Fifteen-Year Outcomes After Bioprosthetic and Mechanical Tricuspid Valve Replacement

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Background. **This study was conducted to compare long-term clinical outcomes of mechanical and bioprosthetic tricuspid valve replacement (TVR).**

Methods. **Two-hundred twenty-six TVR patients were enrolled; 120 patients underwent bioprosthetic TVR (BTV group) and 106 underwent mechanical TVR (MTV group). Early results and long-term clinical outcomes were compared. The median follow-up duration was 99 months (range, 1-295). Propensity score (PS) analyses including PS-adjusted Cox regression models and 1:1 PS matching were performed.**

Results. **Mean ages of the MTV and BTV groups were 50.5 ± 10.3 and 60.8 ± 12.0 years, respectively. There were no significant differences in early mortality (4.9% in total) and postoperative complications between the 2 groups. The overall survival and freedom from cardiac death in the MTV group were similar to those in the BTV group (reference, BTV group; hazard ratio [HR], 0.82 [95% confidence interval {CI}, 0.44-1.53] and 0.91 [95% CI, 0.44-1.87], respectively). The risk of a composite of thromboembolism and bleeding was significantly higher in the MTV group (HR, 2.35; 95% CI, 1.16-4.77; P = .018). However the tricuspid valve reoperation rate was significantly lower in the MTV group (HR, 0.11; 95% CI, 0.02-0.53; P = .007). Overall TV-related event rates in the MTV group were similar to those in the BTV group (HR, 0.79; 95% CI, 0.49-1.28). PS matching extracted 69 pairs. Comparative analyses of early- and long-term outcomes from the matched groups yielded similar findings to those from the entire patient groups.**

Conclusions. **The outcomes of bioprosthetic TVR were comparable with those of mechanical TVR in terms of long-term survival and tricuspid valve-related events over a 15-year postoperative follow-up.**

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In 2017 guidelines for heart valve disease were updated such that the age range of patients potentially eligible for mechanical and bioprosthetic heart valves was widened.[1] European guidelines suggest that the prosthetic valve be chosen according to the risks and benefits associated with the patients' lifestyle and personal preference as well as their age.[2] However, the optimal prosthesis for tricuspid valve replacement (TVR) is still controversial. Previous studies suggest that the long-term outcomes of bioprosthetic TVR might be comparable with those of mechanical valves when considering life expectancy of patients undergoing TVR.[3-7] Our previous study demonstrated that bioprosthetic TVR may be a valid option regardless of patient age.[8] However, a caveat in that study was that the follow-up duration was relatively short, making it difficult to determine tissue valve durability. Therefore, the present study was conducted to compare longer-term outcomes of bioprosthetic TVRs with those of mechanical TVRs over a 15-year postoperative follow-up.

Patients and Methods

Patient Enrollment

The study protocol was reviewed by our Institutional Review Board and approved as a minimal risk retrospective study (approval no. H-1902-013-1006) that did not require individual consent. From January 1994 to December 2017, 257 consecutive patients underwent TVR at our institution. Of these patients, 31 who underwent reoperative TVR (n = 18) or were diagnosed as Ebstein anomaly (n = 13) were excluded. Thus, 226 patients (age 55.9 ± 12.3 years; 46 men and 180 women) were enrolled in the present study.

The indications of TVR were organic tricuspid leaflet pathology precluding valve repair (n = 95), reoperation

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for recurrent tricuspid regurgitation after previous TV repair (n = 39), and surgeon preference to avoid future reoperation related to recurrent functional tricuspid regurgitation (n = 92).

Operative Strategy

Surgical techniques of TVR have been described previously.[8] Briefly, all procedures were performed through a median sternotomy, with aortobicaval cannulation under moderate hypothermia and cold cardioplegic arrest. The prosthesis was selected at the discretion of the attending surgeon. There was a preference toward mechanical valves during the early study period. All patients who already had left-sided bioprosthetic valves underwent bioprosthetic TVR. However, bioprosthetic TVR was not ruled out in patients with left-sided mechanical valves.

Evaluation of Early- and Long-Term Clinical Outcomes

Operative mortality was defined as death within 30 days of operation or during the same hospitalization period. Postoperative low cardiac output syndrome was defined as the need for mechanical supports or inotropic support to maintain systolic blood pressure >90 mm Hg even after correction of reversible factors.

