

## CASE REPORT

# Outcomes of percutaneous balloon pulmonary valvuloplasty in congenital pulmonary valve stenosis

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## Funding information

This study did not receive any financial support from external sources

## Abstract

Percutaneous balloon pulmonary valvuloplasty (PBPV) is the primary treatment for pulmonary valve stenosis (PVS). The study consisted of 228 children with PVS who underwent PBPV from January 2004 to October 2019 at a single center. The risk factors for  $\geq$ moderate pulmonary regurgitation (PR), residual stenosis, and restenosis were analyzed based on the baseline patient characteristics and measured value of corresponding inspection results. Among 228 patients, follow-up results were obtained in 193 patients. The univariate analysis demonstrated that young age, low weight, small pulmonary annulus diameter, higher initial RV-PA PSEG, increased RV/systemic pressure ratio, and severe PVS were associated with  $\geq$ moderate PR. The multivariate analysis demonstrated that higher initial RV-PA PSEG and low weight were independently associated with  $\geq$ moderate PR, while higher initial RV-PA PSEG was independently associated with residual stenosis and restenosis. PBPV is a preferred treatment in PVS children with a higher success rate. Higher initial RV-PA PSEG was a significant factor for  $\geq$ moderate PR, residual stenosis, and restenosis.

## KEYWORDS

pediatric, percutaneous balloon pulmonary valvuloplasty, pulmonary valve stenosis

## 1 | INTRODUCTION

Pulmonary valve stenosis (PVS) is a typical congenital heart disease that represents approximately 8%–10% of cardiac birth defects.<sup>1</sup> The prevalence seems to be steadily increasing over time. Pulmonary stenosis can be valvular, sub-valvular (infundibular), or supra-valvular. Valvular stenosis is by far the most common form.<sup>2</sup> Percutaneous

balloon pulmonary valvuloplasty (PBPV) was first reported by Kan et al. in 1982.<sup>3</sup> Since then, several other studies reported successful application of this technique to treat patients with PVS. They focused on the feasibility, safety, effectiveness, and practicality of PBPV.<sup>4–7</sup> However, these studies were restricted to youths or adults. Thus, our study focused on a retrospective analysis of the pediatric population. In this study, the risk factors of  $\geq$ moderate

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pulmonary regurgitation (PR) and pulmonary restenosis were emphatically analyzed.

## 2 | MATERIALS AND METHODS

### 2.1 | Study population

We presented a retrospective study of 228 PVS children who underwent PBPV at the Cardiology Department of Children's Hospital of Chongqing Medical University from January 2004 to October 2019. All participants in this study were diagnosed with isolated PVS using echocardiography. PVS patients accompanied by patent foramen ovale (PFO), patent ductus arteriosus (PDA), atrial septal defects (ASDs), or ventricular septal defects (VSDs) without hemodynamic compromise were included. Patients with other complex congenital cardiac defects including double-outlet right ventricle, transposition of the great arteries, tetralogy of Fallot, and other heart diseases with hemodynamic compromise were excluded. The study protocol was approved by the Ethics Committee of Children's Hospital of Chongqing Medical University.

### 2.2 | Definition

In this study, quantitative assessment of PVS severity was based mainly on the transpulmonary pressure gradient.<sup>8</sup> Pulmonary stenosis severity was defined based on the 2006 ACC/AHA guidelines on the management of valvular heart disease.<sup>9</sup> The accompanying PR is graded as mild, moderate, or severe.<sup>10</sup>

### 2.3 | Data collection

Patient and procedural data were retrospectively collected from the electronic patient database at the Pediatric Cardiology Department of Children's Hospital of Chongqing Medical University from January 2004 to October 2019. All patients completed the preoperative routine examinations, including blood routine, biochemistry, coagulation time, hepatic and renal function, arterial blood gas, 12-lead electrocardiogram (ECG), chest radiography, abdominal ultrasound, transthoracic echocardiography (TTE), cardiac catheterization, and angiography.

