“AN OBSERVATIONAL STUDY TO ASSESS IMMEDIATE HEMODYNAMIC OUTCOMES IN PATIENTS UNDERGOING PERCUTANEOUS TRANSVENOUS MITRAL COMMISSUROTOMY IN OUR INSTITUTION”

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CERTIFICATE

This is to certify that the dissertation entitled **"AN OBSERVATIONAL STUDY TO ASSESS IMMEDIATE HEMODYNAMIC OUTCOMES IN PATIENTS UNDERGOING PERCUTANEOUS TRANSVENOUS MITRAL COMMISSUROTOMY IN OUR INSTITUTION"** is a bonafide original work done by **Dr.ARTHI.A**, in partial fulfilment of the requirements for M.D.GENERAL MEDICINE BRANCH – I examination of the Tamilnadu Dr.M.G.R Medical University to be held in April 2017, under my guidance and supervision in 2016.

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INTRODUCTION

INTRODUCTION

Rheumatic valvular Heart disease is still epidemic in India. The occurrence rate of rheumatic heart disease in developing countries is substantial. The continued prevalence of rheumatic heart disease is developing counties is not related to limited availability of penicillin but to their socioeconomic status. According to the annual report by the World Health Federation, an estimated 12 million people are currently affected by rheumatic fever and rheumatic heart disease worldwide. Several studies conducted on the prevalence of rheumatic heart disease reported a prevalence of 34.54/1000 in India. Awareness of rheumatic heart disease has also prevailed due to widespread use of transthoracic echocardiography. Furthermore, demands for adequate medical therapies are expanding with increasing use of Percutaneous transvenous mitral valvuloplasty.

In comparison to the surgical mitral commissurotomy Percutaneous mitral valvotomy has shown better success rates, comparable restenosis rates, larger valve area and long term durability.

In the case of moderate to severe MS, one has to assess the anatomy of the mitral valve meticulously with regard to the feasibility and outcome of percutaneous mitral valvotomy. The most widely used

echocardiographic parameter is the Wilkins score which we follow in our institute.

Mitral valve anotomy assessed by 2-D Echo is a strong predictor of the immediate results of percutaneous mitral valvotomy.The binary endpoint of immediate procedural success is a final valve area of 1.5 cm^2 without moderate or severe mitral regurgitation.

Therefore our study aims to analyse the immediate hemodynamic outcomes in patients selected by specific clinical and echo criteria, by assessing mitral valve area and other hemodynamic parameters immediate post Percutaneous mitral valvotomy, by combined retrospective and prospective observational study in our institute, and thus throw a light on the benefits of increasing the outreach of percutaneous transvenous mitral valvotomy in decreasing the morbidity of the Rheumatic heart disease / Mitral stenosis in our country

AIMS AND OBJECTIVES

AIMS AND OBJECTIVES:

PRIMARY OBJECTIVE:

To assess the immediate hemodynamic outcomes of Percutaneous transvenous mitral commisurotomy done at our institution in patients with rheumatic mitral stenosis selected by specific clinical and echocardiographic morphological Criteria

SECONDARY OBJECTIVES:

1. To study clinical outcomes and complications during the procedure
2. To assess the effectiveness of Wilkins echo score in patient selection for PTMC

REVIEW OF LITERATURE

REVIEW OF LITERATURE

Rheumatic heart disease is a major cause of morbidity and mortality among both developed countries and developing countries. The incidence is still high in developing countries due to poor socioeconomic and environmental conditions. Most of the patients with rheumatic heart disease have mitral stenosis, accounting to 40% of isolated mitral stenosis and remaining 35% of patients having mitral stenosis with aortic value disease together. Most common cause of mitral stenosis is also rheumatic etiology. Patients having isolated mitral stenosis give a positive history of rheumatic fever in around 50% of the cases. Incidence of rheumatic mitral stenosis has female preponderance, the reasons are largely unknown. The ratio of female to male incidence 2 : 1. In our institution among the patients selected for the percutaneous transvenous mitral commissurotomy, the 78% were female, 22% were female.

Overcrowding, poor sanitation and environmental pollution are responsible for the high incidence in developing countries. This is because of the higher incidence of group A β hemolytic streptococci in these conditions. Incidence of acute rheumatic fever is higher in children of school going age around 100% of patients developing rheumatic fever will develop rheumatic heart disease.

Brunton was the first person who introduced the concept of mitral valvotomy in 1902. Then Eliot cutler was the first to perform a closed mitral commissurotomy in the year 1923. Harshen and Bailey performed many commissurotomies and improvised the procedure. In 1960, open commissurotomy was started. In 1976, a Japanese surgeon called kanji Inou proposed a new technique using a balloon catheter. Severe trails followed using this balloon technique and first successful percutaneous transvenous mitral commissurotomy was done in the year 1980. In 1986, the double balloon technique was used. Since then many modifications have been done in the balloon technique and now percutaneous transvenous mitral commissurotomy has become the procedure of choice for treating patients with severe mitral stenosis who are carefully selected by specific clinical and echocardiography.

GROSS PATHOLOGY OF MITRAL STENOSIS:

Rheumatic inflammatory changes affect the four parts of mitral value as follows – commissures, cusps, chordae and combined. Out of these commissures are severely affected. This inflammation results in the mitral value becoming a funnel shaped structure. The mitral value opening assumes a button hole or fish mouth structures. Rheumatic inflammation can be followed by speck of calcification. Leaflet calcification and commissural calcification are common. Calcification

can be nodular or plaque type calcification. The chordae tendinae may get shortened or fused. The presence of these changes affecting the subvalvular apparatus makes a candidate less sensitive for percutaneous transvenous mitral commissurotomy. Due to the tight mitral stenosis and high gradient across the mitral value, the left atrium is enlarged with enlargement of the left atrial appendage and thrombus formation. The progressive enlargement of left atrium also leads to increased incidence of atrial fibrillation, with increased severity of the stenosis. The atrial surface of the mitral valve may show vegetations, the chordate tendinae become thickened, firm and shortened and get adhered to each other. Left ventricular dimensions are reduced and in severe cases may be atrophic. The root of the pulmonary artery can also become dilated. Due to pulmonary hypertension right ventricle also becomes dilated and the pressure of ball value thrombus in the right atrium will increase the degree of stenosis. Thrombus may be confined to the appendage alone or can be extending freely into the atrial cavity. In some case left atrial free wall can also be calcified. The hallmark finding of rheumatic mitral stenosis is commissural fusion. Chordal shortening can be severe enough so that the tip of the valve leaflet seems attached directly to the papillary muscles.

Papillary muscles can be fibrosed and atrophic. Lambl's excrescences can be seen which are present over the atrial surface. Vegetations of acute rheumatic fever are seen along the leaflet margins.

In mitral valve which was previously treated with commissurotomy, healed fracture lines can be seen. Restenosis can occur in these valves which can be due to a recurrent episode of rheumatic fever or previous inadequate surgery. When patients develop pulmonary hypertension there is medial hypertrophy of median sized pulmonary arteries.

PATHOPHYSIOLOGY AND HAEMODYNAMICS:

Due to the stenosed valve, the pressure gradient across the mitral valve increases during diastole. The left atrial pressure is normally less than 5mmHg. Left ventricular diastolic is around 5mmHg. In mitral stenosis, the left atrial pressure rises more than 25mmHg. When left atrial pressure raises more than 25mmHg, pulmonary edema develops. The amount of blood flow across the mitral valve also reduced leading to a decreased cardiac output.

SEVERITY OF MITRAL STENOSIS:

In mitral stenosis the mean gradient across the mitral valve, pulmonary artery systolic pressure and the valve area are the three parameters used to assess the severity of mitral stenosis. Mean gradient of

less than 5 is mild, 5-10 is moderate, >10 is severe. Pulmonary artery systolic pressure <30 is considered as mild, 30-50 mmHg is considered as moderate, >50 mmHg is severe. Mitral valve orifice area of >1.5 cm^2 is mild, 1-1.5 cm^2 is moderate, <1.0 cm^2 is severe.

Mitral valve pressure gradient depends on two parameters. These are mitral valve area and the mitral valve flow rate. Flow rate increases in condition producing tachycardia like exercise, pregnancy, hyperthyroidism, infections. This results in increased Trans mitral valve gradient quadruples with increase in flow rate. Tachycardia also results in decreased diastolic filling; the development of atrial fibrillation can also result in onset of symptoms. The transmitral gradient is highest in the early part of diastole. Decreased diastolic filling time also increase the mean left atrial pressure. Narrowing of the mitral valve and extension of pulmonary vascular disease, both result in decreased cardiac output. Intially exercise cardiac output is decreased. Later resting cardiac output is also reduced.

Onset of atrial fibrillation with loss of atrial contraction leads to further deterioration. This is because, atrial fibrillation leads to tachycardia and decreased diastolic filling time. Severity of mitral stenosis, increasing age, dimensions of left atrium, left atrial pressure all determine the onset of atrial fibrillation. Once the patient develops atrial

fibrillation, cardiac output falls by 20%. Left ventricular pressures are usually normal in mitral stenosis. But left ventricular remodeling can occur due to under filling and right ventricular hypertrophy and septal hypertrophy.

DIAGNOSIS OF MITRAL STENOSIS:

Echocardiography is the main investigation to confirm the disease, assessing the degree of involvement of mitral valve and other valves, presence of mitral regurgitation, presence of calcifications or subvalvular disease, assessing severity of mitral stenosis. So it is the gold standard for selecting patients for balloon mitral valvotomy. The parameters in Wilkinson score like valve mobility, leaflet thickening, calcification and subvalvular diseases are assessed by 2D-ECHO. In mitral stenosis the classical findings are thickening of leaflet, fusion of commisures, decreased valve mobility. Severity of mitral stenosis is assessed by 2D-ECHO planimetry by measurement of mitral valve orifice area. Parasternal short axis view is used to measure mitral valve orifice area. The normal mitral valve orifice area is 4-6 cm^2.

Patients with mitral valve orifice area <1.0 cm^2 are considered as severe mitral stenosis. Above 1.5 cm^2 hemodynamics are not significantly affected at rest. 2D-ECHO planimetry is also the most easy and specific method for measuring improvement in mitral valve orifice area post

percutaneous transvenous mitral commissurotomy. One disadvantage of percutaneous transvenous mitral commissurotomy is that it cannot reliably measure mitral valve area if the valve is heavily calcified and irregular. Planimetry can also be useful in intraoperative period to assess the immediate result of the percutaneous transvenous mitral commissurotomy procedures by hand held ECHO probe.

Parasternal short axis view has other uses like finding the degree of subvalvular disease. Rheumatic mitral stenosis always has some degrre of subvalvular disease. Subvalvular pathology means chordal thickening, papillary muscle displacement, chordal fusion, chordal rupture etc. So the feasibility of percutaneous transvenous mitral commissurotomy is dependent on the degree of subvalvular disease. So wilkins score takes into account subvalvular disease as one of the parameter. Patients older than 60 years and those with atrial fibrillation may have variability in mitral value orifice area measured by 2D planimetry, 3D-ECHO or pressure halftime method are preferred in these patients.

Mean and peak mitral valve gradients (MVMG / MVPG) can also be measured by 2D-ECHO. MVPG is not a reliable indicator for assessing severity of mitral stenosis.

ASSESING SUITABLITY OF MITRAL VALVE MORPHOLOGY FOR PTMC:

It is done by 2D-echocardiography. Leaflet thickening is considered as significant if it is >5mm.Leaflet mobility is also assessed in long axis parasternal view. Intraoperative fluoroscopy can show the degree of valvular calcification. Subvalvular disease is assessed by long axis, short axis and apical view. Many ECHO scoring systems are available which are used in patient selection for feasibility of percutaneous transvenous mitral commissurotomy. The most commonly used one is wilkins ECHO score, which we use in our institution. The total score is 16. Minimum are score is 4. Four parameters which are considered in wilkins score are leaflet mobility, leaflet thickening, leaflet calcification and subvalvular disease. Each parameter is given a score of 1 to 4.

In valve mobility, a highly mobile valve with restriction of leaflet tip is given a score of 1, mid and back having normal mobility is given a score of 2. Only back and is mobile is given a score of 3and when there is no mobility given a score of 4.

In leaflet thickening, normal thickness of leaflet is given a score of 1, only margins are thickened is given a score of 2. When whole leaflet is thickened (<8 mm) the score is 3 and thickening of more than 8mm is

given a score of 4. With regard to calcification, only a single speck of calcification, seen as increased echo brightness is given a score of 1. Scattered speck of calcification which is seen along the margins of the mitral leaflet is given a score of 2. ECHO brightness extending up to mid portion of the valve is given a score of 3. Extensive brightness throughout the valve is given a score of 4.

Subvalvular disease is scored as follows: Minimal thickness below the mitral leaflet is scored as 1. The chordate thickening upto one third of the length is 2. Thickening of the distal one third is 3. Extensive thickening and shortening of chordate extending upto the papillary muscle is 4. Other score used is cormier score. But none of the scores are found superior over another since large prospective studies are lacking.

EFFECT OF ATRIAL FIBRILLATION:

Onset of atrial fibrillation with loss of atrial contraction leads to further deterioration; this is because atrial fibrillation leads to tachycardia and decreased diastolic filling time. Severity of mitral stenosis, increasing age, dimensions of left atrium, left atrial pressures all determine the onset of atrial fibrillation. Once the patient develops atrial fibrillation, cardiac output falls by 20%. Left ventricular pressures are usually normal in mitral stenosis. But left ventricular remodeling can occur due to under filling and right ventricular hypertrophy and septal hypertrophy.

ROLE OF ECHOCARDIOGRAPHY IN PATIENTS WITH MITRAL STENOSIS UNDERGOING PERCUTANEOUS MITRAL VALVOTOMY

Echo is the primary modality of patient selection for percutaneous mitral commisurotomy . It is also essential component of intra procedural monitoring and post procedural assessment and follow up. The absolute contraindications for percutaneous mitral commisurotomy are commissural calcium, left atrial thrombus and more than 3+ mitral regurgitation.The primary aim of ECHO is to assess the suitability of the mitral valve for the procedure. The severity of mitral stenosis is primarily determined by the mitral valve orifice area.

Parameters assessed by echocardiography pre-procedure are

1. Severity of Mitral stenosis
2. Pliability or suitability of the valve for PTMC
3. Calcification of the valve
4. Valve thickening
5. Sub valvular pathology
6. Commissural morphology
7. Mitral regurgitation
8. Assessment for presence of left atrial thrombus
9. Diseases of the other valves

10. Assessment of intertribal septum

11. Assessment of pulmonary hypertension

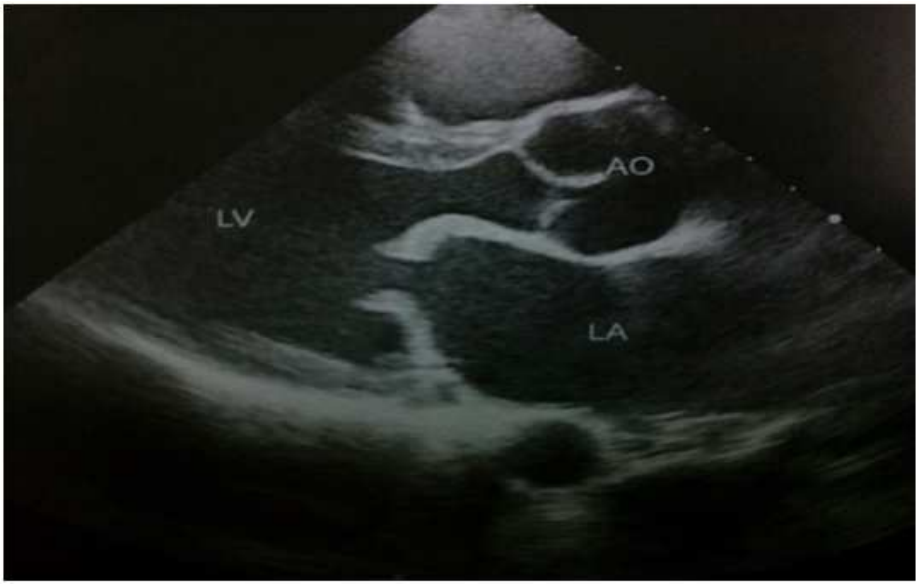
Intra operatively ECHO is used to assess the adequacy of commissural splitting, mitral regurgitation and complications like cardiac tamponade. Post operatively ECHO is used to evaluate the adequacy of commissural splitting, residual mitral stenosis, mitral regurgitation and atrial septal defect

TWO DIMENSIONAL ECHOCARDIOGRAPHY:

The most important and useful echocardiograph if modality in the assessment of suitability of the valve is 2D ECHO. Because valve morphology is the most important predictor of the success of Percutaneous transvenous mitral valvotomy. In Rheumatic heart disease, the mitral valve becomes thickened and mobility of the leaflets becomes restricted. This is seen well on the parasternal long axis view or the PLAX view. The anterior mitral leaflet shows a hockey stick appearance due to coming. The other structures assessed by the 2D ECHO method are the aortic and tricuspid valves. Aortic valve is assessed by the PLAX and PSAX views and tricuspid valve is assessed by the apical four chamber view (A4C)

ASSESSMENT OF MITRAL VALVE ORIFICE AREA BY PLANIMETRY:

The planimetry method gives the most accurate valve area and has best correlation with MVOA measured autopsy. This is considered as the reference method. But it has some limitations because the orthogonality of the imaging plane is assumed and not actual. The level at which the plane intersects the funnel shaped mitral valve cannot be assessed by the measuring person. Presence of commisural calcium makes the measurements difficult.

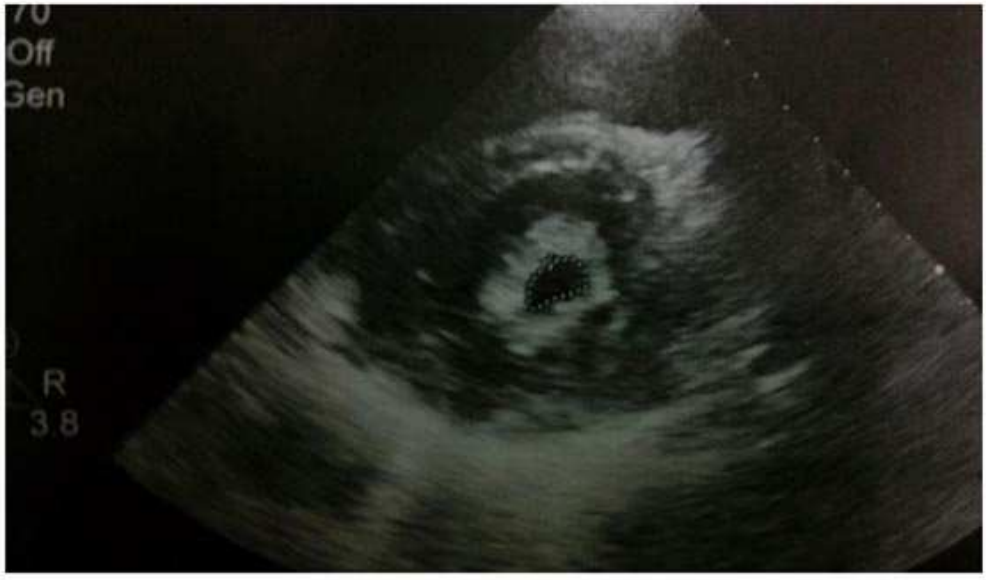


ASSESSMENT OF MITRAL VALVE MORPHOLOGY

The primary mechanism by which PTMC brings its hemodynamic effects is by splitting of the fused mitral commissures. Commissural morphology is the most important determinant factor for outcome of PTMC. Valve morphology is assessed by mobility of the

valve, thickening of leaflets, subvalvular pathology and calcification. Mobility of the valve is assessed by parasternal long axis view or PLAX.

Wilkins score grades the mobility from 1-4. The extent of coming of the mitral valve is assessed. The normal thickness of the mitral valve is less than 4 mm. The thickness of 5-8 mm is considered as mild thickening and more than 8 mm is severe thickening. Thickening can involve the entire leaflet or involves only the margins. Valve thickening is assessed on 2D ECHO by PLAX view.



More than the valvular calcium the calcium in the commissures mostly influences the outcome of PTMC. Commissural calcium is assessed by parasternal short axis view. The echogenecity of aortic root is used as the reference point. Calcium restricted to the belly of the valve is not an absolute contraindication for the procedure. Fibrotic valves usually yield less to balloon dilatation.

ASSESSMENT OF SUBVALVULAR PATHOLOGY

Subvalvular pathology is found be an important predictor of outcome of PTMC, Because the subvalvular region acts as a secondary orifice for the mitral valve. It requires multiple modified views for assessment. Subvalvular apparatus is an integral part of the mitral structural complex. It includes left ventricle free wall, two papillary muscles and chordae tendinae. Both immediate and long term results of PTMC are adversely affected by severe subvalvular deformities. Therefore proper assessment of patients with rheumatic mitral stenosis for the presence of subvalvular disease is important in therapeutic decision making, surgical vs palliative.

Both M mode and two dimensional echocardiography are the two non invasive methods for evaluating subvalvular disease. Scanning in multiple views allows a qualitative assessment of mitral valve apparatus like chordal thickening, fusion and calcification. Two dimensional echocardiography has limitations in measuring the chordal length, differentiating the chordae subgroups and finding the point of insertion.

