

# Experience of Percutaneous Mechanical Mitral Commissurotomy Using Metallic Commissurotome in Patients with Mitral Stenosis at Chest Disease Institute

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**Background:** Percutaneous metallic mitral commissurotomy (PMMC) has been accepted as an alternative to the traditional balloon technique. The advantage of the metallic commissurotome is that it is designed for several reuse and resterization and it is an interesting tool as seen by the authors.

**Objective:** To evaluate the efficacy and safety of PMMC among a wide range of patients with severe mitral stenosis.

**Material and Method:** Between July 2000 and August 2003, patients with severe mitral stenosis who underwent PMMC were enrolled. Interatrial septum was punctured under transesophageal echocardiography guidance in all cases. Demographic data and baseline characteristics were collected. Mitral valve area (MVA) was evaluated by echocardiography and hemodynamic parameters pre and post PMMC were compared.

**Results:** PMMC was performed in 304 patients with a broad range of severe mitral stenosis. Mean age was  $38.7 \pm 10.9$  years and 79% was female. Most were in functional class II (94%) and 43 patients (14%) had prior commissurotomy. Atrial fibrillation was found in 41%. Twenty-six patients were crossed over to the Inoue balloon technique. The rate of success was 81% in all patients (246/304) and 89% in patients when PMMC was actually done (246/278). The MVA increased from  $84 \pm 22$  to  $170 \pm 36$  mm<sup>2</sup> ( $p < 0.0001$ ). Transvalvular gradient decreased from  $17 \pm 6$  to  $7 \pm 4$  mmHg ( $p < 0.0001$ ) and mean left atrial pressure from  $26 \pm 7$  to  $15 \pm 6$  mmHg ( $p < 0.0001$ ). Separation of both commissures was found in 25% and 61% had symptom relief by a reduction in functional class at least one level ( $p < 0.0001$ ). Complications developed in 16 patients (5.3%) including three serious events, one death caused by severe mitral regurgitation followed by emergency surgery, another survivor after surgical repair of left ventricular free wall rupture and the last one with surgical removal of the malfunctioned device stuck in the left atrium.

**Conclusion:** Results of PMMC is not as encouraging as shown in previous studies. The risk of cardiac tamponade is minimized by interatrial septal puncture using transesophageal echocardiography (TEE) monitoring but this technique increased the possibility of crossover. Deterioration of the metallic commissurotome after a few procedures is demonstrated in the author's real practice.

**Keywords:** Mitral stenosis, Metallic commissurotome, Percutaneous metallic mitral commissurotomy, PMMC

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Percutaneous transvenous mitral commissurotomy (PTMC), with either Inoue or double balloon, has been well approved as a standard treatment in patients with severe mitral stenosis with suitable valve score.

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The results are comparable to surgical commissurotomy in relieving the obstructed valve and maintaining a favorable long-term outcome<sup>(1-7)</sup>. The Inoue balloon technique is the most popular one according to its safety and ease to perform but the cost is high. Most centers in developing countries reuse these balloon catheters several times, although they are labeled as disposable catheters, thus leading to potential hazards

due to imperfect sterilization and deterioration of performance.

In 1996, a metallic commissurotome was first introduced by Cribier et al as a new percutaneous valvulotomy device<sup>(8-10)</sup>. The basic principles are similar to those with Tubb's dilator used by surgeons for closed-chest mitral commissurotomy. The effectiveness and safety of percutaneous metallic mitral commissurotomy (PMMC) is comparable to the balloon technique in a few reports<sup>(11-13)</sup>. However, the main advantage of this device would be the possibility of multiple reuses without unchanged performance after proper reesterilization. This property has made the device an attractive alternative to the previous balloon valvulotomy in terms of cost reduction.

Nevertheless, there are still some concerns about the serious complications caused by PMMC, especially the higher risk of hemopericardium due to wrong interatrial puncture, the metallic device, and the presence of the hard guidewire in the left ventricle. In terms of reutilization, the maximal number of reuse is questionable. Moreover, the technique is more demanding for the operator compared to the procedure of Inoue balloon<sup>(14)</sup>. Results of PMMC in the authors' institute are presented and discussed in the present study.

