Door Widening on Potential TAVI Populations

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PARIS – In inoperable patients with severe aortic stenosis, their EuroSCORE – a predicted operative mortality from cardiac surgery – consistently predicted outcomes from transcatheter aortic valve implantation in a prospective, single-center study.

Among 177 consecutive patients declined for surgery, the procedural success rate was 100% in patients with a EuroSCORE of less than 20% and 95.7% in those with a EuroSCORE of more than 20%.

Moreover, there were no deaths at 30 days in the low-risk group, but mortality was 11.1% in the high-risk group. This result was maintained at 1 year (5% vs. 25%), and both differences were highly significant, Dr. Matthieu Godin reported at the congress.

"This may be the first step towards a broader assessment of percutaneous techniques in populations at lower surgical risk, but without forgetting that surgery is currently the … standard," he said.

Transcatheter aortic valve implantation (TAVI) is not commercially avaliable in the United States. In Europe, however, TAVI is considered a less invasive therapeutic option for severe aortic stenosis among nonsurgical and high–surgical-risk patients, as defined by a logistic EuroSCORE (European System for Cardiac Operative Risk) of more than 20% or a Society of Thoracic Surgeons risk score of more than 10%.

TAVI is frequently performed, however, in patients with low to intermediate logistic EuroSCOREs and contraindications to conventional valve replacement due to comorbidities not included in the surgical risk models, said Dr. Godin of Rouen (France) University Hospital–Charles Nicolle Hospital, where the first TAVI was performed in 2002 by coinvestigator Dr. Alain Cribier (Circulation 2002;106:3006-8).

In an effort to address this evolution and an eager marketplace, the American College of Cardiology and Society of Thoracic Surgeons released an expert consensus document that explores key components that will be necessary for successful integration of transcatheter valve therapy into clinical practice (J. Am. Coll. Cardiol. 2011;58:445-55. Epub 2011 Jun 28). While praising the "transformational technology," the societies cite limited evidence from only one randomized trial in aortic stenosis (PARTNER) and one in mitral insufficiency (EVEREST II) in stating that "adoption of these techniques to populations beyond those studied in these randomized

CoreValve Shows No Signs of Degeneration After 3 Years

PARIS – Hemodynamic values were sustained up to 3 years after CoreValve transcatheter aortic valve implantation among 393 patients with severe symptomatic aortic stenosis.

Importantly, there were no signs of unexpected early degeneration of the CoreValve prosthesis, lead author Dr. Anke Opitz reported at the congress.

One of the fundamental questions facing transcatheter aortic valve implantation (TAVI) is whether the durability of transcatheter aortic valves is comparable to that of conventional biological aortic valves, which typically start degenerating at about 10-15 years.

"We expect that the duration will be as long as the conventional biological aortic valves, but this is a completely new style of valve," Dr. Opitz said in an interview. "It's very different from the conventional valves because you have to crimp these valves [on to the catheter] and sometimes you do post dilation, so there's a lot more stress on the valves than on the conventional ones," she added.

The CoreValve (Medtronic) and Edwards Sapien (Edwards Lifesciences) transcatheter valves are limited to investigational use in the United States but have been available in Europe since 2007.

U.S. approval of the Edwards Sapien valve is expected, however, following a July 2011 U.S. Food and Drug Administration advisory panel vote in favor of the valve for treatment of certain inoperable patients.

Dr. Opitz reported on 393 consecutive patients implanted from June 2007 to June 2011 at the German Heart Center in Munich with the CoreValve device, which consists of a self-expandable nitinol stent with a porcine pericardium valve. Femoral access was possible in 87% of patients; 63% of patients were implanted with a 29-mm prosthesis and 37% with a 26-mm prosthesis.

The patients' mean age was 80 years, mean EuroSCORE was 19.1%, and their mean Society of Thoracic Surgeons risk score was 5.8%.

We expect the duration to be as long as the conventional valves, but this is a completely new style.

DR. OPITZ

Transthoracic echocardiography revealed that the effective orifice area increased significantly, from 0.7 cm^2 at baseline to 1.55 cm^2 after TAVI, and remained unchanged through 36 months at 1.57 cm^2 in 20 evaluable patients, Dr. Opitz reported.

