

**ROLE OF REAL TIME 3D ECHOCARDIOGRAPHY FOR
PREDICTION OF SUCCESS OF REDO-PERCUTANEOUS
BALLOON MITRAL VALVULOPLASTY IN PATIENTS WITH
MITRAL RESTENOSIS**

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



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DECLARATION

I, Dr. Walse Rohit Sunil, hereby declare that the project in this book titled **ROLE OF REAL TIME 3D ECHOCARDIOGRAPHY FOR PREDICTION OF SUCCESS OF REDO-PERCUTANEOUS BALLOON MITRAL VALVULOPLASTY IN PATIENTS WITH MITRAL RESTENOSIS** was undertaken by me under the supervision of the faculty, Department of Cardiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology.

Thiruvananthapuram

Date: 29/11/2022



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CERTIFICATE

I, hereby certify that the work in this project titled "ROLE OF REAL TIME 3D ECHOCARDIOGRAPHY FOR PREDICTION OF SUCCESS OF REDO-PERCUTANEOUS BALLOON MITRAL VALVULOPLASTY IN PATIENTS WITH MITRAL RESTENOSIS" is a certified record of original research work undertaken by Dr, Walse Rohit Sunil done in the department of Cardiology, in partial fulfilment of the requirement for the purpose of award of post-doctoral fellowship degree.

Forwarded

The candidate, Dr. Walse Rohit Sunil, has carried out the minimum required project.



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CERTIFICATE

I, hereby certify that the work in this project titled "**ROLE OF REAL TIME 3D ECHOCARDIOGRAPHY FOR PREDICTION OF SUCCESS OF REDO-PERCUTANEOUS BALLOON MITRAL VALVULOPLASTY IN PATIENTS WITH MITRAL RESTENOSIS**" is a certified record of original research work undertaken by Dr, Walse Rohit Sunil done in the department of Cardiology, in partial fulfilment of the requirement for the purpose of award of post-doctoral fellowship degree under my supervision and care.

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TITLE

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SUCCESS OF REDO-PERCUTANEOUS BALLOON MITRAL VALVULOPLASTY
IN PATIENTS WITH MITRAL RESTENOSIS"**

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Dr. Walse Rohit Sunil

ABBREVIATIONS

AF	- Atrial fibrillation
AML	- Anterior Mitral Leaflet
BMV	- Balloon Mitral Valvuloplasty
BSA	- Body Surface Area
Cath	- Catheterization
CMV	- Closed Mitral Valvotomy
CO	- Cardiac Output
CI	- Cardiac Index
EF	- Ejection Fraction
FC	- Functional class
LA	- Left atrium
LAm	- Left atrial mean pressure
LVed	- Left ventricular end-diastolic pressure
LVID	- Left ventricular internal diameter in diastole
MR	- Mitral Regurgitation
MS	- Mitral Stenosis
MV	- Mitral valve
MVA	- Mitral valve area
MVG	- Mitral valve gradient
NYHA	- New York Heart Association Classification
PA	- Pulmonary artery
PASP	- Pulmonary artery systolic pressure
PAm	- Pulmonary artery mean pressure
PBMV	- Percutaneous balloon mitral valvuloplasty
PHT	- Pressure half time
RA	- Right Atrium
RHD	- Rheumatic Heart Disease
RVSP	- Right ventricular systolic pressure
SD	- Standard deviation
SR	- Sinus rhythm
TAPSE	- Tricuspid annular plane systolic excursion
TEE	- Transesophageal echocardiography

SYNOPSIS

INTRODUCTION:

Echocardiographic predictors of redo-percutaneous balloon mitral valvuloplasty (redo-PBMV) have not been well studied, and indications are based mainly on Wilkins score¹. Mahfouz et al² has studied a novel “Redo score” in patients developing mitral restenosis and has found it better predictor of success rate of BMV than Wilkins score. Several studies have reported improved accuracy and superiority of RT3DE over 2DE for MVA estimation³. RT3DE allows a unique “en face” view and morphologic analysis of the entire MV apparatus, including the MV annulus, the subvalvular apparatus, and its anatomic relation to other nearby structures.

AIM: To evaluate the role of real time 3D echocardiography in predicting success rates of redo-BMV.

METHODOLOGY:

We analysed 42 patients who underwent BMV at our centre from Jan 2022 to Nov 2022. These patients were divided into two groups. Group I included patients undergoing redo BMV, whereas Group II included patients who did not have any previous procedure in the past and had undergone BMV for the first time. As a part of pre-procedure evaluation, during trans-oesophageal echocardiography, additional real time 3D data was collected, and 3D echocardiographic score (Figure 1 and 2) was calculated. Based on immediate post procedural outcomes, 3D score was compared with traditional Wilkins score and findings were analysed. Procedural success was defined as an increase of $\geq 50\%$ of MVA or a final area of $\geq 1.5 \text{ cm}^2$, with no more than 1 grade increment in MR severity assessed by echocardiography 24 hours after the procedure.

RESULT:

The median age of patients in Group I was 44.5 (IQR-19) years; whereas in Group II, it was 42.5 (IQR-17) years (P value- 0.548). Both the groups had female preponderance with 68% females in Group-I and 80% females in Group II (P value -0.177). 4 patients (25%) in Group I and 1 patient (4%) in Group II had atrial fibrillation (P value- 0.061). Mean mitral valve gradient was 12 ± 4.6 mmHg in group I and 14 ± 4.5 mmHg in group II (P value- 0.242). There was no statistically significant difference between mitral valve area of both the groups as measured by planimetry (1 ± 0.11 cm² vs 0.93 ± 0.17 cm² [P value- 0.214]) or by pressure half time (0.96 ± 0.12 cm² in group I vs 0.95 ± 0.12 cm² in group II [P value- 0.857]). The median Wilkins score was 10 (IQR-2) in group I, whereas it was 9 (IQR-2) in group II (p value- 0.575). The 3-dimensional echocardiographic analysis revealed a numerically higher 3D score in group I (11 (IQR-3) vs 10 (2) [P value- 0.631]). Mitral valve gradient by simultaneous left atrial and left ventricular pressure assessment was found to be 14.09 ± 5.3 mmHg vs 12.36 ± 4.02 mmHg (P value- 0.352) and subsequent mitral valve area was found to be 0.94 ± 0.23 cm² vs 0.99 ± 0.2 cm² (P value- 0.596). A Wilkin's score < 10 was found to be associated with 84% success rates. [Odds ratio-0.04; [95% CI- 0.008-0.286] (p <0.001). All patients with 3 D Score <10 had procedural success rate of 100% and 59% of patients with 3 D score >10 had unsuccessful BMV. (p value <0.001)

Further subgroup analysis of group I revealed that 11 patients (69%) had a successful outcome whereas 5 patients (31%) had an unsuccessful outcome. The patients with unsuccessful outcome in redo-BMV group had significantly higher Wilkins score [11 (IQR-1) vs 9 (IQR-2) (P value- 0.018)] and 3D score [13 (IQR-2) vs 10 (IQR-2) (P value- 0.002)] than those with successful outcome. Most of the patients (81%) had mild mitral regurgitation after the procedure. Subgroup analysis of group II revealed that 8 patients (69%) had a

successful outcome whereas 8 patients (31%) had an unsuccessful outcome. Most of the patients (77%) had mild mitral regurgitation. No correlation was found between Wilkin's score and 3 D Score in predicting procedural success or postprocedural MVA.

CONCLUSION:

The Real time 3D-echocardiographic score gives a detailed morphological assessment of MV and helps in the proper selection of the therapeutic strategy for patients with MS. A 3D echocardiographic score of ≤ 10 , appeared as a promising tool to predict procedural success irrespective of the traditional 2D-Wilkins score.

INTRODUCTION:

The global burden of Rheumatic heart disease (RHD) is estimated to be 15.6 million cases with mortality of over 233,000 per year¹. Our nation contributes to more than 1 million cases of RHD² and the mortality and morbidity also remains high compared to western population.

Rheumatic mitral valve (MV) disease remains a major health problem, particularly in developing countries³. Mitral stenosis (MS) is a common valvular affection by the rheumatic process, for which percutaneous balloon mitral valvuloplasty (BMV) was firstly introduced by Inoue for treatment of selected patients, as a safe invasive procedure with equivalent or even better results as surgical commissurotomy⁴. In the current European and American guidelines, PBMV is recommended by class I indication in symptomatic patients with severe rheumatic mitral stenosis (mitral valve area $\leq 1.5 \text{ cm}^2$) (NYHA II, III or IV) and with appropriate valve morphology (in the absence of left atrial thrombus) without moderate or severe mitral regurgitation (MR)⁵.

Mitral valve morphology is traditionally evaluated by two-dimensional transthoracic echocardiography (TTE) with Wilkins score (WS) criteria in the selection of suitable patients for PBMV⁶. Low WS in studies was associated with low risk of restenosis in follow-ups; whereas, high WS was associated with a high risk of restenosis⁷. However, the traditional Wilkins score may have many limitations including inability to assess commissural involvement or differentiate nodular fibrosis from calcification, ignoring the distribution of pathologic abnormalities and contribution of each variable and underestimating sub valvular disease⁴. For this purpose, In 2005, Sutaria et al. proposed role of transoesophageal echocardiographic assessment for evaluating commissural fusion and calcification⁸. Later, a

new three-dimensional (3D) echocardiography (3DE) scoring system has been proposed by Anwar et al. for better guiding of MV intervention³.

The introduction of real-time three-dimensional echocardiography (RT3DE) and advances in analysis software have improved MV orientation and evaluation⁹. Several studies have reported improved accuracy and superiority of RT3DE over 2D echocardiography for MVA estimation^{4,9-11}. RT3DE allows a unique “en-face” view and morphologic analysis of the entire MV apparatus, including the MV annulus, the sub valvular apparatus, and its anatomic relation to other nearby structures. However, it is known that mitral stenosis might develop secondary to the progression of the disease in the follow-up of the patients after first PBMV, and there are a limited knowledge about outcome and success in terms of redo PBMV¹²⁻¹⁴. The data regarding role of three dimensional echocardiography in assessing patients undergoing redo PBMV is scarce¹⁵.

In the current study, we assessed the new RT3DE score for the assessment of the MV in patients with re-severe MS in comparison with Wilkins’s score for the prediction of PTMV outcomes.

HYPOTHESIS:

- 3D echocardiographic assessment of mitral valve is noninferior to Wilkins score for mitral valve assessment in patients post Balloon Mitral Valvuloplasty or Closed Mitral Valvotomy with mitral re-stenosis for predicting success of redo-BMV.

AIM:

- To evaluate the role of real time 3D echocardiography in predicting success rates of redo-BMV.

OBJECTIVES:

- i) To study various 3D parameters for mitral valve assessment prior to balloon mitral valvuloplasty in patients undergoing redo BMV and also in patients undergoing BMV for the first time.
- ii) To calculate 3D echocardiographic score (Anwar score)⁴ and compare it with traditional Wilkins score to assess procedural success.

REVIEW OF LITERATURE:

Mitral stenosis first described by Vieussens in 1705, first disease to be diagnosed by echocardiography¹⁶ and the first valve lesion to be treated by surgery¹⁷ and balloon mitral valvotomy(BMV)¹⁸. It is highly prevalent in developing countries because of high prevalence of rheumatic fever. In India, school survey between 1940-1983, the prevalence of rheumatic heart disease was 6 per 1000 children (1.8 to 11/1000 children), and from 1984 to 1995 it was reported to be from 1 to 3.9 per 1000.vs 0.5 per 1000 in developed countries¹⁹. In the largest school survey conducted to date at Vellore during 2001-2002, a total of 2,29,829 children between 6-18 years of age were screened as part of a school health programme²⁰. The prevalence of RHD was 0.68/1,000 school children, which showed a declining prevalence of RHD in rural children in India. In developed countries, prevalence detected by echocardiography is about 0.02-0.2%²¹.

Rheumatic fever (RF)/rheumatic heart disease (RHD) is the result of autoimmune response to group A beta-hemolytic streptococcal pharyngitis leading to immune mediated inflammatory injury to cardiac valves. The inflammatory injury of the pericardium and myocardium is transient and self-limiting, without leaving any sequelae. The valvular injury is the main cause of acute and long-term morbidity and mortality in patients with acute RF and RHD, respectively²². The risk of RF/RHD is primarily determined by the host, agent and environmental factors²³. RF/RHD is considered to be a physical manifestation of poverty. The distribution of the burden of RF/RHD mirrors the distribution of human development index in given geographical region, state, and nation, as well as globally. The socioeconomic state, access, and quality of health-care services are important determinants of the burden of RF/RHD. The incidence of RF/RHD has practically disappeared in developed countries²⁴. However, RF/RHD continues to be a major cause of disease burden among children,

adolescents, and young adults in low-income countries and even in high-income countries with socioeconomic inequalities. The burden of RF/RHD is likely to be variable among countries, within the country, within states depending upon the socioeconomic status and state of health systems²⁵. The major determinant of the persistent burden of RF/RHD in low income and lower-middle income countries are because of poor standards of living conditions, overcrowding, and lack of strong population-based surveillance system for pharyngitis, RF and RHD for effective implementation of primary and secondary preventive interventions.

Although a worldwide decline in health-related burden of RHD was noted, the global burden of rheumatic heart disease continues to be significant although it is largely limited to poor and marginalized populations. The persistence of high rates of RHD in poor regions of the world where RHD remains endemic (defined as having high RHD-related mortality exceeding 0.15 deaths per 100,000 population among children 5–9 years of age). Overall, there were an estimated 38.0 million to 40.8 million cases of RHD globally in 2017, with the highest prevalence, disability, and mortality in Oceania, South Asia, and sub-Saharan Africa²⁶. The prevalence ranged from 3.4 cases per 100,000 population in non-endemic countries to >1000 cases per 100,000 in endemic countries. There are a few reports of sporadic outbreaks of acute rheumatic fever (ARF) in the United States in the 1980s and 1990s and more recent reports from Australia and Italy²⁷.

