Original Article

Balloon Mitral Valvuloplasty in Patients above 60 years age with Mitral Stenosis in Eastern India : A Prospective Analytic Study from IPGME&R and SSKM Hospital, Kolkata

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Introduction : This study is a Prospective Analytic Single-centre study performed at IPGMER & SSKM Hospital, Kolkata, West Bengal, India, to assess the safety and efficacy of Balloon Mitral Valvuloplasty in patients above 60 years age.

Methods : As per the protocol of our institution, after ethical clearance, elderly patients who were subjected to elective BMV from March, 2012 to November, 2016, were analysed with respect to mitral valve area, left atrial pressure and complications if any.

Results : We studied 76 patients of which 48 were female and 28 were male. Likes other series in our study female patients outnumbers male patients, The patients were of the age range of 60 to 75 years with the mean age of 64.5±4.0 years. Dyspnea on exertion was the most frequent symptom in all the patients. The plannimetric and pressure half time measurements of mitral valve area (MVA) increased from 0.76±0.15cm^2 to 1.8±1.0cm2, mean left atrial pressure decreased from 28.8±6.4 mmHg to 8.1±3.1mmHg. No major life threatening complications were noted and only 1 incidence of death was reported.

Conclusion : Our present study shows Percutaneous Transvenous Mitral Commissurotomy (PTMC) / Balloon Mitral Valvuloplasty (BMV) is a safe and easy to perform option in elderly patients with Severe Mitral Stenosis and provides excellent clinical and hemodynamic benefits in most without any major life threatening complications.

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***Key words* : BMV, PTMC, Rheumatic heart disease.**

Rheumatic Heart Disease (RHD) is the Chronic Rheumatic Heart Disease Is the most common cause of mitral valve stenosis, particularly in the developing countries[1]. In a recent Indian study, 41.5% of cases of chronic RHD in adults had mitral stenosis. Medical therapy is the mainstay of treatment in patients with mild to moderate mitral stenosis. On the other hand mitral valve intervention is required for those with symptoms and moderate to severe MS. Surgical closed mitral commissurotomy (CMC) was performed in 1940's for the treatment of severe mitral stenosis. In 1982 Ranji Inou, a Japanese Surgeon with the invention of the Inou Balloon, first developed the idea that an obstructive mitral valve could be dilated using a balloon with different compliance at two chambers, and since then the percutaneous approach of PTMC using Inoue or Accura balloons have become the therapy of choice for suitable valves and offers comparable results to open and closed surgical valvulotomy with a durable hemodynamic improvement.

Editor's Comment :

- Percutaneous Transvenous Mitral Commissurotomy an effective and well established procedure for management of patients with rheumatic mitral stenosis.
- PTMC procedure has revolutionized the management of rheumatic mitral stenosis.

Mitral stenosis usually presents in younger age group, but in India there are patients who present late with advanced rheumatic Mitral Stenosis and mitral stenosis presenting in elderly age group who are of more than 60 years of age is not uncommon in India and the clinical, pathological and hemodynamic profile at this age are to some extent different from those in younger age group. Elderly patients with Mitral Stenosis most commonly present with heart failure, they commonly have atrial fibrillation due to long standing elevated left atrial pressure and they may have associated left ventricular dysfunction due to multiple comorbidities like Diabetes and Hypertension and also associated Coronary Artery Disease. Elderly patients also tend to have more calcified, thickened and relatively immobile valves, often with significant subvalvular disease[3] and

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are usually traditionally considered unsuitable for balloon valvuloplasty. Efficacy of percutaneous ballon mitral valvuloplasty is presented in very few studies in world literature to support its role in elderly.

In an attempt to address this issue, this study was conducted aiming evaluation of the safety and efficacy of Percutaneus Miral valve Commissurotomy in patients above 60 years of age with mitral stenosis.

Materials and Methods

It is a Prospective Analytic study done at IPGMER and SSKM Hospital, Kolkata, West Bengal, India from March, 2012 to November, 2016. From March 2012 to November 2016 study 76 patients were included in our study which was less than 5% of our total number of PTMC done and these valves were not considered for PTMC using traditional Echocardiography scores. *****Elderly patients with symptomatic and severe mitral stenosis, defined by a valve area of 1.5 cm^2 or less with favorable mitral valve morphology were considered for PTMC.

