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ORIGINAL ARTICLE

Immediate Outcome of Balloon Pulmonary Valvuloplasty in Children: Experience at Bangladesh Shishu Hospital & Institute

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Abstract

Introduction*: Isolated pulmonary valve stenosis is a common heart defect (6-9%). Percutaneous balloon pulmonary valvuloplasty (BPV) has become the treatment of choice for the relief of severe valvular pulmonary stenosis (PS).*

Objective: *To assess the immediate outcome of BPV in children with congenital PS at Bangladesh Shishu Hospital & Institute, Dhaka, Bangladesh.*

Methods*: A retrospective longitudinal cohort study was carried out in Bangladesh Shishu Hospital & Institute, Dhaka, Bangladesh from January 2021 to December 2022. Thirty three patients (23 male and 10 female) with severe PS who underwent balloon pulmonary valvuloplasty were included in the study. The gradient across pulmonary valve measured pre and immediate post valvuloplasty at catheterization and by transthoracic echo was compared.*

Results*: A total of 33 patients underwent balloon pulmonary valvuloplasty procedure. Mean age was 2.5±1.2 years while male 23 and female 10 with male female ratio was 2.3:1. Mean weight of the patient was 9.112±4.50 Kg. Majority of the patients (n=22, 66.6 %) were symptomatic and dyspnea on exertion was the dominant symptom (n=18, 54.5%) and 4 (12.1%) patient presented with cyanosis. All of the patients had doming pulmonary valve (n=33, 100%). Mean size of pulmonary valve by transthoracic echo was 10.23 mm and mean size of balloon was 12.6 with balloon to pulmonary valve annulus ratio was 1.22:1. The procedure was successful in 32 (n=32, 97%) as significant reductions in the right ventricular pressure from 80.36±16.45 mm Hg (pre valvuloplasty) to 23.85±8.47 mm Hg by transthoracic echo (p=0.000) and peak-to-peak systolic pressure gradient across the pulmonary valve decreased from 84.03±26.3 mm Hg (pre valvuloplasty) to 22.76±10.42 mm Hg (p<0.001) (post valvuloplasty. One patient developed cardiac arrest during valvuloplasty that patient required CPR. One patient died on 2nd day of valvuloplasty due to severe right ventricular dysfunction. On post procedure echocardiography, 14(42.4%) patient developed mild PR. Mean Fluoroscopy time was 21.66 ±18.22 minute and mean total procedure time was 40.50±20.29 minute.*

Conclusions*: Outcome of balloon pulmonary valvuloplasty in infant and children is a very safe procedure with high success but very low complications rate.*

Keywords*: Pulmonary stenosis, balloon pulmonary valvuloplasty, TTE, catheterization.*

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Introduction

Isolated pulmonary valve stenosis (PVS) is detected in 0.33/1000 newborns and makes up 6-9% of all congenital heart defects among children.[1] Percutaneous trans-catheter balloon pulmonary valvuloplasty (BPV) is the treatment of choice for pulmonary valve stenosis since the introduction of this procedure in 1982 by Kan.[2] BPV has totally replaced the surgical pulmonary valvotomy and is the treatment of choice for moderate to severe valvular pulmonary stenosis in all age groups.[3] It effectively reduces right ventricle-pulmonary artery systolic pressure gradient.[2] It should be considered as the treatment of choice for children with PS based on its excellent outcome, lesser trauma and fewer complications.[4,5] It is generally recommended that the procedure be performed for peak-to-peak gradient in excess of 50 mmHg.[6]

BPV has excellent results because of least trauma to patients with limited clinical presentation.[7] Complications during and immediately after balloon valvuloplasty are usually minimal. Infant and children patients behave differently to balloon pulmonary valvuloplasty ranging from suicidal right ventricle (RV) physiology, reduction in gradients across pulmonary valve and re stenosis. During valvuloplasty transient bradycardia, premature beats and a fall in systemic pressure on balloon inflation are usually noted which return to normal after deflation of balloon. Transient blood loss, complete right bundle branch block, transient or permanent heart block, cerebrovascular accident, loss of consciousness, cardiac arrest, convulsions, balloon rupture at high balloon inflation pressures, rupture of tricuspid valve papillary muscle, and pulmonary artery tears, though rare have been reported.[6] So this study was undertaken to evaluate the immediate results of BPV in children.

