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SURGERY FOR ACQUIRED HEART DISEASE

TRICUSPID VALVE REPLACEMENT

**Fifteen years of experience
with mechanical prostheses
and bioprostheses**

Tricuspid valve replacement is not a common operation. The purpose of this study was to examine the early and late results in 60 patients who underwent 28 (47%) bioprosthetic and 32 (53%) mechanical tricuspid valve replacements. All operations took place between January 1978 and June 1993 during which period a total of 4741 patients underwent valve replacement operation. Mean patient age was 50 ± 15 (18 to 75) years. Forty-one patients (68%) were female and 19 patients (32%) were male. Forty-nine patients (82%) were in New York Heart Association class III or IV before operation. Forty-five patients (75%) were undergoing repeat cardiac valve operation. Seventeen patients (28%) had complex congenital cardiac problems. Operation was urgent in 15 patients (25%). The hospital mortality rate was 27% (16 patients). All patients with hospital death were in New York Heart Association class III or IV, were having repeat operations, or had complex congenital disease. Low output syndrome was observed in 21 patients (35%). Reoperation because of bleeding was required in seven patients (12%). Thirteen patients (22%) required permanent (epicardial lead) pacemaker implantation. Mean follow-up is 75 ± 45 months (maximum 173 months) and 100% complete for the 44 patients who left the hospital. There have been 14 deaths (32%). Nine of these patients (64%) had mechanical valves and five (36%) had bioprostheses. Of the 11 cardiac deaths, three were valve related (bioprostheses). Three patients (10%) required reoperation because of tricuspid valve prosthetic failure (1 thrombosed mechanical valve, 2 failed porcine valves). Of the remaining 30 patients, 20 (67%) are in New York Heart Association class I or II. Seventeen patients have mechanical valves and 13 have bioprostheses. Twenty-six

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patients (90%) are receiving warfarin. Thromboembolism (transient ischemic attack) has occurred in one patient with a mechanical valve who also had a previous cerebrovascular accident. In this group there has been no hemorrhage, endocarditis, or new pacemaker requirement. Actuarial survival for the whole series is $37\% \pm 9\%$ and for the hospital survivors is $50\% \pm 12\%$ at 15 years. Linearized rates of valve-related complications are not different between groups. Tricuspid valve replacement is a beneficial procedure for patients with structural tricuspid valve disease, many of whom have other valvular or congenital disease. Contemporary mechanical prostheses and bioprostheses are equally effective in the tricuspid position. Mechanical valves should be considered for tricuspid replacement in young patients and in patients with mechanical valves implanted in the left side of the heart. (J THORAC CARDIOVASC SURG 1995;109:1035-41)

Replacement of diseased cardiac valves with either mechanical or biologic tissue prostheses has become an established therapeutic procedure since the first aortic and first mitral implants were done by Harken¹ and Braunwald² and their associates in 1960. Many model changes and refinements have been made, and much discussion of the relative merits of different types of heart valves has ensued.^{3,4}

Tricuspid valve surgery has always been a challenging problem, whether in isolation or in combination with the surgical approach to other valve or congenital abnormalities.⁵⁻¹³ When a decision is made to replace the tricuspid valve, the choice of prosthesis remains controversial. The lower pressures and flows in the right side of the heart predispose mechanical prostheses to a high rate of valve thrombosis,¹⁴⁻¹⁷ although design improvements in contemporary mechanical prostheses appear to have ameliorated this problem significantly.¹⁸⁻²⁴ The rate of degeneration of bioprostheses in the tricuspid position has been observed to be appreciably slower than the rate for biological valves placed on the systemic side of the circulation,^{22, 25-29} but calcification does result in late dysfunction.²⁵⁻³⁰ The purpose of this review was to examine our experience with tricuspid valve replacement during the past 15 years and to compare and contrast early and late results in patients who had received either contemporary mechanical prostheses or bioprosthetic heart valves.

