Transapical aortic valve implantation at 3 years

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Objective: Our objective was to analyze the results of transapical aortic valve implantation in high-risk patients with aortic stenosis at up to 3 years after the procedure.

Methods: A total of 299 patients underwent transapical aortic valve implantation from February 2006 until January 2010 using the Edwards SAPIEN transcatheter xenograft. Mean patient age was 82 ± 6 years and 70% were female. Logistic EuroSCORE and Society of Thoracic Surgeons score predicted risks for mortality were 31% ± 16% and 12% ± 8%, respectively. All patients were treated in a hybrid operative theater by a team of anesthetists, cardiologists and cardiac surgeons.

Results: Successful valve implantation was performed in all patients. Transapical aortic valve implantation was uneventful in 267 patients (89.3%), whereas 32 patients (10.7%) required additional interventions. Such interventions included cardiopulmonary bypass support in 18, implantation of a second SAPIEN valve in 15, coronary intervention in 9, conversion to conventional surgery in 6, and annulus perforation in 3 patients (not mutually exclusive). Intraprocedural stroke was not observed in any patient, although 2 (0.7%) patients had a delayed stroke during their hospital stay. Overall survival was 91% at 30 days, 73% at 1 year, 68% at 2 years, and 58% at 3 years.

Conclusions: Transapical aortic valve implantation can be performed with good outcomes in high-risk patients with aortic stenosis. Perioperative complications occur in approximately 10% of patients, and a variety of interventions are required for these events. We believe a team approach is therefore essential for the success of transapical aortic valve implantation (J Thorac Cardiovasc Surg 2012;143:326-31)

Conventional aortic valve replacement (AVR) is a standardized procedure with very good outcomes in patients with aortic stenosis (AS).[1-3] Over time, however, patients requiring AVR have been increasing in age with an increasing number of comorbidities. Parallel to this trend, transcatheter (T) aortic valve implantation (AVI) techniques have been developed for minimally invasive therapy. T-AVI is currently being recommended for elderly high-risk patients only.[4] After CE approval in 2008, these procedures are gaining increasing acceptance in Europe. For example, transapical (TA) AVI is being performed in more than 50% of all German cardiac surgical centers.

For T-AVI a retrograde transfemoral (TF) or an antegrade TA approach is available.[5-11] The CoreValve prosthesis (Medtronic, Inc, Minneapolis, Minn) is being used for TF implantations and the SAPIEN prosthesis (Edwards Lifesciences, Inc, Irvine, Calif) for TF and TA implantations. There is no randomized clinical trial comparing clinical results using the TF and the TA approaches at present; thus the superiority or inferiority of these approaches has not yet been proven. In addition, large-volume single-center results as well as intermediate-term outcome of TA-AVI have not yet been reported. The aim of our study was therefore to analyze the outcomes of TA-AVI in a large number of consecutive patients, as well as to characterize the follow-up status at up to 3 years after the procedure.

METHODS

From February 2006 until January 2010, a total of 299 patients underwent TA-AVI using the Edwards SAPIEN transcatheter xenograft. All patients gave written informed consent and the study was approved by the institutional ethics review board. Elderly patients with severe AS and a high risk profile (additive EuroSCORE ≥ 9) or known risk factors for conventional surgery such as a porcelain aorta, chest radiation, previous cardiac surgery, or previous mediastinitis underwent the screening protocol for T-AVI. Such screening started with transesophageal echocardiography to measure the aortic annulus diameter and determine the pattern of leaflet calcification, as well as to exclude any other significant valve dysfunction. A minimum device oversizing of 1 mm in exceptional cases (ie, patients at very high risk for conventional surgery with a ''borderline'' annulus diameter) and 2 mm in all other patients was required. Cardiac catheterization was performed to exclude coronary artery disease. Patients with suspicion of a short aortic annulus to coronary artery distance on cardiac catheterization underwent additional computed tomographic visualization of the aortic root to more accurately determine this distance. In addition, pulmonary function testing and carotid duplex studies were performed routinely in all patients. All patients who were referred to our department with symptomatic AS that fulfilled the abovementioned risk criteria were screened for potential TA-AVI. Patients were discussed by the transcatheter valve team, consisting of cardiologists and cardiac surgeons, before the implantation