Gender is an important biological determinant of susceptibility to diseases and their outcomes. The sex hormones are known to regulate both adaptive and innate immune responses. It is a well-established fact that autoimmune diseases have gender predilections. RHD is an autoimmune-mediated valvular injury, therefore, the autoimmune response may differ between genders, leading to differences in valvular damage and severity. The

epidemiological studies of RF and RHD report no gender predilection for the incidence of RF; however, RHD is more prevalent in females²⁸.

RHD typically affects left-sided valves, with greater affinity and consequence for the mitral valve. Characteristic acute mitral valvulitis shows mitral annulus dilatation, chordal elongation, and anterior leaflet prolapse, with varying degrees of MR and rarely chordal rupture. Isolated aortic disease occurs in 2% of cases. Right-sided valve disease is not infrequent, typically affects the tricuspid valve (as primary valvulitis or as the result of deleterious hemodynamic consequences of left-sided valve disease), and rarely affects the pulmonic valve. Acute rheumatic valvulitis manifests as valvular regurgitation, but over time, chronic inflammation leads to valve stenosis from commissural fusion with or without associated regurgitation in a subset of patients. MS from commissural fusion, with variable degrees of involvement of other parts of the mitral valve apparatus, is the hallmark lesion of the later stages of RHD. The more malignant fulminant course of RHD, linked to recurrent bouts of ARF, occurs in the most endemic regions of the world²⁹.

MS limits blood flow from the left atrium to the left ventricle, and over the time, leads to development of exertional dyspnoea and exercise intolerance, which worsen gradually. Some serious potential complications are associated with prolonged disease: while the stenosis progresses, pressure in the left atrium rises, resulting in left atrial enlargement and eventually atrial tachyarrhythmia: atrial fibrillation or flutter. These in turn can lead to thromboembolic events, most frequently to the cerebral circulation, resulting in cerebral ischemia and neurological damage. The elevated pressure in the left atrium can also result in pulmonary congestion and hypertension, which affect the right side of the heart, resulting in right ventricle dysfunction and tricuspid regurgitation. In turn, this may result in peripheral edema, ascites, and pleural effusions. Heart failure symptoms develop with progressive heart

valve damage. It should also be considered that because of the slow, progressive nature of many valve lesions, patients may not recognize symptoms because they may have gradually limited their daily activity levels. Although chronic heart valve disease is often manifested in adolescents and young adults, advanced valve damage happens earlier in life in the most endemic regions. Patients may be diagnosed after a known ARF attack, however, a significant portion of RHD patients, well over 50% in low and middle income countries, may present without any prior symptoms or memory of ARF. In these settings, RHD may present for the first time during pregnancy or after a complication such as acute heart failure, atrial arrhythmia, an embolic event, or infective endocarditis (IE). Most patients have heart failure symptoms at the time of clinical diagnosis through auscultation of pathological heart murmurs.

An electrocardiogram and chest radiograph can be helpful in the initial assessment of RHD patients. Although electrocardiography findings are not specific for RHD, they may demonstrate left atrial or right ventricular enlargement and ventricular strain³⁰. In more severe degrees of mitral valve damage, especially in older patients, atrial fibrillation may be present. The chest radiograph may show an enlarged left atrium or right ventricle and radiological signs of pulmonary venous congestion in more advanced cases³¹.

The acceptable tool used to determine stenosis severity is the echocardiogram, based on European Association of Echocardiography /American Society of Echocardiography (EAE/ASE) definitions³². The severity of the stenosis is assessed by echocardiographic findings, with mitral valve area (MVA) as a main parameter and mean gradient and pulmonary artery pressure as supportive findings (**Table 1**).

Table 1 : Grading of severity of mitral stenosis:

	Mild	Moderate	Severe
Mitral valve area (cm ²)	>1.5	1-1.5	<1
Mean Gradient (mmHg)	5	5-10	>10
Pulmonary artery Systolic pressure (mmHg)	30	30-50	>50

As per 2021 ESC/EACTS Guidelines for the Management of Valvular Heart Disease⁵, stages of MS are defined by patient symptoms, valve anatomy, valve hemodynamics, and the consequences of valve obstruction on the left atrium (LA) and pulmonary circulation (**Table 2**).

Table 2 : Stages of mitral stenosis:

Stages	Definition	Valve Anatomy	Valve hemodynamics	Hemodynamic Consequences	Symptoms
A	At risk MS	Mild valve doming during diastole	Normal transmitral flow velocity	None	None
B	Progressive MS	Rheumatic valve changes with commissural fusion and diastolic	Increased transmitral flow velocities MVA > 1.5 cm ²	Mild to moderate LA enlargement Normal PASP at rest	None

		doming of the mitral valve leaflets. Planimetered MVA $>1.5 \text{ cm}^2$	Diastolic PHT $<150 \text{ ms}$		
C	Asymptomatic severe MS	Rheumatic valve changes with commissural fusion and diastolic doming of the mitral valve leaflets. Planimetered MVA $\leq 1.5 \text{ cm}^2$	MVA $\leq 1.5 \text{ cm}^2$ Diastolic PHT $\geq 150 \text{ ms}$	Severe LA enlargement Elevated PASP $>50 \text{ mmHg}$	None
D	Symptomatic severe MS	Rheumatic valve changes with commissural	MVA $\leq 1.5 \text{ cm}^2$ Diastolic PHT	Severe LA enlargement Elevated	Decreased exercise tolerance, exertional

		fusion and diastolic doming of the valve leaflets. Planimetered MVA ≤ 1.5 cm ²	≥ 150 ms	PASP > 50 mmHg	dyspnoea
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[MS- mitral stenosis, mm Hg- millimetres of mercury, MVA- mitral valve area, PHT- pressure half time, PASP- pulmonary artery systolic pressure, LA- left atrium]

Mitral stenosis being a mechanical obstruction to the forward flow of blood, the only definitive therapy is a mechanical relief in this obstruction. Three procedures are effective in providing such therapy, which are percutaneous transvenous mitral commissurotomy (PBMV), surgical mitral commissurotomy, and mitral valve replacement. A successful PBMV results in improvement in mitral valve area, thereby causing a decrease in left atrial pressures, decrease in pulmonary artery (PA) pressures, and increase in left ventricular end diastolic pressure.

As per European society of cardiology (ESC) 2021 guidelines for management of valvular heart disease⁵ indication for intervention in mitral stenosis-

- Should be limited to patients with clinically significant (moderate to severe) mitral stenosis (valve area <1.5 cm²).
- May be considered in symptomatic patients with a valve area >1.5 cm² if symptoms cannot be explained by another cause and if the anatomy is favourable.

As per American college of cardiology (ACC)/ American heart association (AHA) 2020 guidelines for management of valvular heart disease³³ indication for intervention in mitral stenosis

- In symptomatic patients (NYHA class II, III, or IV) with severe rheumatic MS (mitral valve area ≤ 1.5 cm², Stage D) and favourable valve morphology.
- In asymptomatic patients with severe rheumatic MS (mitral valve area ≤ 1.5 cm², Stage C) and favourable valve morphology

Randomized trials have established the safety and efficacy of PBMV as compared with surgical closed or open commissurotomy in patients with a favourable valve morphology with less than 2+ MR in the absence of LA thrombus. Favourable valve morphology consists of

- Mobile and relatively thin valve leaflets
- Free of commissural calcium
- Absence of significant subvalvular fusion

An anatomic mitral morphology score can be used to determine suitability for PBMV and to evaluate the appearance of the commissures and degree of calcification.

Long-term follow-up has shown 70% to 80% of patients with an initial good result after PBMV to be free of recurrent symptoms at 10 years, and 30% to 40% are free of recurrent symptoms at 20 years³⁴.

2D echocardiography, including Doppler, is the most commonly used method of assessment of mitral stenosis (MS) and is the basis of current guidelines on its management^{5,33}. However, the mitral valve is a complex structure with a geometrically

irregular appearance, especially in the presence of significant calcification or rheumatic infiltration. It is therefore difficult to correctly bisect the leaflet tips using 2D transthoracic echocardiography (TTE). Other 2D methods derive the mitral valve orifice area (MVOA) from calculations involving the velocity of blood flow through the stenotic orifice, such as the pressure half-time (PHT) method. These are subject to haemodynamic variables such as loading, left ventricular compliance and coexisting valve disease and must therefore be interpreted in the context of potential confounders³⁵.

Given these inherent issues with 2D, the use of 3D echocardiography is becoming more established. 3D TTE offers an adjustable dataset that can be manipulated with multi-plane reconstruction to more accurately align with the true mitral valve orifice and has been validated against the data obtained by Gorlin's equation at invasive catheterisation³⁶.

The Safety and success of BMV techniques are mainly dependent on the selection of suitable patients. Patient ages, functional class, mitral valve (MV) morphology, pre-procedural MV area (MVA), and the size of the balloon used; all are considered as predictors of procedural outcome. Current scores that target patient selection before BMV particularly the two-dimensional (2D) Wilkins score may have many limitations including inability to assess commissural involvement or differentiate nodular fibrosis from calcification, ignoring the distribution of pathologic abnormalities and contribution of each variable and underestimating subvalvular disease⁴.

As it is well known that not only Wilkins score but mitral valve commissure morphology is also important in the success of PBMV, in 2005, Sutaria et al. came up with a novel method evaluating commissural fusion and calcification by transoesophageal echocardiography (TEE)⁸.

Later on with the introduction of real-time three-dimensional echocardiography (RT3DE) and advances in analysis software have improved MV orientation and evaluation. Several studies have reported improved accuracy and superiority of RT3DE over 2DE for MVA estimation. RT3DE allows a unique “en face” view and morphologic analysis of the entire MV apparatus, including the MV annulus, the subvalvular apparatus, and its anatomic relation to other nearby structures. Anwar et al proposed a new three-dimensional (3D) echocardiography (3DE) scoring system for better guiding of MV intervention. This new RT3DE score was shown to be feasible and highly reproducible for the assessment of MV morphology in patients with MS. It can provide incremental prognostic information in addition to Wilkins’s score³.

Anwar et al conducted a two-staged study, where in the first stage, the feasibility of a new RT3DE score was assessed in 17 patients with MS. The second stage was planned to validate the RT3DE score in 74 consecutive patients undergoing percutaneous mitral valvuloplasty. The new RT3DE score was constructed by dividing each mitral valve (MV) leaflet into 3 scallops and was composed of 31 points (indicating increasing abnormality), including 6 points for thickness, 6 for mobility, 10 for calcification, and 9 for subvalvular apparatus involvement. The total RT3DE score was calculated and defined as mild (<8), moderate (8-13), or severe (≥ 14). MV morphology was assessed using Wilkins’s score and compared with the new RT3DE score. The authors found that in the first stage, the RT3DE score was feasible and easily applied to all patients, with good interobserver and intra-observer agreement. In the second stage, RT3DE improved MV morphologic assessment, particularly for the detection of calcification and commissural splitting. Both scores were correlated for assessment of thickness and calcification ($r = 0.63$, $P < .0001$, and $r = 0.44$, $P < .0001$, respectively). Predictors of optimal percutaneous mitral valvuloplasty success by Wilkins’s score were leaflet calcification and subvalvular apparatus involvement, and those

by RT3DE score were leaflet mobility and subvalvular apparatus involvement. The incidence and severity of mitral regurgitation were associated with high-calcification RT3DE score. The new proposed RT3DE score for the morphologic evaluation of the MV in patients with MS was feasible and reproducible and compared favourably with Wilkins's score. This RT3DE score did appear to provide additional valuable information beyond the standard Wilkins's score, however it could only provide incremental prognostic information in addition to Wilkins's score.

Farrag et al⁴ compared the 3D-Anwar and 2D-Wilkins scores in mitral assessment for BMV, and investigate the additive value of 3DE in prediction of immediate post-procedural outcome. Fifty patients with rheumatic mitral stenosis and candidates for BMV were included in the study. The patients mean age was 29.5 ± 7.8 years (19–55 years old), and 64% of them were females. Thirty percent of patients had atrial fibrillation (AF), 66% were in New York Heart Association (NYHA) functional class III, while 18% were in class II and 16% were in class IV. Patients were subjected to 2D- and real-time 3D-transthoracic echocardiography (TTE) before and immediately after BMV for assessing MV area (MVA), 2D-Wilkins and 3D-Anwar score, commissural splitting, and mitral regurgitation (MR). Transoesophageal echocardiography (TEE) was also undertaken immediately before and intra-procedural. Percutaneous BMV was performed by either multi-track or Inoue balloon technique. The 2DE underestimated post-procedural MVA than 3DE ($p = 0.008$). Patients with post-procedural suboptimal MVA or significant MR had higher 3D-Anwar score compared to 2D-Wilkins score ($p = 0.008$ and $p = 0.03$ respectively). The 3D-Anwar score showed a negative correlation with post-procedural MVA ($r = -0.48$, $p = 0.001$). Receiver operating characteristic (ROC) curve analysis for both scores revealed superior prediction of suboptimal results by 3D-Anwar score ($p < 0.0001$). The 3DE showed better post-procedural posterior-commissural splitting than 2DE ($p = 0.004$). Results of both multi-track and Inoue

balloon were comparable except for favourable posterior-commissural splitting by multi-track balloon ($p = 0.04$). The authors finally concluded that 3DE gave valuable additive data before BMV that may predict immediate post-procedural outcome and suboptimal results.

