LEFT ATRIAL STRAIN AS A SURROGATE PARAMETER FOR SUCCESSFUL PERCUTANEOUS BALLON MITRAL VALVOTOMY

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DEPARTMENT OF CARDIOLOGY

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DECLARATION

I, Dr. Bhagwati Pant, hereby declare that the project in this book titled "**LEFT ATRIAL STRAIN AS A SURROGATE PARAMETER FOR SUCCESSFUL PERCUTANEOUS BALLON MITRAL VALVOTOMY**" 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 **"LEFT ATRIAL STRAIN AS A SURROGATE PARAMETER FOR SUCCESSFUL PERCUTANEOUS BALLON MITRAL VALVOTOMY"** is a certified record of original research work undertaken by Dr. Bhagwati Pant 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. Bhagwati Pant, has carried out the minimum required project.



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TITLE

"LEFT ATRIAL STRAIN AS A SURROGATE PARAMETER FOR SUCCESSFUL PERCUTANEOUS BALLON MITRAL VALVOTOMY"

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ABBREVIATIONS

AF-Atrial fibrillation

AML-Anterior mitral leaflet

ARF-Acute Rheumatic Fever

BMI- Body Mass Index

BSA- Body surface area

CAD- coronary artery disease

CMV- Closed mitral valvuloplasty

CO-Cardiac output

CI- Cardiac index Ejection fraction

Fr-French

GAS- Group A Streptococcus

GLAS- Global Left atrial Strain

LA- Left atrium

LAE-Left atrial enlargement

LAP- Left atrial pressure

LAVI- Left atrium Volume index

LVEDP-Left ventricular end diastolic pressure

LVEF- Left ventricular ejection fraction

MAP-Mean arterial pressure

MPAP-Mean pulmonary artery pressure

MR- Mitral regurgitation

MS- Mitral stenosis

MV-Mitral valve

MVA- Mitral valve area

MVG-Mitral valve gradient

MVR-Mitral valve replacement

NYHA- New York Heart Association

PA-Pulmonary artery

PAH-Pulmonary artery hypertension

PALS- Peak atrial longitudinal strain

PACS- Peak atrial contractile strain

PASP-Pulmonary artery systolic pressure

PADP-Pulmonary artery diastolic pressure

PCWP-Pulmonary Capillary wedge pressure

PHT-Pressure half time

PVR- Pulmonary vascular resistance

RA-Right Atrium

RHD- Rheumatic heart disease

RVSP-Right ventricular systolic pressure

RVEDP- Right ventricular end diastolic pressure

SD- Standard deviation

SR-Sinus rhythm

STE- speckle tracking echocardiography

SVP- Subvalvular pathology

TAPSE-Tricuspid annular plane systolic excursion

TEE- Transesophageal echocardiography

TMG- Transmitral gradient

VCAM-1- Vascular cell adhesion protein

SYNOPSIS

Introduction

Severe mitral stenosis leads to morphological and functional changes in left atrium (LA) causing dysfunction. Relieving mitral obstruction improves the LA mechanics and structural remodelling. However, this is not taken as a measure of successful BMV in clinical practice. Global left atrial strain (LA) has been used as a novel assessment tool to evaluate left atrial function. We studied the relationship between global left atrial (LA) strain and severe mitral stenosis and the effect of BMV on LA strain.

Aim

To assess the relationship between global left atrial (LA) strain and severe mitral stenosis and the effect of BMV on LA strain. We also aimed to study Whether Global LA strain following valvotomy can be taken as a surrogate indicator of successful BMV.

Results

A total of 40 patients satisfying the criteria for severe mitral stenosis underwent balloon mitral valvotomy (77.5 % females; mean age, 39.3 ± 10.6 years). Global left atrial strain was assessed by speckle tracking echocardiography before and after valvuloplasty. Global LA strain was impaired in patients with severe mitral stenosis and improved 24 h following BMV (11.93 ± 3.29 % vs 14.96 ± 3.59 $p < 0.001$). There was a significant decrease in mitral mean gradient (MMG) (12.0 ± 4 mmHg vs 3.2 ± 1.6 mmHg, $p < 0.001$) and systolic pulmonary artery pressure (sPAP) (42.0 ± 8 mmHg vs 40.0 ± 4.8 mmHg, $p < 0.001$) after BMV. Mitral valve area (MVA) (1.03 ± 0.27cm^2 vs 1.81 ± 0.31cm^2, $p < 0.001$) significantly increased after BMV. LA strain failed to predict the success of the procedure(AUC- 0.53 ; 95% CI, 0.32-0.75, $p = 0.791$). A

cutoff value of 11.42% demonstrated a sensitivity of 64.7% and specificity of 66.7% to predict Procedural success. There was a weak correlation between Post procedure LA strain and MV area (R= 0.33 ; 95% CI- 0.09, 0.6,p=0.038).

Conclusion

Left atrial function specially PALS (peak atrial longitudinal strain) is severly impaired in patients with severe Mitral Stenosis. PALS shows a significant improvement following a successful BMV. This increase in PALS values reflects an improvement in clinical status and an improvement in function class in follow up. Thus, it seems reasonable to suggest LA strain as a surrogate marker in evaluating the response to BMV in patients of severe rheumatic MS.

Keywords: Balloon mitral valvotomy, peak atrial longitudinal strain, Speckle tracking echocardiography

INTRODUCTION

Rheumatic heart disease (RHD) accounts for large proportion of prevalent Cardiovascular disease and mortality in developing countries. Recent surveys showed it is the fifth highest-ranked cardiovascular cause of daily adjusted life years for Asia and the ranked sixth around the world.(1)(2) Among all the cardiac valves involved in RHD, mitral valve is most commonly effected by stenosis and or incompetence.(3)

Vieussens described MS (Mitral stenosis) in 1705 first, Surgical mitral commissurotomy and mitral valve replacement were the initial treatment provided to the symptomatic patients. Landmark innovation of Japanese surgeon Kanji Inoue in 1984, changed the perspective of treatment for severe mitral stenosis.(4)(5) Ballon mitral Valvotomy (BMV) has since proven to be effective treatment for suitable valves. However, outcomes of BMV are variable and depend on the anatomy of the valve.

Mitral stenosis leads to both volume and pressure overload of the ventricle. This overload helps in maintaining adequate left atrial pressure (LAP) so that blood flows through the stenotic valve, it is essential that the left atrium functions properly. In Normal individuals, LA contributes around 25-30% to the cardiac output and this contribution gains more importance in patients with LV dysfunction and mitral stenosis. Mitral stenosis gradually leads to remodelling of the left atrium by interstitial fibrosis, myocyte necrosis, and disorganization of atrial muscle bundles,which ultimately leads to the atrial dilatation. Both relaxation and contraction functions of Left atrium are impaired over the period leading to progressive impairment of left atrium mechanics causing dysfunction(6)

Echocardiography remains the mainstay for selection of suitable cases, intra-operative steps and assessment of successful procedure. Prediction of successful BMV procedure is done before the procedure with scores like Wilkins and Padial score. Both short and long term

success of BMV is defined with increase in Mitral valve area and decrease in transmitral gradient. These methods have their own limitations.(7)(8) Relieving mitral obstruction improves the LA functional and structural remodelling. However, this is not taken as a measure of successful BMV in clinical practice.

Both invasive and non invasive methods are available to assess left atrial function.Non invasively, LA mechanics and function can be assessed via various 2D-Echocardiographic techniques including M-mode evaluation and tissue Doppler imaging. The major limitations of these modalities are that they are either time-consuming or difficult to apply. High observer dependency affect their reproducibility, lastly sometimes they tend to be inaccurate as they are load-dependent. (9)(10)

These shortcomings were overcomed by the advent of Tissue Doppler imaging which can accurately evaluate myocardial properties in a load independent manner. These values are also highly reproducible. Tissue Doppler derived Strain Rate and Strain imaging actually reflect the myocardial deformation as it is not affected by translational movements. Strain imaging has been used initially for assessing myocardial deformation in ventricles. (11) It has also been utilised for evaluation of LA function and which includes left atrium reservoir, conduit and contractile mechanics. Strain evaluates regional myocardial deformation while strain rate examines the rate of change in strain. (12) The feasibility of STE for the study of LA function have been validated in several studies, strain values are reproducible in almost 90% of cases. (13)(14) Global LA strain has greater value than LA volume index. LA peak longitudinal strain (PALS) can be easily assessed by speckle tracking echocardiography and it reliably reflects the LA function. In various clinical settings PALS has shown significant association with major cardiovascular events .(15)

Though previous researchers have studied the impact of BMV on various LA parameters like volume, reservoir and pumping function, and but effect on global LA strain is unknown.(16)(17)(18) There is sparse data regarding assessment of LA function by Global LA strain in patients with severe mitral stenosis undergoing BMV. This study aimed to assess LA function by Global LA strain in this patient population. This study will also help in assessing the feasibility of Global LA strain as a surrogate marker of successful BMV.

AIMS & OBJECTIVES

Aim

Study the relationship between global left atrial (LA) strain and severe mitral stenosis and the effect of BMV on LA strain.

Primary objective

To assess LA function by global LA strain in patients with severe MS and change in it post Ballon mitral valvotomy at post Procedure.

Secondary objective

To assess the relation of change in global LA strain with development of atrial fibrillation in short term follow up

Expected outcome and application

1. Global LA strain can be taken as an indicator of left atrial function, and its improvement following valvotomy might be taken as a surrogate indicator of successful BMV.

2. Improvement in left atrial strain might be associated with reduction in rate of atrial fibrillation.

3. Whether LA strain can be taken as surrogate indicator for successful BMV

REVIEW OF LITERATURE

Rheumatic Fever and RHD contribute to a significant proportion of cardiovascular morbidity and mortality worldwide. Despite a notable and continuous decline in the incidence of ARF and RHD in the industrialized, high-income developed nations with high human development indices and improved health systems, it poses a major public health burden in developing countries like India. The rural poor and marginalized populations with limited access to primary health care continue to have high prevalence of the disease.(19)

Rheumatic Fever and Rheumatic Heart Disease are a consequence of delayed immune response to Group A Streptococcal (GAS) pharyngitis, and constitute the non-suppurative complications of streptococcal infection. ARF is characterised by inflammatory process with varying degrees of involvement of the joints and the heart, classically manifesting as migratory polyarthritis and acute onset valvular regurgitation. Basal ganglia is also involved occasionally secondary to the autoimmune process resulting in chorea. The diagnosis of ARF is made based on modified Jones criteria in the presence of two major or one major and two minor criteria with a prerequisite and supportive criteria of preceding GAS infection. Cardiac manifestations, though not the most often involved system, contribute significantly to long term outcomes. Also, most manifestations of acute rheumatic fever except the valve lesions resolve without leaving a sequelae. Though the severity of valvular lesions reduce with the resolution of the acute phase, they may persist or further worsen, resulting in permanent rheumatic heart disease. Mitral Valve is the predominant valve involved in RHD, though involvement of other valves is also known. (20)

Epidemiology

The incidence of acute rheumatic fever is variable and is attributable to the degree of socioeconomic development and general improvements in prompt treatment of GAS

infections. Although the disease incidence has come down in high-income countries, disease resurgence and occasional outbreaks have been reported in some of these countries.(21) An estimated incidence of 470,000 acute RF cases per annum is described globally, of which 60% lead to rheumatic heart disease. Most published prospective studies suggest that acute rheumatic fever annual incidence ranges between 8 and 51 per 100,000 among children and young people. The prevalence of Acute Rheumatic Fever and Rheumatic Heart Disease reported from India varies from very infrequent to very high . Most of the literature is from surveys conducted in schools, Indian registry and hospital admission data. Recent studies from two endemic regions revealed annual rates that are lower than 20 per 100,000 population (22)(23)

Acute rheumatic fever occurs in school going age group. Although RHD does not have any gender predilection but it is more often seen in females. This is explained by the difference in the autoimmune response leading to differences in valvular damage and severity.(24)

Pathogenesis

The exact pathogenesis of acute rheumatic fever remains elusive. Most available evidence supports the view that acute rheumatic fever is mediated through molecular mimicry, because of an exaggerated auto-immune response to Group A Streptococcal pharyngitis. The initial insult in the form of pharyngitis infection by streptococcus leads to the activation of a cascade with increased T & B lymphocytes by Streptococcal antigens and superantigens, resulting in production of antibodies and cytokines directed against Streptococcal carbohydrate and myosin. The clinical manifestations of this autoimmune response and its severity in individual patients is determined by multiple factors like inherent genetic susceptibility of the host, virulence of the infecting organism and presence of a conducive environment. Approximately

0·3–3% of patients with GAS pharyngitis develop acute rheumatic fever, depending on the aforementioned factors. (25)

Another theory proposed involves upregulation of VCAM 1 and other adhesion molecules. The injury to the valvular endothelium by anti-carbohydrate antibodies leads to an overexpression of VCAM 1 and other adhesion molecules. VCAM 1 further interacts with very late antigen present on the activated T and B lymphocytes leading to the extravasation of activated CD4 and CD8 lymphocytes into the milieu of valve tissue. VCAM 1 expression considered as a hallmark of inflammation and it heralds cellular infiltration. The breach in endothelial continuity of a endocardium in heart by anti-streptococcal antibodies further expose subendothelial structures and lead to a chain reaction of valvular destruction. Inflamed and damaged leaflets undergo revascularization, and activated lymphocytes can infiltrate the valve both from outside and from within by means of the revascularization. This vicious cycle perpetuate the valvular injury leading to valvular scarring and chronic lesion s in long term.(2)(26)

In acute stages, acute rheumatic valvulitis manifests as valvular regurgitation, but chronic inflammation leads to valve stenosis and/or associated regurgitation over time. Later stages of RHD are characterized by MS resulting from commissural fusion, involving parts of the mitral valve apparatus to varying degrees. In most endemic regions of the world, RHD manifests as a malignant fulminant course associated with recurrent bouts of ARF.(27)

Pathologic Evolution of Mitral Stenosis

Acute rheumatic fever with active carditis often results in the presence of small, translucent nodules distributed along the line of closure of the mitral valve, less commonly also involving sub valvular chordae. Microscopic sections of these nodular vegetations show proliferation of

fibroblasts and macrophages. These small translucent nodular vegetations eventually become opaque and grey, and in later stages most of the valve leaflet becomes thickened. Hence, changes within the valve structure involves loss of the normal morphology due to fibrin deposition on the cusps, hyalinization, with eventual covering of the leaflets with endothelium. These pathophysiological processes lead to fusion of the valve commissures.

