Patient selection for transcatheter aortic valve implantation: Patient risk profile and anatomical selection criteria

Sélection des patients avant implantation de valves aortiques percutanées: critères cliniques et anatomiques

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Summary Patient selection plays a crucial role in the success of transcatheter aortic valve implantation (TAVI). It requires meticulous attention to the smallest of details and needs to be performed in a systematic manner for every patient. In essence, the patient must be assessed from access to implantation site. Becoming over “complacent” and “routine” may lead to failure and impact patient safety. TAVI is indicated for high or prohibitive surgical risk patients with severe aortic stenosis. Some patients, however, are too high risk even for TAVI. In addition to patient risk evaluation, anatomical selection criteria need to be considered. Multimodality imaging, using a combination of angiography, echocardiography and multislice computed tomography, is necessary to determine the anatomical suitability for the procedure.

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Abbreviations: DEM, Dynamic expansion mechanism; MPR, Multiplanar reconstruction; MSCT, Multislice computed tomography; SFAR, Outer sheath diameter to femoral artery minimal luminal diameter; STS, Society of Thoracic Surgeons; TAVI, Transcatheter aortic valve implantation; TAV-in-SAV, Transcatheter aortic valve-in-surgical aortic valve; TEE, Transoesophageal echocardiography; TTE, Transthoracic echocardiography; VARC, Valve Academic Research Consortium.

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Background

Patient selection plays a crucial role in the success of transcatheter aortic valve implantation (TAVI). It requires meticulous attention to the smallest of details and needs to be performed in a systematic manner for every patient. In essence, the patient must be assessed from access to implantation site. Becoming over "complacent" and "routine" may lead to failure and impact patient safety.

In Europe, TAVI is indicated for high or prohibitive surgical risk patients with severe aortic stenosis. Some patients, however, are too high risk even for TAVI. In addition to patient risk evaluation, anatomical selection criteria need to be considered. Multimodality imaging, using a combination of angiography, echocardiography and multislice computed tomography (MSCT), is necessary to determine the anatomical suitability for the procedure. In particular, assessment of the peripheral vasculature and aortic valvar complex will allow selection of the access route and prosthesis type and size, respectively.

Patient risk evaluation

A number of cardiac surgical risk algorithms have been developed over the last 20 years. Despite their known limitations, the logistic EuroSCORE I and the STS (Society of Thoracic Surgeons) Predicted Risk of Mortality score have guided enrolment of "high surgical risk" patients into TAVI trials. Because low-to-intermediate surgical risk patients characterized the development of these risk models, their reliability when applied to high or prohibitive surgical risk patients has been rightfully questioned. Furthermore, models may not take into account important comorbidities (e.g. porcelain aorta, chest wall radiation, liver cirrhosis, pulmonary hypertension) and frailty variables that may impact clinical outcomes. The newly updated logistic EuroSCORE II and STS score, however, are expected to incorporate frailty variables.

In high surgical risk patients, the logistic EuroSCORE I tends to overestimate the observed mortality risk by a factor of 2 to 3; the new logistic EuroSCORE II appears to provide significantly lower mortality estimates than the logistic EuroSCORE I. The STS score has been found to be more reliable than the logistic EuroSCORE I or the Amblor Risk Score for the prediction of operative and long-term mortality in high-risk patients undergoing surgical aortic valve replacement.

Clinical judgment should supersede any surgical risk algorithm. Risk scores should guide but not dictate clinical decision-making.

A need for a transcatheter aortic valve implantation (TAVI) risk score?

A TAVI risk score for TAVI patients, akin to the logistic EuroSCORE or STS score for surgical patients, is currently not available. A TAVI risk score may provide additional information during the preprocedural screening process to better understand the potential outcomes of patients after TAVI.

Recent publications have identified a number of baseline variables to be independently associated with mortality or poor treatment response in patients undergoing TAVI: low body mass, functional status, left ventricular dysfunction, low gradient aortic stenosis, concentration of N-terminal prohormone of brain natriuretic peptide, diabetes, prior stroke, chronic obstructive pulmonary disease, chronic kidney disease, severe tricuspid and mitral regurgitation and baseline anaemia [1–9]. In addition to baseline demographics, anatomical characteristics may also help to predict treatment response after TAVI.

Anatomical patient selection criteria

The most important aspect of anatomical screening involves assessment of the arterial vasculature and aortic valvar complex (left ventricular outflow tract, aortic annulus, sinus of Valsalva, sinotubular junction and ascending aorta) (Fig. 1). This information will guide physicians to select the most appropriate access route (i.e. transfemoral, subclavian, apical or direct aortic) and transcatheter valve size. Furthermore, it will alert physicians to potential complications that may arise during the procedure. Information about specific anatomical criteria is provided in the paragraphs that follow.
Figure 1. After selecting the appropriate high or prohibitive surgical risk patient, it becomes critical to assess the anatomical eligibility for transcatheter aortic valve implantation (TAVI). This figure demonstrates that every aspect of the vasculature from “skin to heart” needs to be examined with respect to minimal vessel diameter, degree of atherosclerosis, tortuosity and calcification. Furthermore, alternative access sites (e.g. subclavian, transapical direct aortic) should be assessed and kept in mind in case of bail out options.

