

Cardiac Valve Surgery in Octogenarians

Improving Quality of Life and Functional Status

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Background: Although cardiac valve procedures are being performed more frequently in the elderly, long-term functional outcomes have not been well characterized.

Objective: To evaluate changes in quality of life and functional status in octogenarians after cardiac valve surgery.

Design: Retrospective medical record review and patient telephone interview. Median follow-up 30 months (range, 6-95 months).

Setting: Tertiary care university hospital.

Patients: Octogenarians undergoing cardiac valve surgery (N = 61; mean age, 83.5 years; range, 80-89 years).

Interventions: Forty-seven patients had aortic valve replacement, 14 had mitral valve replacement and/or repair, and 27 had a combined procedure with coronary artery bypass grafting.

Outcomes: Actuarial survival, morbidity, length of hospital stay, and discharge disposition were evaluated. Functional status, using the New York Heart Association classification, and Karnofsky performance status were evaluated preoperatively and postoperatively at 1 and 3 months after hospital discharge.

Results: Operative (<30 days) mortality occurred in 7 (11.4%) of 61 patients. Preoperative intensive care unit stay ($P < .001$) and New York Heart Association class 4 ($P < .02$) were independent predictors of early death by

multivariable analysis. Among hospital survivors, there were no major complications in 34 patients (63%), and this group had a mean (\pm SD) postoperative hospital stay of 12.2 ± 5.5 days. Twenty patients (37%) incurred significant complications, the most common of which were bleeding, pneumonia, and renal insufficiency. The mean (\pm SD) postoperative hospital stay in this group was 25 ± 17 days. Although significant complications were associated with an increased postoperative stay, this was not predictive of disposition to a skilled nursing facility or the final score on the postoperative Karnofsky performance scale. Actuarial survival was 85% at 1 year and 66% at 5 years. Patients with perioperative complications had significantly decreased actuarial survival by the Cox proportional hazards regression model ($P < .001$). Among hospital survivors, the score on the Karnofsky performance scale 1 month after discharge had improved 50% from a preoperative median score of 30% (severely disabled, requiring special care) to a postoperative median score of 80% (being able to perform normal activity with only moderate symptoms). The New York Heart Association classification improved a median of 2 classes in this group. These benefits were sustained at the 3-month follow-up.

Conclusion: Although greater resource expenditure is required for the initial perioperative convalescence, octogenarians can be expected to have an excellent functional outcome and long-term performance status after cardiac valve surgery.

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THE PROPORTION of the US population older than 80 years is growing steadily and is expected to be 6.2% by the year 2000.¹ It has been estimated that 40% of individuals in this age group will have symptomatic heart disease; of these, many individuals will be referred for surgical therapy.² To date, a number of studies³⁻⁶ have demonstrated that open heart surgery, including valvular surgery, can be performed in the octogenarian with

significant morbidity but acceptable mortality. However, with the knowledge that the average life expectancy of a person aged 80 years is approximately 88 years,¹ many cardiologists are reluctant to refer patients for elective surgery. Nonsurgical treatment options (drugs and valvuloplasty) are only palliative⁷ and may only increase the cost of care in this age group with little impact on the quality of life.

The purposes of this study were to estimate the improvement of symptoms, long-

PATIENTS AND METHODS

PATIENTS

A retrospective review was conducted of all patients 80 years and older undergoing heart valve surgery at the University of California, San Francisco, between June 1987 and May 1995. All patients were evaluated for surgery using standard clinical and hemodynamic criteria obtained from preoperative cardiac catheterization and transthoracic echocardiography. In contrast to a younger cohort, all patients had significant symptoms before being referred for surgery. Patients with senile dementia or disabling conditions that prevented independent or semi-independent living activities were excluded. There were a total of 61 patients, with a median age of 83.5 years (range, 80-89 years). There were 47 men (77.0%) and 14 women (23.0%). The clinical risk profile of the patients follows: 19 patients (31.1%) had systemic hypertension; 8 (13.1%), cerebrovascular disease; 7 patients (11.4%) were in the intensive care unit before the surgery; 6 patients (9.8%) had peripheral vascular disease; 6 (9.8%), renal insufficiency; 6 (9.8%), diabetes mellitus; 6 patients (9.8%) experienced a myocardial infarction less than 2 weeks before the surgery; 4 (6.6%), a myocardial infarction less than 3 months before the surgery; 5 patients (8.2%) underwent preoperative intra-aortic balloon counterpulsation; 5 (8.2%), a prior interventional procedure; and 8 (13.1%), prior surgery. All patients were symptomatic: 39 patients (63.9%) presented with congestive heart failure, 20 (32.7%) with angina, and 14 (22.9%) with both angina and congestive heart failure. According to the New York Heart Association (NYHA) classification, 23 patients (37.7%) were classified preoperatively as class 3 and 38 patients (62.3%) as class 4.