Study by Brock et al showed that the first point of fusion of the two leaflets of the valve occurred at the "critical area of tendon insertion," described as the point where the most direct and the shortest chordae connect with the cusps. (28) Fusion at these points leads to immobilization of portions of the cusps lateral to them, thereby making way for more commissural fusion. Once Mitral Stenosis is fully established, three distinct types have been recognized:

1. Commissural: fusion of the commissures with minimal involvement of cusps or chordae

2. Cuspal: Leaflets are transformed into stiff, rigid, leathery (later calcified) structures; and

3. Chordal: in which the chordae are fused, shortened, and thickened, thereby interfering with the easy mobility of the leaflets.

In addition to the pure forms, combination of these types occurs. Various anatomic forms of mitral stenosis may affect atrioventricular filling in similar manner. (29)

Pathophysiology of Mitral Stenosis

Normally, the orifice of a Mitral Valve ranges from 4 to 6 square centimetres., which essentially creates a common chamber between left atrium and left ventricle in diastole. During very early diastole, there is a small gradient between the left atrium and the left ventricle, which

rapidly dissipates so that the pressure in the two chambers is equal during most of the filling. In Mitral Stenosis,as the Mitral orifice narrows it decreases free flow of blood from left atrium to left ventricle, and a pressure gradient develops between the 2 chambers.

As a result of this pressure gradient, left ventricular diastolic pressure is increased, resulting in an increase in left atrial pressure, which leads to left atrial enlargement and pulmonary congestion. Left ventricular output is limited by flow restriction as the severity of the stenosis increases.

Since it is primarily the left atrium that generates the force necessary to drive blood across the stenotic Mitral Valve, Mitral Stenosis causes left atrial structural and functional abnormalities. These left atrial abnormalities like left atrial enlargement may lead to various complications associated with Mitral Stenosis like atrial fibrillation, or predisposition to left atrial clot formation. Thus it is essential to understand the importance of Left Atrial function in Mitral Stenosis and methods to assess it.

Table 1 : Grading of severity of mitral stenosis

	Mild	**Moderate**	**Severe**
Mitral valve area (cm^2)	>1.5	1-1.5	<1
Mean Gradient (mm Hg)	5	5-10	>10
Pulmonary Artery Systolic Pressure (mm Hg)	30	30-50	>50

As per 2020 ACC/AHA Guidelines for the Management of Valvular Heart Disease, 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. (30)

Table 2 : Stages of mitral stenosis

Stages	Definition	Valve anatomy	Valve Hemodynamics	Hemodynamics Consequences	Symptoms
A	At risk of MS	Mild valve doming during diastole	Normal transmitral flow velocity	None	None
B	Progressive MS	Rheumatic valve changes with commissural fusion and diastolic doming of the mitral valve leaflets Planimetered mitral valve area >1.5 cm2	Increased transmitral flow velocities Mitral valve area >1.5 cm2 Diastolic pressure half-time <150 ms	Mild to moderate LA enlargement Normal pulmonary pressure at rest	None
C	Asymptomatic severe MS	Rheumatic valve changes with commissural fusion and diastolic doming of the mitral valve leaflets Planimetered mitral valve area ≤1.5 cm2	Mitral valve area ≤1.5 cm2 Diastolic pressure half-time ≥150 ms	Severe LA enlargement Elevated PASP >50 mm Hg	
D	Symptomatic severe MS	Rheumatic valve changes with commissural fusion and diastolic doming of the mitral valve leaflets Planimetered mitral valve area ≤1.5 cm2	Mitral valve area ≤1.5 cm2 Diastolic pressure half-time ≥150 ms	Severe LA enlargement Elevated PASP >50 mm Hg	Decreased exercise tolerance Exertional dyspnea

MS mitral stenosis, mm Hg millimetres of mercury, MVA mitral valve area, PHT pressure half time, PASP pulmonary artery systolic pressure, LA left atrium

These guidelines suggest the following indications for intervention in mitral stenosis

- In symptomatic patients (NYHA class II, III, or IV) with severe rheumatic MS (mitral valve area ≤1.5 cm^2, Stage D) and favourable valve morphology.

- In asymptomatic patients with severe rheumatic MS (mitral valve area ≤1.5 cm^2, Stage C) and favourable valve morphology

Long term outcomes in various studies have shown approximately 70% to 80% of patients with an initial good result following PBMV are free of recurrent symptoms after 10 years, and 30% to 40% are free of recurrent symptoms after 20 years.(31)(32)

LA function

Left Atrial function is influenced by both atrial and ventricular factors. The atrial factors affecting Left Atrial function include Left Atrial contractility & relaxation, Left Atrial pressure & compliance and rhythm abnormalities. Ventricular factors include Mitral annular displacement, Left Ventricular compliance & relaxation.(33)

Left atrium modulates left ventricular filling through three components, a phase of reservoir or expansion during systole, a conduit phase during diastole and an active contractile component during late diastole. This active contractile component of left atrium has an important role in patients with ventricular dysfunction as a ‘booster pump’ to augment ventricular volume. Augmented left atrial booster function is one of the mechanisms compensating for decreased early filling in patients with reduced left ventricular compliance, whereas a loss of atrial

contraction, as a result of atrial fibrillation or ventricular pacing, reduces cardiac output by approximately 15 -20%.An isolated decrease in left atrial compliance is associated with relative increase in the conduit function of the left atrium. The ability to optimally redistribute left ventricular filling among reservoir, conduit and booster pump functions in a potentially important adaptation that may occur in left atrium in response to changing hemodynamics.(33)(34)

Multiple population studies have shown LA volume as a predictive tool for future cardiac events. This event rates persisted even after adjustment for age, gender and other covariates. Left atrial dilatation can occur in a broad spectrum of cardiovascular diseases including hypertension, left ventricular dysfunction, mitral valve disease and Atrial Fibrillation.

Left Atrial function is influenced by both atrial and ventricular factors. The atrial factors affecting Left Atrial function include Left Atrial contractility & relaxation, Left Atrial pressure & compliance and rhythm abnormalities. Ventricular factors include Mitral annular displacement, Left Ventricular compliance & relaxation.(35)

In Framingham Heart study, M-mode derived Left Atrial size was an independent risk factor for development of Atrial Fibrillation. Another study by Mayo clinic group demonstrated that Left Atrial volume was a strong predictor of Atrial Fibrillation, incremental to clinical risk factor. (36)(37)

Current techniques to evaluate LA function

Left atrial function cannot be defined by a single parameter. The routine clinical practice commonly utilizes the Transthoracic echocardiography in assessing the Left Atrial size using numerous methods including the cubical method, area- length method, ellipsoid method and

modified Simpson's rule. Three-dimensional echocardiography is the recent introduction and its feasibility for assessing the Left Atrial volumes has been demonstrated in several studies. During the past few years, multi-slice CT (MSCT) has become increasingly popular for cardiac imaging. The quantification of Left Atrial volumes (by using the modified Simpson's method) is accurate with MSCT as the latter has an excellent spatial & temporal resolution. The radiation exposure and the use of contrast agents, however, restricts the routine use of MSCT in assessing the Left Atrial size. Since MRIs have excellent spatial resolution and can detect myocardial borders, they are considered the most accurate technique for assessing atrial volumes non-invasively. MRI can provide comprehensive data of Left Atrial size and volumes throughout the cardiac cycle using modified Simpson's method as used in MSCT.(38)

There no standardized parameters are available Regional Left Atrial function as it is not routinely assessed perhaps because the relatively thin Left Atrial walls hamper the non-invasive evaluation of regional Left Atrial function. Atrial electromechanical remodelling can be better understood when regional Left Atrial function is assessed and then used to treat Atrial Fibrillation surgically or by catheter ablation. The regional function of the myocardium can be assessed non-invasively using a novel echocardiographic technique, such as Tissue Doppler imaging and Strain (rate) imaging. This technique quantifies the regional tissue velocities of the myocardium. The local tissue deformation and the rate of local deformation is represented by Strain and Strain rate respectively.

Strain and strain rate imaging of the LA

Novel non-invasive imaging tools for assessing regional myocardial deformation of the Left Atrium are Strain and Strain rate imaging. It offers several advantages over conventional echocardiography in the functional evaluation of LA.

Myocardial tethering does not impede strain imaging, unlike tissue doppler imaging. Since strain imaging is not based on transducer position, it can distinguish between active and passive myocardial tissue movement. As compared to traditional parameters of LA function, strain parameters are relatively independent of tethering effects and load dependent. Additionally, strain imaging can distinguish active contraction from passive motion . (39)(40)

There are no validated strain algorithms developed till date for functional evaluation of LA. To evaluate LA strain, several studies have used strain software designed for the left ventricle, adjusted to the width of the 'region of interest' (ROI).(41)(14)

Tissue Doppler imaging (TDI), speckle tracking echocardiography (STE), and velocity vector imaging (VVI) can all be used to measure LA strain. Using the apical four and two chamber views, longitudinal strain and strain rate curves are generated for each of the six atrial segments for STE and VVI. The left ventricular (LV) filling is modulated by LA through 3 components: the reservoir phase of expansion during systole, a conduit phase during early diastole, and an active contractile component during late diastole. These phases account for 40, 35, and 25% respectively, of the atrial contribution to stroke volume in normal subjects.

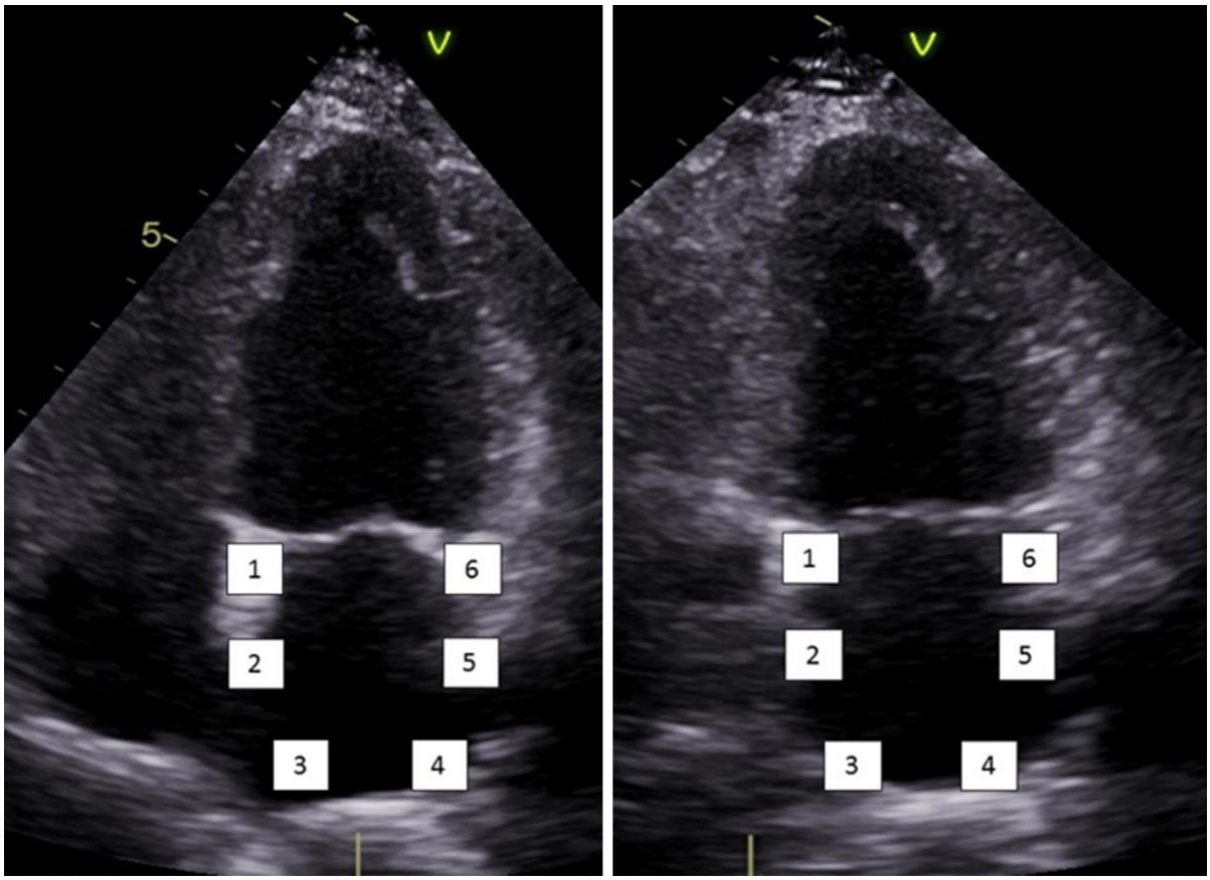


Figure 1 Apical four and two chamber six LA segments. LA, left atrial.

