Clinical Case Reports: Open Access

YumedText — Open Access Journals —

Research | Vol 9 Iss 4
ISSN: 2582-5038
https://dx.doi.org/10.46527/2582-5038.377

A Nine-Year Experience of Transcatheter Balloon Valvuloplasty for Pulmonary Stenosis in Pediatric Population at a Tertiary Care Hospital

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Received: September 17, 2026; **Accepted:** September 30, 2026; **Published:** October 10, 2026

Abstract

Introduction: Congenital pulmonary valve stenosis (PS) has been found in 8-10% of patients with congenital heart diseases. Right ventricular dysfunction, fibrosis or infarction may be seen in patients with severe PS. Over the past few decades, transcatheter balloon valvuloplasty has gained widespread acceptance, especially as a first-line treatment in paediatric populations with pulmonary stenosis.

Objectives: To evaluate the efficacy and safety of balloon pulmonary valvuloplasty (BPV) in pediatric population. Identify the predictors of the outcome of balloon pulmonary valvuloplasty and its complications during and early after the intervention.

Method: This was a retrospective observational study. Between April 2016 and June 2026, 377 pediatric patients with moderate to severe pulmonary stenosis underwent transcatheter balloon valvuloplasty in the pediatric cardiology department of National Heart Foundation Hospital & Research Institute.

Results: A total of 377 pediatric population were included in the study and divided according to age into 3 groups: neonates and early infants (n=30), infants (n=121), and children (n=226). Mean age was 5.60 ± 5.37 years, minimum age 26 day and maximum age 18 yrs and males predominated (61.3%). Mean weight was 18.12 ± 15.37 kg, and the pulmonary valve annulus measured 12.75 ± 4.17 mm before intervention. Catheterization data showed a marked drop in right ventricular pressure (111.38 ± 41.05 mmHg pre-BPV to 61.87 ± 27.97 mmHg post-BPV) and in the pressure gradient across the pulmonary valve (88.87 ± 42.15 mmHg pre-BPV to 34.92 ± 27.11 mmHg post-BPV), while pulmonary artery pressure changed only modestly (22.38 ± 9.81 to 26.84 ± 8.61 mmHg). The mean balloon-to-annulus ratio was 1.08 ± 0.17, within the standard therapeutic range. Procedural success, defined as a drop pressure gradient across the pulmonary valve to less than or equal to 50% of the baseline measurements, was achieved in 76.4% of the patients. Redo intervention or surgery was required in 22.0% of cases. Of the 377

Citation: Chowdhury NAH, Munjerin M, Islam S, et al. A Nine-Year Experience of Transcatheter Balloon Valvuloplasty for Pulmonary Stenosis in Pediatric Population at a Tertiary Care Hospital. Clin Case Rep Open Access. 2026;9(4):377.
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pediatric population included in the study, 238 (63.1%) had no associated cardiac anomalies, while the remaining patients had one or more associated cardiac lesions. Among those with identified lesions, atrial septal defect (ASD) was the most frequently observed isolated lesion, affecting 40 (10.6%) patients, followed by isolated tetralogy of Fallot (TOF) in 20 (5.3%) and S/P TOF repair residual PS 13 (3.5%) in patients. Combined lesions were also observed. The right ventricular (RV) pressure before intervention retained a significant negative relationship, with lower RV pressure associated with better outcomes (p=0.002). The balloon-valve ratio also emerged as a significant predictor in this expanded analysis (p=0.042).

Conclusion: Transcatheter balloon pulmonary valvuloplasty is a safe and effective procedure though having some complication and few cases required redo balloon dilatation and surgery.

Keywords: ***Congenital pulmonary valve stenosis; Balloon pulmonary valvuloplasty***

1. Introduction

Pulmonary stenosis (PS) is almost always congenital in origin. Isolated PS is a rare condition that occurs in about 1 per 2000 live births worldwide and it accounts for approximately 8% of all congenital heart disease (CHD) [1]. And other associated lesions comprise 25%-30% [2].

