TAVI: Which Valve for Which Patient?

A review of the technical challenges and optimal valve choices in different clinical and anatomic scenarios.

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There is now a wide range of commercially available transcatheter aortic heart valves with which clinicians can treat their patients. These valves significantly differ in their design, construction, and mechanism. The functioning bioprosthetic leaflets may be intra- or supra-annular, and the valves may be balloon-expandable, self-expanding, or mechanically expanded. A variety of different skirts aim to enhance sealing and mitigate paravalvular leak (PVL). Frame cell size and construction, frame height, size range, and the design and profile of the delivery system and access sheath all vary. Table 1 illustrates the contemporary transcatheter aortic valves, together with their key properties.

Although many patients can be successfully treated with any one of a number of valves, differences in design features have the potential to translate to important variation in efficacy and safety in specific patient and anatomic subgroups, and in some cases, these theoretical differences are supported by trial and registry data (Table 2). As a consequence, it is important for practicing transcatheter aortic valve implantation (TAVI) operators to clearly understand the advantages, disadvantages, and evidence base for different valve technologies in different settings in order to achieve optimal outcomes for their patients.

DEGENERATIVE SURGICAL BIOPROSTHESES: VALVE-IN-VALVE TAVI

The principal challenges of valve-in-valve (ViV) TAVI are the increased risk of coronary obstruction from the displaced bioprosthetic leaflets and the elevated postprocedural pressure gradients due to the interaction between the transcatheter and surgical valves. By far the greatest experience and evidence in ViV TAVI is with the use of the CoreValve/Evolut (Medtronic) and Sapien (Edwards Lifesciences) valves.

The incidence of coronary obstruction was noted to be 3.5% in the VIVID registry.[1] This risk is primarily determined by the geometry of the surgical valve and the anatomy of the sinuses rather than TAVI valve type. In the VIVID registry, there was no difference between the CoreValve and Sapien valves in the incidence of coronary obstruction.[1] In theory, a fully retrievable valve such as the Lotus device (Boston Scientific Corporation) may confer an advantage in allowing device retrieval in the event of coronary obstruction. However, there are no substantive data to back up this theoretical benefit.

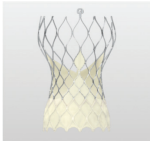
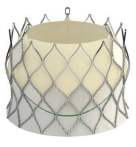
In the VIVID registry, a high postprocedural gradient, defined as a mean gradient ≥ 20 mm Hg, was noted in 28.4% of cases and was an independent predictor of increased late mortality. A mean gradient ≥ 20 mm Hg was seen more frequently after use of Sapien valves than with CoreValve (40% vs 21.3%, respectively; $P < .0001$). This difference was most marked in small (internal diameter < 20 mm) surgical bioprostheses (58.8% vs 20%, respectively; $P = .005$).[1] Sapien use was an independent predictor of an elevated gradient, a finding corroborated in a recent meta-analysis.[2] This is likely to be explained by a fundamental design difference between the two valves; the CoreValve (and its successor Evolut) is a supra-annular device, in contrast to the intra-annular Sapien valve. As a result, the function of the CoreValve is less affected by the constraining surgical sewing ring, allowing for a larger potential orifice area.[1] Although the use of bioprosthetic valve fracture with high-pressure noncompliant balloons has emerged as a treatment option for a high residual gradient after ViV TAVI, data on this strategy remain limited.[3,4]

There are very few data beyond case series describing outcomes with the other available TAVI valves.

BICUSPID AORTIC VALVES

Bicuspid aortic valves are often associated with larger annulus dimensions, an asymmetric valve orifice, heavy calcification, and a dilated and asymmetric aortic root and ascending aorta.[5,6] These anatomic variations present a number of challenges to TAVI, and studies have highlighted poorer outcomes among this population. Complications

