IN-HOSPITAL AND LONG-TERM OUTCOME AFTER PORCINE TRICUSPID VALVE REPLACEMENT

Porcine bioprostheses are often used for tricuspid valve replacement, yet the long-term outcome after this procedure is not well documented. Therefore, the records of 129 patients undergoing tricuspid valve replacement with Carpentier-Edwards ($n = 88$) or Hancock ($n = 41$) prostheses between 1975 and 1993 were reviewed. The operation required a repeat median sternotomy in 66 of 129 (51%) patients, whereas 67 of 129 (52%) underwent double or triple valve replacement. Operative mortality was 14% (2/14) in patients undergoing first-time isolated tricuspid valve replacement and 27% (35/129) overall. Survival at 5, 10, and 14 years was $56\% \pm 5\%$, $48\% \pm 5\%$, and $31\% \pm 9\%$, and freedom from tricuspid reoperation at 5, 10, and 14 years was $96\% \pm 3\%$, $93\% \pm 4\%$, and $49\% \pm 17\%$. No valve thrombosis was observed. In this largest reported series of porcine bioprostheses in the tricuspid position, long-term freedom from valve-related events was excellent because of a low incidence of valve thrombosis and a valve durability of 13 to 15 years in a population with limited life expectancy. (*J THORAC CARDIOVASC SURG* 1995;109:877-84)

Donald D. Glower, MD, William D. White, MPH, L. Richard Smith, PhD, W. Glenn Young, MD, H. Newland Oldham, MD, Walter G. Wolfe, MD, and James E. Lowe, MD, *Durham, N.C.*

Although tricuspid valve replacement was initially performed with mechanical prostheses,¹ the relatively high incidence of thrombosis or pannus ingrowth with mechanical valves in the tricuspid position²⁻⁵ has prompted the use of bioprostheses for tricuspid valve replacement over the past 15 years.⁶ Increasing reports of structural degeneration of bioprostheses in the aortic and mitral positions has rejuvenated consideration of mechanical tricuspid valves,⁷ despite very little data demonstrating the long-term outcome from tricuspid valve replacement with porcine bioprostheses.

A retrospective study was undertaken to define more clearly the clinical outcome from porcine tricuspid valve replacement, both in the hospital and over the long term, based on the experience at a single institution.

Patients and methods

Over the period from 1974 through 1993, 143 patients underwent tricuspid valve replacement at Duke University

Medical Center. Of these 143 patients, 11 received various mechanical prostheses, 3 received pericardial bioprostheses, and 129 patients had porcine prostheses inserted in the tricuspid position. Because the numbers were small for patients receiving valves other than porcine bioprostheses, the current study was limited to those 129 patients undergoing porcine tricuspid valve replacement. Preoperative, in-hospital, and follow-up information was obtained by review of the medical record and/or contact with the patient or referring physician. Follow-up was complete to 1991 in 119 of 129 (91%) patients with a mean follow-up of 4 ± 5 years and maximum follow-up of 16 years. Survival and freedom from reoperation were computed by the technique of Kaplan and Meier.⁸ Operative mortality was defined as any death occurring in the hospital or within 30 days after operation.⁹ The Cox proportional hazards model was used to detect those factors significantly affecting survival or freedom from reoperation over time. Logistic regression analysis was used to examine factors affecting operative mortality.¹⁰ Those variables with univariable significance at the 0.1 level were tested for multivariable significance by forward and backward elimination. Kaplan-Meier survival curves were compared by the log rank test.¹⁰ Kaplan-Meier estimates were given as mean $\pm$ standard error, and all other data were presented as mean $\pm$ standard deviation unless otherwise stated.

Results

The year of operation for patients undergoing porcine tricuspid valve replacement was evenly distributed over the period 1974 to 1993 (Fig. 1). Of the 129 patients undergoing tricuspid valve replacement

From the Departments of Surgery and Community and Family Medicine, Duke University Medical Center, Durham, N.C.

Read at the Twentieth Annual Meeting of The Western Thoracic Surgical Association, Olympic Valley, Calif., June 22-25, 1994.

Address for reprints: Donald D. Glower, MD, Box 3851, Duke University Medical Center, Durham, NC 27710.

