Valve Replacement with the Starr-Edwards and Hancock Prostheses:

Comparative Analysis of Late Morbidity and Mortality

PHILIP E. OYER, M.D., EDWARD B. STINSON, M.D., RANDALL B. GRIEPP, M.D., NORMAN E. SHUMWAY, M.D.

From the Department of Cardiovascular Surgery, Stanford University School of Medicine, Stanford, California

Although the Starr-Edwards caged-ball valve remains a standard of comparison for more recently introduced prostheses, a substantial incidence of thromboembolic and hemorrhagic complications prompted our evaluation of the Hancock glutaraldehyde-fixed porcine xenograft. We have compared the results of 435 aortic valve replacements using the Starr-Edwards valve (SE-AVR), 515 mitral valve replacements (SE-MVR), and 121 double-valve replacements (SE-AVR-MVR) with 251 aortic valve replacements using the xenograft aortic valve (X-AVR), 338 mitral valve replacements (X-MVR), and 88 double-valve replacements (X-AVR-MVR). The Starr-Edwards valves were used during the period 1963 through 1973 and the xenograft valves between 1971 and 1976. No significant differences in patient age, sex, or preoperative hemodynamic data were noted between comparable groups. All patients with Starr-Edwards valves received long-term anticoagulation while anticoagulants were used only for specific indications in patients with xenograft valves. Total follow up was 3944 patient years for the Starr-Edwards patients and 947 patient years for the xenograft patients. Hospital mortality was not significantly different for comparable groups: SE-AVR 6.9% vs. X-AVR 6.4%, SE-MVR 9.7% vs X-MVR 8.6%, and SE-AVR-MVR 7.5% vs. X-AVR-MVR 10.2%. Linearized mortality and morbidity data expressed as percent per patient-year are tabulated below. Pairs which differ significantly ($p < .05$) are italicized.

	SE-AVR	*X-AVR*	*SE-MVR*	*X-MVR*	*SE-AVR-MVR*	*X-AVR-MVR*
Late mortality	*6.3*	*3.4*	*7.9*	*4.5*	7.8	6.2
Thrombo-embolism	*6.0*	*2.6*	*10.9*	*4.1*	6.6	3.1
Hemorrhage	*5.7*	*0.7*	*5.5*	*1.4*	*4.1*	*1.0*
Valve failure	1.8	1.1	2.6	1.7	1.0	3.1
Endocarditis	1.2	1.4	0.4	0.2	0.9	1.0

Our data indicate that valve replacement with the porcine xenograft significantly reduces the incidence of thromboembolic and hemorrhagic complications without off-setting increases in the rates of valve failure or endocarditis. The porcine xenograft therefore results in improved long-term patient survival.

Presented at the Annual Meeting of the American Surgical Association. Boca Raton, Florida, March 23–25, 1977.

Reprint Requests: Philip E. Oyer, M.D., Department of Cardiovascular Surgery, Stanford University Medical Center, Stanford, California 94305.

THE STARR-EDWARDS CAGED BALL value prosthesis has now been utilized widely for longer than 15 years and remains the standard of comparison for prostheses developed more recently. Since its introduction in 1960, various modifications of its original conformation have been made in order to correct deficiencies associated with the original models. Although improvements have been achieved, the Starr-Edwards valve continues to be associated with a substantial incidence of thromboembolic and hemorrhagic complications. For this reason we began to utilize Hancock glutaraldehyde-fixed porcine xenograft valves in the mitral position in 1971. The favorable results in this early series of patients encouraged us subsequently to utilize the xenograft valve for aortic valve replacement as well. This report is intended to update our experience with Hancock bioprostheses and to compare these data with our own experience with the Starr-Edwards Model 1260 aortic and Model 6120 mitral prostheses.[14] For the purposes of this study, we have compared the long-term valve performance of patients receiving Starr-Edwards aortic, mitral, and combined valve replacements with corresponding cohorts receiving Hancock porcine xenograft prostheses. We have analyzed overall patient survival as well as more specific criteria of valve performance including thromboembolism rate, frequency of anticoagulant-associated hemorrhage, and the rate of occurrence of endocarditis. In addition, we have confirmed over an

