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Research Article

Balloon Aortic Valvuloplasty in the First Year of Life: Hemodynamic Outcomes, Risk Factors for Reintervention and the Protective Role of Rapid Pacing

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Abstract

Background: Congenital valvular aortic stenosis is a progressive lesion that can lead to critical heart failure in neonates and infants. While balloon aortic valvuloplasty (BAV) is the preferred primary intervention, long-term success is often limited by restenosis and progressive aortic regurgitation (AR). This study aims to evaluate the time to reintervention and identify risk factors associated with early reintervention in children treated within the first year of life.

Methods: We conducted a retrospective, single-center study (2002-2024) including 63 patients (aged 0-1 year) who underwent primary BAV. Patients were categorized into neonates (0-28 days, n=26) and infants (29-365 days, n=37). Hemodynamic and echocardiographic parameters were analyzed pre-procedure, post-procedure, and at the latest follow-up. The primary endpoint was time to first surgical or catheter-based reintervention.

Results: BAV achieved a significant reduction in echocardiographic peak gradient (from a median of 76.1 mmHg to 34.3 mmHg; $p < 0.0001$). Overall freedom from reintervention was 58.7% at 1 year and 44.9% at 10 years, followed by a stable plateau. Multivariable Cox proportional hazard regression analysis identified neonatal age as a significant independent risk factor for reintervention [HR 2.39; 95% CI: 1.00-5.70; $p = 0.049$], while the use of rapid pacing was a significant protective factor [HR 0.43; 95% CI: 0.19-0.95; $p = 0.037$]. Notably, the use of rapid pacing did not significantly increase AR severity in this population. At the latest follow-up, moderate-to-severe AR was present in 39.9% of the total cohort, and progressive left ventricular dilation was observed, particularly in neonates (median LVEDD z-score 2.1).

Conclusion: Balloon aortic valvuloplasty is an effective initial treatment for congenital valvular aortic stenosis in patients 0-1 years of age, providing substantial acute relief of obstruction and almost 50% freedom from reinterventions after 10 years. While neonates face a twofold higher risk for reintervention, rapid pacing significantly reduces the risk for reinterventions in our population.

Keywords: *Congenital heart disease; Congenital aortic stenosis; Balloon aortic valvuloplasty; Durability; Rapid pacing.*

Introduction

Valvular aortic stenosis (VAS), an obstructive disease of the left ventricular outflow tract (LVOT) at the level of the aortic valve, occurs in approximately 3.8-4.9/ 10.000 live births and accounts for 3-6% of congenital heart defects [1][2]. Fewer than 10% of the congenital AS cases present during the neonatal period or early infancy [3].

Congenital VAS is known to be a progressive lesion with clinical outcomes varying according to severity and age at presentation. Neonates often present with arterial duct-dependent systemic circulation, whereas infants more frequently develop symptoms of congestive heart failure secondary to left ventricular pressure overload [3][4][5]. Without timely intervention, mortality exceeds 70% in severe cases [4].

Since its introduction by *Lababidi* in 1983, balloon aortic valvuloplasty (BAV) has largely replaced open valvotomy as the preferred initial intervention for congenital VAS, providing effective relief of obstruction with lower procedural morbidity [6][7][8]. Nevertheless, restenosis and progressive aortic regurgitation (AR) are common long-term complications often requiring reintervention [9][10][11].

Understanding the time to reintervention and identifying risk factors associated with early reintervention are critical for improving long-term outcomes [12][13]. Such insights may guide individualized treatment strategies, optimize follow-up, and help clinicians better inform families about prognosis and expected disease course.

This study therefore aims to assess the time to reintervention after initial treatment with BAV for congenital VAS in children aged 0-1 year and to identify factors associated with early reintervention.

Methods

Design and study population

This retrospective, single-center study included children who underwent BAV as initial treatment for congenital VAS in the Wilhelmina children's hospital, Utrecht. Patients treated between 2002 and 2024 who met the standard criteria as defined by the *American Heart Association (AHA) Indications for Cardiac Catheterization in Pediatric Cardiac Disease* were included [15]. These indications include newborns with ductal-dependent systemic circulation or depressed left ventricular function, regardless of the measured valve gradient, as well as patients demonstrating a resting peak systolic valve gradient exceeding 50 mmHg on cardiac catheterization. Additionally, infants with a catheter-derived gradient greater than 40 mmHg were included if accompanied by clinical manifestations such as angina, syncope, or ischemic ST-T wave abnormalities on electrocardiography.

Clinical and procedural data were obtained from institutional medical records and the cardiac catheterization database. Follow-up data were reviewed to determine outcome measures. The primary outcome measure was time to reintervention, defined as the duration from the initial BAV procedure to the first subsequent catheter-based or surgical intervention on the aortic valve (including repeat BAV (reBAV), surgical valvotomy, or aortic valve replacement (AVR)). Additionally, Longitudinal changes in aortic valve gradient and overall survival were analyzed.

To focus on the most clinically relevant age group, our analysis was restricted to patients aged 0-1 year at the time of the procedure.

BAV and invasive hemodynamics

BAV was performed under general anesthesia with continuous hemodynamic and ECG monitoring. Vascular access was obtained through the femoral vessels or through the umbilical artery and vein if applicable. Arterial access was used for catheterization of the left ventricle and aorta, for pressure recordings, and for introduction of the balloon catheter. Venous access served for additional hemodynamic monitoring or pacing, and for an antegrade approach to the aortic valve, when the retrograde approach was not feasible. Systemic heparinization was administered after vascular access was secured.

Different types of 4-6Fr catheters were used to advance into the left ventricle for pressure recording. Baseline left ventricular and ascending aortic pressures were obtained through pullback measurement, to determine the preprocedural transvalvular gradient. The aortic annulus diameter was measured angiographically in the left anterior oblique projection at end-systole, from hinge point to hinge point, and balloon size was chosen to achieve a balloon-to-annulus ratio of less than 1, to minimize the risk of AR.

Under fluoroscopic guidance, the balloon was positioned across the aortic valve. To minimize cardiac motion and ensure stability during inflation, rapid pacing via either a right atrial or ventricular pacing wire, or an esophageal electrode was applied. The balloon was inflated one or more times until disappearance of the waist was observed.

Hemodynamic measurements were repeated immediately after BAV to assess residual LV-aortic gradient, LV-end diastolic pressure (LVEDP), and systemic pressures. Aortic root angiography was performed at the end of the procedure to evaluate AR, graded as none, mild, moderate and severe based on jet width and depth seen on cine-angiography.

Procedural success was defined according to institutional standards as achieving a meaningful reduction in the transvalvular gradient while avoiding a significant increase in AR.

Echocardiography

Comprehensive echocardiographic evaluation was performed in all patients before and after BAV using two-dimensional, M-mode and Doppler echocardiography according to established pediatric cardiology outlines [15]. The severity of AS was assessed by measuring the peak Doppler velocity and mean transvalvular gradient. Continuous-wave Doppler recordings were obtained from the apical five-chamber, apical long-axis and suprasternal notch views, and the highest recorded velocity was used for analysis. The mean gradient was calculated from the area under the Doppler velocity curve. Valve morphology was evaluated in the parasternal short-axis view, and the aortic annular diameter was measured during systole in parasternal long-axis view.

The presence and severity of AR were determined, including identification of the regurgitant jet origin in the parasternal short-axis view, semi-quantitative assessment using color Doppler parameters and the quantity of backflow at the level of the aortic isthmus and abdominal aorta. Eventually stratifying AR severity as; 0 = none, 1 = mild, 2 = moderate, 3 = severe.

LV measurements included wall thickness, cavity dimensions and cardiac function. Interventricular septal thickness at end-diastole (IVSd) and left ventricular posterior wall thickness at end-diastole (LVPWd) were obtained from M-mode tracings in the parasternal long- or short-axis views. LV end-diastolic and end-systolic dimensions (LVEDD, LVESD) and volumes (LVEDV, LVESV) were measured to calculate fractional shortening (FS) and ejection fraction (EF). LV-dysfunction was defined as an EF < 50% or a LVSF <28%.

For selected measurements, including LV dimensions, wall thickness, and aortic valve diameter, Z-scores adjusted for body surface area were calculated using the calculators by *Pettersen et al.* and *Gautier et al* to allow comparison across different patient sizes and ages. Z-scores <-2 or > +2 were considered abnormal [16][17]. Additional findings associated with AS, such as endocardial fibroelastosis (EFE) or other structural anomalies, were documented.

Follow-up

Post-procedural follow-up was standardized for all patients. A transthoracic echocardiogram (TTE) was performed on the first day after BAV. Subsequent evaluations were scheduled at progressively increasing (approximately doubled) intervals. Each visit included a clinical assessment and TTE. Follow-up continued according to this expanding-interval schedule until the predefined study outcome measures were reached. Median follow-up durations were recorded for the cohort.

Statistics

Continuous data were tested for normal distribution using the Shapiro-Wilk test. Given the observed skewness in the majority of parameters, continuous variables are reported as the median with the corresponding interquartile range [Q1-Q3].

Differences in the progression of transvalvular gradients and aortic regurgitation grades during follow-up were assessed in three pairwise comparisons of time-points (pre vs post, post vs follow-up/reintervention and pre vs follow-up/reintervention) using paired t-tests, if paired differences met criteria for normal distribution using the Shapiro-Wilk test. If assumptions were not met, a Wilcoxon signed-rank test was used. Comparison of difference in progression of AR grades between the rapid pacing and no rapid pacing groups was performed using the Wilcoxon rank-sum test. To compare distribution of AR severity and development of LV-dilation between the groups at specific time points, Fisher's exact tests were performed.