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0022-5223/95 \$3.00 + 0 12/6/62366

Fig. 1. Number of porcine tricuspid valve replacements performed at Duke University over the period 1974 to 1993.

Table I. Concurrent procedures

	Patients	
	No.	%
Mitral valve repair/replacement	45	34
Mitral and aortic valve replacement	23	18
Closure of atrial septal defect	13	10
Aortic valve replacement	4	3
Closure of ventricular septal defect	4	3
Other	4	3
None	36	28

with porcine bioprostheses, 88 patients received a standard Carpentier-Edwards prosthesis (Baxter Healthcare Corp., Edwards Div., Santa Ana, Calif.), and 41 patients received a Hancock prosthesis (Johnson & Johnson Cardiovascular, King of Prussia, Pa.). The mean age was 53 ± 16 years, and 88 of 129 (68%) patients were female. The cause of tricuspid valvular disease was rheumatic in 55 patients (43%), degenerative in 35 (27%), endocarditis in 13 (10%), Ebstein's anomaly in 13 (10%), and other causes in 13 (10%). Class III or IV congestive heart failure was present in 113 of 129 (88%) patients, and 54 of 129 (42%) patients had other significant medical comorbidity. Chronic atrial fibrillation was present in 66 of 129 (51%) patients.

Cardiac catheterization demonstrated 3+ or greater tricuspid regurgitation in 85 patients, 20 patients had moderate or severe tricuspid stenosis, and 9 patients had combined stenosis and regurgitation. Seventeen patients (13%) had 75% or greater stenosis of 1 or more coronary vessels, and 9 patients had accessory atrioventricular conduction

pathways. A prior median sternotomy had been performed in 66 of 129 (51%) patients, with the most frequent prior procedure being mitral valve repair or replacement in 36 of 129 (28%) patients.

At the time of tricuspid valve replacement, 93 of 129 (72%) patients underwent concurrent procedures (Table I). In combination with the procedures listed in Table I, concurrent coronary bypass grafting was performed in 7 patients, and 7 patients underwent concurrent division of accessory atrioventricular pathways. Double valve replacement was performed in 44 of 129 (34%) patients, and triple valve replacement was performed in 23 of 129 (18%) patients. Operative mortality was 27% (35/129) overall, 14% (2/14) in patients undergoing first-time, isolated tricuspid valve replacement, and 19% (4/21) in patients undergoing repeat median sternotomy for isolated tricuspid valve replacement. According to logistic regression analysis, age, concurrent mitral valve replacement, and increased class of congestive heart failure were univariable predictors of operative mortality. Of these variables, only age and concurrent mitral valve replacement were independent predictors of operative mortality. Mortality increased from 5 of 44 (11%) for age less than 50 years to 8 of 29 (28%) for age 50 to 59 years and 22 of 56 (39%) for age more than 60 years. Concurrent mitral valve replacement increased operative mortality from $18\% \pm 5\%$ to $35\% \pm 6\%$, and isolated triple valve replacement increased mortality to 6 of 19 (32%). Of 86 discharged patients, 44 (51%) received warfarin, 20 (23%) received aspirin alone, and 22 (26%) received neither aspirin nor warfarin.

Late survival was $56\% \pm 5\%$ at 5 years, $48\% \pm$

Fig. 2. Overall survival of patients undergoing tricuspid valve replacement.

5% at 10 years, and $31\% \pm 9\%$ at 14 years (Fig. 2). The most common cause of death, both in the hospital and after discharge, was congestive heart failure (Table II). Univariable predictors of decreased survival were increased age, increased class of congestive heart failure, and increased pulmonary artery systolic pressure. Of these variables, the only independent predictors of decreased survival were increased age ($\chi^2 = 8.7, p = 0.003, \beta = 0.045 \pm 0.015$) and increased class of congestive heart failure ($\chi^2 = 6.1, p = 0.01, \beta = 0.82 \pm 0.33$). Overall survival at 10 years was $23\% \pm 9\%$ for patients older than 60 years, $57\% \pm 11\%$ for patients aged 50 to 59 years, and $68\% \pm 9\%$ for patients less than 50 years old ($p < 0.001$) (Fig. 3). Survival at 10 years was $29\% \pm 8\%$ for patients with class IV symptoms before the operation and $65\% \pm 7\%$ for patients with class III symptoms or less ($p < 0.001$) (Fig. 3).

