JACC: CARDIOVASCULAR INTERVENTIONS
VOL. 3, NO. 11, 2010

ISSN 1936-8798/$36.00
PUBLISHED BY ELSEVIER INC.
DOI: 10.1016/j.jcin.2010.10.001

FOCUS ISSUE: TRANSCATHETER AORTIC VALVE IMPLANTATION
State-of-the-Art Paper

The Global Experience With Percutaneous Aortic Valve Replacement

Martyn Thomas, MD

London, United Kingdom

Transcatheter aortic valve replacement is now a viable option in the treatment of high-risk severe symptomatic aortic stenosis. This review describes the current data with this technology and also the potential for the future role of the technology, including potential ways to yet further improve the short- and longer-term results. (J Am Coll Cardiol Intv 2010;3:1103–9) © 2010 by the American College of Cardiology Foundation

Symptomatic severe aortic stenosis is a lethal condition with high 2-year mortality. Although surgical aortic valve replacement (SAVR) has excellent procedural results in elderly patients, as comorbidities and "risk" of the patients increase, so both the procedural and 1-year outcomes deteriorate (1). In addition, between 30% and 50% of patients with symptomatic aortic stenosis do not receive SAVR, often because they are not referred to a surgeon—generally because of concerns about comorbidities (2,3). Therefore it is highly likely that there might be a hidden population who would benefit from a less invasive way of replacing the aortic valve. Transcatheter aortic valve implantation (TAVI) allows the aortic valve to be replaced without a sternotomy, with a beating heart, and without the need for routine cardiopulmonary support.

The first TAVI with a balloon expandable device was performed in 2002 (4), whereas the self-expanding system was first used in 2005 (5). These 2 devices are now commercially available in Europe. Both the Edwards-SAPIEN Transcatheter Heart Valve (THV) (Edwards Lifesciences, Irvine, California) (balloon expandable) and the Medtronic CoreValve (Medtronic, Minneapolis, Minnesota) (self expanding system) became commercially available in 2007.

Vascular Access

The least invasive way of performing a TAVI is the transfemoral (TF) retrograde approach to the aortic valve (5,6). However, in some patients the peripheral vasculature is not sufficiently large to allow the large bore sheaths and catheters to be used. In this circumstance the alternative approach is the transapical (TA) for the Edwards-SAPIEN THV (Edwards Lifesciences) (7,8) and the subclavian for the CoreValve (9). Further novel approaches are being developed, such as the transaortic. This approach is in development for both the Edwards-SAPIEN THV and the CoreValve (10,11). It involves direct access to the aortic arch via an upper mini-sternotomy and might be useful in patients with severe respiratory disease or deformities of the left chest, both of which are relative contraindications to a mini-thoracotomy of the TA approach.

Where Is the Procedure Performed?

It is generally agreed that top-quality imaging is required to safely perform TAVI. Therefore, the procedure should be performed either in a hybrid theater or in the cardiac catheter laboratory. Performing the procedure in the operating theater

From Cardiovascular Services, Guys and St. Thomas' Hospital, London, United Kingdom. Dr. Thomas is an advisory board member for Edwards Lifesciences and has received research support from Edwards Lifesciences >$10,000 in the last year

Manuscript received September 8, 2010; revised manuscript received September 27, 2010, accepted October 1, 2010.

JACC: CARDIOVASCULAR INTERVENTIONS, VOL. 3, NO. 11, 2010
NOVEMBER 2010:1103–9

with a "C arm" is generally not advised. European guidelines have recommended that the procedure should be performed in centers that perform high volumes of SAVR (12). The U.K. recommendations are that TAVI should be performed in cardiothoracic surgical centers that have the ability to provide immediate access to cardiopulmonary bypass and other specialized services such as vascular surgery and renal support (13).

