Long-Term Results of the Bioprosthesis in Elderly Patients: Impact on Quality of Life

Dennis F. Pupello, MD, Luis N. Bessone, MD, Enrique Lopez, MD, John C. Brock, MD, Mark J. Alkire, MD, Edward G. Izzo, MD, Guillermo Sanabria, MD, David P. Sims, MD, and George Ebra, EdD

St. Joseph Heart Institute, Tampa, Florida

Background. **A wealth of data exists on acceptable mortality and morbidity for valve operations in older patients, yet information documenting quality of life is lacking.**

Methods. **From October 1974 to May 1998, 2,075 patients aged 65 years and older underwent valve replacement using a porcine bioprosthesis. There were 1,126 men (54.3%) and 949 women (45.7%) with a mean age of 73.9 years (range 65 to 104 years).**

Results. **The elective hospital mortality was 8.5% (158 patients), and urgent/emergent/salvage mortality was 25.8% (54 patients). Follow-up was completed for 1,863 patients (98.2%) and extended from 1 month to 23.0 years (mean 60.8 months) with a cumulative follow-up of 9,442.1 patient-years. At follow-up, surviving patients (n = 849) completed the Short Form-36 Quality of Life Survey. Results showed patients had a more favorable quality of life compared with control subjects matched for age and sex. Functional improvement was significant with 96.3% in New York Heart Association functional class I or II at follow-up. There were 74 valves that failed from all causes (33 aortic and 41 mitral valves). Actuarial freedom from valve failure at 9 years was 94.4% ± 1.1% and at 18 years was 83.7% ± 2.4%.**

Conclusions. **Valve replacement in older patients provides excellent functional improvement, reduces late cardiac events, and enhances quality of life.**

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The number of elderly individuals continues to grow at an unprecedented rate. People are living longer and expecting to enjoy an active lifestyle throughout their lifespan. This expectation has resulted in an increasing number of older patients requiring valve replacement operations to maintain maximum functioning and independence.

Valve replacement operations in this group can be performed with acceptable mortality and morbidity [1, 2]. Moreover, there is a wealth of knowledge and long-term clinical follow-up to support the continued use of the porcine bioprosthesis as the valve of choice for elderly patients [3, 4]. However, controversy continues to exist regarding the allocation of a considerable proportion of resources on a growing minority of traditionally high-risk elderly patients and whether this allocation of funds represents a cost-effective strategy in the delivery of health care [5].

This report documents an improved quality of life in elderly patients after valve replacement with a porcine bioprosthesis. Our study further demonstrates the excellent long-term clinical performance of this prosthesis in older patients.

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Address reprint requests to Dr Pupello, PO Box 152169, Tampa, FL 33684-2169; e-mail: dpupello@pupello.net.

Patients and Methods

Patient Population

The population consisted of 2,075 consecutive patients 65 years of age or older who underwent valve replacement with a porcine bioprosthesis between October 1974 and May 1998. There were 1,126 men (54.3%) and 949 women (45.7%). Patients ranged in age from 65 to 104 years (mean 73.9 ± 5.6 years). The clinical characteristics of the patient population are summarized in Table 1.

Operative Data

A total of 2,210 porcine bioprostheses were implanted in this cohort of patients. There were 1,402 implanted in the aortic position, 789 (35.7%) in the mitral position, 17 (0.8%) in the tricuspid position, and 2 (0.1%) in the pulmonic position. There were 100 patients (4.8%) who underwent multiple valve replacements. In addition to valve replacement, 1,004 patients (48.4%) underwent concomitant coronary artery bypass grafting. The distribution of porcine bioprosthesis valves by manufacturer was as follows: 64 Medtronic Intact valves (2.9%) (Medtronic, Minneapolis, MN), 1,428 Carpentier-Edwards valves (64.6%) (Baxter Healthcare, Santa Ana, CA), 448 Hancock valves (20.3%) (Medtronic), and 270 Hancock valves with modified orifices (12.2%) (Medtronic). The mean cardiopulmonary bypass time was 103.2 ± 39.2 minutes (range 34 to 334 minutes). The mean aortic cross-clamping time was 69.4 ± 31.4 minutes (range 15 to 533 minutes).