Materials and Methods

This was a retrospective longitudinal cohort study of 33 patients who were less than 18 years old with severe valvular (peak gradient ≥64 mm of Hg) PS and underwent BPV with Tyshak balloon catheter at Bangladesh Shishu Hospital & Institute, Dhaka, Bangladesh over a period of 2 years from January 2021 to December 2022. All 33 patients who had systolic doming of pulmonary valve with severe valvular PS and underwent balloon pulmonary valvuloplasty were included in the study. Patients having dysplastic pulmonary valve with infundibular and supravalvular PS were excluded from the study. The gradient was measured before and immediately after valvuloplasty. It is a routine of the institute to get informed written consent at time of admission and before start of every procedure. We retrieved the data of the patients from hospital database, including demographic profile and clinical data of the patients, age, gender (male/ female), weight in kilograms (Kg) or symptoms at presentation. Pre procedural findings of trans-thoracic echocardiography (TTE) including valve morphology (doming/ dysplastic), valve annulus, RV systolic function, color flow mapping, presence or absence of tricuspid valve regurgitation (TR), peak pressure gradient across pulmonary valve in millimeter of mercury (mmHg) was also retrieved.

After careful history, clinical examination and informed written consent cardiac catheterization was performed through femoral venous access under general anesthesia in all the enrolled patients. NIH catheter was taken through the venous sheath to RV and then RV angiogram performed in full lateral projection (90^0) to confirm the valvular stenosis, morphology of valve and annulus. Hemodynamic data was assessed. A soft profile low pressure balloon (Tyshak II in all 33 cases), 20% greater in diameter than valve annulus, was selected and inflated across pulmonary valve over an extra stiff exchange length guide wire which already was anchored in a branch pulmonary artery by using a multipurpose catheter. One to three inflations were given in each case depending upon disappearance of waste and the inflation was not more than 30 seconds. Post-procedure pulmonary artery to right ventricular outflow tract (RVOT) pull back gradient that is peak to peak pressure gradient (PPG) across pulmonary valve was measured using an end-hole catheter, carefully excluding any right ventricular outflow obstruction gradient. We define BPV a success if peak-to peak pressure gradient by pull back pressure tracing post BPV was ≤35mm of Hg immediately after the procedure. All patients were given heparin in a dose of 100 units per kg during the procedure. The patient usually stayed in hospital for one day after the procedure, received intravenous antibiotics and was discharged after performing 2D-Echo Doppler evaluation. Procedural complications like syncope, arrhythmias, pericardial effusion, local bleeding / hematoma from femoral

sheath site were recorded. Findings of post procedural echocardiography done on day one were also retrieved for pulmonary valve instantaneous gradient and RV function, RVOT obstruction, pericardial effusion, TR (mild, moderate, severe) and Pulmonary regurgitation (mild, moderate, severe). The clinical stability of patients regarding blood pressure, pulse, temperature, local puncture site wound condition for inflammation and total hospital stay was noted.

All data were expressed as mean±SD or median with range. Paired t- test was used to compare the Pressure gradient across PV before and after procedure by TTE and peak to peak pressure gradient across the pulmonary valve before and after the procedure. A P value less than 0.05, was considered significant.

Results

Mean age was 2.5±1.2 years while male 23 and female 10 with male female ratio was 2.3:1. Majority of patient below one year of age (Table I).

Table I
Age and gender distribution of study population (N=33)

Character	Frequency	Percentage
Sex		
Male	23	69.7
Female	10	30.3
Age (year)		
≤1	14	42.4
>1-<5	13	39.4
≥5	6	18.2
Mean±SD	2.5±1.2	

Most of the patient was below 1 year of age. Mean weight was 9.112±4.509Kg (Table II).

Table II
Mean weight of study population (N=33)

Age (year)	Weight (kg) Mean ± SD	
≤1 (n=14)	5.671	2.0480
>1-<5 (n=13)	9.969	2.5313
≥5 (n=6)	15.283	4.8077

Majority of the patients (n=22, 66.6 %) were symptomatic and shortness of breath on exertion was the dominant symptom (n=18, 54.5%) and 4(12.1%) patients presented with cyanosis (Table III).

Table III
Presenting symptoms of study population (N=33)

Symptoms	Frequency	Percentage
Incidental detection of murmur	11	33.3
Shortness of breath on exertion	18	54.5
Cyanosis	4	12.2

After BPV, there was a significant reduction in pressure gradient across pulmonary valve from 80.36±16.45 mm Hg to 23.85±8.47mm Hg (p=0.000) (Table IV).

After BPV, there was a significant reduction in peak to peak pressure gradient across pulmonary valve from 84.03 ± 26.31 mm Hg to 22.76 ±10.42 mm of Hg (p=0.000) (Table V).

