Efficacy and Safety of Percutaneous Metallic Mitral Valvuloplasty in Rheumatic Mitral Stenosis at Siriraj Hospital

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Abstract

Mitral stenosis is an important problem that leads to heart failure and stroke in Thailand. The options of treatment at present are either surgical or balloon mitral commissurotomy. However, the cost of balloon is very expensive. To reduce the expense of the procedure, the authors prospectively did a study using a new device called the metallic valvulotome in symptomatic severe mitral stenosis to assess the safety, feasibility and immediate outcomes.

Fifty-seven patients were included in the study. The successful outcome achieved by the metallic valvulotome was 96.2 per cent in patients in whom the procedure was actually performed. The mean transmitral gradient, left atrial pressure and pulmonary artery pressure were significantly decreased and the mitral valve area was also significantly increased. Three cases failed the procedure due to inappropriate position of the septal puncture. No death occurred in the study and complications of the procedure included only two cases of hemopericardium.

In the future, it is believed that this new innovative device will provide improvement and reduce the cost of the procedure in patients with severe mitral stenosis.

Key word : Mitral Valve, Valvuloplasty, Catheters

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Mitral stenosis still remains an important cause of heart failure in Southeast Asia, especially in Thailand. Rewat et al, reported that mitral stenosis was the most common cause of heart disease leading to heart failure among the age group 13-89 years at Siriraj Hospital[1]. In addition to heart failure, mitral stenosis can cause atrial fibrillation and stroke which produces morbidity and disability in patients[2-5].

The treatment of mitral stenosis in the past consisted of both open and closed surgical mitral commissurotomy. Subsequently, there has been development of percutaneous balloon mitral valvuloplasty (PBMV) namely the double balloon technique which has produced results comparable to surgical commissurotomy but this technique has some difficulties and depends on the skill of the operator[6-11]. This has led to the innovation of a single balloon technique called the Inoue balloon which is easier to perform and the results are similar to the double balloon technique[12-17]. However, the balloon is very expensive and this is a problem in developing countries, including Thailand.

Cribier et al developed a new percutaneous mitral valvulotomy device featuring a metallic valvulotome whose principle of action is basically similar to the metallic device (Tubbs dilator) used in the closed mitral commissurotomy procedure[18]. This equipment can be reused several times after sterilization by autoclave without any loss in performance, and thus the cost of the procedure can be reduced.

The aim of the study was to assess the safety, feasibility and immediate results of this new technique in Siriraj Hospital.

METHOD

Patients

From June 2000 to January 2001, 80 patients who were diagnosed with symptomatic, severe mitral stenosis were evaluated for percutaneous mitral valvuloplasty in Siriraj Hospital institute. There were 57 patients with a suitable morphological mitral valve score confirmed by echocardiography was prospectively underwent percutaneous mitral valvuloplasty with a new device, the metallic valvulotome. Exclusion criteria for this procedure included left atrial thrombi, unsuitable valve morphology, mitral regurgitation of Seller's grade >2, inablility to perform transeptal puncture, severe concomitant valvular lesions, severe kyphoscoliosis and bleeding disorders.

Study procedures

Echocardiographic study

All patients underwent transthoracic and transesophageal echocardiography with a Hewlett-Packard 5500 on the day before the procedure. The images were obtained in the standard view to assess left atrial thrombi, left atrial appendage function, interatrial septum, morphological score of the mitral valve, spontaneous echo contrast (SEC), mitral valve area, transmitral valve gradient, degree of mitral regurgitation and other co-existing valvular lesions.

Description of the device

The device system is composed of 4 components namely a metallic dilator, a catheter, a metallic guidewire and activating pliers. The metallic dilator made from stainless steel is a cylinder 5 cm long and 5 mm wide (closed position) as shown in Fig. 1. When it is opened (Fig. 2) the distal half consists of 2 hemicylindrical bars 20 mm in length and its maximal extension approaches 40 mm. The metallic head is screwed onto the end of the catheter whose proximal end is connected to the metallic dilator and activating pliers (Fig. 3). The opening of the metallic dilator is adjusted by a knob on the pliers which are set at 37 and 40 mm. The metallic guidewire (Fig. 4) that is inserted through the central port of the catheter serves as the traction system that allows the dilator to be opened when the arms of the pliers are squeezed.

