Percutaneous Transatrial Mitral Commissurotomy by Modified Technique using a JOMIVA Balloon Catheter: A Cost-Effective Alternative to the Inoue Balloon

Satya N. Routray, Trinath K. Mishra, Uttam K. Patnaik, Mrutyunjay Behera

Department of Cardiology, SCB Medical College, Cuttack, Orissa, India

Background and aim of the study: **Percutaneous transatrial mitral commissurotomy (PTMC) is an established non-surgical treatment of rheumatic mitral stenosis. The study aim was to assess the safety and efficacy of PTMC using the Joseph mitral valvuloplasty (JOMIVA) balloon catheter, with a modified technique.**

Methods: **PTMC was performed in 252 patients (88 males, 164 females; mean age 39.2 ± 13.8 years; range: 10-76 years) with symptomatic mitral stenosis. Among patients, 52 (20.6%), 182 (72.2%) and 18 (7.2%) were in NYHA classes II, III and IV, respectively. Atrial fibrillation was present in 52 patients (20.6%), and mild mitral regurgitation (MR) in 26 (10.3%); 92 patients (36.5%) had a mitral valve echo score >8. Patients were followed up with detailed clinical and echocardiography studies at three-month intervals during the first year, and at six-month intervals thereafter.**

Results: **The procedure was technically successful in 247 patients (98%), and an optimal result was achieved in 228 (90.5%), with mean mitral valve area increased from 0.81 ± 0.32 to 1.92 ± 0.39cm^2 (p <0.001). NYHA class was improved in most patients. Seven patients (2.8%) had cardiac tamponade during the procedure; one of these (0.4%) died from left ventricular tear. MR appeared (n = 10) or worsened (n = 20) in 30 patients (11.9%), among whom three (1.2%) developed severe MR. Each JOMIVA balloon catheter was used 10 to 20 times without being damaged. In total, 220 patients were followed up for between six and 54 months (mean 30 months). At follow up, 140 (63.6%) and 67 (30.5%) patients were in NYHA classes I and II, respectively. Seventeen patients (7.7%) developed mitral restenosis.**

Conclusion: **PTMC using the JOMIVA balloon catheter is a cost-effective and safe alternative to the Inoue balloon when treating symptomatic severe mitral stenosis. The hemodynamic benefits were sustained long term in a majority of patients. In particular, cost is important factor in a less wealthy country such as India.**

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Rheumatic heart disease, particularly mitral stenosis, remains a significant health problem in India and many other developing countries (1). Percutaneous transatrial mitral commissurotomy (PTMC) using the balloon technique was first reported by Inoue et al. in 1984 (2), since when the method has become the preferred non-surgical method to treat symptomatic mitral stenosis worldwide. Indeed, during recent years it has replaced closed mitral valvotomy (3-8).

Several different balloons and metal dilators have been used when conducting PTMC. Herein, the present authors' experience is described with the Joseph mitral valvuloplasty (JOMIVA) balloon catheter. Although this instrument was first described by George Joseph of Christian Medical College, Vellore in 1998 (9), it is not currently used to any great extent. Consequently, the general procedure is described here in detail, but was modified in the present study in order to achieve better results.

Address for correspondence:
Dr. Satya N. Routray, Qr. No. 3R-8, Doctors Flat, Near Cancer Wing, SCB Medical College, Cuttack, Orissa, India, Pin 753007
e-mail: drsnroutray@yahoo.co.in

Clinical material and methods

Patients

Between May 1998 and November 2002, 252 patients (88 males, 164 females; mean age 39.2 ± 13.8 years; range: 10 to 76 years) with mitral stenosis underwent PTMC with use of a JOMIVA balloon catheter at the SCB Medical College, Cuttack, Orissa, India. Among these patients, 52 (20.6%) were in NYHA functional class II, 182 (72.2%) in class III, and 18 (7.2%) in class

IV. In addition, 64 patients (25.4%) had atrial fibrillation, 52 (20.6%) had mild mitral regurgitation (MR) and 26 (10.3%) mild aortic regurgitation. Eighteen (7.2%) patients had previously undergone a closed mitral valvotomy, 30 (11.9%) were pregnant (second trimester). The mean pre-procedural mitral valve area (MVA) was 0.81 ± 0.32 cm^2 (range: 0.5 to 1.3 cm^2). The mean echo score for the mitral valve was 7.8 ± 1.7 (range: 4 to 11), and 148 patients (58.7%) had an echo score ≤8. Calcification of the mitral valve was present in 92 patients (36.5%). Patient characteristics before PTMC are listed in Table I.

