Characterization and outcome of patients with severe symptomatic aortic stenosis referred for percutaneous aortic valve replacement

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Objective: Many high-risk patients with severe symptomatic aortic stenosis are not referred for surgical aortic valve replacement. Although this patient population remains ill-defined, many of these patients are now being referred for percutaneous aortic valve replacement. We sought to define the characteristics and outcomes of patients referred for percutaneous aortic valve replacement.

Methods: Between February 2006 and March 2007, 92 patients were screened for percutaneous aortic valve replacement. Clinical and echocardiographic characteristics of patients undergoing surgical aortic valve replacement, percutaneous aortic valve replacement, balloon aortic valvuloplasty, or no intervention were compared. The primary end point was all-cause mortality.

Results: Nineteen patients underwent successful surgical aortic valve replacement, 18 patients underwent percutaneous aortic valve replacement, and 36 patients had no intervention. Thirty patients underwent balloon aortic valvuloplasty, and of these, 8 patients were bridged to percutaneous aortic valve replacement and 3 were bridged to surgical aortic valve replacement. Of the remaining 19 patients undergoing balloon aortic valvuloplasty, bridging to percutaneous aortic valve replacement could not be accomplished because of death (n = 9 [47%)], exclusion from the percutaneous aortic valve replacement protocol (n = 6 [32%]), and some patients improved after balloon aortic valvuloplasty and declined percutaneous aortic valve replacement (n = 4 [21%]). The most common reasons for no intervention included death while awaiting definitive treatment (n = 10 [28%]), patient uninterested in percutaneous aortic valve replacement (n = 10 [28%]), and questionable severity of symptoms or aortic stenosis (n = 9 [25%]). Patients not undergoing aortic valve replacement had higher mortality compared with those undergoing aortic valve replacement (44% vs 14%) over a mean duration of 220 days.

Conclusion: Symptomatic patients with severe aortic stenosis have high mortality if timely aortic valve replacement is not feasible. Twenty percent of the patients referred for percutaneous aortic valve replacement underwent surgical aortic valve replacement with good outcome. Patients undergoing balloon aortic valvuloplasty alone or no intervention had unfavorable outcomes.

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Aortic stenosis (AS) is the most common valvular lesion in the aging population, with a prevalence of 4.6% in adults more than 75 years of age.[1-3] Surgical aortic valve replacement (SAVR) is the recommended treatment for symptomatic patients.[4] After the onset of symptoms, average survival can be as low as 1 to 3 years without SAVR.[4-8] However, many patients with severe symptomatic AS do not undergo surgical intervention for various reasons. Some are not referred for intervention because of the presence of comorbidities or patient preference, and others are deemed inoperable by the surgeon because of the presence of coexisting illnesses. This is particularly the case for the elderly. In the Euro Heart Survey on valvular heart disease, 33% of patients with severe symptomatic AS did not undergo surgical intervention.[9] Other studies have similarly shown that 27% to 41% patients with severe symptomatic AS do not undergo SAVR.[8,10-12]

These studies included patients who were identified by means of screening echocardiographic laboratory databases for severe AS or those who were referred for SAVR. It is possible that there are other patients who do not come to the attention of cardiologists or tertiary care centers for various reasons. With the advent of percutaneous aortic valve replacement (PAVR),[13-18] many of these patients are now being referred for this ''less invasive'' investigational procedure. This provides a unique opportunity to characterize the unmet need for aortic valve replacement. Accordingly, we studied the characteristics and outcomes of patients referred for PAVR.

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Abbreviations and Acronyms

AS = aortic stenosis
BAV = balloon aortic valvuloplasty
MR = mitral regurgitation
PAVR = percutaneous aortic valve replacement
REVIVAL = Transcatheter Endovascular Implantation of Valves
SAVR = surgical aortic valve replacement
STS = Society of Thoracic Surgeons

