

## Results of percutaneous balloon pulmonary valvuloplasty in pediatric valvular pulmonary stenosis

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- Objective** : *To review the results of percutaneous balloon pulmonary valvuloplasty (PBPV) in pediatric patients with moderate or severe valvular pulmonary stenosis (PS).*
- Setting** : *Division of Pediatric Cardiology, Department of Pediatrics, Faculty of Medicine, Chulalongkorn University*
- Research design** : *Retrospective study*
- Patients and Method** : *Between June 1995 and September 1998, PBPV was performed successfully in 20 of 22 cases of moderate or severe PS. Of the 20 successful cases, there were 10 females and 10 males. The mean age was  $6.5 \pm 5.2$  years (ranged from 10 months to 16 years). The mean weight was  $21.2 \pm 13.6$  kg (ranged from 6.3 to 45 kg)*
- Results** : *Immediately after PBPV, there was significant regression of the systolic pressure gradient across the pulmonary valve from  $89.15 \pm 36.37$  to  $26.75 \pm 14.79$  mm Hg ( $p < 0.001$ ) and the right ventricula*

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*systolic pressure from  $110.50 \pm 34.70$  to  $51.90 \pm 13.12$  mm Hg ( $p < 0.001$ ). There was a major complication in one patient who developed right hemiparesis from cerebral emboli after the procedure.*

**Conclusions** : *PBPV is effective in the relief of obstruction secondary to valvular PS. It provides successful and good results in cases of typical valvular PS with the use of an appropriate balloon catheter.*

**Key words** : *Percutaneous balloon pulmonary valvuloplasty, Valvular pulmonary stenosis.*

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พรเทพ เลิศทรัพย์เจริญ, ไพโรจน์ โชติวิทย์ธรรมากร, วิชัย เบญจชลมาศ, จุล ทิษยากร, โชติมา ปัทมานันท์, วิโรจน์ สีบลินวงศ์. ผลของการรักษาโรคลิ้นหัวใจ pulmonary ตีบโดยการขยายด้วยลูกโป่งในเด็ก. จุฬาลงกรณ์เวชสาร 2542 ก.พ; 43(2): 89-97

- วัตถุประสงค์** : เพื่อศึกษาถึงผลของการรักษาโรคลิ้นหัวใจ pulmonary ตีบโดยการขยายด้วยลูกโป่งในผู้ป่วยเด็กที่เป็นโรคลิ้นหัวใจ pulmonary ตีบชั้นปานกลางและชั้นรุนแรง
- สถานที่ที่ทำการศึกษา**: หน่วยโรคหัวใจเด็ก ภาควิชากุมารเวชศาสตร์ คณะแพทยศาสตร์ จุฬาลงกรณ์มหาวิทยาลัย
- รูปแบบการวิจัย** : การศึกษาย้อนหลัง
- วัสดุและวิธีการ** : ระหว่างเดือนมิถุนายน พ.ศ. 2538 ถึงเดือนกันยายน พ.ศ. 2541 ได้ทำการรักษาผู้ป่วยเด็กโรคลิ้นหัวใจ pulmonary ตีบจำนวน 22 ราย โดยการขยายด้วยลูกโป่ง ผู้ป่วยจำนวน 20 ราย ได้รับการขยายลิ้นหัวใจ pulmonary ด้วยลูกโป่งเป็นผลสำเร็จในจำนวนนี้เป็นหญิง 10 ราย และชาย 10 ราย อายุตั้งแต่ 10 เดือน ถึง 16 ปี (เฉลี่ย  $6.5 \pm 5.2$  ปี) น้ำหนักตั้งแต่ 6.3 ถึง 45 กิโลกรัม (เฉลี่ย  $21.2 \pm 13.6$  กิโลกรัม)
- ผลการศึกษา** : หลังการขยายลิ้น pulmonary ด้วยลูกโป่ง พบว่ามีการลดลงอย่างมีนัยสำคัญของค่าความแตกต่างของแรงดัน systole ระหว่างเวนทริเคิลขวา กับเส้นเลือด pulmonary จาก  $89.15 \pm 36.37$  เหลือ  $26.75 \pm 14.79$  มิลลิเมตรปรอท ( $p < 0.001$ ) และค่าแรงดัน systole ของเวนทริเคิลขวา จาก  $110.50 \pm 34.70$  เหลือ  $51.90 \pm 13.12$  มิลลิเมตรปรอท ( $p < 0.001$ ) ผู้ป่วย 1 ราย มีผลแทรกซ้อนจากการรักษาคือ มีอาการอ่อนแรงซีกขวา (right hemiparesis) จาก cerebral emboli.
- สรุป** : การรักษาลิ้นหัวใจ pulmonary ตีบโดยการขยายด้วยลูกโป่งสามารถลดการตีบของทางออกของหัวใจห้องขวาได้ ปัจจัยที่ทำให้การรักษาได้ผลดีคือ โรคลิ้นหัวใจชนิด typical valvular stenosis. และการเลือกใช้ balloon catheter ที่เหมาะสมในการขยายลิ้นที่ตีบ

