Mechanical Mitral Valve Replacement: A Multicenter Study of Outcomes with Use of 15- to 17-mm Prostheses

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Background. **The aim of this study was to evaluate early and mid-term outcomes (mortality and prosthetic valve reintervention) after mitral valve replacement with 15- to 17-mm mechanical prostheses.**

Methods. **A multicenter, retrospective cohort study was performed among patients who underwent mitral valve replacement with a 15- to 17-mm mechanical prosthesis at 6 congenital cardiac centers: 5 in The Netherlands and 1 in the United States. Baseline, operative, and follow-up data were evaluated.**

Results. **Mitral valve replacement was performed in 61 infants (15 mm, n = 17 [28%]; 16 mm, n = 18 [29%]; 17 mm, n = 26 [43%]), of whom 27 (47%) were admitted to the intensive care unit before surgery and 22 (39%) required ventilator support. Median age at surgery was 5.9 months (interquartile range [IQR] 3.2-17.4), and median weight was 5.7 kg (IQR, 4.5-8.8). There were 13 in-hospital deaths (21%) and 8 late deaths (17%, among 48 hospital survivors). Major adverse events occurred in 34 (56%). Median follow-up was 4.0 years (IQR, 0.4-12.5) First prosthetic valve replacement (n = 27 [44%]) occurred at a median of 3.7 years (IQR, 1.9-6.8). Prosthetic valve endocarditis was not reported, and there was no mortality related to prosthesis replacement. Other reinterventions included permanent pacemaker implantation (n = 9 [15%]), subaortic stenosis resection (n = 4 [7%]), aortic valve repair (n = 3 [5%], and aortic valve replacement (n = 6 [10%]).**

Conclusions. **Mitral valve replacement with 15- to 17-mm mechanical prostheses is an important alternative to save critically ill neonates and infants in whom the mitral valve cannot be repaired. Prosthesis replacement for outgrowth can be carried out with low risk.**

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Mitral valve replacement (MVR) may be the only surgical option in some infants with severe congenital MV stenosis or regurgitation, often after failed repair.[1] The prosthesis of choice is often a mechanical prosthesis because these are available in smaller sizes and are more durable than bioprosthetic counterparts, particularly in young pediatric patients.[2] Although mechanical prostheses > 17 mm have been the only available option for MVR in earlier eras, these prostheses were often too large for infants and neonates, where the normative values for lateral mitral annular diameter for neonates (weight, 3 kg; height, 50 cm; body surface area [BSA], 0.2 m^2) ranges from 8 to 12 mm and at 1 year (weight, 7.5 kg; height, 71.5 cm; BSA, 0.4 m^2) from 11 to 17 mm.[3]

Since 1995 mechanical prostheses have been available in 16-mm and 17-mm sizes, and the 15-mm prosthesis has been tested clinically and subsequently approved by the U.S. food and drug administration in March 2018.[4] Despite the use of ≤17-mm mechanical valves in centers across the world, the small numbers in individual centers has resulted in few reports of outcomes in the literature.

Understanding clinical outcome in patients who have undergone MVR with 15- to 17-mm mechanical prosthesis can serve as a benchmark to determine utility and benefits of bioprosthetic options, such as the stented bovine jugular vein conduits, that have been introduced as an alternative.[5] The availability of 15-mm mechanical prostheses for off-label use since 1998 allows us to report a multiinstitutional experience with up to 20 years of follow-up of 15- to 17-mm mechanical mitral prostheses

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in infants and neonates, particularly mortality and valve-related morbidity.

Patients and Methods

Study Design

A multicenter, retrospective cohort study was performed in patients who underwent MVR with 15- to 17-mm mechanical prosthesis between January 1, 1998 and December 31, 2018. These prostheses were implanted for congenital mitral disease in 5 centers in the Netherlands (University Medical Centers in Groningen, Leiden, Nijmegen, Rotterdam, and Utrecht) and 1 in the United States (Boston Children's Hospital). Approval was obtained from the institutional review board at each center, with a waiver of informed consent, before collection of clinical and echocardiographic data.