Percutaneous balloon valvuloplasty represents a major milestone in the field of interventional cardiology. Balloon valvuloplasty is now regarded as the initial treatment of choice for patients of all ages with moderate to severe pulmonary stenosis [2]. This malformation was described by John Baptist Morgagni at 1761, but balloon pulmonary valvuloplasty (BPV) was initiated in 1982 by McCrindle and Kan. Since that time BPV has been the procedure of choice with same effectiveness as surgical correction but less invasive [3-6]. During the past nine years, 377 pediatric populations with moderate-to-severe pulmonary stenosis were treated at our institution. In this study, we describe our experience with balloon pulmonary valvuloplasty in these patients, focusing on procedural outcomes, complications, and predictors of procedural success and adverse events.

The study aimed to evaluate the efficacy and safety of balloon pulmonary valvuloplasty (BPV) in pediatric population. Identify the predictors of the outcome of balloon pulmonary valvuloplasty and its complications during and early after the intervention.

2. Method

This was a retrospective observational study. Between April 2016 and June 2026, 377 pediatric populations with moderate to severe pulmonary stenosis underwent transcatheter balloon valvuloplasty in the pediatric cardiology department of National Heart Foundation Hospital & Research Institute. Patient data were collected from the medical reports and the electronic medical records. A detailed clinical evaluation, electrocardiogram, chest roentgenogram, 2-dimensional and Doppler echocardiography were performed in all these patients before the procedure. An informed written consent was obtained for all the patients. Balloon pulmonary valvuloplasty (BPV) was recommended to all patients with isolated pulmonary valve stenosis as well as associated with other congenital cardiac lesions from birth to 18 years old.

Before procedure valve annulus was measured by echocardiography and during procedure by catheterization; confirming the

measurement. Pressure gradient across the semilunar valve was also measured by echocardiography and re-evaluated by catheterization before and after balloon valvuloplasty. Associated cardiac anomalies were diagnosed and noted before procedure. Femoral vein access was achieved and cannulated by an introducer sheath according to the size and the age of the patient. Right ventricular pressure and Pulmonary artery pressure during BPV were measured by catheterization before and after balloon valvuloplasty. Antero-posterior and straight lateral angiograms were performed. Lateral projection usually provides the optimal image of the valve hinge points at which the pulmonary annulus is measured using the catheter diameter as an internal reference. Tyshak II, Powerflex, Z-med II were used during procedure. .018, .035 mm roadrunner, .035 mm super stiff wire were used as balloon guidewire. Balloon size recommendations were 1 to 1.2 times larger than the pulmonary valve annulus in cases of BPV. In young children, we use 2-cm-long balloons to prevent damage to the right ventricular free wall, branch pulmonary arteries, or tricuspid valve, while in older children, 3-5 cm long balloons are used to facilitate balloon positioning. The balloon is centered across the valve annulus with the help of a road map in most cases. Success is considered achieved when the pressure gradient across the pulmonary valve drops to less than or equal to 50% of the baseline measurements. Repeat balloon pulmonary valvuloplasty was done if it was indicated again at a later time point. Patients were referred to for surgery after failure of more than one balloon valvuloplasty or if surgery was recommended for associated cardiac lesions.

The patient was transferred to the intensive care unit to be observed for next 24 hours, during which the vital signs were monitored, the puncture site was inspected for bleeding or hematoma maintenance IV fluids and parenteral antibiotics, usually I/V Ceftriaxone 50 mg/kg/day were given. Complications during or immediately after balloon valvuloplasty was recorded

3. Follow-Up

All patients underwent Doppler echocardiography on the day after the procedure. Absence of a significant change in clinical status and/or Doppler gradient across the pulmonary valve were indications for a repeat procedure. Subsequent follow-up visits for clinical evaluation and echocardiography were advised at 1 month, 3-6 months and yearly thereafter.

4. Statistical Analysis

Data were analyzed using SPSS ver.25 (SPSS Inc, Chicago, IL, USA). Values were classified as mean ± standard deviation (SD) for the quantitative and percentages for other categorical variables. Pearson correlation was used to evaluate the correlation between parameters. P-value:<0.05

5. Result

Among total 377 pediatric population, mean age was 5.60 ± 5.37 years minimum age 26 day and maximum age 18 yrs and males predominated (61.3%). Mean weight was 18.12 ± 15.37 kg, and the pulmonary valve annulus measured 12.75 ± 4.17 mm before intervention. Catheterization data showed a marked drop in right ventricular pressure (111.38 ± 41.05 mmHg pre-BPV to 61.87 ± 27.97 mmHg post-BPV) and in the pressure gradient across the pulmonary valve (88.87 ± 42.15 mmHg pre-BPV to 34.92 ± 27.11 mmHg post-BPV), while pulmonary artery pressure changed only modestly (22.38 ± 9.81 to 26.84 ±

8.61 mmHg). The mean balloon-to-annulus ratio was 1.08 ± 0.17, within the standard therapeutic range. Across the complete sample (N=377), the procedure was successful in 76.4% of cases. Redo intervention or surgery was required in 22.0% of cases.

