Fifteen-Year Experience with 1678 Hancock Porcine Bioprosthetic Heart Valve Replacements

LAWRENCE H. COHN, M.D., JOHN J. COLLINS, JR., M.D., VERDI J. DISESA, M.D., GREGORY S. COUPER, M.D., PAMELA S. PEIGH, M.D., WENDY KOWALKER, B.S., and ELIZABETH ALLRED, M.S.

The Hancock porcine valve was the first commercially available biologic heart valve and has been in continuous use at the Brigham and Women's Hospital since January 1972. Through December 1987 we implanted 1678 valves in 1533 patients (885 male; 648 female; 17 to 95 years of age, with a mean of 60 years). There were 825 aortic valve replacements (AVR), 562 isolated mitral valve replacements (MVR), and 146 aortic mitral replacements (DVR). Ninety-four per cent of the patients were functional class III or IV. Associated coronary bypass was done in 25% of patients. Four per cent of patients were lost to follow up during a 1- to 16-year period with a mean of 6 years. Morbidity and mortality rates on a actuarial basis were calculated 10 and 15 years after operation for AVR, MVR, and DVR. The data indicates that the probability of reoperation for structural valve failure is quite reasonable as of 10 years, but from 10 to 15 years the numbers sharply fall off so that the probable effective life of the valve is 10 years. However in the elderly age group (equal to or greater than 70 years of age) the incidence of structural valve degeneration is markedly diminished, making this an ideal valve substitute for the elderly. It is also an ideal valve substitute in any patient who has a contraindication to long-term anticoagulation because of current medical or surgical problems.

From the Department of Surgery, Harvard Medical School/ Brigham and Women's Hospital, Division of Cardiac Surgery, Boston, Massachusetts

THE HANCOCK PORCINE BIOPROSTHETIC VALVE, stabilized with Glutaraldehyde (City Chemical, New York, NY), was the first commercially available quality-controlled, biologically derived heart valve used extensively in humans for the treatment of acquired and congenital heart disease (Fig. 1). This device, inserted first in 1970, derived from experimental work by Carpentier et al.,[1] who had shown that porcine valve tissue could be treated with Glutaraldhyde, and demonstrated experimentally and clinically its durability. This work derived from earlier work by Duran and Gunning,[2] who showed that porcine valves could be modeled into usable devices for heart valve replacement. The porcine valve was seen as an alternative to the use of human valve tissue (allografts), which has always been in short supply.[3,4]

In January 1972 the Brigham and Women's Hospital (then the Peter Bent Brigham Hospital) began clinical implantation of the Hancock porcine valve. Since then there have been numerous clinical reports about this valve,[5–7] the most extensively studied heart valve other than the Starr-Edwards ball valve, the first commercially available and quality-controlled heart valve replacement device of any kind.[8]

This report details our experience with 1678 Hancock porcine heart valves inserted in 1533 consecutive patients operated on from January 1972 through December 1987. This long follow-up series allows for conclusions about indications for insertion of this device and its place in the treatment of valvular heart disease.

Materials and Methods

Beginning in January 1972 and concluding on December 31, 1987, this series includes every patient who had a Hancock stabilized Glutaraldehyde porcine bioprosthetic valve inserted during this time period. All demographic data presented is as of the date of implantation of the valve and includes age, sex, functional class, predominant valve hemodynamic lesion, presence or absence of other cardiac conditions, and other cardiac operations (Table 1).

Data retrieval, entry, and analysis were carried out between October and December 1988, providing a follow-up of 1 to 16 years, with a mean of 6 years. Patients not physically seen in the previous 3 months were brought in

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Correspondence and reprint requests to: Lawrence H. Cohn, M.D., Chief, Division of Cardiac Surgery, Brigham and Women's Hospital, 75 Francis Street, Boston, MA 02181.

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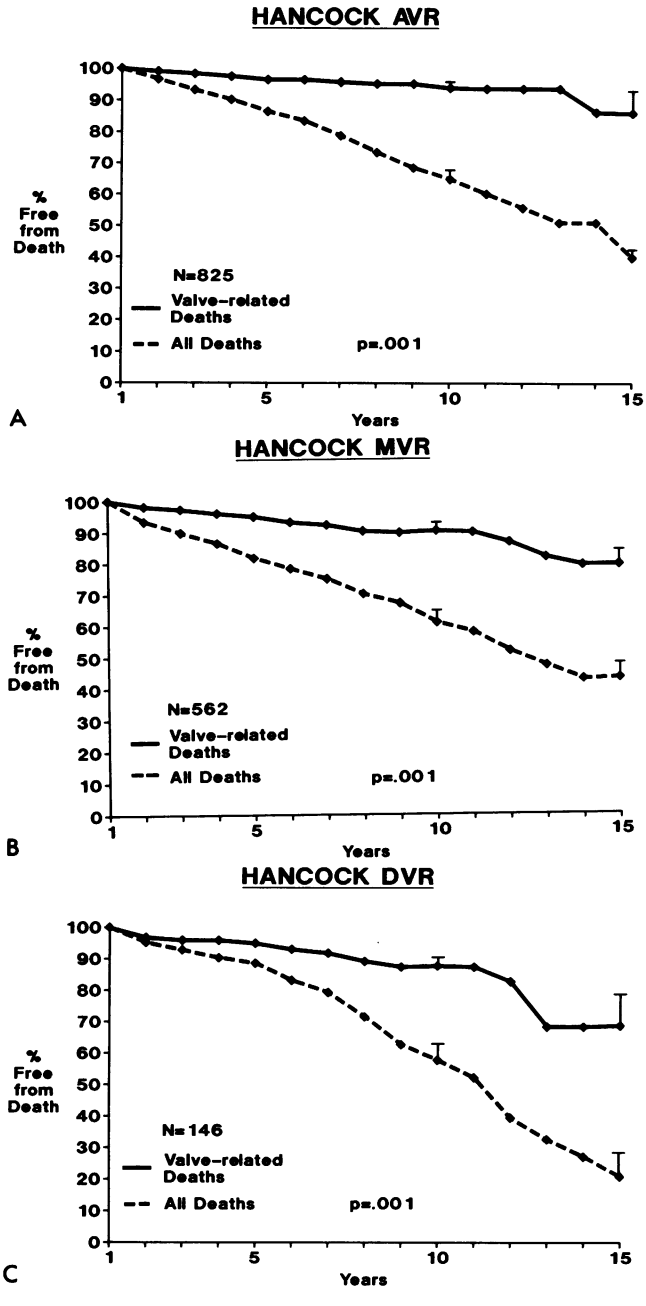