After the procedure, the metallic dilator can be unscrewed from the catheter and can be reused after sterilization along with the activating pliers and guidewire.

Mitral valvulotomy procedure

Informed consent was obtained and percutaneous metallic mitral valvuloplasty was performed in the fasting state. Warfarin and aspirin were discontinued 7 days before the procedure and the INR value was normal.

After local anesthesia, a 6 and 8 French sheath were placed in the right femoral artery and vein, respectively. Heparin 2500 unit was given immediately. A Swan-Ganz catheter was inserted through the venous vascular sheath and placed in the pulmonary artery in order to measure pressure and cardiac output measurement. A 6 French pigtail catheter was inserted *via* the arterial vascular sheath and positioned in the left ventricle for pressure measurement and left ventriculography.

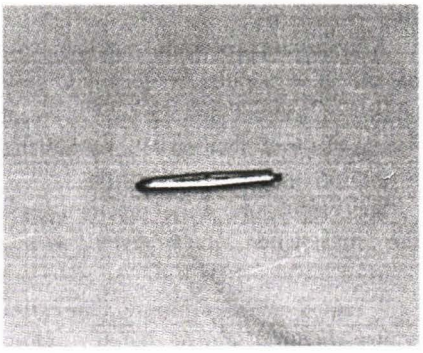

Fig. 1. Metallic valvulotome in closed position.

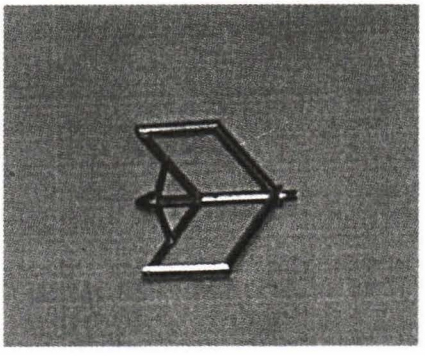

Fig. 2. Metallic valvulotome in open position.

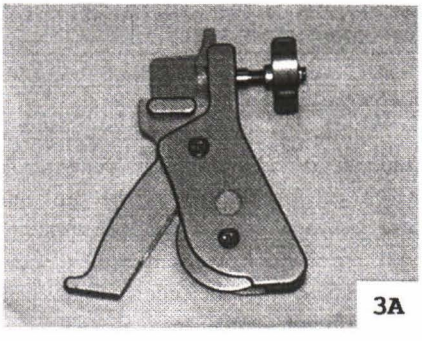

Fig. 3A. Activating pliers.

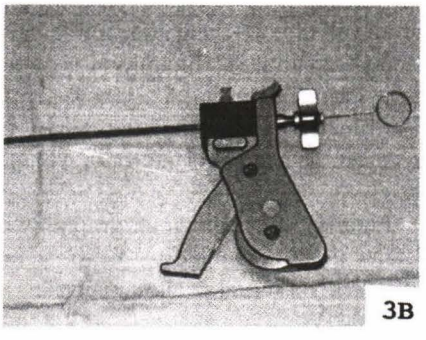

Fig. 3B. Catheter attached to the activating pliers.

Transeptal puncture was performed with the standard technique[19] and the puncture site was located 2 cm below the usual site used in the Inoue technique to provide facilitation of device trackability across the valve. Another of 2,500 units was then administered after successful transeptal puncture. After removing the needle and the dilator, only the Mullin sheath was left in the left atrium and the transmitral valve gradient and mean left atrial pressure were recorded. Subsequently, a floating balloon catheter was inserted through the Mullin sheath and placed at the apex of the left ventricle and the sheath was advanced over it into the left ventricle. The balloon, was then removed and the metallic guidewire was advanced through the sheath into the left ventricle with the metallic head positioned at the mid part of the left ventricle. After that, the Mullin sheath was removed and 14 F and 18 F dilators were used to dilate the interatrial septum respectively. The commissurotome was, then, advanced over the wire until it crossed the mitral valve (Fig. 5A and 5B).