TABLE 1. *Preoperative Clinical Parameters*

	Aortic Valves		Mitral Valves		Double Valves	
	Starr	Xenograft	Starr	Xenograft	Starr	Xenograft
Number of patients	435	251	515	338	121	88
Mean age	58.5	58.0	54.6	54.2	53.8	56.61
Preop NYHA class (mean)	2.87	2.71	3.11	2.94	3.04	3.01
Postop NYHA class (mean)	1.36	1.28	1.63	1.35	1.33	1.41
Male	319	190	191	134	65	39
Female	116	61	324	204	56	49
RA pressure	4.79	4.49	6.77	6.69	6.66	6.39
PA pressure	23.53	21.38	35.64	33.89	35.03	34.53
LA pressure	15.26	13.36	22.03	21.02	21.89	22.07
LVED pressure	21.49	19.75	12.76	12.77	15.73	15.47
Cardiac index	2.58	2.52	2.15	2.21	2.17	2.07

extended observation period the durability of the glutaraldehyde-fixed xenograft valve.

Patients and Methods

The patients in this study were divided into the six groups shown in Table 1. Starr-Edwards Model 1260 aortic valves were utilized in 435 patients between April 1968 and September 1974, while 251 patients received Hancock Model 242 aortic xenograft prostheses between August 1971 and April 1976. Between December 1964 and October 1974, 515 patients received Starr-Edwards Model 6120 mitral prostheses, while 338 patients received Hancock Model 342 mitral xenografts between March 1971 and June 1976. In addition, during corresponding periods, 121 patients underwent Starr-Edwards Model 1260/Model 6120 combined aortic and mitral valve replacement, while 88 patients received combined valvular replacement utilizing xenograft valves.

No significant differences between comparable groups were noted in regard to the patient age, sex, or preoperative hemodynamic values including mean right atrial pressure, mean pulmonary artery pressure, mean left atrial pressure, left ventricular end-diastolic pressure, and cardiac index as shown in Table 1. There was no significant difference in the distribution of preoperative or postoperative New York Heart Association functional classes between comparable groups. The incidence of coronary artery disease was similar between comparable groups; however, aortocoronary bypass grafting was done more frequently in the later xenograft series. Since this additional procedure would be expected to have little impact on the various valve-related events investigated in this study, with the possible exception of overall survival data, we consider it justified to include these patients with combined procedures in the analysis.

The operative techniques for aortic and mitral valve replacement have undergone only minor modification during the course of this study. A median sternotomy was utilized in all cases. The mitral valve was approached through a left atrial incision immediately posterior to the interatrial groove. The aortic valve was exposed through a low oblique aortotomy. Effort was made to debride fully the valvular annulus of all calcium present to ensure secure valve seating and allow placement of the largest appropriate valve size. Myocardial protection during periods of aortic crossclamping was assured by continuous topical irrigation of the heart and intermittant lavage of the interior of the left ventricle with 0.9% saline cooled to 4°.[7] All valves were fixed into position with interrupted Dacron mat-

TABLE 2. *Postoperative Follow-up Data*

	Aortic Valves		Mitral Valves		Double Valves	
	Starr	Xenograft	Starr	Xenograft	Starr	Xenograft
Number of patients	435	251	515	338	121	88
Duration follow-up (patient-years)	1360	269	2159	581	425	97
Maximum follow-up (years)	7.9	5.0	11	5.5	6.9	3.5
Average follow-up (years)	3.3	1.2	4.3	1.8	3.5	1.1
Range of follow-up (years)	2.5–7.9	0.1–5.0	2.3–11	0.1–5.5	2.7–6.9	0.1–3.5
Current survivors	319	226	295	283	79	73
Lost to follow-up	0.5%	0.0%	0.4%	0.9%	0.0%	0.3%

tress sutures. Total cardiopulmonary bypass times and aortic crossclamp times were similar for comparable patient groups.

