Long-Term Clinical Results of Tricuspid Valve Replacement

Byung-Chul Chang, MD, Sang-Hyun Lim, MD, Gijong Yi, MD, You Sun Hong, MD, Sak Lee, MD, Kyung-Jong Yoo, MD, Meyun Shick Kang, MD, and Bum Koo Cho, MD

Department of Thoracic and Cardiovascular Surgery, Cardiovascular Center, Severance Hospital, Yonsei University College of Medicine, Seoul, South Korea

Background. Tricuspid valve replacement (TVR) has been performed with mechanical or bioprosthetic valves. However, the relative advantages of the two types are incompletely known.

Methods. Between 1978 and 2003, we performed 138 TVR (35 bioprosthetic, 103 mechanical) in 125 patients (50 men, 75 women), with a mean age of 43.7 ± 16.6 years. The diseases that required TVR were rheumatic (94), prosthetic valve failure (14), congenital (14), infective endocarditis(5), isolated tricuspid regurgitation (4), and miscellaneous conditions (7). The operations included the following: isolated TVR (41), double valve replacement (58), and triple valve replacement (39). The follow-up rate was 98.3%, and cumulative follow-up was 828.5 patient-years.

Results. There were 22 in-hospital deaths (17.6%) and 13 (10.4%) late deaths. Fourteen patients required additional operations. There were 33 postoperative valve-related events including 11 thromboembolisms and 3 bleeding episodes. Kaplan-Meier survival for the entire group at 15 years was 73.8 ± 8.5% (bioprosthetic: 70.2 ± 10.4%, mechanical: 66.0 ± 19.4%). At 15 years, freedom from reoperation was 66.3 ± 9.4% (bioprosthetic: 55.1 ± 13.8%, mechanical: 86.0 ± 6.2%) and freedom from valve-related events was 49.9 ± 8.0%. The linearized incidence of valve thrombosis was 1.28%/patient-year (bioprosthetic: 0, mechanical: 1.92), anticoagulation-related bleeding was 0.37%/patient-year (mechanical: 0.54), reoperation was 1.71%/patient-year (bioprosthetic: 2.68, mechanical: 1.25), and valve-related events were 4.33%/patient-year (bioprosthetic: 3.83, mechanical: 4.6).

Conclusions. Both bioprosthetic and mechanical valves revealed similar long-term outcomes. However, findings suggest that greater care is needed to prevent valve thrombosis in mechanical valves in the early postoperative period, and there is a greater chance for reoperation in bioprosthetic valves.

(Ann Thorac Surg 2006;81:1317–24)

In most cases of tricuspid valve disease, tricuspid valve repair with annuloplasty is considered the procedure of choice. However, when tricuspid valve repair or annuloplasty is not feasible or not successful tricuspid valve replacement (TVR) should be considered [1]. There are limited numbers of reports about the long-term results of TVR, and controversies still exist regarding prosthesis choice in tricuspid position [2–7]. This study was performed to review our clinical experience of TVR to compare the long-term clinical results between two types of valves, and to evaluate the risk factors for early and late deaths.

Patients and Methods

Between October 1978 and December 2003, 125 patients received 138 TVRs at the Yonsei Cardiovascular Center, Yonsei University College of Medicine. Thirty five bioprosthetic valves in 35, and 103 mechanical valves in 90 patients were implanted. In the early period bioprostheses were implanted in most patients; however, mechanical valves have been implanted more often since 1990 (Fig 1). The mean age of patients was 43.7 ± 16.6 years (range, 3–80 years). Fifty patients were male, and 8 patients were under 16 years of age. Among 138 TVRs, there were 123 cases of primary TVR and 15 cases of re-replacement. The most common cause of TVR was rheumatic (68.1%). Detailed patient profiles are shown in Table 1. Two types of bioprosthetic valves (30 Carpentier-Edward [Edwards Lifesciences, Irvine, CA] and 5 Hancock [Medtronic, Minneapolis, MN]), and 8 types of mechanical valves (43 St Jude Medical [St Jude Medical, St Paul, MN], 27 CarboMedics [CarboMedics, Austin, TX], 15 ATS (ATS Medical, Inc, Plymouth, MN], 8 DuroMedics [Baxter Healthcare, Santa Ana, CA], 7 MIRA [Edwards Lifesciences], 1 ON-X, 1 Bjork Shiley [Shiley, Inc, Irvine, CA], and 1 Sorin [Sorin Biomedica, Saluggia, Italy) were implanted. The type of prosthetic valve was selected according to the surgeon's preference. However, bioprosthesis was preferred in patients of more than 65 years of age. In patients with preexisting mechanical

Accepted for publication Nov 3, 2005.