The dilatation procedure was then performed by compressing the arms of the activating pliers. The degree of bar opening was set at 37 mm for the first dilatation if the patient's height was less than 150 cm, and at 40 mm in patients whose height was more than 150 mm by the caliper on the activating pliers. After dilatation, the device was pulled back into the left atrium and the transmitral gradient was measured. Additional dilatation with a larger opening was made if a suboptimal result from the first dilatation was detected by echocardiography or measuring the transmitral gradient.

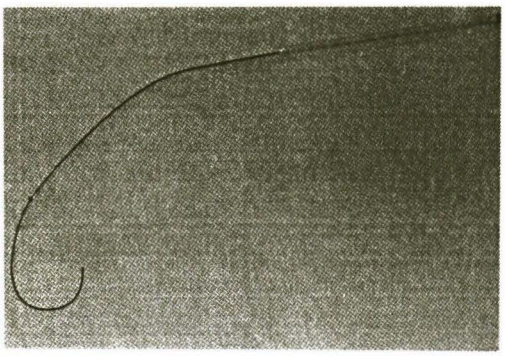

Fig. 4. Metallic guidewire.

The cardiac output was measured pre-and post-mitral valvulotomy and the mitral valve area of pre-and post-mitral valvulotomy was obtained by using the Gorlin Equation. A right heart oximetry saturation run was performed after mitral valvulotomy to detect the degree of left to right shunt at the atrial level.

Finally, left ventriculography was performed after mitral valvulotomy to assess the pressure and severity of mitral regurgitation using Seller's Classification[20].

Definition

A successful procedural outcome was defined as a final mitral valve area, (determined by Gorlin's formulation) of more than 1.5 cm^2 without mitral regurgitation of more than grade 2 by Seller's classification and no major complications.

Successful suboptimal results were accepted when the mitral valve area increased to more than 50 per cent of the pre-dilated mitral valve area without mitral regurgitation of more than grade 2 by Seller's classification and no major complications. An unsuccessful result was considered to have occurred if the mitral valve area was increased less than 50 per cent of the baseline or there was more than Grade 2 of mitral regurgitation by Seller's classification or if any major complications occurred.

Major complications included death, mitral valve replacement, cardiac tamponade and bleeding requiring blood transfusion.

Statistical analysis

Continuous variables are expressed as mean ± SD, and categorical variables as per cent. A paired *t*-test was used for comparison of pre- and post-hemodynamic variables and an independent sample *t*-test was carried out for comparison of continuous variables, respectively. P values ≤0.05 were considered significant.

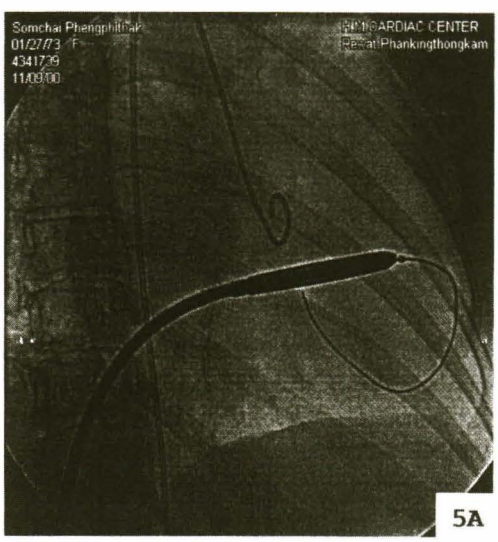

Fig. 5A. Metallic Valvulotome in close position at the level of mitral valve.

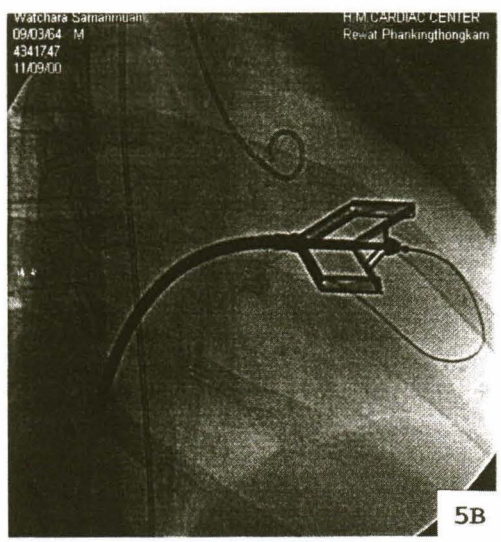

Fig. 5B. Metallic valvulotome in open position at the level of mitral valve.