Pulmonary valvular stenosis (PS) occurs in 8 to 10% of patients with congenital heart diseases.<sup>(1)</sup> Mild PS has a benign course and does not require treatment.<sup>(1-2)</sup> Relief of obstruction is recommended in moderate to severe PS with systolic pressure gradients across the pulmonary valve (PS gradient) greater than 50 mm Hg.<sup>(2)</sup> In the past, surgical valvotomy had been the only available treatment for PS. After Kan's first report of successful percutaneous balloon pulmonary valvuloplasty (PBPV) in 1982,<sup>(3)</sup> there have been other reports of successful treatment of PS using the PBPV technique.<sup>(4-10)</sup> This report describes the results in our 22 cases of PS who were admitted for PBPV to the department of Pediatrics, Chulalongkorn University after April 1995, the time of opening of the new Cardiac Catheterization Laboratory in the Cardiac Center of the H.M. Queen Sirikit Building, King Chulalongkorn Memorial Hospital.

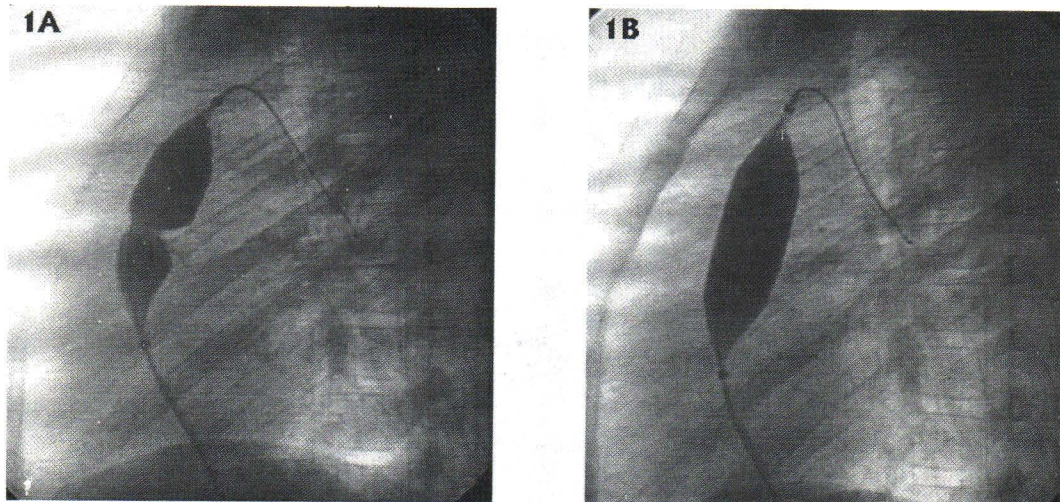
### Patients and Methods

Between June 1995 and September 1998, PBPV was attempted in 22 patients who were diagnosed to have moderate or severe PS. The procedure could not be successfully performed in 2 male patients with severe PS (aged 5 days and 8 months; weights of, 3 kg and 6 kg, respectively) because of an inability to advance the balloon dilation catheter across the pulmonary valve. Both of these patients had successful surgical valvulotomy within 1 week after the failed PBPV. The remaining 20 patients comprised 10 females and 10 males. Patients' age at the time of the PBPV ranged from 10 months to 16 years with a mean age of  $6.5 \pm 5.2$  years. Patients' weights ranged from 6.3 to 45 kg, with a mean weight of  $21.2 \pm 13.6$  kg.