Exclusion criteria : Patients who are unfit for the percutaneous mitral valvuloplasty procedures like who will need intervention of other valves like aortic valve and/or CABG. Patients with Wilkin's scoring, extensive mitral valve calcification and mitral annular calcification, more than moderate mitral regurgitation, persistence of left atrial clot even after 2 months of anticoagulation therapy, short life span with multiple co-morbidities. Patients needing surgical intervention for other indications, patients with valve calcifications or mitral regurgitation $\geq$grade 2/4, patients having left atrial thrombus not responding to oral anticoagulants or patients who had poor life expectancy due to other illnesses were excluded from the study[1].

The clinical profile and demographic variables which were considered for our present study were age, gender, functional status at admission, presence of atrial fibrillation, past history of mitral procedures and heart failure, history of penicillin prophylaxis, type of previous commissurotomy Routinely Echocardiography was done pre-operatively and postoperatively 24-48 hours after performed by an independent echocardiographer. Conventional methods like planimetry, Doppler pressure[1] half-time were used to assess the mitral valve area Echocardiography was done on a Siemense[1] Accuson 300 JPx machine with ap42 probe.

All data were collected and routinely compared pre and post procedure MVA by plannimetry and PHT pre and post procedure change in grading of Mitral regurgitation, left atrio-ventricular gradient across the mitral valve, LA Size and also other parameters assessed by Echocardiography.

Thepatients who left atrial clot documented by Transesophageal Echocardiography (TEE) treated adequately with oral anticoagulations for atleast 2 months and after 2 months of anticoagulations and a repeat TEE was performed TEE procedure was performed routinely in all patients who underwent PTMC procedure

Trans-esophageal echocardiography was performed in all elderly patients undergoing PTMC as part of the routine procedure as good number of patients had permanent atrial fibrillation; some had h/o paroxysmal AF or previous H/o embolic stroke. Patients with left atrial thrombus were PUT ON oral anticoagulant for at least two months, and PTMC was done if resolution of the left atrial thrombus was demonstrated by a repeat Trans-Esophageal echocardiography done usually after 2 months of initiation of anticoagulant therapy[1].

After a formal written informed consent all selected patients were subjected to PTMC using the usual trans-septal antegrade technique. Single balloon (with Inoue/ Acura balloon) technique was used in all patients. Balloon size was determined by using Hung's formula (Maximum balloon diameter (mm) = (patient's height (cm)/10) + 10). Successful PTMC was defined as i) 50% increase in mitral valve area (MVA) and or increase in mitral valve area (MVA) to $\geq$1.5 cm^2 post-procedure, iii) Significant fall in LA-pressure with a decrease in transmitral gradient to half of the initial value iv) no increase in the grade of MR. Suboptimal PTMC was defined as any increment in mitral valve area less than defined as successful[2].

Procedure related complications like operative mortality, patients needing mitral valve replacement (MVR), cardiac tamponade, embolic episodes, post-PTMC rise in the grade of mitral regurgitation were analyzed.

Statistical Analysis :

For statistical analysis data were entered into a Microsoft excel spreadsheet and then analyzed by SPSS 24.0. Data had been summarized as mean and standard deviation for numerical variables and count and percentages for categorical variables. Two-sample t-tests for a difference in mean involved independent samples or unpaired samples. Paired t-tests were a form of blocking and had greater power than unpaired tests (Fig 1 & Tables 1-5).

Results

We studied 76 patients of which 48 were female and 28 were male. Like other different series we observed that female patients outnumber the male patients. All the patients in our series were symptomatic admission for PTMC procedure. Dyspnea

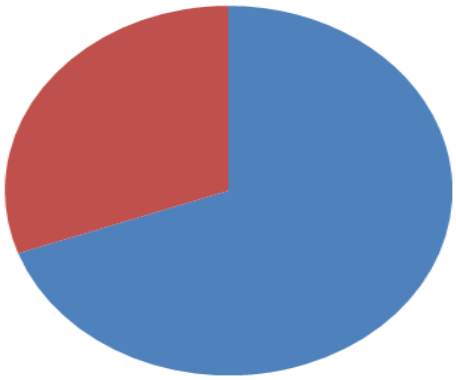

Fig 1 — Male and Female distribution of Elderly Mitral Stenosis patients

Table 1 — *Distribution of Elderly Mitral Stenosis patients according to NYHA class*

Variables	Frequency	Percentage
NYHA class-I	10	13.1
NYHA class-II	11	14.4
NYHA class-III	48	63.1
NYHA class-IV	7	9.2

Table 2 — *The Coronary angiographic, and echocardiographic abnormalities (Left Ventricular Dysfunction, Wilkins score) seen among the Elderly MS patients during the evaluation*