Postoperatively all patients with Starr-Edwards valves were treated with warfarin sodium indefinitely. Approximately one-half of the patients undergoing xenograft mitral valve replacement received anticoagulant therapy during the first three months postoperatively, beginning on the day of chest tube removal. Thereafter anticoagulation was tapered and discontinued. The remaining patients undergoing mitral valve replacement with xenografts received no postoperative anticoagulation. Approximately one-fourth of the xenograft aortic valve group received short-term anticoagulant treatment, while the remainder received none. Patients in whom anticoagulation was contraindicated received no postoperative anticoagulation. Those patients who, at operation, were judged to be at high risk for late thromboembolism were placed on anticoagulants indefinitely. This group, for example, included patients who exhibited significant amounts of intracardiac thrombus formation. Approximately 0.4% of all aortic xenograft valve patients, 17% of all mitral xenograft patients, and 1.4% of all double xenograft patients received long-term anticoagulant therapy.

Current methods of patient follow-up have been described previously.[12] All patients or their referring physicians were contacted during a three month interval at which time various clinical parameters were evaluated including all valve related complications. Table 2 summarizes pertinent follow-up information for each of the patient groups. The total duration of follow-up for all patients with Starr-Edwards valves was 3944 patients years, while the total duration of follow-up for patients receiving xenografts was 947 patient years.

Criteria required for a diagnosis of valve failure in this study have been previously delineated.[11] At least one of the following was considered sufficient for the diagnosis of failure: 1) postoperative development of a new murmur suggestive of valvular regurgitation unless proved to be periprosthetic in origin, 2) thrombotic occlusion of the valve or multiple embolic episodes requiring reoperation, 3) infective endocarditis leading to reoperation or death, or 4) confirmed hemodynamic valvular dysfunction (stenosis and/or regurgitation) sufficient to warrant reoperation. All new episodes of focal neurologic defect, either transient or permanent, were considered to be thromboembolic events.

Rates of patient survival, thromboembolic events, and valve failure incidence were expressed both by standard Kaplan-Meier acturial curves and by linearized occurrence rates.[1,5,9] The Gehan test was used to compare the various sets of acturial data, whereas the Fisher test and X_2 analysis were used as appropriate in the evaluation of other variables.[6]

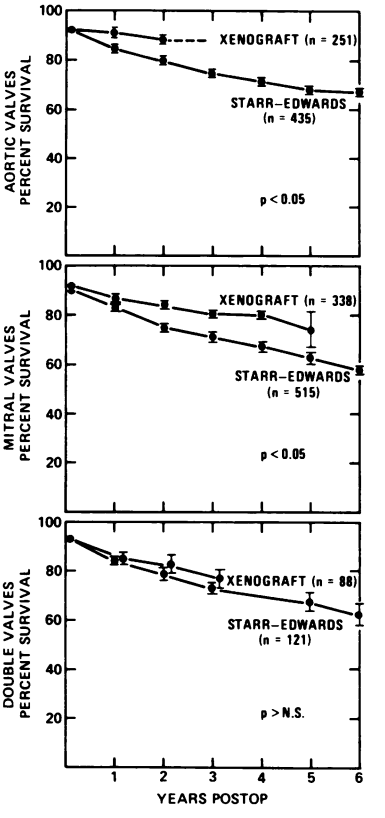

FIG. 1. Actuarial curves depicting overall patient survival, taking into account operative mortality, for each patient group. The brackets at each point on the curve represent the standard error.

Results

Aortic Valve Replacements

Patient survival. The early mortality rate (hospital mortality) for the Starr-Edwards aortic replacement group was 6.9%, while that of the xenograft aortic group was 6.4%. Late mortality in the Starr-Edwards aortic patients expressed as a linearized occurrence rate was 6.3% per patient year while the corresponding mortality rate in the xenograft aortic patients was 3.4% per patient year. These same data expressed acturially are shown in Figure 1; these mortality rates are significantly different at $p < .05$ level. All linearized mortality rates as well as valve-related complication rates reported are summarized in Table 3.