The filling and stretching of LA in the reservoir phase create a positive atrial strain that becomes maximum at the end of LA filling before the mitral valve opens. The opening of the mitral valve leading to passive emptying of LA results in decreased atrial strain with negative deflection of the strain curve up to a plateau period equivalent to diastasis. The strain curve then shows a second deflection and it corresponds to atrial systole.(Fig1)

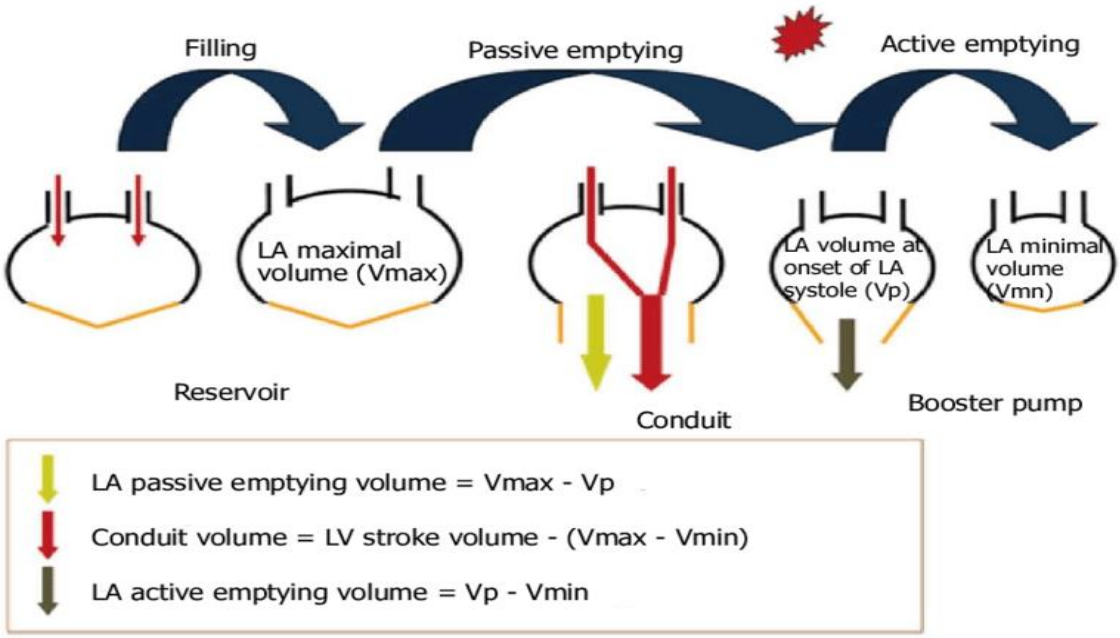


Fig.2 Dynamic structure and functions of left atrium.

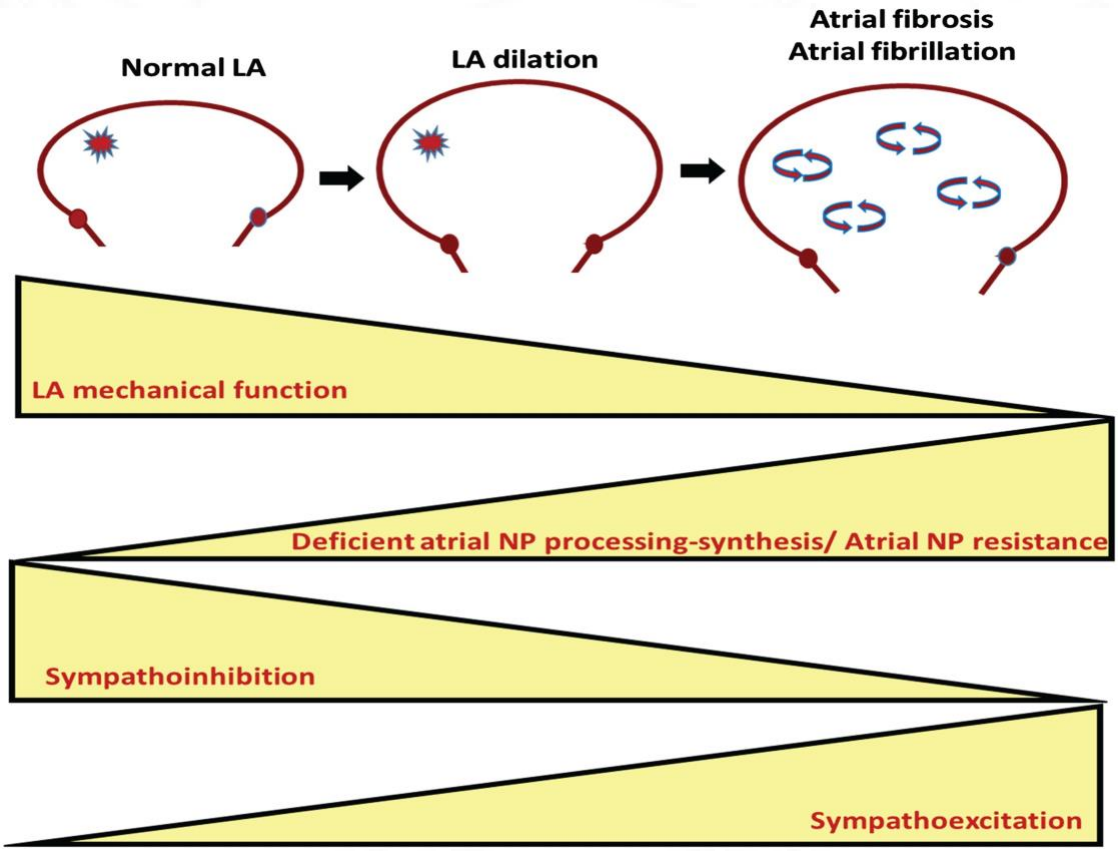


Fig.3. Mechanism of atrial fibrosis and Left atrial dysfunction.

At the conclusion of the reservoir phase, the peak atrial longitudinal strain (PALS) or LA systolic strain is assessed. Following the P wave, the late diastolic strain, also known as peak atrial contraction strain (PACS) is measured and it corresponds to the active atrial contraction (Figure 2)(42)

LA strain and strain rate reference values have been published. Morris et al. observed LA systolic strain (i.e., PALS) to be 45.5%11.4% and LA strain rate during late diastole (i.e., PACS) to be 2.110.61 s^{-1} in a multicenter research involving 329 healthy participants. The lowest expected values (using mean −2 SD) was 23.1 % for LA systolic strain and −0.91 s^{-1} for A sr in late diastole.(43)(44).

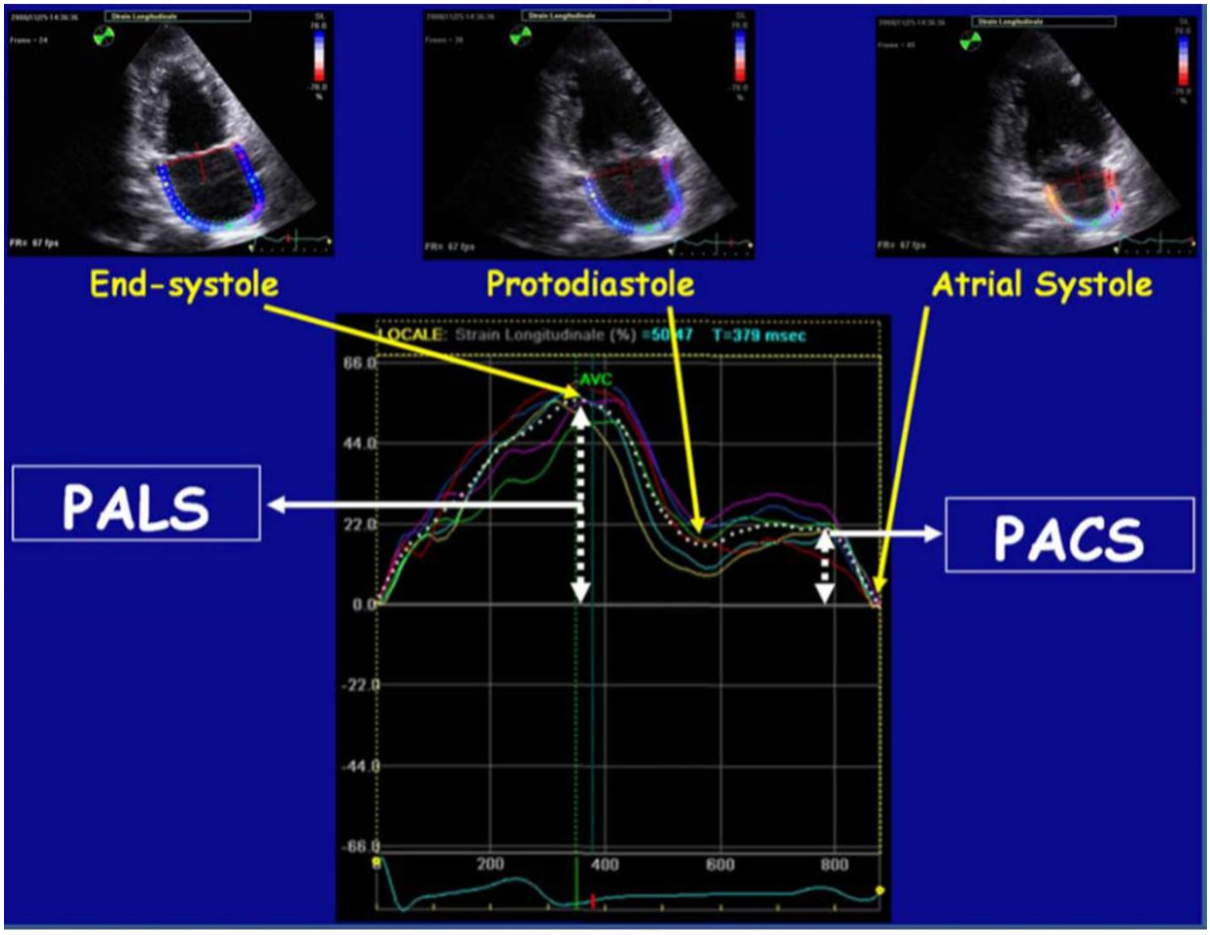


Fig.4. Peak atrial longitudinal strain (PALS) and Peak atrial contractile strain (PACS)

The atrial longitudinal strain, deriving from application of the analysis of myocardial deformation using STE at atrial chambers, results the first parameter useful for functional analysis of the LA and, as shown by recent studies, it presents considerable feasibility and reproducibility (14)(45) Speckle tracking echocardiography (STE) estimates Left atrial (LA) peak longitudinal strain (PALS) which reflects the LA phasic function. In predicting AF in the general population, PALS was found out to be superior to conventional echocardiographic atrial parameters in the previous studies. There is evidence of association of PALS with major cardiovascular outcomes including heart failure (HF)(46)(47). A study by Pavasini et al showed that the PALS is altered in patients with CAD and COPD and is an independent predictor of AF.(48)

Strain imaging in mitral stenosis

Even though LA dilation is a significant predictor for the development of Atrial Fibrillation (AF) in MS, the severity of the MS, atrial dilation, and LA pressure all independently correlate with AF in MS. The fibrosis can be detected early using Atrial 2D strain which may assist in identifying asymptomatic MS patients at risk for developing AF. The utility of decreased LA deformation by 2D strain imaging to stratify risk of stroke in patients with permanent AF is demonstrated in another study. (49)(50)

In patients with severe mitral stenosis reservoir, conduit and contractile strain values are severely decreased signifying severe LA dysfunction as against those with mild mitral stenosis where contractile strain is preserved or in fact increased in initial phase. As LV filling primarily occurs during the LA contractile phase in MS in contrast to normal filling pattern, where LA filling primarily occurs in the early conduit phase in mild MS, the preserved LA contractile

function compensates for the reduced LA reservoir and conduit function in mild MS. (51).The steps of LA strain imaging has been explained in Methodology section.

MATERIALS AND METHODS

Study Design

This was a Prospective Observational single centre study

The protocol was approved by the Institutional Ethics Committee [SCT/IEC/1911]

Setting and Recruitment

All patients during the study period who had severe symptomatic mitral stenosis, suitable for BMV procedure and met inclusion criteria were included in the study. This study was done at the department of Cardiology, Sree Chitra Tirunal Institute for Medical Sciences and Technology, Trivandrum, India between April 2022 and October 2022.

Inclusion criteria

- Age > 18years
- RHD with severe MS planned for BMV as per standard guidelines and institution protocol.

Exclusion criteria

- Atrial fibrillation
- Coexistent valvular abnormality of more than moderate severity
- Coronary artery disease
- Advanced systemic diseases causing LA dysfunction
- Those developing severe MR following BMV requiring immediate surgical intervention were excluded from the study.

Methodology

The clinical, echocardiographic and hemodynamic parameters at the time of BMV were analysed. All the patients prior to the procedure had detailed clinical and echocardiographic evaluation. The data collected included NYHA class and heart rhythm. Mitral valve structural pathology was assessed. Commissural calcification was assessed for the suitability of BMV. Mitral valve area was determined by 2D echo planimetry and doppler pressure half time method. LA diameter measured in parasternal long axis (PLAX) view was taken.

Transmitral gradient was measured in apical four chamber view by continuous wave Doppler. Pulmonary artery hypertension was assessed by the right ventricular systolic pressure with peak tricuspid regurgitation jet velocity using modified Bernoulli's equation ($4v^2$ + Estimated right atrial pressure).