Pre-PTMC investigations

All patients with symptomatic mitral stenosis were subjected to a detailed clinical examination. Routine hematological and biochemical investigations, blood grouping and Rhesus typing were conducted in all patients. Detailed two-dimensional (2D), M-mode and color Doppler echocardiography were carried out, wherein the mitral valve was examined specifically for leaflet mobility, thickening, subvalvular fusion and calcification. Echo scoring was carried out as per a standard procedure (10). Multiplane transesophageal echocardiography was performed in order to rule out any clotting in the left atrium (body and appendage). Informed consent was obtained from each patient included in the study.

Table I: Patient characteristics before percutaneous transatrial mitral commissurotomy (PTMC) (n = 252).

Parameter	Value
Age (years)*	39.2 ± 13.8 (range 10-76)
Gender	
Male	88 (34.9)
Female	164 (65.1)
Cardiac rhythm	
Sinus	188 (74.6)
Atrial fibrillation	64 (25.4)
Pregnancy	30 (11.9)
Previous CMV	18 (7.2)
NYHA class	
I	0
II	52 (20.6)
III	182 (72.2)
IV	18 (7.2)
Echocardiography findings	
Mitral valve area (cm^2)*	0.81 ± 0.32
Mitral valve score	
≤8	148 (58.7)
≥8	104 (41.3)
Left atrial size (mm)	44.5 ± 5.8 (range: 30.2-63.8)
Mild MR	52 (20.6)
Mild AR	26 (10.3)

*Values are mean ± SD.
Values in parentheses are percentages (unless otherwise stated).
AR: Aortic regurgitation; CMV: Closed mitral valvotomy; MR: Mitral regurgitation.

Balloon catheter and accessories

The JOMIVA balloon catheter (Fig. 1) comprises three parts (9,11). The distal part is formed by the balloon, which is made from thin, tough, thermoplastic polymer and has a 4-cm working length with a distal blunt tip. The proximal part has two ports at its proximal end: a white port for guidewire location, and a blue port for balloon inflation and deflation. The 11 Fr shaft with its unique coaxial construction allows for very rapid inflation and deflation of the balloon.

The accessories required include a Brockenbrough needle, Mullins sheath and dilator, septal dilator, left atrial (LA) wire, left ventricular (LV) wire, Cournand, pigtail and Swan-Ganz catheters, Mansfield balloon, sheaths, guidewires, stop cocks and syringes.

Procedure details

For line insertion, the right femoral artery and vein are cannulated with 6 Fr and 7 Fr sheaths, respectively. A 6 Fr pigtail catheter is placed in the aortic root with its tip in the non-coronary aortic sinus; this serves as a landmark during septal puncture and is also used for monitoring systemic pressure.

Septal puncture

Septal puncture (Fig. 2) is then carried out, with pulmonary artery systolic pressure being measured using a 7 Fr Cournand catheter. The 0.032" exchange guidewire is positioned in the superior vena cava (SVC) either directly or with the help of a Cournand or

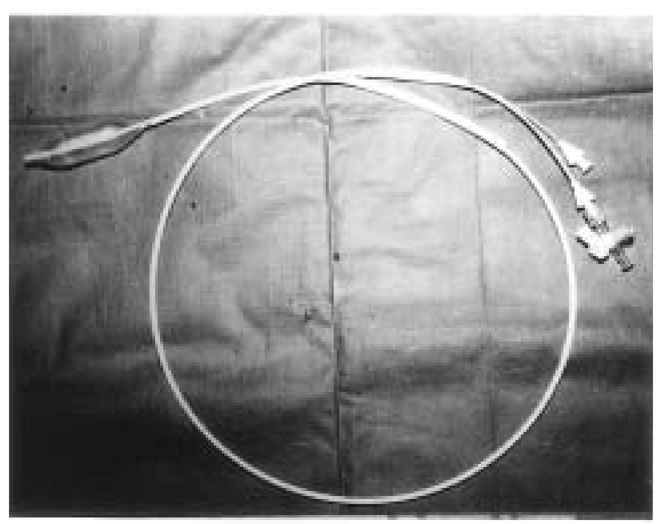

Figure 1: The JOMIVA balloon catheter with an inflated balloon.