Thromboembolism. The occurrence of thromboembolic events, both fatal and nonfatal, expressed as a linearized occurrence rate for the Starr-Edwards aortic group was 6.0% per patient year while that of the xenograft aortic group was 2.6% per patient year. The linearized rate of *fatal* emboli in the Starr-Edwards group was 0.5% per patient year, while no fatal emboli occurred among patients receiving the xenograft valve. Actuarial curves illustrating the occurrence of thromboembolic events in these two patient groups are

TABLE 3. *Linearized Mortality and Morbidity Rates**

	Aortic Valves		Mitral Valves		Double Valves	
	Starr	Xenograft	Starr	Xenograft	Starr	Xenograft
Late Mortality	*6.3*	*3.4*	*7.9*	*4.5*	7.8	6.2
Thromboembolism						
Overall	*6.0*	2.6†	*10.9*	*4.1*†	6.6	3.1
Fatal	0.5	0.0	*1.0*	*0.0*	1.4	0.0
Hemorrhage						
Overall	*5.7*	*0.7*	*5.5*	*1.4*	*4.1*	*1.0*
Fatal	*0.7*	*0.0*	*0.9*	*0.2*	*0.2*	*0.0*
Valve failure	1.8	1.1	2.6	1.7	1.0	3.1
Endocarditis	1.2	1.4	0.4	0.2	0.9	1.0

* All values expressed as percent/patient-year.
† Value skewed by uneven distribution of events in time.
Significant differences underlined ($p < 0.01$).

shown in Figure 2. Comparison of these data reveals significantly fewer emboli among patients receiving xenograft aortic valves.

Seven thromboembolic events occurred in the xenograft group. Five of these occurred during the first month postoperatively, significantly skewing the linearized rate of 2.6% per patient year noted above. In contrast, those patients with Starr-Edwards valves sustained a continuing *constant* risk of thromboembolic events, as illustrated by the actuarial curve.

Valve Failure. The incidence of valve failure was 1.8% per patient year for the Starr-Edwards aortic group and 1.1% per patient year for the xenograft aortic group. Actuarial curves depicting the incidence of valve failure are shown in Figure 3. The difference between the curves is not significant.

Anticoagulant-related hemorrhage. The occurrence of anticoagulant related hemorrhage was calculated as a linearized rate. Since hemorrhagic events were evenly distributed throughout the postoperative course, linearized calculations are meaningful in this instance. This complication occurred at a rate of 5.7% per patient year in the Starr-Edwards aortic group. In addition, these patients were subject to a 0.7% per year risk of *fatal* hemorrhage. In contrast, patients with xenograft aortic valves sustained a 0.7% per patient year risk of anticoagulant-related hemorrhage. No *fatal* hemorrhage related to anticoagulant therapy has occurred in the xenograft group of patients.

Endocarditis. The occurrence of endocarditis was likewise tabulated as a linear rate. Those patients in the S-E aortic group were subject to a 1.2% per year risk of developing endocarditis, while those in the xenograft group had a 1.4% per year risk. No significance can be attached to the slight difference in these figures. The linear mortality rates as well as the occurrence rates of all the above valve-related complications are presented in Table 3.

Mitral Valve Replacement

Patient survival. Early patient mortality rates (hospital deaths) in both the Starr-Edwards mitral replacement group and in the xenograft replacement group were similar at 8.6% and 9.7% respectively. The late mortality rate among Starr-Edwards patients amounted to 7.9% per patient year, while that of the xenograft patient group was 4.5% per patient year. Actuarial curves expressing these data are shown in Figure 1. Gehan comparison revealed a significantly better late survival rate of patients receiving xenograft valves than those receiving the Starr-Edwards valve in the mitral positon ($p < .05$).

Thromboembolism. The overall occurrence rate of thromboembolic events among the Starr-Edwards mitral replacement patients was 10.9% per patient year, while that of the xenograft mitral group was 4.1% per patient year. The rate of occurrence of *fatal* emboli in the Starr-Edwards group was 1.0% per patient year. No patients in the xenograft mitral replacement group sustained a fatal embolus.

