

Is the St. Jude Medical Mechanical Valve an Appropriate Choice for Elderly Patients?: A Long-Term Retrospective Study Measuring Quality of Life

Kevin D. Accola, Meredith L. Scott, S. David Spector, Paul A. Thompson, George J. Palmer, Mark E. Sand, Jorge E. Suarez-Cavalier, George Ebra

Florida Hospital Cardiovascular Institute, Cardiovascular Surgeons, P.A., Orlando, Florida, USA

Background and aim of the study: The selection of a suitable valve substitute in patients requiring valvular heart surgery is an important element in the preoperative decision-making process between cardiologist, surgeon, and patient. Controversy persists regarding the use of mechanical valves in the elderly. With the population living longer, reoperative risk becomes of paramount importance. Quality of life (QOL) considerations are often as important to the patient as longevity. The influence of mechanical valve replacement on QOL in elderly patients has not been well documented.

Methods: Between June 1981 and December 1999, a total of 1,125 consecutive patients aged ≥ 65 years (582 men, 543 women; mean age 71.4 ± 4.9 years) underwent valve replacement with at least one St. Jude Medical (SJM) mechanical valve. Preoperatively, 138 patients (12.3%) were in NYHA class II, 775 (68.9%) in class III, and 212 (18.8%) in class IV. In 535 patients (47.6%), coronary artery disease required surgical intervention. Survivors were administered the Short

Form (SF)-36 QOL Survey at follow up, which was 96.1% complete.

Results: Hospital mortality was 7.6% (85/1,125). Mean follow up was 5.9 years (range: 9 months to 18.4 years). Mean (\pm SEM) actuarial survival was $70.6 \pm 1.4\%$ at five years, and $40.6 \pm 2.0\%$ at 10 years. Male patients scored significantly higher on the SF-36 than controls in physical ($p = 0.012$) and mental health ($p = 0.004$). Comparing female patients with controls revealed no significant difference in physical health; however, they scored higher in mental health than controls ($p = 0.001$).

Conclusion: The study results clearly demonstrate that heart surgery in the elderly with the SJM mechanical valve can be accomplished with acceptable hospital mortality, morbidity, and excellent long-term results. Moreover, long-term QOL in elderly patients with a SJM valve can be expected to meet or exceed that of age- and gender-matched controls.

The Journal of Heart Valve Disease 2006;15:57-66

Many studies have been published on clinical outcomes following valve replacement. The selection of a valve substitute remains perhaps the most important decision that the patient and surgeon must discuss prior to surgery. Considerations for choosing between a mechanical valve and bioprosthesis concentrate on hemodynamic performance, device long-term durability, and the need for continuous anticoagulation therapy. The trade-off considerations between device durability, anticoagulant and valve-related risks and

potential need for reoperation are well defined for survival and other major adverse events.

Patients facing a decision prior to their first operation are understandably concerned about a valve choice that might require a second operation in the future. Moreover, how the valve device is selected and the subsequent need for anticoagulation therapy will affect the patient's quality of life (QOL), and are the principal concerns of most patients and families. These considerations are amplified in elderly patients where tissue valve options are often entertained as the alternative of choice and where anticoagulant management may pose a problem.

As patients continue to live longer, the risk and costs associated with reoperation have become important considerations that must be factored into the algorithm for the selection of a suitable valve substitute. Many patients present with coexisting indications for systemic anticoagulation. The St. Jude Medical (SJM)

Presented at the Third Biennial Meeting of the Society for Heart Valve Disease, 17th-20th June 2005, Vancouver Convention and Exhibition Centre, Vancouver, Canada

Address for correspondence:
Dr. Kevin D. Accola, Cardiovascular Surgeons, P.A., 217 Hillcrest Street, Orlando, Florida 32801, USA
e-mail: KAccola@aol.com

mechanical valve is the most widely implanted mechanical prosthesis worldwide, with numerous studies (1-6) having clearly demonstrated its excellent clinical performance, structural integrity, hemodynamics and acceptable long-term complication rates. However, the long-term influence of the valve on QOL in elderly patients has not been clearly defined.

The aim of the present study was to discern the long-term effects on QOL of the SJM mechanical valve in a large series of elderly patients. Moreover, the study sought to gain insight into the perceived health status and sense of well-being in elderly patients following mechanical valve replacement.

Clinical material and methods

Patient population

The study population comprised 1,125 consecutive patients aged ≥ 65 years (582 men, 543 women; mean age 71.4 ± 4.9 years; range: 65 to 90 years) who underwent valve replacement with at least one SJM mechanical valve between June 1981 and December 1999. During this same period, 5,944 additional patients underwent valvular procedures involving reconstruction, bioprosthesis or other mechanical valve implants with or without coronary artery bypass grafting (CABG). The age distribution of patients at the time of surgery is illustrated in Figure 1; the patients' cardiovascular and coronary risk factors are summarized in Table I.

