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Clinical Research

Outcomes after Mechanical Aortic Valve Replacement in Children with Congenital Heart Disease

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Background: The optimal choice of valve substitute for aortic valve replacement (AVR) in pediatric patients remains a matter of debate. This study investigated the outcomes following AVR using mechanical prostheses in children.
Methods: Forty-four patients younger than 15 years who underwent mechanical AVR from March 1990 through March 2023 were included. The outcomes of interest were death or transplantation, hemorrhagic or thromboembolic events, and reoperation after mechanical AVR. Adverse events included any death, transplant, aortic valve reoperation, and major thromboembolic or hemorrhagic event.
Results: The median age and weight at AVR were 139 months and 32 kg, respectively. The median follow-up duration was 56 months. The most commonly used valve size was 21 mm (14 [31.8%]). There were 2 in-hospital deaths, 1 in-hospital transplant, and 1 late death. The overall survival rates at 1 and 10 years post-AVR were 92.9% and 90.0%, respectively. Aortic valve reoperation was required in 4 patients at a median of 70 months post-AVR. No major hemorrhagic or thromboembolic events occurred. The 5- and 10-year adverse event-free survival rates were 81.8% and 72.2%, respectively. In univariable analysis, younger age, longer cardiopulmonary bypass time, and smaller valve size were associated with adverse events. The cut-off values for age and prosthetic valve size to minimize the risk of adverse events were 71 months and 20 mm, respectively.
Conclusion: Mechanical AVR could be performed safely in children. Younger age, longer cardiopulmonary bypass time and smaller valve size were associated with adverse events. Thromboembolic or hemorrhagic complications might rarely occur.

Keywords: Aortic valve replacement, Congenital heart defects, Child, Mechanical

Introduction

The selection of the most appropriate valve substitute for irreparable aortic valve in children remains a contentious issue [1]. Several options are available for children, including mechanical prostheses, pulmonary autografts (Ross procedure), bioprostheses, and homografts. Bioprosthetic valves have traditionally been deemed unsuitable for children due to their inevitable early degeneration and subsequent calcification [2]. Homografts have also been observed to have a propensity for early degeneration and calcification in younger patients [3]. The pulmonary autograft (Ross procedure), which has been promoted as the ideal prosthesis for aortic valve replacement (AVR) in children, offers benefits such as growth potential, an excellent hemodynamic profile, theoretically no age limit, and no need for lifelong anticoagulation. However, its technical complexity and the potential for autograft failure, which could transform a "1-valve disease" into a "2-valve disease," hinder its widespread use [4]. Conversely, mechanical prostheses are theoretically immune to degeneration, although they do require lifelong anticoagulation, and the valve could fail due to the patient outgrowing it when a small prosthesis is placed in children. Despite the scarcity of studies on the outcomes following mechanical AVR in children, it may still play a role in treating pediatric aortic

valve diseases.

Therefore, the objective of this study was to investigate the outcomes after mechanical AVR in children.

Methods

Patients and definition

The study received approval from the Asan Medical Center Institutional Review Board (IRB no., S2023-0512-0002; IRB approval date: June 27, 2023), and the requirement for individual patient consent was waived. This study included a total of 44 patients, all under the age of 15, who underwent AVR with a mechanical prosthesis between March 1990 and March 2023. The primary outcomes of interest were death or transplant, reoperation, and significant thromboembolic or hemorrhagic events. These events were defined in line with the guidelines published in 1996 [5]. An adverse event was characterized as a composite event that included death, transplant, reoperation of the aortic valve, and significant thromboembolic or hemorrhagic event.