A.A. Alkhouly et al³⁷ performed a pilot, prospective study to evaluate the role of three dimensional transesophageal echocardiography (3D-TEE) in the prediction of MR after PBMV through mitral valve quantification (MVQ). The authors studied 37 patients with rheumatic, moderate-to-severe mitral stenosis, and divided them into two age and sex matched groups. Group I included 25 patients without significant MR following PBMV [vena contract area (VCA) $<0.4 \text{ cm}^2$], while group II included 12 patients with significant MR after PBMV [VCA $>0.4 \text{ cm}^2$]. Both groups were comparable in terms of TEE data, Wilkins score for favourability of PBMV and baseline hemodynamics. Data from MVQ showed that both groups were comparable ($p > 0.05$) in terms of MV annulus quantification (Anteroposterior diameter, annular sphericity, 3D area and height), MV scallops (A1, A2, A3, P1, P2 and P3) areas, as well as A1 and A2 tenting volumes. However, significant differences between the two groups as regard total MV, A2, P2 and P3 tenting volumes ($p < 0.05$) and tenting height ($p = 0.03$), as well as A2, A3 and P2 prolapse volumes ($p < 0.05$) were noted. Moreover, this data showed a significant difference between both groups in terms of MV coaptation heights ($p = 0.01$), but not in anterior coaptation length ($p = 0.13$). They concluded that mitral valve quantification through 3D-TEE is a simple automated method, easily applicable to patients before PBMV. Moreover, MVQ-derived data, such as MV scallops' tenting and prolapse volumes, coaptation heights, and exposed and total A2 lengths may predict the possibility of significant MR after PBMV.

Sancar et al³⁸ studied fifty cases of redo PBMV and evaluated a novel scoring system including three dimensional (3D) transesophageal echocardiography (TEE) of the mitral

valve structure in terms of success of the procedure. The patients were divided into two groups according to the success of the Redo PBMV procedure which was defined as post-procedural MVA ≥ 1.5 cm² and post-procedural mitral regurgitation less than moderate by echocardiographic evaluation after PBMV. A novel score based on 3D TEE findings was created by analyzing the images recorded before Redo PBMV and by evaluating the mitral commissure and calcification. The role of traditional WS and novel score in the success of the procedure were investigated. In the study group, 36 patients (72%) had successful redo PBMV procedure. WS was 8 (IQR 7–9) and novel 3D TEE score was found 4 (IQR 3–4) in the whole study group. While no statistically significant relationship was found between WS and procedural success ($p = 0.187$), a statistically significant relationship was found between novel 3D TEE score and procedural success ($p = 0.042$). Specifically, the procedural successes rate was $> 90\%$ when novel 3D TEE score was < 4 . The novel 3D TEE score might be an informative scoring system in the selection of suitable patients for successful redo PBMV, especially in patients who are considered for surgery due to the high WS.

MATERIALS AND METHODS:

Study design:

- Prospective Cohort Study.

Sample size: 42

Study Period: January 2022 to November 2022

Inclusion Criteria:

- All patients who underwent balloon mitral valvuloplasty for denovo mitral stenosis and those undergoing balloon mitral valvuloplasty for mitral restenosis following BMV/CMV in the past were included in the study.

Exclusion Criteria:

- Those who did not give consent will be excluded.
- Those patients with associated moderate or severe MR or other valve lesions requiring surgical correction, presence of left atrial (LA) and/or LA appendage thrombus, history of recent thromboembolic events within the last month, associated significant coronary artery disease requiring surgical revascularization, and acute rheumatic activity and/or infective endocarditis were excluded.
- Those patients with H/O mitral valve repair, ASD closure, concomitant valve replacement will be excluded.

METHODOLOGY:

We analysed 42 patients who underwent BMV at our centre from Jan 2022 to Nov 2022. These patients were divided into two groups. Group I included patients undergoing redo BMV, whereas Group II included patients who did not have any previous procedure in the past and had undergone BMV for the first time.

Baseline characteristics, demographic & echocardiographic data were collected from all the patients who underwent percutaneous balloon mitral valvuloplasty for re-severe mitral stenosis (Group-I) and for new mitral stenosis (Group-II). As a part of pre-procedure evaluation, during trans-oesophageal echocardiography, additional real time 3D data was collected, and 3D echocardiographic score (Figure 1 and 2) was calculated. Based on immediate post procedural outcomes, 3D score was compared with traditional Wilkins score and findings were analysed.

	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.

Figure 1: Real time 3 D echocardiographic score (Anwar score)3 for mitral valve

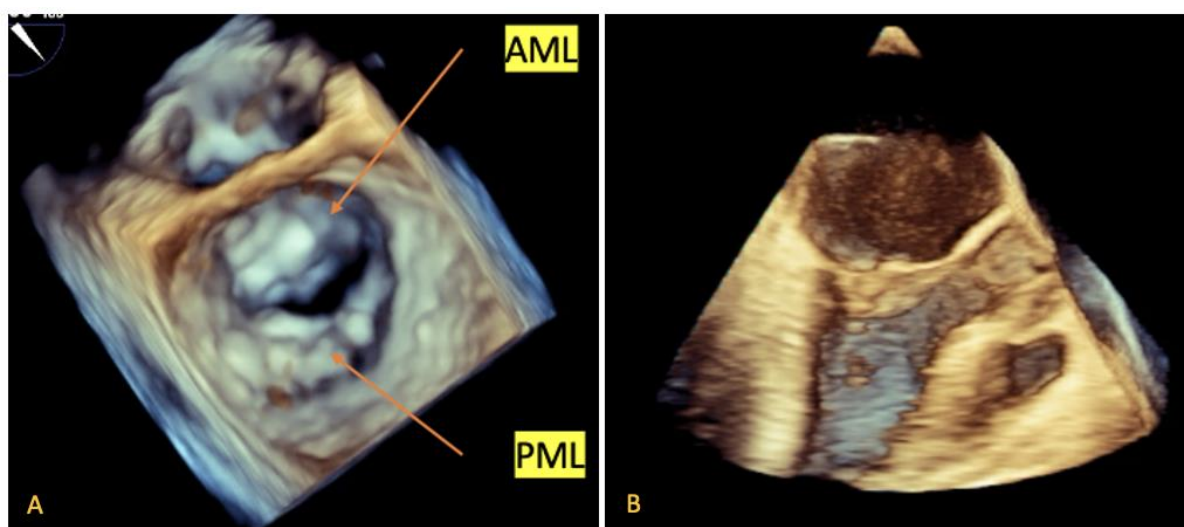


Figure 2: Real time 3D echocardiographic images [Panel A: en face view of mitral valve in closed position as seen from atrial aspect showing stenotic mitral valve with calcification; Panel B: Long axis real time 3 D echocardiographic view showing thickened subvalvar mitral apparatus]

Outcomes/Endpoint:

- Procedural success will be defined as an increase of $\geq 50\%$ of MVA or a final area of $\geq 1.5 \text{ cm}^2$, with no more than 1 grade increment in MR severity assessed by echocardiography 24 hours after the procedure. The reference measurement for MVA was 2-dimensional echocardiography planimetry.

Statistical Analysis:

- Data analysis was done by primary investigator with assistance from a statistician. All statistical analyses were performed using SPSS version 25 (SPSS, Inc, Chicago, IL). Each component of both scores was assessed separately, and then the total scores of 2DE and RT3DE were calculated for every patient. Both scores were investigated for correlations using Pearson's Chi square analysis to demonstrate the basic differences. Paired t test was also used, and $P < .05$ was set as the criterion for significance in all comparisons.

RESULTS:

Baseline Characteristics:

We analysed 42 patients with severe mitral stenosis who underwent balloon mitral valvuloplasty (BMV) during the study period at our centre. Our study was approved by Institutional ethics committee (SCT/IEC/1907). 16 patients who underwent redo BMV were included in Group-I, whereas 26 patients who underwent BMV for the first time for de-novo mitral stenosis were included in group-II. 12 patients (75%) in the Group-I, had undergone prior BMV and 4 patients (25%) had undergone prior closed mitral valvotomy (CMV). The median duration of prior BMV or CMV in Group-I was 15 years.

Most of the patients had isolated mitral stenosis. The median age of patients in Group I was 44.5 years with interquartile range of 19; whereas in Group II, it was 42.5 years with interquartile range of 17 years (P value- 0.548). Both the groups had female preponderance with 68% females in Group-I and 80% females in Group II (P value -0.177). The patients in Group I had a median body surface area of 1.57 (IQR- 0.18) and patients in Group II had median body surface area of 1.6 (IQR-0.21) [P value-0.317]. 1 patient (6%) in Group I and 6 patients (24%) in Group II had history of stroke (P value- 0.222). Similarly, Group I had 1 patient (6%) and Group II had 4 patients (15%) with diabetes (P value- 0.633). 4 patients (25%) in Group I and 1 patient (4%) in Group II had atrial fibrillation (P value- 0.061). Most of the patients in group I had presented with functional class-II (7 patients, 44%) and functional class- III (7 patients, 44%); whereas 2 patients (13%) had presented with functional class- IV. In group II, majority of the patients were in functional class- II (18 patients, 70%) and 8 patients (30%) were in functional class- III.

Baseline 2 -dimensional echocardiographic analysis revealed that, 4 patients (25%) in Group I and 2 patients (8%) in Group II had no mitral regurgitation. Trivial mitral regurgitation was present in 7 patients (44%) in Group I and 9 patients (35%) in Group II. 5 patients (31%) in Group I and 15 patients (58%) in Group II had mild mitral regurgitation. The mean left atrial diameter in group I was 46 ± 5.3 mm and 45 ± 6.7 mm in group II (P value- 0.332). The left ventricular internal diameter in diastole was found to be similar in both the groups [43 ± 5.3 mm vs 44 ± 5.1 mm, (P value- 0.857)]. Similarly, the ejection fractions in either of the groups were comparable [66 ± 7.3 % vs 65 ± 6.4 % (P value- 0.477)]. Mean right ventricular systolic pressure was 42 ± 11 mmHg in group I and 36 ± 17 mmHg in group II (P value-0.058).

Baseline Characteristics	Group I (n=16)	Group II (n=26)	p-value
Age, median(IQR)	44.5 (19)	42.5 (17)	0.548
Height, median(IQR)	162 (23)	152 (5)	0.177
BSA, median (IQR)	1.57 (0.18)	1.6 (0.21)	0.317
Female, n(%)	11 (68%)	21 (80%)	0.465
Stroke, n (%)	1 (6%)	6 (24%)	0.222
DM, n (%)	1 (6%)	4 (15%)	0.633
AF, n (%)	4 (25%)	1 (4%)	0.061
Functional Class, n (%)			0.99
FC-II	7 (44%)	18 (70%)	
FC-III	7 (44%)	8 (30%)	
FC-IV	2 (13%)	0	

Echo parameters	Group I (n=16)	Group II (n=26)	p-value
Mitral Regurgitation, n (%)			0.189
Grade 0	4 (25%)	2 (8%)	
Grade I	7 (44%)	9 (35%)	
Grade II	5 (31%)	15 (58%)	
LA diameter, mm	46 ± 5.3	45 ± 6.7	0.332
LVID, mm	43 ± 5.3	44 ± 5.1	0.857
EF, %	66 ± 7.3	65 ± 6.4	0.477
RVSP, mmHg	42 ± 11	36 ± 17	0.058
TAPSE	20 ± 2.2	19 ± 2.1	0.960
MVA (2D), cm²	1.0 ± 0.11	0.93 ± 0.17	0.214
MVA (PHT), cm²	0.96 ± 0.12	0.95 ± 0.12	0.857
MS gradient, mmHg	12 ± 4.6	14 ± 4.5	0.242

The mean tricuspid annular plane systolic excursion was 20 ± 2.2 mm in group I and 19 ± 2.1 mm in group II (P value- 0.960). Mean mitral valve gradient was 12 ± 4.6 mmHg in group I, whereas patients with newly developed mitral stenosis had numerically higher gradients- 14 ± 4.5 mmHg but was not statistically significant (P value- 0.242). There was no statistically significant difference between mitral valve area of both the groups as measured by planimetry (1 ± 0.11 cm² vs 0.93 ± 0.17 cm² [P value- 0.214]) or by pressure half time (0.96 ± 0.12 cm² in group I vs 0.95 ± 0.12 cm² in group II [P value- 0.857]).

Echo Characteristics	Group I (n=16)	Group II (n=26)	p-value
MC fused	5 (31%)	16 (62%)	0.057
MC split	11 (69%)	10 (39%)	0.057
LC fused	9 (56%)	20 (77%)	0.187
LC split	7 (44%)	6 (23%)	0.187
Bi-commissural fusion	2 (12%)	12 (46%)	0.025
Uni-commissural fusion	10 (62%)	12 (46%)	0.303
Lack of bilateral complete fusion	4 (25%)	2 (8%)	0.180

Detailed valve morphological analysis revealed completely fused medial commissure in 6 patients (31%) in group I vs 16 patients (62%) in group II (P value- 0.057) and fused lateral commissure in 9 patients (56%) in group I vs 20 patients (77%) in group II (P value- 0.187). Partial or complete split of medial commissure was seen in 11 patients (69%) in group I vs 10 patients (39%) in group II (P value- 0.057); whereas split lateral commissure was noted in 7 patients (44%) in group I vs 6 patients (23%) in group II (P value- 0.187). Group II had statistically significant number of patients with bicommissural fusion than group I [46% vs 12 %; P value-0.025]. Patients with uni-commissural fusion were comparable in both the groups (P value- 0.303). Although patients with lack of complete bilateral fusion were more in group I than group II, it was not found to be statistically significant (P value-0.180).

The median Wilkins score was 10 (IQR-2) in group I, whereas it was 9 (IQR-2) in group II (p value- 0.575). On analysing individual components of Wilkins score, mobility, thickening and calcification was found to be similar whereas subvalvar pathology was found to be relatively more in group I than group II; but the difference was not statistically significant (P value- 0.307).

Echo parameters	Group I (n=16)	Group II (n=26)	p-value
Mobility	2 (1)	2 (1)	0.726
Thickening	2 (1)	2 (1)	0.802
Calcification	2 (0.25)	2 (1)	0.610
Subvalvar pathology	3 (1)	2 (1)	0.307
Wilkin's score	10 (2)	9 (2)	0.575
3D Score	11 (3)	10 (2)	0.631

The 3-dimensional echocardiographic analysis revealed a numerically higher score in group I than group II, but it was not statistically different. (Group I- 11 (IQR-3) vs Group II- 10 (2) [P value- 0.631]). Individual component analysis of real time 3-D score in each group showed similar frequencies in both the groups except for mobility in A2 scallop which was found to be restricted more in group II than group I, indicating complex morphology mitral valves.