Assessment of the arterial vasculature

The occurrence of vascular complications associated with TAVI is not surprising given the use of large bore catheters and imperfect vascular closure devices. Vascular complications have been reported in 2% to 30% of patients undergoing TAVI; the conflicting reports are due to heterogeneous end-point definitions [10–13].

Peripheral contrast angiography is practical and associated with relatively lower costs, lower contrast dye injection and lower radiation exposure compared with MSCT [14]. MSCT, however, provides greater appreciation of vessel size, tortuosity and calcific burden [15].

A recent angiographical study identified an outer sheath diameter to femoral artery minimal luminal diameter (SFAR) ratio greater or equal to 1.05 as a predictor of Valve Academic Research Consortium (VARC) major vascular complications as well as 30-day mortality [10]. The SFAR cut-off ratio increased to 1.10 in the absence of calcium and decreased to 1.00 in the presence of calcium. These results need to be confirmed in prospective studies and should also include MSCT.

The femoral artery is typically used as the default vascular access. Peripheral vascular disease is not an absolute contraindication to TAVI; it does, however, increase the risk of complications significantly. Physicians must be skilled or have the necessary resources to treat vascular injuries (percutaneously or surgically). Some physicians attempt to cautiously advance the vascular access sheath and catheter delivery system across the diseased vasculature, implant the valve and repair any complications such as dissections “on the way out” by percutaneous transluminal angioplasty/stent implantation. Alternatively, peripheral vascular interventions (percutaneous transluminal angioplasty or stent implantation) can be performed prior to valve implantation. While this latter approach has been performed successfully in experienced centres, the risk of dislodging the implanted stent during advancement of the vascular access sheath or delivery catheter needs to be considered.

Significant tortuosity alone of the iliofemoral vessels is not necessarily a contraindication to TAVI as long as the vessels are otherwise healthy and compliant—gentle advancement of the stiff guidewire or vascular access sheath will tend to straighten the vessel.

The Edwards eSheath features the innovative “dynamic expansion mechanism” (DEM) that allows for transient sheath expansion during valve delivery. Immediately after the Edwards SAPIEN XT prosthesis passes through the sheath, the DEM allows the sheath to return to a low profile diameter. This reduces the time the access vessel is expanded, thereby minimizing the risk of vascular trauma. The unexpanded eSheath has an inner diameter of 5.3 mm (16F) and an outer diameter of 6.7 mm (20F) for implantation of the 23 mm prosthesis; an inner diameter of 5.9 mm (18F) and an outer diameter of 7.2 mm (21–22F) for implantation of the 26 mm prosthesis; and an inner diameter of 6.7 mm (20F) and an outer diameter of 8 mm (24F) for implantation of the 29 mm prosthesis (Table 1). Acceptable minimal iliofemoral diameters for implantation of the 23, 26 and 29 mm Edwards SAPIEN XT prostheses are 6.0, 6.5 and 7.0 mm, respectively.

In the current version of the Medtronic CoreValve system, a custom introducer sheath is not supplied. Current

<table>
<thead>
<tr>
<th>Table 1</th>
<th>Diameters of the eSheath in its unexpanded and expanded state.</th>
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<tbody>
<tr>
<td>Model</td>
<td>Sheath ID (unexpanded)</td>
</tr>
<tr>
<td>916ES23</td>
<td>16F (5.3 mm)</td>
</tr>
<tr>
<td>918ES26</td>
<td>18F (5.9 mm)</td>
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<tr>
<td>920ES29</td>
<td>20F (6.7 mm)</td>
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a Minimal vessel diameter requirement.

ID: inner diameter; OD: outer diameter; THV: transcatheter heart valve.
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Figure 2. Multislice computed tomography axial cuts of the aortic annulus from 12 patients, demonstrating that the aortic annulus is, in fact, non-circular. The difference between the maximum and minimum diameter measurements of the aortic annulus is on average 6.5 mm with a standard deviation of approximately 2 mm. The non-circularity of the aortic annulus limits applicability of two-dimensional imaging in estimating the annulus diameter for transcatheter valve sizing.

recommendations are to use a Cook 30 cm Check-Flo Performer 18F introducer (Cook, Bloomington, IN, USA). The St. Jude 30 cm Ultimum EV 18F introducer (St. Jude, Minnetonka, MN, USA) is less utilized because it has less column strength and is therefore less kink resistant than the Cook sheath. The acceptable minimal iliofemoral diameter for implantation of the 26, 29 and 31 mm Medtronic CoreValve prostheses is 6.0 mm.

