ORIGINAL ARTICLE

# Long-Term Outcomes of Percutaneous Balloon Aortic Valvuloplasty: Experience in Single Tertiary Center

Chayamon Suwansumrit, MD[1,2], Khwaunrat Whaidee, MD[1,3], Navaporn Phiphattanatikanunt, MD[1,3], Pornthep Lertsapchareon, MD[1,3]

[1] Division of Pediatric Cardiology, Department of Pediatrics, Faculty of Medicine, Chulalongkorn University, Bangkok, Thailand; [2] Division of Pediatric Cardiology, Department of Pediatrics, Faculty of Medicine, Naresuan University, Phitsanulok, Thailand; [3] Cardiac Center, King Chulalongkorn Memorial Hospital, the Thai Red Cross Society, Bangkok, Thailand

**Background:** Percutaneous balloon aortic valvuloplasty (PBAV) has been introduced as a first-line treatment for congenital aortic valvular stenosis. However, complications such as residual valvular stenosis and valvular regurgitation can occur following PBAV, requiring re-intervention or surgery.

**Materials and Methods:** The present study was a retrospective descriptive study that enrolled 34 patients under the age of 18 with a diagnosis of aortic valvular stenosis who underwent PBAV between 2003 and 2023. Medical records, including patients' demographic data, clinical presentations, echocardiographic reports, and cardiac catheterization reports, were reviewed, collected, and analyzed.

**Results:** Median pre-procedural peak-to-peak systolic pressure gradient (PSG) between left ventricle and aorta was 57 mmHg (IQR 39 to 88) and decreased to the median PSG of 15 mmHg (IQR 10 to 28) after the procedure. Median decremental rate of PSG after procedure in overall patients was 74.3%. A significant association was found between the high reduction rate of PSG and the severity of aortic regurgitation (AR) (p=0.03). Median follow-up time was 35.6 months (range 7.4 to 66.9). At the last follow-up, half of the patients had more than moderate AR. Freedom from moderate and severe AR was 85.5% at one year and 64.3% at five years post-procedure. Overall re-intervention-free rate was 94.1% at one year and 75% at five years.

**Conclusion:** PBAV is an effective and safe treatment for congenital aortic stenosis, resulting in a high survival rate. However, it carries long-term risks of aortic valvular dysfunction, restenosis, and significant regurgitation, often leading to re-intervention. Balancing the minimization of residual stenosis and the avoidance of significant regurgitation is crucial for achieving a favorable long-term outcome.

**Keywords:** Aortic stenosis; Percutaneous balloon aortic valvuloplasty; Aortic regurgitation

Received 29 September 2025 | Revised 23 January 2026 | Accepted 28 January 2026

**J Med Assoc Thai 2026;109(4):308-16**

**Website:** http://www.jmatonline.com

Congenital aortic valve stenosis (AVS) is one of the common acyanotic congenital heart diseases with an incidence of 1.1 to 4.3 per 10,000 live births[1]. The stenosis of the aortic valve increases left ventricular (LV) afterload, which results in impaired LV function, especially in patients with severe or critical AVS who need emergency life-saving intervention.

For decades, percutaneous balloon aortic valvuloplasty (PBAV) has been widely considered a first-line treatment for congenital aortic stenosis in pediatric patients[2]. Even though PBAV was reported to have a higher rate of resultant aortic regurgitation (AR) and re-intervention compared to surgical valvotomy in one study[3], the efficacy in stenosis reduction, hospital mortality, and time-related survival is still comparable to surgery[3,4]. However, complications can occur following PBAV, including residual valvular stenosis and valvular regurgitation, which may necessitate re-intervention, such as repeated transcatheter intervention, surgical aortic valvulotomy, Ross operation, or mechanical valve replacement[2,3,5-15]. Aortic valve regurgitation is the most common sequela following the procedure, with a reported incidence of 11% to 30% in numerous studies[2,3,5-15]. The development of this complication is associated with several recognized risk factors, including age at the time of the procedure, bicuspid aortic valve, and multiple balloon inflations[6,11,15]. Moreover, the severity of AR progresses over time, leading to late re-intervention. The reported rate of late re-intervention ranges from 12% to 44%[8,9,12],

**Correspondence to:**

Whaidee K.

King Chulalongkorn Memorial Hospital, 1873 Rama IV Road, Pathumwan, Bangkok 10330, Thailand.

Phone: +66-2-2564966

Email: Khwaunrat.W@Chula.ac.th

**How to cite this article:**

Suwansumrit C, Whaidee K, Phiphattanatikanunt N, Lertsapchareon P. Long-Term Outcomes of Percutaneous Balloon Aortic Valvuloplasty: Experience in Single Tertiary Center. J Med Assoc Thai 2026;109:308-16.

DOI: 10.35755/jmedassocthai.2026.4.03679

and consequently, the freedom-from-re-intervention rate also decreases over time[2,7-9,11,13,14].

The present study aimed to evaluate the long-term outcome and efficacy of PBAV in the present study center and the factors affecting the complication and requirement of repeated intervention following the procedure.

