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Transcatheter Aortic Valve Implantation in Patients With Severe Aortic Stenosis and Small Aortic Annulus

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Objectives Valve hemodynamics and clinical outcomes among patients with a small aortic annulus who underwent transcatheter aortic valve implantation (TAVI) were examined.

Background The presence of a small aortic annulus may complicate the surgical management of patients with severe aortic stenosis (AS). TAVI is an alternative to aortic valve replacement (AVR) in high-risk patients, but few data exist on the results of TAVI in patients with a small aortic annulus.

Methods Between 2007 and 2010, 35 patients (mean age 79.2 ± 9.4 years) with severe AS and an aortic annulus diameter <20 mm (mean 18.5 ± 0.9 mm) underwent TAVI with a 23-mm Edwards SAPIEN bioprosthesis (Edwards Lifesciences, Inc., Irvine, California). Echocardiographic parameters and clinical outcomes were assessed prior to discharge and at 6, 12, and 24 months.

Results Procedural success was achieved in 34 patients (97.1%). There was 1 in-hospital death. Peak and mean transaortic gradients decreased from 76.3 ± 33.0 mm Hg and 45.2 ± 20.6 mm Hg at baseline to 21.8 ± 8.4 mm Hg and 11.7 ± 4.8 mm Hg post-procedure, respectively, both $p < 0.0001$. Mean indexed effective orifice area (IEOA) increased from 0.35 ± 0.10 cm^2/m^2 at baseline to 0.90 ± 0.18 cm^2/m^2 post-procedure, $p < 0.0001$. Severe prosthesis–patient mismatch (IEOA <0.65 cm^2/m^2) occurred in 2 patients (5.9%). At a mean follow-up of 14 ± 11 months, gradients remained low and 30 of the 31 remaining survivors were in New York Heart Association functional class I or II.

Conclusions In high-risk patients with severe AS and a small aortic annulus, TAVI is associated with good post-procedural valve hemodynamics and clinical outcomes. TAVI may provide a reasonable alternative to conventional AVR in elderly patients with a small aortic annulus. (J Am Coll Cardiol 2011;58:1016–24) © 2011 by the American College of Cardiology Foundation

Aortic valve replacement (AVR) in patients with severe aortic stenosis (AS) and a small aortic annulus has been associated with a high incidence of prosthesis–patient mismatch (PPM) (1–3). PPM has in turn been associated with diminished extent of regression of left ventricular hypertrophy, reduced coronary flow reserve, increased incidence of congestive heart failure, diminished functional capacity, and increased risk of early and late mortality (4–7). In order to allow implantation of an appropriately sized prosthetic valve and prevent PPM in a patient with a small aortic annulus, an aortic annular enlargement procedure or a complete replacement of the aortic root may be necessary at the time of AVR. These procedures significantly enhance the complexity of the operation, and may increase morbidity and mortality, especially in elderly patients (8,9).

Transcatheter aortic valve implantation (TAVI) has emerged as an alternative to AVR in high-risk patients with AS (10–12), and implanted prostheses perform well compared with currently available surgical valves with respect to relief of aortic stenosis and post-procedural valve hemodynamics (13). However, no specific data exist on the results of TAVI in patients with a small aortic annulus. In this study, we sought to examine prosthetic valve hemodynamics, as well as early and midterm outcomes of patients with a small aortic annulus who underwent TAVI at our institution.

Methods

Patient population. We identified all patients with severe, symptomatic, native-valve AS and an aortic annular diameter <20 mm who underwent TAVI either by a transfemoral or transapical approach at our institution. Patients that

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were selected for TAVI had been deemed unsuitable for conventional surgery by consultant cardiac surgeons. All patients were initially evaluated for the feasibility of a transfemoral approach; a transapical approach was ultimately selected in the setting of a prohibitively small or diseased iliofemoral arterial tree, and in the presence of mobile plaque, excessive calcification, or extreme tortuosity of the descending thoracic aorta and/or aortic arch. Further details regarding patient selection, use of a transfemoral versus transapical approach, and procedural technique have been previously published (12–14). All patients provided written informed consent, and the study was in compliance with our institutional research ethics board. Preoperative characteristics including patient demographics, cardiovascular risk factors, and comorbid medical illnesses, as well as procedural and post-operative data, were prospectively collected by dedicated personnel and entered into a registry. All patients received a 23-mm Edwards SAPIEN bioprosthesis (Edwards Lifesciences, Inc., Irvine, California). Procedural success was defined as the successful implantation of a functioning prosthesis within the aortic annulus, without procedural mortality or conversion to sternotomy. Longitudinal follow-up was obtained by outpatient clinic visit and/or telephone contact at 6 and 12 months post-procedure and yearly thereafter.

