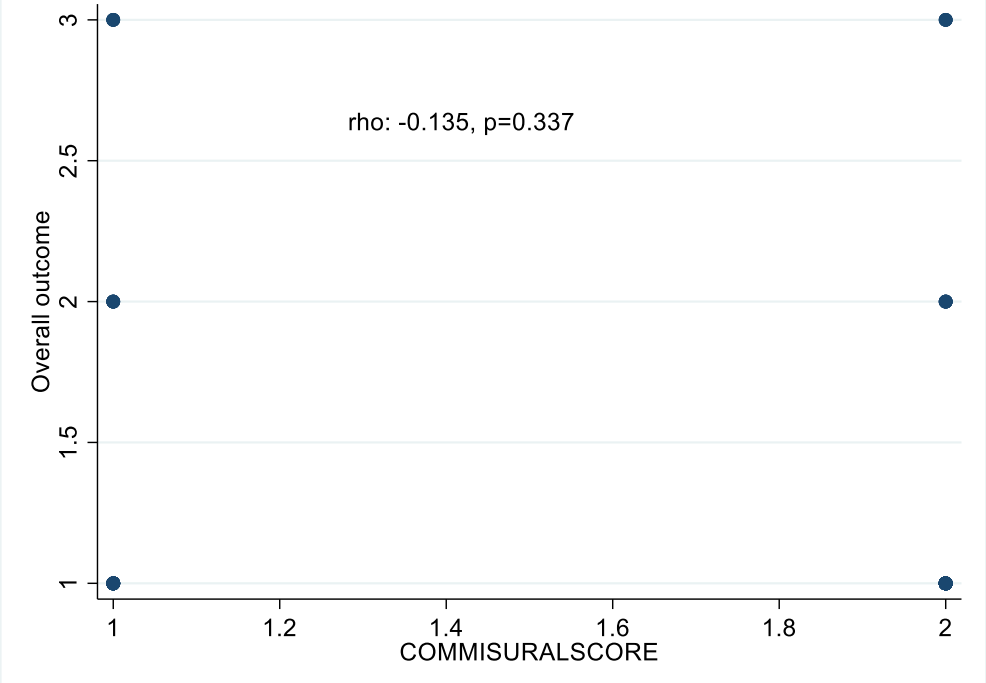


Figure 11: Spearman correlation between commissural score (≤2/>2) and overall outcome

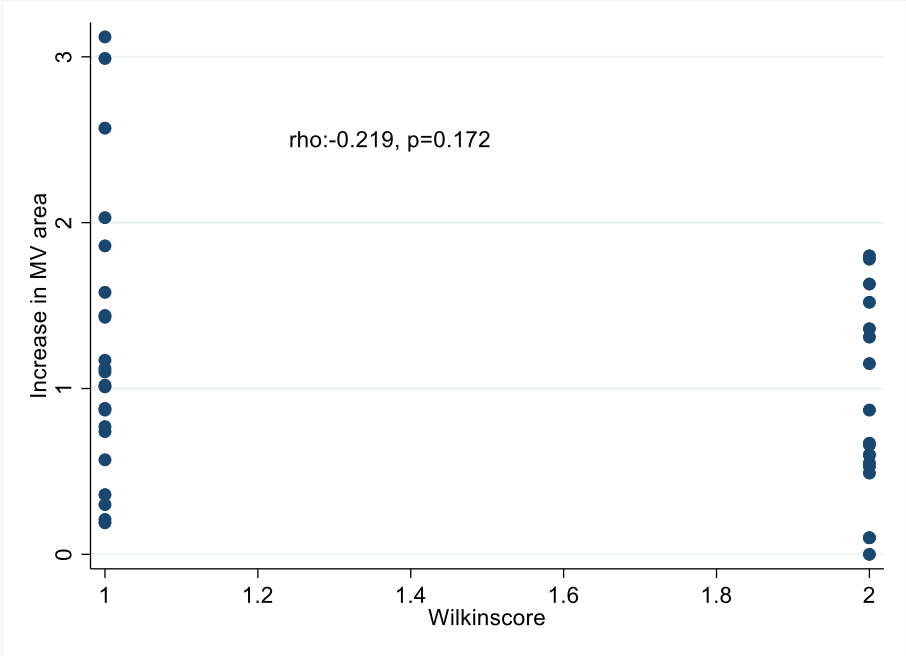


Figure 12: Spearman correlation between Wilkins score (≤8/>8) and increase in MV area

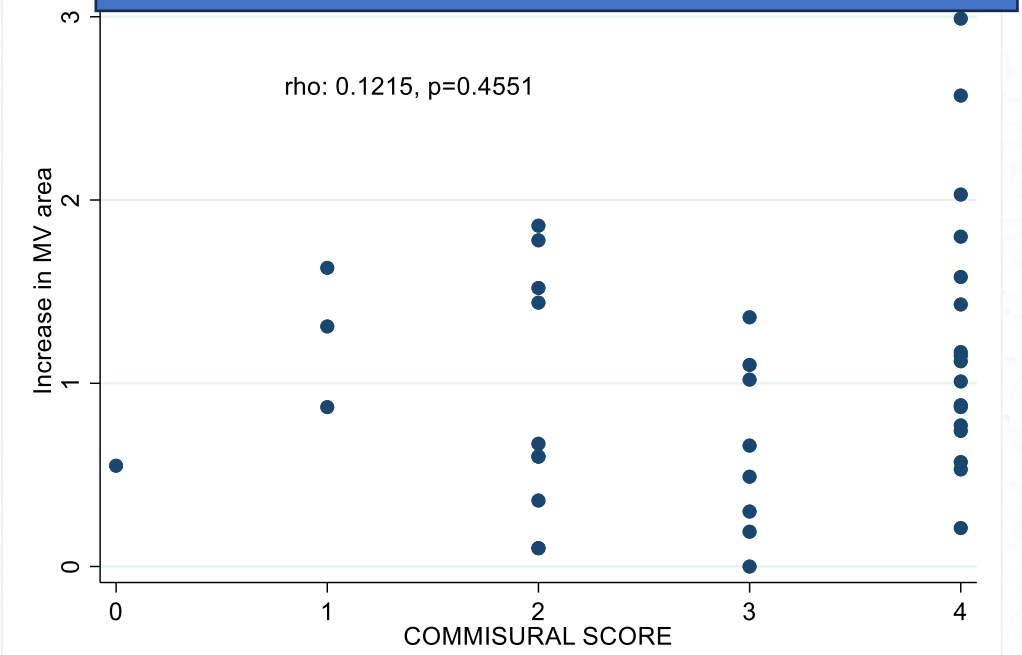


Figure 13: Spearman correlation between commissural score (≤2/>2) and increase in MV area

SCORES	N	Percent	Overall outcome			Increase in MV area (Mean ±SD) Cm2
			Good outcome	Suboptimal outcome	Poor outcome	
Wilkins score <=8 & Commissural score<=2	4	7.69%	4	0	0	1.7 ± 1.14
Wilkins score <=8 & Commissural score>2	24	46.15%	21	2	1	1.14 ± 0.76
Wilkins score >8 & Commissural score<=2	15	28.85%	10	3	2	0.88 ± 0.59
Wilkins score >8 & Commissural score>2	9	17.31%	7	1	1	0.86 ± 0.61

Analysis of Wilkins and commissural score with outcomes and increase in mitral valve area:

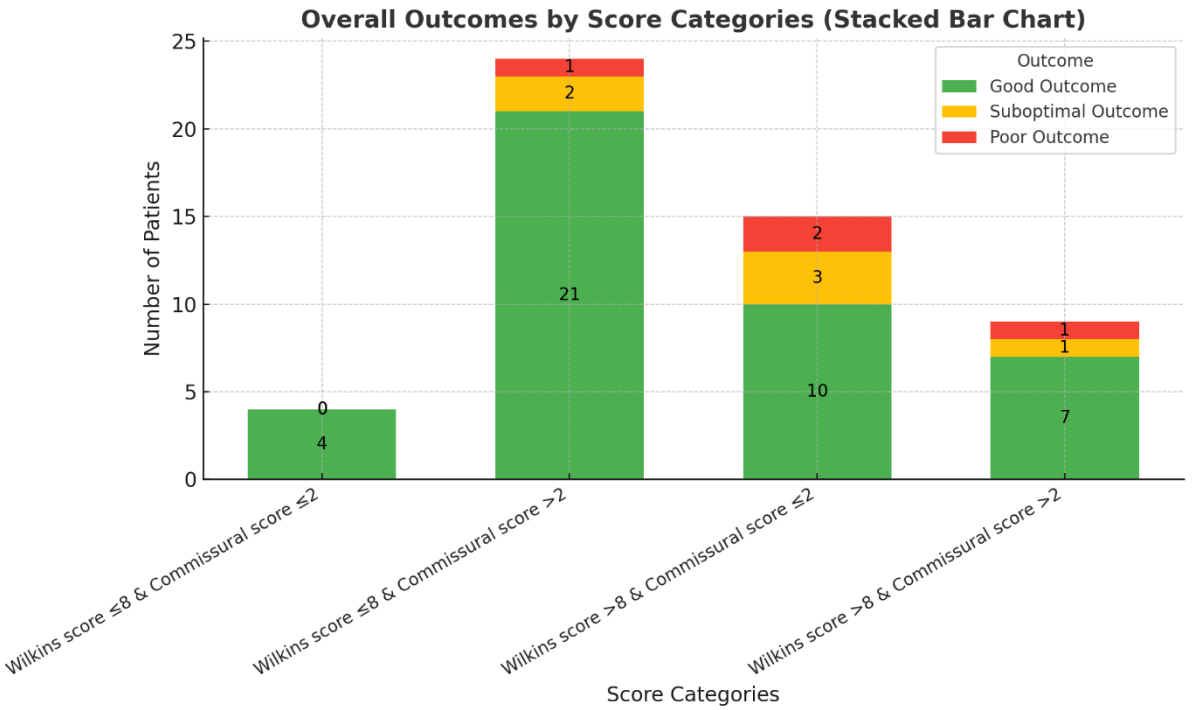


Figure 14: Overall Outcomes in all 4 groups

4

In our study,

All 4 patients (100%) with Wilkins score ≤8 & Commissural score ≤2 achieved good outcome and demonstrated the highest mean increase in MV area (1.7 ± 1.14 cm²), indicating a favorable procedural result.

Among the patients with Wilkins score ≤8 & Commissural score >2 (who are considered to have favourable valve for BMV as per conventional cut off criteria) only 21/24 patients (87.5%) achieved good outcome with relatively favourable increase in MV area (1.14 ± 0.76 cm²) though less than the previous group.

The historical most unfavourable subset is those with patients having Wilkins score >8 & Commissural score ≤2 has the least population that showed good outcome (66.67%) among all the 4 groups with mean increase in MV area of 0.88 ± 0.59 cm².

Among the patients with Wilkins score >8 & Commissural score >2 only 77.78% showed good outcome with mean increase in MV area of 0.86 ± 0.61 cm²

To conclude,

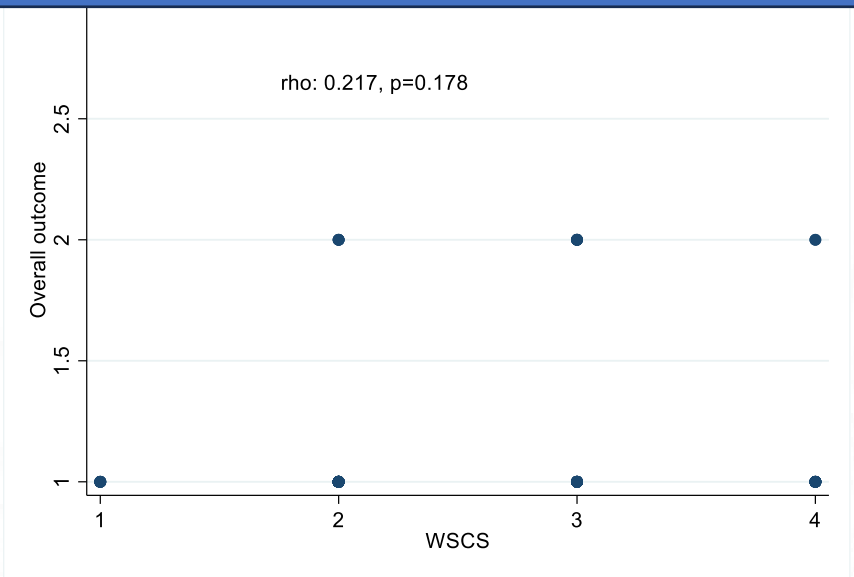
- Higher Wilkins scores (>8) consistently reduced the rate of good outcomes and MV area improvement.
- Higher Commissural scores (>2) alone had a moderate effect on good outcomes.

As the data is non parametric and doesn't follow normal distribution spearman correlation is used to assesses the correlation between.

Both the correlations with outcomes and increase in MV area are weak and are not statistically significant.

Correlation of Wilkins score & Commissural score vs overall outcomes and MV area		
	Overall outcomes	Increase in MV area
Wilkins score & Commissural score	0.2171	-0.2567
P-value	0.1783	0.1099

Table 14: Spearman correlation of Wilkins score & Commissural score vs overall outcomes and MV area



Analysis of Wilkins score and commissural score as a continuous variable with outcome

Figure 15: : Spearman correlation of Wilkins score & Commissural score vs overall outcomes and MV area

1	Correlation of Wilkins score vs Outcomes	
		Overall outcome
	Wilkin score	0.172

	p-value	0.287
2	Correlation of Commissural score vs Outcomes	
	Commissural score	-0.156
	P-value	0.269
	Correlation with Wilkins score vs Mitral valve area	
3		Increase in Mitral valve area
	Wilkin score	-0.343
	P-value	0.0301

Table 15: Correlation of Wilkins score and commissural score as a continuous variable with outcome and increase in mitral valve area

	Good outcome	Suboptimal outcome	Poor outcome
Wilkins score (Mean ±SD)	8.29 ± 2.03	9.00 ± 1.26	9.75 ± 1.71
Commissural score (Mean ±SD)	2.98 ± 1.09	2.83 ± 0.98	2.00 ± 1.83

Table 16: Mean Wilkins and commissural score vs outcomes

The Wilkins score (mean ± SD) across the three outcome groups shows a consistent trend:

- **Good outcome**: 8.29 ± 2.03
- **Suboptimal outcome**: 9.00 ± 1.26
- **Poor outcome**: 9.75 ± 1.71

The Wilkins score increases progressively from the Good to Poor outcome groups. This indicates that patients with higher Wilkins scores, which reflect more unfavourable mitral valve, are more likely to experience poorer outcomes. **A correlation coefficient (r) of 0.172** indicates a weak positive correlation between the Wilkins score and overall outcomes. However, the lack of statistical significance (p=0.287) limits the strength of this conclusion.

This trend highlights the utility of the Wilkins score in risk stratification for predicting procedural or clinical success. Patients with higher Wilkins scores might require more cautious evaluation before intervention.

The Commissural score (mean ± SD) shows the following distribution:

- **Good outcome**: 2.98 ± 1.09

- **Suboptimal outcome**: 2.83 ± 0.98
- **Poor outcome**: 2.00 ± 1.83

The Commissural score decreases progressively from the Good to Poor outcome groups. This suggests that patients with higher Commissural scores (indicating more favourable valve) are more likely to achieve favourable outcomes. Conversely, lower Commissural scores are associated with poorer outcomes. **A correlation coefficient (r) of -0.156** indicates a weak negative correlation between the Commissural score and overall outcomes. The lack of statistical significance limits the strength of this conclusion.

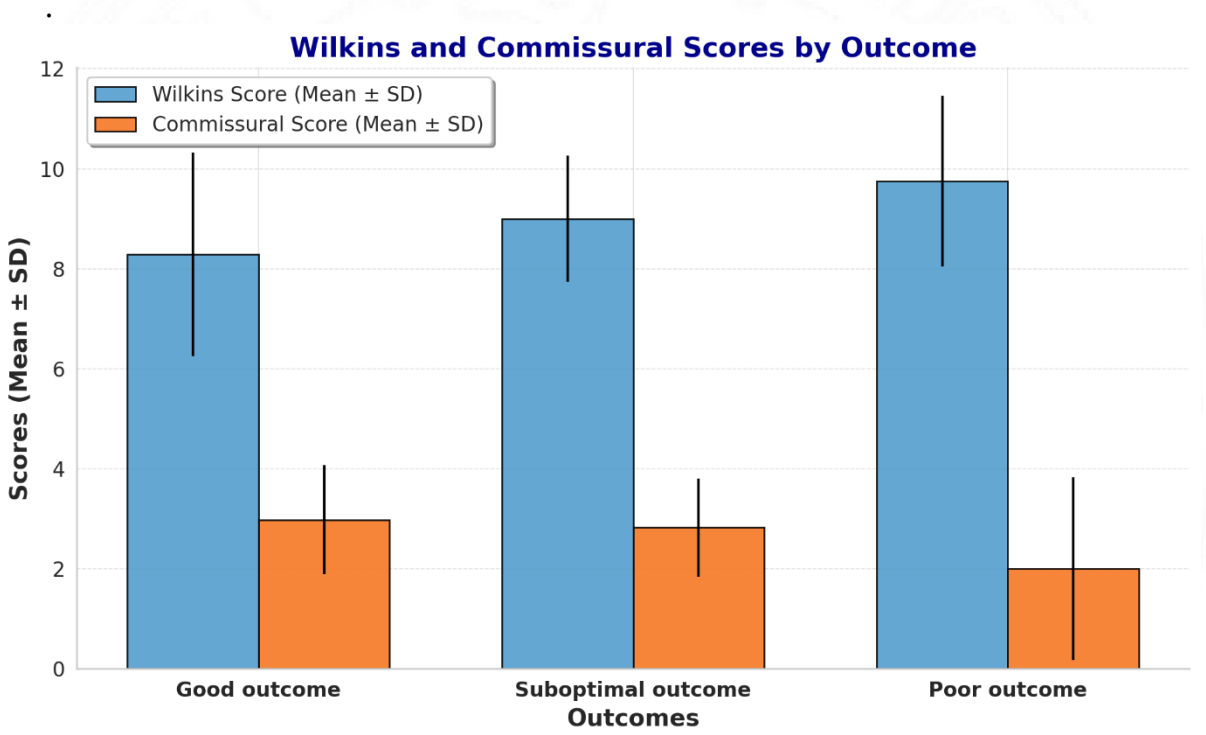


Figure 16: Wilkins and Commissural Score means by Outcomes

- A **negative correlation** is observed between the Wilkins score and the increase in mitral valve area following an intervention with correlation coefficient (r) of -0.343
- This suggests that as the Wilkins score increases (indicating more severe mitral valve pathology), the increase in mitral valve area is smaller.
- Clinically, this indicates that patients with higher Wilkins scores may have less favourable improvement in valve area post-intervention, potentially due to the more complex or calcified nature of the valve.