## Materials and Methods

### Patients

Patients under the age of 18 with a diagnosis of AVS who underwent PBAV at King Chulalongkorn Memorial Hospital between 2003 and 2023 were enrolled in the present study. Medical records, including the patient's demographic data, clinical presentation, echocardiographic report, and cardiac catheterization report, were reviewed and collected with permission from the hospital's dean. Patients with additional levels of aortic stenosis, such as supravalvular or subvalvular aortic stenosis, and patients with univentricular physiology were excluded from the study.

### Pre-procedural evaluation

Aortic valve morphology was determined by echocardiography as normal (tricuspid), bicuspid, and monocuspid. LV systolic function was assessed by ejection fraction and fractional shortening measured in a 2D M-Mode echocardiogram. Left ventricular diameter at the end of diastole (LVIDd) was reported in Z-score based on the patient's body surface area[16]. Aortic valve diameter was measured by inner-to-inner edge measurement of the proximal valve insertion hinge point in parasternal long axis view, and also reported in Z-score.

AVS gradient was measured by peak and mean pressure gradient with continuous flow Doppler in the apical five-chamber view echocardiogram. Significant AVS that required intervention was defined according to the American Heart Association criteria for aortic valvuloplasty: 1) newborns with isolated critical AVS who were ductal dependent or in children with isolated AVS who had depressed LV systolic function, and 2) children with isolated AVS who had a resting peak-to-peak systolic pressure gradient (by catheter) of 50 mmHg or more[17].

The authors classified the AR severity from echocardiography (AR jet width, jet width to LV outflow tract width ratio, aortic leaflets morphology, and LV size) according to criteria defined by the American Society of Echocardiography (ASE): 1) no AR, 2) mild AR, 3) moderate AR, and 4) severe AR[18].

### Cardiac catheterization procedure

PBAV was performed under adequate sedation and local anesthesia in all cases. Vascular access was obtained via the femoral artery, and the aortic valve was approached using a retrograde technique. Systemic unfractionated heparinization was intravenously given at a dose of 50 units per kilogram to all patients after the introducer sheath was inserted. Aortic valve annulus diameter was remeasured by the aortogram or left ventriculogram for balloon size selection. Different balloon brands were utilized depending on availability during the respective time periods, with a maximum balloon diameter-to-annulus diameter ratio (BAR) ranging from 1.0 to 1.2. Balloon lengths ranged from 15 to 40 mm. The shorter balloons were preferentially used in neonates to minimize the risk of injury to the mitral valve or adjacent structures, whereas longer balloons were selected in older children to enhance procedural stability. In the authors' center, rapid ventricular pacing was not performed. Balloon positioning and deployment were instead achieved through manual adjustment and manual inflation. Manual inflation allowed rapid balloon expansion and precise control during inflation, enabling prompt cessation of inflation when no balloon waist was observed. The peak systolic gradient (PSG) between the left ventricle and the ascending aorta was recorded at baseline and immediately after the procedure, and the percentage reduction in PSG was calculated. Procedural success was evaluated using angiography and invasive transvalvular pressure gradient measurements and was defined as achievement of full valve expansion when feasible, or partial expansion with more than 80% aortic valve excursion accompanied by a greater than 50% reduction in transvalvular pressure gradient.

### Post procedural evaluation

An echocardiogram was performed the day after the procedure. Residual gradient across the aortic valve and the degree of AR were recorded.

### Follow-up and re-intervention

All patients' follow-up data were evaluated using echocardiography at their most recent visit or the visit prior to their re-intervention. The authors assessed the residual AS by using peak and mean pressure gradient across the aortic valve and AR regurgitation in the apical five-chamber view by using the jet width to LV outflow tract width ratio. Re-intervention was defined as any additional procedure required either for the residual valvular AS or significant AR, defined

by moderate or severe AR, following the first PBAV, including repeated PBAV, surgical aortic valvotomy, aortic valve replacement (AVR), and Ross operation.

### Ethical approval

Ethical approval was obtained from the Institutional Review Board of Faculty of Medicine, Chulalongkorn University (IRB no. 890/66) and conducted under the Declaration of Helsinki.

### Statistical analysis

Demographic, clinical, and laboratory parameters were recorded. Continuous variables are expressed as median (interquartile range, IQR), while categorical variables are expressed as frequency and percentage. Differences in continuous and categorical variables among four groups were assessed using a Kruskal-Wallis test and chi-square test or Fisher's exact test, respectively. Comparisons of the BAR and the percentage reduction in PSG between the two groups were conducted using the Wilcoxon rank-sum test. Freedom from moderate or severe AR, freedom from any reintervention, and overall survival were estimated using Kaplan-Meier analysis, with group comparisons performed using the log-rank test. Cox proportional hazards regression was used to identify factors associated with reintervention. All reported p-values were two-sided, and a p-value less than 0.05 was considered statistically significant. Statistical analyses were performed using Stata Statistical Software, version 18 (StataCorp LLC, College Station, TX, USA).