Regular (3- to 6-month intervals) postoperative follow-up was performed at the outpatient clinic. Patient condition was checked through telephone calls if they did not attend the scheduled clinic visit. In addition survival data were obtained from the Statistics Korea, a national organization that collects and aggregates quality data about the people and economy in Korea including 100% complete data regarding death and cardiac death of all people, through December 31, 2018. An oral anticoagulant was prescribed to achieve the target prothrombin time-international normalized ratio (PT-INR) of 2.5 to 3.0 for 6 months and over the lifetime for the bioprosthetic TVR (BTV group) and mechanical TVR (MTV group) patients, respectively. However, 70 patients (58%) in the BTV group needed long-term anticoagulation therapy because of the presence of mechanical valves in other heart valves and/or atrial fibrillation.

Cardiac death was defined as any death with a cardiac origin, including sudden death. Tricuspid valve–related events (TVREs) were defined according to the guidelines from Akins and coworkers[9]: (1) cardiac death; (2) a composite of thromboembolism and major bleeding (CTEB), defined as bleeding events that caused death, hospitalization, or permanent injury or necessitated a transfusion; (3) structural valve deterioration (SVD); (4) nonstructural valve dysfunction; (5) prosthetic TV endocarditis; (7) TV reoperation; and (8) permanent pacemaker implantation within 14 days after TVR.

The clinical follow-up period ended on February 28, 2019. The median follow-up duration was 99 months (range, 1-295). Completeness of follow-up was 100% for overall survival and freedom from cardiac death and 96.0% (218/226 patients) for other long-term clinical outcomes.

Statistical Analysis

Statistical analyses were performed using the SPSS software package (version 18.0; SPSS Inc, Chicago, IL) and SAS (version 9.4; SAS Institute Inc, Cary, NC). Comparisons between the 2 groups were performed using the χ^2 test or Fisher's exact test and Student's *t* test for categorical and continuous variables, respectively. Survival rates were estimated using the Kaplan-Meier method. Risk factors for longitudinal data were analyzed using multivariable Cox proportional hazards model.

In the BTV group, patients were divided into subgroups according to anticoagulation status. A subgroup analysis was performed to assess the effect of anticoagulation on CTEB events. Cumulative incidences of cardiac death and TVREs were estimated with noncardiac death as a competing risk for the events. Cumulative incidences of CTEB and reoperation were estimated with all-cause death as a competing risk for the events. Cumulative incidences of the 2 groups for each event were compared using Fine-Gray's test. Variables with a $P < .100$ in the univariate analyses were entered into multivariable models. A $P < .050$ was considered as statistically significant.

Propensity score (PS) analyses were performed to adjust for baseline differences between the 2 groups. The following variables were entered into the logistic regression model to generate a PS: preoperative variables such as age, sex, body surface area, smoking, hypertension, diabetes mellitus, obesity (body mass index $\geq$25 kg/m^2), history of stroke, end-stage renal disease, coronary artery disease, dyslipidemia, New York Heart Association class $\geq$3, previous history of cardiac surgery, atrial fibrillation, and left ventricular dysfunction (ejection fraction <50%) and intraoperative variables including concomitant mitral or aortic valve procedure, concomitant arrhythmia surgery, and concomitant coronary artery bypass grafting. The PS was used as PS-adjusted multivariable models and 1:1 PS-matching analysis. In the PS-matching analysis 69 pairs of scores were extracted in a 1:1 manner using nearest-neighbor matching within a caliper width of 0.20 in PSs. Comparisons between matched groups were performed with the McNemar and paired Student's *t* tests for categorical and continuous variables, respectively. Longitudinal data were compared using the stratified log-rank test.

Results

Patient Characteristics and Operative Data

One hundred twenty patients underwent bioprosthetic TVR (BTV group) and 106 patients underwent mechanical TVR (MTV group). The BTV group patients were older and more likely to have hypertension than the MTV group patients (Table 1).

The mean cardiopulmonary bypass and aortic cross-clamp times were 208 ± 77 minutes and 125 ± 54 minutes, respectively. Concomitant cardiac procedures such as mitral valve operations (n = 96), aortic valve procedures (n = 59), and arrhythmia surgery (n = 54) were