OPERATIVE TECHNIQUES

Operations were carried out using a standard median sternotomy. Cardiopulmonary bypass was performed with a membrane oxygenator, moderate systemic hypothermia, and intermittent cold, substrate-enhanced blood cardioplegia delivered antegrade and retrograde. We routinely

administered antifibrinolytic agents (aminocaproic acid). Bioprostheses (Baxter Healthcare Corp, Irvine, Calif) were used preferentially. Mechanical (St Jude, Medtronic, St Paul, Minn) prostheses were used when the patients were already using anticoagulant therapy for atrial fibrillation or had a small (19-mm) aortic annulus.

FOLLOW-UP

At hospital discharge, patients were assessed for functional status (NYHA class) and Karnofsky performance scale.⁸ The Karnofsky performance scale assigns percentages based on performance as follows: normal activity, 100%; minor symptoms, 90%; moderate symptoms, 80%; self-care only, 70%; needs some help, 60%; needs much help, 50%; disabled, 40%; needs special care, 30%; needs active support, 20%; and moribund, 10%. The disposition of each patient was also recorded (home, home with visiting nurse, discharge to relative's care, or skilled nursing facility). Cross-sectional follow-up was conducted by telephone interview of the patients, family members, and/or referring physicians. Functional status and Karnofsky performance status were reassessed at 3 months. Patient disposition and rehospitalizations were assessed for the remaining follow-up interval.

DATA ANALYSIS

Data are expressed as either mean (\pm SD) or median and range. SPSS-PC (version 6.0, SPSS Inc, Chicago, Ill) was used for all statistical analysis. Outcome measures assessed were early survival, change in NYHA class, Karnofsky score, postoperative disposition, and actuarial survival. The paired *t* test was performed for comparison of preoperative and postoperative Karnofsky score, and the unpaired *t* test was used to compare continuous variables between groups. χ^2 Analysis was used to analyze dichotomous variables for association with early mortality and disposition to a skilled nursing facility. Variables identified as significant by univariate analysis were then entered into forward stepwise multiple logistic regression. Survival analysis was performed using the Kaplan-Meier product-limit method and the Cox proportional hazards regression model.

term quality of life, and functional status in elderly patients undergoing heart valve replacement and to attempt to identify factors that may predict survival, performance status, and medical resource use. These data may provide new information for patient selection decisions, resource allocation, and quality-of-life expectations.

RESULTS

The majority of patients (47 [77.0%]) in this study underwent isolated aortic valve replacement, with 28 patients (45.9%) receiving biological prostheses and 19 (31.1%), mechanical prostheses. The mean transvalvular gradient was 63 ± 21 mm Hg (range, 25-112 mm Hg), and the mean aortic valve area was 0.6 ± 0.2 cm² (range, 0.3-1.2 cm²). Twelve patients (19.7%) underwent mitral valve replacement, with 9 patients (14.8%) receiving biological prostheses and 3 (4.9%), mechanical pros-

theses. Two patients (3.3%) had mitral valve stenosis and 12 (19.7%), mitral valve regurgitation. Associated coronary heart disease was present in 27 patients (44.3%). For the entire group, 27 patients (44.3%) had simultaneous coronary artery bypass grafting, with a mean of 2.4 ± 0.9 grafts per patient. There were 5 emergent (8.2%) and 7 urgent (11.5%) operations; the remaining 49 patients (80.3%) underwent elective repair. The median ejection fraction was 40% (range, 20%-60%). The mean bypass time was 131.2 ± 45 minutes, and the mean cross-clamp time was 83.2 ± 27 minutes.