Presented at the Forty-first Annual Meeting of The Society of Thoracic Surgeons, Tampa, FL, Jan 24–26, 2005.

Address correspondence to Dr Chang, Division of Cardiovascular Surgery, Yonsei Cardiovascular Center, Yonsei University College of Medicine, 134 Shinchon-dong, Seodaemun-gu, Seoul, South Korea 120-752; e-mail: bcchang@yumc.yonsei.ac.kr.

Published by Elsevier Inc

0003-4975/06/$32.00
doi:10.1016/j.athoracsur.2005.11.005

CARDIOVASCULAR

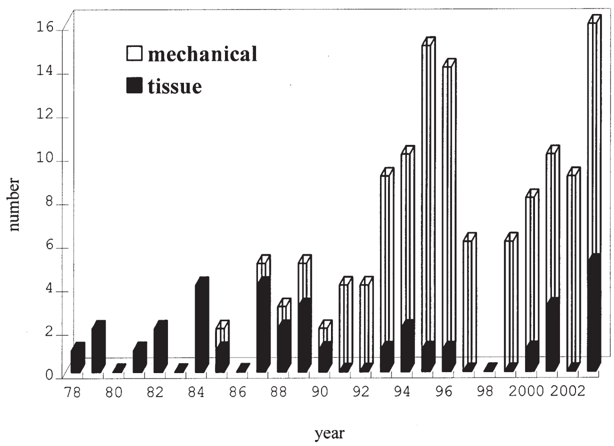

Fig 1. Annual number and prosthetic type of tricuspid valve replacement. Solid bars denote number of bioprostheses and open bars denote number of mechanical valves. Since 1990, pyrolytic carbon bileaflet mechanical valves have been used more frequently.

valves on the left side of the heart, the same type of prosthesis was selected.

Surgical Techniques

All operations were performed by the same group of surgeons. The surgical techniques remained substantially unchanged during the study period. Cardiopulmonary bypass was performed under mild to moderate systemic hypothermia (28–34°C) in a conventional manner. Tricuspid prostheses were implanted with 2-0 Ethibond (Ethicon, Bracknell, UK) interrupted horizontal mattress sutures, with or without pledgets, at the septal annulus and Prolene 3-0 (Ethicon) continuous sutures for the remaining annulus. To prevent heart block, sutures at the septal leaflet were placed at the leaflet tissue and tricuspid prostheses were oriented perpendicular to the septal leaflet.

Table 1. Patients' Profiles

Variables	Bioprostheses	Mechanical	All
Sex			
Male	15	35	50
Female	20	68	88
Age (mean ± SD)	44.5 ± 22.9	43.4 ± 13.9	43.7 ± 16.6
Causes			
Rheumatic	21	73	94
Valve failure	1	13	14
Congenital	10	4	14
Isolated TR	1	3	4
SBE	1	4	5
Prosthetic MV	1	1	2
Leakage			
Chordae	0	2	2
Rupture			
Degenerative	0	2	2
Traumatic	0	1	1
Preoperative NYHA			
II	2	21	23
III	22	56	78
IV	11	26	37
Preoperative rhythm			
Sinus	14	27	41
AF	20	70	90
Heart block	1	5	6
Pacing	0	1	1
Number of previous open heart surgery			
1	8	50	58
2	5	12	17
3	0	3	3
4	1	0	1
Concomitant heart valve replacement			
Single	16	25	41
Double	15	43	58
Triple	4	35	39

AF = atrial fibrillation; MV = mitral valve; NYHA = New York Heart Association; SBE = subacute bacterial endocarditis; TR = tricuspid regurgitation.

Anticoagulation

Heparin infusion was started at the first or second postoperative day, unless there were clinical contraindications, and sodium warfarin was started on the second postoperative day. The prothrombin time was maintained at an international normalized ratio (INR) of 2.5–3.5 for a mechanical valve, and an INR of 1.5–2.5 for a bioprosthetic valve.

Patient Follow-Up

One hundred sixteen patients were followed up periodically by the cardiologists, surgeons, or referring physicians. Follow-up was accomplished by patient visit, by mailing, or by telephone with the patient or the patient's family, with a follow-up rate of 98.3%. The mean follow-up period was 7.1 ± 5.0 years (9.7 ± 6.7 years for bioprostheses and 6.4 ± 4.1 years for mechanical), and the cumulative follow-up was 828.5 patient-year (261.3 for bioprosthesis and 567.2 patient-year for mechanical valve).