Data Collection

Collected data included basic demographic information, descriptive anatomic diagnoses, associated noncardiac or genetic anomalies, preoperative factors, echocardiographic data, mortality, and other clinical adverse events and reinterventions. Procedural details were obtained from operative reports. Data on systemic anticoagulation after mechanical valve implant were also collected.

Outcomes

The primary outcomes evaluated were mortality and prosthesis replacement. Secondary outcomes were major adverse events during index hospitalization; thromboembolic events after valve implantation; resource utilization as measured by postoperative days on ventilator, postoperative intensive care unit (ICU) length of stay, and hospital length of stay; and left ventricular function based on follow-up echocardiography after discharge. Index operation was defined as the first surgery where a 15- to 17-mm mechanical mitral prosthesis was inserted. Major adverse events were defined according to The Society of Thoracic Surgeons Congenital Heart Surgery Database.[6,7] Postoperative days on the ventilator was defined as total number of days on the ventilator after the index operation and included all reintubation days. Postoperative ICU length of stay was defined as total postoperative days in the ICU, including days readmitted to the ICU during hospitalization for the index operation.

Echocardiography

All echocardiographic studies were reviewed before surgery, at discharge, and 0.5, 1, 2, 3, 5, and 10 years after MVR when available. Measurements of the MV annulus diameter in 2 planes, mitral valve gradient and degree of valvular regurgitation and left ventricular function, were performed by an experienced cardiologist applying the recommendations of the American Society of Echocardiography.[8,9] Qualitative assessment of pulmonary artery pressures (based on pulmonary regurgitation jet), right ventricular pressures based on tricuspid regurgitation jet, or septal position were also performed and pulmonary hypertension was scored as none, mild to moderate, and severe. Where echocardiographic images were not available for review, data from an echocardiographic report at the appropriate time point were used.

Statistical Methods

Patient and procedural characteristics are summarized as frequencies and percentages for categorical variables and medians and interquartile ranges (IQRs) and/or ranges for continuous variables. Cumulative incidence of death after MVR was estimated by size of prosthesis using the Kaplan-Meier method. Cumulative incidence of prosthesis replacement after MVR was estimated treating death as a competing risk. The Wilcoxon signed-rank test was used to evaluate change in valve size at the time of prosthesis replacement. All analysis was performed in SAS version 9.4 (SAS Institute Inc, Cary, NC).

Results

Patients

Sixty-one patients were included in the analysis (Table 1), with a median age at surgery of 5.9 months (IQR, 3.2-17.4; range, 1 day to 5.3 years) and a median weight of 5.7 kg (IQR, 4.5-8.8). Primary diagnosis was isolated congenital MV stenosis/regurgitation in 29 (48%), atrioventricular septal defect in 18 (30%), Shone and hypoplastic left heart complex in 9 (15%), and other in 5 (8%). Twenty-seven patients (47%) were treated in the ICU before surgery and 22 (39%) were on mechanical ventilator support. Thirty-four patients (56%) had previous attempts at repair. Median time from repair to replacement was 26 days (IQR, 13-190). Thirteen patients (21%) underwent MVR requiring a second bypass run at the index surgery after failure of the initial mitral repair ($n = 11$), iatrogenic mitral regurgitation (prolapse of the anterior MV leaflet) after an initial resection of the subaortic stenosis ($n = 1$), and severe mitral regurgitation and stenosis after an initial Ross-Konno procedure ($n = 1$).

Surgical Technique

Procedural details and outcomes are outlined in Table 2. Transseptal access (50 [82%]) with excision of all valve tissue (except the posterior leaflet in 9 patients 15%]) with pledgets (if used) on the ventricular side of the annulus was the preferred method. Orientation of the valve was usually "antianatomic." Annular implantation was possible in 47 patients (77%) and supraannular in 14 (23%). Median pump time was 149 minutes (IQR, 110-226), and median cross-clamp time was 99 minutes (IQR, 73-141).