Valve selection

For the replacement of an irreparable aortic valve, the types of valves that can be used as a durable option in this age group include the pulmonary autograft or mechanical prosthesis. The choice of valve for AVR has varied over time, but the recent strategy for valve selection in children is as follows: if the aortic annulus is too small to accommodate a commercial mechanical prosthesis, even after an annular enlargement procedure, or if the pulmonary annulus is 20 mm or larger, allowing for external support with an adult-sized vascular graft, or if the patient or their guardians are not willing to accept lifestyle limitations due to anticoagulation, we proceed with the Ross operation. Conversely, if the pulmonary valve is not competent or if the pulmonary valve is absent in certain congenital heart diseases such as truncus arteriosus or pulmonary atresia with ventricular septal defect (VSD), we perform mechanical AVR. In all other cases, we select the type of valve that minimizes the likelihood of future reoperation or reintervention.

Surgical techniques

A median sternotomy was performed, and moderate hypothermic cardiopulmonary bypass (CPB) was initiated via cannulation of the ascending aorta and either a single atrium or both venae cavae. Following the induction of cardioplegic arrest, a vent cannula was inserted to drain the left heart. An incision resembling a reverse hockey stick was made on the ascending aorta towards the non-coronary sinus, or the ascending aorta was severed for improved visibility as needed. If the aortic valve was beyond repair, the option of a mechanical AVR could be considered. For young children with an aortic valve annulus too small to fit the smallest commercially available prosthetic valve, or for older children whose aortic valve annulus could not accommodate an adult-sized commercial valve, an annular enlargement procedure of any type could be performed prior to the placement of the valve prosthesis. All mechanical prostheses were placed in a supra-annular position using multiple horizontal mattress sutures, with or without reinforcing pledgets. After the patient was weaned from CPB, transesophageal echocardiography was routinely conducted to assess paravalvular leakage, leaflet obstruction by surrounding structures, and the gradient across the prosthetic valve.

Anticoagulation and follow-up

Immediately after AVR, either intravenous unfractionated heparin or subcutaneous low molecular weight heparin was administered until the international normalized ratio (INR) reached the therapeutic range of 2 to 2.5. Long-term anticoagulation was then maintained with warfarin, aiming for a therapeutic INR range between 2 and 2.5. An echocardiographic examination was routinely conducted before discharge and at regular intervals during follow-up.

Statistical analysis

The normality of data distribution was evaluated with the Shapiro-Wilk test. Data were presented as frequency with percentage for categorical variables and mean±standard deviation or median with interquartile range (IQR) for continuous variables. The chi-square test or Fisher exact test was used to compare inter-group differences of categorical variables, and the Student t-test or Mann-Whitney U-test was used to compare continuous variables. Survival analysis was conducted using the Kaplan-Meier method. The risk factors for the primary endpoint were identified through Cox regression analysis. Variables with $p<0.05$ were considered significant. Receiver operating characteristic (ROC) analysis was performed to identify the cutoff values for the significantly associated factors. Statistical

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analyses were performed using R software ver. 3.6.3 (www.r-project.org).

Results

Baseline characteristics

Table 1 shows the patients' baseline characteristics. The median age and body weight at AVR were 139 months (IQR, 68–159 months), and 32 kg (IQR, 15–51 kg), respectively. The modes of valve dysfunction observed were regurgitation in 22 patients (50.0%), stenosis in 6 patients (13.6%), and a combination of both in 16 patients (36.4%). The number of aortic cusps was 3 in 33 patients (75.0%). The most common cause of aortic valve disease was congenital aortic valve disease, found in 16 patients (36.4%), and associated conotruncal anomaly, also found in 16 patients (36.4%). This was followed by other associated congenital heart diseases such as isolated VSD or VSD associated with coarctation of the aorta in 5 patients (11.4%), and connective tissue disorder in 3 patients (6.8%) (Fig. 1). Most of the patients (34 patients [77.3%]) had undergone at least 1 prior catheter-based or surgical intervention. Additionally, roughly one-third of the patients (14 [31.8%]) had previously undergone a catheter-based or surgical intervention specifically for aortic valve issues.