The 30-day operative mortality rate was 11.4% (7/61). Causes of death were pneumonia (*n* = 3), perioperative myocardial infarction (*n* = 2), and cerebrovascular accident (*n* = 2). Significant postoperative complications occurred in 20 patients, with 10 patients experiencing multiple complications. Postoperative bleeding was the most common complication, occurring in 7

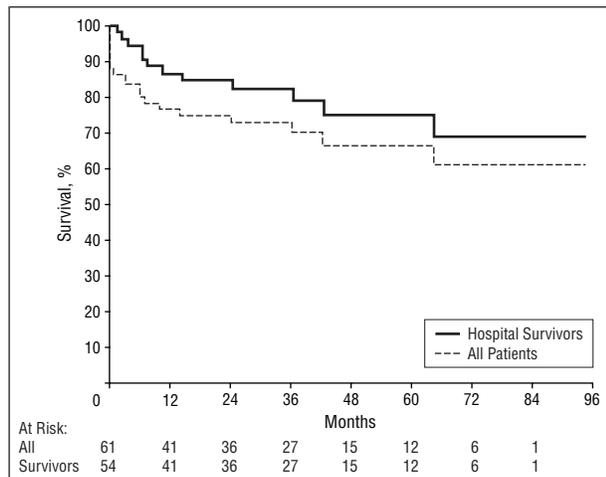


Figure 1. Actuarial survival in 61 octogenarians undergoing cardiac valve surgery. The number of patients at risk at each interval is indicated along the x-axis.

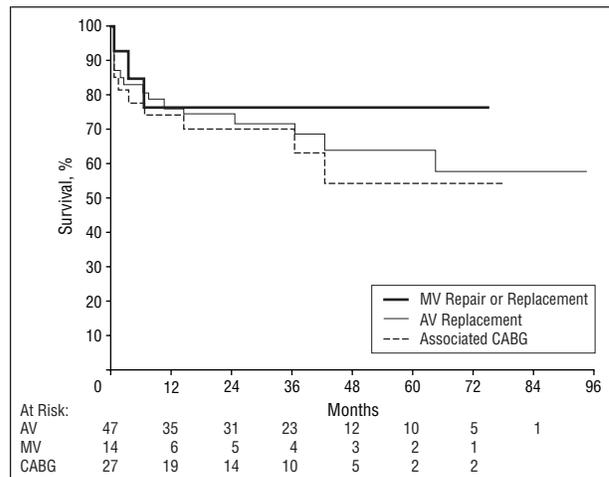


Figure 2. Actuarial survival in 61 octogenarians undergoing cardiac valve surgery according to type of procedure. The number of patients at risk at each interval is indicated along the x-axis. MV indicates mitral valve; AV, aortic valve; and CABG, coronary artery bypass grafting.

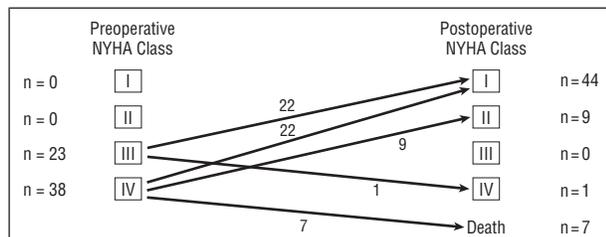


Figure 3. Preoperative to postoperative change in class according to the New York Heart Association (NYHA) classification. Numbers by arrows indicate number of patients changing from one level to another.