Wilkins score gives a semi quantitative assessment of subvalvular apparatus. Lung and Cormier score gives a more quantitative assessment of subvalvular disease. Because it takes into account the chordal length. According to this classification, a pliable, non calcified mitral leaflet with

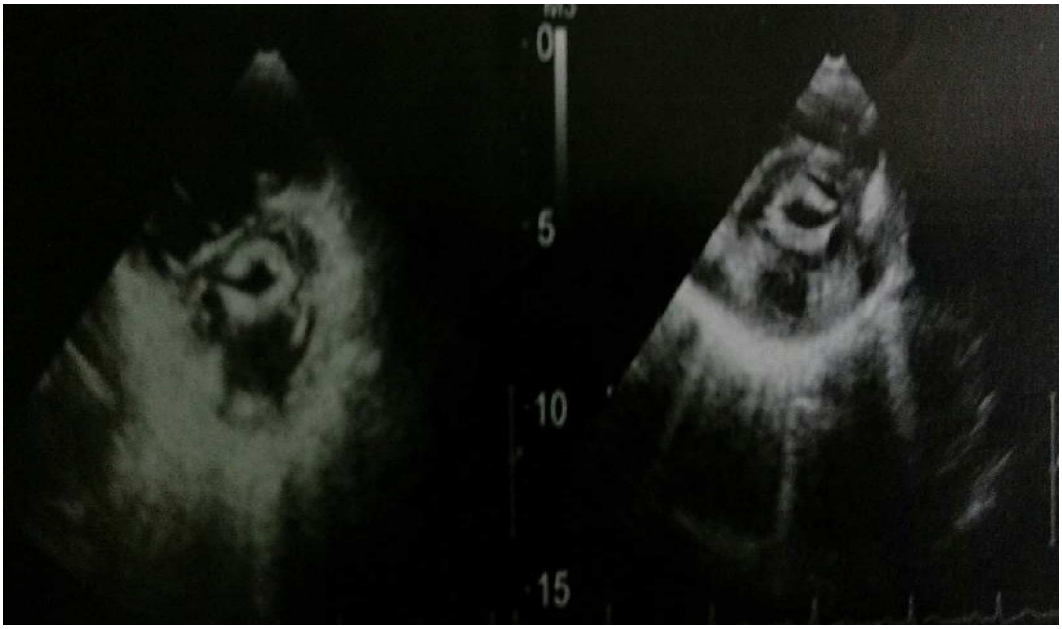
thin chordae of more than ten millimetre long have the best chances of achieving optimal immediate and long term results after PTMC.

Transesophageal echocardiography has been evaluated over transthoracic echocardiography for assessment of subvalvular disease. But the results are controversial. In a study by Haussmann et al, thickening of subvalvular apparatus was graded lower by monoplane transesophageal echocardiography than trans thoracic echocardiography due to acoustic shadowing. But transesophageal Echo has no clear advantage. Multiplane transesophageal echocardiography was evaluated by Stewart et al, and is currently the imaging method of choice for evaluation of subvalvular disease. In last decade three dimensional echocardiography has been evolving as a means of assessing subvalvular disease.

During PTMC two indirect signs indicate the presence of significant subvalvular disease. One is called the balloon impasse sign. This indicates crossing and propagation difficulties of the deflated balloon catheter into the left ventricle apex due to high resistance at the sub mitral region. The balloon compression sign is distortion of inflated balloon configuration at the subvalvular level. The normal hour glass configuration of the balloon is lost.

LEFT ATRIUM, LEFT VENTRICLE, LEFT ATRIAL APPENDAGE AND INTERATRIAL SEPTUM,OTHER VALVES ASSESSMENT FOR PTMC:

Structures other than mitral valve that needs to be assessed are left atrium, left atrial appendage and inter atrial septum. Left atrium will be dilated in mitral stenosis and the size of the left atrium is directly proportional to the severity of mitral stenosis, duration of obstruction and associated mitral regurgitation if any. Sometimes the left atrium can be much enlarged and it is called aneurysmal LA. Left atrial appendage is evaluated for the presence of thrombus. It is best seen in transesophageal echocardiography. In trans thoracic Echo, it is even in PSAX view. Left ventricle is usually normal in size because there is a constant under filling of the LV, but if LV is dilated it signifies associated mitral or aortic regurgitation or coronary artery disease.



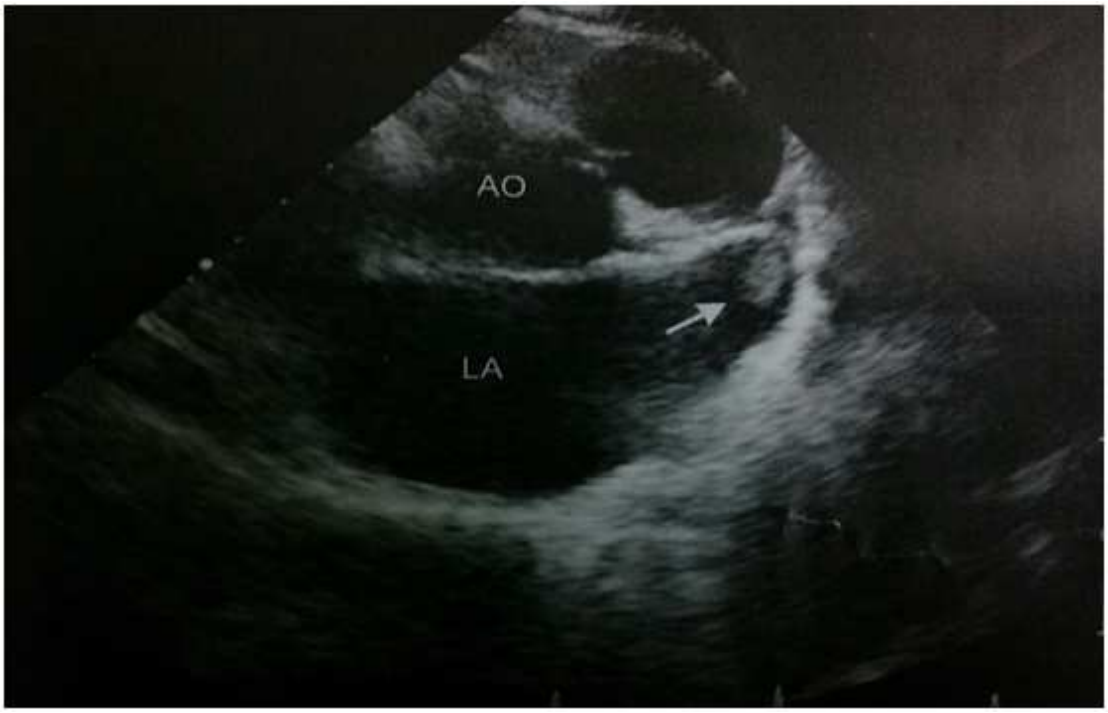
Interatrial septum should be carefully assessed to aid in the planning of technique of septal puncture. In severe MS, due to dilatation of the left atrial chamber, they inter atrial septum bulges into the right atrium. This makes the septal puncture difficult. The orientation of the IAS is also altered. Some patients who are chosen for re- PTMC can have a residual ASD from the previous procedure. Combination of a congenital ASD and mitral stenosis is called the lutembacher syndrome.

Assessment of other valves is critical because it alters the decision regarding choice of surgery. If a patient has a significant aortic valve disease he can undergo a simultaneous percutaneous aortic valvotomy and if significant tricuspid valve disease is present he can undergo simultaneous percutaneous tricuspid valvotomy.

TRANSESOPHAGEAL ECHOCARDIOGRAPHY IN PATIENTS UNDERGOING PTMC

Transesophageal echocardiography is an integral part of the evaluation of patients prior to mitral valvotomy. This is done to rule out left atrial thrombus, left atrial appendage thrombus, assessment of mitral regurgitation, associated lesions like aortic regurgitation, assessment of inter atrial septum to aid in septal puncture. The resolution of trans thoracic echocardiography to image the left atrial appendage and the left atrium is poor. So it is mandatory to perform a transesophageal

echocardiography prior to PTMC, but if TTE shows thrombus transesophageal echocardiography can be avoided. The grade of mitral regurgitation can be very well assessed by the transesophageal echocardiography.



DOPPLER ECHOCARDIOGRAPHY

Doppler echocardiography of the mitral valve is important to assess the severity of mitral stenosis, the response to balloon dilatation and to assess severity of mitral regurgitation. Doppler echocardiography of mitral valve is done by apical four chamber view. Mean and peak mitral gradient which are important parameters in assessment of outcome of surgery are also assessed by the Doppler echocardiography. But these gradients are influenced by the heart rate, mitral regurgitation and cardiac output.

PRESSURE HALFTIME METHOD

It is also one of the methods of assessment of mitral valve orifice area. This is done by Doppler echocardiography. This method has advantages like mitral valve orifice area is less dependent on heart rate, less dependent of flow across the mitral valve. It is more accurate in patients with atrial fibrillation. It is more accurate in patients with residual ASD.

ASSESSMENT OF PULMONARY HYPERTENSION:

Presence of pulmonary hypertension determines one of the indications for PTMC. Its evaluation in very important in management. Pulmonary hypertension is evaluated by echocardiography by indirect method. The tricuspid regurgitation jet velocity is measured and the estimated right atrial pressure and RV RA pressure gradient is added.

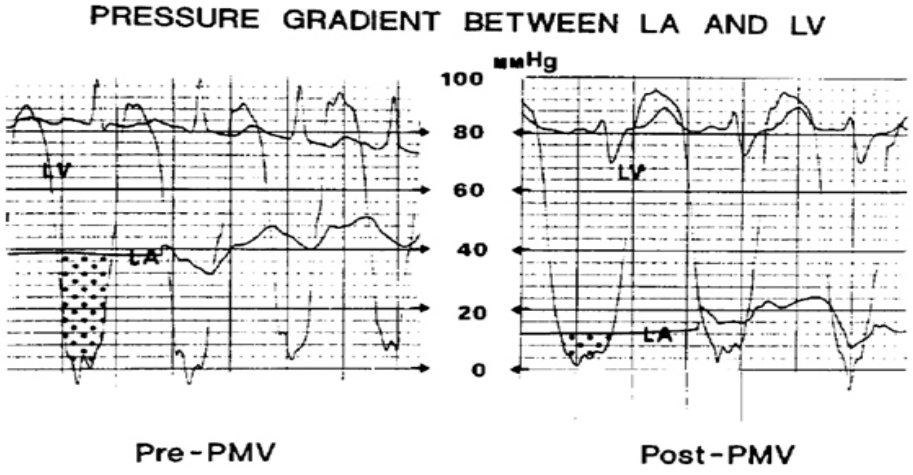
INTRAOPERATIVE ECHOCARDIOGRAPHY:

During PTMC Intraoperative echocardiography is performed. Trans thoracic echocardiography is most commonly used for this purpose because transesophageal echocardiography requires intubation.Trans thoracic echocardiography is used to directly visualise the commissural splitting with each balloon dilatation and facilitates a graded dilatation. Pressure tracing varies according to the heart rate and filling pressure. Intraoperative echocardiography is better than assessing LA pressure.

Intraoperative echocardiography also gives an idea of the degree of mitral regurgitation and increase in the grade of mitral regurgitation by two or development of moderate to severe mitral regurgitation is an indication to stop the procedure. Intraoperative complications like pericardial effusion and tamponade are also assessed. Transseptal puncture is also facilitated by echocardiography in addition to the fluoroscopy.

SUCCESSFUL PTMC

A successful PTMC results in splitting of one or more of the two mitral commissures resulting in increase in MVOA by 50% from baseline or final valve area of more than 1.5 cm^2 . And there should be a fall in left atrial pressure by 50% from baseline. Mean and peak mitral valve gradients should fall 50% from baseline. Post PTMC mitral regurgitation should not be more than grade two (sellers grade).



ECHOCARDIOGRAPHY IN POST OPERATIVE PERIOD

Planimetry is used to measure the improvement in MVOA. The iatrogenic ASD created for the procedure does not affect the measurements done by two dimensional echocardiography. Shunting through the iatrogenic ASD is also not hemodynamically significant. Commissural Mitral regurgitation usually reduces on follow up echocardiography. But mitral regurgitation due to tear of the leaflet or damage to the chordal structure needs surgery.

PREDICTIVE VALUE OF VARIOUS ECHOCARDIOGRAPHIC PARAMETERS OF MITRAL VALVE MORPHOLOGY BEFORE PTMC

Outcome of PTMC is influenced by the valve morphology, severity of the lesion, the presence of associated lesions, chamber anatomy. Mitral valve anatomy is not the only predictor of immediate hemodynamic effects of PTMC. Other factors like old age, previous valvotomy, higher NYHA class, and presence of atrial fibrillation, female gender, small initial MVOA and higher degree of preoperative mitral regurgitation, larger size of the left atrium all have effects on the outcome of the procedure. The four major echocardiography variables assessed are

A. Morphology of the mitral valve
B. Pre-procedural mitral regurgitation

C. Mitral valve area prior to PTMC

D. Left atrial size

MORPHOLOGY OF THE MITRAL VALVE BY VARIOUS SCORING SYSTEMS

Various multi variate scoring systems have been developed to assess the suitability of the valve for PTMC. In 1988, Wilkins scoring system was developed by the team in Massachusetts general hospital in USA by Wilkins and coworkers. It uses four parameters mitral valve calcification, thickening, mobility, and subvalvular fibrosis. Each parameter is given a score of one to four. total score is then calculated. All patients with a score of less than 9 had optimal results and those with score of more than 11 had suboptimal results.

Table 5 Assessment of mitral valve anatomy according to the Wilkins score[84]

Grade	Mobility	Thickening	Calcification	Subvalvular Thickening
1	Highly mobile valve with only leaflet tips restricted	Leaflets near normal in thickness (4-5 mm)	A single area of increased echo brightness	Minimal thickening just below the mitral leaflets
2	Leaflet mid and base portions have normal mobility	Midleaflets normal, considerable thickening of margins (5-8 mm)	Scattered areas of brightness confined to leaflet margins	Thickening of chordal structures extending to one-third of the chordal length
3	Valve continues to move forward in diastole, mainly from the base	Thickening extending through the entire leaflet (5-8 mm)	Brightness extending into the mid-portions of the leaflets	Thickening extended to distal third of the chords
4	No or minimal forward movement of the leaflets in diastole	Considerable thickening of all leaflet tissue (>8-10 mm)	Extensive brightness throughout much of the leaflet tissue	Extensive thickening and shortening of all chordal structures extending down to the papillary muscles

The total score is the sum of the four items and ranges between 4 and 16.

Reid scoring system was developed in 1989 by university of South California in the United States. This scoring system also used four parameters. Leaflet mobility, thickness, subvalvular disease and commissural calcium. Each parameter was given a score of zero to two.

Lung and Cormier score was developed by French interventionists. It divides patients into three groups, based on pliability, calcification and subvalvular disease. This scoring system is unique in that it takes chordal length as a parameter. It is also simple to use.

Another scoring system is used to predict the possibility of developing mitral regurgitation after PTMC. It is called Padial LR mitral regurgitation echocardiography scoring. Three factors in anatomy of the mitral valve are important in determining whether the patients are prone to develop mitral regurgitation. They are uneven mitral valve thickening, extensive subvalvular disease and commissural calcium. This scoring predicts the development of Mitral regurgitation with a high sensitivity and specificity.

Ain shams grading system was developed in Egypt in 2008, as a novel scoring system. It takes only two parameters into account, Calcification and subvalvular involvement. This scoring system has a cut off point of four. It successfully predicted poor outcome with high sensitivity and specificity

Three dimensional echocardiography scoring system was developed by Al- Azhar university in Egypt. It uses real time three dimensional echocardiography score for assessment of mitral valve morphology. The score ranges from 0 to 31 . Mild disease is less than 8, moderate disease is 8- 13, severe disease is more than 13. The major problem with this scoring system is its complexity.

DRAWBACKS OF THE SCORING SYSTEMS

Grading of the various anatomical features is very subjective and therefore not reliable between multiple users. Subvalvular is frequently underestimated by both transesophageal and trans thoracic echocardiography. However more recent studies still hold that echocardiography scores can be independent predictors of outcome. Stefenadis et al found that high echocardiography score, male gender, pre- procedural mitral regurgitation and previous valvotomy were significant unfavourable predictors of outcome. They found that balloon type was also a significant multi variate predictor of outcome. This study also showed that patients with Wilkins score of less than eight, had a greater final MVOA, lower incidence of mitral regurgitation.

Many studies have found that Wilkins score can even predict late outcome, restenosis and event free survival. So echocardiography assessment of mitral valve is still widely used to guide selection of

patients. Wilkins score still remains the most widely used score before PTMC. Limitations of the Wilkins score are does not assess commissural involvement, does not account for Uneven distribution of abnormalities, does not give weightage for each variable. Subvalvular disease is frequently under estimated, does not use three dimensional echocardiography or transesophageal echocardiography.

EFFECT OF PRE-PROCEDURE MITRAL REGURGITATION, MVOA, LEFT ATRIAL SIZE

Zhang et all found that patients with pre existing mitral regurgitation have relatively small improvement in MVOA after PTMC and high incidence of late complications. They also had lower possibility of bi commissural splitting. This is because these patients have a more calcified mitral valve., high incidence of atrial fibrillation, large left atrium.

Patients with a small MVOA prior to the procedure are expected to have a severe valvular and subvalvular pathology. So patients with MVOA in the range of 0.4-1 cm^2 have a poorer outcome.

Left atrial size is also a significant predictor of outcome in most reports. Alfonso et al found that patients with aneurysmal dilatation of left atrium (>6 cm) had the following characters- they were old, more symptomatic, more prone for atrial fibrillation, very severe valve

thickening and subvalvular valvular disease, had large left ventricle and associated mitral regurgitation, more difficulty in doing trans septal puncture, high rate of dilatation failure

Other less proven factors affecting the outcome of PTMC are mitral annulus diameter and the presence of significant tricuspid regurgitation

OTHER VARIABLES WHICH CAN BE ASSESSED TO FIND OUTCOME OF PTMC

Not all patients without adequate commissural splitting had optimal MVOA. So there may be other factors in mitral valve morphology that may have an adjuvant value in assessment of outcome of PTMC. These are valve mobility, subvalvular splitting, degree of commissural splitting. These parameters are again assessed by the two dimensional echocardiography.

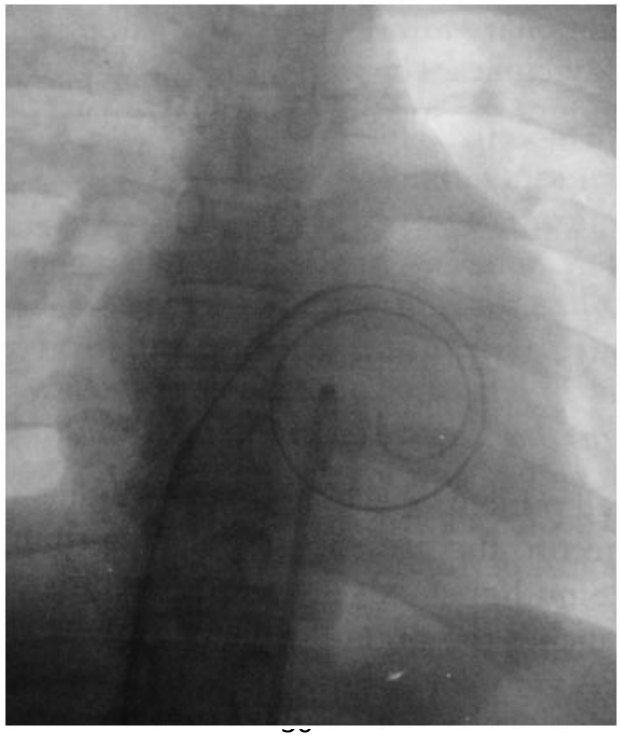
PROCEDURE OF PTMC

PTMC is usually done as an inpatient procedure because there is always a possibility of complications needing mitral valve replacement, so surgical team should be ready in standby. Inoue balloon technique is the most common technique used in our hospital.

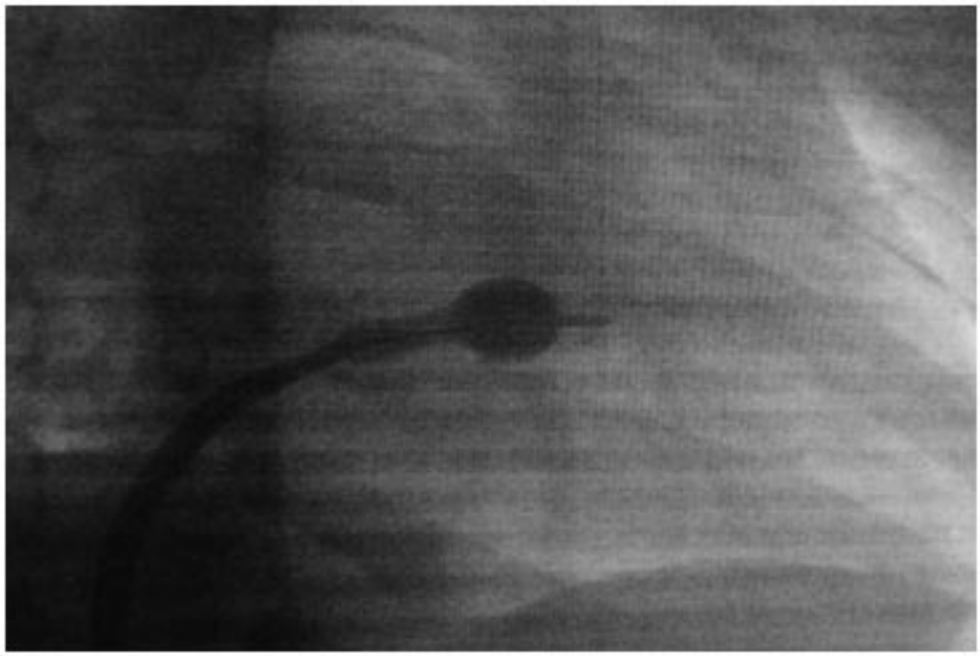
The patient is prepared by Sctimst protocol. Vascular access is obtained by right femoral vein. Right femoral artery is used to introduce a pigtail catheter to locate aorta.