Table 1. Preoperative and Operative data of the Study Patients

Variables	BTV Group (n = 120)	MTV Group (n = 106)	*P*
Age, y	60.8 ± 12.0	50.5 ± 10.3	<.001
Female	102 (85.0)	78 (73.6)	.050
Body surface area, m^2	1.5 ± 0.1	1.6 ± 0.2	.003
Risk factors			
Smoking	4 (3.3)	3 (2.8)	>.999
Hypertension	21 (17.5)	7 (6.6)	.023
Diabetes mellitus	16 (13.3)	10 (9.4)	.479
Body mass index ≥ 25 kg/m^2	11 (9.2)	14 (13.2)	.451
History of stroke	13 (10.8)	12 (11.3)	>.999
End-stage renal disease[a]	5 (4.2)	1 (0.9)	.276
Coronary artery disease	7 (5.8)	1 (0.9)	.104
Dyslipidemia	2 (1.7)	2 (1.9)	>.999
New York Heart Association class ≥ 3	55 (45.8)	55 (51.9)	.438
Previous cardiac surgery	84 (70.0)	75 (70.8)	>.999
Mitral valve procedure	79 (62.7)	71 (67.0)	.967
Bioprosthetic valve replacement	6 (4.8)	11 (10.4)	…
Mechanical valve replacement	67 (53.2)	57 (53.8)	…
Repair	6 (4.8)	3 (2.8)	…
Aortic valve procedure	21 (16.7)	40 (37.7)	.001
Bioprosthetic valve replacement	3 (2.4)	0 (0)	…
Mechanical valve replacement	14 (11.1)	31 (29.2)	…
Repair	4 (3.2)	7 (6.6)	…
Atrial fibrillation	98 (81.7)	91 (85.8)	.504
Endocarditis	9 (7.1)	3 (2.8)	.206
Left ventricle dysfunction (ejection fraction <50%)	18 (15.0)	17 (16.0)	.975
Cardiopulmonary bypass time, min	202 ± 81	216 ± 72	.157
Aortic cross-clamp time, min	118 ± 53	134 ± 54	.023
Concomitant procedure	74 (61.7)	68 (64.2)	.804
Mitral valve procedure	47 (39.2)	49 (46.2)	.349
Bioprosthetic valve replacement	19 (15.1)	1 (0.9)	
Mechanical valve replacement	24 (19.0)	47 (44.3)	
Repair	4 (3.2)	1 (0.9)	
Aortic valve procedure	21 (17.5)	38 (35.8)	.003
Bioprosthetic valve replacement	3 (2.4)	0 (0)	
Mechanical valve replacement	14 (11.1)	31 (29.2)	
Repair	4 (3.2)	7 (6.6)	
Arrhythmia surgery	26 (21.7)	28 (26.4)	.497
Coronary artery bypass grafting	3 (2.5)	1 (0.9)	.704

[a]End-stage renal disease was defined as kidney failure treated by dialysis or transplantation.

Values are mean ± SD or n (%).

performed in 142 patients. The aortic cross-clamp time was longer, and aortic valve procedures were performed more frequently in the MTV group compared with the BTV group (Table 1).

Early Results

Operative mortality occurred in 19 patients (8.4%; 11 patients [9.2%] in the BTV group and 8 patients [7.5%] in the MTV group). Postoperative complications were as follows: low cardiac output syndrome (n = 39, 17.3%), respiratory complications (n = 27, 11.9%), acute renal failure (n = 28, 12.4%), postoperative bleeding requiring reoperation (n = 11, 4.9%), stroke (n = 4, 1.8%), and mediastinitis (n = 4, 1.8%). There were no statistically significant differences in operative mortality rate or incidence rates of postoperative complications between the 2 groups, except for a higher incidence of respiratory complications with a marginal significance in the BTV group (Table 2).

Long-Term Survival

Late death occurred in 65 patients, including 42 cardiac deaths. The 10- and 15-year overall survival rates were 65.0% and 55.5%, respectively. The 10- and 15-year rates of freedom from cardiac death were 72.2% and 68.8%, respectively. Kaplan-Meier curves showed that overall survival and freedom from cardiac death were higher in the MTV group than in the BTV group. However, these differences disappeared after risk factor adjustment (Figure 1). The PS-adjusted multivariable analyses showed that not bioprosthetic TVR but age, sex, and hypertension were significantly associated with overall survival (Supplemental Table 1). Sex was also associated with freedom from cardiac death with a marginal significance (Supplemental Table 2).

In the competing risk analysis for cardiac death, the cumulative incidence was different between the 2 groups with a marginal significance (P = .055). However, it was not statistically significant in the multivariable analysis (reference, BTV group; hazard ratio [HR], 0.69; 95% confidence interval [CI], 0.36-1.027; P = .439).

Tricuspid Valve–related Events

The CTEB events occurred in 16 (12.7%) and 31 (29.2%) patients in the BTV and MTV groups, respectively. Major bleeding events occurred in 16 patients (12.7%) in the BTV group and in 26 patients (24.5%) in the MTV group. In the BTV group, 9 of 16 events (56.3%) were associated with prolonged PT-INR (>3), whereas in the MTV group 13 of 26 events (50%) occurred when the PT-INR was over 3. TV thrombosis occurred in 5 patients (4.7%) in the MTV group between 33 and 188 months after surgery. The PT-INR at the time of presentation was over 2.5 in 3 patients (60%). Another patient was pregnant and had valve thrombosis while she was treated with intravenous heparin. The final patient had a normal PT-INR level because the patient had acute subdural hematoma and anticoagulation was stopped for several days. One patient underwent a redo-TVR as the first-line treatment, and the other 4 patients underwent thrombolytic therapy; 3 of these 4 patients were treated successfully with