### 2.4 | Echocardiographic data

Standard M-mode and two-dimensional echocardiographic views in addition to color Doppler and

continuous-wave Doppler were carried out to examine the velocity flow and morphology of the pulmonary valve, peak PVS gradient, right ventricular dimensions, regurgitation of tricuspid and pulmonary valve in addition to its degree, and systolic and diastolic functions of the left ventricular. Using the simplified Bernoulli equation ( $\Delta p = 4v^2$ ), the maximum peak instantaneous systolic pressure gradient was estimated from the transpulmonary flow velocity curve.

### 2.5 | Cardiac catheterization and angiography

Venous access was usually achieved via the femoral vein and where the pig tail or balloon floating catheter is inserted for right cardiac catheterization. All procedures were performed with a single balloon. The data acquired from initial PBPV cardiac catheterization and postoperative reports included right ventricular (RV) systolic pressure, pulmonary artery (PA) systolic pressure, RV-PA PSEG, and systemic systolic blood pressure.

### 2.6 | Statistical analysis

All statistical tests were performed using SPSS version 23.0. Categorical variables are expressed as frequency with percentage, while continuous variables are expressed as mean and median with interquartile range (IQR). The chi-square or Fisher's exact test was used to compare the categorical variables. The Wilcoxon rank-sum test was used to compare the continuous variables between different groups. Logistic regression analysis was performed to identify the independent risk factors of PR severity and restenosis while adjusting for potential confounding variables. The odds ratios (ORs) and 95% confidence intervals (CI) were obtained. Freedom from repeat PBPV or surgical intervention was evaluated using the Kaplan-Meier curve. Statistical significance was defined as a *p* value of <0.05.

## 3 | RESULTS

### 3.1 | Patients' baseline characteristics

Among the 228 participants, except for 35 patients without follow-up data, the remaining 193 patients had a mean age at initial PBPV of 2.56 years (median: 1.58 years, IQR: 11 months–3.13 years, range: 21 days–14.25 years), mean weight at initial PBPV of 12.80 kg (median: 11 kg, IQR: 9–15 kg, range: 2.24–55 kg), mean

height at initial BPV of 79.21 cm (median: 75 cm, IQR: 68.75–84 cm, range: 46–159 cm), mean BSA at initial BPV of 0.474 m<sup>2</sup> (median: 0.437 m<sup>2</sup>, IQR: 0.384–0.485 m<sup>2</sup>, range: 0.162–1.376 m<sup>2</sup>), mean initial peak echocardiographic PVS gradient of 60.66 mmHg (median: 53 mmHg, IQR: 41.99–73.62), and mean initial RV-PA PSEG of 54.58 mmHg (median: 49 mmHg, IQR: 33–66.25). The mean RV-PA PSEG post-valvuloplasty was 19.19 mmHg (median: 14 mmHg, IQR: 9–22.5 mmHg), mean initial RV/systemic pressure ratio was 0.82 (median: 0.71, IQR: 0.60–0.94), and mean RV/systemic pressure ratio post-valvuloplasty was 0.47 (median:

0.42, IQR: 0.35–0.52). The mean balloon/annulus ratio was 1.23 (median: 1.20, IQR: 1.20–1.25). The average pulmonary annulus diameter was 12.35 mm (median: 12.3 mm, IQR: 10.2 mm–14.08 mm) measured by angiography. (Table 1, Figure 1).

