Factors Determining Immediate and Medium-Term Results after Pulmonary Balloon Valvuloplasty

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Objective: *To determine factors influencing immediate and medium-term results of Pulmonary Balloon Valvuloplasty (PBV) for pulmonary valve stenosis.*
Material and Method: *Between 1995 and 2001, the authors carried out PBV in 25 consecutive patients. Two treatment outcomes including immediate and medium-term results were analyzed. The immediate results were classified into two groups based on the pulmonary systolic pressure gradient (PG) immediately after dilation: group I with a PG ≤ 35 mmHg and group II with a PG > 35 mmHg. At medium-term follow-up of 6 to 60 months, echocardiographic evaluations were analyzed and divided into two groups: group A with a PG ≤ 25 mmHg and group B with a PG > 25 mmHg. Demographic characteristics and hemodynamic parameters of immediate and medium-term results were compared and analyzed.*
Results: *Immediately after PBV, the right ventricular systolic pressure (RVSP) decreased from 115.3 37.6 mmHg to 67.0 28.5 mmHg (p < 0.001). The pulmonary systolic pressure gradient decreased from 90.4 37.9 mmHg to 39.3 25.6 mmHg (p < 0.001). Nine of the 25 patients (group II; 36%), with incomplete immediate relief of the obstruction, had more symptoms, a higher baseline PG, higher right atrial pressure, higher RVSP, and a higher systolic pressure ratio. Six of the 25 patients (group B; 24%), with suboptimal medium-term results, had a higher right ventricular voltage on the electrocardiogram, higher pre-dilation PG, and higher RVSP.*
Conclusion: *Successful medium-term outcomes following pulmonary balloon valvuloplasty were achieved in 76% of the patients, with a greater success rate (91%) in patients with a lower right ventricular voltage electrocardiogram (R wave amplitude in V_1) ≤ 21 mm, a prevalvuloplasty systolic gradient ≤ 90 mmHg, and right ventricular systolic pressure ≤ 125 mmHg.*

Keywords: *Pulmonary valve stenosis, Valvuloplasty, Outcome*

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Isolated pulmonary valve stenosis (PS) accounts for approximately 10% of congenital heart disease in children[1,2]. Pulmonary balloon valvuloplasty (PBV) is now the treatment of choice for patients with PS[1-11]. It is a safe and effective procedure for the relief of moderate to severe pulmonary stenosis in neonates, infants, and children. While previous studies focused on intermediate and long-term results, more recent studies emphasized the factors determining the outcomes after PBV. The purpose of the present study was to determine which factors had an impact on the immediate and medium-term results of PBV in patients with pulmonary valve stenosis.

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Material and Method

Between 1995 and 2001, the authors carried out PBV in 25 consecutive patients with simple PS at

Chiang Mai University Hospital. Diagnosis was made by 2D and color doppler echocardiography. Patients with a pressure gradient > 50 mmHg were selected for PBV. Electrocardiographic findings were evaluated. The height of the R wave in V_1 was carefully measured in all cases. Hemodynamic and angiographic parameters were determined immediately before PBV. Moderate and severe PS were defined as a pressure gradient across the pulmonary valve greater than 40 mmHg and 80 mmHg, respectively[1]. Hemodynamic assessment of the right ventricle to the pulmonary artery peak systolic gradient, and grading of pulmonary regurgitation, was determined by catheterization immediately after PBV. Echocardiographic results were taken from the most recent examinations. Continuous-wave doppler echocardiographic measurement of the pressure gradient was calculated by the Bernoulli equation. Color Doppler echocardiographic assessment of pulmonary regurgitation was graded subjectively as trivial, mild, moderate, or severe. Two treatment outcomes were analyzed as immediate and medium-term results. The immediate results were classified into two groups based on the pulmonary systolic pressure gradient (PG) immediately after dilation: group I with a PG $\leq$ 35 mmHg and group II with a PG > 35 mmHg. According to previous studies[5,17], the residual pressure gradient > 35 mmHg was chosen as indicative of incomplete relief of obstruction. Echocardiographic evaluation with a mean follow-up interval of 17.5 $\pm$ 19.4 months (minimum 6 months) following PBV was analyzed for the medium-term results and divided into two groups: group A with a PG $\leq$ 25 mmHg and group B with a PG > 25 mmHg. The follow-up residual gradient > 25 mmHg was defined as a suboptimal medium-term outcome[21]. Demographic characteristics and hemodynamic parameters of patients with a successful outcome were compared to those with suboptimal outcome in both immediate and medium-term results.