## Material and Method

### Study population

All patients with a diagnosis of severe mitral stenosis who underwent PMMC were recruited. The choice of treatment between PMMC and traditional balloon technique was dependent on the operator's decision. The exclusion criteria were pregnancy, mitral regurgitation (MR) > Sellers' grade 2, recent embolic event, having the procedure as an emergency treatment and large or mobile thrombus in left atrial cavity. However, fixed and very tiny thrombus in left atrial appendage (LAA) was not an absolute contraindication in the present study.

The severity of mitral valve stenosis, valve morphology and MR were assessed by M-mode and 2D echocardiography and Doppler in each case. The mitral valve area (MVA) was determined by planimetry on the parasternal short axis view and by Doppler pressure half-time method. The Wilkins echocardiographic scoring system in 16 grades was used as a reference of grading the severity of mitral valve thickness, leaflet mobility, valvular calcification, and subvalvular disease, each being classified from 1 to 4. A transthoracic echocardiography (TTE) was performed during the procedure to measure MVA and estimate

the severity of MR after each dilatation, at 24 or 48 hours after the procedure and at each follow-up visit. MVA by TTE at day 1 or 2 was used as a reference for assessment of the results.

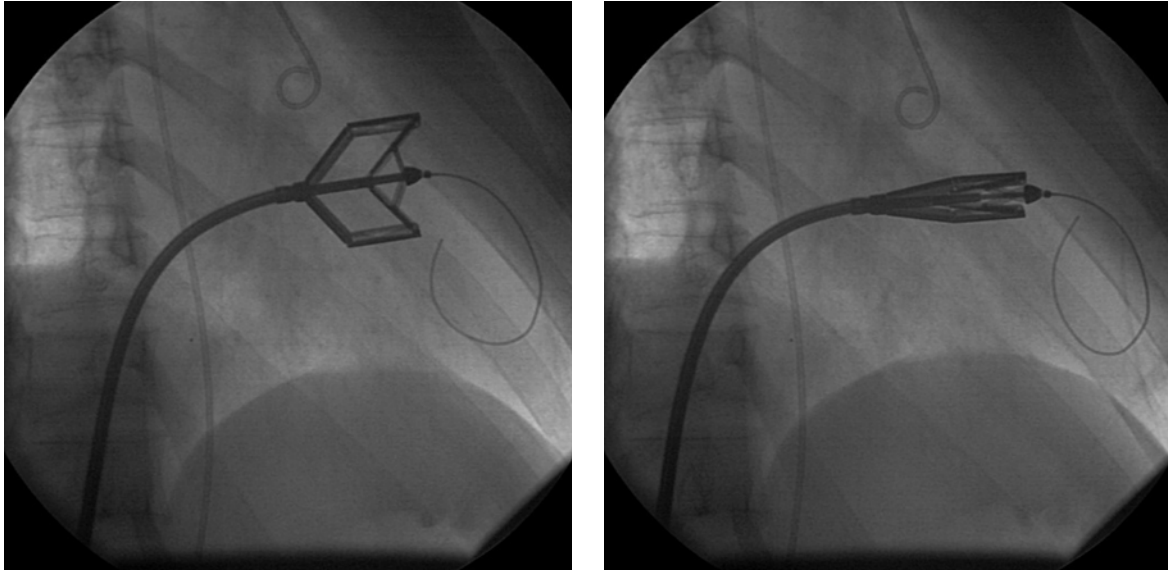
The device and technique of metallic commissurotome (Medicorp Inc, Villers-les-Nancy, Cedex, France) have been described in full details elsewhere<sup>(8-10,12)</sup>. In brief, the device consists of a distal metallic head (5 cm long and 5 mm wide) comprising two hemicylindrical bars 15 mm in length. It is fixed at the tip of a 12F disposable catheter and connected by an internal cable to a proximal hand-operated device, which can open the arms gradually to 33 mm and up to a maximum of 40 mm. The metallic head is detachable and can be reesterilized and reused multiple times.

