UTILITY OF 3D ECHOCARDIOGRAPHY FOR OPTIMISATION 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

SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, THIRUVANANTHAPURAM

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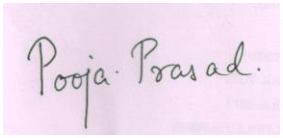
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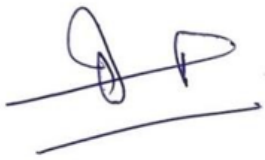


Pooja Prasad

Date: 31/12/2024

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The candidate, Dr.Pooja Prasad, has carried out the minimum required project



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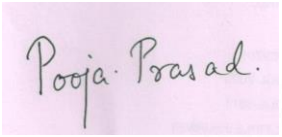
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TITLE

UTILITY OF 3D ECHOCARDIOGRAPHY FOR OPTIMISATION OF BALLOON MITRAL VALVOTOMY

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LIST OF ABBREVIATIONS:

MS: Mitral Stenosis

MR: Mitral Regurgitation

BMV: Balloon mitral valvotomy

MVA: Mitral valve area

2D: 2 Dimensional

3D: 3dimensional

TTE: Transthoracic echocardiography

TEE: Transoesophageal echocardiography

ICD: Intercommissural distance.

ABSTRACT

BACKGROUND: 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 commissurotomy. important determinant of success and safety of BMV is the selection of optimal hardware, particularly the size of the balloon used for the dilatation, in order to achieve maximum valve area post dilatation while minimising periprocedural risks including worsening mitral regurgitation and valvular damage.

OBJECTIVES:

To compare the measurements of valve area and intercommissural distance derived balloon sizing with the balloon sizing derived by conventional height based measurements.

To assess the immediate outcomes of BMV including severity of MR and final valve area obtained after BMV and assess the effect of balloon sizing parameters.

RESULTS:

A total of 47 patients were studied, Mean height based balloon size was 25.3mm, and the intercommisural distance by 3D TEE was 22.77mm. Majority of pateints underwent BMV with a 24 mm balloon, with subsequent dilatations based on hemodynamic parameters. The intercommissural distance showed a positive correlation with the final balloon size used($r(45) = 0.44$, $p = .002$) particularly in those patients with a larger discrepancy. 3 pateints developed severe MR requiring surgery, and 15 patients had worsening of MR post procedure. No significant difference noted in the difference in balloon sizing in these patients.

CONCLUSION:

3D transesophageal echocardiography to assess the mitral valve anatomy is beneficial in patients undergoing BMV, and the intercommisural distance measured by 3D TEE has a strong positive correlation with the Balloon size used for dilatation, and may be used as a method to estimate the

appropriate balloon size to optimise outcomes in patients undergoing BMV.

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. procedure with equivalent or even better results as surgical commissurotomy

However, the safety and success of BMV techniques are mainly dependent on the selection of patients, and assessment of valve morphology is essential for proper selection to optimise outcomes and minimise procedure related risks.

Assessment of the mitral valve is conventionally done using 2D echocardiography, and scoring systems such as the Wilkins score are used to evaluate the mitral valve anatomy for prediction of safety and outcomes.

Another important determinant of success and safety of BMV is the selection of optimal hardware, particularly the size of the balloon used for the dilatation, in order

to achieve maximum valve area post dilatation while minimising periprocedural risks including worsening mitral regurgitation and valvular damage.

The main purpose of BMV is to provide an adequate mitral valve area (MVA) of > 1.5 cm^2 with no significant MR. Definitions of a successful BMV include

- 50–60% reduction in transmitral gradient.
- MVA greater than 1.5 cm^2.
- A decrease in left atrial pressure to less than 18 mmHg in the absence of complications

The most widely used method to decide the size of the dilatation balloon uses an empirical formula to calculate inflated balloon catheter diameter based on the height of the patient [size = 0.1 × height (cm) + 10. This method has its limitations in that it does not take into account the patients overall body habitus. Although this has been a widely accepted criteria for balloon sizing, considerable variations exist in patients with respect to the valve anatomy, severity of MS and the involvement of valve commissures including commissural fusion and calcification, that may significantly alter the anatomy, requiring an individualistic approach for assessment of appropriate balloon sizing based on the valve anatomy assessed by echocardiography.

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**

Severity	Mitral Valve Area (cm^2)	Mean Pressure Gradient (mm Hg)	Pulmonary Artery Systolic Pressure (mm Hg)
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**

Stage	Definition	Valve Anatomy	Valve Hemodynamic	Hemodynamic Consequences	Symptoms
C: Asymptomatic Severe	**Severe MS without 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; pulmonary artery systolic pressure (PASP) >50 mm Hg**	**None**
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.

MITRAL VALVE ANATOMY

The anatomical components of the MV include the annulus, leaflets, chords and papillary muscles. Normal function of the MV de. ends on the integration of these

structures and on the absence of supravalvar pathology or significant disease of the left ventricle.

The annulus is a fibrofatty non-planar ring with a geometric shape similar to a riding saddle, with two axes, the anteroposterior (AP) axis and an orthogonal axis along the commissure.

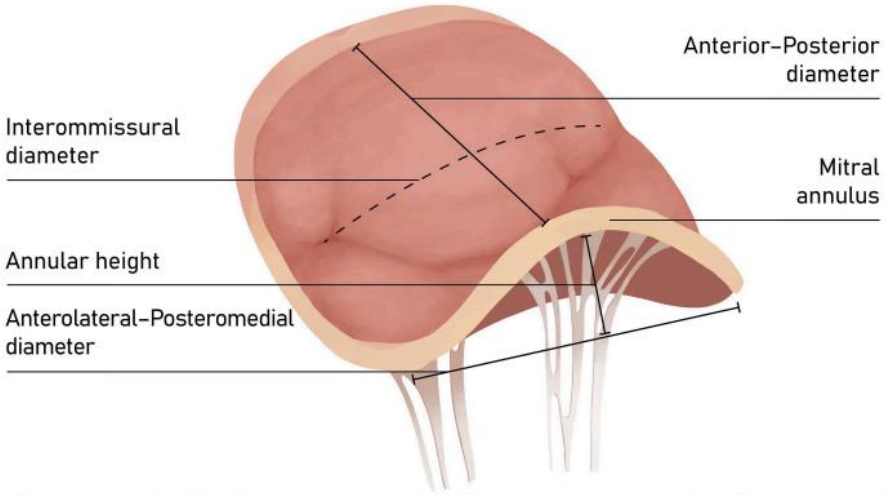


Fig 1. Saddle shaped anatomy of the mitral valve showing the different planes of measurement of the AP dimension, annulus and Intercommissural diameter(ICD).

The AP dimension is usually in a higher plane and is measured in a mid-esophageal aortic valve long-axis (ME AV LAX) view whereas the commissural diameter should be measured in the mid-esophageal bi-commissural (ME bi-com) view.

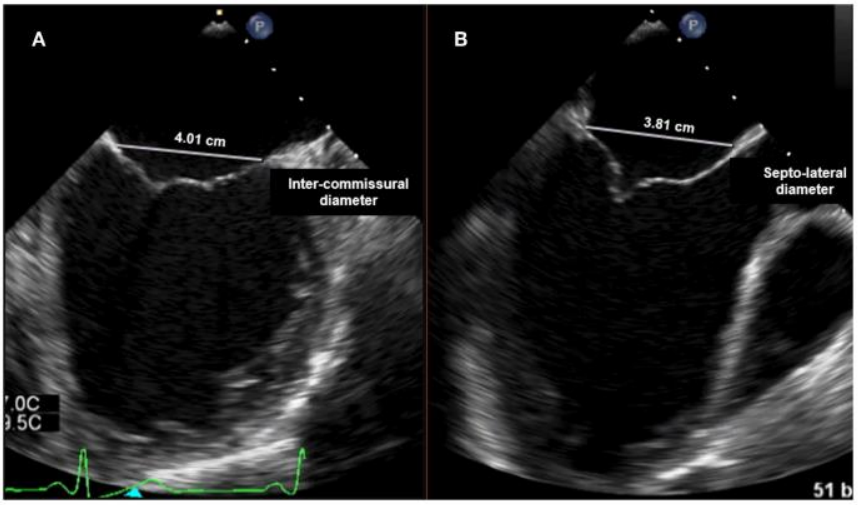


Fig 1. Normal mitral valve TEE showing the bicommisural view (A), and measurement of the intercommisural distance. The Septal-latera diameter measurement is also shown (B).