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Table 1. Patient Profile, October 1974 to May 1998

Variable	n (%)
No. of patients	2,075 (100.0)
Cardiovascular risk factors	
Congestive heart failure	1,262 (60.8)
Angina	949 (45.7)
Arrhythmia	695 (33.5)
Cardiomegaly	372 (17.9)
Prior MI	331 (16.0)
Endocarditis	65 (3.1)
Cardiogenic shock	39 (1.9)
Coronary risk factors	
Family history of CAD	495 (23.9)
Smoking	633 (30.5)
Hypertension	1,196 (57.6)
Diabetes mellitus	330 (15.9)
Hyperlipidemia	240 (11.6)
Pulmonary disease	334 (16.1)
Renal dysfunction (creatinine > 2.0 mg/dL)	91 (4.4)
NYHA class	
II	83 (4.0)
III	1,085 (52.3)
IV	907 (43.7)
Angiography	
Three-vessel disease	476 (22.9)
Two-vessel disease	302 (14.6)
Single-vessel disease	260 (12.5)
Left main disease (> 50% stenosis)	86 (4.1)
Ejection fraction	
> 0.50	1,297 (62.5)
0.30 to 0.50	341 (16.4)
< 0.30	80 (3.8)
Reoperation	356 (17.2)

CAD = coronary artery disease; MI = myocardial infarction; NYHA = New York Heart Association.

Data Sources

Perioperative data were obtained by review of the patient's hospital record, catheterization reports, cine angiograms, and echocardiography. Follow-up data included activity level, current symptoms, diagnostic tests, occurrence of late cardiac events, and medications being taken. Moreover, quality of life assessment was conducted with the Short Form-36 Quality of Life Survey (SF-36) developed by Ware and coworkers [6].

Statistical Analysis

Data are presented as frequency distributions and simple percentages. Values of continuous variables are expressed as mean ± standard deviation. Analysis of discrete variables was accomplished by χ^2, the continuity-adjusted χ^2 analysis, or a two-tailed Fisher's exact test. Comparison of means for continuous variables was conducted by an unpaired Student's *t* test.

Data underwent quantitative and qualitative analyses using the biostatistical capabilities of the Patient Analysis and Tracking Systems (Axis Clinical Software, Inc, Portland, OR) and the Number Cruncher Statistical Systems (Kaysville, UT). A significant difference between measurements was defined as p less than or equal to 0.05.

Results

Hospital Morbidity

Hospital complications included reoperation for bleeding in 170 patients (8.2%), low cardiac output in 249 patients (12.0%), pulmonary insufficiency in 247 patients (11.9%), atrial fibrillation in 384 patients (18.5%), renal insufficiency in 147 patients (7.l1%), stroke in 68 patients (3.3%), and myocardial infarction in 37 patients (1.8%). Approximately one-half of the patients (51.6%; n = 1,070) experienced no hospital complication. The average postoperative length of stay was 12.5 ± 11.5 days.

Hospital Mortality

The elective mortality rate was 8.5% (158 of 1,866), the urgent mortality rate was 15.4% (14 of 91), and the emergent/salvage mortality rate was 33.9% (40 of 118). A significant difference was noted for elective versus urgent ($p < 0.0396$), elective versus emergent/salvage ($p < 0.0001$), and urgent versus emergent/salvage ($p < 0.0032$). The mortality rate for first operation was 9.3% (160 of 1,719) and for reoperation was 14.6% (52 of 356, $p = 0.0314$). The overall hospital mortality rate for the series was 10.2% (212 of 2,075). The hospital mortality rate was significantly higher in women than in men (12.3% versus 8.4%; $p < 0.0045$).