Prior to the procedure, transesophageal echocardiography was performed for every patient to rule out any clot in the left atrial body or the left atrial appendage. In addition transesophageal echocardiography provided additional information on the mitral valve structure and the severity of mitral regurgitation.

Hemodynamic data was obtained from the cardiac catheterization at the time of BMV. Right and left heart catheterization was performed and transseptal puncture was done using Brockenbrough needle. Mean left atrial pressure, left ventricular end diastolic pressure, pulmonary artery pressure, transmitral gradient, mitral valve area, cardiac output and the cardiac index were obtained and compared pre and post procedure.

BMV was done using Accura balloon (Vascular concepts, Essex, UK) using the Inoue technique . Maximum balloon size was chosen using the formula.

Balloon size (mm) = (Patient's height (cm)/10) +10.(52)

Procedural success was defined as increase in mitral valve area of at least 50% from the basal or a final valve area of >1.5 cm^2 with no major complications.

Strain Analysis

Two-dimensional strain uses grayscale (B-mode) sector images and is based on frame-by-frame tracking of small rectangular image blocks with stable speckle patterns. A minimum frame rate of 50 Hz was required for reliable operation of this program, and frame rates of 50 to 90 Hz were used for routine grayscale imaging. The apical four-chamber view was obtained using the same ultrasound system and probe used for standard echocardiography. Eight step approach has been proposed which is common to all vendors.(53)

1) Image acquisition and/or selection.

2) Electrocardiographic orientation "reference"

3) Detection and marking of fiducial landmarks

4) Detection and tracing of the endocardial border

5) Adjustment of regions of interest

6) Evaluating tracking quality

7) Excluding segments of inadequate and/or poor tracking; and

8) Repeating in more than 1 view and then averaging to minimize error.

Accordingly, for each segment, during LV systole, LA wall longitudinal lengthening was represented with a peak positive strain value; it is observed because of filling of the atrial cavity by blood coming from the pulmonary veins while the mitral valve is closed. Myocardial longitudinal shortening was represented with a peak negative strain value; it occurs during LV diastole, when the atrium empties into the LV cavity. The tracking process and conversion to Lagrangian strain was performed offline using dedicated software (Qlab software Phillips Epiq 7). Although this software was validated for the measurement of LV strain, it has been previously used for measuring LA strain with high feasibility and good agreement in many studies.(Figure 5)

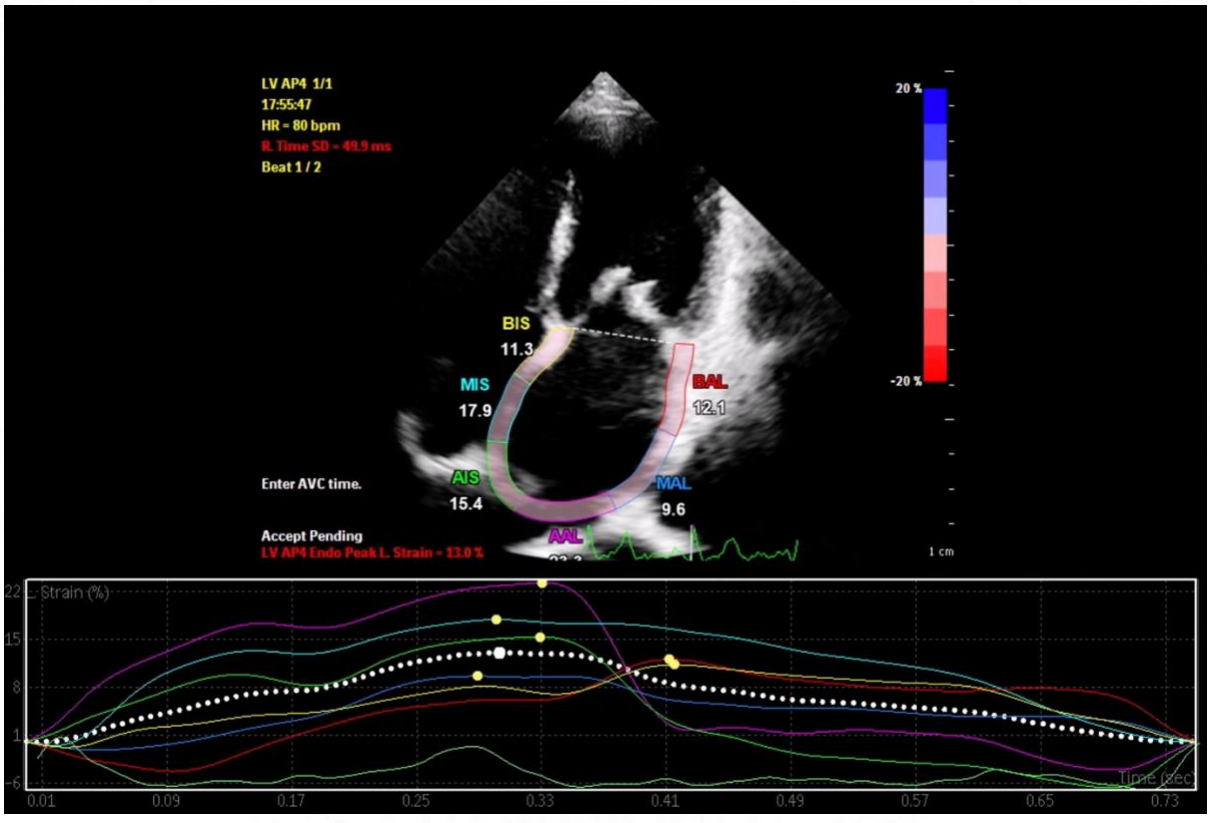


Fig.5.Preoperative LA strain in one of the study patient using Qlab software on Phillips Epiq7 Ultrasound Machine.

Statistical Analysis

We obtained a sample size of 29 in total.Sample size was calculated with alpha of 1%, clinical significant difference (d) of 2, and power of 90% using the following equation:

‘‘$n-2(z1-\alpha/2+z1-\beta)2\ \delta 2/d2$.

Data was analysed by using both descriptive and inferential statistics.Data are expressed as mean ± standard deviation. Continuous variables were analysed using unpaired Student’s t test and categorical variables using Chi-square and Fisher exact test. Comparison of variables before and after the procedure was carried out using paired t test. A p value <0.05 was considered to be significant. All analyses were performed using SPSS 26.

RESULTS

The purpose of this study was to assess LA function by Global LA strain in patients with severe Mitral stenosis undergoing Ballon mitral valvotomy. We Hypothesized that Global LA strain is severely reduced in patients of severe mitral stenosis. Ballon mitral valvotomy improves the LA mechanics and strain and can be taken as a surrogate indicator of successful procedure.

Demographic Data

During the period of 1 year 40 patients were included who underwent detailed echocardiographic assessment pre- and post-balloon mitral valvotomy.

The patients baseline clinical and echocardiographic profiles are shown in Table 1and Fig. 3.. The average age of the participants was 39.3 ± 10.6 years. The study had female preponderance, there were 31 (77.5%) females and 9 (22.5%) male participants .Patients BMI ranged from 13.5-29.4, with mean of 22.56 ± 5.46 kg/m^2

At baseline functional class was evaluated with 24 (60%),15 (37.5%) and 1 (2.5%) patient were in NYHA Class-I,III & IV respectively. Five (12.5%) had past history of cerebrovascular accident and were on oral anticoagulants.(Table 1)

Baseline Echocardiogram

Baseline Echocardiogram showed Mean Ejection fraction of 64.77 ± 6.37 %. All the patient had severe Mitral stenosis with mean Mitral valve area of 0.99 ± 0.16 with planimetry and 1.00 ± 0.10 with pressure half time method. Mean gradient across the Mitral valve was 12.50 ± 4.5 mm Hg. Baseline 6 (15%) did not had any Mitral regurgitation,21(52.5%) had 1+ MR,and 13(32.5%) had 2+ Mitral regurgitation. Average Wilkin's score was 9 ± 1.0. Most of the patients 39 (97.5%) had to Moderate (2+) severe (3+) subvalvular pathology.

Average Left atrial size was 44.60 ± 7.88 mm. Most of the patients had moderate pulmonary hypertension and average RVSP was 39.68 ± 19.72 mm Hg. Baseline peak atrial longitudinal strain was severely reduced in all patients indicating severe LA dysfunction average PALS was 11.93 ± 3.29 %.

Table 1. Baseline characterstics of the study population.

Variables		Frequency (%)
Gender	Male	9 (22.5)
	Female	31 (77.5)
FC Functional class at baseline	2	24 (60.0)
	3	15 (37.5)
	4	1 (2.5)
History of stroke	No	35 (87.5)
	Yes	5 (12.5)
Mobility	2	30 (75.0)
	3	10 (25.0)
Thickening	1	4 (10.0)
	2	25 (62.5)
	3	11 (27.5)
Calcification	1	3 (7.5)
	2	27 (67.5)
	3	10 (25.0)
SVP	1	1 (2.5)
	2	24 (60.0)
	3	15 (37.5)

MR	0	6 (15.0)
	1	21 (52.5)
	2	13 (32.5)
MR Post procedure	0	1 (2.5)
	1	5 (12.5)
	2	27 (67.5)
	3	7 (17.5)
Number of dilations	1	13 (32.5)
	2	21 (52.5)
	3	6 (15.0)

Table 2.Descriptive characterstics of continuous variables in the population

Variables	Mean (SD)/ Median (Q1, Q3)
Age (years)	39.3 ± 10.6
EF – Ejection fraction (%)	64.77 ± 6.37
LA size (mm)	44.60 ± 7.88
MVA by Planimetry(cm^2)	0.99 ± 0.16
RVSP (mm Hg)	39.68 ±19.72
MV Area (cm^2)	1.00 (0.90, 1.10)
MS Grad Mean (mm Hg)	12.50 (10.00, 16.25)
Wilkins Score	9.00 (8.00, 10.00)
TAPSE (mm)	20.00 (19.00, 22.00)

Procedure

There were 34(85%)successful procedure and 6 (15%) cases were deemed failure according to procedural success definition. All patients underwent Right heart catheterization at baseline. Average Ballon size used was 24mm. There were 3 dilatations given in 6 (15%) patients,2 dilatations in 21 (52.5%) patients and single ballon dilatation was given in 13 (32.5%) patients.

Only 5(12.5%) patients did not have any pulmonary hypertension as calculated PA mean pressure was less than 20 mm Hg.However,20 (50%) of the patients had mild pulmonary hypertension,10 (25%) had moderate and 5 (12.5%) had severe pulmonary hypertension.(Table 3)

Table 3. Changes in the parameter Pre and Post BMV

Variable Pressure (mm Hg)	Pre BMV Mean (SD)/ Median (Q1, Q3)	Post BMV Mean (SD)/ Median (Q1, Q3)	P value
RA Mean	6.5 (5.0, 9.0)	6.0 (5.0, 8.0)	0.230
RV ed	8.0 (7.0, 10.0)	8.0 (7.0, 10.0)	0.617
PA sys	42.0 (38.0, 50.0)	40.0 (34.0, 44.8)	<0.001
PA diastolic	18.0 (16.0, 22.0)	16.0 (14.0, 20.0)	0.002
PA mean	26.0 (21.3, 32.0)	26.0 (20.0, 28.0)	<0.001
LA a	30.0 (26.0, 34.8)	22.5 (18.5, 26.0)	<0.001
LA v	26.5 (22.0, 37.5)	20.0 (16.0, 27.5)	<0.001
LA m	24.0 (20.0, 28.0)	16.5 (14.0, 19.0)	<0.001
LV sys	122.43 ± 15.03	122.18 ± 13.62	0.856

LV ed	12.0 (10.0, 14.0)	14.0 (12.0, 16.0)	<0.001
MVG	12.0 (9.3, 16.0)	3.2 (2.0, 4.8)	<0.001
MVA	1.03 ± 0.27	1.81 ± 0.31	<0.001
LA strain	11.93 ± 3.29	14.96 ±3.59	<0.001

Post Procedure

Post Ballon mitral valvotomy right heart catheterization was done in all patients. There were no significant changes in mean RA,RV and LV systolic Pressures. There was statistically significant decrease in Pulmonary systolic,diastolic and Mean pressure. LA mean pressure and LV end diastolic pressure were significantly decreased post procedure. There was statistically significant decrease in MV gradient from 12 ± 4.0 to 3.2 ± 1.6 mm Hg. There was significant improvement noted in MV area from 1.03 to 1.81 cm^2 ($p < 0.001$).Post procedure 7 (17.5%) patients has moderate MR,27 (67.5%) patients had Mild MR while one patient had nil Mitral regurgitation.(Figure 8 ,figure 9)

Post Procedure Echocardiogram and LA strain analysis

Post BMV most of the echocardiographic (mitral valve gradient, mitral valve area,RVSP) and hemodynamic parameters improved significantly . LA strain was measured with previously described methods approximately 24 hours post procedure. There was significant improvement in the peak atrial longitudinal strain from baseline 11.93 ± 3.29 % to 14.96 ± 3.59 % ($p < 0.001$). However, LA strain failed to predict the success of the procedure in univariate analysis. The area under the ROC curve for LA strain was 0.53 (95% CI, 0.32-0.75,p =0.791). A cutoff value of 11.42 demonstrated a sensitivity of 64.7% and specificity of 66.7% to predict the success

of the ballon mitral valvotomy procedure. There was a weak correlation between Post procedure LA strain and MV area with correlation coefficient as 0.33 (95% CI- 0.09, 0.6,p=0.038).(Figure 6)

