Outcomes of surgical aortic valve replacement in moderate risk patients: Implications for determination of equipoise in the transcatheter era

Sebastian A. Iturra, MD, Rakesh M. Suri, MD, DPhil, Kevin L. Greason, MD, John M. Stulak, MD, Harold M. Burkhart, MD, Joseph A. Dearani, MD, and Hartzell V. Schaff, MD

Objective: To determine the contemporary outcomes of surgical aortic valve replacement (SAVR) in a moderate surgical risk population.

Methods: We studied 502 consecutive adults who had undergone isolated SAVR from January 2002 to June 2011 for severe aortic valve stenosis with a Society of Thoracic Surgery predicted risk of mortality of 4% to 8%. We included concomitant coronary artery bypass and aortic annular enlargement but not other concomitant procedures. The updated Valve Academic Research Consortium definitions were used, as appropriate.

Results: The median age was 80 years (range, 49-96), 323 (64.3%) had New York Heart Association class III-IV symptoms, and 101 (20.1%) had undergone previous coronary artery bypass grafting. The mean predicted risk of mortality was 5.6%. Concomitant coronary artery bypass grafting was performed in 270 (53.8%). Re-exploration for bleeding occurred in 29 (5.8%), stroke in 9 (1.8%), and vascular complications in 2 (0.4%). In the cohort, 14 early deaths (2.8%) occurred. During follow-up (1174 days), 175 patients died. Using multivariate logistic regression analysis, the significant independent predictors of mid-term death included chronic pulmonary disease (hazard ratio, 2.00, 95% confidence interval, 1.41-2.84; $P < .001$), peripheral vascular disease (hazard ratio, 1.58; 95% confidence interval, 1.05-2.37; $P = .029$), and atrial fibrillation (hazard ratio, 1.75; 95% confidence interval, 1.16-2.65; $P = .008$).

Conclusions: SAVR in moderate-risk patients is currently performed with one half of the early predicted risk (2.8%) and a low likelihood of complications, including a 1.8% incidence of stroke. Patients counseled for randomization to transcatheter aortic valve insertion should be informed of the excellent early to mid-term outcomes of SAVR, particularly those without pulmonary impairment, peripheral vascular disease, or atrial fibrillation. (J Thorac Cardiovasc Surg 2014;147:127-32)

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Senile calcific aortic valve stenosis is the most frequent heart valve condition of elderly patients and has been associated with an excess mortality once symptoms appear.[1-3] Surgical aortic valve replacement (SAVR) has been proved to improve symptoms and prolong survival, with very low morbidity and mortality.[4] Recent randomized controlled trials have demonstrated that transcatheter aortic valve implantation (TAVR) offers similar rates of survival and symptom improvement to high-risk and inoperable patients at 2 years of follow-up.[5] When considering therapy for patients with aortic stenosis (AS) at lower surgical risk, genuine uncertainty exists regarding the best treatment option, particularly for those at moderate risk of death after SAVR (Society of Thoracic Surgeons [STS] predicted risk of mortality [PROM], 4-8%). Three randomized controlled trials are currently underway to ascertain the differences in outcomes after SAVR versus TAVR in moderate-risk patients: the Placement of Aortic Transcatheter Valve (PARTNER) IIA trial, studying the Edwards SAPIEN XT valve (Edwards Lifesciences, Irvine, Calif); Surgical Replacement and Transcatheter Aortic Valve Implantation (SURTAVI), using the Medtronic CoreValve System (Medtronic, Minneapolis, Minn); and the St Jude Portico trial (St Jude Medical, St Paul, Minn). The accurate prediction of perioperative morbidity and mortality in patients referred for TAVR evaluation remains challenging, however, because no risk model has been validated specifically for TAVR candidates and the currently used surgical scoring systems can either over- or underestimate the actual periprocedural risk.[6]

From the Division of Cardiovascular Surgery, Mayo Clinic, Rochester, Minn.

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Address for reprints: Rakesh M. Suri, MD, DPhil, Division of Cardiac Surgery, Mayo Clinic, 200 First St SW, Rochester, MN 55902 (E-mail: suri.rakesh@mayo.edu).

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Abbreviations and Acronyms

AS = aortic stenosis
AVR = aortic valve replacement
CABG = coronary artery bypass grafting
EuroSCORE = European System for Cardiac Operative Risk Evaluation
PROM = predicted risk of mortality
SAVR = surgical aortic valve replacement
STS = Society of Thoracic Surgeons
TAVR = transcatheter aortic valve implantation

We thus sought to test the hypothesis that the STS PROM would be capable of accurately predicting actual mortality in moderate-risk subgroups to help inform patients' decisions and better prepare cardiac care specialists to ascertain whether equipoise exists in the randomization of patients to TAVR or SAVR in current trials.

