

Immediate, Short, Intermediate and Long-Term Results of Balloon Valvuloplasty in Congenital Pulmonary Valve Stenosis

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Abstract- Transluminal balloon valvuloplasty is an alternative to surgical valvotomy for congenital pulmonary valve stenosis. The aim of this study was to evaluate the long term results (to 13.5 years) of balloon pulmonary valvuloplasty. From June 1998 to January 2012, percutaneous balloon pulmonary valvuloplasty for congenital pulmonary valve stenosis was performed in 98 patients (50 males, 48 females, with a median age of 6.75 years) underwent balloon valvuloplasty of pulmonary valve stenosis. Follow-up was performed based on the Doppler echocardiographic data and clinical findings. Forty three of ninety eight patients were 10 years of age or older. The mean peak to peak pressure gradient across pulmonary valve before and immediately after balloon pulmonary valvuloplasty (BPV) was 88.7 ± 36.4 mmHg and 21.8 ± 15.9 mmHg ($P<0.001$) respectively. Doppler pressure gradient across pulmonary valve before BPV, at 3 month (short term), at 1 year (intermediate term) and long-term follow-up were 93.2 ± 41.3 mmHg, 18.7 ± 15.8 mmHg ($P<0.001$), 15.8 ± 13.1 mmHg ($P<0.001$) and 13.6 ± 7.4 mmHg ($P<0.017$) respectively. Mild pulmonary regurgitation (PR) was observed in 55 (57%) patients immediately after BPV and 30 (31%) patients at late follow up. Rupture of the right ventricular outflow tract was the major complication in two patients with fatal event. Short, intermediate and long-term results of BPV for typical valvular pulmonary stenosis are excellent. Therefore, it can be considered as treatment of choice for patients with typical valvular pulmonary stenosis.

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Keywords: Congenital Pulmonary Valve Stenosis; Balloon Valvuloplasty; Follow up

Introduction

The only method of treatment for valvular pulmonary stenosis (VPS) was surgical valvotomy until 1982. Since 1982, the technique of balloon pulmonary valvuloplasty (BPV) was introduced initially by Kan *et al.* (1). Since then, many other authors reported successful application of this technique to treat patients with pulmonary valve stenosis (2-4). Immediate, short and intermediate results of BPV have been well documented (5-7). However, documented data on long term follow up are scarce (8-11). The purpose of this study is to describe the results of long-term follow up of BPV in 96 patients with congenital pulmonary valve stenosis.

Materials and Methods

From June 1998 to January 2012, one hundred eight consecutive patients with moderate to severe VPS were

considered for BPV. Ten patients were excluded because of dysplastic pulmonary valve in five patients, fixed infundibular stenosis in three patients and impossibility of catheterization of the pulmonary artery in two patients. The remaining 98 patients (50 males and 48 female, aged 0.4 to 52 years, median age 6.75 years, and median weight 18.5 kg range: 6-85 kg) underwent BPV with a Tyshak balloon catheter. The pressure gradients across pulmonary valve measured pre and immediately post BPV with Doppler echocardiography and catheterization. Transthoracic echocardiography was performed at 24 hour, three months, one year and yearly thereafter. Doppler echocardiography assessed the maximum peak instantaneous gradient across the pulmonary valve and pulmonary regurgitation.

The procedure

Informed written consent was obtained from the patients or their parents before the procedure. The

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procedure was done under local anesthesia and moderate sedation for adults and general anesthesia with intravenous ketamine hydrochloride (without endotracheal intubation) for children. A 6-French pigtail catheter was inserted with Seldinger technique, through the right or left femoral venous sheath into the right sized of the heart, in order to right ventriculography. Right ventriculography was done in anteroposterior and left lateral views (Figure 1).

Figure 1, Right ventriculogram in anteroposterior (1A) and (1B) left lateral views showing severe valvular pulmonary stenosis, thickened domed pulmonary valve and post-stenotic dilatation of main pulmonary artery.

The diameter of the orifice and annulus of pulmonary valve was measured from hinge point to hinge point during systole from lateral view of the right ventricular angiogram.