multipurpose catheter. The femoral venous sheath is then removed and the 8 Fr Mullins dilator positioned in the SVC over the exchange wire. The latter is removed, and the Brockenbrough (BB) septal puncture needle is then advanced inside the Mullins dilator, keeping the index finger of the right hand as a guard between the hub of the Mullins and the external pointer of the BB needle so that the tip of the needle does not pass outside the dilator. The hub of the BB needle is connected to fluid-filled tubing for continuous pressure monitoring, with the external pointer directed towards the 4 to 5 o'clock position. The whole assembly is then withdrawn under fluoroscopy guidance from the SVC to the right atrium until it falls into the fossa ovalis. In the right anterior oblique (RAO) 45° position, the puncture site is in between the pigtail catheter and the anterior border of the spine anteroposteriorly, and 1 cm below the tip of the pigtail catheter vertically. The septum is punctured in the RAO 45° or lateral position by advancing the needle along with a sudden jerk. Needle entry to the left atrium is confirmed by the pressure tracing and by contrast injection. The dilator is then advanced over the needle to the left atrium in the posterio-anterior position, and the needle is then withdrawn. Heparin (5,000 U; or 100 units per kg in children) is administered at this stage. Left atrial pressure is measured with the Mullins dilator. After advancing the pigtail catheter into the left ventricle, the LA and LV pressures were recorded simultaneously in order to measure the mean mitral valve gradient. The LA wire is introduced into the left atrium, and the dilator removed. Septal dilatation is performed over the LA wire with the septal dilator by making several to-and-fro movements across the inter-atrial septum (IAS) (in a manner similar to that used in the Inoue technique).

Crossing the mitral valve

To cross the mitral valve (Fig. 3), the short 14 Fr sheath is passed to the femoral vein, after which the Mullins dilator with a sheath is advanced into the left atrium. The LA wire and Mullins dilator are removed, keeping the sheath in the left atrium. A 7 Fr balloon flotation catheter (Swan-Ganz) is then introduced into the left atrium, advanced through the mitral valve into the left ventricle, and positioned half-way between the mitral valve and LV apex. The sheath is then advanced over the flotation catheter.

Shaping the back-up wire

To shape and introduce the LV (back-up) wire (Fig. 4), a 0.035", 200 cm-long wire is used; this serves as the rail over which the JOMIVA balloon catheter is advanced. The wire has a very soft tip with a primary J-curve, proximal to which is a straight 6-cm segment, which is of intermediate stiffness. Proximal to this intermediate segment is the very stiff shaft, which constitutes the rest of the wire. The region of the stiff shaft just proximal to the intermediate segment must be shaped into a smooth secondary curve, so that the wire can be bent by about 70°. This is best done manually by making multiple shallow bends at points close to each other, so that a smooth curve results. The LV wire is then introduced into the lumen of the flotation catheter and advanced until it is just inside the tip of balloon. The balloon is then deflated, and both the Mullins sheath and floatation catheter are removed, leaving behind the back-up wire.

Septal dilatation

For septal dilatation, the 5 × 30 mm Mansfield balloon is introduced over the LV back-up wire and positioned across the IAS. The balloon is inflated at 6

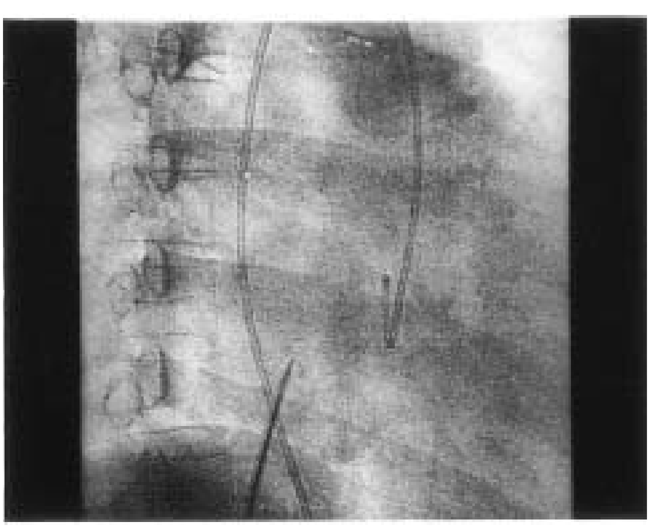

Figure 2: Septal puncture in the right anterior oblique 45° position.