PMMC was performed by anterograde transseptal technique with the right femoral vein as an entry site under local anesthesia in every patient. All procedures were done with a standby facility for emergency surgical commissurotomy. Right and left heart pressures, oximetry samplings were obtained before and after PMMC.

The interatrial septal was punctured by means of the Brockenborough technique under fluoroscopy and transesophageal echocardiography (TEE) guidance in all cases. Description of the technique in full detail has been shown elsewhere<sup>(15,16)</sup>. After left atrial access was achieved, 1,000-1,500 units of heparin were added intravenously after the dosage of 2500 units at the beginning of right heart catheterization. Then, a Mullins sheath was introduced into the left ventricle with the help of a 7F balloon floatation catheter (Arrow international Inc, Reading, Pa) across the mitral valve. A beaded stainless steel wire 270 cm in length and 0.035 inches in diameter (with a metallic bead 2 mm in diameter soldered at the junction of the stiff core and the 10 cm distal floppy end) was positioned in the left ventricle through the Mullins sheath. The commissurotome was tracked over the bead wire across the atrial septum and the mitral valve. Then the bead of the guidewire becomes traction when it is positioned in contact with the distal end of the dilator. The guidewire is locked into the commissurotome on the activating pliers. Squeezing the arms of the pliers allows the bars to spread apart and the bars are in the partially closed position when releasing the arms (Fig. 1).

The extent of the bar opening is determined on the basis of the body surface area (BSA).

The bar opening is set at 40 mm if the patients have a BSA  $\geq 1.5$  m<sup>2</sup>. When a BSA was less than 1.5 m<sup>2</sup>, the initial bar is adjusted at 37 mm and, when needed, it



**Fig. 1** Metallic dilator in the opened (40-mm) and the partially closed position

was increased up to 40 mm. Procedure success was defined as a final mitral valve area  $> 1.5 \text{ cm}^2$  or an increase in valve area of at least 50% from the basal in the absence of MR  $>$  Sellers' grade 2 and immediate surgical correction due to serious complication<sup>(12)</sup>. Transatrial shunting was assessed after the procedure with oxymetry run and on follow-up with color flow imaging.

#### Statistical analysis

Continuous variable are expressed as the mean  $\pm$  SD. Variation in continuous variables from baseline to the first or second day after PMMC was analyzed with the paired samples *t*-test. Wilcoxin Signed Ranks test was used in evaluation of ordinal data. For comparison between groups, the unpaired Student's *t*, Chi-square tests were used. In univariate analyses, the following 2-sided statistical tests were used. The variables that appeared to be significantly associated with the outcome at the 0.10 significance level were further assessed by stepwise multiple linear regression with a threshold corresponding to a 0.05 significance level.

#### Results

##### Demographic and baseline characteristics:

Between July 2000 and August 2003, 818 patients with mitral stenosis underwent mitral valve dilatation percutaneously. PMMC was performed in 304 patients and the rest of the patients were treated with balloon technique. The demographic data are

shown in Table 1. Mean age was 38.7 years and 79% were female. Atrial fibrillation was found in 125 cases. Most of the patients were in functional class II (94%) and 43 patients (14%) had history of prior commissurotomy with either balloon or surgery. There were three patients (1%) with fixed and very small thrombus in LAA detected by TEE in the present study.

#### Crossover

PMMC could be achieved in 278 patients (91.4%). 26 patients had to cross over from PMMC to the Inoue balloon technique for mitral commissurotomy (IBMC). There was no direct cross-over to surgery. Details of crossover are shown in Table 2. The main

**Table 1.** Demographic and baseline characteristics from 304 patients

Age (range)	39 $\pm$ 11 (16-74)
No. of women (%)	239 (79)
NYHA class, n (%)	
1-2	287 (94)
3-4	17 (6)
Atrial fibrillation, n (%)	125 (41)
Previous commissurotomy, n (%)	43 (14)
Echocardiographic score (range)	8.1 $\pm$ 1.6 (5-15)
Left arial diameter, mm	50 $\pm$ 7
Associated MR (grade 1 or 2), n (%)	70 (23)
History of embolic stroke.n (%)	27 (9)

MR indicates mitral regurgitation

reason for technical failure was unable to cross the mitral valve in 22 patients. Two patients developed severe hypotension from guidewire induced multiple ectopic ventricular arrhythmia and could not tolerate the procedure. Air emboli into the right coronary artery was found in one patient while advancing the guidewire into the Mullins sheath to the left ventricle and the operators decided to use IBMC instead after the patient was stable. Only one patient with suboptimal results was crossed over to IBMC.