Statistical Analysis

Valve-related complications were defined in accordance with the guidelines established by the American Association for Thoracic Surgery and the Society of Thoracic Surgeons [8]. Variables of the two groups were compared using an unpaired *t* test. Estimates of survival and event-free survival, and mortality were calculated using the Kaplan-Meier method, and are reported with 95% confidence limits. Late valve-related events were defined as thromboembolism, valve thrombosis, anticoagulation-related bleeding, prosthetic valve endocarditis, paravalvular leakage in the absence of infection, and pannus formation. Valve-related complications were expressed in linearized form (%/patient-year). Estimates were reported with their standard errors. Comparisons of the curves were established using the Wilcoxon test for early and midterm results, and the log-rank test for long-term results. To analyze the risk factors for early and late mortality we reviewed preoperative variables, which are listed in Table 1. Risk factor analysis was performed by χ^2 and Fisher's exact testing, and an unpaired *t* test was used for univariate analysis. Multivariate analysis was performed using a logistic regression method. Results were calculated using a statistical software package (SAS Version 8.1; SAS Institute, Cary, NC). A *p* value less than 0.05 was considered to be significant for all analyses.

Results

Operative Mortality

Twenty-two patients (15.9%) died within 30 days or during hospitalization. Among the 22 deaths, 8 occurred in the bioprosthesis group (22.9%) and 14 in the mechanical group (13.6%). The operative mortality of the bioprosthesis group was higher than that of the mechanical group, probably due to the earlier period of operation; however, the difference was not statistically significant. Seventeen of the 22 deaths occurred in patients who had undergone replacement of previously implanted heart valves. The most common cause of early death was underlying heart failure (n = 8: three bioprostheses and five mechanical). There were 6 early deaths due to sepsis. One patient, who had respiratory tract infection with right heart failure, died due to a tracheostomy tube malfunction. Heart failure was the cause of early death in 12 patients. Other causes of operative mortality are shown in Table 2.

Table 2. Causes of Operative and Late Mortality

Causes	Bioprostheses	Mechanical	All
Early			
Heart failure	5	7	12
Sepsis	2	4	6
Sudden death	0	1	1
Pancreatitis	0	1	1
Postoperative bleeding	0	1	1
T-tube dysfunction	1	0	1
Late			
CHF	2	0	2
Chronic renal failure	0	2	2
Traumatic ICH	1	0	1
Arrhythmia	0	1	1
Unknown	3	4	7

CHF = congestive heart failure; ICH = intracranial hemorrhage; T-tube = tracheostomy tube.

In one patient a complete heart block requiring a permanent pacemaker developed. Univariate analysis revealed that age, sex, previous open heart surgery, preoperative New York Heart Association class, neck vein engorgement, presence of ascites, peripheral edema, preoperative total bilirubin, and serum glutamic oxaloacetic transaminase level were risk factors for early death. Multivariate logistic analysis identified age, sex, and presence of ascites as the risk factors for early death.

Late Death and Patient Survival

Among the 116 patients discharged from the hospital, 13 patients (6 in bioprosthetic [22.2%], 7 in mechanical [7.9%]) died during the follow-up period (late mortality; 11.4%). Nine of the 13 patients had received a previous valve replacement more than once. Five patients received single valve replacement (4 bioprostheses and one mechanical), 6 patients received double valve replacement (2 bioprostheses and 4 mechanical), and two patients received triple valve replacement (2 mechanical). The most common cause of late death was unknown (n = 7) and postmortem examinations were not performed in any cases. However, most of the patients had suffered from heart failure previously, and the causes of these deaths were thought to be underlying heart failure. Other causes of late mortality are shown in Table 2. The Kaplan-Meier survival rates were 94.2 ± 0.6% at five years, 84.3 ± 0.7% at 10 years, and 73.8 ± 1.1% at 16 years (Fig 2). There was no statistical difference in survival rates between the two groups (Wilcoxon, $p = 0.1759$; log-rank,

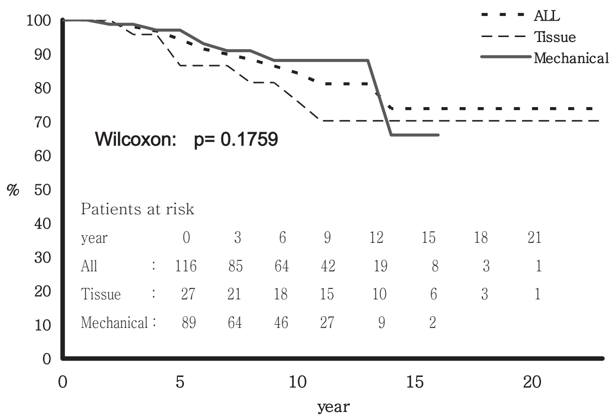

Fig 2. Kaplan-Meier estimated survival curves.