Operative characteristics

Table 2 describes the operative details. The median CPB time and aortic cross-clamp time were 183 minutes (IQR,

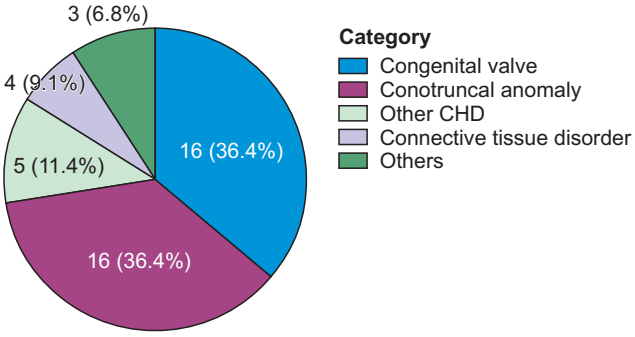

Fig. 1. Proportion of patients who underwent mechanical aortic valve replacement according to the aortic valve disease category. CHD, congenital heart disease.

Table 1. Baseline characteristics

Characteristic	Value
Age at operation (mo)	139 (68–159)
Body weight at operation (kg)	32 (15–51)
Sex (male)	27 (61.4)
Mode of aortic valve dysfunction	
Aortic stenosis	6 (13.6)
Aortic regurgitation	22 (50.0)
Combined	16 (36.4)
No. of aortic cusps	
Bicuspid	8 (18.2)
Tricuspid	33 (75.0)
Quadricuspid	3 (6.8)
Category of aortic valve disease	
Congenital aortic valve disease	16 (36.4)
Associated with conotruncal anomaly	16 (36.4)
Associated with other CHD[a]	5 (11.4)
Connective tissue disorder	3 (6.8)
Others[b]	4 (9.1)
Associated syndrome or chromosomal anomalies[c]	9
Previous any catheter-based or surgical intervention	34 (77.3)
Previous catheter-based or surgical intervention for aortic valve	14 (31.8)

Values are presented as median (interquartile range) or number (%).
CHD, congenital heart disease.
[a]The category of "other CHD" included 3 cases of ventricular septal defects and 2 cases of coarctation of aorta with a ventricular septal defect. [b]The category of "other" included 2 cases of infective endocarditis, 1 case of hypertrophic obstructive cardiomyopathy, and 1 case of Takayasu arteritis. [c]Marfan syndrome in 2; and Loeys-Dietz syndrome, Turner syndrome, Noonan syndrome/CHARGE syndrome, 22q11.2 deletion, 46,XX,dup(9)(p24p13), and X-linked gammaglobulinemia in 1 each.

Table 2. Operative details

Variable	Value
Annular enlargement	11 (25.0)
Konno	4 (9.1)
Manouguian	3 (6.8)
Nick's	3 (6.8)
Others	1 (2.3)
Valve type	
St. Jude (Abbott, Santa Clara, CA, USA)	27 (61.3)
On-X (CryoLife, Kennesaw, GA, USA)	12 (27.3)
ATS (Medtronic, Minneapolis, MN, USA)	4 (9.1)
MIRA (Edward Lifesciences, Irvine, CA, USA)	1 (2.3)
Valve size (mm)	
16	4 (9.1)
17	5 (11.4)
19	12 (27.3)
21	14 (31.8)
23	4 (9.1)
25	4 (9.1)
27	1 (2.3)
Concomitant procedures (in 22 patients)	
Mitral valve replacement	4 (9.1)
Mitral valvuloplasty	4 (9.1)
RV to PA valved conduit or PVR	4 (9.1)
PA angioplasty	2 (4.5)
Bentall	2 (4.5)
TVR	1 (2.3)
TVP	1 (2.3)
Others	7 (15.9)
Cardiopulmonary bypass time (min)	183 (160–237)
Aortic cross clamp time (min)	113 (92–151)
Intensive care unit stay (day)	2 (1–3)
Hospital (day)	12 (10–18)

Values are presented as median (interquartile range) or number (%).
PA, pulmonary artery; PVR, pulmonary valve replacement; RV, right ventricle; TVP, tricuspid valvuloplasty; TVR, tricuspid valve replacement.