RESULTS

Among 57 patients in whom a metallic mitral valvuloplasty was attempted, 3 patients failed due to inappropriate position of the septal puncture and they subsequently crossed over to the Inoue technique. In this group of patients, an Inoue balloon valvuloplasty was successfully performed with optimal results. For the group of patients in which metallic mitral valvuloplasty was attempted, detailed demographic data are shown in Table 1. The maximal exent of bar opening was 40 mm in 51 patients (94.4%) and 37 mm in 3 patients (5.6%) and the mean number of dilatations was 3.17 ± 1.69. Metallic mitral valvuloplasty was successfully achieved in 52 patients (96.2%) in whom the procedure was actually performed. The successful optimal and suboptimal results were 62.9 per cent and 33.3 per cent respectively, as shown in Table 2. The valvuloplasty procedure resulted in a significant increase in mitral valve area as shown in Table 3. The mean transmitral gradient and left atrial pressure were also significantly reduced from 14 to 7 mmHg, and 28.83 to 21.81 mmHg respectively. The mean pulmonary artery pressure was also reduced from 40.38 to 35.66 mmHg. The procedural time was 78 minutes on average.

Complications

There were no deaths in our 57 patients underwent the mitral valvuloplasty procedure, but there were 2 cases of hemopericardium which occurred during the procedure. The first resulted from

Table 1. Demographic data.

		%
Number	54	
Age (yr)	41.37 ± 11.35	
Gender		
Male		20.4
Female		79.6
NYHA Functional class		
I		-
II		81.5
III		18.5
IV		-
Previous PBMV		7.4
Previous open mitral commissurotomy		1.9
Rhythms		
Sinus		50
Atrial fibrillation		50
Associated cardiac disease		
MR grade I-II		44.4
AR grade I-II		40.7
Mild to moderate AS		7.4
Substantial coronary disease		-
Mean LV ejection fraction	65.82 ± 28.89	
Associated noncardiac disease		
DM		5.6
HT		7.4
Previous stroke		7.4
Left atrial diameter (mm)	56.5 ± 7.72	
Mitral valve morphologic score		
Mobility	2.06 ± 0.23	
Thickening	2.31 ± 0.51	
Calcification	2.31 ± 0.54	
Subvalvular thickening	2.83 ± 0.54	
Total echocardiographic score	9.5 ± 0.18 (range 8-14)	
Mitral valve Score >8		85.2
Asymmetrical mitral valve opening		16.7
Spontaneous echo contrast (SEC)		92.6

Table 2. Results and complications of Metallic mitral valvuloplasty.

Outcomes	%
Successful outcome	96.2
- Optimal result	62.9
- Suboptimal result	33.3
Failed procedure*	5.3
Complications	3.7
Death	0

* = Calculated from 57 patients

the procedure of transeptal puncture and the patient was successfully managed by pericardiocentesis and subsequently underwent Inoue balloon valvuloplasty with a successful result. In the second case, hemopericardium occurred after a successful result was achieved and was corrected by pericardiocentesis and blood transfusion. The cause of the hemopericardium in the second patient was believed to be associated with a wire-induced left ventricular injury.

Besides the hemopericardium, no other serious complications occurred during hospitalization including myocardial infarction, stroke, emergency mitral valve replacement due to severe mitral regurgitation, and serious bleeding.

The mean magnitude of the left to right shunt at the atrial level created by the transeptal procedure determined by the right heart oximetry saturation was only 1.20.

The overall changes in the degree of mitral regurgitation are shown in Table 4. There were 2 patients who developed grade 3 mitral regurgitation (by Seller's classification) but without clinical heart failure and they were discharged from the hospital the following day. No grade 4 mitral regurgitation was found after the procedure.