Table 2. Early Clinical Outcomes

Variables	BTV group (n = 120)	MTV group (n = 106)	P Value
Operative mortality	6 (5.0%)	5 (4.7%)	>.999
Complications			
Low cardiac output syndrome	21 (17.5)	18 (17.0)	>.999
Respiratory complication	19 (15.8)	8 (7.5)	.087
Acute kidney injury	18 (15.0)	10 (9.4)	.287
Bleeding reoperation	8 (6.7)	3 (2.8)	.304
Stroke	2 (1.7)	2 (1.9)	>.999
Mediastinitis	3 (2.5)	1 (0.9)	.704

Values are n (%).

thrombolysis, and the remaining patient underwent a redo-TVR after failed thrombolysis.

Ten- and 15-year rates of freedom from CTEB were 77.9% and 66.4%, respectively (83.7% and 67.7%, respectively, in the BTV group vs 72.0% and 63.2%, respectively, in the MTV group; Supplemental Figure 1). The PS-adjusted multivariable model showed that the risk of CTEB was significantly higher in the MTV group than in the BTV group (HR, 2.35; 95% CI, 1.16-4.77; *P* = .018) (Figure 2 and Table 3).

When dividing the BTV group patients according to the need for lifelong anticoagulation, no CTEB event was observed in 24 BTV group patients who did not need long-term anticoagulation. A subgroup comparison between 96 BTV group patients in whom lifelong anticoagulation was needed and 106 MTV group patients demonstrated that freedom rates from CTEB at 5 and 10 years were 92.7% and 83.7% in the BTV group, respectively, and 82.4% and 75.4% in the MTV group, respectively. These differences were marginally significant in the PS-adjusted multivariable analysis (*P* = .099; Supplemental Table 3 and Supplemental Figure 2).

Fourteen patients (11.1%) in the BTV group had SVD between 34 and 147 months after surgery, and none of these patients had end-stage renal disease. Seven of these 14 patients (50%) underwent re-TVR. The other 7 patients have been followed conservatively through the outpatient