For those patients discharged alive, the independent predictors of decreased survival were prior median sternotomy ($\chi^2 = 4.6, p = 0.03, \beta = 1.16 \pm 0.54$) and increased pulmonary artery systolic pressure ($\chi^2 = 4.3, p = 0.03, \beta = 0.022 \pm 0.011$). Prior median sternotomy decreased 10-year survival for hospital survivors from $78\% \pm 7\%$ to $43\% \pm 10\%$ ($p = 0.03$), and preoperative pulmonary artery systolic pressure greater than 50 mm Hg decreased 10-year survival for hospital survivors from $70\% \pm 9\%$ to $51\% \pm 15\%$ ($p = 0.02$) (Fig. 4).

Table II. Causes of death

	Patients	
	No.	%
Congestive heart failure	31	47
Infection	11	17
Other noncardiac	9	14
Unknown	7	11
Hemorrhage	4	6
Other cardiac	4	6
Total	66	100

Only 8 patients required subsequent tricuspid valve reoperation. Four porcine tricuspid valves were reoperated on (9, 11, 12, and 14 years after the operation) for structural deterioration of the tricuspid prosthesis, 1 porcine tricuspid valve was replaced after 1.7 years for pannus ingrowth, and 3 porcine tricuspid valves were replaced at the time of reoperation for aortic valve disease (5, 11, and 13 years after the operation). Mean age for these 8 patients was 41 ± 18 years ($p = 0.02$ versus patients not requiring tricuspid valve reoperation). Freedom from tricuspid valve reoperation was $96\% \pm 3\%$ at 5 years, $93\% \pm 4\%$ at 10 years, and $49\% \pm 17\%$ at 14 years (Fig. 5). Concurrent aortic valve replacement was the only predictor of decreased freedom from tricuspid valve reoperation ($\chi^2 = 7.4, p < 0.02, \beta = 2.3 \pm 0.8$). Concurrent aortic valve replacement decreased 10-year freedom from tricuspid valve

Fig. 3. Effect of age (*left panel*) or preoperative New York Heart Association congestive heart failure class (*right panel*) on overall survival after porcine tricuspid valve replacement.

Fig. 4. Effects of previous median sternotomy (redo) (*left panel*) or preoperative pulmonary artery systolic pressure (PAS, mm Hg) (*right panel*) on survival of patients discharged after porcine tricuspid valve replacement.

reoperation from $98\% \pm 2\%$ to $79\% \pm 14\%$ ($p < 0.01$) (Fig. 5). Five additional patients required subsequent cardiac operations other than tricuspid valve reoperation, and all 5 of these reoperations were replacement of mitral valves that had been operated on previously. Freedom from any cardiac reoperation was $91\% \pm 4\%$ at 5 years, $79\% \pm 7\%$ at

10 years, and $40\% \pm 15\%$ at 14 years. The only predictor of decreased freedom from any cardiac reoperation was concurrent aortic valve replacement ($\chi^2 = 5.3$, $p < 0.02$, $\beta = 1.35 \pm 0.59$), which decreased 10-year freedom from any cardiac reoperation from $85\% \pm 7\%$ to $63\% \pm 18\%$ ($p = 0.02$). No cases of clinical pulmonary embolism, tricuspid

Fig. 5. Freedom from tricuspid valve reoperation after porcine tricuspid valve replacement (left panel) and the effect of concurrent aortic valve replacement (AVR) (right panel).

valve thrombosis, or tricuspid valve endocarditis developed.

Discussion

Although outcome after tricuspid valve replacement is well described, most series have relatively small patient numbers and often combine mechanical, porcine, and other biologic valve prostheses.^{4,11-13} The current series of 129 porcine prostheses in the tricuspid position exceeds previous reports of 45 to 58 porcine tricuspid prostheses^{3,5} and is approached only by the experience of 101 porcine tricuspid prostheses in the mixed series of McGrath and associates.⁴ Because of small patient numbers, few studies have been able to examine the determinants of in-hospital mortality^{4,12,13} or long-term survival^{4,12,14} after tricuspid valve replacement.