Prior to PBPV, two-dimensional echocardiography was performed to diagnose PS and other associated cardiac lesions and to evaluate the pulmonary valve anatomy. Doppler echocardiography was performed to estimate the PS gradient before PBPV for assessing the severity of the PS and after PBPV for evaluating the results. The doppler estimation of PS gradient was calculated by applying a modified Bernoulli equation to the maximum systolic peak flow velocity (Vmax) recording from the right ventricular (RV) outflow tract proximal to the pulmonary valve using continuous wave Doppler.<sup>(11)</sup> The equation is stated as:  $PS \text{ gradient} = 4 \times (Vmax)^2$

**Technique of PBPV:** After initial hemodynamic assessment, a right ventriculogram was performed. The pulmonary valve annulus was measured at the hinge points of the valve from the lateral right ventriculogram. The balloon catheter was advanced over an exchange guide-wire that had previously been positioned in the distal left or right pulmonary artery. An oversized balloon with a balloon diameter ratio of 1 to 1.5 to the pulmonary annulus was used.<sup>(7)</sup> Once the balloon had been centered across the pulmonary valve, it was inflated rapidly by hand until the waist on the balloon disappeared (figure 1), and then deflated. If the pulmonary annulus was more than 20 mm, two balloon catheters were used simultaneously.<sup>(8)</sup> Yeager's formula was used to calculate the effective combined diameter of the two balloons.<sup>(12)</sup> Repeated inflation was performed until no waist appeared during balloon inflation. PS gradient and RV systolic pressure were measured immediately after PBPV to evaluate the result.

Our last three cases were small infants (weights of 7.3, 6.3 and 8.4 kg, respectively) who had



**Figure 1.** PBPV during balloon inflation. 1A) The balloon catheter across the pulmonary valve in the early phase of inflation. The balloon was indented by the stenotic valve. 1B) The balloon was fully inflated until the waist of the balloon disappeared.

severe PS. Two of the 3 cases had cyanosis at rest in room air. We performed successful PBPV in all 3 cases by means of using small balloon catheters (3 mm in balloon diameter) for the initial dilation, followed by oversized balloon catheters for subsequent dilations.

**Statistical analysis:** The continuous data are presented as mean  $\pm$  SD. The PS gradient and RV systolic pressures before and after PBPV are compared by using the Student t-test for paired samples. P values less than 0.05 were considered significant.