Patients were classified symptomatically according to the NYHA and Canadian Cardiovascular Society (CCS) systems. Preoperatively, 138 patients (12.3%) were in NYHA functional class II, 775 (68.9%) in class III, and 212 (18.8%) in class IV. Using the CCS system, 37 patients (3.3%) were in angina class I, 124 (11.0%) in class II, 811 (72.1%) in class III, and 153 (13.6%) in class IV.

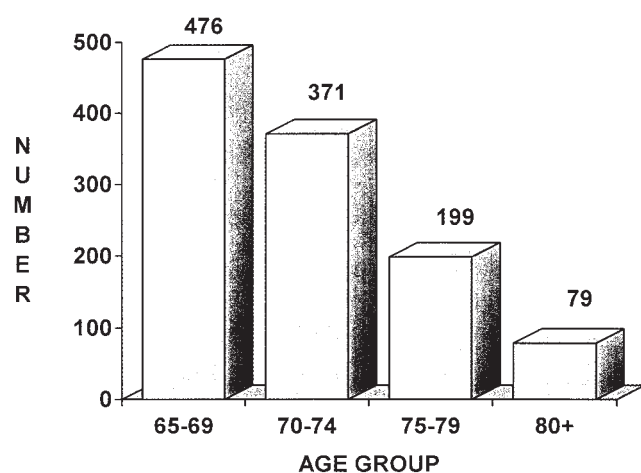


Figure 1: Patient age distribution at the time of surgery.

Significant coronary artery disease (CAD) requiring surgical intervention in the present study was defined as an estimated reduction in luminal diameter of $\geq 50\%$. Preoperative angiographic findings revealed that 167 patients (14.8%) had one-vessel disease, 161 (14.3%) double-vessel disease, and 207 (18.4%) triple-vessel disease. Left main CAD (stenosis $>50\%$) was found in 67 patients (6.0%). The ejection fraction was documented in 1,107 patients (98.4%), and was >0.50 in 701 patients (62.3%), 0.30-0.50 in 369 patients (32.8%), and <0.30 in 37 patients (3.3%).

The current procedure represented a reoperation in 195 patients (17.3%). The operation was performed electively in 1,032 patients (91.7%), urgently in 56 (5.0%), emergently in 24 (2.1%), and as salvage in 13 (1.2%).

Operative technique

The operative technique utilized varied by surgeon and evolved during the course of the study period. Median sternotomy and internal mammary artery harvest was performed during venous conduit harvest. Cardiopulmonary bypass was established after systemic heparinization with aortic and venous cannula-

Table I: Patient clinical profile.

Parameter	Value
No. of patients	1,125 (100.0)
Cardiovascular risk factors	
Congestive heart failure	665 (59.1)
Pulmonary disease	275 (24.4)
Renal dysfunction (creatinine >2.0 mg/dl)	82 (7.3)
Angina	647 (57.5)
Arrhythmia	357 (31.7)
Prior myocardial infarction	180 (16.0)
Prior cerebrovascular accident	85 (7.5)
Peripheral vascular disease	137 (12.2)
Endocarditis	
Active	12 (1.1)
Treated	16 (1.4)
Pulmonary hypertension	511 (45.4)
Cardiogenic shock	40 (3.6)
Coronary risk factors	
Family history of CAD	353 (31.4)
Smoking (current)	111 (9.9)
Hypertension (diastolic pressure >90 mmHg)	645 (57.3)
Diabetes mellitus	196 (17.4)
Dyslipidemia (cholesterol >200 mg/dl)	375 (33.3)
Morbid obesity	186 (16.5)

Values in parentheses are percentages.
CAD: Coronary artery disease.

Table II: Procedure distribution by operative category.

Procedure	n
No. of patients	1,125 (100.0)
AVR	374 (33.2)
MVR	169 (15.0)
AVR + MVR	46 (4.1)
AVR + CABG	349 (31.0)
MVR + CABG	125 (11.1)
Other valve replacement with concomitant procedure	62 (5.5)

Values in parentheses are percentages.
AVR: Aortic valve replacement; CABG: Coronary artery bypass grafting; MVR: Mitral valve replacement.

tion and moderate hypothermia (25-32°C). The predominant method of myocardial protection was cold crystalloid cardioplegia and topical hypothermia, with blood cardioplegia increasing in use during the later part of the surgical experience. Sequencing of the procedure varied, but typically coronary revascularization preceded valve replacement. Mitral procedures were completed prior to aortic valve replacement in the case of double-valve operations. With the advent of transesophageal echocardiography (TEE), its use became routine for operative de-airing and anatomic assessment.

Anticoagulant management

Anticoagulation was initiated with warfarin on the first or second postoperative day, depending on the patient's condition. Postoperative heparin was not utilized routinely. Patients remained in the hospital until such time as an acceptable therapeutic level of anticoagulation was achieved and the patient was stabilized.

Operative data

A total of 1,199 valves was implanted in the series: these included 1,186 SJM valves, four Björk-Shiley valves, four CarboMedics valves, two Carpentier-Edwards porcine bioprostheses, two Medtronic-Hall valves, and one Ionescu-Shiley valve. The distribution of procedures by valve position and associated CABG are shown in Table II.