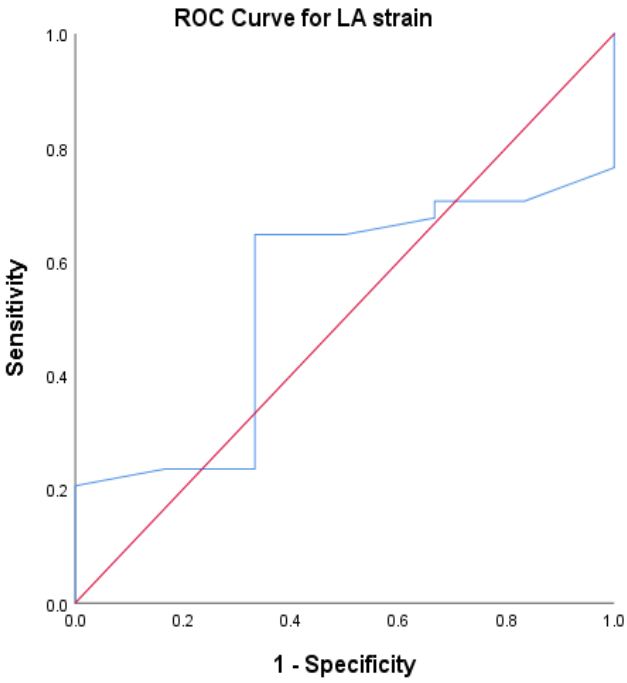


Fig6.ROC Curve for Accuracy of LA strain in prediction of success of procedure

Follow up

Patients were followed up for their function class at first visit, Average duration of their first follow up was 24 ± 3.2 days.All the patients significantly improved in their functional class.There was only 1 (2.5%) patient who was in Class-III on follow up,23 (57.5%) were in Class-II and 16 (40%) of the patients were in Class-I on first visit to hospital post procedure. There were no adverse events noted their follow up and all the patients were in sinus rhythm during the first follow up visit.(figure 7)

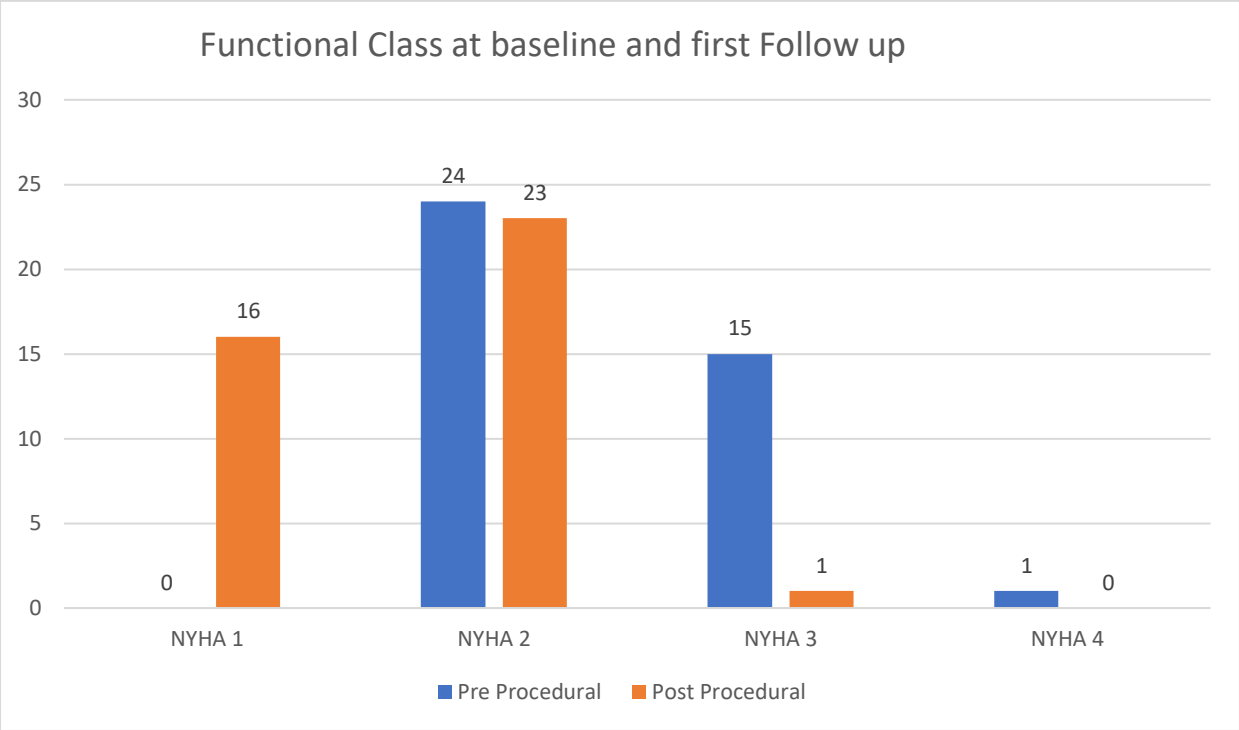


Fig.7.NYHA functional class of the patients at baseline and first follow up.

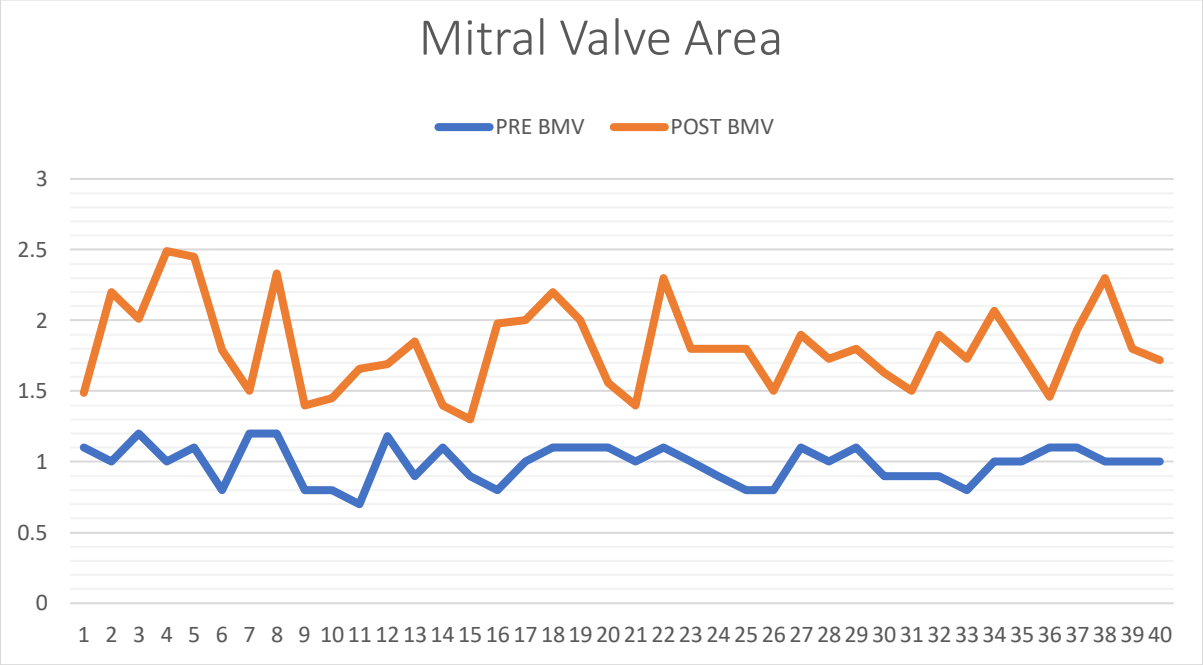


Fig.8.Mitral valve area Pre and Post Procedure.

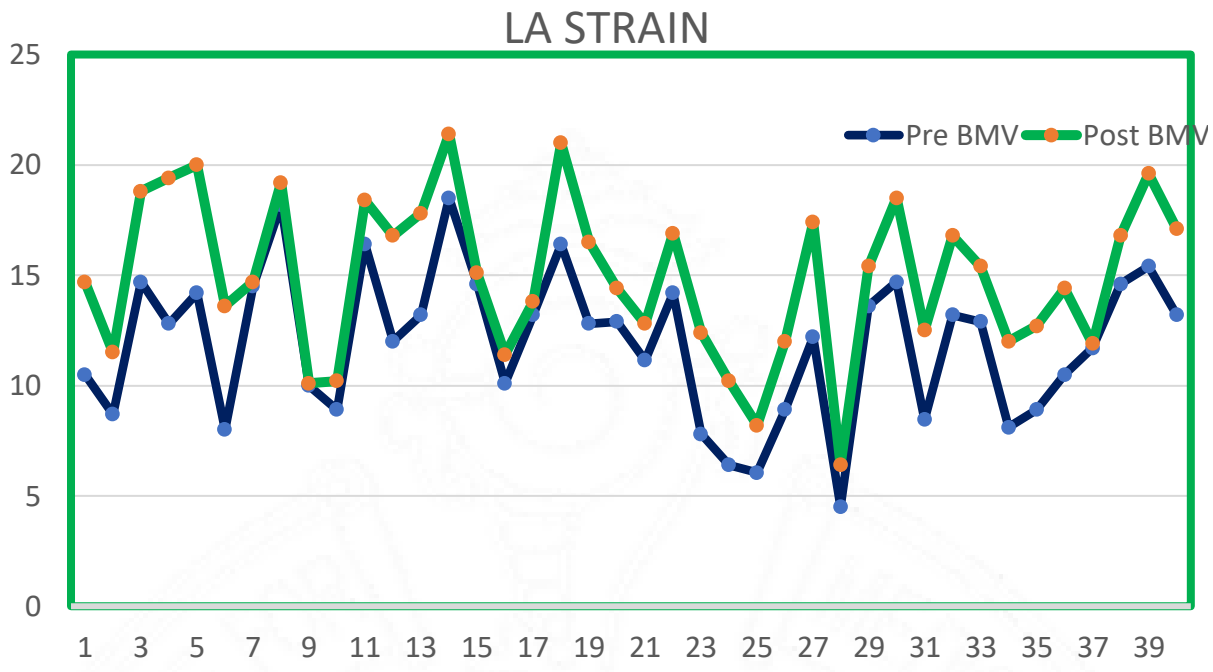


Fig.9. Left atrial strain in patients Pre and Post Procedure.

