Surgical aortic valve replacement (AVR) is the conventional treatment for severe aortic stenosis (AS). However, a high operative mortality of 7% to 10% is well recognized in high-risk groups.1,2 Risk of AVR is increased by a number of factors, including increasing age, and comorbidities, such as heart failure, respiratory and renal disease, prior cardiac surgery, and need for concomitant coronary revascularization.3 As a result, 30% to 40% of elderly patients do not have surgery because of 1 or more of the following reasons: (1) The patient is not referred for AVR by the cardiology team, (2) the patient is not accepted for an operation by the cardiothoracic team, and (3) the patient declines AVR.4,5 Additionally, surgery is more likely to be denied in patients who are elderly and who have left ventricular (LV) dysfunction or multiple comorbidities6 and is contraindicated in cases of porcelain aorta, radiation dermatitis, and liver cirrhosis.6 However, conservative management of patients with severe AS is known to have a poor prognosis.7 Transcatheter aortic valve implantation (TAVI) was developed to address this unmet need. After the demonstration of feasibility of TAVI in 2002,8 it is now widely practiced, with >20 000 patients treated worldwide, and the technique has been recommended as an alternative strategy for patients in high-risk surgical groups.9

Currently, there are 2 CE marked devices with some similar fundamental design features: the self-expanding CoreValve ReValving system (Medtronic Inc; Minneapolis, MN) and the balloon-expandable Edwards SAPIEN prosthesis (Edward Lifesciences Inc; Irvine, CA), which is now available as the new generation, smaller profile, balloon-expandable Edwards SAPIEN XT prosthesis. The CoreValve is available in 2 inflow diameter sizes, 26 and 29 mm, whereas the Edwards SAPIEN and Edwards SAPIEN XT valves are available in 23- and 26-mm diameters. Transfemoral, transapical, and transaxillary/subclavian delivery routes have been developed. Both the transfemoral and the transaxillary/subclavian routes involve a retrograde approach, whereas the transapical route involves an anterograde approach. More recently, the transaortic route also has been introduced, allowing direct aortic access.10 The transfemoral route is the first choice for both prostheses in the majority of patients; however, in patients in whom the transfemoral route is contraindicated, the transapical route can be considered for Edwards SAPIEN or Edwards SAPIEN XT valve implantation, and the transaxillary/subclavian route is an alternative for implantation of the CoreValve.

Multiple trials have assessed the efficacy of TAVI in terms of procedural success, early mortality, and short-term clinical outcomes.11–15 More recently, medium-term outcomes have been reported for the Edwards SAPIEN,16 with the longest published follow-up at 3 years17; more comprehensive long-term survival data are awaited.

Selection criteria have a crucial influence on complication rates and clinical outcomes after TAVI and are focused on the selection of the most appropriate patient group, prosthesis type and size, and delivery route.9 As accepted techniques, experience, and skill of the operators have improved, the indications and criteria for patient selection have become broader. In this review, we aim to provide an overview of the current recommended selection criteria and offer a critical appraisal of these guidelines while delivering a comprehensive and up-to-date outline of the most appropriate investigative pathway pre-TAVI, thereby ensuring that the right valve is implanted into the right patient by the right delivery method.

**Patient Selection**

Evaluation before TAVI should be conducted by a multidisciplinary team encompassing the expertise of interventional cardiologists, imaging cardiologists, cardiac surgeons, and cardiac anesthetists. Because TAVI remains a relatively new procedure, it is currently only recommended for patients who are functionally limited as a result of severe AS, with a life expectancy of >1 year, and in whom surgery is considered to be high risk or contraindicated.9 Current recommended patient-related selection criteria include 1 or more of the following:

- Logistic EuroSCORE18 >20%
- Society of Thoracic Surgeons score19 >10%
Presence of risk factors not covered by surgical risk scores (eg, chest radiation, liver cirrhosis [Child class A or B], previous cardiac surgery [coronary artery bypass graft surgery or valvular surgery], porcelain aorta, and contraindication to open chest surgery [chest radiation])

