Current TAVR Devices

Technical characteristics and evidence to date for FDA- and CE Mark-approved valves.

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Since the first-in-human transcatheter aortic valve replacement (TAVR) performed by Cribier in 2002,[1] this innovative procedure has had widespread recognition as the treatment of choice for severe aortic stenosis in inoperable patients[2] and as a reasonable alternative to conventional surgical aortic valve replacement (SAVR) in patients with intermediate and high surgical risk.[2-4]

The first prototype transcatheter aortic valve (designed by Cribier and his start-up Percutaneous Valve Technologies) was a stainless steel stent (23 mm in diameter and 17 mm in height) that contained a trileaflet valve (at first made of polyurethane, but soon changed to bovine pericardium). The device was compatible with a 24-F introducer sheath and was initially implanted with an anterograde transseptal approach. After a few years, this prototype evolved into the Cribier-Edwards valve (Edwards Lifesciences), and the original transseptal route was abandoned in favor of the more reproducible transfemoral and transapical approaches.[5] At the same time, another device, the self-expandable CoreValve (Medtronic), made of a nitinol frame containing a porcine pericardial valve, had been developed.[6] These two devices, which after a few years obtained CE Mark and US Food and Drug Administration (FDA) approval, can be considered the ancestors of all of the commercial devices now available.

In the last 15 years, TAVR technology has had an impressive advancement, transforming a challenging intervention into a standardized, simple, and streamlined procedure.[6] The latest generation of TAVR devices have incorporated features to reduce the delivery catheter profile, facilitate deployment, and enable repositioning and retrieval capability, with the aim of obtaining the desired position and reducing TAVR-related complications.[6] According to the type of deployment, current TAVR devices can be divided into the categories of balloon-expandable, self-expanding, and mechanically expandable (Figure 1).

SAPIEN 3

The Sapien 3 transcatheter heart valve (THV) (Edwards Lifesciences) is the fourth generation in the balloon-expandable Sapien series of devices.[7-15] It is available in four valve sizes (20, 23, 26, and 29 mm). The Sapien 3 valve is designed with a cobalt-chromium frame, three bovine pericardial tissue leaflets, and a polyethylene terephthalate (PET) skirt at its inflow portion and an outer PET sealing skirt to reduce paravalvular leakage (Table 1). As compared with the previous generation of Sapien XT (Edwards Lifesciences), the design of the Sapien 3 frame has been modified to enhance the geometry for an ultra-low delivery profile (14 F) while maintaining the high radial strength for circularity and optimal hemodynamics.

The transfemoral Commander delivery system (Edwards Lifesciences) incorporates an inner balloon catheter, on which the prosthesis is crimped, and an outer deflectable flex catheter. The catheter offers dual articulation with partial and distal flew that enables crossing the aortic valve in challenging anatomies and controlled coaxial alignment. The handle incorporates a fine adjustment wheel that allows advancing or retracting the balloon and that carries the valve several millimeters up or down within the annulus without pushing or pulling on the entire delivery system. The Commander delivery system is advanced through a 14-F (20-, 23-, 26-mm valves) and 16-F (29-mm valve) expandable eSheath (Edwards Lifesciences) (minimum