Patients were censored at the date of last available follow-up or death, if death occurred before a reintervention. Time to reintervention was estimated using Kaplan-Meier survival analysis, and median time to reintervention with 95% confidence intervals (CI) was reported; patients without reintervention were censored. Potential risk factors for reintervention were evaluated using Kaplan-Meier survival estimates with comparisons between groups performed by log-rank testing. To account for statistical power limitations, multivariable Cox proportional hazards analysis was restricted to covariates demonstrating a p-value <0.10 in univariate testing, with hazard ratios (HR) and corresponding 95% CI reported. A p-value <0.05 was considered statistically significant. All statistical analyses were performed using R (R Foundation for Statistical Computing) in Rstudio.

Results

Cohort Characteristics and Patient Demographics

A total of 82 patients were identified. Two patients were excluded as the initial BAV was abandoned in favor of a diagnostic catheterization. Eventually a total of 63 patients 0-1 year undergoing initial BAV for congenital AS were included in this study (Table 1).

For the total cohort associated genetic syndromes were identified in 5.0% of patients, including Noonan syndrome (1.3%) , 22q11 deletion syndrome (1.3%), and Turner syndrome (2.5%).

A hypoplastic aortic arch presented in 14.3% of patients, of whom 25% of patients were classified within the spectrum of hypoplastic left heart complex (HLHC). Notably, 6.3% of patients had undergone surgical aortic arch repair prior to the initial BAV.

Table 1. Baseline clinical and echocardiographic characteristics.

	Neonates	Infants	Total
Demographics	(N=26)	(N=37)	(N=63)
Gender, n (%) male	20 (76.9)	28 (75.7)	48 (76.2)
Procedural weight (kg), median [Q1-Q3]	3.3 [2.5-3.8]	5.1 [4.3-6.4]	4.3 [3.3-5.5]
Age at procedure (days), median [Q1-Q3]	1.5 [0-5.8]	75.0 [43.5-119.5]	34 [2-85]
Clinical characteristics	(N=26)	(N=37)	(N=63)
Ductal dependent circulation, n (%)	15 (57.7)	2 (5.4)	17 (27.0)
Mitral regurgitation, n (%)	18 (69.2)	6 (16.2)	24 (38.1)
Atrial septal defect, n (%)	5 (19.2)	3 (8.1)	8 (12.7)
Ventricular septal defect, n (%)	1 (3.9)	2 (5.4)	3 (4.8)
Coarctation, n (%)	3 (11.5)	4 (10.8)	7 (11.1)

Table 1 Continued below...

Hypoplastic aortic arch, n (%)	4 (15.4)	5 (13.5)	9 (14.3)
Subaortic ridge, n (%)			1 (1.3)
Genetic syndromes, n (%)			4 (5.0)
PreBAV echocardiogram			
Peak gradient mmHg, median [Q1-Q3]	(N=20)	(N=36)	(N=56)
	71 [31.9-88.1]	78.2 [69.0-98.5]	76.1 [59.8-92.2]
Mean gradient mmHg, median [Q1-Q3]	(N=19)	(n=33)	(N=52)
	23.9 [14.9-23.9]	45 [35.3-58.5]	43.7 [24.4-56.1]
Annular diameter absolute mm, median [Q1-Q3]	(N=22)	(N=35)	(N=57)
	5.7 [5-7]	7.9 [7-9]	7 [5.8-8.0]
Annular diameter Z-score, median [Q1-Q3]	(N=22)	(N=35)	(N=57)
	-2.8 [-4.7 - -1.1]	-0.9 [-1.8-0.4]	-1.3 [-3- -0.3]
Aortic regurgitation	(N=23)	(N=36)	(N=59)
none n (%)	22 (95.6)	31 (86.1)	53 (89.8)
mild n (%)	1 (4.4)	4 (11.1)	5 (8.5)
moderate n (%)	0 (0)	1 (2.8)	1 (1.7)
severe n (%)	0 (0)	0 (0)	0 (0)
LVEDD absolute mm, median [Q1-Q3]	(N=21)	(N=33)	(N=54)
	-0.5 [-2.8-2.4]	0.1 [-1.8-1]	-0.1 [-1.9-1.2]
EF %, median [Q1-Q3]	(N=18)	(N=28)	(N=46)
	58.7 [27.6-67]	67.2 [52.4-77.3]	63.0 [39-77.2]
FS %, median [Q1-Q3]	(N=19)	(N=32)	(N=51)
	29.0 [12.0-34.0]	32.0 [18.0-42.3]	32.0 [18.0-43.3]
IVSd absolute mm, median [Q1-Q3]	(N=21)	(N=33)	(N=54)
	4.1 [3.2-6.6]	5.5 [4.4-6.6]	5.1 [3.9-6.6]
IVSd Z-score, median [Q1-Q3]	(N=21)	(N=33)	(N=54)
	0.9 [-0.5-2.7]	1.7 [0.6-2.5]	1.6 [0.1-2.7]
LVPWd absolute mm, median [Q1-Q3]	(N=21)	(N=33)	(N=54)
	4 [3-5.6]	5 [4.2-6.2]	4.6 [3.7-5.9]
LVPWd Z-score, median [Q1-Q3]	(N=21)	(N=33)	(N=54)
	2 [0.2-3.3]	2.4 [1.5-3.7]	2.2 [1-3.5]
EFE, n (%)	(N=19)	(N=32)	(N=51)
	11 (57.9)	4 (12.5)	15 (29.4)
LV-dysfunction	(N=19)	(N=32)	(N=51)
FS <28%/EF <50%, n (%)	9 (47.4)	8 (25.0)	17 (33.3)

Comparison of demographic, clinical, and preprocedural echocardiographic parameters between neonates (0-28 days) and infants (29-365 days). Data are presented as n (%) for categorical variables and median [Q1-Q3] for continuous variables. AR: aortic regurgitation; EFE: endocardial fibroelastosis; FS: fractional shortening; EF: ejection fraction; IVSd; interventricular septum thickness at end-diastole; LVEDD: left ventricular end-diastolic diameter; LVPWd: left ventricular posterior wall thickness at end-diastole; PreBAV: prior to balloon aortic valvuloplasty.

Procedural Outcomes and Hemodynamics

Various arterial and venous access sites were utilized for the BAV procedure, with the specific distribution across age groups detailed below (Table 2).

Standard diagnostic catheters, guidewires (primarily PT2, BMW, Terumo, and Cook), and Tyshak balloons were used for valve crossing and dilation. Specific equipment usage per case was not consistently recorded due to the study's retrospective nature.

Table 2. Procedural characteristics of balloon aortic valvuloplasty.

	Neonates (N=26)	***Infants (N=37)***	***Total (N=63)***
Procedural access	(N=26)	(N=37)	(N=63)
Femoral artery, n (%)	20 (76.9)	36 (97.3)	56 (88.9)
Femoral vein, n (%)	3 (11.5)	1 (2.7)	4 (6.3)
Umbilical artery, n (%)	2 (7.7)		2 (3.2)
Umbilical vein, n (%)	1 (3.9)		1 (1.6)
Balloon/annulus ratio largest balloon, median [Q1-Q3]	(N=24)	(N=37)	(N=61)
		0.9 [0.9-0.9]	0.9 [0.9-0.9]
	(N=26)	(N=37)	(N=63)
Rapid pacing used, n (%)	7 (26.9)	28 (75.7)	35 (55.6)
Right ventricular, n (%)	4 (57.1)	13 (46.4)	17 (48.6)
Right atrial, n (%)	2 (28.6)	13 (46.4)	15 (42.8)
Esophageal, n (%)	1 (14.3)	2 (7.2)	3 (8.6)

Comparison of vascular access, balloon sizing, and pacing techniques between neonates and infants. Data presented as n (%) for categorical data and as median [Q1-Q3] for continuous data. Annulus ratio refers to the largest balloon diameter relative to the baseline aortic annulus diameter

Baseline invasive hemodynamic parameters, including left ventricular and ascending aortic pressures, are described below (Table 3). The procedure resulted in a significant reduction in transvalvular gradient across the cohort ($p < 0.0001$; Table 3).

A proportion of the cohort exhibited critical clinical status during the procedure. 12.7% of patients (6 neonates, 2 infants) presented with a low cardiac output state, and two neonates demonstrated an akinetic left ventricle. Notably, 3.2% of patients (2 infants) required acute inotropic support due to a decline in gradient following the induction of general anesthesia.

Procedural mortality occurred in none of the patients, and procedural complications in 9 patients (14.3%). As some patients experienced more than one event, the individual complication rates exceed the total complication incidence: these included third degree atrioventricular block (4.8%), Pulseless electrical activity (6.3%), transient left bundle branch block (3.2%) and transient ventricular and atrial arrhythmias (4.8%). In 6.3% of patients, previously unrecognized coarctation of the aorta was identified after relief of valvular obstruction; 50% of these were treated in the same procedural session. In 7.8% of neonates, a simultaneous Rashkind atrial septostomy was performed.

Table 3. Invasive hemodynamic outcomes of balloon aortic valvuloplasty.