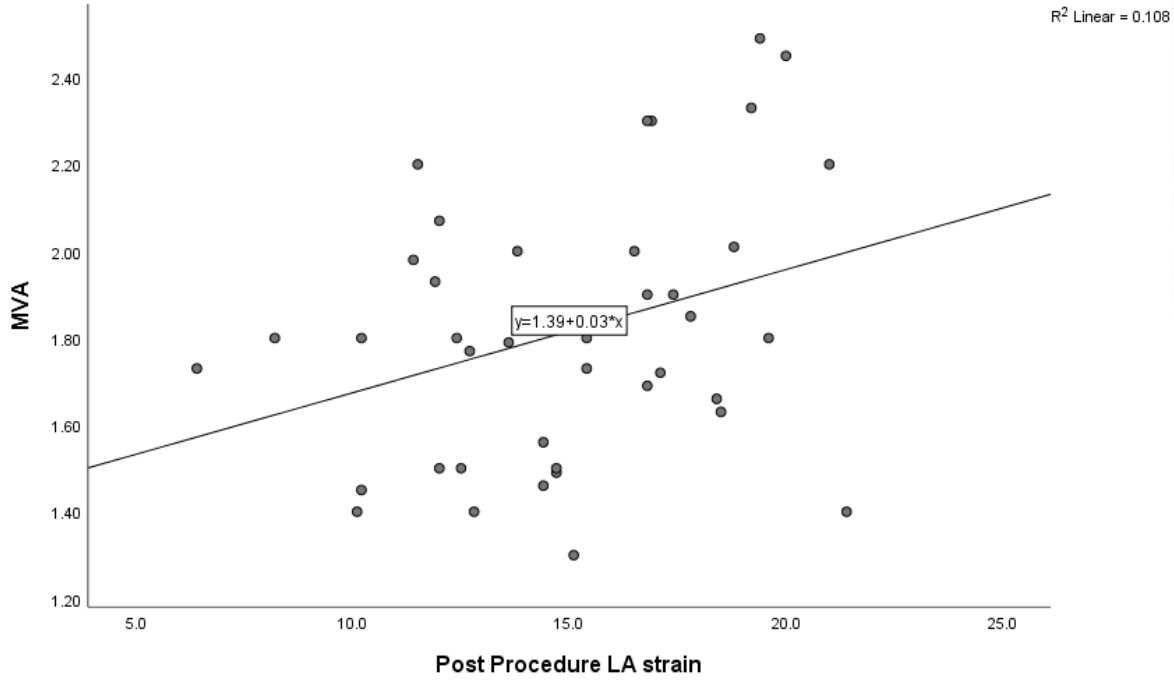


Fig.10 Correlation between LA strain and Mitral valve area Post procedure

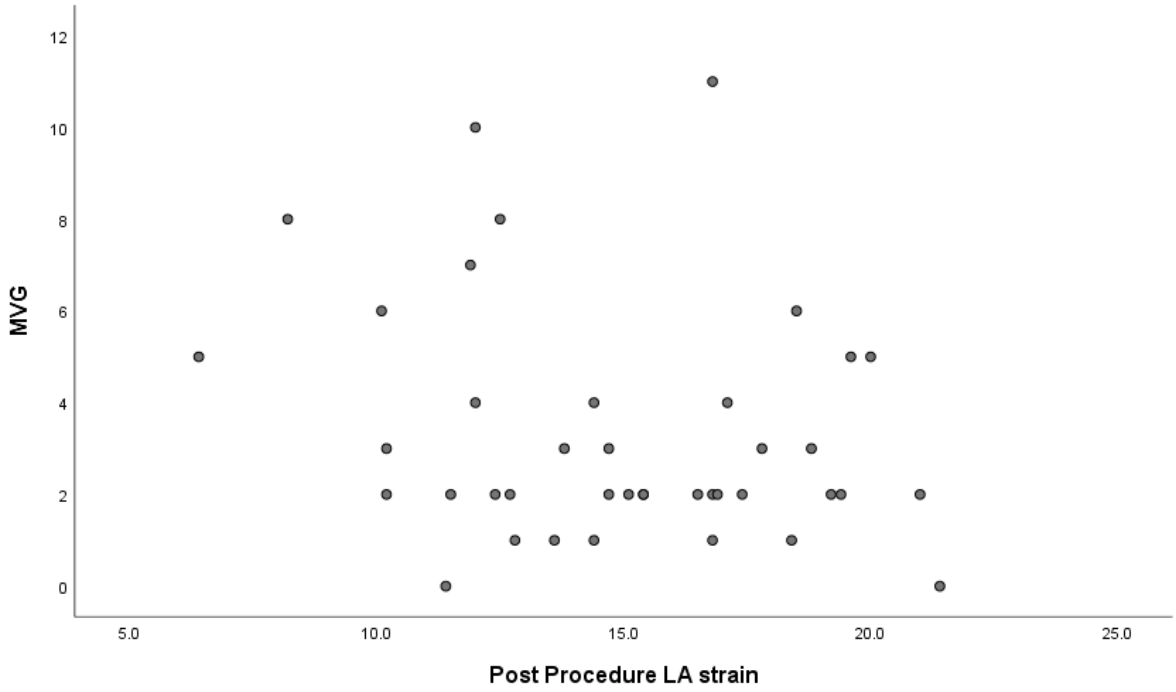


Fig.11. Correlation between LA strain and Mitral valve gradient Post procedure

Table.4. Correlation of Post procedure LA strain with various parameters

Variables		Correlation coefficient (95% Confidence interval)	P value
LA strain	MV area	0.33 (0.09, 0.67)	0.038
LA strain	MV gradient	-0.25 (-0.56, 0.06)	0.128
LA strain	MR severity	-0.06 (-0.37, 0.26)	0.738

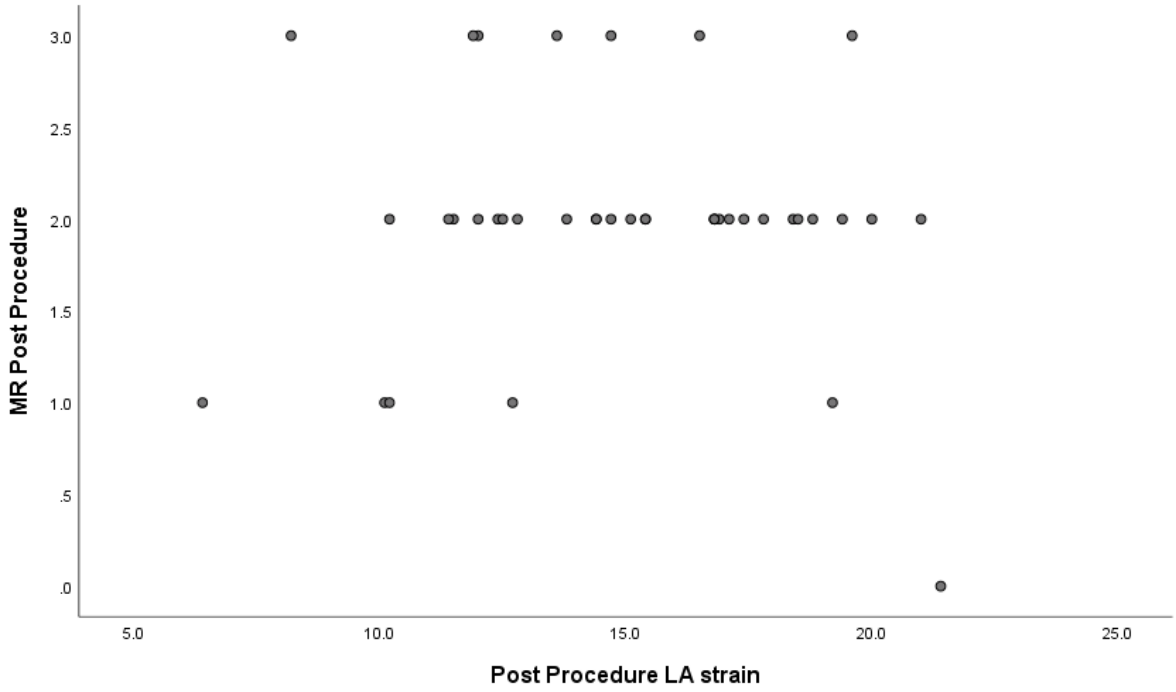


Fig.12.Correlation between LA strain and severity of Mitral Regurgitation Post procedure

DISCUSSION

Index study to our knowledge is one of the few Indian study to assess LA myocardial strain properties in patients with severe MS and effect of BMV on LA mechanics as assessed by Strain analysis . The study demonstrated that peak atrial longitudinal strain is severely reduced in patients with Rheumatic severe MS at baseline and significantly improves after BMV.

Rheumatic Mitral stenosis is one of the common condition in Indian subcontinent associated with LA dilatation and remodelling. Even though the Mitral valve area is similar, Left Atrial Pressure can vary widely in patients with rheumatic Mitral Stenosis because LA compliance is an important factor. Even though patients with rheumatic Mitral Stenosis have similar Mitral Valve areas, their Left Atrial Compliance is depressed to a different degree, and their stiffness is therefore different. (54)

Baseline characterstics

The mean age of the study population 39.3 ± 10.6 years with around 45% of patients with age less than 40 years. Patients in our study were younger than the previous studies (55) (56). The major prerequisite for BMV is favourable valve morphology, whereas elderly patients tend to have greater degree of valve deformity with calcified thickened and relatively immobile valves often with significant sub-valvular disease making the valve unsuitable for BMV.

Like previous studies, in our study also women compromised of 77.5% of the total participants. Although RHD does not have any gender predilection but it is more often seen in females. This is explained by the difference in the autoimmune response leading to differences in valvular damage and severity. (24)(57)(58)

Patients undergoing BMV in our centre were symptomatic and had Severe mitral stenosis. Most of them had mild to moderate pulmonary hypertension,(30 patients,75%) (Mean- 39.6 ± 19.7

mm Hg).Patients included in our study had mean Wilkins score of 9, 39 (97.5%) patients had > 2 scoring for subvalvular pathology. These findings are in agreement with those of previous research demonstrating that patient undergoing ballon mitral valvotomy are symptomatic and have pulmonary hypertension at baseline.(59)(60)

BMV improved the functional class in all patients at one month follow up except 1 (2.5%) who was still having class-III dyspnea. Procedural success was achieved in 85% of the patients who gained Mitral valve area of >1.5cm ^{2} without any increase in moderate Mitral regurgitation. Increment in mitral valve area, decrease in diastolic mitral gradients, and decrease in systolic pulmonary artery pressure were significant.

These results were consistent with the previous major studies where PTMC has a success rate of 80-95% in de novo mitral stenosis. Study by Arora et al in total of 4850 patients of Severe mitral stenosis demonstrated Success rate of 90.9%.(61) (62). Our study demonstrated a success rate of 69% in patients undergo Redo BMV, which were lower than the previous studies and could be explained with findings of severe calcific valve with increased Wilkins score and sub valvular pathology at the baseline.(63)

LA strain

Pressure and volume overload caused by Mitral stenosis lead to progressive intrinsic LA dysfunction. Patients with mild mitral stenosis with slightly elevated LA pressure also have LA dysfunction. Kono et al in his study showed that in this early stage use of conventional echocardiography for evaluating parameters of LA mechanics and contractility could be spurious.(64) Strain imaging in earlier stages and in later stages of mitral stenosis predicts the cardiovascular events in future including atrial fibrillation and stroke.

Initial studies demonstrated that PALS is a more sensible index of left atrial dysfunction than LA volume index or just LA diameter , because change in strain starts earlier than increase in atrial dimensions and volumes. Inaba et al. demonstrated shows left atrial reservoir dysfunction in patients with mitral stenosis using strain imaging. These findings support results of our study that strain imaging is an important concept in patients with severe Mitral stenosis and can predict future events. (35)

Mehta et al studied LA function by 2-D speckle tracking echocardiography in patients with severe rheumatic MS and PAH recently, Their study included LA strain imaging in 80 patients with severe Mitral stenosis. They demonstrated a significant reduction in LA strain indicating severe LA dysfunction in patients with severe mitral stenosis.

Demirkol et al on in their study evaluated 52 asymptomatic MS patients with Mitral valve area of 1.38 ± 0.36 cm^2 and mean transmitral gradient of 7.9 ± 2.8 mm Hg also reported reduced LA reservoir.(6) Compared to above mentioned studies patients in our study had lesser MVA (1.00 ± 0.1cm^2) and we demonstrated similar impairment in Peak atrial longitudinal strain at baseline which improved significantly after ballon mitral valvotomy.

BMV improves the conduit volume and improves the atrial reservoir function. Previous studies have shown improvement in atrial reservoir and pumping functions. Bitigen et al in their study of 20 patients with critical mitral stenosis demonstrated improved LA mechanics post valvotomy procedure.(16) However,the data on effect of Ballon mitral valvotomy on Global LA strain is not well studied.

Study by Rohani et al demonstrated the short term effect of BMV and mitral valve replacement in patients with MS. It showed that the peak atrial longitudinal strain (PALS) was reduced in patients with severe symptomatic MS and improved acutely after procedure. They also

concluded strain analysis may allow evaluation of the recovery of LA reservoir function. Our study also iterate the same finding of significantly improved LA strain post valvotomy procedure ($p < 0.001$)(65)

Sravan et al studied effect of BMV on Left atrium mechanics with strain imaging in 29 patients. They demonstrated significant improvement in PALS after 24-48 hours of BMV. Strain analysis of Left atrium before and after BMV in our study improved significantly. However,in the small subset of patients with critical MS and severely reduced PALS, LA strain failed to predict the success of the procedure.

A cutoff value of 11.42 demonstrated a modest sensitivity (64.7%) and specificity (66.7%) (95% CI, 0.32-0.75,$p = 0.791$) to predict the procedural success.LA strain correlates weakly with the gain in Mitral valve area ($r=0.33$; 95% CI- 0.09, 0.6,$p=0.038$).

To conclude, index study shows significant reduction in the LA strain post-BMV; however, it did not reach normal value. This indicates that there must be other components in LA mechanics which are playing their part.A component of atrial cardiomyopathy can not be ruled out in these patients as described previously.(66)This index study paves the path of larger multicentre study to evaluate whether the LA strain further reduces during long term follow-up and also if this correlates with the reduction in cardiac events, AF incidence and formation of thrombus.

STRENGTHS & LIMITATIONS

Major strength of the study was to include the patients with relatively complex mitral valve anatomy who were high risk for BMV.

The major limitation of our study is that it was a non-randomized single centre study. Although our study reflected the characteristics of population with severe symptomatic mitral stenosis ,small sample size limits extrapolation of results to a larger population. Large multicentre studies are needed to confirm our data. A short short term follow up precluded us to demonstrate long term prognostic effects of Strain analysis.

Lastly, the 2D speckle tracking is restricted to the assessment of ventricle/atrial functions in a single plane and may be affected by geometric assumptions and foreshortening in the apical views.

CONCLUSION & IMPLICATION

Left atrial function specially PALS (peak atrial longitudinal strain) as assessed by 2D Strain analysis is abnormal in patients with severe MS. Along with all echocardiographic and hemodynamic parameters, PALS also showed a significant improvement following a successful BMV. However it fails to predict the success of the procedure.

The increase in PALS values following BMV reflects an improvement in clinical status and an improvement in function class in follow up. Thus, it seems reasonable to suggest LA strain as a surrogate marker in evaluating the response to BMV in patients of severe rheumatic MS. However, We need further large studies to demonstrate whether this improvement in LA strain leads to a reduction in rate of AF during mid- and long-term follow-up.

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ANNEXURES

PROFORMA	
LEFT ATRIAL STRAIN AS A SURROGATE PARAMETER FOR SUCCESSFUL PERCUTANEOUS BALLON MITRAL VALVOTOMY	
Patient ID:	
BASELINE CHARACTERISTICS	
AGE: _____(years) SEX: M ☐ F ☐ HEIGHT_____cm WEIGHT_____kg	
NYHA FUNCTIONAL CLASS I ☐ II ☐ III ☐	
PRE BMV	**POST BMV**

		POST PROCEDURE	6 MONTHS
MVA			
PHT			
Gradient			
MR			
LAVI			
TAPSE			
GLAS			

ABBREVIATIONS

BMV- Ballon Mitral Valvotomy
MVA- Mitral Valve Area
PHT- Pressure Half Time
MR-Mitral regurgitation
LAVI- Left atrium Volume index
TAPSE- Tricuspid Annulus Peak systolic excursion
GLAS- Global Left atrial Strain
NYHA- New York Heart Association

श्री चित्रा तिरुनाल आयुर्विज्ञान और प्रौद्योगिकी संस्थान, त्रिवेन्द्रम
तिरुवनन्तपुरम - ६९५०११, केरल, इंडिया
SREE CHITRA TIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM
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Institutional Ethics Committee
(IEC Regn No. ECR/189/Inst/KL/2013/RR-21)

SCT/IEC/1911/AUGUST-2022

24.08.2022

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

Dear Dr. Bhagwati Prasad Pant,

The project proposal with the title **"LEFT ATRIAL STRAIN AS A SURROGATE PARAMETER FOR SUCCESSFUL PERCUTANEOUS BALLON MITRAL VALVOTOMY"** submitted to Institutional Ethics Committee (IEC) has been reviewed in the IEC Meeting held on 6th August, 2022 and assigned number as IEC/1911.