Statistics

Data were expressed as mean $\pm$ SD and 95% Confidence Interval (CI). The variables between the two groups were compared by using the unpaired t test, and the Mann-Whitney U test as appropriate. The level of statistical significance was set at $p < 0.05$.

Results

Of the 25 patients, 14 were males and 11 females. Their ages ranged from 1 year to 14 years with a mean age of 6.2 years. Sixteen patients (64%) were asymptomatic. Five patients (20%) with cyanosis were more likely to be younger and have more severe obstruction than other symptomatic patients, who presented with diminished exercise tolerance. Associated heart lesions were small atrial septal defect in six patients (24%), and small patent ductus arteriosus (PDA) in one patient (4%). Coil embolization was also performed in a patient with PDA. Eighteen patients (72%) had severe PS. The mean pulmonary valve diameter, measured from the cineangiogram, was 15.4 $\pm$ 3.8 mm. The mean ratio of balloon to pulmonary valve diameter was 1.19 $\pm$ 0.11. Immediately after PBV, right ventricular systolic pressure decreased from 115.3 $\pm$ 37.6 mmHg to 67.0 $\pm$ 28.5 mmHg ($p < 0.001$) while the right ventricular/aortic systolic pressure decreased from 0.96 $\pm$ 0.26 to 0.56 $\pm$ 0.17 ($p < 0.001$). The pulmonary systolic pressure gradient decreased from 90.4 $\pm$ 37.9 mmHg to 39.3 $\pm$ 25.6 mmHg ($p < 0.001$). Incomplete immediate relief of obstruction with a residual gradient > 35 mmHg was noted in nine patients (group II). Demographic characteristics and hemodynamic data of patients who had optimal and suboptimal immediate result were compared in Table 1. Patients with a suboptimal immediate outcome had significantly greater symptoms, higher pre-dilation PG, higher baseline right atrial pressure, higher baseline right ventricular systolic pressure, and higher baseline right ventricular/aortic systolic pressure ratio. The suboptimal immediate result was significantly associated with a residual pressure gradient at the infundibular level. As shown in Table 2, the suboptimal medium-term result with a residual gradient > 25 mmHg was noted in six patients (group B). They had significantly higher Right Ventricular (RV) voltage on the electrocardiogram (R wave amplitude in V_1), a higher pre-dilation PG, and higher baseline RVSP (Fig. 1-3). Five out of six patients with suboptimal medium-term outcome had incomplete immediate relief of obstruction after PBV (Fig. 4). Ten of the eleven patients (91%) who had an R wave amplitude in $V_1 \leq 21$ mm, a prevalvuloplasty systolic gradient $\leq$ 90 mmHg, and RVSP $\leq$ 125 mmHg had an optimal medium-term result. Pulmonary regurgitation was trivial or mild, as documented by color doppler echocardiography upon follow-up in 64% of patients. There was no statistical difference between the two groups. Three patients (12%) had moderate pulmonary regurgitation. Transient cerebral thrombosis with left hemiparesis was noted in one patient with recovery 3 months later. Other transient complications occurred in two patients were an episode of tonic seizure and brief apnea, secondary to hypoxia.

Table 1. Demographic characteristics and hemodynamic data at immediate term

Variables	Group I (PG ≤ 35 mmHg) (N = 16)	Group II (PG > 35 mmHg) (N = 9)	p-value
Male (N)	10	4	NS
Symptoms (N)	3	6	0.03
Patient age (year), mean ± SD	5.6±3.4	7.2±4.9	NS
R wave amplitude in V_1 (mm)	16.9±7.3	21.1±9.1	NS
Pre-PBV PG (mmHg)	69.3±24.5	127.8±26.9	<0.001
Right atrial pressure (mmHg)	10.0±2.3	14.2±3.9	0.01
Pre-PBV RVSP (mmHg)	94.0±23.9	153.2±25.6	<0.001
Pre-PBV ratio of RV to aortic systolic pressure	0.84±0.22	1.19±0.15	0.001
Ratio of balloon to pulmonary valve diameter	1.18±0.12	1.21±0.09	NS
Post-PBV pressure gradient at the infundibular level	8.9±7.6	49.8±23.7	<0.001
Post-PBV pressure gradient at the valvular level	14.3±4.9	18.1±7.9	NS