Procedure	Neonates (N=26)	Infants (N=37)	Total (N=63)	P value
Preprocedural LV-pressure mmHg, median [Q1-Q3]	(N=17)	(N=36)	(N=53)	
	111.0 [95.0-126.0]	127.0 [104.0-140.0]	121.5 [101.3-134.5]	
Postprocedural LV-pressure mmHg, median [Q1-Q3]	(N=23)	(N=30)	(N=53)	
	83.0 [70.0-94.0]	93.0 [83.0-107.0]	90.0 [75.0-98.5]	
Preprocedural Asc.-pressure mmHg, median [Q1-Q3]	(N=17)	(N=36)	(N=53)	
	55.0 [40.5-59.5]	64.0 [56.0-75.0]	60.0 [55.0-69.0]	
Postprocedural Asc.-pressure mmHg, median [Q1-Q3]	(N=23)	(N=30)	(N=53)	
	57.0 [46.0-66.0]	76.0 [64.0-85.5]	66.0 [54.0-78.0]	
Preprocedural LVEDP mmHg, median [Q1-Q3]	(N=17)	(N=36)	(N=53)	
	19.0 [12.5-23.5]	15.0 [12.0-19.0]	16.0 [12.0-21.5]	
Postprocedural LVEDP mmHg, median [Q1-Q3]	(N=17)	(N=19)	(N=36)	
	14.0 [12.5-16.5]	13.0 [11.0-16.0]	14.0 [12.0-16.0]	
Preprocedural gradient mmHg, median [Q1-Q3]	(N=18)	(N=36)	(N=53)	
	60.5 [46.8-73.8]	59.0 [45.0-76.0]	60.0 [45.0-74.5]	
Postprocedural gradient mmHg, median [Q1-Q3]	(N=25)	(N=35)	(N=60)	
	20.0 [15.0-30.5]	15.0 [10.0-20.0]	16.5 [10.0-21.8]	
Procedural absolute reduction mmHg, median [Q1-Q3]	(N=18)	(N=35)	(N=53)	
	34.0 [24.5-50.3]	44.0 [33.0-55.0]	41.0 [29.5-51.5]	p < 0.0001*
Procedural relative reduction %, median [Q1-Q3]	(N=18)	(N=35)	(N=53)	
	56.8 [42.1-71.9]	74.6 [64.3-83.3]	71.7 [56.0-79.9]	p < 0.0001*
Procedural complications, n (%)	*(N=26)*	*(N=37)*	*(N=63)*	
			9 (14.3)	

*Comparison of pre- and postprocedural pressure measurements and gradient reduction between neonates and infants. Data presented as n (%) for categorical variables or median [Q1-Q3] for continuous variables. Procedural gradient refers to the invasive peak-to-peak systolic pressure difference across the aortic valve. *P-value indicates the significance of the absolute and relative gradient reduction within the total cohort. Asc.-pressure: peak ascending aortic pressure; LVEDP: left ventricular end diastolic pressure; LV-pressure: left ventricular peak systolic pressure.*

Longitudinal Echocardiographic Follow-Up

The procedure achieved a significant acute reduction in both peak and mean echocardiographic transvalvular gradients (*p < 0.0001*; Figure 1A + B). The median peak gradient decreased from 76.1 mmHg [IQR 59.8-92.2] pre-BAV to 34.3 mmHg [IQR 25.1-50.5] immediately post-BAV. Similarly, the mean gradient was reduced from a median of 43.7 mmHg [IQR 24.4-56.1] to 17.2 mmHg [IQR 12.0-26.0] (Table 4).

Longitudinal follow-up revealed a gradual increase in gradients over time. At the latest follow-up (FU/Reint), the median peak gradient for the total cohort had risen to 32.9 mmHg [IQR 22.7-52.4]. This trend was particularly evident in the subset of patients requiring reintervention (indicated in red), who frequently demonstrated a more pronounced rebound in gradients compared to the no-reintervention group. Despite observing this longitudinal increase, both peak and mean gradients at latest follow-up remained significantly lowered compared to pre-BAV baseline values (Figure 1A; *p < 0.0001*)(Figure 1B; *p < 0.001*).

A B

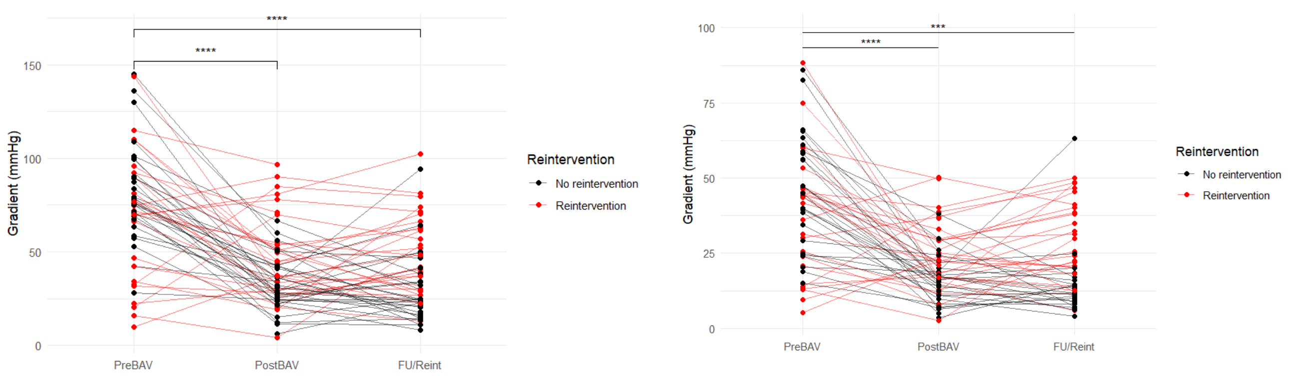

Figure 1. *Longitudinal echocardiographic hemodynamics of the aortic valve following balloon valvuloplasty.*

Individual patient data for peak (A) and mean (B) transvalvular gradients. Black lines represent patients managed conservatively, while red lines indicate patients requiring reintervention during follow-up. Asterisks indicate statistical significance (****p<0.0001; ***p<0.001) for the comparison between timepoints. BAV: balloon aortic valvuloplasty; FU: follow-up; Reint: Reintervention.

The reduction in gradients was accompanied by a progressive increase in AR. While most patients had no AR at baseline, the prevalence of moderate or greater AR rose immediately post-BAV and continued to increase during the follow-up period (Table 1, Table 4). The progression to severe AR was relatively most pronounced in the neonatal subgroup.

Pressure relief following BAV led to structural remodeling, characterized by a regression of left ventricular hypertrophy. Both LVPWd and IVSd Z-scores decreased over time. Conversly, progressive dilation of the left ventricle was observed, with this trend being most pronounced in the neonatal subgroup (Table 1, Table 4).

Table 4. Acute and longitudinal echocardiographic outcomes.

Post-BAV	Neonates (N=26)	Infants (N=37)	Total (N=63)
Peak gradient mmHg, median [Q1-Q3]	(N=23)	(N=37)	(N=60)
	29.4 [24.0-45]	36.2 [21.7-28.1]	34.3 [25.1-50.5]
Mean gradient mmHg, median [Q1-Q3]	(N=23)	(N=36)	(N=59)
	18.3 [13.0-29.1]	17.0 [11.8-24.0]	17.2 [12.4-26.0]
Peak gradient absolute reduction, median [Q1-Q3]	(N=23)	(N=37)	(N=60)
	14.7 [-1.9 -39.2]	45.1 [32.5-64.9]	37.5 [17.4-60.3]
Mean gradient absolute reduction, median [Q1-Q3]	(N=23)	(N=36)	(N=59)
	10.1 [-2.3-21.1]	24.1 [10.7-40.6]	21.1 [7.1-34.2]
Peak gradient relative reduction %, median [Q1-Q3]	(N=23)	(N=37)	(N=60)
	43.2 [14.4-68.8]	54.9 [41.7-64.5]	52.8 [29.7-67.1]
Mean gradient relative reduction %, median [Q1-Q3]	(N=23)	(N=36)	(N=59)
	41.2 [11.8-65.6]	62.3 [37.7-73.8]	54.9 [29.2-69.8]
Aortic regurgitation	(N=25)	(N=37)	(N=62)
none n (%)	7 (28.0)	17 (45.9)	24 (38.6)
mild n (%)	10 (40.0)	10 (27.0)	20 (32.5)
mild-moderate n (%)	3 (12.0)	2 (5.4)	5 (8.1)
moderate n (%)	4 (16.0)	6 (16.2)	10 (16.1)
moderate-severe n (%)	0 (0)	2 (5.4)	2 (3.1)
severe n (%)	1 (4.0)	0 (0)	1 (1.6)

Table 4 Continued below...