FIGS. 1A–C. The actuarial calculation of patient survival in those patients who survive the hospitalization, separated into valve-related deaths and compared to all valve-related deaths. The p value is 0.001 for all three figures. (A) is AVR, (B) is MVR, and (C) is double valve replacement.

for examination or contacted by telephone, or their doctors were contacted during this period for a detailed questionnaire about their clinical status. Data were entered and maintained on a VAX 11/780 computer (Digital Equipment Corporation, Maynard, MA) running the UNIX operating system using the GDVS interactive data entry system. The database consists of patients who have undergone valve replacement since January 1, 1972. For this analysis the subset of patients who underwent replacement with a Hancock valve between January 1, 1972 and December 31, 1987 was extracted and was 53% of the total valve cohort. The data were moved to a Dell System 310 personal computer (Dell Computer Corporation, Austin, TX) and analysis files with end points, time-to-end points, and appropriate strata were created using SAS (Statistical Analysis System, SAS Institute, Cary, NC). Actuarial Kaplan-Meier survival analyses were performed with the SAS Lifetest procedure and differences in survival among strata were examined with the Wilcoxon and log rank tests. Ten- and 15-year survival estimates and standard errors are reported.

Results

Demographics

Between January 1972 and December 1987, 1678 Hancock valves were implanted in 1533 patients. There were 885 male and 648 female patients ranging in age from 17 to 95 years, with a mean of 60 years. Eight hundred twenty-five patients underwent isolated aortic valve replacement, 562 patients underwent isolated mitral valve replacement, and 146 patients underwent simultaneous aortic and mitral valve replacement. Table 1 also includes the percentage of patients who had concomitant coronary artery bypass grafting. Of the aortic valve group, 28% had coronary bypass; 22% of the mitral valve group had bypass; and 11% of the double valve group underwent bypass. In Table 1 is also shown a percentage of patients with stenotic as opposed to regurgitant lesions and the percentage of patients with preoperative atrial fibrillation or heart block *versus* those in sinus rhythm.

Operative Mortality

The variables that were evaluated in this analysis include overall operative mortality based on the position of

TABLE 1. *Demographics*

Demographic Variable	AVR	MVR	DVR
Number of patients	825	562	146
Sex: M/F	611/214	201/361	72/74
Age range, mean	16–95, 61	17–86, 59	19–79, 59
% of FC 3/4	92	98	94
% of CABG	28	22	11
% of AS/AR	69/31	—	55/50
% of MS/MR	0	50/68	50/54
% preop. AF/HB	10	58	50
% preop. NSR	90	42	50

AVR, Aortic valve replacement; MVR, mitral valve replacement; DVR, double valve replacement; M/F, male/female; F/C, functional class; AS, aortic stenosis; AR, aortic regurgitation; MS, mitral stenosis; MR, mitral regurgitation; AF/HB, atrial fibrillation/heart block; NSR, normal sinus rhythm.

TABLE 2. *Operative Mortality*

Factor	AVR	MVR	DVR
Overall	36/825 (4%)	49/562 (9%)	14/146 (10%)
% with CABG	10%	16%	0
% ≤ 1978	8	7	6
% > 1978	3 p = 0.01	9 NS	11 NS

AVR, Aortic valve replacement; MVR, mitral valve replacement; DVR, double valve replacement.

valve implanted, the time of implantation (1972 to 1977 *vs.* 1978 to 1988) with or without coronary bypass, and the age group of the patient related to mortality, and valve-related morbidity (Table 2).

For the entire group the overall operative mortality rate was 6%, (99 of 1533 patients). The overall mortality rates were 4% for aortic valve replacement, 9% for mitral valve replacement, and 10% for double valve replacement. Of 372 patients who had single or multiple valve replacements in conjunction with one or more coronary bypass grafts, there were 26 operative deaths in this group, or an overall mortality rate of 7%. Only in the MVR group was the difference in mortality rate significant between those with no CABG (76%) as those with CABG (12.7%); 7.6% (p = 0.04%) *vs.* 12.7% (p = 0.04).