Systemic Anticoagulation

Systemic anticoagulation included initial intravenous heparin in all patients and was followed when clinically feasible by vitamin K antagonist therapy (acenocoumarol, half-life 8-11 hours; phenprocoumon, half-life 160 hours; or warfarin, half-life 20-60 hours) in 36 (59%), aspirin in 4

Table 1. Patient and Procedural Characteristics (N = 61)

Characteristic	Value
Age at surgery, mo	5.9 (3.2-17.4)
Male sex	31 (51)
Weight at surgery, km	5.7 (4.5-8.8)
Preoperative status	
In intensive care unit	27 (47)
On mechanical ventilator support	22 (39)
Previous surgery	
MV repair	34 (56)
Repair–replacement interval, days	26 (13-190)
Pacemaker implantation	6 (10)
Diagnosis	
Atrioventricular septal defect	18 (30)
Shone syndrome and hypoplastic left heart complex	9 (15)
Isolated congenital MV stenosis and regurgitation	29 (48)
Other[a]	5 (8)
Preoperative anatomy	
Double-orifice MV	1 (2)
Parachute MV	7 (11)
Arcade type MV	1 (2)
Single papillary muscle	7 (11)
Absent or short chordae	20 (33)
Basally displaced papillary muscles	3 (5)
Genetics	
Trisomy 21	3 (5)
Heterotaxy	3 (5)

[a]Included are parachute MV and ventricular septal defect, parachute MV with hypoplastic left ventricle and double-outlet right ventricle, MV stenosis with hypoplastic left ventricle and double-outlet right ventricle, straddling of MV and Taussig Bing malformation, and Noonan syndrome with hypertrophic cardiomyopathy.

Values are n (%) or median (interquartile range).

MV, mitral valve.

Table 2. Operative Outcome Data (N = 61)

Variables	Value
Transseptal access	50 (82)
Posterior leaflet remained intact	9 (15)
Type of valve	
St Jude	44 (72)
Carbomedics	16 (26)
Sorin	1 (2)
Size of valve	
15 mm	17 (28)
16 mm	18 (29)
17 mm	26 (43)
Valve position	
Annular	47 (77)
Supraannular	14 (23)
Emergency procedure	6 (10)
Second bypass run	13 (21)
Perfusion time, min	149 (110-226)
Cross-clamp time, min	99 (73-141)
Concomitant procedure[a]	21 (34)
Condition at discharge	
Atrioventricular block requiring pacemaker	9 (15)
Outcome	
Major adverse events[b]	34 (56)
Prosthesis replacement	27 (44)
First to second replacement interval, y	3.7 (1.9-6.8)
Mortality	
In-hospital	13 (21)
Postdischarge[c]	8[d]
Days on ventilator	5 (1-9)
Intensive care unit length of stay, days	28 (12 - 56)
Hospital length of stay, days	41 (21-70)
Follow-up, y	4.0 (0.4-12.5)

[a]Included variables are Ross-Konno procedure (4), right atrioventricular valve repair (3), resection of subaortic stenosis (2) with left ventricle myectomy (1), aortic valve repair (2), resection of subaortic stenosis (1), implantation of permanent pacemaker (1), coarctectomy with end-to-end anastomosis (1), coarctation repair and arterial switch (1), closure of ventricular septal defect (1) and atrial septal defect (fenestrated, 1), pulmonary vein ostial resection (1), superior vena cava/ innominate vein repair (1), and repair of left lower lobe vein ostium (1); [b]Included variables are death before discharge (13), ventilator support >7 days (17), pacemaker implantation (9), unplanned reoperation before discharge (6), renal failure requiring dialysis (4), mediastinitis requiring reoperation (4), postoperative extracorporeal membrane oxygenation support (3), cardiac arrest requiring resuscitation (3), bleeding requiring reoperation (3), and plication for paralysis or paresis of the diaphragm (1); [c]Among 48 hospital survivors; [d]Mortality rate among hospital survivors at 1, 2, and 5 years was 8.8%, 13.4% and 15.8%, respectively.

Values are n (%) or median (interquartile range).

(7%), and not recorded in 21 (34%). Target international normalized ratio (INR) was 2.5 to 3.5.