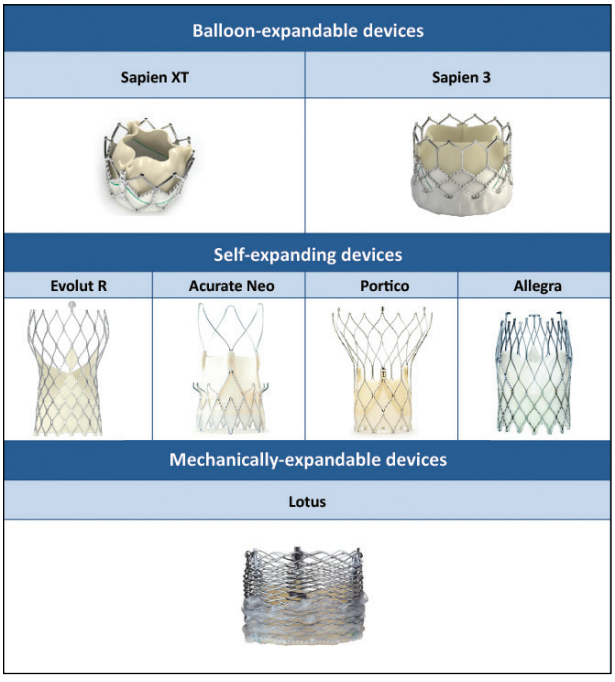

Figure 1. Overview of the current FDA- and CE Mark-approved TAVR devices.

TABLE 1. TAVR DEVICES AND THEIR CHARACTERISTICS

Device Name	Valve Structure	Access Route, Delivery System, and Valve Size	Reference Access Vessel Diameter	Repositionable?	Fully Retrievable?
Sapien 3 (Edwards Lifesciences)	Bovine pericardial tissue valve balloon-expandable cobalt-chromium frame	TF: Edwards eSheath 14 F (20, 23, 26 mm), 16 F (29 mm); TA, TAo: Certitude 18 F (20, 23, 26 mm), 21 F (29 mm)	≥ 5 mm (Sapien 3: 23, 26 mm), ≥ 5.5 mm (Sapien 3: 29 mm)	No	No
Evolut R (Medtronic)	Porcine pericardial tissue valve; self-expanding nitinol frame	TF, TAo, TSc: EnVeo R 14 F outer diameter (23, 26, 29, 34 mm)	≥ 5 mm (Evolut R: 23, 26, 29 mm) ≥ 5.5 mm (Evolut R: 34 mm)	Yes	Yes
Portico (St. Jude Medical, Inc.)	Bovine pericardial tissue valve; self-expanding nitinol frame	TF, TAo, TSc: 18 F (23, 25 mm) 19 F (27, 29 mm)	≥ 6 mm	Yes	Yes
Acurate Neo (Symetis)	Porcine pericardial tissue valve; self-expandable nitinol alloy stent	TF: 18 F outer diameter (small, medium, large); TA: sheathless 28 F (small, medium, large)	≥ 6 mm	No	No
JenaValve (JenaValve Technology GmbH)	Porcine pericardial tissue valve; self-expanding nitinol stent	TA: sheathless 32 F (23, 25, 27 mm)	–	Yes	No
Lotus (Boston Scientific Corporation)	Bovine pericardial tissue valve; self-expanding, braided nitinol frame	TF: 18 F (23 mm), 20 F (25, 27 mm)	≥ 6 mm (Lotus: 23 mm) ≥ 6.5 mm (Lotus: 25, 27 mm)	Yes	Yes
Allegra (NVT AG)	Bovine pericardial tissue valve (annular skirt and leaflets); self-expanding nitinol stent	TF: 18 F (23, 27, 31 mm)	≥ 6 mm	Yes	Yes

Abbreviations: TA, transapical; TAo, transaortic; TF, transfemoral; TSc, transsubclavian.

diameter, 5.5 mm) (Table 1). The Certitude delivery system (Edwards Lifesciences) is also commercially available for alternative access procedures in patients where transfemoral delivery may not be appropriate. The Certitude delivery system is compatible with an 18-F sheath for 20-, 23-, and 26-mm valves and a 21-F sheath for the 29-mm valve.

Appropriate sizing of the THV is crucial to reduce the incidence of paravalvular leak or the risk of life-threatening complications, such as valve embolization or annulus rupture. The Sapien 3 THV is currently available with labeled diameters of 20, 23, 26, and 29 mm to treat an annular size range of 273 to 683 mm^2 by CT area (Figure 2). Sizing recommendations were based on annular area measurements with the percentage of oversizing (positive percentage) or undersizing (negative percentage) calculated using the formula[16]:

% oversizing = (THV nominal area/annular area – 1) X 100

Due to the presence of the outer skirt, a lesser degree of area oversizing might be acceptable for the Sapien 3 THV than the previously recommended value for the Sapien XT THV (Figure 2). This minimal area oversizing provides the advantage of a lower risk of annulus injury without an increased risk of paravalvular regurgitation (PVR).