The steps of the procedure are as follows

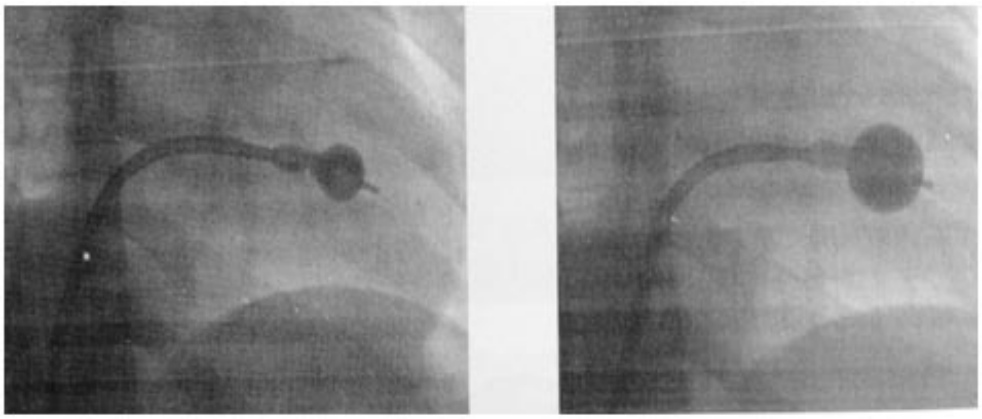
1. Obtaining vascular access
2. Preparation of the septal puncture system and the balloon
3. Assessing hemodynamics with multipurpose catheter(right atrial pressure, pulmonary artery pressure
4. Septal puncture – technique is described below
5. Entering the left atrium and balloon inflation
6. Recording of the pressures in left atrium- after trans septal puncture the mullein sheath is in the left atrium through which we can record the pressure
7. Introducing pigtail shaped left atrial guide wire- the pigtail guide wire forms a nice loop in the left atrium which is freely movable, after placing the loop mullein sheath is withdrawn



8. Dilatation of groin access site and inter atrial septum- a fourteen French dilator is used. Once the septal dilatation is performed Intraoperative echocardiography is done to rule out any pericardial effusion. If there is no effusion then heparin is administered.



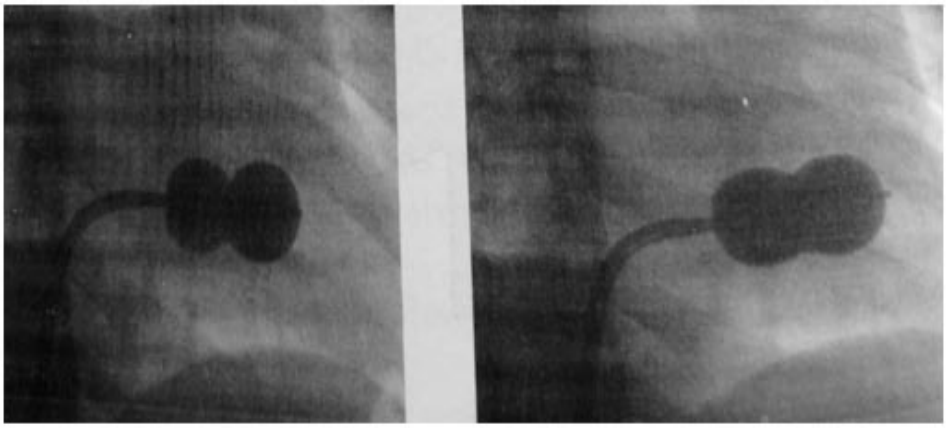
9. Introduction of the balloon into the left atrium



10. Crossing of the mitral valve and balloon dilatation – done in the right anterior oblique view, entry of left ventricle is done, once the balloon reaches left ventricular apex it is inflated partly. Partly

inflated balloon is pulled back so that the waist of the balloon is aligned at the mitral valve orifice. Then the balloon is inflated fully.

11. Assessment after balloon dilatation – left atrial pressure is checked after each dilatation



12. Serial dilatation
13. Assessment of success of the procedure – the success of the procedure is assessed by echocardiography showing splitting of one or more commissures, decreasing grading in Doppler echocardiography, checking the fall in the left atrial pressure.
14. Assessment of mitral regurgitation
15. Removing the balloon from the left atrium
16. Removal of the left atrial guide wire

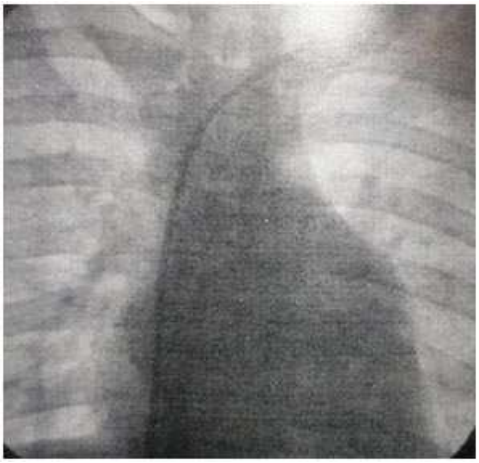
PTMC PROCEDURE- TRANS SEPTAL PUNCTURE

Trans septal puncture is the essential step in performing PTMC through anterograde route. The Trans septal puncture technique was developed by Ross, braunwald and morrow at national institute of health to allow left heart catheterisation. The procedure is visualised by fluoroscopy by left anterior oblique (LAO) or right anterior oblique (RAO) view.

Instruments needed for trans septal puncture are

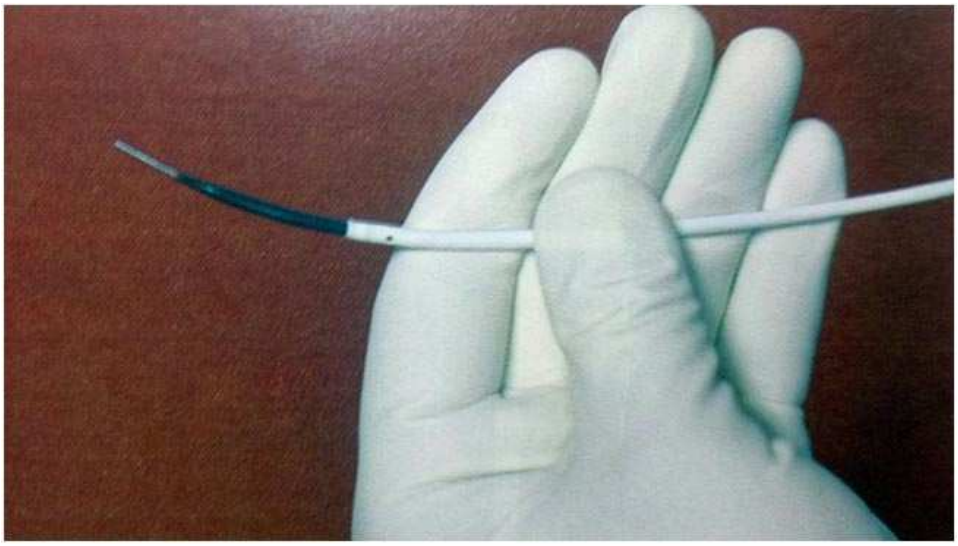
1. mullein sheath and dilator
2. Brockenbrough needle
3. Three way stop cock with saline and contrast

Steps in trans septal puncture are

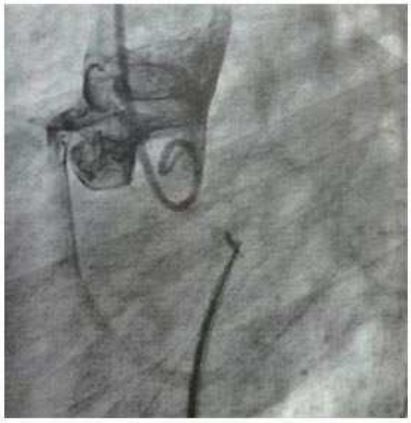


1. Accessing the left innominate vein with a multipurpose catheter
2. An exchange length wire is introduced into the left innominate vein

3. Mullein sheath is introduced into the left innominate vein
4. Removing the exchange wire from mullein sheath
5. Introducing Brockenbrough needle



6. Placing the pigtail catheter in aortic sinus
7. Descending into the fossa ovalis region
8. Confirming needle position in RAO view
9. Confirming needle position in lateral view



10. Aortic root contrast injection
11. Septal puncture

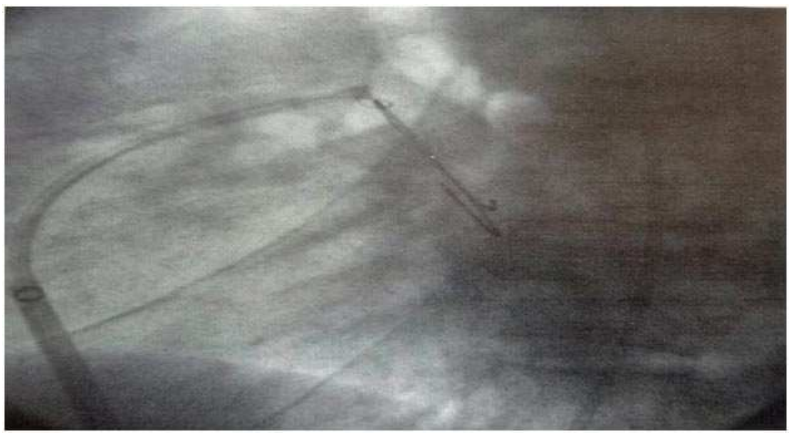
COMPLICATIONS OF MITRAL VALVOTOMY

1. Device related complications like breakage of coiled left atrial wire, entrapment of pigtail guide wire , balloon rupture during PTMC, balloon impasse
2. Complications of transeptal puncture like suspected pericardial tamponade, hemopericardium
3. Neurological complications like systemic embolism
4. New onset arrhythmias- atrial fibrillation or flutter
5. Complications needing emergency surgery are hemopericardium and cardiac tamponade, acute mitral regurgitation, LV perforation

DEVICE RELATED COMPLICATIONS DURING PMV:

BREAKAGE OF COILED LA WIRE:

Left atrial wire has two parts, the distal thin (coiled portion) and the proximal thick portion and both these parts are welded toghther. When the wire is used multiple times there is a greater tendency for breakage and this usually occurs at junction of proximal and distal portion junction from microfractures. The breaked wire may sometime get detached and embolised during manipulation.



The above picture shows the broken wire caught by snare going to be pulled back by the large sheath. This complication can be prevented by use of another left atrial wire made of NITINOL but there are no reports confirming this. Since the wire loop was too big, snares routinely used to catch the broken wire tip was not successful.

ENTRAPMENT OF THE PIGTAIL CATHETER:

It’s a very rare complication; by the tip of guide wire got entrapped between the inner balloon lumen and the ballon stretching tube. While preparing ballon prior to percutaneous mitral valvotomy, it is important to note the following:

1. Should not exceed maximum inflation volume on the syringe provided with balloon catheter.

2. Dilute contrast medium should be injected slowly to inflate the balloon during test inflations to avoid mesh layer over stretching.

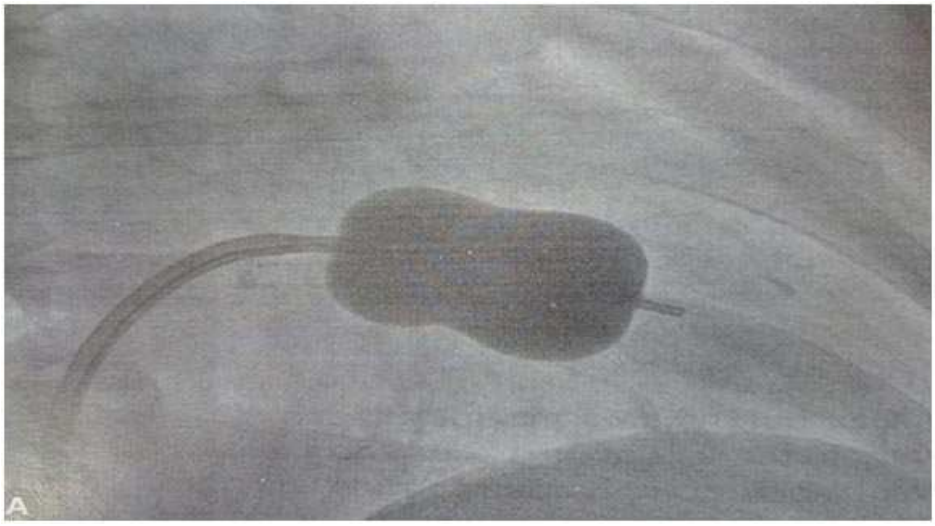
BALOON RUPTURE

It is a rare complication. Occurs commonly in developing world, where balloon catheters are re-used. The two problems resulting from rupture of balloon were:

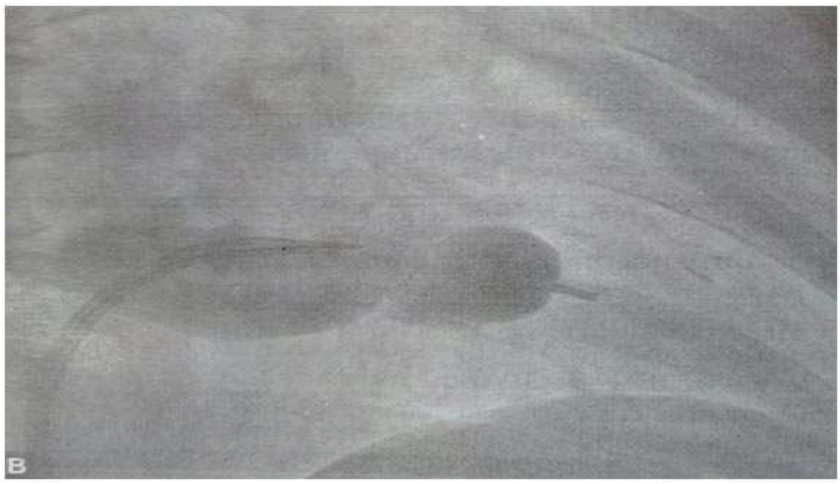
1. Latex material or the wire mesh can be declared and get embolize to the arterial system but very rare possibility.
2. While preparing contrast get mixed with air may embolize and produce air embolism in various organs:

   Balloon rupture during percutaneous mitral valvotomy

   1. Just before rupture:

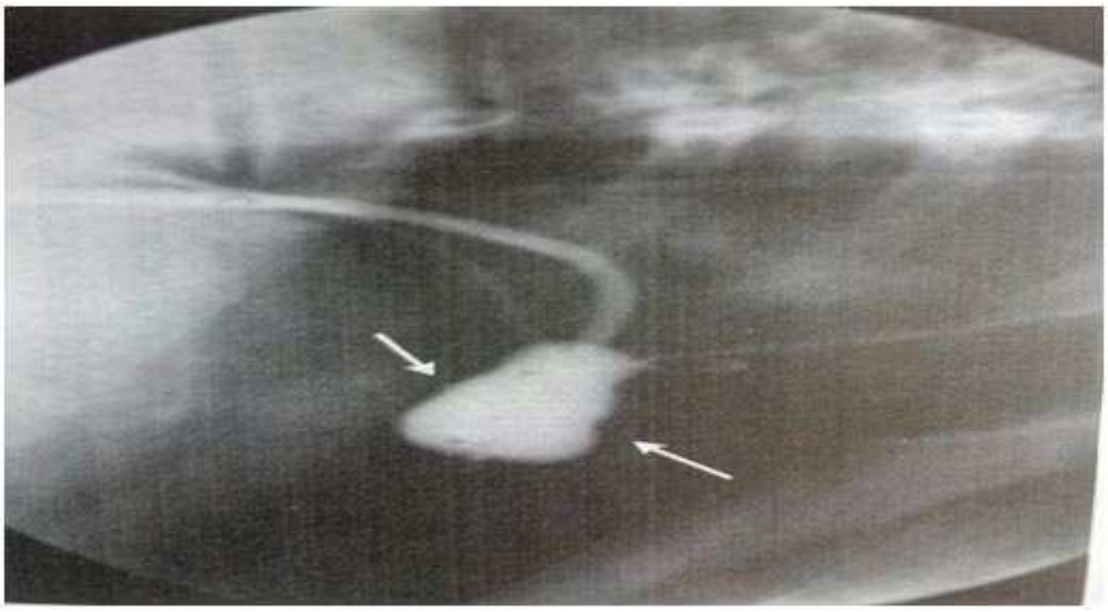


2. Just after rupture:



BALOON IMPASSE:

When INOUE catheter is used in percutaneous mitral valvotomy, sometimes even when properly aligned and defolded got held up or checked at the mitral valve referred to as the “balloon impasse” and it reflects severe obstructive subvalvular disease. This sign indicates severe mitral regurtitation when ballon used is of usual size. This can be averted by switching over to smaller ballons.



MITRAL VALVOTOMY IN SPECIAL SITUATIONS

PERCUTANEOUS MITRAL VALVOTOMY IN PREGNANCY

MITRAL STENOSIS AND PREGNANCY

Rheumatic heart remains the most common type of heart disease in pregnant woman in developing countries, and upto 75% of these will have mitral stenosis. The normal mitral valve has no pressure gradient across, and the increased cardiac output is well tolerated. However in mitral stenosis a gradient exists across the left atrium and left ventricle, the magnitude of which depends upon the severity of the stenosis and blood flow. When the cardiac output increases in pregnancy, mitral valve flow increases resulting in an increased gradient across the valve. So the following increase in left atrial pressure causes the pulmonary venous hypertension and an increased risk of pulmonary edema. The pulmonary arterial and right ventricular pressure is elevated and this eventually results in right ventricular pressure. The significance of mitral stenosis in pregnancy is that it not only leads to low systemic perfusion, but also to pulmonary congestion in about 25 % of the patients.

During labour due to large shift of fluid from the placenta to the maternal circulation results in tachycardia and is accompanied by disproportionate reduction of diastolic filling period across the mitral valve and results in elevated left atrial pressures with consequent increased risk of pulmonary edema. Atrial irritability is increased in

pregnancy and can lead to catastrophe pulmonary edema during late pregnancy as well as thrombus formation and additional risk of cerebrovascular embolization. Hence because of these factors mitral stenosis in pregnancy if not appropriately treated results in high maternal mortality and morbidity. Ideally it is imperative to do percutaneous mitral valvotomy or surgical intervention before the patient conceives if severe symptomatic mitral stenosis is diagnosed in nonpregnant women and who wishes to conceive.

Medical therapy during pregnancy has been implemented as the first line of therapy but it has its own limitations. Diuretics when used will reduce the placental perfusion. Beta blockers can be used effectively to reduce the exertional tachycardia at the cost of fetal growth retardation, bradycardia or hypoglycaemia in newborn infant. The tachycardias of sinus origin and is poorly reponse to digoxin due to the fact that increased sympathetic tone in pregnancy overrides the effect of digoxin.

INTERVENTIONS OF MITRAL STENOSISI IN PREGNANCY:

Relief of mitral valve obstruction is needed when symptoms persist but surgical mitral valvotomy, closed mitral valvotomy or open mitral valvotomy has a significant risk of fetal death. Surgical experience with closed commissurotomy has declined over the past few years and

this is largely replaced by open commissurotomy or percutaneous techniques in most centers.

PERCUTANEOUS MITRAL VALVOTOMY IN PREGNANCY

It's an good alternative in patients of mitral stenosis in pregnancy. The most valuable method is the INOUE TECHNIQUE as the fluoroscopy time is short in this method. Some of the disadvantages of this method in pregnancy is that radiation hazards, complications like mitral regurgitation, hypotension, pericardial tamponade and fetal distress due to various above said reasons. The procedure should not be proceeded during organogenesis due to the various radiation hazard complications. Left ventriculography and right heart catheterization are avoided to reduce fluoroscopy time. The average estimated radiation dose received by the fetus during the procedure is 0.2 rad. There will be some technical problems during pregnancy like hypercoagulable state necessitates a quick transseptal puncture and after that heparin needs to be administered. Percutaneous mitral valvotomy can be performed starting from the 12^{th} week of gestation.

PERCUTANEOUS MITRAL VALVOTOMY IN JUVENILE MITRAL STENOSIS:

Many studies have suggested that percutaneous mitral valvotomy have been a very successful procedure in cases of juvenile rheumatic

mitral stenosis which usually includes age group less than 20 years. Even below the age group of 12 years the procedure has shown successful results and is safe and effective.

Because of the high transmitral gradients and high pulmonary artery pressures in juvenile mitral stenosis, they are candidates for early therapeutic intervention. Juvenile Mitral valve morphology differs from that of adults by having minimal calcification, lesser subvalvular pathology and lower mitral valve score. It is better to do the procedure under general anesthesia with sedation, and using a 4F or 5F sheath to avoid arterial access problems. In practice good results have been obtained while using double balloon technique, Inoue technique cribier's metallic commisurotomy.

As in adults juvenile patients will have significant improvement in hemodynamic parameters after percutaneous mitral valvotomy. Juvenile patients will have lesser incidence of residual stenosis, but with no significant difference in invasively determined mean left atrial pressure, systolic pulmonary arterial pressure or pulmonary vascular resistance.

The complication rate is actually less when compared to adults. The reasons for low complication in juvenile patients are that attributed to more favorable valve anatomy, and also there is low incidence of embolic manifestations. On long term follow up there is no significant difference in pulmonary artery pressure between juvenile and adults.

It is hypothesized that the children's and adolescents patients may be more prone to restenosis because of the increased likelihood of smoldering rheumatic activity or recurrence of rheumatic fever in this age. But midterm and long term studies have proved that there is lower incidence of restenosis and also most restenosis patients will have pliable mitral valve apparatus suitable for a reprocedure.

PERCUTANEOUS MITRAL VALVOTOMY IN MITRAL RESTENOSIS:

Hemodynamic studies states that restenosis can ocuur in those cases when the mitral valvotomy widened the orifice only slightly or when the stenosis was near totally removed. There are two types of stenosis

1. TRUE RESTENOSIS refers to that occurs after one or both commisures have been fully split.
2. FALSE RESTENOSIS is actually not a restenosis and is due to inadequate original procedure and neither commissure was fully split.

Post mitral valvotomy restenosis is defined as valve area of $<1.5cm^2$ or a >50% loss of initial gain in valve area. Restenosis incidence has been reported to be range from 4 to 39%. The pathology of restenosis is not due to recurrence of fusion in the commisures but rather due to end stage

valvular disease such as severe fibrosis and calcification. The wilkins ECHO score representing the degree of both leaflet and subvalvular disease, deteriorated progressively indicating the progressive nature of the disease.

There are two mechanisms by which the mitral apparatus gets restenosed: 1. A more common slow process due to turbulent flow-trauma on the mitral valve and a

2.Rapid process that relates to vasculitis due to subclinical occurrence of low rheumatic activity.

The treatment options for these patients are mitral valve replacement or a repeat closed mitral valvotomy or a percutaneous mitral valvotomy. The treatment of choice in young patients with favorable wilkins score is repeat percutaneous mitral valvotomy, especially those with minimal lesions in subvalvular apparatus in whom the mechanism of restenosis is mainly bilateral commissural fusion. In patients with high wilkins score >7 repeat percutaneous mitral valvotomy may be considered as palliative procedure.