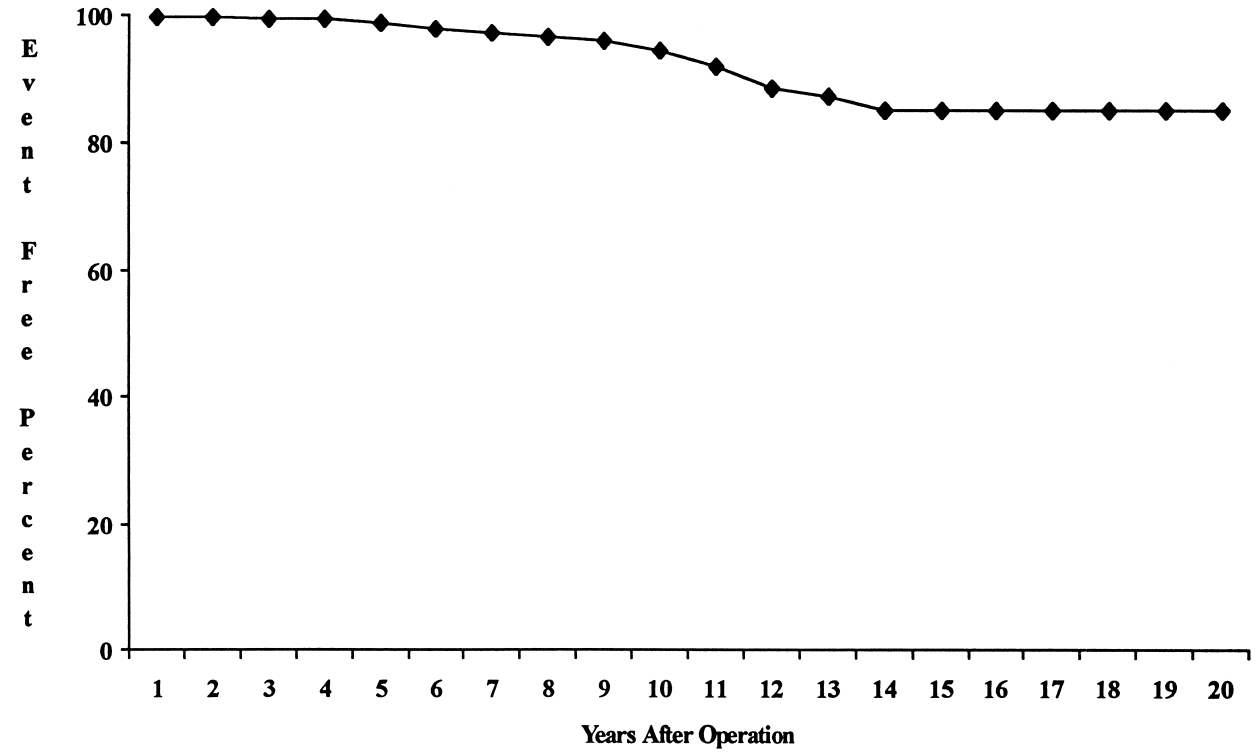
Long-Term Follow-up

Follow-up data were collected for 1,863 patients (98.2%) discharged from the hospital. The follow-up ranged from 1 month to 23.0 years (mean 60.8 months), with a cumulative follow-up of 9,442.1 patient years. The linearized late mortality rate was 9.5% ± 0.31% per patient-year (893 events).

At the completion of the current follow-up, 924 (49.6%) of the hospital survivors were alive. Thirty-four patients (1.8%) were lost to follow-up. Many of the current survivors were clinically and functionally improved with an enhanced quality of life, with 96.3% in New York Heart Association (NYHA) functional class I or II. The linearized occurrence rate and number of late cardiac events in survivors were as follows: nonfatal myocardial infarction, 0.12% ± 0.03% per patient-year (11 events); stroke, 0.21% ± 0.05% per patient-year (20 events); and reoperation for valve replacement 0.07% ± 0.02% per patient-year (7 events).

Analysis of Valve Failure

There were 1,863 hospital survivors in the present series with 1,981 valves at risk at discharge. A total of 74 valves failed from all causes during the follow-up period, resulting in an overall linearized failure rate of 0.78% ± 0.09% per patient-year. There were 33 valve failures in the aortic site with a linearized rate of 0.50% ± 0.07% and 41 in the mitral site with a linearized rate of 1.24% ± 0.11% (Fig 1).



Valves @ Risk	1956	1604	1346	1141	967	819	688	564	459	356	268	211	152	109	72	43	27	19	16	14
Event Free %	100	100	100	99	99	98	97	97	96	94	92	88	87	85	85	85	85	85	85	85
Standard Error	0.1	0.2	0.2	0.2	0.3	0.5	0.6	0.7	0.8	1.0	1.4	1.8	2.1	2.4	2.4	2.4	2.4	2.4	2.4	2.4

Fig 1. Actuarial freedom from valve structural deterioration in patients 65 years of age and older with a porcine bioprosthesis.

The proportionate contribution of various modes of valve failure differed according to position. The incidence of valve failure from all causes was more prevalent in the mitral (55.4%) than the aortic site (44.6%). The most common failure reason was structural deterioration in both the aortic and mitral sites, accounting for most failures (n = 57; 77.0%). Freedom from valve-related morbidity from all causes at 9 and 18 years, by sex, age group, valve site, and surgical category is summarized in Table 2.

