Transcatheter Aortic Valve Implantation

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KEYWORDS

• Aortic valve stenosis • Percutaneous treatment
• Heart valve prosthesis • Bioprosthesis

Surgical valve replacement has so far been the only effective treatment of symptomatic aortic stenosis (AS).[1,2] Charles Dotter[3] first suggested the possibility of transcatheter placement of prosthetic cardiac valves in 1981. Twenty years later, Cribier and colleagues[4] implanted the first transcatheter aortic valve. The introduction of transcatheter aortic valve implantation (TAVI) made it possible to offer a much less invasive alternative for those patients who are high-risk or nonsurgical candidates. Recent advances in percutaneous valve technology and the satisfactory early results of TAVI have led to a dramatic increase in the number of devices being developed[5,6] and the number of patients with severe AS undergoing percutaneous treatment.

Percutaneous aortic valve (PAV) interventions date back to the 1980s, when balloon aortic valvuloplasty (BAV) was first performed. However, this technique rapidly lost popularity because of the limited long-term benefits compared with medical therapy.[7–9] Thereafter, the concept of balloon-expandable and self-expandable transcatheter valve implantation was introduced. The first reported TAVI in humans, by Cribier and colleagues,[4] took place 7 years ago.

In 2009, there are at least 17 TAVI programs undergoing active research (**Table 1**),[5] and 2 of the transcatheter aortic valve prosthesis are currently approved for clinical use outside the United States: the balloon-expandable Edwards SAPIEN (Edwards Lifesciences Inc, Irving, CA) and the self-expandable CoreValve ReValving (Medtronic, Minneapolis, MN). The number of high-risk or nonsurgical candidate patients being treated with this technology has been growing quickly since these companies obtained CE mark approval in 2007, with more than 7000 implants worldwide to date. No valve has yet obtained US Food and Drug Administration (FDA) approval, and therefore all clinical experience in the United States comes from clinical trials. Furthermore, newer devices are being developed, and this article reviews the current status of these technologies.

PATIENT SELECTION

Selection criteria for TAVI are being developed. Currently, TAVI is available to high-risk surgical or nonsurgical candidates. There is no consensus on what constitutes high risk, but risk scoring systems are often used. The most common systems in use are the Logistic EuroSCORE (mostly in European studies) and the Society of Thoracic Surgeons (STS) score (in US studies), both of which have been validated for patients undergoing cardiac surgery, based on data from the 1990s.[10–13]

However, a recent validation of the EuroSCORE (additive and logistic) using contemporaneous surgical outcomes found substantial differences between the observed and expected mortality risks. The EuroSCORE tends to overestimate risk, whereas the STS risk model may underestimate the current risk of surgical aortic valve replacement (AVR).[14] Furthermore, an evaluation of outcomes of isolated surgical AVR in the STS database from 1997 to 2006 has shown a decrease in morbidity and mortality.[13] A third model,

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Table 1
Transcatheter aortic valve technologies

Balloon-expandable	Self-expandable	Other
Edwards SAPIEN	CoreValve ReValving	Direct Flow Medical
Paniagua ETR	Lotus (Sadra	
Entrata ATS 3f	AorTx (Hansen Medical)	
IHT Cordynamics	Sorin Perceval	
	Enable ATS 3f	
	Ventor-Embracer	
	Heart Leaflet Technology	
	JenaValve	
	PercValve (ABPS)	
	Paniagua (ETR)	
	Lutter Tissue	
	IHT Cordynamics	

validated and more specifically designed to predict in-hospital mortality after valve surgery with or without coronary artery bypass graft (CABG), is the Ambler model.[15] Comparisons of the logistic EuroSCORE, STS, and Ambler scores have demonstrated that the STS score is the most sensitive of these 3 models for assessing perioperative and long-term mortality for isolated AVR.[12]

Piazza and colleagues[16] described a patient selection algorithm based on 15 anatomic factors evaluated by noninvasive methods (echocardiography, cardiac tomography angiography [CTA], magnetic resonance imaging [MRI]) and angiography, to categorize patients as acceptable or not acceptable for the CoreValve ReValving system.

Assessment of the peripheral arteries is also crucial in selecting candidates for this procedure, and should be part of the inclusion criteria in any TAVI protocol. In addition to vessel caliber and tortuosity assessment with CTA or aortography, a noncontrast computerized tomography (CT) scan is useful to evaluate calcium in the peripheral vessels and the valve.

None of these scoring systems and imaging selection protocols take into consideration other important factors such as frailty index, and therefore it is expected that the results of the current TAVI studies will lead to the development of more specific risk algorithms to better select patients.

PROSTHESIS FOR TAVI

Clinically Approved (Outside United States) Devices

Edwards SAPIEN prosthesis

Technical background The commercially available Edwards SAPIEN prosthesis is the second generation of the Cribier-Edwards valve (**Fig. 1**B). This is a balloon-expandable valve consisting of a stainless steel frame covered by a Dacron skirt, in which 3 leaflets of pericardium are sutured. It is deployed in a subcoronary position during rapid ventricular pacing, via a retrograde transfemoral (TF) or transapical (TA) approach. The leaflets in the first generation were made of equine pericardium, and in the second generation they are made of bovine pericardium, with improvements in the suture to the frame and an increase in the skirt length to reduce aortic regurgitation. There are 2 commercialized sizes: 23 mm (diameter) × 14 mm (height), and 26 mm × 16 mm. The next-generation, lower-profile Edwards XT valve (not yet available commercially) has a new cobalt-chromium frame with a wider opening and modifications in the design of the leaflets. It is currently being tested in the ongoing PREVAIL EU CE Mark trial, which includes a premarket cohort to evaluate system performance and a postmarket clinical follow-up phase up to 5 years.

The Edwards valve comes expanded and must be crimped carefully on the balloon with a dedicated device. The crimped profile of the valve will determine the size of the delivery sheath, which is a proprietary system (Retroflex) with torque capabilities. Four generations of this Retroflex system have been developed, with progressively lower profiles and increased flexibility to avoid aortic trauma. A 22F Retroflex-2 delivery sheath is needed for the 23-mm Edwards SAPIEN valve, and a 24F sheath for the 26-mm valve. The next-generation 26-mm Edwards XT valve navigates through a 22F Retroflex-2 sheath, and, in the ongoing PREVAIL EU trial, it is being tested with the 18F Retroflex-4 (Novaflex) delivery sheath.

The dedicated TA delivery system is called ASCENDRA. The initial 33F sheath has evolved to a shorter 26F sheath, which is easier to handle and better at confronting TA pitfalls.