## Results

Between January 2003 and December 2023, 34 patients who underwent PBAV at King Chulalongkorn Memorial Hospital were eligible for the study. The median age at the time of procedure was 158 days (IQR 8 to 3,116 days). When categorized by age group, there were 11 neonates (age 0 to 30 days), 10 infants (age 1 to 12 months), 8 children (age 1 to 10 years), and 5 adolescents (age 11 to 18 years). Thirteen patients were presented with clinical symptoms of congestive heart failure, and 76% of these patients were neonates. Eight neonates required prostaglandin infusion for ductal patency and were defined as critical aortic stenosis (cAS). Isolated AVS was presented in most of the patients (82.3%). Associated left-sided heart obstruction was reported in six patients, including five patients with coarctation of the aorta, of whom three were treated by balloon angioplasty in the subsequent cardiac catheterization, and another two were treated surgically. One patient had moderate mitral valve stenosis. Median aortic valve diameter Z-score from echocardiogram was –0.2 (range –1.3 to 1.6). A bicuspid aortic valve was found in most of the participants (25 patients, 73.5%). When compared between age groups, neonates reported significantly impaired LV systolic function with a median left ventricular ejection fraction (LVEF) of 49% and a median left ventricular fractional shortening (LVFS) of 23%. Patient's demographic data and pre-procedural echocardiogram are shown in Table 1.

Cardiac catheterization data from the first PBAV procedure, categorized by age group, are presented in Table 2. No significant differences were observed between the groups, except for the left ventricular to aortic (LV-Ao) gradient, which was higher in older age groups. The median pre-procedural PSG was 57 mmHg (IQR 39 to 88), which decreased to 15 mmHg (IQR 10 to 28) following the procedure. The median percentage reduction in PSG across all patients was 74.3%. When stratified by age group, all groups demonstrated a PSG reduction greater than 70%, except for neonates, who had a median reduction of 51.2%. The median BAR was 1.0 (IQR 0.9 to 1.1).

Post-procedural AR, assessed by transthoracic echocardiography on the following day, showed no AR in 11 patients (33.3%), mild AR in 16 patients (48.5%), moderate AR in five patients (15.2%), and severe AR in one patient (3%). There was no statistically significant association between the BAR and the severity of post-procedural AR (Table 3).

When comparing patients with mild AR or less on the day following the procedure to those with moderate or severe AR, the BAR was not significantly associated with the severity of AR (p=0.38). However, a greater percentage reduction in PSG as measured by cardiac catheterization was significantly associated with increased AR severity (p=0.03), as illustrated in Figure 1.

### Aortic regurgitation following PBAV

Two patients died intraoperatively, and the other 32 patients were available for follow-up analysis. Immediate post-procedural echocardiogram showed one patient (3%) with severe AR, five patients (15.2%) with moderate AR, 16 patients (48.5%) with mild AR, and 11 patients (33.3%) without AR. Median time of follow-up was 35.6 months (range 7.4 to 66.9). The authors found that AR severity progressed over time (Figure 2). On their last follow-up echocardiogram, four patients (12.5%) reported

**Table 1.** Patient demographic and pre-procedural data categorized by age group

| Variable | Total (n=34) | Neonate (n=11) | Infant (n=10) | Children (n=8) | Adolescent (n=5) | p-value |
|---|---|---|---|---|---|---|
| Age (months); median (IQR) | 5.2 (0.06 to 216) | 0.23 (0.06 to 0.26) | 5.2 (2.3 to 5.4) | 93.6 (48 to 114) | 141.6 (142.8 to 216) | |
| Sex; n (%) | | | | | | 0.12 |
| Male | 21 (61.8) | 6 (54.5) | 4 (40.0) | 6 (75.0) | 5 (100) | |
| Female | 13 (38.2) | 5 (45.5) | 6 (60.0) | 2 (25.0) | 0 (0.0) | |
| Body weight (kg); median (IQR) | 4.4 (3 to 20) | 3 (2.4 to 3.3) | 3.8 (3.4 to 6.2) | 18.3 (14.5 to 27.5) | 48 (39 to 64) | <0.01* |
| Height (cm); median (IQR) | 54 (50 to 121) | 50 (48 to 50) | 53 (50 to 60) | 113 (97.5 to 133) | 152 (145 to 160) | <0.01* |
| Genetic disorder; n (%) | 3 (8.8) | 1 (9.1) | 2 (20.0) | 0 (0.0) | 0 (0.0) | 0.67 |
| CHF; n (%) | 13 (38.2) | 10 (90.9) | 1 (10.0) | 2 (25.0) | 0 (0.0) | <0.01* |
| $PGE_1$ infusion; n (%) | 9 (26.5) | 8 (72.7) | 0 (0.0) | 0 (0.0) | 0 (0.0) | NA |
| Inotropic support; n (%) | 11 (32.4) | 10 (90.9) | 0 (0.0) | 1 (12.5) | 0 (0.0) | <0.01* |
| Aortic valve diameter Z-score; median (IQR) | –0.2 (–1.3 to 1.6) | –1.8 (–2.9 to 1.1) | 0.8 (–0.1 to 2.6) | –0.1 (–1.2 to 1.7) | –0.3 (–0.6 to –0.3) | 0.13 |
| Mean AV gradient (mmHg); median (IQR) | 39.5 (24 to 51) | 35 (13 to 42) | 37 (24 to 40) | 51.5 (39.5 to 62) | 47 (36 to 56) | 0.08 |
| Peak AV gradient (mmHg); median (IQR) | 66 (50 to 90) | 56 (21 to 61) | 69.5 (50 to 77) | 94 (69.5 to 123) | 82 (64 to 88) | 0.02* |
| Associated left-sided obstruction; n (%) | 6 (17.7) | 2 (18.2) | 2 (20.0) | 1 (12.5) | 1 (20.0) | 0.98 |
| AR; n (%) | | | | | | 0.21 |
| No AR | 31 (91.2) | 9 (81.8) | 10 (100) | 8 (100) | 4 (80.0) | |
| Mild AR | 3 (8.8) | 2 (18.2) | 0 (0.0) | 0 (0.0) | 1 (20.0) | |
| LVEF (%); median (IQR) | 71.5 (48 to 79) | 49 (29 to 70) | 77 (66 to 83) | 76 (71.5 to 82) | 76 (48 to 77) | 0.04* |
| LVFS (%); median (IQR) | 40 (23 to 45) | 23 (14.9 to 40) | 43.5 (34 to 48) | 41 (39.5 to 47.5) | 43.5 (24 to 45) | 0.03* |
| LVIDd Z-score; median (IQR) | –1.2 (–1.6 to 0.5) | –0.7 (–1.6 to 1.2) | –0.7 (–1.6 to 0.3) | –0.9 (–1.5 to 0.7) | –1.5 (–2.1 to –1.2) | 0.54 |
| Morphology; n (%) | | | | | | 0.78 |
| Tricuspid | 9 (26.5) | 2 (18.2) | 3 (30.0) | 3 (37.5) | 1 (20.0) | |
| Bicuspid | 25 (73.5) | 9 (81.8) | 7 (70.0) | 5 (62.5) | 4 (80.0) | |