Variables	Frequency	Percentage
(a) Coronary Angiography		
Normal coronaries	48	63.1
Minnor CAD	23	30.2
Single or DVD	1	1.31
Coronary Embolism	2	2.62
Multivessel disease	2	2.62
(b) LV Dysfunction, LVEF 40%	11	14.4
(c) Wilkins score > 8	45	59.2

on exertion was the most frequent symptom in all the patients. 89.8% were in NYHA II to III class and rest of the patients was in NYHA class IV. 4 patients were denied surgical intervention due to their associated co-morbidities. All the patients used to get diuretic and those who had atrial fibriilation were receiving antiarrythmic medication and anticoagulation. Pre-PTMC routine echocardiography grade II MR with central jet in two patients and grade I MR in 32 patients. 3 patients presented with atrial fibrillation with fast ventricular rate which was adequately controlled before the procedure. Ten (20.4%) patients had moderate Pulmonary Arterial Hypertension (Pulmonary Artery Systolic Pressure >50 mmHg) and 9 (18.3%) patients had severe Pulmonary Arterial Hypertension (Pulmonary Artery Systolic Pressure >70 mmHg), Mean PASP was 55.1±24.7 mmHg. Coronary Angiography was done as a routine catheterization procedure prior to PTMC. One patient had severe triple vessel disease including critical left main coronary artery disease. 8 patients had severs LV dysfunction and 2 patients of severe left ventricular

Table 3 — *The echocardiographic variables Post- PTMC*

Variables	Pre PTMC	Post PTMC	p-value
MVA (cm^2)	0.76± 0.15	1.8±1.0	<0.001
Mean Left Atrial Pressure (mmHg)	28.8± 6.4	8.1± 3.1	<0.001
Left Atrio- ventricular PG (mmHg)	16.1± 4.1	4.2± 1.3	<0.001
PASP(mmHg)	60.0± 18.0	36.6 ± 7.4	<0.001

Table 4 — *Procedure related complications during PTMC*

Variables	Frequency	Percentage
Severe MR requiring MVR	1	1.3
Cardiac Tamponade	1	1.3
Mortality	1	1.3
Embolism	0	0.0
Moderate MR	2	2.6

Table 5 — *Success Rate of PTMC in Elderly Patients with MS*

Variables	Frequency	Percentage
Death	1	1.3
Severe MR	1	1.3
Moderate MR	2	2.6
Tamponade	1	1.3
Successful	71	93.4

dysfunction and had documented Ventricular Tachycardia and ICD was implanted. The mean mitral valve area increased from 0.76±0.15cm^2 to 1.8±1.0cm2, mean left atrial pressure decreased from 28.8±6.4mmHg to 8.1±3.1mmHg. No major life threatening complications were noted and only 1 incidence of death was reported. In one patient who presented with STEMI, mitral stenosis was diagnosed after hospital admission during routine work-up. Post procedure severe MR occurred in 1 patients and moderate MR in 2 patients. Optimum and desirable results observed in 71 (93.5%) patients compared to suboptimum results in 5 patients. Suboptimum results were achieved in 7 (14.25%) patients as assessed by mitral valve area (MVA<1.5cm^2) on Echocardiography. Post-procedure MR of more than moderate in 1(2%) patient, and moderate in 2 patients.

Though female predominance was observed in this series the difference was not very much significant likes other series. The patients were of the age range of 60 to 75 years with the mean age of 64.5±4.0 years. Dyspnea on exertion was the most frequent symptom in all the patients. Few patients present with left heart failure NYHA Class IV before the procedure, rest of them (89.8%) were in NYHA II to III (all the patients were symptomatic). 4 patients were denied surgical intervention due to their associated comorbidities. 3 patients presented with atrial fibrillation with fast ventricular rate which was adequately controlled before the procedure. All patients were taking diuretics in different doses to control the symptoms. Electrocardiography (ECG) findings were normal sinus