Rheumatic mitral stenosis affects all the components of the mitral valve. It leads to valve leaflet thickening and calcification with reduced movement of valve leaflets. The commissures are fused, and often times calcific, leading to a reduction in the overall valve area. The subvalvar apparatus including the chordae are fibrotic and shortened, leading to a funnel shaped valvular orifice with the subchondral area being smaller than the area at the valve annulus. This fibrosis and shortening also leads to restriction of leaflet movements, restricting valve opening and contributing to mitral stenosis creating a gradient between Left atrium and left ventricle.

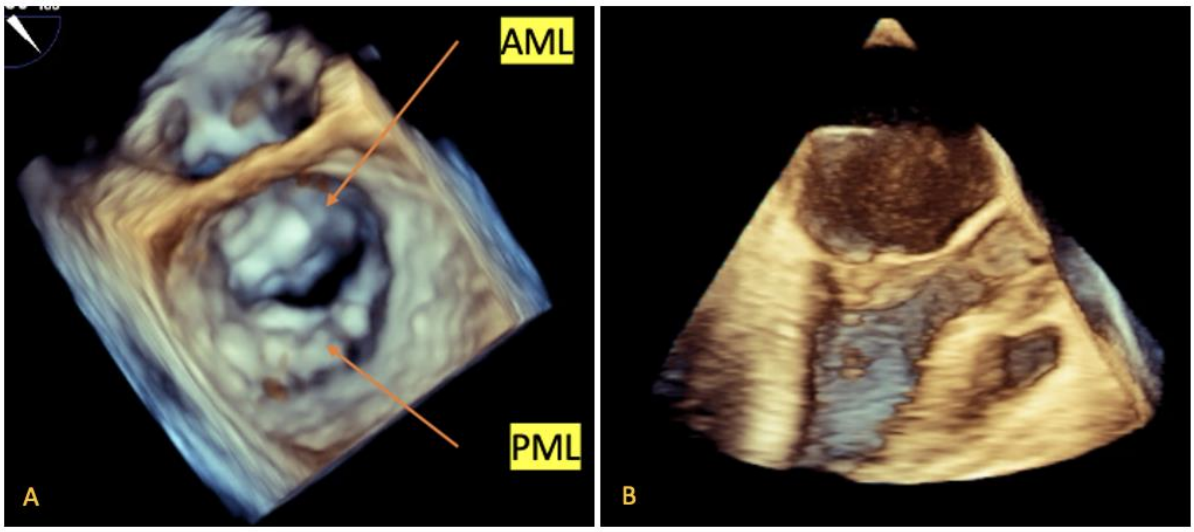


Fig 2. 3D TEE image of a patient with mitral stenosis, showing the short axis view demonstrating leaflet thickening and commissural fusion(A) and the long axis view showing subvalvar involvement in rheumatic pathology (B).

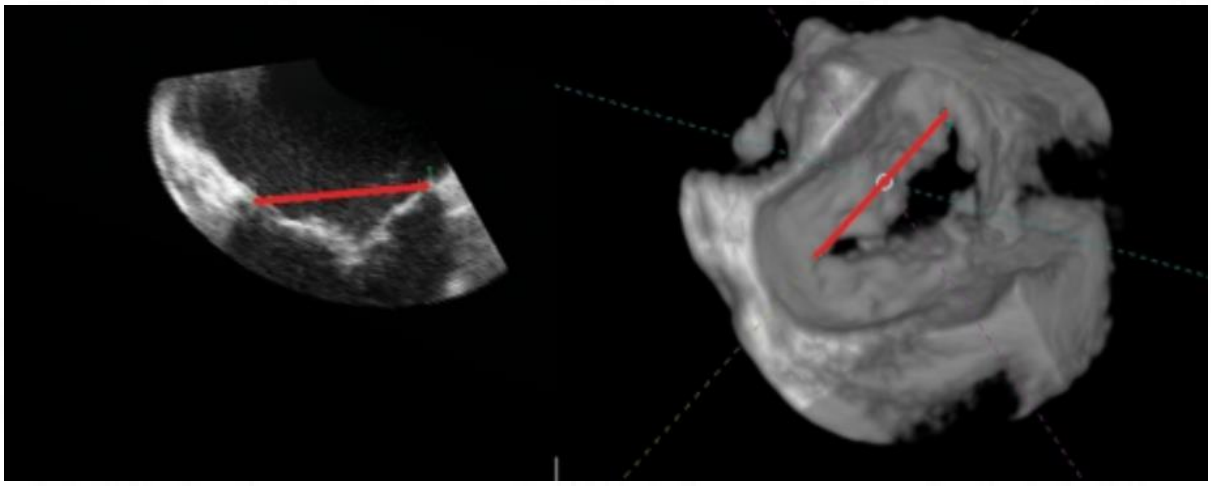


Fig 3. TEE showing the assessment pf Intercommisural distance in a patient with mitral stenosis. The left side image (A) shows the measurement taken in 2D TEE bicommisural view, and the right panel (B) shows the measurement taken in 3D image of the mitral valve.

REVIEW OF LITERATURE

Initial work on the utility of TEE in assessing the mitral valve anatomy in MS came as early as 1998, when Applebaum et al studied and performed TEE in 50 patients with severe MS prior to BMV, And studied the effects of the procedure on mitral valve anatomy. They found that The three-dimensional echocardiographic reconstruction enabled visualization of the mitral valve so that commissural splitting and leaflet tears not seen on the two-dimensional echocardiogram became visible.

Subsequently, TEE became routine practice to assess the anatomy prior to BMV, and to also assess for LA thrombus and LA appendage thrombus prior to procedure.

3D Echo variables complement 2D echo in MV pre-BMV assessment. Anwar *et al*. proposed a 3D echo score to predict BMV outcome more accurately.[29] Individual RT3DE score points of leaflets and subvalvular apparatus summed to calculate the total score, ranging from 0 to 31 points. Total score of mild MV involvement was defined as <8 points, moderate MV involvement 8–13, and severe MV involvement >14. Higher scores correlated with poor BMV outcome.

Balloon sizing by different methods has been studied, and a study by Sanati et al in 2005 with 85 patients showed that Selection of balloon size according to echocardiographic commissural diameter is a good alternative method. Assuming the possible discrepancy between height-based and commissural-based estimated balloon sizes in some cases, adjustment of balloon sizes according to the maximal commissural diameter may result in acceptable results and fewer complications.

Further studies by Tastan et al showed that Choosing Inoue balloon size by measuring maximal diastolic annulus diameter by echocardiography for BMV may be an acceptable method for appropriate final MVA and to avoid risk of significant MR.

Hani M. Mahmoud et al in 2017 published their study on the use of 3 D echocardiography in mitral stenosis to accurately determine valve area, however the clinical implications and therapeutic utility of the same were not elucidated.

Most studies have used conventional 2D echo based measurements, and there is limited data on the role of 3D TEE based measurements of intercommisural distance to accurately determine the balloon size for BMV.

