Percutaneous Valves Gaining Ground

BY RICHARD M. KIRKNER

FROM AORTIC SYMPOSIUM 2010

NEW YORK — Percutaneous placement of aortic valves is rising rapidly, and the two approach techniques each offer advantages.

"Percutaneous aortic valve replacement using the transapical approach and the newer transfemoral artery approach provide an option for patients who have severe aortic valve stenosis and comorbid disease and who would otherwise not be candidates for aortic valve replacement," Dr. Lars Svensson of the Cleveland Clinic said at the symposium sponsored by the American Association for Thoracic Surgery.

Percutaneous aortic valve replacement evolved because up to 60% of patients with severe aortic valve stenosis were too ill to have an open operation for aortic valve replacement, Dr. Svensson said.

Hence, the new percutaneous valves have largely been used in patients aged older than 85 years, particularly for reoperations. He cited results for patients at the Cleveland Clinic from the Transcatheter Endovascular Implantation of Valves (REVIVAL) trial. Those who had percutaneous aortic valve replacements fared better than did those who had balloon aortic valvuloplasty alone or no intervention. For the entire series studied at the three primary Cleveland Clinic sites, patients who had percutaneous valve replacement via the transfemoral artery had 7% mortality and 9% incidence of stroke, compared with 17% mortality and 2.5% incidence of immediate stroke in those who had repair via the transapical left ventricular insertion.

The Food and Drug Administration–approved trials, REVIVAL and Placement of Aortic Transcatheter Valve Trial (PARTNER), use transfemoral percutaneous aortic valve replacement as the primary approach if patients have iliac artery access, Dr. Svensson said. "In the United States, a patient only gets a transapical valve if the patient does not have access for valve insertion via the femoral arteries," he said.

Dr. Svensson also reported results from the first 40 patients in a FDA-approved study of transapical insertion of balloon-expandable stent valves. All valves were successfully placed and 35 valves were successfully seated. A total of 17% of patients died within 30 days, but the stroke rate was very low. ■

Disclosures: *Dr. Svensson stated that he had no conflicts.*

MY TAKE

A Potential 'Game Changer'

Catheter-based aortic valve replacement was the "hottest" topic in adult cardiac surgery at this year's meeting. Traditional open-chest aortic valve replacement using cardiopulmonary bypass remains the preferred method for aortic stenosis, but a significantly large group of patients has not been referred for AVR because of the perceived operative risk related to advanced age and comorbidities. Some of these very-high-risk patients could benefit from a less invasive percutaneous approach. Follow-up on such patients has been relatively short. The percutaneous approach probably will be tried in progressively less complex patients, but it remains to be proved that results will be equivalent to those of standard AVR. Still, technology is rapidly evolving, and the percutaneous approach has the potential to be a "game changer" in the management of aortic valve disease.

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Transapical Aortic Valve Implant An Option in High-Risk Patients

BY MITCHEL L. ZOLER

FROM THE ANNUAL MEETING OF THE AMERICAN ASSOCIATION FOR THORACIC SURGERY

TORONTO — A transapical approach for aortic valve implantation yielded safety and efficacy outcomes as good as those of transfemoral aortic valve replacement in a series of 299 patients at the University of Leipzig, Germany, the largest series of transapical aortic valve replacements collected to date.

"There is no evidence for a 'transfemoral first' approach. I would go 50:50," Dr. Thomas Walther said at the meeting.

"There are some clear indications" for each approach. Transapical works better for patients with poor peripheral vessels, while transfemoral holds the edge for patients with poor lung function because it doesn't require intubation. "But otherwise you can do either, and you should do a 50:50 split," said Dr. Walther, formerly with the Leipzig group and now medical director of thoracic and cardiovascular surgery at the Kerckhoff Clinic in Bad Nauheim, Germany.

"Transapical is slightly better [than transfemoral] because it uses an antegrade approach so you can better direct and more precisely implant the valve," he said in an interview. The antegrade approach also makes wire adjustments easier, and the stepwise inflation that transapical makes possible is another advantage.