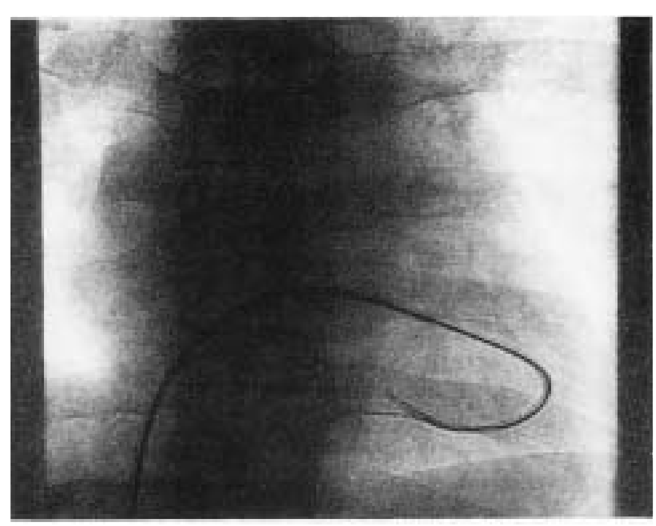

Figure 3: Crossing the mitral valve with the balloon flotation catheter (Swan-Ganz).

atmospheres pressure for 10 s to dilate the IAS, after which the Mansfield balloon is deflated and removed.

In balloon sizing, the stage is set for the introduction of the JOMIVA balloon. The size of the balloon is determined by using the same calculation as for the Inoue technique (12,13); that is, the patient's height (in cm) is divided by 10, adjusted to the nearest whole number, and then 10 is added to obtain the appropriate balloon size.

Balloon insertion

For insertion of the JOMIVA balloon catheter and mitral valve dilatation (Fig. 5), the balloon catheter is advanced over the back-up wire and positioned across the mitral valve. Rapid inflation of balloon is carried out with 30-35 ml of diluted contrast (contrast:saline ratio, 1:3) in a 50-ml plastic syringe until the waist of the balloon has disappeared. The balloon is then deflated, the back-up wire pulled out, and the balloon brought to the left atrium. Left atrial pressure is then measured, and the pigtail catheter advanced to the left ventricle to perform simultaneous LA and LV pressure tracings; this permits the post-balloon mitral valvotomy gradient across the mitral valve to be measured. Echocardiography is then carried out to measure the MVA by planimetry and to identify any MR or pericardial effusion. On completion of the balloon mitral valvotomy, the pulmonary artery pressure is recorded before sheath removal.

Method variation

The present procedure differed from that originally described by Joseph in the following manner. During septal puncture, Joseph et al. used the Mullins sheath with dilator and a BB needle. After puncturing the septum with the BB needle, the sheath was advanced into the left atrium while pulling out the dilator and needle. The present authors used a Mullins dilator alone and, after advancing the dilator into the left atrium, the LA wire was introduced to the left atrium. The Mullins dilator was then removed and the septum dilated with a septal dilator, before introducing the sheath into the left atrium. This allowed free manipulation of the balloon flotation catheter and sheath inside the left atrium, for entering the left ventricle.

After positioning the LV wire, Joseph et al. introduced a 50 cm-long 14 Fr valved sheath (with a radio-opaque tip marker) and its dilator into the left atrium over the back-up wire. After removing the dilator, they introduced the JOMIVA balloon to dilate the mitral

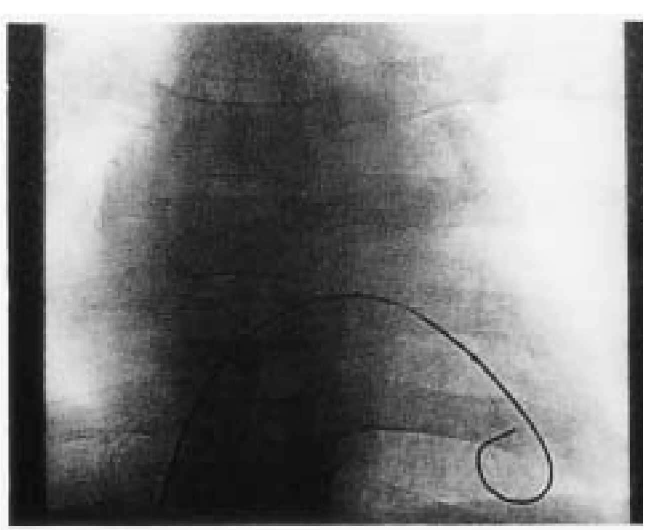

Figure 4: The left ventricular (back-up) wire in position. The deflated JOMIVA balloon is marked by two dots over the wire.