FU/Reintervention	***Neonates (N=26)***	***Infants (N=37)***	***Total (N=63)***
Peak gradient mmHg, median [Q1-Q3]	(N=23)	(N=35)	(N=58)
	40.6 [24.8-63.0]	29.6 [17.5-46.6]	32.9 [22.7-52.4]
Mean gradient mmHg, median [Q1-Q3]	(N=21)	(N=32)	(N=53)
	24.9 [14.0-40.3]	13.4 [9.9-20.9]	18.3 [11.5-31.8]
Annular diameter absolute mm, median [Q1-Q3]	(N=20)	(N=29)	(N=49)
	7.0 [6.0-12.8]	14.6 [10.0-18.7]	11.0 [7.0-18.0]
Annular diameter Z-score, median [Q1-Q3]	(N=20)	(N=29)	(N=49)
	-1.6 [-3.3 - -0.1]	0.6 [-0.5-1.4]	-0.1 [-1.4- 1.2]
Aortic regurgitation	(N=23)	(N=37)	(N=60)
none n (%)	6 (26.1)	4 (10.8)	10 (16.7)
mild n (%)	7 (30.4)	14 (37.8)	21 (35.1)
mild-moderate n (%)	3 (13.0)	2 (5.4)	5 (8.3)
moderate n (%)	1 (4.4)	7 (18.9)	8 (13.3)
moderate-severe n (%)	0 (0)	2 (5.4)	2 (3.3)
severe n (%)	6 (26.1)	8 (21.6)	14 (23.3)
LVEDD absolute mm, median [Q1-Q3]	(N=20)	(N=33)	(N=53)
	27.4 [21.8-34.6]	39.2 [28.3-45.0]	32.1 [26.2-44.3]
LVEDD Z-score, median [Q1-Q3]	(N=20)	(N=33)	(N=53)
	2.1 [0.1-3.6]	1.0 [0.2-1.7]	1.3 [0.1-2.3]
IVSd absolute mm, median [Q1-Q3]	(N=20)	(N=28)	(N=48)
	5.2 [4.0-5.9]	6.0 [4.8-7.7]	5.4 [4.6-7.0]
IVSd Z-score, median [Q1-Q3]	(N=20)	(N=28)	(N=48)
	0.7 [-0.5-1.6]	0.5 [-0.4-1.4]	0.5 [-0.4-1.4]

Table 4 Continued below...

LVPWd absolute mm, median [Q1-Q3]	(N=20)	(N=33)	(N=53)
	5.2 [4.0-5.9]	6.0 [4.8-7.7]	5.2 [4.0-7.0]
LVPWd Z-score, median [Q1-Q3]	(N=20)	(N=33)	(N=53)
	1.6 [0.8-2.9]	0.8 [-0.2-1.5]	1.3 [0.3-2.3]

Comparison of hemodynamic gradients, valvular regurgitation and left ventricular remodeling between neonates and infants. Categorical data presented as n (%) and continuous data presented as median [Q1-Q3]. Absolute and relative reductions refer to the change from pre-procedural to the immediate Post-BAV measurement. Follow-up (FU) data represent the latest echocardiographic assessment or the measurement immediately prior to reintervention. AR: aortic regurgitation; IVSd: interventricular septum thickness at end-diastole; LVEDD: left ventricular end-diastolic diameter; LVPWd: left ventricular posterior wall thickness at end-diastole.

Impact of Rapid Pacing on Postprocedural Aortic Regurgitation and Ventricular Dilation

To evaluate the influence of rapid pacing on valvular competence, the progression of AR was analyzed in the subset of patients with preserved LV-function prior to the initial procedure (n=41). A longitudinal increase in AR was observed from pre-BAV to latest follow-up (*p < 0.0001).* This progression was characterized by a significant acute increase in AR severity from pre- to post-BAV (*p < 0.001),* followed by a further significant increase from the postprocedural measurement to the latest follow-up (*p < 0.0001).*

When stratified by rapid pacing, both 'rapid pacing' and 'no rapid pacing' groups demonstrated a similar significant progression in the severity of AR (Figure 2). The magnitude of AR increase did not differ significantly between those treated with rapid pacing and those without immediately after BAV and at last follow-up. Furthermore, no significant differences were observed in the distribution of AR grades between the groups at post-BAV or latest follow-up (*p > 0.05*). Specifically, the prevalence of severe AR (grade 3) immediately following the procedure and at last follow-up did not significantly differ between both groups.

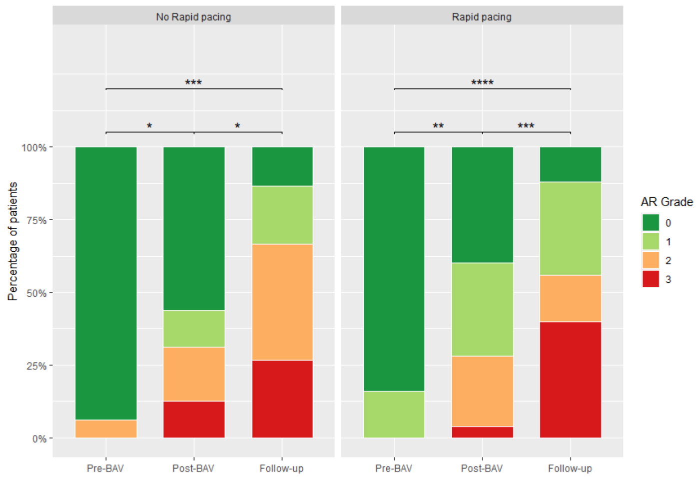

Figure 2. *Progression of aortic regurgitation stratified by rapid pacing.*

Stacked bar charts illustrating the distribution of AR grades at baseline (pre-BAV), immediately following the procedure (post-BAV), and at latest follow-up/reintervention in patients with preserved baseline LV function. While both the 'no rapid pacing' (left) and 'rapid pacing' (right) groups show a significant acute and longitudinal increase in AR severity, no significant differences in AR distribution and magnitude of progression were observed between the two techniques. AR grades: 0 (none), 1 (mild), 2 (moderate), 3 (severe). Asterisks indicate significant longitudinal progression within groups (*p < 0.05; **p < 0.01; ***p < 0.001; ****p < 0.0001).

Freedom from Reintervention

The postprocedural course of BAV is marked by heterogeneity regarding the requirement for further valvular therapy. Out of the total cohort of 63 patients, 52.4% maintained a stable clinical course without the need for secondary procedure over a median follow-up period of 22.2 months [IQR 1.4-94.1]. For the remaining 47.6% of patients, the initial BAV necessitated a transition to a secondary surgical or catheter based therapy (Figure 3). Overall survival for the cohort was 87.3% at the end of the follow-up period. Mortality was predominantly early after the initial procedure, with 7 deaths (11.1%) occurring within the first 28 days. Following this period, late survival was excellent, with only one death recorded after the first 28 days following the initial procedure.

These early deaths were primarily driven by hemodynamic instability and the limitations of cardiopulmonary support. Two patients died despite maximal cardiopulmonary supportive therapy, both presented with poor LV function and persistent hypotension requiring recurrent resuscitation, one after Ross-Konno procedure and one after the initial BAV. One patient died during Ross-Konno due to a previously unknown coronary anomaly and three patients died after withdrawal of treatment. These three patients all deceased after the initial procedure.

The single late death was recorded 494 days after a repeat BAV. This patient died suddenly following a two-day illness due to a massive pulmonary hemorrhage, requiring resuscitation.

The indications for reinterventions were residual or recurrent AS in 40.0%, progressive AR in 23.3%, and a combination of both AS and AR in 36.7%. A Ross-Konno procedure was performed in 25.4%, a Ross procedure in 9.5%, and a repeated BAV in 6.3% of patients.

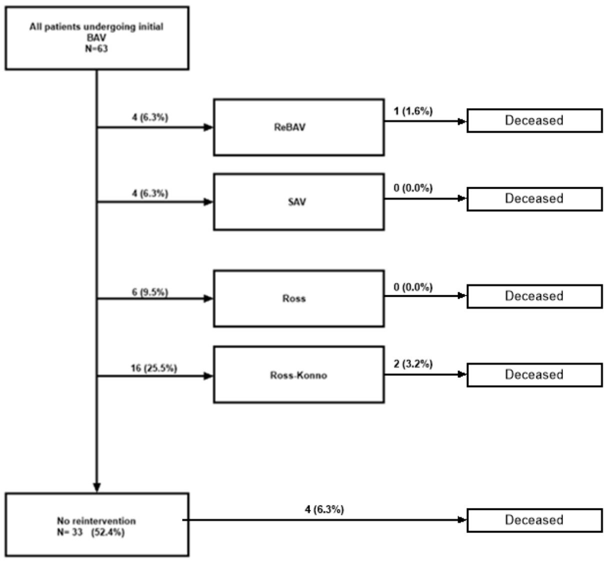

Figure 3. *Patterns of reintervention after initial BAV.*

Schematic representation of the clinical course in 63 patients. While 52.4% (n=33) of the cohort maintained stable valvular function without requiring a secondary procedure, 47.6% (n=30) necessitated further intervention. Mortality following each treatment pathway is depicted. BAV: balloon aortic valvuloplasty; SAV; surgical aortic valvuloplasty; ReBAV: repeat balloon aortic valvuloplasty.

Surgical aortic valvuloplasty (SAV) was performed in 6.3% of the cohort, including an anterior commissurotomy in 1.6%, and an anterior cusp repair with pericardial patch augmentation in 4.7% of patients.

To assess the durability of BAV, Kaplan-Meier estimates were generated (Figure 4). Freedom from reintervention was 64.1% [95% CI: 52.9%-77.7%] at six months, 58.7% [95% CI: 47.3%-72.9%] at 1 year, 54.4% [95% CI: 42.8%-69.3%] at 5 years, and 44.9% [95% CI: 33.1%-61.0%] at 10 years. The Kaplan-Meier estimate shows a steep decline in the first 6 months after the initial intervention. Beyond 80 months of follow-up, the estimate remains at a plateau of 44.9% through 200 months.