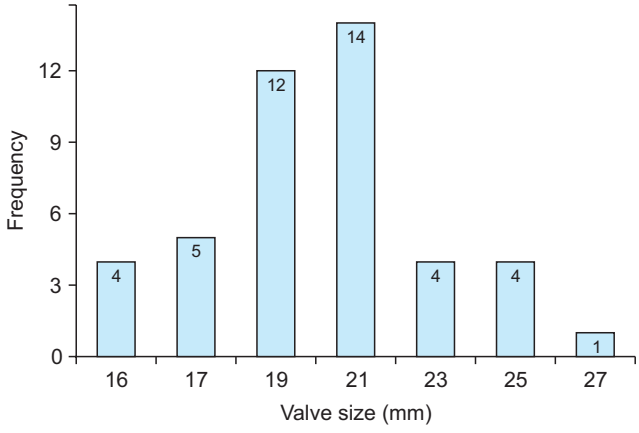

Fig. 2. Size distribution of aortic valve prostheses in patients who underwent mechanical aortic valve replacement.

Table 3. Details of the patients who died or required transplant after aortic valve replacement

Patient	Diagnosis	Associated anomalies	Age (mo)	Weight (kg)	Annulus size (mm)	Annular enlargement	Previous cardiac procedure	CPB time (min)	ACC time (min)	Valve type[a]	Valve size (mm)	Concomitant procedure	Interval (mo)	Cause of death
Patient 1	HOCM	-	66	10.5	16.8	Konno	LVOT relief	281	157	SJ	19	MVR	0	LCOS
Patient 2	Loeys-Dietz syndrome	-	140	32.6	23.2	-	VSD closure	300	104	SJ	22	Bentall operation	0	LCOS
Patient 3	Infective endocarditis	X-linked gamma-globulinemia	65	15.3	19.2	-	-	188	113	On-X	17	Left atrial thrombus removal	7	Sepsis after HTPL
Patient 4	Marfan syndrome	-	46	10.0	21.4	-	David's operation, MVP, TAP	164	114	SJ	19	MVR	17	VT

CPB, cardiopulmonary bypass time; ACC, aortic cross clamp time; HOCM, hypertrophic obstructive cardiomyopathy; LVOT, left ventricular outflow tract; SJ, St. Jude Medic, MVR, mitral valve replacement; LCOS, low cardiac output syndrome; VSD, ventricular septal defect; HTPL, heart transplantation; MVP, mitral valvuloplasty; TAP, tricuspid annuloplasty; VT, ventricular tachycardia.
[a]St. Jude (Abbott, Santa Clara, CA, USA); On-X (On-X life Technologies Inc., Austin, TX, USA).

160–237 minutes) and 113 minutes (IQR, 92–151 minutes), respectively. Eleven patients (25.0%) required annular enlargement procedure including the Konno procedure in 4 patients (9.1%), the Manouguian procedure in 3 (6.8%), the Nick procedure in 3 patients (6.8%) and another procedure in 1 patient (2.3%). All the implanted prostheses were bi-leaflet valves regardless of the manufacturer. The most commonly used valve size was 21 mm (14 patients [31.8%]). Fig. 2 depicts a distribution of valve size. Twenty-two patients (50.0%) required concomitant procedures including mitral valve repair or replacement in 8 patients (18.2%), pulmonary outflow procedures in 6 patients (13.6%), and the Bentall operation in 2 patients (4.5%).

Perioperative outcomes

Among the hospital survivors (41 [93.2%]), the median intensive care unit stay was 2 days (IQR, 1–3 days) and the median hospital stay was 12 days (IQR, 10–18 days). There were 2 in-hospital deaths and 1 in-hospital transplantation (Table 3). The first death involved a 5-year-old girl with a history of surgery for hypertrophic obstructive cardiomyopathy. Despite undergoing AVR, a modified Konno procedure, and concurrent mitral valve replacement, she could not be weaned off CPB. She ultimately passed away 1 day postoperatively while on extracorporeal membrane oxygenation (ECMO). The second death was an 11-year-old boy diagnosed with Loyes-Diez syndrome. He had a history of VSD repair but could not be weaned off CPB following a Bentall operation. He died 10 days postoperatively while on ECMO. The final case involved a 5-year-old boy with X-linked gammaglobulinemia. He underwent an emergency AVR and left atrial thrombus removal due to infective endocarditis and a left atrial thrombus. On the day of AVR, he required ECMO due to severe left ventricular dysfunction. He underwent a heart transplantation while on ECMO 5 months post-AVR. However, he ultimately died from fungal sepsis 2 months after the transplantation.