Of 26 patients, 24 underwent IBMC successfully. Compared to patients with PMMC, patients in the crossover group were less frequently to be female (62% vs. 80%,  $p=0.03$ ) and had larger left atrial diameter ( $53 \pm 10$  vs.  $50 \pm 7$  mm,  $p=0.04$ ). There was no statistical significance between both groups in other baseline characteristics, success rate, MVA pre and post dilatation and complications. Half of the crossovers (13 procedures) were found in the first 140 case series.

#### ***Echocardiographic and hemodynamic results and predictors of success:***

A successful result was achieved in 246 of the 304 patients enrolled (81%) and in 246 patients out of the 278 patients (89%) in whom PMMC was actually performed. The average number of left ventricular entry was two (range of 1-7). The detachable metallic head was reused after proper sterilization in 35 (10-41) procedures. The procedure resulted in improvement of acute hemodynamic parameters as shown in Table 3. Transmitral valve gradient decreased significantly from  $17 \pm 6$  to  $7 \pm 4$  mmHg and mean left atrial pressure from  $26 \pm 7$  to  $15 \pm 6$  mmHg ( $p < 0.0001$ ). The MVA by 2-D planimetry increased from  $84 \pm 22$  to  $170 \pm 36$  mm<sup>2</sup> ( $p < 0.0001$ ). After PMMC, the most favorable final mitral valve area was obtained in patients with successful procedure and low valve score. Patients with suitable valve score ( $< 8$ ) had higher final MVA and net gain in valve area compared to those with higher valve score (Post-MVA at  $180 \pm 30$  mm<sup>2</sup> vs.  $161 \pm 38$  mm<sup>2</sup>,  $p < 0.0001$ ). The difference of MVA before and after PMMC is illustrated in Fig. 2. Data of MVA and transmitral valve pressure gradient before and after PMMC according to subset of successful procedure and valve score are demonstrated in Fig. 3 and 4. Most of the patients (167 of 275, 61%) had clinical improvement by a reduction in functional class at least one level ( $p < 0.0001$ ). This technique produced bilateral separation of commissures in 25% and separation of one commissure in 68%. The mean fluoroscopy time was  $18.5 \pm 7.5$  minutes in all cases. There were five variables identified as predictors

**Table 2.** Reasons for crossover of 26 patients

Not possible to cross the mitral valve (22)
- with the balloon catheter (4)
- the guidewire (9)
- the commisurotome (9)
Guidewire induced severe hypotension and multiple ectopic ventricular arrhythmia (2)
Air emboli into RCA (1)
Suboptimal results (1)

**Table 3.** Immediate change in echocardiographic and hemodynamic parameters after PMMC (275 cases): mitral valve area (MVA) by 2D planimetry, MVA by pressure half-time (PHT), left atrial diameter (LAD), mean transmitral valve gradient (MVG), mean left atrial (LA) pressure and mean pulmonary arterial (PA) pressure

Parameters	Pre	Post	p-value
	PMMC	PMMC	
MVA by 2D-planimetry(mm <sup>2</sup> )	$84 \pm 22$	$170 \pm 36$	$<0.0001$
MVA by PHT (mm <sup>2</sup> )	$85 \pm 21$	$178 \pm 47$	$<0.0001$
LAD (mm)	$50 \pm 7$	$46 \pm 8$	$<0.0001$
MVG (mmHg)	$17 \pm 6$	$7 \pm 4$	$<0.0001$
Mean LA pressure (mmHg)	$26 \pm 7$	$15 \pm 6$	$<0.0001$
Mean PA pressure (mmHg)	$33 \pm 12$	$28 \pm 10$	$<0.0001$