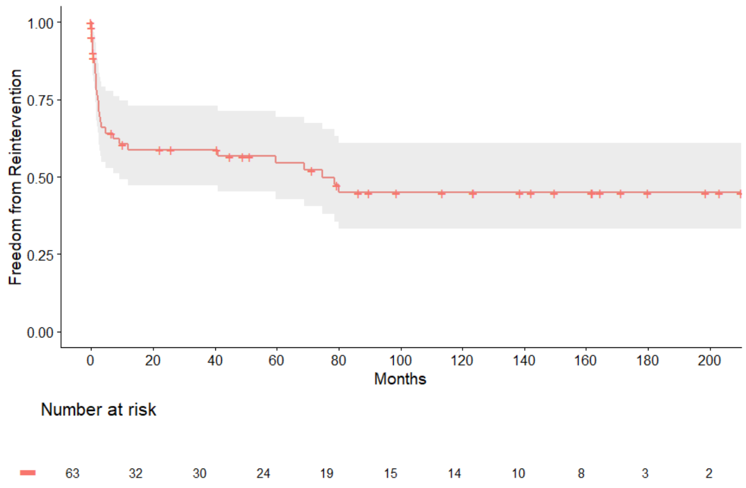

Figure 4. *Kaplan-Meier estimate of freedom from reintervention following BAV.*

The solid line represents the estimated percentage of patients free from surgical or catheter-based reintervention. The shaded area indicates the 95% confidence interval. An early attrition phase is observed within the first 6 months, eventually followed by a stable plateau of 44.9% beyond 80 months of follow-up. Crosses (+) denote censored patients. The 'Number at Risk' Table at the bottom indicates the remaining patients under surveillance at each time interval.

Kaplan-Meier estimates were also generated for both the total cohort and the subgroup of patients presenting with preserved baseline LV function. The pattern of freedom from reintervention is nearly identical between both groups, indicating that baseline LV function was not a primary determinant of long-term valvular durability in this population compared to the total cohort (Figure 5).

Given the clinical similarity in freedom from reintervention observed in Figure 5, this subgroup of patients with preserved LV function was utilized for the subsequent analysis of risk factors, specifically the impact of rapid pacing.

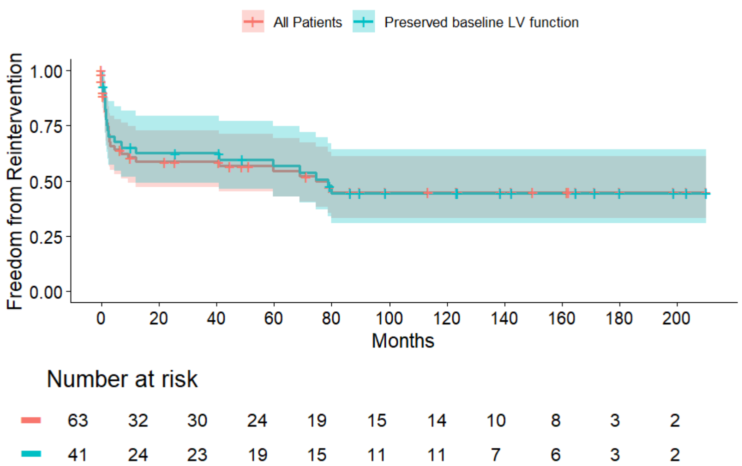

Figure 5. *Kaplan-Meier estimates of freedom from reintervention comparing the total cohort and patients with preserved baseline LV function.*

The red line represents the total cohort (n=63), while the blue line represents the subgroup of patients with preserved baseline LV function (n=41). Shaded areas indicate the 95% confidence intervals. The overlapping trajectories and confidence intervals demonstrate no significant difference in freedom from reintervention between the two groups. The 'Number at Risk' Table at the bottom shows the longitudinal surveillance for both groups.

Demographical and Clinical Association

To evaluate the impact of baseline characteristics on valvular durability, various clinical and demographic factors were analyzed. The presence of EFE was associated with reduced procedural durability in univariate analysis. Patients presenting with EFE demonstrated a significantly shorter freedom from reintervention compared to those without EFE (Figure 6A; *p = 0.013*). At 1-year follow-up, 35.7% [95% CI 17.7%-72.2%] of patients presenting with EFE were free from reintervention versus 70.5% [95% CI 56.7%-87.7%] in the group without EFE.

Procedural age was also significantly associated with freedom from reintervention in univariate analysis. Neonates required secondary interventions significantly earlier than the infant subgroup, with a 1-year freedom from reintervention of 32.4% [95% CI 17.6%-59.3%] in the neonatal group versus 74.8% [95% CI 61.8%-90.5%] in infants. (Figure 6B; *p=0.00011).*

In contrast, gender did not exert a significant influence on the requirement of a secondary intervention in our population. No statistical divergence was observed between male and female patients (Figure 6C; *p = 0.65*).

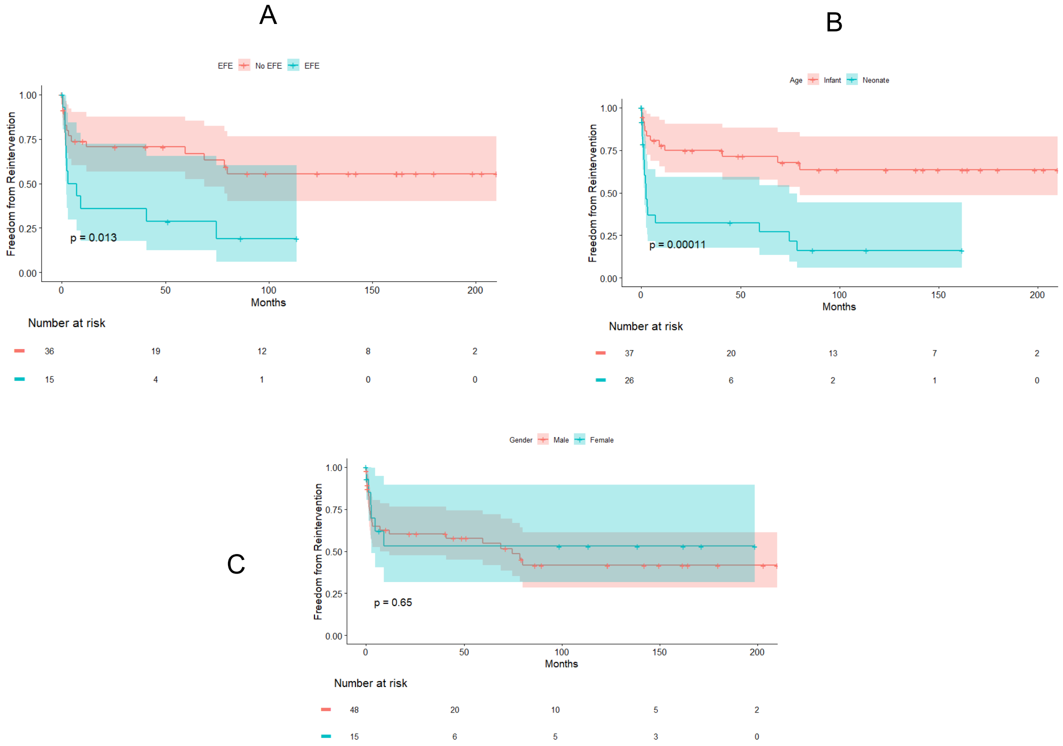

Figure 6. *Kaplan-Meier estimates of freedom from reintervention stratified by baseline clinical and demographical characteristics.*

(A): The presence of EFE at baseline was associated with a significantly lower freedom from reintervention compared to patients without EFE (p = 0.013). (B): Neonates exhibited a markedly higher requirement for secondary interventions compared to the infant cohort (p = 0.00011). (C): No significant difference in freedom from reintervention was observed between male and female patients (p =0.65).

Baseline Echocardiographic and Procedural Determinants Associated with Reintervention

Comprehensive analysis of structural and hemodynamic preprocedural echocardiographic parameters was performed to identify anatomic and hemodynamic markers associated with freedom from reintervention.

The baseline dimensions of the aortic annulus and the left ventricle were significantly associated with outcome in univariate analysis. A preprocedural aortic annular z-score < -2 was associated with reduced durability of the initial procedure (Figure 7A; *p = 0.013*). At 1-year follow-up, freedom from reintervention for these patients was 39.4% [95% CI: 22.7%-68.3%], compared to 70.1% [95 CI: 56.1%-87.5%] for those with z-scores ≥ -2.

Similarly, patients presenting with a preprocedural LVEDD z-score < -2 exhibited a significantly shorter freedom from reintervention compared to those with a z-score ≥ -2 (Figure 7B; *p = 0.029*). With a freedom from reintervention at 1-year follow-up of 50% [95% CI 28.4%-88.0%] for patients with a LVEDD z-score < -2, versus 60.5% [95% CI: 46.7%-78.3%] for those with LVEDD z-scores ≥ -2. Other structural markers, including IVSd and LVPWd did not have a significant impact on freedom from reintervention.

The severity of transvalvular gradient and the functional status of the left ventricle at baseline were further analyzed as potential markers of outcome. Patients presenting with a preprocedural echocardiographic peak gradient ≥ 70 mmHg demonstrated significantly superior freedom from reintervention compared to those with lower initial gradients in univariate analysis (Figure 7C; *p = 0.034*). At 1-year follow-up the freedom from reintervention in this group was 74.5% [95% CI: 61.4%-90.4%], compared to 31.8% [95% CI: 15.9%-63.9%] in the group with lower preprocedural gradients.