DISCUSSION

At present, percutaneous balloon mitral valvuloplasty compared with closed surgical mitral commissurotomy can produce the same beneficial results and is safe but more costly in patients with symptomatic severe rheumatic mitral stenosis[9-11]. The metallic valvutome, a new innovation designed by Cribier et al has been reported in some studies to improve the beneficial effect of the mitral valvuloplasty procedure[21,22]. The present study demonstrated the efficacy of this procedure in 57 patients with severe mitral stenosis. There were only 3 patients in which metallic valvuloplasty failed due to inappropriately high septal puncture. Those in whom metallic valvuloplasty was successfully completed an overall success rate of 96.2 per cent (optimal 62.91% and suboptimal 37%) was achieved with a low incidence of complications. There were only two patients who developed mitral regurgitation by grade III of Seller's classification. The possible mechanism might be related to the asymmetrical calcification at the mitral valve commissure demonstrated by echocardiography before the procedure in both patients. The presence of asymmetrical calcification of commissure was reported associated with the increased incidence of severe mitral regurgitation after the Inoue and Double balloon mitral valvuloplasty[23, 24]. This fact might be true in the case of metallic mitral valvuloplasty as was shown in the present study. However, in the present study, only 9 patients with asymmetrical calcification underwent metallic mitral valvuloplasty and two of them developed mitral regurgitation more than grade III after the procedure. The authors, therefore, need more cases with asymmetrical calcification who underwent this procedure before a conclusion can be made as to whether the mitral stenosis with asymmetrical calcification of the commissure should be performed by

Table 3. Hemodynamic and procedural variables pre and post mitral valvuloplasty.

	Pre	Post	P-value
Mean left atrial pressure (mmHg)	28.83 ± 6.55	21.81 ± 6.52	<0.001
Mean transmitral gradient (mmHg)	14.03 ± 5.86	7.24 ± 2.37	<0.001
Mean pulmonary artery pressure (mmHg)	40.38 ± 11.90	35.66 ± 11.00	<0.001
Mitral valve area (cm^2)	0.91 ± 0.28	1.78 ± 0.59	<0.001
Cardiac output (litres/min/M^2)	3.64 ± 0.84	4.60 ± 1.06	<0.001
Pulmonary vascular resistance (dyne-sec-cm^{-5})	316.57 ± 206.17	259.75 ± 181.38	0.002
System vascular resistance (dyne-sec-cm^{-5})	1,683.81 ± 671.58	1,418.00 ± 429.97	0.005

Table 4. Degree of mitral regurgitation pre- and post- mitral valvuloplasty.

Degree of mitral regurgitation (Seller's classification)	Pre – valvuloplasty %	Post - valvuloplasty %
O	53.7	14.8
I	42.6	57.5
II	3.7	25.9
III	0	1.9
IV	0	0

Table 5. Comparison of the results of metallic and Inoue balloon mitral valvuloplasty.

	Metallic valvuloplasty	Inoue valvuloplasty
N	54	638
Age (yr)	41 ± 12.25	36.91 ± 11.39
Atrial fibrillation (%)	79.6	74.4
Previous commissurotomy (%)	9.3	38.3
Left atrial size (mm)	56.50 ± 7.72	53.59 ± 9.64
Mitral valve morphology		
Total mitral valve score	9.54 ± 1.16*	8.37 ± 1.39*
Mobility	2.06 ± 0.23	1.94 ± 0.41
Thickening	2.50 ± 1.41*	2.12 ± 0.47*
Subvalvular thickening	3.39 ± 4.14*	2.29 ± 0.53*
Calcification	2.31 ± 0.54*	2.00 ± 0.59*
Asymmetrical opening (%)	16.7*	0*
Hemodynamic data		
Mean PA (mmHg)	40.38 ± 11.99	36.93
Mean LA (mmHg)	28.83 ± 6.55	25.48
Mean gradient (LA-LV) (mmHg)	14.03 ± 5.86	14.96
Cardiac output (litres/min/M^2)	3.64 ± 0.84	3.66
Mitral valve area (cm^2)	0.91 ± 0.28	0.79
Result		
Successful outcome		
Optimal result (%)	62.90*	48.3*
Suboptimal result (%)	33.3*	51.7*
Failed procedure (%)++	5.3*	0.47*
Complications (%)	3.7	4.2
Death (%)	0	0

NB : * = $P < 0.05$
++ = Calculated from 57 patients

the metallic valvulotome. When comparing the present study with previous Siriraj data using the Inoue balloon technique[25], it was noted that despite a worse mitral valve morphological score, the hemodynamic profile of metallic valvuloplasty was better and the complications were also fewer as shown in Table 5. However, there was limitation for this comparison due to many factors such as the different time of the procedure, the number of patients and experience of the operators which could probably explain the higher incidence of failed procedure in the metallic valvuloplasty as shown in Table 5.