These recommendations were stated in a position statement by a European committee of the European Association of Cardio-Thoracic Surgery and the European Society of Cardiology,9 are still open to debate, and should not be considered binding. It also should be remembered that multivariate risk scoring schemes were developed for surgical procedures, and their use in estimation of risk has limitations.20 Although there is moderate correlation between logistic EuroSCORE and Society of Thoracic Surgeons score in patients receiving TAVI, the logistic EuroSCORE frequently provides a higher estimated mortality score. The Society of Thoracic Surgeons score seems to offer a more accurate assessment of risk; however, both systems have suboptimal predictive power for mortality after TAVI.21 Clinical judgment is still paramount in patient selection for any intervention and should be used in association with a combination of quantitative tools. After clinical assessment, patients will then go on to have a series of investigations to assess a number of anatomic and functional characteristics to evaluate their suitability for TAVI.

Assessment of Severity of AS
Before consideration of TAVI, all patients must have investigations to confirm severe AS requiring intervention. Transthoracic echocardiography (TTE) is mandatory. In the presence of clear data, further investigation may not be necessary, but there are cases in which at least 2 investigative modalities are required to confirm severe AS. In these instances, transesophageal echocardiography (TEE) can be used. Cardiac catheterization can be used to perform aortography and measure the transaortic valvular gradient in borderline cases; however, this generally is not recommended and is contraindicated if adequate data can be obtained noninvasively. The following criteria for severe AS should be satisfied:

- Aortic valve area <1 cm²
- Aortic valve index <0.6 cm²/m²

In addition, in the presence of a LV ejection fraction >50%:

- Aortic peak jet velocity >4.0 m/s
- Aortic mean pressure gradient >40 mm Hg

In the presence of low-gradient AS, dobutamine stress echocardiography may be required to allow further assessment of severity of aortic valve disease. Failure of the stroke volume or ejection fraction to increase by at least 20% with dobutamine administration indicates an absence of LV contractile reserve and a high risk for aortic valve intervention.22

Assessment of Concomitant Coronary Artery Disease
Coexistent significant coronary artery disease may increase the risk of TAVI. Additionally, it is likely to affect clinical outcomes postprocedure if left untreated and, therefore, requires investigation as part of the routine screening of potential patients. Patients with associated significant coronary artery disease may require percutaneous coronary intervention before undergoing TAVI. Importantly, TAVI generally is considered to be inappropriate in patients with severe coronary artery disease that is not amenable to intervention and may affect prognosis. The following investigations are used:

- Coronary angiography, which is the gold standard investigative modality and is performed in the majority of patients
- Multislice coronary CT (MSCT), which can be considered in patients where there is a need to lower the risk of the preassessment process

Furthermore, all patients must be clinically stable before a TAVI procedure; therefore, patients with decompensated heart failure should have optimal medical therapy and may need balloon valvuloplasty to ensure improvement of their clinical status and LV function before TAVI.

Valve Type and Size Selection
The Edwards SAPIEN valve consists of a stainless steel balloon-expandable stent with 3 integrated valve leaflets composed of bovine pericardium. It is available worldwide and is implanted through the transfemoral route using the Retroflex 3 delivery system or through the transapical route using the Ascendra delivery system. The latest generation, smaller-profile, Edwards SAPIEN XT valve received a CE mark in March 2010 and has been launched in Europe. It consists of a new cobalt-chromium design and is delivered using the Novaflex system for transfemoral route or the Ascendra 2 system for the transapical route. Both the Edwards SAPIEN and the Edwards SAPIEN XT valves are currently available in 23- and 26-mm sizes (Table 1).

The CoreValve consists of a self-expanding nitinol frame with 3 integrated porcine pericardial leaflets. It is currently available in 26- and 29-mm sizes (Table 1).

Assessment of the Aortic Annulus
Measurement of the size of the aortic annulus requires precise assessment to allow appropriate valve selection and to minimize the risks of paravalvular leak and device migration. The size of the chosen prosthesis must be slightly larger than the size of the aortic annulus to reduce the risk of paravalvular aortic insufficiency. There is currently no validated gold standard; therefore, a number of investigations can be used for this measurement, as follows:

- TTE normally is the primary investigative modality but generally is not used in isolation because it can lead to imprecise measurements.23 The annulus is measured at the level of the basal attachment of the leaflets (inferior virtual basal ring).
- TEE is particularly helpful in borderline cases where clear imaging is required to allow accurate measurements and in which TTE quality is inadequate.