TABLE 1. CONTEMPORARY VALVE TYPES AND DESIGN FEATURES

Device Image*	Device Name	Device Characteristics	Regulatory Approval Status by Region
	Evolut family	• Self-expanding, supra-annular valve • Wide range of annular sizes • Ability to recapture and reposition when < 80% deployed • Good durability data; extensive evidence base	• FDA approved • CE Mark approved
	Sapien family	• Balloon-expandable, intra-annular valve • Low frame height and outer skirt to limit paravalvular leak • No ability to recapture • Good durability data; extensive evidence base	• FDA approved • CE Mark approved
	Acurate neo	• Self-expanding, supra-annular valve • Top-down deployment provides hemodynamic stability • Upper crown that caps native leaflets below coronary ostia • Low pacemaker rates • Flexible delivery system • Moderate evidence base	• CE Mark approved
	Allegra (NVT AG)	• Self-expanding, supra-annular valve • Early valve functionality minimizes outflow obstruction during deployment • Leaflet stress reduction through flexible commissures • Flexible delivery system • Limited evidence base	• CE Mark approved
	Centera	• Self-expanding, intra-annular valve • Low frame height • Motorized delivery system enables stable valve deployment by a single operator • Low rates of paravalvular leak and pacemaker • Ability to recapture and reposition when < 80% deployed • Limited evidence base	• CE Mark approved
	JenaValve	• Self-expanding, intra-annular valve (porcine pericardial tissue; size range: 65–92 mm) • Calcium-independent anchoring • Attaches to native leaflets, moving them away from coronary ostia • Transfemoral delivery • Limited evidence base	• Currently in trial in the United States and Europe
	Lotus Edge	• Mechanically expandable, intra-annular valve • Lowest rates of paravalvular leak • Fully repositionable, even after deployment • Moderate evidence base	• FDA approval anticipated Q2 2019 • CE Mark approved
	Portico	• Self-expanding, intra-annular valve • Ability to recapture and reposition when ≤ 80% deployed • Flexible delivery system • Moderate evidence base	• Approved for investigational use only in the United States • CE Mark approved

*All product images provided courtesy of their respective manufacturers.

arising more frequently after TAVI in this cohort include significant PVL, nonuniform/noncircular valve deployment, device migration/embolization, and annular rupture.[7-13]

When selecting a valve for TAVI within bicuspid anatomy, a number of specific attributes can be useful in mitigating these complications. A device with minimal PVL is desirable, given its increased incidence and the association of moderate to severe PVL with increased mortality.[14] The ability to retrieve and reposition is also favorable in view of the elevated risk of malpositioning. Finally, a self-expanding or mechanically expanded valve may be preferable to a balloon-expandable device, both to conform to an asymmetric valve orifice and to reduce risk of annular rupture.

The Lotus valve has a number of attractive features for bicuspid anatomy, specifically very low rates of PVL, minimal need for postdilatation, slow and controlled deployment, and full retrievability and repositionability. An analysis of 31 patients with bicuspid anatomy included in the RESPOND postmarket Lotus valve registry showed good clinical and echocardiographic outcomes up to 1 year after implantation.[15] The latest iteration, the Lotus Edge, is due to be rereleased in Europe and the United States in the first half of 2019.

The largest published experience in bicuspid anatomy is with the Sapien 3 valve, in which outcomes in 2,691 bicuspid cases from the TVT registry were compared in a recent propensity-matched analysis with 2,691 tricuspid patients. The Sapien valve appears to have some design features that are ill-suited to bicuspid anatomy (no repositionability, balloon-expandable). However, although this study did show an increase in periprocedural complications with bicuspid versus tricuspid anatomy, they remained infrequent (annular rupture [0.3% vs 0%; P = .02], conversion to open surgery [0.9% vs 0.4%; P = .03], and 30-day stroke [2.4% vs 1.6%; P = .02]). Furthermore, PVL rates were equally low in both groups, and overall outcomes were good, with no difference in stroke or mortality at 1 year.[16] An earlier registry showed better outcomes, with less PVL, with the newer-generation Sapien 3 and Lotus valves compared to the early generation Sapien XT and CoreValve valves.[17]

More studies are needed on the efficacy of different valve types in bicuspid anatomy, and ongoing device-specific studies in low-risk bicuspid patients will provide valuable further data.

SEVERE LEFT VENTRICULAR OUTFLOW TRACT AND ANNULAR CALCIFICATION

Heavy calcification of the left ventricular outflow tract and annulus is associated with an increased risk of PVL[18] and, most significantly, of annular rupture—a rare but often fatal complication. Annular rupture occurs most frequently during deployment of a balloon-expandable valve[19-22] or with postdilatation for PVL.[23]

The ideal valve in heavily calcified landing-zone anatomy would be self-expanding or mechanically expanded to minimize the risk of annular rupture, and it would offer a low incidence of PVL without the need for postdilatation.

The valve that best fits this template is Lotus. In the 1,014-patient RESPOND registry, Lotus was associated with a rate of moderate or greater PVL of only 0.3%.[24] Other established self-expanding valves, such as CoreValve/Evolut, Portico (Abbott Vascular), and Acurate neo (Boston Scientific Corporation), have minimal risk of annular rupture on valve deployment, but their PVL rates are higher and potentially hazardous postdilatation is more frequently employed. In the REPRISE III randomized controlled trial, the 1-year incidence of moderate or severe PVL was 6.8% with CoreValve/Evolut versus 0.9% with Lotus, and postdilatation was performed in 31.2% versus 1.5%, respectively.[25]

The Centera valve (Edwards Lifesciences) is a novel, skirted, self-expanding system that has demonstrated extremely low rates of PVL in an initial 203-patient study (moderate or higher PVL in 0.6% of patients), although postdilatation was required in 33% of patients.[26] More data are needed on this and other newer-generation, skirted, self-expanding devices, such as the Evolut Pro, Acurate neo 2, and the next-generation Portico, which may have a role in heavily calcified anatomy in the future.