In addition, when the result of the metallic valvuloplasty in the groups that had a mitral valve morphological score >8 and ≤8 were carefully analysed, it was observed that the group with score ≤8 had better results (Table 6). This observation was similar to other studies using Inoue or Double balloon

Table 6. Comparison of hemodynamic variables post mitral valvuloplasty between patients with mitral valve scores ≤ 8 and > 8.

	Mitral valve score ≤8 (N=8)	Mitral valve score >8 (N=46)	P-value
Mean Left atrial pressure (mmHg)	20.50 ± 8.50	22.04 ± 6.20	0.54
Mean transmitral gradient (mmHg)	6.50 ± 3.25	7.37 ± 2.21	0.34
Mean pulmonary artery pressure (mmHg)	27.75 ± 5.39	37.04 ± 11.18	0.06
Mitral valve area (cm^2)	2.17 ± 0.70	1.71 ± 0.55	0.04
Cardiac output (litre/min/M^2)	4.89 ± 1.04	4.55 ± 1.07	0.40
Pulmonary vascular resistance (dyne - sec - cm^{-5})	156.36 ± 91.76	278.13 ± 187.76	0.07
Systemic vascular resistance (dyne - sec - cm^{-5})	1,542.77 ± 601.26	1,396.92 ± 397.14	0.21

Table 7. Baseline characteristics and hemodynamic variables pre- and post- mitral valvuloplasty in the present study, Cribier study and the Inoue technique study at Siriraj Hospital.

Variable	Present Study		Cribier et al[19]		Inoue Technique Siriraj Study[21]	
N	54		153		638	
Age (yr)	41.37 ± 11.35		36 ± 15		36.91 ± 11.39	
No of Women (%)	79.6		64		74.40	
NYHA Fc, n (%)						
I - II	81.5		52		81.69	
III - IV	18.5		48		18.02	
AF (%)	50		22		38.3	
Previous commissurotomy (%)	9.25		16		2	
Echo score (mean)	9.5 ± 0.18		7.4 ± 2.3		8.37 ± 1.39	
LA diameter (mm)	56.5 ± 7.72		47 ± 8		53.59 ± 9.64	
Mitral valve area (cm^2)	0.91 ± 0.28**		0.95 ± 0.21*		0.79**	
	Pre	Post	Pre	Post	Pre	Post
Mean Left atrial pressure (mmHg)	28.83 ± 6.55	21.81 ± 6.52	26 ± 9	12 ± 7	25.48	17.39
Mean transmitral gradient (mmHg)	14.03 ± 5.86	7.24 ± 2.37	19.6 ± 8.9	3.7 ± 3.8	14.96	6.11
Mean pulmonary artery pressure (mmHg)	40.38 ± 11.90	35.66 ± 11.00	56 ± 24	39 ± 17	36.93	31.64
Mitral valve area (cm^2)	0.91 ± 0.28**(a)	1.78 ± 0.59**(b)	0.95 ± 0.21**(c)	2.16 ± 0.37*(d)	0.79(e)	1.59(f)

* = Measured by planimetry from echocardiography
** = Measured by Gorlin's formula
P = 0.27; (a) compared with (c)
P < 0.0001; (b) compared with (d)
P = 0.002; (a) compared with (e)
P = 0.021; (b) compared with (f)

technique that demonstrated poor immediate results and an increased incidence of restenosis in patients with a mitral valve score (Wilkins score[26]) of more than 8[27-29]. Because the mechanism of the metallic valvulotome to enlarge the mitral valve area was commissural splitting and fracturing of nodular deposits, therefore, in cases of severe mitral valve score which had more restricted valvular mobility caused by valve fibrosis or severe subvalvular disease, the ability of the metallic valvulotome to enlarge the mitral valve area was less.