Valve pathology including the dysfunction and etiology by site are presented in Table III. There were 33 associated mitral and tricuspid valve reconstruction procedures in the series, and 515 patients (45.8%) underwent concomitant CABG (mean 2.1 grafts per patient; range: one to six grafts).

The mean cardiopulmonary bypass time was 112.9 ± 47.8 min (range: 39 to 486 min), and the mean aortic cross-clamp time 76.3 ± 31.7 min (range: 30 to 377 min).

Definitions

Preoperative variables

Congestive heart failure was defined as paroxysmal nocturnal dyspnea, dyspnea on exertion due to heart failure, or chest X-radiograph showing pulmonary congestion. Pulmonary hypertension was defined as systolic pulmonary artery pressure >60 mmHg or pulmonary vascular resistance >260 dynes·s cm⁻⁵. Hypertension was defined as blood pressure ≥140 mmHg systolic or ≥90 mmHg diastolic on two occasions, or the patient currently receiving antihypertensive medication. Renal insufficiency was defined as a documented history of renal failure with a serum creatinine level ≥2.0 mg/dl, or undergoing dialysis. Dyslipidemia was defined as a serum cholesterol level >200 mg/dl on admission to hospital.

Elective surgery was defined as an operation which could be deferred without increased risk of compro-

Table III: Distribution of valve pathology by site among patients (n = 1,125).

Valve pathology	Aortic	Mitral	Tricuspid
Dysfunction			
Stenosis	386 (34.3)	41 (3.6)	0 (0.0)
Insufficiency	81 (7.2)	210 (18.7)	1 (0.1)
Stenosis and insufficiency	350 (31.1)	142 (12.6)	0 (0.0)
Etiology			
Rheumatic	64 (5.7)	112 (10.0)	5 (0.4)
Congenital	22 (2.0)	2 (0.2)	0 (0.0)
Ischemic	3 (0.3)	37 (3.3)	0 (0.0)
Myxomatous degeneration	52 (4.6)	109 (9.7)	8 (0.7)
Calcific	633 (56.3)	87 (7.3)	0 (0.0)
Endocarditis	11 (1.0)	9 (0.8)	0 (0.0)
Prolapse	1 (0.1)	13 (1.2)	0 (0.0)
Prosthetic valve dysfunction	31 (2.8)	23 (2.0)	0 (0.0)
Other	1 (0.1)	1 (0.1)	0 (0.0)

Values in parentheses are percentages.

mised cardiac outcome. An urgent operation was defined as being required within 48 h in an effort to prevent further clinical deterioration. An emergency operation was defined as those instances where the patient did not respond to aggressive clinical measures and clinical decompensation continued to occur. A salvage operation was defined as those in which the patient was undergoing cardiopulmonary resuscitation en route to the operating room, prior to anesthesia induction, or was in cardiogenic shock.

Postoperative variables

Respiratory insufficiency was defined as patients requiring ventilatory support for more than 48 h. Cerebrovascular accident was defined as a focal neurologic deficit that remained unresolved and persisted for more than 24 h. Perioperative myocardial infarction was defined as the occurrence of a new onset of Q waves with or without increased myocardial enzyme levels. Renal insufficiency was defined as a serum creatinine level ≥ 2.0 mg/dl. Low cardiac output referred to clinical evidence of hypotension, oliguria and peripheral vascular constriction with normal or supranormal left ventricular filling pressure or a measured cardiac index of less than 2 l/min/m², necessitating the administration of catecholamines or the use of the intra-aortic balloon pump (IABP), or both.

Hospital mortality was defined as death occurring during the operation or the hospitalization during which the procedure was performed, or death occurring after discharge from the hospital but within 30 days of the surgical procedure, unless the cause was clearly unrelated to the operation.

Data sources

Perioperative data were obtained by retrospective review of the patient's hospital record, catheterization reports, and cine angiograms. Follow up information was obtained through comprehensive questionnaires and by telephone interview with surviving patients, family members, or the patient's personal physician. Follow up data included activity level, current symptoms, diagnostic tests, occurrence of late cardiac events and medications being taken. Patients were asked to describe their symptoms and ranked according to the NYHA classification system. When necessary, the Social Security Death Index was used to obtain patient mortality information. Autopsy reports, when available, were used to furnish additional information relating to death.

A Patient Registration Form and a Patient Follow Up Form were completed for each participant in the study. These data collection instruments provided standardized reporting of each patient's clinical status before and after the operation. The QOL assessment was conduct-

ed with the SF-36 developed by Ware and associates (7). The SF-36 is a standardized instrument which comprises 36 items designed to measure eight dimensions of overall health. These include physical functioning, social functioning, role limitations attributed to emotional problems, mental health, vitality (energy/fatigue), bodily pain, and general health perception. For each dimension, item scores are computed, totaled and converted into a scale, which ranges from 0 for worst health to 100 representing best-perceived health.