TABLE 1. **Demographic and catheterization parameters before and after valvuloplasty (N=377).**

Parameter studied	**Mean±SD or n (%)**
Age, years, Mean ± SD	5.60 ± 5.37
Gender	
Male	231 (61.3%)
Female	146 (38.7%)
Weight in kg, Mean ± SD	18.12 ± 15.37
PV annulus before, mm, Mean ± SD	12.75 ± 4.17
Catheterization data before BPV	
Right ventricular pressure, mmHg	111.38 ± 41.05
Pulmonary artery pressure, mmHg	22.38 ± 9.81
Pre-pressure gradient, mmHg	88.87 ± 42.15
Catheterization data after BPV	
Right ventricular pressure, mmHg	61.87 ± 27.97
Pulmonary artery pressure, mmHg	26.84 ± 8.61
Post pressure gradient, mmHg	34.92 ± 27.11
Balloon-PV annulus ratio	1.08 ± 0.17
Successful	288 (76.4%)
Redo or surgery cases	83 (22.0%)

PV=Pulmonary valve, BP=Balloon pulmonary valvuloplasty, mm=Millimeter, SD=Standard deviation, kg=kilogram
Values are expressed as frequency with percentage or mean ± SD.

TABLE 2: The total samples (N=377) were further classified according to age groups as: neonates and early infancy, infants, and children. Here males predominated in all groups. Pre-intervention right ventricular pressures were highest in children (121.48 ± 44.25 mmHg) compared to neonates (99.23 ± 36.64 mmHg) and infants (95.50 ± 27.62 mmHg), and post-intervention pressures decreased across all groups (children 67.63 ± 30.90, neonates 47.80 ± 16.18, infants 54.70 ± 20.39 mmHg). All groups showed a reduction in these pressures after the procedure. Success rates were good among all age groups of the

population, children (75.2%), neonates and early infancy (80.0%) and infants (77.7%). Redo intervention or surgery was needed most often in neonates (46.7%), decreasing with age to 23.1% in infants and 18.1% in children (TABLE-2).

TABLE 2. **Demographic data and parameters across three age groups: neonates and early infancy, infants, and children (N=377).**

Parameter studied	**Neonates and early infancy, Mean ± SD or n (%)**	**Infants, Mean ± SD or n (%)**	**Children, Mean ± SD or n (%)**
Percentage of different Age groups	30 (7.9%)	121 (31.8%)	226 (59.9%)
Mean age according to age groups (in days/month/years)	64.73 ± 24.72 days	11.86 ± 5.77 M	8.79 ± 4.75 Y
Gender			
Male	18 (60.0%)	74 (61.2%)	139 (61.5%)
Female	12 (40.0%)	47 (38.8%)	87 (38.5%)
Weight in kg	4.36 ± 0.85	7.89 ± 5.10	25.42 ± 15.68
PV annulus before	10.15 ± 4.40	10.78 ± 4.00	14.16 ± 3.62
Catheterization data before BPV			
Right ventricular pressure	99.23 ± 36.64	95.14 ± 27.78	121.48 ± 44.25
Pulmonary artery pressure	19.57 ± 5.93	21.44 ± 11.95	23.24 ± 8.85 (n=225)
Pre-pressure gradient	79.67 ± 35.76	73.69 ± 31.75	98.06 ± 45.18 (n=225)
Catheterization data after BPV			
Right ventricular pressure	47.80 ± 16.18	54.40 ± 20.54	67.63 ± 30.90
Pulmonary artery pressure	24.13 ± 6.31	25.65 ± 8.08 (n=119)	27.83 ± 9.01 (n=225)
Post pressure gradient	23.67 ± 15.90	28.67 ± 20.21	39.70 ± 30.23 (n=225)
Balloon-PV annulus ratio	1.04 ± 0.12	1.10 ± 0.19	1.08 ± 0.16
Successful	24(80.0%)	94 (77.7%)	170 (75.2%)
Redo or surgery cases	14 (46.7%)	28 (23.1%)	41 (18.1.7%)

BPV= Balloon pulmonary valvuloplasty

Values were expressed in frequency with percentage and mean±SD.

