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# Long-Term Clinical Follow-Up Results in Patients with Pediatric Valvular Aortic Stenosis: A Single Center Experience

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**Abstract**

**Objective:** This study aimed to evaluate the long-term clinical outcomes of pediatric patients with valvular aortic stenosis (VAS) treated at a single tertiary center, with a focus on the efficacy and safety of balloon aortic valvuloplasty (BAV).

**Materials and Methods:** A total of 450 pediatric patients diagnosed with VAS between 2001 and 2023 were retrospectively reviewed. Clinical, echocardiographic, and angiographic data were analyzed. Among these, 130 patients who underwent BAV for moderate-to-severe or critical stenosis were evaluated in detail. Hemodynamic changes, procedural complications, development of aortic regurgitation (AR), and reintervention rates were recorded.

**Results:** The cohort had a mean age of 120.6 ± 55.8 months, and 74.5% were male. The mean follow-up duration was 5.2 years (range: 1–17 years). The bicuspid aortic valve was the most common morphology (75.5%). Among the 130 patients who underwent balloon aortic valvuloplasty (BAV), the age at angiography was <1 month in 27.6%, 1–12 months in 16.9%, 12–60 months in 16.1%, 60–120 months in 20.7%, and >120 months in 15.3% of cases. BAV resulted in a significant reduction in left ventricular pressure (from 171.6 to 135.2 mmHg) and systolic gradient (from 83.9 to 32.3 mmHg). AR developed in 84.6% of patients post-BAV, but only 2.5% had severe regurgitation. Repeat BAV was required in 10.7% of patients, and 3.2% were referred for surgical intervention. Four neonates with critical of and pre-existing LV dysfunction died.

**Conclusion:** BAV is an effective and minimally invasive intervention for pediatric VAS, offering substantial short- to mid-term relief from obstruction. However, the risks of AR and reintervention warrant careful patient selection and long-term follow-up.

**Keywords** Valvular aortic stenosis · balloon valvuloplasty · follow-up

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## INTRODUCTION

Congenital valvular aortic stenosis (VAS) is a relatively rare yet clinically significant form of left ventricular outflow tract (LVOT) obstruction in pediatric patients, accounting for approximately 3%–6% of all congenital heart defects (1). While mild cases may remain asymptomatic and hemodynamically stable over extended periods, moderate to severe stenosis often progresses, potentially leading to left ventricular hypertrophy, dysfunction, and eventual heart failure (2).

Surgical aortic valve replacement and percutaneous balloon aortic valvuloplasty (BAV) constitute the primary therapeutic strategies for managing congenital VAS. BAV, a minimally invasive intervention, has demonstrated favorable short-term efficacy in alleviating obstruction in pediatric patients (3). However, the existing literature indicates variable long-term outcomes following balloon aortic valvuloplasty (BAV). Freedom from reintervention has been reported as approximately 83% at 10 years and decreases to around 65% at 15 years. Factors influencing these outcomes include valve morphology, patient age at initial intervention, and residual post-procedural gradient. Patients who underwent neonatal intervention or who had depressed baseline left ventricular function exhibited higher reintervention rates (4).

In this study, we aimed to evaluate the long-term follow-up outcomes of pediatric patients with valvular aortic stenosis managed at our institution. The clinical course, post-procedural hemodynamic changes, complications, and the need for reintervention in patients undergoing balloon aortic valvuloplasty (BAV) were analyzed to assess the long-term efficacy and safety of BAV. Our study intends to provide a comprehensive assessment of the clinical progression of pediatric valvular aortic stenosis and clarify the role of BAV in its management.

## MATERIALS AND METHODS

This retrospective study included pediatric patients aged 0–18 years who were diagnosed with valvular aortic stenosis (VAS) and followed at our institution between January 2001 and December 2023. Demographic data (such as age and sex), clinical course, and treatment approaches were reviewed. Patients were categorized into four groups based on the severity of stenosis: mild, moderate, severe, and critical. Among these, patients with moderate-to-severe and critical stenosis who underwent balloon aortic valvuloplasty (BAV) were further evaluated in detail using angiographic records.

