

Transcatheter Aortic Valve Implantation in Patients With Bicuspid Aortic Valve Stenosis

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Objectives We evaluated transcatheter aortic valve implantation (TAVI) in high-risk patients with bicuspid aortic valve (BAV) stenosis.

Background TAVI shows promise in the treatment of severe stenosis of tricuspid aortic valves, especially in high-risk patients. However, BAV stenosis has been considered a contraindication to TAVI.

Methods Eleven patients (age 52 to 90 years) with symptomatic severe BAV stenosis underwent TAVI at 3 Canadian tertiary hospitals between May 2006 and April 2010. All patients were considered high risk for surgical aortic valve replacement. Edwards-SAPIEN transcatheter heart valves (Edwards Lifesciences, Inc., Irvine, California) were used. Transfemoral or transapical access was selected, depending on the adequacy of femoral access.

Results Access was transfemoral in 7 patients and transapical in 4 patients. There were no intraprocedural complications. Significant symptomatic and hemodynamic improvement was observed in 10 of 11 patients. Baseline aortic valve area of 0.65 ± 0.17 cm² and mean transaortic pressure gradient of 41 ± 22.4 mm Hg were improved to 1.45 ± 0.3 cm² and 13.4 ± 5.7 mm Hg, respectively. Two patients had moderate perivalvular leaks. At the 30-day follow-up there were 2 deaths due to multi-system failure in 2 transapical patients. In 1 patient an undersized, suboptimally positioned, unstable valve required late conversion to open surgery.

Conclusions TAVI in selected high-risk patients with severe BAV stenosis can be successfully performed with acceptable clinical outcomes but will require further evaluation. (J Am Coll Cardiol Intv 2010;3:1122–5) © 2010 by the American College of Cardiology Foundation

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Bicuspid aortic valves (BAV) occur in approximately 1% of the population (1), making this the most common congenital cardiac anomaly. Although silent until adulthood, stenosis and/or incompetence often develop in mid-life, requiring aortic valve replacement. Transcatheter aortic valve implantation (TAVI) is an emerging alternative technique that has shown promise in the treatment of severe aortic stenosis in patient populations at high risk with conventional surgery (2). The presence of a BAV has been considered an exclusion for TAVI. We describe our experience with TAVI in high-risk patients of severe aortic stenosis due to BAV.

Methods

Patients referred with severe symptomatic aortic stenosis due to BAV were assessed for TAVI in 3 Canadian tertiary hospitals. All patients were considered to be ineligible or high risk for conventional aortic valve replacement surgery by a multidisciplinary group of cardiologists and cardiac surgeons. Informed, written consents were obtained. Patients with adequate femoral access underwent transfemoral TAVI; otherwise, transapical access was used.

The details of the TAVI procedure have been described elsewhere (3,4). General anesthesia, transesophageal echocardiography (TEE), pre-implantation balloon aortic valvuloplasty, and rapid ventricular pacing to reduce cardiac output were routinely used (5). In transarterial procedures, the Retroflex delivery system was used, followed by percutaneous or surgical closure of the femoral artery. In transapical procedures, the Ascendra delivery system was used with surgical closure of the left ventricular apex and thoracotomy.

Edwards-SAPIEN transcatheter heart valves (Edwards Lifesciences, Inc., Irvine, California) were used. Two sizes were available, with an external diameter of 23 or 26 mm. An echocardiographic annulus diameter between 18 and 21 mm was considered suitable for the smaller valve and between 21 and 26 mm for the larger valve. Transthoracic echocardiography was used for screening purposes, and intraprocedural TEE was used for final measurement of the diameter of the aortic annulus.

Results

Patients. TAVI was performed in 11 patients with stenotic BAV between May 2006 and March 2009 at St. Paul's Hospital (n = 8), Quebec Heart and Lung Institute (n = 2), and Hamilton Health Sciences Centre (n = 1). Mean age was 73.2 ± 12.5 years (range 52 to 90 years); there were 6 men and 5 women. The Society of Thoracic Surgeons (STS) estimated surgical mortality was $4.4 \pm 2.6\%$. Although STS scores do not reflect a high-risk population, many patients had comorbidities that are not fully accounted for by the STS score, including end-stage liver failure (n = 2) and frailty (n = 4).

Baseline transthoracic echocardiography before the TAVI reported a mean aortic valve area of 0.65 ± 0.17 cm² and mean gradient of 41.0 ± 22.4 mm Hg. No patient had more than mild aortic incompetence. One patient had severe mitral regurgitation. Ten of these patients had congenital bicuspid valves, whereas the other had a functional bicuspid valve. Seven of them had severely calcified valves, whereas the other 4 had moderate calcification. Left ventricular ejection fraction was $46.7 \pm 16.1\%$. The diameters of the aortic root were approximately the upper limits of normal; left ventricular outflow tract was 22.1 ± 1.9 mm (transthoracic echocardiography), aortic annulus was 24.0 ± 2.3 mm (TEE), aortic root at the level of sinuses of Valsalva was 39.4 ± 5.8 mm (aortography), and ascending aorta was 38.3 ± 4.6 mm (aortography).

Procedural outcome. Valves were successfully implanted in all 11 patients. Access was transfemoral in 7 patients and transapical in 4 patients. The 26-mm Edwards-SAPIEN valve (Edwards Lifesciences, Inc.) was used in 10 patients, whereas a 23-mm valve was used in 1 patient. Pre-implantation balloon valvuloplasty was done with a balloon 2 to 3 mm smaller in diameter compared with the aortic annular size. Full balloon expansion could be achieved in all the cases. None of the patients developed significant aortic incompetence after balloon valvuloplasty.

The position of the implanted valve was optimal in 10 patients. In these 10 patients, there was significant hemodynamic improvement with a reduction in mean pressure gradient to 13.4 ± 5.7 mm Hg and an increase in mean valve area to 1.45 ± 0.3 cm². All valves appeared to open relatively symmetrically with a circular appearance on TEE (Fig. 1). No patient had significant valvular aortic incompetence after valve implantation. Three patients had moderate perivalvular leaks. In the single patient with severe mitral regurgitation, this was reduced to moderate and remained stable. Left ventricular ejection fraction rose from $46.7 \pm 16.1\%$ to $56.0 \pm 16.3\%$.

In 1 transapical case the annulus was thought to be suitable for a 26-mm valve on the basis of transthoracic echocardiography. However, intraprocedural echocardiography documented a 28-mm annulus. The valve was deployed too ventricular with a native leaflet incompletely covered by and extending over the valve frame. There was an initial modest improvement in valve area and gradient.

Follow-up. The 30-day survival was 82%. At a median follow-up of 208 days (interquartile range: 21.5 to 534.5 days, longest follow-up: 1,172 days), 7 patients (all transfemoral access patients) remained alive. They also remained with minimal symptoms (New York Heart Association

Abbreviations and Acronyms

BAV = bicuspid aortic valve(s)

STS = Society of Thoracic Surgeons

TAVI = transcatheter aortic valve implantation

TEE = transesophageal echocardiography

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