Two summary components - a physical score and mental health score - are also computed. A high score in the Physical Health Summary component indicates no physical limitations, disabilities, decrements in well-being, and/or high energy levels. A low score indicates substantial limitations in self-care, physical, social and role activities, severe bodily pain, or persistent tiredness. In the Mental Health Summary component, a high score demonstrates recurring positive affect, absence of psychological distress, and a sense of emotional well-being. A low score is indicative of the presence of psychological disturbance and substantial social and role dysfunction due to emotional instability (8). The SF-36 has been used in a number of public health studies. It is generally completed in approximately 10-15 min, and may be administered in person, by telephone, or by mail.

A 96.1% follow up on patients discharged alive from the hospital (n = 1,040) was obtained in the present study, with only 41 patients (3.9%) being lost to follow up.

Statistical analysis

Data were presented as frequency distributions and simple percentages. Values of continuous variables were expressed as mean \pm SD. Univariate analysis of selected preoperative and postoperative discrete variables was accomplished by chi-square test, continuity-adjusted chi-square analysis, or a two-tailed Fisher's exact test with the appropriate degrees of freedom to test for the equality of proportions in the case of categorical variables. Comparison of means for continuous variables was conducted by an unpaired Student's *t*-test. A Cox proportional hazards regression model was developed to identify preoperative and intraoperative factors associated with late death (9).

Patient survival was expressed by actuarial analysis according to the method of Cutler and Ederer (10) using time zero as the date of operation and late death as the end point (with variability expressed as SEM). Linearized occurrence rates with standard errors were used to describe selected events, and reported as % per patient-year (pt-yr). The equality of survival distribution was computed using the algorithm of Lee and Desu (11).

Data collected were subjected to both quantitative and qualitative analysis using the biostatistical capabilities of the Patient Analysis and Tracking Systems (PATS; Axis Clinical Software, Inc., Portland, OR, USA) and the Number Cruncher Statistical Systems (NCSS; Kaysville, UT, USA). A p-value ≤ 0.05 was considered to be statistically significant.

Results

Hospital morbidity

Hospital complications included reoperation for bleeding in 53 patients (4.7%), perioperative myocardial infarction in nine (0.8%), cerebrovascular accident in 39 (3.5%), pulmonary insufficiency in 197 (17.5%), renal dysfunction in 106 (9.4%), low cardiac output in 93 (8.3%), and cardiac arrest in 36 (3.2%). Placement of the IABP was required in 145 patients (12.9%) in the series. Ninety-one patients (8.1%) had an IABP placed preoperatively, 44 (3.9%) intraoperatively, and 10 (0.9%) postoperatively. None of the patients requiring use of the IABP experienced a major complication.

The overall incidence of postoperative morbidity was low, with over two-thirds of the patients (69.2%; n = 729) experiencing no hospital complications. The average postoperative duration of the hospital stay was 12.2 ± 12.0 days.

Hospital mortality

The overall hospital mortality was 7.6% (85 deaths), and was significantly higher (p = 0.010) in women (9.8%; n = 53) than in men (5.5%; n = 32).

The elective mortality rate was 6.0% (62/1,032), the urgent mortality rate 16.1% (9/56), the emergent mortality rate 29.2% (7/24), and the salvage mortality rate

53.8% (7/13). A between-group comparison of the mortality rates for elective (6.0%; 62/1,032) and non-elective surgery (24.7%; 23/93) categories achieved statistical significance (p = 0.001). The mortality rate for first operation was 6.8% (63/930), and 11.3% (22/195) for reoperation. A comparison of the influence of surgical history on hospital mortality rates revealed a significant difference (p = 0.044).

The mortality rate in patients undergoing isolated aortic valve replacement (AVR) was 3.5% (13/374), and 6.5% (11/169) for isolated mitral valve replacement (MVR). This difference did not achieve statistical significance. The mortality rate in patients undergoing AVR and CABG was 6.9% (24/349), and 14.4% (18/125) for MVR and CABG (p = 0.018).

The double-valve replacement (aortic + mitral) mortality rate was 15.2% (7/46), while that for associated CABG was 28.56% (8/28). The remaining hospital mortality rate in the series was 13.2% (5/38); this included patients with other procedure combinations associated with at least one valve replacement.

Long-term follow up

Follow up data were collected for 1,040 patients (96.1%) discharged from the hospital. The mean follow up was 6.0 years (range: 9 months to 18.4 years), and cumulative follow up 6,267.9 pt-yr. There were 454 late deaths (43.7%), generating a linearized late mortality rate of $7.2 \pm 0.3\%$ per pt-yr. On completion of the current follow up, 545 patients (52.4%) of the hospital survivors were alive. This large cohort of surviving elderly patients comprised the subset for the QOL evaluation.

In order to determine the predictors of late mortality, 22 preoperative and intraoperative variables (see

Table IV: Variables influencing late mortality in patients aged ≥ 65 years undergoing valve replacement with a St. Jude Medical mechanical valve: Cox regression analysis.