RESEARCH QUESTION

How can 3D echocardiography be utilised in patients with severe MS undergoing BMV for assessment of mitral valve anatomy and for the choice of BMV balloon sizing to optimise the outcomes by achieving higher Mitral valve are with minimal MR post BMV?

How do the analytical measurements including 3D Mitral valve area and intercommissural distance compare with the measurements obtained by traditional height based measurements used for balloon sizing in BMV?

OBJECTIVES

To compare the measurements of valve area and intercommissural distance derived balloon sizing with the balloon sizing derived by conventional height based measurements.

To assess the immediate outcomes of BMV including severity of MR and final valve area obtained after BMV and assess the effect of balloon sizing parameters.

MATERIALS AND METHODS

STUDY DESIGN AND PROTOCOL

Study design: Observational study.

Study duration: 10 months

Patients were clinically examined, and subjected to an echocardiographic study at:

- Admission/ prior to the procedure
- Discharge following the procedure

After obtaining informed consent, patients were then recruited and the data was processed and analysed.

STUDY PARAMETERS

- Clinical functional assessment
- Echocardiographic data:
    - Severity of MS and MR
    - Associated valvular leisons
    - Mitral valve area by 2 D planimetry
    - Wilkins score
    - Intercommisural distance
    - MV gradients
    - Transesophegeal echocardiography and 3D MV area and anatomy assessment

- 3D intercommissural distance
- Mitral valve navigator tool derived MVA
- LA/ LAA clot.

The above echocardiographic data were obtained on Philips Epiq 7 system. Post analysis of 3 D data was performed on the same system and measurements recorded.

3D intercommissural distance was recorded, as well as TEE recorded 2D and 3 D mitral annular measurements. Balloon size for BMV was assessed as per the conventional height based sizing method and recorded.

The patients then underwent the procedure as per routine protocol under local anaesthesia and fluoroscopic guidance. Balloon sizes for dilatation were chosen as per height based sizing, taking into account the size availability operator preference. Based on hemodynamics, periprocedural transthoracic echo and assessment of MR, subsequent dilatations were given until an adequate acceptable result reached, with transmitral gradient being less than 5.

Patients were then monitored in the ICU for 24 hours, and a preprocedural 2 D thransthoracic echocardiogram was performed prior to discharge, to look for valve area, mitral regurgitation and ventricular function, and rule out pericardial effusion.

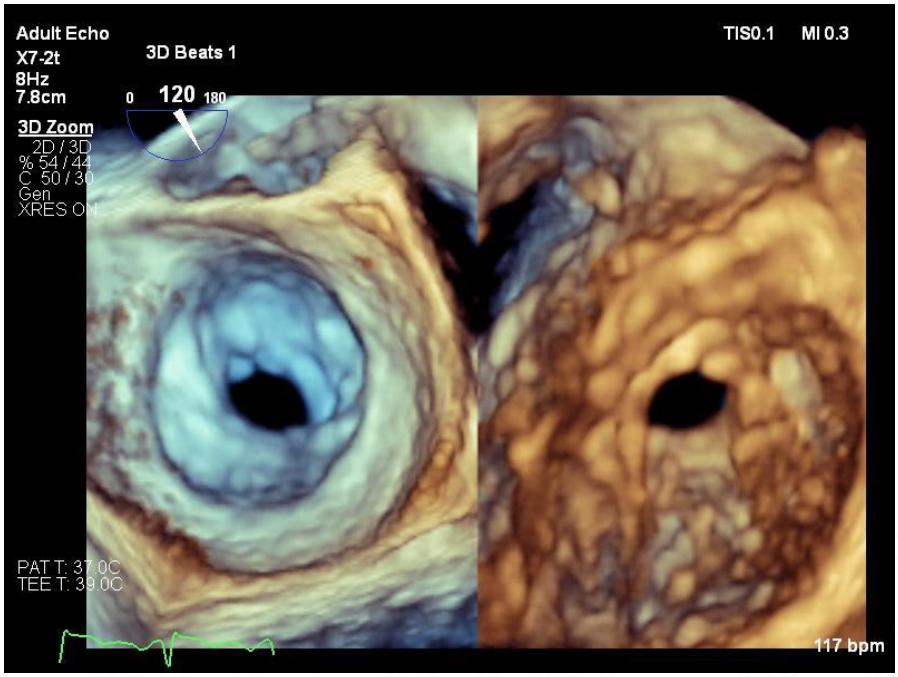


Fig 4: 3D transesophageal echocardiographic images obtained from a patient with severe MS, and from the left panel(LA view), the intercommisural distance was calculated.

STATISTICS

- Continuous variables are expressed as mean ± standard deviation (SD) or median (interquartile range, IQR).
- Paired t-test or Wilcoxon signed-ranks test is used to compare the differences between two-time points during the follow-up.
- Categorical data- described as number (%)
- Bland Altman plot is used to assess the difference in the two methods
- Spearmans and Kendall Rau correlation coefficients were used to assess the relation between different methods.

RESULTS

A total of 47 patients undergoing BMV at our centre between January 2024 and November 2024 were analysed. The preprocedural TEE was analysed and measurements taken.

DEMOGRAPHIC DETAILS:

The mean age of patients recruited was 45.3 years, and 35 female patients and 12 male patients were included.

	AGE	HEIGHT	WEIGHT	MS MEAN	MS GRAD PRE	LVEF	LA SIZE	MVA BY PHT	MVA 2D	MV ANNULUS
Mean	45.38	156.23	60.84	14.43	23.34	61.13	44.72	0.99	0.97	32.03
Mean ± Std.	45.38 ± 10.74	156.23 ± 6.73	60.84 ± 13.02	14.43 ± 4.69	23.34 ± 7.18	61.13 ± 7.04	44.72 ± 5.79	0.99 ± 0.22	0.97 ± 0.28	32.03 ± 3.35

Table 1. Baseline demographic details of the overall cohort. Abbreviations: MS- mitral stenosis, Grad- gradient, Pre- pre procedure, LVEF- Left ventricular ejection fraction, LA- Left atrium, MVA- Mitral valve area, PHT- Pressure half time . 2D: 2 dimensional echocardiography.

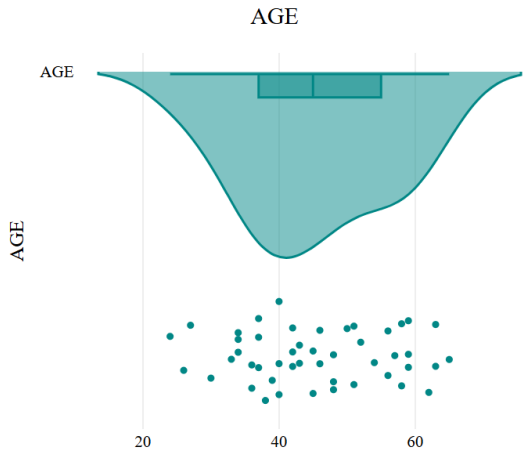


Fig 5: Raincloud plot showing the mean age of patients recruited.

There were no significant differences in the baseline parameters across both genders.

The baseline LV ejection fraction was a mean of 61%, and mean mitral stenosis gradient of 14.43 mmHg, and LA size of 44mm. The mitral valve area by 2D echocardiography was 0.97cm2, and by Pressure half time method was 0.99cm2.

Measurements of mitral valve were compared.

Mitral valve area was assessed by 3 different methods: MVA by 2 D echocardiography, MVA by 3 D echocardiography and MVA by Pressure half time.