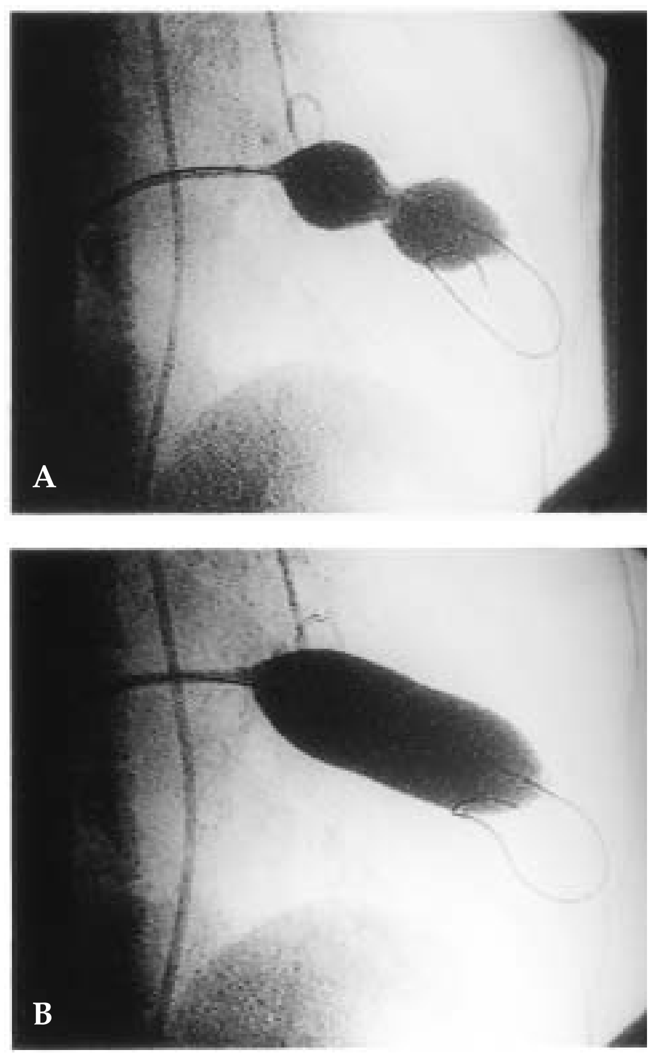

Figure 5: Left: Partially inflated JOMIVA balloon across the mitral valve, showing the waist. Right: Fully inflated JOMIVA balloon across the mitral valve after commissurotomy.

valve. In the present study, the long 14 Fr sheath was not used; rather, a 5 × 30 mm Mansfield balloon was used to dilate the atrial septum further, so that entry of the JOMIVA balloon to the left atrium was made easier. When using this method, there were no occasions when the atrial septum could not be crossed with the JOMIVA balloon. This allowed successful balloon entry to the left atrium whilst avoiding the potential danger of air embolism with a long 14 Fr sheath.

Follow up

Patients were re-evaluated at three-month intervals for the first year, and at six-month intervals thereafter. A detailed clinical and echocardiographic assessment was performed at each visit. Mitral valve restenosis was defined as >50% loss in the MVA increase achieved, a valve area of <1.5cm^2, or both (14).

Results

The procedure was technically successful in 247 patients (98%) (Table II). Septal puncture was not possible in four patients, but the mitral valve could be crossed with the Swan-Ganz catheter in all patients. The LV wire flipped out of the left ventricle repeatedly in one patient. Successful outcome was achieved in 228 patients (90.5%), and the result was suboptimal in eight (3.1%).