At this time, the PARTNER II S3 trial is the largest available study reporting on controlled outcomes of the Sapien 3 THV.[8] This study looked at data from two nonrandomized studies embedded in the PARTNER II trial on 1,076 intermediate-risk patients and 583 inoperable or high-risk patients who underwent TAVR with the Sapien 3 valve.[8] Mortality and stroke at 30 days were low in both study groups (1.6% mortality and 0.8% disabling stroke in the inoperable/high-risk population and 1.1% mortality and 1% disabling stroke in the intermediate-risk population).

Putting these results into perspective with previous PARTNER trials (that included previous-generation devices), a remarkable downshifting of mortality from 6.3% at 30 days to approximately 1% to 2% presently was observed. Other event rates, including bleeding, were low in both groups, and there were no annular ruptures. Permanent pacemaker rates were 13% and 10.1% in the high- and intermediate-risk cohorts, respectively. Overall, moderate (3.2%) and severe (0.6%) PVR rates were very low at 30 days. A recent propensity score-based analysis comparing this population with the surgical cohort of the PARTNER II trial showed that TAVR with the Sapien

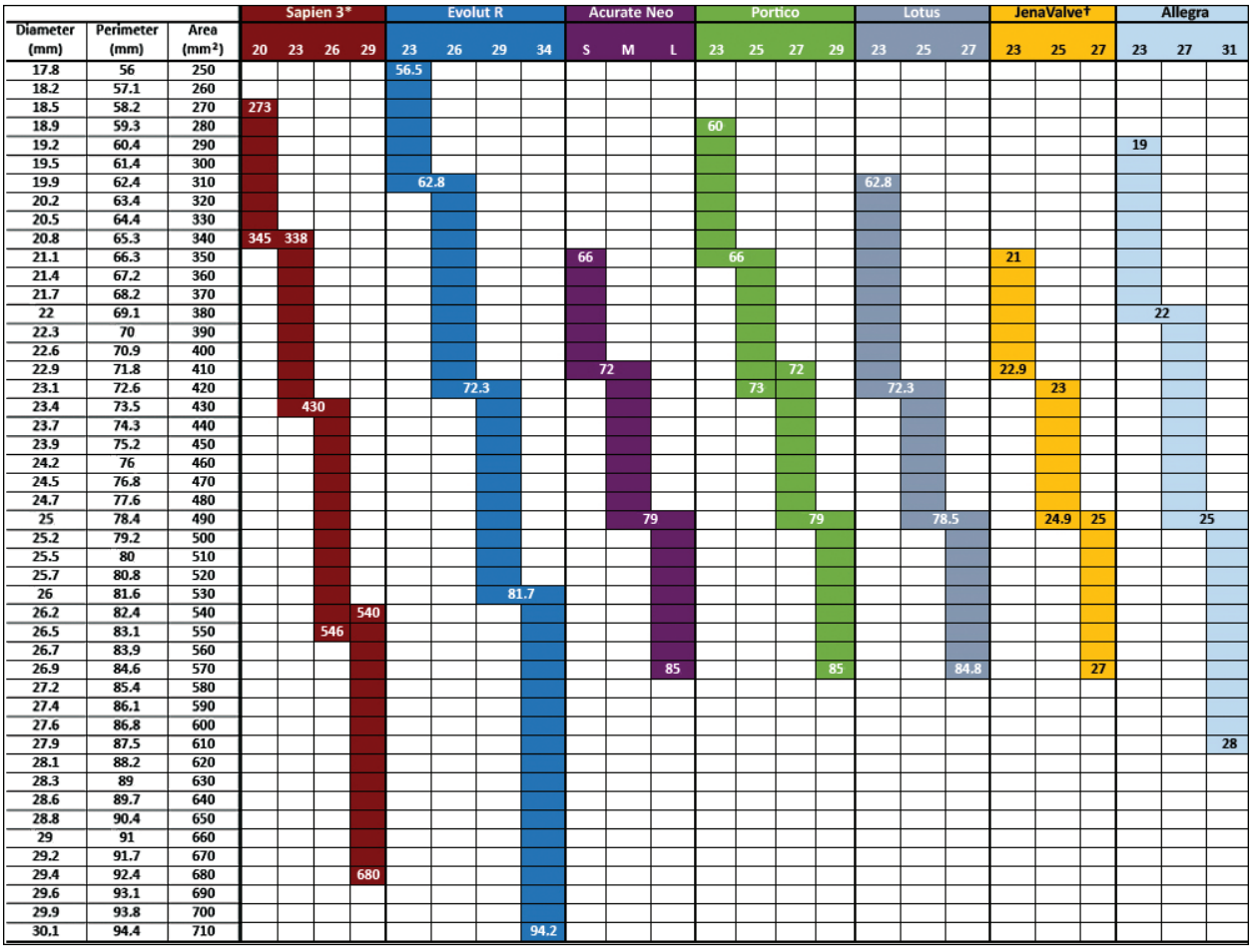

Figure 2. Sizing chart of the current new-generation TAVR devices. *Cut-off expressed by area, †cut-off expressed by diameter. Otherwise, cut-offs are expressed by perimeter.

3 demonstrated a 75% lower risk of mortality and stoke at 30 days compared to surgical aortic valve replacement. At 1 year, TAVR also demonstrated lower rates of mortality (7% vs 12.4%) and stroke (4.5% vs 7.9%) at 1 year (Figure 3) as compared to SAVR.[4]

EVOLUT R

The CoreValve Evolut R device (Medtronic) (currently available in four device sizes of 23, 26, 29, and 34 mm, allowing the treatment of native valves with a perimeter of 56.5–94.2 mm) (Figure 2) consists of a tricuspid valve obtained from porcine pericardial tissue, mounted and sutured inside a self-expandable nitinol frame (Table 1).[17] The lower part of the device has a high radial force that allows for the self-expansion and exclusion of native calcified valve leaflets. The central portion of the stent supports the valve.