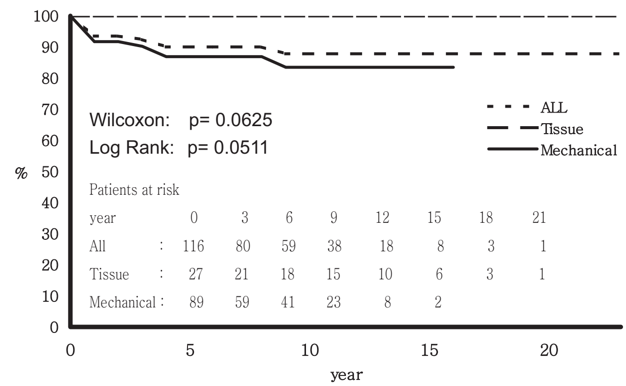

Fig 3. Kaplan-Meier estimated freedom from thromboembolic events.

$p = 0.2796$). The linearized incidence of late mortality for all patients was 1.57%/patient-year (2.30%/patient-year for bioprostheses vs 1.23%/patient-year for mechanical valves). Univariate analysis identified peripheral edema as a risk factor, while multivariate logistic analysis identified preoperative ascites and peripheral edema as risk factors for late death (Table 3).

Thromboembolism

During the follow-up period, 11 episodes of thromboembolism (valve thrombosis: 10, cerebral infarction: 1) occurred in the mechanical group. Freedom from thromboembolism was observed in 90.2 ± 0.6% of patients at five years, 87.8 ± 0.7% at ten years, and 87.8 ± 0.9% at 16 years. There was no statistical difference between the two groups (Fig 3). Among the ten patients with valve thrombosis, thrombolytic therapy was successfully performed in nine patients and valve replacement was inevitable in one patient. Linearized incidences of valve thrombosis and overall thromboembolism were 1.28% and 1.41%/patient-year for all patients, and 1.92% and 2.11%/patient-year for the mechanical group, respectively. Among 10 valve thromboses, three CarboMedics (11.1%), three St Jude (4.7%), three DuroMedics (37.5%), and two ATS (13.3%) valves were included.

Bleeding Events

There were three episodes of intracranial hemorrhage in the mechanical group. Among them, two patients recov-

Table 3. Risk Factor Analysis for Operative Death and Late Death

Variables	Operative Death		Late Death	
	Univariate	Multivariate	Univariate	Multivariate
Sex (male)	0.0150[a]	0.0107[a]	0.4342	
Age	0.0262[a]	0.0286[a]	0.1881	
Number of previous OHS	0.0266[a]		0.5980	
Previous TAP	0.0778		0.7044	
Number of TVR	0.0652		0.3601	
Number of valve replacement	0.9151		0.5299	
Type (bioprostheses or mechanical)	0.1958		0.0930	
Preop. NYHA class	0.0020[a]		0.6566	
Ascites	< 0.0001[a]	< 0.0001[a]	0.5136	0.0306[a]
Neck vein engorgement	0.0075[a]		0.0653	
Hepatomegaly > 2 FB	0.1788		1.0000	
Peripheral edema	0.0005[a]		0.0106[a]	0.0017[a]
Cyanosis	1.0000		1.0000	
Preop. rhythm	0.0746		0.5422	
Preop. bilirubin level	0.0201[a]		0.9337	
Preop. SGOT	0.0316[a]		0.4294	
Preop. SGPT	0.8304		0.1103	

[a] statistically significant

OHS = open heart surgery; TAP = tricuspid annuloplasty; TVR = tricuspid valve replacement; NYHA = New York Heart Association; FB = finger breath; Preop. = preoperative; SGOT = serum glutamic-oxaloacetic transaminase; SGPT = serum glutamic-pyruvic transaminase.