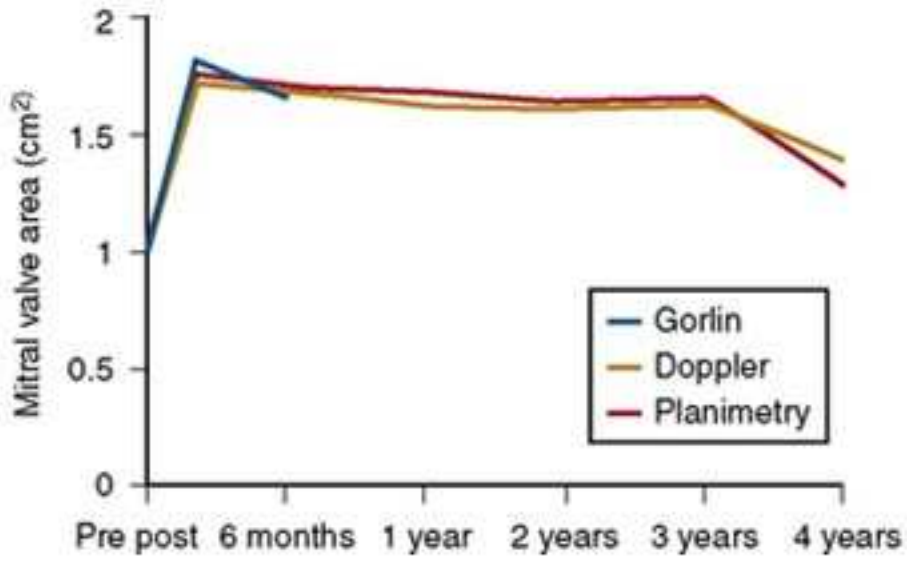
The success rate for percutaneous mitral valvotomy is 80-95% in denovo mitral stenosis, whereas it is about 50-90% in the case of restenosis. The percutaneous mitral valvotomy with mitral valve restenosis after a prior percutaneous valvuloplasty has a lesser event rates

compared to patients with restenosis after prior surgical commissurotomy.

The major issues technically dealt while doing percutaneous mitral valvotomy as follows:

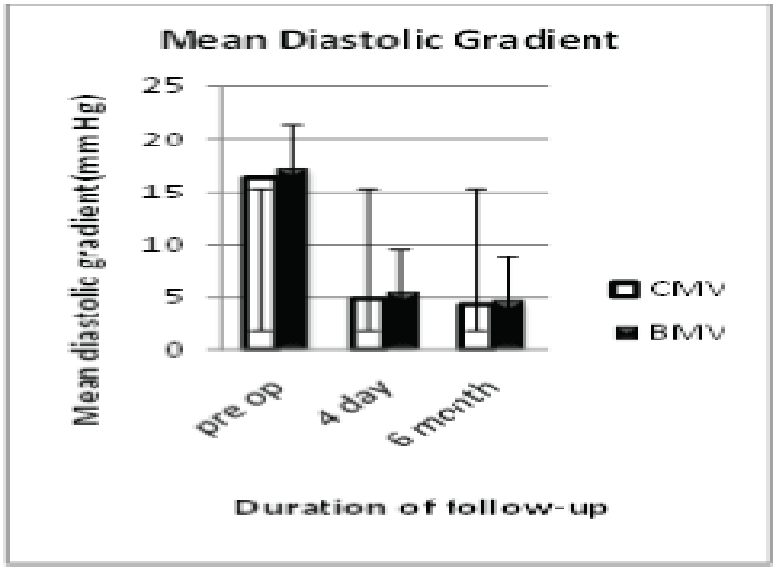
1. Septal puncture
2. Multiple slow dilations may be needed to dilate the subvalvular region and this may increase the risk of mitral regurgitation
3. Restenosis patients are usually older and with associated comorbidities.

COMPARISON OF PTMC AND SURGICAL VALVOTOMY

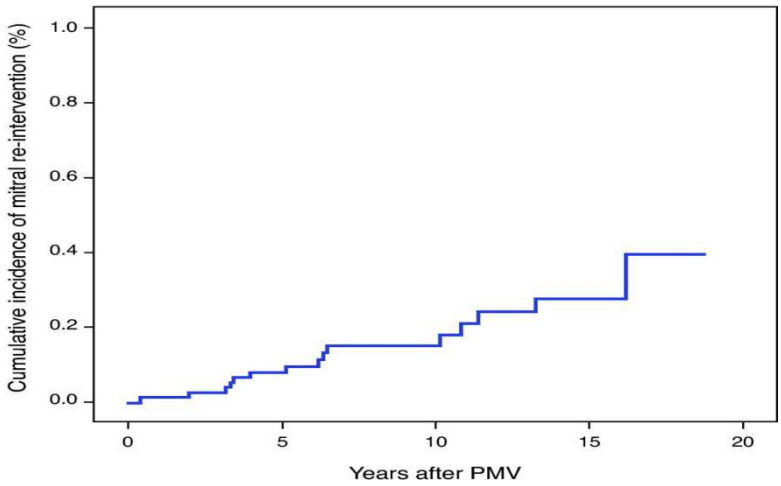


After its introduction in 1984 by Inoue in 1984, percutaneous mitral valvotomy has become the treatment of choice in the management of selected patients with mitral stenosis, which is severe and symptomatic. Many studies have established the superiority of PTMC over surgical commissurotomy. But surgical commissurotomy still remains the treatment of choice in patients with left atrial thrombus or disease of other valves like significant aortic disease.

Studies comparing percutaneous mitral valvotomy with surgical commissurotomy shows similar outcomes following both, with respect to immediate hemodynamic outcomes and MVOA. Turi et al have proved this in their study. The procedure related complications like mitral regurgitation were similar between two procedures. Patel et al showed that patients undergoing mitral valvotomy had better outcomes in mitral valve orifice area.



Studies which did late follow up of the two procedures like Ben Farhan et al showed better outcomes of the PTMC and OMC procedures when compared to closed mitral commissurotomy. Mitral valve area increased much more with PTMC and OMC than CMC . There was a less successful splitting of commissures on closed mitral commissurotomy when compared to open mitral valvotomy and PTMC. Residual mitral stenosis was about zero percent in PTMC and OMC when compared to 27 % in CMC .at seven years follow up the mitral valve area by echocardiography were equally higher in the PTMC and OMC groups when compared to CMC group. Re stenosis rate was 6.6% after PTMC or OMC versus 37 % of CMC. Freedom from re intervention was 90% after PTMC, 93% after OMC and 50% after CMC. The mean preprocedural echocardiography score were not

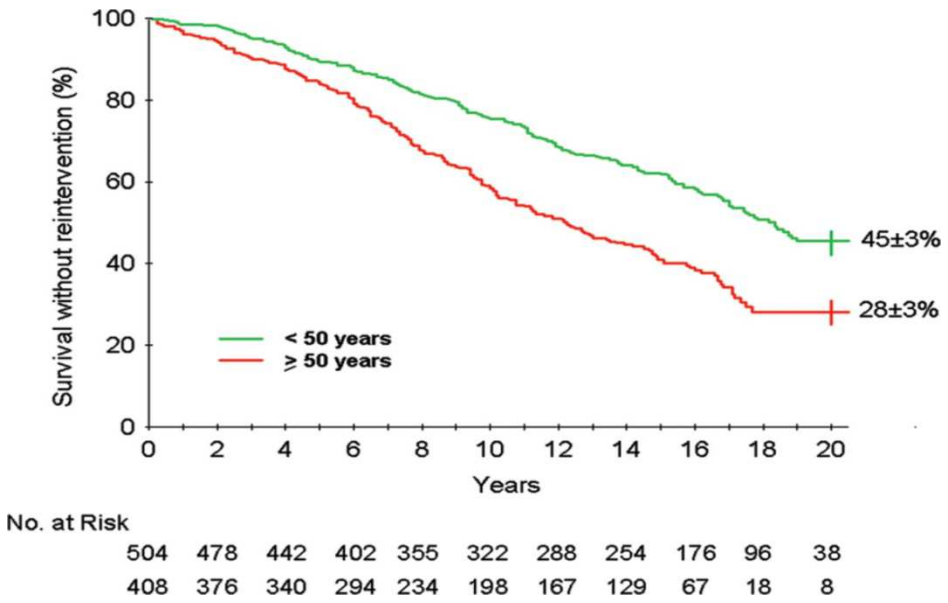


different between the groups of PTMC, OMC and CMC.

Another study comparing 7 year results of PTMC and OMC reported better functional recovery, better mitral valve area and lesser

mitral regurgitation after OMC. A long term follow up of randomised study for nine months by rifaie et al comparing PTMC and CMC in patients with pliable mitral valves reported similar immediate and long term results in both the groups . Mitral restenosis occurred in 26% of PTMC group and 27.8% in CMC group. None of the patients in either group developed significant mitral regurgitation

Song et al have sought to compare the long term results of PTMC and surgical treatment. Patients with higher echocardiography scores and atrial fibrillation had better results with surgery.



PTMC VERSUS SURGICAL COMMISSUROTOMY IN PREGNANCY

Of the available studies cumulatively involving around 515 pregnant patients women who underwent PTMC, procedural success

was attained in about 98% patients, with one maternal death and ten fetal abnormalities. In an observational study comparing PTMC and open mitral commissurotomy the fetal outcomes were better with PTMC with fetal mortality rates of 6% in PTMC group versus 33 % in OMC group with similar procedural success between the two groups.

Pavan Kumar et al in their study of 126 pregnant patients who underwent CMC reported full term normal deliveries in 82 % and fetal loss in 6%.

PTMC VERSUS SURGICAL COMMISSUROTOMY IN CALCIFIC MITRAL VALVE

Heavily calcified mitral valve with bicommissural calcification is best dealt with valve replacement. OMC has the advantage in view of the feasibility of debridement of the valve calcification. There is no direct comparison of PTMC of PTMC and surgical commissurotomy in patients with lesser degree of calcification. Leaflet calcification was found to be a predictor of late mortality in a study by hickey et al . Another study by deter et al reported the association of higher late mortality as well as late re operation risk with leaflet calcification.

Some studies have assessed the effect of fluoroscopic valve calcification on PTMC. As expected these subset of patients with

significantly calcified valves on fluroscopy had poorer procedural outcome and in hospital mortality. The estimated two year survival was significantly lower for patients with heavily calcified mitral valve than those with non calcified valve. Freedom from mitral valve replacement at two years was also significantly lower for patients with calcified valves. In the study by lung et al for those patients who had a good immediate outcome, survival without reintervention at eight years was 48 percent only where as it was 40 percent for those who had poor hemodynamic outcome

The effect of commissural calcification was analysed in an observational study by Sutaria et al. The authors classified commissural calcium from a grade of 0-3. They found that the PTMC results were better among patients with echocardiography score of less than eight and either grade zero or grade one calcification. Significant mitral regurgitation occurred in 4.1 percent of patients with grade 2 or grade 3calcification.

PTMC VERSUS SURCAL COMMISSUROTOMY IN PATIENTS WITH MITRAL RESTENOSIS:

There are no direct head to head comparisons of PTMC and surgical commissurotomy for mitral restenosis. The study by Nair et al reported procedural success of 59% for PTMC in mitral restenosis as

against 80-95 percent in native valves. Procedural successes varying from 59-90% have been reported for PTMC in restenosed valves. There was no difference in outcome between the post PTMC restenosis versus post surgical restenosis groups. The reported rates of severe mitral regurgitation after PTMC in the group of patients range from 2.5 to 10 percent. Repeat surgical commissurotomy has an operative risk mortality of 2.5 to 10%. High risk of systemic embolism upto four percent was seen. Operative success and functional class improvement were 50-85 percent.

MATERIALS AND METHODS

MATERIALS AND METHODS:

In this following hospital based observational study titled “AN OBSERVATIONAL STUDY TO ASSES IMMEDIATE HEMODYNAMIC OUTCOMES IN PATIENTS UNDERGOING PERCUTANEOUS TRANSVENOUS MITRAL COMMISUROTOMY IN OUR INSTITUTION ”, fifty patients who were admitted as inpatients for the above procedure in the department of cardiology where followed up during intraoperative and postoperative period.

Period of study: April 2016 to September 2016

Study design: Observational study

Study centre: Department of cardiology,MMC, RGGGH.

Sample size: 50

Conflict of interest : none

INCLUSION CRITERIA:

Patients with rheumatic mitral stenosis:

1. Symptomatic patients in NYHA Class II-IV
2. Moderate to severe mitral stenosis as assessed by Echocardiography (MVOA</= 1.5cm2)
3. Suitable mitral valve morphology with Wilkins score less than or equal to 8

EXCLUSION CRITERIA:

1. Asymptomatic patients.
2. Presences of left atrial thrombus in transesophageal ECHO.
3. More than moderate MR
4. Severe TR
5. Severe concomitant aortic valve disease

DATA COLLECTION AND METHODS:

Data collection was performed by preoperative and intraoperative follow up. Patients who had a Wilkins score of less than 8 who were posted for PTMC where considered in the study. Immediate functional outcome of the procedure in terms of hemodynamic improvement was assessed by measuring the percentage of improvement in mitral valve orifice area, Left atrial pressure and mitral valve peak gradient. Intraoperative complications if any were noted.

PROCEDURE / INVESTIGATION DETAILS:

PATIENT SELECTION:

A) Clinical criteria used for symptom assessment –NYHA classification

B) Severity assessment- 1.MVOA assessed by 2D transthoracic ECHO planimetry

C) Valve morphology assessment- Wilkins ECHO score by 2D TTE

D) Assessment for left atrial clot- Transesophageal ECHO

E) Atrial fibrillation-12 lead standard ECG

HEMODYNAMICS ASSESSMENT:

1. MVOA-2D ECHO planimetry

2. Mitral peak flow gradient- 2 D Doppler ECHO

3. MR/TR-2D TTE

4. LA pressure assessed by intraoperative cardiac catheter.

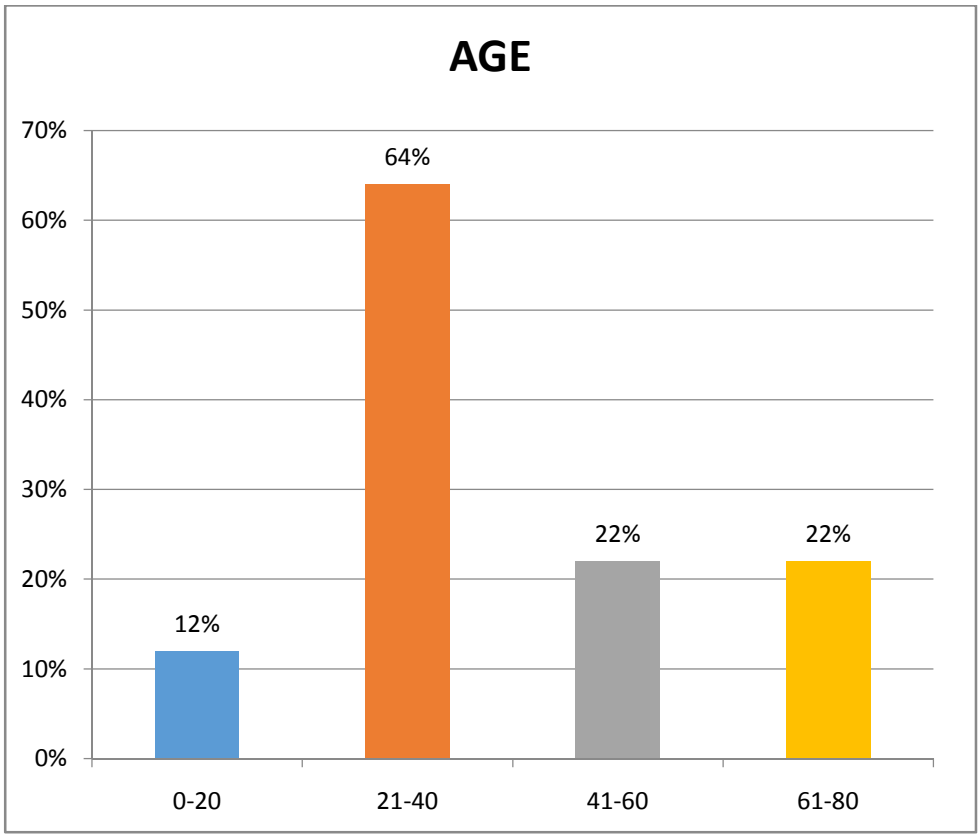
OBSERVATIONS AND RESULTS

RESULTS

AGE DISTRIBUTION

Out of the 50 patients of our study group, 64% of patients lie in the 21-40 age, only 2% of the patients lie in the 61-80 age group.

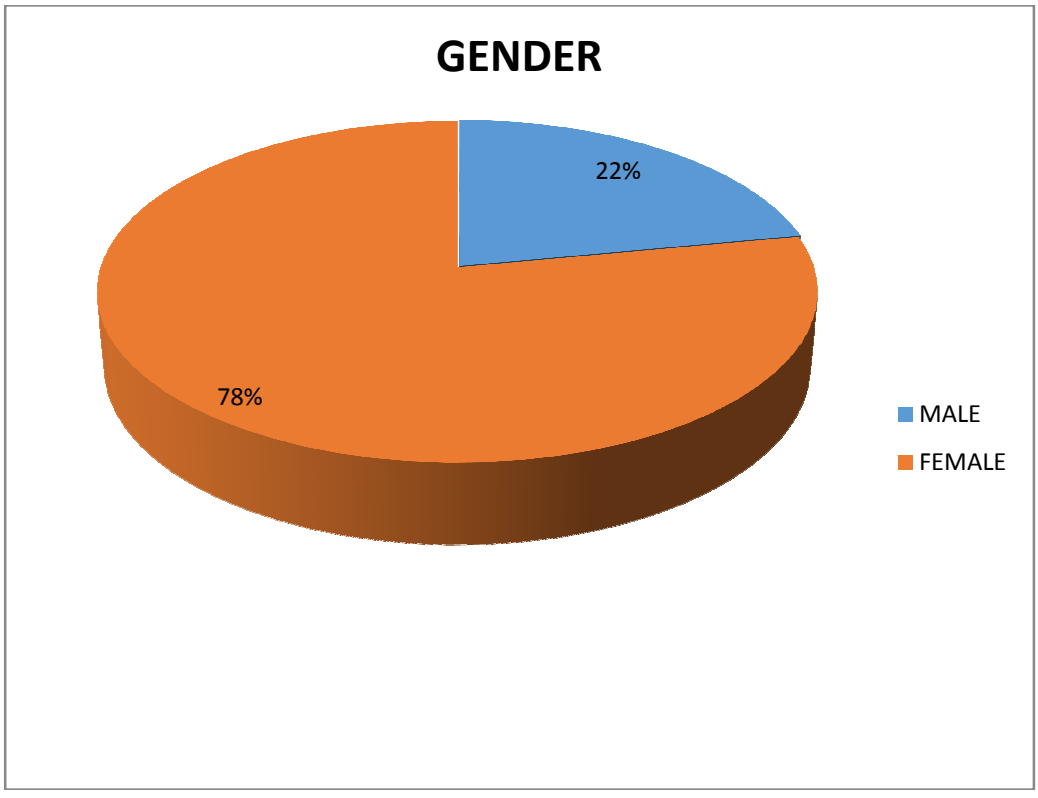
		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	0-20	6	12.0	12.0	12.0
	21-40	32	64.0	64.0	76.0
	41-60	11	22.0	22.0	98.0
	61-80	1	2.0	2.0	100.0
	Total	50	100.0	100.0	



SEX DISTRIBUTION

Out of the 50 patients of our study group 78 % were female and 22% were male

		Frequency	Percent	Valid Percent	Cumulative Percent
Valid	MALE	11	22.0	22.0	22.0
	FEMALE	39	78.0	78.0	100.0
	Total	50	100.0	100.0	



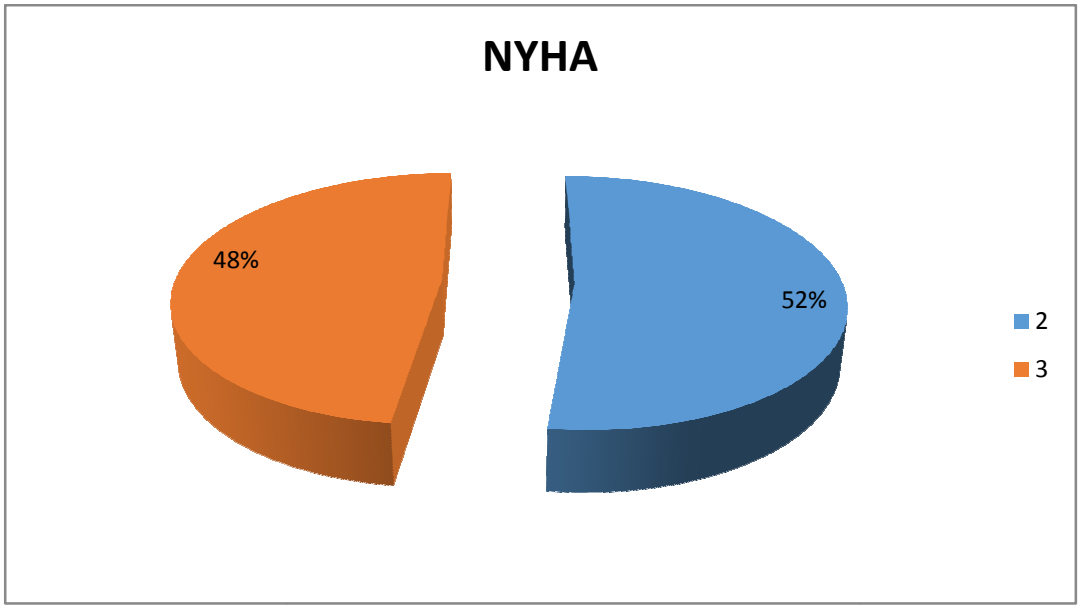
NYHA CLASS

Out of the 50 patients in our study group 52 % had symptoms in class II

NYHA and 41% had symptoms in class III NYHA and 0% in class I and IV

NYHA

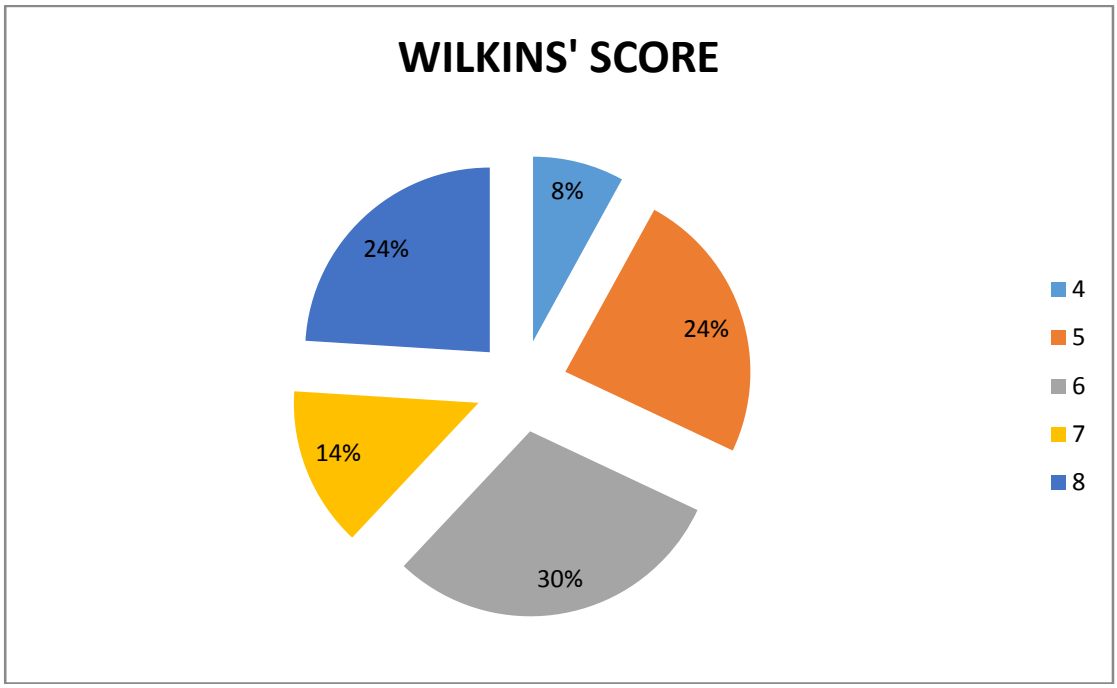
		Frequency	Percent	Valid Percent	Cumulative Percent
NYHA	2.00	26	52.0	52.0	52.0
	3.00	24	48.0	48.0	100.0
	Total	50	100.0	100.0	