Patient Selection for the TAVI Procedure

Patients are selected for TAVI on the basis of their surgical risk and anatomical suitability. The risk of the patient is generally measured by the logistic European System for Cardiac Operative Risk Evaluation (EuroSCORE) (14) or the Society of Thoracic Surgeons (STS) score (15). Patients are, broadly speaking, considered suitable if they have a logistic EuroSCORE of >20% or an STS score of >10. The anatomical suitability is decided after a number of specialized imaging techniques. These include transthoracic and transoesophageal echocardiography, coronary and peripheral angiography, and computed tomography scanning from the aortic root to the common femoral artery. After the risk assessment and the specialized imaging, the patient should be reviewed by a multidisciplinary team to decide on the best approach to the treatment of the aortic stenosis. Treatment options include open SAVR, TAVI, or medical therapy. Both SAVR and TAVI might be preceded by coronary intervention or balloon aortic valvuloplasty (BAV). The BAV has reestablished itself as a bridge to TAVI especially in patients with poor left ventricular function—the aim being to improve function and reduce the risk of the TAVI procedure. In addition, it might be used to treat patients (at least in the short term) who are not considered suitable for SAVR or TAVI. Finally, BAV might be used when there is diagnostic uncertainty as to whether the principal cause of symptoms is the stenotic aortic valve, such as patients with both important aortic stenosis and respiratory disease who are breathless. Response to BAV in addition to the measurement of pro–B-type natriuretic peptide might be useful in these circumstances. Coronary angioplasty is generally limited to those patients presenting with significant angina or, again, those with poor left ventricular function in an attempt to optimize function before TAVI.

Abbreviations and Acronyms

BAV = balloon aortic valvuloplasty
EuroSCORE = European System for Cardiac Operative Risk Evaluation
SAVR = surgical aortic valve replacement
STS = Society of Thoracic Surgeons
TA = transapical
TAVI = transcatheter aortic valve implantation
TF = transfemoral

Current Procedural and Outcome Data for TAVI: First-in-Man/Early Feasibility Studies

The first-in-man and early feasibility studies for TAVI represent the pioneering work and learning curve of centers throughout the world who developed the TAVI technique. The initial report of the Edwards-SAPIEN TF (Edwards Lifesciences) retrograde approach in 18 patients indicated a procedural success rate of only 78% and a 30-day mortality of 2 of 17 (11.1%) (6). A similar report for the CoreValve TF system (Medtronic) reported a procedural success rate of 84% and a 30-day mortality of 5 of 25 (20%) (5). The alternative vascular approach (generally with higher-risk patients) for the 2 devices are the TA approach for the Edwards-SAPIEN Valve and the subclavian approach for the Medtronic CoreValve. The first TA Report indicated a 90% procedural success rate and 13.6% mortality at 30 days (8). The data for the subclavian approach seem particularly encouraging. In 54 patients the procedural success was 100%, procedural mortality 0%, 30-day mortality 0%, and 6-month mortality 9.4% (9).

The Partner EU Registry was a pre-CE mark registry in 130 patients (61 TF and 69 TA), which has now reported 18-month outcomes, respectively (16). The 30-day survival was 92% for the TF approach and 81% for the TA approach. Eighteen-month survival was 71% for the TF approach and a disappointing 43% for the TA approach. These results might at least partly be explained by the higher risk nature of the TA versus TF patients (logistic EuroSCORE 33.8% for TA vs. 25.7% for TF). Importantly, much of the post-procedural mortality was noncardiac in nature and related to the comorbidities of the patients. Similar data from 126 patients in the early CoreValve (Medtronic) experience showed a 30-day survival of 84.8% and a 1-year survival of 71.4% (17).

Most Recent Data on Outcomes After TAVI

The most up-to-date data on the clinical outcomes of TAVI comes from a number of single center reports and multicenter and national registries.

Procedural and 30-day outcomes. The largest registry to report to date is the SOURCE (SAPIEN Aortic Bioprosthesis European Outcome) Registry. This is a post–CE-mark registry reporting on the results of 1,038 patients undergoing TAVI with the Edwards-SAPIEN THV (Edwards Lifesciences) (18,19). The Edwards-SAPIEN valve is currently commercially available in 23- and 26-mm sizes. Most of the published reports and presentations for the TF approach use the Edwards-SAPIEN valve and require a 22-F or 24-F sheath, and for the TA approach, a 26-F TA delivery system is used. The commercially available Medtronic CoreValve system is 18-F–compatible, and much of the reported CoreValve data is with this system.