The peak aortic valve gradient decreased significantly after TAVI (78 mm Hg vs. 21 mm Hg), as did the mean aortic valve gradient. Both gradients remained low through the 36 months. Severity of stenosis rises with the gradients.

Septal wall thickness also decreased significantly, from 14.9 mm preoperatively to 13.1 mm at 36 months follow-up.

Left ventricular end diastolic diameter remained unchanged from baseline at 12-, 24-, and 36-month follow-ups. The percentage of patients with a left ventricular ejection fraction less than 35% decreased significantly, from 19% at baseline to 4% at 12 months, 6% at 24 months, and 7% at 36 months, Dr. Opitz said.

Paravalvular aortic valve regurgitation occurred in 64% of patients after TAVI but was trivial or mild in 65%, mild to moderate in 20%, and moderate in 15%, she noted.

Dr. Opitz reported no conflicts of interest. ■

One-Year Survival Better in Women Than Men After TAVI

PARIS – Although female sex is a risk factor for worse outcomes after conventional cardiac surgery, the opposite appears to be true following transcatheter aortic valve implantation.

Among 260 consecutive patients undergoing TAVI for severe aortic stenosis, female sex was linked with significantly better 1-year survival (76% vs. 65%).

The study, described as the first analysis of sex difference with this emerging technique, also identified female sex as an independent predictor of long-term survival, Dr. Kentaro Hayashida and his colleagues reported at the congress.

The increased survival rate in women treated with TAVI may represent a paradox in the cardiovascular disease gender gap.

"Surgical aortic valve replacement in female patients is technically demanding because of their smaller stature and body surface area, higher body mass index, and smaller aortic root," Dr. Hayashida of the Institut Cardiovasculaire Paris-Sud (ICPS) in Massy, France, said in an interview. "In our study cohort, TAVI was performed with a similar device success rate, compared to males, because of the procedural feasibility inherent in this novel technique."

TAVI was successfully achieved in 91% of women and 88.4% of men, a nonsignificant difference. Similarly, no significant sex differences were observed for 30-day mortality (12% for women and 18% for men).

Longer life expectancy and early detection of aortic stenosis in women may, in part, have contributed to their improved survival, coauthor and colleague Dr. Philippe Garot said. He pointed out that despite both sexes having made gains in cardiovascular disease mortality from 1950 to 1999, an 80-year-old man in France can expect to live 8.3 more years, compared with 10.5 additional years for an 80-year-old French woman.

The average age at the time of surgery was 83 years in both study groups.

At baseline, women had a significantly lower logistic EuroSCORE (European System for Cardiac Operative Risk Evaluation, 22% vs. 26%), higher left ventricular ejection fraction (54% vs. 47%) and less coronary artery disease (49% vs. 79%), peripheral artery disease (27% vs. 40%), and previous cardiac surgery (14% vs. 26.4%) than did men.

Women, however, also had a significantly smaller femoral artery size (7.74 vs. 8.55 mm), annulus size (20.9 vs. 22.9 mm), and valve size (23.9 vs. 26.3 mm) than did men, Dr. Garot said.

Longer life expectancy may partially explain the increased TAVI survival in women.

DR. GAROT

In a multivariate analysis, male sex was identified as an independent predictor of long-term mortality (odds ratio, 1.80), the authors reported. Other significant risk factors were previous cardiac surgery (OR, 2.3), postprocedural aortic regurgitation (OR, 2.3), transfusion of four or more units (OR, 2.5), acute kidney injury (OR, 6.9), and conversion to open surgery (OR, 5.1).

Notably, vascular complications were not associated with mortality in the study, Dr. Garot said.

Data were prospectively collected on 131 women and 129 men with severe aortic stenosis who were treated at the ICPS from September 2006 through December 2010. TAVI was performed using the Edwards Sapien or Sapien XT valves (85%) or the third-generation CoreValve Revalving system (15%), with 65% of valves placed via the transfemoral approach.

Dr. Hayashida and his coauthors report no conflicts. ■

To see an interview with Dr. Garot, scan this QR code using your smartphone.

Pages 16a—16b