Transcatheter aortic valve implantation (TAVI) was first introduced by Alan Cribier in 2002.1 Since their introduction, the two available devices (the Cribier-Edwards aortic valve [Edwards Lifesciences] and the CoreValve [Medtronic]) have decreased in size and are more flexible, improving deliverability. It is estimated that >20,000 patients have had TAVI since it was first approved for use in Europe in 2007.2 Based on the results of the pivotal US Placement of Aortic Transcatheter Valve (PARTNERS) trial, the Sapien valve (an improved version of the Cribier-Edwards valve) was recommended for approval by the Food and Drug Administration Circulatory Systems Devices Panel on July 20, 2011 and awaits final Food and Drug Administration approval.3 It is widely anticipated that this valve will be available for use in the United States in 2012. There are 7 new valves in development that are expected to further improve deliverability and outcomes.

The growth of TAVI is not surprising, because it can be categorized as a breakthrough technology. With the aging of the population, the number of elderly patients with severe symptomatic aortic stenosis has grown, and a significant proportion of high-risk patients are not candidates for surgical aortic valve replacement because of age and comorbidities. Without surgery, the outcome is extremely poor in such patients.4 Currently, in countries where it is approved, the primary indication is for the treatment of symptomatic severe aortic stenosis in a patient who is believed to have a very high surgical risk or whose aortic stenosis is inoperable. TAVI has been shown to be successful in patients with poor left ventricular function, as well.5 In addition to native aortic valve disease, studies have demonstrated that these devices can be used to treat degenerated surgical bioprostheses.6 The procedure is not without risk, in particular in very elderly patients with significant comorbidities. The physician deciding to use TAVI in a high-risk patient needs to consider the risks and complications of the procedure balanced against the short- and long-term benefits.

The current versions of the Sapien valve and the CoreValve are smaller and more deliverable via the femoral artery than earlier prototypes. However, 10% to 20% of patients have tortuous or small femoral arteries or significant peripheral vascular disease that precludes the use of the 18 to 25F delivery systems. A transapical approach has been used, but this approach requires surgical exposure and has been associated with an increased risk of complications.7 More recently, the axillary and subclavian approaches have also been used successfully.8 Defining and properly sizing the valve annulus is important in ensuring that the prosthetic valve is well seated to prevent dislodgement or significant aortic insufficiency.9 Assessment of the annulus is aided by transesophageal echocardiography, computed tomography, or MRI imaging, with the latter 2 providing more accurate measurements.10 Following balloon valvuloplasty, optimal placement is critical, because too high or too low delivery can result in dislodgement, significant aortic regurgitation, and compromise of the coronary arteries.11 The CoreValve device, with its mesh structure that anchors above and below the valve, is more stable and has the advantage of being able to be retrieved and moved if not in the proper position. With compression on the conduction system, complete or secondary heart block requiring a permanent pacemaker occurs in 3% to 7% of patients receiving the Sapien valve and in 20% to 30% of those receiving the CoreValve.3,12 Given the return of conduction in some patients, a more conservative approach to pacemaker placement has been recently recommended.

Other important complications include severe aortic regurgitation, major vascular complications, major bleeding, myocardial infarction, acute kidney injury, and stroke.13 The incidence of stroke is 1% to 10%, and is often attributable to embolization of friable material on the valve. The Valve Academic Research Consortium has recommended definitions for each of the major complications of the procedure, and studies using these definitions suggest that 30-day adverse event rates, including death, are in the 18% to 20% range, with the death rate ranging from 5% to 10%.7,14–16

The technique has been shown in nonrandomized trials to significantly reduce the aortic pressure gradient, to improve symptoms and functional capacity, and to improve long-term outcome.7,14,15,17 Whether the procedure has an important impact on mortality in comparison with medical therapy was tested in the PARTNERS trial using the Sapien valve.3 This study randomly selected 358 patients with aortic stenosis who were not considered to be suitable for surgery. At 1 year, the mortality rate was 50.7% for those treated medically and 30.7% for those treated with TAVI. Stroke and vascular complications were higher with TAVI (5% versus 1% and 16.2% versus 1.1%, respectively). A significant improvement in New York Heart Association functional classification was realized. The study served as the basis for the Food and Drug Administration panel recommendations for approval of the device. The second phase of the study compared TAVI with the Sapien valve with surgical aortic valve replacement in

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699 high-risk patients.\(^{18}\) The 1-year mortality rate was not different between groups (24.2% versus 26.8% for TAVI and aortic valve replacement, respectively). Major stroke was higher with TAVI, but this was not statistically significant (5.1% versus 2.4%), whereas vascular complications were more frequent with TAVI, and major bleeding was more common with surgery. The study demonstrated noninferiority, but a significant difference in major complications that may be important in deciding which procedure would be best in an individual patient. The randomized Medtronic CoreValve trial is ongoing, and it is planned to enroll 467 extreme-risk patients in a nonrandomized observational trial of CoreValve and 789 high-risk patients assigned to either TAVI with the CoreValve or to surgical aortic valve replacement. It is expected that the trial will be completed in the next year. If the findings are similar to the PARTNER trial, it is likely that this valve will also be available in the future.

The introduction of transcatheter aortic valve implantation over the past 10 years and the recent demonstration of the clear efficacy of its use in high-risk patients with severe aortic stenosis who otherwise would have had no adequate treatment is an exciting and important advance. Whether the technique will be suitable for patients with aortic stenosis who are less risky or whether other types of valve disease can be treated effectively with a similar technique remains to be demonstrated.

Disclosures

None.

References


**KEY WORD:** transcatheter aortic valve implantation
Transcatheter Aortic Valve Implantation: Coming of Age
David P. Faxon

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