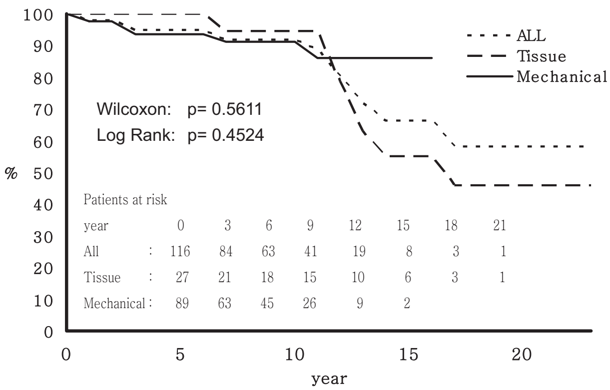

Fig 4. Kaplan-Meier estimated freedom from reoperation.

ered without sequelae and one patient had permanent deficit. The 5, 10, and 16 year freedom from anticoagulation-related bleeding rates for the mechanical group was 96.2 ± 0.8%, 93.0 ± 1.0%, and 93.0 ± 1.4%, respectively. Linearized incidences of anticoagulation-related bleeding for all patients and for the mechanical valve group were 0.37% and 0.54%/patient-year, respectively.

Prosthetic Valve Failure

During the follow-up periods, prosthetic valve failure occurred in 11 patients, including seven structural failures in the bioprosthetic and four pannus formations in the mechanical groups. Pannus formation occurred in patients once each with the St Jude and ATS valves, and twice with DuroMedics valves. All structural bioprostheses valve failures were due to valve cusp tearing or severe leaflet calcification between 83.9 and 196.5 months after TVR. In all cases re-replacements were performed using a mechanical valve. The linearized incidence of structural valve failure was 0.84%/patient-year for all patients and 2.68%/patient-year for the bioprostheses group. The linearized incidence of nonstructural valve failure was 0.48%/patient-year for all patients and 0.71%/patient-year for the mechanical group.

Reoperation

Reoperation was required in 14 patients. The causes of reoperation were structural valve failure in the bioprostheses group (7), and pannus formation (4), valve thrombosis (1), re-replacement of tissue valve during mitral valve replacement using a mechanical valve (1), and paravalvular leakage (1) in the mechanical group. Among 14 reoperations, 13 patients underwent tricuspid valve re-replacement and one patient underwent repair for paravalvular leakage. The Kaplan-Meier analysis for freedom from reoperation is shown in Figure 4. In the bioprosthetic group survival without reoperation declined 10 years after operation. The linearized incidence of reoperation for all patients was 1.71%/patient-year (2.68%/patient-year in bioprosthetic, 1.25%/patient-year in mechanical).

Freedom From Valve-Related Mortality

During the follow-up periods, 7 valve-related deaths occurred (3 in bioprosthetic, 4 in mechanical). The 5, 10, and 16 year freedom from valve-related death rates for all patients were 96.2 ± 0.6%, 89.5 ± 0.7%, and 89.5 ± 0.9%, respectively (bioprostheses: 90.5 ± 0.6%, 84.4 ± 0.9%, and 84.4 ± 0.9% vs mechanical: 98.3 ± 0.8%, 92.1 ± 1.0%, and 92.1 ± 1.4%). There was no statistical difference between the two groups (Wilcoxon, $p = 0.4317$; log-rank, $p = 0.4029$). The linearized incidence of valve-related death for all patients was 0.84%/patient-year (1.15%/patient-year in bioprosthetic, 0.71%/patient-year in mechanical).

Freedom From Valve-Related Events

The rate of event-free survival is shown in Figure 5. There was no statistical difference between the two groups. The linearized incidence of valve-related events for all patients was 4.33%/patient-year (3.83%/patient-year in bioprostheses, 4.6%/patient-year in mechanical). There was no statistical difference between the two groups.

Comment

Tricuspid valve replacement is an uncommon procedure because tricuspid valve regurgitation (TR) is usually functional and can be repaired properly with annuloplasty. Furthermore, most patients can successfully tolerate even significant tricuspid regurgitation for a long time. Thus conservative management has been preferred in patients who are able to tolerate significant regurgitation.

Severe TR related to left side heart valve disease may be one of the important manifestations of heart failure and early surgical correction should be considered. Tricuspid valve surgery concomitant with left side heart valve surgery is associated with a high operative mortality, especially in patients requiring TVR. Most of these patients received one or more previous procedures, including tricuspid valve repair, and were in advanced stages of functional deterioration [1]. For the past several decades, results of heart valve surgery have improved

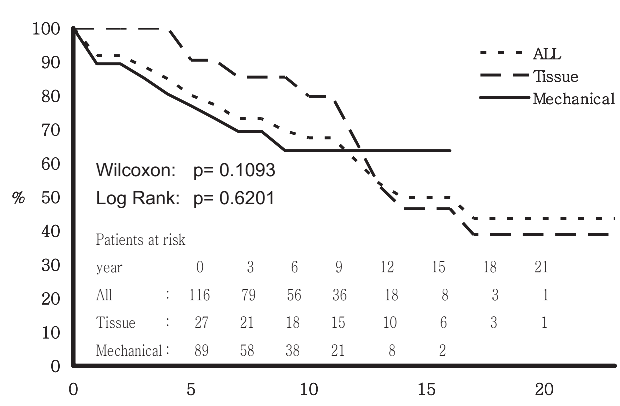

Fig 5. Kaplan-Meier estimated freedom from valve-related events.