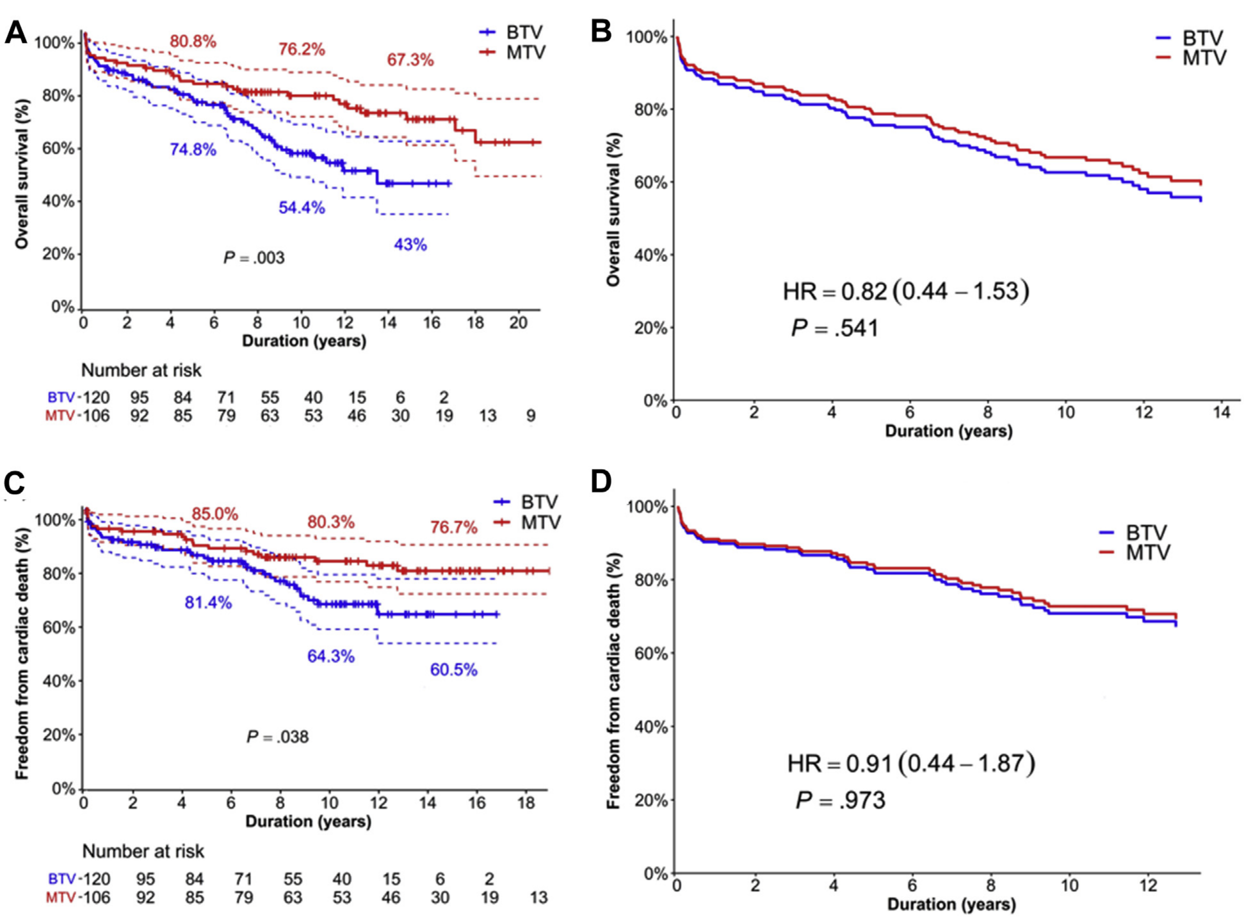

Figure 1. (A) Kaplan-Meier curve and (B) risk factor–adjusted curve by Cox proportional hazards model for overall survival in the bioprosthetic tricuspid valve (BTV) and mechanical tricuspid valve (MTV) groups. (C) Kaplan-Meier curve and (D) risk factor–adjusted curve by Cox proportional hazards model for cardiac death in the BTV and MTV groups. Freedom rates at 5, 10, and 15 years are given. BTV was used as a reference for hazard ratio in all graphs. (HR, hazard ratio.)

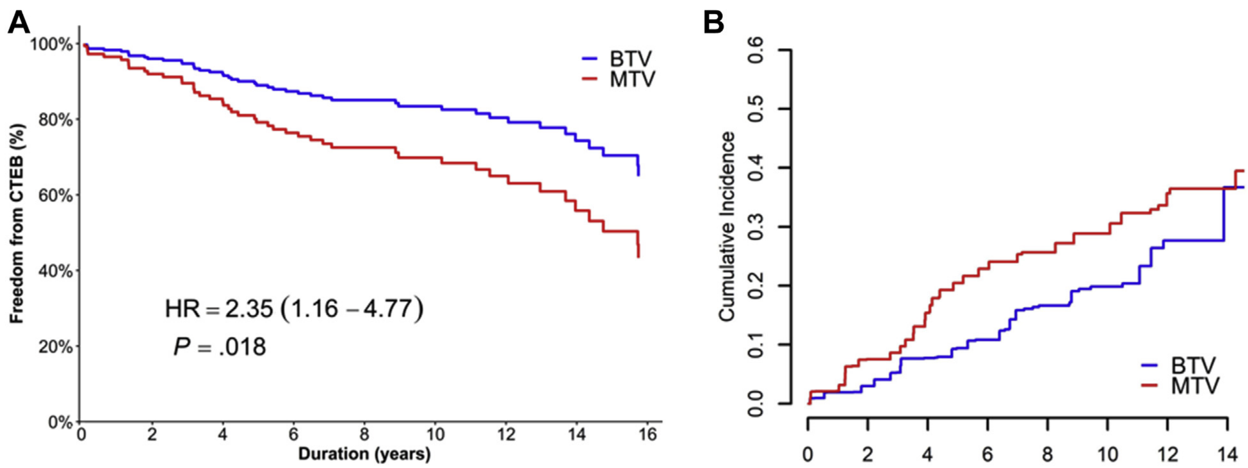

Figure 2. (A) Risk factor–adjusted curve by Cox proportional hazards model and (B) cumulative incidence function for composite of thromboembolism and bleeding in the bioprosthetic tricuspid valve (BTV) and mechanical tricuspid valve groups. BTV was used as a reference for hazard ratio. (CTEB, composite of thromboembolism and bleeding; HR, hazard ratio; MTV, mechanical tricuspid valve.)

clinic. Freedom rates from SVD were 96.1% and 77.6% at 5 and 10 years, respectively.