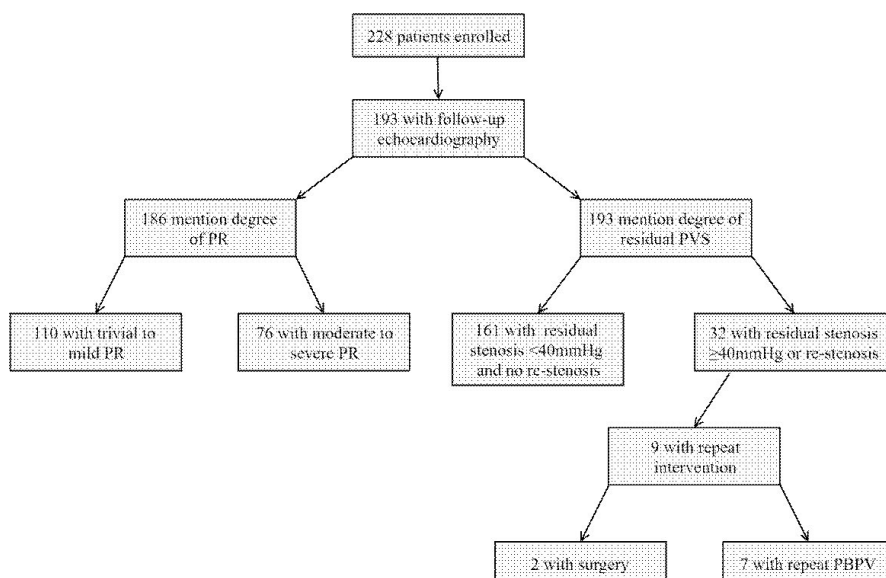
### 3.2 | Immediate results of percutaneous balloon pulmonary valvuloplasty

All 193 patients with follow-up data had preoperative and postoperative cardiac catheterization results.

**TABLE 1** Patients' baseline characteristics

Variable	Mean (median, IQR)
Age (years)	2.56 (1.58, 0.96–3.13)
Weight (kg)	12.8 (12.8, 9–15)
Height (cm)	79.21 (75, 68.75–84)
BSA	0.474 (0.437, 0.384–0.485)
Peak echocardiographic PVS gradient (mm Hg)	60.66 (53, 41.99–73.62)
RV to PA peak catheter gradient (mm Hg)	54.58 (49, 33–66.25)
RV/systemic pressure ratio	0.82 (0.71, 0.60–0.94)
Pulmonary annulus diameter (mm)	12.35 (12.3, 10.2–14.08)
Balloon/annulus ratio	1.23 (1.20, 1.20–1.25)
	<i>N</i> (%)
Male gender	99 (51.30%)
Critical PVS	56 (29.02%)
Clinical symptoms	52 (26.94%)

Note: *N* = 193 patients. Data are presented as mean (median, interquartile range) for continuous variables and number of patients (percentage) for categorical variables.



**FIGURE 1** Flow diagram of PBPV patient outcomes. Notes. Of 228 patients, 193 had available follow-up echocardiography results, 32 had residual PVS of  $\geq 40$  mmHg, 9 had repeat intervention (7 had repeat PBPV; 2 had surgery), 76 had  $\geq$  moderate PR and 0 had pulmonary valve replacement

TABLE 2 Immediate results of percutaneous balloon pulmonary valvuloplasty measured by cardiac catheterization

Hemodynamic parameter	Before PBPV	After PBPV	<i>p</i> value
RVSP (mmHg)	77.23 (71, 56–91)	43.81 (40, 33.5–48)	<0.01
SPAP (mmHg)	22.40(22, 19–26)	24.27 (24, 21–27)	<0.01
RV-PA PSEG (mmHg)	54.84 (49, 33–67)	19.50 (14, 9–23)	<0.01

Note: : RVSP: right ventricular systolic pressure, SPAP: systolic pulmonary artery pressure, RV-PA PSEG: RV-PA peak systolic ejection gradient.

Immediately after PBPV, the right ventricular (RV) systolic pressures reduced significantly from 77.23 mmHg (median: 71 mmHg, IQR: 56–91 mmHg) to 43.81 mmHg (median: 40 mmHg, IQR: 33.5–48 mmHg), the pulmonary artery (PA) systolic pressure increased from 22.40 mmHg (median: 22 mmHg, IQR: 19–26 mmHg) to 24.27 mmHg (median: 24 mmHg, IQR: 21–27 mmHg), and RV-PA PSEG reduced significantly from 54.84 mmHg (median: 49 mmHg, IQR: 33–67 mmHg) to 19.50 mmHg (median: 14 mmHg, IQR: 9–23 mmHg) (Table 2). Immediate success was defined as a pulmonary gradient of <40 mmHg after PBPV, and the immediate success rate was 89.6%.