Actuarially determined rates of occurrence of thromboembolic events in these two mitral replacement groups are shown in Figure 2. There was a significantly lesser incidence of thromboemboli in the xenograft patients relative to that sustained by Starr-Edwards patients ($p < .001$).

As noted in the xenograft aortic replacement group, a clustering of embolic events occurred during the

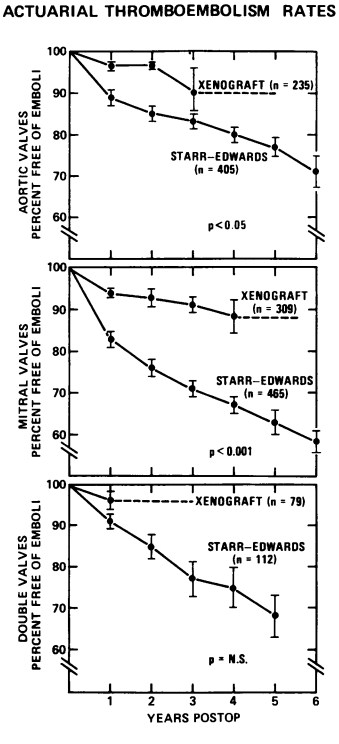

FIG. 2. Actuarial curves depicting thromboembolism rates among patients with xenograft valves and patients with Starr-Edwards valves. The brackets at each point represent standard error.

early postoperative period. A total of 24 thromboemboli occurred among all patients receiving mitral xenograft valves. Of these 24 events, 16 or 67% of the total number occurred within the first three months after operation, while the remaining eight episodes were distributed randomly over the ensuing years of follow-up.

Valve failure. The incidence of valve failure among the Starr-Edwards mitral group was 2.6% per patient year, whereas that occurring among the xenograft mitral patients was 1.7% per patient year. Figure 3 depicts the actuarial occurrence rate of valve failure within each group. The difference between the two mitral replacement groups is not significant.

Anticoagulant related hemorrhage. The rate of occurrence of anticoagulant related hemorrhage was 5.5% per patient year among those patients receiving Starr-Edwards mitral valve replacement. The corresponding rate in those with xenograft valves was 1.4% per patient year. *Fatal* hemorrhagic events occurred at a rate of 0.9% per patient year in the Starr-Edwards groups, while similar episodes occurred at a rate of 0.2% per patient year among the xenograft patients.

Endocarditis. Those patients having Starr-Edwards mitral valves exhibited a 0.4% per patient year rate of postoperative endocarditis, while those with xenograft valves showed a rate of 0.2% per patient year. The slightly lower occurrence in the xenograft group is not significantly different.

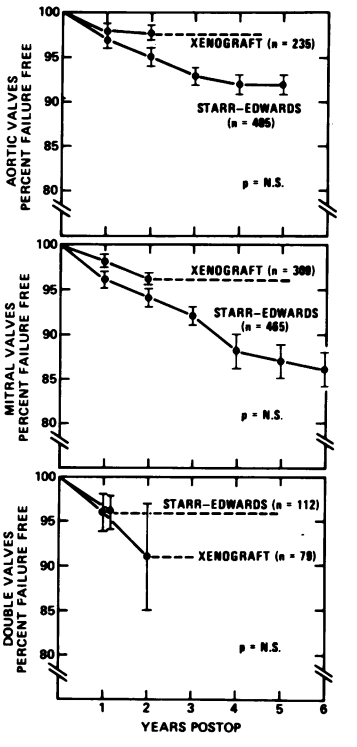

FIG. 3. Actuarial curves depicting valve failure rates in patients with xenograft valves and patients with Starr-Edwards valves. The standard error of each point is represented by the brackets.