The significant operative mortality of 27% in the current series is not unlike operative mortalities of 11% to 37% reported for tricuspid valve replacement in recent series.^{3-5,12,13,15,16} Incremental risk factors for early mortality in previous reports included peripheral edema, use of a Hancock prosthesis, functional disability, white race, high cardiothoracic ratio, age, female gender, New York Heart Association class, tricuspid regurgitation, pulmonary dysfunction, and abnormal liver function tests.^{12,13,17} The increased operative mortality after tricuspid valve replacement relative to aortic or mitral valve replacement has been speculated to

result from the high percentage of concurrent aortic or mitral valve operations^{3,4,13,15} and from the high number of patients with previous median sternotomies.⁴ Right ventricular dysfunction has been proposed as a potential contributor to operative mortality after tricuspid valve replacement for tricuspid regurgitation,⁴ yet difficulties assessing preoperative right ventricular function have prevented clarification of the influence of right ventricular dysfunction on operative mortality. An additional factor potentially contributing to operative mortality is that, early in the current series, tricuspid valve replacement instead of repair was reserved for high-risk patients with functional tricuspid regurgitation caused by severe biventricular failure and multivalvular heart disease.

Long-term survival after tricuspid valve replacement has varied considerably. Ten-year survival has been reported to be between 36% and 71%, with most series finding long-term survival to be relatively poor as in the current series.^{3-5,11,15,16} Long-term survival after tricuspid valve repair^{4,11,12} or after mechanical tricuspid valve replacement¹⁶ has in fact been quite similar to the survival reported after bioprosthetic tricuspid valve replacement. In all series, congestive heart failure and cardiomyopathy were the most common causes of death after tricuspid valve replacement.^{4,11-13} Previous studies found that risk factors for late death included preoperative edema, increased crossclamp time, high

pulmonary artery pressure, earlier date of operation, larger tricuspid valve size, prior cardiac operation, age greater than 55 years, and advanced functional disability.^{12, 14, 17} The current study generally concurred with prior studies in finding age, congestive heart failure class, pulmonary artery systolic pressure, and prior median sternotomy to decrease overall or long-term survival.

Relatively few series provide data regarding long-term freedom from reoperation after tricuspid valve replacement.^{3, 4, 12} In the mixed series of tricuspid valve replacements that included bovine pericardial valves, McGrath and associates¹⁷ found that freedom from reoperation fell dramatically from 85% $\pm$ 7% at 8 years to 65% $\pm$ 8% at 10 years after valve replacement. On the other hand, Barratt-Boyes and colleagues¹² found freedom from reoperation to be 70% $\pm$ 10% at 10 years for homograft tricuspid valve replacement, and Guerra and coworkers³ reported that freedom from structural deterioration in Hancock tricuspid bioprostheses was 78% $\pm$ 10% at 10 years and 68% $\pm$ 13% at 14 years. The current study confirmed that freedom from reoperation was excellent 10 years after porcine tricuspid valve replacement, with some deterioration after 10 years (see Fig. 5). The series of McGrath,⁴ Barrett-Boyes,¹² and Guerra,³ and their associates all found that death before 10 years was significantly more likely than tricuspid valve reoperation at 10 years. Although tricuspid valve repair remains preferable to tricuspid valve replacement in patients with repairable valves,^{4, 11, 12} freedom from reoperation has been similar between tricuspid valve repair and tricuspid valve replacement.^{4, 12} In a comparison of tricuspid versus mitral versus aortic valve replacement with Carpentier-Edwards prostheses, several authors noted that reoperation was less likely^{3, 18} and that valve degeneration was less¹⁹ for porcine valves in the tricuspid position than in mitral or aortic positions. The lower pressures on the right side of the heart have been speculated to contribute to the relative durability of porcine prostheses in the tricuspid position. The current series demonstrated that, in patients undergoing porcine tricuspid valve replacement, the primary determinant of reoperation was concurrent aortic valve replacement, and reoperation for aortic or mitral valve disease was more likely than reoperation for tricuspid valve dysfunction. This result suggests that mechanical prostheses should be strongly considered for aortic or mitral valve replacement at the time of porcine tricuspid valve replacement.