PURE AORTIC REGURGITATION

The primary challenge for TAVI valves in the treatment of pure aortic regurgitation (AR) is the absence of calcification, leading to difficulty in anchoring, and hence to an increased risk of valve malposition, migration, or even embolization. This risk is compounded by the hyperdynamic left ventricle and regurgitant jet that make controlled positioning and release of the valve more challenging.[27] A recently published registry reported device malpositioning in 19.3% of patients. There was a significant difference in the rate of device malposition when comparing early and new-generation devices, highlighting the importance of appropriate valve selection.[28]

The ideal transcatheter valve for treatment of pure AR would have an anchoring mechanism independent of calcium and be repositionable. The JenaValve (JenaValve Technology GmbH) is a self-expanding device that fixes to the annulus without use of calcium by engaging the native aortic cusps through an active clipping mechanism. It is also fully repositionable during the first step of implantation. The JUPITER registry demonstrated the JenaValve to be safe and effective,[29] and its successful use in the treatment of pure AR has been reported.[28,30] However,

TABLE 2. SUMMARY OF THE TECHNICAL CHALLENGES, THEORETICAL VALVE DESIGN CONSIDERATIONS, AND OPTIMAL VALVES FOR EACH PATIENT SUBGROUP

Patient or Anatomic Subgroup	Technical Challenges	Theoretical Considerations for Valve Design	Valves of Choice
Degenerative surgical bioprostheses: "valve-in-valve"	• Interaction between transcatheter and bioprosthetic valves causes elevated pressure gradients after TAVI • Risk of coronary obstruction	• Supra-annular valves less affected by surgical bioprosthesis, resulting in a lower post-TAVI gradient and larger valve area	• CoreValve/Evolut: lower gradients post-TAVI, particularly in small (internal diameter < 20 mm) surgical bioprostheses
Bicuspid aortic valves	• Increased risk of PVL due to eccentricity, calcification, and large annulus • Increased risk of malposition or embolization due to distorted root anatomy • Increased risk of annular rupture	• Devices with minimal PVL are preferable • Self-expanding valves better able to conform to asymmetric valve orifice and less likely to cause annular rupture • Valves with the ability to be retrieved and repositioned to reduce risk of migration/embolization	• Lotus: minimal PVL, minimal rupture risk, fully repositionable, supportive data • Sapien 3: supportive data despite some theoretically unfavorable design characteristics
Severe left ventricular outflow tract and annular calcification	• Increased risk of annular rupture • Increased risk of PVL	• Self-expanding valves that reduce risk of annular rupture • Effective mitigation of PVL both to minimize PVL and to obviate the need for postdilatation, which may risk annular rupture	• Lotus: minimal PVL, minimal risk of annular rupture, minimal need for postdilatation • Other self-expanding skirted valves may represent an alternative (eg, Evolut Pro, Centera, and the next-generation Portico and Acurate neo)
Pure aortic regurgitation	• Absence of calcification renders difficulty in anchoring the device and increases risk of malposition, migration, or embolization	• Devices with an anchoring mechanism independent of calcium • Self-expanding valves less reliant on calcification • Valves with the ability to be retrieved and repositioned, which reduces risk of migration/embolization	• JenaValve (if available): independent anchoring, supportive data • CoreValve/Evolut: self-expanding, partially repositionable, some anchoring in ascending aorta, some data • Other self-expanding, repositionable valves (eg, Portico, Lotus, Centera): may have a role but data are sparse
Mitigating coronary obstruction	• Displacement of valve leaflets can obstruct coronary ostia	• Patient anatomy is the dominant consideration, rather than valve design • Valve design that actively controls the deflection of the native leaflets can mitigate risk of obstruction • Valves with the ability to be repositioned in the event of occlusion are preferred	• Acurate neo: upper crown assists in capping displaced leaflets below coronary ostia • Lotus: fully repositionable and retrievable in the event of coronary obstruction
Preservation of coronary access	• Accessing coronary arteries can be challenging after TAVI • Should be a specific consideration in patients with existing CAD and younger patients • Coronary access should be straightforward even in non-TAVI centers and emergency settings (eg, primary PCI)	• Low frame height to sit below the coronary ostia • Low-density mesh with large cells enable easier access • Orientation of commissures can impede coronary access	• Sapien 3: relatively short frame, with large cells at the level of the coronary ostia • Acurate neo: short frame that sits below the coronary ostia in most cases • Centera: short frame that sits below the coronary ostia in most cases
Young patients	• Long-term valve durability is essential • May require subsequent TAVI-in-TAVI • More likely to require subsequent coronary access • Greater potential long-term consequences of PVL and conduction abnormalities	• Evidence of long-term durability • Shorter frame and intra-annular leaflets to facilitate TAVI-in-TAVI without risk of coronary obstruction; low frame height and low-density mesh allowing for easier coronary access • Low incidence of PVL/conduction abnormalities	• Sapien 3: strong data on durability, favorable design for TAVI-in-TAVI, favorable for coronary access, minimal rate of ≥ moderate PVL, low pacemaker rate