After PTMC, the mean MVA was increased from 0.81 ± 0.32 to 1.92 ± 0.39 cm^2 ($p < 0.001$) and there was a reduction in mean transmitral gradient, from 19.6 ± 4.8 to 4.4 ± 1.7 mmHg ($p < 0.001$). The mean LA pressure was decreased, from 34.3 ± 8.6 to 11.8 ± 6.5 mmHg ($p < 0.001$), while the mean PA pressure decreased from 48.4 ± 16.4 to 25.4 ± 10.4 mmHg ($p < 0.001$). One commissure was split in 164 patients (66.4%). In general, the MVA obtained after PTMC was less in restenosed and calcific valves, but it was statistically significant between non-calcific and calcific valves (2.02 ± 0.32 and 1.74 ± 0.22 cm^2, respectively; $p < 0.005$). Patients showed significant symptomatic improvement after the procedure, with 133 (52.8%) being in NYHA class I and 105 (41.7%) in class II, while the remainder (5.5%) stayed in class III. The mean fluoroscopy time in the present series was 8.2 ± 3.8 min, and the mean procedure time 43.4 ± 12.6 min.

Complications

Seven patients (2.8%) had cardiac tamponade during the procedure; this was due to incorrect septal puncture in five cases (2%), tear of the right superior pulmonary vein at its opening to the left atrium in one case (0.4%), and LV tear in one case (0.4%). These patients were managed by immediate pericardiocentesis. Later, two of these patients needed surgical repair; the patient with the LV tear died in spite of an attempt at surgical repair. Atrial septal defect (ASD) was detected in 188 patients (74.6%) by color flow map-

Table II: Results of percutaneous transatrial mitral commissurotomy (PTMC).

Outcome	No. of patients
Procedural (technical) success	247 (98)
Successful outcome (MVA >1.5 cm^2 without major complication)	228 (90.5)
Suboptimal result (MVA <1.5 cm^2 without major complications)	8 (3.1)
Major complications	11 (4.4)
Cardiac tamponade	7 (2.8)
Severe MR	3 (1.2)
Thromboembolism	1 (0.4)
Death	1 (0.4)
Fluoroscopy time (min)*	8.2 ± 3.8
Procedure time (min)*	43.4 ± 12.6

MVA and pressure data*	Before	After	p-value
MVA (cm^2)	0.81 ± 0.32	1.92 ± 0.39	<0.001
Mean mitral valve gradient (mmHg)	19.6 ± 4.8	4.4 ± 1.7	<0.001
Mean LA pressure (mmHg)	34.3 ± 8.6	11.8 ± 6.5	<0.001
PA systolic pressure (mmHg)	48.4 ± 16.4	25.4 ± 10.4	<0.001

*Values are mean ± SD.
Values in parentheses are percentages (unless otherwise stated).
AR: Aortic regurgitation; LA: Left atrial; MR: Mitral regurgitation; MVA: Mitral valve area; PA: Pulmonary artery.

ping. The QP/QS was ≤1.5 in all patients. MR either appeared (n = 10) or worsened (n = 20) in 30 patients (11.9%), of whom three (1.2%) developed severe MR, though none required emergency mitral valve replacement. One patient (0.4%) had a left hemiparesis which recovered in three days, albeit with a residual sensory neural problem.

Follow up

A total of 220 patients was followed up for between six and 54 months (mean 30 ± 11 months). Mean MVA measurement by 2D and Doppler methods was 1.67 ± 0.38 cm^2. Cardiac function improved further to NYHA class I in 140 patients (63.6%), and to class II in 67 (30.5%). Mitral restenosis (as assessed by echocardiography) was seen in 17 patients (7.7%), of whom 13 (5.9%) were in NYHA class III. Eight patients (3.2%) had a small ASD (QP/QS ≤1.5), as assessed by color Doppler during follow up. Elective mitral valve replacement was carried out in one of three patients with severe MR during follow up. MR disappeared in four of the 10 patients in whom it appeared for the first time after PTMC, and was improved in 12 of the 20 patients in whom it had worsened following PTMC.

Discussion

Device and procedure

Currently, PTMC has gained rapid acceptance among cardiologists and is now regarded as an established technique for the treatment of mitral stenosis (2-5). The use of double balloon, different single balloons and metal dilators have all been attempted, while retrograde non-transseptal mitral valvuloplasty has been used by Stefanadis and colleagues, with good results (15). In India, Bahl and others have used the above technique in a considerable number of patients (16).