CARDIOVASCULAR

significantly with the development of myocardial protection and surgical techniques. However, surgical results of TVR are still poor and need to be improved. The surgical mortality rate of 15.9% in this series is very high compared with mitral or aortic valve replacement but is comparable with previously reported TVR series, which range from 7.7% to 27% [2–15]. The high operative mortality of TVR appears to have several important factors. As we experienced previously in patients with mitral regurgitation, patients can tolerate severe TR for a long time as well. However, when the symptoms of right heart failure, such as peripheral edema and ascites occur, we can anticipate that their conditions may rapidly deteriorate, thus decreasing the likelihood of a positive surgical result. Recently our policy has been early surgical correction for severe TR in order to prevent progressive right heart failure.

Our results show that surgical mortality for bioprostheses was higher than that of mechanical prostheses, but without statistical significance ($p = 0.1985$). This result is comparable with previous reports [6, 7, 12]. The most common cause of early death in this series was persistent underlying heart failure (54.5% of operative deaths). Although recent advances in myocardial protection during surgery might reduce the incidence of myocardial failure during the early postoperative period, myocardial dysfunction before surgery seems to be a major cause of death. Operation before the development of ventricular failure is thought to be important for reducing early death after TVR.

The long-term survival after TVR with mechanical valves has been reported to be similar to TVR with tissue valves [9, 10]. In this series there was also no statistical difference between two types of valve prostheses in terms of long-term survival. The major cause of late death was preexisting heart failure. If these patients had been treated before developing heart failure, a better long-term survival may have been expected.

The late mortality of 11.4% is comparable with or lower than other reports, which range from 9.2% to 57% [2, 7, 12, 16]. Some authors reported that there was no late mortality during their follow-up period [5, 12]. In these 13 patients, nine underwent two or more valve operations. Among the 13 deaths, two patients died of heart failure and seven patients died of unknown causes. But a significant number of the patients with unknown causes of death were in poor clinical condition before death. Thus the unknown deaths are thought to be related to the progression of underlying heart failure. Therefore, early operation before development of heart failure seems to be very important. Regarding the type of prosthesis, there was no statistical difference between the two groups in valve-related mortality ($p = 0.4029$). However, there was a tendency to develop more valve-related mortality in the bioprosthetic group (11.1% in bioprosthetic vs 4.5% in mechanical valve group).

Valve thrombosis and pannus formation have been important valve-related complications after TVR with mechanical valves. The higher incidence of tricuspid valve thrombosis in previously designed tilting disc mechanical valves has been confirmed by several authors [17–21]. Recently, Kawano and colleagues [5] reported six cases of valve thrombosis among 19 patients who had received TVR with the St. Jude Medical valve (linearized incidence of 2.9%/patient-year). Two of these patients did not take warfarin sodium regularly. Dalrymple-Hay and colleagues [6] also reported a high prevalence of valve thrombosis in TVR with mechanical valves. However, Nakano and colleagues [3] reported only one valve thrombosis with 96.9% freedom from valve thrombosis 14 years after surgery. Furthermore, Singh and colleagues [4] reported no occurrence of valve thrombosis. In this report 102 bileaflet pyrolytic carbon valves were used, with one exception of tilting disk. There were 10 episodes of valve thrombosis between one and 46 months after TVR. At 48 months after TVR, there was no further valve thrombosis. Among 10 valve thromboses, three cases occurred in the patients with the DuroMedics valve (3 in 8 patients), which may be related to structural problems of this valve or surgical techniques. The linearized incidence of valve thrombosis in the mechanical valve group was 1.92%/patient-year, which is higher than previously reported results of other valve positions (MVR: 0.54%/patient-year and AVR: 0.33%/patient-year) [22]. As Kawano and colleagues [5] already described, there may be a higher incidence of prosthetic valve thrombosis with the low-pressure chamber at the tricuspid position. Anticoagulation measures should be strictly regulated even with low thrombogenic bileaflet pyrolytic carbon prostheses.

Valve thromboses and thromboembolic complications are affected by several factors, such as ventricular function, rhythm, valve position, prosthetic valve type, coagulation status (protein C, S, AT III, etc, level), and patient compliance, which may be the most important factor. As we have previously mentioned in another study [22], tight control of individualized anticoagulation level and regular education of the patients are the most important measures to prevent thrombotic complications. Further studies for the development of an ideal prosthesis to prevent valve thrombosis and pannus formation are necessary.