However, the hemodynamic profile, procedural variables and successful outcome of the present study were not as good as the study of Cribier et al,[21] who developed this equipment. (Table 7). One reason might be related partly to the difference

in the number and baseline characteristics of the study population. The patients in the present study had more severe mitral valve scores, larger left atrium and were older, whereas, the patients in the study of Cribier et al[18] had more history of previous commissurotomy and mean pulmonary artery pressure but the mitral valve area was comparable. However, the method for assessing the severity of mitral valve area was different. Gorlin's formula, which is more accurate to assess the mitral valve area was used in the present study but planimetry from echocardiography was used in the study of Cribier et al[18]. The other factor leading to the different outcome between these two studies might be due to the authors' limited experience with the procedure.

Finally, when the cost of metallic mitral valvuloplasty was compared with the Inoue technique, it was noted that mitral valvuloplasty by the metallic valvulotome can reduce the cost by 3 times.

Limitations of the study

The authors' experience with the metallic valvulotome is limited as this device has just begun in Siriraj Hospital, therefore, the series is small. More experience is needed before conducting a clinical trial comparing the effectiveness of metallic valvulotome and the Inoue balloon valvuloplasty in patients with severe mitral stenosis especially in cases of severe mitral valve score (mitral valve score $\geq$10) or asymmetrical calcification of the mitral commissure.

SUMMARY

The present study demonstrated that metallic mitral valvuloplasty is a safe and effective procedure to treat rheumatic mitral stenosis with few complications. Because this device is reusuable, it is probably more cost-effective when compared with the Inoue technique.

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การขยายลิ้นหัวใจไมตรัลตีบด้วยสายสวนหัวใจชนิดโลหะ

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โรคลิ้นหัวใจไมตรัลตีบยังคงเป็นปัญหาที่สำคัญในประเทศไทย และทำให้ผู้ป่วยมีอันตรายถึงชีวิตได้ การรักษาโรคนี้ในปัจจุบันได้มีการพัฒนาไปมากเมื่อเทียบกับในอดีต การรักษาด้วยวิธีการผ่าตัดซ่อมหรือเปลี่ยนลิ้นหัวใจรวมทั้งการขยายลิ้นหัวใจไมตรัลด้วยบอลลูนนับเป็นวิธีมาตรฐานที่ใช้ในการรักษาโรคนี้ในปัจจุบัน อย่างไรก็ตามค่าใช้จ่ายในการรักษายังคงมีราคาแพง โดยเฉพาะวิธีการรักษาด้วยบอลลูน ผู้วิจัยจึงได้ศึกษาสายสวนหัวใจชนิดใหม่ที่ทำจากโลหะสเตนเลส (Metallic valvulotome) มาใช้ในการขยายลิ้นหัวใจไมตรัลในผู้ป่วย 57 ราย พบว่าสามารถขยายได้ผลสำเร็จถึง 96.2% มีผู้ป่วย 3 รายที่ไม่สามารถทำการขยายลิ้นหัวใจไมตรัลได้เนื่องจากตำแหน่งที่เจาะผนังหัวใจห้องบนสูงเกินไป ภาวะแทรกซ้อนรุนแรงที่เกิดขึ้นมีน้อย กล่าวคือ มี cardiac tamponade 2 รายซึ่งสามารถแก้ไขได้โดยไม่ต้องส่งผู้ป่วยไปผ่าตัด และจากการศึกษานี้ไม่มีผู้ป่วยรายใดเสียชีวิต นอกจากนั้นอุปกรณ์ชนิดนี้สามารถนำกลับมาใช้ได้ใหม่ หลังจากผ่านขบวนการทำความสะอาดและปลอดเชื้อทำให้สามารถลดค่าใช้จ่ายที่เกิดขึ้นในการรักษาผู้ป่วยลิ้นหัวใจไมตรัลตีบได้

คำสำคัญ : ลิ้นหัวใจไมตรัล, การขยายลิ้นหัวใจ, สายสวนหัวใจ

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