When using TTE and TEE for annulus size measurement, it is important to measure the annulus in the preferred views: the
parasternal long-axis view and the 120° to 140° long-axis view (3-chamber view), respectively (Figure 1).

- MSCT can be used to combine the measurement of the size of the aortic annulus while also performing an assessment of cardiac anatomy and the peripheral arteries.\(^{24,25}\) MSCT studies have demonstrated that the aortic annulus often is oval with significant differences in the minimal and maximum diameter. In these cases, the minimum diameter as measured in the sagittal view on MSCT is used for device sizing. In addition, the patient’s body surface area and body mass index should be taken into account. MSCT also can be used to provide additional information, for example, the distance between the annulus and the coronary artery ostia and the degree of annular calcification\(^ {24,26}\) (Figure 2).

- Aortography with graded pigtail catheter can be performed in the right anterior oblique and left anterior oblique 15° projections.

In addition, the following investigations are not routinely used but can be useful adjunctive tests to add to our knowledge of valve anatomy:

- Rotational angiography as a tool for annular size assessment
- Cardiac MRF\(^ {27}\)
- Three-dimensional TEE for a more detailed assessment of the anatomy of the aortic valve

It may be pragmatic to evaluate the annular size first in the preassessment sequence because a size > 27 mm or < 18 mm will make the patient unsuitable for any TAVI. In addition, a size between 23 and 26 mm would demand a CoreValve, and a size between 23 and 25 mm the new-generation Edwards SAPIEN XT implanted using the Novaflex delivery system (Figure 3).

An integrated approach with the use of multiple modalities for annular assessment is recommended because there are cases in which significant discrepancies in the measurements made using any 1 of the standard imaging techniques\(^ {26}\) may exist (Figure 4). We must remember that whereas a surgeon uses direct vision to control the adaptation of the aortic root to the valve prosthesis, the interventional cardiologist does not have this luxury. Although the correlation of aortic annular measurements among TTE, TEE, and MSCT are relatively close, the absolute difference between values obtained on MSCT and echocardiography are larger than those observed between TTE and TEE, potentially resulting in a change in the choice of device for TAVI.\(^ {28}\) It is generally believed that the assessment of size of the aortic annulus by the 3 modalities is largest in the following order of magnitude: MSCT > TEE > TTE.
Assessment of Cardiac Anatomy

Although it is crucial to evaluate the aortic annular size, there are a number of additional structural factors in the cardiac anatomy that affect procedural success or complication rates. These must be considered as part of the overall risk-benefit analysis before TAVI. They can be identified using a combination of TTE, TEE, MSCT, angiography, and cardiac MRI:

- An LV outflow tract diameter of 18 to 21 mm requires a 23-mm Edwards SAPIEN or Edwards SAPIEN XT device, and one of >21 mm requires a 26-mm Edwards SAPIEN or Edwards SAPIEN XT device or CoreValve implantation. This is particularly important in the presence of LV hypertrophy and a sigmoid septum. In cases of a pronounced sigmoid septum, the transapical approach may be preferred to allow adequate positioning and anchorage of the prosthesis.9
- Bicuspid aortic valve where the valvular orifice is elliptical may cause significant paravalvular insufficiency after implantation of a cylindrical prosthesis.29 However, this may represent a relative rather than an absolute contraindication to TAVI in selected cases in experienced centers and may possibly result in less aortic insufficiency if implanted in a relatively high position in cases of CoreValve implantation to allow greater contact between the widest portion of the valve and the native aortic valve. Additionally, the operator must be more vigilant when assessing for paravalvular leaks and must take into account the higher risk of ascending aorta dissection, particularly in cases of a dilated ascending aorta.30
- Degree of angulation between the aorta and the heart can make accurate positioning more demanding, particularly in instances of a horizontal aortic root with a vertical aortic annulus.
- Calcified aortic wall (porcelain aorta) often occurs in conjunction with a horizontal aortic root; therefore, delivery through the transfemoral or transaxillary/subclavian routes may increase the risk of aortic dissection or distal embolization. For this reason, the transapical route often is selected in these cases.
- Ventricular thrombus increases the risk of thromboembolic complications as a result of guidewire and device manipulation.