Hospital Course

Sixty-three major adverse events occurred in 34 patients (56%), including death prior to discharge (13, 21%), ventilator support more than 7 days (17, 28%), permanent pacemaker implantation (9, 15%), unplanned reoperation before discharge (6, 10%), renal failure requiring dialysis (4, 7%), mediastinitis requiring reoperation (4, 7%), postoperative extracorporeal membrane oxygenation support (3, 5%), bleeding requiring reoperation (3, 5%), cardiac arrest requiring resuscitation (3, 5%), and plication for paralysis or paresis of the diaphragm (1, 2%). Patients had 1 (18, 30%), 2 (11, 18%), 3 (1, 2%), 4 (1, 2%), 5 (2, 3%), or 6 (1, 2%) major adverse events. Major adverse events are depicted in Table 3.

Unplanned reoperation before discharge included repair of paravalvular leak (2, 3%), prosthetic valve replacement for thrombosis (2, 3%), closure of VSD and debanding of pulmonary artery (1, 2%), and implantation of left ventricular assist device (1, 2%). Median postoperative days on the ventilator and in the ICU were 5 (IQR, 1-9) and 28 (IQR, 12-56), respectively.

Mortality

In-hospital death occurred in 13 patients (21%). Death was attributed to heart failure in all patients. Postdischarge death occurred in 8 patients. Mortality rate

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Table 3. Major Adverse Events

Patient No.	Death or Heart Transplantation Before Discharge	Postoperative Extracorporeal Membrane Oxygenation Support	Bleeding Requiring Reoperation	Plication for Paralysis or Paresis of the Diaphragm	Mediastinitis Requiring Reoperation	Ventilator Support > 7 Days	Cardiac Arrest Requiring Resuscitation	Renal Failure Requiring Dialysis	Unplanned Cardiac Reoperation Before Discharge	Pacemaker
1						x			x	
2						x				
3						x				
4	x									
5	x									
6	x					x				x
7	x									
8						x				
9						x				x
10	x									
11									x	x
12			x							x
13					x					x
14	x					x				
15	x									
16						x	x			
17						x		x		
18										x
19	x	x				x	x	x	x	
20						x	x	x	x	
21			x			x				
22	x									
23	x									
24				x						
25		x								
26					x	x				
27	x		x			x		x	x	
28	x				x	x			x	x
29						x				
30		x								
31					x					
32	x									
33										x
34						x				x

among hospital survivors at 1, 2, and 5 years was 8.8%, 13.4%, and 15.8%, respectively. Death was attributed to heart failure in 2 patients and to a noncardiac cause in 6 patients (pneumonia, 2; respiratory insufficiency, 2; and intracerebral bleeding, 2). Figure 1 shows the cumulative incidence of death after MVR by size of prosthesis (log-rank test $P = .079$). Time to death did not differ significantly between patients with annular or supraannular valves ($P = .36$).

Prosthetic Valve Replacement

Prosthesis replacement was required in 27 patients (44%). The main indication for prosthesis replacement was patient–prosthesis mismatch in 17 (28%). Other indications were prosthesis thrombosis in 5 (8%) and (para) valvular leak in 3 (5%), leaflet immobility and failure of prosthesis in 1 (2%), and pannus in 1 (2%). Among the 27 patients with replacement, median time to prosthetic valve replacement was 3.7 years (IQR, 1.9-6.8). Estimated freedom from prosthesis replacement at 1, 2, and 5 years was 90%, 85%, and 60%, respectively. Most prostheses were replaced by mechanical valves (24, 39%). Other valves used for prosthesis replacement were porcine (2, 3%) and pericardial valves (1, 2%). Sizes used were 15 mm (1, 4%), 16 mm (3, 12%), 17 mm (1, 4%), 19 mm (8, 31%), 21 mm (5, 19%), 23 mm (8, 31%), and 25 mm (1, 4%). Larger prostheses could be used for prosthesis replacement in all cases except for 1 (downsized 1-mm because of prosthesis thrombosis after 1.5 years) and 3 (same size because of prosthesis thrombosis in 2 after 1 and 1.5 months and because of prosthesis dysfunction in 1 after 1.5 months).