Long-term outcomes

The median follow-up duration was 56 months (IQR, 13–139 months). There was 1 late death: a 3-year-old boy who had a history of valve-sparing aortic root replacement and mitral valve repair 11 days before AVR and died of ventricular arrhythmia 17 months after AVR (Table 3). The overall transplantation-free survival rates at 1, 5, and 10 years postoperatively were 92.9%, 90.0%, and 90.0%, respectively (Fig. 3A). Reoperation or reintervention was necessary for 8 patients, with 4 of these patients requiring aortic valve reoperation at a median of 70 months post-AVR (Table 4). No major hemorrhagic or thromboembolic events were reported during the follow-up period. The adverse event-free survival rates at 1, 5, and 10 years were 92.9%, 86.1%, and 72.2%, respectively (Fig. 3B).

Factors associated with adverse events

In the univariable analysis, factors such as younger age, lower body weight, extended CPB time, and smaller valve size were linked to adverse events during the follow-up period (Table 5). The ROC analysis revealed that the age threshold for the occurrence of adverse events was 71 months (area under the curve, 0.745; 95% confidence interval [CI], 0.572–0.918; p=0.032) (Fig. 4A). Similarly, the valve size

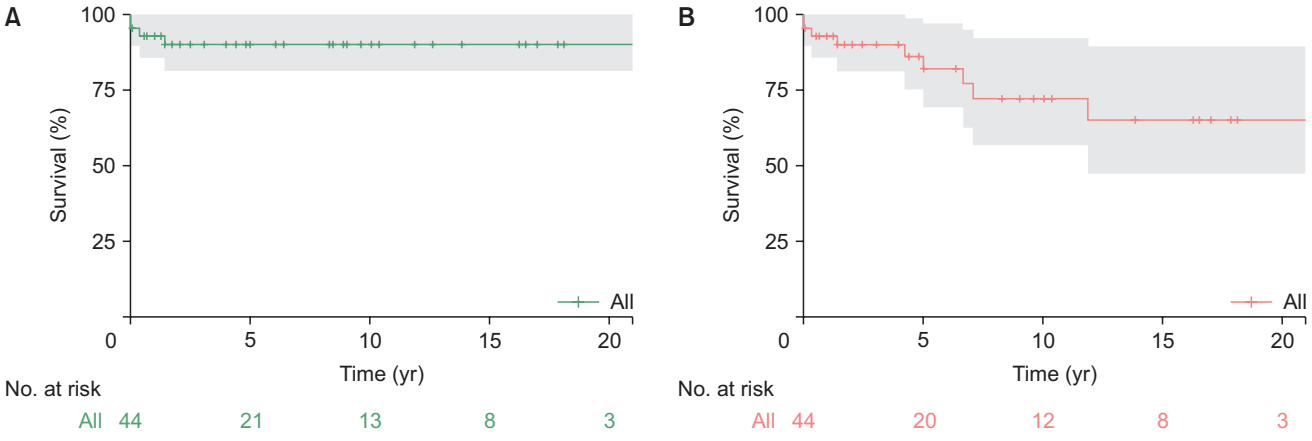

Fig. 3. Kaplan-Meier survival curves. (A) Overall survival and (B) adverse event-free survival curves after aortic valve replacement with mechanical prosthesis in children under 15 years of age. Shaded area represents 95% confidence interval.