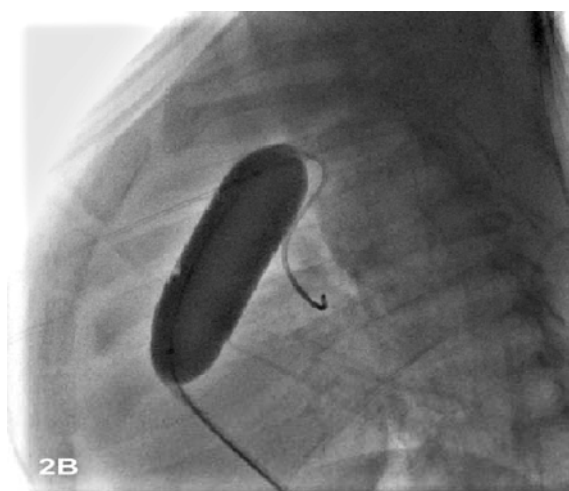


Figure 1. Right ventriculogram in anteroposterior (1A) and (1B) left lateral views showing severe valvular pulmonary stenosis, thickened domed pulmonary valve and post-stenotic dilatation of main pulmonary artery.

Figure 2. Left lateral view of a partially inflated balloon catheter positioned across the pulmonary valve. As the balloon is inflated a waist appears at the site of pulmonary valve (2A). The balloon waist completely disappeared on the left lateral view, suggesting valvuloplasty had been effective (2B).

Table 1. Demographic and catheterization data of patients.

	Mean	Median	SD	Range
Age (yrs)	10.56	6.75	10.37	0.4-52
Weight (kg)	28.54	18.5	22.97	6.3-85
Pulmonary annulus (mm)	10.86	16	4.33	10-27
Balloon size (mm)	19.24	18	4.91	12-30
Balloon/annulus ratio	1.45	-	0.10	-
PG across PV (BBV) mmHg	88.68	-	36.44	52-220
PG across PV (IABV) mmHg	21.80	-	15.91	-
PG across PV (LFU) mmHg	13.55	-	7.43	-

PG: pressure gradient, PV: pulmonary valve, BBV: before balloon valvuloplasty, IABV: immediate after valvuloplasty, SD: standard deviation, LFU: late follow up.

The maximal diameter of the Tyshak balloon was chosen in accordance with the diameter of pulmonary valve annulus. The diameter of the balloon catheter was 10-20% larger than that of the pulmonary valve annulus. With a long Schneider exchange guide wire, the pigtail catheter was then replaced with multipurpose catheter, in order to measure and facilitated blood sampling, and then multipurpose catheter was replaced with a Tyshak balloon catheter which was advanced to the main pulmonary artery and left or right pulmonary artery branch. When the exchange wire was stabilized, balloon catheter was pulled back until the middle portion of the balloon was positioned just across the pulmonary valve. The balloon was fully inflated within few seconds and then quickly deflated. Inflations were repeated until a satisfactory reduction in the gradients was detected (Figure 2).

Statistical analysis

Normally distributed continuous variables were expressed as mean ± SD. When the data are not normally distributed, medians (range) are given. Mean pressure gradients before and immediately after BPV and at short, intermediate and long- term follow up were compared by two tailed or paired student’s t-tests. A P-value less than 0.05 was considered statistically significant. Transcatheter closure of ASD’s and PDA’s was performed with Amplatzer device.

Results

Pulmonary balloon valvuloplasty was done in 98 patients (48 males, 50 females) of median age 6.8 years (range: 0.4-52 years) and of median weight 18.5 kg (range: 6.3-85 kg) with congenital pulmonary valve stenosis. There were associated defect in nine patients included: ASD in 5 patients, PDA in 3 patients and LPA

and RPA stenosis in one patient. There were two immediate deaths due to right ventricular out flow perforation, one boy 2.2 year and other adolescent girl of 16 years. Therefore, the follow up results of 96 patients was assessed by echocardiography 2 to 13.5 years (6.5±3.5 years, median: 4.1 years). At the table 1, we showed the demographic and catheterization data of patients. (Table 1).