TABLE 3 Follow-up echocardiographic data

Variable	<i>N</i> (%)
Pulmonary regurgitation	
None	7 (3.63%)
Trivial to mild	110 (56.99%)
Moderate to severe	76 (39.38%)
Tricuspid regurgitation	
Mild	136 (70.47%)
Mild to moderate	51 (26.42%)
Moderate to severe	6 (3.11%)
RV size	
RV dilation	94 (48.7%)
Normal RV	99 (51.3%)
	<b>Mean ± SD</b>
Pulmonary transvalvular peak gradient (mmHg)	
1 months	29.08 ± 13.61
3 months	26.49 ± 14.59
6 months	22.00 ± 13.12
1 year	21.34 ± 9.51
2 year	16.98 ± 10.88
3 year	19.50 ± 9.33
5 year	18.64 ± 10.38
6 year	17.92 ± 11.65
7 year	16.00 ± 7.00
8 year	17.42 ± 13.55

Note: *N* = 193 patients. Data are presented as mean ± SD for continuous variables and number of patients (percentage) for categorical variables.

## 4 | FOLLOW-UP

### 4.1 | Echocardiographic results

In most patients with recent echocardiogram reports, 186 (96.4%) had PR and 7 (3.6%) were free from PR. None of the patients had absence of tricuspid regurgitation (TR), 136 (70.5%) had mild TR, 51 (26.4%) had mild-to-moderate TR, 4 (2.1%) had moderate TR, 1 (0.5%) had moderate-to-severe TR, and 1 (0.5%) had severe TR. Nearly half of the cohort (48.7%) had RV dilation, and 99 (51.3%) had normal RV size on most recent echocardiogram reports, some had significant right ventricular enlargement at the beginning, but the extent of the enlargement gradually diminished during follow-up. In follow-up, the pulmonary transvalvular peak gradients were dropped obviously. (Table 3).

### 4.2 | Risk factors for ≥moderate pulmonary regurgitation

Among the 193 patients who had follow-up echocardiography results, PR occurred in 186 patients, including 110 with mild PR and 76 with moderate to severe PR.

Univariate analysis results demonstrated that patients with ≥moderate PR during follow-up had a younger age, shorter height, lower weight, and smaller body surface area at the time of initial PBPV ( $p < 0.05$ ). Moreover, patients in this group were inclined to have a smaller pulmonary annulus diameter at baseline, higher RV-PA PSEG, and increased RV/systemic pressure ratio ( $p < 0.05$ ). Severe PVS will more likely result in ≥moderate PR ( $p < 0.05$ ), while no significant difference was observed between the balloon and annulus ratio (1.20 (IQR: 1.20–1.25) and 1.24 (IQR: 1.20–1.30),  $p > 0.05$ ). Of the 76 patients with ≥moderate PR, 11 (14.5%) presented with pulmonary artery valve dysplasia or abnormal valve morphology, of whom 7 had pulmonary valves with two lobes and 4 had pulmonary valves with dysplasia. (Table 4).

Multivariate analysis results illustrated that low weight (OR: 0.668, 95% CI: 0.518–0.862) and higher initial RV-PA PSEG (OR: 1.017, 95% CI: 1.003–1.031) were independent risk factors for ≥moderate PR ( $p < 0.05$ ) (Table 5).

### 4.3 | Residual stenosis and restenosis during follow-up

Among 193 patients with follow-up data, 32 (16.6%) had residual stenosis following initial PBPV or restenosis during follow-up, of whom 9 required re-intervention. The other 9 children underwent re-intervention including 7 who underwent repeat PBPV at an average of 2.12 years (range: 6 months to 5 years) after initial PBPV, and 2 children underwent surgical intervention at 6 months and 1.33 years after initial PBPV (Figure 2).

