Transcatheter Aortic Valve Implantation: Experience with the Edwards SAPIEN Device

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KEYWORDS

• Aortic stenosis • Transcatheter valve • Valve replacement
• Cardiac catheterization

It is recognized that about one-third of patients with symptomatic aortic stenosis (AS) are not offered surgical valve replacement.[1] Transcatheter aortic valve implantation (TAVI) was introduced in 2002[2] with the goal of offering an alternative treatment to patients with severe symptomatic AS who are poor candidates for conventional aortic valve replacement (AVR) because of their elevated mortality risk. The concept was validated by the authors' group in patients in whom implantation was done on a compassionate basis[3,4] with a first generation of balloon expandable valves (Percutaneous Valve Technologies, NJ, USA) and a transseptal venous approach. Since then, the devices and implantation techniques have considerably improved and TAVI has entered a common clinical reality. Two valve models, the balloon-expandable Edwards SAPIEN Valve (Edwards Lifescience, Irvine, CA, USA) and the self-expandable CoreValve Revalving System (CoreValve Inc, Irvine, CA, USA) are currently commercialized in Europe and have been used in more than 40,000 cases worldwide, and multiple other devices are under investigation.

Several feasibility trials and postmarket registries[5–13] have shown that using the Edwards SAPIEN prosthesis, TAVI can be performed safely and effectively using either the transfemoral retrograde or the transapical antegrade approaches with the potential for durable benefit. Recently, using the Edwards SAPIEN device, the prospective pivotal randomized Placement of Aortic Transcatheter Valve (PARTNER)-US trial has confirmed these findings.[14,15]

As a larger number of centers become involved in TAVI, careful patient selection and a meticulously performed procedure are required to maintain the outcomes published in clinical trials.

PRODUCT OVERVIEW

The Edwards SAPIEN Transcatheter Heart Valve

The Edwards SAPIEN Transcatheter Heart Valve (THV) consists of a tubular slotted stainless steel balloon expandable stent with an integrated unidirectional trileaflet bovine tissue valve with a polyethylene terephthalate fabric cuff (**Fig. 1**). The valve is made of 3 equal sections of bovine pericardium manufactured with the anticalcium ThermaFix treatment. The prosthesis is available in 2 sizes, with an expandable diameter of 23 or 26 mm and a length of 14 and 16 mm, respectively. The valve is compressed over the delivery balloon catheter using a crimping tool (**Fig. 2**) to symmetrically reduce its overall diameter from its expanded size to its mounted size (**Fig. 3**).

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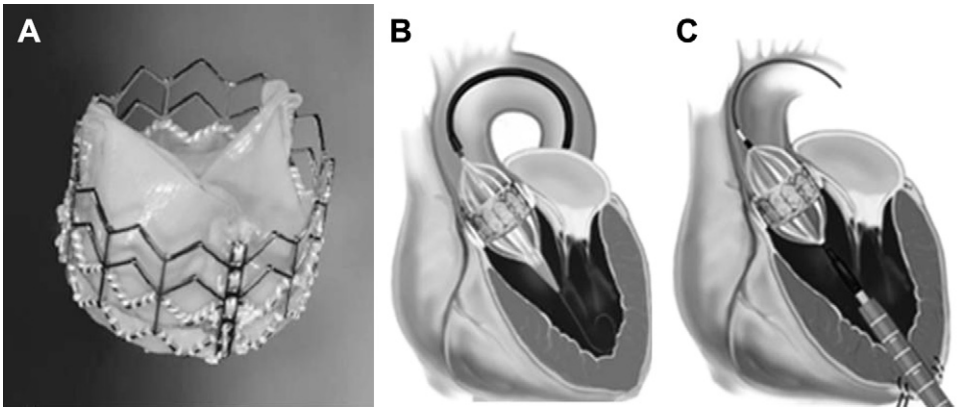

Fig. 1. (*A*) The Edwards-SAPIEN transcatheter heart valve consists of 3 bovine pericardial cusps treated with ThermaFix mounted into a stainless steel balloon expandable stent with a lower portion covered with polyethylene terephthalate cuff. Two approaches are used for THV implantation: (*B*) transfemoral and (*C*) transapical. (*Courtesy of* Edwards Lifesciences, Irvine, CA, USA; with permission.)

The Edwards SAPIEN THV can be delivered via a transfemoral or transapical approach (see **Fig. 1**) using the RetroFlex and Ascendra delivery systems (Edwards Lifesciences, Irvine, CA, USA), respectively.

The last generation of transfemoral delivery systems, the RetroFlex 3 (Edwards Lifesciences, Irvine, CA, USA) (see **Fig. 3**), consists of a deflectable balloon catheter with a distal nose cone that helps advancing the THV across vascular tortuosity, reducing the friction at the level of the aortic arch, crossing the native valve and increasing stability for accurate THV placement and delivery. Other components of the transfemoral kit are a 30 cm long hydrophilic-coated introducer sheath of 22F or 24F for the 23- and 26-mm THVs, respectively; polyethylene dilators of 16F to 28F for smooth arterial dilatation; and a RetroFlex balloon catheter of 20 or 23 mm in diameter, depending on the THV size, for predilatation of the native aortic valve (**Fig. 4**).

The transapical Ascendra delivery system (**Fig. 5**) allows a direct access to the native valve. The Ascendra introducer sheath is 26F in size and provides controlled insertion through the apex of the left ventricle. A 20-mm Ascendra balloon catheter is used for aortic valve predilatation.

PATIENT SELECTION

Clinical Criteria

Appropriate patient selection is crucial for a successful procedure. Clinical, anatomic, and functional characteristics affect procedural outcomes and have to be considered when evaluating potential candidates. TAVI should be restricted to patients with severe symptomatic AS who have a potential for functional improvement after the procedure, whereas using TAVI in patients with comorbidities affecting survival or quality of life remains questionable. In active elderly patients, TAVI adds important symptom relief and a survival advantage, but older

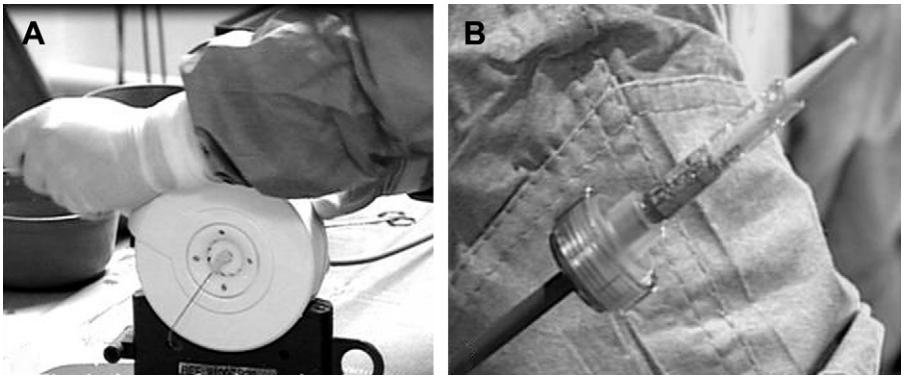

Fig. 2. (*A*) The crimping tool used for reducing the valve size to the mounted size. (*B*) After crimping, the valve is covered by a loader to facilitate its introduction within the arterial introducer.