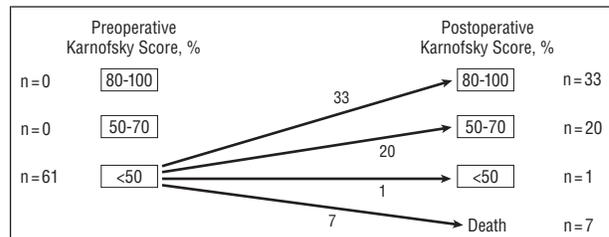


Figure 4. Change in Karnofsky score from preoperative to postoperative. Numbers by arrows indicate number of patients changing from one level to another.

patients (11.5%). The following significant complications developed postoperatively: pneumonia (6 [9.8%]); renal insufficiency (5 [8.2%]); transient ischemic attack (3 [4.9%]), low output (3 [4.9%]); peripheral vascular problems (2 [3.3%]); arrhythmia (2 [3.3%]); and renal failure (1 [1.6%]). The mean hospital stay for all patients was 20.5 ± 5.5 days. Among the 32 patients free of complications, the mean hospital stay was 12.2 ± 5.5 days, which was significantly shorter than the mean hospital stay of patients who had a complicated course (25.0 ± 17) ($P < .001$).

Among the 54 hospital survivors, 39 (72%) were discharged home with a visiting nurse, 8 (15%) were discharged to a skilled nursing facility for less than 3 months, and 7 (13%) spent 3 months or longer at a skilled nursing facility. Of the 15 patients, 6 who were discharged to a skilled nursing facility were placed for social reasons, while the others were placed due to functional disability.

Follow-up was 100% complete for all 54 hospital survivors at a median of 30 months (range, 6-95 months). There were 12 late deaths due to heart failure ($n = 4$), cerebrovascular accident ($n = 3$), myocardial infarction ($n = 2$), trauma ($n = 1$), pneumonia ($n = 1$), and peripheral vascular disease ($n = 1$). Excluding the late deaths, the other 42 hospital survivors have required a total of 18 hospital admissions for the following reasons: congestive heart failure (7 [11.5%]); pneumonia (3 [4.9%]);

transient ischemic attack (2 [3.3%]); gastrointestinal tract bleeding (2 [3.3%]); myocardial infarction (2 [1.5%]); peripheral vascular disease (1 [1.6%]); and trauma (1 [1.6%]). One patient was admitted 3 times for congestive heart failure due to noncompliance with diuretic use. Actuarial survival among hospital survivors was 85% at 1 year and 66% at 5 years (**Figure 1**). There was no significant difference in actuarial survival according to the type of procedure performed (**Figure 2**).

The overall postoperative hospitalization burden was 0.12 admissions per patient per year (18 admissions for 42 patients during 145 patient-years of follow-up), which was significantly fewer than the mean of 2.1 admissions per patient during the year preceding the operation ($P < .001$).

The NYHA classification improved a median of 2 classes (**Figure 3**). The Karnofsky performance status improved 1 month after discharge by a median of 50% from a preoperative level of 30% (severely disabled, requiring special care) to a postoperative median of 80% (able to perform normal activity with only moderate symptoms) (**Figure 4**). These results were sustained at 3 months.

Postoperative complications were associated with longer duration of hospital stay but were not predictive of disposition to a skilled nursing facility or final postoperative Karnofsky performance status. Thirty-one variables were analyzed by univariate methods to deter-

Results of Univariate and Multivariable Analyses of Predictors of Outcome (*P* Values Listed)*