PBV, pulmonary balloon valvuloplasty; PG, pulmonary systolic pressure gradient; RV, right ventricle; RVSP, right ventricular systolic pressure

Table 2. Demographic characteristics and hemodynamic data at medium term

Variables	Group A (PG ≤ 25 mmHg) (N = 19)	Group B (PG > 25 mmHg) (N = 6)	p-value
Male (N)	10	4	NS
Symptoms (N)	6	3	NS
Patient age (year), mean ± SD	5.6±3.4	9.2±4.5	NS
R wave amplitude in V_1 (mm)	16.7±8.1	23.8±5.5	0.03
Pre-PBV PG (mmHg)	79.8±31.7	123.7±39.1	0.02
Right atrial pressure (mmHg)	10.7±2.8	14.0±4.6	NS
Pre-PBV RVSP (mmHg)	104.7±30.2	148.8±41.6	0.01
Pre-PBV ratio of RV to aortic systolic pressure	0.92±0.25	1.10±0.26	NS
Ratio of balloon to pulmonary valve diameter	1.21±0.09	1.13±0.15	NS
Patients with suboptimal immediate result (N)	4	5	0.01

PBV, pulmonary balloon valvuloplasty; PG, pulmonary systolic pressure gradient; RV, right ventricle; RVSP, right ventricular systolic pressure; NS, not statistically significance

Discussion

Although several studies documented good to excellent immediate and long-term results[4-13], few studies focused on the factors determining these results[14-17]. The data obtained from the present study provided factors that determined immediate and medium-term outcomes of PBV in 25 patients with moderate to severe PS. The majority of patients (64%) were asymptomatic. Cyanotic patients were younger and have more severe obstruction than other symptomatic patients. Cyanosis may be secondary to diminished cardiac output or right-to-left shunting through patent foramen ovale[1,2]. In the present study, PBV is a very effective procedure in relieving pulmonary valvular obstruction. The immediate statistically significant reductions of pulmonary systolic pressure gradient, RVSP, and right ventricular/aortic systolic pressure ratio after PBV were similar to many previous studies[4-6,9-11,13,15,17]. When the immediate pressure gradient of less than 36 mmHg was used for defining successful result, the immediate success rate in the present study was 64%. This cut point value was chosen because it corresponded to a continuous-wave Doppler peak velocity of 3 m/sec[5,17]. As shown in

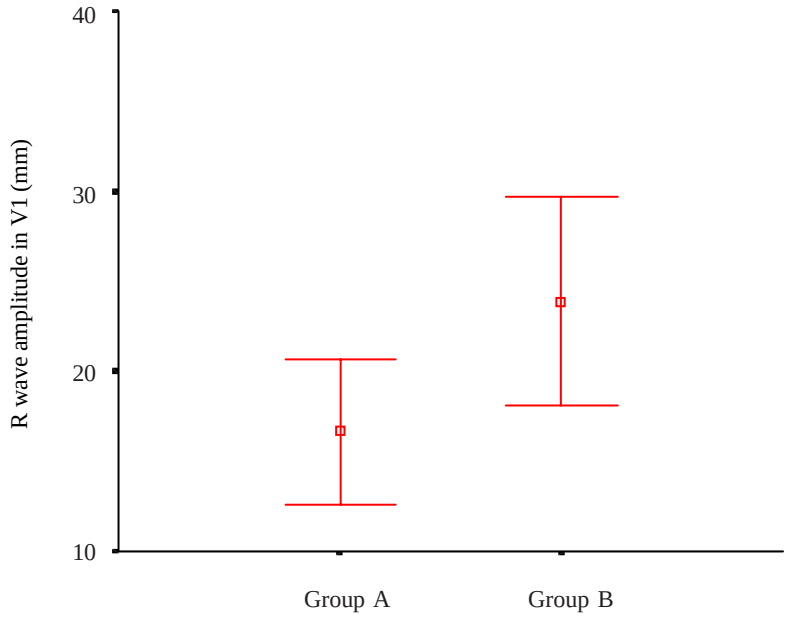

Fig. 1 Mean and 95%CI of pre-dilation R wave amplitude in V_1 (mm) of group A (PG ≤ 25 mmHg) and group B (PG > 25 mmHg), p=0.03. *PG*, pulmonary systolic pressure gradient