Double Valve Replacement

Patient survival. Hospital mortality rates were similar for patients who received either Starr-Edwards or Hancock xenograft combined aortic and mitral replacement (7.5% and 10.2% respectively). The linearized late mortality among the Starr-Edwards patients was 7.8% per patient year and among the xenograft patients amounted to 6.2% per patient year. The actuarially calculated late survival rates in these two patient groups are depicted in Figure 1. The difference between the two groups is not significant.

Thromboembolism. The linearized frequency of thromboembolic events occurring in patients with Starr-Edwards valves was 6.6% per patient year while that among xenograft patients was 3.1% per patient year. Again, however, the linearized rate calculated for the xenograft patients is markedly skewed since all three embolic events that occurred in this group were limited to the first postoperative month. The maximum follow-up for this group was three and one-half years. The 28 thromboembolic events that occurred among the Starr-Edwards patients, however, were evenly distributed throughout the entire 6.9 year follow-up period for that group. This is illustrated by the actuarial curves depicted in Figure 2. As more patients enter the xenograft double valve group, the difference between the respective thromboembolic rates may be expected to achieve statistical significance.

Valve failure. The frequency of valve failure among those patients who received combined Starr-Edwards aortic and mitral valve replacement was 1.0% per patient year compared to 3.1% per patient year for those receiving xenograft valves. These values are not significantly different. Actuarial curves expressing this data appear in Figure 3.

Anticoagulant related hemorrhage. Anticoagulant related hemorrhage occurred as a rate of 4.1% per patient year among Starr-Edwards patients and 1.0% per patient year among xenograft patients. These rates do not differ significantly. No fatal hemorrhages occurred among xenograft patients, while that group receiving Starr-Edwards valves exhibited a 0.2% per patient year fatality rate due to anticoagulant therapy.

Endocarditis. Bacterial endocarditis occurred at similar rates in both Starr-Edwards and xenograft patient groups, 0.9% per patient year and 1.0% per patient year, respectively.

Discussion

This analysis extends our previously reported experience with the Hancock xenograft valve, and confirms in several aspects the superiority of the xenograft bioprosthesis in comparison to the Starr-Edwards

models we have previously employed. Although we recognize that more recently introduced permutations of Starr-Edwards valves are reported to have significantly fewer associated complications, the older noncloth-covered models 1260 and 6120 valves have continued in widespread use now for nearly ten years. They justifiably, therefore, remain the standard by which newer valves are judged. For this reason we feel that this study of comparative data from a single institution is useful.

Actuarially determined overall survival rates of patients receiving xenograft valves in both aortic and mitral positions remain significantly better than those of similar patients with Starr-Edwards noncloth-covered valves in place. Although preoperative patient-associated variables are primary determinants of late mortality,[12] and thus comparison of inter-institutional data may be misleading when preoperative patient status is not statistically similar, it is noteworthy that the actuarially calculated survival rate of 88% (excluding operative mortality) at five years among our xenograft mitral patients compares favorably with the 81% five-year survival rate reported by Bonchek and Starr for the more recently introduced cloth-covered composite-seat prothesis.[2] Similarly, the projected three year actuarial survival rate for patients receiving aortic xenograft valves is 95% (excluding operative deaths) while that reported by Bonchek for composite-seat cloth-covered Starr-Edwards aortic valves was 85% at three years.[2] These comparative data imply no significant difference between xenograft valves and the later model Starr-Edwards cloth-covered prostheses as determined by survival data.

Although the incidence of thromboembolism has been markedly reduced since the original prosthetic valves were introduced, no valve currently available has completely eliminated its occurrence. Our data reveal a significantly lower thromboembolic rate in those patients having xenograft valves, as compared to patients with Starr-Edwards noncloth-covered valves. Furthermore, we have observed no fatal thromboembolic events in any patient who has received a xenograft aortic or mitral valve in 947 patient years of observation. The importance of anticoagulant therapy during the initial two to three months postoperatively was not fully appreciated early in our experience with xenograft valves. It is reasonable to assume that our recently adopted policy of prescribing short-term anticoaguiation for all patients receiving xenograft valves should eliminate some of these early embolic events.