Variables	Early Mortality	Disposition to SNF	Postoperative Karnofsky Score	5-Year Survival
Univariate Analysis				
Demographic and preoperative				
Age	.13	.18	.49	.10
Transaortic valve gradient	.57	.26	.15	.60
Effective aortic valve area	.72	.21	.24	.67
Ejection fraction	.11	.73	.17	.14
Diabetes mellitus	.002	.54	.66	<.001†
Systemic hypertension	.01*	.54	.11	.14
Congestive heart failure	.97	.85	.37	.71
Coronary artery disease	.80	.89	.79	.25
Myocardial infarction	.16	.17	.77	.40
Pulmonary hypertension	.41	.34	.14	.65
COPD	.23	.38	.76	.73
Cerebrovascular accident	.68	.69	.85	.27
Peripheral vascular disease	.23	.81	.79	.17
Renal insufficiency	.01	.85	.25	.09
Hospitalization time	.009	.96	.25	.06
ICU stay	<.001†	.50	.23	<.001†
Mechanical ventilation	.02	.85	.25	.02
IABP	.36	.31	.05	.02
Karnofsky score	<.001	.002†	<.001†	.004
NYHA classification	.005†	.01	.01	.07
Operative				
Procedure	.65	.29	.18	.57
Concurrent CABG	.50	.50	.46	.34
Mechanical valve	.58	.06	.04	.42
Cardiopulmonary bypass time	.10	.48	.57	.04
Aortic cross-clamp time	.96	.36	.11	.51
Postoperative				
Significant complications	.61	.37	.02	.81
Reoperation for bleeding	.81	.53	.98	.41
Arrhythmia	.32	.005	.009	.88
Duration of hospital stay53	.13	.02
Disposition to SNF003	.45
SNF ≥3 mo002†	.36
Multivariable Analysis				
Diabetes mellitus	.02	NS	NS	.003
Preoperative ICU stay	<.03	NS	NS	<.001
Preoperative NYHA classification	.05	NS	NS	NS
Preoperative Karnofsky score	NS	.01	.01	NS
SNF ≥3 mo	NS	NS	.01	NS
Systemic hypertension	.02	NS	NS	NS

*Multivariable analysis was performed on all variables, with a level of significance of $P < .05$. SNF indicates skilled nursing facility; COPD, chronic obstructive pulmonary disease; ICU, intensive care unit; IABP, intra-arterial blood pressure; NYHA, New York Heart Association; CABG, coronary artery bypass grafting; ellipses, not applicable; and NS, not significant.

†Significant predictors.

mine predictors of operative mortality, disposition at time of discharge, postoperative functional status, and actuarial survival. Subsequent multivariable analysis of significant factors revealed the following independent predictors: (1) early mortality: systemic hypertension ($P = .02$), diabetes mellitus ($P = .02$), preoperative intensive care unit stay ($P < .001$), and NYHA class 4 ($P = .05$); (2) discharge disposition: preoperative Karnofsky score ($P = .01$); (3) postoperative performance status: preoperative Karnofsky score ($P = .01$) and placement in a skilled nursing facility for longer than 3 months ($P = .01$); and (4) 5-year survival: diabetes mellitus ($P = .003$) and preoperative intensive care unit admission ($P < .001$) (**Table**).

COMMENT

Recent national trends have shown a steady decrease in the operative mortality for isolated aortic valve replacement, and it is now less than 4% (Society of Thoracic Surgeons National Database, 1995-1996). Similar improvements for valve replacement in elderly patients have been documented, but the average mortality rate remains about twice as high in this group.^{5,9-12} Furthermore, the mortality rate alone does not accurately reflect the significant resource investment required for successful recovery from valve replacement in elderly patients. Since octogenarians are close to their maximum life expectancy, emphasis on long-term survival in these patients

following heart surgery may not be appropriate. Instead, patient selection criteria, quality of life, and future hospital use may be more important factors that will influence surgical recommendation.

Our data indicate that surgery for valvular heart disease can be performed safely in the octogenarian. However, the typical hospital stay is longer and more complicated, and the patient is more likely to require supervised medical care after discharge. Although the majority of the patients in this series underwent elective operations, most had severe heart failure preoperatively. This condition, along with the need for preoperative intensive care, were most predictive of early mortality. Our data suggest that while many other risk factors were present in these patients, they were not helpful in including or excluding patients for surgical consideration. Nevertheless, it is likely that the aggregate of risk profile variables have an important contribution to the preoperative quality of life and performance status of the patient.

Quantification of life and performance status following surgery is difficult and inherently subjective.¹³ Our study used the Karnofsky scale⁸ to estimate performance status preoperatively and postoperatively. This scale was originally designed to assess overall performance status in patients with cancer, although it has been used in some cardiac studies.¹⁴ Our study demonstrated a significant improvement in the Karnofsky score following successful heart valve replacement. Once fully recovered, our patients were more likely to resume independent activities with fewer symptoms. Not surprisingly, patients with low scores preoperatively were more likely to need skilled nursing care in the postoperative period.