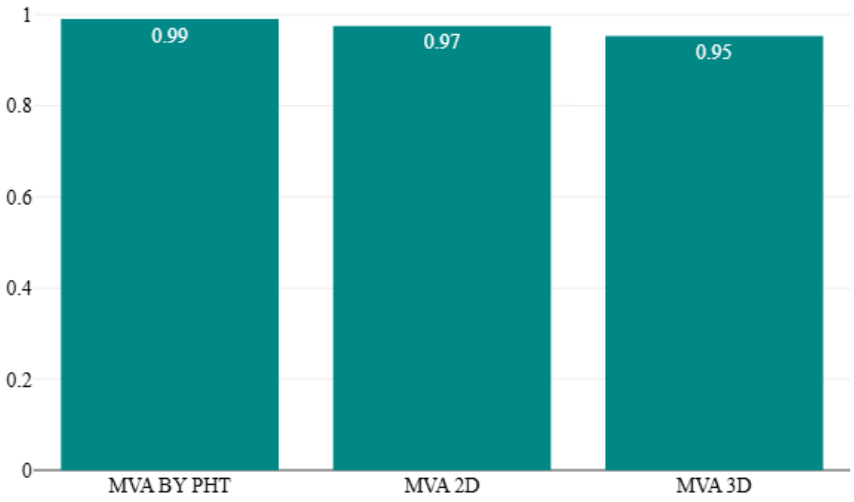


Fig 6- Mitral valve area by 3 different methods as assessed ny echocardiography.

		Mean diff.	Std. Error		p
MVA BY PHT	MVA 2D	0.02	0.031	0.511	1
MVA BY PHT	MVA 3D	0.04	0.027	1.373	.53
MVA 2D	MVA 3D	0.02	0.034	0.641	1

Table 2: Anova test for comparison of the different methods of mitral valve area estimation

With a p-value of .477, the results are not statistically significant at the conventional alpha levels of 0.05, indicating that there are no significant differences among the means of the 3 levels *MVA BY PHT*, *MVA 2D* and *MVA 3D*.

Following this, the balloon sizing methods were then assessed. Conventional balloon sizing using height based calculation was done, and also the intercommissural distance as measured by 3 d echocardiography was compared.

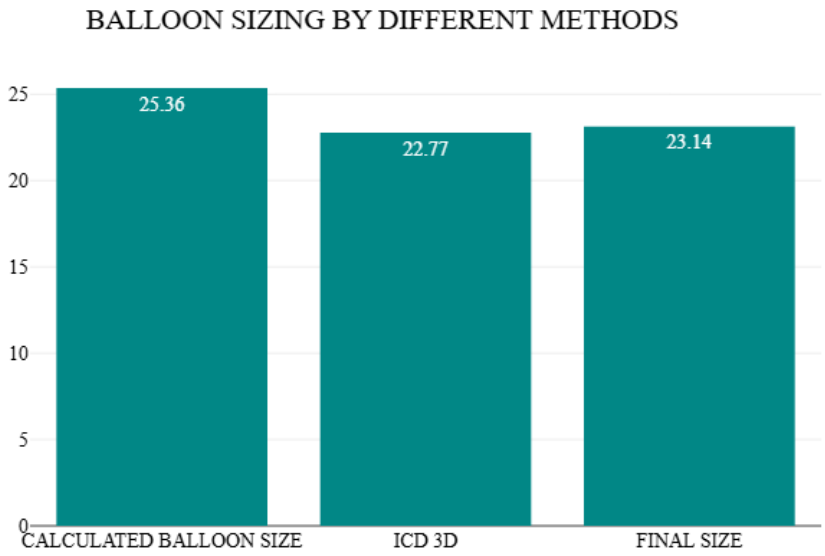


Fig 7- Bar chart showing the measurements ontained by different methods for balloon sizing, and the final size of the balloon used for dilatation during BMV.

The calculated balloon size by height based measurements was larger, with a difference of 2.49 mm. However, the final balloon size used during the BMV procedure had a mean value of 23.14mm, which correlated better with the intercommissural distance than the conventional balloon sizing.

		Mean diff.	Std. Error	t	p	95% CI lower limit
CALCULATED BALLOON SIZE	ICD 3D	2.59	0.315	8.208	<.001	1.95
CALCULATED BALLOON SIZE	BALLOON SIZE	1.32	0.149	8.834	<.001	1.02
ICD 3D	BALLOON SIZE	-1.27	0.281	-4.524	<.001	-1.84

Table 3: Mixed ANOVA test comparing the different methods for balloon size estimation and comparing with the final balloon size used for dilatation.

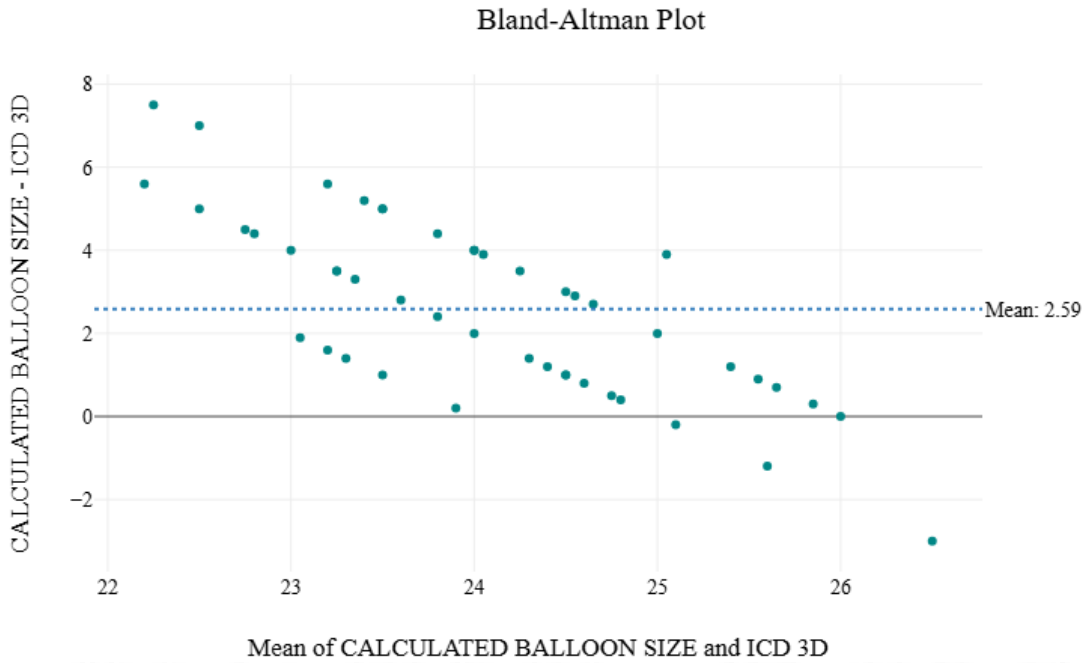


Fig 8- Bland Altman plot showing the relation between the values obtained by Intercommissural distance to the conventional height based formula for balloon sizing.

There is a significant disagreement between the two methods, with the ICD measurements being smaller than the height based measurements. Kendall Tau correlation analysis showed that there is no significant correlation between the two valvues(p=0.998).

The details of the BMV procedure were then analysed. The mean size of the Accura Balloon selected for the BMV was 24 mm, and 22 patients underwent 3 successive dilatations with increasing balloon volume and size, and 9 patients underwent 3 successive dilatations.

	NO of dilatations	Frequency	Mean	Std. Deviation	Maximum
BALLOON SIZE	2	22	24.09	0.75	26
	1	16	24	0.73	26
	3	9	24	1	26
FINAL SIZE	2	22	23.45	0.86	25
	1	16	22.19	0.54	24
	3	9	24.06	1.01	25

Table 4 showing the details of the procedure including balloon size and number of dilatations.

