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Minimally invasive aortic valve replacement in octogenarian, high-risk, transcatheter aortic valve implantation candidates

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Objective: Risk-stratifying algorithms are currently used to determine which patients may be at prohibitive risk for surgical aortic valve replacement, and thus candidates for transcatheter aortic valve implantation. Minimally invasive surgical approaches have been successful in reducing morbidity and improving survival after aortic valve replacement, especially in octogenarians. We documented outcomes after minimally invasive aortic valve replacement in high-risk octogenarians who may be considered candidates for percutaneous/transapical aortic valve replacement.

Methods: From 1996 to 2009, minimally invasive aortic valve replacement was performed in 249 consecutive octogenarians. We used the modified European System for Cardiac Operative Risk Evaluation and Society of Thoracic Surgeons score to risk-stratify patients and characterize all early and late results.

Results: The mean age at operation was 84 ± 3 (range 80–95) years, and 111 patients (45%) were male. Twenty-one percent (n = 52) had previous cardiac surgery. Operative mortality was 3% (n = 8/249). The median modified European System for Cardiac Operative Risk Evaluation (11%; interquartile range, 6–14) and Society of Thoracic Surgeons score (10.5%; interquartile range, 7–17) were not predictive of 30-day mortality in this cohort of patients (European System for Cardiac Operative Risk Evaluation c-index = 0.527, $P = .74$, Society of Thoracic Surgeons score c-index = 0.67, $P = .18$). Despite their poor predictive power, the Society of Thoracic Surgeons score and European System for Cardiac Operative Risk Evaluation were correlated with each other ($r = 0.40$, $P < .0001$). Postoperative complications included stroke in 10 patients (4%), pneumonia in 3 patients (1%), renal failure requiring dialysis in 2 patients (1%), cardiac arrest in 2 patients (1%), pulmonary embolism in 1 patient (1%), and sepsis in 1 patient (1%). Follow-up was available for 238 patients (96%) and extended up to 12 years. Overall, long-term survival after minimally invasive aortic valve replacement at 1, 5, and 10 years was 93%, 77%, and 56%, respectively. There was no significant difference in long-term survival compared with that of a US age- and gender-matched population (standardized mortality ratio, 1.01; 95% confidence interval, 0.76–1.37; $P = .88$). A multivariate Cox-proportional hazards model indicated that increasing age (hazard ratio, 1.10; $P = .008$) and severe chronic obstructive pulmonary disease (hazard ratio, 2.52; $P < .007$) were significant predictors of survival. By using these factors, a clinical prediction model ($P = .02$) was developed and demonstrated that low-risk patients (first quartile prediction score) had 1-, 5-, and 8-year survival of 94%, 84%, and 67%, whereas high-risk patients (third quartile prediction score) had 1-, 5-, and 8-year survival of 89%, 74%, and 49%, respectively.

Conclusions: Patients thought to be high-risk candidates for surgical aortic valve replacement have excellent outcomes after minimally invasive surgery with long-term survival that is no different than that of an age- and gender-matched US population. These data provide a benchmark against which outcomes of transcatheter aortic valve implantation could be compared. (J Thorac Cardiovasc Surg 2011;141:328-35)

Aortic valve replacement (AVR) for the treatment of severe and symptomatic aortic stenosis (AS) is the standard of care. In recent years, however, there has been rapid technologic advancement in percutaneous approaches to achieve aortic valve implantation.[1-6] However, because of excellent outcomes after AVR even in high-risk patients,[7] innovative approaches such as transcatheter aortic valve implantation (TAVI) have been reserved for patients with severe AS deemed to be at very high or prohibitive surgical risk. In this inoperable cohort, a recent prospective multicenter TAVI trial demonstrated a procedural success rate exceeding 90%, with a 30-day and 1-year cumulative mortality rate of 10.4% and 22.1%, respectively.[6] These statistics are consistent with other single-institution studies that have gained a vast experience in TAVI.[5,8]

The decision-making process that ultimately determines which patients are at prohibitive risk for AVR has recently

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Disclosures: Authors have nothing to disclose with regard to commercial support.

Read at the 90th Annual Meeting of The American Association of Thoracic Surgery, Toronto, Ontario, Canada, May 1–5, 2010.

Received for publication April 16, 2010; revisions received Aug 1, 2010; accepted for publication Aug 23, 2010; available ahead of print Nov 8, 2010.