Methods

Between January 1978 and June 1993, 4741 patients underwent valve replacement at The Toronto Hospital. Sixty patients (1.3%) required tricuspid valve replacement (Table I). Twenty-eight (47%) biologic valves and 32 (53%) mechanical valves were implanted. Patient demo-

graphics are presented in Table II. For 38 patients (63%) this was a first-time tricuspid valve operation. Complex congenital problems involving the right side of the heart and the tricuspid valve were present in 17 patients (28%). Forty-five patients (75%) had undergone a cardiac operation at least once before (Table III). Eight of these patients had undergone tricuspid valve repairs that had failed. Fourteen patients had had failure of tricuspid prostheses. Eleven of the failures were of mechanical valves: eight Starr-Edwards* ball cage prostheses (ball entrapment, prosthetic stenosis), two spherical disc Björk-Shiley† valves (valve thrombosis), and one Beall‡ model 104 floating disc prosthesis (valve thrombosis and disc wear). Three were of porcine valves that had failed after 9, 13, and 14 years of implantation, respectively. The tricuspid valve abnormality encountered at the time of tricuspid valve replacement is shown in Table IV. Tricuspid insufficiency treated conservatively (nonoperatively) at initial mitral or mitral and aortic valve operation, or as a consequence of failed annuloplasty or repair, or both, at a previous operation, was present in 14 patients. The prevalent congenital disease was Ebstein's malformation. Two of the patients with endocarditis abused intravenous drugs. In one of the patients in the "trauma" category the tricuspid valve had "burst" in a motor vehicle accident. The other trauma case was iatrogenic and involved irreparable damage to the tricuspid valve during a repeat operation for a recurrent or residual left atrial myxoma. The range of operations done on these 60 patients is presented in Table V. Sixteen of the 21 patients undergoing isolated tricuspid valve replacement had undergone a previous cardiac operation. Concomitant procedures at this operation were done in 39 patients (65%).

All patients underwent median sternotomy or re sternotomy. Intraoperative myocardial protection was provided by moderate hemodilution, systemic hypothermia to 28° to 32° C, and cold crystalloid potassium-rich cardioplegic solution (before 1984) or cold blood cardioplegic solution (after 1984) infused in an antegrade fashion under pressure either into the aortic root (mitral or

*Baxter Healthcare Corp., Edwards Division, Santa Ana, Calif.

†Shiley Inc., Irvine, Calif.

‡Surgitool, Inc., Pittsburgh, Pa.

Table I. Tricuspid valve replacement by type and model (total of 60 patients: 1.3% of 4741)

	No.	%
Biologic (n = 28, 47%)		
Hancock II porcine*	14	50.0
Carpentier-Edwards porcine†	8	28.6
Ionescu-Shiley pericardial‡	3	10.7
Medtronic Intact§	2	7.1
Hancock pericardial	1	3.6
Mechanical (n = 32, 53%)		
Björk-Shiley Monostrut‡	23	71.9
Björk-Shiley welded outlet strut, 60- and 70-degree‡	5	15.6
St. Jude Medical bileaflet#	4	12.5

*Johnson & Johnson Cardiovascular, King of Prussia, Pa.

†Baxter Healthcare Corp., Edwards Division, Santa Ana, Calif.

‡Shiley, Inc., Irvine, Calif.

§Medtronic, Inc., Minneapolis, Minn.

#St. Jude Medical, Inc., St. Paul, Minn.

Table II. Patient demographics

	No.	%
Mean age (yr): 50 ± 15 (18-75)		
Sex		
Female	41	68
Male	19	32
Repeat operation	45	75
Urgent operation	15	25
NYHA class III and IV	49	82

tricuspid valve operation or operation for congenital disease) or directly into the coronary ostia (aortic valve operation). All valves were secured in position by an interrupted horizontal mattress suture technique reinforced by Teflon felt pledgets placed on the ventricular aspect of the valve annulus.