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METHODS

Study Design and Population

The Mayo Clinic investigational review board approved the present study. Informed consent was waived according to the investigational review board specifications. From January 2002 to June 2011, 4499 SAVR procedures were performed at the Mayo Clinic (Rochester, Minn) to treat aortic valve stenosis. We included those with severe aortic valve stenosis (mean gradient $\geq$ 40 mm Hg) and an STS PROM of 4% to 8% (current version data set, 2.73 of the STS risk calculator). The records were excluded if they included multiple valve procedures or other major nonvalve-related operations, other than coronary artery bypass grafting (CABG) and aortic annular enlargement.

Clinical Data

The Division of Cardiovascular Surgery database, patient medical records, follow-up questionnaires, and Social Security Death Index were reviewed for patient demographics, medical history, baseline symptoms, cardiac status, perioperative complications, readmission, and early and mid-term mortality. The variables evaluated during the study period included gender, age, left ventricular ejection fraction, STS PROM, body mass index, diabetes mellitus, hypertension, chronic lung disease, peripheral vascular disease, cerebrovascular disease, renal failure, atrial fibrillation, mitral regurgitation, coronary artery disease, previous CABG, previous pacemaker, previous percutaneous coronary intervention, previous aortic valve balloon-plasty, previous myocardial infarction, aortic valve gradient, New York Heart Association heart failure functional class, aortic annular enlargement, associated CABG, and urgent surgery. Data on these variables were collected in keeping with the standard definitions set forth by the STS as a part of the National Adult Cardiac Surgery Database. We used the clinical endpoint definitions recommended by the updated Valve Academic Research Consortium.[7] We performed clinical follow-up examinations and sent surveys to all patients at regular intervals of 1, 3, and 5 years after surgery to ascertain their clinical status and postoperative complications.

Statistical Analysis

Continuous data are expressed as the mean $\pm$ standard deviation or median and range. The determined values were compared with the early and mid-term mortality. Variables significant on univariate analysis were used during stepwise selection to create the final multivariate model. Statistical significance was considered at $P < .05$. Early operative mortality was defined as death occurring within 30 days of surgery or at any point during the index hospitalization.

RESULTS

A total of 502 patients who met the inclusion criteria were included in the present analysis. The baseline characteristics of the patients are listed in Table 1. The median patient age was 80 years (range, 49-96), and 277 patients (55.2%) were men. The mean STS PROM was 5.6% (standard deviation $\pm$ 1.09). Hypertension was present in 415 patients (82.7%), diabetes mellitus in 157 (31.3%), chronic pulmonary disease in 119 (23.7%), and renal failure, defined as a basal creatinine $\geq$ 2.0 mg/dL, in 20 (4.0%). Only 2 patients (0.4%) were dialysis dependent preoperatively. Atrial fibrillation was present in 45 patients (9.0%), previous myocardial infarction in 43 (8.6%), previous percutaneous coronary intervention in 79 (15.7%), and previous percutaneous aortic balloon-plasty in 2 (0.4%). Of the 502 patients, 323 (64.3%) presented with New York Heart Association class III-IV heart failure symptoms. The mean left ventricular ejection fraction was 60%. Previous CABG had been performed in 101 patients (20.1%).

Urgent surgery was required in 64 patients (12.7%). The median crossclamp and cardiopulmonary bypass time was 60 and 82 minutes, respectively. Aortic valve bioprostheses were implanted in 477 patients (95.0%). Concomitant CABG was necessary in 270 patients (53.8%). Aortic annular enlargement with a pericardial patch was necessary in 25 patients (5.0%). Red blood cell transfusion was required in 296 patients (59.0%). The median mechanical ventilation and intensive care unit admission duration was 13.5 hours (range, 3-1092) and 28 hours (range, 5-849), respectively.

The frequencies of early complications are listed in Table 2. These included re-exploration for bleeding in 29 (5.8%), atrial fibrillation or flutter in 207 (41.2%), perioperative myocardial infarction in 2 (0.4%), stroke in 9 (1.8%), acute kidney injury stage II in 23 (4.6%), new-onset dialysis in 11 (2.1%), pneumonia in 20 (4.0%), major vascular complications in 2 (0.4%; lower extremity ischemia secondary to the use of a femoral intra-aortic balloon pump), and deep sternal infection in 1 patient (0.2%).

There were 14 (2.8%) early deaths, of which 9 (64.3%) were cardiac related. Three were immediate procedural mortalities according to the updated Valve Academic Research Consortium criteria. Of the 232 patients who had undergone isolated aortic valve replacement, 6 (2.58%) died compared with 8 of 270 (2.96%) who undergone associated CABG ($P = .798$). We were unable to identify univariate predictors of early death, including previous CABG, concomitant CABG, and STS PROM