Operative mortality was analyzed before and after we began to use cold hyperkalemic cardioplegia in 1978. The operative mortality rate was 8% after AVR before the use of cardioplegia, and 3% following its use (p = 0.01). There was no difference in the operative mortality rate after MVR or DVR before or after the routine use of cardioplegia, except in mitral valves with or without CABG, reported previously.[9]

Operative deaths naturally varied significantly with age. The percentages of operative mortality in the three groups was 2% under 40 years, 4% between 40 and 70 years, and 7% for patients older than 70 years. For mitral valve replacement it was 2% for patients less than 40 years, 9% for patients between 40 and 70 years, and 10% for patients older than 70 years.

The major cause of operative death in this experience was due to cardiac failure manifested by acute low cardiac output, acute myocardial ischemia, or congestive heart failure, the three most common causes of death accounting for over 70% of the postoperative deaths.

Late Mortality

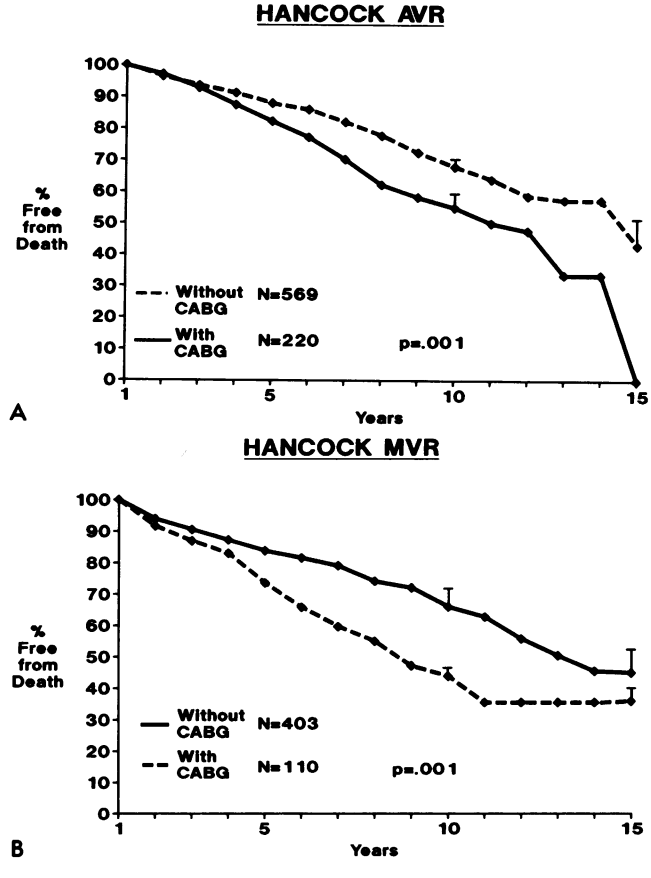
Late deaths again resulted primarily from myocardial factors contributing to congestive failure, severe arrhythmias, and acute myocardial infarction. There were 459 late deaths of which 21% (96 of 459) were noncardiac. Any patient whose cause of death was unknown was considered to be cardiac- and valve-related in origin. The incidence of late death was highest in the group undergoing concomitant coronary bypass. One hundred thirty-six of 459 (or 30%) late postoperative deaths were in patients who had concomitant coronary bypass.

These survival relationships are shown in Figures 1 and 2, acturial fashion after AVR, MVR, and DVR. These curves consider all deaths and valve-related deaths (Fig. 1) and survival with or without coronary bypass (Fig. 2).

As anticipated, the percentage of late deaths in the three age groups (less than 40, 40 to 70, and more than 70 years) correlated directly with increasing age. However there was no significant difference between valve-related deaths by age with the percentages after AVR, 5%, 3%, and 5%, respectively, and after MVR, 4%, 8%, and 8%, respectively.

Postoperative Functional Class

Postoperative functional class was evaluated in all survivors. After AVR 96% of surviving patients were functional classes 1 and 2, while 4% were classes 3 or 4 (Table 3). In this latter group, persistent class 3 or 4 was usually



FIGS. 2A and B. The actuarial calculation of patient survival divided according to whether a concomitant coronary bypass graft was done for coronary artery disease. The probability of survival in the two groups in both the (A) AVR, and (B) MVR is significant to the 0.001 level.

