Tricuspid Valve Replacement With Bioprostheses: Long-Term Results and Causes of Valve Dysfunction

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Background. Although the clinical performance of bioprostheses after valve replacement in the aortic and mitral position has been reported, little is known of the performance of tricuspid bioprostheses. The mechanism of bioprosthetic valve dysfunction after tricuspid valve replacement (TVR) is not clear.

Methods. We reviewed 98 cases of TVR with bioprostheses. To clarify the causes of valve dysfunction, pathologic examination of the explanted valve at the reoperation was performed.

Results. Actuarial survival at 18 years was $68.7\% \pm 5.8\%$. There were 12 redo TVRs. In six of the 12 cases, isolated redo TVR was performed. In the other cases, concomitant cardiac procedures were performed. The causes of prosthetic valve dysfunction were pannus formation on the cusps of the right ventricle side (four

B ecause the hemodynamic, anatomical, and histological characteristics of the right side of the heart are different from those of the left side, the durability of bioprostheses and the mechanism of the prosthetic valve failure in the tricuspid position might differ from those in the aortic and mitral position. Although the long-term results of valve replacement with bioprostheses in the aortic and mitral position have been reported, little is known of those in the tricuspid position. Further, to clarify the mechanism of valve dysfunction, pathological examinations of the explanted valve at reoperation were performed.

Material and Methods

From July 1978 to October 1995, 98 bioprostheses were implanted in the tricuspid position in 96 patients. The cases with corrected transposition of the great arteries were excluded. Age at operation ranged from 8 to 74 years, with an average age of 52 ± 13 years (38 males and 60 females). Previous cardiac operations had been per-

cases), native valve attachment (two cases), pannus formation + native valve attachment (two cases), sclerotic change (one case), pannus formation + sclerotic change (one case), and native valve attachment + valve infection (one case). Freedom from reoperation, structural valve deterioration, and nonstructural dysfunction at 18 years was 62.7% \pm 10.7%, 96.0% \pm 2.9%, and 76.7% \pm 8.3%, respectively.

Conclusions. In our 18 years of experience, although the survival after TVR with bioprostheses is acceptable, the reoperation free rate is not satisfactory. Pannus formation on the cusps of the ventricular side seems to be a serious problem that causes bioprosthetic dysfunction in the tricuspid position.

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formed in 58 patients. Previous tricuspid valve replacement (TVR) had been performed in 4 patients. The causes of the tricuspid lesions were as follows: Ebstein's anomaly (n = 14), tricuspid regurgitation (TR) after the repair of congenital anomalies (n = 7), congenital TR, including atrioventricular defect (n = 5), cardiomyopathy (n = 3), infective endocarditis (n = 2), trauma (n = 1), constrictive pericarditis (n = 1), and degenerative disease (n = 1). In 64 cases, the patients had concomitant mitral valve disease. In the majority of the patients, previous procedures for the tricuspid valve had been performed or TR was caused by dilatation of the tricuspid annulus and elongation of the chordae, probably as a result of mitral valve disease.

The prostheses used were Carpentier-Edwards pericardial valve (CEP; 72 cases), Ionescu-Shiley (IS; 9), Ionescu-Shiley low profile (ISL; 8), Mitroflow (MF; 3), Hancock (HK; 2), Hancock pericardial valve (HKP; 2) and Carpentier-Edwards suprannular porcine valve (CESA; 2). Additional procedures are shown in Table 1. Concomitant mitral valve replacement (MVR), concomitant MVR and aortic valve replacement (AVR), and AVR with previous MVR or concomitant AVR were performed in 35, 25, and 3 patients, respectively.

TVR was performed with standard cardiopulmonary bypass. The valve was assessed and excised. The bioprosthesis was implanted with multiple everting mattress

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Table 1. Operative Procedure

Procedure(s)	No. of patients
Isolated TVR	17
TVR with concomitant procedures	
MVR	32
MVR + aortic repair	3
MVR + AVR	25
Mitral repair	5
AVR + mitral repair	2
AVR + shunt closure	1
Mitral and aortic repair	1
PVR	3
ASD closure	2
Pericarditectomy	3
VSD closure	1
Sealy	1
Cox-maze	1
Repair of sinus valsalva	1
Total	98

ASD = atrial septal defect; AVR = aortic valve replacement; MVR = mitral valve replacement; PVR = pulmonary valve replacement; VSD = ventricular septal defect.

sutures with pledget in the tricuspid annulus, except for a segment along the conduction bundle, where sutures were laid on the septal leaflet.