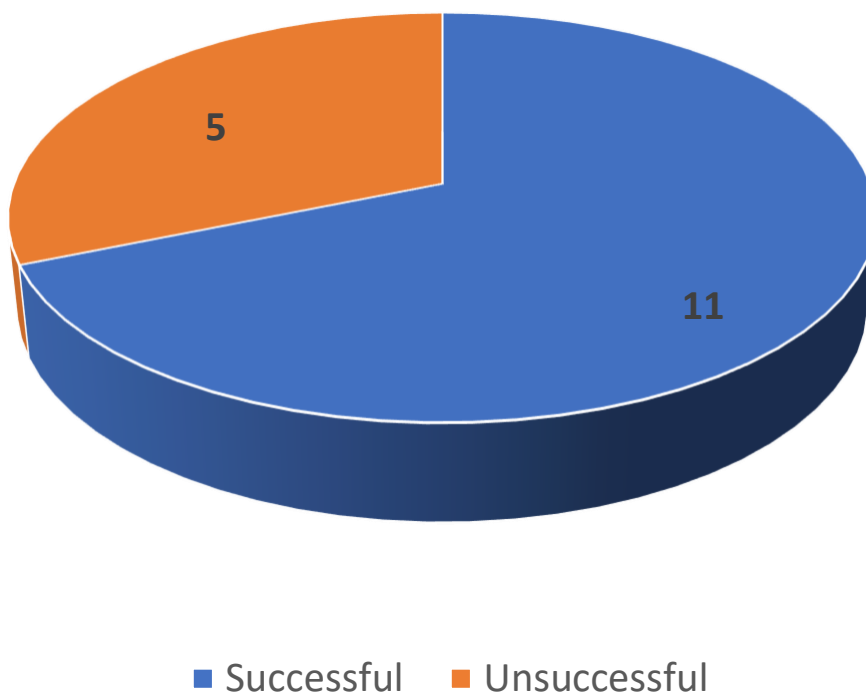
3D echo Characteristics	Group I (n=16)	Group II (n=26)	p-value
Leaflet thickness A1	15 (94%)	21 (81%)	0.380
Leaflet thickness A2	9 (56%)	12 (46%)	0.525
Leaflet thickness A3	10 (62%)	9 (35%)	0.078
Leaflet thickness P1	10 (62%)	13 (50%)	0.429
Leaflet thickness P2	10 (62%)	12 (46%)	0.303
Leaflet thickness P3	12 (75%)	15 (58%)	0.256
Leaflet Mobility A1	13 (81%)	15 (58%)	0.180
Leaflet Mobility A2	2 (12%)	11 (42%)	0.042
Leaflet Mobility A3	8 (50%)	9 (35%)	0.324
Leaflet Mobility P1	10 (62%)	15 (58%)	0.758
Leaflet Mobility P2	6 (38%)	15 (58%)	0.204
Leaflet Mobility P3	12 (75%)	18 (69%)	0.740
Leaflet Calcification A1	6 (38%)	12 (46%)	0.847
Leaflet Calcification A2	4 (25%)	7 (27%)	1.000
Leaflet Calcification A3	4 (25%)	6 (23%)	0.506
Leaflet Calcification P1	4 (25%)	8 (31%)	0.740
Leaflet Calcification P2	5 (31%)	8 (31%)	1.000
Leaflet Calcification P3	8 (50%)	13 (50%)	0.675
Subvalvar thickness Prox	15 (94%)	24 (93%)	1.000
Subvalvar thickness Mid	3 (19%)	9 (35%)	0.316
Subvalvar thickness Dist	1 (6%)	6 (23%)	0.222
Subvalvar separation Prox	10 (62%)	16 (62%)	1.000
Subvalvar separation Mid	2 (12%)	3 (12%)	1.000
Subvalvar separation Distal	0	0	NA

Hemodynamic data prior to BMV, was also found to be largely comparable between the groups. The mean pulmonary arterial systolic pressure was 46.5 ± 14.9 mmHg in group I vs 45.2 ± 15.1 mmHg in group II (P value- 0.81). Left atrial mean pressure was found to be 25.81 ± 7.7 mmHg in group I vs 24 ± 4.2 mmHg in group II; whereas mean left ventricular end-diastolic pressure was 10.97 ± 2.8 mmHg in group I vs 12.19 ± 2.9 mmHg in group II (P value- 0.332). Mitral valve gradient by simultaneous left atrial and left ventricular pressure assessment was found to be 14.09 ± 5.3 mmHg vs 12.36 ± 4.02 mmHg (P value- 0.352) and subsequent mitral valve area was found to be $0.94 \pm 0.23\text{cm}^2$ vs $0.99 \pm 0.2\text{ cm}^2$ (P value- 0.596).

Hemodynamics	Group I (n=16)	Group II (n=26)	P-value
RA mean	7.13 ± 2.5	6.92 ± 2.6	0.756
PA systolic pressure	46.5 ± 14.9	45.2 ± 15.1	0.81
PA mean	30.5 ± 11.2	27.7 ± 9.2	0.596
LA mean	25.81 ± 7.7	24 ± 4.2	0.357
LV Ed	10.97 ± 2.8	12.19 ± 2.9	0.332
MVG	14.09 ± 5.3	12.36 ± 4.02	0.352
MVA by cath	0.94 ± 0.23	0.99 ± 0.20	0.596

Further subgroup analysis of group I revealed that 11 patients (69%) had a successful outcome whereas 5 patients (31%) had an unsuccessful outcome.

Group I- Redo-16 patients



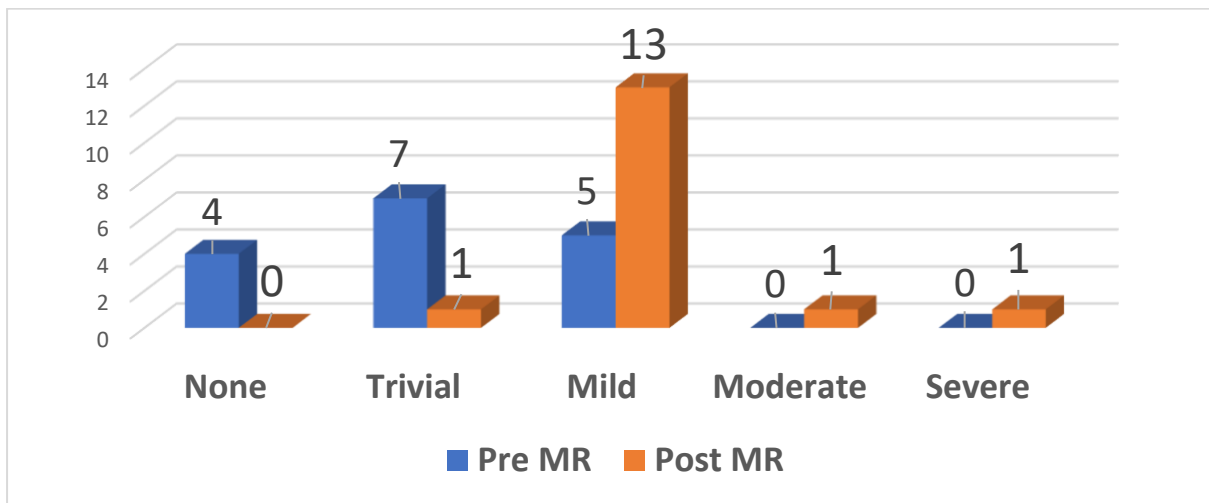
In the subgroup analysis, the baseline parameters were found to be similar between unsuccessful and successful categories. Echocardiographic parameters revealed similar dimensions of left atrium and left ventricle; comparable ejection fraction and right ventricular function. Mitral stenosis gradient was relatively higher in patients with successful outcome than those with unsuccessful outcome, however the difference was not statistically significant (P value- 0.332). The patients with unsuccessful outcome in redo-BMV group had significantly higher Wilkins score [11 (IQR-1) vs 9 (IQR-2) (P value- 0.018)] and 3D score [13 (IQR-2) vs 10 (IQR-2) (P value- 0.002)] than those with successful outcome.

Echo Characteristics	Unsuccessful (n=5)	Successful(n=11)	p-value
Mitral regurgitation, n (%)			0.912
Grade 0	2 (40%)	2 (18%)	
Grade I	1 (20%)	6 (55%)	
Grade II	2 (40%)	3 (27%)	
LA diameter, mm	48 ± 6.2	45 ± 4.24	0.459
LVID, mm	40 ± 5.4	43 ± 5.5	0.253
EF, %	64 ± 8.7	67 ± 6.4	0.420
RVSP, mmHg	40 ± 7.6	43 ± 13.4	0.776
TAPSE	21 ± 3.3	20 ± 1.7	0.861
MVA (2D), cm2	0.99 ± 0.12	1.0 ± 0.11	0.770
MVA (PHT), cm2	0.93 ± 0.13	0.97 ± 0.13	0.445
MS gradient, mmHg	11 ± 3.6	13 ± 4.9	0.332
Mobility	3 (1)	2 (1)	0.031
Thickening	3 (1)	2 (1)	0.280
Calcification	2 (1)	2 (0)	0.186
Subvalvar pathology	3 (1)	3 (1)	0.671
Wilkin's score	11 (1)	9 (2)	0.018
3D Score	13 (2)	10 (2)	0.002
MC fused	1 (20%)	4 (36%)	0.622
MC split	4 (80%)	7 (64%)	0.622
LC fused	1 (20%)	8 (72%)	0.106
LC split	4 (80%)	3 (28%)	0.106
Bi-commissural fusion	0	2 (18%)	1.000
Uni-commissural fusion	2 (40%)	8 (73%)	0.299
Lack of bilateral complete fusion	3 (60%)	1 (9%)	0.063

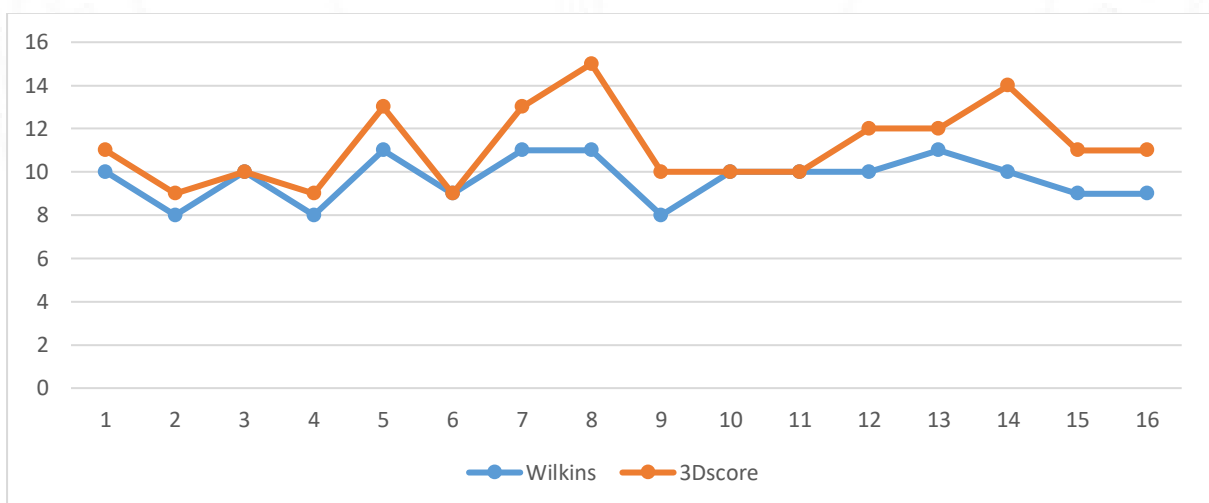
Characteristics	Unsuccessful (n=5)	Successful(n=11)	p-value
Leaflet thickness A1	4 (80%)	11 (100%)	0.313
Leaflet thickness A2	4 (80%)	5 (46%)	0.308
Leaflet thickness A3	4 (80%)	6 (55%)	0.588
Leaflet thickness P1	2 (40%)	8 (73%)	0.299
Leaflet thickness P2	5 (100%)	5 (46%)	0.093
Leaflet thickness P3	5 (100%)	7 (64%)	0.245
Leaflet Mobility A1	3 (60%)	10 (91%)	0.214
Leaflet Mobility A2	1 (20%)	1 (9%)	0.547
Leaflet Mobility A3	3 (60%)	5 (46%)	1.000
Leaflet Mobility P1	3 (60%)	7 (64%)	1.000
Leaflet Mobility P2	2 (40%)	4 (36%)	1.000
Leaflet Mobility P3	4 (80%)	8 (73%)	1.000
Leaflet Calcification A1	3 (60%)	3 (27%)	0.229
Leaflet Calcification A2	3 (60%)	1 (9%)	0.063
Leaflet Calcification A3	2 (40%)	2 (18%)	0.547
Leaflet Calcification P1	2 (40%)	2 (18%)	0.547
Leaflet Calcification P2	1 (20%)	4 (36%)	1.000
Leaflet Calcification P3	4 (80%)	4 (36%)	0.282
Subvalvar thickness Prox	5 (100%)	10 (91%)	1.000
Subvalvar thickness Mid	1 (20%)	2 (18%)	1.000
Subvalvar thickness Dist	1 (20%)	0	0.313
Subvalvar separation Prox	4 (80%)	6 (55%)	0.588
Subvalvar separation Mid	1 (20%)	1 (9%)	1.000
Subvalvar separation Distal	0	0	NA

Hemodynamics	PRE-BMV	POST- BMV	p-value
RA mean, mmHg	7.12 ± 2.5	7.11 ± 2.2	0.565
PASP, mmHg	46.5 ± 14	40.18 ± 9.4	0.039
PA mean, mmHg	30.5 ± 11	24.56 ± 6.1	0.014
LA mean, mmHg	25.81 ± 7.7	17.56 ± 5.1	0.001
LV Ed, mmHg	10.87 ± 2.8	13.06 ± 2.8	0.005
MVG, mmHg	14.09 ± 5.3	5.26 ± 4.07	0.001
MVA by cath	0.94 ± 0.23	1.7 ± 0.34	0.001

Hemodynamic assessment after BMV procedure revealed significant fall in pulmonary artery systolic pressure (P value- 0.039), pulmonary artery mean pressure (P value- 0.014), left atrial mean pressure (0.001) and mitral valve gradient (P value- 0.001). A significant rise in left ventricular end-diastolic pressure (P value- 0.005) was also noted along with increase in mitral valve area (P value- 0.001).