MATERIALS AND METHODS

All patients screened at our institution for PAVR have been included in a prospective registry. These were patients who were thought to be at very high risk for SAVR by the referring doctors. Ninety-two consecutive patients screened for PAVR from February 2006 through March 2007 were included in this prospective cohort study. At baseline, all patients underwent a structured assessment, including history and physical examination, electrocardiogram, Doppler echocardiography, and coronary and peripheral angiography. All patients with severe AS, irrespective of the previous recommendations from referring institutions, were independently evaluated by 2 surgeons for aortic valve replacement. The decision to perform either SAVR or PAVR was made by a multidisciplinary team consisting of cardiologists with expertise in clinical, interventional, and imaging fields; cardiothoracic surgeons; and cardiac anesthesiologists with extensive experience in SAVR in high-risk patients. The decision-making process was a complex interplay of clinical presentation, physical examination, and various diagnostic tests, along with consideration of social situation (Figure 1). If patients were not candidates for cardiac surgery, they were evaluated for the Transcatheter Endovascular Implantation of Valves (REVIVAL) trial. The Society of Thoracic Surgeons (STS) score was primarily used to make this determination; however, factors that are not captured in the STS score, such as prior chest radiation, porcelain aorta, anatomic issues (eg, grafts or cardiac chambers adherent to sternum and lack of sternum), and severe debilitation, were also taken into account to determine the candidacy for SAVR. Under the REVIVAL study protocol, PAVR was performed only in patients who were deemed inoperable or had an estimated operative mortality of greater than 15%, as per the inclusion criteria. Patients who were excluded from PAVR for reasons such as thrombocytopenia (n = 2), cancer (n = 2), severe left ventricular dysfunction with an ejection fraction of less than 20% (n = 1), and age of less than 70 years (n = 1) underwent balloon aortic valvuloplasty (BAV). Patients who were neither accepted for cardiac surgery nor for the REVIVAL trial were clinically evaluated and medically managed. BAV was offered to those patients who could be considered for surgical intervention in the future if their general status improved and to those who could not leave the hospital because of AS-related congestive heart failure. All patients who underwent BAV were re-evaluated for SAVR. For analysis, patients who were bridged to SAVR or PAVR after BAV were included in the respective groups (SAVR or PAVR). Clinical and echocardiographic characteristics were compared among these patients based on the modality of treatment. The primary end point for outcome was all-cause mortality. Mortality was assessed by querying the Social Security Death Index or by directly referring to patient charts in case of in-hospital mortality. Length of hospital stay and postoperative complications were determined by means of chart review. The institutional review board waived requirements for informed consent.

Continuous data are presented as means ± standard deviation. Student's *t* test was used to compare mean values for continuous variables. Multiple groups were compared by using 1-way analysis of variance. Post-hoc analysis was performed with the Newman–Keuls test. The χ^2 or Fisher's exact test was used to find significant associations between categorical variables.

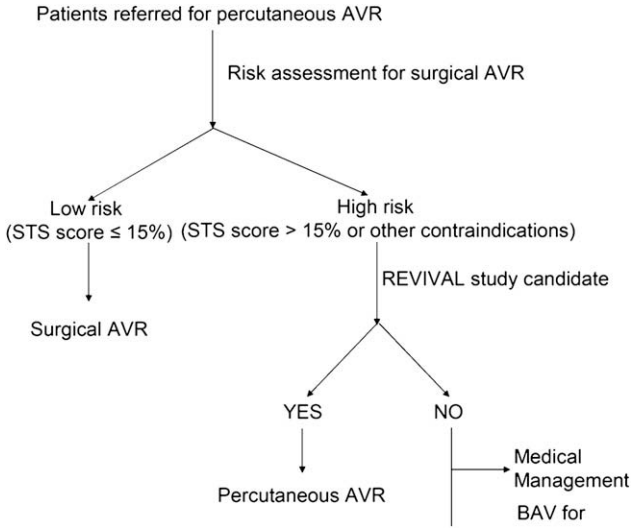

FIGURE 1. Decision process. *AVR*, Aortic valve replacement; *REVIVAL*, Transcatheter Endovascular Implantation of Valves; *STS*, Society of Thoracic Surgeons; *BAV*, balloon aortic valvuloplasty.

All tests were 2-tailed. Statistica 6.1 (Statsoft, Inc, Tulsa, Okla) software was used for analysis.

RESULTS

Patient Characteristics

Baseline characteristics of the 4 groups are shown in Table 1. Of the 92 patients screened, 53 (58%) were 80 years or older, and 36 (39%) were 85 years or older. There were 35 (39%) patients who had at least 1 prior cardiac surgery, 30 (34%) who had previously diagnosed severe lung disease (forced expiratory volume in 1 second ≤1 L or on home oxygen), and 10 (11%) who had chronic kidney disease (serum creatinine value, >2 mg/dL). There were 23 (25%) patients with a left ventricular ejection fraction of 30% or less and 10 (11%) patients with an ejection fraction of 20% or less. Additionally, 14 (15%) patients had severe mitral regurgitation (MR), and 33 (36%) patients had severe pulmonary hypertension (systolic pulmonary artery pressure, ≥50 mm Hg; Figure 2). The mean Logistic EuroSCORE of all patients was 26, with 51% of patients having a score of greater than 20. The mean STS score of all patients was 12.8, with 43% of patients having a score of 10 or greater.

Patient Management

Further information on patient management is shown in Figure 3. Of the 92 patients who were screened for possible PAVR, 19 (21%) underwent SAVR, and 18 (20%) underwent PAVR. Of the patients who underwent aortic valve replacement, 3 were bridged to SAVR after BAV, and 8 were bridged to PAVR after BAV. Nineteen (21%) patients could not be bridged to aortic valve replacement after BAV. Of these 19 patients who underwent BAV alone, 9 (47%) died while waiting for PAVR, 4 (21%) improved after

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