Surviving patients have been examined in the outpatient clinic at least once every 3 months. All survivors have been followed up yearly by questionnaire. Two patients were unavailable for follow-up. We were successful in following up 98% of the patients. Follow-up duration ranged from 1 year and 2 months to 17 years and 3 months. The mean follow-up duration was 7.1 years.

Definitions of events and methods of analyzing the results follow the guidelines published in this journal [6]. Thromboembolism was restricted to pulmonary embolism, excluding systemic thromboembolism. The actuarial curves were constructed by standard nonparameteric Kaplan-Meier methods. The results are presented with standard error.

To evaluate prosthetic valve function, the echocardiographic examination was currently performed in 35 of 58 survivors. Doppler echocardiographic scans were obtained with a phased-array two-dimensional sector scanner and color-flow imager (SSH160A, SSA270A; Toshiba America Medical System, Tusten, CA). The grade of TR was examined by the method based on previous studies from this center [7]. The mean transvalvular gradient was also estimated.

To clarify the cause of prosthetic dysfunction, the bioprostheses excised at the reoperation were macroscopically and microscopically examined. The tear, mural thrombus, pannus formation, calcification, native valve attachment, and loss of leaflet coaptation were assessed and graded from mild to severe.



Fig 1. Actuarial survival curve, including operative deaths. Numbers above the horizontal axis represent the number of patients eligible for analysis.

Results

Fourteen hospital deaths and 12 late deaths occurred. All hospital deaths were not related to the tricuspid prosthetic valve. The causes of late death were as follows: congestive heart failure (6 patients), cerebral bleeding (1 patient), infective endocarditis (1 patient), liver cirrhosis (1 patient), agranulocytosis (1 patient), sudden death of unknown cause (1 patient), and unknown (1 patient). The actuarial survival after TVR was 77.1% \pm 4.3% at 5 years, 68.7% \pm 5.8% at 10 years, and at 18 years (Fig 1).

Redo TVR (ReTVR) was performed in 12 patients. In 6 patients, the isolated reTVR was performed for valve dysfunction of tricuspid bioprosthesis. In 6 patients, concomitant procedures for other cardiac complications, including reMVR for the structural valve deterioration (SVD) of the mitral bioprosthesis (2 patients), reAVR for structural valve deterioration of the aortic bioprosthesis, leakage repair for a perivalvular leakage of the mitral valve prosthesis, Cox-maze procedure for paroxysmal atrial fibrillation, and AVR and CABG for aortic regurgitation and angina pectoris, were performed. In the patient with aortic regurgitation and angina pectoris, although preoperative echocardiography did not show valve dysfunction of the tricuspid bioprosthesis (Mitroflow 31 mm), an additional procedure of reTVR was performed because the valve had a history of 12 years after implantation. In the other cases, preoperative echocardiography demonstrated obvious TR or tricuspid stenosis with restricted leaflet motion. The characteristics of the reoperation cases are summarized in Table 2. The valve explanted from the tricuspid position was as follows: CEP (eight cases), IS (two cases), CESA (one case), and MF (one case). The duration between TVR and the reTVR ranged from 2 years and 4 months to 10 years. The mean duration was 7 years and 11 months. Table 3 shows macroscopic findings and pathological examinations of the explanted valve. A tear was detected in one case (MF). There was a moderate to severe grade of fibrous pannus on the ventricular side of the cusps in 7 patients. Moderate or severe calcification was observed in only 2 patients. The native valve attachment was observed in 5