### 4.4 | Risk factors for residual stenosis or restenosis

All study participants with follow-up echocardiography were classified into two groups. The first group (83.4%) included patients with a residual stenosis of <40 mmHg after initial PBPV. The other group (16.6%) included patients with residual stenosis after initial PBPV or restenosis of ≥40 mmHg during follow-up, and some of them underwent repeat intervention.

Univariate analysis results showed that the group with residual stenosis or restenosis had younger age, lower weight, and smaller body surface area at the time of initial

PBPV. Moreover, patients in that group had small pulmonary annulus diameter at baseline, higher RV-PA PSEG, and increased RV/systemic pressure ratio ( $p < 0.05$ ). Critical PVS was statistically associated with residual stenosis or repeat intervention, while BAR had no significant association. (Table 6).

Multivariate analysis results showed that higher initial RV-PA PSEG (OR: 1.056, 95% CI: 1.035–1.078) was a significant independent risk factor for residual stenosis after initial PBPV or restenosis of ≥40 mmHg during follow-up ( $p < 0.05$ ) (Table 7).

## 5 | DISCUSSION

Since 1982,<sup>3</sup> PBPV is a primary technique that has been extensively used for PVS treatment. Several studies have discussed the safety, effectiveness, feasibility, and practicality of this technique. We performed a retrospective review of all pediatric population definitively diagnosed with PVS, and all study participants underwent PBPV at our institution. This is one of the largest series to describe the outcomes of the pediatric population diagnosed with PVS after PBPV.

Several studies reported the immediate, short-, intermediate-, and long-term effectiveness and safety of

**TABLE 4** Univariate comparison of baseline characteristics based on degree of PR

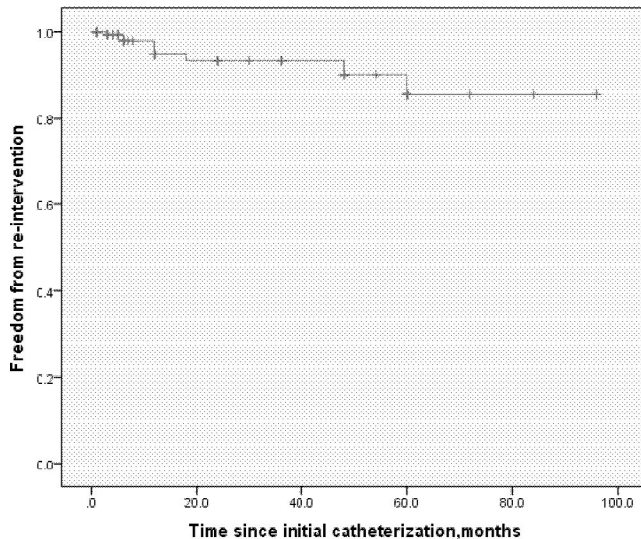
Variable	Trivial to mild PR (N = 110)	Moderate to severe (N = 76)	p value
Age (years)	1.33 (1.04–2.34)	0.82 (0.53–1.56)	<0.001
Weight (kg)	10 (9.25–13)	8.75 (7.23–10.88)	<0.001
Height (cm)	76 (72–91)	70.5 (65.25–79.75)	<0.001
BSA	0.446 (0.417–0.553)	0.392 (0.347–0.463)	<0.001
RV-PA peak catheter gradient (mm Hg)	49 (32–63)	51 (39.25–83.25)	0.001
RV/systolic pressure ratio	0.71 (0.62–0.90)	0.88 (0.65–1.14)	0.001
Pulmonary annulus diameter (mm)	12 (10.15–13.20)	10.25 (9.10–12.63)	<0.001
Balloon/annulus ratio	1.2 (1.2–1.25)	1.24 (1.2–1.3)	0.054
Critical PVS	23 (20.91%)	32 (42.11%)	<0.001
Abnormal pulmonary artery valve	6 (5.5%)	11 of the 76 (14.5%)	<0.001

Notes: N = 186 patients. Data are presented as median (interquartile range) for continuous variables and number of patients (percentage) for categorical variables.