Table 4. Details of the patients who required reoperation for aortic valve

Patient	Diagnosis	Associated anomalies	Age (mo)	Weight (kg)	Valve type[a]	Valve size (mm)	Annular enlargement	Cause of AoV reoperation	Interval (mo)
Patient 1	Congenital AS, AR	-	153	41.0	St. Jude	17	Nick's	Pannus formation	85
Patient 2	Truncus arteriosus	-	12	9.0	ATS	16	-	Pannus formation	80
Patient 3	Truncus arteriosus, IAA	22q11.2 deletion	9	5.3	ATS	16	-	Pannus formation	51
Patient 4	Congenital AS	Noonan syndrome	130	40.0	St. Jude	19	Manouguian	Pannus formation	60

AoV, aortic valve; AS, aortic stenosis; AR, aortic regurgitation; IAA, interrupted aortic arch.
[a]St. Jude (Abbott, Santa Clara, CA, USA); ATS (Medtronic, Minneapolis, MN, USA).

Table 5. Univariable analysis to identify factors associated with adverse events

Variable	HR (95% CI)	p-value
Age	0.99 (0.98–1.00)	0.039
Sex	3.13 (0.74–13.23)	0.120
Body weight	0.95 (0.91–1.00)	0.038
Body surface area	0.16 (0.03–0.84)	0.030
Mode of aortic valve dysfunction		0.907
Category of aortic valve disease		0.117
Previous aortic valve intervention	0.99 (0.24–4.16)	0.988
Concomitant other valve surgery	2.47 (0.61–9.99)	0.204
Cardiopulmonary bypass time	1.02 (1.00–1.03)	0.017
Aortic cross clamp time	1.01 (1.00–1.03)	0.182
Annular enlarge when AVR	1.60 (0.38–6.76)	0.522
Valve type		
St. Jude	1.06 (0.22–5.15)	0.942
On-X	0.32 (0.04–2.97)	0.319
ATS	5.67 (0.66–48.33)	0.113
Valve size (continuous)	0.64 (0.46–0.90)	0.010
Valve size (Z-score)	0.97 (0.86–1.09)	0.554

HR, hazard ratio; CI, confidence interval; AVR, aortic valve replacement.

threshold for the occurrence of adverse events was determined to be 20 mm (area under the curve, 0.799; 95% CI, 0.646–0.951; p=0.009) (Fig. 4B). The survival curves for freedom from adverse events showed significant differences according to the thresholds for age (71 months) and valve size (20 mm) obtained through the ROC analysis (Fig. 5).

Discussion

The ideal treatment option for aortic valve diseases in growing children would provide perfect recovery of valve function, good hemodynamic performance, growth potential and maximum durability. At most centers, valve repair is often the first line of treatment for children with aortic valve disease. However, aortic valve repair may not always be feasible and is frequently viewed as a palliative measure to delay the need for AVR until the child is older, at which point a definitive mechanical AVR with an adult-sized prosthesis can be performed [6]. If aortic valve repair is not possible or fails, AVR should be considered, with various prosthesis options available, including mechanical prosthesis, pulmonary autograft, and other biological valves such as homografts or commercial bioprostheses [6,7]. Given the inevitable accelerated degeneration of homografts or commercial bioprostheses compared to other prostheses, the use of a bioprosthesis or homograft in pediatric AVR should be limited to patients who do not have a suitable