The diagnosis of VAS was established by transthoracic echocardiography. Patients with complex congenital heart defects (other than isolated atrial septal defect, ventricular septal defect, or patent ductus arteriosus) or those who underwent cardiac surgery for other indications were excluded from the study.

### Statistical Analysis

The dataset was subjected to analysis using the SPSS (Statistical Package for the Social Sciences) version 26.0 for Windows. The Kolmogorov-Smirnov test was employed to assess the appropriateness of the data for a normal distribution. Continuous variables that adhered to a normal distribution are presented as mean ± standard deviation (SD). Categorical variables are documented as frequency (n) alongside percentage (%). In assessing the differences between groups, the independent samples t-test was applied for data conforming to a normal distribution, while the Mann-Whitney U test was utilized for data that did not conform to a normal distribution.

## RESULTS

### Patient Characteristics

A total of 450 patients diagnosed with VAS were included in the study. The age range was 12 to 228 months, with a mean age of 120.62 ± 55.8 months. The mean age at diagnosis was 42.2 ± 24.3 months (range: 0–192 months). Of the cohort, 74.5% were male (n = 335) and 25.5% were female (n = 115). The mean follow-up duration was 5.2 years (range: 1–17 years). Patients were divided into five age groups based on age at diagnosis: 19.5% were diagnosed at <1 month (n = 88), 20.2% at 1–12 months (n = 91), 24.8% at 12–60 months (n = 112), 20% at 60–120 months (n = 90), and 15.5% after 120 months of age (n = 69) (Table 1).

**Table 1.** Distribution of Patients Diagnosed with Valvular Aortic Stenosis (VAS)

| Variable | | Min–Max | Mean ± SD |
|---|---|---|---|
| Age (months) | | 12–228 | 120.62 ± 55.8 |
| Age at Diagnosis (months) | | 0–192 | 42.2 ± 24.3 |
| | | **n** | **%** |
| **Sex** | **Female** | 115 | 25,5 |
| | **Male** | 335 | 74,5 |
| **Age at Diagnosis** | **0–1 month** | 88 | 19,5 |
| | **1–12 months** | 91 | 20,2 |
| | **12–60 months** | 112 | 24,8 |
| | **60–120 months** | 90 | 20 |
| | **> 120 months** | 69 | 15,5 |

### Initial Echocardiographic Findings

Echocardiography revealed bicuspid aortic valve morphology in 75.5% of the patients, tricuspid in 20.1%, and unicuspid in 4.4%. In terms of stenosis severity, 48% had mild, 32%

moderate, 15.1% severe, and 4.9% critical stenosis. The most common associated anomaly was aortic coarctation (4.4%, n = 20), followed by atrial septal defect or patent foramen ovale (2.2%, n = 10), patent ductus arteriosus (5.9%, n = 27), mitral regurgitation (6.6%, n = 30), and ventricular septal defect (0.9%, n = 4) (Table 2).

**Table 2.** Initial Echocardiographic Findings of the Patients

| | | n | % |
|---|---|---|---|
| **Aortic Valve Morphology** | **Unicuspid** | 20 | 4,4 |
| | **Bicuspid** | 344 | 75,5 |
| | **Tricuspid** | 86 | 20,1 |
| **Severity of Stenosis on Echocardiography** | **Mild** | 216 | 48 |
| | **Moderate** | 144 | 32 |
| | **Severe** | 68 | 15,1 |
| | **Critical** | 22 | 4,9 |
| **Additional Findings** | **Aort Coarctation** | 20 | 4,4 |
| | **ASD/PFO** | 10/45 | 2,2 |
| | **PDA** | 27 | 1 |
| | **MY** | 30 | 6,6 |
| | **VSD** | 4 | 0,9 |

