How the newest iteration of this self-expanding technology fits into the United States TAVR landscape.

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Sclerotic aortic valve disease affects approximately 29% of the United States adult population who are older than 65 years and 37% of patients older than 75 years, while the prevalence of moderate aortic stenosis patients who are 70 to 80 years of age is estimated to be 2%. Surgical aortic valve replacement (SAVR) was developed almost half a century ago. Techniques and valves have been refined, but such procedures can carry up to a 10% risk of death in patients older than 80 years perioperatively. Mortality rates can be threefold higher than in younger patients in such a population. In patients older than 90 years, mortality rates can be as high as 20% at 1 year. However, outcomes in the average population of those 65 years of age or older who undergo surgical aortic valve replacement are relatively robust, with operative mortality rates in the 4% range, as reported from the Society of Thoracic Surgeons Adult Cardiac Surgery Database. The development and subsequent approval of transcatheter aortic valve replacement (TAVR) has been a major advancement in the treatment of severe aortic stenosis. The first-in-human implantation took place in 2002. Conservative estimates indicate that since 2007, more than 750 centers have treated nearly 100,000 aortic stenosis patients using TAVR technologies.

Since the Sapien device (Edwards Lifesciences) was approved by the US Food and Drug Administration in 2012, TAVR devices have undergone numerous design changes. The initial study evaluating the CoreValve system (Medtronic) principally involved patients with severe aortic stenosis who were deemed to be at extreme risk for SAVR with New York Heart Association class II or greater symptoms and suitable aortic annular diameters (18–29 mm). TAVR was performed in 486 patients at 41 clinical sites. The primary endpoint of all-cause mortality or major stroke at 12 months was lower with CoreValve (26% vs 43%; \( P < .0001 \)) compared to a prespecified objective performance goal based on previous and contemporary studies at that time. A cohort of patients deemed to be at high risk for SAVR were randomized to SAVR or CoreValve. At 1 year, mortality was lower with TAVR (14.2% vs 19.1%; \( P = .04 \)). These data from the pivotal trials supported the US Food and Drug Administration’s decision to approve the device without an advisory panel.

The newest iteration of the self-expanding CoreValve is the Evolut R system. The CoreValve Evolut R CE Mark clinical study evaluated safety and clinical performance of the CoreValve Evolut R system. The study evaluated 60 patients with a 26- or 29-mm Evolut valve in a single-arm, multicenter study of high- or extreme-risk patients with a mean Society of Thoracic Surgeons (STS) score of 7% ± 3.7% with symptomatic aortic stenosis. The results showed that overall Valve Academic Research Consortium-2 device success rate was 78.6%, and paravalvular regurgitation after TAVR was mild or less in 96.6%, moderate in 3.4%, and severe in 0% at 30 days. Major vascular complications were seen in 8.3%, and permanent pacemaker implantation was required in 11.7% of patients. The 1-year follow-up of this study was presented at the Transcatheter Cardiovascular Therapeutics (TCT) annual meeting in October 2015.
and reported a survival rate of 93.3% and a stroke rate of 3.4%. Paravalvular regurgitation after TAVR was mild or less in 95.7%, moderate in 4.3%, and severe in 0%, and the permanent pacemaker implantation rate was 15.2%.

The Evolut R device was approved in mid-2015 for use in patients with severe native calcific aortic stenosis or failure of a surgical bioprosthetic aortic valve who are judged by a heart team, including a cardiac surgeon, to be at high or greater risk for open surgical therapy (ie, STS predicted risk of operative mortality score ≥ 8% or a ≥ 15% risk of mortality at 30 days).

**EVOLUT R DESIGN FEATURES**

The valve comes in 23-, 26-, and 29-mm sizes to treat annular diameters of 18 to 26 mm. The more ergonomic EnVeo delivery system replaced the less responsive AccuTrak delivery system used for the initial CoreValve, and the device profile was reduced substantially from 18 F (22-F outer diameter) to 14 F (18-F outer diameter). The reduced profile was, in part, accomplished through utilization of an inline sheath (Figure 1).

With the capsule covering the valve flares during deployment, coupled with the flexible shaft, the device is able to self-center within the aortic annulus better than its predecessor. After initial deployment and before the valve is released from the delivery mechanism, the device can be completely recaptured and repositioned if the operator is not satisfied with the position of the valve (Figure 2). Ease of positioning, extension of the sealing skirt, and enhanced conformability below the annulus improved fit and reduced incidence of moderate-to-severe paravalvular leak to 3.4% at 30 days in the CE Mark study. The retention hooks were also redesigned to allow easier and more reproducible release of the valve from the delivery catheter.

**TECHNIQUE**

A standard preprocedure workup is performed and, if transfemoral access is selected, standard femoral arterial access procedures are performed. When using the CoreValve’s InLine sheath, predilation may be performed by a 14-F sheath or an 18-F dilator before inserting the loading catheter. Next, the InLine sheath is maintained flush against the capsule while it is inserted into the vessel. It is important to position the handle so that it conforms to the patient’s anatomy as it is advanced. Aortic valvuloplasty may be performed, particularly if the valves are heavily calcified.

Fluoroscopic examination of the prosthesis loading system should always be performed. Because the CoreValve EnVeo R delivery system does not allow direct visual inspection of the loaded valve, fluoroscopic examination is necessary. Fluoroscopy can be
Figure 5. Marker position and distal valve frame position depend on valve size. Gray arrowheads depict the marker position, and the black arrowheads depict the distal valve frame position.

has a safety feature: a component connects the tip retrieval system with the delivery system handle and is held in place with two plastic tabs and slots. Any maneuver causing excessive deployment forces may cause a separation of the two components. Although a valve can still be retrieved if this were to occur, deployment should not be attempted. The nose cone is reapplied to the capsule and withdrawn to the InLine sheath. The sheath and delivery system are removed while maintaining the wire in the body. A 14-F sheath is reinserted, and final hemodynamic measurements are made. Adjunctive balloon valvuloplasty is performed if necessary.

IMPACT ON PRACTICE

The Evolut R valve, like other contemporary TAVR valves, is approved for high- and extreme-risk patients with severe aortic stenosis involving native and failed surgical bioprosthetic aortic valves. The ability to reposition the valve represents an improvement in accurate deployment, and the lower profile expands the number of patients who can be treated transfemorally. Coupled with ease of use, these changes represent significant improvements for the operator, as well as several advantages in streamlining the procedural and postprocedural care of the patient.

FUTURE PERSPECTIVES

The design improvements implanted in the CoreValve Evolut R device represent significant technological advances in TAVR. Many challenges remain as this technology evolves, including the need to further reduce the delivery profile to accommodate patients with poor iliofemoral vessels and to reduce the incidence of vascular complications. There is still a need to reduce periprocedural stroke rates, the incidence of paravalvular leak, and the need for permanent pacemakers. Presently, an Evolut R system does not exist for annulae that require a valve larger than 29 mm; however, a 34-mm Evolut R valve is in development to address this issue. As this exciting technology moves into intermediate- and low-risk populations, issues such as durability, coronary access, and leaflet thrombosis will require further investigation.


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