Transcatheter Aortic Valve Implantation: Upcoming New Devices

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KEYWORDS

• Aortic stenosis • CoreValve • Edwards-SAPIEN
• Embolic protection • Periprosthetic regurgitation • TAVI

Inspired by the first percutaneous transcatheter pulmonary valve replacement,[1] the first transcatheter heart valve implantation in the aortic position via trans-septal access with a balloon-expandable prosthesis was performed in 2002.[2] In 2005, the first self-expandable transcatheter aortic valve was implanted via retrograde passage of the aortic valve.[3]

Since then, more than 40,000 transcatheter aortic valve prostheses have been implanted worldwide. Transcatheter aortic valve implantation (TAVI) has been established as an alternative to surgical aortic valve replacement (SAVR) for patients with symptomatic severe aortic stenosis and high or prohibitive operative risk.[4,5] The PARTNER (Placement of Aortic Transcatheter Valve) trial was the first randomized controlled trial to show that TAVI is not only superior to conservative management in inoperable patients but also is equivalent to SAVR in high-risk patients, with similar rates of survival at 1 year.

According to the German TAVI registry, approximately one-third of all aortic valve prostheses in 2011 will be transcatheter heart valves.[6] Among cardiac surgeons, a trend toward the use of bioprosthetic heart valves has been noted: younger patients are more frequently treated with a surgical bioprosthetic heart valve, because these valves might be treated by valve-in-valve implantation with transcatheter heart valves in case of degeneration and patients do not necessarily have to undergo repeat surgery. Thus, patients are able to do without life-long, oral anticoagulation.

Although the PARTNER trial recently underscored the value of TAVI for high-risk patients, with similar outcomes compared with SAVR, important differences in periprocedural risks and several TAVI-associated drawbacks have been identified, which should be addressed before the use of TAVI can be extended to younger and healthier patients. These drawbacks include, for example, the occurrence of periprocedural and postprocedural stroke but also the higher incidence of vascular complications, conduction disturbances, and periprosthetic aortic regurgitation after TAVI compared with SAVR. Upcoming devices will focus on these issues to optimize the outcome after TAVI.

PERIPROSTHETIC AORTIC REGURGITATION

Up to 40% of all patients after SAVR have trace or mild periprosthetic aortic regurgitation; approximately 5% suffer from moderate or severe

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periprosthetic aortic regurgitation.[7] In TAVI, paravalvular leaks occur in 50% to 70% of all patients.[8] 15% to 20% of all TAVI patients suffer from moderate or severe periprosthetic aortic regurgitation after the procedure, independent of valve type and access route.[5,8–11]

The self-expanding Medtronic CoreValve Re-Valving System (Medtronic, Minneapolis, MN, USA) will soon be available in 4 sizes (23, 26, 29, and 31 mm) for annulus diameters from 18 to 29 mm (**Fig. 1**A). The balloon-expandable Edwards-SAPIEN XT valve prosthesis (Edwards Lifesciences, Irvine, CA, USA) is now available in 3 different sizes for the treatment of annulus diameters from 18 to 27 mm (see **Fig. 1**B). Because oversizing plays a pivotal role for the fixation of transcatheter heart valves in the annulus of the native valve, implantation depth and prosthesis size are essential to reduce the rate and the severity of periprosthetic aortic regurgitation. Thus, larger prosthesis sizes improve postprocedural results in patients with a borderline annulus. If the stent frame of the valve is not fully expanded because of heavily calcified cusps of the native aortic valve, a postdilation with balloon valvuloplasty helps to reduce periprosthetic aortic regurgitation in most cases.

Next-generation Transcatheter Heart Valves

Repositionable and recapturable transcatheter heart valves will provide another step toward optimal positioning of the prosthesis and prevention

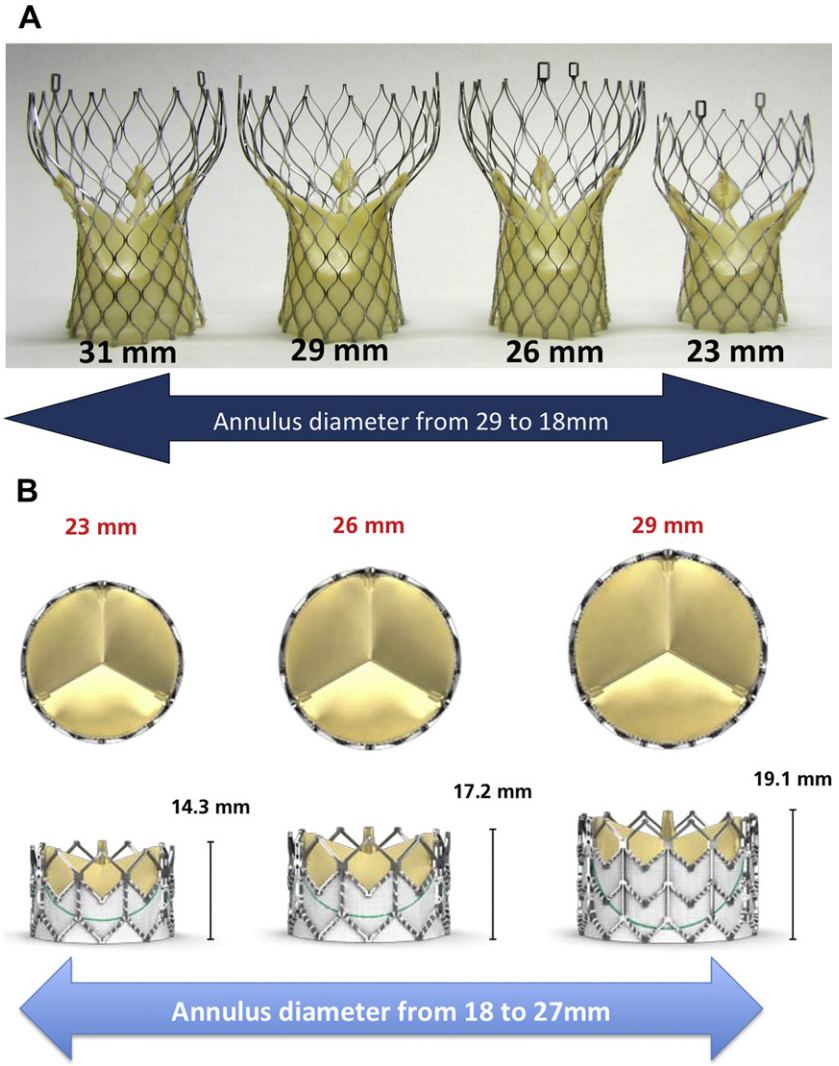

Fig. 1. (*A*) CoreValve prosthesis in 4 different sizes. (*B*) Edwards-SAPIEN valve prosthesis in 3 different sizes. ([*A*] *Courtesy of* Medtronic, Minneapolis, MN; with permission. [*B*] *Courtesy of* Edwards Lifesciences, Irvine, CA; with permission.)