List of documents submitted:

1. Responses/ amendments made based on the reviewer's comments
2. Covering letter addressed to the Chairperson, IEC, SCTIMST dated 02.04.2022
3. Checklist Form
4. Declaration form
5. IEC Application Form
6. Study Proposal
7. Patient Information Sheet in English and Malayalam
8. Study Consent Form in English and Malayalam
9. CV of PI and Co-PIs
10. Proforma
11. SRC Recommendation letter

IEC Recommendations

- Sample size calculation to be provided.

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

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

LA STRAIN AS A SURROGATE PARAMETER FOR SUCCESSFUL PERCUTANEOUS BMV

by Bhagwati Prasad Pant

General metrics

32,292	4,826	308	19 min 18 sec	37 min 7 sec
characters	words	sentences	reading time	speaking time

Score

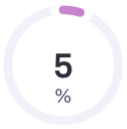


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Writing Issues

571	323	248
Issues left	Critical	Advanced

Plagiarism



19 sources

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STUDY CONSENT FORM

TITLE OF THE STUDY: LEFT ATRIAL STRAIN AS A SURROGATE PARAMETER FOR SUCCESSFUL PERCUTANEOUS BALLON MITRAL VALVOTOMY

Study number: All patients undergoing BMV at SCTIMST will be included in study Participant's name:
Date of Birth / Age (in years):
I_____ _____,
son/daughter of _____

(Please tick boxes).
[ ] Declare that I have read the above information provided to me regarding the study: "left atrial strain as a surrogate Parameter for successful percutaneous ballon Mitral valvotomy" 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. Bhagwati Prasad Pant
PDF, Adult Cardiology and Interventions

Dept. of Cardiology SCTIMST

For any technical clarifications, please contact For any technical clarifications, please Dr. Srinivas G, Member Secretary, iec.mem.sec@sctimst.ac.in , Phone No. 0471-2524689).

SREE CHITRA THIRUNAL INSTITUTE FOR MEDICAL SCIENCES AND TECHNOLOGY, TRIVANDRUM STUDY
CONSENT FORM

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 benefits and risk that may reasonably be expected to occur. I further certify that I encouraged the participant to ask questions and that all questions asked will answered.

_____

Name and Signature of Person Obtaining Consent
Dr. Bhagwati Prasad Pant, Post-Doctoral Fellow in Cardiac Electrophysiology Department of Cardiology, SCTIMST

Witness:

ശ്രീ ചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആന്റ് ടെക്നോളജി, തിരുവനന്തപുരം

പഠന സമ്മതപത്രം

പഠനശീർഷകം: ഇടത് എട്രിയൽ സ്ട്രെയിൻ അളവുകളുടെ ഘടകങ്ങൾ വിജയകരമായ പെർക്യൂട്ടേനിയസ് ബലൂൺ മിട്രൽ വാൽവോട്ടമി ശസ്ത്രക്രിയയിൽ ഉപയോഗിക്കുക.

ഗവേഷകരുടെ പേരുകൾ: ഡോ. ഭഗവതി പ്രസാദ് പന്ത്, ഡോ. ഹരികൃഷ്ണൻ എസ്, ഡോ. സഞ്ജയ് ജി

പഠന നമ്പർ: SCTIMSTയിൽ ബിഎംവിക്ക് വിധേയരാകുന്ന എല്ലാ രോഗികളെയും പഠനത്തിലുൾപ്പെടുത്തും.

പങ്കെടുക്കുന്നയാളുടെ പേര്

ജനനതീയതി/വയസ്സ് (വർഷത്തിൽ

ഞാൻ……..

മകൻ/മകൾ……...

(ദയവായി കോളങ്ങളിൽ അടയാളപ്പെടുത്തുക.)

- മുകളിൽ നൽകിയ ഇടത് എട്രിയൽ സ്ട്രെയിൻ അളവുകളുടെ ഘടകങ്ങൾ വിജയകരമായ പെർക്യൂട്ടേനിയസ് ബലൂൺ മിട്രൽ വാൽവോട്ടമി ശസ്ത്രക്രിയയിൽ ഉപയോഗിക്കുക എന്ന പഠനത്തിന്റെ വിവരങ്ങൾ വായിച്ചുമനസ്സിലാക്കിയതായും എനിക്ക് ചോദ്യങ്ങൾ ചോദിക്കാൻ അവസരം കിട്ടിയതായും ഞാൻ പ്രസ്തിവിക്കുന്നു. [ ]

- 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 ചെയ്യില്ലെന്ന് ഞാൻ മനസ്സിലാക്കുന്നു. [ ]
- ഞാൻ സ്വമേധയാ പഠനത്തിൽ പങ്കെടുക്കാൻ സമ്മതം നൽകുന്നു. [ ]
- സമ്മതപത്രത്തിന്റെ ഒപ്പിട്ട ഒരു പ്രതി എനിക്ക് ലഭിച്ചു. [ ]

പങ്കെടുക്കുന്നയാളുടെ ഒപ്പ് തീയതി
പഠനഗവേഷകന്റെ ഒപ്പ് 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, ഉണ്ടാവാൻ സാദ്ധ്യതയുള്ള അപായങ്ങളും ദോഷകരമായ പ്രത്യാഘാതങ്ങളുമുൾപ്പെടെ ഞാൻ ചർച്ചചെയ്തു. പങ്കെടുക്കുന്നയാളെ ചോദ്യങ്ങൾ ചോദിക്കാൻ പ്രേരിപ്പിക്കുകയും അവയ്ക്ക് ഉത്തരം നൽകുകയും ചെയ്തു എന്നും ഞാൻ രേഖപ്പെടുത്തുന്നു.

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സമ്മതപത്രം വാങ്ങുന്നയാളുടെ ഒപ്പ്

ഡോ. ഭഗവതി പന്ത്, പോസ്റ്റ് ഡോക്ടറൽ ഫെല്ലോ, അഡൾട്ട് കാർഡിയോളജി ആന്റ് ഇന്റർവെൻഷൻസ്, കാർഡിയോളജി, ഡിഷാർട്ട്മെന്റ്, SCTIMST

ഡോ. ശ്രീനിവാസ് ജി,

മെമ്പർ സെക്രട്ടറി, ഇൻസ്റ്റിറ്റ്യൂഷണൽ എത്തിക്സ് കമ്മിറ്റി, SCTIMST

ശ്രീ ചിത്ര തിരുനാൾ ഇൻസ്റ്റിറ്റ്യൂട്ട് ഫോർ മെഡിക്കൽ സയൻസസ് ആന്റ് ടെക്നോളജി, തിരുവനന്തപുരം

പഠന സമ്മതപത്രം

പഠനശീർഷകം: ഇടത് എട്രിയൽ സ്ട്രെയിൻ അളവുകളുടെ ഘടകങ്ങൾ വിജയകരമായ പെർക്യൂട്ടേനിയസ് ബലൂൺ മിട്രൽ വാൽവോട്ടമി ശസ്ത്രക്രിയയിൽ ഉപയോഗിക്കുക.

ഗവേഷകരുടെ പേരുകൾ: ഡോ. ഭഗവതി പ്രസാദ് പന്ത്, ഡോ. ഹരികൃഷ്ണൻ എസ്, ഡോ. സഞ്ജയ് ജി

പ്രിയ സുഹൃത്തേ,

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 ഇലക്ട്രോകാർഡിയോഗ്രഫി പ്രോബുപയോഗിച്ച് ഹൃദയചിത്രീകരണം നടത്തുന്ന പഠനമാണ് ട്രാൻസ് തൊറാസിക് ഇലക്ട്രോകാർഡിയോഗ്രഫി. ബലൂൺ മിട്രൽ വാൽവോപ്ലാസ്റ്റിക്കു മുമ്പും ശേഷവും, മിട്രൽ വാൽവിന്റെ ഘടനയും ഹൃദയഅറകളിലെ രക്തക്കട്ടകളും പരിശോധിക്കാനായി പതിവ് നടപടിക്രമങ്ങളുടെ ഭാഗമായി ഈ നടപടി ചെയ്യും. ഇലക്ട്രോകാർഡിയോഗ്രാം ചെയ്യുമ്പോൾ സോഫ്റ്റ്വെയറുകളുടെ സഹായത്തോടെ ഇടത് എട്രിയൽ സ്ട്രെയിൻ കണക്കെടുപ്പും നടത്തും. നെഞ്ചുവേദന, ക്ഷീണം, ശ്വാസതടസ്സം, വ്യായാമം ചെയ്യുമ്പോഴുള്ള ബുദ്ധിമുട്ടുകൾ, തലകറക്കം ബോധം നഷ്ടപ്പെടൽ എന്നീ ലക്ഷണങ്ങൾ കുറയ്ക്കാനും മിട്രൽ സ്റ്റെനോസിസ് ചികിത്സയ്ക്കുമുള്ള ഒരു നടപടിയാണ് പിബിഎംവി. ഒരു പ്ലാസ്റ്റിക്കുഴൽ (ഇൻട്രൊഡ്യൂസർ) താങ്കളുടെ ഫെമറൽ ആർട്ടറിയിലൂടെ കടത്തും. താങ്കളുടെ മിട്രൽ വാൽവിലേയ്ക്ക് ലക്ഷ്യമാക്കി ഒരു ബലൂൺ കത്തിറ്റർ അതിലൂടെ കടത്തുന്നു. താങ്കളുടെ മിട്രൽ വാൽവ് തുറക്കാനായി ബലൂൺ വീർപ്പിക്കും. എന്നിട്ട് ഇ ബലൂൺ കത്തിറ്റർ മാറ്റും. താങ്കളുടെ അസുഖമുള്ള വാൽവ് മുറിക്കുകയോ മിറ്റുകയോ ചെയ്യുകയില്ല. എക്റേയും ട്രാൻസിസോഫേജിയൽ എക്കോയും ഈ നടപടിയോടൊപ്പം ചെയ്യും.

ഇപ്പോഴത്തെ പഠനത്തിൽ ഉൾക്കൊള്ളുന്നതെന്ത്?

പതിവ് തയാറെടുപ്പുകളുടെ ഭാഗമായ ക്ലിനിക്കൽ, ഇല്കട്രോഗ്രാഫി 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 പങ്കെടുക്കുനവർക്കുണ്ടാകാവുന്ന 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 സഹായയകമായേക്കാം. 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?

താങ്കൾക്കതിന് കഴിയും. താങ്കളുടെ പതിവ് ചികിത്സയെ ആതീരുമാനം ബ്ധിക്കില്ല.

ഏതെങ്കിലും പുതിയകണ്ടെത്തലുകളോ വിവരങ്ങളോ ഉണ്ടായാൽഅത് അറിയിക്കുമോ?

അറിയിക്കും.

പഠനസംബന്ധമായ പരിക്കുണ്ടായാലെന്ത് സംഭവിക്കും?

പഠനസംബന്ധമായി പരുക്കുകളൊന്നും ഉണ്ടാകില്ല.

സൂചിപ്പിച്ച ചികിത്സയ്ക്ക് പകരമായി മറ്റെന്തെങ്കിലുമുണ്ടോ?

ബാധകമല്ല.

താങ്കൾക്ക് കൂടുതലെന്തെങ്കിലും ചോദ്യങ്ങളുണ്ടെങ്കിൽ ദയവായി ബന്ധപ്പെടുക, ഡോ. ഭഗവതി പന്ത് (പ്രധാന ഗവേഷകൻ) സീനിയർ റെസിഡന്റ്, കാർഡിയോളജി ഡിപ്പാർട്ട്മെന്റ് ഇമെയിൽ: drbhagwatipant@sctimst.ac.in ഫോൺ: 9999236416

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Academic Qualifications (Most recent qualification first)

Degree/Certificate	Year	Institution, Country
DM CARDIOLOGY	2018-2021	JIPMER,Pondicherry
MD (GENERAL MEDICINE)	2011-2014	Pt.JNMMC Raipur,C.G.
MBBS	2004-2010	BMCRI,Bangalore

Details of professional registration : (MCI/State Registration/Bar Council/DCI/etc including Registration Number and Year of Registration: DMC-73374(TCMC App No- **2225321)**

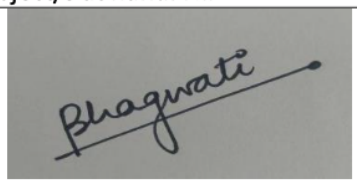
Current and previous positions (most recent position first)

Month and Year	Title	Institution/Company, Country
From 01/01/2022	PDF, Adult Cardiology & Interventions	SCTIMST, INDIA
1/1/2018 TO 31/03/2021	Senior Resident, Department of cardiology	JIPMER,Pondicherry
22/07/2011 TO 30/07/2014	Resident, Department of General Medicine	Pt.JNMMC Raipur,C.G.