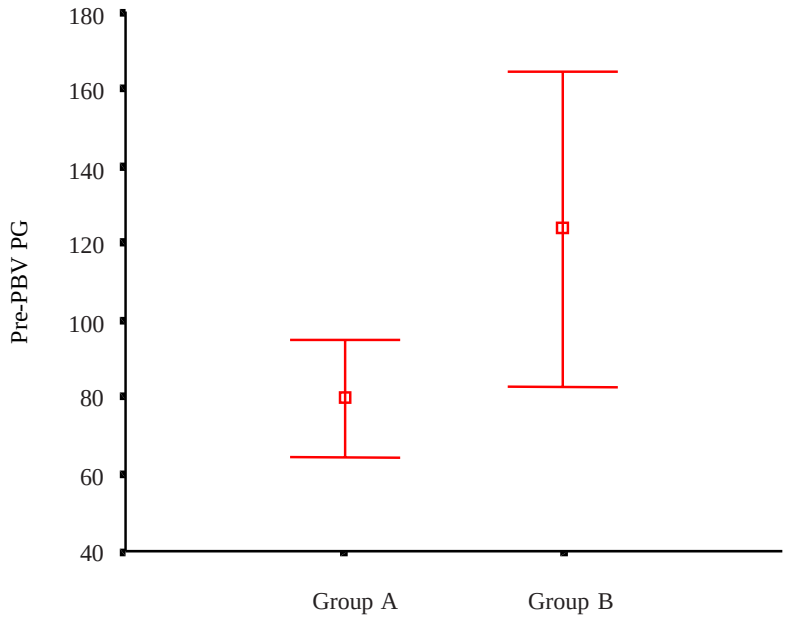

Fig. 2 Mean and 95% CI of pre-PBV pulmonary systolic pressure gradient of group A (PG ≤ 25 mmHg) and group B (PG > 25 mmHg), p=0.02. *PBV*, pulmonary balloon valvuloplasty; *PG*, pulmonary systolic pressure gradient

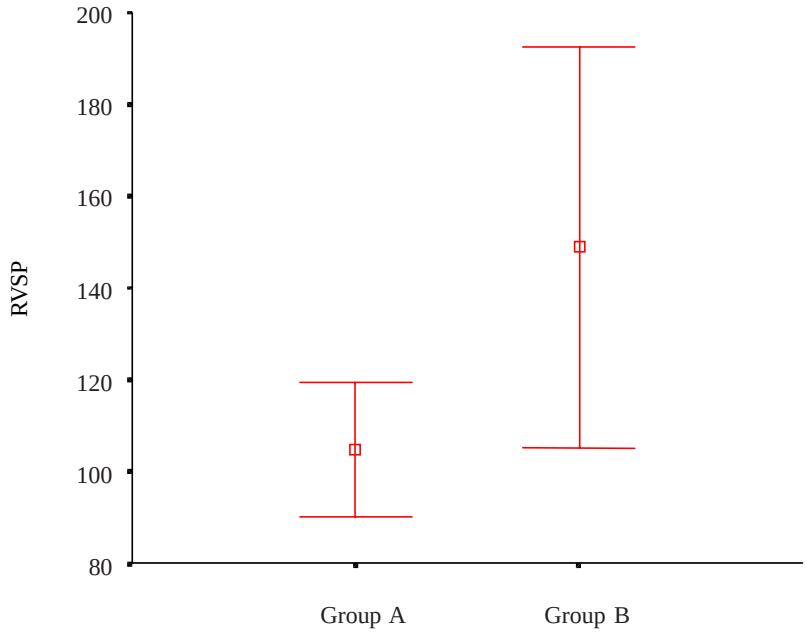

Fig. 3 Mean and 95%CI of pre-dilation right ventricular systolic pressure (RVSP) of group A (PG ≤ 25 mmHg) and group B (PG > 25 mmHg), p = 0.01. *PG*, pulmonary systolic pressure gradient