TABLE 3: Among the 377 pediatric population 238 (63.1%) had no associated cardiac anomalies. Among those with identified lesions, atrial septal defect (ASD) was the most frequently observed isolated lesion, affecting 40 (10.6%) patients, followed by isolated tetralogy of Fallot (TOF) in 20 (5.3%) and S/P TOF repair residual PS 13 (3.5%) in patients. Combined lesions were also observed.

TABLE 3. **Associated cardiac anomalies obtained by echocardiography before balloon pulmonary valvuloplasty among participants (N=377).**

Lesion	Number	Percentage
ASD	40	10.6
ASD + PDA	3	0.8
ASD + VSD	2	0.5
ASD + VSD + PDA	19	5.0
PDA	13	3.6
PDA + VSD	21	5.6
TOF	20	5.3
VSD	8	2.1
S/P TOF repair residual PS	13	3.5
No associated anomalies present	238	63.13

ASD=Atrial septal defect, VSD=Ventricular septal defect, PDA=Patent ductus arteriosus, TOF=Tetralogy of Fallot, TR=Tricuspid regurgitation, PR=Pulmonary regurgitation

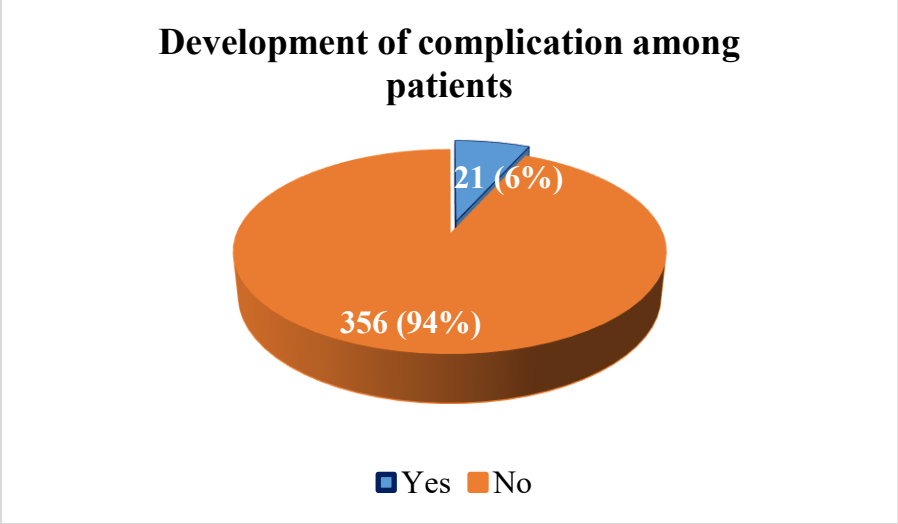

FIG. 1. **Development of complications among participants after ballon pulmonary valvuloplasty (N=377).**

Only 6% of patients developed complications among all participants making the treatment successful for pulmonary stenosis patients.

TABLE 4: This table presented the relationship between various factors and treatment success, now with PV annulus data available for all. Age, sex, and weight showed no significant association with the outcome. The right ventricular (RV) pressure before intervention retained a significant negative relationship, with lower RV pressure associated with better outcomes (p=0.002). The balloon-valve ratio also emerged as a significant predictor in this expanded analysis (p=0.042). The multivariate logistic regression analysis assessed potential predictors of intervention outcomes, but no variables reached statistical significance.

TABLE 4. **Multivariate logistic regression model to explore predictors of success of catheterization intervention.**

	OR	95% CI for OR	p value
Age	1.071	0.940-1.219	0.302
Sex	1.222	0.683-2.189	0.499
Weight	0.987	0.944-1.031	0.555
PV diameter measured by cath	1.046	0.965-1.134	0.276
Balloon-valve ratio	0.015	0.000-0.851	0.042
RV pressure before intervention	0.988	0.980-0.996	**0.002**

PV=Pulmonary valve; RV=Right ventricle, CI=confidence interval; OR=odds ratio

No statistically significant associations were observed for age, gender, weight or balloon size.