TV reoperations were performed in 8 and 2 patients in the BTV and MTV groups, respectively, between 35 and 138 months after the index operation. One BTV group patient of these 10 patients died after re-TVR. In the BTV group, the indications for reoperation were SVD (n = 7) and prosthetic valve endocarditis (n = 1). In the MTV group TV reoperations were performed because of TV thrombosis as described above (n = 2). The level of PT-INR at the presentation of thrombosis was over 2.5 in both patients, and none of these patients had any coagulation disorder. Ten- and 15-year rates of freedom from TV reoperation were 95.2% and 88.9%, respectively

Table 3. Cox Proportional Hazard Models for Factors Associated With Composite of Thromboembolism and Bleeding and Tricuspid Valve–Related Events

	Univariate Analysis		Propensity Score–adjusted Multivariable Analysis	
Variables[a]	Hazard Ratio [95% Confidence Interval]	*P*	Hazard Ratio [95% Confidence Interval]	*P*
Composite of thromboembolism and bleeding				
MTVR vs BTVR	2.21 [1.09-4.47]	.027	2.35 [1.16-4.77]	.018
Hypertension	0.29 [0.07-1.23]	.092	0.22 [0.05-1.02]	.054
Body mass index ≥25 kg/m^2	2.01 [0.94-4.32]	.073	2.40 [1.11-5.23]	.027
End-stage renal disease	7.86 [1.73-35.60]	.008	12.11 [2.49-59.05]	.002
Factors associated with tricuspid valve–related events				
MTVR vs BTVR	0.90 [0.57-1.43]	.664	0.79 [0.49-1.28]	.340
Age, y	1.03 [1.00-1.07]	.048	1.04 [1.01-1.08]	.023
End-stage renal disease	5.50 [2.12-14.27]	<.001	3.66 [1.19-11.23]	.023
Dyslipidemia	3.05 [0.97-9.67]	.058	2.89 [0.90-9.29]	.074
Arrhythmia surgery (reference, patients in normal sinus rhythm)	…	.029	…	.076
Atrial fibrillation but no arrhythmia surgery	1.24 [0.73-2.10]	.436	0.81 [0.43-1.54]	.519
Atrial fibrillation with arrhythmia surgery	0.56 [0.27-1.15]	.114	0.43 [0.20-0.94]	.035
Previous MV procedure (reference, no previous MV surgery)	…	.002	…	.111
Mechanical MV replacement	1.29 [0.82-2.04]	.270	0.95 [0.57-1.57]	.833
Bioprosthetic MV replacement	3.14 [1.66-5.94]	<.001	2.00 [0.95-4.18]	.068
MV repair	0.62 [0.19-2.04]	.426	0.52 [0.15-1.73]	.283

[a]All variables from Table 1 were analyzed and factors that entered into the multivariable analysis are shown.

BTVR, bioprosthetic tricuspid valve replacement; MTVR, mechanical tricuspid valve replacement; MV, mitral valve.

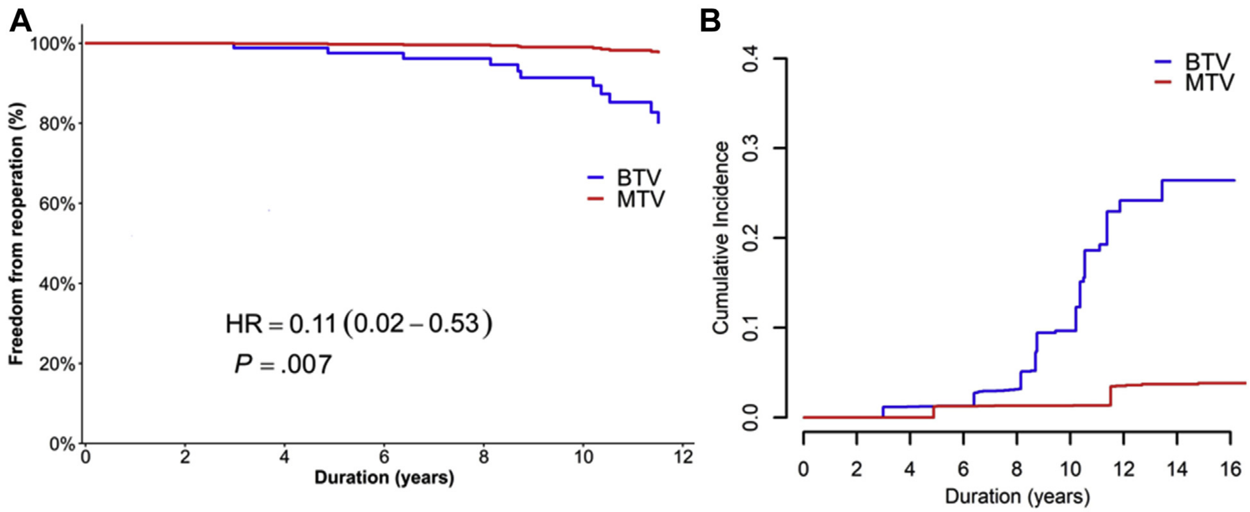

Figure 3. *(A) Risk factor–adjusted curve by Cox proportional hazards model and (B) cumulative incidence function for tricuspid valve reoperation in the bioprosthetic tricuspid valve (BTV) and mechanical tricuspid valve groups. BTV was used as a reference for hazard ratio. (HR, hazard ratio; MTV, mechanical tricuspid valve.)*