Figure 2 represents the cumulative incidence of prosthetic valve replacement based on size of prosthesis, treating death as a competing risk. Risk of prosthesis replacement is greater for subjects with 15-mm valves when compared with those with larger valves (Fine and Gray model, $P = .019$). Time to prosthetic valve replacement did not differ significantly between patients with annular and supraannular valves ($P = .70$). There was no

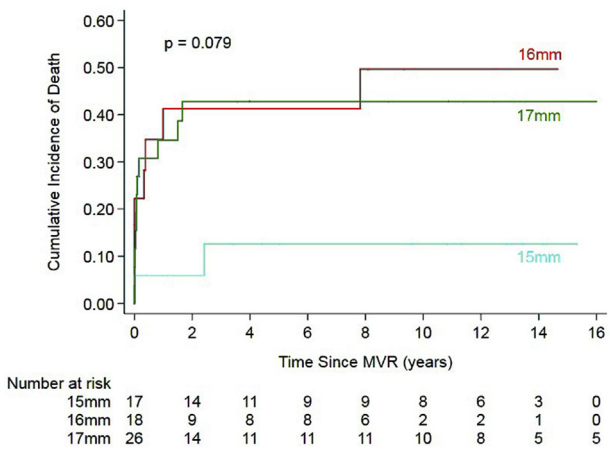

Figure 1. Cumulative incidence of death after mitral valve replacement (MVR) by size of prosthesis. Prosthesis size of 15 mm is depicted in blue, 16 mm in red, and 17 mm in green.

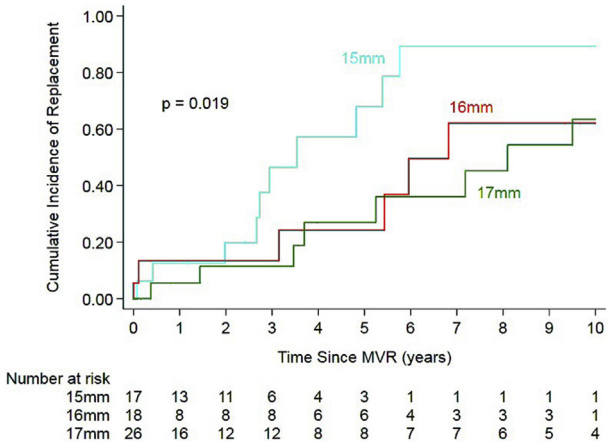

Figure 2. Cumulative incidence of prosthetic valve replacement based on size of prosthesis, treating death as a competing risk. Prosthesis size of 15 mm is depicted in blue, 16 mm in red, and 17 mm in green. (MVR, mitral valve replacement.)

significant difference in BSA across valve sizes ($P = .22$) (Figure 3). In patients with initial MVR at the annular and supraannular level, prosthesis could be upsized by a median of 4 mm (signed-rank test $P < .001$) and 5 mm (signed-rank test $P = .031$), respectively.

Other indications for reoperation were resection of subaortic stenosis (4 [7%]), aortic valve repair (3 [5%]), and aortic valve replacement (6 [10%]). One patient underwent aortic valve repair and replacement during separate procedures.

Thromboembolic/Bleeding Events

Six patients (10%) had prosthesis thrombosis, including 1 patient with a thrombosis after prosthesis replacement with a 23-mm St Jude Medical prosthesis, 3 of whom had persisting neurologic deficit. One of these thromboembolic events was related to a malfunctioning prosthesis (reduced cusp mobility of 15-mm prosthesis 1 week after implantation). Prosthesis inspection during replacement revealed absent mobility of the posterior leaflet and small thrombi on the leaflet and in the hinge mechanism. The prosthesis was removed and a new 15-mm prosthesis implanted (Table 4, patient 1). Another prosthesis thrombosis was related to subtherapeutic INR level (infection). In the other patients the cause of the prosthesis thrombosis remained unclear. There was a single bleeding event reported (1, 1.6%), related to an elevated INR level (inadvertent intake of higher than prescribed medication dose).