![Figure 2. Assessment of aortic annulus size using multislice coronary CT. A, Sagittal view. B, Coronal view. Ao indicates aorta; LA, left atrium; LV, left ventricle.](image)

![Figure 3. A scheme for assessment of optimum valve and delivery method based on assessment of aortic annular size and peripheral anatomy. TAVI indicates transcatheter aortic valve implantation. *Represents preferred strategy for transcatheter aortic valve implantation.](image)
Subaortic stenosis can mimic true aortic stenosis and requires surgical intervention.

Height of coronary ostia from the base of the aortic valve leaflets ideally need to be >10 mm to prevent coronary arterial occlusion on implantation of the prosthesis. The mean position of the right coronary ostium is 15 to 17 mm, whereas the left coronary ostium is positioned 13 to 17 mm from the base of the annulus. In some situations, this can be compensated for by controlled deep deployment of the CoreValve, thereby implanting a valve 1 or 2 mm lower than the recommended position, which results in positioning of the waist (the narrowest portion of the valve) adjacent to the position of the coronary ostia. However, this may increase the risk of atrioventricular conduction disturbance and need for permanent pacemaker implantation.

Calcific valvular nodules can be a contraindication to TAVI. A degree of annulus calcification is present in all patients with degenerative AS, but the presence of large calcific nodules can predispose to a risk of coronary occlusion or paravalvular leak.

Mitral prosthesis can potentially interfere with the positioning of the prosthesis; therefore, it is imperative not to position the valve too low because it can affect mitral prosthesis function.

Assessment of the Peripheral Arterial System
The type of device chosen and the ideal delivery method is based on an assessment of the peripheral arteries in the first instance. The transfemoral route allows minimally invasive vascular access through a percutaneous approach or surgical arterial exposure. This route shortens the length of hospital stay and has higher 1-year survival rates than the transapical route; however, this may be due to higher rates of comorbidity in the transapical group. It is important to make an accurate assessment of the minimal luminal diameter of the aortic, iliac, and common femoral arteries. Additionally, the operator needs to know the degree of calcification and tortuosity of these arteries because the transfemoral route is contraindicated in those patients with severely calcified and tortuous peripheral arteries. The following investigative modalities can be used:

- Peripheral angiography is a simple technique that allows assessment of vessel size and tortuosity and gives some indication of the degree of vascular calcification.
- Contrast-enhanced MSCT provides excellent noninvasive evaluation with good vessel resolution, allowing assessment of vessel size, calcification, and tortuosity. Furthermore, it allows cross-sectional evaluation of vessels and 3D reconstruction to enhance the procedural planning process.
- Noncontrast-enhanced MSCT can be used as an alternative in patients in whom contrast load should be minimized (eg, patients with chronic kidney disease or contrast allergy), although it does not offer the same degree of definition between the vessel wall and blood interface as contrast-enhanced MSCT.
- MRI is most informative when performed with gadolinium enhancement; therefore, it should be used with caution in patients with chronic kidney disease because gadolinium nephrotoxicity is similar to that of regular contrast agents.

Although in general, patients with small, heavily calcified, tortuous arteries may require TAVI to be conducted through the transapical or transaxillary/subclavian routes, in the hands of experienced operators, there are cases in which the transfemoral route can still be considered. In arteries with circumferential calcification, transfemoral access can be attempted, but the operator should select cases with a minimal vessel diameter that is greater than the required reference ranges for each device. In vessels in which there are only focal areas with a small diameter, the transfemoral approach is still possible as long as the diameter mismatch is minimal. Vessel tortuosity also can be addressed in some cases by the careful use of a stiff guidewire to straighten out the arteries.
Table 2. Contraindications to Each TAVI Delivery Method