## Angiographic and Procedural Characteristics

Among the 130 patients who underwent balloon aortic valvuloplasty (BAV), the age at angiography was <1 month in 27.6%, 1–12 months in 16.9%, 12–60 months in 16.1%, 60–120 months in 20.7%, and >120 months in 15.3% of cases. Angiography revealed moderate stenosis in 3.8%, severe in 79.2%, and critical in 16.9% (Table 3). The most commonly used vascular access route was the femoral artery (89.2%), followed by the femoral vein (6.1%), umbilical vein (3%), and right axillary artery (1.5%). The balloon used fort he procedure was a Tyshak 2 balloon. The mean annulus/balloon ratio was 1 (range 0.9-1.1). The balloondiameter ranged from 4 to 25 mm (mean: 12.21 ± 4.07 mm), and the balloon length ranged from 20 to 60 mm (Table 4).

## Hemodynamic Outcomes

In patients with moderate-to-severe stenosis, the pre-procedure left ventricular pressure ranged from 70 to 240 mmHg (mean: 171.63 ± 39.52 mmHg) and decreased to 135.25 ± 39.32 mmHg post-procedure. The systolic gradient was reduced from 83.85 ± 25.12 mm Hg to 32.35 ± 22.15 mm Hg after BAV (Table 5).

**Table 3.** Demographic and Procedural Characteristics of Patients Undergoing Balloon Aortic Valvuloplasty (BAV)

| | | N | % |
|---|---|---|---|
| **Age at Angiography** | **0–1 Month** | 36 | 27,6 |
| | **1–12 Months** | 22 | 16,9 |
| | **12–60 Months** | 21 | 16,1 |
| | **60–120 Months** | 27 | 20,7 |
| | **> 120 Months** | 24 | 15,3 |
| **Severity of Aortic Stenosis (at Angiography)** | **Moderate** | 5 | 3,8 |
| | **Severe** | 103 | 79,2 |
| | **Critical** | 22 | 16,9 |
| **Access Route for Balloon Valvuloplasty** | **Femoral Artery** | 116 | 89,2 |
| | **Femoral Vein** | 8 | 6,1 |
| | **UmbilicaL Vein** | 4 | 3 |
| | **Right Axillary Artery** | 2 | 1,5 |
| **Balloon Specifications** | | **Min–Max** | **Mean±SD** |
| **Balloon diameter (mm)** | | 4–25 | 12,21±4,07 |
| **Balloon length (mm)** | | 20-60 mm | |

**Table 4.** Balloon Sizes Used During Valvuloplasty

| Balloon Diameter (mm) | Corresponding Balloon Length (mm) |
|---|---|
| < 10 mm | 20 mm |
| 10-15 mm | 30 mm |
| 15-20 mm | 40 mm |
| > 20 mm | 50-60 mm |

**Table 5.** Hemodynamic Outcomes of BAV in Patients with Moderate-to-Severe Stenosis

| Hemodynamic Parameter | Min–Max | Mean±SD |
|---|---|---|
| **Pre-balloon Left Ventricle (LV) pressure (mmHg)** | 70–240 | 171,63±39,52 |
| **Pre-balloon systolic gradient (mmHg)** | 38–152 | 83,85±25,12 |
| **Post-balloon LV pressure (mmHg)** | 72–208 | 135,25±39,32 |
| **Post-balloon systolic gradient (mmHg)** | 4–143 | 32,35±22,15 |

In cases of critical stenosis, the pre-balloon left ventricular pressure was 72 ± 3.6 mm Hg and decreased to 60.5 ± 9.6 mm Hg post-procedure. The systolic gradient decreased from 31.7 ± 3.2 mm Hg to 12.5 ± 2.0 mm Hg (Table 6). Four newborns with left ventricular dysfunction died—two during the procedure and two in the early post-intervention period. Following BAV, aortic regurgitation was observed in most patients, with mild or moderate regurgitation present in 62% of cases, while only 2.5% developed severe regurgitation (Table 7).