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Abbreviations and Acronyms

AVI = aortic valve implantation
AS = aortic stenosis
AVR = aortic valve replacement
CPB = cardiopulmonary bypass
FEV_1 = functional expiratory volume in 1 second
STS = Society of Thoracic Surgeons
T-AVI = transcatheter aortic valve implantation
TA = transapical
TF = transfemoral

was scheduled. However, patients who were referred directly to our cardiology department were investigated with a "TF first" intention whereas those who were referred directly to our cardiac surgery department were investigated with a "TA first" approach. Patient-specific factors were also considered when deciding on the procedural approach. For example, patients with severe peripheral vascular disease or small femoral arteries (<7 mm in diameter) were preferentially treated with TA-AVI and patients with severe respiratory dysfunction (functional expiratory volume in 1 second [FEV_1] < 50% of predicted) were preferentially treated with TF-AVI. TA-AVI was performed in a hybrid operative theater by a team of cardiac anesthetists, cardiologists, and cardiac surgeons in a standard fashion as described previously.[12] Heparin (100 IU/kg) was administered during the procedure to achieve an activated clotting time of 300 seconds. Transthoracic echocardiography was performed before discharge in all patients and at yearly intervals thereafter in the majority of patients. Follow-up consisted of mail and/or telephone interview of patients and/or their family members and was supplemented by information from the patients' cardiologists and/or family physicians. Postoperative medication consisted of aspirin (100 mg/d) only in patients who were in sinus rhythm and of additional clopidogrel or warfarin treatment if required for other indications, for example, stent placement or chronic atrial fibrillation.

During the study period of 4 years, a total of 1700 patients underwent isolated conventional AVR at our center. The annual number of isolated AVR procedures increased slightly over the study period, in parallel with the increasing number of T-AVI procedures. Approximately 700 high-risk patients were entered into the screening process for T-AVI, and approximately half of those patients were treated with TF-AVI and the other half with TA-AVI.

STATISTICAL ANALYSIS

Continuous variables are expressed as mean ± standard deviation for those variables with a gaussian distribution or as median values only for nonnormally distributed data. Categorical data are expressed as proportions. Independent continuous variables were compared by the 2-tailed Student *t* test or Mann-Whitney *U* test as appropriate. Cumulative survival was calculated by Kaplan-Meier methods with 95% confidence limits. Statistical calculations were performed using the 17.0 SPSS (SPSS, Inc, Chicago, Ill) and Microsoft Excel 2007 (Microsoft, Redmond, Wash) software packages.

RESULTS

A total of 299 patients received TA-AVI during the study period. The mean age was 82.1 ± 6.4 years and 209 patients (70%) were female. Additive EuroSCORE predicted risk of mortality was 11.8 ± 2.2, logistic EuroSCORE was 31% ± 16%, and Society of Thoracic Surgeons (STS) score was 12% ± 8%. Preoperative New York Heart Association functional status was II in 49 (16.4%), III in 199 (66.6%), and IV in 51 (17%) patients. Data on preoperative patient characteristics are supplied in Table 1. Perioperative and follow-up outcome data are displayed in Table 2.

Stroke occurred in 2 patients during the in-hospital stay. Both were extubated initially without any symptoms or lateralizing neurologic signs, but then sudden incomplete hemiparesis developed on postoperative day 1. Functional recovery was good in both patients. During the overall follow-up period, another 3 patients had a stroke. Temporary renal replacement therapy (continuous venovenous hemodialysis or dialysis) was required in 15% of patients

TABLE 1. Preoperative patient characteristics

N	299
Age (y)	82.1 ± 6.4
Female (n/%)	209 (70%)
Ejection fraction	55 ± 14
Prior CVA/TIA	56 (18.7%)
Pulmonary hypertension	80 (26.8%)
Previous cardiac surgery	84 (28.1%)
Peripheral vascular disease	141 (47.2%)
Porcelain aorta	39 (13%)
Chronic pulmonary disease	129 (43.1%)
FEV_1 < 50% of normal	18 (6%)
FEV_1 50%-70% of normal	50 (16.7%)
VC < 50% of normal	25 (8.4%)
VC 50%-70% of normal	63 (21.1%)
Creatinine > 200 μmol/L	26 (8.7%)
Chronic dialysis	8 (2.7%)

CVA, Cerebrocascular accident; *TIA,* transitory ischemic attack; *FEV_1,* functional expiratory capacity in 1 second; *VC,* vital capacity.

TABLE 2. Perioperative parameters and outcomes

N	299
Logistic EuroSCORE	31% ± 15.8%
STS score	12% ± 7.7%
Thirty-day mortality	8.7%
Annulus diameter	22.7 ± 1.5 mm
SAPIEN valve diameter	25.2 ± 1.5 mm
Surgical bleeding	
Chest wall	1% (n = 3)
Left ventricular apex	1% (n = 3)
Conversion to sternotomy and conventional AVR	2% (n = 6)
Contrast dye	99 ± 64 mL
Endocarditis	0.4% (n = 1)
Perioperative stroke	0.7% (n = 2)
Reoperation for > moderate AI	0.7% (n = 2)
New onset pacemaker implantation	4% (n = 12)

STS, Society Thoracic Surgeons; *AVR,* aortic valve replacement; *AI,* aortic incompetence.