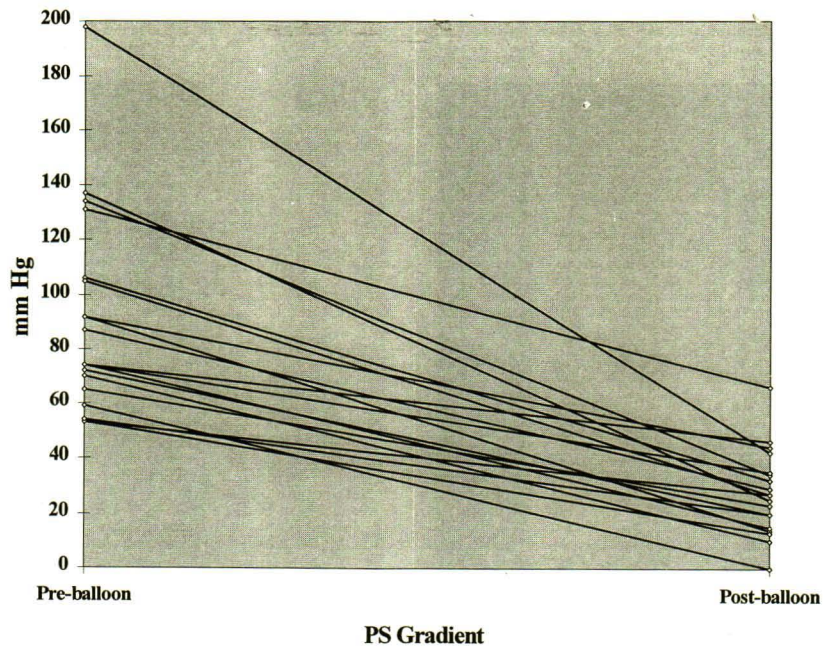
## Results

Of the 20 patients, who underwent successful PBPV, there were 12 cases of severe PS (PS gradients greater than 80 mm Hg) and 8 cases of moderate PS (PS gradients greater than 35 but less than 80 mm Hg).<sup>(1)</sup> One patient with moderate PS also had a small patent ductus arteriosus (minimal diameter of 1.8 mm) which was occluded in the same setting by the coil embolization technique using one Gianturco steel coil.

Among the 12 severe PS cases, there were 3 cases who had cyanosis at rest in room air (percutaneous oxygen saturation around 70%) due to right to left shunt via patent foramen ovale.

The mean PS gradient before PBPV, measured by Doppler echocardiography, was  $94.55 \pm 24.20$  mm Hg (ranged from 60 to 164 mm Hg) and that measured in cardiac catheterization before PBPV was  $89.15 \pm 36.37$  mm Hg (ranged from 53 to 198 mm Hg). There was no significant difference in PS gradients before PBPV measured by both methods ( $p = 0.12$ ).

A single-balloon valvuloplasty procedure was performed in 15 cases and a double-balloon procedure in 5 cases. The ratio of the balloon diameter to the pulmonary valve annulus was  $1.24 \pm 0.12$ , ranging from 1 to 1.5. The PS gradient reduced immediately after PBPV from  $89.15 \pm 36.37$  mm Hg (ranges of from 53 to 198 mm Hg) to  $26.75 \pm 14.79$  mm Hg (ranges of from 0 to 66 mm Hg) ( $p < 0.001$ ) as shown in figure 2. Similarly, the RV systolic pressure reduced from

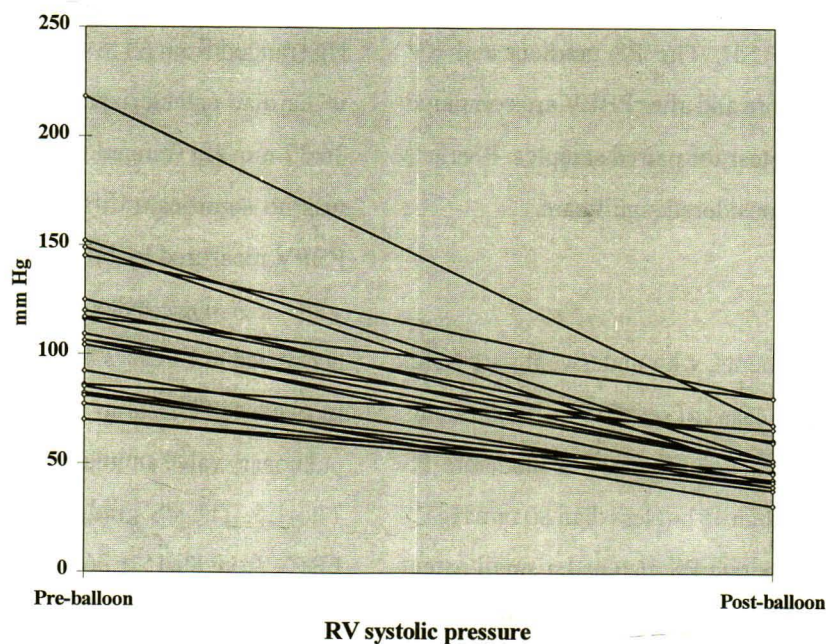


**Figure 2.** PS gradient measured during cardiac catheterization before (pre-balloon) and immediately after (post-balloon) PBPV.

$110.50 \pm 34.70$  mm Hg (ranges of from 70 to 218 mm Hg) to  $51.90 \pm 13.12$  mm Hg (ranges of from 31 to 80 mm Hg) ( $p < 0.001$ ) as shown in figure 3.