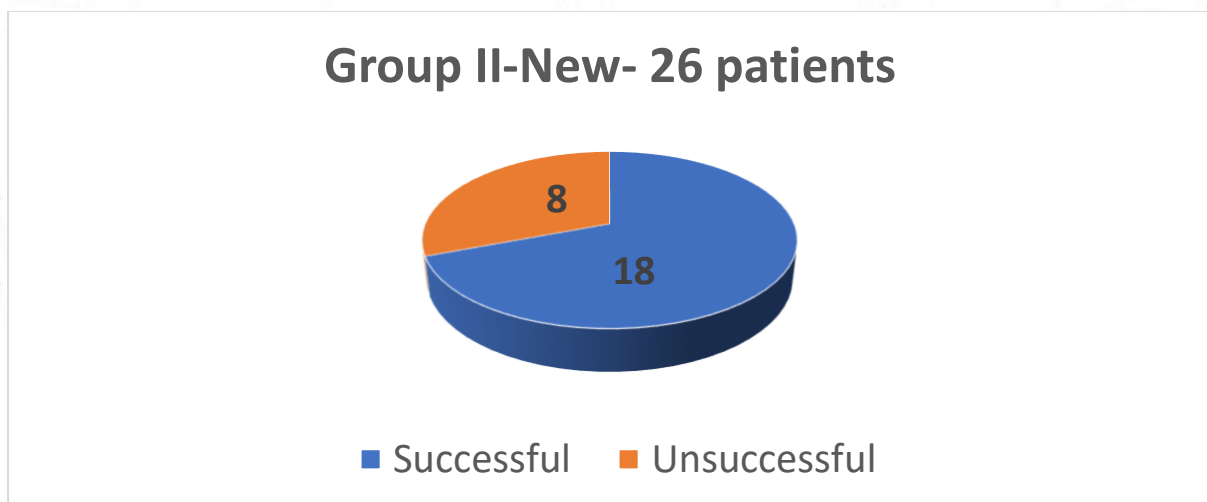


After the procedure, 1 patient (6%) developed acute severe mitral regurgitation due to leaflet tear and required mitral valve replacement surgery. Most of the patients (81%) had mild mitral regurgitation.



- When the echocardiographic scores were compared, it was found that the 3D score was higher than Wilkins score (P value-0.026). However, no statistically significant correlation was found between either Wilkins score with procedural success or post procedural MVA. (p value>0.05) or 3D Score with procedural success or postprocedural MVA. (p value>0.05)
- Similarly, no correlation was found between Wilkin's score and 3 D Score in predicting procedural success or postprocedural MVA.

Subgroup analysis of group II revealed that 8 patients (69%) had a successful outcome whereas 8 patients (31%) had an unsuccessful outcome.

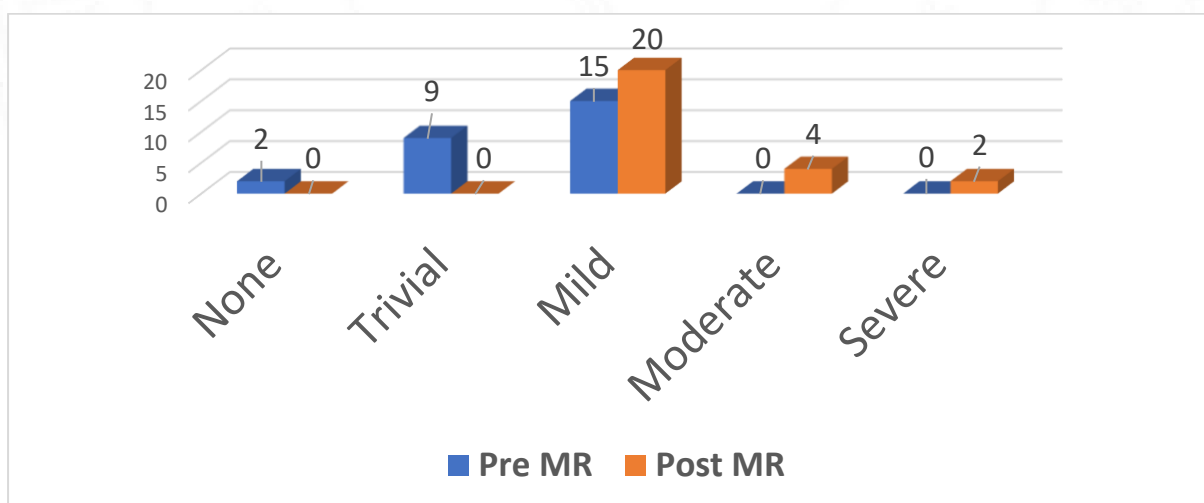


Baseline parameters	Unsuccessful (n=8)	Successful(n=18)	p-value
Mitral Regurgitation, n (%)			0.692
Grade 0	1 (12%)	1 (6%)	
Grade I	2 (25%)	7 (39%)	
Grade II	5 (62%)	10 (56%)	
LA diameter, mm	46 ± 3.2	43 ± 8.4	0.676
LVID, mm	42 ± 4.9	44 ± 5.2	0.372
EF, %	67 ± 7.6	68 ± 5.7	0.978
RVSP, mmHg	33 (46)	36 (21)	0.697
TAPSE	19 ± 0.51	21 ± 2.7	0.020
MVA (2D), cm2	0.78 ± 0.23	0.94 ± 0.13	0.114
MVA (PHT), cm2	0.86 ± 0.17	0.95 ± 0.09	0.438
MS gradient, mmHg	13 ± 4.8	14 ± 4.5	0.716
Mobility	3 (1)	2 (0)	0.001
Thickening	3 (1)	2 (1)	0.274
Calcification	2 (1)	2 (1)	0.281
Subvalvar pathology	3 (1)	2 (1)	0.054
Wilkin's score	11 (2)	9 (2)	0.013
3D Score	12 (2)	10 (1)	0.001
MC fused	4 (50%)	12 (67%)	0.664
MC split	4 (50%)	6 (33%)	0.664
LC fused	6 (75%)	14 (78%)	1.000
LC split	2 (25%)	4 (22%)	1.000
Bi-commissural fusion	3 (38%)	9 (50%)	0.683
Uni-commissural fusion	4 (50%)	8 (44%)	1.000
Lack of bilateral complete fusion	1 (12%)	1 (6%)	0.529

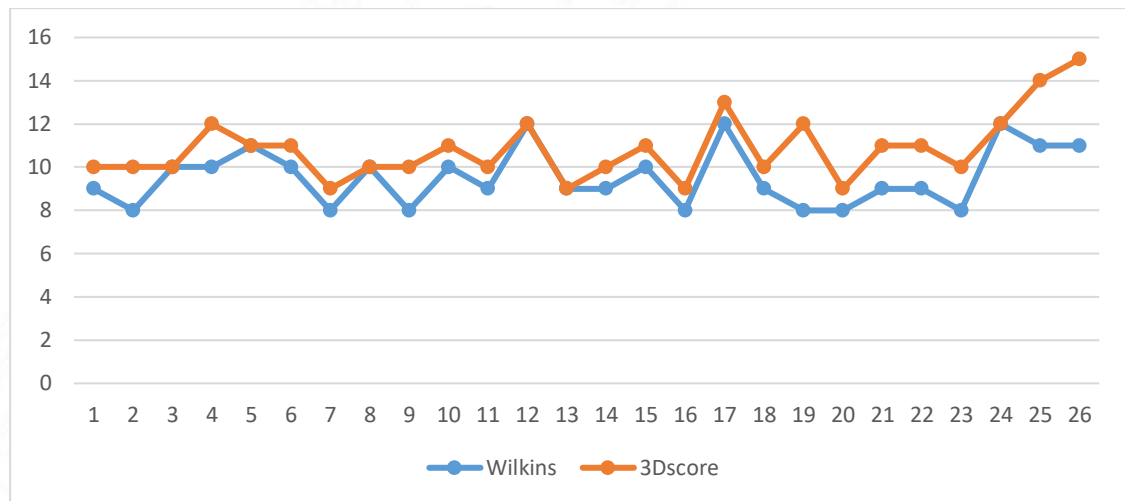
Characteristics	Unsuccessful (n=8)	Successful(n=18)	p-value
Leaflet thickness A1	7 (88%)	14 (78%)	1.000
Leaflet thickness A2	4 (50%)	8 (44%)	1.000
Leaflet thickness A3	3 (38%)	6 (33%)	1.000
Leaflet thickness P1	6 (75%)	7 (39%)	0.202
Leaflet thickness P2	3 (38%)	9 (50%)	0.683
Leaflet thickness P3	2 (25%)	13 (72%)	0.038
Leaflet Mobility A1	5 (63%)	10 (56%)	1.000
Leaflet Mobility A2	4 (50%)	7 (39%)	0.683
Leaflet Mobility A3	5 (63%)	10 (56%)	0.078
Leaflet Mobility P1	5 (63%)	10 (56%)	1.000
Leaflet Mobility P2	5 (63%)	10 (56%)	1.000
Leaflet Mobility P3	6 (75%)	12 (67%)	1.000
Leaflet Calcification A1	5 (63%)	7 (39%)	0.258
Leaflet Calcification A2	3 (38%)	4 (22%)	0.635
Leaflet Calcification A3	2 (25%)	4 (22%)	0.076
Leaflet Calcification P1	2 (25%)	6 (33%)	1.000
Leaflet Calcification P2	1 (13%)	7 (39%)	0.360
Leaflet Calcification P3	5 (63%)	8 (44%)	0.159
Subvalvar thickness Prox	8 (100%)	16 (89%)	1.000
Subvalvar thickness Mid	4 (50%)	5 (28%)	0.382
Subvalvar thickness Dist	2 (25%)	4 (22%)	1.000
Subvalvar separation Prox	7 (88%)	9 (50%)	0.099
Subvalvar separation Mid	2 (25%)	1 (6%)	0.215
Subvalvar separation Distal	0	0	NA

Hemodynamics	PRE-BMV	POST- BMV	p-value
RA mean, mmHg	6.9 ± 2.6	6.7 ± 1.8	0.855
PASP, mmHg	45.26 ± 15	43.07 ± 12.9	0.015
PA mean, mmHg	27.7 ± 9.2	26.5 ± 7.8	0.096
LA mean, mmHg	24 ± 4.2	18.34 ± 7.2	0.001
LV Ed, mmHg	12.19 ± 2.9	14.23 ± 2.4	0.001
MVG, mmHg	12.36 ± 4.1	4.83 ± 6.7	0.001
MVA by cath	0.99 ± 0.2	1.88 ± 0.2	0.001

Hemodynamic assessment after BMV procedure revealed significant fall in pulmonary artery systolic pressure (P value- 0.015), left atrial mean pressure (0.001) and mitral valve gradient (P value- 0.001). A significant rise in left ventricular end-diastolic pressure (P value- 0.001) was also noted along with increase in mitral valve area (P value- 0.001).

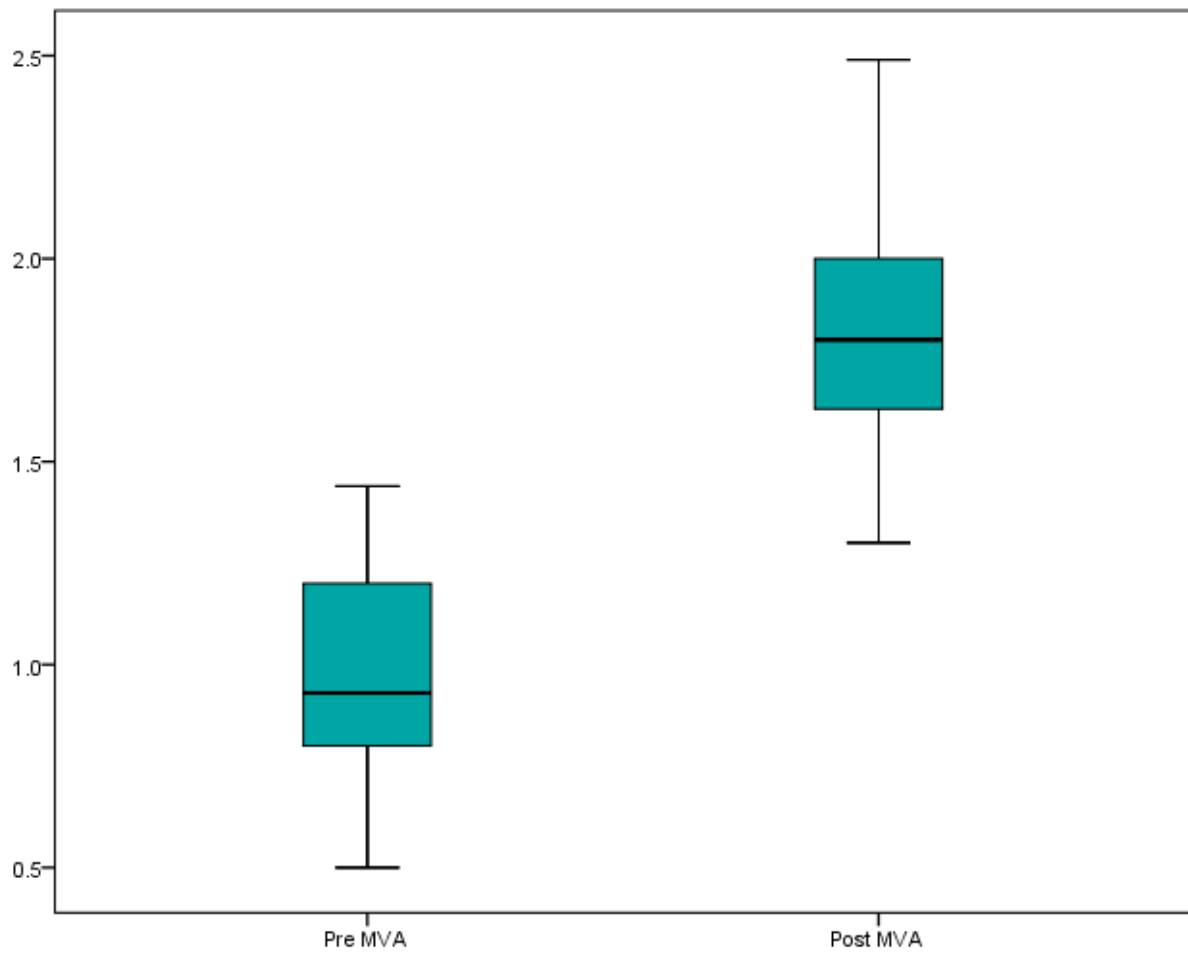


After the procedure, 2 patient (4%) developed acute severe mitral regurgitation due to leaflet tear and required mitral valve replacement surgery. Most of the patients (77%) had mild mitral regurgitation.