**Table 6.** Outcomes of BAV in Cases with Critical Aortic Stenosis

| Hemodynamic Parameter | Min–Max | Mean±SD |
|---|---|---|
| **Pre-balloon LV pressure (mmHg)** | 50–85 | 72±3,6 |
| **Pre-balloon systolic gradient (mmHg)** | 24-36 | 31,7±3,2 |
| **Post-balloon LV pressure (mmHg)** | 50–78 | 60,5±9,6 |
| **Post-balloon systolic gradient (mmHg)** | 0-21 | 12,5±2 |

Aortic regurgitation (AR) was observed at varying degrees in patients following balloon aortic valvuloplasty (BAV), as summarized in Table 7. Among the 130 patients who underwent BAV, severe AR developed in 3 patients (2.3%), moderate AR in 28 patients (21.5%), mild AR in 52 patients (40.0%), and trivial AR in 27 patients (20.8%). Notably, no AR was detected in 20 patients (15.4%) after the procedure. These findings highlight that while the majority of patients developed some degree of post-procedural AR, severe regurgitation remained infrequent.

**Table 7.** Incidence of Aortic Regurgitation Following BAV

| Degree of Aortic Regurgitation | n | % |
|---|---|---|
| **None** | 20 | 15,5 |
| **Trivial** | 27 | 20 |
| **Mild** | 52 | 40 |
| **Moderate** | 28 | 22 |
| **Severe** | 3 | 2,5 |

During the procedure, transient arrhythmias were observed in 3 of our patients. Supraventricular tachycardia (SVT) developed in 2 patients and non-sustained ventricular tachycardia (VT) in 1 patient. VT regressed spontaneously without compromising hemodynamics without medical treatment. In 2 SVT case, adenosine was administered, and SVT ended with adenosine. Temporary pacing was required during the procedure in 4 adolescent patients. Doppler USG was performed because of femoral artery occlusion in 20% of patients under 1 year of age. Most patients were treated with heparin perfusion. TPA was used in 1 patient. In recent years, low-molecular-weight heparin has begun to be preferred. No major complications were observed after the procedure in our patients who underwent valvuloplasty due to moderate and significant aortic stenosis, except for 4 patients with critical aortic stenosis and those who died.

## Need for Reintervention

Repeat BAV was required in 14 patients (10.7%). Of these, 6 patients (4.6%) underwent repeat intervention before the age of 1 year and 8 patients (6.1%) after 1 year. The interval between procedures ranged from 15 days to 12 months (mean: 5 ± 4.2 months) in the <1-year group and from 6 months to 8 years (mean: 3.8 ± 2.7 years) in the >1-year group. Four patients required a third BAV, including three under 1 year of age and one older than 1 year (Table 8).

**Table 8.** Characteristics of Patients Requiring Repeat BAV

| | Age Group | n | % |
|---|---|---|---|
| **Number of Patients Requiring Repeat Procedure** | <1 year | 6 | 4.6% |
| | ≥ 1 year | 8 | 6.1% |
| | **Age Group** | **Min-Max** | **Mean±SD** |
| **Time to Repeat Valvuloplasty** | <1 year | 15 days to 12 months | 5 ± 4,2 (months) |
| | ≥ 1 year | 6 months to 8 years | 3,8 ± 2,7 (years) |

## Follow-up Status

At the last follow-up, 68% of the patients (n = 306) were being managed medically, 28.8% (n = 130) were under follow-up after BAV, and 3.2% (n = 14) had been referred for surgical intervention (Table 9).

**Table 9.** Follow-up Status of the Patients

| Follow-up Category | n | % |
|---|---|---|
| **Medically managed** | 306 | 68 |
| **Underwent balloon valvuloplasty** | 130 | 28,8 |
| **Referred for surgery** | 14 | 3,2 |

# DISCUSSION

Aortic valve stenosis accounts for approximately 5%–6% of all congenital cardiac anomalies. Its incidence is notably higher among males compared to females. Although the underlying pathology of stenosis demonstrates considerable variability, it most frequently presents as a bicuspid valve characterized by the fusion of the valve commissures. Unicuspid aortic valves are predominantly observed in neonates exhibiting critical obstruction, whereas bicuspid valves are more prevalent during childhood, adolescence, and adulthood (5). The severity of aortic stenosis escalates concomitantly with advancing age.