Reoperation for tricuspid position is an important consideration during prosthetic valve selection. In this study, there was no statistical difference between the two types of prostheses 16 years after operation in terms of reoperation. Reoperations took place at different times depending on prosthesis type, with reoperations in the mechanical valve group occurring within seven years, while reoperations in the bioprosthetic valve group occurred beyond 12 years, with one exception. Rizzoli and colleagues [9] reported that the risk of reoperation was 4.7 %/patient-year for bioprostheses and 2.2 %/patient-year for mechanical prostheses. They also reported that bioprosthetic valve degeneration increased at a steeper rate after seven years. Dalrymple-Hay and colleagues [6] insisted that the first 10 years after TVR are crucial in the decision making process for selecting an optimal implant, and that the risk of reoperation due to structural degeneration of a bioprosthetic valve is significantly lower than the risk of death during this period. In this study, freedom from reoperation using the mechanical prostheses 16 years after the initial operation (86.0 ± 1.4%) was comparable to other reports [5–7]. Although there was no statistical difference, the linearized incidence of reoperation was somewhat higher in the bioprosthetic valve group (2.68%/patient-year) than in the mechanical valve group (1.25%/patient-year).

Still, controversy exists as to the most suitable prosthesis for the tricuspid position. Some authors have reported good results with bioprostheses [5–7, 14], while others have shown good results with mechanical valves [2, 12, 23]. Early operation must be considered in patients with bioprostheses before significant degeneration of the bioprostheses and ventricular dysfunction develops. We also must consider the balance between the risk of valve-related complications when using the mechanical valve and the risk of reoperations when using the bioprosthetic valve.

Tricuspid valve replacement still carries a high operative mortality and poor long-term survival. The poor results are influenced by preoperative and postoperative patient conditions especially in patients with preexisting right heart failure. Correcting tricuspid regurgitation before irreversible heart failure occurs is thought to be important. Both bioprosthetic and mechanical valves demonstrated similar long-term clinical results in the tricuspid position. However, findings suggest that greater care is needed to prevent valve thrombosis in pyrolytic carbon-coated bileaflet mechanical valves, and greater concern is warranted for reoperation in bioprosthetic valves.