In conclusion, we believe that heart valve replacement can be performed safely in the octogenarian. Significant improvements in symptoms, functional status, and quality of life of the patient can be expected. However, the patient and his or her family must be willing to invest in a longer and more complicated recovery. It is likely that fewer hospitalizations will be needed in the future, and there may be modest gains in long-term survival. Our data also suggest that further improvements in operative mortality may result from a reduction in the acuity (functional status) of the preoperative candidate. This may be achieved by earlier referral for surgery before advanced heart failure develops.

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DISCUSSION

R. Pat Cochran, MD, Seattle, Wash: The authors have addressed a very timely issue in an increasingly cost-conscious health care environment. If rationalization of health care is ever considered, one possible area would be reduction of services to the elderly. As the authors pointed out, in the next few years there will be a markedly increased population that will be considered candidates for these surgical interventions. As such, the authors are helping us sort out the difficult issue of whether high-dollar surgery is truly beneficial in the elderly.

In choosing valvular heart disease, the authors selected a population that has been shown in a number of series previously to have reasonable survival. The authors have gone to the next level by looking at return to function, which is a critical issue in the benefit of surgery for these patients. I am particularly impressed with the authors' use of the Karnofsky scale for assessing patient function. Other criteria that have been used for younger patient populations have been fraught with difficulty when applied to the elderly. The percentage of function used in the Karnofsky scale works very well for this population.

At the University of Washington, Seattle, we, too, have looked at this patient group. We are impressed that our octogenarian population is increasing at a geometric rate. We have reviewed 3 years of all cardiac operations in patients 80 years or older from 1992 to 1995. In that period, we operated on 130 patients, not just for valvular heart disease but for all types of cardiac surgery. In the very next year, 1996, the total number of octogenarians was 78. So in 1 year, we had almost a 2-fold increase in the number of octogenarians who were undergoing cardiac surgery.

Our experience is very similar to that of the authors. Overall, these patients do well, although they do require a longer hospitalization and have a higher need for rehabilitation or skilled nursing home support. Unfortunately, those patients who do not do well have many complications and an even greater hospital stay. These patients, although a small group, are large consumers of health care dollars and workforce. Herein lies the challenge that faces all of us as we consider caring for larger numbers in this age group. As such, I would like to ask the authors a few questions.

The first question is about the difference in actuarial survival by valve types. I was surprised to see better survival in

the patients with mitral rather than aortic valve types. Do you have an explanation?

The second question is about prosthesis choice. There is a surprisingly large number of mechanical valves for this age group, 22 of 61. Can you explain this choice, and what is your feeling about the risk of anticoagulant therapy in this group?

Finally, do you have any suggestions for means of screening the patients at higher risk? You have identified some risk factors that are statistically significant, both univariate and multivariate. Are you using those risk factors to screen patients in any way?

Dev R. Manhas, MD, Seattle: In our own practice we also are seeing more and more octogenarians. Most of these patients can be done with low operating room mortality; however, the 30-day mortality rate can be high and quality of life can be poor in this group because of high incidence of associated diseases. These patients may have a severely atherosclerotic and calcified aorta, carotid stenosis, which may be masked by the aortic stenosis, and renal insufficiency.

My questions are as follows: (1) are you performing routine carotid Doppler examinations in this group? If there is significant carotid disease, how are you managing such patients? (2) how do you handle the patients with severely diseased and calcified aorta?

Christopher R. Shackleton, MD, Vancouver, British Columbia: I would like to commend the authors on the rigor of their statistical analysis. I have one comment and one question. The use of logistic regression analysis may be a satisfactory method when you are looking at early mortality because often one has the specified follow-up period on all subjects. However, I would submit that for the longer-term mortality analysis, it is more correct to use Cox regression because it includes the element of time. As with logistic regression, it can handle both categorical and continuous variables.

What was the median follow-up in this patient group?

William P. Schecter, MD, San Francisco, Calif: This is a very high-risk group of patients. Do you have a discussion with them before surgery about what their wishes are if you get caught postoperatively? Do you have any criteria or anything to guide you about how long you leave a patient in limbo in the ICU and how you decide whether or not to withdraw support?

