PERCUTANEOUS TRANSVENOUS MITRAL COMMISSUROTOMY (PTMC) INOUE VERSUS NON-INOUE TECHNIQUE

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SUMMARY

Percutaneous transvenous mitral commissurotomy (PTMC) has emerged as an alternative to closed mitral valvotomy for selected symptomatic patients of mitral stenosis. 191 patients underwent PTMC at Cardiology department, Postgraduate Medical Institute, Peshawar. Acute haemodynamic results showed fall of left atrial pressure from 25.27 ± 5.2 to 10.22 ± 4.7 mmHg, mitral valve gradient decreased from 19.5 ± 4 to 7.22 ± 3.6 mmHg, pulmonary artery pressure fell from 57.85 ± 8 to 41.7 ± 9 mmHg. The results are comparable to other international reports, complications rate was similar to other major studies. PTMC is a safe and effective tool to dilate selected stenosed mitral valve.

INTRODUCTION

Inspite of the so-called improvements in the social structure, rheumatic heart disease remains highly prevalent in most of the developing countries. Mitral valve is predominantly targeted in this disease. Percutaneous transvenous mitral commissurotomy (PTMC) has emerged as an alternative technique to closed mitral valvuloplasty (CMV). PTMC was introduced by Inoue and Lock, since then it has evolved as an effective method for the treatment of patients with symptomatic mitral stenosis (MS).[1,2] The technique has undergone various modifications with improvement and refinement in the technology. Initially a single balloon was employed,[1,3] later two balloon were utilised to open up mitral valve.[4] Introduction of new Inoue balloon has now replaced older balloons. Inoue balloon offers the advantage of being safer, more effective and shorter procedure time.[1]

The safety and efficacy of PTMC employing single, double and Inoue balloons has been established in many acute, midterm and long follow-up trials.[5-7] The benefits of PTMC out weighs CMV in many clinical situations like restenosis following CMV, young age, pregnancy and when CMV is contraindicated.[8]

This study was undertaken to study the efficacy and safety of both techniques in randomised patients with severe and symptomatic mitral stenosis from both sexes and all age groups.

MATERIAL AND METHODS

Study population

This study includes 191 patients, 93 were males and 98 were females from December 1991 to December 1996. Mean age was 25 ± 3.2 years (10-62). All patients were symptomatic, NYHA class III-IV with evidence of severe mitral stenosis. Mean

mitral valve area (MVA) on 2 dimensional echocardiography was 0.9 ± 0.15cm^2 and calculated on doppler was 0.92 ± 02 cm^2. Peak mitral valve gradient (MVG) was 23.90 ± 7.1 and mean MVG was 183 ± 6.6 as determined by doppler echocardiography. All patients underwent trans-esophageal echocardiography (TEE) prior to the procedure to document severity of mitral stenosis and regurgitation and exclude the presence of clot in left atrium or atrial appendage. Fifteen percent had mild regurgitation, none had moderate or severe regurgitation. None of the patients had significant valvular calcification. Patients with severe subvalvular involvement were not included in the study.

One hundred and ten underwent non-Inoue balloon mitral valvuloplasty and eighty one underwent Inoue balloon valvuloplasty.

Technique Non Inoue balloon:

A Swan–Ganz Thermodilution catheter is introduced percutaneously via femoral vein and a Pigtail catheter is introduced retrogradely through femoral artery. Simultaneous mitral valve gradient is recorded and pulmonary artery pressure and cardiac output are documented. Left ventriculogram is performed to determine left ventricular function and mitral regurgitation. Mullen's sheeth loaded with Brokenborough needle is parked in SVC. It is withdrawn slowly using Pigtail catheter in the root of aorta as a landmark. The position of tip of Mullens sheeth is confirmed in right anterior oblique 30° and left lateral position. Inter-atrial septum is punctured with the needle taking all the precautions. An optimal septal puncture is crucial to the success of the procedure. Entry to left atrium is confirmed by pressure monitoring, contrast injection and oxygen saturation measurement. A Bermans catheter is introduced into left atrium and manipulated to left ventricle through the sheeth. A long 260 cm exchange 0.38 guidewire is positioned in left ventricle via Berman catheter. Inter-atrial septum is dilated by septum dilating balloon. A large balloon, according to the annulus measurement is then positioned across mitral valve over the exchange guidewire. The balloon is inflated with half contrast till the waist gives way. Mitral valve gradient, pulmonary artery pressure and cardiac output are re-estimated. A left ventriculogram is repeated to look for mitral regurgitation.