<table>
<thead>
<tr>
<th>Contraindication</th>
<th>Transfemoral</th>
<th>Transapical</th>
<th>Transaxillary/Subclavian</th>
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<tbody>
<tr>
<td>Iliac artery diameter</td>
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<tr>
<td>CoreValve</td>
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<tr>
<td>Edwards SAPIEN</td>
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<tr>
<td>Edwards SAPIEN XT device</td>
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<td></td>
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<tr>
<td>Iliac artery diameter</td>
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<tr>
<td>&lt; 6 mm for CoreValve</td>
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<tr>
<td>&lt; 6 mm for Edwards SAPIEN XT device</td>
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<tr>
<td>&lt; 7 mm for Edwards SAPIEN</td>
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<tr>
<td>Severe calcified iliac or femoral arteries</td>
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<tr>
<td>Severe respiratory disease</td>
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<tr>
<td>Difficulty in accessing LV (eg, obesity, chest wall deformity)</td>
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<tr>
<td>Severe aortic arch atheroma</td>
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<tr>
<td>Coarctation of aorta</td>
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<tr>
<td>Abdominal aortic aneurysm with associated mural thrombus</td>
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<tr>
<td>Transverse ascending aorta for Edwards SAPIEN device</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Iliac or femoral arteries</td>
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<tr>
<td>Subclavian diameter</td>
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<tr>
<td>&lt; 6.5 mm from origin of subclavian artery to ostia of LIMA/RIMA</td>
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<tr>
<td>Severe angulated aorta</td>
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<tr>
<td>Subclavian diameter proximal to LIMA/RIMA</td>
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<tr>
<td>LIMA indicates left internal mammary artery; LV, left ventricle; RIMA, right internal mammary artery; TAVI, transcatheter aortic valve implantation.</td>
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In all cases, particular care must be given when steering guidewires or introducer sheaths through those areas that are most commonly involved in vessel damage, namely, at the bifurcation of the iliac arteries and at the area of origin of the iliac arteries.

Delivery Method Selection

The method of delivery generally is based on local expertise and availability of the various methods. It relies on a tailored approach to procedural planning by the multidisciplinary team because there are no comparative studies of the 3 approaches. The transaxillary/subclavian approach was introduced as an alternative route in patients with difficult transfemoral access for implantation of the CoreValve. Initial studies reported excellent procedural success rates that suggest that this technique may provide a safer alternative to the transapical route in patients in whom the transfemoral route is contraindicated.\(^{37}\) When selecting the best delivery method, the most commonly used pathway starts with an assessment of the transfemoral route. However, if there are contraindications to the transfemoral route or the patient has borderline characteristics for this approach, alternative delivery methods should be considered if feasible. However, there are specific contraindications to each technique (Table 2).

Indications for Pacing

Temporary pacing wire implantation is a necessity for all TAVI procedures because the atrioventricular node and its left bundle branch lie adjacent to the noncoronary cusp of the aortic valve, leading to a potential risk of atrioventricular conduction block postintervention.\(^{38}\) After conventional surgical AVR in octogenarians, 8.5% of patients required pacemaker implantation\(^{39}\) compared with a reported 5.4% pacing risk with implantation of the Edwards SAPIEN valve\(^{13}\) and 9.3% to 33% after CoreValve implantation.\(^{12,40}\) It is widely accepted that the requirement for permanent pacing is greatest with the CoreValve prosthesis. However, it should be noted that the reported frequency of permanent pacemaker requirement varies between studies because of differences in the clinical threshold and timing of pacing at TAVI centers. Furthermore, the incidence of new left bundle branch block is \(\approx 40\%\) after CoreValve implantation\(^{41}\) compared to an incidence of 15.6% after surgical AVR,\(^{42}\) but the significance of this finding remains unknown. Atrioventricular conduction may improve over time after TAVI, but studies of this phenomenon have been limited. Data on the physiological and anatomic factors that may predict pacing requirement are preliminary, but there seems to be an increased risk in patients undergoing CoreValve implantation with evidence of conduction system disease at baseline, the presence of severe septal hypertrophy, increased thickness of the noncoronary cusp, and the presence of rate limiting-medication preprocedure.\(^{43-45}\) As more studies are conducted in this field, we may find that pacing-predictive parameters become a further factor influencing the choice of the most appropriate valve prosthesis (Table 3).