WILKINS SCORE

Out of the 50 patients in our study group, all 100 % had a Wilkins score of less than or equal to 8. 30% patients had a score of 6 which was the maximum, 8% patients had a score of 4 which was the minimum

		Frequency	Percent	Valid Percent	Cumulative Percent
Wilkins score	4.00	4	8.0	8.0	8.0
	5.00	12	24.0	24.0	32.0
	6.00	15	30.0	30.0	62.0
	7.00	7	14.0	14.0	76.0
	8.00	12	24.0	24.0	100.0
	Total	50	100.0	100.0	

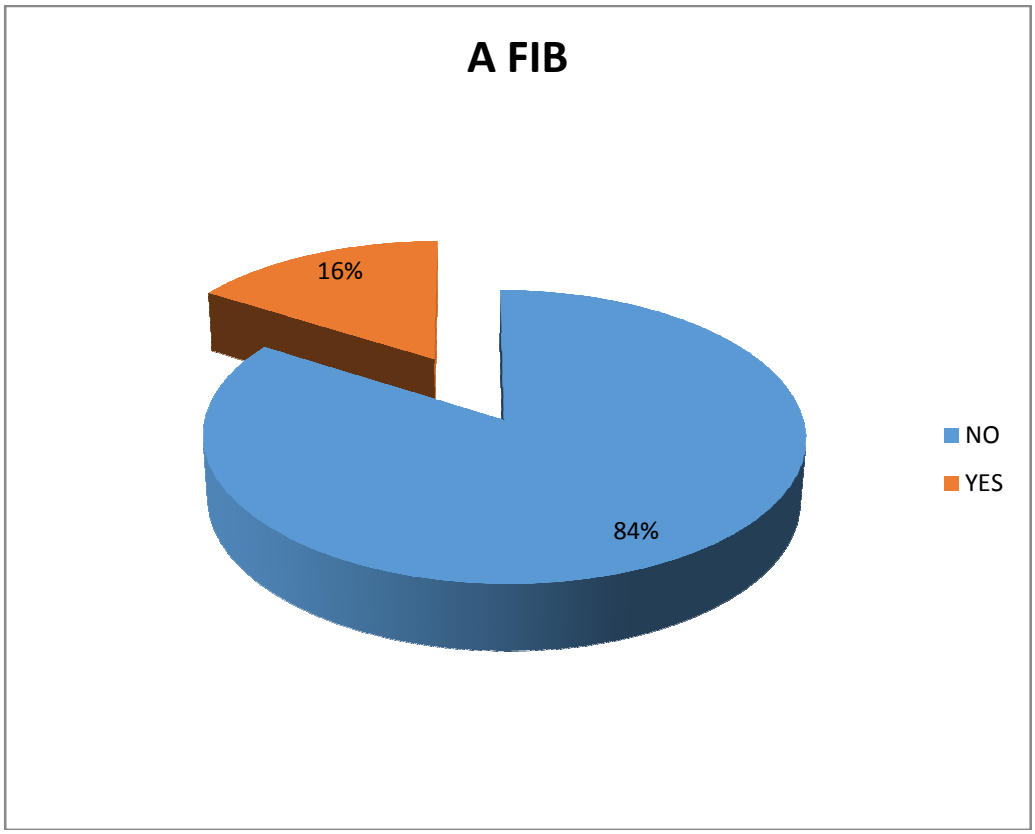


INCIDENCE OF ATRIAL FIBRILLATION

Out of 50 patients in our study group, 16% had atrial

fibrillation and 84 % had no atrial fibrillation

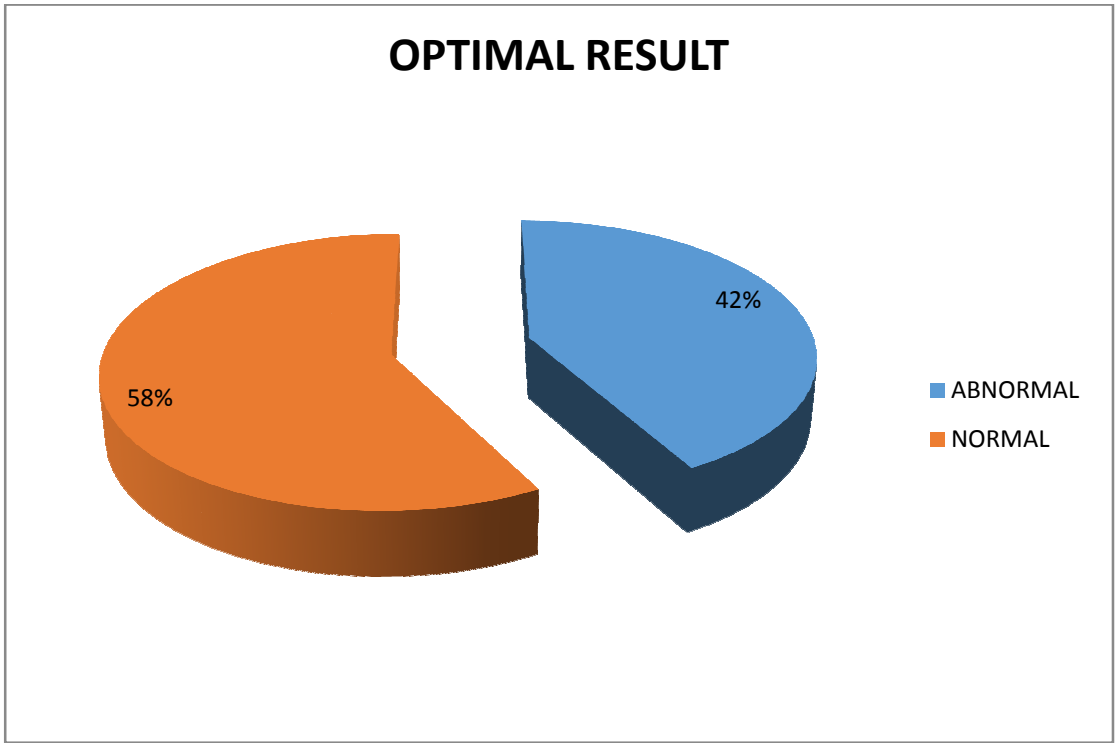
		Frequency	Percent	Valid Percent	Cumulative Percent
A.fib	No	42	84.0	84.0	84.0
	Yes	8	16.0	16.0	100.0
	Total	50	100.0	100.0	



OPTIMAL RESULT WITH REGARD TO MITRAL VALVE ORIFICE AREA, LA PRESSURE AND MITRAL VALVE PEAK GRADIENT

Optimal result is defined as doubling of MVOA, that is a fifty percent increase in mitral valve orifice area, a fifty percent reduction in LA pressure and 50 percent reduction in MVPG

		Frequency	Percent	Valid Percent	Cumulative Percent
result	abnormal	21	42.0	42.0	42.0
	normal (optimal result)	29	58.0	58.0	100.0
	Total	50	100.0	100.0	

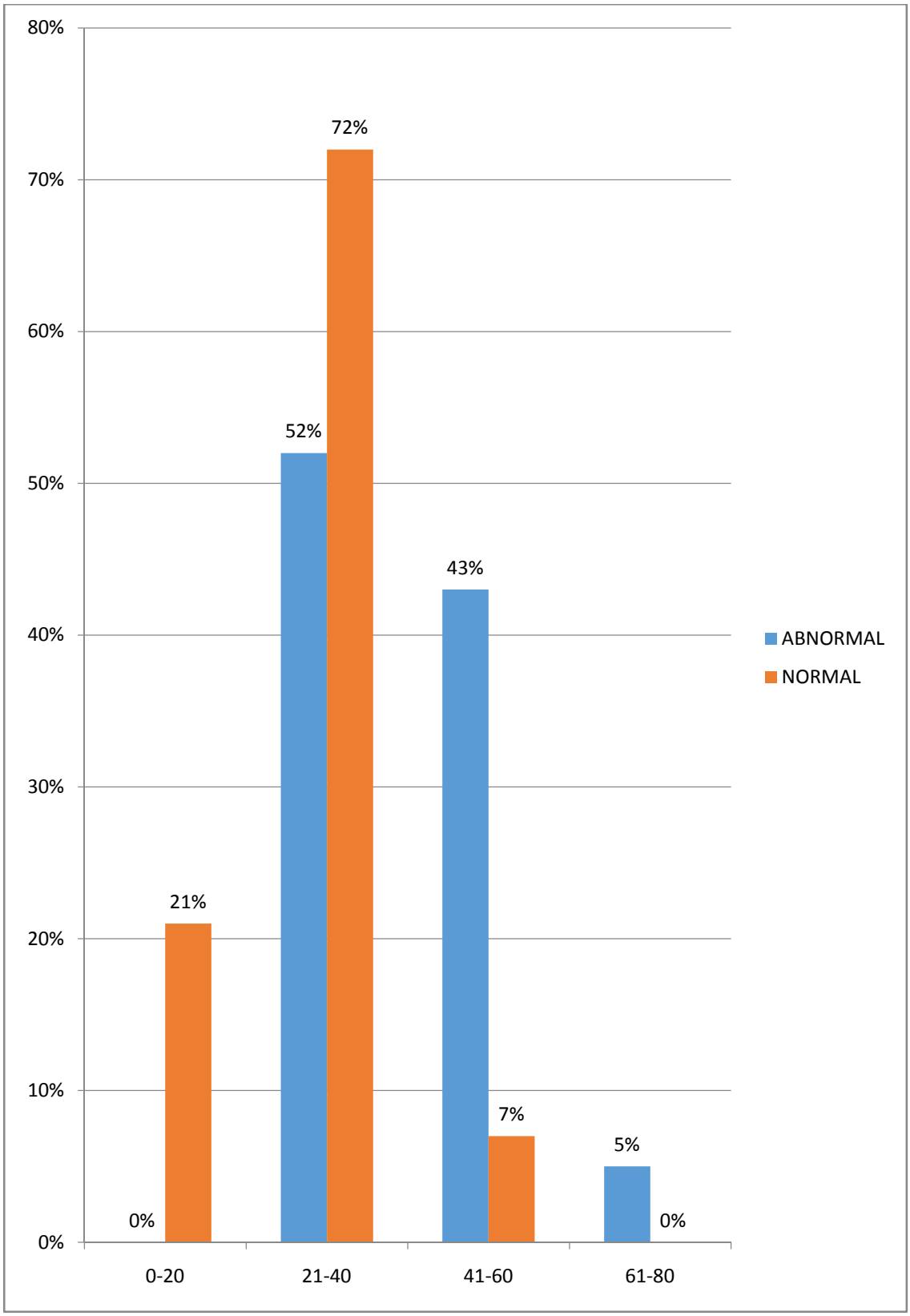


OPTIMAL RESULT IN AGE GROUPS

Age group of 0 – 20 yrs had the maximum overall optimal result of the procedure

			optimal result		Total
			abnormal	normal (optimal result)	
Age group	0-20	Count	0	6	6
		% within optimal result	0.0%	20.7%	12.0%
	21-40	Count	11	21	32
		% within optimal result	52.4%	72.4%	64.0%
	41-60	Count	9	2	11
		% within optimal result	42.9%	6.9%	22.0%
	61-80	Count	1	0	1
		% within optimal result	4.8%	0.0%	2.0%
Total		Count	21	29	50
		% within optimal result	100.0%	100.0%	100.0%

Pearson Chi-Square= 13.649* P=0.003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7%
5%
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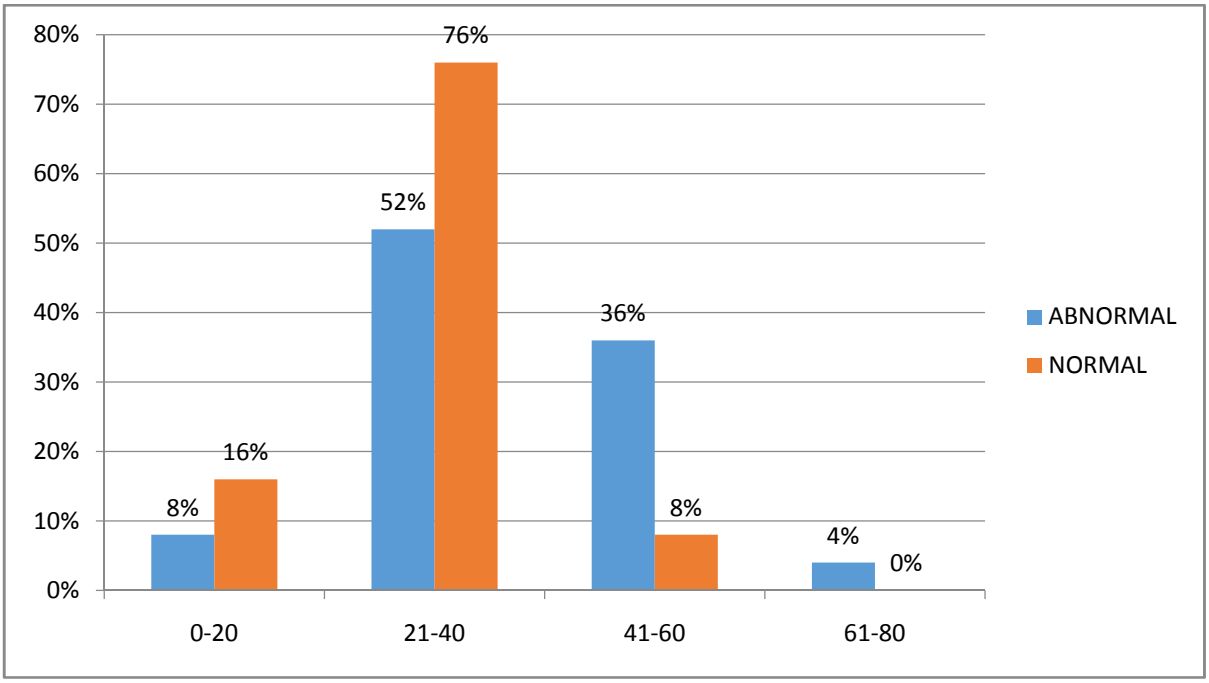
0%
0-20
21-40
41-60
61-80
ABNORMAL
NORMAL

OPTIMAL MVOA IN AGE GROUP

Age group 0 – 20 had the maximum improvement with regard to MVOA

			MVOA group		Total
			Abnormal (<50%)	Normal (>50%)	
age group	0-20	Count	2	4	6
		% within MVOA group	8.0%	16.0%	12.0%
	21-40	Count	13	19	32
		% within MVOA group	52.0%	76.0%	64.0%
	41-60	Count	9	2	11
		% within MVOA group	36.0%	8.0%	22.0%
	61-80	Count	1	0	1
		% within MVOA group	4.0%	0.0%	2.0%
Total		Count	25	25	50
		% within MVOA group	100.0%	100.0%	100.0%

Pearson Chi-Square= 8.016* P=0.046

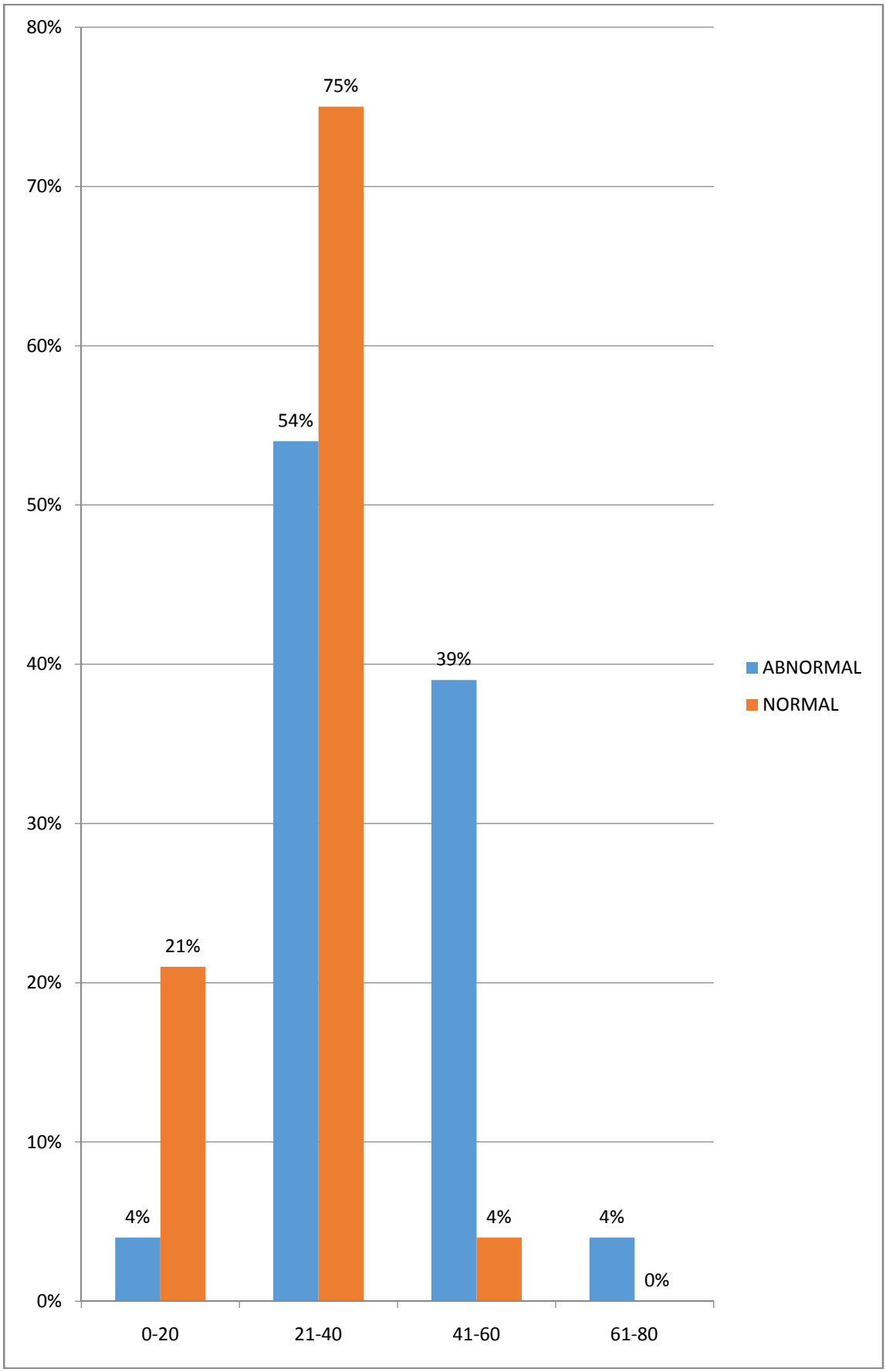


Age group of 0-20 had the maximum optimal result with regard to LA pressure but the association was not statistically significant

			LA PRESSURE group		Total
			Abnormal (50%)	Normal (>50%)	
age_group	0-20	Count	1	5	6
		% within LA PRESSURE group	3.8%	20.8%	12.0%
	21-40	Count	14	18	32
		% within LA PRESSURE__group	53.8%	75.0%	64.0%
	41-60	Count	10	1	11
		% within LA_PRESSURE__group	38.5%	4.2%	22.0%
	61-80	Count	1	0	1
		% within LA_PRESSURE__group	3.8%	0.0%	2.0%
Total		Count	26	24	50
		% within LA_PRESSURE__group	100.0%	100.0%	100.0%