- When the echocardiographic scores were compared, it was found that the 3D score was higher than Wilkins score (P value-0.003). However, no statistically significant correlation was found between either Wilkins score with procedural success or post procedural MVA. (p value>0.05) or 3D Score with procedural success or postprocedural MVA. (p value>0.05)
- Similarly, no correlation was found between Wilkin's score and 3 D Score in predicting procedural success or postprocedural MVA.
- On comparing overall data there was significant improvement in MVA after BMV ($0.97 \pm 0.21 \rightarrow 1.81 \pm 0.31$) [Paired t test, p value <0.001]
- A Wilkin's score < 10 was found to be associated with 84% success rates. [Odds ratio-0.04; [95% CI- 0.008-0.286] (p <0.001)]

- All patients with 3 D Score <10 had procedural success rate of 100% and 59% of patients with 3 D score >10 had unsuccessful BMV. (p value <0.001)



DISCUSSION:

In patients with severe mitral stenosis, clinical evaluation and mitral valve anatomy assessment are essential for correctly selecting therapeutic strategies³⁹⁻⁴¹. 2D (Two dimensional) transthoracic echocardiography allows to classify patients into anatomic groups for prediction of immediate and long-term outcomes of BMV^{42,43}. Although Wilkins's score is the most commonly used score, several other 2D echocardiographic scoring systems have been suggested for the assessment of MV anatomy⁴⁴⁻⁴⁶; however none of the available scores has shown to be superior to any of the others^{3,43}.

Real time three dimensional echocardiography provides an en-face view of mitral valve. In addition to this, rotation and orientation of the mitral valve to the desired plane are easy and are not dependent on the orientation of the acoustic window in which image acquisition is done¹¹. Many studies have demonstrated the superiority of real time 3D echocardiography for the qualitative morphologic description of mitral valve³⁶. RT3DE provides a unique orientation of MV leaflets, commissures, and MVA that could be obtained in a high percentage of the population and may become the standard echocardiographic technique in the future for the assessment of patients with MS³.

For patients with severe mitral stenosis undergoing redo balloon mitral valvuloplasty, the traditional Wilkins score is currently used, although no clear cut-off is defined. With 2D echocardiography, a redo score was proposed by Mustafa et al⁴⁷ with a cut-off value of <8, which was found to be 96% sensitive and 85% specific in predicting BMV success. Although 3D echocardiography appears to be beneficial in the assessment of mitral valve anatomy prior to BMV in patients new mitral stenosis^{4,35}, it has not been widely studied in patients undergoing redo BMV¹⁵. In this study, we tried to analyse the real time 3D score (Anwar score) in patients undergoing redo BMV and compare it with the traditional 2D echocardiographic Wilkin's score.

We analysed 42 patients with severe mitral stenosis who underwent balloon mitral valvuloplasty (BMV) during the study period. 16 patients who underwent redo BMV were included in Group-I, whereas 26 patients who underwent BMV for the first time for de-novo mitral stenosis were included in group-II. 12 patients (75%) in the Group-I, had undergone prior BMV and 4 patients (25%) had undergone prior closed mitral valvotomy (CMV). The median duration of prior BMV or CMV in Group-I was 15 years.

Median age of our redo patients was comparable to study by Sancar et al³⁸ [44.5 years vs 44 years], whereas Mostafa et al⁴⁷ had more of older patients [44.5 years vs 65.8 years]. The patients undergoing BMV for the first time, however were older than those in Farrag et al⁴ group [42.5 years vs 29.5 years]. Majority of the patients in our study groups were females, which was similar with studies by Sancar et al and Farrag et al; whereas Mostafa et al group had more of male preponderance. Atrial fibrillation was found to be in lesser proportion in our study group of patients undergoing BMV for the first time than those reported by Farrag et al [4% vs 30%]. However, in redo group, atrial fibrillation was relatively comparable with other studies^{4,47} except for study by Sancar et al who reported only 2.8% of atrial fibrillation. Our study group had lesser proportion of diabetic individuals (6%) than Mostafa et al (29%) group and Sancar et al (16%). Majority of our patients were in functional class II and III which was a similar finding as previously reported studies^{3,15}.

Two dimensional echocardiographic assessment of patients in our study revealed that the left atrial and left ventricular dimensions between redo and new groups were similar and were consistent with other studies^{3,15}. Mean left ventricular ejection fraction was also found to be comparable to Sancar et al group whereas Mostafa et al had reported an ejection of 44.2 ± 13.8 %. Our study reported average 2D mitral valve area of 1 ± 0.11 in group I and 0.93 ± 0.17 cm²; which was similar to Sancar et al (1.1 cm²), Farrag et (0.96 $\pm$ 0.14 cm²) and also Mostafa et al group (0.94 $\pm$ 0.14 cm²). Mitral valve area by pressure half time was also

reported to be similar to other previous studies^{15,38,47}. Mitral valve gradient in our study was numerically greater in group II than group I (14 vs 12 mmHg, p value- 0.242), indicating that patients who underwent redo BMV had relatively less mitral valve gradient with lesser measured mitral valve area. Mean mitral valve gradient in other reported studies however, was relatively high^{4,35}. Median Wilkins score in our study was 10 and 9 in group I and group II respectively; which was higher than the one reported by Mustafa et al and Sancar et al group whereas it was comparable with Farrag et al group. Preprocedural mitral regurgitation was reported to be less than grade II in 69% of patients in group I and 58% of patients in group II had grade II mitral regurgitation. Similarly, Sancar et al had reported almost 94% patients with none to mild preprocedural mitral regurgitation, whereas Anwar et al group had reported 84% patients with less than mild mitral regurgitation.

Three dimensional echocardiographic assessment of mitral valve anatomy in terms of mobility, thickness, calcification and subvalvar pathology revealed median real time 3D scores of 11 and 10 in group I and group II respectively. Farrag et al had reported 3D score in patients with optimum results as 7.58 ± 2.18 ; whereas 3D score was 19.16 ± 3.86 in patients with suboptimal post procedural mitral valve area and a 3D score of 16 ± 2.83 in patients with significant post procedural mitral regurgitation. In our study, there were 3 patients who had developed severe mitral regurgitation requiring surgical valve replacement; all of them had a 3D score of more than 14. 3D score in our study was found to be significantly higher than Wilkins score as it allows detailed assessment of mitral valve anatomy. Similar association was also reported by Farrag et al where only patients undergoing BMV for the first time were studied.

After balloon mitral valvotomy with a median of 24 mm Accura balloon and on an average two dilatations, the procedural success rate in our study was 69% in group I and 70% in group II. This was largely comparable with Farrag et al group (72%) [28 size balloon] and

Sancar et al (72%). Suboptimal results were noted in 25% and 23% in group I and group II, respectively, which was comparatively higher than those reported by Farrag et al (12%). The same group also reported 16% incidence of postprocedural mitral regurgitation, which was higher than our study (6% in group I vs 7% in group II). In group I, there was significant fall in pulmonary artery systolic pressure (P value-0.03), pulmonary artery mean pressure (P value- 0.014), left atrial mean pressure (P value- 0.001) and mitral valve gradient (P value <0.001), whereas a significant rise in left ventricular end diastolic pressure (P value- 0.005) and mitral valve area (P value- 0.001) was noted. Patients in group II, post procedure showed significant fall in pulmonary artery systolic pressure (P value-0.015), left atrial mean pressure (P value-0.001) and trans mitral gradient (P value- 0.001), whereas a significant rise in left ventricular end-diastolic pressure (P value- 0.001) and mitral valve area (P value- 0.001) was noted. Similar to our study, Farrag et al also reported significant fall in mitral valve gradient (P value <0.0001), pulmonary artery systolic pressure (P value < 0.0001) and a significant rise in post procedural mitral valve area (P value < 0.0001). Anwar et al had also reported a significant rise in mitral valve area by 2D as well as 3D echocardiographic assessment and fall in trans mitral gradient (P value< 0.0001).

Sancar et al studied a novel 3D score which was a modification of transesophageal echocardiographic score by Sutaria et al and proposed it as an alternative option for treatment of patients who are primarily considered for surgery due to high Wilkins score. In our study, although no correlation could be established between 3D score and Wilkins score, the 3D score was significantly higher in patients having successful outcomes than those who had poor outcomes; indicating its role in assessment of patients prior to BMV. Since our study had more of complex valve morphology, we arrived at a higher cut-off of ≥ 10 for Wilkins score (Odds ratio- 0.04 [95% CI- 0.008-0.286]), which was also demonstrated in previous in vivo study³⁹. Similarly, when 3D data was analysed, it was found that 100% patients with 3D

score <10 , had 100% procedural success, whereas 59% of patients with 3D score >10 had unsuccessful outcomes (0.001). Based on our limited study data, we propose a new cut-off of 3D score ≤ 10 , likely to be associated with better outcome even if the Wilkins score is high. Under dilating the valve with one size less balloon can still help in achieving good result post BMV.

LIMITATIONS:

- It was a single center prospective study, constrained by usual potential confounders of limited sample size.
- In particular, the causal link with clinical outcomes, though not significant, should be interpreted with some caution as the applied analysis will have been less robust than with a larger sample.
- Being a tertiary care center, our study population included a lot of patients with relatively complex mitral valve anatomy who were deemed unsuitable for BMV.
- There is lack of long term follow up data of patients after BMV.
- It would be interesting to study the association between 3D measures and clinical outcomes on follow up in a larger study.

CONCLUSION:

- The Real time 3D-echocardiographic score gives a detailed morphological assessment of MV and helps in the proper selection of the therapeutic strategy for patients with MS.
- A 3D echocardiographic score of ≤ 10 , appeared as a promising tool to predict procedural success irrespective of the traditional 2D-Wilkins score.

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PROFORMA

Role of real time 3D echocardiography for Prediction of Success of Redo-Percutaneous Balloon Mitral Valvuloplasty in Patients with Mitral Restenosis

Sr. No.-

Patient ID-

Age-

Sex-

Weight-

Height-

BMV date-

Clinical Parameters-

Functional Class	
Rhythm	
Prior BMV date	
Duration	

Transthoracic Echocardiographic parameters-

Ejection Fraction	
LA size	
Indexed LA size	
MVA by 2D	
Indexed MVA by 2D	
MVA by PHT	
Indexed MVA by PHT	
MS gradient	
Mobility	
Thickening	
Calcification	
Subvalvar pathology	
Wilkins score	
Medical commissure	
Lateral commissure	
Mitral Regurgitation (0-1)	
RVSP	
TAPSE	

3 D Transoesophageal echocardiographic parameters-

Leaflet-

	A1	A2	A3	P1	P2	P3
Thickness (0-6)						
Mobility (0-6)						
Calcification (0-10)						

Subvalvular apparatus-

	Prox third	Mid third	Distal third
--	------------	-----------	--------------

Thickness (0-3)			
Separation (0-6)			

CATH data-

	PRE	POST
PAP		
LA		
LV		
MG		
MVA		
INDEXED MVA		
CO		
CI		
PVR		
SVR		
DILATOR/BALLOON USED		
SIZE		
No. OF DILATATIONS		
MR SEVERITY		



श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
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Institutional Ethics Committee
(IEC Regn No. ECR/189/Inst/KL/2013/RR-21)

SCT/IEC/1907/AUGUST-2022

24.08.2022

Dr. Walse Rohit Sunil
Post Doctoral Fellow
Department of Cardiology
SCTIMST, Thiruvananthapuram

Dear Dr. Walse Rohit Sunil,

The project proposal with the title "ROLE OF REAL TIME 3D ECHOCARDIOGRAPHY FOR PREDICTION OF SUCCESS OF REDO-PERCUTANEOUS BALLOON MITRAL VALVULOPLASTY IN PATIENTS WITH MITRAL RESTENOSIS" submitted to Institutional Ethics Committee (IEC) has been reviewed in the IEC Meeting held on 6th August, 2022 and assigned number as IEC/1907.

List of documents submitted:

- | | |
|---|---|
| 1. Covering letter addressed to the Chairperson, IEC, SCTIMST dated 02.04.2022 Checklist Form | 6. Study Consent Form in English and Malayalam |
| 2. Checklist Form | 7. Patient Information Sheet in English and Malayalam |
| 3. IEC Application Form | 8. CV of PI and Co-PIs |
| 4. Project Proposal | 9. Proforma |
| 5. Declaration form | 10. SRC Recommendation letter |

IEC Recommendations

- The study seems to be exploratory in nature and limitations of sample size (n=30) given the frequency of Redo BMVs in the setting. This can be acknowledged as the study will be generating limited information on the research question
- This is proposed as a "prospective cohort" study. In this context, the investigator may add clarity on (methods section of the brief proposal and that of the participant information sheet) whether the entire data will be based on records and "research" nature of the study (as compared to "routine" procedures)
- As a consequence, to the above point, please clarify whether the cost of the procedures and investigations will be borne by the patients (as research participants) or by the hospital.
- Study period should be mentioned as six months after getting the IEC clearance.