CHF=congestive heart failure; $PGE_1$=prostaglandin E1; AV=aortic valve; AR=aortic regurgitation; LVEF=left ventricular ejection fraction; LVFS=left ventricular fractional shortening; LVIDd=left ventricular internal diameter at end diastole; IQR=interquartile range

**Table 2.** Cardiac catheterization data during the first PBAV categorized by age group

| | Total (n=34) | Neonate (n=11) | Infant (n=10) | Children (n=8) | Adolescent (n=5) | p-value |
|---|---|---|---|---|---|---|
| AV diameter Z-score; median (IQR) | 1.2 (0.2 to 2.1) | 0.1 (–0.8 to 1.2) | 1.9 (0.2 to 3.5) | 1.5 (0.9 to 3) | 0.4 (–0.4 to 1.8) | 0.13 |
| LV-Ao gradient (mmHg); median (IQR) | | | | | | |
| Pre-PBAV | 57 (39 to 88) | 41.5 (27 to 50) | 55 (37 to 81) | 79 (60.5 to 96.5) | 79 (71 to 109) | 0.04* |
| Post-PBAV | 15 (10 to 28) | 20 (10 to 23) | 10 (7 to 15) | 20 (11.5 to 48.5) | 28 (17 to 30) | 0.12 |
| Decremental rate (%); median (IQR) | 74.3 (50 to 82.7) | 51.2 (33.3 to 76.9) | 82.4 (72.2 to 86.2) | 75.6 (38.2 to 82.8) | 74.3 (62 to 76.1) | 0.07 |
| Balloon to annulus ratio; median (IQR) | 1 (0.9 to 1.1) | 1 (0.9 to 1.1) | 1 (0.9 to 1.1) | 1 (0.8 to 1.1) | 1 (0.9 to 1.1) | 0.84 |
| New-onset of AR severity by echocardiogram; n (%) | | | | | | 0.58 |
| No | 11 (33.3) | 2 (20.0) | 2 (20.0) | 5 (62.5) | 2 (40.0) | |
| Mild | 16 (48.5) | 6 (60.0) | 5 (50.0) | 3 (37.5) | 2 (40.0) | |
| Moderate | 5 (15.2) | 2 (20.0) | 2 (20.0) | 0 (0.0) | 1 (20.0) | |
| Severe | 1 (3.0) | 0 (0.0) | 1 (10.0) | 0 (0.0) | 0 (0.0) | |

AV=aortic valve; LV=left ventricle; Ao=aorta; PBAV=percutaneous balloon aortic valvuloplasty; AR=aortic regurgitation; IQR=interquartile range

no or trivial AR, and 12 patients (37.5%) reported mild AR. The number of patients with moderate and severe AR increased over time, as eight patients (25%) reported moderate AR and eight patients (25%) reported severe aortic valve regurgitation. Kaplan-Meier freedom from moderate and severe AR was 85.5% at one year and declined to 64.3% at five years (Figure 3).

### Re-intervention after the first PBAV

Ten patients underwent repeated intervention. Among these, eight patients had residual AS and underwent the second PBAV. One patient underwent surgical aortic valvulotomy 27 days after PBAV due to residual significant AS with severe AR. One patient also had severe AR at the time of follow-up and underwent AVR at 3.6 years following his first