OPTIMAL RESULT IN AGE GROUP WITH REGARD TO IMPROVEMENT IN LA PRESSURE

Pearson Chi-Square= 11.469* P=0.009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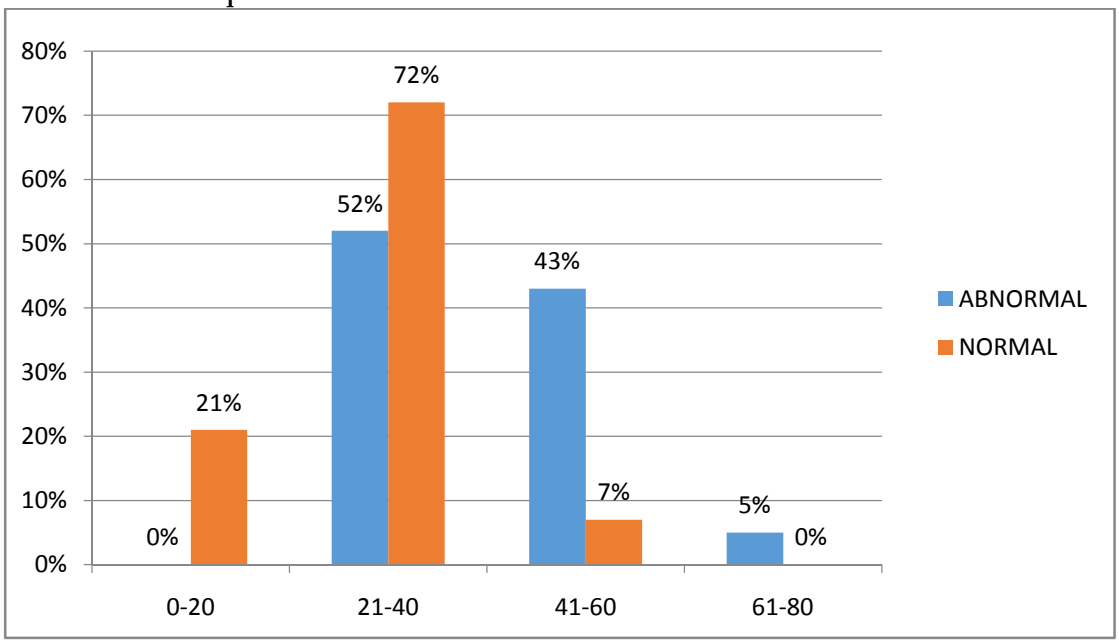
4%
0%
0-20
21-40
41-60
61-80
ABNORMAL
NORMAL

OPTIMAL RESULT IN MVPG WITH REGARD TO AGE GROUP

Age group of 0-20 yrs has the maximum optimal result with regard to MVPG

			MVPG_group		Total
			Abnormal (<50%)	Normal (>50%)	
age_group	0-20	Count	0	6	6
		% within MVPG_group	0.0%	20.7%	12.0%
	21-40	Count	11	21	32
		% within MVPG_group	52.4%	72.4%	64.0%
	41-60	Count	9	2	11
		% within MVPG_group	42.9%	6.9%	22.0%
	61-80	Count	1	0	1
		% within MVPG_group	4.8%	0.0%	2.0%
Total		Count	21	29	50
		% within MVPG_group	100.0%	100.0%	100.0%

Pearson Chi-Square= 13.649* P=0.003

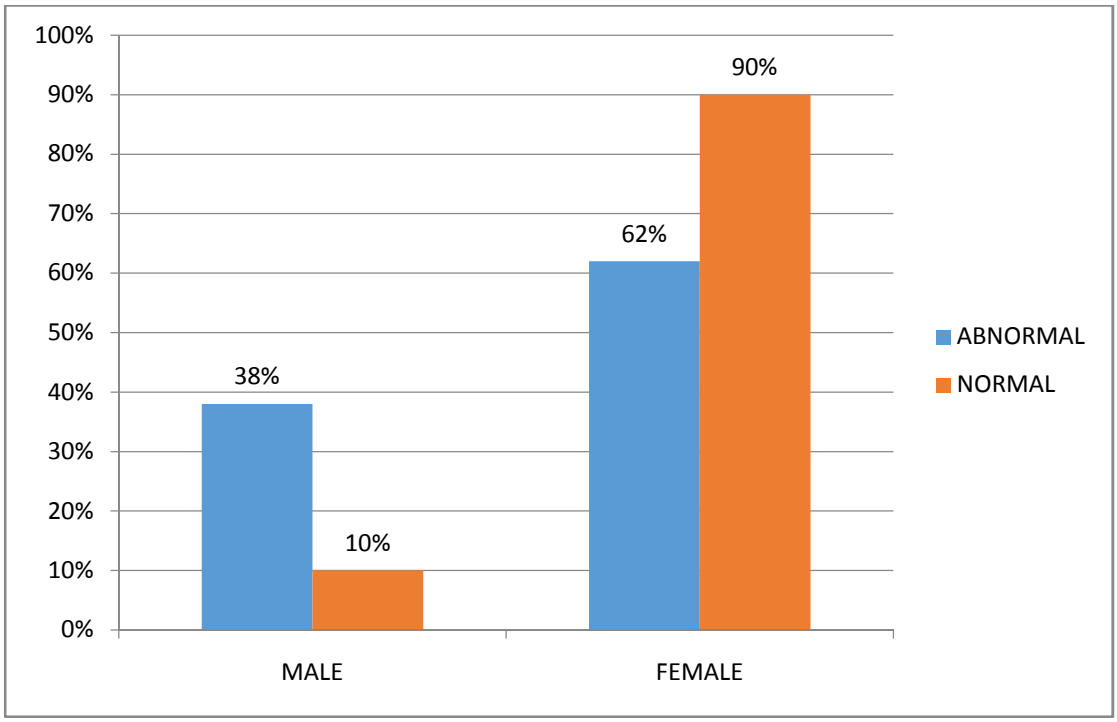


OVERALL OPTIMAL RESULT IN SEX GROUPS

No significant association with sex groups and overall better outcomes with regard to optimal results

			optimal_result		Total
			abnormal	normal (optimal result)	
SEX	MALE	Count	8	3	11
		% within optimal_result	38.1%	10.3%	22.0%
	FEMALE	Count	13	26	39
		% within optimal_result	61.9%	89.7%	78.0%
	Total	Count	21	29	50
		% within optimal_result	100.0%	100.0%	100.0%

Pearson Chi-Square= 5.466 * P=0.019

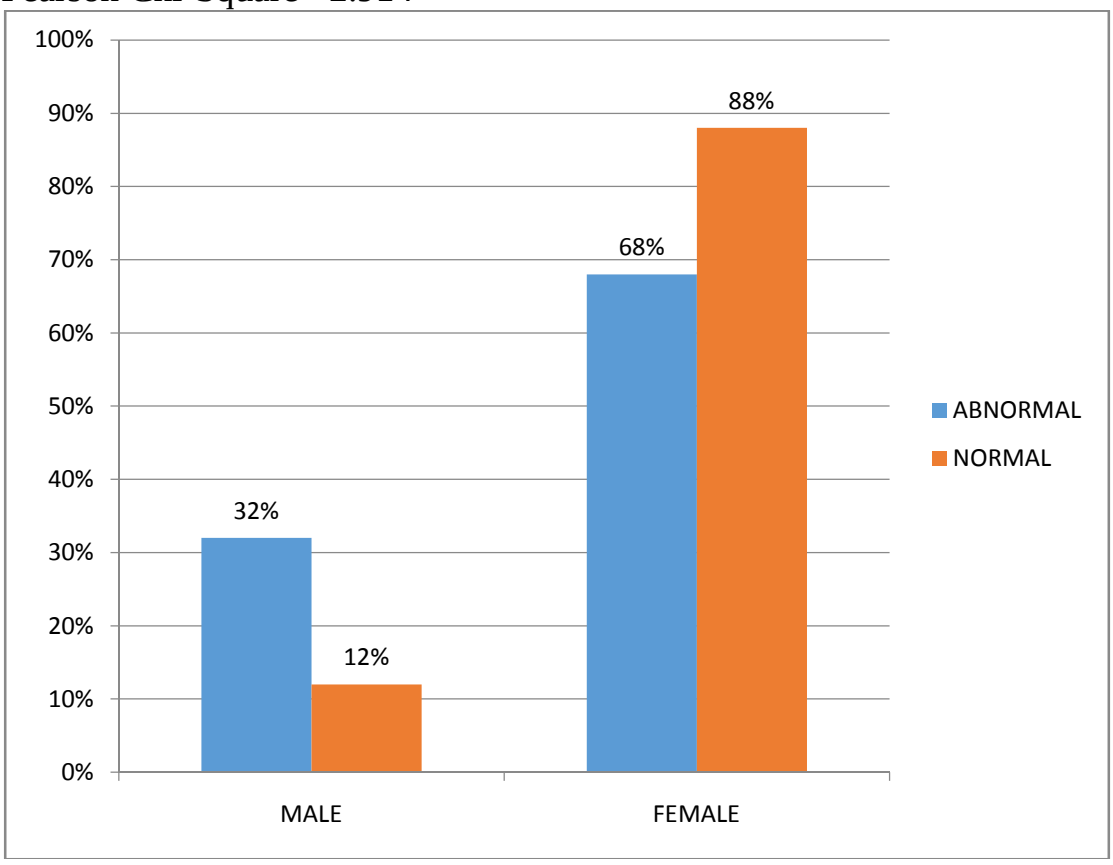


OPTIMAL RESULT WITH REGARD TO MVOA IN SEX GROUPS

No significant association with sex group and overall better outcome with regard to MVOA

			MVOA_group		Total
			Abnormal (<50%)	Normal (>50%)	
SEX	MALE	Count	8	3	11
		% within MVOA_group	32.0%	12.0%	22.0%
	FEMALE	Count	17	22	39
		% within MVOA_group	68.0%	88.0%	78.0%
Total		Count	25	25	50
		% within MVOA_group	100.0%	100.0%	100.0%

Pearson Chi-Square= 2.914

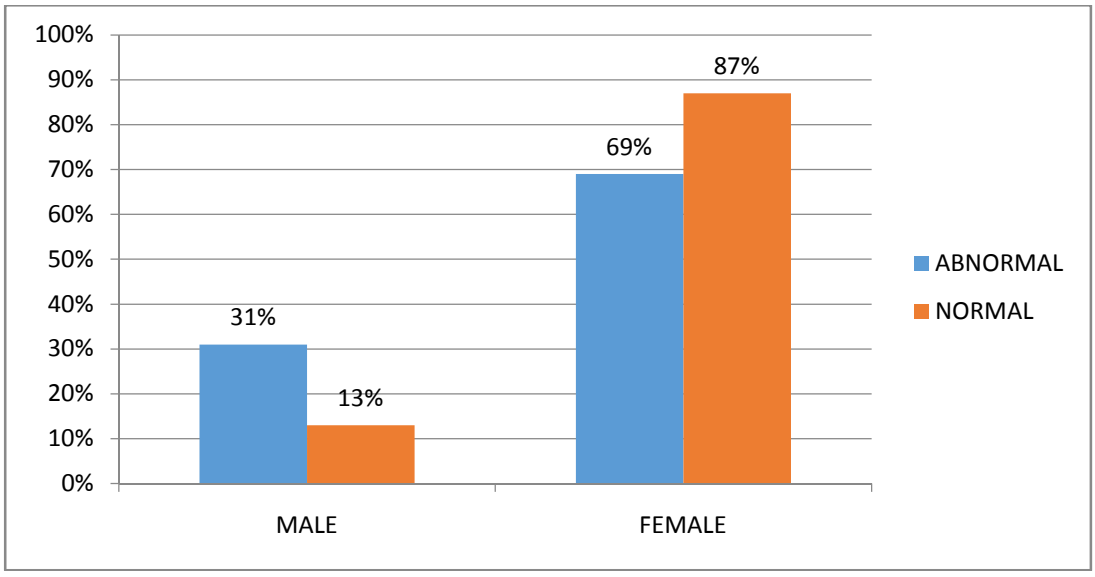


OPTIMAL RESULT WITH REGARD TO LA PRESSURE IN SEX GROUPS

No significant association was found

			LA_PRESSURE__group		Total
			Abnormal (<50%)	Normal (>50%)	
SEX	MALE	Count	8	3	11
		% within LA_PRESSURE__group	30.8%	12.5%	22.0%
	FEMALE	Count	18	21	39
		% within LA_PRESSURE__group	69.2%	87.5%	78.0%
Total		Count	26	24	50
		% within LA_PRESSURE__group	100.0%	100.0%	100.0%

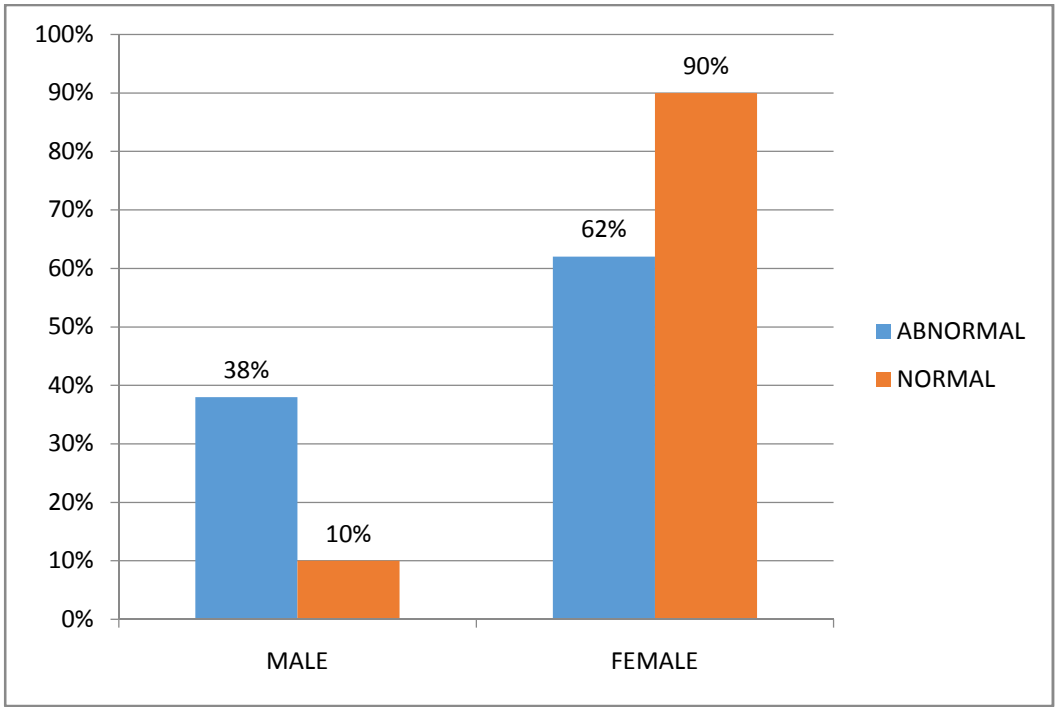
Pearson Chi-Square= 2.427 * P=0.119



OPTIMAL RESULT WITH REGARD TO MVPG IN SEX GROUPS

			MVPG_group		Total
			abnormal (<50%)	normal (>50%)	
SEX	MALE	Count	8	3	11
		% within MVPG_group	38.1%	10.3%	22.0%
	FEMALE	Count	13	26	39
		% within MVPG_group	61.9%	89.7%	78.0%
Total		Count	21	29	50
		% within MVPG_group	100.0%	100.0%	100.0%

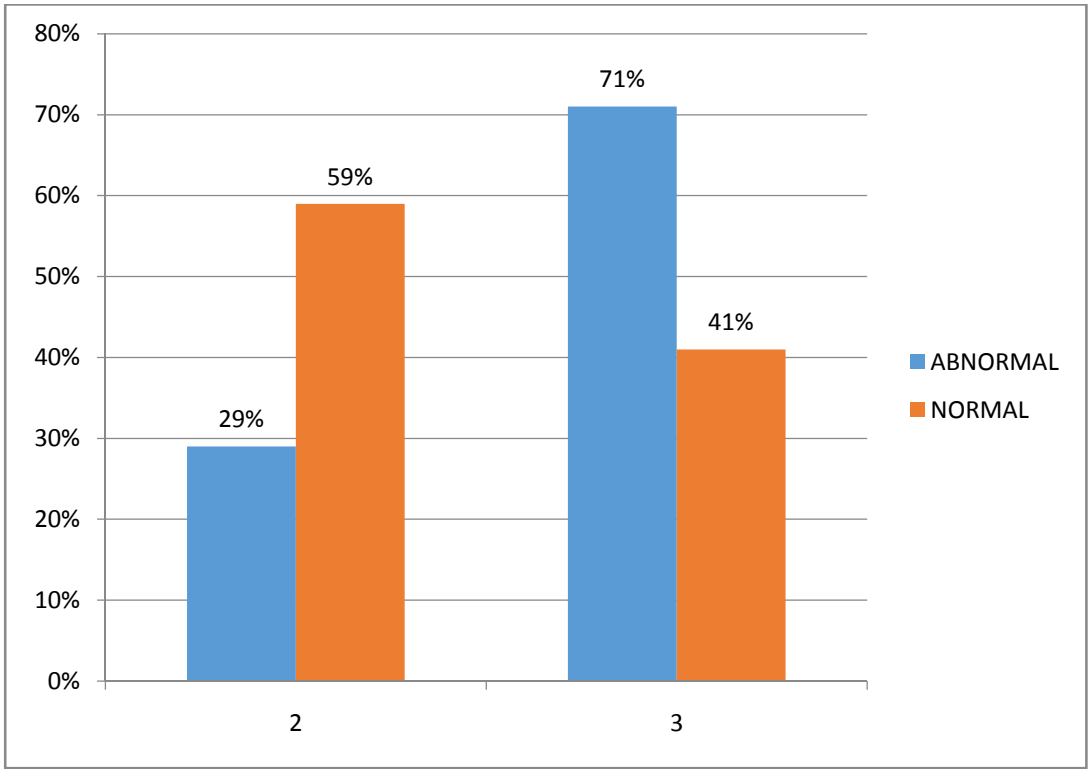
Pearson Chi-Square= 5.466 * **P**=0.019



OVERALL OPTIMAL RESULTS WITH REGARD TO NYHA CLASS

			optimal_result		Total
			abnormal	normal (optimal result)	
NYHA CLASS	2.00	Count	6	17	23
		% within optimal_result	28.6%	58.6%	46.0%
	3.00	Count	15	12	27
		% within optimal_result	71.4%	41.4%	54.0%
Total		Count	21	29	50
		% within optimal_result	100.0%	100.0%	100.0%

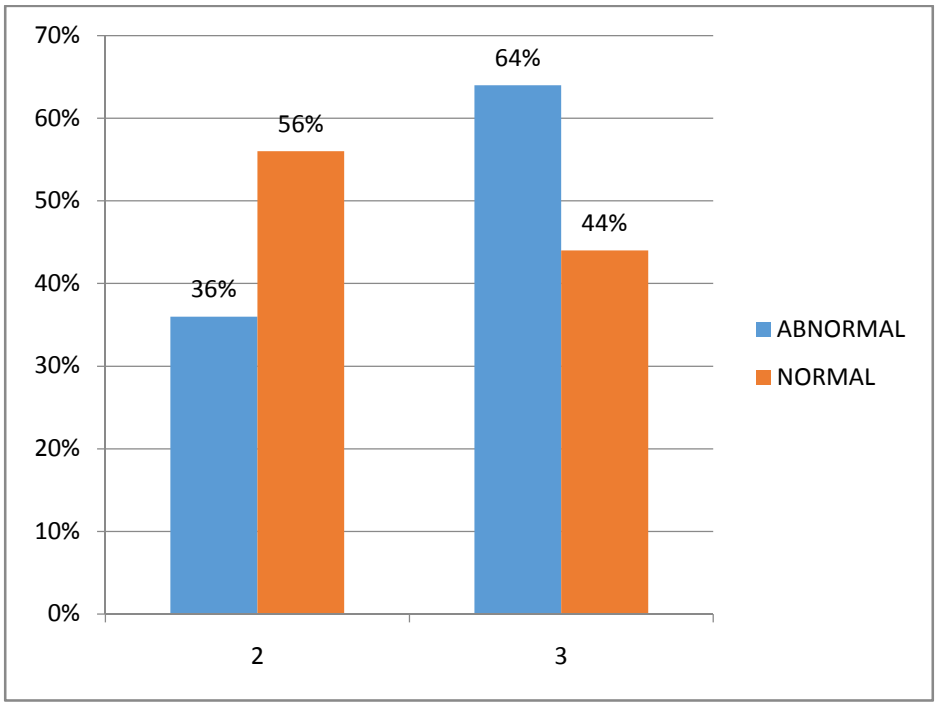
Pearson Chi-Square= 4.428 * P=0.035



OPTIMAL RESULT IN MVOA WITH REGARD TO NYHA CLASS

			MVOA_group		Total
			Abnormal (<50%)	Normal (>50%)	
NYHA CLASS	2.00	Count	9	14	23
		% within MVOA_group	36.0%	56.0%	46.0%
	3.00	Count	16	11	27
		% within MVOA_group	64.0%	44.0%	54.0%
Total		Count	25	25	50
		% within MVOA_group	100.0%	100.0%	100.0 %

Pearson Chi-Square= 2.013 * P=0.156



OPTIMAL RESULTS IN LA PRESSURE WITH REGARD TO NYHA CLASS

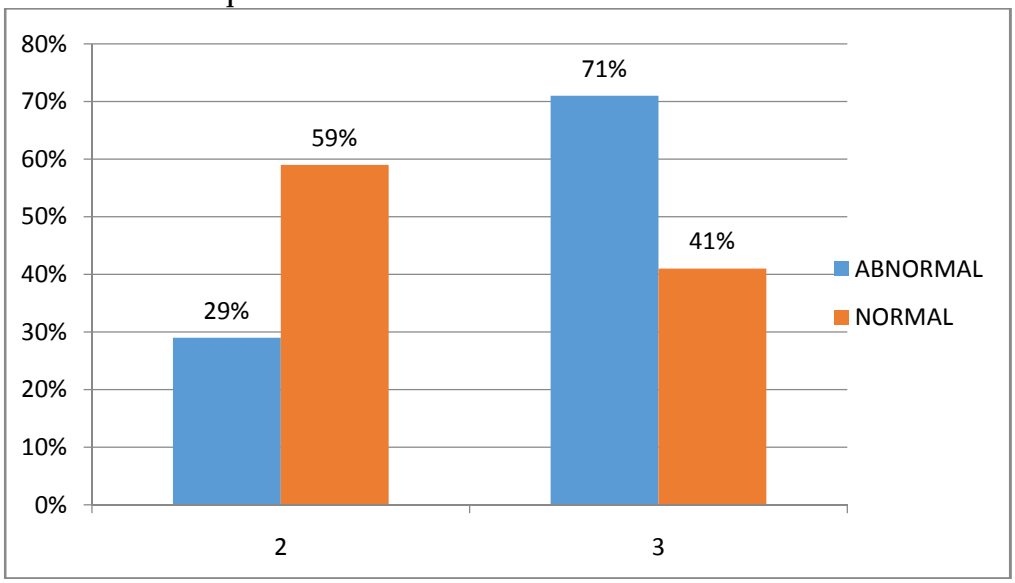
			LA_PRESSURE__group		Total
			Abnormal (<50%)	Normal (>50%)	
NYHA_CLASS	2.00	Count	10	13	23
		% within LA_PRESSURE__group	38.5%	54.2%	46.0%
	3.00	Count	16	11	27
		% within LA_PRESSURE__group	61.5%	45.8%	54.0%
Total		Count	26	24	50
		% within LA_PRESSURE__group	100.0%	100.0%	100.0%