There were 4 patients who still had PS gradients greater than 36 mm Hg, measured by both

cardiac catheterization immediately after PBPV and Doppler echocardiography within 24 hours after PBPV. However, the PS gradient measured by Doppler echocardiography declined to less than 36 mm Hg within 12-month follow - up in all 4 cases. For the 3



**Figure 3.** RV systolic pressure measured during cardiac catheterization before (pre-balloon) and immediately after (post-balloon) PBPV.

cases who had cyanosis before PBPV, the oxygen saturation increased to low 90% in 2 cases within 3 days after PBPV and in all 3 cases within 3 months after treatment.

One patient (a one year old girl) had major complications after the procedure. She developed a high fever with convulsions two hours after PBPV. A neurological examination revealed right hemiparesis. A CT scan performed six hours after PBPV suggested embolic cerebral infarction of the left middle cerebral artery. The other patients had no significant complications.

## Discussion

Patients with mild PS usually continue to have mild PS (PS gradient less than 35 mm Hg), and usually without progression, although occasionally the stenosis has been known to progress. In patients with moderate to severe PS, the obstruction has a tendency to progress. Patients who have PS gradients greater than 50 mm Hg are candidates for either surgical or balloon pulmonary valvuloplasty.<sup>(2)</sup> Nowadays, PBPV remains the treatment of choice for typical valvular PS. Several reports have shown that PBPV is effective in reducing the degree of right ventricular outflow obstruction.

<sup>(3-10,13-14)</sup> The results of PBPV are as effective as surgical valvulotomy but with less valvular pulmonary insufficiency and less late ventricular ectopic activity.<sup>(13)</sup>

Because the patient who had mild PS (PS gradient less than 35 mm Hg) need no further intervention, we use a cut-point of residual PS gradient less than 36 mm Hg or the Doppler peak systolic flow across the pulmonary valve of less than 3 m/sec to be the criterion for successful result. All of the 20 patients who underwent PBPV had a significant reduction of

RV systolic pressures and PS gradients after the procedure. We had 16 of the 20 cases (75%) who had PS gradients less than 36 mm Hg immediately after PBPV, comparable to 74% from the results of the Valvuloplasty and Angioplasty of Congenital Anomalies Registry.<sup>(10)</sup> Our 4 cases who had residual PS greater than 36 mm Hg may be explained by the development of subvalvular or infundibular obstruction immediately after the procedure, same as that mentioned in the previous reports.<sup>(14-15)</sup> However there was a regression of the PS gradient to less than 36 mm Hg in those 4 cases within a one year follow -up as measured by Doppler echocardiography. This decrease reflected resolution of the infundibular component to outflow obstruction.<sup>(14-15)</sup>

Regarding the two failed cases where the balloon catheter could not be passed across the valve orifice, the reasons for the failure may be due to 1) tiny valve orifice in both cases, or 2) lack of low profile and smaller balloon catheter. The last three cases who were small infants (weights of 6.3-8.4 kg) with severe PS, had successful outcomes by means of using small balloon catheters for the initial dilation, followed by oversized balloon catheters for subsequent dilations.

The factors that provide successful and good results in our cases are 1) we used oversized balloons, with the mean balloon diameter to the pulmonary valve annulus ratio of  $1.24 \pm 0.12$  (ranged from 1.0 to 1.5), 2) there was no dysplastic valvular PS in our cases. 3) we used low profile and small balloon catheter for the initial dilation followed by oversized balloon in subsequent dilation, in case of severe PS with tiny valve orifice, and 4) we used double-balloon technique to provide adequate balloon size in case of pulmonary annulus larger than 20 mm.

Major complications (cerebral emboli) occurred in one patient. The patient had severe PS without cyanosis. Only a right heart catheterization was performed in this case. How the patient had cerebral emboli could not be clearly explained. This patient was lost to follow-up after discharge. But telephone contact (two years after the procedure), with her parents indicated that she was doing well but had a neurological sequel of mild weakness of the right upper extremity.