Inoue balloon:

Having gained entry into left atrium a special stainless steel guide wire is placed in left atrium. The site of entry and atrial septum is dilated with a long 14 F dilator. A stretched and prepared Inoue balloon is introduced into left atrium over the guide wire. The guide wire, lengthener and straightener are withdrawn. With the help of a special stylet the balloon is maneuvered into left ventricle. Once in left ventricle, the balloon is inflated with half contrast. Distal part of the balloon initially inflates which is retracted against mitral valve. The balloon is further inflated in stepwise fashion to open up the mitral valve optimally. Left atrial pressure and mitral valve gradient are checked after every inflation to avoid severe MR and check the efficacy of the balloon dilatation. The balloon is stretched and lengthened with special lengthener before withdrawal on the guide wire. A repeat ventriculogram is performed to look for any MR. Bleeding is arrested by manual pressure.

RESULTS

PTMC produces immediate haemodynamic results with decrease in left atrial pressure, mitral valve gradient and pulmonary artery pressure and increase in mitral valve area.

Acute haemodynamic results:

Mean left atrial pressure (LAP) measured 25.27 ± 5.2 mmHg, decreased to

TABLE – I

ACUTE HAEMODYNAMIC AND MVA PRE AND POST PTMC

	LAP		MVG		PAP		MVP	
	PRE	POST	PRE	POST	PRE	POST	PRE	POST
Inoue[23]	—	—	11.9	5.5	—	—	1.1	1.9
Hung[13]	24.2	15.1	13.0	5.7	39	31	1.0	2.0
Chen[14]	22.1	10	17.4	2.7	34	23	1.1	2.0
Nobuyoshi[15]	18	11	12	7	—	—	—	—
Ours	25.3	10.2	19.5	7.2	43	32	0.8	1.6

10.22 ± 4.7 mm Hg following PTMC (p <.0001). Mean mitral valve gradient (MVG) reduced from 22.2 ± 4mmHg to 7.22 ± 36 mmHg after the procedure (p <0.0001). Systolic pulmonary artery pressure when measured registered a fall from 57.85 ± 7 mmHg to 41.7 ± 5.3 mmHg (p <.001). Fall in LAP and MVG correlated with the success of the procedure. (Figure 1)

Non-Inoue balloon:

A single balloon, size determined by mitral annulus measurement on trans-thoracic and trans-esophageal echocardiography, was used in the majority of cases. Two balloons were used in 15 subjects. Bifoil and trifoil balloons were employed in 07 patients. Improvement in haemodynamic parameters like MVG, LAP and PAP were observed immediately after valve dilatation.

LAP reduce from 22.95 ± 3.5 mmHg to 10.2 ± 2.8 mmHg and MVG when decreased from 18.9 ± 2.9 mmHg to 7.9 ± mmHg 2.2 mmHg. SPAP when measured, dropped from 60.53 ± 7.8 mmHg to 41.65 ± 6.3 mmHg.

Inoue balloon:

Introduction of Inoue balloon witnessed a new learning curve. Balloon size is determined by height. Step wise dilatation was practised with haemodynamic monitoring and left ventriculogram to avoid mitral regurgitation.

LAP reduced from 29.97 ± 5.6 mmHg to 11.65 ± 3.2 mmHg, MVG registered a fall from 20.86 ± mmHg to 7.7 ± 3.3 mmHg and SPAP decreased from 58.96 ± 7.4 mmHg to 39.9 ± 5.9 mmHg.

With more experience Inoue balloon became the favoured technique with marked economy of time.

Non-Inoue versus Inoue Balloon:

Both techniques were found to be equally effective in terms of acute haemodynamic gain. Fall in LAP, MVG and PAP was comparable and not statistically

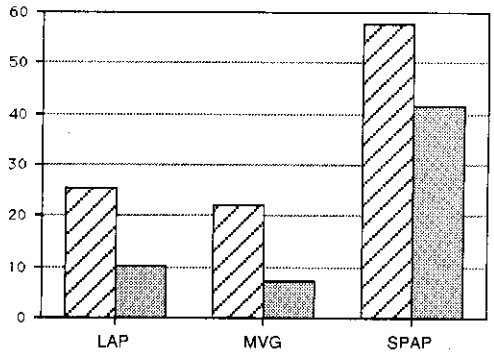

Figure 1

Mean Mitral Valve Gradient (Doppler)
Follow-up over two years

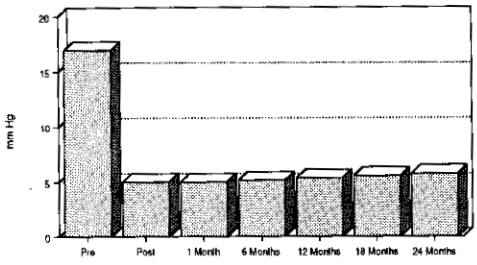

Figure 2

Mitral Valve Area (2-D Echo)
2 years follow-up

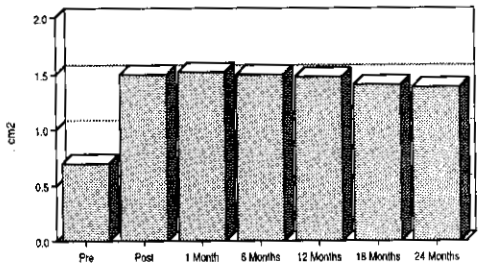

Figure 3

significant. Complications encountered cannot be compared directly as when Inoue balloon technique was introduced the operators had passed their learning curve of trans-septal puncture and balloon handling. However new complications pertaining to Inoue technique like entry into femoral vein, entry into left atrium and manipulation of balloon from left atrium to left ventricle were encountered and mastered with the passage of time.