Case	Age/Gender	Prosthesis	Duration	Concomitant Proc	Hemo	Second Valve
1	34/F	IS	10 yr	Re-MVR	TSr	SJM
2	45/F	IS	8 yr, 2 mo	None	TSR	CEP
3	47/F	Mitroflow	12 yr, 4 mo	$AVR + CABG \times 2$	Tr	SJM
4	56/F	CEP	10 yr, 9 mo	None ^a	TS	SJM
5	50/M	CEP	8 yr, 5 mo	Mitral leak repair ^a	TR	CarboMedics
6	61/F	CEP	9 yr, 1 mo	Re-MVR	Tsr	SJM
7	55/M	CEP	7 yr	None ^a	TSR	SJM
8	66/F	CEP	8 yr, 5 mo	None ^a	TSr	SJM
9	50/M	CESA	2 yr, 4 mo	ReAVR ^a	TSR	CEP
10	61/F	CEP	8 yr, 6 mo	None ^a	TSr	CarboMedics
11	50/F	CEP	5 yr, 3 mo	Cox-maze	TR	CEP
12	13/M	CEP	4 yr, 9 mo	None	TSR	SJM

Table 2. Summary of reTVR Cases

^a Mechanical prostheses in the mitral or aortic position were not explanted.

Age = age (years) at the operation when the explanted valve prosthesis was implanted; Prosthesis = explanted valve prosthesis; IS = Ionescu-Shiley; CEP = Carpentier-Edwards pericardial valve; CESA = Carpentier-Edwards supraannular valve; Duration = duration between previous operation and the operation at this time; Concomitant proc = concomitant procedures at the reTVR; Hemo = hemodynamic examination of the tricuspid bioprosthesis; Second valve = the valve prosthesis implanted at the reTVR; reTVR = redo tricuspid valve replacement.

patients. The cusp on which the native valve was attached was located adjacent to the intraventricular septum. Judging from the operative and pathological findings of the explanted valve, the causes of valve dysfunction were pannus formation on the ventricular side of the cusp in 4 patients (CEP), pannus formation and native valve attachment in 2 patients (CEP), native valve attachment in 2 patients (IS, 1; CESA, 1) native valve attachment and prosthetic valve infection in 1 patient (CEP), sclerotic change with severe calcification in 1 patient (IS), and pannus formation and sclerotic change with moderate calcification in 1 patient (CEP). The case with pannus formation and sclerotic change of the cusps with moderate calcification was a young patient in whom the CEP was implanted when he was 13 years old. Figures 2 to 4 show the explanted valves in which the causes of valve dysfunction are pannus formation (case 10), sclerotic change (case 2), and native valve attachment and pannus formation (case 8). Figure 5 shows a photomicrograph of both pannus formation and sclerotic change (case 12).

Two cases with sclerotic change were categorized as structural valve deterioration. Other cases with pannus formation or native valve attachment were categorized as nonstructural dysfunction. The case with native valve attachment and prosthetic valve infection was categorized as prosthetic valve endocarditis. Reoperation-free rate at 5, 10, and 18 years was 97.2% \pm 1.9%, 75.5% \pm 7.5%, and 62.7% \pm 10.6%, respectively. The freedom from structural valve deterioration at 5, 10, and 18 years was 98.4% \pm 1.5%, 96.0% \pm 2.9%, and 96.0% \pm 2.9%, respectively. The freedom from nonstructural dysfunction at 5, 10, at 5, 10, and 15, 10, 20% at 2.9%, respectively.

Table 3. Macroscopic Findings and Pathological Examinations of the Explanted Valve

Case	Tear	Thro	mbus	Par	nus	Calcification	NVA	Poor Coapt	Cause of Dysfunction
		RA	RV	RA	RV				
1	_	_	_	Mild	Moderate	Mild	Moderate	Mild	NVA
2	—	—	—	Mild	Mild	Severe		Severe	Sclerosis
3	Mild	Mild	Mild	—		Mild		Mild	Not deteriorated
4	_	Mild	Mild	_	Moderate	Mild		Mild	Pannus
5	_	Mild	_	Mild	Moderate	_	Mild	Mild	Pannus
6 ^a	—	Mild	_	_	Mild	Mild	Mild	Moderate	NVA + PVE
7	_	Mild	_	_	Severe	_	Moderate	Severe	NVA + pannus
8	_	_	Mild	_	Moderate	_	Severe	Moderate	NVA + pannus
9 ^b	—						Severe		NVA
10	_	Mild	_	Mild	Severe	Mild	Mild	Moderate	Pannus
11	_	_	Mild	Mild	Moderate	_		Mild	Pannus
12	_	_	Mild	Moderate	Mild	Moderate	_	Moderate	Sclerosis + pannus

^a Tricuspid prosthesis is infected; there was vegetation on the cusps. ^b Pathological examinations were not performed; only the operation record was available.