Table IV
Pressure gradient across pulmonary valve after BPV

	Mean ± SD	p value
Pressure gradient across PV before procedure by TTE	80.36 ± 16.45	0.000
Pressure gradient across PV after procedure by TTE	23.85 ± 8.47	

Significance p =<0.05

Table V
Comparison of angiographic pressure gradient before and immediately after BPV

Pressure gradient	Mean ± SD	p value
Peak to peak pressure across pulmonary valve before BPV	84.03 ± 26.31	0.000
Peak to peak pressure across pulmonary valve after BPV	22.76 ± 10.42	

Significance p=<0.05

Mean size of PV was 10.239 and mean size of Tyshak II balloon used in this study was 12.5. balloon to annulus ratio was 1.22 (Table VI).

Table VI
Mean Size of Tyshak-II balloon and mean size of pulmonary valve ratio

Mean size of Tyshak II balloon	Mean size of PV by TTE	Ratio
12.5	10.239	1.22

Mean Fluoroscopy time was 21.66±18.22 minute and mean total procedure time was 40.50±20.29 minute. Fluoroscopy time and total procedure time was comparatively more in infant (Table VII).

Table VII
Mean fluoroscopy time and mean total procedure time

Age (year)	Fluoroscopy time (min) ± SD	Total Procedure time (min) ± SD
≤1 (n=14)	23.97±20.01	47.07 ±22.73
>1-<5 (n=13)	20.14 ±15.29	44.08 ±17.29
≥5 (n=6)	19.53 ± 22.28	40.50 ± 20.29
Total (n=33)	21.66 ± 18.22	44.70 ± 19.81

One patient developed cardiac arrest during procedure that patient required cardio-pulmonary resuscitation, 14 (42.4%) patient develop mild PR and one patient died on 2nd day of procedure (Table VIII).

Table VIII
Complications of Balloon pulmonary valvuloplasty

Complication	Frequency	Percentage
Cardiac arrest	1	3.0
Mild PR	14	42.4
Died	1	3.0

Discussion

Pulmonary stenosis is one of the common congenital heart diseases.[7] The traditional method of treatment was surgical valvotomy until 1982, when Kan et al[2] introduced the technique of percutaneous balloon valvuloplasty. Since then, it has replaced the surgical option.[3,8] This study showed mean age was 2.5±1.2 years while male 23 and female 10 with male female ratio was 2.3:1. Majority of patient below one year of age which is differing from other study.[9] This study confirms the safety and effectiveness of BPV in children with PS. After BPV, there was a significant reduction in pressure gradient across pulmonary valve from 80.36±16.45 mm Hg to 23.85±8.47mm Hg (p=0.000) by TTE and significant reduction in peak to peak pressure gradient across pulmonary valve from 84.03±26.31 mm Hg to 22.76±10.42 mm of Hg (p=0.000) which is comparable to studies from other countries.[10,11]

Majority of the patients (n=22, 66.6 %) were symptomatic and shortness of breath on exertion was the dominant symptom (n=18, 54.5%) and 4 (12.1%) patient presented with cyanosis which was comparable with other study.[12]

Good outcome defined as a residual catheter gradient <36 mm Hg, was achieved in 97.0% of patient in this study. One study from Iran found 77% of their patient has residual catheter gradient <36 mm Hg.[13] But when the residual pressure gradient (PG) after BPV <25 mmHg is considered successful in Sri Lankan study.[14] This study showed 97% success rate which is higher than their study (60%).[14] In This study, no procedure failure was found but one patient died on 2nd day of procedure due to right ventricular dysfunction. In general, after BPV, there is a decrease of RV pressure ranging from 39 to 71% and peak pressure gradient across pulmonary valve ranging from 45 to 93%.[15] Mean Fluoroscopy time was 21.66±18.22 minute and mean total procedure time was 40.50±20.29 minute. Fluoroscopy time and total procedure time was depends on age of the child. Infant required more fluoroscopy time and procedure time. One patient developed cardiac arrest during procedure that patient required cardio-pulmonary resuscitation, 14 patients develop mild PR and one patient died on 2nd day of procedure. Complications are common when balloon to annulus ratio exceeds 30%. However, in our study we used a balloon to annulus ratio exceeds 22%.

Conclusions

The immediate outcomes of balloon pulmonary valvuloplasty in children are excellent. BPV is a safe, effective and reliable treatment for patients with PS and is the treatment of choice in patients with symptomatic pulmonary stenosis.

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