**TABLE 5** Multivariate analysis identifying the independent risk factors for ≥moderate PR

Variable	Odds ratio	95% confidence interval	p value
Age (years)	1.33	0.81–2.17	0.261
Weight (kg)	0.67	0.52–0.86	0.002
RV-PA peak catheter gradient (mm Hg)	1.02	1.00–1.03	0.014
Pulmonary annulus diameter (mm)	1.03	0.87–1.34	0.014

Notes: Height, BSA, RV/systolic pressure ratio, and critical PVS were not included in the final multiple logistic regression model due to the collinearity between variables.



**FIGURE 2** Kaplan-Meier curve demonstrating freedom from repeat intervention. Repeat intervention included repeat PBPV, surgery for residual PVS, or pulmonary valve replacement for PR

PBPV in different centers.<sup>11,12</sup> A previous study conducted by Dian Hong et al.<sup>13</sup> reported a restenosis rate of 6.4% (10 of 158) and re-intervention rate of 3.7% (6 of 158) and indicated that PBPV was the primary treatment as it was safe and minimally invasive. Recently, Hansen et al.<sup>14</sup> conducted a multicenter study with the longest follow-up duration of up to 25 years, in this study, 83% of the study patients ( $n = 207$ ) had a significant decrease in PVS after undergoing initial PBPV, while 17% required repeat intervention.

The adverse reactions caused by chronic PR were unclear. In a previous study conducted by Merino-Ingelmo et al.<sup>15</sup> which included 53 patients who underwent PBPV, the majority of patients did not experience PR before the procedure; however, none of the patients showed absence of PR at the end of the study. In a larger study, David M. Harrild et al.<sup>16</sup> showed that severe PR and mild RV dilation occurred after PBPV. In this study, 34% of patients had a PR fraction of  $>15\%$ , and 40% had an RV end-diastolic volume z-score of  $\geq 2$ . However, severe PR or RV dilation rarely occurred. In the latest multicenter research by Hansen et al.<sup>14</sup> which included a larger sample size ( $n = 248$ ), 42% ( $n = 33$ ) of them had  $\geq$ moderate PR. This study indicated that young age, low weight, higher baseline RV-PA PSEG, increased baseline RV/systemic pressure ratio, and critical PVS were the risk factors for higher PR.

Our research showed that 76 (39.4%) of the follow-up patients had  $\geq$ moderate PR. In the multivariate analysis, lower weight and higher initial RV-PA PSEG were independent risk factors for  $\geq$ moderate PR. Although the degree of PR was increasing, it was well tolerated, and none

of our study patients underwent pulmonary valve replacement for severe PR.

Several studies have been conducted to determine the target BAR. In previous studies, the finding that significant PR was uncommon in patients with a BAR of  $<1.4$  support the appropriateness of 1.2 to 1.4 as a target BAR range. In a study by David M. Harrild et al.<sup>16</sup> patients with a smaller pulmonary valve z-score were more likely treated with a larger BAR. However, the results showed that using a BAR of  $>1.4$  was more likely to cause severe PR. Sagar J. Pathak et al.<sup>17</sup> suggested that using a BAR of  $<1.2$  significantly decreased the PR rate than a BAR of  $>1.2$  without affecting the procedure efficacy and increasing the need for repeat intervention for residual PVS. A latest study by Dian Hong et al.<sup>13</sup> showed that the choice of BAR could affect the immediate therapeutic effects and medium-term follow-up results. The BAR they selected was 1.2–1.4, which was widely accepted and has already been widely recommended in some guidelines. Our study showed that BAR was not a risk factor for  $\geq$ moderate PR.

Some limitations exist in the present study. This study had a short follow-up duration, was retrospective in nature, and was conducted at a single center. This study had a relatively short follow-up period after initial PBPV, and the maximum follow-up time was no more than 9 years. The participants were from a single center rather than a multicenter, and a data bias may exist. Due to the retrospective cohort design of this study, the collection of clinical data was inadequate. Notwithstanding, this research can still be used as a reference for future studies. Therefore, with these limitations, a more comprehensive assessment is required for future work.