Pearson Chi-Square= 1.239 P=0.266

OPTIMAL RESULT WITH REGARD TO MVPG AND NYHA CLASS

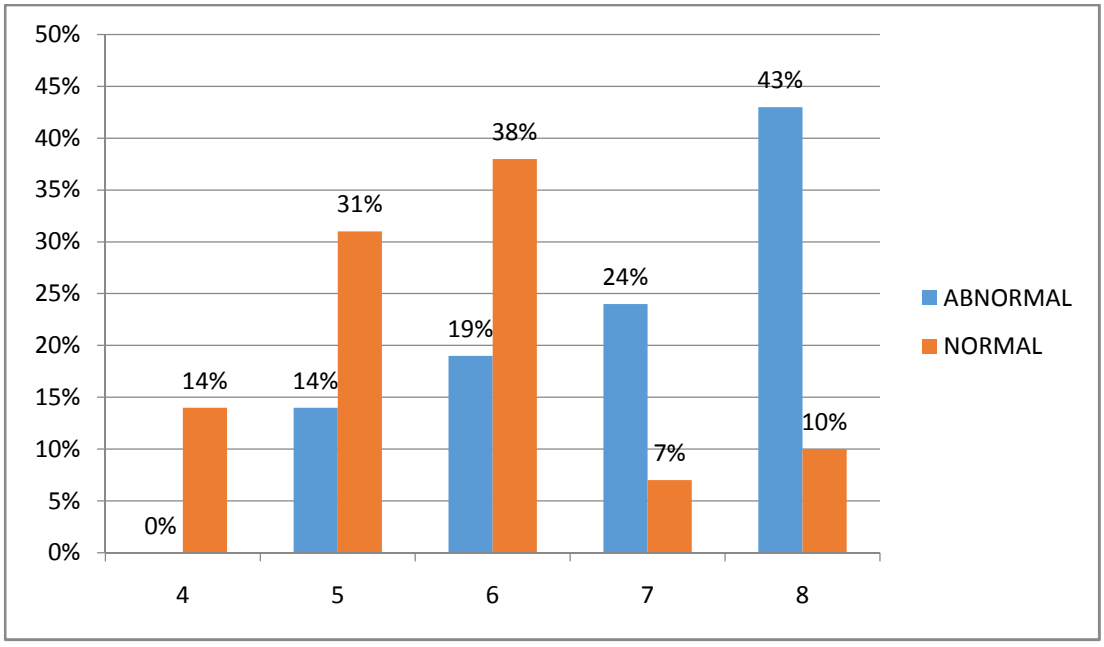
			MVPG_group		Total
			Abnormal (<50%)	Normal (>50%)	
NYHA_CLASS	2.00	Count	6	17	23
		% within MVPG_group	28.6%	58.6%	46.0%
	3.00	Count	15	12	27
		% within MVPG_group	71.4%	41.4%	54.0%
Total		Count	21	29	50
		% within MVPG_group	100.0%	100.0%	100.0%

Pearson Chi-Square= 4.428 * P=0.035



			optimal_result		Total
			abnormal	normal (optimal result)	
WILKINS_SCORE	4.00	Count	0	4	4
		% within optimal_result	0.0%	13.8%	8.0%
	5.00	Count	3	9	12
		% within optimal_result	14.3%	31.0%	24.0%
	6.00	Count	4	11	15
		% within optimal_result	19.0%	37.9%	30.0%
	7.00	Count	5	2	7
		% within optimal_result	23.8%	6.9%	14.0%
	8.00	Count	9	3	12
		% within optimal_result	42.9%	10.3%	24.0%
Total		Count	21	29	50
		% within optimal_result	100.0%	100.0%	100.0%

Pearson Chi-Square= 13.621 * P=0.009

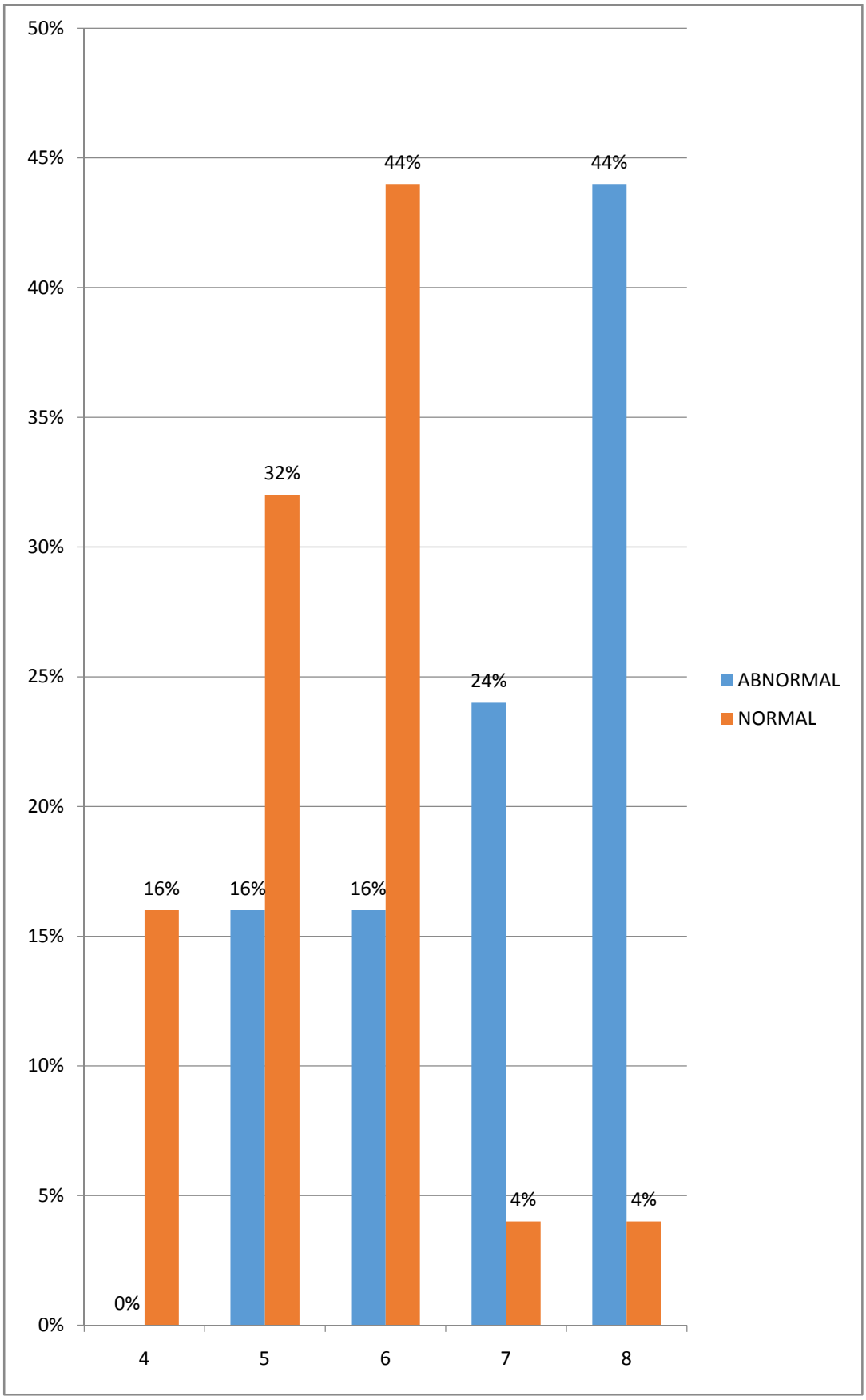


OPTIMAL RESULT IN INCREASE IN MVOA WITH REGARD TO WILKINS SCORE

The association between Wilkins score and outcome of PTMC with regard to optimal result in mitral valve orifice area was statistically significant with patients having a lower Wilkins score having a better outcome of the surgery. Optimal result of PTMC with regard to MVOA is an increase in MVOA of 50 % of the baseline valve area.

			MVOA_group		Total
			abnormal (<50%)	normal (>50%)	
WILKINS_SCORE	4.00	Count	0	4	4
		% within MVOA_group	0.0%	16.0%	8.0%
	5.00	Count	4	8	12
		% within MVOA_group	16.0%	32.0%	24.0%
	6.00	Count	4	11	15
		% within MVOA_group	16.0%	44.0%	30.0%
	7.00	Count	6	1	7
		% within MVOA_group	24.0%	4.0%	14.0%
	8.00	Count	11	1	12
		% within MVOA_group	44.0%	4.0%	24.0%
Total		Count	25	25	50
		% within MVOA_group	100.0%	100.0%	100.0%

Pearson Chi-Square= 20.505* P<0.001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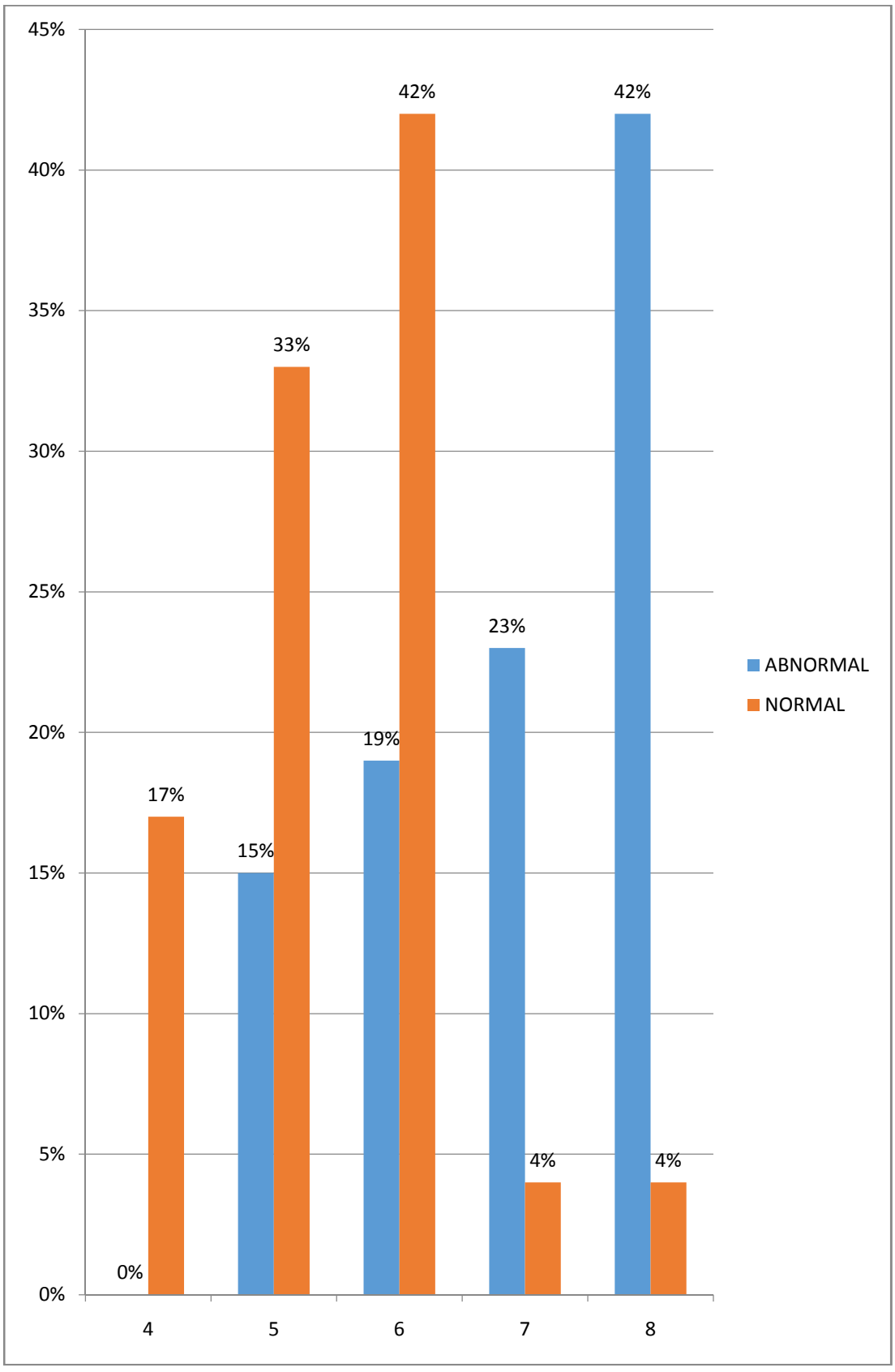
ABNORMAL
NORMAL

OPTIMAL RESULTS OF PTMC WITH REGARD TO REDUCTION IN LA PRESSURE AND WILKINS SCORE

The association between the optimal reduction in LA pressure post PTMC and Wilkins score was found to be statistically significant . The results were optimal with lower Wilkins scores. The optimal reduction is LA pressure is 50% from the base line

			LA_PRESSURE__group		Total
			abnormal (<50%)	normal (>50%)	
WILKINS_SCORE	4.00	Count	0	4	4
		% within LA_PRESSURE__group	0.0%	16.7%	8.0%
	5.00	Count	4	8	12
		% within LA_PRESSURE__group	15.4%	33.3%	24.0%
	6.00	Count	5	10	15
		% within LA_PRESSURE__group	19.2%	41.7%	30.0%
	7.00	Count	6	1	7
		% within LA_PRESSURE__group	23.1%	4.2%	14.0%
	8.00	Count	11	1	12
		% within LA_PRESSURE__group	42.3%	4.2%	24.0%
Total		Count	26	24	50
		% within LA_PRESSURE__group	100.0%	100.0%	100.0 %

Pearson Chi-Square= 18.855* P=0.001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ABNORMAL
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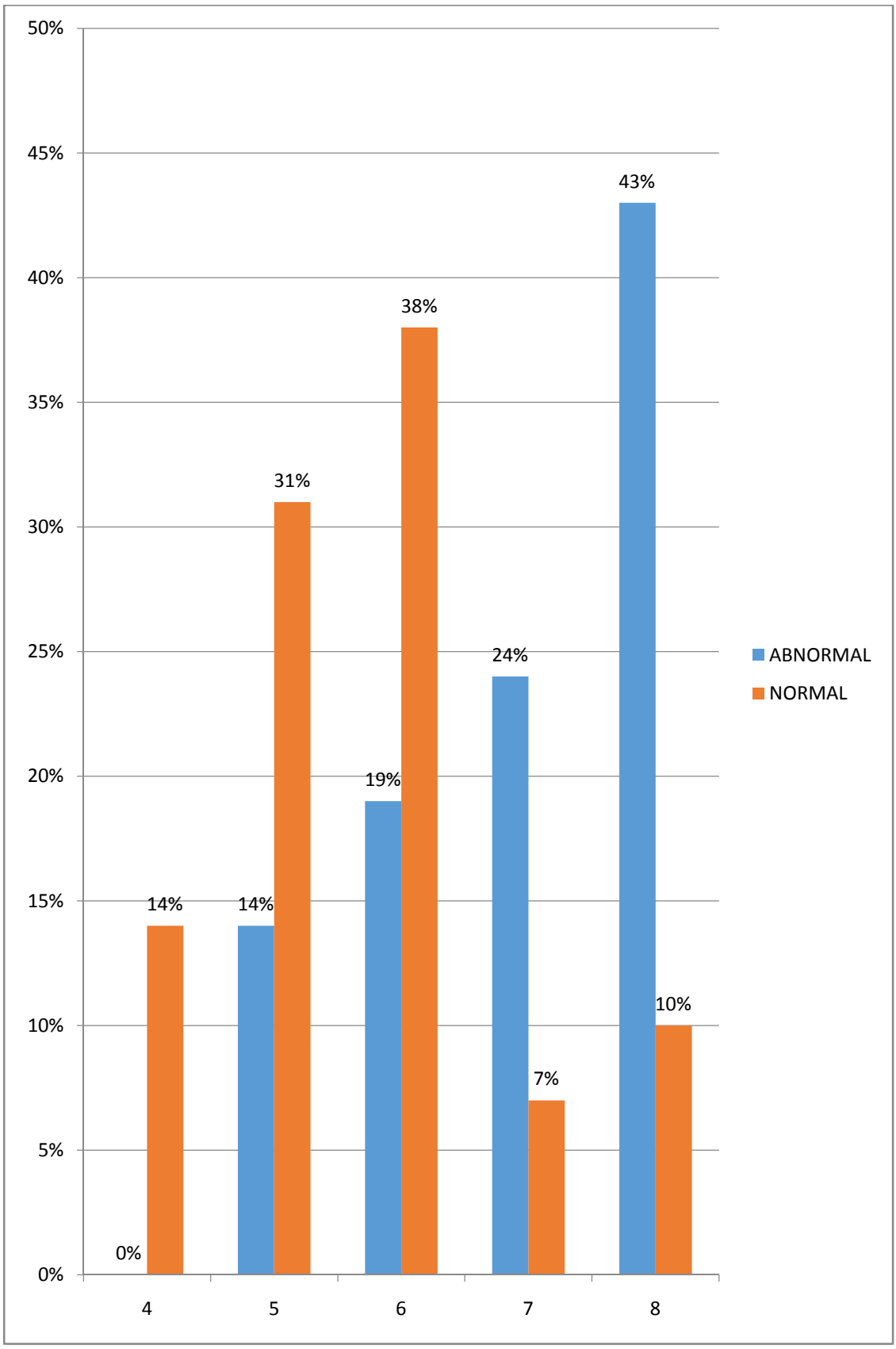
OPTIMAL RESULT WITH REGARD TO MVPG AND WILKINS SCORE

The association was found to be statistically significant and patients with Lower Wilkins score had a better outcome in terms of MVPG. Optimal MVPG is a decrease of 50% from the baseline

			MVPG_group		Total
			abnormal (<50%)	normal (>50%)	
WILKINS_SCORE	4.00	Count	0	4	4
		% within MVPG_group	0.0%	13.8%	8.0%
	5.00	Count	3	9	12
		% within MVPG_group	14.3%	31.0%	24.0%
	6.00	Count	4	11	15
		% within MVPG_group	19.0%	37.9%	30.0%
	7.00	Count	5	2	7
		% within MVPG_group	23.8%	6.9%	14.0%
	8.00	Count	9	3	12
		% within MVPG_group	42.9%	10.3%	24.0%
Total		Count	21	29	50
		% within MVPG_group	100.0%	100.0%	100.0%

Pearson Chi-Square= 13.621*p<0.001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38%
24%
7%
43%
10%
ABNORMAL
NORMAL

ATRIAL FIBRILLATION AND OUTCOME OF PTMC

			optimal_result		Total
			abnormal	normal (optimal result)	
ATRIAL FIBRILLATION	N	Count	16	26	42
		% within optimal_result	76.2%	89.7%	84.0%
	Y	Count	5	3	8
		% within optimal_result	23.8%	10.3%	16.0%
Total		Count	21	29	50
		% within optimal_result	100.0%	100.0%	100.0%

Pearson Chi-Square= 1.643 p=0.200

ATRIAL FIBRILLATION AND MITRAL VALVE ORIFICE AREA

			MVOA_group		Total
			abnormal (<50%)	normal (>50%)	
ATRIAL FIBRILLATION	N	Count	19	23	42
		% within MVOA_group	76.0%	92.0%	84.0%
	Y	Count	6	2	8
		% within MVOA_group	24.0%	8.0%	16.0%
Total		Count	25	25	50
		% within MVOA_group	100.0%	100.0%	100.0%

Pearson Chi-Square= 2.381 P=0.123

ATRIAL FIBRILLATION AND ITS EFFECT ON LA PRESSURE

			LA_PRESSURE__group		Total
			abnormal (<50%)	normal (>50%)	
ATRIAL FIBRILLATION	No	Count	20	22	42
		% within LA_PRESSURE__group	76.9%	91.7%	84.0%
	Yes	Count	6	2	8
		% within LA_PRESSURE__group	23.1%	8.3%	16.0%
Total		Count	26	24	50
		% within LA_PRESSURE__group	100.0%	100.0%	100.0%

Pearson Chi-Square= 2.018 P=0.155

Crosstab

			MVPG_group		Total
			Abnormal (<50%)	Normal (>50%)	
A#FIB	N	Count	16	26	42
		% within MVPG_group	76.2%	89.7%	84.0%
	Y	Count	5	3	8
		% within MVPG_group	23.8%	10.3%	16.0%
Total		Count	21	29	50
		% within MVPG_group	100.0%	100.0%	100.0%

Pearson Chi-Square= 1.643 P=0.200

RELATIONSHIP BETWEEN WILKINS SCORE AND THREE PARAMETERS FOR OUTCOME OF SURGERY

		MVOA INCREASE	LA PRESSURE DECREASE	MVPG DECREASE
WILKINS_SCORE	Pearson Correlation	-.548**	-.569**	-.566**
	P VALUE	.000	.000	.000
	N	50	50	50

** CORRELATION IS significant AT P<0.001

DISCUSSION

DISCUSSION

Out of the 50 patients who were included in the study group 64% were in 21-40 age group, 78% were females, 52% have symptoms and NYHA II, 48% have symptoms in NYHA class III, 0% in NYHA class I & IV. All the patients had wilkins score of 8 or below. Out of the 50 patients 84% had no atrial fibrillation.

Optimal results of the procedure was taken as 50% increase in mitral valve orifice area, 50% decrease in left atrial pressure, 50% decrease in mitral valve peak gradient. The outcome of the procedure in terms of all the three parameters was studied.