A further point regarding thromboembolic rates reported by various institutions is worthy of mention. In order to compare interinstitutional rates meaningfully, explicit definition of the criteria required for the diagnosis of a thromboembolic event must be clearly provided. Starr has recently stated that his current reports of thromboembolic rates associated with Starr-Edwards prostheses do not always include those cerebral ischemic events which are transient in nature.[13] Since at our institution all cerebral ischemic events, regardless of duration, are considered to be thromboembolic in origin, unless proved otherwise, direct comparison of the embolic rates reported herein with those reported by other institutions must take into consideration these differences of definition.

It is now well recognized that previous experience with tissue valves, both at Stanford and elsewhere, was often initially quite good, with adequate hemodynamic performance and significantly lower thromboembolism rates even in the absence of anticoagulant therapy. However, within a short time, most often between one and two years postoperatively, an unacceptably high rate of valve failure became evident.[4] The most common failure mode was tissue degeneration with consequent valvular regurgitation. Occasionally, valve tissue disruption occurred suddenly with catastrophic result, as in the case of formalin-fixed tissue valve prostheses.[3] The evolution of the present Hancock xenograft valve, which was designed to alleviate the problem of limited tissue durabilty and yet retain the athrombogenicity of earlier tissue valves, has been summarized previously.[4,14]

Analysis of our follow-up data suggests that this goal has been achieved, at least within the constraints of our observation period which has now been extended to more than five and one-half years. During this time only three proved primary tissue failures have occurred in 667 patients. All occurred in xenografts in the mitral position. One consisted of an idiopathic perforation of a single leaflet. The remaining two tissue failures consisted of acquired bioprosthetic valvular stenoses. In one case dense fibrin deposits within the valve sinuses impeded opening, while in the other instance, exhuberant fibrous tissue ingrowth over the xenograft leaflets resulted in poor leaflet motion and significant hemodynamic obstruction. There has been no instance of sudden, catastrophic tissue disruption in our experience with glutaraldehyde-fixed valves.

Any consideration of the relative merits of various prosthetic valves presently available must include the requirement for anticoagulant therapy. Because of the significant frequency of anticoagulant-associated hemorrhage, both fatal and non-fatal, observed in our patients who have received Starr-Edwards prostheses and similar frequencies of such events reported by

others,[8] we consider the requirement for indefinite anticoagulation to be a considerable disadvantage. These figures do not take into account, of course, the substantial amount of time and inconvenience required for the long-term maintenance of proper anticoagulation control.

In our experience there have been no known instances of hemolysis in patients receiving xenograft valves in the absence of periprosthetic leak. We have noted this complication in approximately three percent of our patients receiving Starr-Edwards prostheses, although in no case has it been necessary to replace a noncloth-covered valve for this problem alone. The rate of occurrence of hemolysis associated with fully cloth-covered Starr-Edwards valves is not well defined; however, a finite incidence of low-grade ongoing hemolysis does exit in patients receiving these valves.[2] The long-term implications of this process are not known at present.

Endocarditis is a complication to which all patients with prosthetic valves remain susceptible indefinitely. Our data suggest that the rate at which endocarditis occurs in patients with xenograft valves does not differ significantly from the occurrence rate in those patients with Starr-Edwards valves, in either the aortic or mitral position. We have observed a total of six cases of endocarditis involving xenograft valves. Five of these cases involved aortic prostheses and one a mitral prosthesis. One of the aortic cases and the single case of mitral xenograft endocarditis underwent re-replacement of the infected prosthesis during the acute phase of endocarditis. Both patients died postoperatively. The remaining four patients recovered with antibiotic therapy alone; thus, bacterial invasion of the tissue valve does not necessarily lead to valve leaflet disruption.

Summary

We conclude on the basis of comparative data generated in our own institution that the Hancock xenograft valve compares quite favorably to the Starr-Edwards prostheses in regard to durability and susceptibility to endocarditis,and that it appears superior when thromboembolic rates, overall survival rates, and morbidity and mortality due to anticoagulant-associated hemorrhage are considered. The complications of thromboembolism and anticoagulation associated with Starr-Edwards valves have contributed importantly to the lower survival rates we have observed in such patients. The Hancock xenograft bioprosthesis appears, therefore, to be the valve of choice.