(91.2% and 78.8%, respectively, in the BTV group vs 98.7% and 96.5%, respectively, in the MTV group; Supplemental Figure 1). The risk of TV reoperation was significantly lower in the MTV group than in the BTV group (HR, 0.11; 95% CI, 0.02-0.53; $P = .007$) (Figure 3). Prosthetic TV endocarditis was diagnosed in 3 and 2 patients in the BTV and MTV groups, respectively. Except for 1 patient in the BTV group who required a redo-TVR, all patients responded well to medical treatment. Overall, freedom rates from TVREs were 56.8% and 41.5% at 10 and 15 years, respectively (49.5% and 28.5%, respectively, in the BTV group vs 63.1% and 51.2%, respectively, in the MTV group; Supplemental Figure 1). The PS-adjusted multivariable analysis demonstrated that age ($P = .023$) and end-stage renal disease ($P = .023$) but not the type of TV prosthesis ($P = .340$) were associated with TVREs (Figure 4 and Table 3).

Competing risk analyses showed similar results. In the multivariable analyses MTV group patients were at a higher risk of CTEB (HR, 2.24; 95% CI, 1.92-2.56; $P = .023$) but at a lower risk of TV reoperation (HR, 0.46; 95% CI, 0.43-0.50; $P < .001$) (Figures 2 and 3). Although the cumulative incidence curve for TVREs showed a significant difference in the univariate analysis ($P = .048$), the multivariable analysis demonstrated that type of prosthesis was not a significant factor for TVREs (reference, BTV group; HR, 0.99; 95% CI, 0.71-1.33; $P = .898$) (Figure 4).

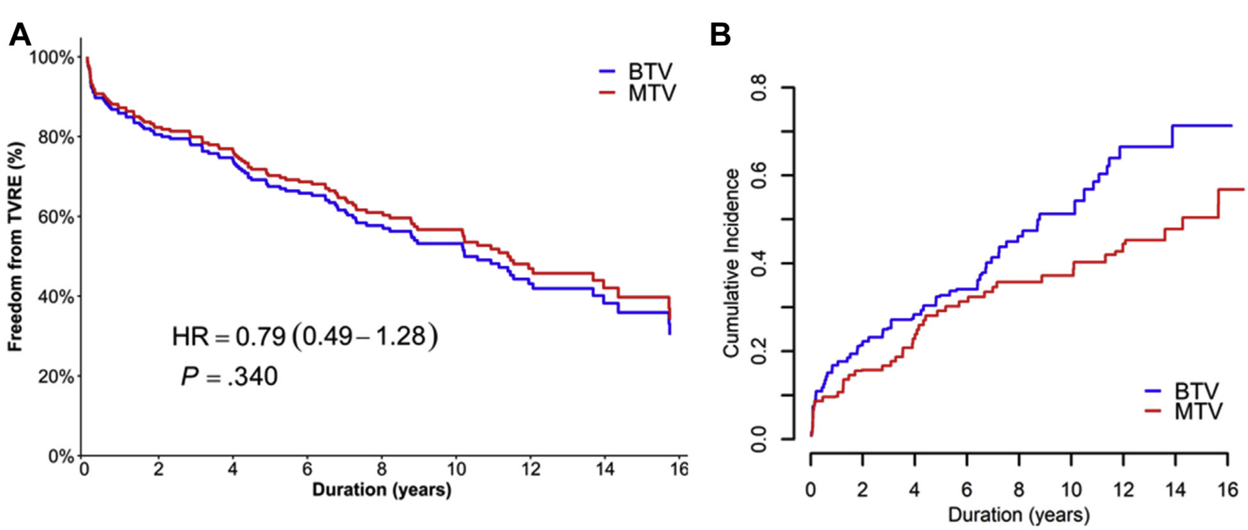

Figure 4. *(A) Risk factor–adjusted curve by Cox proportional hazards model and (B) cumulative incidence function for freedom from tricuspid valve–related events in the bioprosthetic tricuspid valve (BTV) and mechanical tricuspid valve groups. Freedom rates at 5, 10, and 15 years are given. BTV was used as a reference for hazard ratio. (HR, hazard ratio; MTV, mechanical tricuspid valve; TVRE, tricuspid valve–related event.)*

PS-matching Analysis

There were no significant differences in preoperative characteristics or operative data between the PS-matched patients (Supplemental Table 4). Early clinical outcomes were comparable between the 2 matched groups (Supplemental Table 5). Overall survival (P = .667) and freedom rates from cardiac death (P = .810) were not significantly different between the 2 matched groups (Supplemental Figure 3). The BTV group showed a significantly higher incidence of reoperation compared with the MTV group (P = .032), whereas the rate of CTEB events was higher in the MTV group than in the BTV group, with a marginal significance (P = .083). There was no significant difference in freedom rates from TVREs between the matched groups (P = .673; Supplemental Figure 4).