Alternative routes to the transfemoral include the subclavian artery [16,17], apex of the heart [18,19] and ascending aorta [20,21]. In selected cases, non-transfemoral routes may be safer and just as effective. Transapical approaches with the Edwards SAPIEN device, JenaValve and Symetis Acurate system, and the subclavian and direct aortic approaches with the Medtronic CoreValve System are Conformité Européenne (CE) mark approved.

The left subclavian artery (as opposed to the right) is selected in more than 95% of Medtronic CoreValve subclavian cases [16]. In most cases, the approach from the left subclavian is straightforward irrespective of the aortic root angulation. In contrast, if the angulation between the plane of the annulus and a horizontal reference line is more than 30 degrees (suggesting a horizontal aorta or vertical annulus plane), an approach from the right subclavian will be technically challenging [22]. The presence of an internal mammary coronary artery bypass graft is a relative contraindication to the subclavian approach. Having said that, successful cases have been performed in its presence with a minimum vessel diameter requirement of 6.5 to 7.0 mm [23]. In order to reduce the risk of retrograde dissection of the internal mammary artery graft, the segment of the subclavian artery proximal to the internal mammary artery should be free of atherosclerotic disease.
Measurement of the aortic valve annulus

Surgeons commonly define the aortic valve annulus as the semilunar crown-like ring demarcated by the "draping" leaflet attachment line that runs across the aortic root. For the purposes of TAVI, the enigmatic "aortic valve annulus" corresponds to a virtual ring formed by joining the basal attachment points of the leaflets within the left ventricle [24]. This plane represents the inlet from the left ventricular outflow tract into the aortic root. The fact that the aortic valve annulus has a non-circular shape has led to a great deal of debate over the optimal imaging modality for measuring its diameter [25,26] (Fig. 2).

The aortic valve annulus diameter can be measured using various imaging modalities. These include transthoracic echocardiography (TTE), transesophageal echocardiography (TEE), MSCT, contrast aortography and magnetic resonance imaging (Fig. 3).

Transcatheter aortic bioprostheses are typically oversized by 5 to 30% relative to the aortic valve annulus diameter. The intention of oversizing is to create enough interference (or radial force) between the prosthetic valve and aortic valvar complex to ensure adequate anchoring and sealing.

According to MSCT data, the aortic valve annulus is non-circular in the vast majority of patients [25]. The mean difference between the maximum and minimum diameter of the aortic annulus is 6.5 mm (95% confidence interval, 5.7–7.2) [26]. This fact explains the potential shortcomings of relying on two-dimensional measurements of the aortic annulus for transcatheter aortic valve sizing (Fig. 4).

MSCT multiplanar reconstructions (MPRs) can provide coronal, sagittal and axial images of the aortic root. Methodologies for MPRs of the aortic valve annulus have been previously described [27]. In the axial view, the aortic valve annulus lies at a level just below the basal attachment points of the three leaflets (Fig. 5). From this view, the maximum and minimum diameter, perimeter and area of the annulus can be measured (Figs. 5B and 6C). The maximum and minimum diameters typically correspond to coronal and sagittal planes cut across the annulus, respectively. Depending on the orientation of the chord cut across the annulus, two-dimensional echocardiography provides a "one-dimensional view" of the aortic annular dimensions; typically underestimating the annulus diameter with respect to MSCT. Despite this knowledge, we are still left with the conundrum of how to appropriately apply MSCT aortic annular measurements to existing echocardiographic sizing criteria.
Aortography during preimplantation balloon aortic valvuloplasty (i.e. balloon sizing) is a simple way to confirm the optimal valve size depending on the presence or absence of aortic regurgitation [28].

Having said all of this, two-dimensional echocardiography (TTE or TEE) remains the most commonly used and practical method to assess the aortic valve annulus diameter. Nonetheless, as we acquire more data in the near future, MSCT will likely become the primary imaging modality to measure the dimensions of the aortic valve complex and guide transcatheter aortic valve size selection.

The Edwards SAPIEN XT THV is currently available in four sizes (20, 23, 26 and 29 mm) and can be implanted in native annuli with diameters of 16 to 27 mm (Fig. 6). The CoreValve is currently available in three sizes (26 mm, 29 mm and 31 mm) and can be implanted in native annuli with diameters ranging from 20 to 29 mm (Fig. 7).

**It’s not just about the aortic valve annular measurements — the aortic valvar complex**

In addition to the aortic annulus diameter, other measurements of the aortic valvar complex, such as the height and width of the Sinus of Valsalva, take-off heights of the coronary arteries, left ventricular outflow tract diameter, ascending aorta diameter and calcification tract diameter, may influence the feasibility, safety and effectiveness of the procedure (Table 2).

