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Mid- and long-term outcomes of balloon aortic valvuloplasty in pediatric patients. A single-center experience

Short title: Outcomes of balloon aortic valvuloplasty in pediatric patients

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INTRODUCTION

Since its introduction, balloon aortic valvuloplasty (BAV) has shown good short- and long-term outcomes in isolated congenital aortic stenosis (AS) comparable to surgery [1], making it the preferred treatment in many centers. However, patients undergoing BAV often require reinterventions, and risk factors for suboptimal outcomes remain unclear. We analyzed our single-center experience to assess the mid- and long-term outcomes of BAV and to identify risk factors for suboptimal results.

MATERIALS AND METHODS

Between 1998 and 2023, 170 patients with AS underwent primary BAV at our center. Of these, 117 patients were included in the study; exclusion criteria were neonatal age at the time of the procedure, previous BAV, or complex heart defect. Follow-up data were available for 90 patients (77%) with median follow-up time of 7 years (interquartile range [IQR] 1.0–13 years). Follow-up was collected up to May 31, 2024. Data were obtained from inpatient and outpatient records. The primary long-term endpoint was the need for reintervention. The study protocol was approved by the Local Ethics Committee (approval no. BNW/NWN/0052/KB/152/24).

At our institution, BAV is the preferred treatment for patients with AS who meet widely accepted criteria [2].

The balloon was selected to achieve a balloon-to-annulus ratio between 0.8 and 1.0. If the initial valvuloplasty did not yield satisfactory results (gradient exceeding 35 mm Hg or a gradient reduction <50%) a subsequent valvuloplasty was performed using the same or a 1–2 mm larger balloon. The degree of aortic regurgitation (AR) was assessed using both echocardiography and aortography.

Early procedural success was defined according to previously established criteria [3]. A suboptimal outcome was defined for patients meeting at least one of the following conditions: a residual gradient <35 mm Hg, <50% gradient reduction and more than minor (≥1 grade) change in AR.

Echocardiographic Z-scores were derived from the study by Lopez et al. [4].

Statistical analysis

Statistical analyses were performed using MedCalc (MedCalc Software, Ostend, Belgium). Normality of data distribution was assessed using the Shapiro–Wilk test. Data are presented as median with IQR to account for the non-normal distribution of variables in study group. Quantitative data were compared using Mann–Whitney U for independent samples test or Wilcoxon test for paired samples. Categorical variables were compared using the Pearson χ^2 test or the Fisher’s exact test. Kaplan–Meier survival curves were used to assess survival and freedom from reintervention, with the log-rank test comparing curves between subgroups. Potential predictors of reintervention after BAV were assessed using Cox proportional hazards regression analysis. A two-tailed P <0.05 was considered statistically significant.

RESULTS AND DISCUSSION

Out of the 117 patients included in the study (83% male, n = 97), 61 (52.14%) were infants. The median age was 1 year (IQR 0.17–9 years), and the median weight was 10.9 kg (IQR 5.8–39 kg). The median aortic valve (AV) diameter measured 13 mm (IQR 9.5–19 mm), corresponding to a median Z-score of +1.3 (range +0.4 to +2.5). The AV morphology was predominantly bicuspid in 56 patients (47.9%), tricuspid in 38 patients (32.5%), and undefined in 23 patients (19.7%).

Prior to the procedure, mild AR was observed in 19 patients (16.2%) and moderate AR was identified in one individual.

Vascular access was obtained *via* the femoral artery in 114 patients and the carotid artery in 3 patients. To ensure balloon stability during the procedure, rapid ventricular pacing was used in 37 patients (31.6%), while adenosine injection was administered to 7 patients (6%), particularly in smaller children. After BAV median peak-to-peak gradient decreased from 69 mm Hg (IQR 55–82.5) to 30 mm Hg (IQR 18–38; P <0.001).

Comprehensive baseline characteristics and early effects of BAV are shown in Supplementary material, *Table S1*. After BAV non-trivial (more than mild) AR was observed in 14 patients (12%) out of which in 8 (6.8%) patients AR was moderate and in 6 (5.1%) moderate/severe, none of those patients required immediate surgery.

Significant complications occurred in 4 patients (3.4%) — persistent femoral artery occlusion (n = 2), balloon catheter rupture (n = 1) and acute pulmonary edema after induction of anesthesia in hemodynamically unstable patient (n = 1).

An optimal BAV outcome was achieved in 60 patients (51.3%). Among the 57 patients (48.7%) with suboptimal outcomes, non-trivial AR (more than mild) was identified in 14 patients (12%), less than 50% gradient reduction in 34 patients (29%), and a residual gradient exceeding 35 mmHg in 36 patients (30.7%). Some patients exhibited multiple contributing factors associated with suboptimal outcomes. No risk factors for suboptimal early outcome were found. Univariate analysis of variables affecting early outcomes is available in Supplementary material, *Table S2*.

No mortality was observed among patients following BAV.

Thirty-four out of 90 patients with long-term follow-up (38.2%) required reintervention. The median time from BAV to reintervention was 13.4 years (95% CI, 9.2–17.3). Reinterventions included: surgical aortic valve replacement in 27 patients (30%), repeated BAV in 5 patients (5.5%), Ross surgery in one and Ozaki surgery in another patient indications and timing of reintervention is available in Supplementary material, *Table S3*. At 5 and 10 years following BAV, the proportion of patients without reintervention was 80.3% and 61%, respectively (Figure 1A). The cumulative incidence of freedom from reintervention at 20 years post-BAV was 31%. In the subgroup of patients with optimal early result, 18 (52.2%) required reintervention compared to 16 (47.8%) patients with suboptimal early effect (P = 0.92).