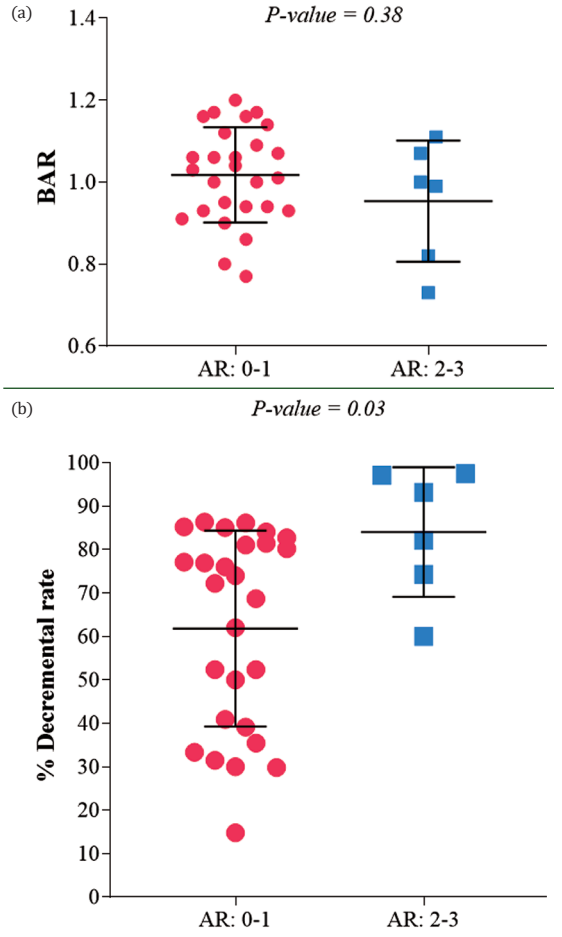


**Figure 1.** (a) Balloon diameter-to-annulus diameter ratio (BAR) and (b) percentage of decremental rate of peak-to-peak systolic gradient compared between patients with mild aortic regurgitation or less and patients with moderate to severe aortic regurgitation. The median was represented by the middle line and the whiskers represented the interquartile range.

AR, aortic regurgitation

**Table 3.** Comparison between balloon to annulus ratio and occurrence of aortic regurgitation at immediate post-catheterization and at the follow-up time

| | Median (IQR) | p-value |
|---|---|---|
| Immediate post catheterization AR severity | | 0.72 |
| No (n=11) | 0.94 (0.96 to 1.16) | |
| Mild (n=16) | 1.03 (0.97 to 1.08) | |
| Moderate (n=5) | 1.00 (0.82 to 1.07) | |
| Severe (n=1) | 0.99 | |
| Follow-up AR severity by echocardiogram | | 0.91 |
| No (n=4) | 0.98 (0.88 to 1.13) | |
| Mild (n=12) | 0.95 (0.86 to 1.11) | |
| Moderate (n=8) | 1.03 (0.94 to 1.09) | |
| Severe (n=8) | 1.01 (1 to 1.05) | |

AR=aortic regurgitation; IQR=interquartile range

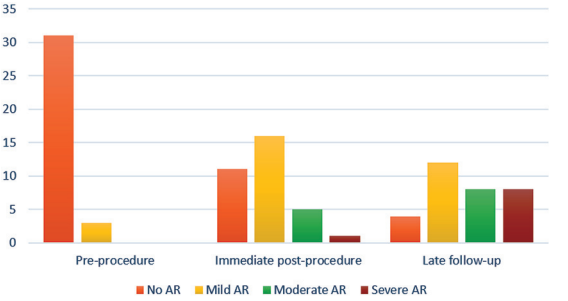


**Figure 2.** Distribution of the degree of aortic regurgitation prior to the procedure and at the time of follow-up among all patients.

AR, aortic regurgitation

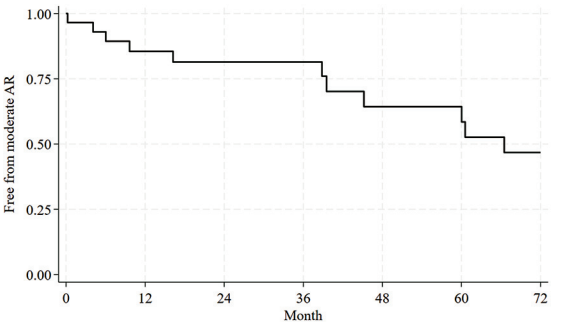


**Figure 3.** Freedom from moderate and severe aortic regurgitation.

AR, aortic regurgitation

PBAV. There was one patient who required Ross operation due to severe AR as a third intervention at 4.2 years following the second PBAV and 5.3 years after the first PBAV.

Overall free-from-reintervention rate analyzed by Kaplan-Meier was 94.1% at one year and 75% at five years in all patients (Figure 4). When comparing patients who underwent the PBAV within the first year of age and after the first year of age, the free-from-reintervention rate were 70.1% and 83.1%, respectively, with no statistical significance (p=0.49). When comparing those who required re-intervention and those who were not by using univariate analysis, we found no significant factor related to increasing risk of re-intervention (Table 4).

## Mortality

Two neonates expired intraoperatively, one neonate died from hospital-acquired sepsis in the same admission, and one patient who died intraoperatively during percutaneous balloon coarctation of the aorta at five days following the first PBAV. All of them