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**Figure 4.** Short-axis superior view of the human aortic valve seen from the ascending aorta. Depending on the orientation of the chord transecting the aortic annulus, and whether or not the chord transects the centre of the aortic valve, different measurements of the aortic annulus can be made by two-dimensional imaging.

**Figure 5.** Serial axial cuts across the aortic valvar complex. A. Basal attachments of the aortic valvar leaflets. B and C. Slice (approximately 0.85 mm) below the basal attachments of the aortic valvar leaflets and the level at which the aortic annulus is measured. In (B), the maximum and minimum diameters are obtained whereas in (C), a tracing of the “aortic valve annulus” provides the perimeter and cross-sectional area measurements.

**Figure 6.** The Edwards SAPIEN XT valve is currently available in four sizes (20, 23, 26 and 29 mm) and can treat aortic annuli diameters ranging from 16 to 27 mm.
Coronary artery disease

According to published case series, up to three-quarters of patients undergoing TAVI may have documented coronary artery disease. Expectedly, patients with coronary artery disease have higher surgical risk scores and associated comorbidities than patients without coronary artery disease [29]. Percutaneous coronary intervention in association with TAVI has been reported in 0 to 44% of patients. Although concomitant and staged strategies have been reported successfully, the latter approach appears to be more commonly used [30–34]. Discrepancies exist amongst studies as to whether coronary artery disease negatively impacts survival post-TAVI [30,35–37]. A recent study showed no differences in VARC clinical outcomes between 70 patients who underwent isolated TAVI versus 55 who underwent concomitant TAVI and percutaneous coronary intervention [38].

Optimal management of patients with concomitant coronary artery disease undergoing TAVI is currently a subject of debate. It appears that a staged approach (percutaneous coronary intervention followed by TAVI) is prudent in patients with lesions in a dominant proximal right coronary artery, left main, proximal left anterior descending and dominant proximal circumflex artery.

Transcatheter aortic valve implantation (TAVI) in special subgroups

Failing surgical bioprosthetic valves

The operative mortality for elective re-do aortic valve surgery is reported to range from 2 to 7%; but this percentage can increase to more than 30% in high-risk and non-elective patients [39–41]. Understanding the basic construction and dimensions, radiographic identification and potential failure modes of surgical aortic valve bioprostheses is fundamental for understanding the key principles involved in transcatheter aortic valve-in-surgical aortic valve (TAV-in-SAV) implantation [42]. One important fact is that the labelling size of surgical bioprostheses does not correspond to their internal stent diameter; the internal stent diameter determines the transcatheter aortic valve size. Reference tables relating labelling sizes and internal stent diameters have already been published [42]. Over 100 successful TAV-in-SAV implantations have been reported with the Medtronic CoreValve and Edwards SAPIEN transcatheter heart valve for failing stented and stentless surgical bioprostheses [43]. Transaortic valvular gradients after TAV-in-SAV implantation are around 20 mmHg (higher than TAVI for native aortic valve stenosis or surgical aortic valve replacement) and paravalvular leaks are typically trivial to mild.
Bicuspid valves

Although congenital or acquired bicuspid aortic valve stenosis is considered a contraindication to TAVI, several successful case reports have been documented [44–51]. Anecdotally, stenotic bicuspid aortic annuli are usually larger and more eccentric than stenotic tricuspid aortic valves. As such, three-dimensional imaging is strongly advised for transcatheter aortic valve sizing. Furthermore, assessment of the ascending aorta and its treatment require special attention.

Lower surgical risk patients

TAVI was initially conceived for the treatment of high surgical risk or inoperable patients. A recent observational report noted a paradigm shift toward the selection of lower surgical risk patients for TAVI. Furthermore, significantly better clinical outcomes were observed in the lower (mean STS score 4%) than higher (mean STS score 7%) surgical risk patients undergoing TAVI, at 30-day and 6-month follow-up [52]. With increasing volumes and continued encouraging results, it appears that lower surgical risk patients are receiving TAVI. This is further corroborated by the ongoing preparation of the SURGical aortic valve replacement versus Transcatheter Aortic Valve Implantation (SURTAVI) trial and Placement of AoRtIC tranScatheterER (PARTNER II) valve trial, which are expected to randomize intermediate surgical risk patients with an STS score of 4 to 8% to TAVI or surgical aortic valve replacement.

Disclosure of interest

Nicolo Piazza is a consultant and proctor for Medtronic CoreValve and Ruediger Lange is a consultant for Medtronic CoreValve.

References

[23] De Marco F, Bruschi G, Klugmann S. Transcatheter aortic valve implantation by left subclavian access in the presence...