Variable	Regression coefficient	SE	Relative hazard	p-value*
Preoperative				
Age	0.0575	0.0093	1.0590	0.001
Congestive heart failure	0.2351	0.1033	1.2651	0.023
Pulmonary disease	0.2590	0.1097	1.2957	0.018
Diabetes	0.4533	0.1245	1.5734	0.001
Ejection fraction	0.2226	0.1021	1.2494	0.029
Intra-aortic balloon pump	0.3625	0.1395	1.4369	0.009
Peripheral vascular disease	0.3549	0.1443	1.4261	0.014
Renal insufficiency	0.4078	0.1709	1.5035	0.017
Reoperation	0.3342	0.1203	1.3968	0.006
Intraoperative				
Perfusion time	0.0027	0.0012	1.0027	0.020

*Only significant variables (p < 0.05) are listed.

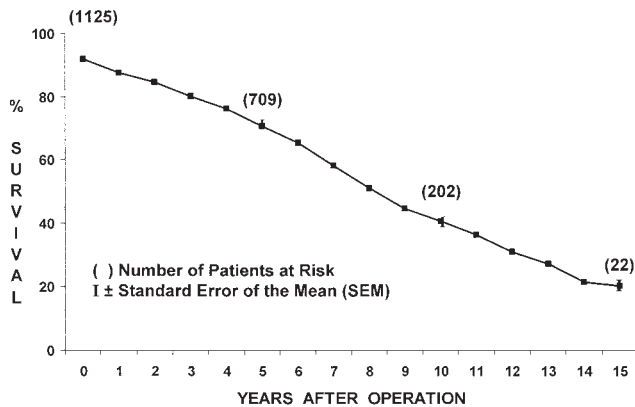


Figure 2: Actuarial survival of patients aged ≥ 65 years who received a St. Jude Medical mechanical valve.

Appendix I) were entered into a Cox proportional hazards regression model to explore their relationship to late death (>30-day mortality). Cox regression analysis demonstrated the independent influence of 10 covariates: age ($p < 0.001$), congestive heart failure ($p < 0.023$), pulmonary disease ($p < 0.018$), diabetes ($p < 0.001$), ejection fraction ($p < 0.029$), IABP ($p < 0.009$), peripheral vascular disease ($p < 0.014$), renal insufficiency ($p < 0.017$), reoperation ($p < 0.006$), and perfusion time ($p < 0.020$). The complete results of this analysis are presented in Table IV.

The actuarial survival data for the entire series are shown in Figure 2. Mean (\pm SEM) survival was $70.6 \pm 1.4\%$ at five years, $40.6 \pm 2.0\%$ at 10 years, and $20.3 \pm 2.8\%$ at 15 years. An analysis was conducted to discern the influence of gender on long-term survival, and no significant difference was demonstrated in the equality of survival distribution. To examine the influence of

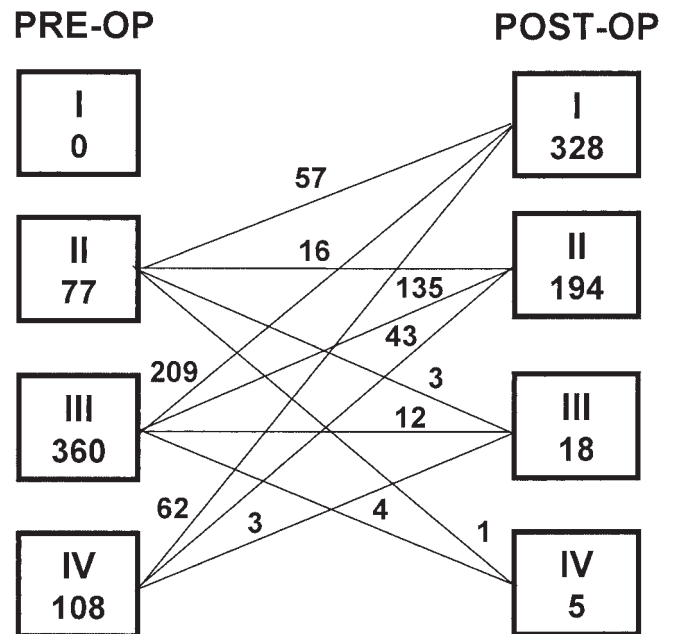


Figure 3: Preoperative and postoperative NYHA class for patients aged ≥ 65 years who received a St. Jude Medical mechanical valve (current survivors).

CAD on long-term survival, a comparison of patients who underwent CABG, and those that did not, was conducted. Patients undergoing valve replacement without CABG showed a trend towards enhanced survival ($p = 0.073$)

The linearized occurrence rate and number of late major adverse cardiac events (MACE) were as follows: non-fatal myocardial infarction, $0.10 \pm 0.04\%$ per pt-yr (six events); stroke, $0.26 \pm 0.06\%$ per pt-yr (16 events); and reoperation, $0.06 \pm 0.03\%$ per pt-yr (four events).

Table V: Follow up SF-36 Quality of life age- and gender-adjusted mean scores for patients aged ≥ 65 years with a St. Jude Medical mechanical valve.