TABLE 5. **Multivariate logistic regression model to explore predictors of complications.**

	OR	95% CI for OR	p value
Age	1.183	0.874-1.600	0.276
Gender	1.973	0.798-4.878	0.141
Weight	0.931	0.819-1.059	0.279
PV diameter measured by echo	0.961	0.842-1.095	0.548
Balloon size	0.92	0.823-1.040	0.191
RV pressure before intervention	0.898	0.827-0.976	0.011
Immediate drop of RV pressure difference after intervention	1.098	1.006-1.199	0.036

PV=Pulmonary valve; RV=Right ventricle, CI=confidence interval; OR=odds ratio

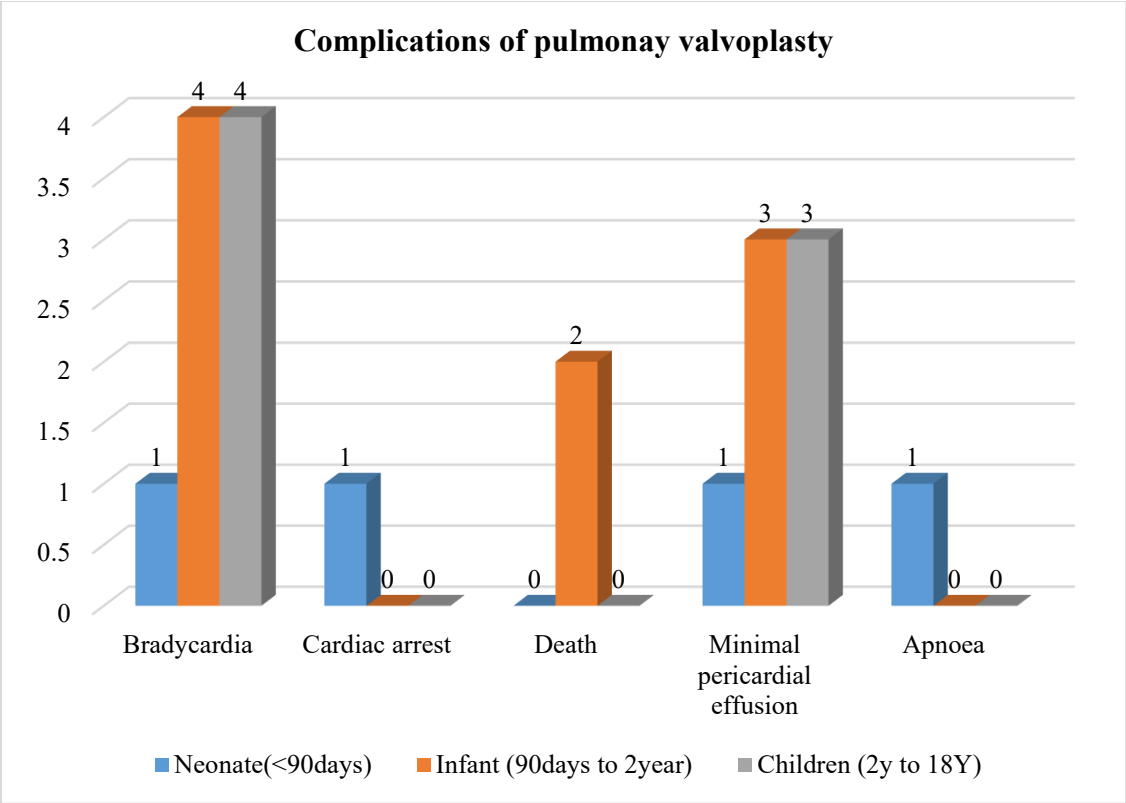

FIG. 2. **Complications after BPV among different age groups.**

Among the 21 participants who developed complications, bradycardia (n=9) and minimal pericardial effusion (n=7) were the most frequent, occurring almost equally among infants and children. However, among the neonates, one patient experienced cardiac arrest and another developed apnea; both patients responded to appropriate management in the post-intensive cardiac care unit (PICU). Two deaths were recorded among the infants. Both patients were critically ill before the intervention and had severe right ventricular failure. Therefore, palliative balloon valvuloplasty was performed; unfortunately, both patients died in the PICU despite appropriate post-procedural management.