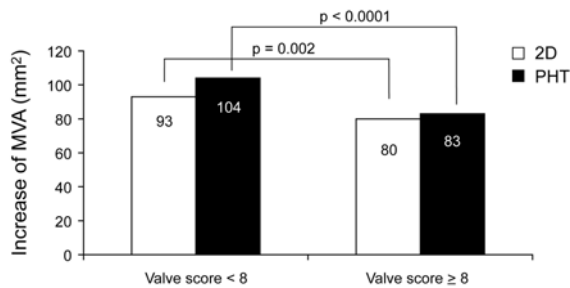
**Table 4.** Independent predictors of success by multivariate analyses

Variables	p-value	OR (95% CI)
LA diameter before procedure	0.544	
AF	0.330	
Age	0.022	0.96
High valve score	0.019	0.38
Prior commissurotomy	0.008	0.32

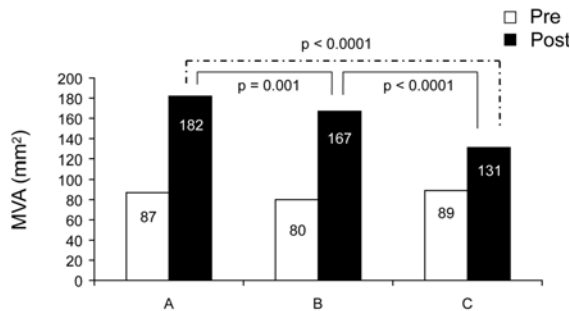
**Table 5.** Complications of 16 patients (from 304 patients)

MR grade $\geq 3$ (10) including:
- 1 underwent emergent surgery and died in the following day
- 3 required surgical valve replacement later
LV free wall rupture and cardiac tamponade (1)
Malfunctioned device stuck in LA (1)
Air emboli (1)
Tear of femoral vein (2)
TIA (1)

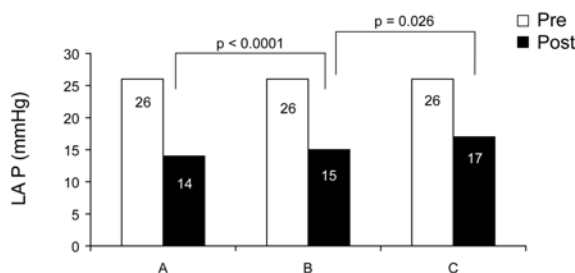




**Fig. 2** A net gain in mitral valve area (MVA) evaluated by 2D planimetry and pressure half-time (PHT) after PMMC according to the Wilkins echocardiographic valve score (n = 132 and 143 respectively)

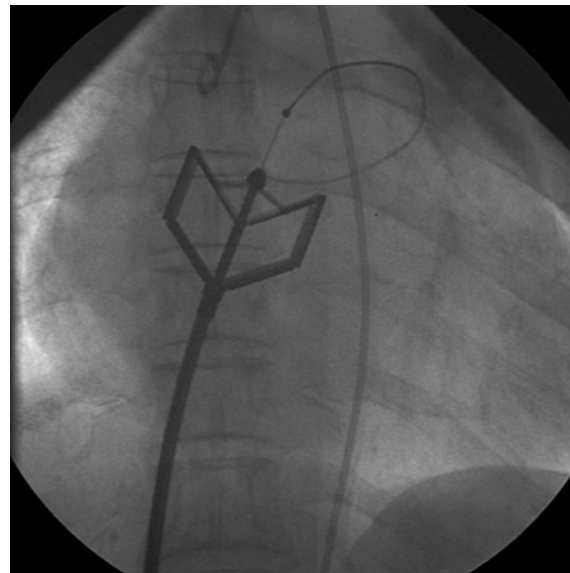


**Fig. 3** Pre and Post-PMMC mitral valve area (MVA) evaluated by 2D planimetry in each subset: A= successful procedures with valve score < 8, B = successful procedures with valve score ≥ 8, C = unsuccessful procedures (n = 123, 123 and 29 respectively)



**Fig. 4** Pre and Post-PMMC left atrial pressure (LAP) in each subset: A = successful procedures with valve score < 8, B = successful procedures with valve score ≥ 8, C = unsuccessful procedures (n = 123, 123 and 29 respectively)

of success by univariate analyses. However, only age, high mitral valve score and history of prior commissurotomy remained independent predictors of success when using multivariate analyses (Table 4).