TABLE 3. *Late Follow-up*

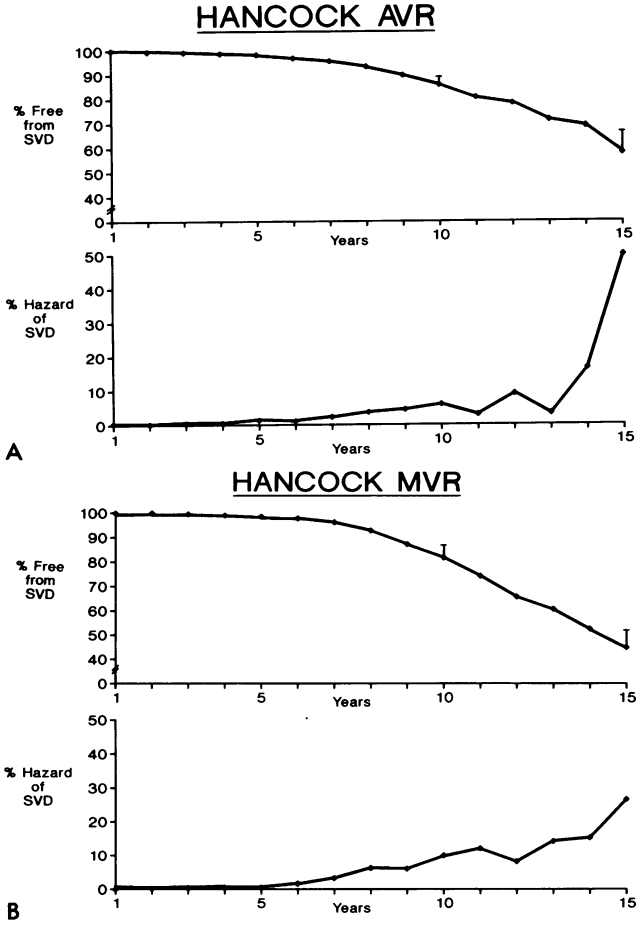
Factor	AVR	MVR	DVR
% LTFU	4	5	6
% FC 1/2	96	94	100
% FC 3/4	4	6	0
% postop. AF/HB	19	37	36
NSR	81	63	64

LTFU, lost to follow-up; FC, functional class.

related to longstanding chronic congestive heart failure that did not improve after valve replacement. In patients who were evaluated for postoperative cardiac rhythm, there was a similar percentage after AVR, but after MVR and DVR there was a shift toward a higher incidence of sinus rhythm in the survivors.

Structural Valve Degeneration (SVD)

Structural valve degeneration is defined as any change in valve function resulting from an intrinsic abnormality causing stenosis or regurgitation.[10] In the case of the Hancock porcine valve, this usually means calcification, leaflet tear, disruption, or stenosis by stent "creep."[11] It excludes infected or thrombosed valves and was determined by reoperation, autopsy, or clinical investigation. Sixty-eight patients after AVR (9%), 73 patients after MVR (14%) and 14 patients after DVR (11%) had SVD.



FIGS. 3A and B. This shows the probability of freedom from structural valve degeneration on the top half of the figures and the per cent hazard of SVD for each year of follow-up in both AVR (Fig. 4A) and MVR (Fig. 4b).

TABLE 4. *Probability of Freedom (n = 825)*

Factor	10 Years	15 Years
All death	65 ± 2	40 ± 6
VR death	94 ± 3	86 ± 5
Reoperation	87 ± 2	57 ± 8
SVD	82 ± 2	58 ± 8
TE	86 ± 2	68 ± 8
AcH	98 ± 1	97 ± 1
Thrombosis	99 ± 1	99 ± 1
Hemolysis	99.7 ± 1	99.7 ± 1
IVD	94 ± 1	93 ± 2
PVL	95 ± 1	87 ± 4
All M&M	60 ± 3	49 ± 4
All valve M&M	81 ± 2	54 ± 9

VR, valve related; SVD, structural valve degeneration; TE, thromboembolism; AcH, anticoagulant hemorrhage; IVD, infection valve degeneration; PVL, perivalvar leak.

Figure 3(AVR and MVR) shows the probability of freedom from SVD and the percentage of hazard risk of SVD per year. These calculations indicate that the probability of SVD increases with time, as does the hazard of this complication. The probability of freedom from SVD is noted in Tables 4 to 6 of morbid events associated with each valve. At 10 years this was 82±2 for AVR, 75±3 for MVR, and 89±4% for DVR.

Results of SVD are also correlated with the age of the patient. It has been well documented by a number of previous series that there is a higher rate of SVD in the patients under age 40 years who receive a porcine valve,[12] especially teenagers. Conversely it has been shown that

TABLE 5. *MVR: Probability of Freedom (n = 562)*

Factor	10 Years	15 Years
Death	61 ± 3	43 ± 4
VR death	90 ± 2	79 ± 4
Reoperation	79 ± 3	41 ± 7
SVD	75 ± 3	45 ± 7
TE	81 ± 2	70 ± 6
ACH	96 ± 1	94 ± 2
Thrombosis	100	100
Hemolysis	99 ± 1	99 ± 1
IVD	93 ± 2	91 ± 2
PVL	95 ± 2	91 ± 3
All M&M	52 ± 2	28 ± 5
All valve M&M	78 ± 3	66 ± 5

VR, value related; SVD, structural valve degeneration; TE, thromboembolism; ACH, anticoagulant hemorrhage; IVD, infection valve degeneration; PVL, perivalvar leak.

TABLE 6. *DVR: Probability of Freedom (n = 146)*

Factor	10 Years	15 Years
Death	58 ± 5	21 ± 8
VR death	88 ± 3	69 ± 10
Reoperation.	78 ± 5	57 ± 8
SVD	89 ± 4	69 ± 7
TE	91 ± 4	88 ± 5
ACH	94 ± 3	89 ± 6
Thrombosis	99 ± 1	99 ± 1
Hemolysis	100	100
IVD	84 ± 5	76 ± 9
PVL	97 ± 3	97 ± 3
All M&M	62 ± 6	42 ± 7
All valve M&M	80 ± 5	57 ± 11

VR, valve related; SVD, structural valve degeneration; TE, thromboembolism; ACH, anticoagulant hemorrhage; IVD, infection valve degeneration; PVL, perivalvar leak.