The Inoue balloon is used worldwide because of its many advantages (14-17), which include a low profile (4.5 mm), short balloon length, and the capability of the latex balloon to be stretched and slenderized by the insertion of a metal cannula. In this way it is easily placed across the mitral orifice, and does not slip from the valve during inflation. It also allows sequential stepwise mitral valve dilatation. Moreover, the balloon is quickly inflated and deflated, and consequently hypotension does not develop during balloon inflation. The Inoue balloon is also user-friendly and cost effective (mainly because of its reusability), while the technique has shorter total procedure and fluoroscopy times. Furthermore, the incidence of post-procedural MR and ASD is much less.

The Inoue balloon does have some disadvantages, however. First, it is difficult to flow-direct the balloon towards the left ventricle in very severe cases of mitral stenosis. Indeed, in many cases it is necessary to cross the valve with a deflated balloon, but this may pass through the chordae and result in chordal rupture and MR during balloon dilatation. The other major problem is the difficulty of sterilization. The balloon has a hole which opens in between two layers of balloon material and is supposed to prevent deflation failure. However, blood which is able to pass through the hole and between the two balloon layers is almost impossible to remove after use, making sterilization extremely difficult. In addition, compliance with the balloon tends to change on repeated use, raising doubts about the efficacy of reused balloons. Deflation failure is also an occasional problem.

The JOMIVA balloon catheter functions as an over-the-wire system, having at its distal end a cylindrical balloon that expands to a fixed size (9,11). It is cheap, tough, durable, short with a low crossing profile, and has a distal short blunt tip which protects against LV perforation by the balloon catheter. The JOMIVA also has a short inflation/deflation time, and as it passes

Table III: Acute complications of percutaneous transatrial mitral commissurotomy (PTMC).

Reference	Year	No. of patients	Tamponade (%)	Severe MR (%)	Systemic embolization (%)	Death (%)
Vahanian et al. (28)	1989	200	0.5	4	4	0
Hung et al. (12)	1991	219	0	6	6	0.5
Cohen et al. (26)	1992	146	4	1.5	2	1
Chen and Cheng (5)	1995	4832	0.8	1.4	0.5	0.12
Palacios (7)	2000	860	0.6	3.3	1	0.3
Stefanadis (15)	2000	893	0	3.1	0	0.3
Arora et al. (8)	2002	4850	0.2	1.4	0.1	0.2
Joseph (11)*	2002	1025	0.6	2.6	0.1	0.5
Present study*	-	252	2.8	1.2	0.4	0.4

*JOMIVA balloon catheter used.

over the back-up wire there is less chance of MR, so that the question of the balloon not crossing the mitral valve does not arise. Under-sizing of the balloon by 2-4 mm is recommended in patients with severe pulmonary arterial hypertension (PAH), pregnancy, pre-existing aortic stenosis and/or mitral regurgitation, age <18 and >55 years, a highly deformed mitral valve and mitral restenosis after surgical valvotomy.

However, the most important advantage of the JOMIVA balloon is its low cost, ease of sterilization, and reusability. As the structure of balloon is simple it can be sterilized easily either with ethylene oxide gas or cidex solution. The mechanical characteristics of the JOMIVA balloon catheter remain excellent, despite resterilization and repeated use. In fact, the present authors have used the resterilized JOMIVA balloon several times (10 to 20 occasions) and have not encountered problems such as balloon rupture, catheter shaft fracture, inability to remove the balloon catheter, or failure of the balloon to deflate. A similar experience was reported by Joseph et al. with 1,035 cases of PTMC (11). A minor problem is that many cycles of ethylene oxide gas sterilization causes a gradual reduction in the diameter of the JOMIVA balloon; consequently, the current diameter should be measured on each occasion before resterilization and confirmed as being that stated on the original packet.

The modifications made to the procedure by the present authors as described herein have the following advantages. Dilatation of the septum with a septal dilator over the LA wire allows easy maneuvering of the Swan-Ganz catheter and Mullins sheath inside the left atrium, so that crossing the mitral valve with the Swan-Ganz is made easier, particularly in the setting of a large left atrium and an inappropriate site of septal puncture. Indeed, by using this revised method, problems of non-crossing the mitral valve have not been encountered. Joseph et al. used a long 14 Fr sheath for the easy introduction of JOMIVA balloon catheter across the IAS. The LV wire can flip out of the left ventricle into the left atrium while inserting a long 14 Fr sheath and dilator into the left atrium. Removal of the dilator creates a low pressure in the sheath and allows the blood to flow from the left atrium to fill the vacuum inside the sheath; however, air can be sucked in through the valve, and this may potentially result in systemic air embolism. By not using the long 14 Fr sheath, the potential risk of air embolism is avoided. Further dilatation of the atrial septum with a Mansfield peripheral balloon (reusable) allows easy entry of the JOMIVA balloon across the IAS.