Doppler echocardiography. Aortic annulus diameter was measured preoperatively using transesophageal echocardiography (TEE) in the long-axis, mid-esophageal view, from leaflet insertion to leaflet insertion in mid-systole (15). Post-procedural prosthetic transvalvular pressure gradients and effective orifice area (EOA) were measured prior to hospital discharge and at 6 and 12 months post-procedure and yearly thereafter. The left ventricular outflow tract diameter was measured immediately proximal (ventricular) to the valve prosthesis stent insertion site for calculation of the post-procedural EOA by the continuity equation (16). EOA was indexed for the patient's body surface area. Severe PPM was defined as an indexed EOA (IEOA) <0.65 cm^2/m^2, and moderate PPM was defined as an IEOA between 0.65 and 0.85 cm^2/m^2 (2,17). Post-procedural aortic insufficiency (AI) was classified as paravalvular, transvalvular, or mixed, depending on the origin of the regurgitant jet(s). The severity of regurgitation was graded as mild, moderate, or severe (18).

Statistical analysis. Statistical analysis for the study was performed using Statistical Analysis System (SAS) software version 9.2 (SAS Institute, Inc., Cary, North Carolina). Continuous variables were expressed as mean ± SD and were compared using paired *t* tests or nonparametric equivalents where appropriate. Mixed effects modeling was used to determine the statistical significance of transaortic gradients and aortic valve areas at different time periods. An unrestricted covariance structure was used to measure the dependence among repeated measurements. The multivariate normality assumptions were verified with the Shapiro-Wilk test after a Cholesky factorization. Categorical variables were expressed as percentages. Mixed effects ordinal regression was performed to test for significant changes in AI over time. All-cause mortality at mid-term follow-up was evaluated using the Kaplan-Meier technique. All p values were 2-sided, and differences were considered statistically significant when $p < 0.05$.

Abbreviations and Acronyms

AI = aortic insufficiency
AS = aortic stenosis
AVR = aortic valve replacement
CI = confidence interval
EOA = effective orifice area
IEOA = indexed effective orifice area
NYHA = New York Heart Association
PPM = prosthesis–patient mismatch
TAVI = transcatheter aortic valve implantation
TEE = transesophageal echocardiography

Results

Between April 2007 and July 2010, 164 patients with severe symptomatic AS underwent TAVI at our institution. Excluding patients with failed bioprosthetic aortic prostheses, a total of 68 patients received a 23-mm valve, and among these, 35 patients (51.5%) with an aortic annular diameter <20 mm (mean 18.5 ± 0.9 mm, range 16 to 19.5 mm) were identified (Fig. 1). Eleven patients underwent a transfemoral approach (31.4%), and the remainder underwent a transapical procedure. Reasons for selecting a transapical approach were small iliofemoral arteries (n = 18), extensive thrombus or mobile atherosclerotic plaque in the abdominal or thoracic aorta (n = 4), horizontal ascending aorta (n = 1), and extreme tortuosity of the descending thoracic aorta (n = 1). The mean age of patients was 79.2 ± 9.4 years, ranging from 55 to 96 years. Eleven patients (31.4%) had undergone previous cardiac surgery (coronary artery bypass graft surgery in 10 patients, mitral valve replacement in 1 patient). Other baseline clinical and echocardiographic characteristics of the patient cohort are shown in Table 1.

Procedural success was achieved in all but 1 patient (97.1%). This patient was a 96-year-old female with a severely calcified aortic valve, severe pulmonary hypertension, and logistic EuroSCORE of 70.6. Transapical TAVI was complicated by residual post-procedural moderate paravalvular aortic regurgitation and left ventricular apical bleeding requiring surgical repair with multiple pledgeted sutures. Delayed balloon aortic valvuloplasty was performed, but the patient remained in cardiogenic shock leading to death on the third post-operative day. Autopsy revealed a large anteroapical myocardial infarction that was likely iatrogenic, related to the left ventricular apical repair, given the absence of coronary artery disease on preoperative coronary angiography. This was the only in-hospital death. This patient was excluded from subsequent analyses of post-procedural prosthetic valve hemodynamics.

Major procedural and 30-day complications were severe paravalvular aortic regurgitation requiring implantation of a second 23-mm Edwards SAPIEN prosthesis within the