As compared with the previous generation of CoreValve devices, the Evolut R provides several refinements to improve anatomical fit, annular sealing, and durability. In particular, the device is designed to enable recapturability and repositionability. The Evolut R frame is tailored to reduce the overall height, while preserving the height of the pericardial skirt (13 mm) with an extended skirt of the inflow tract to provide a seal against PVR. In addition, cell geometry has been redesigned to achieve optimized radial force.

The Evolut R has also been designed to be implanted through a 14-F compatible delivery system, the EnVeo R delivery system (Medtronic), which integrates an InLine sheath (Medtronic). This sheath slides against the capsule to allow vascular access that is the equivalent of a 14-F system (16 F for the Evolut R 34 mm). This means that the Evolut R system is now indicated to treat minimum access vessels of ≥ 5 mm (Evolut R 23, 26, 29 mm) and ≥ 5.5 mm (Evolut R 34 mm) (Table 1). Positioning accuracy is aided by the EnVeo R delivery system's 1:1 response. The EnVeo R provides the option to recapture and reposition up to three times before reaching the "point of no recapture."

Recently, two studies conducted in Europe and the United States showed low rates of 30-day mortality (< 2.5%) and stroke (< 5%). The frequency of a permanent pacemaker implantation remained < 17% in both studies, while the rate of mild PVR was identified in 7.7% and 5.3% of cases, respectively (Figure 3).[18,19]

Figure 3. Major outcomes of the current new-generation TAVR devices. Outcomes are derived from a weighted meta-analysis of 30 studies including 5,923 patients achieved with a comprehensive search of multiple electronic databases from January 2011 to March 2016.[8-35] Cumulative rates for each outcome (pooled measures were calculated assuming a DerSimonian and Laird random-effects model weighted by inverse variance incorporating both between and within study variance) and 95% confidence intervals are reported. AR, aortic regurgitation; CI, confidence interval; PPM, permanent pacemaker.