But transcatheter valve replacement currently sits on procedural turf that's split between cardiologists and cardiothoracic surgeons. Cardiologists generally favor the transfemoral approach, and it's diplomatic to let them do roughly half the cases, while surgeons handle the rest, usually with the transapical approach, Dr. Walther said.

Deciding whether to perform aortic valve replacement by a transcatheter approach or by open surgery raises another issue that requires careful judgment. Dr. Walther and his former colleagues in Leipzig adhere to the 2008 recommendations of the European Society of Cardiology and the European Association for Cardio-Thoracic Surgery, which favored transcatheter valve replacement over open surgery only for elderly, high-risk patients or those with contraindications for open surgery (Eur. Heart J. 2008;29:1463-70). The recommendations said that clinical judgement should be the main determinant of which patients had high risk, along with quantitative scoring methods such as the logistic EuroScore and the Society of Thoracic Surgeons (STS) predicted risk of mortality score.

These limitations for transcatheter valve replacement continue to make sense because open surgical repair has a very low mortality rate of 1%. "What could do better than that?" he said. Open replacement "gives good hemodynamic function and has proven long-term durability. With the transcatheter approach you always have the risk of a paravalvular leak, which may pose problems especially in younger patients who exercise. Plus, new procedures [such as transcatheter valve replacement] have some inherent risks. To match a mortality rate of 1% is very difficult," Dr. Walther said.

Transcatheter valve implantation has not yet received marketing approval from the Food and Drug Administration.

The Leipzig group performed 299 transapical aortic valve implantations since it started in 2006 through the beginning of 2010, and a roughly equal number of transfemoral implantations. The average age of the transapical patients was 82; 70% were women. Their average logistic EuroScore was 31%, and average STS score was 12%. Ninety percent of the procedures occurred off pump. Thirty-day mortality was 8.7%. A total of 28% died during an average follow-up of 16 months (the longest follow-up was 4 years). Cardiac mortality predominated, followed by respiratory causes of death.

Thirty-two patients had a periprocedural complication, such as need for a second valve, conversion to open surgery, or need for cardiopulmonary bypass. Thirty-day mortality in this subgroup was 31%. In the remaining 267 patients, 30-day mortality was 6%.

The logistic EuroScore provided a good indication of how likely patients were to die following valve implantation. The series included 80 patients with a EuroScore of less than 20%; their average EuroScore was 15%, and average STS score was 9%. Thirty-day mortality was 5%, and total mortality during complete follow-up was 22%.

A second subgroup of 142 patients had a EuroScore of 20%-40%, with an average score of 29% and average STS score of 12%. Thirty-day mortality was 10%, with 25% overall mortality during complete follow-up. The remaining 77 patients had a EuroScore of more than 40%, with an average EuroScore of 53% and an average STS score of 17%. In this sickest group, 30-day mortality was also 10%, but 39% died during complete follow-up. Two patients had a stroke within the first 30 days following the procedure, with one additional stroke occurring during full follow-up. One patient developed endocarditis. Two patients required reoperation for aortic insufficiency within the first 6 weeks, and 15% of patients needed temporary renal replacement therapy.

Using echocardiography, the surgeons found mild aortic insufficiency in 37% of patients immediately after surgery, and in 54% after 1 year. During longer follow-up, prevalence remained at about the same level. Moderate aortic insufficiency appeared in 4% right after surgery, and held at a level of 4%-5% during up to 3 years of follow-up.

Follow-up telephone interviews of 80 patients showed that on average these long-term survivors had a quality of life that closely matched historical octogenarian controls who had not undergone aortic valve implantation.

Transapical aortic valve implantation is a reasonable, minimally invasive option for high-risk patients, Dr. Walther concluded.

Disclosures: *Dr. Walther has received honoraria from Edwards Lifesciences.*