**Fig. 5** Malfunction of the metallic device located in left atrium. Note the metallic in the opened position after pressure release at the activating pliers. Surgical removal was performed in this case

### Complications

Of 304 patients, complications happened in 16 patients (5.3%) as shown in Table 5. MR grade ≥ 3 occurred in 10 including one who underwent emergency surgery and died in the following day and three who required surgical valve replacement later. The rest of the patients as well as one patient in crossover to Inoue balloon who developed mitral regurgitation grade 3 were stable without surgical intervention. PMMC resulted in serious cardiac tamponade caused by left ventricular free wall rupture in one who survived after immediate surgical closure and valve replacement. The bars of metallic dilator could not be closed after releasing the arms of hand-operated device in one patient (Fig. 5). Emergent surgical removal of the metallic commissurotome and valve replacement were performed successfully. While introducing the guidewire into the Mullins sheath to the left ventricle, a large amount of air emboli accidentally dislodged in the right coronary artery was noted in one patient. The patient was treated by manual air aspiration through catheter and the PMMC was changed to IBMC with good results. There were two patients including one in crossover who developed severe bleeding from tear of femoral vein requiring surgical repair. TIA happened in one who had no left atrial thrombus and full heparinization. Iatrogenic ASD after PMMC was seen by TTE in 80.9% 246 (246/275) and all of them were restrictive pattern.

## Discussion

The efficacy of PMMC in the authors' series was lower with a success rate of 81% compared to 91% from the previous report<sup>(8-10)</sup>. Candidates with suitable valve score (< 8) earned more favorable final valve area than those with higher valve score. The inferiority of effectiveness resulted from the high incidence of crossover rate than the prior study (9% vs. 2%)<sup>(8-10)</sup>. Half of the crossover took place during the last 164 procedures when the operators were familiar with this technique. The possible reason was the different technique in transeptal puncture. The septal puncture site greatly influences effectiveness of delivering the metallic device into the left ventricle for dilatation<sup>(8-10)</sup>. According to the original recommendation of PMMC, the puncture site is ideally located one or two centimeters below the point suitable for IBMC. It is the authors' tradition to puncture the interatrial septum under TEE guidance<sup>(15)</sup>. The authors did not strictly adopt all blind transeptal puncture technique using tip of the pigtail at the aortic cusps and the right hemidiaphragm in the lateral position recommended by the first operator as a landmark in achieving the ideal site for delivering the device into the left ventricle. Although the crossover rate was greater under septal puncture using TEE guidance, there was no case of cardiac tamponade due to a wrong septal puncture which was reported as high as 1.4% in some series of PMMC under blind interatrial septal puncture<sup>(9,10)</sup>. The serious cardiac tamponade in one patient resulted from the perforation of left ventricular free wall caused by protruding of the hard guidewire out of the ventricle. MR > 2 was observed in 10 (3.3%) which was in acceptable number similar to MR caused by balloon (3%-15%)<sup>(17)</sup>: only one needed emergency surgery and elective surgery later in three. Surprisingly, bilateral commissural separations were markedly lower compared to the previous report (25% vs. 86%). There is no clear answer for this finding. However, 93% of the patients achieved splitting of at least one commissure. The fluoroscopy time was 2 or 3 times higher than the average of IBMC performed in the authors' institute. This reflected that PMMC was more technically demanding than IBMC.

After sterilization, the detachable metallic head allows multiple reuses as for metallic surgical tool. Some investigators have performed 35 or up to 40 procedures per a single device without deterioration of the performance<sup>(8-10)</sup>. Thus, the final cost per patient is markedly lower. Nevertheless, the maximal number of reuse without harm per a single metallic head is still in

question. The authors found a case of failure to close the metallic device after 10 procedures with a proper technique of sterilization and a new catheter. This serious complication could be correctable with only surgical removal. In case of failure to deflation of the Inoue balloon, there are many approaches including rupturing the balloon instead of surgery<sup>(18)</sup>.