One set of all the documents including those revised are to be submitted to the IEC Office. The covering letter should indicate the revisions made.

Sincerely,

Dr. G. Srinivas
Member Secretary, IEC



STUDY CONSENT FORM

TITLE OF THE STUDY: ROLE OF REAL TIME 3D ECHOCARDIOGRAPHY FOR PREDICTION OF SUCCESS OF REDO-PERCUTANEOUS BALLOON MITRAL VALVULOPLASTY IN PATIENTS WITH MITRAL RESTENOSIS

Study number: All patients undergoing redo PBMV at SCTIMST will be included in study

Participant's name:

Date of Birth / Age (in years):

I _____,

son/daughter of _____

(Please tick boxes).

☐ I Declare that I have read the above information provided to me regarding the study:

“ROLE OF REAL TIME 3D ECHOCARDIOGRAPHY FOR PREDICTION OF SUCCESS OF REDO-PERCUTANEOUS BALLOON MITRAL VALVULOPLASTY IN PATIENTS WITH MITRAL RESTENOSIS” and have clarified any doubts that I had.

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

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

☐ I understand that my identity may not be revealed in any information released to third parties or published.

☐ I voluntarily agree to take part in this study.

☐ I received a copy of this signed consent form.

Name:

Signature:

Date:

Name of witness:

Relation to participant:

Date:

I attest that the requirements for informed consent for the medical research project described in

this form have been satisfied. I have discussed the research project with the participant and explained to him or her in nontechnical terms all of the information contained in this informed

consent form, including any risks and adverse reactions that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked were answered.

Name and Signature of Person Obtaining Consent

Dr. Walse Rohit Sunil

PDF, Adult Cardiology and Interventions

Dept. of Cardiology SCTIMST

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

ശ്രീ ചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസ് ആൻ്റ് ടെക്നോളജി,
തിരുവനന്തപുരം

പഠന സമ്മതപത്രം

മിട്രൽ വാൽവ് വീണ്ടും ചുരുങ്ങുന്ന രോഗികളിലെ റെഡോ- പെർക്യൂട്ടേനിയസ് ബലൂൺ മിട്രൽ വാൽവോപ്പാസ്റ്റി ശസ്ത്രക്രിയയുടെ വിജയസാധ്യത പ്രവചിക്കുന്നതിൽ റിയൽ ടൈം എക്കോകാർഡിയോഗ്രഫിയുടെ പങ്ക്.

ഗവേഷകരുടെ പേരുകൾ: ഡോ. വൽസെ രോഹിത് സുനിൽ, ഡോ. ഹരികൃഷ്ണൻ എസ്, ഡോ. സഞ്ജയ് ജി

പഠന നമ്പർ: SCTIMSTയിൽ റിഡു-ബിഎംവിക്ക് വിധേയരാകുന്ന എല്ലാ രോഗികളെയും പഠനത്തിലുൾപ്പെടുത്തും.

പങ്കെടുക്കുന്നയാളുടെ പേര്

ജനനതീയതി/വയസ്സ് (വർഷത്തിൽ

ഞാൻ.....

മകൻ/മകൾ.....

(ദയവായി കോളങ്ങളിൽ അടയാളപ്പെടുത്തുക.)

- മുകളിൽ നൽകിയ ഇടത് എട്രിയൽ സ്ക്രെയിൻ അളവുകളുടെ ഘടകങ്ങൾ വിജയകരമായ മിട്രൽ വാൽവ് വീണ്ടും ചുരുങ്ങുന്ന രോഗികളിലെ റെഡോ- പെർക്യൂട്ടേനിയസ് ബലൂൺ മിട്രൽ വാൽവോപ്പാസ്റ്റി ശസ്ത്രക്രിയയുടെ വിജയസാധ്യത പ്രവചിക്കുന്നതിൽ റിയൽ ടൈം എക്കോകാർഡിയോഗ്രഫിയുടെ പങ്ക് എന്ന പഠനത്തിന്റെ വിവരങ്ങൾ വായിച്ചു മനസ്സിലാക്കിയതായും എനിക്ക് ചോദ്യങ്ങൾ ചോദിക്കാൻ അവസരം കിട്ടിയതായും ഞാൻ പ്രസ്തിവികുന്നു. []
- എന്റെ ഈ പഠനത്തിലെ പങ്കാളിത്തം പൂർണ്ണമായും സ്വമേധയായാണെന്നും അനുവാദം എനിക്ക് ഏതു സമയത്തും എന്റെ ചികിത്സയെയും നിയമപരമായ അവകാശങ്ങളെയും ബാധിക്കാതെ പിൻവലിക്കാൻ അവകാശമുണ്ടെന്നും ഞാൻ മനസ്സിലാക്കുന്നു. []
- ഞാൻ പഠനത്തിൽ നിന്നും പിൻമാറിയാലും പഠനം നടത്തുന്നവർക്കും സ്ഥാപനത്തിലെ നൈതിക കമ്മിറ്റി അംഗങ്ങൾക്കും നിയന്ത്രണാധികാരമുള്ള അധികാരികൾക്കും എന്റെ ആരോഗ്യരേഖകൾ പരിശോധിക്കുന്നതിന് എന്റെ അനുവാദം ആവശ്യമില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. അതിനോട് ഞാൻ യോജിക്കുന്നു. []
- എന്നെ തിരിച്ചറിയാനുതകുന്ന വിവരങ്ങൾ ഒന്നും മറ്റുള്ളവർക്ക് നൽകുകയോ പ്രസിദ്ധീകരിക്കുകയോ ചെയ്തില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. []
- ഞാൻ സ്വമേധയാ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതം നൽകുന്നു. []
- സമ്മതപത്രത്തിന്റെ ഒപ്പിട്ട ഒരു പ്രതി എനിക്ക് ലഭിച്ചു. []

പങ്കെടുക്കുന്നയാളുടെ ഒപ്പ്
പഠനഗവേഷകന്റെ ഒപ്പ്

തീയതി
തീയതി

സാക്ഷിയുടെ ഒപ്പ്
സാക്ഷിയുടെ പേര്

രോഗിയുമായുള്ള ബന്ധം
പഠനഗവേഷകന്റെ പേര്

(സമ്മതം വാങ്ങുന്നയാൾ)

വൈദ്യശാസ്ത്ര ഗവേഷണത്തിന്റെ കാര്യവിവരണപത്രത്തിനാവശ്യമായ വിവരങ്ങൾ തൃപ്തികരമായ വിധം ഈ പത്രികയിൽ വിവരിച്ചിട്ടുണ്ടെന്ന് ഞാൻ സാക്ഷ്യപ്പെടുത്തുന്നു. പങ്കെടുക്കുന്നയാളോട് സാങ്കേതികേതരമായ പദങ്ങളുപയോഗിച്ച് ഗവേഷണ പദ്ധതിയുടെ എല്ലാ വിവരങ്ങളും, ഉണ്ടാവാനുണ്ടാവുന്ന സാധ്യതയുള്ള അപായങ്ങളും ദോഷകരമായ പ്രത്യാഘാതങ്ങളുമുൾപ്പെടെ ഞാൻ ചർച്ചചെയ്തു. പങ്കെടുക്കുന്നയാളെ ചോദ്യങ്ങൾ ചോദിക്കാൻ പ്രേരിപ്പിക്കുകയും അവയ്ക്ക് ഉത്തരം നൽകുകയും ചെയ്തു എന്നും ഞാൻ രേഖപ്പെടുത്തുന്നു.

സമ്മതപത്രം വാങ്ങുന്നയാളുടെ ഒപ്പ്

ഡോ. വത്സെ രാഹുൽ സുനിൽ, അഡ്മിനിസ്ട്രേറ്റീവ് കൗൺസിലർ, ആന്റ് ഇന്റർവെൻഷൻസ്, കൗൺസിലർ, ഡിസാർട്ട്മെന്റ്, SCTIMST

ഡോ. ശ്രീനിവാസ് ജി,

മെമ്പർ സെക്രട്ടറി, ഇൻസ്റ്റിറ്റ്യൂഷണൽ എത്തിക്സ് കമ്മിറ്റി, SCTIMST

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

PATIENT INFORMATION SHEET

**TITLE: ROLE OF REAL TIME 3D ECHOCARDIOGRAPHY FOR PREDICTION OF
SUCCESS OF REDO-PERCUTANEOUS BALLOON MITRAL VALVULOPLASTY IN
PATIENTS WITH MITRAL RESTENOSIS**

Name of Investigators: DR WALSE ROHIT SUNIL, DR HARIKRISHNAN S., DR
SANGAY G.

Dear Patient/Parent

We welcome you and thank you for your interest in this research project titled “ROLE OF REAL TIME 3D ECHOCARDIOGRAPHY FOR PREDICTION OF SUCCESS OF REDO-PERCUTANEOUS BALLOON MITRAL VALVULOPLASTY IN PATIENTS WITH MITRAL RESTENOSIS”. 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.

Transesophageal echocardiography is an imaging study of heart using an echocardiographic probe. During this procedure, with local anaesthesia, a plastic tube will be inserted through your mouth into the oesophagus. This procedure is done as a part of routine protocol to look for any clot in chambers of heart before going ahead for balloon mitral valvuloplasty. While performing the echocardiogram, a 3-dimensional assessment of your mitral valve will be done using an in-built software and real time 3D score will be calculated. This score will be compared with 2-dimensional score obtained from transthoracic echocardiography and assessed for predicting success rate of PBMV. PBMV is a procedure to treat mitral stenosis and reduce symptoms such as chest pain, fatigue, shortness of breath, difficulty when exercising, dizziness and fainting. A plastic tube (introducer) is inserted into an artery in your groin (femoral artery). A balloon catheter is passed through the introducer sheath and directed to your mitral heart valve. The balloon is inflated to open your valve. This balloon catheter is removed. Your own diseased valve will not be cut or removed. In addition, xrays and a transeosophageal echo are performed during the procedure.

What does the present study involve?

It involves collection of clinical and echocardiographic data as a routine workup and compared to post procedure data.

How long does it take?

The hospital visit will be a routine consultation, and the echocardiogram done will be part of routine follow up. This may take upto 2-3 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 case records, pre and post procedure. There will be no risks for the participants because of participation in the study. They will be managed according to the hospital protocol. No specific additional intervention will be done.

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

The participants are evaluated in detail for any cardiac cause for functional impairment. A follow up examination and evaluation may be helpful in identification of any risk factors for poor outcomes or functional deterioration. It may be helpful in detecting patients who require early intervention or addition of medical therapy. The data derived from the study may be helpful in planning appropriate timing and surgical strategies 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 study will be kept confidential. Your 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.

If there are any new findings / information, would i be informed?

Yes.

What happens in case of a study related injury?

There will be no study related injury.

Is there any alternative to the treatment mentioned?

Not applicable.

If you have any further questions, please ask: Dr. Walse Rohit Sunil (Principal investigator), Senior Resident, Department of Cardiology (Email: walserohit@sctimst.ac.in Ph No: 9029649379)

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

**ശ്രീ ചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസ് ആന്റ് ടെക്നോളജി,
തിരുവനന്തപുരം**

രോഗിക്കുള്ള കാര്യവിവരണപത്രം

പഠനശീർഷകം: മിട്രൽ വാൽവ് വീണ്ടും ചുരുങ്ങുന്ന രോഗികളിലെ റെഡോ- പെർക്യൂട്ടേനിയസ് ബലൂൺ മിട്രൽ വാൽവോപ്ലാസ്റ്റി ശസ്ത്രക്രിയയുടെ വിജയസാധ്യത പ്രവചിക്കുന്നതിൽ റിയൽ ടൈം എക്കോകാർഡിയോഗ്രഫിയുടെ പങ്ക്.

ഗവേഷകരുടെ പേരുകൾ: ഡോ. വൽസെ രോഹിത് സുനിൽ, ഡോ. ഹരികൃഷ്ണൻ എസ്, ഡോ. സഞ്ജയ് ജി

മിട്രൽ വാൽവ് വീണ്ടും ചുരുങ്ങുന്ന രോഗികളിലെ റെഡോ- പെർക്യൂട്ടേനിയസ് ബലൂൺ മിട്രൽ വാൽവോപ്ലാസ്റ്റി ശസ്ത്രക്രിയയുടെ വിജയസാധ്യത പ്രവചിക്കുന്നതിൽ റിയൽ ടൈം എക്കോകാർഡിയോഗ്രഫിയുടെ പങ്ക് എന്ന ഈ ഗവേഷണത്തിൽ പങ്കെടുക്കൻ താങ്കൾ മുന്നോട്ട് വന്നത് സ്വാഗതം ചെയ്യുകയും നന്ദി പ്രകാശിപ്പിക്കുകയും ചെയ്യുന്നു. താങ്കൾ ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നതിനുമുമ്പ് ഈ ഗവേഷണം എന്തുകൊണ്ട് നടത്തുന്നു എന്ന് മനസ്സിലാക്കേണ്ടത് പ്രധാനമാണ്. ഈ ഗവേഷണത്തെന്റെ പ്രസക്തമായ എല്ലാ വിശദാംശങ്ങളും ഈ പത്രിക നൽകും. ഈ പദ്ധതിയുടെ സ്വഭാവം, ഉദ്ദേശം, നേട്ടങ്ങൾ, അപായങ്ങൾ, അസ്വസ്ഥതകൾ, മുൻകരുതലുകൾ, എങ്ങനെയാണ് ഇത് നടപ്പാക്കുക എന്നിവ ഇത് വിശദീകരിക്കും. താങ്കൾ ഈ പത്രിക ശ്രദ്ധയോടെ വായിക്കുകയും മനസ്സിലാക്കുകയും ചെയ്യേണ്ടത് പ്രധാനമാണ്. ഈ പത്രികയിൽ ശാസ്ത്രീയപദങ്ങളുണ്ടായേക്കാം, ആകയാൽ താങ്കൾക്ക് എന്തെങ്കിലും സംശയങ്ങളുണ്ടെങ്കിലോ കൂടുതൽ വിവരം ആവശ്യമോ എങ്കിൽ പഠനം നടത്തുന്നയാളോടോ താഴെ നൽകിയിരിക്കുന്ന ബന്ധപ്പെടാനുള്ള വ്യക്തിയോടോ സമ്മതം നൽകുന്നതിനു മുമ്പോ പദ്ധതിയുടെ ഏത് ഘട്ടത്തിലോ ചോദിക്കാൻ താങ്കൾക്ക് സ്വതന്ത്ര്യമുണ്ട്.