Brief summary of relevant research experience:

1. **Pant B**, Ramesh A, Selvaraj R. Hydatid cyst of the interventricular septum - A rare cause of heart block. Indian Pacing Electrophysiol J.2019 Mar-Apr;19(2):79-80. doi: 10.1016/j.ipej.2019.01.002.
2. Pillai AA, Thiyagarajan M, Sharma DK, **Pant BP**, Keerti Priya SB, Keepanasseril A. Maternal cardiovascular dysfunction in women with early onset preeclampsia: a cross-sectional study. J Matern Fetal Neonatal Med. 2021 Sep 5:1-6. doi: 10.1080/14767058.2021.1974834.
3. Monica Thiagarajan, Ajith.Ananthakrishna Pillai, **Bhagwati P**, Keerti Priya B, Anish Keepanasseril Maternal Cardiovascular Dysfunction in Women with Early Onset Preeclampsia: A Cross-Sectional Study, The Journal of Maternal-Fetal & Neonatal Medicine, DOI: 10.1080/14767058.2021.1974834
4. Malhotra Y,**Pant BP**,Khare R,Prabhakar A. "Study of severity assessment and risk stratification of Falciparum Malaria in terms of hospital mortality in adults." *Journal of Evolution of Medical and Dental Sciences*, vol. 4, no. 61, 30 July 2015, pp. 10648+
5. .Diuretic Therapy in Heart Failure: Initiation, Titration, and Maintenance, Santhosh S.,**Bhagwati Prasad Pant** Chapter 18,Heart failure manual by Heart failure association of India.

Current project/s at hand: Nil

Signature: 

Date :: 06/04/2022
Place :: Trivandrum

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MASTER CHART

Sr No.	Pt ID	Age	Sex-1-M 2	BMV date	FC-Functic	FC Follow	H/o STROI	EF	LA size mr	MVA (2D)	MV Area (PI	MS Grad M
1	506323	31	2	17/01/22	2	1	0	66	61	1.07	1.1	10
2	506582	45	2	07/02/22	2	2	0	68	37	0.8	1	11
3	509415	38	2	07/02/22	2	2	0	62	36	1.04	1.2	14
4	509472	30	1	21/02/22	2	1	0	58	48	1.18	1	12
5	255729	30	2	21/02/22	2	2	0	77	55	0.9	1.1	14
6	505985	37	2	28/02/22	2	1	0	67	45	0.9	0.8	9
7	497640	31	2	28/02/22	3	1	0	69	34	1.3	1.2	12
8	507420	26	2	07/03/22	2	1	0	60	32	1.1	1.2	8
9	508340	43	2	14/03/22	3	2	1	64	46	0.6	0.8	17
10	180351	45	2	21/03/22	2	2	0	62	39	0.98	0.8	9
11	508920	22	2	28/03/22	3	1	0	64	35	0.82	0.7	10
12	477899	41	2	28/03/22	2	1	0	66	50	1	1.18	10
13	432439	23	2	11/04/22	3	2	0	67	43	1.2	0.9	13
14	511654	16	1	28/04/22	3	2	0	54	46	1.2	1.1	9
15	510262	32	1	02/05/22	2	1	0	70	48	0.8	0.9	21
16	505022	26	1	02/05/22	2	2	1	57	66	0.8	0.8	14
17	513347	29	1	09/05/22	2	2	0	60	42	1	1	25
18	393439	40	2	13/05/22	3	2	0	67	40	1.2	1.1	13
19	508705	43	2	30/05/22	3	1	0	64	46	1	1.1	25
20	298586	55	2	30/05/22	4	2	0	72	36	1.2	1.1	10
21	387166	46	1	30/05/22	3	2	0	60	56	0.9	1	10
22	482995	28	2	06/06/22	2	1	1	55	48	1.1	1.1	11
23	502267	46	1	20/06/22	2	1	1	62	48	1	1	13
24	370577	48	2	24/06/22	2	3	0	67	37	0.9	0.9	17
25	508031	39	2	27/06/22	2	2	0	54	45	0.7	0.8	17
26	397601	65	2	27/06/22	3	2	0	72	32	0.96	0.8	20
27	315713	39	1	04/07/22	3	2	0	56	49	1.2	1.1	7
28	262157	44	2	11/07/22	2	1	0	67	44	1.1	1	13
29	362597	46	2	17/06/22	2	2	0	65	46	1	1.1	13
30	274217	41	2	18/06/22	2	1	0	76	36	0.9	0.9	12
31	9407999	53	2	07/08/22	2	2	0	72	48	1	0.9	13
32	514691	42	2	08/08/22	3	1	0	70	40	1	0.9	10
33	518357	57	2	22/08/22	3	2	0	60	39	0.83	0.8	13
34	516186	54	2	29/08/22	2	2	1	68	52	1.1	1	19
35	518241	46	1	19/09/22	2	2	0	58	56	0.9	1	10
36	520697	46	2	21/10/22	2	2	0	57	37	1	1.1	8
37	507008	26	2	10/01/22	2	1	0	76	46	1.2	1.1	12
38	339953	30	2	31/10/22	3	1	0	58	55	0.9	1	22
39	468367	44	2	31/10/22	3	2	0	75	44	1.04	1	18
40	518794	46	2	07/11/22	3	2	0	69	41	0.77	1	10

Mobility	Thickening	Calcificatio	SVP	Wilkins	MR	MR Post P	RVSP	TAPSE	RA mean	RV ed	PA sys	PA dia
2	2	1	2	7	2	2	32	20	5	9	55	20
2	2	2	3	9	2	2	24	18	4	8	38	16
2	1	1	2	6	1	2	27	22	6	8	32	8
2	2	2	2	8	1	2	24	24	11	11	40	20
2	3	2	3	10	1	2	42	18	7	7	40	18
2	2	3	2	9	1	3	26	20	5	7	30	12
2	2	2	2	8	1	3	19	22	5	7	32	10
2	1	2	1	6	0	1	24	20	6	8	34	10
2	3	2	2	9	1	1	75	20	10	16	116	40
3	2	3	3	11	0	1	38	27	5	10	48	22
3	1	1	2	7	1	2	15	22	5	7	40	16
2	1	2	3	8	1	2	23	18	10	10	42	16
3	2	2	3	10	1	2	54	18	6	10	54	18
2	2	2	2	8	0	0	100	18	5	5	43	20
2	2	3	2	9	0	2	25	20	5	8	40	18
2	3	2	3	10	1	2	28	22	6	8	42	19
2	3	3	2	10	2	2	50	22	6	8	50	16
2	2	2	2	8	2	2	30	16	7	7	34	16
3	2	2	3	10	1	3	20	24	7		46	15
3	2	2	2	9	1	2	67	19	6	6	42	16
2	3	3	2	10	2	2	36	22	9	8	40	16
2	2	2	2	8	1	2	18	22	5	6	36	23
2	3	3	2	10	1	2	24	22	8	8	37	14
2	3	2	2	9	1	2	24	24	14	8	32	17
3	3	3	3	12	1	3	100	20	12	10	110	28
3	2	2	3	10	1	2	36	19	10	10	84	38
2	2	2	2	8	1	2	38	22	8	10	38	17
3	2	2	2	9	0	1	46	20	5	8	42	20
2	2	2	3	9	2	2	38	22	5	6	44	16
2	2	3	2	9	0	2	50	24	5	10	54	20
2	3	3	3	11	1	2	56	19	9	12	56	20
3	2	2	3	10	2	2	42	25	4	5	30	14
2	2	2	2	8	2	2	24	19	5	6	38	22
3	3	3	3	12	2	3	60	19	5	8	60	28
2	3	2	2	9	1	1	35	25	5	5	46	14
2	2	2	2	8	2	2	42	20	7	8	45	22
2	2	2	3	9	2	3	50	22	7	11	50	16
2	2	2	3	9	1	2	46	20	11	12	70	34
2	2	2	2	8	2	3	44	21	11	10	46	22
2	2	2	2	8	2	2	35	20	9	8	45	26

PA mean	LA a	LA v	LA m	LV sys	LV ed	MVG	MVA	CO	Balloon si:	No. of dlat	RA mean	RV ed
32	26	25	21	102	12	9	0.9	1.64	24	3	5	8
20	25	34	21	150	13	8	1.6	5.308	24	2	6	8
16	26	48	32	126	10	22	1.1		24	1	6	8
25	42	16	26	110	18	8	1.2	3.41	24	1	11	12
24	40	32	30	110	14	16	1.3	5.2	24	3	6	6
16	24	20	16	116	8	8	1.78		24	2	5	7
18	24	22	20	110	13	7	1.5		24	2	6	7
20	35	34	29	110	14	15	1.1	2.44	24	2	10	7
66	35	42	30	145	15	15	0.4		24	2	11	16
28	20	30	24	154	8	14	0.98	4.02	24	3	5	10
25	32	24	20	116	12	10	0.9	4.36	24	2	4	8
22	27	22	20	104	14	6	1.06	4.16	24	2	10	10
16	32	42	28	136	18	10	0.9	3.4	24	1	8	12
31	25	15	19	90	7	12	1.2	3.1	24	2	4	5
26	44	36	32	120	12	20	0.8	3.8	24	2	5	8
26	26	22	21	102	10	11	0.8	4.67	24	2	6	8
26	32	24	20	116	10	10	0.8	4.36	24	1	6	8
20			24		10	14	1.1		24	2	7	7
32	40	36	30	116	14	16	1	3.3	24	2	8	8
22	20	18	16	110	8	8	1.2		24		6	6
24	25	24	22	116	12	10	0.9	7.1	24	2	7	8
31	32	27	22	124	8	16.6	1.44	6.7	24	2	5	6
26	24	22	23	118	10	10	0.92	3.72	26	2	8	8
20	29	24	22	108	12	10	0.9	4.2	24	1	8	8
63	35	32	24	130	12	12	0.7	3.8	24	1	11	10
54	32	54	32	138	12	20	0.8	3.5	24	1	10	10
26	26	24	20	118	14	6	1.1		24	2	6	8
27	35	42	28	114	14	14	0.93	4.2	24	2	5	8
26	26	40	24	120	12	12	0.93	3.82	24	2	5	6
38	30	54	28	130	12	16	1.07	4.86	24	3	5	8
40	34	38	32	124	12	18	0.6	3.03	24	3	7	8
21	25	20	18	110	10	18	1	4.2	24	2	5	5
18	26	22	18	150	10	8	1	2.45	24	3	5	6
38	32	40	28	136	10	18	1.2	3.37	24	1	5	8
28	30	34	26	120	12	14	0.76	3.48	24	1	5	7
30	28	22	18	140	12	6	1	3.93	24	2	7	10
30	45	32	28	114	18	10	1.2		24	1	6	11
46	46	52	42	140	12	30	1.2	3.79	24	2	11	10
32	34	25	23	132	14	11	1.23	4.64	24	1	10	10
32	34	22	26	146	12	15.9	0.62	3.7	24	1	8	8

PA sys	PA dia	PA mean	LA a	LA v	LA m	LV sys	LV ed	MVG	MVA	Successful	Pre Procec	Post Proce
55	20	32	26	25	19	104	17	2	1.49	1	10.5	14.7
32	14	18	20	26	16	136	14	2	2.2	1	8.7	11.5
30			18	22	17	126	14	3	2.01	1	14.7	18.8
40	13	26	32	30	22	116	20	2	2.49	1	12.8	19.4
36	18	22	28	22	20	110	15	5	2.45	1	14.2	20
30	12	16	17	12	8	128	7	1	1.79	1	8	13.6
30	14	18	20	16	13	112	16	3	1.5	0	14.5	14.7
24			28	20	18	108	16	2	2.33	1	18.2	19.2
110	40	60	20	43	28	146	22	6	1.4	0	10	10.1
45	20	26	18	16	14	159	12	2	1.45	0	8.9	10.2
34	12	20	23	16	12	126	10	1	1.66	1	16.4	18.4
		18	23	20	18	108	16	2	1.69	1	12	16.8
46	20	28	26	32	21	138	18	3	1.85	1	13.2	17.8
42	18	27	11	10	7	98	7	0	1.4	1	18.5	21.4
40	18	26	26	22	18	116	16	2	1.3	0	14.6	15.1
38	16	20	20	18	16	120	16	0	1.98	1	10.1	11.4
50	16	26			15		12	3	2	1	13.2	13.8
34	16	20			14		12	2	2.2	1	16.4	21
46	15	32	26	20	16	108	14	2	2	1	12.8	16.5
42	16	22	12	12	10	110	8	4	1.56	1	12.9	14.4
36	14	20	16	20	16	118	15	1	1.4	0	11.15	12.8
32	21	27	16	10	8	110	10	10.6	2.3	1	14.2	16.9
37	14	26	20	17	17	118	15	2	1.8	1	7.8	12.4
32	17	20	24	20	17	110	14	3	1.8	1	6.4	10.2
95	26	48	32	42	28	102	20	8	1.8	1	6.05	8.2
64	20	38	24	50	26	126	16	10	1.5	1	8.9	12
28	14	18	18	16	14	120	12	2	1.9	1	12.2	17.4
42	20	27	25	28	17	120	12	5	1.73	1	4.5	6.4
40	14	20	22	26	14	124	12	2	1.8	1	13.6	15.4
44	14	26	21	32	16	138	14	6	1.63	1	14.7	18.5
			28	30	22	130	14	8	1.5	1	8.45	12.5

30	14	21	15	12	10	110	12	1	1.9	1	13.2	16.8
38	18	22	18	16	13	146	12	2	1.73	1	12.9	15.4
60	28	38	24	34	20	140	16	4	2.07	1	8.1	12
35	14	22	20	24	16	126	14	2	1.77	1	8.9	12.7
44	20	28	24	20	15	140	14	1	1.46	0	10.5	14.4
44	16	28	26	28	18	112	11	7	1.93	1	11.7	11.9
35	22	28	30	25	32	120	14	11	2.3	1	14.6	16.8
40	20	30	30	25	19	126	14	5	1.8	1	15.4	19.6
42	20	24	28	20	18	136	14	4	1.72	1	13.2	17.1