Even though lower age group, female sex, no atrial fibrillation and lower NYHA class seemed to have better outcomes the association was not statistically significant. The association between wilkins score and outcome with regard to all three parameters was statistically significant.

CONCLUSION

CONCLUSION

It was the findings of the study that patients with lower age, lower NYHA class, patient not in atrial fibrillation, female sex, lower ECHO cardiographic score were all found to have better hemodynamic outcomes. But patients with lower Wilkins score had a statiscally significant hemodynamic improvement. This shows that even though ECHO cardiographic scores are not the only parameters determining the outcome of PTMC, they still have a significant role in patient selection for PTMC.

From all the discussions above, it is evident that PTMC is the procedure of choice for the management of uncomplicated and pliable mitral stenosis. Even in unfavourable situations PTMC has a place in the treatment of the disease especially in the developing world, where the facilities for mitral valve replacement are limited.

Problems of anticoagulation are also common in these settings. So PTMC can overcome this problem. PTMC has an advantage over closed mitral commissurotomy and may be on par with open mitral commissurotomy for a pliable valve.

It is a better option than surgical mitral commissurotomy in pregnant patients. In the presence of an LA thrombus, PTMC has no role and open mitral commissurotomy is the procedure of choice in this setting.

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BIBLIOGRAPHY

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ABBREVIATIONS

PTMC	-	Percutaneous transvenous mitral commissurotomy
MVOA	-	Mitral valve orifice area
RHD	-	Rheumatic heart disease
MS	-	Mitral stenosis
MVMG	-	Mitral valve mean gradient
MVPG	-	Mitral valve peak gradient
OMC	-	Open mitral commisurotomy
CMC	-	Closed mitral commisurotomy

ANNEXURES

PRO-FORMA

NAME: AGE: SEX: CD No:

ADDRESS: MRD No:

ANGIO No:

DIAGNOSIS-

NYHA CLASS-
WEIGHT-

PROCEDURE DONE-
HEIGHT-

DATE-

WILKINS ECHO SCORE

PARAMETERS	POINTS
THICKENING	
MOBILITY	
SUBVALVULAR FUSION	
CALCIFICATION	
TOTAL SCORE	

TRANSESOPHAGEAL ECHO-

TECHNIQUE USED- DOUBLE BALOON/ INOUE/ OTHERS

HARDWARE USED-

BALOON SIZE-

IAS PUNCTURE- RAO/ LATERAL/AP

ANTICOAGULANTS/ INR-

HEPARIN-

ATRIAL FIBRILLATION- PRE PROCEDURE/ DURING/ POST PROCEDURE

POST CMC or POST BMV- YES/ NO IF YES-

PREGNANCY- YES/ NO

PARAMETER	PRE BMV	POST BMV
MVOA (PLANIMETRY)		
MITRAL FLOW PEAK GRADIENT		
MITRAL REGURGITATION		
TRICUSPID REGURGITATION		
LA PRESSURE		

COMPLICATIONS IF ANY- TECHNICAL FAILURE/ SUBOPTIMAL RESULT/ SEVERE MR/TAMPONADE/CVA/ DEATH/ OTHERS

INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE, CHENNAI 600 003

EC Reg.No.ECR/270/Inst./TN/2013
Telephone No.044 25305301
Fax: 011 25363970

CERTIFICATE OF APPROVAL

To
Dr.A.Arthi
Post Graduate in M.D. (General Medicine)
Institute of Internal Medicine
Madras Medical College
Chennai 600 003

Dear Dr.A.Arthi,

The Institutional Ethics Committee has considered your request and approved your study titled **"AN OBSERVATIONAL STUDY TO ASSESS IMMEDIATE HEMODYNAMIC OUTCOMES IN PATIENTS UNDERGOING PERCUTANEOUS TRANSVENOUS MITRAL COMMISSUROTOMY IN OUR INSTITUTION" - NO. (II) 02032016.**

The following members of Ethics Committee were present in the meeting hold on **22.03.2016** conducted at Madras Medical College, Chennai 3

1.Dr.C.Rajendran, MD.,	:Chairperson
2.Dr.R.Vimala,MD.,Dean,MMC,Ch-3	:Deputy Chairperson
3.Prof.Sudha Seshayyan,MD., Vice Principal,MMC,Ch-3	: Member Secretary
4.Prof.P.Raghumani,MS, Dept.of Surgery,RGGGH,Ch-3	: Member
5.Dr.Baby Vasumathi, Director, Inst. of O&G,Ch-8	: Member
6.Prof.M.Saraswathi,MD.,Director, Inst.of Path,MMC,Ch-3	: Member
7.Prof.Srinivasagalu,Director,Inst.of Int.Med.,MMC,Ch-3	: Member
8.Tmt.J.Rajalakshmi, JAO,MMC, Ch-3	: Lay Person
9.Thiru S.Govindasamy, BA.,BL,High Court,Chennai	: Lawyer
10.Tmt.Arnold Saulina, MA.,MSW.,	:Social Scientist

We approve the proposal to be conducted in its presented form.

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

MADRAS MEDICAL COLLEGE
31 MAR 2016
CHENNAI-600 003

31/3/16
Member Secretary - Ethics Committee

MEMBER SECRETARY
INSTITUTIONAL ETHICS COMMITTEE
MADRAS MEDICAL COLLEGE
CHENNAI-600 003

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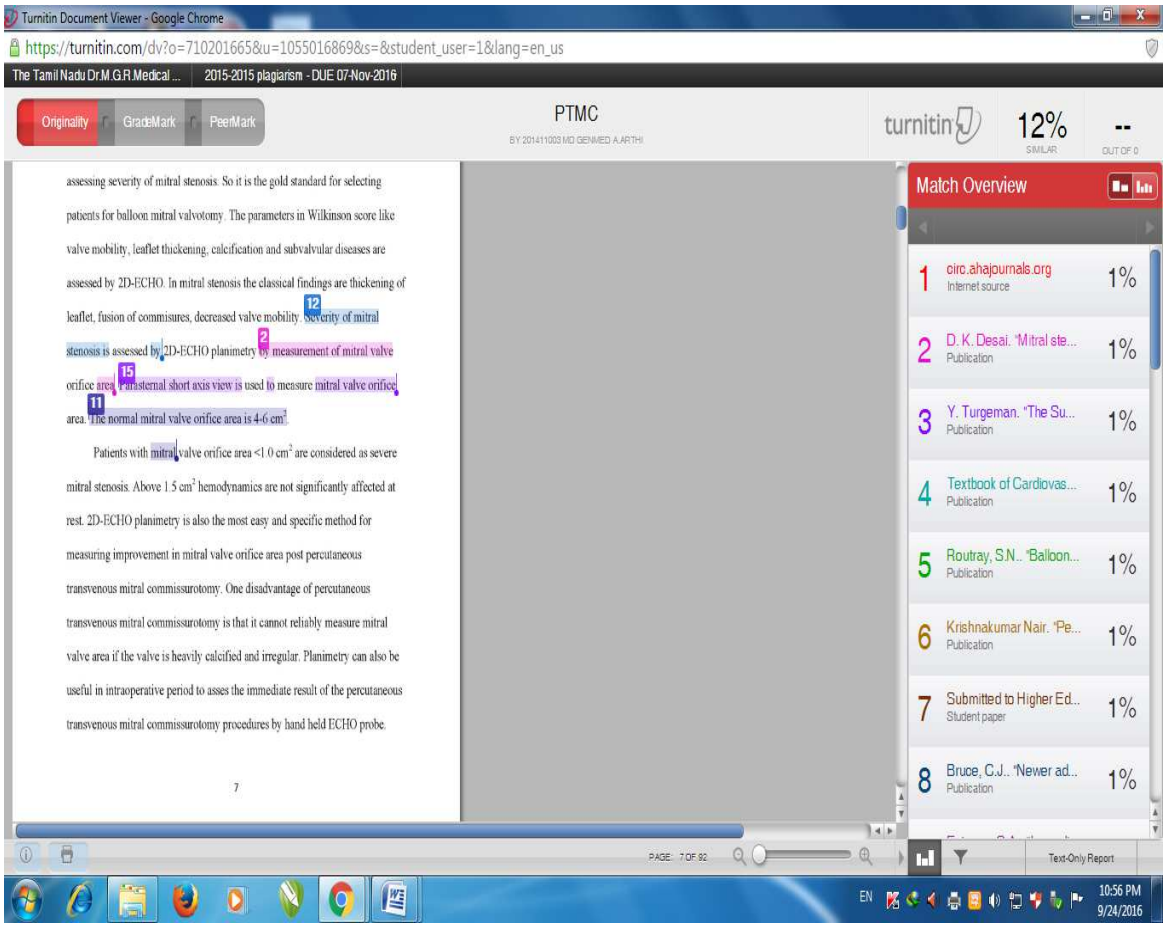

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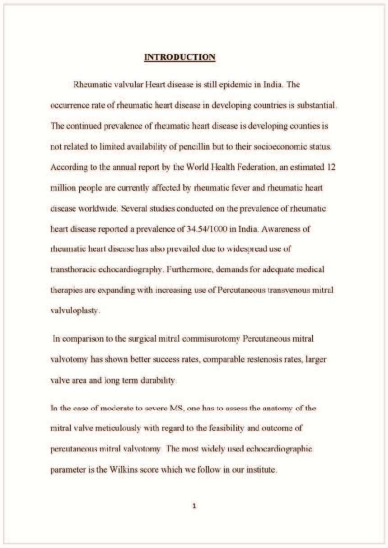

INTRODUCTION

Rheumatic valvular Heart disease is still epidemic in India. The occurrence rate of rheumatic heart disease in developing countries is substantial. The continued prevalence of rheumatic heart disease is developing counties is not related to limited availability of pencillin but to their socioeconomic status. According to the annual report by the World Health Federation, an estimated 12 million people are currently affected by rheumatic fever and rheumatic heart disease worldwide. Several studies conducted on the prevalence of rheumatic heart disease reported a prevalence of 34.54/1000 in India. Awareness of rheumatic heart disease has also prevailed due to widespread use of transthoracic echocardiography. Furthermore, demands for adequate medical therapies are expanding with increasing use of Percutaneous transvenous mitral valvuloplasty.

In comparison to the surgical mitral commisurotomy Percutaneous mitral valvotomy has shown better success rates, comparable restenosis rates, larger valve area and long term durability.

In the case of moderate to severe MS, one has to assess the anatomy of the mitral valve meticulously with regard to the feasibility and outcome of percutaneous mitral valvotomy. The most widely used echocardiographic parameter is the Wilkins score which we follow in our institute.

1

PATIENT INFORMATION SHEET

We are conducting a study on "AN OBSERVATIONAL STUDY TO ASSESS IMMEDIATE HEMODYNAMIC OUTCOMES IN PATIENTS UNDERGOING PERCUTANEOUS TRANSVENOUS MITRAL COMMISUROTOMY IN OUR INSTITUTION" among patients who meet the selection criteria for PTMC and undergoing PTMC at Rajiv Gandhi Government General Hospital, Chennai

The purpose of this study is to assess the success rate of the procedure and patients hemodynamic and clinical outcomes in our institution.

We are selecting certain cases and if you are found eligible, we would like to collect preoperative assessment data, intraoperative data, postoperative assessment data, which in any way do not affect your final report or management.

The privacy of the patients in the research will be maintained throughout the study. In the event of any publication or presentation resulting from the research, no personally identifiable information will be shared.

Taking part in this study is voluntary. You are free to decide whether to participate in this study or to withdraw at any time; your decision will not result in any loss of benefits to which you are otherwise entitled.

The results of the special study may be intimated to you at the end of the study period or during the study if anything is found abnormal which may aid in the management or treatment.

Signature of the Investigator

Signature left thumb impression participant

Date:

Place:

ஆராய்ச்சி தகவல் தாள்

சென்னை ராஜீவ்காந்தி அரசு பொது மருத்துவமனையின் இருதய மருத்துவத்துறையில் "எங்கள் நிறுவனத்தில் தோல்வழி சிரையினூடாக செய்யப்படும் மைட்ரல் பிணைப்பு நீக்கம் என்ற சிகிச்சை பெற்ற நோயாளிகளின் உடனடி இரத்த ஓட்ட விளைவுகளை மதிப்பீடு செய்ய ஓர் கூர்நோக்கு ஆய்வு" பற்றிய ஆய்வு நடைபெறுகிறது.

நீங்களும் இந்த ஆராய்ச்சியில் பங்கேற்க நாங்கள் விரும்புகிறோம். இதனால் தங்களது சிகிச்சையில் பாதிப்பு ஏற்படாது என்பதையும் தெரிவித்துக்கொள்கிறோம்.

தோல்வழி சிரையினூடாக செய்யப்படும் மைட்ரல் பிணைப்பு நீக்கம் என்ற சிகிச்சை பெற்ற நோயாளிகளின் உடனடி இரத்த ஓட்ட விளைவுகளை மதிப்பீடு செய்யவதே இந்த ஆய்வின் நோக்கமாகும்.

சிகிச்சைக்கு முன்னும் சிகிச்சையின்போதும் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்தப்படும்.

முடிவுகளை அல்லது கருத்துக்களை வெளியிடும்போதோ அல்லது ஆராய்ச்சியின்போதோ தங்களது பெயரையோ அல்லது அடையாளங்களையோ வெளியிட மாட்டோம் என்பதை தெரிவித்துக்கொள்கிறோம்.

இந்த ஆராய்ச்சியில் பங்கேற்பது தங்களுடைய விருப்பத்தின்பேரில்தான் இருக்கிறது. மேலும் நீங்கள் எந்த நேரமும் இந்த ஆராய்ச்சியிலிருந்து பின்வாங்கலாம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

இந்த சிறப்பு பரிசோதனைகளின் முடிவுகளையும் நோயின் தன்மை பற்றியும் ஆராய்ச்சியின்போது அல்லது ஆராய்ச்சியின் முடிவின்போது தங்களுக்கு அறிவிப்போம் என்பதையும் தெரிவித்துக்கொள்கிறோம்.

ஆராய்ச்சியாளர் கையொப்பம் **பங்கேற்பாளர் கையொப்பம்**

நாள் :

இடம் :

PATIENT CONSENT FORM

Study Detail	:	"AN OBSERVATIONAL STUDY TO ASSESS IMMEDIATE HEMODYNAMIC OUTCOMES IN PATIENTS UNDERGOING PERCUTANEOUS TRANSVENOUS MITRAL COMMISUROTOMY IN OUR INSTITUTION"
Study Centre	:	Institute of cardiology, Rajiv Gandhi Government General Hospital, Chennai.
Patient's Name	:	
Patient's Age	:	
Identification Number	:	

Patient may check (☑) these boxes

I confirm that I have understood the purpose of procedure for the above study. I have the opportunity to ask question and all my questions and doubts have been answered to my complete satisfaction. ❑

I understand that my participation in the study is voluntary and that I am free to withdraw at any time without giving reason, without my legal rights being affected. ❑

I understand that sponsor of the clinical study, others working on the sponsor's behalf, the ethical committee and the regulatory authorities will not need my permission to look at my health records, both in respect of current study and any further research that may be conducted in relation to it, even if I withdraw from the study I agree to this access. However, I understand that my identity will not be revealed in any information released to third parties or published, unless as required under the law. I agree not to restrict the use of any data or results that arise from this study. ❑

I agree to take part in the above study and to comply with the instructions given during the study and faithfully cooperate with the study team and to immediately inform the study staff if I ❑

suffer from any deterioration in my health or well-being or any unexpected or unusual symptoms.

I hereby consent to participate in this study. ❑

I hereby give permission to undergo complete clinical examination,and necessary investigations. ❑

Signature of Investigator
Study Investigator's Name:
Dr.A.ARTHI

Signature/thumb impression
Patient's Name and Address:

ஆராய்ச்சி ஒப்புதல் படிவம்

ஆராய்ச்சியின் தலைப்பு

எங்கள் நிறுவனத்தில் தோல்வழி சிரையினூடாக செய்யப்படும் மைட்ரல் பிணைப்பு நீக்கம் என்ற சிகிச்சை பெற்ற நோயாளிகளின் உடனடி இரத்த ஓட்ட விளைவுகளை மதிப்பீடு செய்ய ஓர் கூர்நோக்கு ஆய்வு

ஆய்வு நிலையம் : இருதய மருத்துவத்துறை,
சென்னை மருத்துவக் கல்லூரி சென்னை - 3.

பங்கு பெறுபவரின் பெயர் :

உள்நோயாளி எண் :

பங்குபெறுபவர் இதனை (✓) குறிக்கவும்

மேலே குறிப்பிட்டுள்ள மருத்துவ ஆய்வின் விவரங்கள் எனக்கு விளக்கப்பட்டது. என்னுடைய சந்தேகங்களை கேட்கவும், அதற்கான தகுந்த விளக்கங்களை பெறவும் வாய்ப்பளிக்கப்பட்டது. ☐

நான் இவ்வாய்வில் தன்னிச்சையாகதான் பங்கேற்கிறேன். எந்த காரணத்தினாலோ எந்த கட்டத்திலும் எந்த சட்ட சிக்கலுக்கும் உட்படாமல் நான் இவ்வாய்வில் இருந்து விலகி கொள்ளலாம் என்றும் அறிந்து கொண்டேன். ☐

இந்த ஆய்வு சம்பந்தமாகவோ, இதை சார்ந்த மேலும் ஆய்வு மேற்கொள்ளும் போதும் இந்த ஆய்வில் பங்குபெறும் மருத்துவர் என்னுடைய மருத்துவ அறிக்கைகளை பார்ப்பதற்கு என் அனுமதி தேவையில்லை என அறிந்து கொள்கிறேன். நான் ஆய்வில் இருந்து விலகிக் கொண்டாலும் இது பொருந்தும் என அறிகிறேன். ☐

இந்த ஆய்வின் மூலம் கிடைக்கும் தகவல்களையும், பரிசோதனை முடிவுகளையும் மற்றும் சிகிச்சை தொடர்பான தகவல்களையும் மருத்துவர் மேற்கொள்ளும் ஆய்வில் பயன்படுத்திக்கொள்ளவும் அதை பிரசுரிக்கவும் என் முழு மனதுடன் சம்மதிக்கின்றேன். ☐

இந்த ஆய்வில் பங்கு கொள்ள ஒப்புக்கொள்கிறேன். எனக்கு கொடுக்கப்பட்ட அறிவுரைகளின்படி நடந்து கொள்வதுடன், இந்த ஆய்வை மேற்கொள்ளும் மருத்துவ அணிக்கு உண்மையுடன் இருப்பேன் என்று உறுதியளிக்கிறேன். ☐

பங்கேற்பவரின் கையொப்பம் ..... இடம்..... தேதி.....

இடது கை பெருவிரல் ரேகை

பங்கேற்பவரின் பெயர் மற்றும் விலாசம் .....

ஆய்வாளரின் கையொப்பம் ..... இடம்..... தேதி.....

ஆய்வாளரின் பெயர் .....

MASTER CHART

S.No	AGE	SEX	NYHA CLASS	WILKINS SCORE	A.FIB	MVOA	LA PRESSURE	MVPG	MR	COMPLICATIONS
						% INCREASE	% DECREASE	% DECREASE		
1	42	F	2	8	N	22	33	21	—	—
2	38	F	3	5	N	250	53	69	—	—
3	40	F	2	6	N	137	58	65	—	—
4	30	F	2	4	N	125	50	80	—	—
5	23	F	3	8	N	50	16	29	—	—
6	21	F	2	5	N	157	53	64	—	—
7	27	M	3	5	N	171	52	73	—	—
8	40	F	3	7	N	67	20	33	—	—
9	45	F	2	8	N	75	21	41	—	—
10	42	F	2	6	N	137	53	65	—	—
11	21	M	3	5	N	50	29	46	—	—
12	14	M	3	6	N	100	55	52	—	—
13	36	M	3	4	N	125	67	62	—	—
14	21	M	2	8	N	60	36	30	—	—
15	30	F	2	8	N	75	41	29	—	—
16	34	F	3	6	N	157	56	63	—	—
17	21	F	3	5	N	150	27	64	—	—

S.No	AGE	SEX	NYHA CLASS	WILKINS SCORE	A.FIB	MVOA	LA PRESSURE	MVPG	MR	COMPLICATIONS
						% INCREASE	% DECREASE	% DECREASE		
18	18	F	2	6	N	150	62	58	—	—
19	30	F	2	7	N	100	50	50	—	—
20	49	M	2	6	Y	55	42	21	—	—
21	30	F	3	5	N	100	50	54	—	—
22	48	F	3	8	Y	37	19	37	—	—
23	40	F	2	8	N	44	31	27	—	—
24	45	F	3	8	N	71	41	36	—	—
25	35	F	3	6	N	100	50	57	—	—
26	22	F	2	8	N	100	50	50	—	—
27	13	F	2	4	N	144	50	68	—	—
28	35	F	2	7	N	80	48	50	—	—
29	50	F	2	7	Y	50	36	39	—	—
30	70	M	3	6	N	85	41	29	—	—
31	48	M	3	8	N	85	24	30	—	—
32	16	M	2	5	N	66	61	55	—	—
33	26	F	3	6	N	171	61	63	—	—

S.No	AGE	SEX	NYHA CLASS	WILKINS SCORE	A.FIB	MVOA	LA PRESSURE	MVPG	MR	COMPLICATIONS
						PRE BMV	PRE BMV	PRE BMV	PRE BMV	
34	60	F	2	5	N	56	36	25	—	—
35	23	F	3	6	N	125	62	64	—	—
36	29	F	3	5	Y	133	67	50	—	—
37	35	F	2	6	N	80	38	33	—	—
38	23	F	2	8	Y	40	20	57	—	—
39	30	F	2	7	N	88	46	47	—	—
40	21	M	3	5	N	185	62	55	—	—
41	19	F	2	5	N	137	56	57	—	—
42	37	F	3	6	Y	60	36	30	—	—
43	28	F	3	6	N	125	59	52	—	—
44	50	F	2	5	Y	50	40	32	—	—
45	36	F	3	7	N	44	36	40	—	—
46	28	F	2	6	N	128	55	54	—	—
47	40	M	3	7	N	50	41	33	—	—
48	45	F	2	6	N	100	48	50	—	—
49	20	F	2	8	N	86	47	50	—	—
50	36	F	3	4	Y	100	52	54	—	—