The mean peak to peak pressure gradient across pulmonary valve before and immediately after BPV was 88.7±36.4 mmHg (range: 52-195 mmHg) and 21.8±15.9 mmHg (range: 0-100 mmHg) (P<0.001) respectively. Doppler maximum peak instantaneous gradient across the pulmonary valve before BPV, at three month, (short-term), 1 year (Intermediate-term) and long-term follow up were 93.2±14.3 mmHg (range 52-202 mmHg), 18.7±15.8 mmHg (range: 0-85) (P<0.001), 15.8±13.1 mmHg (range: 0-65 mmHg) (P<0.001) and 13.6±7.4 mmHg (range: 0-33) (P<0.017) respectively. Mild pulmonary regurgitation was observed in 55 (57%) patients, immediately after BPV, 40 (43%) patients at short, 30 (31%) at intermediate and 30 (31%) at long-term follow up. Moderate pulmonary regurgitation was noted in two (2.1%) patients immediately after BPV. Moderate PR did not regress at long-term follow up. On short and intermediate follow- up three patients required a second balloon dilatation with excellent results. None of patients had significant pulmonary regurgitation at long term follow up. Therefore pulmonary valve replacement for treatment of pulmonary regurgitation was not required.

Discussion

This study shows that BPV provides long-term relief of stenosis of in the majority of patients with moderate to severe valvular pulmonary stenosis. There were re-

stenosis or residual gradient ≥ 30 mmHg only in 16 (16.7%) patients at short, in 11 (11.4%) patients at intermediate and in 6 (6.3%) patients at long term follow up. Therefore in current study incidence of re-stenosis or residual stenosis was low that can be related to the use of large balloon (ratio of the diameter of the balloon catheter to the annulus diameter was between 1.1–1.2). The balloons larger than the pulmonary annulus appear to produce more sustained relief of pulmonary stenosis. Therefore balloon catheter larger than the annulus diameter is recommended for pulmonary valvuloplasty. In current study incidence of pulmonary annular hypoplasia was lower than other study (5.2% versus 8%) (12). In our study, we demonstrated a further decrease in systolic pressure gradient, across pulmonary valve at short, intermediate and long-term follow up, a finding comparable to results of other reports that describe follow up (9-11,13-15). In this study, incidence of pulmonary regurgitation was 57% immediately after BPV and 31% at long term follow up. This result is comparable to studies of Jarrar *et al.* (12) and O'Connor *et al.* (16). Pulmonary regurgitation after BPV was higher in many studies (9,16-18). Despite the use of large balloon catheter, incidence pulmonary incompetence was relatively low in our study. The valvular incompetence is certainly less frequent after balloon valvuloplasty than after surgical valvotomy (16,19). PR has usually benign course for many years. Patient often remains free of symptoms until marked RV dilatation and systolic dysfunction ensue (20). However, careful longer follow up (≥ 20 years) to evaluate of pulmonary regurgitation and right ventricular dysfunction is recommended. Perforation of right ventricular outflow tract (RVOT) was the major complication in two (2%) patients with fatal event. This complication is rare and usually occurs in patients with annular hypoplasia and fixed infundibular pulmonary stenosis (21-23). These patients were one infant with annular hypoplasia and one adolescent with fixed infundibular stenosis. In our study rate of major complication (perforation of RVOT) was 2%, while in some studies was higher (6.4%-7.3%) than our study (10,21,24) but it was lower in most studies (9,11,12,18,25). In conclusion, the results of BPV have been so successful that in recent year it has large replaced surgical valvotomy except in patients with dysplastic pulmonary valves and fixed (non-functional) infundibular stenosis. It is a nonsurgical procedure and is associated with shorter hospital stays, less psychological discomfort and avoiding scar. Although in our study result of balloon valvuloplasty, immediately

after balloon valvuloplasty was not acceptable, but the short, intermediate and long-term results were excellent. There BPV can be considered as the treatment of choice for patients with typical valvular pulmonary stenosis and cases with annular hypoplasia and fixed infundibular stenosis should be referred to cardiovascular surgeon. We recommend careful longer term follow up (15-20 year) to evaluate the re-stenosis, PR and right ventricular dysfunction.

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Balloon pulmonary valvuloplasty

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