In present case series, three patients had very small and fixed thrombus in LAA. All patients underwent PMMC very carefully under TEE guidance without complications. To the authors' knowledge there are no prior case reports describing the use of metallic valvulotome technique in severe mitral stenosis with fixed thrombus. PTMC using balloon technique can be performed in these patients with acceptable risks in a few reports<sup>(16)</sup>. Owing to a very small number of patients, it is too early to generalize this technique in such patients. Intervention with PMMC in critically ill patients with mitral stenosis, respiratory failure, and cardiogenic shock was also achieved under TEE guidance in one case report<sup>(19)</sup>.

## Study limitations

Only immediate results were studied because there were inherent difficulties in obtaining follow-up information for some patients who were underprivileged and lived in remote areas. Nevertheless, long-term effectiveness of this technique has been reported up to three years in one recent study<sup>(20)</sup>. The number of population was small and it was not a randomized study. The option of treatment was dependent on the preference of the operators so selection bias could not be excluded. A large randomized study comparing this technique with the current balloon valvulotomy is mandatory before the concept of the device is generalized.

## Conclusion

The effectiveness of PMMC in immediate relieving of stenotic mitral valve is not promising as it was demonstrated in the previous study. Technique of interatrial septal puncture under TEE guidance minimizes the risk of cardiac tamponade but increases the crossover rate. The role of reusability in several procedures may not be safe due to loss of function of metallic dilator presented in the authors' experience.

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**ประสบการณ์การรักษาผู้ป่วยลิ้นหัวใจไมตรัลตีบ (mitral stenosis) ด้วยอุปกรณ์ขยายชนิดโลหะ (metallic commissurotome) ผ่านทางหลอดเลือดดำ femoral vein ในสถาบันโรคทรวงอก**

บุญจง แซ่จิ่ง, สุदारตัน ตันสุภสวัสดิกุล, เกรียงไกร เสงร์ตมี, วิรัช เคหสุขเจริญ, จรินทร์ อัครหาญฤทธิ, เอนก กนกศิลป์

**ภูมิหลัง:** การขยายลิ้นหัวใจไมตรัลตีบด้วยอุปกรณ์ขยายชนิดโลหะผ่านทางขาหนีบหรือ Percutaneous metallic mitral commissurotomy (PMMC) เป็นการรักษาผู้ป่วยลิ้นหัวใจไมตรัลตีบ (mitral stenosis) ที่มีประสิทธิภาพอีกวิธีหนึ่ง นอกเหนือจากการใช้อุปกรณ์ชนิดลูกโป่ง อุปกรณ์ขยายชนิดโลหะ (metallic commissurotome) มีข้อได้เปรียบในเรื่องสามารถนำกลับมาใช้ซ้ำได้หลายครั้งภายหลังการฆ่าเชื้อโดยยังคงประสิทธิภาพที่ดีอยู่

**วัตถุประสงค์:** เพื่อศึกษาถึงประสิทธิภาพและความปลอดภัยของอุปกรณ์ขยายชนิดโลหะในผู้ป่วยลิ้นหัวใจไมตรัลตีบ **วัสดุและวิธีการ:** ผู้ป่วยโรคลิ้นหัวใจไมตรัลตีบจำนวน 304 ราย ณ สถาบันโรคทรวงอกในระหว่างปีพุทธศักราช 2543-2546 ที่ได้รับการรักษาด้วยอุปกรณ์ขยายชนิดโลหะ ผู้ป่วยทุกรายได้รับการแทงผนังกันหัวใจห้องบนด้วยวิธี Transesophageal echocardiography guidance ทำการเก็บรวบรวมข้อมูลพื้นฐานของผู้ป่วยทุกราย เปรียบเทียบข้อมูลก่อนและหลังการขยายลิ้นหัวใจ รวมถึงภาวะแทรกซ้อนที่เกิดขึ้น