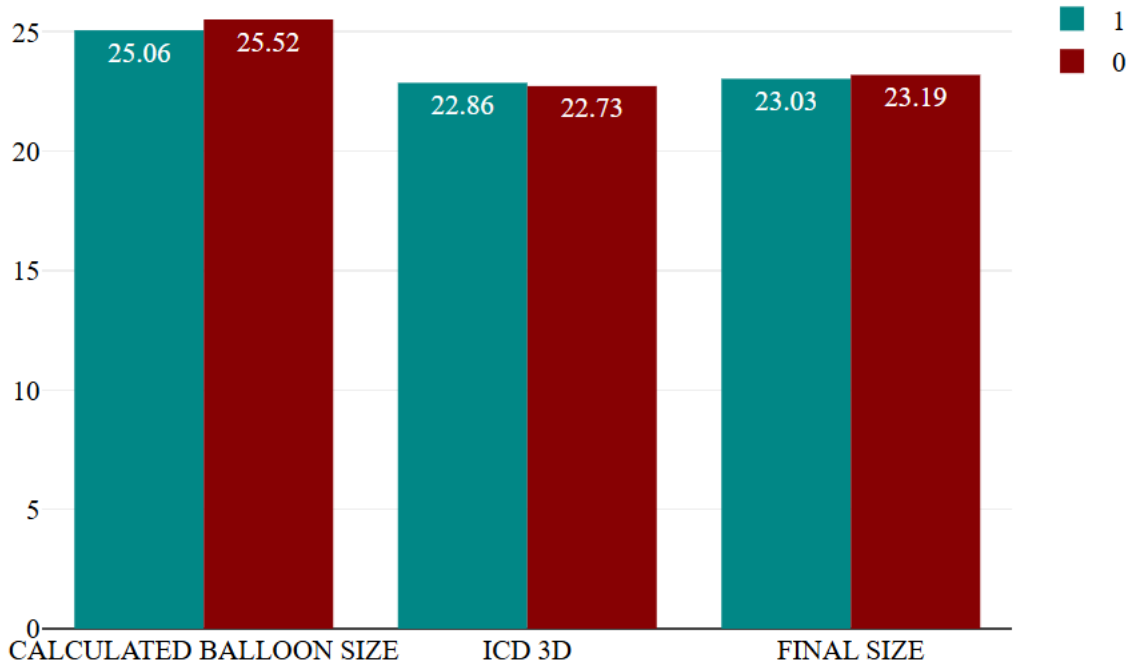


Fig – Showing the balloon sizes in patients who ad worsening MR and those with no worsening MR post procedure.

3 patients had progression to severe Mitral regurgitation(MR) during BMV, requiring urgent Surgical MVR. 16 patients had worsening MR by more than one grade, but did not require further intervention and tolerated the MR.

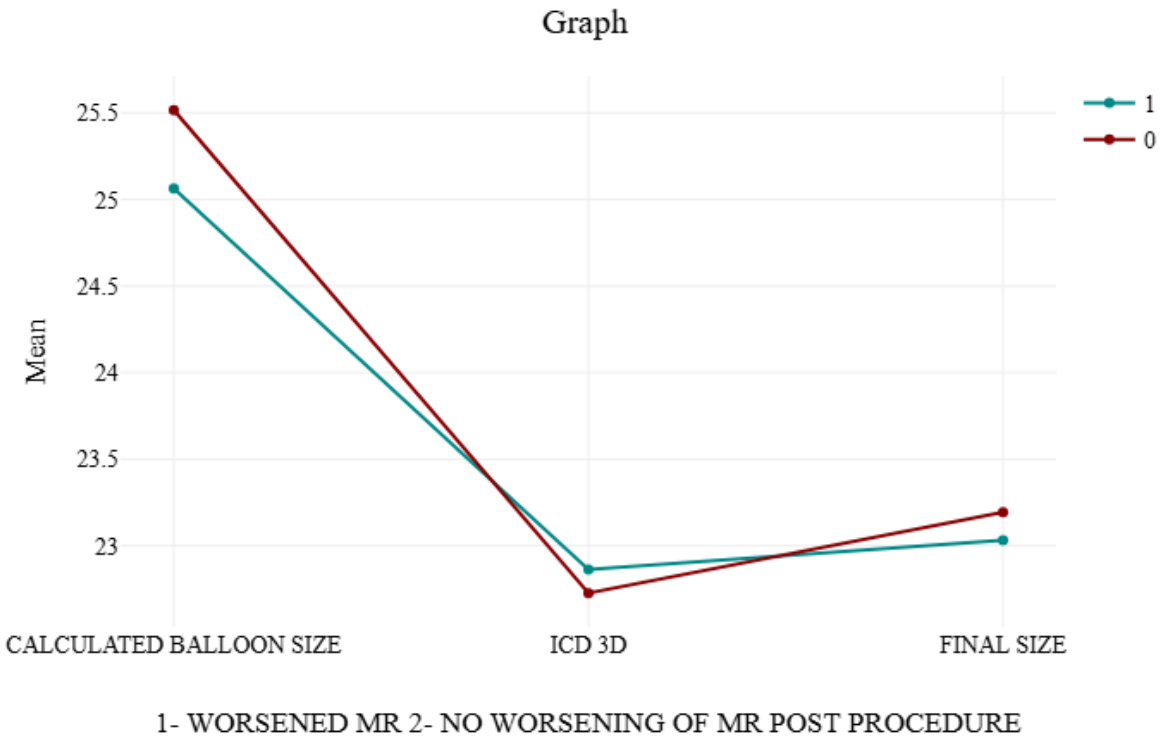


Fig 9- Line diagram showing the calculated balloon size, intercommisural distance and the final balloon size for dilatation among 2 groups—1 with worsened MR by more than one grade post BMV and Group 0 with no worsened MR.

Analysis of the intercommissural distance(ICD 3D) with respect to the final balloon size for dilatations that gave the optimal BMV results was performed using Spearmans correlation test.

The correlation coefficient indicates the strength and direction of the linear relationship between *ICD 3D* and *FINAL SIZE*. The coefficient 0.44 suggests a moderate, positive correlation. This means that, generally, as *ICD 3D* increases, *FINAL SIZE* also tends to increase.

Here, the p-value of .002 is less than 0.05, which suggests that the correlation observed in the sample (r = 0.44) is unlikely to be due to chance. The null hypothesis that there is no correlation between *ICD 3D* and *FINAL SIZE* in the population is therefore rejected. The result of the Spearman correlation

thus showed that there was a statistically significant correlation between *ICD 3D* and *FINAL SIZE*.

The result of the Spearman correlation showed that there was a moderate, positive correlation between *ICD 3D* and *FINAL SIZE*. The correlation between *ICD 3D* and *FINAL SIZE* was statistically significant, $r(45) = 0.44$, $p = .002$..

	Final MV area (Calculated)	Increase in MVA (Calculated Excel)	Maximum dilation given	Increase in MV area	% Increase in MV area	Post MR severity Echo
Mean	2.04	1.09	23.24	1.09	27.71	2.22
Std. Deviation	0.98	0.77	1.05	0.76	38.28	0.85
Maximum	4.6	3.12	25	3.12	83	4

Table 6- Post procedure parameters and outcomes.

The outcomes of BMV were analysed, and successful BMV and suboptimal BMV were identified.

3 patients had severe Mitral regurgitation requiring Surgical intervention, and one of them had a papillary muscle rupture causing severe MR, while the other 2 patients had Anterior mitral leaflet tears which led to severe Mitral Regurgitation.

Out of 47 patients, 1 patient had a suboptimal BMV with residual gradient of more than 5 mmHg, and a valve area of less than 1 cm2 post procedure.

Although 16 patients had worsening MR by more than one grade/ more than moderate MR, this was well tolerated in all but 3 patients who required surgical intervention.

6 out of the 47 patients had a partial commissural splitting, while 38 of them had splitting of both commissures post procedure.