ഒരു ഇലക്ട്രോകാർഡിയോഗ്രാഫി പ്രോബുപയോഗിച്ച് ഹൃദയചിത്രീകരണം നടത്തുന്ന പഠനമാണ് ട്രാൻസ് തൊറാസിക് ഇലക്ട്രോകാർഡിയോഗ്രാഫി. പ്രാദേശികമായി മയക്കി താങ്കളുടെ വായിലൂടെ അന്നനാളത്തിലേക്ക് കടത്തും. ബലൂൺ മിട്രൽ വാൽവോപ്ലാസ്റ്റിക്ക് മുമ്പ് ഹൃദയഅറകളിൽ രക്തക്കട്ടകളുണ്ടോ എന്ന് പരിശോധിക്കാനായി പതിവ് നടപടിക്രമങ്ങളുടെ ഭാഗമായി ഈ നടപടി ചെയ്യും. ഇലക്ട്രോകാർഡിയോഗ്രാം ചെയ്യുമ്പോൾ സോഫ്റ്റ്വെയറുകളുടെ സഹായത്തോടെ ഒരു ത്രിമാന വിലയിരുത്തൽ നടത്തി, ത്രിമാന സ്കോറുകൾ കണക്കാക്കും. ഇവ 2ഡി ട്രാൻസ് തൊറാസിക് എക്കോകാർഡിയോഗ്രഫിയുടെ സ്കോറുമായി താരതമ്യം ചെയ്ത് പിബിഎംവിയുടെ വിജയസാധ്യതാ തോത് വിലയിരുത്തും. നെഞ്ചുവേദന, ക്ഷീണം, ശ്വാസതടസ്സം, വ്യായാമം ചെയ്യുമ്പോഴുള്ള ബുദ്ധിമുട്ടുകൾ, തലകറക്കം ബോധം നഷ്ടപ്പെടൽ എന്നീ ലക്ഷണങ്ങൾ കുറയ്ക്കാനും മിട്രൽ സ്റ്റേനോസിസ് ചികിത്സയ്ക്കുമുള്ള ഒരു നടപടിയാണ് പിബിഎംവി. ഒരു പ്ലാസ്റ്റിക് കുഴൽ (ഇൻട്രാഡ്യൂസർ) താങ്കളുടെ ഫെമറൽ ആർട്ടറിയിലൂടെ കടത്തും. താങ്കളുടെ മിട്രൽ വാൽവിലേക്ക് ലക്ഷ്യമാക്കി ഒരു ബലൂൺ കത്തിറ്റർ അതിലൂടെ കടത്തുന്നു. താങ്കളുടെ മിട്രൽ വാൽവ് തുറക്കാനായി ബലൂൺ വീർപ്പിക്കും. എന്നിട്ട് ഇ ബലൂൺ കത്തിറ്റർ മാറ്റും. താങ്കളുടെ അസുഖമുള്ള വാൽവ് മുറിക്കുകയോ മിറ്റളകയോ ചെയ്യുകയില്ല. എക്റേയും ട്രാൻസിസോഫേജിയൽ എക്കോയും ഈ നടപടിയോടൊപ്പം ചെയ്യും.

ഇപ്പോഴത്തെ പഠനത്തിൽ ഉൾക്കൊള്ളുന്നതെന്ത്?

പതിവ് തയാറെടുപ്പുകളുടെ ഭാഗമായ ക്ലിനിക്കൽ, ഇലക്ട്രോഗ്രാഫി വിവരങ്ങൾ ശേഖരിക്കുകയും അവ നടപടിക്കു ശേഷമുള്ള വിവരങ്ങളുമായി താരതമ്യം ചെയ്യുകയും ചെയ്യും.

ഇതിനെത്ര സമയമെടുക്കും?

ആശുപത്രി സന്ദർശനവും ഇടക്ട്രോകാർഡിയോഗ്രാം പരിശോധനയും പതിവ് തുടർ ചികിത്സയുടെ ഭാഗമാണ്. ഇതിന് 2-3 മണിക്കൂർ എടുത്തേക്കാം. ആ സമയത്ത് ആശുപത്രി ഒപിഡിയിലുണ്ടാകാൻ തയ്യാറാകുക.

പങ്കെടുക്കുന്നയാളുടെ ഉത്തരവാദിത്തങ്ങളെന്തെല്ലാം?

ഈ പഠനത്തിൽ പങ്കെടുക്കാനുള്ള താങ്കളുടെ തീരുമാനം സ്വമേധയായാണ്, താങ്കളുടെ വ്യക്തിപരമായ തീരുമാനം. മുന്നറിയിപ്പില്ലാതെ, ഏതുകാരണത്താലും ഏതു സമയത്തും താങ്കൾക്ക് പഠനത്തിൽ തുടരാതിരിക്കാം.

പങ്കെടുക്കുന്നതിലൂടെ പ്രതീക്ഷിക്കുന്ന അപായങ്ങളെന്തെല്ലാം?

നടപടിക്കുമുമ്പും ശേഷവുമുള്ള വിവരങ്ങൾ ആശുപത്രിരേഖകളിൽ നിന്നും ശേഖരിക്കുകയാണ് ചെയ്യുന്നത്. ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നതുകൊണ്ട് അപായമൊന്നുമില്ല. അവ ആശുപത്രി നടപടിക്രമപ്രകാരം കൈകാര്യം ചെയ്യും. അധികമായ പ്രത്യേക ഇടപെടലുകളൊന്നും ചെയ്യില്ല.

ഗവേഷണത്തിൽ നിന്നും പങ്കെടുക്കുന്നവർക്കുണ്ടാകാവുന്ന നേട്ടങ്ങളെന്തൊക്കെ?

പങ്കെടുക്കുന്നവരിലെ പ്രവർത്തനപരമായ തകരാറുകളിൽ ഹൃദയത്തിന്റെതായ എന്തെങ്കിലും കാരണങ്ങളുണ്ടോ എന്ന് വിശദമായി വിലയിരുത്തും. മോശം നേട്ടങ്ങൾക്കും, പ്രവർത്തനപരമായ തകർച്ചയ്ക്കും എന്തെങ്കിലും അപായഘടകങ്ങളുണ്ടോയെന്ന് കണ്ടെത്താൻ തുടർ പരിശോധനയും വിലയിരുത്തലും സഹായകമായേക്കാം. നേരത്തെയുള്ള ഇടപെടലോ മരുന്ന് ചികിത്സ വർദ്ധിപ്പിക്കുന്നതോ ആവശ്യമായ രോഗികളെ കണ്ടെത്താൻ അത് സഹായകമായേക്കാം. പഠനത്തിൽ നിന്നുണ്ടാകുന്ന വിവരങ്ങൾ, ഭാവിയിൽ സമാനമായ അവസ്ഥയുള്ള രോഗികളുടെ ശസ്ത്രക്രിയാ തന്ത്രങ്ങൾ ആസൂത്രണം ചെയ്യുന്നതിന് സഹായകമായേക്കാം.

ഈ പരീക്ഷണത്തിൽ പങ്കെടുക്കുന്നവർക്ക് നഷ്ടപരിഹാരം നൽകുമോ?

ഈ പഠനത്തിൽ പങ്കെടുക്കുന്നതിന് താങ്കൾക്ക് പ്രതിഫലം നൽകില്ല.

ഈ പഠനത്തിലെ എന്റെ പങ്കാളിത്തം രഹസ്യമായി സൂക്ഷിക്കുമോ?

പഠനത്തിലെ താങ്കളുടെ രേഖകളെല്ലാം രഹസ്യമായി സൂക്ഷിക്കും. പഠനഫലങ്ങളുടെ പ്രസിദ്ധീകരണങ്ങളിലോ പ്രദർശനങ്ങളിലോ താങ്കളുടെ വ്യക്തിവിവരങ്ങൾ നൽകില്ല. പഠനരേഖകൾ വിലയിരുത്തലുകൾക്കും തുടർ പഠനങ്ങൾക്കുമായി അനന്തമായി സൂക്ഷിക്കും.

പഠനകാലയളവിൽ ഏതു സമയത്തും എനിക്ക് പിൻമാറാനാകുമോ?

താങ്കൾക്കത് കഴിയും. താങ്കളുടെ പതിവ് ചികിത്സയെ ആതീരുമാനം ബാധിക്കില്ല.

ഏതെങ്കിലും പുതിയ കണ്ടെത്തലുകളോ വിവരങ്ങളോ ഉണ്ടായാൽ അത് അറിയിക്കുമോ?

അറിയിക്കും.

പഠനസംബന്ധമായ പരിക്കുണ്ടായാലെന്ത് സംഭവിക്കും?

പഠനസംബന്ധമായി പരക്കുകളൊന്നും ഉണ്ടാകില്ല.

സൂചിപ്പിച്ച ചികിത്സയ്ക്ക് പകരമായി മറ്റെന്തെങ്കിലുമുണ്ടോ?

ബാധകമല്ല.

താങ്കൾക്ക് കൂടുതലൊന്നെങ്കിലും ചോദ്യങ്ങളുണ്ടെങ്കിൽ ദയവായി ബന്ധപ്പെടുക, ഡോ. വൽസെ രോഹിത് സുനിൽ (പ്രധാന ഗവേഷകൻ) സീനിയർ റെസിഡന്റ്, കാർഡിയോളജി ഡിപ്പാർട്ട്മെന്റ് ഇമെയിൽ: walserohit@sctimst.ac.in ഫോൺ: 9029649379

സാങ്കേതിക വിശദീകരണങ്ങൾക്ക് ദയവായി ബന്ധപ്പെടുക, ഡോ. ശ്രീനവാസ് ജി, മെമ്പർ സെക്രട്ടറി, IEC, SCTIMST, ഇമെയിൽ: iec.mem.sec@sctimst.ac.in ഫോൺ: 0471-2524689

CURRICULUM VITAE

LAST NAME	FIRST NAME	MIDDLE NAME
WALSE	ROHIT	SUNIL
Date of Birth (dd/mm/yy)- 13/08/1991		Sex- Male
Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordinator) Principal investigator		
Professional Mailing Address(Include Institution name)	Study Site Address(Include Institution name)	
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Academic Qualifications (Most recent qualification first)		
Degree/Certificate	Year	Institution, Country
DM CARDIOLOGY	2019-2021	SCTIMST, TRIVANDRUM, KERALA
MD (GENERAL MEDICINE)	2015-2018	GMC, AURANGABAD, MAHARASHTRA, INDIA
MBBS	2009-2014	SETH G S MEDICAL COLLEGE & KEMH, MUMBAI, MAHARASHTRA, INDIA
Details of professional registration : (MCI/State Registration/Bar Council/DCI/etc including Registration Number and Year of Registration: TCMC 80882		
Current and previous positions (most recent position first)		
Month and Year	Title	Institution/Company, Country
From 01/01/2022	PDF, Adult Cardiology & Interventions	SCTIMST, INDIA
8/1/2019 TO 31/12/2021	Senior Resident, Department of cardiology	SCTIMST, INDIA
17/07/2015 TO 17/07/2018	Resident, Department of General Medicine	GMC, AURANGABAD, MAHARASHTRA, INDIA
Brief summary of relevant research experience: Gopalakrishnan A, Sunil WR, Sasikumar D, Kurup HK, Krishnamoorthy KM, Tudo o que bifurca não é artéria pulmonar (All that bifurcates is not pulmonary artery), Revista Portuguesa de Cardiologia (2022), doi: https://doi.org/10.1016/j.repc.2021.12.016 Walse Rohit Sunil, Arun Gopalakrishnan, Bijulal Sasidharan, Kavassery Mahadevan Krishnamoorthy, Sivasankaran Sivasubramonian, Progressive coarctation after device closure of arterial duct – Case report, IHJ Cardiovascular Case Reports (CVCr), Volume 5, Issue 3, 2021 Dr. Rohit Walse, Dr. Mangala Borkar Sonavani. “ADVERSE EVENTS AMONG PATIENTS OF DRUG RESISTANT TUBERCULOSIS IN INTENSIVE PHASE		

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Kharat, Dr.Akash, Dr.Srikrushna A. Khandagale, Dr.Nilesh A. Wagh, & Dr.Rohit S. Walse. "TAKAYASU ARTERITIS: PRESENTED AS HEADACHE, A RARE CASE REPORT." INDIAN JOURNAL OF APPLIED RESEARCH [Online], 7.7 (2017)

Dr.MangalaBorkarSonavani, Dr.Shailaja Rao, Dr.AkshayKashid, Dr.SunitaPatil, Dr.Vimlesh Pandey, Dr.RohitWalse A Rare Genetic Disorder ♦ Bardet Biedl Syndrome Indian Journal of Applied Research, Vol.5, Issue : 9 September 2015

Current project/s at hand: Nil

Signature: 		Date :: 13/01/2022 Place :: Trivandrum
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ROLE OF REAL TIME 3D ECHOCARDIOGRAPHY FOR PREDICTION OF SUCCESS OF REDO-PERCUTANEOUS BALLOON MITRAL VALVULOPLASTY IN PATIENTS WITH MITRAL RESTENOSIS

by Rohit Walse

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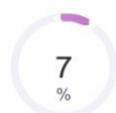


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