Scale score	Male study group (n = 285)	Male age-adjusted norm (n = 293)	p-value	Female study group (n = 244)	Female age-adjusted norm (n = 413)	p-value
Physical functioning	67.6 \pm 30.1	65.8 \pm 28.3	NS	56.5 \pm 30.4	61.9 \pm 28.9	0.026
Role-physical	70.2 \pm 40.8	59.7 \pm 42.5	0.002	63.6 \pm 44.1	56.4 \pm 42.5	0.041
Bodily pain	76.9 \pm 26.5	68.8 \pm 25.4	0.001	75.2 \pm 27.5	63.4 \pm 27.1	0.001
General health	70.0 \pm 24.4	58.6 \pm 22.1	0.001	64.4 \pm 24.7	61.6 \pm 22.1	NS
Vitality (energy/fatigue)	63.3 \pm 22.9	57.8 \pm 22.6	0.004	58.8 \pm 22.5	55.5 \pm 23.5	NS
Social functioning	81.4 \pm 27.6	79.7 \pm 26.0	NS	78.6 \pm 28.9	77.0 \pm 27.7	NS
Role-emotional	84.7 \pm 32.4	66.7 \pm 34.5	0.001	83.3 \pm 33.7	73.4 \pm 39.7	0.001
Mental health	83.0 \pm 16.3	77.4 \pm 17.4	0.001	79.6 \pm 16.4	74.7 \pm 19.9	0.001
Physical health summary	44.5 \pm 12.6	42.0 \pm 11.4	0.012	41.3 \pm 13.4	41.0 \pm 11.5	NS
Mental health summary	54.7 \pm 8.6	52.5 \pm 9.8	0.004	54.2 \pm 8.4	51.4 \pm 10.5	0.001

Values are mean \pm SD.

SF-36: Short Form 36 Quality of Life Survey; NS: Not significant.

On completion of follow up, many current survivors were clinically and functionally improved and experiencing an enhanced QOL, with 95.8% of the patients in NYHA classes I or II. The preoperative and postoperative NYHA functional class for current survivors and their migration pattern are shown in Figure 3.

At follow up, QOL assessment was conducted on survivors (n = 529) willing and capable of completing the SF-36. The mean (\pm SD) for each of the eight health scales, as well as the Physical and Mental Health Summary scales for SJM mechanical valve patients and age-adjusted norms, are listed in Table V.

In the male cohort, study group patients scored higher on all health scale scores and the two Health Summary scores. They scored significantly better than age-adjusted norms in role-physical ($p = 0.002$), general health ($p = 0.001$, vitality ($p = 0.004$), role-emotional ($p = 0.001$), and mental health ($p = 0.001$). Moreover, a significant difference was noted in the Physical ($p = 0.012$) and Mental Health ($p = 0.004$) Summary scale scores.

In the female group, patients scored higher on all scales except in physical functioning, where the study group scored significantly lower ($p = 0.026$) than age-adjusted norms. Study group patients scored significantly higher than age-adjusted norms on role-physical ($p = 0.041$), role-emotional ($p = 0.001$) and mental health ($p = 0.001$). No significant difference was noted in the Physical Health Summary score; however, a significant difference was found in the Mental Health Summary score ($p = 0.001$), with female study group patients scoring higher than age-adjusted norms.

Discussion

The selection of an appropriate prosthetic device for a patient has evolved over the course of the past three decades due to concerns regarding the risks, inconvenience, and the expense of lifelong anticoagulation therapy. Historically, the bioprosthesis has been increasingly recommended as the valve substitute of choice in elderly patients (12-14). Concern over the adverse effects of life-long anticoagulation therapy with mechanical valves has limited their use in the elderly. However, it has been documented that a significant number of elderly patients with porcine bioprostheses continue to receive warfarin (12). As patients continue to live longer, the risks and costs associated with reoperation become important considerations to be factored into the algorithm for the selection of a suitable valve substitute. In addition, the patient's QOL following the implantation of a prosthetic heart valve is of paramount importance. Several studies (15,16), including the current series, have demonstrated excellent clinical outcomes in elderly

patients undergoing mechanical valve replacement.

QOL or health-related well-being is a multidimensional construct which refers to the patient's physical, psychological, and social domains (17). Standardized questionnaires addressing the multidimensional nature of QOL have proven beneficial in defining the measurement of outcomes following valvular heart surgery (12,15,18-21). Early attempts by cardiac surgeons to measure outcomes focused on patient hospital mortality and morbidity, survival, and the occurrence of late morbid events as end points. The inadequacy of this approach for describing the multifaceted, potential outcomes of cardiac surgery has more recently been recognized, leading to considerations in the use of other objective criteria.

Traditionally, the cardiac surgeon has assessed the patient's QOL without the benefit of any validated or standardized evaluation instrument. Often, the patient's own evaluation or perception of the outcomes of the cardiac surgery has been overlooked. As a result, clinical bias may have influenced the outcomes of various interventions in the patient's health status and sense of well-being. With the advent of valid and reliable instrumentation to assess health status, a more definitive and quantifiable measurement of the patient's QOL can be achieved.