DISCUSSION:

Our study aimed to assess the utility of 3D echocardiography in patients undergoing BMV and particularly focussed on the utility of measurements obtained by 3 D echocardiography to assist in the selection of balloon size in BMV.

We studied a total of 47 patients, of whom only 3 had serious adverse events of severe MR post procedure who required surgical intervention.

This was a descriptive study, where we compared the conventional height based sizing method with the echo based methods, and our results showed that there is no agreement with the values. This is probably due to the differences in values obtained by the echocardiographic method based on the valve anatomy and extent of the rheumatic pathology affecting the mitral valve, a factor that is not taken into consideration with traditional height based calculation.

We also looked at the relation of the ICD measurements to the final size of the balloon that was used for dilatation during BMV and found that the ICD had a moderate, positive correlation with the balloon size that achieved best outcomes, suggesting that the initial sizing based on this method may be accurate, This correlation was statisticaly significant.

The adoption of this new method would be especially worthwhile in cases with a great difference between the balloon sizes estimated by the two methods, such as those in our study.

Although the numbers are very small, in the 2 patients who had severe MR due to leaflet injury, the balloon used for dilatation was larger than the size estimated by the intercommissural distance calculation.

A study by Sanati et al, also looked at the echocardiogram based ballon sizing in relation to traditional balloon sizing, and described a concept- 'height–commissure mismatch.'- where the height based sizing showed much higher values than the echocardiogram based methods, and they identified this in a significant proportion of patients who developed severe MR.

The number of patients in our study who developed severe MR is small, and thus the statistical analysis could not be performed, and these remain observational data.

It can be postulated that although selecting BMV balloon size using the height-based formula is a reasonable and relatively safe method, adjustment of balloon sizes according to the commissural diameter—especially in those with considerable discrepancy between height-based versus commissural based estimated balloon sizes—may result in even fewer cases of significant MR due to oversized ballooning.

The findings of this study show that the Intercommisural distance by 3 D echocardiography correlates with the balloon size that can achieve best results, and this paves the way for utilising this method of balloon sizing.

Further comparative studies of the two methods need to be undertaken, to compare the outcomes.

LIMITATIONS

The limitations of this study are the small sample size, and the nature of the study as it an observational descriptive study.

However the results are promising, and further larger studies and comparative studies can be undertaken to optimise outcomes in patients undergoing BMV.

CONCLUSION:

3D transesophageal echocardiography to assess the mitral valve anatomy is beneficial in patients undergoing BMV, and the intercommisural distance measured by 3D TEE has a strong positive correlation with the Balloon size used for dilatation, and may be used as a method to estimate the appropriate balloon size to optimise outcomes in patients undergoing BMV.

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ANNEXURES

IEC CLEARANCE CERTIFICATE

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

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

16.12.2024

SCT/IEC/2279/NOVEMBER-2024

Dr. Pooja Prasad
Post Doctoral Fellow
Department of Cardiology
SCTIMST, Thiruvananthapuram

Dear Dr. Pooja Prasad,

The Institutional Ethics Committee held on 2nd November, 2024, reviewed and discussed your application to conduct the study titled "**UTILITY OF 3DIMENSIONAL ECHOCARDIOGRAPHY FOR *OPTIMISATION OF BALLOON MITRALVALVOTOMY* (IEC /2279)**".

Principal Investigator	Dr. Pooja Prasad, PDF - Adult Cardiology and Interventions, Department of Cardiology, SCTIMST
Co-Principal Investigator(s)	Dr. Harikrishnan S, Professor, Senior Grade, Department of Cardiology, SCTIMST
Duration of the study	10 months

The following members of the Ethics Committee were present at the meeting held on 2nd November, 2024

SL. No.	Member Name	Highest Degree	Gender	Scientific /Non Scientific	Affiliation with Institution(s)
1.	Dr. Annapurna.Y	MD	Female	Basic Medical Scientist	No
2.	Dr. Manoj Murhekar	MD (Preventive & Social Medicine)	Male	Social Scientist	No
3.	Dr. Indu PV	MBBS, DPM, MPhil, PhD	Female	Clinician	No
4.	Adv. N Anand	BAL, L.LB	Male	Legal Expert	No
5.	Smt. Rekha Radhakrishnan	M.A (Eng.); B.Ed	Female	Lay person	No
6.	Dr. Manikandan.S	MBBS,MD,PDCC	Male	Clinician	Yes
7.	Dr. Syam K	MBBS, MD, DM	Male	Clinician	Yes
8.	Dr. Biju Soman	MBBS,MD, DPH, MSc, DLSHTM	Male	Basic Medical Scientist	Yes
9.	Dr. Srinivas G	PhD	Male	Basic Medical Scientist (Member Secretary)	Yes

The following documents were reviewed:

Original submission

1. Covering letter addressed to the Chairman, IEC, SCTIMST
2. IEC Application Form
3. Informed Consent Form in English and Malayalam
4. Patient Information Sheet in English and Malayalam
5. Declaration form
6. CV of PI and Co-PI
7. Study Proposal

Revised submission

1. Covering letter addressed to the Chairman, IEC, SCTIMST
2. Study Proposal
3. IEC Application Form
4. Patient Information Sheet in English and Malayalam
5. Informed Consent Form in English and Malayalam
6. CV of PI and Co-PI

IEC Decision

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

Remarks:

The Institutional Ethics Committee expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

There was no member of the study team who participated in voting / decision making process. The ethics committee is organized and operated according to the requirements of Good Clinical Practice and the requirements of the Indian Council of Medical Research (ICMR).

Sincerely,

Dr. G. Srinivas
Member Secretary, IEC

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE (IEC)
SCTIMST, THIRUVANANTHAPURAM

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

2

CONSENT FORMS

PARTICIPANT INFORMATION SHEET

TITLE OF THE STUDY: UTILITY OF 3D ECHOCARDIOGRAPHY FOR OPTIMISATION OF BALLOON MITRAL VALVOTOMY

You are being requested to participate in this study where we will assess the symptoms before and after the BALLOON MITRAL VALVOTOMY(BMV) for Mitral Stenosis. This is a procedure done to relive the stenosis of the left sided heart velve- the mitral valve, using a balloon, which is placed across the diseased valve via a small incision in the groin, through the femoral vein, to reach the heart. The balloon is then positioned across the valve and inflated, to relieve the valvular obstruction and improve patient symptoms. This procedure is performed in selected patients who are deemed suitable for the procedure after having assessed the valve anatomy and characteristics by transthoracic and transesophageal echocardiography. Both transthoracic echocardiography and transesophageal echocardiography will also be performed before the procedure, and data will be collected. Transthoracic echocardiography will be done after the procedure to see the outcomes and changes in valve area.

Your participation in this study would contribute immensely to improving future care of patients with mitral stenosis who are eligible to undergo BMV . We will be able to identify new methods based on echo derived measurements to make the procedure safe and effective in future.

If you take part what will you have to do?

The study will require your consent after clarifying all related queries.All treatment that you have and will be receiving shall be as per routine protocols of the institution and it will not be changed during this study. The participation in the study is purely voluntary and there will be no difference in your treatment or follow up if you decide not to cooperate for the study.

Will you have to pay for the investigations?

No additional investigations will be needed apart from routine protocols.

What happens if you are detected to have any fresh problems during the study?

No additional risks are anticipated due to the study

Will your personal details be kept confidential?

The results of this study may be published in a medical journal for advancement of medical sciences and surgical standards of care.You will not be identified by name in any publication or presentation of results. However, your medical notes may be reviewed by people associated with the study, without your additional permission.