Quality of Life Assessment

At follow-up quality of life assessment was conducted for all survivors (n = 849) willing and capable of completing the SF-36. Table 3 gives the means and standard deviations for each of the eight health scales as well as physical and mental health summary scales for male and female patients with porcine bioprosthesis and age-adjusted norms.

In the male cohort, porcine bioprosthesis patients scored significantly better than the age-adjusted norm group in bodily pain ($p = 0.001$), general health ($p = 0.001$), role-emotional ($p = 0.001$), and mental health ($p = 0.001$). In the female cohort, porcine bioprosthesis patients scored significantly higher than the age-adjusted norm group on bodily pain ($p = 0.001$), general health ($p = 0.001$), and social functioning ($p = 0.003$).

Male porcine bioprosthesis patients scored significantly higher in physical health summary ($p = 0.001$) than the male age-adjusted norm group. Similar findings were noted when female patients were compared ($p = 0.012$). No significant difference was found in the mental health summary scores when male and female porcine bioprosthesis patients were compared with age-adjusted norms. These findings indicate that in physical health, porcine bioprosthesis patients in the study achieved an enhanced level of functioning when compared with age-adjusted norms. Further, their mental health summary scores showed that they are functioning at least at the level of age-adjusted norms.

Comment

The evolution of the surgical treatment of valvular heart disease in the elderly has achieved remarkable progress with improvements in hospital morbidity and mortality rates and enhanced long-term clinical outcomes. In to-

Table 2. Actuarial Freedom From Valve Failure From All Causes in Patients 65 Years of Age and Over With Porcine Bioprostheses

Variable	9 Years[a]	18 Years[a]	*p*
Total series	94.4% ± 0.9% (n = 453)	83.7% ± 2.4% (n = 19)	...
Sex			
Male	95.5% ± 1.0% (n = 239)	82.5% ± 3.6% (n = 8)	NS
Female	93.0% ± 1.4% (n = 214)	84.9% ± 3.2% (n = 11)	
Age group			
65–74 years	93.5% ± 1.1% (n = 344)	81.0% ± 2.9% (n = 18)	0.0001
75+ years	96.9% ± 1.0% (n = 109)	96.9 ± 1.0% (n = 1)	
Valve site			
Aortic	97.5% ± 0.9% (n = 169)	89.4% ± 3.5% (n = 12)	0.0001
Mitral	83.1% ± 3.6% (n = 75)	72.3% ± 5.8% (n = 2)	
Surgical category			
Isolated VR	92.9% ± 1.3% (n = 280)	82.1% ± 3.1% (n = 14)	0.0386
VR + CABG	96.8% ± 0.9% (n = 74)	87.0% ± 3.5% (n = 5)	

[a] Numbers in parentheses are valves at risk.

CABG = coronary artery bypass grafting; NS = not significant; VR = valve replacement.

day's health care environment, greater attention is being focused on the patient's quality of life and sense of well being after valve replacement [7, 8].

Quality of life is a multidimensional construct. More specifically, the terms "quality of life" and "health-related well being" refer to the patient's physical, psychological, and social domains of health [9]. The patient's subjective perceptions and expectations of these concepts translate into an objective assessment of his or her actual quality of life. Standardized questionnaires have demonstrated reliability, validity, responsiveness, and sensitivity to various cohorts of patients. A structured health status assessment provides the clinician with a useful adjunct to assess clinical status and evaluate treatment outcomes [10]. Objective quantification of the impact of valve replacement on the elderly patient's daily life in a formal and standardized manner can be used to discern what prosthetic devices can be associated with favorable patient outcomes, including an enhanced quality of life.

This study confirms previous findings that age is clearly a determinant of long-term valve durability and that porcine bioprosthetic dysfunction, as a result of structural deterioration in the elderly patient, is a rare event [4, 11]. There were 1,941 valves at risk in the present study, of which 57 (2.9%) failed as a result of structural deterioration, generating a linearized failure rate of 0.6% ± 0.08% per patient-year. Consequently, the risk associated with reoperation is low and in most instances, the porcine bioprosthesis will generally outlive the elderly patient. In our experience, the underlying mechanism of valve failure in most patients was commissural disruption or tear, rather than calcification/stenosis as has been often found in younger patients.