- The p-value is **less than 0.05 (0.0301)** indicating that this correlation is statistically significant.

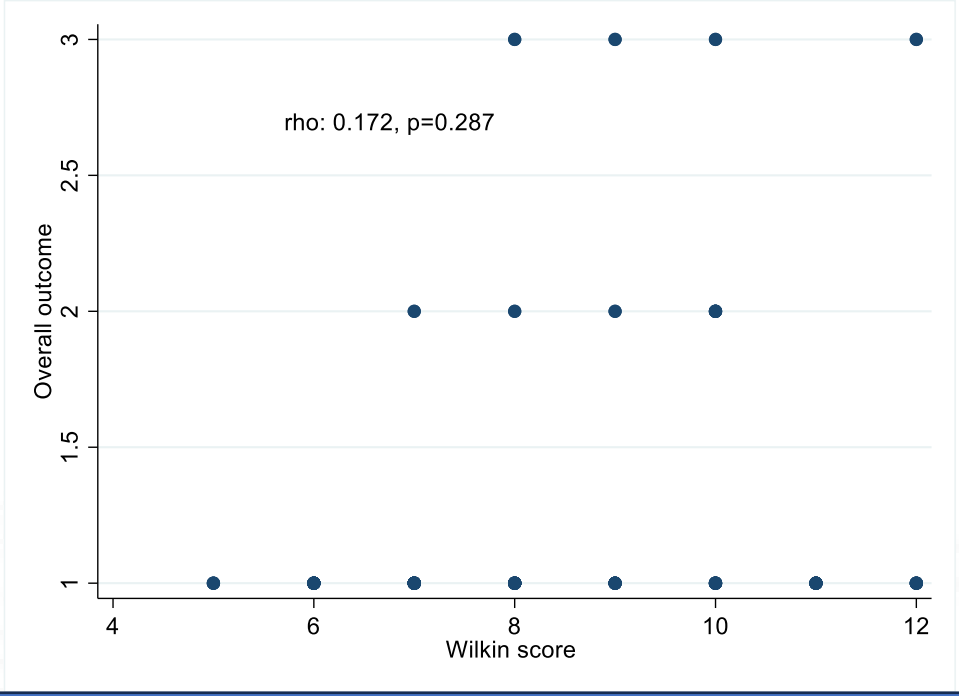


Figure 17: Spearman correlation between Wilkins score (As continuous variable) with outcome

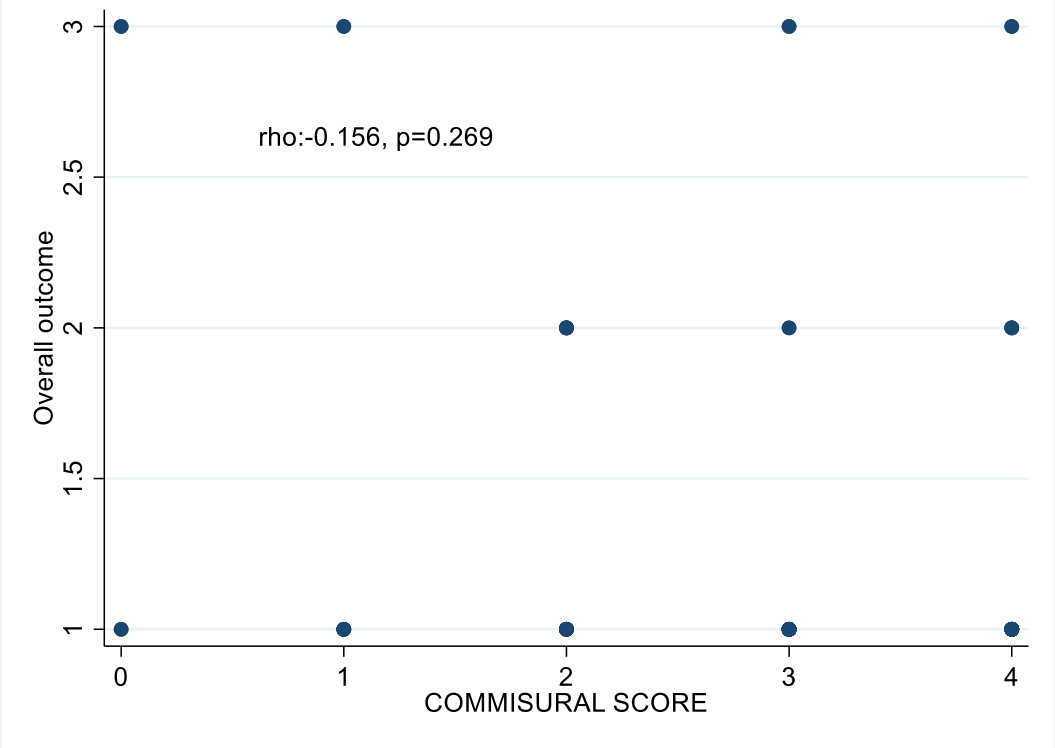


Figure 18: Spearman correlation between mean commissural score (As continuous variable) with outcome

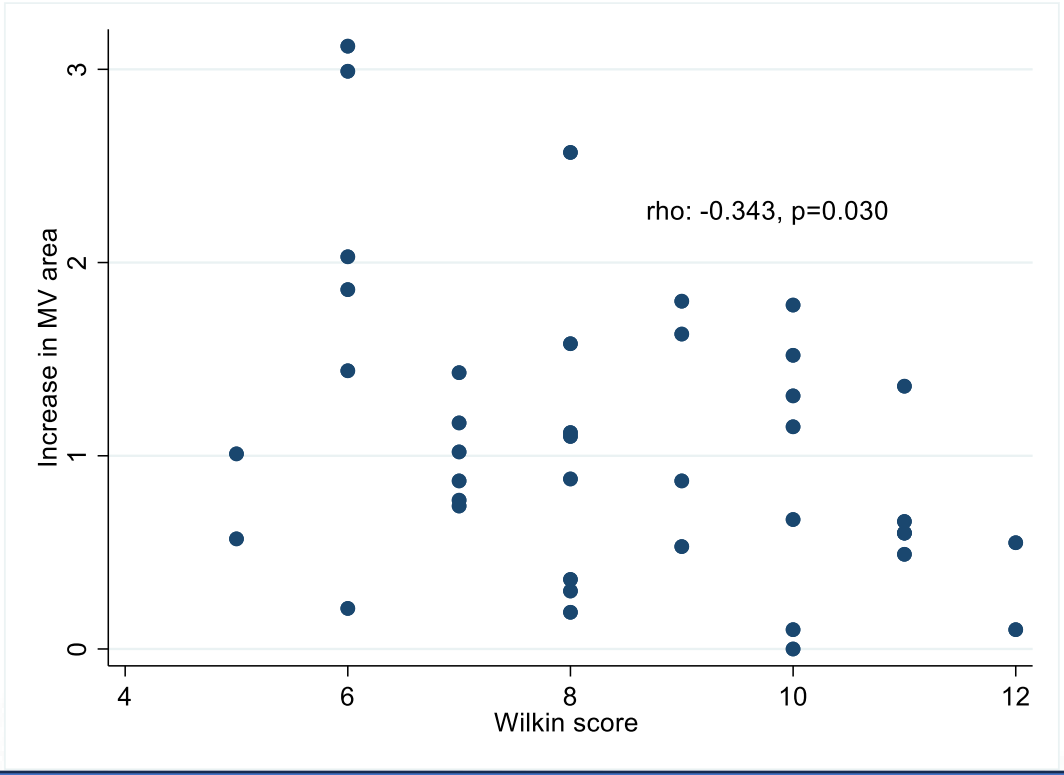


Figure 19: Spearman correlation between mean Wilkins score (As continuous variable) with increase in MV area

Sub-group analysis of Wilkins and commissural score with outcomes and increase in mitral valve area:

Naïve group:

NAÏVE BMV PATIENTS	N	Percent	Overall outcome			Increase in MV area (Mean ±SD) Cm2
			Good outcome	Suboptimal outcome	Poor outcome	
Wilkins Score <= 8	20	64.5%	18	1	1	1.109±0.729
Wilkins Score > 8	11	35.5%	8	1	2	0.939±0.602
Commissural score <= 2	8	25.8%	7	0	1	1.04±0.604

Commissural score > 2	23	74.2%	19	2	2	1.06±0.721

Table 17: Outcomes and increase in mitral valve area in naïve group based on their Wilkins and commissural score

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found that patients with Wilkins Score ≤ 8 has 90% (18/20) had good outcome and they showed better increase in mitral valve area post BMV with mean of 1.109 cm^2 ± 0.729

However, in the same subgroup with Wilkins score > 8 it is observed that only 72.7% (8/11) patients had good outcome and the increase in mitral valve area post BMV is smaller than the previous group with mean of 0.939 cm^2 ± 0.602.

When spearman correlation is used to assess the significance of correlation of Wilkins score with overall outcome and increase in mitral valve area it showed the weak positive correlation (r = 0.2298), where higher WS tends to predict poorer outcomes. However, the statistical insignificance (p = 0.2137) limits the strength of this conclusion. Similarly, a weak negative correlation (Correlation coefficient (**r**): -0.0766) exists between Wilkins Score and the increase in mitral valve area, suggesting that higher Wilkins scores might lead to slightly less improvement in MV area. However, the relationship is not statistically significant (**P-value**: 0.7219).

Similarly, when the analysis was made with only naïve BMV patients it is found that those with Commissural Score ≤ 2, 87.5% (7/8 patients) had good outcome with a reasonable increase in MV area of 1.04 cm^2 ± 0.604. Among those with commissural score of >2 82.6% (19/23) achieved a good outcome with mean increase in mitral valve area of 1.06 cm^2 ± 0.721.

When spearman correlation is used to assess the any correlation between commissural score and overall outcomes it is found that there is no significant correlation between Commissural Score and overall outcomes (p=0.807). It is also found that There is a weak positive correlation between Commissural Score and the increase in mitral valve area. Higher

CS values may indicate slightly better improvements in MV area. However, as the p-value is well above 0.05 (p=0.5234), the observed trend is not statistically significant.

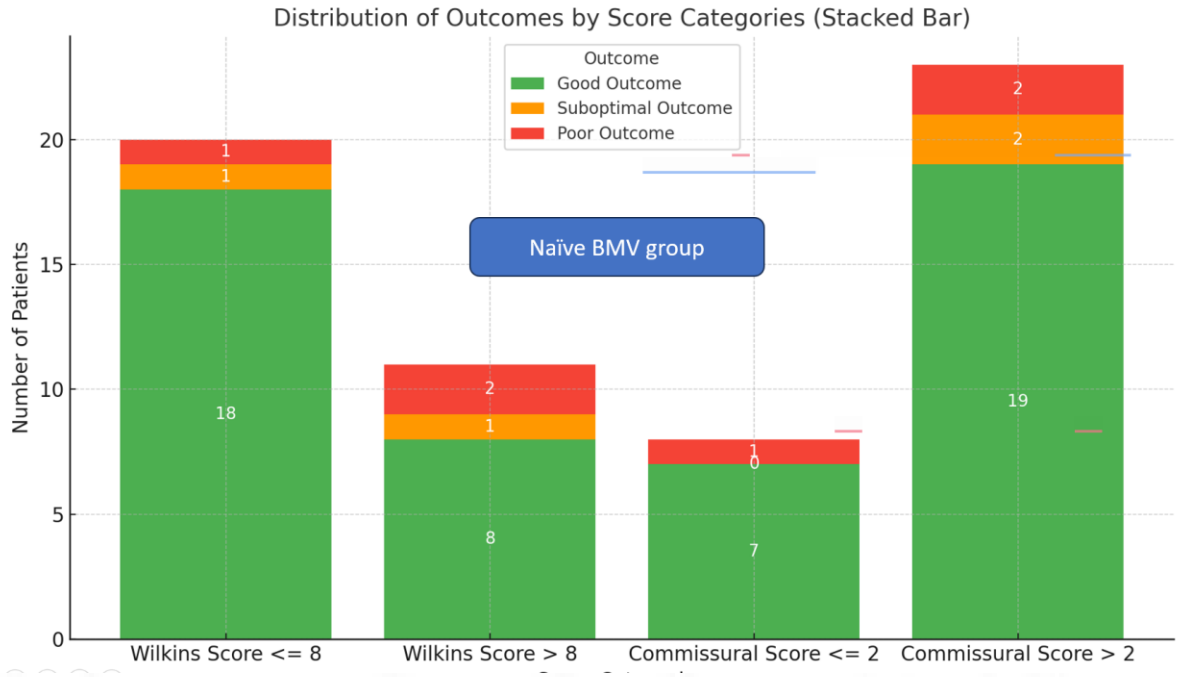


Figure 20: Outcome data in naïve BMV group

NAÏVE BMV PATIENTS	N	Percent	Overall outcome			Increase in MV area (Mean ±SD) Cm2
			Good outcome	Suboptimal outcome	Poor outcome	
Wilkins score <=8 & Commissural score<=2	2	6.5%	2	0	0	1.110±1.061
Wilkins score <=8 & Commissural score>2	18	58.1%	16	1	1	1.109±0.726
Wilkins score >8 & Commissural score<=2	6	19.4%	5	0	1	1.008±0.478
Wilkins score >8 & Commissural score>2	5	16.1%	3	1	18	0.870±0.778

Table 18: Outcomes and increase in mitral valve area in naïve group based on their Wilkins and commissural score

Among the naïve BMV subgroup, only 2 patients had Wilkins score ≤ 8 and Commissural score ≤ 2 and both had a good outcome with mean increase in Mitral Valve Area (MV area) 1.110 ± 1.061 cm² suggesting effective improvement.

18 patients in the naïve BMV subgroup had Wilkins score ≤ 8 and Commissural score > 2 which is the largest subset in the naïve group and 88.88% (16/18) had good outcome with mean increase in MV area of 1.109 ± 0.726 cm².

6 patients in the naïve BMV subgroup had Wilkins score > 8 and Commissural score ≤ 2 and among them 83% patients had good outcomes with mean increase in MV area 1.008 ± 0.478 cm².

5 patients have Wilkins score > 8 and Commissural score > 2 only 60% had good outcomes with mean increase in MV area of 0.870 ± 0.778 cm².

The combination of lower Wilkins and higher Commissural scores (Wilkins ≤ 8 & Commissural > 2) seems to represent the most favourable outcomes in terms of achieving a good result with a significant increase in MV area.