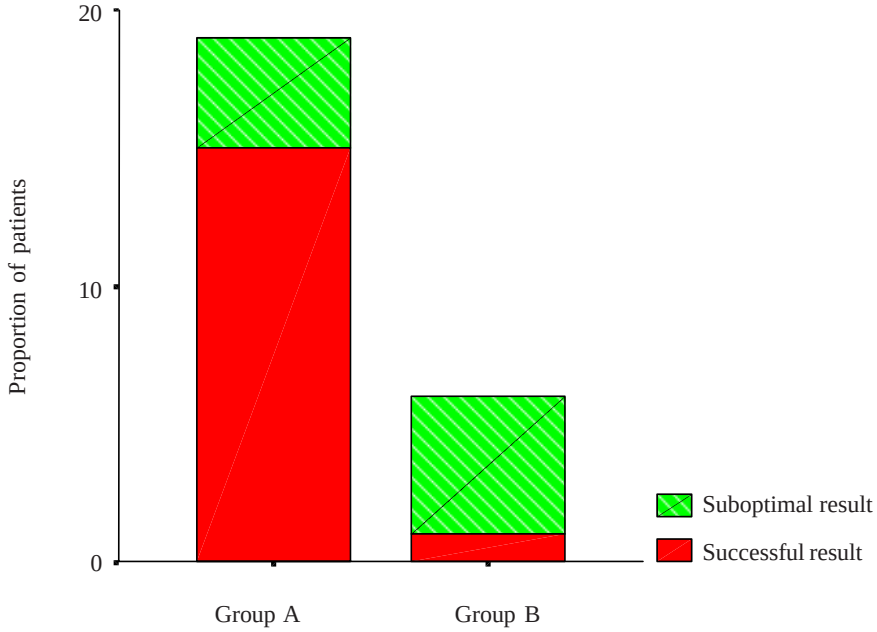

Fig. 4 Proportion of patients with suboptimal immediate result of group A and group B (p = 0.01)

Table 1, the patients with suboptimal immediate results (group II) had significant pressure gradient at infundibular level. This was proved to be a reactive infundibular obstruction after PBV occurred in 12%-24% of patients[10,18]. Resolution of residual gradients has been attributed to the regression of infundibular hypertrophy[10,18-20]. To evaluate factors determining medium-term outcome, a residual gradient of greater than 25 mmHg was chosen as indicative of the suboptimal result because patients with a gradient of ≤ 25 mmHg usually did not experience a progressive obstruction[21]. The significant factors that had an impact on medium-term outcome were a higher RV voltage on the electrocardiogram (R wave amplitude in V_1), and hemodynamic indicators of more severe degrees of obstruction. Other factors in several studies included the patients' age of less than 2 years, symptoms, hypoplastic pulmonary valve with dysplastic morphology, and a smaller ratio of balloon to valve hinge point diameter[5,14,15,20]. In the present study, the patients' age, symptoms, and the ratio of balloon to pulmonary valve diameter were not statistically significant in determining the success rate in medium-term outcome. Mendelsohn demonstrated that patients with greatest long-term success had prevalvuloplasty systolic gradients < 60 mmHg, and a systolic right ventricular/aortic pressure ratio < 0.8[15]. Successful medium-term results were achieved in 76% of the presented patients, with greater success rate (91%) in patients with an R wave amplitude in $V_1 \leq 21$ mm, a pre-dilation pulmonary systolic gradient $\leq$ 90 mmHg, and right ventricular systolic pressure $\leq$ 125 mmHg. These values of the prevalvuloplasty pressure gradient, and right ventricular systolic pressure were higher than a previous study because there were more patients with severe degrees of obstruction in the present study. McCrindle observed a significant rise in the incidence of significant pulmonary regurgitation with the use of a balloon to PV diameter ratio of > 1.4[14]. In the authors' experience, the balloon diameter size 1.0 to 1.3 times (mean 1.19 $\pm$ 0.11) the diameter of the pulmonary valve was used, and the resulting pulmonary regurgitation was trivial or mild. The optimal ratio for a PBV of approximately 1.2 provided good medium-term results, and also can avoid the production of significant pulmonary regurgitation. The limitation of the present study was the small number of studied patients. Despite these good results, long-term follow-up is necessary to document factors that determine the eventual long-term outcome of pulmonary balloon valvuloplasty for the relief of pulmonary valve stenosis.