Bruce M. Wolfe, MD, Sacramento, Calif: I note that none of the patients died of cancer, which would be expected in such an elderly patient population. Did you make a special effort to screen the elective patients for cancer along with the cardiovascular screening that is done to select appropriate candidates?

John R. Benfield, MD, Sacramento: This is a very important article because outcomes research is becoming increasingly important in today's environment. In the states of New York and Pennsylvania, there is now regular publication of outcomes in cardiac surgery. Mortality rates of various institutions and even various surgeons are reported. To my knowledge, this kind of reporting is now limited to thoracic surgery, but I anticipate that this kind of information is going to become more widely available in all fields of surgery.

The Society of Thoracic Surgeons began the cardiac surgery database approximately 2 decades ago in response to reporting that was misleading because it was not risk stratified and therefore incomplete. On the basis of reporting outcomes without risk stratification, it was not really possible to know what the significance of the outcome was. Therefore, this article is very important.

I have one question: Were you able to assess any socioeconomic factors that influenced the outcome? We all know that factors that are manifested by the postoperative level of family support do exist, and yet we have a very difficult time measuring the effect of these factors on outcomes.

John T. Vetto, MD, Portland, Ore: I liked this article because it brings up the fact that we do more quality-of-life research as surgeons than we realize in the area of observer-assessed quality of life. For example, surgical oncologists usually publish data using the Karnofsky scale. Cardiac surgeons often publish NYHA scale data, and we often refer to the American Society of Anesthesiologists scale, which is recognized as a very valid quality-of-life instrument. So we are doing more of this research than we realize.

My question is, tell us again a little bit more about how you came to use the Karnofsky scale and how you came to make that transition with an oncology scale to this area of surgery, and is there established validity for the Karnofsky scale in heart surgery?

James E. Goodnight, Jr, MD, Sacramento: To echo the comments of Dr Benfield, cardiothoracic surgery has led the surgical profession in outcome data, and there is much for the rest of us to learn. The quality-of-life assessments are from the viewpoint of the surgeon and from the viewpoint of the physician. It may be worth adding some type of tool, and looking for the right tool is difficult, that would assess quality of life from the patient's viewpoint and then I would challenge them and challenge all of us to look at those cost data: the cost of the surgery and subsequent hospitalization vs ongoing medical therapy.

Dr Merrick: In response to Dr Cochran's questions, all of which are very important, our decision as to what type of valve to use in this patient group follows fairly standard guidelines. That is to say, in the older age group, we would like to avoid the use of long-term anticoagulant therapy if possible. To that end, we typically recommend a biological prosthetic valve. The patients who received a mechanical valve did so for 1 of several reasons: either they were experiencing chronic atrial fibrillation and were using anticoagulant therapy beforehand or their native aortic valve annulus was small. As you know, the gradient across a small mechanical valve is less than that of a bioprosthetic valve, and a lower gradient may contribute to a more favorable long-term result. So, we tried to use biological prostheses whenever possible, but that wasn't always the case.

As Dr Khan alluded, the difference in actuarial survival was actually not significant according to the type of procedure performed. If we had treated more patients, those curves may have reached statistical significance. In that situation, one might speculate that there is not enough time in elderly patients for ventricular remodeling after aortic valve replacement as opposed to mitral valve replacement. This factor could influence survival, especially when it is fairly short as it is in this age group.

How do we screen patients preoperatively, and do we use any of our data to guide surgical recommendation? Well, that is a very good question. For this group of patients, we had no special screening methods, except to say that we did not operate on patients with severe dementia or medical conditions causing severe disability. Obviously, however, our cardiologists prescreen these patients for us. Unfortunately, the screening process typically sends us the more complicated and sicker patients. We hope that from these data that we can tell our referral sources that it is better to refer the elderly patient sooner, particularly before severe heart failure develops. That may well reduce the perioperative mortality.

To the other discussants, again I appreciate your questions. Dr Manhas asked if we used carotid ultrasonography routinely in the preoperative assessment. The answer is no, unless the patients had symptoms of cerebral ischemia or a history of stroke. If the patient was found to have a symptomatic, critical carotid stenosis, it is a bit of a dilemma. Fortunately, we haven't had too many of those patients, but we would follow the general principle to operate on the most symptomatic le-

sion first, if possible. We did not perform any combined carotid and valve procedures in this group.