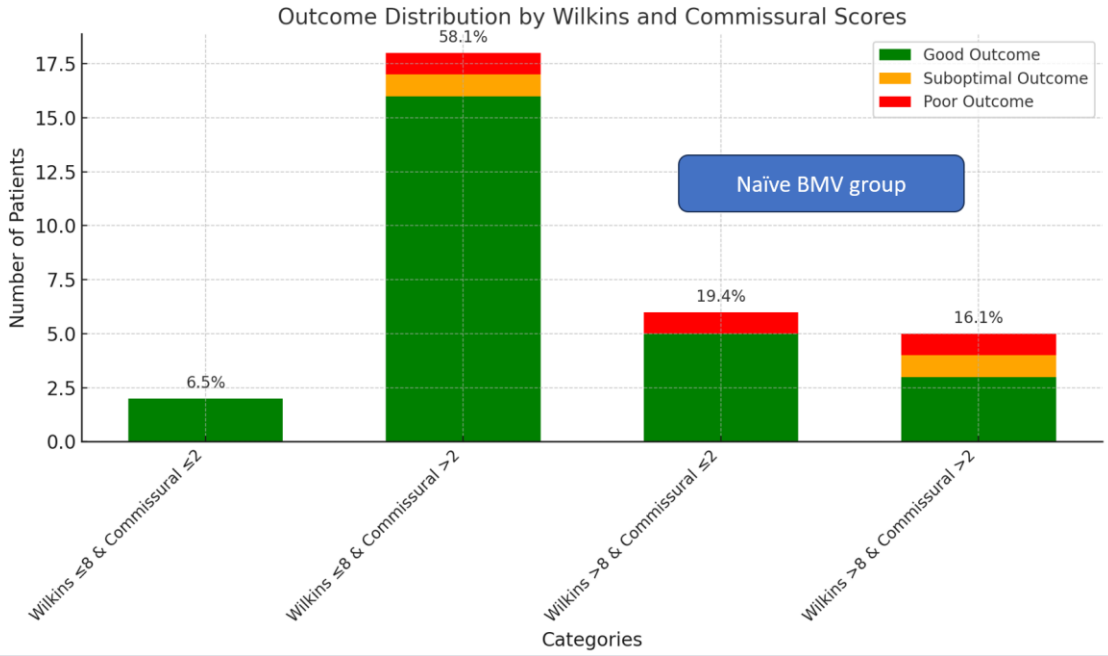


Figure 21: Outcome Distribution by Wilkins and Commissural Scores in naïve BMV group

Redo			Naive		
1	Correlation with Wilkins score vs Outcomes		1	Correlation with Wilkins score vs Outcomes	
		Overall outcomes			Overall outcomes
	WS	0.218		WS	0.2298
	p-value	0.3425		p-value	0.2137
2	Correlation with Commissural score vs Outcomes		2	Correlation with Commissural score vs Outcomes	
	CS	-0.3179		CS	0.0451
	P-value	0.1602		P-value	0.8097
3	Correlation with Wilkins score vs MVAS			Correlation with Wilkins score vs MVAS	
		Increase in MV area	3		Increase in MV area

	WS	-0.3924		WS	-0.0766
	P-value	0.1328		P-value	0.7219
4	Correlation with Commissural score vs increase in MV area			Correlation with Commissural score vs increase in MV area	
		Increase in MV area	3		Increase in MV area
	WS	0.0707		WS	0.1369
	P-value	0.7946		P-value	0.5234

Table 19: Correlation of Wilkins and commissural score with outcomes and increase in mitral valve area in naïve group

Redo group:

In our study, redo BMV done for 21 patients (40.38% of the study population). 8 patients had Wilkins Score ≤ 8 (38.1% of the redo group). Among these 8 patients 7 had good outcome (87.5%) and they showed much better increase in mitral valve area post procedure with mean increase of 1.598 ± 1.068 cm^2. 13 patients had wilkins score of > 8 and among them 9 patients had good outcome (69%) and they had only mild increase in mitral valve area post procedure with mean increase of 0.821 ± 0.591 cm^2. While the positive correlation (Correlation Coefficient (r): 0.218) indicates a slight trend where higher Wilkins Scores might be associated with worse outcomes, the correlation is weak and not statistically significant (p =0.218). The negative correlation (Correlation Coefficient (r): -0.3924) suggests that higher Wilkins Scores are associated with smaller increases in mitral valve area. However, the correlation is moderate and not statistically significant (p=0.1328). Lower Wilkins Scores (≤ 8) were associated with better clinical outcomes and larger MV area increases though statistically insignificant.

In the redo group, 11 patients had commissural score ≤ 2 (52.4% of the redo group) and among them 7 patients (63.6%) had good outcome with mean increase in MV area post procedure 1.14 ± 0.966 cm^2. 10 patients has commissural score > 2 and among them 9 patients had good outcome (90%) and they showed slightly lower increase in mitral valve area post procedure with mean increase of 1.08 ± 0.777 cm^2 when compared to whose with commissural score ≤ 2 . The negative correlation (Correlation Coefficient (r): -0.3179) implies that higher Commissural Scores might be associated with better outcomes (as indicated by fewer poor

results). However, the association is moderate and not statistically significant (p=0.16). The weak positive correlation suggests no meaningful relationship between Commissural Score and the increase in mitral valve area (r=0.07) and p value 0.79 in our study.

REDO BMV GROUP	N	Percent	Overall outcome			Increase in MV area (Mean ±SD) Cm2
			Good outcome	Suboptimal outcome	Poor outcome	
Wilkins Score <= 8	8	38.1%	7	1	0	1.598±1.068
Wilkins Score > 8	13	68.9%	9	3	1	0.821±0.591
Commissural score <= 2	11	52.4%	7	3	1	1.14±0.966
Commissural score > 2	10	47.6%	9	1	0	1.08±0.777

Table 19: Outcomes and increase in mitral valve area in redo group based on their Wilkins and commissural score

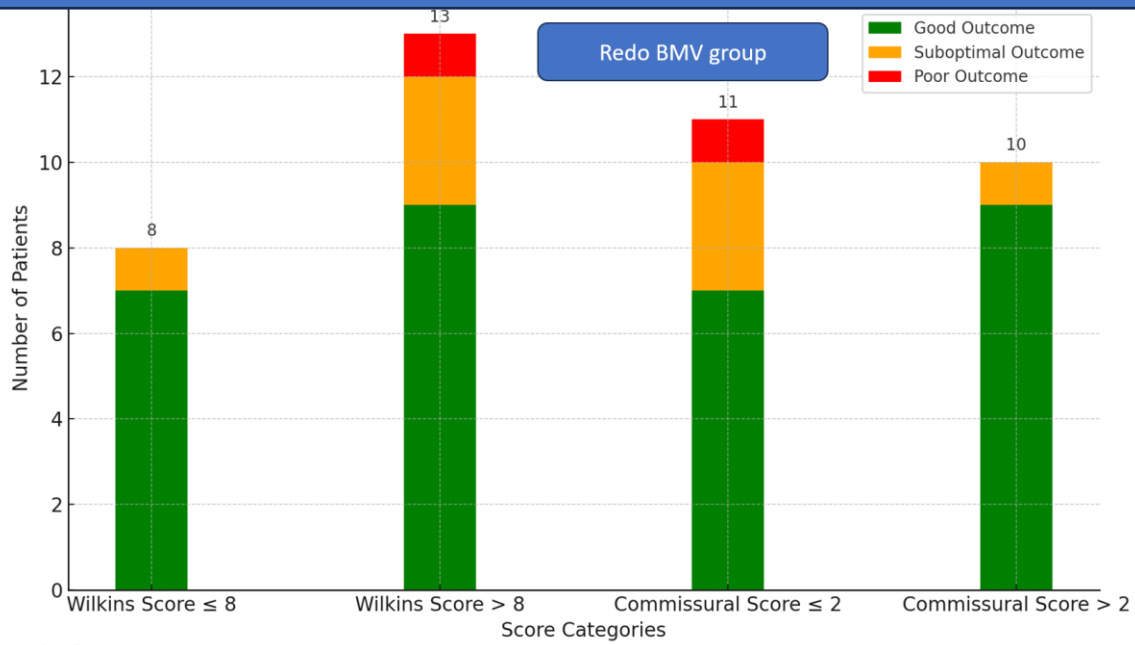


Figure 22: Redo BMV Group Outcomes by Score Categories

REDO BMV GROUP	N	Percent	Overall outcome			Increase in MV area (Mean ±SD) Cm2
			Good outcome	Suboptimal outcome	Poor outcome	
Wilkins score <=8 & Commissural score<=2	2	9.5%	2	0	0	2.280±1.188
Wilkins score <=8 & Commissural score>2	6	28.6%	5	1	0	1.258±0.982
Wilkins score >8 & Commissural score<=2	9	42.9%	5	3	1	0.814±0.672
Wilkins score >8 & Commissural score>2	4	19.0%	4	0	0	0.837±0.461

Table 20: Outcomes and increase in mitral valve area in redo group based on their Wilkins and commissural score

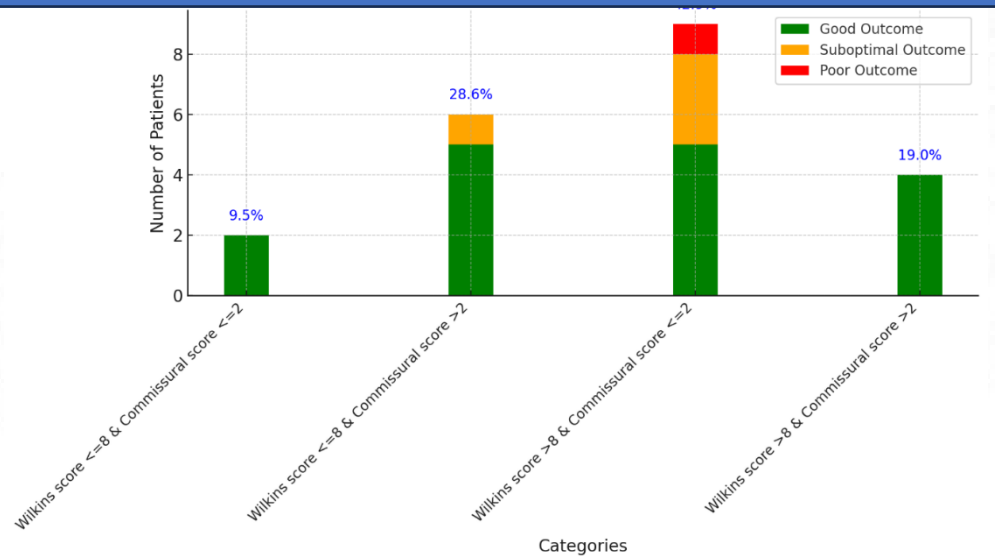


Figure 23: Outcomes Distribution in REDO BMV Group

When we divide the redo patients into 4 groups it is found that those in group 1 (Wilkins score ≤8 & Commissural score ≤2) which comprises of 2 patients (9.5%) 100% had good

outcome with highest mean increase in MV area: 2.280 ± 1.188 cm².

Group 2 are the population with Wilkins score ≤8 & Commissural score >2 which includes 6 patients and 83.3% (5/6) had good outcome while 1 patient (16.7%) had suboptimal outcome. The mean increase in MV area in this group is 1.258 ± 0.982 cm².

Group 3 (Wilkins score >8 & Commissural score ≤2) comprises of maximum study population in the redo group with 9 patients (42.9%). Only 5 patients (55.6%) achieved a Good outcome, 3 (33.3%) had a Suboptimal outcome, and 1 (11.1%) experienced a Poor outcome. The Mean increase in MV area in this group is 0.814 ± 0.672 cm².

Group 4 (Wilkins score >8 & Commissural score >2) comprises of 4 patients (19.0%) and all had good outcome. The mean increase in MV area is 0.837 ± 0.461 cm².

To conclude patients with Wilkins score ≤8 had predominantly good outcomes and no poor outcomes noted even in the redo cases. Moreover these patients attained maximum increase in MV area post BMV.

Naïve vs redo continuous

Redo			Naive		
1	Correlation with Wilkins score vs Outcomes		1	Correlation with Wilkins score vs Outcomes	
		Overall outcomes			Overall Outcomes
	WS	-0.017		WS	0.266
	p-value	0.948		p-value	0.207
2	Correlation with Commissural score vs Outcomes		2	Correlation with Commissural score vs Outcomes	
	CS	-0.3005		CS	-0.0455
	P-value	0.1856		P-value	0.8079
	Correlation with Wilkins score vs MVAS			Correlation with Wilkins score vs MVAS	
3		Increase in MV area	3		Increase in MV area
	WS	-0.5737		WS	-0.1711
	P-value	0.0201		P-value	0.424

Table 21: Correlation between Wilkins and commissural score with outcome and increase in mitral valve in redo group

Naïve subgroup analysis:

NAÏVE BMV PATIENTS	Good outcome	Suboptimal outcome	Poor outcome
Wilkins score (Mean ±SD)	7.81±1.919	8.00±1.414	10.00±2.000
Commissural score (Mean ±SD)	3.31±0.970	4.00±0.00	2.67±1.528

Table 22

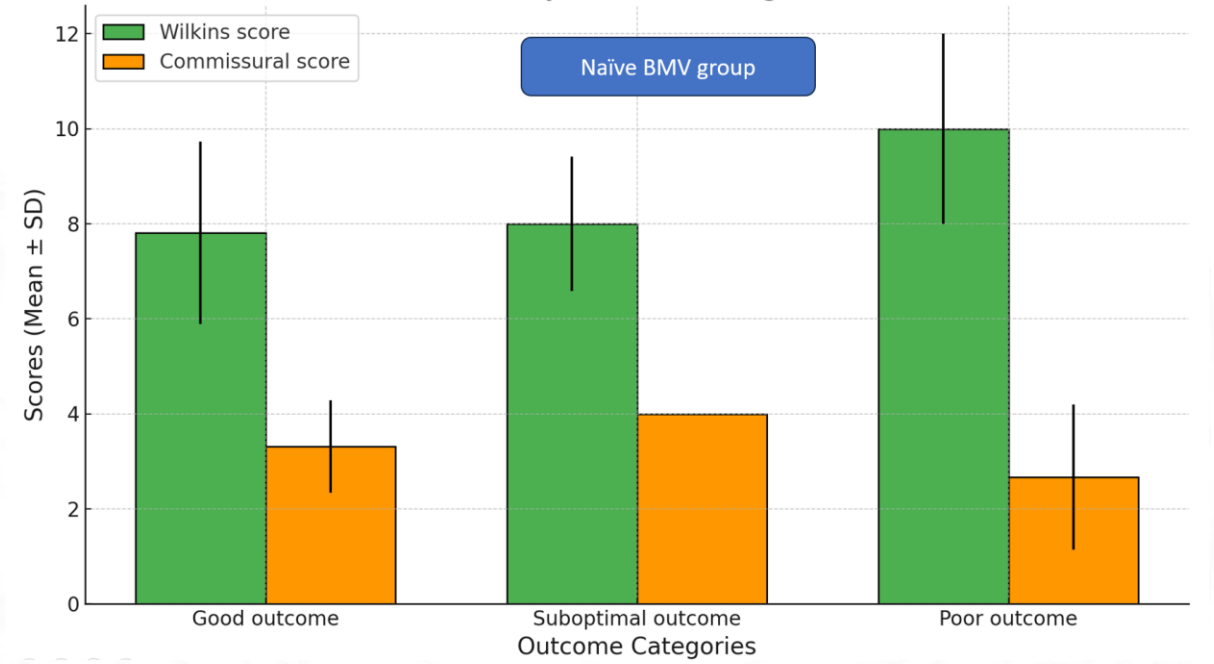


Figure 24: Scores by Outcomes Categories in Naïve BMV group

dichotomous variable based on historical classification of favourable vs unfavourable valves (Wilkins score <=8 vs Wilkins score >8) it is found that patients achieving a good outcome had relatively lower Wilkins scores with mean of 7.81 ± 1.919. Patients with suboptimal outcomes had slightly higher Wilkins scores compared to the good outcome group with mean score of 8.00 ± 1.414. The highest Wilkins scores were seen in the poor outcome group reflecting severely unfavourable valve characteristics. Though numerically significant there is only weak

correlation between Wilkins score with outcome (Correlation coefficient (r): 0.266) and is not statistically significant (p = 0.207). To conclude as the Wilkins score increases, the likelihood of achieving a good outcome decrease. This reinforces the importance of lower scores for procedural success.

A weak negative correlation (Correlation coefficient (r): -0.1711) is observed between the Wilkins score and the increase in mitral valve area. Higher Wilkins scores tend to result in a slightly smaller increase in MV area, reflecting less effectiveness of the procedure in patients with more severe pathology. However, it is not statistically significant with p value of 0.424.

REDO BMV GROUP	Good outcome	Suboptimal outcome	Poor outcome
Wilkins score (Mean ±SD)	9.06±2.016	9.50±1.00	9.0±0.0
Commissural score (Mean ±SD)	2.44±1.094	2.25±0.500	0

Table 23: Outcomes in redo BMV group based on mean Wilkins and commissural score

Similarly, if commissural score is taken as continuous variable instead of dichotomous variable (based on historical favourable and unfavourable valves as score > 2 vs ≤ 2) it is found that patients with good and suboptimal outcomes had higher mean commissural score (3.31± 0.97 and 4 respectively) than those who got poor outcome (2.67 ± 1.53). Very weak negative correlation exist between commissural score and outcomes, means, lower commissural score had poor outcomes with correlation coefficient (r) of -0.0455 with p value of 0.8079.

Redo subgroup analysis:

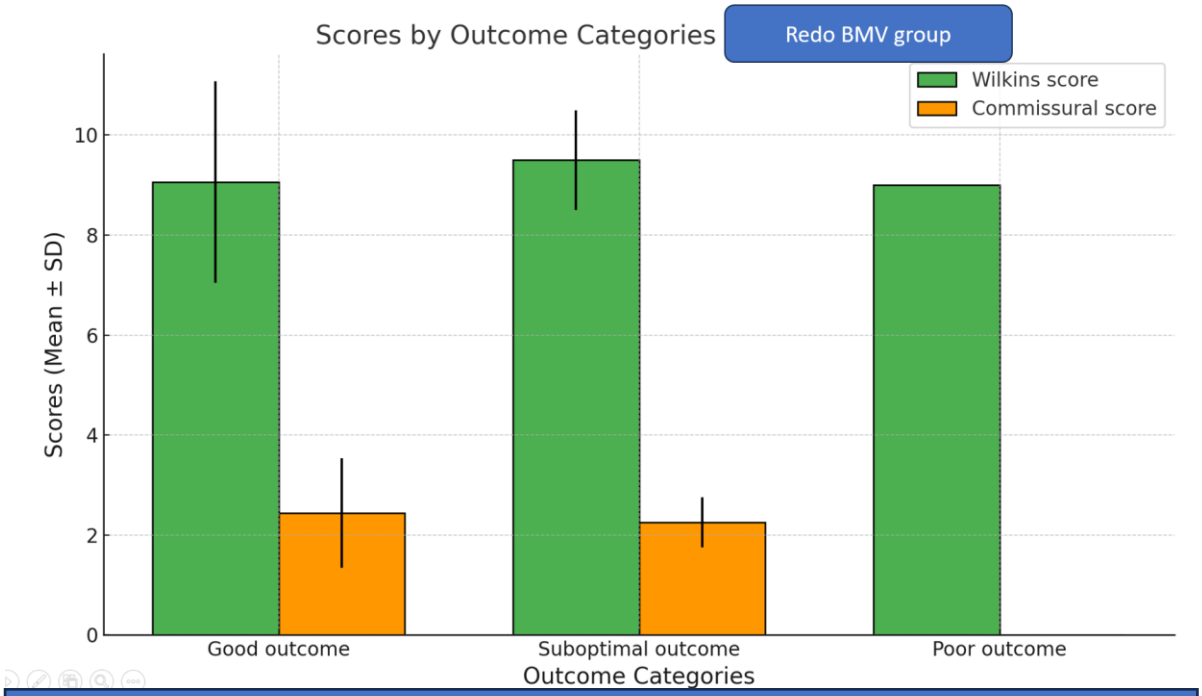


Figure 25: Scores by Outcomes Categories-REDO BMV group

When Wilkins score is analysed as a continuous variable in our redo BMV cases there is no significant trend visualised. However commissural score is higher for those who had good response than those who had suboptimal or poor response. There is a weak negative correlation (Correlation coefficient (r): -0.3005) between the commissural score and outcomes. As the commissural score increases the outcomes tend to improve slightly however it is not statistically significant (p=0.186).