SVD is significantly less in the elderly patients who receive a porcine valve.[13] In our series we analyzed all three valve positions for SVD, for ages less than 40 years, 41 to 69 years, and more than 70 years (Fig. 4, Table 7). At 15 years the probability of freedom from SVD is 55% in patients aged less than 40 years, 82% in patients in the 40-to-70 year range, and 90% in patients older than 70 years (Table 7). At 15 years the probability of freedom from SVD in patients less than 40 years for aortic valve replacement is only 35%, *versus* 58% for patients who are 41 to 69 years old, and 90% for the patients who are 70 years or older.

Thromboemboli

Thromboemboli are noninfectious emboli and include all neurologic events noted after operation including

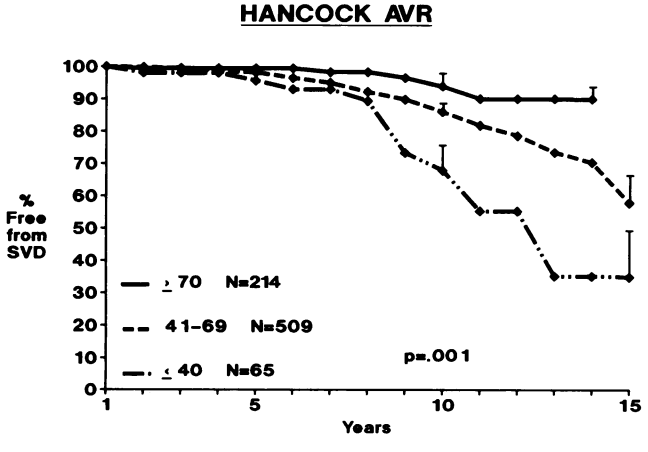


FIG. 4. This figure shows the probability of freedom from structural valve degeneration separated according to the age of the patient at implantation of the aortic valve. The figure shows statistically significant differences between those patients who are 70 years or older compared to those 41 to 69 years and to those who are 40 years or younger. The p value is 0.001.

TABLE 7. *Age* Versus *Incidence of SVD (% Freedom from SVD at 10 Years)*

	≤40	41–69	≥70	p value
AVR	68 ± 9	86 ± 2	94 ± 3	(p = 0.001)
MVR	68 ± 10	84 ± 3	84 ± 10	(p = NS)
DVR	89 ± 10	87 ± 5	100	(p = NS)
All	69 ± 7	85 ± 2	92 ± 3	(p = 0.001)

AVR, aortic valve replacement; MVR, mitral valve replacement; DVR, double valve replacement.

transient neurologic findings. As noted in the Tables 4 to 6 and Figure 5 for AVR, MVR, DVR, the risk of thromboembolism varies for each valve type. Thromboembolism is a relatively low risk factor after AVR, notwithstanding that more than 90% of the patients with aortic valve replacement are off chronic anticoagulation therapy. About 50% of patient after MVR or DVR are on anticoagulation therapy.