The objective of managing valvular aortic stenosis in pediatric populations is to maintain the functionality of the left ventricle and avert both acute and chronic complications, notably the risk of sudden mortality (6). Historically, the therapeutic approach to congenital aortic valve stenosis involved surgical valvotomy; however, the introduction of balloon aortic valvuloplasty (BAV) has transformed this paradigm (7,8). BAV has emerged as the primary therapeutic intervention in the management of congenital aortic stenosis (AS) following its introduction into the medical domain (9,10). Recent registry data indicate that the application of balloon aortic valvuloplasty (BAV) has seen a significant rise over the last ten years, as a substantial cohort of high-risk individuals

afflicted with severe aortic stenosis is being evaluated for percutaneous valve intervention methodologies (11-13).

The transvalvular gradient as assessed through echocardiography serves as a critical metric for evaluating the severity of aortic stenosis. Nevertheless, it is noteworthy that the presence of ST-T wave alterations and episodes of syncope, which suggest subendocardial ischemia during exercise testing, signifies that the stenosis is clinically significant and necessitates therapeutic intervention (6). In neonates, the presence of endocardial fibroelastosis and heart failure renders gradient treatment a non-essential criterion (14).

In our study, BAV demonstrated significant efficacy in reducing left ventricular outflow tract obstruction, with a marked decrease in both left ventricular pressure and systolic pressure gradients post-procedure. These findings agree with previous reports showing immediate hemodynamic improvement following BAV in children (15).

However, the development of aortic regurgitation (AR) remains a key concern. In our cohort, moderate-to-severe AR was a common post-procedural complication, in line with prior literature that identifies AR as one of the major long-term adverse outcomes after BAV (15-16).

Despite the fact that balloon valvuloplasty facilitates the immediate alleviation of pressure gradients, it is associated with a spectrum of procedure-related adverse events, including mortality, aortic regurgitation, thrombosis or trauma of the femoral artery, significant hemorrhage, and potentially fatal arrhythmias or other forms of cardiac tissue damage (17-19).

In our series, 10.7% of patients required repeat BAV during follow-up. This rate is comparable to previous studies, which have reported reintervention rates ranging from 10% to 30%, depending on patient age, valve morphology, and the balloon-to-annulus ratio (20).

Long-term data suggest that while BAV provides initial relief of stenosis, there is a progressive need for surgical aortic valve repair or replacement over time, especially in patients with significant residual or recurrent stenosis and/or AR (21).

Our findings also demonstrated a predominance of bicuspid aortic valve morphology (75.5%) among pediatric VAS patients. This is in agreement with the epidemiological data reporting that bicuspid valves are the most common congenital aortic valve anomaly (5).

In addition, the presence of associated congenital heart defects such as coarctation of the aorta, ASD, and PDA was not uncommon, emphasizing the importance of comprehensive evaluation and multidisciplinary management (5).

This study has several limitations. First, its retrospective design carries the risk of selection and information bias. Second, echocardiographic evaluations were performed by multiple clinicians over two decades, introducing potential inter-observer variability. Finally, long-term functional outcomes, including exercise capacity and quality of life, were not assessed and should be addressed in future studies.

Future prospective multicenter studies with standardized protocols are needed to better define which patients will benefit most from BAV and when it should be performed. Research should also focus on improving techniques to reduce post-BAV aortic regurgitation and on using imaging tools to predict restenosis and valve-related complications.

## CONCLUSION

In conclusion, our study supports the use of BAV as an effective and relatively safe first-line intervention for pediatric valvular aortic stenosis. Nevertheless, the potential for significant AR and the need for reintervention underline the importance of individualized treatment strategies and long-term follow-up to ensure optimal outcomes.


| | |
|---|---|
| Ethics Committee Approval | This study was approved by the ethics committee of Istanbul University, Clinical Research Ethics Committee (2025/787). |
| Informed Consent | Written consent was obtained from the participants. |
| Peer Review | Externally peer-reviewed. |
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