Conclusion

Pulmonary balloon valvuloplasty is an effective procedure for the immediate and medium-term relief of obstruction in moderate to severe pulmonary valve stenosis. In patients with severe degrees of obstruction, significant immediate residual gradients may persist at infundibular level, but some were resolved spontaneously. This was due to regression of the infundibular hypertrophy. Successful medium-term outcome after PBV was achieved in 76% of patients, with a greater success rate (91%) in those with a lower right ventricular voltage on the electrocardiogram (R wave amplitude in V_1) $\leq$ 21 mm, a prevalvuloplasty pulmonary systolic pressure gradient $\leq$ 90 mmHg, and RVSP $\leq$ 125 mmHg using a balloon to pulmonary valve diameter ratio of approximately 1.2.

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ปัจจัยที่มีผลต่อการรักษาโรคลิ้นหัวใจพัลโมนารีย์ตีบด้วยวิธีขยายลิ้นด้วยลูกโป่ง

สุชญา ศิลป์วิไลรัตน์, ยุพดา พงษ์พรต, แรกขวัญ สิทธิวางค์กูล, ชาลี พรพัฒน์กุล

ได้ทำการวิเคราะห์ผลการรักษาโรคลิ้นหัวใจพัลโมนารีย์ตีบด้วยวิธีขยายลิ้นด้วยลูกโป่งในผู้ป่วย 25 ราย ที่ได้รับการรักษาระหว่าง พ.ศ. 2538 ถึง 2544 เมื่อใช้ความต่างความดันระหว่างลิ้นหัวใจพัลโมนารีย์ 35 มม.ปรอท ทันทีหลังขยายลิ้นเป็นตัวตัดสินผลการรักษา พบว่าผู้ป่วย 9 ราย (36%) ผลการรักษาดีไม่มากนัก นั่นคือความต่างความดันระหว่างลิ้นหัวใจพัลโมนารีย์มากกว่า 35 มม.ปรอท ปัจจัยที่มีผลต่อการรักษาในกลุ่มนี้คือ 1. อาการมาก 2. ความดันระหว่างลิ้นหัวใจพัลโมนารีย์สูง (กว่า) 3. ความดันเลือดในหัวใจห้องขวาบนสูง (กว่า) 4. ความดันเลือดในหัวใจห้องขวาล่างสูง (กว่า) และ 5. อัตราส่วนความดันเลือดในหัวใจห้องขวาล่างต่อความดันในหลอดเลือดเอออร์ต้าสูง (กว่า) ส่วนในผู้ป่วย 16 ราย ผลการรักษาดีมาก

เมื่อติดตามการรักษาในระยะต่อมา 6 ถึง 60 เดือน (mean 17.5 เดือน) ด้วยวิธีการตรวจทางคลินิก คลื่นเสียงสะท้อนความถี่สูง และดอปเปอร์ ผลปรากฏว่าเมื่อใช้ตัวเลขความต่างความดันระหว่างลิ้นหัวใจพัลโมนารีย์ 25 มม.ปรอทเป็นตัวตัดสินผลการรักษา พบว่าผู้ป่วย 19 ราย (76%) ผลการรักษาดีมาก ส่วนผู้ป่วย 6 ราย (24%) ผลการรักษาดีไม่มากนัก ปัจจัยที่มีผลต่อการรักษาในกลุ่มนี้คือ 1. R wave amplitude ใน ECG lead V1 สูง (กว่า) 2. ความดันระหว่างลิ้นหัวใจพัลโมนารีย์สูง (กว่า) และ 3. ความดันเลือดในหัวใจห้องขวาล่างสูง (กว่า) ในผู้ป่วยกลุ่มที่มี R wave ใน V1 $\leq$ 21 มม. ความดันระหว่างลิ้นหัวใจพัลโมนารีย์ $\leq$ 90 มม.ปรอท และความดันเลือดในหัวใจห้องขวาล่าง $\leq$ 125 มม.ปรอท ผลการรักษาให้ผลดีสูงถึง 91%