While the peak transvalvular showed to be associated with outcome in univariate analysis, the preprocedural mean gradient did not serve as a significant determinant of durability in our cohort. Regarding systolic ventricular performance, a trend was observed toward lower freedom from reintervention in patients with baseline LV dysfunction (Figure 7D: *p = 0.077*). In this subgroup, the freedom from reintervention at 1-year follow-up was 33.5% [95% CI: 16.4%-68.4%], compared to 67.7% [95% CI: 55.2%-83.2%] for those with no LV dysfunction.

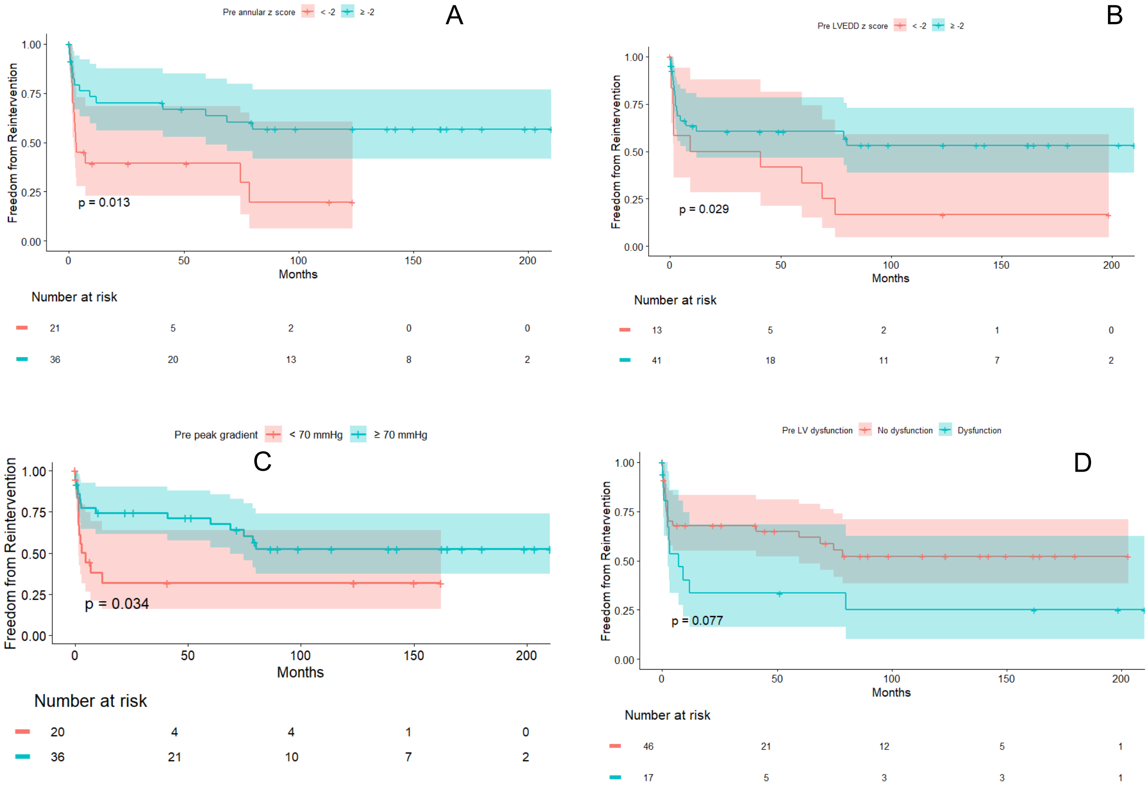

Figure 7. *Kaplan-Meier estimates of freedom from reintervention stratified by echocardiographic parameters.*

The curves demonstrate the impact of baseline anatomic and hemodynamic markers on procedural durability. (A) Patients with a preprocedural aortic annular z-score <-2 showed significantly lower freedom from reintervention compared to those with a z-score ≥ -2 (p = 0.013). (B) A preprocedural LVEDD z-score < -2 was associated with lower freedom from reintervention (p = 0.029). (C) Higher preprocedural peak gradients (≥ 70 mmHg) were associated with superior freedom from reintervention compared to lower gradients (p = 0.034). (D) A trend toward reduced freedom from reintervention was observed in patients presenting with baseline LV dysfunction (p = 0.077). Shaded areas represent 95% confidence intervals. The number of patients at risk is indicated below each time interval.

The immediate procedural results were evaluated to determine their impact on long-term freedom from reintervention.

A significant reduction in invasive transvalvular gradient during the procedure emerged as a associator of freedom from reintervention in univariate analysis. Patients achieving a procedural gradient reduction of ≥ 50% demonstrated significant freedom from reintervention compared to those with a reduction < 50% *(*Figure 8; *p = 0.0013)*. With an estimated freedom from reintervention at 1-year follow-up of 72.9% [95% CI: 60.9%-87.2%] in the group with ≥ 50% reduction, compared to 12.5% [95% CI: 2.0%-78.2%] in the other group.

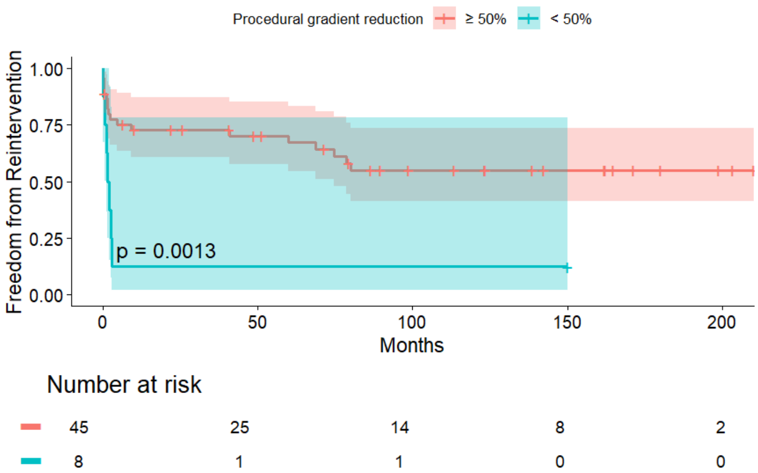

Figure 8. Procedural gradient reduction as a marker of freedom from reintervention.

Impact of relative invasive peak gradient reduction on freedom from reintervention. A reduction of ≥ 50% was associated with significantly superior freedom from reintervention compared to reduction of < 50% (p = 0.0013). Note the high rate of early attrition in the low-reduction group within the first year. Shaded areas represent the 95% confidence intervals. Numbers at risk are provided below the x-axis.

Procedural Factors and Follow-Up Structural Remodeling in Relation to Freedom from Reintervention

Univariate analyses were performed to identify procedural and structural factors associated with freedom from reintervention, specifically focusing on the use of rapid pacing, post-procedural AR, and long-term LV remodeling.

In the subgroup of patients with preserved baseline LV function (n=41), the use of rapid pacing was significantly associated with improved durability of the initial procedure compared to those treated without pacing (Figure 9A; *p = 0.031*). At 1-year follow-up, estimated freedom from reintervention in the rapid pacing group was 79.5% [95% CI: 64.9%-97.3%], versus 37.5% [95% CI: 19.9%-70.6%] in the group without rapid pacing.

The degree of postprocedural AR was not a significant factor associated with the time to reintervention. Freedom from reintervention rates remained comparable between patients with postprocedural AR grade < 2 and those with AR grade ≥ 2 (Figure 9B; *p =0.89)*.

The structural status of the LV at latest follow-up showed a strong association with clinical durability. Patients presenting with significant LV dilation (LVEDD z-score > 2) at the time of latest follow-up demonstrated a significantly lower freedom from reintervention compared to those with an LVEDD z-score ≤ 2 (Figure 9C; *p = 0.0022)*