Follow-up

Median follow-up time was 4.0 years (IQR, 0.4-12.5). Eight patients (13%) experienced a thromboembolic/bleeding event (Table 4) (7 [11%] after index surgery, 1 [2%] after prosthesis replacement with a 23-mm mechanical prosthesis). Among 25 patients with echocardiographic data at 10 years, left ventricular function was normal in 17 (68%), mildly depressed in 7 (28%), and moderately depressed in

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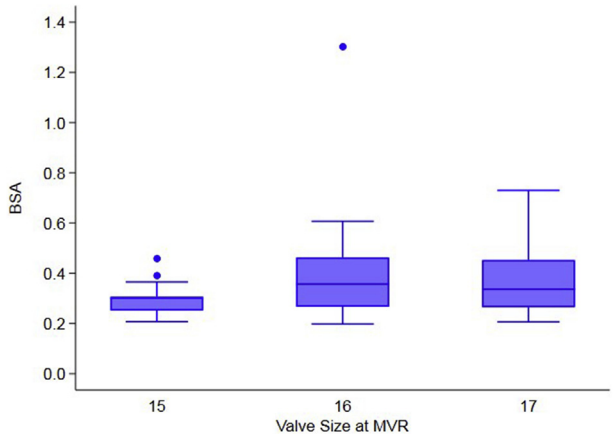

Figure 3. Body surface area (BSA) across valve size. There was no significant difference in BSA across valve size (P = .22). (MVR, mitral valve replacement.)

1 (4%). In a separate cohort of 22 patients with echocardiographic measurements of pulmonary/right ventricular pressures there was no evidence of pulmonary/right ventricular hypertension in 16 patients (73%), mild to moderate in 5 (23%), and severe in 1 (4%).

Comment

This multicenter, retrospective review reports a 20-year experience with mechanical MVR using small prosthesis (15-17 mm) in children, with particular emphasis on mortality and valve-related morbidity. The in-hospital mortality (21%) was high but comparable with studies with similarly sized mechanical prostheses (18%-19%)[10,11] and was higher compared with studies where larger-diameter mechanical prostheses were used (6%-11%),[12-14] albeit in older and larger patients. High mortality is likely related to the poor preoperative clinical condition of the patients in our cohort, with 39% ventilated preoperatively for cardiorespiratory failure.

Mortality rates (both in-hospital [21%] and post-discharge [17%]) in our cohort were higher compared with the rates reported by Pluchinotta and colleagues[15] of 12% (early) and 8% (late) in a recent multicenter study among 59 slightly older and larger patients who underwent MVR with a stented bovine jugular vein conduit. High in-hospital mortality rates in our cohort may be explained by worse preoperative risk status and the greater number of concomitant procedures (21 [34%]) in our cohort. Most patients who suffered an early cardiac death were admitted to the ICU and on ventilator support before surgery, indicative of compromised hemodynamics. The elevated postdischarge mortality rate in our cohort may be explained by a longer duration of follow-up in our cohort compared with the Pluchinotta's cohort (median of 4.0 years vs mean of 23 months). Furthermore Pluchinotta and colleagues[15] reported the development of structural bovine jugular vein conduit deterioration in a significant number (35%) of patients, requiring prosthesis replacement at median of 22 months after implantation. Of note the rate of prosthesis replacement in our cohort, although similar (44%), occurred later with a median time to prosthesis replacement of 44 months.

A trend of better survival in patients with 15-mm valves compared with those with 16- and 17-mm valves was seen, although it did not achieve statistical significance ($P = .079$). Of note we found no significant difference in BSA across valve size (Figure 3), indicating valve oversizing in patients where 16- and 17-mm valves were used. We speculate that using a 16- or 17-mm valve carries the risks associated with oversizing, that is, left ventricular outflow tract obstruction or compression of the circumflex coronary to name a few, which may eventually result in low cardiac output syndrome and death. However missing data on preoperative mitral valve diameters did not permit an analysis to confirm or reject this hypothesis. The finding of higher incidence of mortality with 16- and