Abbreviations: CAD, coronary artery disease; PCI, percutaneous coronary intervention; PVL, paravalvular leak; TAVI, transcatheter aortic valve implantation.

the major limitation of the device is its requirement to be deployed via transapical access, a route known to be associated with increased mortality. A transfemoral iteration of the JenaValve is under investigation, but neither the transapical nor transfemoral devices are currently available outside of clinical trials.

In the absence of a dedicated device for pure AR, a valve that is self-expanding (and therefore somewhat less dependent on calcium to anchor) and repositionable is favored. The Portico and Evolut valves are self-expanding and partially repositionable, and they both offer some anchoring in the ascending aorta. CoreValve/Evolut were the most frequently used valves in the De Backer et al study. Acceptable results were noted with careful sizing of the valve, but an increased risk of device malposition was associated with either undersizing or oversizing.[28] The fully repositionable Lotus valve may also have a role in pure AR, but its successful use has only been reported in isolated cases to date.

MITIGATING CORONARY OBSTRUCTION

Coronary obstruction during TAVI is caused by displacement of the aortic valve leaflets leading to occlusion either at the coronary ostia or at the sinotubular junction (STJ).[31] Its occurrence is predominantly determined by patient anatomy, specifically coronary and STJ height, sinus of Valsalva and STJ diameter, and (to a lesser extent) length and bulk of the displaced leaflets.[31] However, valve selection may also have a role in mitigating this catastrophic complication.

A systematic review demonstrated that coronary obstruction is more common after TAVI with a balloon-expandable valve than a self-expanding valve,[32] a finding corroborated by a subsequent multicenter registry.[33] The inability to reposition or retrieve also makes the Sapien family of balloon-expandable valves an unattractive choice in patients at high risk of coronary obstruction.

Features that may be helpful in preventing coronary obstruction are a valve design that actively controls leaflet deflection and the ability to reposition or retrieve the valve if obstruction occurs. During deployment of the JenaValve, the device clips and attaches to the native leaflets, thus moving them away from the coronary ostia.[34] As a result, the reported rate of coronary obstruction using the JenaValve is low, with none of the 180 patients involved in the JUPITER registry experiencing this complication.[29] The Acurate neo device has an upper crown that caps the native leaflets below the coronary ostia.[35] This feature is designed to mitigate the risk of coronary obstruction, but its effectiveness is unconfirmed because the rate of this complication was not disclosed in the postmarket SAVI-TF registry.[36]

The Lotus valve is the only fully repositionable and retrievable device, and it is therefore also a favorable choice in patients at high risk of coronary obstruction.

PRESERVATION OF CORONARY ACCESS

The prevalence of coronary artery disease (CAD) in patients with severe aortic stenosis is high,[37] and facilitating access for possible future percutaneous coronary intervention (PCI) in patients with CAD is essential. This includes the possible need for emergency primary PCI in the setting of acute ST-segment elevation myocardial infarction and/or the need for PCI in non-TAVI centers by non-TAVI operators. Clinicians should, therefore, favor a TAVI valve that allows easy coronary access in all patients with existing CAD and in younger patients.

The principal factors determining ease of coronary access are frame height and frame mesh density. Devices with tall frames that extend into the ascending aorta, such as the Evolut and Portico valves, do not prohibit coronary access but undoubtedly render it more challenging. A number of studies have demonstrated greater difficulty in achieving coaxial coronary engagement after TAVI with a self-expanding device as compared to a balloon-expandable device.[38,39]

The current generation of Sapien 3 and Sapien Ultra valves usually extend above the coronary ostia, but they have a low-density mesh and large cells that facilitate coronary cannulation. The Centera valve has a low overall frame height, and the Acurate neo valve has a short stent component that usually sits below the ostia. Both of these devices are also favorable in this patient group. Finally, the Lotus valve will often sit below the coronary ostia, but it has an extremely dense mesh. Coronary access will be difficult whenever the top of the valve frame is above the ostia, and it may be impossible if the device sits at or above the STJ. With this device, as well as with all of the other valves, careful consideration of the aortic root dimensions and a clear knowledge of the device dimensions are essential both in device selection and deployment if coronary access is to be maintained.