Table 3. Proposed Pacing Predictors From Published TAVI Studies

<table>
<thead>
<tr>
<th>Device</th>
<th>Jilaihawi et al(^{40})</th>
<th>Bleiziffer et al(^{44})</th>
<th>Piazza et al(^{41})</th>
<th>Erkapic et al(^{43})</th>
<th>Sinhal et al(^{45})</th>
</tr>
</thead>
<tbody>
<tr>
<td>Proposed predictors of pacing risk after TAVI</td>
<td>Left-axis deviation and associated left bundle branch block.</td>
<td>Intraoperative AV block; borderline annulus; valve size diameter; Valve type: CoreValve. Larger valvuloplasty balloon size. No statistical association between preexisting ECG changes and pacing risk.</td>
<td>Right bundle branch block. Depth of CoreValve implantation.</td>
<td>Valve type, CoreValve.</td>
<td>No statistical association between preexisting ECG changes and pacing risk.</td>
</tr>
<tr>
<td>CoreValve</td>
<td>CoreValve</td>
<td>CoreValve</td>
<td>CoreValve</td>
<td>CoreValve</td>
<td>CoreValve SAPIEN.</td>
</tr>
<tr>
<td>Edwards SAPIEN</td>
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AV indicates atrioventricular; TAVI, transcatheter aortic valve implantation.
Overall Contraindications to TAVI

Industry recommendations and guidelines\(^9\) suggest that there are cases in which TAVI cannot be considered, and either surgical or conservative therapy is indicated instead. Many of these contraindications to TAVI are based on the exclusion criteria for the initial TAVI trials and the PARTNER (Placement of Aortic Transcatheter Valve) randomized trial comparing surgical versus TAVI versus medical treatment:

- Bicuspid aortic valve
- Aortic annular size \(< 18\) mm or \(> 25\) mm for the Edwards SAPIEN valve
- Aortic annular size \(< 20\) mm or \(> 27\) mm for the CoreValve
- Apical LV thrombus
- Subaortic stenosis
- Grade 3 to 4 mitral regurgitation because it is believed that untreated severe mitral regurgitation may lead to incomplete valvular intervention with poor long-term clinical outcomes
- Calcific valvular nodules that may be dislocated toward the coronary ostia
- Height of take-off of coronary ostia \(< 10\) mm
- Aortic root dimension \(> 45\) mm at the sinotubular junction for the CoreValve
- Life expectancy \(< 1\) year

It should be noted that this list is not considered by most experienced operators to represent a series of absolute contraindications to TAVI. Some of these factors only represent relative contraindications that should be studied carefully before implantation; they may make the procedure more challenging but often can be overcome in the hands of experienced physicians. However, these contraindications also may lead to a greater incidence of complications, and therefore, the operator must be cautious before considering a TAVI in these patients. Of note, very short life expectancy is considered to be an absolute contraindication to TAVI worldwide.

Off-Label Indications

Although the on-label guidelines for TAVI are important, it is well recognized that with the improvement in the proficiency of TAVI centers and individual operators worldwide, this procedure may be considered in a wider array of patients. Our enhanced experience level in the treatment of patients with a range of comorbid factors and anatomic and functional variables has resulted in the application of TAVI for the following off-label indications:

- Valve-in-valve TAVI: TAVI is useful in the treatment of bioprosthetic aortic valve failure, resulting in severe AS or regurgitation. These valve-in-valve procedures have been performed with good result, and although they represent an off-label indication for TAVI, they provide a growing application of the technique in this high-risk surgical subgroup. The largest published cohort showed promising procedural outcomes in 10 high-risk patients with 100% survival at 30-day follow-up and improvement in aortic valve function in all patients.\(^{46}\)
- Bicuspid aortic valve: Although initial studies reported an increased incidence of incomplete and asymmetrical expansion of a percutaneous valve in patients with a bicuspid aortic valve due to its predominantly elliptical shape,\(^7\) an increasing number of operators now believe that with careful case selection, TAVI can be considered in this group.\(^{30}\)
- Medium- and low-risk surgical groups: It seems that centers are now performing percutaneous valve implantation in patients who have a lower surgical risk than those in the initial study cohorts. This is to be expected as confidence grows and as the use of TAVI is expanded to address a wider proportion of the population. However, we must not overlook the fact that we currently only have up to 3-year follow-up data from the initial TAVI patient cohorts. We will need to have studied the complication rates and longer-term clinical outcomes from large registries and randomized trials before we can begin to offer TAVI as a viable alternative to conventional AVR in patients with moderate or low surgical risk.
- Patients with contraindications to conventional delivery approaches: A new TAVI approach through the transaortic route has been described in a small number of patients in whom transfemoral, transapical, or transaxillary/subclavian options are not available.\(^{10}\) This approach appears to be feasible for the delivery of the CoreValve prosthesis with promising procedural and short-term results and may be a possibility for patients with no other TAVI delivery options.
- Aortic regurgitation: Currently, the main indication of TAVI is for patients with severe, symptomatic AS, but there are reports of successful TAVI for the treatment of severe native aortic valve regurgitation in patients at high surgical risk.\(^{48}\) Although this indication for TAVI currently is off label, it may represent a growing field in the future as TAVI technology improves and we have more long-term outcome data.