**Table 4.** Univariate analysis of risk factors associated with re-intervention

| Factors | HR (95%CI) | p-value |
|---|---|---|
| Age ≥1 years | 0.62 (0.16 to 2.41) | 0.49 |
| Female | 1.47 (0.42 to 5.13) | 0.54 |
| Body weight | 0.99 (0.05 to 1.03) | 0.64 |
| Genetic disorder | 1.08 (0.14 to 8.51) | 0.94 |
| Congestive heart failure | 0.66 (0.17 to 2.58) | 0.55 |
| Prostaglandin E1 infusion | 0.34 (0.04 to 2.73) | 0.31 |
| Inotropic support | 0.54 (0.11 to 2.53) | 0.43 |
| Echo AV diameter Z score | 1.17 (0.95 to 1.44) | 0.14 |
| Mean pressure gradient at AV* | 1.00 (0.97 to 1.04) | 0.87 |
| Max pressure gradient at AV* | 1.09 (0.98 to 1.02) | 0.89 |
| Left obstruction | 1.07 (0.22 to 5.11) | 0.93 |
| LVEF | 1.00 (0.97 to 1.04) | 0.83 |
| LVFS | 1.01 (0.96 to 1.06) | 0.67 |
| LVIDd Z score | 0.93 (0.63 to 1.36) | 0.71 |
| BAR | 0.48 (0.01 to 46.28) | 0.75 |
| Pre LV-Ao ≥95 | 3.48 (1.0 to 12.12) | 0.050 |
| Valve morphology | 0.99 (0.26 to 3.84) | 0.99 |

AV=aortic valve; LVEF=left ventricular ejection fraction; LVFS=left ventricular fractional shortening; LVIDd=left ventricular internal diameter at end diastole; BAR=balloon diameter-to-annulus diameter ratio; LV=left ventricle; Ao=aorta; HR=hazard ratio; CI=confidence interval

* By echocardiogram

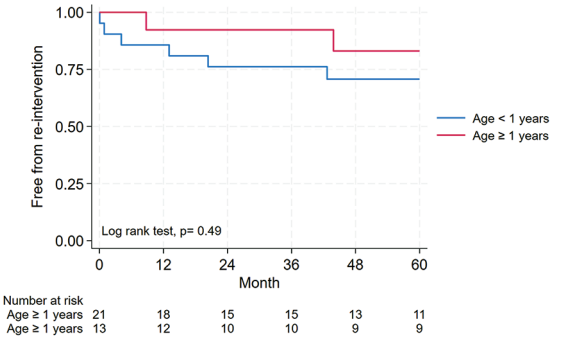


**Figure 4.** Freedom from any reinterventions after the first PBAV compared between age group.

PBAV, percutaneous balloon aortic valvuloplasty

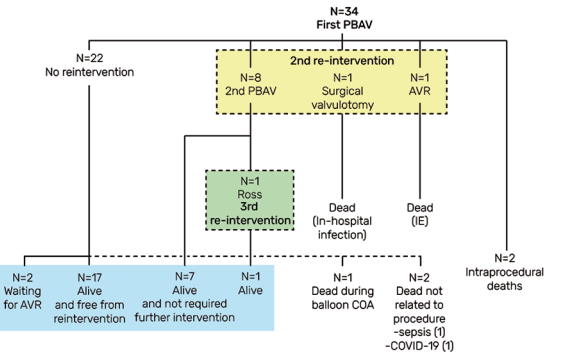


**Figure 5.** Outcomes and re-intervention strategies following initial PBAV.

PBAV, percutaneous balloon aortic valvuloplasty

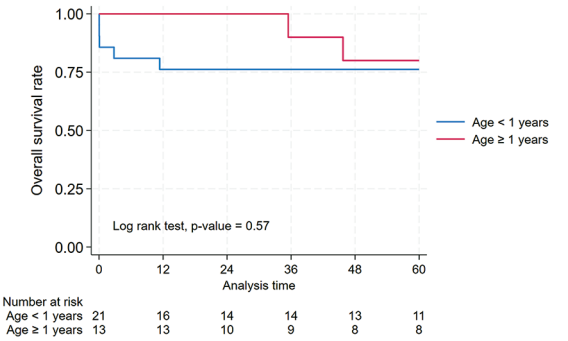


**Figure 6.** Kaplan-Meier survival curve after the first PBAV compared between age group.

were cAS requiring prostaglandin E1 ($PGE_1$) to provide adequate systemic perfusion. Late mortality occurred in three patients due to infective endocarditis at the mechanical aortic valve, severe sepsis following pneumonia, and COVID-19 infection. Therefore, the overall survival rate was 78% (Figure 5, 6).

## Discussion

Over the past decades, with the advancement in techniques and equipment, PBAV has become widely accepted as the first-line therapy for aortic valvular stenosis worldwide. This retrospective study investigated the long-term outcomes following this procedure at a single center. The authors' findings demonstrate that PBAV is an effective treatment for AVS, as evidenced by a significant reduction in post-procedural PSG. These results are comparable to those reported in the existing literature[6-14]. Additionally, all surviving neonates with cAS no longer required $PGE_1$ for ductal patency after the procedure. However, residual AS and new-onset AR developed in some patients, which were the major sequelae following the PBAV, leading to the need for repeated transcatheter or surgical interventions.

When comparing age groups, the authors observed that neonates had more impaired LV systolic function, as measured by LVFS and LVEF, compared to infants and children. This finding correlated with a lower pre-procedural PSG in neonates and can be attributed to two main factors. First, in fetal circulation, the LV does not serve as a systemic ventricle, which makes it poorly adapted to the increased afterload from AVS. Second, this

diminished function leads to a lower initial baseline LV pressure and, consequently, a lower PSG compared to older age groups.