### Conclusions

PBPV is effective for the relief of obstruction secondary to valvular PS. It provides successful and good results in cases of typical valvular PS with the use of appropriate balloon catheter

### References

1. Rocchini AP, Emmanouilides GC. Pulmonary stenosis. In: Emmanouilides GC, Riemenschneider TA, Allen HD, Gutgesell HP, eds. Moss and Adams: Heart Disease in Infants, Children, and Adolescents Including the Fetus and Young Adult. 5<sup>th</sup> ed. Baltimore: Williams & Wilkins, 1995: 930-61
2. Hayes CJ, Gersony WM, Driscoll DJ, Keane JF, Kidd L, O'Fallon M, Pieroni DR, Wolfe RR, Weidman WH. Second natural history study of congenital heart defects: results of treatment of patients with pulmonary valvar stenosis. *Circulation* 1993 Feb; 87(2 Suppl 1): I28-I37
3. Kan JS, White RI Jr, Mitchell SE, Gardner TJ. Percutaneous balloon valvuloplasty: a new method for treating congenital pulmonary valve stenosis. *N Engl J Med* 1982 Aug 26; 307(9): 540-2
4. Lababidi Z, Wu JR. Percutaneous balloon pulmonary valvuloplasty. *Am J Cardiol* 1983 Sep; 52(5): 560-2
5. Kan JS, White RI Jr, Mitchell SE, Anderson JH, Gardner TJ. Percutaneous balloon valvuloplasty for pulmonary valve stenosis. *Circulation* 1984 Mar; 69(3): 554-60
6. Kveselis DA, Rocchini AP, Snider AR, Rosenthal A, Crowley DC, Dick M. Results of balloon valvuloplasty in the treatment of congenital valvar pulmonary stenosis in children. *Am J Cardiol* 1985 Sep; 56(8): 527-32
7. Radtke W, Keane JF, Fellows KE, Lang P, Lock JE. Percutaneous balloon valvulotomy of congenital pulmonary stenosis using oversized balloons. *J Am Coll Cardiol* 1986 Oct; 8(4): 909-15
8. Ali Khan MA, Yousef SA, Mullins CE. Percutaneous transluminal balloon pulmonary valvuloplasty for the relief of pulmonary valve stenosis with special reference to double-balloon technique. *Am Heart J* 1986 Jul; 112(1): 158-66
9. Stanger P, Cassidy SC, Girod DA, Kan JS, Lababidi Z, Shapiro SR. Balloon pulmonary valvuloplasty: results of the Valvuloplasty and Angioplasty of Congenital Anomalies Registry. *Am J Cardiol* 1990 Mar 15; 65(11): 775-83
10. McCrindle BW. Independent predictors of long-term results after balloon pulmonary valvuloplasty. *Circulation* 1994 Apr; 89(4):1751-9.
11. Lima CO, Sahn DJ, Valdes-Cruz LM, Golberg SJ, Barron JV, Allen HD, Grenadier E. Noninvasive prediction of transvalvular pressure gradient in patients with pulmonary



- stenosis by quantitative two-dimensional echocardiographic Doppler studies. *Circulation* 1983 Apr; 67 (4): 866-71
12. Yeager SB. Balloon selection for double balloon valvulotomy. *J Am Coll Cardiol* 1987 Feb; 9 (2): 467-8
13. O'Connor BK, Beekman RH, Lindauer A, Rocchini A. Intermediate-term outcome after pulmonary balloon valvuloplasty: comparison with a matched surgical control group. *J Am Coll Cardiol* 1992 Jul; 20(1): 169-73
14. Ben-Shachar G, Cohen MH, Sivakoff MC, Portman MA, Riemenschneider TA, Van Heeckeren DW. Development of infundibular obstruction after percutaneous pulmonary balloon valvuloplasty. *J Am Coll Cardiol* 1985 Mar; 5(3): 754-6
15. Thapar MK, Rao PS. Significance of infundibular obstruction following balloon valvuloplasty for valvar pulmonic stenosis. *Am Heart J* 1989 Jul; 118(1): 99-103