Statistical analysis. Actuarial analysis was done by life-table methods, and linearized rates of valve-related complications were calculated for each type of prosthesis. Actuarial survival including hospital mortality was calculated for the 60 original patients and for the 44 hospital survivors, with analysis of each type of prosthesis. The generalized Wilcoxon and Mantel-Haenszel tests were used to examine differences in actuarial rates. Continuous data are presented as mean plus or minus the standard deviation. The number of patients in this study was not sufficient to allow for meaningful calculation of *p* values.

Results

Hospital results. The hospital mortality and morbidity were not significantly different between the patients undergoing biologic tricuspid valve replacement and those in whom mechanical valves were implanted (Table VI). The hospital mortality rate was 27% (16 patients). All 16 of these patients were

Table III. Previous cardiac operations: 45 patients (75%)

	No.	%
Tricuspid operation		
Repair	8	17.8
Replacement	14	31.1
Mitral operation		
Repair (closed/open)	10	22.2
Replacement	23	51.1
Aortic valve operation		
Replacement	10	22.2
Congenital defect repair	9	20.0
Aorta-coronary bypass	3	6.7

Table IV. Tricuspid valve disease or injury

	No.	%
Rheumatic tricuspid stenosis	22	36.7
Congenital	17	28.3
Tricuspid insufficiency	14	23.3
Failed tricuspid prosthesis	14	23.3
Failed tricuspid repair	8	13.3
Endocarditis	5	8.3
Trauma	2	3.3

in New York Heart Association (NYHA) functional class III or IV. Five patients underwent triple valve replacement. Four of the five patients undergoing isolated tricuspid replacement also had concomitant cardiac procedures. Twelve of the 16 patients who died in the hospital had undergone previous cardiac operations, as had all 7 patients who required reoperation because of bleeding. Of the 21 patients (35%) who had low output syndrome, all had undergone repeat operation, combined procedures, or both.

Late results. Follow-up through a constantly updated Valve Patient Registry at The Toronto Hospital that uses personal interviews and assessments, telephone contact, and review of hospital and physician patient records is 100% complete for the 44 patients discharged from the hospital. The mean follow-up interval was 75 ± 45 months (maximum 173 months). The causes of the 14 late deaths are presented in Table VII. Three patients died of malignancy or accident or other disease unrelated to the valve or to the heart. Eight patients died of cardiac causes unrelated to the implanted valve: progressive myocardial failure (6), ischemic heart disease (1), and, in one patient, pulmonary edema caused by catastrophic failure of a mitral Ionescu-Shiley* bovine pericardial prosthesis 63 months

*Shiley, Inc., Irvine, Calif.

Table V. Operations performed

	Biologic (n = 28, 47%)		Mechanical (n = 32, 53%)	
	No.	%	No.	%
Isolated TVR	7	25.0	14	43.8
Concomitant procedures				
MVR + TVR	7	25.0	7	21.9
AVR + MVR + TVR	5	17.8	6	18.8
Congenital defect repair + TVR	7	25.0	3	9.4
MV repair + TVR	1	3.6	1	3.1
AVR + TVR (endocarditis)	1	3.6	0	
Aorta-coronary operation (+AVR, MVR, TVR)	0		1	3.1

TVR, Tricuspid valve replacement; MVR, mitral valve replacement; AVR, aortic valve replacement; MV, mitral valve.

Table VI. Hospital results

	Biologic (n = 28, 47%)		Mechanical (n = 32, 53%)	
	No.	%	No.	%
Mortality	9	31.2	7	21.9
Morbidity				
Low output syndrome	9	31.2	12	37.5
Reoperation because of bleeding	4	14.3	3	9.4
Permanent pacemaker	7	25.0	6	18.8
Deep sternal infection	1	3.6	0	
Cerebrovascular accident	1	3.6	0	

after implantation (at autopsy the tricuspid bovine pericardial valve was structurally and functionally intact).