PORTICO

The Portico valve (St. Jude Medical, Inc.) is composed of a self-expanding stent, bovine leaflets, and a porcine pericardial sealing cuff. The large cell area and the annular positioning allow easy engagement of the coronary ostia after implantation (Table 1). The large cell area also minimizes the risk of paravalvular leakage by allowing valve tissue to conform around calcific nodules at the annulus. The valve uses Linx anticalcification technology (as used on Trifecta and Epic surgical valves; St Jude Medical, Inc.). The 23- and 25-mm valves are loaded onto an 18-F delivery system, whereas the 27- and 29-mm valves are loaded onto a 19-F delivery system (Figure 2). The Portico valve can be delivered by transfemoral access, and when used with the SoloPath recollapsible introducer (St. Jude Medical, Inc.), has a low 13.5-F insertion profile. Clinical studies have been reported on alternative access sites including transaxillary, transaortic, and subclavian access, and case studies are currently underway to support this issue. The Portico valve is designed to be

recaptured and repositioned at the implantation site, until it is fully deployed.

The Portico Valve TF EU study studied patients in Europe and Australia. The 30-day results of this large trial (n = 222) demonstrated excellent safety and efficacy of the complete Portico valve family. The valve had exceptional hemodynamic performance (8.3 mm Hg) as well as improvement in New York Heart Association class functional status. There were also lower rates of mortality (3.6%), disabling stroke (3.2%), and 94.7% of patients had less than mild paravalvular leak, and no patients had severe paravalvular leak.

ACURATE NEO

The Acurate Neo aortic bioprosthesis (Symetis) is a second-generation valve with flaps composed of porcine pericardium sewn onto a stent made of self-expanding nitinol, covered both externally and internally by a porcine pericardium skirt antileak (Table 1). The device includes three stabilization arches for the axial alignment to aortic annulus, a top crown for capping the aortic annulus, and a bottom that is open to the full distribution on the native valve. The prosthesis can be implanted through both the transapical (28 F) and the transfemoral (18 F) routes using a simple two-step deployment and stable positioning. The Acurate Neo comes in three different sizes: small (21- to 23-mm aortic annulus), medium (23- to 25-mm aortic annulus), and large (25- to 27-mm aortic annulus) (Figure 2).

After first-in-human and small single-center studies,[20-22] the results of the post-CE SAVI 2 registry, which enrolled 1,000 patients, were presented at the EuroPCR 2016 meeting. At 30 days, the mortality rate was 1.3%, stroke and pacemaker implantation rates were very low (1.9% and 8.2%, respectively), and more than mild paravalvular leak was reported in 4% of patients (Figure 3).[23]

LOTUS

The Lotus valve system (Boston Scientific Corporation) consists of a trileaflet bovine pericardial valve supported on a braided nitinol frame. A central radiopaque marker facilitates positioning of the prosthesis within the aortic root. The frame is covered with an adaptive seal at the inflow segment that adapts to aortic root irregularities and minimizes paravalvular leak (Table 1). This transcatheter heart valve is currently available in three sizes, 23, 25, and 27 mm, covering a range of annulus diameters from 19 to 27 mm (Figure 2). In the fully deployed state, all sizes have a frame height of 19 mm. The 23-mm model can be delivered through an 18-F sheath (small), while the 25- and 27-mm valves require a 20-F sheath (large). The Lotus device is typically inserted via a transfemoral approach, although direct aortic and transaxillary alternative access is possible. This is the only new-generation TAVR device that it is fully recapturable and repositionable even after the valve has been fully deployed.