Immediate results

Optimal valvotomy was achieved in 90.5% of patients in the present series, and excellent statistically significant ($p < 0.001$) acute hemodynamic benefits were achieved. The hemodynamic improvement obtained was comparable with that reported previously (5-8,19-21). Following PTMC, the MVA was significantly higher in non-calcific valves compared with their calcific counterparts ($p < 0.005$). Others have shown that a higher patient age, greater calcification and higher echo score are related to a relatively lower final MVA after PTMC (22-24). In addition, a significant improvement in NYHA class was reported among the present patients which was of similar magnitude to that reported in other large series (5-8).

Complications

Among the present patients, 2.8% developed cardiac tamponade during the procedure, though this occurred predominantly in the initial 100 cases and was deemed due to inexperience of the cardiographers during the early stages of the study. Two patients required surgical repair. This was successful in one case with a LA tear, but a second patient with a LV tear died while a repair was being attempted. The present incidence of cardiac tamponade was higher when compared to a selected number of large clinical series (Table III), but this may have been due to the fact that

Table IV: Restenosis following percutaneous transatrial mitral commissurotomy (PTMC).

Study	Year	No. of patients	Mean age (years)	Follow up (months)	Restenosis (%)
Abascal et al. (32)	1989	20	52	7.5	20
Vahanian et al. (28)	1989	91	43	9	4
Desideri et al. (29)	1992	57	52	19	21
Chen and Cheng (5)	1995	4832	36.8	32.3	5.2
Ben Farhat et al. (30)	1998	30	29	84	6.6
Hernandez et al. (31)	1999	561	53	39	10
Arora et al. (8)	2002	3500	27.2	94	4.8
Present study*	-	220	39.2	30	7.7

*JOMIVA balloon catheter used.

many of the present patients had severe PAH, and a large left atrium with abnormal orientation of the IAS, which may lead to inappropriate septal puncture.

The frequency of ASD (25) following PTMC ranges from 10% to 90%, and according to the technique used for its detection, these shunts are found in 10-30% of cases by oximetry and in 38-90% by color follow imaging. ASD was detected in 74.6% of the present patients by color flow mapping immediately after the procedure. The incidence of ASD was higher in the present series as the atrial septum was dilated twice in these patients - once with a septal dilator (the Inoue technique), and again with 5 × 30 mm Mansfield balloon.

The development of MR due to leaflet tear, chordal damage, mitral annular stretching or edema of the papillary muscles can be seen as a complication of PTMC. Although most centers have reported an increase in MR of at least one grade in 32-50% of patients (5,8,12,26), the incidence of severe MR is relatively small (Table III). In the present series, MR appeared or worsened in 11.9% of cases, of which 1.2% developed severe MR and 0.4% required MVR during follow up.

Follow up

Functional improvements have been shown in the majority of patients in follow up studies after PTMC (5,8,12,13,14,22,26). In the present study, at a follow up period ranging from six to 54 months (mean 30 ± 14 months), clinical examination and echocardiography have shown gratifying results, with more than 94% of cases being in NYHA classes I and II. In the case of ASD, most such defects close after 3 to 12 months (27), though Arora et al. (13) reported persistence of ASD in 4% of patients after six months. Only 3.2% of the present patients had ASD during follow up, while one of three patients with severe MR underwent elective mitral valve replacement. Seventeen patients (7.7%) had echocardiographically proven restenosis - a value similar to that reported elsewhere (8,28-32) (Table IV).

In conclusion, PTMC using the JOMIVA balloon catheter (with a modified technique) is an effective and safe procedure that achieves an optimal result in a high proportion of patients, and the benefits were sustained in a majority of cases at follow up. Although the immediate and long-term results achieved with the JOMIVA and Inoue balloon were similar, the former scores over the latter on the basis of its low cost, ease of sterilization and repeated reusability. Thus, the JOMIVA balloon catheter is a cost-effective alternative to Inoue balloon - an important factor in less wealthy countries such as India.

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