**ผลการศึกษา:** ผู้ป่วยมีอายุเฉลี่ย  $38.7 \pm 10.9$  ปีและร้อยละ 79 เป็นเพศหญิง มีผู้ป่วยจำนวน 43 ราย (ร้อยละ 14) ที่เคยได้รับการขยายลิ้นหัวใจไมตรัลมาก่อน พบผู้ป่วยที่มีจังหวะการเต้นหัวใจผิดปกติชนิด atrial fibrillation จำนวนร้อยละ 41 มีอาการเหนื่อยในระดับ functional class II คิดเป็นร้อยละ 94 ในระหว่างการศึกษามีผู้ป่วย 26 ราย ต้องกลับไปใช้วิธีการขยายลิ้นหัวใจโดยใช้ลูกโป่งแบบดั้งเดิม (crossover) การรักษาด้วยวิธีนี้สามารถขยายลิ้นหัวใจไมตรัลที่ตีบได้อย่างมีประสิทธิภาพคิดเป็นจำนวนร้อยละ 81 (246 ใน 304 ราย) และร้อยละ 89 (246 ใน 278 ราย) โดยทำให้พื้นที่ของลิ้นเพิ่มขึ้นจาก  $84 \pm 22$  ตารางเซนติเมตรเป็น  $170 \pm 36$  ตารางเซนติเมตร ( $p < 0.0001$ ) ค่า Transmitral valvular gradient ลดลงจาก  $17 \pm 6$  มิลลิเมตรปรอทเป็น  $7 \pm 4$  มิลลิเมตรปรอท ( $p < 0.0001$ ) ค่า mean left atrial pressure ลดลงจาก  $26 \pm 7$  มิลลิเมตรปรอทเป็น  $15 \pm 6$  มิลลิเมตรปรอท ( $p < 0.0001$ ) พบรอยแยกบริเวณลิ้นหัวใจไมตรัลทั้งสองด้านเป็นร้อยละ 25 ของผู้ป่วย และผู้ป่วยร้อยละ 61 มีอาการเหนื่อยดีขึ้น ( $p < 0.0001$ ) ภาวะแทรกซ้อนเกิดขึ้นในผู้ป่วยจำนวน 16 รายหรือ (ร้อยละ 5.3) โดยมีภาวะแทรกซ้อนขั้นรุนแรงจำนวน 3 ราย รายแรกเกิดภาวะลิ้นหัวใจไมตรัลรั่วเฉียบพลันชนิดรุนแรงและเสียชีวิตภายหลังได้รับการผ่าตัดฉุกเฉิน รายที่สองมีภาวะเลือดออกในเยื่อหุ้มหัวใจเฉียบพลันจากการฉีกขาดของผนังกล้ามเนื้อหัวใจห้องล่างซ้าย ผู้ป่วยได้รับการผ่าตัดซ่อมผนังที่ขาดและรอดชีวิต รายที่สามพบความผิดปกติของอุปกรณ์โลหะโดยไม่สามารถหุส่วนหัวของอุปกรณ์ลงได้ ทำให้ผู้ป่วยต้องได้รับการผ่าตัดฉุกเฉินเพื่อนำอุปกรณ์ที่ค้างในหัวใจห้องซ้ายบนออกด้วยความปลอดภัย

**สรุป:** ผลการรักษาผู้ป่วยลิ้นหัวใจไมตรัลตีบด้วยอุปกรณ์ขยายชนิดโลหะผ่านทางขาหนีบ PMMC มีประสิทธิภาพต่ำกว่ารายงานอื่น ๆ ที่เคยมีผู้ศึกษาไว้ โดยสามารถขยายลิ้นหัวใจได้ดีในผู้ป่วยที่มีค่า valve score น้อยกว่า 8 การใช้คลื่นเสียงสะท้อนหัวใจผ่านทางหลอดเลือดอาหาร (transesophageal echocardiography, TEE) ในระหว่างการแทงผนังกันหัวใจห้องบนสามารถลดอัตราการเกิดเลือดออกในเยื่อหุ้มหัวใจชนิดเฉียบพลันลงได้ แต่มีผลทำให้ไม่สามารถนำอุปกรณ์โลหะผ่านลิ้นหัวใจไมตรัลได้สูงขึ้น ควรเพิ่มความระมัดระวังในการนำอุปกรณ์โลหะมาใช้หลายครั้ง เนื่องจากอุปกรณ์อาจเสื่อมประสิทธิภาพได้