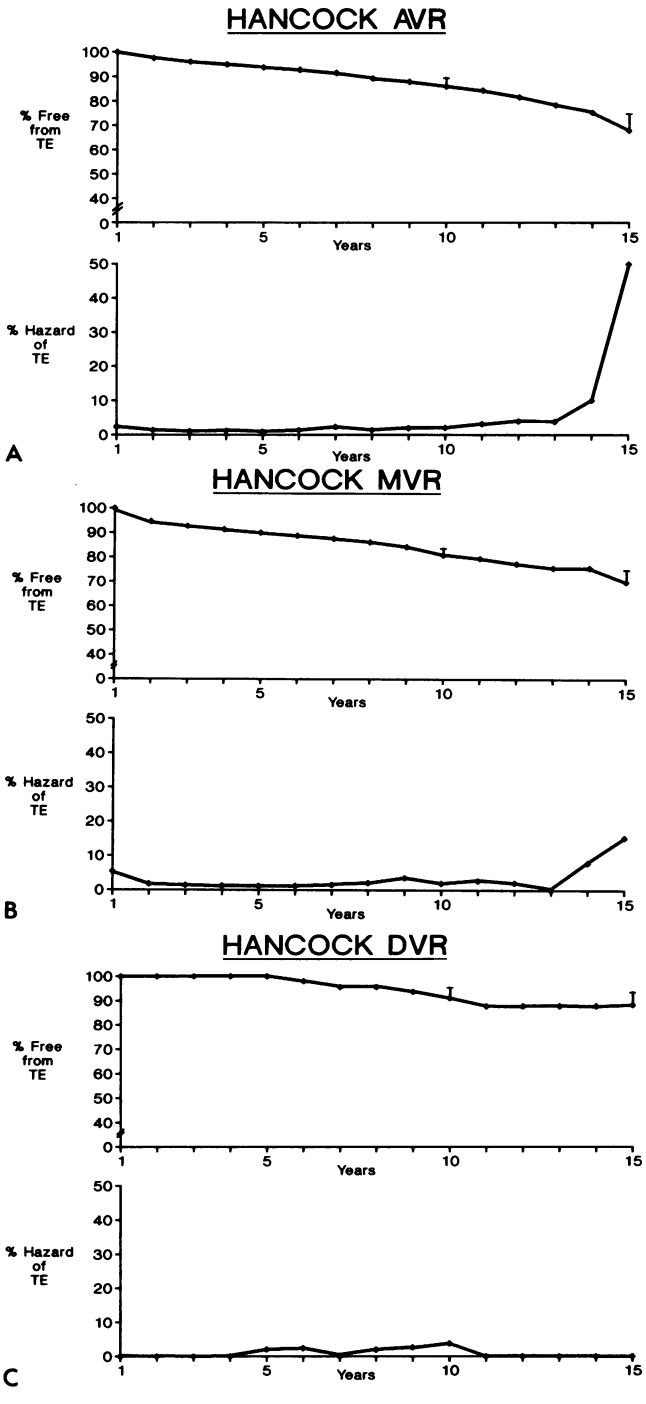
Other Morbidity

Tables 4 to 6 note the risk of thrombosis, hemolysis, infectious valve degeneration, perivalvar leak, and reoperation for each valve. Figure 6 shows the probability of freedom from reoperation at 10 and 15 years, increasing significantly with time. Overall 194 patients had a secondary replacement of a porcine valve with 79 AVR (10%), 91 MVR (16%), and 24 DVR (17%), with 14 mortalities (7%). Finally Figure 7 shows the freedom from all valve-related morbidity.

Discussion

The Hancock valve has proved to be a very important valve replacement device in the treatment of hundreds of thousands of patients with valvular heart disease. At this time after more than 18 years of continuous clinical use, we may state with reasonable certainty its benefits, disadvantages, limitations, and indications for its use. The operative mortality data correlate well with patient variables, especially coronary artery disease, time of operation, and method of myocardial protection, factors that have been previously emphasized.[14,15]

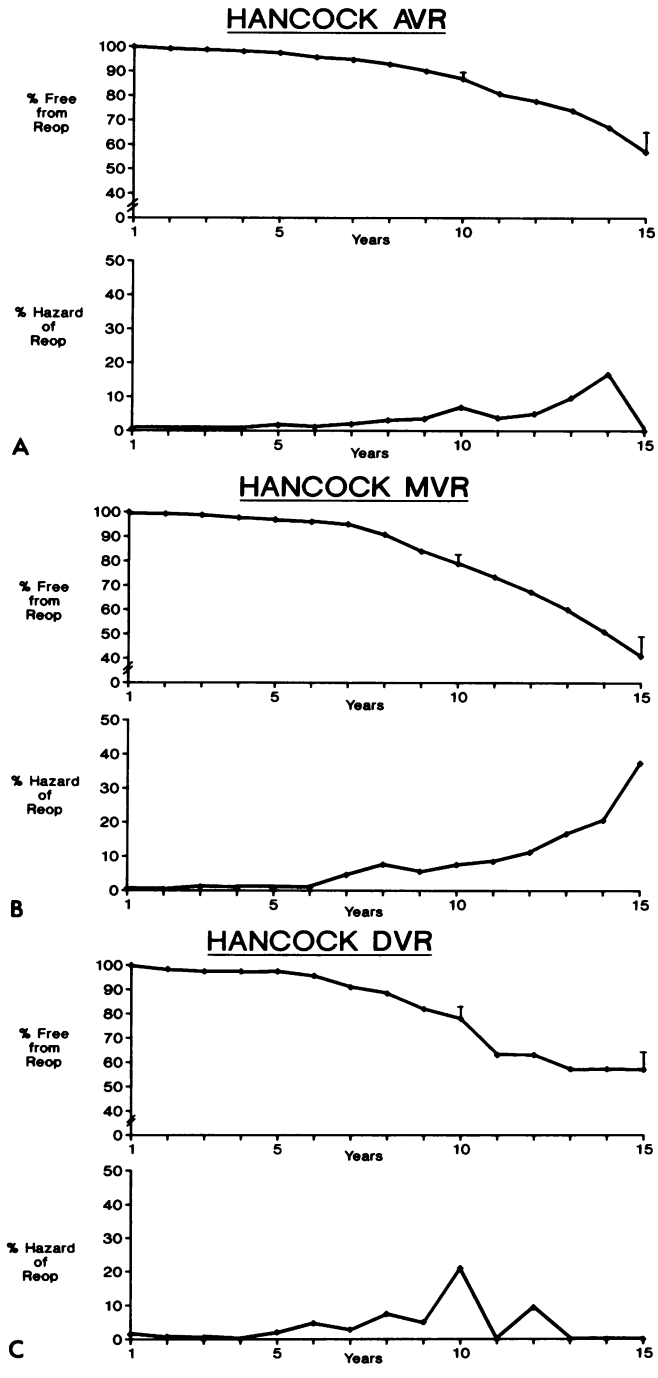
The long-term data presented here correlates with data from other centers.[16–18] Structural valve degeneration is the main risk factor of this valve, as it is with all biologic valves beginning 8 to 10 years after operation. The Glutaraldhyde treatment has markedly improved longevity of porcine valves over formalin-treated valves, but it now appears that in the general adult population in whom it is used the probability of its failure begins to accelerate very markedly at 10 years and rapidly increases at 15 years. When one examines SVD by age categories, it degenerates faster in patients younger than 40 years, but the