The incidence of other valve-related morbidity was extremely low in this and other series of tricuspid valve replacements with bioprostheses.^{3-5, 15} No episodes of endocarditis, valvular thrombosis, or thromboembolism occurred in the current series despite frequent lack of anticoagulation. Thromboembolism from porcine prostheses occurred in only 2 of 101 patients reported on by McGrath and colleagues.⁴ Thus tricuspid valve reoperation was the primary source of tricuspid valve-related long-term morbidity after porcine tricuspid valve replacement, yet tricuspid valve reoperation occurred infrequently in the population of patients receiving porcine tricuspid valve replacement.

The current study does have limitations in evaluating the long-term outcome for porcine tricuspid valve replacement. Although this is the world's largest series of porcine tricuspid valve replacements, the relatively small numbers limited the ability to detect those variables resulting in adverse outcome, especially the unusual adverse outcome of reoperation. As with all retrospective analyses, the comparability between patients in this series and others is not easy to quantify, although preoperative patient characteristics are probably among the most significant determinants of postoperative results.

The present study does, however, provide insight into outcome after porcine tricuspid valve replacement. In this population, the durability of the porcine tricuspid prosthesis clearly exceeded the life expectancy of most patients receiving tricuspid prostheses. As a result, adverse outcomes of reoperation and other valve-related morbidity were unusual. The porcine bioprosthesis therefore was clearly a good choice for the patients in the present study, especially for patients over 60 years old, with class IV symptoms, with prior median sternotomy, or with pulmonary artery systolic pressures greater than 50 mm Hg. Caution should be used in generalizing this study to other patient subgroups, such as significantly younger patients whose life expectancy might well exceed the durability of the porcine prosthesis in the tricuspid position, as suggested by the fact that patients requiring reoperation in the current series were significantly younger than those not needing reoperation. However, even in these younger patients, the likelihood of reoperation must be weighed against the continuous risk of anticoagulant-related hemorrhage²⁰ and the troubling incidence of tricuspid valve thrombosis or pannus ingrowth with mechanical tricuspid valve replacement.^{2, 16} In the small subset of young patients with

excellent life expectancy, the choice of a porcine versus mechanical prosthesis for tricuspid valve replacement will await better long-term data regarding reoperation and valve-related complications between 10 and 20 years after operation. The current study further suggests that, in patients undergoing concurrent aortic or mitral valve replacement, strong consideration should be given to use of mechanical aortic or mitral prostheses, because the likelihood of reoperation for aortic or mitral valve replacement was actually greater than the likelihood of replacement of a dysfunctional tricuspid prosthesis. Improved means to assess and follow right ventricular function may assist in decreasing mortality for patients needing tricuspid valve replacement.

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Discussion

Dr. Kent W. Jones (*Salt Lake City, Utah*). I would like to congratulate Dr. Glower and his associates from Duke on compiling and reporting the results of a large group of patients undergoing tricuspid valve replacement with a porcine prosthesis. This represents a very difficult group of patients to treat from a number of standpoints: whether anything operatively should be done with the tricuspid valve either solely or in conjunction with repair or replacement of other valves, whether to repair or to replace the valve, and if the decision is made for replacement, what prosthesis to use.

I have the following questions. Given the fact that the majority of reoperations were done in patients having had previous mitral valve operations, are you more aggressive with treatment of the tricuspid valve at the time of the initial mitral valve operation?

Dr. Glower. That is a good point. This series extends

from 1975 to 1993, and our practice has changed over that period. At this point we do tend to be relatively aggressive with patients with severe tricuspid regurgitation, but decisions have to be made. In the case of moderate regurgitation that we believe is functional because of a mitral valve lesion, we often will leave patients with mild regurgitation and find that they do well. The fact that a number of these patients had had previous mitral procedures is reason for caution, however. For patients who have severe regurgitation at their initial mitral valve operation, strong consideration should be given to either repair or replacement of the tricuspid valve. Also, many of the patients requiring reoperation for their tricuspid valve after a previous procedure had had rheumatic disease early in this series. These patients may have more native tricuspid valve disease than some of the other patients with other causes for regurgitation.