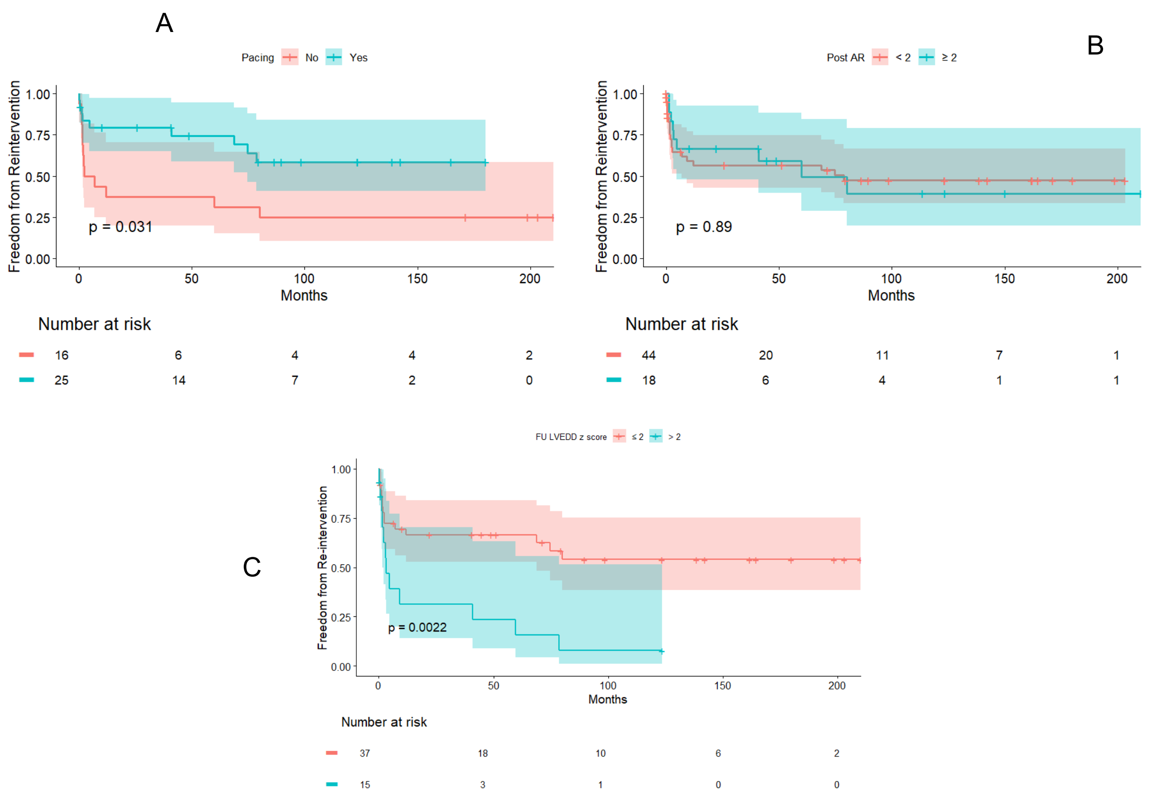

Figure 9. *Evaluation of procedural and longitudinal structural factors in relation to freedom from reintervention.*

Univariate Kaplan-Meier analyses were performed to compare freedom from reintervention across different procedural and follow-up groups. (A) In the subgroup of patients with preserved baseline LV function, a significant difference in freedom from reintervention was observed between those with and without rapid pacing (p = 0.031). (B) No significant difference in freedom from reintervention was found between patients with postprocedural AR grade < 2 versus AR grade ≥ 2 (p = 0.89). (C) A significant difference in clinical durability was observed between patients with LVEDD z-scores > 2 and ≤ 2 at latest follow-up (p = 0.0022). Shaded areas represent 95% confidence intervals. The number of patients at risk is indicated below each time interval.

Multivariable Analysis of Freedom from Reintervention

To identify independent predictors of freedom from reintervention, a multivariable Cox proportional hazards regression analysis was performed, adjusting for clinical and anatomical variables (Figure 10). Neonatal age at the time of procedure was identified as a significant independent risk factor, with neonates exhibiting a more than twofold increased risk for secondary intervention compared to infants [HR 2.39; 95% CI: 1.00-5.70; *p = 0.049*]. Conversely, the procedural use of rapid pacing emerged as a significant protective factor, associated with a 57% reduction in the hazard of reintervention [HR 0.43; 95% CI: 0.19-0.95; *p = 0.037*]. While a preprocedural aortic annular z-score of < -2 was associated with reduced durability in univariate analysis, it did not reach statistical significance as an independent predictor in the multivariable model [HR 0.53; 95% CI: 0.22-1.26; *p = 0.20*].

Variable	HR	95% CI	p-value
Age at procedure			
Infant	—	—	
Neonate	2.39	1.00, 5.70	0.049
Rapid pacing			
No	—	—	
Yes	0.43	0.19, 0.95	0.037
Annular z-score			
< -2	—	—	
>= -2	0.53	0.22, 1.26	0.2

Abbreviations: CI = Confidence Interval, HR = Hazard Ratio

Figure 10. *Multivariable Cox proportional hazards regression analysis of factors associated with freedom from reintervention.*

The table presents independent predictors for the requirement of secondary intervention following initial BAV. A hazard ratio (HR) > 1 indicates increased risk of reintervention, while an HR < 1 indicates a protective effect. Neonatal age emerged as an independent risk factor, whereas the use of rapid pacing was significantly associated with improved procedural durability. CI: confidence interval; HR: hazard ratio.

Discussion

Principal Findings

The present study provides a comprehensive longitudinal evaluation of balloon aortic valvuloplasty (BAV) outcomes in patients treated between 0 and 1 year of age with congenital valvular aortic stenosis. Our results confirm that BAV achieves substantial immediate relief of valvular obstruction and provides durable long-term palliation in a considerable proportion of patients. Specifically, nearly half of the cohort remained free from reintervention during long-term follow-up. A finding consistent with previous longitudinal series [9][11].

These findings highlight the heterogeneous durability of BAV, as a substantial proportion of patients nonetheless required reintervention, reflecting the anatomical and physiological complexity of congenital AS in early life. Within this context, the most salient finding in our present study is the independent protective effect of rapid pacing on procedural durability [HR 0.43; 95% CI: 0.19-0.95]. Importantly, this benefit occurred without measurable differences in aortic regurgitation (AR) severity, suggesting that rapid pacing improves durability through mechanisms other than these in this population. This apparent "pacing paradox" supports the hypothesis that procedural stabilization enhances the quality of the commissurotomy, thereby prolonging freedom from reintervention.

To specifically assess the impact, analyses which included rapid pacing were restricted to patients with preserved baseline left ventricular (LV) function. This methodological approach was driven by the fact that rapid pacing was rarely applied in patients with impaired LV function due to concerns about hemodynamic instability, making direct comparison prone to confounding by indication. Importantly, freedom from reintervention did not differ significantly between the total cohort and the subgroup with preserved LV function, supporting the representativeness of this subgroup. Indicating that patients with preserved LV function were representative with respect to the primary outcome. This allowed procedural factors such as rapid pacing to be interpreted alongside clinical and anatomical covariates derived from the overall cohort.

Technical Optimization and the Pacing Paradox

Since its introduction, BAV, as an initial therapy, has become strongly integrated in the clinical trajectory of patients with congenital AS. However, the procedure in neonates and infants remains technically demanding due to high cardiac output and small stroke volumes, which frequently cause balloon instability- the so-called "melon-seed" effect [18].

While rapid pacing has been utilized in various specialized centers to improve balloon stability, its routine application in neonatal and infant BAV is not yet universally established as the standard of care. In our multivariable analysis, rapid pacing was independently associated with a 57% reduction in the risk of reintervention, highlighting its clinical relevance as a modifiable procedural factor. Importantly, this association persisted despite the absence of significant differences between postprocedural AR severity and long-term LV dilation in both rapid pacing and no rapid pacing groups. These findings indicate that the beneficial effect of rapid pacing on procedural durability cannot be explained by differences in postprocedural valvular incompetence or ventricular remodeling in our population.

Our plausible explanation is that rapid pacing enhances procedural stability during balloon inflation by transiently reducing LV output. This stabilization may limit uncontrolled balloon movement within the valve orifice and reduce excessive leaflet trauma. Experimental studies of balloon angioplasty have demonstrated that irregular or uncontrolled tissue injury can provoke a pronounced fibroproliferative response, promoting restenosis over time [19][20][21]. In the context of valvular intervention, such mechanisms may contribute to earlier loss of procedural durability.

By contrast, rapid pacing may allow for a more controlled balloon expansion, potentially minimizing leaflet injury and subsequent fibrotic remodeling. While this hypothesis cannot be directly tested within the scope of the present study, it offers a biologically plausible explanation for the observed dissociation between the rapid pacing and no rapid pacing groups in terms of freedom from reintervention. Future studies incorporating detailed valve morphology and procedural imaging may help to further elucidate the mechanistic basis of this association.

Neonatal Presentation and Anatomical Spectrum

Our findings corroborate the established literature, identifying the neonatal population as a distinct high-risk subgroup [1][3]. In our cohort, neonates faced a significantly higher risk of reintervention [HR 2.39; 95% CI: 1.00-5.70]. Reflecting the combined impact of dysplastic valve morphology and adverse hemodynamic conditions.

Additionally, a small aortic annulus (z-score < -2), a small LV (LVEDD z-score < -2), and the presence of endocardial fibroelastosis at baseline were all associated with reduced freedom from reintervention in univariate analyses. Although only a small subset of our cohort met the full formal criteria for hypoplastic left heart complex (HLHC), the significant association between these smaller dimensions and reduced durability aligns with the concept proposed in established literature [22]. This suggests that even subtle degrees of left-sided hypoplasia may reflect a more complex anatomical phenotype with limited potential for a durable result after isolated valvuloplasty.

Importantly, the significance of the aortic annulus z-score being associated with durability reflects the mechanical and physiological constraints of the procedure. A smaller annulus not only limits the maximum permissible balloon size it also serves as a surrogate for more severe valvular dysplasia and limited potential to accommodate somatic growth [9]. Despite these inherent anatomical limitations, our finding that rapid pacing remains an independent predictor of success suggests that technical stabilization can mitigate some of the risks associated with small LV dimensions by ensuring the most efficient commissurotomy possible.

Long-Term Durability and the Plateau Phenomenon

The pattern of freedom from reintervention observed in our cohort provides important insights in disease trajectory in our population. After an initial high-risk period within the first 6 months, freedom from reintervention stabilized at approximately 45% beyond 80 months of follow-up, which is comparable with previously published studies [9][22].

This early attrition phase mirrors findings seen in previous studies [9-12][22]. Conversely, the sustained plateau suggests that in a substantial subset of patients, BAV results in a stable valve orifice capable of accommodating somatic growth. These data support the concept that BAV can function not merely as a temporizing measure, but as a durable long-term palliation in carefully selected patients.