Patients who underwent BAV during infancy had higher reintervention-free survival vs. older children, with 10-year freedom from reintervention rates of 84.2% vs. 41.7% (*P* <0.001) (Figure 1B). Patients with tricuspid aortic valve fared better than with bicuspid valve, showing 10-year freedom from reintervention rates of 73.5% versus 54.8% (*P* = 0.046) (Figure 1C). Additionally, patients achieving a residual peak-to-peak gradient reduction of ≥50% after BAV had better outcomes than those with less than 50% reduction, with 10-year freedom from reintervention rates of 67.7% versus 41% (*P* = 0.04) (Figure 1D). Long term outcomes of BAV are presented in Figure 1. The univariate analysis of variables associated with the need for reintervention is detailed in Supplementary material, *Table S4*. Bicuspid AV emerged as the only predictor of reintervention in Cox regression model, with HR of 3.2 (95% CI, 1.0–9.9; *P* = 0.049) Results of Cox proportional regression analysis is provided in Supplementary material, *Table S5*.

BAV remains a safe and effective treatment for pediatric AS, offering outcomes comparable to surgical interventions [1]. Advantages of BAV include faster patient recovery and the absence of surgical scarring and adhesions, which is crucial given that many patients may require future cardiac surgeries such as Ross procedure or surgical aortic valve replacement.

Despite its benefits, long-term outcomes of BAV are variable, with 10-year freedom from reintervention rates ranging from 46% [1] to 89% [5]. Despite advancements, long-term results of BAV in pediatric patients have remained relatively consistent over the years [6]. This unpredictability in long-term results is also observed in adult BAV procedures [7], where early improvements do not consistently correlate with sustained benefits, emphasizing the need for close and precise follow-up in both pediatric and adult patients. Our study reinforces that patients with bicuspid aortic valves have worse long-term outcomes compared to those with tricuspid valves. This finding supports that valve morphology plays a significant role in long-term prognosis.

The most novel finding of our study, is that we found that infants had a higher probability of freedom from reintervention, which has only been hinted at in previous studies [8, 9]. While this contrasts with some studies reporting poorer outcomes in very young children, those studies often included neonates with critical valve stenosis and hypoplastic valves [6]. In infants, the valve tissue may be more responsive to dilation before significant fibrosis of fused comissures occurs, potentially explaining the better outcomes observed [10].

Attempts to improve BAV outcomes, such as the use of right ventricular pacing (RVP), have yielded inconsistent results. Our study did not demonstrate a significant benefit of RVP, aligning with other research that questions its efficacy in this context [6].

Our study's findings should be viewed considering their limitations: retrospective design, limited follow-up retention, small sample size (especially affecting the results of multivariable regression analysis), basic characterization of aortic valve morphology, and the long duration of patient enrollment.

Overall, BAV continues to be an effective palliative procedure with satisfactory mid- to long-term results. Future improvements may come from enhanced patient selection based on aortic valve morphology, timing of the procedure and further research into techniques like RVP to optimize long-term outcomes.

Suplementary material

Supplementary material is available at https://journals.viamedica.pl/kardiologia_polska.

Article information

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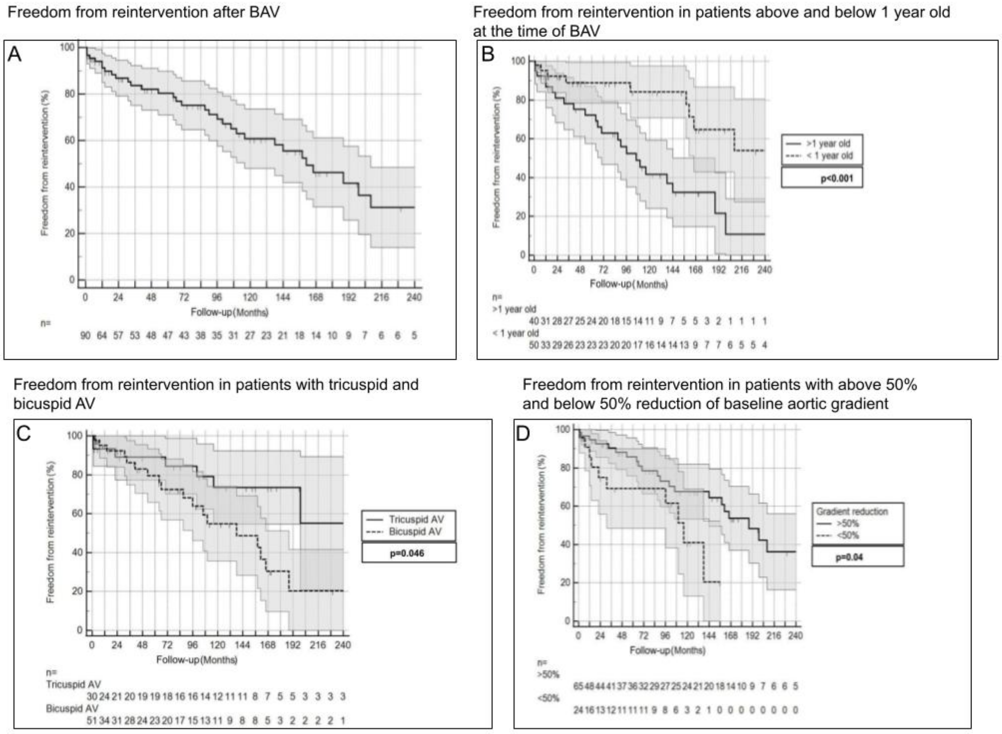
Figure 1. Long term outcomes of BAV.



Abbreviations: BAV - balloon aortic valvuloplasty, AV - aortic valve