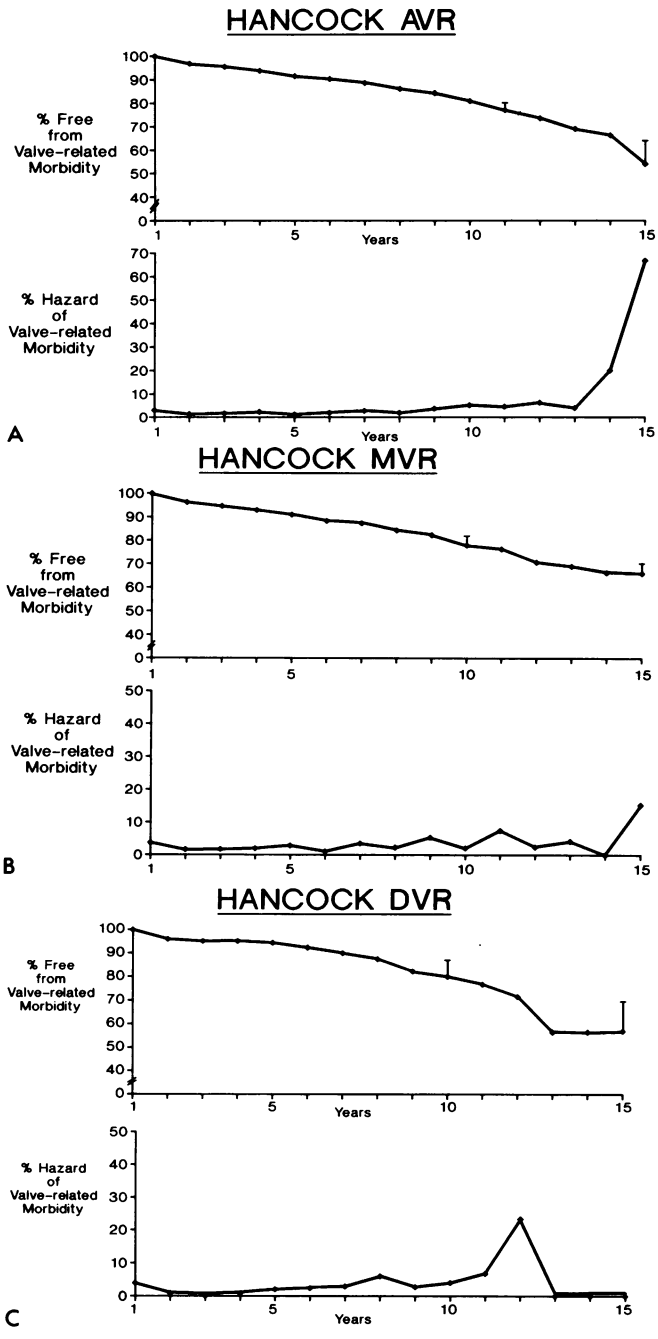
FIGS. 5A–C. Shows the probability of freedom from thromboembolism and the per cent hazard of thromboembolism after (A) AVR, (B) MVR, and (C) DVR.

elderly age group does quite well with this valve and the incidence of SVD is quite low.[7,13]

One of the questions that comes up in analysis of SVD with biologic valves, particularly in long-term data, is whether the incidence of this problem is totally accurate. Despite operative, autopsy, and clinical examinations it is probably not totally accurate as a result of a variety of factors, but certain assumptions have been made in calculations of the data here and may neutralize inaccuracies. For example in the calculation of survival, all deaths that are not known to have a specific cause are considered to be valve related as determined by the joint committee on valve guidelines.[10] Obviously patients who have died and have not been autopsied may have some valvular degen-



FIGS. 6A–C. Shows the probability of freedom from reoperation after (A) AVR, (B) MVR, and (C) DVR.



FIGS. 7A–C. Shows the probability of freedom from all valve-related morbidity in hospital survivors after (A) AVR, (B) MVR, and (C) DVR.

eration and a few will be unknown to us. Most importantly, as Grunkemeir has pointed out (personal communication), patients in our series and other American series may die before the valve degenerates so that valve survival from an acturial standpoint may be higher than it actually would be if all patients survived until their valve degenerated.

The figures presented probably represent the best-case situation given these limitations. The numbers described here are similar to that of Foster et al.[18] (75% freedom at 10 years—MVR). Miller et al.[19] indicate 80% freedom from SVD at 10 years for AVR, and Magilligan[20] reports 10-year freedom from SVD after AVR of 75% and MVR of 65%. The relatively high rate of dysfunction in the younger age groups obviously mitigates its use, except in selected instances in which there are concerns about anticoagulation with prosthetic valves. As follow-up increases in an individual patient, follow-up visits with the patient should be more frequent so as not to miss onset of valve deterioration. We have shown in unpublished observations that if patients are neglected, they may present with "acute" SVD and require urgent operation about 10% of the time.