Aortic Regurgitation and LV Remodeling

Progressive AR remains a substantial limitation of BAV as stated in previously published studies [10][11]. In our cohort , the prevalence of ≥ moderate AR increased from 20.8% directly postprocedural to 39.9% at latest follow-up. Interestingly, the acute severity of postprocedural AR was not predictive of reintervention, suggesting that AR grade alone does not dictate clinical failure.

Instead, significant LV dilation (LVEDD z-score > 2) at follow-up emerged as a strong predictor of reintervention. This finding indicates that clinical decision-making is primarily driven by the ventricular response to chronic volume overload rather than isolated valve competence, aligning with established literature and guidelines [10][23].

Limitations

This study has several limitations. Its retrospective, single-center design introduces inherent selection bias and limits causal inference. Although the sample size is comparable to other pediatric BAV single-center studies, the number of reintervention events restricted the complexity of multivariable analyses and limited adjustment for all potential confounders.

The evaluation of rapid pacing was limited to patients with preserved baseline LV function, reflecting its selective use in clinical practice. Although, freedom from reintervention was comparable between this subgroup and the overall cohort, residual confounding by indication cannot be fully excluded.

Conclusions

Balloon aortic valvuloplasty is an effective initial treatment for congenital valvular aortic stenosis in patients 0-1 years of age, providing substantial acute relief of obstruction and almost 50% freedom from reinterventions after 10 years. While neonates face a twofold higher risk for reintervention, rapid pacing significantly reduces the risk for reinterventions in our population.

Ethics Approval and Consent to Participate

In accordance with national legislation and institutional guidelines, this retrospective study using de-identified data did not require formal approval. Patient confidentiality was maintained by ensuring that no identifying information was included in the manuscript; therefore, the requirement of informed consent was waived.

Author Contributions

LS and JB conceived and designed the study. LS collected and analyzed the data and drafted the manuscript, while the initial procedures were performed by the treating physicians; MM, GK, and JB. All authors revised the manuscript and approved the final version.

Conflict of Interest

The authors declare there is no conflict of interest.

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References

1. Hoffman JI, Kaplan S. The incidence of congenital heart disease. J Am Coll Cardiol. 2002 Jun 19;39(12):1890-900. doi: 10.1016/s0735-1097(02)01886-7. PMID: 12084585.

2. Hoffman JI, Kaplan S, Liberthson RR. Prevalence of congenital heart disease. Am Heart J. 2004 Mar;147(3):425-39. doi: 10.1016/j.ahj.2003.05.003. PMID: 14999190.

3. Brown JW, Stevens LS, Holly S, Robison R, Rodefeld M, Grayson T, Marts B, Caldwell RA, Hurwitz RA, Girod DA, et al. Surgical spectrum of aortic stenosis in children: a thirty-year experience with 257 children. Ann Thorac Surg. 1988 Apr;45(4):393-403. doi: 10.1016/s0003-4975(98)90012-1. PMID: 3355281.

4. Campbell M. The natural history of congenital aortic stenosis. Br Heart J. 1968 Jul;30(4):514-26. doi: 10.1136/hrt.30.4.514. PMID: 5659398; PMCID: PMC487660.

5. Singh GK. Congenital Aortic Valve Stenosis. Children (Basel). 2019 May 13;6(5):69. doi: 10.3390/children6050069. PMID: 31086112; PMCID: PMC6560383.

6. Lababidi Z, Wu JR, Walls JT. Percutaneous balloon aortic valvuloplasty: results in 23 patients. *Am J Cardiol.* 1983;52(7):884–888.

7. Lababidi Z, Weinhaus L, Stoeckle H. Balloon valvuloplasty for congenital aortic stenosis. *Circulation.* 1984;69(4): 840–847.

8. Lababidi Z, Laks H, Bartley TD. Percutaneous balloon valvuloplasty for congenital aortic stenosis: long-term results. *J Am Coll Cardiol.* 1986;7(4): 869–874.

9. Moore P, Egito E, Mowrey H, Perry SB, Lock JE, Keane JF. Midterm results of balloon dilation of congenital aortic stenosis: predictors of success. J Am Coll Cardiol. 1996 Apr;27(5):1257-63. doi: 10.1016/0735-1097(95)00608-7. PMID: 8609353.

10. Galal O, Rao PS, Al-Fadley F, Wilson AD. Follow-up results of balloon aortic valvuloplasty in children with special reference to causes of late aortic insufficiency. Am Heart J. 1997 Apr;133(4):418-27. doi: 10.1016/s0002-8703(97)70183-2. PMID: 9124163.

11. Reich O, Tax P, Marek J, Rázek V, Gilík J, Tomek V, Chaloupecký V, Bartáková H, Skovránek J. Long term results of percutaneous balloon valvoplasty of congenital aortic stenosis: independent predictors of outcome. Heart. 2004 Jan;90(1):70-6. doi: 10.1136/heart.90.1.70. PMID: 14676248; PMCID: PMC1768014.

12. 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 Jun;18(2):154-161. doi: 10.5114/aic.2022.118532. Epub 2022 Aug 19. PMID: 36051839; PMCID: PMC9421511.

13. Christensen AH, Chaturvedi RR, Callahan CP, Lee KJ, Wan A, Barron DJ, Honjo O, Benson LN. Current-Era Outcomes of Balloon Aortic Valvotomy in Neonates and Infants. JACC Adv. 2022 Mar 16;1(1):100004. doi: 10.1016/j.jacadv.2022.100004. PMID: 38939081; PMCID: PMC11198319.

14. Lopez L, Saurers DL, Barker PCA, et al. Guidelines for Performing a Comprehensive Pediatric Transthoracic Echocardiogram: Recommendations From the American Society of Echocardiography. J Am Soc Echocardiogr. 2024 Feb;37(2):119-170. doi: 10.1016/j.echo.2023.11.015. PMID: 38309834.

15. Feltes TF, Bacha E, Beekman RH 3rd, Cheatham JP, Feinstein JA, Gomes AS, Hijazi ZM, Ing FF, de Moor M, Morrow WR, Mullins CE, Taubert KA, Zahn EM; Indications for cardiac catheterization and intervention in pediatric cardiac disease: a scientific statement from the American Heart Association. Circulation. 2011 Jun 7;123(22):2607-52. doi: 10.1161/CIR.0b013e31821b1f10. Epub 2011 May 2. PMID: 21536996.

16. Pettersen MD, Du W, Skeens ME, Humes RA. Regression equations for calculation of z scores of cardiac structures in a large cohort of healthy infants, children, and adolescents: an echocardiographic study. J Am Soc Echocardiogr. 2008 Aug;21(8):922-34. doi: 10.1016/j.echo.2008.02.006. Epub 2008 Apr 11. PMID: 18406572.

17. Gautier M, Detaint D, Fermanian C, Aegerter P, Delorme G, Arnoult F, Milleron O, Raoux F, Stheneur C, Boileau C, Vahanian A, Jondeau G. Nomograms for aortic root diameters in children using two-dimensional echocardiography. Am J Cardiol. 2010 Mar 15;105(6):888-94. doi: 10.1016/j.amjcard.2009.11.040. PMID: 20211339.

18. Witzke C, Don CW, Cubeddu RJ, Herrero-Garibi J, Pomerantsev E, Caldera A, McCarty D, Inglessis I, Palacios IF. Impact of rapid ventricular pacing during percutaneous balloon aortic valvuloplasty in patients with critical aortic stenosis: should we be using it? Catheter Cardiovasc Interv. 2010 Feb 15;75(3):444-52. doi: 10.1002/ccd.22289. PMID: 19937778.

19. Isner JM. Vascular remodeling. Honey, I think I shrunk the artery. Circulation. 1994 Jun;89(6):2937-41. doi: 10.1161/01.cir.89.6.2937. PMID: 7911405

20. Adler M, Mayo A, Zhou X, Franklin RA, Meizlish ML, Medzhitov R, Kallenberger SM, Alon U. Principles of Cell Circuits for Tissue Repair and Fibrosis. iScience. 2020 Feb 21;23(2):100841. doi: 10.1016/j.isci.2020.100841. Epub 2020 Jan 16. PMID: 32058955; PMCID: PMC7005469.

21. Kornowski R, Hong MK, Tio FO, Bramwell O, Wu H, Leon MB. In-stent restenosis: contributions of inflammatory responses and arterial injury to neointimal hyperplasia. J Am Coll Cardiol. 1998 Jan;31(1):224-30. doi: 10.1016/s0735-1097(97)00450-6. PMID: 9426044.

22. McElhinney DB, Lock JE, Keane JF, Moran AM, Colan SD. Left heart growth, function, and reintervention after balloon aortic valvuloplasty for neonatal aortic stenosis. Circulation. 2005 Feb 1;111(4):451-8. doi: 10.1161/01.CIR.0000153809.88286.2E. PMID: 15687133.

23. Baumgartner H, De Backer J, Babu-Narayan SV, Budts W, Chessa M, Diller GP, Lung B, Kluin J, Lang IM, Meijboom F, Moons P, Mulder BJM, Oechslin E, Roos-Hesselink JW, Schwerzmann M, Sondergaard L, Zeppenfeld K; ESC Scientific Document Group. 2020 ESC Guidelines for the management of adult congenital heart disease. Eur Heart J. 2021 Feb 11;42(6):563-645. doi: 10.1093/eurheartj/ehaa554. PMID: 32860028.