Intermediate Term Follow-up

Mitral valve area measured on two dimensional echocardiography prior to PTMC was 0.89 ± 0.2 cm^2. It increased to 1.55 ± 0.3 immediately after the procedure ($p < .001$). Though there was trend to decrease but at the end of two years the change was not statistically significant. Mitral valve area derived on doppler by pressure half time increased from 0.86 + 0.18 cm^2 to 1.72 + 0.33cm^2 immediately after the procedure. At the end of two years MVA calculated by doppler was 1.67 + 0.3 $cm.^2$ This decrease was not found to be statistically significant. (Figure 2, 3)

Mitral valve gradient estimated on doppler echocardiography before the procedure was peak 23.90 ± 7.1 mmHg and mean 18.3 ± 6.6 mmHg. After PTMC peak MVG decreased to 9.3 ± 3.3 mmHg where as mean MVG reduced to 6.2 ± 2.1 mmHg. Subsequent follow-up data shows trend to increase but at the end of two years peak MVG was 9.5 ± 3.5 mmHG and mean MVG wa 6.8 ± 2.4 mmHg. This slight increase was not found to be statistically significant.

Complications

Every invasive procedure is fraught with certain complications. We lost one patient (0.55%) due to severe mitral regurgitation with Inoue technique. The patient was being worked up for surgery but she had sudden cardiac arrest and succumbed to it. We were unable to successfully dilate the valve in 6.8% of cases, as we went through two learning curves, first with non-Inoue technique and later with Inoue technique. Initial failures were mainly due to unsuccessful trans-septal punctures, resulting in high or low punctures or no puncture at all. Inappropriately low or high punctures make it difficult to maneuver the catheter from left atrium to left ventricle. We were unable to puncture in 08 patients, could not enter left ventricle in 03 cases with non-Inoue balloon and 02 cases with Inoue balloon.

Mild increase in mitral regurgitation was seen in 15 patients (7.8%), all these patients tolerated the increase in MR well and none required any surgical intervention. Severe mitral regurgitation was seen in two patients with non-calcified valves, one succumbed to it and the other boy of 13

TABLE - II

COMPLICATIONS AND COMPARISON WITH OTHER STUDIES

STUDY	NO.	MORTALITY	TAMPONADE	EMBOLISM	SEVERE MR	LV PERFO-RATION
Nobuyoshi[15]	106	0	2	0	5	—
Ruiz[18]	285	1	2	1.4	7	—
Tuzco[17]	311	1.7	—	—	8.7	—
Vahanian[18]	600	0.5	0.8	3.3	3.8	—
NHLBI[19]	738	3	4	3	3	—
French cop[20]	114	0	5.3	1.8	2.6	—
M-heart[21]	75	2.7	6.7	2.7	13	2
Hermann[22]	200	0.5	1	1.5	2.4	—
Ours	191	0.5	2.6	2.1	1.4	0.5

years of age is tolerating it well and the severity has decreased with time with no associated left atrial and ventricular enlargement. Five (2.6%) of our patients had cardiac tamponade on the table requiring surgical intervention, all were operated upon successfully along with CMV. Most of these complications occurred in the first forty cases.

Four patients (2.09%) had cerebral embolism resulting in mild hemiparesis, three of them recovered completely and one has mild residual deficit. All our patients undergo trans -esophageal echocardiography prior to PTMC. All patients with LA/LAA clots are treated with oral anticoagulants and re-examined by TTE and TEE before PTMC is undertaken.

In one patient (0.52%) exchange guide wire perforated through left ventricular wall causing cardiac tamponade necessitating urgent surgery.

Complications with non-Inoue and Inoue balloon cannot be compared as by the time Inoue technique was introduced we had already done more than hundred cases and were well versed with trans-septal punctures and balloon handling. Later problems were mainly encountered with manipulation of used Inoue balloons.

DISCUSSION

Closed surgical mitral commissurotomy was shown to improve haemodynamics and symptoms in patients with mitral stenosis by Harken and Bailey nearly four decades ago[9-11]. The technique reigned supreme till recently, as it produced sustained clinical improvement at relatively low risk.[12] In most of the developed countries 'closed' mitral commisurotomy has given way to 'open' mitral commissurotomy. However it remains unknown whether open mitral commissurotomy offers any real benefit in terms of haemodynamics and long terms clinical follow-up.