There were three valve-related deaths, all in patients with bioprostheses. One patient who abused intravenous drugs died of recurrent endocarditis. One patient with poorly controlled warfarin (Coumadin) anticoagulation died of cerebrovascular hemorrhage. One patient whose porcine tricuspid valve failed in the tenth year after implantation died at third-time tricuspid valve replacement. The complications that occurred in the 44 hospital survivors are presented in Table VIII. Structural failure occurred in two of the tricuspid bioprosthetic valves implanted in 19 hospital survivors. The patient noted earlier, whose tricuspid valve failed in the tenth year (112 months), also had a failing mitral porcine valve. The other patient, whose porcine tricuspid valve failed in the fifteenth implant year (171 months), had a coexisting porcine mitral valve. This patient remains well after rereplacement with a

Table VII. Late results: mortality (N = 14/44, 32%)

Cause of death	Biologic (n = 19)		Mechanical (n = 25)	
	No.	%	No.	%
Valve related	3	15.8	0	
Cardiac (nonvalve)	1	5.3	7	28.0
Other	1	5.3	2	8.0

Table VIII. Late results: complications

	Biologic (n = 19)		Mechanical (n = 25)		Linearized rate (%/100 pt-yr)
	No.	%	No.	%	
Structural failure	2	10.5	0		0.73
Thrombosis/thrombo- embolism	0		2	8.0	0.73
Anticoagulant-related hemorrhage	1	5.3	0		0.36
Prosthetic valve en- docarditis	1	5.3	0		0.36

CarboMedics* valve. None of the mechanical valves failed structurally, including the five convexo-concave disc 60- or 70-degree Björk-Shiley valves "at risk" with welded outlet struts. None of the 28 patients still alive who are receiving life-long warfarin anticoagulant therapy have had any significant anticoagulant-related hemorrhage. Warfarin dosage is monitored with use of the international normalized ratio. Twenty (67%) of the 30 patients still alive are in NYHA functional class I or II. Subjectively 80% of patients feel better than they did before the operation. Actuarial survival for the entire group of 60 patients is $37\% \pm 9\%$ at 15 years (Fig. 1), and actuarial survival of the 44 hospital survivors is $50\% \pm 12\%$ (Fig. 2). Linearized rates of valve-related complications were not different between the two types of valves implanted (Table VIII).

Discussion

In recent years, as in this series, tricuspid valve replacement is uncommon.^{5, 8, 10, 11, 22} It is generally agreed that tricuspid annuloplasty is the preferred treatment for moderate to severe tricuspid insufficiency. Tricuspid valve replacement is usually reserved for those patients with significant organic tricuspid valve disease that is unlikely to improve if more conservative measures are taken.⁵⁻¹³

*CarboMedics, Inc., Austin, Tex.

Fig. 1. Actuarial survival for all patients.

Fig. 2. Actuarial survival for hospital survivors.

The hospital mortality rate has been reported to be between 10% and 54%.^{7, 8, 10-12, 22, 26} The hospital mortality rate of 27% in this series was higher than some, but is consistent with the reality that most of these patients were undergoing complex repeat operations. In a comparison of the hospital mortality and postoperative morbidity between patients who were undergoing biologic or mechanical prosthetic tricuspid replacement, we found no difference. Although others have noted a higher hospital mortality with the use of mechanical prostheses,^{26, 28} other things being equal, it is logical that

there would be no difference. There was no difference in the early morbidity between the two groups of patients. Again, other things being equal, none would be expected. The late mortality of 14 patients (32%) in the series compares well with that of other reports.^{7, 8, 22-24} All of the patients have been followed up closely with early adjustment of medications as required.

There was an apparent difference in the rates of late death between the nine patients with mechanical tricuspid prostheses and the five patients with bioprostheses. However, the deaths in patients with