References

1. Anderson, R. P., Bonchek, L. I., Grunkemeier, G. L., et al.: The Analysis and Presentation of Surgical Results by Actuarial Methods. J. Surg. Res., 16:224, 1974.
2. Bonchek, L. and Starr, A.: Ball Valve Prostheses: Current Appraisal of Late Results. Am. J. Cardiol. 35:843, 1975.
3. Buch, W. S., Kosek, J. C. and Angell, W. W.: Deterioration of Formalin-Treated Aortic Valve Heterografts. J. Thorac. Cardiovasc. Surg., 60:763, 1970.
4. Carpentier, A. and Dubost, C.: From Xenograft to Bioprosthesis: Evolution of Concepts and Techniques of Valvular Xenografts. *In* Biological Tissue in Heart Valve Replacement, Ionescu, M. I., Ross, D. N., Wooler, G. H., (eds.) Butterworth and Co., Ltd., London, 1972; p. 515.
5. Cutler, S. J. and Ederer, F.: Maximum Utilization of Life Table Method in Analyzing Survival. J. Chronic Dis., 8:699, 1968.
6. Gehan, E. A.: Generalized Wilcoxon Test for Comparing Arbitrary Singly-Censored Samples. Biometrika, 52:203, 1965.
7. Griepp, R. B., Stinson, E. B. and Shumway, N. E.: Profound Local Hypothermia for Myocardial Protection During Open Heart Surgery. J. Thorac. Cardiovasc. Surg., 66:731, 1973.
8. Isom, O. W., Williams, C. D., Falk, E. A., et al.: Evaluation of Anticoagulant Therapy in Cloth-Covered Prosthetic Valves. Circulation, *47, 48* (Suppl. III): 48, 1973.
9. Kaplan, E. L. and Meier, P.: Non-Parametric Estimation from Incomplete Observations. J. Am. Stat. Assoc., 53:457, 1958.
10. Reis, R. L., Hancock, W. D. Yarbrough, J. W., et al.: The Flexible Stent: A New Concept in the Fabrication of Tissue Heart Valve Prostheses. J. Thorac. Cardiovasc. Surg., 62:683, 1971.
11. Salomon, N. W., Stinson, E. B., Griepp, R. B. and Shumway, N. E.: Mitral Valve Replacement: Long Term Evaluation of Prosthesis-Related Morbidity and Mortality. Circulation, in press.
12. Salomon, N. W., Stinson, E. B., Griepp, R. B. and Shumway, N. E.: Patient-Related Risk Factors as Predicators of Results Following Isolated Mitral Valve Replacement. Ann. Thorac. Surg., in press.
13. Starr, A.: Symposium on Cardiac Valve Replacement. Am. College of Cardiology, Las Vegas, Nevada. March, 1977.
14. Stinson, E. B., Griepp, R. B., Oyer, P. E. and Shumway, N. E.: Long-Term Experience with Porcine Aortic Valve Xenografts. J. Thorac. Cardiovasc. Surg., 73(1):54, 1977.

Discussion

DR. ALBERT STARR (Portland, Oregon): These two presentations demonstrate the current choice that we now have in valvular prosthetic substitutes. On the one hand, we have bioprostheses capable of acting hemodynamically in a satisfactory manner and with a low incidence of thromboembolism, without the need for long-term anticoagulants; on the other hand, the durable type of mechanical prostheses.

Certainly, our current practice is to be certain that both of these types of approaches are available in the operating room, so that a prosthesis can be chosen for a patient, depending upon the patient's requirements and his ability to take anticoagulation.

I'd like to focus some attention on the problem of cloth wear. In Dr. Spencer and Dr. Isom's series of patients they noted this in only a small percentage of patients; but in those patients who were subject to reoperation for any reason, cloth tear is frequently noted. In our own experience, in about three out of four patients who