AR is a significant complication following PBAV that tends to worsen over time, often necessitating re-intervention. Sullivan et al. found that patients experiencing moderate or severe AR after the procedure were more likely to need AVR, even when the residual PSG was low[13]. They also noted that acute AR was a stronger predictor of the need for valve replacement than residual stenosis[13]. Similarly, a study from Boston Children's Hospital indicated that the degree of immediate post-balloon AR and residual PSG was crucial in determining the need for further dilation. The authors recommended against additional dilation in cases of significant regurgitation, even if the residual PSG remained high, and instead recommended surgical consultation[5]. In the present study, the authors found that patients with moderate or severe AR post-procedure had a greater reduction in PSG compared to those with less than mild regurgitation. However, the authors did not observe a correlation between significant post-procedural regurgitation and the risk of re-intervention or AVR among the patients. With the median follow-up time of 35.6 months (range 7.4 to 66.9), the authors observed an overall reintervention-free rate of 94.1% in the first year, which decreased to 75% by the fifth year. These results are comparable to findings from other studies[2,7,9,11,12,14]. Factors such as neonatal age, bicuspid valves, additional left-sided heart lesions, high pre- and post-procedural PSG, and immediate AR have been reported as risk factors for re-intervention[13,15]. However, the authors did not identify any significant risk factors for re-intervention among the patients, due to the small sample size. Further studies with a larger cohort may be necessary to identify relevant risk factors.

BAR was rarely found to be associated with an increased risk of new-onset AR post-procedurally. There were studies reported that higher BAR was significantly related to the occurrence and progression of AR severity[19,20], while most studies, with a range of BAR from 0.8 to 1.2, did not find any correlation[4,7-10]. However, the actual mechanism of new-onset AR following PBAV was not clearly identified. Although Rocchini et al. reported perforated aortic valve leaflets and avulsion of cusp tissue from the annulus in two cases who died from severe AR following PBAV, the BAR of both expired cases was 1 and 0.91, respectively, which were comparable to most of the studies[19]. In the present study, the authors calculated the balloon size from the aortic valve annulus diameter demonstrated by real-time angiogram, and the maximum BAR was 1.2. The authors found no correlation between BAR and the progression of AR immediately after the procedure and during follow-up.

The present study's analysis reported seven mortalities, resulting in an overall survival rate of 78% at five years following the procedure, which is slightly lower than the previous studies[2,14]. Focusing on procedure-related deaths, the authors observed that two patients died during the operation. Both were neonates diagnosed with cAS and severely impaired cardiac output. Additionally, one patient died from infective endocarditis at the mechanical aortic valve, which was a repeated surgical intervention following his first PBAV. Therefore, the number of procedural-related deaths in the present study was small. The authors did not identify any risk factors associated with mortality.

## Limitation

The present retrospective study, conducted at a single center with a small number of enrolled patients compared to the previous single-center studies, suggested the need for further research with larger sample sizes or multi-center studies to enhance study outcomes. Additionally, due to the limited number of patients who underwent this operation, data collection spanned a long time period during which different equipment and techniques may have been employed, potentially influencing the results. It is important to note that the present study center utilizes PBAV as the first-line management for congenital aortic stenosis, making it impractical to compare outcomes between transcatheter and surgical valvotomy.

## Conclusion

PBAV is an efficient and safe treatment for congenital aortic stenosis, resulting in a high survival rate. However, it carries long-term risks of aortic valvular restenosis and significant regurgitation, which may necessitate re-intervention, including AVR. Even when the goal of fully reducing stenotic severity is achieved, as evidenced by a significant reduction of the PSG, resultant regurgitation can still occur, leading to the need for further interventions or surgery. These findings emphasize the importance for operators to strike a balance between minimizing residual AS and avoiding significant AR to achieve favorable long-term outcomes.

## What is already known about this topic?

PBAV is the first-line treatment for congenital aortic stenosis, effectively reducing pressure gradients and improving early outcomes. However, it carries risks of AR and re-intervention, particularly in neonates and patients with a bicuspid aortic valve or higher BAR.

## What does this study add?

This single-center study demonstrates the long-term safety and efficacy of PBAV, particularly in neonates and infants with severe aortic stenosis and ductal-dependent systemic circulation. Using balloons sized 1.0 to 1.2 times the annulus with manual inflation, a technique that may affect outcomes, no correlation was found between BAR and AR progression, nor were predictors of re-intervention or mortality identified. These findings support the continued use of PBAV with this technique in this patient population.

## Authors' contributions

CS: Conceptualization, data collection, formal analysis, and writing-original draft preparation. KW: Conceptualization, methodology, and critically revised manuscript. NP: Critically revised manuscript. PL: Critically revised manuscript. All authors read and approved the final manuscript.

## Data availability statement

The datasets used and analyzed during the current study are available from the corresponding author on reasonable request.

## Ethics approval and consent to participate

Ethical approval for this study was obtained from the Institutional Review Board of the Faculty of Medicine, Chulalongkorn University (IRB no. 890/66). The study was conducted in accordance with the ethical standards of the Declaration of Helsinki.

## Clinical trial registration

Not applicable. As this is a retrospective study, clinical trial registration was not required.

## Use of artificial intelligence

The authors declare that no artificial intelligence was used in this study.

## Conflicts of interest

The authors declare no conflict of interest.