The frequency and outcomes with TAVI for off-label indications were assessed by Piazza et al\(^49\) in a group of 200 patients referred for TAVI of whom 69 went on to have CoreValve implantation. On-label indications for TAVI were defined as the widely reported standard criteria, as described within this review. In this group, 42 (67%) patients had at least 1 off-label criterion. A significant number of patients had at least 1 anatomic feature that may be regarded as a contraindication to TAVI, with the most common of these being the presence of grade 3 to 4 mitral regurgitation in 31% and an annulus diameter outside the 20- to 27-mm range in 40%. Additionally, the CoreValve was implanted through the transfemoral route in 8 patients with an iliofemoral diameter of \(< 6\) mm. Comparison was made of the overall technical and procedural success between the on-label group (n=21) and the off-label group (n=42), with a mean logistic EuroSCORE of 19% and 14%, respectively. Results showed that the overall technical and procedural success was highest in the off-label group, although this difference was not significant and may have been a reflection of a small overall sample size. Given that a large proportion of patients had an aortic annular size outside the on-label limits, it is interesting to note that there was no significant difference in the frequency of moderate to severe aortic regurgitation, post-valve dilatation, or implantation of a second valve between
the 2 groups. There was also no significant difference in the 30-day rate of death, stroke, myocardial infarction, or bleeding, with a similar survival rate between the 2 groups at 1-year follow-up and an overall cumulative survival rate of 69%. However, it should be stressed that comparisons between the off-label and on-label groups are crude and can be misleading because the off-label group is very heterogeneous and may contain patients at the opposite ends of the spectrum in terms of baseline risk. Although this study was the first to evaluate the off-label use of TAVI, and the sample size was very small, it possibly raises some questions with regard to the current guidelines for TAVI. If a more liberal approach is adopted with the inclusion of lower-risk patients, we strongly believe that such a strategy should be undertaken within the context of a dedicated prospective trial.

Future Technology

Given the success and widespread use of TAVI worldwide, new generations of the Edwards SAPIEN and the CoreValve are being developed. The 29-mm version of the Edwards SAPIEN is now available through the transapical route, and the 23-mm and 31-mm CoreValve devices will be launched in the near future. Furthermore, the CoreValve delivery sheath will be introduced as a smaller, 16-F version. In addition, a balloon-expandable transfemoral sheath (Solopath; Onset Medical Corporation; Irvine, CA) recently has been introduced for use with both CoreValve and Edwards SAPIEN XT devices, allowing controlled expansion of the delivery catheter. In addition, further devices are being developed aimed at producing design innovations that may allow treatment of patients with smaller arteries, freedom to reposition and retrieve the prosthesis, and techniques to decrease the degree of paravalvular insufficiency. These devices are in the preliminary stages of evaluation, and as yet, none of them are CE marked. The advent of new technologies may mean improved procedural success rates with better long-term outcomes, but as yet, it is too early to ascertain the exact details of the next generation of widely available transcatheter valve devices.

Conclusions

Current guidelines for patient selection for TAVI are based on early trials and experience with initial device implantation. Since that time, the field of TAVI has continued to grow and develop, with operators becoming progressively more skilled in the various techniques. As experience has increased, the previously published absolute contraindications to TAVI have become more relative, with operators choosing to implant devices in a growing number of high-risk cases. Furthermore, in the past 3 years, the number of implantations has increased progressively, with an increasing length of follow-up and no reported cases of valve failure. Although the initial guidelines were appropriate to address the initial learning curve and the need for a growing level of experience in TAVI, it may be that we now need to readdress the patient selection criteria for TAVI in light of a wider level of expertise.

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Disclosures

None.

References


33. Al-Lamee et al TAVI: Patient and Device Selection 395
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