Entry of balloons into the catheterization laboratory has revolutionised the world of invasive Cardiology. Percutaneous transvenous mitral commissurotomy has emerged as an alternative treatment for selected patients of mitral stenosis.

Pioneer work of Inoue introduced PTMC to invasive cardiologists as an effective and safe procedure to dilate stenosed mitral valve.[1] Large single balloon and two balloons with separate septal punctures or a single puncture were used in other centres with equally good results.[2-4] Refinements in guide wire technology, reduction of balloon catheter shaft sizes and improvements in balloon material lead to more wide spread application of PTMC.

Acute haemodynamic results following successful dilatation of stenosed mitral valves include reduction of MVG, LAP and pulmonary artery pressure. In our series, both non-Inoue and Inoue balloon techniques resulted in marked haemodynamic improvement with highly significant reduction of MVG, LAP and PAP. These results compare very favourably with PTMC results from other centres. Results of Inoue balloon can be very favourably compared with non Inoue balloons. (Table I)

Follow-up echocardiographic data showed substantial acute gain in mitral valve area as determined by planimetry on two dimensional echocardiography and derived by doppler data. With the passage of time there is trend towards reduction in MVA but this reduction is not statistically significant. Mitral valve gradient (peak and mean) reveals reduction in the gradients immediately after PTMC. In subsequent follow-up MVG shows trend to increase but the increments are not statistically significant. Further long-term studies might reveal evidence of restenosis which is dependent on many factors.

Chen and Cheng reported sustained haemodynamic and clinical improvements consistent with acute haemodynamic results after PTMC in a cohort of 139 patients followed for 29.4 ± 7.2 months (2-61 months), assessed by clinical, echocardiography and exercise testing substantiates sustained haemodynamic results.[14]

The cumulative cardiovascular events free rate by the Kaplan-Meir method for 302 patients with pliable valve followed for 67 months was 100 percent and for calcified valves or subvalvular disease was 92 percent at 24 months in 251 patients followed for 56 months.[15]

The complications of PTMC fall into two main categories: those related to trans septal puncture and those related to PTMC itself. Pericardial tamponade as a complication of trans septal puncture has been reported as 1-6%. This is higher in multicentre studies and during the early learning curve. In established centres it should be less than 1%. Most of the cases can be managed by pericardiocentesis but in cases of haemodynamic instability, surgery remains another alternative. Most of the failures are due to improper or unsuccessful trans-septal puncture and are usually encountered in early learning curve.

Complications related to PTMC itself include mortality, systemic embolism, atrial septal defect (ASD), severe mitral regurgitation (MR) perforation of left ventricular apex and potential risk of infective endocarditis. Mortality figures reported are 0-3% mainly due to severe MR and cardiac tamponade. We lost 1 patient because of severe MR. Every patient undergoes TEE before the procedure to exclude any LA/LAA clots. We had 03 patients who developed hemiparesis with good recovery. Different centres have reported incidence of embolism as 1-2.2%. None of our patients developed significant ASD. Severe mitral regurgitations remain the most dreaded complication 2.4-8.7%. Its more common in patients with calcified mitral valve and sub-valvular involvement. Step wise dilatation with constant monitoring of haemodynamics can minimise the risk of severe MR. Two of our patients developed severe MR, one succumbed to it and the other is so for tolerating it well and is being considered for mitral valve replacement.

With non Inoue technique with guide wire in left ventricle, there existed a possibility of LV rupture as reported 0-2% and 0.6% in our series. With the introduction of Inoue balloons and no guidewire sticking out it is not being encountered any more.

The cost of Inoue balloons is prohibitive and it is escalating every day. This leaves us, in developing countries, with no choice but to re-use it after re-sterilisation. There is a real risk for infective endocarditis and it is strongly recommended that the balloon should be cleaned immaculately and preferably gas sterilised meticulously. Routine use of prophylactic antibiotics pre and for 48 hours after the procedure is strongly advocated.

The risks of complication like mortality, thombo-embolism and severe MR are comparable to surgical mitral commissurotomy. The incidence of complications reduce markedly as more experience accumulates and careful selection of patients is made. We encounter patients with more advanced disease, younger age, poor nutritioned status, restenosis following CMV and have to reuse the hard ware but our complication rate is comparable with other centres. (Table II)

PTMC is the preferred technique in patients with pliable valves, younger age group, pregnancy, restenosis following CMV, those with contraindication to general anaesthesic and in emergent or urgent settings.[8] The beauty of technique is that the patients can actually leave the hospital in 24 hours without any disfiguring scars and the procedure can be repeated with good success rates in those with restenosis. PTMC is a safe and effective technique in our setup with good long term results.

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