When assessing correlation Between Wilkins Score (WS) and Increase in Mitral Valve Area (MVAS) it is noted that there is moderate to strong negative correlation between the Wilkins score and the increase in mitral valve area after the procedure. This p-value is below 0.05 (p = 0.0201), meaning the correlation is statistically significant. Higher Wilkins scores are significantly associated with less improvement in mitral valve area (MVAS).

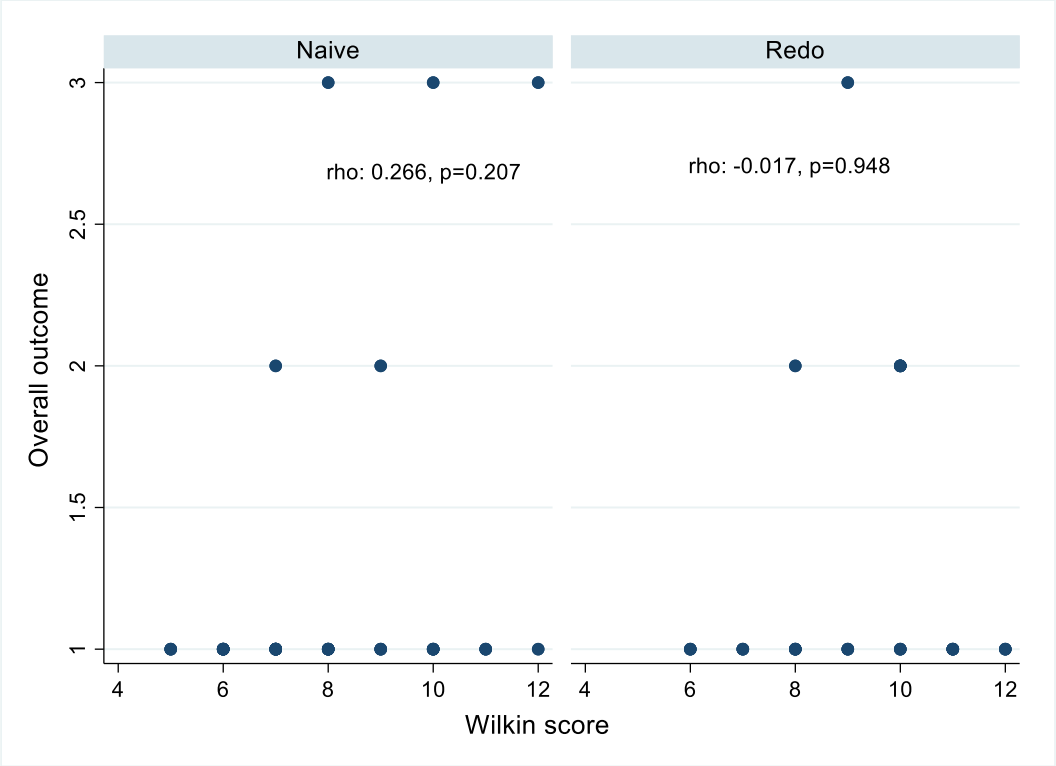


Figure 26: Correlation between Wilkins score vs overall outcome in naïve and redo group

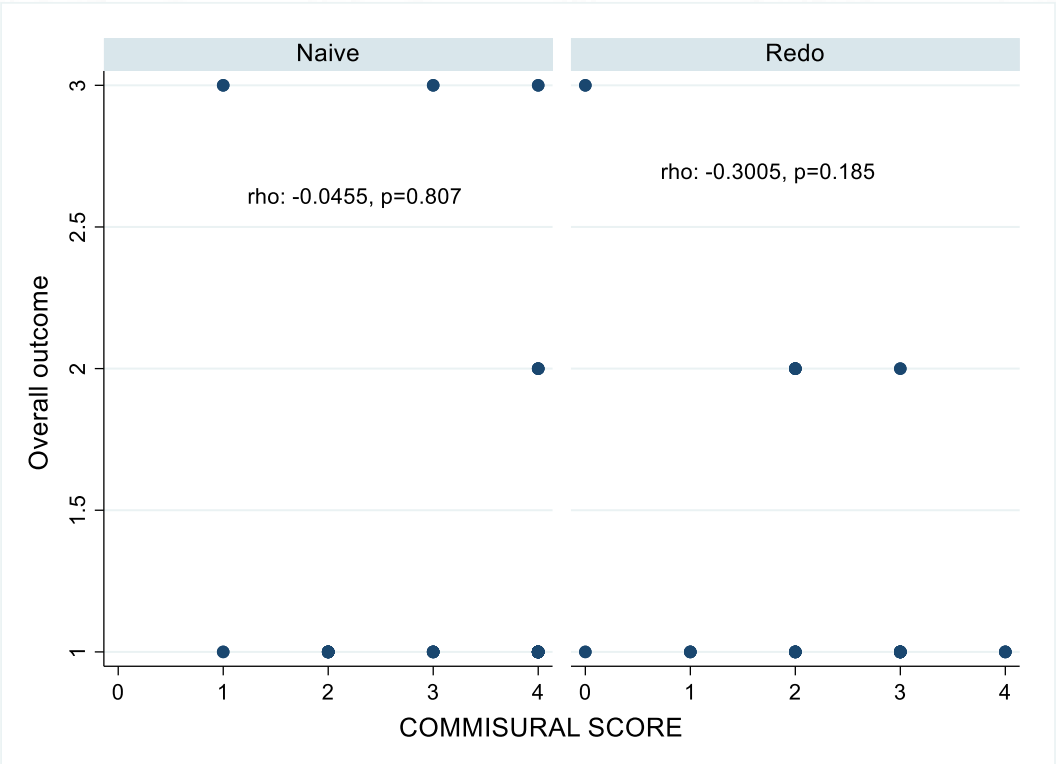


Figure 27: Correlation between Commissural score vs overall outcome in naïve and redo group

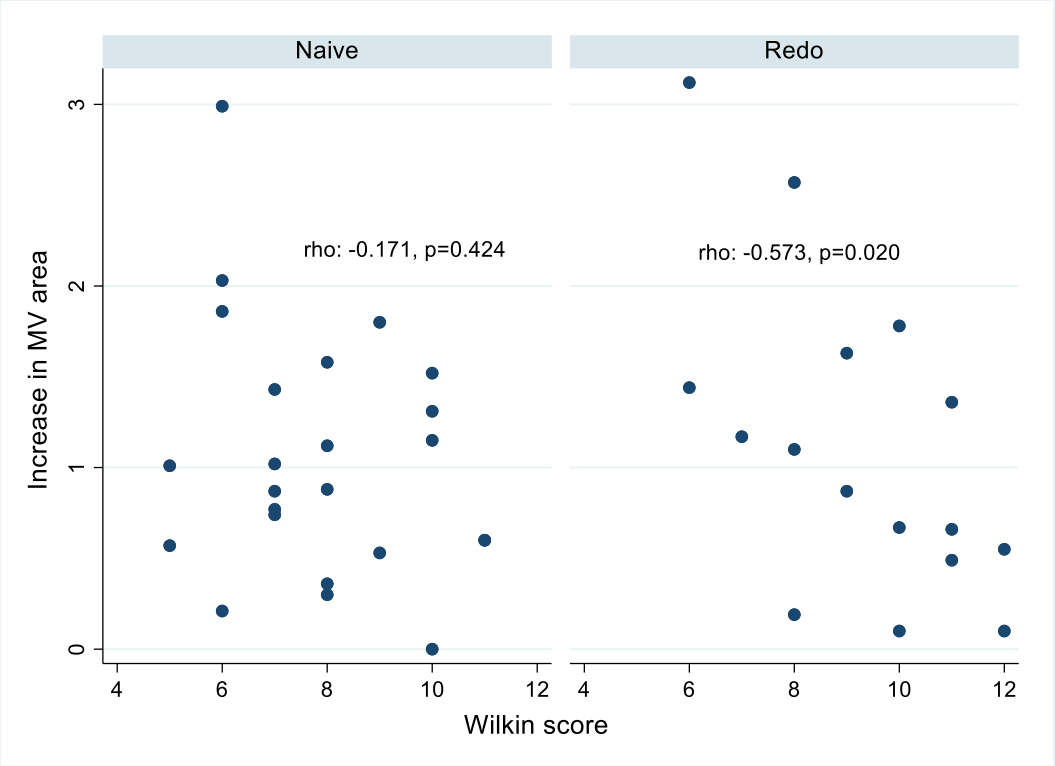


Figure 28: Correlation between Wilkins score vs increase in MV area in naïve and redo group

Commissural anatomy pre and post-BMV:

Pre-BMV Medial commissure	Post BMV medial commissure				
	Split N (%)	Partly split N (%)	Not Split N (%)	Total N (%)	P-value (by fisher xact test)
Fused	24(63.16)	8(88.89)	0(0)	32(62.75)	<0.001
Partly fused	7(18.42)	0(0)	0(0)	7(13.73)	
Split	7(18.42)	0(0)	0(0)	7(13.73)	
Fused and Calcific	0(0)	1(11.11)	4(100)	5(9.8)	

Table 24: Medial commissure pre and post procedure

This table presents the results of a study examining the relationship between pre-BMV (before balloon mitral valvuloplasty) medial commissure status (e.g., fused, partly fused, split,

fused and calcific) and outcome after BMV categorized as "Split," "Partly Split," and "Not Split".

Post-BMV - 24 cases with a fused medial commissure resulted in the valve being split and 8 cases with a fused commissure resulted in the valve being partly split. 7 cases with a partly fused commissure resulted in the valve being split post BMV. 1 case with a fused and calcific commissure resulted in the valve being partly split and 4 cases with a split and calcific commissure resulted in the valve being not split.

Fused commissures have the highest likelihood of successful splitting, but some may only partially split. Partly fused commissures consistently transition to fully split states, likely due to less severe fusion pre-BMV. Fused and calcific commissures show the poorest outcomes, with most remaining unsplit, highlighting calcification as a major procedural barrier. The very low p-value (<0.001) from Fisher's exact test indicates a highly significant association between pre-BMV commissural morphology and post-BMV splitting outcomes.

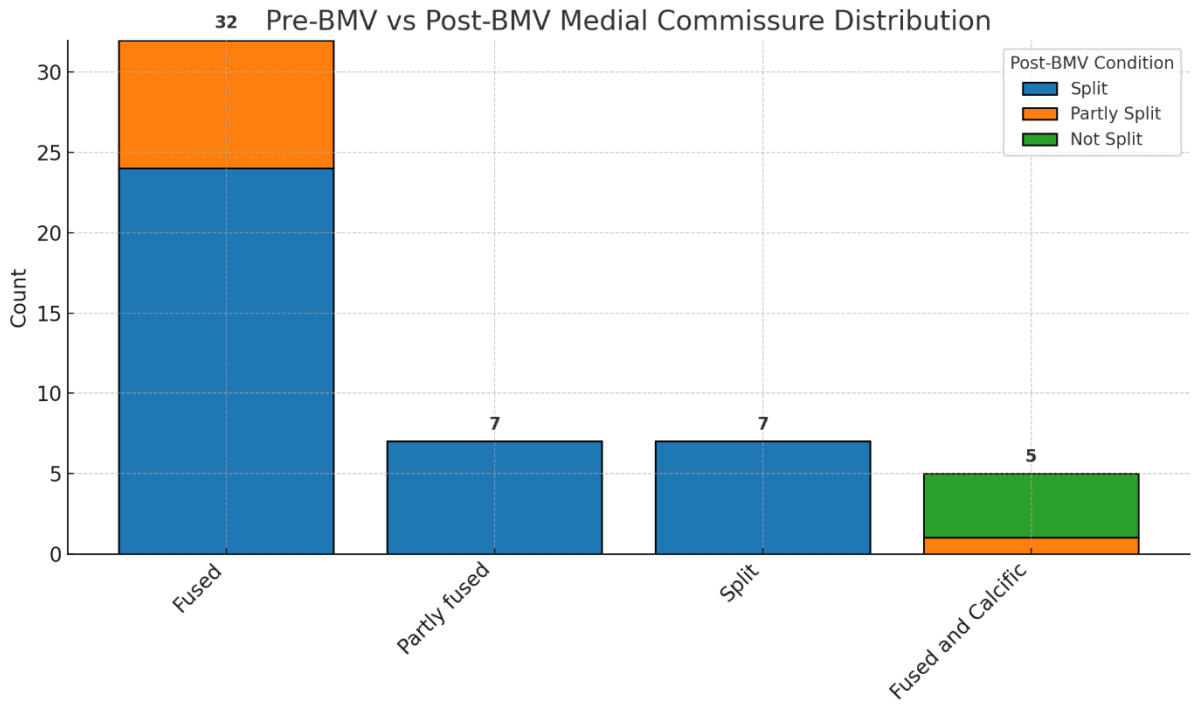


Figure 29: Pre-BMV vs Post BMV Medial Commissure Distribution

Lateral Commissure pre and post BMV:

Pre-BMV Lateral Commissure	Post BMV Lateral commissure				
	Split N (%)	Partly split N (%)	Not Split N (%)	Total N (%)	P-value (by fisher xact test)
Fused	29(69.05)	6(75)	0(0)	35(68.63)	0.135
Partly fused	7(16.67)	1(12.5)	0(0)	8(15.69)	
Split	3(7.14)	0(0)	0(0)	3(5.88)	
Fused and Calcific	3(7.14)	1(12.5)	1(100)	5(9.8)	

Table 25: Pre-BMV vs Post BMV lateral Commissure Distribution

Similarly, as shown in the above table post-BMV 29 cases with a fused lateral commissure resulted in the valve being split. 6 cases with a fused commissure resulted in the valve being partly split. The success of splitting fused lateral commissures shows promise, but a portion may remain only partly split. 7 cases with a partly fused commissure resulted in the valve being split and 1 case remained partly split. Among the patients who has fused and calcific commissure 3 cases resulted in the valve being split, 1 case resulted in the valve being partly split and 1 case resulted in the valve not splitting. Fused and calcific commissures are less likely to split successfully compared to non-calcific fused commissures, as calcification significantly reduces the effectiveness of BMV.

To conclude a fused commissure strongly correlates with the commissure being split or partly split after the procedure. A partly fused commissure leads to a split result. The calcific and fused condition seems to lead to partial splits, with some valves not splitting at all. Calcification is a major barrier to successful splitting, which should be considered during pre-procedural planning. However $p = 0.135$ indicates that these observations in lateral commissure would have occurred by chance and is not statistically significant.

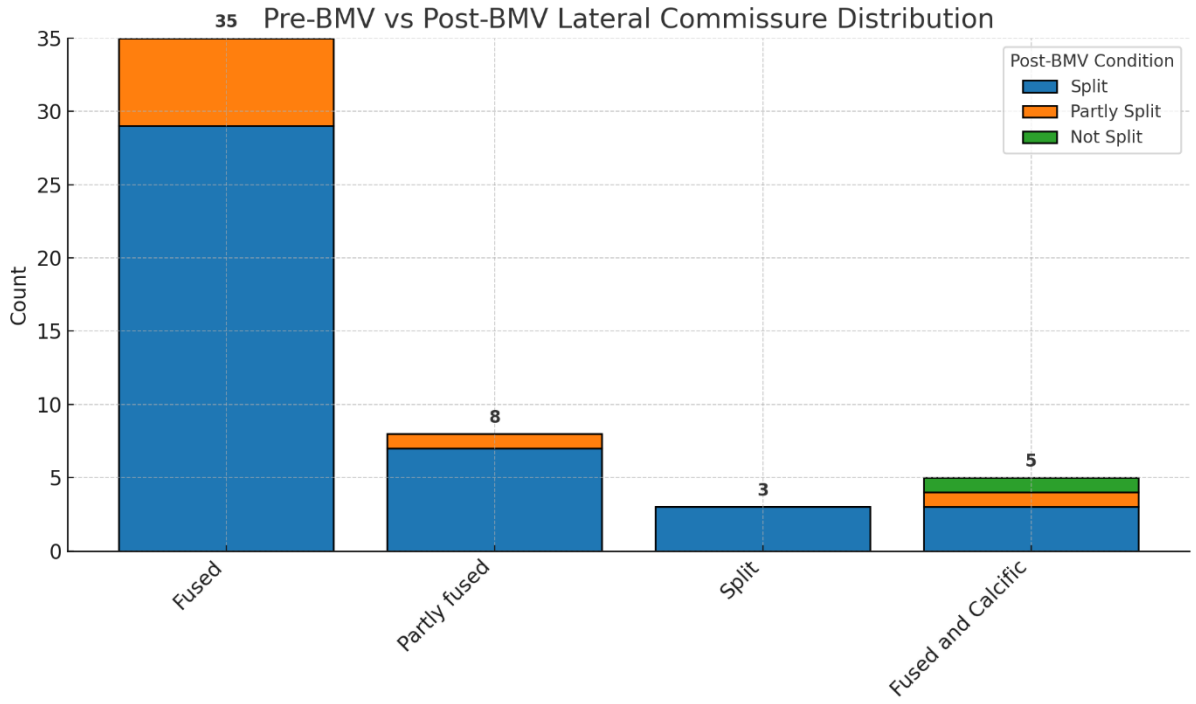


Figure 30: Pre-BMV vs Post BMV Lateral Commissure Distribution

Post BMV MR severity:

Post MR echo severity score with >/= 3	Wilkins score			P-value (by fisher xact test)
	Wilkins Score </= 8	Wilkins Score > 8	Total	
<3	19(67.86)	10(41.67)	29(55.77)	0.093
≥3	9(32.14)	14(58.33)	23(44.23)	
Total	28(100)	24(100)	52(100)	

From the above table, it is noted that,

- Among patients with **Wilkins Score ≤8**, 19 patients (67.86%) had a post-procedure MR severity <3.
- Among patients with **Wilkins Score ≤8**, 9 patients (32.14%) had a post-procedure MR severity ≥3+.

