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Transapical Implantation of a Second-Generation Transcatheter Heart Valve in Patients With Noncalcified Aortic Regurgitation

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Objectives This study sought to report on the feasibility and early results of transcatheter aortic valve implantation employing a second-generation device in a series of patients with pure aortic regurgitation.

Background Efficacy and safety of transcatheter aortic valve implantation in patients with calcific aortic stenosis and high surgical risk has been demonstrated. However, experience with implantation for severe noncalcified aortic regurgitation has been limited due to increased risk for valve dislocation or annular rupture.

Methods Five patients (mean age: 66.6 ± 7 years) underwent transapical implantation of a JenaValve (JenaValve Technology GmbH, Munich, Germany) transcatheter heart valve for moderate to severe, noncalcified aortic regurgitation. All patients were considered high risk for surgical aortic valve replacement after evaluation by an interdisciplinary heart team (logistic EuroSCORE [European System for Cardiac Operative Risk Evaluation] range 3.1% to 38.9%). Procedural and acute clinical outcomes were analyzed.

Results Implantation was successful in all cases without relevant remaining aortic regurgitation or signs of stenosis in any of the patients. No major device- or procedure-related adverse events occurred and all 5 patients were alive with improved exercise tolerance at 3-month follow-up.

Conclusions Noncalcified aortic regurgitation continues to be a challenging pathology for transcatheter aortic valve implantation due to the risk for insufficient anchoring of the valve stent within the aortic annulus. This report provides first evidence that the JenaValve prosthesis may be a reasonable option in these specific patients due to its unique stent design, clipping the native aortic valve leaflets, and offering promising early results. (J Am Coll Cardiol Intv 2013;6:590–7) © 2013 by the American College of Cardiology Foundation

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Efficacy and safety of transcatheter aortic valve implantation (TAVI) in patients with severe aortic stenosis and contraindications or high risk for conventional surgery have been demonstrated (1,2). However, off-label treatment of severe noncalcified aortic regurgitation using the self-expanding Medtronic CoreValve prosthesis (Medtronic, Minneapolis, Minnesota) or the balloon-expandable Edwards Sapien XT valve (Edwards Lifesciences, Irvine, California) has only been described infrequently (3–6). Although feasibility has been demonstrated, pure regurgitation poses a challenge on TAVI due to the absence of annular or leaflet calcifications required for secure anchoring of transcatheter heart valves (THV), increasing the risk of dislocation.

With the recent CE-mark (Conformité Européenne) approval of second-generation devices for TAVI, new stent designs and technologies have become available. The JenaValve prosthesis (JenaValve Technology GmbH, Munich, Germany) features a unique clip fixation mechanism of the native aortic valve leaflets that may offer secure anchorage of the THV even in the absence of calcifications (7). Therefore, this device may be an appropriate option, even in patients with noncalcified aortic regurgitation.

We report for the first time on the feasibility and early results of TAVI using the JenaValve THV in a series of patients with pure aortic regurgitation.

Methods

Patient population and diagnostic work-up. Between September 2007 and December 2012, 750 TAVI procedures have been performed at our institution, almost exclusively for severe symptomatic aortic stenosis. From May through September 2012, 5 patients were admitted; 4 presented with symptomatic noncalcified aortic regurgitation, and 1 patient with severe heart failure scheduled for implantation of a left ventricular assist device (LVAD) and concomitant moderate aortic regurgitation. All patients presented with severe comorbidities or previous operations, yielding an increased operative risk for surgical aortic valve replacement as determined by an interdisciplinary heart team (Table 1). In addition to routine work-up, pre-operative transesophageal echocardiography was performed to determine valve pathology and to assess ventricular function and dimensions. The aortic annulus diameter was measured in the short-axis view. Aortic regurgitation was assessed in the parasternal long-axis view and graded according to the Doppler vena contracta width (8,9). Additionally, the color Doppler jet width was indexed to the left ventricular outflow tract width, as obtained in the parasternal short-axis view (9,10). A contrast-enhanced multislice computed tomography with prospective electrocardiogram-gating was employed to assess aortic valve and root morphology (Fig. 1). Area- and perimeter-derived aortic annulus diameters, optimal C-arm angulation, and transapical access location were determined using the 3mensio valves software (3mensio Medical Imaging BV, Bilthoven, the Netherlands), as previously described (11).

Procedure. TAVI was performed in a specially equipped hybrid suite under general anesthesia by an interdisciplinary heart team of cardiac surgeons, interventional cardiologists, and anesthesiologists. Transapical access was gained in the usual fashion through a left lateral minithoracotomy and purse-string sutures were applied to the left ventricular apex. The delivery catheter was introduced and positioned over a stiff guidewire. The THV size was selected according to the annulus diameters gained from multislice computed tomography. Following the manufacturer's recommendations, a 23-mm prosthesis was chosen for an aortic annulus of 21 to 22.9 mm, a 25-mm prosthesis for an aortic annulus of 23 to 24.9 mm, and a 27-mm prosthesis for an aortic annulus of 25 to 27 mm. Anatomically oriented implantation of the JenaValve prosthesis, a trileaflet porcine root tissue valve attached to a nitinol stent, was performed without the use of rapid ventricular pacing under fluoroscopic control (Fig. 2, Online Video 1), as previously described (12). Briefly, the delivery catheter with the loaded JenaValve prosthesis was advanced through the native valve into the ascending aorta and the positioning feelers were released and placed into the corresponding sinuses of the aortic root. After correct orientation had been verified in 2 different fluoroscopic angulations, the lower stent part was subsequently released, resulting in the clipping and attachment of the noncalcified aortic valve leaflets to the device and expansion of the stent. Subsequently, valve performance was assessed by transesophageal echocardiography and fluoroscopy. We refrained from balloon valvuloplasty of the native aortic valve before THV implantation except for 1 patient with secondary commissural fusion (Patient #2). In another patient, TAVI was followed by subsequent implantation of an LVAD (HVAD, HeartWare, Framingham, Massachusetts).

Abbreviations and Acronyms

LVAD = left ventricular assist device

TAVI = transcatheter aortic valve implantation

THV = transcatheter heart valve

Data management and clinical follow-up. All relevant baseline, procedural, and follow-up data were prospectively collected. Clinical and echocardiographic examinations were performed prior to discharge, at 30 days, and at 3 months. Outcomes were analyzed in accordance with the updated standardized endpoints defined by the Valve Academic Research Consortium-2 consensus document (13).

Ethics. All patients were fully informed about the procedure and this off-label use of the THV, and they signed written consent forms.

Results

Baseline characteristics. Five patients (mean age: 66.6 ± 7 years, 80% men) presented with noncalcified aortic