Table 4. Thromboembolic/Bleeding Events

Patient No.	Thromboembolic Events	Time Since Valve Replacement (mo)	Anticoagulation	Persisting (Neurologic) Deficit
1	Prosthesis thrombosis	0.9	Fenprocoumon (INR, 3.1-4.5)	No
2	Prosthesis thrombosis	3.9	Fraxiparine	Yes
3	Prosthesis thrombosis	21.9	Acenocoumarol (INR, 1.8-3.3)	Yes
4	Prosthesis thrombosis[a]	88.7	Acenocoumarol	No
5	Stroke	6.0	Other[b]	Yes
6	Prosthesis thrombosis	6.6	Fraxiparine and Ascal	Yes
7	Prosthesis thrombosis	17.3	Warfarin	No

Patient No.	Bleeding Events	Time Since Valve Replacement (y)	Anticoagulation	Persisting (Neurologic) Deficit
1	Subdural hemorrhage	2.8	Fenprocoumon (INR, 7)	Yes

[a]23mm mechanical prosthesis; [b]Perioperative stroke (Ross-Konno procedure with postoperative mechanical circulatory support) during separate hospitalization.

INR, international normalized ratio.

17-mm valves may be related to chance alone, so we hesitate to make any inferences.

Patients in our series remained free from prosthesis replacement for a median of 3.7 years, with patient–prosthesis mismatch being the most common indication for prosthesis replacement. Prosthetic valve endocarditis was not reported, and there was no mortality related to prosthesis replacement. A larger prosthesis could be used in most patients, with a median increase in prosthesis size by 4 mm during prosthesis replacement. This finding is consistent with other studies that have demonstrated mitral annular growth despite the restriction induced by a prosthetic ring because complete removal of the initial prosthesis allows the native annulus to expand.[16-18]

One of the concerns associated with prosthetic valve replacement in children with a small mitral annulus is that the annulus can rarely be surgically enlarged due to proximity to vital structures, and annular implantation of larger prosthesis has been associated with heart block, compression of the circumflex coronary, or left ventricular outflow tract obstruction.[10,19] Supraannular prosthesis implantation remains an alternative option in patients with small MV annulus sizes, with poor[20] to excellent[21] results reported in small series of patients. In our cohort heart block requiring pacemaker (9 [15%]), subaortic stenosis resection (4 [7%]), and circumflex artery compression (1 [1.6%]) did occur, despite the fact that most prostheses were implanted at the annular level. We used the supraannular technique in 14 patients (23%) so that an adequately sized prosthesis could be implanted while avoiding the complications of an oversized prosthesis in the true annulus. Both time to death and time to prosthesis replacement did not significantly differ between patients with prosthesis implanted at the annular or supraannular level.

The choice of prosthesis (ie, a small mechanical prosthesis vs a bioprosthesis such as a stented bovine jugular vein conduit) is best determined by the individual surgeon and cardiologist. In the short term the morbidity and mortality risks for 15- to 17-mm mechanical prostheses are comparable with that of a bovine jugular vein contegra conduit.[15] The incidence of thromboembolic complications and difficulty of managing anticoagulation in a small child are clearly important disadvantages with mechanical valves when compared with bioprosthetic valves such as the stented bovine jugular vein conduit, especially in countries with limited INR monitoring options where easy access and low costs may favor the mechanical prosthesis. Furthermore endocarditis has been reported after transcatheter bovine jugular vein contegra conduit implantation[15,22] in both mitral and pulmonary positions, whereas in our cohort infectious endocarditis was not documented in any of the patients. Long-term outcome of the stented bovine jugular vein conduit are needed and can contribute to clinical decision-making on choice of prosthesis.

Study Limitations

This is a retrospective cohort study with inherent limitations of missing data. Echocardiography protocols differed among the participating centers, resulting in missing data for some echocardiographic variables. However to avoid interobserver variability the studies when available were reviewed by experienced cardiologists from the 2 coordinating centers. The surgery reports did not always document details on whether pledgets were used at the time of the implant. We therefore were unable to analyze for differences in outcomes when pledgets were used versus not used. Furthermore there was no bioprosthetic valve comparator group in this study.

Conclusions

Small-sized mechanical prosthetic valves may be an important alternative in critically ill neonates and infants who require MVR. Inevitable prosthesis replacement for outgrowth was required at a median of 3.7 years and could be carried out with low risk. Anticoagulation and associated morbidity remains a challenge.

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