Among the approved TAVR devices, the Lotus valve was associated with the lowest rate of PVR. Mortality, stroke, and vascular complication rates compare favorably with those reported with other new-generation valves.[24-29] However, the high rate of conduction disturbances requiring pacemaker implantation with this valve (approximately 30%) remains a concern that should be addressed with the development of the newer-generation Lotus Edge device (Boston Scientific Corporation) (Figure 3).

Boston Scientific recently announced a voluntary removal of all Lotus TAVR devices from global commercial and clinical sites. The action is a response to reports of the premature release of a pin connecting the Lotus valve to the delivery system. As with the previously announced suspension of the Lotus Edge valve system device, it is believed that the issue is caused by excess tension in the pin mechanism introduced during the manufacturing process. The company expects to bring the Lotus valve platform back to Europe and other relevant international markets by Q4 of 2017.

JENAVALVE

The JenaValve (JenaValve Technology GmbH) consists of a porcine valve mounted on a low-profile, self-expanding nitinol stent (Table 1).[30-35] The valve used in this device is commercially available as either a stentless (Elan valve, Vascutek Ltd.) or stented (Aspire valve, Vascutek Ltd.) surgical bioprosthesis, both of which perform well in long-term studies. The porcine root leaflets are connected to flexible stent posts to reduce leaflet stress during the diastolic phase. Three different sizes are available (23, 25, and 27 mm) for implantation in aortic annuli that are 21 to 27 mm in diameter (Figure 2). A sheathless 32-F delivery system is used for a three-step deployment procedure through the transapical route.

The unique characteristic of this prosthesis is that the implantation relies on active clip fixation of the native aortic leaflets, thus eliminating the radial forces on cardiac and aortic structures. The unique clip fixation mechanism of the JenaValve to the native aortic valve leaflets could provide secure anchorage even in the absence of calcifications. In fact, the JenaValve is the only TAVR device to have obtained CE Mark approval for noncalcified aortic regurgitation. The JUPITER postmarket registry enrolled a total of 180 patients and showed promising 1-year results. Procedure success was 95%, and all-cause mortality at 30 days was 11.1%. At 1-year follow-up, more than mild paravalvular leak was observed in two patients (3.2%) (Figure 3).

The next-generation JenaValve Pericardial TAVR system (JenaValve Technology GmbH) is currently under clinical evaluation with both transapical (22 F) and transfemoral (19 F) delivery systems.

It must be noted that the CE Mark for the JenaValve expired in 2016, and the company stopped commercial distribution in June 2016. At the moment, both the pericardial TA and TF system are in the study phase.

ALLEGRA

The Allegra THV (NVT AG) is a self-expandable valve consisting of a nitinol stent frame and bovine pericardium (annular skirt and leaflets). The annular portion of the frame is covered with a sealing skirt, above which the leaflets are sewn (ie, the functional portion of the prosthesis is supra-annular). In addition, six radiopaque gold markers are incorporated to the stent frame indicating the level of the skirt/leaflet transition. The valve is available in three sizes (23, 27, and 31 mm) (Figure 2), with a frame height of 37.3, 41.3, and 43 mm, respectively (Figure 1). The stent frame uses a variable cell size design to allow for axially tailored radial force distribution with higher force in the annular sealing section of the valve for secure anchoring. The upper section of the stent frame has larger cells, which was deliberately engineered to allow for flexure of the stent frame and accommodation of conformational changes during the cardiac cycle, ultimately dissipating leaflet stresses.

The transfemoral delivery system incorporates an 18-F cartridge and a 15-F catheter shaft. The grip uses a "squeeze-to-release" mechanism, avoiding any rotation during the entire implantation, which is performed in a stepwise manner. The Allegra device obtained CE Mark approval in April 2017.

CONCLUSION

These next-generation TAVR devices are proving to be considerably safer and more efficient than their ancestors, constituting a large spectrum of valves with different features that allows for almost every different clinical and anatomical scenario and the treatment of an increasing number of patients. ■

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