Dr. Jones. I agree with that. All of us are being more aggressive and regarding the tricuspid valve as a second primary problem, not a problem resulting from the mitral valve disease.

The mean age at operation of your patients was 53 years, but there was a distinct dropoff in the curve documenting prosthesis durability in the period of 10 to 15 years after the operation. The operative mortality for reoperation solely for tricuspid valve replacement was 19%, and there was a significant increase in the operative mortality for patients older than age 60 years. Reports in the literature advocate the use of the St. Jude Medical prosthesis (St. Jude Medical, Inc., St. Paul, Minn.) in the tricuspid position as opposed to other mechanical prostheses used in earlier reports. Do these facts change your choice of prosthesis, especially if aortic and/or mitral valve replacement with a mechanical prosthesis is necessary?

Dr. Glower. Other prostheses are available, such as the St. Jude Medical valve, that have not been available in much of the older data. Much of the limited literature regarding the use of mechanical valves for tricuspid valve replacement does relate to series from the late 1970s and early 1980s. Not much information concerning the St. Jude Medical prosthesis has been published. However, the potential risk of valve thrombosis, about 10% per patient-year or less, must be counterbalanced against the extra risk of having to reoperate and replace a porcine prosthesis in 10 to 15 years in a younger patient. That decision has to await more complete data on the risk of thrombosis over the long term with the St. Jude Medical valve in the tricuspid position. It is also contingent on making a reasonable estimation of survival in these patients. Although many of them were young, the patients in this series tended to have end-stage heart disease. Their chance for survival was not good because of advanced rheumatic cardiac disease.

Dr. Jones. Only 51% of your patients receive postoper-

ative anticoagulation. What is your indication for anticoagulation?

Dr. Glower. Our current indications are the same as those in most institutions. Patients with a mitral prosthesis and atrial fibrillation are given anticoagulants. Any patient with a mechanical prosthesis is given anticoagulants. In this series, that includes half of the patients at the time of discharge. At latest follow-up, about three quarters of these patients ultimately were receiving anticoagulation. The porcine prosthesis may or may not avoid the need for anticoagulation, but the major reason for choosing this valve over the mechanical prosthesis was to avoid the risk of tricuspid thrombosis.

Dr. Jones. Even in patients who lack atrial ventricular synchrony, if they have only a tricuspid prosthesis in place, you do not anticoagulate?

Dr. Glower. We do not. In fact, we have traditionally prescribed aspirin alone for the majority of them and have had very good results with that.

Dr. Jones. My last question has three parts, but they all intertwine.

You did not address morbidity, significantly and specifically heart block, which is a significant potential morbidity problem with the tricuspid valve and can lead to an increase in mortality. What percentage of your patients had heart block that resulted from the operation? Do you place a permanent epicardial electrode at the time of tricuspid valve repair or specifically replacement? If you need to use a pacemaker system after the operation, do you use an epicardial system or do you use an endocardial electrode through the tricuspid prosthesis?

Dr. Glower. You bring up a small subset of these patients who are difficult to manage. In this series of about 129 patients, five required placement of a pacemaker after the operation. However, three of those had a ventricular pacing wire in place preoperatively that had to be removed so that the tricuspid valve could be replaced. Two patients required a new pacemaker postoperatively for heart block that they did not have before the operation. This is a small number of patients, and our experience is not large. In one patient we were actually able to leave the preoperative pacemaker wire in place and put the valve in around that. Our first choice is to use temporary wires for the vast majority of patients in the absence of heart block. If we detect heart block in the operating room, we strongly consider putting permanent epicardial wires on the patient after the operation. That has probably been done about half the time. Our cardiologists also have had relatively good success in a small number of patients in placing ventricular wires through the tricuspid prosthesis after the operation as necessary. If the patient is in the operating room with complete heart block and tricuspid valve replacement, our first choice is to put at least some epicardial wires on and have that as an option.