The case number corresponds to that in Table 2. Thrombus = mural thrombosis; RA = right atrial side; RV = right ventricular side; NVA = native valve attachment; Poor coapt = poor coaptation of the cusps.



Fig 2. Gross view of the CEP explanted 8 years and 6 months after implantation (case 10 in Tables 2 and 3). Left, ventricular aspect; right, atrial aspect. Fibrous pannus is observed on the cusps of both sides.

10, and 18 years was 98.9% \pm 1.3%, 82.1% \pm 6.9%, and 76.7% \pm 8.3%, respectively (Fig 6).

Besides the reoperation cases, prosthetic valve endocarditis in the tricuspid position occurred twice in 1 patient who had undergone triple-valve replacement. The event was fatal. Cerebral bleeding occurred in another patient who had undergone triple-valve replacement. The patient received warfarin anticoagulation for the mechanical prosthesis in the aortic and mitral positions. There was no other valve-related complications. The freedom from valve-related events at 5, 10, and 18 years was $88.8\% \pm 4.6\%$, $74.9\% \pm 7.5\%$, and $64.8\% \pm 9.3\%$, respectively (Fig 7).

Echocardiographic examination was performed in 35 of the 58 survivors. Grade 3 TR was detected in 2 patients. A transprosthetic gradient of more than 5 mm Hg with restricted cuspal motion was detected in 6 patients. Two patients had both TR and transprosthetic gradient of more than 5 mm Hg. In total, 28.6% of the 35 patients, in whom echocardiography examination was performed, had TR or tricuspid stenosis. The patients were followed up medically.

Comment

This study demonstrated that the mortality and morbidity after TVR with bioprostheses were acceptable in our 18 years of experience. However, reTVR was required in 12 patients among 58 survivors. In six of the 12 cases,



Fig 3. Gross view of the IS valve explanted 8 years and 2 months after implantation (case 2 in Tables 2 and 3). Left, ventricular aspect; right, atrial aspect. Severe sclerotic change with calcification of the cusps is observed.



Fig 4. Gross view of the CEP explanted 8 years and 5 months after implantation (case 8 in Tables 2 and 3). Left, ventricular aspect; right, atrial aspect. Native valve attaches the cusp where the forceps indicates. Moderate grade of fibrous pannus on the ventricular side is observed.

valve dysfunction in the tricuspid position was the primary reason for reoperation. Pannus formation of the cusps on the ventricular side was related to the cause of the reoperation in seven of the 12 cases.

Regarding the durability of the bioprosthesis in the tricuspid position, several authors have reported excellent long-term results. Guerra and colleagues reviewed 45 patients with a 14-year follow-up. The actuarial freedom from structural deterioration of a Hancock tricuspid porcine bioprostheses at 14 years was 68% [1]. Kawachi and associates also reported excellent durability of the Hancock valve in the tricuspid position [2]. Eng and colleagues reported long-term results of the TVR with the Ionescu-Shiley valve in 73 patients [3]. In up to 18 years of follow-up, primary tissue failure occurred in only 1 patient. Munro and associates compared clinical performance of TVR with bioprostheses and mechanical valve prosthesis [4]. Bioprostheses were used in 83 operations. The freedom from structural valve deterioration was 97.1% at 7 years for bioprostheses.

In our previous report of clinical performance with the Carpentier-Edwards pericardial xenograft, freedom from



Fig 5. A photomicrograph of the cross section of the CEP explanted 4 years and 9 months after implantation (case 12 in Tables 2 and 3). Nodular intrinsic calcification is seen at the atrial site of the prosthetic valve (top). A pannus, composed of fibrous tissue, is attached to the ventricular site (bottom). Mild collagen bundle separation of the xenograft is recognized (Elastica van Gieson staining, \times 5).