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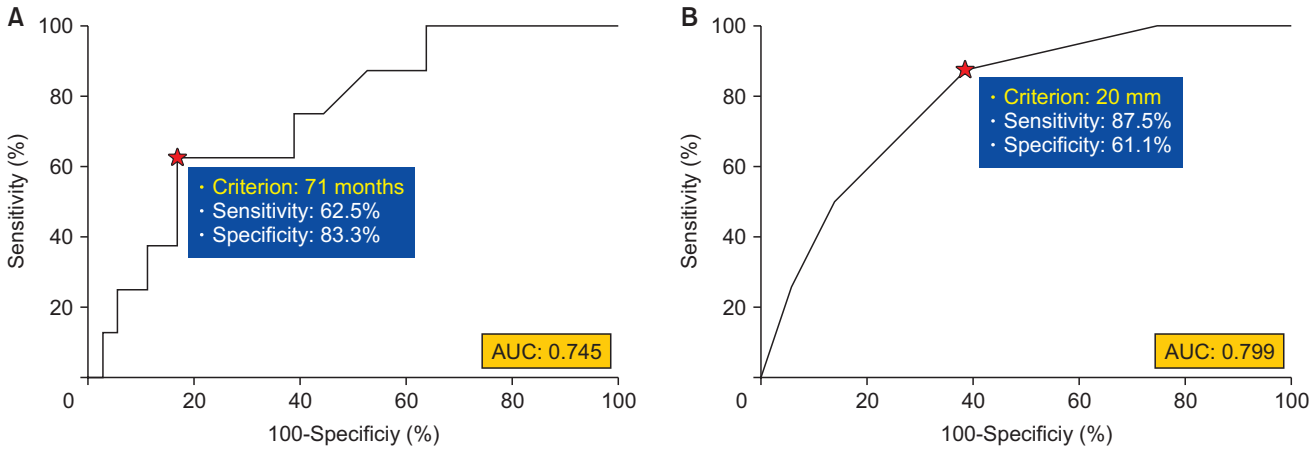

Fig. 4. Receiver operating characteristic curve to identify cutoff values of age and valve size to minimize the occurrence of adverse outcomes. The cutoff value of age was 71 months (p=0.032; area under the curve [AUC], 0.745; 95% confidence interval [CI], 0.572–0.918; sensitivity, 62.5%; specificity, 83.3%), and the cutoff value of valve size was 20 mm (p=0.009; AUC, 0.799; 95% CI, 0.646–0.951; sensitivity, 87.5%; specificity, 61.1%).

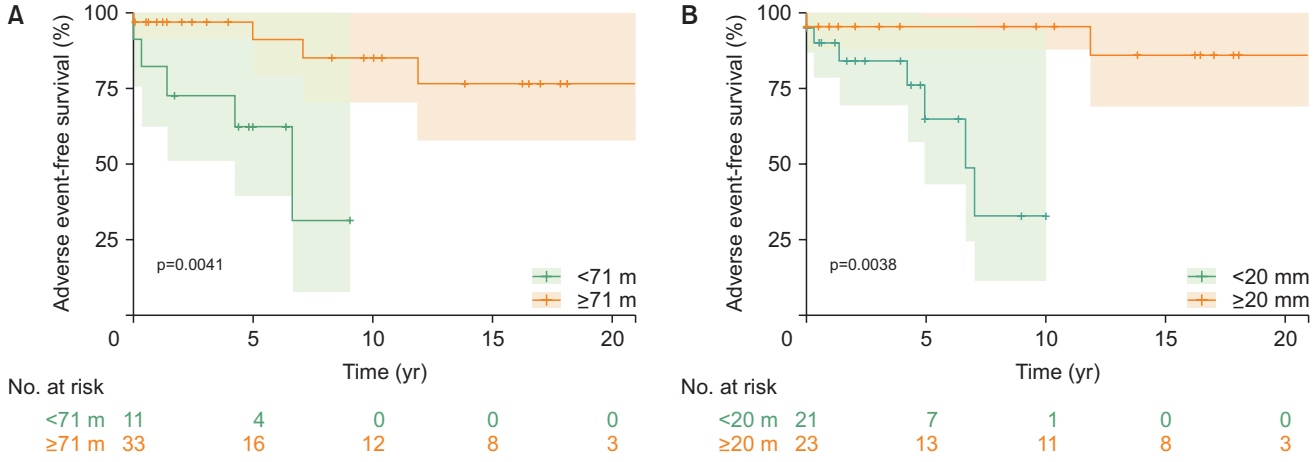

Fig. 5. Adverse event-free survival curves according to the calculated cutoff values of valve size (A) and age (B). Shaded area represents the 95% confidence interval.

pulmonary autograft and for whom anticoagulation is contraindicated [7,8]. Consequently, a pulmonary autograft and mechanical prosthesis are often the only options for most children requiring AVR for aortic valve diseases.