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0022-5223/$36.00

doi:10.1016/j.jtcvs.2010.08.056

Abbreviations and Acronyms

AS	= aortic stenosis
AVR	= aortic valve replacement
COPD	= chronic obstructive pulmonary disorder
EuroSCORE	= European System for Cardiac Operative Risk Evaluation
HR	= hazard ratio
MiniAVR	= minimally invasive aortic valve replacement
OR	= odds ratio
STS	= Society of Thoracic Surgeons
STS-PROM	= Society of Thoracic Surgeons Predicted Risk of Mortality
TAVI	= transcatheter aortic valve implantation

come into question.[9] Ideally, clinical decision-making would consist of a physician's assessment of a patient's overall health and his/her suitability to tolerate cardiac surgery. In recent years, surgical scoring systems have been developed to use a wide array of preoperative variables in an effort to accurately determine a patient's risk of mortality.[10,11] The models that have been predominantly implemented into clinical practice are the European System for Cardiac Operative Risk Evaluation (EuroSCORE)[10] and the Society of Thoracic Surgeons Predicted Risk of Mortality (STS-PROM) score.[11] Although some studies have found these models to be highly accurate and predictive of operative morbidity and mortality,[12,13] there is increasing evidence that these models may be less accurate at predicting outcomes in patients who are at extreme ends of the risk spectrum.[14,15] Recent studies have found that these scoring systems do not account for clinical and anatomic characteristics (ie, patient frailty and a porcelain aorta[6]) that are thought to be highly relevant to a patient's ability to tolerate AVR. As a result, there is concern in the surgical community that reliance on these prediction models may inappropriately direct patients to TAVI when in fact, they may be good surgical candidates.

It is our contention and that of others[14] that AVR can be performed safely in high-risk patients.[14,16-18] Although retrospective in nature and limited by treatment bias, studies have shown that AVR in octogenarians can be achieved with an operative mortality as low as 5.9%[17] and 1- and 5-year survivals of up to 90% and 70%, respectively.[18] Since the introduction of minimally invasive cardiac surgery by Svensson,[19] Cosgrove and Sabik,[20] and our group at Brigham and Women's Hospital,[21] we have continued to perform the majority of isolated AVRs through a minimally invasive approach (MiniAVR) in almost all circumstances, including reoperations.[16-18,22,23] Our experience with MiniAVR has demonstrated that patients benefit from decreased length of hospital stay, as well as decreased morbidity and dependence on rehabilitation services after discharge.[24] As such, we believe these favorable outcomes are likely to be amplified in patients at high risk of perioperative morbidity.

We hypothesized that the current trend in cardiac surgery to move toward percutaneous restorative interventions may have failed to acknowledge the success and safety of open replacement. Furthermore, we believe that current risk-prediction models may overestimate risk in appropriately chosen and optimized patients, leading some to recommend interventional techniques over traditional approaches. As such, the purpose of this study is to assess the reliability of the current risk-prediction models for patients undergoing MiniAVR. In addition, we aim to evaluate immediate perioperative outcomes after isolated MiniAVR in octogenarians who might otherwise be considered candidates for TAVI. Finally, our third objective is to document long-term survival to serve as a benchmark for outcomes after TAVI.

MATERIALS AND METHODS

The main objective of this study is to identify and examine a cohort of patients who would serve as comparable group of patients to those being offered TAVI currently, and potentially in the future. Our inclusion criteria consisted of all patients aged more than 80 years who underwent AVR using a minimally invasive hemi-upper sternotomy (MiniAVR) approach. Exclusion criteria consisted of those who underwent concomitant surgical procedures, because these patients are generally not offered TAVI and outcomes would not be directly comparable to high-risk patients undergoing isolated TAVI.

On the basis of these criteria, 249 consecutive octogenarians underwent isolated MiniAVR by 12 surgeons between August 29, 1996, and March 17, 2009. Preoperative, hemodynamic, operative, and postoperative characteristics were captured via a prospectively collected database modeled after STS national database criteria.[11] To risk stratify patients, the STS-PROM[11] was calculated for each patient. Because of significant limitations in interpretability of both the additive and logistic EuroSCORE, the modified EuroSCORE[25] (a distinct score from both the additive and logistic score), which has been shown to enhance the accuracy and clinical relevance of both the additive and logistic EuroSCORE,[25] was calculated for all patients. Primary end points included all-cause 30-day mortality, 180-day mortality, stroke, sepsis, reoperation for bleeding, need for hemodialysis, and long-term survival. Survival data were obtained from clinical visits and correspondence from consulting physicians. The Brigham and Women's Institutional Review Board approved this study.

Statistical Analysis

Demographic and other patient-related data were obtained from Brigham and Women's Hospital medical records. Continuous variables are expressed as a mean ± standard deviation or median with interquartile range (IQR) in situations where covariates are not normally distributed. Categoric variables are expressed as a percentage. Because our prospective clinical research database is modeled after the STS national database, the STS-PROM score was directly calculated for each patient according to the most recently released formula.[11] The logistic and additive EuroSCOREs were calculated after the necessary STS covariate manipulation[26]; these