If you have any further questions, please ask Dr.Pooja Prasad(Tel 9945713382, pooja90prasad@gmail.com)

For any clarifications regarding the study's ethics clearance you may contact the Member Secretary of the SCTIMST-IEC. The phone number is: 0471- 2524689 and the email id is iec.mem.sec@sctimst.ac.in

പഠനത്തിൻ്റെ പേര്: ബലൂൺ മിട്രൽ വാൽവോട്ടോമി ഒപ്റ്റിമൈസേഷനായി 3D എക്കോകാർഡിയോഗ്രാഫിയുടെ പ്രയോജനം

മിട്രൽ സ്റ്റെനോസിസിനായുള്ള ബലൂൺ മിട്രൽ വാൽവോട്ടോമി(ബിഎംവി) എന്ന ചികിത്സക്ക് മുമ്പും ശേഷവുമുള്ള ലക്ഷണങ്ങൾ വിലയിരുത്തുന്നതിനായുള്ള ഈ പഠനത്തിൽ പങ്കെടുക്കാൻ നിങ്ങളോട് അഭ്യർത്ഥിക്കുന്നു.

ഇടത് വശത്തുള്ള ഹൃദയ വെൽവായ മിട്രൽ വാൽവിലെ തകരാറുകളെ പരിഹരിക്കാനുള്ള ഒരു ചികിത്സാരീതിയാണ് ബലൂൺ മിട്രൽ വാൽവോട്ടോമി.

തുടയിലെ ധമനികൾ വഴി ഒരു ബലൂൺ വാൽവിനു കുറുകെ സ്ഥാപിക്കുകയും വാൽവിലെ തടസ്സം ഒഴിവാക്കുകയും രോഗ ലക്ഷണങ്ങൾ മെച്ചപ്പെടുത്തുകയും ചെയ്യുന്നു.

ട്രാൻസ്തോറാസിക്, ട്രാൻസ്ഈസോഫാഗൽ എക്കോകാർഡിയോഗ്രാഫി എന്നിവയിലൂടെ വാൽവിൻ്റെ ഘടനയും സവിശേഷതകളും വിലയിരുത്തിയ ശേഷം നടപടിക്രമത്തിന് അനുയോജ്യമെന്ന് കരുതുന്ന തിരഞ്ഞെടുത്ത രോഗികളിലാണ് ഈ ചികിത്സ നടത്തുന്നത്.

2d എക്കോകാർഡിയോഗ്രാഫി- ട്രാൻസ്തോറാസിക് എക്കോകാർഡിയോഗ്രാഫി, ട്രാൻസ്ഈസോഫാഗൽ എക്കോകാർഡിയോഗ്രാഫി എന്നിവ ബലൂൺ മിട്രൽ വാൽവോട്ടോമിക്ക് മുമ്പ് നടത്തുകയും ഡാറ്റ ശേഖരിക്കുകയും ചെയ്യും. ഈ ചികിത്സക്കു ശേഷം ട്രാൻസ്തോറാസിക് എക്കോകാർഡിയോഗ്രാഫിയും നടത്തുന്നു.

ഈ പഠനത്തിലെ നിങ്ങളുടെ പങ്കാളിത്തം, ബിഎംവിക്ക് വിധേയരാകാൻ

യോഗ്യതയുള്ള മിട്രൽ സ്റ്റെനോസിസ് രോഗികളുടെ ഭാവി പരിചരണം മെച്ചപ്പെടുത്തുന്നതിന് വളരെയധികം സംഭാവന ചെയ്യും. പഠനത്തിൽ നിന്ന് പ്രതിധ്വനിക്കുന്ന വിവരങ്ങൾ അടിസ്ഥാനമാക്കി ഭാവിയിൽ ഈ ചികിത്സ സുരക്ഷിതവും ഫലപ്രദവുമാക്കുന്നതിനും പുതിയ രീതികൾ തിരിച്ചറിയാനും ഞങ്ങൾക്ക് സാധിക്കും.

ഈ പഠനത്തിൽ പങ്കെടുക്കുകയാണെങ്കിൽ നിങ്ങൾ എന്താണ് ചെയ്യേണ്ടത്?

ബന്ധപ്പെട്ട എല്ലാ സംശയങ്ങളും വ്യക്തമാക്കിയതിന് ശേഷം ഈ പഠനത്തിന് നിങ്ങളുടെ സമ്മതം ആവശ്യമാണ്. നിങ്ങൾക്ക് നിലവിൽ കിട്ടിക്കൊണ്ടിരിക്കുന്ന എല്ലാ ചികിത്സകളും ആശുപത്രിയുടെ പതിവ് പ്രോട്ടോക്കോളുകൾ അനുസരിച്ചായിരിക്കും. പഠന സമയത്ത് അതിന് മാറ്റമുണ്ടാകില്ല. പഠനത്തിലെ പങ്കാളിത്തം പൂർണ്ണമായും സ്വമേധയാ ഉള്ളതാണ്. പഠനത്തിനായി സഹകരിക്കേണ്ടതില്ലെന്ന് നിങ്ങൾ തീരുമാനിക്കുകയാണെങ്കിൽ നിങ്ങൾക്ക് നിലവിൽ കിട്ടിക്കൊണ്ടിരിക്കുന്ന ചികിത്സയിൽ യാതൊരു വ്യത്യാസവും ഉണ്ടാകില്ല.

പരിശോധനകൾക്ക് പണം നൽകേണ്ടിവരുമോ?

പതിവ് ചികിത്സക്ക് പുറമെ അധിക പരിശോധനകൾ ആവശ്യമില്ല.

പഠനത്തിനിടെ നിങ്ങൾക്ക് എന്തെങ്കിലും പുതിയ പ്രശ്നങ്ങളുണ്ടെന്ന് കണ്ടെത്തിയാൽ എന്ത് സംഭവിക്കും?

പഠനം കാരണം അധിക അപകടസാധ്യതകളൊന്നും പ്രതീക്ഷിക്കുന്നില്ല

നിങ്ങളുടെ സ്വകാര്യ വിവരങ്ങൾ രഹസ്യമായി സൂക്ഷിക്കുമോ?

ഈ പഠനത്തിന്റെ ഫലങ്ങൾ മെഡിക്കൽ സയൻസസിന്റെ പുരോഗതിക്കും ശസ്ത്രക്രിയാ നിലവാരം മെച്ചപ്പെടുത്തുന്നതിനുമായി ഒരു മെഡിക്കൽ ജേണലിൽ പ്രസിദ്ധീകരിച്ചേക്കാം. ഏതെങ്കിലും പ്രസിദ്ധീകരണത്തിലോ ഫലങ്ങളുടെ അവതരണത്തിലോ നിങ്ങളെ പേരുകൊണ്ട് തിരിച്ചറിയാൻ കഴിയില്ല. എന്നിരുന്നാലും, അധിക അനുമതിയില്ലാതെ പഠനവുമായി ബന്ധപ്പെട്ട ആളുകൾ നിങ്ങളുടെ മെഡിക്കൽ കുറിപ്പുകൾ അവലോകനം ചെയ്തേക്കാം.

നിങ്ങൾക്ക് കൂടുതൽ ചോദ്യങ്ങളുണ്ടെങ്കിൽ, ദയവായി ഡോ.പൂജ പ്രസാദിനോട് ചോദിക്കുക (9945713382, pooja90prasad@gmail.com)

പഠനത്തിന്റെ ധാർമ്മികതയുമായി ബന്ധപ്പെട്ട എന്തെങ്കിലും വ്യക്തതകൾക്കായി നിങ്ങൾക്ക് ഇൻസ്റ്റിറ്റ്യൂട്ട് എത്തിക്സ് കമ്മിറ്റിയുടെ മെമ്പർ സെക്രട്ടറിയുമായി ബന്ധപ്പെടാവുന്നതാണ്. ഫോൺ നമ്പർ: 0471- 2524689, ഇമെയിൽ ഐഡി: iec.mem.sec@sctimst.ac.in

INFORMED CONSENT FORM

Title of the study: UTILITY OF 3D ECHOCARDIOGRAPHY FOR OPTIMISATION OF

BALLOON MITRAL VALVOTOMY

Participant's name: Age (in years): I_____, son/ daughter/husband/wife/ —

————————————————————of _____ declare

that (Please tick boxes)

• I have read the above information provided to me regarding the study:[ ]

• I 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 will not need my permission to look at my health records even if I withdraw from the study. I agree to this access [ ]

• I understand that my identity will not be revealed in any information released to third parties or published [ ]

• I voluntarily agree to take part in this study [ ]

• I have been provided with the contact numbers of the principle investigator, in case I want to know more about the study and participants rights [ ].