Quantification of the impact of valve replacement on the patient's daily life and well-being, in a formal and standardized manner, can be utilized to discern what treatment alternatives can be associated with favorable outcomes, including an enhanced QOL. Ultimately, the elderly patient's QOL and sense of well-being following valve replacement and an ability to carry out activities of daily living in an independent manner is essential.

The current trend is to recommend a mechanical valve in younger patients and a bioprosthesis in older patients (22). There are many patient-related clinical factors that must be considered in the selection of a valve substitute. Of critical importance is the patient's QOL following heart valve replacement surgery. The selection of an appropriate valve substitute must go far beyond the patient's age. Serious consideration must be given to the long-term benefits of the procedure and the patient's perceived QOL.

The SJM valve is the most widely implanted mechanical prosthetic device in the United States and, to date, over 1.5 million SJM valves have been implanted worldwide (23). In recognizing the safety, efficacy and long-term durability of the SJM mechanical valve, the focus of the present study was the elderly patients' perceived QOL and sense of well-being following valvular heart replacement.

The surgical management of valvular heart disease in symptomatic elderly patients can be accomplished

with acceptable hospital mortality and morbidity rates. The outcomes in the present study compared favorably with those of other large series of elderly patients (12,24,25). Moreover, postoperative hospital morbidity in the present study was low, with over two-thirds of the patients (69.2%; n = 729) experiencing no in-hospital complications.

Considering a mean age of 71.4 years in the present study, an actuarial survival of $70.6 \pm 1.4\%$ at five years and of $40.6 \pm 2.0\%$ at 10 years supports a continued aggressive surgical approach in the treatment of valvular heart disease in this cohort of patients. Moreover, the outcomes demonstrated a reduced rate of MACE, with 99.4% of patients free of known non-fatal myocardial infarction (0.10%/pt-yr), 98.5% free of stroke (0.26%/pt-yr), and 99.6% free of reoperation (0.06%/pt-yr).

Using Cox proportional regression hazard analysis, age ($p = 0.001$) was determined to be a powerful predictor of late mortality. Moreover, congestive heart failure ($p = 0.023$), pulmonary disease ($p = 0.018$), diabetes ($p = 0.001$), ejection fraction ($p = 0.029$), IABP use ($p = 0.009$), peripheral vascular disease ($p = 0.014$), renal insufficiency ($p = 0.017$), and reoperation ($p = 0.006$) were also found to influence late mortality. Intraoperatively, the duration of perfusion time ($p = 0.020$) was also found to be an independent predictor of late mortality. In contrast to the findings of other studies (26,27), the presence of CAD requiring concomitant CABG was not found to be associated with late mortality. However, patients in this study undergoing valve replacement without CABG demonstrated a trend towards enhanced survival ($p = 0.073$).

In the present study, 529 patients completed the SF-36, with male patients scoring significantly higher ($p = 0.012$) in physical health than age-control norms (45.5 ± 12.6 versus 42.0 ± 11.4). Moreover, male patients also scored significantly higher ($p = 0.004$) than age-control norms (54.7 ± 8.6 versus 52.5 ± 9.8) in mental health. A comparative analysis of female patients revealed no significant difference in physical health; however, female patients in the present study scored significantly higher ($p = 0.001$) in mental health, than female age-matched controls (54.2 ± 8.4 versus 51.4 ± 10.5).

Pupello and associates (12) conducted a similar study assessing QOL in elderly patients receiving a porcine bioprosthesis. A comparison of the Physical and Mental Health Summary scores of male patients with those in the present study revealed no significant difference in physical health. However, male patients with mechanical valves scored significantly higher ($p = 0.001$) than those with porcine bioprostheses (54.7 ± 8.6 versus 52.4 ± 10.0). An analysis of the two female groups revealed no significant difference in physical health. However, again a difference was noted with

female patients, with a mechanical valve patients scoring significantly higher ($p = 0.001$) than those with a bioprosthesis (54.2 ± 8.4 versus 51.2 ± 10.7).

These data provide strong support that elderly patients with a mechanical valve can be expected to have a perceived QOL that meets or exceeds that of gender- and age-matched controls. Moreover, the patient's self-perceived QOL supports their significant improvement in functional status, as demonstrated by the NYHA classification, which revealed that 95.8% of the patients in the present study were in class I or II at follow up. While valve replacement surgery can prove to be a traumatic experience, following a period of recovery, the patient's perceived QOL can be expected to return to that of gender- and age-control norms.

The present study, and the investigations of De Feo et al. (28) clearly demonstrate that age alone should not be considered a contraindication to the use of a mechanical valve in elderly patients. Moreover, Schelbert et al. (29) identified that hospital volume was a determinant of the use of mechanical valves in elderly patients. The decision regarding which type of prosthesis should be used for a particular form of valvular heart disease must be individualized on a patient-by-patient basis. The choice of an appropriate valve substitute should be the product of a joint decision by the cardiologist, cardiac surgeon and, more recently, the well-informed patient.