- Among patients with **Wilkins Score >8**, 10 patients (41.67%) had a post-procedure MR severity <3
- Among patients with **Wilkins Score >8**, 14 patients (58.33%) had a post-procedure MR severity ≥3+.

Patients with **Wilkins scores ≤8** are more likely to have mild MR post-BMV (67.86%), indicating favourable outcomes. Patients with **Wilkins scores >8** are more likely to experience moderate to severe MR post-BMV (58.33%), suggesting that higher scores correlate with higher grades of MR. Though there is potential trend where higher Wilkins scores are associated with worse post-procedural MR outcomes it is not statistically significant (p = 0.093).

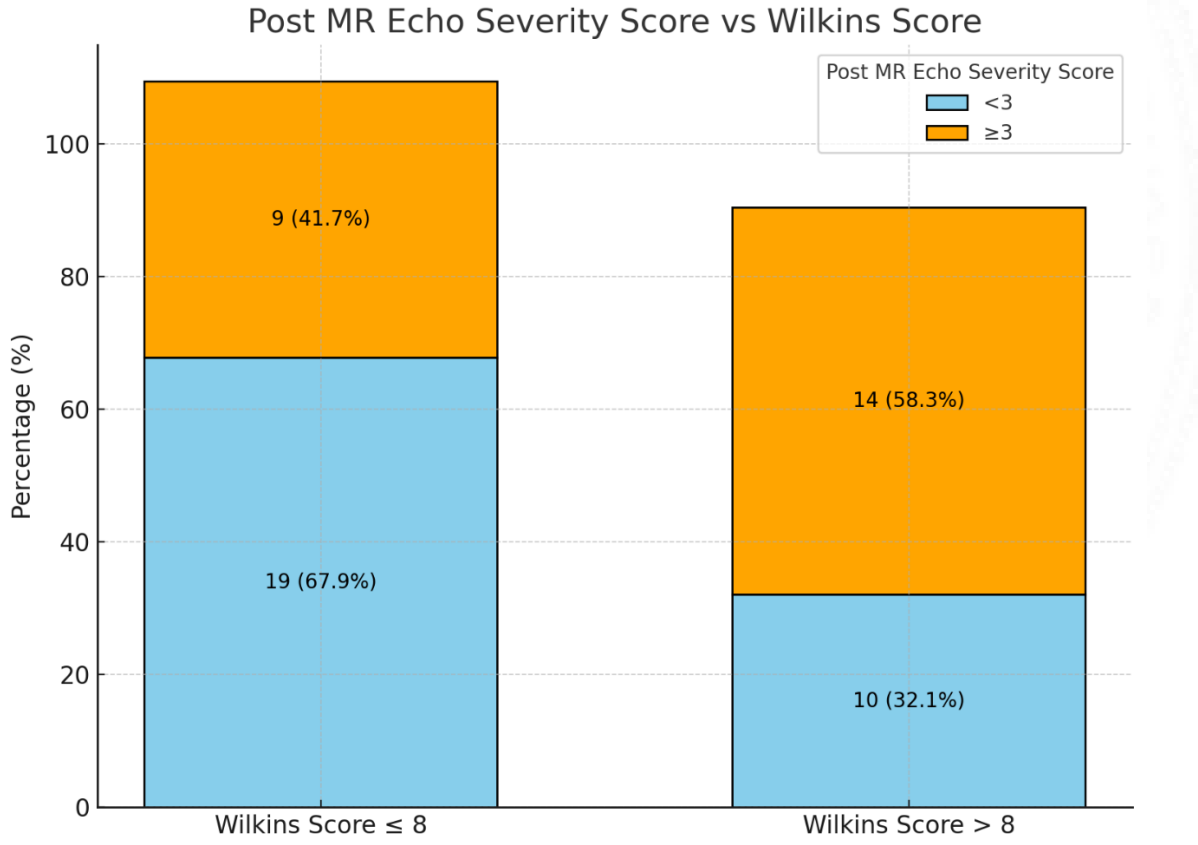


Figure 31: Post MR Echo Severity Score vs Wilkins Score

Post MR echo severity score with >/= 3	Commissural score			P-value (by fisher xact test)
	Commissural Score </= 2	Commissural Score > 2	Total	
<3	10(52.63)	19(57.58)	29(55.77)	0.787
≥3	9(47.37)	14(42.42)	23(44.23)	
Total	19(100)	33(100)	52(100)	

Table 27: Assessment of post-procedure MR vs commissural score

From the above table, it is noted that,

- Among patients with **commissural Score ≤2**, 10 patients (52.63%) had a post-procedure MR severity <3.
- Among patients with **commissural Score ≤2**, 9 patients (47.37%) had a post-procedure MR severity ≥3+.
- Among patients with **commissural Score >2**, 19 patients (57.58%) had a post-procedure MR severity <3
- Among patients with **commissural Score >2**, 14 patients (42.42%) had a post-procedure MR severity ≥3+.

The distribution of MR severity is relatively similar across both Commissural Score categories. Our data show that commissural score does not provide sufficient evidence to predict the severity of MR following BMV.

Table 26: Assessment of post-procedure MR vs Wilkins score

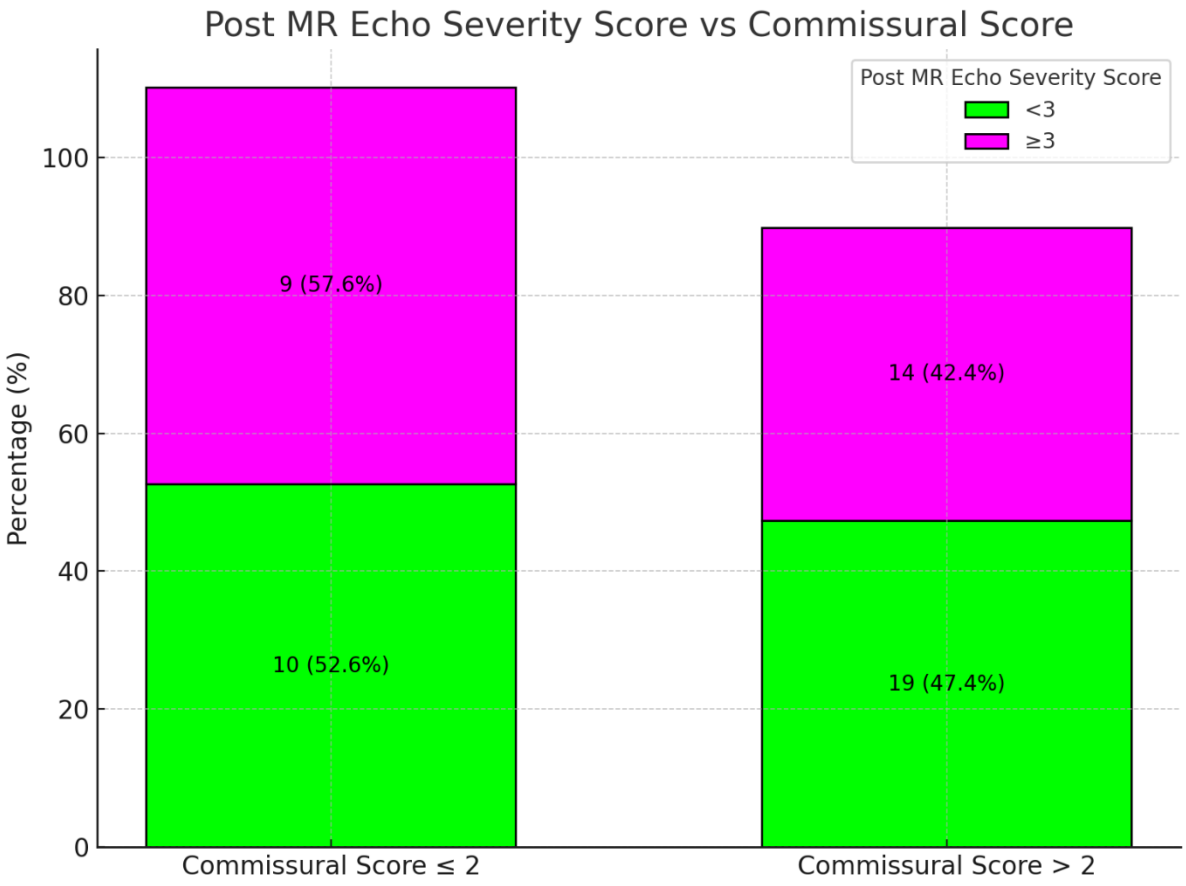


Figure 32: Post MR Echo Severity Score vs commissural Score

Requirement of Mitral valve replacement	Wilkins score			P-value (by fisher xact test)
	Wilkins Score </= 8	Wilkins Score > 8	Total	
No	27(96.43)	21(87.5)	48(92.31)	0.324
Yes	1(3.57)	3(12.5)	4(7.69)	
Total	28(100)	24(100)	52(100)	

Table 28: Wilkins score vs requirement of MVR

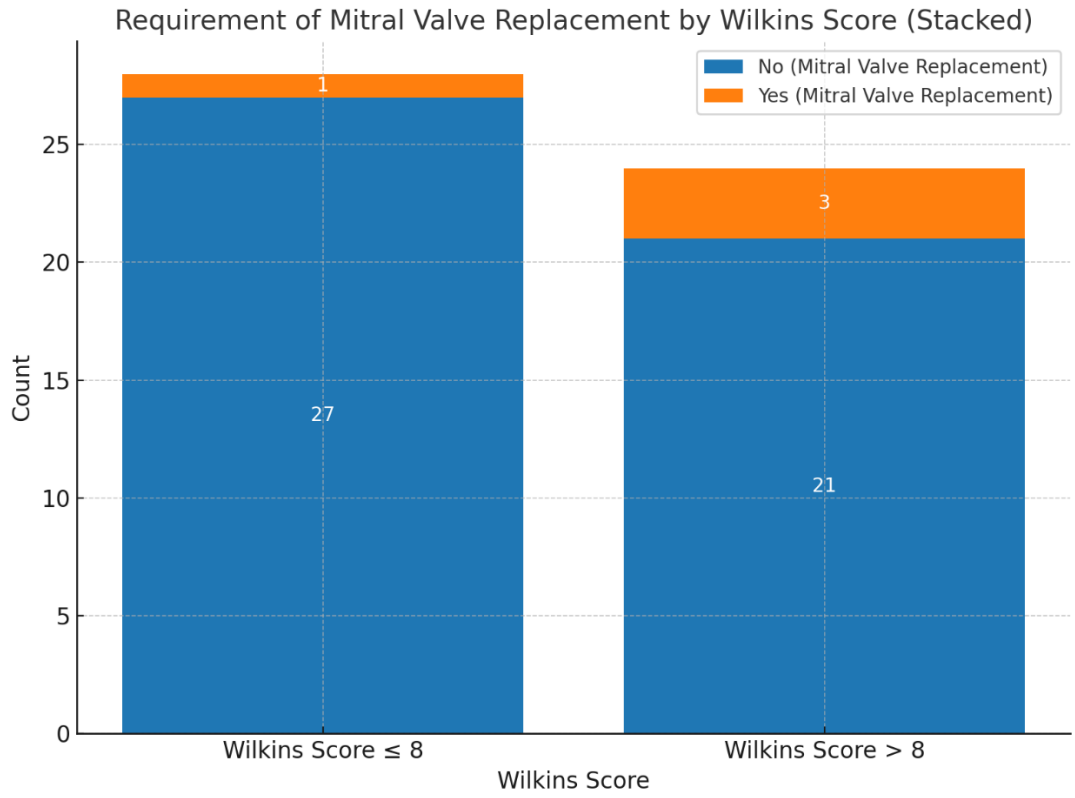


Figure 33: Requirement of Mitral Valve Replacement by Wilkins Score

but only 1 had Wilkins score </= 8. Higher Wilkins score had the trend towards increased requirement of MVR. However, it is not statistically significant.

Requirement of Mitral valve replacement	Commissural score			P-value (by fisher xact test)
	Commissural Score </= 2	Commissural Score > 2	Total	
No	17(89.47)	31(93.94)	48(92.31)	0.617
Yes	2(10.53)	2(6.06)	4(7.69)	
Total	19(100)	33(100)	52(100)	

Table 29: Commissural score vs requirement of MVR

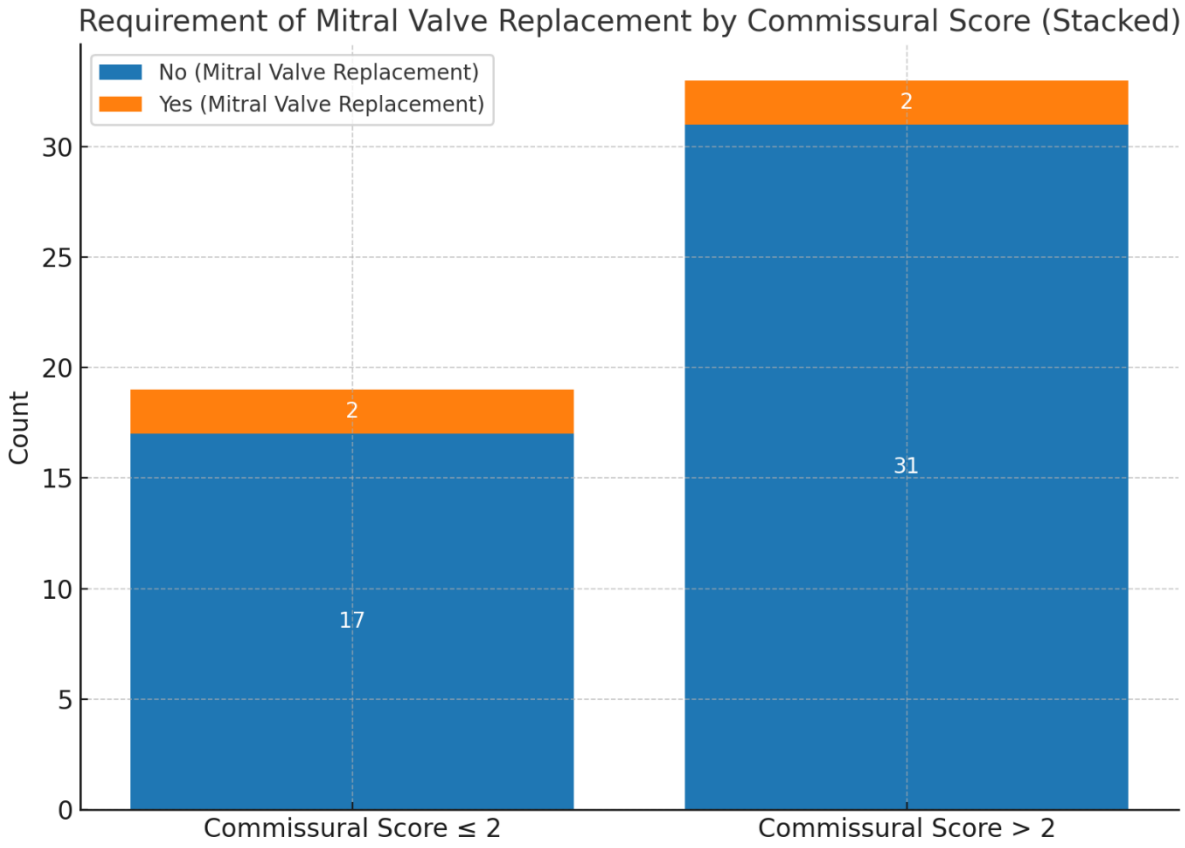


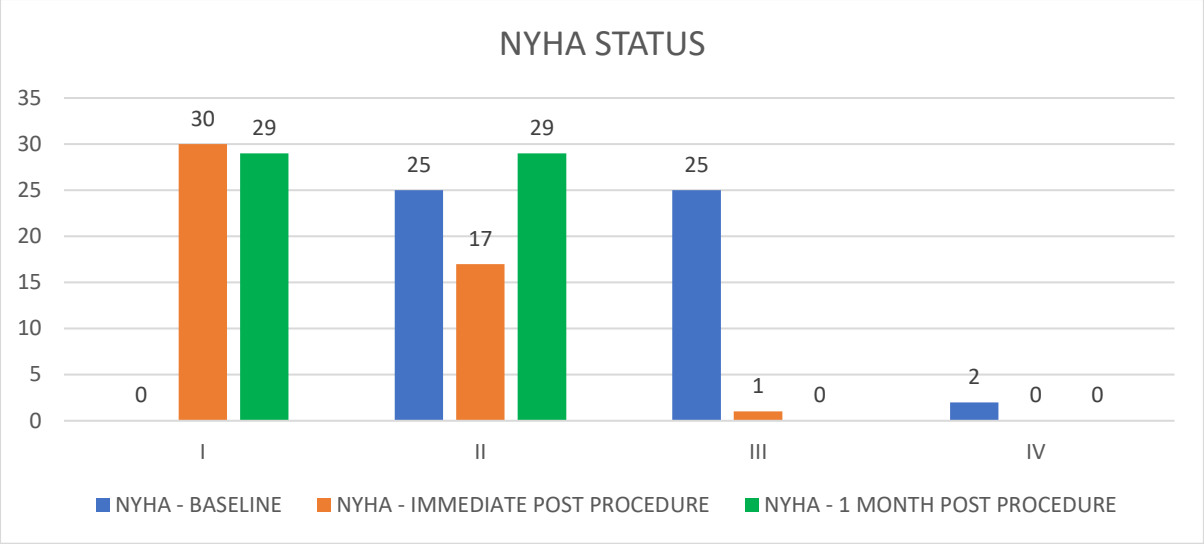
Figure 34: Requirement of Mitral Valve Replacement by commissural Score

6% of the patients with commissural score > 2 whereas 10.53% of patients with commissural score ≤ 2 has requirement of MVR. However, it is not statistically significant (P = 0.617).