Fig 6. Actuarial rates for freedom from reoperation, structural valve deterioration, and nonstructural dysfunction. Numbers above the horizontal axis represent the number of patients eligible for analysis. (R = reoperation; SVD = structural valve deterioration; ND = nonstructural dysfunction.)

structural valve deterioration and nonstructural dysfunction at 9 years was 100% and 72.8%, respectively. The cause of nonstructural dysfunction was pannus formation on the cusps of the ventricular side. Besides the reoperation cases, echocardiographic examination revealed subclinical prosthetic dysfunction in 35% of patients who were followed up for longer than 5 years [5]. After this report, we experienced another six cases of reTVR in which the CEP was implanted. In all cases, moderate or severe fibrous pannus on the cusps of the ventricular side was detected in the explanted valve (Table 3). Severe sclerotic change was observed in only one explanted valve. The causes of the valve dysfunction were concluded to be pannus formation (two cases), pannus formation + native valve attachment (two cases), pannus formation + sclerotic change (one case), and pannus formation + prosthetic valve infection (one case). Thus, only one case with severe sclerotic change is categorized as structural valve deterioration. The other cases are categorized as nonstructural dysfunction or prosthetic valve endocarditis.

The major cause of reTVR, in 3 patients who were implanted with IS and CESA, was considered to be sclerotic change (1 patient) and native valve attachment (2 patients), although mild or moderate fibrous pannus was observed on the cusps of the vernacular side. These findings might suggest that the CEP is more vulnerable to pannus formation and tissue overgrowth on the cusps than the other types of bioprostheses.

Guerra and colleagues reported morphologic examination of explanted Hancock porcine valve in their experience with nine reoperation cases [1]. The prostheses explanted from the tricuspid position had lower degrees of calcification and less severe structural change than did those simultaneously explanted from the mitral position. The finding peculiar to the tricuspid position that was not observed in the mitral position was the presence of fibrous pannus on the ventricular side, growing into one or more sinuses and impairing pliability of the corresponding cusp. These findings correspond with those



Fig 7. Actuarial rates for freedom from valve-related events. Numbers above the horizontal axis represent the number of patients eligible for analysis. (SVD = structural valve deterioration; ND = non-structural dysfunction; PVE = prosthetic valve endocarditis; ACH = anticoagulant-related hemorrhage.)

observed in our series and demonstrate that the pannus formation occurs not only on the CEP but on the Hancock porcine valve. This evidence suggests that pannus formation is more common in the tricuspid position than in the mitral position. Cohen and associates also reported similar findings observed in six explanted Hancock porcine valves that were simultaneously implanted [8]. Although the degenerative changes were less extensive for the prosthesis in the tricuspid position than for that in the mitral position, thrombus formation was observed in more cases in the tricuspid position than in the mitral position. The pannus formation, interpreted as organized thrombotic material, may be related to the anatomic and hemodynamic characteristics of the right ventricle.

References

- 1. Guerra F, Bortolotti U, Thiene G, et al. Long-term performance of Hancock porcine bioprosthesis in the tricuspid position: a review of forty-five patients with fourteen-year follow-up. J Thorac Cardiovasc Surg 1990;99:838–45.
- Kawachi Y, Tominaga R, Hisahara M, Nakashima A, Yasui H, Tokunaga K. Excellent durability of the Hancock porcine bioprosthesis in the tricuspid position. J Thorac Cardiovasc Surg 1992;104:1561–6.
- 3. Eng J, Ravichandran PS, Kay PH, Murday AJ. Long-term results of Ionescu-Shiley valve in the tricuspid position. Ann Thorac Surg 1991;51:200–3.
- Munro AI, Jamieson WRE, Tyers GFO, Germann E. Tricuspid valve replacement: porcine bioprostheses and mechanical prostheses. Ann Thorac Surg 1995;59:S470–4.
- 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.
- Edmunds LH Jr, Clark RE, Cohn LH, Grunkemeier GL, Miller DC, Weisel RD. Guidelines for reporting morbidity and mortality after cardiac valvular operations. Ann Thorac Surg 1996;62:932–5.
- 7. Miyatake K, Okamoto M, Kinoshita N, at al. Evaluation of tricuspid regurgitation by pulsed Doppler and twodimensional echocardiography. Circulation 1982;66:777–84.
- Cohen SR, Silver MA, McIntosh CL, Roberts WC. Comparison of late (62 to 140 months) degenerative changes in simultaneously implanted and explanted porcine (Hancock) bioprostheses in the tricuspid and mitral valve positions in six patients. Am J Cardiol 1984;53:1599–602.