6. Discussion

The pulmonary valve dilatation by a percutaneous balloon is the method of choice for treatment of pulmonary valve stenosis in pediatric populations. It is an effective and safe method, with low mortality and morbidity [7-8]. In our study, isolated pulmonary stenosis (PS) was observed in 63.1% of patients, whereas 36.9% had associated cardiac anomalies. Among the associated cardiac lesions, atrial septal defect (ASD) was the most frequently observed, accounting for 10.6% of cases, followed by isolated tetralogy of Fallot (TOF) in 5.3% and residual pulmonary stenosis (PS) following TOF repair in 3.5% of patients. In a study by Convertino VA et.al pulmonary stenosis was commonly associated with other congenital heart defects, affecting 25% to 30% of patients [2]. PS may also occur as part of complex congenital lesions (i.e., tetralogy of Fallot, complete atrioventricular canal, double outlet RV, univentricular heart) [9].

From the point of view, in our study, mean right ventricular pressure was (111.38 ± 41.05 mmHg pre-BPV to 61.87 ± 27.97 mmHg post-BPV) and in the pressure gradient across the pulmonary valve (88.87 ± 42.15 mmHg pre-BPV to 34.92 ± 27.11

mmHg post-BPV). In a study by Li H et.al peak right ventricular pressure gradient declined from 112.0 ± 21.0 to 50.4 ± 15.9 mmHg (P < 0.001) [10]. In the study of Petersen et al. the mean peak to peak pulmonary valve pressure gradient dropped from 66.2 ± 21.4 to 21.5 ± 15.9 mmHg after BPV [11]. Our study showed similar result where pressure gradient dropped significantly. Our study demonstrated an overall procedural success rate of 76.4%. In our neonatal group success rate was high (80%). Our success rate is comparable to that of Ahmadi and Sabri, who reported an immediate dilation success rate of 77% [12]. One study from Iran also found 77% of their patient has residual catheter gradient <36 mmhg [13]. Tynan et al, reported balloon pulmonary valvuloplasty successfully performed to neonates with critical pulmonary stenosis [14]. This is also comparable with our study. Our findings and the results of previous studies indicated the effectiveness of balloon pulmonary valvuloplasty in the treatment of pulmonary valves.

Repeat intervention or surgical intervention was required in 22.0% of cases in our study. One postoperative tetralogy of Fallot (TOF) patient required right ventricular outflow tract (RVOT) stent implantation because a significant residual gradient persisted despite repeat balloon dilatation. Another patient subsequently required transcatheter pulmonary valve replacement due to severe residual pulmonary stenosis with regurgitation with right sided chamber dilatation. Larry A reported that approximately 15%-30% of patients with an initially successful balloon pulmonary valvuloplasty show evidence of significant residual or recurrent right ventricular outflow tract obstruction within 1-2 years [15]. So the initial success does not guarantee that the pressure gradient will remain the same, as most of the studies reported that.

Palliative pulmonary valvuloplasty was performed in 25 (6.6%) patients with significant right ventricular (RV) dysfunction, dysplastic valves and when there is associated severe tricuspid regurgitation. Following the procedure, improvement in RV function and tricuspid regurgitation was observed in 17 (4.5%) patients.

The overall complication rate in our study was 6%. Two patients (0.53%) died, while major complications occurred in four cases (1.0%). The Valvuloplasty and Angioplasty of Congenital Anomalies (VACA) registry analyzed the outcomes of 822 BPVs undertaken at 26 institutions and found death rate of 0.24 % and major complication rate of 0.35 % [16]. The results were almost identical to those reported in the previous study.

Our study revealed the right ventricular (RV) pressure before intervention retained a significant negative relationship, with lower RV pressure associated with better outcomes (p=0.002). The balloon-valve ratio also emerged as a significant predictor in this expanded analysis (p=0.042). But age, sex had no impact on success. Mendelsohn et al. who found no significant difference in these parameters between successful and unsuccessful balloon pulmonary valvuloplasty groups by comparing the age or weight. However, Mendelsohn et al. observed that the successful balloon pulmonary valvuloplasty group had significantly lower pre balloon pulmonary valvuloplasty gradients and lower systolic pressure ratios than the unsuccessful balloon pulmonary valvuloplasty group [17].

7. Conclusion

Balloon pulmonary valvuloplasty is the treatment of choice for pulmonary valve stenosis in all age groups. Overall, BPV appears to be an effective and relatively safe minimally invasive treatment for pediatric pulmonary stenosis, providing substantial immediate hemodynamic benefit with low major complication and mortality rates.

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