## 6 | CONCLUSIONS

PBPV is a definitive therapy in the pediatric population with PVS based on its safety, effectiveness, feasibility, and practicality. Although PBPV was effective in relieving PVS with a low risk of residual stenosis and restenosis, there was a considerable risk of moderate and severe PR in the late follow-up. Although PBPV was efficient in alleviating PVS with lower risk of residual stenosis and restenosis, there was still a significant risk of  $\geq$ moderate PR in the late follow-up. Furthermore, PR may be aggravated with time; hence, further studies are essential to explore the mechanism underlying the development of PR.

## ACKNOWLEDGEMENTS

Not applicable. Published with written consent of the patient.

**TABLE 6** Univariate comparison of baseline characteristics for residual PVS gradient  $\geq 40$  mm Hg or restenosis

Variable	Residual PVS gradient <40 mm Hg and no restenosis (N = 161)	Residual PVS gradient $\geq 40$ mm Hg or restenosis (N = 32)	p value
Age (years)	1.25 (0.75–2.67)	1.00 (0.72–1.19)	0.482
Weight (kg)	10 (9–13)	8 (9–10)	0.181
Height (cm)	77 (70–91)	72 (68.88–75)	0.181
BSA	0.447 (0.39–0.562)	0.407 (0.38–0.437)	0.092
RV-PA peak catheter gradient (mm Hg)	42 (32–60)	90.5 (61–115)	<0.001
RV/systolic pressure ratio	0.69 (0.61–0.89)	1.07 (0.88–1.53)	<0.001
Pulmonary annulus diameter(mm)	12.1 (10.2–13.2)	10 (8.9–10.35)	0.007
Balloon/annulus ratio	1.2 (1.2–1.25)	1.2 (1.2–1.33)	0.399
Critical PVS	32 (19.88%)	24 (75%)	<0.001

Notes: N = 193 patients. Data are presented as median (interquartile range) for continuous variables and number of patients (percentage) for categorical variables.

**TABLE 7** Multivariate analysis identifying the independent risk factors for residual PVS gradient of  $\geq 40$  mm Hg or restenosis

Variable	Odds ratio	95% confidence interval	p value
Age (years)	0.66	0.30–1.18	0.317
Weight (kg)	1.23	0.96–1.57	0.101
RV-PA peak catheter gradient (mm Hg)	1.06	1.04–1.08	<0.001
Pulmonary annulus diameter (mm)	0.8	0.60–1.07	0.133

Notes: Height, BSA, RV/systolic pressure ratio, and critical PVS were not included in the final multiple logistic regression model due to the collinearity between variables.

## CONFLICT OF INTEREST

The authors of this article have no conflict of interest with other products or organizations.

## AUTHOR CONTRIBUTIONS

Dan Yin contributed to conception and design, acquisition of data, analysis and interpretation of data, drafting of the article, and manuscript revision. Xiaoyun Wu contributed to conception and design and manuscript revision. Ping Xiang contributed to conception and design and acquisition of data. Yu Zhang contributed to acquisition of data. Jie Tian contributed to analysis and interpretation of data. Tiewei LV contributed to conception and design and manuscript revision. Qijian Yi contributed to conception and design. Mi Li contributed to conception and design and final approval of the version to be published.

## DATA AVAILABILITY STATEMENT

The processed data and material used to support the findings of this study are included within the article, and they can be accessed.

## CONSENT FOR PUBLICATION

Consent for publication.

## ETHICS APPROVAL AND CONSENT TO PARTICIPATE

The study protocol was approved by the Ethics Committee of Children's Hospital of Chongqing Medical University.

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**How to cite this article:** Yin D, Wu X, Xiang P, et al. Outcomes of percutaneous balloon pulmonary valvuloplasty in congenital pulmonary valve stenosis. *Clin Case Rep.* 2021;9:e04705. <https://doi.org/10.1002/ccr3.4705>