Thromboembolism in the patient with sinus rhythm is low after use of the Hancock porcine valve. The difficulty with obtaining completely accurate rhythm differentiation did not allow us to separate these patients out in terms of thromboemboli,[14] but in previous experiences AVR and MVR[15] data indicate that this is the case and it is logical to assume that a patient in chronic atrial fibrillation will have a higher incidence of thromboemboli despite anticoagulation. Our current indications for use of the Hancock valve suggests that if a patient is in chronic atrial fibrillation and should require chronic anticoagulation, exposing the patient to the increased risk of structural valve degeneration is not warranted and the patient should have a prosthestic mechanical heart valve. Thromboembolism is probably also under reported because of silent emboli and difficulty obtaining detailed neurologic examinations.[21,22]

The incidence of other comorbidity such as infection, hemolysis, and thrombosis are low with this valve. When calculating all valve-related morbidity and mortality, this valve compares favorably to other reports of prosthestic and bioprosthestic valves.

What are the indications for use of the Hancock porcine valve as we now enter the 1990s? The porcine bioprosthetic valve should be used primarily in the elderly age group. The incidence of structural valve degeneration is significantly reduced in this patient group. The obviation of the use of anticoagulation is also a distinct advantage in the elderly age group because they obviously will have more concomitant medical and surgical problems. However in any patient, regardless of age, in whom long-term anticoagulation is relatively or absolutely contraindicated, it is preferential to use a biologic valve such as the Hancock porcine valve. For example a woman in the child-bearing years who requires valve surgery would be a perfect candidate for this valve inasmuch as Coumadin (DuPont Laboratories, Wilmington, DE) is teratogenic and thus contraindicated and a mechanical valve requires anticoagulation. A patient would have to undergo a second operation in 10 years but has the ability to have children in

that interim period with a considerably reduced maternal and fetal risk.

This valve has been shown to have an effective life of about 10 years. However the probability of valve failure is clearly dependent on age and type of use. It has a low incidence of thromboemboli, particularly in the aortic position without anticoagulation. The Hancock porcine valve should be the valve of choice in the elderly age group or in any patient in whom there may be present or future contraindications to anticoagulation from serious medical or surgical problems.

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Discussion

Dr. D. Craig Miller (Stanford, California): Today you have heard some new terms, and I rise to compliment Larry and his colleagues for applying most of the new valve-reporting definitions and guidelines recently promulgated by the AATS and STS (as published in *The Journal of Thoracic and Cardiovascular Surgery, Annals of Thoracic Surgery,* and *European Journal of Thoracic and Cardiovascular Surgery*). Finally after 3 or 4 years of work on behalf of many individuals, we have a "universal language" to discuss valve complications. The term he used today, structural valve degeneration, or SVD, is all-inclusive with regard to the prosthesis *per se* and has replaced older parlance. Another important aspect of this new scheme is that all sudden, unexpected late deaths are included as valve-related deaths unless proved otherwise. I was interested to see that this did not drop your valve-related death rate curves very much, Larry. You have also conformed to the guidelines by exceeding the minimum 95% complete follow-up threshold; we all know how hard that is when you are talking about 16 years of follow-up.

Indeed we do need to know the clinical performance characteristics of these old "Model T," first generation porcine valves at 15 years. Previously reported series from Detroit and Padua have primarily concentrated on younger patients and many with endocarditis. Many of us have not been certain that these results are truly applicable to the patients you and I see today. My first question is: Will the new porcine valves implanted today (from all manufacturers) perform better in the long term as expected? That is, will the subtle improvements in tissue procurement, preservation, stent design, and quality control procedures actually translate into increased clinical durability?

My second question concerns your belief that this is a "10-year valve" (at least in most patients) and your disappointment at these 15-year clinical results. I would like to propose an alternative reinterpretation of your data that indicates that this valve is actually a reasonable choice for most patients older than 40 years, as manifested by your AVR valve-related death rate of 14% at 15 years (21% for the mitrals). For comparison Dr. Albert Starr just gave me his updated long-term actuarial estimates for the silastic ball valve. After 15 years, the valve-related death rate was 9% for the aortics and 22% (after 20 years) for the mitrals. These figures may actually be somewhat similar to your data. Furthermore 5% of the AVR silastic ball valve patients had required reoperation, as had 25% of the mitral patients; 44% of the AVR and 33% of the MVR patients had had an anticoagulant-related bleed; and 16% and 55%, respectively, had sustained a thromboembolic complication.

I was pleased to see that you alluded to Gary Grunkemeier's and Albert Starr's application of the Weibull equation, which is an engineering method used to examine questions of failure analysis as a function of time. The key point here is that 15 years may be more than several potential lifetimes for many of our patients. I believe all of us should consider this when we discuss long-term valve durability.

I also have some questions pertaining to your age information. (1) I was interested to note that there was no difference in valve-related death rates according to age; perhaps you could elaborate on this intriguing observation. (2) In terms of what specific threshold age below which the durability of a porcine valve will not meet the patient's or the surgeons's expectations, all of us have the same problem in that nobody has 100 or so patients operated on at each year of age across the spectrum; this sampling problem leads to skewed patient populations, so we may never