Comment

The present study demonstrated 2 main findings. First, the clinical outcomes of bioprosthetic TVR were comparable with those of mechanical TVR in terms of long-term survival and TVREs over a 15-year postoperative follow-up. Second, bioprosthetic TVR was associated with a higher reoperation rate but lower CTEB rate compared with mechanical TVR.

The optimal prosthesis for TVR is a subject of ongoing debate, because the clinical outcomes of TVR have generally been suboptimal and the life expectancy of patients undergoing TVR is poor.[3-7] Consistent with other published studies,[10-12] the early mortality rate in the present study was 4.9% and the overall survival rates at 15 and 20 years were 55.5% and 48.3%, respectively.

Advocates for mechanical TVR point to the increased rate of reoperation after bioprosthetic TVR due to SVD. However mechanical TVR is associated with a higher incidence of valve thrombosis and bleeding due to anticoagulation.[4] The increased risk of valve thrombosis and bleeding observed after mechanical TVR has been well reported by previous studies.[3,6,8] Observed rates of mechanical valve thrombosis range from 3% to 18%.[4,10,13] In the present study there was an approximately 5% chance of valve thrombosis in the MTV group. Despite a paucity of data, explanations for the higher rate of mechanical valve thrombosis in the tricuspid position have been suggested, such as a low concentration of prostacyclin in the venous blood or low pressure in the right heart system.[14] Although 96 patients (80%) with bioprosthetic TVR required anticoagulation for reasons other than the TV prosthesis itself, such as atrial fibrillation or the presence of other mechanical prosthetic valves, the MTV group still showed an overall higher incidence of thromboembolic or bleeding complications, and the subgroup analysis between the 96 BTV group patients who needed lifelong anticoagulation and 106 MTV group patients showed that the CTEB-free rates were higher in the BTV group patients with a marginal significance.

On the contrary, other studies[6,15,16] support bioprosthetic TVR even in young patients because of the poor life expectancy of patients with TV diseases. Furthermore, it has been suggested that low pressure in the right side of the heart may be associated with longer durability of bioprosthetic valves and a lower rate of reoperation in the TV position.[6] Previous meta-analyses[12,17] reported no significant difference in reoperation rate between bioprosthetic and mechanical TVR groups. Our previous study[18] also showed that the reoperation rate was not significantly different between those 2 groups up to 10 years after surgery. However, a caveat of the previous study is that 10 years is a relatively short period of time over which to draw definite conclusion because reoperation after bioprosthetic TVR is a time-dependent event and occurs long term after surgery. The present study was conducted to address this limitation; the reoperation rate increased over the course of the 15-year postoperative follow-up. The present study included relatively young patients, even in the BTV group. Although reoperation rates were higher in the BTV group, overall survival, freedom from cardiac death, and freedom from TVREs were not significantly different between the 2 groups in multivariable models, and the CTEB rate was lower in the BTV group.

Several limitations to the present study must be noted. First, this study was limited by its retrospective design and the heterogeneity of the patients. Although PS analyses were performed to minimize bias, the baseline complexity of the patient cohort could not be completely adjusted, and unmeasured confounders may have affected the study results. Second, the indications for valve selection could not be precisely defined because of the retrospective nature of the study. Third, preference of the mechanical valves in the early study period might affect clinical outcomes because perioperative care might have been improved over time, and follow-up duration was different between the 2 groups because of this preference. Fourth, less than 25% of patients underwent concomitant arrhythmia surgery, although more than 80% of patients had atrial fibrillation, because surgical ablation was not a common procedure in the early study period, and many patients had a history of cardiac surgery or had a history of atrial fibrillation for decades. The lack of performance of surgical ablation may affect clinical outcomes presented in this study. Fifth, we did not discuss other factors such as hypertension and end-stage renal disease associated with long-term clinical outcomes because these findings were beyond of the scope of the present study and overfitting phenomenon might affect our study results.

In conclusion, the present study showed that the 15-year clinical outcomes after bioprosthetic TVR were comparable with those after mechanical TVR in terms of long-term survival and freedom from TVREs. Bioprosthetic TVR was associated with a higher rate of reoperation but a lower rate of CTEB compared with mechanical TVR.

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