YOUNGER PATIENTS

Increasing evidence confirming the safety and effectiveness of TAVI in intermediate- and low-risk patient populations will inevitably translate to the use of TAVI in younger patients with a life expectancy measured in decades. The three principal factors TAVI operators must consider when selecting a TAVI valve for a younger patient are durability, the feasibility of TAVI-in-TAVI if and when structural valve degeneration (SVD) occurs, and the ability to access the coronary arteries if required. The last of these considerations is discussed in the previous section.

The CoreValve/Evolut and Sapien platforms have significantly more data on long-term durability than other valve types. Five-year data from the pivotal PARTNER I study found that of the 348 patients treated with a Sapien valve, none experienced SVD requiring reintervention. Furthermore, there was no significant difference with respect to hemodynamic valve parameters when comparing TAVI to surgical aortic valve replacement (SAVR) at 5 years after the procedure.[40] Similarly, 5-year data from the ADVANCE study demonstrated excellent durability of the CoreValve device; SVD was reported in only 0.9% of patients and paired echocardiographic measurements demonstrated stable valve hemodynamics.[41] The NOTION study comparing TAVI and SAVR in low-risk patients demonstrated superior hemodynamics with CoreValve in the TAVI group. There was also a lower incidence of SVD in the TAVI group, mainly driven by a larger valve area and lower incidence of prosthesis-patient mismatch.[42]

These studies provide encouraging 5-year results for TAVI, but less is known about valve durability beyond this. Recently published data from the UK TAVI registry have given some insight into longer-term durability. Of the 241 patients included in this study assessing the incidence of SVD at 5 to 10 years postprocedure, 149 (64%) were treated with CoreValve and 80 (34.7%) with Sapien. Only one patient (0.4%) developed severe SVD and 21 (8.7%) had moderate SVD, meaning that 91% of patients remained free of SVD at 5 to 10 years after TAVI.[43]

In cases where significant SVD occurs, a redo TAVI-in-TAVI procedure may be required. The feasibility of this will largely depend on the patient's anatomy, because implantation of a new prosthesis risks coronary obstruction due to displacement of the leaflets of the existing device, in particular at the level of the STJ. In patients with a large aortic root and/or high STJ, this risk will be trivial; however, in those with a small and/or low STJ, TAVI-in-TAVI in a supra-annular valve with a tall frame, such as the CoreValve/Evolut, will carry a prohibitive risk of complete obstruction of coronary flow at the level of the STJ. Operators need to consider the anatomic feasibility of TAVI-in-TAVI when treating younger patients. In general, and particularly in patients with small anatomy, the use of a valve with a shorter frame and intra-annular leaflets, such as Sapien, should be considered.

Finally, a low incidence of significant PVL and conduction abnormalities, including left bundle branch block as well as permanent pacemaker implantation, are of particular relevance to younger patients. In this regard, Sapien 3 would be favored over Evolut.

UNCOMMON ANATOMIC SUBGROUPS

It is beyond the scope of this article to address every anatomic consideration in patients undergoing TAVI. However, in addition to the larger patient groups already discussed, operators should be aware of a number of other challenging scenarios where some valve types may confer advantages. These include extreme iliac or aortic tortuosity, in which a flexible delivery system such as Portico or Acurate neo may be advantageous; mechanical mitral valve replacement and marked septal bulge, in which a self-expanding prosthesis may be preferred to avoid the risk of valve displacement due to interaction during deployment of a balloon-expandable device; and small iliofemoral vessels, in which a low-profile system such as the 14-F Evolut R may be favorable.

CONCLUSION

Technical advances, increased experience, and a growing evidence base have led to an expansion of TAVI into increasingly diverse and challenging anatomic and patient subgroups. Many patients can be successfully and effectively treated with any one of a number of valve types. Furthermore, each TAVI operator needs to strike a balance between the number of different valve types used and personal experience with each one. Nonetheless, an appreciation of the technical challenges associated with different anatomic scenarios, along with the strengths and weaknesses of the various transcatheter aortic valves, will allow an optimal valve to be selected for each and every patient, minimizing complications and maximizing success. ■

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