How do we handle the calcified aorta? I don't think there are any easy answers to that question. In our opinion, much depends on whether or not you can safely apply the aortic cross clamp. If you can't, then you are faced with replacement of the ascending aorta using deep hypothermia and circulatory arrest. Dr Manhas, the median follow-up was 30 months.

Yes, Dr Schechter, we do have a very extensive discussion with the family preoperatively and a lot of that revolves around the ability of the patients to take independent care of themselves postoperatively. If they can't do that, it is not necessarily a reason to deny them surgery, but at least it prepares them for the eventuality of being in a skilled nursing facility, which all of you know is usually not a pleasant experience for patients.

In terms of support withdrawal, I would say that a fraction of these patients, not enough, already have advanced directives so that it is easier to deal with a hopeless situation.

Do we see cancer more frequently in this patient population? Well, I have seen 2 patients in the last year who had aortic valve replacements and have developed acute leukemia late postoperatively, but we have not seen any other cancers to date. Other than the usual screening tools used in the preoperative assessment, we don't do anything special.

We agree that Cox regression is best for long-term outcome, and we did use this method for assessing actuarial survival.

Dr Benfield, you asked a very important question. In our opinion, the psychosocial makeup of the patient and his or her family is a critical determinant of resource utilization and allocation. We observed that our length of stay, for example, is very dependent on the family's willingness to care for the patient at home. That is not to say that home care is an easy task, but many families would rather send the patient to a skilled care facility and that often takes some time to arrange. The best patient is one who has a devoted family and who is having an elective procedure.

In answer to Dr Vetto's question about our use of the Karnofsky score, there really is not anything else out there that is any better. Although it is a subjective score, it does take into account the patient's activity status, which as all of you know can be a critical factor in determining the long-term functional status of patients after any type of major operation. If you perform a major operation, one of the obvious objectives is to return the patient to a productive or functional lifestyle. The Karnofsky score as it exists now is one of the only tools to measure this. Should it be administered by staff other than the surgeons? The answer is yes. If we had that resource, we would definitely use it.

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Sexual Transmission of the Hepatitis C Virus and Efficacy of Prophylaxis With Intramuscular Immune Serum Globulin: A Randomized Controlled Trial

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Objectives: To estimate the risk of sexual transmission of hepatitis C and to assess the value of prophylaxis with periodic intramuscular immune serum globulin administration.

Methods: Of 1102 steady heterosexual partners of patients with antibodies to the hepatitis C virus (HCV), 899 were enrolled in a single-blind, randomized, controlled trial. All the partners tested negative for antibodies to HCV and had normal baseline serum aminotransferase concentrations. The partners were assigned to receive 4 mL of 16% polyvalent immune serum globulin prepared from unscreened donors every 2 months (n=450) or a placebo (n=449). Tests for HCV infection were performed every 4 months.

Results: Eight hundred eighty-four partners completed the study. Seven partners became infected with HCV: 6 in the control group (incidence density, 12.00 per 1000 person-years; 95% confidence interval, 3.0-21.61) and 1 in the immune serum globulin group (incidence density, 1.98 per 1000 person-years; 95% confidence interval, 0-5.86). The risk of infection was significantly higher for partners in the control group ($P=.03$): for each year approximately 1% of the partners became infected. Sequence homology studies strongly suggest the sexual transmission of HCV. All immune serum globulin lots used had high enzyme-linked immunosorbent assay titers of neutralizing antibodies to HCV envelope glycoproteins and high neutralization titers in the neutralization of binding assay.

Conclusions: Hepatitis C can be sexually transmitted. Immune serum globulin prepared from unscreened donors significantly reduced the risk. The treatment was safe and well tolerated. Because only immune serum globulin from unscreened donors (and not from those screened for HCV) contain anti-HCV neutralizing antibodies, hyperimmune anti-HCV immune serum globulin should be prepared from blood testing positive for antibodies to HCV, which is currently discarded. *Arch Intern Med.* 1997;157:1537-1544

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