In conclusion, advances in the surgical management of valvular heart pathology have extended reproducible benefits of enhanced survival and symptomatic relief to patients of all ages. Excellent outcomes in valvular heart surgery are now being achieved for elderly patients in most developed countries. However, the cost of such procedures is currently high, and continues to increase. Demonstrating the benefits of not only enhancing long-term survival but also returning patients - particularly the elderly - to a functional and enjoyable QOL is critical in an era of diminishing healthcare resources.

As patients continue to live longer and life expectancy increases, the risk and costs associated with reoperation become of paramount importance. The use of a mechanical valve with low-intensity anticoagulation could be a viable alternative for elderly patients. The improved clinical and functional status of patients undergoing mechanical valve replacement in the present study is impressive. The dramatic clinical benefits and enhanced QOL experienced by patients clearly suggest that the use of a mechanical valve in elderly patients is an appropriate choice.

Acknowledgements

The authors thank Dr. Debra D. Guest for technical

assistance in the preparation of this report. In addition, the authors thank Wayne Mutch, PA-C for his assistance in follow up data collection.

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Meeting discussion

DR. GUY FRADET (Vancouver, BC, Canada): You presented data on the incidence of stroke, which was low, but in that particular age population most of us would be concerned about possible complications from anticoagulants and perhaps the wider spectrum of neurologic events such as TIAs and RINDs. First, do you have data for that; and second, do you have a system or protocol to manage anticoagulation in those patients, or is that done by their general practitioner?

DR. JORGE E. SUAREZ-CAVELIER (Orlando, Florida, USA): This study was performed mainly in a private practice setting. The management of warfarin anticoagulation is carried out mainly by the cardiologists or primary care physicians, and in some hospitals there is a special warfarin clinic. We don't have adequate and clear data about postoperative complications due to warfarin in these patients.

DR. A. P. KAPPETEIN (Rotterdam, The Netherlands): In a previous presentation the Euroscore was not very well calibrated, as would be expected for aortic valve replacement. You identified several risk factors which are not in the Euroscore - for example, intra-aortic balloon pump use. Based on your data, do you think that we should have an adjusted score for aortic valve replacement?

DR. SUAREZ-CAVELIER: Yes, I think so. There are completely different types of patients here. In the case of single aortic valve patients, whether they have combined coronary disease, whether you have to replace other valves, such as the mitral valve, and whether you have to combine the aortic valve replacement with a mitral repair or replacement. Unfortunately, there are different pathologies in different patients.

DR. KAPPETEIN: You identified both congestive heart failure and intra-aortic balloon pump as risk factors. These were in the multivariate analysis and they were clearly not associated with each other. Can you explain that? Why did these patients have intra-aortic balloon pumping?

DR. SUAREZ-CAVELIER: I think about 12% of the patients had intra-aortic balloon pumping, and most of these were placed before surgery. Sometimes that indication was by the cardiologist. In 15% of the cases the intra-aortic balloon pump was placed during surgery, when the indication was by the surgeon if the patient was not coming off bypass adequately. Only 10% of the patients had an intra-aortic balloon pump placed post-

operatively, and that was probably due to a low cardiac output after surgery, despite inotropic support.

DR. JAN PIRK (Prague, Czech Republic): During the mean follow up of six years, almost 50% of the patients died. Do you know the causes of death? How many patients died from cerebral bleeding because of this treatment?

DR. SUAREZ-CAVELIER: We were surprised by these results. Increasingly, the tendency is to place bioprostheses in elderly patients, but one of our group did not like bioprostheses and so used more mechanical valves. Unfortunately, we don't have sufficient information for the patients who died.

DR. NEAL KON (Winston-Salem, North Carolina, USA): What is it about a St. Jude valve that makes the patient's quality of life even better? Has this changed your practice? Do all of your group now like to implant mechanical valves in elderly people?

DR. SUAREZ-CAVELIER: During the time that we implanted 1,100 St. Jude valves, almost 6,000 more valves were implanted - these were a combination of different bioprosthetic and mechanical valves, but increasingly the trend is towards bioprostheses.

DR. KON: So your recommendation is that this is a reasonable option, but not one that you would offer to everybody?

DR. SUAREZ-CAVELIER: It's not a recommendation, but with these data we should look in more detail at the use of mechanical valves - and St. Jude valves are always a good thing to consider.

Appendix I: Covariates used to predict late mortality.

Preoperative variables

1. Female gender
2. Age
3. Family history of coronary artery disease
4. Hypertension (diastolic pressure >90 mmHg)
5. Dyslipidemia (cholesterol >200 mg/dl)
6. Smoking history
7. Diabetes mellitus
8. Renal insufficiency
9. Cerebral vascular disease
10. Peripheral vascular disease
11. Pulmonary disease
12. History of congestive heart failure
13. Arrhythmia
14. Unstable angina
15. NYHA class III/IV
16. Ejection fraction
17. Surgical urgency (urgent/emergent)
18. Surgical history
19. Intra-aortic balloon pump inserted

Intraoperative variables

20. Perfusion time (min)
 21. Cross-clamp time (min)
 22. Coronary artery bypass grafting
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