NYHA STATUS:

NYHA	I	II	III	IV
NYHA - BASELINE	0	25	25	2
NYHA - IMMEDIATE POST PROCEDURE	30	17	1	0
NYHA - 1 MONTH POST PROCEDURE	29	29	0	0

Table 30: Assessment of NYHA on follow up



There is a notable improvement in the functional status of patients immediately following the procedure:

- The number of patients in **Class III** (marked limitations) decreased significantly from 25 to 1.
- **Class IV** (severe limitations) patients decreased from 2 to 0.
- The number of patients in **Class I** (no symptoms) increased from 0 to 30, suggesting significant relief of symptoms after the procedure.

One month after the procedure, patients' functional status generally remained improved compared to baseline:

- **Class I** remained high at 29 patients (55.77%).
- **Class II** patients also increased to 29 (55.77%), showing that more patients had mild symptoms but no significant limitations.
- The number of patients in **Class III** and **Class IV** remained at zero, indicating sustained improvement and no return to marked or severe symptoms.

DISCUSSION

DISCUSSION

1. Demographics and Baseline Characteristics

   a. Age and Gender

      Our study population has a mean age of 45.92 years, with a standard deviation of 10.76 years. A significant majority (75%) were female. These findings are consistent with previous studies that show BMV is frequently performed in relatively younger populations, particularly in developing countries where rheumatic heart disease remains a significant cause of mitral stenosis (MS). A study by Iung et al. (2004) (28) in the Euro Heart Survey showed that patients undergoing BMV often present in their 40s and 50s, with a higher prevalence among women due to the greater susceptibility of females to rheumatic heart valve disease.

   b. NYHA functional class

      NYHA Functional Class (FC): Nearly 45% of your patients presented with NYHA FC II and III, indicating moderate to severe symptoms, while only 3.85% were in NYHA FC IV. This distribution suggests that most patients underwent the procedure before severe functional limitation developed, which aligns with guidelines recommending early intervention in symptomatic patients.

   c. Redo Procedures

      Redo BMV Cases: Approximately 40.38% of your patients underwent redo procedures, with most having had a prior BMV (80.9%), and the rest (19.1%) having undergone closed mitral valvotomy (CMV). Redo cases are increasingly common due to restenosis following the

initial procedure, especially in regions where rheumatic MS is endemic. According to reports by Vahanian et al. (2012) (29), redo BMVs are often successful in alleviating symptoms and improving valve area, with outcomes dependent on Wilkins and commissural scores. However, procedural challenges such as commissural calcification and atrial fibrillation (AF) are more common in redo cases.

d. Atrial Fibrillation (AF)

Prevalence of AF: 14 patients (26.92%) had either current or past AF. Among these, 10 patients had AF during the procedure, while 4 were in sinus rhythm. AF is a known complication of MS due to atrial enlargement from chronic pressure overload.Studies such as by Fawzy et al. (2007) (30) have reported similar rates of AF in patients undergoing BMV, with AF prevalence increasing in cases with more advanced disease or prolonged mitral stenosis duration. Effective BMV often leads to symptomatic improvement, though rhythm control strategies are needed in persistent AF cases.

e. Pharmacological Management

Medications: Our study notes high usage of beta-blockers (90.38%) and loop diuretics (94.23%), with digoxin prescribed in 30.77% of patients. This reflects standard practice, where beta-blockers are used for rate control in AF or symptom management in MS, and loop diuretics address pulmonary congestion. Digoxin is reserved for specific cases requiring enhanced contractility or additional rate control. Similar pharmacological strategies are described in the ACC/AHA guidelines (2020) for valvular heart disease, where beta-blockers and diuretics form

the cornerstone of symptomatic management in MS, especially in the presence of AF.

f. Comparison of Immediate and Long-Term Outcomes

NYHA Improvement: Our data shows a significant improvement in NYHA FC immediately after the procedure, sustained at 1 month. This aligns with large studies like the Inoue experience, which documented immediate symptomatic relief and sustained improvement in the majority of patients. Fawzy et al. (2007) (30)reported that 80-90% of patients achieved NYHA Class I or II post-BMV, consistent with our findings.

2. ECG characteristics

a. MORRIS Index:

The MORRIS index measures the duration and depth of the P-wave terminal force in lead V1, which is a marker of LA abnormality. A higher MORRIS index is associated with significant LA enlargement due to prolonged and exaggerated atrial depolarization caused by increased atrial pressure or volume. The mean MORRIS index in our study is 0.08 seconds, with a standard deviation of 0.04 seconds, indicating low variability. Normal values for the MORRIS index are typically below 0.04 seconds. In patients with rheumatic mitral stenosis or significant LA enlargement, the MORRIS index often exceeds these thresholds, as seen in other studies (31).

a. MACRUZ Index

The MACRUZ index, defined as the ratio of the duration of the P-wave to the PR interval, is a surrogate marker of atrial enlargement. Values >1.6 are considered indicative of significant LA enlargement. The mean MACRUZ index in our study is 1.9, with a standard deviation of 0.72. The range is 0.50 to 3.0. This indicates significant LA enlargement in our study population, that is consistent with severe mitral stenosis.

b. QRS axis

i. The QRS axis values range from -30 to +120 with the mean QRS axis of +71.34, with a Standard Deviation of 27.42. This indicates wide variability in the QRS axis in our study population. As the mean is slightly towards rightward axis it means most of the patients had some form of pulmonary hypertension.

II. Commissural assessment:

Commissural fusion is a hallmark of rheumatic mitral stenosis (MS), resulting from chronic inflammation and fibrosis. The degree of fusion influences the technical success of BMV, as commissural splitting is critical for achieving adequate mitral valve area (MVA) expansion. Calcification of commissures complicates this process, reducing procedural efficacy and increasing the risk of complications such as residual stenosis or mitral regurgitation (MR).

A majority of patients (77%) exhibited some degree of medial commissural fusion (fully or partly fused). Fused and calcific pathology was present in 9.62%, indicative of more advanced disease.

A higher prevalence of complete fusion was observed in the lateral commissure (67.31%) compared to the medical commissure. Fused and calcific pathology was present in 11.54%, slightly higher than the medical commissure.

Palacios et al. (32)and Abascal et al. (1988) (33) reported similar findings, with commissural fusion observed in approximately 60-80% of rheumatic MS patients undergoing BMV which is similar to our study.

A study by Cannan et al. (1997) (34) has highlighted that calcified commissures are present in 10-15% of patients which is similar to our study, leading to poorer outcomes due to reduced commissural splitting during BMV.

III. Assessment of mitral valve by Wilkins score and Commissural score:

The Wilkins score evaluates the mitral valve's structural characteristics, including leaflet mobility, thickening, calcification, and subvalvular thickening. Wilkins et al. (1988) demonstrated that patients with Wilkins scores ≤8 have better outcomes, with higher post-procedural mitral valve area (MVA) and lower complication rates. Our study's mean Wilkins score of 8.5 suggests that a significant portion of your cohort had suboptimal valve morphology.

The commissural score assesses the degree of commissural fusion, a critical determinant of procedural success in BMV. Commissures with moderate-to-severe fusion (scores ≥2) are more amenable to splitting, enabling significant post-procedural improvement in MVA. Commissural splitting is a key mechanism for successful BMV. Studies have shown that patients with commissural scores ≥2 exhibit more pronounced post-procedural improvement compared to those with low scores (0–1) (7).

IV. RESULTS

The mean MVA pre procedure in our study is 0.97 cm2 which correlated with severe MS. Mean MVA increased to 1.78 cm^2 (SD: 0.34; Range: 1.04–2.78 cm^2). with the mean increase of 1.12 cm^2 (SD: 0.75). Our findings are similar with the previous literature by Wilkins et al. (1988) (6) who reported an average increase in MVA of 1.0–1.2 cm^2 post-BMV and the observed post-procedure MVA values ranging from 1.6 to 1.9 cm^2 as observed by Fawzy et al. (2007) (30).

There is significant drop in transvalvular gradient from 13.2 mmHg (SD: 4.3) to 5.8 mmHg (SD: 2.96). Palacios et al. (32)documented a reduction in mean gradients from 12–14 mmHg to 4–6 mmHg which is consistent with our findings. Abascal et al. (33) observed similar reductions, emphasizing the gradient decrease as a predictor of symptom relief.

The mean MR grade pre procedure is 1.63 which has increased to 2.31 post procedure. While MR has slightly increased in our study, the benefits in MVA and gradient outweigh this drawback, as seen in prior studies.

Mean PA pressure pre procedure was 33.78 mmHg that has decreased to 30.13 mmHg. The reduction is statistically significant ($p < 0.001$), indicating an improvement in pulmonary hemodynamics due to the reduction in left atrial pressure after BMV. Fawzy et al. (30) reported a reduction in mean PA pressure from 32–35 mmHg pre-BMV to 28–30 mmHg post-BMV, aligning closely with your findings. Similarly, Palacios et al. (32) found a similar decrease in PA pressure, emphasizing the role of BMV in reducing pulmonary congestion and associated symptoms. The post-procedure PA pressure in our study remained above normal levels, reflecting residual pulmonary hypertension, which may be attributable to chronic vascular remodelling in long-standing mitral stenosis.

Mean LA pressure pre BMV is 23.48 mmHg that has significantly reduced post procedure to 16.53 mmHg. Wilkins et al. (6) observed a reduction in mean LA pressure by 30–40% post-BMV, consistent with our observed decrease. Cannon et al. (34) emphasized that reduced LA pressure is directly correlated with symptomatic relief in dyspnoea and pulmonary congestion.

V. Outcomes:

In this study, the majority of patients with a **Wilkins Score ≤8** (considered favourable for BMV) showed a **high percentage of good outcomes** (89.29%, 25/28) and a **substantial increase in MV area** (**1.24 ± 0.84 cm²**). Conversely, patients with a **Wilkins Score >8** demonstrated a **lower percentage of good outcomes** (70.83%, 17/24) and a **smaller increase in MV area** (**0.87 ± 0.58 cm²**).

These findings align with earlier studies that show patients with **favourable mitral valve characteristics** (low Wilkins scores) tend to have **better procedural outcomes**. For instance, **Wilkins et al.** (6) found that a Wilkins Score ≤8 is strongly associated with significant improvements in symptoms and an increase in MV area after BMV. On the other hand, higher scores (>8) suggest more **severe valve calcification** and **restricted valve mobility**, leading to poorer procedural outcomes, as also observed in studies by **Fawzy et al.** (30).

In this study, patients with a Commissural Score >2 (which indicates more favorable valve morphology) showed a higher percentage of good outcomes (84.85%, 28/33) and a similar increase in MV area (1.06 ± 0.72 cm²) when compared to those with a Commissural Score ≤2 (73.68%, 14/19).

The Spearman's correlation coefficient for Commissural Score and overall outcomes is $\rho = -0.1357$, indicating a weak negative correlation, suggesting that higher Commissural Scores might be associated with better

outcomes. However, the p-value of 0.3376 is much higher than the conventional threshold of 0.05, making this correlation statistically insignificant.

In a near similar study by sutaria et al (7) they found that higher commissural score especially > 2 is associated with good outcome and higher increase in post procedure mitral valve area and is statistically significant. As the sample size in our study is less we were not able to prove it statistically though there is a trend towards good outcome for higher commissural score.

The correlation between Wilkins Score and the increase in MV area is $\rho = -0.2199$, indicating a weak negative correlation. This suggests that higher Wilkins scores are associated with a smaller increase in MV area after BMV.

The correlation between Commissural Score and the increase in MV area is $\rho = 0.1215$, suggesting a very weak positive correlation. This indicates that a greater degree of commissural involvement might slightly correlate with a greater increase in MV area, though the p-value of 0.4551 suggests that this association is not statistically significant. Larger study population would have helped in proving the statistical significance of the analysis.

In our study, patients with Wilkins score ≤8 & Commissural score ≤2 achieved 100% good outcome with maximum increase in MV area of 1.7 ± 1.14 cm^2. The so-called historically favourable valves for good outcome, Wilkins score ≤8 & Commissural score >2 group achieved only 87.5% good outcomes with increase in MV area of 1.14 ± 0.76 cm^2. This difference can be negligible as only 4 patients in our study population had Wilkins score ≤8 & Commissural score ≤2. It can be due to the fact that the lower commissural score indicates unfused commissures / calcific commissures and combined with lower Wilkins score indicated it could be more of unfused valve rather than calcific valve and

hence the good outcome would have been driven by lower Wilkins score rather than commissural score itself.

Patients in Wilkins score >8 & Commissural score ≤2 group had 66.67% good outcome which is lowest among all the groups.

The progressive increase in the mean Wilkins score from the good to poor outcome groups reflects the role of mitral valve morphology in procedural success.

The Commissural score showed a declining trend across the outcome groups, indicating that higher scores are associated with better outcomes. Higher Commissural scores (>2) are traditionally linked to favorable commissural morphology, which allows for more effective separation during the BMV procedure.

A statistically significant negative correlation ($r = -0.343$, $p = 0.0301$) was observed between the Wilkins score and the increase in MV area post-intervention. This finding indicates that as the Wilkins score increases, the improvement in MV area diminishes. Higher Wilkins scores reflect more advanced pathological changes, including calcification and fibrosis, which can hinder the effectiveness of BMV in achieving significant valve dilation similar to previous studies (6).

VI. Naïve sub group:

The subgroup analysis involving only naïve patients for BMV shows that lower Wilkins scores are strongly associated with better outcomes and larger increases in MV area. These findings are consistent with prior research emphasizing the role of Wilkins score in determining BMV success. However, it is not statistically significant.

Although both groups show comparable outcomes and MV area improvements, higher Commissural scores are slightly associated with better outcomes and larger MV area increases. However, the lack of statistical significance ($p = 0.5234$) limits the strength of this observation.

Patients with higher scores (Wilkins score >8) have more extensive pathological changes, such as calcification and fibrosis, which hinder procedural success.

VII. Redo sub group:

Similar to naïve group it is found that patients in redo group also showed similar findings. i.e., Patients with Wilkins scores ≤8 had a significantly higher likelihood of achieving good outcomes and demonstrated greater MV area improvements post-procedure compared to those with scores >8.

Similarly, patients with higher Commissural Scores (>2) showed a higher rate of good outcomes but slightly lower MV area improvements compared to those with lower scores.

VIII. Pre and post commissure – Medical commissure

a. Fused Commissures:
    i. Represent a favourable condition for splitting during BMV, with high success rates. A small subset may only partially split, possibly due to the degree of fusion or associated fibrosis.
b. Partly Fused Commissures:
    i. Demonstrate a consistent transition to fully split states, likely reflecting milder commissural involvement pre-BMV.
c. Calcific and Fused Commissures:

i. Exhibit the poorest outcomes, as calcification impedes balloon expansion and commissural tearing, often leaving the valve unsplit.

IX. Pre and post-commissure – Lateral commissure

a. Fused Commissures:

i. Most fused lateral commissures successfully split post-BMV, although some remain only partly split.

b. Calcific Commissures:

i. Similar to medial commissures, calcification significantly reduces the success rate, with a portion remaining unsplit or only partially split.

c. Palacios et al. (32) reported that fused medial commissures are highly responsive to BMV, consistent with this study's findings of 63.16% successful splits. Calcific commissures showed reduced success rates, aligning with the current observation that 80% of fused and calcific medial commissures remained unsplit (7).

X. Mitral regurgitation

a. Among patients with Wilkins Score ≤ 8 32.14% (9/28) developed moderate-to-severe MR (MR severity ≥ 3) in our study whereas in patients with Wilkins >8 almost 58.33% (14/24) developed moderate-to-severe MR (MR severity ≥ 3). The Fisher's exact test yielded a p-value of 0.093, indicating that while there is a trend towards higher Wilkins scores being associated with worse MR outcomes, the result is not statistically significant.vSarath babu et al found that patients with lower Wilkins scores were less likely to experience significant MR after BMV due to the preserved elasticity of mitral leaflets and reduced calcification which is similar to our present study. This aligns with the observed 67.86% mild MR cases in patients with Wilkins scores ≤ 8 (27). It is noted that

commissural splitting and subvalvular stress during BMV are primary mechanisms contributing to MR. Patients with high Wilkins scores often exhibit less effective splitting and more leaflet damage, increasing MR severity. The observed lack of correlation in this study may also reflect the relatively small sample size and the variability in commissural calcification's impact.