References

1. McGrath LB, Gonzalez-Lavin L, Bailey BM, et al. Tricuspid valve operation in 530 patients. J Thorac Cardiovasc Surg 1990;99:124–33.
2. Van Nooten GJ, Caes F, Taeymans Y, et al. Tricuspid valve replacement: postoperative and long-term results. J Thorac Cardiovasc Surg 1995;110:672–9.
3. Nakano K, Koyanagi H, Hashimoto A, Ohtsuka G, Nojiri C. Tricuspid valve replacement with the bileaflet St. Jude Medical valve prosthesis. J Thorac Cardiovasc Surg 1994;108: 888–92.
4. Singh AK, Feng WC, Sanofsky SJ. Long-term results of St. Jude Medical valve in tricuspid position. Ann Thorac Surg 1992;54:538–40.
5. Kawano H, Oda T, Fukuma S, et al. Tricuspid valve replacement with St. Jude Medical valve: 19 years of experience. Eur J Cardiothorac Surg 2000;18:565–9.
6. Dalrymple-Hay MJR, Leung Y, Ohri SK, et al. Tricuspid valve replacement: bioprostheses are preferable. J Heart Valve Dis 1999;8:644–8.
7. Munro AI, Jamieson WR, Tyers GF, Germann E. Tricuspid valve replacement: porcine bioprostheses and mechanical prostheses. Ann Thorac Surg 1995;59:S470–4.
8. Edmunds LH Jr, Clark RE, Cohn KH, Grunkemeier GL, Miller CM, Weisel RD. Guidelines for reporting morbidity and mortality after cardiac valvular operations. Ann Thorac Surg 1996;62:932–5.
9. Rizzoli G, De Perini L, Bottio T, Minutolo G, Thiene G, Casarotto D. Prosthetic replacement of the tricuspid valve: biological or mechanical? Ann Thorac Surg 1998;66:S62–7.
10. Ratnatunga CP, Edwards MB, Dore CJ, Taylor KM. Tricuspid valve replacement: UK heart valve registry mid-term results comparing mechanical and biological prostheses. Ann Thorac Surg 1998;66:1940–7.
11. Aoyagi S, Nishi Y, Kawara T, et al. Tricuspid valve replacement with the St. Jude Medical valve. Surgery Today 1994; 24:6–12.
12. Scully HE, Armstrong CS. Tricuspid valve replacement: fifteen years of experience with mechanical prostheses and bioprostheses. J Thorac Cardiovasc Surg 1995;109:1035–41.
13. Nakano K, Ishibashi-Ueda H, Kobayashi J, Sasako Y, Yagihara T. Tricuspid valve replacement with bioprostheses: long-term results and causes of valve dysfunction. Ann Thorac Surg 2001;71:105–9.
14. Kuwaki K, Komatsu K, Morishita K, Tsukamoto M, Abe T. Long-term results of porcine bioprostheses in the tricuspid position. Surgery Today 1998;28:599–603.
15. Nakano K, Eishi K, Kosakai Y, et al. Ten-year experience with the Carpentier-Edwards pericardial xenograft in the tricuspid position. J Thorac Cardiovasc Surg 1996;111:605–12.
16. Kawachi Y, Tanaka J, Tominaga R, Kinoshita K, Tokunaga K. More than ten years' follow-up of the Hancock porcine bioprosthesis in Japan. J Thorac Cardiovasc Surg 1992;104: 5–13.
17. Sanfelippo PM, Giuliani ER, Danielson GK, Wallace RB, Pluth JR, McGoon DC. Tricuspid valve prosthetic replacement: early and late results with the Starr-Edwards prosthesis. J Thorac Cardiovasc Surg 1976;71:441–5.
18. Jugdutt BI, Fraser RS, Lee SJ, Rossall RE, Callaghan JC. Long-term survival after tricuspid valve replacement: results with seven different prostheses. J Thorac Cardiovasc Surg 1977;74:20–7.
19. Wellens F, Goldstein J. Tricuspid valve replacement. Cardiovasc Clin 1987;17:111–5.
20. Thorburn CW, Morgan JJ, Shanahan MX, Chang VP. Long-term results of tricuspid valve replacement and the problem of prosthetic valve thrombosis. Am J Cardiol 1983;51:1128–32.
21. Van der Veer JB, Rhyneer GS, Hodam RP, Kloster FE. Obstruction of tricuspid ball-prosthesis. Circulation 1971; 44(suppl):I62–7.
22. Chang BC, Lim SH, Kim DK, et al. Long-term results with St. Jude Medical and CarboMedics Prosthetic Heart Valves. J Heart Valve Dis 2001;10:185–95.
23. Kaplan M, Kut MS, Damirtas MM, Cimen S, Ozler A. Prosthetic replacement of tricuspid valve: bioprosthetic or mechanical? Ann Thorac Surg 2002;73:467–73.

DISCUSSION

DR RALPH J. DAMIANO (St. Louis, MO): You had a quite small number of bioprostheses in this study, only 35 patients. You had an operative mortality of over 20%, which left a very small number of valves available for long-term follow-up. Is it possible that the reason you didn't see any statistically significant differences was that this study simply was not powered with enough patients to find a statistically significant difference? Once you got out to 10 to 16 years you really had a very small number of patients in the bioprosthetic group and is it possible that this study would be prone to a Type II statistical error?

Also, it looked like at 16 years there was a difference, though not statistically significant, in reoperation-free survival between tissue and mechanical valves, which we probably would expect, and I wonder if you would comment on that? Finally, at the present time, what is your clinical practice with implantation of valves into the tricuspid position?

DR CHANG: Thank you. For the first question and comment, thank you very much, the tissue valve has small numbers, only 35 cases; however, we followed them up more than 20 years, and 10 years after most of the patients required reoperation. Although the statistical power is low, the requirement of reoperation is necessary in most of the patients.

And for the second question, the long-term results after five years look better with mechanical valves, and also recently a high profile housing mechanical valve has come out and we may assume that it will prevent pannus formation for patients requiring tricuspid valve. Thus, if the patient is young, we would choose a mechanical valve instead of a tissue valve for prevention of reoperation.

DR JONATHAN HAMMOND (Hartford, CT): Probably most of us either have directly dealt with or have a partner who has dealt with an acutely thrombosed mechanical valve in the tricuspid position, and it is not a pretty sight. Do you think in the current era of the bovine pericardial valve that some of the durability problems might be solved and we would still feel comfortable with putting bioprosthetic valves in the tricuspid position?

DR CHANG: Thank you. Among 35 cases, half of them received a valve replacement before 1990. So most of them had a first generation tissue valve. We believe that the pericardial tissue may be more durable. However, recently we found that pericardial valves have some problems for durability in several patients, especially in young patients. So we have to follow them up more I think.