A significant number of recent studies have shown that the Ross procedure boasts excellent overall transplant-free survival, aortic valve reoperation-free survival, and event-free survival [9-11]. Moreover, some reports have highlighted the superiority of the Ross procedure in terms of survival and freedom from reoperation or event, compared to mechanical AVR in children and young adults [12-14]. However, the Ross procedure is technically challenging, carries a long-term risk of autograft dilatation and subsequent failure, and has a high likelihood of necessitating reoperation or reintervention in the right ventricular outflow tract [11,15]. Additionally, procuring a high-quality pulmonary autograft may not always be feasible in children suffering from aortic valve disease.

Once valve repair and the Ross procedure are excluded, mechanical AVR could be a viable surgical option for children with aortic valve disease. Recent large-scale studies on mechanical AVR in children and adolescents have consistently reported a good survival rate, ranging between 85% and 95% at 10 years [16-18]. In this study, the overall transplant-free survival rate at 10 years was 90%, which aligns with the results of previous studies. Earlier studies identified factors associated with death or transplantation, including younger age, the need for an annular enlarge-

ment procedure, and associated congenital heart diseases [12,14,19]. However, in our study, we were unable to identify any factors associated with death or transplantation. This could be due to the small size of our study cohort and the limited number of events. It is worth noting that 3 out of the 4 cases of death or transplantation (75%) involved patients with a syndrome or chromosomal anomaly. These included Marfan syndrome, Loyes-Diez syndrome, and X-linked gammaglobulinemia. Despite this observation, the association did not reach statistical significance.

A major disadvantage of mechanical prostheses is the requirement for lifelong anticoagulation. If the anticoagulation level is insufficient, there is an increased risk of potentially fatal thromboembolic or hemorrhagic events. Our target anticoagulation level (INR, 2–2.5) is slightly below the guideline [20], yet there were no thromboembolic or hemorrhagic events during follow-up. This suggests that maintaining a well-controlled and stable anticoagulation level may be crucial in preventing anticoagulation-related events.

During the follow-up period, no thromboembolic or hemorrhagic events were observed. The adverse events that did occur were related to aortic valve reoperations or reinterventions, death, and transplantation. Previous studies have identified younger age, lower body weight, and smaller prosthesis size as risk factors associated with death, transplantation, and aortic valve reoperation or reintervention [12,18]. Consistent with these studies, our univariable analysis also identified younger age, lower body weight, and smaller prosthesis size as factors associated with adverse events. Furthermore, we found a correlation between longer CPB time and adverse events. This may be due to the complexity of the disease, which necessitates challenging procedures. However, the need for annular enlargement was not associated with adverse outcomes [19].

Among factors associated with adverse events in our study, we tried to identify cut-off values for age and prosthetic valve size to minimize the risk of adverse events. Our findings suggest that if patients older than 6 years undergo mechanical AVR using a prosthesis of 21 mm or larger, the risk of adverse events during follow-up could be minimized.

Limitations

This study was limited by the inherent disadvantages of a retrospective research design. The small size of the study cohort and the limited number of events prevented a multivariable analysis. Throughout the study period, the criteria for aortic valve intervention in children, as well as the guidelines for choosing a valve prosthesis for AVR in children, varied among surgeons and over time.

Conclusion

AVR with mechanical prosthesis could be performed safely in children younger than 15 years. Younger age, longer CPB time, and smaller valve size were associated with adverse events. Mechanical AVR could be performed with a low risk of adverse events using a prosthesis that is 21 mm or larger, in children older than 6 years. Thromboembolic or hemorrhagic complications were rare occurrences.

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Conceptualization: PCS, KJY. Data curation: PCS, KJY. Formal analysis: PCS, KJY, KDH. Methodology: PCS, KJY, KDH, CES. Visualization: KJY, KDH. Writing–original draft: PCS, KJY. Writing–review & Editing: all authors. Final approval of the manuscript: all authors.

Conflict of interest

No potential conflict of interest relevant to this article was reported.

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