mechanical valves were not valve related. The three late valve-related deaths all occurred in patients with bioprosthetic valves, although one death as a result of cerebral hemorrhage was not related to the valve type but caused by poor warfarin control. By the mid-1970s there were reports of significant valve-related problems with valve thrombosis of (tilting) disc valves¹⁵⁻¹⁷ or pannus formation and ball entrapment with ball-cage valves implanted in the tricuspid position.^{8, 14, 16} By comparison there was relative freedom from degeneration or structural failure of bioprostheses implanted in the right side of the heart.²² Conventional wisdom was that a porcine bioprosthesis should be implanted when tricuspid valve replacement was indicated, regardless of the prostheses implanted in the left side of the heart.^{22, 25-29} The lag in valve leaflet opening caused by lower flows to overcome valve inertia in the right side of the heart and the ultimate degeneration of the valves were considered reasonable risks by comparison. In the late 1970s there were reports of improved hemodynamics, less transprosthetic stasis and turbulence in the redesigned disc, and new bileaflet valves with documented improvements in rates of valve thrombosis and thromboembolism.^{3, 18-21, 23, 24} It seemed reasonable to again implant contemporary mechanical prostheses in the tricuspid position, particularly in association with implantation of mechanical valves in the systemic circulation or in other circumstances in which the patients would require life-long warfarin anticoagulation therapy.

In this series there were two structural failures of porcine bioprostheses in the tricuspid position at intervals of 9 years and 14 years. Three of the original 60 patients required repeat tricuspid valve replacement because of porcine valve failure at similar intervals. As noted by others,^{8, 14, 16} these failures were delayed beyond what might have been expected in the left side of the heart. However, both patients required reoperation. One of these reoperations was successful and involved failed tricuspid bioprosthetic replacement by a mechanical valve. One patient died: the mitral bioprosthesis had also failed at 9 years and the third-time operation to replace both failed bioprostheses was not successful. One hospital survivor in whom bioprostheses had been implanted in both the mitral and tricuspid positions died as a consequence of catastrophic failure of the mitral bioprosthesis. If contemporary mechanical prostheses had been used in these six patients who had structural bioprosthetic valve failure, it is likely that they would have continued to do well.

On the other hand, one of the Monostrut Björk-

Shiley valves did develop thrombus to the extent that significant tricuspid prosthetic stenosis developed. Thrombolytic treatment was successful in clearing lesser thrombus compromise of the coexisting mitral Monostrut Björk-Shiley valve. The tricuspid valve thrombus proved refractory, and the prosthesis was successfully replaced. There was one transient ischemic attack in a patient with a mechanical valve. However, the patient was also in atrial fibrillation, had a history of preoperative embolic cerebrovascular accident, and never manifested any evidence of pulmonary embolus. Valve type was likely irrelevant to this complication.

In conclusion, the important finding of this study is that at 15 years there is no difference in patient survival or valve-related complications in patients in whom tricuspid valves have been replaced with either contemporary mechanical or bioprosthetic valves. There was a tendency to late failure in the bioprostheses and others may fail with the passage of time. Should this be the situation, it would add strength to the argument that contemporary mechanical valves should be used preferentially for tricuspid replacement in patients who can tolerate warfarin anticoagulation therapy. However, because tricuspid valve replacement represents such a small percentage of valve operations, it would be desirable to combine the results from several centers to produce sufficient numbers for good statistical analysis. From the results of our study, we recommend consideration of implantation of contemporary mechanical prostheses in the tricuspid position in younger patients, in patients in whom mechanical valves are also being implanted in the mitral or aortic position, and in patients who require life-long warfarin anticoagulation therapy.

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Discussion

Dr. Norberto G. De Vega (*Málaga, Spain*). I fully agree with the authors' conclusions. In our experience, in the past 14 years, out of more than 4000 valve operations, we have had to replace the tricuspid valve on only 10 occasions. In only one of those patients was the replacement done as a primary valve operation. We have always used a bileaflet valve, either a St. Jude Medical or, more recently, the new A.T.S. valve. Except for one patient in whom a partial thrombosis of the St. Jude Medical tricuspid valve developed on two occasions, and resolved with thrombolysis, all patients are doing well. Therefore we agree that if a tricuspid valve has to be replaced, it is better to use a bileaflet valve than a bioprosthesis.

Dr. Scully. Thank you, Dr. De Vega. We are now favoring mechanical valves rather than bioprostheses for tricuspid valve replacement.