## References


1. Hoffman JI, Christianson R. Congenital heart disease in a cohort of 19,502 births with long-term follow-up. Am J Cardiol 1978;42:641-7.
2. Materna O, Tax P, Tomek V, Koubský K, Chaloupecký V, Janoušek J, et al. Long-term results of congenital aortic stenosis treatment in the era of percutaneous balloon valvuloplasty: Up to 33 years follow-up. J Am Heart Assoc 2023;12:e028837.
3. Hill GD, Ginde S, Rios R, Frommelt PC, Hill KD. Surgical valvotomy versus balloon valvuloplasty for congenital aortic valve stenosis: A systematic review and meta-analysis. J Am Heart Assoc 2016;5:e003931.
4. McCrindle BW, Blackstone EH, Williams WG, Sittiwangkul R, Spray TL, Azakie A, et al. Are outcomes of surgical versus transcatheter balloon valvotomy equivalent in neonatal critical aortic stenosis? Circulation 2001;104(12 Suppl 1):I152-8.
5. Porras D, Brown DW, Rathod R, Friedman K, Gauvreau K, Lock JE, et al. Acute outcomes after introduction of a standardized clinical assessment and management plan (SCAMP) for balloon aortic valvuloplasty in congenital aortic stenosis. Congenit Heart Dis 2014;9:316-25.
6. Boe BA, Zampi JD, Kennedy KF, Jayaram N, Porras D, Foerster SR, et al. Acute success of balloon aortic valvuloplasty in the current era: A National Cardiovascular Data Registry study. JACC Cardiovasc Interv 2017;10:1717-26.
7. Varan B, Yakut K, Erdoğan İ, Özkan M, Tokel K. Aortic balloon valvuloplasty and mid-term results in newborns: a single center experience. Turk J Pediatr 2020;62:233-43.
8. Tyc F, Galeczka M, Białkowski J, Kulig K, Fiszer R. Balloon aortic valvuloplasty in neonates: short- and long-term effects and predictors of successful outcome. Postepy Kardiol Interwencyjnej 2022;18:154-61.
9. Charafeddine FA, Houssein HB, Kibbi NB, El-Rassi IM, Tabbakh AM, Abutaqa MS, et al. Balloon valvuloplasty for congenital aortic stenosis: Experience at a tertiary center in a developing country. J Interv Cardiol 2021;2021:6681693. doi: 10.1155/2021/6681693.
10. Torres A, Vincent JA, Everett A, Lim S, Foerster SR, Marshall AC, et al. Balloon valvuloplasty for congenital aortic stenosis: Multi-center safety and efficacy outcome assessment. Catheter Cardiovasc Interv 2015;86:808-20.
11. Brown DW, Dipilato AE, Chong EC, Lock JE, McElhinney DB. Aortic valve reinterventions after balloon aortic valvuloplasty for congenital aortic stenosis intermediate and late follow-up. J Am Coll Cardiol 2010;56:1740-9.
12. Ewert P, Bertram H, Breuer J, Dähnert I, Dittrich S, Eicken A, et al. Balloon valvuloplasty in the treatment of congenital aortic valve stenosis--a retrospective multicenter survey of more than 1000 patients. Int J

Cardiol 2011;149:182-5.
13. Sullivan PM, Rubio AE, Johnston TA, Jones TK. Long-term outcomes and re-interventions following balloon aortic valvuloplasty in pediatric patients with congenital aortic stenosis: A single-center study. Catheter Cardiovasc Interv 2017;89:288-96.
14. Soulatges C, Momeni M, Zarrouk N, Moniotte S, Carbonez K, Barrea C, et al. Long-term results of balloon valvuloplasty as primary treatment for congenital aortic valve stenosis: A 20-year review. Pediatr Cardiol 2015;36:1145-52.
15. Reich O, Tax P, Marek J, Rázek V, Gilík J, Tomek V, et al. Long term results of percutaneous balloon valvoplasty of congenital aortic stenosis: independent predictors of outcome. Heart 2004;90:70-6.
16. Lopez L, Colan S, Stylianou M, Granger S, Trachtenberg F, Frommelt P, et al. Relationship of echocardiographic Z scores adjusted for body surface area to age, sex, race, and ethnicity: The pediatric heart network normal echocardiogram database. Circ Cardiovasc Imaging 2017;10:e006979.
17. Feltes TF, Bacha E, Beekman RH 3rd, Cheatham JP, Feinstein JA, Gomes AS, et al. Indications for cardiac catheterization and intervention in pediatric cardiac disease: a scientific statement from the American Heart Association. Circulation 2011;123:2607-52.
18. Zoghbi WA, Adams D, Bonow RO, Enriquez-Sarano M, Foster E, Grayburn PA, et al. Recommendations for noninvasive evaluation of native valvular regurgitation: A report from the American Society of Echocardiography developed in collaboration with the society for cardiovascular magnetic resonance. J Am Soc Echocardiogr 2017;30:303-71.
19. Rocchini AP, Beekman RH, Ben Shachar G, Benson L, Schwartz D, Kan JS. Balloon aortic valvuloplasty: results of the Valvuloplasty and Angioplasty of Congenital Anomalies Registry. Am J Cardiol 1990;65:784-9.
20. Sholler GF, Keane JF, Perry SB, Sanders SP, Lock JE. Balloon dilation of congenital aortic valve stenosis. Results and influence of technical and morphological features on outcome. Circulation 1988;78:351-60.