Name:

Signature:

Name of witness:

Date:

Signature:

Relation to participant:

Person Obtaining Consent:

I attest that the requirements for informed consent for the medical research project described in this form have been satisfied. I have discussed the research project with the participant 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 :

Signature :

Date :

Place : SCTIMST, Thiruvananthapuram

പഠനത്തിന്റെ പേര്: ബലൂൺ മിട്രൽ വാൽവോട്ടോമി ഒപ്റ്റിമൈസേഷനായി

3D എക്കോകാർഡിയോഗ്രാഫിയുടെ പ്രയോജനം

പങ്കെടുക്കുന്നയാളുടെ പേര്:

പ്രായം (വർഷങ്ങളിൽ):

ഞാൻ _____

* പഠനവുമായി ബന്ധപ്പെട്ട് എനിക്ക് നൽകിയ മേൽപ്പറഞ്ഞ വിവരങ്ങൾ ഞാൻ വായിച്ചു.

. എനിക്ക് ഉണ്ടായിരുന്ന എല്ലാ സംശയങ്ങളും ഞാൻ വ്യക്തമാക്കിയിട്ടുണ്ട്.

. ഈ പഠനത്തിലെ എന്റെ പങ്കാളിത്തം പൂർണ്ണമായും സ്വമേധയാ ഉള്ളതാണെന്നും എന്റെ പതിവ് ചികിത്സയെയോ നിയമപരമായ അവകാശങ്ങളെയോ ബാധിക്കാതെ എപ്പോൾ വേണമെങ്കിലും പങ്കാളിത്ത അനുമതി പിൻവലിക്കാൻ എനിക്ക് സ്വാതന്ത്ര്യമുണ്ടെന്നും ഞാൻ മനസ്സിലാക്കുന്നു.

. ഞാൻ പഠനത്തിൽ നിന്ന് പിന്മാറിയാലും എന്റെ ആരോഗ്യ രേഖകൾ നോക്കാൻ പഠനം നടത്തുന്നവർക്കും സ്ഥാപനത്തിലെ ധാർമ്മിക സമിതി അംഗങ്ങൾക്കും എന്റെ അനുമതി ആവശ്യമില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. ഈ നടപടിയോട് ഞാൻ യോജിക്കുന്നു.

* മൂന്നാം കക്ഷികൾക്ക് നൽകുകയോ പ്രസിദ്ധീകരിക്കുകയോ ചെയ്യുന്ന ഒരു വിവരത്തിലും എന്റെ വ്യക്തിപരമായ വിവരങ്ങൾ വെളിപ്പെടുത്തില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു.

. ഈ പഠനത്തിൽ പങ്കെടുക്കാൻ ഞാൻ സ്വമേധയാ സമ്മതിക്കുന്നു.

*പഠനത്തെക്കുറിച്ചും പങ്കെടുക്കുന്നവരുടെ അവകാശങ്ങളെക്കുറിച്ചും കൂടുതൽ അറിയാൻ ആഗ്രഹിക്കുന്നുവെങ്കിൽ പ്രധാന അന്വേഷകന്റെ കോൺടാക്റ്റ് നമ്പറുകൾ എനിക്ക് നൽകിയിട്ടുണ്ട്.

പേര്:

കയ്യൊപ്പ്:

സാക്ഷിയുടെ പേര്:
കയ്യൊപ്പ്:

സ്റ്റാഫിന്റെ പേര്:

ഈ ഫോമിൽ വിവരിച്ചിരിക്കുന്ന മെഡിക്കൽ ഗവേഷണ പദ്ധതിക്ക് അറിവോടെയുള്ള സമ്മതത്തിനുള്ള ആവശ്യകതകൾ തൃപ്തികരമാണെന്ന് ഞാൻ സാക്ഷ്യപ്പെടുത്തുന്നു. പങ്കെടുക്കുന്നയാളോട് ഗവേഷണ പദ്ധതി ചർച്ച ചെയ്യുകയും ന്യായമായും സംഭവിക്കുമെന്ന് പ്രതീക്ഷിക്കാവുന്ന അപകടസാധ്യതകളും പ്രതികൂല പ്രതികരണങ്ങളും ഉൾപ്പെടെ സമ്മതപത്രത്തിൽ അടങ്ങിയിരിക്കുന്ന എല്ലാ വിവരങ്ങളും സാങ്കേതികമല്ലാത്ത പദങ്ങളിൽ ഞാൻ വിശദീകരിക്കുകയും ചെയ്തു. ചോദ്യങ്ങൾ ചോദിക്കാൻ ഞാൻ പങ്കെടുക്കുന്നവരെ പ്രോത്സാഹിപ്പിച്ചുവെന്നും ചോദിച്ച എല്ലാ ചോദ്യങ്ങൾക്കും ഉത്തരം

നൽകിയിട്ടുണ്ടെന്നും ഞാൻ സാക്ഷ്യപ്പെടുത്തുന്നു.

പേര്:

കയ്യൊപ്പ്.

തീയതി:

സ്ഥലം: SCTIMST, തിരുവനന്തപുരം

CURRICULUM VITAE

Prasad	Pooja	
Last Name	First Name	Middle Name
Date of Birth (dd/mm/yy) 25/09/90		Sex Female
Study Site Affiliation (e.g. Principal Investigator, Co-Investigator, Coordinator): Principal Investigator		
Professional Mailing Address (Include Institution name)		Study Site Address (Include Institution name)
pooja90prasad@gmail.com		Post Doctoral Fellow Department of Cardiology, SCTIMST
Telephone (Office):		Mobile Number:9945713382
Telephone (Residence):		Email pooja90prasad@gmail.com

Academic Qualifications (Most recent qualification first)

Degree/Certificate	Year	Institution, Country
MD internal Medicine	2018	RGUHS, India
MBBS	2014	RGUHS, India
DM cardiology	2023	SCTIMST, TVM

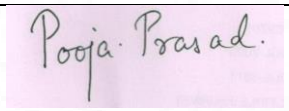
Details of professional registration : (MCI/State Registration/Bar Council/DCI/etc includingRegistration Number and Year of Registration
Travancore-Cochin Medical Council registration; 79077

Current and previous positions (most recent position first)

Month and Year	Title	Institution/Company, Country
2020 march-dec	Registrar, Cardiology	KIMS, TVM
February 2019- Feb 2020	Senior Resident, Department of Medicine	Bowring Hospital, Bangalore
July 2019- Feb2020	Senior Resident, Department of Medicine	Vydehi Institute of Medical Sciences, blr
January 2021 to Dec 2023	Senior Resident, Department of Cardiology	SCTIMST, TVM

Brief summary of relevant research experience:
Dessertation undertaken as a part of postgraduate course, titled “Comparision Of Accuracy Of Light’s Criteria, Adenosine Deaminase And Pseudocholinesterase Levels In The Etiological Diagnosis Of Pleural Effusion”.

Current project/s at hand:

Signature: 	Date: 29.06. 2024 Place: TVM