Among patients with Commissural Score ≤2 47.37% had moderate-to-severe MR (severity ≥3) whereas only 42.42% had moderate-to-severe MR (severity ≥3) in patients with commissural score < 2. Though there is trend towards higher grade of MR with reduced commissural score it is not statistically significant in our study (p = 0.787). Our study aligns with previous findings that commissural morphology alone, as quantified by the Commissural Score, is not a reliable predictor of MR severity post-BMV. Factors beyond commissural status as assessed by Wilkins score, such as subvalvular involvement and leaflet integrity, likely play a more critical role in determining MR outcomes.

XI. Mitral valve replacement

a. In our study, only 3.57% of patients with a Wilkins Score ≤8 required MVR, whereas 12.5% of patients with a Wilkins Score >8 required MVR. A higher Wilkins Score (>8) shows a trend toward increased MVR requirement compared to lower scores (≤8), but the association lacks statistical significance. The overall MVR requirement in this study is 7.69%, consistent with the 5-10% rate reported in previous literatures(35).

b. In our study 6.06% of patients with Commissural Score >2 required MVR whereas 10.53% of patients with Commissural Score ≤2 required MVR. Although the proportion of patients requiring MVR is slightly higher in the ≤2

Commissural Score group, the difference is small and may occur by chance given the p-value ($p = 0.617$) and sample size.

XII. No mortality reported in our study

XIII. NYHA

In our study at baseline Majority of patients (50%) were in NYHA Class III (marked limitations). 48.08% were in NYHA Class II (mild limitations) and 3.85% of patients were in Class IV (severe limitations).

Immediate post-procedure (excluding the patients who underwent MVR) it is observed that patients in NYHA Class I (no symptoms) increased from 0% to 57.69% (30 patients), Class III decreased dramatically to 1.92% (1 patient) and Class IV (severe limitations) completely resolved (0 patients).

Sustained Improvement is also observed at 1-month follow-Up: NYHA Class I remained high at 55.77% (29 patients). Class II accounted for 55.77% (29 patients), indicating mild residual symptoms but no functional limitations. No patients reverted to NYHA Class III or IV, demonstrating sustained symptomatic and functional relief.

The dramatic improvement in NYHA functional class following BMV observed in this study aligns with findings in prior studies by Wilkins et al (6).: Demonstrated that over 70% of patients experience significant symptomatic improvement immediately after BMV, with most patients improving by at least one NYHA class. Arora et al. (36): Reported that NYHA Class I patients increased from 0% at baseline to 60% immediately post-procedure, similar to the findings of this study where 57.69% achieved Class I status.

CONCLUSION

STRENGTH AND LIMITATION

The study's major strength was its inclusion of patients with relatively complex mitral valve anatomy and many redo patients at high risk for BMV.

It was a single-center prospective study, constrained by the usual potential confounders of limited sample size. This study would have been more robust if inter- and intra-observer variability analysis had been performed. As a tertiary care centre, our study population included many patients with relatively complex mitral valve anatomy deemed unsuitable for BMV. There is a lack of long-term follow-up data of patients after BMV. Extensive multicentre studies are needed to confirm our data.

CONCLUSION

Both Commissural and Wilkins scores may not precisely predict the outcomes of BMV. The Wilkins score better predicts the increase in mitral valve area post-BMV, while the Commissural score is a poor predictor of this increase.

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BIBILIOGRAPHY

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ANNEXURES

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
Thiruvananthapuram - 695 011, Kerala, India
(An Institute of National Importance under Govt. of India)
Grams : Chitramet, Phone : +91-471-2443152, Fax : +91-471-2550728 / 2446433, E-mail : sct@sctimst.ac.in, Website : www.sctimst.ac.in

Institutional Ethics Committee

CDSCO Registration No: ECR/189/Inst/KL/2013/RR-24
DHR Registration No:EC/NEW/INST/2022/2775

SCT/IEC/2323/ER/DECEMBER/2024 23.12.2024

Dr. Karthikeyan T
Post Doctoral Fellow
Department of Cardiology
SCTIMST, Thiruvananthapuram

Dear Dr. Karthikeyan,

The Institutional Ethics Committee reviewed your project titled **"ASSESSMENT OF COMMISSURAL MORPHOLOGY OF MITRAL VALVE WITH COMMISSURAL SCORE AND ITS PREDICTION ON THE OUTCOME OF BALLOON MITRAL VALVOTOMY"** (IEC/2323)" on 23rd December 2024.

Principal Investigator	Dr. Karthikeyan T, PDF, Department of Cardiology, SCTIMST
Co-Principal Investigators	Dr. Harikrishnan S, Professor, Department of Cardiology, SCTIMST
Duration of the study	6 months

The following documents were reviewed:

1. Covering letter addressed to the Chairperson, IEC, SCTIMST forwarded by HOD
2. IEC Application Form
3. Study Proposal
4. Participant Consent Form in English and Malayalam
5. Information Sheet for Study participants

The IEC Review Criteria
The study fulfils the expedited criteria from ethics review criteria vide section 9.1 of the Standard Operating Procedures (August 2021) of the SCTIMST-IEC.

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

Remarks:
The Institutional Ethics Committee expects to be provided a copy of the final report/publication.

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

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES & TECHNOLOGY
INSTITUTIONAL ETHICS COMMITTEE (IEC)
SCTIMST
THIRUVANANTHAPURAM

PLAGIARISM REPORT

ASSESSMENT OF COMMISSURAL MORPHOLOGY OF MITRAL VALVE WITH COMMISSURAL SCORE AND IT'S PREDICTION ON THE OUTCOME OF BALLOON MITRAL VALVOTOMY

by Kaviya Mohan

General metrics

17,139	2,491	186	9 min 57 sec	19 min 9 sec
characters	words	sentences	reading time	speaking time

Score

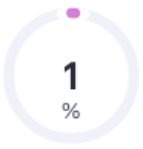


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Writing Issues

52	19	33
Issues left	Critical	Advocated

Plagiarism



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1 INFORMATION SHEET FOR STUDY PARTICIPANTS

TITLE OF THE STUDY: Assessment of commissural morphology of mitral valve with commissural score and its prediction on the outcome of balloon mitral valvotomy.

SERIAL NUMBER:

Name of the participant:

Gender: Date of birth: Age in years:

Dear Patient,

We welcome you and thank you for your interest in your participation in this research project titled "Assessment of commissural morphology of mitral valve with commissural score and its prediction on the outcome of balloon mitral valvotomy". We hope to include as many patients as possible in the study. Before you participate in this study, it is important for you to understand why this research is being carried out. This form will provide you all the relevant details of this research. It will explain the nature, the purpose, the benefits, the risks, the discomforts, the precautions and the information about how this project will be carried out. It is important that you read and understand the contents of the form carefully. This form may contain certain scientific terms and hence, if you have any doubts or if you want more information, you are free to ask the study personnel or the contact person mentioned below before you give your consent and also at any time during the entire course of the project.

What is Mitral stenosis?

Mitral stenosis is the narrowing of the mitral valve, which is the heart valve that controls the flow of blood from the heart's left atrium to the left ventricle. Because those with mitral valve stenosis have a narrowed mitral valve, blood flow to the left ventricle — the heart's main pumping chamber — is decreased or, in severe cases, is blocked entirely. This then requires the heart to work harder to compensate for a lack of blood flow, risking heart failure.

The mitral valve is one of the heart's four main heart valves. These heart valves are responsible for controlling the direction of blood through the valves to the heart's chambers for optimal pumping. When your mitral valve isn't functioning correctly, blood and pressure build up, causing the left atrium to enlarge and fluid to enter the lungs.

What are the causes of mitral stenosis?

The most common cause of mitral stenosis is rheumatic fever — a complication of strep throat. This infection can scar the mitral valve, causing it to thicken with scar tissue and narrow. While rheumatic fever is now rare in the developed, it is still seen in developing countries like India.

Other causes of mitral stenosis are age (calcium deposits build up on the valve over time), radiation to the chest, congenital heart defects and autoimmune diseases like lupus.

What are the treatment options for mitral stenosis?

While no medication can correct the mechanical narrowing of the valve (mitral stenosis), Initially medications are prescribed to control the symptoms associated with mitral stenosis. In general, the treatment options are

- Balloon valvuloplasty, a catheter-based treatment option for rheumatic mitral stenosis that uses an expanded balloon to open a narrowed mitral valve.
- Mitral valve replacement surgery, which is performed as traditional open-chest surgery or minimally invasive heart surgery, depending on your health and diagnosis.

What does the present study involve?

Any patient planned for BMV will undergo series of tests including transoesophageal echocardiography to assess the suitability of mitral valve for BMV. If the valve is suitable for BMV they will be recruited for the study. A specialist doctor will explain the proposed study design to you and ask you to sign the consent form to confirm that you understand the procedure and agree to go ahead with it. The clinical details of the patient will be recorded in detail and the echocardiographic scores are calculated to predict the outcome of these patients. Please ask any questions you want.

How long does it take?

The hospital visit will be a routine consultation, and the tests done will be part of routine follow up. This may take up to 1-2 hours. Please be prepared to be in the hospital OPD during that time.

What are the responsibilities of participants?

Your decision to participate in this study is voluntary, your own personal choice. You may choose not to continue at any time, for any reason, without notice.

What are the expected risks for the participants?

The study involves collection of data from the patient participants and a follow up evaluation to assess the functional status and outcome of BMV. There will be no added risks for the participants because of participation in the study apart from the standard of care risk for BMV. They will be managed according to the hospital protocol.

What are the expected benefits of the research to the participants?

The participants are evaluated in detail for assessment of the commissural score in assessing outcome of BMV. It may be helpful in detecting patients who are at risk of suboptimal outcomes or development of complication post BMV.

The data derived from the study may be helpful in planning appropriate need of medical

therapy and follow up for patients with similar conditions in the future.

Will participants be compensated for participation in this trial?

You will not be paid for participation in the study.

Will my participation in this study be kept confidential?

All records of your/your child's study will be kept confidential. Your personal identity will not be revealed in any publication or release of results. Study records will be kept indefinitely for analysis and follow-up.

Can I withdraw from the study at any time during the study period?

Yes, you can. Your decision will not affect your regular medical care.

What happens in case of a study related injury?

There will be no study related injury.

If you have any further questions, please ask: Dr. Karthikeyan T (Principal investigator), PDF (Adult cardiology and Interventions), Department of Cardiology (Email: karthithangaraj@sctimst.ac.in Ph No:9789040614)

For any technical clarifications, please contact Dr. Srinivas G, Member Secretary, IEC, SCTIMST, Thiruvananthapuram.

Translated from English to Malayalam - www.onlinedoctranslator.com

2 പഠനത്തിൽ പങ്കെടുക്കുന്നവർക്കുള്ള വിവര ഷീറ്റ്

പഠനത്തിന്റെ തലക്കെട്ട്: മിട്രൽ വാൽവിന്റെ കമ്മിഷറൽ മോർഫോളജിയുടെ മൂല്യനിർണ്ണയം, കമ്മീഷണൽ സ്കോറും ബലൂൺ മിട്രൽ വാൽവോട്ടോമിയുടെ ഫലത്തെക്കുറിച്ചുള്ള അതിന്റെ പ്രവചനവും.

സീരിയൽ നമ്പർ:യുടെ പേര് പങ്കാളി:

ലിംഗഭേദം: തീയതി ജനനം:
വർഷങ്ങളിൽ പ്രായം:

പ്രിയ രോഗി,
ഞങ്ങൾ നിങ്ങളെ സ്വാഗതം ചെയ്യുന്നു, "മിട്രൽ വാൽവിന്റെ കമ്മീഷണൽ വാൽവിന്റെ കമ്മീഷണൽ സ്കോറും ബലൂൺ മിട്രൽ വാൽവോട്ടോമിയുടെ ഫലത്തെക്കുറിച്ചുള്ള അതിന്റെ പ്രവചനവും" എന്ന തലക്കെട്ടിലുള്ള ഈ ഗവേഷണ പ്രോജക്റ്റിലെ നിങ്ങളുടെ പങ്കാളിത്തത്തിലുള്ള നിങ്ങളുടെ താൽപ്പര്യത്തിന് നന്ദി. പഠനത്തിൽ കഴിയുന്നത്ര രോഗികളെ ഉൾപ്പെടുത്തുമെന്ന് ഞങ്ങൾ പ്രതീക്ഷിക്കുന്നു. ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നതിന് മുമ്പ്, എന്തുകൊണ്ടാണ് ഈ ഗവേഷണം നടത്തുന്നത് എന്ന് മനസ്സിലാക്കേണ്ടത് പ്രധാനമാണ്. ഈ ഗവേഷണത്തിന്റെ പ്രസക്തമായ എല്ലാ വിശദാംശങ്ങളും ഈ ഫോം നിങ്ങൾക്ക് നൽകും. ഇതിന്റെ സ്വഭാവം, ഉദ്ദേശ്യം, നേട്ടങ്ങൾ, അപകടസാധ്യതകൾ, അസ്വാസ്ഥ്യങ്ങൾ, മുൻകരുതലുകൾ, ഈ പദ്ധതി എങ്ങനെ നടപ്പാക്കും എന്നതിനെക്കുറിച്ചുള്ള വിവരങ്ങൾ എന്നിവ വിശദീകരിക്കും. ഫോമിലെ ഉള്ളടക്കങ്ങൾ ശ്രദ്ധാപൂർവ്വം വായിക്കുകയും മനസ്സിലാക്കുകയും ചെയ്യേണ്ടത് പ്രധാനമാണ്. ഈ ഫോമിൽ ചില ശാസ്ത്രീയ നിബന്ധനകൾ അടങ്ങിയിരിക്കാം, അതിനാൽ, നിങ്ങൾക്ക് എന്തെങ്കിലും സംശയങ്ങളുണ്ടെങ്കിൽ അല്ലെങ്കിൽ നിങ്ങൾക്ക് കൂടുതൽ വിവരങ്ങൾ വേണമെങ്കിൽ, നിങ്ങളുടെ സമ്മതം നൽകുന്നതിന് മുമ്പ്, മുഴുവൻ കോഴ്സിനിടയിലും ഏത് സമയത്തും പഠന ഉദ്യോഗസ്ഥരോടോ അല്ലെങ്കിൽ ബന്ധപ്പെടുന്ന വ്യക്തിയോടോ ചോദിക്കാൻ നിങ്ങൾക്ക് സ്വാതന്ത്ര്യമുണ്ട്. പദ്ധതിയുടെ.

എന്താണ് മിട്രൽ സ്റ്റെനോസിസ്?

ഹൃദയത്തിന്റെ ഇടത് ആട്രിയത്തിൽ നിന്ന് ഇടത് വെൻട്രിക്കിളിലേക്കുള്ള രക്തപ്രവാഹം നിയന്ത്രിക്കുന്ന ഹൃദയ വാൽവ്

ആയ മിട്രൽ വാൽവിന്റെ സങ്കോചമാണ് മിട്രൽ സ്റ്റെനോസിസ്. മിട്രൽ വാൽവ് സ്റ്റെനോസിസ് ഉള്ളവർക്ക് ഇടുങ്ങിയ മിട്രൽ വാൽവ് ഉള്ളതിനാൽ, ഇടത് വെൻട്രിക്കിളിലേക്കുള്ള രക്തയോട്ടം - ഹൃദയത്തിന്റെ പ്രധാന പമ്പിംഗ് ചേമ്പർ - കുറയുന്നു അല്ലെങ്കിൽ കഠിനമായ കേസുകളിൽ പൂർണ്ണമായും തടസ്സപ്പെടുന്നു. ഇത് പിന്നീട് രക്തപ്രവാഹത്തിന്റെ അഭാവം നികത്താൻ ഹൃദയം കഠിനമായി പ്രവർത്തിക്കേണ്ടതുണ്ട്, അപകടസാധ്യതയുണ്ട് **ഹൃദയസ്തംഭനം**.

ഹൃദയത്തിന്റെ നാല് പ്രധാന ഹൃദയ വാൽവുകളിൽ ഒന്നാണ് മിട്രൽ വാൽവ്. ഒപ്റ്റിമൽ പമ്പിംഗിനായി ഹൃദയത്തിന്റെ അറകളിലേക്കുള്ള വാൽവുകളിലൂടെ രക്തത്തിന്റെ ദിശ നിയന്ത്രിക്കുന്നതിന് ഈ ഹൃദയ വാൽവുകൾ ഉത്തരവാദികളാണ്. നിങ്ങളുടെ മിട്രൽ വാൽവ് ശരിയായി പ്രവർത്തിക്കുന്നില്ലെങ്കിൽ, രക്തവും സമ്മർദ്ദവും വർദ്ധിക്കുകയും ഇടത് ആട്രിയം വലുതാകുകയും ശ്വാസകോശത്തിലേക്ക് ദ്രാവകം പ്രവേശിക്കുകയും ചെയ്യുന്നു.

മിട്രൽ സ്റ്റെനോസിസിന്റെ കാരണങ്ങൾ എന്തൊക്കെയാണ്?