rhythm in 29 (38.7%) patients and atrial fibrillation in 47(61.84%) patients. Patients with atrial fibrillation were on anticoagulation. Left atrial size ranged from 4.2 cm to 10.2 cm with the mean of 5.8±2.8 cm. In almost all cases left atrial size were above the normal value (<4cm) and in more than 50% of cases left atrium was hugely dilated (>52cm). Mild MR was present in 32(42.1%) patients, moderate MR in two (2.6%) patient, and trace MR in 6 (12.2%) patients whereas rest 26.7% patients didn't have any MR. Mild to moderate AR was present in 16 patients. Ten (20.4%) patients had moderate PH (>50 mmHg PASP) and 9 (18.3%) patients had severe PH (>70 mmHg PASP), Mean PASP was 55.1±24.7 mmHg. Coronary Angiography was done as a routine catheterization procedure prior to PTMC. One patient had severe triple vessel disease including critical left main coronary artery disease. 8 patients had severs LV dysfunction and 2 patients of severe left ventricular dysfunction and had documented Ventricular Tachycardia and ICD was implanted. The mean mitral valve area increased from 0.76±0.15cm^2 to 1.8±1.0cm^2, mean left atrial pressure decreased from 28.8±6.4mmHg to 8.1±3.1mmHg. No major life threatening complications were noted, and only 1 incidence of death was reported. In one patient who presented with STEMI, mitral stenosis was diagnosed after hospital admission during routine work-up. Post procedure severe MR occurred in 1 patients and moderate MR in 2 patients. Successful results were observed in 71 (93.5%) patients compared to unsuccessful results in 5 patients. Unsuccessful results were due to suboptimal MVA <1.5 cm^2 in 7 (14.25) patients and postprocedure MR of more than moderate in 1(2%) patient, and moderate in 2 patients.

Discussions

Chronic Rheumatic Heart Disease most commonly complicated by and presented with Mitral Stenosis. PTMC procedure has revolutionized the therapy of rheumatic mitral stenosis and after the introduction of Inoue Balloon After the introduction of the PTMC procedure by Inoue *et al* in 1984 PTMC has become the most effective and popular therapeutic technique for 4^0 symptomatic patients with moderate to severe mitral stenosis . PTMC is recommended as a Class I indication for symptomatic patients of mitral stenosis as the immediate results of PTMC are similar to those of closed and open surgical mitral commissurotomy. But in elderly patients mitral stenosis valve morphology gets deformed with high Wilkin's score and with other related complication like low LVEF, and they become less suitable for PTMC. In our present study MS is predominantly presents in females. The mean mitral valve area usually got doubled post PTMC procedure, with a 60% to 70% reduction in left atrioventricular gradient. Our success rate was upto 93.5% which is comparable to other studies done in children with juvenile MS and adults.

Different literature showed that increase in severity of Mitral Regurgitation during Percutaneous Mitral Valvulopasty (PTMC) procedure inwith patients needing the of Mitral Valve Replacement in few. The development of severe MR in our series was extremely low and only one patient developed severe MR. Overall success in this aspect may be related to our patients having suitable mitral valve morphology and also using the strategy of stepwise up-titration of PTMC Balloon.

A similar low volume study with 13 elderly patients with MS done in Japan by Tsuchioka Y *et al* revealed percutaneous procedure in comparison to surgical procedure has the advantages of low complication rate and short hospital stay in elderly patients. Using injection Heparin during the periprocedural period the incidence of embolic episode during the procedure of percutaneous mitral commisurotomy is 0.3% and 3% In our study we didn't experience a single embolic episode during the PTMC procedure or postprocedure. These remarkable results may be related to our protocol of routine pre-procedure Trans-esophageal Echocardiography

Conclusion

PTMC is an effective and well established procedure for management of patients[4] with rheumatic mitral stenosis in young and adult. Our present study shows percutaneous transvenous mitral commissurotomy is safe and easy to perform even in elderly patients with MS and provides excellent clinical and hemodynamic benefit in most of the elderly MS patients.

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Conflict of Interest : None

References

1 Olson LJ, Subramanian R, Ackermann DM — Surgical pathology of the mitral valve; a study of 712 cases spanning 21 years. *Mayo clinics proc* 1987; **62:** 22-7.
2 Iung B, Baron G, Butchart EG —A prospective survey of patients with valvular heart disease in Europe: The Euro Heart Survey on Valvular Heart Disease. *Eur Heart J* 2003; 24: 1231-43.
3 Hildick-Smith DJ, Shapiro LM— Balloon mitral valvuloplasty in the elderly. *Heart* 2000; **83:** 374-5.
4 Inoe J, Owaki T, Nakamura T — Clinical application of transvenous mitral commissurotomy by a new balloon catheter. *J Thoracic Cardiovasc Surg* 1984; **87:** 394-4.
5 Tsuchioka Y, Yamagata T, Matsuura H — Percutaneous transvenous mitral commissurotomy in elderly patients with mitral stenosis. *Nihon Ronen Igakkai Zasshi* 1993; **30:** 688-92.
6 Harrison JK, Wilson JS, Hearne SE — Complications related to percutaneous transvenous mitral commissurotomy. *Cathet Cardiovasc Diagn* 1994; **(Suppl2):** 52-60.