An advantage of the porcine bioprosthesis in this age group is the freedom from anticoagulation therapy. Approximately two-thirds (67.7%) of the patients in this study did not require long-term oral anticoagulation therapy. Long-term anticoagulant therapy requires a major commitment on the part of the patient in terms of time and financial resources [12]. Freedom from the risks of anticoagulant-related hemorrhage and a lifetime commitment to Coumadin and blood testing, and elimination of related costs, are distinct advantages of the bioprosthesis.

This study further demonstrates that treatment of symptomatic elderly patients who undergo valve re-

Table 3. SF-36 Quality of Life Age- and Sex-Adjusted Mean Scores for Patients With Bioprostheses at Follow-up

	Male			Female		
Scale score	Study group (n = 468)	Age-adjusted norm (n = 293)	*p*	Study group (n = 376)	Age-adjusted norm (n = 413)	*p*
Physical functioning	69.2 ± 26.4	65.8 ± 28.3	NS	59.4 ± 27.0	61.9 ± 28.9	NS
Role-physical	65.1 ± 41.2	59.7 ± 42.5	NS	58.1 ± 45.6	56.4 ± 42.5	NS
Bodily pain	81.4 ± 24.7	68.8 ± 25.4	0.001	76.5 ± 26.4	63.4 ± 27.1	0.001
General health	68.0 ± 23.4	58.6 ± 22.1	0.001	66.7 ± 22.6	61.6 ± 22.1	0.001
Vitality (energy/fatigue)	57.6 ± 24.4	57.8 ± 22.6	NS	53.4 ± 24.3	55.5 ± 23.5	NS
Social functioning	86.1 ± 24.4	79.7 ± 26.0	0.001	82.3 ± 25.9	77.0 ± 27.7	0.003
Role-emotional	76.2 ± 37.8	66.7 ± 34.5	0.001	70.0 ± 40.7	73.4 ± 39.7	NS
Mental health	79.4 ± 18.2	77.4 ± 17.4	0.001	76.0 ± 20.0	74.7 ± 19.9	NS
Physical health summary	45.5 ± 10.8	42.0 ± 11.4	0.001	42.8 ± 10.9	41.0 ± 11.5	0.012
Mental health summary	52.4 ± 10.0	52.5 ± 9.8	NS	51.2 ± 10.7	51.4 ± 10.5	NS

Data are presented as mean ± standard deviation.

NS = not significant; SF-36 = Short Form-36 Quality of Life Survey.

placement can be managed with acceptable hospital mortality and morbidity rates. Considering that this study spans 24 years, that patients had a mean age of 73.9 years at operation, and that nearly one-half (48.4%) had concomitant coronary bypass grafting, the elective mortality rate of 8.5% compares favorably with other large studies involving similar patient populations [13, 14]. Clearly, emergency or salvage operations in this cohort of patients carry a high mortality. One-third (33.9%) of the patients in this category sustained a hospital death.

Although there is a wealth of data documenting event-free survival after valve replacement in the elderly, little has been written concerning the patient's perceived quality of life after the operation. In the present study, male and female patients scored significantly higher in physical health summary than the age-adjusted norm group. No significant differences were found in the mental health summary scores when comparing porcine bioprosthesis recipients with the age-adjusted norms. These data suggest a strong relationship between NYHA and the patient's perceived functional status. Preoperatively, most patients (96.1%) were NYHA class III or IV and postoperatively, most (96.3%) were class I or II.

Until recently, the patient's quality of life has been assessed by the cardiac surgeon, without the benefit of any validated or standardized evaluation instrument. Traditionally, cardiac surgeons have looked to survival and the occurrence of late events as end points in assessing clinical outcomes. Today, the focus is on optimizing the patient's quality of life. Only by looking beyond mortality and morbidity rates and objectively documenting the patient's quality of life is it possible to justify expanding the indications for valve replacement operation.

The surgical treatment of valvular heart disease in the elderly can be accomplished with low hospital mortality and morbidity rates without excluding high-risk patients. It represents a cost-effective treatment strategy for a growing segment of the population. The SF-36 can provide increased sensitivity in assessing the outcomes of treatment alternatives in older patients requiring heart valve replacement. Moreover, the SF-36 demonstrates that valvular operation in elderly patients is successful in improving not only clinical but functional outcomes as well. Patients in the present study experienced few late cardiac events, excellent functional improvement, enhanced quality of life, and superior long-term valve durability.

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