മിട്രൽ സ്റ്റെനോസിസിന്റെ ഏറ്റവും സാധാരണമായ കാരണം റുമാറ്റിക് ഫീവർ ആണ് - ഒരു സങ്കീർണത**തൊണ്ടവേദന**. ഈ അണുബാധയ്ക്ക് മിട്രൽ വാൽവ് മുറിവുണ്ടാക്കാം, ഇത് വടുക്കൾ ടിഷ്യു കൊണ്ട് കട്ടിയാകുകയും ഇടുങ്ങിയതാക്കുകയും ചെയ്യും. വികസിത രാജ്യങ്ങളിൽ റുമാറ്റിക് പനി ഇപ്പോൾ അപൂർവമാണെങ്കിലും, ഇന്ത്യയെപ്പോലുള്ള വികസ്വര രാജ്യങ്ങളിൽ ഇത് ഇപ്പോഴും കാണപ്പെടുന്നു.
പ്രായം (കാലക്രമേണ വാൽവിൽ അടിഞ്ഞുകൂടുന്ന കാൽസ്യം), നെഞ്ചിലേക്കുള്ള വികിരണം, ജന്മനായുള്ള ഹൃദയ വൈകല്യങ്ങൾ, സ്വയം രോഗപ്രതിരോധ രോഗങ്ങൾ എന്നിവയാണ് മിട്രൽ സ്റ്റെനോസിസിന്റെ മറ്റ് കാരണങ്ങൾ.**ലൂപ്പസ്**.

മിട്രൽ സ്റ്റെനോസിസിനുള്ള ചികിത്സാ ഓപ്ഷനുകൾ എന്തൊക്കെയാണ്?

വാൽവിന്റെ മെക്കാനിക്കൽ സങ്കോചം (മിട്രൽ സ്റ്റെനോസിസ്) ശരിയാക്കാൻ ഒരു മരുന്നിനും കഴിയില്ലെങ്കിലും, തുടക്കത്തിൽ മിട്രൽ സ്റ്റെനോസിസുമായി ബന്ധപ്പെട്ട ലക്ഷണങ്ങളെ നിയന്ത്രിക്കാൻ മരുന്നുകൾ നിർദ്ദേശിക്കപ്പെടുന്നു. പൊതുവേ, ചികിത്സാ ഓപ്ഷനുകൾ

- ബലൂൺ വാൽവുലോപ്ലാസ്റ്റി, ഇടുങ്ങിയ മിട്രൽ വാൽവ് തുറക്കാൻ വികസിപ്പിച്ച ബലൂൺ ഉപയോഗിക്കുന്ന റുമാറ്റിക് മിട്രൽ സ്റ്റെനോസിസിനുള്ള കത്തീറ്റർ അധിഷ്ഠിത ചികിത്സാ ഓപ്ഷൻ.

- മിട്രൽ വാൽവ് മാറ്റിസ്ഥാപിക്കൽ ശസ്ത്രക്രിയ, പരമ്പരാഗത ഓപ്പൺ-നെസ്റ്റ് സർജറി അല്ലെങ്കിൽകുറഞ്ഞ ആക്രമണാത്മക ഹൃദയ ശസ്ത്രക്രിയ, നിങ്ങളുടെ ആരോഗ്യവും രോഗനിർണയവും അനുസരിച്ച്.

ഇപ്പോഴത്തെ പഠനത്തിൽ എന്താണ് ഉൾപ്പെടുന്നത്?

ബിഎംവിക്കായി ആസൂത്രണം ചെയ്ത ഏതൊരു രോഗിയും ബിഎംവിക്ക് മിട്രൽ വാൽവിന്റെ അനുയോജ്യത വിലയിരുത്തുന്നതിന് ട്രാൻസോസോഫേജൽ എക്കോകാർഡിയോഗ്രാഫി ഉൾപ്പെടെയുള്ള ടെസ്റ്റുകളുടെ പരമ്പരയ്ക്ക് വിധേയമാകും. വാൽവ് ബിഎംവിക്ക് അനുയോജ്യമാണെങ്കിൽ അവരെ പഠനത്തിനായി റിക്രൂട്ട് ചെയ്യും. ഒരു സ്പെഷ്യലിസ്റ്റ് ഡോക്ടർ നിങ്ങൾക്ക് നിർദ്ദേശിച്ച പഠന രൂപരേഖ വിശദീകരിക്കുകയും നടപടിക്രമം നിങ്ങൾ മനസ്സിലാക്കിയിട്ടുണ്ടെന്നും അതുമായി മുന്നോട്ട് പോകാൻ സമ്മതിക്കുന്നുവെന്നും സ്ഥിരീകരിക്കാൻ സമ്മത ഫോമിൽ ഒപ്പിടാൻ നിങ്ങളോട് ആവശ്യപ്പെടും. രോഗിയുടെ ക്ലിനിക്കൽ വിശദാംശങ്ങൾ വിശദമായി രേഖപ്പെടുത്തുകയും ഈ രോഗികളുടെ ഫലം പ്രവചിക്കാൻ എക്കോകാർഡിയോഗ്രാഫിക് സ്കോറുകൾ കണക്കാക്കുകയും ചെയ്യും. നിങ്ങൾ ആഗ്രഹിക്കുന്ന എന്തെങ്കിലും ചോദ്യങ്ങൾ ചോദിക്കൂ.

എത്തിച്ചേരുന്നതിന് എത്ര സമയമെടുക്കും?

ആശുപത്രി സന്ദർശനം ഒരു പതിവ് കൺസൾട്ടേഷനായിരിക്കും, കൂടാതെ നടത്തിയ പരിശോധനകൾ പതിവ് ഫോളോഅപ്പിന്റെ ഭാഗമായിരിക്കും. ഇതിന് 1-2 മണിക്കൂർ വരെ എടുത്തേക്കാം. ആ സമയത്ത് ആശുപത്രി ഒപിഡിയിൽ കഴിയാൻ തയ്യാറാകണം.

പങ്കെടുക്കുന്നവരുടെ ഉത്തരവാദിത്തങ്ങൾ എന്തൊക്കെയാണ്?

ഈ പഠനത്തിൽ പങ്കെടുക്കാനുള്ള നിങ്ങളുടെ തീരുമാനം സ്വമേധയാ ഉള്ളതാണ്, നിങ്ങളുടെ സ്വന്തം തിരഞ്ഞെടുപ്പ്. ഒരു കാരണവശാലും, അറിയിപ്പ് കൂടാതെ, എപ്പോൾ വേണമെങ്കിലും തുടരേണ്ടതില്ലെന്ന് നിങ്ങൾക്ക് തീരുമാനിക്കാം.

പങ്കെടുക്കുന്നവർക്ക് പ്രതീക്ഷിക്കുന്ന അപകടസാധ്യതകൾ എന്തൊക്കെയാണ്?

ബിഎംവിയുടെ പ്രവർത്തന നിലയും ഫലവും വിലയിരുത്തുന്നതിന് രോഗി പങ്കാളികളിൽ നിന്നുള്ള ഡാറ്റ ശേഖരണവും ഫോളോ അപ്പ് മൂല്യനിർണ്ണയവും ഈ പഠനത്തിൽ ഉൾപ്പെടുന്നു. ബിഎംവിയുടെ പരിചരണ അപകടസാധ്യതയുടെ നിലവാരം കൂടാതെ പഠനത്തിൽ പങ്കെടുക്കുന്നതിനാൽ പങ്കെടുക്കുന്നവർക്ക് അധിക അപകടസാധ്യതകളൊന്നും ഉണ്ടാകില്ല. ആശുപത്രി പ്രോട്ടോക്കോൾ അനുസരിച്ചായിരിക്കും ഇവ കൈകാര്യം ചെയ്യുക.

ഗവേഷണത്തിൽ പങ്കെടുക്കുന്നവർക്ക് പ്രതീക്ഷിക്കുന്ന നേട്ടങ്ങൾ എന്തൊക്കെയാണ്?

ബിഎംവിയുടെ ഫലം വിലയിരുത്തുന്നതിനുള്ള കമ്മീഷണൽ സ്കോർ വിലയിരുത്തുന്നതിന് പങ്കെടുക്കുന്നവരെ വിശദമായി വിലയിരുത്തുന്നു. ഉപോൽപ്പന്ന ഫലങ്ങളുടെ അപകടസാധ്യതയുള്ള രോഗികളെ കണ്ടെത്തുന്നതിനും അല്ലെങ്കിൽ ബിഎംവിക്ക് ശേഷമുള്ള സങ്കീർണതകൾ വികസിപ്പിക്കുന്നതിനും ഇത് സഹായകമായേക്കാം.
പഠനത്തിൽ നിന്ന് ഉരുത്തിരിഞ്ഞ ഡാറ്റ, വൈദ്യചികിത്സയുടെ ഉചിതമായ ആവശ്യകത ആസൂത്രണം ചെയ്യുന്നതിനും ഭാവിയിൽ സമാനമായ അവസ്ഥകളുള്ള രോഗികൾക്ക് ഫോളോ അപ്പ് ചെയ്യുന്നതിനും സഹായകമായേക്കാം.

ഈ ട്രയലിൽ പങ്കെടുത്തതിന് പങ്കാളികൾക്ക് നഷ്ടപരിഹാരം ലഭിക്കുമോ?
പഠനത്തിൽ പങ്കെടുത്തതിന് നിങ്ങൾക്ക് പണം നൽകില്ല.

ഈ പഠനത്തിലെ എൻ്റെ പങ്കാളിത്തം രഹസ്യമായി സൂക്ഷിക്കുമോ?

നിങ്ങളുടെ/കുട്ടിയുടെ പഠനത്തിൻ്റെ എല്ലാ രേഖകളും രഹസ്യമായി സൂക്ഷിക്കും. ഏതെങ്കിലും പ്രസിദ്ധീകരണത്തിലോ ഫലങ്ങളുടെ പ്രകാശനത്തിലോ നിങ്ങളുടെ വ്യക്തിത്വം വെളിപ്പെടുത്തില്ല. പഠനരേഖകൾ ആയിരിക്കും

വിശകലനത്തിനും തുടർനടപടികൾക്കുമായി അനിശ്ചിതമായി സൂക്ഷിച്ചിരിക്കുന്നു.

പഠന കാലയളവിൽ എപ്പോൾ വേണമെങ്കിലും എനിക്ക് പഠനത്തിൽ നിന്ന് പിന്മാറാൻ കഴിയുമോ?

അതെ, നിങ്ങൾക്ക് കഴിയും. നിങ്ങളുടെ തീരുമാനം നിങ്ങളുടെ പതിവ് വൈദ്യ പരിചരണത്തെ ബാധിക്കില്ല.

പഠനവുമായി ബന്ധപ്പെട്ട പരിക്കിന്റെ കാര്യത്തിൽ എന്ത് സംഭവിക്കും?

പഠനവുമായി ബന്ധപ്പെട്ട പരിക്കുകളൊന്നും ഉണ്ടാകില്ല.

നിങ്ങൾക്ക് കൂടുതൽ ചോദ്യങ്ങളുണ്ടെങ്കിൽ, ദയവായി ചോദിക്കുക: ഡോ. കാർത്തികേയൻ ടി (പ്രിൻസിപ്പൽ ഇൻവെസ്റ്റിഗേറ്റർ), PDF (അഡൽറ്റ് കാർഡിയോളജി ആൻഡ് ഇന്റർവെൻഷൻസ്), കാർഡിയോളജി വിഭാഗം (ഇമെയിൽ: karthithangaraj@sctimst.ac.in Ph No:9789040614)

എന്തെങ്കിലും സാങ്കേതിക വിശദീകരണങ്ങൾക്ക്, ഡോ. ശ്രീനിവാസ് ജി, മെമ്പർ സെക്രട്ടറി, IEC, SCTIMST, തിരുവനന്തപുരം എന്നിവരുമായി ബന്ധപ്പെടുക.

Assessment of commissural morphology of mitral valve with commissural score and its prediction on the outcome of balloon mitral valvotomy.

Principal Investigator: Dr Karthikeyan T, PDF (Adult and Interventional cardiology), SCTIMST, Trivandrum

3 Participant consent form

Please tick as appropriate

I confirm that **I have read and understood the information sheet** forstudy participantsfor this study on .....(date) and have had the opportunity to ask questions which have been answered fully and to my satisfaction	**Yes / No**
I understand that **my participation is voluntary and I am free to withdraw at any time**, without giving any reason, without my medical care or legal rights being affected.	**Yes / No**
I understand that sections of any of my medical notes may be looked at by responsible individuals from **Sree Chitra Institute for Medical Sciences and Technology**, where it is relevant to my taking part in this research. I give permission for these individuals to access my records that are relevant to this research.	**Yes / No**
I agree to take part in the above study.	**Yes / No**

Name of the participant **Signature** **Date**

In case the patient is illiterate, representative / next of kin shall sign on his / her behalf

Name **Relationship with the patient** **Signature** **Date**

Name of the Principal Investigator **Signature** **Date**

മിട്രൽ വാൽവിന്റെ കമ്മിഷറൽ മോർഫോളജിയുടെ മൂല്യനിർണ്ണയം, കമ്മീഷണൽ സ്കോറും ബലൂൺ മിട്രൽ വാൽവോട്ടോമിയുടെ ഫലത്തെക്കുറിച്ചുള്ള അതിന്റെ പ്രവചനവും.

പ്രിൻസിപ്പൽ ഇൻവെസ്റ്റിഗേറ്റർ: ഡോ കാർത്തികേയൻ ടി, PDF (അഡൾട്ട് ആൻഡ് ഇന്റർവെൻഷണൽ കാർഡിയോളജി), SCTIMST, തിരുവനന്തപുരം

4 പങ്കാളിയുടെ സമ്മതപത്രം

ദയവായി ഉചിതമായ രീതിയിൽ ടിക്ക് ചെയ്യുക

ഞാൻ വിവര ഷീറ്റ് വായിക്കുകയും മനസ്സിലാക്കുകയും ചെയ്തുവെന്ന് ഞാൻ സ്ഥിരീകരിക്കുന്നു ഈ പഠനത്തിനായി പഠന പങ്കാളികൾക്കായി .....(തീയതി) പൂർണ്ണമായി ഉത്തരം ലഭിച്ച ചോദ്യങ്ങൾ ചോദിക്കാനുള്ള അവസരവും എന്റെ സംതൃപ്തിയും ലഭിച്ചു	**അതെ/ അല്ല**
എന്റെ പങ്കാളിത്തം സ്വമേധയാ ഉള്ളതാണെന്നും ഒരു കാരണവും പറയാതെ, എപ്പോൾ വേണമെങ്കിലും പിൻവലിക്കാൻ എനിക്ക് സ്വാതന്ത്ര്യമുണ്ടെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. വൈദ്യസഹായം അല്ലെങ്കിൽ നിയമപരമായ അവകാശങ്ങൾ ബാധിക്കുന്നു.	**അതെ/ അല്ല**
എന്റെ ഏതെങ്കിലും മെഡിക്കൽ കുറിപ്പുകളുടെ ഭാഗങ്ങൾ ശ്രീചിത്ര ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആൻഡ് ടെക്നോളജിയിൽ നിന്നുള്ള ഉത്തരവാദിത്തപ്പെട്ട വ്യക്തികൾ പരിശോധിച്ചേക്കാമെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു, ഈ ഗവേഷണത്തിൽ ഞാൻ പങ്കെടുക്കുന്നതിന് ഇത്	**അതെ /അല്ല**

പ്രസക്തമാണ്. ഈ വ്യക്തികൾക്ക് ആക്സസ് ചെയ്യാൻ ഞാൻ അനുമതി നൽകുന്നു ഈ ഗവേഷണത്തിന് പ്രസക്തമായ എൻറെ രേഖകൾ.	
മുകളിലുള്ള പഠനത്തിൽ പങ്കെടുക്കാൻ ഞാൻ സമ്മതിക്കുന്നു.	**അതെ/ അല്ല**

പങ്കെടുക്കുന്നയാളുടെ പേര് കയ്യൊപ്പ് തീയതി

രോഗി നിരക്ഷരനാണെങ്കിൽ, അവൻറെ / അവൾക്കുവേണ്ടി പ്രതിനിധി / അടുത്ത ബന്ധു ഒപ്പിടണം:

പേര് യുമായുള്ള ബന്ധം രോഗി കയ്യൊപ്പ് തീയതി

പ്രധാന അന്വേഷകൻറെ പേര് കയ്യൊപ്പ് തീയതി

CURRICULUM VITAE

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Academic Qualifications (Most recent qualification first):		
Degree/Certificate	Year	Institution, Country
DM CARDIOLOGY	2021-2023	Sree chitra Tirunal Institute for medical sciences and technology, Trivandrum.
SR General Medicine	2020	All India Institute of Medical Sciences, Jodhpur, India
MD (General Medicine)	2017-2020	All India Institute of Medical Sciences, Jodhpur, India
MBBS	2009-2015	Madras Medical College, Chennai, India
Details of professional registration: (MCI/State Registration/Bar Council/DCI/etc including Registration Number and Year of Registration: 79423, TCMC (09/02/2021)		
Current and previous positions (most recent position first)		

Month and Year	Title	Institution/Company, Country
1/1/2024 - Contiuing	PDF (Adult Cardiology and Intervention)	SCTIMST, India
01/01/2021 – 31/12/2023	Senior Resident (DM Cardiology)	SCTIMST, India
June 2020	Senior Resident (MD General Medicine)	All India Institute of Medical Sciences, Jodhpur, India
June 2017-2020	Junior Resident (MD General Medicine)	All India Institute of Medical Sciences, Jodhpur, India

Brief summary of relevant research experience: Thesis in MD Internal Medicine – A study of platelet indices with clinical and laboratory parameters of patients with dengue in western Rajasthan. Thesis in DM Cardiology - Comparative analysis of long-term outcome in post coronary artery bypass surgery with and without new-onset atrial fibrillation	
Current project/s at hand: n i l	
Signature:	Date: Place: Thiruvananthapuram